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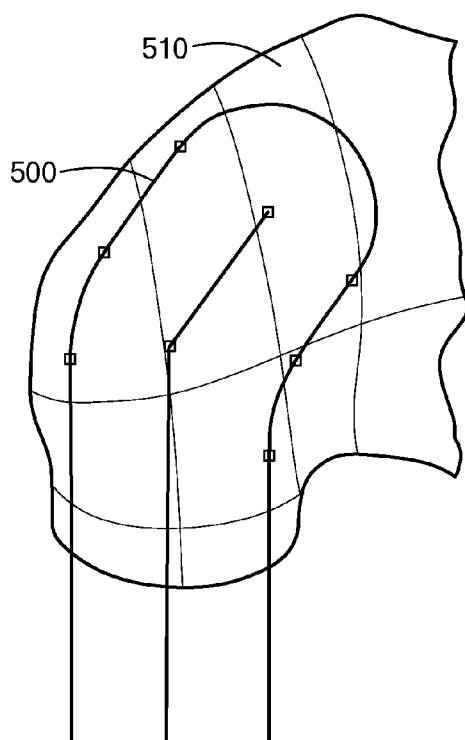
(57) Abstract: Disclosed herein are devices, systems and methods for the automated design and manufacture of patient-specific / patient-matched orthopedic implants. While the embodiments described herein specifically pertain to unicompartmental resurfacing implants for the knee, the principles described are applicable to other types of knee implants (including, without limitation, other resurfacing implants and joint replacement implants) as well as implants for other joints and other patient-specific orthopedic applications.

FIG. 20

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AUTOMATED SYSTEMS FOR MANUFACTURING PATIENT-SPECIFIC ORTHOPEDIC IMPLANTS AND INSTRUMENTATION

RELATED APPLICATIONS

[0001]   This application claims priority to U.S. Provisional Application 61/208,440, filed February 24, 2009, entitled "Automated Systems for Manufacturing Patient-Specific Orthopedic Implants and Instrumentation."

[0002]   This application claims priority to U.S. Provisional Application 61/208,444, filed February 24, 2009, entitled "Automated Systems for Manufacturing Patient-Specific Orthopedic Implants and Instrumentation."

[0003]   This application relates to U.S. Patent Application No. U.S. Ser. No. 11/671,745, filed February 6, 2007, entitled "Patient Selectable Joint Arthroplasty Devices and Surgical Tools", which in turn claims the benefit of U.S Ser. No. 60/765,592 entitled "Surgical Tools for Performing Joint Arthroplasty" filed February 6, 2006; U.S Ser. No. 60/785,168, entitled "Surgical Tools for Performing Joint Arthroplasty" filed March 23, 2006; and U.S Ser. No. 60/788,339, entitled "Surgical Tools for Performing Joint Arthroplasty" filed March 31, 2006.

[0004]   U.S. Ser. No. 11/671,745 is also a continuation-in-part of U.S Ser. No. 11/002,573 for "Surgical Tools Facilitating Increased Accuracy, Speed and Simplicity in Performing Joint Arthroplasty" filed December 2, 2004 which is a continuation-in-part of U.S. Ser. No. 10/724,010 for "Patient Selectable Joint Arthroplasty Devices and Surgical Tools Facilitating Increased Accuracy, Speed and Simplicity in Performing Total and Partial Joint Arthroplasty" filed Nov. 25, 2003 which is a continuation-in-part of U.S. Serial No. 10/305,652 entitled "Methods and Compositions for Articular Repair," filed November 27, 2002, which is a continuation-in-part of U.S. Serial No. 10/160,667, filed May 28, 2002, which in turn claims the benefit of U.S. Serial Number 60/293,488 entitled "Methods To Improve Cartilage Repair Systems", filed May 25, 2001, U.S. Serial Number 60/363,527, entitled "Novel Devices For Cartilage Repair, filed March 12, 2002 and U.S. Serial Numbers 60/380,695 and 60/380,692, entitled "Methods And Compositions for Cartilage Repair," (Attorney Docket Number 6750-0005p2) and "Methods for Joint Repair," (Attorney Docket Number 6750-0005p3), filed May 14, 2002.

[0005]   U.S. Ser. No. 11/671,745 is also a continuation-in-part of U.S. Ser. No. 10/728,731, entitled "Fusion of Multiple Imaging Planes for Isotropic Imaging in MRI and Quantitative

Image Analysis using Isotropic or Near-Isotropic Imaging," filed December 4, 2003, which

claims the benefit of U.S. Ser. No. 60/431,176, entitled "Fusion of Multiple Imaging Planes for

Isotropic Imaging in MRI and Quantitative Image Analysis using Isotropic or Near Isotropic

Imaging," filed December 4, 2002.

[0006]   U.S. Ser. No. 11/671,745 is also a continuation-in-part of U.S. Ser. No. 10/681,750,

entitled "Minimally Invasive Joint Implant with 3-Dimensional Geometry Matching the

Articular Surfaces," filed October 7, 2003, which claims the benefit of U.S. Ser. No. 60/467,686,

entitled "Joint Implants," filed May 2, 2003 and U.S. Ser. No. 60/416,601, entitled Minimally

Invasive Joint Implant with 3-Dimensional Geometry Matching the Articular Surfaces," filed

October 7, 2002.

[0007]   This application also relates to U.S. Patent Application No. 12/398,753, filed March

5, 2009, entitled "Patient Selectable Joint Arthroplasty Devices and Surgical Tools," which in

turn claims priority to U.S. Provisional Patent Application No. 61/034,048, filed March 5, 2008,

entitled "Patient Selectable Joint Arthroplasty Devices and Surgical Tools," and U.S. Provisional

Patent Application No. 61/034,048, filed March 5, 2008, entitled "Patient Selectable Joint

Arthroplasty Devices and Surgical Tools,"

[0008]   Each of the above-described applications is hereby incorporated by reference in their

entireties.

BACKGROUND

Technical Field

[0009]   The embodiments described herein relate to automated systems for designing and

manufacturing patient-specific orthopedic devices, such as implants and instrumentation, based

on data, such as imaging data, representing an existing joint.

Description of the Related Art

[00010]   Personalized medicine is one of the fastest growing trends in the healthcare industry.

While this trend has mainly been seen in the drug sector, medical device manufacturers have also

recognized the benefits of individualizing their products to meet the needs of different patient

groups. The orthopedic implant manufacturers have recently launched implants optimized for

different genders or geographies, or combining patient-specific instruments with standardized implants. However, these are not truly personalized, patient-specific or patient-matched approaches. Technological advances now allow for the design and manufacture of implants and associated instrumentation optimized for a specific individual. Such implants fall on a spectrum from, e.g., implants that are based on one or two aspects or dimensions of a patient's anatomy (such as a width of a bone, a location of a defect, etc.) to implants that are designed to conform entirely to that patient's anatomy and/or to replicate the patient's kinematics.

[00011]   One example of such patient-specific or patient-matched technology is the ConforMIS iFit® technology used in the iUni® (unicompartmental knee resurfacing implant) and iDuo® (dual compartmental knee resurfacing implant). This technology converts Computed Axial Tomography ("CT") or Magnetic Resonance Imaging ("MRI") scans into individualized, minimally invasive articular replacement systems capable of establishing normal articular shape and function in patients with osteoarthritis. By starting with imaging data, the approach results in implants that conform to bone or cartilage, and reduce the need for invasive tissue resection. The implant is made to fit the patient rather than the reverse. By designing devices that conform to portions of the patient's anatomy, the implants allow the surgeon to resurface rather than replace the joint, providing for far more tissue preservation, a reduction in surgical trauma, and a simplified technique.

[00012]   The image-to-implant process begins with the patient having a medical image such as a CT or MRI scan, which can be done on commonly available machines, using a standardized protocol that ensures the data needed to design the implant is captured properly. The image data is then combined with computer-aided design (CAD) methods to generate a patient-specific model of the knee from which a patient-specific implant and/or patient-specific instrumentation can be designed and manufactured. The electronic design file created during this process is used to fabricate the patient-specific implant and custom instrumentation, which is a process that takes approximately four to six weeks.

[00013]   The development and manufacture time associated with all types of patient specific devices could be significantly reduced if some or all aspects of the design and manufacture process were fully automated or more fully automated. Automation of some or all aspects of the process, including, without limitation, imaging, diagnosis, surgical planning, instrumentation design, implant design, manufacture, quality systems and distribution could result in, among

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other advantages, faster and less costly production, which could result in patient's being able to have surgery sooner and at a lower cost. Additionally, such systems could improve productivity of designers, which would have several advantages such as improving profitability of manufacturing such implants. Further, such systems would both directly and indirectly improve the quality of such implants by, example, providing defined rules to ensure patient-specific implant designs meet specification, and also indirectly by improving the cost effectiveness of skilled designers, which makes the technically skilled employees found in more developed countries such as the United States more economically competitive and thereby reducing the impetus to outsource such production to countries with less technically skilled but cheaper labor that may result in reduced quality in the design process.

SUMMARY

[00014]   Some embodiments described herein include new computer-based methods used to generate the designs for personalized joint implants that are custom-tailored to a patient's individual anatomy. The anatomic information is derived from medical images, such as CT or MRI scans. Other types of images also could be used, including, without limitation, x-ray images. A variety of segmentation methods can be applied to extract the relevant anatomic information.

[00015]   In one embodiment, the anatomic information resulting from the segmentation can be composed of individual points, surface information, or solid bodies, preferably in 3 or more dimensions. In another embodiment, the anatomic information results in a virtual model of the patient's anatomy.

[00016]   The processing of the anatomic information and the generation of the custom-fit implant design can have different degrees of automation. It can be fully automated, thus not requiring any user input. It can provide default settings that may be modified and fine-tuned by the operator. In any automated step performed by the system, constraints pertaining to a specific implant model, to a group of patients or to the individual patient may be taken into account. For example, the maximum implant thickness or allowable positions of implant anchors may depend on the type of implant. The minimum implant thickness can depend on the patient's bone quality.

[00017]   In another embodiment, the system supports the operator by guiding him/her through the design workflow and prompting the user for required input. For example, the system follows

a predefined step-by-step design protocol. It performs automated calculations whenever possible. For certain steps that require operator intervention, the system presents the operator with all information necessary to provide his input. This can include, without limitation, showing the design status from a specific viewpoint that allow the operator to best make the required decision on the particular design step. Once the information has been entered by the operator, the system can continue the automated design protocol until further operator interaction becomes necessary.

[00018]   In another embodiment, the system uses anatomic landmarks to generate an implant design. The system can, for example, merge the patient's anatomic information with a generic atlas or model containing the landmark information. By merging the two pieces of information, the landmark information is transferred into the patient information, thus allowing the system to use the landmark information as reference in the implant design. Alternatively, the landmark information may be derived directly from the patient's anatomical data, for example and without limitation, by locating curvature maxima or minima or other extrema.

[00019]   In another embodiment, the system automatically finds the best viewpoint to allow the user to perform a design step. This can be facilitated by using the landmark information derived from the patient's anatomical information. For example, the system can find the best view to allow the operator to define the implant's outer profile or contour.

[00020]   In another embodiment, the implant profile is defined using a virtual template. The template may be fitted automatically to the patient's anatomical model, for example, by using the generic atlas, which may have the virtual template integrated into it. The anatomical model can be represented by a series of 2D images or a 3D representations. The model typically, but not always, will have at least one of bone or cartilage already segmented.

[00021]   Alternatively, the virtual template can be user-adjustable. The system can provide an initial default fit of the template and then allow the user to make adjustments or fine-tune the shape or position. The system can update the implant as the operator makes adjustments to the template, thus providing real-time feedback about the status of the implant design. The adjustments can be made, for example, for irregularities of the articular surface including osteophytes or subchondral cysts, or flattening of an articular surface.

[00022]   The virtual template can be a 3D template. In another embodiment, the virtual template is a 2D template that is projected onto a 2D or 3D anatomical model of the patient's anatomy. The template can be a composite of standard geometric shapes, such as straight lines,

arcs or other curved elements in 2D and planes, spherical shapes or other curved elements in 3D. Alternatively, the template may have an irregular, free-form shape. To adjust the shape of the template, the system or the operator can move the standard shapes or adjust the radius of the curved elements. In another embodiment, the virtual template may have a number of control points that can be used to adjust its shape. In yet another embodiment, the center line of the profile can be used to adjust its shape.

[00023]   In another embodiment, the final implant includes one or more bone cuts. The cut planes for these bone cuts can be automatically determined by the system, for example using anatomical landmarks. The cut planes can also be built into a generic virtual atlas that is merged with the patient's anatomical information. Optionally, the cut planes can be adjusted by the operator.

[00024]   The system can also construct the implant surfaces. Surfaces may be composed of different elements. In one embodiment, elements of the surfaces will conform to the patient's anatomy. In these situations the system can build a surface using the patient's anatomical model, for example by constructing a surface that is identical with or mostly parallel to the patient's anatomical surface. In another embodiment, the system uses geometric elements such as arcs or planes to construct a surface. Transitions between surfaces can be smoothed using tapers or fillets. Additionally, the system may take into account constraints such as minimum or maximum thickness or length or curvature of parts or aspects of the implant when constructing the surfaces.

[00025]   In another embodiment, the system can automatically or semi-automatically add other features to the implant design. For example, the system can add pegs or anchors or other attachment mechanisms. The system can place the features using anatomical landmarks. Constraints can be used to restrict the placement of the features. Examples of constraints for placement of pegs are the distance between pegs and from the pegs to the edge of the implant, the height of the pegs that results from their position on the implant, and forcing the pegs to be located on the center line.

[00026]   Optionally, the system can allow the user to fine-tune the peg placement, with or without enforcing the constraints.

[00027]   In another embodiment, the additional features are embedded with the generic virtual atlas and merged with the patient-specific anatomical information, thus overlaying the

information about the position of the feature embedded in the atlas on top of the patient's anatomical model.

[00028]   In other embodiments, devices that are tailored to only one or a few dimensions or aspects of a patient's anatomy are designed using automated processes.

[00029]   The principals can also be applied to other devices, such as the design and manufacture of patient-specific instruments, such as jigs used in orthopedic surgeries or other instrumentation. Similarly, the concepts can be applied to portions of the design of an implant or instrument, such as the design of an articular surface of a patient-specific and/or patient-engineered articular implant.

BRIEF DESCRIPTION OF THE DRAWINGS

[00030]   FIG. 1 is a graphic representation of a virtual model illustrating a front perspective view of a proximal portion of a tibia;

[00031]   FIG. 2 is a graphic representation of a virtual model illustrating a front perspective view of a portion of the tibial bone of FIG. 1 to be removed along a cutting place;

[00032]   FIG. 3 is a graphic representation of a virtual model illustrating a front perspective view of the tibia of FIG. 1 with a portion of bone removed;

[00033]   FIG. 4 is a graphic representation of a virtual model illustrating a side perspective view of the tibia of FIG. 3 with the portion of bone removed;

[00034]   FIG. 5 is a graphic representation of a virtual model illustrating a top perspective view in an axial direction of the tibia of FIG. 3;

[00035]   FIG. 6 is a graphic representation of a virtual model illustrating a top perspective view of the tibial of FIG. 3 and an implant placed where the portion of bone was removed;

[00036]   FIG. 7 is a graphic representation of a virtual model illustrating an end perspective view of a condyle portion of a femur;

[00037]   FIG. 8 is a graphic representation of a virtual model illustrating an end perspective view in an axial direction of the femur of FIG. 7 with an initial form of an implant placed on one of the condyles of the femur;

[00038]   FIG. 9 is a graphic representation of a virtual model illustrating a side perspective view of the initial form of the implant of FIG. 8

[00039]   FIG. 10 is a graphic representation of a virtual model illustrating a side perspective view of the implant of FIG. 8 in a later stage of design;

[00040]   FIG. 11 is a graphic representation of a virtual model illustrating a side perspective view of the implant of FIG. 11 in a later stage of design;

[00041]   FIG. 12 is a graphic representation of a virtual model illustrating a side perspective view of the implant of FIG. 10 in a still later stage of design and attached to the femur of FIG. 7;

[00042]   FIG. 13 is a graphic representation of a virtual model illustrating a side perspective view of the final design of the implant;

[00043]   FIG. 14 is a schematic view of a unicompartmental implant;

[00044]   FIG. 15 is a cross-sectional schematic view in the coronal plane of a femoral component of the implant of FIG. 14;

[00045]   FIG. 16 is a cross-sectional schematic view in the coronal plane of an alternate embodiment of a femoral component of a unicompartmental implant;

[00046]   FIG. 17 is a cross-sectional schematic view in the coronal plane of an alternate embodiment of a femoral component of a unicompartmental implant;

[00047]   FIG. 18 is a cross-sectional schematic view in the coronal plane of an alternate embodiment of a femoral component of a unicompartmental implant;

[00048]   FIG. 19 is a cross-sectional schematic view in the coronal plane of an alternate embodiment of a femoral component of a unicompartmental implant;

[00049]   FIG. 20 is a graphic representation of a virtual model illustrating a side perspective view of a condyle of a femur having an implant contour on a profile plane superimposed;

[00050]   FIG. 21 is a graphic representation of a virtual model illustrating a side perspective view of the condyle of the femur of FIG. 20 having an implant contour superimposed on the femur surface;

[00051]   FIG. 22 is a graphic representation of a virtual model illustrating a side perspective view of the condyle of the femur of FIG. 20 having cross-sections of the condyle in an anterior taper zone of the implant superimposed;

[00052]   FIG. 23 is a graphic representation of a virtual model illustrating a side perspective view of the condyle of the femur of FIG. 20 showing an alternative view of the anterior taper zone shown in FIG. 22;

[00053]   FIGS. 24A and 24B graphic representations of a virtual model illustrating a front and a side perspective view respectively of a surface of a condyle of FIG. 20 for use in designing an implant;

[00054]   FIG. 25 is a graphic representation of a virtual model illustrating a side perspective view of the condyle of the femur of FIG. 20 having a set of arcs superimposed to loft an outer surface of an implant from the surface of the condyle;

[00055]   FIG. 26 is a graphic representation of a virtual model illustrating a side perspective view of inner and outer surfaces of an implant derived from the condyle of FIG. 20;

[00056]   FIG. 27 is a graphic representation of a virtual model illustrating a side perspective view of an implant in an initial stage of design and having the inner and outer surfaces of FIG. 26;

[00057]   FIG. 28 is a graphic representation of a virtual model illustrating a side perspective view of an outline of the implant of FIG. 27 having a cross section noted by a lighter-colored line;

[00058]   FIG. 29 is a graphic representation of a virtual model illustrating a bottom schematic view of the outline of FIG. 27 in a later stage of development during which pegs are added to the implant;

[00059]   FIG. 30 is a graphic representation of a virtual model illustrating a side perspective view of the implant of FIG. 27 in a later stage of development with the pegs added; and

[00060]   FIG. 31 is a graphic representation of a virtual model illustrating a side perspective view of the implant of FIG. 30 in final form and with fillets added around the pegs.

DETAILED DESCRIPTION

[00061]   Various embodiments of the invention can be adapted and applied to implants and other devices associated with any anatomical joint including, without limitation, a spine, spinal articulations, an intervertebral disk, a facet joint, a shoulder joint, an elbow, a wrist, a hand, a finger joint, a hip, a knee, an ankle, a foot and toes. Furthermore, various embodiments can be adapted and applied to implants, instrumentation used during surgical or other procedures, and methods of using various patient-specific implants, instrumentation and other devices.

[00062]   One embodiment is a nearly-fully automated system to design a patient-specific implant that requires minimal input from a designer or other operator and that is capable of

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designing an implant in a small fraction of the time it takes for a designer to design such an implant using computer aided design (CAD) tools.

Automated Design of a Patient-Specific Unicompartmental Femoral Implant

[00063]   Referring to FIGS. 1-13 below, an exemplary patient-specific implant is illustrated, including references to the bone cuts made to implant the device. The implant is designed based on a medical image, such as a CT scan of a particular patient, and includes both a resurfacing component that attaches to the femoral condoyle of the patient and a tibial tray component that attaches to the top of the tibia as illustrated. When implanted, the unicompartmental resurfacing component and the tibial tray form an articular surface of the knee joint in the patient.

[00064]   Such an implant can be designed and manufactured using traditional CAD-based design rules. However, in the present embodiment, it is designed using an automated system that, for example, partially automates the design process. The specifics attributes of such a system are more fully described below. Similarly, other devices, such as patient-specific instrumentation, other types of knee resurfacing devices, other types of knee joint replacement devices, and other orthopedic implants and instrumentation for other joints or other parts of the anatomy can be designed and manufactured using such partially or fully automated design and manufacturing processes.

[00065]   FIGS. 1-6 illustrate the design process for an exemplary tibial component of a patient-specific unicompartmental knee implant. The image data from the CT scan is transferred to the system and used to build a virtual model of the patient's anatomy. Referring to FIG. 1, the virtual model includes the tibial surface 200 of the patient, which is derived from the image data. An image of the surface of the tibia 200 can be generated from the virtual model and displayed on a computer screen during the design process.

[00066]   Referring also to FIG. 2, the tibial surface 200 can be used to define mathematically the natural slope of the patient's tibia. In this embodiment, the slope is graphically illustrated by a plane 210. Referring to FIG. 3, a horizontal cut is then designed. First, an anatomical axis 230 of the tibia is determined, and the positions of a horizontal cut 240 and vertical cut 250 are determined. In the coronal plane, the horizontal cut 240 preferably is perpendicular to the anatomical axis 230, but many other orientations and positions are possible. As shown in FIG. 4, with respect to the sagittal plane, the horizontal tibial cut 240 can be derived with respect to the

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patient's slope 260. Preferably, the cut 240 is approximately 11.5 degrees relative to the patient's existing tibial slope 250 in the sagittal plane.

[00067]   Referring to FIGS. 5 and 6, the resulting cut leaves a shelf 260 upon which the tibial component 270 of a unicondylar knee implant will be placed. The tibial component 270 preferably is designed to maximize coverage of the tibial shelf 260. In some embodiments, a tibial component can be designed to exactly match a perimeter of the tibial shelf.

[00068]   Referring to FIGS. 7-13, a femoral component of the patient-specific unicompartmental knee implant is also designed using automated design principles. As with the tibial, the surface 300 of the patient's femur is derived from the image data, including a virtual representation of the condyle 320 of the femur. Referring to FIG. 8, a coronal profile 310 of the implant can be superimposed on the condyle 320 of the femur to assess the orientation and sizing of the implant to be designed.

[00069]   As shown in FIGS. 9-10, a virtual interim implant 330 is used to design a posterior cut into the implant. The virtual interim implant 330 allows the system to optimize the placement of the posterior cut, and includes a posterior cut surface 350 to align the posterior cut on the virtual model of the condyle. Once the posterior bone cut surface 350 is properly positioned, a posterior tray 360 is filled in on the virtual implant and trimmed to optimize the design of the implant. As shown in FIG. 11, fixation pegs 370 and 380 can then be added. Preferably, the pegs 370 and 380 are positioned in a flexed position relative to the mechanical axis and/or the primary direction of the forces on the knee applied by the femur.

[00070]   Referring to FIG. 12, the virtual model of the femoral component of the unicompartmental implant 390 is then fit to the virtual model of the condyle 320, and the proper orientation of the implant relative to the condyle is finalized. A tapering portion 400 is included in an anterior portion of the implant to provide a gradual transition from an articular surface 410 of the implant and an articular surface 420 of the implant.

[00071]   Referring to FIG. 13, a virtual model of the final femoral component 440 is created by position a cement pocket 450 in a bone-facing surface 460 of the posterior tray 360.

Automated Design of an Implant with a "Patient-Engineered" Articular Surface

[00072]   Preferably, patient-specific implants include articular surface and other attributes that are engineered from the patient's own anatomy, but that provide an improved function. For example, an articular surface can create a healthy and variable "J" curve of the patient in the

sagittal plane and a constant curvature in the coronal plane that is based on the patient's specific anatomy, but that does not seek to mimic or precisely recreate that anatomy, may be preferred. For example, referring to FIGS. 14-15, in another exemplary embodiment of a patient-specific device, a unicompartmental resurfacing implant has an enhanced articular surface that is engineered based on the specific anatomy of a patient. A unicompartmental implant10 similar to the device in Example 1, having a femoral resurfacing component 20 and a tibial tray component 30, is designed based on patient-specific data. An inner, femoral-facing surface 40 of the resurfacing component 20 conforms to the corresponding surface of the femoral condoyle. However, the outer, articular surface 50 of the resurfacing component 20 is enhanced to incorporate a smooth surface having a nearly constant radius in the coronal plane. The corresponding articular surface 70 of the tibial tray 30 has a surface contour in the coronal plane that is matched to the outer articular surface 50. In this embodiment, the articular surface 70 has a radius that is five times the radius of outer articular surface 50.

[00073]   The design of implant 10 has several advantages. First, the design of articular surface 50 allows the thickness of femoral component to be better controlled as desired. For example, referring to FIG. 16, if a curve of an articular surface 80 of a femoral component 90 is too large, the thickness of the femoral component may be too thick along a centerline 100 of the implant, thereby requiring an excessive amount of bone to be removed when the implant is placed on the femoral condoyle. On the other hand, referring to FIG. 17, if the same curve 80 is applied to a device having an appropriate centerline thickness 110, the margins or sidewalls 120 and 130 of the device may be too thin to provide proper structural support. Similarly, referring to FIG. 18, if the curve of the outer articular surface 120 of a femoral component 130 is too flat, the device will not exhibit the tapering from a centerline 140 to the margins or sidewalls 150 and 160 of the device and may not function well.

[00074]   Referring again to FIGS. 14 and 15, a second advantage of the implant 10 over certain other embodiments of patient-specific devices is that the smooth articular surface 50 is thought to provide better kinematics than a true representation of the surface of the patient's femoral condoyle may provide.

[00075]   For example, referring also to FIG. 19, one method of making patient specific implants is to use a simple offset, in which a femoral component 170 is designed using a standard offset from each point of the modeled surface of the patient's femoral condoyle. Using

such a design, the thickness of the device will remain essentially constant, and an outer surface
180 will essentially match or conform to the underlying inner femoral-facing surface 190, as well
as the modeled surface of the femoral condoyle on which it is based. While this provides a truly
patient-matched outer surface, it is not necessarily optimal for the kinematics of the resulting
implant, due to, for example, rough areas that may produce higher, more localized loading of the
implant. By using a smooth surface with an essentially pre-determined shape, the loading of the
implant can be better managed and distributed, thereby reducing the wear on the tibial tray
component 30.

[00076]   The third advantage, which is also related to the loading and overall kinematics of the
implant, is in the matching of the tibial articular surface 70 to the femoral articular surface 50 in
the coronal plane. By providing a radius that is predetermined, e.g., five times the radius of the
femoral articular surface 50 at its centerline in the present embodiment, the loading of the
articular surfaces can be further distributed. Thus, the overall function and movement of the
implant is improved, as is the wear on the tibial tray, which is polyethylene in this embodiment.
While the present embodiment uses a ratio of five times the radius of the outer surface at its
centerline (note that the radius of the outer surface may be slightly different at other locations of
the outer surface 50 away from the centerline), other embodiments are possible, including an
outer tibial surface that, in the coronal plane, is based on other ratios of curvature, other
curvatures, other functions or combinations of curves and/or functions at various points.
Additionally, while the embodiments shown in FIGS. 16-19 are not considered to be optimal
designs generally, they are embodiments that can be generated using automated systems and may
have preferable characteristics in some instances.

An Exemplary Automated System for Designing Patient-Specific Implants

[00077]   The implants described in both Examples 1 and 2 can be designed and manufactured
using CAD-based design rules or other largely manual procedures, i.e., procedures that are either
entirely manual, or that may contain certain automated components but that are still
predominately manual in nature.

[00078]   Alternatively, those implants, as well as essentially any type of patient-specific
implant, can be designed and manufactured using an automated system that, for example,
partially or fully automates the design process. Such an automated process is more fully

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described below. Similarly, other devices, such as patient-specific instrumentation, other types of knee resurfacing devices, other types of knee joint replacement devices, and other orthopedic implants and instrumentation for other joints or other parts of the anatomy can be designed and manufactured using such partially or fully automated design and manufacturing processes. In the following example, an embodiment of an automated process is described. This embodiment is one of many potential embodiments that may vary in many ways, each having its own specifications, design goals, advantages and tradeoffs.

Automated Design of a Femoral Component

a. Sketching a Sulcus Line

[00079]   Referring to FIGS. 20-31, a sulcus line can be sketched as a curve on a condylar surface of a femur before sketching a femoral implant contour. The sulcus point can be viewed more easily in a view other than a profile view. It is preferable to start sketching the sulcus line in a view where the sulcus point is easily visible and then change the view with each new segment, finally making the line visible in the profile view.

[00080]   The automation system constructs the curve segment by segment, interpolating the sketch points by a local cubic spline. The spline does not lie on the surface, and typically will not be close to it. The curve will pass near the surface on the outside part of it to make it highly visible in any view. To do this, the spline segments are interpolated, and, for each intermediate point, a ray extending from an essentially infinitely distant point and perpendicular to the screen plane intersects with the surface. As the view can be different for each segment, the directions of projects may also be different for each segment.

[00081]   When a new sketch point is added, the spline is changed only at its last created segment. But the sketch points and the directions of projection are kept until the curve construction is complete. This allows the system to reject as many segments as the system wants and redefine the spline until the system has developed a satisfactory shape using an iterative process.

[00082]   The cubic spline is a local cubic spline with a special rule of defining tangent vectors of interpolating points. By way of example in this particular embodiment:

[00083]   Suppose there are $n + 1$ points $p0$, $p1$, . . . , pn.

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[00084]   For inner points (i = 1,..., n-1), the system defines tangent vector as a bisect of a triangle formed by two neighbor chord vectors starting from the point:

(a) $v_0 = p_i - p_{i-1}$ incoming chord

(b) $v_1 = p_{i+1} - p_i$ outgoing chord

(c) $h_0 = |v_0|$ length of the incoming chord

(d) $h_1 = |v_1|$ length of the outgoing chord

(e) $tn_i = \dfrac{h_1 * v_0 + h_0 * v_1}{h_0 + h_1}$ tangent at the inner point

[00085]   For the first and the last points the system define the tangent vector from the constraint of zero curvature at the end points:

(f) $v_0 = p_1 - p_0$ first chord

(g) $tn_i = \dfrac{3 * v_0 - tn_1}{2}$ first tangent

(h) $v_{n-1} = p_n - p_{n-1}$ last chord

(i) $tn_n = \dfrac{3 * v_{n-1} - tn_{n-1}}{2}$ last tangent

[00086]   The interpolation inside each segment is done according a classic cubic segment formula:

(j) $f0 = 1 - 3u^2 + 2u^3$

(k) $f1 = 3u^2 - 2u^3$

(l) $g0 = u^3 - 2u^2 + u$

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$$(m) \quad g1 = u3 - u^2$$

$$(n) \quad pt = f_0 * pt_0 + g_0 * tn_0 +$$

$$(o) \quad f_1 * pt_1 + g_1 * tn_1$$

[00087]   When the system has sketched the sulcus line 520, it then begins to develop the curve of the shape of the implant. This is performed by an object that interpolates points lying close to the surface. In the present embodiment, the spline or the projection directions array is not used for this purpose, but many other implementations are possible. This curve serves as an indicator of approximate position where the femoral implant should stop.

b.   Making Profile View

[00088]   In the next phase of the design, a profile view is created. The system defines the profile view using the following steps:

- Set bottom view
- Rotate it 180 degrees around the z-axis
- Rotate it 15 degrees around x-axis
- Find common tangent to both condoyles in that view
- Change the view to make the common tangent horizontal
- Offer class for making additional rotations around x-axis and z-axis

[00089]   In the present embodiment, all steps except the last one are done automatically. (But, this step could also be automated.) Here, the user interface for making additional rotations is done using a UI class derived from CManager. The view can be rotated around x-axis and around z-axis either by moving the sliders or by setting the rotation angles in the toolbar edit boxes. This allows the designer to better view and examine the implant surfaces during the automated design process. When a designer, customer or other user clicks "Accept" in the toolbar, the system stores the entity of the view information in the document. The entity contains the view parameters and two correction angles.

c.   Sketching Implant Contour

[00090]   Referring to FIG. 20, the profile view discussed above is used to sketch the implant. Designing the contour occurs in three steps:

- Sketch the original contour
- Preview the contour in 3d

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• Modify the contour

The second and third steps can be repeated until the contour shape is acceptable.

[00091]   The initial implant contour 500 is sketched in the profile plane of condyle 510 of the femur of the patient. The contour is projected onto the femur surface orthogonally to the screen plane (profile plane). To close the contour on the posterior side, there are two points on the vertical edges of the contour which are the closest to a so-called 93 degrees plane. The system computes the cutting plane as the plane passing through those two points and forming minimal angle with 93 degrees plane. Making a cross-section by the cutting plane allows us to close the implant contour.

[00092]   The two dimension contour to be projected on the femur surface consists of lines and arcs. There are two vertical lines, two slopped parallel lines, one horizontal line, two fillet arcs and two 90 degrees arcs on the top, forming one 180 degrees arc. Each of these arcs and lines is called a contour element; the contour consists of nine elements. The system also considers center-line elements, including two center lines and two points (shown as bold markers on the screen).

[00093]   The members of this data structure are called "defining elements." The system can uniquely compute contour elements based on this information. When the software stores the profile contour in an external file, the software stores the defining elements. The defining elements can include those listed below in Table 1, but other embodiments are possible.

Table 1 – Exemplary Defining Elements Used In Automated Design Process

Defining Element	Definition
pt0, pt1, pt2	ends of two center lines, from bottom to top
h1	half distance between two vertical lines
h2	half distance between two slopped lines
r0 and r1	radii of fillet arcs
bFixedRad	Boolean flag
True	means preserving the radii during modification
False	re-compute the radii after modifications

[00094]   If the system wants to adjust fillets, the system sets a flag to true. The system then leaves the radii being to the original value and does not re-compute them automatically.

[00095]   The initial sketching starts with indicating the upper point of the first vertical line. Then the system indicates the upper end of the first slopped line and makes the first fillet

automatically. The last action in the initial sketching is indicating the upper point of the second slopped line – the rest of the contour can be uniquely defined automatically with the assumption that **h1** = **h2**. This condition can be changed during modification phase. After the initial sketch is complete, the contour is projected on the femur surface and is displayed.

[00096]   In most cases the contour built after the initial sketch requires some modification, which can be automated using an iterative process that checks against a predefined set of rules and compares to a specification. Alternatively, a designer can intervene to check to progression of the automated design. To switch to modification phase, the user clicks a "Modify" button in the toolbar. When a user moves the mouse over some contour element, the element is highlighted by displaying in bold lines. The user can drag the element along the direction, associated with each element, by pressing left button, moving the mouse and releasing it in a new position. The whole contour will be rebuilt accordingly.

[00097]   When the contour shape, which serves as the footprint and starting point of the implant, is satisfactory, the user clicks the button "Make" in the toolbar and the process of constructing the implant starts.

d.   Making Implant

[00098]   Constructing of the implant is done by the following main steps of the process:

- Projecting the contour on femur surface
- Making vertical sections
- Computing posterior cutting plane
- Making posterior section
- Making the contour on femur surface
- Making a center line
- Making side lines
- Approximating inner surface
- Constructing an outer surface
- Making the implant BREP
- Marking inner and outer surfaces
- Cutting by posterior cylinder
- Flattening the cutting area
- Filleting

[00099]   In the present embodiment, the process starts with projecting the sketched contour on the femur surface. This function does two things. First, it traverses all contour elements,

computes 30 points on each of them and projects them onto femur BREP. Second, it takes two center line elements, extends the top one up to the top arcs, makes a fillet between the two lines and projects the resulted center line onto femur BREP. This is a first step in constructing the femur center line.

[000100] When the system projects contour and center line points onto the femur BREP, some points may miss the surface. This happens on a portion of a region where the contour elements are vertical lines. As the system constructs the contour on the femur in this area, the system will make cross-sections of the femur by those vertical lines. The system also finds the "lowest" (the closest to the 93 degrees plane) points on the side sections.

[000101] When the system calculates the two "lowest" points on the side sections, the system computes the cutting plane. It computes a temporary plane passing through the two lowest points perpendicular to the 93 degrees plane and then makes a cutting plane as passing through two lowest points perpendicular to the temporary plane. As the result, the cutting "profile" plane forms a minimal angle of 93 degrees from all planes passing through the two lowest points.

[000102] The next step is cutting the femur with the profile plane. The function finds a cross-section as an array of curves, discards the ones belonging to the other condoyle, approximates the best curve with a single spline and re-orients it so that it has the same direction at the starting lowest point as the projected contour.

[000103] The final step in making the contour on the femur is assembling all aspects together. This is done by a function that forms the contour from the main portion of the projection, i.e., the two segments of the vertical sections which start where the projection portion finishes and end at the "lowest" points, and the portion of the cutting plane cross-section.

[000104] FIG. 21 shows the resulting contour 530 superimposed on the condyle 510 of the femur. Now, when the system has the implant contour, it completes the center line. So far the system has the center line in the form of a point array on the femur from one end of the contour to the other. The function extends this array behind both ends along the corresponding cross-sections and approximates the resulted array with a relatively large tolerance (e.g., 0.5). A larger tolerance leads to a smoother outer-femoral curve, which is a design goal of the present embodiment (although other embodiments may have different implementations and/or design goals). However, while using a larger tolerance in the approximation make a smoother outer curve, but it may result in deviation from the vertical center line. To accommodate this

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phenomenon, a function is implemented that corrects the control points of the center line B-spline -- adjusting them into the vertical line starting at some point.

[000105]   As shown in FIGS. 22-23, the system then computes the tapering arcs 550. Two functions compute the arcs 550 lying on the outer surface 560 of condyle 510. The arcs 550 are not connected to the center line 570, which passes closer to the inner surface of the implant being designed.

[000106]   The system then computes the side rails of the implant by extending the side lines of the contour behind the end points to provide good intersection of the inner and outer surfaces with the cutting surfaces.

[000107]   Referring also to FIGS. 24A and 24B and 26, the system then constructs the inner and outer surfaces 580 and 590. The inner surface 580 is constructed by a function that computes 15 points on the portion of a center line 600 between the end point of anterior taper and the end of the center line 570. For each of these points it makes a cross-section of the femur BREP by the plane, passing through the point and perpendicular to the center line. This cross-section is trimmed by the side rails, extended a little behind the side rails and added as single B-spline curve to the section array. Now, the system adds the cross-sections in the tapered zone. To do that, the system takes the first computed cross-section and creates additional sections. The system inserts the additional sections in the beginning of the section array.

[000108]   Referring to FIGS. 25-26, the system then constructs a loft surface 620 using an array of cross-sections. A center line 630 and cross-sections 640 are used for making the outer surface 580 of the implant.

[000109]   The outer surface 590 is constructed by sweeping an arc of the constant radius and angle along a center line trajectory. The trajectory is defined by the center line curve and an offset value. The ending portions of the trajectory are defined by the tapering arcs. The system function assumes that the arc radius and the offset value are given; for example, the system may use a radius = 25.0 and offset = 3.5.

[000110]   The function then determines the angle of the sweeping arc. To find the angle, the system uses a heuristic approach. It computes several (e.g., 10) points on the center line in between tapering zones. For each of these points the system makes a plane perpendicular to the center line and find two points where the plane intersects with two side curves. Then the system computes the "center" by offsetting the point on the center line against the surface normal by a

value equal the difference (radius - offset). The system then makes two lines from the center to the points on side curves and computes the angle between them. This angle approximates the possible sweeping arc angle at this cross-section. The system sets the angle of the sweeping arc to the maximum of those arcs angles.

[000111]   Once the system determines the sweeping arc angle, it processes the anterior taper arc, the portion of the center line between taper zones, and the posterior taper arc. For taper arcs, the system computes an array of points on the curve and constructs an arc of the given radius and angle, lying in the plane perpendicular to the curve and having the calculated point as its middle point. The center line that the system processes is almost the same, except that the system offsets the point on the curve along the femur normal to the offset value. This results in a set of arcs as shown. Thus, the outer surface 590 is created as a loft surface using the set of created arcs as cross-sections.

[000112]   Referring now to FIG. 27, after the system has designed the inner and the outer surfaces 580 and 590, it creates the side walls 650 of the implant. The system generates the side wall 650 by making two additional surfaces: a tabulated cylinder passing through the implant contour with an axis perpendicular to the profile plane, and a half of a regular cylinder with an axis perpendicular to the 93-degree plane.

[000113]   Ideally, in this embodiment, the radius of the cylinder should be the half of the distance between the side lines, although other embodiments may employ different implementations. The implementation of this embodiment allows the cylinder to be tangential to the walls of the tabulated cylinder, and thus to create a smooth side surface.

[000114]   The system then eliminates the angles of the side surfaces. The system can do this either by filleting the angles, or by using Boolean subtraction. Boolean operation will provide a more exact result, but risks instability in some cases. The system then flattens the posterior area 660 of the inner surface.

e.   Measuring Thickness

[000115]   Referring to FIG. 28, the next step after the implant is created is controlling its thickness. With a sweeping arc radius that is small enough (e.g., 25 mm), the thickness may need to be altered in some portions. If the system keeps the thickness of the implant along the spine of the implant at about 3.5 mm, the thickness may be too small thickness along the edges. Generally, the thickness of the implant along the center line should be bigger than at the edges,

but neither the center line nor the edges of the implant should get too thick or too thin. The design rules may result in such a condition, however, in the process of constructing other parts of the implant. Thus, the system checks the final thickness and makes adjustments to ensure the thickness meets the specifications of the implant.

[000116] In this embodiment, a functions to check the implant thickness is provided as a menu item that a user can select, but the feature could be automated to run automatically. As shown in FIG. 28, the menu item allows the system to move an implant cross-section 670 along a center line 690 and to move a line across that section and measure the distance between inner and outer surfaces along that line.

[000117] When the system begins to measure the implant thickness, it can display the implant in wireframe mode 680 and display the cross-section 670 in some initial position. The cross-section 670 is displayed, for example, in white, and the center-line 690 is displayed, for example, in red. The initial position of the cross-section is at the point on the center line 690 where anterior taper begins. The cross-line default position is in the middle of the cross-section 670.

f.   Making Attachment Pegs

[000118] Referring to FIGS. 29 and 30, the system provides a function for positioning of pegs 700, 705 for attachment of the implant 710 to bone. The system allows a user to control the distances and the pegs heights, but these aspects could also be automated in other embodiments.

[000119] When started, the class displays the implant in the wireframe mode in the profile view and suggests default positions 720, 730 for the pegs, marked on the screen as circles:

[000120] The user can move the pegs by dragging them. The pegs are moved along the center lines keeping constant distance between them. The toolbar displays the distances between the cutting plane and the first peg (d1), between the two pegs (d2), and between the second peg and the apex point of the implant contour (d3). It also displays the pegs heights.

[000121] The pegs 700, 705 can be pre-viewed with dynamic view changing by clicking button **Preview** and made with filleting their intersection with the implant inner surface by clicking **Accept**.

[000122] The class automatically computes initial positions of the pegs, trying to make equal all three distances d1, d3, d3. The distance d2 should be integer number, so it is rounded to the nearest integer. The other two, d1, and d3, are updated accordingly. A user can set the distance d2 right in the toolbar; again, the other two distances will be updated.

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[000123] The toolbar has a button "Constraints". Clicking on this button invokes a modal dialog with a set of conditions. It sets the minimum value for d1 (11), the min/max values for d2 (11-18) and the min/max values for pegs heights (11-12). If one (or more) of conditions is violated, the corresponding value is displayed in red and moving the pegs produces an alarm.

[000124] The system requires that the distances from pegs apex points to the profile plane be equal. Although many other embodiments are possible. For every position of the pegs, the system extends them up to a plane, parallel to the profile plane and measure their heights, h1 and h2. Then the system adjusts them so that $(h1 + h2)/2$ becomes 11.5. This allows the system to place both of pegs in the range 11-12 and their heights differ from 11.5 the same distance.

g.   Inserting a Cement Pocket

[000125] Referring to FIG. 31, a cement pocket 740 is then placed in the posterior section of the implant 710 as shown below.

[000126] The embodiments disclosed herein are exemplary only, and one skilled in the art will realize that many other embodiments are possible, including, without limitation, many variations on the embodiments described above as well as other entirely different applications of automated systems for designing patient specific implants of various types and for various joints and other parts of a patient's anatomy. The embodiments described herein are not intended to limit the scope of the claims.

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What is claimed is:

1.   A method of automatically designing a patient-specific orthopedic implant using a computer system, comprising:

obtaining image data of a joint of a patient;

creating a virtual model of at least a portion of the patient's joint from the image data; and

processing automatically the virtual model to design a patient-specifc implant based at least in part on the virtual model.

2.   The method of claim 1, wherein the computer system processes the virtual model without human intervention.

3.   The method of claim 1, wherein the computer system processes the virtual model without human intervention, and further comprising, checking the design to determine whether the parameters of the design meet predetermined specifications.

4.   The method of claim 1, wherein the virtual model is processed predominately without human intervention.

5.   The method of claim 1, wherein the step of process further comprises identifying anatomic landmarks to generate an implant design.

6.   The method of claim 5, wherein identifying anatomic landmarks includes locating maxima or minima on the curvature of a surface portion of the virtual model.

7.   The method of claim 1, wherein the step of process further comprises:

identifying anatomic landmarks; and

merging information regarding the anatomic landmarks with a generic model containing to create an implant design.

8. The method of claim 1, further comprising automatically determining an optimal viewpoint to allow the user to perform a design step.

9. The method of claim 1, further comprising combining a virtual template with the virtual model to design the patient-specific implant.

10. The method of claim 9, wherein the template may be adjusted by a user.

11. The method of claim 1, wherein the template is three dimensional.

12. The method of claim 1, wherein the patient-specific implant has one or more planar surface portions to accommodate one or more corresponding bone cuts.

13. The method of claim 12, wherein the position of the bone cuts is automatically determined.

14. The method of claim 12, wherein the position of the bone cuts is automatically determined using anatomical landmarks.

15. The method of claim 1, wherein the computer system automatically designs in attachment features.

16. The method of claim 15, wherein the attachment features are at least one of pegs and anchors.

17. A method of automatically designing a patient-specific orthopedic implant using a computer system, comprising:

    obtaining image data of at least a portion of a patient's joint;

    creating a virtual model of an articular surface of the joint;

    processing automatically the virtual model to engineer an articular surface for a patient-specifc implant based at least in part on the virtual model;

    including the engineered articular surface in an implant design.

18.   The method of claim 17, wherein the computer system processes the virtual model without human intervention.

19. The method of claim 17, wherein the computer system processes the virtual model without human intervention, and further comprising, checking the design to determine whether the parameters of the design meet predetermined specifications.
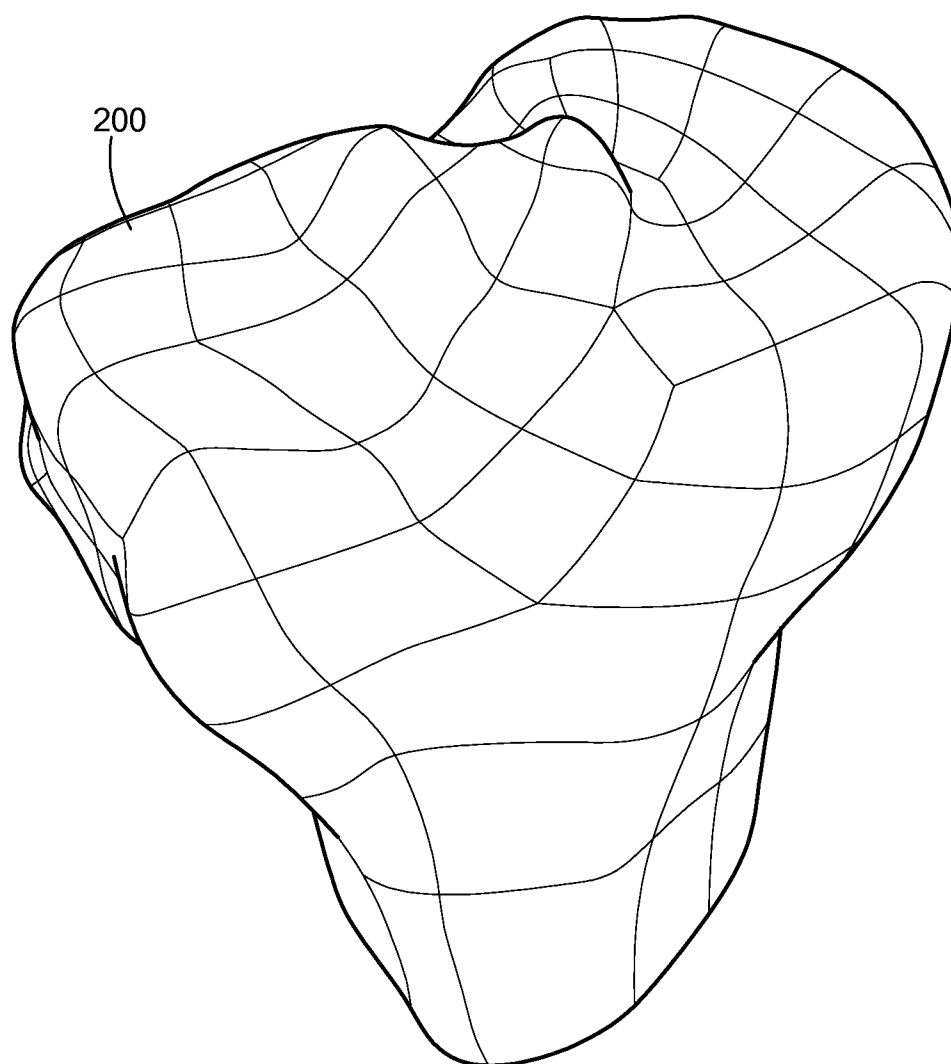
20. The method of claim 17, wherein the virtual model is processed predominately without human intervention.

21. The method of claim 17, wherein the step of process further comprises identifying anatomic landmarks to generate an implant design.

22. The method of claim 21, wherein identifying anatomic landmarks includes locating maxima or minima on the curvature of a surface portion of the virtual model.

23. The method of claim 17, wherein the step of process further comprises:
    identifying anatomic landmarks; and
    merging information regarding the anatomic landmarks with a generic model containing to create an implant design.

24. The method of claim 17, further comprising automatically determining an optimal viewpoint to allow the user to perform a design step.

25. The method of claim 17, further comprising combining a virtual template with the virtual model to design the patient-specific implant.

26. The method of claim 25, wherein the template may be adjusted by a user.

27. The method of claim 17, wherein the template is three dimensional.

28. The method of claim 17, wherein the patient-specific implant has one or more planar surface portions to accommodate one or more corresponding bone cuts.

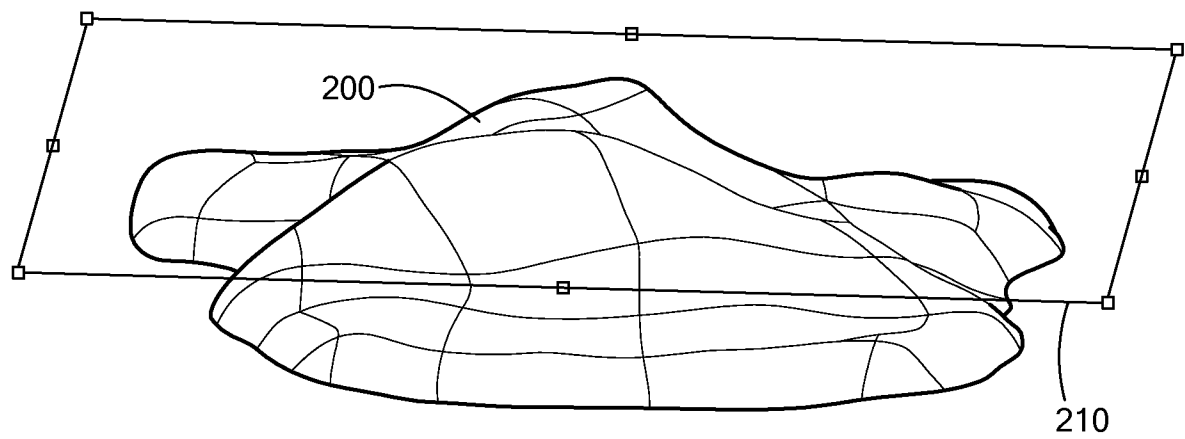29. The method of claim 28, wherein the position of the bone cuts is automatically determined.

30. The method of claim 28, wherein the position of the bone cuts is automatically determined using anatomical landmarks.

31. The method of claim 17, wherein the computer system automatically designs in attachment features.

32. The method of claim 31, wherein the attachment features are at least one of pegs and anchors.

33. A method of automatically designing a patient-specific orthopedic implant using a computer system, comprising:

   obtaining image data of at least a portion of a patient's joint;

   creating a virtual model of at least a portion of the joint;

   processing automatically the virtual model to design a patient-specifc instrument based at least in part on the virtual model.

34. The method of claim 33, further comprising producing the patient-specific instrument from the design.

35. The method of claim 33, wherein the computer system processes the virtual model without human intervention.

36. The method of claim 33, wherein the computer system processes the virtual model without human intervention, and further comprising, checking the design to determine whether the parameters of the design meet predetermined specifications.

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37. The method of claim 33, wherein the virtual model is processed predominately without human intervention.

38. The method of claim 33, wherein the step of process further comprises identifying anatomic landmarks to generate an instrument design.

39. The method of claim 38, wherein identifying anatomic landmarks includes locating maxima or minima on the curvature of a surface portion of the virtual model.

40. The method of claim 33, wherein the step of process further comprises:

    identifying anatomic landmarks; and

    merging information regarding the anatomic landmarks with a generic model containing to create an instrument design.

41. The method of claim 33, further comprising automatically determining an optimal viewpoint to allow the user to perform a design step.

42. The method of claim 33, further comprising combining a virtual template with the virtual model to design the patient-specific instrument.

43. The method of claim 42, wherein the template may be adjusted by a user.

44. The method of claim 34, wherein the template is three dimensional.

45. The method of claim 34, wherein the patient-specific instrument has one or more planar surface portions to accommodate one or more corresponding bone cuts.

46. The method of claim 45, wherein the position of the bone cuts is automatically determined.

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47. The method of claim 45, wherein the position of the bone cuts is automatically determined using anatomical landmarks.

48. The method of claim 33, wherein the computer system automatically designs in attachment features.

49. The method of claim 48, wherein the attachment features are at least one of pegs and anchors.

50. A method of automatically designing a patient-specific orthopedic implant using a computer system, comprising:

obtaining image data of a portion of a patient's anatomy;

creating a virtual model of the portion of the patient's anatomy from the image data;

processing automatically the virtual model to design a patient-specifc implant based at least in part on the virtual model;

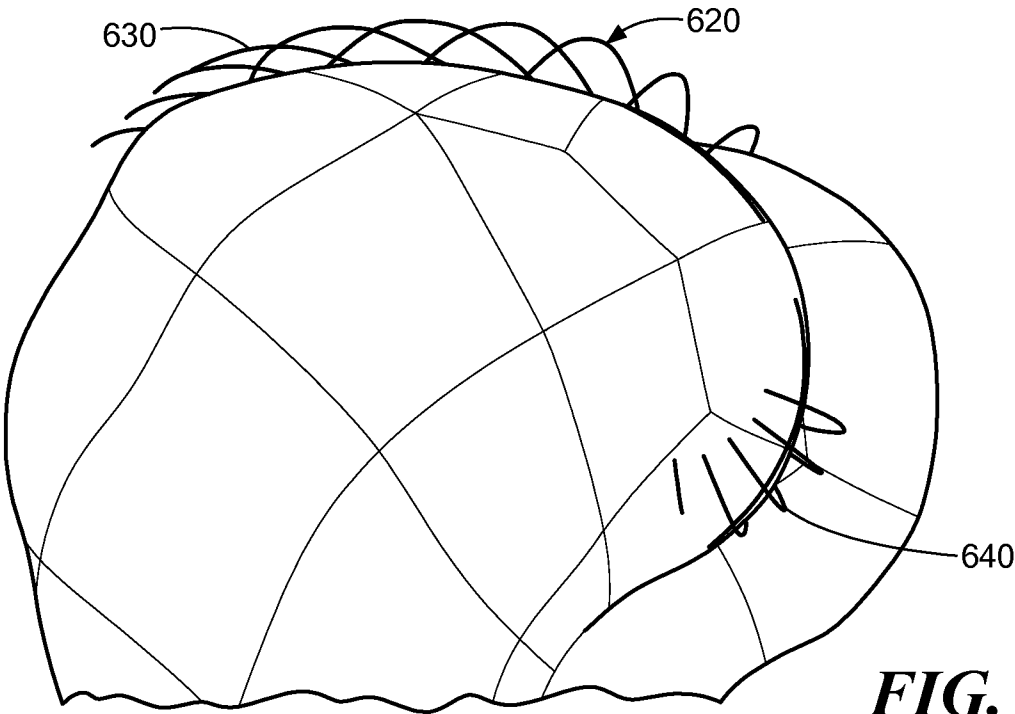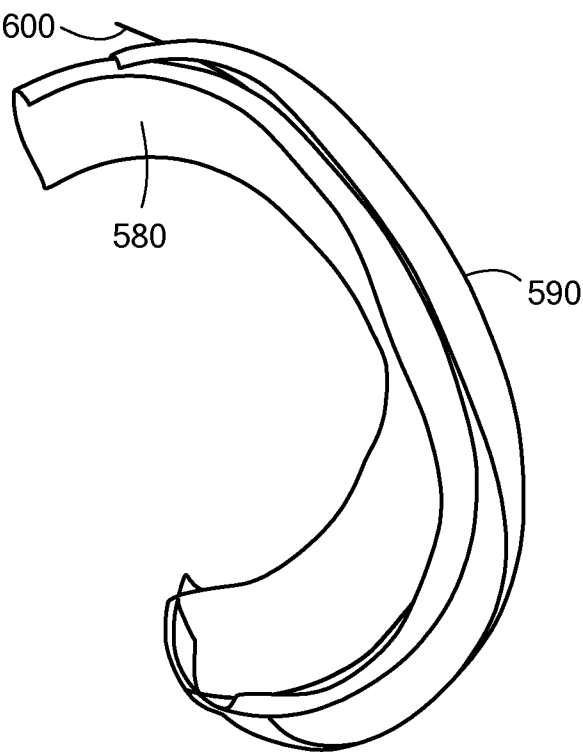adjusting the design to meet predetermined specifications.
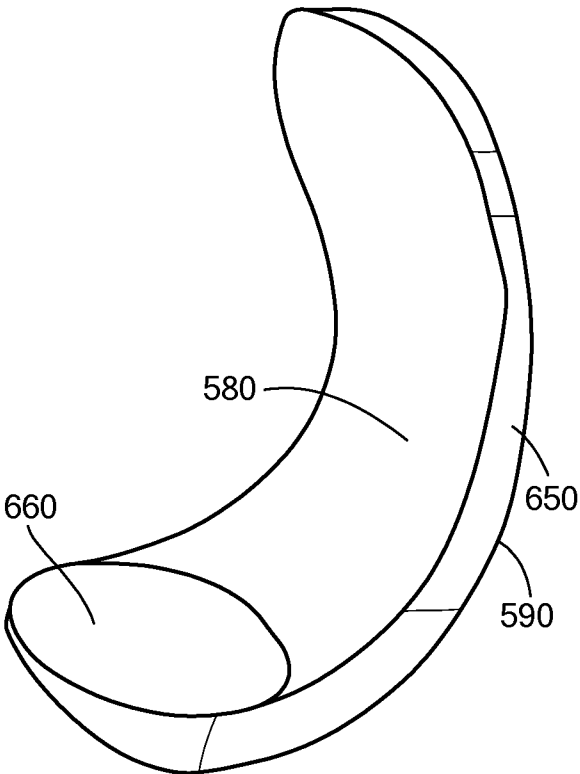
FIG. 1

2/12

200

210

FIG. 2

230

250

240

200
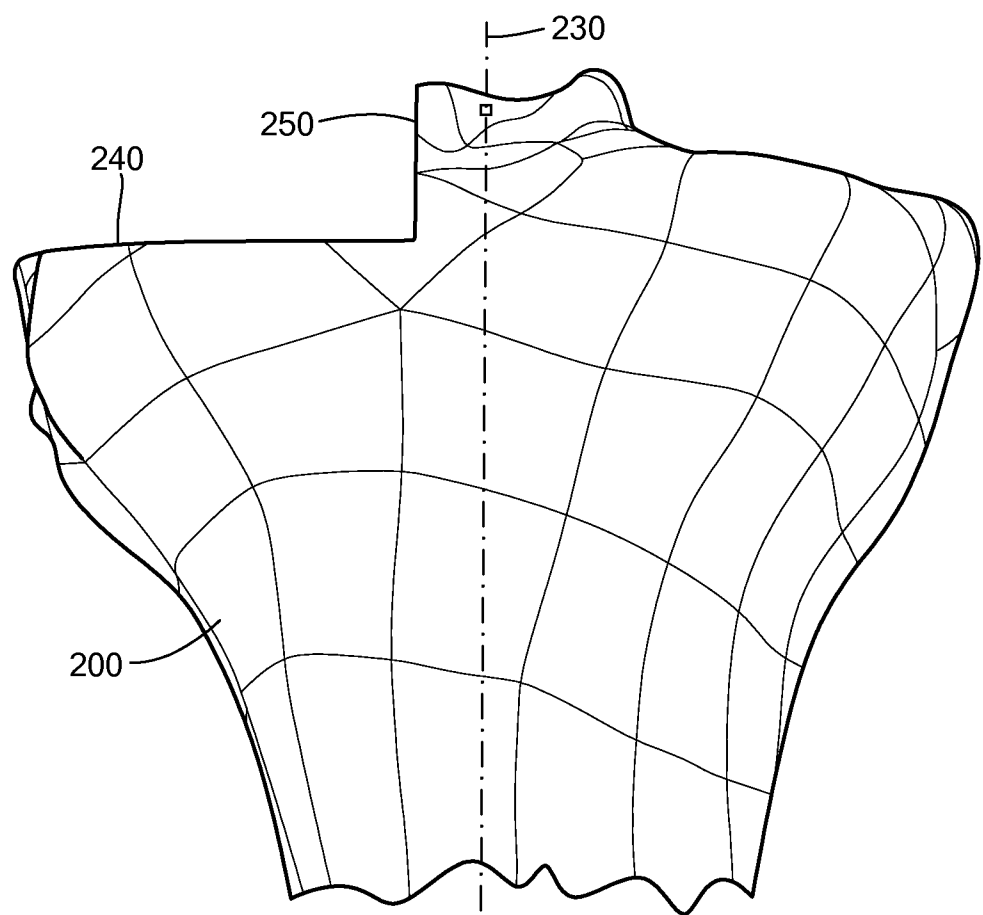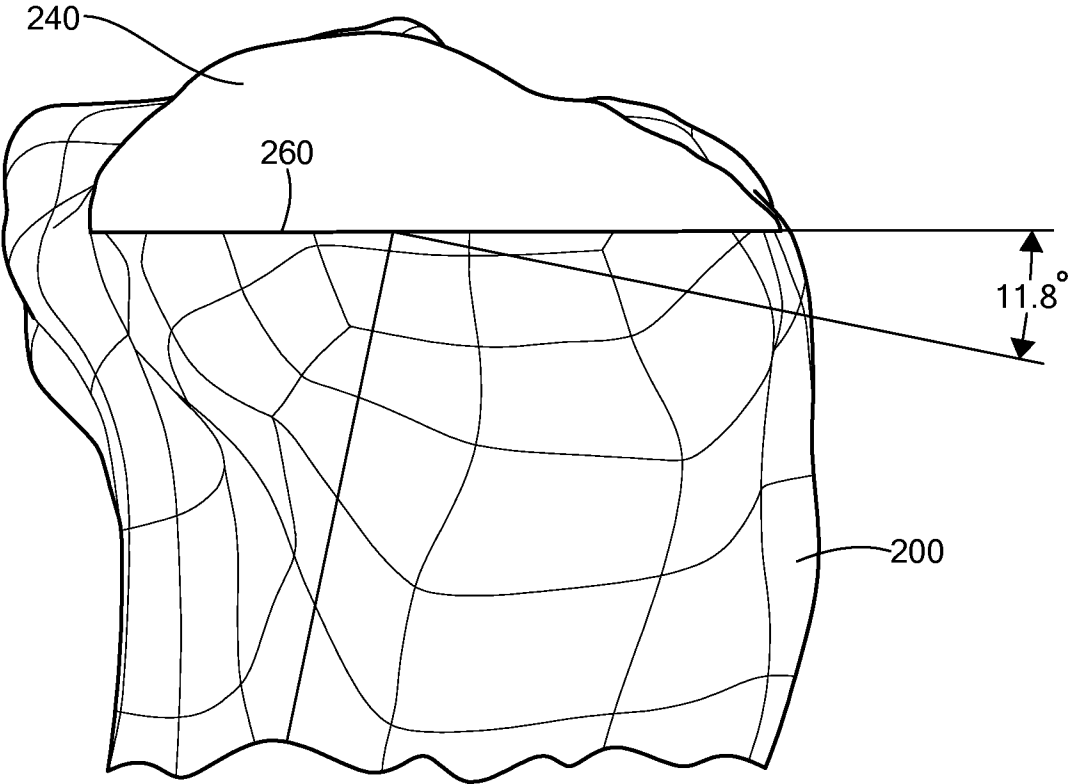
FIG. 3

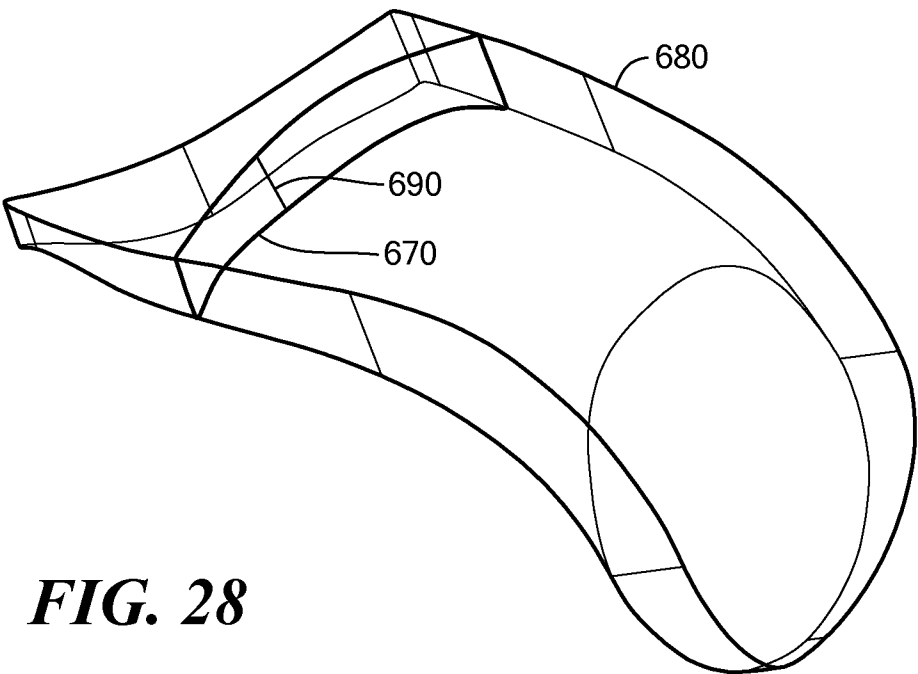**FIG. 4**

FIG. 5
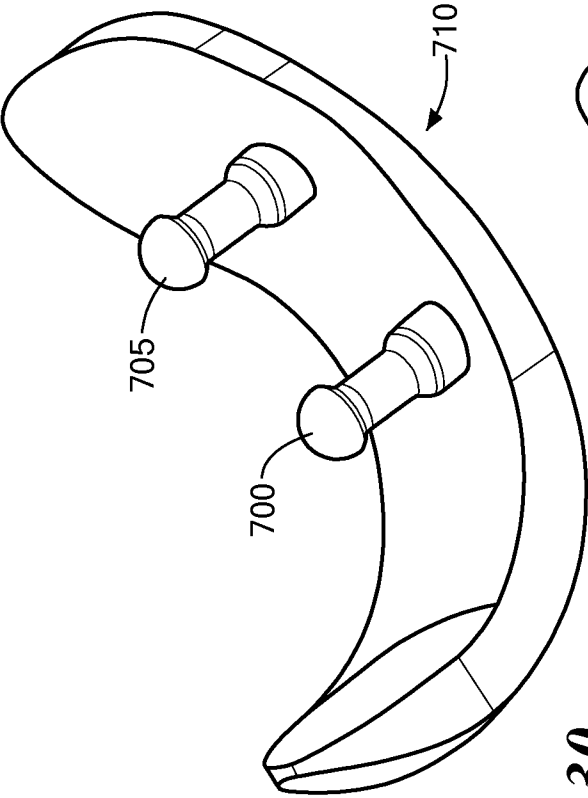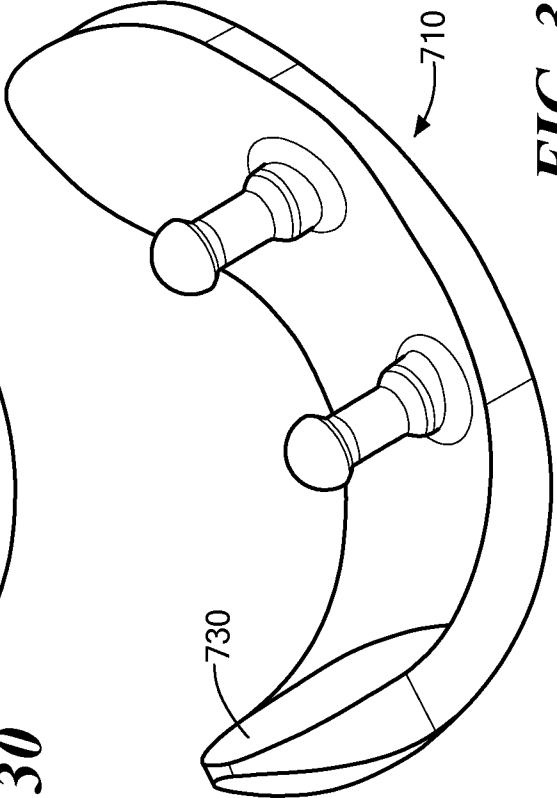
FIG. 6

FIG. 7

5/12
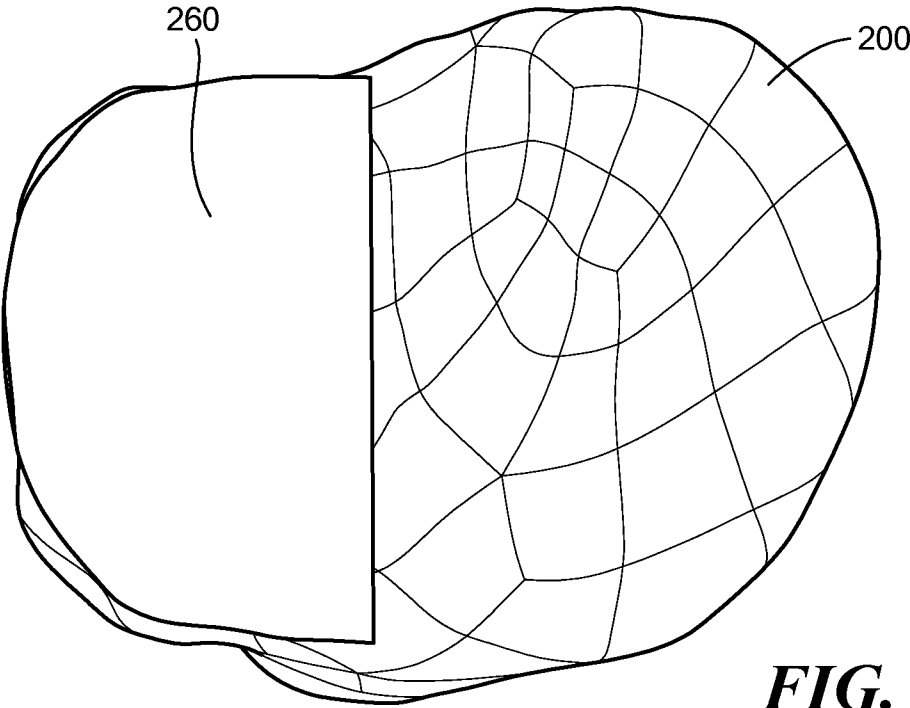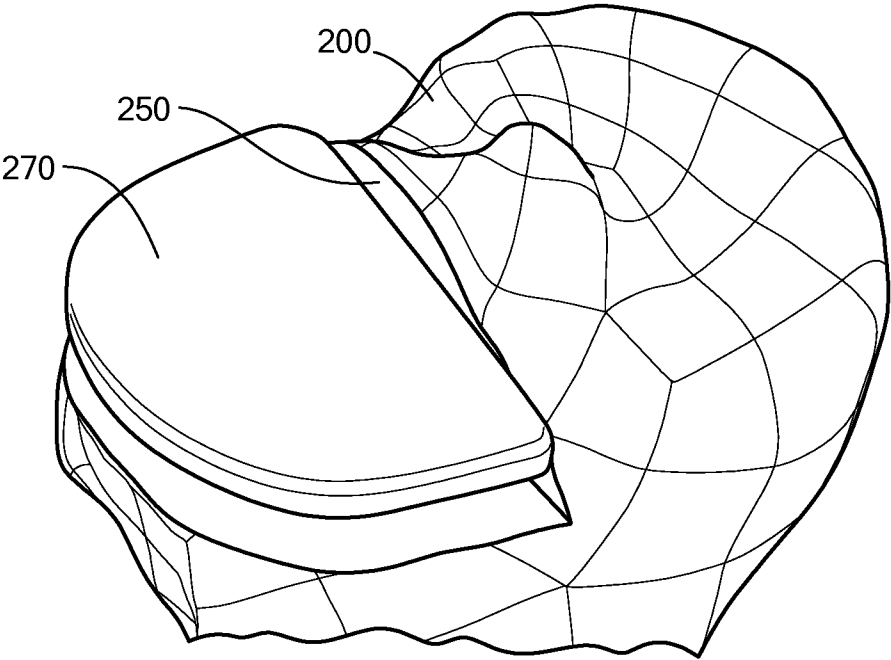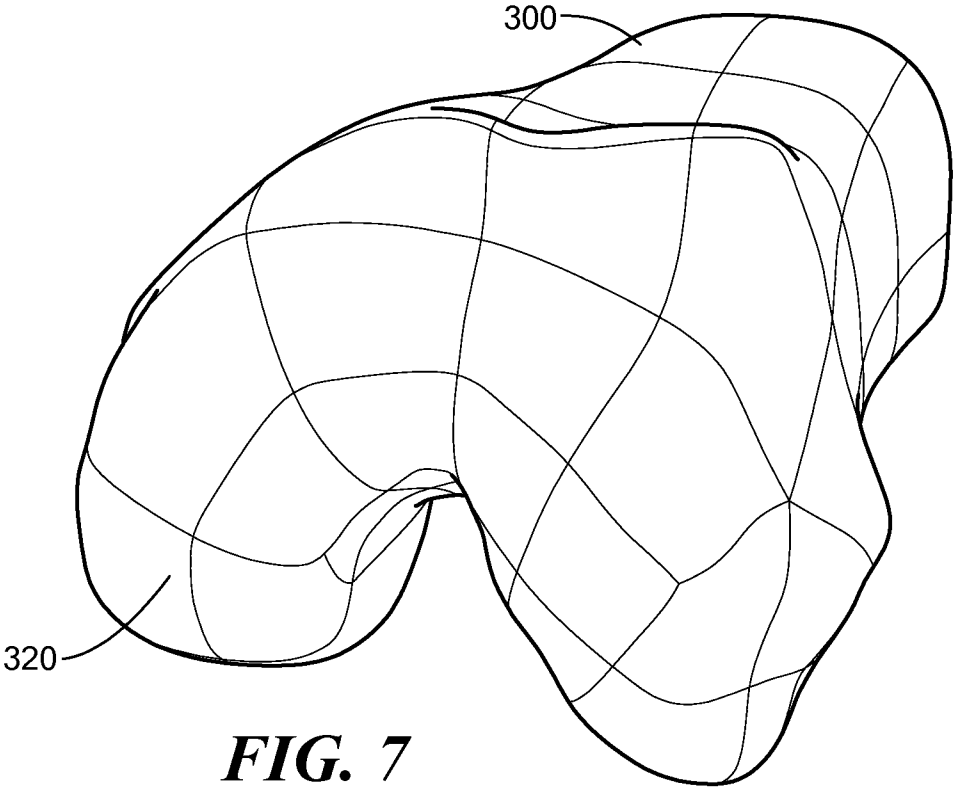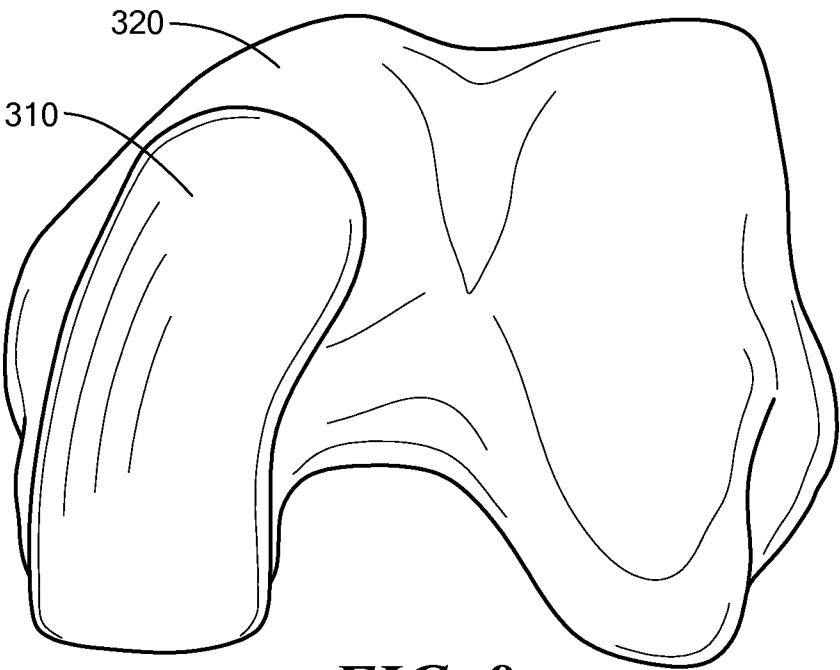
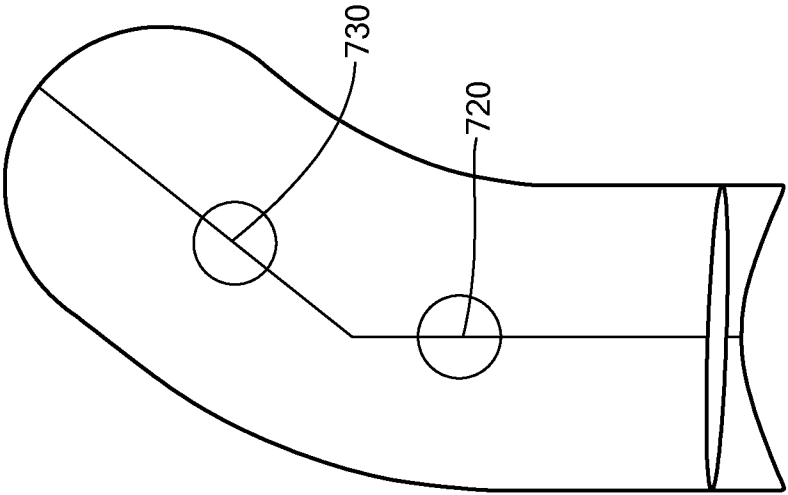**FIG. 8**
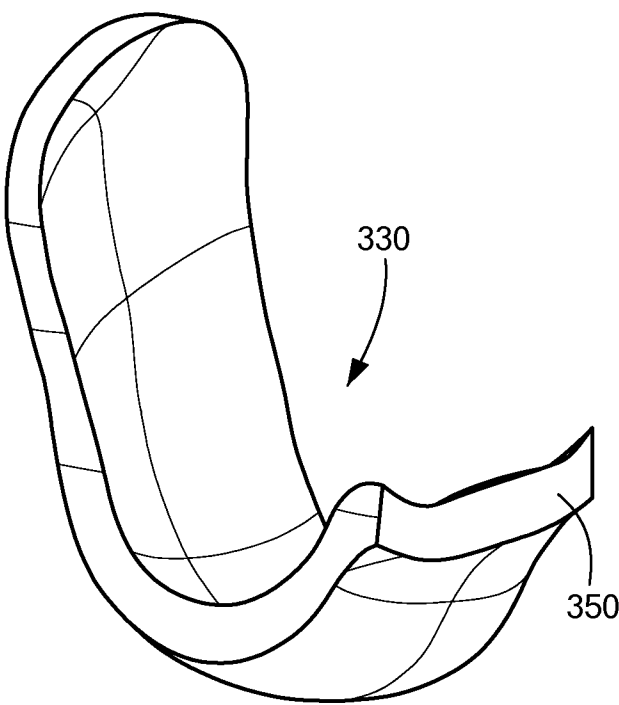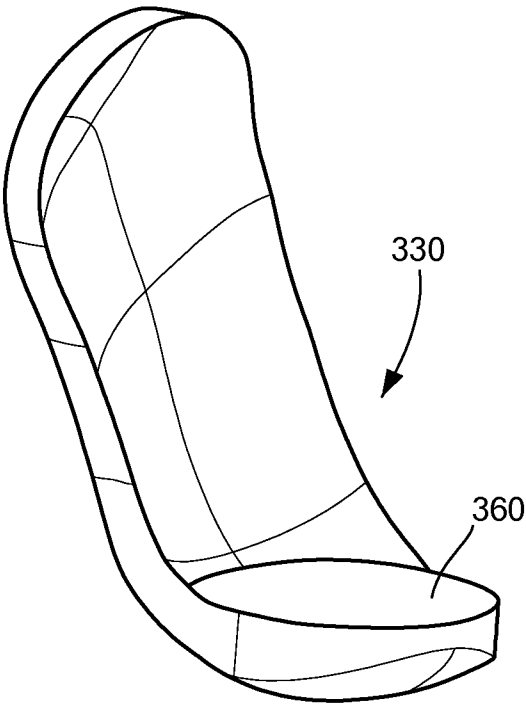
FIG. 9   **FIG. 10**

FIG. 11

FIG. 13

FIG. 12

FIG. 16

FIG. 17

FIG. 18

FIG. 19

FIG. 14

FIG. 15
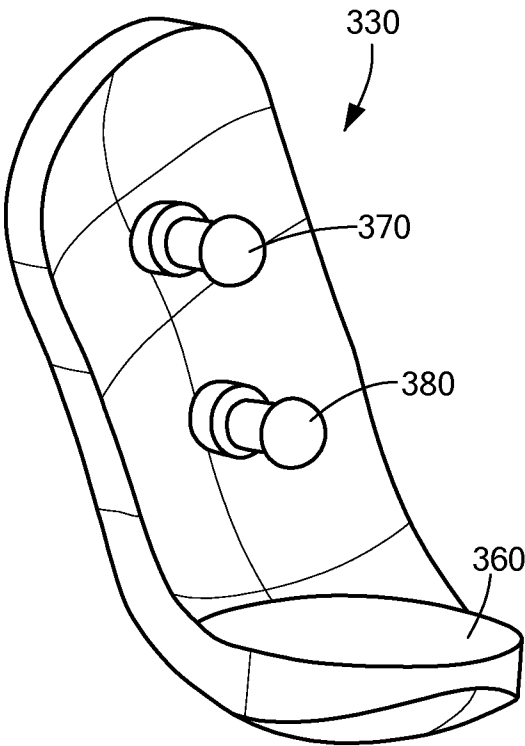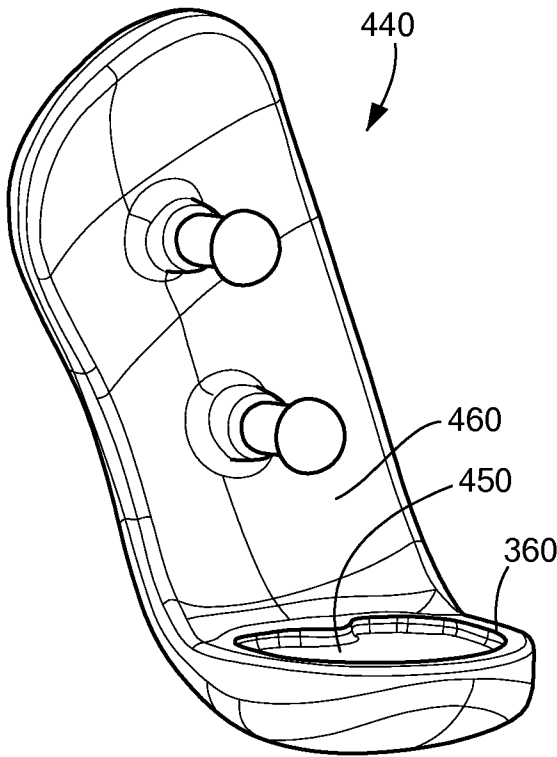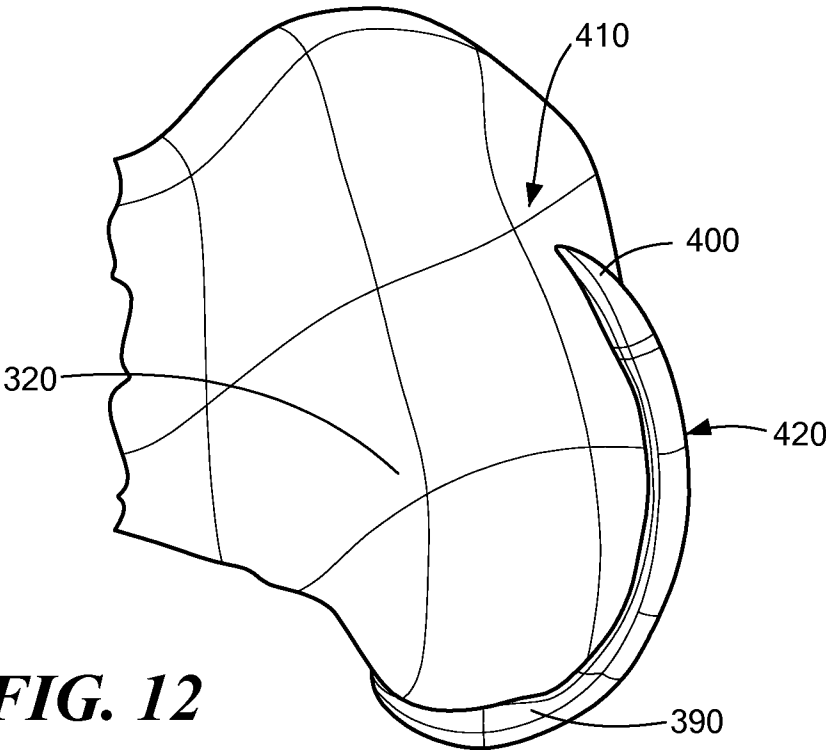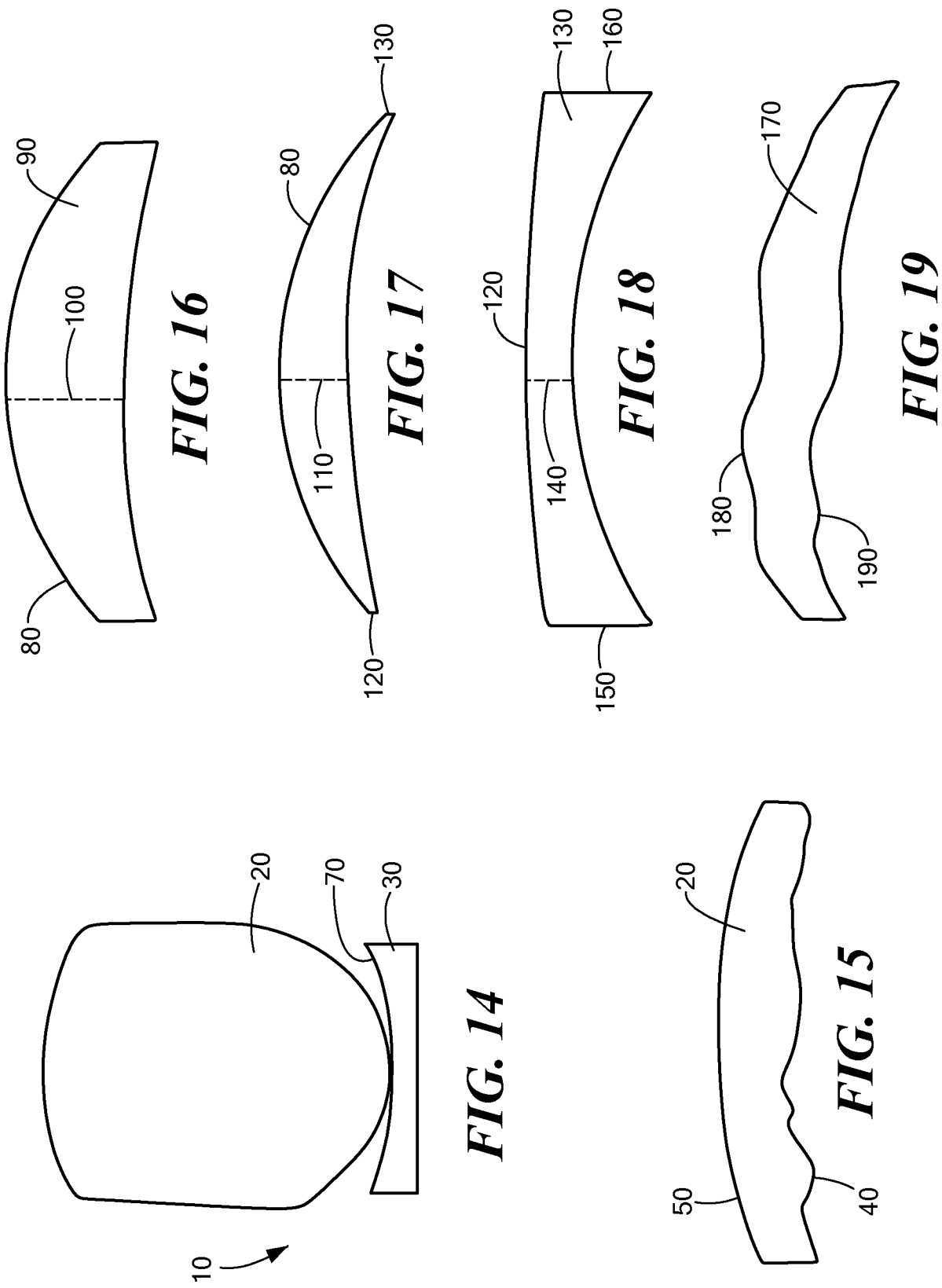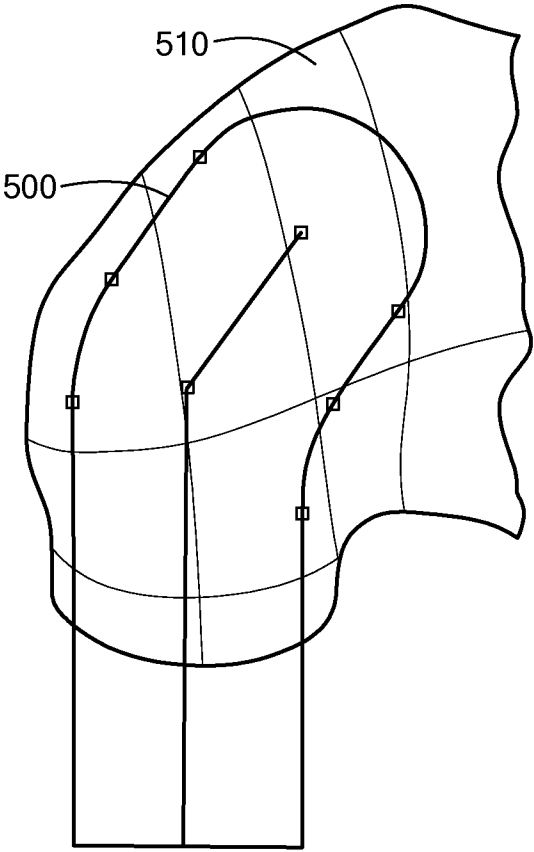
FIG. 20
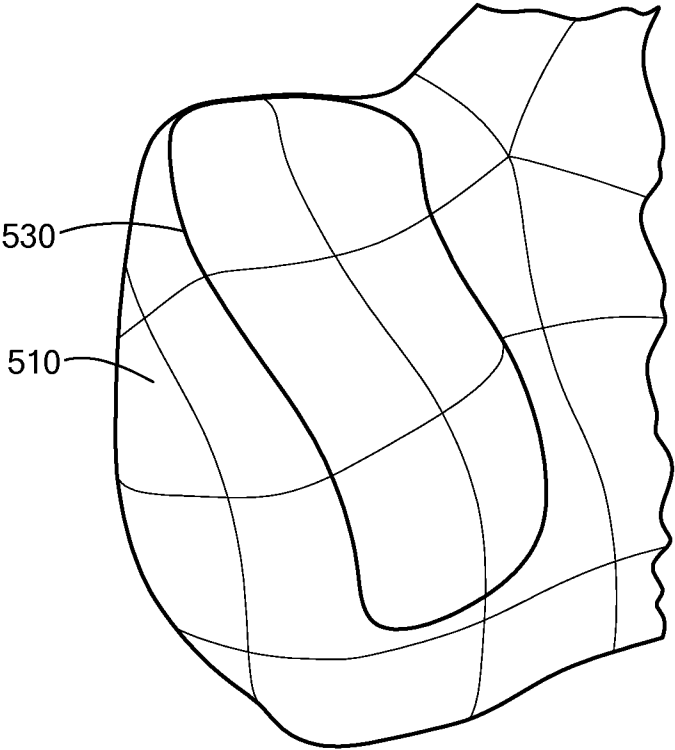
FIG. 21
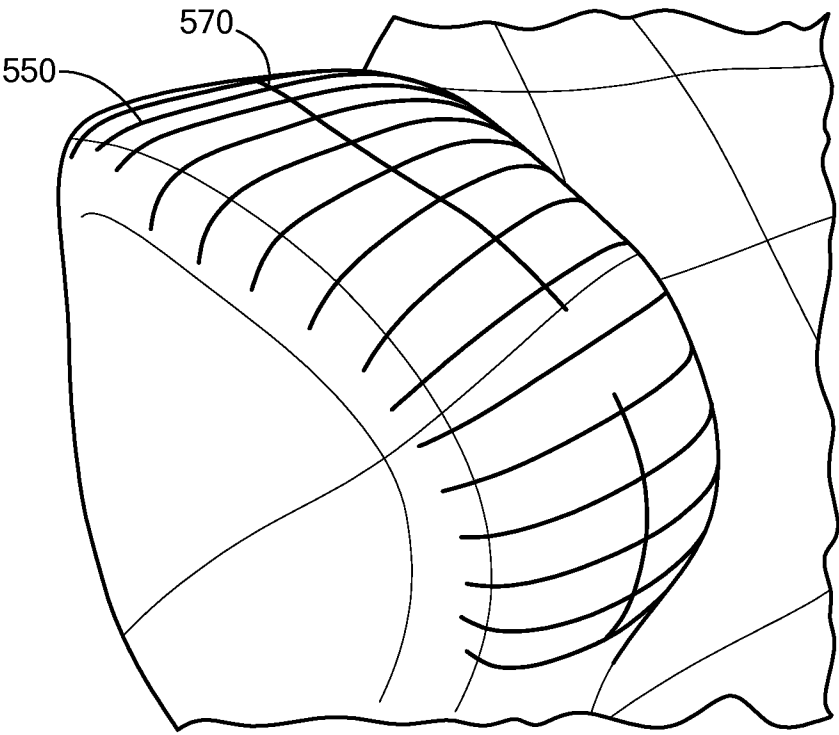
FIG. 22
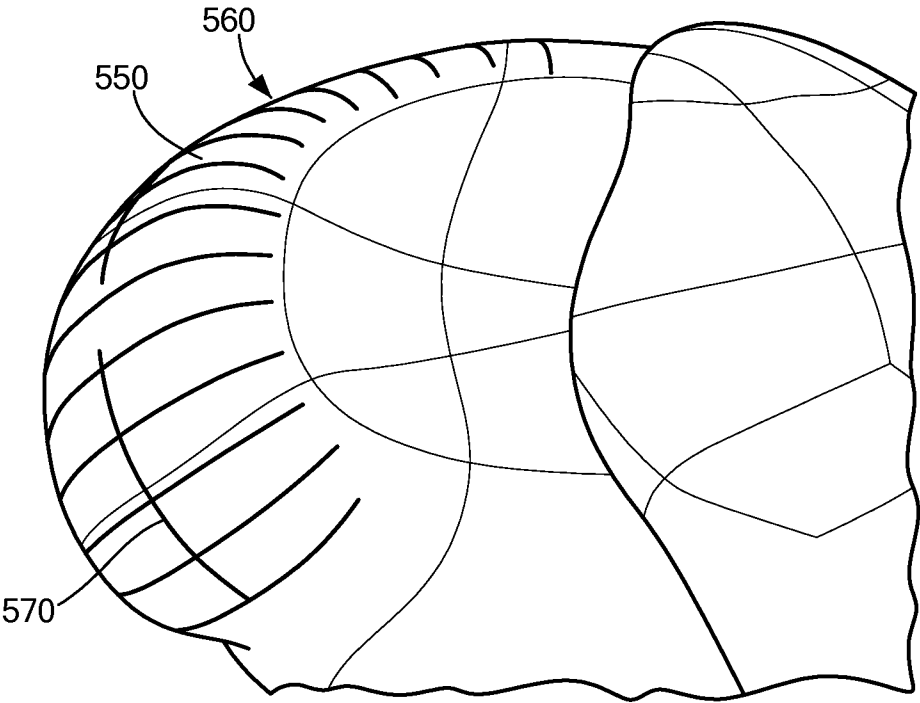
FIG. 23
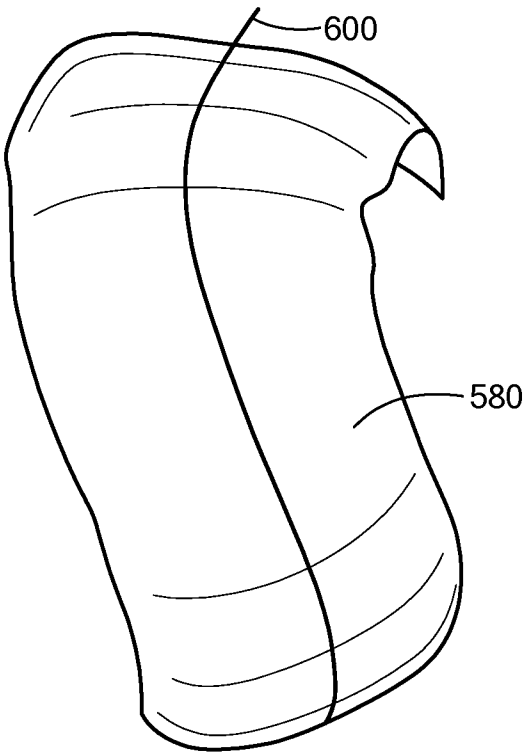
FIG. 24A
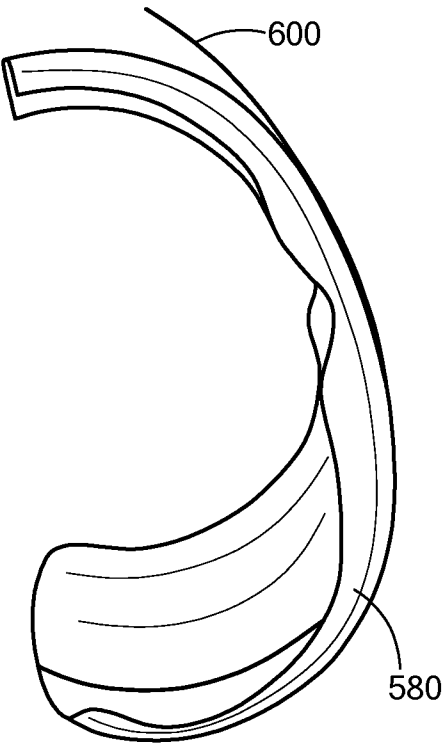
FIG. 24B

FIG. 25

FIG. 26

FIG. 27

FIG. 28

FIG. 31

FIG. 30

FIG. 29