A Comparison of Spinal Robotic Systems and Pedicle Screw Accuracy Rates: Review of Literature and Meta-Analysis

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Abstract

Introduction The motivation to improve accuracy and reduce complication rates in spinal surgery has driven great advancements in robotic surgical systems, with the primary difference between the newer generation and older generation models being the presence of an optical camera and multijointed arm. This study compares accuracy and complication rates of pedicle screw placement in older versus newer generation robotic systems reported in the literature.

Methods We performed a systemic review and meta-analysis describing outcomes of pedicle screw placement with robotic spine surgery. We assessed the robustness of these findings by quantifying levels of cross-study heterogeneity and publication bias. Finally, we performed meta-regression to test for associations between pedicle screw accuracy and older versus newer generation robotic spine system usage.

Results Average pedicle screw placement accuracy rates for old and new generation robotic platforms were 97 and 99%, respectively. Use of new generation robots was significantly associated with improved pedicle screw placement accuracy (p = 0.03).

Conclusion Accuracy of pedicle screw placement was high across all generations of robotic surgical systems. However, newer generation robots were shown to be significantly associated with accurate pedicle screw placement, showing the benefits of upgrading robotic systems with a real-time optical camera and multijointed arm.

Keywords ► surgical robotics ► spine surgery ► pedicle screw placement accuracy

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Introduction

Each year, approximately 4.83 million spinal surgeries are performed globally.\(^1\) Pedicle screws are often used within these procedures, allowing for spine stabilization and fusion.\(^2\) Considering the surgical field’s proximity to main blood vessels and the central nervous system, consistent accuracy with minimal invasion is vital. Given these concerns, engineers developed robotic surgical systems to aid spine surgeons in attaining increased accuracy and precision while minimizing radiation exposure during surgery.\(^1\)

Mazor Robotics released the first spine robot, SpineAssist, which received U.S. Food and Drug Administration (FDA) approval in 2004.\(^2\) SpineAssist can be programmed to follow a predetermined trajectory, allowing surgeons to drill screws manually. Within the surgical apparatus, surgeons often use Kirschner wire (K-wires) to attach the patients’ spinal processes and improve stabilization. Mazor then enhanced this model by adding image recognition algorithms and other software and hardware improvements, replacing the SpineAssist model with the Renaissance model in 2011.\(^2\) These two robotic systems have reported accuracy rates of 85 to 100% with skiing being the most significant problem reported.\(^2\)

To improve limitations such as skiing encountered with SpineAssist and Renaissance that have been associated with cases of pedicle screw misplacement, the Mazor X was introduced in 2016. It possesses a linear optical camera for the robot to detect its location relative to the surgical field. It also has a serial robotic arm that increases its range of motion relative to the previous robots that possess parallel robotic arms. The ROSA spine robot, developed by Zimmer Biomet Robotics, was approved by the FDA in 2016 and has many similarities with the Mazor X robot. Both robot systems have a navigation camera and multifunctional robotic arm. The newer ROSA Spine robot, however, remains less well studied compared with Mazor X.\(^2,3\) The ExcelsiusGPS robot, developed by Globus Medical, Inc., was FDA-approved in 2019. With intraoperative imaging and tracking for patient movement, it is similar to the Mazor X and ROSA spine robots. The ExcelsiusGPS robot also allows for direct screw insertion through a rigid robot arm, removing the need for K-wires or clamps. Finally, TINAVI is a general orthopaedic robot developed in China and approved by the National Medical Products Administration of China.\(^4-7\)

This machine has optical tracking in real time, in addition to three-dimensional navigation. It is used for pelvic, limb, and spinal procedures.\(^4,5\)

Given the evolution of these robots, comparisons should be made to determine whether the added enhancements of a linear optic camera and serial articulating robotic arm have significantly improved patient outcomes. From the authors’ knowledge, no article has compared the accuracy rates and complications between the old generation of robots (SpineAssist and Renaissance) with those of the new generation (Mazor X, Excelsius GPS, and ROSA Spine, TINAVI). We provide a comprehensive review and meta-analysis of the literature to compare accuracy rates and complications associated with robotic spine surgery between these different robot generations.

Methods

Literature Search

A comprehensive review of the literature was conducted via PubMed, Medline, Embase, Scopus, and Google Scholar in July 2021, with the last search performed in July 30, 2021. The following intersectional search strategy was utilized: (“robot” or “robotic” or “robot-assisted” or “mazor” or “[globus” or “excelsius”] or “[tinavi” or “tirobot”] or “ROSA spine” or “spineassist” or “rennaissance”) and “spine surgery.” English full-text observational clinical studies, clinical trials, and randomized controlled studies focused on humans were included. Studies that focused on pediatrics and that lacked information concerning accuracy and complications of these different robot systems were excluded. Studies involving 2T-alar-iliac screws only were also excluded. Two authors (VO and AR) both evaluated these studies and determined respective level of evidence independently. Level of evidence for each study was graded based on the Evidence-Based Spine-Care Journal criteria.\(^8\) The senior author served as the final arbiter of any discrepancies between the two reviewing authors.

Data Extraction

General patient demographic information was extracted from each article, including the numbers of patients, gender distribution, average age, and indication for spine surgery. Reported indications for pedicle screw placement included degenerative disease, fracture/trauma, scoliosis, tumor, and infection as described by the authors. Degenerative disc disease included stenosis, disc degeneration, spondylolisthesis, and adjacent segment disease. Intraoperative measurements included region of spinal surgery, estimated blood loss (EBL), and operative time. Postoperative outcome measures considered included the number of screws placed, screw placement accuracy, complications, average length of stay (LOS), and average follow-up time. Screw placement accuracy was defined as a Gertzbein and Robbins scores of A or B divided by total screws placed.\(^9\)\(^10\) A score of “A” notes no signs of breach, while a score of “B” notes a breach of less than 2 mm. Both scores of A and B are clinically acceptable.\(^11\)\(^12\)

Statistics

All unpaired t-tests, meta-analysis summary statistics, and models were generated using the meta package in R.\(^13-15\) Heterogeneity between studies was quantified with I\(^2\), r\(^2\), and Cochran’s Q with a significance level of 0.05. Publication bias was visualized through funnel plot analysis and Egger’s tests.\(^16\)\(^17\) Meta-regression was indicated for analyses containing significant heterogeneity using available variables as found in the collected studies.\(^18\)

Results

Literature Search

From the initial electronic search strategy, 378 papers were found overall. Following removal of duplicates and screening, 279 papers remained. After the title, abstract, and full-text
screensings, 22 papers remained. After manual bibliographic searches and manual searches of Google Scholar, 10 additional papers were added and overall amounted to 32 papers (Fig. 1). Of these, 20 studies were retrospective, 4 were prospective, and 8 were randomized control studies (Tables 1 and 2). Papers concerning the old generation robots include nine studies utilizing SpineAssist1,13–26 and seven utilizing Renaissance.12,27–32 In terms of the new generation of robots, two studies focused on Mazor X,33,34 five about ExcelsiusGPS,35–39 eight about TINAVI,4,5,7,40–44 and one about ROSA Spine.3

Patient Demographics
From the analysis, 2,244 patients were examined overall, with 1,500 treated with old generation robots and 744 treated with new generation robots (Tables 1 and 2). Across available studies, 833 patients were females (54%) and 722 were males (46%). Within the old generation robot pool, there is a ratio of 455 females (54%) to 392 males (46%). Within the new generation, 378 women (53%) and 330 men (47%) were identified. Indications for pedicle screw placement included degenerative disc disease (n = 724), fracture/trauma (n = 56), Scoliosis (n = 3), and infection (n = 1).5,7,12,25,27,30–33,36–38,42,43 Overall average age was 60 ± 5 years, with the old generation group individually averaging 61 ± 5 years and the new generation robots group averaging 60 ± 5 years. Upon unpaired t-test comparison, no significant significance of age mean of means was found (t(25) = 0.6, p = 0.59). Overall operative time was 198 ± 62 minutes, with the old and new generation robot groups averaging at 194 ± 29 and 200 ± 70 minutes, respectively. No significant difference was found for operative time mean of means between these groups (t(16) = 0.3, p = 0.78). Average overall EBL was 297 ± 260 mL. EBL mean of means for the older generation and newer generation robotic systems were 406 ± 169 and 251 ± 283 mL, respectively. No significant difference was found between these two groups for EBL (t(15) = −1.1, p = 0.28). Average overall LOS was at 6 ± 2 days. Patients treated with older generation robots had a significantly higher LOS compared with patients treated with newer generation robots (7 vs. 5 days, t(6) = 2.6, p = 0.02).

Screw Demographics
From all pooled studies, specific information about screw location was found for 3,574 placed screws (Table 3).3,5,7,19–22,24,28,36–39,42–44 Of these 3,574, 186 were cervical, 488 thoracic, 2,560 lumbar, and 320 sacral. Additionally, 1,149 of the 3,574 screws were placed with the old generation of robots. From the screws placed under these particular machines, 426 were thoracic, 613 were lumbar, and 110 were sacral. The remaining 2,425 screws of the 3,574 total were placed under the second generation of robots with 186 cervical, 82 thoracic, 1,947 lumbar, and 210 sacral. Seven studies explicitly stated the number of levels operated on.7,12,25,27,34,43 Only Schatlo et al and Mao et al reported average number of levels, with values at 2.3 and 5.4, respectively.23,34 Pedicle screw accuracy was evaluated through forest plot analysis and is summarized in Figs. 2A and 3A. Older generation spine robots were seen to have an accuracy rate of 97% (96–97%). Newer generation spine robots were seen to...
<table>
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<tr>
<th>Author and year</th>
<th>Type of study</th>
<th>LoE</th>
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<th>No. of patients</th>
<th>No. of females</th>
<th>Mean age (years)</th>
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<th>EBL (mL)</th>
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Abbreviations: LoE, level of evidence; EBL, estimated blood loss; LOS, length of stay; NA, not available.

Median value extracted instead of mean.
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Average values: EBL, estimated blood loss; LoE, level of evidence; LOS, length of stay; NA, not available.
### Spinal Robotic Systems and Pedicle Screw Accuracy Meta-Analysis

Ong et al.

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**Complications**

Out of the 16 papers covering the older generation of robots, seven studies reported associated complications.\(^{12,19,25,29–32}\) Of these seven studies, only one study stated no observed complications.\(^{19}\) Out of the 16 papers covering the new generation of robots, 11 studies assessed for complications,\(^{3,5,7,33,35,37,39,41–45}\) with 5 reporting no complications.\(^{3,7,33,35,37}\)

From the intraoperative complications of old generation robots, there were ten transfusion events, seven dural tears, and three intraoperative screw revisions.\(^{12,25,29,32}\) Postoperative complications included four wound infections, two neurological complications, two cage dislodgements, two unspecified issues, one case of spinal cord stroke, and one case of bowel obstruction with renal injury.\(^{12,25,30–32}\)

Newer generation of robots was intraoperatively associated with two dural tears, one case of K-wire skidding, and two unspecified issues.\(^{5,39,43}\) Postoperative complications included five cases of muscle numbness of anterior thigh, five wound revisions, two 30-day readmissions, one seroma, one infection, and one unspecified reason.\(^{5,39,43}\)

More studies reported surgical revision rates of patients as compared with general complications.\(^{3–5,7,12,19,20,22,24,29,30,34,35,39–42}\) Seven of 16 older generation robot studies reported the number of patients requiring surgical revisions,\(^{12,19,20,22,24,29,30}\) with 3 studies reporting zero need for any revisions.\(^{19,22,24}\) Eighteen revision surgeries out of 386 (4.7%) were reported that addressed issues such as surgical wounds and screw malposition.\(^{12,19,20,22,24,29,30}\) Nine of 16 newer generation robot studies reported the number of patients requiring surgical revisions,\(^{4,5,7,34,35,39–42}\) with 6 studies lacking any needed revisions. Seven revision surgeries out of 480 (1.5%) were reported. Overall reasons for revision involved wound revisions, cage dislodgements, and screw repositioning.\(^{5,12,29,34,36}\)

**Discussion**

In the twenty-first century, technological advancements have been pursued to improve surgical accuracy and consistency.\(^{46}\) Improvement in patient outcome and efficient allocation of hospital resources served as motivators in developing spine robots.\(^{47}\) SpineAssist and Renaissance were two of the pioneering systems that initiated the use of robotics for pedicle screw placement in spine surgery. As time progressed, these older generation of robots were replaced by updated systems that possessed an optical camera and multijointed arm. This second generation of robots includes Mazor X, Excel-siusGPS, TINAVI, and ROSA Spine.

From our statistical analyses, the use of the second-generation robots appeared to significantly improve pedicle screw accuracy. This is consistent with the current literature. For example, Du et al compared the accuracy of pedicle screw placement between TINAVI and Renaissance. The main stated differences between the two robot models are the presence of an optical camera and multijointed arm in TINAVI and a lack of this enhancement in Renaissance. Overall, TINAVI was shown to perform significantly better relative to the Renaissance robot (94.9–98.7 vs. 91.2–94.5%, \(p < 0.05\)), showing optical tracking in robotic system could potentially increase accuracy. Additionally, patients operated on with the TINAVI system were noted to have less pedicle screw surgical revisions as compared with patients operated with Renaissance (\(p < 0.05\)).\(^{31}\) From our meta-regression, our results similarly suggest a benefit of accuracy from the addition of an optical lens and multijointed robotic arm.
Within the old generation, Ringel et al appeared as an outlier as this study with reported skidding due to the use of only one K-wire. Statistical analyses were rerun without this data to examine whether the overall average would change greatly. Forest plot analyses showed a weighted pedicle screw accuracy of 98%. Meta-regression analyses showed still showed significant study heterogeneity ($Q(29) = 77.8, p < 0.0001$) and usage of new generation robot was significant for improved pedicle screw placement. Overall, results both with and without the relatively lower
accuracy rate of 85% within Ringel 2013 did not impact the significance of our findings.

Additionally, three articles presented pedicle screw accuracy rates from combined pools of patients who either underwent open or percutaneous surgeries. Although these values could have potentially inflated factors such as EBL and intraoperative time, the pedicle screw accuracy rates remained at 0.97 and 0.99 for the older and newer generation of spine robots, respectively. New generation robot use remained as a significant predictor for pedicle screw accuracy \( (QM[df = 1] = 4.11, p = 0.04) \). The only different finding was significant publication bias for the newer generation group upon removal of Devito et al\(^1\) \( (p = 0.02) \).

Meta-analysis revealed high levels of cross-study heterogeneity among the reviewed studies. This could have resulted from any number of differences across reviewed studies, including heterogeneous patient populations across studies, including varying indications for surgery, differences in baseline patient risk factors, surgeon experience, differing spine levels, or differing extents of pedicle screw placement. The presence of heterogeneity adds value to this study and reinforces the need for robust statistical methods such as meta-analysis for synthesizing literature outcomes.

In terms of complications, many studies did not comment on their cohort’s intraoperative and postoperative issues,
with complication rates seldom reported in the older generation until 2017.\textsuperscript{19,21,25} Additionally, the overall LOS for patients treated with the older generation of robots was significantly higher than that of patients treated with the newer generation of robots (7 vs. 5 days, \(t(6)=2.6, p=0.02\)). This difference could potentially be explained by unreported postoperative issues. This lack of reported complications within the literature limits the potential for a true comparison between complication rate between the old and new generation robots. Although revision surgeries were more documented than general complications, general intraoperative and postoperative complications, or the lack thereof, should be explicitly stated as to further the public knowledge of the effectiveness of these robotic systems.

Limitations

Since most papers were single-institution, retrospective studies, it is not surprising that high heterogeneity was present among the pooled studies. For example, three articles combined patient data from those who received either open or minimally invasive surgery, therefore potentially increasing average EBL, operative time, among other outcome measures.\textsuperscript{1,34,44} Further analysis, however, showed no changes with pedicle screw placement accuracy rates. Additionally, most studies varied in their reporting of average operative times, each possessing different definitions of which portions of the surgery were included. In terms of extracting average operative time, studies include total operative time rather than focusing on the average time using the robot systems. Also, there were different numbers of papers for each robot model. For example, only one paper described ROSA Spine, while eight studies described TINAVI. Additionally, TINAVI has not received FDA-approval and may therefore have different interfaces compared with the other newer generation robotic spine systems. Additionally, we only provided a comparison between robotic accuracy and different generations of robots, and we did not include a comparison to freehand technique.

Finally, complications were largely not mentioned in the literature until around 2017. This lack of transparency limits the potential for a credible comparison between complication rate between the old and new generation robots.

Conclusion

The new generation of robotic spine surgical systems have been updated with real-time optical cameras and multifunctional arms. While pedicle screw accuracy is high across generations of robotic systems discussed, this study demonstrates a significant improvement in the state of the art, further pushing the envelope in accuracy and precision of pedicle screw placement with robotic spine surgery.

Conflict of Interest

None declared.

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