



Cervical pedicle screw placement with patient-specific 3D-printed guides: accuracy and safety in a clinical experience

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Abstract

Purpose Cervical pedicle screw (CPS) instrumentation offers significant biomechanical advantages compared to lateral mass or transarticular fixation. Nonetheless, malpositioning complications constitute a relevant concern. Customized patient-specific 3D-printed templates have been developed to improve CPS placement accuracy and safety. The aim of this study is to present our experience with this surgical technique and its accuracy and safety in a clinical setting.

Methods This single-center retrospective observational study of prospectively collected data included patients undergoing CPS fixation surgery using a patient-specific 3D template guide system. All patients underwent a 3D-volumetric high-resolution CT scan of the cervical spine for preoperative surgical planning. Postoperative CT scans were used to evaluate pedicle perforation, CPS trajectories, and deviations between the planned and the actual screw position.

Results A total of 115 CPS were implanted in 25 patients, with 107 (93.1%) of the screws completely placed inside the pedicle. Cortical breach within 2 mm was observed in 8 (6.9%) cases, with no cases of more severe pedicle infractions or perioperative neurovascular complication. No differences of CPS accuracies were found between each metameric fusion level, and between monolateral or bilateral templates. Mean total deviations were 0.75 mm vertically and 0.51 mm horizontally at the screw entry point, and 0.72 mm vertically and horizontally at the narrowest pedicle point. Mean total sagittal and transverse angular deviations were 2.94° and 3.04°, respectively.

Conclusion Cervical pedicle screw placement using patient-specific guides is safe and accurate, supporting the feasibility of this technique in posterior cervical spine fusion surgery.

Keywords Cervical pedicle screw · Pedicle screw instrumentation · Patient-specific template · Three-dimensional model

Introduction

The first reports of successful use of cervical pedicle screws (CPS) date back to the 1990s. These devices were found to be the best alternative to posterior plates and rods, lateral plates and screws or wiring in traumatic, degenerative, and neoplastic diseases of the cervical spine [1]. Compared

to lateral mass screw (LMS) or transarticular facet screw (TFS) fixation, CPS showed increased biomechanical stability and pull-out strength [2]. Nonetheless, despite multiple attempts to minimize neurovascular injuries during CPS placement, malpositioning complications always constitute a relevant concern.

Cervical vertebrae complex anatomy represents a significant hurdle for correct cervical pedicle screw positioning. The high intrinsic morphological variability between individuals and the small size of cervical body and pedicles are responsible for significant difficulties in identifying reliable anatomical landmarks. In addition, proximity to vital neurovascular anatomical structures together with narrow pedicles with high screw-to-pedicle ratio contribute to significantly restrict the error interval during screw positioning to avoid potential severe complications. Advances in medical technology have led to significant improvement of

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CPS accuracy and safety compared to freehand techniques, which still can be associated to rates of screw malpositioning up to 50% [3]. Spinal robot- and neuronavigation-assisted systems for CPS positioning have significantly improved screw accuracy and safety, with clinically and radiologically acceptable results as high as 97.7% of the cases [4]. Nevertheless, despite its undoubtable advantages, the use of spinal robotics and navigation tools require considerable efforts in terms of cost-effectiveness and technical support and maintenance.

In this context, to improve CPS placement accuracy and safety, customized patient-specific 3D-printed templates have been developed and proposed. Nowadays they represent a reliable guide system during CPS positioning, with favorable cost-effectiveness and healthcare sustainability [5]. The templates design is based on a cervical 3D-high resolution CT scan to fit the dorsal bony surface of the vertebra, with guide holes positioned to accurately match the preoperative surgical planning.

Since the first promising studies on cadaveric samples, more clinical studies on in vivo use of 3D-templates have been published with encouraging results. Nevertheless, the literature still offers a limited number of clinical studies regarding the safety and accuracy of CPS placement using patient-specific 3D templates [6, 7, 8, 9, 10, 11]. This single-center retrospective study aims to present our experience with this surgical technique and its accuracy and safety in a clinical setting.

Materials and methods

This single-center retrospective observational study of prospectively collected data included patients underwent CPS fixation for traumatic, degenerative, deformity correction, infectious, and neoplastic diseases from January 2020 to December 2023. All CPS were positioned using a patient-specific 3D template guide system (MySpine; Medacta International SA, Switzerland).

Each patient underwent preoperative clinical and radiological evaluation, with subsequent postoperative follow-up at 1 month and 3 months after surgery. Postoperative radiological follow-up included static radiography of the cervical spine and computed tomography (CT). Early (<48 h after surgery) and late (1 month after surgery) complications were evaluated in all patients. The availability of all preoperative and postoperative imaging and clinical data was mandatory for patient inclusion.

This study was conducted following the Guidelines for Good Clinical Practice and the Declaration of Helsinki (2002) of the World Medical Association. Written informed

consent was obtained from all the patients for each diagnostic and surgical procedure.

Preoperative planning and surgical technique

Before surgery, careful CT evaluation was performed by senior surgeons to exclude unfavorable anatomy for pedicle trajectory. Pedicle transverse angle $>45^\circ$ (need for excessive muscle retraction and difficulty to obtain a proper convergence), pedicle outer width <3.5 mm (instrumentation not available for smaller diameters), and absence of adequate intrapedicular cancellous bone (higher risk of vibrations during drilling with potential loss of adequate template fitting to the bony surface) were considered as exclusion criteria for this surgical technique, as well as vertebral artery anatomical variations with invasion of the pedicle or the body.

All patients underwent a 3D-volumetric high-resolution CT scan of the cervical spine with a slice thickness of <1 mm for preoperative surgical planning. The templates were patient specific and customized based on preoperative radiological information. Preoperative surgical planning software (MySpine Surgical Planning Report, Medacta, Rancate, Switzerland) was used to identify the optimal screw entry point, trajectory, and dimensions in terms of biomechanical features (Fig. 1). All templates were printed using Polyamide-PA12 and sterilized before surgery. Each template was designed with a central and distal lateral cylindrical point of contact with the dorsal surface of the vertebra, providing optimal stability of the guide system by matching the bone anatomy. The bilateral guides provided a central bony point of contact and two additional bilateral bony points of contact on the lateral aspect of the vertebral laminae and articular processes. The monolateral guides provided a central and unilateral bony point of contact and were specifically designed to reduce volume encumbrance of the device, thus minimizing the need for muscle retraction (Fig. 2). In all surgical plans, the choice of bilateral or monolateral templates was mutually exclusive.

In all cases, a posterior cervical midline incision, paravertebral musculature dissection, and retraction were performed. Accurate removal of soft tissue from bony landmarks without injury to the bone tissue is crucial to maximize the adherence of the template to the dorsal surface of the vertebrae. Additional customized 3D-models of the vertebrae of interest were available during the procedure, allowing the surgeon to confirm the exact locations of the CPS entry points. Once the template was steadily secured to the vertebrae, a drill bit with a specific depth stopper was used to delineate the pedicle trajectory following preoperative surgical planning. In all cases, an intraoperative

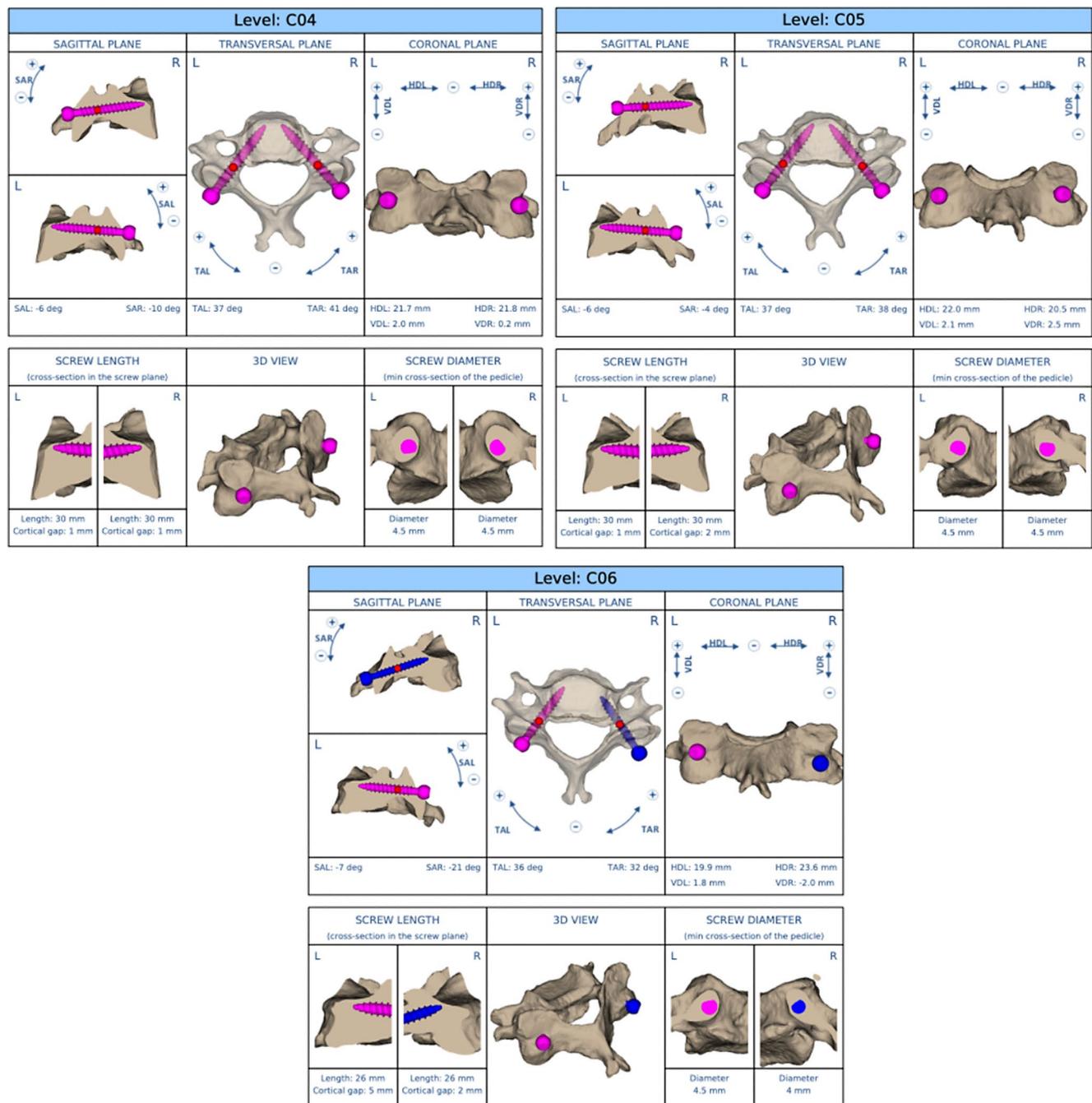


Fig. 1 Illustrative case of C4-C6 posterior fusion with CPS insertion: preoperative surgical planning using MySpine Surgical Planning Report software

CT scan of the cervical spine was performed to evaluate the accuracy of the CPS placement.

Postoperative CPS accuracy evaluation

All patients underwent a high-resolution CT of the cervical spine with a slice thickness of <1 mm within the first postoperative day. 3D-Multiplanar Reconstruction was used to

evaluate CPS trajectories in the axial, sagittal, and coronal planes. Gertzbein and Robbins classification was used to categorize transpedicular screw position and accuracy [12]. Data from the postoperative CT scan were successively compared to preoperative planning with a specific software to evaluate the accuracy of CPS trajectories (Fig. 3). In all cases, deviations from preoperative planning were evaluated at the entry point and narrowest pedicle section. The

Fig. 2 Three-dimensional printed replicas of monolateral (A) and bilateral (B) guides

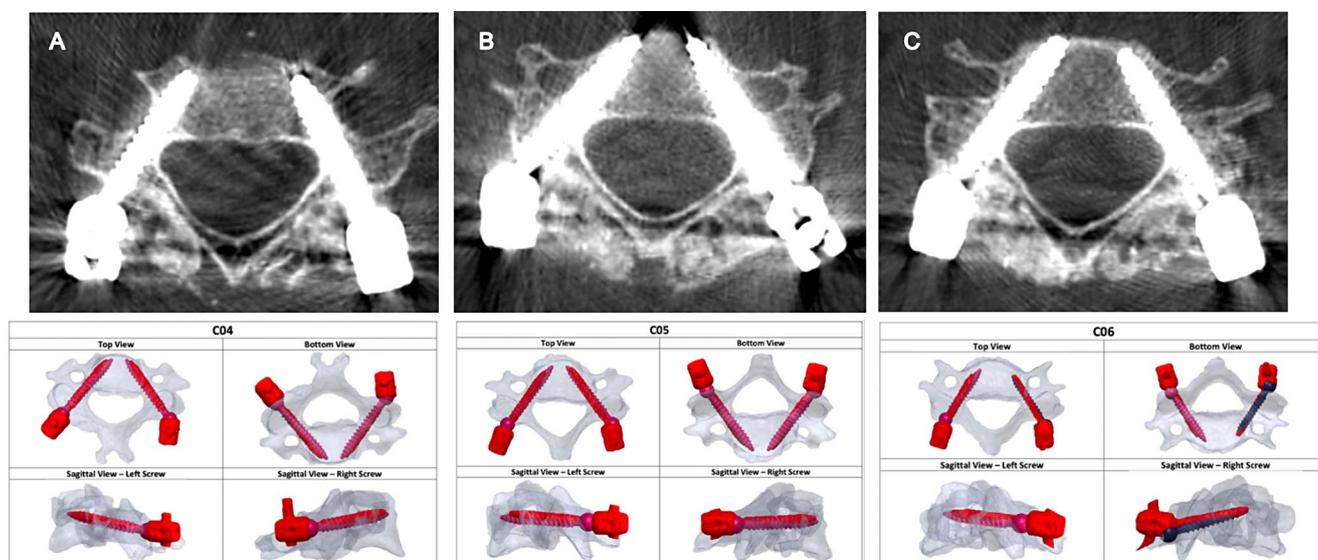
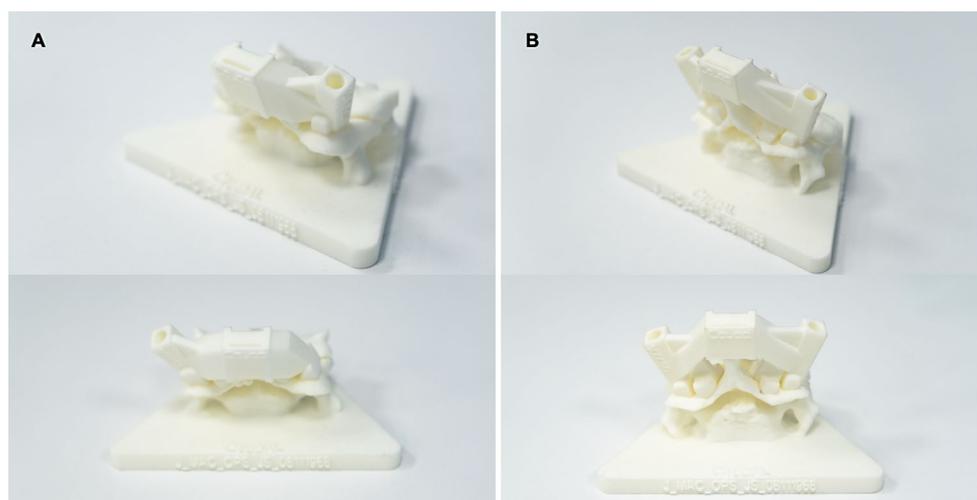


Fig. 3 Illustrative case of C4-C6 posterior fusion with CPS insertion: postoperative axial CT scan of C4 (A), C5 (B), and C6 (C) cervical pedicle screws without cortical infraction (Gertzbein grade 0) with superimposed analysis for vertical, horizontal, and angular deviation assessment

vertical and horizontal deviations were evaluated in the sagittal and axial planes, respectively. Depth deviations in the axial plane and sagittal and transverse angle deviations were evaluated. Finally, the localization of cortical breaches, if present, was categorized as lateral or medial.

Statistical analysis

Descriptive statistics were reported as mean and standard deviation for cardinal variables and as frequency and percentage for categorical variables. The Shapiro-Wilk test was used to test the data for normal distribution. Statistical analysis was performed using the Mann-Whitney U test to compare the accuracy of screw trajectories between monolateral and bilateral 3D template guides. One-way analysis of variance (ANOVA) was used to analyze the accuracy of

the screw position between different levels. Statistical analysis was performed using the SPSS software V26.0 (IBM, New York, USA).

Results

In total, 115 cervical pedicle screws were implanted in 25 patients. The demographic and preoperative features of the cohort are summarized in Table 1. The mean age at the time of surgery was 59 ± 19 years. Regarding indications for cervical spine fusion surgery, 6 (24%) patients were surgically treated for cervical trauma, 6 (24%) for degenerative cervical spine disease, 8 (32%) for neoplastic cervical disease, 1 (4%) for cervical infectious disease, and 4 (16%) for cervical spine deformity correction. No perioperative neurovascular

Table 1 Cohort demographic features, indications for surgery, and postoperative complications

Total number of patients, <i>n</i>	25
Mean age (\pm SD)	59 (\pm 19)
Sex, female, <i>n</i> (%)	7 (28%)
Sex, male, <i>n</i> (%)	18 (72%)
Indication to cervical fixation surgery, <i>n</i> (%)	
- Trauma	6 (24%)
- Neoplastic	8 (32%)
- Degenerative	6 (24%)
- Infectious	1 (4%)
- Deformity correction	4 (16%)
Postoperative early complications, <i>n</i>	0
Postoperative late complications, <i>n</i>	1

Table 2 Number of screws and placement accuracy according to the Gertzbein and Robbins classification

Total number of CPS implanted, <i>n</i>	115
Total number of CPS implanted per level, <i>n</i>	
Total number of CPS implanted per level, <i>n</i>	16 (13.9%)
- C2	21 (18.2%)
- C3	29 (25.3%)
- C4	24 (20.9%)
- C5	17 (14.8%)
- C6	8 (6.9%)
- C7	
Gertzbein and Robbins grading, <i>n</i> (%)	
- Grade 0 (completely intrapedicular)	107 (93.1%)
- Grade 1 (<2 mm cortical breach)	8 (6.9%)
- Grade 2 (<4 mm cortical breach)	0
- Grade 3 (<6 mm cortical breach)	0
- Grade 4 (>6 mm cortical breach)	0
Direction of cortical breaches, <i>n</i> (%)	
- Lateral	7 (87.5%)
- Medial	1 (12.5%)
Cortical breaches related to the type of 3D-template, <i>n</i> (%)	
- Bilateral template	5 (62.5%)
- Monolateral template	3 (37.5%)

or early postoperative complications have been reported. Late postoperative complications were reported in only one case with anterior prevertebral cervical infectious collection and subsequently treated with surgical evacuation and targeted antibiotic therapy.

A total of 107 (93.1%) screws were placed inside the pedicle (Gertzbein Grade 0). Minimal cortical breach (Gertzbein Grade 1) was observed in 8 (6.9%) screws. No cases of

Table 4 Mean total deviations in bilateral and monolateral 3D templates between preoperative surgical planning and postoperative screw positioning

	BILATERAL	MONOLATERAL
Mean total Δ Vertical deviation - Entry point (mm)	0.71	0.78
Mean total Δ Horizontal deviation - Entry point (mm)	0.45	0.55
Mean total Δ Vertical deviation - Pedicle narrowest point (mm)	0.73	0.66
Mean total Δ Horizontal deviation - Pedicle narrowest point (mm)	0.83	0.61
Mean total Δ Depth (mm)	1.41	1.81
Mean total Δ Sagittal angle ($^{\circ}$)	2.80	2.92
Mean total Δ Transversal angle ($^{\circ}$)	2.87	3.28

more severe cortical breaches have been reported (Gertzbein Grades 2–4). The Gertzbein grading and data regarding the number of screws are presented in Table 2. Regarding the direction of cortical breaches, in 7 (87.5%) cases a lateral pedicle wall infraction was observed, while medial pedicle wall infraction was reported in only 1 (12.5%) case. Overall, 5 (62.5%) of the cortical infractions were reported with bilateral templates, while the 3 (37.5%) remaining cases of cortical breaches were reported with monolateral templates.

Statistical analysis

The mean total deviations and mean deviations per single level from the preoperative plan are shown in Table 3. The mean total deviations in the sagittal and axial planes at the screw entry point were 0.75 mm vertically and 0.51 mm horizontally, and at the narrowest pedicular point they were 0.72 mm, both vertically and horizontally. The mean total angular deviations in the sagittal and transverse planes were 2.94 $^{\circ}$ and 3.04 $^{\circ}$, respectively. The mean total variation in the depth was 1.72 mm. Data regarding the mean total deviations in the bilateral and monolateral 3D templates are summarized in Table 4. No statistically significant differences were found in the comparison of CPS accuracies between

Table 3 Mean total deviations and mean deviations per level between preoperative surgical planning and postoperative screw position

	TOTAL	C2	C3	C4	C5	C6	C7
Mean total Δ Vertical deviation - Entry point (mm)	0.75	0.71	0.60	0.70	0.72	0.94	1.32
Mean total Δ Horizontal deviation - Entry point (mm)	0.51	0.52	0.53	0.37	0.60	0.53	0.79
Mean total Δ Vertical deviation - Pedicle narrowest point (mm)	0.72	0.99	0.74	0.73	0.51	0.63	1.12
Mean total Δ Horizontal deviation - Pedicle narrowest point (mm)	0.72	0.69	0.81	0.88	0.57	0.60	0.61
Mean total Δ Depth (mm)	1.72	1.81	2.12	1.94	1.45	1.48	0.46
Mean total Δ Sagittal angle ($^{\circ}$)	2.94	2.43	3.37	3.12	2.61	2.20	5.30
Mean total Δ Transversal angle ($^{\circ}$)	3.04	2.92	3.06	3.63	2.57	2.08	5.06

each metameric fusion level and between cases treated with monolateral or bilateral templates.

Discussion

The present study reports data regarding the safety and accuracy of CPS in a cohort of patients who were surgically treated for posterior cervical spine fusion using patient-specific 3D-printed guides. To the best of authors' knowledge, this is the first study which analyzes the accuracy and safety of bilateral and monolateral 3D templates. Our results demonstrate that cervical pedicle screw instrumentation using patient-specific guides is safe and accurate, thus supporting the feasibility of this technique in posterior cervical spine fusion surgery.

Evidence shows that CPS provides significant biomechanical advantages in terms of pull-out strength and fixation stability, when compared to lateral mass screws [2, 13]. Nevertheless, placement of CPS remains a technical challenge due to the small diameter of the cervical pedicles and contiguity to neurovascular structures. The incidence of clinically significant complications following CPS misplacement varies from 0 to 6%, with a revision surgery rate of 1.0–2.4% of all the cases [14]. Radiological misplacement does not necessarily correlate with clinical consequences, yet potential complications of misplaced CPS may be severe and irreversible. Several guiding tools, such as spinal navigation and patient-specific 3D templates, have been proposed to facilitate CPS positioning and reduce the rate of screw misplacement. Cadaveric experiments have demonstrated accuracies up to 98.1% with the use of patient-specific guides, compared to significantly lower results with free-hand techniques [15, 16]. Clinical studies on posterior cervical spine instrumentation with CPS have demonstrated comparable results, with accuracies varying from 95.3 to 98.3% with the use of the template-guided technique [6, 7, 8, 10, 17]. In a recent meta-analysis by Azimi et al. (2021) performed on a total of 1323 CPS it is reported on overall accuracy of 97.3% in the template group, which is comparable to similar results obtained with computer-navigated system such O-arm navigation with accuracy rates of 95.2% [5].

In the present study, we report the overall accuracy of CPS positioning with 3D templates of 93.1%, with 107 screws correctly placed inside the pedicle without cortical breaches. Minimal cortical infraction <2 mm was observed in 6.9% of cases, with no cases of more advanced cortical breaches (Gertzbein grading ≥ 2). The mean total deviations in the horizontal and vertical axes at the entry point and the narrowest pedicle point were all <1 mm. The mean total deviation in the sagittal and transverse angles was <3°. No

neurovascular complications were observed, which supports the safety of this surgical technique. Our results are comparable to those of other similar clinical studies.

No statistically significant differences were observed between single cervical metamere accuracies or between the use of bilateral or monolateral 3D templates. When considering the direction of pedicle cortical breaches, our results have demonstrated a significant prevalence of lateral violations (87.5%) compared to medial violations (12.5%), which is in line with data from other similar studies [18, 19]. Conceivable explanations could be related to thicker cortical bone on the medial surface of the cervical pedicles and to a paravertebral muscle-pushing effect resulting in the tendency to medialize the distal extremity of the instruments during the surgical procedure, thus determining a slight lateralization of the screw trajectory [20, 21]. When considering the factors associated with the deviations from preoperative planning in addition to the direction of cortical breaches, several mechanisms could be considered. In general, the dorsal surface anatomy of the cervical vertebrae is remarkably variable, with fewer anatomical landmarks and limited bony surface available compared to thoracolumbar vertebrae [22, 23]. Moreover, the average ratio between the screw and pedicle diameter is significantly higher in the cervical vertebrae compared to the thoracolumbar ones, thus increasing the difficulty of freehand screw positioning.

Another relevant aspect of this surgery is the insufficient or inadequate soft tissue removal from the bony surfaces that could determine suboptimal adherence and fitting of the templates on the vertebrae. The absence of curarization for intraoperative neurophysiological monitoring could determine an incomplete paravertebral muscle retraction due to the increased muscular tension, thus compromising the engagement of the templates on the bony surfaces. To overcome these difficulties, monolateral 3D templates have been developed to reduce the extent of paravertebral muscle retraction, mainly in the more cranial subaxial vertebrae, where the screw entry points become progressively more lateral, requiring wider muscular exposure. This is the first study in scientific literature exploring the advantages of using a monolateral 3D templates in CPS.

When performing a cervical stabilization surgery, the template guides provide several advantages in addition to their high accuracy and safety. Furthermore, the availability of 3D models of the vertebrae in the operative room allows for real-time confirmation of the exact position of the screw entry points and the fitting conditions of the templates on the bony surfaces [20]. Compared to other navigational tools, such as robotic-assisted pedicle screw placement or optical navigation, the use of 3D templates has proven to be more user-friendly in terms of operating room management. Furthermore, no expensive and cumbersome intraoperative

devices are required. Moreover, the reliability of this system is based on a one-to-one relationship between the vertebra and the customized guide, while most navigation systems often impose constant attention to avoid unnecessary movement of the frames, thus potentially compromising the accuracy of the navigation [24]. In a recent meta-analysis and systematic review, Bindels et al. demonstrated no significant improvement in screw accuracy with spine navigation compared to the other techniques, tentatively explaining these results with the complex setup of navigation for CPS placement, and with the high mobility of the cervical spine with a relatively small surgical working field [25]. The use of 3D templates could potentially represent a way to empower the advantages of a guided trajectory by easing technique setup. Despite these advantages, the use of patient-specific templates also presents some inconveniences. The manufacturing of the templates, including sterilization, can only be performed after a validated surgical plan has been executed, and the whole process requires a significant amount of time (7–10 working days), thus limiting the applicability of this technique to situations where urgency is required. In addition, adequate exposure of the bony surfaces for optimal fitting of the templates requires more dissection and retraction of the paravertebral muscles and wider skin incisions. Nonetheless, the constant improvement of the software and hardware used in the preoperative processes will hopefully reduce the time needed for surgical planning.

This study has several limitations. This was a single-center retrospective study without a control group, thus lacking the possibility of obtaining a statistically significant comparison between patient-specific templates and other techniques, such as free-hand or spinal navigation-guided screw positioning. No cost–benefit analysis was performed because of the different purposes of the study. Finally, all surgical procedures were performed by multiple surgeons with different levels of experience and confidence in the surgical technique.

Conclusions

This is the largest clinical study in Europe regarding the accuracy and safety of cervical pedicle screw positioning using patient-specific template guides. To the best of our knowledge, this is the first study to present results on the use of monolateral 3D templates. The results of this study demonstrate the high accuracy and safety of cervical pedicle instrumentation using 3D templates, supporting the feasibility of this technique for posterior cervical fusion surgery. Furthermore, our data encourage the use of monolateral templates, considering the comparable accuracy and safety with bilateral guides and the advantages derived from the

reduced muscle retraction necessary for adequate surgical exposure.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s00586-025-08679-2>.

Author contributions NM, and FC designed the study; SC, MA, and AS collected the data; NM, FC, and SC analyzed and interpreted the data; SC, ELB, and AS wrote the initial draft of the manuscript; AP and SC performed the statistical analyses. NM, MA, GM, DG, and FC participated in revising the manuscript. NM, FC, and DG supervised the study. All authors have read and approved the final manuscript.

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Data availability The study data and details of materials used may be made available upon reasonable request by sending an e-mail to the first author.

Declarations

Ethics approval This retrospective study involving human participants was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Competing interests The authors have no competing interests to declare that are relevant to the content of this article.

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