Comparison of Glenoid Implant Positioning in Total Shoulder Arthroplasty using SmartBones: A randomized clinical trial

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Introduction

Glenoid component loosening is the most common complication of total shoulder arthroplasty. Loosening is associated with malposition of the implant as well as glenoid bone quality. Past studies from our research group have addressed these problems by investigating novel surgical technologies to increase the accuracy of glenoid implant placement. Our efforts to quantify bone quality and correlate bone quality with implant survival continue. Over the course of multiple IRB approved clinical trials, use of our pre-operative planning software in combination with patient specific instrumentation (PSI, #10-582), intelligent reusable instrumentation (IRI, #12-997) or real-time instrumentation (RTI, #13-652) has proven to more accurately place the glenoid guide pin than conventional standard of care techniques.(Figure 1)

Background and Significance

Developments at Cleveland Clinic have 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 commercially available implants and the optimal location of that implant within the bone. Two ongoing clinical trials, IRB #12-997 and #13-652, examine the use of the pre-operative plan in conjunction with either an intelligent reusable instrument (IRI) or a real time instrument (RTI) to transfer the surgical plan information from the surgical model (SmartBone) to the surgical site. The IRI in the 12-997 study is a tool provided to the surgeon with plastic adjustable legs to be adjusted onto a sterile model of the patient's pre-operative glenoid anatomy (SmartBone), which contains a surgical guide pin in the orientation specified from the pre-operative plan. The RTI in the 13-652 study also utilizes a SmartBone of the patient's pre-operative glenoid anatomy, and PMMA bone cement is used to create a mold of the glenoid and guide pin for transfer to the surgical site.

In the 97 total patients treated in the PSI, IRI and RTI studies there has not been the need to abort the use of the novel instrumentation, nor has there been a complication during or after surgery related to the technology. Moreover the objective data of post-operative implant position has proven the PSI, IRI and RTI technology to be better than control groups.

Study Design

Methods

Continuing our work, we propose a randomized clinical trial to evaluate the accuracy of glenoid implant placement comparing four groups of patients. Group 1 consists of 3D imaging and computer-generated surgical planning using standard DePuy instrumentation for placement of the glenoid implant. This group is considered the standard of care group (SOC). Group 2 consists of 3D imaging and computer-generated surgical planning, with use of a SmartBone to trial the standard DePuy instrumentation. (Group 2 is Group 1 with addition of the use of a SmartBone.) Group 3 consists of 3D imaging and computer-generated surgical planning, with use of the IRI technology including a SmartBone, but with metal legs instead of plastic legs, which were used in the IRB#13-652 study. Group 4 consists of 3D imaging and computer-generated surgical planning, with use of the RTI technology including a SmartBone.

We will measure implant placement with RSA (bi-planar x-rays) and 3D CT imaging. We will measure pre-operative bone quality using quantitative CT to measure trabecular bone volume and correlate these findings with bone samples removed from the humeral head and measured by microCT, and mechanical testing of the bone samples. These bone samples will be obtained as part of the routine preparation of the humeral head for implant placement. 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 implant. We have performed all of the work required to define both the safety of all components of the proposed study in the completed PSI study and the ongoing IRI and RTI studies (#s 10-582, 12-997 and 13-652, respectively). Since application to the IRB for study of the IRI technology Custom Orthopaedic Solutions (Cleveland Clinic NewCo) has received in April 2013 FDA approval for this technology.

Glenoid Instrumentation and Pre-operative planning

All patients will receive a Standard of Care pre-operative CT scan that will be used for the 3D imaging-based computer modeling to determine the best location for the glenoid implant. The surgeon will approve the surgical plan, and the printed surgical plan will be available in the OR for consultation by the surgeon. The four groups differ in the way that this pre-operative plan is used during the surgical procedure to position the glenoid implant.

Group 1 (SOC, control group):
In this group the surgeon will use standard DePuy instrumentation provided with the implant to implement the pre-operative surgical plan.

Group 2 (SOC plus SmartBone):
In this group the surgeon will use standard DePuy instrumentation provided with the implant and the use of a patient-specific SmartBone that contains a guide pin inserted into the SmartBone that mimics the pre-operative surgical plan to implement the pre-operative surgical plan.

Group 3 (SOC plus IRI with metal legs and SmartBone):
This group is a variation on the IRI study protocol (IRB #12-997). In the IRI study, the IRI tool has plastic legs of different lengths to conform to the contours of the patient's glenoid anatomy, which is reproduced in the SmartBone model. In group 3, the legs of the IRI tool will be fabricated from metal.

Group 4 (SOC plus RTI and SmartBone):

This group is identical to the RTI study protocol (IRB #13-652). In group 4, PMMA bone cement will be used to create a cognate mold of the patient's glenoid anatomy, which is reproduced in the SmartBone model, to implement the pre-operative surgical plan.

Group 5 (SOC plus IRI using SmartBase instead of SmartBone):
This group is a variation of Group 3 of this study. We have designed a new component, "SmartBase", which takes the place of the 3D-printed SmartBone. The SmartBase is a metal base with adjustable metal tabs that support each of IRI legs. In the 3D modeling software, an impact detection function is used to place the IRI tool on the computer model of the patient's glenoid, and the appropriate metal leg is chosen for each slot of the IRI so that the IRI is in the correct position to place the guidepin in the position dictated by the pre-operative plan. The computer software also calculates the height from the tip of the IRI to the point of contact on the computer model of the patient's glenoid for each of the legs. These distances are included in the pre-operative plan provided to the surgeon. In the operating room, the metal tabs of the SmartBase are adjusted to the proper height for each of the corresponding legs of the IRI. The surgeon then uses the IRI to drill the guidepin in the correct position and orientation into the patient's glenoid.

This method has been shown to be equivalent to the IRI group in pre-clinical testing. The rationale for testing this methodology in the current clinical trial is that the SmartBase does not require fabrication of a sterile SmartBone, which will provide a much faster delivery of the patient-specific instrument.

In all enrolled cases the surgeon will have full control to define the optimal position of the guide pin and the final implant. The surgeon can default to standard of care technology in any case in which the IRI or RTI technology cannot be used or results in guide pin position that, in his best medical opinion, is not consistent with the pre-operative plan. Therefore, the surgeon is in full control of all intra-operative decision making and execution of the procedure.

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. We anticipate that the accuracy of these second generation imaging techniques will be improved from our earlier work.

To extend the studies of implant position of the IRI study (IRB# 12-997) and the RTI study (IRB# 13-652), RSA imaging will be obtained from up to 20 subjects at these same time points. RSA imaging uses bi-planar 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 manufacture of the implant to better identify the implant

and its location on post-operative imaging. The three additional beads that we place in the implant will add accuracy to the post-operative imaging.

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. We have placed these metallic markers in the glenoid implant (three beads) and in the bone (4-5 beads) in 66 patients to date under the ongoing IRI and RTI studies. We have not had any problems with bead placement or any adverse events during or after surgery.

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 humeral head bone samples from all patients. These bone samples will be assessed by microCT to measure trabecular bone volume and connectivity as well as by mechanical testing. These 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.
In order to acquire consistent information on bone quality across the patients, a custom-made calibration phantom object will be located between the CT bed and the patient. The phantom object consists of three cylindrical rods, each with a known density of hydroxyapatite (0, 500, and 1,000 mgHA/cm^3) embedded in a soft foam block. The grey-level of pixel from the rods will be used to calibrate the Hounsfield units and the corresponding bone density using custom-written software.

Patient Enrollment

The proposed clinical trial will randomly enroll patients indicated for standard of care anatomic total shoulder arthroplasty into one of the four treatment groups. Our goal is to have 20 subjects in each treatment group. To accomplish this goal, we will enroll up to 120 subjects to control for subject withdrawal after enrollment. To enroll at least 20 patients into each group, including Group 5 (SmartBase), new randomization envelopes will be generated that start at number 34. The distribution of patients into Groups 1 – 4 at the time that Group 5 was begun is:
Group 1: 8
Group 2: 7
Group 3: 7
Group 4: 10

Thus, to reach 20 in each group, randomization envelopes will be created by the statistician, Colin O'Rourke (QHS), that have 12, 13, 13, 10 and 20 in Groups 1-5, respectively. The change in the odds of being assigned to a particular group will change from 25% previously, to 15 to 19% in Groups 1-4, and to 29% in Group 5. 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 patient decisions for care. The only change for this clinical trial will be the type of surgical instruments used to place the glenoid guide pin, retention of the humeral head for bone quality analysis, placement of the beads and post-operative CT scanning. 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 all cases, the surgeon can use any and all of the standard instruments or guides provided by the implant manufacturer as the surgeon would use if the patient were not enrolled in the study. If the surgeon chooses not to use the IRI or RTI technique then this would be noted as a deviation in plan, the reasons would be recorded and the patient would be excluded from the study without post-operative imaging and their pre-

operative and intra-operative data would be analyzed for the purpose of understanding the reasons for failure of the RTI technology to provide assistance for refinement of the technology.

Detailed Study Design:

The study will randomly enroll 20 patients into each of the four treatment groups. We will have three surgeons with experience in shoulder arthroplasty; two of these have extensive experience with the IRI, RTI and SmartBones technology. 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 one week prior to surgery. Scan quality must meet study specific criteria and we expect that the scans will be performed at Cleveland Clinic. The pre-operative CT scan will be placed within our pre-operative planning software (OrthoVis, Custom Orthopaedic Solutions, Cleveland, OH). The surgeon will use this software to assess the glenoid bone pathology and select the optimal implant and placement of that implant.

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 performed at 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.

Prior to implanting the glenoid component, three 1mm tantalum beads will be inserted into the backside peripheral pegs of the glenoid component. We have developed methods to place the beads in a manner that has been used by other investigators and validated in our own experience in 66 cases enrolled in the IRI and RTI clinical study. Placement of tantalum beads in the glenoid implant is now standard of care for Cleveland Clinic. The desired implant will be placed into a holding device and, using a drill guide, a 0.9 mm hole measuring 4 mm deep will be placed in each of the three peripheral pegs of the implant. 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, four to five 1mm tantalum beads will be placed in the coracoid, acromion and glenoid. 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 number of beads in a specific location. 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 shoulder joint kinematics and implant position have used this methodology of bead placement with successful study related outcomes. We have successfully placed bone beads in 66 patients currently treated in the IRI and RTI clinical studies without any difficulty or adverse events during or after surgery.

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 RSA imaging, provided they originally got RSA, performed 2 to 3 years (± 2 months) after surgery. The second CT scan will be performed with MAR techniques and with the patient in the arm by the side position again using metal artifact reduction techniques. 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 Cleveland Clinic, we will compare the position of the actual glenoid component placed in the patient with the desired position specified by the pre-operative 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 studies (IRBs 10-582, 12-997 and 13-652).

Pre-operatively, the high resolution quantitative CT will measure volumetric bone mineral density and the trabecular network of the glenoid. When available, this will be applied to the pre-operative CT for those patients at Main Campus. Patients who have their pre-operative CT completed at non-Main Campus facilities will have the standard of care pre-operative CT. This will be done at the 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 the cause and effect of bone quality on glenoid component loosening.

The participating surgeons will be Drs. Joseph Iannotti, Eric Ricchetti and Peter Evans. Patients 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 performed at main campus within 3 weeks. The patient will be made aware of this at the time of enrollment and consent.

IRI technology:
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 SmartBone 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 patient's 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 surgeon's 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

RTI technology:
Using the Smartbone surrogate model, the surgeon visually compares the exposed glenoid surface to the Smartbone model to ensure that the two match for size and shape. Any adjustments to the surgical site may be

done by the surgeon to optimize the match between the model and the exposed glenoid surface. Prior to molding the bone cement, bone wax is wiped onto the model to ensure proper release of the cement mold. The surgeon will then mold bone cement around the pin in the Smartbone, capturing the trajectory of the pin and the unique contours of the glenoid rim. A small pin sleeve is inserted over the pin to be embedded within the cement model. Once the bone cement has cured, it is removed from the model and placed onto the patient's glenoid surface. The bone morphology captured in the mold aligns the mold to the patient's anatomy. When the surgeon feels that the model has good fit of the glenoid surface, he may continue with pin placement. After placement of the guide pin, the RTI mold is removed and the remainder of the procedure is completed using the implant manufacturer's equipment and standard surgical protocols. 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 RTI then the patient will be excluded from this study and the reasons for failure of the RTI technology to provide accurate pin placement based upon the surgeon's 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.

SmartBase technology:
The IRI legs are placed virtually (manually) on a virtual SmartBone using an impact detection function in the 3D modeling software. From there the height of each IRI leg is measured and correlated to a number on the SmartBase. The SmartBase has hashes in 1/2 mm increments. The surgeon is then given a pre-operative plan that includes virtual photos of the IRI placement, the IRI leg lengths and numbers of each SmartBase height as calculated. Intra-operatively the IRI is assembled as normal and placed onto the SmartBase after each adjustable tab has been set to the appropriate height for each leg. The IRI is then used as normal.

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-operative component placement, we will be looking at three outcomes. First, we will compare the overall difference in component placement between the four treatment groups: SOC instrumentation, SOC instrumentation with SmartBone, intelligent reusable instrument with metal instead of plastic legs, and real time instrumentation. Secondly, we will compare the placement between the technologies within and between surgeons. All of the surgeons have extensive experience with anatomic total shoulder arthroplasty. Two of the surgeons have extensive experience with the pre-operative planning and the IRI and RTI technology. Thirdly, we will evaluate the difference in implant position between technologies based on severity of pathology. The quality of the bone core samples will be correlated to the possible loosening of the implants.

Sample Size:
We intend to have approximately 20 subjects in each of the 4 treatment groups. We expect to randomize up to 120 subjects to achieve 20-25 subjects in each treatment group.

Data Analysis
Average deviations from plan for the four treatment groups will be compared using mixed-effects ANOVA methods. Random effects will be included to account for correlation between observations introduced as a consequence of multiple observations of deviation being taken on a particular surgeon. If significant differences are found, multiple comparisons based on the ANOVA model will be made to compare each pair of groups, and will use Holm's step-down procedure to control the family-wise error rate of the tests.

All analyses will be done using R software (version 3.0.0, Vienna, Austria). A significance level of 5% will be used for all testing.

Data Sheets

Clinical data collected pre- and post-operatively 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 (± 2 months) 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 ease of use and accuracy of the 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 the location of the center peg of the implant in the superior/inferior (SI), anterior/posterior (AP) and medial/lateral (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. Peg perforation and the location of the peg perforation will be recorded. The tantalum beads within each implant will be measured for translational or rotational movement.

Changes in implant position from post-operative CT scan (CT 1) vs the first post-operative CT scan (CT 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.

Study data will be collected and managed using REDCap (Research Electronic Data Capture). Tracking data will be stored in an Excel spreadsheet, which will exist only on password-protected computers or on restricted-access CCF servers. Only study personnel will have access to the data.

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 1 year 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 Informed Consent, witness, sign and send the original to the study coordinator. A copy of each Informed Consent form will be sent home with the patient for their records. Informed 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.

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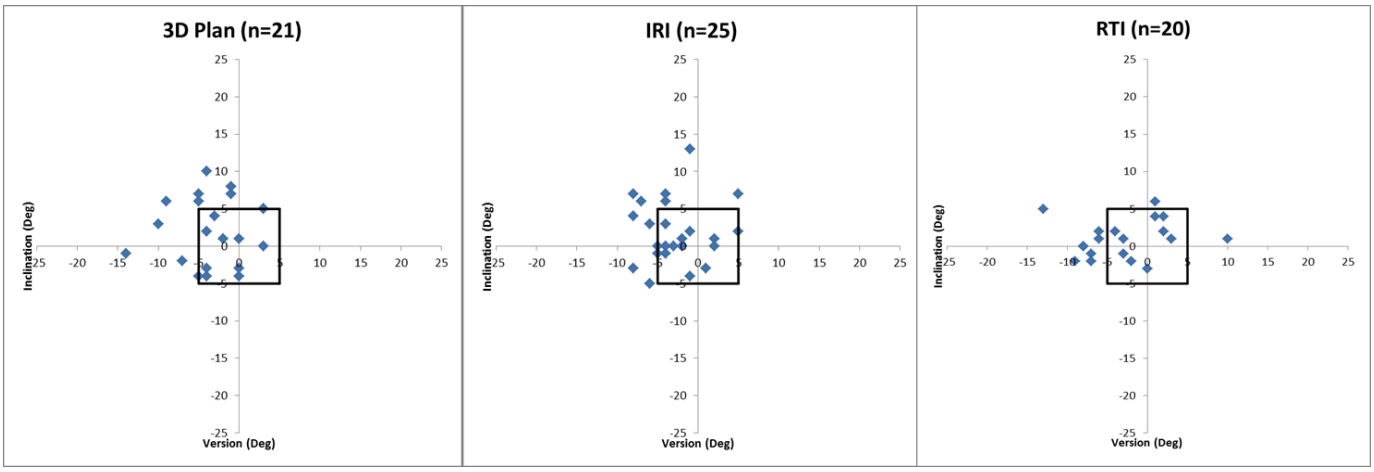

Figure 1. Comparison of actual glenoid implant position versus pre-operative plan among 3D computer templating only (left), templating with use of IRI device (middle) and templating with RTI device (right).