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Higher Accuracy and Better Clinical Outcomes in Navigated Thoraco-Lumbar Pedicle Screw Fixation *Versus* Conventional Techniques

A Systematic Review and Meta-Analysis

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Study Design. A systematic review and meta-analysis.

Objective. This study aims to compare pedicle screw accuracy, clinical outcomes, and complications between navigated and conventional techniques.

Summary of Background Data. In the last decades, intraoperative navigation has been introduced in spinal surgery to prevent risks and complications.

Materials and Methods. The search was executed on Cochrane Central Library, PubMed, and Scopus on April 30, 2023. Randomized controlled trials, prospective and retrospective studies that compared pedicle screw accuracy in the thoracic-lumbar-sacral segments, blood loss, operative time, hospital stay, intraoperative and postoperative revision of screws, neurological and systemic complications, Visual Analogue Scale (VAS), and Oswestry Disability Index (ODI) between navigated and freehand or fluoroscopy-assisted techniques were included in this study. The meta-analysis was performed using Review Manager software. Clinical outcomes were assessed as continuous outcomes with mean difference, while pedicle screw accuracy and complications were assessed as dichotomous outcomes with odds ratio, all with 95% CIs. The statistical significance of the results was fixed at $P<0.05$.

Results. This meta-analysis included 30 studies for a total of 17,911 patients and 24,600 pedicle screws. Statistically significant results in favor of the navigated technique were observed for the accuracy of pedicle screws ($P=0.0001$), hospital stay ($P=0.0002$), blood loss ($P<0.0001$), postoperative revision of pedicle screws ($P<0.00001$), and systemic complications ($P=0.0008$). In particular, the positioning of the screws was clinically acceptable in 96.2% of the navigated group and 94.2% with traditional techniques. No significant differences were found in VAS, ODI, and operative time between the two groups.

Conclusion. Navigated pedicle screw fixation has been demonstrated to be a safe and effective technique with high improvement in clinical outcomes and accuracy in patients undergoing spinal fusion compared with conventional techniques.

Level of Evidence. Level III.

Key words: pedicle screw, navigation, fluoroscopy-freehand accuracy, meta-analysis

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Spondylodesis, or the internal fixation of two or more vertebral segments, is accomplished by stabilizing and immobilizing the affected vertebral segments. Pedicle screws are fixation devices used in spinal surgery.[1] They have been utilized more frequently during the past few decades to support the spine in different spinal disorders, such as degenerative disease, deformity, trauma, tumors, and infection. Incorrect screw placement might result in severe consequences.[2] A malposition of the pedicle screw can increase the risk of the onset of neurological, vascular, and visceral injuries as well as instrumentation failure.[3] Misaligned pedicle screws can also significantly increase

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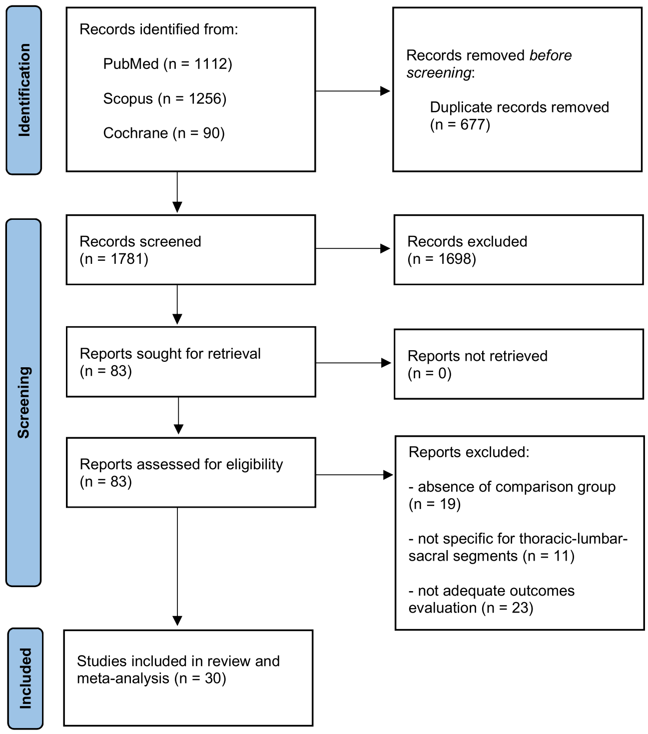

Figure 1. Preferred Reporting Items for Systematic Review and Meta- Analysis (PRISMA) 2020.

medical resource utilization.[4] Apparent malposition is commonly corrected during surgery, extending the duration of the operation, increasing radiation time and tissue trauma as well as blood loss, and reducing pullout strength.[5,6] Moreover, in case of postoperative neurovascular sequelae caused by malpositioned screws, revision surgery may be necessary, increasing costs and morbidity. However, not all incorrectly positioned pedicle screws necessitate revision.[7,8] To prevent these risks and complications, surgeons can use image-guided navigation and other forms of guidance to work safely and effectively. Nowadays, freehand (FH), fluoroscopy-assisted (FA), CT-assisted navigation (NV), and robotic-assisted (robotic-guided, RG) are the techniques used in such procedures.[9,10] Traditionally, pedicle screws have been implanted either freehand or with the help of fluoroscopy, in which case the surgeon uses only specific anatomic landmarks to pinpoint the pedicle entry site and direct the screw trajectory. These techniques may increase the risk of misplacement, especially in thoracic segments, deformities, or pediatric patients, whose anatomy confers distinct variations and higher complexity. NV was first applied to spine surgery in 1995.[11] The modern NV technologies, which rely on advanced software for screws preoperative planning, can be approximately distinguished into three types according to the principle they are based on: preoperative CT with intraoperative surface matching, preoperative CT with real-time fluoroscopic matching, and intraoperative CT.[12–14] However, there is a dearth of information in the literature on the incidence of incorrectly positioned pedicle screws in lower clinical outcomes, neurological problems and associated revision procedures. Therefore, this systematic review and meta-analysis aimed to compare clinical scores, intraoperative and postoperative outcomes, pedicle screw accuracy, and complications between navigated (NV) and conventional techniques (FH and FA).

MATERIALS AND METHODS

This study was carried out according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.[15]

Inclusion Criteria

In this study, randomized controlled trials (RCTs), prospective and retrospective studies that compared pedicle screw accuracy in the thoracic-lumbar-sacral segments, operative time, perioperative and postoperative clinical outcomes, and complications between NV and conventional FH or FA were included.

Search Methods

The Cochrane Central Library, PubMed, and Scopus online databases were searched using the following strings: ("pedicle screws"[MeSH Terms] OR ("pedicle"[All Fields] AND "screws"[All Fields]) OR "pedicle screws"[All Fields] OR ("pedicle"[All Fields] AND "screw"[All Fields]) OR "pedicle screw"[All Fields]) AND ("navigability"[All Fields] OR "navigable"[All Fields] OR "navigate"[All Fields] OR "navigated"[All Fields] OR "navigates"[All Fields] OR "navigating"[All Fields] OR "navigation"[All Fields] OR "navigational"[All Fields] OR "navigations"[All Fields] OR "navigator"[All Fields] OR "navigator s"[All Fields] OR "navigators"[All Fields]). The search was conducted on April 30, 2023. After removing duplicates, two reviewers (G.F.P. and G. M.) checked the abstracts of potentially included studies and read the full articles to select the included studies for this review and meta-analysis. Any divergence was discussed with a third reviewer (F.R.).

Data Collection, Analysis, and Outcome

Two reviewers (G.F.P. and G.M.) conducted data extraction. The following data were extracted from the included studies: authors, year of publication, type of study, level of evidence, indications, involved spinal segments, type of fusion, imaging and navigation devices, numbers of patients, age and sex of participants, and number of screws per procedure. Moreover, Visual Analogue Scale (VAS) back, VAS leg, Oswestry Disability Index (ODI), hospital stay, operative time, blood loss, screw accuracy, intraoperative revision of screws, postoperative revision of screws, neurological complications, and systemic complications were assessed as outcomes in the two groups.

Statistical Analysis

The meta-analysis was performed using Review Manager (RevMan) software Version 5.4. Clinical scores

TABLE 1. Characteristics of Included Studies

Study	Year	Type of study	LOE	Indication	Spinal segment	Guidance	No. patients	M (%)	F (%)	Mean age (yr)	No. screws
Amiot *et al*[16]	2000	RS	III	DG, TF, NP, IN	T, L, S	Preoperative CT with surface matching	50	NR	NR	50.7	294
						Fluoroscopy	100		NR	47.3	544
Fichtner *et al*[17]	2017	RS	III	DG, TF, NP, IN	T, L	Intraoperative 3D fluoroscopy	1112		NR	65	7548
						Fluoroscopy	1120	NR	NR	65	6155
Noriega *et al*[18]	2016	RCT	I	DG	T, L, S	Intraoperative CT	58	32 (55%)	26 (45%)	60.3	305
						Fluoroscopy	56	42 (75%)	14 (25%)	62.1	320
Shin *et al*[19]	2015	RCT	I	DG, NP	T, L, S	Intraoperative CT	20	12 (60%)	8 (40%)	57.5	124
						Fluoroscopy	20	11 (55%)	9 (45%)	55.3	138
Silberman *et al*[20]	2011	RS	III	DG	L, S	Intraoperative 3D fluoroscopy	37	21 (56.7%)	16 (43.3%)	64.4	187
						FH	30	15 (50%)	15 (50%)	60.1	152
Yang *et al*[21]	2012	RS	III	TF	L, S	Intraoperative 2D fluoroscopy	42	NR	NR	52.7	210
						Fluoroscopy	34	NR	NR	51.9	152
Peng *et al*[22]	2019	RS	III	DG	L	Intraoperative O-arm	18	5 (27.7%)	13 (72.3%)	55.6	72
						Fluoroscopy	22	5 (22.7%)	17 (77.3%)	56.6	88
Chen *et al*[23]	2019	RS	III	DG	L	Intraoperative O-arm	21	9 (42.9%)	12 (57.6%)	52.7	84
						Fluoroscopy	24	13 (54.2%)	11 (45.8%)	51.7	96
Wang *et al*[24]	2016	RCT	I	DG	L, S	Intraoperative 3D fluoroscopy	20	7 (35%)	13 (65%)	50.6	80
						Conventional	20	10 (50%)	10 (50%)	51.5	80
Wang *et al*[25]	2016	RCT	I	DG	L, S	Intraoperative 3D fluoroscopy	20	9 (45%)	11 (55%)	64.7	120
						Conventional	20	6 (30%)	14 (70%)	62.9	120
Ohba *et al*[26]	2016	RS	III	DG, NP	T, L	Intraoperative CT	19	9 (47.4%)	10 (52.6%)	67	122
						Fluoroscopy	9	7 (77.7%)	2 (22.3%)	58.8	72
Boon Tow *et al*[27]	2015	PS	II	DG	L	Intraoperative O-arm	19	6 (31.6%)	13 (68.4%)	60	76
						FH	19	13 (68.4%)	6 (31.6%)	62	76
Wang *et al*[28]	2018	RS	III	DG	L	Intraoperative O-arm	20	9 (45%)	11 (55%)	72.2	168
						FH	21	12 (57%)	9 (43%)	72.6	160
Elmi-Terander *et al*[29]	2020	PS	II	DF	T, L	Augmented reality with intraoperative cone beam CT	20	9 (45%)	11(55%)	30	262
						Fluoroscopy	20	9 (45%)	11 (55%)	30	288
Konieczny *et al*[30]	2019	RS	III	NP		Intraoperative 3D cone beam CT	12	NR	NR	68.5	118
						Fluoroscopy	10	NR	NR	58.3	87
Garcia-Fantini *et al*[31]	2018	RS	III	DG	L, S	Intraoperative 3D fluoroscopy	96	22 (22.9%)	74 (77.1%)	58.7	576
						Fluoroscopy	39	9 (23%)	30 (77%)	60.6	234
Bovonratwet *et al*[32]	2017	RS	III	DG	L	Stereotactic computer-assisted navigation	1.161	471 (40.6%)	690 (59.4%)	58.8	N.R.
						Conventional	10.950	4.829 (44%)	6.121 (56%)	59.2	N.R.
Budu *et al*[33]	2020	RS	III	DG, TF, NP	T, L, S	Intraoperative 3D fluoroscopy/preop CT	176	NR	NR	NR	296
						Fluoroscopy		NR	NR	NR	535
Hohenhaus *et al*[34]	2020	RS	III	DG, IN	L	Intraoperative 3D Fluoroscopy	93	84 (45.2%)	102 (54.8%)	68	186
						Fluoroscopy	291	270 (46.4%)	312 (53.6%)	66	582
Fu *et al*[35]	2007	RS	III	DG, TF	T, L, S	Preoperative CT with surface matching	11	NR	NR	NR	76
						Computer-assisted fluoroscopic navigation	13	NR	NR	NR	74
Houten *et al*[36]	2012	RS	III	DG, NP	T, L, S	Intraoperative O-arm	52	NR	NR	NR	205

						Fluoroscopy	42	NR	NR	NR	141
Laudato *et al*[37]	2018	RS	III	DG, TF	T, L, S	Intraoperative O-arm	25	NR	NR	63	191
						Fluoroscopy	48	NR	NR	60.7	314
Fan *et al*[38]	2017	RS	III	DG	L	Intraoperative 3D fluoroscopy	51	20 (39.2%)	31 (60.8%)	65.1	234
						Fluoroscopy	72	33 (45.8%)	39 (54.2%)	62.4	346
Ver *et al*[39]	2020	RS	III	DG	L	Intraoperative O-arm	52	21 (40.4%)	31 (59.6%)	54.4	N.R.
						FH	52	13 (25%)	39 (75%)	53.1	N.R.
Wang *et al*[40]	2020	RS	III	DG	L	Intraoperative CT	12	33.3%	66.7%	63.4	N.R.
						Open	56	61.8%	38.2%	60.6	N.R.
						Fluoroscopy	35	54.20%	45.70%	50.6	N.R.
Chatelain *et al*[41]	2023	RS	III	DG, TF, NP, IN	T, L	Intraoperative CT	54	24 (44%)	30 (56%)	63	287
						Fluoroscopy	102	48 (47%)	54 (53%)	64	438
Ansari *et al*[42]	2022	RS	III	DF	T, L	Intraoperative navigation	456	152 (33%)	304 (66,7%)	NR	NR
						Conventional	456	153 (34%)	303 (66,4%)	NR	NR
Singhatanadgige *et al*[43]	2022	RS	III	DG	L	Intraoperative CT	36	13 (36.1%)	23 (63.9%)	65.89	172
						Fluoroscopy	61	20 (32.8%)	41 (67.2%)	65.67	270
La Rocca *et al*[44]	2022	RS	III	DG	L	Intraoperative CT	91	47 (52%)	44 (48%)	61	450
						Fluoroscopy	101	56 (55%)	45 (45%)	61	502
Rohe *et al*[45]	2022	RS	III	DG	L	Intraoperative cone-beam navigation	108	38 (35%)	70 (65%)	62.8	NR
						Fluoroscopy	106	53 (50%)	53 (50%)	60.8	NR

DF indicates deformity; DG, degenerative; F, female; FH, freehand; IN, infection; L, lumbar; LOE, level of evidence; M, male; MISS, minimally invasive spine surgery; NR, not reported; NP, neoplastic disease; PLIF, posterior lumbar interbody fusion; PS, prospective study; RCT, randomized controlled trial; RS, retrospective study; S, sacral; T, thoracic; TF, traumatic fracture; TLIF, transforaminal lumbar interbody fusion.

	NV			FH				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Chen 2019	1.09	0.77	21	1.16	0.7	24	24.9%	−0.09 [−0.68, 0.49]
Singhatanadgige 2022	0.11	0.11	36	0.78	0.26	61	24.9%	−3.06 [−3.66, −2.46]
Wang 2018	1.7	0.73	20	1.86	0.85	21	24.8%	−0.20 [−0.81, 0.42]
Yang 2012	2.24	2.78	42	2.55	2.73	34	25.4%	−0.11 [−0.56, 0.34]
Total (95% CI)			**119**			**140**	**100.0%**	**−0.86 [−2.23, 0.51]**

Heterogeneity: $Tau^2 = 1.86$; $Chi^2 = 72.08$, df = 3 ($P < 0.00001$); $I^2 = 96\%$
Test for overall effect: Z = 1.23 (P = 0.22)

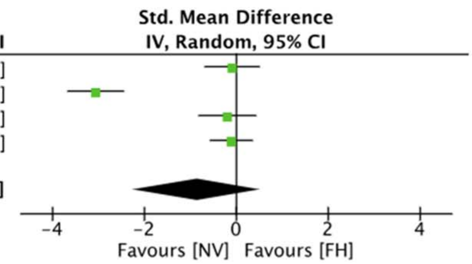

Figure 2. Visual Analogue Scale leg.

were assessed as continuous outcomes with a standardized mean difference (SMD) or mean difference (MD) with 95% CIs. Perioperative and postoperative clinical outcomes were assessed as continuous outcomes with MD with 95% CIs. Pedicle screw accuracy, pedicle screw revisions, and complications were assessed as dichotomous outcomes with an odds ratio (OR) of 95% CIs. For the calculation of heterogeneity, the I^2 test was used. This used a random-effect model for I^2 higher than 60%. The statistical significance of the results was fixed at $P<0.05$.

RESULTS

Results of the Search

The literature search identified a total of 2458 articles. After removing duplicates, 1781 articles were screened, and among them, we chose 83 articles that were read in full and assessed for eligibility. Afterward, 52 studies were excluded for the following reasons: absence of comparison group (n = 19); not specific for thoracic-lumbar-sacral segments (n = 11); not adequate outcomes evaluation (n = 23). Finally, this systematic review and meta-analysis included 30 studies (Fig. 1).

Characteristics of Included Studies

The detailed characteristics of the studies are summarized in Table 1. A total of 24,600 pedicle screws were inserted, of which 12,492 with NV, and 12,108 with conventional FH or FA techniques. The total number of participants in all the studies was 17,911, divided into 3786 in the study group and 13,949 in the control group. Patients' mean age ranged from 30 to 72.2 years in the study group and from 30 to 72.6 years in the control group. The percentages of men ranged from 22.9% to 60% in the study group and from 22.7% to 77.7% in the control group. The most frequent indication for surgery was degenerative disease (in 26 studies), followed by neoplastic disease (in eight studies), trauma (in seven studies), infective disease (in three studies) and deformity (in three studies). The lumbar spine was the most treated spinal segment, followed by the thoracolumbosacral, the lumbosacral, and the thoracolumbar.

Effects of Intervention

Leg pain was assessed in only four studies, using VAS leg. The meta-analysis showed better improvement in the NV group compared with the FH group but without statistical significance (SMD: −0.86, 95% CI: −2.23 to 0.51, $I^2=96\%$, $P=0.22$) (Fig. 2).

Back pain was assessed in only five studies, using VAS back. It has been shown higher pain reduction in the NV group compared with the FH group, but without statistical significance (SMD: −0.75, 95% CI: −1.84 to 0.34, $I^2=95\%$, $P=0.18$) (Fig. 3).

Patient's disability was assessed in only five studies using ODI. No significant difference was found between the two groups regarding postoperative disability (SMD: −0.53, 95% CI: −2.02 to 0.97, $I^2=96\%$, $P=0.49$) (Fig. 4).

Hospital stay was assessed in 12 studies. Hospital days were significantly lower in a navigated group compared with conventional techniques (MD: −1.14, 95% CI: −1.75 to −0.53, $I^2=87\%$, $P=0.0002$) (Fig. 5).

Operative time was assessed in 14 studies and showed a nonsignificantly lower value in the FH group compared with the NV group (MD: 13.64, 95% CI: −4.91 to 32.18, $I^2=94\%$, $P=0.15$) (Fig. 6).

Blood loss was assessed in nine studies and was expressed in mL. Blood loss was significantly lower in favor of the NV group (MD: −100.58, 95% CI: −148.92 to

	NV			FH				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Chen 2019	0.71	0.56	21	0.87	0.68	24	20.0%	−0.25 [−0.84, 0.34]
Peng 2019	0.61	0.5	18	0.86	0.63	22	19.8%	−0.43 [−1.06, 0.20]
Singhatanadgige 2022	0.11	0.11	36	0.63	0.2	61	19.9%	−2.99 [−3.59, −2.40]
Wang 2018	1.8	0.62	20	1.9	0.62	20	19.8%	−0.16 [−0.78, 0.46]
Yang 2012	5.72	2.54	42	5.6	2.9	34	20.5%	0.04 [−0.41, 0.50]
Total (95% CI)			**137**			**161**	**100.0%**	**−0.75 [−1.84, 0.34]**

Heterogeneity: $Tau^2 = 1.46$; $Chi^2 = 73.16$, df = 4 ($P < 0.00001$); $I^2 = 95\%$
Test for overall effect: Z = 1.35 (P = 0.18)

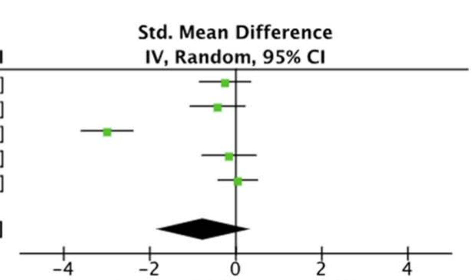

Figure 3. Visual Analogue Scale back.

Study or Subgroup	NV Mean	NV SD	NV Total	FH Mean	FH SD	FH Total	Weight	Std. Mean Difference IV, Random, 95% CI
Chen 2019	15.85	1.42	21	16.08	1.28	24	20.1%	−0.17 [−0.75, 0.42]
Peng 2019	12.94	1.58	18	13.41	0.96	22	20.0%	−0.36 [−0.99, 0.27]
Singhatanadgige 2022	0.49	0.49	36	5.21	1.69	61	20.0%	−3.40 [−4.04, −2.76]
Wang 2016 (1)	12	2	20	9	2	20	19.8%	1.47 [0.76, 2.18]
Wang 2018	18.2	4	20	18.85	3.8	21	20.1%	−0.16 [−0.78, 0.45]
Total (95% CI)			**115**			**148**	**100.0%**	**−0.53 [−2.02, 0.97]**

Heterogeneity: Tau² = 2.80; Chi² = 111.41, df = 4 (P < 0.00001); I² = 96%
Test for overall effect: Z = 0.69 (P = 0.49)

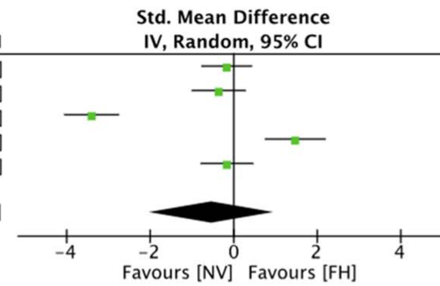

Figure 4. Oswestry Disability Index.

Study or Subgroup	NV Mean	NV SD	NV Total	FH Mean	FH SD	FH Total	Weight	Mean Difference IV, Random, 95% CI
Ansari 2022	6	9.9	456	6.1	6.7	456	8.6%	−0.10 [−1.20, 1.00]
Bovonratwet 2017	3	1.8	1161	3.2	2.2	10950	11.9%	−0.20 [−0.31, −0.09]
Chen 2019	10.61	2.52	21	13.83	3.89	24	5.5%	−3.22 [−5.11, −1.33]
Elmi-Terander 2020	5.3	1.7	20	6.8	3.6	20	6.0%	−1.50 [−3.24, 0.24]
Fan 2017	7.9	1.1	51	8.9	1.8	72	11.0%	−1.00 [−1.51, −0.49]
Peng 2019	10.33	2.47	18	13.64	3.91	22	5.2%	−3.31 [−5.30, −1.32]
Singhatanadgige 2022	5.03	2.46	36	5.2	2.41	61	9.0%	−0.17 [−1.18, 0.84]
Ver 2020	2.71	1.49	52	3.58	1.65	52	10.7%	−0.87 [−1.47, −0.27]
Wang 2016 (1)	8.8	2.1	20	12.3	2.3	20	7.4%	−3.50 [−4.86, −2.14]
Wang 2016 (2)	9.2	1.8	20	12.3	2.3	20	7.8%	−3.10 [−4.38, −1.82]
Wang 2018	14.9	2.63	20	15.43	2.2	21	6.9%	−0.53 [−2.02, 0.96]
Wang 2020	4.75	1.14	12	3.89	1.74	91	10.1%	0.86 [0.12, 1.60]
Total (95% CI)			**1887**			**11809**	**100.0%**	**−1.14 [−1.75, −0.53]**

Heterogeneity: Tau² = 0.80; Chi² = 82.62, df = 11 (P < 0.00001); I² = 87%
Test for overall effect: Z = 3.69 (P = 0.0002)

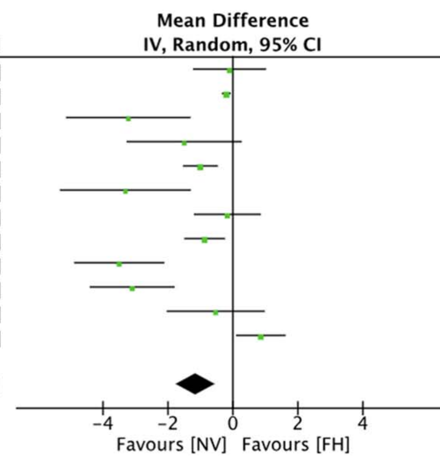

Figure 5. Hospital stay.

Study or Subgroup	NV Mean	NV SD	NV Total	FH Mean	FH SD	FH Total	Weight	Mean Difference IV, Random, 95% CI
Ansari 2022	383.5	154.7	456	353.8	154.4	456	7.5%	29.70 [9.64, 49.76]
Bovonratwet 2017	188	78	1161	183	78	10950	8.1%	5.00 [0.28, 9.72]
Chen 2019	217.6	33	21	129.79	17.97	24	7.7%	87.81 [71.97, 103.65]
Elmi-Terander 2020	403	101	20	361	150	20	3.3%	42.00 [−37.25, 121.25]
Fan 2017	194	38	51	178	55	72	7.7%	16.00 [−0.44, 32.44]
Hounten 2012	200	44	52	221	62	42	7.3%	−21.00 [−43.24, 1.24]
Peng 2019	201.6	29.1	18	132.3	23.6	22	7.7%	69.30 [52.63, 85.97]
Rohe 2022	143.62	43.87	108	171.1	48.91	106	7.9%	−27.48 [−39.94, −15.02]
Singhatanadgige 2022	163.64	52.06	36	173.91	52.93	61	7.4%	−10.27 [−31.85, 11.31]
Ver 2020	189.57	42.8	52	233.6	78.9	52	7.2%	−44.03 [−68.43, −19.63]
Wang 2016 (1)	134.4	27.9	20	124.5	23	20	7.7%	9.90 [−5.95, 25.75]
Wang 2016 (2)	160.7	40.5	20	144.4	20.8	20	7.5%	16.30 [−3.65, 36.25]
Wang 2018	222.5	38	20	255.2	40.3	21	7.2%	−32.70 [−56.67, −8.73]
Wang 2020	303.5	67.5	12	229.9	60	56	5.8%	73.60 [32.30, 114.90]
Total (95% CI)			**2047**			**11922**	**100.0%**	**13.64 [−4.91, 32.18]**

Heterogeneity: Tau² = 1093.78; Chi² = 236.27, df = 13 (P < 0.00001); I² = 94%
Test for overall effect: Z = 1.44 (P = 0.15)

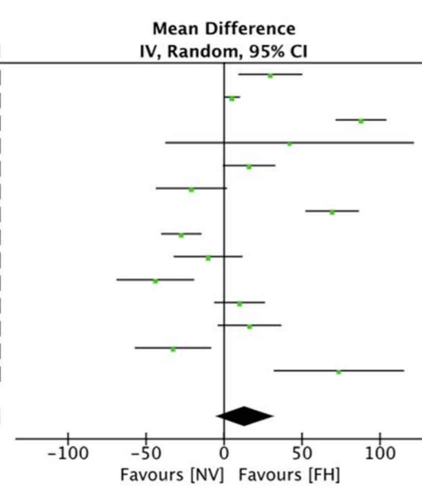

Figure 6. Operative time.

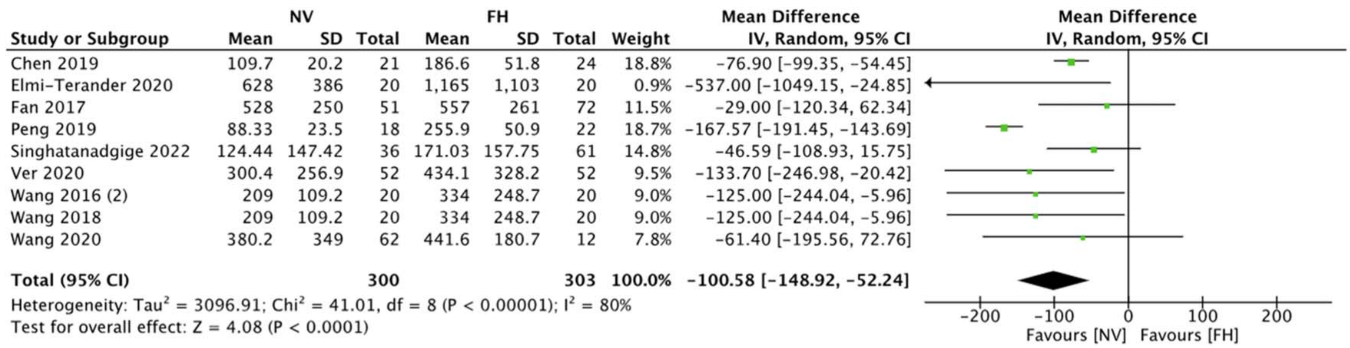

Figure 7. Blood loss.

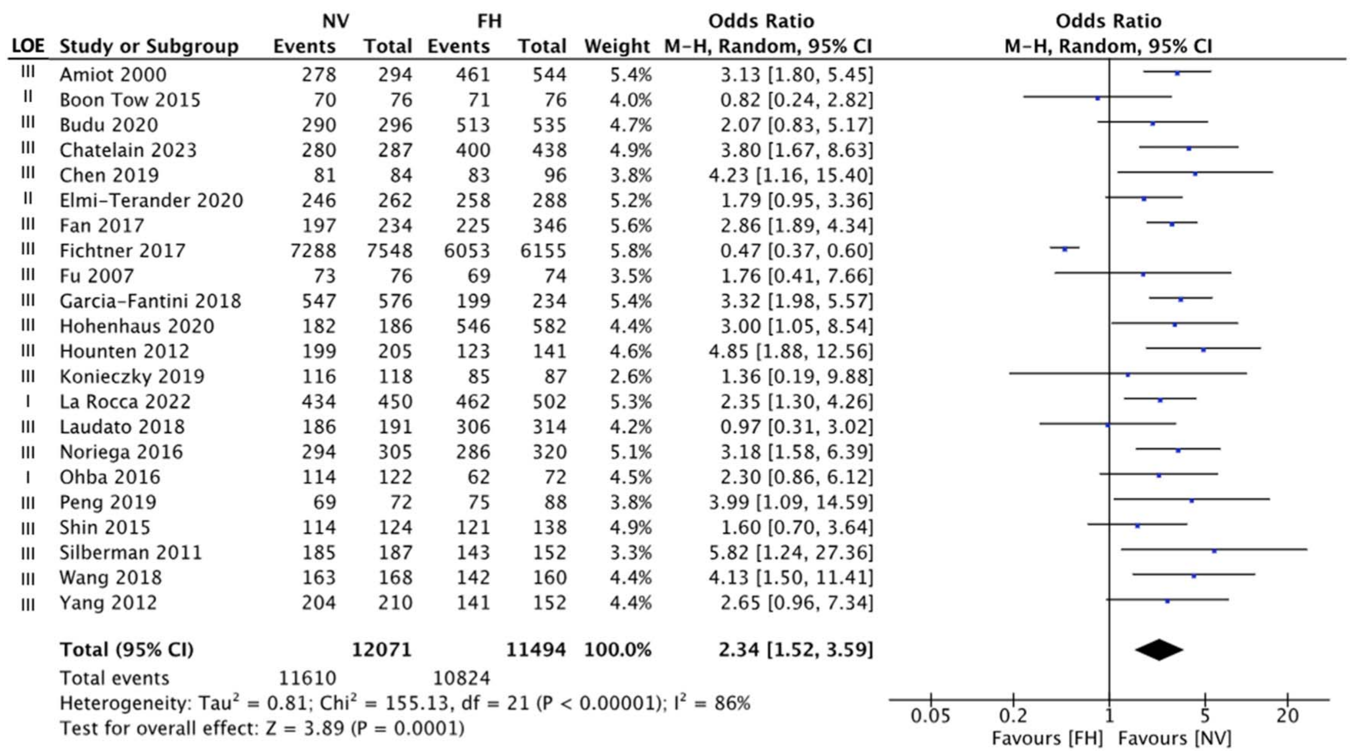

Figure 8. Accuracy.

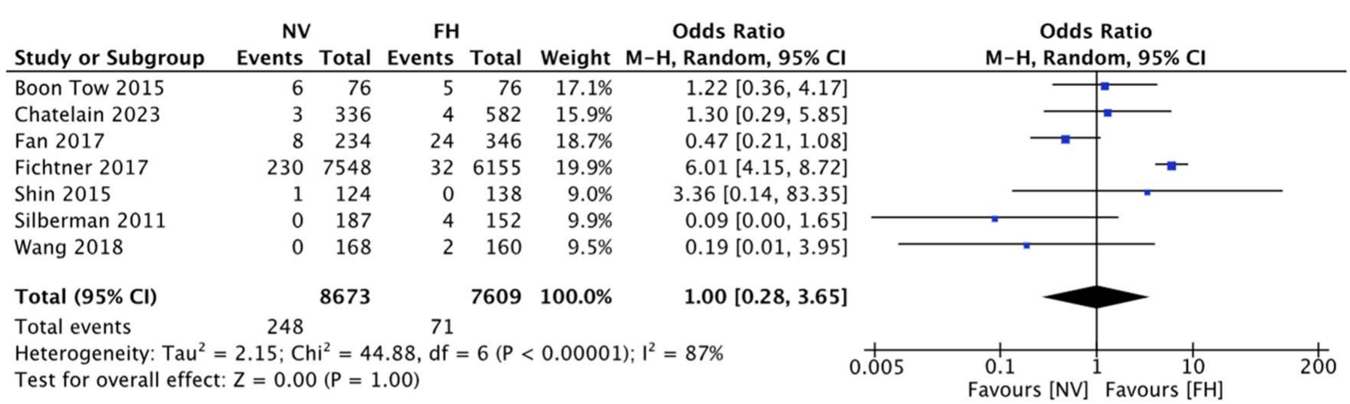

Figure 9. Intraoperative revision of pedicle screws.

Study or Subgroup	NV Events	NV Total	FH Events	FH Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Amiot 2000	0	294	7	544	6.0%	0.12 [0.01, 2.14]
Chatelain 2023	1	336	4	582	3.3%	0.43 [0.05, 3.88]
Fichtner 2017	30	7548	70	6155	87.7%	0.35 [0.23, 0.53]
Noriega 2016	0	305	1	5320	0.2%	5.80 [0.24, 142.77]
Shin 2015	0	124	1	138	1.6%	0.37 [0.01, 9.12]
Wang 2016 (1)	1	120	1	120	1.1%	1.00 [0.06, 16.17]
Total (95% CI)		**8727**		**12859**	**100.0%**	**0.35 [0.24, 0.53]**
Total events	32		84			

Heterogeneity: $Chi^2 = 4.04$, df = 5 (P = 0.54); $I^2 = 0\%$
Test for overall effect: Z = 5.04 (P < 0.00001)

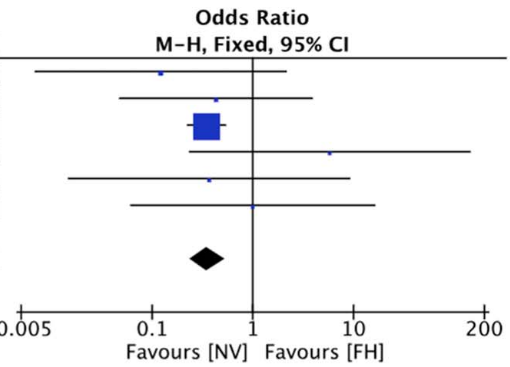

Figure 10. Postoperative revision of pedicle screws.

Study or Subgroup	NV Events	NV Total	FH Events	FH Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Ansari 2022	53	456	67	456	27.6%	0.76 [0.52, 1.12]
Bovonratwet 2017	55	1161	739	10950	63.0%	0.69 [0.52, 0.91]
Fichtner 2017	6	1112	18	1120	8.3%	0.33 [0.13, 0.84]
Konieczky 2019	1	12	1	10	0.5%	0.82 [0.04, 15.00]
Wang 2016 (1)	1	20	0	20	0.2%	3.15 [0.12, 82.16]
Wang 2016 (2)	2	20	1	20	0.4%	2.11 [0.18, 25.35]
Total (95% CI)		**2781**		**12576**	**100.0%**	**0.69 [0.56, 0.86]**
Total events	118		826			

Heterogeneity: $Chi^2 = 4.28$, df = 5 (P = 0.51); $I^2 = 0\%$
Test for overall effect: Z = 3.34 (P = 0.0008)

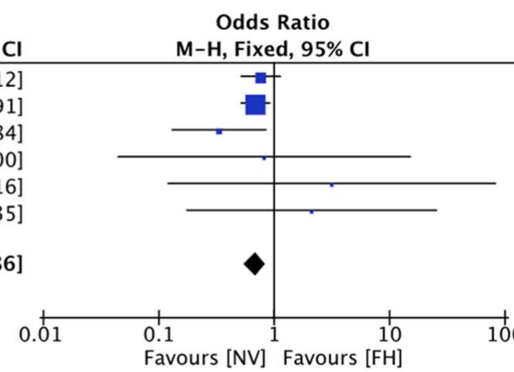

Figure 11. Systemic complications.

Study or Subgroup	NV Events	NV Total	FH Events	FH Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Amiot 2000	0	50	4	100	8.6%	0.21 [0.01, 4.02]
Chen 2019	1	21	0	24	1.3%	3.59 [0.14, 92.83]
Fichtner 2017	6	1112	18	1120	51.2%	0.33 [0.13, 0.84]
La Rocca 2022	2	91	4	101	10.6%	0.54 [0.10, 3.05]
Noriega 2016	1	58	0	56	1.4%	2.95 [0.12, 73.90]
Shin 2015	1	20	2	20	5.5%	0.47 [0.04, 5.69]
Wang 2016 (1)	1	20	1	20	2.7%	1.00 [0.06, 17.18]
Wang 2016 (2)	0	20	1	20	4.2%	0.32 [0.01, 8.26]
Wang 2018	0	20	2	21	6.8%	0.19 [0.01, 4.22]
Yang 2012	8	42	3	34	7.7%	2.43 [0.59, 9.99]
Total (95% CI)		**1454**		**1516**	**100.0%**	**0.60 [0.35, 1.03]**
Total events	20		35			

Heterogeneity: $Chi^2 = 8.75$, df = 9 (P = 0.46); $I^2 = 0\%$
Test for overall effect: Z = 1.84 (P = 0.07)

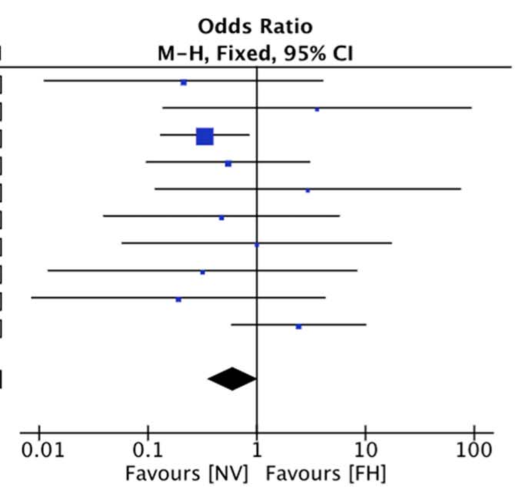

Figure 12. Neurological complications.

−52.24, $I^2 = 80\%$, $P < 0.0001$) (Fig. 7).

Pedicle screw accuracy in 22 studies. It was evaluated as the number of clinically acceptable screws (grade A+B) out of the total positioned screws. Pedicle screw accuracy was significantly higher in the NV group in comparison with the FH group (OR: 2.34, 95% CI: 1.52–3.59, $I^2 = 86\%$, $P = 0.0001$) (Fig. 8). Moreover, the positioning of the screws was clinically acceptable in 96.2% of the navigated group, and 94.2% with traditional techniques.

The rate of intraoperative pedicle screw revisions was assessed in seven studies. No difference was reported between the two groups regarding intraoperative screw revision (OR: 1.00, 95% CI: 0.28– 3.65, $I^2 = 87\%$, $P = 1.00$) (Fig. 9).

The rate of postoperative pedicle screw revisions was assessed in six studies, and it was significantly lesser in navigated surgeries compared with traditional (OR: 0.35, 95% CI: 0.24–0.53, $I^2 = 0\%$, $P < 0.00001$) (Fig. 10).

Six studies assessed systemic complications. The rate of systemic complications was significantly lower in the navigated group than in traditional surgeries (OR: 0.69, 95% CI: 0.56–0.86, $I^2 = 0\%$, $P = 0.0008$) (Fig. 11).

Neurological complications were assessed in 10 studies. The rate of neurological complications resulted lower in the NV group; however, without statistical significance compared with the FH group (OR: 0.60, 95% CI: 0.35–1.03, $I^2 = 0\%$, $P = 0.07$) (Fig. 12).

DISCUSSION

This study aims to compare intraoperative and postoperative outcomes of spinal fusion performed with image-guided navigation systems versus conventional techniques, to assess the effectiveness of navigation technology in spine instrumentation.

Pedicle screw accuracy represents a crucial outcome to be obtained in spinal surgery. Screws with clinically acceptable accuracy are classified as grade A or B according to the Gertzbein and Robbins classification.[46] Grade A corresponds to a screw completely contained within a pedicle, while grade B corresponds to a screw with a violation of the cortex of the pedicle of less than 2 mm. Regarding accuracy, this study highlighted a clear benefit of the NV ($P = 0.0001$), demonstrating the importance of navigation for the safe and effective positioning of pedicle screws. Previous meta-analyses have shown similar results, finding that screws fixed via navigational systems present a risk and rate of pedicle cortex breach lower than conventional techniques.[11,47,48] In spinal fusion, achieving high accuracy is essential to reduce the rate of complications and the number of intraoperative and postoperative revisions. Indeed, the results showed that the rate of postoperative revisions was significantly lesser in patients treated with the navigation technique ($P < 0.00001$). An analysis of hospital data by Watkins *et al*[49] showed a mean cost of revision surgery for screw malposition of $23,762. Similarly, Parker *et al*[50] and Adogwa *et al*[51] reported $32,915 and $23,865 as mean costs for revision procedures from retrospective data, respectively. Therefore, besides affecting the patient's physical well-being, it is plausible that reducing pedicle screw malpositions using an effective NV system can determine lower health care costs.[4] Furthermore, screws positioned with high precision lead to a decrease in operative and postoperative complications. This analysis found a lower neurological and systemic complication rate in patients with the navigated technique ($P = 0.07$ and 0.0008, respectively).

Regarding the operative parameters, it was demonstrated that the operative time is lesser with the conventional techniques; however, this data is not statistically significant ($P = 0.15$). This result is in line with other studies,[11,52] and it can be explained by considering the time needed to acquire CT scans or calibrate the instrumentation for intraoperative navigation, and the learning curve to use the device. Supporting this explanation, Meng *et al*[48] found a shorter screw insertional time in thoracic spine instrumentation using intraoperative navigation compared with fluoroscopy in their meta-analysis. Therefore, the operative time could be longer due to the navigation setting or the surgeons' learning curve.

Both blood loss and hospitalization days were significantly lower with the navigated technique than conventionals ($P < 0.0001$ and 0.0002, respectively). These results are likely due to the minimally invasive surgery performed using navigation systems. Navigation has increased spinal fusions performed through percutaneous approach, which allows reaching the vertebral segment with less damage to the soft tissues.[53,54] The minimally invasive technique in spinal fusion surgery is associated with both a reduction in blood loss and hospital days.[55,56]

In addition to the surgical and radiological aspects, this study aims to analyze the clinical outcomes. These aspects have only been assessed in five articles. The lack of studies analyzing these outcomes could affect the significancy of these results. The parameters included VAS back, VAS leg, and ODI. Although not statistically significant, these clinical scores appear better in patients undergoing interventions assisted by navigated systems. These results are also probably due to the lesser soft tissue trauma and shorter muscle retraction time with percutaneous approaches used in navigated surgery. Therefore, the large number of articles included and the several perioperative and postoperative clinical parameters analyzed are the main strengths of this meta-analysis. The main limitation of the study is represented by the low level of evidence of the included studies. Due to the design of the procedure, most studies were retrospective, while few RCTs were identified through the literature search. Moreover, a high heterogeneity was reported among the studies for the surgical indication and the surgical approach; despite this, it was not possible to perform a subgroup analysis. Furthermore, the forest plots showed heterogeneity of the data concerning the operative time and intraoperative revision outcomes. Several possible causes of heterogeneity may be suspected, such as differences in the surgeon's expertise or learning curve. These factors may have primarily influenced studies with a low number of patients.

CONCLUSION

Navigated pedicle screw fixation is a safe and effective technique, which has been shown to result in statistically significant higher screw accuracy, better intraoperative outcomes such as blood loss, lower complications, and better postoperative clinical outcomes such as hospital days and revisions in patients undergoing spinal fusion compared with conventional FH and FA techniques. VAS, ODI, and operative time did not show significant differences between the two different techniques.

➢ Key Points

- ❑ In the last decades, intraoperative navigation has been introduced in spinal surgery to prevent risks and complications. This study aims to compare pedicle screw accuracy, clinical outcomes, and complications between navigated and conventional techniques.
- ❑ The search was executed on Cochrane Central Library, PubMed, and Scopus on April 30, 2023. This meta-analysis included 30 studies for a total of 17,911 patients and 24,600 pedicle screws.
- ❑ Statistically significant results in favor of the navigated technique were observed for the accuracy of pedicle screws, hospital stay, blood loss, postoperative revision of pedicle screws, and systemic complications.
- ❑ No significant differences were found in VAS, ODI, and operative time between the two groups.
- ❑ Navigated pedicle screw fixation is a safe and effective technique with high improvement in clinical outcomes and accuracy in patients undergoing spinal fusion compared with conventional techniques.

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