Use of Real Time Instrumentation (RTI) in Total Shoulder Arthroplasty: A Clinical Case Series

NCT01905241

01/10/2014

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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 the quality of the glenoid bone. Past studies from our research group have addressed these problems by investigating novel surgical technologies to increase the accuracy of glenoid implant placement. Over the course of multiple IRB approved clinical trials, use of our preoperative planning software in combination with patient specific instrumentation (PSI) or intelligent reusable instrumentation (IRI) has proven to more accurately place the glenoid guide pin than conventional standard of care techniques.(Figure 1) (Figure 2)

Continuing our work, we propose a clinical case series to evaluate a new surgical instrumentation technique that combines the features of PSI with the IRI technology that we have termed Real Time Instrumentation (RTI). 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 findings 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 head component. 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 study. Since application to the IRB for study of the IRI technology Custom Orthopaedic Solutions (Cleveland Clinc NewCo) has received in April 2013 FDA approval for this technology.

Glenoid Instrumentation and Pre-operative planning

Developments at the 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 commercial available implants and the optimal location of that implant within the bone. An ongoing clinical trial, IRB #12-997, is examining the use of the preoperative plan in correlation with an intelligent reusable instrument (IRI) to transfer the surgical plan information from the surgical model to the surgical site. The IRI is a tool provided to the surgeon with plastic adjustable legs to be adjusted onto to a sterile model of the surgical site having within the model the information needed from the pre-operative computer simulation of the surgical procedure. In the proposed new clinical trial we propose to create in the operating room a mold of the bone model that we call a Real Time Instrument (RTI) that the surgeon can place onto the patient glenoid bone to transfer the guide pin in the bone in a location defined to be optimal for the placement of the glenoid implant. Using the RTI, the surgeon can directly

determine the best features of both the patient's bone and the feature on the bone model that is within the surgical exposure to capture information within the RTI mold. The proof of the RTI concept for glenoid pin placement has been demonstrated in pre-clinical sawbone models and surgical trainers that simulate the surgical environment.

In a pre-clinical sawbones trial, we demonstrated a significant improvement in the accuracy of glenoid pin placement between Real Time Instrumentation and the standard of care instruments. Two surgeons were asked to place a guide pin in nine different pathologic models utilizing the two surgical techniques. The sawbone models were housed in our novel shoulder surgical trainer to simulate operative exposure. Standard of care with pre-surgical CT (n=36) and RTI (n=36) were performed to assess deviation from the preoperative plan. (Figure 3)

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, as we have for our completed PSI clinical trial and currently active IRI study, post-operative 3D CT Scanning to precisely define the location of the implant as compared to pre-operative plan. We propose to compare the accuracy of implant placement using the RTI - SmartBone technology to the use of IRI and PSI groups as well as the two control groups from these trials. Specifically we are proposing a non-randomized clinical case series. Patients enrolled in this study will be operated on by surgeons involved in the pre-clinical trial and the ongoing IRI study. In all enrolled RTI 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 RTI technology cannot be used or results in a guide pin position that in his view is not consistent with the pre-operative plan. Therefore the surgeon is in full control of all intraoperative decision making and execution of the procedure.

In the 60 patients treated in the PSI and IRI study there has not been the need to abort the use of the novel instrumentation, nor has there been a complication during or after surgery relating to the technology. Moreover the objective data of post-operative implant position has proven the PSI and IRI technology to be better than control groups. It is for these reasons that we do not propose to do a randomized clinical trial.

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.

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 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 22 patients to date under the ongoing IRI study. We have not had any problems with bead placement nor 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 trabecular bone samples from all patients. 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 micro CT 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 change for the case series will be the type of surgical instruments used to place the glenoid guide pin, coring of the bone to obtain bone tissue, 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 was not enrolled in the study. If the surgeon chooses not to use the RTI technique 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 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 enroll 20 patients directly into the RTI group. We will have two surgeons with experience in shoulder arthroplasty and the RTI and SmartBones technology. We will require a minimum of five patients from any one surgeon. 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.

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 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.

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 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.

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 and validated in our own experience in 22 cases enrolled in the ongoing IRI clinical study. The desired implant will be placed into a holding device 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. 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 amount 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 should joint kinematics and implant position have used this methodology of bead placement with successful study related outcomes. We have successfully placed bone beads in 22 patients currently treated in the ongoing IRI clinical study 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 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 cannot 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).

Preoperatively, 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 preoperative CT for those patients at Main Campus. Patients who have their preoperative CT completed at non Main Campus facilities will have the standard of care preoperative CT. 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. 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 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, intelligent reusable instrument (IRB#12-997), patient specific instruments (IRB #10-582) and real time instrumentation will be compared. Secondly, we will compare the placement between the 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:
We expect to enroll 20 patients for this clinical case series. Data collected will be analyzed in association with the enrollees from IRB#12-997 and IRB#10-582.

Statistical Methods
Average deviations from plan for the RTI, IRI, and freehand 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-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 ease of use and accuracy of the RTI 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. 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 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.

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 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 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

Funding source: State of Ohio Biomedical Research and Development Grant- Products to Improve Orthopaedic Patient Outcomes (PIOPO)- JP Iannotti Principle Investigator.

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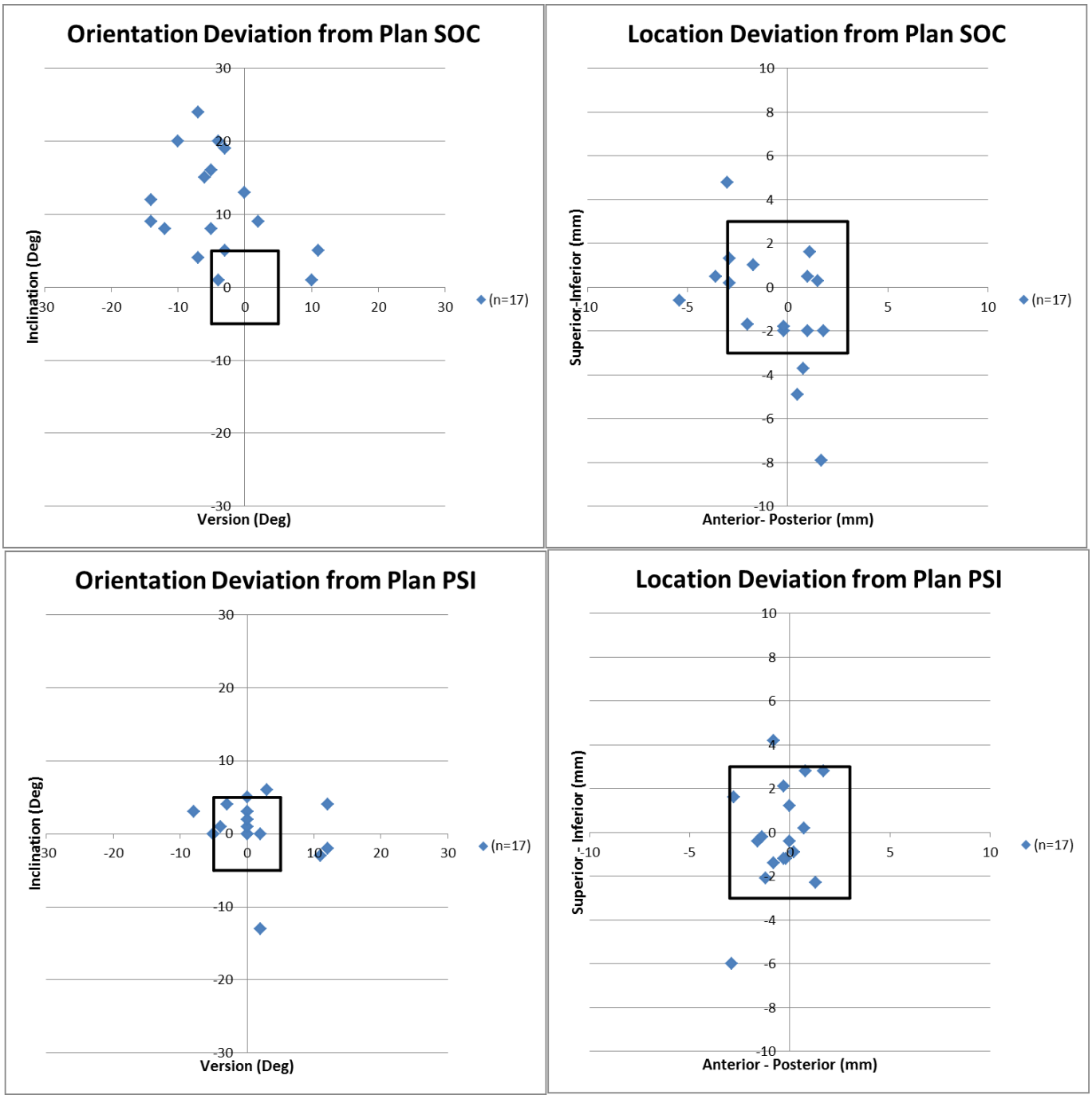

Figure 1: Data from IRB#10-582, Patient Specific Instrument vs Standard of Care

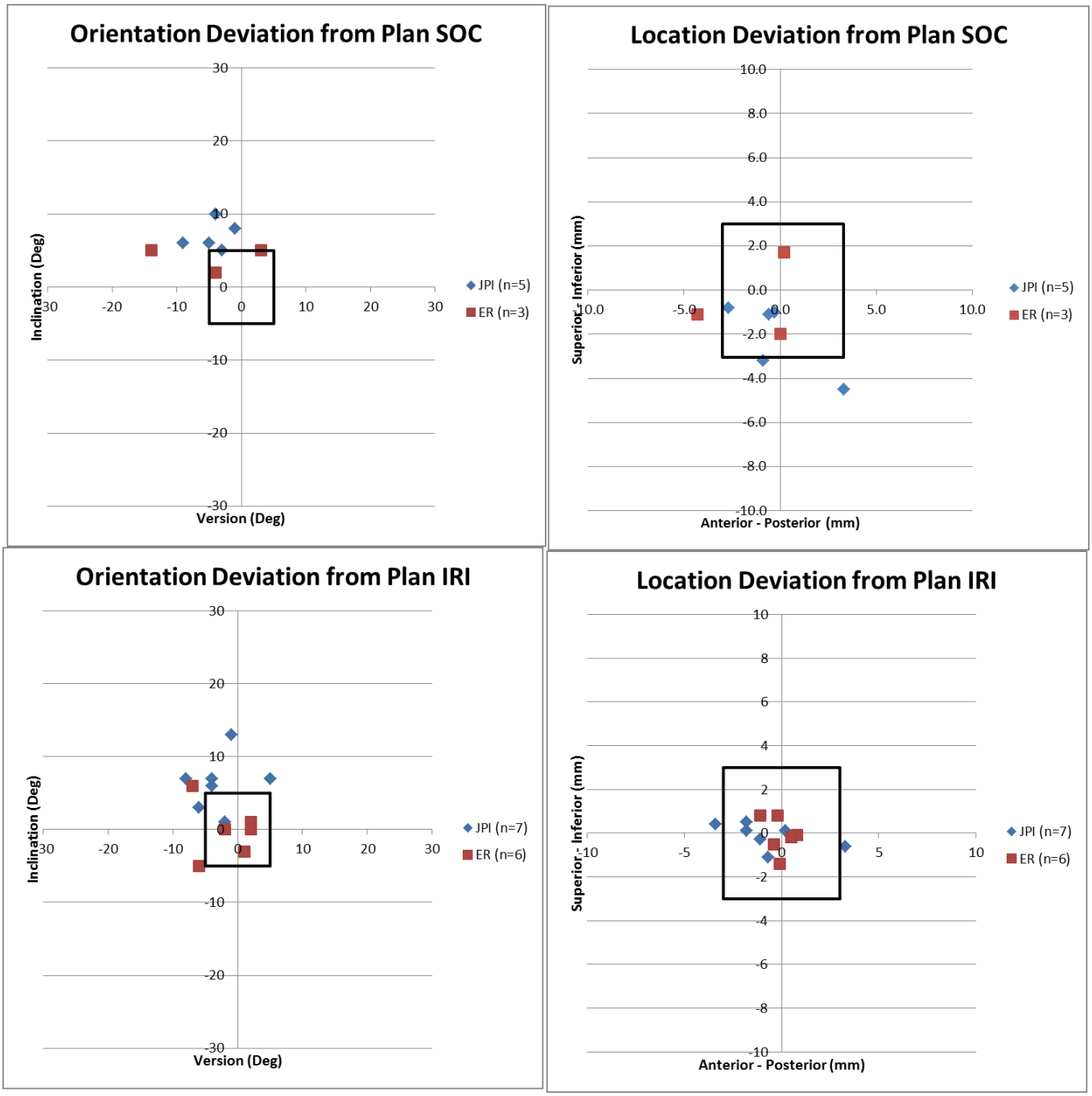

Figure 2: Preliminary data from IRB #12-997, Intelligent Reusable Instruments vs Standard of Care

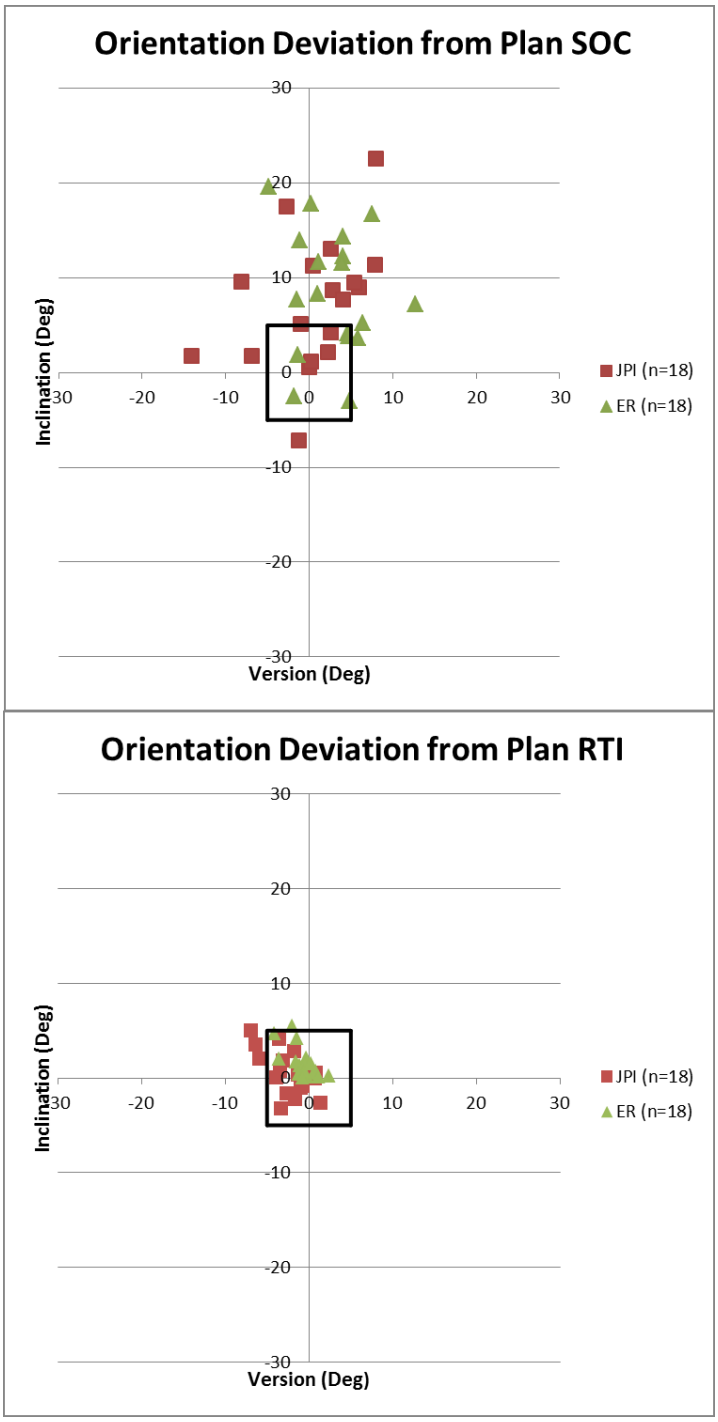

Figure 3: Data from RTI sawbone study, Real Time Instrumentation vs Standard of Care