Comparison of Glenoid Component Position Using Intelligent Reusable Instrument vs. Standard Surgical Instruments

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Principle Investigator
Joseph P. Iannotti MD, PhD
Co Investigators
Eric Ricchetti MD
Scott Weiner DO
Study coordinator
Michelle Hines

Summary Work and Proposed Study:

Overall Summary

Glenoid component loosening is the most common complication of total shoulder arthroplasty. Loosening is associated with malposition of the implant as well as to the quality of the glenoid bone. In order to evaluate glenoid component loosening, the motion of the glenoid implant relative to the scapula post-operatively must be accurately measured. We will study the effect of a novel method of surgical planning and surgical technique on position of the implant and the quality of the bone on early implant movement. We propose a randomized clinical trial to compare two methods of surgical instrumentation. We will measure implant placement with RSA and 3D CT imaging. We will measure pre operative bone quality using quantitative CT Scan to measure trabecular bone volume and correlate these finding with bone samples removed from the humeral head and measured by microCT and mechanical testing of the bone samples. This bone tissue is normally removed and discarded as part of the standard of care for preparation of the bone for placement of the humeral component.

Glenoid Instrumentation and Pre operative planning

Currently, implantation of total shoulder arthroplasty components relies on a combination of pre-surgical planning using routine radiographs and CT scanning along with the use of generic surgical instruments provided by the implant manufacture and surgical experience. New developments at the Cleveland Clinic has allowed our surgeons to use pre operative planning software for simulation of the surgical plan to select the optimal implant from an inventory of FDA approved and commercial available implants and the optimal location of that implant within the bone. However, there remains a void in transferring the pre-surgical planning information from the computer simulation to the surgical site. Development at the Cleveland Clinic of an intelligent reusable instrument system (IRIS) in conjuncture with smart bone surrogate models (SmartBones) have demonstrated the ability to transfer the information from the software to the surgical site. The proof of this concept has been demonstrated in pre clinical plastic sawbone models and cadavers that simulate the surgical environment. An FDA application for approval of this technology for commercial use was submitted in early October of this year.

We are proposing the first in man use of this technology for placement of the glenoid component in anatomic total shoulder arthroplasty. We will use post operative 3D CT Scanning to precisely

define the location of the implant as compared to plan. We propose to compare the accuracy of implant placement using the IRIS and SmartBone technology when compared to the use of the same pre operative planning software for selection of the desired implant and its optimal location with standard of care surgical instrumentation. This will be a randomized clinical trial and in all cases the surgeon will have full control to define the optimal implant and its location as well as have full control of the placement of the guide wire, bone preparation and location and placement of the final implant. In this regard the new technology assists the surgeon in pre operative planning and surgical execution it does not substitute for the surgeon performing the planning or surgery in a manner that it believed to be best for the patient.

Using the intelligent reusable instrument (IRIS) and SmartBone system in a pre-clinical sawbones trial, we demonstrated a statistically and clinically significant improvement in the accuracy of glenoid pin placement. Three surgeons were asked to place a guide pin in nine different pathologic models utilizing three separate surgical techniques. The sawbone models were covered to show only that part of the scapula that is seen at the time of surgery. Standard of care (n=59 cases), standard of care with pre-surgical CT (n=59 cases) information and the use of IRIS and SmartBone system (n=89 cases) were performed to assess deviation from the pre-surgical plan.

Measurement of Implant Position

Post operatively we will obtain a CT scan with metal artifact reduction technology within the first few weeks after surgery and will generally obtain this scan prior to discharge from the hospital. A second CT scan will be obtained at two years after surgery. We have used these methods of 3D CT imaging to determine implant position in several prior studies. We have defined the accuracy of these measurements using first generation techniques to be within 1 millimeter and 3 degrees.

RSA imaging will be obtained at these same points in time. RSA imaging uses biplanar fluoroscopic imaging within a calibration grid and image software to define implant position. This technology has been a standard for precise implant position for the last 20 years and has been used in thousands of patients. RSA imaging uses metallic markers placed in the implant and in the surrounding bones. The beads implanted in the bone and implant, do not move, and are then used as markers to define the location of the implant to the bone and the bones to one another. The accuracy of RSA measurement has been reported to be +/- 0.006mm in translation and 0.5 degrees in rotation. For RSA measurements a minimum of three 1mm radiopaque tantalum beads into an implant and at least three beads into the surrounding bone when using the RSA system.

Placement of three beads into the implant will also improve the ability of the post operative 3D CT imaging to define the location of the implant and will be an improvement over our first generation technology. A metal wire is placed in the center peg of the implant by the identification of the implant.

The risk of the bead becoming loose has been shown to be very small and there is no adverse effects related to bead movement or loosening. Both study groups will receive glenoid components with three 1mm tantalum beads inserted into the back pegs.

RSA and 3D CT measurements will be correlated and compared. Our goal is to define the accuracy of second generation 3D CT scanning when compared to a gold standard of RSA measurements.

Bone Quality Measurements

To assess bone quality and its effect on glenoid component loosening, we will take trabecular bone samples from both the experimental and standard of care groups. Humeral heads, which are normally discarded as standard of care medical waste will be kept and evaluated with mechanical testing. These bone samples will be assessed by microCT to measure trabecular bone volume and connectivity as well as by mechanical testing. This data will be correlated with the trabecular bone volume of the glenoid defined by the pre operative CT scans. In addition all bone quality measurements will be correlated with CT scan imaging of the glenoid at the time of surgery and at two year follow up.

Patient Enrollment

The proposed clinical study will enroll patients indicated for standard of care anatomic total shoulder arthroplasty. They will receive all pre operative testing, intra-operative care including all implants and post operative care that is standard of care and specific to the surgeon and patients decisions for care. The only difference between the study groups will be type of surgical instruments used to place the glenoid guide pin. In all cases the surgeon is able and allowed to use their own surgical judgment to place the guide pin, prepare the bone and place the desired implant. In cases that are randomized to the IRIS group the surgeon can use any and all of the standard instruments or guides provided by the implant manufacturer as the surgeon would use in the group of patients randomized to the standard surgical group. If the surgeon chooses not to use the IRIS instruments then this would be noted as a deviation in plan, the reasons recorded and the patient would be excluded from the study without post operative imaging and there pre – operative and intra – operative data would be analyzed for the purpose of understanding the reasons for failure of the IRIS technology to provide surgical assistance for guide pin placement.

Detailed Study Design:

The study will enroll 60 patients, 30 standard surgery group and 30 in the IRI surgical group, into a randomized clinical trial. We will have two surgeons with experience in shoulder arthroplasty and the IRIS and SmartBones technology. We will require a minimum of ten patients in each surgical group (n=20) from any one surgeon. Enrollment by any one surgeon will be limited so that all surgeons achieve a minimum of 20 cases enrolled. All patients will have the standard of care indications for an anatomic total shoulder arthroplasty and will give informed consent for both the surgery and participation in this study. Consent and enrollment will be obtained by the surgeon during a routine office evaluation. All patients will get standard of care pre operative x-rays and CT scan at least three weeks prior to surgery. Scan quality must meet study specific criteria and we expect that the scans will be performed at the Cleveland Clinic. The pre operative CT scan will be placed within our pre operative planning software (OrthoVis Cleveland Clinic). The surgeon will use this software to assess the glenoid bone

pathology and select the optimal implant and placement of that implant. After pre operative planning each patient will be randomized into either an IRIS group which will use the pre-operative 3D surgical planning software and the data from this software to create a sterile SmartBone model containing the desired location of the glenoid guide pin and instructions for use of an intelligent reusable instrument to assist the surgeon in placement of the guide pin within the patients glenoid. In the standard treatment group the surgeon will receive the data from the pre operative surgical simulation and use the instruments provided by the implant manufacturer. Statistician provided randomization envelopes will be provided to sort the patients into experiment and standard of care groups

Patients will have standard of care indications for primary anatomic arthroplasty and be able to get a pre-operative shoulder CT scan at the Cleveland Clinic or at an outside facility so long as the study includes the entire scapula and has 1mm or thinner sections. These parameters are required for accurate pre operative planning as well as comparison with the post operative CT scans. Standard of care pre- and post-operative x-rays (AP and axillary views) will also be obtained and can be preformed at the Cleveland Clinic or acquired from another health care facility. In all patients the standard x-rays and CT images provided by the radiology department will be available to the surgeon before and during the surgery.

For the experimental group, the cannulated IRIS instrument designed for glenoid pin placement is placed over the guide wire that is contained within the sterile SmartBone and the legs of the instrument are adjusted to record the relationship (location and trajectory) of the guide pin in relation to the patient specific glenoid anatomy. This is done at the time of surgery to properly mimic the desired pin placement. The location of each leg of the IRI is marked on the SmartBone with a surgical pen. The instrument is then removed from the smart bone model. The SmartBone model is visually compared by the surgeon to the exposed bone surface to ensure that the two match for shape and size. Any adjustments to the surgical site may be done by the surgeon to optimize the match between the model and the exposed glenoid surface. The marks placed by the surgeon on the model are then transferred to the patient bone using a surgical marker or bovie. These marks are in a general location as determined by the surgeon and assist in the placement of the IRI. The IRI is placed onto the patient bone surface in the same manner as it was placed on the SmartBone model and a guide pin provided by the manufacturer is placed into the desired position. The surgeon then removes the IRI and compares by visual inspection the location and trajectory of the guide pin in relation to the patients bone surface and that within the SmartBones model. Any adjustments in guide pin position can be performed by the surgeon based upon surgical judgment. The surgeon can make any change needed and use any means or instrument that would otherwise be used for standard of care surgery to place the guide pin in any position that the surgeon believed to be best for the patient. If the pin is changed without the use of the IRI then the patient will be excluded from this study and the reasons for failure of the IRI technology to provide accurate pin placement based upon the surgeons sole determination of accuracy will be recorded and later analyzed as a failure to treat. These patients will not receive post operative CT Scans as we would not be able to use the data within any one group as defined by this study. After placement of the guide pin the remainder of the procedure is completed in the same manner for both groups, using the implant manufacturer's equipment.

In the standard instrument group, the surgeon will use the pre operative CT Scan at least two weeks prior to surgery to define the glenoid pathology, select the implant of choice and place that implant in the desired position. This information will be available to the surgeon at the time

of surgery but the SmartBone models and the IRI will not be available. The surgeon will have the pre operative x-rays and the pre operative CT scan provided by the radiology department for intra – operative use. The surgeon will perform the surgery using any of the instruments provided for guide pin placement. These include a wide variety of free hand and adjustable guides that assist the surgeon for placement of the guide pin for location and trajectory. Which tools are used for each case will be recorded at the time of surgery.

Prior to implanting the glenoid component, three 1mm tantalum beads will be inserted into the backside pegs of the component. We have developed methods to place the beads in a manner that has been used by other investigators. The desired implant will be placed into a holding device (figure 1) and using a drill guide, a 0.9 mm hole measuring 2 mm deep will be placed in each of the three peripheral pegs of the implant (figure 2). A 1 mm tantalum bead (RSA biomedical, Umsa Sweden) supplied by the company will then be press fit into the component hole. The implant will then be placed in the glenoid, aligned with the previously drilled peg holes. As standard of care, these peg holes are cemented, thus locking the beads within the implant.

Using manufacturer (RSA biomedical, Umsa Sweden) provided beads and injector gun (figure 3), four to five 1mm tantalum beads will be placed in the coracoid, acromion and glenoid.[9] Exact placement of these beads is at the discretion of the surgeon. Patient anatomy and operative exposure will guide the surgeon to the best places to inject the beads; however the surgeon will not be confined to a specific amount of beads in a specific location.(figure 4) The beads just need to be spread out amongst the coracoid, acromion, and glenoid to establish reference points for the RSA imaging. Prior studies looking at should joint kinematics and implant position have used this methodology of bead placement with successful study related outcomes.[9,10,13]

Post operatively, all patients will receive a CT with MAR and RSA (if chosen) within 3 weeks of surgery. This will be a CT Scan performed with the patients arm by the side in a supine position using metal artifact reduction techniques. In addition patients will receive a second CT scan and RSA imaging, provided they originally got RSA, performed 2 years (± 1 month) from surgery. The second CT scan will be performed with MAR techniques and with the patient in the lateral decubitus position with their arm in the overhead position again using metal artifact reduction techniques. The second set of images produce with a different body and arm position also decreases metal artifact than those obtained with the arm placed by the side. This position can not be comfortably obtained until 3- 6 months after surgery and require healing of the tissues and rehabilitation of the shoulder. We have shown that in a small number of patients the glenoid component can shift in position within the first 3-6 months after surgery making the first CT Scan more accurate for implant position. The images obtained from the post-operative CT scans are placed back into the surgical software and the 3D reconstruction of the post-operative scapula with the implants is compared to the pre-operative plan. Using measurement tools within the software, developed at the Cleveland Clinic, we will compare the position of the actual glenoid component placed in the patient with the desired position specified by the plan. The use and validation of these imaging methods to precisely measure implant position has been performed at the Cleveland Clinic in a prior IRB approved clinical trial (IRB 10-582). Similarly, the post operative CT scans will be compared to find any micromotion of the tantalum beads previously placed in the glenoid implant.

Preoperatively, the high resolution quantitative CT will measure volumetric bone mineral density and the trabecular network of the glenoid. This will be done at same visit for the standard of care pre operative CT. Micro CT imaging, which creates a 3D reconstruction of the fine bone structure, in addition to microarchitecture analysis and mechanical testing, will allow assessment of the bone tissue taken from the bone core sample. Between the preoperative imaging and the bone tissue analysis, we will have data to properly determine the quality of the bone stock surrounding the implant. Further correlating this with RSA and 3D CT imaging of implant movement, we can fully develop cause and effect of bone quality on glenoid component loosening.

The participating surgeons will be Dr. Joseph Iannotti and Dr. Eric Ricchetti. Patient may have surgery at either Cleveland Clinic main campus or at Euclid Hospital. If the procedure is performed at Euclid Hospital, post operative CT scan and RSA (if chosen), will need to be taken at main campus within 3 weeks. The patient will be made aware of this at the time of enrollment and consent.

Inclusion/Exclusion Criteria:
To be eligible for inclusion, a primary anatomic total shoulder arthroplasty must be indicated for the patient.

Outcome Measures:
By comparing computer generated pre-operative plan to post op component placement, we will be looking at three outcomes. First, the overall difference in component placement between standard of care instrumentation and intelligent reusable instrumentation will be compared. Secondly, we will compare the placement between the two technologies within and between surgeons. Thirdly, we will evaluate the difference in implant position between technologies based on severity of pathology. The quality of the bone core sampled will be correlated to the possible loosening of the implants.

Sample Size:
Using statistical analysis of the previous saw bone study data, a study pool of 26 patients per group, 52 patients total, is needed to achieve 80% power. However to increase the power of the study we propose enrolling 60 total patients with 30 patients in each surgical group, IRI vs. Standard of Care.

Statistical Methods
Two groups of patients will be compared on the outcome of interest using Student T-test or Wilcoxon rank sum test as appropriate. Summary statistics will be presented as Mean +/- SD or Median (25^{th} percentile, 75^{th} percentile).

Subgroup analysis by surgeon and severity of disease will also be conducted as above as secondary aims.

The significance level for each hypothesis will be 0.05. SAS software, Carey, NC, will be used for all analyses.

Data Sheets

Clinical data collected pre and post operative will be Passive and Active range of motion, manual muscle strength testing and shoulder functional scores, and co-morbidities all of which are standard of care. Post operative data will be collected at two years (± 1 month) after surgery. We will collect at the time of surgery the implant used, the time for surgical care glenoid exposure to end of pin placement. The implant used, the surgical instruments used and any comments from the surgeon as to the easy of use and accuracy of the IRI instruments or the standard instruments. Verbatim comments will be solicited and recorded by a research assistant attending all surgical procedures.

Pre operative imaging data will include: Glenoid version and inclination, estimated pre morbid inclination, version and depth of glenoid bone loss using the glenoid vault model. Preferred implant type inclination and version.

Post operative implant placement to desired location will be defined for location of the center peg of the implant in the SI, AP and ML dimension in millimeters and the trajectory of the center peg actual vs plan in version and inclination. The location of the implant in relation to the joint line as measured by the glenoid vault model will be measured in millimeters. Back side contact of the implant to the bone will be measured as a surface area in direct contact with the bone and any lucent lines around the implant pegs will be measured as defined by Youderian et al. Peg perforation and the location of the peg perforation will be recorded.

Changes in implant position from post operative CT scan 1 vs CT Scan 2 will be correlated with back side seating, implant type, medialization of the joint line and peg perforation and severity of the post operative pathology. The tantalum beads within each implant will be measured for translational or rotational movement.

Bone biopsy samples will be evaluated based on mechanical properties such as Young's modulus, yield stress/strain, maximum elastic strain energy, ultimate stress/strain, and energy absorbed at failure.

Study data will be collected and managed using REDCap (Research Electronic Data Capture).

Adverse Events and Data Monitoring Committee (DMC):

A Data Monitoring Committee will not be used. Patient safety will be protected by following surgical standards of care. The IRB will be notified in writing of any adverse clinical event related to the use of the IRI or the standard instrumentation. Adverse events include excessive bleeding, infection, fracture nerve injury or need for revision surgery during the term of this study which is expected to be approximately two years from the time of surgery.

Consent:

During a pre-operative office visit the patient's primary surgeon will conduct the consent interview, obtain the signed consent, witness and send the original to the study coordinator. A copy of each consent form will be sent to the surgeon for their records. Consent forms may also be sent to patients if they are located out of town. Research personnel will send multiple copies of the informed consent along with a self-addressed stamped envelope to the patient home for review, signature and return. Prior to the patient signing the informed consent, research personnel or the surgeon will call the patient to discuss the study, answer questions and ensure that the patient fully understands all aspects of the study. After being contacted, the patient may then sign and send back the informed consent.

Funding Sources and Budget

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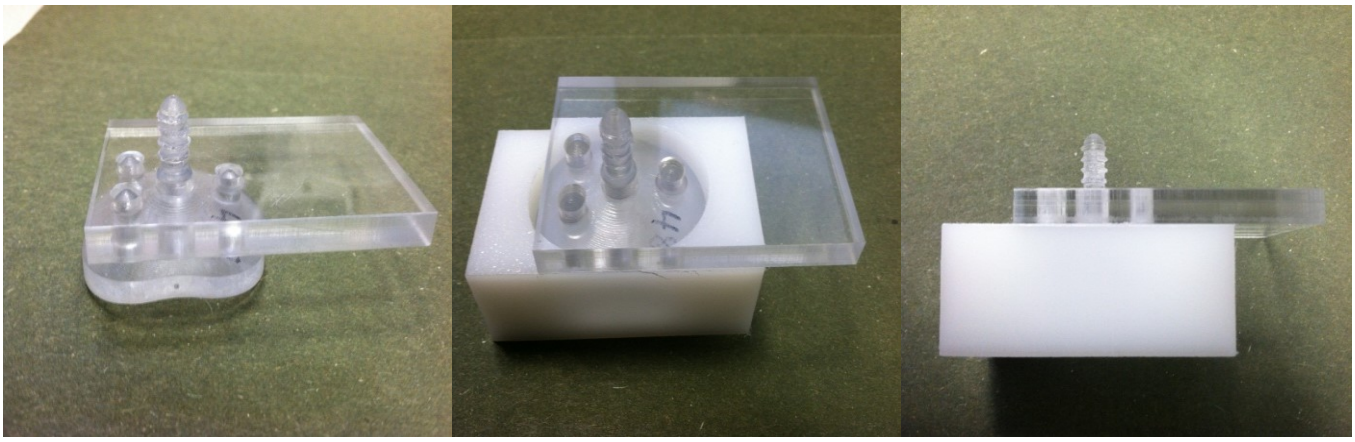

Figure 1: Holding block for glenoid component

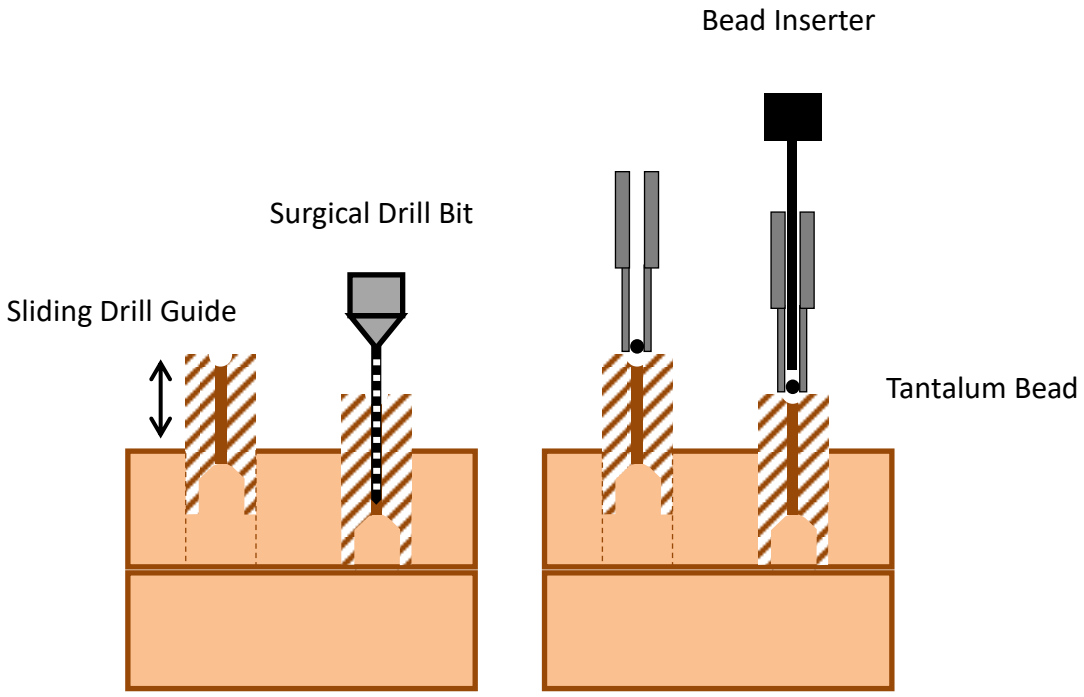

Figure 2: Holding block and drill guide for tantalum bead insertion into glenoid component

Figure 3: Tantalum bead injector (RSA Biomedical, Umsa Sweden)

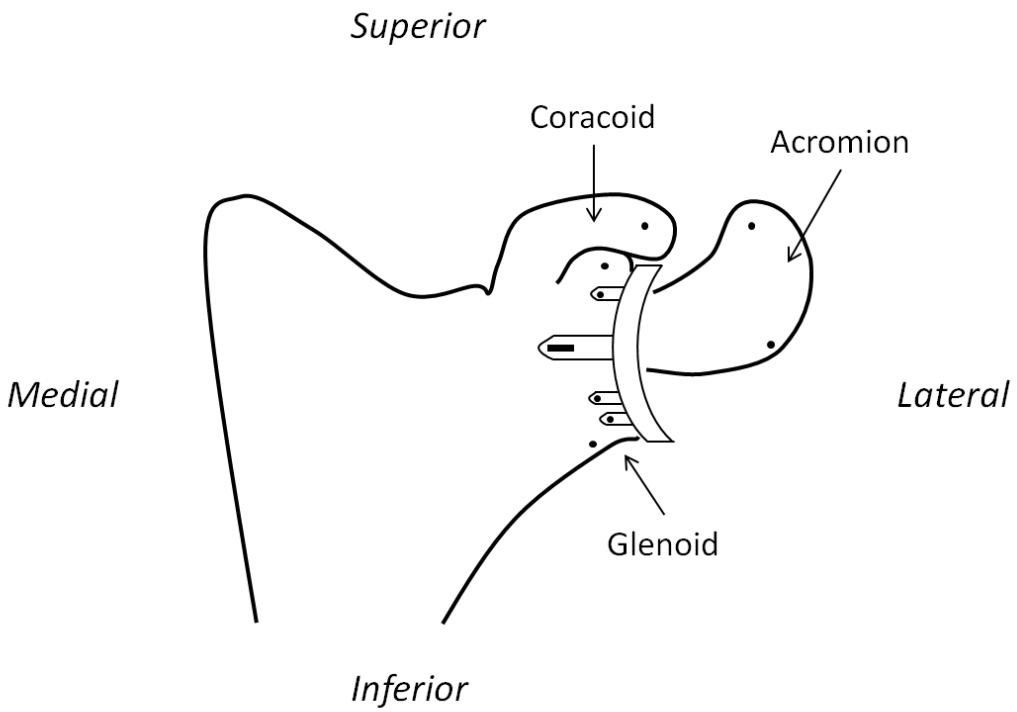

Figure 4: Bead positioning in scapula