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Analysis of Pedicle Screw Placement in The Surgical Correction of Adolescent Idiopathic Scoliosis: Does Pedicle Screw Malpositioning Lead to Increased Requirement for Post-Operative CT Imaging and Revisional Surgery?

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Abstract:

Background:

Adolescent Idiopathic Scoliosis (AIS) is the most common type of scoliosis and severe cases are corrected surgically utilising implants which are typically anchored using pedicle screws. Published literature varies widely with regards to identifying the incidence of pedicle screw malpositioning, however accurate research into this is important for informing patients of risk prior to surgery and identifying potential avenues for the improvement of patient outcomes.

Aims:

The aims of this study were to establish the incidence of pedicle screw malpositioning, and the impact screw malpositioning has had on patient outcomes.

Methods:

Patients who underwent corrective surgery for AIS between January 2013 and March 2019 within Cardiff and Vale University Health Board (n=152) were included in a retrospective review of clinical and radiological data. Variables included number of pedicle screws implanted per patient, number of malpositioned screws identified on post-operative X-Ray per patient, whether post-operative CT imaging was required, and whether revisional surgery was required. Collected data was then subjected to statistical analysis using IBM SPSS Statistics, version 26.

Results:

2,864 pedicle screws were analysed which revealed 392 (14%) of these were deemed to be malpositioned on post-operative X-Ray. 45 patients underwent post-operative CT imaging, and 19 patients required revisional surgery. Patients who had more pedicle screws implanted were shown to be more likely to have at least one malpositioned screw identifiable on post-operative X-Ray ($r(152) = .178, p = .028$). There was no statistically significant correlation between presence or number of malpositioned screws identifiable on post-operative X-Ray and requirement for either post-operative CT Imaging or revisional Surgery.

Conclusions:

Whilst the results of this study did not demonstrate a statistically significant correlation between the rate of pedicle screw malpositioning and requirement for post-operative CT imaging or revisional surgery, it has both established the incidence of pedicle screw malpositioning as visible on post-operative X-Ray and identified the discrepancy in visibility of malpositioned screws on both X-Ray and CT imaging.

Background:

Adolescent Idiopathic Scoliosis (AIS) is the most common type of scoliosis and affects children between the ages of 10 and 18, with curve progression occurring predominantly through periods of growth¹. Whilst initial management generally consists of monitoring and the use of external braces, curves of greater magnitude can require surgery due to the progressive nature of AIS, with long-term complications including loss of pulmonary function and even respiratory failure². Surgical intervention is indicated in patients with AIS with progressive curves which do not respond to bracing or present with a Cobb angle greater than 45 degrees³.

As scoliosis is a three-dimensional deformity, the objective of corrective surgery is to achieve balance in the coronal, sagittal, and axial planes and this is generally done through posterior instrumentation: generating correctional force onto the spine with surgical implants typically anchored by pedicle screws, thus enabling vertebral fusion across the levels of deformity in a physiologically normal position^{2,4}

As with any major surgery, scoliosis correction is not without its risks, a recent review of over 8,400 AIS surgical cases revealed a complication rate of 1.5%, most commonly: surgical site infection, new neurological deficit, and implant related complications⁵. Within these risks, there have been several complications noted to associate with the use of pedicle screws alone, such as pseudarthrosis, adjacent segmental degeneration, screw loosening, and screw malpositioning⁶. It is important to establish the incidence of pedicle screw malpositioning in order to provide an accurate assessment of risk to patients, in addition to identifying how best to minimise the occurrence of screw malpositioning, and consequently, post-operative complications.

Study Aims:

The primary aim of this study was to identify the incidence of pedicle screw malpositioning in the surgical correction of AIS and establish whether pedicle screw

malpositioning resulted in a significant increase in the requirement for post-operative CT imaging and revisional surgery. The null hypothesis was therefore: **Malpositioning of pedicle screws does not result in increased post-operative imaging or revisional surgery.**

Study Design and Method:

In order to assess the placement of pedicle screws and consequent post-operative outcomes a retrospective review of clinical information and radiological imaging was carried out. Information was collated from across a range of data sources including surgical notes, referral letters, clinic letters, discharge summaries and radiological imaging.

Cardiff and Vale University Health Board (CAV UHB) is the hub for scoliosis correction within South Wales, acting as the exclusive provider of surgical intervention. An audit was carried out of all scoliosis surgery within CAV UHB between January 2013 and March 2019 in order to provide a sufficiently large study population whilst maintaining a minimum post-operative follow up period of two years. Only patients with a diagnosis of AIS were included, all of whom were under the age of 18 years at the time of surgery. During this period, scoliosis correction surgery was performed by six consultant spinal surgeons, with a minimum of two surgeons per operation.

This yielded a sample of 152 patients: 130 female, 22 male, mean age at surgery 14 years (SD1.63, range 6 years). Following this, clinical details and patient demographics were collected by the junior author utilising clinical notes, prior to assessment of screw placement by the senior author through analysis of all post-operative plain film X-Rays, MRI, and CT scans.

Collected variables include: age at surgery, curve severity (cobb angle) and curve type (Lenke classification)⁷, operative details (e.g. operation performed, implants used, and use of intra-operative image intensifier), screw placement, presence of screw loosening, reported post-operative inter-scapular pain, post-operative CT/MRI imaging, requirement for revision surgery, and radiological and clinical outcomes.

Collected data was subsequently analysed using IBM SPSS Statistics version 26⁸ in order to identify which statistical relationships were present within the data set.

Results:

A sample of 152 patients was analysed, this encompassed 2864 inserted pedicle screws with an average of 19 screws per patient (SD \pm 3.58). Following assessment of immediate post-operative X-Rays, 14% (392) of these screws were deemed to have been malpositioned, with 84% (128) of patients having at least one malpositioned screw and a mean of 3 malpositioned screws per patient (SD 1.91). The most commonly missed screw site was the Right T6 pedicle where 28.1% (16) of screws implanted were deemed to have been malpositioned on post-operative X-Ray, the least commonly missed screw sites were the L5 pedicles bilaterally where 0% of screws were deemed to have been malpositioned on post-operative X-Ray. Additionally, comparison of CT and X-Ray imaging for patients who required post-operative CT imaging revealed a mean of one additional malpositioned screw per patient (SD \pm 3.30) which was not visible on X-Ray. Analysis shows a small correlation ($r(152) = .178, p=.028$) between total number of screws implanted per patient, and the presence of at least one malpositioned screw visible on post-operative X-Ray. An overview of screw malpositioning across the sample group is displayed below in Tables 1a-1d and Chart1.

	Number of Screws Implanted	Number of Malpositioned Screws	Number of Malpositioned Screws Laterally	Number of Malpositioned Screws Medially	Number of Malpositioned Screws Superiorly	Number of Malpositioned Screws Inferiorly
Total	2,864	392	285	15	35	41
Mean	19	3	2	0	0	0
Std. Deviation	3.58	1.91	1.61	0.49	0.61	0.73

Table 1a – Incidence of Pedicle Screw malpositioning

Total Number of Screws		
	Frequency	Percent
11	1	0.6
12	2	1.3
13	3	1.9
14	10	6.5
15	12	7.8
16	16	10.4
17	17	11.0
18	14	9.1
19	13	8.4
20	19	12.3
21	13	8.4
22	8	5.2
23	7	4.5
24	9	5.8
25	2	1.3
26	2	1.3
27	3	1.9
28	2	1.3

Total Number of Malpositioned Screws		
	Frequency	Percent
0	21	15.6
1	23	14.9
2	32	20.8
3	29	18.8
4	26	16.9
5	6	3.9
6	7	4.5
7	3	1.9
8	3	1.9

Table 1c – Frequency of number of pedicle screws identified as malpositioned on post-operative X-Ray per patient

Table 1b – Frequency of number of pedicle screws implanted per patient

	Total Implanted	Total Malpositioned	Percent		Total Implanted	Total Malpositioned	Percent
RT1	0	0	0	LT1	0	0	0.0
RT2	75	14	18.7	LT2	76	18	23.7
RT3	81	20	24.7	LT3	87	21	24.1
RT4	91	21	23.1	LT4	99	20	20.2
RT5	76	21	27.6	LT5	88	14	15.9
RT6	57	16	28.1	LT6	84	13	15.5
RT7	84	13	15.5	LT7	91	13	14.3
RT8	87	11	12.6	LT8	92	19	20.7
RT9	92	11	12.0	LT9	90	17	18.9
RT10	79	6	7.6	LT10	102	21	20.6
RT11	80	6	7.5	LT11	99	10	10.1
RT12	88	8	9.1	LT12	117	11	9.4
RL1	121	10	8.3	LL1	127	7	5.5
RL2	134	13	9.7	LL2	137	11	8.0
RL3	123	14	11.4	LL3	126	7	5.6
RL4	73	2	2.7	LL4	75	4	5.3
RL5	16	0	0.0	LL5	17	0	0.0

Table 1d – Incidence of pedicle screw malpositioning per site

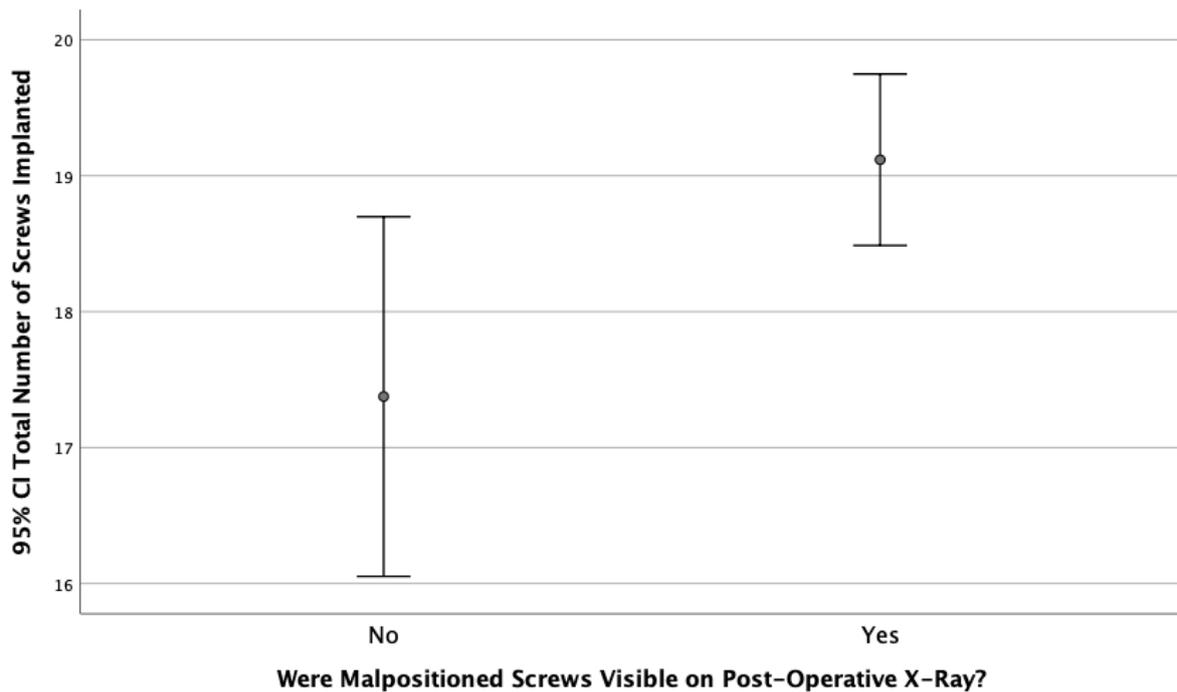


Chart 1 – Error bars demonstrating the relationship between total number of pedicle screws implanted per patient and the incidence of pedicle screw malpositioning per patient

Post-operative CT imaging was required for 30% (45) of patients, and 6 of these patients required CT SPECT imaging. Of the patients who underwent CT imaging, 98% (44) had CT images saved and available for review, and 95% (42) of these images confirmed at least one malpositioned screw with a mean of 4 malpositioned screws per patient (SD ± 2.67). Additionally, 70% (28) were noted to have at least one screw breaching into the costovertebral joint, with a mean of 3 screws within the costovertebral joint (SD ± 1.5).

There was no statistically significant correlation between requirement for post-operative CT imaging and either presence of malpositioned screws on post-operative X-Ray ($r(152)=.008$, $p=.923$), or number of malpositioned screws on post-operative X-Ray ($r_{pb}(152) = .015$, $p = .857$), despite patients requiring CT imaging having a greater number of malpositioned screws (2.62 ± 2.04) than those which did not (2.56 ± 1.86). This is displayed in Table 2 and Chart 2.

Were Missed Screws Present on Post-Operative X-Ray? * Was Post-Operative CT Imaging Required? Crosstabulation

Count

		Was Post-Operative CT Imaging Required?		Total
		No	Yes	
Were Missed Screws Present on Post-Operative X-Ray?	No	17	7	24
	Yes	88	38	126
Total		105	45	150

Table 2 – Crosstabulation demonstrating the incidence of pedicle screw malpositioning across patients who did or did not require post-operative CT Imaging

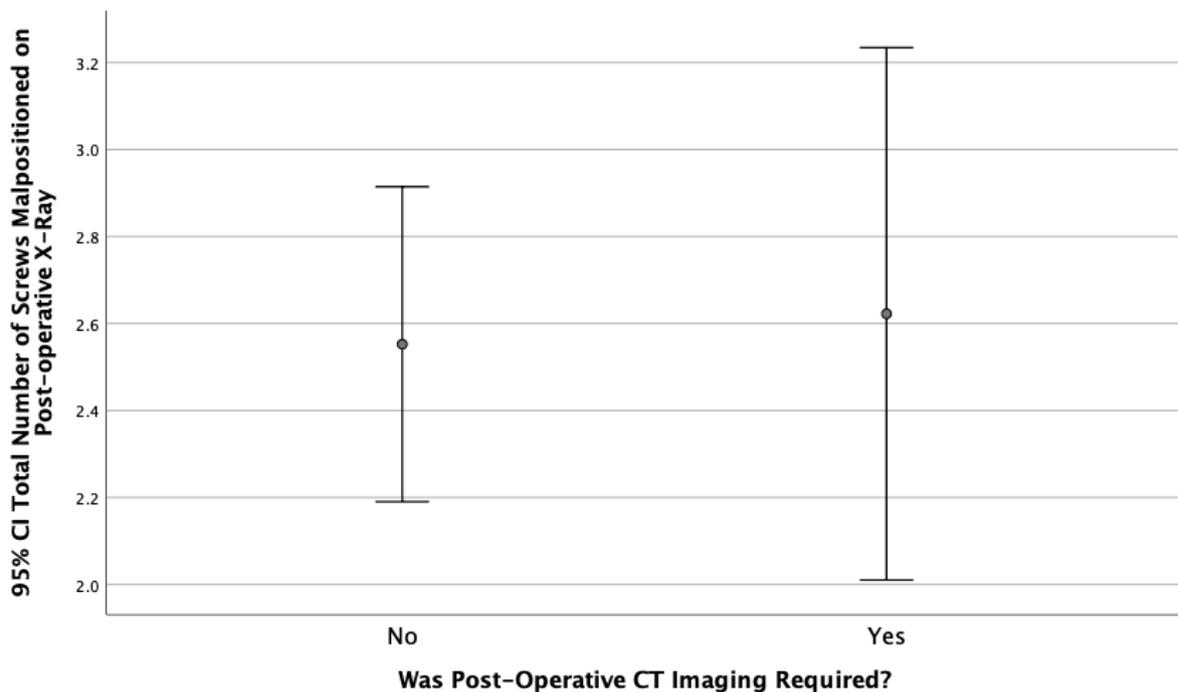


Chart 2 – Error bars demonstrating the relationship between total number of malpositioned pedicle screws visible on post-operative X-Ray and the requirement for post-operative CT Imaging

Revisional surgery was required for 19 patients, 84% (16) of these patients also underwent post-operative CT imaging. Malpositioned screws were identifiable on post-

operative X-Rays for 84% (16) of patients requiring revisional surgery, and 100% (16) of patients who had both revisional surgery and post-operative CT imaging had malpositioned screws identifiable on CT images; 81% (13) were additionally noted to have at least one screw breaching into the costovertebral joint.

There was no statistically significant correlation between requirement for revisional surgery and presence of malpositioned screws on post-operative X-Ray ($R(152)=.049$, $p=.553$), or number of malpositioned screws visible on X-Ray ($r_{pb}(152) = .010$, $p = .898$), despite patients requiring revisional surgery having a greater number of malpositioned screws (2.63 ± 2.01) than those which did not (2.57 ± 1.90). This is displayed in Table 3 and Chart 3.

Were Missed Screws Present on Post-Operative X-Ray? * Was Revisional Surgery Imaging Required? Crosstabulation

Count		Was Revisional Surgery Required?		Total
		No	Yes	
Were Missed Screws Present on Post-Operative X-Ray?	No	20	4	24
	Yes	108	15	123
Total		128	19	147

Table 3 – Crosstabulation demonstrating the incidence of pedicle screw malpositioning across patients who did or did not require revisional surgery

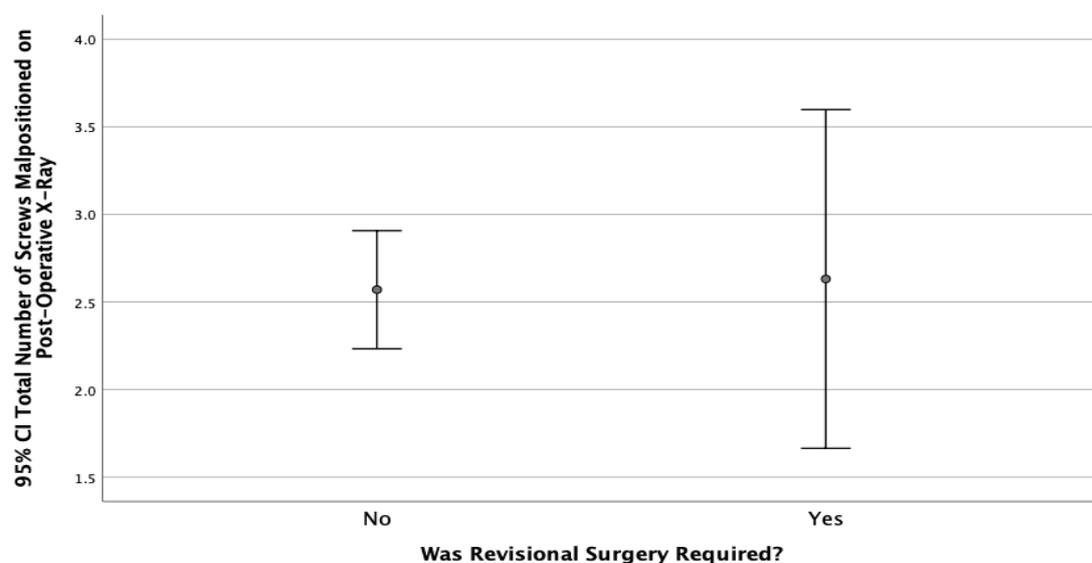


Chart 3 – Error bars demonstrating the relationship between total number of malpositioned pedicle screws visible on post-operative X-Ray and the requirement for revisional surgery

Discussion:

This study revealed that 14% of pedicle screws implanted during correctional surgery for AIS in CAV UHB between 2013-2019 were malpositioned to an extent visible on post-operative X-Ray. Furthermore, analysis of post-operative CT imaging revealed a mean of one additional malpositioned screw per patient (SD ± 3.30) when compared to malpositioned screws identified through analysis of post-operative X-Rays, and therefore the true prevalence of pedicle screw malpositioning within this sample is likely to in fact be greater than 14%. Within wider literature, the incidence of screw malpositioning has been shown to vary widely with figures ranging from 1.2% and 20%⁹, it is therefore difficult to draw comparisons between sample groups which have been analysed with such a range of study designs, surveillance methods, and classifications of malpositioning.

Whilst a greater mean number of malpositioned screws was present in both patients who required CT imaging and revisional surgery; analysis has shown that there is no statistically significant correlation between the number of malpositioned pedicle screws a patient had and their requirement for either post-operative CT imaging, or revisional surgery; thus proving the null hypothesis: **'malpositioning of pedicle screws does not result in increased post-operative imaging or revisional surgery.'**

Despite, the results of this analysis, other studies have shown the wide variety of complications which pedicle screw malpositioning can lead to, including: dural lesions, nerve root irritation, vascular injury, cerebrospinal fluid leak, visceral injury and pedicle fracture¹⁰. However, it has also been observed that many of these pedicle screw complications do not present symptomatically, and therefore, as with screw malpositioning itself, are more frequently detected in studies which utilise a database where postoperative CT imaging was carried out systematically¹⁰. Additionally, a study by Flocarri et al.¹¹, has demonstrated that whilst surgeons are generally in agreement regarding which screws are malpositioned on post-operative imaging, indication for revisional surgery carried a lesser degree of agreement. This perhaps explains the proving of the null hypothesis; the decision to conduct post-operative imaging or revisional surgery would have been initiated by patient reported symptoms or pain prior to consideration by different surgeons across the sample group – these added elements of subjectivity will potentially serve as confounding factors.

Limitations:

Key limitations of this study design include variability of available data and scope of analysis. The retrospective nature of the study has rendered data collection reliant on the post-operative imaging available which varies across the sample both in terms of imaging captured and images saved to patients' electronic records. Having demonstrated the discrepancy in visibility of malpositioned screws between X-Ray and CT imaging, the lack of universal CT imaging and subsequent reliance on X-Ray for identification of malpositioned screws is clearly a limiting factor on the accuracy of results produced, indeed research by Piazzolla et al.¹² suggest that X-Ray has a 71% sensitivity for identifying malpositioned pedicle screws when compared to CT. Furthermore, as highlighted above the variability across each patient's journey from diagnosis to surgery to follow-up introduces a myriad of potentially confounding factors which are impossible to control within a retrospective study of this nature.

A future longitudinal study could identify patients at initial referral and introduce CT-imaging across the entire sample, in addition to establishing a controlled and consistent measure of post-operative outcomes with the inclusion of qualitative data to provide insight into the reasons behind the conduction of further post-operative imaging or revisional surgery in order to more accurately answer the question of whether pedicle screw malpositioning leads to poorer patient outcomes.

Conclusion

Whilst the results of this study did not demonstrate a statistically significant correlation between the rate of pedicle screw malpositioning and requirement for post-operative CT imaging or revisional surgery, it has both established the incidence of pedicle screw malpositioning as visible on post-operative X-Ray and identified the discrepancy in visibility of malpositioned screws on both X-Ray and CT imaging. The results therefore hold value in their ability to guide surgeons in providing their patients with a more accurate assessment of some of the risks associated with having a surgical correction of AIS within South Wales.

Whilst pedicle screws used in surgery within South Wales have traditionally been implanted using free-hand techniques with or without intra-operative imaging guidance, robot-assisted systems are now beginning to be utilised elsewhere in order to improve accuracy of pedicle screw positioning, and this has shown to be effective¹³. Additionally, these systems have shown to reduce operative time, and radiation exposure to theatre staff in comparison to traditional free-hand fluoroscopy guided techniques¹⁴. As evidence surrounding these systems grows, and their use becomes more widely adopted this may well offer insight into the future of spinal surgery across the UK and render the very question of pedicle screw malpositioning impacting patient outcomes moot.

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