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ACTIVE ROBOTIC PIN PLACEMENT IN TOTAL KNEE ARTHROPLASTY

Abstract

A surgical device is provided includes a hand-held portion with a working portion movably coupled to the hand-held portion for driving a tool. Actuators are provided for moving the working portion with each of the actuators having a travel range. An indicator notices a user when at least one of actuators is: (i) within the travel range; (ii) approaching a travel limit of the travel range; or (iii) outside the travel range. A surgical system is also provided inclusive the surgical device and a computing system configured to activate the indicator.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATIONS [0001] This application claim is a continuation of U.S. application Ser. No. 17/850,133, filed Jun. 27, 2022; that in turn is a continuation of U.S. application Ser. No. 15/778,811, filed May 24, 2018, now U.S. Pat. No. 11,457,980 B2, issued Oct. 4, 2022; that in turn is a US National Phase Application of Serial Number PCT/US2016/062020, filed Nov. 15, 2016; which claims priority to U.S. Provisional Application Ser. No. 62/349,562, filed Jun. 13, 2016 and U.S. Provisional Application Ser. No. 62/259,487, filed Nov. 24, 2015; the contents of which are hereby incorporated by reference in their entirety.

FIELD OF THE INVENTION
[0002] The present invention generally relates to computer assisted surgery, and more specifically to systems and methods for actively aligning cut guides for total knee arthroplasty.
BACKGROUND
[0003] Total knee arthroplasty (TKA) is a surgical procedure in which the articulating surfaces of the knee joint are replaced with prosthetic components, or implants. TKA requires the removal of worn or damaged articular cartilage and bone on the distal femur and proximal tibia. The removed cartilage and bone is then replaced with synthetic implants, typically formed of metal or plastic, to create new joint surfaces.
[0004] The position and orientation (POSE) of the removed bone, referred to as bone cuts or resected bone, determines the final placement of the implants within the joint. Generally, surgeons plan and create the bone cuts so the final placement of the implants restores the mechanical axis or kinematics of the patient's leg while preserving the balance of the surrounding knee ligaments. Even small implant alignment deviations outside of clinically acceptable ranges correlates to less than optimal outcomes and increased rates of revision surgery. In TKA, creating the bone cuts to correctly align the implants is especially difficult because the femur requires at least five planar bone cuts to receive a traditional femoral prosthesis. The planar cuts on the distal femur must be aligned in five degrees of freedom to ensure a proper orientation: anterior-posterior translation, proximal-distal translation, external-internal rotation, varus-valgus rotation, and flexion-extension rotation. Any malalignment in any one of the planar cuts or orientations may have drastic consequences on the final result of the procedure and the wear pattern of the implant.
[0005] Cutting guides, also referred to as cutting blocks or cutting jigs, are commonly used to aid in creating the bone cuts. The cutting guides include guide slots to restrict or align a bone removal device, such as an oscillating saw, in the correct bone resection plane. Cutting guides are advantageous for several reasons. One such advantage is that the guide slots stabilize the bone

removal device during cutting to ensure the bone removal device does not deflect from the desired plane. Second, a single cutting guide may include multiple guide slots (referred to herein as an N-in-1 cutting block) which can define more than one cutting plane to be accurately resected, such as a 4-in-1 block, 5-in-1 block . . . N-in-1 block. Thus, the surgeon can quickly resect two or more planes once the cutting guide is accurately oriented on the bone. Still another advantage is that the guide slots and the working end of the oscillating saw are typically planar in shape and relatively thin, which make them ideal for creating planar bone cuts. The advantages of using a cutting guide are apparent, however, the cutting guide still needs to be accurately positioned on the bone prior to executing the cut. In fact, it is the placement of the guide slots on the bone that remains one of the most difficult, tedious and critical tasks for surgeons during TKA.

[0006] Various techniques have been developed to help a surgeon correctly align the guide slots on the bone. Typical cutting guide systems include a number of manual adjustment mechanisms that are used in conjunction with passive navigation, image-guidance, or anatomical landmark referencing. Guide pins are used to temporarily fix the cutting guide in the general orientation on the bone, and additional fine tuning adjustments are then made. One of the main drawbacks however, is the complexity of the cutting guides. The manual adjustment mechanisms are usually quite elaborate since the guide slots need to be oriented in six degrees of freedom. This requires extensive user training, which often predisposes a surgeon to use a particular implant or implant line that is specific for a given cutting guide system even if another implant affords other advantages. Additionally, when orienting the cutting guides using anatomical references, variations of the anatomy from patient to patient may cause difficulty in accurately aligning the cutting guides consistently. Passive navigation and image-guidance may be useful, but the surgeon has to constantly reference a monitor or other feedback mechanism, introducing error and prolonging the operating procedure. A typical total knee arthroplasty procedure may take approximately 60 minutes to complete.

[0007] Other methods have also been developed to alleviate the use of cutting guides. Haptic and semi-active robotic systems allow a surgeon to define virtual cutting boundaries on the bone. The surgeon then manually guides a cutting device while the robotic control mechanisms maintain the cutting device within the virtual boundaries. One disadvantage of the robotic system however, is the deflection of the cutting device that may occur when attempting to create a planar cut on the bone. The cutting device may encounter curved surfaces on the bone causing the device to skip or otherwise deflect away from the resection plane. The resulting planar cuts would then be misaligned, or at least difficult to create since the cutting device cannot be oriented directly perpendicular to the curved surface of the bone to create the desired bone cut. Cutting guides on the other hand are removably fixed directly against the bone, and therefore deflection of the cutting device is greatly decreased. In addition, the costs associated with haptic or semi-active robotic systems are considerably higher than manual instrumentation.

[0008] Thus, there is a need for a system and method to take advantage of using a cutting guide without the current time consuming and labor intensive burden of orienting the cutting guide on the bone.

SUMMARY OF THE INVENTION

[0009] An alignment system for surgical bone cutting procedures includes a plurality of bone pins inserted within a virtual plane relative to a cut plane to be created on a subject's bone, a cutting guide configured to be received onto the plurality of bone pins, and one or more guide slots within said cutting guide, the one or more guide slots configured to guide a surgical saw to make surgical cuts on the subject's bone.

[0010] A method for aligning a cutting guide on a subject's bone includes determining one or more cut planes from a surgical plan obtained with planning software. Determining one or more virtual planes relative to each of the one or more cut planes to be created on the subject's bone. Aligning and inserting a plurality of bone pins within a virtual plane from the one or more virtual planes.

Attaching a cutting guide configured to clamp onto the plurality of inserted bone pins, and wherein one or more guide slots are within the attached cutting guide, the one or more guide slots configured to guide a surgical saw to make surgical cuts on the subject's bone that correspond to the one or more cut planes.

[0011] A surgical device for pin insertion in a subject's bone to aid in performing a bone cutting procedure includes a working portion configured to articulate a pin for insertion in the subject's bone. A hand-held portion pivotably connected to the working portion by a front linear rail and rear linear rail, where the front linear rail and the rear linear rail are actuated by a set of components in the hand-held portion to adjust pitch and translation of the working portion relative to the hand-held portion, the front linear rail and the rear linear rail each having a first end and a second end. A tracking array having a set of three or more fiducial markers rigidly attached the working portion to permit a tracking system to track a position and orientation (POSE) of the working portion. The POSE of the pins upon insertion in the bone being used to assemble and align a cutting guide thereon to facilitate the creation of a desired cut plane.

Description

BRIEF DESCRIPTION OF THE DRAWING

[0012] The present invention is further detailed with respect to the following drawings. These figures are not intended to limit the scope of the present invention but rather illustrate certain attribute thereof wherein;

[0013] FIG. **1** depicts a surgical system to perform a procedure on a bone;

[0014] FIGS. **2**A and **2**B depicts a surgical device used in the surgical system;

[0015] FIG. **3** illustrates a virtual plane defined relative to a planned cut plane on a three dimensional model of a bone in accordance with embodiments of the invention;

[0016] FIGS. **4**A and **4**B depicts a universal distal cutting guide for creating a distal cut on a bone in accordance with embodiments of the invention as a front view (FIG. **4**A) and perspective view (FIG. **4**B);

[0017] FIG. **4**C depicts bone pins positioned in the context of a bone;

[0018] FIG. **4**D depicts the universal distal cutting guide of FIGS. **4**A and **4**B secured to bone using the bone pins of FIG. **4**C;

[0019] FIGS. **5**A-**5**D depicts a 4-in-1 cutting block for creating multiple cut planes on a bone in accordance with embodiments of the invention in perspective view (FIG. **5**A), side view (FIG. **5**B), bottom view (FIG. **5**C), and top view (FIG. **5**D);

[0020] FIGS. **6**A and **6**B depicts a planar alignment guide for aligning a N-in-1 block on a bone in accordance with embodiments of the invention in perspective view (FIG. **6**A), and top view (FIG. **6**B);

[0021] FIGS. **7**A and **7**B depicts an offset alignment guide for aligning a N-in-1 block on a bone in accordance with embodiments of the invention in perspective view (FIG. **7**A), and top view (FIG. **7**B);

[0022] FIGS. **8**A-**8**D depicts a channel created on the distal surface of the femur in perspective view (FIG. **8**A) and in side view (FIG. **8**B) for receiving an alignment guide in accordance with embodiments of the invention with the alignment guide depicted in the channel in perspective view (FIG. **8**C) and top view (FIG. **8**D);

[0023] FIGS. **9**A and **9**B depicts a universal distal cutting guide with a N-in-1 cutting block alignment guide in a top perspective view (FIG. **9**A), bottom perspective view (FIG. **9**B), and in accordance with embodiments of the invention;

[0024] FIG. **9**C depicts bone pins positioned in the context of a bone;

[0025] FIG. **9**D depicts the universal cutting guide with a N-in-1 cutting block alignment guide of

FIGS. **9**A and **9**B secured to bone using the bone pins of FIG. **9**C;
[0026] FIGS. **10**A and **10**B depict a slotted alignment guide for aligning a N-in-1 cutting block in accordance with embodiments of the invention in perspective view (FIG. **10**A), and top view (FIG. **10**B);
[0027] FIG. **10**C depicts bone pins positioned in the context of a bone;
[0028] FIG. **10**D depicts the universal cutting guide with a N-in-1 cutting block alignment guide of FIGS. **10**A and **10**B secured to bone using the bone pins of FIG. **10**C;
[0029] FIGS. **11**A-**11**E depict a 5-degree-of-freedom chamfer cutting guide for creating multiple planar bone cuts in accordance with embodiments of the invention;
[0030] FIGS. **12**A-**12**D illustrate the placement of pins to receive a 5-degree-of-freedom chamfer cutting guide in accordance with embodiments of the invention;
[0031] FIGS. **13**A and **13**B depicts a pin alignment guide for aligning a pin in a specific location on a bone in accordance with embodiments of the invention;
[0032] FIGS. **14**A and **14**B depicts a cutting guide with attachment holes spaced a distance apart in accordance with embodiments of the invention;
[0033] FIGS. **15**A and **15**B illustrates at least two perpendicular channels created on the bone to receive the pin alignment guide in accordance with embodiments of the invention;
[0034] FIGS. **16**A and **16**B depicts a referencing clamp alignment guide for creating pilot holes on the bone to align a N-in-1 cutting block in accordance with embodiments of the invention;
[0035] FIGS. **16**C and **16**D illustrates the use of the referencing clamp alignment guide in accordance with embodiments of the invention;
[0036] FIG. **16**E illustrates a stepped diameter drill bit for use with the reference alignment guide in accordance with embodiments of the invention;
[0037] FIG. **17**A and **17**B depict a plane clamp alignment guide for creating pilot holes on a distal cut surface to align a N-in-1 cutting block in accordance with embodiments of the invention;
[0038] FIG. **17**C illustrates the use of the plane alignment guide in accordance with embodiments of the invention;
[0039] FIG. **18**A and **18**B depict a cross-section of a articulating pin-driver device, where FIG. **18**A depicts the device having a pin in a retracted state, and FIG. **18**B depicts the device having a pin in an extended state in accordance with embodiments of the invention;
[0040] FIG. **18**C is an exploded view that illustrates the components of a working portion of the pin-driver device in accordance with embodiments of the invention;
[0041] FIGS. **19**A and **19**B depicts and illustrate a bone stability member attached to the pin-driver device and the use thereof in accordance with embodiments of the invention;
[0042] FIGS. **20**A and **20**B depicts a partial enclosure enclosing the working portion in accordance with embodiments of the invention; and
[0043] FIGS. **21**A and **21**B depicts a full enclosure enclosing the working portion in accordance with embodiments of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0044] The present invention has utility as a system and method to aid a surgeon in efficiently and precisely aligning a cutting guide on a patient's bone. The system and method is especially advantageous for total knee arthroplasty and revision knee arthroplasty, however, it should be appreciated that other medical applications may exploit the subject matter disclosed herein such as high tibial osteotomies, spinal reconstruction surgery, and other procedures requiring the precise placement of a cutting guide to aid a surgeon in creating bone cuts.
[0045] The following description of various embodiments of the invention is not intended to limit the invention to these specific embodiments, but rather to enable any person skilled in the art to make and use this invention through exemplary aspects thereof.
[0046] Embodiments of the present invention may be implemented with a surgical system. Examples of surgical systems used in embodiments of the invention illustratively include a 1-6

degree of freedom hand-held surgical system, a serial-chain manipulator system, a parallel robotic system, or a master-slave robotic system, as described in U.S. Pat. Nos. 5,086,401, 7,206,626, 8,876,830 and 8,961,536, U.S. Pat. App. No. 2013/0060278, and U.S. Prov. App. No. 62/054,009. In a specific embodiment, the surgical system is a serial-chain manipulator system as described in U.S. Pat. No. 6,033,415 assigned to the assignee of the present application and incorporated by reference herein in its entirety. The manipulator system may provide autonomous, semi-autonomous, or haptic control and any combinations thereof. In a specific embodiment, a tool attached to the manipulator system may be manually maneuvered by a user while the system provides at least one of power, active or haptic control to the tool.

[0047] With reference to the figures, FIG. **1** illustrates a 2-degree-of-freedom (2-DOF) surgical system **100**. The 2-DOF surgical system **100** is generally described in PCT App. Num. US2015/051713, assigned to the assignee of the present application and incorporated by reference herein in its entirety. The 2-DOF surgical system **100** includes a computing system **102**, an articulating surgical device **104**, and a tracking system **106**. The surgical system **100** is able to guide and assist a user in accurately placing pins coincident with a virtual pin plane that is defined relative to a subject's bone. The virtual plane is defined in a surgical plan such that a cut guide when assembled to the inserted pins align one or more guide slots with the bone cuts required to receive a prosthetic implant in a planned position and orientation.

Articulating Surgical Device

[0048] FIGS. **2**A and **2**B illustrate the articulating surgical device **104** of the 2-DOF surgical system **100** in more detail. The surgical device **104** includes a hand-held portion **202** and a working portion **204**. The hand-held portion **202** includes an outer casing **203** of ergonomic design to be held and manipulated by a user. The working portion **204** includes a tool **206** having a tool axis **207**. The tool **206** is readily attached to and driven by a motor **205**. The hand-held portion **202** and working portion **204** are connected by a front linear rail **208***a* and a back linear rail **208***b* that are actuated by components in the hand-held portion **202** to control the pitch and translation of the working portion **204** relative to the hand-held portion **202**. A tracking array **212**, having three or more fiducial markers, is rigidly attached to the working portion **142** to permit a tracking system **106** to track the POSE of the working portion **204**. The fiducial markers may be active markers such as light emitting diodes (LEDs), or passive markers such as retroreflective spheres. An input/output port in some inventive embodiments provides power and/or control signals to the device **104**; or the device may receive power from batteries and control signals via a wireless connection alleviating the need for electrical wiring to be connected to the device **104**. In a particular embodiment, the device may receive wireless control signals via visible light communication as described in Int'l Pat. App. WO 2016/081931 assigned to the assignee of the present application and incorporated by reference herein in its entirety. The device **104** may further include one or more user input mechanisms such as a trigger **214** or a button.

[0049] Within the outer casing of the hand-held portion **202** are a front actuator **210***a* that powers a front ball screw **216***a* and a back actuator **210***b* that powers a back ball screw **216***b*. The actuators (**210***a*, **210***b*) may be servo-motors that bi-directionally rotate the ball screws (**216***a*, **216***b*). A first end of the linear rails (**208***a*, **208***b*) are attached to the working portion **204** via hinges (**220***a*, **220***b*), where the hinges (**220***a*, **220***b*) allow the working portion **204** to pivot relative to the linear rails (**208***a*, **208***b*). Ball nuts (**218***a*, **218***b*) are attached at a second end of the linear rails (**208***a*, **208***b*). The ball nuts (**218***a*, **218***b*) are in mechanical communication with the ball screws (**216***a*, **216***b*). The actuators (**210***a*, **210***b*) power the ball screws (**216***a*, **216***b*) which cause the ball nuts (**218***a*, **218***b*) to translate along the axis of the ball screws (**216***a*, **216***b*). Accordingly, the translation ‘d’ and pitch ‘a’ of the working portion **204** may be adjusted depending on the position of each ball nut (**218***a*, **218***b*) on their corresponding ball screw (**216***a*, **216***b*). A linear guide **222** may further constrain and guide the motion of the linear rails (**208***a*, **208***b*) in the translational direction ‘d’.

Computing System and Tracking System

[0050] With reference back to FIG. **1**, the computing system **102** generally includes hardware and software for executing a surgical procedure. In particular embodiments, the computing system **102** provides actuation commands to the actuators (**210***a*, **210***b*) to control the position and orientation (POSE) of the tool **206**. The computing system **102** can thus maintain the tool axis **207** with a virtual plane defined in a surgical plan independent of the POSE of the hand-held portion **202**.
[0051] The computing system **102** in some inventive embodiments includes: a device computer **108** including a processor; a planning computer **110** including a processor; a tracking computer **111** including a processor, and peripheral devices. Processors operate in the computing system **102** to perform computations associated with the inventive system and method. It is appreciated that processor functions are shared between computers, a remote server, a cloud computing facility, or combinations thereof.
[0052] In particular inventive embodiments, the device computer **108** may include one or more processors, controllers, and any additional data storage medium such as RAM, ROM or other non-volatile or volatile memory to perform functions related to the operation of the surgical device **104**. For example, the device computer **108** may include software, data, and utilities to control the surgical device **104** such as the POSE of the working portion **204**, receive and process tracking data, control the speed of the motor **205**, execute registration algorithms, execute calibration routines, provide workflow instructions to the user throughout a surgical procedure, as well as any other suitable software, data or utilities required to successfully perform the procedure in accordance with embodiments of the invention.
[0053] The device computer **108**, the planning computer **110**, and the tracking computer **111** may be separate entities as shown, or it is contemplated that their operations may be executed on just one or two computers depending on the configuration of the surgical system **100**. For example, the tracking computer **111** may have operational data to control the device **104** without the need for a device computer **108**. Or, the device computer **108** may include operational data to plan to the surgical procedure with the need for the planning computer **110**. In any case, the peripheral devices allow a user to interface with the surgical system **100** and may include: one or more user interfaces, such as a display or monitor **112**; and various user input mechanisms, illustratively including a keyboard **114**, mouse **122**, pendent **124**, joystick **126**, foot pedal **128**, or the monitor **112** may have touchscreen capabilities.
[0054] The planning computer **110** is preferably dedicated to planning the procedure either pre-operatively or intra-operatively. For example, the planning computer **110** may contain hardware (e.g. processors, controllers, and memory), software, data, and utilities capable of receiving and reading medical imaging data, segmenting imaging data, constructing and manipulating three-dimensional (3D) virtual models, storing and providing computer-aided design (CAD) files, planning the POSE of the implants relative to the bone, generating the surgical plan data for use with the system **100**, and providing other various functions to aid a user in planning the surgical procedure. The planning computer also contains software dedicated to defining virtual planes with regards to embodiments of the invention as further described below. The final surgical plan data may include an image data set of the bone, bone registration data, subject identification information, the POSE of the implants relative to the bone, the POSE of one or more virtual planes defined relative to the bone, and any tissue modification instructions. The device computer **108** and the planning computer **110** may be directly connected in the operating room, or may exist as separate entities. The final surgical plan is readily transferred to the device computer **108** and/or tracking computer **111** through a wired or wireless connection in the operating room (OR); or transferred via a non-transient data storage medium (e.g. a compact disc (CD), a portable universal serial bus (USB drive)) if the planning computer **110** is located outside the OR. As described above, the computing system **102** may act as a single entity, with multiple processors, capable of performing the functions of the device computer **108**, the tracking computer **111**, and the planning computer **110**.

[0055] The computing system **102** may accurately maintain the tool axis **207** in 3-D space based on POSE data from the tracking system **106** as shown in FIG. **1**. The tracking system **106** generally includes a detection device to determine the POSE of an object relative to the position of the detection device. In a particular embodiment, the tracking system **106** is an optical tracking system as described in U.S. Pat. No. 6,061,644, having two or more optical receivers **116** to detect the position of fiducial markers arranged on rigid bodies. Illustrative examples of the fiducial markers include: an active transmitter, such as an LED or electromagnetic radiation emitter; a passive reflector, such as a plastic sphere with a retro-reflective film; or a distinct pattern or sequence of shapes, lines or other characters. A set of fiducial markers arranged on a rigid body is referred to herein as a fiducial marker array (**120***a*, **120***b*, **120***c*, **212**), where each fiducial marker array (**120***a*, **120***b*, **120***c*, **212**) has a unique geometry/arrangement of fiducial markers, or a unique transmitting wavelength/frequency if the markers are active LEDS, such that the tracking system **106** can distinguish between each of the tracked objects. In a specific embodiment, the fiducial marker arrays (**120***a*, **120***b*, **120***c*, **212**) include three or more active emitters or passive reflectors uniquely arranged in a known geometry on each rigid body.

[0056] The tracking system **106** may be built into a surgical light **118**, located on a boom, stand, or built into the walls or ceilings of the operating room. The tracking system computer **111** includes tracking hardware, software, data, and utilities to determine the POSE of objects (e.g. bones such as the femur F and tibia T, the surgical device **104**) in a local or global coordinate frame. The POSE of the objects is referred to herein as POSE data, where this POSE data is readily communicated to the device computer **108** through a wired or wireless connection. Alternatively, the device computer **108** may determine the POSE data using the position of the fiducial markers detected directly from the optical receivers **116**.

[0057] The POSE data is determined using the position of the fiducial markers detected from the optical receivers **116** and operations/processes such as image processing, image filtering, triangulation algorithms, geometric relationship processing, registration algorithms, calibration algorithms, and coordinate transformation processing.

[0058] POSE data from the tracking system **106** is used by the computing system **102** to perform various functions. For example, the POSE of a digitizer probe **130** with an attached probe fiducial marker array **120***c* may be calibrated such that tip of the probe is continuously known as described in U.S. Pat. No. 7,043,961. The POSE of the tip or axis of the tool **206** may be known with respect to the device fiducial marker array **212** using a calibration method as described in Int'l Pat. App. No. WO 2016/141378. Registration algorithms are readily executed using the POSE data to determine the POSE and/or coordinate transforms between a bone, a surgical plan, and a surgical system. For example, in registration methods as described in U.S. Pat. Nos. 6,033,415 and 8,287,522, points on a patient's bone may be collected using a tracked digitizer probe to transform the coordinates of a surgical plan, coordinates of the bone, and the coordinates of a surgical device, The bone may also be registered using image registration as described in U.S. Pat. No. 5,951,475. The coordinate transformations may be continuously updated using the POSE data from a tracking system tracking the POSE of the bone post-registration and the surgical device.

[0059] It should be appreciated that in certain inventive embodiments, other tracking systems are incorporated with the surgical system **100** such as an electromagnetic field tracking system, ultrasound tracking systems, accelerometers and gyroscopes, or a mechanical tracking system. The replacement of a non-mechanical tracking system with other tracking systems should be apparent to one skilled in the art. In specific embodiments, the use of a mechanical tracking system may be advantageous depending on the type of surgical system used such as the one described in U.S. Pat. No. 6,322,567 assigned to the assignee of the present application and incorporated by reference in its entirety.

[0060] In the surgical system **100**, an optical tracking system **106** with optical receivers **116** is used to collect POSE data of the femur and tibia during total knee arthroplasty. The distal femur F and proximal tibia T are exposed as in a typical TKA procedure. Tracking arrays **120***a* and **120***b* are attached thereto and the femur F and tibia T are subsequently digitized and registered to a surgical plan. The POSE of the femur F and tibia T are tracked in real-time by the tracking system **106** so the coordinate transformation between the surgical plan and the surgical device are updated as the bones and surgical device move in the operating space. Therefore, a relationship between the POSE of the tool **206** and the POSE of any coordinates defined in the surgical plan may be determined by the computing system **102**. In turn, the computing system **102** can supply actuation commands to the actuators (**210***a*, **210***b*) in real-time to accurately maintain the tool axis **207** to the defined coordinates.

[0061] Additionally, user input mechanisms, such as the trigger **214** or foot pedal **128**, may be used by the user to indicate to the computing system **102** that the tool axis **207** needs to be maintained to other coordinates defined in a surgical plan. For example, the tool axis **207** may be maintained in a first defined plane, and the user may step on the foot pedal **128** to relay to the computing system **102** that the tool axis **207** needs to be maintained in a second defined plane.

Surgical Planning and Execution for a Total Knee Arthroplasty (TKA) Application

[0062] The surgical plan is created, either pre-operatively or intra-operatively, by a user using planning software. The planning software may be used to a generate three-dimensional (3-D) models of the patient's bony anatomy from a computed tomography (CT), magnetic resonance imaging (MRI), x-ray, ultrasound image data set, or from a set of points collected on the bone intra-operatively. A set of 3-D computer aided design (CAD) models of the manufacturer's prosthesis are pre-loaded in the software that allows the user to place the components of a desired prosthesis to the 3-D model of the boney anatomy to designate the best fit, position and orientation of the implant to the bone. For example, with reference to FIG. **3**, a 3-D model of the patient's distal femur **302** and a 3-D model of the femoral prosthesis **304** are shown. The final placement of the femoral prosthesis model **304** on the bone model **302** defines the bone cut planes (shaded regions of the bone model **302**) where the bone is cut intra-operatively to receive the prosthesis as desired. In TKA, the planned cut planes generally include the anterior cut plane **306**, anterior chamfer cut plane **308**, the distal cut plane **310**, the posterior chamfer cut plane **312**, the posterior cut plane **314** and the tibial cut plane (not shown).

[0063] The surgical plan contains the 3-D model of the patient's operative bone combined with the location of one or more virtual planes **316**. The location of the virtual plane(s) **316** is defined by the planning software using the position and orientation (POSE) of one or more planned cut planes and one or more dimensions of a cutting guide or alignment guide. Ultimately, the location of the virtual plane(s) **316** is defined to aid in the placement of a cutting guide such that one or more guide slots of the cutting guide are in the correct POSE to accurately guide a saw in creating the bone cuts. Embodiments of the various inventive cutting guides, alignment guides, defining of the virtual planes, and use of the bone pins are further described in detail below.

[0064] In general, embodiments of the inventive cutting guides and alignment guides disclosed herein may be made of a rigid or semi-rigid material, such as stainless steel, aluminum, titanium, polyetheretherketone (PEEK), polyphenylsulfone, acrylonitrile butadiene styrene (ABS), and the like. Embodiments of the cutting guides and alignment guides may be manufactured using appropriate machining tools known in the art.

Distal Cutting Guide, Alignment Guide and N-in-1 Cutting Block

[0065] A particular inventive embodiment of a cutting guide to accurately create the planned distal cut **310** is the universal distal cutting guide **400** as depicted in FIG. **4**A and FIG. **4**B. The distal cutting guide **400** includes a guide portion **402** and an attachment portion **404**. The guide portion **402** includes a guide slot **406** and a bottom surface **410**. The guide slot **406** is for guiding a surgical saw in creating the distal cut **310** on the femur. The bottom surface **410** abuts against one or more bone pins **412** that are placed on the bone. The attachment portion **404** and the guide portion **402** clamp to the bone pins **412** using fasteners **408** as shown in FIG. **4**B and FIG. **4**D.

[0066] A surgical system is used to place the longitudinal axis of the bone pins **412** on a virtual pin plane **414**. In a particular embodiment, the 2-DOF surgical system **100** is used, wherein the tool **206** of the surgical device **104** is a drill bit rotated by the drill **205**. As the user manipulates the surgical device **104**, the computing system supplies actuation commands to the actuators to align the tool axis **207** with the pin plane **414**.
[0067] The virtual pin plane **414** is defined in the surgical plan by the planning software using the POSE of the planned distal cut plane **310**, and the distance between the guide slot **406** and the bottom surface **410** of the guide portion **402**. The planning software may also use the known width of the bone pins **412**. For example, the pin plane **414** can be defined by proximally translating the planned distal cut plane **310** by the distance between the guide slot **406** and the bottom surface **410** of the distal cutting guide **400**. The software may further proximally translate the planned distal cut plane **310** by an additional half width of the pins **412**. Therefore, when the cutting guide **400** is clamped to the bone pins **412**, the guide slot **406** is aligned with the planned distal cut plane **310**.
[0068] The user or the computing system **102** may activate the drill when properly aligned with the pin plane **414** to drill pilot holes for the pins **412**. The pins **412** are then drilled into the pilot holes using a standard drill. In a specific embodiment, the tool **206** is the pin **412**, wherein the pin **412** is attached to the drill **205** of the surgical device **104** and drilled directly into the bone on the pin plane **414**. At least two bone pins **412** may be drilled on the pin plane **414** to constrain the distal cutting guide **400** in the proper position and orientation when clamped to the pins **412** however three or more bone pins **412** can be used for further stability.
[0069] There are multiple advantages to using the 2-DOF surgical system **100** to accurately place the bone pins **412**. For one, the surgical device **104** is actuating in real-time, therefore the user is actively guided to the POSE of the pin plane **412**. In addition, the correct position and orientation of the bone pins **412** is accurately maintained regardless of the surgeon's placement of the hand-held portion **204** of the 2-DOF surgical system **100**.
[0070] One main advantage of the cutting guide **400** is its universality because the cutting guide **400** may be used for any type of implant and any type of patient. This is particularly advantageous, because the universal distal cutting guide **400** can be sterilized and re-used for multiple surgeries, greatly reducing the cost of TKA, which otherwise requires either patient specific cutting guides or implant specific cutting guides for each surgery.
[0071] The advantageous part of using pin planes, rather than defining a specific location for the bone pins **412**, is the user can place the longitudinal axes of the pins in any arbitrary orientation and position on the plane **414** and still attach the cutting guide **400** such that the guide slot **406** is accurately aligned with the planned distal cut plane **310**. This greatly reduces the operational time of the procedure. In addition, the user can avoid any particular landmarks coincident with the virtual plane if so desired.
[0072] After the cutting guide **400** is assembled on the bone pins **412**, the user can saw the distal cut **416** on the femur F by guiding a surgical saw through the guide slot **406**. Subsequently, the bone pins **412** and cutting guide **400** are removed from the bone to create the remaining bone cuts.
[0073] In a particular embodiment, with respect to FIGS. **5**A-**5**D, a prior art 4-in-1 cutting block **500** is used to create the remaining bone cuts. FIG. **5**A is a perspective view of the 4-in-1 cutting block, FIG. **5**B is a side elevation view thereof, FIG. **5**C is a top plan view thereof, and FIG. **5**D is a bottom plan view thereof. The 4-in-1 cutting block **500** may be made of materials similar to that of the distal cutting guide **400**. The 4-in-1 cutting block **500** is manufactured to include a body **502**, a posterior guide slot **504**, a posterior chamfer guide slot **506**, an anterior chamfer guide slot **508**, and an anterior guide slot **510**. The cutting block **500** also includes two pegs **512** to fit into pilot holes to be drilled on the distal cut plane **416**, and two pin securing guides **514** to receive pins **412′** to secure the cutting block **500** to the femur F. Although a 4-in-1 cutting block **500** is described herein, it should be appreciated that any N-in-1 cutting block for creating additional cut-planes on the bone may be aligned and assembled on the bone using the embodiments described herein. An

N-in-1 cutting block can account for femoral prostheses having greater than 5 planar contact surfaces (for reference and clarity, the femoral prosthesis **304** shown in FIG. **3** has 5 planar contact surfaces including the posterior contact surface **318** that mates with the posterior cut plane **314**).

[0074] The 4-in-1 cutting block **500** may be aligned on the bone using an alignment guide. A particular embodiment of the alignment guide is a planar alignment guide **600** as shown in FIG. **6**A and FIG. **6**B. FIG. **6**A is a perspective view of the planar alignment guide **600**, and FIG. **6**B is a top plan view of thereof. The planar alignment guide **600** includes a body **602**, and two holes **604** integrated with the body **602**. The body **602** includes a bottom portion **606** adapted to fit in a channel **800** (shown in FIG. **8**A) to be milled on the distal cut plane **416**. The distance between the centers of the holes **604** correspond to the distance between the centers of the pegs **512** of the 4-in-1 block **500**.

[0075] With reference to FIGS. **7**A and **7**B, a particular embodiment of the alignment guide is an offset alignment guide **700**. FIG. **7**A is a perspective view of the alignment guide **700**, and FIG. **7**B is a bottom plan view thereof. The alignment guide **700** includes a body **702**, at least one ridge **704** at the edge and extending from the body **702**, and two holes **604′** bored through the body **702**, where the two holes **604′** are located a known distance from the ridge **604**. The distance between the centers of the two holes **604′** correspond to the distance between the pegs **512** of the 4-in-1 cutting block **500**. The at least one ridge **704** is adapted to fit in a channel **800** (shown in FIG. **8**A) to be milled on the distal cut plane **416**.

[0076] The location of the pegs **512** on the distal cut plane **310** is determined based on the planned size and location of the prosthesis such that the guide slots of the 4-in-1 cutting block **500** align with the remaining bone cut planes. The planning software can define a virtual channel plane in the surgical plan, in which a channel **800** will be milled to receive the alignment guide (**600**, **700**). In a particular embodiment, the channel plane is defined by a plane that is perpendicular to the distal cut plane and aligned with the medial-lateral direction of the prosthesis. In another embodiment, the channel plane is defined based on the POSE of the planned anterior cut plane **306** or posterior cut plane **314**, and the location of the pegs required to align the guide slots for the remaining bone cuts. For example, if the planar alignment guide **600** is used, the planning software can define a virtual channel plane by anteriorly translating the planned posterior cut plane **314** to the location of the center of the pegs **512** of the 4-in-1 cutting block **500**. If the offset alignment guide **700** is used, then, the virtual channel plane is defined by anteriorly translating the planned posterior cut plane **314** to the location of the pegs **512**, and then posteriorly/anteriorly translating the planned plane by the known distance between the center of the holes **604′** and the ridge **704**.

[0077] The virtual channel plane defined in the surgical plan is used to create a channel **800** on the distal cut plane **310** of the femur F with a surgical system as shown in FIGS. **8**A-**8**D. In a particular embodiment, the 2-DOF surgical system **100** is used wherein the tool **206** of the surgical device **104** is actuated such that the tool axis **207** remains substantially coincident with the channel plane. To mill the channel **800**, the tool **206** is a bone cutting tool such as an end mill, burr or a rotary cutter. The tool **206** may further include a sleeve to prevent the tool **206** from cutting the channel **800** too deep. After the channel **800** is milled, the alignment guide is placed in the channel, whereby the holes **604′** are aligned with the position for the pegs **512** of the 4-in-1 cutting block **500**. When using the planar alignment guide **600**, the bottom portion **606** of the body **602** fits directly in the channel. When using the offset alignment guide **700**, the ridge **704** fits directly into the channel **800** as shown in FIGS. **8**C and **8**D. In both cases, a standard drill is then used to drill pilot holes for the pegs **512** by drilling through the holes **604′** of the alignment guide.

[0078] After the holes for the pegs **512** have been drilled, the alignment guide is removed from the femur F. The 4-in-1 block **500** is attached to the femur F via the pegs **512**. The remaining four bone cuts on the femur F are created using a surgical saw guided by the guide slots of the 4-in-1 cutting block **500**. The 4-in-1 block **500** is then removed, and the femoral prosthesis can be fixed to the femur F in a conventional manner.

[0079] A particular advantage in using the offset alignment guide **700** as opposed to the planar alignment guide **600**, is the created channel **800** to receive the ridge **704** can be removed with one of the four planar cuts, depending on the distance between the ridge **704** and the holes **604**′. In general, the use of the channel plane with an alignment guide (**600**, **700**) is advantageous because position of the cutting block **500** in the medial-lateral direction does not need to be precise on the distal cut **416** as long as the guide slots of the 4-in-1 cutting block **500** span enough of the bone to create the remaining bone cuts. Additionally, by using a surgical system, the channel can be quickly and accurately created. In combination, all of these are highly advantageous over the traditional cutting alignment guides because there is no need to reference a monitor if passive navigation was otherwise used, there is no need to locate multiple anatomical landmarks to drill the holes for the pegs of a 4-in-1 block, and the overall surgical time is reduced.

Distal Cutting Guide with Alignment Guide

[0080] In a particular embodiment of the cutting guide, a distal cutting and alignment guide **900** is illustrated in FIG. **9**A and FIG. **9**B. A front perspective view of the distal cutting guide **900** is shown in FIG. **9**A, and a rear perspective view thereof is shown in FIG. **9**B. The distal cutting and alignment guide **900** includes a guide portion **902** and an attachment portion **904**. The guide portion **902** may be in the shape of an inverted “L”, with a distal guide slot **906** and a pair of holes **908** bored through. The distance between the centers of the two holes **908** correspond to the distance between the pegs **512** of the 4-in-1 block **500**. The guide portion **902** also includes an abutment face **912** adapted to abut against alignment pins **914**. The attachment portion **904** attaches to the guide portion **902** with fasteners **910** to clamp bone pins **912** to the distal cutting and alignment guide **900**.

[0081] The planning software defines two virtual planes to accurately place the cutting and alignment guide **900** to the femur F. A first pin plane is defined such that the guide slot **906** aligns with the planned distal cut plane **310** when the cutting guide **900** is assembled to the bone pins **912**. A second pin plane is defined such that when the face **912** abuts against the alignment pins **914** second pin plane, the holes **908** align with the POSE for the pegs **512** of the 4-in-1 cutting block **500**. For example, in FIG. **9**C, the first pin plane is defined for the bone pins **912** and the second pin plane is defined for the alignment pins **914**. The second pin plane is defined in the planning software as follows: 1) a plane is defined perpendicular to the planned distal cut plane **310** and parallel with the planned position for the pegs **512**, and 2) that plane is then posteriorly translated by the distance between the centers of the holes **908** and the face **912** of the distal cutting and alignment guide **900**. Therefore, when the face **912** abuts against the alignment pins **914**, the holes **908** are accurately aligned in the anterior/posterior direction and internal-external rotation.

[0082] The bone pins **912** and alignment pins **914** are accurately placed on the first and second pin planes using a surgical system as described above. The cutting guide **900** is then assembled to the femur F, wherein the face **912** abuts against the alignment pins **914** as shown in FIG. **9**D. Before the surgeon creates the distal cut **416**, two pilot holes are drilled through the holes **908**. The alignment pins **914** are removed and the distal cut **416** is made by guiding a surgical saw through the guide slot **906**. The cutting guide **900** is removed from the femur F, and the 4-in-1 guide block can be directly assembled in the pilot holes to aid in creating the remaining cuts.

Slot Alignment Guide

[0083] In a particular embodiment of the alignment guide, a slot alignment guide **1000** is shown in FIG. **10**A and FIG. **10**B. FIG. **10**A is a perspective view of the slot alignment guide **1000**, and FIG. **6**B is a top plan view thereof. The slot alignment guide **1000** includes two holes **1002**, and a pin receiving slot **1004**. The slot alignment guide **1000** may further include a lip **1006**. The distance between the centers of the two holes **1002** correspond to the distance between the pegs **512** of the 4-in-1 block **500**. The pin receiving slot **1004** is of sufficient width to be received on the bone pins **1008**. The distance between the center of the slot **1004** and the holes **1002** are known to define a virtual pin plane for the bone pins **1008**.

[0084] The slot alignment guide **1000** may be used if the cancellous bone on the distal surface **416** of the femur F is particularly soft, weak, or more flexible. In these cases, the planar alignment guide **600** or the offset alignment guide **700** in the channel **800** may become misaligned due to the flexible nature of this cancellous bone. Therefore, bone pins **1008** may be inserted on the channel plane as defined above. The bone pins **1008** are aligned and inserted on the channel plane using the methods previously described as shown in FIG. **10**C. A ring **1010** such as a washer or spacer may be placed on the bone pins **1008** to further protect the distal surface **416** of the femur F. The pin receiving slot **1004** of the slot alignment guide **1000** is placed on the bone pins **1000**. The lip **1006** may interact with the ring **1010** such that the alignment guide **1000** lies flat on the distal surface **416** of the femur F. A user may then drill pilot holes through the holes **1002** using a standard drill. The alignment guide **1000** and the bone pins **1008** are removed from the femur F and the pegs **512** of the 4-in-1 guide block **500** is assembled to the pilot holes to aid in creating the remaining bone cuts.

[0085] It should be appreciated that the 4-in-1 block may have other features, other than the pegs **512**, to interact and attach with the distal cut surface **416** of the femur F. The pegs **512** may instead be a body extruding from the bottom surface of the 4-in-1 block **500** and adapted to fit in a corresponding shape created on the distal cut surface **416**. The extruding body may have a variety of shapes including an extruded rectangle, triangle, the shapes manufactured for a keel of a tibial base plate implant, and any other extruding body/bodies. Therefore, the alignment guides described herein may have the same corresponding shape, instead of the holes (**604**, **604′**, and **908**), to guide a user in creating that shape on the distal cut surface **416** so the 4-in-1 block can be accurately placed thereon.

Clamp Alignment Guide

[0086] With reference to FIGS. **16**A-**17**C, a clamp alignment guide (**1600**, **1700**) is used to aid in the alignment of an N-in-1 cutting block on the femur. The clamp alignment guides (**1600**, **1700**) are configured to clamp onto their own set of pins in a POSE that permits a user to accurately create the pilot holes for the cutting block pegs **512**. In a particular embodiment, with reference to FIGS. **16**A-**16**E, a referencing clamp alignment guide **1600** and the use thereof is shown. The referencing clamp alignment guide **1600** includes a guide portion **1602** and a clamping portion **1604**. The guide portion **1602** has a pair of referencing feet **1606** that reference a top surface **409** of the universal distal cutting guide **400′**, and two or more holes **1608** spaced a distance apart corresponding to the distance between the pegs **512** of a cutting block.

[0087] In general, the virtual pin plane for the clamp alignment guides (**1600**, **1700**) is defined by: 1) defining a plane perpendicular to the planned distal cut plane **310** and parallel with the planned position for the pegs **512**; 2) posteriorly translating that plane by the known distance between the centers of the holes **1608** and a bottom surface **1609** of the alignment portion **1602**; and 3) further posteriorly translating that plane by an additional half-width of the pins **1610**.

[0088] Use of the reference clamp alignment guide **1600** is shown with respect to FIGS. **16**C and **16**D. A universal cut guide **400′** is first assembled on the femur F as described above. The pins **1610** are positioned on the virtual pin plane using a surgical system, such as the 2-DOF surgical system **100**. The clamp guide **1600** is assembled on the pins **1610** with the feet **1606** referencing the top surface **409** of the universal cut guide **400′**. The user then drills the pilot holes for the cutting block pegs **512** using the holes **1608** as a guide. After which, the clamp alignment guide **1600** and pins **1610** are removed from the bone and the user creates the distal cut via the guide slot **406**. Subsequently, the distal cut guide **400′** and distal pins **412** are removed from the bone, the cutting block pegs **512** are inserted in the pilot holes, and the remaining cut planes are created on the femur.

[0089] There is one issue a user may encounter when using the clamp alignment guides (**1600**, **1700**). The drill and drill bit for creating the N-in-1 pilot holes need to have sufficient clearance so as to not interfere with the placement of the pins **1610**, while also permitting the drill bit to traverse all of the bone distal to the distal cut plane and create a hole beyond the distal cut plane that is deep enough to fully receive the cutting block pegs **512**. In a particular embodiment, with reference to FIG. **16**E, this problem is solved using a stepped diameter drill bit **1617**. FIG. **16**E depicts the distal cut guide **400**′and reference clamp guide **1600** assembled on the bone, and a drill **1618** driving a stepped diameter drill bit **1617** through the guide holes **1608**. Because the exact distance between the planned distal cut plane **1612** and the top of the guide **1614** is known (this is geometrically known because the distance from i) the guide slot **406** and the distal guide's top surface **409** is known, and ii) the distance from the bottom of the referencing feet **1606** stabilized on the top surface **409**, to the top of the guide **1614** is also known, therefore i+ii=the distance between the top of the guide **1614** and the planned cut plane **1612**), a drill bit **1617** having a stepped diameter can simultaneously clear the length of the pins **1610** and also set the engagement in the bone beyond the distal cut plane **1612** so the user does not have to determine how deep to drill. Here the drill bit **1617** has a distal portion **1619** having a diameter less than a proximal portion **1620**. The distal portion **1619** has a diameter that fits through the guide holes **1608** and large enough to create a hole for receiving the cutting block pegs **512**. The distal portion **1619** has a length capable of traversing the bone distal of the distal cut plane **1619** and extend beyond the distal cut plane **1612** enough to create a pilot hole deep enough to fully receive the pegs **512**. The proximal portion **1620** has a diameter larger than the diameter of the guide holes **1608** and a length that ensures the bulky drill **1618** does not interfere with pins **1610**. In another embodiment, to solve this clearance issue, the drill **1618** is tracked by a tracking system and a monitor provides visual feedback to the user. When the tip of the drill extends beyond a certain depth (e.g. breaks the planned distal cut plane **1612**), the monitor displays this information and/or provides depth information.

[0090] In a specific embodiment, with reference to FIGS. **17**A-**17**C, a plane clamp alignment guide **1700** is used to aid in the creation of the pilot holes to receive the cutting block pegs **512**. The plane alignment guide **1700** is placed directly on the distal cut plane **416** and includes a guide portion **1702** and a clamping portion **1704**. The guide portion **1700** includes two or more holes **1706** similar to the reference alignment guide **1600**. The guide **1700** may further include a projection **1708** to increase the contact surface area between the guide **1700** and the distal cut surface **416** to increase the stability of the guide on the distal surface **416**. Accordingly, the bottom surface **1712** of the plane alignment guide **1700** is flat to mate with the planar distal cut surface **416**. Fasteners **1710** or a clamping mechanism allows the plane guide **1700** to assemble to the pins **1714** inserted on the bone.

[0091] The procedure for using the plane alignment guide **1700** is as follows. The user first creates the distal cut using a universal distal cutting guide **400**. The user then inserts pins **1714** on a virtual pin plane, where the virtual pin plane is defined as described above for the clamp alignment guides (**1600**, **1700**). The pins **1714** are inserted directly on the distal cut surface **416**. The plane alignment guide **1700** is then clamped to the pins **1714** where the bottom surface **1712** of the guide **1700** lies flush with the cut surface **416**. The user drills the pilot holes for the pegs **512** using the holes **1706** as a guide. Subsequently, the pins **1714** and the plane alignment guide **1700** are removed, the pegs **512** of an N-in-1 cutting block are placed in the pilot holes, and the remaining cut planes are created. The clearance issue described above for the reference alignment guide **1600** can be readily solved in a similar manner for the plane alignment guide **1700**.

5-DOF Chamfer Guide

[0092] In a specific embodiment of the cutting guide, a 5-DOF chamfer cutting guide **1100** is shown in FIGS. **11**A-**11**E. FIG. **11**A is a perspective view of the top of the chamfer cutting guide **1100**, FIG. **11**B is a perspective view of the bottom thereof, FIG. **11**C is a top plan view, FIG. **11**D is a front elevation view, and FIG. **11**E is a side elevation view. The chamfer cutting guide **1100** includes a guide body **1102** in the shape of an inverted “L”. The guide body **1102** includes a first attachment slot **1104***a*, a second attachment slot **1104***b*, a distal guide slot **1106**, an anterior guide slot **1108**, and a chamfer guide slot **1110**. One side of the attachment slots **1104** is open, so the chamfer cutting guide **1100** can slide onto the bone pins. The attachment slot opening is best visualized in FIG. **11**D on the right side of the attachment slots **1104**.

[0093] The planning software defines the location of 5-DOF chamfer cutting guide **1100** in the location necessary to place the guide slots in the correct position and orientation to accurately execute the planned cut planes. The surgical plan also includes two pin planes (**1202***a*, **1202***b*, as shown in FIGS. **12**A-**12**B), on which bone pins (**1204***a*, **1204***b*) are placed that are defined relative to the cut planes; the two planes have an intersection axis that is parallel to all of the cut planes. The pin planes (**1202***a*, **1202***b*) may be defined using the known dimensions of the chamfer cutting guide **1100**, and the POSE of the planned cut planes. For example, the planning software knows the position and orientation of the attachment slots **1104** with respect to the guide slots. Using these dimensions the planning software may define a first pin plane **1204***a* and a second pin plane **1204***b*. By defining two pin planes with four or more pins, 5 degrees of freedom are constrained, which is sufficient to perform a TKA procedure using a surgical saw if the unconstrained degree of freedom is in the medial-lateral direction, which is parallel to all of the cut planes.

[0094] A surgical system, such as the one described above, is then used to place the bone pins (**1204***a*. **1204***b*) substantially coincident on the pin planes (**1202***a*, **1202***b*). Once again, the pins **1204** can be inserted at an arbitrary position and orientation on that plane. The attachment slots **1104** of the chamfer cutting guide **1100** slide over the bone pins (**1204***a*. **1204***b*) as shown in FIG. **12**C. The user then creates the distal cut plane, anterior cut plane, posterior cut plane, and the chamfer cut planes by guiding a surgical saw through the respective guide slots. The chamfer guide **1100** and the bone pins **1204** are then removed. A second cut guide (not shown), which fits against the distal and posterior cut surfaces can guide the anterior cut using similar embodiments of the cutting guides, pin planes, and bone pins as described herein.

Pin Alignment Guide

[0095] In a particular embodiment of the alignment guide, a pin alignment guide **1300** is shown in FIG. **13**A and FIG. **13**B. The pin alignment guide **1300** includes a tubular body **1302** and fins **1304** extruding outwardly from the tubular body **1302**. The pin alignment guide **1300** aids a user in aligning bone pins for use with a cutting guide that requires the bone pins to be placed a specific distance apart. For example, the cutting guide **1400** shown in FIG. **14**A and **14**B includes a guide slot **1402**, and two holes **1404** that receive bone pins placed a specific distance apart.

[0096] To use the pin alignment guides **1300**, with respect to FIG. **15**A, at least two perpendicular channel planes are defined in the planning software. A first channel plane, to create a first channel **1502** on the bone, is defined as described above using the planned distal cut plane **310** and the distance between the guide slot **1402** and the center of the holes **1404**. A second channel plane, to create a second channel **1504** on the bone, is defined perpendicular to the first channel plane. A third channel plane is defined perpendicular to the first channel plane and medially/laterally translated by the distance between the centers of the holes **1404** of the cutting guide **1400**. The channels (**1502**, **1504**) are precisely milled on the bone using a surgical system as described above.

[0097] The intersection of the first channel **1502** and the second channel **1504** (shown at **1506**), receives the pin alignment guide **1300** as shown in FIG. **15**B, wherein the fins **1304** fit directly into the channels. A user can then drill a pilot hole, or a bone pin directly through the tubular body **1302** of the pin alignment guide **1300**. The procedure is repeated to place any additional bone pins on the bone. Subsequently, the holes **1404** of the cutting guide **1400** are placed on the bone pins, and the bone cut is created as planned. It should be appreciated that this technique can similarly be used for other cutting guides. For example, the pin alignment guide technique can be used to create pilot holes on the distal cut **416** of the femur F for the pegs **512** of a 4-in-1 block **500**.

Tibial Cut Plane

[0098] The tibial cut plane may be created using similar embodiments as described above and should be apparent to one skilled in the art after reading the subject matter herein.

[0099] In a particular embodiment, the tibial cut guide may be aligned in varus-valgus rotation, internal-external rotation, flexion-extension rotation, and proximal-distal position. The anterior-posterior position is not important. The tibial cut guide is positioned using two or more pins positioned on two planes that have an intersection axis that is aligned with the planned anterior-posterior direction. For example, two planes oriented ±45° in varus-valgus, such that when the guide is placed on the pins, all degrees of freedom except the anterior-posterior are constrained.

[0100] Example: Distal Cutting Guide, Alignment Guide and 4-in-1 Block

[0101] Testing was conducted on femoral and tibia saw bones using the 2-DOF surgical system **100**, the universal distal cutting guide **400**, the offset alignment guide **700** and the 4-in-1 block **500**. Artificial ligaments were attached between the saw bones to mimic the kinematics of the knee. The purpose of the testing was to assess the overall time required to create the planar cuts on the femoral saw bone, referred to hereafter as femur. The timing began prior to fixing the femoral tracking array **120***b* and ended once the last cut plane on the femur was completed.

[0102] To begin, the femoral tracking array **120***b* was fixed to the lateral side of the femur. A tracked digitizer probe was used to collect various points on the distal femoral surface. The collected points were used to register the POSE of the femur to a surgical plan. The 2-DOF surgical device **104** was used to drill two holes in the virtual pin plane **414**, the virtual pin plane **414** being defined in the planning software prior to testing. A standard drill was then used to insert pins **412** in the drilled holes. The universal distal cutting guide **400** was clamped to the pins **412** and the distal cut **416** was created using a surgical saw guided through the slot **406** of the distal cutting guide **400**. The distal cutting guide **400** and pins **412** were then removed from the femur.

[0103] The 2-DOF surgical device **104** was then used to mill a channel **800** on the distal cut surface **416** along the virtual channel plane, the virtual channel plane being defined in the planning software prior to testing. The ridge **704** of the offset alignment guide **700** was placed in the channel **800** and a standard drill was used to drill two holes on the distal surface **416** guided by the two holes **604**′ of the offset alignment guide **700**. The offset alignment guide **700** was removed from the channel **800** and the pegs **512** of the 4-in-1 block **500** were placed in the two drilled holes. The remaining four planar cuts were created using a surgical saw guided by the guide slots (**504**, **506**, **508**, and **510**) of the 4-in-1 block **500**. The recorded time from femoral tracking array **120***b* fixation to the creation of the final cut plane was approximately 18 minutes.

[0104] It is worthy to note, that during testing the standard drill had lost power and required charging. The timing was not stopped during the charging step. It is presumed that an experienced surgeon could execute this testing procedure in approximately 10 to 15 minutes.

Articulating Pin-Driving Device

[0105] The articulating device **204** of the 2-DOF surgical system **100** described above can accurately align a tool/pin to be coincident with one or more virtual planes. However, the surgeon still has to manually advance the device **204** towards the bone to insert the pin or to create a pilot hole for the pin, which may be uncomfortable for the surgeon. In addition, it is possible that extreme or sudden movements by the surgeon or bone while operating the device may introduce small errors in the pin alignment. A contributing factor to the extreme or sudden movements may be a lacking of real-time information, during use, as to the articulating travel range, or workspace, in which the device operates **204** within.

[0106] To provide further control and feedback for the user, the 2-DOF surgical device **104** may be modified to include a third pin-driving degree-of-freedom, which will be referred to hereinafter as an articulating pin-driver device **104**′. With reference to FIGS. **18**A-**18**C in which like reference numerals have the meaning ascribed to that numeral with respect to the aforementioned figures, a particular embodiment of the articulating pin driver device **104**′ is shown. In addition to the components of the 2-DOF surgical device **104**, the working portion **204**′ of the articulating pin driver device **104**′ further includes components configured to drive a pin **206**′ into a bone. Specifically, with reference to FIG. **18**C, the working portion **204**′ includes the motor **205**, a motor coupler **1808**, a pin-driving ball screw **1804**, a pin holder **1806**, and the pin **206**′. A specially adapted carriage **1810** is configured to support and carry the working portion **204′** and may include mechanisms for actuating the pin. In some inventive embodiments, the carriage **1810** includes a pin-driving ball nut **1812** and connection members **1814** such as holes, bearings, or axle supports to receive a rod, a dowel, or an axel to act as the hinges (**220***a*, **220***b*) that are connected with the first end of the linear rails (**208***a*, **208***b*). The motor coupler **1808** couples the motor **205** with the pin-driving ball screw **1804**. The pin-driving ball screw **1804** is in mechanical communication with the pin-driving ball nut **1812**. The pin holder **1806** connects the pin-driving ball screw **1804** with the pin **206′**. The pin **206′** is removably attached with the pin holder **1806** to allow the pin **206′** to remain in the bone when inserted therein. The motor **205** may bi-rotationally drive the pin-driving ball screw **1804** and the pin **206′** to advance and drive the pin **206′** into a bone. The components may further include a motor carriage (not shown) operably connected with a motor linear rail (not shown). The motor carriage is secured to the motor **205** to keep the motor **205** from rotating while allowing the motor **205** to translate along the motor linear rail. The motor linear rail may extend from the carriage **1810**. FIG. **18**A illustrates the pin **206′** in a retracted state and FIG. **18**B illustrates the pin **206′** in an extended state, where the pin **206′** can translate a distance “d2”. An outer guard **1802** may be present to guard the user from the actuating mechanisms in the working portion **204′**. If an outer guard **1802** is present, the guard **1802** may be dimensioned to conceal the entire pin **206′** when the pin **206′** is in the retracted state, or the guard **1802** may only conceal a portion of the pin **206′** to allow the user to visualize the tip of the pin **206′** prior to bone insertion.

[0107] In a specific embodiment, the working portion **204′** may include a first motor **205** for rotating the pin **206′**, and a second motor (not shown) for translationally driving the pin **206′**. The second motor may rotate a ball screw or a worm gear that is in communication with an opposing ball nut or gear rack configured with the first motor **205**. As the second motor bi-rotationally drives the ball screw or worm gear, the first motor **205** and the pin **206′** translate accordingly.

[0108] The device computer **108** of the articulating pin driving device **104′** may further include hardware and software to control the pin-driving action. In an embodiment, the device computer **108** includes two motor controllers for independently controlling the front actuator **210***a* and back actuator **210***b*, respectively, to maintain the POSE of the working portion (**204**, **204′**). A third motor controller may independently control the motor **205** for driving and rotating the pin **206′** into the bone. In the specific embodiment where a first motor **205** rotates the pin **206′** and a second motor (not shown) translates the pin **206′**, the device computer **108** may include two separate motor controllers to independently control the first motor **205** and the second motor.

[0109] In a specific embodiment, with reference to FIGS. **19**A-**19**B, the articulating device **104′** includes a bone stabilizing member **1902** attached or integrated with the hand-held portion **202**. The bone stabilizing member **1902** includes bone contacting elements (**1904***a*, **1904***b*) which are configured to contact the bone and stabilize the hand-held portion **202** while the working portion **204′** articulates. The bone contacting elements (**222***a*, **222***b*) may be a flat surface, a pointed protrusion, or a surface having jagged edges to interact with the bone and stabilize the hand-held portion **202**. The bone contacting element(s) (**1904***a*, **1904***b*) project just beyond the working portion **204′** such that the element(s) (**1904***a*, **1904***b*) may contact the bone without negatively impacting how deep the pin **206′** may be inserted in the bone. When the user is in the approximate region for driving the pin **206′**, the user may stabilize the hand-held portion **202** to the bone via the bone contacting elements (**1904***a*, **1904***b*). With the hand-held portion stabilized, the working portion **204′** further articulates until the pin **206′** is precisely coincident with a virtual pin plane. In a specific embodiment, once the pin **206′** aligns with the virtual pin plane **214**, the system **100** automatically locks the actuators (**210***a*, **210***b*) and activates the motor **205** to drive the pin **206′** into the bone. In another embodiment, the user activates a user input mechanism such as a trigger **214** or a button before the system **100** either locks the actuators (**210***a*, **210***b*), drives the pin **206′**, or both. Therefore, the user can anticipate and control when the pin **206′** is driven into the bone. This user input mechanism may similarly be used by the user to control the amount of extension or retraction of the pin **206**′ in general.

[0110] In a particular embodiment, with reference to FIG. **19**A, one or more indicators **1906**, such as an LED or a display, is attached or integrated with the device **104**′. The indicator **1906** may be attached to the outer guard **1802**, the working portion **204**′, or the hand-held portion **202** for example. The indicator(s) **1906** provide feedback to the user as to a current position of the device **104**′ with respect to a desired position for the device **104**′. For example, the indicator **1906** may emit a red light to indicate that the device **104**′ is outside of the travel ranges of the three ball screws (**216***a*, **216***b*, **1804**). In other words, a red light is emitted when the working portion **204**′ and pin **206**′ can no longer be articulated to reach a desired position, orientation, or a desired depth to insert the pin **206**′. The indicator **1906** may emit a yellow light when the user is approaching the travel ranges and a green light when the pin **206**′ is aligned with a virtual pin plane. The indicator **1906** may further produce a blinking light that changes in blinking frequency based on how close the device **104**′ is to exceeding the travel range, or how close the pin **206**′ is to a virtual pin plane. The indicator **1906** may also indicate when the device **104**′ is ready to autonomously place the pin inside the bone. In a particular embodiment, the working portion **204**′ does not actuate until the indicator **1906** is in an active state, where the active state is triggered when the device **104**′ is within the travel limits of the ball screw. This data conveyed by the indicator **1906** is readily available based on either: a) local data collected directly from the device **104**′, such as the device kinematics; b) the tracking data collected from the tracking system **106**; c) a comparison of the POSE of the device **104**′ with the surgical plan; or d) a combination thereof.

[0111] In a specific embodiment, with reference to FIGS. **20**A and **20**B, the articulating device **104**′ includes a partial enclosure **2002**. FIG. **20**A is perspective view of the articulating device **104**′ with the partial enclosure **2002** and FIG. **6**B is a cross-section view thereof. The partial enclosure **2002** is attached to the hand-held portion **202** and partially encloses the working portion **204**′. The working portion **204**′ is able to articulate within the partial enclosure **2002**. The partial enclosure **2002** has an internal dimension (i.e. height or diameter) of ‘h’ that corresponds to the travel range of the working portion **204**′. This dimension ‘h’ may account for the translation ‘d’ of the working portion **204**′ and any additional height required to account for the pitch ‘a’ of the working portion **204**′. The advantage of the partial enclosure **2002** is to provide the user with a guide as to the workspace or travel range of the working portion **204**′. The user can simply place a front end of the partial enclosure **2002** on the bone to stabilize the hand-held portion **202**, at which time the working portion **204**′ can articulate to a virtual pin plane and drive the pin **206**′ into the bone. The user is no longer trying to aim the small pin **206**′ directly to a pin plane, but is rather using a larger guide, the partial enclosure **2002**, to get the pin **206**′ in the general vicinity of a pin plane and allowing the working portion **204**′ to perform the alignment. In addition, the user no longer has to worry about exceeding the travel limits of the working portion **204**′ while aligning the pin **206**′.

[0112] The front end of the partial enclosure **2002** may act as a bone contacting element (**1904***a*, **1904***b*) to stabilize the hand-held portion **202** and may further include features such as a jagged edge or one or more pointed protrusions.

[0113] The pin **206**′ extends beyond the partial enclosure **2002** in the extended state to allow the pin to be driven into the bone as shown in FIG. **6**B. When the pin **206**′ is in the retracted state, the pin **206**′ is enclosed within the partial enclosure **2002**.

[0114] The partial enclosure **2002** may further include the indicator **1906** to aid the user in positioning the device **104**′ to a desired pin plane as described above.

[0115] The partial enclosure **2002** is further configured to allow the tracking array **212** to attach with the working portion **204**′, or an outer guard **1802**′ of the working portion **204**′, to permit the tracking system **106** to track the POSE of the working portion **204**′ as it articulates.

[0116] In a particular embodiment, with reference to FIGS. **21**A and **21**B, the articulating device **104**′ includes a full enclosure **2102**. FIG. **7**A is a perspective view of the articulating device **102** with the full enclosure **2102** and FIG. **7**B is a cross-section view thereof. The full enclosure **2102** is configured with the same principles and has the same advantages as the partial enclosure **2002**, except the tracking array **212** is attached directly to the full enclosure **2102**. Since the tracking array **212** is attached to the full enclosure **2102**, the control scheme for controlling the working portion **204**′ must be modified, where the device kinematics are used to determine the POSE of the working portion **204**′. Particularly, the tracking system **106** tracks the hand-held portion **202** based on the geometric relationship between the array **212** and the hand-held portion **202**, and the actuator (**210***a*, **210***b*) positions (i.e. the rotational position of the actuators that corresponds to the position of the ball nuts (**218***a*, **218***b*) on the ball screws (**216***a*, **216***b*)) are used to determine the POSE of the working portion **204**′ with respect to the hand-held portion **202**. Therefore, the computing system **102** can determine new actuator positions to control and align the pin **206**′ with a virtual pin plane.

[0117] It should be appreciated that the partial enclosure **2002** and full enclosure **2102** may be sized and adapted for assembly to a hand-held system having greater than two degrees of freedom with similar advantages. For example, it is contemplated that the inner dimensions of the enclosure (**226**, **228**) may accommodate the travel limits of a device having an articulating portion that articulates in one or more translational directions, pitch, and yaw such as the system described in U.S. Pat. App. No. 20130060278. However, as the number of degrees of freedom increase, so does the size of the enclosure (**226**, **228**) which may impede the operating workspace.

[0118] It should be further appreciated that the embodiments of the bone stabilizing member **1902**, the indicator **1906**, the partial enclosure **2002**, and full enclosure **2102**, can all be adapted for use with the 2-DOF surgical device **104** as shown in FIGS. **2**A-**2**B.

Bi-Cortical Drilling

[0119] To further stabilize the bone pins in the bone it may be desirable to drill the pins through two cortical regions of the bone, also referred to as bi-cortical drilling. However, if a drill bit or a pin is drilled beyond the second cortical region and into the soft tissue, patient harm can occur. Therefore, it is proposed that the third pin-driving actuation axis can also be used to retract the drill bit/pin if the drill bit/pin breaks through the second cortical region.

[0120] In a particular embodiment, bone breakthrough is detected using an existing method, such as the method described in Taha, Zahari, A. Salah, and J. Lee. “Bone breakthrough detection for orthopedic robot-assisted surgery.” *APIEMS* 2008 *Proceedings of the* 9*th Asia Pacific Industrial Engineering and Management Systems Conference.* 2008, which is hereby incorporated by reference in its entirety. The articulating pin-driving device **104**′ then automatically retracts the drill bit/pin at a constant optimal retraction speed relative to the bone, regardless of how the user is moving the hand-held portion **202**. This ensures that if the drill bit/pin breakthrough the second cortical region, that the drill bit/pin is retracted so as to not cause any patient harm. The retraction speed is a function of the optimal retraction speed combined with the current speed of the hand-held portion **202**.

[0121] The relative speed between the hand-held portion **202** and the bone can be measured several different ways. In one embodiment, the speed of the hand-held portion **202** relative to the bone is not detected and instead a speed is assumed. In another embodiment, a simple linear distance measuring tool is used, such as a laser distance measurement device. In a particular embodiment, the tracking system **106** is used to track both the bone and the hand-held portion **202** using one or more fiducial markers on each of the bone and the hand-held portion **202**.

Other Embodiments

[0122] While at least one exemplary embodiment has been presented in the foregoing detailed description, it should be appreciated that a vast number of variations exist. It should also be appreciated that the exemplary embodiment or exemplary embodiments are only examples, and are not intended to limit the scope, applicability, or configuration of the described embodiments in any way. Rather, the foregoing detailed description will provide those skilled in the art with a convenient roadmap for implementing the exemplary embodiment or exemplary embodiments. It should be understood that various changes can be made in the function and arrangements of elements without departing from the scope as set forth in the appended claims and the legal equivalents thereof.

[0123] The foregoing description is illustrative of particular embodiments of the invention, but is not meant to be a limitation upon the practice thereof. The following claims, including all equivalents thereof, are intended to define the scope of the invention.

Claims

1. A surgical system for inserting a pin in a bone coincident with a virtual plane having a predetermined location relative to a bone, comprising: a robotic surgical device for aligning or maintaining alignment of an axis of the pin coincident with the virtual plane in response to control signals; a computer configured to receive inputs that comprise the predetermined location of the virtual plane, and a location of at least one of the bone and the robotic surgical device, wherein the computer comprises a processor configured to generate the control signals using the inputs; and a cutting guide configured to couple to one or more pins already inserted in the bone, wherein the cutting guide comprises an opening configured to receive a bone removal tool.

2. The surgical system of claim 1 wherein the pre-determined location of the virtual plane is oriented with respect to a predetermined location for a cut surface to be created on the bone.

3. The surgical system of claim 2 wherein the virtual plane orientation is offset by a pre-determined distance from the pre-determined location for the cut surface.

4. The surgical system of claim 3 wherein the pre-determined distance is based at least in part on a geometry of the cutting guide.

5. The surgical system of claim 1 wherein the robotic surgical device is a hand-held robotic device comprising: a hand-held portion; a working portion movably connected to the hand-held portion and comprising a motor for driving the pin; and an actuator system for moving the working portion relative to the hand-held portion in response to the control signals to align or maintain alignment of the axis of the pin coincident with the virtual plane.

6. The surgical system of claim 1 wherein the cutting guide comprises: a first portion; a second portion comprising the opening for receiving the bone removal tool; and a space between the first portion and the second portion, wherein the space has a height and width, the width being greater than the height, and wherein the space is configured to receive a portion of the pin.

7. The surgical system of claim 6 wherein the cutting guide further comprises a fastener for moving the first portion relative to the second portion to change the height of the space in order to clamp the cutting guide onto the one or more pins already inserted in the bone.

8. The surgical system of claim 1 wherein the input corresponding to the location of the robotic surgical device is an input corresponding to a position and orientation (POSE) of at least a portion of the robotic surgical device comprising at least one of: (i) the pin; (ii) the axis of the pin; or (iii) a set of fiducial markers coupled to the robotic surgical device.

9. The surgical system of claim 1 wherein the input corresponding to the location of at least one of the bone and the surgical device is received from a tracking system.

10. The surgical system of claim 9 further comprising the tracking system.

11. The surgical system of claim 1 further comprising the pin.

12. The surgical system of claim 1 wherein the robotic surgical device comprises at least one of: a hand-held robotic device; a serial-chain robotic device; a parallel robotic device; or a master-slave robotic device.

13. The surgical system of claim 12 wherein the robotic surgical device is controlled autonomously, semi-autonomously, haptically, or a combination thereof.

14. The surgical system of claim 1 wherein the robotic surgical device further comprises a motor configured to drive rotation of the pin and the control signals further comprise power signals that activate or deactivate the motor depending on a position of the pin relative to the virtual plane.

15. A surgical system for inserting a pin in a bone coincident with a virtual plane having a predetermined location relative to a bone, comprising: a hand-held device, comprising a hand-held portion; a working portion movably connected to the hand-held portion and comprising a motor for driving the pin; and an actuator system for moving the working portion relative to the hand-held portion in response to control signals to align or maintain alignment of an axis of the pin coincident with the virtual plane; a computing system configured to receive inputs that comprise the predetermined location of the virtual plane, and a location of at least one of the bone and the hand-held device, wherein the computing system comprises one or more processors configured to generate the control signals using the inputs; a tracking system for determining the location of the at least one of the bone and the hand-held device; and a cutting guide configured to couple to one or more pins already inserted in the bone, wherein the cutting guide comprises an opening configured to receive a bone removal tool.

16. The surgical system of claim 15 wherein the tracking system determines the location of the hand-held device by detecting a set of fiducial markers coupled to the hand-held device.

17. The surgical system of claim 16 wherein the one or more processors are configured to determine, based on the determined location of the hand-held device, a location of at least one of the one or more pins or the axis of the pin.

18. The surgical system of claim 15 wherein the cutting guide comprises: a first portion; a second portion comprising the opening for receiving the bone removal tool; and a space between the first portion and the second portion, wherein the space has a height and width, the width being greater than the height, and wherein the space is configured to receive a portion of the pin.

19. The surgical system of claim 18 wherein the cutting guide further comprises a fastener for moving the first portion relative to the second portion to change the height of the space in order to clamp the cutting guide onto the one or more pins already inserted in the bone.

20. The surgical system of claim 15 wherein the pre-determined location of the virtual plane is oriented with respect to a pre-determined location for forming a cut surface on the bone.

21. The surgical system of claim 20 wherein the virtual plane orientation is offset by a pre-determined distance from the pre-determined location for forming the cut surface.

22. The surgical system of claim 21 wherein the pre-determined distance is based at least in part on a geometry of the cutting guide.