

Learning curve and safety of cortical bone trajectory using 3D patient-specific guides for transforaminal lumbar interbody fusion

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INTRODUCTION

Cortical bone trajectory (CBT) is a novel method of pedicle screw insertion. CBT screw follows a mediolateral and caudocranial screw path through the pedicle^[1]. The advantages of CBT screw are reduced dissection of the skin and paraspinal muscles, increased pullout strength, and reduced superior facet violation^[2]. However, traditional pedicle screw-rod constructs were biomechanically stiffer in axial rotation and lateral bending compared to CBT screw-rod constructs^[3,4]. Matsukawa et al. demonstrated that longer and thicker screws increase the fixation strength of CBT screws^[5]. However, the identification of the optimal entry point and direction can be challenging for inexperienced surgeons. Recently, three-dimensional (3D) patient-specific guides were developed to assist surgeons with pedicle screw placement^[6]. This system could help doctors planning the screws trajectories for optimal positioning, and the dimensions of implants. The efficacy of CBT using 3D patient-specific guides have been demonstrated in a cadaver study^[7]. The purpose of this study was to investigate the accuracy of CBT screw placement and learning curve using a 3D patient-specific guide for transforaminal lumbar interbody fusion (TLIF) in our initial experience.

METHODS

Patient population

We retrospectively reviewed data from 30 consecutive patients who underwent transforaminal lumbar interbody fusion (TLIF) with CBT using a 3D patient-specific guide (MySpine MC - Midline Cortical). Fusion surgery was advised for patients with degenerative spondylolisthesis and foraminal stenosis with degenerative lumbar scoliosis. Exclusion criteria are as follows; 1) patient couldn't wait 3-weeks for production and shipment of the guide due to severe leg pain or paralysis, 2) severe hypertrophic facet joint, 3) spondylolysis, 4) previous surgery of wide laminectomy. This study was approved by our Institutional Review Board (IRB). Patient demographic and surgical data were obtained from medical records and operative reports.

Preoperative planning

At least three weeks before surgery, computed tomography (CT) scans were taken. The 3D models were created using medical software (Mimics; Materialise NV, Leuven, Belgium). For each vertebra, the screw entry point, sagittal and cranial trajectory, diameter, and length were planned by the surgeon using a 3D design software (Solidworks; Dassault Systèmes, Ve'lizy-Villacoublay, France). The surgeon planned to insert longer (>35mm) and thicker (>5mm) screws to reduce nonunion of MC screw construct.

Our surgical technique (case of L4-L5)

A 5-cm posterior midline skin incision was made between the cranial edge of the proximal spinous process and distal spinous process. The paravertebral muscles from the lamina to the medial aspect of the facet joints were exposed at L4-L5. Soft tissues and osteophytes were radically removed from the lamina surface to identify the entry points and 3D model fitting. The guide was fit onto the lamina surface. Then, a blunt tip K-wire (2.5mm in diameter and 7cm in length) was used to check the trajectory by lateral fluoroscopy (fig 1a, b). The drill holes were created about 1.5cm deep using 2.7mm drill (fig 1c).

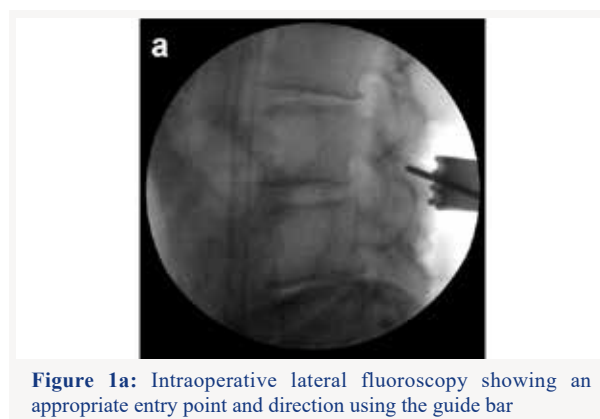


Figure 1a: Intraoperative lateral fluoroscopy showing an appropriate entry point and direction using the guide bar



Figure 1b: The guide bar facilitated stabilization of the 3D-model

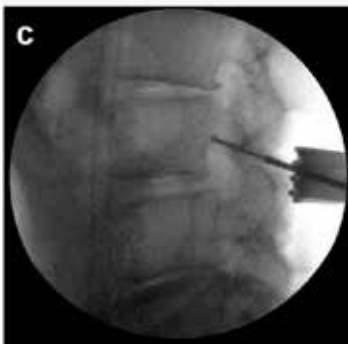


Figure 1c: The drill holes were created about 1.5cm deep using 2.7mm drill

In the first 10 cases, a pedicle probe was used after removal of the guide. In the last 20 cases, a 2.5mm K-wire was gently inserted to the vertebral endplate using a hammer (figure 2).

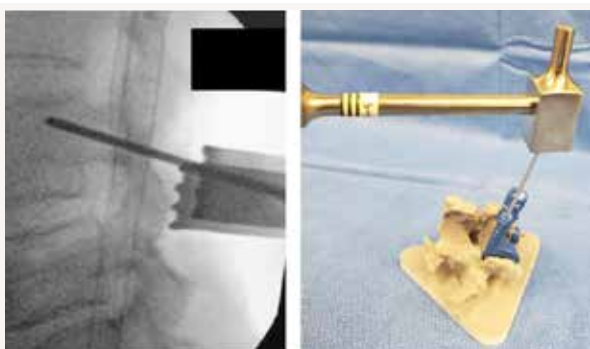


Figure 2: 2.5mm K-wire was gently inserted in the vertebral endplate using a hammer

A second K-wire was inserted contralateral using the first K-wire as a guide. This technique facilitates the stabilization of the drill guide as well as helps in determining the direction of the second K-wire. The entry points were visually confirmed by comparing the K-wire holes and the 3D Bone Model after removal of K-wire and guide.

The penetrating sacral endplate technique was used for S1 screw^[8]. Preoperatively planned cannulated screws were used after cannulated taps of the same size were inserted.

A partial laminectomy and removal of the ligamentum flavum were performed to decompress the spinal canal using the standard technique. Subsequently, removal of vertebral disc and lumbar interbody fusion was performed. The rods and a transversal connector were implanted after applying compression force.

Radiographic evaluation

Radiological assessment was performed by CT scan immediately after surgery and 3 months after surgery. The cranial angle (CA) was defined as the angle between the superior endplate and each screw by sagittal reconstruction CT. The lateral angle (LA) was defined as the angle between the anteroposterior axis of vertebra and each screw by axial view (figure 3).

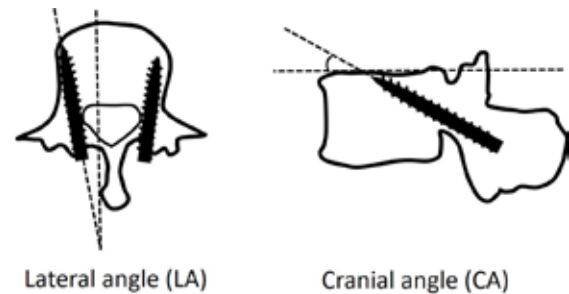


Figure 3: The cranial angle (CA) was defined as the angle between the superior endplate and each screw by sagittal reconstruction CT. The lateral angle (LA) was defined as the angle between the anteroposterior axis of vertebra and each screw by axial view.

LA and CA values were measured for each screw. Deviations from the preoperative planning and inserted screws in each vertebra were measured. The accuracy of MC screw was categorized into four groups based on the location of perforation. Anterior column (AC) was defined as perforation of anterior column of vertebra. Middle column was defined as perforation of central column of vertebra. Pedicle lateral (PL) was defined as perforation of lateral wall of the pedicle. Pedicle medial (PM) was defined as perforation of medial wall of the pedicle (figure 4).

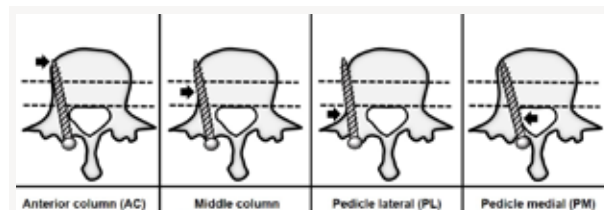


Figure 4: Classification of MC screw misplacement

Loss of correction at fused segment, endplate cyst, cage subsidence, and screw loosening were assessed at 3 months post operation by CT scan and X-ray.

Comparison among the three groups

To assess the learning curve, patients were divided into three groups: the first 10 cases were the early experience group (early group), the subsequent 10 cases were the middle experience group (middle group), and the last 10 cases were the late experience group (late group). The rate of screw misplacements, operative time, estimated blood loss, intraoperative fluoroscopy time were compared among these three groups.

Statistical Analysis

Continuous variables were expressed as means with ranges, and the mean differences between the groups were compared by t-test. For categorical variables between the groups, the Fisher exact test was used as appropriate. The one-way analysis of variance (ANOVA) with post hoc Tukey test was used to compare the three groups. Statistical analyses were performed using SPSS v19.0.1 (SPSS Inc., Chicago IL), and a value of $p < 0.05$ was considered statistically significant.

RESULTS

Patients and surgical characteristics

The mean age at surgery was 72.7 ± 7.1 years (range: 56-86 years), and the group was composed of 15 males and 15 females. The preoperative diagnosis were degenerative spondylolisthesis in 18 cases, degenerative lumbar scoliosis in 4 cases, foraminal stenosis in 4 cases, destructive spondyloarthropathy in 2 cases, and failed back surgery in 2 cases. There were one-level TLIF in 26 cases and two-level TLIF in 4 cases. The operated level was L3-L4 in 9 levels, L4-L5 in 20 levels, and L5-S1 in 5 cases (Table 1).

Table 1

Number of patients	30
Age (years)	72.7 ± 7.1 years
Gender	Male 15cases, Female 15cases
Preoperative diagnosis	
Degenerative spondylolisthesis	18 cases
Degenerative scoliosis	4 cases
Lumbar foraminal stenosis	4 cases
Destructive spondyloarthropathy	2 cases
Failed back surgery	2 cases
Number of fused levels	1 level: 26cases, 2 levels:4cases
Operative levels	
L3-L4	9 levels
L4-L5	20 levels
L5-S1	5 levels

The mean operative time was 146.3 ± 27.3 min (one-level; 139.2 ± 19.9 min, two-level; 192.5 ± 25.9 min) and estimated blood loss was 114.3 ± 89.5 ml (one-level; 97.9 ± 77.8 min, two-level; 221.3 ± 96.8 min). The number of screws used and its corresponding diameters and length are as follows. 5mm diameter screws, 6; 6mm diameter screws, 122. 30mm length screws, 4; 35mm length screws, 16; 40mm length screws, 80; and 45mm length screws, 28 ; an average of 40.2mm screw length (Table 2).

Table 2

Operative time (min)	146.3 ± 27.3 (single level, 139.2 ± 19.9 , two-level, 192.5 ± 25.9)
Estimated blood loss (ml)	114.3 ± 89.5 (single level, 97.9 ± 77.8 , two-level, 221.3 ± 96.8)
Screw diameter	
5mm	6 screws
6mm	122 screws
Screw length	
30mm	4 screws
35mm	16 screws
40mm	80 screws
45mm	28 screws

Accuracy of MC screws

Overall, the accuracy of MC screw placement was 91% (116/128). Out of 12 misplaced screws, AC was observed in 7 screws, Middle Column was observed in 3 screws, and PL was observed in 3 screws (Figure 5).

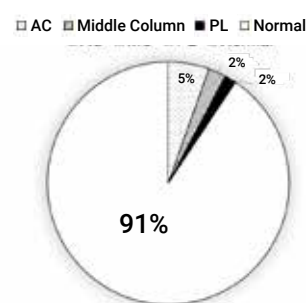


Figure 5: Accuracy of MC screws

There were no cases of PM. The mean deviation of the LA was $0.6 \pm 2.5^\circ$. The mean deviation of the CA was $-1.3 \pm 2.9^\circ$. The mean deviation of each vertebra and its corresponding sides are indicated in fig 6,7.

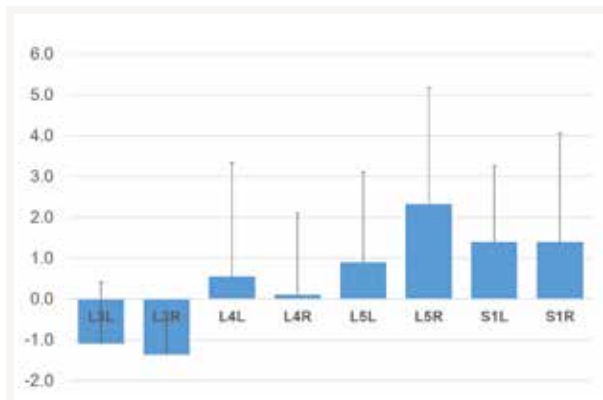


Figure 6: The mean deviation of the lateral angle (LA) in each vertebra

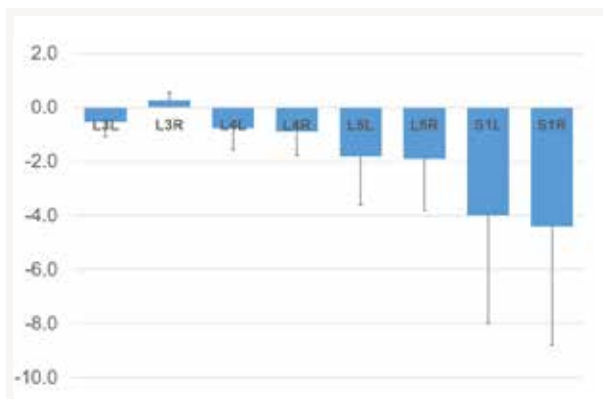


Figure 7: The mean deviation of the cranial angle (CA) in each vertebra

Comparison among the three groups

Misplacement of screw was 21% in the early group, 5% in the middle group, and 2% in the late group, respectively (Fig 8).

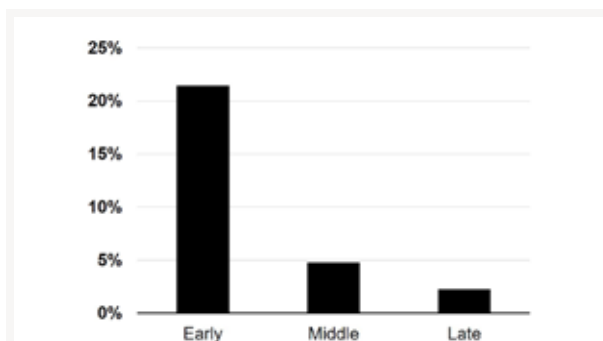


Figure 8: Comparison of MC screw misplacement between three groups

Operative time was 8.4 minutes shorter in the late group than the middle group, and 18.5 minutes shorter in the early group (Fig 9).

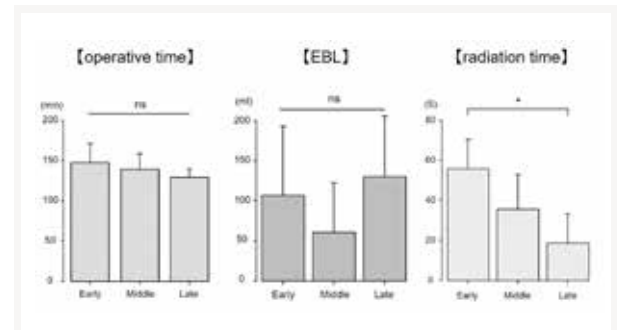


Figure 9: Comparison of operative time, estimated blood loss, and intraoperative fluoroscopy time

However, there were no significant differences among the three groups (early; 147.8 ± 24 min, middle; 139.4 ± 19.6 min, late; 129.3 ± 10.5 min, $P=0.161$). There were no significant differences in estimated blood loss among the three groups (early; 106.7 ± 86.1 ml, middle; 60.6 ± 61.9 ml, late; 130 ± 75.5 ml, $P=0.172$). In terms of the intraoperative fluoroscopy time, significant differences were detected between the early group and the late group (early; 55.7 ± 14.9 sec, middle; 35.7 ± 17.1 sec, late; 18.5 ± 14.8 sec, $P=0.001$).

Perioperative complications

Intraoperative and perioperative complications associated with MC technique included pedicle fracture in 1 patient, infection in 1 patient, and dural tear in 1 patient. No MC screw was converted to traditional pedicle screw. No screw-related neurological or vascular complications were observed intraoperatively and postoperatively.

DISCUSSION

The present study demonstrates that MC screw placement using a 3D patient-matched guide achieved an accuracy of 91%. In a recent cadaveric study, over 90% of MC screws using a 3D patient-matched guide were inserted inside of the pedicle and pedicle perforation was within 2mm. We evaluated the accuracy of MC screws using new classification based on the location of screw perforation. PL and PM pose risks for nerve root injury. Dayani et al. described learning curves associated with middle column. A 6% medial perforation was observed in the early phase^[9]. They concluded that the use of screws with smaller diameter and lateralization of entry point reduce the risk of medial perforation. Santoni et al. indicated that 20% of MC screws perforated the medial wall^[1]. In our study, there were no medial perforation of the pedicle despite lack of experience in MC. PL were observed in 2 cases (4%) due to lateral slippage of the drill tip in the early group. The guide bar method improved guide stability which prevented lateral slip of the drill tip. Therefore, misplacement rate had markedly decreased in the middle and late group.

MC screws have been proposed as an alternative to traditional screws^[1]. Characteristics of MC screws include increased pullout strength due to greater contact with the cortical bone, and decreased risk of damage to paravertebral muscle associated with the posterior approach. A new screw design which is shorter and smaller in diameter than the traditional trajectory pedicle screw has been proposed. Thereafter, several researches demonstrated that longer and thicker screws are required to increase stability in terms of screws and screw-rod constructs. Matsukawa et al. recommended the ideal screw size for MC as a diameter larger than 5.5 mm and the length longer than 35mm^[5]. The vast majority of screws which were used in this study were larger than 5.5mm and longer than 35mm. Preoperative planning and 3D patient-matched guide enabled the use of longer and thicker screws and an optimal entry point.

There are some limitations to this guide. First, the waiting period for this 3D patient-specific guide is 3-weeks including production and shipping. Patients were excluded in cases of emergency surgery due to severe leg pain or paralysis. Second, there are some difficult cases due to problems with identification of entry point caused by severe hypertrophic facet joint.

CONCLUSION

The accuracy of MC screw placement was 91%. There were no cases of medial wall perforation. There was a trend in decreased operative time and significantly decreased intraoperative fluoroscopy time with experience. These results suggest the possibility of efficacy and safety in using 3D patient-specific guides for Middle Cortical technique.



Figure 10a: One year postoperatively, there was no evidence of screw loosening



Figure 10b: Postoperative CT at 1 year showed complete fusion

Notes

[illegible]

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References

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