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Development and Clinical Feasibility of a Computer-Assisted Shape Design and Bending System for Spinal Fixation Rods

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Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

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Background: Spinal pedicle screw-rod fixation is widely used, but manual rod bending is time-consuming and prone to contour inconsistencies. Although computer-assisted technologies have been explored, existing systems remain limited by cost, complexity, and insufficient precision. This study evaluated a novel computer-assisted rod design and bending system, with the goal of testing whether computer-assisted rod bending reduces bending plus installation time vs manual bending in unilateral paired cases and to evaluate safety, feasibility, and rod-screw fitting accuracy.

Material/Methods: A prospective trial enrolled 26 patients (18-75 years) undergoing spinal pedicle screw-rod fixation (≥4 segments) for fractures or degenerative diseases. Twenty patients received unilateral computer-assisted bending (contralateral manual for comparison) and 6 received bilateral assisted bending. The primary outcome was bending plus installation time; secondary outcomes included complications and fitting accuracy. Wilcoxon signed-rank test was used ($P < 0.05$).

Results: No instrument-related complications were observed (n = 26; median age 60.5 years). For 20 unilateral cases, computer-assisted bending (183.3 ± 70.8 seconds) was significantly shorter than manual bending (236.1 ± 119.1 s; mean reduction 52.75 seconds, $P = 0.017$). Subgroup analyses indicated signals of greater time savings in more than 4 segments (93.9 seconds, $P = 0.039$) and BMI of 25 kg/m^2 or higher (95.3 seconds, $P = 0.005$), although these were exploratory and not adjusted for multiplicity.

Conclusions: The computer-assisted system reduced bending plus installation time vs manual bending, with no instrument-related complications. Subgroup findings were exploratory and require further validation.

Keywords: Clinical Trial • Computer-Assisted Design • Orthopedics • Spinal Fusion • Spinal Implants • Validation Studies

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Introduction

Spinal pedicle screw-rod fixation remains the gold standard for treating spinal fractures, degenerative diseases, and deformities, and it is widely performed worldwide [1-3].

The shape compatibility of the fixation rod is critical to surgical stability [4], corrective efficacy [5,6], and long-term fusion outcomes [7]. Traditional rod bending is performed manually using handheld benders, which is often time-consuming. Variations in rod contouring may lead to undercorrection in different planes [5], and improper rod bending increases stress at the screw-rod interface, thereby elevating the risk of complications such as screw loosening, screw pull-out, or rod fracture [8,9]. Recent benchtop evidence further demonstrates that computer-supported rod contouring improves mechanical conformity and reduces residual forces at the screw-bone interface [10].

With the advancement of robotic and computer-assisted technologies in spine surgery, several systems have been developed to improve the accuracy and efficiency of screw placement [11,12] and rod contouring [13-16]. Comparative studies have systematically evaluated the accuracy of multiple navigation modalities for spinal instrumentation [17]. These systems typically utilize preoperative planning or real-time navigation to generate rod geometries that match actual screw positions [18].

Previous studies have focused on technical accuracy or complication profiles rather than operative time [19]. However, although computer-assisted rod-bending technologies have been explored, existing systems remain limited by high cost, cumbersome operation, and insufficient bending precision, which precludes their widespread clinical adoption [20]. This critical gap prevents the realization of a closed-loop data-driven workflow in computer-assisted spinal surgery.

The primary objective of this study is to conduct a prospective clinical trial to test the confirmatory hypothesis that computer-assisted rod bending reduces bending plus installation time vs manual bending in unilateral paired cases. Secondary exploratory aims include evaluating short-term safety, feasibility, and descriptive fitting observations in a single-center cohort undergoing spinal pedicle screw-rod fixation surgery.

The present contribution is incremental clinical feasibility of a self-developed system with prospective paired efficiency data, representing a meaningful step toward evidence-based assessment of computer-assisted rod-bending technology for routine spinal fixation surgery.

Material and Methods

Computer-Assisted Rod Bending System Composition

The computer-assisted fixation rod shape design and bending system includes 3 core interdependent components: an infrared optical tracking module, a digital bending device, and specialized software (**Figure 1**). The system uses an infrared optical tracking system (Northern Digital Inc [NDI]-compatible, standard in spinal surgery navigation), equipped with reflective marker spheres and a dynamic reference frame (DRF) mounted on the screw tail localizer. The multi-gear rod bending device is a modular digital bending device that was custom-developed to accommodate clinically prevalent titanium alloy and cobalt-chromium-molybdenum fixation rods (**Figure 2**). The software platform runs on a workstation, allows real-time data integration and processing, rod shape design, and parameter output for bending execution.

Clinical Trial Design

The study received approval from our institution's Ethics Committee (Ji Lun [K2025] No. [222]-00). All participants included in this study have provided informed consent.

Twenty-six patients were enrolled in this prospective study, with the following inclusion criteria:
(1) indication for spinal pedicle screw-rod fixation for fracture or degenerative spinal disease at our institution; (2) surgical fixation spanning 4 or more vertebral segments; and (3) age 18 to 75 years.

Exclusion criteria included severe cardiovascular or cerebrovascular disease, coagulation disorders, mental illness, or inability to comply with follow-up. The trial was to be discontinued if the computer-assisted rod-bending process could not proceed due to a technical error persisting for more than 3 minutes.

The patients' demographic background, diagnosis, surgical segments were recorded. All patients were fully informed that the system used in the study is a research prototype with no commercial availability and provided written informed consent prior to enrollment in accordance with the Declaration of Helsinki.

Application of Assisted Rod Insertion

Among the 26 patients, 20 (76.9%) underwent unilateral computer-assisted rod insertion (with the contralateral side receiving manual bending for paired comparison), and 6 (23.1%) underwent bilateral computer-assisted rod insertion.

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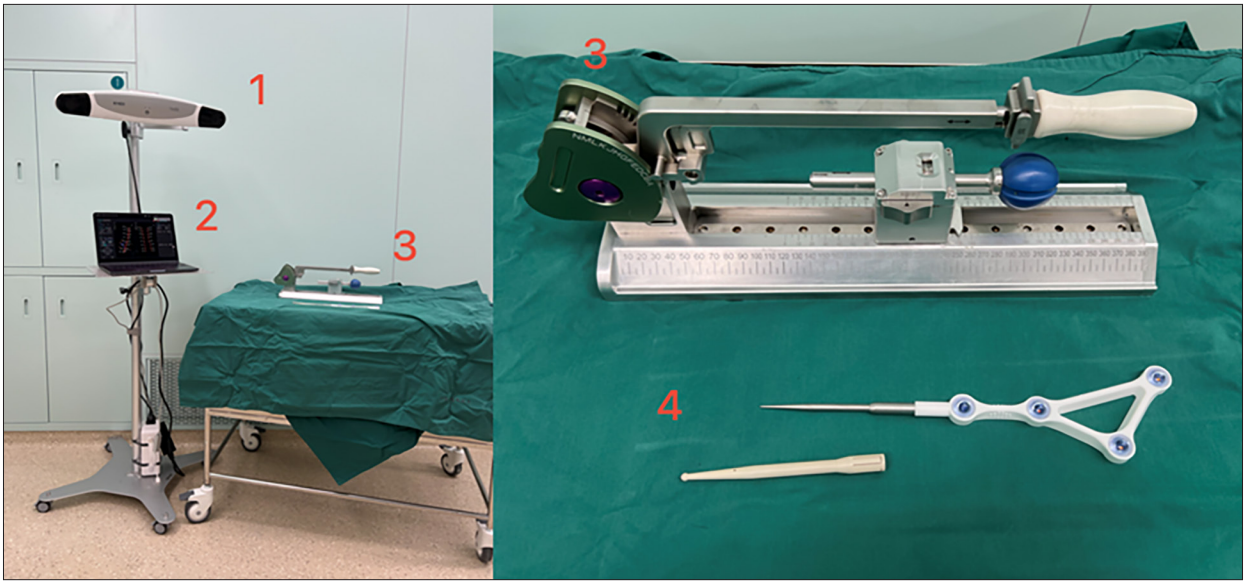

Figure 1. Schematic of the computer-assisted fixation rod shape design and bending system. The Northern Digital Inc (NDI) infrared optical tracking system (1) and screw tail locator (4) form the data acquisition module for capturing spatial screw position data; the main control console (2) serves as the data processing and control center running the shape optimization software; and the multi-gear rod bending device (3) functions as the execution module, performing rod bending according to the generated output parameters.

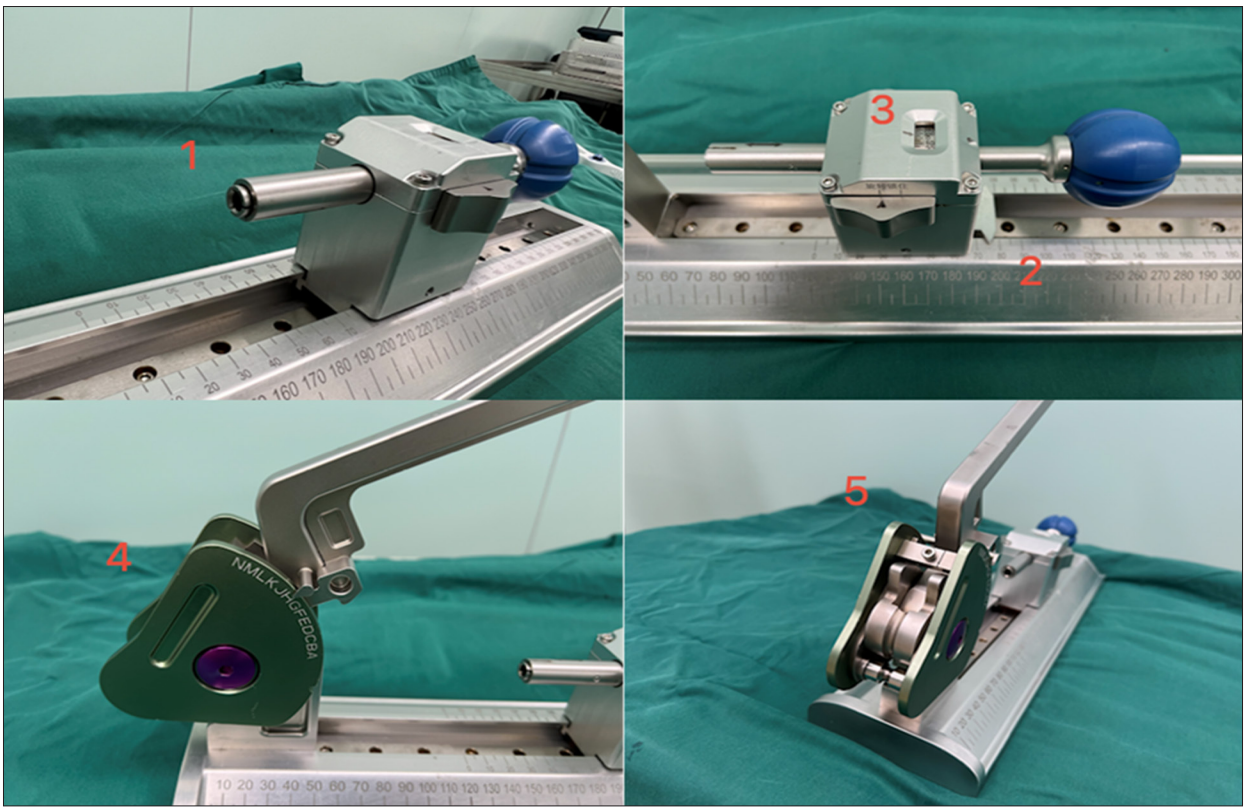

Figure 2. Core functional components of the multi-gear rod bending device. Each component is designed to address key challenges in manual rod bending: the fixation rod clamp (1) ensures stability, the length adjustment scale (2) provides positional accuracy, the rotation adjustment indicator (3) enables multi-planar curvature, the angle adjustment scale (4) controls bending precision, and the bending mechanism (5) enables controlled deformation of the rod.

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Table 1. Baseline demographic and clinical characteristics.

	Mean ± SD	Median (IQR)	Range
Age (years)	57.6 ± 13.8	60.5 (52.2-67.0)	19.0-74.0
Height (cm)	162.5 ± 7.7	160.0 (158.0-169.5)	148.0-180.0
Weight (kg)	67.4 ± 10.8	65.5 (60.0-74.8)	47.0-88.0
BMI (kg/m^2)	25.5 ± 3.4	25.2 (23.4-28.3)	19.1-31.8
Surgical segments (n)	4.7 ± 1.2	4.0 (4.0-5.0)	4.0-8.0
Sex, n (%)	–	–	–
Female	–	–	15 (57.7)
Male	–	–	11 (42.3)
Diagnosis, n (%)	–	–	–
Fracture	–	–	13 (50.0)
Degenerative disease	–	–	13 (50.0)
Assisted rod insertion, n (%)	–	–	–
Unilateral	–	–	20 (76.9)
Bilateral	–	–	6 (23.1)

Outcome Measures

The primary outcome was total time required for bending plus installation, compared between manual and computer-assisted techniques (focused on the 20 patients with unilateral paired data).

The secondary outcomes were intraoperative complications (eg, screw loosening, rod fracture, excessive bleeding), postoperative complications at 14 days after surgery (eg, infection, wound dehiscence), and rod-screw fitting accuracy. Fitting accuracy was assessed intraoperatively after final rod insertion and before wound closure by the operating surgeon as acceptable (rod engages all screws with minimal adjustment), good (immediate congruent engagement), or excellent (perfect anatomic fit without manipulation), with all ratings recorded in the case report form. Fluoroscopic confirmation required anteroposterior and lateral views showing congruent rod-screw engagement without additional screw repositioning.

Statistical Analysis

Continuous variables are presented as mean ± standard deviation (SD), median (interquartile range [IQR]), and range to fully reflect data distribution. Categorical variables (eg, sex, diagnosis, assisted rod insertion type) are presented as counts and percentages. Normality was assessed using the Shapiro-Wilk test. Paired comparisons between manual and computer-assisted bending times (for the 20 unilateral cases) were performed using the Wilcoxon signed-rank test due to non-normal data distribution. Subgroup analyses were exploratory and conducted without prespecified hypotheses or multiplicity adjustment, stratified by surgical segment count (≤ 4 vs > 4 segments) and BMI (< 25 vs ≥ 25 kg/m^2). Procedural consistency was summarized descriptively using coefficients of variation without formal inferential testing. Post hoc effect size was quantified using Cohen's d for paired differences, and statistical power was calculated for the primary outcome. A post-hoc exploratory sequence analysis was performed using the Mann-Whitney U test to evaluate potential procedural order effects. Bootstrap 95% confidence intervals for mean paired differences were calculated using SPSS 26.0. The exact-method Wilcoxon signed-rank test statistic (T = sum of positive ranks) was reported as output by SPSS 26.0. Deployment time was defined as the interval from device positioning at the surgical field (bending device and optical tracking array placed within operative reach) to system readiness for screw tail registration (completion of dynamic reference frame fixation and software initialization confirmed by the workstation interface). Training proficiency was determined by a coordinator-administered checklist: the surgeon or scrub nurse independently completed device setup, calibration, and reference frame placement without verbal prompting or physical assistance across 2 consecutive sessions of approximately 30 minutes. Device deployment time and training proficiency were recorded intraoperatively by the surgical coordinator. Statistical significance was defined as $P < 0.05$. All analyses were performed using SPSS 26.0 software (IBM Corp, Armonk, NY, USA).

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Results

Baseline Demographic and Clinical Characteristics

All 26 enrolled patients had complete data records, with no missing information on demographic features, clinical diagnoses, surgical segments, or assisted rod installation sides. As shown in **Table 1**, the cohort had a balanced sex distribution (15 women, 11 men) and equal proportions of fracture and degenerative diagnoses (13 cases each). The age range was 19.0 to 74.0 years (median 60.5 years), consistent with the typical age spectrum of patients requiring spinal fixation. Anthropometrically, the mean height was 162.5 ± 7.7 cm, mean weight 67.4 ± 10.8 kg, and mean BMI 25.5 ± 3.4 kg/m^2, with 54.0% classified as having overweight or obesity (BMI ≥ 25 kg/m^2). Surgical segments ranged from 4 to 8 (mean 4.7 ± 1.2 segments), with most cases (73.1%) involving 4 to 5 segments (mid-to-long segment fixation). In terms of assisted rod insertion, 20 patients (76.9%) received unilateral computer-assisted rod bending (paired with manual bending on the contralateral side), and 6 patients (23.1%) received bilateral computer-assisted rod bending.

Comparison of Operational Time

For the 20 patients with unilateral paired data (assisted vs manual bending), the mean total time for computer-assisted bending was 183.3 ± 70.8 seconds, which was significantly shorter than the 236.1 ± 119.1 seconds for manual bending (mean reduction 52.75 seconds; Wilcoxon signed-rank test, exact method: T = 42, P = 0.017, 95% bootstrap CI for the mean reduction 14.5-95.6 seconds) (**Figure 3**). Computer-assisted bending was faster in 70% (14/20) of cases, and manual bending was faster in 30% (6/20). The coefficient of variation for computer-assisted bending time (38.6%, 70.8/183.3) was notably lower than that for manual bending (50.4%, 119.1/236.1), indicating greater consistency and predictability in system performance.

Shapiro-Wilk testing indicated that paired time differences were non-normally distributed (W = 0.901, P = 0.044), supporting the use of non-parametric testing for the primary comparison.

Among these 20 patients, 9 underwent computer-assisted rod bending first, while 11 received manual rod bending first. An exploratory post hoc sequence analysis was performed using the Mann-Whitney U test, stratified by the initial bending approach. No statistically significant difference was observed in the time difference (manual bending time minus computer-assisted bending time) between the 2 sequence groups (P = 0.305, n = 9 vs n = 11). The mean time difference was higher in the manual-first group (80.45 seconds) than in the assisted-first group (18.89 seconds), but this comparison is limited by small sample size and should be interpreted cautiously.

The observed mean time difference between manual and assisted sides was 52.75 ± 96.64 seconds (mean ± SD), corresponding to a medium effect size (Cohen's d = 0.546) per Cohen's criteria (d = 0.2 indicates small, d = 0.5 indicates medium, d = 0.8 indicates large). The overall statistical power was calculated as 0.685 (68.5%).

For the 6 patients with bilateral assisted bending (no manual comparison), the mean unilateral bending time was 93.4 ± 58.2 seconds, and the mean total time (bending + insertion) per side was 170.2 ± 92.5 seconds. This subset included complex cases such as T10-L5 long-segment fixation and lumbar degenerative scoliosis correction, where the system maintained efficient rod manipulation despite challenging anatomical conditions (eg, deep-seated screws in muscular patients). The mean device deployment time was 5.2 ± 1.3 minutes, and the surgical team (surgeons and scrub nurses) achieved operational proficiency after 1 to 2 training sessions of 30-minute duration.

Subgroup Analyses

Stratification by Number of Surgical Segments

Subgroup analyses were conducted for the 20 patients with unilateral paired data, stratified by surgical segment count: 4 segments or fewer (n = 12), and more than 4 segments (n = 8).

For patients with 4 segments or fewer, the mean time for manual bending was 203.9 ± 58.8 seconds, compared with 178.6 ± 78.2 seconds for computer-assisted bending (mean reduction 25.3 seconds. The Wilcoxon signed-rank test (exact method) showed no statistically significant difference (T = 23; P = 0.233), with a 95% bootstrap confidence interval for the mean reduction ranging from -14.8 to 68.4 seconds.

For patients with more than 4 segments, the mean time for manual bending was 284.4 ± 169.2 seconds, compared with 190.5 ± 62.5 seconds for computer-assisted bending (mean reduction 93.9 seconds. The Wilcoxon signed-rank test (exact method) showed a statistically significant difference (T = 3; P = 0.039), with a 95% bootstrap confidence interval for the mean reduction ranging from 12.3 to 156.8 seconds (**Figure 4**).

Stratification by BMI

For the 20 unilateral paired patients, stratified by BMI using 25 kg/m^2 as the cutoff, the groups were patients with a BMI below 25 kg/m^2 (n = 9) and those with a BMI of 25 kg/m^2 or higher (n = 11):

For the group with a BMI below 25 kg/m^2, no significant difference was observed between manual and computer-assisted bending times (manual: 179.3 ± 68.0 seconds; assisted: 178.6 ± 63.2 seconds; mean reduction 0.8 ± 62.6 seconds. The Wilcoxon

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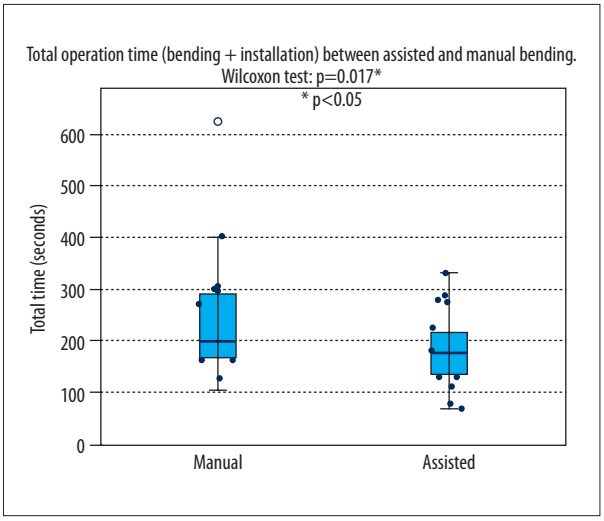

Figure 3. Boxplot of total operational time (bending + installation) between unilateral assisted and manual bending (n = 20). Boxes represent interquartile ranges (IQR, Q1-Q3), horizontal lines inside boxes denote medians, whiskers extend to minimum/maximum values (excluding outliers), and dots represent individual patient data. The x-axis indicates operation modes (manual vs computer-assisted), and the y-axis denotes total time (seconds). The computer-assisted group showed significantly shorter total time (183.3 ± 70.8 seconds) than the manual group (236.1 ± 119 seconds; Wilcoxon signed-rank test: $P = 0.017$, with smaller variability.

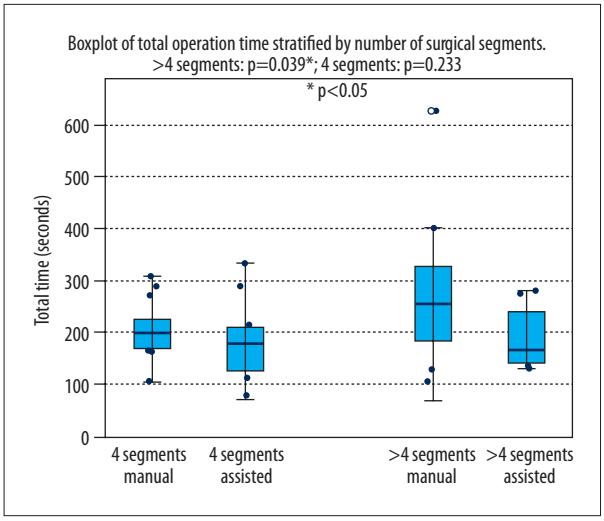

Figure 4. Boxplot of total operational time (bending + installation) between assisted and manual bending stratified by number of surgical segments (n = 20). Boxes represent interquartile ranges (IQR, Q1-Q3), horizontal lines inside boxes denote medians, whiskers extend to minimum/maximum values (excluding outliers), and dots represent individual patient data. The x-axis indicates the group of segments (4 segments vs > 4 segments) and operation modes (manual vs computer-assisted) and the y-axis denotes total time (seconds). The computer-assisted group showed significantly shorter total time in patients with > 4 surgical segments.

signed-rank test (exact method) showed no statistically significant difference (T = 21; $P = 0.911$), with a 95% bootstrap confidence interval for the mean reduction ranging from -47.5 to 42.3 seconds.

For the group of patients with a BMI of 25 kg/m^2 or higher, the mean time for computer-assisted bending was significantly shorter than that for manual bending (manual: 282.6 ± 134.1 seconds; assisted: 187.3 ± 79.3 seconds; mean reduction 95.3 seconds. The Wilcoxon signed-rank test (exact method) showed a statistically significant difference (T = 3; $P = 0.005$), with a 95% bootstrap confidence interval for the mean reduction ranging from 34.1 to 148.7 seconds (**Figure 5**).

These exploratory findings suggest that the time-saving advantage of the computer-assisted system may be more pronounced in longer-segment surgeries and in patients with obesity or overweight, likely due to reduced surgical field exposure and increased manual operation difficulty in this population (**Table 2, Figure 6**).

Safety and Feasibility

Across all 26 patients, no instrument-related complications were reported, including intraoperative events (screw loosening, rod fracture, excessive bleeding) and 14-day postoperative events (infection, wound dehiscence). Postoperative anteroposterior and lateral radiographs confirmed acceptable to excellent rod-screw fitting in all cases, with no need for additional adjustments to screw depth or position during rod insertion, as assessed by subjective surgeon evaluation and intraoperative fluoroscopy.

No intraoperative case met the predefined trial abortion criterion (technical interruption exceeding 3 minutes).

The safety data (including the complete records of 26 patients) have been reported to the ethics committee of our hospital.

Discussion

This study provides preliminary evidence of reduced operative time, procedural consistency, and favorable short-term safety and feasibility with the computer-assisted system in spinal pedicle screw-rod fixation surgery, with these signals being more pronounced in specific clinical subgroups.

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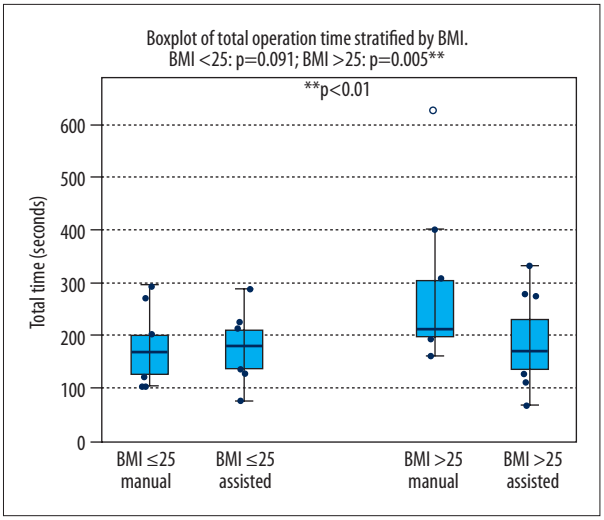

Figure 5. Boxplot of total operational time (bending + installation) between assisted and manual bending stratified by body mass index (BMI) (n = 20). Boxes represent interquartile ranges (IQR, Q1-Q3), horizontal lines inside boxes denote medians, whiskers extend to minimum/maximum values (excluding outliers), and dots represent individual patient data. The x-axis indicates the group of segments (BMI ≤ 25 kg/m² vs > 25 kg/m²) and operation modes (manual vs computer-assisted) and the y-axis denotes total time (seconds). The computer-assisted group showed significantly shorter total time in patients with BMI > 25 kg/m².

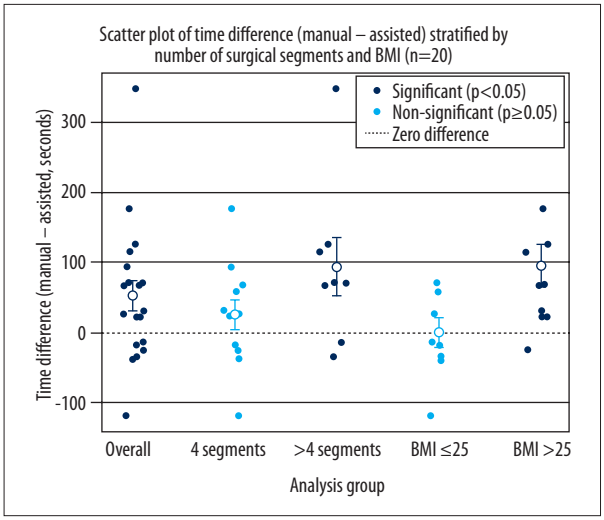

Figure 6. Scatter plot of the time difference (manual minus computer-assisted bending) stratified by surgical segment count and body mass index (BMI) (n = 20). The plot shows the time difference (in seconds) across 5 analysis groups: overall cohort, ≤ 4 segments or fewer, > 4 segments, BMI < 25 kg/m², and BMI ≥ 25 kg/m². Data points are color-coded by statistical significance (black, $P < 0.05$; gray, $P \geq 0.05$), and the dashed line indicates zero time difference (no difference between methods). White circles represent group means, with error bars indicating standard deviations.

Table 2. Subgroup analyses of total operational time (bending + installation) for paired cases (n = 20).

Subgroup category	Sample size (n)	Manual bending time (s) mean ± SD	Assisted bending time (s) mean ± SD	Mean time reduction (s) mean ± SD	Wilcoxon signed-rank test results
Surgical segment count					
≤ 4 segments	12	203.9 ± 58.8	178.6 ± 78.2	25.3 ± 73.7	$P = 0.233$
> 4 segments	8	284.4 ± 169.2	190.5 ± 62.5	93.9 ± 116.6	$P = 0.039$*
BMI (kg/m²)					
< 25	9	179.3 ± 68.0	178.6 ± 63.2	0.8 ± 62.6	$P = 0.911$
≥ 25	11	282.6 ± 134.1	187.3 ± 79.3	95.3 ± 101.0	$P = 0.005$*

"Mean time reduction" was calculated as manual bending time minus computer-assisted bending time; positive values indicate time saved using the computer-assisted method. Statistical significance was defined as $P < 0.05$ and is indicated by an asterisk (*). Body mass index (BMI) classification follows World Health Organization criteria (normal, 18.5-24.9 kg/m²; overweight/obese, ≥ 25 kg/m²).

Regarding operative efficiency, the computer-assisted approach achieved a statistically significant mean time reduction of 52.75 seconds per rod compared with manual bending in 20 patients with unilateral paired data ($P = 0.017$). Subgroup analyses indicated preliminary signals of time-saving benefit in long-segment surgeries (> 4 vertebral segments, 93.9-second reduction, $P = 0.039$) and patients with overweight or obesity (BMI ≥ 25 kg/m², 95.3-second reduction, $P = 0.005$), although these subgroup comparisons were exploratory and not adjusted for multiplicity. These subgroups represent clinical scenarios in which manual rod bending is inherently challenging: long-segment fixation demands complex multi-planar contouring adjustments,

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while overweight and obesity present limited surgical field exposure that impairs visual estimation and manual manipulation of fixation rods. For patients with 4 segments or fewer or normal BMI (BMI < 25 kg/m^2), no statistically significant time difference was observed between the 2 approaches, suggesting marginal or no efficiency benefit in these less complex clinical settings.

The coefficient of variation for bending time was descriptively lower for computer-assisted bending (38.6%) than for manual bending (50.4%), suggesting greater procedural consistency; however, this comparison is descriptive and was not subjected to formal inferential testing. While consistent rod contouring could theoretically optimize rod-screw fitting accuracy and reduce stress concentration at the screw-rod interface, a known contributor to hardware-related complications including screw loosening and rod fracture [8,9], this study did not measure objective 3D fit metrics or biomechanical stresses, and the relationship between procedural consistency and improved hardware performance remains hypothetical, pending future studies with quantitative alignment and long-term outcome data.

Notably, the computer-assisted system exhibited favorable clinical feasibility for routine surgical adoption. The mean device deployment time was only 5.2 ± 1.3 minutes, and the surgical team (surgeons and scrub nurses) achieved operational proficiency after just 1 to 2 training sessions of 30-minute duration, regardless of unilateral or bilateral assisted rod insertion. This addresses a key limitation of existing computer-assisted rod-bending technologies, which are often hampered by cumbersome setup and long learning curves [21]. The system interfaces with commercially available NDI infrared optical tracking systems, avoiding the need for proprietary, high-cost hardware and reducing adoption barriers for hospitals with existing spinal navigation infrastructure.

A post hoc analysis of bending sequence was conducted to address potential procedural bias, with surgical records revealing 9 patients underwent computer-assisted bending first and 11 received manual bending first in the unilateral paired cohort. Mann-Whitney U test results showed no statistically significant difference in the time difference (manual minus computer-assisted bending time) between these 2 sequence groups ($P = 0.305$), indicating bending order did not exert a meaningful impact on the primary outcome. The mean time difference was 80.45 seconds in the manual-first group and 18.89 seconds in the computer-assisted-first group, a finding that may be attributed to the learning effect inherent to spinal fixation surgery, an effect acknowledged as a realistic factor in clinical practice. For the computer-assisted-first group, the standardized rod contouring and parameter output of the system provided surgeons with objective reference points for subsequent manual bending (eg, rod length, approximate curvature angles), conferring a modest time advantage to the manual approach. In contrast, the computer-assisted bending process adheres to fixed, software-guided procedural steps, and prior manual bending conferred no discernible time advantage on the subsequent computer-assisted procedure, as the system relies on objective anatomical data rather than subjective surgical experience. This pattern is observational and should not be interpreted causally given the small sample and nonrandomized sequence allocation; the primary outcome of reduced operative time remained statistically significant independent of bending sequence.

This study has several limitations. First, the small sample size (n = 26) and single-center design limit generalizability. The post hoc power was 68.5%, indicating that the study was underpowered to detect smaller effect sizes reliably. Consequently, the observed effect size may be inflated and the estimates are subject to considerable uncertainty, warranting cautious interpretation. Second, follow-up was limited to 14 postoperative days, with no long-term data on fusion rates, hardware complications, or patient-reported outcomes. Third, rod-screw fitting accuracy was assessed subjectively without objective quantitative metrics. Fourth, the study excluded patients with spinal deformities (eg, scoliosis, kyphosis) and traumatic spinal cord injury. Fifth, the unilateral paired comparison assumed symmetrical rod contours between sides; in deformity or asymmetric pathology, required contours may differ, introducing task asymmetry that could affect bending time comparability. Multicenter trials with larger samples and extended follow-up (≥ 1 year) are needed to validate these preliminary findings.

Subsequent investigations should prioritize multicenter trials with larger sample sizes to validate the system's performance across diverse clinical settings, levels of surgical expertise, and complex spinal pathologies (eg, scoliosis, kyphosis). They should also include extended follow-up (≥ 1 year) to assess long-term outcomes, such as spinal fusion rates, hardware durability, and patient-reported functional measures (eg, visual analog scale, Oswestry Disability Index). Additionally, future research should evaluate the system's applicability in ultra-long–segment fixation and morbidly obese cohorts, as well as its cost-effectiveness for routine clinical adoption.

Conclusions

The computer-assisted shape design and bending system for spinal fixation rods demonstrated reduced bending plus installation time relative to manual bending in the unilateral paired cohort, and no instrument-related complications were observed during the 14-day follow-up. Preliminary subgroup signals suggest potential feasibility in longer-segment surgeries and in patients with a BMI of 25 kg/m^2 or above, although these observations require further prospective validation.

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Statement

To clarify, this computer-assisted fixation rod shape design and bending system is developed solely for academic research and clinical feasibility purposes, as approved by the Ethics Committee of Beijing Jishuitan Hospital, Capital Medical University. All components (software, bending device, tracking module) are research prototypes.

The research team has no current plans to pursue commercialization of the system. The primary objective of this study is to advance scientific knowledge in computer-assisted spinal surgery.

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Data Availability Statement

The data presented in this article can be obtained by contacting the corresponding author via email.

Declaration of Figures' Authenticity

All figures submitted have been created by the authors who confirm that the images are original with no duplication and have not been previously published in whole or in part.

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