Journal of Orthopaedics 70 (2025) 252–257

Contents lists available at ScienceDirect

Journal of Orthopaedics

journal homepage: www.elsevier.com/locate/jor

Expanding implant options in robot-assisted thoracolumbar spine surgery through novel customized instrumentation

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ARTICLE INFO

Keywords:
Robotic surgical procedures
Pedicle screws
Spinal fusion
Feasibility studies
Surgical instruments
Equipment design

ABSTRACT

Background: Robot-assisted pedicle screw placement demonstrates superior accuracy over conventional techniques, yet proprietary ecosystems limit implant compatibility and surgical choice. Can a custom screwdriver enable third-party instrumentation while maintaining navigational precision within the Mazor X Stealth Edition robotic system?

Methods: This retrospective comparative single-center study analysed 100 consecutive patients undergoing robot-assisted thoracolumbar fusion using custom screwdriver instrumentation (July–December 2024) versus 100 historical controls using standard proprietary instrumentation (October 2023–June 2024). The custom screwdriver had shaft dimensions matched to the robotic arm guide and navigation tracker compatibility. Primary outcomes included pedicle screw placement accuracy using Gertzbein-Robbins classification and technical feasibility.

Results: A total of 708 screws were placed in the custom screwdriver group versus 760 in controls. Clinically acceptable screw placement (Gertzbein-Robbins grades A&B) was achieved in 99.15 % (702/708) versus 99.07 % (753/760) respectively (difference: 0.08 %, 95 % CI: 1.14 %–1.30 %, $p = 0.880$). Non-inferiority was demonstrated with the lower confidence interval (−1.14 %) exceeding the predefined margin (−3 %). Technical feasibility was 100 % with no conversion required. Operative time (142.3 ± 38.5 vs 148.7 ± 40.2 min, $p = 0.239$), blood loss (537.2 ± 328.0 vs 550.0 ± 359.0 ml, $p = 0.793$), and per-screw placement time (6.2 ± 1.8 vs 6.4 ± 1.7 min, $p = 0.426$) were comparable. Implant costs were significantly lower in the custom screwdriver group (USD 559.50 ± 224.35 vs 1973.47 ± 934.80, $p < 0.001$).

Conclusions: Custom instrument design successfully maintained surgical precision while enabling third-party implant integration within robotic spine surgery workflows. This approach demonstrates enhancement of robotic system modularity without compromising accuracy, safety, or operational efficiency.

Clinical relevance: This innovation enables surgeons to select optimal implants based on clinical evidence rather than proprietary constraints, potentially improving patient outcomes while reducing healthcare costs through enhanced system flexibility.

Level of evidence: III.

1. Introduction

Robot-assisted pedicle screw placement has established superiority over freehand, fluoroscopic, and computer-assisted navigation techniques, with meta-analyses demonstrating accuracy rates of 97.9 % and significantly reduced breach risks.[1,2] However, a critical limitation constrains the full potential of robotic spine surgery: dependence on proprietary ecosystems that restrict implant compatibility and surgical choice. Current robotic systems create closed environments where surgeons must select from manufacturer-specific instruments rather than optimal patient-specific solutions.[3,4]

This proprietary lock-in creates significant barriers to optimal healthcare delivery. Economic constraints emerge as robotic surgeries add $8000-$9000 per case in supply costs[5(p202)], while closed systems

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https://doi.org/10.1016/j.jor.2025.08.031
Received 26 July 2025; Accepted 16 August 2025
Available online 18 August 2025

fundamentally limit innovation by prioritizing profitability over health outcomes.[3] Clinical autonomy becomes restricted as evidence-based implant selection takes a secondary role to compatibility requirements, and supply chain vulnerabilities intensify as manufacturer dependence creates delivery bottlenecks while superior local alternatives remain artificially blocked. These challenges are particularly pronounced in low-resource settings where regulatory frameworks inadequately support device access.[6,7]

Recent advances in patient-specific instrumentation demonstrate potential pathways to overcome proprietary constraints.[8,9] While robotic technology represents significant advancement in surgical precision,[1] ongoing innovation remains essential to address existing limitations. The surgical community's continued efforts to refine and enhance existing technologies have consistently driven improvements in patient outcomes and procedural efficiency, as demonstrated through innovations in custom robotic surgical instruments, including novel mechanisms for enhanced dexterity in robot-assisted minimally invasive surgery and specialized instruments for endoscopic spine procedures, which improve surgical precision while expanding procedural capabilities.[10,11] Building on these developments, we developed a custom screwdriver specifically designed for the Mazor X Stealth Edition (MXSE) robotic system to enable third-party implant integration while maintaining navigational accuracy. This study validates the feasibility, safety, and accuracy of utilizing non-proprietary instruments within robot-assisted thoracolumbar spinal fusion procedures, demonstrating that enhanced system modularity can be achieved without compromising surgical precision and opening new possibilities for robotic spine surgery innovation.

This retrospective comparative study analysed 100 consecutive patients undergoing thoracolumbar fusion with custom screwdriver instrumentation versus 100 historical controls using standard robotic instrumentation. Our findings demonstrate maintained surgical precision (99.15 % vs 99.07 % acceptable screw placement) while also achieving cost reduction (71.6 %), validating the potential for enhanced robotic system modularity without compromising patient safety.

2. Materials and methods

2.1. Study design and setting

This retrospective comparative single-center study analysed outcomes of 100 consecutive patients who underwent robot-assisted thoracolumbar fusion using custom screwdriver instrumentation between July 1, 2024, and December 31, 2024. Clinical and radiographic outcomes were compared with a historical control group comprising 100 patients who underwent similar robot-assisted procedures using standard proprietary instrumentation between October 15, 2023, and June 30, 2024, at our institution. The historical control period was selected to ensure adequate sample size while maintaining consistency in surgical team, robotic platform (MXSE), and institutional protocols. A minimum 6-month washout period separated the two study periods to allow for complete implementation of the custom instrumentation workflow.

Ethical approval was obtained from the Institutional Review Board (ECR/34/Inst/KA/2013/RR-19) prior to study initiation, in accordance with the STROBE guidelines, Declaration of Helsinki, and Good Clinical Practice guidelines. Historical controls were deemed appropriate given the established nature of the robotic platform and the purely technical modification represented by the custom screwdriver, with no changes to patient selection criteria, surgical indications, or perioperative protocols between study periods.

2.2. Patient selection and study population

2.2.1. Inclusion criteria

- Planned robot-assisted thoracolumbar fusion using third-party implants
- Age 18–80 years with skeletal maturity
- Degenerative disc disease, spinal stenosis, spondylolisthesis, or other spinal pathologies requiring thoracolumbar fusion
- Intraoperative CT scan or Scan & plan workflow for robotic registration

2.2.2. Exclusion criteria

- Previous thoracolumbar spinal surgery at the same level
- Non-robotic thoracolumbar fusion
- Severe osteoporosis (T-score < -3.0) or metabolic bone diseases compromising instrumentation

2.2.3. Control group selection

Controls were selected through stratified sampling matched on age (±5 years), sex, BMI (±3 kg/m^2), primary diagnosis, fusion levels, and ASA status. Controls were selected sequentially from the institutional database working backward from June 30, 2024, until 100 appropriately matched patients were identified.

2.3. Custom instrument design

A custom-designed screwdriver was developed for the MXSE robotic guidance system to integrate third-party pedicle screws (Fig. 1). The instrument was fabricated from surgical grade stainless steel 316 L, meeting all biocompatibility and sterilization requirements for spinal instrumentation. The external diameter of the custom screwdriver was matched to the internal diameter of the robotic arm guide, to be able to

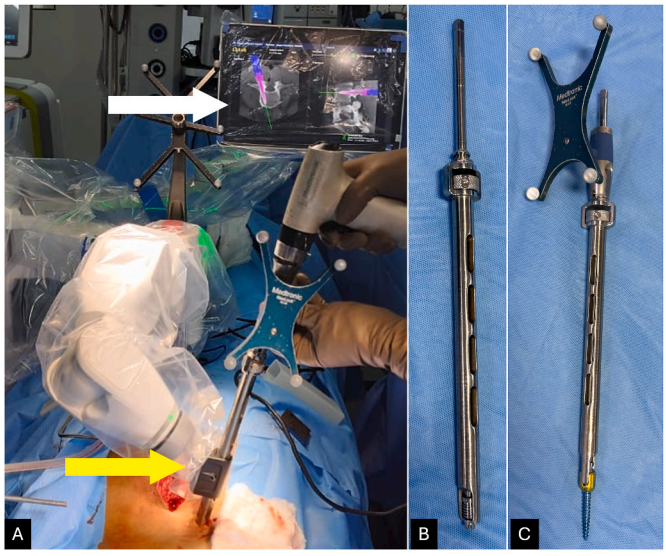

Fig. 1. Integration of Custom Screwdriver into Robotic Spine Surgery Workflow. (A) Intraoperative view of the Mazor X Stealth Edition (MXSE) robotic arm guiding a custom screwdriver through the robotic arm guide (yellow arrow). Real-time navigation is visible on the console screen, confirming trajectory alignment (white arrow). The navigation tracker is attached to the screwdriver to facilitate optical tracking. (B) Close-up of the custom-designed screwdriver, fabricated from surgical-grade stainless steel, with shaft length and diameter tailored for compatibility with third-party implants and robotic arm guide. (C) Fully assembled custom screwdriver with navigation tracker and a third-party pedicle screw mounted, illustrating alignment and functional compatibility with the robotic navigation system.

pass smoothly through the robotic arm guide, maintaining a snug fit without toggle, thereby ensuring precision and minimizing deviation during screw insertion.

To leverage the intraoperative navigation capabilities of the Mazor X platform, the custom screwdriver was designed to accommodate the Medtronic NavLock™. This integration allows the navigation system to visualize the instrument in real-time, thereby maintaining the robot's navigational accuracy while using third-party implants.

A major design consideration was differences in length between proprietary and third-party screwdriver and screw combined unit—particularly due to differences in the geometry of the screw head and tulip. To address this, the shaft length of the custom screwdriver was adjusted in accordance with the measured difference in overall construct length when compared to the proprietary system. This calibration ensured that the final navigated tip position corresponded accurately to the true physical depth of the pedicle screw.

As the robotic platform utilizes the distance of Navlock™ tracker from reference frame-based recognition protocol for its proprietary instrumentation; any deviation from the predefined length parameters leads to registration failure or navigational inaccuracy. So, altering the instrument length poses a challenge for navigation system registration. The Mazor X platform relies on a predefined instrument library for navigation verification, with no current provision for custom instrument calibration or new instrument registration. To overcome this limitation, the following workaround was implemented: initial navigation verification was performed using the proprietary screwdriver provided by the manufacturer. Once the screwdriver NavLock™ was successfully recognized and validated, it was then transferred to the custom screwdriver. Since the tracker is applied in the same spatial configuration relative to the instrument shaft, the navigation system continued to track the custom screwdriver accurately under the assumption of the verified (proprietary) length. This allowed uninterrupted use of navigation and robotic guidance with the third-party screw construct.

2.4. Surgical procedure

All procedures were performed with the patient in a prone position under general anesthesia. The robot was mounted to the Allen advance spine table using bedrail clamps. A "3 define" scan which scanned the 3D space around patient anatomy for any obstacles was performed, meanwhile navigated instruments were verified by keeping their tips over the divot of the reference frame which was mounted in the robot. A "snapshot" was then taken by attaching a snapshot tracker to robotic arm guide, to register the reference frame and robotic arm's position. A fiducial "star marker" was applied to the robotic arm guide and kept as close to the patient anatomy as possible and then an intra-operative CT was performed after confirming the visibility of the star marker in the orthogonal scout images. After the CT the images were transferred to the robotic console, and the trajectories were planned. After planning, the robotic arm was sent to the trajectory, after which the skin and fascia were incised using a 22 number robot compatible knife. Next, a trocar and sleeve were passed through the arm guide into the incised skin and fascia and advanced till the bone. High speed drill was used to create a pilot hole, followed by navigated tapping to prepare the pedicle for screw insertion. Finally, the custom screwdriver was used to insert the pedicle screws, through the robotic arm guide under navigation guidance. Post-insertion fluoroscopic images were routinely acquired to confirm optimal screw placement.

Intraoperative CT was used to assess screw placement accuracy using the Gertzbein-Robbins Scale (GRS), with screws graded C to E revised using robotic guidance. Image analysis was conducted by an independent neuroradiologist blinded to the instrumentation group.

2.5. Data collection and outcome measures

2.5.1. Primary outcome measures

- Pedicle screw placement accuracy (proportion of screws graded GRS A & B)
- Technical feasibility (successful completion rate using custom screwdriver)

2.5.2. Secondary outcome measures

- Intraoperative screw revision rate (GRS C–E requiring revision)
- Per-screw placement time (total robotic time divided by number of screws)
- Operative time, estimated blood loss, and workflow efficiency
- Resource utilization (implant costs per case)

2.5.3. Data collection protocol

Demographic data (age, sex, BMI, comorbidities), intraoperative parameters (operative time, blood loss, fluoroscopy duration), and postoperative outcomes (hospital stay, complications) were extracted from electronic health records using standardized case report forms. All screw placement assessments were performed by an independent neuroradiologist blinded to the instrumentation group. Follow-up data were collected at standard intervals per institutional protocol.

2.6. Statistical methods

Sample size calculation was based on published literature demonstrating robotic-assisted pedicle screw accuracy rates of 91.7 %–96 % for Gertzbein-Robbins grades A and B classification. Assuming a baseline accuracy rate of 95 % and setting a non-inferiority margin of 3 % (clinically acceptable threshold), with $\alpha = 0.05$ (two-sided) and power = 80 %, the calculated sample size was 92 patients per group. Our enrolment of 100 consecutive patients per group provided >85 % power for detecting the predefined non-inferiority threshold. The non-inferiority margin of 3 % was selected based on clinical consensus that accuracy differences below this threshold would not represent clinically meaningful deterioration in surgical precision.

All continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. For continuous variables, unpaired t-tests or Mann-Whitney U tests were employed depending on data distribution as assessed by Shapiro-Wilk tests. Categorical variables were analysed using chi-square tests or Fisher's exact tests as appropriate.

The primary endpoint (screw placement accuracy) was analysed using non-inferiority testing with a predefined margin of 3 %. Non-inferiority was established if the lower bound of the 95 % confidence interval for the difference in accuracy rates was above −3 %. For continuous secondary outcomes, effect sizes were calculated using Cohen's d. All tests were two-sided with significance set at $p < 0.05$. No adjustment for multiple comparisons was applied given the clear primary endpoint hierarchy.

All statistical analyses were performed using R statistical software (version 4.2.2; R Foundation for Statistical Computing, Vienna, Austria). The dataset was complete with no missing data for any analysed variables.

3. Results

3.1. Patient demographics and surgical characteristics

A total of 100 patients underwent thoracolumbar fusion with a custom screwdriver from July to October 2024. When compared to historical data from our institution on 100 procedures using standard instrumentation, the two groups were comparable in terms of age, sex

distribution, BMI, and levels fused ($p > 0.05$ for all comparisons) (Table 1). The most common indication for surgery in both groups was degenerative spine disease, followed by trauma, tumor, and infection.

3.2. Primary outcomes

3.2.1. Pedicle screw placement accuracy

A total of 708 pedicle screws were implanted in the custom screwdriver group and 760 screws in the standard instrumentation group. Pedicle screw placement accuracy was assessed using intraoperative CT imaging and graded according to the Gertzbein-Robbins classification.

The rate of clinically acceptable screws (GRS Grade A & B) was 99.15 % (702/708 screws) in the custom screwdriver group and 99.07 % (753/760 screws) in the standard instrumentation group (Table 2). The difference between groups was 0.08 % (95 % CI: 1.14 %–1.30 %; $\chi^2 = 0.023$, $p = 0.880$). Non-inferiority was demonstrated as the lower bound of the 95 % confidence interval (−1.14 %) was above the predefined non-inferiority margin of −3 %.

The custom screwdriver was successfully utilized for all planned screw insertions (100 % technical feasibility rate). No cases required conversion to standard instrumentation due to technical failure or incompatibility issues.

3.2.2. Secondary outcomes

3.2.2.1. Screw revision requirements. The number of screws requiring revision due to clinically unacceptable placement (GRS Grade C–E) was 6 out of 708 screws (0.85 %) in the custom screwdriver group and 7 out of 760 screws (0.93 %) in the standard instrumentation group ($\chi^2 = 0.023$, $p = 0.880$).

3.2.2.2. Operative efficiency measures. Mean blood loss was 537.2 ± 328.0 ml versus 550.0 ± 359.0 ml ($p = 0.793$), and per-screw placement time was 6.2 ± 1.8 versus 6.4 ± 1.7 min ($p = 0.426$). Total operative time was 142.3 ± 38.5 min in the custom screwdriver group and 148.7 ± 40.2 min in the standard instrumentation group ($t = -1.181$, $p = 0.239$, Cohen's $d = 0.17$).

Table 1
Patient demographics and surgical characteristics.

Parameter	Custom Screwdriver Group (n = 100)	Standard Instrumentation Group (n = 100)	Test Statistic	p-value
Demographics				
Age (years), mean ± SD	53.1 ± 11.7	50.5 ± 13.0	t = 1.492	0.137
Sex (M:F), n	65:35	60:40	$\chi^2 = 0.341$	0.559
BMI (kg/m^2), mean ± SD	27.3 ± 4.2	28.2 ± 5.1	t = −1.362	0.175
Surgical Complexity				
Levels Fused, mean ± SD	2.5 ± 1.6	2.8 ± 1.8	t = −1.074	0.284
Blood Loss (ml), mean ± SD	537.2 ± 328.0	550.0 ± 359.0	t = −0.263, d = 0.04	0.793
Operative Time (min), mean ± SD	142.3 ± 38.5	148.7 ± 40.2	t = −1.181, d = 0.17	0.239
Indication of Surgery, n (%)				
Trauma	3 (3.0)	2 (2.0)	$\chi^2 = 0.000$	1.000
Degenerative	87 (87.0)	86 (86.0)	$\chi^2 = 0.000$	1.000
Tumor	4 (4.0)	5 (5.0)	$\chi^2 = 0.000$	1.000
Deformity	1 (1.0)	2 (2.0)	$\chi^2 = 0.000$	1.000
Infection	5 (5.0)	5 (5.0)	$\chi^2 = 0.000$	1.000

Values are presented as mean ± standard deviation or number (percentage) unless otherwise specified.
Statistical analysis: Unpaired t-tests for continuous variables, chi-square tests for categorical variables.
BMI = body mass index; M = male; F = female.

Table 2
Screw placement accuracy and technical performance.

Gertzbein-Robbins Grade	Custom Screwdriver Group (n = 708)	Standard Instrumentation Group (n = 760)	Test Statistic	p-value
Clinically Acceptable Screws (GRS A&B), n (%)	702 (99.15)	753 (99.07)	$\chi^2 = 0.023$	0.880
Revised Screws (GRS C-E), n (%)	6 (0.85)	7 (0.93)	$\chi^2 = 0.023$	0.880
Per-screw placement time (min), mean ± SD	6.2 ± 1.8	6.4 ± 1.7	t = 0.789, d = 0.11	0.426

Values are presented as number (percentage) or mean ± standard deviation unless otherwise specified.
Non-inferiority analysis: Primary endpoint with predefined non-inferiority margin of 3 %. Non-inferiority demonstrated as the lower bound of the 95 % confidence interval (−1.14 %) exceeded the predefined margin (−3 %).
GRS = Gertzbein-Robbins Scale; Grade A = completely within pedicle; Grade B = cortical encroachment <2 mm; Grades C-E = cortical breach ≥2 mm requiring revision.
Statistical analysis: Chi-square tests for categorical variables, unpaired t-tests for continuous variables.
Difference calculation: Custom screwdriver group minus standard instrumentation group.

3.2.2.3. Safety profile. No significant intraoperative or postoperative complications occurred in either group. No cases of permanent neurological injury were reported. No patients required unplanned revision surgery during the follow-up period.

As a secondary observation, implant costs per case were lower in the custom screwdriver group (USD 559.50 ± 224.35) compared to the standard instrumentation group (USD 1973.47 ± 934.80) ($p < 0.001$).

3.2.2.4. Statistical analysis validation. The study achieved 85 % power for the primary endpoint based on the observed accuracy rate of 99.07 % in the standard instrumentation group, exceeding the originally planned 80 % power threshold.

4. Discussion

The field of spine surgery continues to evolve through innovations in surgical instrumentation, with recent advances including 3D-printed surgical guides,[8,12,13] patient-specific implants,[8,14] novel navigation systems,[15] and robotic system enhancements,[1,2] driving improvements in surgical precision and patient outcomes. Contemporary literature demonstrates that novel surgical instruments and implants in spine surgery are primarily driven by enhanced surgical precision, patient-specific anatomy accommodation, reduced morbidity, and improved safety profiles.[10,16,17] This study demonstrates that custom instrument development can expand system compatibility without compromising robotic guidance accuracy. Our findings show that a custom-designed screwdriver maintained equivalent screw placement accuracy (99.15 % vs 99.07 %) while enabling integration of third-party implants within the MXSE workflow.

The preservation of robotic accuracy while enabling third-party implant integration addresses a critical limitation in current robotic spine surgery platforms. Published literature demonstrates robotic systems achieve 91.7–96 % accuracy rates,[18,19] with multiple meta-analyses confirming superior precision compared to conventional freehand techniques,[20–22] yet these benefits remain constrained within proprietary ecosystems that limit surgical flexibility. Our custom screwdriver maintained accuracy within this established range (99.15

%) while successfully expanding system compatibility through innovative instrument design and navigation protocol modifications. This achievement represents a meaningful advancement in robotic platform versatility, demonstrating that the precision advantages of robotic guidance can be preserved while overcoming proprietary limitations.

Custom instrumentation addresses fundamental challenges where evidence-based implant selection may be constrained by platform compatibility, enabling patient-centered decision-making based on clinical evidence rather than technological limitations. This aligns with the experience-neutralizing effect of robotic assistance demonstrated in recent literature, where surgeons with varying experience levels achieved comparable accuracy outcomes.[23,24] Our study demonstrated that this enhanced surgical autonomy can be achieved without compromising operational efficiency, with comparable operative times (142.3 vs 148.7 min, $p = 0.239$), blood loss (537.2 vs 550.0 ml, $p = 0.793$), and per-screw placement times (6.2 vs 6.4 min, $p = 0.426$) between custom and standard instrumentation groups. The preserved workflow efficiency and safety profile demonstrated in our study suggest that enhanced system modularity can be achieved without compromising the operational benefits that have established robotic guidance as a preferred approach for complex spinal instrumentation.

This study establishes a framework for enhancing robotic system modularity that could inform future platform development and surgical technology innovation. The validation of custom instrumentation within established robotic workflows demonstrates that targeted modifications can achieve meaningful improvements in system versatility without requiring wholesale technological replacement. Future robotic systems and implant companies designing instruments could benefit from incorporating these modularity principles during initial design phases, potentially creating more adaptive platforms that accommodate evolving surgical techniques and implant technologies. The concept of online dissemination of novel surgical instruments, as demonstrated with 3D-printed spine localizers,[25] could facilitate broader adoption of custom instrumentation approaches. Similarly, innovations in minimally invasive surgical techniques[26] and modified surgical instruments[27] demonstrate the ongoing evolution toward more versatile and adaptable surgical tools. To support future technological advances without requiring complete system replacement, robotic companies could develop more flexible and adaptable arm guides with multiple diameter configurations and modular attachments to accommodate diverse instrumentation. Additionally, enhanced navigational capabilities could incorporate modular attachment systems that interface with any instrument, allowing the system to register basic parameters such as instrument length and diameter to integrate seamlessly with existing setups. This approach would significantly enhance system utility and versatility across multiple surgical applications. The concurrent observation of substantial cost advantages with third-party implants suggests that enhanced system openness may provide both clinical and economic benefits, supporting broader adoption of robotic technologies across diverse healthcare settings.

5. Limitations

Several limitations must be considered when interpreting these findings. The retrospective design and single center setting limit broader generalizability, and the use of historical controls may introduce temporal bias despite efforts to maintain consistent surgical protocols. The platform-specific nature of the custom instrumentation limits direct applicability to other robotic systems, each of which may require unique technical modifications based on their specific workflow and instrument recognition requirements. Future studies should explore the adaptation of similar modularity principles across different robotic platforms and surgical applications to maximize the clinical impact of this innovation approach. Within these constraints, this study provides compelling evidence that custom instrumentation can enhance robotic system versatility while maintaining the precision and safety advantages of robotic guidance.

6. Conclusions

This study successfully demonstrates that robotic system modularity can be enhanced through custom instrumental modifications while maintaining the precision, safety, and workflow advantages of robotic spine surgery. The equivalent accuracy achieved with custom instrumentation (99.15 % vs 99.07 %) validates the technical feasibility of third-party implant integration and establishes a framework for overcoming proprietary limitations in robotic platforms. These findings contribute to the advancing field of surgical innovation by demonstrating that targeted engineering solutions can expand system versatility without compromising established clinical benefits. The successful implementation of enhanced modularity principles provides a foundation for developing more adaptable robotic surgical systems that better serve diverse clinical applications and evolving technological requirements.

Patient consent declaration

Individual patient consent forms are NOT APPLICABLE for this study.

CRediT author statement

Abhishek Soni: Conceptualization: Data Curation, Formal Analysis, Writing – Original Draft, Writing – Review & Editing. Vidyadhara S: Conceptualization, Methodology, Project Administration, Resources, Supervision, Writing – Original Draft, Writing – Review & Editing, Validation. Balamurugan T: Methodology, Data Curation, Formal Analysis, Investigation, Writing – Review & Editing, Validation. Alia Vidyadhara: Data Curation, Investigation, Writing – Review & Editing, Resources.

Ethics approval

This study was approved by the Institutional Review Board (ECR/34/Inst/KA/2013/RR-19) and conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines.

Compliance

The study was conducted in accordance with:

- Declaration of Helsinki principles
- Good Clinical Practice (GCP) guidelines
- International Committee of Medical Journal Editors (ICMJE) ethical standards
- Institutional policies for clinical research

External funding

None.

Internal support

Standard institutional resources from Manipal Hospital, including access to surgical facilities, robotic equipment, and medical records as part of routine clinical operations.

Custom instrument development

Self-funded using departmental operational budget.

Financial disclosures

- No grants or contracts from government agencies
- No funding from medical device or pharmaceutical companies
- No commercial partnerships or consulting agreements
- No patent applications or intellectual property agreements
- All research conducted as part of routine academic and clinical duties

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflicts of interest

All authors declare no financial or personal conflicts of interest related to this research.

Acknowledgements

The authors express their sincere gratitude to the dedicated staff of Manipal Hospital who contributed to the success of this research, including the skilled operating theater staff, surgical technologists, anesthesia technicians, and OR nursing staff for their expertise in robotic spine surgery procedures and perioperative care; the outpatient department nursing staff and clinical coordinators for assistance with patient scheduling, data collection, and follow-up coordination; the ward nursing staff and spine care unit nurses for exceptional patient care and documentation support; the biomedical engineering staff and robotic system technicians for maintaining optimal equipment performance; and the medical records staff for assistance with data management and secure access to patient information. The authors also acknowledge the patients whose clinical care provided the foundation for advancing robotic spine surgery techniques.

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