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Systematic Review / Meta-Analysis

Robotic and navigated pedicle screws are safer and more accurate than fluoroscopic freehand screws: a systematic review and meta-analysis

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Abstract

BACKGROUND CONTEXT: Navigated and robotic pedicle screw placement systems have been developed to improve the accuracy of screw placement. However, the literature comparing the safety and accuracy of robotic and navigated screw placement with fluoroscopic freehand screw placement in thoracolumbar spine surgery has been limited.

PURPOSE: To perform a systematic review and meta-analysis of randomized control trials that compared the accuracy and safety profiles of robotic and navigated pedicle screws with fluoroscopic freehand pedicle screws.

STUDY DESIGN/SETTING: Systematic review and meta-analysis

PATIENT SAMPLE: Only randomized controlled trials comparing robotic-assisted or navigated pedicle screws placement with freehand pedicle screw placement in the thoracolumbar spine were included.

OUTCOME MEASURES: Odds ratio (OR) estimates for screw accuracy according to the Gertzbein-Robbins scale and relative risk (RR) for various surgical complications.

METHODS: We systematically searched PubMed and EMBASE for English-language studies from inception through April 7, 2022, including references of eligible articles. The search was conducted according to PRISMA guidelines. Two reviewers conducted a full abstraction of all data, and one reviewer verified accuracy. Information was extracted on study design, quality, bias, participants, and risk estimates. Data and estimates were pooled using the Mantel-Haenszel method for random-effects meta-analysis.

RESULTS: A total of 14 papers encompassing 12 randomized controlled trials were identified (n=892 patients, 4,046 screws). The pooled analysis demonstrated that robotic and navigated pedicle screw placement techniques were associated with higher odds of screw accuracy (OR 2.66, 95% CI 1.24−5.72, p=.01). Robotic and navigated screw placement was associated with a lower risk of facet joint violations (RR 0.09, 95% CI 0.02−0.38, p<.01) and major complications (RR 0.31, 95% CI 0.11−0.84, p=.02). There were no observed differences between groups in nerve root injury (RR 0.50, 95% CI 0.11−2.30, p=.37), or return to operating room for screw revision (RR 0.28, 95% CI 0.07−1.13, p=.07).

CONCLUSIONS: These estimates suggest that robotic and navigated screw placement techniques are associated with higher odds of screw accuracy and superior safety profile compared with fluoroscopic freehand techniques. Additional randomized controlled trials will be needed to further validate these findings.

Keywords: Complications; Fluoroscopy-assisted; Pedicle screw; Robotics; Screw accuracy; Spine fixation

FDA device/drug status: Not applicable.

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Introduction

Pedicle screw placement is one of the most common interventions in spine surgery, providing firm 3-column control and high reconstruction stability in the management of several degenerative, traumatic, and oncologic spinal conditions [1,2]. Originally performed with a freehand approach using anatomical and radiographic landmarks, the current freehand technique for screw placement consists of a combination of anatomic and fluoroscopy guidance, showing superior accuracy outcomes [3]. However, rates of screw misplacement range from 8.3% to 50.6% across published series, often resulting in major neurological, vascular, and visceral complications [4,5].

Advances in medical imaging, navigated techniques, and robotic systems are seeing increased utilization within the field of spine surgery, with the primary purpose of providing more precise anatomical guidance for augmenting surgeons' performance and reducing the risks of perioperative complications [6]. Since the introduction of these systems the literature discussing robotic and navigated screw fixation has been controversial. Whereas some systematic reviews and trials found less favorable outcomes after robotic-assisted techniques compared with freehand techniques [7−9], more recent trials and meta-analyses demonstrated higher accuracy rates and fewer complication rates with robotic-assisted screw placement [10,11]

In this study, we performed an updated systematic review and meta-analysis to compare accuracy and safety profiles of robotic and navigated pedicle screw placement with freehand fluoroscopy-assisted pedicle screw placement. Given the recent advances in technology, we hypothesize increased accuracy of screw placement and an improved safety profile

Methods

Literature search

A systematic review was conducted using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [12]. PubMed and EMBASE were searched for English-language studies from database inception through April 7, 2022, according to the following search terms for any field of the text: ([{Safety OR accuracy OR complication OR outcomes} AND {conventional OR freehand}] AND [robotic OR navigated]) AND (pedicle screw placement). PubMed and Embase citations were imported into Rayyan.ai to remove duplicates and facilitate study selection.

Study selection

A priori inclusion and exclusion criteria were set. Included studies were RCTs assessing the safety and accuracy of robotic or navigated screw placement with traditional "freehand" fluoroscopy-guided techniques. Navigated and robotically placed pedicle screws were grouped together as both rely on three-dimensional visualization and have similar drawbacks related to registration. Unlike two-dimensional fluoroscopic guided screw placement, navigation and robotic screw placement require surgeons to visualize anatomy in 3D and thus require a similar understanding of the visualized anatomy. Only RCTs of patients undergoing thoracolumbar surgery were included. Two investigators (A.V.M. and H.O.D) independently screened each abstract for inclusion in full-text-review. Discrepancies between reviewers were resolved by consensus, then by a senior investigator (P.P.) if consensus could not be reached. Reference lists of all included articles and recent reviews were searched to identify any additional relevant studies.

Data extraction

One reviewer (A.V.M.) extracted data from each article, then confirmed independently by one additional reviewer (H.O.D.). Missing data were not reported by the authors. Data included: author, study design, sample size, country, journal, patients' age and gender, number of placed screws, number of screws placed with the freehand fluoroscopy-guided technique, number of screws placed with the robotic or navigated technique, screw accuracy, complications, estimated blood loss (EBL), and procedure time. Screw accuracy was appraised according to the Gertzbein-Robbins scale [13], which defines the transpedicular screw position into grades: A, fully intrapedicular position without breach of the pedicle cortex; B, exceeding the pedicle cortex <2 mm; C, exceeding the pedicle cortex 2−4 mm; D, exceeding the pedicle cortex 4−6 mm; E, exceeding the pedicle cortex >6 mm or is outside of the pedicle. Grades A-B were evaluated as accurate, whereas grades C-D-E are evaluated as inaccurate.

Data synthesis and quality assessment

The primary outcomes of interest were screw accuracy, complications, EBL, and procedure time based on each screw placement technique. For each article, two independent authors (A.V.M. and H.O.D.) appraised level of evidence using the 2011 Oxford Centre For Evidence-Based Medicine guidelines, and risk of bias applying the Joanna Briggs Institute checklists [14,15]. Publication bias was assessed using funnel plots with the Egger test for symmetry.

Statistical analysis

Meta-analysis was performed using R version 4.1.0 (The R Foundation for Statistical Computing). A two-tailed p-value <.05 was used to determine significance. When comparing fusion rates between studies, rates of successful radiographic fusion as determined by each study were used for comparison. Dichotomous outcomes of accurate screw placement and procedural complications were pooled via the Mantel-Haenszel method, and the Paule-Mandel estimator was used for τ^2. A random-effects meta-analysis model was then used to give a pooled estimate of the outcomes either as an odds ratio (OR) for screw accuracy or relative risk (RR) for complications. For continuous variables the inverse variance method was used to pool data and the DerSimonian-Laird estimator was used for τ^2. Outcomes were assessed as mean difference (MD) for continuous variables. The random-effects model was chosen over a fixed-effects model for all study variables due to differences in study design, patient selection, and measurement of outcomes, which may result in significant variation between studies not due to chance.

Results

A flow diagram outlining the systematic review process is provided (Fig. 1). The initial literature review identified 369 citations for screening. Of these 173 were duplicates and rejected. Of the remaining 184 articles, 170 did not meet the inclusion criteria. Therefore, 14 fully extracted primary studies, all categorized as level IIB of evidence were available for meta-analysis (Table 1) [8−10,16−26].

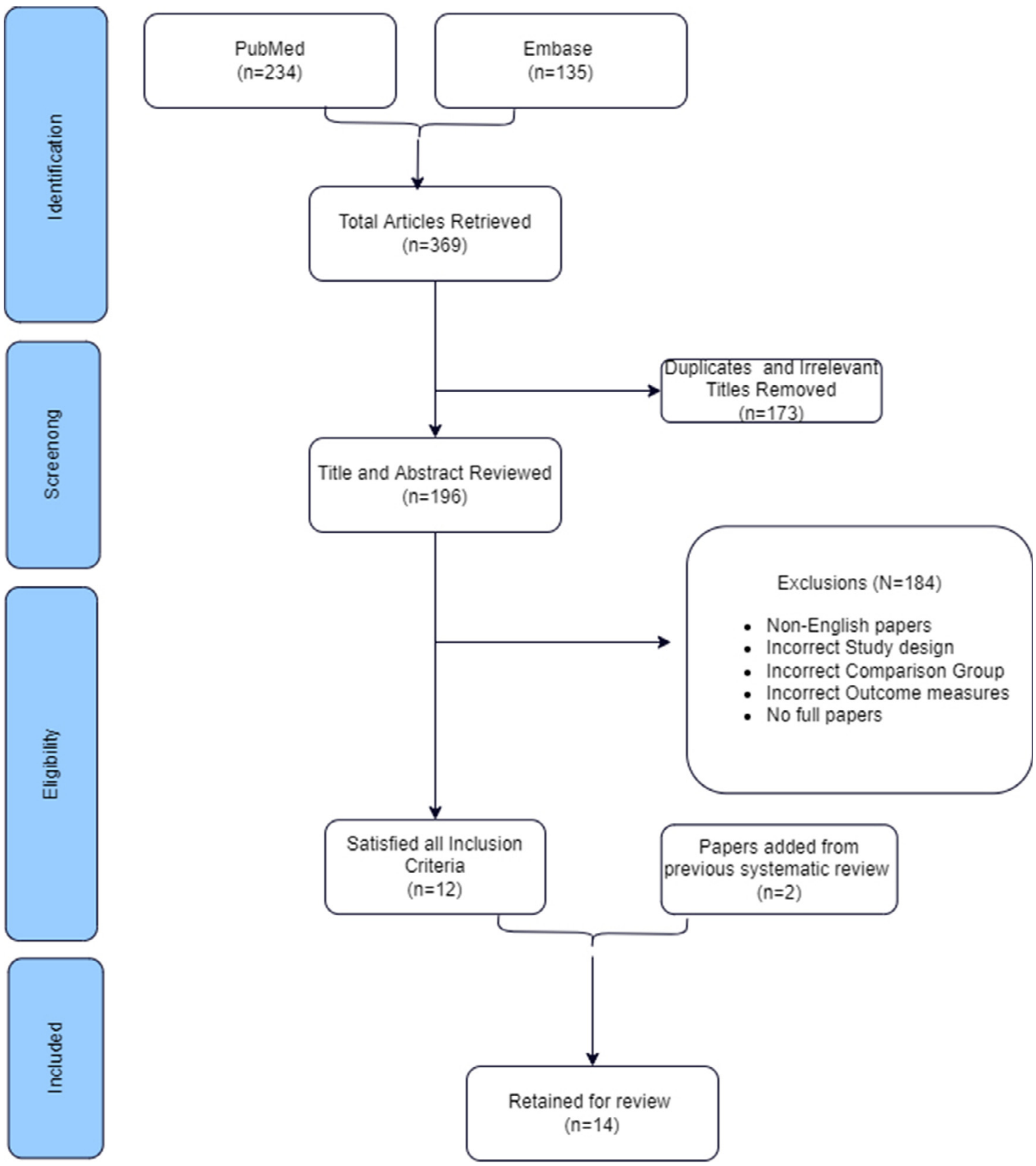

Fig. 1. PRISMA 2020 flow diagram.

Table 1
Overview of all included studies

Author	Year	Journal	Country of study population	Guidance	Robotic/navigation system	Region & indications	Average age Robot/ Nav	Average Age Freehand	Total patients	Total Robotic/ Navigated patients	Total Freehand patients	Sex (F/M)	Total Robotic/ Nav screws	Total freehand screws
Laine	2000	Eur Spine J	Finland	Navigation	optoelectronic navigation system	Thoracolumbosacral (fusions)	54	53	91	41	50	60/40	219	277
Rajasekaran	2007	Spine	India	Navigation	Iso-C based navigation	Thoracic (deformity)	N/A	N/A	33	17	16	23/10	242	236
Feng	2020	Orthop Surg	China	Robot	TiRobot	Lumbar (OLIF)	63.45	64.22	80	40	40	49/31	170	174
Li Z.	2020	J Orthop Trans	China	Robot	Orthbot	Lumbar (posterior fusion for degenerative disc disease or stenosis)	47.4	49.9	17	7	10	44841	32	50
Kim*	2017	Int J Med Robotics Comput Assist Surg	South Korea	Robot	Renaissance (Mazor)	Lumbar (stenosis and spondylolisthesis)	65.4	66	78	37	41	37/41	158	172
Ringel	2012	Spine	Germany	Robot	SpineAssist robot	Lumbosacral surgery (1-2 level lumbosacral fusions)	68 (median)	67 (median)	60	30	30	34/26	146	152
Li J.	2020	Int J Med Robotics Comput Assist Surg	China	Robot	Orthbot	Lumbar (stenosis)	48.89	50.76	56	27	29	27/29	128	136
Roser	2013	Neurosurgery	Germany	Both	SpineAssist robot, Brainlab navigation	Lumbar surgery (degenerative instability)	N/A	N/A	37	18 Robotic 9 Navigated	10	N/A	108	40
Hyun	2017	Spine	South Korea	Robot	Renaissance (Mazor)	Lumbar (1-2 level interbody fusion)	66.5	66.8	50	30	30	37/41	130	140
Wu	2010	Chin J Traumatol	China	Navigation	spiral-mode 3D CT scans	Thoracic (degenerative, tumors, trauma)	NA	NA	42	22	20	NA	92	84
Han	2019	J Neurosurg Spine	China	Robot	TiRobot system	Thoracolumbar (posterior fusion for degeneration or trauma)	54.6	56.1	234	115	119	121/113	532	584
Kim*	2018	Int J Med Robotics Comput Assist Surg	South Korea	Robot	Renaissance (Mazor)	Lumbar (stenosis and spondylolisthesis)	65.4	66	78	37	41	37/41	158	172
Noriega	2017	Spine J	Spain	Navigation	(CT) scan assisted-navigation	Thoracolumbosacral (Degenerative)	60.31	62.05	114	58	56	40/74	11	33
Park*	2018	Yonsei Med J	South Korea	Robot	Renaissance (Mazor)	Lumbar (stenosis and spondylolisthesis)	65.4	66	78	37	41	37/41	158	172

* Denotes the same study with published data representing different time points of follow up.

Table 2
Quality appraisal according to the Joanna Briggs Institute appraisal tool for RCTs. Most studies achieved at least a fair rating

Study	1	2	3	4	5	6	7	8	9	10	11	12	13	Appraisal
Laine et al. 2000	Unclear	Yes	Yes	Unclear	No	Yes	Yes	yes	No	Yes	Yes	Yes	Yes	7
Rajasekaran et al. 2007	Yes	Unclear	Yes	Unclear	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	8
Feng 2020	Unclear	Unclear	Yes	Unclear	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	7
Li Z 2020	No	Unclear	Yes	Unclear	No	Yes	Yes	Unclear	No	Yes	Yes	Yes	Yes	6
Kim* 2017	Yes	Yes	Yes	Unclear	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	10
Ringel 2012	Unclear	Unclear	Yes	Unclear	No	Yes	Yes	No	No	Yes	Yes	Yes	No	6
Li J. 2020	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	11
Roser 2013	No	Unclear	Unclear	Unclear	No	Unclear	Yes	Yes	No	Yes	Yes	No	No	4
Hyun 2017	Yes	Yes	Yes	Unclear	No	Unclear	Yes	Yes	No	Yes	Yes	Yes	Yes	9
Wu 2010	No	Unclear	Unclear	Unclear	No	Unclear	Yes	No	No	Yes	Yes	Yes	No	4
Han 2019	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	11
Kim* 2018	Yes	Yes	Yes	Unclear	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11
Noriega 2017	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Unclear	No	Yes	Yes	Yes	No	7
Park* 2018	Yes	Yes	yes	Unclear	No	Unclear	yes	Yes	Yes	Yes	Yes	Yes	Yes	10

Quality Rating: Poor 0 − 4; Fair 5 − 9; Good 10 − 13.

In total, 892 patients with 4,046 screws placed were analyzed. The quality appraisal returned five studies achieved good rating, seven fair rating, and two poor rating (Table 2), predisposing this meta-analysis to an overall low risk of bias. To assess publication bias, a contoured funnel plot for screw accuracy outcomes was constructed (Fig. 2). The Egger's test (p=.7793) did not suggest asymmetry of the funnel plot, which indicates a low risk of publication bias. Publication bias assessment was only conducted for screw accuracy as this was the only category used for meta-analysis with greater than 10 studies.

Screw accuracy

Data with regards to screw were dichotomized during extraction such that a Gertzbein-Robbins grades A-B were assessed as accurate whereas Gertzbein-Robbins grades C-D-E were assessed as inaccurate. The meta-analysis of pooled ORs for accurate screw placement is summarized in the forest plot in Fig. 3 and Table 3. There was a statistically significant association between robotic or navigated screw placement and accurate screw placement when compared with freehand fluoroscopy-assisted screws (OR: 2.66; 95% CI: 1.24−5.72; p=.01).

Complications

Data on total reported complications and pedicle screw specific complications were collected and compared between robotic and navigated screw placement with freehand fluoroscopy-assisted screw placement. These complications included surgical complications such as nerve injury and dural injury as well as periprocedural complications such as DVT and PE. The total reported complication

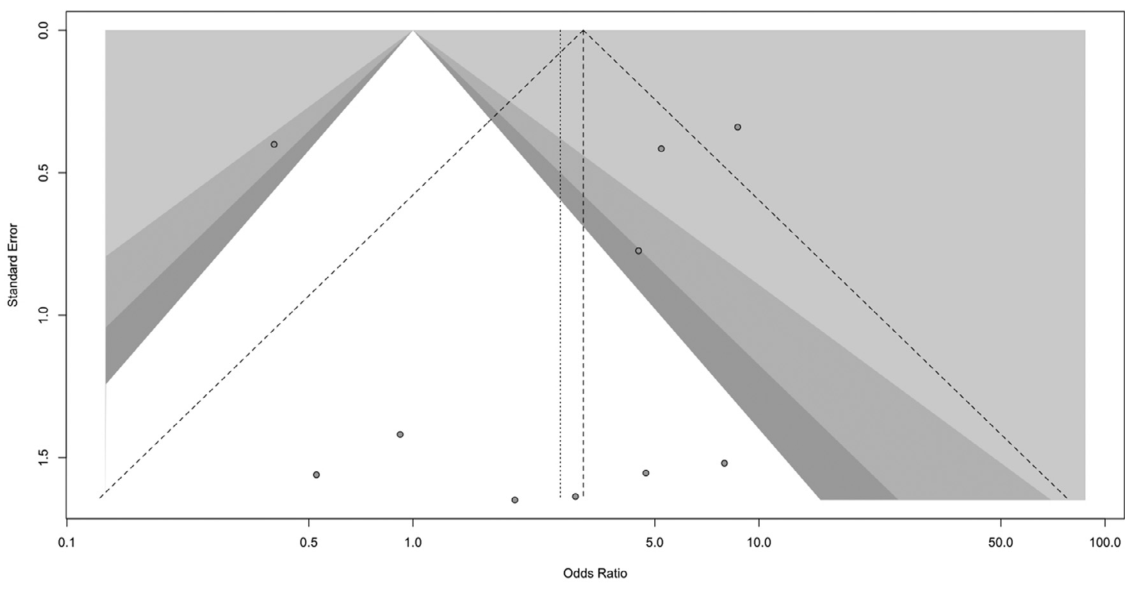

Fig. 2. Funnel plot of publication outcomes for screw accuracy. The relative symmetry of the plot indicates a low risk of publication bias. This is supported by Egger's test (p=.7793).

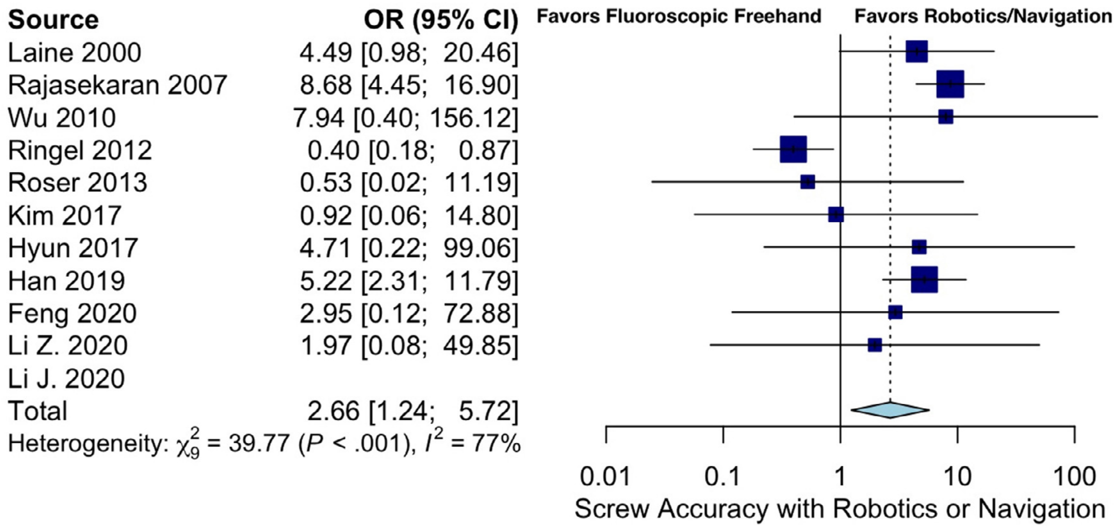

Fig. 3. Forest plot representing the odds of achieving Gertzbein-Robbins A or B screw accuracy with robotic or navigated screws versus fluoroscopic freehand screws.

rate was 2.7% of aggregate patients from studies which reported complications. There were significantly fewer major complications associated with robotic and navigated screws compared with freehand screws (RR: 0.31; 95% CI: 0.11−0.84; p=.02) (Fig. 4A). Robotic and navigated screw placement was also associated with a lower risk of facet joint violations (RR: 0.09; 95% CI: 0.02−0.38; p<.01; Fig. 4B). No differences were found in nerve root injury (RR: 0.50; 95% CI: 0.11−2.30; p=.37) (Fig. 4C) or return to operating room for pedicle screw revision (RR: 0.28; 95% CI: 0.07−1.13; p=.07; Fig. 4D). These results are summarized in Table 3.

Procedural time and estimated blood loss

There were no observed differences between groups in procedure time (MD: 7.73 minutes; 95% CI: −15.24 to 30.70; p=.51; Fig. 5A). For the two studies of navigation with mean screw insertion time and standard deviation available the use of navigation was associated with shorter screw insertion time (MD: −2.13 minutes; 95% CI: −2.73 to −1.53; p<.01; Fig. 5B). There was insufficient data to assess mean robotic screw insertion time. EBL was also significantly lower for robotic and navigated screws compared with traditional freehand technique (MD: −47.18 mL; 95% CI: −86.97 to −7.40; p=.02; Fig. 5C). However, this is of minor clinical significance. The results of continuous variable meta-analysis are summarized in Table 4.

Discussion

The recent technological advances and introduction of new robotic systems for screw placement, coupled with the routine use of instrumented spine fixation surgery, require a detailed evaluation of all available techniques to define which offers the best outcomes, with the goal to optimize treatment plans. For the same reason, an analysis of the most recent literature on the topic, which is in some cases controversial, may guide the standardization of a training curriculum for all residents and fellows interested in pursuing a career in spine surgery [27]. In this updated meta-analysis of RCTs, we found that robotic and navigated techniques showed significantly higher rates of accuracy in screw placement and significantly lower rates of major complications. Robotic and navigated techniques were also associated with a small reduction in EBL. Although there was no difference in procedure time between the two groups, there was a 2-minute reduction in average screw insertion time for navigated screws only. This suggests that the time needed for CT scan could be offset by reduced time needed for screw placement, especially in larger cases.

Accurate placement of pedicle screws is of primary importance in spine fixation and is necessary to provide 3-column stability in the management of a wide range of spinal disorders. Freehand fluoroscopy-assisted techniques are currently accepted as the gold-standard, however, the variable rates in screw misplacement and consequent debilitating complications have stimulated the development of newer technology for improving surgeon performance and patient outcomes [28]. Over the last decades, several spine robotic systems have been developed and introduced in surgical practice, comprising SpineAssist®[9,25] and Reinassance [8,19,21,23] from Mazor Robotics (Mazor Robotics Ltd., Caesarea, Israel), Orthbot [22,24] (Xin Junte Surgical Technologies, Beijing, China), and TiRobot [10,18] (TINAVI Medical Technologies Co. Ltd., Beijing, China) [29]. Similarly, multiple navigation-assistance protocols are now available to improve the intraoperative identification of anatomical landmarks and the real-time evaluation of the correct trajectory of the placed screws, including optoelectronic navigation [16], CT-based navigation [17,20,26], and BrainLab navigation [25] Indications for using robotic and navigated techniques mostly comprised degenerative and

Table 3
Summary of binary variable meta-analysis of screw accuracy and complications

	Study	Robotic or Navigated	Fluoroscopic Freehand	Odds ratio (95% CI)	p-value	I^2
Gertzbein-Robbins Grade A or B screws	Laine 2000	217/219	266/277	2.66 (1.24−5.72)	**.01**	77%
	Rajasekaran 2007	231/242	167/236			
	Wu 2010	92/92	81/84			
	Ringel 2012	124/146	142/154			
	Roser 2013	106/108	40/40			
	Kim 2017	157/158	171/172			
	Hyun 2017	130/130	138/140			
	Han 2019	525/532	546/584			
	Feng 2020	170/170	173/174			
	Li Z. 2020	32/32	49/50			
	Li J. 2020	128/128	136/136			
	Total	1912/1957	1909/2045			
Overall complications	Study	Robotic or Navigated	Fluoroscopic Freehand	Relative risk (95% CI)	p-value	I^2
	Laine 2000	1/41	5/50	0.31 (0.11−0.84)	**.02**	0%
	Wu 2010	0/22	3/20			
	Kim 2017	0/37	1/41			
	Hyun 2017	1/30	1/30			
	Noriega 2017	0/58	1/56			
	Han 2019	0/115	2/119			
	Feng 2020	1/40	3/40			
	Total	3/343	16/356			
Facet joint violations	Study	Robotic or Navigated	Fluoroscopic Freehand	Relative risk (95% CI)	p-value	I2
	Wu 2010	0/92	3/84	0.09 (0.02−0.38)	**<.01**	0%
	Hyun 2017	0/130	1/140			
	Kim 2018	0/158	13/172			
	Han 2019	0/532	12/584			
	Total	0/912	29/980			
Nerve root injury	Study	Robotic or Navigated	Fluoroscopic Freehand	Relative risk (95% CI)	p-value	I^2
	Laine 2000	0/219	1/277	0.50 (0.11−2.30)	.37	0%
	Wu 2010	0/92	1/84			
	Kim 2017	0/158	1/172			
	Feng 2020	1/170	1/174			
	Li Z. 2020	0/32	0/50			
	Total	1/671	4/757			
Return to OR	Study	Robotic or Navigated	Fluoroscopic Freehand	Relative risk (95% CI)	p-value	I^2
	Laine 2000	0/219	0/277	0.28 (0.07−1.13)	.07	0%
	Wu 2010	0/92	1/84			
	Hyun 2017	0/130	1/140			
	Noriega 2017	0/305	1/320			
	Park 2018	0/158	2/172			
	Han 2019	0/532	2/584			
	Li Z. 2020	0/32	0/50			
	Total	0/1468	7/1627			

deformity surgeries across all included studies, with two RCTs also including patients with traumatic and oncological pathologies [18,26]. Although the variability in treated spine conditions may suggest an intrinsic between-study heterogeneity with potential repercussions in the assessment of pooled outcomes, this also reflects the large variance in the most common disorders treated routinely with spine fixation surgery.

Contrary to previous reviews, this meta-analysis included only RCTs and also collected outcomes of the most recent RCTs that were not comprehensively analyzed previously. We found that robotic and navigated screw placement techniques correlated with significantly higher rates of accuracy when compared with fluoroscopy-assisted freehand approaches. The only exceptions were the early studies of Ringel et al in 2012 [9] and Roser et al in 2013 [25], which demonstrated significantly lower accuracy rates after robotic-assisted surgeries. Such differences were likely ascribed to the initial limitations of the SpineAssist system, as Molliqaj et al [30] noticed that the system's

Table 4
Summary of continuous variable meta-analysis for procedure time, screw insertion time, and EBL

	Study	Robotic or Navigated (mean)	Robotic or Navigated (standard deviation)	Fluoroscopic Freehand (mean)	Fluoroscopic Freehand (standard deviation)	MD (95% CI)	p-value	I^2
Procedure time	Laine 2000	179	74	160	73	7.73 minutes (−15.24 to 30.70)	.51	74%
	Kim 2017	220.1	55.9	189.8	45.1			
	Han 2019	149.5	50.8	138	48.6			
	Feng 2020	195.25	62.85	230.63	55.06			
	Li Z. 2020	289	87	266	92			
Screw insertion time (Navigation Only)	Study	Robotic or Navigated (Mean Minutes)	Robotic or Navigated (Standard Deviation)	Fluoroscopic Freehand (Mean Minutes)	Fluoroscopic Freehand (Standard Deviation)	MD (95% CI)	p-value	I^2
	Rajasekaran 2007	2.37	0.72	4.51	1.05	−2.13 minutes (−2.73; −1.53)	**<.01**	0%
	Wu 2010	2.54	5.59	4.56	1.03			
Estimated blood loss	Study	Robotic or Navigated (Mean mL)	Robotic or Navigated (Standard Deviation)	Fluoroscopic Freehand (Mean mL)	Fluoroscopic Freehand (Standard Deviation)	MD (95% CI)	p-value	I^2
	Laine 2000	1,107	809	1,270	1,325	−47.18 mL (−86.97 to −7.401)	**.02**	0%
	Han 2019	186	255.3	217	174.3			
	Feng 2020	165	102.03	237.5	167.47			
	Li Z. 2020	257	181	245	140			

percutaneous cannula for screw placement interacted with the vertebral bony surface, leading to change in pedicle screw trajectory and decreased accuracy. Newer robotic systems were adapted to overcome these hurdles, offering better mechanical-arm guidance with high degree of freedom and improved force sensor device, providing the surgeons with constant haptic feedback in regard to tip deflection or skiving, leading to increased accuracy rates in the latest studies [24]. In addition, the superior accuracy observed with robotic and navigated techniques, may be attributed to the fact that freehand techniques mainly depend on the surgeon's practice and bi-planar fluoroscopy, whereas the robotic and navigated techniques depend on pre- and intraoperative imaging registration and planning for selecting the optimal starting point and screw trajectory, facilitating the avoidance of the facet joint. Although out of the scope of this study, a previous meta-analysis found that robotic techniques correlate with significantly superior accuracy than CT-navigated techniques but with comparable accuracy to 3D-fluoroscopy navigated techniques [11]. These findings are promising but require further evaluation before being used to direct medical and policy decisions, as the large inter-user variability based on the different modalities needs to be considered and explicitly addressed.

Similar to previous meta-analyses, we also found that robotic and navigated techniques had significantly lower rates of major complications, facet joint violation, and estimated blood loss, and nonsignificantly lower rates of nerve root injuries [31,32]. Unsurprisingly, the improved accuracy in screw placement likely correlated with lower occurrence of perioperative injuries and better postoperative management of treated patients, which significantly reduced the number of adverse events as compared with freehand techniques [33] The decreased blood loss noted among robotic and navigated screws may be related to more minimally invasive techniques used for robotic and navigated screws. Although some of the included RCTs controlled for this, the application of minimally invasive techniques was not always consistent between freehand and robotic groups. This may also explain the lower blood loss and decreased complications rates seen for robotic and navigated screws. It is also important to note that this benefit of robotic and navigated techniques uniquely depends on the accuracy in image acquisition, image registration, and equipment registration, and, thus, inexperienced surgical teams have higher chances of introducing technical errors when bringing new technologies into the operating room [34].

Of interest, we found no significant differences in rates of screw revision between the two techniques, contrary to previous meta-analyses that found significantly higher rates of screw revision after robotic and navigated approaches [31,32]. These differences in pooled outcomes likely derive from the increasing experience with robotic and navigated systems reported in the most recent RCTs [35]. Similarly, we found that procedure time and screw insertion time

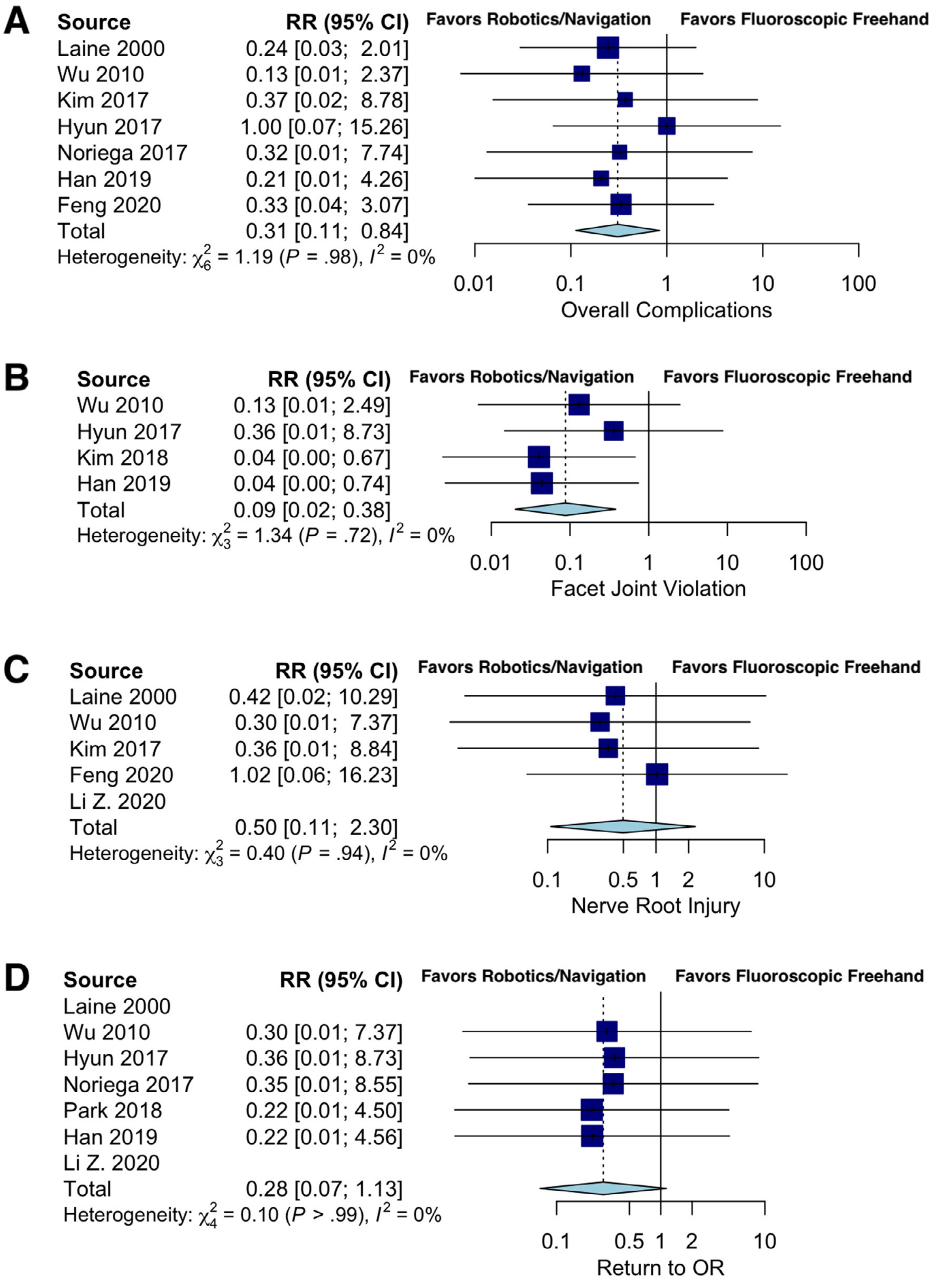

Fig. 4. (A) Relative risk of all complications in robotic or navigated screws vs. freehand; (B) relative risk of facet joint violation between robotic or navigated screws vs. freehand screws; (C) relative risk of nerve root injury between robotic or navigated screws vs. freehand screws; (D) relative risk of needing a return to the operating room for screw revision between robotic or navigated screws vs. freehand screws.

were not significantly different between the two groups, whereas previous meta-analysis reported longer times related to robotic and navigated approaches [31,32]. Collectively these findings suggest that previous results which were previously unfavorable to robotic and navigation may have been related to the learning curve with these

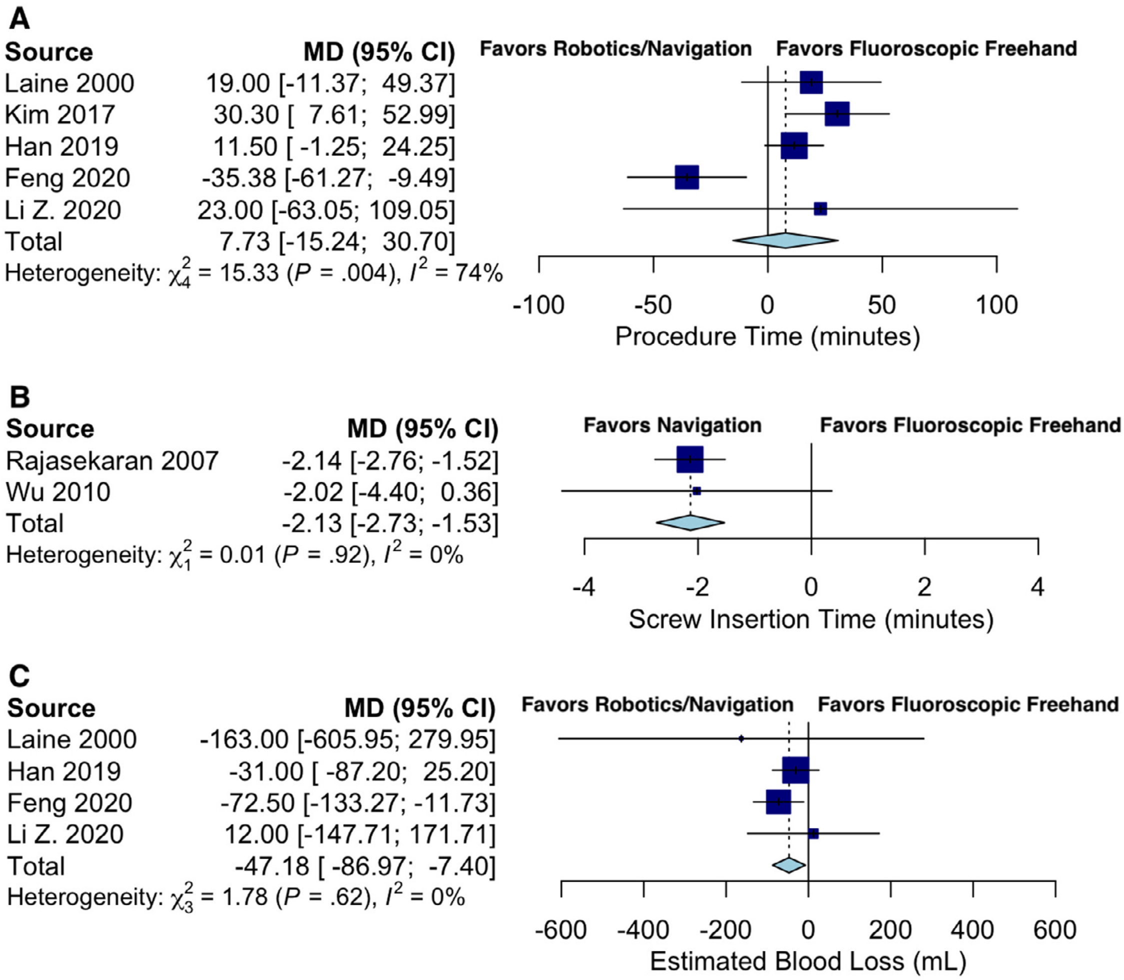

Fig. 5. (A) Mean difference in procedure time (minutes) between robotic or navigated screws vs. freehand screws; (B) mean difference in screw insertion time (minutes) between navigated screws only vs. freehand screws; (C) mean difference in estimated blood loss (mL) between robotic or navigated screws vs. freehand screws.

technologies, as the most recent RCTs also reported significantly shorter operating times with robotic and navigated surgeries as compared with earlier RCTs.

Although patient-reported outcomes and radiation exposure comprise two of the most important variables in evaluating the safety and efficacy of different surgical techniques in spine surgeries, the high variability between-RCTs in reported results prevented additional specific meta-analyses. Previous reviews, which also included non-RCT studies, found similar rates of functional outcomes in patients treated with fluoroscopy-assisted freehand screw placement techniques and patients treated with robotic and navigated techniques, however also expressed the need to access to more standardized follow-up clinical assessments before making definite conclusions [11,32]. In contrast, previous meta-analyses found significantly lower radiation exposure after robotic and navigated techniques as compared with fluoroscopy-assisted freehand techniques, as the former do not require repetitive fluoroscopy scans but only rely on pre- and intraoperative imaging data for registration and planning [32,36]. Of interest, two multicenter prospective registries on robotic spine surgery are ongoing, with the purpose to collect several long-term clinical and technical outcomes and provide a more detailed analysis of the benefits and drawbacks of the current robotic systems used in spine surgery [37,38].

Limitations

Our study has some limitations. Although all included studies were RCTs, risks of bias were variable due to their surgical nature. Yet, the vast majority of included RCTs had low risk of bias, predisposing this meta-analysis to a low overall risk of bias. Owing to the recent introduction of multiple robotic and navigated systems across the literature, different protocols were included in this meta-analysis to collect the highest number of cases and provide the most in-depth evaluation of current technologies in spine fixation surgery compared with fluoroscopic-assisted freehand screw placement techniques. However, this aggregation may have determined decreased effect sizes for each individual technique under analysis. Although we did not identify any differences in procedure time between the two groups, the procedure time does not take into consideration the time required for the preoperative CT scan and registration. The reduced screw insertion time associated with navigation may help to offset this time, but this data was only available for navigation and suggests that this time may only be offset to a significant degree in larger cases. Robotics and navigation may also suffer registration failures and may need to be abandoned for various reasons. These drawbacks could not be addressed in this study but should be considered when weighing the advantages and disadvantages of robotics and navigation. Due to the limited and heterogeneous data across included RCTs, patient-reported functional outcomes and radiation exposure could not be assessed. Finally, the lack of granular data prevented individual meta-analyses based on indications, different robotic and navigated systems, and freehand techniques.

Conclusions

These meta-analyses demonstrated that robotic and navigated screw placement techniques are associated with higher odds of screw accuracy and superior safety profile compared with traditional fluoroscopic freehand techniques. Ongoing multi-institutional prospective registries are expected to provide additional relevant information on long-term clinical outcomes, whereas future RCTs are needed to further validate these findings.

Declarations of Competing Interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.spinee.2022.10.006.

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