Does adequate intraoperative imaging impact on subsequent returns to theatre for the revision of malplaced pedicle screws?

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Abstract

Objective: To quantitatively assess whether having adequate AP and lateral intraoperative imaging during pedicle screw insertion impacts on returns to theatre within 90 days due to screw malplacement.
Design: A retrospective observational cohort study.
Setting: Llandough Hospital and University Hospital Wales, Spinal Orthopaedics Department.
Population: Patients who had undergone thoracolumbar instrumentation with pedicle and medial cortical screws between January 2013 and December 2022.
Results: 9016 pedicle screws were inserted into 1335 patients. 82 screws were deemed malplaced in 52 patients. 46 returned to theatre due to malplacement, 37 within 90 days of the primary surgery. Of the 37 who returned within 90 days, 35.1% (13/37) had both AP and lateral imaging saved, compared to 57.8% (21/37) who had lateral imaging only ($p<0.01$).
Conclusions: The findings suggest that adequate AP and lateral intraoperative imaging reduces the likelihood of patients returning to theatre within 90 days due to screw malplacement.

Introduction

The use of pedicle screws in spinal surgery has proven to be a safe and effective method of fusing, stabilising and correcting deformities of the spine (1-5). The concept has been reported from as early as 1959 (6), and since then the technique has evolved to incorporate the use of radiological guidance, computerised navigation and robotics (7-11).

Pedicle screws are inserted posteriorly through the pedicle directly into the vertebral body, and can then be used as an anchor in order to “correct deformity and stabilise the spine until solid fusion has occurred”. There are a number of indications including fractures, tumours, infections, spondylolisthesis and scoliosis (12). Previous research has found these procedures to have a relatively low risk of complications, although neurological, vascular and visceral injuries are of course a possibility (13-15). Screw malplacement has been reported at varying frequencies, from 1.7% to 35% (16), but it is important to note that misplacement does not always necessitate revision surgery, and can be asymptomatic (15).

There are a range of techniques used within pedicle screw surgery, regarding both the method of insertion and imaging used. In Cardiff and Vale University Health Board (CVUHB), the “free-hand” technique has been adopted with the use of conventional fluoroscopy with C-arm image Intensifier to confirm screw placement post insertion. Postoperatively, CT scans are the Gold Standard when assessing pedicle screw placement, but due to cost, time and

radiation exposure, plain radiographs are used in routine cases (17,18), despite questions surrounding their adequacy (19). There is research on the accuracy of fluoroscopic intraoperative imaging (20,21), but data is lacking when it comes to its impact on rates of revisional surgeries. Therefore, the aim of this study was to assess whether adequate AP and lateral imaging intraoperatively impacts on return to theatre rates within 90 days due to screw malplacement.

Aims and Objectives

To assess whether unplanned return to theatre within three months is more common in patients who did not receive intraoperative imaging, or if there was only one radiological view. The null hypothesis was: "***inadequate intraoperative imaging does not lead to an increase in patients having an unplanned return-to-theatre event within 90 days for symptomatically malplaced screw revision or removal surgery***".

Methods

Using the Bluespier database all spinal operations performed at University Hospital of Wales and University Hospital Llandough between January 2013 and December 2022 were identified. Inclusion criteria: all patients over the age of 18 years receiving thrpoacolumbar instrumentation with pedicle or medial cortical screws into the thoracic, lumbar or first sacral vertebrae for any indication between 2013 and 2022. Surgeries not involving pedicle screws, surgeries of the cervical vertebrae or from S2 and below, patients under the age of 18, and patients with buck or pars screws were excluded. Revision surgeries were included up until 31st March 2023 (a minimum of 90 days after the primary surgery). The following data was extracted; patient identification number, date of surgery, age at time of surgery, indication for surgery, surgical procedure carried out, type of screw used, number of screws inserted, and any intraoperative adverse events that took place. For those patients who returned to theatre during the given time frame, information was gathered regarding the reason for their return to theatre, what revisional procedure was carried out, and how much time had elapsed between their primary surgery and revision. Synapse Radiological Software (Fujifilm) was used to view intraoperative and postoperative imaging. The radiological data collected included; whether intraoperative imaging carried out and saved, whether there were AP and lateral views, whether they showed adequate visulisation of the spine / screws, and whether there was any screw malplacement. The same was completed for postoperative imaging. If there was only post operative MRI or CT imaging, this was noted, as were the patients who had received postoperative imaging more than 3 weeks after their surgery (these were still recorded as receiving postoperative imaging). Imaging was deemed "adequate" if all screws and pedicles could be visualised clearly at an appropriate angle. Intraoperative imaging was carried out using conventional fluoroscopy using a C-arm image intensifier. Once all data had been collected, it was analysed using SPSS (v25) to determine whether to reject or accept the null hypothesis.

Results

1335 patients met the inclusion criteria, with a total of 9016 new screws being inserted throughout the 10-year period (excluding screws that were inserted in revision surgeries into the same tracts). Of these, 229 (2.54%) were midline cortical screws, and an average of

6.75 screws were inserted per patient. Over the 10 years and 3-month time frame, 16.3% (218/1335) of the patients had at least one return to theatre. Based on notes, intraoperative and postoperative imaging, 82 screws were deemed “significantly” malpaced in 52 patients (3.9%) (an average of 1.41 malplaced screws per patient with a known malplacement). Overall, 46 (3.4%) of these patients returned to theatre due to symptomatic screw malplacement; 39 for screw revision and 7 for screw removal. Six patients did not return to theatre.

In 74 of the patients, there was no imaging saved to view on Synapse (despite 23 of their surgical notes stating that intraoperative imaging was used). 727 patients had both AP and lateral intraoperative imaging accessible to view (621 of which were deemed adequate), whilst 48 patients had AP images only, and 485 had lateral only. 118 cases had reports of adverse events, 52 of which involved the pedicle screws (such as the need to re-site a screw intraoperatively), and 67 were not related to the screw (for example a dural tear or excessive blood loss).

When looking at return to theatre rates within 3 months, 37 patients (2.77%) returned for the revision or removal of malplaced screws. Of these, 35.1% (13/37) had AP and lateral intraoperative imaging saved, 56.8% (21/37) had lateral imaging only, 2.7% (1/37) had AP imaging only, and 5.4% (2/37) had no imaging saved to view. Compared with the patients who did not return within 90 days due to malplacement, 55.0% (714/1298) had AP and lateral imaging, 35.7% (464/1298) had only lateral, 3.6% (47/1298) had only AP and 5.6% (73/1298) had no imaging recorded. See Table 1 below.

	Number of patients who returned within 90 days due to screw malplacement	Number of patients who did not return within 90 days for screw malplacement	Total
AP and lateral intraoperative imaging saved	13 (1.8% RTT at 3 months)	714	727
Only lateral intraoperative imaging saved	21 (4.3% RTT at 3 months)	464	485
Only AP intraoperative imaging saved	1	47	48
No intraoperative imaging available to view	2	73	75
Total	37 (2.8%)	1298	1335

Table 1: comparing intraoperative imaging saved for patients who returned to theatre within 90 days due to screw malplacement versus those who did not.

From this data, there is a 1.8% (13/727) chance of returning to theatre within 3 months due to screw malplacement if both AP and lateral imaging was taken and saved intraoperatively. If only lateral imaging was taken there was a 4.3% (21/485) chance of return, if only AP imaging then a 2.08% (1/48) chance of return, and a 2.67% (2/75) chance if no imaging was taken at all.

SPSS statistical analysis uncovered two significant results ($p<0.05$); (1) those with both AP and lateral intraoperative imaging (13/727 patients) were statistically less likely to return to theatre within 90 days due to screw malplacement ($p=0.017$) than those who did not have both AP and lateral imaging (24/608 patients) and, (2) those with only lateral imaging (21/485 patients) were more likely to return to theatre than those who did not receive only lateral imaging (16/850 patients, $p=0.009$). Interestingly there was no significant finding for those who received AP imaging alone or no imaging at all ($p=0.767$ and $p=0.955$ respectively).

Discussion

Lack of AP and lateral intraoperative imaging is statistically more likely to lead to a return to theatre within 3 months due to symptomatic thoracolumbar screw malplacement, with patients who received only lateral imaging having the highest risk of return to theatre. We can therefore reject the null hypothesis that “inadequate intraoperative imaging does not lead to an increase in patients having an unplanned return-to-theatre event within 90 days of pedicle screw revision or removal surgery”.

The findings from this study highlight the need for guidance which recommends the use of both AP and lateral intraoperative imaging to reduce rates of returns to theatre for the revision or removal of malplaced screws. Only 54.5% of patients received both AP and lateral intraoperative imaging, demonstrating that there is much variation within CVUHB and standardisation is needed. Despite this, the study supports previous research (16,21,22) in demonstrating that malplacement and intraoperative adverse events are rare (8.8% and 0.9% respectively), and not all malplacements require returns to theatre (**6 of the 52** patients with malplaced screws never returned to theatre for revision or removal). This is in keeping with previous data that also suggests that only severe malplacement requires revisional surgery (24).

Despite these low rates of malplacements, new technology and techniques are being developed to further reduce the risk of complications resulting from malplaced pedicle screws. Firstly, low-dose CT scans are a topic of interest as they would reduce the risks associated with radiation exposure whilst providing more accurate imaging of postoperative screw placement (25). The use of ultrasound guidance is being considered as a safer and cheaper intraoperative imaging technique with no radiation exposure (26), and intraoperative CT navigation is being researched as a more accurate method to aid screw insertion, although currently it does not seem to reduce rates of returns to theatre (27). Finally, research is emerging regarding the use of augmented reality to improve accuracy rates; a study in the Global Spine Journal found that 98.2% (218/222) of screws inserted using augmented reality were placed accurately (28). In terms of the use of robotics, there is promising data that suggests its benefit particularly to less experienced surgeons – operating time is less and accuracy rates are high. However, there is a steep learning curve and the

results don't show an increase in accuracy compared to experienced surgeons using the "free-hand" technique (29,30).

A limitation of this study is that the term "adequate" is rather subjective, and with two different observers compiling the data, it is possible that interobserver reliability may have affected results. However, with pre-decided criteria for "adequacy" and such a large dataset, it is unlikely that interobserver differences would have skewed the results. It is also worth considering that there may have been other factors affecting screw placement. For example, patients with spondylolisthesis, scoliosis, osteoporosis or osteopenia were included in the study even though their surgeries may have been more challenging, with previous research suggesting that complications such as screw loosening and malplacement are more common in these patient groups (16,21,23). This may have caused returns to theatre no matter what intraoperative imaging took place.

Conclusion

The results from this study highlight the need for standardisation and guidelines for the intraoperative imaging necessary for pedicle screw surgery. Both AP and lateral imaging reduces the chance of patients returning to theatre for the revision or removal of malplaced screws. Such guidelines could reduce the economic implications of increased theatre use, and decrease the stress experienced by patients caused by returns to theatre.

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