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Clinical Studies

Template guided cervical pedicle screw instrumentation[☆]

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ABSTRACT

Background: Pedicle screw instrumentation of the cervical spine, although technically challenging due to the potential risk of serious neurovascular injuries, is biomechanically favorable for stabilization purposes. Patient-specific templates are increasingly used in the thoracolumbar spine with excellent accuracy. The aim of this study was to evaluate the accuracy of cervical pedicle screw placement with patient-specific templates in a clinical setting and to report the European experience so far.
Methods: Multicentric, retrospectively obtained data of twelve patients who underwent dorsal instrumentation of the cervical spine with 3D-printed patient-specific templates were analyzed. Postoperative computed tomography (CT) scans were used to evaluate pedicle perforation and screw deviations between the planned and actual screw position. Furthermore, surgical time, radiation exposure, blood loss and immediate postoperative complications were analyzed.
Results: A total of 86 screws were inserted, of which 82 (95.3%) were fully contained inside the pedicle. All perforations (four screws, 4.7%) were within the safe zone of 2 mm and did not result in any neurovascular complications. Overall, median deviation from planned entry point (Euclidean distance) was 1.2 mm (0.1 - 11 mm), median deviation from the planned trajectory (Euler angle) was 4.4° (0.2-71.5°), median axial and sagittal trajectory deviation from the planned trajectory were 2.5° (0 - 57.5°) and 3.3° (0 - 54.9°), respectively. Median operative time was 168 minutes (111 - 564 minutes), median blood loss was 300 ml (150 - 1300 ml) and median intraoperative fluoroscopic dose was 321.2 mGycm^2 (102.4 - 825.0 mGycm^2). Overall complications were one adjacent segment kyphosis, one transient C5 palsy and one wound healing disorder.
Conclusion: Patient-specific 3D-printed templates provide a highly accurate option for placing cervical pedicle screws for dorsal instrumentation of the cervical spine.

Introduction

Accurate pedicle screw placement, especially in the cervical spine is of major importance to minimize the risk of neurovascular injuries and reduce biomechanical disadvantages of screw malpositioning [1]. Various techniques are available for placement of cervical pedicle screws (CPS), providing different advantages and drawbacks in terms of accuracy of screw placement, radiation exposure, intraoperative blood loss, and surgical time [2,3].

In recent years, there has been a search for alternatives to free-hand or navigated techniques that provide the same or greater accuracy in screw placement and less radiation exposure for patients and surgeons. For this purpose, techniques using 3D-printed patient-specific templates have been proposed and developed, providing promising results [4–6]. These patient-specific templates are produced on the basis of a preoperative CT scan to fit precisely the dorsal bony surface of the corresponding vertebra. The included guide holes enable drilling and pedicle screw placement according to the preoperatively planned trajectory.

Currently, most literature regarding precision and [5,7-9] accuracy of screw placement using patient-specific templates is based on cadaveric studies . Clinical studies are lacking or are solely based on small case series from Asia [10,11]. Therefore, the aim of this study is to present

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Table 1
Demographics and indications for posterior cervical spinal fusion.

Age[§]	59 (28-80)
Weight[§]	82kg (50-96)
Height[§]	175.5cm (162-185)
Trauma	3
Tumor	4
Junctional degeneration (fracture, kyphosis)	4
Screw loosening after anterior cervical spinal fusion	2

§ Values in median and ranges ().

Table 2
Number of screws per level and placement accuracy of the inserted screws.

Level	No perforation	Grade 1	Grade 2	Grade 3
C2	4	0	0	0
C3	11	1	0	0
C4	19	0	0	0
C5	16	2	0	0
C6	20	0	0	0
C7	12	1	0	0
Total	82 (95.3%)	4 (4.7%)	0	0

a European experience with this surgical technique in terms of accuracy and safety in a retrospective multicenter study. The hypothesis of this study is that cervical pedicle screw placement with patient-specific templates is accurate and safe to use in a clinical setting.

Materials and methods

The study was approved by the responsible investigational review board (KEK-ZH-Nr. 2021-01464) and conducted following the Helsinki Declaration. Multicentric, radiographic data of patients who underwent dorsal instrumentation of the cervical spine with patient-specific templates at the three involved University Hospitals between 2019 and 2021, were analyzed in a retrospective fashion. Informed consent was obtained from all patients for the use of their health-related data. During this timeframe, a total of 86 cervical pedicle screws using a 3D-printed template guide system for the cervical spine (Medacta SA International, Switzerland) were inserted in twelve patients. Patients' demographics are listed in Table 1. In total, 13 surgeries were performed, of which one included a revision surgery.

The indications for posterior cervical spine fusion are listed in Table 1.

Preoperative planning and template fabrication

As specified by the manufacturer's protocol, a CT scan with a slice thickness of <1mm was performed preoperatively for each cervical spine. The CT data set was sent to a web platform to develop a digital screw trajectory plan for each vertebra. Fig. 1 illustrates the planning report for one cervical level. The planning was reviewed and validated by the operating surgeons. Three-dimensional printed replicas of all vertebrae and level-specific templates were produced (Print material: Polyamide-PA12; Fig. 2). They were sterilized in a standardized manner before surgery.

Surgical technique

In all cases a dorsal midline incision was performed over the corresponding vertebrae, including dissection and retraction of the paravertebral musculature to expose the anatomical bony landmarks. The lamina, the lateral mass and the spinous process served as the main contact areas for the templates. To achieve a stable fit and prevent malpositioning of the screws, the posterior elements must be meticulously removed of soft tissue. Damage to the bone surface must be prevented. Once the template position was satisfactory, a 2.7 mm drill bit with a depth stopper was used to drill the template guided trajectory to a depth that corresponded to the preoperative plan of the screw length. The template was then removed and a pedicle probe with a small ball tip was used to palpate the bony integrity of the surrounding walls. After tapping, a predefined CPS was inserted. After the pedicle screws were securely inserted, decompression was performed.

Postoperative evaluation of screw position

Postoperatively, a spiral 128-slice multidetector CT scan (SOMATOM Edge Plus, Siemens Healthcare GmbH, Erlangen, Germany) with a slice thickness of < 1mm of all in this study included cervical spines was performed within the first postoperative weeks. Pedicle screw positions were evaluated in the postoperative CT-scan in the sagittal, transversal and coronal plane using Merlin 5.2. (Phoenix-PACS, Freiburg, Germany) by an independent, board-certified musculoskeletal radiologist with >10 years of experience in musculoskeletal imaging. For equivalent data collection and assessment, anonymized CT scans were collected in one center and assessed by the same radiologist.

Pedicle screw perforations were categorized by a grading system based on a two mm increment scale as proposed by Gertzbein et al. [12]. A perforation less than two mm (Grade 1) was considered acceptable (safe zone). Additionally, the localization of the perforation, if present, was categorized into superior, inferior, lateral or medial.

Pre- and postoperative CT scans were compared and the deviation between the planned and performed entry point and trajectory was analyzed and quantified. Parameters of interest were the deviation (in mm) at the entry point of the pedicle in 3D space (= entry point deviation) as well as the deviation of the screw angle in 3D space (= direction deviation), the axial plane (= axial trajectory deviation) and sagittal plane (= sagittal trajectory deviation). The evaluation of these parameters was performed in CASPA (CASPA, version 5.26, blinded). In two cases (two C6 and two C7 screws), the screw position could not be assessed due to artifacts, thus they had to be excluded.

Postoperative CT-scans were segmented with Mimics to create 3D models of each vertebra and of the implanted screws. The postoperative 3D vertebra-models were then registered to the corresponding preoperative models using the iterative closest point (ICP) method [13,14]. Cylinders with the same diameter as the implanted screw were aligned to the screw-models in order to quantify the screw trajectories. The performed entry points were defined as the intersection between the bony surface of the preoperative models and the postoperative screw trajectories. The 3D distance (Euclidean distance) between planed and performed entry point was calculated to get the entry point deviation (Fig. 3). Similarly, the 3D angle (Euler's angle) was calculated between planed and performed screw trajectory to quantify trajectory deviation (Fig. 4).

The deviations of the different cervical spine levels were compared with each other. Furthermore, operative time, radiographic exposure, blood loss and immediate postoperative complications were assessed.

Statistical analysis

Statistical analysis was conducted with SPSS software v26.0 (IBM, New York, USA). The Shapiro-Wilk test was applied to test the data for normal distribution. The variables are reported with median and ranges. The accuracy of the screw position of each level was compared to that of the level above using a Mann-Whitney U test. The alpha level was set at 0.05, and all p-values were 2-tailed.

Results

Pedicle perforation rates, grading and screw trajectory

Of the 86 screws inserted, 82 (95.3%) were fully contained inside the pedicle. Four screws showed a grade 1 (<2mm) perforation (Table 2).

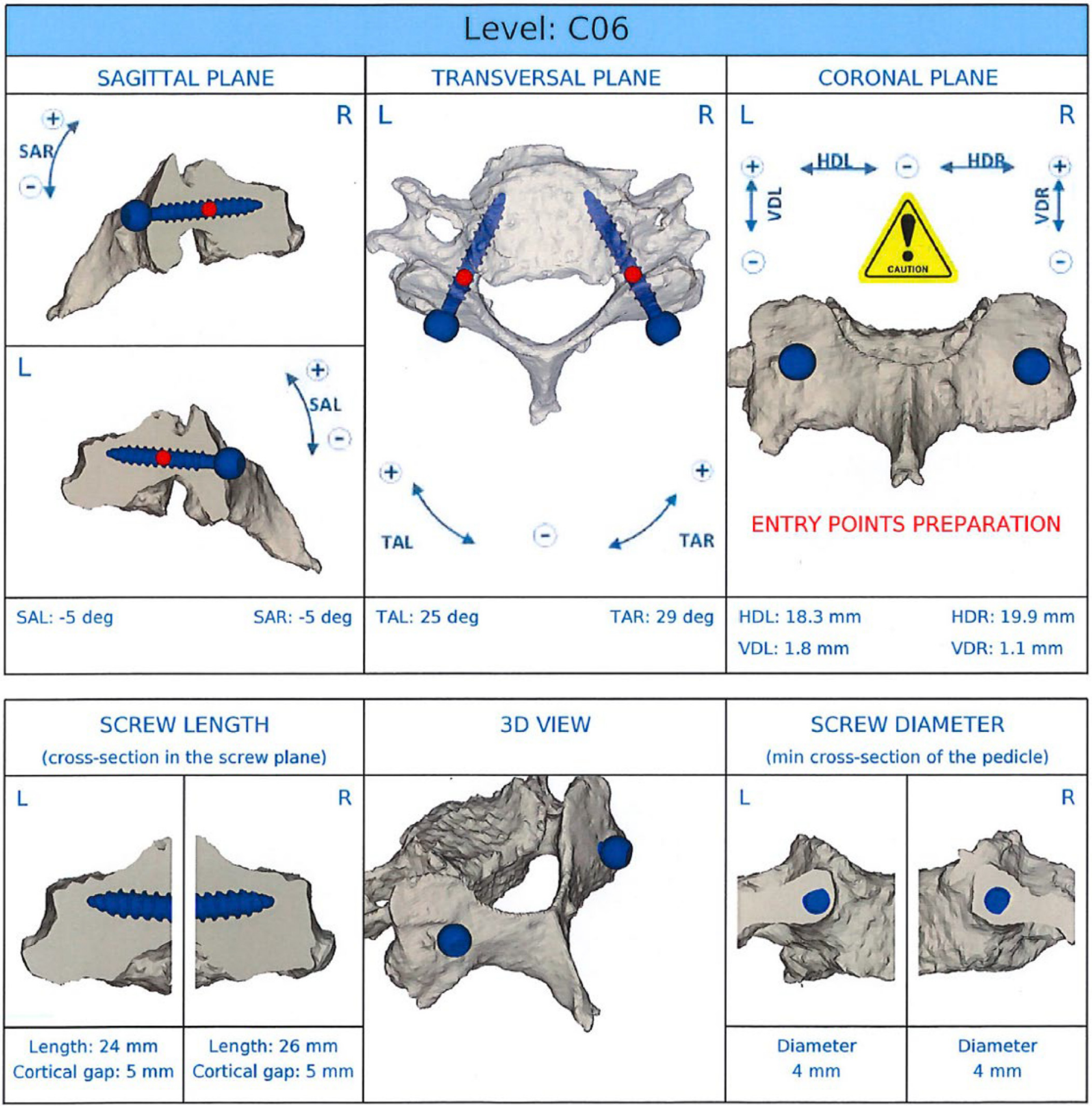

Fig. 1. Planning report for one cervical level (C6).

Thereof, two screws showed a perforation medial-inferior, one medial-superior, and one medial. No neurovascular complications were noted due to these deviations. A representative case of a perforation is shown in Fig. 3.

The calculated deviation values for each screw are shown in Table 3. The deviations from the planned trajectory showed no tendency to increase in cranial or caudal vertebrae. However, some outliers were found, especially in the C6 segment, which affected all accuracy measurements. Sagittal angular deviations to cranial and axial angular deviations to lateral were found. A comparison of deviations between the different spinal levels showed no significant differences. The deviations from the planned trajectory could not be attributed to a single surgeon.

Operative time, radiation dose and postoperative complications

The median operative time was 168 minutes (range: 111 to 564 minutes) with a median blood loss of 300 ml (range: 150 to 1300 ml). The median intraoperative fluoroscopic dose was 321.2 mGycm^2 (range: 102.4 to 825.0 mGycm^2).

Postoperative complications were: One patient required revision four months postoperatively due to progressive cervical kyphosis. This case involved a tumor patient who had multiple prior surgeries and initially received a C2-4 dorsal fusion that had to be extended to C2-Th2. One patient showed a mild incomplete C5 palsy on the left side not related to the screw position since the screws did not show any perforation at these

Table 3
Median deviation between planned and actual screw position overall and by level.

	Total (all levels)§	C2	C3	C4	C5	C6	C7
Entry point deviation*	1.2 (0.1 - 11)	1.0 (0.5 - 1.7)	0.9 (0.3 - 2.4)	1.2 (0.2 - 3.9)	1.3 (0.5 - 3.5)	0.9 (0.1 - 11)	1.7 (0 - 2.5)
Direction deviation**	4.4 (0.2 - 71.5)	6.8 (2.9 - 10.6)	4.3 (0.2 - 9.3)	4.8 (0.4 - 9.1)	4.2 (1.1 - 17.3)	4.9 (0.4 - 71.5)	5.3 (1.7 - 9.4)
Axial trajectory deviation***	2.5 (0 - 57.7)	2.7 (1.1 - 9.3)	3.1 (0.1 - 8.7)	3 (0 - 8.7)	2.3 (0 - 8.2)	2.8 (0.3 - 57.7)	1.1 (0.1 - 4.6)
Sagittal trajectory deviation****	3.3 (0 - 54.9)	3.7 (0.3 - 11.8)	3.1 (0.1 - 9.4)	3.2 (0 - 10.2)	3.2 (0 - 16.3)	3.2 (0.1 - 54.9)	6.3 (0.8 - 10.4)

§ Values in median and ranges ().
* smallest distance in 3D space (Euclidean distance) between planned and actual entry point (mm).
** smallest angle in 3D space (Euler angle) between the planned and actual trajectory (°).
*** deviation of the planned trajectory from the actual trajectory in the axial plane (°).
**** deviation of the planned trajectory from the actual trajectory in the sagittal plane (°).

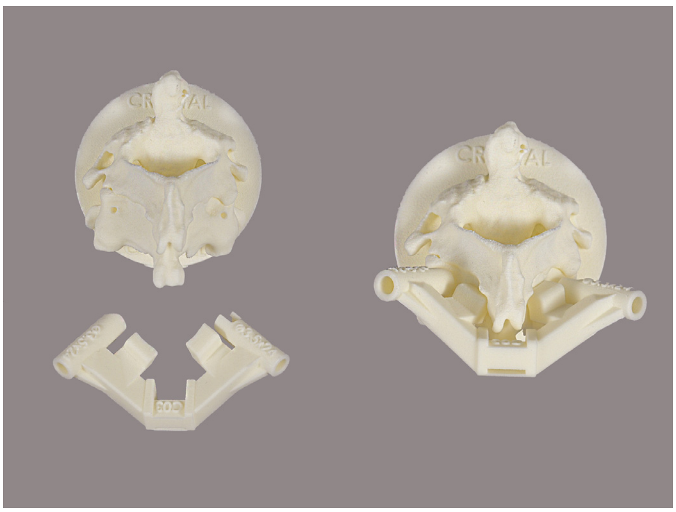

Fig. 2. Three-dimensional printed replicas of C2/3 and the level-specific template.

levels. The symptoms completely resolved within the first postoperative months. Furthermore, another patient required revision surgery three months postoperatively due to a wound healing disorder. The wound was debrided and treated with a vacuum assisted closure-therapy with complete wound healing three weeks later.

Discussion

The present study reports the radiographic results of the largest multicenter series of patients who underwent dorsal pedicle screw instrumentation of the cervical spine using patient-specific templates in Europe. The main finding of our study is that using patient-specific templates is accurate and safe with only four screws partially breaching the pedicle by less than two millimeters. Therefore, the hypothesis can be confirmed.

Biomechanical studies have shown up to four times greater fixation strength with CPS when compared with lateral mass screws [15]. Therefore, this fixation technique is sought when strong fixation is needed such as in deformity, trauma or tumor cases. However, due to the small pedicles and proximity to neurovascular structures, insertion of CPS remains technically challenging [16–18]. To help overcome these technical difficulties, patient-specific templates have been developed as a navigational tool. In cadaveric experiments good results have been demonstrated [8,9,19], with reported accuracies up to 98.1% compared to the freehand technique where accuracies down to 50% are reported [7]. The results of the present study showed an accuracy of 95.3 %, which is slightly higher than the accuracies noted in most cadaver studies using the template guided technique [7,20,21].

Other clinical studies have further shown similar results of patient-specific instrumentation of the cervical spine [10,11] with 97.5 - 98.3% of screws correctly placed in the pedicles without any breaching [4,22,23]. However, these results are based on an Asian population and no European data have been reported so far.

When analyzing the direction of pedicle wall violation, studies reported lateral wall breaching in 78.7-79.7% of malpositioned CPS [24,25]. The reason for this could be the anatomically thicker cortical bone on the medial pedicle wall compared to the lateral one [26]. Another reason might be the paravertebral muscles pushing the screw holder medially while inserting the screws and thereby deviating the screw tip to the lateral site. Finally, it could also be the surgeon's greater fear of injuring the spinal cord on the medial site than one of the two vertebral arteries on the lateral. In our study, all four breaching screws solely perforated the medial cortex of the pedicles (two medial-inferior, one medial-superior, one medial) and not the lateral one. This might be a coincidence since more frequent breaching [7] of the lateral wall has also been reported in a cadaver study using template guides for CPS .

Possible reasons for deviations are intervening soft tissue preventing proper fitting of the template on the bone, not pressing the template firmly against the bone resulting in losing the fit while drilling or pressing the template too firmly resulting in deformation of the template [7].

In our study, the median operative time was 168 minutes with an observed median blood loss 300 ml and intraoperative fluoroscopic dose of 321.2 mGycm^2. These results were comparable to those reported in the literature [22, 26]. However, a direct comparison might be difficult as the complexity and extent of the operations were not considered.

Beside its high accuracy, patient specific instrumentation has also its drawbacks. More dissection of the paraspinal muscle and soft-tissue for proper placement of the templates onto the bone is needed. Significant amount of time is necessary to plan the trajectory and print the templates. However, improved software and newer, more efficient 3D printers are expected in the future to decrease the time required for the preparation of these templates. The advantages compared to other current navigational tools such as optical navigation systems or robotic-assisted pedicle screw placement are the independence of expensive intraoperative hardware and set-up and their maintenance costs. Additionally, current navigation systems can appear bulky [27] and are still prone to errors in certain scenarios such as in obese patients or in patients with severe deformities [28,29].

There are some limitations of this study. First, due to the study design, no control group existed. Therefore, a direct comparison to a freehand or another navigational technique cannot be made. Our results however, were compared to the existing literature. Secondly, this is a multicenter study including multiple surgeons with different levels of experience. However, the same planning and production system was used in all centers.

To the best of the author's knowledge, this is the largest study analyzing the precision and safety of patient-specific instrumentation of the cervical spine in Europe. As shown in the results of this study, high precision and safety can be achieved with the use of this system, making

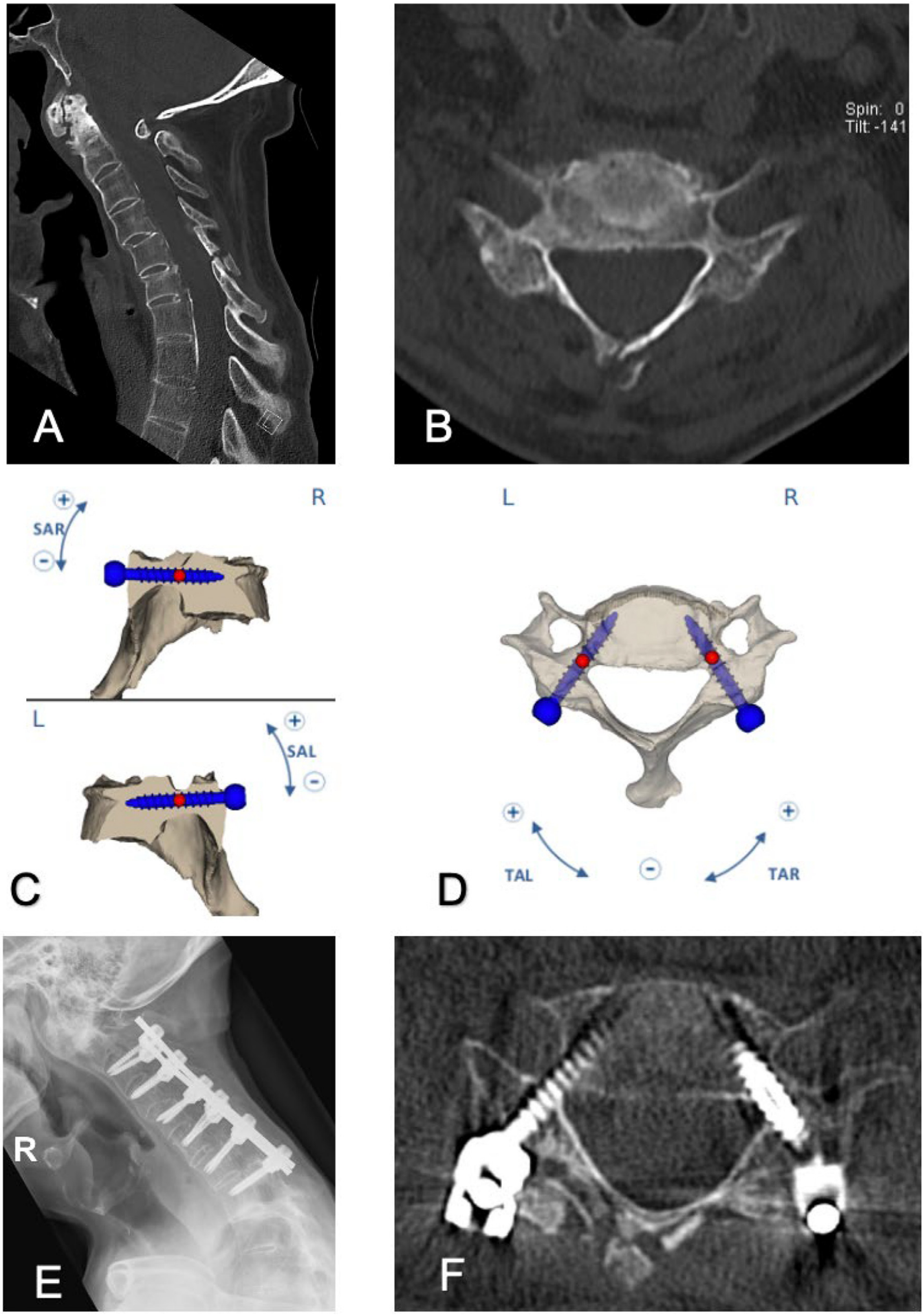

Fig. 3. Illustrative case of pedicle screw insertion. The patient suffered a flexion/extension injury C5/6 in an ankylosing spondylitis during a fall. Posterior fusion was performed using the patient-specific guidance system. Preoperative sagittal (A) and axial (B; C6) CT scan, planning report (C, D; C6), and postoperative images (E; F; C6). Postoperative axial CT shows a grade 1 pedicle perforation on the left side; it was within the safe zone and did not cause any complications. Critical deviations were not present.

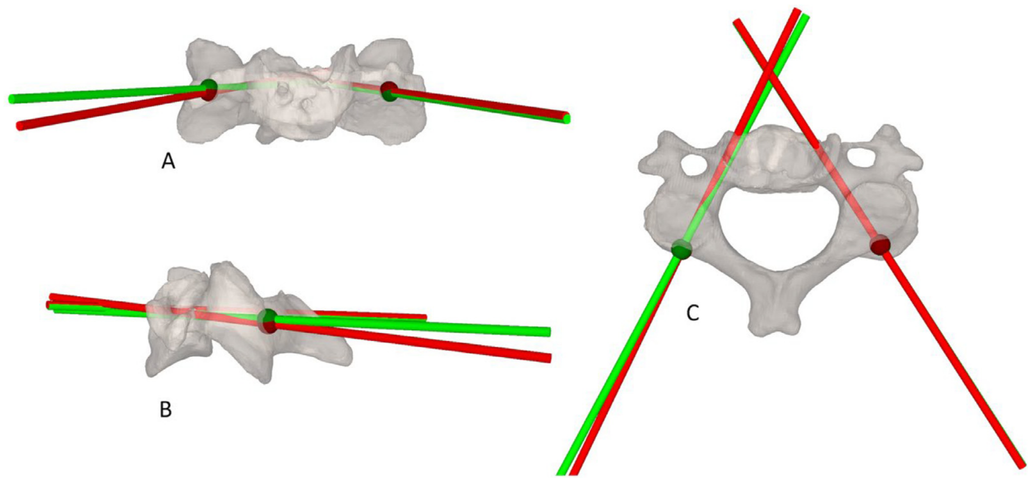

Fig. 4. Red line = performed screw trajectory; green line = planed screw trajectory; red sphere = performed entry point; green sphere = planed entry point. Entry point deviation is defined as Euclidean distance between green and red sphere, direction deviation as Euler's angle between green and red line. A = posterior; B = sagittal; C = axial view.

it a valuable navigational tool in pedicle screw instrumentation of the cervical spine.

Conclusion

Patient-specific 3D-printed templates provide a highly accurate option for placing cervical pedicle screws for dorsal instrumentation of the cervical spine.

Disclaimer

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

Ethical committee approval

Kantonale Ethikkommission Zürich had given the approval for the study. (Basec No. KEK-ZH-Nr. 2021-01464).

Declaration of Competing Interest

None.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.xnsj.2022.100120.

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