

**PATIENT-ADAPTED AND IMPROVED ARTICULAR IMPLANTS, DESIGNS,
SURGICAL PROCEDURES AND RELATED GUIDE TOOLS**

RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application Serial Number 61/443,155, entitled "Patient-Adapted and Improved Articular Implants, Designs and Related Guide Tools," filed February 15, 2011, the disclosure of which is hereby incorporated herein by reference in its entirety.

[0002] This application incorporates by reference the entirety of the disclosures of the following co-pending PCT Patent Applications, which are filed herewith:

[0003] PCT Ser. No. _____, Attorney Docket Number 2960/A67WO, filed February 15, 2012, entitled "Modeling, Analyzing and Using Anatomical Data for Patient-Adapted Implants, Designs, Tools and Surgical Procedures";

[0004] PCT Ser. No. _____, Attorney Docket Number 2960/A68WO, filed February 15, 2012, entitled "Patient-Adapted and Improved Articular Implants, Procedures and Tools to Address, Assess, Correct, Modify and/or Accommodate Anatomical Variation and/or Asymmetry";

[0005] PCT Ser. No. _____, Attorney Docket Number 2960/A70WO, filed February 15, 2012, entitled "Patient-Adapted and Improved Articular Implants, Designs and Related Guide Tools"; and

[0006] PCT Ser. No. _____, Attorney Docket Number 2960/A71WO, filed February 15, 2012, entitled "Patient-Adapted and Improved Articular Implants, Designs and Related Guide Tools".

[0007] Each of the above-described applications is hereby incorporated herein by reference in its entirety

TECHNICAL FIELD

[0008] The invention relates to improved orthopedic implants and guide tools, including patient-adapted (e.g., patient-specific and/or patient-engineered) designs and procedures, as well as related methods, designs and models.

BACKGROUND AND SUMMARY OF THE INVENTION

[0009] Traditionally, diseased, injured or defective joints, including joints exhibiting osteoarthritis, have been repaired and/or replaced using standard off-the-shelf implant components and/or other surgical devices. Such implants typically employ a one-size-fits-all or few-sizes-fit-all approach to implant design (including modular and assemble able designs) and utilize gross anatomical measurements such as the maximum bone dimensions at the implant site, as well as the patient weight and age, to determine a “suitable” implant. Due to the limited number of sizes and/or shapes of such implant components (previously stockpiled for patient use), these pre-existing implants are typically only able to approximate, but not match, the particular patient’s biological features. Accordingly, it is likely to have various amounts of “mismatching” between the implant and the patient, which could result in various complications during and after surgery, including pain, discomfort, soft tissue impingement and unnatural feeling of the joint during motion (e.g., so-called mid-flexion instability), as well as an altered range of movement and an increased likelihood of implant failure. Often, the surgical procedure would concentrate on altering the underlying bony anatomical support structures (i.e., by cutting, drilling and/or otherwise modifying the bone structures) to accommodate the existing bone-contact surfaces of the pre-manufactured implant components, which often necessitated removal of a large amount of bony support structure to accommodate the closest available implant dimensions.

[00010] The use of such pre-existing systems often resulted in suboptimal repair to a patient’s joint for a wide variety of reasons, including (1) where one or more of the pre-existing implant components was not available or was not selected in a suitable size and/or shape, (2) where the underlying anatomical measurements were inaccurate and/or incorrect, (3) where the underlying bony or other anatomical

support structures were unsuitable or incorrectly modified to accommodate the implant components, (4) where the resulting component placement and/or implant design resulted in undesirable performance and/or nonperformance of the implant, and/or (5) where the chosen implant design required excessive removal of underlying anatomical support structures and/or bone, rendering the implant unstable and/or the support structure unsuitable for long term support of the implant components.

[00011] The use of traditional off-the-shelf implants to replace a patient's joint, for example, a knee joint, hip joint, or shoulder joint, would often reduce or eliminate the opportunity for further joint repairs if the primary implant failed. In order to fit a traditional implant component to a patient's articular bone, surgeons typically remove substantially more of the patient's bone than is necessary to merely clear diseased bone from the site. This removal of substantial portions of the patient's bone frequently diminishes the patient's bone stock to the point that only one subsequent revision implant is possible, and even many of these revision implants would require medullary stems or other auxiliary support features.

[00012] More recently, the joint repair and replacement field has come to embrace the concept of "patient-specific" and "patient-engineered" implant systems. With such systems, the surgical implants and associated surgical tools and procedures are designed or otherwise modified to account for and accommodate one or more features of the individual anatomy of the patient undergoing the surgical procedure. Such systems typically utilize non-invasive imaging data, taken of the individual pre-operatively, to guide the design and/or selection of the implant, surgical tools, and the planning of the surgical procedure itself. Various objectives of these newer systems include: (1) reducing the amount of bony anatomy removed to accommodate the implant, (2) designing/selecting an implant that replicates and/or improves the function of the natural joint, (3) increasing the durability and functional lifetime of the implant, (4) simplifying the surgical procedure for the surgeon, (5) reducing patient recovery time and/or discomfort, and (6) improving patient outcomes.

[00013] Various embodiments described herein include advancements relevant to both traditional implants as well as patient-adapted articular implants, allowing such implants to be tailored (to varying degrees) to better address the needs of individual patients as well as various patient groupings. While patient-adapted articular implants offer numerous advantages over traditional one-size-fits-all or few-sizes-fit-all approaches, various embodiments described herein can be used to improve surgical outcomes for all types of implants.

[00014] Advantages of the various embodiments described herein can include better fit, more natural movement of the joint, reduction in the amount of bone removed during surgery and less invasive surgical procedures. If desired, patient-adapted articular implants can be selected, designed and/or created from images of the patient's joint and/or other anatomical structures. Based on the images, patient-adapted implant components can be selected and/or designed to include features (e.g., surface contours, curvatures, widths, lengths, thicknesses, and other features) that match existing features in the single, individual patient's joint as well as features that approximate an ideal and/or healthy feature that may not exist in the patient prior to a procedure. Moreover, by altering the design and/or selection approach to address various potential and actual design implant issues, non-traditional design approaches have been identified that offer improvements over traditional implant designs and surgical procedures.

[00015] Patient-adapted features can include patient-specific features as well as patient-engineered features. Patient-specific (or patient-matched) implant component or guide tool features can include features adapted, designed, modified and/or manufactured to match or substantially 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 include features adapted, designed modified and/or manufactured (e.g., preoperatively designed and manufactured) based at least partially on patient-specific data in combination with various other data sources and/or various engineering and design principles to substantially enhance or improve one or more of the patient's anatomical and/or biological features.

[00016] In various embodiments, features of an implant component, guide tool or related surgical method can be achieved by analyzing patient imaging data and designing and/or selecting (e.g., preoperatively selecting from a physical or electronic library of implant components and/or component designs) an implant component, a guide tool, and/or a procedure having a feature that is matched, optimized and/or otherwise modified for a particular patient's biology. Such features can include pre-primary or primary articular implant components having (a) an outer, joint-facing surface, (b) an inner, bone-facing surface, (c) a peripheral edge, and (d) assorted internal physical characteristics of the implant. The outer, joint-facing surface can include a bearing surface or other surfaces, while the inner joint facing surface and/or the peripheral edge can be designed and/or selected to accommodate one or more patient-engineered bone cuts selected and/or designed from patient-specific data.

[00017] In various embodiments, the implant components, tool and surgical procedures can be applied to any joint including, without limitation, a spine, spinal articulations, an intervertebral disk, a facet joint, a shoulder, an elbow, a wrist, a hand, a finger, a hip, a knee, an ankle, a foot, or a toe joint. For example, one articular implant component can be a femoral implant component for a knee joint. Moreover, the implant components can be selected and/or designed to accommodate any number and/or shape of prepared anatomical support surfaces, include accommodating no prepared surfaces (i.e., attaching to the pre-existing surfaces of the patient's articular anatomy).

[00018] Furthermore, various embodiments described herein can apply to methods and procedures, and the design of methods and procedures, for resectioning or otherwise preparing the patient's anatomy in order to implant the implant components described herein and/or to using the guide tools described herein

[00019] It is to be understood that the features of the various embodiments described herein are not mutually exclusive and may exist in various combinations and permutations.

BRIEF DESCRIPTION OF THE DRAWINGS

[00020] The foregoing and other objects, aspects, features, and advantages of embodiments will become more apparent and may be better understood by referring to the following description, taken in conjunction with the accompanying drawings, in which:

[00021] **FIG. 1** illustrates a coronal plane of the knee with exemplary resection cuts that can be used to correct lower limb alignment in a knee replacement;

[00022] **FIG. 2** illustrates a virtual model of a patient's limb that is misaligned in the sagittal plane, for example, a genu antecurvatum deformity, and the virtually corrected limb;

[00023] **FIGS. 3A** and **3B** illustrate models for one particular patient receiving a single compartment knee implant and in need of osteophyte removal prior to placement of the implant components;

[00024] **FIGS. 4A** and **4B** illustrate models for one particular patient receiving a bicompartamental knee implant and in need of osteophyte removal prior to placement of the implant components;

[00025] **FIG. 5** is a flow chart illustrating the process of assessing and selecting and/or designing one or more implant component features and/or feature measurements, and, optionally assessing and selecting and/or designing one or more resection cut features and feature measurements, for a particular patient;

[00026] **FIG. 6A** depicts the generation of one or more patient-specific curves for a first direction;

[00027] **FIG. 6B** depicts a bearing surface constructed using the one or more patient-specific curves of **FIG. 6A**;

[00028] **FIGS. 7A** through **7J** depict various steps in one exemplary method of planning an anterior bone cut on a targeted femur of a patient, in preparation for receiving a patient-specific implant.

[00029] **FIG. 8** depicts a femoral implant component having six bone cuts with the intersect of bone cuts on the inner, bone-facing surface of the implant highlighted;

[00030] **FIG. 9** illustrates a computer model of a distal femur having optimized bone cuts for a pre-primary implant overlaid with a traditional primary implant (shown in outline);

[00031] **FIGS. 10A-10C** depict designs of implant components that have six bone cuts (**FIG. 10A**), seven bone cuts (**FIG. 10B**), and three bone cuts with one being a curvilinear bone cut (**FIG. 10C**);

[00032] **FIG. 11A** illustrates a distal femur and a distal resection plane parallel to the epicondylar axis; **FIG. 11B** shows an example of an anterior oblique resection plane **8830**.

[00033] **FIGS. 12A to 12E** show optimized resection cut planes to a patient's femur based on the medial condyle.

[00034] **FIGS. 13A and 13B** show resection cut planes for a patient's lateral condyle posterior chamfer (**FIG. 13A**) and lateral condyle posterior (**FIG. 13B**) cut planes that are independently optimized based on patient-specific data for the lateral condyle;

[00035] **FIGS. 14A and 14B** illustrate two exemplary distal resection cut planes for two different cut designs;

[00036] **FIGS. 15A and 15B** illustrate five femoral resection cuts for the two designs shown in **FIGS. 14A and 14B**, respectively;

[00037] **FIGS. 16A and 16B** illustrate the completed cut femur models for each of two cut designs;

[00038] **FIG. 17A** illustrates an embodiment of a cut plane design having anterior and posterior cut planes that diverge from the component peg axis; **FIG. 17B** illustrates an implant component design that includes a peg diameter of 7 mm with a rounded tip;

[00039] **FIGS. 18A** and **18B** illustrate exemplary bone-facing surfaces of femoral implant component designs that include a patient-adapted peripheral margin;

[00040] **FIGS. 19A** and **19B** illustrate side views of exemplary femoral implant component designs;

[00041] **FIG. 20** illustrates a femoral implant component (PCL-retaining) having seven bone cuts;

[00042] **FIG. 21A** and **FIG. 21B** illustrate the resection cut planes for the implant component of **FIG. 20**;

[00043] **FIG. 22** illustrates the implant component of **FIG. 20** from a different angle to show cement pocket and peg features;

[00044] **FIG. 23A** shows a five-cut-plane femoral resection design for a femoral implant component having five bone cuts; **FIG. 23B** shows a seven-cut-plane femoral resection design for a femoral implant component having seven bone cuts;

[00045] **FIG. 24A** shows a patient's femur having five, flexed resection cuts; **FIG. 24B** shows the same femur but with five, not flexed resection cuts;

[00046] **FIGS. 25A** to **25D** show outlines of a traditional five-cut femoral component (in hatched lines) overlaid with, in **25A**, a femur having seven optimized resection cuts for matching an optimized seven-bone-cut implant component; in **FIG. 25B**, a femur having five optimized resection cuts for matching to an optimized five-bone-cut implant component; in **FIG. 25C**, a femur having five, not flexed resection cuts for matching to an optimized five-bone-cut implant component; and in **FIG. 25D**, a femur having five, flexed resection cuts for matching to an optimized five-bone-cut, flexed implant component;

[00047] **FIGS. 26A** and **26B** illustrate a patient-specific femoral model and posterior and anterior resection cut lines for a patient-specific implant component having a curvilinear cut;

[00048] **FIG. 27A** to **FIG 27C** illustrate steps for performing a curvilinear resection cut between planar anterior and posterior cuts on a medial condyle;

[00049] **FIGS. 28A to 28C** illustrate steps for performing a curvilinear resection cut between planar anterior and posterior cuts on a lateral condyle;

[00050] **FIG. 29A** illustrate a model of a femur having predetermined resection cuts including a curvilinear cut; **FIGS. 29B** and **29C** illustrate the corresponding patient-specific implant component for the resection cuts depicted in **FIG. 29A**;

[00051] **FIG. 30A** shows a model of a bone along with a jig that allows preparation of predetermined resection holes and, optionally, resection cuts surfaces to match predetermined resection cuts specific to a patient's particular anatomy; **FIGS. 30B** and **30C** show an alternative set of jigs that can be used with a router-type saw;

[00052] **FIGS. 31A** shows a model of the prepared bone following jig-guided bone cuts; **FIG. 31B** shows the model of **FIG. 31A** with a two-piece patient-specific implant component designed with an inner bone-facing surface that substantially negatively-matches the patient's resected bone surface, including curvilinear bone and resection cuts;

[00053] This example illustrates exemplary implant components having enhanced articular surfaces (i.e., joint-facing surfaces). **FIG. 32A** is a front schematic view of engaging portions of a single compartment (e.g., a single condyle) of a knee implant; **FIG. 32B** is a cross-sectional schematic view in the coronal plane of the femoral component of **FIG. 32A**; **FIGS. 32C to 32F** show cross-sectional schematic views in the coronal plane of respective alternate embodiments of the femoral component;

[00054] **FIG. 33** illustrates a guide tool having one or more apertures for establishing resected holes in a patient's biological structure;

[00055] **FIG. 34A** illustrates a variety of peg configurations that can be used for the implant components described herein; **FIG. 34B** illustrates an embodiment of a peg having a cross-section that includes a "+" or cross-like configuration;

[00056] **FIG. 35** illustrates a guide tool having a moveable aperture and bushing;

[00057] **FIG. 36** shows a guide tool for making distal and posterior resection cuts to the distal femur;

[00058] **FIGS. 37A** and **37B** show two options for a third guide tool for making anterior and posterior chamfer cuts;

[00059] **FIG. 38** illustrates a single, “all-in-one” guide tool that can be used to establish all the resection cuts associated with installation of a femoral implant component;

[00060] **FIGS. 39A** and **39B** illustrate optional guide tool attachments that can be used to enhance one or more cutting or drilling surfaces;

[00061] **FIG. 40A** illustrates an embodiment of a single guide tool that can be used to establish the peg holes and all the resection cuts associated with installation of a femoral implant component; **FIGS. 40B** and **40C** illustrate three optional guide tool attachments for enhancing the cutting or drilling surfaces of the single guide tool;

[00062] **FIG. 41** illustrates a set of resection cut guide tools that together can be used to facilitate peg holes and resection cuts for a patient’s femur;

[00063] **FIGS. 42A** to **42D** show another embodiment of a single guide tool and attachments that can be used to establish the peg holes and all the resection cuts associated with installation of a femoral implant component;

[00064] **FIGS. 43A** to **43F** illustrate a tibial guide tool, a tibial guide rod, and a tibial + 2mm additional resection cut guide; **FIGS. 43G** and **43H** illustrate one or more additional guide tools that can be included and used to remove additional bone from the proximal surface of the tibia;

[00065] **FIG. 44A** shows a tibial guide tool for making a resection cut; **FIG. 44B** shows a tibial guide tool to resect into the resected tibial surface to create a notch for accepting the keel of a tibial implant component;

[00066] **FIGS. 45A** through **45D** show exemplary tools for intraoperatively preparing a rotated tibial implant component;

[00067] **FIGS. 46A** through **46D** show the same front view of the guide tools and inserts shown in **FIGS. 45A** through **45D** and, in addition, show front and back view of three exemplary inserts;

[00068] **FIGS. 47A** and **47B** illustrate a first femur jig used to establish peg holes and pin placements for a subsequent jig used for a distal cut;

[00069] **FIGS. 48A** and **48B** illustrate a distal femoral resection cut performed with a second femur jig;

[00070] **FIGS. 49A** illustrates an anterior cut, posterior cut, and chamfer cut performed with a third femur jig; **FIG. 49B** illustrate an additional femoral jig for making additional resection cuts;

[00071] **FIGS. 50A** and **50B** illustrate an exemplary tibial jig;

[00072] **FIG. 51** illustrates an exemplary balancing chip;

[00073] **FIGS. 52A** and **52B** illustrate an exemplary balancing chip attached to a tibial jig;

[00074] **FIG. 53** illustrates a first jig used to establish placement and alignment of femoral implant peg holes;

[00075] **FIG. 54** illustrates a second jig used to establish placement pins for the distal cut jig;

[00076] **FIG. 55** illustrates a distal cut jig positioned based on the placement established by the previous jig;

[00077] **FIG. 56** illustrates remaining resection cuts performed with a chamfer cut jig;

[00078] **FIGS. 57A** through **57D** depict embodiments of series of jigs designed to make patient-specific cuts to the tibia;

[00079] **FIGS. 57E** and **57F** depict one alternative embodiment of a tibial jig designed to make patient-specific cuts to the tibia;

[00080] **FIGS. 58A through 58K** depict various views of one embodiment of a set of alignment jigs and associated tools for guiding a surgeon in performing various femoral cuts in preparation for the implantation of a femoral implant;

[00081] **FIG. 59** depicts one embodiment of a flexion gap balancer block for use in a knee brought into flexion;

[00082] **FIGS 60A, 60B and 60C** depict an alternative embodiment of a femoral jig incorporating adjustable contact surfaces that can be extended and/or retracted;

[00083] **FIGS. 61A, 61B and 61C** depict views of an additional balancing technique to properly align a desired external rotation to the knee prosthesis prior to insertion of a tibial tray and tibial insert;

[00084] **FIG. 62** depicts an implant or implant design that includes a straight distal cut, a straight anterior cut, a straight posterior cut, and curvilinear chamfer cuts;

[00085] **FIG. 63A** depicts a medial balancer chip insert from top view to show the superior surface of the chip; **FIG. 63B** depicts a side view of a set of four medial balancer chip inserts; **FIG. 63C** depicts a medial balancing chip being inserted in flexion between the femur and tibia; **FIG. 63D** depicts the medial balancing chip insert in place while the knee is brought into extension; **FIG. 63E** depicts a cutting guide attached to the medial balancing chip; **FIG. 63F** shows that the inferior surface of the medial balancing chip can act as cutting guide surface for resectioning the medial portion of the tibia;

[00086] **FIG. 64A** depicts a set of three medial spacer block inserts having incrementally increasing thicknesses; **FIGS. 64B** depicts a set of two medial femoral trials having incrementally increasing thicknesses; **FIGS. 64C** depicts a medial femoral trial in place and a spacer block being inserted to evaluate the balance of the knee in flexion and extension;

[00087] **FIGS. 65A** depicts a set of three medial tibial component insert trials having incrementally increasing thicknesses; **FIG. 65B** depicts the process of placing and adding various tibial component insert trials; **FIG. 65C** depicts the process of placing the selected tibial component insert;

[00088] **FIG. 66** shows a coronal view of a patient's femoral bone and, in dashed lines, standard bone cuts performed with a traditional total knee implant;

[00089] **FIG. 67A** shows a femoral implant component with the thinnest part of the implant component appearing at the intersection of the implant component's distal bone cut and a posterior chamfer bone cut; **FIG. 67B** illustrates an FEA analysis of the same implant component;

[00090] **FIG. 68A** through **68C** illustrate femoral implant components includes five bone cuts, six bone cuts, and six flexed bone cuts, respectively;

[00091] **FIGS. 69A** through **69F** show exemplary cross-sections of femoral implant components with bone cuts shown as dashed lines;

[00092] **FIGS. 70A-70C** illustrate a femoral implant component having six bones cuts that include one or more parallel and non-coplanar facets;

[00093] **FIGS. 71A-71B** illustrate a femoral implant component having seven bones cuts that include one or more parallel and non-coplanar facets;

[00094] **FIG. 72** illustrates a resection cut facet separated from one or more corresponding facets by an intercondylar space and/or by a step cut;

[00095] **FIGS. 73A** and **73B** are schematic views of a femur and patella and exemplary resection cut planes;

[00096] **FIG. 74** is a schematic view of a sagittal plane of a femur with facet cuts indicated;

[00097] **FIGS. 75A** and **75B** illustrate a femoral implant component comprising an intercondylar housing (sometimes referred to as a "box");

[00098] **FIGS. 76A** and **76B** illustrate a femoral implant component comprising and intercondylar box (**FIG. 76A**) or intercondylar bars (**FIG. 76B**) and an engaging tibial implant component;

[00099] **FIG. 77** illustrates a femoral implant component comprising modular intercondylar bars or a modular intercondylar box;

[000100] **FIGS. 78A to 78C** illustrates how a patellar resection depth alters the resultant patellar resection profile;

[000101] **FIGS. 79A to 79F** illustrate an exemplary design of a knee implant, including a femoral component and a patella component;

[000102] **FIGS. 80A to 80C** depict three different types of step cuts separating medial and lateral resection cut facets on a patient's proximal tibia;

[000103] **FIGS. 81A through 81K** 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;

[000104] **FIG. 82** shows proximal tibial resection cut depths of 2 mm, 3 mm and 4 mm;

[000105] **FIG. 83** illustrates two embodiments of tibial implant components having slopped sagittal J-curves;

[000106] **FIGS. 84A through 84K** show various embodiments and aspects of cruciate-sacrificing femoral implant components and **FIGS. 84L through 84P** show lateral views of different internal surfaces of intercondylar boxes;

[000107] **FIGS. 85A and 85B** 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;

[000108] **FIG. 86A** is a flow chart for adapting a blank implant component for a particular patient; **FIG. 86B** illustrates various tibial cuts and corresponding surface features;

[000109] **FIG. 87A** 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. 87B** 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. 87C** illustrates sketched overlays used to identify the centers of tubercles and the centers of one or both of the lateral and medial plateaus;

[000110] **FIGS. 88A to 88C** illustrate one or more axes that can be derived from anatomic sketches;

[000111] **FIG. 89A** 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. 89B** and **89C** illustrate an implant selected and/or designed to have 90% coverage of the patient's cut tibial surface;

[000112] **FIGS. 90A to 100C** describe exemplary steps for performing resection cuts to the tibia using the anatomical references identified above;

[000113] **FIGS. 101A to 101C** show exemplary strategies for establishing proper tibial rotation for a patient;

[000114] **FIG. 102** illustrates exemplary stem design options for a tibial tray;

[000115] **FIGS. 103A** and **103B** 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 applied in the selection and/or design of the tibial tray perimeter profile and/or the tibial insert perimeter profile;

[000116] **FIGS. 104A** and **104B** show the same approach as described for **FIGS. 103A** and **103B**, but applied to a different patient having a smaller tibia (e.g., smaller diameter and perimeter length);

[000117] **FIGS. 105A to 105D** show four different exemplary tibial implant profiles, for example, having different medial and lateral condyle perimeter shapes;

[000118] **FIGS. 106A to 106F** illustrate patient-adapted femoral implants and resection cuts for each of the three patients.

[000119] **FIGS. 107A** and **107B** illustrate all-in-one femoral resection guide tools for each of two patients;

[000120] **FIG. 108** illustrates a drill guide attachment for attaching to the all-in-one guide tool;

[000121] **FIGS. 109A, 109B,** and **109C** show various too attachments for the all-in-one guide tool to extend one or more cutting surfaces;

[000122] **FIGS. 110A, 110B, and 110C** illustrate a set of three guide tools, which collectively supplied all of the guide slots and holes to perform each of several predetermined femoral resection cuts and peg hole placements;

[000123] **FIGS. 111A through 111F** illustrate a different set of femoral guide tools to perform each of several predetermined femoral resection cuts and peg hole placements;

[000124] **FIGS. 112A and 112B** illustrate an anterior profile guide tool for assessing the peak profile at the anterior portion of the femur in the installed implant as compared to the patient's native knee;

[000125] **FIG. 113A** illustrates a cutting guide tool for accurately resectioning the proximal tibia; **FIG. 113B** illustrates an alternate tibial cutting guide tool; **FIG. 113C** illustrates a tibial alignment guide tool and down rod for confirming prior the alignment of the cutting guide tool; **FIG. 113D** illustrates a resected tibia marked with a pen or other instrument to establish landmarks for placement of subsequent tools;

[000126] **FIG. 114A** illustrates a tibial keel prep guide tool; **FIG. 114B** illustrates a set of tibial keel prep insert guides;

[000127] **FIG. 115** illustrates a tibial keel prep guide tool for establishing the keel slot in the patient's resected proximal tibial surface;

[000128] **FIG. 116A and 116B** illustrates an alternative tibial keel prep guide tool;

[000129] **FIG. 117A** illustrates a set of tibial trial spacers; **FIG. 117B** illustrates a set of tibial implant component trial inserts;

[000130] **FIGS. 118A through 118D** show exemplary steps in a surgical implantation procedure;

[000131] **FIG. 119A** illustrates a set of patella sizers; **FIG. 119B** illustrates a patellar cutting tool to cut the patella to a predetermined depth of resection; **FIG. 119C** illustrates implant trials; **FIG. 119D** illustrates a patellar implant;

[000132] **FIG. 120** is a flow chart illustrating a process that includes selecting and/or designing an initial patient-adapted implant;

[000133] **FIG. 121** is a flow chart illustrating a process that includes selecting and/or designing a second patient-adapted implant;

[000134] **FIG. 122A** depicts a normal humeral head and upper humerus which forms part of a shoulder joint;

[000135] **FIG. 122B** depicts a humeral head having an alignment jig designed to identify and located various portions of the humeral anatomy;

[000136] **FIG. 122C** depicts an alternative embodiment of a humeral head jig that utilizes an alternative conforming surface to align the jig;

[000137] **FIG. 123A** depicts a humeral head with osteophytes;

[000138] **FIGS. 123B** and **123C** depict the humeral head of **FIG. 123A** with a more normalized surface that has been corrected by virtual removal of the osteophytes;

[000139] **FIG. 124A** depicts a humeral head with voids, fissures or cysts;

[000140] **FIGS. 124B** and **124C** depict the humeral head of **FIG. 124A** with a more normalized surface that has been corrected by virtual removal of the voids, fissures or cysts;

[000141] **FIG. 125A** depicts a healthy scapula of a shoulder joint;

[000142] **FIG. 125B** depicts a normal glenoid component of a shoulder joint;

[000143] **FIG. 125C** depicts an alignment jig for use with the glenoid of **FIG. 125B**;

[000144] **FIG. 125D** depicts a milling and/or reaming operation of the glenoid of **FIG. 125C**;

[000145] **FIG. 126A** depicts a glenoid component with osteophytes;

[000146] **FIG. 126B** depicts the glenoid component of **FIG. 126A** with a more normalized surface that has been corrected by virtual removal of the osteophytes;

[000147] **FIGS. 126C** and **126D** depict two alternative embodiments of a glenoid jig for use with the glenoid of **FIG. 126A**, each of which incorporates conforming surfaces that accommodate the osteophytes;

[000148] **FIG. 127A** depicts a glenoid component with voids, fissures or cysts;

[000149] **FIG. 127B** depicts the glenoid component of **FIG. 127A** with a more normalized surface that has been corrected by virtual “filling” of the voids, fissures or cysts;

[000150] **FIG. 127C** depicts an embodiment of a glenoid jig for use with the glenoid component of **FIG. 127A**, which incorporates various conforming surfaces that accommodate the voids, fissures and/or cysts (and other surfaces) of the glenoid component;

[000151] **FIG. 128A** and **128B** show exemplary unicompartmental medial and lateral tibial implant components without (**FIG. 128A**) and with (**FIG. 128B**) a polyethylene layer or insert; and

[000152] **FIGS. 129A** and **129B** show exemplary flow charts for deriving a medial tibial component slope (**FIG. 129A**) and/or a lateral tibial component slope (**FIG. 129B**) for a tibial implant component.

[000153] 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; “A” and “P” in certain figures indicate anterior and posterior sides of the view, and “S” and “I” in certain figures indicate superior and inferior sides of the view.

HEADINGS

[000154] The headings used herein are for convenience only. The headings do not purport to define, limit, or extend the scope or intent of the language of the sections and/or the paragraphs to which they pertain.

INCORPORATION BY REFERENCE

[000155] 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

[000156] 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.

DETAILED DESCRIPTION**DESIGN AND/OR SELECTION OF SURGICAL PROCEDURES AND TOOLS**

[000157] The preoperative imaging, anatomical modeling and design/selection of surgical implants, tools and procedural steps provides an opportunity for the creation of a wide variety of surgical procedures, guide tools and associated implant components to accommodate various treatment goals including the correction of joint and extremity defects and/or deformities as well as the accommodation of a wide variety of anatomical structures. The virtually unlimited number of potential implant sizes and/or shapes that can be designed and/or selected, in combination with the opportunity for a personalized surgical plan and guide tools, allows a physician to optimize the joint repair in many ways, including (1) minimizing unnecessary bone resection, (2) restoring and/or improving joint kinematics and alignment, (3) reducing or minimizing implant wear, fracture and/or fatigue, (4) improving aesthetics of the joint repair, and (5) simplifying the surgical procedure and removing a significant amount of surgical "guesswork."

[000158] In various embodiments, designs and strategies for resectioning a patient's biological structure 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.

[000159] In various embodiments, the patient-engineered bone cuts can be selected and/or designed from patient-specific data to minimize the amount of bone resected in one or more corresponding predetermined resection cuts. In certain embodiments, the patient-engineered bone cuts substantially negatively-match one or more predetermined resection cuts. The predetermined resection cuts can be made at a first depth that allows, in a subsequent procedure, removal of additional bone to a second depth required for a traditional primary implant component.

[000160] In another aspect, embodiments described herein provide methods for minimizing resected bone from, and/or methods for making an articular implant for, a single patient in need of an articular implant replacement procedure. These methods can include (a) identifying unwanted tissue from one or more images of the patient's joint; (b) identifying a combination of resection cuts and implant component features that remove the unwanted tissue and also provide maximum bone preservation; and (c) selecting and/or designing for the patient a combination of resection cuts and implant component features that provide removal of the unwanted tissue and maximum bone preservation. In certain embodiments, the unwanted tissue is diseased tissue or deformed tissue.

[000161] In certain embodiments, a measure of bone preservation can include total volume of bone resected, volume of bone resected from one or more resection cuts, volume of bone resected to fit one or more implant component bone cuts, average thickness of bone resected, average thickness of bone resected from one or more resection cuts, average thickness of bone resected to fit one or more implant

component bone cuts, maximum thickness of bone resected, maximum thickness of bone resected from one or more resection cuts, maximum thickness of bone resected to fit one or more implant component bone cuts.

[000162] In other aspects, embodiments described herein include procedures selected and/or designed to accommodate a femoral implant component that includes (a) a joint-facing surface comprising a bearing surface portion, and (b) a bone-facing surface comprising a distal bone cut having two or more planar facets or portions that are non-coplanar with each other. In certain embodiments, the two or more facets or portions are non-parallel with each other. The first of the two or more facets or portions can be on a lateral condyle bone-facing surface and the second can be on a medial condyle bone-facing surface.

[000163] In other aspects, embodiments described herein include procedures selected and/or designed to accommodate a femoral implant component that includes (a) a joint-facing surface comprising a bearing surface portion, and (b) a bone-facing surface comprising an anterior bone cut having two or more planar facets or portions that are non-coplanar with each other. In certain embodiments, the two or more planar facets or portions are non-parallel with each other.

[000164] In other aspects, embodiments described herein include procedures selected and/or designed to accommodate a femoral implant component that includes (a) a joint-facing surface comprising a bearing surface portion, and (b) a bone-facing surface comprising a posterior bone cut having two or more facets or portions that are non-parallel with each other. In certain embodiments, the first of the two or more facets or portions can be on a lateral condyle bone-facing surface and the second can be on a medial condyle bone-facing surface.

[000165] In other aspects, embodiments described herein include procedures selected and/or designed to accommodate a femoral implant component that includes (a) a joint-facing surface comprising a bearing surface portion, and (b) a bone-facing surface comprising an anterior chamfer bone cut having two or more planar facets or portions that are non-coplanar with each other. In certain embodiments, the two or more planar facets or portions are non-parallel with each

other. The first of the two or more facets or portions can be on a lateral condyle bone-facing surface and the second can be on a medial condyle bone-facing surface.

[000166] In other aspects, embodiments described herein accommodate a femoral implant component that includes (a) a joint-facing surface comprising a bearing surface portion, and (b) a bone-facing surface comprising a posterior chamfer bone cut having two or more facets or portions that are non-parallel with each other. In certain embodiments, the first of the two or more facets or portions can be on a lateral condyle bone-facing surface and the second can be on a medial condyle bone-facing surface.

[000167] In other aspects, embodiments described herein accommodate a femoral implant component that includes (a) a lateral and medial condylar portions, and (b) a bone-facing surface comprising a distal bone cut facet that is asymmetric about its center line in a sagittal plane. In certain embodiments, the asymmetric distal bone cut facet lies on the bone-facing surface of the lateral condyle. In certain embodiments, the femoral implant component can include asymmetric distal bone cut facets that lie on the bone-facing surface of the medial condyle.

[000168] In other aspects, embodiments described herein accommodate a femoral implant component that includes a femoral implant component having a bone-facing surface comprising one or more bone cuts, wherein at least one of the one or more bone cuts comprises two planar bone cut facets separated by at least one step cut. In certain embodiments, the step cut is substantially perpendicular to at least one of the bone cut facets. In certain embodiments, the step cut can rise or fall at about 30 degrees or more from at least one of the bone cut facet planes.

[000169] Accordingly, certain embodiments described herein are directed surgical procedures and methods, and associated tool and implant components, 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.

GENERATING AN ANATOMICAL MODEL

[000170] One initial step in the design and/or selection of a surgical plan and guide tools (and associated implant components) is the creation of an anatomical model (or other image/data set) of a targeted patient anatomy. A variety of methods, systems and techniques for obtaining and using image data and/or deriving anatomical models are described herein, and the use of such techniques with the procedures and methods described herein is intended.

[000171] 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. 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). 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 and, 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.

[000172] If desired, various types of data can be presented as part of a model, for example, a patient-specific virtual model that includes the biological feature of interest. Optionally, the data associated with one or more biological features can be transferred to one or more resection cuts, drill holes, guide tools, and/or implant

components, which also can be included as part of the same model or in a different model. The virtual model(s) can be used to generate one or more patient-adapted guide tools and/or implant components for surgical use, for example, using computer-aided design (CAD) software and/or one or more of the several manufacturing techniques described below, optionally in conjunction with computer-aided manufacturing (CAM) software.

[000173] As described herein, the various models contemplated herein can include one or more patient-specific models reflecting an actual patient's anatomy, as well as one or more modified models that reflects variations, modifications and/or optimizations of the patient's anatomy. The patient-specific model and/or modified model data can be used for selection and/or design of resection cuts, guide tools, and/or implant components, which can be included in the same model or in a different model.

[000174] For example, the various models and/or model data can be exported to a CAD program, for example, SolidWorks, to design one or more patient-engineered resection cuts, patient-specific guide tools, and/or patient-adapted implant components. Alternatively or in addition, the models and/or model data can be exported to a library, for example, to be included in the library as a template model for future assessments and/or for selecting from the library one or more resection cut strategies, guide tools, and/or implant components.

MODIFYING, ALTERING AND/OR OPTIMIZING AN ANATOMICAL MODEL

[000175] Various disclosures herein encompass and contemplate the use of modified, altered and/or optimized patient-specific models (i.e., variations) in creating surgical procedures that address, modify and/or correct anatomical features including abnormalities, defects, mis-alignments and/or for other purposes. Once a proper or otherwise desirable 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., designed and/or selected

components, including components having variable thicknesses to address misalignment).

[000176] In various embodiments, models including variations can be used to select and/or design a patient-adapted surgical procedure to address the deformity or abnormality. For example, the variation can include surgical alterations to the joint, such as virtual resection cuts, virtual drill holes, virtual removal of osteophytes, and/or virtual building of structural support in the joint deemed necessary or beneficial to a desired final outcome for a patient.

[000177] Correcting a joint deformity and/or a limb alignment deformity can include, for example, generating a virtual model of the patient's joint, limb, and/or other relevant biological structure(s); virtually correcting the deformity and/or aligning the limb; and selecting and/or designing one or more surgical steps (e.g., one or more resection cuts), one or more guide tools, and/or one or more implant components to physically perform and/or accommodate the correction.

[000178] Preserving or restoring one or more features of a patient's biology can include, for example, selecting and/or designing one or more surgical steps (e.g., one or more resection cuts), one or more guide tools, and/or one or more implant components so that one or more of the patient's postoperative implant features substantially match the patient's preoperative biological features or the patient's healthy biological features (e.g., as identified from a previous image of the patient's joint when it was healthy or from an image of the patient's contralateral healthy joint).

[000179] Enhancing one or more features of a patient's biology can include, for example, selecting and/or designing one or more surgical steps (e.g., one or more resection cuts), one or more guide tools, and/or one or more implant components so that the implant component(s), once implanted, includes features that approximate one or more features of a healthy biological feature for the particular patient.

[000180] Preservation or restoration of the patient's joint kinematics can include, for example, selecting and/or designing one or more surgical steps (e.g., one or more resection cuts), one or more guide tools, and/or one or more implant components so that the patient's post-operative joint kinematics substantially match the patient's pre-

operative joint kinematics and/or substantially match the patient's healthy joint kinematics (e.g., as identified from previous images of the patient's joint when it was healthy or from an image of the patient's contralateral healthy joint) and/or match a desired kinematics derived from anatomical models or other sources.

[000181] Enhancing the patient's joint kinematics can include, for example, selecting and/or designing one or more surgical steps (e.g., one or more resection cuts), one or more guide tools, and/or one or more implant components that provide healthy joint kinematics estimated for the particular patient and/or that provide proper joint kinematics to the patient. Optimization of joint kinematics also can include optimizing ligament loading or ligament function during motion.

[000182] Preservation or restoration of the patient's joint-line location and/or joint gap width can include, for example, selecting and/or designing one or more surgical steps (e.g., one or more resection cuts), one or more guide tools, and/or one or more implant components so that the patient's joint-line and or joint-gap width substantially match the patient's existing joint-line and or joint-gap width or the patient's healthy joint-line and/or joint-gap width (e.g., as identified from previous images of the patient's joint when it was healthy or from an image of the patient's contralateral healthy joint).

[000183] Enhancing the patient's joint-line location and/or joint gap width can include, for example, selecting and/or designing one or more surgical steps (e.g., one or more resection cuts), one or more guide tools, and/or one or more implant components that provide a healthy joint-line location and/or joint gap width and/or estimated for the particular patient and/or that provide proper kinematics to the patient.

PROCEDURES TO CORRECT MISALIGNMENT

[000184] In various embodiments, it may be desirable to modify or alter the alignment and/or kinematics of a treated joint or limb, as compared to its pre-operative condition. 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 an surgical procedure, including associated tools and

surgical joint implant components. For example, based on the difference between a detected patient's misalignment and a determined "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.

[000185] A preoperatively designed and/or selected implant or implant component, resection dimension(s), and/or cutting jig(s) can be employed in various combinations to correct a patient's alignment deformity in a single plane, for example, in the coronal plane or in the sagittal plane, in multiple planes, for example, in the coronal and sagittal planes, and/or in three dimensions. Various embodiments described herein describe virtual models of a patient's misaligned lower limb and virtually corrected models of the limb. In particular, the patient's lower limb may be misaligned in the coronal plane, for example, a valgus or varus deformity. The deformity correction can be achieved by designing and/or selecting one or more of a resection dimension, an implant component thickness, and an implant component surface curvature that adjusts the mechanical axis or axes into alignment in one or more planes. For example, a lower limb misalignment can be corrected in a knee replacement by designing or selecting one or more of a femoral resection dimension, a femoral implant component thickness, a femoral implant component surface curvature, a tibial resection dimension, a tibial implant component thickness, a tibial implant component insert thickness, and a tibial implant component surface curvature to adjust the femoral mechanical axis and tibial mechanical axis into alignment in the coronal plane.

[000186] **FIG. 1** illustrates a coronal plane of a 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. Selected and/or designed resection dimensions can be achieved using 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. 1**, certain combinations of resection cuts can aid in bringing the femoral mechanical axis **1612** and tibial mechanical axis **1614** into alignment **1616**.

[000187] **FIG. 2** illustrates a virtual model of a patient's limb that is misaligned in the sagittal plane, for example, a genu antecurvatum deformity, and the virtually corrected limb. As previously discussed, the deformity correction can be achieved using a similar design approach as described for a coronal plane deformity.

[000188] The resection cuts and guide tools, and optionally the joint implant components, including the bone-facing surface(s), can be selected and/or designed to include one or more features that achieve an anatomic or near anatomic fit with the existing surface or with a resected surface of the joint. Moreover, the joint implant component joint-facing surface, and optionally the resection cuts and guide tools, can be selected and/or designed, for example, to replicate the patient's existing joint anatomy, to replicate the patient's healthy joint anatomy, to enhance the patient's joint anatomy, and/or to optimize fit with an opposing implant component.

Accordingly, both the existing surface of the joint and the desired resulting surface of the joint can be assessed. This technique can be particularly useful for implants that are not anchored into the bone.

[000189] From a three-dimensional perspective, the lower extremity of the body ideally functions within a single plane known as the median anterior-posterior plane (MAP-plane) throughout the flexion-extension arc. In order to accomplish this, the femoral head, the mechanical axis of the femur, the patellar groove, the intercondylar notch, the patellar articular crest, the tibia and the ankle remain within the MAP-plane during the flexion-extension movement. During movement, the tibia rotates as the

knee flexes and extends in the epicondylar axis, which is perpendicular to the MAP-plane.

[000190] Various features of the patient-adapted implant components, including bone cut angles, bone cut slopes, bone cut number, implant thickness in one or more portions, joint facing curvature, implant component thickness, and other features, can be selected and/or designed, at least in part, to optimize the parameter of deformity correction and/or limb alignment, for example, using the virtual alignment method described herein. Optionally, one or more other parameters can simultaneously be factored into the selection and/or design of implant component features. For example, in addition to limb alignment, the implant component features also can be selected or designed meet one or more of the following parameters: (1) preserving, restoring, or enhancing the patient's joint kinematics; (2) deformity correction; (3) maximizing preservation of bone cartilage, or ligaments (e.g., resulting from the resection); (4) maximizing preservation and/or optimization of other features of the patient's anatomy, such as trochlea and trochlear shape; (5) restoration or optimization of joint-line location and/or joint gap width, and (6) preservation, restoration, or enhancement of other target features.

MODELS FOR PATIENT/PHYSICIAN USE

[000191] In certain embodiments, models can be generated to show defects of interest in a patient's joint. For example, a model or set of models of a patient's joint can be generated showing defects of interest and, optionally, another model or set of models can be generated showing no defects (e.g., as defect and reference, or before and after models). Alternatively, or in addition, the same or additional models can be generated with and/or without resection cuts, guide tools, and/or implant components positioned in the model. Moreover, the same or additional models can be generated to show defects of interest that interfere with one or more resection cuts, guide tools, and/or implant components. Such models, showing defects of interest, resection cuts, guide tools, implant components, and/or interfering defects of interest, can be particularly useful as a reference or guide to a surgeon or clinician prior to and/or during surgery, for example, in identifying proper placement of a guide

tool or implant component at one or more steps in a surgery, and/or in identifying features of a patient's anatomy that he or she may want to alter during one or more steps in a surgery. Accordingly, such models that provide, for example, patient-specific renderings of implant assemblies and defects of interest (e.g., osteophyte structures) together with bone models, are useful in aiding surgeons and clinicians in surgery planning and/or during surgery.

[000192] In various embodiments, a patient-specific *bone-surface model* is obtained and/or rendered. Desirably, the bone surface model provides basic patient-specific features of the patient's biological structure and can be used for a wide variety of purposes, including as a source of patient anatomical surface information as well as a reference for comparison against a model or value that may include a defect(s) of interest. As an illustrative example, previously generated patient-specific files, for example, STL files exported from "SOLID" IGES files in SolidWorks, can be loaded, for example, as triangulation points with sequence indices and normal vectors. The triangles then can be rendered (e.g., using Matlab TRISURF function) to supply or generate the bone-surface model. The bone surface model can include corrections of defects, such as osteophytes removed from the bone. In a similar fashion, one or more guide tool models can be obtained and/or rendered.

[000193] Next, optionally, the models can be used to detect interference between any defect volume and the placement of one or more guide tools and/or implant components. For example, guide tool model triangulation points can be transformed onto an image volume space to obtain a binary representation of the guide tool. The binary structure then can be manipulated (e.g., dilated and eroded using voxel balls having pre-set diameters) to obtain a solid field mask. The solid field mask can be compared against the defect volume, for example, the *osteophyte binary volume*, to identify interfering defect volume, for example, *interfering osteophyte binary volume*. In this way, interfering defect volume and non-interfering defect volume can be determined (e.g., using Matlab ISOSURFACE function), for example, using representative colors or some other distinguishing features in a model. See, e.g., **FIGS. 3A and 4A**. The resulting model image can be rendered on a virtual rendering

canvas (e.g., using Matlab GETFRAME function) and saved onto a computer-readable medium.

[000194] Finally, optionally, as exemplified by **FIGS. 3A-3B** and **4A-4B**, one or more combinations of model features can be combined into one or models or sets of models that convey desired information to the surgeon or clinician. For example, patient-specific bone models can be combined with any number of defects or defect types, any number of resection cuts, any number of drill holes, any number of axes, any number of guide tools, and/or any number of implant components to convey as much information as desired to the surgeon or clinician. The patient-specific bone model can model any biological structure, for example, any one or more (or portion of) a femoral head and/or an acetabulum; a distal femur, one or both femoral condyle(s), and/or a tibial plateau; a trochlea and/or a patella; a glenoid and/or a humeral head; a talar dome and/or a tibial plafond; a distal humerus, a radial head, and/or an ulna; and a radius and/or a scaphoid. Defects that can be combined with a patient-specific bone model can include, for example, osteophytes, voids, subchondral cysts, articular shape defects (e.g., rounded or flattened articular surfaces or surface portions), varus or valgus deformities, or any other deformities known to those in the art.

[000195] The models can include virtual corrections reflecting a surgical plan, such as one or more of removed osteophytes, cut planes, drill holes, realignments of mechanical or anatomical axes. The models can include comparison views demonstrating the anatomical situation before and after applying the planned correction. The individual steps of the surgical plan can also be illustrated in a series of step-by-step images wherein each image shows a different step of the surgical procedure.

[000196] In certain embodiments, a model or set of models of a patient's biological structure are obtained and/or generated to show one or more defects of interest, one or more resection cuts, one or more guide tools, one or more implant components, and/or a combination of any of these. For models that include defects of interest, the defects can be categorized and differentiated into various groups and

displayed on the model or set of models in any way that conveys the appropriate information to a surgeon or clinician. For example, two or more defects can be differentiated into categories based on defect type, defect location, severity of the defect, potential interference with a guide tool or implant component, and/or any one or more other useful categories.

[000197] In certain embodiments, one or more additional models or set of models of the patient's biological structure also can be generated and conveyed to the surgeon or clinician to show an additional presence, or absence, of one or more defects of interest, one or more resection cuts, one or more guide tools, and/or one or more implant components, or any combination of these, including models shown in **FIGS. 3A, 3B, 4A and 4B**.

ASSESSMENT AND WEIGHTING OF PARAMETERS IN SELECTION/DESIGN

[000198] Assessment and/or weighting of various parameters, either alone or in combination with other 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 resection cut features and feature measurements and one or more selected guide tool features and feature measurements (as well as selected implant component 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. Assessment of parameters can include any combination of features within and/or between implant components, guide tools and/or surgical procedure steps.

[000199] The assessment process can be iterative in nature. For example, one or more first parameters can be assessed and the related implant component and/or resection cut features and feature measurements tentatively or conditionally can be

determined. Next, one or more second parameters can be assessed and, optionally, one or more features and/or feature measurements determined. Then, the tentative or conditional features and/or feature measurements for the first assessed parameter(s) optionally can be altered based on the assessment and optional determinations for the second assessed parameters. The assessment process can be fully automated or it can be partially automated allowing for user interaction. User interaction can be particularly useful for quality assurance purposes.

[000200] In the assessment, different weighting can be applied to any of the parameters or parameter thresholds, for example, based on the patient's age, the surgeon's preference or the patient's preference. Feedback mechanisms can be used to show the user or the software the effect that certain feature and/or feature measurement changes can have on desired changes to parameters values, e.g., relative to selected parameter thresholds. For example, a feedback mechanism can be used to determine the effect that changes in features intended to maximize bone preservation (e.g., implant component thickness(es), bone cut number, cut angles, cut orientations, and related resection cut number, angles, and orientations) have on other parameters such as limb alignment, deformity correction, and/or joint kinematic parameters, for example, relative to selected parameter thresholds. Accordingly, implant component features and/or feature measurements (and, optionally, resection cut and guide tool features and/or feature measurements) can be modeled virtually and modified reiteratively to achieve an optimum solution for a particular patient.

[000201] 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.

[000202] Certain embodiments described herein include generating and/or using a model, for example, a virtual model, of the patient's joint that includes selected parameters and/or parameter measurements and virtually selecting and/or designing one or more implant components, and optionally resection cuts and/or guide tools to fit the virtual model in accordance with the selected parameters and/or parameter measurements. This approach allows for iterative selection and/or design improvement and can include steps to virtually assess fit relative to the selected parameters and/or parameter measurements, such as (1) correction of a 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.

[000203] **FIG. 5** is a flow chart illustrating the process of assessing and selecting and/or designing one or more implant component features and/or feature measurements, and, optionally assessing and selecting and/or designing one or more resection cut features and feature measurements, for a particular patient. Using the techniques described herein or those suitable and known in the art, one or more of the patient's biological features and/or feature measurements are obtained **2600**. In addition, one or more variable implant component features and/or feature measurements are obtained **2610**. Optionally, one or more variable resection cut features and/or feature measurements are obtained **2620**. Moreover, one or more variable guide tool features and/or feature measurements also can optionally be obtained. Each one of these step can be repeated multiple times, as desired.

[000204] The obtained patient's biological features and feature measurements, implant component features and feature measurements, and, optionally, resection cut and/or guide tool features and/or feature measurements then can be assessed to determine the optimum implant component features and/or feature measurements, and optionally, resection cut and/or guide tool features and/or feature measurements, that achieve one or more target or threshold values for parameters of interest **2630** (e.g., by maintaining or restoring a patient's healthy joint feature). As noted, parameters of interest can include, for example, one or more of (1) joint deformity correction; (2) limb alignment correction; (3) bone, cartilage, and/or ligaments preservation 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. This step can be repeated as desired. For example, the assessment step **2630** can be reiteratively repeated after obtaining various feature and feature measurement information **2600**, **2610** and **2620**.

[000205] Once the one or more optimum implant component features and/or feature measurements are determined, the implant component(s) can be selected **2640**, designed **2650**, or selected and designed **2640**, **2650**. For example, an implant component having some optimum features and/or feature measurements can be designed using one or more CAD software programs or other specialized software to optimize additional features or feature measurements of the implant component. One or more manufacturing techniques described herein or known in the art can be used in the design step to produce the additional optimized features and/or feature measurements. This process can be repeated as desired.

[000206] In a similar manner, various embodiments of the assessment process can include selecting and/or designing one or more features and/or feature measurements of an implant component and, optionally, of a corresponding resection cut strategy and/or guide tool that is adapted (e.g., patient-adapted based on one or

more of a particular patient's biological features and/or feature measurements) to achieve or address, at least in part, the previously-listed parameters for the particular patient, each of which can be given a different relative weight, if desired.

[000207] In various additional steps, one or more resection cut features and/or feature measurements can optionally be selected **2660**, designed **2670**, or selected and further designed **2660**, **2670**. For example, a resection cut strategy selected to have some optimum features and/or feature measurements can be designed further using one or more CAD software programs or other specialized software to optimize additional features or measurements of the resection cuts, for example, so that the resected surfaces substantially match optimized bone-facing surfaces of the selected and designed implant component. This process can be repeated and/or various features can be modified, as desired.

[000208] Once optimum features and/or feature measurements for the implant component, and optionally for the resection cuts and/or guide tools, have been selected and/or designed, the implant site can be prepared, for example by removing cartilage and/or resectioning bone from the joint surface, and the implant component can be implanted into the joint **2680**.

COMPUTER AIDED OPTIMIZATON

[000209] Optimization of multiple parameters may result in conflicting constraints; for example, optimizing one parameter may cause an undesired deviation to one or more other parameters. In cases where not all constraints can be achieved at the same time, parameters can be assigned a priority or weight in the software program. The priority or weighting can be automated (e.g., part of the computer program) and/or it can be selected by a user depending on the user's desired design goals, for example, minimization of bone loss, or retention of existing joint-line to preserve kinematics, or combination to accommodate both parameters in overall design. As an illustrative example, in certain embodiments, selection and/or design of a knee implant can include obtaining patient-specific information (e.g., from radiographic images or CT images) of a patient's knee and inputting that information into the computer program to model features such as minimum thickness of femoral

component (to minimize resected bone on femur), tibial resection cut height (to minimize resected bone on tibia), and joint-line position (preferably to preserve for natural kinematics). These features can be modeled and analyzed relative to a weighting of parameters such as preserving bone and preserving joint kinematics. As output, one or more resection cut features, guide tool features, and/or implant component features that optimize the identified parameters relative to the selective weightings can be provided.

[000210] Any one or more steps of the assessment, selection, and/or design may be partially or fully automated, for example, using a computer-run software program and/or one or more robots. For example, processing of the patient data, the assessment of biological features and/or feature measurements, the assessment of implant component features and/or feature measurements, the optional assessment of resection cut and/or guide tool features and/or feature measurements, the selection and/or design of one or more features of a patient-adapted implant component, and/or the implantation procedure(s) may be partially or wholly automated. For example, patient data, with optional user-defined parameters, may be inputted or transferred by a user and/or by electronic transfer into a software-directed computer system that can identify variable implant component features and/or feature measurements and perform operations to generate one or more virtual models and/or implant design specifications, for example, in accordance with one or more target or threshold parameters. Implant selection and/or design data, with optional user-defined parameters, may be inputted or transferred by a user and/or by electronic transfer into a software-directed computer system that performs a series of operations to transform the data and optional parameters into one or more implant manufacturing specifications. Implant design data or implant manufacturing data, optionally with user-defined parameters, may be inputted or transferred by a user and/or by electronic transfer into a software-directed computer system that directs one or more manufacturing instruments to produce one or more implant components from a starting material, such as a raw material or starting blank material. Implant design data, implant manufacturing data, or implant data, optionally with user-defined parameters, may be inputted or transferred by a user and/or by electronic transfer

into a software-directed computer system that performs a series of operations to transform the data and optional parameters into one or more surgical procedure specifications or instructions. Implant design data, implant manufacturing data, implant data, or surgical procedure data, optionally with user-defined parameters, may be inputted or transferred by a user and/or by electronic transfer into a software-directed computer system that directs one or more automated surgical instruments, for example, a robot, to perform one or more surgical steps. In certain embodiments, one or more of these actions can be performed as steps in a single process by one or more software-directed computer systems.

[000211] In certain embodiments, the implant component includes one or more bone cuts on its bone-facing surface. Features of these bone cuts, and optionally features of corresponding resection cuts, can be optimized by a computer system based on patient-specific data. For example, the bone cut number and one or more bone cut planes, angles, or depths, as well as the corresponding resection cut number and one or more resection cut planes, angles, or depths, can be optimized, for example, 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 articular anatomy and geometry and/or on a target limb alignment and/or deformity correction. Optionally, one or more of the bone cut features and/or resection cut features can be adjusted by the operator.

RELATIONSHIPS BETWEEN PROCEDURE DESIGN AND IMPLANT

[000212] The design of an appropriate surgical procedure, and associated surgical tools, can occur at various points in the process of planning and/or preparing for a surgical procedure. In many cases, a chosen procedure can influence the ultimate design of the implant components in a variety of ways, and chosen implant designs can similarly influence one or more of the ultimate surgical procedure steps in a variety of ways. Various embodiments address many of the inter-relationships between the design and/or selection of the various implant components, surgical tools and/or surgical procedural steps of joint replacement and/or repair procedures as described herein.

“IMPLANT FIRST” DESIGN/SELECTION

[000213] In various embodiments, a surgeon and/or designer can design and/or select one or more implant components appropriate for a patient anatomy (or desired anatomy), and then design and/or select a series of appropriate surgical steps and procedures for preparing the patient's anatomy for placement and proper securement of the implant components. If desired, one or more implant components can be initially designed and/or selected using one or more models (or other image data) of the relevant patient anatomy. The selected implant components, and their effect upon the patient anatomy (or models thereof) can then be utilized to design and/or select one or more surgical procedures and surgical tools appropriate to creating the desired final joint anatomy structure, alignment and/or kinematics. In this approach, if the subsequent design/selection of the procedures/tools encounters difficulties and/or constraints, the implant components may be re-assessed and/or modified, and the design/selection process repeated.

[000214] An “implant first” approach may be particularly useful where an implant component and/or design thereof already exists and/or one or more components are manufactured/stockpiled. In such a case, it may be desirable to determine if one or more surgical procedures can be designed/selected that allow the use of one or more of the pre-existing component/design to accomplish the desired surgical repair/replacement, which could significantly reduce various costs and/or delays possible in designing and/or manufacturing a new component. In a similar fashion, this approach may be especially useful where a “blank” is utilized to create the implant component, as the chosen manufacturing process or processes can limit the final implant component's permitted variation from that of the one or more blank dimensions. Such constraints could also be due to surgical access limitations for introducing implant components. 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 and/or perimeter, and (c) implant composition and thickness.

[000215] 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. 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.

[000216] 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) can be designed (e.g., designed and manufactured) to include one or more patient-specific features and/or optimized features for a particular patient. 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) can be both selected and designed (e.g., designed and manufactured) to include one or more patient-specific features and/or optimized features for the particular patient. For example, an implant component having features that achieve certain parameter thresholds but having other features that do not achieve other parameter thresholds (e.g., a blank feature or a smaller or larger feature) can be selected, for example, from a library of implant components. The selected component then can be further designed (e.g. virtually designed and machined) to alter the blank or smaller or larger feature to be achieve the selected parameter, for example, a patient-specific or patient-engineered feature or feature measurement.

[000217] In various embodiments, implant bearing surfaces can combine patient-specific with standard features. For example the bearing surface of a femoral implant in the knee can have a patient-specific curvature in one direction and a standard curvature in another direction. One way to construct such a bearing surface is to generate one or more patient-specific curves for the first direction as shown in **FIG. 6A** (cyan, magenta and gray curves). These curves can be derived directly from the patient's 2D or 3D images such as CT or MRI scans or radiographs. The curves may also be constructed using measurements derived from the patient's anatomy, such as curvature radii or dimensions.

[000218] Once the patient-specific curves for the first direction have been constructed, a set of standard cross section profile curves can be calculated in the second direction along the patient-specific curves as illustrated in **FIG. 6A** (green curves). Each of the cross section profile curves can be the same. The curves can also be rotated with respect to each other. The standard properties of the cross section profile curves such as the curvature radius can change in a step by step fashion from profile to profile.

[000219] The profile curves can consist of standard segments, e.g. segments with a standard curvature radius. Different segments may have different curvature radii. The segments can be convex or concave. They can be connected to form smooth transitions between the segments.

[000220] Once the cross section profile curves have been defined, the bearing surface can be constructed, for example using a sweep operation, wherein the cross section profile curves are moved along the paths of the patient-specific curves to form a continuous surface as shown in **FIG. 6B**.

[000221] An implant component can include one or more selected features and one or more designed features. Alternatively or in addition, an implant component can include one or more features that are selected and designed or altered to be patient-specific or patient-engineered. Moreover, an implant component can include any number of selected and/or designed features derived from any number of patient-specific measurements, including one or more of the exemplary measurements

described above in **Table 1**. Depending on the clinical application a single or any combination or all of the measurements described in **Table 1** 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.

Table 1: 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

[000222] The patient-specific measurements selected for the evaluation can be used to select and/or design any selected implant features, including one or more of the exemplary features described in **Table 2**. The features can be selected and/or designed to be either patient-specific and/or patient-engineered.

Table 2: 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

Anatomical feature	Exemplary measurement
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 - 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

Anatomical feature	Exemplary measurement
Lateral condyle	- Resection surface at an intended resection level - 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 - 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

Anatomical feature	Exemplary measurement
	- 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 - 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

Anatomical feature	Exemplary measurement
	- 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 - 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

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
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 - 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
Femoral head	- 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

Anatomical feature	Exemplary measurement
Femoral neck	- Angle, e.g., resection cut angle - Anteversion or retroversion - Portions or all of bone perimeter at an intended resection level - Resection surface at an intended resection level
	- 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
	- Angle in one or more locations
	- Neck axis 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
	- Anteversion or retroversion
	- Leg length
	- Portions or all of cortical bone perimeter at an intended resection level
	- Resection surface at an intended resection level
Femoral shaft	- 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
	- Angle in one or more locations
	- Shaft axis in one or more locations
	- Curvature in one or more locations
	- Angle, e.g., resection cut angle
	- Anteversion or retroversion
	- Leg length
	- Portions or all of cortical bone perimeter at an intended resection level
	- Resection surface at an intended resection level
Acetabulum	- 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

Anatomical feature	Exemplary measurement
	- Slope in one or more locations and/or directions - Angle, e.g., resection cut angle - Anteversion or retroversion - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level
Glenoid	- 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 - Anteversion or retroversion - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level
Humeral head	- 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 - Anteversion or retroversion - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level
Humeral neck	- 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 - Angle in one or more locations - Neck axis 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

Anatomical feature	Exemplary measurement
Humeral shaft	- Anteversion or retroversion - Arm length - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level - 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 - Angle in one or more locations - Shaft axis in one or more locations - Curvature in one or more locations - Angle, e.g., resection cut angle - Anteversion or retroversion - Arm length - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level
Ankle joint	- 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
Elbow	- 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

Anatomical feature	Exemplary measurement
Wrist	- Resection surface at an intended resection level
	- 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
	- Resection surface at an intended resection level
Hand	- 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
	- Resection surface at an intended resection level
	- Resection surface at an intended resection level
Finger	- 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
	- Portions or all of cortical bone perimeter at an intended resection level
	- Resection surface at an intended resection level
	- Resection surface at an intended resection level
	- Resection surface at an intended resection level
Spine	- 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
Spinal facet joint	- 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

[000223] For example, one or more of an M-L measurement, an A-P measurement, and an S-I measurement of a patient's joint can be obtained from the subject preoperatively, for example, from one or more images of the subject's joint. Then, based on the one or more measurements, an implant or implant component for the subject's joint can be selected and/or designed preoperatively to include an M-L, A-P, and/or S-I measurement that is selected from a library to match the patient's M-L, A-P, and/or S-I measurement.

[000224] 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.

[000225] 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.

[000226] 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.

[000227] Once one or more of the implant components have been designed and/or selected, the process can include generating and/or using a model, for example, a virtual model, of the patient's joint that includes the selected measurements and virtually fitting one or more selected and/or designed implants into the virtual model. The selected/designed implant components, and their effect upon the patient anatomy (or models thereof) can then be utilized to design and/or

select one or more surgical procedures and surgical tools appropriate to creating the desired final joint anatomy structure, alignment and/or kinematics.

[000228] In this approach, if the subsequent design/selection of the procedures/tools encounters difficulties and/or constraints, the implant components may be re-assessed and/or modified, and the design/selection process repeated. This approach allows for iterative selection and/or design improvement and can include steps to virtually assess the fit, such as virtual kinematics assessment.

[000229] One exemplary embodiment describes methods and rationales for performing an anterior bone cut on a targeted femur of a patient, in preparation for receiving a patient-specific implant. The anterior cut can be placed to satisfy one or more conditions and/or constraints, which can include: (1) placement relative to anterior cortex, e.g. to avoid notching, (2) angle with a selected biomechanical axis, (3) angle with a selected anatomical axis, (4) desired angle with a peg axis, (5) desired angle relative to a posterior cut, (6) angle with epicondylar axis or posterior condylar axis, (7) desired patellar coverage, (8) desired thickness of the implant, (9) desired thickness of bone resection (e.g. medial trochlear peak, lateral trochlear peak, trochlear groove), and (10) desired position relative to femoral shaft to avoid notching. If desired, the intended cut can be shifted along one, two, three or more degrees of freedom.

[000230] For example, a desired anterior cut can be placed by: (1) determining the flexion-extension angle to be divergent from the mechanical axis (e.g. in the sagittal plane), (2) determining the internal-external rotation to balance the resection of the medial and lateral trochlear surfaces, or alternatively, the lateral trochlear resection may be larger than the medial trochlear resection, and (3) determining the A-P position (depth) depth of cut plane to maximize patellar coverage without notching femoral cortex. In an alternative embodiment, the internal-external rotation and depth of the anterior cut can be determined to minimize implant thickness without compromising fatigue strength. In another embodiment, the anterior cut angle can be determined to maximize cement compression. In another embodiment, the anterior cut angle can be determined to facilitate implant insertion.

[000231] In many embodiments, the anterior cut can “drive” the ultimate design of at least a portion of the implant, and because the implant profile is typically designed to satisfy different (often competing) criteria, the anterior cut can be critical to proper implant design. For example, the implant profile can be shaped to optimize patellar tracking. The profile on the contralateral condyle can be shaped to optimize patellar coverage while also avoiding impingement with the contralateral meniscus/tibia, for example with a “teardrop” extension near the femoral notch that curves anteriorly away from the meniscal edge along the sulcus. The implant may also be tapered into the bone on the contralateral condyle to smoothen the transition between implant and articular surface for patellar tracking.

[000232] **FIG. 7A** depicts a first step of rotating the implant 2 degrees about the profile view x-axis to create the anterior cut. A default line appears on the model along with a set of three distance values listed in the top toolbar. These numbers represent the bone resection values in millimeters above the line to the highest point of the femur at the left, middle, and right of the femur in the current view. The middle value can be adjusted from 1.5mm to 4mm to achieve the best patella coverage. The operator can try to minimize resection by starting with the 1.5mm value; the value will highlight in red if it falls below 1.5mm. The line pivots at the center of the femur as the designer drags the line. The operator will pivot the line until the resection value on the lateral side is approximately 2mm greater than the value on the medial side.

[000233] **FIG. 7B** depicts a preview of the cut, showing a desired characteristic “butterfly” shape. In this view the two sides of the condyle are connected and the lobes are not necessarily equal in size; the lateral lobe is generally larger.

[000234] **FIG. 7C** shows an example of where the anterior cut stretches too far beyond the anterior ridge of cartilage. It is recommended that an operator reduce the central thickness of the cut to the minimum 1.5mm, and if that does not bring the cut closer to the anterior ridge, increase the Profile View X-angle by increments of 1 degree and create the anterior cut again.

[000235] **FIG. 7D** shows a display of the patella surface in transparency mode. The design goal is to have a minimum 1/3 coverage area of the patella - larger area if

possible - with the smallest resection value. Looking normal to the anterior cut surface, the operator may imagine a line linking the two sides of the anterior cut as shown below. The operator can adjust the middle value sparingly on the ***Make Anterior Cut*** function to increase coverage.

[000236] **FIG. 7E** assists the operator by sketching the contra-lateral profile (“left” in this example) when the operator clicks on the mesial border of the existing condyle sketch in the notch area. The sketch should hug the mesial edge of the notch within 1-2mm of the visible edge. To create an arc as in the teardrop area, click at the start point of the arc, then press “a” on the keyboard to continue the spline as an arc. The teardrop falls below the sulcus to the “9:00” or the “3:00” position depending on the condyle. The operator may need to look at and adjust the position of the teardrop in relation to the tibia: it should fall within the anterior rise of the spine. The teardrop is typically 5-6mm in diameter and transitions to an approximate 15mm diameter arc across the contra-lateral condyle and is capped by an approximate 4-5mm diameter arc tangent to the sulcus on medial implants. On lateral implants, the final point of the arc on the contra-lateral sketch falls below the anterior cut and therefore below the sulcus. The operator can finish the contra-lateral profile by crossing over the distal edge of the anterior cut and sketching within 2mm of the side cut edge until the sketch crosses over the anterior cut.

[000237] **FIGs 7F and 7G** show medial and lateral views, respectively, of a taper sketch outline that displays the starting location for the taper on the contra-lateral condyle. The operator will follow the curvature of the implant sketch of the contra-lateral taper, offsetting the sketch 6-10mm toward the trochlea; cross over both sides of the taper area as shown. The taper offset in lateral implants will fall in the narrower end of the 6-10mm range and wrap on to the anterior cut surface

[000238] **FIGS. 7H, 7I and 7J** depict an operation of virtually cutting an anterior plane. The goal of the final steps is to define an anterior cutting plane. The program first displays the inner surface in profile view, then rotates it in the screen plane so that the common tangent to both condyles becomes horizontal, then rotates it 2 degrees around X-axis in the current view to provide divergence with posterior cutting

plane. **FIG. 7H** depicts an anterior view. The operator can modify the position and orientation of the cutting plane by moving the cutting line up and down (picking the line closer to its middle point) or by rotating it in the screen plane (picking it closer to its end point). For every position during this modification, the program can display the distances from the lowest horizon point and from two peak points.

[000239] **FIG. 7I** depicts the program displaying the cutting contour in 3d-mode. When the operator accepts the position and orientation of the cutting plane, the program will virtually cut off the portion of the inner surface above the cutting plane and closes the hole with planar face. The result of this step, showing the inner surface and the flat anterior cut surface, is shown in **FIG. 7J**.

“PROCEDURE/TOOLS FIRST” DESIGN/SELECTION

[000240] In various embodiments, a surgeon and/or designer can initially design and/or select a series of appropriate surgical steps and/or procedures for preparing a patient's anatomy, and then design and/or select one or more implant components appropriate for the designed/selected surgical steps and/or procedures. In various embodiments, a surgical procedure and surgical tools can be initially designed and/or selected using one or more models (or other image data) of the relevant patient anatomy. The selected procedures/tools, and their effects upon the patient anatomy (or models thereof) can then be utilized to design and/or select one or more implant components appropriate to creating the desired final joint anatomy structure, alignment and/or kinematics. In this approach, if the subsequent design/selection of the implant components encounters difficulties and/or constraints, the procedures/tools may be re-assessed and/or modified, and the design/selection process repeated.

[000241] The “procedure/tools first” approach may be particularly useful where minimal resection and/or maximum preservation of anatomical structures are desired, or where various anatomical and/or structural constraints require a given amount, type and/or orientation of anatomical support structures. Such constraints could also be due to surgical access limitations for surgical tools and/or approaches. The surgical procedure 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. Once a desired procedure has been designed and/or selected, associated guide tools and/or appropriate implant components can be selected and/or designed, including patient-adapted implants having one or more patient-specific and/or patient-engineered features.

[000242] Traditional orthopedic implants incorporate bone cuts. These bone cuts achieve two main objectives: they establish a shape of the bone that is adapted to the implant and they help achieve a normal or near normal axis alignment. For example, bone cuts can be used with a knee implant to correct an underlying varus or valgus deformity and to shape the articular surface of the bone to fit a standard, bone-facing surface of a traditional implant component. With a traditional implant, multiple bone cuts are placed. However, since traditional implants are manufactured off-the-shelf without use of patient-specific information, these bone cuts are pre-set for a given implant without taking into consideration the unique shape of the patient. Thus, by cutting the patient's bone to fit the traditional implant, more bone is discarded than is necessary with an implant designed to address the particularly patient's structures and deficiencies.

[000243] In certain embodiments, resection cuts can be 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.

[000244] 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.

[000245] These optimizations can be performed for one, two, or three opposing articular surfaces, for example, in a knee they can be performed on a tibia, a femur and a patella.

[000246] In a knee, different resection cuts can be planned for a medial and lateral femoral condyle. In certain embodiments, a single bone cut can be optimized in a patient to maximize bone preservation in that select area, for example, a posterior condyle. Alternatively, multiple or all resection cuts can be optimized. Since a patient's medial and lateral femoral condyles typically have different geometries, including, for example, width, length and radii of curvature in multiple planes, for example, the coronal and the sagittal plane, then one or more resection cuts can be optimized in the femur individually for each condyle, resulting in resection cuts placed at a different depths, angles, and/or orientations in one condyle relative to the other condyle. For example, a horizontal cut in a medial condyle may be anatomically placed more inferior relative to the limb than a horizontal cut in a lateral condyle. The distance of the horizontal cut from the subchondral bone may be the same in each condyle or it can be different in each condyle. Chamfer cuts in the medial and lateral condyle may be placed in different planes rather than the same plane in order to optimize bone preservation. Moreover, chamfer cuts in the medial and lateral condyle may be placed at a different angle in order to maximize bone preservation. Posterior cuts may be placed in a different plane, parallel or non-parallel, in a medial and a lateral femoral condyle in order to maximize bone preservation. A medial condyle may include more bone cut facets than a lateral condyle in order to enhance bone preservation or vice versa.

[000247] In certain embodiments, a measure of bone preservation can include total volume of bone resected, volume of bone resected from one or more resection

cuts, volume of bone resected to fit one or more implant component bone cuts, average thickness of bone resected, average thickness of bone resected from one or more resection cuts, average thickness of bone resected to fit one or more implant component bone cuts, maximum thickness of bone resected, maximum thickness of bone resected from one or more resection cuts, maximum thickness of bone resected to fit one or more implant component bone cuts.

[000248] Certain embodiments of femoral implant components described herein include more than five bone cuts, for example, six, seven, eight, nine or more bone cuts on the inner, bone-facing surface of the implant component. These bone cuts can be standard, in whole or in part, or patient-adapted, in whole or in part.

Alternatively, certain embodiments include five bone cuts that are patient-adapted based on one or more images of the patient's knee. A femoral implant component with greater than five bone cuts of and/or with patient-adapted bone cuts can allow for enhanced bone preservation over a traditional femoral implant with five standard bone cuts and therefore can perform as a pre-primary implant.

[000249] A weighting optionally can be applied to each bone with regard to the degree of bone preservation achieved. For example, if the maximum of bone preservation is desired on a tibia or a sub-segment of a tibia, femoral bone cuts can be adapted and moved accordingly to ensure proper implant alignment and ligament balancing. Conversely, if maximum bone preservation is desired on a femoral condyle, a tibial bone cut can be adjusted accordingly. If maximum bone preservation is desired on a patella, a resection cut on the opposing trochlea can be adjusted accordingly to ensure maximal patellar bone preservation without inducing any extension deficits. If maximum bone preservation is desired on a trochlea, a resection cut on the opposing patella can be adjusted accordingly to ensure maximal patellar bone preservation without inducing any extension deficits. Any combination is possible and different weightings can be applied. The weightings can be applied using mathematical models or, for example, data derived from patient reference databases.

[000250] Once the desired surgical procedure has been defined/selected, their effects upon the patient anatomy (or models thereof) can then be utilized to design and/or select one or more implant components appropriate to creating the desired final joint anatomy structure, alignment and/or kinematics. In this approach, if the subsequent design/selection of the implant components encounters difficulties and/or constraints, the procedures/tools may be re-assessed and/or modified, and the design/selection process repeated. In a manner similar to the previous approach, this approach allows for iterative selection and/or design improvement and can include steps to virtually assess the fit, such as virtual kinematics assessment.

[000251] In various embodiments, the surgical procedure may be designed and/or selected to be ligament sparing. In such a case, the 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. 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.

[000252] In various embodiments, virtually any combination of bone cuts, including asymmetric bone cuts on similar anatomical regions, can be planned, designed and/or selected, and an appropriate implant component utilized to accommodate the combination, or "filler material" of various types can be utilized to accommodate misalignment of the implant component. For example, a patient-specific implant having bone cuts that are non-parallel to the cuts of a subsequent primary implant can result in the primary implant having small gaps between the bone and the inner, bone-facing surface of the primary implant. These small gaps can result in misalignment intersects between the pre-primary implant and the

subsequent primary implant. For example, as shown in **FIG. 9**, the bone cuts (shown in red) for a pre-primary implant component having a 5-flex cut can retain bone as compared to a traditional primary implant (shown in outline), but a small gap **2110** also can be created by the pre-primary cut. Any such small gaps **2120** can be filled with bone cement when fitting a subsequent primary implant.

PLANNING AND MODIFYING BONE CUTS

[000253] In various 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.

[000254] **FIG. 10A** illustrates an exemplary femoral implant component **600** having six bone cuts. **FIG. 10B** illustrates a femoral implant component **600** having seven bone cuts. In **FIG. 10A** and **FIG. 10B**, the six or seven respective bone cuts are identified by arrows on the inner, bone-facing surface **602** of the implant component **600**. The bone cuts can include, for example, an anterior bone cut **A**, a distal bone cut **D**, and a posterior bone cut **P**, as well as one or more anterior chamfer bone cuts between the anterior bone cut **A** and distal bone cut **D**, and/or one

or more posterior chamfer bone cuts between the distal posterior bone cut **P** and the distal bone cut **D**. The implant component depicted in **FIG. 10A** includes one anterior chamfer bone cut and two posterior chamfer bone cuts, in addition to anterior, posterior and distal bone cuts. The implant component depicted in **FIG. 10B** includes two anterior chamfer bone cuts and two posterior chamfer bone cuts, in addition to anterior, posterior and distal bone cuts.

[000255] Any one or more bone cuts can include one or more facets. For example, the implant components exemplified in **FIG. 10A** and **FIG. 10B** depict corresponding condylar facets for each of the distal bone cut, posterior bone cut, first posterior chamfer bone cut and second posterior chamfer bone cut. In **FIG. 10A**, distal bone cut facets on lateral and medial condyles are identified by **604** and **606**, respectively. Facets of a bone cut can be separated by a space between corresponding regions of an implant component, as exemplified by the condylar facets separated by the intercondylar space **608** in **FIG. 10A** and **FIG. 10B**.

Alternatively or in addition, facets of a bone cut can be separated by a step cut, for example, a vertical or angled cut connecting two non-coplanar or non-facets of a bone cut. As shown by the implant components exemplified in each of **FIG. 10A** and **FIG. 10B**, each bone cut and/or bone cut facet can be substantially planar. Two substantially planar facets of the same bone cut can be non-coplanar (i.e., not lying in the same cut plane) and/or non-parallel (i.e., not lying in the same cut plane and not lying in a substantially parallel cut plane).

[000256] In certain embodiments, one or more bone cut facets, bone cuts, and/or the entire bone-facing surface of an implant can be non-planar, for example, substantially curvilinear. **FIG. 10C** illustrates a femoral implant component **610** having two planar bone cuts **612** and one curvilinear bone cut **614**. In the figure, the femoral implant component **610** is shown attached to resected surfaces **616** of a femur **618**.

[000257] In one example, two embodiments describe methods for designing resection cuts to a patient's femur and related bone cuts on the bone-facing surface of a femoral implant component designed for the patient. In particular, in both

methods, a model of a patient's distal femur is created based on data from patient-specific two- or three-dimensional images of the patient's femur. As shown in **FIG. 11A**, the epicondylar axis **8810** is determined for the patient's femur. Then, the resection cut planes and cut angles (and corresponding implant component cut planes and cut angles) are assessed and selected using the epicondylar axis **8810** as a reference. Specifically, four of the five cut planes - the distal cut, posterior cut, posterior chamfer cut, and anterior chamfer cut - are designed to be parallel with the epicondylar axis **8810**. **FIG. 11A** shows the distal cut plane **8820** parallel to the epicondylar axis **8810**. However, for the particular patient, the anterior cut plane is designed to be oblique to the epicondylar axis **8810**, which can minimize the amount of bone resected on the lateral side of the cut. **FIG. 11B** shows an example of an anterior oblique cut plane **8830**.

[000258] For each of the five cut planes, optimized cuts (i.e., resection cuts) tangent to the bone surface at the angle of each resection plane also is determined. The optimized cuts as shown in **FIGS. 12A to 12E** included a maximum cut depth of 6 mm for the distal cut plane (**FIG. 12A**), the anterior chamfer cut plane (**FIG. 12B**), the posterior chamfer cut (**FIG. 12C**), and the posterior cut plane (**FIG. 12D**). The maximum cut depth is 5 mm for the anterior cut plane (**FIG. 12E**). Optimized cuts can be determined based on one or more parameters, including those described above. In this example, optimized cut were determined, at least in part, to minimize resected bone while providing greater than a threshold minimum implant thickness. Deeper resection cuts allow for a thicker implant, but require greater bone loss. Typically, the thinnest resection cut depth and, accordingly, the minimum implant thickness occurs at the intersections between cut planes. Accordingly, alternatively or in addition to altering cut plane depths, the number of cut planes, the cut plane angles and/or the cut plane orientations can be altered to provide deeper cut plane intersections and corresponding greater minimum implant thickness at the bone cut intersections while also minimizing the amount of bone resected from the patient.

[000259] The optimized number of cut planes, depths of cut planes, angles of cut planes and/or orientations of cut planes can be determined independently for each of the medial and lateral femoral condyles. For example, **FIGS. 12A to 12E** show

optimized cut planes based on the medial condyle. However, **FIGS. 13A** and **13B** show cut planes for the lateral condyle posterior chamfer (**FIG. 13A**) and lateral condyle posterior (**FIG. 13B**) cut planes that are independently optimized (i.e., relative to the medial condyle posterior chamfer and medial condyle posterior cut planes, respectively) based on patient-specific data for the lateral condyle. This type of independent optimization between condyles can result in a different number of cut plane facets, different angles of cut plane facets, and/or different depths of cut plane facets on corresponding portions of medial and lateral condyles.

[000260] Two exemplary resection cut designs (and corresponding implant component bone cut design e.g., that includes substantially matching cut features of the resection cut design) is based on five cut planes are described in this example. In the first design, shown in **FIG. 14A**, a distal cut plane is designed perpendicular to the sagittal femoral axis **9100**. In the second design, referred to as a “flexed” or “flex-fit” design” and shown in **FIG. 14B**, the distal cut plane is rotated 15 degrees in flexion from the perpendicular to the sagittal femoral axis. The additional four cut planes are shifted accordingly for each design method, as shown in **FIGS. 15A** and **15B**.

[000261] **FIGS. 16A** and **16B** show the completed cut femur models for each cut design. For each design, the maximum resection depth for each cut plane was 6 mm, except for the anterior cut plane, which was 5 mm. The “flex-fit” design can provide more posterior coverage in high flexion. However, it also may require more anterior bone resectioning to achieve sufficient coverage and may require particular attention during actual bone cutting to avoid any incomplete bone removal at the trochlear notch **9310**. In certain embodiments of a cut plane design, the anterior and posterior cut planes diverge from the component peg axis by five degrees each, as shown in **FIG. 17A**. With a traditional femoral implant component, the posterior and anterior cut planes diverge 2 degrees and 7 degrees, respectively, from the peg axis. Moreover, in certain embodiments, the peg can be designed to have various dimensions. For example, the design in **FIG. 17B** includes a peg diameter of 7 mm tapering to about 6.5 mm, a length of 14 mm with a rounded tip, and a base with a 1 mm fillet **9410**.

[000262] An exemplary bone facing surface of the femoral implant component design is shown in **FIGS. 18A** and **18B**. In addition to optimized cut planes described above, these implant components also include a patient-adapted peripheral margin **9510** that is 0.5 mm from the edge of cut bone. The designs also can include engineered coronal curvatures on the condyles. Side views of the resulting femoral implant component designs for the first and second design methods are shown in **FIGS. 19A** and **19B**. This sagittal view of the implant components shows the difference in anterior and posterior coverage for the two designs. As seen by a comparison of the two figures, the flexed cut design provides greater posterior coverage, which enhances deep knee flexion for the patient. Accordingly, as shown by this example, one or more features or measurements derived from patient-specific data are used to preoperatively select and/or design implant component features that target and achieve more than one parameter, in this case preservation of the patient's bone and preservation, restoration, or enhancement of the patient's joint kinematics.

[000263] As mentioned above, the optimization of resection cuts and implant component bone cuts can result in a cut design that has any number of cut planes or facets, depths of cut planes or facets, angles of cut planes or facets, and/or orientations of cut planes or facets. In addition to optimizing the cut planes to minimize bone loss and maximize implant thickness, various other parameters can be included in the cut plane optimization. In this example, the flexed cut design was used to help preserve, restore, or enhance the patient's joint kinematics. Additional parameters that may be included in the determination of optimized resection and bone cuts can include, but are not limited to, one or more of: (1) deformity correction and/or limb alignment (2) maximizing preservation of cartilage, or ligaments, (3) maximizing preservation and/or optimization of other features of the patient's anatomy, such as trochlea and trochlear shape, (4) further restoration and/or optimization of joint kinematics or biomechanics (5) restoration or optimization of joint-line location and/or joint gap width, and (6) preservation, restoration, or enhancement of other target features.

[000264] In another exemplary embodiment, a femoral component can include seven bone cuts on its inner, bone-facing surface. A femoral implant component (PCL-retaining) is designed with seven bone cuts for a femur-first implantation technique. The design of the implant component is depicted in **FIG. 20**. The seven bone cuts on the inner, bone-facing surface of the implant component include a distal bone cut **9701** (including lateral and medial facets) that is perpendicular to the sagittal femoral axis, and an anterior cut **9702**. The corresponding resection cut planes are shown in **FIG. 21A** and in **FIG. 21B**. Specifically, a first anterior chamfer cut plane is at 25 degrees, a second anterior chamfer cut plane is at 57 degrees, and an anterior cut plane is at 85 degrees relative to the distal femoral cut plane, as shown in **FIG. 21A**. Moreover, a first posterior chamfer cut plane is at 25 degrees, a second posterior chamfer cut plane is at 57 degrees, and a posterior chamfer cut plane is at 87 degrees relative to the distal femoral cut plane, as shown in **FIG. 21B**. The femoral implant includes bone cuts that substantially negatively-match (e.g., in cut angle, area, and/or orientation) the resection cuts on these cut planes. The femoral implant component also can include on its bone-facing surface cement cutouts **9704** that are 0.5 mm deep and offset from the outer edge by 2 mm, and a peg protruding from the each of the lateral and medial distal bone cuts facets. The pegs are 7 mm in diameter, 17 mm long and are tapered by 0.5 degrees as they extend from the component. **FIG. 22** shows the cement pocket and peg features.

[000265] In a traditional femoral implant component, the bone-facing surface consists of five standard bone cuts. However, the femoral component in this example includes seven bone cuts on the bone-facing surface. The additional bone cuts can allow for the corresponding resection cut planes be less deep from the bone surface to insure that the cut plane intersections have a depth below the bone surface that allows for a minimum implant thickness. Accordingly, less bone can be resected for a seven-bone-cut implant component than for a traditional five-bone-cut implant component to provide the same minimum implant component thickness, e.g., at the bone cut intersections. Moreover, the outer, joint-facing surface of the implant component described in this example includes a combination of patient-adapted features and standard features.

[000266] **FIG. 23A** shows a five-cut-plane femoral resection design for a femoral implant component having five bone cuts. **FIG. 23B** shows a seven-cut-plane femoral resection design for a femoral implant component having seven bone cuts. Each cut design was performed on the same patient femur model (i.e., having identical bone volumes). In addition, the corresponding five-bone-cut implant component and seven-bone-cut implant component were both designed meet or exceed the same minimum implant thickness. After performing the resection cuts, the model of the patient's femur having five resection cuts retained bone volume of $103,034 \text{ mm}^3$, while the model of the patient's femur having seven bone cuts retained a bone volume of $104,220 \text{ mm}^3$. As this analysis shows, the seven-bone-cut implant component saved substantially more of the patient's bone stock, in this case more than $1,000 \text{ mm}^3$, as compared to the five-bone cut implant component.

[000267] A similar analysis was performed to assess relative bone loss between a five-cut design and a five-flexed cut design. **FIG. 24B** shows a patient's femur having five, not flexed resection cuts and **FIG. 24A** shows the same femur but with five, flexed resection cuts. As shown, the model having five, not flexed resection cuts retains a bone volume of $109,472 \text{ mm}^3$, while the model having five, flexed resection cuts retains a bone volume of $105,760 \text{ mm}^3$. As this analysis shows, the not-flexed-five-bone-cut implant component saved substantially more of the patient's bone stock, in this case nearly $4,000 \text{ mm}^3$, as compared to the flexed-five-bone-cut cut implant component. However, the flexed cut design can offer other advantages, such as greater posterior coverage and enhanced deep-knee flexion, which can be weighed relative to all selected parameters and accordingly integrated in the selection and/or design of an implant component.

[000268] **FIGS. 25A to 25D** show outlines of a traditional five-cut femoral component (in hatched lines) overlaid with, in **25A**, a femur having seven optimized resection cuts for matching an optimized seven-bone-cut implant component; in **FIG. 25B**, a femur having five optimized resection cuts for matching to an optimized five-bone-cut implant component; in **FIG. 25C**, a femur having five, not flexed resection cuts for matching to an optimized five-bone-cut implant component; and in **FIG. 25D**, a femur having five, flexed resection cuts for matching to an optimized five-bone-cut,

flexed implant component. As shown in each of these figures, the designed bone cuts save substantial bone as compared to those required by a traditional implant component.

[000269] In summary, the component designs described in this example can save patient bone stock as compared to a traditional implant component and thereby allow the implant to be pre-primary. Alternatively or in addition, the implant components may include cut planes (i.e., of resection cuts and bone cuts) that are optimized based on patient-specific data to meet one or more user-defined parameters, as described above. For example, cut planes can be symmetric or asymmetric, parallel or non-parallel, aligned perpendicular to the sagittal plane or not perpendicular, varied from medial to lateral condyle, and/or can include other orientations. The cut plane designs may include a “flexed” (i.e., rotated or offset relative to the biomechanical or anatomical axes) orientation. Moreover, the design of attachment pegs may also be flexed relative to the biomechanical or anatomical axes.

PLANNING NON-PLANAR BONE CUTS

[000270] Various embodiments may include procedures and implant components having both straight and curvilinear bone cuts on one or more bone-facing surface. Specifically, a femoral implant can be designed to include 3 mm curvilinear cut depths and corresponding implant thicknesses along the distal portion of each condyle. The cut depth and implant thickness along each condyle are designed independently of the other condyle. In addition, jigs for performing the curvilinear cuts to the articular bone surface are described.

[000271] Using a computer model generated from patient-specific data, posterior and anterior resection cut lines are created in the model, as shown in **FIGS. 26A** and **26B**. To design the curvilinear bone cut line corresponding to the resection cut on the medial condyle, a medial split line is identified on the condyle, as shown in **FIG. 27A**, and then a 3 mm deep cut line is generated to follow the split line, as shown in **FIG. 27B**. The resulting virtual curvilinear cut is shown in **FIG. 27C**. The same steps are performed independently for the lateral condyle, as shown in **FIGS. 28A** to **28C**.

[000272] The resulting resection cut model, as shown in **FIG. 29A** establishes predetermined resection cuts for the surgical procedure and it also can be used to engineer the bone-facing surface of the corresponding patient-specific implant component, as shown in **FIGS. 29B** and **29C**. Specifically, the inner, bone-facing surface of the implant component can be designed and engineered to substantially negatively-match the resection cut surface on the model. Optionally, and as shown in the figures, the outer, joint-facing surface of the implant also can include one or more patient-specific features.

[000273] The resulting cut model also can be used to design one or more cutting jigs that are fitted to the bone to guide the bone cutting procedure. For example, **FIG. 30A** shows a model of a bone along with a jig that allows preparation of predetermined resection holes and, optionally, resection cuts surfaces to match the predetermined resection cuts specific to a patient's particular anatomy. **FIGS. 30B** and **30C** show an alternative set of jigs that can be used with a router-type saw. Specifically, a router-type bit can fit into the central channel of the jig shown in **FIG. 30B** to cut along the channel to a specific depth, for example, 3 mm. Then, as shown in **FIG. 30C**, a second jig having two channels that circumvent the channel of the first jig can be applied. The router-type bit can fit into these two channels to cut medial and lateral to the first channel to the same depth, for example, 3 mm.

[000274] **FIGS. 31A** shows a model of the prepared bone following jig-guided bone cuts. **FIG. 31B** shows the model of **FIG. 31A** with a two-piece patient-specific implant component designed with an inner bone-facing surface that substantially negatively-matches the patient's resected bone surface.

“HYBRID” OR COMBINED IMPLANT/PROCEDURE DESIGN/SELECTION

[000275] In various embodiments, the design and/or selection process can incorporate various combinations of “implant first” and/or “procedure/tools first” design/selection procedures (or various combinations of steps therein), or a hybrid process can perform variations of both such operations in serial and/or parallel (or otherwise concurrently) to derive one or more sets of implant components, guide tools and surgical procedure steps. The resulting surgical plans/tools and/or implants

resulting from each process could then be assessed, rated and/or otherwise evaluated, which could include the use of user-defined factors and/or ratings of the relative importance of the various constraints (i.e., how important is cost relative to anatomy preservation). If desired, the various processes could be repeated using various combinations and/or features of the resulting procedure/tools and/or implant designs.

[000276] In various embodiments, the design/selection of the individual surfaces of an implant component can be “driven” or otherwise influenced by a combination of “implant first” and “procedure/tools” design/selection considerations, and thus a single individual component can be designed and/or selected using a plurality of approaches. For example, the joint-facing or articulating surface of the implant (the outer implant surface) can be defined by one or more anatomical models (measured, derived and/or otherwise developed). Concurrently, the inner or bone-facing surface of the implant (the inner implant surface) can be defined by one or more surfaces of the supporting anatomical structure(s), where these supporting surfaces correspond to surgical resection surfaces created by the surgeon. If desired, the resulting hybrid structure can be further designed and/or selected and or otherwise defined using a wide variety of additional considerations, such as minimum and/or maximum implant thicknesses, material types, etc., which may mandate and/or otherwise influence and/or require modification of the hybrid structure or potentially impact the surgical procedure and/or desired anatomical models (or both) in various ways.

[000277] For example, in various embodiments a surgical procedure design/selection may desirably seek to optimize bone preservation in determining the depth, number, and/or orientation of resection cuts and/or implant component bone cuts while a concurrent implant component design/selection will seek to maintain a desired implant thickness and/or joint line balancing. A minimum implant thickness can be included as part of the resection cut and/or bone cut design to ensure a threshold strength for the implant in the face of the stresses and forces associated with joint motion, such as standing, walking, and running. An analysis, such as shown in **Table 3**, could quantify the results of a finite element analysis (FEA) assessment for femoral implant components of various sizes and with various bone

cut numbers and orientations. If the results were as depicted, the maximum principal stress observed in a FEA analysis could be used to establish an acceptable minimum implant thickness for an implant component having a particular size and, optionally, for a particular patient (e.g., having a particular weight, age, activity level, etc.).

Before, during, and/or after establishing a minimum implant component thickness, the optimum depth of the resection cuts and the optimum number and orientation of the resection cuts and bone cuts, for example, for maximum bone preservation, could be designed.

Table 3: Finite Element Analysis for Various Implant Designs

Implant Description	Distal Condyle Geometry	Relative Size	Scan #	Maximum Principal Stress, mPa
6-Cut, non-flexed	coplanar	Sigma #1.5	3017	161
5-Cut, non-flexed	coplanar	Sigma #1.5	3017	201
6-Cut, flexed 5 degrees	coplanar	Sigma #1.5	3017	229
6-Cut, non-flexed	coplanar	Sigma #3	2825	221
5-Cut, non-flexed	coplanar	Sigma #3	2825	211
6-Cut, flexed 5 degrees	coplanar	Sigma #3	2825	198
5-Cut, non flexed	coplanar	Sigma #7	1180	292
6-Cut, non-flexed	coplanar	Sigma #7	1180	221
6-Cut, flexed 5 degrees	coplanar	Sigma #7	1180	214
7-Cut non-flexed	coplanar	Sigma #7	1180	203
6-Cut, non-flexed	non-coplanar, w/step	Sigma #7	1180	173
7-cut, flexed 5 degrees	non-coplanar, w/out step	Sigma #7	1180	202

[000278] In various embodiments, resection cuts also can be designed to meet or exceed a certain minimum material thickness of an implant, for example, the minimum amount of thickness required to ensure biomechanical stability and durability of an implant. In certain embodiments, the limiting minimum implant thickness can be defined at the intersection of two adjoining bone cuts on the inner, bone-facing surface of an implant component. For example, in the femoral implant component **2000** shown in **FIG. 8**, the minimum thickness of the implant component appears at one or more intersections **2100**. In certain embodiments of a femoral

implant component, the minimum implant thickness can be less than 10 mm, less than 9 mm, less than 8 mm, less than 7 mm, and/or less than 6 mm.

[000279] In one embodiment, bone preservation can be 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 (and/or modifying) 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.

[000280] This exemplary process can yield 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, may include 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. For example, this design process can be applied to a total knee, cruciate retaining, posterior stabilized, and/or ACL/PCL retaining knee implants, bicompartamental knee implants, unicompartamental knee implants, and other joint implants, for example, for the shoulder, hip, elbow, spine, or other joints. For example, the thickness of an acetabular cup, either metal backing or polyethylene or ceramic or other insert, can be adapted based on the patient's geometry, e.g. depth of the acetabular fossa, AP, ML, SI dimensions or other parameters including femoral parameters. In alternative embodiments, a multiplicity of implant and/or surgical procedure designs can be generated, compared and/or assessed, as described herein.

[000281] The exemplary processes, including the resulting patient-adapted implants and predetermined bone resectioning designs, offers several advantages over traditional primary and revision implants and related processes. For example, such procedures allow for one or more pre-primary implants such that a subsequent replacement or improvement can take the form of a primary implant. Specifically, because the process described herein can minimize the amount of bone that is resected (or can resect bone from a desired portion of the underlying anatomy), enough bone stock in desirably locations may remain such that a subsequent procedure may be performed with a traditional, primary, off-the-shelf implant. This offers a significant advantage for younger patients who may require in their lifetime

more than a single revision for an implant. In fact, the exemplary process described above may allow for two or more pre-primary implants or procedures before so much bone stock is sacrificed that a traditional, primary implant is required.

[000282] The advantageous minimal bone resectioning and therefore minimal bone loss that is achieved with various processes described herein can arise from embodiments where the bone-facing surfaces of the implants are derived for each patient based on patient-specific data, such as, for example, data derived from images of the patient's joint, size or weight of the patient, size of the joint, and size, shape and/or severity of defects and/or disease in the joint. This patient-adapted approach allows for the bone-facing surface of the implant components to be optimized with respect to any number of parameters, including minimizing bone loss, using any number of resection cuts and corresponding implant component bone cuts and bone cut facets to conserve bone for the patient. With traditional implants, the implant's bone-facing surface includes standard bone cuts and the resection cuts to the patient's bone are made to fit those standard bone cuts.

[000283] Another advantage of various embodiments is that the selection and/or design process can incorporate any number of target parameters such that any number of implant component features and resection cuts can be selected and/or designed to meet one or more parameters that are predetermined to have clinical value. For example, in addition to bone preservation, a selection and/or design process can include target parameters to restore a patient's native, normal kinematics, or to provide optimized kinematics. For example, the process for selecting and/or designing an implant and/or resection cuts can include target parameters such as reducing or eliminating the patient's mid-flexion instability, reducing or eliminating "tight" closure, improving or extending flexion, improving or restoring cosmetic appearance, and/or creating or improving normal or expected sensations in the patient's knee. The design for a tibial implant can provide an engineered surface that replicates the patient's normal anatomy yet also allows for low contact stress on the tibia.

[000284] For surgeons and medical professionals, the various processes described herein can provide simplified surgical techniques, as well as possibly minimize costs, time delay and/or a host of other factors. The selected and/or designed bone cuts and, optionally, other features that provide a patient-adapted fit for the implant components eliminates the complications that arise in the surgical setting with traditional, misfitting implants. Moreover, since the process and implant component features are predetermined prior to surgery, model images of the surgical steps can be provided to the surgeon as a guide.

[000285] In various embodiments, any combination of one or more of the parameters identified herein, 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.

[000286] In various exemplary embodiments, the design of implant component **12601** (see **FIGS. 32A-32E**) can incorporate several advantages. First, the design of articular surface **12605** allows the thickness of femoral component to be better controlled as desired. For example, referring to **FIG. 32C**, if a curve of an articular surface **12608** of a femoral component **12609** is too large, the thickness of the femoral component may be too thick along a centerline **12610** of the implant, thereby requiring an excessive amount of bone to be removed when the implant is placed on the femoral condyle. On the other hand, referring to **FIG. 32D**, if the same curve **12608** is applied to a device having an appropriate centerline thickness **12611**, the margins or sidewalls **12612**, **12613** of the device may be too thin to provide proper structural support. Similarly, referring to **FIG. 32E**, if the curve of the outer articular surface **12612** of a femoral component **12613** is too flat, the device does not exhibit the tapering from a centerline **12614** to the margins or sidewalls **12615**, **12616** of the device and may not function well.

SURGICAL GUIDE TOOLS AND JIGS

[000287] Once a surgical procedure has been designed/selected (and optionally after appropriate implant components have been designed/selected), a variety of guide tools or other surgical instruments can be designed and/or selected to assist with preparation of the anatomical structures for the various implant components. In various embodiments, one or more guide tool features and/or feature measurements can be selected, designed and/or selected and further designed or modified (such as, for example, selecting a guide tool or guide tool component from an inventory, library and/or database and further modifying the component in a desired manner as described herein). For example, a guide tool having some optimum features and/or feature measurements can be designed further using one or more CAD software programs or other specialized software to optimize additional features or feature measurements of the guide tool. One or more manufacturing techniques described herein or known in the art can be used in the design step to produce the additional, optimized features and/or feature measurements, for example, to facilitate one or more resection cuts that, optionally, substantially match one or more optimized bone-facing surfaces of a selected and designed implant component. This process can be repeated as desired.

[000288] A variety of traditional guide tools are available to assist surgeons in preparing a joint for an implant, for example, for resectioning one or more of a patient's biological structures during a joint implant procedure. However, these traditional guide tools typically are not designed to match the shape (contour) of a particular patient's biological structure(s). Moreover, these traditional guide tools typically are not designed to impart patient-optimized placement for the resection cuts. Thus, using and properly aligning traditional guide tools, as well as properly aligning a patient's limb (e.g., in rotational alignment, in varus or valgus alignment, or alignment in another dimension) in order to orient these traditional guide tools, can be an imprecise and complicated part of the implant procedure.

[000289] Certain embodiments described herein provide improved surgical guide tools and methods for preparing a patient's biological structure during a joint implant

procedure. The guide tools described herein can include any combination of patient-specific features, patient-engineered features, and/or standard features. For example, a patient-specific guide tool includes at least one feature that is preoperatively designed and/or selected to substantially match one or more of the patient's biological features. A patient-engineered guide tool includes at least one feature that is designed or selected based on patient-specific data to optimize one or more of the patient's biological features to meet one or more parameters, for example, as described elsewhere here, such as in Section 4. A standard guide tool includes at least one feature that is selected from among a family of limited options, for example, selected from among a family of 5, 6, 7, 8, 9, or 10 options. Accordingly, any one guide tool can be both patient-specific in view of its patient-specific features and patient-engineered in view of its patient-engineered features. Such a guide tool also can include standard features as well. **Table 4** describes the various combinations of three features of a single guide tool with regard to being patient-specific features, patient-engineered features, and/or standard features of the exemplary guide tools. Moreover, in certain embodiments a set or kit of guide tools is provided in which certain guide tools in the set or kit include patient-specific, patient-engineered, and/or standard features. For example, a set or kit of guide tools can include any two or more guide tools described in **Table 4**.

Table 4: Patient-specific, patient-engineered, and standard features of exemplary guide tools

Exemplary Guide tool	Feature #1	Feature #2	Feature #3
A guide tool that includes at least 3 PS features	P	P	P
A guide tool that includes at least 3 PE features	PE	PE	PE
A guide tool that includes at least 3 S features	St	St	St
A guide tool that includes at least 2 PS features and at least 1 PE feature	P	P	PE
	P	PE	P
	PE	P	P
A guide tool that includes at least 2 PS	P	P	St

Exemplary Guide tool	Feature #1	Feature #2	Feature #3
features and at least 1 S feature	P	St	P
	St	P	P
A guide tool that includes at least 1PS feature and at least 2 PE features	PE	PE	P
	PE	P	PE
A guide tool that includes at least 1PS feature and at least 2 S feature	P	PE	PE
	St	St	P
	St	P	St
A guide tool that includes at least 2PE features and at least 1 S feature	P	St	St
	PE	PE	St
	PE	St	PE
A guide tool that includes at least 1PE feature and at least 2 S features	St	PE	PE
	St	St	PE
	St	PE	St
A guide tool that includes at least 1PS feature, at least 1 PE feature, and at least 1 S feature	PE	St	St
	P	PE	St
	P	St	PE
	PE	P	St
	PE	St	P
	St	P	PE
	St	PE	P

P indicates a patient-specific feature, PE indicates a patient-engineered feature, and St indicates a standard feature

PATIENT-SPECIFIC ASPECTS OF TOOLS AND/OR TOOL PORTIONS

[000290] Certain embodiments include a guide tool having at least one patient-specific bone-facing surface portion that substantially negatively-matches or otherwise substantially conforms to or accommodates at least a portion of a biological surface at the patient's joint. The guide tool further can include at least one aperture for directing movement of a surgical instrument, for example, a securing pin or a cutting tool. One or more of the apertures can be designed to guide the surgical instrument to deliver a patient-optimized placement for, for example, a securing pin or resection cut. In addition or alternatively, one or more of the apertures can be designed to guide the surgical instrument to deliver a standard placement for, for

example, a securing pin or resection cut. As used herein, “jig” also can refer to guide tools, for example, to guide tools that guide resectioning of a patient’s biological structure. Alternatively, certain guide tools can be used for purposes other than guiding a drill or cutting tool. For example, balancing and trial guide tools can be used to assess knee alignment and/or fit of one or more implant components or inserts.

[000291] Certain embodiments can include a guide tool that includes at least one patient-specific bone-facing surface that substantially negatively-matches at least a portion of a biological surface at the patient’s joint. The patient’s biological surface can include cartilage, bone, tendon, and/or other biological surface. For example, in certain embodiments, patient-specific data such as imaging data of a patient’s joint can be used to select and/or design an area on the articular surface that is free of articular cartilage. The area can be free of articular cartilage because it was never cartilage covered or because the overlying cartilage has been worn away. The imaging test can be specifically used to identify areas of full or near full thickness cartilage loss for designing the contact surface on the bone-facing surface of a patient-specific guide tool. Alternatively, the area can be free of articular cartilage because an osteophyte has formed and is extending outside the cartilage. The guide tool then can rest directly on the bone, e.g., subchondral bone, marrow bone, endosteal bone or an osteophyte. By selecting and/or designing an area of the articular surface that is free of articular cartilage, it is possible to (a) reference the guide tool against the articular surface and (b) reference it against bone rather than cartilage.

[000292] In certain embodiments, patient-specific data such as imaging test data or other models of a patient’s joint can be used to identify a contact area on the articular surface for deriving an area on the bone-facing surface of a guide tool to substantially negatively-match the contact area on the subchondral bone surface. While the area may be covered by articular cartilage, the guide tool surface area can be specifically designed to match the subchondral bone contact area. The guide tool can have one or multiple areas that substantially negatively-match one or multiple contact areas on the subchondral bone surface. Intraoperatively, the surgeon can

elect to place the guide tool on the residual cartilage. Optionally, the surgeon then can mark the approximate contact area on the cartilage and remove the overlying cartilage in the marked area before replacing the guide tool directly onto the subchondral bone. In this manner, the surgeon can achieve more accurate placement of the guide tools that substantially negatively-matches subchondral bone.

[000293] In certain embodiments, patient-specific image data and/or models (as described herein) can be used to identify a contact area on the articular surface for deriving an area on the bone-facing surface of a guide tool that substantially negatively-matches the endosteal bone or bone marrow contact area. While the area may be covered by articular cartilage, the guide tool surface area can be specifically designed to match the endosteal bone or bone marrow. The guide tool can have one or multiple areas that substantially negatively-match one or multiple areas on the endosteal bone or bone marrow. Intraoperatively, the surgeon can elect to place the guide tool on the residual cartilage. Optionally, the surgeon then can mark the approximate contact area on the cartilage and subsequently remove the overlying cartilage in the marked area before replacing the guide tool directly onto the endosteal bone or bone marrow. In this manner, the surgeon can achieve more accurate placement of guide tools that match endosteal bone or bone marrow.

[000294] In certain embodiments, the articular surface or the margins of the articular surface can include one or more osteophytes. The guide tool can rest on the articular surface, e.g., on at least one of normal cartilage, diseased cartilage or subchondral bone, and it can include the shape of the osteophyte. In certain embodiments, patient-specific data such as imaging test data of a patient's joint can be used to derive an area on the bone-facing surface of the guide tool that substantially negatively-matches the patient's articular surface including the osteophyte. In this manner, the osteophyte can provide additional anatomic referencing for placing the guide tool. In certain embodiments, the osteophyte can be virtually removed from the joint on the 2D or 3D images and the contact surface of the guide tool can be derived based on the corrected surface without the osteophyte. In this setting, the surgeon can remove the osteophyte intraoperatively prior to placing the guide tool.

[000295] Certain embodiments can include a guide tool that is flexible. The guide tool's flexibility, optionally in combination with a patient-specific bone-facing surface, can allow it to snap-fit into position onto the patient's biological structure. For example, the guide tool can be snap-fit to a patient's biological structure by applying force to the guide tool to cause it to expand and engage the structure. During or following the expansion and engagement, the tool can be adjusted so that the bone-facing surface engages the corresponding surface of the biological structure.

[000296] The flexibility of the guide tool can be altered or enhanced using materials and processes known in the art. For example, various types and/or combinations of polymers and polymer manufacturing techniques can be used to make a guide tool with the appropriate flexibility to provide a snap-fit.

[000297] The bone-facing surface of the guide tool can be patient-specific (e.g., substantially negatively-match) for one or more surface dimensions or features of the patient's biological surface including, for example, width, area, height, distance, angle, and curvature. For example, in certain embodiments, a dimension or feature of the patient's biological structure can be assessed to include the cartilage on its surface. In certain other embodiments, a dimension or feature can be assessed based on the patient's bone surface, for example, subchondral bone surface.

[000298] If a subchondral bone surface is used to assess the patient's biological surface, a standard cartilage thickness (e.g., 2 mm), or an approximate cartilage thickness derived from patient-specific data (e.g., age, joint-size, contralateral joint measurements, etc.) can be used as part of the design for the guide tool, for example, to design the size and bone-facing surface of the guide tool. The standard or approximate cartilage thickness can vary in thickness across the assessed surface area. In certain embodiments, this design can be used with a similarly designed implant, for example, an implant designed to include a standard or approximate cartilage thickness.

PATIENT-ENGINEERED ASPECTS OF TOOLS AND/OR TOOL PORTIONS

[000299] In various embodiments, a guide tool includes at least one feature for

directing a surgical instrument to deliver a patient-engineered feature to the patient's biological structure, for example, a resected hole or a resection cut for engaging a patient-engineered implant peg or a patient-engineered implant bone-facing surface. In addition to the patient-engineered feature, in certain embodiments one or more of the guide tool's bone-facing surfaces can be designed to be patient-specific so that it substantially negatively-matches a portion of the patient's joint surface. In addition or alternatively, one or more of the guide tool's bone-facing surfaces can be standard in shape. In other embodiments, the guide tool's bone-facing surface can include one or more engineered surfaces that correspond to prepared and/or artificial surfaces of the patient's anatomy, such as, for example, anatomical surfaces that have been resected and/or otherwise prepared at an earlier point in the surgical procedure as well as surfaces of already implanted existing implant components from the current and/or previous surgical procedures.

[000300] Various embodiments described herein include a set of patient-optimized guide tools that can be used to perform patient-optimized resection cuts to the femur in preparation for implanting a femoral knee implant component having patient-optimized bone cuts. If desired, one or more guide tools can be used to prepare a joint for a patient-engineered implant.

[000301] In various embodiments, guide tools may include at least one patient-engineered feature, such as a patient-engineered bone-facing surface portion that substantially negatively-matches or otherwise substantially conforms to or accommodates at least a portion of a biological surface at the patient's joint that has been altered or otherwise modified by the surgeon at some prior point in the procedure. Similarly, the one or more patient-engineered features could include a patient-engineered surface portion that substantially negatively-matches an existing surface of an artificial material, such as a pre-existing implant component from a prior surgery, or a pre-existing implant component from the present surgery (i.e., a first component inserted earlier in the surgery is used to align a guide tool for use in preparing a surface for a second implant component to be positioned).

EXEMPLARY GUIDE TOOL CONFIGURATIONS/DESIGNS

[000302] A guide tool can be used for one or more purposes during an implant procedure. For example, one or more guide tools can be used to establish resected holes in a patient's biological structure, to establish resected cuts in a patient's biological structure, and/or to balance or estimate fit of a joint implant. The following subsection describes exemplary guide tools and guide tool features that can help to establish resected holes, to establish resected cuts, and to balance or estimate fit of a joint implant.

[000303] Various embodiments of guide tools described herein can include features and apertures for various steps in a joint replacement procedure. For example, in certain embodiments, one or more guide tools can be used to establish all the resection cuts associated with installation of a particular implant component. If desired, one or more of the guide tools can include one or more patient-specific features and/or one or more patient-engineered features and/or one or more standard features.

[000304] One or more resection cut slots in a particular guide tool can be substantially, horizontal, substantially diagonal, or substantially vertical, for example, as compared to the patient's mechanical axis and/or anatomical axis. Moreover, one or more of the resection cut slots can allow for a complete resection cut or a partial resection cut, e.g., scoring of the patient's bone to establish a resection cut that can be finished after removing the tool. This approach can be advantageous by allowing for faster resection in the absence of the guide tool. Moreover, one or more resection cut slots can include a blade-depth stop. This is particularly useful for step resection cuts, for example, vertical step resection cuts, that connect two facets or planes of a resected surface.

[000305] As shown in **FIG. 33**, a guide tool **7600** can include one or more apertures **7602** for establishing resected holes in a patient's biological structure. One or more of these resected holes can be used to engage a peg, which can be used to secure one or more subsequently used guide tools, e.g., guide tools for establishing resection cuts, into proper position on the biological surface. For example, a

subsequently used guide tool can include one or more attached pegs that correspond to the one or more holes resected using, for example, using the guide tool of **FIG. 33**. In particular, the subsequently used guide tool can be secured onto the biological surface by sliding the pegs into the appropriate resected holes. Alternatively, an independent peg can be placed into the resected hole and, then, a subsequently used guide tool having apertures corresponding to the independent pegs can be secured onto the biological surface by sliding the apertures over the independent pegs. In certain embodiments, the exemplary guide tool shown in **FIG. 33** can include anterior and posterior portions that are extended and the material is pliable so that the guide tool can snap-fit onto the femur.

[000306] In certain embodiments, one or more attached pegs (i.e., attached to a guide tool) can be detachable, so that, once detached, they can be used to secure a subsequent guide tool or implant component having a corresponding aperture. In certain embodiments, a first guide tool can be secured to the biological structure and a second guide can be secured to the first guide tool. For example, an attached or independent peg can extend from the resected hole, through the aperture of the first guide tool and into a corresponding aperture of the second guide tool. Alternatively or in addition, the second guide tool can include a feature that engages an aspect of the aperture on the first implant. For example, a portion of the aperture on the second guide tool can be wider than the aperture on the first guide tool and engage a raised aperture collar surrounding the aperture on the first guide tool. Alternatively, the second aperture can include a sleeve that slide into the aperture on the first guide tool.

[000307] Alternatively or in addition, one or more of these resected holes can be used to secure an implant component. For example, one or more pegs projecting from the bone-facing surface of the implant component can be placed into the resected hole to fix the placement of the implant component. In certain embodiments, cement can be applied to the resected hole and/or the implant component peg to secure the placement of the implant.

[000308] A variety of aperture configurations can be used for the guide tools

described herein. In certain embodiments, a guide tool aperture configuration can be patient-engineered to engage a particular patient-engineered peg configuration on the corresponding implant component. Moreover, aperture features such as size, shape, angle, and optionally, stop depth, can be designed to substantially match the peg features for the corresponding implant component. For example, in certain embodiments the aperture cross-section can be round to match a round peg on the implant component. However, in certain embodiments, as suggested by **FIGS. 34A** and **34B**, the aperture cross-section can include a "+" or cross-like configuration to match the corresponding peg on the implant component.

[000309] A variety of aperture sizes can be used. For example, a 7 mm diameter aperture can be used. Moreover, the aperture can be oriented to establish a resected hole at any angle. For example, an aperture can be oriented to establish a resected hole in line with the femoral mechanical axis. Alternatively, an aperture can be oriented to establish a resected hole at an anterior-leaning angle to match the angle of the corresponding implant peg. For example, one or more apertures can be oriented anteriorly to establish a 5 degree, 5-10 degree, 10 degree, 10-15 degree, and/or 15 degree anterior-leaning angle relative to the femoral mechanism axis. The aperture can be oriented to establish a resected hole that is oriented at the same angle or at different angles as one or both of the anterior and posterior cuts of the implant component. In certain embodiments, a depth-stop can be used so that the aperture allows a resected hole having a certain maximum depth.

[000310] In certain embodiments, a guide tool includes at least one moveable aperture and, optionally, a moveable corresponding bushing. **FIG. 35** depicts a guide tool having a moveable lateral aperture and bushing. Specifically, the lateral aperture and bushing in the figure are moveable in the A-P direction. However, a moveable aperture (and, optionally, a moveable bushing) can be moveable in the A-P direction, in the M-L direction, or in all directions from the aperture center (e.g., can be rotated in a circular pattern). Moreover, the guide tool can include two or more moveable apertures. For example, a lateral aperture and a medial aperture, and optionally one or both corresponding bushings, can be moveable. Alternatively, one or more apertures (and optional bushings) can be fixed, for example, as is the medial aperture

and bushing in **FIG. 35**.

[000311] The guide tool that includes one or more moveable apertures also can include one or more patient-specific features, one or more patient-optimized features, and/or one or more standard features. Moreover, the guide tool can be used with a subsequently used guide tool or implant that includes one or more patient-specific features, one or more patient-optimized features, and/or one or more standard features.

[000312] A guide tool that includes one or more moveable apertures for establishing resected holes can be used during surgery to adjust the orientation of subsequently placed guide tools and/or implant components. For example, one or more moveable apertures in a femoral guide tool can be used to adjust the femoral flexion, femoral rotation, and/or tibial external rotation of the particular patient's femoral implant.

[000313] With reference to the exemplary guide tool shown in **FIG. 35**, a surgeon can snap-fit the guide tool on the femur, observe placement of the moveable aperture as well as other guide tool features relative to one or more biological landmarks, and, if appropriate, move the moveable aperture in order to adjust the orientation of the subsequently installed femoral implant component on the femur. For example, if the surgeon moves the lateral aperture posteriorly to the 3 degree mark, as shown in the figure, the lateral resected hole and engaging lateral peg of the subsequently installed femoral implant component also would be shifted posteriorly. With the medial aperture fixed, this would posteriorly flex the lateral side of the implant component and axially rotate the orientation of the implant component on the femur. As shown in **FIG. 35**, the movable bushing can be limited to one or more ranges of motion and can be accompanied by markings and/or values displayed on the tool surface indicating the rotation in relation to one or more axes. Moreover, in certain embodiments, patient-specific information and/or standard rules can be used to limit the extent of movement of the moveable aperture. For example, the limit of posterior movement of the aperture in the guide tool can be established as the point that allows a subsequent guide tool to guide a lateral posterior bone resection that removes

some minimum amount of bone, for example, so that the intersect between the posterior resection cut and posterior chamfer cut is below the bone surface.

[000314] In certain embodiments, the movable aperture also could allow for a balancing technique. For example, a navigation chip can be placed into the lateral joint in flexion, e.g., as a laminar spreader. This rotates the femur internally and the joint gap can be balanced by moving the lateral aperture, for example, posteriorly. In various embodiments, multiple combinations of the tools necessary for accomplishing these techniques can be integrated or incorporated into a single system, allowing the surgeon to decide which he wants to utilize right there at the surgery.

[000315] In certain embodiments, the extent limit of movement of the moveable aperture in the A-P direction can be limited to 3 degrees, less than 3 degrees, 5 degrees, less than 5 degrees, 7 degrees, and/or less than 7 degrees.

[000316] In certain embodiments, instead of including a moveable aperture, the guide tool can include one or more alternative apertures and/or an extended opening, for example, and opening that includes the approximate area through which a moveable aperture can move. Then, a bushing (e.g., metal or plastic) or other device can snap, slide, or lock into place onto one of the alternative apertures or at a certain location in the extended opening. For example, the bushing or other device could lock into place at alternative apertures or in the extended opening at 3, 5 and 7 degrees. In this way, the surgeon can alter the implant orientation as he or she deems appropriate. Alternatively, a guide tool can include an aperture bushing that is fixed in one location but can swivel (e.g., tilt). For example, in certain embodiments, a bushing can swivel or tilt in one direction, in two directions, or all directions about a fixed point. The amount of swivel or tilt can be, for example, between 0 and 7 degrees, up to 7 degrees, between 1 and 7 degrees, and/or between 3 and 7 degrees in one or more directions.

[000317] In certain embodiments, a set of three guide tools can be used to establish all the resection cuts associated with installation of a particular implant component. For example, the guide tools shown in **FIGs. 33** or **35**, **FIG. 36**, and **FIGS. 37A** and **37B** can be used together to establish all the resection cuts

associated with installation of a femoral implant component. In particular, **FIGS. 33** and **35** each shows a peg hole driver guide tool for establishing pin or peg holes for subsequent guide tools and, optionally, for the femoral implant component. This tool can be used to establish the direction of pegs used by subsequent tools and/or the implant component and can be specifically matched to the patient just like the implant component. Subsequently placed guide tools can be placed with respect to these peg hole features to ensure that the bone preparation is performed per the intended implant design. **FIG. 36** shows a guide tool for making distal and posterior resection cuts to the distal femur and **FIGS. 37A** and **37B** show two options for a third guide tool for making anterior and posterior chamfer cuts. The particular set of guide tools shown in these figures is designed for a tibia first technique; however, the features of the guide tools for preparing a knee joint as described herein can be applied to both a tibia first technique and to a femur first technique.

[000318] Furthermore, a spacer, such as a lateral spacer, can be used for balancing to equal distal asymmetry. The spacer can include patient-specific and/or patient-engineered features. A series of balancer chips with thicknesses can be included, for example a series of chips having 1 mm increases in thickness. Alternatively or in addition, a guide tool can include an integrated spacer thickness to allow surgeon to assess tension without needing a spacer. For example, a guide tool for establishing femoral resection cuts can include an integrated space having a tibial resection depth added to the guide tool external surface.

[000319] One or more guide tools can be selected and/or designed to include patient-specific and/or patient-engineered features. For example, the peg hole driver guide tool shown in **FIG. 33** can include, at least in part, a patient-specific bone-facing surface that substantially matches a particular patient's femoral surface. Moreover, such guide tools can include flexible material, such as nylon plastic, to allow the tool to snap-fit onto the particular patient's femur, as suggested by the peg hole driver guide tool shown in **FIG. 33**. Other features, such as peg hole angle, peg hole placement, peg hole size, tool thickness, joint-facing surface, and other features can be patient-specific or patient-engineered. Alternatively or in addition, one or more features can be standard. For example, for the peg hole driver guide tool

shown in **FIG. 33**, the peg size is 6 mm, which can accommodate a quarter-inch drill size; however, any peg hole size can be used.

[000320] Resection cut guide tools can be designed to be patient-specific on their bone-facing surface to allow a snap-fit onto a particular patient's femur. Moreover, other features, such as thickness, joint-facing surface, and peg placement and size, also can be patient-specific or patient-engineered. Alternatively or in addition, one or more features can be standard. The cut guide tool shown in **FIG. 36** can be designed to rest on 2 mm thick cartilage relative to CT data and can include a standard tool thickness of 4 mm; however other standard thicknesses can be used, for example, a 2 mm or a 3 mm thickness. Moreover, the cut guide tool shown in **FIG. 36** can include three optional pin placements for stabilization and a posterior beam to give stability and rigidity to the tool. The lateral spacer shown on the left side of **FIG. 36** can rest on cut tibia to approximate the thickness of asymmetry.

[000321] The cut tools shown in **FIGS. 37A** and **37B** are designed to follow the cut tool shown in **FIG. 36** and can complete the remaining chamfer cuts for the distal femur. Each of the cut tools shown in the figure includes two pin placements for stabilization. The tool on the left includes short pegs to be positioned in the peg holes established by a peg hole driver guide tool, for example, as shown in **FIGS. 33** and **35**. The tool on the right includes no lateral peg to allow for external rotation of the guide tool to establish rotated chamfer cuts.

[000322] In certain embodiments, fewer than three guide tools, for example, two guide tools or one guide tool can be used to establish the peg holes and all the resection cuts associated with installation of a particular implant component. For example, the single guide tool shown in **FIG. 38** can be used to establish all the resection cuts associated with installation of a femoral implant component, including, for example, a distal cut with one more facets, a posterior cut with one or more facets, an anterior cut, an anterior chamfer cut with one or more facets, one or more posterior chamfer cuts each with one or more facets, and one or more step cuts, for example, between two facets of a cut. The apertures (e.g., holes and slots) in the guide tool and edges of the guide tools can be used to guide peg hole placement and

resection cuts. For example, the posterior surface of the guide tool shown in **FIG. 38** can be used to establish the posterior resection cuts. Optional guide tool attachments can be used to enhance the guidance for one or more of the cutting holes or slots in the cut guide tool. For example, the optional guide tool attachments shown in **FIGS. 39A** and **39B** can be used to enhance one or more cutting or drilling surfaces.

[000323] **FIG. 40A** shows an additional embodiment of a single guide tool that can be used to establish the peg holes and all the resection cuts associated with installation of a femoral implant component. In particular, the single guide tool is presented with three different thicknesses, which corresponds to each of images shown on the figure. Having the single guide tool in different thicknesses allows a surgeon to select the optimum thickness for balancing before initiating the resection cuts. The guide tool can come in 2, 3, 4, 5, 6, 7, 8, 9, 10, or more thicknesses. Once the surgeon has selected the guide tool with the appropriate thickness, the distal resection cut and all subsequent resection cuts can be made using the selected guide tool. This allows the distal resection cut to be placed at the appropriate position from the joint-line. In addition, **FIGS. 40B** and **40C** show three optional guide tool attachments **8210**, **8220**, **8230** for enhancing the cutting or drilling surfaces of the single guide tool. One or more guide tool attachments can be used to enhance the cutting and/or drilling surfaces for one, two, more than two, or all of the apertures in a single guide tool. In this embodiment, numbers are included on the surface of the guide tools to indicate the order of the resection cuts. **FIG. 41** shows a set of resection cut guide tools that together can be used to facilitate the same peg holes and resection cuts that can be facilitated with the single guide tool described above. The middle three guide tools (labeled A, B, and C) include the same resection cuts but have different thicknesses to allow for balancing, as described above. This group of guide tools can be included in a kit along with the single guide tool described above, for example, to act as a back-up set of guide tools.

[000324] **FIGS. 42A to 42D** show another embodiment of a single guide tool and attachments that can be used to establish the peg holes and all the resection cuts associated with installation of a femoral implant component. In particular, the guide

tool shown in **FIG. 42A** includes three reinforcement bars between the implant component condyles. This guide tool can be presented in one or more thicknesses. As noted above, a guide tool having an appropriate thickness can be used to balance the knee before the surgeon performs any femoral cutting. **FIG. 42B** shows the guide tool of **FIG. 42A** with an additional attachment to supply additional surface area to guide to a drilling tool in making the two peg holes. **FIG. 42C** shows the guide tool of **FIG. 42A** with an additional attachment to supply additional surface area to guide a cutting tool in making the numbered resection cuts. As shown in the figure, the attachment covers the entire surface area of the guide tool. The attachment also include flanges adjacent to each cutting hole that supply additional surface area for guiding the cutting tool. **FIG. 42D** shows the reverse side of the guide tool and attachment shown in **FIG. 42C**. As shown, the attachment can be fixed in place on the guide tool using an interface that can include fitting a peg from the attachment into one or both peg guide holes of the guide tool.

GUIDE TOOLS INCORPORATING INDICIA OR MARKINGS

[000325] In certain embodiments, one or more guide tools described herein can include markings to identify relevant features, for example, alignment indicators for anatomical and/or biomechanical axes. Such markings can intraoperatively guide a surgeon in the installation procedure. For example, the guide tool shown in **FIG. 35** includes on its surface alignment indicators for the patient's Whiteside's AP trochlear line, the transepicondylar axis (TEA), and the posterior condylar axis (PEA). These indicators can be in colors and/or in raised geometries to strengthen the guide tool.

[000326] Moreover, as shown in **FIG. 40A**, resection cut apertures on a guide tool can include numbers or other instructions to direct a surgeon in the proper resection procedure.

[000327] Guide tools for establishing tibial resection cuts can include one or more patient-specific features and/or one or more patient-engineered features, and/or one or more standard features. For example, the bone-facing surface of a tibial resection guide tool can include patient-specific features that conform to the uncut tibial surface, e.g., bone and/or cartilage surface. Embodiments of patient-specific tibial

resection guide tools are shown in **FIGS. 43A to 43H** and in **FIGS. 44A and 44B**.

[000328] **FIGS. 43A to 43G** show a tibial guide tool **8310**, a tibial guide rod **8320**, and a tibial + 2mm additional resection cut guide **8330**. The tibial guide tool having a large anterior portion provide a patient-specific surface area that matches a portion of the contour of the tibia. The anterior portion also is relatively thin to make the tool low profile. As shown in the figures, the guide tool includes parallel pins for ease of removal and installation, and a cutting slot that extends laterally (e.g., 10 mm laterally) and is 1.32 mm in diameter to better control the blade flex during cutting. In certain embodiments, the tibial guide tool includes a large medial surface that can be patient-specific for a portion of the patient's corresponding biological structure (e.g., bone or cartilage surface). In this way, the conforming guide tool fits optimally on the particular patient's bone and thereby provides a secure cutting surface. In certain embodiments, the tibial guide tool can include a feature for attaching a tibial guide rod, for example, at the anterior portion of the guide tool. In particular, the tibial guide rod can mate with the anterior feature of the tibial guide via a rectangular boss and hole. As with the guide tool, the guide rod can include one or more patient-specific features and/or one or more patient-engineered features and/or one or more standard features. For the example, the diameter and/or length of the guide rod can be designed based on the specific patient information, such as information derived from one or more patient images. The guide rod depicted in the figure includes a diameter of 8.5 mm and a length of 250 mm.

[000329] As shown in **FIGS. 43G and 43H**, one or more additional guide tools can be included and used to remove additional bone from the proximal surface of the tibia. For example, as shown in the figure, an additional guide tool can provide a 2 mm deeper resection than is available with a first guide tool. Alternatively, one or more additional guide tools can allow for resection of an additional 1 mm, 3 mm, 4 mm, and/or 5 mm (or any amount in between these values) off the patient's proximal tibia. A single additional guide tool can include one or more resection slots to allow for more than one additional resection depth to be achieved with that single guide tool. The one or more additional guide tools can include one or more patient-specific features, one or more patient-engineered features, and one or more standard

features.

[000330] **FIG. 44A** shows a tibial guide tool for making the same resection cut as shown for **FIGS. 43A to 43F**. However, the guide tool shown in **FIG. 44A** includes additional patient-adapted surface area that conforms to the patient's biological surface. This patient-adapted surface area can be designed to conform with the patient's biological structure, e.g., subchondral bone and/or cartilage surface, based on one or more images of the patient's joint. Alternatively, this conforming surface area can be engineered based on patient-specific images to conform to an expanded outline of the patient's biological structure, e.g., the patient's subchondral bone surface expanded to include estimated amount of cartilage, for example, expanded 1 mm, 1.5 mm, or 2 mm. For example, the guide tool shown in **FIG. 44A** can be used to make a 2 mm cut at a 5 degree A-P slope. The guide rod can be as described above.

[000331] **FIG. 44B** shows a tibial guide tool to resect into the cut tibial surface to create a notch for accepting the keel of a tibial implant component. In certain embodiments, the perimeter of this tool can be patient-specific to match the perimeter of the patient's cut tibial surface. In certain embodiments, the perimeter of this tool can match the perimeter of the tibial implant component that will rest on the cut tibial surface. Alternatively, the perimeter of this tool can be engineered to be some amount less than the perimeter of the patient's cut tibia. The amount that the perimeter is less than the cut tibia can be, for example, a percentage of surface area or circumferential distance, for example, 2% less, 4% less, 5% less, 6% less, 8% less, 10% less, or some other percent less than the corresponding measure on the patient's cut tibia. Alternatively, the tibial guide tool and also, optionally, the tibial implant component, can include a perimeter that is less than the corresponding measure on the patient's cut tibia by an amount calculated to allow for a certain level of intraoperative rotation of the tibial implant component without any overhang of the tibial implant component perimeter.

[000332] Various methods can be used to allow for intraoperative rotation of the tibial implant component during installation of the implant. Being able to rotate and

install a rotated tibial implant component can be important in balancing the joint with the implant. One example of a method for intraoperatively preparing a rotated tibial implant component is shown in **FIGS. 45A** through **45D**. In particular, **FIGS. 45A** through **45D** show the front and back views of the same tibial guide tool to resect into the cut tibial surface to create a notch for accepting the keel of a tibial implant component. **FIGS. 45B** through **45D** each additionally show an insert with holes for guiding a drilling tool. The holes in each figure are oriented at different angles. Specifically, the insert in **FIG. 45B** can create holes at a 0 degree rotation angle; the insert in **FIG. 45C** can create holes at a 5 degree rotation angle; and the insert in **FIG. 45D** can create holes at a 10 degree rotation angle. Accordingly, by supplying along with the guide tool a series of inserts with holes at various angles, the resected holes and subsequent notch can be rotated at any desired angle (for which an insert has been supplied), which in turn will rotate the tibial implant component by the same angle as its keel is placed into the notch. Inserts can be included to have any degree of rotated holes, for example, inserts can be included to rotate the notch and implant 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 degrees or more. Any number of inserts with different hole rotations can be included. In certain embodiments, the maximum rotation for a given tibial implant component can be calculated as the rotation at which an undersized component perimeter extends beyond (i.e., overhangs) the perimeter of the patient's cut tibial surface, and inserts can be limited to this maximum rotation. **FIGS. 46A** through **46D** show the same front view of the guide tools and inserts shown in **FIGS. 45A** through **45D** and, in addition, show front and back view of three exemplary inserts. As shown in the figures, in certain embodiments the inserts can include differently keyed insert shapes.

PERFORMING THE SURGICAL PROCEDURE

[000333] Once an appropriate surgical plan has been selected and/or designed, and associated surgical guide tools and implant components has been manufactured and/or obtained, the surgical procedure can begin.

[000334] In various embodiments, a surgeon will initially prepare the underlying anatomical support structure(s) using a set of jigs designed in connection with the

design of a patient-specific implant component. The designed jigs guide the surgeon in performing one or more patient-specific cuts to the bone so that those cut bone surface(s) negatively-match the patient-specific bone cuts of the implant component.

ALIGNING SURGICAL CUTS AND IMPLANT COMPONENTS

[000335] One important consideration during surgery concerns the alignment of surgical cuts and implant components. Where surgeons employing traditional implant components and surgical tools seek to align implant components from one or more commonly-accepted landmarks, the use of preoperative surgical procedure planning (using image data and models) and patient-specific implants and tools allows a surgeon and/or designer the opportunity to select a wide variety of reference structures, anatomical features and/or reference points, as well as a variety of referencing techniques, to guide preparation of anatomical surfaces and/or placement of the implant components during surgery. These chosen reference features may be selected due to their unique features, due to their increased accuracy on imaging, or for accessibility and/or suitability for use during a desired surgical step.

[000336] In various embodiments, a set of jigs can be designed to accommodate a “femur-first” surgical cutting and preparation technique. This can include methods and devices for performing a series of bone cuts to receive a patient-specific implant. Specifically, a set of jigs can be designed in connection with the design of a patient-specific implant component. The designed jigs guide the surgeon in performing one or more patient-specific cuts to the bone so that those cut bone surface(s) negatively-match the patient-specific bone cuts of the implant component.

[000337] In a first step, shown in **FIGS. 47A** and **47B**, a first femur jig is used to establish peg holes and pin placements for a subsequent jig used for a distal cut. In this example, the first jig is designed to circumvent 3 mm of cartilage thickness. In a second step, shown in **FIGS. 48A** and **48B**, the distal cut is performed with a second femur jig. In this example, the second jig is patient-specific. However, in certain embodiments that apply a traditional distal cut, a standard jig can be used. In a third step, as shown in **FIGS. 49A**, the anterior cut, the posterior cut, and the chamfer cuts are performed with a third femur jig. In this example, the jig includes slots that are

1.5 mm wide to allow for a saw blade thickness (i.e., no metal guides). As shown in **FIG. 49B**, in certain embodiments, for implant component designs having six or more inner, bone-facing surfaces, for example, having one or two additional chamfer cuts, the additional cuts can be performed using one or more additional jigs. In this example, the additional jig is designed to accommodate two steep additional chamfer cuts.

[000338] Next, the tibia is cut using one or more jigs designed to make patient-specific cuts to the tibia. An exemplary tibial jig is depicted in **FIGS. 50A** and **50B**. A tibial alignment pin **16900** is used to help properly orient the jig. The portion **16910** of the jig inserted between the femur and tibia can have a variable thickness. In certain embodiments, the tibial jig can be designed to accommodate for composite thickness from the distal cut femur **16920**. Alternatively or additionally, a balancing chip can be used to address differences in the distance between the tibia and femur surfaces. For example, in certain embodiments a tibia jig may be designed to rest on 2 mm of cartilage, while a balancing chip is designed to rest on the distal cut femur.

[000339] A balancing chip is shown in **FIG. 51**. If a varus deformity of the knee is observed, virtual realignment can be addressed by including added thickness to the balancing chip in the area that would produce a leg in neutral alignment **17010**. For a grossly mal-aligned contra-lateral leg, correction can be per a surgeon's order. The balancing chip can include a feature **17020** to attach it to the tibia jig, and thereby allow for accurate distal placement of the tibial cut while at the same time accommodating for composite thickness. An exemplary balancing chip attached to a tibia jig is shown in **FIGS. 52A** and **52B**. To facilitate attachment, the balancing chip handle **17000** matches the tibial slope designed into the tibial cut and tibial implant. Preferably, the balancing chip is designed to enter into the joint easily.

[000340] In other embodiments, a set of jigs can be designed to accommodate a "tibia-first" surgical cutting and preparation technique. This example describes methods and devices for performing a series of bone cuts to receive a patient-specific implant. Specifically, a set of jigs is designed in connection with the design of a patient-specific implant component. The designed jigs guide the surgeon in

performing one or more patient- specific cuts to the bone so that those cut bone surface(s) negatively-match the patient-specific bone cuts of the implant component.

[000341] In a first step, shown in **FIG. 53**, a first jig is used to establish placement and alignment of femoral implant peg holes. In the example, the placement is flexed 5 degrees with respect to the sagittal femoral axis. In a second step, shown in **FIG. 54**, a second jig is used to establish placement pins for the distal cut jig. The second jig can have different thicknesses **17300** to accommodate composite thickness from the cut tibial surface. In a third step, as shown in **FIG. 55**, a distal cut jig is positioned based on the placement established by the previous jig. The distal cut jig can be patient-specific or standard. Lastly, as shown in **FIG. 56**, remaining cuts are performed with a chamfer cut jig. In the example, the anterior cut is not oblique.

[000342] In another embodiment, shown in **FIGS. 57A** through **57D**, a series of jigs can be designed to guide patient-specific cuts to the tibia. An exemplary tibial jig, depicted in **FIG. 57A**, is first placed on the anterior tibial cortex, with extenders onto the tibial plateau. The extenders can include cartilage or bone facing surfaces that are patient specific. A Steinmann or other pin can be placed in the medial and/or lateral tibial plateau through a hole in the extender. The Steinmann pin can then be used to core or surgically remove the cartilage surrounding the pin. In this manner, it is possible to design the extenders so that the patient specific shape is derived from the subchondral bone rather than the cartilage and so that the extender can rest on the subchondral bone after the coring procedure. This technique can be beneficial when various degrees of cartilage loss in one plateau or differences in cartilage loss between a medial plateau and a lateral plateau are not well visualized on a CT scan or MRI scan.

[000343] **FIGS. 57E** and **57F** depict side and top plan views of alternate embodiments of the tibial jig of **FIG. 57A**. In these embodiments, a pair of alignment notches **17550** are formed in an upper surface of the tibial jig arms **17540**. Desirably, the alignment notches will align with the anterior (or other) lateral surface or cortex of the tibia, thereby confirming the proper alignment and placement of the tibial jig to the surgeon prior to resection of underlying bone tissues. In an additional embodiment,

best seen in **FIG. 57E**, the alignment jig incorporates an anterior flange **17555** which can abut against the anterior lateral tibial surface, thereby further confirming and ensuring proper alignment of the tibial jig.

[000344] In various other embodiments, such as shown in **FIGS. 58A** through **58K**, alignment jigs and an associated tool for guiding the surgeon in performing various femoral cuts can be used in preparation for the implantation of a femoral implant. In a first step, shown in **FIG. 58A**, a first femur jig **18000** is used to align and locate guide pins (i.e., Steinman Pins) for placing various jigs used for aligning subsequent femoral cuts. This jig **18000** desirably incorporates an inner surface (not shown) that substantially conforms to some or all of the outer surface of the uncut distal femur **18001** (e.g. cartilage or subchondral bone), whereby the jig fits onto the femur in desirably only one position and orientation. In various embodiments, the jig **18000** can comprise a flexible material which allows the jig **18000** to flex and “snap fit” around the distal femur. In addition, the inner surface of the jig is intentionally designed to avoid and/or accommodate the presence of osteophytes and other anatomical structures on the femur **18001**. A pair of pin openings **18010**, extending through the surface of the jig, desirably provide position and orientation guidance for a pair of guide pins **18020** (see **FIG. 58B**) that are inserted into the distal surface of the femur (not shown). The jig **18000** is then removed from the femur **18001**.

[000345] After insertion of the pins **18020** and subsequent removal of the jig **18000**, **FIG. 58B** depicts the introduction of a cannulated drill or coring tool **18030** over each of the pins **18020**. Desirably, the drill or coring tool will remove any layer of cartilage adjacent the pins **18020**, thereby exposing the subchondral bone surface adjacent to the pins. Because subchondral bone can be readily visualized through various imaging methods, and because subchondral bone is significantly rigid, it provides a reliable reference surface for the placement of additional jigs.

[000346] **FIGS. 58C** and **58D** depict perspective views of a second femur jig **18050** which is subsequently placed over the pins **18020** and advanced into direct contact with the subchondral bone. Desirably, contact surfaces **18060** will contact the subchondral bone surfaces which were exposed by the cannulated drill. In

addition, the bone-facing surface of jig **18050** can conform to the surrounding surface of the femur, if desired.

[000347] **FIGS 60A, 60B and 60C** depict an alternative embodiment of this second femur jig, which incorporates adjustable contact surfaces that can be extended and/or retracted to account for differing thicknesses of the articular cartilage including normal and diseased cartilage. Where the patient-specific imaging information has been collected using x-rays and/or CT scans or the like, it is often difficult (if not impossible) to visualize the articular cartilage and other soft tissues, which potentially results in an unknown depth of cartilage during the surgical procedure. In this embodiment, the subchondral bone contact surfaces comprise an adjustable screw arrangement, which can be advance and/or retracted as desired, to account for varying thickness of articular cartilage. One or more such screws can be advanced to equal depths, or can be asymmetric lengths, as desired by the surgeon. Optionally, the screws can be printed during the generation of the disposable jig with a 3D printing process. In various alternative embodiments, the patient-specific surgical tool can be designed to contain portions that rest on cartilage, while other portions rest on bone. For example, a tool may rest on the articular cartilage of a femoral condyle and also curve around the condylar edges to contact bone. The surgical tool can also rest on areas that include osteophytes.

[000348] The patient's anatomical information for the surgical tool may be derived using different 2D or 3D imaging techniques. Since some imaging techniques do not display soft tissue, cartilage surface information may be estimated by offsetting the underlying bone surface by the expected cartilage thickness. If a surgical tool is designed to rest on cartilage and on bone, offset and non-offset surfaces may have to be combined to design the patient-specific tool. This can be achieved by calculating smooth transitions between portions of offset and non-offset surfaces. Alternatively, an offset surface may be used to trim a non-offset surface or vice versa.

[000349] **FIG. 58E** depicts a third femur jig **18070** which connects to and aligns with a flange **18065** (see **FIG. 58D**) extending from the second jig **18050**. The third

femur jig **18070** desirably is used to place a pair of anterior guide pins (i.e., Steinman Pins) (not shown), which are subsequently used to align and position a distal cut guide jig **18100**. The third femur jig **18070** includes a pair of pin guides **18080** having openings extending therethrough, which desirably guide and align the anterior guide pins into the femur **18001**.

[000350] In various disclosed embodiments, after placement of the anterior guide pins, the second and third femur jigs **18050** and **18070** can be removed and distal cut guide jig **18100** (see **FIG. 58F**) can be placed over the anterior guide pins. The distal cut guide jig **18100** desirably comprises a substantially conforming bone-or cartilage facing surface (not shown) and one or more cut alignment surfaces **18110**, **18120**. The distance between the cut alignment surface can correspond to the offset in distal cuts of a femoral component or the offset between the medial and lateral femoral condyle that the patient has, or combinations thereof. The bone or cartilage facing surface or perimeter can reflect the shape of the patient's trochlear cartilage or subchondral bone **18122**. In this embodiment, the jig **18100** comprises a pair of cut alignment surfaces **18110**, **18120** of different alignments, corresponding to different distal cuts on the medial and lateral condyles of the femur **18001**. If desired, the perimeter of the jig may match the perimeter of the uncut trochlear shape.

[000351] **FIG. 58G** depicts a sizing tool or spacer **18150** for use in adjusting and optimizing alignment, tension, balance, and position (e.g., including various approaches and techniques described in **Table 5**) during a knee implant surgery. The sizing tool **18150** may be one of a series of spacers utilized to determine an optimal size and shape for a tibial tray insert for ultimate placement in the knee joint. Desirably each spacer corresponds to one or more of a plurality of tibial inserts in the surgical kit, although various embodiments could include one or more "adjustable" spacers having detents or other mechanisms that facilitate adjustment and measurement of the of the joint space (with the medial and lateral sides independently adjustable, if desired). In particular, a first side **18160** of the spacer has a first height and/or alignment, and a second side **18170** of the spacer has a second height and/or alignment (allowing for medial/lateral distal femoral component bearing surface or cut asymmetry). The superior surfaces of the spacer desirably

engage the cut surface of the femur and the inferior surfaces engage the cut surfaces of the tibia. In various embodiments, the various spacers can be patient-adapted to fit the particular patient, and may incorporate perimeter matching or other indicia to correspond to some or all of the perimeter of the cut and/or uncut bone surfaces (i.e., the outer perimeter of the jig matches the outer perimeter of the bone surfaces – cut and/or uncut). In certain embodiments, the spacers can include a resection surface to guide a subsequent surgical bone cut. Desirably, the thinnest insert that properly balances the knee will be chosen, reducing the chance for “overstuffing” of the knee joint.

Table 5: 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.

[000352] **FIG. 58G** depicts a spacer being inserted in extension between the femur and tibia. **FIG. 59** depicts a flexion gap balancer block for use in a knee brought into flexion. As best seen in **FIG. 58H**, one or more balancer blocks **18200** (of varying heights) can be placed between the cut surface of the tibia and the uncut posterior femoral condyles of the femur (with the femur in flexion) until proper alignment and orientation of the flexion gap is reached, and then an AP cut guide **18210** is positioned relative to the balancer block **18200** (at the surgeon's preference) and then the guide **18200** is pinned in place and the block **18200** removed. The guide **18210** includes a pair of cutting guides **18220**, **18230** which can be used by the surgeon to align the posterior femoral cuts. The cuts may be asymmetric, as desired, typically representing asymmetric posterior cut locations on the implant, and they allow fine-tuning of the external femoral rotation of the joint replacement. In various embodiments, the outer perimeters of the various jigs and blocks may matching some or all of the perimeter (cut and/or uncut) of the adjacent bone or bones, or may otherwise incorporate indicia identifying the margins of such adjacent surfaces.

[000353] **FIGS. 58J** and **58K** depict chamfer cut jigs **18250** and **18260** that have bone-facing surfaces that conform to the patient's cut anatomy, and one or more angled surfaces that serve as alignments guides for a surgeon's chamfer cuts on the bone. Desirably, the peripheral sides of the jigs **18250** and **18260** are sized to align with the outer margins of the cut bone surface, providing an additional alignment and reference guide to assure the surgeon the procedure is proceeding as planned. One or more handles **18270** are provided with each jig, to facilitate placement and handling of the jigs by the surgeon.

[000354] If desired, one of more of the jigs could incorporate visual or physical markings or other indicia to identify anatomical or biomechanical axes of the joint or joint components (i.e., transepicondylar axis). Such axes may be derived from the patient-specific information and then identified and incorporated into the various jigs to assist the surgeon in identifying such anatomical features and/or properly aligning and performing the joint replacement procedure. In a similar manner, various jigs could incorporate indicia that identify the anterior, medial, later and/or posterior directions of anatomy adjacent to the jig, as well as areas of other potential interest (i.e., areas to avoid or possibly draw samples – biopsies, etc.) to the surgeon.

[000355] **FIGS. 61A, 61B and 61C** depict an additional balancing technique to properly align a desired external rotation to the knee prosthesis prior to insertion of a tibial tray and tibial insert. **FIG. 61A** depicts the spacer of **FIG. 58G** in a desired position between a cut femur and cut tibia. **FIG. 61B** depicts a flexion block **18300** between the cut femur (now incorporating a femoral implant) and the cut tibial surface. Desirably, the first and second sides of this block are positioned and aligned such that, when the replacement femoral condyle surfaces contact the block, the implant “tilts” or externally rotates the femoral component a desired amount, which in this example is approximately 5.77 degrees (**FIG. 61C**). Once the proper size of block **18300** is determined, the surgeon can choose a corresponding tibial spacer (not shown) and tibial tray combination that achieves this same desired alignment for the femoral component.

[000356] In various embodiments, the knee rotation axis may be derived from various patient-specific data or combinations of patient-specific data, including from the imaged and/or derived and/or normalized medial/lateral J-curve data (i.e., medial or lateral or combinations of both). Moreover, the knee rotation axis can be derived from J-curve data from the femur and/or tibia or combinations thereof. In alternative embodiments, the knee rotation axis may be derived from various other axes, including the transepicondylar axis and/or the posterior condylar axis. In a similar manner, the implant motion (i.e., flexion, extension, translation and/or rotation) can be derived off medial and/or lateral tibial slope of the patient and/or from an engineered

design and/or combinations thereof, and well from as various combinations of the knee rotation axis and implant motion, as described above.

[000357] If desired, the implant design can alter the kinematics of the patient knee as desired, such as, for example, by altering a condyle location and/or surface to alter the implant motion and ultimately the kinematics of the patient's limb.

LIBRARIES

[000358] A surgical procedure and/or a virtual or physical implant component can be selected from a library or database 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).

[000359] For example, various exemplary designs and implant components for tibial trays and inserts for certain embodiments can include 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).

OPTIMIZATION OF JOINT-LINE AND GAP WIDTH

[000360] 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.

[000361] 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. As previously noted, surgeons can address a widened joint gap by pulling the second biological structure toward the first biological structure 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.

[000362] As previously discussed, the matching thickness profile can be designed based on one or more of the following considerations: the thickness 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.

[000363] In certain embodiments, the implant component thickness can range from about 2 mm to about 3 mm. Therefore, for patients that require only minimal bone resectioning of no more than 2-3 mm depth from the joint-line, an implant component designed with a thickness to substantially positively-match the 2-3 mm bone resectioning can maintain the joint-line location. Moreover, a subsequent traditional primary implant, for example, of 5 mm or greater thickness can be applied later with an additional cut depth of 3-2 mm or greater (for a total 5 mm cut depth).

This can allow for maintenance of the joint-line with the subsequent, traditional primary as well.

[000364] Certain embodiments directed to implants or implant designs optimized to achieve minimal implant thickness can include a higher number of bone cuts, for example, six, seven, eight, nine or more bone cuts, on the inner, bone-facing surface of the implant. The bone cuts can be oriented in various dimensions, for example, in a flexed-orientation. Moreover, certain embodiments can include on the inner, bone-facing surface any combination of straight cuts and curvilinear cuts. One or more curvilinear cuts can be designed to substantially positively-match the patient's uncut articular surface, such as a subchondral bone surface exposed by resurfacing. Alternatively, one or more curvilinear cuts can be designed to substantially positively-match a cut surface of the patient's bone, for example, a cut curvilinear surface. Various embodiments herein describe examples of implants and implant designs that include a straight anterior cut, a straight posterior cut, and a curvilinear cut in between. **FIG. 62** depicts an implant having a planar distal cut, a straight anterior cut, a straight posterior cut, and curvilinear chamfer cuts in between two substantially negatively-match corresponding resected surface(s) of the femur. Various other embodiments contemplate an implant or implant design that includes on the inner, bone-facing surface one or no straight cuts and portions that substantially positively-match an uncut articular bone surface.

[000365] The inner, bone-facing surface of the implant component can be designed to substantially negatively-match the cut bone surface, both curved and straight portions. The curved cuts to the bone can be performed with a router saw or other surgical tool. Any number of the cuts can have a depth of 2-3 mm, and the implant component thickness can be designed to positively-match the cut depth across a portion of the implant or across the entire implant.

[000366] If the thickness of an implant component is greater than the depth of the corresponding bone cut, then the thicker implant component can shift the joint-line down. However, as previously discussed the joint gap width can be retained by designing a second implant component to offset the greater thickness of the first

implant component. For example, in total knee replacements that include both a femoral implant component and a tibial implant component, if the femoral implant component is thicker than the depth of the corresponding bone cut, more tibial bone can be cut and/or a thinner tibial implant can be used.

OPTIMIZATION AND BALANCING OF JOINT

[000367] In various embodiments, the surgeon has the option and ability to 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 5**.

[000368] 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.

[000369] 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.

[000370] 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.

[000371] 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 thicknesses described in **Table 6** can be inserted.

Table 6: Exemplary medial and lateral spacer, trial, and/or insert heights that can be used in combination

Medial spacer, trial, and/or insert height	Lateral spacer, trial, and/or insert height	Note
6 mm	6 mm	Same medial and lateral spacer, trial, and/or insert height
7 mm	7 mm	
8 mm	8 mm	
9 mm	9 mm	
10 mm	10 mm	
11 mm	11 mm	
12 mm	12 mm	
13 mm	13 mm	
14 mm	14 mm	
15 mm	15 mm	
16 mm	16 mm	

Medial spacer, trial, and/or insert height	Lateral spacer, trial, and/or insert height	Note
6 mm	7 mm	Different medial and lateral spacer, trial, and/or insert (6 mm medial spacer, trial, and/or insert height with various lateral spacer, trial, and/or insert heights)
6 mm	8 mm	
6 mm	9 mm	
6 mm	10 mm	
6 mm	11 mm	
6 mm	12 mm	
6 mm	13 mm	
6 mm	14 mm	
6 mm	15 mm	
6 mm	16 mm	
7 mm	6 mm	Different medial and lateral spacer, trial, and/or insert height (7 mm medial spacer, trial, and/or insert height with various lateral spacer, trial, and/or insert heights)
7 mm	8 mm	
7 mm	9 mm	
7 mm	10 mm	
7 mm	11 mm	
7 mm	12 mm	
7 mm	13 mm	
7 mm	14 mm	
7 mm	15 mm	
7 mm	16 mm	
8 mm	6 mm	Different medial and lateral spacer, trial, and/or insert height (8 mm medial spacer, trial, and/or insert height with various lateral spacer, trial,
8 mm	7 mm	
8 mm	9 mm	

Medial spacer, trial, and/or insert height	Lateral spacer, trial, and/or insert height	Note
8 mm	10 mm	and/or insert heights)
8 mm	11 mm	
8 mm	12 mm	
8 mm	13 mm	
8 mm	14 mm	
8 mm	15 mm	
8 mm	16 mm	Different medial and lateral spacer, trial, and/or insert height (9 mm medial spacer, trial, and/or insert height with various lateral spacer, trial, and/or insert heights)
9 mm	6 mm	
9 mm	7 mm	
9 mm	8 mm	
9 mm	10 mm	
9 mm	11 mm	
9 mm	12 mm	
9 mm	13 mm	
9 mm	14 mm	
9 mm	15 mm	
9 mm	16 mm	
10 mm	6 mm	Different medial and lateral spacer, trial, and/or insert height (10 mm medial spacer, trial, and/or insert height with various lateral spacer, trial, and/or insert heights)
10 mm	7 mm	
10 mm	8 mm	
10 mm	9 mm	
10 mm	11 mm	
10 mm	12 mm	

Medial spacer, trial, and/or insert height	Lateral spacer, trial, and/or insert height	Note
10 mm	13 mm	
10 mm	14 mm	
10 mm	15 mm	
10 mm	16 mm	
11 mm	6 mm	Different medial and lateral spacer, trial, and/or insert height (11 mm medial spacer, trial, and/or insert height with various lateral spacer, trial, and/or insert heights)
11 mm	7 mm	
11 mm	8 mm	
11 mm	9 mm	
11 mm	10 mm	
11 mm	12 mm	
11 mm	13 mm	
11 mm	14 mm	
11 mm	15 mm	
11 mm	16 mm	Different medial and lateral spacer, trial, and/or insert height (12 mm medial spacer, trial, and/or insert height with various lateral spacer, trial, and/or insert heights)
12 mm	6 mm	
12 mm	7 mm	
12 mm	8 mm	
12 mm	9 mm	
12 mm	10 mm	
12 mm	11 mm	
12 mm	13 mm	
12 mm	14 mm	
12 mm	15 mm	

Medial spacer, trial, and/or insert height	Lateral spacer, trial, and/or insert height	Note
12 mm	16 mm	
13 mm	6 mm	Different medial and lateral spacer, trial, and/or insert height (13 mm medial spacer, trial, and/or insert height with various lateral spacer, trial, and/or insert heights)
13 mm	7 mm	
13 mm	8 mm	
13 mm	9 mm	
13 mm	10 mm	
13 mm	11 mm	
13 mm	12 mm	
13 mm	14 mm	
13 mm	15 mm	
13 mm	16 mm	
14 mm	6 mm	Different medial and lateral spacer, trial, and/or insert height (14 mm medial spacer, trial, and/or insert height with various lateral spacer, trial, and/or insert heights)
14 mm	7 mm	
14 mm	8 mm	
14 mm	9 mm	
14 mm	10 mm	
14 mm	11 mm	
14 mm	12 mm	
14 mm	13 mm	
14 mm	15 mm	
14 mm	16 mm	
15 mm	6 mm	Different medial and lateral spacer, trial, and/or insert height (15 mm medial spacer, trial, and/or
15 mm	7 mm	

Medial spacer, trial, and/or insert height	Lateral spacer, trial, and/or insert height	Note
15 mm	8 mm	insert height with various lateral spacer, trial, and/or insert heights)
15 mm	9 mm	
15 mm	10 mm	
15 mm	11 mm	
15 mm	12 mm	
15 mm	13 mm	
15 mm	14 mm	
15 mm	16 mm	
16 mm	6 mm	Different medial and lateral spacer, trial, and/or insert height (16 mm medial spacer, trial, and/or insert height with various lateral spacer, trial, and/or insert heights)
16 mm	7 mm	
16 mm	8 mm	
16 mm	9 mm	
16 mm	10 mm	
16 mm	11 mm	
16 mm	12 mm	
16 mm	13 mm	
16 mm	14 mm	
16 mm	15 mm	

[000372] Thus, 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.

[000373] **FIGS. 63A** through **65C** show various exemplary spacers or trials or inserts for adjusting and optimizing alignment, tension, balance, and position (e.g., as described in **Table 5** above) during a knee implant surgery. In particular, **FIG. 63A** depicts a medial balancer chip insert from top view to show the superior surface of the chip. **FIG. 63B** 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.

[000374] **FIG. 63C** depicts a medial balancing chip being inserted in flexion between the femur and tibia. **FIG. 63D** 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. 63C** and **63D**, until a desired tension is observed medially and laterally throughout the patient's range of motion. As shown in **FIG. 63E**, 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. 63F**, the inferior surface of the medial balancing chip can act as cutting guide surface for resectioning the medial portion of the tibia.

[000375] **FIG. 64A** 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 trial 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.

[000376] **FIG. 64B** 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.

[000377] **FIG. 64C** 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.

[000378] **FIG. 65A** 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. 65B** depicts the process of placing and adding various tibial component insert trials and **FIG. 65C** depicts the process of placing the selected tibial component insert.

[000379] The sets of exemplary spacers, trials, and inserts described in connection with **FIGS. 63A** through **65C** 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.

[000380] 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.

FIXATION

[000381] 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.

EXEMPLARY PROCEDURES

[000382] In certain embodiments, implant components and/or related methods described herein can include a combination of patient-specific and patient-engineered features. For example, patient-specific data collected preoperatively can be used to engineer one or more optimized surgical cuts to the patient's bone and to design or select a corresponding implant component having one or more bone-facing surfaces or facets (i.e., "bone cuts") that specifically match one or more of the patient's resected bone surfaces. The surgical cuts to the patient's bone can be optimized (i.e., patient-engineered) to enhance one or more parameters, such as: (1) deformity correction and limb alignment (2) maximizing preservation of bone, cartilage, or ligaments, (3) maximizing preservation and/or optimization of other features of the patient's anatomy, such as trochlea and trochlear shape, (4) restoration and/or optimization of joint kinematics or biomechanics, (5) restoration or optimization of joint-line location and/or joint gap width, (6) and/or addressing one or more other parameters. Based on the optimized surgical cuts and, optionally, on other desired features of the implant component, the implant component's bone-facing surface can be designed or selected to, at least in part, negatively-match the shape of the patient's resected bone surface.

[000383] 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.

[000384] Optionally, other data including anthropometric data may be added for each patient. These data can include but are not limited to the patient's age, gender, weight, height, size, body mass index, and race. Desired limb alignment and/or deformity correction can be added into the model. The position of bone cuts on one or more articular surfaces as well as the intended location of implant bearing surfaces on one or more articular surfaces can be entered into the model.

[000385] 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

[000386] 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.

[000387] 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.

[000388] 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.

[000389] 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.

[000390] Similarly, if a patellar component radius is widened, this can be accompanied by a widening of an opposing trochlear bearing surface radius, or vice-versa.

[000391] These linked changes also can apply for hip and/or shoulder implants. For example, in a hip, if a femoral implant shape is changed, for example on an external surface, this can be accompanied by a change in an acetabular component shape. This is, for example, applicable when at least portions of the acetabular bearing surface negatively-match the femoral joint-facing surface. In a shoulder, if a glenoid implant shape is changed, for example on an external surface, this can be accompanied by a change in a humeral component shape. This is, for example, particularly applicable when at least portions of the humeral bearing surface negatively-match the glenoid joint-facing surface, or vice-versa.

[000392] Any combination is possible as it pertains to the shape, orientation, and size of implant components on two or more opposing surfaces.

EXEMPLARY FEMORAL IMPLANT PROCEDURES

[000393] A traditional femoral implant component used in a primary total knee arthroplasty (“TKA”) includes: an outer, joint-facing surface (i.e., inferior surface) having a standard topography; an inner, bone-facing surface (i.e., superior surface) that includes five standard bone cuts; and a standard implant thickness between the joint-facing surface and the bone-facing surface. **FIG. 66** shows a coronal view of a patient’s femoral bone **2900** and (in dashed lines) the five standard resection cuts

used to remove portions of the subject's distal femur in order to fit the traditional femoral implant component. As shown by the dashed lines in the figure, a traditional resection performed in a TKA includes a horizontal resection cut **2910**, an anterior resection cut **2920**, a posterior resection cut **2930**, an anterior chamfer resection cut **2940**, and a posterior chamfer resection cut **2950**. The anterior and posterior resection cuts **2920**, **2930** typically are placed in a substantially coronal plane. With a traditional implant, the five standard resection cuts are performed so that the patient's distal femur approximately negatively-matches the standard five bone cuts on the inner, bone-facing surface of the traditional femoral implant component. In other words, the patient's bone is resected to fit the shape of the traditional femoral implant component.

[000394] Dissimilarly, in various embodiments described herein, one or more features of an implant component and/or implant procedure are designed and/or selected to provide a patient-adapted implant component. For example, in certain embodiments, one or more features of an implant component and/or implant procedure are designed and/or selected preoperatively, based on patient-specific data, to substantially match (e.g., substantially negatively-match and/or substantially positively-match) one or more of the patient's biological structures or a predetermined percentage thereof. For example, in certain embodiments, a femoral implant component can include an outer, joint-facing surface (i.e., inferior surface) having a sagittal or j-curve on one or both condyles that, at least in part, positively-matches the corresponding bone or cartilage curvature on the patient's uncut femur. This patient-specific implant component feature can be preoperatively selected and/or designed based on 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.

[000395] In preferred embodiments, the minimum implant component thickness can be engineered based on, or together with, other patient-engineered dimensions or features of the implant component, for example, one or more of implant component size, implant component condyle width, and one or more implant component surface curvatures. For example, as shown in **FIGS. 67A**, the thinnest part of a femoral

implant component frequently appears at the intersection of the implant component's distal bone cut and a posterior bone cut **3100**. This portion of an implant component also frequently shows the highest stress load, as exemplified by the FEA analysis results shown in **FIG. 67B**. Accordingly, the minimum implant component thickness for this or any portion of the implant component can be engineered based on one or more factors related to stress load, for example: the size of the patient; the size of the patient's femur; the size of the patient's condyle; the size of the patient-engineered implant component; the size of the implant component condyle; and the implant component's joint-facing surface curvature in the region that is opposite the intersection of the distal bone cut and posterior bone cut. In this way, a patient-specific minimum implant thickness can be engineered from patient-specific data, such as image data, and designed into the patient-adapted implant. This allows for minimal bone to be resected in the implant procedure and thereby can help to maximize bone preservation for any particular patient. Preservation of bone can allow for a subsequent knee implant to be a primary knee implant procedure, rather than a revision procedure. The above embodiments are not only applicable to knee implants, but are applicable to implants in other parts of the body, e.g. an acetabulum, a femoral head, a glenoid, a humeral head, an elbow joint, a wrist joint, an ankle joint, a spine etc.

[000396] In patients in need of knee replacement, the lateral condyle is sometimes deformed or hypoplastic, which can contribute to a valgus deformity. In fact, hypoplastic lateral condyles may be present in 20% of patients that require knee replacement. An implant that is engineered from patient-specific data to address this deformity, by correcting or optimizing the lateral condyle, can include one or more expanded curvatures in one or more locations on the lateral condyle, relative to the patient's corresponding uncut medial or lateral condyle. Accordingly, the implant is engineered to include additional material on the outer, joint-facing surface of the implant component's lateral condyle. The expanded curvature(s) and/or material on the outside of the condyle can be used to design a material savings on the inside of the corresponding section of the implant component, for example, by maintaining a minimum material / implant thickness from the outside (joint-facing surface) to the

inside (bone-facing surface) of the implant component. In this way, by adding material to the external contour of the implant component and maintaining a minimum material thickness of the implant component, bone preservation can be maximized. Specifically, with more material on the joint-facing surface of the implant and less material on the inner, bone-facing surface of the implant, the resection cuts are made closer to the surface of the bone. Accordingly, this approach uses the patient-adapted design of the implant component to both correct a condyle shape abnormality, such as a lateral condyle abnormality, such as hypoplasia, and to maximize bone preservation.

[000397] Similarly, a maximum thickness, and/or maximum edge thickness and/or maximum chamfer cut thickness and/or maximum bone-cut thickness can be predetermined. The shape or curvature or width of the one or more bearing surfaces of the implant then can be altered in order to achieve the predetermined maximum thickness and/or maximum edge thickness and/or maximum chamfer cut thickness and/or maximum bone cut thickness criterion. By optimizing against a maximum bone-cut thickness, the implant can be selected or designed so that it is sufficiently bone preserving to be a pre-primary implant, e.g., where, for example, a distal bone cut is distal to the bone cut with a standard off the shelf femoral component implant, thereby enabling later revision to a standard total knee system.

[000398] Patellar revision can be very challenging and bone preservation is preferred in the patella. In certain embodiments, two or more patellar resection facets and two or more patellar implant component bone cuts are employed to preserve patellar bone stock. One or both of the two or more patellar facets can be substantially tangent or parallel to the medial and/or lateral uncut patellar surfaces. Optionally, particularly with more than two patellar resection facets, facets can be substantially tangent or parallel to uncut patellar superior and/or inferior surfaces. In certain embodiments, the patellar-facing surface of an implant component can be patient-specific, i.e., designed to match the patient's normal trochlear groove or patellar shape (e.g. patellar cartilage or subchondral bone). Alternatively, the patellar-facing surface of the implant component can be engineered or, for example, derived or engineered from patient-specific data to optimize one or more parameters,

for example, kinematics or wear between component surfaces. A method for designing a patient-adapted implant to optimize tracking of the patella along the trochlear groove of a femoral implant component is described herein. Specifically, one exemplary implant design can use a patient-specific sagittal curvature, at least in part, and an engineered coronal curvature, at least in part, to allow the patella component to track properly in the trochlear groove. In certain other embodiments, the coronal curvature additionally can be patient-specific. In certain embodiments, the coronal curvature is patient-specific and the sagittal curvature is standard or engineered.

[000399] As noted above, with traditional knee implants the patient's bone is resected to fit the standard shape of the bone-facing surface of the traditional femoral implant component. On its bone-facing surface, the traditional femoral implant component includes five standard bone cuts, as exemplified by the implant shown in **FIG. 68A**. Specifically, a traditional total knee implant includes a distal or horizontal cut **4210**, an anterior cut **4220**, a posterior cut **4230** along each femoral condyle, an anterior chamfer cut **4240**, and a posterior chamfer cut **4250**.

[000400] In certain embodiments, one or more portions of the bone-facing surface of the femoral implant are designed based on patient-specific data to substantially negatively-match the uncut surface of the patient's femur, for example, the subchondral bone surface of the femur. In such embodiments, the surgical procedure includes resurfacing (i.e., removing cartilage, at least in part, while substantially retaining the surface of subchondral bone (i.e. cutting away bone), the joint-facing surface of the patient's femur. In certain embodiments, the bone-facing surface(s) of the implant component are designed and/or selected preoperatively, based on patient-specific data, to optimize one or more parameters, such as bone preservation (e.g., minimizing the amount of bone that is resected during the implant procedure).

[000401] In certain embodiments one or more portions of the bone-facing surface of the femoral implant includes two or more bone cuts, for example, two, three, four, five, six, seven, eight, nine, or more bone cuts. For example, a femoral implant

component can include less than or greater than five bone cuts. In a preferred embodiment, the femoral implant includes six bone cuts, as shown in **FIG. 68B**. In another preferred embodiment, the femoral implant includes seven bone cuts, as shown in **FIG. 10B**. One or more of the implant bone cuts can be curvilinear or the entire bone-facing surface of the implant component can be curvilinear bone cut.

[000402] As exemplified in **FIG. 68C**, in certain embodiments the femoral implant and design can include bone cuts that are rotated or oriented based on a certain flexion angle of the knee, e.g., rotated in the sagittal plane. An example of a flexed-fit cut design is described in various embodiments herein. Any number of bone cuts can be included in an implant device designed with flexed-fit cuts. For example, two, three, four, five, six, seven, eight, nine or more cut planes can be included in a flexed-fit design. One or more of the cuts can be curvilinear or the entire bone-facing surface can be curvilinear. Moreover, any one or more bone cuts can include two or more non-coplanar facets, as described below. The cuts can be oriented at any rotation, for example, at 5, greater than 5, 10, greater than 10, 15, greater than 15, 20, greater than 20, 25, or greater than 25 degrees flexion.

[000403] In certain embodiments, the femoral implant component can include one or more bone cuts oriented one or more dimensions, e.g., not only in the sagittal plane, but also in the coronal plane and/or in the axial plane. **FIGS. 69A** through **69F** show exemplary cross-sections of femoral implant components with bone cuts shown as dashed lines. **FIGS. 69A** and **69B** show an implant component with traditional bone cuts (**FIG. 69A**) as compared to an implant component with bone cuts rotated in the sagittal plane (**FIG. 69B**). **FIGS. 69C** and **69D** show an implant component with traditional bone cuts (**FIG. 69C**) as compared to an implant component with bone cuts rotated in the coronal plane (**FIG. 69D**). **FIGS. 69E** and **69F** show an implant component with traditional bone cuts (**FIG. 69E**) as compared to an implant component with bone cuts rotated in the axial plane (**FIG. 69F**). Such bone cut rotations can help to further optimize bone preservation.

[000404] As shown in **FIGS. 70A-70C** and **71A-71B**, in certain embodiments an implant component bone cut can include one or more non-parallel and non-coplanar

facets. As shown, the implant component in **FIG. 70A** includes six bone cuts while the implant component in **FIG. 71A** includes an extra posterior chamfer bone cut for a total of seven bone cuts. Non-coplanar facets can include facets that lie in parallel but different planes and/or facets that lie in non-parallel planes. As exemplified by the implant component shown in **FIGS. 70A-70B** and by the implant component shown in **FIGS. 71A-71B**, the medial and lateral facets of a bone cut can be non-parallel and non-coplanar for one or more bone cuts, for example, for one or more of the distal bone cut **4410**, the posterior bone cut **4430**, the first posterior chamfer bone cut **4452**, and the second posterior chamfer bone cut **4454**. Alternatively or in addition, one or more corresponding facets of a bone cut can include different thicknesses. For example, the implant component shown in **FIG. 70A** includes a maximum distal medial facet thickness of 6.2 mm and a maximum distal lateral facet thickness of 6.3 mm. The independent and optionally patient-derived thicknesses on corresponding bone cut facets can apply to one or more thickness measurements, for example, one or more of maximum thicknesses, minimum thickness, and an average thickness, for example, to match or optimize the particular patient's anatomy. Moreover, a single bone cut or bone cut facet can include a variable thickness (e.g., a variable thickness profile across its M-L and/or A-P dimensions). For example, a bone cut or bone cut facet can include a thickness profile in one or more dimensions that is patient-derived (e.g., to match or optimize the patient's anatomy). The implant component in **FIG. 71A** includes an anterior chamfer with an 11 mm thickness on the medial side (which includes the medial implant component peg or post **4465**) and a different thickness on the lateral side. As shown, the implant component in **FIG. 71A** was selected and/or designed to have a flex-fit (e.g., having bone cuts rotated posteriorly about the transepicondylar axis, which can enhance implant component coverage of the posterior portion of the femur and provide the patient with deeper knee flexion with the implant).

[000405] Alternatively or in addition, one or more corresponding facets of a bone cut can include different surface areas or volumes. For bone cuts having facets separated by the intercondylar space and asymmetric with respect to the A-P plane bisecting the implant component, the asymmetric facets appear dissimilar in shape

and/or size (e.g., two-dimensional area). For example, the implant components shown in **FIGS. 70A** and **71A** include one or more corresponding facets (e.g., distal medial and lateral facets, posterior medial and lateral facets, and/or posterior chamfer medial and lateral facets) having different medial facet and lateral facet bone-facing surface areas, joint-facing surface areas, and/or volumes in between the two surfaces. In particular, as shown in **FIGS. 70A** and in **71A**, the medial and lateral facets of the distal bone cut **4410** are asymmetric and appear dissimilar in both shape (e.g., surface area perimeter shape) and size (e.g., volume under the surface area). The independent facet surface areas and/or volumes optionally can be patient-derived (e.g., to match or optimize the patient's anatomy).

[000406] As shown in **FIG. 70A**, non-coplanar facets can be separated by an intercondylar space **4414** and/or by a step cut **4415**. For example, as shown in the figure, the distal bone cut **4410** includes non-coplanar medial and lateral facets that are separated, in part, by the intercondylar space **4414** and, in part, by a step cut **4415**.

[000407] In certain embodiments, one or more resection cuts can be selected and/or designed to so that one or more resected cut or facet surfaces substantially matches one or more corresponding bone cuts or bone cut facets. For example, **FIG. 70C** shows six resection cut facets that substantially match the corresponding implant component bone cut facets shown in **FIG. 70A**. **FIG. 71B** shows seven resection cut facets that substantially match the corresponding implant component bone cut facets of the medial side of the implant component shown in **FIG. 70A**. The portion **4470** represents additional bone conserved on the lateral side of the of the femur corresponding to the bone-cut intersection between the lateral distal bone cut facet **4410** and the adjacent anterior chamfer bone cut **4440**.

[000408] In certain embodiments, a bone-cut facet and/or a resection cut facet can span the intercondylar space and be separated from another facet by a step cut. For example, as exemplified in **FIG. 72**, predetermined resection cuts can be selected and/or designed to include a facet or part of a facet **4680** separated from

one or more corresponding facets by an intercondylar space **4614** and/or by a step cut **4615**.

[000409] In addition or alternatively, in certain embodiments one or more of the implant bone cuts can be asymmetric, for example, asymmetric with respect to a sagittal or A-P plane, or to a coronal or M-L plane, bisecting the implant component. For example, as shown in **FIGS. 70A** and **71A**, the anterior chamfer bone cut **4440** is asymmetric with respect to an A-P plane bisecting the implant component. In addition, in both figures the lateral distal bone cut facet **4410** is asymmetric with respect to an A-P plane bisecting the implant component.

[000410] The bone cut designs described above, for example, an implant component bone-facing surface having various numbers of bone cuts, flexed bone cuts, non-coplanar bone cut facets, step cuts used to separate facets, and asymmetric bone cuts and bone cut facets, can be employed on a bone-facing surface of a femoral implant component to save substantial portions of bone. **Table 7** shows the different amounts of bone to be resected from a patient for fitting an implant component with bone cuts shown in **FIG. 70A**, an implant component with bone cuts shown in **FIG. 70A**, and a traditional implant component with traditional bone cuts. As compared to the traditional implant component, the implant component shown in **FIG. 70A** saves 44% of resected patient bone and the implant component shown in **FIG. 71A** saves 38% of resected patient bone. However, the implant component in **FIG. 71A** is flexed, which can provide enhanced deep knee flexion for the patient. In certain embodiments, the surgeon or operator can select or apply a weighting to these two parameters (bone preservation and kinematics) and optionally other parameters to identify an optimum patient-adapted implant component and, optionally, a corresponding resection cut strategy that meets the desired parameters and/or parameter weightings for the particular patient.

Table 7: Bone preservation comparison using different bone cut designs

Bone Cut	FIG. 9D Implant (Stepped)	FIG. 9E Implant (Flexed no step)	Traditional Implant
Distal Medial	3626	2675	5237

Distal Lateral	2593	3077	2042
Medial Posterior Chamfer 1	942	694	3232
Lateral Posterior Chamfer 1	986	715	648
Medial Posterior Chamfer 2	816	921	--
Lateral Posterior Chamfer 2	612	582	--
Medial Posterior Cut	945	1150	2816
Lateral Posterior Cut	770	966	649
Anterior Chamfer 1	1667	6081	9872
Anterior Chamfer 2	--	1845	--
Anterior Cut	3599	2717	4937
Total bone resection (mm³)*	16556	18346	29433
Reduction in bone resected as compared to traditional implant	44%	38%	--

[000411] In traditional femoral implant components, the anterior or trochlear bone cut is located substantially in the coronal plane and is parallel to the posterior condylar bone cut, as indicated by the dashed anterior resection cut **4710** and dashed posterior resection cut **4712** shown in **FIG. 73A**. This can result in a substantial amount of bone lost from those portions of the patient's femur **4714**, **4716**. However, in certain embodiments described herein, the implant's anterior or trochlear bone cut is substantially non-parallel to the coronal plane, as shown by the dashed and straight line **4718** in **FIG. 73B**. For example, the implant's anterior or trochlear bone cut can substantially match the patient's resected trochlear surface, which can be selected and/or designed to be parallel to a tangent through the corresponding peak **4720** and an uncut trochlear surface portion of the patient's trochlea, as shown in **FIG. 73B**. By placing the implant bone cut **4718** and the resected surface at an angle relative to the patient's coronal plane, for example, parallel to a tangent of one or both medial and lateral trochlear peak and/or the adjacent trochlear surface, a substantial amount of bone can be preserved.

[000412] In certain embodiments, the implant component can include a trochlear bone cut with two or more non-coplanar facets, as shown by the intersecting solid

lines **4722, 4724** in **FIG. 73B**. For example, one of the two or more facets (and the patient's corresponding resected surface) can be substantially parallel to the patient's lateral uncut trochlear peak **4720** and/or the adjacent uncut trochlear surface. A second facet (and the patient's corresponding resected surface) can be substantially parallel to the patient's medial uncut trochlear peak **4726** and/or the adjacent uncut trochlear surface. This can further enhance the degree of bone preservation.

[000413] In certain embodiments, two or more trochlear bone cut facets can be substantially tangent to the lateral and medial patellar surfaces **4728, 4730** of the patient's uncut bone. In addition or alternatively, two or more trochlear bone cuts can be substantially tangent or parallel to the superior and inferior patellar facets, in particular, when more than two implant trochlear bone cut facets are used. In certain embodiments, one or more trochlear bone cut facets can be curvilinear.

[000414] In a traditional femoral implant component, the posterior bone cut includes portions on the medial and lateral condyles that are in the same plane and parallel to each other, and substantially parallel to the anterior cut. However, in certain embodiments described herein, the implant component can include posterior condylar bone cut facets on the medial and lateral condyles, respectively, that are non-coplanar **4732, 4734**. Alternatively, or additionally, the implant component can include one or more posterior condylar facets that are substantially non-parallel with one or more facets of the anterior bone cut.

[000415] In certain preferred embodiments, the posterior condylar bone cut includes a facet on the medial condyle that is substantially perpendicular to the long axis of the medial condyle. Optionally, the facet on the lateral condyle can be perpendicular to the long axis of the lateral condyle. As depicted in **FIG. 74**, in certain embodiments, the anterior bone cut and corresponding resection cut **4810** and posterior bone cut **4820** can be substantially non-parallel to the coronal plane **4830** in the superoinferior orientation.

[000416] In certain embodiments, the posterior bone cut medial and lateral facets of an implant component can be asymmetric with respect to an A-P plane bisecting

the implant component. Moreover, one or more posterior bone cut facets can be curvilinear.

[000417] In certain embodiments, the distal bone cut of a femoral implant component includes medial and lateral condylar facets that are in the same plane as each other and/or are substantially parallel to each other. The facets can be separated by the intercondylar space and/or by a step cut. In certain embodiments, the implant component can include a distal bone cut having medial and lateral condylar facets that are non-coplanar and/or non-parallel.

[000418] In certain embodiments, the distal bone cut or bone cut facets is/are asymmetric with respect to an A-P plane bisecting the implant component. Moreover, the distal bone cut and/or one or more distal bone cut facets can be curvilinear.

[000419] Traditional femoral implant components include one anterior chamfer bone cut and one posterior chamfer bone cut. However, in certain embodiments described herein, additional chamfer bone cuts can be included. By increasing the number of chamfer bone cuts on the implant and placing the cuts in close proximity to the tangent of the articular surface, additional bone can be preserved. One or more additional chamfer bone cuts can be substantially tangent to the articular surface. For example, in certain embodiments, the implant component can include one or more additional anterior chamfer cuts and/or one or more additional posterior chamfer cuts.

[000420] In certain embodiments, the implant component can include a posterior chamfer bone cut that includes medial and lateral condylar facets that are non-coplanar and/or non-parallel. In certain embodiments, a posterior chamfer bone cut of the implant component can include facets that are asymmetric with respect to an A-P plane bisecting the implant component. Moreover, one or more posterior chamfer bone cuts and/or one or more posterior chamfer bone cut facets can be curvilinear.

[000421] In certain embodiments, the implant component can include an anterior chamfer bone cut that includes medial and lateral condylar facets that are non-coplanar and/or non-parallel. In certain embodiments, an anterior chamfer bone cut

of the implant component can be asymmetric and/or can include facets that are asymmetric with respect to an anterior-posterior (A-P) plane bisecting the implant component. Moreover, one or more anterior chamfer bone cuts and/or bone cut facets can be curvilinear.

[000422] In certain embodiments, the cut plane for one or more bone cuts of the implant component, for example, the distal bone cut and/or one or more of the anterior chamfer bone cuts, can be defined, in part, by the extent of the trochlear gap in the patient's joint. Specifically, one or more of these bone cuts can be designed based on patient-specific data to include a perimeter that matches the contour of the patient's trochlear notch. In certain embodiments, the implant component is patient-adapted so that there is no exposed implant surface on the bone-facing side of the implant component at the trochlear gap. Moreover, one or more of these bone cuts can be designed so that there is no, or minimally exposed, resected bone surface at the trochlear notch.

[000423] Computer software can be used that calculates the closest location possible for resected surfaces and resected cuts relative to the articular surface of the uncut bone, e.g., so that all intersects of adjoining resected surfaces are just within the bone, rather than outside the articular surface. The software can move the cuts progressively closer to the articular surface. When all intersects of the resected cuts reach the endosteal bone level, the subchondral bone level, and/or an established threshold implant thickness, the maximum exterior placement of the resected surfaces is achieved and, with that, the maximum amount of bone preservation.

[000424] 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, an intercondylar housing (sometimes referred to as a "box") **4910**, as shown in **FIGS. 75A** and **75B**, and/or one or more intercondylar bars **5010**, as shown in **FIGS. 76A** and **76B**, 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. 76A** and **76B**, 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.

[000425] 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. 77**, 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.

[000426] 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.

[000427] 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.

[000428] 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.

EXEMPLARY PATELLA IMPLANT PROEDURES

[000429] In a traditional patellar implant procedure, the articular surface (i.e., the bearing surface and/or joint-facing surface) of a patient's patella can be resected, typically using a bone cut across the patella, and a patellar implant component having standard dimensions can be mounted to the resected surface of the remaining portion of the patient's patella. The patella implant components have off-the-shelf standard dimensions and are typically selected intraoperatively.

[000430] In certain embodiments, an imaging test such as x-ray imaging, digital tomosynthesis, cone beam CT, a CT scan including a spiral CT scan, MRI scan including 3D acquisitions, ultrasound scan, laser scan, optical coherence tomography or combinations thereof can be used to define the shape or geometry of a patient's patella and, optionally one or more other biological or kinematic features. The scan data can be utilized to measure or derive information on the shape or geometry of the patient's patella. For example, a superoinferior or mediolateral or oblique dimension

or an anteroposterior width can be measured. One or more patellar axes can be determined, e.g., a sagittal axis, coronal axis, axial axis, a tracking axis, one or more axes describing patellar motion in relationship to the trochlea, e.g., mediolateral or superoinferior or oblique, as well as select femoral axes, e.g., a posterior condylar axis, epicondylar axis, Whiteside's line, a mechanical axis and/or one more other axes. Someone skilled in the art will recognize other patellar- and axis-related measurements that can be obtained. In principal, any anatomic or functional measurement applicable to a patellar geometry or function and kinematics can be obtained or derived. Once one or more geometric, functional, and kinematic measurements have been obtained or derived, the information can be utilized to select or design a patellar implant or component that is best suited for a particular patient.

[000431] For example, an AP dimension of the patella can be measured and a patellar implant or component best matching the AP dimension can be selected and/or designed. The selection or design can be adapted based on an intended resection depth. An ML dimension of a patellar implant or component can be measured and a patellar implant or component best matching the ML dimension can be selected or designed. The selection or design can be adapted based on an intended resection depth. The AP measurement or ML measurement or any other measurement can be adapted or derived for a preferred resection depth or cut depth. Resection for placing the patellar implant or component can be achieved with any technique known in the art, such as sawing, burring, drilling, and/or other known techniques.

[000432] **FIGS. 78A to 78C** demonstrate how a patellar resection depth alters the resultant patellar resection profile (e.g., the profile of the cut surface on the remaining patella). In general, as the resection plane moves away from the patellar articulating surface cartilage or subchondral bone and deeper into the patella, a greater resultant AP and/or ML resection dimension is produced until about the half point has been crossed; at which point, typically, the resection profile starts to decrease in thickness resulting in a decrease in the AP and/or ML dimension of the resected profile. Thus, as shown in **FIGS. 78A** and **78B**, a patellar implant or component can include a

perimeter selected and/or designed for a particular resection depth. The resection can be planned on a 2D image or a series of 2D images, or a 3D image or representation. The implant can be selected and/or designed on the 2D image or series of 2D images, or 3D image or representation, for example by superimposing a 2D or 3D outline of the implant. Multiple outlines can be available. Alternatively, as shown in **FIG. 78C**, a 2D or 3D outline can be smoothed or deformed to achieve the best or desired fit.

[000433] For example, in certain embodiments, the patellar implant or implant component can be selected and/or designed so that it substantially matches one or more AP or ML or oblique or other dimensions in at least a portion of the uncut patella and/or in at least a portion of the patella resection profile. Alternatively or in addition, the patellar implant or component can be selected and/or designed so that it is smaller than one or more of the AP or ML or oblique or other dimensions in at least a portion of the uncut patella and/or in at least a portion of the patella resection profile. For example, in one or more select dimensions the patellar implant or component can be selected and/or designed to be less than 5%, 10%, 15%, 20%, or other percentage relative to the patellar profile or resected patellar profile for a given resection depth. The patellar implant can be selected and/or designed to achieve a desired fit in one or more of those dimensions or other dimensions so that the fit is applicable to two or more resection depths. In this manner, the surgeon has the ability to change his resection depth intraoperatively, while, for example, still avoiding implant overhang.

[000434] A patellar implant also can be selected or designed, for example, based on the patient's original patellar surface shape. For example, if the patellar has a dome shape, a substantially dome shaped implant or component can be selected or designed. If the patella has a relatively flat shape, a more flat implant or component can be selected or designed. If the patella has a relatively spherical shape, a more spherical implant or component can be selected or designed. The patellar implant or component can be round or elliptical. Other shapes are possible. The patellar implant or component can be longer laterally than medially. The lateral and medial lengths can be matched to the native patella. Alternatively, the lateral or medial lengths can

be matched to the patient's trochlea. Alternatively, the lateral or medial lengths can be matched to the trochlear implant dimensions, which can be patient adapted or standard off the shelf. In this embodiment, a patellar shape can be selected or designed that closely mimics the patient's original patellar shape, for example by following, at least in part, the shape or contour of the cartilage or subchondral bone or portions thereof, for example in a median ridge, lateral facet, medial facet, trochlea, trochlear groove, and/or in one or more other dimensions. In instances when the patella has been distorted in shape by arthritic deformity, the patient's original patellar shape can be derived or estimated based on patient-specific data, for example, based on data regarding the patient's surrounding or contralateral biological features and/or on data regarding the patient's distorted biological features. Mathematical computations can be performed using the data to estimate or derive an approximate shape. Such mathematical computations can use, for example, patella dimensions, trochlear dimensions or femoral dimensions to estimate the original or a preferred patellar shape. Any of these dimensions can be matched to a reference database of normal individuals to select a trochlear or patellar shape for any of the implant components. The database can be age matched, gender matched, weight matched, race matched and/or matched with respect to one or more other features known in the art.

[000435] The resection depth determination can be based on the desired thickness of the patellar implant or patellar component. For example, the resection depth can be at a distance from the native articulating surface patellar cartilage or subchondral bone that is substantially equal to the thickness of the patellar implant or component. In another embodiment, for example if a femoral component is chosen that removes more of the patient's trochlear bone and that has, for example, a femoral component trochlear articulating surface that is posterior to the patient's uncut trochlea, the patellar resection depth may be further posterior, i.e., less bone is removed from the articulating surface the patellar implant or component to extend the patellar implant further toward the femur than the native patella. In this instance, the patellar resection depth can be derived using the following exemplary approach:

1. Start at the patellar articular cartilage or subchondral bone surface.

2. Move resection cut plane into the patella to the point that it substantially matches the patellar implant / component thickness.
3. Move the resection cut plane back toward the patellar articular surface (or, in select circumstances anterior) by an amount sufficient to offset the difference between the femoral component trochlear articulating surface and the native trochlear cartilage or subchondral bone surface.

[000436] In certain embodiments, the step of (a) determining a patellar resection depth can be performed by determining minimal implant material thickness based on patient-specific data. For example, patient-specific information, such as one or more of weight, activity level, femur size, femur implant aspects such as surface geometry (e.g., trochlear geometry), patellar size, patellar bone decay, femoral shape or geometry, patellar and/or trochlear and/or femoral kinematics, and other information can be used to determine a minimal implant material thickness appropriate for the patient. Alternatively or in addition, the step of (a) determining a patellar resection depth can be determined based on the features of one or more resection cuts or other implant components selected for the patient, which have patient-specific features, patient-engineered, or combinations thereof. Then, the patella resection depth and the patella implant can be designed or selected to match this minimal material thickness. Alternatively, once the implant minimal material thickness is determined, a patella implant can be selected from a family of implants having variable thicknesses and the patellar resection depth is designed to match the thickness of the selected patellar implant. For example, a family of patellar implants can include implants with thicknesses of two or more of 4 mm, 6 mm, 8 mm, 10 mm, 10.5 mm, and 11 mm. **FIGS. 78A** through **78C** illustrate this procedure.

[000437] In certain embodiments, the step of designing, selecting, and/or making (e.g., cutting from a blank) the implant perimeter to be substantially positively-match the determined resected perimeter or a percentage thereof in one or more dimensions can include smoothing the line of the surface perimeter on the implant, as illustrated in **FIGS. 78A** and **78C**.

[000438] Accordingly, certain embodiments are directed to patellar implants and procedures that include one or more of (a) a preoperatively selected minimal implant thickness based on patient-specific information, such as femoral geometry and patellar size, (b) a preoperatively determined patellar resection depth that matches the selected minimal implant thickness and/or trochlear component thickness and/or external femoral component trochlea surface, and (c) a perimeter on patellar bone-facing surface of the implant that substantially positively-matches the perimeter of the resected surface, with optional smoothing of the implant perimeter. A significant advantage to having matching implant surface and resected surface perimeters is that it minimizes exposed resected bone and thereby minimizes bleeding, clot formation, and scar formation. Moreover, it can result in more bone preservation and/or improved kinematics.

EXEMPLARY FEMORAL/PATELLAR KNEE PROCEDURE

[000439] Various embodiments can include patient-adapted and/or engineered trochlea designs, such as depicted in **FIGS. 79A to 79F**, which show an exemplary design of a knee implant, including a femoral component and a patella component, with a material cutaway region highlighted (darker) in certain figures. The placement of the patella and material removal was as follows: As shown in **FIG. 79A**, the flat bone-bearing surface of the patella **12700**, was made parallel to the epicondylar axis **12710** in the coronal view. As shown in **FIG. 79B**, the center plane of the patella implant was made collinear with the epicondylar axis **12720**. This allows for general positioning at the peak area of the trochlea. As shown in **FIG. 79C**, in this position the medial-lateral center or sulcus of the trochlea is identified **12730**, and the patella implant component is brought down so the lowest points are coincident **12740**. As shown in **FIGS. 79D through 79F**, the patella profile is swept along the sagittal curve of the trochlear region **12750**.

[000440] This exemplary implant design uses a patient-specific sagittal curvature and an engineered coronal curvature to allow the patella component to track properly in the trochlear groove. This exemplary implant design for the femoral component and a patella component can allow various advantages including a reduction of

lateral overstuffing of the P-F joint and a post-operative patella tracking that is normal or close to the patient's pre-operative and/or pre-disease state. In certain embodiments, the lateral peak can be retained, which may minimize dislocation events. In certain embodiments, the patella implant bone-bearing surface can be or appear to be approximately parallel to the osteochondral junction of the native patella.

EXEMPLARY TIBIAL IMPLANT PROCEDURES

[000441] 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.

[000442] 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. 128A** and **128B** show exemplary unicompartamental medial and lateral tibial implant components without (**FIG. 128A**) and with (**FIG. 128B**) 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.

[000443] 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. 128A** and **FIG. 128B**, 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.

[000444] **FIGS. 129A** and **129B** show exemplary flow charts for deriving a medial tibial component slope (**FIG. 129A**) and/or a lateral tibial component slope (**FIG. 129B**) for a tibial implant component.

[000445] 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. 80A** to **80C** 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.

[000446] The exemplary combinations described in **Table 8** are applicable to implants that use two unicompartamental 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.

Table 8: 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

MEDIAL SIDE IMPLANT SLOPE	LATERAL SIDE IMPLANT SLOPE
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

[000447] 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.

[000448] 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. 1** and **FIGS. 80A to 80C** show several exemplary tibial

resection cuts, which can be used in any combination for the medial and lateral plateaus.

[000449] 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.

[000450] 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. 81G – 81K**). 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.

[000451] 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.

[000452] 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.

[000453] 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.

[000454] The tibial cut height can differ medially and laterally, as shown in **FIGS. 1** and **FIGS. 80A to 80C**. 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 preservation on the medial and/or lateral sides of the proximal tibia as well as on the opposing femoral condyles.

[000455] 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. 82**, 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.

[000456] 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.

[000457] 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.

[000458] 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. 1** and **FIGS. 80A to 80C**.

[000459] In certain embodiments, the sagittal curvature of the femoral component can be designed to be tilted, as suggested by **FIG. 83**. 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.

[000460] 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.

[000461] **FIGS. 75A and 75B, 76A and 76B, 77, and 84A through 84P** depict various features of intercondylar bars or in intercondylar housing for a cruciate-substituting femoral implant component. In addition, **FIGS. 76A and 76B** 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.

[000462] **FIGS. 85A and 85B** 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. 85A** 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. 85B** shows (a)-(e) tibial implant components having posts or projections oriented medially, with varying thicknesses, lengths, and curvatures.

[000463] 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.

[000464] 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.

[000465] 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.

[000466] 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.

[000467] 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.

[000468] 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.

[000469] 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.

[000470] 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. 86B**, 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).

[000471] 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.

[000472] 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.

[000473] In various embodiments, the surgical procedure will include methods and tibial implant components 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. 87A**, 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. 87B**, 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. 87C**, 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. 88A to 88C**, 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. For example, M-L and AP planes can be determined as described herein.

[000474] As shown in **FIG. 89A**, 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. 89B** 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.

[000475] **FIGS. 90A to 100C** describe exemplary steps for performing resection cuts to the tibia using the anatomical references identified above. For example, as shown in **FIGS. 90A** and **90B**, 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. 91A** and **91B**, a second step can include drilling and pinning the tibial axis (see arrow). As shown in **FIG. 92**, a third step can include drilling and pinning the medial pin (see arrow). As shown in **FIG. 93**, a fourth step can include removing the stylus. As shown in **FIG. 94**, 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. 95**, a sixth step can include removing the resected portion of the patient's tibial plateau. As shown in **FIG. 96**, a seventh step can include assembling stem and keel guide(s) onto the tibial cut guide. As shown in **FIG. 97**, 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. 98**, a ninth step can include using a saw or

osteotome to create a keel slot, for example, a 3.5mm wide keel slot. **FIG. 99** shows the finished tibial plateau with guide tools still in place. **FIGS. 100A – 100C** show each of a guide tool (**FIG. 100A**), a tibial implant component (**FIG. 100B**), and tibial and femoral implant components (**FIG. 100C**) in the aligned position in the knee.

[000476] 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.

[000477] Additional embodiments of tibial implant components can be selected and/or designed to address tibial rotation. **FIGS. 101A to 101B** describe exemplary techniques for determining tibial rotation for a patient and **FIG. 101C** shows resulting alignment data for the second technique.

[000478] Various tibial implant component features can be optimized to ensure proper tibial rotation. For example, **FIG. 102** 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).

[000479] 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. 103A and **103B** 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. 104A** and **104B** show the same approach as described for **FIGS. 103A** and **103B**, but applied to a different patient having a smaller tibia (e.g., smaller diameter and perimeter length).

[000480] Similarly, **FIGS. 105A to 105D** 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.

[000481] 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.

EXEMPLARY TOTAL KNEE PROCEDURE

[000482] In various embodiments, patient-adapted femoral, tibial, and patellar implant components can be designed and implanted, using associated implant components and guide tools having certain patient-specific, patient-engineered, and/or non-traditional standard features. In the studies described in this example, patient-adapted femoral, tibial, and patellar implant components were designed and implanted for each of three cadaveric patients. In addition, corresponding resection cut strategies were designed and performed. Moreover, several different patient-adapted guide tools were designed and used for the implantation procedure.

[000483] The implant components and guide tools (also referred to as “jigs” or “iJigs”) for each patient were designed based on patient-specific CT-derived data from each patient. Specifically, data from CT images of each patient’s knee was selected and imported into computer modeling software. The software was used to generate a model of the biological structures in the patient’s knee and to design (e.g., using CAD software) a femoral implant component, a tibial implant component, and related guide tools. The design of the implant components and guide tools included manufacturing, for example, using CAM software and additive and/or casting manufacturing techniques as described above. In addition, predetermined resection cuts to each patient’s femur and tibia were designed based on the patient’s biology and in conjunction with the patient-adapted features of the implant component. For example, the resection cuts and the corresponding component’s bone-facing surfaces were designed based on patient-specific data to substantially negatively match (e.g., in surface area, surface angle, and/or other feature). Then, surgery was performed on the cadaveric patient to perform the predetermined (e.g., designed) resection cuts and to implant the components designed for the particular patient. In addition, one or more guide tools were designed and used for the procedure which also were designed to include patient-adapted features, for example, a bone-facing surface that substantially negatively-matched the patient’s anatomy and/or cutting guide slots or drilling guide holes that provided accurate placement for the predetermined resection cuts and holes for the particular patient.

[000484] Three surgical procedures were performed to implant femoral and tibial implant components for three different cadaveric patients. Prior to each surgery, patient-adapted implant components (femoral and tibial implant components) and guide tools were designed (including manufacturing) in conjunction with a resection cut design. Then, the guide tools were used during surgery to prepare the predetermined resection cuts and place the implant components.

Femoral Procedure and Guide Tools

[000485] The patient-adapted femoral implant components each included six bone cuts. The bone cut design was designed in conjunction with corresponding resection cuts. **FIGS. 106A** and **106B**, **FIGS. 106C** and **106D**, and **FIGS. 106E** and **106F**, show the patient-adapted femoral implant and resection cuts, respectively, for each of the three patients. As exemplified in **FIG. 106A**, the six bone cuts included an anterior bone cut **10310**, medial **10320M** and lateral **10320L** facets of a distal bone cut, medial **10330M** and lateral **10330L** facets of a posterior bone cut, an anterior chamfer bone cut **10340**, medial **10350M** and lateral **10350L** facets of a first posterior chamfer bone cut, and medial **10360M** and lateral **10360L** facets of a second posterior chamfer bone cut. In addition, the femoral implant component **10305** included a stepped (or “step”) cut **10320** between the medial facet **10320M** and lateral facet **10320L** of the distal bone cut in order to provide enhanced preservation of distal medial bone stock. **FIG. 106C** relating to the second patient and **FIG. 106E** relating to the third patient include similar features as those numbered in **FIGS 106A**. As the figures show, the non-coplanar distal bone cut facets, which can be connected by a stepped cut, allow for independent and optionally minimum resection depths on the medial and lateral portions of an otherwise continuous bone cut (e.g., anterior bone cut, anterior chamfer bone cut, or distal bone cut).

[000486] Comparison between each of the three patient-adapted implant components and corresponding resection cuts shows various features of the implant component that specifically match features of the resection cuts and/or of the patient’s anatomy. For example, each implant component includes a width, height, and condylar width that is patient-specific (i.e., matches the patient’s anatomy) or

patient-engineered (i.e., derived from patient-specific data to achieve one or more predetermined parameter thresholds, for example, an implant component peripheral margin that does not overhang the cut surface of the bone and provides no more than 1mm or 0.5 mm or 0.3 mm exposed resection cut surface **10361**).

[000487] Moreover, as shown by a comparison of the figures, the implant component bone cuts for each patient was engineered to specifically-match the resection cuts for the patient (e.g., in cut and/or facet surface areas, angles, relative orientations, and/or other features). For example, as exemplified in **FIG. 106B**, the resection cuts included an anterior resection cut **10310'**, medial **10320M'** and lateral **10320L'** facets of a distal resection cut, medial **110330M'** and lateral **10330L'** facets of a posterior resection cut, an anterior chamfer resection cut **10340'**, medial **10350M'** and lateral **10350L'** facets of a first posterior chamfer resection cut, and medial **10360M'** and lateral **10360L'** facets of a second posterior chamfer resection cut. In addition, the femoral implant component included a stepped (or "step") resection cut **10370'** between the medial facet **10320M'** and lateral facet **10320L'** of the distal resection cut. **FIG. 106D** relating to the second patient and **FIG. 106F** relating to the third patient include similar features as those numbered in **FIGS 106B**. As shown by the figures, the stepped cut **10320'** saves substantial bone stock, for example, at the distal medial facet **10320M'** in comparison to a distal medial facet cut having the same depth as the distal lateral facet cut.

[000488] The guide tool designs were based on a tibial-cut-first technique. For the first two patients, a femoral all-in-one guide tool was designed to include guide slots and holes to perform all of the predetermined (e.g., designed based on patient-specific data) femoral resection cuts and peg hole placements. The all-in-one guide tools for each of the two patients are shown in **FIGS. 107A** and **107B**, respectively. As shown in the figures, the guide slots were numbered sequentially 1-11 to guide the surgeon in the cutting steps and to maximize ease of use. The all-in-one guide tools **10402** also were prepared and provided to the surgeon in three different thicknesses denoted by different letters **10404**, which allowed the surgeon to select the tool having the best fit, e.g., between the femur in tibia with the knee in extension. Accordingly, this guide tool **10402** aided the surgeon in assessing balance and

implant fit, as well as providing guide slots for all cuts and drill holes for the patient's femur. In addition, the bone-facing surface of each all-in-one guide tool was designed to be patient-specific (i.e., designed based on patient-specific data to substantially match the corresponding biological surface of the patient). Moreover, a comparison of the two patient's guide tools, shown in **FIGS. 107A** and **107B**, respectively, shows guide slots in different orientations from each other. These unique guide slot orientations are provided to establish the predetermined resection cuts specifically designed in conjunction with a patient-adapted implant component for each patient based on patient-specific data.

[000489] In addition, several guide tool attachments were designed and included for the for the all-in one guide tools **10402**. For example, as shown in **FIG. 108**, a drill guide attachment **10502** was designed and included for attaching to the guide tool **10402** to extend the drilling surface. Moreover, as shown in **FIGS. 109A, 109B**, and **109C**, various tool attachments **10602, 10604, 10606, 10608** were designed and included for attaching to the all-in-one guide tool to extend one or more cutting surfaces. For example, the attachment **10602** in **FIG. 109A** extends the cutting surface area for all cutting slots. The attachment **10604** in **FIG. 109B** extends the surface area for the posterior resection cut slots **10610** and for posterior chamfer resection cut slots **10612**. The attachment **10606** in **FIG. 109B** extends the surface area for the posterior resection cut slots **10610**. In addition, guide peg attachments **10608** were designed and included to provide additional surface area for the posterior chamfer resection cut slots **10612**. As shown, the guide pegs **10608** can be integrated with a guide attachment **10604** or can be used independently and, optionally, integrated with the guide tool **10402**. In addition or as an alternative to extending a cutting surface, the guide pegs can be used to aid in securing the guide tool **10402** to the patient's femur after peg holes are drilled into the patient's femur.

[000490] As an alternative to the all-in-one guide tool **10402**, a set of three guide tools also was designed and included for each of the first two patients. **FIGS. 110A, 110B**, and **110C** illustrate the set of three guide tools, which collectively supplied all of the guide slots and holes to perform each of the predetermined femoral resection cuts and peg hole placements available in the single all-in-one guide tool **10402**.

This set of guide tools was included, for example, in case the all-in-one guide tool **10402** did not suit the needs of the surgeon. As with the all-in-one guide tool **10402**, each of the three guide tools in the set included one or more patient-adapted features. As shown in **FIG. 110A**, the first guide tool **10780** in the set provided guide holes **10782** for drilling into the patient's femur predetermined holes for receiving the femoral implant component pegs. As shown in the figure, the guide tool **10780** is attached to the patient's femoral bone **10784**. The bone-facing surface of the first guide tool was designed to snap-fit to 3 mm of cartilage on the patient's distal femur. As shown in **FIG. 110B**, a second balancing chip guide tool **10786** provided distal facet resection guide slots **10788**, a slot to mark the termination of the distal lateral resection **10790** (which can be used to establish the step cut between the distal lateral and medial resection facets), and a guide surface **10792** for making the posterior resection cut. As with the all-in-one guide tool, this tool **10786** also can be used for balancing and assessing implant fit (e.g., based on the fit of the guide tool between the femur and cut tibia in knee extension). As shown in **FIG. 110C**, a third chamfer cutting guide tool **10794** provided guide slots for the remaining predetermined resection cuts. As shown, the cutting guide slots were identified with numbers 1-6 to identify the order for performing the resection cuts.

[000491] For the third patient, a different set of femoral guide tools was designed and included to perform the predetermined femoral resection cuts and peg hole placements, as shown in **FIGS. 111A** through **111F**. As shown in **FIG. 111A**, a femoral trial guide tool **10830** was designed and included to guide the hole placement for the pegs on the subsequently used guide tools and on the femoral implant component. As shown, this guide tool **10830** includes marks incorporated into its joint-facing surface to indicate to the surgeon the locations representing the Whiteside Line **10832** and Epicondylar Axis **10834**. As shown in **FIG. 111B**, the second guide tool, a balancer chip guide tool **10836**, was designed and included for guiding independent distal medial **10838** and distal lateral **10840** facet cuts, as well as the step cut **10842**. Both the femoral trial guide tool **10830** and the balancer chip guide tool **10836** included a bone-facing surface derived from patient-specific data and designed to rest on 3 mm of cartilage atop the patient's femoral bone surface.

The balancer chip guide tool **10836** was provided in six different thicknesses to allow the surgeon to use the tool **10836** for ligament balancing and assessment of the implant fit (e.g., by observing the space or tightness of the tool **1636** positioned between the femur and cut tibia during flexion and extension). In addition, a spacing paddle tool **10844**, as shown in **FIG. 111C**, was designed and included for representing the extra asymmetric lateral poly thickness when balancing. As shown in **FIG. 111D**, a chamfer cut guide tool **10846** was designed and included for guiding an anterior resection cut **10848**, an anterior chamfer resection cut **10850**, and independent posterior medial **10852** and posterior lateral **10854** facet cuts. The a chamfer cut guide tool **10846** was designed with pegs to fit into the previously prepared peg holes in the patient's femur and with each cutting slot numbered for the order in which the cuts were to be performed. As shown in **FIGS. 111E** and **111F**, a pair of angled cut guides **10856**, **10858** was designed and included to facilitate the first and second posterior chamfer cuts. As shown, each angled cut guide **10856**, **10858** includes a first surface that matches the distal resection surface and, optionally, includes pegs to fit into the previously prepared peg holes in the patient's femur. In the figures, the distal resection surface includes two non-co-planar facets, which first cut guide surface matches. In addition, each angled cut guide **10856**, **10858** also includes a second cutting guide surface angled at the predetermined angle of the corresponding chamfer cut such that a cutting tool placed against the surface cuts into the patient's bone at the predetermined angle.

[000492] For the first two patients, and as shown in **FIGS. 112A** and **112B**, an anterior profile guide tool **10902** also was designed and included to compare the peak profile at the anterior portion of the femur in the installed implant as compared to the patient's native knee. As discussed above, the trochlear area of the femoral implant component was patient-engineered (e.g., derived and/or optimized from patient-specific data) to include a trochlear groove offset 2 mm laterally and designed to accommodate a dome-shaped patellar implant component. Accordingly, as shown in the figures, the anterior profile of the implant differs from the anterior profile of the patient's native femur, particularly in providing relief on the lateral side of the implant relative to the patient's femur.

[000493] On the femoral side, the single all-in-one guide tool used with the first two patients was found to have a patient-specific bone-facing surface that fit well to each patient's biological surface. The posterior and distal thickness of the tool was useful to assess balance and tightness/looseness of the joint. The set of femoral guide tools used to resect the third patient's femur were found to be useful for making the predetermined resection cuts. Regarding the patient-adapted femoral implant components, once in place the component for each patient was shown to have good coverage of the resected surfaces of the patient's femur and proper articulation with the tibial component.

Tibial Procedure and Guide Tools

[000494] Several guide tools for resectioning the tibia and/or placing the tibial implant component were designed and included for each patient's surgery. For example, as shown in **FIG. 113A**, for each patient a cutting guide tool **11002** was designed and included for accurately resectioning the proximal tibia to a predetermined resection depth and angle (e.g., 2 mm below the lowest point of the medial plateau, with an AP slope of 5 degrees and perpendicular to the mechanical axis). The anterior part of the tibial cutting guide tool **11004** was designed with a patient-specific bone-facing surface to substantially negatively-match the corresponding anterior portion of the patient's tibia when the medial edge of the guide was aligned to the medial one-third of the patient's tibial tubercle **11006**. The proximal part **11008** of the tibial cutting guide tool **11002** was designed to rest on an estimated 2 mm thick cartilage layer atop the patient's proximal tibia that was identified from patient-specific data. For the first two patients, an alternate tibial cutting guide tool **11010** shown in **FIG. 113B** also was designed and included. The alternate tibial cutting guide tool **11010** included the same features of tibial cutting guide **11002** except that the proximal part **11008** of the alternate tibial guide tool **11010** was designed to rest directly on the bone surface of the patient's proximal tibia that was identified from patient-specific data, rather than on a cartilage surface.

[000495] The tibial cutting guide tools **11002**, **11010** were designed to include a dovetail mating feature **11012** that was attachable to a tibial alignment guide tool

11014 and down rod **11016** to visually check the alignment of the guide tools with the patient's mechanical axis. **FIG. 113C** depicts the tibial alignment guide tool **11014** and down rod **11016** attached via the dovetail connection to a tibial cutting guide tool **11002**, **11010** to confirm prior to cutting the alignment of the cutting guide tool **11002**, **11010** with respect to the patient's mechanical axis. The tibial alignment guide tool **11014** included a complementary dovetail mating feature to attach to the tibial cutting guide tools.

[000496] For the third patient, as shown in **FIG. 113D**, the tibial cutting guide tool **11002** includes two small holes on the anterior portion of the tool through which the patient's femur was marked with a pen or other instrument. The two markings on the surface of the cut tibia, as shown in **FIG. 113D**, served as landmarks for placement of subsequent tools.

[000497] For each patient, tibial keel preparation guide tools were designed and included to facilitate preparation of the holes and slots into the proximal, resected tibial surface and thereby ensure proper placement of the tibial tray keel and tibial implant component generally. A different set of tibial keel preparation guides were used for each of the three patients. For the first patient and as shown in **FIG. 114A**, a tibial keel prep guide tool **11108** was designed and included. To help ensure proper placement, the perimeter (except for the handle portion) of the tool **11108** was designed to substantially match the perimeter of the tibial tray implant component, which itself was patient-adapted to substantially match the perimeter of the patient's resected tibial surface. Accordingly, the proper placement of the tibial prep guide tool **11108** could be discerned by the surgeon by aligning the perimeter of the tibial prep guide tool with the perimeter of the patient's resected tibial surface (not shown). In addition, the medial edge of the handle **11110** of the tibial prep guide tool **11108** was designed to align with the medial 1/3 of the tibial tubercle **11006** to further ensure proper tibial implant rotational alignment. The central hole was drilled using a 0.5 inch diameter drill bit. As shown in **FIG. 114B**, a set of tibial keel prep insert guides **11112**, **11112'**, **11112''** was designed to mate with the tibial prep guide **11108** once the central hole was drilled. The tibial keel prep insert guides **11112**, **11112'**, **11112''** allow for controlled intra-operative tibial implant rotational alignment according to

predetermined amounts of rotation. For example, as indicated in the figure, the set of tibial prep guides included a first tibial keel prep insert guide **11112** that provided 0 degrees of rotation, a second tibial keel prep insert guide **11112'** that provided 5 degrees of rotation, and a third tibial keel prep insert guide **11112''** that provided 10 degrees of rotation. After the surgeon selected the tibial keel prep guide that desired predetermined amount of rotation, slots were created using the guide holes in the selected tibial keel prep guide to drill multiple angled holes (e.g., six holes corresponding to the six guide holes in the tibial keel prep guide) using a 4mm drill bit. Once the 4mm holes were drilled into the patient's resected proximal tibial surface, an osteotome was used to create a rectangular slot for the keels of the tibial tray implant component.

[000498] For the second patient and as shown in **FIG. 115**, a tibial keel prep guide tool **11208** was designed and included for establishing the keel slot in the patient's resected proximal tibial surface. Similar to the tibial keel prep guide tool **11108** for the first patient, the tibial keel prep guide tool **11208** for the second patient included a perimeter (except for the handle portion) designed to substantially match the perimeter of the tibial tray implant component, which itself was patient-adapted to substantially match the perimeter of the patient's resected tibial surface. However, for the second patient an optional drill guide **11210** and a keel saw guide **11212** also were designed and included. The drill guide was available to be inserted into the central opening of the tibial keel prep guide tool **11208** to provide an accurately placed central hole. In addition, once the central hole was established, the keel saw guide **11212** was available to be inserted to provide a narrow channel for sawing an accurately slot for receiving the keel of the tibial implant component.

[000499] As shown in **FIG. 116A** and **116B**, the tibial keel prep guide tool **11308** for the third patient incorporated features from the first patient's tibial keel prep guide tool **11108** and insert guide tool **11112**. However, unlike the tibial keel prep guide tools for the first two patients, this tool **11308** did not include a handle. In certain embodiments, more than one such tool **11308** can be included having different orientations of holes to provide different degrees of rotation for the keel and tibial tray. Similar to the tibial keel prep guide tools for the first two patients, this tool **11308** also

included a perimeter designed to substantially match the perimeter of the tibial tray implant component, which itself was patient-adapted to substantially match the perimeter of the patient's resected tibial surface. As shown in the figures, an arrow was located on the proximal surface of the tool **11308** that indicated alignment to the medial 1/3 of the tibia tubercle for proper tibial implant rotational alignment (which itself had been marked, as described above). The central hole was drilled using an 9/16" drill bit and the keel holes were drilled using a 1/8" drill bit, before cutting between them with an osteotome to establish the keel slots.

[000500] As shown in **FIG. 117A**, a set of tibial trial spacers was designed and included for the second and third patients. Specifically, for the second patient, two medial trial spacers were provided in thicknesses of 6 mm and 8mm, respectively (second patient) or 8 mm and 10 mm, respectively (third patient) and three lateral trial spacers were provided in thicknesses of 9 mm, 10 mm, and 11 mm, respectively (second patient) or 10 mm, 11 mm, and 12 mm, respectively (third patient). The spacers were used to assess balance and fit, for example, to assess the tightness and balance of the joint with the spacer in place to represent tibial implant thickness between the cut tibia and femur (and optionally other components in place representing femoral thickness) during flexion and extension of the knee.

[000501] For each patient and as shown in **FIG. 117B**, a set of tibial implant component trial inserts was designed and included for each patient in order for the surgeon to assess the appropriate thicknesses to use for medial and lateral tibial implant component inserts for properly balancing the patient's knee joint. As shown in the figure, two medial trial inserts **111408**, **11408'** and three lateral trial inserts **11420**, **11420'**, **11420''** were designed and included. The two medial trial inserts had thicknesses of 6 mm and 8 mm, respectively, and the lateral trial inserts had thicknesses of 8.5 mm, 9.5 and 10.5 mm, respectively (first patient) or 9 mm, 10 mm, and 11 mm, respectively (second patient) or 8 mm, 9 mm, and 10 mm, respectively (third patient). After assessing the trial inserts and deciding on an appropriate medial and lateral insert thickness for balancing, the surgeon positioned the tibial implant tray and inserts having the appropriate thicknesses medially and laterally.

[000502] The patient-adapted implant components were successfully implanted using the resection cuts and patient-adapted guide tools that were specifically designed for each cadaveric patient based on particular patient data (e.g., image data). Specifically, the tibial cut guide tools showed good fit with the patient's tibial plateau. The alignment guide tool and the drop down rod helped to confirm proper tibial alignment of the cut guide tool prior to resectioning for each patient. The different guide tools used to prepare the stem holes and keel slots in the proximal, resected surface of each patient's femur were found to be useful. The tibial guide tools designed to include a patient-derived perimeter were found to fit well with the perimeter of each patient's resected tibia. The matching perimeter was helpful in properly aligning the cut tools to establish the predetermined resection cuts and/or for balancing. Regarding the patient-adapted tibial implant components, the tibial tray perimeter was shown to have a perimeter profile that substantially matched the perimeter of the patient's resected proximal tibial surface, with no excessive overhang or underhang. The tibial trial inserts were helpful in selecting the proper medial and lateral tibial inserts for balancing and fit. The tibial inserts were easily fit into the locking mechanism of the tibial tray. Overall, the predetermined tibial resection cuts, patient-adapted tibial guide tools, and patient-adapted tibial implant components provided a well-fit and aligned implant component.

[000503] **FIGS. 118A** through **118D** show exemplary steps in the surgical procedures described above. In particular, **FIG. 118A** shows the use of a tibial cut guide tool attached to an alignment guide tool for guiding the predetermined resection cut to the proximal tibia (for patient #2). **FIG. 118B** shows the placement of a tibial tray having a patient-adapted perimeter (for patient #2). **FIG. 118C** shows the use of an all-in-one guide tool for guiding the predetermined resection cuts to the femur (for patient #2). **FIG. 118D** shows a fluoroscopic image of the implanted femoral and tibial implant components (for patient #3).

Patellar Procedure and Guide Tools

[000504] In addition to the patient-adapted femoral and tibial implant components that were designed and included, a patient-adapted patellar implant component and

related guide tools also were designed and included for the third patient's surgery. For example, as shown in **FIG. 119A**, a set of patella sizers was designed and included to assess the diameter of the patella. As shown in **FIG. 119B**, a patellar cutting tool was designed and included to cut the patella to a predetermined depth of resection. In addition, various patella implant trials also were designed (e.g., using 3D print manufacturing) and included. As shown in **FIG. 119C**, the implant trials included diameters of 32 mm, 35 mm, 38 mm, and 41 mm, respectively. As shown in **FIG. 119D**, a patellar implant of 41 mm was selected and implanted for the third patient.

REVISION PROCESSES

[000505] Certain embodiments are directed to implants, guide tools, and/or related methods that can be used to provide to a patient a pre-primary procedure and/or a pre-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.

[000506] In one illustrative embodiment, a first pre-primary joint-replacement procedure includes a patient-adapted implant component, guide tool, and/or related method. The patient-adapted implant component, guide tool, and/or related method can be preoperatively selected and/or designed from patient-specific data, such as one or more images of the patient's joint, to include one or more features that are patient-specific or patient-engineered. The features (e.g., dimensions, shape, surface contours) of the first pre-primary implant and, optionally, patient-specific data (e.g., features of the patient's resected bone surfaces and features of the patient's contralateral joint) can be stored in a database. When the first pre-primary implant fails, for example, due to bone loss or osteolysis or aseptic loosening at a later point in time (e.g., 15 years after the original implantation) a second implant can be

implanted. For the second implant procedure, the amount of diseased bone can be assessed. If the amount of diseased bone to be resected is minimal, the patient-specific data can be used to select and/or design a second pre-primary procedure and/or a pre-primary implant. If the amount of diseased bone to be resected is substantial, a traditional primary procedure and a traditional implant can be employed.

[000507] Alternatively, 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 used as part of a traditional revision procedure. Certain embodiments are directed to implants, guide tools, and/or related methods that can be used to provide a patient-adapted revision implant. For example, following a traditional implant, a subsequent revision can include a patient-adapted procedure and/or a patient-adapted implant component as described herein.

[000508] As previously discussed herein, **FIG. 120** is a flow chart illustrating a process that includes selecting and/or designing a first patient-adapted implant, for example, a pre-primary implant. **FIG. 121** is a flow chart illustrating a process that includes selecting and/or designing a second implant. In certain embodiments, the second implant can be a traditional primary implant. Alternatively, the second implant can be a patient-adapted implant, which optionally can be used as second pre-primary implant that allows for a subsequent (i.e., third) primary implant using a traditional implant.

[000509] The second implant can have standard attachment mechanisms, e.g., a stem and or pegs or other attachment means known in the art. Alternatively, the attachment mechanisms can be patient-specific by deriving shape information on the residual bone, e.g., of a femur and acetabulum or of a femur and a tibia or of a humerus and a glenoid, using image data, e.g., CT or MRI data. One or more dimensions or shapes or joint-facing surfaces of the second implant can be adapted to include, at least in part, information reflective of the corresponding dimension(s) or shape(s) or joint-facing surface(s) of the first implant. In this manner, a better

functional result can be achieved with the revision implant by maintaining patient-specific shapes and/or geometry in the revision implant by accessing data in the patient database.

ADDITIONAL JOINT-SPECIFIC PROCEDURES

[000510] If desired, one or more sets of jigs can be designed to facilitate and accommodate surgical procedures on bones and joint other than the knee.

Desirably, the jigs are designed in connection with the design of a patient-specific implant component. The designed jigs guide the surgeon in performing one or more patient-specific cuts to the bone so that those cut bone surface(s) negatively-match the patient-specific bone cuts of the implant component.

HIP SPECIFIC PROCEDURES

[000511] For example, in a **hip**, an acetabular component (metal backed, ceramic or all plastic, e.g. polyethylene, or any other known in the art or developed in the future) can be designed or selected or adapted so that its peripheral margin will be closely matched to the patient specific acetabular rim or perimeter. Optionally, reaming can be simulated for placement of an acetabular cup and the implant can then be designed or selected or adapted so that it will be closely matched to the resultant acetabular rim after reaming or other bone removal. Thus, the exterior dimensions of the implant, e.g. the rim and/or curvature(s) can be matched to the patient's geometry in this fashion. Curvatures of the exterior, bone facing shape of the acetabular cup can have constant or variable radii in one, two or three dimensions. At least one or more of these curvatures or surfaces can be selected or adapted to the patient's shape in one or more dimensions, optionally adapted to the result of a simulated surgical alteration of the anatomy, e.g. reaming, the removal of osteophytes or cutting. The acetabular component can be selected, adapted or designed to rest on the acetabular rim or extend beyond the acetabular rim, resting on portions of cortical bone or, for example, also osteophytes. In this embodiment, the acetabular fossa facing portion of the component can have standard dimensions, e.g. approximating those of a reamer used for reaming the acetabular fossa, while the peripheral portions, e.g. those facing the acetabular rim or cortical bone, e.g. on

the acetabulum or ilium or ischium, can be patient specific or patient adapted. Any of these embodiments can be applicable to hip resurfacing techniques and implants as well as hip replacement techniques and implants.

[000512] If desired, the patient-specific data can be utilized to create a reaming guide or other tools for preparing the acetabular space for an implant component. To avoid cutting/reaming through an acetabulum in a reaming operation, it may be desirable to have a guide or other tool that limits reamer motion or movement in various manners to one or more predetermined depths that were previously determined using patient-specific data, e.g. pre-operative CT or MRI or intraoperative ultrasound measurement of acetabular wall thickness. Such a tool can comprise a patient-matched surface on the acetabulum and/or other acetabular head or other anatomical structures. Desirably, the tool can control both placement and depth of reaming tools to a desired degree. Moreover, the planning and design phase of such a guide tool can potentially identify any “at risk” operations for patients especially susceptible to such dangers, and possibly the implant design can be redesigned to accommodate the special needs of such patients as well.

[000513] In replacing a hip joint, the implant and related surgical instruments and surgical technique, can include the following components, features and/or steps.

[000514] A patient specific mold can be generated based on the patient's image data, e.g., CT or MRI, ultrasound, laser imaging or combinations thereof or other imaging techniques available in the future. The patient specific mold can include at least one surface that is at least partially shaped to be substantially a negative of an acetabular fossa. The patient specific mold can be shaped to include shape features of the articular cartilage or subchondral bone or acetabular rim. The patient specific shape of the mold can include shape information of osteophytes or geodes or cysts; alternatively, the patient specific shape of the mold can be shaped to avoid these structures or it can be corrected to a shape after removal of one or more of these structures. Moreover, the acetabular mold can be shaped to avoid contact with the ligamentum teres, the transverse acetabular ligament or the pulvinar; by avoiding contact with one or more of these structures, the spatial registration of the acetabular

mold will be more accurate and will not lose accuracy of registration due to misplacement of the mold by impinging soft-tissue.

[000515] The mold can fill portions or all of the acetabulum. The mold can include various receptacles or guides for receiving various surgical instruments, including but not limited to drills, saws, and reamers. The position and / or orientation of said one or more guides can be adapted based on the patient's anatomy, e.g.:

[000516] – 2D or 3D orientation of the acetabulum on the side being operated on

[000517] – 2D or 3D orientation of the acetabulum on the contralateral side

[000518] – Acetabular anteversion of retroversion

[000519] – Acetabular osteophytes

[000520] – Acetabular thickness in selected regions

[000521] – ML or oblique ML dimension of the acetabulum

[000522] – AP or oblique AP dimension of the acetabulum

[000523] – SI or oblique SI dimension of the acetabulum

[000524] – Femoral features, e.g.

a. Femoral anteversion

b. Femoral neck shaft angle

c. Femoral offset (e.g., distance from femoral neck to center of femoral head)

d. Femoral sagittal angle

[000525] The mold can be adapted to other 2D or 3D parameters of the pelvis including, for example, lumbosacral angle, pelvic tilt, etc.

[000526] The mold can include a central guide for accepting a drill. The guide can have a metal insert or bushing. In various embodiments, the central guide can be adapted to be at a predefined angle of abduction, e.g. 45 degrees, 40 degrees or 50 degrees, and / or anteversion, e.g. 20 degrees, 15 degrees, 10 degrees, 25 degrees, 30 degrees or 35 degrees.

[000527] In one embodiment, a drill or a pin or other instrument is inserted into the guide and advanced into the acetabulum. The drill or pin or instrument can define the center of the acetabulum. The orientation of the drill or guide defines the desired acetabular cup orientation, e.g., with regards to abduction, anteversion, or rotation.

[000528] A reamer can optionally be inserted into the guide wherein the guide has a metal bushing and the reamer has a protrusion to fit into and rotate within the metal bushing. Alternatively, the reamer can have an opening or hole that fits over a drill or pin that was previously placed in the acetabular fossa using the patient specific mold and guide. With this approach, the orientation of the reamer, e.g., with regards to acetabular abduction / adduction, ante-/retroversion, can be controlled, thereby ultimately controlling and achieving accurate placement of the acetabular cup.

[000529] Optionally, the surgeon can use an interactive computer display to select the desired acetabular cup abduction, adduction, anteversion, retroversion, rotation and other orientation, which is then transferred or translated into the position and orientation of one or more guides attached to or directly or indirectly linked to the mold.

[000530] The mold can have peripheral support features, e.g., anchors, screw attachments, lips or edges or other features that can help stabilize the mold against the pelvis. These support features can be inside or outside the acetabular fossa or combinations thereof. The mold or at least portions of the mold, e.g., extra-acetabular support features, can remain in place while the reamer is reaming the acetabulum. Thus, for example, the reamer can be guided via the central acetabular hole or pin, but also via an external support, e.g., a metal cover on an extra-acetabular support structure.

[000531] The pin or instrument or metal bushing can be removed after reaming is complete.

[000532] Optionally, overhanging bone can be removed prior to or after reaming to avoid iliopsoas or other tendon impingement. The amount and location of bone removed can be determined via the same or another mold which is fitted to the

acetabulum or extra-acetabular bone with one or more guide that allow insertion of a surgical instrument, e.g., a burr or reamer or saw, to remove such overhanging or other bone.

[000533] A mold or a feature created by a mold, e.g., a hole or pin inserted into a hole, can be used to guide an impactor when impacting the acetabular cup for fixation. The position and orientation of the mold or feature created by the mold can be optimized for changes induced by reaming or other surgical alteration.

[000534] The femoral component can be off-the-shelf, preformed or it can, optionally, include patient specific features. The stem can have one or more dimensions adapted in shape to the femoral medullary cavity after reaming. Alternatively, the stem can be off-the-shelf. The neck portion can be affixed to the stem or it can be a modular neck that can be attached to the stem. The neck, fixed or modular, can be available in different lengths and different anteversion, retroversion, abduction or adduction. Optionally, one or more of these features can be adapted to the patient intraoperatively or pre-operatively by shaping or selecting the component(s) with the best fit for a particular patient. The articular surfaces may be patient-specific (i.e., femoral head diameter, etc.) or one or more dimensions may be engineered to reduce fatigue and wear (i.e., femoral head surface composition and/or design). The neck length, width and offset, e.g., distance from the femoral neck to the center of the femoral head, can optionally be patient specific or can be selected from pre-manufactured parts based on patient derived measurements, e.g., from a CT scan or MRI scan. Moreover, the femoral head, neck, shaft width/length/angle can be patient specific or can be selected from pre-manufactured parts based on patient derived measurements, e.g., from a CT scan or MRI scan. One or more patient specific molds can be used for placing the femoral component. For example, a first mold can be placed against an uncut femoral neck with a guide that includes a predetermined orientation for guiding a saw blade and cutting the femoral neck at a desired angle and orientation in one or more dimensions. A second mold can optionally be patient adapted and can be placed on top of the cut femoral neck or adjacent to the femoral neck with a guide to direct the orientation of a reamer for reaming the femoral medullary cavity.

SHOULDER SPECIFIC PROCEDURES

[000535] In another embodiment, in a **shoulder**, a glenoid component (metal backed, ceramic or all plastic, e.g. polyethylene, or any other known in the art or developed in the future) can be designed or selected or adapted so that its peripheral margin will be closely matched to the patient specific glenoid rim or perimeter. Optionally, reaming can be simulated for placement of a glenoid component and the implant can then be designed or selected or adapted so that it will be closely matched to the resultant glenoid rim after reaming or other bone removal. Thus, the exterior dimensions of the implant, e.g. the rim and/or curvature(s) can be matched to the patient's geometry in this fashion. Curvatures of the exterior, bone facing shape of the glenoid component can have constant or variable radii in one, two or three dimensions. At least one or more of these curvatures or surfaces can be adapted to the patient's shape in one or more dimensions, optionally adapted to the result of a simulated surgical alteration of the anatomy, e.g. reaming, the removal of osteophytes or cutting. For example, if a cut is performed, the implant can be adapted to the perimeter of the bone resulting after the cut has been placed. In this setting, at least a portion of the perimeter of the implant can be adapted to the perimeter of the patient's cut bone. The undersurface of the implant can then be flat, facing the cut bone. The glenoid component can be selected, adapted or designed to rest on the glenoid rim or extend beyond the glenoid rim, resting on portions of cortical bone or, for example, also osteophytes. In this embodiment, the glenoid fossa facing portion of the component can have standard dimensions, e.g. approximating those of a reamer used for reaming the glenoid fossa, while the peripheral portions, e.g. those facing the glenoid rim or cortical bone, e.g. on the anterior or posterior aspect of the scapula, can be patient specific or patient adapted. Any of these embodiments can be applicable to shoulder resurfacing techniques and implants as well as shoulder replacement techniques and implants, including primary and revision shoulder systems, as well as reverse or inverse shoulder systems.

[000536] If desired, the patient-specific data can be utilized to create a reaming guide or other tools for preparing the glenoid for an implant component. To avoid cutting/reaming through a glenoid in a reaming operation, it may be desirable to have

a guide or other tool that limits reamer motion or movement in various manners to one or more predetermined depths that were previously determined using patient-specific data, e.g. pre-operative CT or MRI or intraoperative ultrasound measurement of glenoid depths. Such a tool can comprise a patient-matched surface on the glenoid and/or other anatomical structures. Desirably, the tool can control both placement and depth of reaming tools to a desired degree. Moreover, the planning and design phase of such a guide tool can potentially identify any “at risk” operations for patients especially susceptible to such dangers, and possibly the implant design can be redesigned to accommodate the special needs of such patients as well.

[000537] Similarly, a glenoid component can be selected for, adapted to or matched to the glenoid rim, optionally after surgically preparing or resectioning all or portions of the glenoid rim including osteophytes.

[000538] **FIG. 122A** depicts a normal humeral head and upper humerus which forms part of a shoulder joint. **FIG. 122B** depicts the humeral head having an alignment jig designed to identify and located various portions of the humeral anatomy. In this embodiment, a jig having a plurality of conforming surfaces has been designed using patient-specific information regarding one or more of the humerus, the humeral neck, the greater tuberosity and/or the lesser tuberosity of the humerus. Desirably, the conforming surfaces will fit onto the humerus on only one position and orientation, thereby aligning to the humerus in a known position. This embodiment desirably incorporates an alignment hole **18400** which aligns with an axis **18410** of the humeral head. After proper positioning of the jig, a pin or other mechanism (i.e., drill, reamer, etc.) can be inserted into the hole **18400**, and provide a secure reference point for various surgical operations, including the reaming of the humeral head and/or drilling of the axis **18400** in preparation for a humeral head resurfacing implant or other surgical procedure. The alignment mechanisms may be connected to the one or more conforming surfaces by linkages (removable, moveable and/or fixed) or other devices, or the entire jig may be formed from a single piece and extend over a substantial portion of the humeral head and/or other bone.

[000539] **FIG. 122C** depicts an alternative embodiment of a humeral head jig that utilizes a single conforming surface to align the jig. In this embodiment, one or

more protrusions or osteophytes is mirrored by the conforming surfaces, which permits alignment and positioning of the jig in a known manner.

[000540] **FIG. 123A** depicts a humeral head with osteophytes, and **FIGS. 123B** and **123C** depict the humeral head with a more normalized surface that has been corrected by virtual removal of the osteophytes. **FIG. 124A** depicts a humeral head with voids, fissures or cysts, and **FIGS. 124B** and **124C** depict the humeral head with a more normalized surface that has been corrected by virtual removal of the voids, fissures or cysts.

[000541] **FIG. 125A** depicts a health scapula of a shoulder joint, **FIG. 125B** depicts a normal glenoid component of the shoulder, and **FIG. 125C** depicts an alignment jig for use with the glenoid. As previously noted, the jig may comprise one or more conforming surfaces that are shaped to mirror the patient-specific anatomy of the glenoid, allowing the jig to be positioned on the glenoid in a known position and orientation. An alignment hole **18450** in the glenoid jig provides a desired pathway for orienting and inserting a pin or other alignment mechanism, or provide a pathway for a drilling or reaming device. After pin insertion, the jig can be removed and the pin utilized as a secure reference point for various surgical operations, including the milling and/or reaming of the glenoid in preparation for a glenoid component of a shoulder joint replacement/resurfacing implant (see **FIG. 125D**).

[000542] **FIG. 126A** depicts a glenoid component with osteophytes, and **FIG. 126B** depicts the glenoid component with a more normalized surface that has been corrected by virtual removal of the osteophytes. **FIGS. 126C** and **126D** depict two alternative embodiments of a glenoid jig for use with the glenoid, each of which incorporates conforming surfaces that accommodate the osteophytes. If desired, the jig of **FIG. 126C** can be formed from an elastic or flexible material to allow it to “snap fit” over the glenoid component and associated osteophytes. As previously noted, the jigs can include various alignment holes, slots, etc., to allow placement of pins or other surgical actions.

[000543] **FIG. 127A** depicts a glenoid component with voids, fissures or cysts, and **FIG. 127B** depicts the glenoid component with a more normalized surface that

has been corrected by virtual “filling” of the voids, fissures or cysts. **FIG. 127C** depicts an embodiment of a glenoid jig for use with the glenoid component, which incorporates various conforming surfaces that accommodate the voids, fissures and/or cysts (and other surfaces) of the glenoid component.

ANKLE SPECIFIC PROCEDURES

[000544] In another embodiment, in an **ankle** joint, a talar or tibial component (metal backed, ceramic or all plastic, e.g. polyethylene, or any other material known in the art or developed in the future) can be designed or selected or adapted so that its peripheral margin will be closely matched to the patient specific bony rim or perimeter in one or two or more dimensions. Optionally, reaming or cutting can be simulated for placement of a component and the implant can then be designed or selected or adapted so that it will be closely matched to the resultant bony contour or surface after reaming or cutting or other bone removal. Thus, the exterior dimensions of the implant, e.g. the rim and/or curvature(s) can be matched to the patient's geometry in this fashion. Curvatures of the exterior, bone facing shape of the talar or tibial component can have constant or variable radii in one, two or three dimensions. At least one or more of these curvatures or surfaces can be adapted to the patient's shape in one or more dimensions, optionally adapted to the result of a simulated surgical alteration of the anatomy, e.g. reaming, the removal of osteophytes or cutting. For example, if a cut is performed, the implant can be adapted to the perimeter of the bone resulting after the cut has been placed. In this setting, at least a portion of the perimeter of the implant can be adapted to the perimeter of the patient's cut bone. The undersurface of the implant can then be flat, facing the cut bone. The tibial or talar component can be selected, adapted or designed to rest on the bony rim or surface or extend beyond the bony rim of the articular surface, resting on portions of cortical bone or, for example, also osteophytes. In this embodiment, the articular bone facing portion of the component can have standard dimensions, e.g. approximating those of a reamer used for reaming the bone, while the peripheral portions, e.g. those facing the bony rim or cortical bone, e.g. on the anterior tibia or lateral or medial aspect of the talus, can be patient specific or patient adapted. Any of these embodiments can be applicable to ankle resurfacing techniques and

implants as well as ankle replacement techniques and implants, including primary and revision ankle systems.

ELBOW SPECIFIC PROCEDURES

[000545] In another embodiment, in an **elbow** joint, a humeral or radial or ulnar component (metal backed, ceramic or all plastic, e.g. polyethylene, or any other material known in the art or developed in the future) can be designed or selected or adapted so that its peripheral margin will be closely matched to the patient specific bony rim or perimeter in one or two or more dimensions. Optionally, reaming or cutting can be simulated for placement of a component and the implant can then be designed or selected or adapted so that it will be closely matched to the resultant bony contour or surface after reaming or cutting or other bone removal. Thus, the exterior dimensions of the implant, e.g. the rim and/or curvature(s) can be matched to the patient's geometry in this fashion. Curvatures of the exterior, bone facing shape of the humeral or radial or ulnar component(s) can have constant or variable radii in one, two or three dimensions. At least one or more of these curvatures or surfaces can be adapted to the patient's shape in one or more dimensions, optionally adapted to the result of a simulated surgical alteration of the anatomy, e.g. reaming, the removal of osteophytes or cutting. For example, if a cut is performed, the implant can be adapted to the perimeter of the bone resulting after the cut has been placed. In this setting, at least a portion of the perimeter of the implant can be adapted to the perimeter of the patient's cut bone. The undersurface of the implant can then be flat, facing the cut bone. The humeral or radial or ulnar component(s) can be selected, adapted or designed to rest on the bony rim or surface or extend beyond the bony rim of the articular surface, resting on portions of cortical bone or, for example, also osteophytes. In this embodiment, the articular bone facing portion of the component can have standard dimensions, e.g. approximating those of a reamer used for reaming the bone, while the peripheral portions, e.g. those facing the bony rim or cortical bone, e.g. on the anterior humerus or lateral or medial aspect of the radius or ulna, can be patient specific or patient adapted. Any of these embodiments can be applicable to elbow resurfacing techniques and implants as well as elbow replacement techniques and implants, including primary and revision elbow systems.

WRIST SPECIFIC PROCEDURES

[000546] In another embodiment, in a **wrist** joint, a radial or ulnar or scaphoid or lunate component (metal backed, ceramic or all plastic, e.g. polyethylene, or any other material known in the art or developed in the future) can be designed or selected or adapted so that its peripheral margin will be closely matched to the patient specific bony rim or perimeter in one or two or more dimensions. Optionally, reaming or cutting can be simulated for placement of a component and the implant can then be designed or selected or adapted so that it will be closely matched to the resultant bony contour or surface after reaming or cutting or other bone removal. Thus, the exterior dimensions of the implant, e.g. the rim and/or curvature(s) can be matched to the patient's geometry in this fashion. Curvatures of the exterior, bone facing shape of the radial or ulnar or scaphoid or lunate component(s) can have constant or variable radii in one, two or three dimensions. At least one or more of these curvatures or surfaces can be adapted to the patient's shape in one or more dimensions, optionally adapted to the result of a simulated surgical alteration of the anatomy, e.g. reaming, the removal of osteophytes or cutting. For example, if a cut is performed, the implant can be adapted to the perimeter of the bone resulting after the cut has been placed. In this setting, at least a portion of the perimeter of the implant can be adapted to the perimeter of the patient's cut bone. The undersurface of the implant can then be flat, facing the cut bone. The radial or ulnar or scaphoid or lunate component(s) can be selected, adapted or designed to rest on the bony rim or surface or extend beyond the bony rim of the articular surface, resting on portions of cortical bone or, for example, also osteophytes. In this embodiment, the articular bone facing portion of the component can have standard dimensions, e.g. approximating those of a reamer used for reaming the bone, while the peripheral portions, e.g. those facing the bony rim or cortical bone, e.g. on the anterior radius, can be patient specific or patient adapted. Any of these embodiments can be applicable to wrist resurfacing techniques and implants as well as wrist replacement techniques and implants, including primary and revision wrist systems.

CLAIMS

1. A method for designing a surgical plan and orthopedic device to alter the joint anatomy of a patient, comprising

receiving image data associated with the joint;

creating a first electronic model of the anatomy of the joint utilizing at least a portion of the image data and altering the first electronic model of the joint anatomy to create a desired anatomical model of a desired anatomy of the joint;

utilizing the first electronic model and the desired anatomical model to design the orthopedic device; and

utilizing the first electronic model, the desired anatomical model and the orthopedic device design to design the surgical plan.

2. The method of claim 1, further comprising modifying the orthopedic device design using the first electronic model, the desired anatomical model and the designed surgical plan.

3. A method for designing a surgical plan and orthopedic device to alter the joint anatomy of a patient, comprising

receiving image data associated with the joint;

creating a first electronic model of the anatomy of the joint utilizing at least a portion of the image data and altering the first electronic model of the joint anatomy to create a desired anatomical model of a desired anatomy of the joint;

utilizing the first electronic model and the desired anatomical model to design the surgical plan; and

utilizing the first electronic model, the desired anatomical model and the designed surgical plan to design the orthopedic device.