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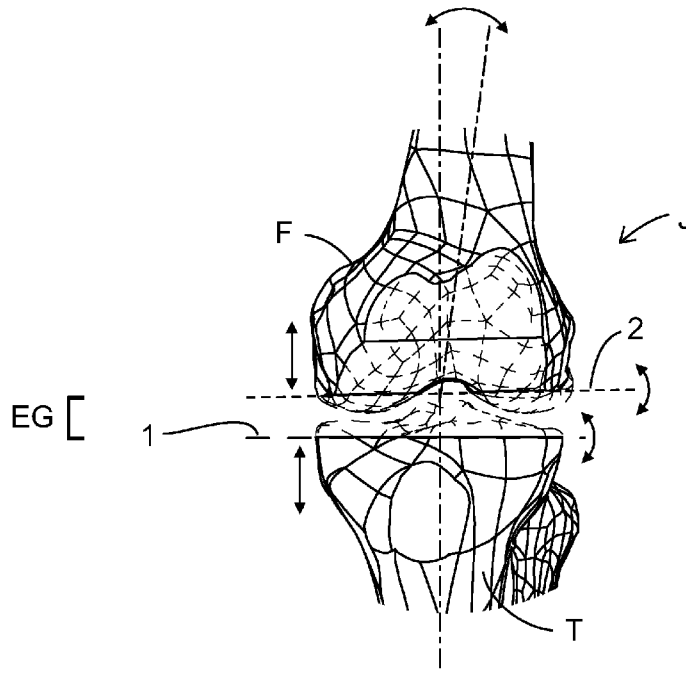


Fig. 1

(57) Abstract: An apparatus for evaluating soft tissue of a human joint which includes two or more bones and ligaments, wherein the ligaments are under anatomical tension to connect the bones together, creating a load-bearing articulating joint, the apparatus including: a tensioner-balancer insertable between the bones of the joint, the tensioner-balancer including a means of controlling a distraction force, and sensors operable for collecting displacement and distraction load data of the bones while the joint is moved through at least a portion of its range of motion using a controlled distraction force; an electronic receiving device configured for data communication with the sensors; and a software application programmed to processing the collected data to produce a digital geometric model of the joint, wherein the model includes ligament displacement data along a range of flexion angles and ligament load data along a range of flexion angles.



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JOINT SOFT TISSUE EVALUATION METHOD

BACKGROUND

[0001] This invention relates generally to medical devices and instruments, and more particularly to methods for soft tissue evaluation.

[0002] Total knee arthroplasty ("TKA") is a procedure for treating an injured, diseased, or worn human knee joint. In a TKA, an endoprosthetic joint is implanted, replacing the bearing surfaces of the joint with artificial members. Proper alignment of the joint and substantially equal tension in the soft tissues surrounding the joint are important factors in producing a good surgical outcome.

[0003] A human knee joint "J" is shown in FIGS. 1-4. The joint J is prepared for implantation by cutting away portions of the femur "F" and the tibia "T". FIGS. 1 and 2 show the joint in extension, with cutting planes for a tibial cut 1 and a distal femoral cut 2. The tibial cut 1 and the distal femoral cut 2 cooperate to define an extension gap "EG". FIGS. 3 and 4 show the joint J in flexion, with a cutting plane 3 shown for a posterior cut. The tibial cut 1 and the posterior cut 3 cooperate to define a flexion gap "FG".

[0004] FIG. 5 depicts an exemplary endoprosthetic 10 (i.e., implant) of a known type. The endoprosthetic 10 includes a tibial component 12 and a femoral component 14. The tibial component 12 is made up of a tibial tray 16 and an insert 18. The insert 18 has a back surface 20 which abuts the tibial tray 16 and an opposed articular surface 22. The tray includes a prominent keel 24 protruding in the inferior direction (i.e. down a longitudinal axis of the tibia). The tibial tray 16 may be made from a hard, wear-resistant material such as a biocompatible metal alloy. The insert 18 may be made from a low-friction material such as a biocompatible plastic.

[0005] The femoral component 14 includes a back surface 36 shaped to abut a surface of the femur F that has been appropriately shaped and an articular surface

38 comprising medial and lateral contact surfaces 39 and 41, respectively. The femoral component 14 may be made from a hard, wear-resistant material such as a biocompatible metal alloy.

[0006] The back surface 36 includes multiple faces collectively defining a rough "U" or "J" shape. The back surface 36 includes protruding locator pins 50.

[0007] The tibial tray 16 is implanted into the tibia T and the femoral component 14 is implanted into the femur F. The insert 18 is placed into the tibial tray 16. The articular surface 22 of the insert 18 bears against the articular surface 38 of the femoral component 14, defining a functional joint.

[0008] In the illustrated example, the endoprosthesis 10 is of the cruciate-retaining ("CR") type. It includes a cutout or notch 26 in the posterior aspect of the tibial component 12 which provides a space for the posterior cruciate ligament ("PCL").

[0009] A goal of total knee arthroplasty is to obtain symmetric and balanced flexion and extension gaps FG, EG (in other words, two congruent rectangles). These gaps are generally measured in millimeters of separation, are further characterized by a varus or valgus angle measured in degrees, and are measured after the tibia cut, distal femoral cut, and posterior femoral cut have been done (to create flat surfaces from which to measure). It follows that, to achieve this balance, the ligament tension in the lateral and medial ligaments would be substantially equal on each side or have a surgeon-selected relationship, and in each position.

[0010] One problem with prior art arthroplasty techniques is that it is difficult and complex to achieve the proper balance. Current state-of-the-art gap balancing devices do not enable balancing with the patella in-place and are large, overly-complicated devices that work only with their respective knee implant systems.

BRIEF SUMMARY OF THE INVENTION

[0011] According to one aspect of the technology described herein, an apparatus is described for evaluating soft tissue of a human joint which includes two or more bones and ligaments, wherein the ligaments are under anatomical tension to connect the bones together, creating a load-bearing articulating joint. The apparatus includes: a tensioner-balancer insertable between the bones of the joint, the tensioner-balancer including a means of controlling a distraction force, and sensors operable for collecting displacement and distraction load data of the bones while the joint is moved through at least a portion of its range of motion using a controlled distraction force; an electronic receiving device configured for data communication with the sensors; and a software application programmed to processing the collected data to produce a digital geometric model of the joint, wherein the model includes ligament displacement data along a range of flexion angles and ligament load data along a range of flexion angles.

[0012] According to another aspect of the technology described herein, a method is described of evaluating a human knee joint which includes a femur bone, a tibia bone, and ligaments, wherein the ligaments are under anatomical tension to connect the bones together, creating a load-bearing articulating joint. The method includes: using a software application to define a virtual primary datum comprising a coordinate framework having fixed origins relative to the femur and relative to a physical tracking device affixed to the femur; using the software application to define a virtual software secondary datum comprising a coordinate framework, the secondary datum having fixed origins relative to the tibia and relative to a physical tracking device affixed to the tibia; inserting between the femur and the tibia at least one force sensor having a femoral interface surface; providing an electronic receiving device; while moving the femur and tibia relative to each other, using the electronic receiving device to collect data from the tracking devices and from the at least one force sensor, wherein the data includes information describing the position and movement in six degrees of freedom of the secondary datum relative to the primary

datum to produce a digital geometric model of at least a portion of the joint, wherein the data further includes: a medial spline representing a locus of points of contact of a medial condyle of the femur with the femoral interface surface, over a range of knee flexion angles; and a lateral spline representing the locus of points of contact of the femur with the femoral interface surface over a range of knee flexion angles; and storing the digital geometric model for further use.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] The invention may be best understood by reference to the following description taken in conjunction with the accompanying drawing figures in which:

[0014] FIG. 1 is a view of the anterior aspect of the human knee joint in extension showing cutting planes for a total knee arthroscopy;

[0015] FIG. 2 is a view of the lateral aspect of the human knee joint of FIG. 1;

[0016] FIG. 3 is a view of the anterior aspect of the human knee joint in flexion showing cutting planes for a total knee arthroscopy;

[0017] FIG. 4 is a view of the lateral aspect of the human knee joint of FIG. 3;

[0018] FIG. 5 is an exploded perspective view of a representative knee endoprosthesis;

[0019] FIG. 6 is a perspective view of a human knee joint in an extended position, with a tensioner-balancer inserted therein;

[0020] FIG. 7 is a view of the knee joint and tensioner-balancer of FIG. 6, in a flexed position;

[0021] FIG. 8 is a top plan view of a top plate of the tensioner-balancer of FIG. 6;

[0022] FIG. 9 is a front elevation view of the top plate of FIG. 8;

[0023] FIG. 10 is a perspective view of the top plate of FIG. 8, in a deflected position;

[0024] FIG. 11 is a perspective view of the top plate of FIG. 8, showing movement of contact points superimposed thereon;

[0025] FIG. 12 is a perspective view of an alternative top plate configuration of the tensioner-balancer of FIG. 6;

[0026] FIG. 13 is a perspective top plan view of an alternative top plate configuration of the tensioner-balancer of FIG. 6;

[0027] FIG. 14 is a perspective view of the human knee joint with a tensioner-balancer inserted therein and coupled to a instrument;

[0028] FIG. 15 is a perspective view of a human knee joint with a load cell disposed contact with the patella;

[0029] FIG. 16 is a perspective view of a tensioner-balancer inserted into human knee joint, in combination with a spotting apparatus;

[0030] FIG. 17 is a perspective view showing a femur in contact with a tensioner-balancer;

[0031] FIG. 18 is a perspective view showing plots of collected spline data superimposed on the top plate of a tensioner-balancer;

[0032] FIG. 19 is another perspective view showing plots of collected spline data superimposed on the top plate of a tensioner-balancer;

[0033] FIG. 20 is a diagram showing a tensioner-balancer labeled with data parameters;

[0034] FIG. 21 is a diagram showing a knee joint and tensioner-balancer labeled with data parameters;

[0035] FIG. 22 is a diagram showing a knee joint and tensioner-balancer labeled with data parameters;

[0036] FIG. 23 is a diagram showing example of data collected using a tensioner-balancer and tracking markers;

[0037] FIG. 24 is a perspective view of a tibia having a reference datum superimposed thereupon;

[0038] FIG. 25 is a perspective view of a femur having a reference datum superimposed thereupon;

[0039] FIG. 26 is a perspective view of a knee joint having reference datums superimposed thereupon;

[0040] FIG. 27 is a diagram illustrating data collected by tensioner-balancer and tracking markers;

[0041] FIG. 28 is a perspective view of a human knee joint in conjunction with an exploded view of an endoprosthesis;

[0042] FIG. 29 is a perspective view of a human knee joint showing proposed cutting planes, in conjunction with a mixed reality display device;

[0043] FIG. 30 is a perspective view of a human knee joint in conjunction with a mixed reality display device and an instrumented bone saw;

[0044] FIG. 31 is a perspective view of a human knee joint in conjunction with an instrumented bone saw coupled to a robot;

[0045] FIG. 32 is a perspective view of a human knee joint in conjunction with a mixed reality display device and an instrumented drill;

[0046] FIG. 33 is a perspective view of a human knee joint in conjunction with an instrumented drill coupled to a robot;

[0047] FIG. 34 is a perspective view of a human knee joint in conjunction with a robot that is manipulating an endoprosthesis;

[0048] FIG. 35 is a perspective view of a human knee joint having a trial endoprosthesis device implanted, in conjunction with a tensioner-balancer;

[0049] FIG. 36 is a perspective view of a posterior aspect of a human knee joint having a posterior cruciate ligament reinforced by artificial tensile member;

[0050] FIG. 37 is a view of the medial aspect of the human knee joint of FIG. 36;

[0051] FIG. 38 is a view of the anterior aspect of the human knee joint in combination with an instrument for tensioning an artificial tensile member;

[0052] FIG. 39 is a schematic diagram of a human leg having a body-worn tracking system placed thereon;

[0053] FIG. 40 is a schematic diagram of a human leg having a body-worn tracking system placed thereon, in conjunction with tracking sensors;

[0054] FIG. 41 is a schematic diagram of a human leg having a body-worn tracking system thereon, in conjunction with a mixed reality display device, where the leg is in an extended position;

[0055] FIG. 42 is a schematic diagram of a human leg having a body-war tracking system thereon, where the leg is in a flexed position;

[0056] FIG. 43 is a diagram of a human knee joint showing the MCL, in an extended position;

[0057] FIG. 44 is an enlarged view of FIG. 43, with virtual sockets superimposed over the MCL;

[0058] FIG. 45 is a view of the socket and tensile member virtual construct of an MCL, in the extended position;

- [0059] FIG. 46 is a diagram of a human knee joint showing the MCL, in a flexed position;
- [0060] FIG. 47 is an enlarged view of FIG. 46, with virtual sockets superimposed over the MCL;
- [0061] FIG. 48 is a view of the socket and tensile member virtual construct of an MCL, in the flexed position;
- [0062] FIG. 49 is a view of a human knee joint with a tensioner-balancer inserted therein, with virtual sockets superimposed over the joint;
- [0063] FIG. 50 is a view of the human knee joint with a tensioner-balancer inserted therein, with virtual sockets representing a PCL;
- [0064] FIG. 51 is a view of the human knee joint showing an instrumented probe being used to register a position of a ligament of the joint;
- [0065] FIG. 52 is a representative stress-strain curve of a ligament of a human joint;
- [0066] FIG. 53 is a series of stress-strain curves of human ligaments for different individuals;
- [0067] FIG. 54 is a 3D plot of stress-strain curves of human ligaments for a human knee joint of a specific individual, over a range of knee flexion angles;
- [0068] FIG. 55 is a flowchart of an example surgical process;
- [0069] FIG. 56 is a diagram of a software algorithm;
- [0070] FIG. 57 is a schematic diagram of a human shoulder joint;
- [0071] FIG. 58 is a schematic diagram of the human hip joint;

[0072] FIG. 59 is a schematic diagram of a knee joint in an extended position, with a tensioner-balancer inserted therein;

[0073] FIG. 60 is a schematic diagram of the knee joint of FIG. 59, in a flexed position;

[0074] FIG. 61 is a schematic diagram of a knee joint in an extended position, with a tensioner-balancer inserted therein;

[0075] FIG. 62 is a schematic diagram of the knee joint of FIG. 61, in a flexed position;

[0076] FIG. 63 is a chart showing ligament load and stress versus displacement at a variety of knee flexion angles, for both medial and lateral ligaments;

[0077] FIG. 64 is a chart showing ligament load and stress versus displacement at a variety of knee flexion angles for a medial ligament;

[0078] FIG. 65 is a chart showing ligament load and stress versus displacement at a variety of knee flexion angles, for a lateral ligament;

[0079] FIG. 66 is a chart showing ligament stress or load for a variety of knee flexion angles;

[0080] FIG. 67 is a chart showing ligament displacement for a variety of knee flexion angles;

[0081] FIG. 68 is a chart showing ligament stress or load for a variety of knee flexion angles;

[0082] FIG. 69 is a chart showing ligament deflection for a variety of knee flexion angles;

[0083] FIG. 70 is a perspective view of a knee joint J in an extended position, with a tensioner-balancer inserted therein;

[0084] FIG. 71 is a perspective view of a knee joint J in a flexed position, with a tensioner-balancer inserted therein;

[0085] FIG. 72 is a perspective view of a knee joint in an extended position, with a tensioner-balancer inserted therein, and a marking guide attached to the tensioner-balancer;

[0086] FIG. 73 is a perspective view of a knee joint in a flexed position, with a tensioner-balancer inserted therein, and a marking guide attached to the tensioner-balancer;

[0087] FIG. 74 is a perspective view of a knee joint in a flexed position, with a alternative marking guide attached thereto;

[0088] FIG. 75 is a perspective view of a knee joint in an extended position, with a guide block attached to and anterior aspect thereof;

[0089] FIG. 76 is a perspective view of the knee joint in a flexed position, with a guide a block attached to a distal aspect thereof;

[0090] FIG. 77 is a graph of computed ligament tension versus knee joint flexion angle.

DETAILED DESCRIPTION OF THE INVENTION

[0091] Now, referring to the drawings wherein identical reference numerals denote the same elements throughout the various views, FIGS. 6 and 7 depict an exemplary embodiment of a tensioner-balancer 40 (alternatively referred to in various embodiments as a gap balancer, distractor, distractor-tensioner, or jack) which is useful for balancing a gap in a human knee joint as part of a total knee arthroplasty and for other therapeutic procedures.

[0092] Solely for purposes of convenient description, the tensioner-balancer 40 may be described as having a length extending along a lateral-to-medial direction

"L", a width extending along an axial direction "A", and a height extending along a vertical direction "H", wherein the lateral direction, the axial direction, and the vertical direction are three mutually perpendicular directions. These directional terms, and similar terms such as "top", "bottom", "upper", "lower" are used merely for convenience in description and do not require a particular orientation of the structures described thereby.

[0093] In one aspect, the tensioner-balancer 40 may be described as having the ability to control the movement of one degree of freedom (e.g., translation along H) and measure the movement of a second degree of freedom (rotation about A) while constraining or fixing the remaining four degrees of freedom (translation along A and L; rotation about H and L).

[0094] The tensioner-balancer 40 comprises a baseplate 42 and a top plate 44 interconnected by a linkage 46. The linkage 46 and the tensioner-balancer 40 are movable between a retracted position in which the top plate 44 lies close to or against the baseplate 42, and an extended position in which the top plate 44 is spaced away from the baseplate 42. As described in more detail below, a means is provided to actuate the linkage 46 in response to an actuating force in order to separate the baseplate 42 and the top plate 44 in a controllable manner. This separation enables it to extend so as to apply a load to a knee joint. While the illustrated tensioner-balancer 40 includes a mechanically-operated linkage 46, it will be understood that this is just one operative example of a "distracting mechanism" operable to move the tensioner-balancer between retracted and extended positions. It is envisioned that the mechanical linkage could be replaced with other types of mechanical elements, or electrical, pneumatic, or hydraulic devices.

[0095] The top plate 44 includes a femoral interface surface 48 and is mounted to the linkage 46 in such a manner that it can freely pivot about pivot axis 47 (an axis corresponding to a varus/valgus angulation of the knee).

[0096] The baseplate 42 includes a tensioner-balancer coupler 51 having a first interface 53. In the illustrated example, the first interface 53 is configured as a mechanical coupling. The coupler 51 is interconnected to the linkage such that an actuating force applied to the coupler 51, such as a torque, actuates the linkage 46. A drive shaft (not shown) passes through this coupler and connects with the linkage.

[0097] Optionally, the tensioner-balancer 40 may incorporate means for measuring a force input. For example, the coupler 51 may incorporate a sensor (not shown) such as a strain gage operable to produce a signal representative of the torque applied to the coupler 51.

[0098] As a further option, the tensioner-balancer 40 may incorporate a separate measuring linkage (not shown) connected to the top plate and arranged to follow the movement of the top plate 44. The measuring linkage would be connected to a crank which would be in turn connected to an indicating shaft coaxial to the coupler. The measuring linkage may be arranged such that pivoting movement of the top plate results in rotation of the indicating shaft. The movement of the indicating shaft may be observed visually, or it may be detected by a sensor such as an RVDT or rotary encoder or resolver, which may be part of an instrument described below. This permits measurement of plate angle and/or vertical position.

[0099] The tensioner-balancer may be supplied with an appropriate combination of transducers to detect physical properties such as force, tilt angle, and/or applied load and generate a signal representative thereof. For example, the tensioner-balancer may be provided with sensors operable to detect the magnitude of extension (i.e. "gap height"), the angle of the top plate about the pivot axis 47 (i.e. varus/valgus), and/or the applied force in the extension direction. Nonlimiting examples of suitable transducers include strain gages, load cells, linear variable differential transformers ("LVDT"), rotary variable differential transformers ("RVDT"), or linear or rotary encoders or resolvers.

[0100] FIGS. 8 and 9 illustrate an exemplary configuration in which the top plate 44 includes grooves 54 which define medial and lateral cantilevered pads 56A, 56B respectively. Two or more spaced-apart strain gages 58 are mounted to the top plate 44 in a first left-right row 60A at the intersection between the medial pad 56A and the forward portion 62 of the top plate 44. Two or more spaced-apart strain gages 58 are mounted to the top plate 44 in a second fore-aft row 60B at the intersection between the lateral pad 56B and the forward portion 62 of the top plate 44.

[0101] FIG. 10 shows the medial and lateral cantilevered pads 56A, 56B in a deflected position under load. The magnitude of deflection is greatly exaggerated for illustrative purposes.

[0102] Referring to FIG. 8, when the knee joint is articulated it is possible to identify an instantaneous point of peak contact pressure. There is one such point for each of the condyles. These positions are mapped onto the medial and lateral cantilevered pads 56A, 56B and labeled "MC" (standing for "medial load center") and "LC" (standing for "lateral load center").

[0103] Analysis by the inventors has shown that using the depicted configuration, with one or more strain gauges provided for each of the cantilevered pads 56A, 56B, it is possible to resolve the position of the load centers LC, MC in two axes. Stated another way, using this hardware, it is possible to identify the instantaneous lateral-medial and anterior-posterior position of the load centers LC, MC. More complex sensors may permit the resolution in two axes using one or more strain gage for each cantilevered pad. Referring to FIG. 11, and as will be described further below, this enables the ability of the tensioner-balancer 40 to track certain relative movements of the femur F. One of these is referred to as "medial pivot" shown by arrow 64 and the other is referred to as "rollback", shown by arrow 66.

[0104] Various physical configurations of the top plate with cantilevered pads are possible with similar functionality. For example, FIG. 12 illustrates medial and lateral cantilevered pads 56A', 56B' which are cantilevered along an anterior-

posterior axis (as opposed to a lateral-medial axis as shown in FIGS. 8-10). As another example, FIG. 13 illustrates medial and lateral cantilevered pads 56A", 56B" which are cantilevered along both an anterior-posterior axis and a lateral-medial axis. As another alternative (not separately illustrated), the lateral pad could be cantilevered along one axis and the medial pad could be cantilevered along a different axis.

[0105] FIG. 14 illustrates an exemplary actuating instrument 70 for use with the tensioner-balancer 40. The actuating instrument 70 includes a barrel 72 with an instrument coupler 74 at its distal end defining a second interface (hidden in this view) which is complementary to the first interface 53 of the tensioner-balancer 40. The interior of barrel 72 includes an appropriate internal mechanism to apply torque to the instrument coupler 74, through a shaft 78, such as a servo or stepper motor 80 with related control electronics including a rotary encoder coupled to a planetary gearset 76 that interconnects the servo motor 80 and shaft 78.

[0106] The internal mechanism is operable to apply an actuating load to the tensioner-balancer 40. The actuating instrument 70 includes an electronic data transceiver, shown schematically at 82. The transceiver 82 may operate over a wired or wireless connection. The actuating instrument 70 may be supplied with an appropriate combination of transducers (not shown in FIG. 14) to detect physical properties such as force, tilt angle, and/or applied load and generate a signal representative thereof. For example, the tensioner-balancer 40 may be provided with sensors operable to detect the magnitude of extension (i.e. "gap height"), the angle of the top plate about the pivot axis (i.e. varus/valgus), and/or the applied force in the extension direction. Nonlimiting examples of suitable transducers include strain gages, load cells, linear variable differential transformers ("LVDT"), rotary variable differential transformers ("RVDT"), or linear or rotary encoders or resolvers.

[0107] Displacement of the tensioner-balancer 40 may be derived from the encoder signals, knowing the kinematics of the linkage 46. The transceiver 82 is operable to transmit the signal.

[0108] A remote display 84 is configured to receive the signal and produce a display of the transducer data. As one example, the remote display 84 may be embodied in a conventional portable electronic device such as a "smart phone" or electronic tablet with suitable software programming. Optionally, the remote display 84 or other suitable transmitting device may be used to send remote operation commands to the actuating instrument 70.

[0109] In use, the remote display 84 permits the surgeon to observe the physical properties of the tensioner-balancer 40 in real time as the actuating instrument 70 is used to operate the tensioner-balancer 40.

[0110] Optionally, the actuating instrument 70 may incorporate a tracking marker 86. The tracking marker 86 is operable such that, using an appropriate receiving device, the position and orientation of the receiving device relative to the tracking marker 86 may be determined by receipt and analysis at the receiving device of signals transmitted by the tracking marker 86.

[0111] As illustrated, the tracking marker 86 may be configured as an inertial navigation device including one or more accelerometers and gyroscopic elements capable of providing angular rate information and acceleration data in 3D space.

[0112] In an alternative embodiment which is not illustrated, the tracking marker may include one or more tracking points which may be configured as transmitting antennas, radiological markers, or other similar devices.

[0113] 6 degree-of-freedom, local NAV, non-line-of sight, tracking markers 86 and appropriate receivers are known within the state-of-the-art.

[0114] A tracking marker 88 would be attached to the femur F in such a way that it has a substantially fixed position and orientation relative to the femur F. For example, a tracking marker 88 may be attached directly to the femur F.

[0115] In addition to the femur-mounted tracking marker 88, at least one additional tracking marker is provided which has a substantially fixed position and orientation relative to the tibia T. Where the actuating instrument 70 is rigidly coupled to the tensioner-balancer 40, the tibial tracking function may be provided by the tracking marker 86 of the actuating instrument 70. Alternatively, a tracking marker 90 may be attached directly to the tibia T.

[0116] In addition to collecting force, pressure, and/or displacement data between the femur F and the tibia T, an additional device may be used to collect force, pressure, and/or displacement data between the femur F and the patella P. FIG. 15 shows a human knee joint J in flexion. A patella force sensor 120 is shown disposed between the patella P and the femur F. The patella force sensor 120 may include one or more individual sensors operable to detect force, pressure, and/or displacement and produce representative signals, as described above with respect to the sensors of the gap balancer embodiments. This data may be transmitted through a flexible cable as shown in FIG. 15, or over a wireless connection.

[0117] The utility of the tensioner-balancer 40 may be extended by various attachments. As an example, FIG. 16 illustrates a spotting apparatus 180. This comprises a bar 181 extending from an articulated mount 182 which is in turn coupled to the tensioner-balancer 40. The mount 182 includes an actuator 184 permitting the bar 180 to pivot about a first axis 186. The bar 181 is formed in two telescoping sections 188, 190 which may be extended or retracted using an internal actuator (not shown). The first telescoping section 188 carries a first spotting element 192 such as a rotary center drill, and the second telescoping section 190 carries a second spotting element 194 such as a rotary center drill. Movement of the spotting apparatus 180 permits the first and second spotting elements 192, 194 to

be driven to selected locations relative to the condyles of the femur F. The spotting elements 192, 194 may then be used to form identifiable reference features in the femur F, such as small blind center drill holes. These reference features may then be used to provide a fixed position reference on the femur F for further surgical procedures.

[0118] The apparatus described above is suitable for various surgical procedures.

[0119] In one procedure, the tensioner-balancer 40 is used to evaluate the knee and to model and digitize the articular surfaces of the knee over its range of motion.

[0120] More particularly, the locus of points of contact of the femur F and the top plate 44 are modeled as a medial spline and the lateral spline.

[0121] To carry out this modeling, the tensioner-balancer is inserted between the femur F and the tibia T. As shown in FIG. 14, this is accomplished after having first made the tibial plateau cut. However, the tibial plateau cut is not required.

[0122] The actuating instrument 70 is coupled to the tensioner-balancer 40. Femoral tracking marker 88 is implanted to the femur F. At least one of tibial tracking marker 90 and instrument tracking marker 86 is placed.

[0123] The tensioner-balancer 40 is extended to apply a load to the knee joint. While different modes of operation are possible, one exemplary mode is to extend the tensioner-balancer 40 until a predetermined distraction load is applied. Feedback control or mechanical spring preload may then be used to maintain this distraction load, while the top plate 44 is permitted to pivot freely and translate vertically while the degrees of pivot and vertical displacement are measured, tracked, and recorded by the feedback control hardware and software. One example of a suitable distraction load is approximately 130 N (30 lb.) to 220 N (50 lb.). Another exemplary mode is to extend the tensioner-balancer 40 until a predetermined distraction distance is applied. Feedback control may then be used to maintain this distraction distance, while the top plate 44 is permitted to pivot freely

and while the degrees of pivot and distraction load are measured, tracked, and recorded by the feedback control hardware and software.

[0124] The knee joint J is then moved through its range of motion from full extension to full flexion while collecting data from the tensioner-balancer 40 and tracking markers 86, 88, 90. Specifically, the instantaneous location of the load centers LC and MC are recorded and correlated to the flexion angle of the knee joint (as determined from the tracking marker data). The recorded data is represented by the medial spline "MS" and the lateral spline "LS" as shown in FIG. 17. FIGS. 18 and 19 show the splines superimposed on the top plate of the tensioner-balancer 40. FIG. 18 illustrates idealized or nominal shape splines. FIG. 19 illustrates splines indicative of discontinuities, "notching", articular irregularities and incongruencies which may be found in an actual or pathological knee joint J. The splines may be characterized by two or more points (a Starting point and Terminal point, with zero or more Intermediary points in between), each with a location (defined by cartesian or polar coordinates relative to a fixed reference point defined by tracker on the tensioner-balancer baseplate), a direction, and a first and second derivative. Each spline point may also have an associated flexion angle and load. Given the datum of the tibia cut surface, and the fact that the tensioner balancer is fixed relative to the tibia and fixed relative to the tibia cut surface, the tracking system is functional with tracker 86 or 90 individually, or using both synchronously.

[0125] The spline information may be used to select an appropriate endoprosthesis, specifically a femoral component. Multiple femoral components of different sizes and articular surface profiles may be provided, and the one which has the best fit to the splines MS, LS may be selected for implantation. Alternatively, the spline information may be used to generate a profile for manufacture of a patient-specific femoral component.

[0126] The spline information may be used in conjunction with other information to determine appropriate cutting planes for the femur F. For example,

the back surface 28 of the femoral component 14 has a known relationship to the articular surface 30. The desired final location and orientation of the articular surface 30 is known in relation to the top plate 44 of the tensioner-balancer 40, which serves as a proxy for the tibial component 12. The final location of the tibial component 12 is known in relationship to the position of the tibial tracking marker 90. Finally, the actual orientation and location of the femur F in relation to the other parts of the joint J is known from the information from the femoral tracking marker 88. Using appropriate computations, the orientation and location of the cutting planes of the femur F can be calculated and referenced to the position the tensioner-balancer 40 or its tracker 86, or referenced to the position of the tibia or its tracker 90. With reference to FIGS. 20-22, it will be understood that the tensioner-balance 40 and associated tracking apparatus may be used to collect the following data related to the knee joint: distraction height "Z" of the top plate 44, tilt angle "A" (i.e., varus-valgus) of the top plate 44), medial and lateral distraction heights "ZM", "ZL" (e.g., derived from the top plate distraction height and top plate tilt angle), the medial and lateral spline data, the position of the contact points of the femur F on the top plate (medial-lateral and anterior-posterior) (MX, MY, LX, LY), the distraction load on the medial and lateral condyles (MD, LD), the knee joint flexion angle "FA", and the abovementioned 6-DoF position data for each tracking marker (X, Y, Z position and X_r , Y_r , Z_r rotation).

[0127] FIG. 23 is a chart illustrating how the real-time data from the tensioner-balancer 40 and the tracking markers can be recorded, with multiple data channels are parameters being recorded for each time step.

[0128] In collecting the spline information and tracking information, it is helpful to make reference to one or more positional datums. Each datum is a 6 DoF reference (e.g. position and orientation about three mutually perpendicular axes). The datum may refer to a geometrical construct as well as a virtual software construct.

[0129] FIG. 24 shows an example of a datum 700 superimposed on a tibia T. As illustrated, the datum 700 is a coordinate framework with X, Y, and Z axes, as well as rotations about each of those three axes. Some respects of the position and orientation of the datum 700 relative to the tibia T may be arbitrary selected. In one example, the Z-axis may be positioned in a predetermined relationship to a known anatomical reference such as the tibia anatomical axis or tibia mechanical axis. The XY plane may be positioned normal to the Z axis and intersecting the tibia at the position of an actual or assumed tibial plateau cutting plane, or oriented at some defined angular displacement relative to an actual or assumed tibia cutting plane. Thus positioned, the datum 700 provides a reference for measurements using the tracking markers and/or the tensioner-balancer 40.

[0130] FIG. 25 shows an example of a datum 702 superimposed on a femur F. As illustrated, the datum 702 is a coordinate framework with X, Y, and Z axes, as well as rotations about each of those three axes. Some respects of the position and orientation of the datum 702 relative to the femur F may be arbitrary selected. In one example, the Z-axis may be positioned in a predetermined relationship to a known anatomical reference such as the femur anatomical axis or femur mechanical axis. The XY plane may be positioned normal to the Z axis. Longitudinally, the XY plane may be positioned, for example intersecting an anatomical reference such as Whiteside's line. Thus positioned, the datum 702 provides a reference for measurements using the tracking markers and/or the tensioner-balancer 40.

[0131] FIG. 26 shows the assembled knee joint J with the two datums 700, 702. For measurement and computational purposes, one of the datums may be designated a "primary" datum, with the remaining data being designated as "secondary" datums. In one example, the datum 700 associated with the tibia T may be designated a primary datum. With the position and orientation of the datum 700 known in space (i.e., from tracking marker information), the position and orientation of the datum 702 associated with the femur F may be reported as a relative position and orientation to the datum 700 (primary data).

[0132] In another example, an arbitrary primary datum 704 may be positioned at arbitrary predetermined location outside of the body. With the position and orientation of the primary datum 704 known in space, the position and orientation of the datum 700 associated with the tibia T (considered a secondary datum in this case) may be reported as a relative position and orientation to the datum 704. In this example, the position and orientation of the datum 702 associated with the femur F would also be considered a secondary datum and would be reported as a relative position and orientation to the datum 704.

[0133] FIG. 27 illustrates the organization of the data collected by the tracking markers in the tensioner-balancer 40. It can be seen that the overall modeling of the complex 3D knee geometry can be reduced for practical purposes to a relatively small set of elements including: tibial plateau cut plane, the medial and lateral splines, the position of the medial and lateral spine contacts on the tibial plateau cut plane, and axis or vector passing from the ankle center through the tibial plateau cut plane, and a femoral axis passing through the femoral head.

[0134] A nominal distal femoral cutting plane 2 (FIG. 30) may be determined by anatomical analysis using known anatomical references and techniques. For example, this plane 2 could be uniformly spaced away from and parallel to the tibial cutting plane 1 (i.e., a nominal cut). Alternatively, this plane 2 could be at an oblique angle to the tibial cutting plane 1, in one or more planes (i.e., simple or compound tilted cut, potentially usable as a corrective cut).

[0135] Information from the tensioner-balancer 40 and tracking markers may be used with hand-held equipment. Once the cutting planes are determined, the tracking markers 86, 88, or 90 may be used to guide a bone saw 250 equipped with a tracking marker 252 to make the distal femoral cut 2 at appropriate angle and location, as depicted in FIG. 30. In this context, the cutting plane (or a portion thereof) defines a computed tool path. This guidance is possible because intercommunication between the bone saw 250 and the associated tracking marker

252 will give the relative position and orientation of the bone saw 250 to that tracking marker. The cutting guidance may be provided in the form of information displayed on the remote display 84 described above. For this purpose, 2-way data communications may be provided between and among the bone saw 250 (or other surgical instrument), the tracking markers 86, 88, or 90, and the remote display 84.

[0136] It should be noted that the bone saw 252 can be guided with reference to only a single tracking marker 88 coupled to the femur F. Alternatively, the cutting guidance (optionally along with other information, such as the virtual future position of the drilled holes and implants used) may be displayed on a body-worn display providing 2D or 3D graphics or providing a holographic heads-up display with an information panel (e.g., a Virtual Reality or augmented reality or mixed reality headset 300). Alternatively, the cutting guidance may be provided to a conventional robot 301 (FIG. 31) to which the bone saw is mounted.

[0137] Information from the tensioner-balancer 40 and tracking markers may optionally be used for drilling holes, for example to anchor tensile elements. Referring to FIG. 32, once a position of a hole to be drilled is determined, the tracking markers 86, 88, or 90 may be used to guide a cordless drill 254 equipped with a tracking marker 256 to drill a hole, with the drill bit 258 extending an appropriate angle. In this context, the hole to be drilled (or a portion thereof) defines a computed tool path. Guidance along the tool path is possible because intercommunication between the cordless drill 254 and the tracking marker 256 will give the relative position and orientation of the cordless drill 254 to those markers. The drilling guidance may be provided in the form of information displayed on the remote display 84 described above. For this purpose, two-way data communications may be provided between and among the cordless drill 254 (or other surgical instrument), the tracking markers 86, 88, or 90, the actuating instrument 70, and the remote display 84. It should be noted that the drill 254 can be guided with reference to only a single tracking marker 88 coupled to the femur F. Alternatively, the drilling guidance (optionally along with other information, such as the virtual future position

of the drilled holes and implants used) may be displayed on a body-worn display providing 2D or 3D graphics or providing a holographic heads-up display with an information panel (e.g., a Virtual Reality or augmented reality or mixed reality headset 300). Alternatively, the drilling guidance may be provided to a conventional robot 301 (FIG. 33) to which the bone saw is mounted.

[0138] Information from the tensioner-balancer 40 and tracking markers may optionally be used for automated placement of components. Referring to FIG. 34, the tracking markers 86, 88, or 90 may be used to guide a robot 301 to implant one or more of the endoprosthesis components into the knee joint J, such as the tibial tray 16, insert 18, and/or femoral component 14 to which the bone saw is mounted.

[0139] As seen in FIG. 35, the tensioner-balancer 40 may be used with a trial implant (femoral component 14) to collect data and evaluate the femoral component 14.

[0140] In addition to retaining the patients' PCL in a knee arthroplasty, it may be augmented (reinforced) using one or more artificial tensile members. The term "tensile member" as used herein generally refers to any flexible element capable of transmitting a tensile force. Nonlimiting examples of known types of tensile members include sutures and orthopedic cables. Commercially-available tensile members intended to be implanted in the human body may have a diameter ranging from tens of microns in diameter to multiple millimeters in diameter. Commercially-available tensile members may be made from a variety of materials such as polymers or metal alloys. Nonlimiting examples of suitable materials include absorbable and resorbable polymers, nylon, ultrahigh molecular weight polyethylene ("UHMWPE") or polypropylene titanium alloys, or stainless steel alloys. Known physical configurations of tensile members include monofilament, braided, twisted, woven, and wrapped. Optionally, the tensile member may be made from a shape memory material, such as a temperature-responsive or moisture-response material.

[0141] FIGS. 36 and 37 illustrate a tensile member passing through transosseous passages formed in bone (e.g., by drilling), fixed by anchors, and routed across the posterior aspect of a human knee joint J. The tensile member replaces or augments or reinforces or tethers the PCL.

[0142] In the illustrated example, two tensile members are present, referred to as first and second tensile members 440, 440' respectively.

[0143] The first tensile member 440 has a first end 442 secured to the femur F on the outboard side thereof, by a first anchor 444. (With reference to this example, the terms "inboard" and "outboard" are used to describe locations relative to their distance from the meeting articular surfaces of the joint J. For example, the endoprosthesis 10 would be considered "inboard" of the joint J, while the anchor 444 would be considered "outboard"). The first tensile member 440 passes through a first femoral passage 446 formed in the femur F, exiting the inboard side of the femur F.

[0144] The second tensile member 440' has a first end 442' secured to the femur F on the outboard side thereof, by a second anchor 448. The second tensile member 440' passes through a second femoral passage 450 formed in the femur F, exiting the inboard side of the femur F.

[0145] The first and second tensile members 440, 440' span the gap between femur F and tibia T and enter a tibial passage 452 at an inboard side. The first and second tensile members 440, 440' pass through the tibial passage 452 at a single entry 453, exiting the outboard side of the tibia T. Second ends 454, 454' of the first and second tensile members 440, 442' are secured with a third anchor 456.

[0146] The term "anchor" as it relates to elements 444, 448, and 456 refers to any device which is effective to secure a tensile member passing therethrough. Nonlimiting examples of anchors include washers, buttons, flip-anchors, adjustable

loop devices, fixed loop devices, interference screw devices, screw plates, ferrules, swages, or crimp anchors.

[0147] The tensile members 440, 440' can be routed through or along the PCL.

[0148] FIG. 38 illustrates an exemplary insertion instrument 500 which may be used to insert, tension, and activate swage-type anchors. The basic components of the insertion instrument 500 are a body 502, a stem 504 extending from the body 502 and having an anchor connection mechanism 506 disposed at a distal end thereof, a hollow pushrod 508 extending through the stem 504 and slidably movable between retracted and extended positions, and a driving mechanism 510 for moving the pushrod 508 between retracted and extended positions. The stem 504 and the pushrod 508 may be rigid or flexible.

[0149] In the illustrated example, the driving mechanism 510 comprises an internal threaded mechanism which is manually operated by a star wheel 512.

[0150] A tensioner 514 is part of or connected to the insertion instrument 500. It has a housing 516. A shuttle assembly 518 including an adjustment knob 520 and a grooved spool 522 is received inside the housing 516. A compression spring 524 is captured between the shuttle assembly 518 and the housing 516. The shuttle assembly 518 can translate forward and aft relative to the housing 516 in response to rotation of the adjustment knob 520.

[0151] In use, a first end of a tensile member 440 passes through the hollow interior of tensioner 514 and is secured to the spool 522. The tension applied to the tensile member 440 may be indicated, for example, by observing the position of the shuttle assembly 518 relative to a calibrated scale 526 on the housing 516. When a suitable final tension is achieved, the star wheel 512 may be operated to actuate the pushrod 508, swaging the tensile member 440 and fracturing the breakaway structure of the anchor. In the illustrated example, two separate tensioners 514 are

provided, allowing the tension of each of the tensile members to be set independently.

[0152] In one example procedure where two tensile members are used, a first provisional tension is applied to the first tensile member and a second provisional tension is applied to the second tensile member. The second tensile member may have the same or different tension as the first tensile member. Next, the provisional tensions evaluate to determine if they are suitable. In response to the evaluation, they may be increased or decreased. Finally, the anchor may be swaged to secure the tensile members and finalize the tension. In one example, the tension may be from about 0 N (0 lb.) to about 220 N (50 lb.)

[0153] In addition to or as an alternative to other devices and methods described herein, the range of motion of the knee joint J may be evaluated using non-image-based devices and methods. As it is used, the phrase “image-based” refers to common preoperative and intraoperative imaging techniques including x-ray, fluoroscopy, radiograph, CT scan, CAT Scan, MRI, or digital registration. For example, FIG. 39 illustrates schematically a human leg which has been instrumented for measurement using a body-worn tracking apparatus, indicated generally at 600.

[0154] At least one upper leg garter 602 is secured around the upper leg. The upper leg garter 602 includes a band 604 configured to be secured around the upper leg, for example by elastic tension, or an adjustable mechanism such as hook and loop fasteners or a buckle (not shown). It further includes at least one tracking marker 606. The tracking marker 606 is operable such that, using an appropriate receiving device, the position and orientation of the receiving device relative to the tracking marker 606 may be determined by receipt and analysis at the receiving device of signals transmitted by the tracking marker 606.

[0155] As illustrated, the six degree-of-freedom, local NAV, non-line-of sight tracking marker 606 may be operable to determine six degree-of-freedom position information in a local coordinate system. For example, it may be configured as an

inertial navigation device including one or more accelerometers and gyroscopic elements capable of providing angular rate information and acceleration data in 3D space.

[0156] In an alternative embodiment shown in FIG. 40, the tracking marker 606 may include one or more tracking points which may be configured as transmitting antennas, radiological markers, or other similar devices. Tracking markers 606 and appropriate receivers are known within the state-of-the-art. Nonlimiting examples of known tracking methods include LIDAR, time-of-flight sensors, infrared detectors, moiré patterns, and ultrasonic trackers. FIG. 40 illustrates exemplary receiving devices 608.

[0157] By securing the upper leg garter 602 around the upper leg, the tracking marker 606 would have a substantially fixed position and orientation relative to the femur F.

[0158] At least one lower leg garter 610 is secured around the lower leg. The lower leg garter 610 is of similar or identical construction to the upper leg garter 602. It includes a band 612 and at least one tracking marker 614. Thus secured, the tracking marker 614 would have a substantially fixed position and orientation relative to the tibia T.

[0159] Once the upper and lower leg garters 602, 610 are secured, they may be placed in data communication with a suitable electronic receiving device by a wired or wireless connection. Appropriate processors and software may be provided for interpretation of the signals from the garters 602, 610.

[0160] Appropriate processing of signals generated by the garters 602, 610 may be used to generate kinematics of the knee joint J in numeric and/or graphical form.

[0161] The received data may be displayed on a display providing 2D or 3D graphics or providing a holographic heads-up display with an information panel (e.g., a Virtual Reality or augmented reality or mixed reality headset 300), or on a

conventional display such as a computer monitor (not shown).

[0162] The body-worn tracking apparatus 600 can be used for several kinds of measurement, which may be referred to herein as "dynamic imaging". For example, it can be used to quantify the range of motion of the knee joint J, i.e., by measuring the flexion angle from the patient's most extended position to the patient's most flexed position. In another example, the body-worn tracking apparatus 600 can be used to quantify the results of a "drawer test" in which the patient's lower leg is pulled axially away from the upper leg, by measuring the amount of deflection when a force is applied. This quantifies the "tightness" of the knee joint J. And in another example the tracking apparatus 600 can be used to pinpoint the femoral head center, the ankle center, the mechanical axes of the tibia and femur, and the knee center along with the instantaneous axis of rotation of the knee, which changes position but is traceable throughout the arc of motion.

[0163] The body-worn tracking apparatus 600 can be used pre-operatively in order to evaluate the patient's normal or pathological knee. The body-worn tracking apparatus 600 can be used post-operatively in order to evaluate the results of a knee procedure. Nonlimiting examples of biological markers that may be tracked include actual range of motion, swelling in and around the joint, and patellar movement. Nonlimiting examples of known methods to visualize and track the described kinematics include the drawer test, varus-valgus stress test, hyperextension, range of motion analysis, and standing-walking-running and stairstep tests.

[0164] In addition to the modeling of the joint surfaces and joint kinematics described above, the inventors have discovered that the complexity and totality of the soft tissue of the knee joint J may be modeled with high fidelity producing actionable results by using a simplified construct of six-degree of freedom points with centroids, orientations, directions of momentum and acceleration, referred to as "sockets" coupled by digital or mathematically modeled tensile members representing individual ligament, tendons, ligament or tendon masses, ligament or

tendon bundles, or tissue bundles having defined properties. An individual ligament or tendon can be modeled with one or more sockets for each end of the ligament. Each socket may be defined instantaneously. FIGS. 43 and 44 illustrate the MCL of human knee joint J. The MCL J is relatively broad and flat, extending some distance in the superior-inferior direction. It has a proximal end 800 that originates at the femur F and a distal end 802 having its insertion in the tibia T. FIGS. 43 and 44 show the knee J and MCL in the extended position, while FIGS. 46 and 47 show the knee J and MCL in the flexed position. It can be observed that the MCL is not purely under tension but undergoes some bending during the movement. In the flexed position, the footprint of its proximal end 800 is bent over or twisted or inverted as seen in FIG. 46. It can also be observed that the complex mechanical dynamics of the MCL can be simplified for computational purposes with one or more distinct tensile members, each with programmed nonlinear stress-strain properties and definitions of starting point tangency and terminal point tangency.

[0165] FIGS. 45 and 48 illustrate a modeling configuration for the MCL. In this model, a first socket 804 is disposed at the anterior portion of the proximal end 800 of the MCL. A second socket 806 is disposed at the posterior portion of the proximal end 800 of the MCL. A third socket 808 is disposed at the distal end 802 of the MCL.

[0166] As noted above, each socket is a mathematical construct which can be manipulated by conventional modeling software, including but not limited to finite element analysis. The accuracy, repeatability, and reliability of these mathematical constructs may be confirmed through empirical imaging and analysis using known techniques, including Biplanar fluoroscopy or shear wave and strain sonoelastography. Each socket defines a point in space which has properties of position in three axes e.g. X, Y, Z and orientation and three axes, e.g., X, Y, Z. Each socket may translate along any of three axes, rotate about any of the three axes, or have forces or torques applied to or reacted from any of the three axes.

[0167] The modeling configuration further includes tensile members

representing the MCL interconnecting the sockets. In the illustrated example, a first tensile member 810 extends from the first socket 804 to the third socket 808. A second tensile member 812 extends from the second socket 806 to the third socket 808. Each tensile member 810, 812 is associated with a set of properties i.e. a ligament stiffness, more specifically a stress versus strain curve, described in more detail below.

[0168] FIG. 49 further illustrates the mathematical socket construct overlaid onto a knee joint J having a tensioner-balancer 40 inserted therein, with the patella P in place. The socket-based model is thus also useful Intraoperatively.

[0169] It is noted that the socket construct may be used with any soft tissue member. For example, FIG. 50 shows a pair of sockets 814, 816 and a tensile member 818 being used to model the PCL of the human knee joint J.

[0170] The position of the sockets (or at least their initial assumed position) may be an input into the software arbitrarily or may be measured. For example, FIG. 51 illustrates an instrumented probe 820 having a tip 822 and a tracking marker 824 as described above. The probe 820 may be used preoperatively or intraoperatively to collect actual position data of the insertion and/or origin of the soft tissue such as the MCL. This position data within be used in the software for the position of the associated socket.

[0171] FIG. 52 is a schematic diagram representing the stiffness of a human knee ligament. This is a stress-strain curve illustrating ligament percent strain on the X-axis and ligament stress on the Y-axis. Beginning at the current origin can be seen that there is an initial nonlinear range is the individual ligament fibers are strained and tend to “align” themselves from laxity to parallel paths under a very low initial tension when a load is applied (i.e. strain is applied without any resultant loading), followed by a generally linear region where the ligament is seen to behave more elastically and/or viscoelastically. As stress is increased, microscopic failures began giving way to macroscopic failure and finally to rupture of the ligament when its

breaking strength is exceeded. This curve indicates the overall characteristic of a given ligament. However, it will be understood that the specific tensile characteristics will vary for an individual patient or patient population based on numerous factors such as age, gender, body mass, physique, level of athletic training, and existence or absence of pathology. In FIG. 53, the solid line is representative of a healthy young athlete, while the dotted line is representative of an elderly person, and the dot-dash line is representative of a person having soft tissue damage.

[0172] It will be understood that the stress-strain characteristics are dynamic in nature and can vary with the flexion angle of the knee joint J. Referring to FIG. 54, this is a three-dimensional plot of ligament stress versus strain over a range of flexion angles. This is due to the fact that the ligaments are in fact not point to point lines but are masses of soft tissue which engage and disengage different parts of their bone attachment “footprints” as the joint is flexed.

[0173] It will be understood that the ligament properties and characteristics described above can be determined by the tensioner-balancer device as a stand-alone measurement apparatus with the use of mathematical computations derived from an understanding of forces acting on the joint and anatomical measurements.

[0174] It will be understood that anatomical measurements may include ligament geometry including length, width, diameter, cross-sectional-area, angle, and footprint area. Mechanical and anatomical axes, as well as a live reading of the flexion angle of the knee, may be measured in 6 degrees of freedom with body-worn tracking markers, non-line-of-sight trackers, inertial measurement units, goniometers, or the like.

[0175] An example of a nonlinear equation with associated variables and coefficients:

$$[0176] \quad y(x, z) = \left(B1 + \frac{(z-\omega)^f}{B2} \right) \times \left[A1 + A2 \times \frac{1}{(1 + e^{-k*(x-\phi)})^a} \right]$$

x = ligament displacement

ϕ = ligament displacement correction

z = flexion angle

ω = flexion correction

k = "stiffness factor" (affects the slope of the curve)

a = "strain skew" (affects the shift of the inflection points in the Strain axis)

f = "flexion power" (affects the amplitude [curviness vs flatness] of the curve through the 3rd dimension, Flexion Angle)

A1 = Strain Intercept

A2 = Strain Coefficient

B1 = Flexion Intercept

B2 = Flexion Coefficient

[0177] In modeling the soft tissue of a specific patient as described above, an appropriate patient specific set of intraoperative and postoperative parameters for a plan of care may be developed. The parameters may be influenced or selected by populational and demographic data such as age, gender, stature, pathology, disease state, activity level, outcome goals, and lifestyle. The parameters described may include the total distraction load to be used for balancing the knee, patient-specific medial and lateral contact loads, patient-specific prosthesis geometry and sizing,

flexion-angle-specific loads, ligament-specific loads, or position and tension applied to any implanted tensile members for ligament augmentation or reinforcement. Patient-specific parameters will also be influenced by a patient's individual anatomy and kinematics and may be used to generate three-dimensional plots driven by nonlinear equations. An appropriate three-dimensional plot may also be proposed by a teaching and learning system. A Machine Learning system may be allowed to compute and define patient specific stress and strain characteristics for patient specific analysis.

[0178] One or more of the methods described herein may be incorporated into a complete surgical flow process. FIG. 55 illustrates an exemplary process as it applies to knee joint J. For purposes of explanation, the pre-operative knee joint J is assumed to have some wear, injury, or disease process and is referred to as a "pathological knee".

[0179] At block 2000, optionally pre-operative dynamic imaging may be used to evaluate the overall characteristics of the knee joint J, including for example the range of motion. The body-worn tracking apparatus 600 described above may be used for this purpose.

[0180] At block 2002, a software application is used to compute socket locations throughout the range of motion for the pathological knee. At this point, the software application may be used to predict the ligament stiffness and joint kinematics. An operative plan may be proposed or predicted or computed. Socket matrices may be created, this may serve as a seed for machine learning components (if used).

[0181] At the block 2004 the software application assigns parameters for patient-specific operative workflow based on the pre-op dynamic imaging.

[0182] At block 2006, the surgeon will operatively measure the pathological knee by using the tensioner-balancer 40, tracking marker, and related apparatus described above and sweeping the knee through a range of motion while using the

apparatus to collect data. Optionally during this process, ligament stiffness and socket locations may be measured operatively (block 2008). If measured, the socket matrices are updated with real-time information.

[0183] One method of measuring ligament stiffness may be understood with reference to FIGS. 59-62. FIG. 59 is a schematic diagram of a knee joint J with a tensioner-balancer 40 inserted therein in an extended position (e.g., 0 degrees flexion), while FIG. 60 shows the knee joint J in a flexed position. Various measurements and parameters are labeled on diagram. Dimension "HL" is a measured height at the lateral condyle. Dimension "HM" is a height at the medial condyle. "H" is a height at the pivot axis 47 of the top plate 46. Arrow "LC" represents compressive force acting through the pivot axis 47 of the top plate 46 (see FIG. 7). Arrow "LC" represents compressive force acting through the lateral condyle, and arrow "LCV" is a vertical component of LC. Arrow "LA" represents compressive force acting through the pivot axis 47 of the top plate 46. Arrow LA vector is normal to the base plate 42 and represents a "vertical" direction for purposes of explanation. Arrow "MC" represents compressive force acting through the medial condyle, and arrow "MCV" is a vertical component of MC. Dimension "DL" represents the distance between the pivot axis 47 of the top plate 46 and the line of action of compressive force LC. Dimension "DM" represents the distance between the pivot axis 47 of the top plate 46 and the line of action of compressive force MC. Dimension "AV" represents the tilt angle of the top plate 46. It will be understood from the description above that the tensioner-balancer 40 is sufficiently instrumented that the values HL, HM, LA, LC, MC, DL, and DM can all be determined either through direct sensing or computation of values based on sensor inputs, such as inputs from the strain gages 58 described above. This information can be used to compute pertinent physical characteristics of the soft tissue, namely the medial collateral ligament (MCL) and the lateral collateral ligament (LCL).

[0184] In FIG. 59, the dimension "RM" represents the distance between the pivot axis 47 of the top plate 46 and the lateral location of the area centroid of the MCL

(designated by a cross-hair symbol). The dimension "RL" represents the distance between the pivot axis 47 of the top plate 46 and the lateral location of the area centroid of the LCL (designated by a cross-hair symbol). Dimension "AM" represents the angle in the coronal plane of the line of action of the MCL measured from vertical. Dimension "AL" represents the angle in the coronal plane of the line of action of the LCL measured from vertical. Dimension "SM" represents the overall length of the MCL. Dimension "SL" represents the overall length of the LCL. Arrow "ML" represents the tensile load on the MCL. Arrow "LL" represents the tensile load on the LCL.

[0185] In one example, knowing the medial-side deflection (i.e., the change in dimension HM) as well as distance DM and distance RM, a geometric transformation may be performed to determine the deflection of the MCL (i.e., the change in dimension SM). The required computations may be carried out using a software application. A similar geometric transformation may be carried out to determine the deflection of the LCL (i.e., the change in dimension SL) when the change in dimension HL, distance DM, and distance RL are known). In another example, knowing the medial-side compressive load MC, as well as distance DM and distance RM, computation may be performed to determine the medial-side tensile load ML. In another example, knowing the lateral-side compressive load LC, as well as distance DL and distance RL, computation may be performed to determine the lateral-side tensile load LL. In computing the deflections and loads on the MCL and/or LCL, the orientation of the ligaments may be taken into account. The above-described computations will result in the vertical components of ML or LL, or vertical components of change in SM or SL. If the angles AM or AL are non-zero, a geometric transformation may be performed to determine the actual values of the ligament parameters acting along their lines of action.

[0186] For the purposes of the above-described computations, the distances RM and RL may be measured directly, measured indirectly, or may be determined by reference to a database or other source of statistical information. For example, a

database may contain average joint dimensions based on population characteristics. E.g., a 5 percentile female or a 95 percentile male.

[0187] The following is an example of a computation for determining the vertical ligament load from calculated or measured contact load orthogonal to the top plate 46. This method uses trigonometric relationships to convert between orthogonal component and vertical component.

- a. $LCV = LC / \cos(AV)$
- b. $MCV = MC / \cos(AV)$
- c. $LL = (LA * (RL / (RL+RM))) / \cos(AL)$
- d. $ML = (LA * RM / (RL+RM)) / \cos(AM)$
- e. $HL = H * (1 + \sin(AV))$
- f. $HM = H * (1 - \sin(AV))$

[0188] The above-described computations may be extended to the stress (force/area) in the ligaments by dividing the measured or computed load (force) by the cross-sectional area of the relevant ligament. The cross-sectional areas of the ligaments may be measured directly, measured indirectly, or may be determined by reference to a database or other source of statistical information.

[0189] In the example shown in FIGS. 59 and 60, the top plate angle AV is approximately zero. Accordingly, the values LC and MC as sensed have only a vertical component and may be used directly for additional computations. In other circumstances, the top plate angle AV may be nonzero. Examples experienced in actual patients can include angles of up to about 7 degrees. FIG. 61 and 62 illustrate any joint J where top plate angle AV has a substantial nonzero value, for example about 5 degrees. As can be seen in FIG. 61, this has the consequence that values LC and MC act along non-vertical lines. It will be understood that in subsequent

computations, it is desirable to know the vertical components of these values. Accordingly, where top plate angle AV is nonzero, a trigonometric transformation may be performed on the values LC and MC to derive their vertical components.

[0190] FIGS. 63-69 illustrate ligament stiffness data that can be obtained using the above-described methods. FIG. 63 illustrates load and stress, versus displacement, for the MCL (solid lines) and the LCL (dashed lines). FIGS. 64 and 65 illustrate the same data separately for the MCL and the LCL, respectively. The data is plotted for a variety of knee flexion angles. These data may be obtained by using the tensioner-balancer 40 with the knee in a variety of flexion angles. Various specific methods are possible. For example in one procedure, the tensioner-balancer may be inserted into a knee in a retracted position, the knee joint J may be positioned at a desired flexion angle, then the tensioner-balancer 40 may be extended and data collected. This procedure may be repeated in a variety of flexion angles. Alternatively, the tensioner-balancer 40 may be driven by instrument 70 described above to alternate between extended and retracted positions on a preprogrammed time interval. The operator would then move the knee joint J to desired flexion angles when the tensioner-balancer 40 was in the retracted position, wait for the tensioner-balancer 40 to extended at the preprogrammed interval, allow data to be collected by the tensioner-balancer 40, and then move the knee joint J to a different flexion angle when the tensioner-balancer 40 retracted.

[0191] The data in FIGS. 63-65 illustrate a characteristic that is commonly observed in patients' needs, namely that the LCL exhibits greater deflection at a given load, i.e. it is more "lax". This could also be described as having a lower effective spring rate.

[0192] The ligament stiffness data can show important characteristics of the knee joint J, especially when data is taken at flexion angles other than 0 degrees or 90 degrees, i.e. when data is taken at mid-flexion angles. For example, figs. 66 and 67 illustrate a knee joint exhibiting mid-flexion laxity. It can be seen at flexion angle

of approximately 45 degrees, that the displacement is substantially greater as compared to the fully extended position and the fully flexed position. This information is helpful to a surgeon in determining the kind and magnitude of ligament augmentations, cutting plane adjustments, implant sizing, and so forth to account for a "design point" in operation of the knee. For example, it may be desired to provide a minimum predetermined degree of "tautness" for the knee joint J in all positions. In the example illustrated in FIGS. 66 and 67, a desired minimum tautness would not be present at all flexion angles if the ligament stiffness data were used based on the extended or fully flex positions. In this example, a surgeon may elect to make surgical decisions based on the 45 degree flexed position data.

[0193] FIGS. 68 and 69 illustrate another knee having variable ligament stiffness characteristics over a range of flexion angles. This particular example is a characteristic opposite or inverted to that of the one shown in FIG. 66 and 67. More specifically, this knee joint exhibits mid-flexion tautness. It can be seen at a flexion angle of approximately 45 degrees, that the displacement is substantially less as compared to the fully extended position in the fully flexed position. In this example, a surgeon may elect to make surgical decisions based on the fully extended or fully flexed position data in order to avoid excessive tightness in the mid-flexion position.

[0194] The above-described ligament evaluation methods have focused on information detailed in a view orthogonal to the coronal plane. It is also possible to determine physical characteristics of the ligaments and their influence on knee kinematics in a view orthogonal to the sagittal plane. FIGS. 70 and 71 illustrate a knee joint J having a tensioner-balancer 40 as described above inserted therein. Given that the anterior-posterior location of condylar contact may be resolved as described above, the movement of ligaments in a view orthogonal to the sagittal plane may also be resolved. Ligament angles as viewed orthogonal to the sagittal plane may be measured and used in addition to coronal plane measurements to compute ligament stress and load with the addition of a second trigonometric operation on the measured load values LC and MC.

[0195] It will be understood that the patellofemoral tendon and PCL (posterior cruciate ligament) may also play a role in the knee kinematics and may be accounted for in the ligament characterization model. For example, a portion of the distraction load applied may be realized as stress in the patellofemoral tendon or PCL. It is understood that this stress is dependent on flexion angle and may depend on flexion angle. In general, the patellofemoral tendon will have a greater influence on knee kinematics in flexion than it will in extension. Similarly, in general the PCL will have a greater influence in mid-flexion and deep flexion (e.g., beyond 90 degrees).

[0196] FIG. 77 shows example plots of how the sensor data could be displayed. This is a graph of actual ligament tension versus knee joint flexion angle following the computations described above.

[0197] At block 2010 (Fig. 55), if a machine learning component is utilized, the information collected from the patient's knee would be used to reinforce that component.

[0198] At block 2012, the software application performs a socket update cycle. Within the cycle performs the following functions (1) augmented reality frame refresh; (2) surgical feature refresh; (3) check limits/constraints.

[0199] At block 2014, the software application builds a surgical plan. The surgical plan includes implant positioning and augmentation computation. Fundamentally, the surgical plan embodies an algorithm (block 2017) which takes as input the pre-existing conditions of the pathological knee, the desired end condition (i.e. the repaired knee), and computes one or more corrections necessary to achieve the desired end condition. Nonlimiting examples of required corrections are implant size selection, implant contact surface/articular surface best curve fit, and soft tissue augmentations.

[0200] At block 2016, guided surgical workflow is carried out this could be using augmented reality, robotic guidance, or the like.

[0201] Finally, at block 2018 optionally post-operative dynamic imaging may be carried out.

[0202] Some or all of the functions of the surgical flow process may be performed by a machine learning system. Numerous types of machine learning software are known in the art which are capable of correlating multiple inputs to multiple outputs without the necessity for manually programming the exact interrelationships of the inputs and the outputs.

[0203] In one example, inputs to the machine learning system may be the position of the sockets and the ligament loads and stiffnesses (e.g. stress versus strain curve).

[0204] The Machine Learning system may assign and compute a Hierarchy of Ligament Significance to overall knee motion, action, stability, and kinematics. The Machine Learning system may assign and compute tunability sensitivities of various ligaments in the six degrees of motion of the knee to define the kinematic relationship of the tibia to femur. Nonlimiting examples of ligaments include deep and superficial MCL (medial collateral ligament), deep and superficial LCL (lateral collateral ligament), anterolateral ligament, Fibula collateral ligament, popliteal ligament, patella-femoral ligament, lateral patellar retinaculum, both bundles of the ACL and PCL, and menisci of the knee.

[0205] The output may be the kinematics of the pathological or native knee joint or the kinematics of the repaired knee joint with prosthetic components included.

[0206] Machine learning systems may be provided with initial seed data, and trained with known reinforcement learning (e.g., supervised or semi-supervised) methodologies. Unsupervised learning methods may also be deployed in laboratory settings to explore potential kinematic outcomes rapidly and in bulk (without having to wait many months to study large populations). The machine learning system may incorporate historical populational data to make decisions. Furthermore, patient-

specific inputs to the evaluation may be collected digitally over some or all of the lifetime of the patient. The machine learning system may be improved with patient feedback by evaluating qualitatively and quantitatively the postoperative the patient result as a dataset; using the result dataset as an input into a large database; and using the database to develop future procedural pathways and to use as inputs into machine learning-based decisions. Reward functions may be used as inputs to the machine learning system to drive better qualitative and quantitative patient outcomes.

[0207] While the methods described herein have been explained using a knee joint as an example, it will be understood that at least some of the methods are applicable to other joints having two or more bones connected together by soft tissue to form an articulating joint. For example, the socket modeling construct could be used to model the soft tissue of a shoulder joint having a scapula and a humerus and associated ligaments and tendons as shown in FIG. 57, or a hip joint having a pelvis and a femur and associated ligaments and tendons as shown in FIG. 58.

[0208] As part of the surgical procedure which may be the guiding workload described above or a manual or semi-automated surgical workflow, one or more marketing and guiding devices may be used to locate cutting planes and make cuts on the knee joint J. FIG. 72 illustrates knee joint J with a tensioner-balancer 40 inserted therein and the instrument 70 coupled to the tensioner-balancer 40. Tensioner-balancer 40 is in the extended position and can be seen that a tibial plateau cut has already been made. A T-shaped marking guide 3000 has a shaft 3002 which is mounted to the tensioner-balancer 40 by an appropriate mechanical connection and a cross-beam 3004. The shaft 3002 is adjustable in a vertical direction V. The cross-beam 3004 carries a pair of spaced-apart guide bushings 3006. These are adjustable in a lateral direction L relative to the cross-beam 3004. The marking guide 3000 may be used by coupling it to the tensioner-balancer 40, adjusting in the vertical and lateral directions such that each of the guide bushings

3006 are at a desired location relative to the femur F, and then marking or spotting locations on the anterior aspect of the femur F. In the illustrated example, this may be carried out by using the guide bushings 3006 to guide drills 3008 to form holes in the femur F. These holes may subsequently receive guide pins used to mount a guide block (described below).

[0209] Similarly, as shown in FIG. 73, the marking guide 3000 may be used to mark guide holes in a distal aspect of the femur F. To do this, the marking guide 3000 would be used to described above, with the knee J in a flexed position.

[0210] FIG. 74 illustrates an alternative marking guide 4000. This includes a U-shaped baseplate 4002 with a central hub 4004. Each leg of the baseplate 4002 includes a guide bushing 4006 slidably adjustable in a slot 4008, in a vertical direction V. An adjustable shaft 4010 extends perpendicular to the plane of the baseplate 4002. A cross-beam 4012 extends from an end of the adjustable shaft 4010. The cross-beam 4012 carries a pair of spaced-apart guide bushings 4014. These are adjustable in a lateral direction L relative to the cross beam 4012. The marking guide 4000 may be used by first coupling it to the femur F. For example, the central hub 4004 may be aligned with the trochlear groove of the femur F. Optionally, a locating instrument may be passed through the central hole of the central hub 4004, or if a medullary nail is present, it could be used to line the central hub 4004. The guide bushings 4006 will then be adjusted in the vertical direction such that each of the guide bushings 4006 is in a desired position relative to the posterior aspect of the femur F. The guide bushings 4014 would then be adjusted in axial and lateral directions such that each of the guide bushings 4014 are at a desired location relative to the anterior aspect of the femur F, locations within the market were spotted on the anterior into distal aspects of the femur F. In the illustrated example, this may be carried out by using the guide bushings 4006 and 4014 to guide drills 3008 to form holes in the femur F. These holes may subsequently receive guide pins used to mount a guide block (described below).

[0211] Once the guide holes are spotted, they may be used to mount guide blocks for making cuts on the femur F. For example, FIG. 75 illustrates a guide block 4050 having a reference surface 4052 positioned and aligned to guide a distal femoral cut. The guide block 4050 has holes 4054 which receive guide pins 4056 that pass through the guide block 4050 and are received in guide holes formed as described above. When mounted to the femur F, the blade of a cutting tool (not shown) may be placed in contact with the reference surface 4052 and used to make a distal femoral cut.

[0212] As another example, FIG. 76 illustrates a guide block 4060 having a reference surface 4062 positioned and aligned to guide a posterior femoral cut. The guide block 4060 has holes 4064 which receive guide pins 4066 that pass through the guide 4060 and are received in guide holes formed as described above. When mounted to the femur F, the blade of a cutting tool (not shown) may be placed in contact with the reference surface 4062 and used to make a posterior femoral cut.

[0213] The methods and apparatus described herein have numerous advantages. They will permit the repair or reconstruction of the knee joint or other joints with good post-operative results without requiring unusual skill from the surgeon.

[0214] The foregoing has described a joint soft tissue evaluation and arthroplasty method. All of the features disclosed in this specification, and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive.

[0215] Each feature disclosed in this specification may be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Thus, unless expressly stated otherwise, each feature disclosed is one example only of a generic series of equivalent or similar features.

[0216] The invention is not restricted to the details of the foregoing

embodiment(s). The invention extends, or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

WHAT IS CLAIMED IS:

1. An apparatus for evaluating soft tissue of a human joint which includes two or more bones and ligaments, wherein the ligaments are under anatomical tension to connect the bones together, creating a load-bearing articulating joint, the apparatus comprising:

a tensioner-balancer insertable between the bones of the joint, the tensioner-balancer including a means of controlling a distraction force, and sensors operable for collecting displacement and distraction load data of the bones while the joint is moved through at least a portion of its range of motion using a controlled distraction force;

an electronic receiving device configured for data communication with the sensors; and

a software application programmed to processing the collected data to produce a digital geometric model of the joint, wherein the model includes ligament displacement data along a range of flexion angles and ligament load data along a range of flexion angles.

2. The apparatus of claim 1, wherein the software application is further programmed to generate a graphical representation of at least one ligament of the joint, the graphical representation including:

ligament displacement along a range of flexion angles; and

ligament stress or force along a range of flexion angles.

3. The apparatus of claim 1, further comprising at least one tracking marker connectable to the joint, wherein the electronic receiving device is operable to collect data from the at least one tracking device while the joint is moved.

4. The apparatus of claim 1, wherein the tensioner-balancer is configured to distract a knee joint with the patella in place.

5. The apparatus of claim 1, wherein:

the tensioner-balancer includes a tibial interface surface and an opposed femoral interface surface; and

the digital model further includes:

a medial spline representing a locus of points of contact of a medial condyle of a femur with the femoral interface surface, over a range of knee flexion angles; and

a lateral spline representing the locus of points of contact of the femur with the femoral interface surface over a range of knee flexion angles.

6. The apparatus of claim 5, wherein the femoral interface surface is defined by a top plate, the top plate including a lateral cantilevered pad and a medial cantilevered pad, wherein each cantilevered pad is provided with two or more spaced-apart strain gages at the intersection between the respective cantilevered pad and a stationary portion of the top plate.

7. The apparatus of claim 1, wherein the tensioner-balancer includes a tibial interface surface, an opposed femoral interface surface, and an array of femoral force sensors disposed on the femoral interface surface.

8. A method of evaluating a human knee joint which includes a femur bone, a tibia bone, and ligaments, wherein the ligaments are under anatomical tension to connect the bones together, creating a load-bearing articulating joint, the method comprising:

using a software application to define a virtual primary datum comprising a coordinate framework having fixed origins relative to the femur and relative to a physical tracking device affixed to the femur;

using the software application to define a virtual software secondary datum comprising a coordinate framework, the secondary datum having fixed origins relative to the tibia and relative to a physical tracking device affixed to the tibia;

inserting between the femur and the tibia at least one force sensor having a femoral interface surface;

providing an electronic receiving device;

while moving the femur and tibia relative to each other, using the electronic receiving device to collect data from the tracking devices and from the at least one force sensor, wherein the data includes information describing the position and movement in six degrees of freedom of the secondary datum relative to the primary datum to produce a digital geometric model of at least a portion of the joint, wherein the data further includes:

a medial spline representing a locus of points of contact of a medial condyle of the femur with the femoral interface surface, over a range of knee flexion angles; and

a lateral spline representing the locus of points of contact of the femur with the femoral interface surface over a range of knee flexion angles; and storing the digital geometric model for further use.

9. The method of claim 8, further including inserting into the joint a tensioner-balancer that includes the femoral interface surface, an opposed tibial interface surface, and a means of controlling distraction force.

10. The method of claim 9, further comprising using the tensioner-balancer to distract the knee joint.

11. The method of claim 8, wherein an array of tibial force sensors is disposed on the tibial interface surface, and the at least one force sensor comprises an array of femoral force sensors disposed on the femoral interface surface.

12. The method of claim 8, wherein the primary datum is established by physically registering bony landmarks on the femur.

13. The method of claim 8, wherein:
the knee joint further includes a patella bone; and
the patella remains in its native anatomical position during all steps of the method.

14. The method of claim 8, wherein a difference is computed between the data collected and a final defined desired set of geometric position data.

15. The method of claim 12, wherein the computed difference is used to compute a desirable final best-fit position of an endoprosthesis with known geometry.

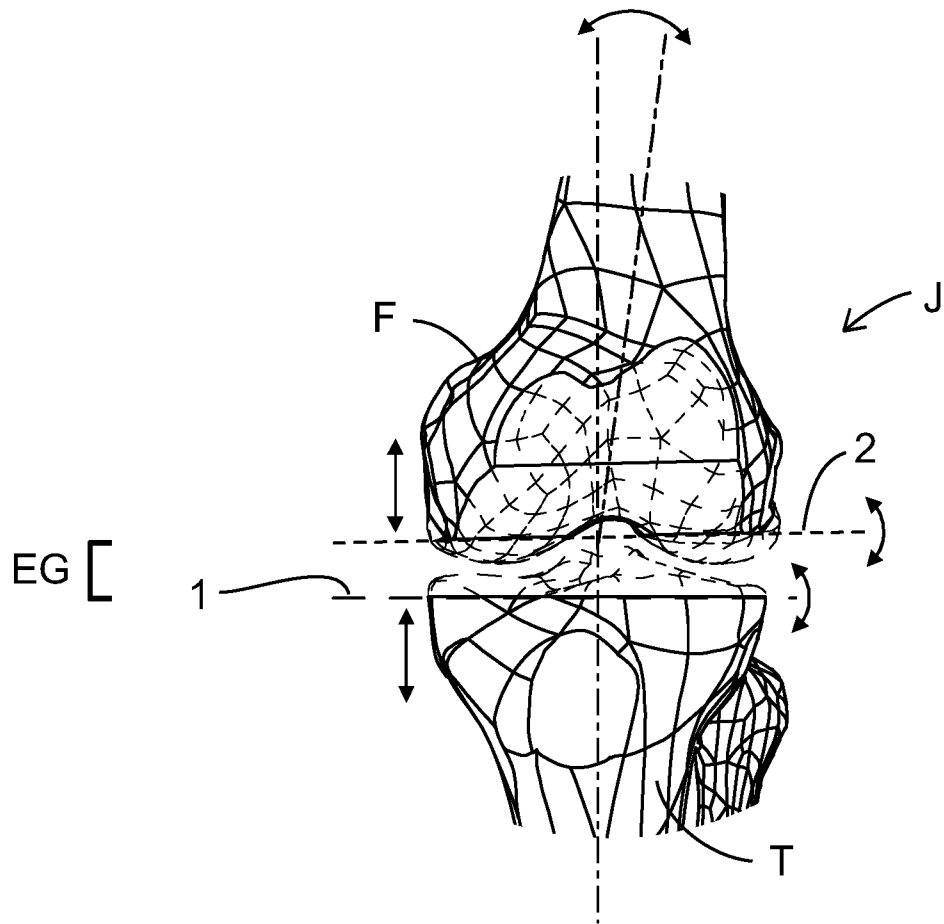


Fig. 1

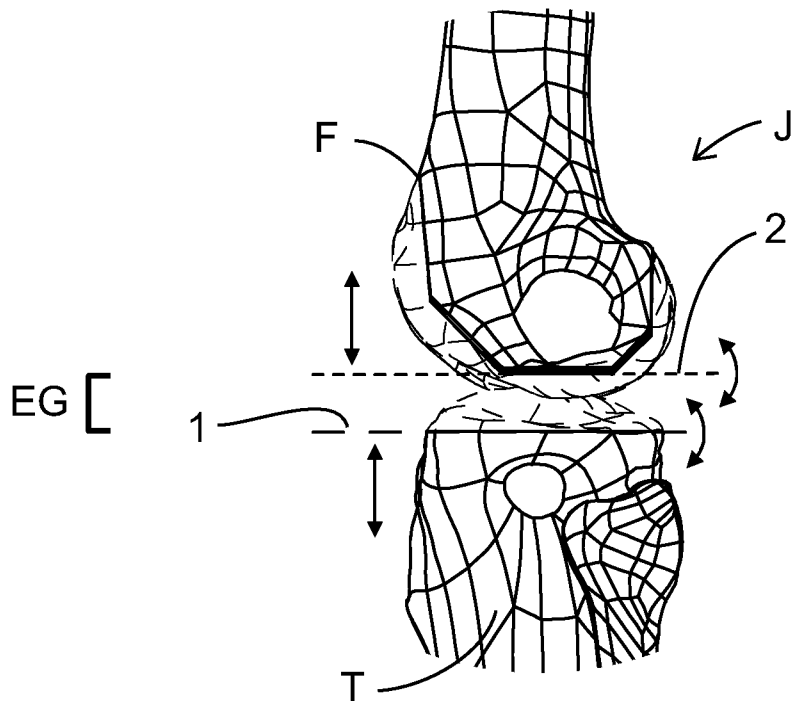


Fig. 2

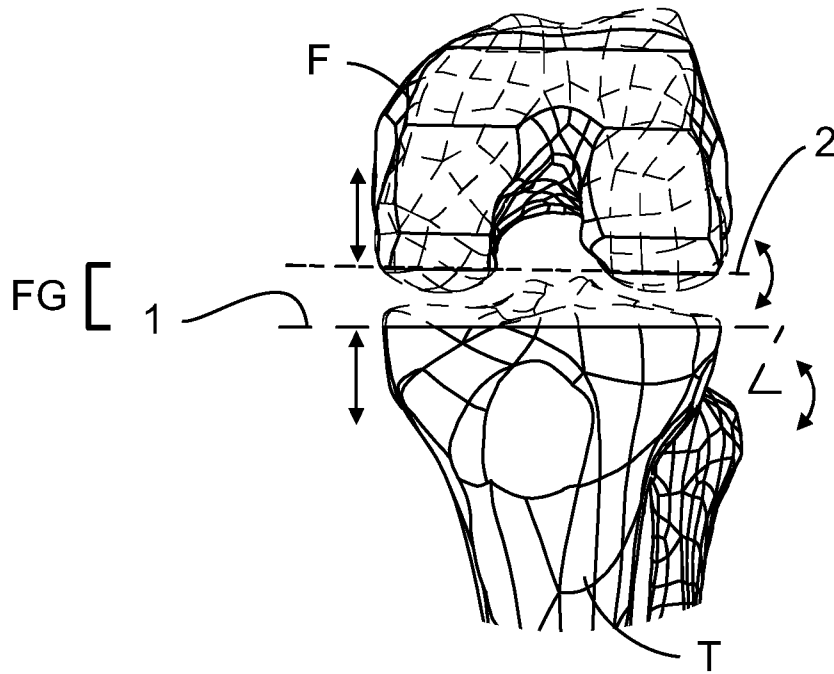


Fig. 3

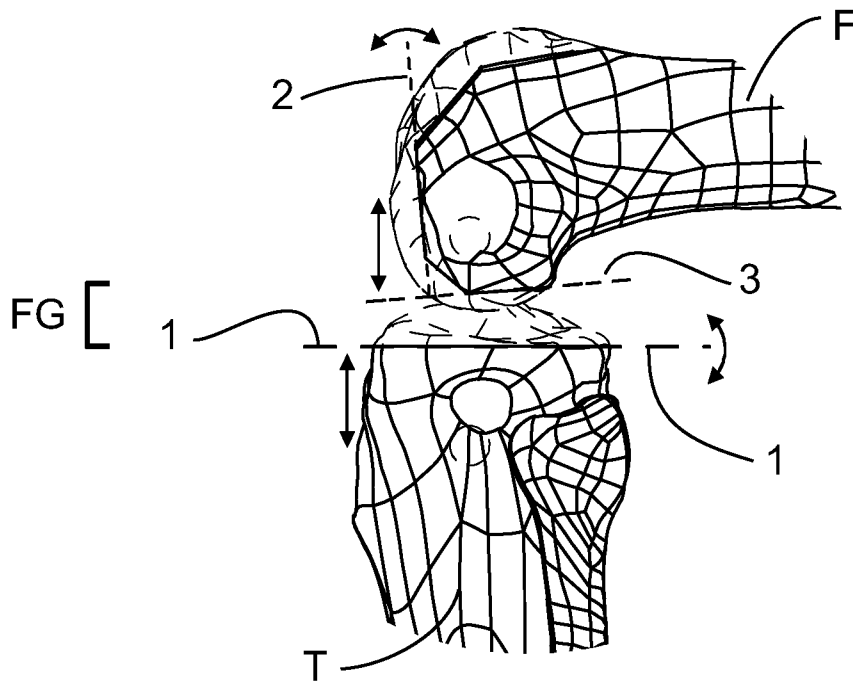


Fig. 4

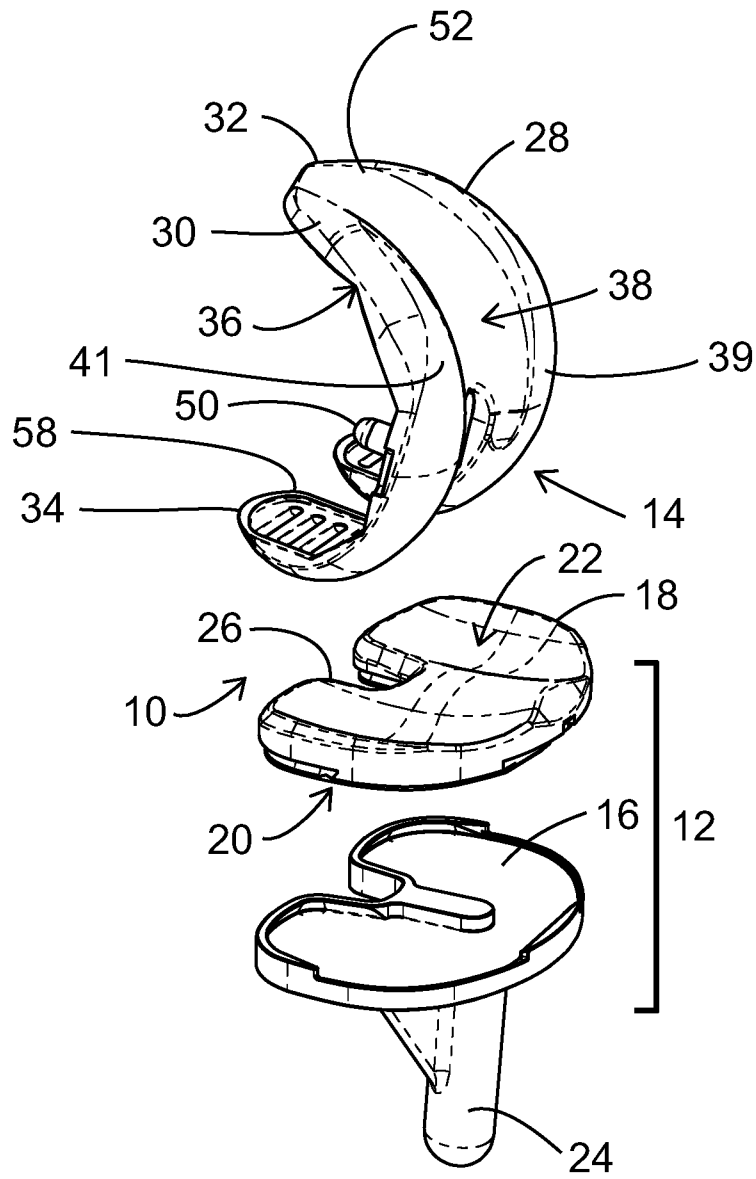


Fig. 5

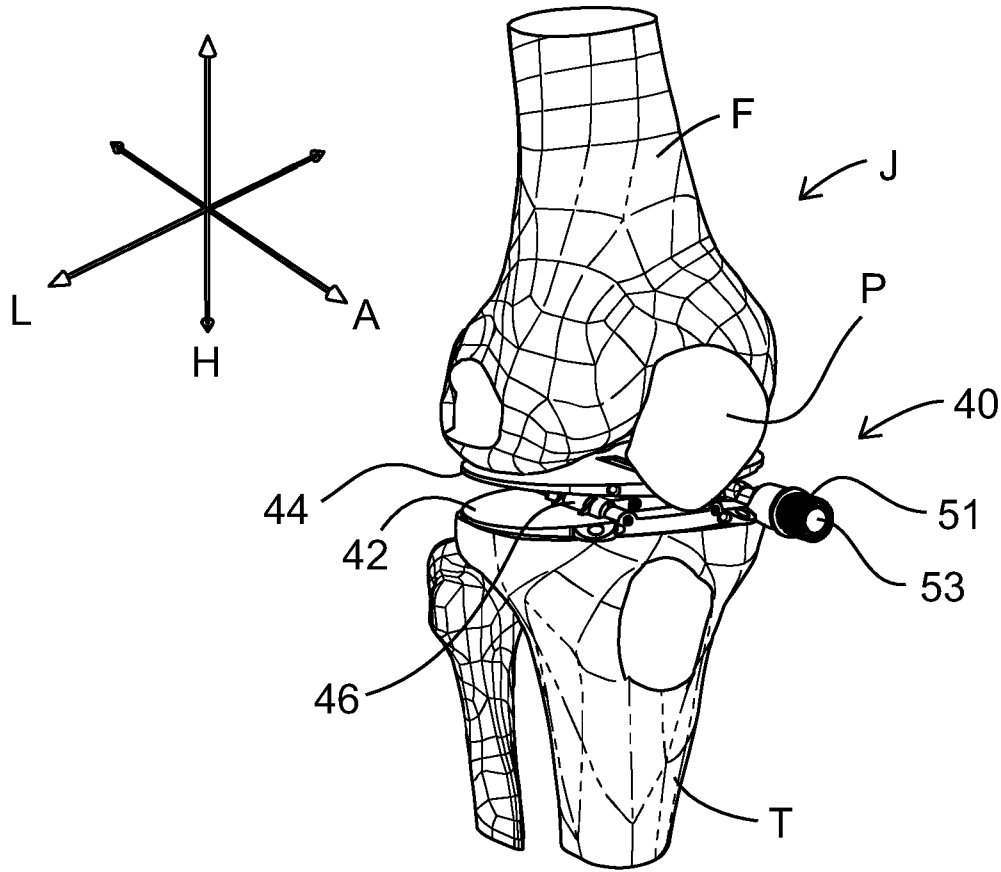


Fig. 6

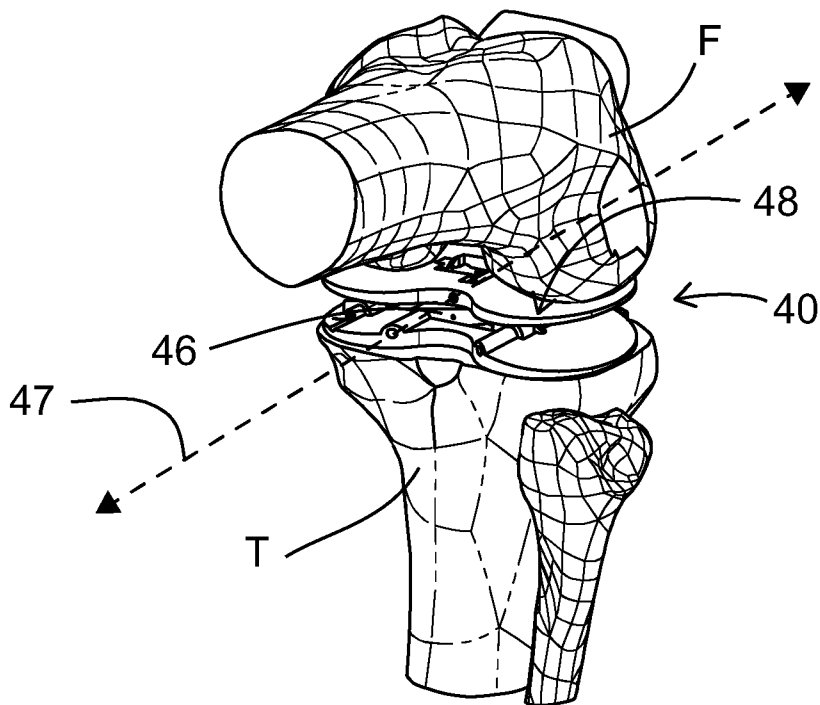


Fig. 7

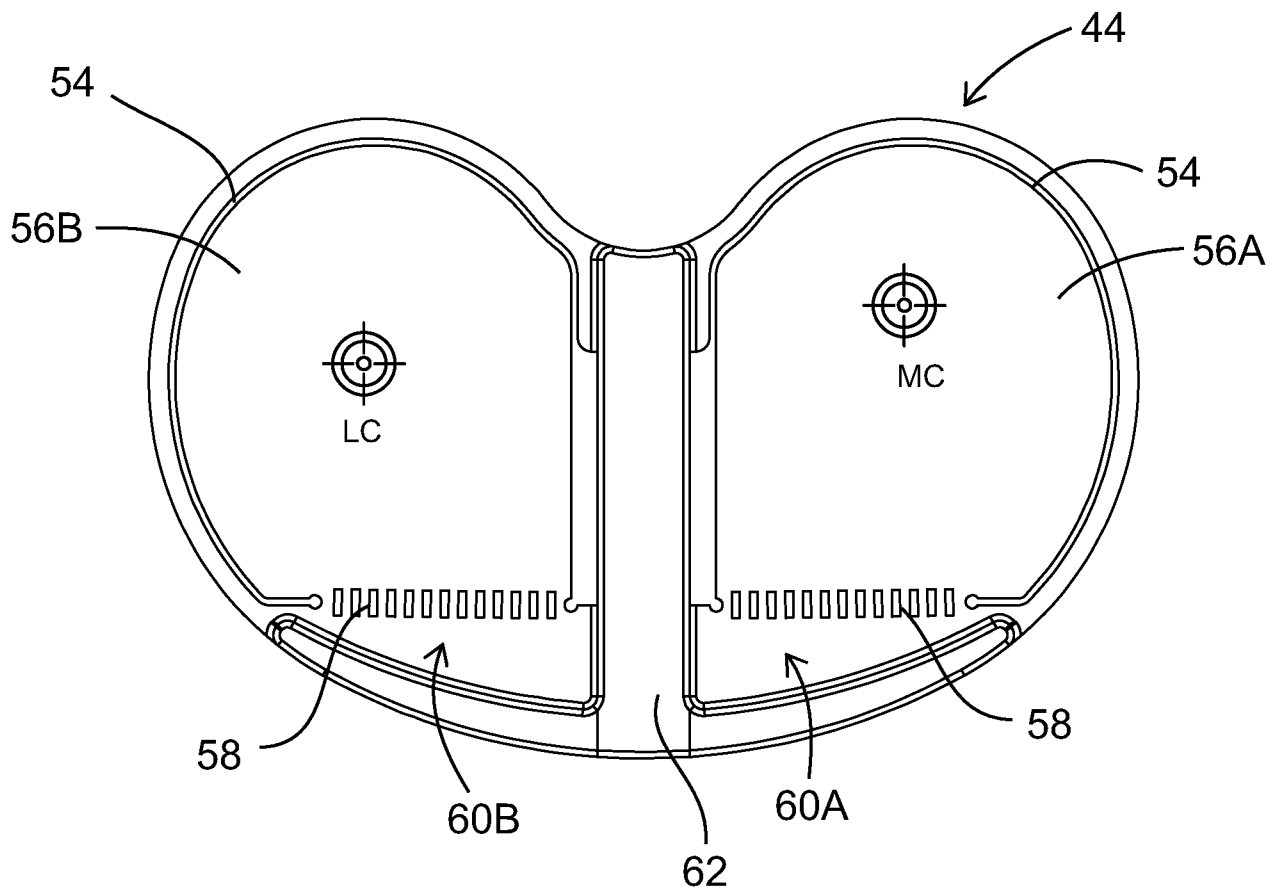


Fig. 8

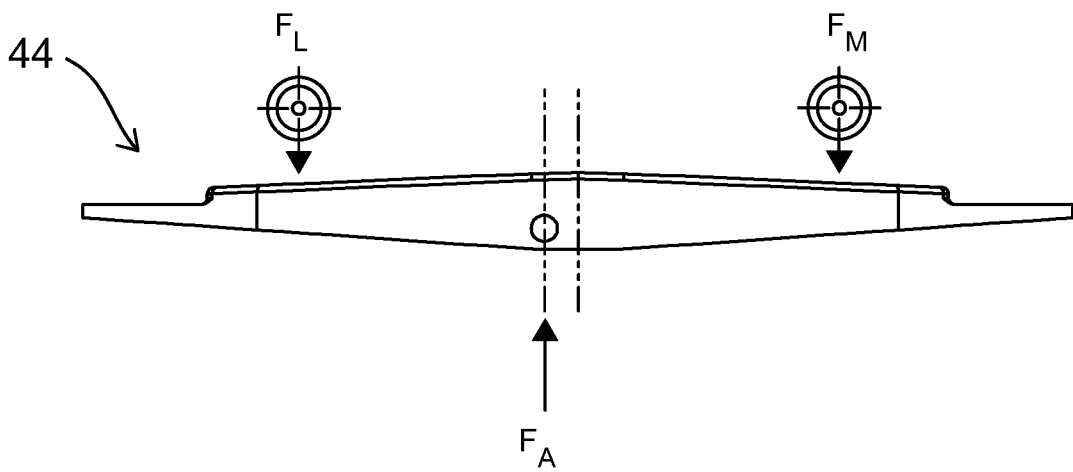


Fig. 9

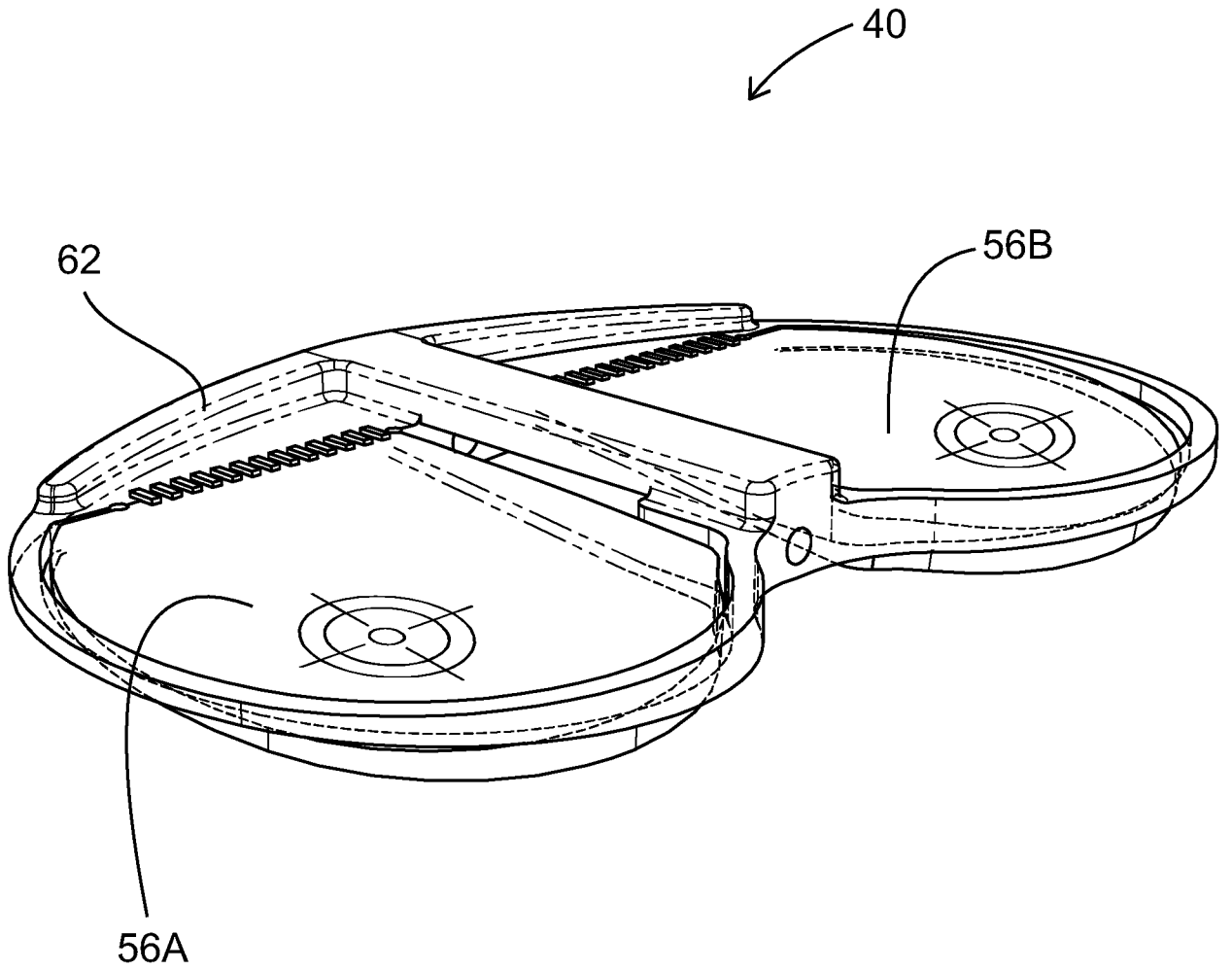


Fig.10

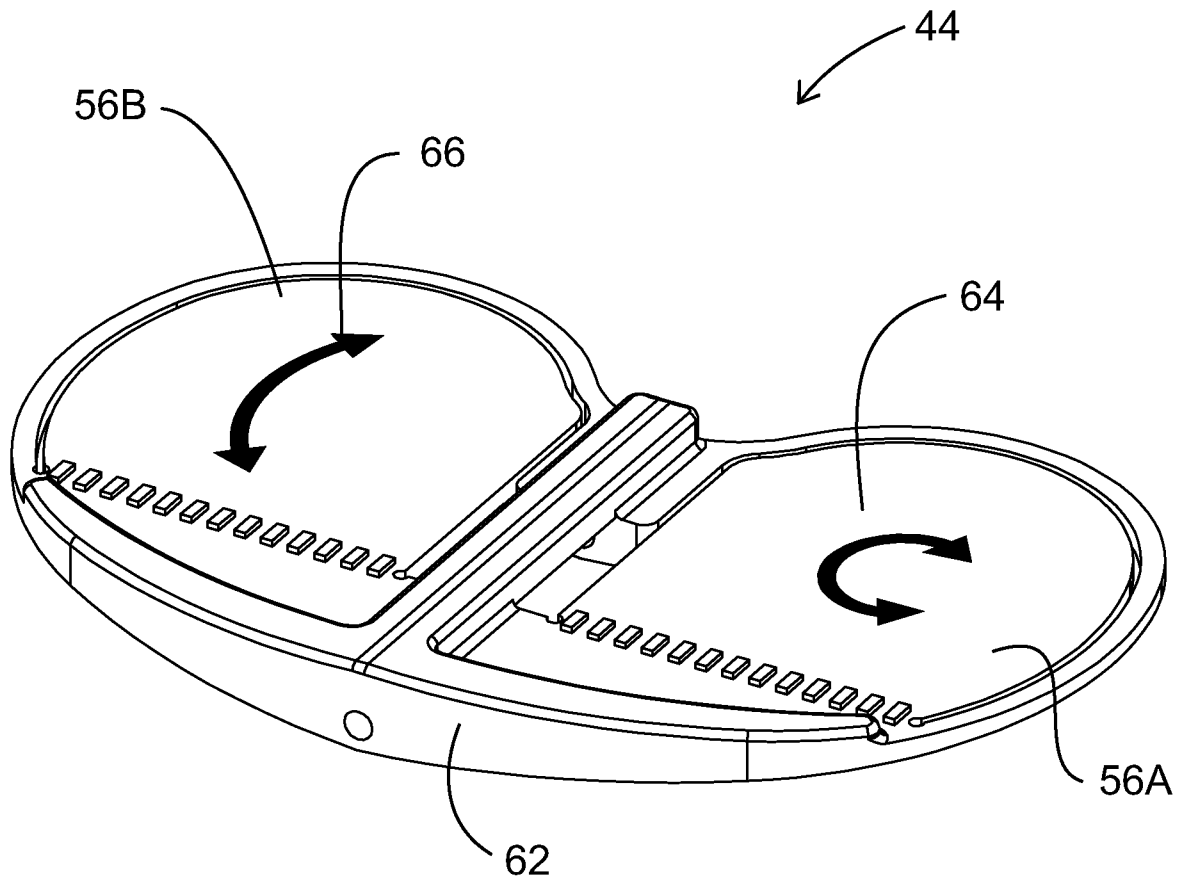


Fig. 11

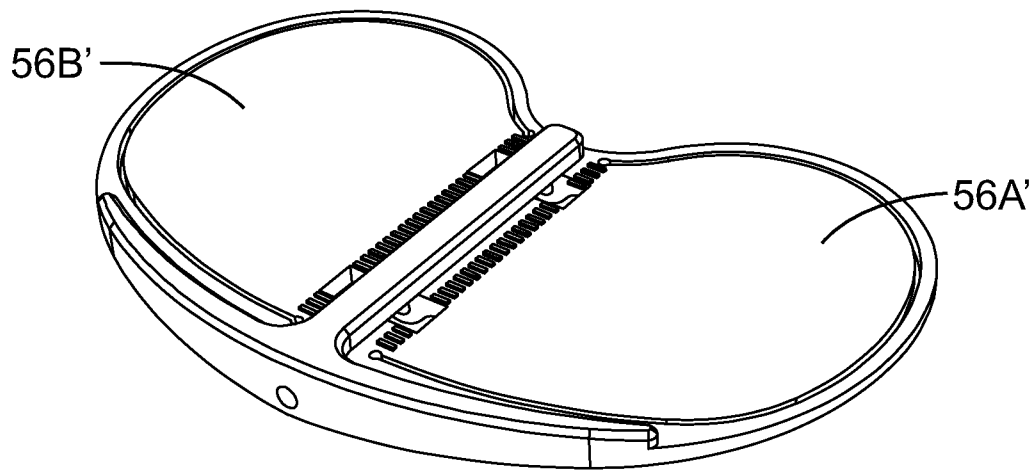


Fig. 12

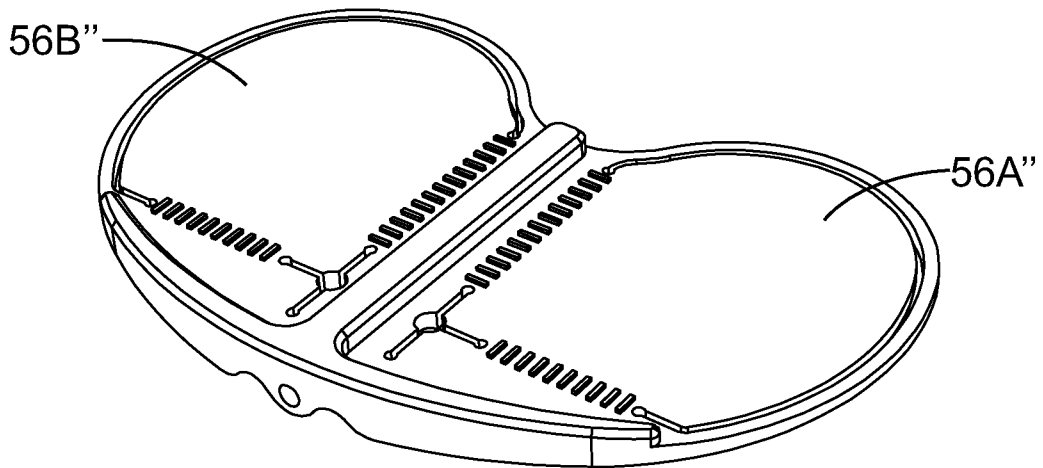


Fig.13

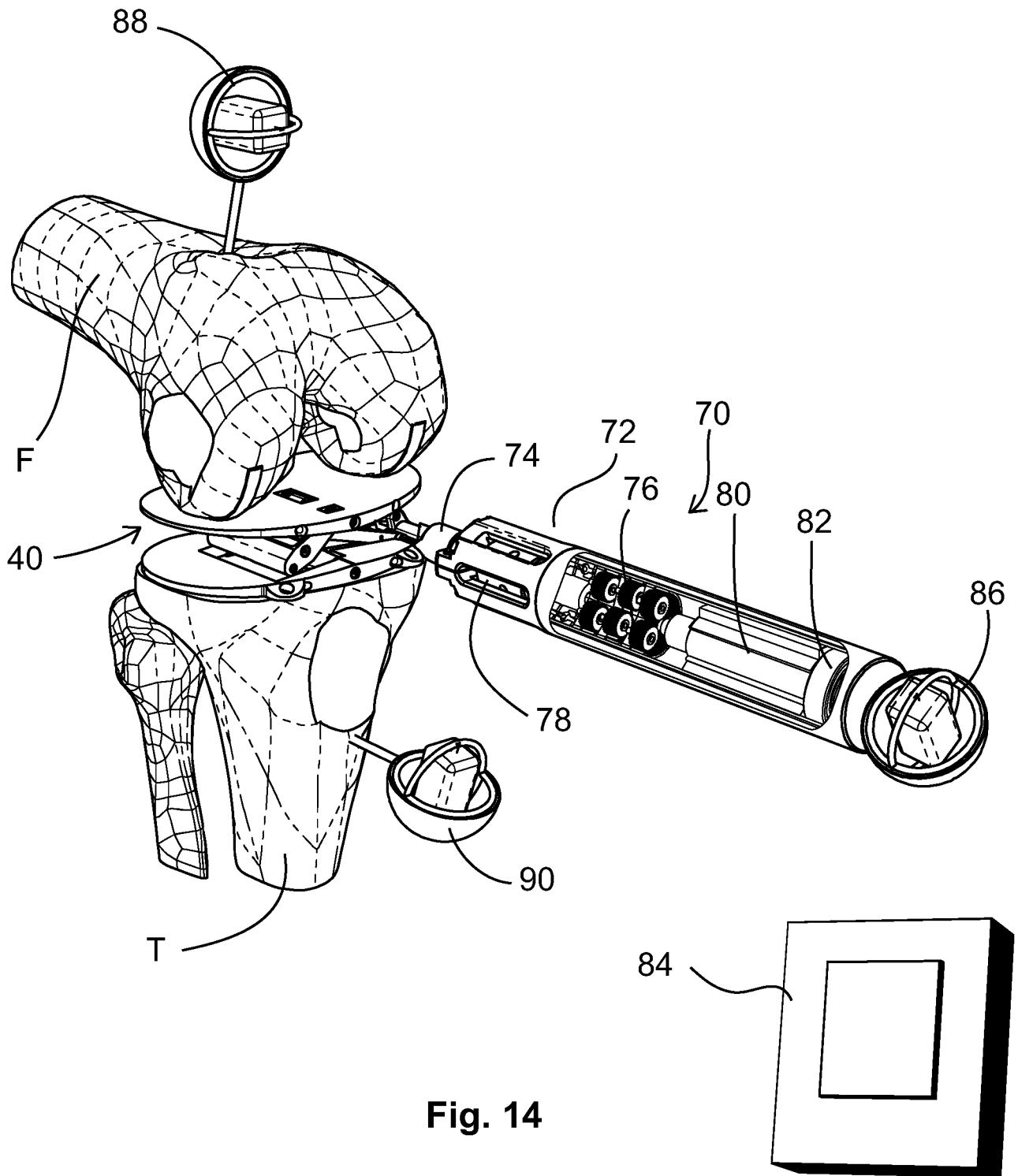


Fig. 14

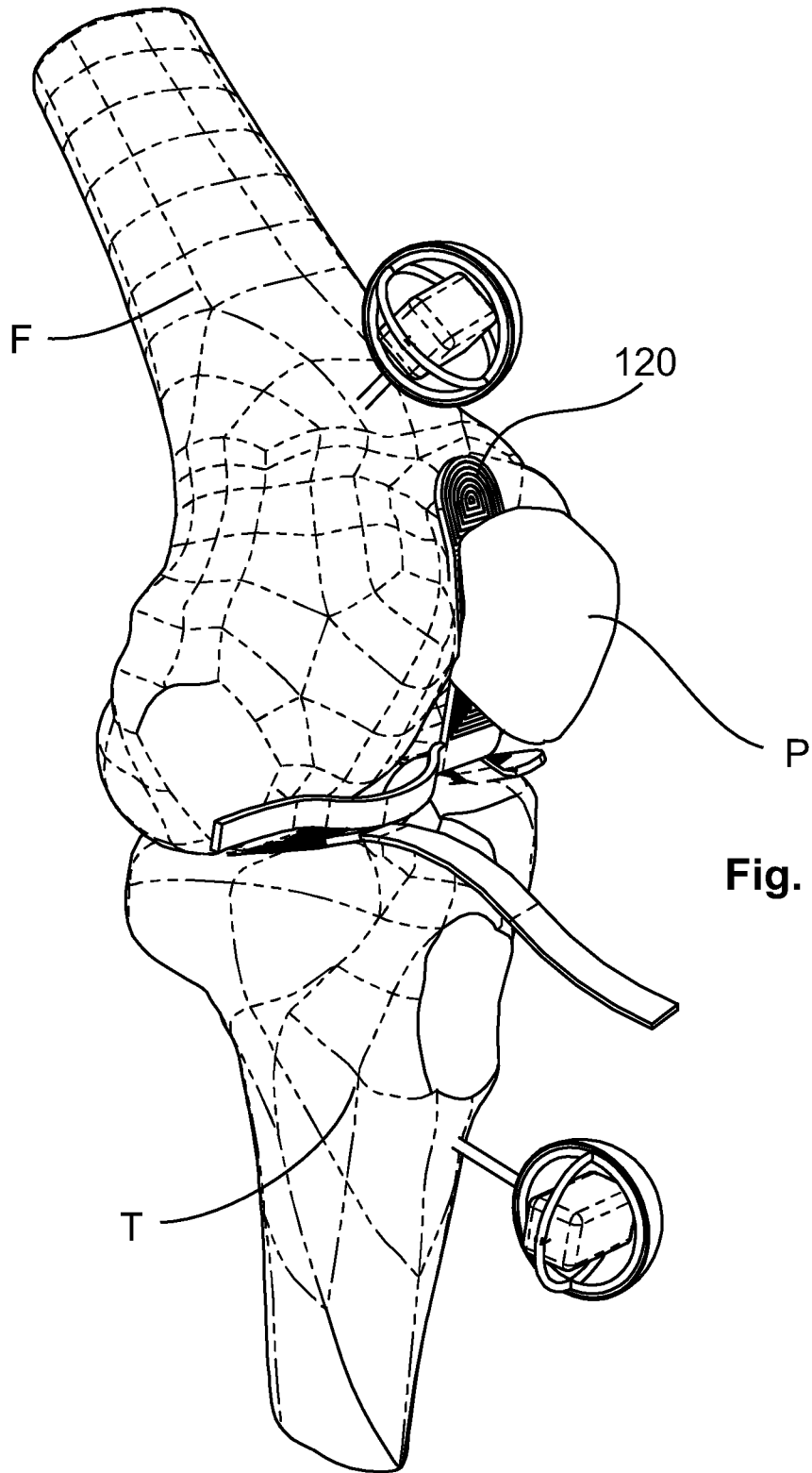


Fig. 15

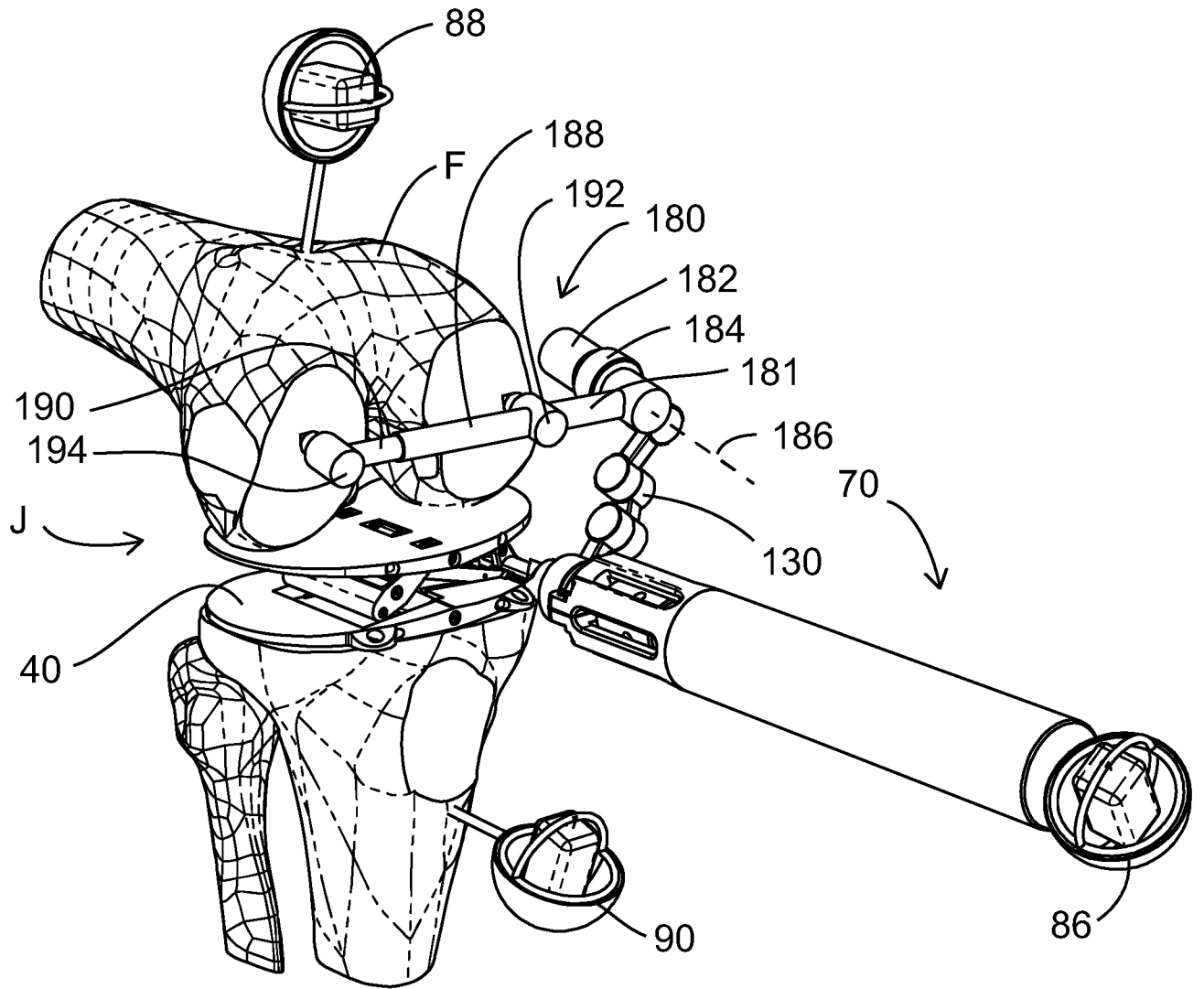


Fig. 16

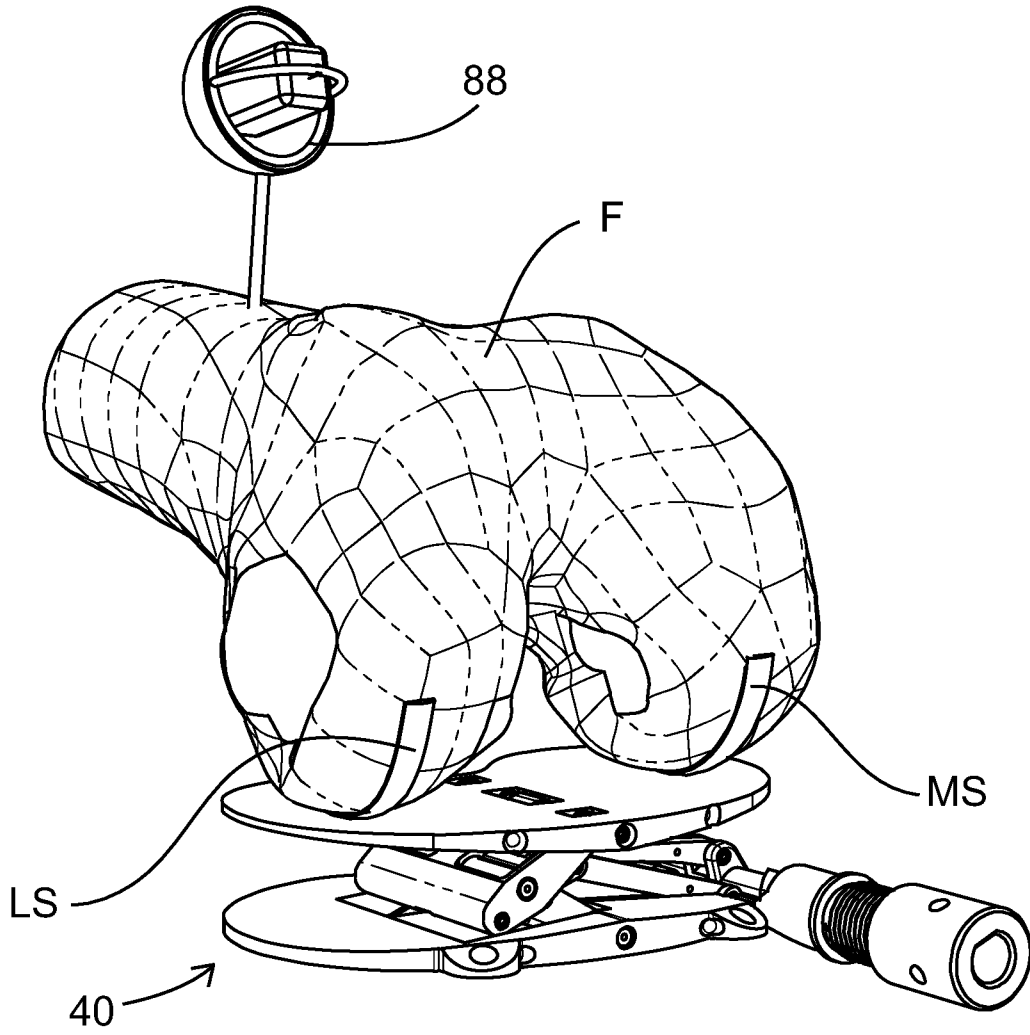
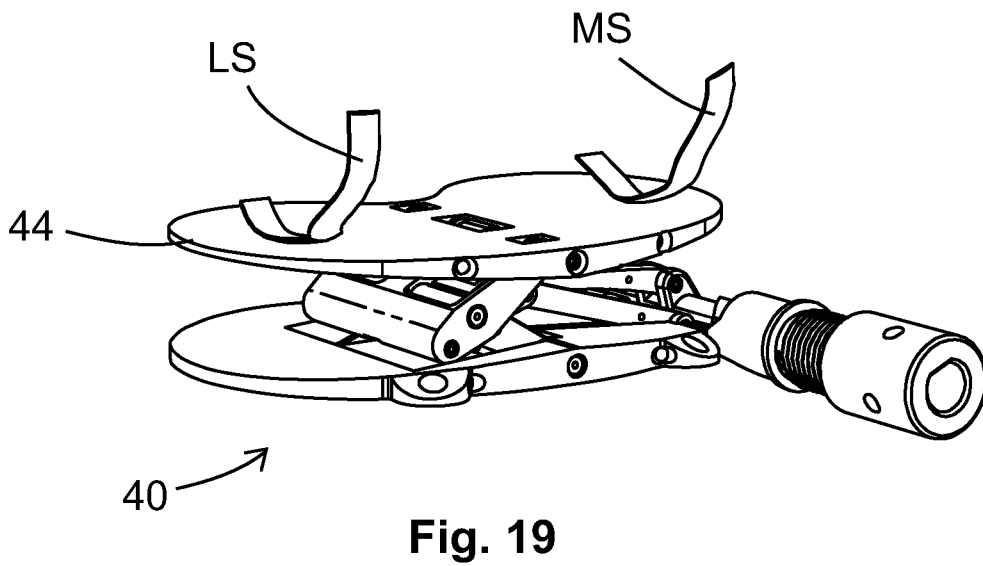
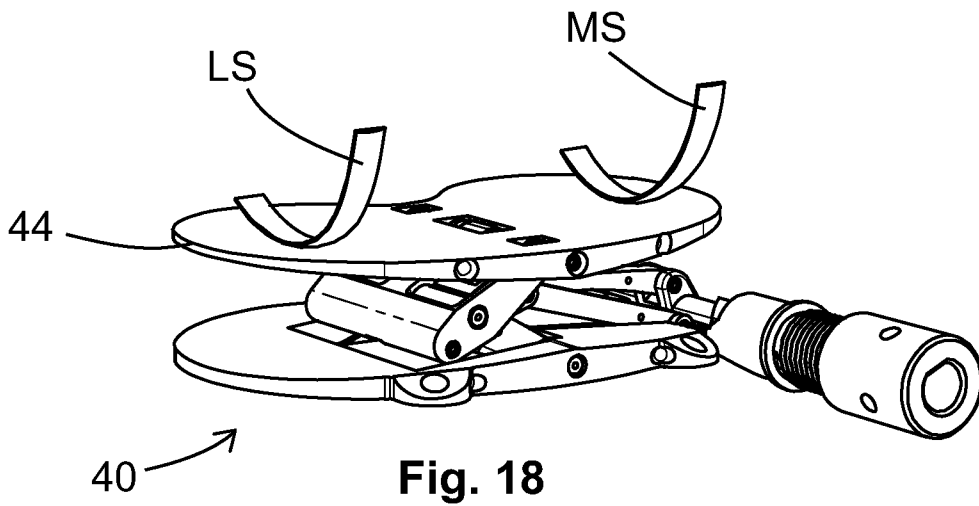


Fig. 17



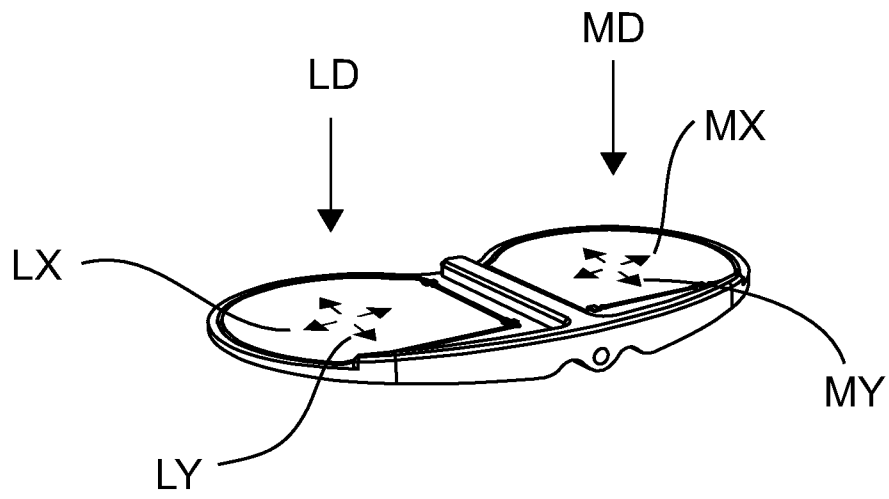


Fig. 20

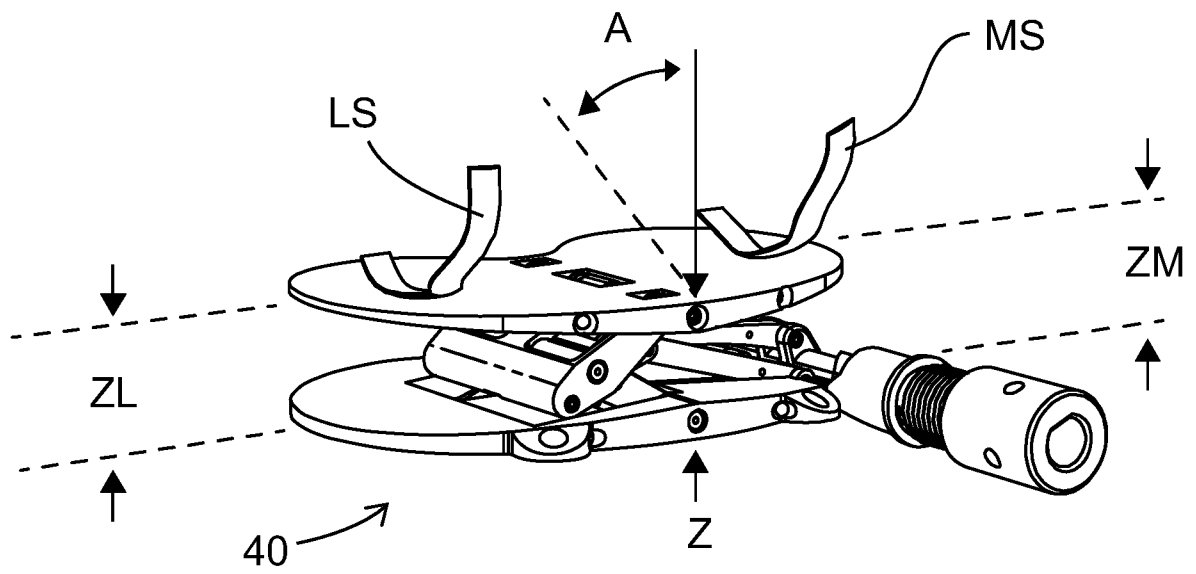


Fig. 21

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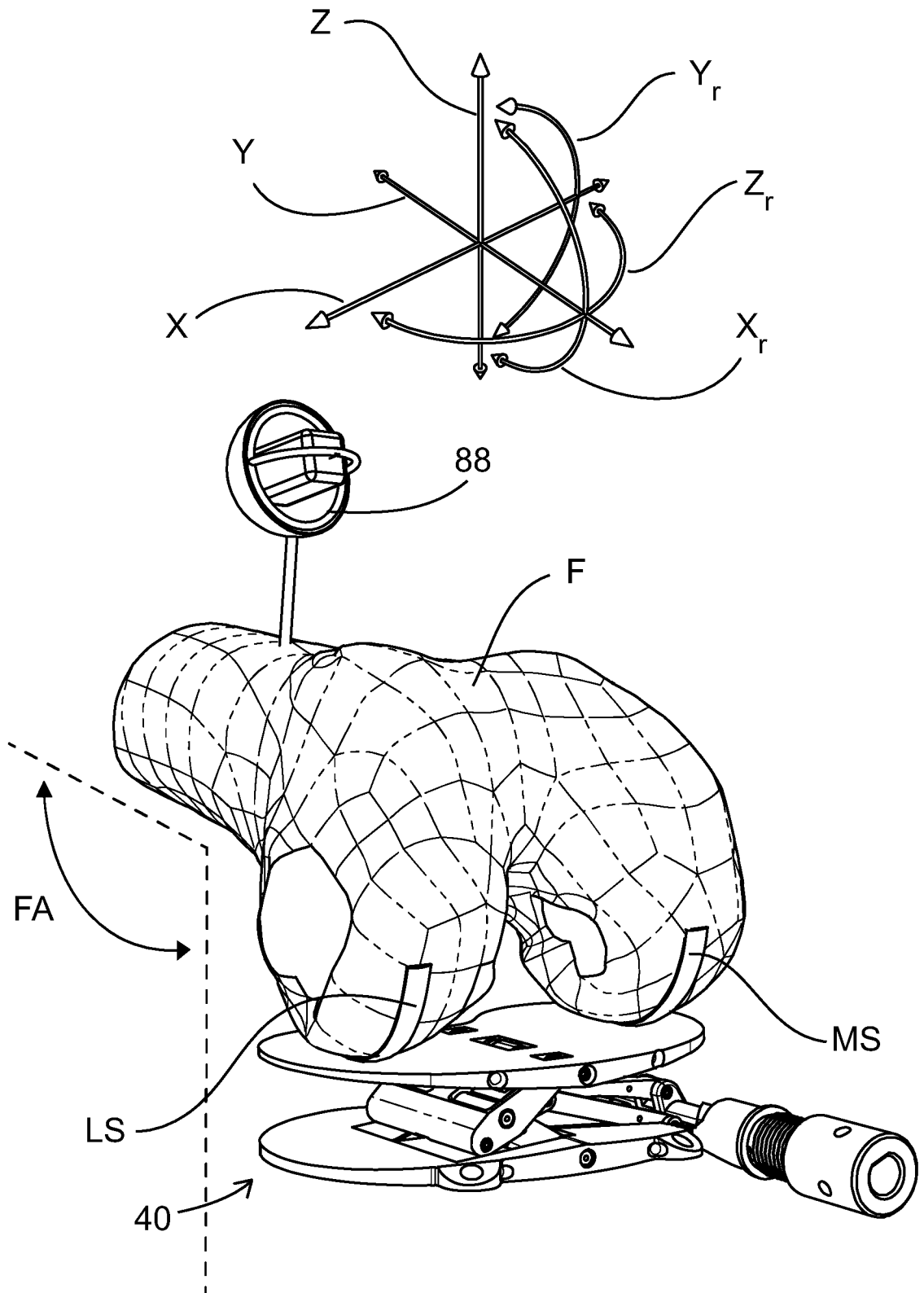


Fig. 22

Data Captured - these Values are inputs sent to Algorithm:	Timestamp	Flexion Angle	Load [lbs]	Centerline Height [mm]	Gap Medial [mm]	Gap Lateral [mm]
Datasource: A = Auto, M = Manual	Control System	A: Tracking System (NAV [local or global] M: "leg protractor"	A: Measured Current [mA] from Motor M: T-Handle Driver (torque)	A: Encoder Counts M: T-Handle Driver (angle)	A: Tracking System (NAV [local or global] or Transducer along top plate pivot axis M: "plate protractor"	
	44:37.0	0	45		12.0	12.4
	44:37.1	2	45		11.9	12.4
	...					
	44:42.9	118	45		13.3	13.9
	44:43.0	120	45		13.3	14.0

Fig. 23

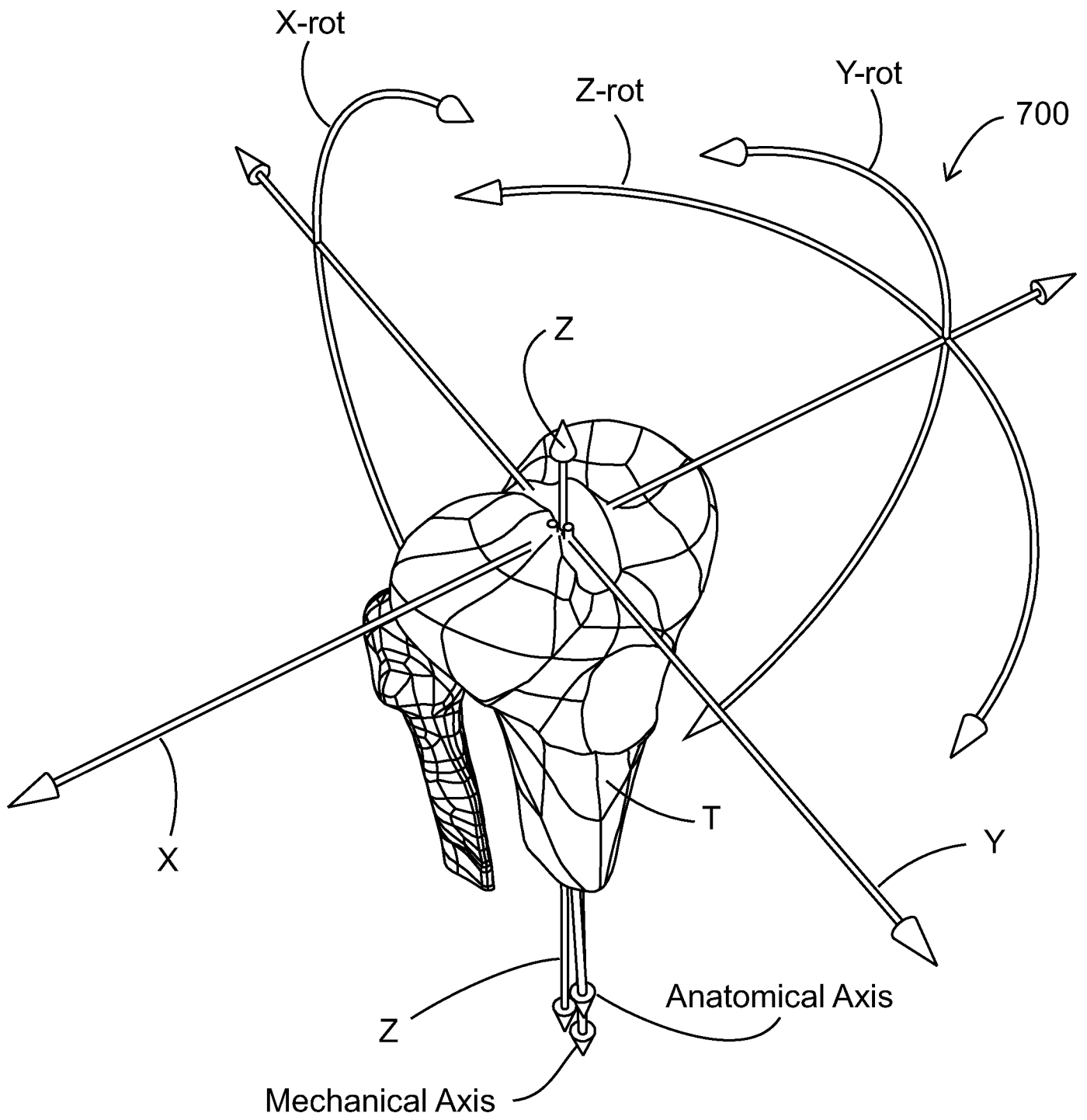


Fig. 24

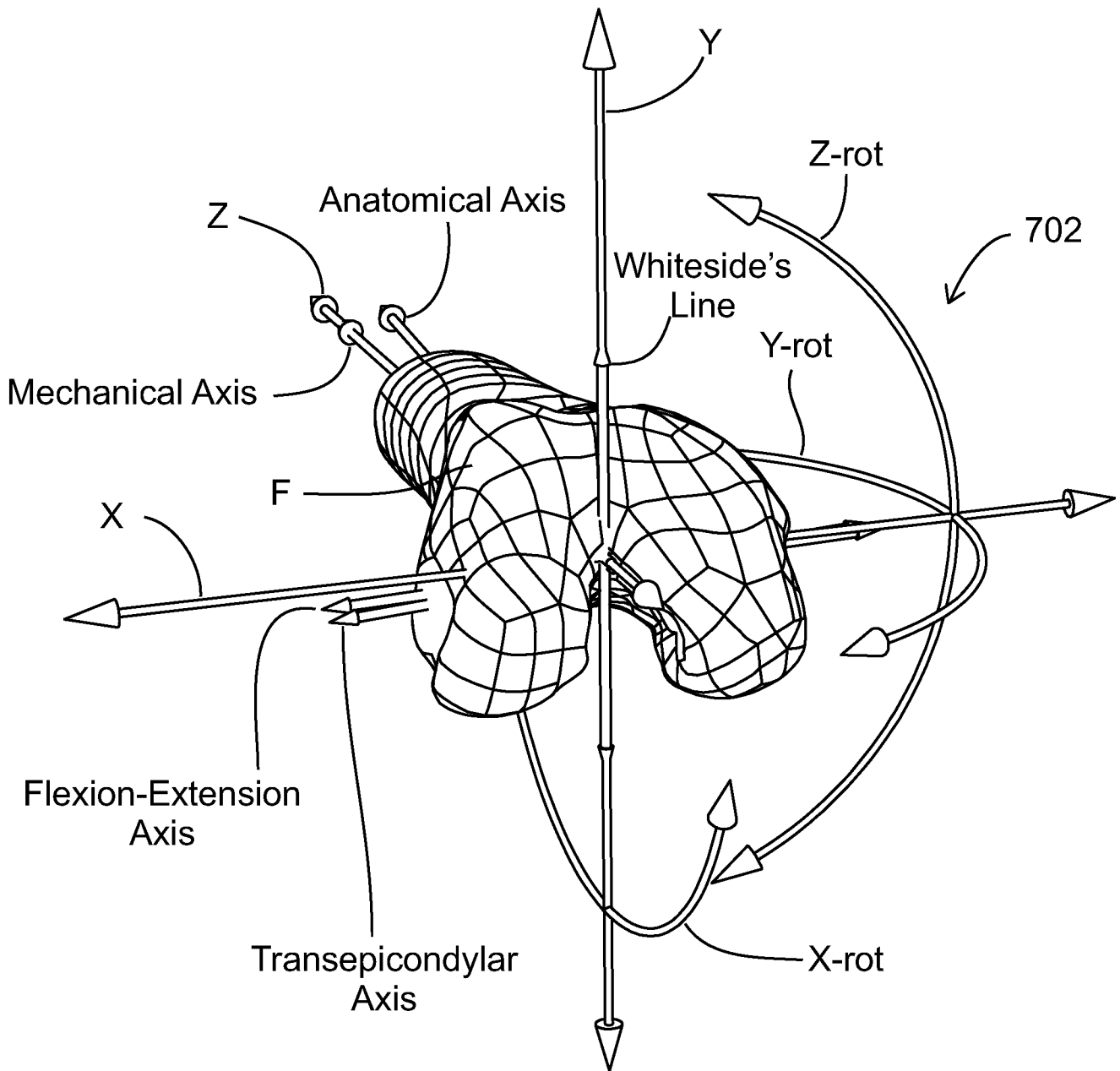


Fig. 25

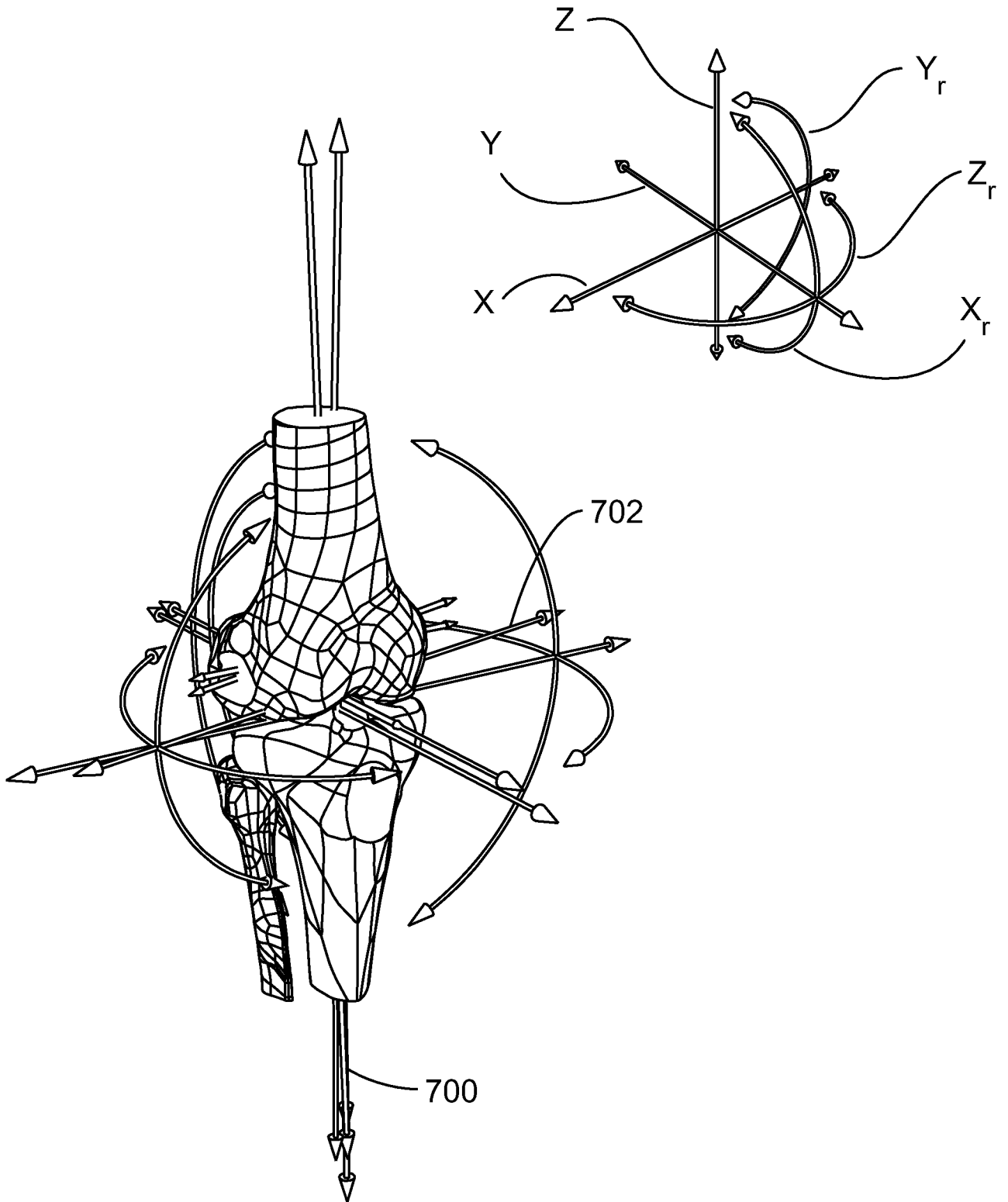


Fig. 26

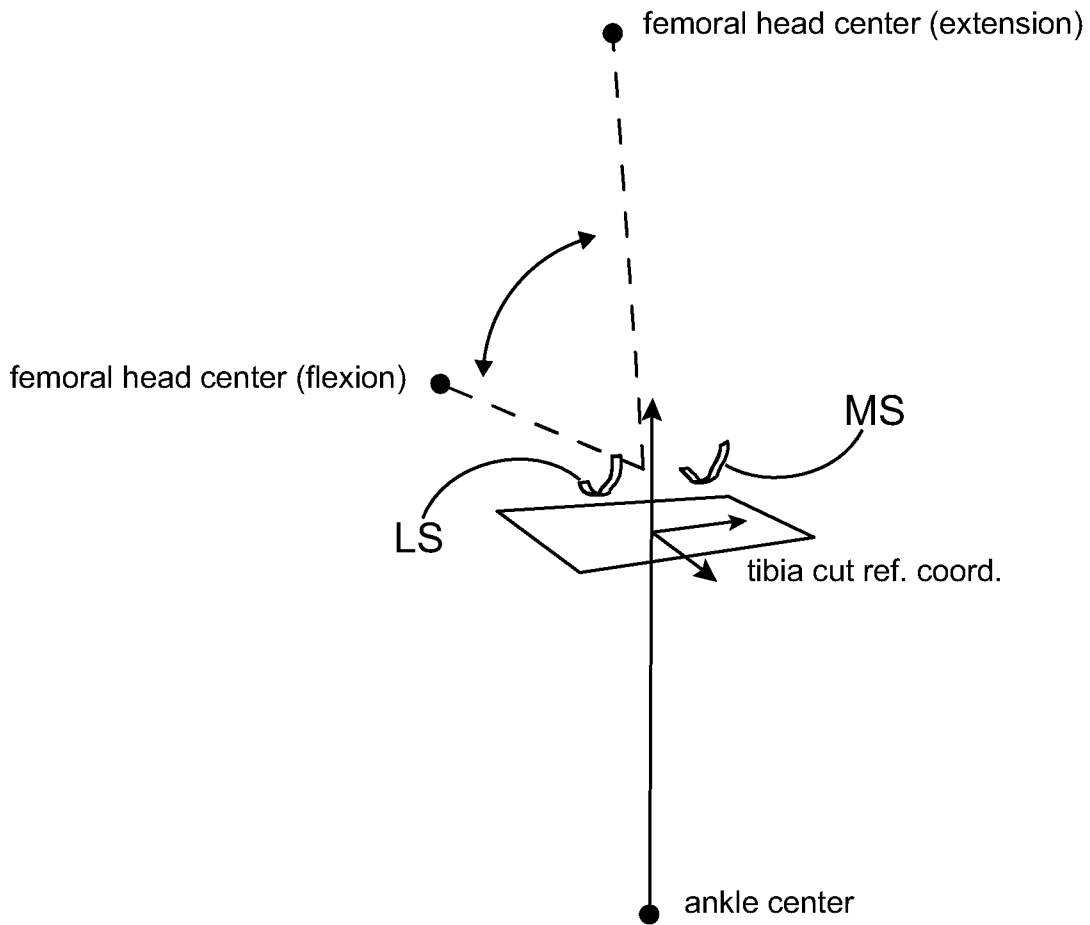


Fig. 27

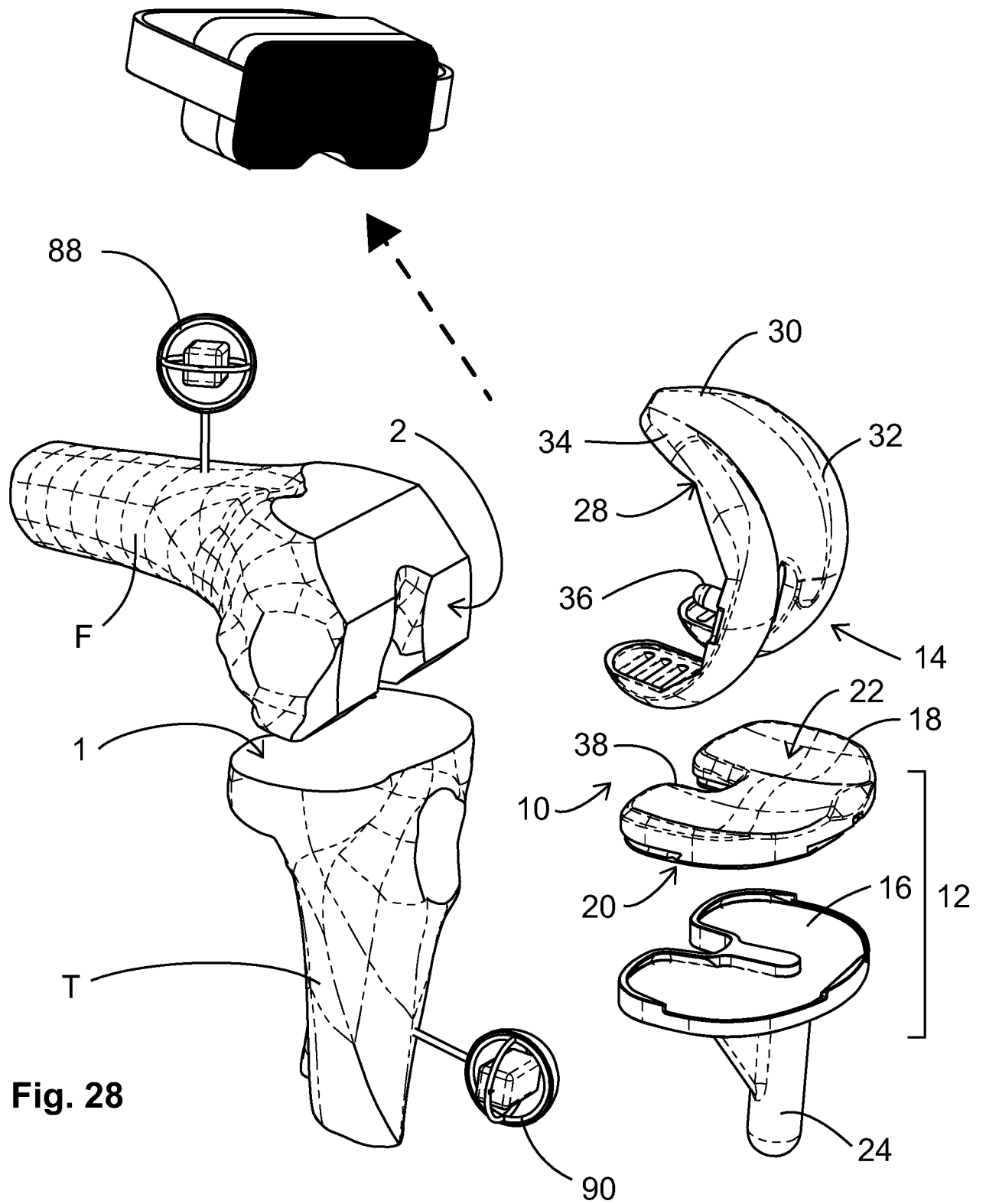
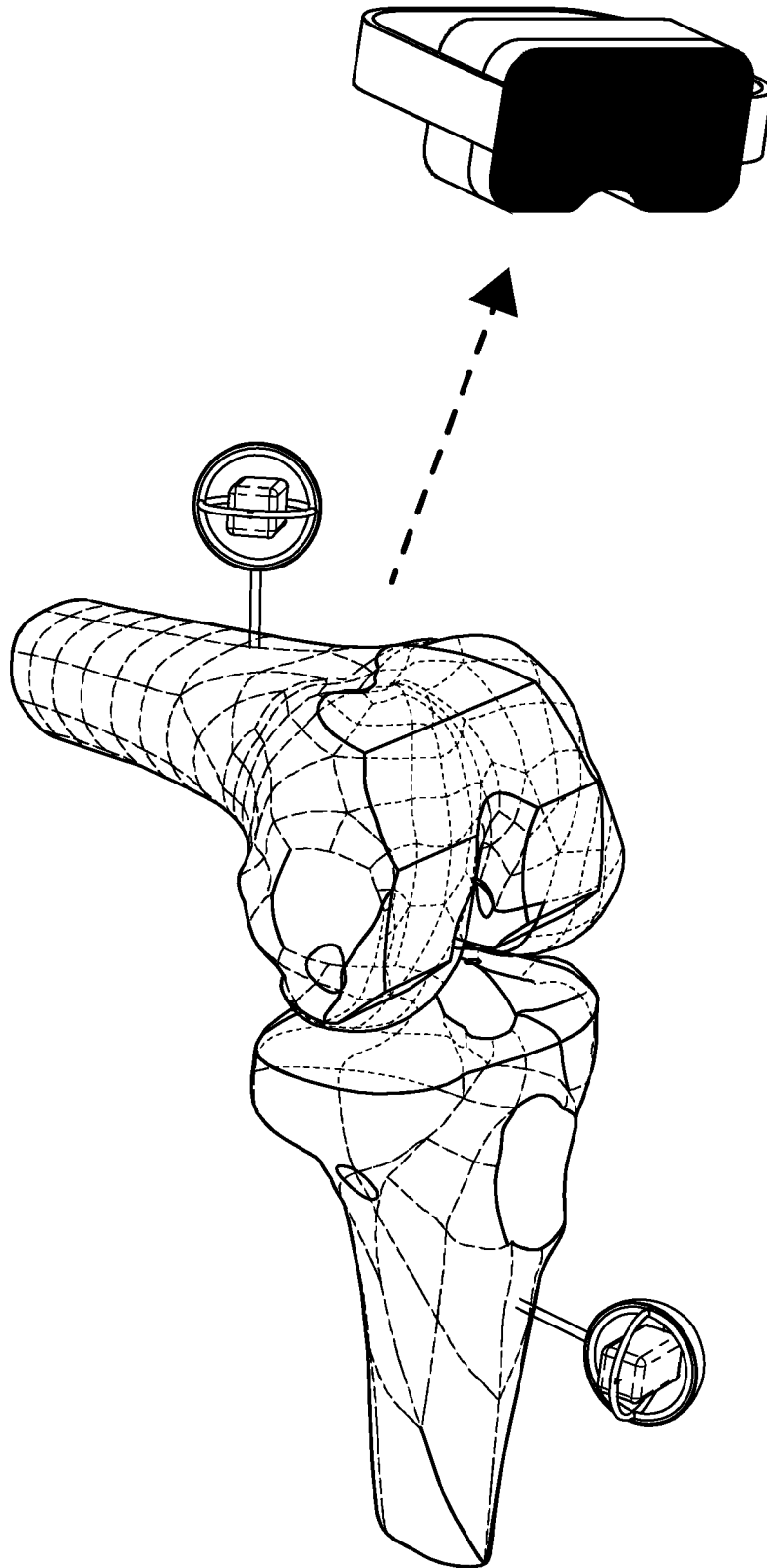


Fig. 28

23/60

Fig. 29



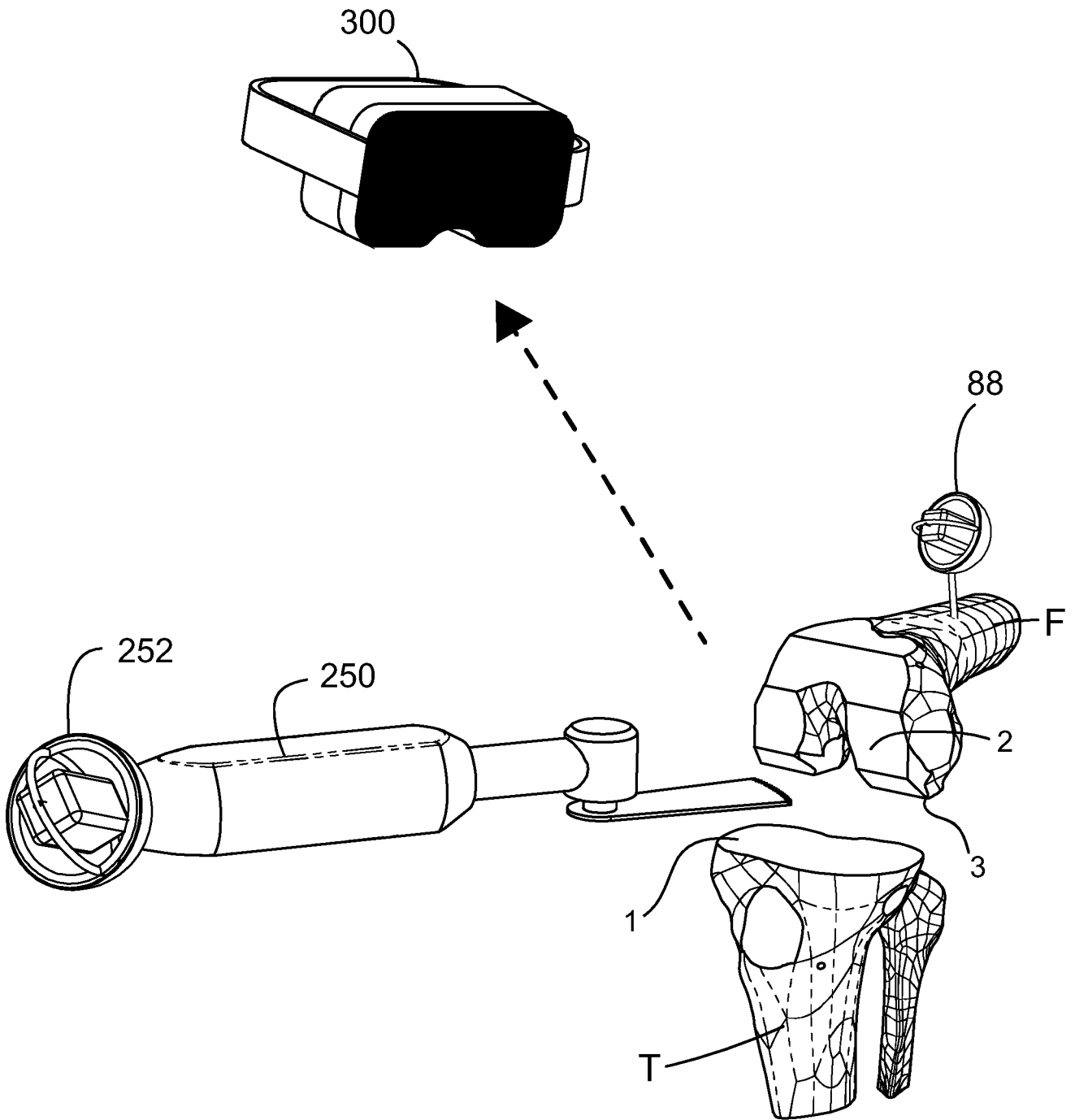


Fig. 30

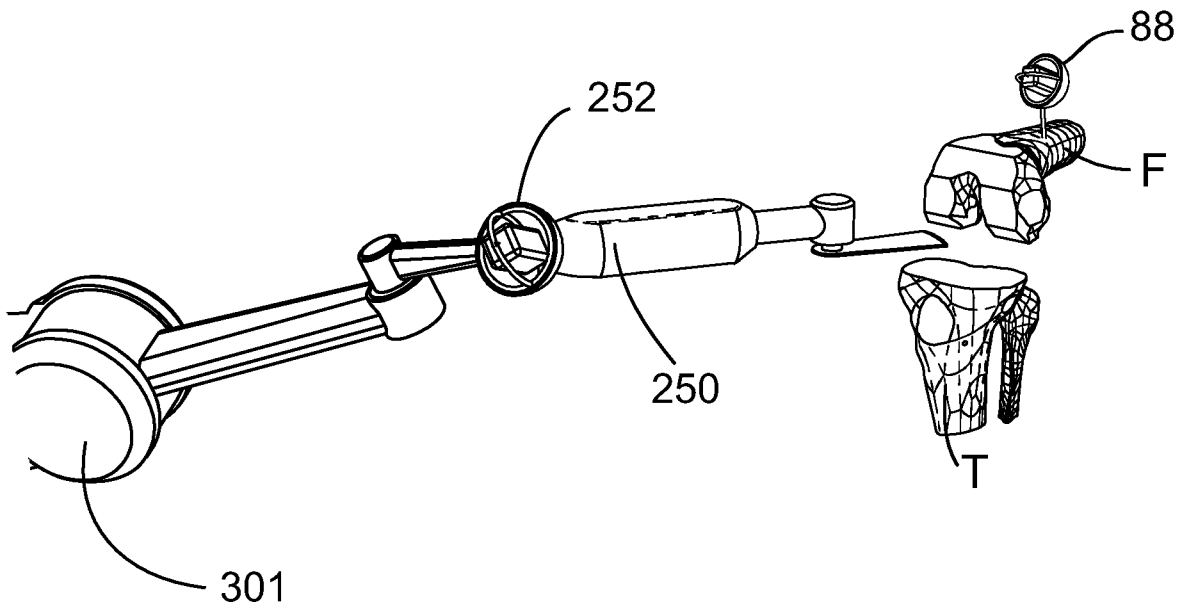


Fig. 31

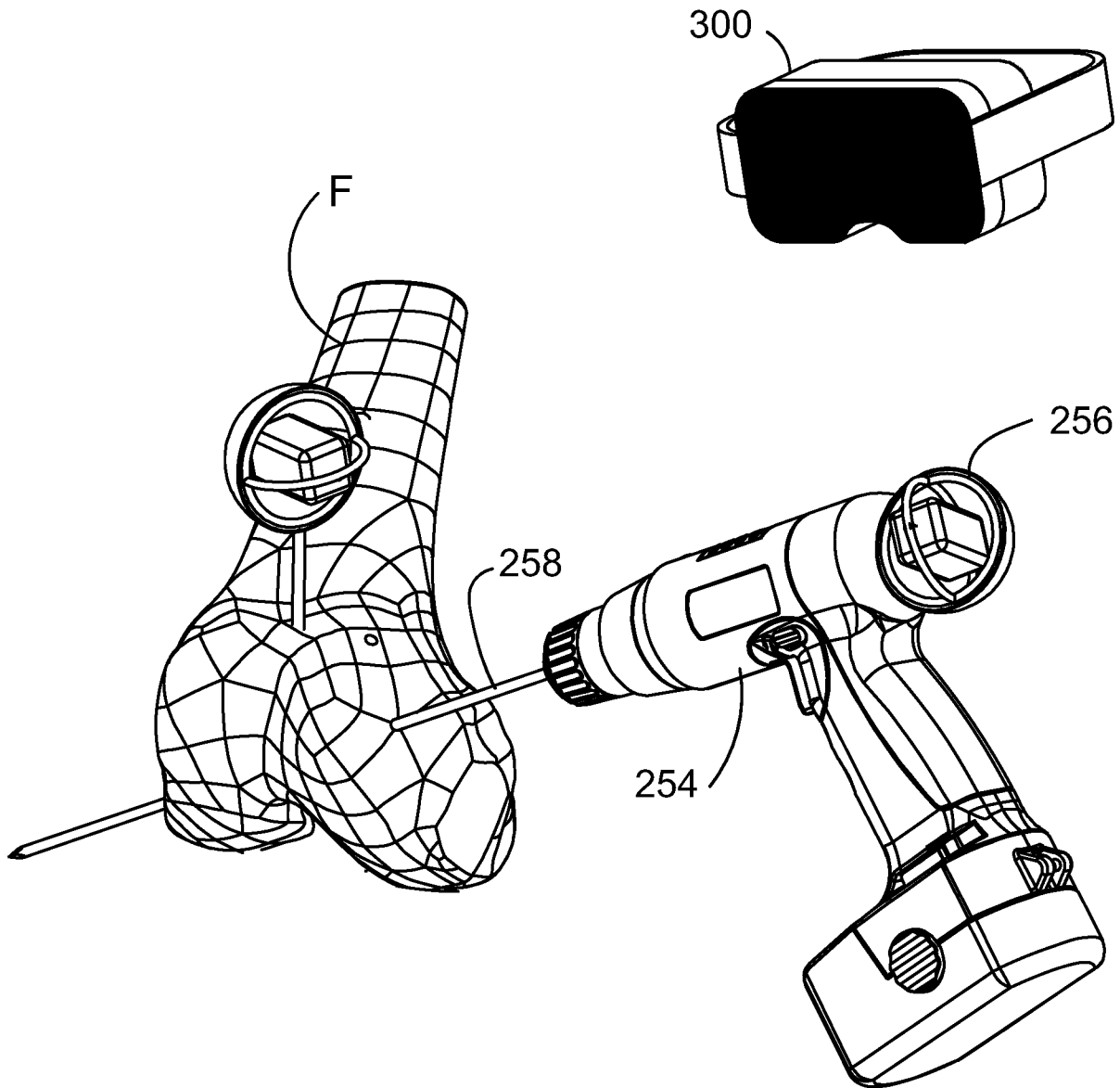


Fig. 32

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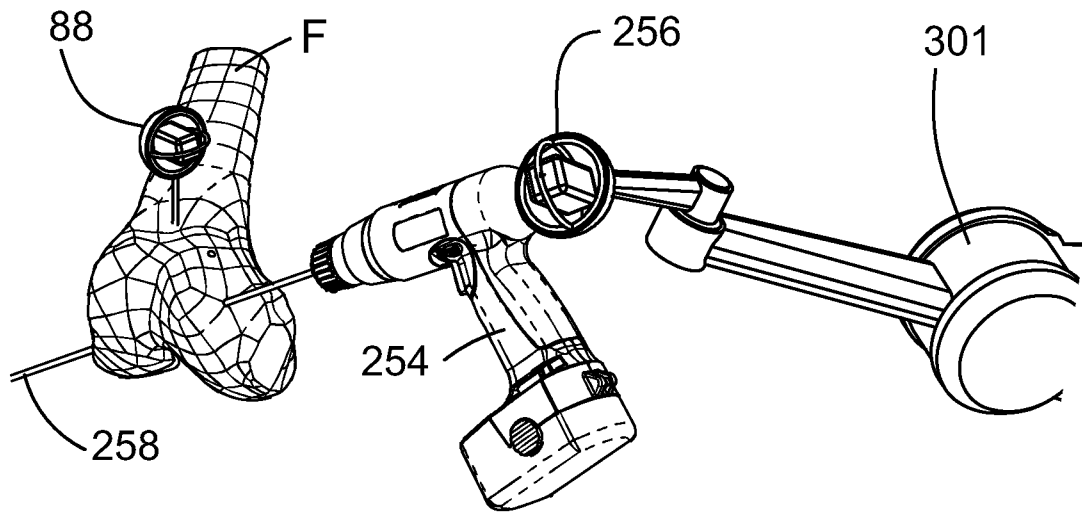


Fig. 33

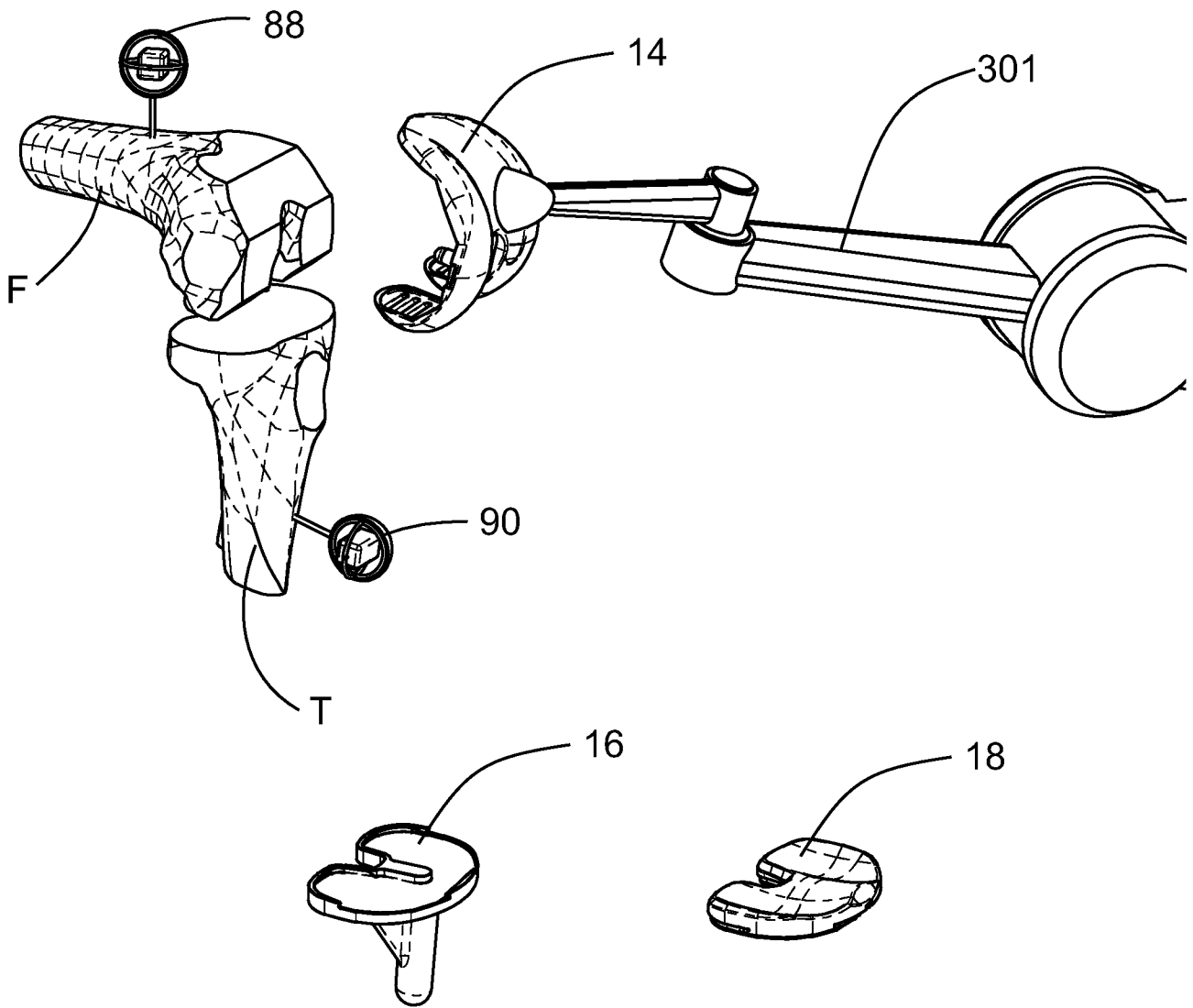


Fig. 34

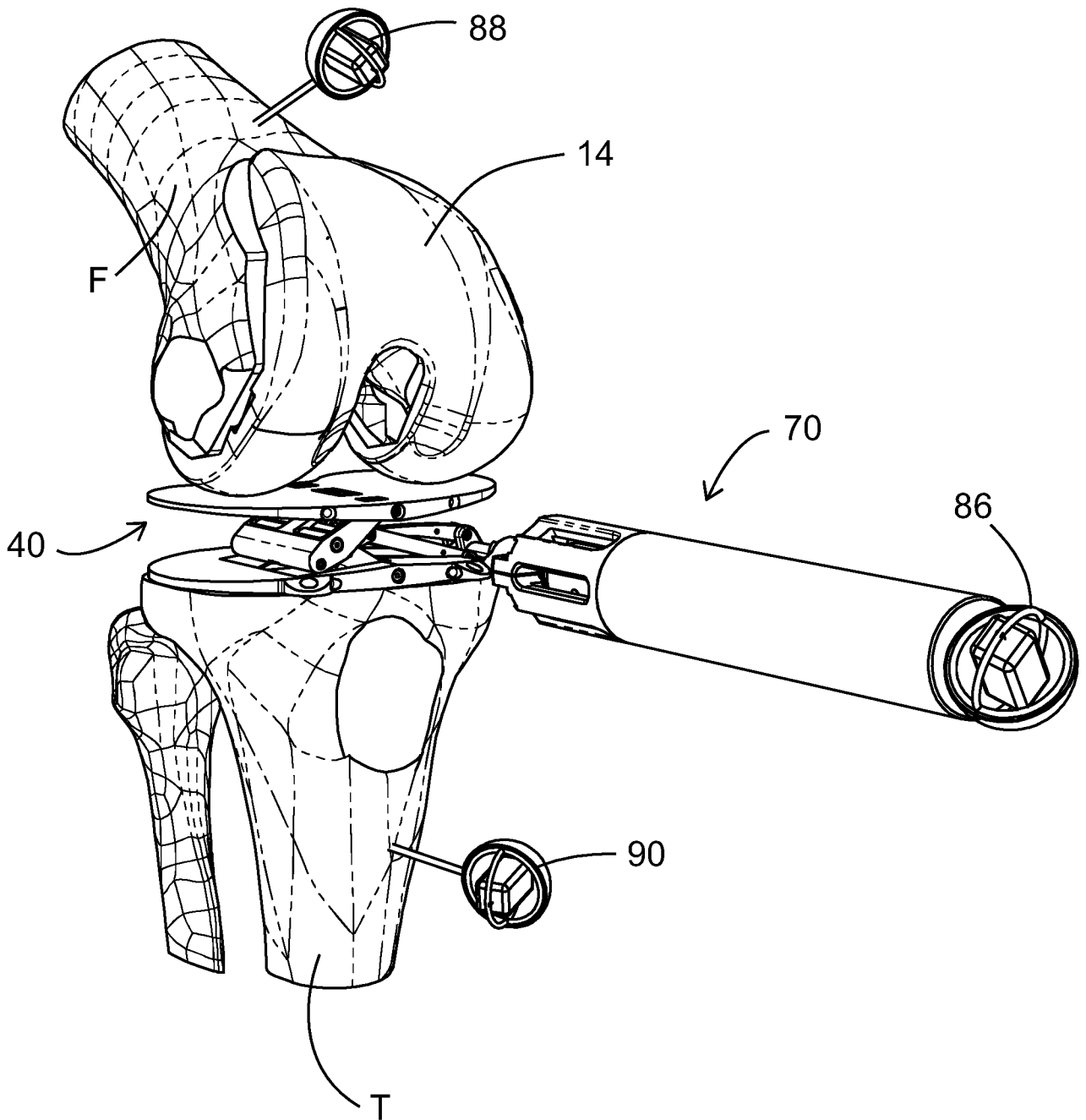


Fig. 35

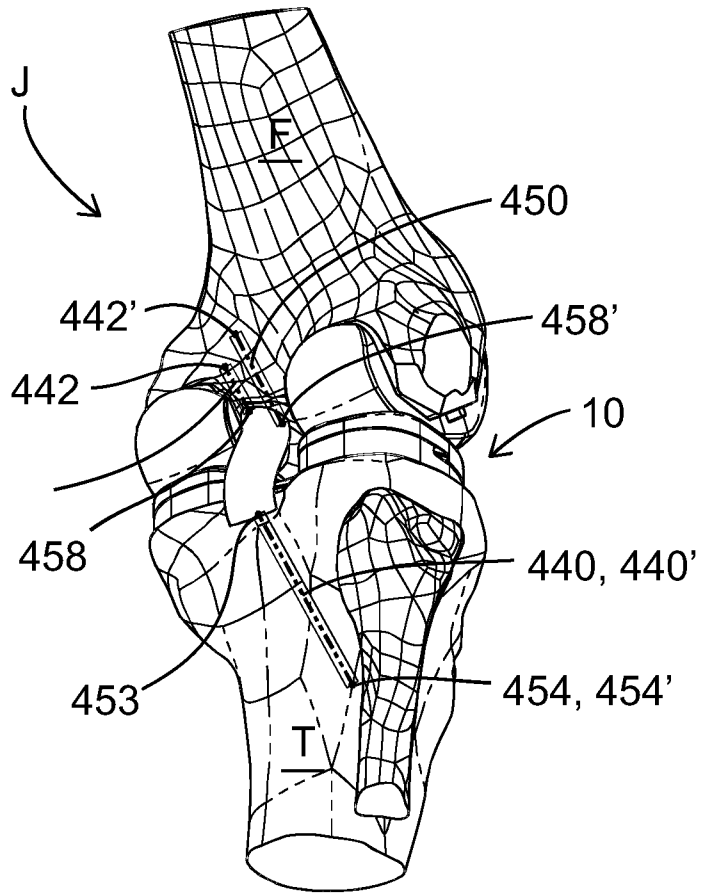


Fig. 36

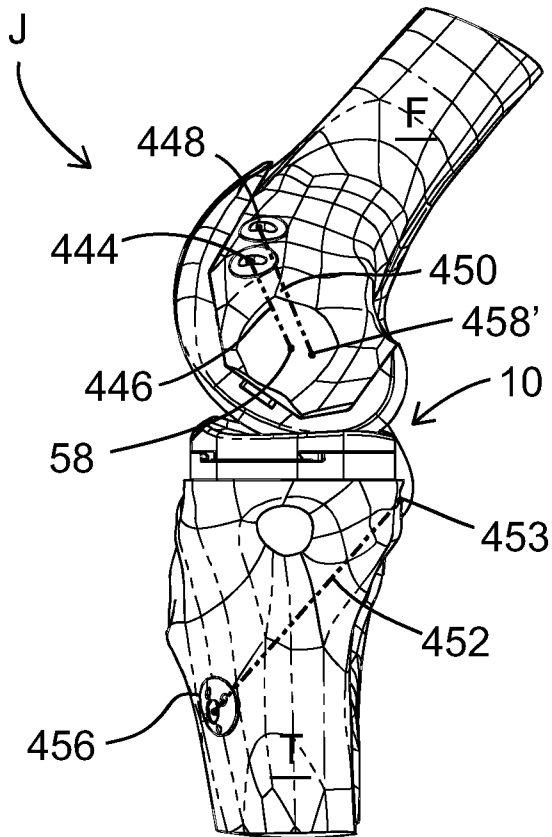


Fig. 37

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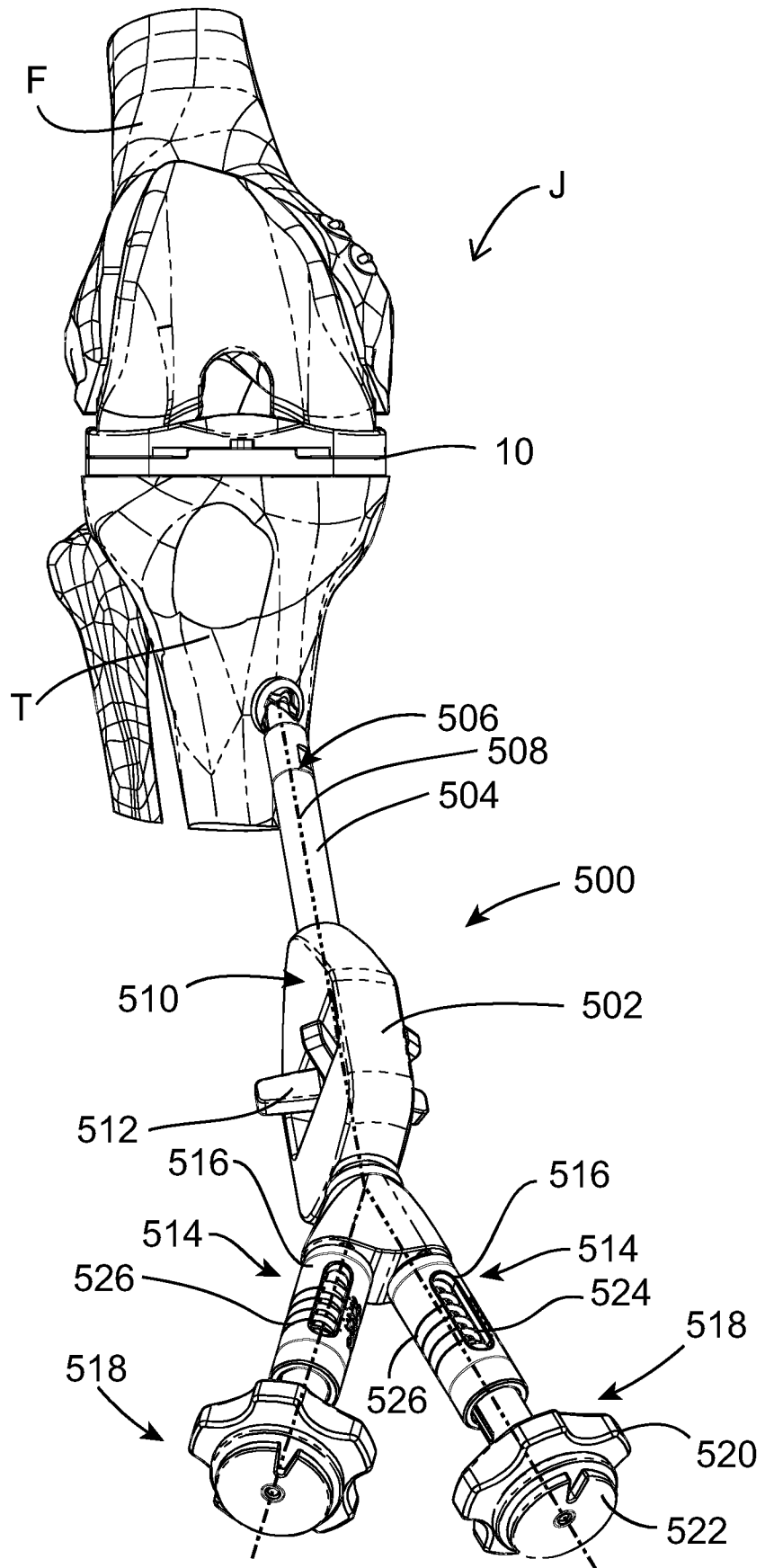


Fig. 38

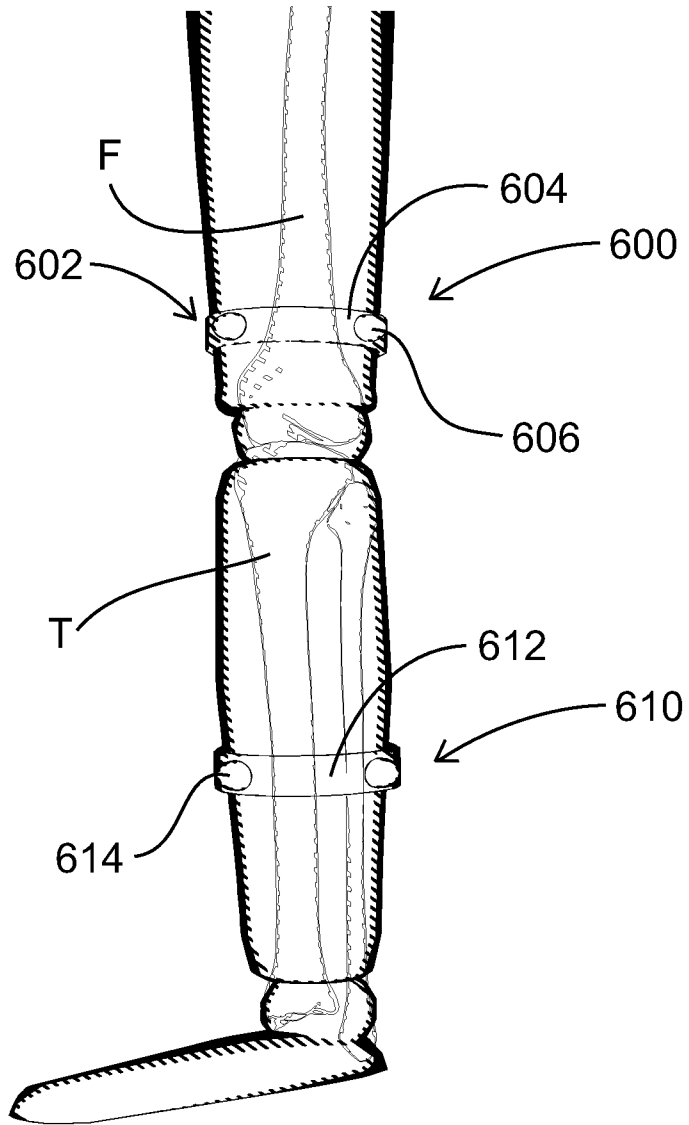


Fig. 39

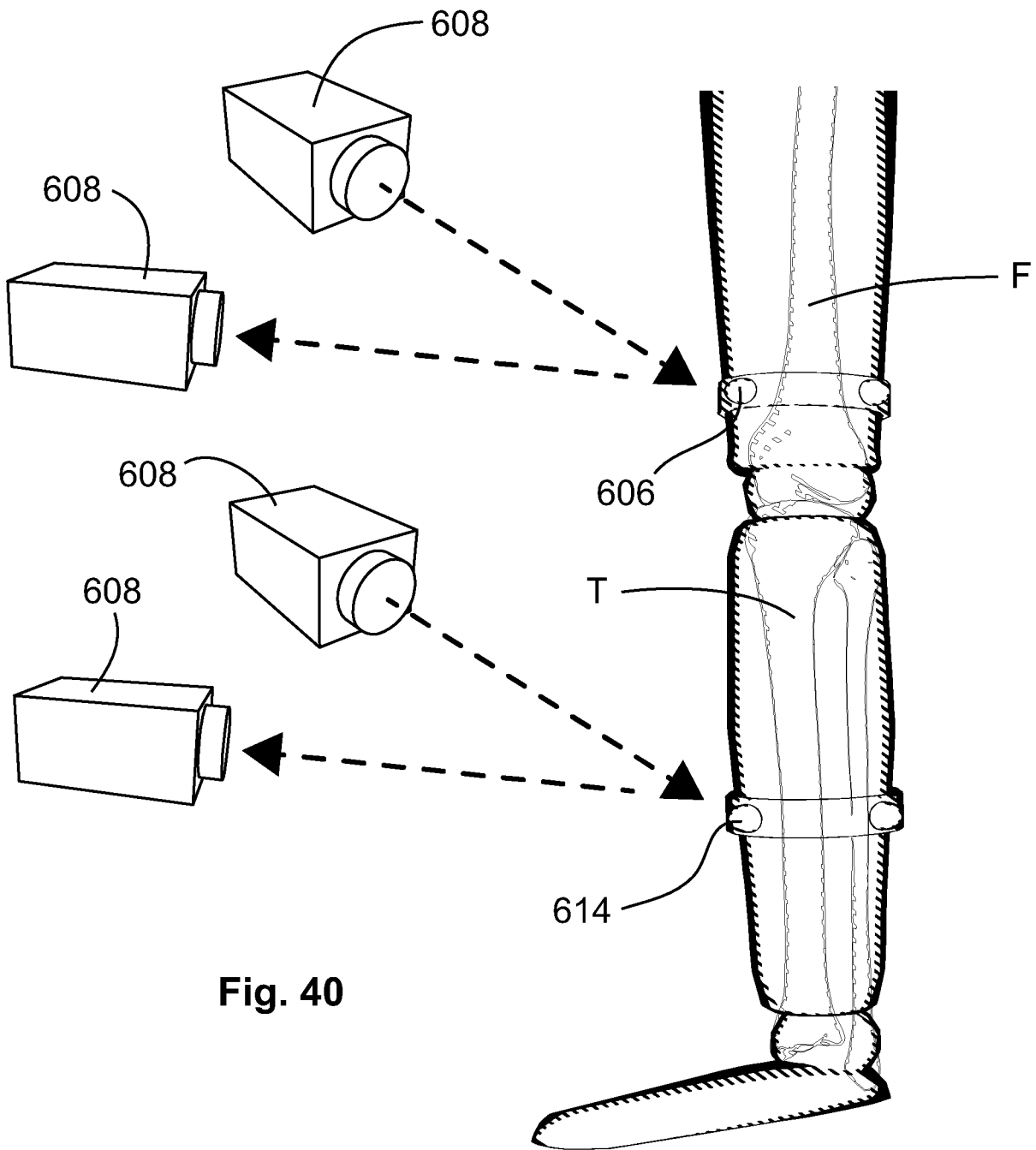
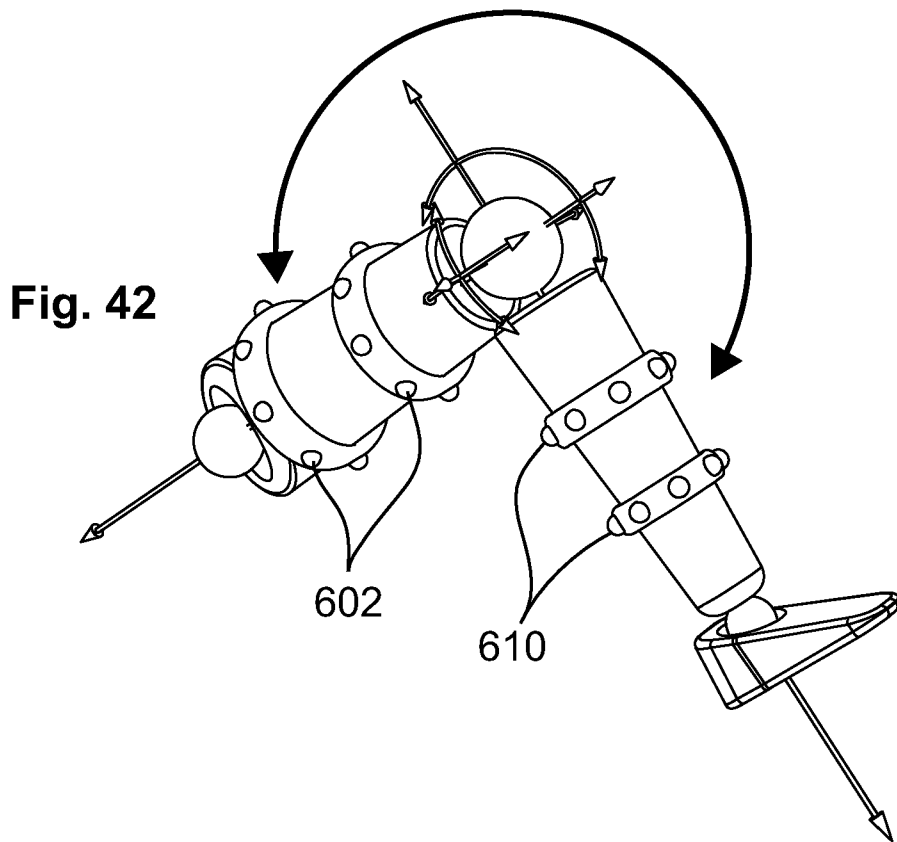
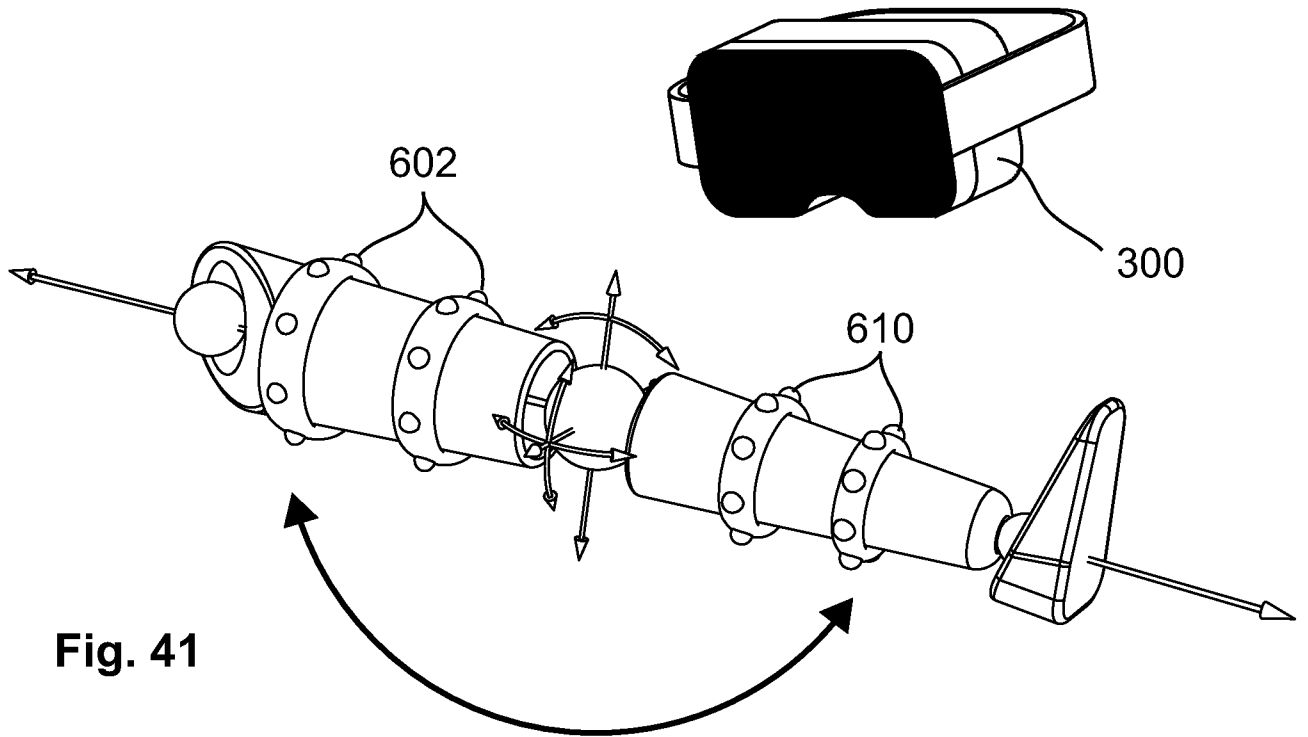


Fig. 40



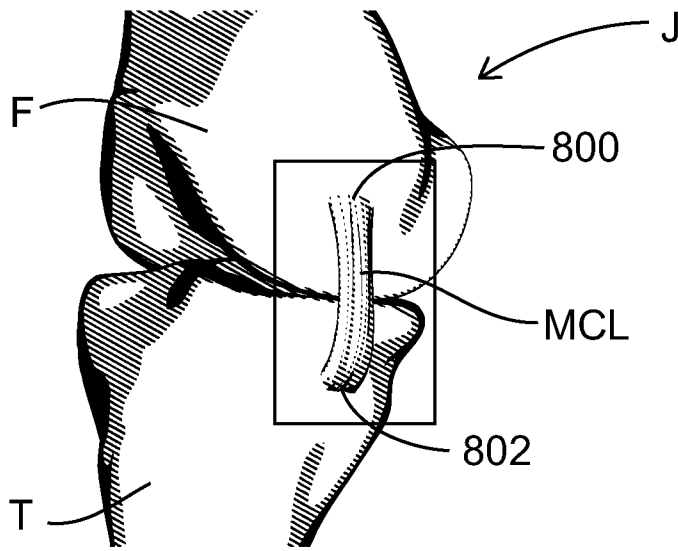


Fig. 43

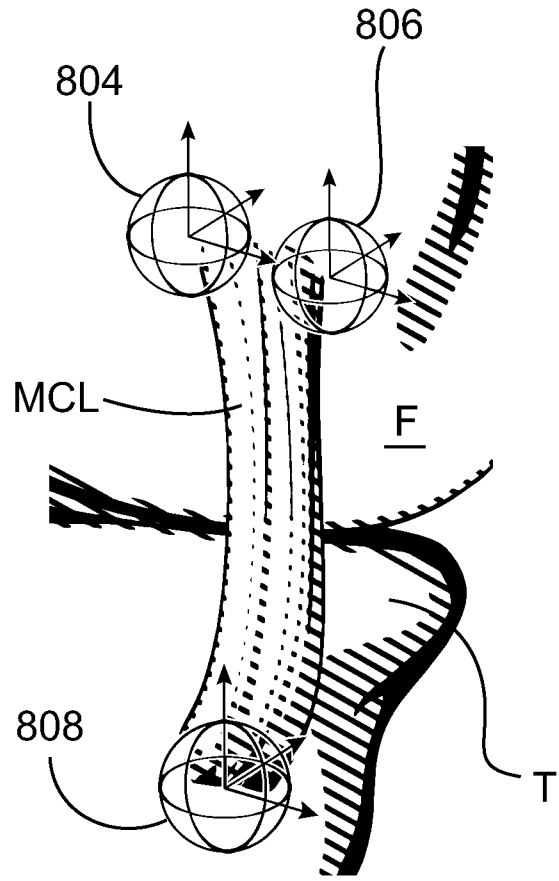


Fig. 44

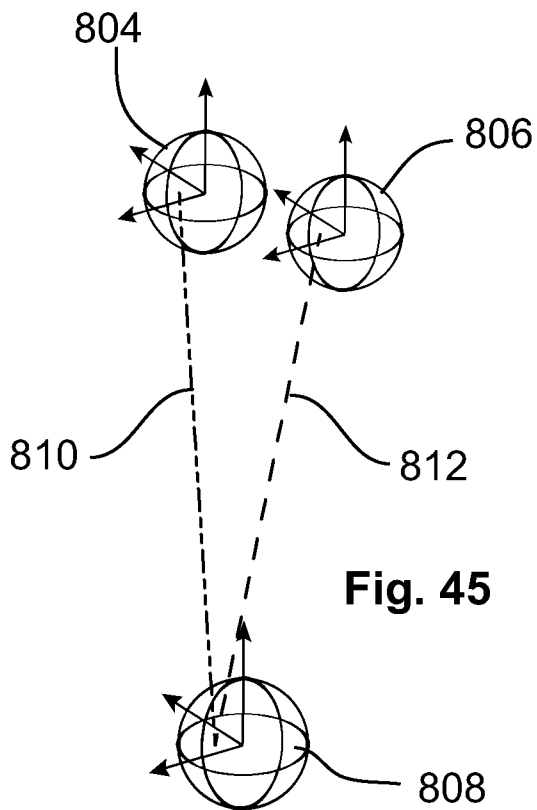


Fig. 45

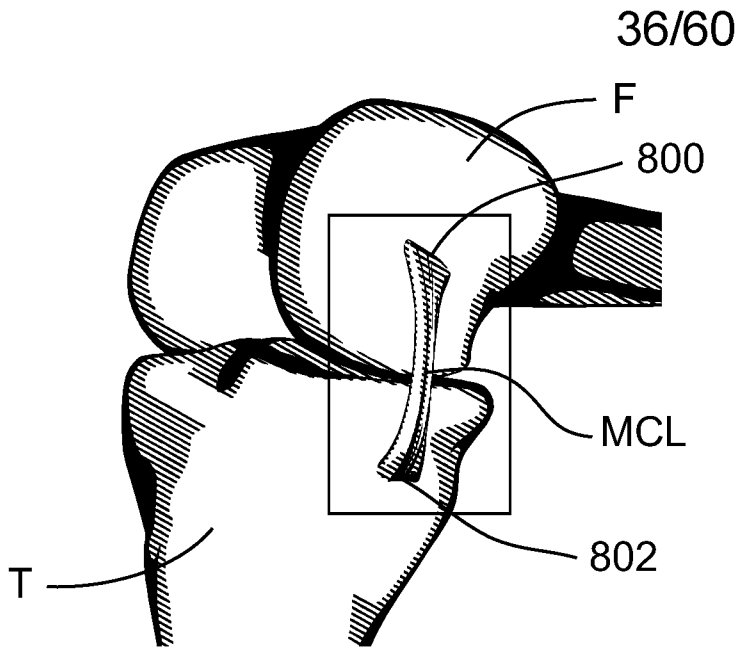


Fig. 46

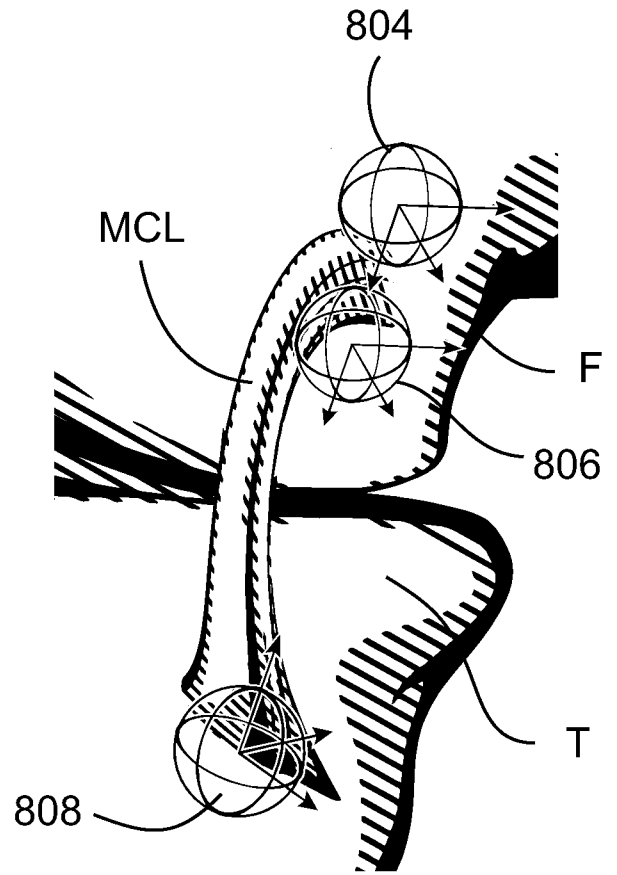


Fig. 47

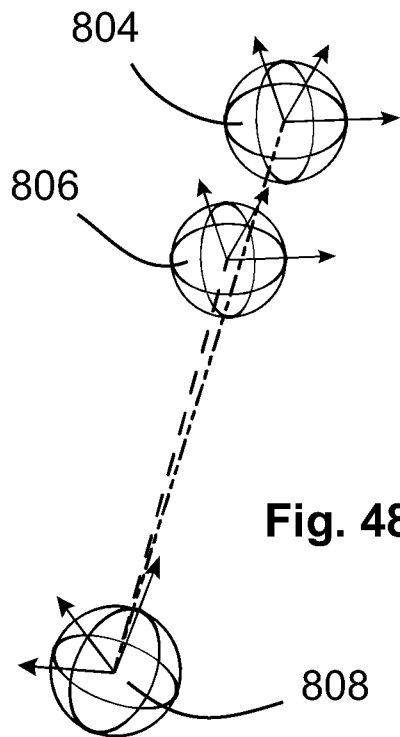


Fig. 48

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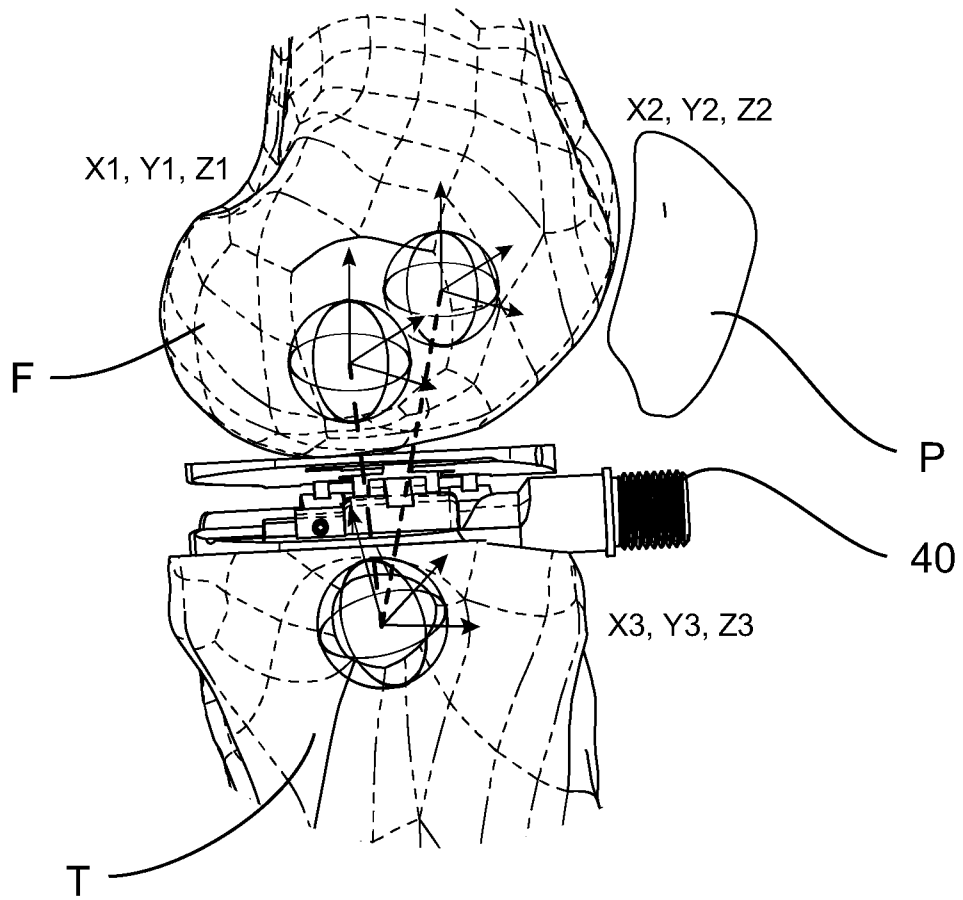


Fig. 49

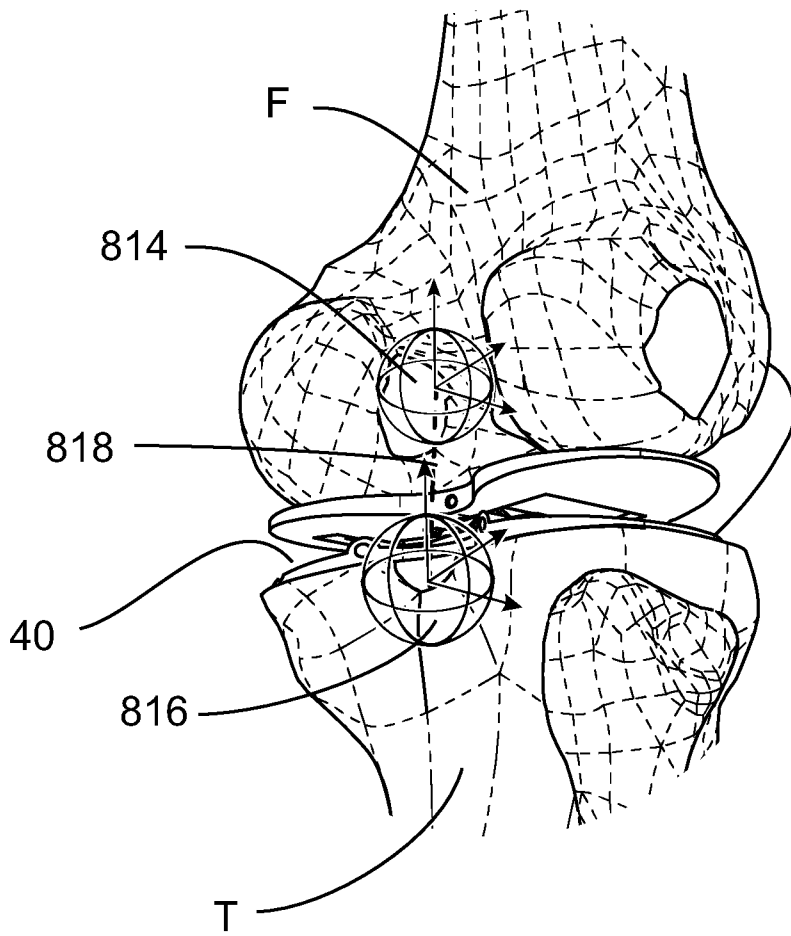


Fig. 50

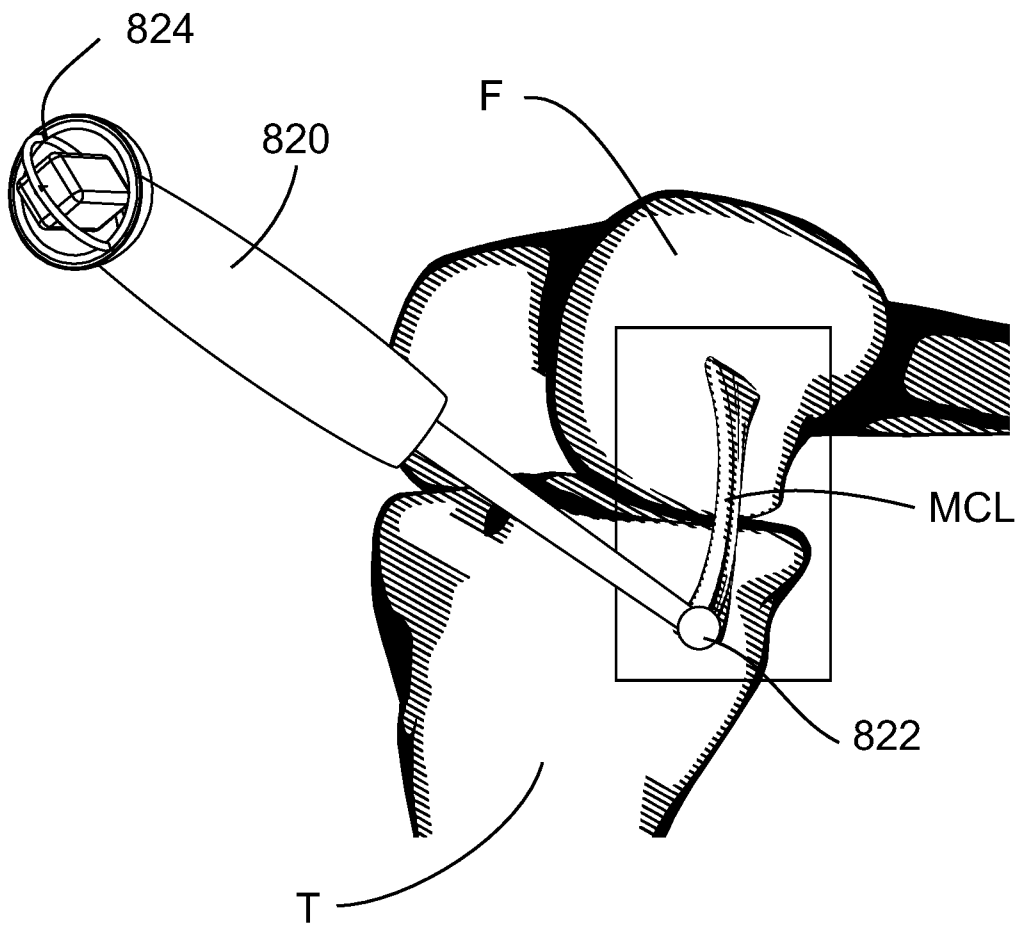


Fig. 51

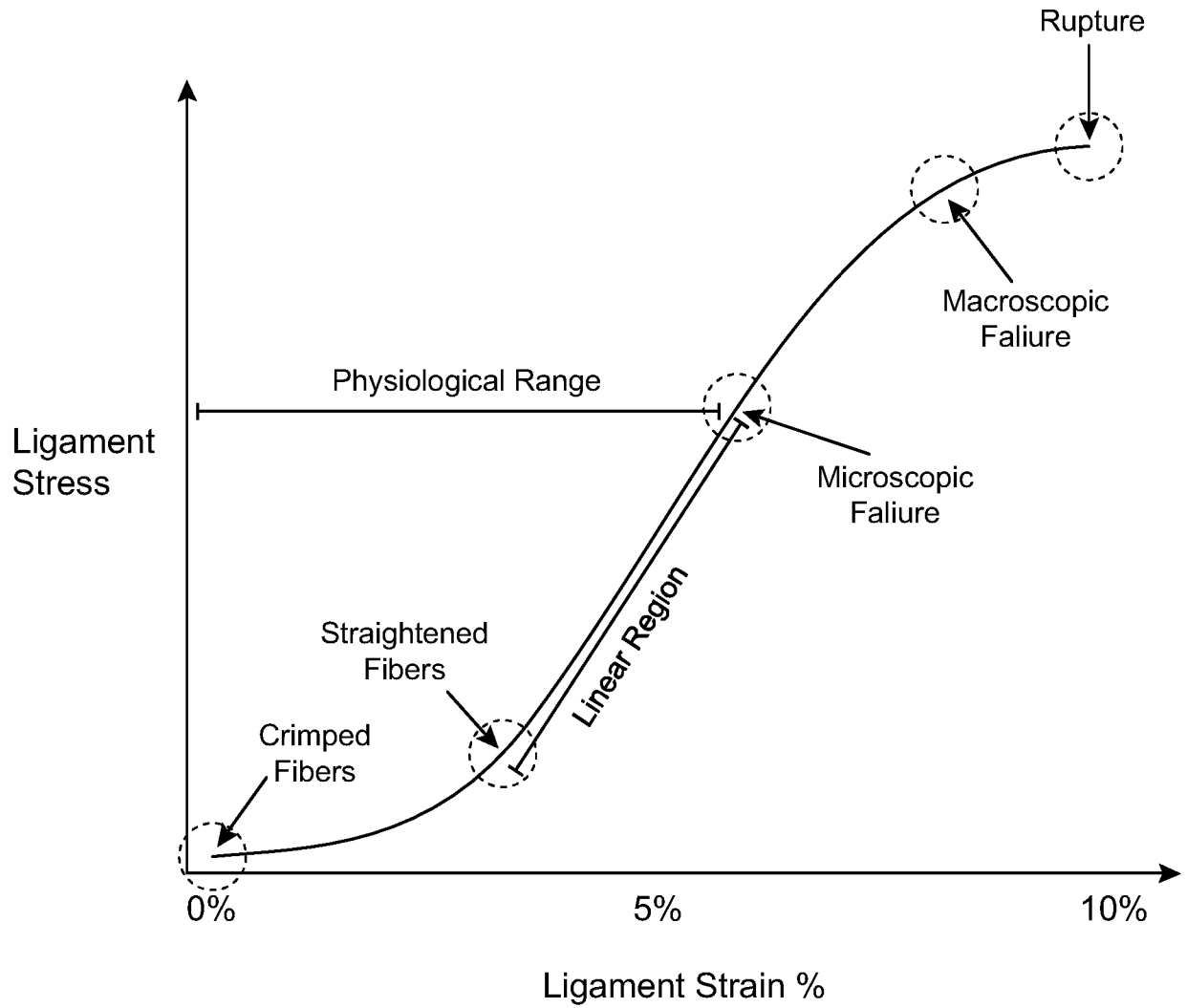


Fig. 52

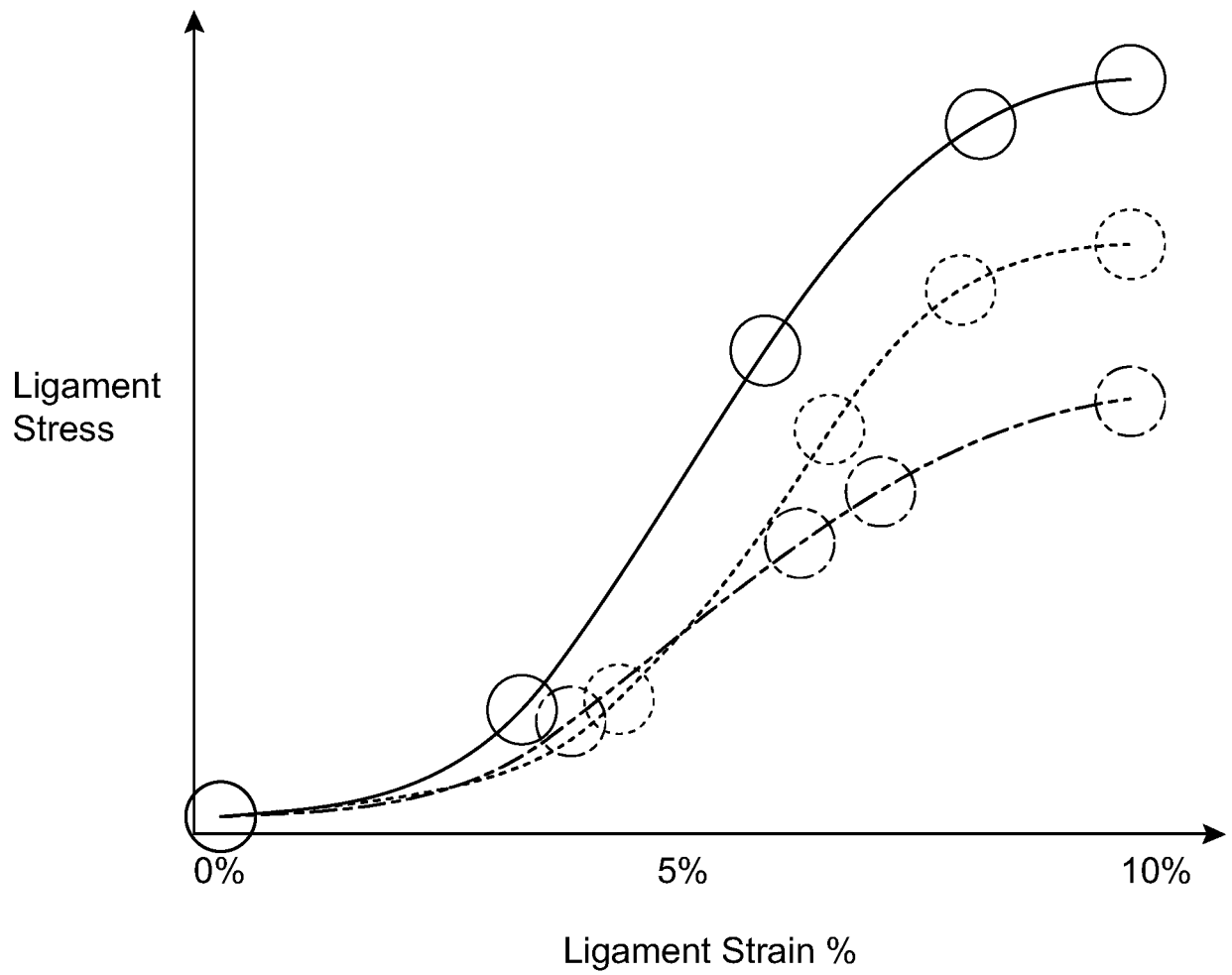


Fig. 53

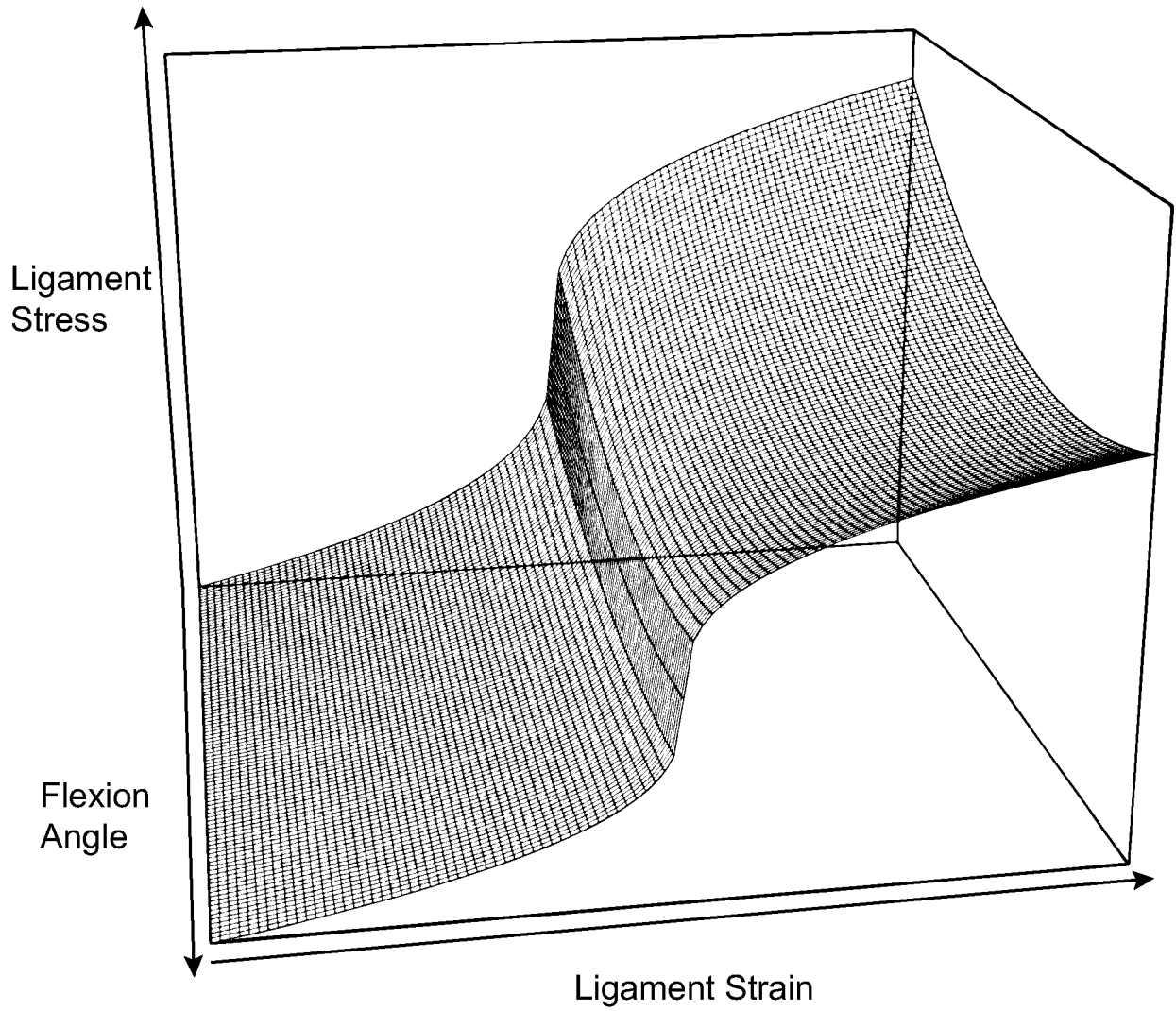


Fig. 54

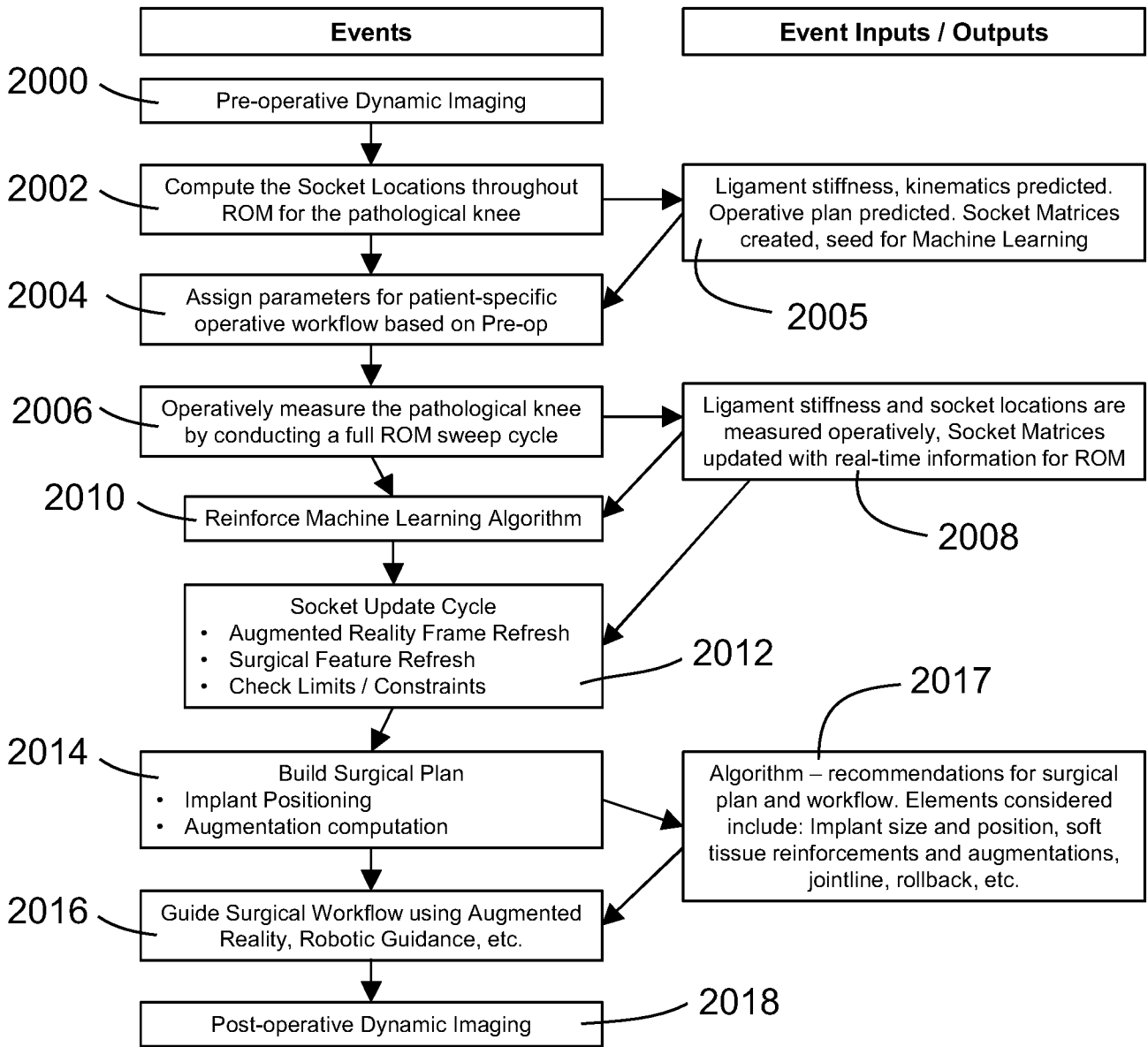


Fig. 55

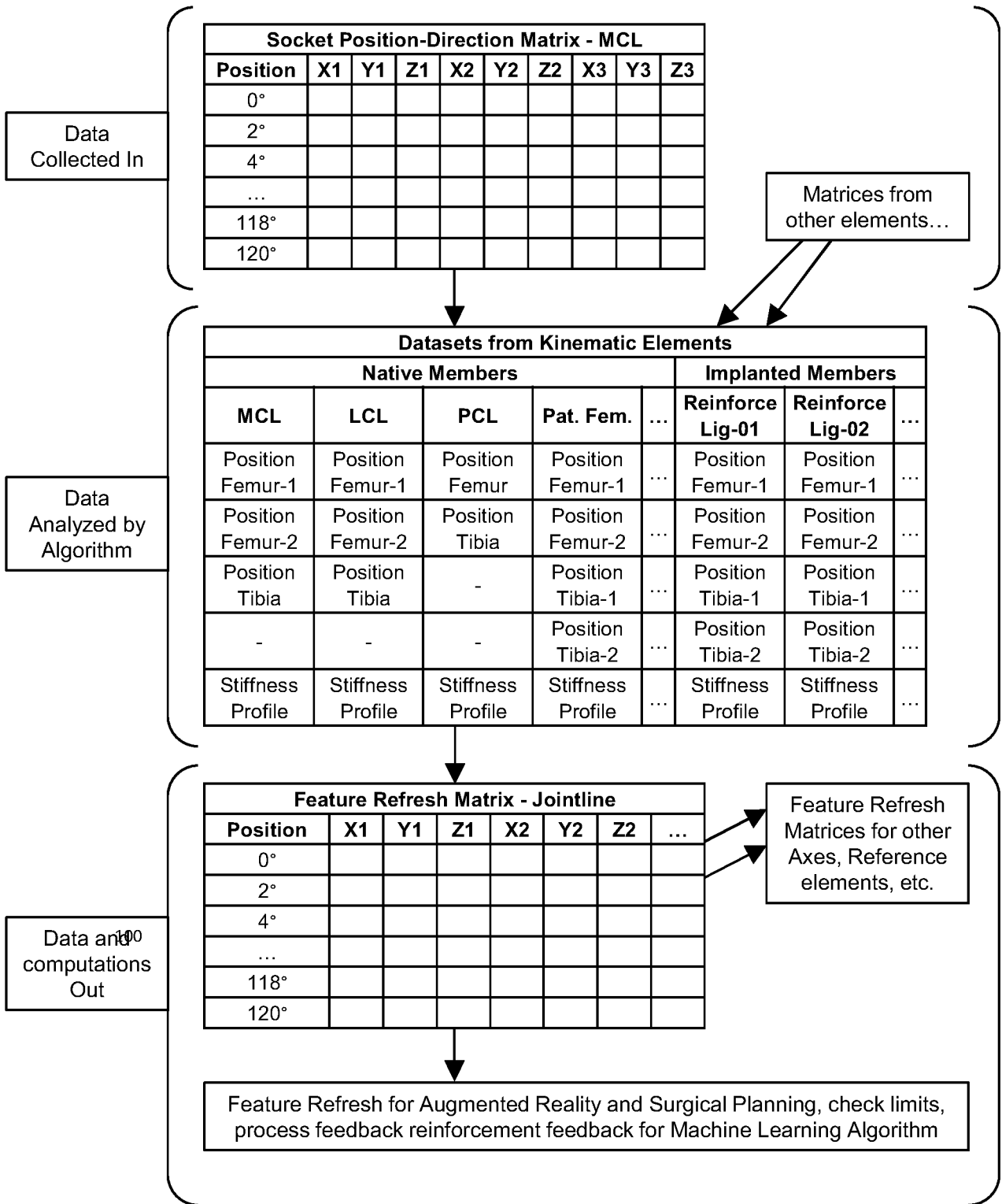


Fig. 56

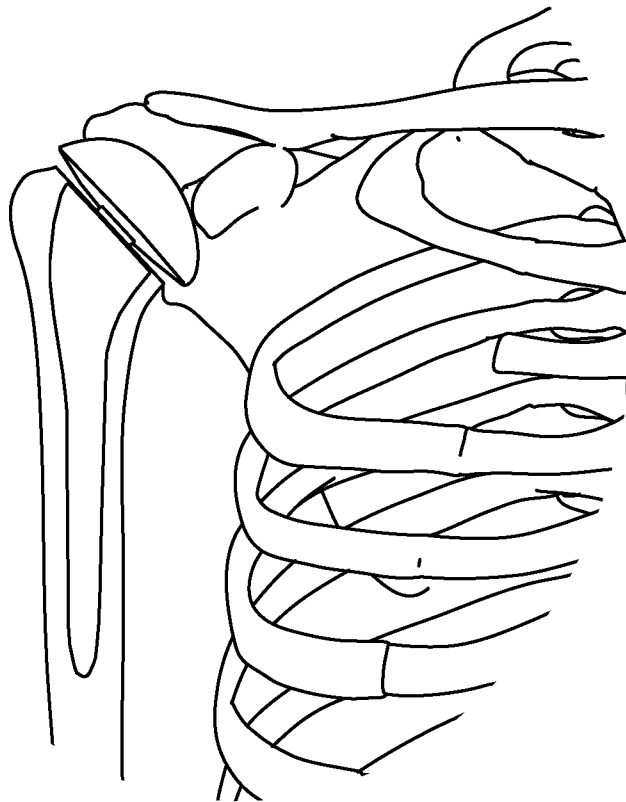


Fig. 57

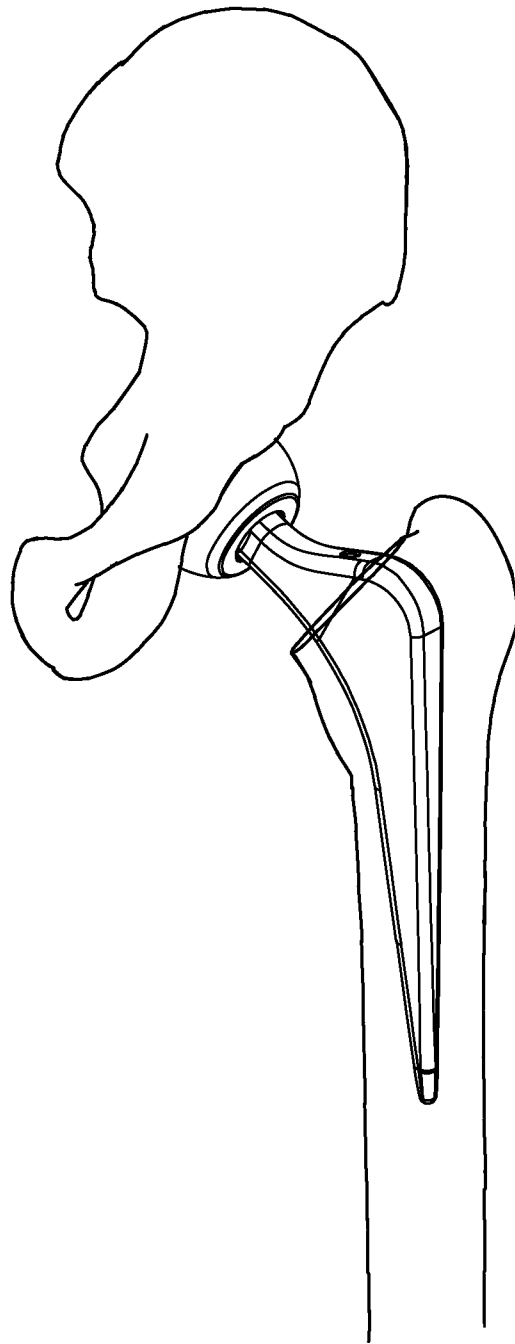
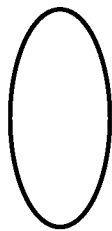
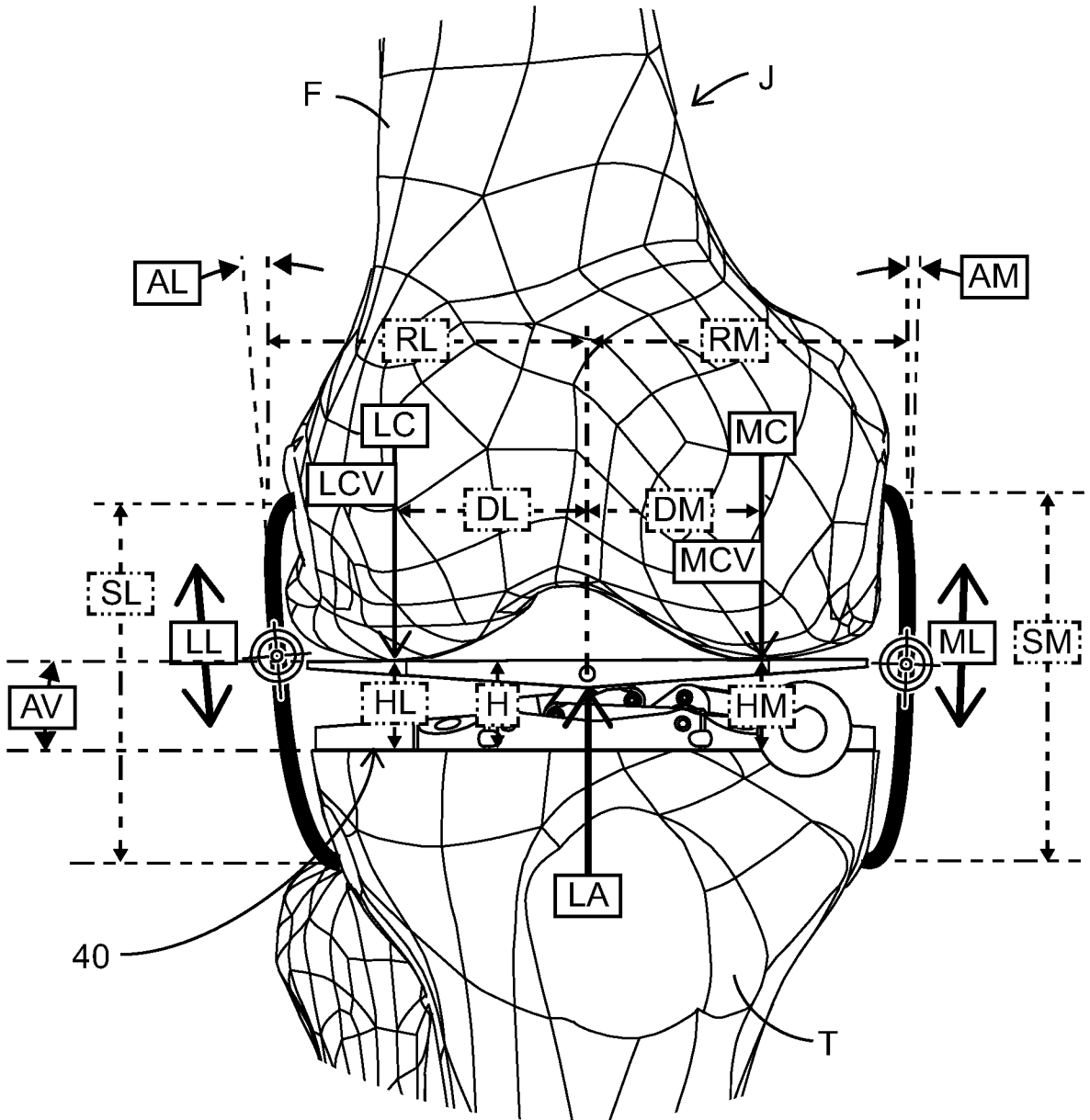


Fig. 58

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Lateral Collateral Ligament
Cross Section

Fig. 59



Medial Collateral Ligament
Cross Section

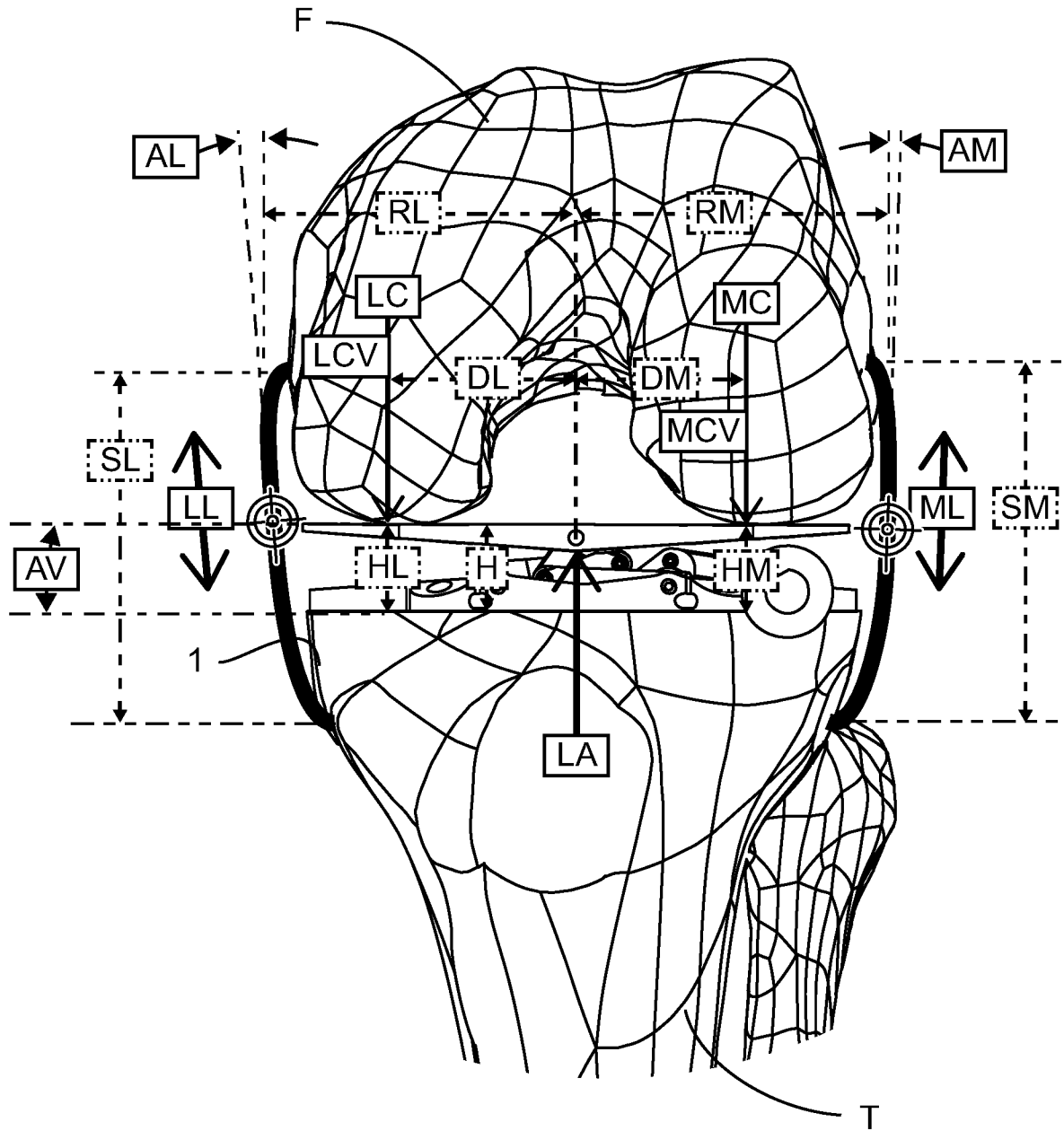


Fig. 60

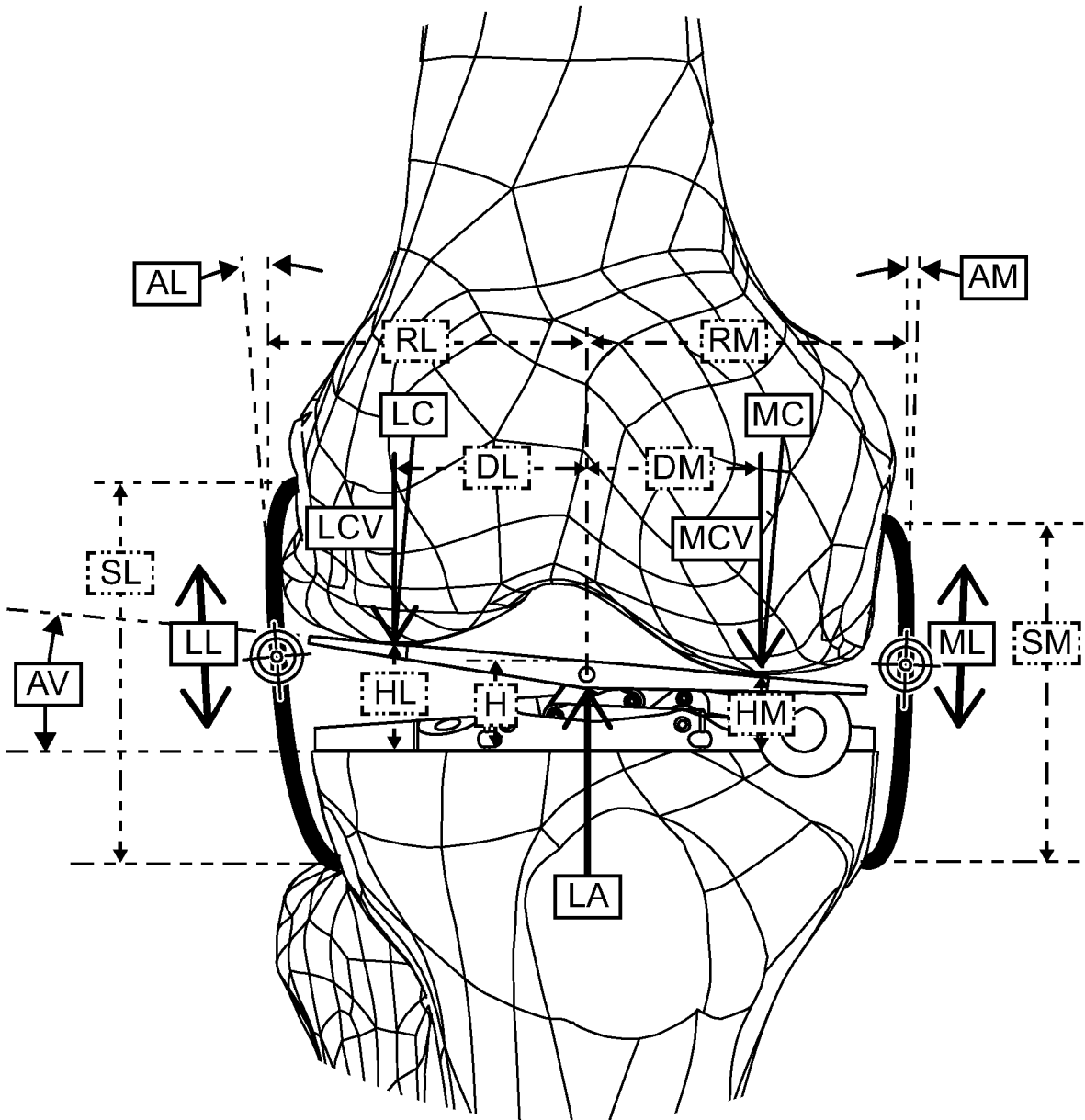


Fig. 61

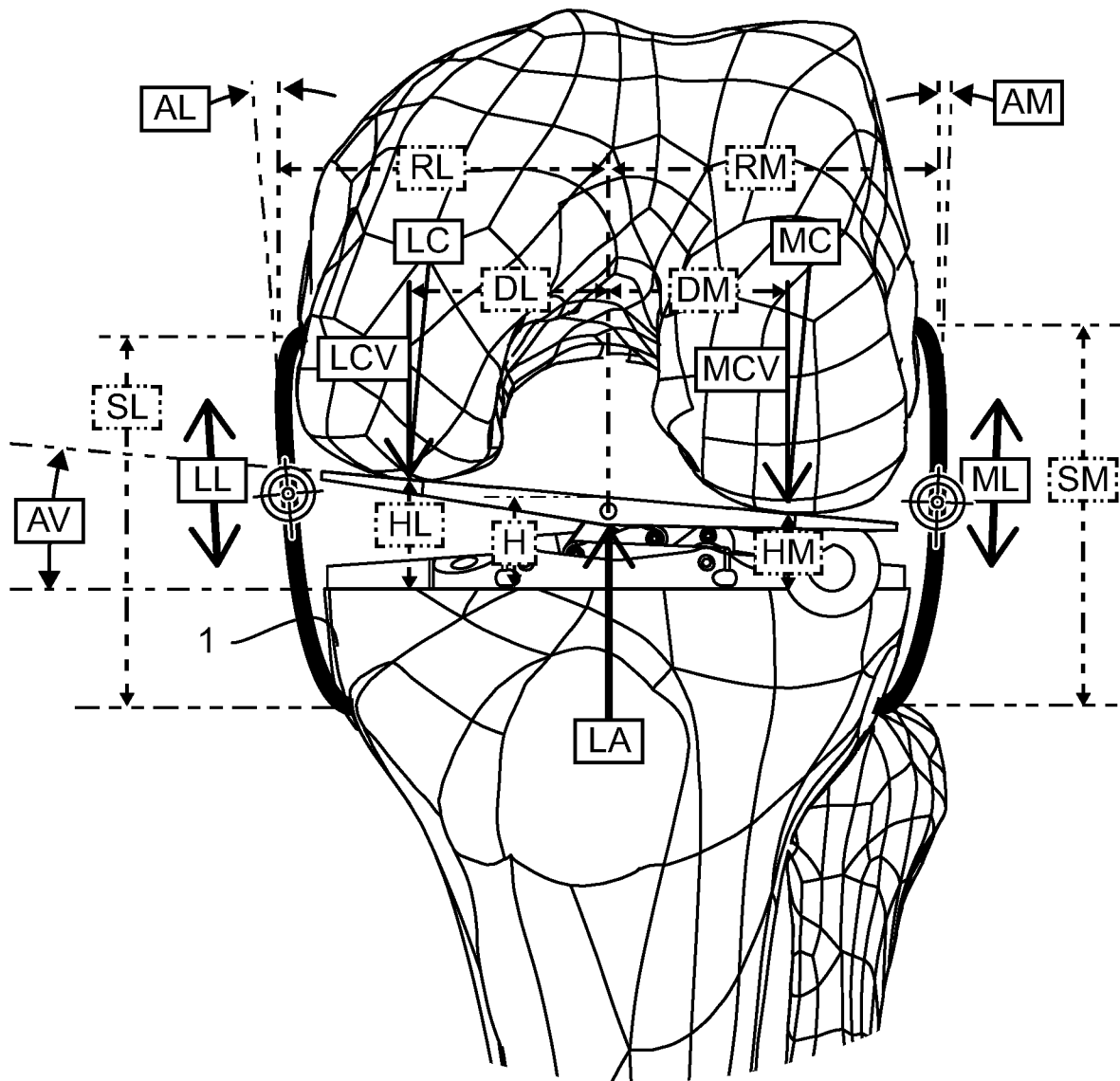


Fig. 62

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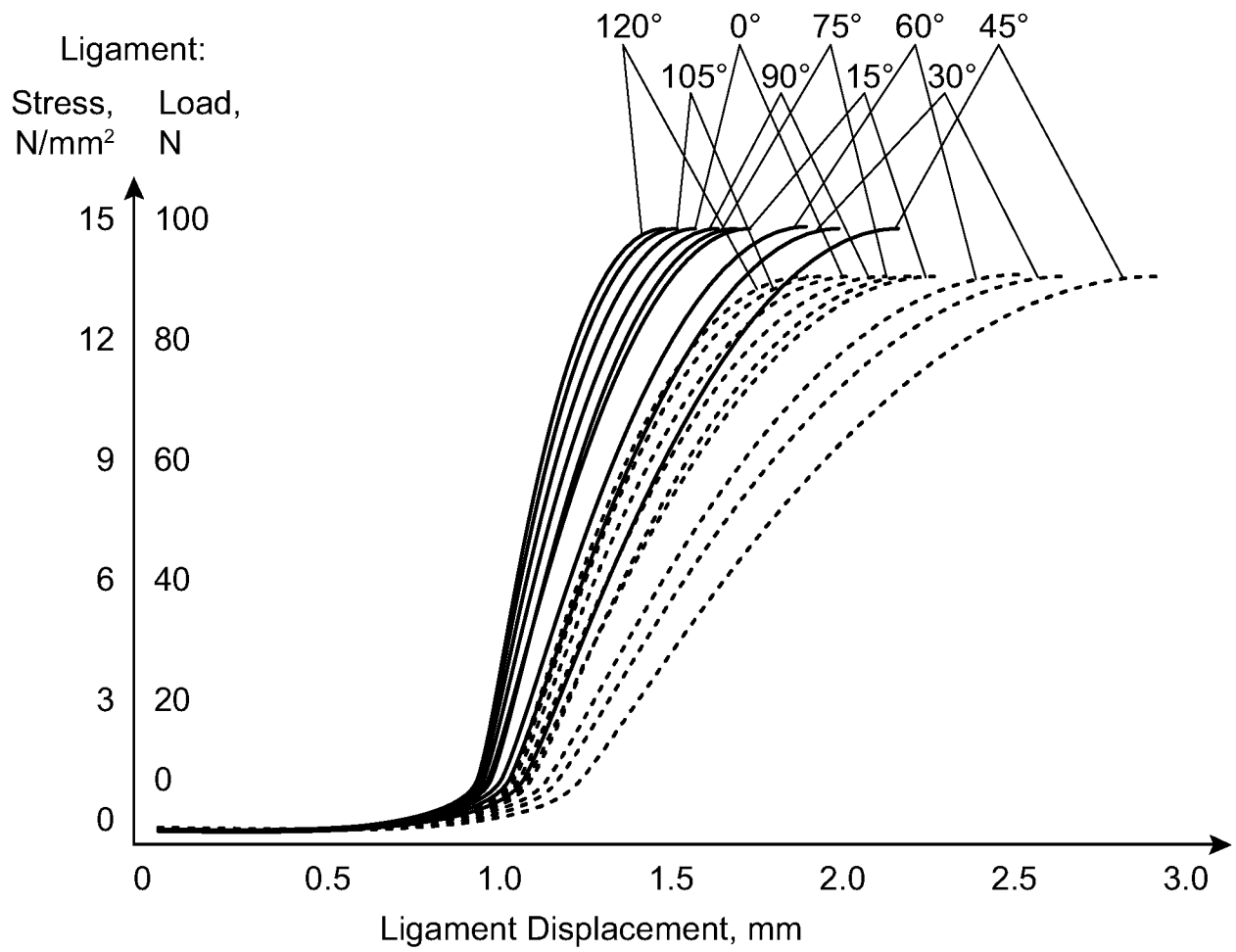
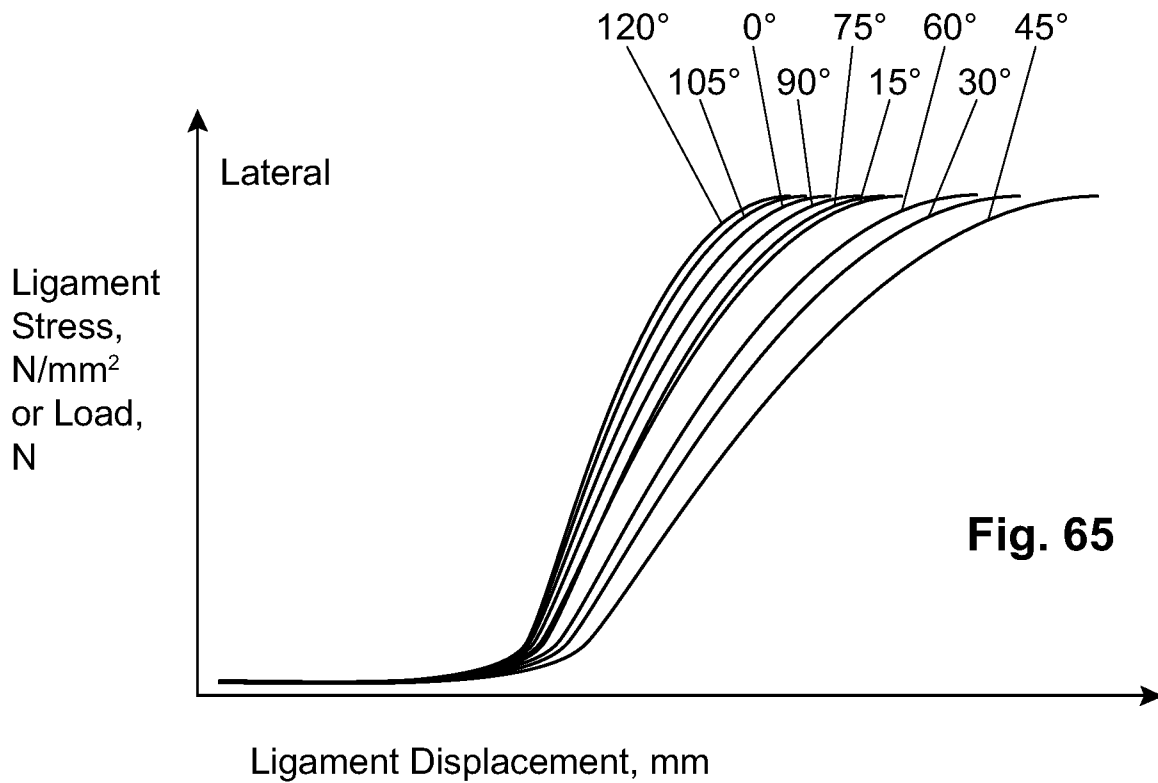
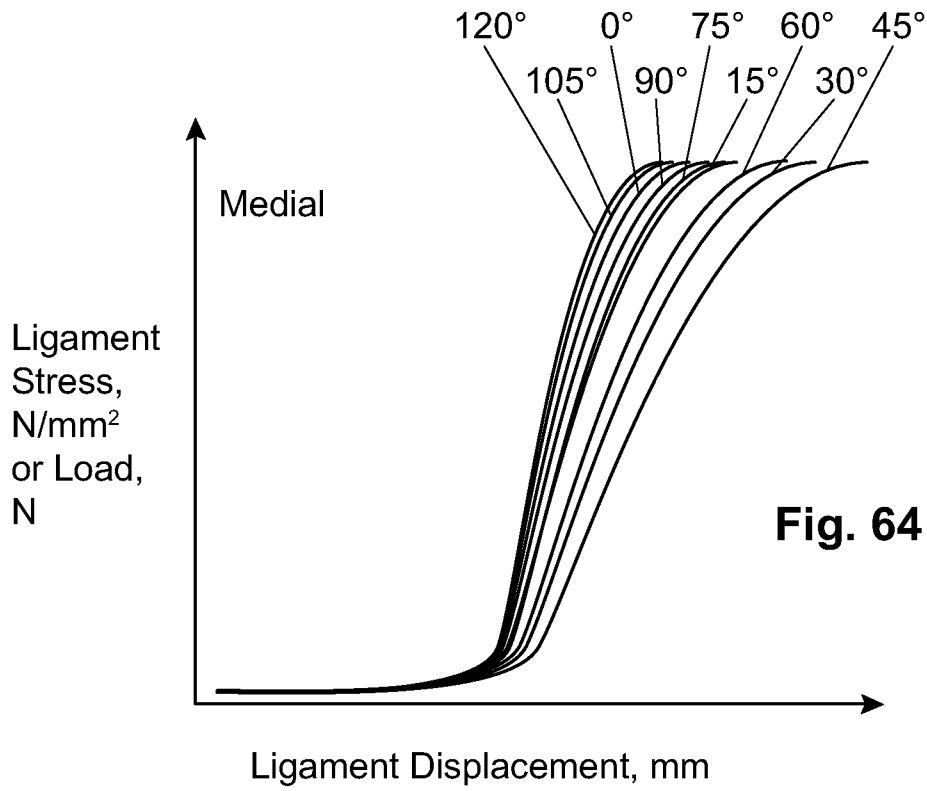


Fig. 63

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Legend:

MCL —————
LCL - - - - -

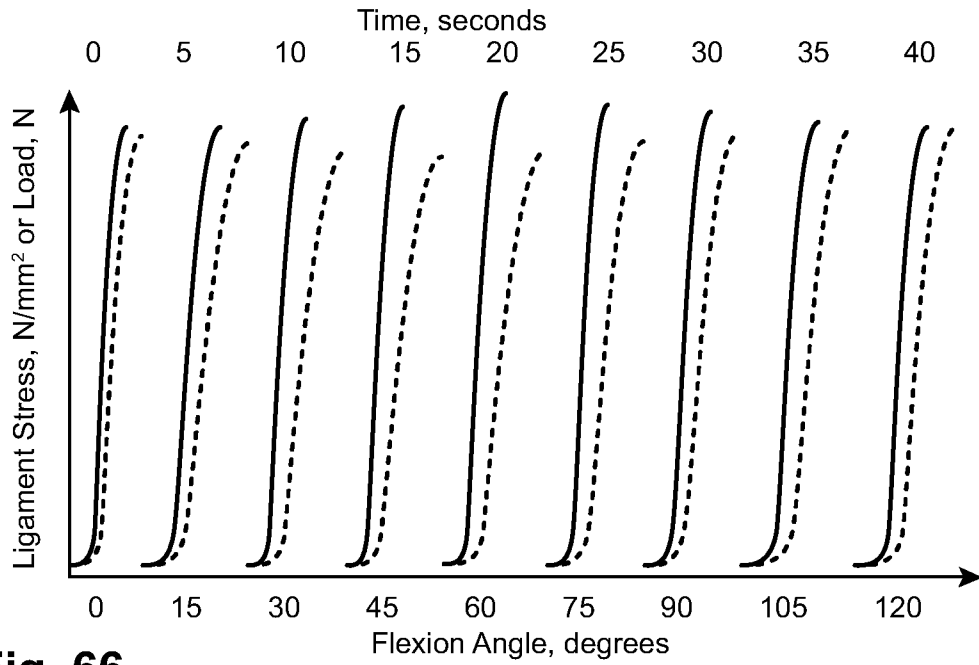


Fig. 66

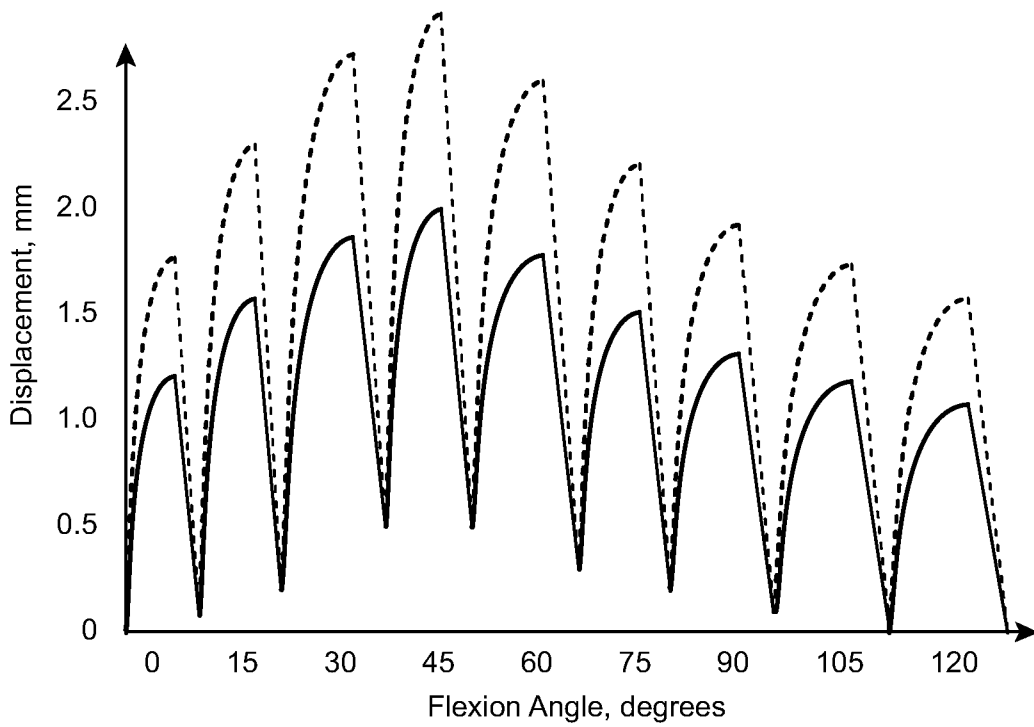




Fig. 67

Legend:

MCL 
LCL 

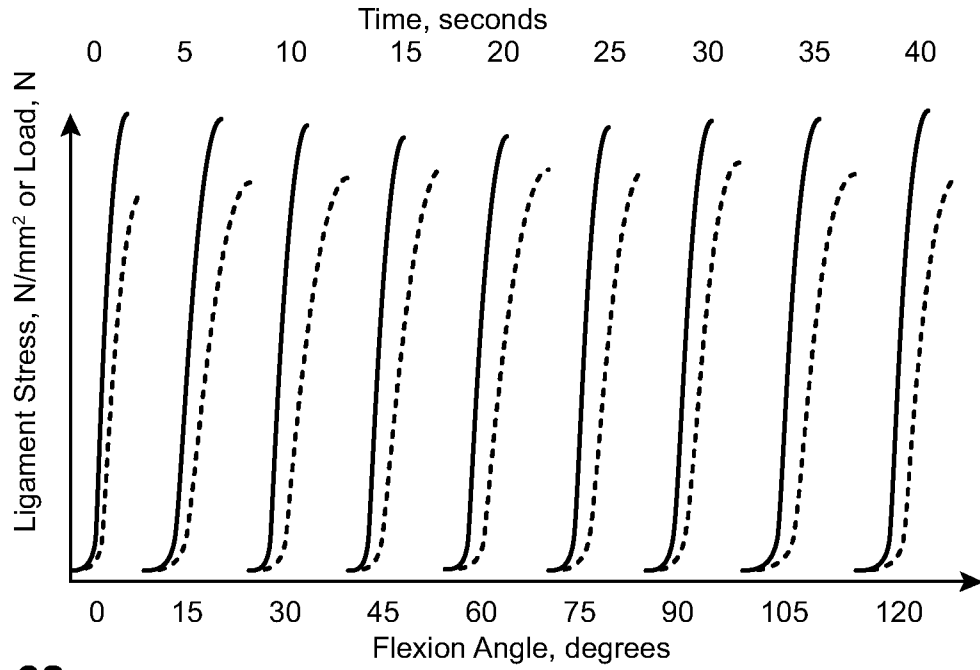


Fig. 68

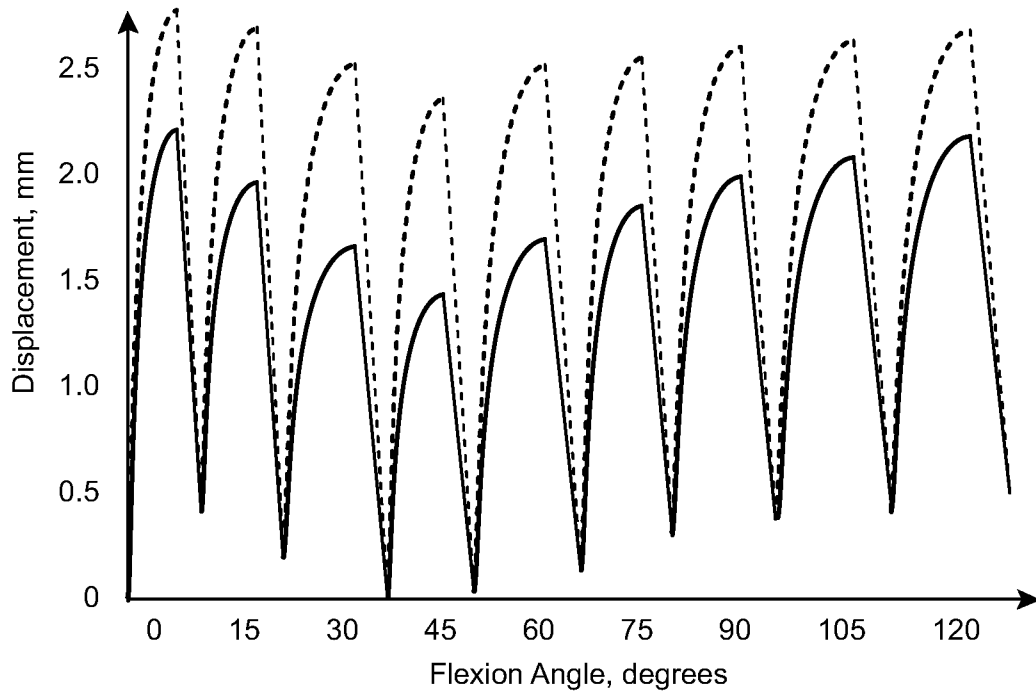


Fig. 69

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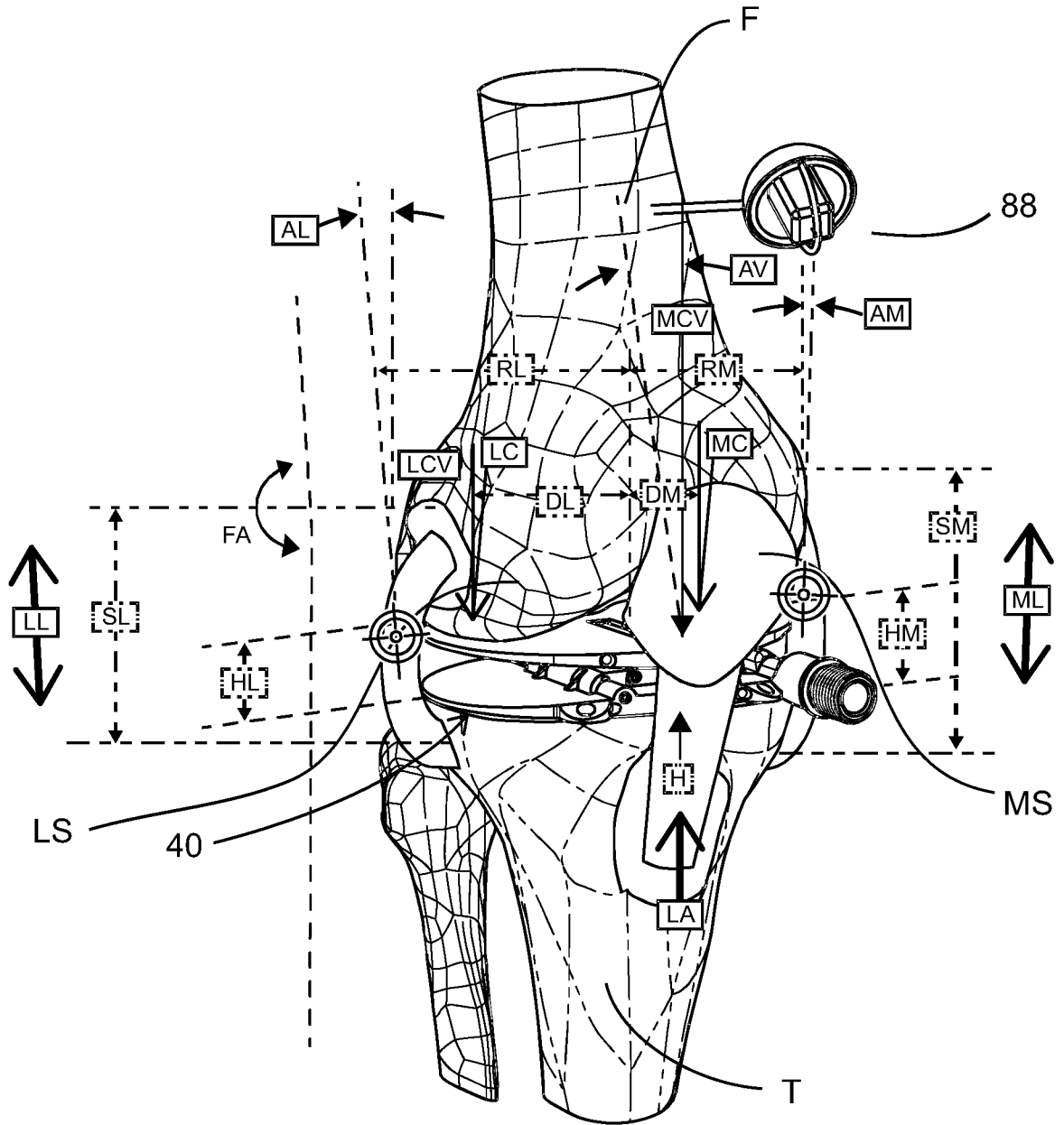


Fig. 70

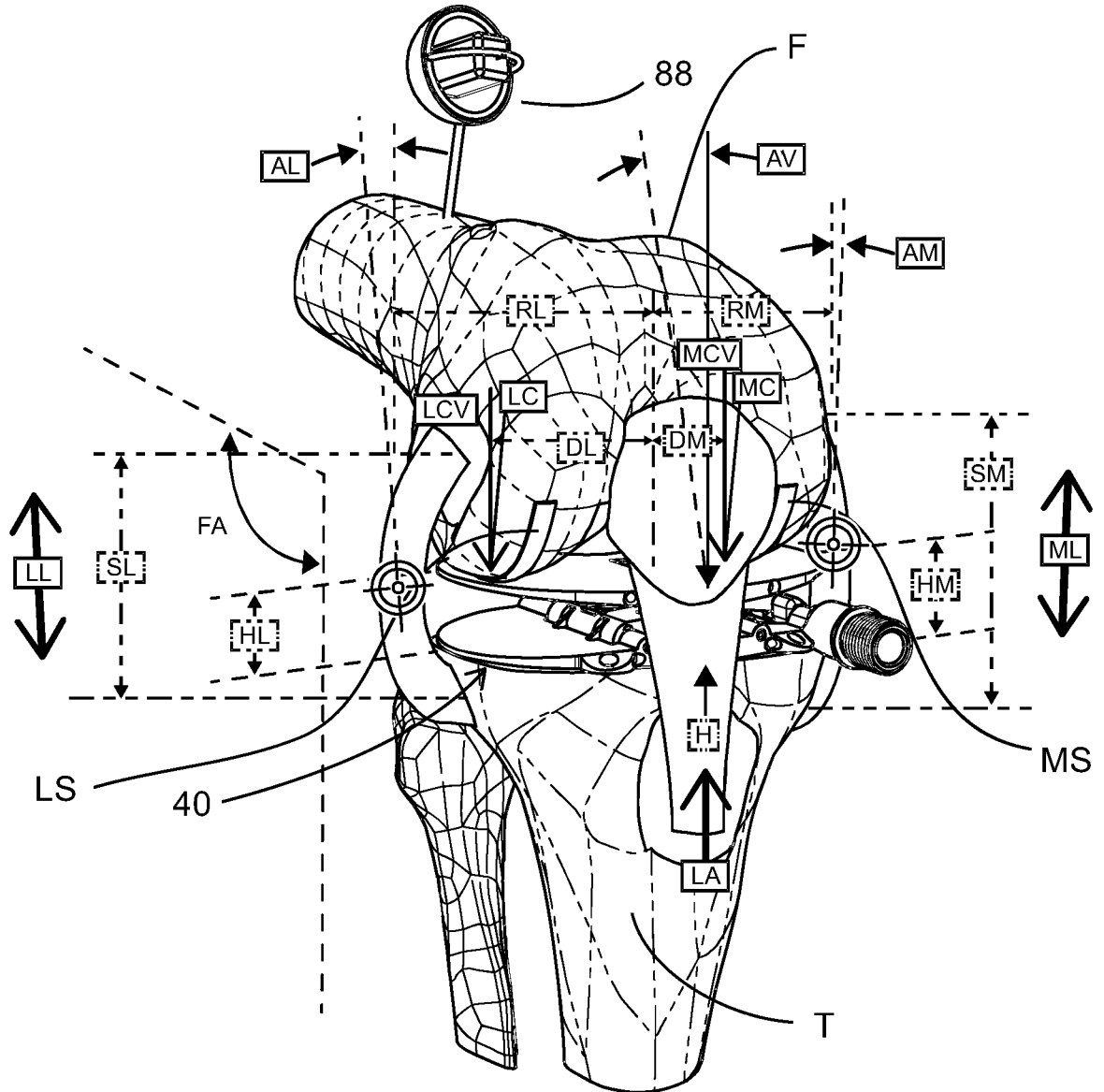
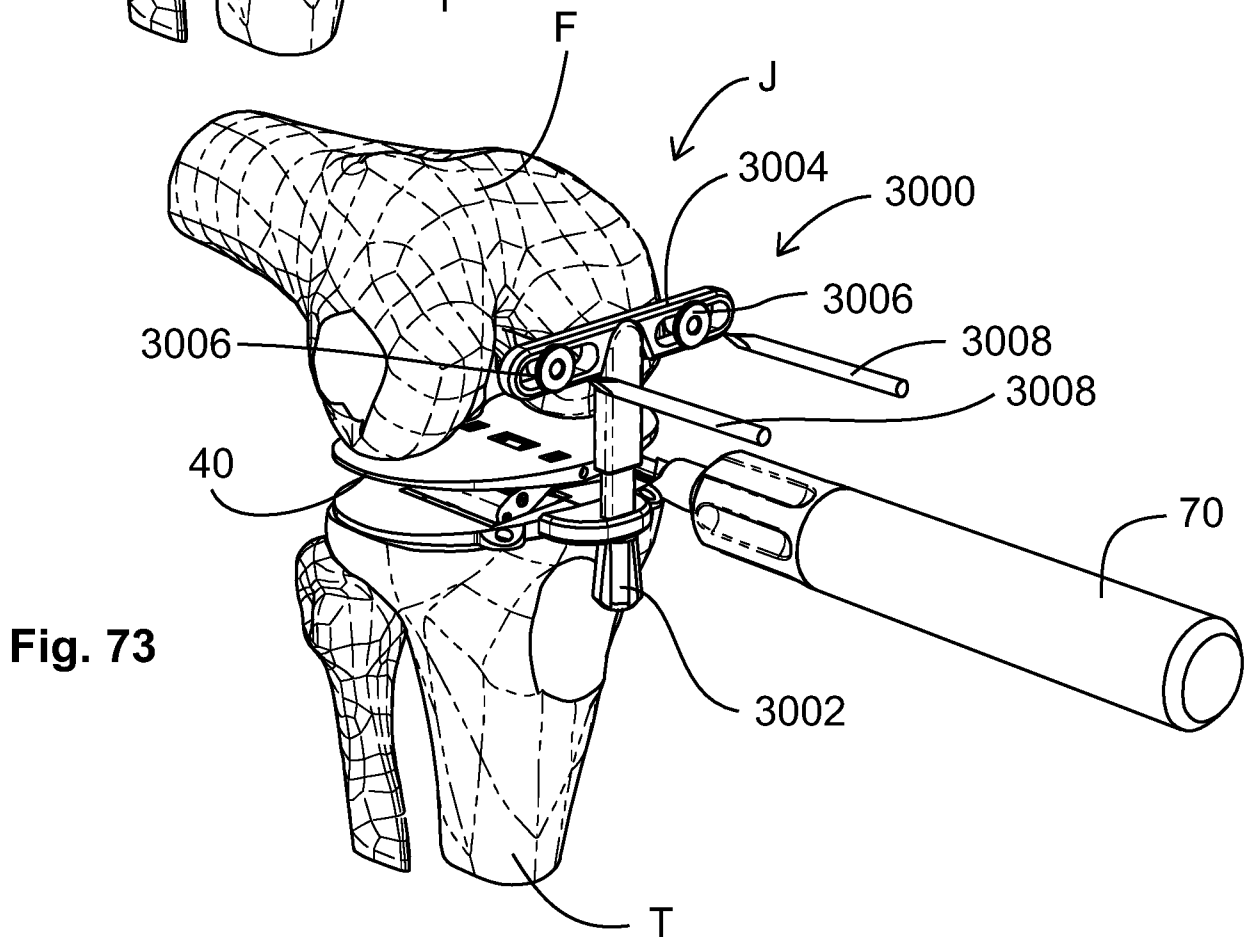
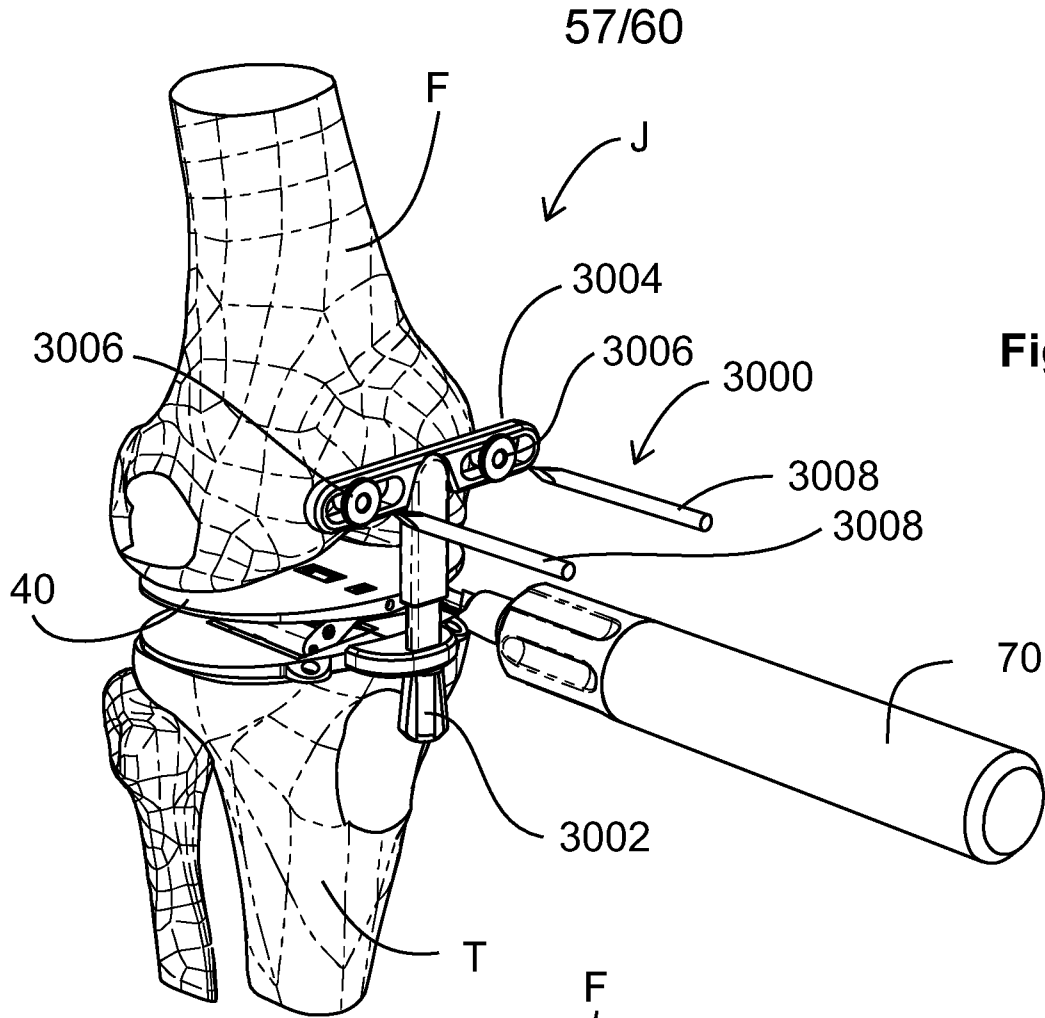


Fig. 71



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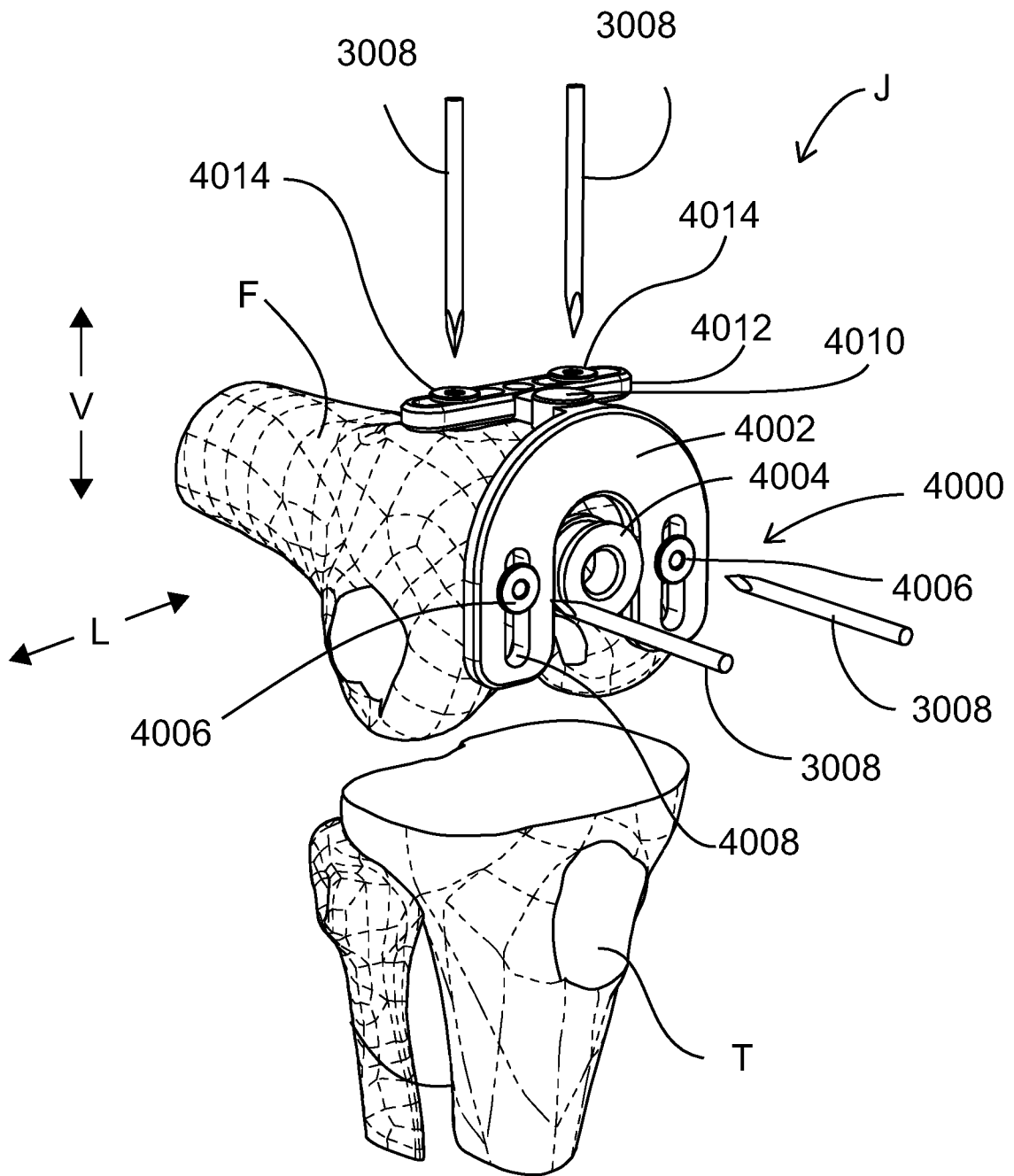


Fig. 74

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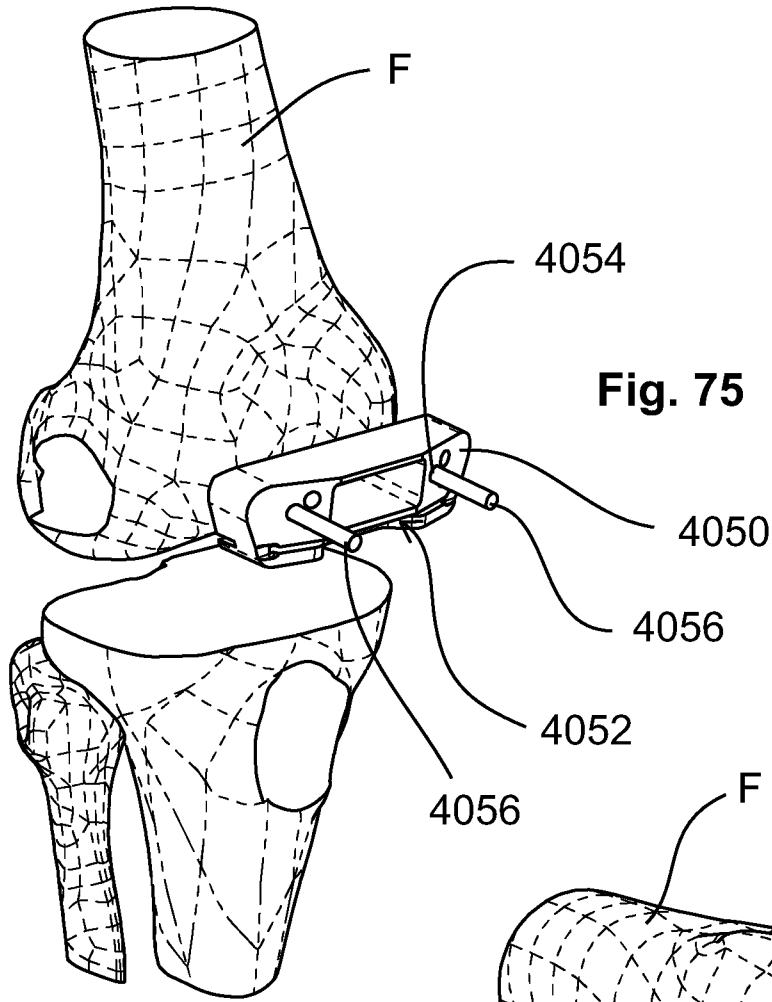


Fig. 75

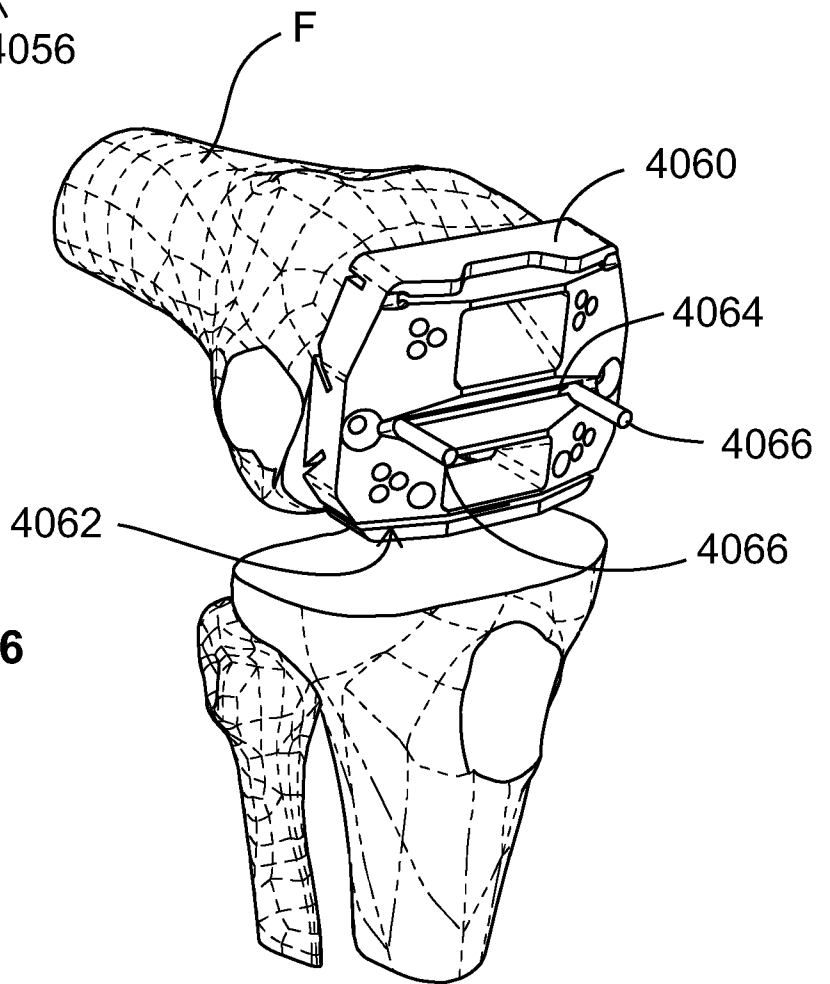


Fig. 76

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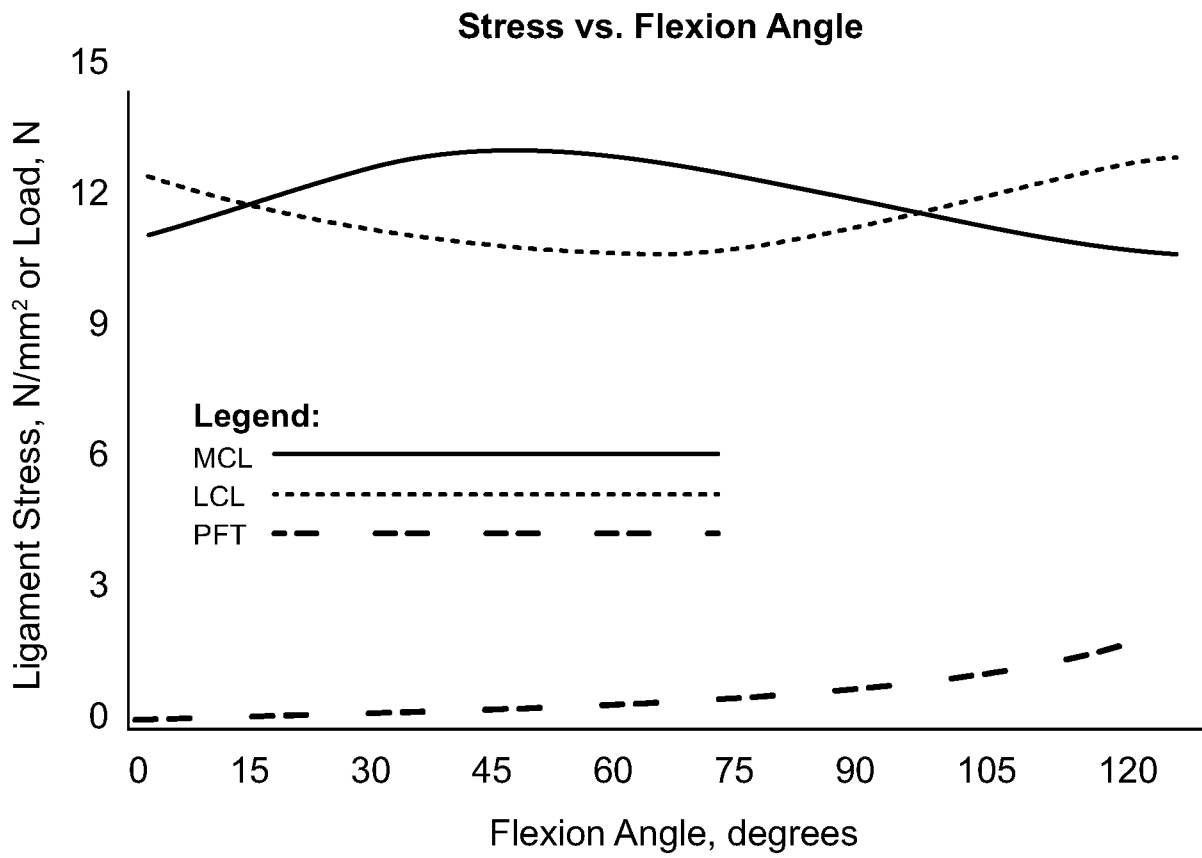


Fig. 77

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 23/24684

A. CLASSIFICATION OF SUBJECT MATTER
 IPC - INV. A61B 5/00, A61F 2/46 (2023.01)
 ADD. A61B 17/68, A61B 34/10, G01L 5/16 (2023.01)
 CPC - INV. A61B 5/4533, A61F 2/4657, A61B 5/1036, A61B 5/4585
 ADD. A61B 17/68, A61B 34/10, G01L 5/16

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y -- A	US 11,298,246 B1 (LITTLE ENGINE, LLC) 12 April 2022 (12.04.2022); entire document, especially col 5 ln 31-53, and Fig. 6-10.	8-15 -- 1-5, 7 -- 6
Y -- A	US 10,789,858 B2 (HOSPITAL FOR SPECIAL SURGERY) 29 September 2020 (29.09.2020); especially col 10 ln 18-36, and Fig. 1 and 6.	1-5, 7 -- 6
A	US 9,208,263 B2 (OTISMED CORPORATION) 8 December 2015 (08.12.2015); entire document.	1-15
A	US 2009/0299483 A1 (AMIROUCHE et al.) 3 December 2009 (03.12.2009); entire document.	1-15

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"D" document cited by the applicant in the international application	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"E" earlier application or patent but published on or after the international filing date	"&" document member of the same patent family
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
 16 October 2023

Date of mailing of the international search report

NOV 08 2023

Name and mailing address of the ISA/US
 Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
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 Facsimile No. 571-273-8300

Authorized officer
 Kari Rodriguez
 Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 23/24684

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

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

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-7 directed to an apparatus for evaluating soft tissue of a human joint which includes two or more bones and ligaments, having a tensioner-balancer insertable between the bones of the joint, the tensioner-balancer including a means of controlling a distraction force.

Group II: Claims 8-15 directed to a method of evaluating a human knee joint, having a step of using the software application to define a virtual software secondary datum comprising a coordinate framework.

-*- See Supplemental Box -*-

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

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

-*- Box III.0 - Explanations where unity of invention is lacking -*-

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a tensioner-balancer insertable between the bones of the joint, the tensioner-balancer including a means of controlling a distraction force, not required by the claims of Group

The invention of Group II includes the special technical feature of using the software application to define a virtual software secondary datum comprising a coordinate framework, not required by the claims of Group

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of evaluating soft tissue of a human joint which includes two or more bones and ligaments, wherein the ligaments are under anatomical tension to connect the bones together, creating a load-bearing articulating joint, sensors;

an electronic receiving device configured for data-communication with the sensors; and

a software application programmed to processing the collected data to produce a digital geometric model of the joint.

However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 11,298,246 B1 (LITTLE ENGINE, LLC) (hereinafter Little), which discloses evaluating soft tissue of a human joint (col 2 ln 31-46) which includes two or more bones and ligaments (knee joint; Fig. 1-4; col 1 ln 24-32),

wherein the ligaments are under anatomical tension to connect the bones together, creating a load-bearing articulating joint (load-bearing articulating knee joint; Fig. 1-4; col 2 ln 31-46),

sensors (instances of 22; Fig. 6-10; col 5 ln 66 to col 6 ln 13);

an electronic receiving device configured for data communication with the sensors (electronic receiving device not shown; Fig. 6-10; col 6 ln 14-33); and

a software application programmed to processing the collected data to produce a digital geometric model of the joint (software upon 1162, 1164; Fig. 43; col 10 ln 16-33).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.