Use of three-dimensional fluoroscopy to determine intra-articular screw penetration in proximal humeral fracture model

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Background: Proximal humeral locking plates have significantly improved the treatment of proximal humeral fractures in recent years; however, they are not devoid of complications. Inadvertent screw penetration into the joint is a well-documented complication. Intraoperative 3-dimensional (3D) imaging may assist in detecting intra-articular implant penetration. This study compared the performance of a standard C-arm fluoroscope with a novel 3D imaging fluoroscope in detecting penetrating implants in a proximal humeral fracture model.

Methods: Zinc-sprayed proximal humerus sawbones were affixed with a proximal humeral locking plate. Six different constructs were assembled. In each specimen, 1 screw, 2 screws, or no screws were inserted 2-mm proud of the articular surface. Each specimen was imaged with a conventional fluoroscope and a 3D imaging fluoroscope. Overall, 36 image sets were prepared for each modality. These were evaluated by 2 fellowship-trained surgeons for intraobserver and interobserver reliability as well for the accuracy of detecting prominent implants in the 2 imaging methods.

Results: Overall accuracy for observer A was 89.9% compared with 100% for C-arm fluoroscopy and 3D imaging fluoroscopy (P < .01) and for observer B was 91.1% and 100% (P = .01), respectively. The κ values were 0.74 with C-arm fluoroscopy and 1.0 for the 3D imaging fluoroscopy for observer A, and 0.93 and 1.0, respectively, for observer B.

Conclusions: In a proximal humeral fracture model, C-arm fluoroscopy is a highly accurate imaging modality that can minimize the incidence of penetrating screws into the joint. Further clinical studies are required to establish this modality.

Level of evidence: Basic Science Study, Imaging, Surgical Technique.

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reduction and internal fixation (ORIF) of proximal humeral fractures has gained popularity.\textsuperscript{1,6,13} ORIF has achieved excellent results in many patients; however, many recent reports describe a considerably high complication rate, especially in treating 3-part and 4 part-fractures with ORIF.\textsuperscript{2,7,8,19,23} These complications include loss of reduction, varus collapse, avascular necrosis, and screw cutout of the humeral head.\textsuperscript{7,8,15} The latter complication can occur as a primary complication or secondary to fracture settling due to medial instability.\textsuperscript{9} The screws in some patients, however, are originally placed penetrating into the glenohumeral joint, with a reported incidence of up to 10\% to 15\%.\textsuperscript{7,15} Because most of these procedures rely on conventional C-arm fluoroscopy as the single means of intraoperative imaging, missing intra-articular screw penetration is not avoidable.

In recent years, more sophisticated intraoperative imaging devices emerged that have enabled 3-dimensional (3D) imaging using specialized fluoroscopes. These were most useful in delineating the complex anatomy of intra-articular fracture reduction\textsuperscript{10,16,22} but also assisted in detecting inadvertent violation of joint spaces by screws.\textsuperscript{3} However, despite the potential advantages, clinicians did not commonly use these systems, probably due to their high cost, inferior image quality, and the at time, considerable radiation dose delivered to the patient and staff during each scan.\textsuperscript{21}

Recently, a prototype software module, C-InSight (Mazor Surgical Technologies, Caesarea, Israel), has emerged that allows the use of a conventional 2-dimensional C-arm fluoroscope, coupled with a target array, to capture and produce 3D fluoroscopic images similar to the ones produced by currently available 3D devices such as the Siremobil ISO-C3D (Siemens, Erlangen, Germany). Thus, intra-operative 3D imaging can now be performed with conventional fluoroscopes with the potential advantages of decreased cost and reduced radiation time. The goal of this study was to assess the accuracy and feasibility of the use of intraoperative 3D fluoroscopy compared with conventional 2D fluoroscopy in detecting intra-articular screw penetration in a proximal humeral fracture model.

Materials and methods

Zinc sprayed humeral sawbones (Sawbones, Vashon, WA, USA) were used. A PHILOS proximal humeral locking plate (Synthes, Oberdorf, Switzerland) was fixed to the bone using 6 locking screws inserted through its proximal part through holes designated A-I (Fig. 1).

Overall, 6 different constructs were created. Four constructs were made with a single, predefined screw (A, B, E, or I) inserted 2-mm proud of the articular surface, as measured using a caliper. The fifth construct had 2 predefined screws (F and H) inserted 2-mm proud of the articular surface, and the sixth construct had no penetrating screws.

Figure 1 A zinc sprayed sawbone with 6 screws fixed to the bone. The screws were designated A-I. Overall, 6 such constructs were assembled.

Each construct underwent C-arm fluoroscopy with a 12-inch OEC 9800 fluoroscope (GE, St. Giles, UK) using an anteroposterior, lateral, and 2 oblique views of 45° (Fig. 2).

3D fluoroscopic process

The C-InSight system consists of a computer station that feeds directly from the video output to a conventional C-arm unit, an image adaptor that mounts onto the C-arm image intensifier, and a multiuse plastic target, draped in a disposable sterile sheath, which is placed over the anatomic region of interest (Fig. 3). This plastic target is identical to the one placed during spine robotic surgery\textsuperscript{4} and was successfully tried clinically in our center in other anatomic regions such as the pelvis and wrist.

A continuous 20-second fluoroscopic scan is performed as the C-arm is moved through its entire arc of rotation (120°), while translating the C-arm forwards or backwards to keep the target at the image’s center. The software then calculates the position of the scanned anatomic object relative to the plastic target array. During the C-InSight scan, the system captures a real-time video stream of X-ray scans, and the frames are processed sequentially to determine the target array location because the region of interest may shift due to C-arm rotation. Once all frames are processed, the system can colocate them in space relative to the target array. Then, the image reconstruction process iteratively builds slabs similar to computed tomography (CT). Volume reconstruction and reformating produces axial, sagittal, and coronal images as well
as a 3D model in the Digital Imaging and Communications in Medicine format (Fig. 4).

Each construct was scanned 6 times using both imaging modalities. The specimens were repositioned after each scan to simulate a more realistic scenario in the operating room. Altogether, 36 sets of scans were produced for each modality and were archived on the C-InSight station.

Evaluation of scans

Of the 36 conventional fluoroscopic image sets, 6 PowerPoint (Microsoft Corp, Redmond, WA, USA) presentations were constructed, each containing 9 scans (4 images each) placed in a random order. Three of these image sets were duplicates selected in a random order by using the randomize option in Excel software (Microsoft Corp).

The C-InSight scans were stored in the computer comprising the station and sorted in a random order while the 18 duplicates were placed in between the scans.

Two shoulder and elbow fellowship-trained surgeons evaluated the conventional C-arm image sets and were asked to designate which screw(s), if at all, were penetrating the humeral head into the joint. Their decisions were marked on a special form. In addition, each evaluator, after a short introductory training, was instructed to evaluate the different 3D construct scans (including duplicates), and designate, in a similar manner, which screw(s), if at all, were penetrating into the joint.

Statistical analysis

The data were analyzed for interobserver reliability, intraobserver reliability, and accuracy. The power was 98%. Significance was set at a level of 0.05.

Accuracy was defined as the amount of detection of penetrating screws. For calculation purposes, the term “agreement with truth” was defined as complete (2 screws in cases of 2 screws or accurate screw detection), partial (1 of 2 screws), or null (no correlation with truth). The McNemar test was used for statistical analysis and interclass coefficient (κ value) was calculated.

SPSS 18 software (SPSS/IBM Corp, Chicago, IL, USA) was used for the analysis. All statistical analyses were performed by a biostatistician.
Results

The overall accuracy of both observers in detecting the correct protruding screw(s) using the conventional fluoroscopic images is summarized in Table I. Observer A had an overall agreement with truth, including complete and partial, of 88.9%, whereas observer B achieved 91.7% of overall agreement with truth.

When tested for accuracy using the C-InSight system, both observers achieved 100% agreement with truth, whereas observer A had 1 case of partial agreement and observer B achieved 100% complete agreement in all 36 scans (Table II).

The interobserver reliability was 72.2% using conventional fluoroscopy and 97.2% for the C-InSight system. These differences were statistically significant ($P < .01$).

Intraobserver reliability ($k$ values) were 0.74 with fluoroscopy and 1.0 for the C-InSight system for observer A and 0.93 and 1.0, respectively, for observer B ($P < .01$).

Discussion

Our study demonstrated a significantly better interpretation of screw penetration when using 3D fluoroscopy than a conventional 2D fluoroscopy in a proximal humeral fracture model. Despite conventional fluoroscopy being the gold standard imaging device in fracture surgery, it has an inherent limitation in detecting penetrating implants in 3D spherical structures. The fact that using this 3D novel system reduced the error of detection of penetrating implants from 9% to 10% to almost 0% confirms our initial hypothesis. The misdetection of 9% to 10% in the conventional 2D fluoroscopy is similar to the clinically described incidence of misplaced implants in the proximal humerus. Although it may be argued that many of the protruding screws are a result of secondary collapse and cutout, we and others argue that a certain proportion of cases result from initial screw malpositioning during surgery.

The phenomenon of misdetection of penetrating implants into joints is well described in experimental and clinical examples in the acetabulum, distal radius, and ankle. Although authors generally agree that fluoroscopy is limited in this respect, possible suggested solutions in case of suspected intra-articular implants are repositioning it intraoperatively or performing a postoperative CT scan. The authors of a study of the proximal humerus suggest using a blunt-tipped wire to assess the tactile impact of the bone to avoid penetration. The use of postoperative imaging can result in unnecessary secondary anesthesia and surgery that could have been prevented with appropriate intraoperative imaging.

The use of 3D fluoroscopy has been described as changing intraoperative decision making, not only for articular fracture reduction but also for repositioning of the implant. Despite the potential advantages of this modality, it has not gained vast popularity for several reasons. First, most systems require an isocentric movement (ie, rotation of the robotic C-arm around a fixed center of rotation). This may be performed rather easily in the foot and ankle on a radiolucent table but would be hard to achieve in shoulder surgery in a beach chair position. Possible collision with the patient’s head and torso would make this mode of imaging almost impossible. However, the C-InSight system used in this study does not depend on an isocentric axis but calculates it using the plastic
target array. Therefore, changes of axis during fluoroscopy are possible, avoiding collisions and making 3D fluoroscopy technically feasible in the clinical scenario.

Another potential advantage of the new system is the lower radiation dose delivered to the patient (approximately 20 seconds of standard fluoroscopic time) compared with a dose equivalent to 50% of limb CT delivered in other corresponding systems.  

Although intra-operative 3D fluoroscopes are often criticized for their poor image quality, we found it sufficient for 2 surgeons to detect intra-articular screw prominence. A previous study using the same system found it was inferior to other 3D imaging modalities, such as CT, but sufficient for detection of a clinically relevant articular malreduction in a cadaveric model.

A limitation of the study is the use of a high-contrast good-quality sawbones as a model that might positively bias the results compared with an osteoporotic bone with a thick soft-tissue envelope that may obscure the bone borders as seen on the image. Improving image quality with newer image-processing algorithms and better hardware may be required to solve this issue. Also, cadaveric studies with osteoporotic specimens, followed by clinical studies, are needed to validate our preliminary results. However, we stress that even with the high-quality bone image, the newer imaging modality improved detection of implant penetration missed by the 2D fluoroscopy.

Also, a limitation of the system is that the operation requires knowledge of the plastic target position and scan. Future improvement should make it more user-friendly and operable by common C-arm technicians rather than by special operators. In addition, the conventional fluoroscopy was done using 4 static images rather than a “continuous” fluoroscopy mode. Thus, theoretically, fewer missed screws would have been detected. However, even if the latter technique is being used in common practice, the rate of penetrating implants is still high. Also, for the ease of image analysis, the 2D fluoroscopic method had to be simplified for the purpose of image analysis.

Conclusions

Intraoperative 3D fluoroscopic imaging has a promising potential for significantly reducing the incidence of misplaced implant penetrating into the glenohumeral joint in ORIF of proximal humeral fractures. Future clinical studies and improvements in the systems are required to support this.

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References


