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(54) **IMAGELESS ROBOTIZED DEVICE AND METHOD FOR SURGICAL TOOL GUIDANCE**

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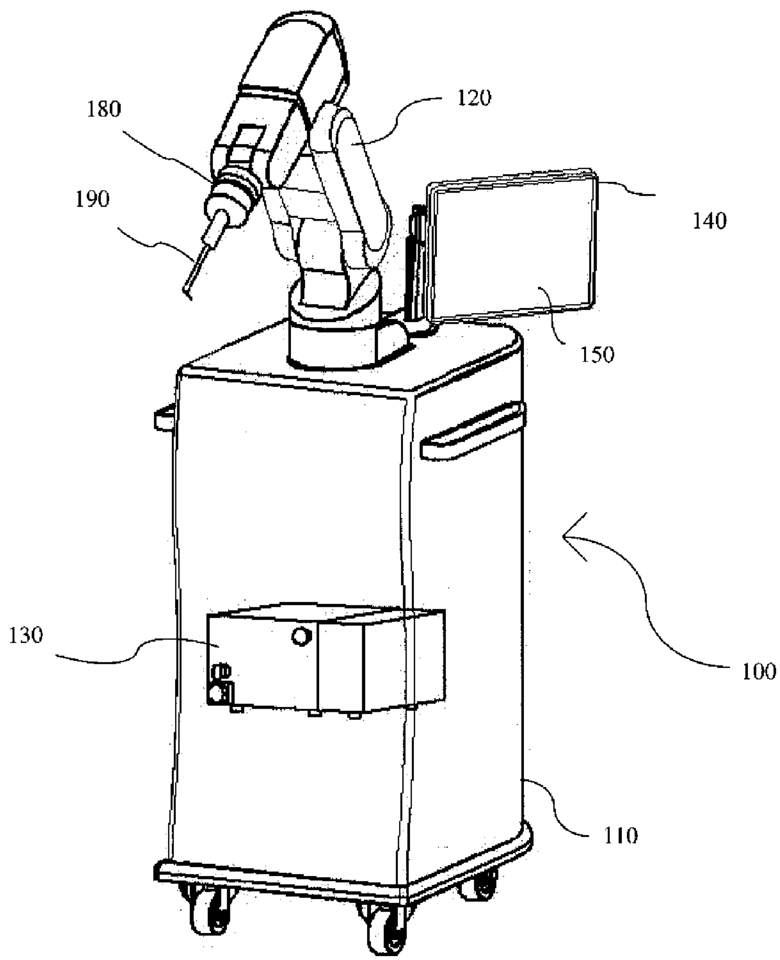
(57) **ABSTRACT**

An imageless robotized device for guiding surgical tools to improve the performance of surgical tasks is provided. The method of using the robotized device may include the steps of: collecting anatomical landmarks with a robot arm; combining landmarks data with geometric planning parameters to generate a position data; and automatically positioning a guiding tool mounted to the robot arm. Particular embodiments for a limb fixation device are also described.



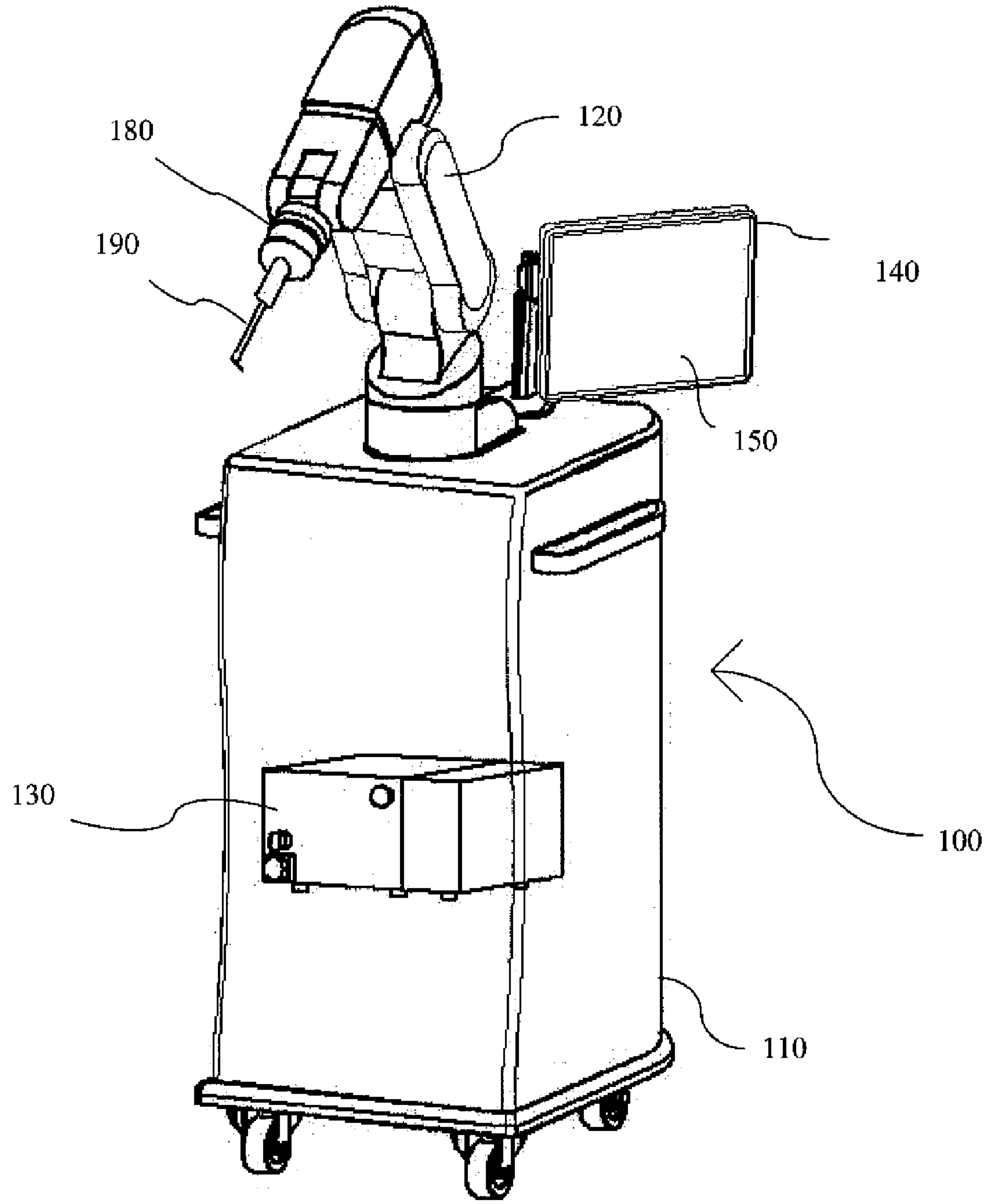


FIG. 1

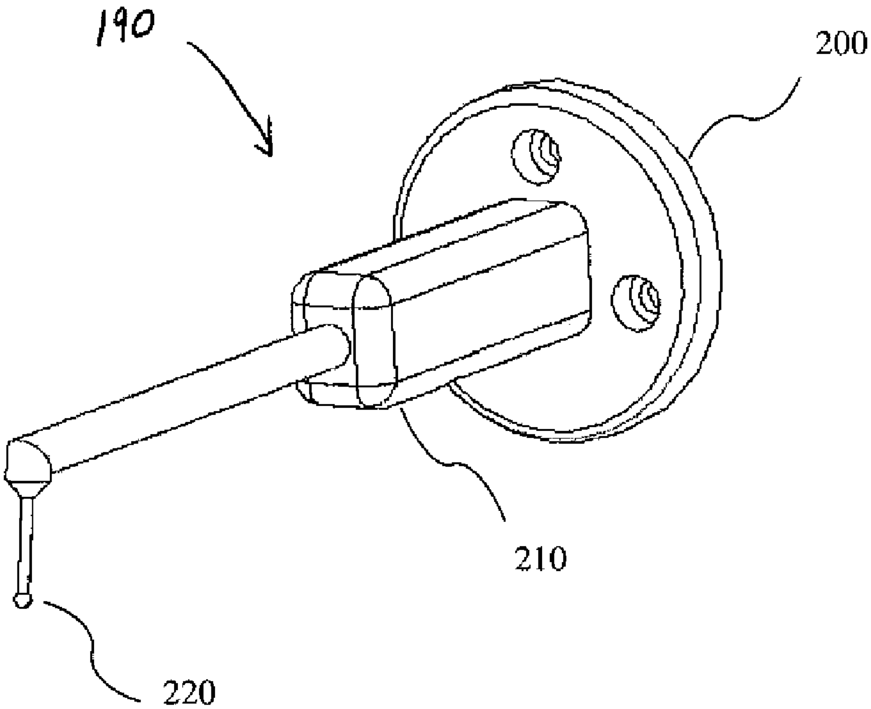


FIG. 2A

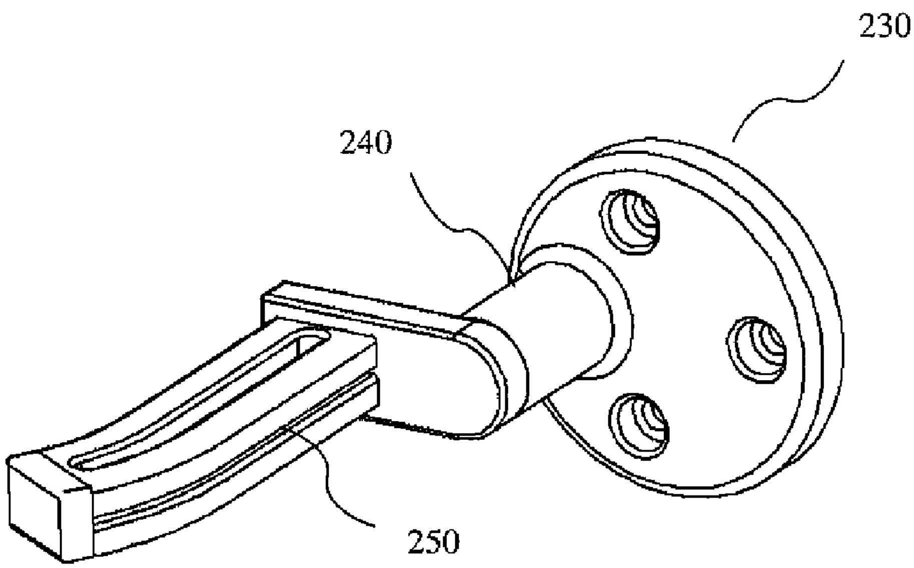


FIG. 2B

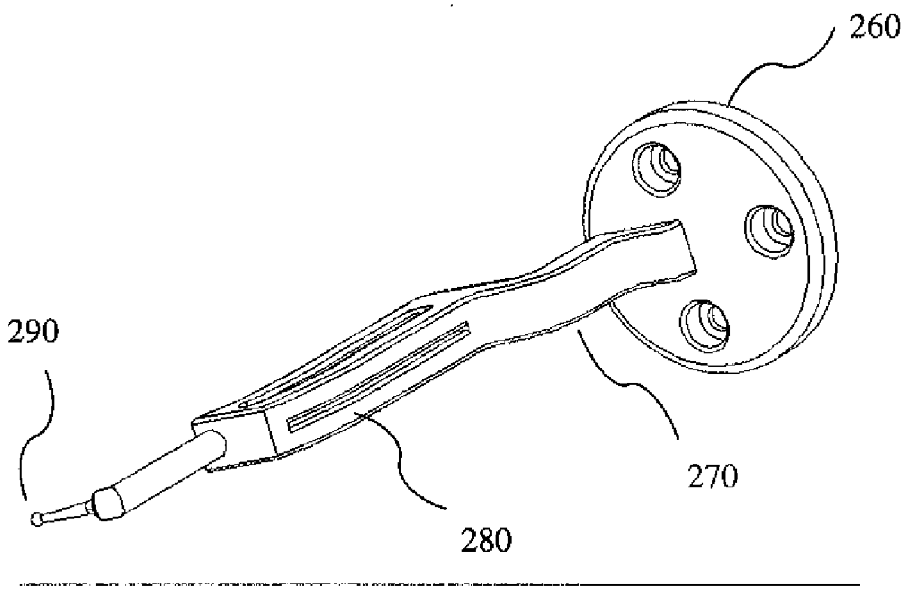


FIG. 2C

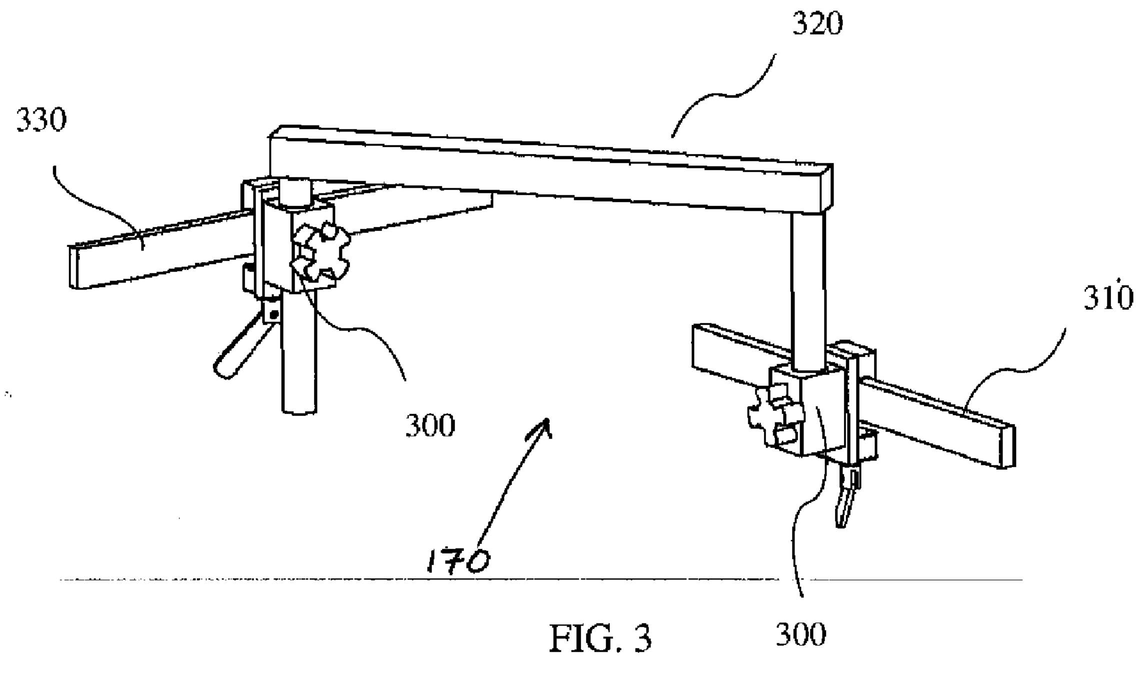


FIG. 3

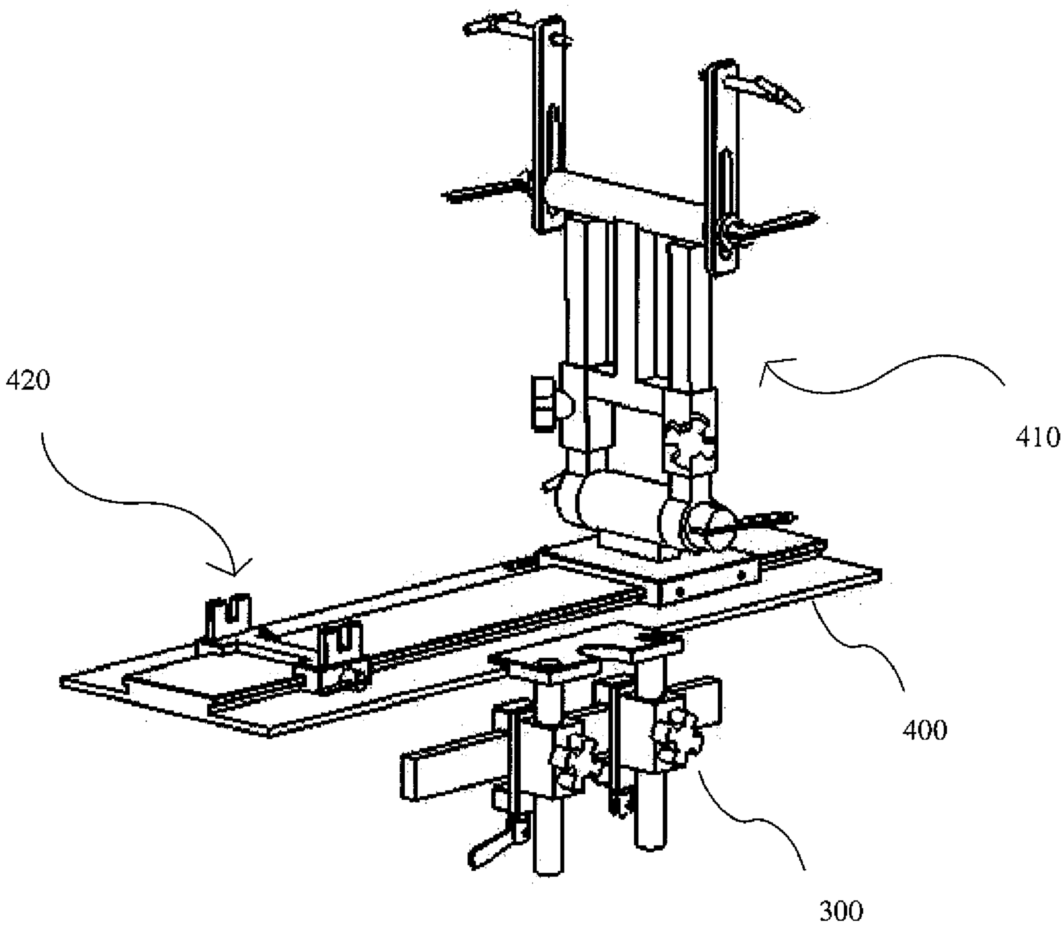


FIG. 4A

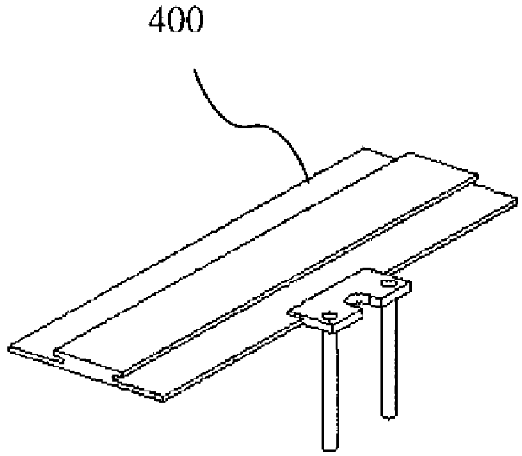


FIG. 4B

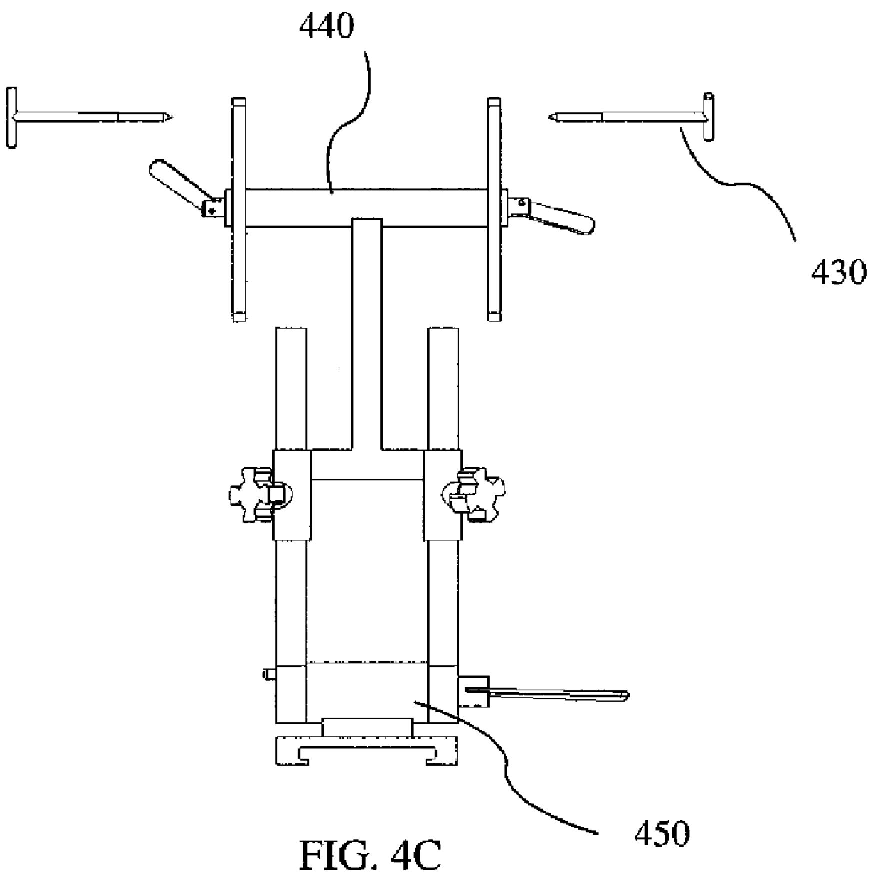


FIG. 4C

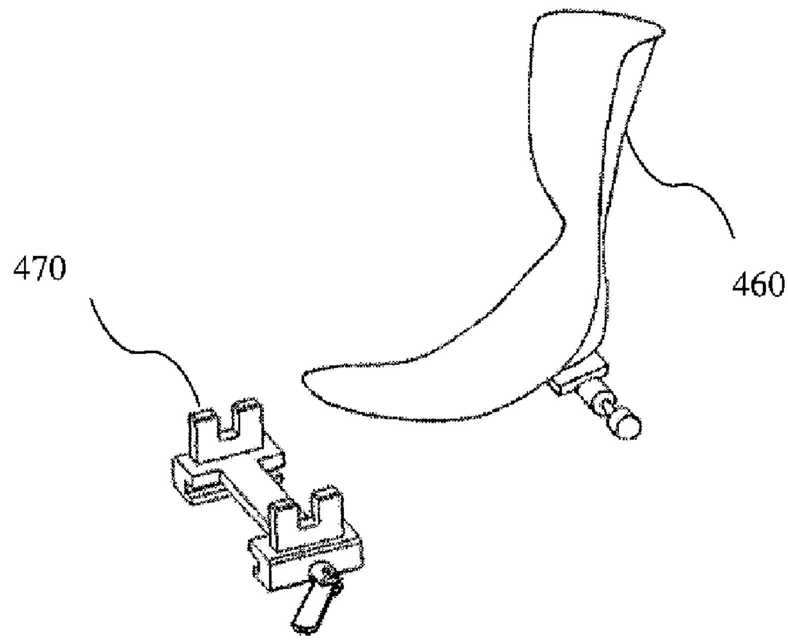


FIG. 4D

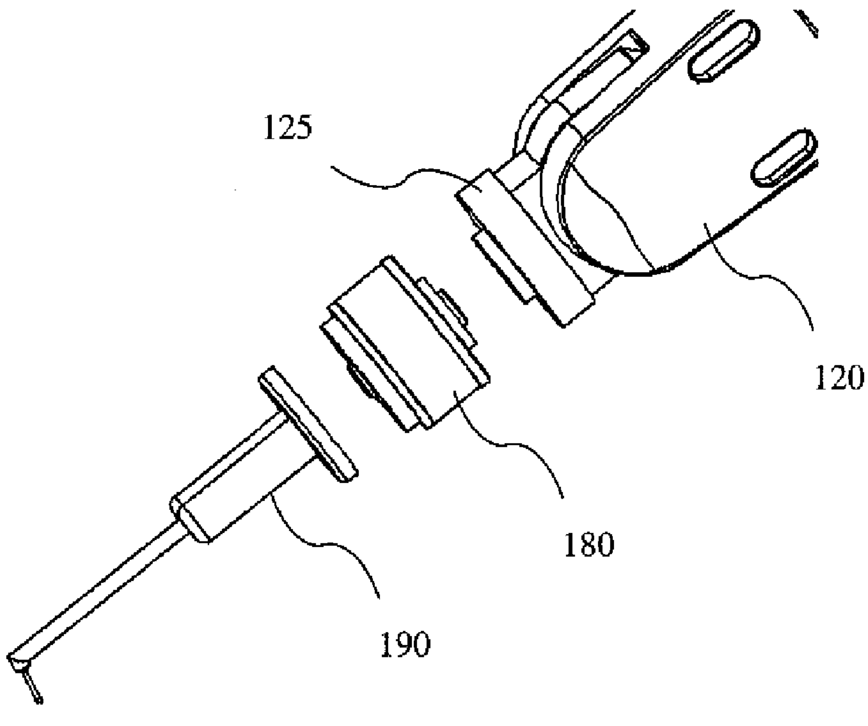


FIG. 5

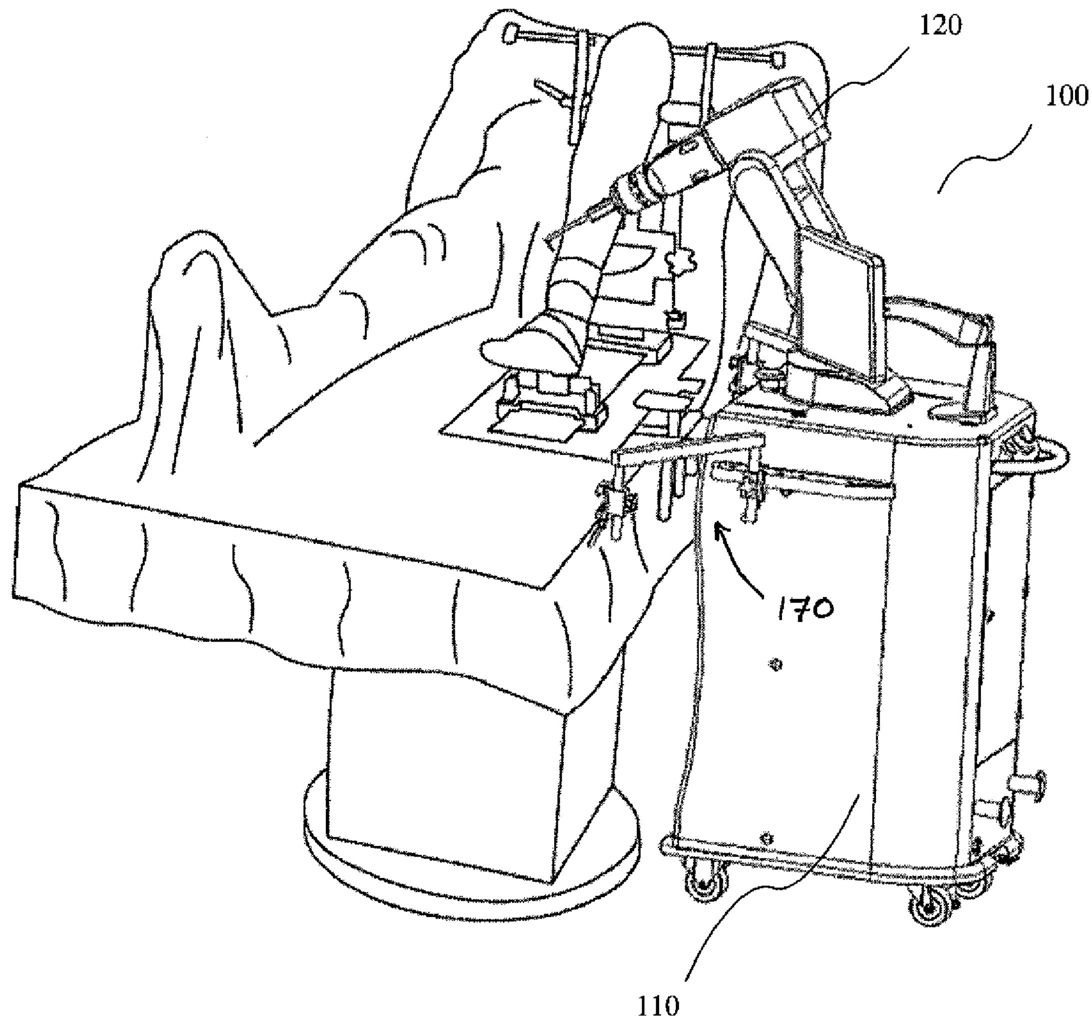


FIG. 6

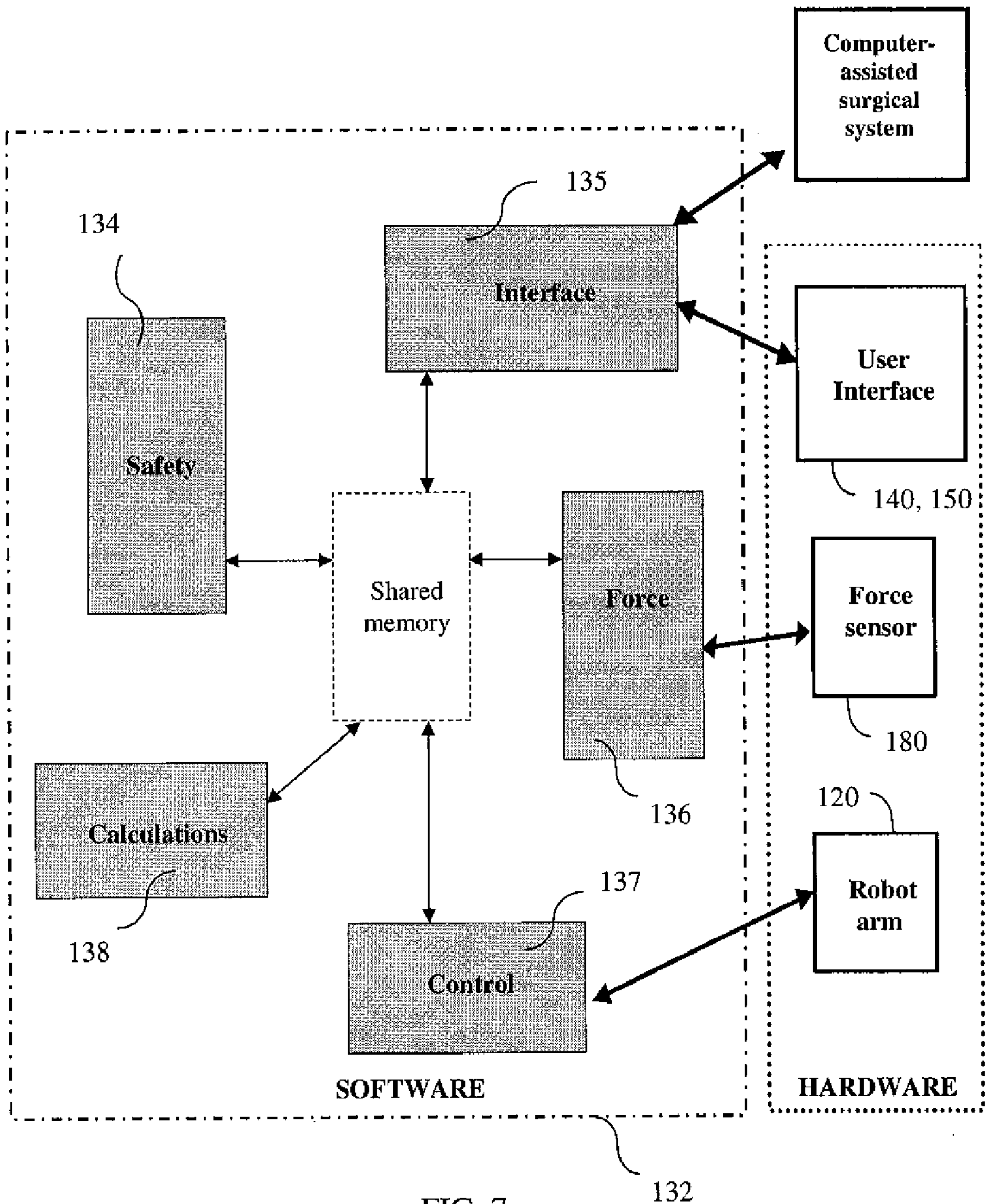

Computer-assisted surgical system
135
134
Interface
Safety
User Interface
140, 150
Shared memory
Force
Force sensor
180
120
Calculations
136
137
Robot arm
138
Control
SOFTWARE
HARDWARE
132

FIG. 7

IMAGELESS ROBOTIZED DEVICE AND METHOD FOR SURGICAL TOOL GUIDANCE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a Continuation of International Application Number PCT/EP2005/052751, with an international filing date of Jun. 14, 2005, entitled AN IMAGELESS ROBOTIZED DEVICE AND METHOD FOR SURGICAL TOOL GUIDANCE, the disclosure of which is hereby expressly incorporated herein by reference.

BACKGROUND

[0002] 1. Field of the Invention

[0003] The present invention relates to the field of robotic-aided surgical systems and methods. More particularly, the present invention relates to mechanical guidance for an oscillating saw blade or a drill in a variety of surgical applications.

[0004] 2. Description of the Related Art

[0005] Many surgical procedures in various specialties, such as orthopaedics, neurosurgery, and maxillofacial, for example, require precise bone cutting and/or drilling. For example, precise bone cutting and/or drilling may be required for knee surgeries, e.g., knee arthroplasty, tibial osteotomy, femoral osteotomy, or ligamentoplasty, for spine surgery, e.g., pedicular screw placement procedures, or for neurosurgery.

[0006] These procedures are traditionally carried out using motorized instruments, such as a surgical drill or an oscillating saw, for example, positioned and maintained either directly by the surgeon or using basic mechanical guides.

[0007] Total knee replacement (TKR) is an example of a surgical procedure that requires accurate cuts. In TKR, the surgeon resects the distal femur and the proximal tibia and implants prosthetic components to restore correct functionality of the knee joint.

[0008] Different approaches have been proposed to assist the surgeon during TKR. Navigation systems are based on a tracking system that locates the spatial position of trackers. Trackers are fixed on the femur, on the tibia, and on mechanical devices, such as cutting blocks and pointing tools, for example. The surgeon can visually follow the relative position of the tool with respect to the bones. In a first step, the surgeon registers anatomical landmarks and surfaces with a tracked pointer and defines the center of the hip joint by a kinematic procedure. The navigation system is then able to compute the mechanical axes of the bones and the optimal position for the different cuts. The surgeon fixes the cutting blocks on the bone with fixation pins and with the visual help provided by the navigation system.

[0009] Robotic systems have also been proposed to improve bone cutting during knee replacement surgery. One such robotic system utilizes a computer-assisted surgical system using a calibrated robot. The system uses a workstation which displays a 3D model of the patient's bones obtained from a CT scan of the leg and a modified industrial robot which directs the placement of prosthetic components. Positions of fiducial markers fixed on the bones are measured with a probe attached to the robot mounting flange. They serve to register the preoperative image data, e.g., a CT scan frame, with the position of the patient, e.g., a robot reference frame. After computing the optimal placement of the prosthetic component, the robot positions a drill guide where the holes for the cutting block are to be placed.

[0010] Another robotic device is disclosed in U.S. Pat. No. 5,403,319. This device includes a bone immobilization device, an industrial robot and a template attached to the robot mounting flange. The template has a functional interior surface corresponding to the exterior surface of the femoral component of a knee prosthesis. In the first step, the surgeon positions the template in the desired position of the prosthesis and the robot registers the position. In the second step, the system combines the registered position with a geometric database to generate coordinate data for each cutting task. The robot then positions a tool guide aligned for each specific task. The actual surgical task is carried out by the surgeon through the tool guide.

[0011] Other robotic systems have been proposed for performing total knee replacement, many of them using pre-operative image data of the patient. For example, ROBODOC™ and CASPAR™ surgical systems are active robots that automatically mill the bones, thereby autonomously realizing the surgical gesture. The Acrobot™ surgical system is a semi-active robot assisting the surgeon during the milling. The ROBODOC™, CASPAR™, and Acrobot™ systems are image based.

[0012] Other automated systems are proposed in combination with a navigation system. For example, the Praxiteles™ device from PRAXIM, the Galileo™ system from Precision Implants, and the GP System™ from Medacta International™ are all bone-mounted, require a large incision, and cannot work without a navigation system.

[0013] Other surgeries around the knee, such as a tibial osteotomy and ligament repairs, typically share the same issues as TKR: accurate cuts or drillings are required to restore knee functionality. In a tibial osteotomy, for example, a bone wedge is removed from the tibia to change the axis of the bone. The angular correction is determined pre-operatively on an X-ray. As for TKR, conventional instrumentation includes very basic mechanical guides.

SUMMARY

[0014] The present disclosure provides an imageless system and method for surgical tool guidance by accurately positioning a guide mounted to a robot arm, such as a cutting guide, for example, used in knee replacement surgery for guiding an oscillating saw.

[0015] The method for surgical tool guidance may include the steps of collecting anatomical landmarks with a robot arm; combining landmarks data with geometric planning parameters to generate a position data; and automatically positioning a tool guide mounted to the robot arm.

[0016] In an exemplary embodiment, the device is a robotized surgical device used for the optimal positioning of a cutting or drilling guide.

[0017] The robotized device may be rigidly attached to the operating table by a specific fixation device.

[0018] In an exemplary embodiment, the robot arm presents at least six degrees of freedom and is adapted to receive a cutting and/or drilling guide and/or a pointing tool. The same instrument can be used both for pointing and guiding.

[0019] The robotized device positions the guide at the place where cutting or drilling may be carried out. Bone cutting or drilling is realized through the guide by a surgeon using an oscillating saw or a surgical drill.

[0020] In an exemplary embodiment, the robot arm includes a force sensor and can work in a cooperative mode in which the user has the ability to move the robot arm manually by grabbing it by its final part.

[0021] In another exemplary embodiment, movements of the guide in the cooperative mode can be restricted either to a plane for a cutting guide or to an axis for a drilling guide.

[0022] In another exemplary embodiment, the system may include a display monitor provided with a user communication interface to receive planning parameters from a user.

[0023] Anatomical landmarks data and planning parameters are combined to define the optimal position of the guide. For example, in TKR, the internal rotation of the femoral component is a planning parameter for implant positioning. The user communication interface could be, for example, a keyboard, a touch screen and/or a mouse.

[0024] In another embodiment, the device may also include an interface with a surgical navigation system being able to work from preoperative images of the bone, such as CT scan images or radiographic images, for example, or from intra-operative data. Data provided by the surgical navigation system are then used to generate position data for the guide. In this case, the use of a navigation system supplements the step of collecting anatomical landmarks with the robot. Data is provided from the navigation system through a communication interface in accordance to a predefined protocol.

[0025] In an exemplary embodiment, the guiding tool includes limited surfaces to reduce contact and friction with an oscillating saw while preserving an efficient guidance.

[0026] In another exemplary embodiment, the robotized device includes a limb fixation device adapted to ensure immobilization of the leg at two levels: at the level of the ankle with a toothed rack; and at the level of the knee with two pins screwed in the femoral or tibial epiphysis.

[0027] These means of fixation of the limb facilitate immobility of the leg during the steps of anatomical landmarks collection and bone cutting and/or drilling.

[0028] In one form thereof, the present disclosure provides an imageless device for guiding a surgical instrument relative to an anatomical structure, the device including an arm; a pointing tool releasably attachable to the arm, the pointing tool configured to provide data about the anatomical structure; and a control unit in communication with the arm, the control unit configured to receive information from the pointing tool and calculate a desired position for the arm.

[0029] In another form thereof, the present disclosure provides an imageless device for guiding a surgical instrument relative to an anatomical structure, the device including acquisition means for acquiring coordinates of a plurality of landmarks on the anatomical structure; processing means for processing the coordinates of the landmarks and generating a desired position for the surgical instrument relative to the anatomical structure based on the coordinates of the landmarks; and positioning means for positioning the surgical instrument in the desired position.

[0030] In yet another form thereof, the present disclosure provides a method for positioning a surgical instrument relative to an anatomical structure, the method including the steps of acquiring coordinates of a plurality of landmarks on the anatomical structure; calculating a desired position of the surgical instrument relative to the anatomical structure based on the acquired coordinates of the anatomical structure landmarks; and positioning the surgical instrument at the desired position relative to the anatomical structure based on the calculation step.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] The above-mentioned and other features of this disclosure, and the manner of attaining them, will become more apparent and will be better understood by reference to the following description of embodiments of the disclosure taken in conjunction with the accompanying drawings, wherein:

[0032] FIG. **1** is a perspective view of the system of one embodiment of the present invention showing a mobile base, a robot arm with a force sensor and a tool mounted thereon, and a display monitor;

[0033] FIG. **2**A is a perspective view of a pointing tool;

[0034] FIG. **2**B is a perspective view of a guiding tool;

[0035] FIG. **2**C is a perspective view of a pointing and guiding tool;

[0036] FIG. **3** is a perspective view of a fixation device for rigidly fixing the mobile base to the operating table;

[0037] FIG. **4**A is a perspective view of a limb fixation device that rigidly holds the leg to the operating table;

[0038] FIG. **4**B is a perspective view of the plate of the limb fixation device described in FIG. **4**A;

[0039] FIG. **4**C is a perspective view of the knee part of the limb fixation device described in FIG. **4**A;

[0040] FIG. **4**D is a perspective view of the ankle part of the limb fixation device described in FIG. **4**A;

[0041] FIG. **5** is an exploded view of the pointing tool, the force sensor and the robot arm mounting flange;

[0042] FIG. **6** is a perspective view of the system of one embodiment of the present invention, further showing a patient positioned on an operating table; and

[0043] FIG. **7** is a block diagram showing various modules of the control software.

[0044] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate embodiments of the disclosure and such exemplifications are not to be construed as limiting the scope of the invention in any manner.

DETAILED DESCRIPTION

[0045] With reference to FIG. **1**, it can be seen that an exemplary embodiment of the present invention generally includes robotized device **100** including mobile base **110**; robot arm **120**; control unit **130** inside mobile base **110** which controls robot arm **120** and allows a surgeon to manually input data through the use of interface **150**, such as a touch screen, a mouse, a joystick, a keyboard or similar device, for example; display monitor **140**; tool or instrument **190** and force sensor **180** mounted to a mounting flange of robot arm **120**; and specific fixation device **170** (FIG. **6**) to fix robotized device **100** to an operating table (FIG. **6**).

[**0046**] Mobile base **110** ensures easy handling of robotized device **100** with its wheels and handles. In an exemplary embodiment, mobile base **110** includes immobilization pads or an equivalent device.

[**0047**] In an exemplary embodiment, robot arm **120** is a six joint arm. Each joint is provided with an encoder which measures its angular value. These data, combined with the known geometry of the six joints, allow computation of the position of the mounting flange of robot arm **120** and the position of the tool or instrument mounted to robot arm **120**, which may be either a pointing tool, a guiding tool, or a pointing and guiding tool.

[**0048**] FIG. **2**A illustrates pointing tool or instrument **190**. The pointing tool **190** includes base plate **200**; handle **210**; and pointing sphere **220**.

[**0049**] FIG. **2**B illustrates a cutting guide or instrument. The cutting guide includes base plate **230**; handle **240**; and slit **250** to guide a saw blade.

[**0050**] FIG. **2**C illustrates a pointing and guiding tool or instrument. The pointing and guiding tool includes base plate **260**; handle **270**; slit **280** to guide a saw blade; and pointing sphere **290**.

[**0051**] The tools described in FIGS. **2**A to **2**C are three examples of pointing and/or guiding tools that may be utilized with the device shown in FIG. **1**.

[**0052**] In an exemplary embodiment, robot arm **120** is rigidly attached to the operating table by specific base fixation device **170** (FIGS. **3** and **6**). As shown in FIG. **3**, base fixation device **170** may include two sets of clamps **300** adapted to operating table rail **310** and U-shape bars **320**. Initially, the user installs one clamp **300** on operating table rail **310** and another clamp on mobile base rail **330**. When clamps **300** are in place, the user inserts U-shape bar **320** in the cylindrical holes of clamps **300**, locks clamps **300** in place, and locks U-shape bar **320** inside clamps **300** using the knobs.

[**0053**] In an exemplary embodiment and referring to FIGS. **4**A-**4**D, the system may include a limb fixation device to ensure immobility of the leg during the procedure. This limb fixation device allows an immobilization of the leg at two levels: at the level of the ankle with a toothed rack (FIG. **4**D); and at the level of the knee with two pins screwed on the femoral or tibial epiphysis (FIG. **4**C).

[**0054**] FIG. **4**B shows main plate **400** of the limb fixation device. Main plate **400** is fixed on the operating table with two clamps **300**. Knee fixation part **410** and ankle fixation part **420** can slide along the main plate **400** and be locked in place by screws.

[**0055**] FIG. **4**C is a front view of the immobilizer for immobilizing the patient's leg at the level of the knee. The knee may rest on support bar **440**. As bones are exposed in a knee replacement surgery, two pins **430** may be screwed either in the femoral epiphysis or in the tibial epiphysis. The position of support bar **440** can be adjusted vertically and locked with two knobs. The orientation can be adjusted from 0 to 90° by rotating around main axis **450** and locked with one knob. The whole system can slide along plate **400**.

[**0056**] FIG. **4**D illustrates the immobilizer for immobilizing the patient's leg at the level of the ankle. The patient's foot and ankle are rigidly fixed with surgical tape or other sterile means to lock the foot in boot **460**. Boot **460** is adapted to be clamped in carriage **470** that can slide along main plate **400** and be locked in place with a knob.

[**0057**] Both parts of the limb fixation device (ankle part and knee part) are independent but are used in combination to facilitate immobilization of the lower limb during the procedure.

[**0058**] In an exemplary embodiment, control unit **130** can set robot arm **120** in a cooperative mode in which a user is able to move robot arm **120** manually by grabbing it by its final part. With reference to FIG. **5**, the system of the present invention may include force sensor **180** mounted to robot arm mounting flange **125**. Force sensor **180** is adapted to receive a tool, such as pointing tool **190**, for example. When the user grabs the tool and tries to move it in a direction, control unit **130** receives efforts measured by force sensor **180** and combines them with the position of robot arm **120** to generate the movement desired by the user.

[**0059**] Once robotized device **100** has been fixed to the operating table, the first step of the procedure is collecting anatomical landmarks on the patient. These anatomical landmarks are known by the surgeon. For example, in a TKR procedure, the malleoluses, the internal part of tibial tuberosity, the middle of the spines and the tibial plateaus are collected on the tibia; and the notch middle point, the distal and posterior condyles, and the anterior cortex are collected on the femur. FIG. **6** illustrates positions of the patient and of robotized device **100** at the beginning of the landmarks collection step for a TKR procedure.

[**0060**] During the landmarks collection step, control unit **130** sets robot arm **120** in cooperative mode and indicates through display monitor **140** the anatomical landmarks to acquire. The surgeon moves pointing tool **190** until contacting the required anatomical landmark. The surgeon validates the acquisition of the point coordinates using user interface **150**. Control unit **130** then memorizes the coordinates of the point and its anatomical significance.

[**0061**] After the landmarks collection step, the surgeon inputs planning parameters through user interface **150**. For example, in a TKR procedure, the surgeon chooses the model and the size of the prosthesis components and defines their positions and orientations relative to the mechanical axes of the femur and the tibia. Typical geometric parameters are varus/valgus angle, posterior slope and thickness of resection for the tibia and varus/valgus angle, flexion/extension angle, external rotation and thickness of resection for the femur.

[**0062**] In another embodiment, control unit **130** includes a data-processing interface that enables the system to be connected with another computer-assisted surgical system, like a navigation system. Navigation systems work with preoperative images of the bone, such as CT scan images, X-ray images, and fluoroscopy images, for example, or with intra-operative data. In the latter case, the system uses a 3D reconstruction algorithm based on the digitization of the bone. Data provided by the navigation system then replaces, or is combined with, the landmarks collection step data. Position of the guiding tool may be generated by the navigation system and transmitted to robotized device **100** in accordance with a predefined communication protocol.

[0063] Once the required position of the guide has been generated, the user mounts the guiding tool to robot arm **120**. In an exemplary embodiment, a pointing and guiding tool is used such that the user does not need to change the tool between the landmarks collection step and the cutting or drilling step.

[0064] Robotized device **100** aligns the guide relative to the patient's anatomy, in accordance with the surgeon's planning. If the guiding tool is a cutting guide for a saw blade, robot arm **120** holds it in the chosen cutting plane. If the guiding tool is a drilling guide, robot arm **120** holds it along the chosen drilling axis.

[0065] In an exemplary embodiment, a planar cooperative mode can then be activated by the user to restrict movements of the guide in the plane. Similarly, an axial cooperative mode restricts movements of the guide along the axis. The user moves the guiding tool to an estimated optimal position, as control unit **130** restricts movements of robot arm **120** to a plane or an axis. Once this optimal position is reached, control unit **130** stops robot arm **120**, thereby holding the guiding tool in place. Surgical tasks, such as bone cutting or drilling, for example, are carried out by the surgeon using a conventional instrument, such as an oscillating saw or a surgical drill, for example, through the guide.

[0066] In a TKR procedure, the same guiding tool may be used for the tibial cut and the five femoral cuts. In a tibial osteotomy procedure, the same guiding tool may be used for both tibial cuts.

[0067] With reference to FIG. **7**, control unit **130** runs control software **132** which exchanges data with elements of robotized device **100**. Software **132** may communicate with the user through user interface **150** and display monitor **140**. Software **132** may communicate with another computer-assisted surgical system, as described above, through a data-processing interface. Software **132** may communicate with force sensor **180** to regularly measure the efforts exerted by the user at the tool mounted to robot arm **120**. Software **132** may communicate with robot arm **120** to control the position of robot arm **120**.

[0068] Control software **132** may include five independent modules **134** to **138**. In an exemplary embodiment, these modules run simultaneously under a real time environment and use a shared memory to ensure a good management of the various tasks of control software **132**. Modules have different priorities, such as safety module **134** having the highest priority, for example.

[0069] Safety module **134** monitors the system status and stops robot arm **120** when a critical situation is detected, such as an emergency stop, software failure, or collision with an obstacle, for example.

[0070] Interface module **135** manages the communication between the surgeon and control software **132** through user interface **150** and display screen **140**. Display screen **140** displays a graphical interface that guides the user through the different steps of the procedure. User interface **150** enables the user to have permanent control during the procedure, such as validating landmarks collection, defining planning parameters, and stopping robot arm **120** if needed, for example.

[0071] Force module **136** may monitor the forces and torques measured by force sensor **180**. Force module **136** may be able to detect a collision with an obstacle and alert safety module **134**.

[0072] Control module **137** manages the communication with robot arm **120**. Control module **137** receives data encoder values of each joint and sends position commands.

[0073] Calculations module **138** does all the calculations necessary for the procedure. For example, in a TKR procedure, calculations module **138** reconstructs the mechanical axes of the bones combining anatomical landmarks data and statistical data. Calculations module **138** also defines the trajectory of robot arm **120** using direct and inverse kinematics.

[0074] While this disclosure has been described as having exemplary designs, the present disclosure can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the disclosure using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this disclosure pertains and which fall within the limits of the appended claims.

What is claimed is:

1. An imageless device for guiding a surgical instrument relative to an anatomical structure, the device comprising:

an arm;

a pointing tool releasably attachable to said arm, said pointing tool configured to provide data about the anatomical structure; and

a control unit in communication with said arm, said control unit configured to receive information from said pointing tool and calculate a desired position for said arm.

2. The device of claim 1, further comprising a surgical instrument, said surgical instrument releasably attachable to said arm.

3. The device of claim 2, wherein said surgical instrument comprises a guide instrument.

4. The device of claim 3, wherein said guide instrument is integrally formed with said pointing tool.

5. The device of claim 1, wherein said arm provides at least six degrees of freedom.

6. The device of claim 1, further comprising a force sensor, said force sensor connected to said arm proximate said pointing tool, said force sensor in communication with said control unit.

7. The device of claim 1, further comprising a user interface in communication with said control unit.

8. The device of claim 1, further comprising an anatomical structure fixation device, said fixation device configured to immobilize the anatomical structure at two distinct locations.

9. The device of claim 8, wherein the anatomical structure is a leg, said fixation device configured to immobilize the leg proximate an ankle of the leg and proximate a knee joint of the leg.

10. An imageless device for guiding a surgical instrument relative to an anatomical structure, the device comprising:

acquisition means for acquiring coordinates of a plurality of landmarks on the anatomical structure;

processing means for processing the coordinates of the landmarks and generating a desired position for the surgical instrument relative to the anatomical structure based on the coordinates of the landmarks; and

positioning means for positioning the surgical instrument in said desired position.

11. The device of claim 10, further comprising force sensing means for sensing a force exerted on the surgical instrument.

12. The device of claim 10, further comprising input means for inputting a plurality of surgical parameters.

13. The device of claim 12, wherein said processing means comprises means for processing the coordinates of the landmarks and the plurality of surgical parameters and generating a desired position for the surgical instrument relative to the anatomical structure based on the coordinates of the landmarks and on the plurality of surgical parameters.

14. A method for positioning a surgical instrument relative to an anatomical structure, the method comprising the steps of:

acquiring coordinates of a plurality of landmarks on the anatomical structure;

calculating a desired position of the surgical instrument relative to the anatomical structure based on the acquired coordinates of the anatomical structure landmarks; and

positioning the surgical instrument at the desired position relative to the anatomical structure based on said calculation step.

15. The method of claim 14, further comprising the step of inputting surgical parameters into a controller associated with the surgical instrument, said calculating step further comprising calculating the desired position of the surgical instrument relative to the anatomical structure based on the acquired coordinates of the anatomical structure landmarks and on the surgical parameters.

16. The method of claim 14, wherein said acquiring step comprises manually moving an arm connected to the surgical instrument to contact the plurality of landmarks on the anatomical structure with the surgical instrument.

17. The method of claim 16, wherein said acquiring step further comprises the step of confirming contact between the surgical instrument and each of the plurality of landmarks.

18. The method of claim 16, wherein said manually moving step comprises sensing a force exerted on the arm and controlling movement of the arm based at least in part on said sensed force.

19. The method of claim 14, wherein said acquiring step comprises storing the coordinates of the plurality of landmarks on the anatomical structure in a control unit.

20. The method of claim 14, further comprising the step of, subsequent to said positioning step, manually moving the surgical instrument in one of a single plane of movement or a single axis of movement.

* * * * *