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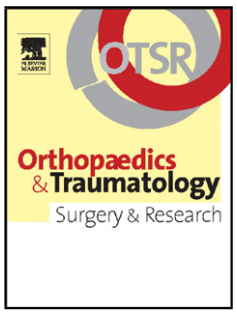

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ORIGINAL ARTICLE
Accuracy of Patient-Specific Guided Implantation of the Glenoid Component in Reversed Shoulder Arthroplasty

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Abstract:
Background: The aim of this study was to assess the accuracy of patientspecific guided glenoid component implantation in reverse shoulder arthroplasty
Materials and methods: 32 reverse shoulder arthroplasties were done using pre-operative 3D planning and 4 patient-specific guides to prepare the glenoid and position the glenoid component. Baseplate version, inclination and entry point as well as angulation of the screws were compared to the pre-operative plan measured on CT by independent observers.
Results: The mean deviation in baseplate version from the preoperative plan was 4.4° + 3.1° (range, 0.3°-13.7°), in baseplate inclination 5.0° + 4.2° (range, 0.1° to 14.5°) and in baseplate entry point 2.4mm + 1.4mm (range, 0.4° to 6.3°). The average screw superior-inferior angulation deviation for the superior screw was 2.8° + 2.6° (range, 0.0° - 10.1°) and 2.8 + 2.6° in the anteroposterior plane (range, 0.1° - 11.6°). For the inferior screw the superior-inferior angle deviation was 5.3° + 3.8°(range, 0.1°- 15.2°); the anteroposterior angle deviation was 4.1°+ 3.1°(range, 0.0° - 9.8°).
Conclusions: Patient-specific instrumentation (PSI) for the glenoid component in reverse shoulder arthroplasty allows the shoulder surgeon to accurately execute the pre-operative 3D plan.

Level of evidence: Level 3

Key words: shoulder, arthroplasty, reverse, glenoid, patient-specific targeting guides

Introduction

Reverse shoulder arthroplasty has been proven to be a successful treatment for end-stage cuff tear arthropathy in the elderly patient [1;2;3]. The correct positioning and fixation of the glenoid component remains however one of the most important challenges of the procedure that will dictate early and long-term results [1;4;5;6;7;8]. In primary shoulder cases that need a reverse arthroplasty, Frankle et al have demonstrated that in 40 % of the patients there is an abnormal morphology of the glenoid [9]. These numbers could even increase since the reverse prosthesis is being used more and more often in complex and revision cases as the only surgical option left [10].

Current methods to assess glenoid wear patterns are based on 2-dimensional reconstruction of a computed tomography scan of the native glenoid. However, accuracy of this method to measure glenoid version is limited and values vary by 10-15° depending on the position of the scapular position in the gantry [11,12]. Furthermore, there are only few radiological methods to assess glenoid inclination [13] and these measurements are rarely applied in clinical practice.

In addition, the use of patient specific instruments (PSI) helps to intraoperatively accomplish implantation of the glenoid baseplate according to the preoperative plan in anatomical and reverse shoulder replacement [14-23]. In one study, PSI reduced average deviation in glenoid version from 6.9° to 4.3°. Particularly in patients with excessive retroversion (>16°) the effect was highly significant. Furthermore, the

average deviation for glenoid inclination with the use of patient specific instrumentation was significantly superior (11.6° vs 2.9°) compared to the standard technique [16].

The aim of this prospective multicenter study was to assess accuracy of base plate implantation with regard to version and inclination as well as precision of screw positioning. We hypothesized that 3D preoperative planning and patient specific instrumentation would allow component positioning with less than 10° of deviation compared to the preoperative plan.

MATERIAL AND METHODS

2.1 Patients

This study is an institutional review board-approved, multicenter, prospective clinical trial. All subjects provided written informed consent prior to enrollment and randomization. The three participating surgeons started collecting data of their patients after being trained on the PSI procedure. Patients who were scheduled for a reverse shoulder arthroplasty were included after they agreed to participate and have follow-up computed tomographic imaging (CT) within 3 months after surgery. Revision and fracture cases were excluded.

2.2 Methods

Prior to surgery, all patients underwent a preoperative standard 2-dimensional CT scan of the full scapula (0.5 mm thickness cuts). The scapula was segmented from 2-dimensional images in the Digital Imaging and Communications in Medicine (DICOM) format and was reconstructed into 3D models (PSI Shoulder Segmentation Application, Zimmer Biomet, Inc., Warsaw, IN USA). This patient-specific 3D model of the scapula

was uploaded into an interactive surgical planning software program (PSI Planner, Zimmer Biomet, Inc., Warsaw, IN USA), enabling the surgeon to virtually plan the ideal position of the glenoid component preoperatively (Fig. 1). Based on the native anatomy, shape, and location of the glenoid vault, the glenoid component was placed in the desired version and inclination. From this surgical plan, a patient-specific glenoid replica was created to allow the surgeon to visualize the optimal PSI guide position during the surgery. Additionally, four patient-specific polyamide guides were manufactured to control the position and orientation of baseplate component and screws intraoperatively.

At the time of surgery, a standard deltopectoral approach was used in all patients. For the humerus, standard preparation techniques with standard instrumentation were used. For the preparation of the glenoid, the remaining glenoid cartilage and remnants of the labrum were removed, as the PSI guidance is a CT-based system. Specifically the antero-superior corner of the glenoid rim was prepared as this area must be free of interfering soft tissue to allow optimal seating of the PSI pin guide. Next, the native glenoid was compared with the PSI bone model to ensure that all of the soft tissue was removed and that the PSI pin guide has a good fit on the glenoid (Fig 2.a).

Subsequently, the four PSI guides were used to execute the pre-operative planning for glenoid component implantation. The first PSI pin guide was placed on the surface of the glenoid. Care was taken to ensure that it was sitting tightly on the glenoid surface and once it was positioned correctly, that it was locked in place. The inferior 2.5 mm pin was inserted through the central hole of the PSI guide until the depth mark on the pin met the top of the metal bushing (Fig.2.b). Next, the superior 2.5 mm pin was inserted

through the superior hole in the same manner. The bushings and PSI pin guide were removed and the insertion points of the two pins were checked with the planned position on the bone model. After the pilot hole for the glenoid reamers was created using the 6 mm cannulated drill, the baseplate reamer with the PSI ream guide was used to prepare the glenoid surface (Fig 2.c). Reaming was performed until the subchondral bone was exposed matching the pre-operative plan and until the PSI ream guide reached the lateral end of the cannulated straight driver. At that time, the reamed glenoid surface was compared with the image provided in the pre-operative plan. The PSI roll guide was used to insert the definitive baseplate component in the pre-operatively determined correct rotation (Fig. 2.d). This further determined the insertion points and orientation of the locking screws. The baseplate inserter was struck with a mallet until the back of the component was completely flushed with the prepared surface. Finally the screw PSI guide (Fig. 2.e) was used to drill the screw pilot holes in the exact orientation as planned pre-operatively. Superior and inferior screws were inserted and locked with locking caps (Fig. 2.f). The glenosphere was impacted, and the humeral component was further implanted following standard principles.

2.3 Methods of assessment

After surgery, the actual device position was compared with the planned position based on standardized measurements in a standardized coordinate system. All measurements were performed independently by an imaging core lab (Medical Metrics, Inc., Houston, TX). The first 7 subjects were analyzed by two analysts working independently. After inter-and intra-observer agreement was confirmed, the remaining 25 subjects were analyzed by a single analyst.

To obtain a standard coordinate system for measurements, all component positions (preoperative planned and postoperative actual) were first registered to the preoperative CT coordinate space. Following the registrations, the standardized coordinate system was defined based on the scapula and baseplate for measurements described below. All registrations and analyses were performed using Mimics® (v17.0, Materialise NV, Leuven, Belgium).

3D CAD models of the individual device components (i.e. baseplate, glenoid head and screws) were superimposed on, and manually registered to the postoperative CT. Registration was achieved by matching the outer contours of the implant geometry to the outer edges of the device components as visualized on the CT. Following registration, the actual device position relative to the scapula could be visualized and measured. The main focus of the component registrations was on the ends of the baseplate and screw stems, trajectory of the stems, and the surface curvature of the glenosphere. Registrations were confirmed based on logical and appropriate fits between components. Once the CAD models were positioned in the CT coordinate space, the position of each component was exported along with a 3D model of the scapula. Next, this "assembly" of device components and scapular geometry was spatially registered in the preoperative CT space in order to align the preoperative and postoperative scapula in the same position. 3D models of the planned component positions and the preoperative scapula were also spatially registered in the preoperative CT space to render the scapula in the same position.

After both preoperative and postoperative 3D component models were registered to the same co-ordinate system, a scapular co-ordinate system was defined for measurements.

The scapular coronal plane was defined by 3 anatomic landmark points: the glenoid center point, the trigonum spinae, and the inferior scapula angle point [18]. The scapular axial plane was defined by a plane containing the glenoid center and the trigonum spinae, orthogonal to the scapular coronal plane. The scapular sagittal plane was defined as the plane orthogonal to the coronal and axial planes.

The following measurements were produced for the planned and actual device positions in the scapular coordinate system : 1) Baseplate version was measured as the angle between the baseplate stem axis and the coronal plane, measured in the scapula axial plane; 2) Baseplate inclination was measured as the angle between the baseplate stem axis and the axial plane, measured in the scapula coronal plane 3) Baseplate entry point was measured as the distance between the center of the baseplate face and the glenoid center. Baseplate entry point was measured in the coronal plane for anterior-posterior position, and in the scapula sagittal plane for the medial-lateral and superior-inferior positions.

A second co-ordinate system was defined based on the baseplate to assess positioning of the superior and inferior screws. The baseplate sagittal plane was defined as the plane of the baseplate face. The baseplate coronal plane was defined as the plane containing both screw holes and the axis of the baseplate stem, and the baseplate axial plane was defined as the plane orthogonal to the coronal and sagittal planes. Screw angle was measured as the angle between the screw axis and the baseplate stem axis. Superior-inferior screw angle was determined in the baseplate coronal plane, and anterior-posterior screw angle was determined in the baseplate axial plane.

Results were subdivided in 3 groups: < 5° off plan, between 5 and 10 ° off plan, and > 10° off plan. The effect of patient's BMI, age, gender and surgeon's experience on accuracy of baseplate version and inclination were also analyzed.

2.4 Statistical analysis

All statistical analysis was performed with SPSS Statistics 22 (IBM, Armonk, NY, USA). The absolute difference between the measurements of the planned and the implanted position of the components and screws were compared using Student's t test. Pearson correlation for continuous data and ANOVA for categorial data were used to measure the effect of BMI, age, gender and surgeon on accuracy of baseplate version and inclination. The results were considered to be significant at p-value < 0.05.

RESULTS

Thirty-two patients were enrolled in the study. 81 % had primary cuff tear arthropathy or irreparable cuff tears, 13% primary osteoarthritis and 6% posttraumatic arthritis. According to Favard's glenoid classification there were 16 E0, 5 E1, 8 E2, 2 E3 and 1 E4. Mean age was 73 years (range: 54 years to 88 years). 72% were women and 28% were men.

Table 1 depicts the mean deviation (planned versus actual) from the ideal preoperative planned component placement for version, inclination and baseplate entrypoint.

The mean deviation in version was 4.4°$\pm$ 3.1°. Twenty of 32 of cases showed version within 5° off plan, 11 of 32 between 5° and 10°, and 1 component was more than 10° off plan. The mean deviation in inclination was 5.0° $\pm$ 4.2°. In 19 of 32 baseplates, the inclination was less than 5° off plan, in 8 of 32 between 5° and 10° off plan, and in 5 of 32

more than 10° off plan. The average deviation of the entry point of the baseplate was 2.4mm ± 1.4 mm.

Based on previously established criteria, a component was considered malpositioned if the component position deviated more than 10° from the planned optimal position [16;24;25] . Applying these criteria, the use of glenoid positioning system technology resulted in 84 % correctly positioned components and 16 % malpositioned components.

For the angulation of the superior screw, in 28 of 32 cases the supero-inferior (SI) angle was within 5° off plan, and for the anterior-posterior (AP) angle 31 of 32 cases was within 5° off plan. For the inferior screw 24 of 32 cases showed SI angle within 5° off plan, and for the AP angle 25 of 32 cases was within 5° off plan. (Table 2).

Five surgery-related complications were reported. Two patients had transient neurological symptoms (hypoesthesia in the hand palm and neuropraxia of the ulnar nerve), in one patient a fracture of the glenoid occurred during baseplate impaction, and two patients experienced persistent radiating shoulder pain. There were no complications reported related to the PSI procedure.

Patient's BMI, age or gender or surgeon's experience had no statistically significant influence on accuracy of baseplate version and inclination.

DISCUSSION

The current study shows a high accuracy in glenoid component and screw positioning in reverse shoulder arthroplasty using preoperative 3D planning and patient-specific

instrumentation using 4 PSI guides for component implantation. Comparing pre-operative planning with actual post-operative placement showed good to excellent positioning in 85 % of the cases with appropriate baseplate and screw position within the glenoid vault.

Hendel et al. reported up to 75% malpositioning for glenoid implantation when using standard instrumentation and the malpositioning was directly related to the degree of deformity. Therefore, the use of 3D software systems and PSI for positioning of the glenoid was suggested as a possible solution [16]. For TSA, they concluded in a randomized prospective clinical trial that there was a significant improvement in the accuracy of glenoid component placement using patient-specific guides in patients who had bone deformity and glenoid retroversion exceeding 16° [16]. No difference was found in patients with glenoid retroversion <7°. In an *in vitro* study on the use of PSI for glenoid component placement in TSA, Walch et al. demonstrated a good correlation between the preoperative planning and the achieved position of the guide pin. [26]. Recently, these authors confirmed the use of the single PSI guide for central pin placement in a clinical study observing a mean error of 3.4° (SD 5.1°) in the version and 1.8° (SD 5.3°) for inclination of the final glenoid implant [22]. For RSA, Levy et al reported that PSI was highly accurate in reproducing the surgical plan for positioning of the glenoid baseplate [23]. They found an average error of 1 mm for the guide pin insertion point and a 3° error for the guide pin angulation. Heylen et al. demonstrated that 3D preoperative surgical planning and PSI guidance reduces variability in glenoid component inclination and avoids extreme inclination errors for TSA and RSA [21].

The currently available standard guiding instrumentation specifically help in finding the correct entry point on the glenoid articular surface for the first central pin. However, its version and inclination are more difficult to control, especially when the native glenoid is not neutrally aligned because of wear or aberrant morphology. Difficult exposure, variable scapular anatomy, and patient positioning on the operating room table can make the introduction of the first central pin potentially challenging, and this procedure also relies on the skills of the surgeon and the surgeon's interpretation of the scapular position and morphology. The advantage of this PSI guiding system is that there are 4 specific steps and guides for successful implantation of the glenoid baseplate (Fig. 3): 1). pin guide: for insertion of the central pin in the desired version and inclination; 2). ream guide: to control reaming angle and depth; 3). roll guide: for guidance of component rotation orientation and screw entry points; and 4). screw guide providing the drill direction to achieve planned screw orientation and length.

In both the planning and execution phase of the process, the role of the surgeon remains crucial and cannot be replaced by technology. Preoperative planning using computer software requires surgical experience that cannot be outsourced, it needs to be validated by the surgeon himself. The peroperative use of PSI guides cannot control the variability completely and the surgeon's intuition remains crucial in the preparation and final component implantation. Furthermore, the technology does not completely eliminate variability due to the pure geometric nature of a PSI approach in general, not taking soft-tissue status into account. In some cases, the segmentation process of the bone in the software cannot remove calcified or ossified parts of the glenoid rim or anterosuperior labrum, and these same structures may or may not be removed by the surgeon at the time of the procedure. Lastly, the use of this technology adds 10-20% extra cost to the

surgical procedure that, depending on the country, will need to be paid by the patient, hospital or insurance. Therefore, long-term clinical results are needed to analyse its cost-benefit and justify its use.

In conclusion, 3D preoperative computer planning coupled with patient-specific and implant-specific instrumentation allows the shoulder surgeon to accurately execute the plan at the time of surgery. This novel technique may increase accuracy and reproducibility of shoulder reconstructive procedures but future clinical outcome studies will be needed to determine whether this can positively affect long-term functional outcomes.

Conflict of interest

All authors except Kristien Vuylsteke and Mathieu Ferrand have a consultancy agreement with ZimmerBiomet.

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Dr. Joan Armengol Barallat, deceased January 4, 2015.

Pr Philippe Hardy, deceased Septembre 2, 2017

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Legends

Figure 1.

Pre-operative 3D planning using the shoulder planner software

Figure 2

Intra-op pictures showing the 4 PSI guides to execute the pre-operative planning for glenoid component implantation

Figure 3.

Registered preoperative planned (yellow) and postoperative actual (red) positions of the device in the base plate coordinate system. (A) 3-D surface model of planned and actual device positions. (B-D) Outlines of the planned and actual device positions overlaid on the preoperative CT in the (B) base plate sagittal, (C) base plate coronal, and (D) baseplate axial planes. The preoperative planning model includes an outline of the scapula and long rods to indicate planned screw trajectories.

Table 1 Results for baseplate version, inclination and entry point

Table 2 Results for superior and inferior screw angulation

Table 1

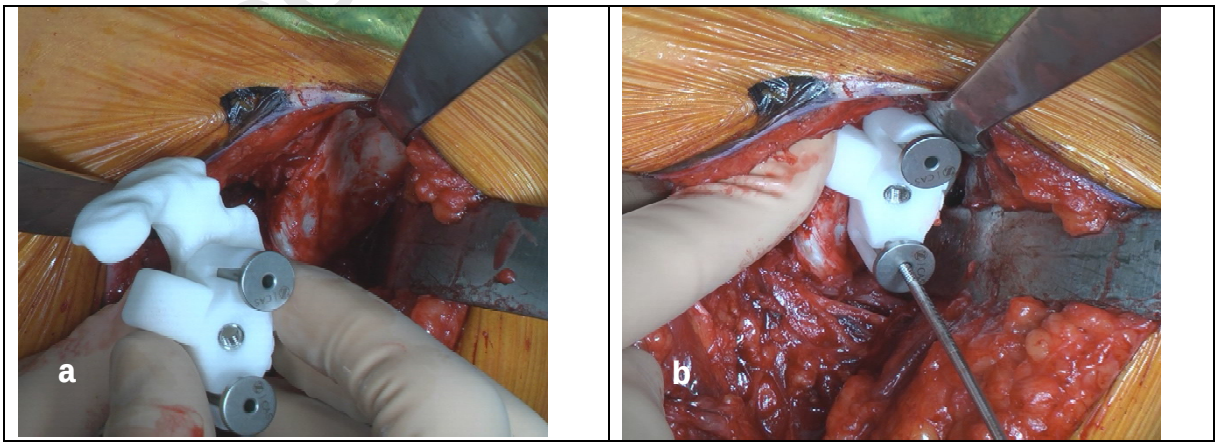
Variables	**Outcome**	**Data**
Base plate version	< 5° deviation	20/32 (63%)
	5°-10° deviation	11/32 (34%)
	> 10° deviation	1/32 (3%)
Base plate inclination	< 5° deviation	19/32 (59%)
	5°-10° deviation	8/32 (25%)

	> 10° deviation	5/32 (16%)
Base Plate		
Mean deviation from planned version [deg] (SD; range)		4.4 (3.1; 0.3 to 13.7
Mean deviation from planned inclination [deg] (SD; range)		5.0 (4.2; 0.1 to 14.5
Mean deviation from planned base plate entry point [mm] (SD; range		2.4 (1.4; 0.4 to 6.3)

Table 2

Variables	Data
Superior Screw Mean deviation from planned SI angle (deg) (SD;range) Mean deviation from planned AP angle (deg) (SD;range)	 2.8 (2.6; 0.0 to 10.1) 2.8 (2.6; 0.1 to 11.6)
Inferior Screw Mean deviation from planned SI angle (deg) (SD;range) Mean deviation from planned AP angle (deg) (SD;range)	 5.3 (3.8; 0.1 to 15.2) 4.1 (3.1; 0.0 to 9.8)
SI angle: superior-inferior angle AP angle: anterior-superior angle	

Figure 2



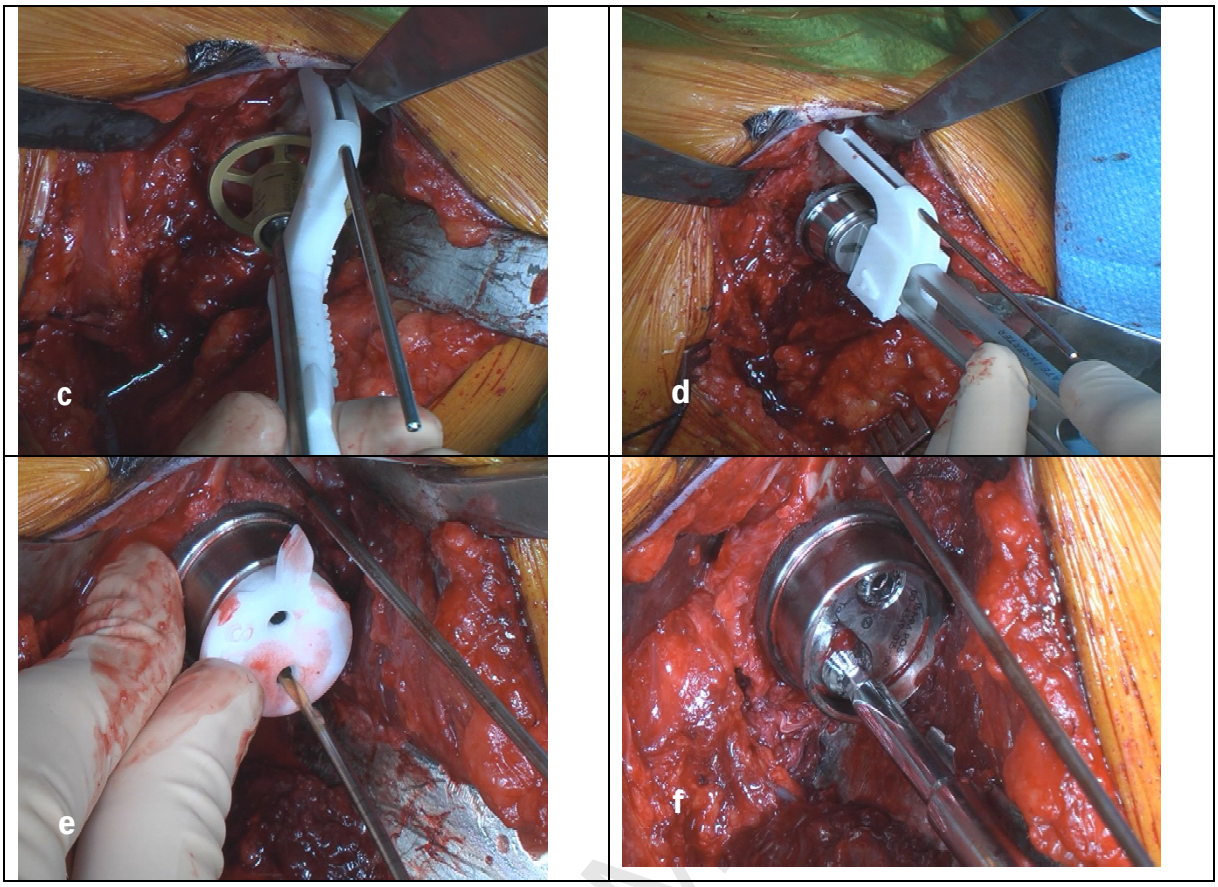


Figure 3.

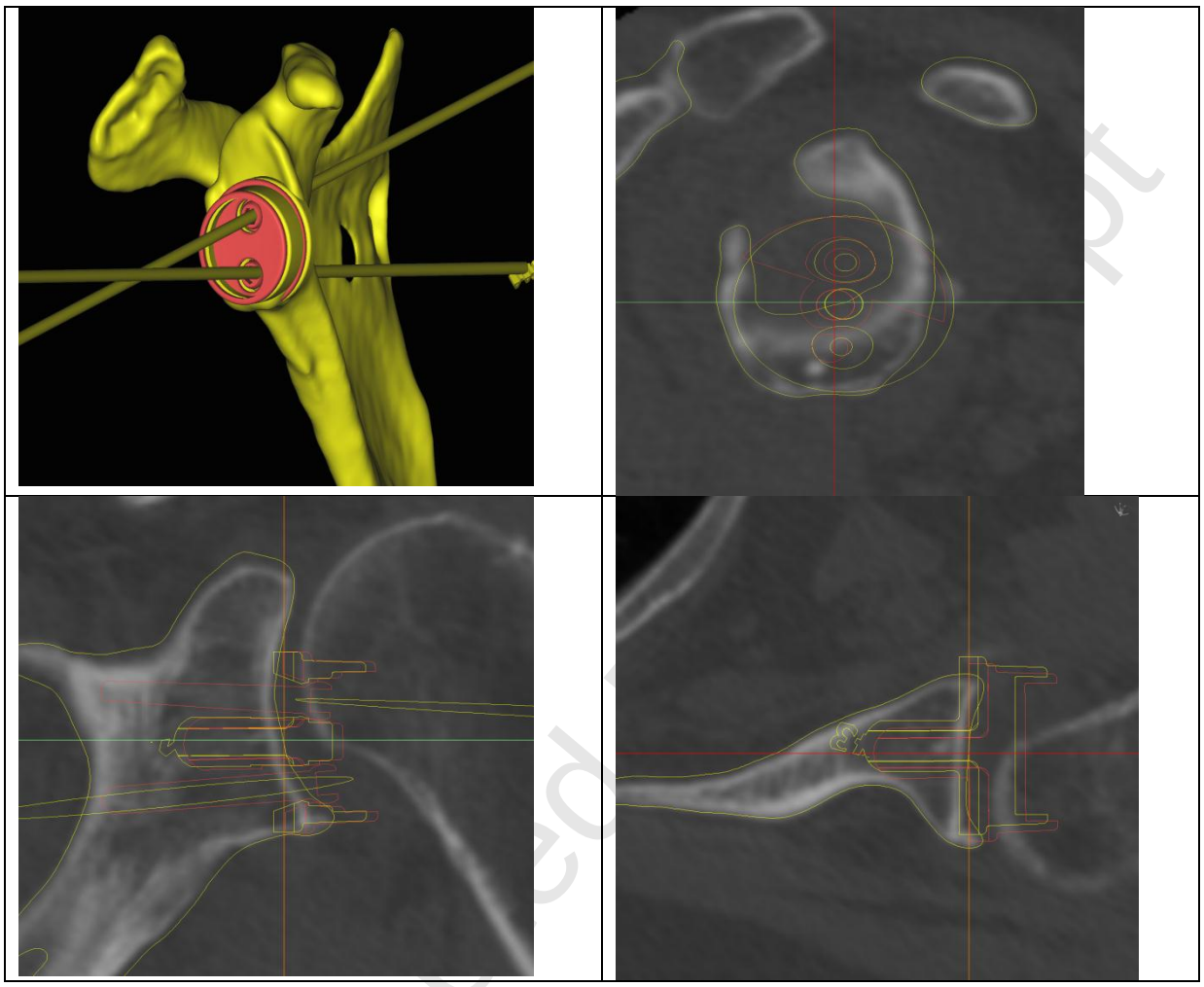


Figure 1.