IS THE IMPLANT IN BONE? THE ACCURACY OF CT AND FLUOROSCOPIC IMAGING FOR DETECTING MALPOSITIONED PELVIC SCREW AND SI FUSION IMPLANTS

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ABSTRACT

Background: Spine fusions to the pelvis have been associated with increased strain to the sacroiliac joint (SI) and possibly continued postoperative low back pain. To minimize this, concomitant SI joint fusion at the time of lumbopelvic fixation has been advocated. This requires concomitant placement of sacral alar iliac screws (S2AI) for lumbopelvic fixation and triangular titanium rods (TTR) for the SI joint fusion. Traditionally, surgeons have mostly relied on fluoroscopic images to confirm final implant position and patient safety after pelvic instrumentation, although computer tomography (CT) has also been used.

Methods: We wanted to know which imaging modality, if any, was superior in helping to identify malpositioned implants during concomitant lumbopelvic fixation and SI joint fusion. We instrumented pelvic sawbones models with S2AI screws, TTR's, or both in the correct anatomic positions or malpositioned variants that led to known cortical breaches. Pelvic models were then imaged with fluoroscopy and CT, and the images assessed by blinded reviewers (spine surgeons and a musculoskeletal radiologist) for the presence of cortical breaches, the identity of the breached implant, and its direction. The responses of the blinded reviewers were then compared to the known position of the implants and Kappa coefficient calculated to determine agreement.

Results: We found that thorough evaluation of implant position with multiple fluoroscopic views (kappa 0.641) or CT imaging (kappa 0.906) al-

lowed reviewers to assess implant position, identity, and breach direction

Conclusion: These findings suggest that intraoperative CT imaging allows surgeons to make the best decision regarding implant position prior to leaving the operating room, thus potentially improving patient safety and unplanned returns to the operating room.

Level of Evidence: V

Keywords: spinopelvic fixation, SI joint fusion, intraoperative CT, sacral alar 2 iliac screws, triangular titanium rods

INTRODUCTION

Pelvic instrumentation is a common practice amongst spine surgeons. Most commonly, this is pursued during lumbopelvic fixation to increase construct rigidity and fusion rates in fusion surgeries extending to the sacrum.^{1,4} Extension of spine fusions to the sacrum has been associated with increased strain of the SI joint and continued postoperative low back pain.¹⁷ To minimize the pain from SI joint irritation after long fusions to the sacrum, surgeons have advocated performing concomitant SI joint fusion at the time of spinopelvic fixation. This technique involves placement of a triangular titanium rod (TTR) across the SI joint, just cephalad to an S2-Alar-Iliac (S2AI) pelvic screw. A prospective, randomized clinical trial is underway in order to investigate the clinical efficacy of this technique (SILVIA Study, clinicaltrials.gov, #NCT04062630). However, this emerging technique poses new challenges for spine surgeons, one of them being how to best determine implant containment within the narrow supra-acetabular bony corridor during concomitant lumbopelvic fixation and SI joint fusion (Figure 1). Pelvic anatomy is complex and its proximity to vital structures makes its instrumentation challenging. Traditionally, surgeons have relied on intraoperative fluoroscopic imaging for correct placement of implants. However, adequate imaging is not always possible and the difficulties with intraoperative fluoroscopic pelvic imaging are well documented in the orthopaedic literature.^{6-8,12} Obesity, bowel gas, and sacral dysmorphism have all been identified as negative predictors for obtaining useful fluoroscopic images that would allow for correct and safe placement of implants.⁹ In an effort to

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Figure 1. Intraoperative radiographs of open SI joint fusion with TTR in conjunction with S2AI spinopelvic fixation. (A) Inlet and (B) teardrop view, showing containment of implants within the supraacetabular bony corridor.

Figure 2. Example of instrumented pelvic model used for analysis. Fluoroscopic views: (A) Ap, (B) lateral, (C) outlet, (D) inlet, (E) Right iliac oblique, (F) right teardrop view. CT axial cuts showing (G) TTR's and (H) S2AI screws. (I) Picture of the imaged model showing the lateral TTR and medial S2AI screw breaches.

improve accurate implant placement and patient safety, some surgeons have adopted the use of intraoperative CT-based imaging. This has been shown to decrease the number of malpositioned implants, return to the operating room for revisions, as well as improving the safety of surgical interventions.^{10,8} The benefits of intraoperative CT imaging are not foreign to spine surgeons, where it has also been shown to reduce returns to the operating room to revise malpositioned pedicle screws.¹¹

Concomitant lumbopelvic fixation and SI joint fusion is a promising technique to help minimize continued postoperative back pain. Adequate visualization of the S2AI screw and TTR in the narrow supra-acetabular bony corridor is a technical challenge. Specifically, the presence of a second implant can cast radiographic shadows and obscure visualization, thus complicating imaging verification of implant position. To this date there is no published study on the ideal imaging modality, if any, to ensure accurate implant placement during this procedure and, thus, patient safety. With this in mind, we instrumented pelvic sawbones models with both S2AI and TTR's both in ideal positions, as well as various breached malpositions. We then used both fluoroscopy and computer tomography (CT) to image these pelvic models and asked blinded reviewers to determine the position of the implants and breaches, if any. The results

of this study will provide surgeons with guidance as to which intraoperative imaging modality, fluoroscopy versus CT, is superior at detecting malpositioned pelvic implants, particularly during concomitant lumbopelvic fixation and SI joint fusion.

METHODS

The design of this study was submitted and approved by the Institutional Review Board at our institution. Three female human sawbones pelvic models (SI Bone, Santa Clara, CA) were used for this study. S2AI Screws were placed into sawbones models in one of the following positions: 1) optimal anatomic placement in which the screw is entirely in bone, (2) violation of the sciatic notch, (3) hip joint violation, (4) medial wall violation, and (5) lateral wall violation. We then obtained anteroposterior (AP), lateral, inlet, outlet, iliac oblique, and teardrop fluoroscopic views of each specimen, and followed this with a CT scan (O-Arm, Medtronic, Minneapolis, MN). Next, TTR's (I-Fuse 3D, SI Bone, Santa Clara, CA) were placed cephalad to the S2AI implants trajectory in the same specimens in one of the following positions: (1) Optimal anatomic position, (2) medial wall violation, (3) lateral wall violation, (3) superior violation. The imaging was then repeated, as previously. Lastly, we then removed the S2AI implants, and imaged the

Table 1. Kappa Values of Single and Multiple Image Analysis for Fluoroscopy Versus CT Imaging

	Breach vs. No Breach	Identity of breached implant	Direction of breached implant
Fluoroscopy single view	-0.0987 (P = 0.9505)	0.0981 (p value not available)	N/A
Fluoroscopy multiple views	0.641 (0.344 - 0.923, p< 0.001)	0.521 (0.259 - 0.804, p<0.001)	0.576 (0.372 - 0.802, p<0.001)
CT imaging multiple views	0.906 (0.646 - 1.0, p<0.001)	0.776 (0.563 - 0.947, p<0.001)	0.7 (0.529 - 0.901, p<0.001)

Confidence interval and p value in parentheses.

TTR implants alone in a similar fashion. In all cases, the breached implant extended from the cortical margin by approximately 5mm, which is a distance shown to exceed tolerable anterior breaches into the abdominal or thoracic cavity from pedicle screws.¹³

Images from the CT scans and fluoroscopy were de-identified, randomized, and mounted in a PowerPoint presentation (Microsoft Office, Redmond WA). The fluoroscopic image analysis was performed in two different ways: single view and multiple view approach. In the single view analysis two reviewers, J.S and T.T, were asked to screen 41 individual images and make a determination on implant position based on a single fluoroscopic view (AP, lateral, inlet, outlet, iliac oblique, or teardrop view); one set of images was missing an AP view. In the multiple view fluoroscopic analysis, three reviewers (J.S.N, T.T, and D.P) were asked to screen seven sets of images with AP, lateral, inlet, outlet, iliac oblique, and teardrop view for any given pelvis model and implant combination. (Figure 2). The same pelvic models were reviewed in the single and multiple view analyses. Lastly, the reviewers evaluated the same pelvic models with CT scans, which included axial, sagittal, and coronal reconstructions. For the single view analysis, reviewers were provided with 21 axial, sagittal, or coronal stack images in video format for the given pelvic model and implant combination. For the multiple view analysis, the reviewers were provided with 7 different axial, sagittal, and coronal image stack for the same implant in video format. For each individual CT view or set of views, the reviewer was asked to state if there was an implant breach, and if so, which implant was breached, and lastly, which direction it was breached in.

For each analysis, agreement between the master key and the reviewer's responses was quantified with the kappa statistic using Stata software (College Station, TX) for three categories: 1) cortical breach or no cortical breach, 2) identity of breached implant (none, S2AI, TTR), and 3) breach direction (medial, lateral, superior, inferior). When significant (greater agreement than that due to chance, $P < 0.05$), the classic interpretation

of kappa as given by Landis and Koch was used as a guide: <0 = poor, 0-0.2 slight, 0.2-0.4 fair, 0.4-0.6 moderate, 0.6-0.8 substantial, 0.8-1 almost perfect.¹⁴ The kappa statistics were then averaged across the reviewers, and our results are presented as the mean.

RESULTS

Analysis of individual fluoroscopic images

When asked to analyze individual fluoroscopic views and determine if there was a breach, the reviewers' assessment of implant position yielded a mean kappa value of -0.0987 consistent with poor agreement. When there was a breach, their assessment of breach direction yielded a mean kappa value of 0.0981 (Table 1). When the analysis of single images was further broken down to assess if particular views (e.g: AP versus Inlet) were associated with a higher level of agreement with the master key, no view was found to help reviewers achieve a higher level of agreement with the master key.

Analysis of grouped fluoroscopy images

When asked to perform the analysis with the complete set of fluoroscopic images (AP, lateral, inlet, outlet, iliac oblique, and teardrop view), the reviewers' mean kappa value was 0.641, consistent with moderate agreement with the master key. Identification of implant identity, S2AI screw or TTR, yielded a mean value at 0.521, consistent with a fair agreement with the master key. Finally, determining breach direction yielded a mean kappa value of 0.576, consistent with fair agreement with the master key (Table 1).

Analysis of computed tomography images

Determination of presence of cortical breach yielded a mean kappa value of 0.906, consistent with an almost perfect agreement with the master key. Identification of implant identity yielded a mean kappa value of 0.776 consistent with substantial agreement with the master key. Finally, direction of implant breach yielded a mean kappa value of 0.7, consistent with substantial agreement with the master key (Table 1).

DISCUSSION

Pelvic anatomy is complex and intra-operative imaging can be difficult to interpret, making instrumentation technically challenging, particularly in patients with high BMI, large amounts of bowel gas, and dysmorphic pelvic anatomy. The aim of this study was to evaluate fluoroscopy and CT imaging as modalities to determine the accuracy of pelvic instrumentation intraoperatively. To this end, we instrumented pelvic sawbones models with S2AI screws, TTR's, or a combination of these, which were then imaged with both fluoroscopy and CT-based imaging. These images were then evaluated by blinded reviewers to determine whether there were cortical breaches, and if so, the identity of the breached implant and its direction.

When reviewers were provided with single fluoroscopic images, determination of implant position was poor with a kappa value of -0.0987. On the other hand, when reviewers were provided with a complete set of fluoroscopic images for the implant in question, their assessment improved significantly for both determination of implant breach and identity, kappa value of 0.641 (moderate agreement) and 0.521 (fair agreement), respectively.

These findings highlight one of the caveats of fluoroscopic imaging of complex three-dimensional structures such as the pelvis, namely the superimposition of anatomy. For example, when placing implants in the supra-acetabular region of the pelvis, a lateral view of the pelvis is appropriate to assess for breach into the sciatic notch; however, a lateral breach would not be necessarily apparent. Thus, by capturing a three-dimensional structure in a two-dimensional image, fluoroscopy can create the false impression that implants are located within bone, leading surgeons to make erroneous determinations about the location of placed implants. Along similar lines, this issue is compounded when more than one implant is placed into the supra-acetabular corridor. In the case of an S2AI screw and a TTR, the radiographic shadow casted by one implant can further obscure the anatomic landmarks that surgeons use to estimate the location, and thus safeness, of their implants. Based on our results. Based on our results, when using fluoroscopy surgeons need to obtain a complete set of views to ensure safe pelvic instrumentation during spinopelvic fixation, SI joint fusion, or both.

In contrast to fluoroscopy, CT imaging provides a high-resolution cross-sectional image, in different planes, of the target area, as well as its relationship to the implants placed. Our results are a testament of the power of CT at making anatomy more apparent, as it allowed reviewers to make the most accurate assessment when identifying cortical breaches (kappa 0.906),

the identity of the breached implant (kappa 0.776), and its direction (kappa 0.7). The cross-sectional nature of the images obtained with CT allows reviewers to have a higher resolution view of the relationship of implants to cortical anatomy. In turn, this would allow surgeons to minimize injury to nearby critical structures by leaving malpositioned implants. These findings are particularly relevant when performing concomitant spinopelvic fixation and SI joint fusion. During this procedure, a TTR (average implant size 7mm x 90 mm) and a S2AI screw (average implant size 9.5 mm x 90 mm) are placed in the supra-acetabular region of the pelvis. This bony corridor is very narrow, particularly along its cephalad aspect, and is bounded by critical neurovascular structures that can easily be injured by misplaced implants. As such, it is crucial that surgeons have the certainty that their implants are appropriately positioned before the patient leaves the operating room.

Our results echo those of most literature on intra-operative imaging during pelvic instrumentation. Recent studies have shown that surgeons tend to overestimate the accuracy of safe implant position when using fluoroscopy for pelvic instrumentation during orthopaedic trauma cases.¹⁵ Malpositioned screws during instrumentation for pelvic fractures have been documented to be as high as 15%, while neurologic injury has been as high as 7.7%.⁸ Obtaining quality fluoroscopic imaging is not always possible, and as such, some trauma surgeons have adopted intraoperative CT imaging for instrumentation of pelvic fractures, which has led to improvement in the accuracy of placed implants.⁸ Similarly, spine surgeons have shown that intraoperative CT imaging is associated with lower pedicle screw malposition rates, when compared to fluoroscopy, particularly in the thoracic spine.^{11,16}

This study provides guidance to surgeons during imaging of pelvic implants; however, some limitations should be noted. First, this is an in-vitro study using pelvic sawbones models. The sawbones models, although a reproduction of a human pelvis, do not replicate human bone density in magnitude or distribution. This factor could have affected the identification of anatomical landmarks used by reviewers to assess the position of their implants. CT imaging, with its higher resolution, can compensate for this and make identification of landmarks easier. In the future, an alternative to this would be to replicate the study with cadaveric pelvises. Second, we have a homogeneous group of pelvic sawbones models. Pelvic dysmorphisms is a known factor that complicates imaging and instrumentation of the pelvis, as such it is possible that our results and interpretation may be skewed towards non-dysmorphic pelvises. If this was the case and given the known difficulties with imaging

and instrumentation of dysmorphic pelvises, we would expect this to further widen the accuracy gap in favor of CT imaging at identifying malpositioned implants. As such, we felt that the small differences in morphology between normal and dysmorphic pelvic models were unlikely to change the core conclusion of this project, which is that CT was superior to fluoroscopy in detecting small breaches. And finally, how clinically relevant is the 5mm breach chosen for this study? We could not find a study addressing this question for pelvic instrumentation, yet during placement of pedicle screws in the thoracic spine a 5mm breach was considered to be clinically relevant.¹³ The supra-acetabular bony corridor where the S2AI screw and the TTR are placed is bounded by critical structures that can lead to death or severe disability, if injured. As such, we felt that the 5mm threshold was appropriate, particularly inferiorly and medially.

In summary, when fluoroscopy was used, single radiographic views in isolation were not useful in identifying breached implants or their direction. However, a complement of radiographs including AP, lateral, inlet, outlet, iliac oblique, and tear drop views improved the accuracy of reviewers' assessment significantly. Nonetheless, CT-imaging proved far superior for detection of malpositioned implants when performing open SI joint fusion in conjunction with S2AI screws for spinopelvic fixation.

CONCLUSION

When performing open SI joint fusion with TTR in conjunction with spinopelvic fixation using S2AI screws, CT-based imaging allows for the most accurate assessment of malpositioned implants. Fluoroscopy can also identify breaches, but if chosen it would be beneficial to have a complete radiographic review, including AP, lateral, inlet, outlet, iliac oblique and teardrop images.

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