A New Navigational Tool for Pedicle Screw Placement in Patients With Severe Scoliosis

A Pilot Study to Prove Feasibility, Accuracy, and Identify Operative Challenges

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Study Design: Pilot study.

Objective: To develop and validate the feasibility and accuracy of a newly designed navigational spinal instrument guiding tool for patient-matched thoracic and lumbar pedicle screw placement in patients with severe scoliosis, and to identify intraoperative challenges that may be relevant.

Summary of Background Data: Pedicle screw placement is challenging in severely rotated scoliotic spine with small diameters and asymmetrical shape of the pedicles and vertebrae. Patient-specific drill/positioning guides with preplanned trajectory have been developed as a promising solution in spinal surgery for precise screw insertion.

Methods: In 4 patients with severe scoliosis, navigational templates and models of all vertebrae to be instrumented were manufactured using a computed tomography (CT)-based 3-dimensional model of the thoracic and lumbar spine. The guides were designed differently for thoracic and lumbar segments according to the individual anatomy to achieve an optimal coupling to the surface of the patient's spine, to maximize the stability of the device itself, and to increase user friendliness for the complete screw positioning process. Intraoperative challenges and opportunities for device and process improvements regarding the handling of the guides during the surgery were recorded. Postoperatively, the intrapedicular screw positions were evaluated versus the preoperative plan and evaluated for cortical violation based on CT scans.

Results: A total of 76 pedicle screws were implanted (56 thoracic, 20 lumbar). Two screws (2.6%) were assessed to be misplaced intraoperatively and repositioned. Eighty-four percent of the pedicle screws were completely intrapedicular, 96.1% within <2 mm cortical breach. CT scans did not demonstrate myelopathy, pedicle violation, or misplaced screw contact to neurovascular structures. No screw-related clinical complaints were reported postoperatively.

Conclusions: The new custom-made positioning guide is a feasible navigational tool that permits a safe and accurate implantation of pedicle screws in patients with severe scoliosis.

Key Words: pedicle screw guide, 3D-printing, positioning tool, navigation, scoliosis, deformity

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Pedicle screw fixation is the state-of-the-art in spinal deformity correction.1−3 However, in severely rotated scoliotic spine with small diameters and asymmetrical shape of the pedicles and vertebrae, pedicle screw placement is challenging.4−7 The proximity of nearby neurovascular structures, including the great vessels and the spinal cord, increases the risk for serious complications because of malpositioned pedicle screws.5 In 2 recent reviews, the rate of screw misplacement based on postoperative computed tomography (CT) scans averaged at about 15%;8,9 with the majority of studies presenting even higher values for the thoracic spine (up to 50%).10−12 Implant-associated neurological deficits leading to reoperation occurred in up to 7% of the patients.12 Furthermore, malposition with cortical breach, extrapedicular position, or pedicle fracture may cause a biomechanical drawback14–16 with screw pullout during the reduction maneuver or secondary loss of correction due to screw loosening.8,9

Navigation systems that provide intraoperative assistance have been shown to improve pedicle screw insertion accuracy and safety in many clinical and cadaveric studies. The superiority of navigated surgery was most obvious when applied to abnormal spinal anatomy and structures. The best results have been reported for 3-dimensional (3D)