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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.^{1,2} 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' spinous 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 skiving being the most significant problem reported.²

To improve limitations such as skiving 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 multijointed 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 "renaissance") 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 S2-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, spondylosis, spondylolisthesis, disc herniation, 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 , τ^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

screenings, 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 SpineAssist^{1,19–26} 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 Three papers pooled patients treated either with open surgery or minimally invasive surgery as one cohort.^{1,34,44}

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.^{7,12,25,27,29,34,43} 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

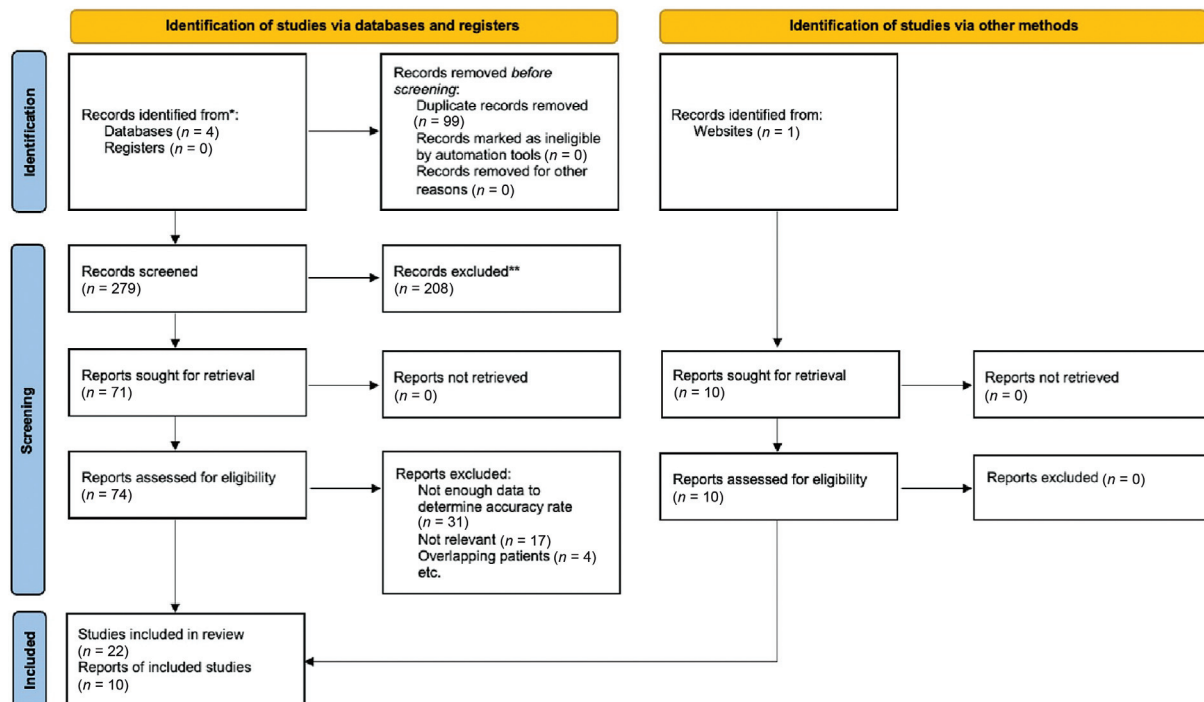


Fig. 1 Literature screen and review from five online databases: PubMed, Medline, Scopus, Embase, and Google Scholar. Upon completion, 32 relevant articles were included.

Table 1 Patient demographics for older generation robotic systems

Author and year	Type of study	LoE	Robot model	No. of patients	No. of females	Mean age (years)	Operative time (min)	EBL (mL)	LOS
Pechlivanis et al, 2009 ¹⁹	Prospective	2	SpineAssist	31	20	52.8	NA	NA	NA
Devito et al, 2010 ¹	Retrospective	4	SpineAssist	635	369	52	NA	NA	NA
Ringel et al, 2012 ²⁰	Randomized control	2	SpineAssist	30	16	68 ^a	151	NA	7
Roser et al, 2013 ²¹	Randomized control	2	SpineAssist	18	NA	NA	NA	NA	NA
Onen et al, 2014 ²²	Retrospective	3	SpineAssist	27	23	55	NA	NA	9.8
Schatlo et al, 2014 ²³	Retrospective	3	SpineAssist	55	29	52 ^a	205	375	NA
Kim et al, 2015 ²⁷	Randomized control	2	Renaissance	20	9	64.4	217.75	NA	NA
van Dijk et al, 2015 ²⁴	Retrospective	4	SpineAssist	112	45	56.8	154	216	4.9
Tsai et al, 2016 ²⁸	Retrospective	4	Renaissance	35	27	67.8	NA	NA	NA
Fan et al, 2017 ²⁵	Retrospective	2	SpineAssist	39	20	60.6	201	362	6.3
Hyun et al, 2017 ²⁹	Randomized control	2	Renaissance	30	21	66.5	208.5	NA	6.8
Molliqaj et al, 2017 ²⁶	Retrospective	3	SpineAssist	98	48	58.3	NA	NA	NA
Fan et al, 2018 ¹²	Retrospective	3	Renaissance	83	48	61.6	239	681	9.3
Kam et al, 2019 ³⁰	Retrospective	4	Renaissance	73	46	66.6	NA	NA	NA
Du et al, 2021 ³¹	Retrospective	3	Renaissance	175	85	63.7	181.5	NA	4.1
Zhang et al, 2021 ³²	Retrospective	3	Renaissance	39	18	65.95	189.23	397	NA
Average values	-	-	-	-	-	61 ± 5	194 ± 28	406 ± 169	7 ± 2

Abbreviations: EBL, estimated blood loss; LoE, level of evidence, LOS, length of stay; NA, not available.

^aMedian value extracted instead of mean.

Table 2 Patient demographics for newer generation robotic systems

Author and year	Type of study	LoE	Robot model	No. of patients	No. of females	Mean age (years)	Operative time (min)	EBL (mL)	LOS (days)
Lonjon et al, 2016 ³	Prospective	3	ROSA Spine	10	6	63.4	336	NA	6.67
Tian , 2017 ⁴⁰	Randomized control	2	TINAVI	23	NA	NA	138.9	NA	NA
Le et al, 2018 ⁴¹	Retrospective	3	TINAVI	20	14	65.2	199.1	372	5.6
Feng et al, 2019 ⁴²	Randomized control	2	TINAVI	40	55	67.71	196.25	255	5.7
Han et al, 2019 ⁴	Randomized control	2	TINAVI	115	60	55.6	149.5	186	4.8
Jain et al, 2019 ³⁵	Prospective	4	ExcelsiusGPS	13	NA	NA	NA	NA	NA
Khan et al, 2019 ³³	Retrospective	4	Mazor X	20	13	60.3	NA	104	1.5
Wallace et al, 2020 ³⁶	Retrospective	4	ExcelsiusGPS	101	56	64.8	142.3	165	4.6
Wu et al, 2019 ⁴³	Prospective	3	TINAVI	10	7	60.2	198	90	NA
Benech et al, 2020 ³⁷	Retrospective	4	ExcelsiusGPS	52	15	49.8	103.3	10	NA
Fan et al, 2020 ⁴⁴	Randomized control	2	TINAVI	61	18	49	220	200	5
Fayed et al, 2020 ³⁸	Retrospective	2	ExcelsiusGPS	20	13	62.8	NA	NA	NA
Jiang et al, 2020 ³⁹	Retrospective	3	ExcelsiusGPS	28	14	61.9	229	266	3.5
Mao et al, 2020 ³⁴	Retrospective	3	Mazor X	39	25	59.5	377	1098	NA
Du et al, 2020 ⁵	Retrospective	3	TINAVI	136	62	58.6	150	184	4.3
Chen et al, 2021 ⁷	Retrospective	3	TINAVI	52	20	57.98	169.67	92	6.9
Average values	-	-	-	-	-	60 ± 5	200 ± 70	252 ± 283	5 ± 2

Abbreviations: EBL, estimated blood loss; LoE, level of evidence, LOS, length of stay; NA, not available.

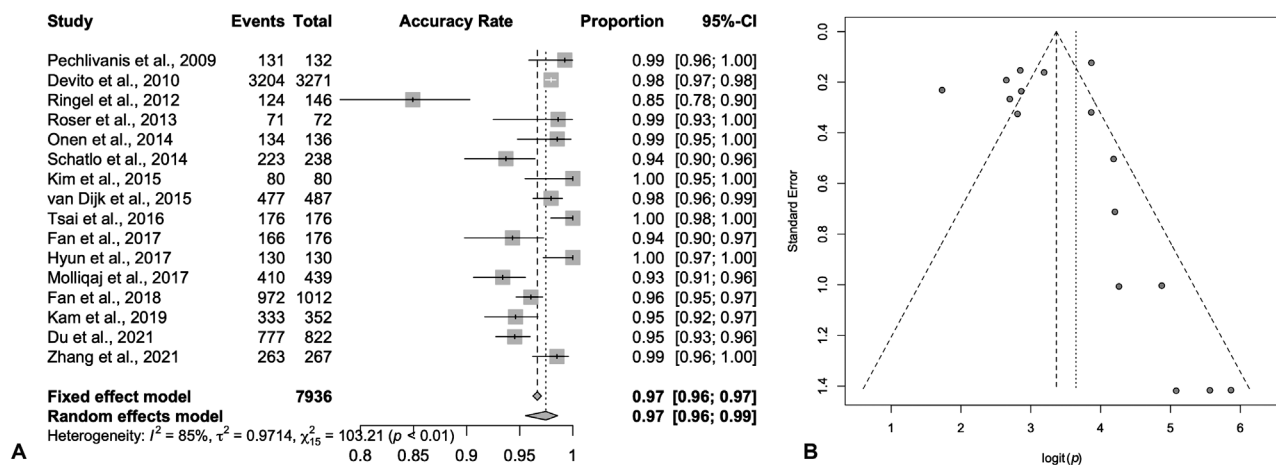


Fig. 2 (A) Forest plot analysis of pedicle screw placement accuracy within the older generation of robotic systems. (B) Funnel plot analysis of pedicle screw placement accuracy within the older generation of robotic systems ($t(14) = 0.77$, $p = 0.46$). CI, confidence interval.

have an accuracy rate of 99% (98–99%). Funnel plot analysis and Egger's tests showed no significant publication bias in either older or newer generations (► **Figs. 2B** and **3B**). Meta-regression revealed that use of newer generation surgical robots was significantly associated with accurate pedicle screw placement ($QM(df = 1) = 4.6743$, $p = 0.03$). When comparing between the old and new generations of robots, significant heterogeneity remained between studies ($Q[30] = 118$, $p < 0.0001$).

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,^{3,5,7,33,35,37,39,41,43–45} 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}

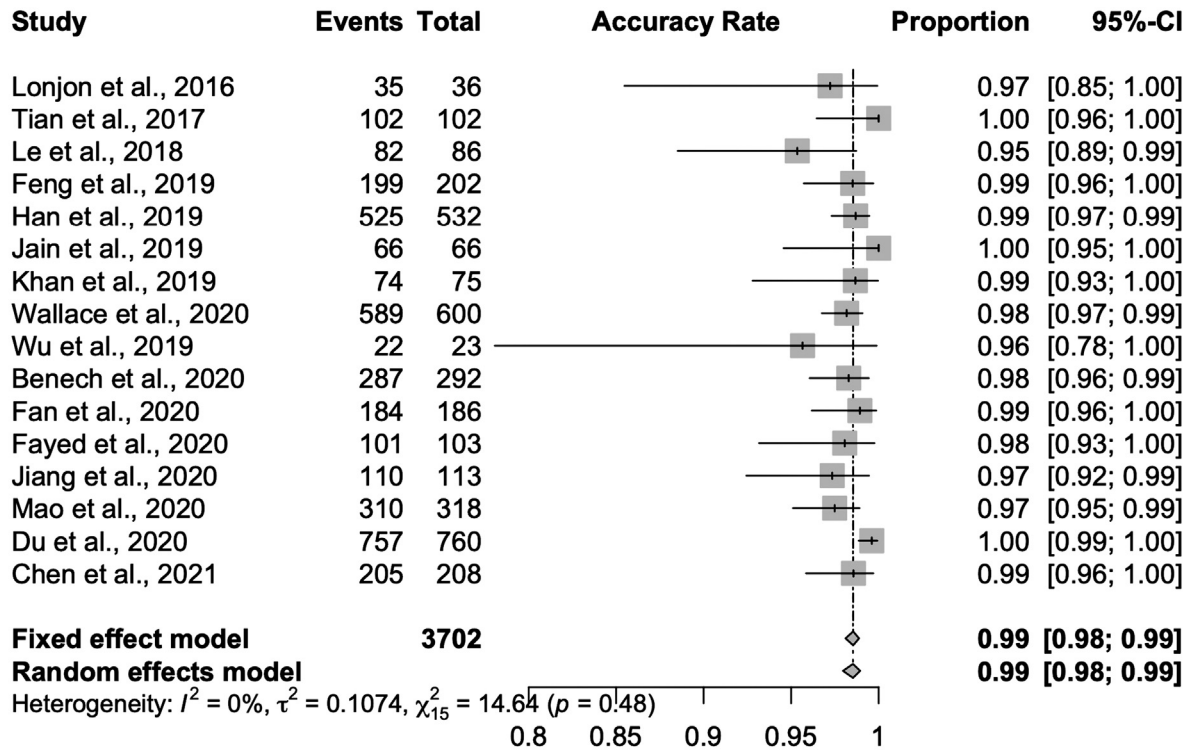
More studies reported surgical revision rates of patients as compared with general complications.^{3–5,7,12,19,20,22,24,29,30,34,35,39–42} Seven of 16 older generation robot studies reported the numbers of patients requiring surgical revisions,^{12,19,20,22,24,29,30} with 3 studies reporting zero need 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 malposi-

tion.^{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}

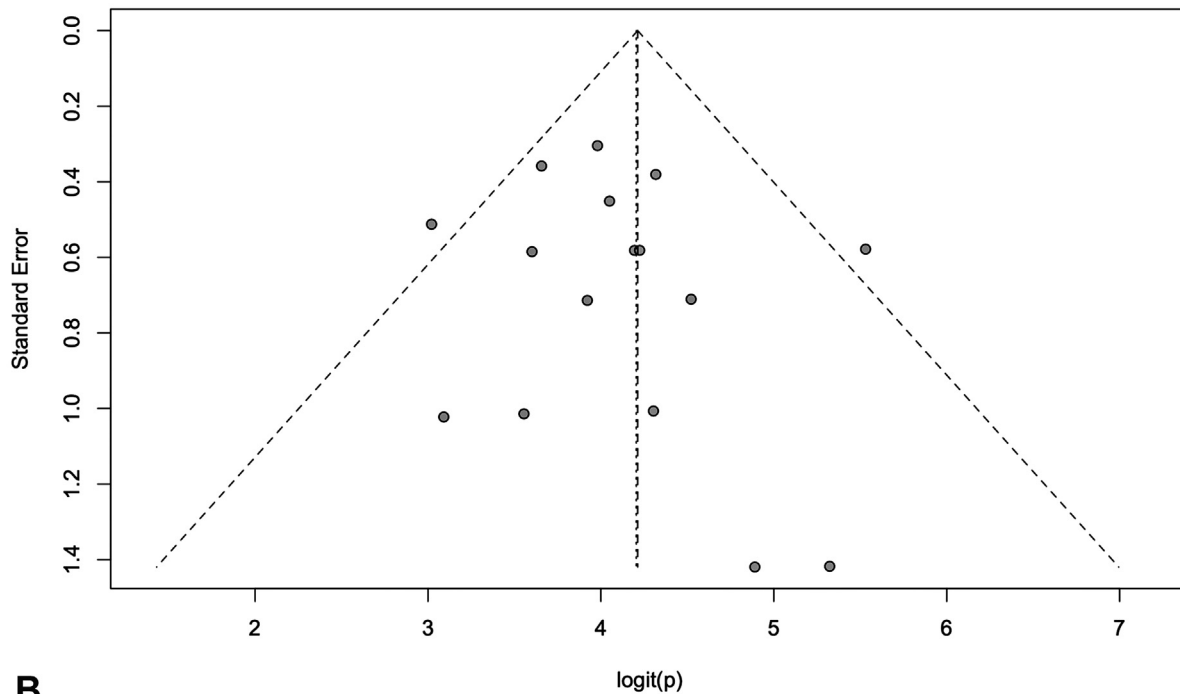
Discussion

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, ExcelsiusGPS, 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 multi-jointed robotic arm.



A



B

Fig. 3 (A) Forest plot analysis of pedicle screw placement accuracy within the newer generation of robotic systems. (B) Funnel plot analysis of pedicle screw placement accuracy within the older generation of robotic systems ($t(14) = 0.68$, $p = 0.51$). CI, confidence interval.

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.²⁰ 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 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

Table 3 Pedicle screw accuracy rates and complications

Author and year	Robot model	No. of screws	Accurately placed screws	Accuracy rate
Pechlivanis et al, 2009 ¹⁹	SpineAssist	132	131	0.99
Devito et al, 2010 ¹	SpineAssist	3,271	3,204	0.98
Ringel et al, 2012 ²⁰	SpineAssist	146	124	0.85
Roser et al, 2013 ²¹	SpineAssist	72	71	0.99
Onen et al, 2014 ²²	SpineAssist	136	134	0.99
Schatlo et al, 2014 ²³	SpineAssist	238	223	0.94
Kim et al, 2015 ²⁷	Renaissance	80	80	1.00
van Dijk et al, 2015 ²⁴	SpineAssist	487	477	0.98
Tsai et al, 2016 ²⁸	Renaissance	176	176	1.00
Fan et al, 2017 ²⁵	SpineAssist	176	166	0.94
Hyun et al, 2017 ²⁹	Renaissance	130	130	1.00
Molliqaj et al, 2017 ²⁶	SpineAssist	439	410	0.93
Fan et al, 2018 ¹²	Renaissance	1,012	972	0.96
Kam et al, 2019 ³⁰	Renaissance	352	333	0.95
Du et al, 2021 ³¹	Renaissance	822	777	0.95
Zhang et al, 2021 ³²	Renaissance	267	263	0.99
Lonjon et al, 2016 ³	ROSA Spine	36	35	0.97
Tian, 2017 ⁴⁰	TINAVI	102	102	1.00
Le et al, 2018 ⁴¹	TINAVI	86	82	0.95
Feng et al, 2019 ⁴²	TINAVI	202	199	0.99
Han et al, 2019 ⁴	TINAVI	532	525	0.99
Jain et al, 2019 ³⁵	ExcelsiusGPS	66	66	1.00
Khan et al, 2019 ³³	Mazor X	75	74	0.99
Wallace et al, 2020 ³⁶	ExcelsiusGPS	600	589	0.98
Wu et al, 2019 ⁴³	TINAVI	23	22	0.96
Benech et al, 2020 ³⁷	ExcelsiusGPS	292	287	0.98
Fan et al, 2020 ⁴⁴	TINAVI	186	184	0.99
Fayed et al, 2020 ³⁸	ExcelsiusGPS	103	101	0.98
Jiang et al, 2020 ³⁹	ExcelsiusGPS	113	110	0.97
Mao et al, 2020 ³⁴	Mazor X	318	310	0.97
Du et al, 2020 ⁵	TINAVI	760	757	1.00
Chen et al, 2021 ⁷	TINAVI	208	205	0.99

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 al¹ ($p = 0.02$).

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.^{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.^{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 are 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 multijointed 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.

Funding

None.

Conflict of Interest

None declared.

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