Jessica Smith

1504498

Cardiff and Vale University Health Board – Trauma and Orthopaedics Department

Tutor/senior author:

Mr Michael McCarthy, Consultant Orthopaedic Spinal Surgeon

Project:

"An analysis of pedicle screw placement and subsequent return to theatre: was the intraoperative imaging adequate?"

Ethical Approval: Not Required

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Abstract

***Background**:* Pedicle screw instrumentation is commonly employed in spinal surgery and is generally considered a safe and effective method of spine instrumentation according to the literature. Standard methods of pedicle screw insertion and intraoperative imaging vary by centre – a "free-hand" technique with conventional fluoroscopy is standard within CVUHB. Published information relating to assessment of pedicle screw placement intraoperatively using conventional fluoroscopy alone is scarce, but information relating to whether the adequacy of such imaging impacts upon unplanned return-to-theatre events for pedicle screw revision or removal surgery could not be found.

***Aims and objectives**:* To quantitatively assess whether views and adequacy of intraoperative imaging taken and saved impacts upon subsequent return-to-theatre events in a population of adults undergoing pedicle screw instrumentation in the pedicles of the thoracic or lumbar vertebrae, or the first sacral vertebra, irrespective of indication.

***Methods**:* All patients meeting the inclusion criteria were identified. These were adult patients who were operatively managed at either of the 2 main CVUHB hospitals by consultant spinal surgeons using pedicle screw instrumentation of the thoracolumbar and first sacral vertebrae between 1st January 2013 and 31st December 2017 inclusive, for any indication. Osteoporotic and osteopaenic patients were also included. Paediatric patients (those under the age of 18 at the time of their first operation within the 5-year specified period) were excluded. Patients who were instrumented using pars or buck screws were also excluded. Data was collected based on pre-determined variables including: number and type of screws; imaging modality and views used to assess screw placement, intraoperatively and post-operatively; imaging adequacy; return-to-theatre events and details. Statistical analysis was carried out using IBM SPSS Software Version 23.

***Results**:* A total of 5,833 screws were placed into 889 patients with a mean age of 52.5. 58 screws (0.99%) were identified as having been malplaced. 35 patients had an unplanned return-to-theatre event within 90 days of their operation for pedicle screw revision or removal (URTT90), 31 of whom had not had adequate imaging taken and saved intraoperatively in both AP and lateral views. This confers statistical significance towards

more patients having an URTT90 if they did not have adequate imaging taken and saved intraoperatively in both AP and lateral views ($p = 0.001$, $\chi 2$).

***Conclusions**:* Whilst overall incidence of screw malplacement is low, the results confer favour towards taking and saving adequate intraoperative imaging in both AP and lateral views to reduce occurrence of an URTT90. Ensuring that all intraoperative image views and adequacy meet expected standards may help to minimise distress caused to patients needing revision surgeries, as well as reducing the cost burden associated with patients returning to theatre.

1. Introduction

Although the first use of pedicle screws is largely credited to Boucher[1], it is believed that the first deliberate use of long-axis-purchase pedicle screws in spinal surgery was by Harrington and Tullos[2]. Pedicle screw instrumentation is commonly employed in surgical practice today[3,4] and is largely considered a safe and effective method of spine instrumentation[5-9]. Pedicle screw use is widely indicated: examples include promoting spine fusion, correcting spinal deformities such as spondylolistheses, scolioses and kyphoses, and stabilising fracture and tumour sites[5,10]. Utilising the pedicle for indications such as the aforementioned stands to reason – the pedicle has various morphological and kinesiological characteristics contributing to its strength and durability, rendering it a suitable site for instrumentation[9-11]. Computerised Tomography (CT) has been dubbed the "gold standard" for assessing for pedicle screw malplacement post-operatively[12], and the comparative value of plain radiographs has been questioned[13]. However, due to cost, time, resources and radiation exposure, CT may only feasibly be used suspect cases[14] or in centres with sufficient resources and specifically developed low-dose protocols[15,16]. Intraoperatively, appropriate assessment of pedicle screw placement is also needed to help reduce the number of malplaced screws and subsequent return-to-theatre events. There are various methods of assessing pedicle screw placement intraoperatively, including conventional fluoroscopic guidance and more novel navigation techniques, such as 2D and 3D fluoroscopic navigation systems. Insertion technique and intraoperative screw placement assessment varies on a centre-specific basis. The 2 main hospitals within Cardiff and Vale University Health Board (CVUHB) both adopt a conventional, "free-hand" technique of pedicle screw insertion, using conventional fluoroscopy (with C-arm Image Intensifier) as the standard method of intraoperative imaging. Published data relating to assessment of pedicle screw placement intraoperatively using conventional fluoroscopy alone is present[17,18] but scarce. An extensive literature search, using combinations of relevant key words, gleaned little relevant published information relating to whether adequacy of intraoperative imaging – using conventional fluoroscopy alone – impacts upon unplanned return-to-theatre events for pedicle screw revision or removal surgery.

This study was primarily designed, therefore, to assess whether having both adequate AP and adequate lateral images taken and saved intraoperatively, using conventional fluoroscopy

alone, affects the likelihood of patients having unplanned return-to-theatre events within 90 days for pedicle screw revision or removal.

2. Aims and objectives

The primary aim of this study was to quantitatively assess whether the views and adequacy of intraoperative imaging taken and saved, or a lack thereof, using conventional fluoroscopy alone impacts upon subsequent return-to-theatre events in a population of adults undergoing pedicle screw instrumentation, in the pedicles of the thoracic or lumbar vertebrae, or the first sacral vertebra, irrespective of indication. The null hypothesis posed was as follows: **"inadequate intraoperative imaging does not lead to an increase in patients having an unplanned return-to-theatre event within 90 days for pedicle screw revision or removal surgery"**.

3. Methods and materials

3.1. Study design:

A retrospective review of information and imaging relating to all patients having undergone pedicle screw instrumentation, meeting the established inclusion criteria, was carried out. Information was collated from a number of sources: operative notes (Bluespier); intraoperative and post-operative imaging (IMPAX); clinic letters, discharge summaries and other written communications (Clincal Portal). The study was designed, primarily, to quantitatively assess whether taking and saving adequate intraoperative imaging in both AP and lateral views, using conventional fluoroscopy, had an impact on unplanned return-to-theatre rate within 90 days for pedicle screw revision in the specified population.

3.2. Population selection – inclusion criteria:

Patients meeting the inclusion criteria were identified. The inclusion criteria were as follows: any adult (aged 18 or over at the time of their first relevant operation within the specified 5-year period) who was operatively managed at either of the 2 main CVUHB hospitals between 1st January 2013 and 31st December 2017 inclusive, for any indication necessitating insertion of pedicle screws into pedicles of any of the thoracic or lumbar vertebrae or the first sacral

vertebra. The study included osteoporotic and osteopaenic patients. Patients under the age of 18 and patients instrumented with buck or pars screws were excluded from the study. The minimum follow-up period was 90 days (31st March 2018). The population to be analysed was identified from a list of all spinal operations that had taken place within the specified 5-year period, under all consultant spinal surgeons, at either of the 2 main CVUHB hospitals.

3.3. Data review, collection and analysis:

The unique patient number, admission date, age, named consultant and indication for surgery for each patient were identified from Bluespier. This rendered around 4,500 results, which were manually filtered to leave only patients having undergone relevant operations (inclusion and exclusion criteria stated above). Duplicate entries and revision procedures were collated under the same entry. 889 patients met the defined parameters for inclusion in the study. Data was collected by reviewing the relevant notes and radiology. Variables collected for included: the number and type of pedicle screws inserted; imaging modality and views used to assess pedicle screw placement intraoperatively and post-operatively; adequacy of imaging; details relating to intraoperative adverse events and future return-to-theatre events. Intraoperative and post-operative images reviewed were defined as being adequate or inadequate. 'Adequate' in this context of imaging was defined as: an AP or lateral view in which all relevant screws and pedicles were visualised clearly, within images of sufficient quality. The intraoperative imaging modality was conventional fluoroscopy using a C-arm Image Intensifier. The data collected was analysed for statistical significance using IBM SPSS Software Version 23.

4. Results

A total of 889 adult patients with a mean age of 52.5 years were included in the study. Over the specified 5-year period, a total of 5,833 pedicle screws (mean 6.56 screws per patient, SD ± 4.516) were inserted, excluding any additional screw placement in revision surgeries. 5,634 (96.6%) of these were standard pedicle screws and the other 199 (3.4%) were midline cortical screws (MCS). Of the 5,833 screws inserted, 58 (0.99%) were identified as having been malpositioned on radiological review on intraoperative or post-operative imaging, in 4.4% of all patients (39/889). Of these, 36 returned to theatre for pedicle screw revision (29/36,

80.6%) or removal (7/36, 19.4%). 35 of the 36 returned to theatre within 90 days of their initial operation.

Of all 889 patients, 6.5% (58) had no intraoperative imaging saved to view on IMPAX, although the image intensifier was used in 24.1% (14/58) of these operations with no imaging saved. 44.3% of all patients (394) had both AP and lateral imaging taken and saved in theatre, where 87.6% of these (345/394) were deemed adequate in both views. 48.3% (429/889) of patients had only lateral images taken and saved intraoperatively, of which 88.3% (379/429) were deemed adequate. 0.90% (8/889) patients had only AP imaging taken and saved intraoperatively and, of these, 75% (6/8) were recorded as adequate. Table 1 details the above.

Table 1 – detailing intraoperative imaging accessible that was reviewed for all patients.

Sub-groups 1-4 ↓	**Total number** (and proportion as a % of all patients)	Sub-groups 1a-4b ↓	**Number** (and proportion as % of subgroup)
1. No intraoperative imaging to review?	**58** (6.52%)	1a. No imaging **taken or saved?** (ie image intensifier was **not used** IO)	**44** (75.86%)
		1b. No imaging **accessible to view**? (ie images **may have been taken** but were **not saved**)	**14** (24.14%)
2. AP images only taken and saved intraoperatively?	**8** (0.90%)	2a. Deemed **adequate**?	**6** (75.00%)
		2b. Deemed **inadequate**?	**2** (25.00%)
3. Lateral images only taken and saved intraoperatively?	**429** (48.26%)	3a. Deemed **adequate**?	**379** (88.34%)
		3b. Deemed **inadequate**?	**50** (11.66%)
4. Both AP and lateral images taken and saved intraoperatively?	**394** (44.32%)	4a. Deemed **adequate**?	**345** (87.56%)
		4b. Deemed **inadequate**?	**49** (12.44%)
	Total (n) = 889 (100%)		**Total (n) = 889**

5.5% of patients who did not have both AP and lateral images taken and saved in theatre (27/495, sub-groups 1, 2 and 3) had an unplanned return-to-theatre event within 90 days for pedicle screw revision or removal (URTT90). This is compared to a 2.0% return rate in patients

who had both AP and lateral images taken and saved in theatre (8/394, sub-group 4). These results confer statistical significance – those patients who did not have both AP and lateral images taken and saved in theatre were more likely to have an URTT90 (**p = 0.009**, $\chi 2$). These results are detailed in Table 2. This difference reaches a greater level of statistical significance when comparing the 5.7% of patients who did not have both **adequate** AP and **adequate** lateral images taken and saved in theatre and had an URTT90 (31/544, sub-groups 1a, 1b, 2a, 2b, 3a, 3b and 4b) with the 1.2% of patients who had both adequate AP and adequate lateral images taken and saved and had an URTT90 (4/345, sub-group 4a) (**p = 0.001,** $\chi 2$). These results are detailed in Table 3.

Table 2. URTT90 * Were both AP and lateral imaging taken intraoperatively (irrespective of adequacy) Crosstabulation

			Were both AP and lateral imaging taken intraoperatively? (irrespective of adequacy)		
			No	Yes	Total
URTT90?	No	Count	468 (94.5%)	386 (98.0%)	854
	Yes	Count	27 (5.5%)	8 (2.0%)	35
Total		Count	495 (100.0%)	394 (100.0%)	889

Table 3. URTT90 * Were both adequate AP and adequate lateral imaging taken intraoperatively Crosstabulation

			Were both adequate AP and adequate lateral imaging taken intraoperatively?		
			No	Yes	Total
URTT90?	No	Count	513 (94.3%)	341 (98.8%)	854
	Yes	Count	31 (5.7%)	4 (1.2%)	35
Total		Count	544 (100.0%)	345 (100.0%)	889

Comparing patients that had both AP and lateral images (sub-group 4) with those that had lateral images only (sub-group 3) taken and saved intraoperatively, (irrespective of adequacy for both sub-groups) includes 823 patients. 5.8% of patients who had lateral images only taken and saved intraoperatively (25/429, sub-group 3) had an URTT90, in contrast to 2.0% of those who had both AP and lateral images taken and saved intraoperatively (8/394, sub-group 4). Patients in sub-group 3 were statistically significantly more likely to have an URTT90 than patients in sub-group 4 (**p = 0.006**, $\chi 2$). These results are detailed in Table 4. Again, this difference is more statistically significant when comparing those patients who had both adequate AP and adequate lateral images taken and saved in theatre (sub-group 4a) with those that had lateral images only, irrespective of adequacy (sub-group 3) – this includes 774 patients. 5.8% of patients that had only lateral images taken and saved had an URTT90 (25/429, sub-group 3), while 1.2% of patients that had both adequate AP and adequate lateral images taken and saved intraoperatively had an URTT90 (4/345, sub-group 4a) (**p = 0.001**, $\chi 2$). These results are detailed in Table 5. Furthermore, comparing the 724 patients from sub-groups 3a and 4a – adequate images only, in either both AP and lateral views or lateral view only – still indicates a lower risk of an URTT90 if intraoperative images are taken in both views. 5.3% of patients that had only adequate lateral images taken intraoperatively had an URTT90 (20/379, sub-group 3a), whereas 1.2% of patients that had both adequate AP and adequate lateral images taken intraoperatively had an URTT90 (4/345, sub-group 4a) (**p = 0.002**, $\chi 2$). These results are detailed in Table 6. Figure 1 visually details proportions of patients from sub-groups 3, 4, 3a and 4a that had an URTT90.

Table 4. URTT90 * Did the patient have both AP and lateral imaging OR lateral imaging only, taken and saved intraoperatively (irrespective of adequacy for both sub-groups) Crosstabulation

			Did the patient have both AP and lateral imaging or lateral imaging only taken and saved intraoperatively? (irrespective of adequacy for both sub-groups)		
			Lateral only	AP and lateral	Total
URTT90?	No	Count	404 (94.2%)	386 (98.0%)	790
	Yes	Count	25 (5.8%)	8 (2.0%)	33
Total		Count	429 (100.0%)	394 (100.0%)	823

Table 5. URTT90 * Did the patient have both adequate AP and adequate lateral imaging OR lateral imaging only (irrespective of adequacy), taken and saved intraoperatively Crosstabulation

			Did the patient have both adequate AP and adequate lateral imaging OR lateral imaging only (irrespective of adequacy), taken and saved intraoperatively?		
			Lateral only	Both adequate AP and adequate lateral	Total
URTT90?	No	Count	404 (94.2%)	341 (98.8%)	745
	Yes	Count	25 (5.8%)	4 (1.2%)	29
Total		Count	429 (100.0%)	345 (100.0%)	774

Table 6. URTT90 * Did the patient have both adequate AP and adequate lateral imaging OR adequate lateral imaging only taken and saved intraoperatively Crosstabulation

			Did the patient have both adequate AP and adequate lateral imaging OR adequate lateral imaging only taken and saved intraoperatively?		
			Adequate lateral only	Adequate AP and adequate lateral	Total
URTT90?	No	Count	359 (94.7%)	341 (98.8%)	700
	Yes	Count	20 (5.3%)	4 (1.2%)	24
Total		Count	379 (100.0%)	345 (100.0%)	724

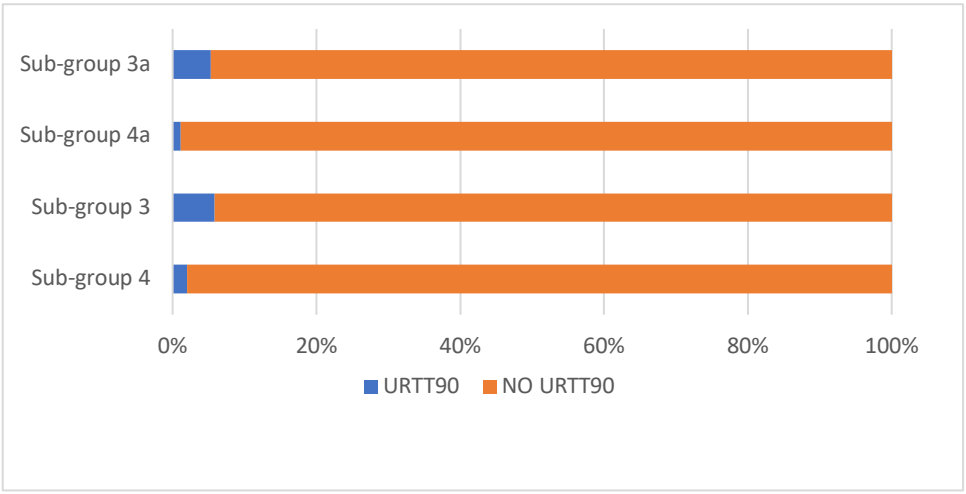

Figure 1 Chart detailing visually the proportions of patients from various sub-groups that had an URTT90

Of the 8 patients who had only AP images taken and saved intraoperatively (6/8, 75% adequate), none had an URTT90 conferring no statistical significance ($p>0.05$). Similarly, of the 58 patients who had no intraoperative imaging available to review, 2 returned to theatre which, again, confers no statistical significance ($p>0.05$).

5. Discussion

5.1. Study results and significance

Overall, less than 1 in every 100 screws inserted were identified as having been malplaced (58/5833) in the population studied, based on radiographic review. In keeping with this low rate, only 36 patients had an unplanned return-to-theatre event for pedicle screw revision or removal – 35 of these within 90 days of their original operation, suggesting that issues relating to pedicle screws necessitating further surgery were identified quickly in nearly all cases. It is important to note that less than half of the 889 patients included in the study had both AP and lateral images taken and saved intraoperatively, showing that consistency in intraoperative imaging within CVUHB requires further improvement and standardisation.

Despite these findings, the results obtained prove – with a high level of statistical significance – that adequacy of intraoperative imaging does have an impact on subsequent return-to-theatre events. Patients who had both AP and lateral images taken and saved in theatre were less likely to have an unplanned return-to-theatre event within 90 days for pedicle screw revision or removal (URTT90) when compared with those patients who did not have both AP and lateral images taken and saved (**$p = 0.009$**). The results show that patients are even less likely to have an URTT90 if they had both adequate AP and adequate lateral imaging taken and saved in theatre when compared with those that did not (**$p = 0.001$**). Of the 4 sub-groups detailed in Table 1, the sub-group with the largest proportion of patients was sub-group 3 – patients that had only lateral imaging taken and saved intraoperatively. Again, the results from the analysed data show that taking and saving both AP and lateral images intraoperatively reduces the chance of patients having an URTT90 – with adequate images in both views conferring greater statistical significance (**$p = 0.006$, $p = 0.002$, $p = 0.001$** – Tables 4, 6 and 5 respectively). From these results, we can conclusively disprove the original null hypothesis: **"inadequate intraoperative imaging does not lead to an increase in patients having an unplanned return-to-theatre event within 90 days for pedicle screw revision**

surgery". The results confer clear favour towards taking and saving both adequate AP and adequate lateral images intraoperatively over any of the other sub-groups included in the analysis.

5.2. Relevant findings from other studies

A study by Koktekir et al.[17] demonstrates the value of using fluoroscopic guidance to reduce pedicle screw malplacement. Pedicle screw malplacement can cause vascular[19] or visceral injury[14,20], as well as neurological complications[4,6,21,10] that have potential to be serious and necessitate revision surgery, resulting in increased expenditure and causing avoidable patient distress.

Standard methods of intraoperative imaging vary on a centre-specific basis. The 2 main CVUHB hospitals encompassed in this study both use a "free-hand" technique of pedicle screw insertion, using conventional fluoroscopy (with C-arm Image Intensifier) as standard. Numerous authors have reported findings of significant benefit in using novel navigation techniques intraoperatively with regards to assessing screw placement accuracy[6,22,23,21,24] and reducing rates of revision surgery[3]. Conversely, some studies found no significant clinical benefit in novel navigation techniques over more conventional techniques. Results from these studies show that using navigation systems intraoperatively not only increases operating time[25,26], but also fails to reduce post-operative complications and rates of revision surgery[25]. A further study[5] found that 3D navigation offered no significant benefit over the conventional free-hand technique in single level listhesis. Additionally, Kosmopoulos et al.[21] found no significant benefit to novel navigation techniques in the thoracic spine.

5.3. General study limitations

An important limitation identified whilst designing the study was defining adequacy of imaging. To help standardise results, simple and generalisable adequacy criteria were pre-defined, as follows: *'*Adequate' in this context of imaging was defined as an AP or lateral view in which all relevant screws and pedicles were visualised clearly, within images of sufficient quality.

Only images saved intraoperatively are accessible to review on IMPAX – any images taken but not saved are automatically deleted. This means that although the C-arm Image Intensifier may have been used throughout any given operation, images taken but not saved are impossible to review. Consequently, a proportion of the patients in all sub-groups other than sub-group 4a (that is, all patients that did not have both adequate AP and adequate lateral images taken and saved intraoperatively) may well have had adequate imaging in both views taken in theatre. However, as stated, if these images were not saved then they could not be reviewed. A further limitation identified was that the data collected regarding pedicle screw placement and revision rates were not classified by spinal level – rather, they were analysed irrespective of the level(s) of screw insertion. Analysing by vertebral level may have generated significant results, as vertebrae at each level have differing anatomical characteristics[27,9] that could lead to differences in revision rates. The results also did not discriminate between indication for pedicle screw insertion, neither did they classify patients based on their bone stock, for example osteoporotic or osteopaenic bone. Finally, availability of operating tables with appropriate structure to permit both AP and lateral images to be taken using the C-arm may have limited the ability of the radiographer to take adequate images from both views.

6. Conclusions

The results from this study have demonstrated the benefit taking and saving both AP and lateral images intraoperatively when using conventional fluoroscopy – it significantly reduces the likelihood of a patient having an unplanned return-to-theatre event within 90 days for pedicle screw revision or removal, when compared with patients who did not have both AP and lateral images taken and saved intraoperatively. The statistical significance becomes even greater when comparing patients that had both adequate AP and adequate lateral images taken and saved intraoperatively, with those that did not. Intraoperative imaging should therefore be utilised as far as is possible to help to minimise distress caused to patients needing revision surgeries, as well as to reduce the financial burden associated with patients returning to theatre[28] for revision surgery. There is potential to benefit not only local health boards, but the health care system as a whole.

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