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(54) Title: BONE REGISTRATION USING BONE ROTATION AXIS

(57) Abstract: A method for registering bone data to a bone is provided that includes the recordation of tracking element locations. The tracking element being associated with the bone while the bone is rotated about an axis. The axis of rotation is determined using the recorded locations. The bone data is registered to the bone and includes a bone landmark located at a determinable or pre-determined location with respect to the bone data, wherein an approximate alignment of the bone landmark with the determined axis is used for the registration. A system for performing the registration is also provided. The system includes a tracking system for tracking locations of a tracking element, the tracking element configured to be affixed to a bone. A computer having a processor is included and configured to perform the computational steps of the method.

BONE REGISTRATION USING BONE ROTATION AXIS

RELATED APPLICATIONS

[0001] This application claims priority benefit of US Provisional Application Serial Number 63/521,248 filed June 15, 2023; the contents of which are hereby incorporated by reference.

TECHNICAL FIELD

[0002] The present invention generally relates to computer-assisted orthopedic surgery, and in particular to a system and method for registering bone data to a bone using an axis of rotation of the bone as determined by rotating the bone about the axis.

BACKGROUND

[0003] Throughout a lifetime, bones and joints become damaged and worn through normal use, disease, and traumatic events. Arthritis is a leading cause of joint damage, which can cause cartilage degradation, pain, swelling, stiffness, and bone loss over time. If the pain associated with the dysfunctional joint is not alleviated by less-invasive therapies, the joint may need to be replaced with a procedure called joint arthroplasty (JR) (e.g., total joint arthroplasty, unicompartmental arthroplasty). JA is an orthopedic surgical procedure, which requires the removal of the worn articular cartilage of the joint including a varying amount of bone. This cartilage and bone are then replaced with synthetic implants, typically metal and plastic, which form the new synthetic joint surfaces.

[0004] In conventional joint replacement surgeries including knee joints and hip joints, a surgeon may use planar x-rays to plan the position and orientation (POSE) for an implant relative to the bone. Implant templates are overlaid on the radiographs to determine the proper implant size for an implant to fit a patient's bone. The surgeon then uses cutting jigs, or cut

guides, with manual cutting tools to make the bone cuts to form the cut surfaces on the remaining bone on which the implant is mounted in the planned POSE. However, these techniques result in a significant amount of error. Any misalignment in any one of the cut surfaces from the planned POSE may have drastic consequences on the final result of the procedure and the wear pattern of the implant. The results of such misalignment might include discomfort, limited range of motion, revision, and reduced implant longevity.

[0005] To reduce the error of the implant placement on the bone according to a planned POSE for the implant on the bone, several computer-assisted surgical systems have been developed to assist in the formation of the cut surfaces on the remaining bone. Examples of such computer-assisted surgical systems include the TSolution One® Surgical System (THINK Surgical, Inc., Fremont, CA), the RIO Robotic Arm, and the 2-DoF Hand-Held Surgical System illustrated U.S. Pat. No. 11,457,980 and incorporated herein by reference in its entirety. The TSolution One® Surgical System aids in the planning and execution of total hip arthroplasty (THA) and total knee arthroplasty (TKA). The 2-DoF Hand-Held Surgical System robotically aligns a pin coincident with a virtual plane for insertion of the pin in the bone to align a cutting guide on the bone in a pre-determined POSE. Computer-assisted surgical systems generally include a planning software program and a computer-assisted surgical device (e.g., a surgical robot) for executing a surgical plan. The planning software generally includes a graphical user interface (GUI) for displaying bone data (e.g., 3-D models of the bone, also referred to as 3-D bone models), and 3-D implant models to assist in planning a POSE for the implant with respect to the bone. The planning software may generate 3-D bone models of the patient's bone using imaging data such as computed tomography (CT), ultrasound, or magnetic resonance imaging (MRI) data. The planning software may be used by a user, or automatically programmed, to determine: (i) an optimal implant size for the bone; and (ii) the best fit, fill, and/or alignment for a given implant relative to the bone, all according to clinically established alignment goals..

The planning software may also have the option to a design a custom implant relative to the bone. Based on the planned POSE for the implant relative to the bone, operating instructions for the computer-assisted device are defined relative to the bone model. For example, the operating instructions may be a cut-file storing cutting instructions (e.g., cut paths, orientations, and spindle speeds) for an end-effector of a robot. The location of the cut-file is defined relative to the bone model such that when the bone model is registered to the location of the bone in the operating room (OR), the surgical robot can make bone cuts to form the cut surfaces on the remaining bone to mount the implant in the planned POSE. In another example, the operating instructions may be a set of virtual planes. The location of the virtual planes are defined with respect to the bone model such that when the bone model is registered to the location of the bone in the OR, a surgical robot can align a pin coincident with the virtual plane for inserting pins in the bone, where the accurately place pins are used to align a cut guide on the bone for forming the cut surfaces on the remaining bone to mount the implant in the planned POSE.

[0006] As previously mentioned, the 3-D bone model must be registered to the target bone in order for the computer-assisted surgical device to assist in accurately forming the cut surfaces. The registration procedure maps the 3-D bone model to the location of the bone in a coordinate system recognizable by the surgical system. For example, the current method for registering a femoral bone for a knee replacement surgery relies on the collection of a plurality of points on the distal portion of the exposed femur and locating the femoral head center of the femur. Corresponding points on the distal portion of the 3-D femoral bone model and the identified location of the femoral head center on the 3-D femoral bone model are matched to these collected and located points on the femur to register the 3-D femoral bone model to the femoral bone. The current method for locating the femoral head center is as follows. First, a tracking array is affixed to the distal femur and the distal femur is physically moved around in a spherical motion (e.g., movement in flexion-extension (F-E) and abduction-adduction)

throughout a large range of motion, or generally moved in all degrees-of-freedom (DoF) that the femur will allow. A tracking system tracks and records the locations of the tracking array during this motion. The goal is to move the bone enough in order for the system to fit a sphere to the recorded locations of the tracking array. Next, a sphere is fitted to the recorded locations of the tracking array and the femoral head center is calculated as the center of the fitted sphere. The main assumptions associated with calculating the femoral head center using this technique include: (i) assuming the femoral head is a perfect sphere; and (ii) assuming that the pelvic bone remains stationary while the distal femur is moved in the spherical motion. However, these assumptions are not usually correct, particularly the assumption that the pelvic bone remains stationary since movement of the distal femur in such a large range of motion may very well cause the pelvis to move. This leads to errors in the calculation of the femoral head center and therefore errors in the registration. Errors in the registration causes error in the formation of the cut surfaces and therefore errors in the final implant placement.

[0007] Further problems associated with the existing technique to locate the femoral head center on the femur include: (i) the large field of view required by the tracking system to capture the movement of the bone in such a large range of motion; and (ii) the longer time required for implementing this registration technique (e.g., time spent on moving the bone in a large range of motion and computer processing time) which can be expensive given that use of operating rooms are expensive and this registration must take place in an operating room.

[0008] Thus, there exists a need for a method for registering a position of a bone that is simplified, and more accurate than existing registration methods. There also exists a need for a method that accounts bone geometries and variations in movement that are unique to an individual patient.

SUMMARY OF THE INVENTION

[0009] A method for registering bone data to a bone is provided that includes the recordation of tracking element locations. The tracking element being associated with the bone while the bone is rotated about an axis. The axis of rotation is determined using the recorded locations. The bone data is registered to the bone and includes a bone landmark located at a determinable or pre-determined location with respect to the bone data, wherein an approximate alignment of the bone landmark with the determined axis is used for the registration.

[0010] A system for performing the registration is also provided. The system includes a tracking system for tracking locations of a tracking element, the tracking element configured to be affixed to a bone. A computer having a processor is included and configured to perform the computational steps of the above method.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The present invention is further detailed with respect to the following drawings that are intended to show certain aspects of the present of invention, but should not be construed as limit on the practice of the invention, wherein:

[0012] FIG. 1 depicts a method for registering bone data to a bone of a subject for a surgical procedure in accordance with embodiments of the invention;

[0013] FIG. 2 depicts a sagittal view of a femur with a tracking array positioned on the distal end thereof where a circle is fitted to the movement of the tracking array as the bone is flexed and extended according to embodiments of the present invention;

[0014] FIG. 3 shows a schematic for determining a flexion-extension (F-E) rotation axis when torque for moving the bone is perfectly parallel to the sagittal plane;

[0015] FIG. 4 shows a schematic for determining a F-E rotation axis when torque for moving the bone is out of the sagittal plane;

[0016] FIG. 5 shows the result of a first registration of bone data to a bone;

[0017] FIG. 6 shows residual translational errors as a result of refining the first registration by rotating the bone data to approximately align a bone landmark with a determined F-E axis.

[0018] FIG. 7 depicts a computer-assisted surgical system for performing a surgical procedure on a bone in accordance with embodiments of the inventions.

[0019] FIGs 8A and 8B depict a computer-assisted surgical (CAS) device of the computer assisted surgical system of FIG. 7, where FIG. 8A depicts the CAS device in a first working position and orientation (POSE) and FIG. 8B depicts the CAS device in a second working position.

DETAILED DESCRIPTION OF THE INVENTION

[0020] The present invention has utility as a system and method for registering bone data to a position of a bone in order to perform a computer-assisted surgical procedure on the bone. The bone data is registered to the bone, at least in part, by approximately aligning a bone landmark associated with the bone data to a determined rotational axis of the bone as determined by rotating the bone in part about the rotational axis. Advantageously, the bone only needs to be rotated about a single axis of rotation, which removes the need to move the bone in a large range of motion for fitting a model mathematical sphere to the motion, as is currently required for registration in knee arthroplasty. Embodiments of the inventive method are therefore simplified, fast, less expensive to carry out, more accurate than existing registration methods, and account for bone geometries and variations in movement that are unique to an individual patient. This method has implications not only in surgery, but also the manufacture of orthotics or prosthetics, and in orthopedics research.

[0021] While the present invention is depicted herein in the context of a knee replacement surgery for a human patient, it is appreciated that the present invention is applicable to a variety

of anatomical joint replacements that also include shoulder, ankle, hip, finger, toe, elbow for any species of mammal with similar skeletal joints including, but not limited to, dogs, cats, and horses.

[0022] The present invention will now be described with reference to the following exemplary embodiments. As is apparent by these descriptions, this invention can be embodied in different forms and should not be construed as limited to the embodiments set forth herein. For example, features illustrated with respect to one embodiment can be incorporated into other embodiments, and features illustrated with respect to a particular embodiment can be deleted from that embodiment. In addition, numerous variations and additions to the embodiments suggested herein will be apparent to those skilled in the art in light of the instant disclosure, which do not depart from the instant invention. Hence, the following specification is intended to illustrate some particular embodiments of the invention, and not to exhaustively specify all permutations, combinations, and variations thereof.

[0023] Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. The terminology used in the description of the invention herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. [0021] All publications, patent applications, patents and other references mentioned herein are incorporated by reference in their entirety.

[0024] It is to be understood that in instances where a range of values are provided that the range is intended to encompass not only the end point values of the range but also intermediate values of the range as explicitly being included within the range and varying by the last significant figure of the range. By way of example, a recited range of from 1 to 4 is intended to include 1-2, 1-3, 2-4, 3-4, and 1-4.

[0025] Definitions

[0026] Unless indicated otherwise, explicitly or by context, the following terms are used herein as set forth below.

[0027] As used in the description of the invention and the appended claims, the singular forms "a," "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise.

[0028] Also, as used herein, "and/or" refers to and encompasses any and all possible combinations of one or more of the associated listed items, as well as the lack of combinations when interpreted in the alternative ("or").

[0029] As used herein, the term "bone data" refers to data related to one or more bones. The bone data may be determined: (i) prior to making modifications (e.g., bone cuts, insertion of a pin or screw in the bone, etc.) to one or more bones; and/or (ii) determined after one or more modifications have been made to a bone. The bone data may be collected, generated, and/or determined preoperatively, intraoperatively, or a combination of pre-operatively and intraoperatively. The bone data may include: the shapes of the one or more bones; the sizes of the one or more bones; angles and axes associated with the one or more bones (e.g., epicondylar axis of the femoral epicondyles, longitudinal axis of the femur, the mechanical axis of the femur); angles and axes associated with two or more bones relative to one another (e.g., the mechanical axis of the knee); anatomical points associated with the one or more bones (e.g., femoral head center, knee center, ankle center, tibial tuberosity, epicondyles, most distal portion of the femoral condyles, most proximal portion of the femoral condyles); bone density data; bone architecture data; and stress/loading conditions of the bone(s). By way of example, the bone data may include one or more of the following: an image data set of one or more bones (e.g., an image data set acquired via fluoroscopy, computed tomography (CT), magnetic resonance imaging (MRI), ultrasound, other x-ray modalities, laser scan, etc.); three-dimensional (3-D) bone models, which may include a virtual generic 3-D model of the bone, a

physical 3-D model of the bone, a virtual patient-specific 3-D model of the bone generated from an image data set of the bone; and a set of data collected directly on the bone intra-operatively commonly used with imageless computer-assisted surgical devices (e.g., laser scanning the bone, collecting a cloud of points on the bone with a digitizer, "painting" the bone with a digitizer).

[0030] As used herein, the terms "computer-assisted surgical device" and "CAS device" refer to devices used in surgical procedures that are at least in part assisted by one or more computers.

[0031] Examples of CAS devices illustratively include tracked/navigated instruments and surgical robots. Examples of a surgical robot illustratively include robotic hand-held devices, serial-chain robots, bone mounted robots, parallel robots, or master-slave robots, as described in U.S. Patent Nos. 5,086,401; 6,757,582; 7,206,626; 8,876,830; 8,961,536; 9,707,043; and 11,457,980; which patents and patent application are incorporated herein by reference. The surgical robot may be active (e.g., automatic/autonomous control), semi-active (e.g., a combination of automatic and manual control), haptic (e.g., tactile, force, and/or auditory feedback), and/or provide power control (e.g., turning a robot or a part thereof on and off). It should be appreciated that the terms "robot" and "robotic" are used interchangeably herein. The terms "computer-assisted surgical system" and "CAS system" refer to a system comprising at least one CAS device and may further include additional computers, software, devices or instruments. An example of a CAS system may include: i) a CAS device and software used by the CAS device (e.g., operational data, bone data); ii) a CAS device and software used with a CAS device (e.g., surgical planning software); iii) one or more CAS devices (e.g., a surgical robot); iv) a combination of i), ii), and iii); and iv) any of the aforementioned with additional devices or software (e.g., a tracking system, tracked/navigated instruments, tracking arrays,

bone pins, rongeur, an oscillating saw, a rotary drill, manual cut guides, manual cut blocks, manual cutting jigs, etc.).

[0032] As used herein, the term, "operational data" refers to software instructions that direct a CAS device to operate with respect to a bone. Examples of "operational data" include a cut-file, virtual boundaries, virtual planes, or virtual paths. A "cut-file" may include instructions (e.g., end effector cut paths, points, orientations, feed rates, or spindle speeds, and any combination thereof as well as other factors) that direct the CAS device during the formation of the cut surfaces on the bone automatically (e.g., a surgical robot executes the instructions to control movement of an end effector). It should be appreciated that cut-files may be generated with the aid of computer-aided manufacturing (CAM) software. The "operational data" may be virtual boundaries defined relative to the bone which direct a CAS device to provide feedback (e.g., active, semi-active, haptic, or power control) to a user to assist in the prevention of cutting bone beyond the virtual boundary while the user maneuvers an end-effector of the CAS device with respect to the bone. The "operational data" may be virtual paths defined relative to the bone, which direct a CAS device to provide feedback (active, semi-active, haptic, or power control) to a user to assist in maintaining an end-effector of the CAS device along the virtual path while the user maneuvers the end-effector with respect to the bone. The "operational data" may be a virtual plane or virtual axis defined relative to the bone, which direct a CAS device to maintain alignment of hardware (e.g., bone pin) coincident with the virtual plane or virtual axis for inserting the hardware in the bone.

[0033] Also referenced herein is a "surgical plan." A surgical plan is generated using planning software. The surgical plan may be generated pre-operatively, intra-operatively, or pre-operatively and then modified intra-operatively. The planning software may be used to plan the location for an implant with respect to a bone and/or plan a location to make one or more modifications (e.g., bone cuts, location for inserting bone pins) to the bone. The planning

software may include various software tools and widgets for planning the surgical procedure. This may include, for example, planning: (i) a location for a 3-D implant model with respect to a 3-D bone model to define a location for the implant with respect to the bone; (ii) a location for one or more cuts to be made relative to a 3-D bone model to define the locations for one or more cuts to be made on the bone, and/or (ii) one or more locations on a 3-D bone model for inserting hardware (e.g., bone pins, screws) to define locations for one or more virtual references (e.g., a virtual plane, virtual boundary, a virtual axis) with respect to the bone, where a CAS device is directed to align an end-effector (e.g., the hardware, a burr, end-mill, drill bit) with the location of the virtual reference(s) registered to the bone.

[0034] As used herein, the term "digitizer" refers to a device capable of measuring, collecting, recording, and/or designating the position of physical locations (e.g., points, lines, planes, boundaries, etc.) in three-dimensional space. By way of example but not limitation, a "digitizer" may be: a "mechanical digitizer" having passive links and joints, such as the high-resolution electro-mechanical sensor arm described in U.S. Patent No. 6,033,415 (which U.S. patent is hereby incorporated herein by reference); a non-mechanically tracked digitizer probe (e.g., optically tracked, electromagnetically tracked, acoustically tracked, and equivalents thereof) as described for example in U.S. Patent 7,043,961 (which U.S. patent is hereby incorporated herein by reference); an end-effector of a robotic device; or a laser scanner.

[0035] As used herein, the term "digitizing" refers to the collecting, measuring, designating, and/or recording of physical locations in space with a digitizer.

[0036] As used herein, the term "registration" refers to: the determination of the spatial relationship between two or more objects; the determining of a coordinate transformation between two or more coordinate systems associated with those objects; determining a transformation matrix, or mathematical mapping, between the location of one object to the location of another object; and a combination thereof. Examples of objects routinely registered

in an operating room (OR) illustratively include: CAS systems/devices; anatomy (e.g., bone); bone data (e.g., 3-D bone models); a surgical plan (e.g., location of virtual planes defined relative to bone data, cutting instructions defined relative to bone data); and any external landmarks (e.g., a tracking array affixed to a bone, an anatomical landmark, a designated point/feature on a bone, etc.) associated with the bone (if such landmarks exist). Methods of registration known in the art are described in U.S. Pat. No. 6,033,415; 8,010,177; 8,036,441; and 8,287,522; and 10,537,388. Traditional methods for registering bone data to a bone relies on the manual collection of several points (i.e., point-to-point, point-to-surface) on the bone using a tracked digitizer where the surgeon is prompted to collect several points on the bone that are readily mapped to corresponding points or surfaces on a 3-D bone model. A computer then registers the 3-D bone model to the bone by matching the points collected on the surface of a bone to corresponding points/surfaces on the 3D bone model using iterative closest point (ICP) algorithms to generate a transformation matrix. This transformation matrix and various other transformation matrices provide the mathematical locational relationships between: (i) one or more targets or boundaries defined in a surgical plan (e.g., a location for a virtual plane that was defined with respect to bone data, a location of cutting instructions that was defined with respect to bone data); (ii) the coordinate system of a tracking array affixed to the bone (if present); (iii) a CAS device (e.g., the base coordinate system of the CAS device; or a coordinate system of a tracking array affixed to the CAS device and, if needed, calibration data and/or kinematic data that define the location of an end-effector relative to this tracking array); and any other coordinate system or object required to perform the procedure. In other embodiments, the registration is performed using image or imageless registration. [0034] The following description provides examples related to knee joint replacement; however, it should be appreciated that the embodiments described herein are readily adapted for use in a myriad of applications where it is desirous to register bone data to a bone.

[0037] Embodiments of the present invention describe a system and method for registering bone data to a bone using a rotational axis of the bone. Prior methods of registration using a calculated location of the femoral head center, which requires moving the bone all around and fitting a sphere to the recorded locations of the bone, is not the most accurate registration method and has problems associated therewith as described above, including unintentionally moving the pelvis around and requires a large field of view for the camera. It has been surprisingly found that the location of the femoral head center on the femur is not needed to accurately register the bone data to the bone. In fact, only the axis of rotation during flexion of the knee that goes through the femoral head center is needed, where this axis of rotation can be easily determined based on data collected while the knee is flexed and extended when the subject is positioned on the operating table. This axis of rotation is commonly referred to as the hip flexion-extension axis. According to embodiments, the bone data is registered to the bone using conventional registration techniques on the exposed distal region of the femur and then post-processing the registration to approximately align the location of the femoral head center on the bone data to the determined axis of rotation. The conventional registration technique may use an iterative closest point (ICP) algorithm to match points collected on the exposed distal femur to corresponding points on the bone data. ICP algorithms are known the art and illustratively include those detailed in Rodriguez y Baena, F., Hawke, T., & Jakopec, M. (2013). A bounded iterative closest point method for minimally invasive registration of the femur. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine, 227(10), 1135-1144; Liang, Luming, et al. "Nonrigid iterative closest points for registration of 3D biomedical surfaces." Optics and Lasers in Engineering 100 (2018): 141-154; and Haddad, Oussama, et al. "Initialized Iterative Closest Point for bone recognition in ultrasound volumes." 2016 23rd International Conference on Pattern Recognition (ICPR). IEEE, 2016. According to embodiments, the resulting transform (e.g., transformation matrix)

calculated from the conventional registration technique is post processed to refine the registration by rotating the resulting transform in only flexion-extension until the femoral head center associated with the femoral bone data is at its closest point (i.e., approximately aligned) to the determined axis of rotation (i.e., hip flexion-extension (E-F) axis), where this determined axis of rotation goes through the actual femoral head center on the femur. According to embodiments, the registration is then further refined to reduce or minimize registration errors in one or more areas of the bone (e.g., the anterior region of the bone, the distal region of the bone) to improve the registration.

[0038] Referring now to the figures, FIG. 1 depicts a particular embodiment of a method for registering bone data to a bone. The registration method begins by recording, with a tracking system, locations of a tracking element (e.g., a tracking array, electromagnetic sensor) affixed to the bone while the bone is rotated about an axis as shown at Block 100. According to certain inventive embodiments, the site of the surgical procedure is a joint of the subject that is to be replaced in a total joint replacement (TJR) surgery, for example the joint to be replaced may be a knee and therefore the tracking element is affixed on the distal end of a femur. According to still other inventive embodiments, the bone is exposed through a surgical incision to gain access to the distal end of the femur prior to placing the tracking element. The distal end of the femoral bone may be rotated about a flexion-extension axis located at the proximal end of the femur (e.g., the hip flexion-extension axis). A surgeon may flex and extend the subject's knee, which is routine practice during a TKA procedure, to rotate the femur about the flexion-extension axis. The axis of rotation is then determined using the recorded locations of the tracking element as shown at Block 102. A computer may determine the axis of rotation by fitting a circle to the recorded locations of the tracking element and then calculating an axis normal to the circle and located at the center of the circle, where the calculated axis represents the axis of rotation. The computer then performs a first registration of the bone data to the bone

as shown in Block 104. The first registration may be accomplished using conventional registration techniques to register the bone data to the bone. For example, the computer may match points digitized on the exposed distal femur with corresponding points on the bone data using an ICP algorithm. The computer then refines the first registration by rotating the bone data to approximately align the bone landmark with the determined axis of rotation as shown in Block 106. The bone data may be rotated in a single rotational degree-of-freedom (DoF) (e.g., rotation in flexion-extension) to position the bone landmark at the closest distance (i.e., approximal alignment) to the determined axis of rotation. Specific embodiments of the system and method are described below.

[0039] A computer-assisted TKA procedure starts with surgical planning using a planning software program. First, bone data of the femoral bone and tibia bone are obtained and/or generated. The bone data of the femur may be a femoral bone model generated from an image data set of the femur. Various bone landmarks, also referred to herein as anatomical landmarks, are located on the femoral bone model to orient the bone and to define the anatomical references commonly used to plan the location of an implant relative to the femur according to clinically established alignment goals. One of these bone landmarks includes the femoral head center (as shown in FIG. 3). The location of the bone landmarks may be located on the femoral bone model using software tools in the planning software, while in other embodiments, the planning software may automatically locate the bone landmarks. 3-D implant models may be positioned relative to the femoral bone model to plan the final POSE for the implant with respect to the bone. Operational data for a CAS device is also defined with respect to the femoral bone model, which when registered to the bone will direct the CAS device to assist in forming the cut surfaces on the bone for mounting the implant on the bone in the planned POSE. The bone data and any additional data (e.g., the location of one or more bone landmarks, the planned POSE

for an implant, location of operational data) defined with respect to the bone data is then saved, transferred, and/or stored to a computer associated with a CAS system.

[0040] In the operating room (OR), the distal end of the femoral bone is exposed in a conventional manner and a tracking element is affixed to the bone. Examples of a tracking element include: a tracking array comprising three or more fiducial markers to permit an optical tracking system to track the location of the tracking array; an electromagnetic (EM) sensor for EM tracking; acoustic tracking elements; and radiofrequency tracking elements. The tracking element may be affixed to the distal portion of the bone, either in the exposed region of the bone or through a percutaneous incision. At this point, the bone is ready to be registered with the bone data. [0039] With reference to FIG. 2, a femur 10 is shown having a tracking element affixed to a distal portion 14 of the femur 10. Also shown are the femoral head 16 and the femoral head center 18 of the femur 10. To determine the flexion-extension (F-E) axis 22 of the femur 10 that runs through the femoral head center 18, the distal portion 14 of the femur 10 is flexed and extended to rotate the femur 10 about the flexion-extension axis 22. A surgeon may flex and extend the femur as part of a routine portion of the surgical procedure. This simple movement of the femur helps keep the adjoining bones stationary, such as in keeping the pelvic bone stationary when the femur is being moved. A tracking system (as shown in FIG. X) records the locations of the tracking element 12 while the femur is flexed and extended, where this recording may occur at any time following the affixation of the tracking element 12 to the femur 10. A computer then fits a circle 20 to the recorded locations of the tracking element 12 since the movement of the distal portion 14 of the femur 10, and the tracking element 12 affixed thereto, follows a circular path when the femur is rotated in this single degree-of-freedom (DoF) (i.e., flexion and extension). The computer then calculates an axis normal to the fitted circle and located at the center of the fitted circle. The calculated axis is the F-E axis 24 of the femur 10 that runs through the femoral head center 18. It should be appreciated that the center

of the fitted circle is only used to calculate the location of the axis and is not used for the registration.

[0041] It is appreciated that the procedures detailed with respect to FIGs. 1 and 2 are also performed in a physical therapy setting and without surgical intervention to create an external brace, an exercise regime, or a combination thereof that promote subject-specific and proper movement of a bone joint. In this context, the tracking element 12 is adhesively attached to the skin of the subject overlying the placement as shown in FIG. 2 with appropriate compensation for the intervening body tissue.

[0042] [0040] As shown in FIG. 3, if the torque for moving the bone (with the attached tracking element 12) is perfectly parallel to the sagittal plane, then the determined F-E axis 24 is on the coronal plane and passes through femoral head 18. However, moving the femur in flexion and extension is a manual step so it is not realistic to assume that torque is perfectly parallel to the sagittal plane. Nonetheless, the determined F-E axis still passes through the femoral head of the femur even if the femur 10 is rotated out-of-plane from the sagittal plane. An example of out-of plane movement is shown in FIG. 4. A first fitted circle 20 is shown that was calculated using the recorded locations of the tracking element 12 as the femur 10 was flexed and extended perfectly parallel to the sagittal plane (the fitted circles are shown as if the femur was moved in and out of the page). A second fitted circle 28 is shown (in dotted lines) that was calculated using the recorded locations of the tracking element 12 as the femur was flexed and extended out-of-plane from the sagittal plane. In either case, the calculated F-E axis 24 normal to the center of first fitted circle 20 and the calculated F-E axis 24' normal to the center of the second fitted circle 28 both run through the femoral head center 18. While this might introduce a small amount of error "β" when refining the registration, it has been determined through experimentation that these errors have a minimal effect on the registration accuracy and this method is still more accurate than conventional registration methods.

[0043] Either before or after the F-E axis 24 is determined, the computer may perform a first registration of the bone data to the bone. Here, the bone data is a bone model 30, where the bone model 30 includes a bone landmark (femoral head center 35) located at a pre-determined, or saved, location with respect to the bone model 30. The bone landmark may be saved in the software as a point on the bone model 30, where the location of this saved point represents the location of the femoral head center 35 with respect to the bone model 30. As shown in FIG. 5, the computer may perform the first registration by matching a plurality of digitized points 31 collected on the surface of the distal femur to a plurality of corresponding points on the bone model using an ICP algorithm. Alternatively, the first registration may be performed using other registration techniques known in the art including, for example: matching digitized points collected on the surface of the bone to a surface of a bone model; morphing a generic bone model to a plurality of digitized points collected on the bone; shape matching a bone model to a plurality of digitized points collected on the bone; mapping the bone data to light data collected from a camera system viewing structured light projected on the bone; using machine vision, machine learning, or artificial intelligence to map the bone data to the bone; as well as any other techniques to determine a first registration, or transformation matrix, of the bone data to the bone. It should be appreciated that the points may be collected on the surface of the bone using a digitizer, laser scanner, or the surface of the bone may captured with a camera system, as well as any other technique. Performing the first registration provides a transformation matrix between the bone model 30 and the bone 10. As can be seen in FIG. 5, the distal region of the bone model 30 is closely mapped to the distal region of the bone 10 since the digitized points were collected on the exposed distal region of the bone 10 and mapped to corresponding points on the distal region of the bone model 30. After the first registration, the transformation matrix is post-processed to refine the registration by rotating the bone model 30 (or transformation matrix) in flexion-extension to approximately

align the femoral head center 32 associated with the bone model 30 to the determined F-E axis 24.

[0044] As used herein, the term "approximately align" refers to at least one of: aligning a bone landmark associated with the bone data to the closest point possible to the determined axis 24, which may also be referred to as minimizing the distance between: (i) a bone landmark associated with the bone data; and (ii) the determined axis 24; aligning a bone landmark associated with the bone data within a predefined distance, or a pre-defined range of distances, from the determined axis 24; and aligning a bone landmark associated with the bone model coincident with the determined axis 24. In particular embodiments, the registration is refined by rotating the bone data, or transformation matrix, in only the flexion-extension DoF. This refining of the registration may also be referred to herein as performing a second registration of the bone data to the bone.

[0045] Rotating the bone data in a single rotational DoF to align the femoral head center 32 associated with the bone model 30 to the determined F-E axis 24 may introduce translational errors to the registration. The first registration (e.g., using an ICP algorithm) may be programmed to make a balance between rotational DoFs and translational DoFs to keep the distances of all the corresponding points between the bone model and the bone as minimal as possible. Modifying the rotational part of the registration (when refining the first registration) without changing the translation part may further increase the translational error of the registration. FIG. 6 shows the distal portion of the bone model 30 registered to the distal portion of the bone 10 following the refined registration (e.g., the second registration). Here, the refined registration introduced anterior-posterior (A-P) translation error 24 and proximal-distal (P-D) translational error 36 to the first registration. To reduce these translational errors (34, 36), the refined registration may be re-refined. This re-refinement may also be referred to herein synonymously as performing a third registration of the bone data to the bone. According to

some inventive embodiments, the translation error in the refined registration (e.g., the second registration) is reduced by: (i) calculating the mean of signed residuals in the anterior region and the mean of signed residuals in the distal region; (ii) translating the bone data in the anterior direction toward the calculated mean of signed residuals in the anterior region; and translating the bone data in the distal direction toward the calculated mean of signed residuals in the distal region. Re-refining the registration may be accomplished by translating the transformation matrix that resulted from the refined registration in the anterior/distal directions and the calculated amount. This may be repeated several times to reduce the overall error to a minimum or a pre-selected threshold. It should be appreciated that for certain applications, translational errors may be introduced in other areas of the bone (e.g., in the medial-lateral direction of the bone) where the same process may be executed to reduce errors in those translational DoF. Likewise, rotational errors may be introduced by either the first registration or the refined registration, where the residual errors in the registration may be determined to rotate the bone data in one or more DoF to reduce the calculated errors.

[0046] In particular inventive embodiments, the first registration and the second registrations, as described above, may be re-ordered. For example, a first registration may be performed where a bone landmark associated with the bone model is approximately aligned to a determined axis of rotation of the bone, and then a second registration is performed with a conventional registration technique (e.g., ICP). In other embodiments, the first registration and the second registration, regardless of order, may be performed simultaneously.

[0047] While the embodiments described herein refer to a flexion-extension axis, rotating the femur in flexion/extensions, and rotating the bone data in flexion-extension, it is appreciated that other rotational axes and degrees of freedom may be advantageous for other applications. In computer-assisted TKA, it has been found that the registration errors using conventional registration techniques are particularly high in the flexion-extension DoF

compared to the other DoF. In addition, the flexion-extension DoF is particularly important from a clinical standpoint when positioning the implant on the femur and has particular implications on balancing the gaps of the knee and the anterior notching of the implant. Therefore, improving the registration in the flexion-extension DoF is particularly advantageous for TKA procedures. However, as previously mentioned, there may be other applications, bone types, or surgical procedures where the system and methods described herein may be applied to improve registration of bone data to a bone in other rotational degrees-of-freedom (e.g., varus-valgus rotation, internal-external rotation). It should further be appreciated that more than one rotational axis may be determined for registration. For example, in certain applications, it may be beneficial to determine the F-E rotational axis and the varus-valgus (V-V) rotational axis, where a bone landmark associated with the bone data is first approximately aligned with the F-E axis and then the V-V axis.

[0048] Furthermore, it should be appreciated that other bone landmarks associated with bone data may be used to refine the registration, either for the examples described herein or for other applications/situations. It is contemplated that the bone landmarks may be any point, axis, or plane associated with bone data. Examples of these bone landmarks illustratively include: a F-E axis associated with the bone data that runs through the femoral head center; a mechanical axis of the bone data; an anatomical axis of the bone data; a condylar axis of the bone data; a coronal, sagittal, or axial plane associated with the bone data; and anatomical points associated with bone data (e.g., femoral head center associated with a femoral bone model, most distal portion of a bone model, intercondylar notch of a femoral bone model, etc.).

[0049] Overall, embodiments of the methods and system described herein circumvent the conventional need to fit a mathematical model sphere to wide ranging movements of a tracked bone in order to calculate the femoral head center of the bone for registration. Moving the bone in only a single rotational DoF (e.g., flexion-extension) to fit a circle to the tracked motion

requires much less bone range of-motion and tracking field-of-view. The simulated accuracy of the F-E axis registration as described herein is better than fitting a mathematical model sphere to find the femoral head center on the bone because the impact of the two main assumptions, as described above (i.e., the femoral head is a perfect sphere and the pelvis remains stationary during the movement of the femur), are decreased. Again, with the system and methods described herein, there is no need to use or calculate the femoral head center on the bone, instead only the F-E rotation axis that runs through the femoral head is needed to accurately register bone data to the bone.

[0050] According to still other inventive embodiments, after the bone data is registered to the bone with the methods described herein, a CAS device may execute operating data, also registered to the bone, to assist in forming cut surfaces on the remaining bone according to the surgical plan. The operating data is also registered to the bone by way of: (i) the operating data is defined relative to the bone data; and (ii) the bone data is registered to the bone using the registration methods described herein.

Computer-Assisted Surgical System

[0051] Referring now to FIG. 7, an embodiment of an inventive computer-assisted surgical (CAS) system 100 is shown. The CAS system 100 generally includes a CAS device, a computing system 104, and a tracking system 106. Examples of a CAS device include a serial-chain surgical robot for controlling an end-effector, a parallel surgical robot for controlling an end-effector, and other CAS devices as described herein. In particular embodiments, the CAS device is a 2-DoF device 102, as shown in greater detail in FIGs. 8A and 8B. The computing system 104 generally includes hardware and software for executing a surgical procedure. By way of example but not limitation, the computing system 104 is configured to control the actuation of the working portion 204 relative to the hand-held portion 202 of the 2-DoF device

102 to maintain alignment of the end-effector axis 207 (FIG. 8B) coincident with a virtual plane having a pre-defined location with respect to the bone. The computing system 104 may generate control signals to accurately maintain the end-effector axis 207 coincident with the virtual plane based on: a) a tracked location of the virtual plane as registered to the location of the bone; and b) the tracked POSE of the 2-DoF device 102. The computing system 104 in some inventive embodiments includes a non-transitory memory in which data, software, or a combination thereof are stored.

[0052] The computing system 104 of the computer-assisted surgical system 100 may include: one or more device computers (108, 109); a planning computer 110; a tracking computer 111; and peripheral devices. Each computer may include one or more processors. In some inventive embodiments, a device computer 109 is mounted on or housed in the 2-DoF device 102. Processors operate in the computing system 104 to perform computations and execute software associated with the methods described herein. The device computer(s) (108, 109), the planning computer 110, and the tracking computer 111 may be separate entities as shown in FIG. 7, or it is also contemplated that the computations described herein may be executed on one (or more) computers depending on the configuration of the computer-assisted surgical system 100. For example, the tracking computer 111 may record locations of a tracking element, determine an axis of rotation of the bone, register bone data to the bone, and have operational data to control the 2-DoF device 102, all without the need for a device computer (108, 109). In other words, a single computer or multiple computers may perform the computations described herein. Furthermore, if desired, any combination of the device computers (108, 109), planning computer 110, and/or tracking computer 111 may be connected together via a wired or wireless connection. In addition, the data gathered by, and/or the operations performed by, the tracking computer 111 and device computer(s) (108, 109) may work together to control the 2-DoF device 102 and, as such, the data gathered by, and/or the

operations performed by, the tracking computer 111 and device computer(s) (108, 109) to control the 2-DoF device 102 may be referred to herein synonymously as a "control system." It is further appreciated that one or more of the computers may be readily located remote from the surgical site. Cloud-based computation is also contemplated in the present invention.

[0053] The peripheral devices allow a user to interface with the computing system 104 and may include, but are not limited to, one or more of the following: one or more user-interfaces, such as a display or monitor 112 to display a graphical user interface (GUI); and user-input mechanisms, such as a keyboard 114, a mouse 122, a pendent 124, a joystick 126, or a foot pedal 128. If desired, the monitor 112 may have touchscreen capabilities, and/or the 2-DoF device 102 may include one or more input mechanisms (e.g., buttons, switches, virtual reality or haptic glove controller, etc.). Another peripheral device may include a tracked digitizer 130 to assist in the registration process. Tracking array 120c is assembled to the digitizer 130 to permit the tracking system 106 to track the POSE of the digitizer 130 in space. The digitizer 130 may further include one or more user input mechanisms to provide input to the computing system 104. For example, a button on the digitizer probe 130 may allow the user to signal to the computing system 104 to digitize a point on the bone during the point collection process during a first registration of the bone data to the bone.

[0054] The device computer(s) (108, 109) may include one or more processors, controllers, software, data, utilities, and/or storage medium(s) such as RAM, ROM or other non-volatile or volatile memory to perform functions related to registration and/or the operation of the 2-DoF device 102. By way of example but not limitation, one or more of the device computers (108, 109) may include software to control the 2-DoF device 102, e.g., generate control signals to move the working portion 204 relative to the hand-held portion 202 to a targeted POSE, receive and process tracking data, control the rotational or oscillating speed of the end-effector 206 by controlling motor 205, execute calibration routines, provide workflow instructions to the user

throughout a medical procedure, as well as any other suitable software, data or utilities required to successfully perform the procedure in accordance with embodiments of the invention. In particular embodiments, the device computer comprises a processor for executing software to register the bone data to the bone. The computer may be configured to perform the steps of the methods described herein, including: determine an axis of rotation of a bone using recorded locations of a tracking element affixed to the bone while the bone is rotated about the axis; perform a first registration of bone data to the bone, the bone data comprising a bone landmark; and refining the registration by rotating the bone data to approximately align the bone landmark with the determined axis of rotation. The computer may be further configured to fit a circle to recorded locations of the tracking element and calculate an axis normal to the fitted circle and located at the center of the circle, where the axis represents the axis of rotation of the bone. The computer may be further configured to perform at least one or more of the following: perform a first registration of the bone as described herein; refine the first registration using the methods described herein; and re-refine the refined registration using the method described herein. It should be appreciated that the tracking computer 111 may also be configured to perform any of the aforementioned registration steps, or any other steps associated with the methods described herein.

[0055] In some inventive embodiments, the system 100 may include a first device computer 108 located separate from the 2-DoF device 102 and a second device computer 109 housed in the 2-DoF device 102 to provide on-board control. The first device computer 108 may be dedicated to the control of the surgical workflow via a GUI, the registration process and the associated calculations, the display of 3-D models and 3-D model manipulation or animation, as well as other processes. The second device computer 109, also referred to herein as an on-board device computer, may be dedicated to the control of the 2-DoF device 102. For example, the on-board device computer 109 may compute and generate the control signals for the

actuator motors (210a, 210b) based on: i) received signals/data corresponding to the real-time POSE of the 2-DoF device from the tracking system; and ii) received signals/data corresponding to the real-time POSE of the virtual plane computed by first device computer 108. The on-board device computer 109 may also send internal data (e.g., operational data, actuator/screw position data, battery life, etc.) via a wired or wireless connection. In some inventive embodiments, wireless optical communication is used to send and receive the signals/data described herein. Details about bi-directional optical communication between a 2-DoF device 102 and a tracking system 106 are further described below.

[0056] The planning computer 110 in some inventive embodiments is dedicated to planning the procedure. By way of example but not limitation, the planning computer 110 may contain hardware (e.g., processors, controllers, memory, etc.), planning software, data, and/or utilities capable of: receiving, reading, and/or manipulating medical imaging data; segmenting imaging data; constructing and manipulating three-dimensional (3D) virtual models; defining the location of one or more bone landmarks associated with bone data; storing and providing computer-aided design (CAD) files such as 3-D implant models or other hardware CAD files; planning the POSE of implant models relative to bone data; defining the location of operational data (e.g., cut-files, virtual planes, virtual boundaries, virtual axes, virtual targets) relative to bone data; generating the surgical planning data for use with the system 100; and providing other various functions to aid a user in planning the surgical procedure. Any of the aforementioned capabilities may be performed automatically by the planning software or based on user input by way of one or more software tools available in the planning software. The final surgical plan data may include: one or more images of the bone or virtual models of the bone; bone registration data (e.g., an identified location of the femoral head center associated with the bone data); subject identification information; the POSE of one or more pins, screws,

implants, grafts, fixation hardware defined relative to the bone data; and/or the POSE of operational data defined relative to the bone data.

[0057] The device computer(s) (108, 109) and the planning computer 110 may be directly connected in the operating room, or the planning computer 110 may exist as separate entities outside the operating room. The final surgical plan is readily transferred to a device computer (108, 109) and/or tracking computer 111 through a wired (e.g., electrical connection) or a wireless connection (e.g., optical communication, WiFi, Bluetooth); or transferred via a non-transient data storage medium (e.g., a compact disc (CD), or a portable universal serial bus (USB drive)). As described above, the computing system 104 may comprise one or more computers, which multiple processors capable of performing the functions of the device computer 108, the tracking computer 111, the planning computer 110, or any combination thereof.

[0058] The tracking system 106 of the present invention generally includes a detection device to determine the POSE of an object relative to the position of the detection device. In some inventive embodiments, the tracking system 106 is an optical tracking system such as the optical tracking system described in U.S. Pat. No. 6,061,644 (which is hereby incorporated herein by reference), having two or more optical detectors 107 (e.g., cameras) for detecting the position of fiducial markers arranged on rigid bodies or integrated directly on the tracked object. By way of example but not limitation, the fiducial markers (120a, 120b, 120c, 120d, 212) may include an active transmitter, such as a light emitting diode (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 (120a, 120b, 120c, 120d, 212) arranged on a rigid body, or integrated on a device, is sometimes referred to herein as a tracking array, where each tracking array has a unique geometry/arrangement of fiducial markers (120a, 120b, 120c, 120d, 212), 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.

[0059] In specific embodiments, the tracking system 106 may be incorporated into an operating room light 118 as shown in FIG. 1, located on a boom, a stand, or built into the walls or ceilings of the operating room. The tracking system computer 111 includes tracking hardware, software, data, and/or utilities to determine the POSE of objects (e.g., bone structures, the 2-DoF device 102) in a local or global coordinate frame. The output from the tracking system 106 (i.e., the POSE of the objects in 3-D space) is referred to herein as tracking data, where this tracking data may be readily communicated to the device computer(s) (108, 109) through a wired or wireless connection. In a particular embodiment, the tracking computer 106 processes the tracking data and provides control signals directly to the 2-DoF device 102 and/or device computer 108 based on the processed tracking data to control the position of the working portion 204 of the 2-DoF device 102 relative to the hand-held portion 202. In another embodiment, the tracking computer 106 sends tracking data to a receiver located on the 2-DoF device 102, where an on-board device computer 109 generates control signals based on the received tracking data. In a specific embodiment, the tracking computer 106 is configured to record locations of a tracking element affixed to the bone while the bone is rotated about an axis in accordance with embodiments of the present invention. The recorded locations may be transferred to the device computer (108, 109) for further processing. In some embodiments, the device computer (108, 109) receives the raw data generated from the optical detectors 107 of the tracking system 106 and based on the raw data, records the locations of the tracking element affixed to the bone while the bone is rotated about an axis.

[0060] The tracking data is determined in some inventive embodiments using the position of the fiducial markers detected from the optical detectors and operations/processes such as image processing, image filtering, triangulation algorithms, geometric relationship processing,

registration algorithms, calibration algorithms, and coordinate transformation processing. [0057] It should be appreciated that in some embodiments of the present invention, other tracking systems are incorporated with the surgical system 100. By way of example but not limitation, the surgical system 100 may include an electromagnetic field tracking system, ultrasound tracking systems, accelerometers and gyroscopes, and/or a mechanical tracking system. The replacement of a non-mechanical tracking system with other tracking systems will be apparent to one skilled in the art in view of the present disclosure. In one form of the present invention, the use of a mechanical tracking system may be advantageous depending on the type of surgical system used such as the computer-assisted surgical system described in U.S. Pat. No. 6,322,567; assigned to the assignee of the present application and incorporated herein by reference in its entirety.

[0061] FIGS. 8A and 8B are schematic views showing the 2-DoF prior art device 102 in greater detail. More particularly, FIG. 8A shows the 2-DOF device 102 in a first working POSE, and FIG. 8B illustrates the 2-DOF device 102 in a second working POSE. The 2-DoF device 102 includes a hand-held portion 202 (or handle) and a working portion 204. The hand-held portion 202 includes an outer casing 203 of ergonomic design which can be held and wielded by a user (e.g., a surgeon). In particular inventive embodiments, the 2-DoF device 102 is intended to be fully supported by the hands of the user in that there are no additional supporting links connected to the 2-DoF device 102 and the user supports the full weight of the 2-DoF device 102. The working portion 204 comprises an end-effector 206 having an end-effector axis 207. The end-effector 206 may be removably coupled to the working portion 204 (via a coupler (e.g., chuck)) and driven by a motor 205. The hand-held portion 202 and working portion 204 are connected to one another; for example, by a first linear actuator 207a and a second linear actuator 207b in order to control the pitch and translation of the working portion 204 relative to the hand-held portion 202, as will hereinafter be discussed in further detail. In

a particular embodiment, the working portion 204 is removably coupled to the hand-held portion 202 to permit different types of working portions to be assembled to the hand-held portion 202. For example, a first working portion 204 may illustratively be a laser system having components to operate a laser for treating tissue, a second working portion 204 may illustratively be a drill for rotating a bone pin, and a third working portion 204 may illustratively be an oscillating saw.

[0062] A tracking array 212, having three or more fiducial markers, is preferably rigidly attached to the working portion 204 in order to permit the tracking system 106 (FIG. 1) to track the POSE of the working portion 204. The three or more fiducial markers may, alternatively, be integrated directly with the working portion 204. The 2-DoF device 102 may further include one or more user input mechanisms such as triggers (e.g., trigger 214) or button(s). The user input mechanisms may permit the user to perform various functions illustratively including: activating or deactivating the motor 205, activating or deactivating the actuation of the working portion 204 relative to the hand-held portion 202, notifying the computing system 104 to change from targeting one virtual plane to a subsequent virtual plane, and pausing the medical procedure.

[0063] Within the outer casing of the hand-held portion 202 is the first linear actuator 207a and the second linear actuator 207b. Each linear actuator (207a, 207b) may include a motor (210a, 210b) to power a screw (216a, 216b) (e.g., a lead screw, a ball screw), a nut (218a, 218b), and a linear rail (208a, 208b). In some inventive embodiments, the motors (first motor 210a, second motor 210b) are electric servo-motors that bi-directionally rotate the screws (216a, 216b). Motors (210a, 210b) may also be referred to herein as linear actuator motors. The nuts (218a, 218b) (e.g,, ball nuts, elongated nuts) are operatively coupled to the screws (216a, 216b) to translate along the screws (216a, 216b) as each screw is rotated by its respective motor (210a, 210b). A first end of each linear rail (208a, 208b) is coupled to a corresponding nut

(216a, 216b) and the opposing end of each linear rail (208a, 208b) is coupled to the working portion 204 via hinges (220a, 220b) such that the hinges (220a, 220b) allow the working portion 204 to pivot relative to the linear rails (208a, 208b). The motors (210a, 210b) power the screws (216a, 216b) which in turn cause the nuts (218a, 218b) to translate along the axis of the screws (216a, 216b). Translation of nuts (218a, 218b) along ball screws (216a, 216b), respectively, causes translation of front linear rail 208a and back linear rail 208b, respectively, whereby to permit (a) selective linear movement of working portion 204 relative to hand-held portion 202, and (b) selective pivoting of working portion 204 relative to hand-held portion 202 of 2-DoF device 102. Accordingly, the translation "d" and pitch "α" (FIG. 2B) of the working portion 204 may be adjusted depending on the position of each nut (218a, 218b) on their corresponding screw (216a, 216b). A linear guide 222 (FIG. 2A) may further constrain and guide the motion of the linear rails (208a, 208b) in the translational direction "d". In a particular embodiment, the nuts (216a, 216b) are elongated and couple directly to the working portion 204 via the hinges (220a, 220b), in which case the linear rails (208a, 208b) are no longer a component of the linear actuators (207a, 207b). It should be appreciated that other linear actuation mechanisms/components may be used to adjust the POSE of the working portion 204 relative to the hand-held portion 202 such as linear motors, pneumatic motors, worm drives and gears, rack and pinion gears, and other arrangements of motors and transmissions.

[0064] The 2-DoF device 102 may receive power via an input/output port (e.g., from an external power source) and/or from on-board batteries (not shown).

[0065] The motors (205, 210a, 210b) of the 2-DoF device 102 may be controlled using a variety of methods. By way of example but not limitation, according to one method of the present invention, control signals may be provided via an electrical connection to an input/output port. By way of further example but not limitation, according to another method of the present invention, control signals are communicated to the 2-DoF device 102 via a

wireless connection, thereby eliminating the need for electrical wiring. The wireless connection may be made via optical communication. In certain inventive embodiments, the 2-DoF device 102 includes a receiver for receiving control signals from the computing system 104 (FIG. 3). The receiver may be, for example, an input port for a wired connection (e.g., Ethernet port, serial port), a transmitter, a modem, a wireless receiver (e.g., Wi-Fi receiver, Bluetooth® receiver, a radiofrequency receiver, an optical receiver (e.g., photosensor, photodiode, camera)), or a combination thereof. The receiver may send control signals from the computing system 104 directly to the motors (205, 210a, 210b) of the 2-DoF device 102, or the receiver may be in communication with a computer (e.g., an onboard device computer 109), where the computer processes signals received by the receiver and then generates the control signals for the motors (205, 210a, 210b) based on the received signals (e.g., the received signals may be a current location of the working portion 204 relative to the tracked location of the virtual plane as registered to the bone as determined by a tracking system, where the on-board computer 109 calculates the current error between the end-effector axis and the virtual plane based on those signals to determine the motor controls needed to re-align the end-effector axis with the virtual plane).

Other Embodiments

[0066] 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. It should be understood that various changes may be made in the function and arrangement of elements without departing from the scope as set forth in the appended claims and the legal equivalents thereof.

CLAIMS

1. A method for registering bone data to a bone, comprising:

recording locations of a tracking element associated with the bone while the bone is rotated about an axis;

determining the axis of rotation using the recorded locations; and

registering the bone data to the bone, the bone data comprising a bone landmark located at a determinable or pre-determined location with respect to the bone data, wherein an approximate alignment of the bone landmark with the determined axis is used for the registration.

2. The method of claim 1 wherein determining the axis of rotation comprises:

fitting a circle to the recorded locations; and

calculating an axis normal to the fitted circle and located at the center of the circle.

3. The method of claim 1 wherein the axis of rotation is a flexion-extension axis.

4. The method of claim 1 wherein registering the bone data to the bone further comprises translating the bone data in at least one translational degree-of-freedom (DoF) to reduce residual registration errors.

5. The method of claim 1 wherein the bone data is a bone model.

6. The method of claim 1 wherein the bone is a femur bone, and the bone data is a femoral bone model.

7. The method of claim 6 wherein the bone landmark is the femoral head center of the femoral bone model.

8. The method of any one of claims 1 to 7 wherein the axis is a flexion-extension axis that intersects with the femoral head center of the bone.

9. The method of claim 1 wherein registering the bone data to the bone, comprises:

performing a first registration of the bone data to the bone; and

refining the first registration by rotating the bone data to approximately align the bone landmark with the determined axis.

10. The method of claim 9 wherein bone data is rotated in only one rotational degree of-freedom to approximately align the bone landmark with the determined axis.

11. The method of claim 10 wherein performing the first registration comprises performing at least one of the following registration techniques: (i) point-to-point iterative closest point (ICP); (ii) point-to-surface ICP; (iii) laser scanning; (iv) machine vision; and (v) shape morphing.

12. The method of any one of claims 1 to 7 wherein the tracking element is a tracking array comprising three or more fiducial markers.

13. The method of any one of claims 1 to 7 wherein the locations of the tracking element are recorded while a first end of the bone is rotated about the axis, where the axis is located at an opposing end of the bone.

14. The method of any one of claims 1 to 7 wherein the association between the tracking element and the bone is fixation.

15. A system for registering bone data to bone, comprising:

a tracking system for tracking locations of a tracking element, the tracking element configured to be affixed to a bone; and

a computer comprising a processor configured to:

record locations of the tracking element when the tracking element is affixed to the bone and the bone is rotated about an axis;

determine the axis of rotation using the recorded locations; and

register the bone data to the bone, the bone data comprising a bone landmark located at a determinable or pre-determined location with respect to the bone data, wherein an approximate alignment of the bone landmark with the determined axis is used for the registration.

16. The system of claim 15 wherein the axis of rotation is determined by:

fitting a circle to the recorded locations; and

calculating an axis normal to the fitted circle and located at the center of the circle.

17. The system of claim 16 wherein registering the bone data to the bone further comprises translating the bone data in at least one translational degree-of-freedom to reduce residual registration errors.

18. The system of claim 15 wherein the bone data is a bone model.

19. The system of claim 15 wherein the bone is a femur bone, and the bone data is a femoral bone model.

20. The system of claim 19 wherein the bone landmark is a femoral head center of the femoral bone model.

21. The system of 20 wherein the axis is a flexion-extension axis that intersects with the femoral head center of the bone.

22. The system of claim 15 wherein registering the bone data to the bone, comprises:

performing a first registration of the bone data to the bone; and

refining the first registration by rotating the bone data to approximately align the bone landmark with the determined axis.

23. The method of claim 22 wherein bone data is rotated in only one rotational degree of-freedom to approximately align the bone landmark with the determined axis.

24. The method of claim 22 wherein performing the first registration comprises performing at least one of the following registration techniques: (i) point-to-point iterative closest point (ICP); (ii) point-to-surface ICP; (iii) laser scanning; (iv) machine vision; and (v) shape morphing.

25. The system of any one of claims 15 to 24 wherein the tracking element is a tracking array comprising three or more fiducial markers.

26. The system of any one of claims 15 to 24 wherein the locations of the tracking element are recorded while a first end of the bone is rotated about the axis, wherein the axis located at an opposing end of the bone.

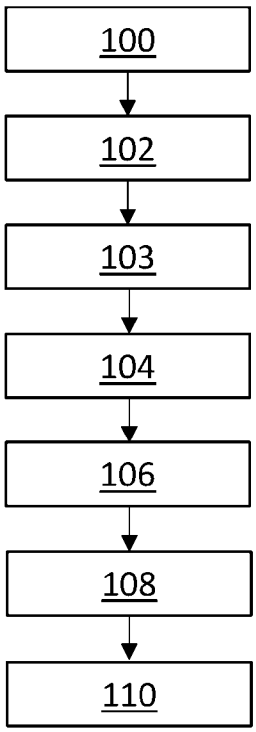

FIG. 1

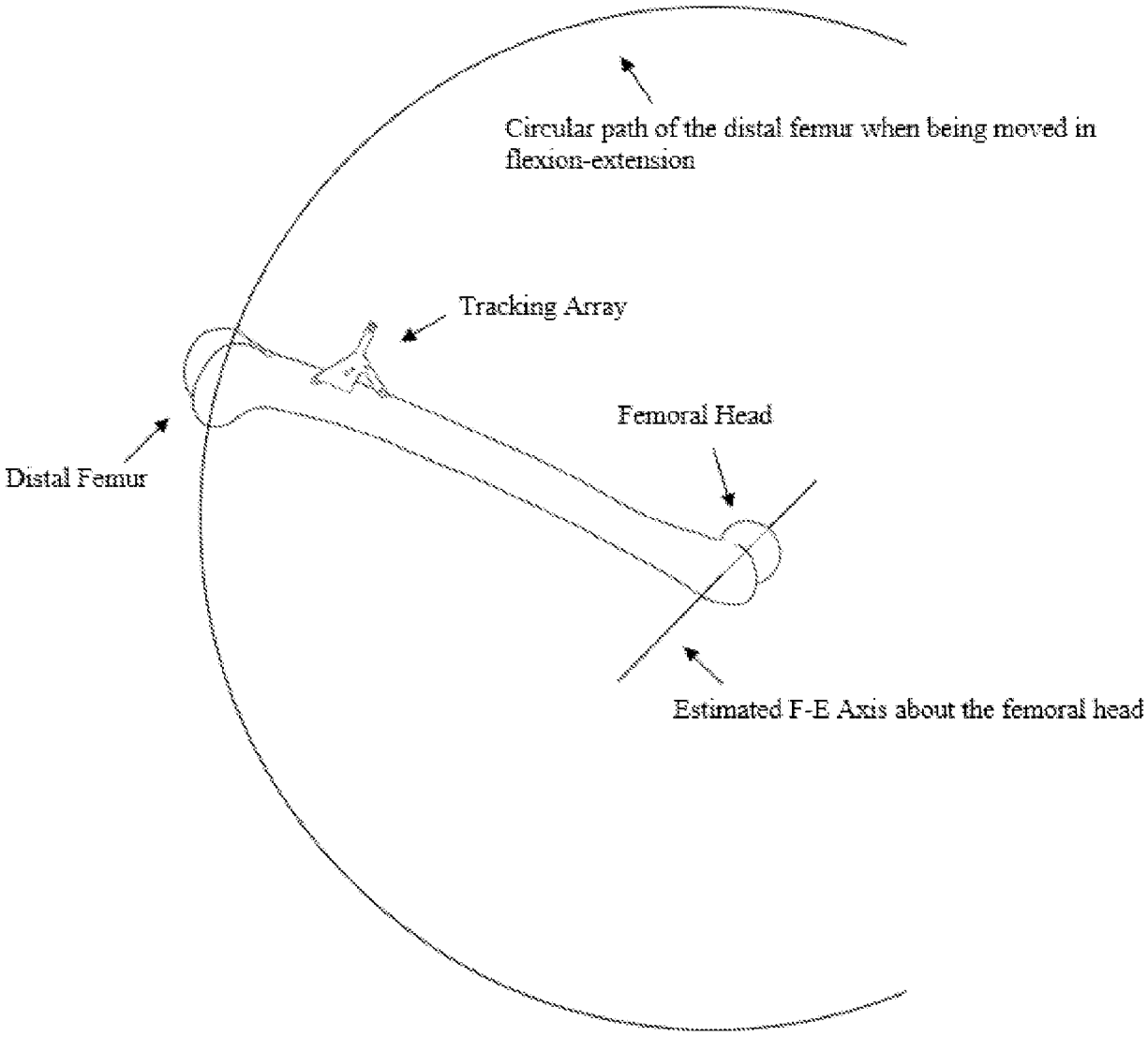
Circular path of the distal femur when being moved in flexion-extension
Tracking Array
Femoral Head
Distal Femur
Estimated F-E Axis about the femoral head

FIG. 2

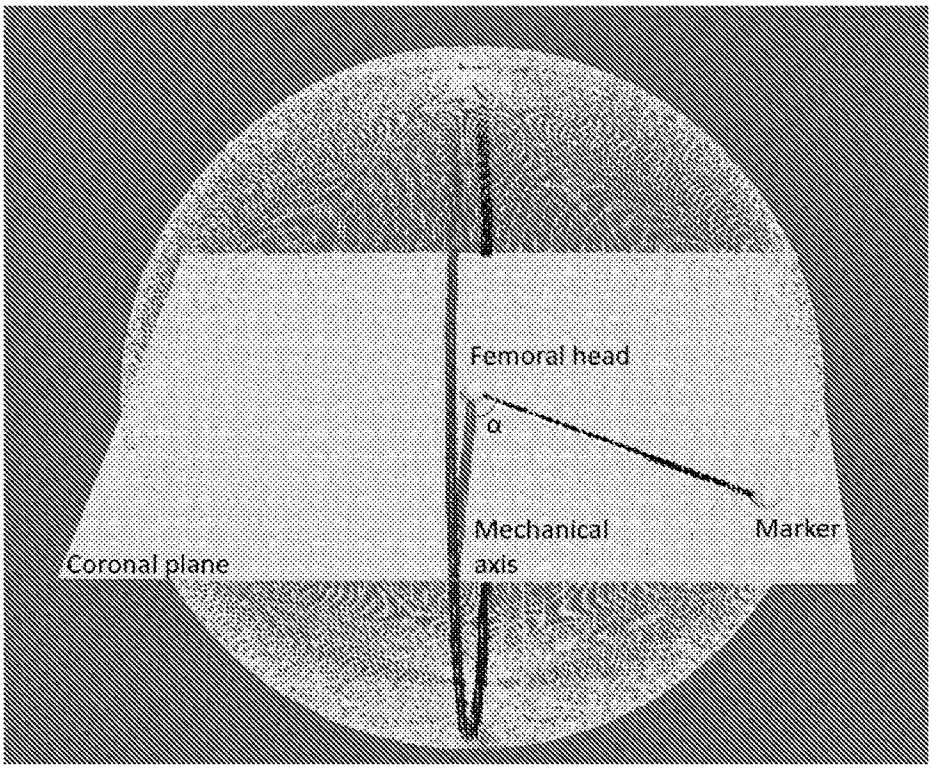

FIG. 3

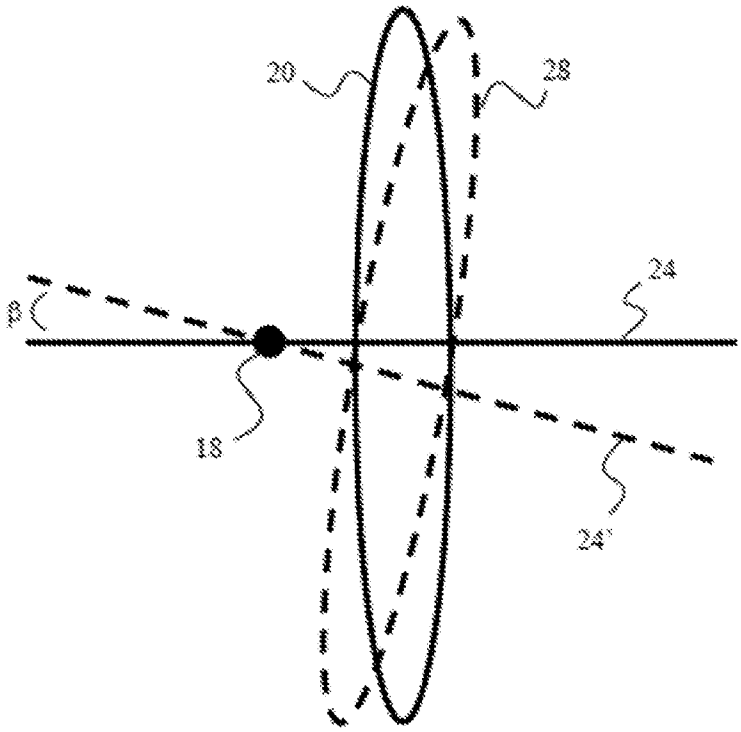

FIG. 4

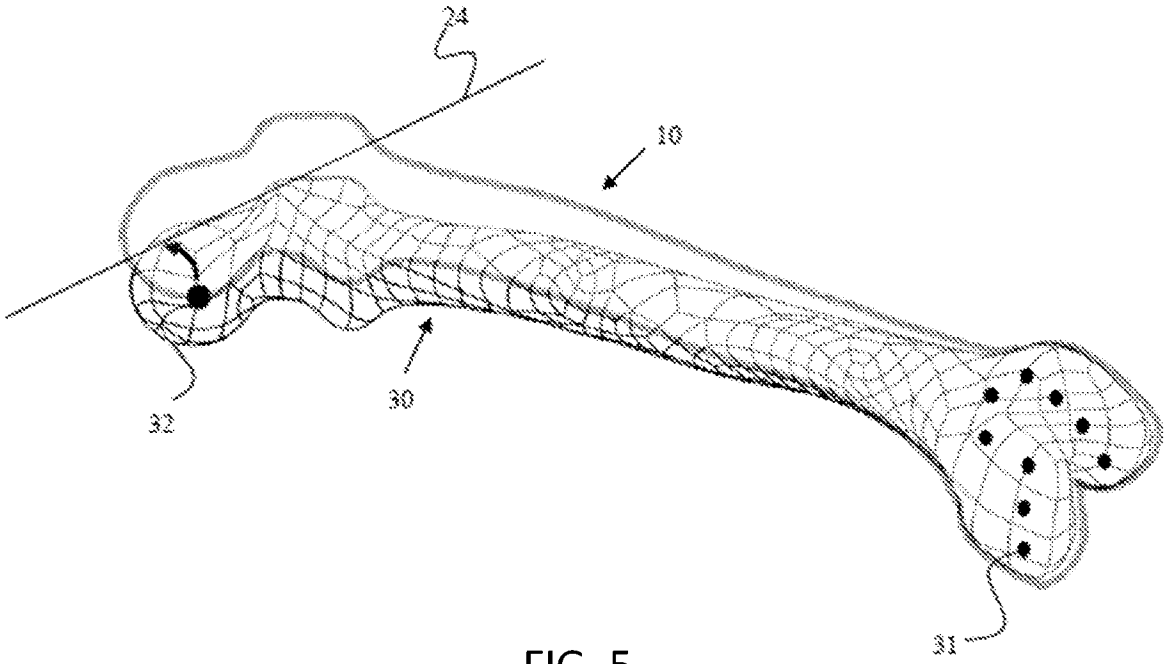

FIG. 5

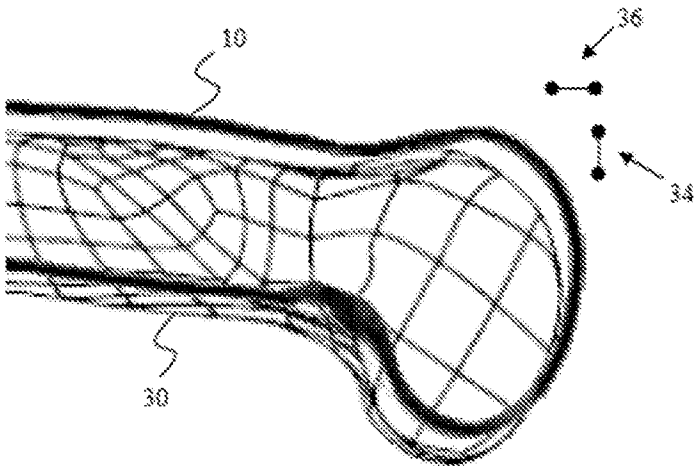

FIG. 6

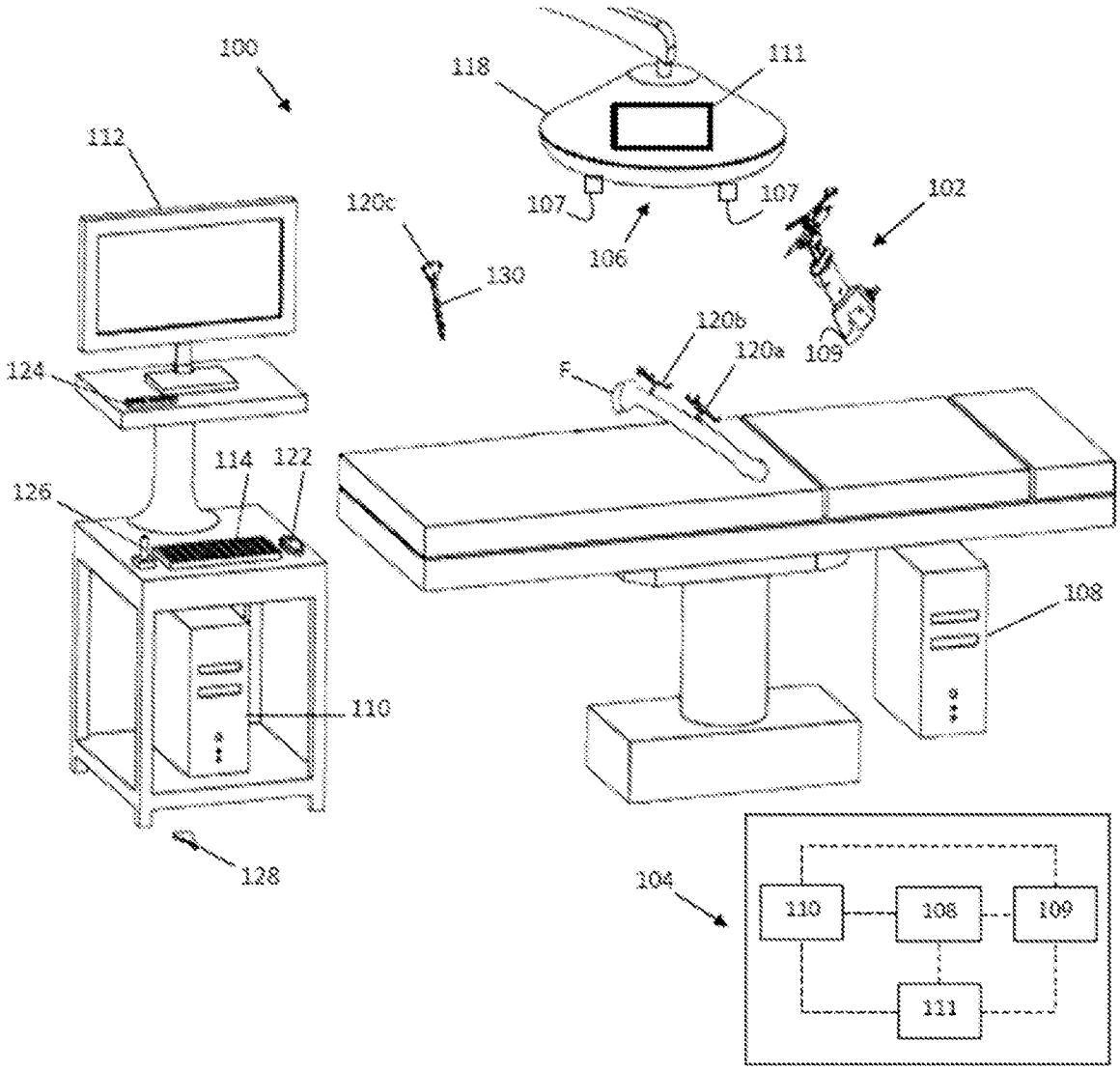
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FIG. 7

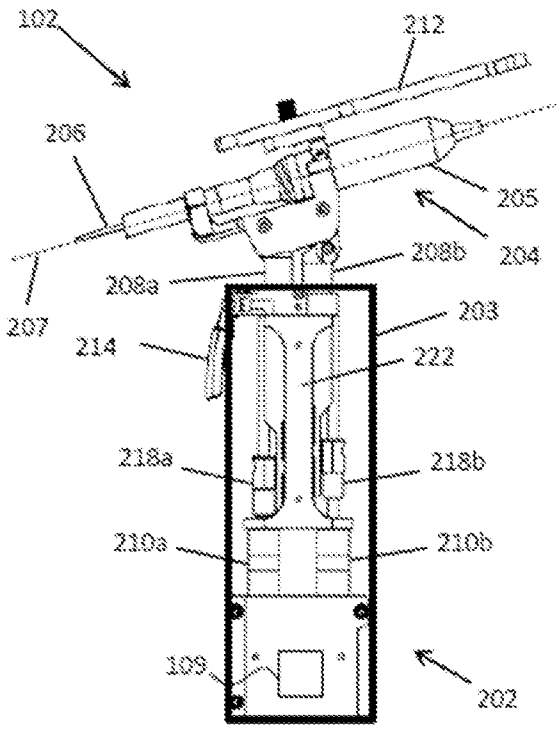
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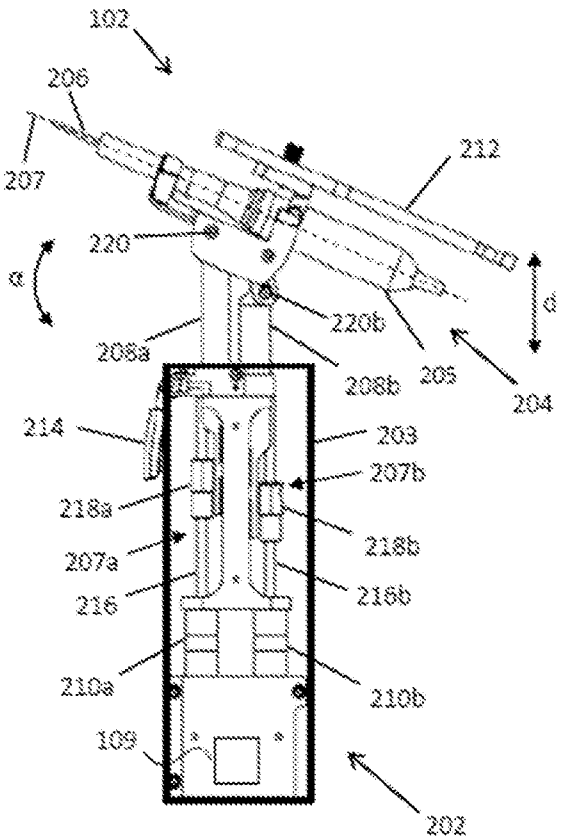
FIG. 8A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202

FIG. 8B