

# A new 3-dimensional method for measuring precision in surgical navigation and methods to optimize navigation accuracy

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## Abstract

**Purpose** Description of a novel method for evaluation of pedicle screws in 3 dimensions utilizing O-arm<sup>®</sup> and StealthStation<sup>®</sup> navigation; identifying sources of error, and pearls for more precise screw placement.

**Methods** O-arm and StealthStation navigation were utilized to place pedicle screws. Initial and final O-arm scans were performed, and the projected pedicle probe track, projected pedicle screw track, and final screw position were saved for evaluation. They were compared to evaluate the precision of the system as well as overall accuracy of final screw placement.

**Results** Thoracolumbar deformity patients were analyzed, with 153 of 158 screws in adequate position. Only 5 screws were malpositioned, requiring replacement or removal. All 5 were breached laterally and no neurologic or other complications were noted in any of these patients. This resulted in 97 % accuracy using the navigation system, and no neurological injuries or deficits. The average distance of the screw tip and angle of separation for the predicted path versus the final pedicle screw position were analyzed for precision. The mean screw tip distance from the projected tip was 6.43 mm, with a standard deviation of 3.49 mm when utilizing a navigated probe alone and 5.92 mm with a standard deviation of 3.50 mm using a navigated probe and navigated screwdriver ( $p = 0.23$ ).

Mean angle differences were 4.02° and 3.09° respectively ( $p < 0.01$ ), with standard deviations of 2.63° and 2.12°.

**Conclusions** This new technique evaluating precision of screw placement in 3 dimensions improves the ability to define screw placement. Pedicle screw position at final imaging showed the use of StealthStation navigation to be accurate and safe. As this is a preliminary evaluation, we have identified several factors affecting the precision of pedicle screw final position relative to that predicted with navigation.

**Keywords** Pedicle screw · Navigation · Free-hand · O-arm

## Introduction

Pedicle screw placement has evolved since King first described internal fixation of the spine with screws, Boucher directed these screws into the pedicle, and Roy-Camille combined screws into the pedicle with plate fixation [1–3]. Over time several techniques for placement of these screws have been employed, including the use of anatomic landmarks, laminotomy with palpation of the pedicle, plain radiography, standard fluoroscopic imaging, fluoroscopic image guidance, and computed tomography (CT) image guidance. However, with each technique, variability in patient anatomy continues to make the accurate and precise placement of screws difficult. Morphometric analysis of the thoracic and lumbar spine has identified variability in the pedicle anatomy throughout the spine [4–7]. Differences in pedicle anatomy have been shown to vary with many parameters including patient height [8]. This variation is even greater in the setting of deformity, leading to increased risks with the placement of

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pedicle screws [9]. Evaluation of the relationship between pedicle anatomy and pedicle screw placement has identified landmarks used to assist in the placement of pedicle screws, but pedicle breaches and misplaced screws continue to be an issue [4–7, 10].

Misplaced screws can lead to vascular injury, neurologic injury, dural tears, and pedicle fractures that can compromise stable fixation [11]. The incidence of neurological complications associated with pedicle screw placement has been reported to be between 1 and 3 % [11, 12]. Studies evaluating the use of anatomic, open laminotomy, radiographic and fluoroscopic techniques have shown significant variation in the accuracy of screw placement. In a study by Vaccaro et al. [13], 90 screws were placed in T4–T12 pedicles with a reported rate of 41 % screw misalignment. In the study by Weinstein et al. [14], they reported 21 % screw misalignment in cadaveric specimens. Other in vivo and cadaveric studies have shown a wide range of pedicle screw breach rates ranging from 16 to 55 % [15–18]. In patients with vertebral rotation and anatomic dysmorphism secondary to scoliosis, these rates have been documented to be in a similar range [19–21]. In a comparative study by Belmont et al. [22] 59 % of screws were found to be fully contained in the pedicle from T9–T12 (42 % for all pedicles) in patients with coronal imbalance versus 73 % (and 62 % for all pedicles) in those without coronal deformity. For this reason many studies have suggested the use of preoperative CT scans to improve the accuracy of pedicle screw placement [4–6, 17]. With the advent of computer-assisted systems, preoperative CT scans can be used intraoperatively to navigate pedicle screw placement. Several studies have reported misplacement rates ranging from 4.5 to 8.5 % using such systems [23–26]. Youkilis et al. [26] reported their experience using computer navigation in 224 pedicle screws, with only 19 (8.5 %) cortical breaches. Of those, only five (2.2 %) were reported to represent unintentional structural breach. In a larger cohort, Nottmeier et al [25] reported on 1084 screws placed with either BrainLAB Vector Vision® (BrainLAB Inc., Munich Germany) or Medtronic StealthStation Treon® (Medtronic Inc., Minneapolis MD). Of the 1084 screws, 951 were graded by an independent evaluator and a breach rate was found to be 7.5 %. Of note, two nerve root injuries were reported in the cohort (0.2 % screw incidence rate and 0.9 % patient rate.) Another advance has been the use of Isocentric 3-D fluoroscopy. Reported rates of screw malpositioning have been between 1.7 and 5 % [27, 28]. Intraoperative CT-based navigation systems have also been developed and are the method utilized in this study. Evaluation of pedicle breach rates have ranged from 2.5 to 5.2 % in several studies looking specifically at O-arm® (Medtronic Inc, Minneapolis MN) and StealthStation navigation [29, 30].

In a comparative analysis done by Amiot et al. [31], computer-assisted pedicle screw placement was found to be statistically more accurate, with 95 % of pedicle screws fully contained, compared to 85 % in the conventional techniques. In the conventional group, 5 screws were found to be >4 mm out of the pedicle cortex, and 7 patients required repeat surgical management due to neurologic deficits compared to 0 in the computer-assisted group. In a more recent comparison of patients undergoing pedicle instrumentation with scoliosis by Kotani et al. [32] the perforation rate was 11 % with the use of fluoroscopy and 1.8 % for computer-assisted navigation. A recent systematic literature review showed the use of CT-based navigation provided the greatest overall accuracy compared to fluoro-based navigation, fluoroscopy techniques, and free-hand pedicle screw placement [33].

The apparent value of various computer-assisted guidance systems has been born out in the literature. However, the systems used for gradation of pedicle screw placement are limited. As with reported data in this study, pedicle breaches may be documented but non-consequential. Documenting breaches alone does not guide the surgeon in techniques to correct screw placement. Further, these systems fail to take in account the pedicle screw angulation in multiple planes, and ultimately the three-dimensional position of the screw in the pedicle and vertebral body. It has been suggested that a better grasp of the pedicle isthmus is more likely to improve screw placement [34]. The inherent lack of valuable information was suggested by Ortel et al. [35] who indicated that further evaluation of the precision of navigated projections are needed.

As described above, previous research has investigated the accuracy of pedicle screw placement using various techniques. However, these studies have focused specifically on the accuracy of screw placement in terms of breaches, rather than the precision of virtual projections compared to final screw positions. Thus, the purpose of this study was to describe a new method for assessing the precision of navigated pedicle screw placement, and to provide initial results of our analysis on the precision of virtual projections and final pedicle screw placements. We also describe several potential causes of error, and provide recommendations to minimize error when using the O-arm and StealthStation Navigation.

## Materials and methods

After local IRB approval, a consecutive series of patients undergoing posterior spinal fusion were recruited and consented for inclusion in the study. Patients from aged 18–75 already scheduled to undergo thoracic and/or lumbar posterior spinal fusion procedures with instrumentation

using O-arm and StealthStation (Medtronic Inc, Minneapolis, MN) at the University of Colorado Hospital were included in the study. Exclusion criteria included (1) pregnancy, and (2) revision surgeries with previous pedicle screw instrumentation.

Surgeries were performed at The University of Colorado Hospital in Denver, Colorado by two attending surgeons, V.P. and E.B. and their physician's assistants, residents and/or fellows. After standard preparation and surgical exposure, a reference array was attached to a selected spinous process for registration and the O-arm was brought in for initial imaging (1st scan.) Images were transferred to the StealthStation system for navigation and a navigated probe was used to verify the pedicle entry point. Pilot holes were made with a high-speed burr. The navigated pedicle probe was then used to create a path down the pedicle into the vertebral body in the ideal screw position. This path projection was saved. Screw length was chosen based on the depth marks etched on the probe and based on a projection of a simulated screw over the probe. The pedicle tract was palpated using a ball-tipped feeler probe and screws were placed with either a standard or a navigated screwdriver. The projected path of the screw based on the navigated screwdriver was also saved. We did not delineate the use of Medtronic's navigated driver, from the SureTrak device with driver, or the use of a driver without navigation in this initial evaluation. After all screws were placed, a final intraoperative O-arm CT scan (2nd scan) of the region was obtained to confirm proper placement of the screws. Somatosensory evoked potential (SSEPs) and stimulus-evoked EMG was monitored during surgery in all patients. Rods and setscrews were then placed on each side to complete the screw rod construct.

### Pedicle screw accuracy analysis

Final intraoperative O-arm CT scans were assessed for screw placement accuracy by two independent observers. The grading scale for pedicle screw positioning is shown in Table 1, and is similar to that described in several previous studies [36]. The direction of breaches, as well as the vertebral level of the breaches, was noted. A separate analysis of screws based on the method of placement (Medtronic navigated driver, SureTrak with a driver, or driver without navigation) was not calculated for this initial

**Table 1** Grading for pedicle screw placement

Grade
I. In pedicle
II. Breach <2 mm
III. Breach 2–4 mm
IV. Breach >4 mm

study. Three systems were used; Medtronic Solera, DePuy-Synthes Matrix, and Medicrea Pass LP.

### Navigation projection analysis

Intraoperative O-arm navigation datasets from the 1st scan were compared to the 2nd scan (final intraoperative O-arm CT scan) datasets to assess precision of the virtual projection as compared to final screw position. The first part of data extraction consisted of merging the 1st scan and 2nd scan to put them in the same coordinate system. After importing the data, Medtronic StealthMerge software (Medtronic Inc, Minneapolis, MN) was used to lay the 1st and 2nd scans on top of each other in all three dimensions. If there was no significant movement between the 1st and 2nd scans, the process was relatively straightforward. In some cases, however, the process was more complicated. For example, in deformity correction cases, it was only possible to overlay a few vertebrae at a time; so multiple merges were required to obtain relevant coordinate data. The process of sliding and rotating these images was recorded by the software, and was later output as a transform matrix. This matrix was used to link 1st scan coordinates to 2nd scan coordinates.

Once this was completed, the trajectories were created to describe the final screw position. This was achieved by going through the 2nd scans in all cross sections to locate the screw tips and entry coordinates. Final trajectories and the transform matrix in the final screw placement space/coordinate system were extracted to Excel. Matrix multiplying the post-operative coordinates by the transform matrix (using Excel function "MMULT") outputted all the entry and target coordinates, but now in reference to the 1st scan coordinates. The 1st scan data: the probe and screwdriver plans were then similarly extracted to Excel. Using Excel, we measured the distances and angles between the 1st scan targets and 2nd scan screw trajectories.

To calculate the distances between the targets of the various trajectories, the three-dimensional distance formula was used:

$$\text{Distance} = \sqrt{(x_1 - x_2)^2 + (y_1 - y_2)^2 + (z_1 - z_2)^2}$$

where the subscripts correspond to the desired trajectory and their  $x$ ,  $y$ , and  $z$  coordinates.

To calculate the angle ( $\theta$ ) between the various vectors, the following formula was used:

$$\vec{A} \cdot \vec{B} = \|\vec{A}\| \|\vec{B}\| \cos \theta$$

$$\cos \theta = \frac{\vec{A} \cdot \vec{B}}{\|\vec{A}\| \|\vec{B}\|}$$

$$\theta = \cos^{-1} \left( \frac{\overline{A} \cdot \overline{B}}{\|\overline{A}\| \|\overline{B}\|} \right)$$

Target distances and trajectory angles were then calculated from the coordinate data extracted from the StealthStation.

## Results

### Pedicle screw accuracy analysis

A total of 158 screws (118 with final-probe and final-screwdriver analysis and 34 with final-probe only analysis) were studied. After analyses, 153 of 158 screws were found to be in an acceptable position. Overall, 94 % of the screws were grade I/II when final positions were analyzed and 97 % of the screws were in a safe position without need to reposition based on intra-op O-arm CT images. Eighty-one percent of the screws were fully contained in the pedicle, and 13 % of screws had breached by <2 mm. Only 5 of 158 screws were grade IV and were removed or repositioned; this was performed during the same procedure without need for return to the OR. Of these, all 5 were lateral breaches. There were no neurologic complications noted from the mal-positioned screws. Table 2 shows the distribution of screw grades and the direction of screw mal-positioning.

### Navigation projection analysis

The results of navigation precision analysis, which compared virtual projections to final screw positions, are shown in Table 3. In regards to three-dimensional mean differences between the tip of the projected track and the final screw tip position, the navigated screwdriver showed a non-significant trend towards increased precision as compared to the probe (5.92 mm difference vs. 6.43 mm, respectively;  $p = 0.23$ ). This measurement did not include directional analysis and therefore can include differences in screw depth. In regards to angular measurements, the navigated screwdriver projection was significantly closer to

the final screw position than that of the probe (3.09° difference vs. 4.02°, respectively;  $p < 0.01$ ).

The boxplots show where the bulk of the data lies, but they also identify statistical outliers (the starred points in Fig. 1). Overall, final screw placement compared to planned trajectories fell within a small area. Figure 2 shows the technique utilized for analysis.

## Discussion

Proposed advantages of intraoperative navigation methods include decreased radiation to the surgeon and staff, improvement in accuracy of screw placement, and the ability to intraoperatively evaluate and correct pedicle screw position. At least four studies have reported on decreased radiation exposure to the surgeon and operative staff with the use of computer-assisted navigation techniques, even with the use of intraoperative three-dimensional imaging [37–40]. They have also evaluated patient radiation doses with O-arm imaging prior to and after instrumentation placement. While the intraoperative dose of radiation is higher, overall radiation dosing is similar to fluoroscopic techniques requiring either a single pre- or post-operative CT scan [38]. With a second O-arm CT image, after instrumentation placement, final screw position can be evaluated and malpositioned screws can be adjusted prior to closure of the wound.

Previous studies have investigated the accuracy of navigation systems for pedicle screw placement. However, these studies have primarily focused on measuring the accuracy of the screw relative to the pedicle, rather than the precision of the virtual projection compared to the final screw position. In the present study, we describe a new method for accuracy analysis in which O-arm navigation datasets are merged and the 3-dimensional placement of pedicle screws relative to their planned trajectories is quantified. By evaluating the placement of pedicle screws relative to their planned trajectories, we are attempting to improve the precision with which such systems may be utilized and provide detailed analysis of screw placement. While the “perfect” screw placement has not been described, analysis has been limited. This technique provides a detailed analysis, which can be combined with further research to determine the most appropriate position for pedicle screw placement.

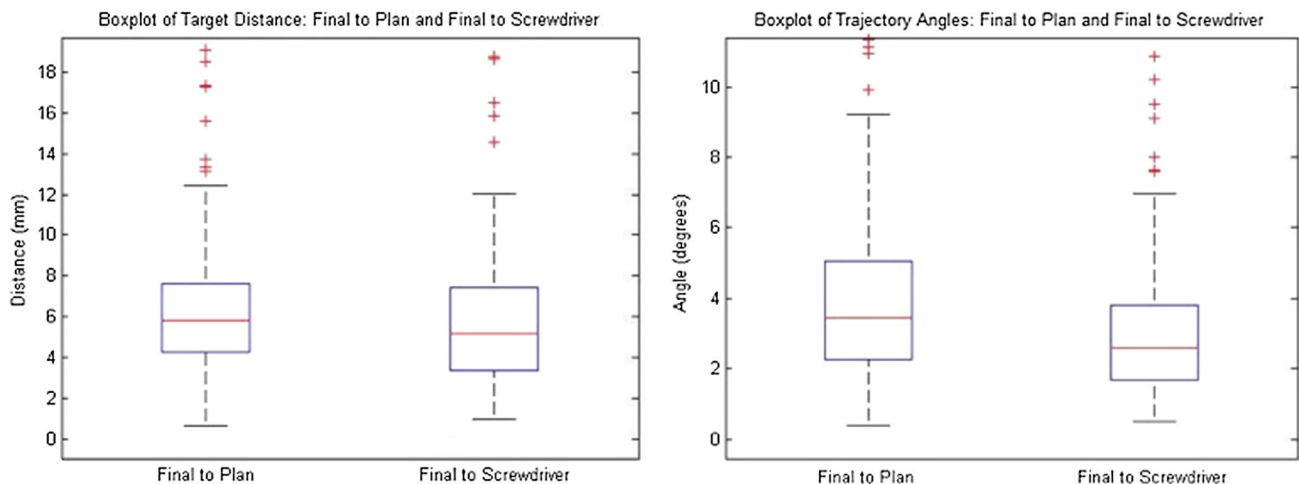
We found small changes between the navigation projection and final screw position; however, these differences were magnified by small angular differences. These were in part due to measurement of the tip position of the screw rather than the in-pedicle accuracy. Even with this the navigated screwdriver showed a trend toward increased precision compared to the probe, and was significantly

**Table 2** Screw grades and positions

Grade	# Screws	Percent	Position
1	128	81	
2	21	13	13 Lateral/8 medial
3	4	3	4 Lateral
4	5	3	5 Lateral

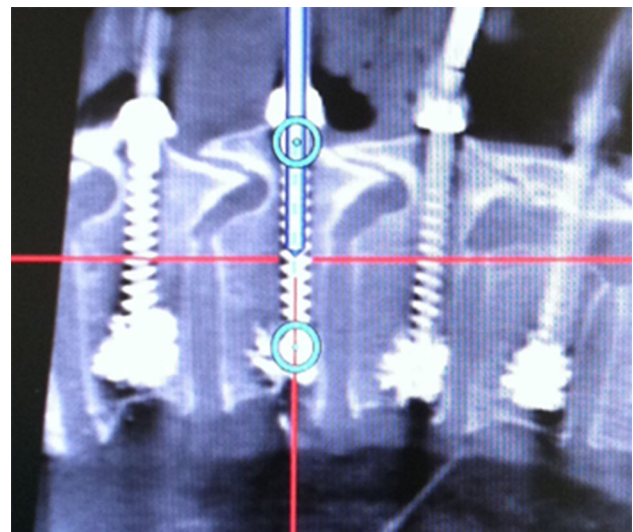
**Table 3** Data means and standard deviations

Comparison	Mean	Standard deviation
Distance: final target to probe target (mm)	6.43	3.49
Distance: final target to screwdriver target (mm)	5.92	3.50
Angle: final trajectory to probe trajectory	4.02°	2.63°
Angle: final trajectory to screwdriver trajectory	3.09°	2.12°

**Fig. 1** Boxplots of target distances and trajectory angles respectively

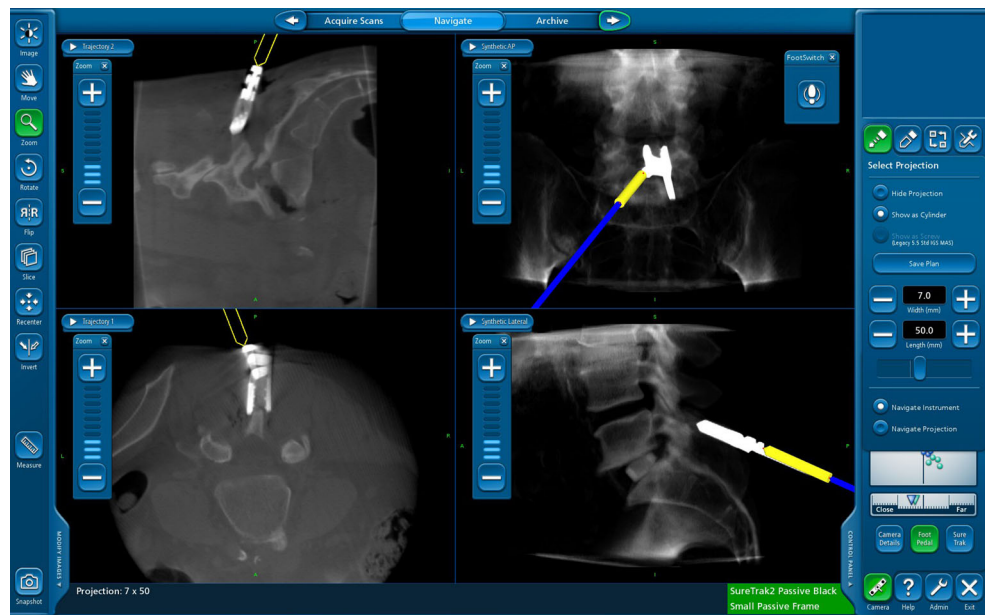
closer to the final screw position when looking at the angular measurement. Because our initial evaluation was performed at the tip of the projections and screws, not within the pedicles, it is difficult to compare our results directly with published data in the literature. Thus, further 3-dimensional analysis will be performed in future studies utilizing tip position and the position within the pedicle.

The rate of pedicle breaches was higher in the present study than previously reported literature evaluating the accuracy of O-arm. We used the O-arm imaging after placement of instrumentation to evaluate screw positions postoperatively. Two independent observers evaluated the pedicle screw position, but because only axial images were saved to our PACS system, the evaluation may have been somewhat limited. Also, the observers were asked to grade a pedicle breach for any image in which the cortical bone of the pedicle could not be clearly identified. For these reasons, we likely over-reported the number of grade II breaches recorded. Additionally, many of these surgical cases were deformity patients with varied pedicle morphology. Also, with the added confidence of the navigation, screw placement was attempted in all pedicles, even if they may have otherwise been deemed too small or difficult without the navigation. In the end, the accuracy of O-arm images for evaluation of instrumentation placement has been found to be comparable to a postoperative CT scan [41–43], and the number of screws felt to be in an appropriate position was comparable to

**Fig. 2** Representative merged image of planned trajectory and final screw placement. This shows a case in which visualization of screw tips were obscured by cement

previously reported data. All grade III/IV breaches were noted to be lateral, which is likely due to the ability for direct visualization of more difficult pedicles and placement of instrumentation toward the safer lateral cortex. These findings highlight the need for a more comprehensive evaluation of pedicle screws within the pedicle.

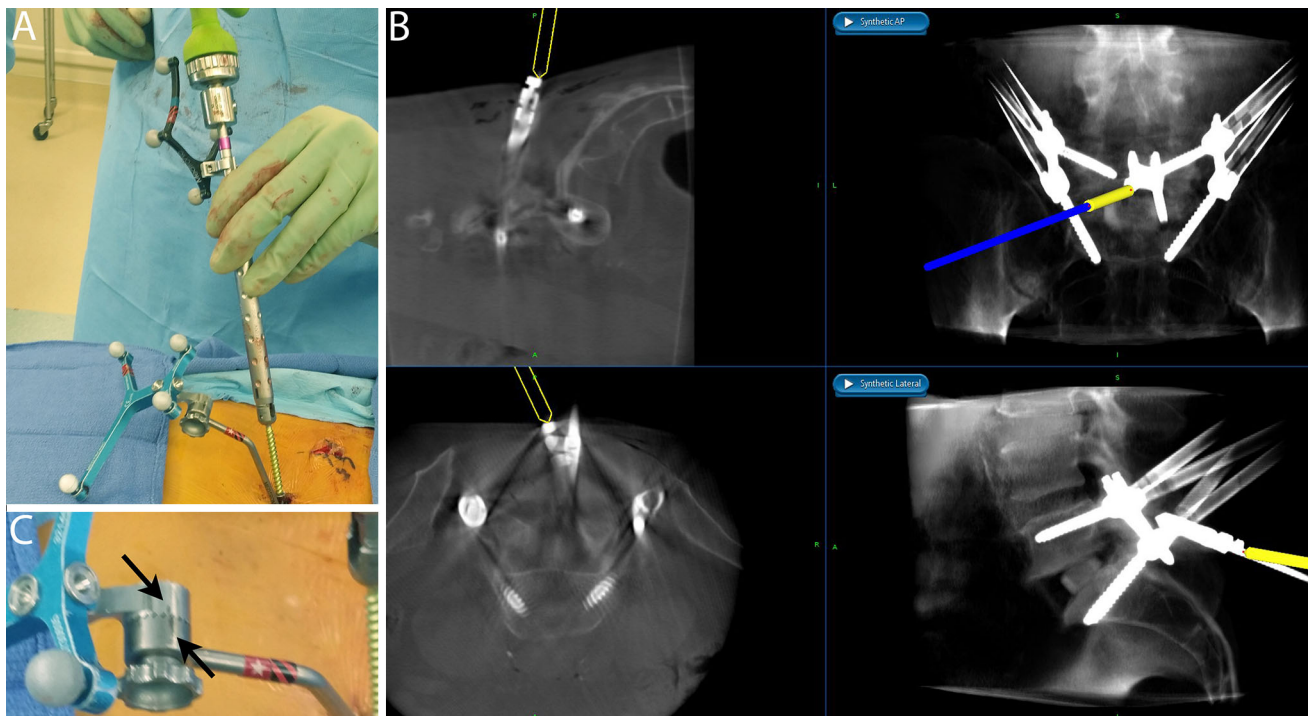
**Fig. 3** StealthStation screenshot showing the screw projection (yellow) with the pedicle screw tip in the center of the reference frame fastener screw, this correlates with the actual screw position



Several potential contributing factors to the discrepancies seen between navigation projections and final screw placement were identified during the study. One global confounder of accurate screw placement is the lack of secure attachment of the navigation reference frame to a stable bony landmark. Reference frame loosening during the procedure can lead to inaccuracy within the navigation system, and subsequent misplacement of instrumentation. This was noted in cases in which direct observation of the patient's anatomy revealed an apparent inaccuracy of the system, which was confirmed by either fractures of the spinous process at the site of clamp placement or loosening of the clamp/array. For this reason, increased vigilance of stable clamp placement throughout the procedure should be implemented. Furthermore, it is important to select the most stable segment available in the face of instability. When necessary, such as with revision cases, this may require placement of the clamp onto stable, intact instrumentation. To reduce global inaccuracy and loss of precision due to clamp loosening, the attachment points on the system should be tightened initially, and then verified prior to the initial imaging (Fig. 3). These connections should be checked periodically throughout the case to verify they have not loosened with manipulation of the spine over time. We noted a small amount of loosening in early cases, thought to be due to repetitive percussion as the pedicle awls were advanced (Figs. 4, 5 with Fig. 3 showing the typical images without issues.) Although this may not be a significant source of inaccuracy, constant observation is necessary to avoid complications over time.

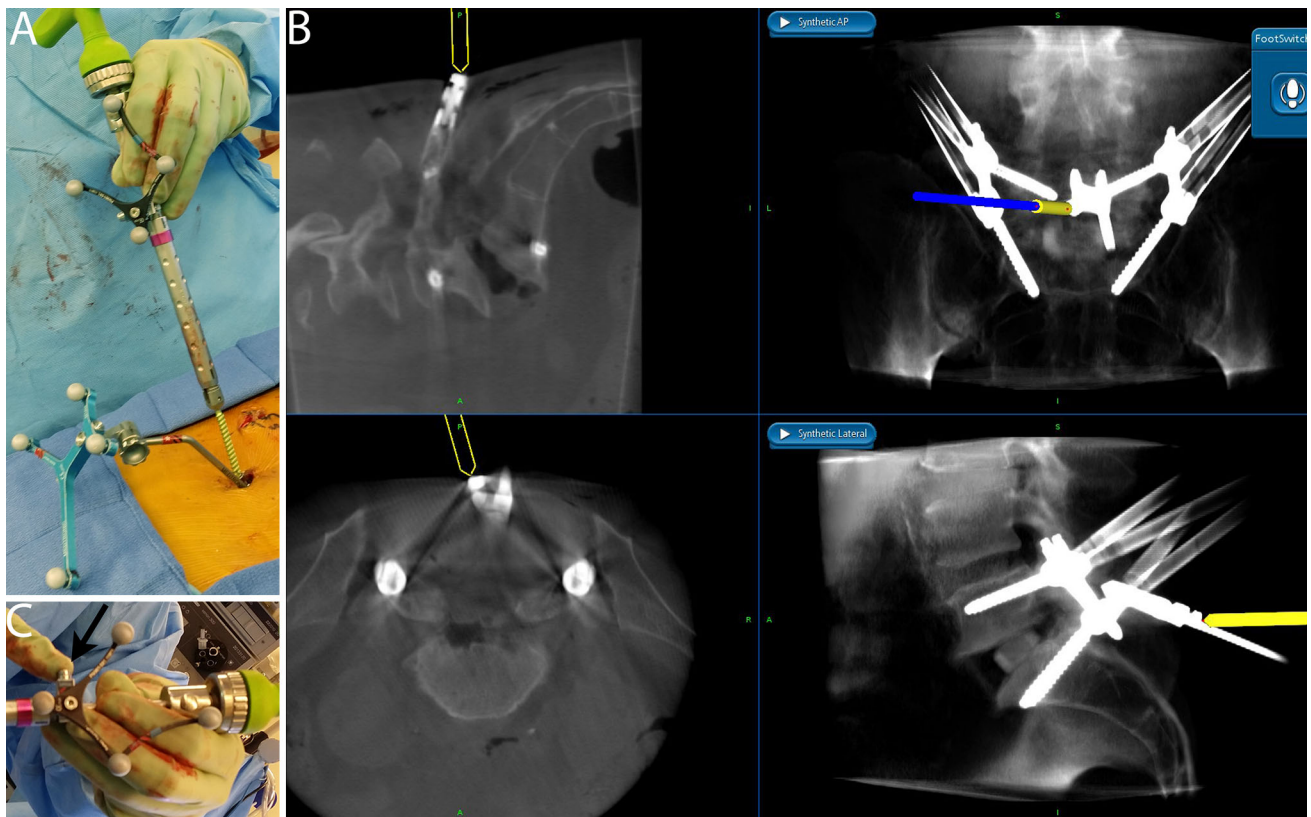
Placement of the navigation array and the SureTrak® (Medtronic Inc., Minneapolis MN) devices at a greater

distance from the area of interest can also increase the risk of inaccurate screw placement. The industry recommendation for the use of O-arm and StealthStation navigation in cranial surgery is for the array to be placed within 30 cm of the intended area of navigation. In the spine, an added concern is that inter-segmental motion may occur after the O-arm CT has been acquired. This risk increases with the number of segments away from the array and/or the number of segments being instrumented. While this risk is intuitive, to our knowledge it has not been specifically studied. However, the studies that have investigated O-arm and StealthStation navigation accuracy have evaluated multi-level procedures [29, 30]. At our institution, to decrease this risk, the array is either attached to a spinous process in the area of screw placement, or within as few motion segments as possible. In the event of long spine fusions, two or more arrays are used in combination with multiple O-arm scans shortening the distance from instrumented pedicles to the attachment point of the array. The industry suggestion is that the reference frame be placed on the level of interest. Previous studies of the O-arm have placed the navigation frame on the PSIS as well, without evidence of significant inaccuracy [30, 35]. The second consideration is for placement of the SureTrak device on pedicle screw drivers. The industry recommendations for the distance from the array to the tip of the instrument are based on the array being used; ranging from 130 mm or less for the small passive fighter to 260 mm or less for the large passive fighter. While Fig. 5 shows a loose array, we have also found that placing the SureTrak II as close to the instrument tip as possible has a significant overall effect on accuracy.

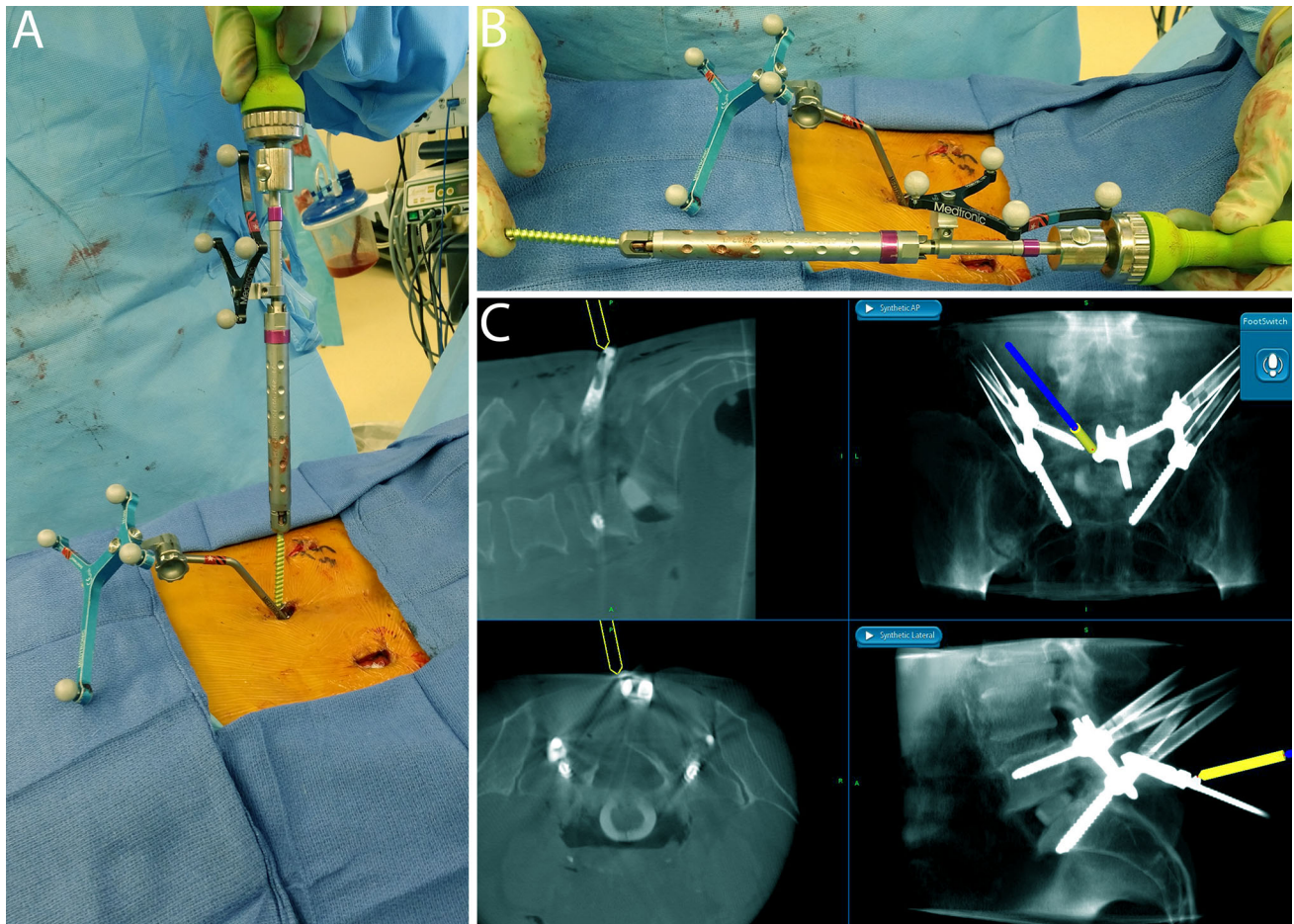


**Fig. 4** Placement of the pedicle screw in the center of the frame fastener screw (a); zoomed in view showing the subtle gapping of the teeth and arrows showing the slight misalignment of the original mark

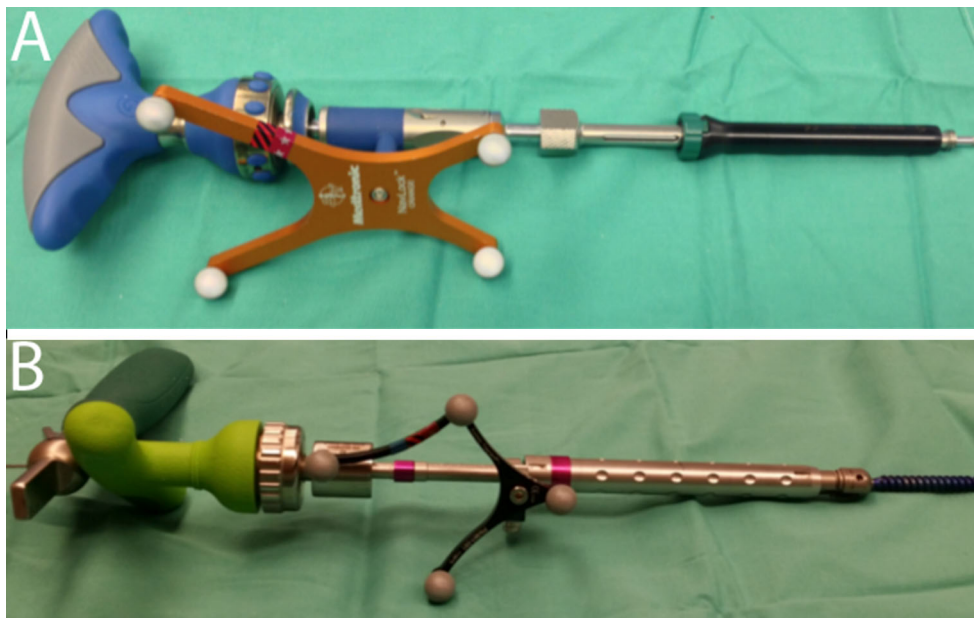
(b); StealthStation screenshots (c); note the subtle shift in the screw tip projection (yellow) compared to the actual position



**Fig. 5** Pedicle screw placed centrally in the frame fastener screw (a); Loose SureTrak on the driver shaft (c); StealthStation screenshot showing the screw projection (yellow) off from predicted position (b)

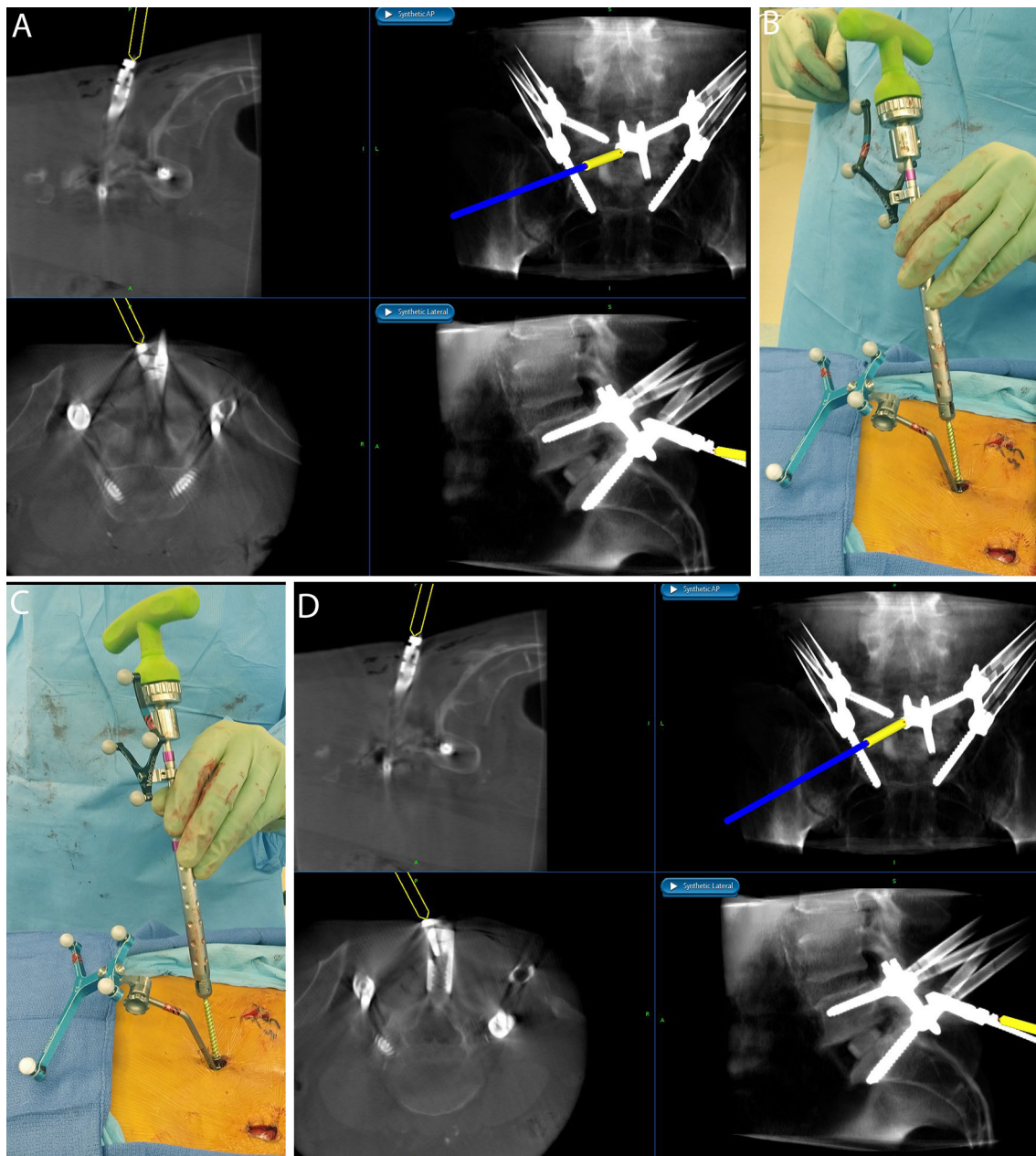


**Fig. 6** Pedicle screw sitting centrally in the frame fastener screw (a); loose connection between the screw and the driver shaft allowing angulation (b); StealthStation screen shot showing the screw projection (yellow) significantly off from actual position (c)



**Fig. 7** Medtronic driver with NavLock navigation array attached (a); DePuy Viper driver with SureTrak II navigation array attached (b)





**Fig. 8** Pedicle screw placed centrally in the frame fastener screw with approximately 90° rotation of the driver between the images (*upper right* and *lower left*); respective StealthStation screenshots showing

the pedicle screw (*yellow projection*) to be in two different positions, both off from the actual position

With regard to the precision of screw placement with a navigated driver, several contributing factors were noted during the study. In particular, the interface between the pedicle screws and the driver is essential for accurate screw placement. If screws are not firmly attached and tightened onto the screwdriver, they can toggle and result in predicted screw trajectories that are significantly off course from the true final resting position of the screw (Fig. 6). If recognized, tightening the connection between the screw and the driver allows the system to more precisely predict

the final resting position of the screw and decrease the difference between the probe track and the pedicle screw position on final analysis.

In this study, screws may have also been placed deeper or shallower than the exact position of the pedicle awl, adding to the discrepancy of the screw tip position. Though this adds to the discrepancy in our study, this difference was not calculated as direction of difference was not recorded.

When using a separate, non-integrated frame for navigation of the screwdriver, such as the SureTrak II (Fig. 7), the placement of the navigation reference guide on the driver shaft was found to affect the predicted and final screw placement results. Based on the placement of the navigation frame, the projected screw path was observed to change with rotation of the driver shaft. This resulted in a “moving target” as the screws were placed. In one view, the screw path position would appear to line up with the path of the pedicle probe. But as the screw was advanced, the rotation of the screwdriver would create an effect whereby the predicted screw path would appear to translate and/or angulate (Fig. 8). This effect would improve and worsen through a 360° revolution of the screw and screwdriver shaft. This would be predicted, as the center of the axis of rotation is down the center of the shaft; however, the array must be attached at an external point on the driver, and is offset in its placement. This source of error is more difficult to improve, as it is inherent to the system. However, recognizing this potential confound and understanding its underlying mechanism can allow surgeons to overcome this source of error and accurately place screws with navigated screwdrivers.

It is important to appreciate the fact that the pedicle screw track is projected based off the pedicle awl. If a curved awl is placed eccentrically, the projected screw path may necessarily be different from the actual screw placement. As the pedicle screw is placed, it may be preferentially directed into the cancellous portion of the pedicle and, thus, into a final resting position that is more centered in the pedicle and significantly different in placement than predicted by the projection. In such cases, the lack of precision would not be a flaw, but an expected outcome with placement of pedicle screws. In this instance, it is more important to evaluate the position of the screw in the pedicle and compare it to the pedicle position of the awl. To minimize this potential for error, we transitioned to using straight awls whenever possible.

Finally, the O-arm is a cone beam CT system. The CT scan images produced by the system can have both beam hardening and scatter/noise effects. While these do not change the accuracy, they can lead to decreased image quality at the periphery of the CT scan. This can be worsened in larger patients. This limited visibility can make it more difficult to properly identify and place pedicle screws. Again, this may be more a theoretical issue, as we have not found this to be a significant issue at our institution. Still, if multiple levels are being instrumented, a small overlap is incorporated with each O-arm scan to decrease artifacts that may be seen on the periphery of the images. In an evaluation for the possible use of O-arm and StealthStation navigation in other fields, Petrov et al. found that none of these caused effects on the geometric accuracy [44].

## Conclusion

The use of O-arm and StealthStation Navigation is a safe method for placement of pedicle screws. There are pearls to the use of these tools, as with any technique. Proper vigilance, and understanding of possible confounding factors, allows the operator to improve accuracy and ultimately, patient safety.

## Compliance with ethical statements

**Conflict of interest** The authors have received funding from Medtronic for this investigation regarding O-Arm® and StealthStation® navigation.

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