A comparison of freehand pedicle screw placement and 3D-printed guides in paediatric scoliosis surgery

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Abstract
Objective: To quantitatively compare freehand pedicle screw placement with the use of Medacta 3D-printed guides in terms of safety and accuracy in paediatric scoliosis surgery.
Design: A retrospective observational cohort study.
Setting: Llandough Hospital and University Hospital of Wales, Spinal Orthopaedics Department.
Participants: Patients aged 21 and younger undergoing pedicle screw instrumentation for scoliosis.
Results: 70 cases were performed freehand and 48 cases used 3D-printed Medacta guides. There were no significant differences in operation time, blood loss or change in Cobb angle between the groups. An average of 0.5 screws per patient were deemed malplaced postoperatively in the freehand group, and 0.15 screws per patient in the Medacta group ($p<0.001$). Intraoperative malplacement was also significantly lower in the Medacta group.
Conclusions: Rates of screw malplacement are significantly higher in the freehand technique compared to the 3D-printed guides, with no change in operation time or blood loss.

Introduction

Pedicle screw instrumentation is an effective method for the correction of spinal deformity (1,2). It is considered safe and the rates of screw malplacement are low (3). However, the consequences of screw malplacement can be severe, including chronic pain, neurological deficit and vascular injury (4). This has led to the development of many techniques which aim to reduce the rates of malplacement, ranging from simple intraoperative fluoroscopy, to CT navigation and robotics, to personalised 3D-printed jigs which guide screw placement intraoperatively (5-7). Research has suggested that 3D-printed guides increase the accuracy of screw placement and improve patient outcomes, whilst reducing operation times and blood loss (8-11), even when used by inexperienced surgeons (12).

The procedure involves a preoperative CT scan which is used to create personalised templates that are positioned onto the vertebrae intraoperatively and guide the insertion of pedicle screws. The CT also allows the correct screw length to be chosen. This technique was implemented in Cardiff and Vale University Health Board in November 2022, using Medacta 3D-printed guides. In this research, the initial 48 Medacta cases were compared to the 70 freehand cases performed prior to introducing the guides. The aim was to determine whether the use of 3D-printed guides increased accuracy of pedicle screw placement and reduced complication rates.

Aims

The aim of this research is to compare the freehand technique with the use of 3D-printed guides for inserting pedicle screws in paediatric scoliosis surgery with regards to accuracy, operation times, blood loss and complication rates.

Methods

We looked at 118 cases of pedicle screw scoliosis surgery performed by 3 surgeons in a tertiary centre between January 2018 and May 2024. 70 of the cases were performed using the freehand technique, and the remaining 48 cases used Medacta 3D-printed guides. Patients over

the age of 21 were excluded, as were those with growing rods. Patient notes and radiological imaging were used to gather the following information; number and location of screws inserted, operation time, blood loss, screw accuracy (both intraoperative and postoperative malplacement, and any long screws, defined as more than one screw thread extending past the anterior cortex), radiation exposure, length of hospital stay, and any issues using the guides. All radiological imaging was interpreted by a medical student and then again by a consultant spinal surgeon to ensure accurate assessment of pedicle screw position. We used SPSS to statistically analyse the data to determine whether personalised 3D-printed guides reduced complications and operation times and increased screw accuracy compared to the freehand technique.

Results

In total, 2290 pedicle screws were inserted into 118 patients; 1237 in the freehand group, and 1053 in the Medacta group (although 44 of these were inserted freehand due to problems with or lack of 3D-printed guides). The freehand group had a total of 36 screws (3%) deemed malplaced post-operatively, compared to 7 (0.7%) in the Medacta group. On average this was 0.5 malplaced screws per patient in the freehand group and 0.15 in the Medacta group ($p<0.001$) - see table 1. The average blood loss in the freehand group was 778 ml, and 767 ml in the Medacta group. In terms of radiation, the freehand group received a mean dose of 54.1mGycm2 from CT scans and 93.8mGycm2 from intraoperative imaging, and the Medacta group received a mean CT dose of 549.9mGycm2 and mean intraoperative imaging dose of 140.5mGycm2. The mean operation time in the freehand group was 175 minutes and was 169 minutes in the Medacta group.

The key statistically significant findings from our analysis are that both intraoperative and postoperative imaging showed that there were significantly higher rates of screw malplacement in the freehand group compared to the Medacta group ($p<0.001$). Also, the Medacta group received significantly more radiation from CT scans than the freehand group, and they had a significantly lower average time per screw (7.8 minutes compared to 10 minutes) and significantly more screws per patient (average of 21.9 versus 17.7). Otherwise, all differences in operative time, blood loss, intraoperative imaging radiation dose, change in Cobb angle, length of hospital stay were not statistically significant.

		Freehand	Medacta guides
Intraoperative	Number of patients	68	47
	Mean number of malplaced screws per patient	1.46	0.85
Postoperative	Number of patients	70	48
	Mean number of malplaced screws per	0.51	0.15

	patient		

Table 1 - mean number of malplaced pedicle screws intraoperatively and postoperatively. Note: 2 patients in the freehand group and 1 patient in the Medacta group had no intraoperative imaging or notes saved for viewing so we were unable to determine how many screws were malplaced intraoperatively.

Aetiology	Freehand	Medacta guides
Adolescent idiopathic	49	32
Early onset	0	4
Neuromuscular	13	5
Syndromic	8	7
Total	70	48

Table 2 - Distribution of scoliosis aetiology between the freehand and Medacta groups.

Discussion

Our significant findings are in line with existing research; 3D-printed guides increase the accuracy of pedicle screw placement and are quicker than insertion using the freehand technique (7,8,10,11,12). (We found significantly more screws were inserted into patients in the Medacta group, and each screw on average took significantly less time to insert - so despite no difference in total operation time as demonstrated in other research, it still seems to be a more efficient method of instrumentation.) This suggests that 3D-printed guides have the potential to become more common in the treatment of paediatric scoliosis as the rates of malplacement are lower (leading to lower rates of revision surgeries and better surgical outcomes) without causing additional surgical complications. Despite this, radiation doses are significantly higher in the Medacta group because every patient must receive a pre-operative CT scan as well as intraoperative fluoroscopy. Whilst some research has argued that the use of 3D-printed guides reduces the need for as much intraoperative imaging and radiation, thus reducing overall radiation exposure (8), our results show the opposite; the Medacta group received more radiation both from CT scans *and* intraoperative fluoroscopy (although the difference in intraoperative radiation was not significant). This needs to be considered when looking at the risk versus benefit analysis, as this is a population already thought to be at an increased risk of iatrogenic malignancy due to the high levels of radiation exposure required for their investigations and treatment (13).

Potential limitations of this research are that we included only 118 patients and 3 surgeons; our results may not be representative due to individual differences in surgeon performance and case complexity. The distribution of aetiologies may have also had some influence (see table 2 above), although there was no statistical difference in preoperative Cobb angle between the two groups (72.7° in the freehand group versus 75.2° in the Medacta group). Furthermore, our data

collection was limited by what information was available in the notes; for example some cases were lacking detailed surgical notes on complications, blood loss and specific instrumentation. There were also some patients where there were radiological studies missing from the notes - 7 patients had no intraoperative imaging saved to view on Synapse, which meant we were unable to see intraoperative screw positioning or their radiation exposure. Moreover, rates of postoperative malplaced screws may be affected by what imaging patients received; those who had a postoperative CT may be more likely to have malplaced screws identified. Therefore, further analysis of the data is required to determine the effect of imaging modality on malplacement rates. Further analysis of the learning curve associated with use of the guides would also be beneficial to understand the implications of recommending the technique for wider use, and this is an area with very little existing research.

Conclusions

Our findings show that personalised 3D-printed guides lead to lower rates of pedicle screw malplacement in paediatric scoliosis surgery compared to the freehand technique, without causing additional complications. There is certainly potential for it to be used more frequently in the surgical management of paediatric scoliosis.

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