Clinical Accuracy of the HipXpert System with the 3D Display and Anchoring Application; A Cadaveric Study

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Purpose:
The current study aims to determine the overall orientation and position accuracy of the HipXpert System using the 3D Display and Anchoring Application during clinical use.

Methods:
The entire process of clinical care was tested in this cadaver study including use of the HipXpert Planning Application, docking of the anterior and lateral HipXpert tools on the specimens, the HipXpert 3D Display and Anchoring Application running on the Hololens2, performing the surgical tasks in accordance with the projected files, and calculating the resulting angular and positional accuracy achieved on post-operative CT.

Eight hips from four cadaveric specimens were used for this study. Two of the specimens were male and two were female. Ages of the donors at the time of death were 29, 63, 69 and 71 years. Fiducial markers were placed (4.0mm titanium screws) so that co-registration of pre-operative and post-operative imaging studies could be achieved. CT studies of each specimen were performed pre-operatively. Each surgery was planned using the HipXpert Planning Application including creating 3D surface models, establishing the anterior pelvic plane coordinate system, and planning the docking of the anterior and lateral HipXpert tools. In addition, six 6.5mm cannulated Titanium screws were planned to be placed into the acetabulum of each hip. Screw placement was chosen to emulate cup placement for three reasons. First, planning and execution of screw placement is directly analogous to cup placement. Second, screw placement was the method performed for a predicate device (K190929). Third, placement of a cup allows for only one measurement per hip and screw placement allowed for the assessment of six measurements per hip.

Three-dimensional files for the pelvis, HipXpert tool, and screw trajectory for each screw was created and loaded onto the target device (Hololens2, MicroSoft Inc.) using a USB cable for projection using the HipXpert 3D Display and Anchoring Application. For each hip, two surgical procedures were performed to test the system using both the anterior and lateral HipXpert tools. The QR code tracker was 87.5mm^2. For the anterior tool, an anterior exposure was performed, the anterior tool was docked to bone and secured with two pins as described in the IFU, and then three screws were placed in accordance with the screw trajectory as projected using the HipXpert 3D Display and Anchoring Application. For the lateral tool, a posterior exposure was performed, the lateral tool was docked to bone and secured with two pins as described in the IFU (HipXpert Navigation System Instructions For Use Version LL-024 rev03), and then three screws were also placed in accordance with the screw trajectory again as projected by the HipXpert 3D Display and Anchoring Application.

The 6.5mm cannulated titanium screws (Synthes Inc) were placed by using a 2.8mm guide wire, drilling over the guide wire, and inserting the screws by hand using a hex-head screw driver. The bioskills methodology is depicted in the sequence of Figures 1-6. Please note that the photographs are taken using a camera from the right eye's vantage point during use of the application running on the target device.

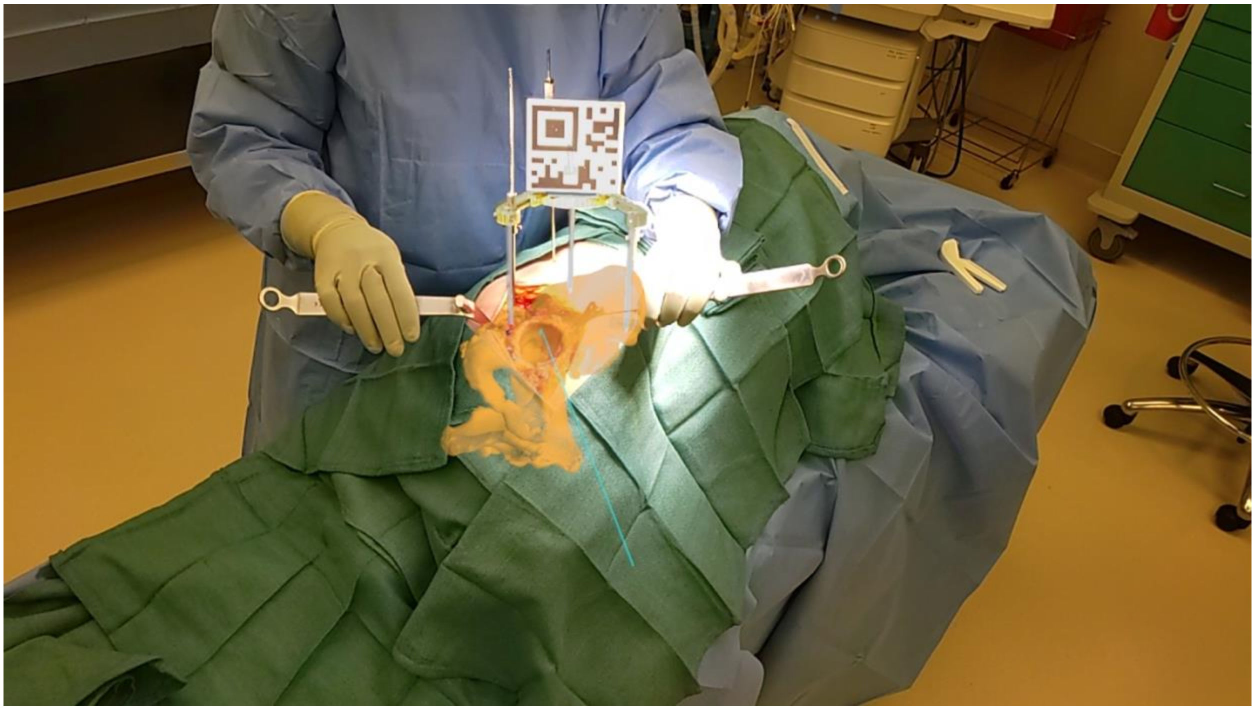


Figure 1. A bioskills specimen with an attached lateral HipXpert tool with superimposed projections of the pelvis, tool, and trajectory of a screw path displayed using the HipXpert 3D Display and Anchoring Application running on Hololens2.

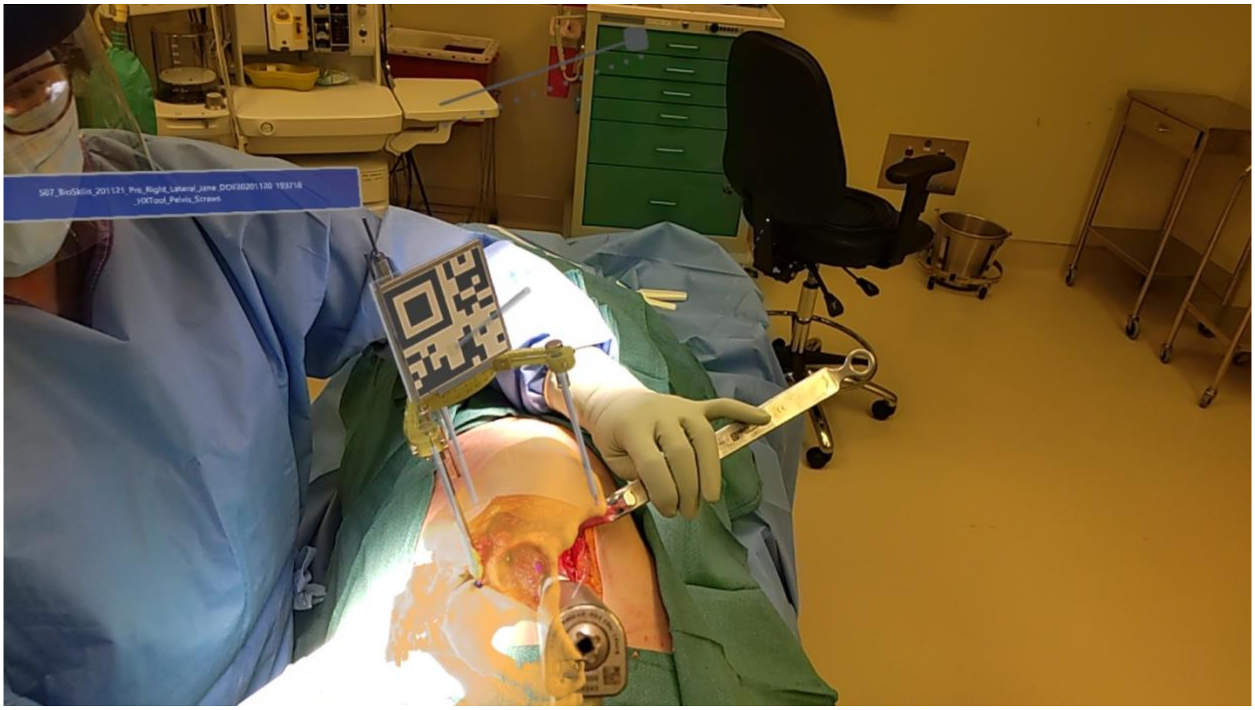


Figure 2. A bioskills specimen with an attached lateral HipXpert tool with superimposed projections of the pelvis, tool, and trajectory of a screw path (purple) and with a guide wire and drill aligned with the screw path trajectory.

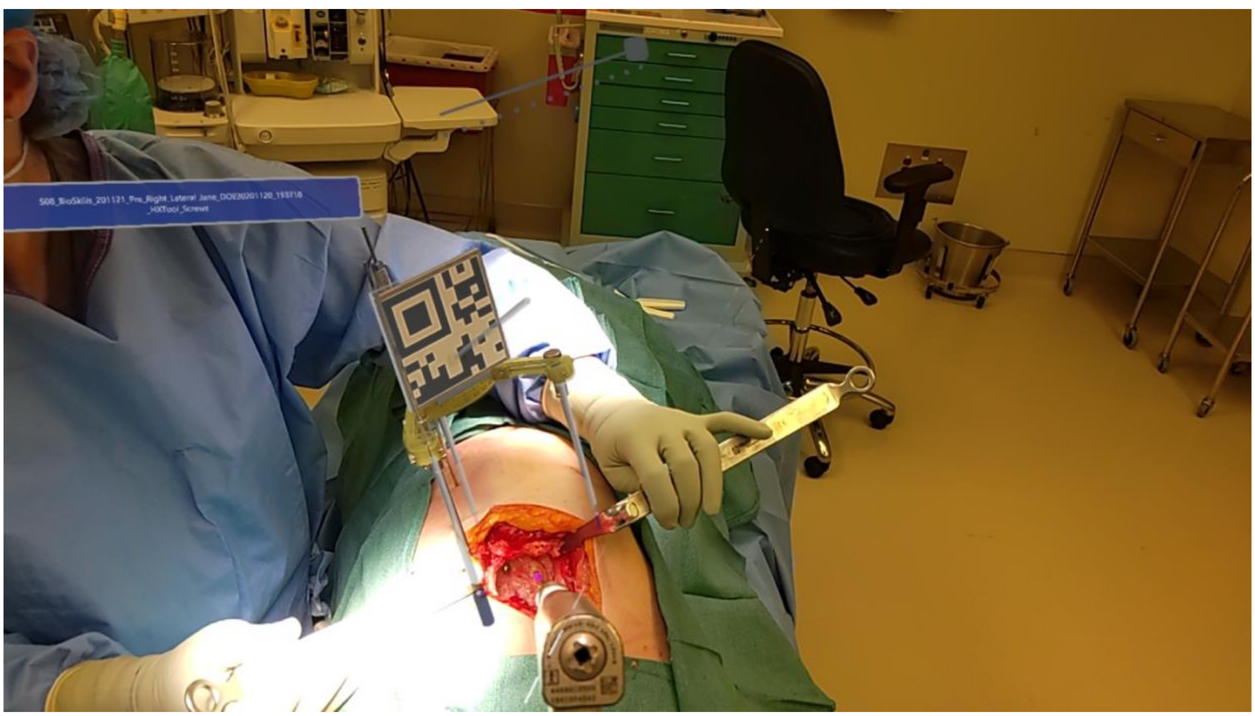


Figure 3. A bioskills specimen with an attached lateral HipXpert tool with superimposed projections of the tool, and trajectory of a screw path (purple) and with a guide wire and drill aligned with the screw path trajectory. This image is similar to Figure 2, but without display of the 3D file of the pelvis.

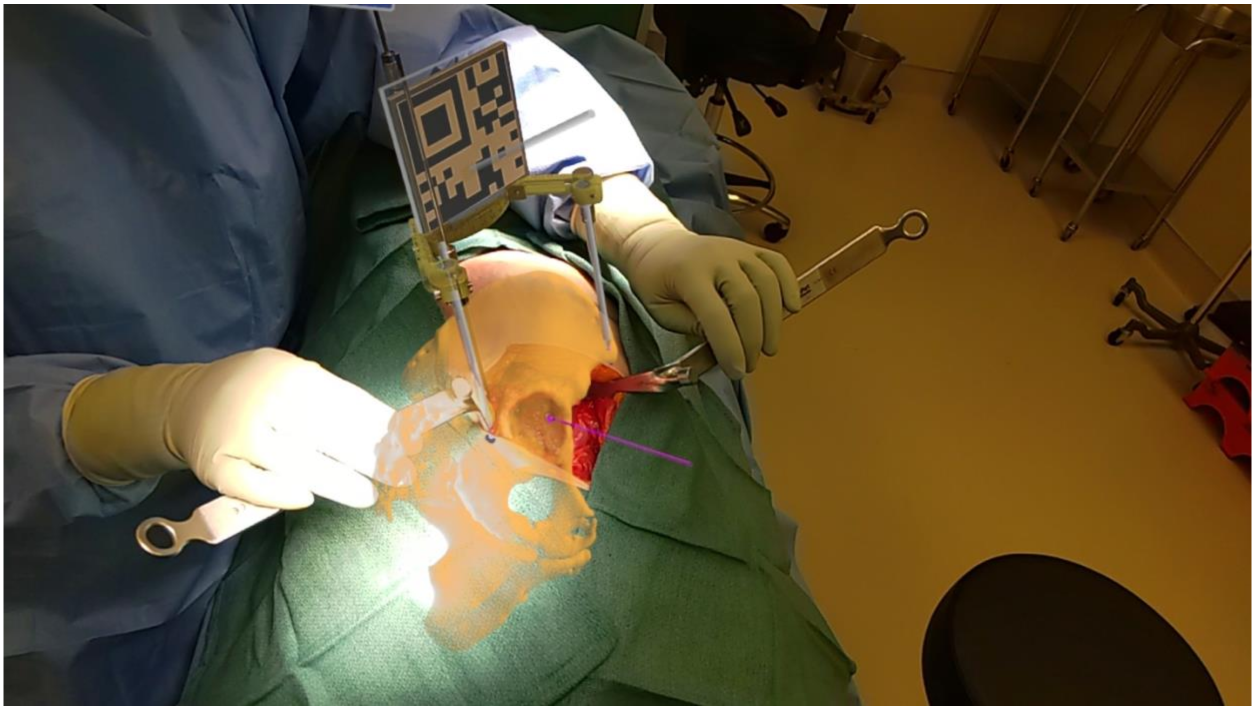


Figure 4. A 6.5mm cannulated screw placed in the pelvis. Superimposed are 3D projections of the HipXpert tooland planned screw trajectory (with 3D pelvis).

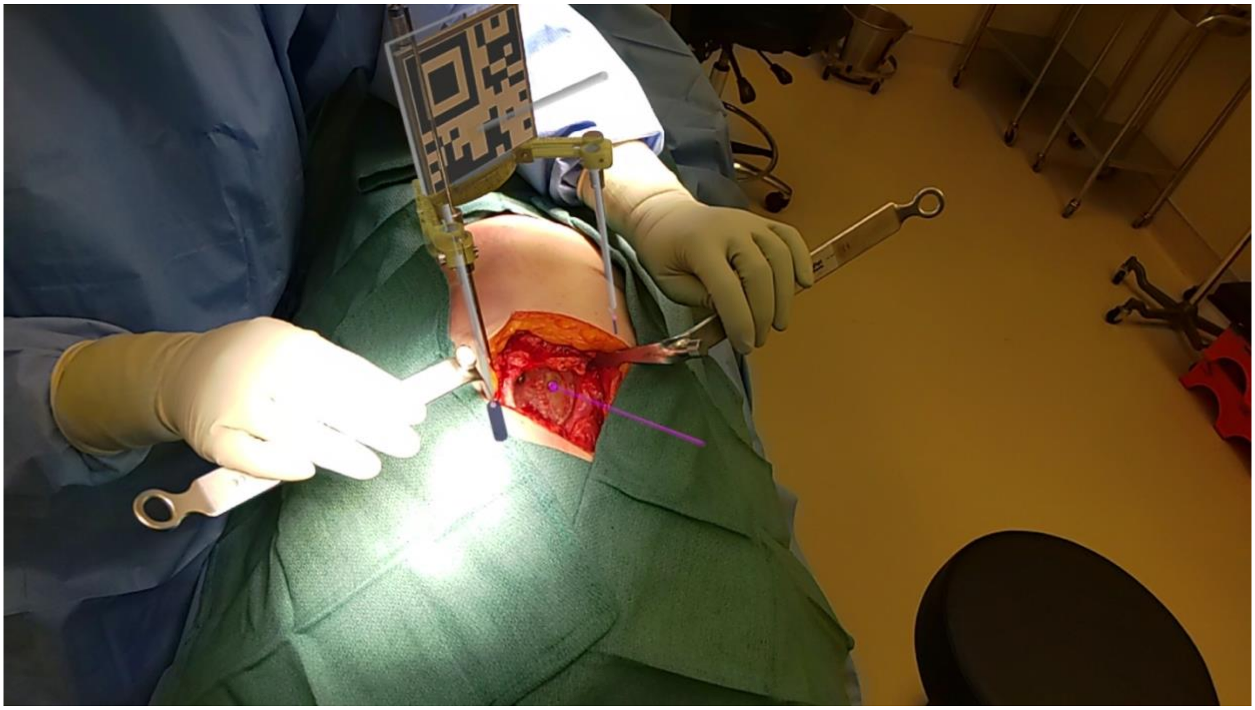


Figure 5. A 6.5mm cannulated screw placed in the pelvis. Superimposed are 3D projections of the HipXpert tool and planned screw trajectory (without 3D pelvis).

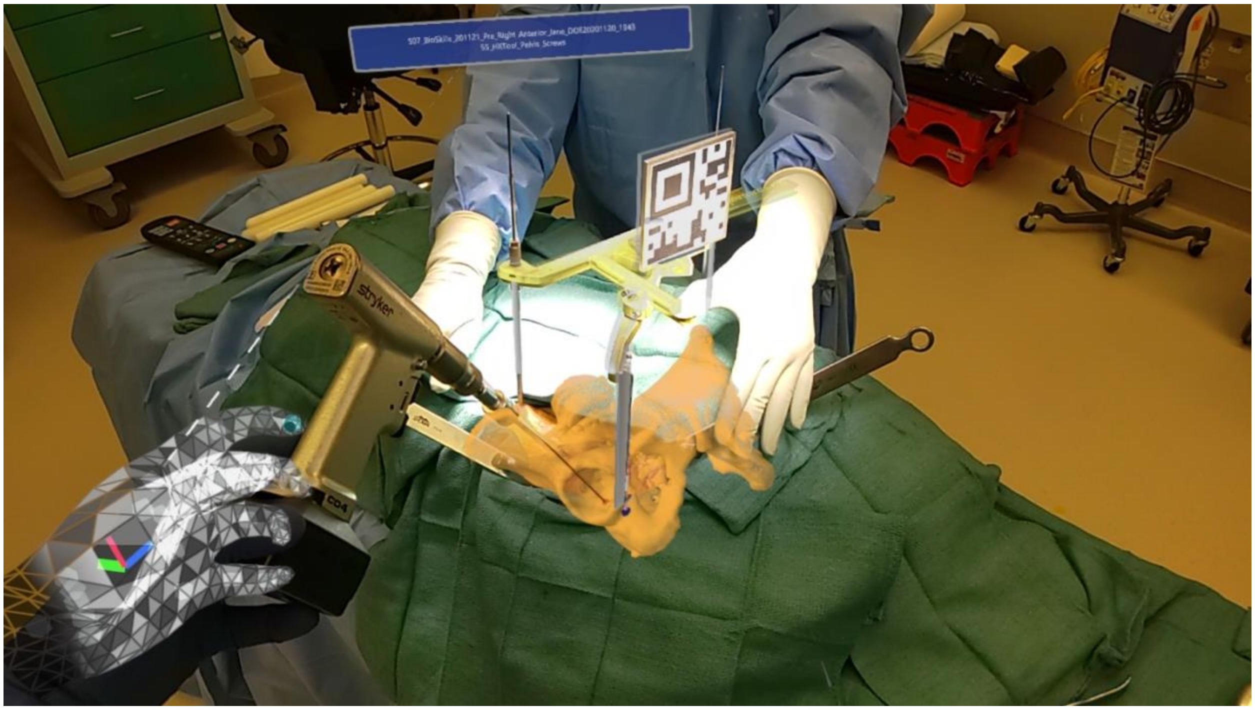


Figure 6. A bioskills specimen with an attached anterior HipXpert tool, a 2.8mm guidewire and a 6.5mm cannulated screw being placed in-line with superimposed projections of the screw trajectory, pelvis and tool.

For the first two specimens, 3D files of the trajectory with a 6.5mm screw head were projected (Figure 7).

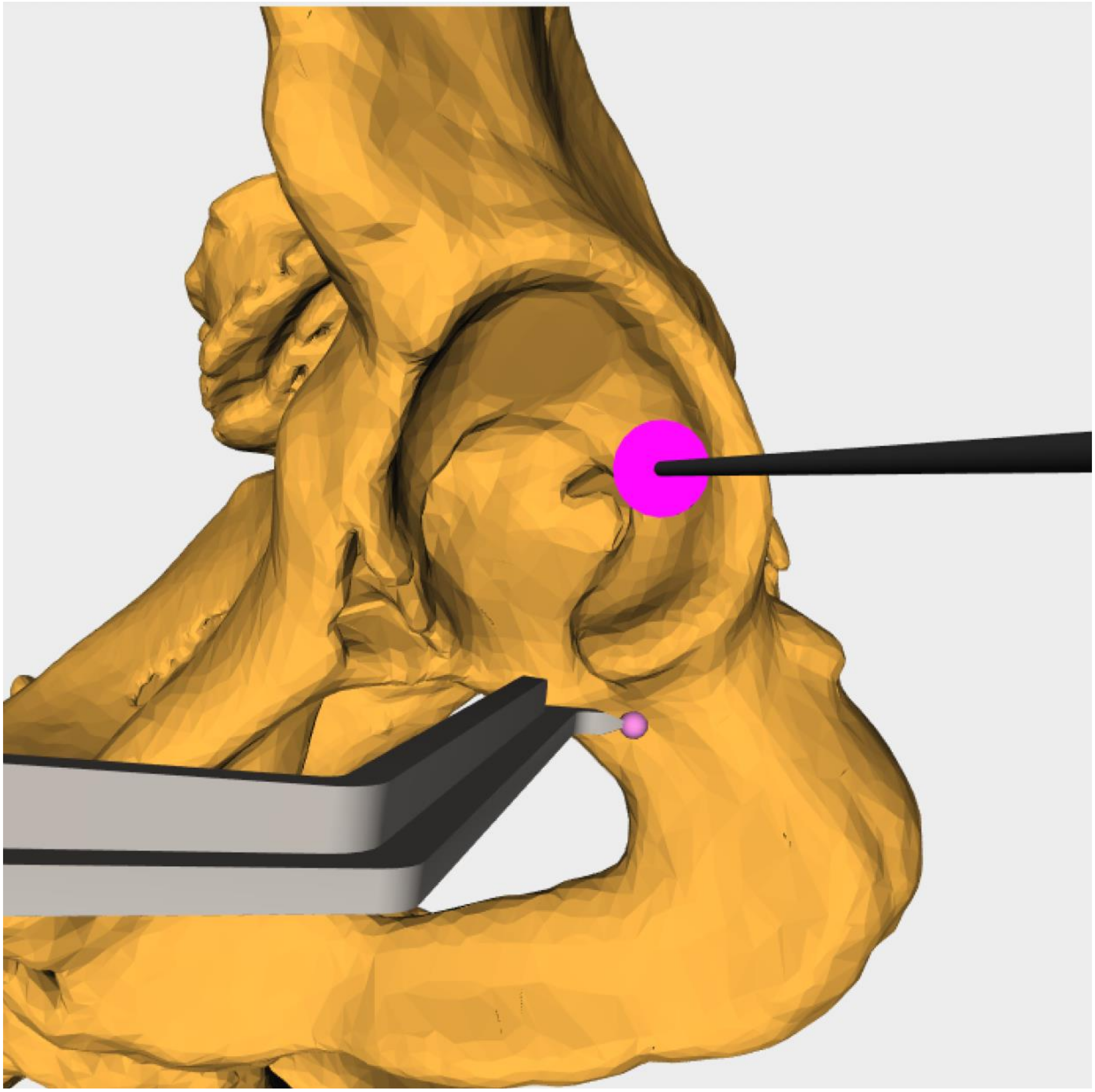
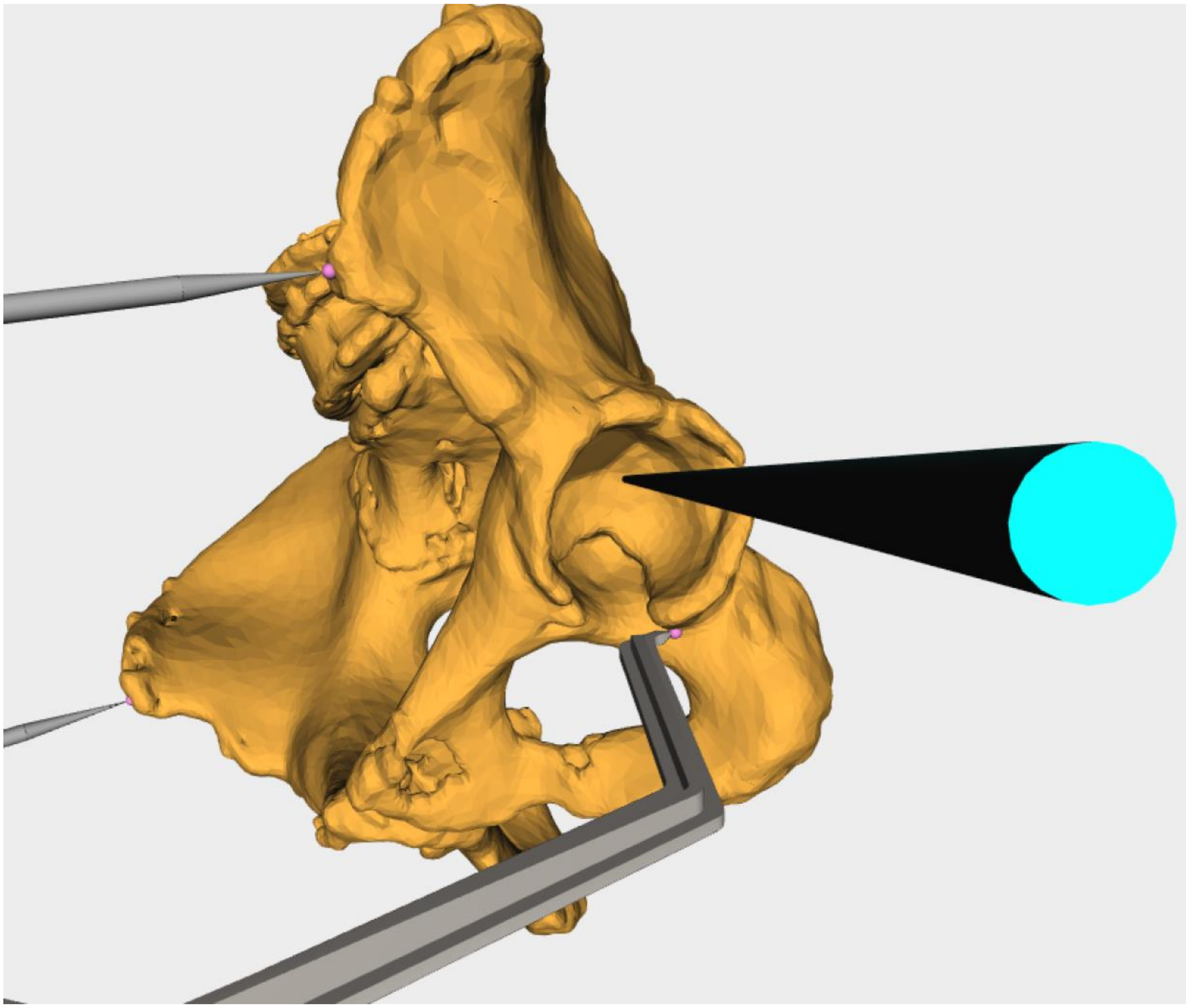


Figure 7. A 3D plan showing the planned trajectory of a 6.5mm screw using the anterior HipXpert tool. Note that the 3D file shows a 6.5mm diameter screw head.

This allowed for good visualization of screw trajectory, but we learned that the 6.5mm screw head display made it difficult to find the exact location of the planned entry point. As a result, the planning application was updated for the 3rd and 4th bioskills tests to display the 2.8mm guide wire without the 6.5mm screw head. This allowed for excellent visualization of the planned entry point and for us to be able to calculate the accuracy of both trajectory and bone entry position (Figure 8).



(Figure 8). Planning of the position and trajectory of the 2.8mm guide pin for placement of a 6.5mm titanium screw in a bioskills specimen. These plan files allowed the user to clearly see both the entry position and trajectory of the planned screw placement. This method was used for the third and fourth cadaver surgeries.

Postoperative Measurement:

Following each bioskills session with screw implantation, a post-operative CT was performed and the same anterior pelvis plane coordinate system was established using the fiducial markers (Figures 9A and B).

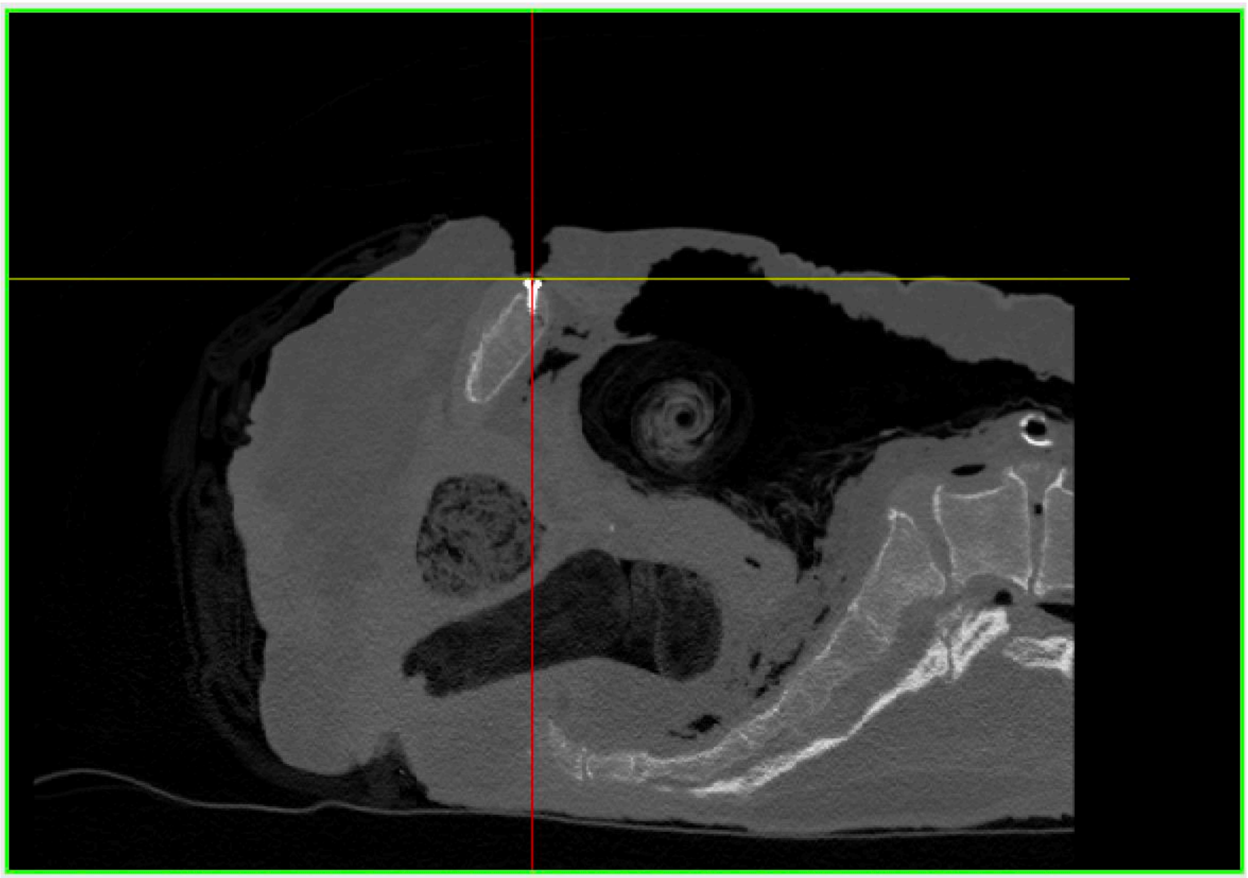


Figure 9A.

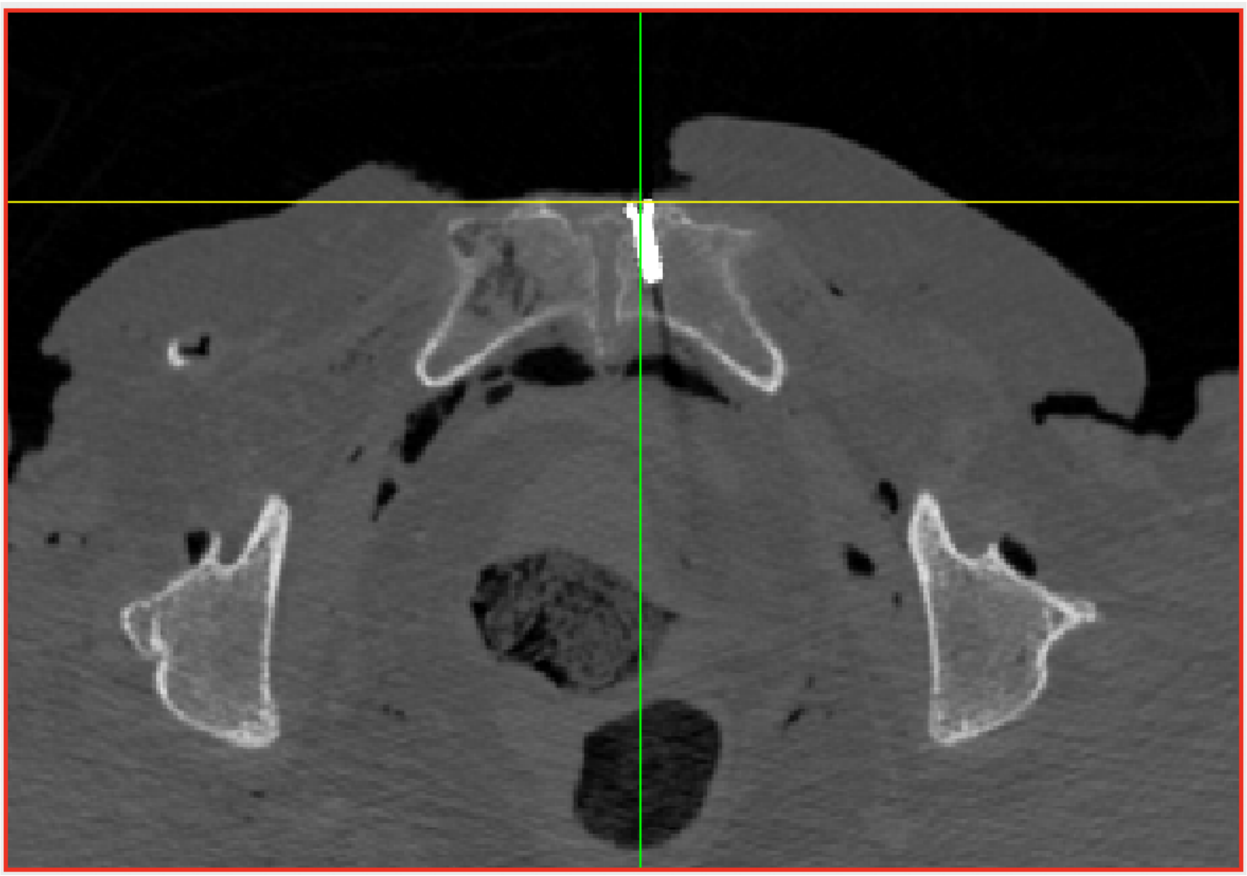


Figure 9B.

Figures 9A and B. These figures depict a 4.0mm screw used as a fiducial to mark the location near the pubis symphysis to allow for synchronization of the pre- and post-op CT studies. 9A: Sagittal view. 9B. Transaxial view.

For all eight hips in the four specimens, the achieved screw angle was calculated and compared to the planned screw angle to determine angular orientation accuracy. For the four hips in the later two specimens, achieved screw entry position was compared to the planned screw entry position to determine positional accuracy. The distance error was calculated as the three-dimensional linear distance between the planned screw entry point and the achieved screw entry point (Figures 10A and B).

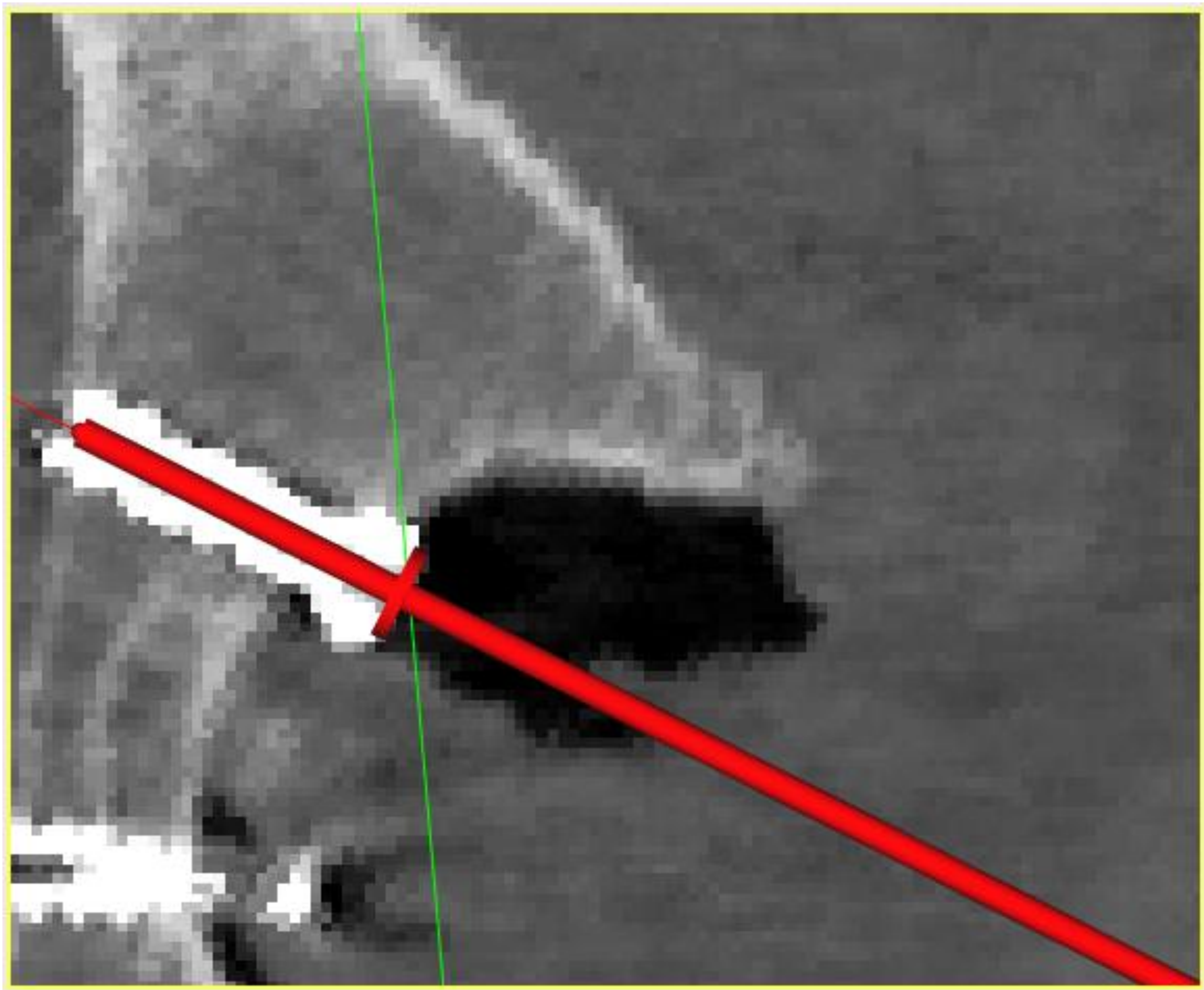


Figure 10A. 2D cross-sectional view of CT study showing calculation of the post-operative screw placement.

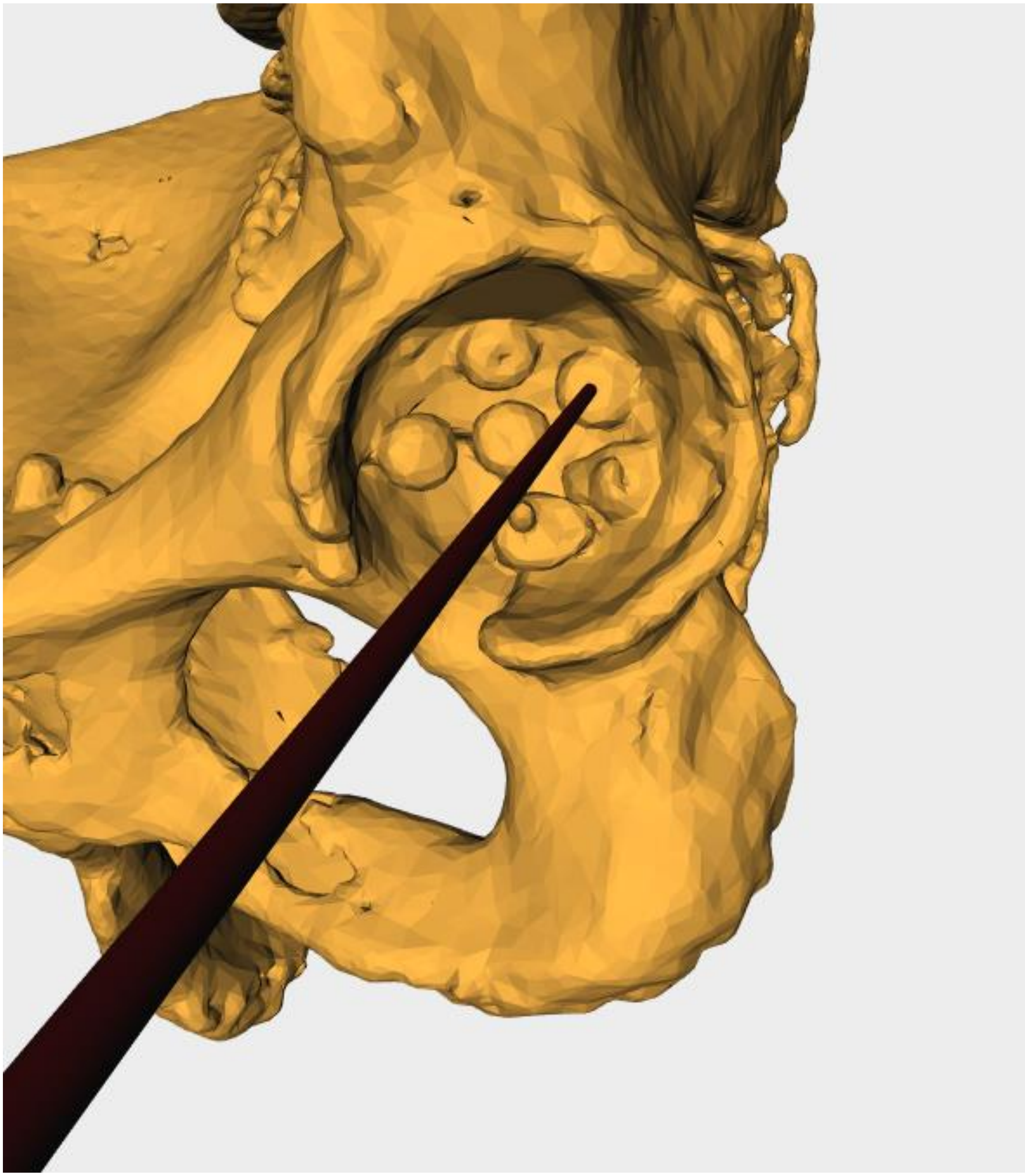


Figure 10B. 3D view of the Post-Operative CT study showing the trajectory of the achieved screw placement.

Results:

Orientation Accuracy
For the twenty-four screws implanted using the anterior HipXpert tool, compared to the planned trajectory, the achieved screw trajectory results are shown in Table 1.

Anterior HipXpert Tool	Anteversion Error (Degrees)	Inclination Error (Degrees)
Average (N=24)	-0.2	-0.5
Standard Deviation	1.4	1.7
Minimum	-3	-4
Maximum	2	2

Table 1. Orientation accuracy of screws placed using the HipXpert System with HipXpert 3D Display and Anchoring Application using the anterior tool.

For the lateral tool, there were twenty-three total measurements as one screw loosened during transport to the CT scanner. Compared to the planned trajectory, the achieved screw trajectory results are shown in Table 2.

Lateral HipXpert Tool	Anteversion Error (Degrees)	Inclination Error (Degrees)
Average (N=23)	1.4	-0.5
Standard Deviation	1.8	1.5
Minimum	-1	-4
Maximum	5	1

Table 2. Orientation accuracy of screws placed using the HipXpert System with HipXpert 3D Display and Anchoring Application using the lateral tool.

Position Accuracy
For the 12 screws implanted using the anterior HipXpert tool and HipXpert 3D Display and Anchoring Application, the distances between the planned and achieved screw entry positions are shown in Table 3.

Anterior HipXpert Tool	Distance Error (mm)
Average (N=12)	2.4
Standard Deviation	0.9
Minimum	0.3
Maximum	3.5

Table 3. Positional accuracy of screws placed using the HipXpert System with HipXpert 3D Display and Anchoring Application using the anterior tool.

For the 11 screws implanted using the lateral HipXpert tool and HipXpert 3D Display and Anchoring Application, the distances between the planned and achieved screw entry positions are shown in Table 4.

Lateral HipXpert Tool	Distance Error (mm)
Average (N=11)	**2.8**
Standard Deviation	**1.1**
Minimum	**1.2**
Maximum	**4.2**

Table 4. Positional accuracy of screws placed using the HipXpert System with HipXpert 3D Display and Anchoring Application using the lateral tool.

Discussion and Conclusion

The current study tested the clinical accuracy of the HipXpert system with the HipXpert 3D Display and Anchoring Application in a cadaveric study. This study aimed to incorporate all potential cumulative errors of the system including 3D model and coordinate system creation, the registration accuracy of the smart tools, the anchoring and 3D projection accuracy of the HipXpert 3D Display and Anchoring Application, and the physical ability to place an implant in the same trajectory and position as projected by the application.

The original HipXpert smart tool system was designed to solve the problem of cup malorientation in surgery and it does so[1,3]. The current cadaveric study demonstrates that the HipXpert system with the HipXpert 3D Display and Anchoring Application resulted in implant orientation accuracy of less than 5 degrees error for both anteversion and inclination for all 47 screw implantations using both the anterior and lateral tools. These results compare favorably to the prior clinical studies of the HipXpert system. Jennings et al[1] reported no cases of cup anteversion or inclination errors of more than 10 degrees, 12.8% of cases with inclination errors between 5 and 10 degrees, and 23.4% with anteversion errors between 5 and 10 degrees. Similarly, use of the system with the HipXpert 3D Display and Anchoring Application also compares favorably to a commonly used robotic system. Kanawade et al[2] showed that 12% of the cups implanted had inclination errors between 5 and 10 degrees and 16% had anteversion errors between 5 and 10 degrees when using the robotic system studied.

While the goal of the system is to solve the problem of cup orientation in surgery, we also tested positional accuracy. While positional accuracy of both the anterior and lateral tools using the HipXpert 3D Display and Anchoring Application was less than 3mm on average, we did have positional errors of more than 4mm. We designed the study to be able to place 6 screws into each acetabulum. This study has the advantage of being able to acquire more data per specimen. Such a study design does require that flexible (2.8mm) guide wires be placed into oblique surfaces which can be challenging to accomplish. Overall, we feel that current study demonstrates that the HipXpert system with the HipXpert 3D Display and Anchoring Application can be used to successfully achieve accurate implant orientation in the acetabulum.

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References:

1. **Jennings JM, Randell TR, Green CL, Zhen G, Wellman S. Independent Evaluation of a Mechanical Hip Socket Navigation System in Total Hip Arthroplasty. Journal of Arthroplasty. 31 (2016) 658-661.**

2. **Kanawade V, Dorr LD, Banks SA, Zhang Z, Wan Z. Precison of Robotic Guided Instrumentation for Acetabular Component Positioning. Journal of Arthroplasty. 30 (2015) 392-397.**

3. **Steppacher SB, Kowal JH, Murphy SB. Improving Cup Positioning Using a Mechanical Navigation Instrument. Clin Orthop Relat Res (2011) 469:423-428.**