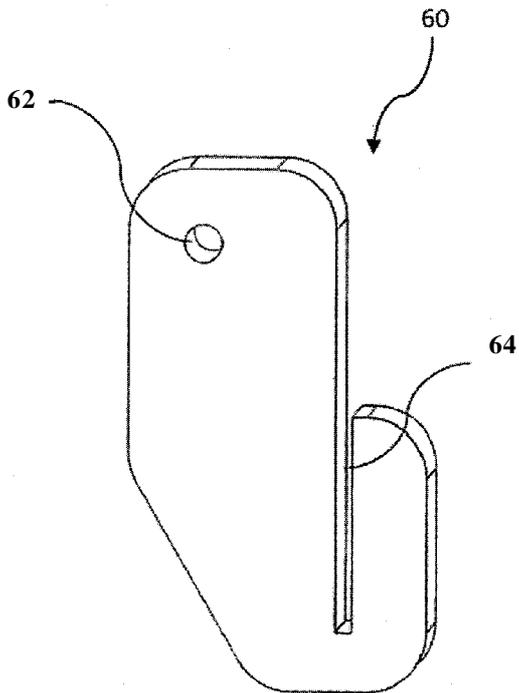




- (51) **International Patent Classification:**
A61F 2/30 (2006.01) A61F 2/38 (2006.01)
A61F 2/28 (2006.01) A61F 2/32 (2006.01)
- (21) **International Application Number:**
PCT/US20 13/041556
- (22) **International Filing Date:**
17 May 2013 (17.05.2013)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
61/648,762 18 May 2012 (18.05.2012) US
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- (81) **Designated States** (*unless otherwise indicated, for every
kind of national protection available*): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP,
KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD,
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI,

[Continued on nextpage]

(54) **Title: DEVICES AND METHODS FOR KNEE ARTHROPLASTY**



(57) **Abstract:** The present invention provides, in certain embodi-
ments, a device for positioning and orienting the femoral cutting
block. The present invention also provides a device for setting rota-
tion of sagittal resection for unicompartmental knee arthroplasty.
The present invention further provides methods for setting the rota-
tion of the tibial implant by kinematic measurements.

FIG. 9



DEVICES AND METHODS FOR KNEE ARTHROPLASTY

INCORPORATION BY REFERENCE TO ANY PRIORITY APPLICATIONS

[0001] Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application are hereby incorporated by reference under 37 CFR 1.57.

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] The present application includes inventions that provide devices and/or methods to assist in the distal femur resection and/or the proximal tibial resection during knee arthroplasty.

Description of the Related Art

[0003] The knee joint often requires replacement in the form of prosthetic components due to strain, stress, wear, deformation, misalignment, and/or other conditions in the joint. Prosthetic knee joint components are designed to replace a distal portion or portions of a femur and/or a proximal portion or portions of a tibia. Prior to replacing the knee joint with prosthetic components, surgical cuts commonly called resections are generally made with a cutting tool or tools along a portion or portions of both the proximal tibia and distal femur. These cuts are made to prepare the tibia and femur for the prosthetic components. After these cuts are made, the prosthetic components can be attached and/or secured to the tibia and femur.

[0004] Resecting a portion or portions of the distal femur can provide a location for placement and/or attachment of a femoral knee joint prosthetic ("distal femoral resection"). The orientation of a cutting block, and/or cutting plane or planes, can be pre-operatively determined in order to provide a desired fit and/or orientation for the femoral knee joint prosthetic. Properly orientating the cutting plane or planes along the distal femur can facilitate alignment of the femoral knee joint prosthetic with the tibial knee joint prosthetic. This alignment can create a set of knee joint prosthetics which function smoothly, continuously, and/or without substantial wear during their life of use.

[0005] Similarly, resecting a portion or portions of the proximal tibia can provide a location for placement and/or attachment of a femoral knee joint prosthetic ("proximal tibial resection"). The orientation of a cutting block, and/or cutting plane or

planes, can be pre-operatively determined in order to provide a desired fit and/or orientation for the tibial knee joint prosthetic. Properly orientating the cutting plane or planes along the proximal tibia can facilitate alignment of the tibial knee joint prosthetic with the femoral knee joint prosthetic. This alignment can create a set of knee joint prosthetics which function smoothly, continuously, and/or without substantial wear during their life of use.

[0006] Joint replacement procedures described above often use a system or systems of surgical tools and devices, including but not limited to cutting guides (e.g. cutting blocks) and surgical guides, to make surgical cuts along a portion or portions of the patient's bone. Current systems and methods often use expensive, complex, bulky, and/or massive computer navigation systems which require a computer or computers, as well as three dimensional imaging, to track a spatial location and/or movement of a surgical instrument or landmark in the human body. These systems are used generally to assist a user to determine where in space a tool or landmark is located, and often require extensive training, cost, and room.

[0007] Where such complex and costly system are not used, simple methods are used, such "eyeballing" the alignment of rods with anatomical features, such as leg bones. These simple methods are not sufficiently accurate to reliably align and place implant components and the bones to which such components are attached.

[0008] Accordingly, there is a lack of devices, systems and methods that can be used to accurately position components of prosthetic joints without overly complicating the procedures, crowding the medical personnel, and/or burdening the physician of health-care facility with the great cost of complex navigation systems.

[0009] During conventional knee arthroplasty, the surgeon often visually aligns the various components required for the femoral and tibial implants.

SUMMARY OF THE INVENTION

[0010] In one embodiment, a system is provided for cutting a tibia of a leg of a patient in a uni-condylar procedure. The system includes a guide pin and a sagittal saw guide. The guide pin has a first end configured to be embedded in a distal aspect of a femur and a second end configured to protrude from the femur when the first end is so placed. The sagittal saw guide has a first portion configured to couple with the second portion of the guide pin and a second portion comprising a saw registration feature.

Wherein when the first portion of the sagittal saw guide is coupled with the second portion of the guide pin, the second portion of the sagittal saw guide projects distally away from the guide pin to position the saw registration feature over the tibia in a generally sagittal plane.

[0011] In another embodiment, a method of cutting a tibia of a leg of a patient in a uni-condylar procedure is provided. The mechanical axis of a femur is located based on output from at least one inertial sensor coupled with the leg. A pin is placed in the femur at an orientation corresponding to the mechanical axis of the femur based on output from at least one inertial sensor. A sagittal saw guide is coupled with the pin such that a saw registration feature is disposed over the tibia in a generally sagittal plane. The tibia is resected along the saw registration feature. Whereby the sagittal resection is made based on the orientation of the mechanical axis of the femur.

[0012] In another embodiment, a system for preparing a femur for a femoral cutting block is provided. The system includes a first guide and a second guide. The first guide has a first portion configured to contact a posterior condyle surface and a second portion extending away from the first portion. The second portion is configured to be disposed adjacent to a resected distal femoral surface. The second portion has a drill guide feature spaced from the first portion a distance to provide a mounting position for a femoral cutting block. The second guide has a first portion having a spike member and a second portion extending away from the first portion. The second portion comprises a drill guide feature. The second guide has a linear structure configured to be aligned with a tibial plateau. Whereby the system enables the formation of a plurality of holes for mounting a femoral cutting block to the femur.

[0013] In another embodiment, a method of preparing a femur for a femoral cutting block is provided. Resection planes are formed on a distal portion of a femur and a proximal portion of a tibia. A first portion of a first guide is contacted with a posterior condyle of the femur. A second portion of the first guide is positioned over the resection plane of the femur. A first hole is formed in the femur extending superiorly (e.g., toward the hip joint) from the resection plane of the femur through the second portion of the first guide. A first portion of a second guide is coupled with the first hole. A second portion of the second guide is positioned such that a feature of the second guide is aligned with the resection plane of the tibia. A second hole is formed in the femur extending superiorly

(e.g., toward the hip joint) from the resection plane of the femur through the second portion of the second guide.

[0014] In another embodiment, a system is provided for setting tibial implant rotation. The system includes at least one orientation device and a plurality of tibial trial components. The orientation device(s) is or are configured to be coupled with one or both of a femur and a tibia. Each of the tibial trial components of the plurality is configured to be placed between the tibia and the femur. The system also includes a processor configured to perform one or more of the following functions:

[0015] (i) gathering measurements from one or more inertial sensors of the orientation device(s);

[0016] (ii) performing calculations to convert the measurements from the inertial sensors to tibio-femoral kinematic information;

[0017] (iii) comparing the tibio-femoral kinematic information to target values of tibio-femoral kinematics; and

[0018] (iv) transmitting user output corresponding to one or both of the tibio-femoral kinematic information and the target values.

[0019] In another embodiment, a method for setting tibial implant rotation is provided. In the method, at least one inertial sensor is coupled with at least one of a tibia and a femur of a leg of a patient. An implant is positioned on a resected surface of the tibia of the patient. The leg is moved to position the tibia in a plurality of positions differing in flexion, axial rotation, and/or varus-valgus relative to the femur. Values based on output of the sensors indicative of tibio-femoral kinematics are compared with tibio-femoral kinematic target values for one or more of flexion, axial rotation, and/or varus-valgus.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. 1 shows a perspective view of an anterior-posterior positioning guide of one embodiment of the present invention;

[0021] FIG. 2 shows a perspective view of a human femur;

[0022] FIG. 3 shows a perspective view of the positioning guide shown in FIG. 1 attached to the femur shown in FIG. 2, with a tibia in an anatomically correct relative location;

[0023] FIG. 4 shows a perspective view of a drill guide of one embodiment of the present invention;

[0024] FIG. 5 shows a perspective view the drill guide shown in FIG 4 positioned on the femur and tibia shown in FIG. 3;

[0025] FIG. 6 shows a perspective view of a reference device of one embodiment of the present invention;

[0026] FIG. 7 shows a perspective view of a femur, tibia, and a guide pin of one embodiment of the present invention;

[0027] FIG. 8 shows a front view of a surgical orientation device of one embodiment of the present invention;

[0028] FIG. 9 shows a front view of a cutting block of one embodiment of the present invention; and

[0029] FIG. 10 shows a top view of a tibia including contact point lines.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0030] To overcome the problems described above, the certain embodiments of the present invention include devices and/or methods to assist in distal femur resection and proximal tibial resection during knee arthroplasty.

1. Devices for positioning and orienting femoral cutting block

[0031] The rotation of the femoral implant in total knee arthroplasty (TKA) is set by the placement of the 4-in-1 femoral cutting block, a standard component of the knee system's instrument set. This cutting block is used to guide the creation of the anterior, posterior, anterior chamfer, and posterior chamfer resections. The cutting block usually includes either two fixed spikes, or two holes for bone pins, which are used to secure it to the femur after the distal resection has been completed. Drilling or marking two holes for

these features orient and locate the cutting block. The locations of these holes are typically defined by a drill guide device which the surgeon visually aligns with anatomical landmarks on the femur, but which does not account for the mechanical alignment of the femur with the tibia. A drill guide that references the tibia may improve implant function.

[0032] Following completion of the tibial resection 41 and the distal femoral resection 22, an AP (anterior-posterior) positioning guide 10 is placed on the distal surface 22 of the femur 20. Referring to FIGS. 1-3, this instrument includes a paddle 12 to reference either the medial or the lateral posterior condyle 24, and a hole 14 to position a drill at a fixed distance anterior to the paddle 12. The distance from the paddle 12 to the hole 14 is determined by the implant system's 4-in-1 cutting block dimensions: The distance is equal to the distance from the posterior cutting slot to the cutting block spike, plus the posterior thickness of the femoral implant. The surgeon drills a hole in the femur 20 through the AP positioning guide 10.

[0033] Now referring to FIGS. 4-5, a spike 32 on one end of a drill guide 30 is placed in the hole in the distal femur 22. The drill guide 30 is rotated around the spike 32 until its edge 36 is parallel to the tibial resection 41, then a second hole is drilled into the femur 20 through the hole 34 in the drill guide 30. The drill guide 30 is configured to space the two holes at the correct distance to accommodate the 4-in-1 cutting block's mounting pins.

[0034] Preferably, the technique described would include the use of some commonly-used tensioning instrument (e.g., laminar spreader) to hold the femur 20 in the correct rotational alignment with the tibia 40 while aligning the drill guide 30 with the tibial resection 41.

2. Devices for setting rotation of sagittal resection for UKA tibial implant

[0035] In unicompartmental knee arthroplasty (UKA), the tibial implant replaces only the (usually) medial compartment of the tibia. Accordingly, two tibial resections are performed, one in a transverse plane, and one in a sagittal plane. This sagittal resection both defines the medial-lateral position of the implant, and sets the rotation of the implant relative to the tibia. The rotation of this sagittal resection is typically visually aligned according to surgeon preference and experience. This visual

alignment does not account for the mechanical alignment of the femur with the tibia. A cutting guide that references the femur may improve implant function.

[0036] Referring to FIGS. 6-7, the mechanical axis 28 of the femur 20 is calculated by a reference device 100, which contains accelerometers and gyroscopes to sense its angular orientation and rate, and which is fixed to the femur 20. The reference device 100 incorporates generally the same components and basic measurement functions as described in U.S. Patent No. 8,118,815 for its reference device (e.g., 16), and may be identical to this device. A surgical orientation device 200, such as the device shown in FIG. 8, communicates with the reference device and displays the angle of the surgical orientation device relative to the calculated mechanical axis 28. The surgical orientation device 200 incorporates generally the same components and basic measurement functions as described in U.S. Patent No. 8,118,815 for its surgical orientation device (e.g., 14). U.S. Patent No. 8,118,815 is hereby incorporated by reference in its entirety.

[0037] With reference to FIG. 7, a guide pin 50 is then placed in the distal femur 20, with its axis parallel to the mechanical axis 28 of the femur 20, as determined by the reference device 100. Alternatively, the guide pin 50 may be placed to align its axis toward the femoral head 26. The surgical orientation device 200 may be used to guide placement of the pin 50.

[0038] This guide pin 50 is used to position a cutting block 60, which references the pin 50 by a mating hole 62 in the cutting block 60, and which also includes a cutting slot 64 for the sagittal resection on the tibia 40. The cutting slot 64 guides the saw during resection of the tibia 40.

[0039] Optionally, the cutting block 60 could be configured to allow medial-lateral translation between the guide hole 62 and the cutting slot 64. This would allow the rotation and position of the sagittal resection to be set independently. Also optionally, the cutting block 60 could include a second cutting slot oriented in a transverse plane. This second cutting slot would provide guidance for the saw during resection of the tibia 40 in the transverse plane.

[0040] As an alternative method, the surgical orientation device 200 could be mounted on the cutting block 60 and used to align it relative to the mechanical axis 26 without using the guide pin 50. The surgical orientation device 200 would display real-time orientation to the user during placement and pinning of the cutting block 60. If the

cutting block 60 included a second (transverse) cutting slot as described above, the angular display from the surgical orientation device could also be used to align this second slot relative to the mechanical axis of the tibia 40.

3. Methods for setting the rotation of the tibial implant by kinematic measurements

[0041] The rotation of the tibial implant in TKA is set following completion of the tibial resection. The tibial implant can be rotated in any direction on the resected tibial surface. Final rotation of the implant is typically determined by the surgeon by one or more of three methods: 1) visually maximizing coverage of the resected surface in an attempt to place the implant as nearly as possible on the outer rim of the bone; 2) visually aligning the anterior-posterior (AP) axis of the implant with an anatomic landmark such as the tibial tubercle; 3) allowing the implant to rotate freely, then fixing the tibial implant in the rotational alignment dictated by contact with the femur with the knee in full extension (hereinafter referred to as "traditional methods"). A more precise and/or quantifiable alignment method is likely to improve implant performance and patient satisfaction. The present invention provides, in certain embodiments, such more precise and/or quantifiable alignment methods to improve implant performance and patient satisfaction.

[0042] The present invention provides, in one embodiment, a method for setting the rotation of the tibial implant by kinematic measurements based upon femur-tibia contact points. In this method of the present invention and referring to FIG. 7, the femur 20 contacts the tibia 40 at two points: one medial, and one lateral. As the knee flexes through its range of motion, the location of these contact points on the tibia 40 are recorded. At any instantaneous flexion angle, a line connecting the two contact points can be constructed, as shown in FIG. 10. Lines 42-45 represent the lines connecting the medial and lateral contact points throughout the range of motion, from line 42 at full extension, to line 45 at full flexion. At any flexion angle, a line 46-49 perpendicular to the instantaneous contact point lines 42-45 defines an AP axis that can be used as a reference for tibial component alignment.

[0043] The contact points are identified using one of several art-disclosed methods and devices including, without limitations, (i) pressure-sensitive film (e.g., "Prescale" film manufactured by Fujifilm® Corp.); and (ii) use of knee implant

measurement devices such as those described by D'Lima et al., "Tibial Forces Measured In Vivo After Total Knee Arthroplasty," *Journal of Arthroplasty* p. 255-262 (Vol. 21 No.2 February 2006), which contain load cells able to measure contact forces. Once the contact points and connecting line 42-45 are identified, the AP axis of the tibial component is aligned with any one of the perpendicular AP axes 46-49 chosen according to surgeon preference. Alternatively, an AP axis could be calculated as an average of all axes throughout the range of motion, or could be a weighted average with greater weight given to a specific range of flexion angles.

[0044] The present invention also provides, in one embodiment, a method for setting the rotation of the tibial implant by kinematic measurements based on inertial measurement of tibio-femoral kinematics. In this method of the present invention and referring to FIGS. 6-7, one reference device 100 is securely attached to each of the femur 20 and tibia 40. The reference device 100 attached to the femur 20 is aligned approximately with the femoral mechanical axis 28. The reference devices are preferably mounted in a manner which allows normal function of the patella to reproduce normal knee kinematics. A medialized attachment is preferred on both the tibia 40 and femur 20 to better accommodate the typical surgical exposure. Optionally, the orientation of the mechanical axis 28 is calculated relative to the reference device 100 following the method described in U.S. Patent No. 8,118,815. If desired, this offset angle can be applied to the reference device 100 for greater measurement accuracy.

[0045] In order to establish the characteristics of the knee joint prior to resection, the surgeon brings the knee into full extension and moves the leg through a short arc of motion, pivoting about the femoral head 26 in all directions and rotating about the long axis of the leg. During this motion, the two reference devices 100, stationary relative to each other, perform a "transfer alignment" to calculate the relative misalignment between the two reference devices 100, allowing the orientation of the tibial device to be established in the frame of reference of the femoral device.

[0046] The knee is then taken through a range of motion. Relative rotations between the tibia 40 and femur 20 are measured by comparing the angular changes recorded by their respective reference devices 100 throughout the range of motion. These rotations are resolved into three directions corresponding to the flexion, axial rotation, and varus/valgus directions. The rotations are transmitted to the surgical orientation device

200 as shown in FIG. 8, which graphically displays to the user plots of axial rotation and varus/valgus rotation vs. flexion angle. The surgical orientation device 200 may also display numerical values for the rotation angle at various flexion angles of interest, such as 90 degrees or 120 degrees.

[0047] During trial reduction, the surgeon repeats the above procedure. The surgical orientation device 200 then displays the aforementioned kinematic data graphically and superimposes the trial curves upon the pre-operative curves and/ or calculates the appropriate amount by which the tibial component should be rotated about the tibial axis in order to best approximate the pre-operative curves. An optimization algorithm can be employed for this purpose.

[0048] The surgeon then adjusts the rotational alignment of the tibial implant and repeats the measurements above until the rotations of the tibia 40 relative to the femur 20 match the target rotations. These target rotations may be based on published averages for healthy knees, or on kinematic measurements taken from the same patient prior to resection.

[0049] As an additional optional step, the surgeon applies alternating varus and valgus torque to the knee in order to gauge the tibio-femoral rotation allowed in each direction. This varus or valgus rotation is displayed on the surgical orientation device 200, supplementing the traditional visual estimation of knee laxity in the varus/valgus direction. This rotation information provides a means to quantitatively compare the varus and valgus laxity, towards the traditional goal of balancing the two by means of soft tissue releases. This measurement can be used to quantify the laxity of the knee joint in full extension, 90 degrees flexion or any other angle to which the knee can be flexed.

[0050] The present invention further provides, in one embodiment, a method for setting the rotation of the tibial implant by kinematic measurements using load cells to measure contact forces between the tibial implant and the femoral implant. In this method of the present invention, the trial tibial implant is fitted with load cells able to measure contact forces between the tibial implant and the femoral implant. Such devices have been developed previously, and function similarly to the instrumented implant described by D'Lima et al., "Tibial Forces Measured In Vivo After Total Knee Arthroplasty," *Journal of Arthroplasty* p. 255-262 (Vol. 21 No.2 February 2006).

[0051] This instrumented trial tibial component is fixed to the tibia 40 in a rotation determined by the traditional methods described above. As the knee is taken through a range of motion, the trial component transmits the measured contact forces to a surgical orientation device 200, which stores and displays the force data, either as a peak force number, a force vs. flexion angle history, or both. The surgeon then iteratively adjusts the alignment of the trial tibial component and repeats the force measurement steps. The tibial component alignment that provides the best fit with the soft tissue kinematic envelope will be identified as the configuration that produces the minimum tibio-femoral contact force.

[0052] The present invention also provides, in one embodiment, a method for setting the rotation of the tibial implant by kinematic measurements based upon measurement of tibial interface torque. In this method of the present invention, the trial tibial implant is fitted with a torque transducer able to measure axial torque between the tibial articular surface and the tibia 40. Such devices have been previously demonstrated, such as the instrumented implants described by Heinlein et al. in the Journal of Biomechanics (Vol. 41 No. 10). For the purposes of the present invention, the torque is measured around an axis approximately parallel to the long axis of the tibia 40. This instrumented trial tibial component is fixed to the tibia 40 in a rotation determined by the traditional methods described above. As the knee is taken through a range of motion, the trial component transmits the measured torque to a surgical orientation device 200, which stores and displays the torque data, either as a peak torque number, a torque vs. flexion angle history, or both. The surgeon then iteratively adjusts the alignment of the trial tibial component and repeats the torque measurement steps. The tibial component alignment that provides the best fit with the soft tissue kinematic envelope will be identified as the configuration that produces the minimum axial torque.

[0053] Many other variations than those described herein and/or incorporated by reference will be apparent from this disclosure. For example, depending on the embodiment, certain acts, events, or functions of any of the algorithms described herein can be performed in a different sequence, can be added, merged, or left out altogether (e.g., not all described acts or events are necessary for the practice of the algorithms). Moreover, in certain embodiments, acts or events can be performed concurrently, e.g., through multi-threaded processing, interrupt processing, or multiple processors or

processor cores or on other parallel architectures, rather than sequentially. In addition, different tasks or processes can be performed by different machines and/or computing systems that can function together.

[0054] The various illustrative logical blocks, modules, and algorithm steps described in connection with the embodiments disclosed herein or incorporated herein by reference can be implemented as electronic hardware, computer software, or combinations of both. To clearly illustrate this interchangeability of hardware and software, various illustrative components, blocks, modules, and steps have been described above generally in terms of their functionality. Whether such functionality is implemented as hardware or software depends upon the particular application and design constraints imposed on the overall system. The described or incorporated functionality can be implemented in varying ways for each particular application, but such implementation decisions should not be interpreted as causing a departure from the scope of the disclosure.

[0055] The various illustrative logical blocks and modules described in connection with the embodiments disclosed herein or incorporated by reference can be implemented or performed by a machine, such as a general purpose processor, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field programmable gate array (FPGA) or other programmable logic device, discrete gate or transistor logic, discrete hardware components, or any combination thereof designed to perform the functions described herein. A general purpose processor can be a microprocessor, but in the alternative, the processor can be a controller, microcontroller, or state machine, combinations of the same, or the like. A processor can also be implemented as a combination of computing devices, e.g., a combination of a DSP and a microprocessor, a plurality of microprocessors, one or more microprocessors in conjunction with a DSP core, or any other such configuration. Although described herein primarily with respect to digital technology, a processor may also include primarily analog components. For example, any of the signal processing algorithms described herein may be implemented in analog circuitry. A computing environment can include any type of computer system, including, but not limited to, a computer system based on a microprocessor, a mainframe computer, a digital signal processor, a portable computing device, a personal organizer, a device controller, and a computational engine within an appliance, to name a few.

[0056] The steps of a method, process, or algorithm described in connection with the embodiments disclosed herein can be embodied directly in hardware, in a software module executed by a processor, or in a combination of the two. A software module can reside in RAM memory, flash memory, ROM memory, EPROM memory, EEPROM memory, registers, hard disk, a removable disk, a CD-ROM, or any other form of non-transitory computer-readable storage medium, media, or physical computer storage known in the art. An example storage medium can be coupled to the processor such that the processor can read information from, and write information to, the storage medium. In the alternative, the storage medium can be integral to the processor. The processor and the storage medium can reside in an ASIC. The ASIC can reside in a user terminal. In the alternative, the processor and the storage medium can reside as discrete components in a user terminal.

[0057] Conditional language used herein, such as, among others, "can," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment. The terms "comprising," "including," "having," and the like are synonymous and are used inclusively, in an open-ended fashion, and do not exclude additional elements, features, acts, operations, and so forth. Also, the term "or" is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term "or" means one, some, or all of the elements in the list. Further, the term "each," as used herein, in addition to having its ordinary meaning, can mean any subset of a set of elements to which the term "each" is applied.

[0058] While the above detailed description has shown, described, and pointed out novel features as applied to various embodiments, it will be understood that various omissions, substitutions, and changes in the form and details of the devices or algorithms illustrated can be made without departing from the spirit of the disclosure. As will be

recognized, certain embodiments of the inventions described herein can be embodied within a form that does not provide all of the features and benefits set forth herein, as some features can be used or practiced separately from others.

WHAT IS CLAIMED IS:

1. A system for cutting a tibia of a leg of a patient in a uni-condylar procedure, comprising:

a guide pin having a first end configured to be embedded in a distal aspect of a femur and a second end configured to protrude from the femur when the first end is so placed; and

a sagittal saw guide having a first portion configured to couple with the second portion of the guide pin and a second portion comprising a saw registration feature,

wherein when the first portion of the sagittal saw guide is coupled with the second portion of the guide pin, the second portion of the sagittal saw guide projects distally away from the guide pin to position the saw registration feature over the tibia in a generally sagittal plane.

2. The system of Claim 1, further comprising an orientation device comprising an inertial sensor, the orientation device configured to couple with the guide pin during placement of the guide pin such that the guide pin can be placed with reference to an axis of the femur.

3. The system of Claim 1, wherein the second portion of the sagittal saw guide is configured to move relative to the first portion to adjust the medial-lateral position of the saw registration feature.

4. A method of cutting a tibia of a leg of a patient in a uni-condylar procedure, comprising:

locating the mechanical axis of a femur based on output from at least one inertial sensor coupled with the leg;

placing a pin in the femur at an orientation corresponding to the mechanical axis of the femur based on output from at least one inertial sensor;

coupling a sagittal saw guide with the pin such that a saw registration feature is disposed over the tibia in a generally sagittal plane; and

resecting the tibia along the saw registration feature;

whereby the sagittal resection is made based on the orientation of the mechanical axis of the femur.

5. The method of Claim 4, wherein coupling the sagittal saw guide includes fixing the position and orientation of a first portion of the sagittal saw guide, and further

comprising adjusting a second portion of the sagittal saw guide relative to the first portion in a direction generally transverse to the sagittal plane, the second portion of the saw guide including the saw registration feature.

6. A system for preparing a femur for a femoral cutting block, comprising:
a first guide having a first portion configured to contact a posterior condyle surface and a second portion extending away from the first portion configured to be disposed adjacent to a resected distal femoral surface, the second portion having a drill guide feature spaced from the first portion a distance to provide a mounting position for a femoral cutting block;

a second guide having a first portion having a spike member and a second portion extending away from the first portion, the second portion comprising a drill guide feature, the second guide having a linear structure configured to be aligned with a tibial plateau;

whereby the system enables the formation of a plurality of holes for mounting a femoral cutting block to a femur.

7. The system of Claim 6, further comprising a tensioner configured to be placed between the femur and the tibia to adjust the rotation of one or both of the femur and the tibia

8. A method of preparing a femur for a femoral cutting block, comprising:
forming resection planes on a distal portion of a femur and a proximal portion of a tibia;

contacting a first portion of a first guide with a posterior condyle of the femur;

positioning a second portion of the first guide over the resection plane of the femur;

forming a first hole extending superiorly from the resection plane of the femur through the second portion of the first guide;

coupling a first portion of a second guide with the first hole;

positioning a second portion of the second guide such that a feature of the second guide is aligned with the resection plane of the tibia; and

forming a second hole extending superiorly from the resection plane of the femur through the second portion of the second guide.

9. The method of Claim 8, further comprising positioning a tensioner between the femur and the tibia and actuating the tensioner to rotationally align the femur with the tibia prior to positioning the second portion of the second guide such that the feature of the second guide is aligned with the resection plane of the tibia.

10. The method of Claim 8, further comprising locating the mechanical axis of the femur, tibia, or leg using inertial sensors prior to forming at least one of the resection planes on the femur and tibia with reference to the mechanical axis.

11. A system for setting tibial implant rotation, comprising:

at least one orientation device configured to be coupled with one or both of a femur and a tibia;

a plurality of tibial trial components configured to be placed between the tibia and the femur; and

a processor configured to perform one or more of the following functions:

(i) gathering measurements from one or more inertial sensors of the orientation device(s);

(ii) performing calculations to convert the measurements from the inertial sensors to tibio-femoral kinematic information;

(iii) comparing the tibio-femoral kinematic information to target values of tibio-femoral kinematics; and

(iv) transmitting user output corresponding to one or both of the tibio-femoral kinematic information and the target values.

12. A method for setting tibial implant rotation, comprising:

(a) coupling at least one inertial sensor with at least one of a tibia and a femur of a leg of a patient;

(b) positioning an implant on a resected surface of the tibia of the patient;

(c) moving the leg to position the tibia in a plurality of positions differing in flexion, axial rotation, and/or varus-valgus relative to the femur; and

(d) comparing values based on output of the sensors indicative of tibio-femoral kinematics with tibio-femoral kinematic target values for one or more of flexion, axial rotation, and/or varus-valgus.

13. The method of Claim 12, wherein comparing further comprises comparing values based on output of the sensors with a model of values for a healthy knee.

14. The method of Claim 12, wherein comparing further comprises comparing values based on output of the sensors with one or more patient-specific values.

15. The method of Claim 14, further comprising recording patient-specific values of tibio-femoral kinematics of the knee prior to resecting the tibia.

16. The method of Claim 14, further comprising recording patient-specific values of tibio-femoral kinematics of a contralateral knee prior to resecting the tibia.

17. The method of Claim 12, further comprising adjusting the rotation of the knee and repeating steps (c)-(d).

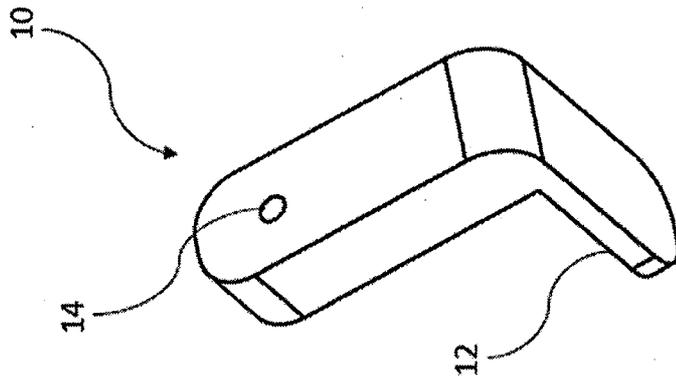


FIG. 1

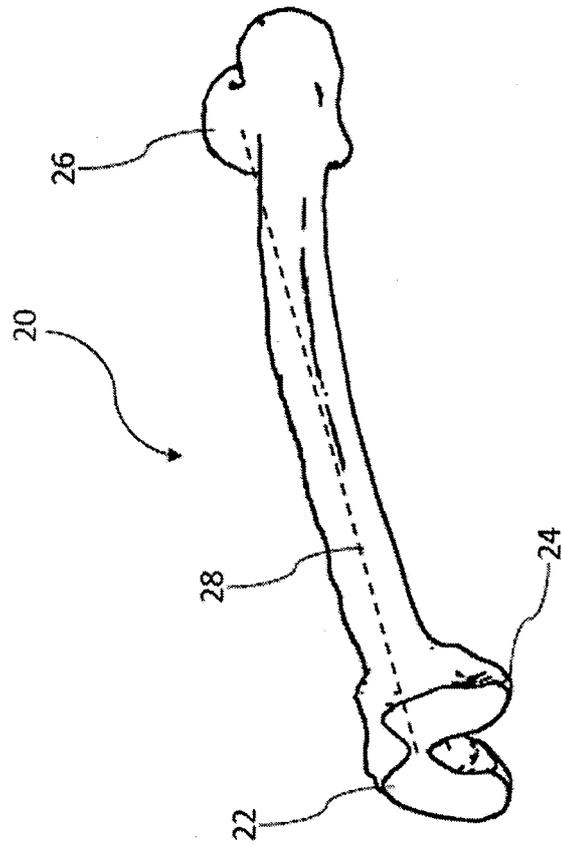


FIG. 2

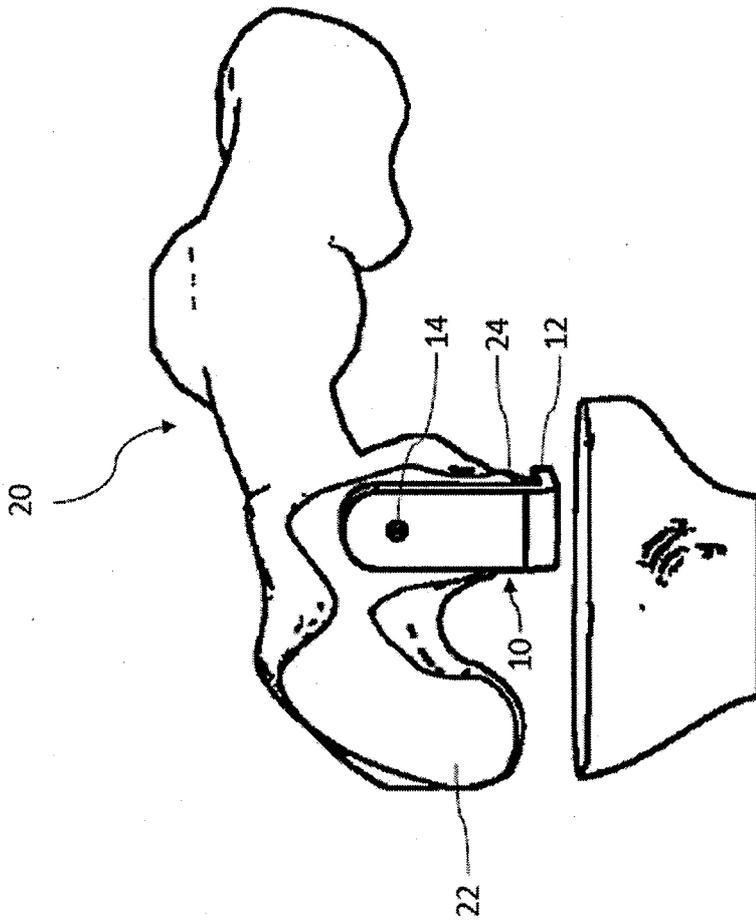


FIG. 3

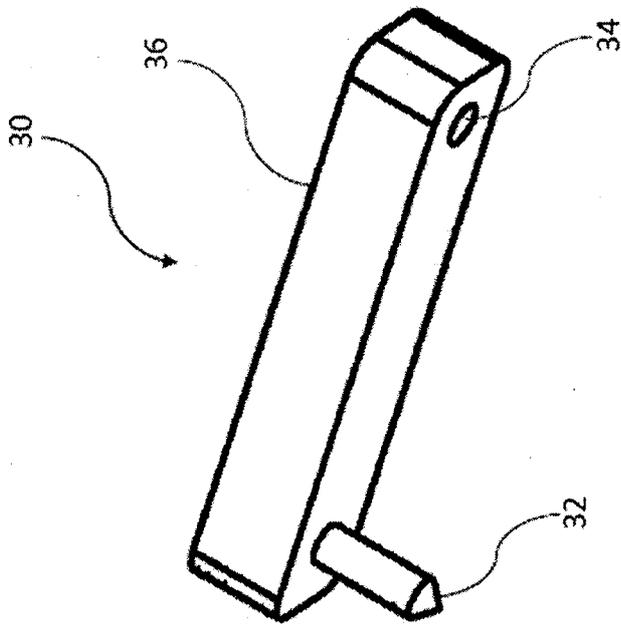


FIG. 4

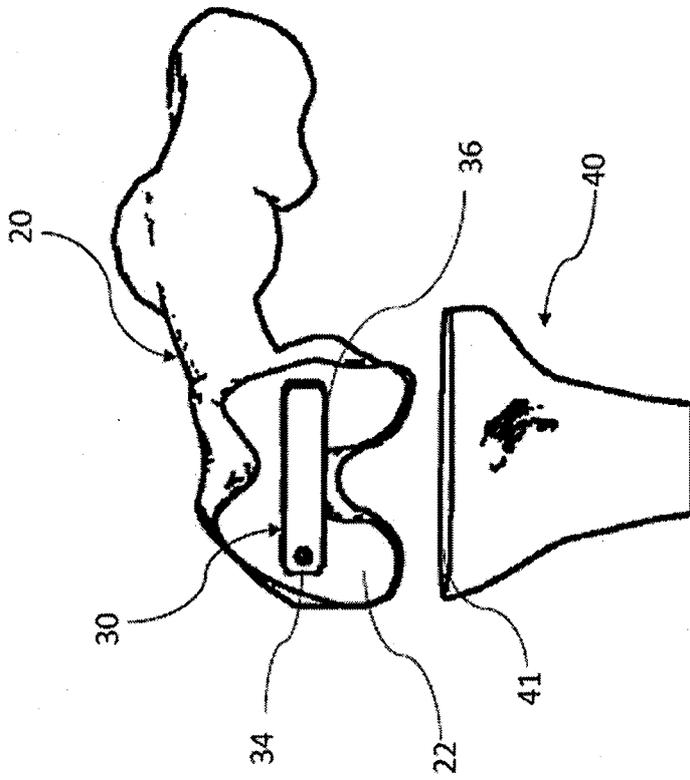


FIG. 5

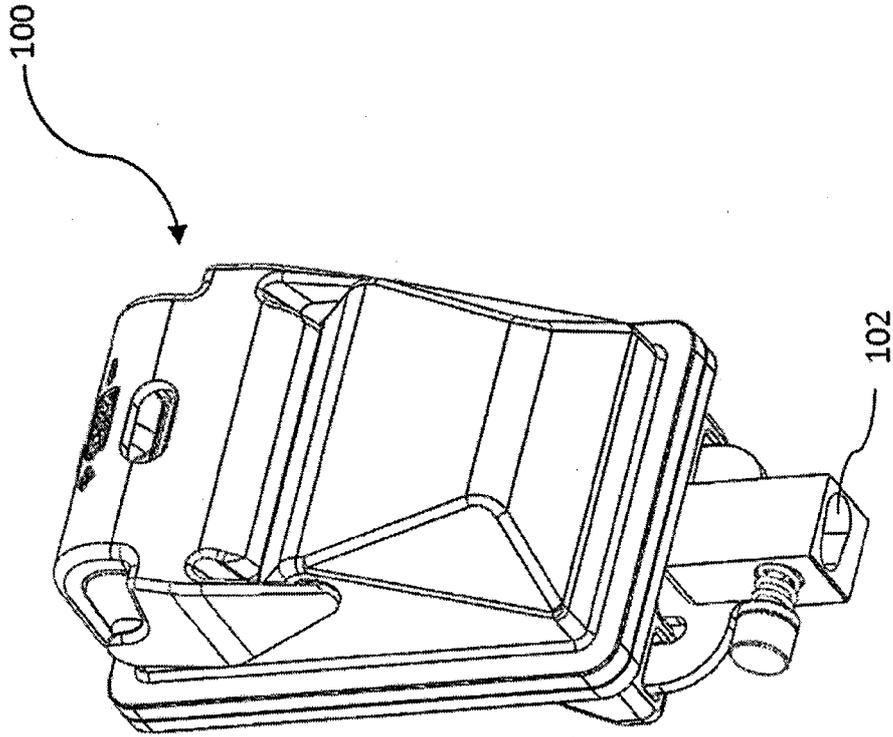


FIG. 6

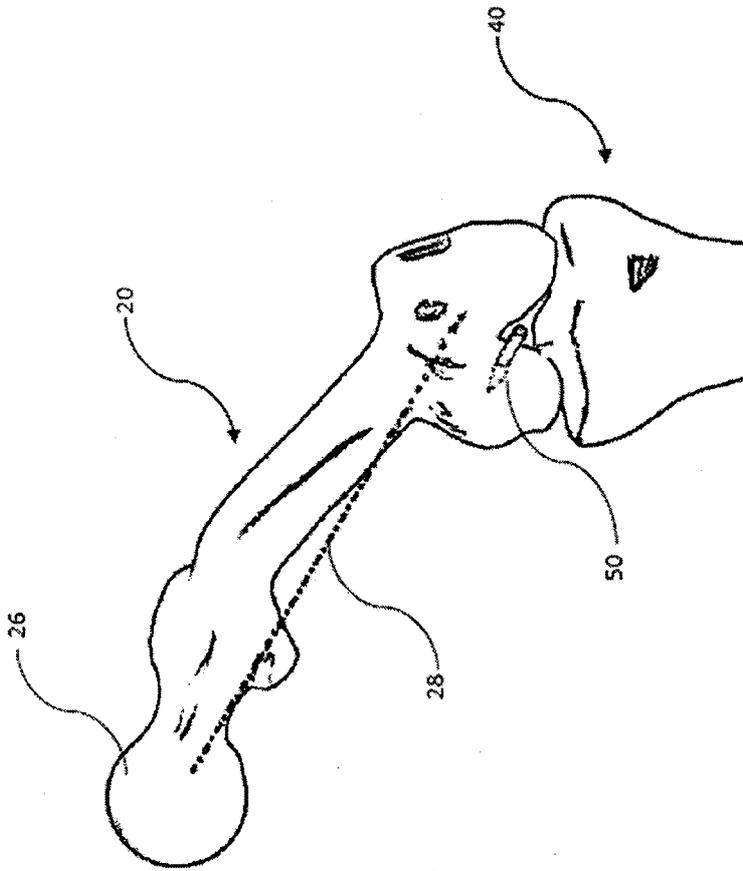


FIG. 7

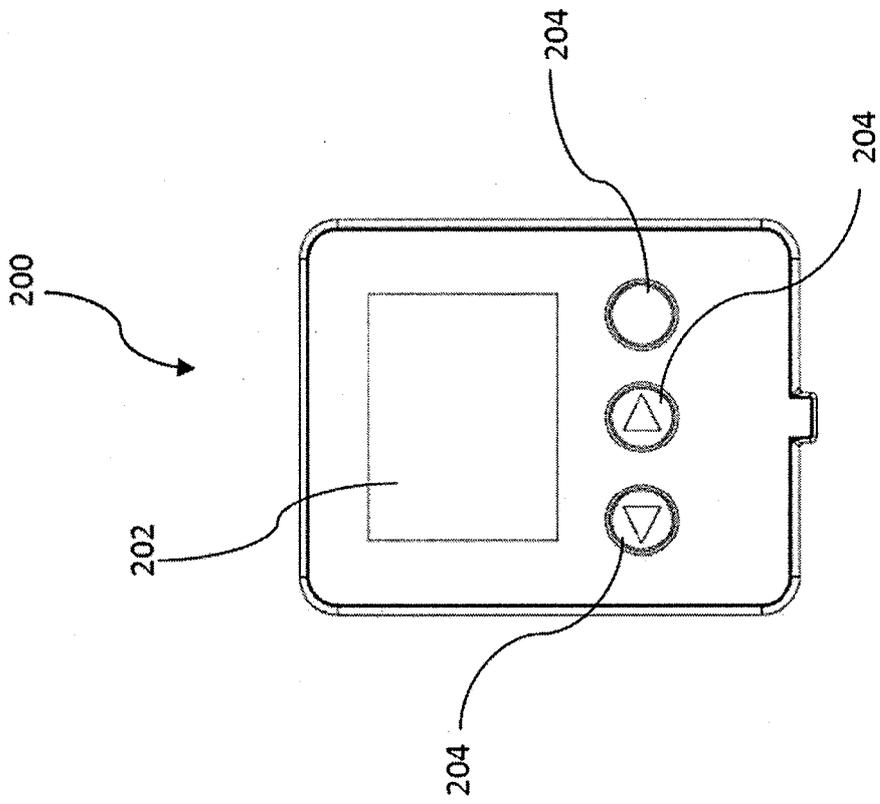


FIG. 8

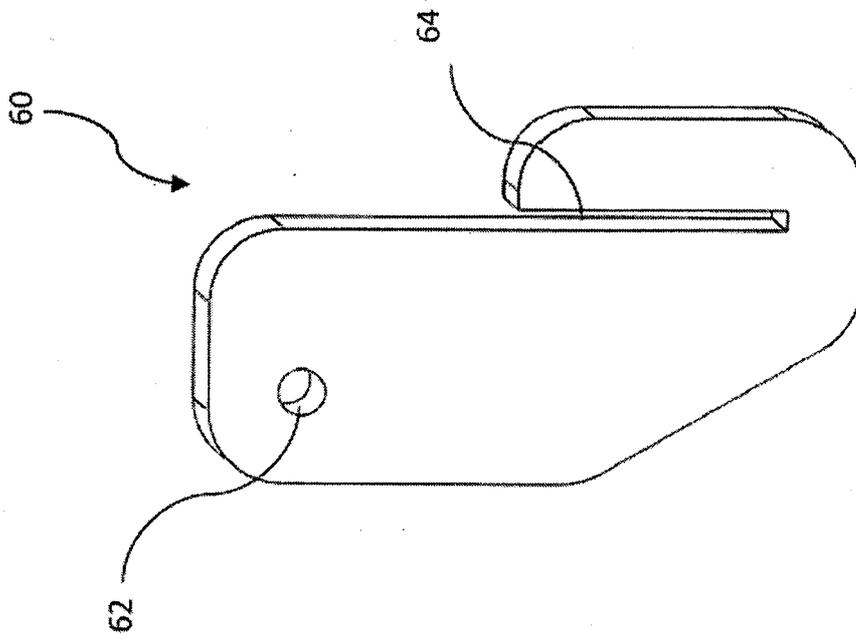


FIG. 9

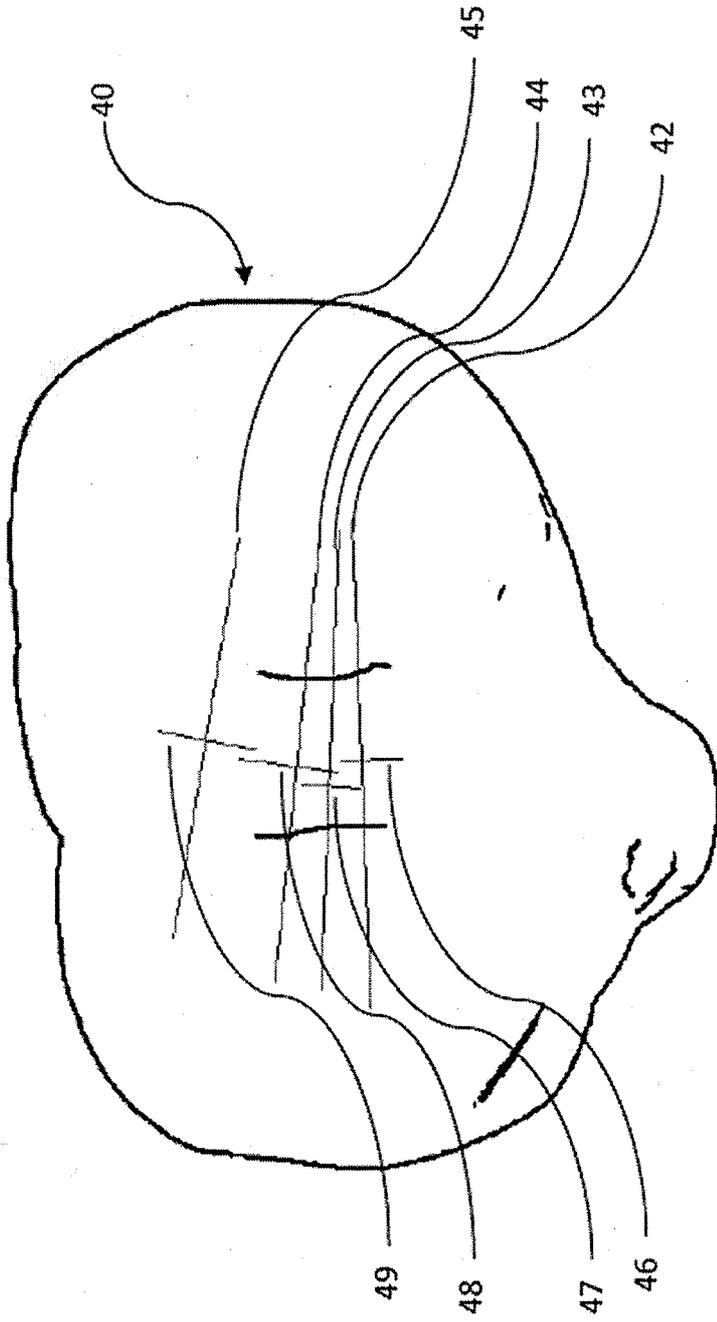


FIG. 10

A. CLASSIFICATION OF SUBJECT MATTER**A61F 2/30(2006.01)i, A61F 2/28(2006.01)i, A61F 2/38(2006.01)i, A61F 2/32(2006.01)i**

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F 2/30; A61B 19/00; A61B 17/00; A61F 5/00; A61B 17/58; A61B 17/15; A61B 17/56; A61F 2/28; A61F 2/38; A61F 2/32

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & Keywords; tibia, femur, cut, saw, resect, guid, pin, orientation, inertial

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009-0088753 AI (ARAM, L. J. et al.) 02 April 2009 See abstract ; figure 39; paragraphs [0327] - [0328] ; and claims 20, 31.	1,3
Y		2
A		6,7,11
Y	US 2009-0248044 AI (AMIOT, L. et al.) 01 October 2009 See abstract ; figures 15-17 ; and claim 1.	2
A	US 2005-0209605 AI (JAMES, G. et al.) 22 September 2005 See abstract ; figures 1-3 ; paragraph [0022] ; and claim 1.	1-3 ,6,7,11
A	US 2006-0217734 AI (SANFORD, A. H. et al.) 28 September 2006 See abstract ; figure 5; paragraph [0024] ; and claim 1.	1-3 ,6,7,11
A	US 5683398 A (CARLS, T. A. et al.) 04 November 1997 See abstract ; figure 1; column 5, lines 16-27 ; and claim 1.	1-3 ,6,7,11
A	US 2011-0218543 AI (VAN DER WALT, N.) 08 September 2011 See abstract ; figure 8A; paragraph [0093] ; and claim 1.	1-3 ,6,7,11

I Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

13 September 2013 (13.09.2013)

Date of mailing of the international search report

13 September 2013 (13.09.2013)

Name and mailing address of the ISA/KR


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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 4-5, 8-10, 12-17
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 4-5, 8-10 and 12-17 pertain to methods for treatment of the human body, as well as diagnostic methods, and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the regulations under the PCT, to search.
2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2013/041556

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