Robotic-assisted Cervical Pedicle Screw Fixation With Custom Instruments

An Analysis of 206 Screws in 22 Patients

Madhava Pai, MS,† Vidyadhara Srinivasa, FNB,‡ Balamurugan Thirugnanam, FNB,‡ Abhishek Soni, FNB,‡ Anjana Kashyap, MD,§ Alia Vidyadhara, MD,|| and Sharath K. Rao, MS†*

Study Design: Prospective study

Objective: This study aims to describe a workflow and custom instruments for robotic-assisted cervical pedicle screw placement using the MazorX Stealth Edition.

Summary of Background Data: Posterior cervical spinal instrumentation using pedicle screws offers biomechanical advantages but carries risks of injury to the vertebral artery and nerve roots. Fluoroscopic and navigation aids exist, yet robotic assistance for cervical pedicle screw placement lacks a defined workflow. While previous generations of spine robots have been used in placing pedicle screws, there are no papers in literature that described the use of third-generation spine robots in placing them.

Methods: Twenty-two patients undergoing cervical pedicle screw placement with custom instruments and robotic assistance were included. Screw trajectories were planned and executed by the robotic arm, with postoperative O-arm scans assessing accuracy. Clinical and radiologic outcomes at 3-month follow-up were measured.

Results: A total of 206 screws were placed with a 98.1% accuracy rate. Four screws breached the pedicle without resulting in nerve root injury. Average surgical time was 190 minutes, with 6 minutes per screw insertion. Blood loss averaged 180 mL. NDI scores improved from 42.3 to 28.2. Complications included superficial wound infections in 2 patients, deep wound infection in 1, and 1 nondominant vertebral artery injury.

Conclusions: Robotic-assisted cervical pedicle screw placement demonstrates high accuracy and significant clinical improvements, validating the workflow and custom instruments developed.

Key Words: cervical spine, pedicle screws, robotic surgery

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Posterior cervical spinal instrumentation using both lateral mass and pedicle as anchor points has been studied extensively.[1–4] Various authors have demonstrated the biomechanical superiority of pedicle screws over other fixations, favoring their use in correction of cervical and cervicothoracic deformities or in the case of deficient or incompetent lateral masses.[5,6] The lateral wall of the cervical pedicle is the thinnest, and any lateral breach can result in injury to the vertebral artery, while a superior or inferior breach of the pedicle risks injury to the cervical nerve roots.[7]

Fluoroscopic and virtual 3D navigation assistance have been used to increase the safety of cervical pedicle screw placement. But as yet, no workflow has been described for their placement using robotic assistance.[7–10] Spine robots are capable of drilling accurate trajectories while providing real-time navigation guidance. Their use in the placement of thoracic and lumbar pedicle screws has been extensively studied with well-defined workflows, using either preoperative or intraoperative image acquisition and registration.[11,12]

The lack of cervical-specific instruments and a robust workflow has hindered the widespread adoption of the spine robot in placing cervical pedicle screws. In the current study, we describe the workflow and custom instruments used in the placement of cervical pedicle screw in 22 patients.

METHODS

Institutional ethical committee clearance was obtained before commencement of the study. Twenty-two consecutive patients who underwent cervical pedicle screw placement using custom instruments along with the MazorX stealth edition (Medtronic Ltd.) were included. Preoperative patient-reported outcome measures and anthropometric data were collected. All surgeries were performed by the senior author (V.S.), with experience of over 400 cases of thoracolumbar

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From the *Department of Orthopaedics, Kasturba Medical College, Manipal, Manipal Academy of Higher Education, Manipal; †Manipal Comprehensive Spine Care Center, Manipal Hospital, Bangalore; ‡Manipal Comprehensive Spine Care Center, Manipal Hospital, Bangalore; §Department of Anesthesiology, Kasturba Medical College, Manipal Academy of Higher Education, Manipal; and ||Department of Spine Anesthesia, Manipal Hospital, Bangalore, India.

The authors declare no conflict of interest.

Reprints: Vidyadhara S, FNB, Manipal Comprehensive Spine Care Center, Manipal Hospital, Old Airport Road, Bangalore 560008, India
(e-mail: vidya007@gmail.com).

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spine surgeries using robotic assistance. The custom instruments were developed after our initial experience of 40 cases with robotic assistance in cervical spine surgery.

Steps of Robotic-assisted Cervical Pedicle Screw Fixation

With patients prone under general anesthesia, the head was secured using a Mayfield clamp, and the patient's torso was strapped to the radiolucent table. The cervical spine was exposed through a conventional midline approach. The robot was then software "mounted," which stopped all manual movement of the robotic arm while getting it ready to acquire the necessary spatial information required to drill trajectories. The surface contour of the surgical field was mapped using infrared and optical cameras in the robotic arm (3Define scan). This step defines the "no-fly-zones" and areas of possible collision of the robot arm with the patient's anatomy. The robot navigation registration is done with the "snapshot" tracker attached to the robotic arm and the navigation tracker attached to the robot. The "star-marker" fiduciary array was then attached to the robotic arm, which allows the robot to determine the exact location of vertebrae in space and the 4 metallic beads in this array were adequately visualized on the O-arm (Medtronic Ltd.) scan. The O-arm scan was transferred to the robot console where the screws were planned. The scan is then manually segmented, with each segment containing one vertebra and its 2 pedicles. We use C2 for reference and label the remaining segments automatically. The screw is planned on the axial, coronal, and sagittal sections ensuring there is no violation of the pedicle wall. The software allows adjusting the mediolateral and cranio-caudal angulation to ensure the appropriate trajectory.

After the surgeon was satisfied with the planning, the robotic arm was then sent to the trajectory of the screw at each level. A knife was used to create a paramedian incision, to prevent soft tissue pressure from altering the screw trajectory. A single incision allowed placement of screws from C5 to C7, and another incision was used to place screws at C3 and C4. At C2, the pedicle screws could be placed through the incision. The high speed, low-skive drill with a 3x30 mm drill bit was used to drill the trajectory of the cervical pedicle screw with minimal pushing force as moving the spine can result in a conflict between the virtual image and real patient on the operating table. A custom 3.5 mm tap was used to tap the screw hole, and screws 4 mm in diameter were placed in the vertebrae using a custom screwdriver (Fig. 1, Video 1, Supplemental Digital Content 1, http://links.lww.com/CLINSPINE/A385). The implant position was confirmed on fluoroscopic imaging, after which laminectomy was performed at the areas of compression through the primary midline incision and rods were placed connecting the cervical screws. Postoperative O-arm scans were done to determine accuracy of cervical pedicle screws (Fig. 2).

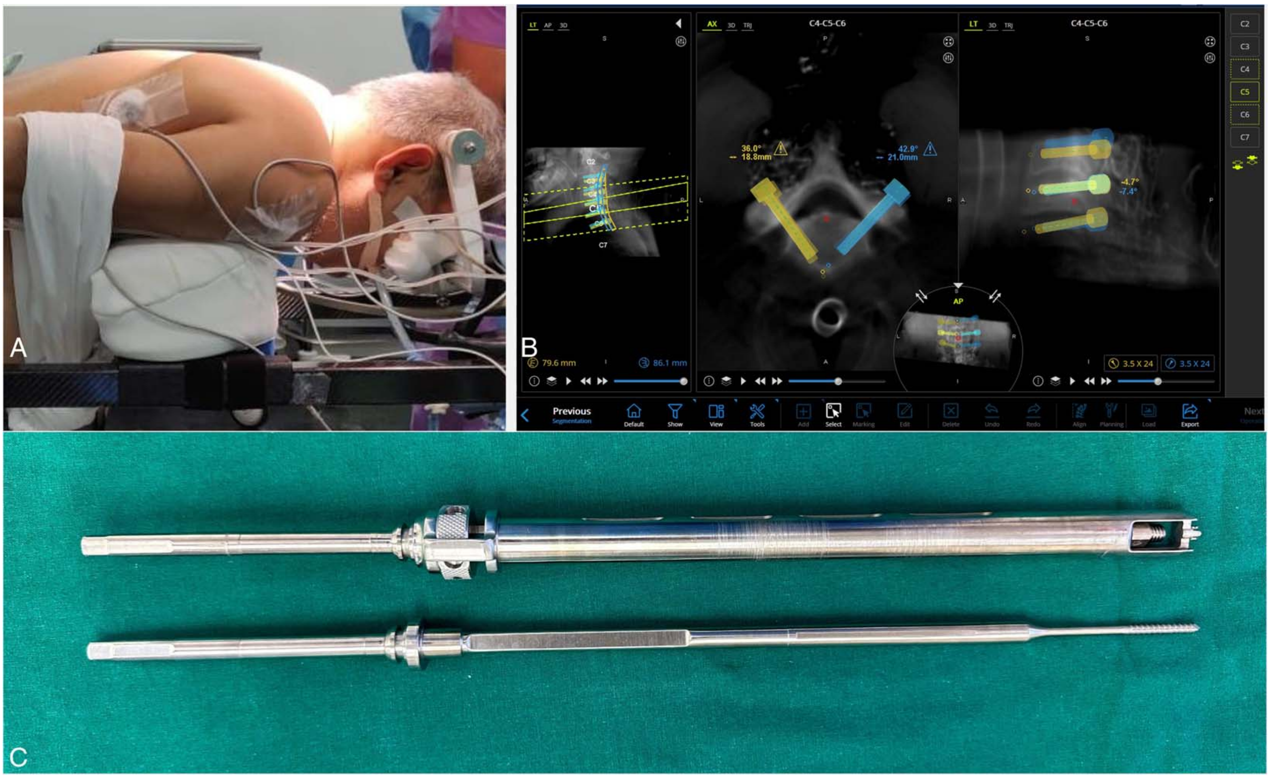

FIGURE 1. Clinical photograph showing patient positioned prone with Mayfield clamp (A). Screenshot of robotic workstation showing planning of cervical screws (B). Custom made screwdriver and tap for placement of cervical pedicle screws (C). full color online

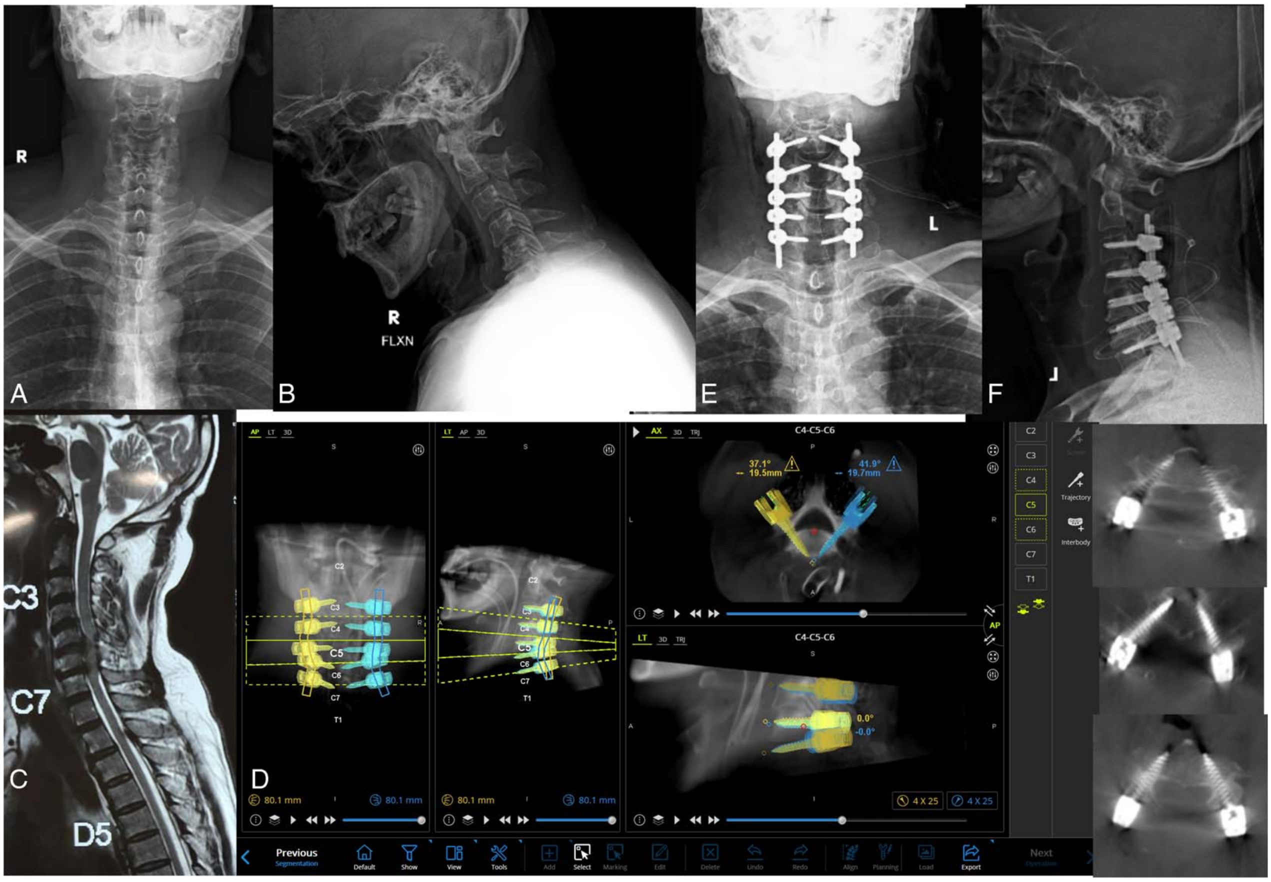

FIGURE 2. Preoperative radiographs (A,B) and magnetic resonance imaging of a patient with cervical myelopathy. Screenshot of intraoperative screw planning (C). Postoperative radiographs (D, E) and O-arm scans (F) showing accurately placed pedicle screws. full color online

Demographic and anthropometric measurements of patients were recorded. "Cut-to-close time" was the total time elapsed from the initial skin incision to closure of the surgical site. "Exposure time" was defined as the time taken for exposure of the cervical spine. "Time per screw" was measured as the average time taken to insert each pedicle screw. "Robot Time" from software mounting the robotic arm to the completion of robot registration before the O-arm scan plus the time taken for planning screws, and "O-arm Time" included time from positioning the O-arm for the anteroposterior fluoroscopy image to finalizing the acquisition of the cone beam CT image. The time taken for decompression was also noted. The amount of blood loss during the surgery was documented in all patients. To assess screw placement accuracy, we used Digimizer version 6.3. This software compared planned screw trajectories from the preoperative workstation image with the actual screw positions captured in the postoperative O-arm image. The process involved overlaying the images, and both a neuroradiologist and a surgeon independently verified the accuracy and angle of screw insertion.

The planned and executed trajectories of posterior screws were compared and graded using the modified Gertzbein and Robbins classification, with grades A and B considered "clinically acceptable."[13] Statistical analysis was performed using SPSS version 20, with qualitative variables expressed as percentages and continuous variables expressed as mean ± SD.

RESULTS

The study included 22 patients, comprising 13 males and 9 females with an average age of 56 years (range 35–75 y). The mean body mass index (BMI) was 27.4 kg/m^2 (range 21.8–33.2 kg/m^2). Fourteen patients had cervical myelopathy, and 8 patients had myeloradiculopathy. Twelve patients suffered from ossification of the posterior longitudinal ligament, and 10 patients had degenerative cervical spondylosis.

A total of 206 cervical pedicle screws were placed using robotic assistance. Four screws (1.9%) breached the pedicle: 2 breaches were lateral, 1 was inferior, and 1 was superior. One screw was removed following lateral breach, and one screw could not be placed due to severely narrow pedicle. There were no injuries to the cervical nerve roots in any of the cases. The majority of screws (98.1%) were accurately placed, confirmed by postoperative O-arm scans and further analysis with overlapped images showed no significant difference in angle of insertion between the planned and executed trajectories.

The average total surgical time was 190 minutes (range: 150–240 min). The mean time taken for cervical spine exposure was 40 minutes (range: 30–55 min). The average time taken to insert each pedicle screw was 6 minutes (range: 5–8 min). The mean time from software mounting the robotic arm to completion of robot registration and planning screws was 25 minutes (range 20–30 min). The average time for O-arm positioning and image acquisition was 10 minutes (range 8-15 min). The time taken for decompression procedures averaged 45 minutes (range 35–60 min). The mean intraoperative blood loss was 180 mL (range 120–300 mL).

Two patients experienced superficial wound infections that were managed successfully with regular dressings and antibiotics. One patient developed a deep wound infection, which required wound exploration and lavage. One patient suffered a nondominant vertebral artery injury, which was managed with intraoperative tamping of the screw hole with bone wax. The patient did not have any neurological sequelae.

DISCUSSION

While various anchor points have been used in posterior stabilization of the cervical spine, the pedicle screw is biomechanically superior compared with others. This makes its use preferable in cases where the implants require higher pull-out strength like deformities.[5,6] Spine robots are able to accurately drill trajectories for placing screws in the thoracolumbar spine; however, there are no described workflows in placing cervical pedicle screws.

The present study highlights the feasibility and efficacy of using a robotic-assisted system for the placement of cervical pedicle screws, utilizing custom instruments designed specifically for this procedure. The results demonstrate a high accuracy rate in screw placement and significant clinical improvements in patients with various cervical pathologies, which underscores the potential of this technology to enhance surgical outcomes in complex cervical spine surgeries.

Our study reports a 98.1% accuracy rate in the placement of cervical pedicle screws, with only four screws (1.9%) breaching the pedicle. This accuracy is comparable to or even superior to traditional freehand or fluoroscopic-assisted techniques, where reported breach rates range from 5% to 20%.[14,15] The breaches observed were lateral, inferior, and superior, but none resulted in cervical nerve root injury. This high level of precision can be attributed to the rigid immobilization of the cervical spine using Mayfield clamps, and real-time navigation guidance provided by the robotic system, which provides visual feedback during screw placement. The utilization of the Digimizer software for postoperative verification further validated the accuracy of screw placement.

The average surgical time was 190 minutes, which was comparable to other studies.[14,15] The mean time for screw insertion was 6 minutes per screw, which is efficient considering the complex anatomy and the precision required in the cervical region. The overall operative time is comparable to traditional methods, suggesting that the robotic-assisted approach does not unduly prolong surgery while providing the added benefit of enhanced accuracy.[14] Moreover, the mean intraoperative blood loss of 180 mL is relatively low, indicating that the robotic system aids in minimizing surgical trauma and improving overall safety.[16]

While the study shows promising results, there are challenges and potential complications associated with the use of robotic assistance. The occurrence of wound infections in 3 patients (13.6%) and a vertebral artery injury in 1 patient (4.5%) highlights the need for meticulous surgical technique and postoperative care. Although these complications were managed effectively, they underscore the importance of a steep learning curve and the necessity for surgeons to be adept with the robotic system and custom instruments before attempting complex robotic spine surgery.[17]

One of the significant contributions of this study is the establishment of a robust workflow and the development of custom instruments tailored for cervical pedicle screw placement using robotic assistance. This addresses a critical gap in existing literature, where the absence of cervical-specific tools and protocols has limited the widespread adoption of robotic systems in cervical spine surgery. The detailed workflow, from patient positioning to screw insertion and postoperative verification, provides a valuable framework for other surgeons to replicate and build upon. It is also prudent to note that for routine cases, lateral mass screws provide sufficient biomechanical stability and due to the catastrophic risks involved in placing cervical pedicle screws, their use should be limited to cases warranting higher biomechanical stability.

The findings from this study lay the groundwork for further research and development in robotic-assisted cervical spine surgery. Future studies should focus on larger patient cohorts and longer follow-up periods to validate the long-term benefits and potential risks of this approach.

The use of robotic assistance for cervical pedicle screw placement, facilitated by custom instruments and a well-defined workflow, demonstrates high accuracy, improved clinical outcomes, and acceptable operative efficiency. Despite the challenges and complications encountered, the results are promising and suggest that with further refinement, robotic-assisted techniques could become the standard of care for complex cervical spine surgeries.

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