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(54) **SHOULDER ARTHROPLASTY
INSTRUMENTATION**

Publication Classification

(76) Inventors: **Darrick Lo**, Green Brook, NJ (US);
Joseph Lipman, New York, NY
(US); **Andrew D. Pearle**, Rye, NY
(US)

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(60) Provisional application No. 61/319,484, filed on Mar.
31, 2010, provisional application No. 61/325,435,
filed on Apr. 19, 2010.

(57) **ABSTRACT**

Patient specific shoulder component implant instruments are
described for hemi and total, normal and reverse shoulder
arthroplasty.

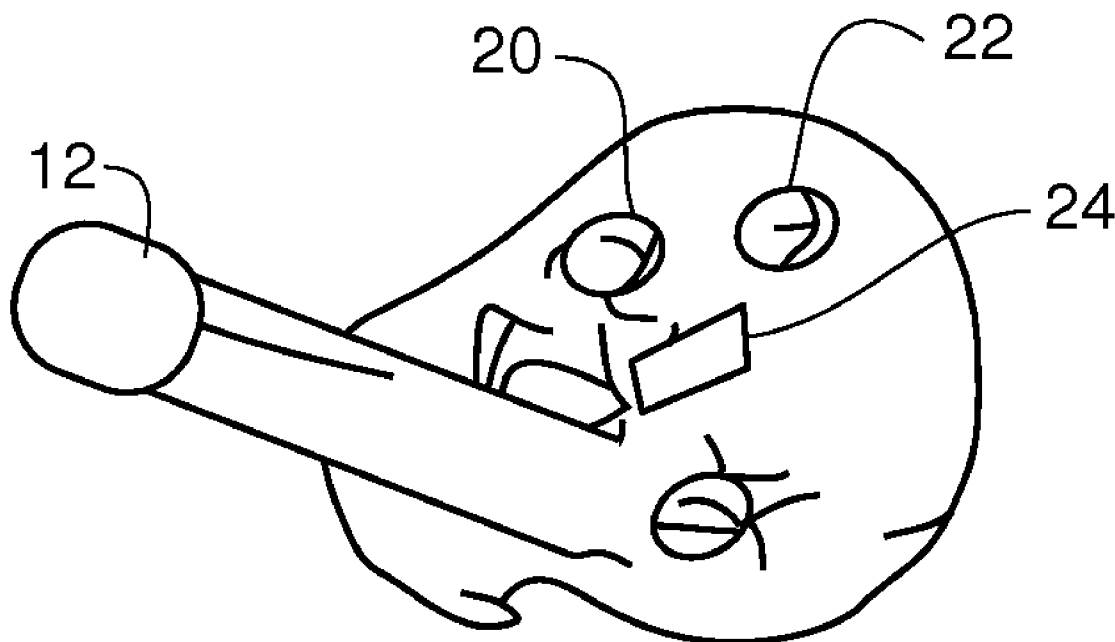


Fig. 1

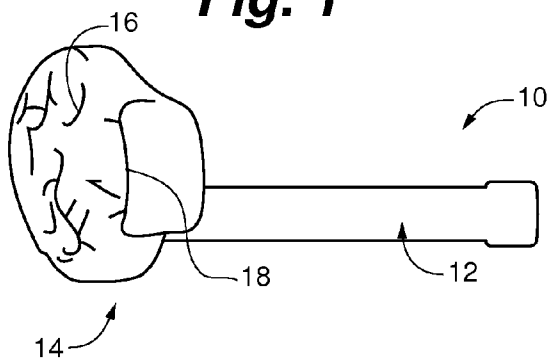


Fig. 2

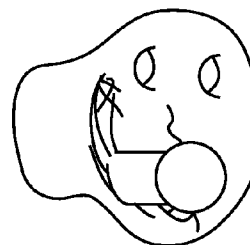


Fig. 3

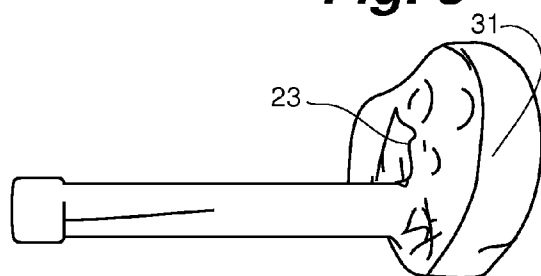


Fig. 4

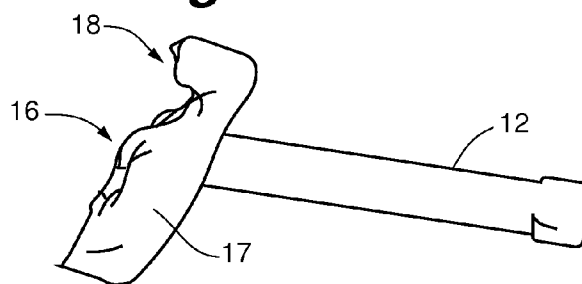
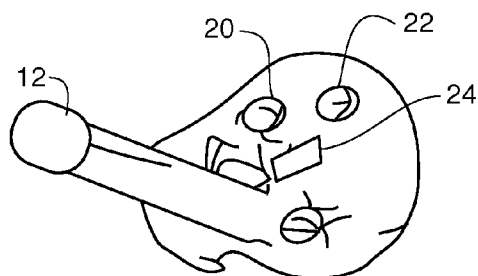
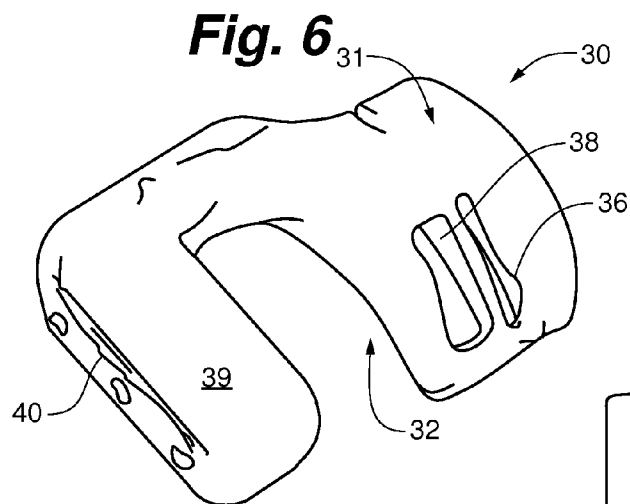
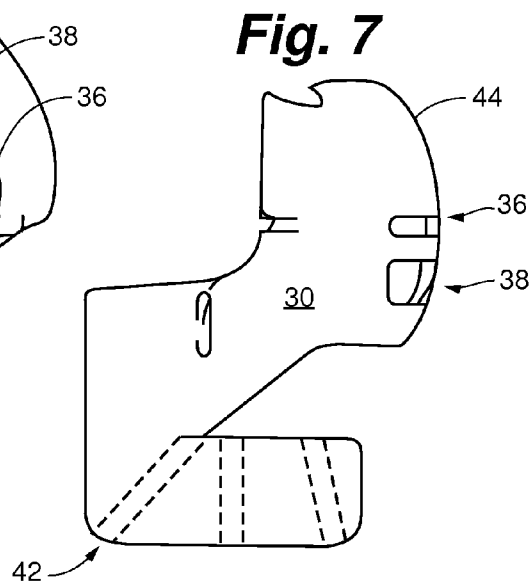
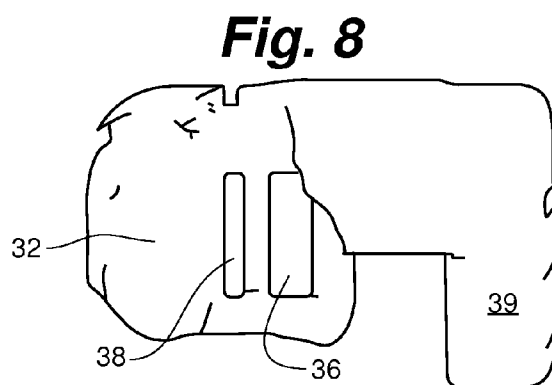
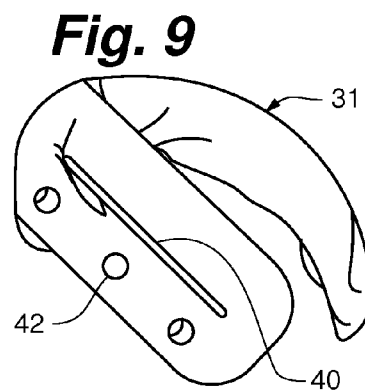
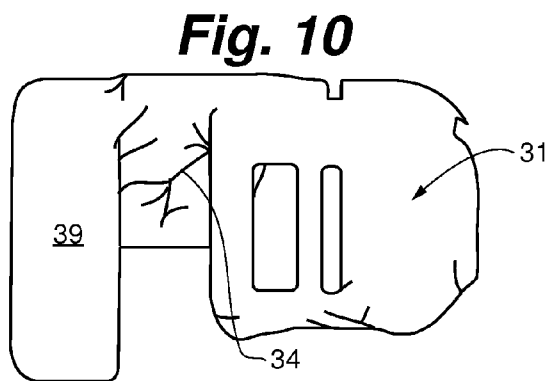


Fig. 5





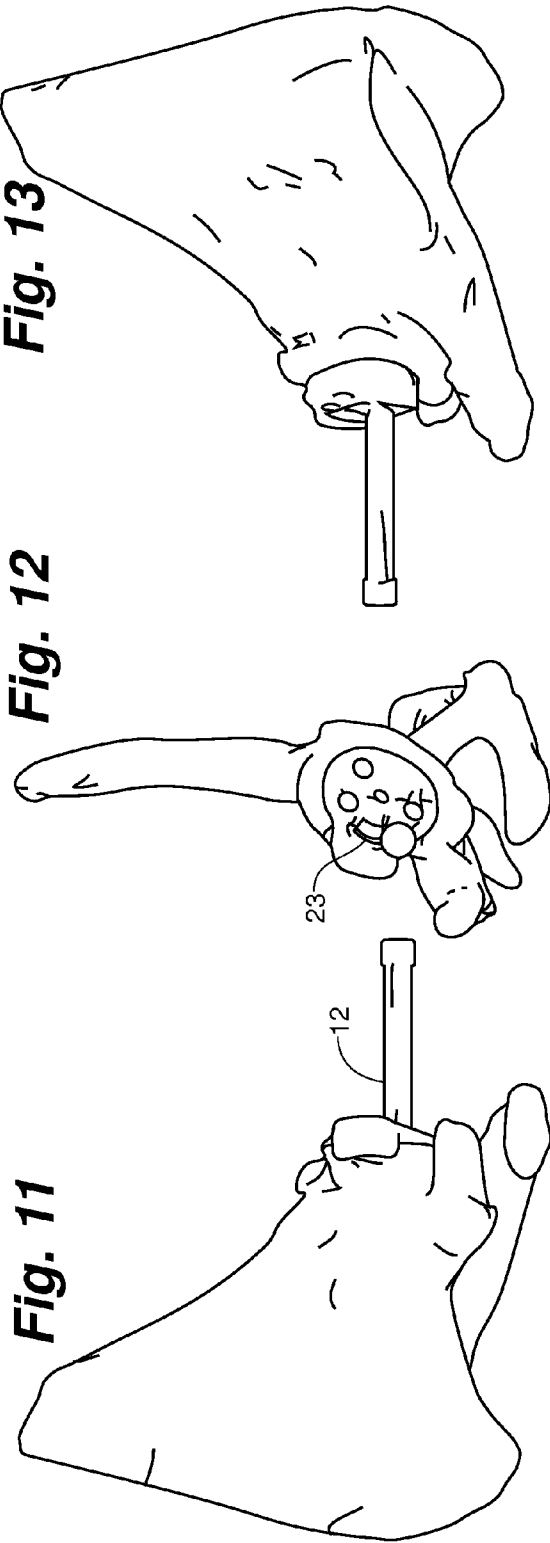
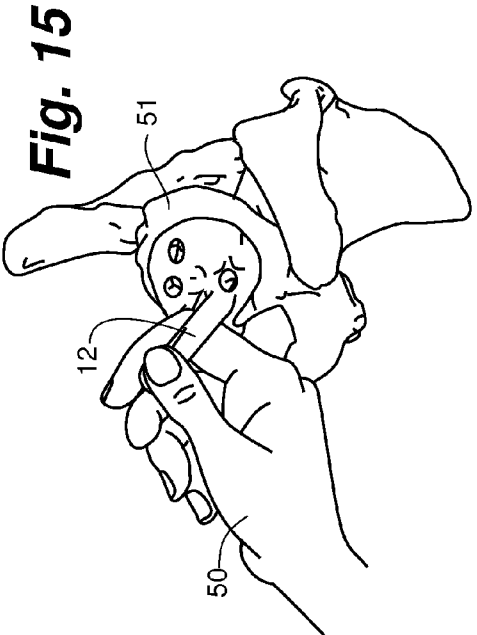
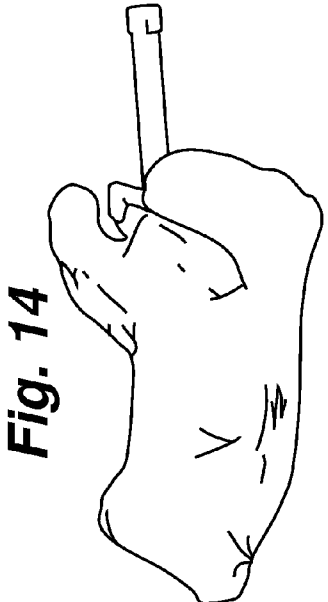


Fig. 16

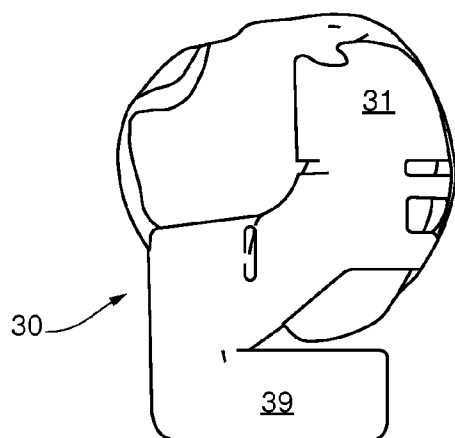


Fig. 17

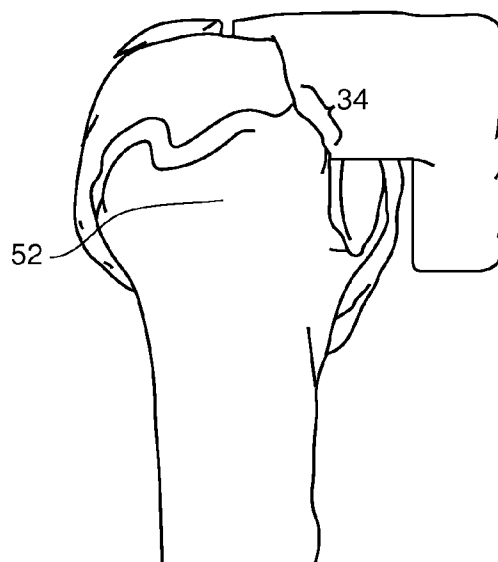


Fig. 18

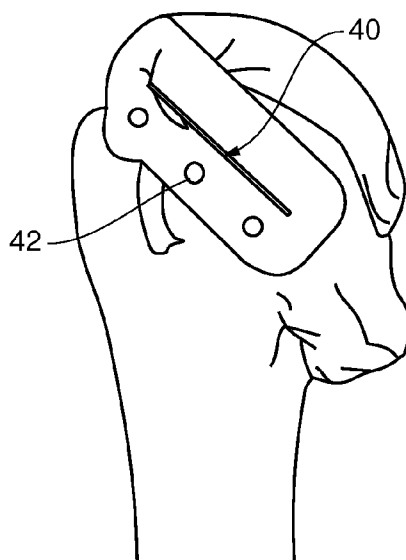


Fig. 19

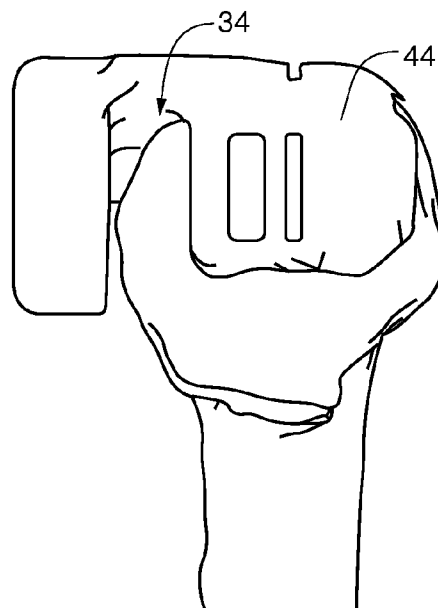


Fig. 20

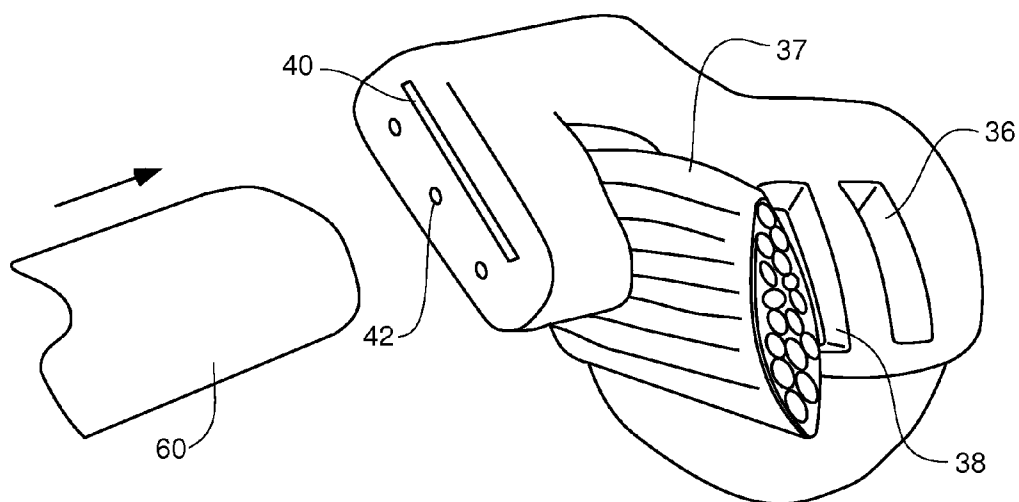


Fig. 21

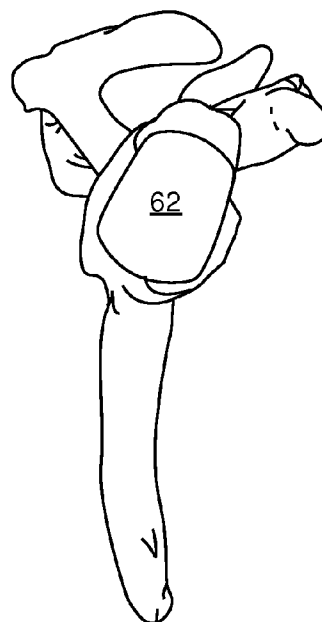


Fig. 22

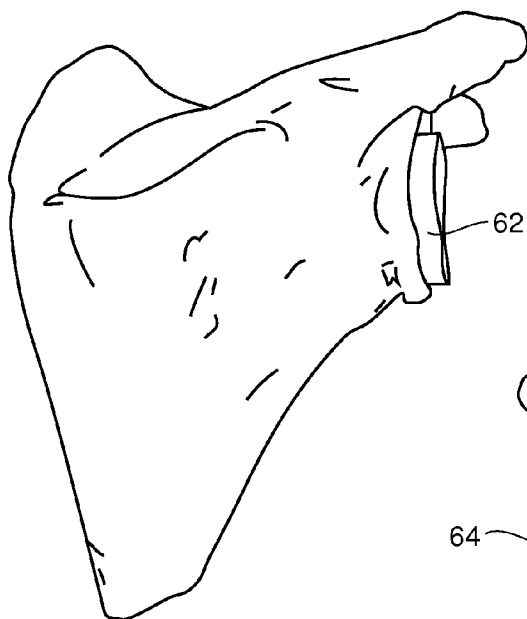


Fig. 23

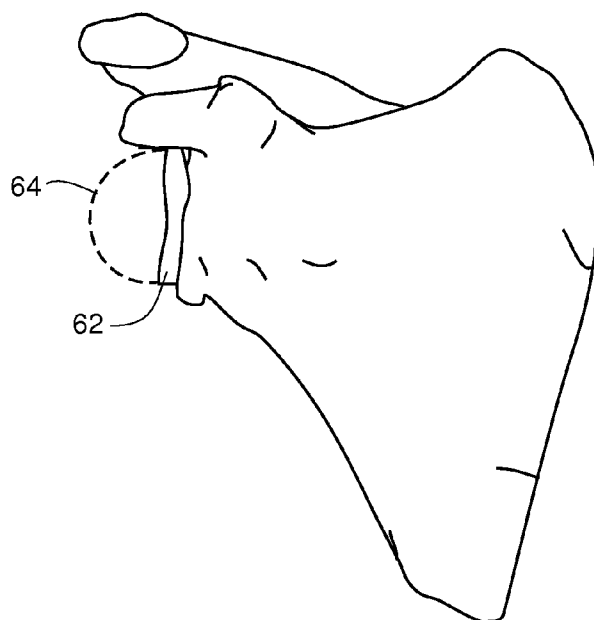


Fig. 24

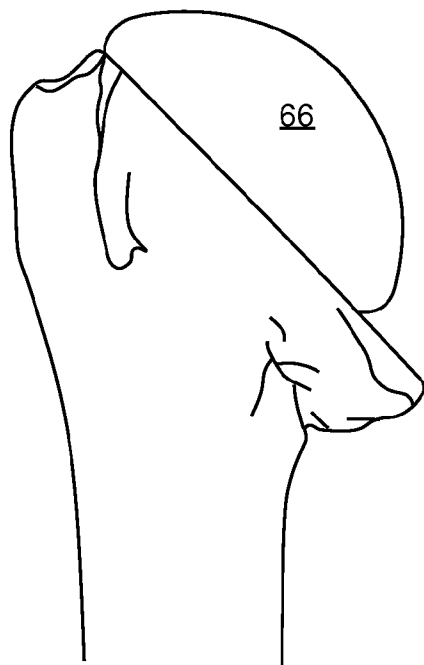


Fig. 25

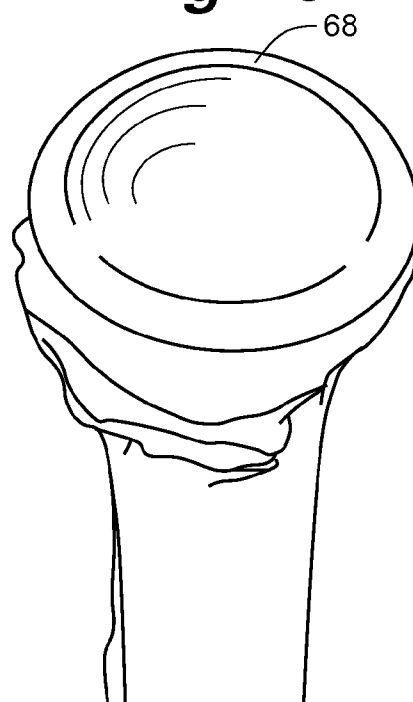


Fig. 26

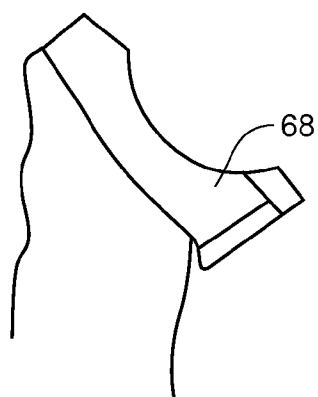


Fig. 27

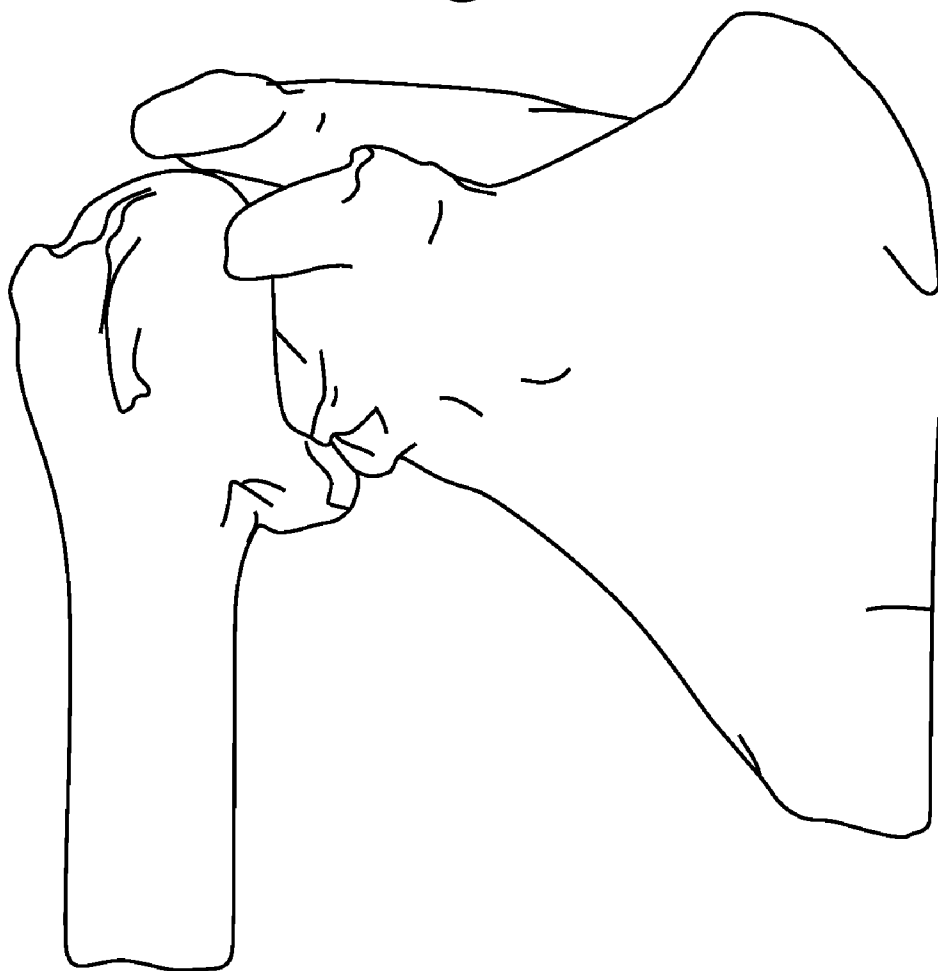


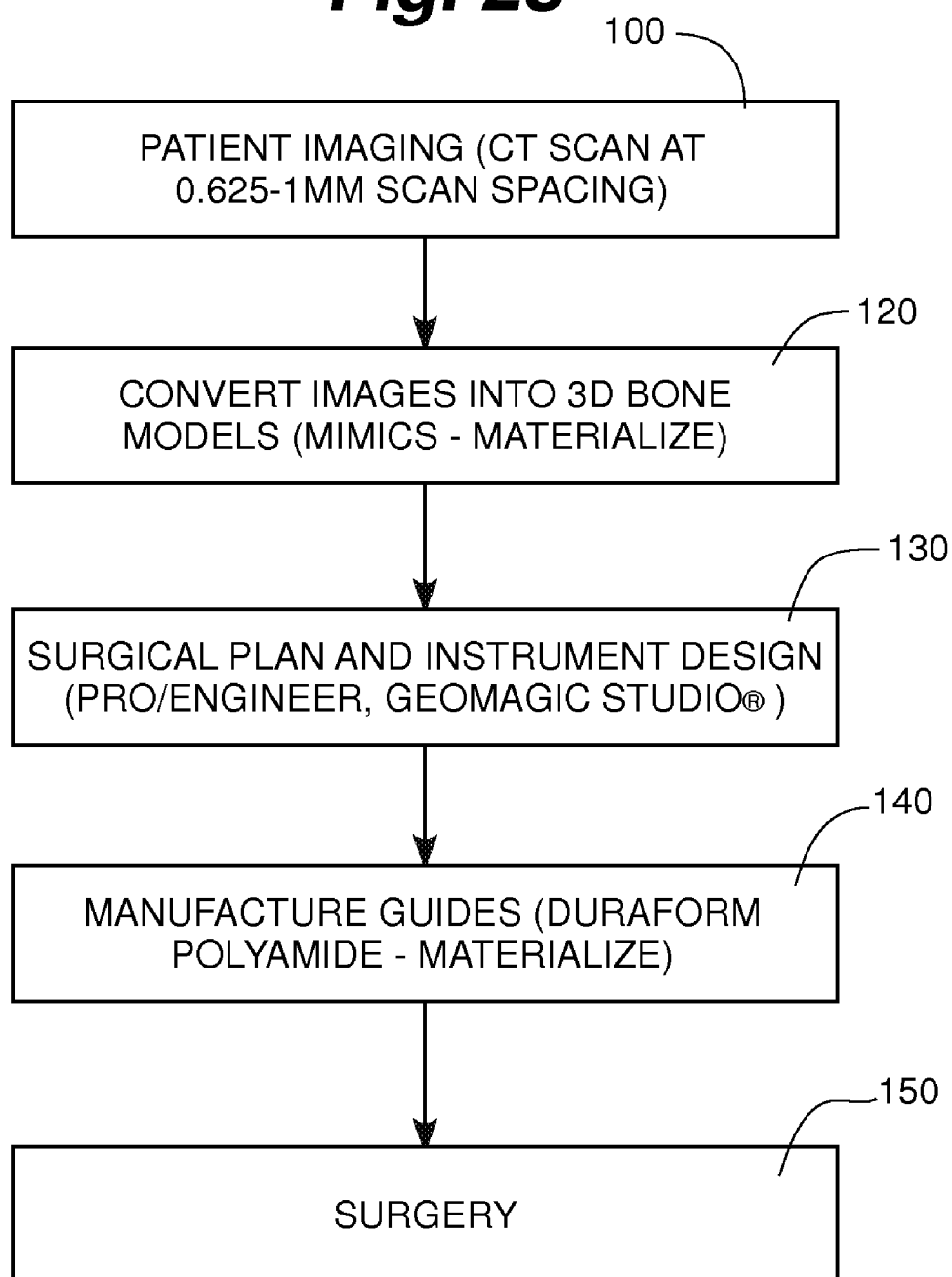
Fig. 28

Fig. 29

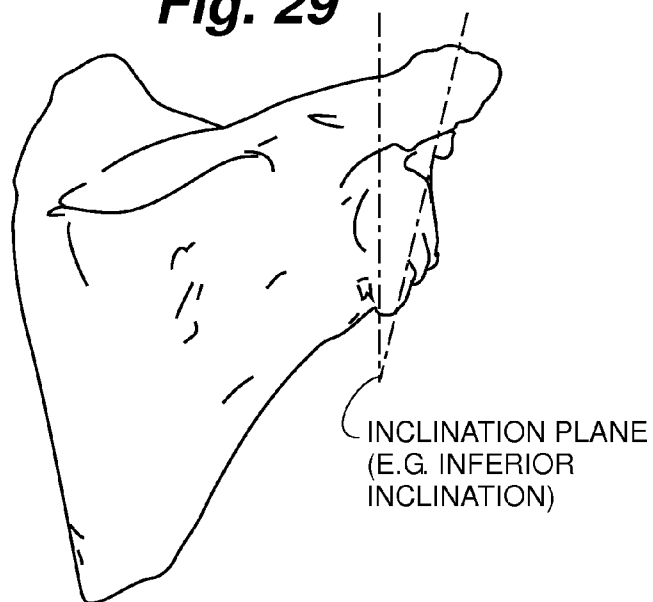


Fig. 31

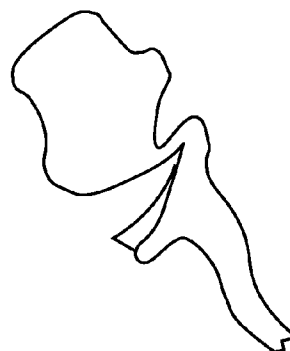


Fig. 30

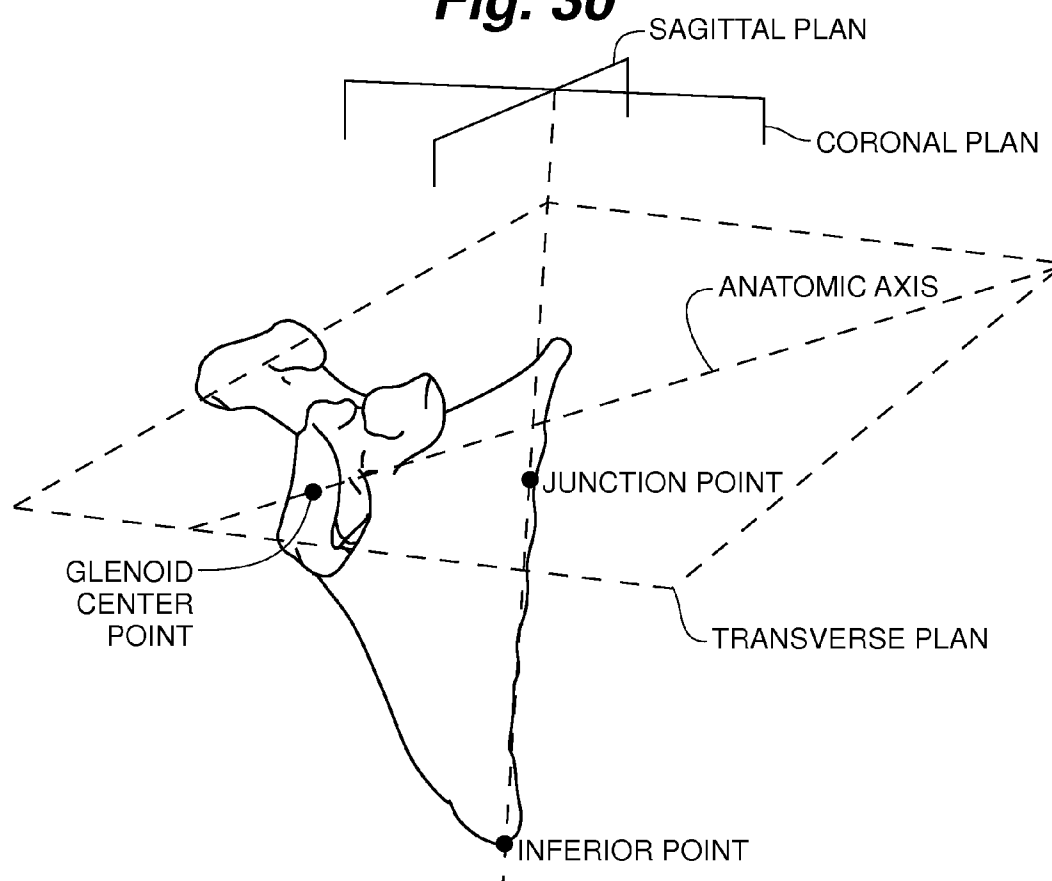
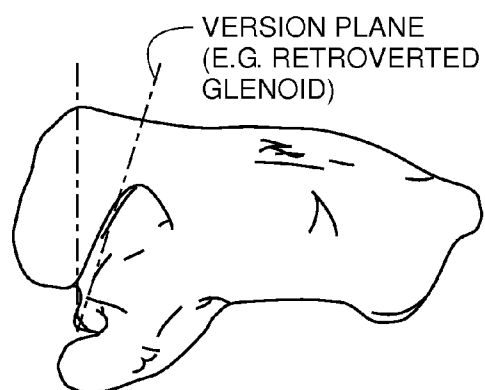
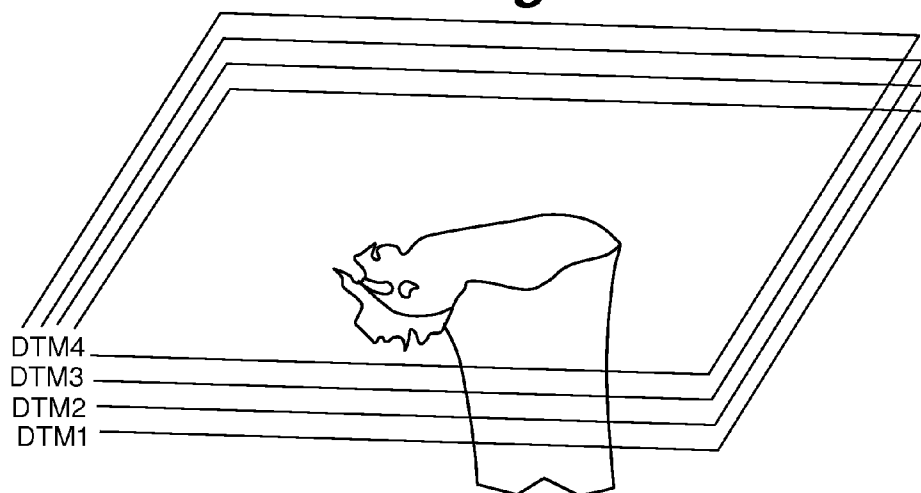
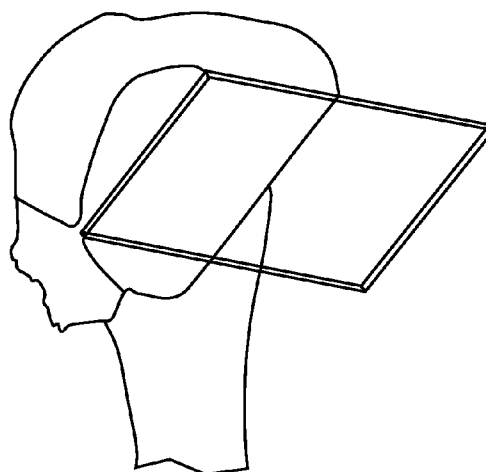


Fig. 32**Fig. 33****Fig. 34**

SHOULDER ARTHROPLASTY INSTRUMENTATION

CROSS-REFERENCE TO RELATED CASES

[0001] The present case claims the benefit of and incorporates by reference both U.S. Provisional Patent Application 61/319,484, filed Mar. 31, 2010 entitled "Patient Specific Instruments" and U.S. Provisional Patent Application 61/325,435, filed Apr. 19, 2010 entitled "Total Shoulder Arthroplasty Instrumentation".

FIELD OF THE INVENTION

[0002] The present invention relates to patient specific instrumentation to facilitate implantation of a total shoulder joint and to the process and technique for creating the instruments.

BACKGROUND OF THE INVENTION

[0003] Shoulder hemiarthroplasty is commonly used to treat patients with glenohumeral joint arthrosis. Total shoulder arthroplasty may be indicated for patients without a good articular surface on the glenoid at the time of surgery. For patients with glenohumeral joint arthrosis and an additional deficient rotator cuff, reverse total shoulder arthroplasty may be indicated. The 12%, 15%, and 22% revision rates, respectively, remains high compared to hip and knee arthroplasty. Glenoid component loosening and instability are important complications and may be caused by poor positioning of the component. An accurate placement of the complementary humeral cut is also important to achieve a stable joint.

[0004] There is a continuing need to improve the instruments used to facilitate the implantation of total shoulder joint components.

SUMMARY OF THE INVENTION

[0005] Patient specific instruments according to the invention carry surfaces and features that facilitate implantation of shoulder implant components. These surfaces are patient specific and they conform to the actual diseased joint surfaces presented by the patient. In use the physician uses the instruments to align and direct surgical cuts, to prepare the patient to receive an otherwise standard and conventional joint components of either "normal" or "reverse" configurations.

[0006] The process of the invention that results in the creation of a set of patient specific instruments takes a computed tomographic (CT) or magnetic resonance imaging (MRI) file of the patient's shoulder and presents it to a user on a computer screen. The user using a mouse or other pointing device defines reference points on the image to define geometric axes, planes and offsets. Next the user imports and aligns a computer automated design (CAD) file of the implant component with the native anatomy. The image of the implant component is merged and displayed with the anatomy image. Using a rule based system the user finds an optimum location for the glenoid component of the implant. Once the optimum location for the glenoid component is defined a custom instrument CAD file is created and a glenoid placement instrument or tool is generated from the file using conventional techniques. The tool is formed from plastic and/or metal that can be sterilized and used directly in the surgery.

[0007] In general the glenoid instrument consists of an oval or egg shaped "disk" with a protruding stalk like "handle". The disk has an upper surface and a lower surface, and a side wall separating the two.

[0008] In general the humeral instrument consists of a "cap" like structure connected to an offset "block" feature. There is a clearance volume between the "cap" and "block". The cap has an inner surface and an outer surface.

[0009] With the glenoid instrument defined and created a companion humeral cutting instrument is generated to guide the resection of bone in preparation for the implantation of the humeral component of the total shoulder implant system. The humeral instrument is likewise defined and manufactured from sterilizable plastic and/or metal in a process similar to the glenoid component. The instruments are used together and they share several characteristics.

[0010] The glenoid instrument has a complementary surface to a surface of the diseased joint formed in the lower surface.

[0011] The glenoid instrument has one or more index surfaces adjacent to its articular lower surface that facilitate placement of the tool during surgery.

[0012] The glenoid instrument has windows to permit visual confirmation of placement.

[0013] The glenoid instrument has a handle to assist in proper positioning of the instrument.

[0014] The glenoid instrument has holes that aid in defining the direction of screws should screw placement be pre-operatively determined.

[0015] The humeral resection guide instrument or humeral instrument has a complementary surface matching the humeral head contour on its inner surface.

[0016] The humeral resection guide instrument has one or more index surfaces adjacent to its articular inner surface of the cap portion that facilitates the placement of the tool during surgery.

[0017] The humeral resection guide instrument has an block offset from the cap that includes a saw slot that directs the use of a surgical saw to remove the humeral head.

[0018] The humeral resection guide instrument has holes that accept pins or other fasteners which connect the block portion of the humeral instrument to the proximal humerus bone.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] In the figures of the drawings like reference numerals indicate identical structure, wherein:

[0020] FIG. 1 is a view of the glenoid component instrument;

[0021] FIG. 2 is a view of the glenoid component instrument;

[0022] FIG. 3 is a view of the glenoid component instrument;

[0023] FIG. 4 is a view of the glenoid component instrument;

[0024] FIG. 5 is a view of the glenoid component instrument;

[0025] FIG. 6 shows the humeral component cutting block instrument;

[0026] FIG. 7 shows the humeral component cutting block instrument;

[0027] FIG. 8 shows the humeral component cutting block instrument;

[0028] FIG. 9 shows the humeral component cutting block instrument;

[0029] FIG. 10 shows the humeral component cutting block instrument;

[0030] FIG. 11 shows the glenoid instrument in use placed against the glenoid;

[0031] FIG. 12 shows the glenoid instrument in use placed against the glenoid;

[0032] FIG. 13 shows the glenoid instrument in use placed against the glenoid;

[0033] FIG. 14 shows the glenoid instrument in use placed against the glenoid;

[0034] FIG. 15 shows the glenoid instrument in use placed against the glenoid;

[0035] FIG. 16 shows the humeral cutting guide block in use against the humeral head;

[0036] FIG. 17 shows the humeral cutting guide block in use against the humeral head;

[0037] FIG. 18 shows the humeral cutting guide block in use against the humeral head;

[0038] FIG. 19 shows the humeral cutting guide block in use against the humeral head;

[0039] FIG. 20 shows the humeral cutting guide block in use against the humeral head;

[0040] FIG. 21 shows glenoid components in place;

[0041] FIG. 22 shows glenoid components in place;

[0042] FIG. 23 shows glenoid components in place;

[0043] FIG. 24 shows humeral components in place;

[0044] FIG. 25 shows humeral components in place;

[0045] FIG. 26 shows humeral components in place;

[0046] FIG. 27 shows a human shoulder joint;

[0047] FIG. 28 is a flowchart of the process for making the instruments;

[0048] FIG. 29 shows anatomic geometry;

[0049] FIG. 30 shows part of a step in the process;

[0050] FIG. 31 shows part of a step in the process;

[0051] FIG. 32 shows anatomic geometry;

[0052] FIG. 33 shows part of a step in the process; and,

[0053] FIG. 34 shows part of a step in the process.

DETAILED DESCRIPTION

Glenoid Component Instrument

[0054] FIG. 1 through FIG. 5 should be considered together as they show the same glenoid component instrument 10 from several different perspectives. The glenoid component instrument 10 has a handle 12 attached to a generally oval or egg shaped disk shaped instrument body 14. The disk shaped body 14 has a patient specific conformal lower surface 16 that matches the surface of the articular portion of the glenoid joint. Adjacent the patient specific bottom surface 16 is a hook like feature that matches an off articular bony portion of the glenoid. This hook 18 is also patient specific and one or more such hooks may be formed depending on the patient anatomy. These features are placed on the sidewall 17 of the disk shaped instrument body. Also present are holes passing through the disk element of the instrument body from the lower surface to the upper surface. Holes useful for directing screws or the like are seen at reference numeral 20 and 22. A hole or slot for cutting a keel slot or peg hole is seen at reference numeral 24. Additional holes acting as windows to allow visualization of the native surface are shown at refer-

ence numeral 23. Holes for bone pins can also be used to hold the glenoid instrument in place.

Humeral Component Cutting Block Instrument

[0055] FIG. 6 through FIG. 10 should be considered together as they show the same humeral component instrument from several different perspectives. The humeral component instrument 30 has a generally cap shaped element 31 with a patient specific conformal inner surface 32 that can wrap around the humeral head. There is also at least one guide surface 34 feature that is patient specific and off the articulating surface of the joint. Apertures labeled 36 and 38 in the form of windows are cut through the cap from the inner surface to the outer surface to permit visualization of the joint surface. Adjacent to cap 31 is a block feature 39 having a saw guiding slot 40 that overlies several pin holes typified by hole 42. These holes may be used to place Steinman pins or other fixation devices. There will usually be three holes at differing inclinations to rigidly attach the cutting block 30 to the bone. The block element 39 is offset from the cap 31 element by a clearance space. The fixation devices traverse this clearance space when they are pushed in to position.

Use of the Glenoid Instrument

[0056] FIG. 11 through FIG. 15 should be considered together as they show the same glenoid instrument in contact with the glenoid portion of the glenohumeral joint. Typically the physician holds the handle with his hand 50 and presses the instrument body against the joint surface 51. Tactile and visual clues that result from the patient conformal surfaces allow and facilitate registration of the instrument body with the native anatomy.

Use of the Humeral Head Cutting Block Guide

[0057] FIG. 16 through FIG. 20 should be considered together as they show the same cutting block in contact with the humeral head. In use the cap feature overlays the humeral head 52 and the conformal inner surface and index surface 34 align the instrument with the bone. Once the instrument is fastened to the bone via fixation holes 42, the saw may enter slot 40 and resect the bone. As seen best in FIG. 20 the clearance space allows the humeral instrument to accommodate muscle 37 and other tissue with minimal injury.

Glenoid Component in Position

[0058] FIG. 21 through FIG. 23 should be considered together as they show the glenoid implant component 62 in place on the glenoid. Both a "normal" glenoid component 62 is shown as well as a "reverse" glenoid component 64 in dotted outline.

Humeral Component in Position

[0059] FIG. 24 through FIG. 26 should be considered together as they show the "normal" humeral implant component 66 in place on the humerus. FIG. 26 and FIG. 25 depict a "reverse" humeral component 68 in place on the bone.

Overview of Instrument Creation and Use

[0060] FIG. 27 shows a human shoulder joint.

[0061] FIG. 28 shows a flowchart of the process beginning with the collection of patient data in process step 100. This data is used by process 120 to convert and display the native

anatomy to a user. In process step **130** the image data is used with implant specific data to design the two instruments. In process step **140** instrumentation data is used to manufacture physical instruments. In process step **150** the surgeon uses the physical instruments to carry out the surgery.

Glenoid Component Instrument Creation Process

[0062] A software program Mimics® is used to take MRI or CT data and to create a 3-dimensional image of the glenoid and scapular spine that can be manipulated on the computer screen. The user defines three points, including a glenoid center point in the center of the glenoid articular surface, a junction point along the ridge of the scapular spine where the medial border and scapular spine meet, and an inferior point at the most distal end of the scapular spine. These three reference points depicted in FIG. **30** are used to define a coronal plane, which may be displayed on the image. A transverse plane orthogonal to the coronal plane is created through the glenoid center point and scapular spine junction point. Next a sagittal plane is created orthogonal to said two planes and centered on the center point of the glenoid as seen in FIG. **30**. A reference anatomic axis may then be defined as the intersection of the transverse and sagittal planes. These steps may also be performed in a conventional software package such as “Pro/E” from PTC software company in Needham MA which is widely used to define parts in the CAD industry.

[0063] In order to reproduce the normal anatomic orientation of the glenoid after TSA, the ideal orientation of the glenoid component should have 4 degrees of superior inclination and 1 degree of retroversion. Therefore, the central peg or keel should achieve this orientation given adequate bone stock. In reverse total shoulder arthroplasty, the glenoid component should have 5 degrees of inferior inclination, close to neutral version, and slight inferior translation to minimize notching. This is seen in FIG. **29** and FIG. **32**. Therefore, the inclination and version of the glenoid component will be referenced from the sagittal plane as defined. For example, the inclination plane can pass through an axis created by the intersection of the sagittal and transverse planes at 4 degrees of superior inclination. A second axis can then pass through the coronal and inclination plane. The version plane can pass through said second axis at 1 degree of retroversion. At this point, the version plane will represent the proper orientation of the glenoid component; the glenoid component plane.

[0064] The alignment of the implant with the native bones is depicted in FIG. **31**. At this point the operator and likely physician will review the position and size of the implant customized for this patient. With the implant location and size determined, Pro/E is used to create a template instrument that will be used to help align the glenoid component during the surgery. A portion of the glenoid component instrument is designed to conform to the native bone. The first surface of said portion of the glenoid component instrument has a surface that is 3D inverse of the native surface of the glenoid created via a Boolean subtraction operation where the native surface of the glenoid is subtracted from the template instrument. An approximately 1 mm gap between the bony surface of the glenoid and the inverse surface of the glenoid component instrument is added when using CT data to accommodate cartilage and/or slight errors in the reconstruction. This surface is created in Geomagic®. A second surface of said portion of the glenoid component instrument captures a bony surface close to but outside of the glenoid articular surface. Said second surface is an extending feature that is similarly

created using a Boolean subtraction operation, and is used to help in the proper positioning of the instrument with respect to the bone. Said second surface wraps around the anterior aspect of the glenoid surface because it is easy to reference with a traditional delto-pectoral surgical approach, and can be used to lever the instrument over the glenoid. At least one and perhaps as many as three such features around the perimeter of the glenoid will be defined for the instrument depending largely upon the condition of the bone structure, its geometry, and surgical exposure.

[0065] The glenoid component instrument has a set of apertures that can function as windows to observe tissue and or as guide to direct cutting tools into the glenoid. For example, the instrument may carry a center hole for a drill bit to pass for a central peg designed glenoid component, or a slot to facilitate cutting a keel slot designed for a glenoid component. The orientation of the center aperture will be normal to glenoid component plane and be centered based on pre-operative plan. Peripheral holes in the instrument can be added to match any peripheral pegs/keels/screws or the like that the glenoid component may require. The peripheral holes will control the orientation of the glenoid component in rotation about the central axis for the glenoid component. The location of the holes or windows or slots will determine the rotation of the glenoid component. Next, the location of viewing slot(s) is defined for the instrument. These slots will be positioned so that they can be observed by the physician during the surgery and will communicate with the bony surface so that the presence or absence of a bony surface in the window helps verify the seating of the instrument. The remainder of the glenoid component instrument includes an extending handle that is directed away (usually anteriorly) from the axis of the peg/keel, as depicted in FIG. **15**, in order to allow the drill to access the instrument.

[0066] For reverse total shoulder arthroplasty, a second glenoid component instrument can be used to target peripheral fixation screws for the glenoid component. After pre-operatively determining the depth of the reaming operation used to seat the glenoid component, the surgeon or engineer can pre-operatively determine the number, length, and alignment of said peripheral fixation screws. Said second glenoid component instrument will have a mating surface that is the 3D inverse of the reamed surface. The second instrument has a center hole in line with the central peg hole. In addition, peripheral holes in the second instrument will be in line with the pre-operatively planned screw locations. Drill taps will pass through said peripheral holes. The second instrument can also have as few as one mark on the visible (lateral) surface (e.g. a mark pointing superiorly) to aid in the rotational alignment of second instrument. During surgery, the surgeon can use electrocautery to mark the surface of the glenoid (e.g. a mark pointing superiorly). The second instrument's mark can now be aligned to the glenoid's surface mark. Viewing slots on the instrument will allow the surgeon to verify the seating of the instrument on the reamed bone. A handle extends laterally from second instrument but will not interfere with drill.

[0067] Bone modulus can be characterized from the Hounsfield unit obtained from CT scans. Bone with higher modulus is stronger, and would be ideal locations for peg/screw fixation. The surgeon or engineer can use this information to pre-operatively design the first and/or second instruments to direct the peg/screw into bone of higher modulus.

[0068] The process has created an instrument that can be used to define the location of a glenoid implant based upon an analysis of the native bone structure in conjunction with a representation of the glenoid implant.

Humeral Head Cutting Block Creation Process

[0069] Similar to the glenoid component instrument, the humeral head cutting block utilizes MRI or CT data to determine the appropriate orientation and size of the orthopaedic component. For shoulder hemiarthroplasty and total shoulder arthroplasty, the position of the humeral component will be 20 degrees in retroversion. For reverse total shoulder arthroplasty, it will be closer to neutral. In order to properly correct the version of the humeral head, it is recommended that a MRI or CT scan of the elbow (same side) be taken as well. The diaphysis of the humerus will be approximated to be a cylinder with its long axis to be defined as the long axis of the humerus. Landmark points will be placed on the medial and lateral epicondyles of the distal humerus. A humeral coronal plane passes through said landmark points and is parallel to said long axis. The version of the humeral head will be offset from the coronal plane. If the elbow is not scanned, the calcar of the humerus can be used as a reference when determining version angle as depicted in FIG. 33. A calcar landmark point is identified. In this case, the version plane of the humeral component is defined as the plane that passes through said calcar point and the long axis of the humerus. Pre-operative sizing of the humeral head and humeral component can be performed. Humeral head resection and implant sizing performed pre-operatively on a left humerus.

[0070] The level of resection is built into the humeral head cutting block. Using MRI or CT data, this block engages with the humeral head by having a backside face that is a 3D inverse of the native humeral head created via a Boolean subtraction operation where the native surface of the humeral head is subtracted from a template block instrument. An approximately 1 mm gap between the bony surface of the humeral head and the inverse surface of the humeral head cutting block is added when using CT data to accommodate cartilage and/or slight errors in the reconstruction. Said block engages the superior-medial aspect of the head and has an additional feature that wraps around the lateral side of the lesser tubercle (subscapularis attachment sight) to additionally aid in the alignment of the block. The instrument has openings to allow the subscapularis and rotator cuff to pass without impingement as depicted in FIG. 20. The slot for the saw blade 40 is located approximately anterior to the humerus, and its cutting angle (approximately 45 degrees) is dependent on the implant system being used. Said slot has enough width to ensure that the blade remains parallel to the slot.

[0071] Other features include a minimum of two non-parallel pin holes for additional stability of the block to the proximal humerus. Said pin holes are located distal to the saw blade slot, and can accept pins screws or other fasteners. Viewing slots/portals on the block are used to visually ensure that the instrument is fully seated onto the humeral head. A targeting sight in line with the long axis of the humerus on the superior surface of the humeral head cutting block is used to target the humeral stem reamer.

[0072] The instruments will be steam sterilizable and bio-compatible (e.g. DuraForm polyamide). Both the glenoid component instrument and the humeral head cutting block have been prototyped and manufactured. For the proper

execution of these instruments during surgery, it is necessary to minimize the profile and volume of these instruments as much as possible, as the surgical exposure for these types of procedures are small. Modifications to these instruments continue to be made to make the operative procedure more efficient and accurate.

What is claimed is:

- 1) A patient specific surgical instrument comprising:
 - an instrument body having a surface conformal to native joint anatomy;
 - an index feature formed in the periphery of said instrument body for hooking over said native joint, to position and locate said body on said native joint anatomy;
 - at least one aperture to visualize the native joint surface;
 - at least one cutting guide to locate and direct cutting tools for fixing a joint component to native bone.
- 2) The device of claim 1 further including a handle coupled to said instrument body to facilitate placement during surgery.
- 3) A patient specific instrument for facilitating the implant of a glenoid component comprising:
 - an instrument body having a disk like shape with an upper surface and a lower surface and a side wall;
 - said lower surface matching the glenoid joint articular surface of said patient;
 - said instrument body having one or more holes passing from said upper surface to said lower surface;
 - a handle coupled to said instrument body to facilitate application of said lower surface to said articular surface.
- 4) The device of claim 3 further including a hook surface feature coupled to said annulus matching the glenoid joint non-articular joint surface.
- 5) A patient specific instrument for facilitating the implant of a humeral component comprising:
 - an instrument body having a cap like shape with an inner surface and an outer surface;
 - said inner surface matching the humeral joint articular surface of said patient;
 - a hook surface feature located proximate said inner surface matching the humeral joint non-articular joint surface;
 - said instrument body having one or more holes passing from said inner surface to said outer surface;
 - a cutting block formed integrally with said instrument body;
 - said cutting block having one or more pin guides for directing pins into the humeral head;
 - said cutting block having a saw slot located above said pin guides for directing a surgical saw.
- 6) A method of creating a glenoid instrument comprising:
 - acquiring imaging data of the patient's glenohumeral joint;
 - converting imaging data to bone models of the glenoid having patient specific surface information.
 - acquiring geometry data for a standard shoulder joint components;
 - merging and displaying the joint components contextually with said models to identify an appropriate component position;
 - forming an image of an instrument in contact with articular and non articular portions of the glenoid that corresponds to said appropriate component position;

exporting to a manufacturing process a file that forms said glenoid instrument.

7) A method of creating a humeral head cutting block instrument comprising:

acquiring imaging data of the patient's glenohumeral joint;
converting imaging data to bone models of the humeral head having patient specific surface information.

acquiring geometry data for a standard shoulder joint components;

merging and displaying the joint components contextually with said models to identify an appropriate component position;

forming an image of an instrument in contact with articular and non articular portions of the humeral head that corresponds to said appropriate component position;

exporting to a manufacturing process a file that forms said humeral cutting block instrument.

8) A method of creating a glenoid instrument comprising:
acquiring imaging data of the patient's glenohumeral joint;
converting imaging data to bone models of the glenoid having patient specific surface information.

acquiring geometry data for a standard shoulder joint components;

merging and displaying the joint components contextually with said models to identify an appropriate component position; including the step of acquiring Hounsfield units data of bone density to direct section of fixation components;

forming an image of an instrument in contact with articular and non articular portions of the glenoid that corresponds to said appropriate component position;

exporting to a manufacturing process a file that forms said glenoid instrument.

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