Error rate of multi-level rapid prototyping trajectories for pedicle screw placement in lumbar and sacral spine

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【**Abstract**】**Objective:** Free-hand pedicle screw placement has a high incidence of pedicle perforation which can be reduced with fluoroscopy, navigation or an alternative rapid prototyping drill guide template. In our study the error rate of multi-level templates for pedicle screw placement in lumbar and sacral regions was evaluated.

Methods: A case series study was performed on 11 patients. Seventy-two screws were implanted using multi-level drill guide templates manufactured with selective laser sintering. According to the optimal screw direction preoperatively defined, an analysis of screw misplacement was performed. Displacement, deviation and screw length difference were measured. The learning curve was also estimated.

Results: Twelve screws (17%) were placed more than 3.125 mm out of its optimal position in the centre of pedicle. The tip of the 16 screws (22%) was misplaced more than 6.25 mm out of the predicted optimal position. According to our predefined goal, 19 screws (26%) were implanted inaccurately. In 10 cases the screw length was selected incorrectly: 1 (1%) screw was too long and 9 (13%) were too short. No clinical signs of neurovascular lesion were observed. Learning curve was insignificantly noticeable (P=0.129).

Conclusion: In our study, the procedure of manufacturing and applying multi-level drill guide templates has a 26% chance of screw misplacement. However, that rate does not coincide with pedicle perforation incidence and neurovascular injury. These facts along with a comparison to compatible studies make it possible to summarize that multi-level templates are satisfactorily accurate and allow precise screw placement with a clinically irrelevant mistake factor. Therefore templates could potentially represent a useful tool for routine pedicle screw placement.

Key words: ***Drill guide; Template; Inaccuracy; Perforation; Radiation exposure***

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The use of pedicle screw systems for vertebral fusion is becoming increasingly common in spine surgery.[1] The golden standard for pedicle screw placement is the free-hand technique, however it has a high associated rate of unplanned perforation, which is the major specific complication of pedicle screw implantation and causes a high risk of bone weakening or lesions of the spinal cord, nerve roots or blood vessels.[2]

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Another routinely used method during pedicle screw placement is image guidance (navigation). The principle is to register the patient's preoperative computed tomography (CT) scans, thus permitting the surgeon to be guided when placing screws. Such navigation systems have shown good clinical results.[3-5] There are, however, several disadvantages, especially an increased overall operation time and a higher risk of intraoperative infection.[6] Few hospitals can bear the costs of sensor- or robot-based systems.[7,8]

Considering these drawbacks, ideas of producing personalized templates for pedicle screw implantation are introduced. They are designed using a preoperative CT scan to fit in a unique position in the individual's bone and these precisely designed holes guide the drill through a preplanned trajectory. But these methods are applied mainly on animal or human cadavers and only in a limited number of clinical studies. These studies present a very variable template error rate mainly dependent on the specific design of the drill guide. Basically templates that match the posterior surface of the spine in large area show greater accuracy in comparison to templates that touch the spine just in some points when applied. Furthermore, multi-level (multiguide) templates are not as accurate as drill guides designed for single level screw placement. [9-23]

Due to limited clinical reports providing accuracy of drill trajectories, our another study[24] evaluated the accuracy of pedicle screw placement in the lumbar and sacral spine using a rapid prototyping drill guide template in comparison with the free-hand technique. Therefore a multi-level drill guide template significantly reduced the perforation risk of the pedicle in comparison with the free-hand technique.

According to literature, all types of drill trajectories suffer from a failure rate and errors that prevent ideal positioning of the screw in comparison to the pre-designed screw direction defined by the engineer. Consequently, this study was to measure an in vivo error rate of pedicle screws implanted with the multi-level drill guides in comparison with the pre-defined virtual screw's direction designed in the lab, and to estimate the clinical importance of such a failure rate and the effect of learning curve on screw position accuracy.

METHODS

A retrospective case series study was performed on 11 patients, and an implantation of 72 pedicle screws using multi-level drill guide templates was performed. The study was classified according to the declaration of Helsinki for medical research involving human subjects. It was approved by the local ethics committee. Patients were acquainted with the study procedure, potential risk factors and radiation exposure due to CT scan. All subjects invited to take part in the study had voluntarily decided to participate and gave their informed consent. None of the patients had declined to participate in the study. The criterion for using a drill guide template and for inclusion in the study was an indication for lumbar or lumbosacral fusion because of degenerative disorders resulting in spondylolysis/listhesis or severe spinal stenosis. The exclusion criterion was a previous operating procedure on the observed spinal level (e.g. previous spinal fusion).

Design of the drill guide template

A CT scan of the lumbar and sacral spine with the slice thickness of 0.5 mm was performed on patients lying in the prone position to simulate similar facet joint relations during the operating procedure. The images were stored in DICOM format and transferred to a workstation EBS software version 2.2.1 (Ekliptik, Slovenia) software to generate a 3D reconstruction model for the targeted lumbar or sacral vertebra. The 3D spine model was exported in STL format to determine the optimal screw size and orientation. Firstly, the 3D model was opened and the image of the pedicle was exposed. Secondly, the pedicle circumference and direction were investigated. Lastly, a circle was found with the smallest diameter of this ellipse. The centre of this circle was then virtually connected with the corpus vertebrae and the facet joint to obtain the optimal pedicle screw trajectory (Figure 1). The virtual screw was pointed towards the centre of each half of the corpus vertebrae. Then, a 3D vertebral model was reconstructed with virtual screws placed on both sides and on different levels. The optimal screw length was also determined so that the end of the screw reached 50%-80% of the vertebral diameter. We used Click’X stabilization system (Synthes, Swiss) with 6.25 mm diameter screws which were delivered in lengths increasing by 5 mm.

A drill guide template was constructed with a surface designed to be inverse of the dorsal part of the facet joint. That was intended to enable a lock-and-key mechanism fitting the dorsal part of the facet to achieve minimal overlap. The parts of the template for each pedicle screw were connected to each other in the sagittal and transversal plane to achieve maximum stability of the template. Additionally, cylinders fitting a trajectory hole had been manufactured allowing temporary fixation of the drill guide with K-wires. A virtual drill guide template was exported in STL format. Finally, it was manufactured using the selective laser sintering with 0.1 mm printing accuracy (Figure 2).[24]