Eur Spine J (2012) 21:247–255
DOI 10.1007/s00586-011-2011-3

ORIGINAL ARTICLE

Accuracy of pedicle screw placement: a systematic review of prospective in vivo studies comparing free hand, fluoroscopy guidance and navigation techniques

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Received: 18 January 2011 / Revised: 23 July 2011 / Accepted: 23 August 2011 / Published online: 7 September 2011

Abstract
Introduction With the advances and improvement of computer-assisted surgery devices, computer-guided pedicle screws insertion has been applied to the lumbar, thoracic and cervical spine. The purpose of the present study was to perform a systematic review of all available prospective evidence regarding pedicle screw insertion techniques in the thoracic and lumbar human spine.
Materials and methods We considered all prospective in vivo clinical studies in the English literature that assessed the results of different pedicle screw placement techniques (free-hand technique, fluoroscopy guided, computed tomography (CT)-based navigation, fluoro-based navigation). MEDLINE, OVID, and Springer databases were used for the literature search covering the period from January 1950 until May 2010.
Results 26 prospective clinical studies were eventually included in the analysis. These studies included in total 1,105 patients in which 6,617 screws were inserted. In the studies using free-hand technique, the percentage of the screws fully contained in the pedicle ranged from 69 to 94%, with the aid of fluoroscopy from 28 to 85%, using CT navigation from 89 to 100% and using fluoroscopy-based navigation from 81 to 92%. The screws positioned with free-hand technique tended to perforate the cortex medially, whereas the screws placed with CT navigation guidance seemed to perforate more often laterally.
Conclusions In conclusion, navigation does indeed exhibit higher accuracy and increased safety in pedicle screw placement than free-hand technique and use of fluoroscopy.

Keywords Pedicle screw · Free hand · Fluoroscopy · Fluoro-based · Computed tomography · Navigation

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Introduction

The advances of technology in terms of imaging have widened the field of image guidance in several surgical techniques. It is well established that image-guidance techniques have improved the clinical results in various fields such as knee, hip and spine surgery.

Computer-guided pedicle screws insertion was primarily applied to the lumbar spine. Classic free-hand technique for screw positioning is based on vertebral bone landmarks for screw insertion without the assistance of any intraoperative imaging as fluoroscopic guided technique uses a C-arm for screw insertion and positioning evaluation. Newer techniques such as computed tomography and fluoroscopy-based navigation were also introduced. With the advances and improvement of computer-assisted surgery devices, the application of pedicle screws has been expanded to the thoracic and cervical spine. This eliminated the need of multiple fluoroscopic images to update instrument positioning and also improved significantly pedicle screw insertion accuracy [1–5].

Because of close proximity to spinal canal and surrounding vessels, misplacement of pedicle screw can lead to disastrous complications, thus accurate and safe placement of the screw within the pedicle is a crucial step during surgery. High pedicle screw misplacement rates, various pedicle morphometry and vertebral body size variations have led to a search of image-guided systems to improve the surgical accuracy of pedicle screw insertion.

Although pedicle screw fixation is a well-established technique for the lumbar spine, pedicle screws have been used with caution in the thoracic spine due to its complex anatomy and the decreased pedicle dimensions. These unique characteristics of thoracic spine have highlighted the value of precision in pedicle placement during spine surgery. In vitro and in vivo studies in which conventional surgical techniques were used, have reported pedicle screw misplacement rates from 5 to 41% for the lumbar spine and 3–55% for thoracic spine [6–9]. It is generally shown that the percentage of incorrect placement of pedicle screws can be remarkably high. It is also believed that the extent of misplacement could be related to damage of the nervous elements [6]. Even experienced surgeons misdirect the screws medially in 5% and inferolaterally in 15% of the cases when using standard fluoroscopic imaging [10]. It has been shown that medial pedicle perforation more than 4 mm may endanger the neural elements presenting neurological deficits. Although there is not strong evidence in the literature ensuring that pedicle violation less than 2 mm is safe, most surgeons consider it as safe zone of pedicle perforation [11, 12]. Therefore, the importance of accuracy in screw placement meaning that the screw is fully included in the pedicle and there is no cortex violation has been recognized early.

Computed tomography-based navigation and fluoroscopic-based navigation with its two and three-dimensional options are the most popular spine navigation systems. These image-guided modalities have increased the pedicle screw placement accuracy and reduced the imaging intraoperative time and radiation exposure [1, 4, 10]. Recently, a trend of better accuracy in the thoracic spinal level with the assistance of computed tomography compared to the 2D fluoroscopy-based navigation has been reported [13].

The purpose of the present study was to perform a systematic review of the English literature prospective evidence regarding pedicle screw insertion techniques in the thoracic and lumbar human spine.

Materials and methods

Identification and eligibility of relevant studies

We considered all prospective in vivo clinical studies that assessed the results of pedicle screw placement techniques regardless of the etiology for surgery. All types of studies (case series, case control, randomized controlled trials) were considered eligible for the systematic review. A detailed description of the technique of screw insertion (free-hand technique, fluoroscopy guided, CT-based navigation, fluoro-based navigation) should be available. All studies should have a postoperative CT evaluation of pedicle screw placement with a detailed description of the grade of screw perforation. Cadaveric and animal studies as well as studies that used spine models and morphologic articles were excluded. Studies on pedicle screw placement at the cervical spine were also excluded, due to differences in cervical spine anatomy and the fact that mainly lateral mass and not pedicle screws are inserted in this area. However, we accepted studies that included instrumentation at the C7 and S1 vertebrae. We also accepted studies where the cervical spine was involved along with the thoracic and/or lumbar spine in case where we could obtain separate results for the thoracic-lumbar spine, excluding the cervical spine.

MEDLINE, OVID, and Springer databases were used for the literature search covering the period from January 1950 until May 2010. Only studies in the English language were included in the search. The search strategy was based on the combinations of the following key words: "pedicle", "screw", "spine", "lumbar", "thoracic", "accuracy", "computer assistance", "image guidance" and "navigation". Screening included titles, subtitles and abstracts. Additionally all references of the retrieved articles were also reviewed. Investigators were contacted and asked to supplement additional data and clarifications when key information was missing.

Data extraction

Two reviewers independently screened the titles and abstracts of all publications, which were obtained by the search strategy. All potentially eligible studies were obtained as full articles and were assessed independently for inclusion by the two reviewers. In doubtful or controversial cases, the reviewers discussed all identified discrepancies and reached consensus on all items. If consensus was not reached, they referred to the senior reviewer to solve the problem.

We extracted data on characteristics of studies and patients, measurements, and results. Specifically, the following data were collected: Type of study (case series, case control, randomized control trial), number of patients, indication for surgery, age, gender, type of screw placement methods used (free hand, fluoroscopy, CT-based navigation, and fluoro-based navigation), number and specific vertebral levels instrumented with pedicle screws, number of pedicle screws inserted, number of misplaced screws, grade of pedicle screw perforation, type of pedicle screw perforation (medial or lateral), type of interpretation of CT images (independent observer, surgeon), number and type of neurological complications.

Definitions and standardizations

The techniques of screw insertion that were evaluated in the present study were free-hand technique, fluoroscopy guided, CT-based navigation and fluoro-based navigation. Free-hand technique refers to the surgical technique that uses bone landmarks for screw insertion without the assistance of any imaging intraoperatively. In fluoroscopy-guided technique, we accepted studies regardless the type of fluoroscopy views used for screw insertion (AP, and/or lateral) and the time that these were used (before, during or after screw insertion). Computed tomography-based navigation refers to the use of optoelectronic navigators with the use of computed tomography scans to create a 3-dimensional image of the spine.

The grade of pedicle screw violation was classified into four groups: screws fully contained into the pedicle, perforated screws up to 2 mm misplacement (Grade A), 2–4 mm (Grade B), and greater than 4 mm misplacement (Grade C) [14]. This was the classification used by the vast majority of eligible studies. In only two studies, the grade was classified in groups of 0–3, 3–6 and >6 mm [15, 16]. In the first study, there were data on screws with 0–2 mm misplacement, and we were able to classify all screws into the four groups, while in the other study, there were no available data, therefore it was excluded. One study provided data for screws with medial perforation [17], whereas all remaining studies evaluated both medial and lateral perforation.

Results

Our literature search identified 85 possible eligible studies. Fifty-nine studies (68.6%) were omitted due to the fact that they did not fulfill the inclusion criteria. Therefore, 26 prospective clinical studies were eventually included in the analysis [4–6, 8, 15, 17–36] (Table 1).

These studies included in total 1,105 patients in which 6,617 screws were inserted. Specifically, there were 5 studies evaluating screw placement without image assistance. Computed tomography-based navigation was used in 5 of the studies, fluoroscopy guidance in 7 and fluoro-based navigation in 3 studies. Five studies were comparing the

Table 1 Clinical trials included in the analysis

	Author	Patients	Age	Level	Levels instrumented	No. of screws
1.	Rajan et al. [18]	17	19.6 (10–52)	Thoracic crews	12	242
2.	Modi et al. [19]	43	17.6 (9–41)	T1–T12	11	854
3.	Beck et al. [20]	95	54 (11–82)	T1–L5	16	414
4.	Karapinar et al. [21]	98	36.1 (13–73	T10–L3	5	640
5.	Wang et al. [22]	21	53.3 (22–77)	T9–L4	7	140
6.	Upendra et al. [23]	60	14.5 and 32.1	T1–T12	11	314
7.	Schizas et al. [15]	15		L2–S2	6	60
8.	Rampersaud et al. [24]	24		T10–L4	6	102
9.	Merloz et al. [25]	26 vs. 26		T10–L5	7	140 vs. 124
10.	Rajasekaran et al. [36]	17 vs. 16	19.6 vs. 15.4	T1–T12	11	236 vs. 242
11.	Rampersaud et al. [26]	45		T2–S1	16	360
12.	Vougioukas et al. [27]	41	70.2	T1–T12	11	328
13.	Kuntz et al. [28]	28	44 (19–94)	T1–T12	11	199
14.	Fu et al. [29]	12	59 (39–77)	T9–S1	9	66
15.	Halm et al. [30]	12		T10–L4	6	104
16.	Carl et al. [31]	8		T1–L5	16	32
17.	Laine et al. [32]	41 vs. 50	54 (22–82)	T8–S2	11	277 vs. 219
18.	Amiot et al. [5]	50	50.7	T2–S1	16	294
19.	Girardi et al. [33]	62		L1–S1	5	171
20.	Merloz et al. [34]	38 vs. 26		T10–L5	7	52 + 28
21.	Schwarzenbach et al. [8]	29		T11–S2	8	150
22.	Laine et al. [4]	30	47 (29–73)	L2–S1	4	152
23.	Laine et al. [32]	30 vs. 30	50 (29–73)	L2–S1	4	35 vs. 152
24.	Gastro et al. [6]	30		L2–S1	4	123
25.	Sim [17]	45		T8–S1	10	200
26.	Gertzbein and Robbins [14]	40		T8–S1	10	167

accuracy between an image-guidance technique and free-hand method, while one study was comparing navigation with fluoroscopy. In four of the seven studies [6, 15, 23, 27] where fluoroscopy guidance was used, only lateral views were obtained intraoperatively to confirm screw placement. In two studies, both AP and lateral views were used [28, 30], while 3D fluoroscopy was used in one study [20].

A total number of 240 spine levels were assessed among the included studies (range from 3 to 16 levels) (Table 1). In 14 studies both thoracic and lumbar levels were evaluated. In six studies only the thoracic levels were instrumented, while in five studies pedicle screws were inserted in the lumbar spine. In the remaining study, pedicle screw accuracy placement was assessed in the cervical and thoracic spine. Though, the data referring to the thoracic spine were independently presented and therefore only these data were included in our analysis. Sacral vertebrae were instrumented in 12 of the studies with the S2 level being instrumented in two studies.

From 6,617 screws in 1,105 patients, 2,412 screws were placed with free-hand technique in 362 patients, 1,902 screws with the use of fluoroscopic guidance in 323 patients, 1,635 screws were inserted with the aid of CT-based navigation system in 313 patients and 668 screws were inserted with the use of fluoroscopy-based navigation system in 107 patients.

In all 26 studies, postoperative CT scan was used to assess the accuracy of pedicle screw placement (Table 2). In 16 studies, an independent observer evaluated the CT images, while in 2 studies the evaluation was performed by one of the surgeons. In eight studies, there were no data regarding who was reading the CT images. In the studies using free-hand technique, the percentage of the screws fully contained in the pedicle without perforation ranged from 69 to 94%. In the studies where the screws were placed with the aid of fluoroscopy a range from 28 to 85% was reported. The percentage of screws fully contained into the pedicle in the studies using CT navigation was significantly higher, ranging from 89 to 100%. Similar results were reported in studies where fluoroscopy-based navigation was used with 81–92% of screws fully included in the pedicle. In the comparative studies, the number of CT navigation guided screws fully included in the pedicle ranged from 90 to 95% compared with the range from 57 to 86% for the screws without imaging guidance.

When evaluating the position of perforation, in the studies using free-hand technique, a range from 32 to 87% was found for medial perforation compared to 12–67% for lateral perforation. When fluoroscopy was used, the pedicles were perforated medially in a percentage ranged from 14 to 100% and laterally from 16 to 79%. In patients where CT navigation was used the proportion of screws medially perforated was significantly increased ranging from 8 to 29%, compared to the percentage of screws with lateral perforation with a range from 29 to 80%. In the studies evaluating fluoroscopy-based navigation, there was no difference between medial and lateral perforation proportion with medial ranging from 37 to 80% while lateral ranged from 20 to 63%.

In relation to the grade of perforation, when free-hand technique was used, most of the screws were grade A (range 7–71%). The percentage of screws with grade B perforation ranged from 15 to 46%, while grade C perforated screws ranged from 12 to 46%. In studies where CT navigation was used, there was a 42–100% range of grade A violation, 12–57% grade B violation and 12–31% grade C violation. When the screws were instrumented with the use of fluoroscopy technique screws with grade A perforation represented the largest proportion with a range from 25 to 100%. Grade B ranged from 10 to 53% and grade C ranged from 2 to 40%. In studies evaluating fluoroscopy-based navigation, most of the perforated screws were grade A (range 60–85%), as grade B and grade C screws were significantly less with a range from 13 to 40% and 2 to 10%, respectively.

When assessing the number of screws exceeding 4 mm violation (Grade C), it was interesting that in studies using navigation, the percentage ranged from 0 to 3.3% for CT navigation and 0 to 2% for fluoroscopy-based navigation. In contrast, the percentage of grade C screws in studies without navigation systems ranged from 1 to 6.5%, while in studies using fluoroscopy the range was 0–40%. Furthermore, the percentage of screws that were fully included in the pedicle plus these that had less than 2 mm cortex violation ranged from 80 to 97% for free-hand technique, 93–100% for CT navigation, 71–100% for fluoroscopy technique and 95–97% for fluoroscopy-based navigation.

In all studies, 24 patients presented with neurological complications. In free-hand technique studies, eight patients developed complications such as L5 root irritation (two patients), paresis and headache (one patient). In fluoroscopy group studies, eight patients had a degree of neurological deficit such as paresis or paresthesia. In three patients the symptoms resolved without surgery and in the five patients remaining surgery was required. Eight patients developed neurological symptoms when CT navigation was used. Six presented with transient ischialgic pain, two with dysesthesia, as in five patients symptoms resolved and only one patient required re-operation. On the contrary, none of the 107 patients in the fluoro-based navigation group presented with neurological deficit.

Discussion

The advantages of transpedicular screw fixation prevent the need of placing instrumentation within the spinal canal,

Table 2 Outcomes of the trials included in the analysis

Author	Method of navigation	Accurate positioned (%)	Perforation	Medial perforation	Lateral perforation	Other perforation	Grade A 0–2 mm (%)	Grade B 2–4 mm (%)	Grade C >4 mm (%)	Neurological symptoms
Modi et al. [19]	Free hand	586 (69)	268	88 (32.8%)	180 (67.2%)	0	147 (54.8)	81 (30.2)	40 (14.9)	0
Karapinar et al. [21]	Free hand	603 (94)	37	12 (32.4%)	18 (48.6%)	7 (19.0%)	19 (51)	11 (30)	7 (19)	0
Laine et al. [4]	Free hand	120 (79)	32	9 (28.1%)	15 (46.8%)	8 (25.1%)	4 (66) vs. 3 (60)	2 (33) vs. 1 (20)	0 vs. 1 (20)	0 vs. 1/30 (3.3)
Sim [17]	Free hand	183 (92)	17	13 (76.4%)	4 (23.6%)	0				
Gertzbein and Robbins [14]	Free hand	119 (71)	48	42 (87.5%)	6 (12.5%)	0	16 (38)	15 (36)	11 (26)	2/40 (5)
Vougioukas et al. [27]	Fluoroscopy 2D	255 (78)	73	73 (100%)	0	0	92 (64)	34 (24)	18 (12.5)	0
Kuntz et al. [28]	Fluoroscopy 2D	55 (28)	144	27 (18.8%)	114 (79.2%)	3 (2.0%)	3 (60)	2 (40)	0	0
Upendra et al. [23]	Fluoroscopy 2D	156 (50)	158	90 (57.0%)	54 (34.2%)	14 (8.8%)	68 (47)	36 (25)	40 (28)	2/60 (3.3)
Schizas et al. [15]	Fluoroscopy 2D	30 (50)	30	7 (23.3%)	14 (46.7%)	9 (30%)	25 (83)	3 (10)	2 (6)	1/30 (6.7)
Halm et al. [30]	Fluoroscopy 2D	85 (82)	19	4 (21.1%)	10 (52.6%)	5 (26.3%)	0	0	0	0
Gastro et al. [6]	Fluoroscopy 2D	74 (60)	49	35 (71.4%)	14 (28.6%)	0	1 (7)	6 (46.1)	6 (46.1)	0
Beck et al. [20]	Fluoroscopy 3D	323 (78)	91	36 (39.5%)	55 (60.5%)	0	71 (78)	18 (20)	2 (2)	0
Schwarzenbach et al. [8]	CT navigation [Orthopaedic Surgery Planning System (OSPS)] (Optotrak 3020; Northern Digital, Waterloo, Ontario, Canada)	133 (89)	17	5 (29.4%)	10 (58.9%)	2 (11.7%)	23 (71.8)	5 (15.6)	4 (12.5)	1/30 (3.3)
Girardi et al. [33]	CT navigation (Stealth navigation system, Microsoft Inc, Redmond, Washington)	171 (100)	0	0	0	0	4 (50) + 7 (32)	3 (38) + 12 (55)	1 (12) + 3 (14)	0
Carl et al. [31]	CT navigation (GE navigational research computer software GE Medical Systems, Milwaukee, WI, USA)	32 (100)	0	0	0	0	8 (80) vs. 26 (70)	2 (20) vs. 7 (19)	0 vs. 4 (11)	0 vs. 2/50 (4)
Rajan et al. [18]	CT navigation (computer navigation platform-Vector Vision (Spine version 2.0 Brain Lab, Germany)	216 (89)	26	2 (7.6%)	15 (57.7%)	9 (34.6%)	10 (38)	8 (31)	8 (31)	0
Wang et al. [22]	CT navigation (optoelectronic navigator, VectorVision® Spine, Brain LAB GmbH, Kapellenstr. 12, 85622 Feldkirchen, Germany)	135 (96)	5	1 (20%)	4 (80%)	0	5 (100)	0	0	0
Laine et al. [32]	CT vs. free hand SurgiGATE Spine 2.1, Medivision, Oberdorf, Switzerland	209 (95.4) vs. 240 (86.6)	10 vs. 37	1 vs. 21	9 vs. 9	0 vs. 7	16 (100)	0	0	2/50 (4)
Amiot et al. [5]	CT vs. free hand retrosp (not incl) (Navitrack computer system Sulzer Orthopedics, Baar, Switzerland)	278 (94.5)	16	8 (50%)	4 (25%)	4 (25%)	0	0	0	0
Merloz et al. [34]	CT vs. free hand (Stealth Station system (Sofamor-Danek, Memphis, TN)	72 (90) + 30 (57.6)	8 vs. 22	3 vs. 8	4 vs. 9	1 vs. 5	13 (76)	2 (12)	2 (12)	6/29 (20.6)

Table 2 continued

Author	Method of navigation	Accurate positioned (%)	Perforation	Medial perforation	Lateral perforation	Other perforation	Grade A 0–2 mm (%)	Grade B 2–4 mm (%)	Grade C >4 mm (%)	Neurological symptoms
Laine et al. [32]	CT vs. free-hand CT scanning (Picker PQ 2000, Cleveland, Ohio and Ce~ max workstation, Cemax VIP 1.7 software, Fremont, Calif.)	133 (95.6) vs. 30 (85.7)	6 vs. 5	0 vs. 3	6 vs. 1	0 vs. 1	33 (67)	7 (14)	9 (18)	5/30 (16.6)
Fu et al. [29]	Fluoroscopic-based navigation VectorVision2 Fluoro (BrainLAB, Inc., Munich, Germany)	61 (92)	5	4 (80%)	1 (20%)	0	9 (47)	10 (53)	0	0
Rampersaud [24]	Fluoroscopic-based navigation (FluoroNav-Medtronic Surgical Navigation Technology, Louisville, CO)	83 (81)	19	7 (36.8%)	12 (63.1%)	0	14 (74)	3 (16)	2 (10)	0
Rampersaud et al. [26]	Fluoroscopic-based navigation FluoroNavTM system (Medtronic Surgical Navigation Technologies, Louisville, CO)	305 (85)	55	25(45.5%)	30 (54.5%)	0	73 (100)	0	0	0
Rajasekaran et al. [36]	Fluoroscopy 3D vs. CT navigation SIREMOBIL Iso-C3D C-arm (Siemens, Medical Solutions, Erlangen, Germany)	144 (61) vs. 235 (97)	92 vs. 7	13 vs. 2	15 vs. 2	64 vs. 3	45 (85)	7 (13)	1 (2)	0
Merloz et al. [25]	Fluoroscopic-based navigation vs. fluoroscopy 2D [three-dimensional optical localizer (Polaris system; Northern Digital; Ontario; Canada) and workstation computer (Fluologics system, Praxim, France)]	133 (95) vs. 106 (85.4)	7 vs. 18				5 (71) vs. 4 (22)	2 (29) vs. 14 (78)	0 vs. 0	0

provides three column purchace which minimizes via a stable construct the percentage of pseudarthrosis and enhances the operative correction in deformity surgery [37–39].

The literature does not lack of studies that evaluate the accuracy of pedicle screw placement with different guidance methods [2–6, 8, 10–12, 16]. There are three meta-analyses published in the field of pedicle screw accuracy [13, 40, 41]. Although these studies contribute significantly in the field, there are some issues that lead us to the selection of our inclusion criteria. All these studies include studies with retrospective analysis of the screw placement. Their main disadvantage remains the higher risk of bias that limits the level of evidence. Furthermore, Kosmopoulos et al. [40] and Tian et al. [13] include cadaveric studies in their inclusion criteria. In these studies, the results obtained from the in vitro operations were significantly different to those of clinical studies. We included only prospective in vivo patient studies of pedicle screw accuracy insertion which was evaluated postoperatively with the use of computer tomography, as the exact position of pedicle screws can be determined with this method of imaging.

Our study indicates that navigation exhibits higher accuracy than free-hand technique and fluoroscopy. Specifically, CT navigation seems to have the highest accuracy compared to the other techniques evaluated. These results are also in accordance with the data provided by the comparative studies included in our analysis, where CT navigation provided superior accuracy (as measured by screws fully included to the pedicle compared to free-hand technique). Most of the studies evaluating pedicle screw insertion have shown superiority of the navigation systems in accurate placement comparative to the conventional methods. Recent meta-analyses [40, 41] in the field clarify the existing vague impression for the usage of the imaging guidance techniques.

In our study, we identified some differences in outcome among the different studies in certain techniques. These differences are usually associated with the heterogeneity among these studies resulting from different patient demographic characteristics and different indications for surgery. Furthermore, technical issues, such as differences in surgeons' skills, varying complexity of surgery and screw/pedicle dimensions could be responsible for this issue [13, 28, 41].

One important finding of our review is that the screws positioned with free-hand technique tend to perforate the cortex medially, whereas the screws placed with CT navigation guidance seem to perforate more often laterally. To our knowledge, there is no previous correlation of a specific technique used to the location of cortex violation (medial or lateral). Normally if the unintended perforations using CT navigation would be the result of the inherent inaccuracy of the navigation system, the perforations should be randomly distributed medially and laterally. The explanation for a preponderance of lateral perforations in CT-based navigation could be the difference between the longitudinal midline axis of the pedicle (ideal screw trajectory) and the anatomically feasible axis. To avoid too close contact to the facet joint, the surgeon accepts in some cases a lateral perforation, i.e. those are intended perforations. This is unavoidable especially, in cases where the screw diameter is very close or even bigger than the diameter of the isthmus of the pedicle. In certain studies, a correlation between medially malpositioned screws and neurological complications has been proposed [42, 43]. Therefore, the increased safety proven when navigation techniques are used could be related not only to the more accurate screw positioning, but also to the lateral cortex violation is related with less neurological complications.

The importance of accurate screw placement has been highlighted on the base of increased complication rate in cases where the screws were significantly displaced. For this reason, the perforation is classified into grades in accordance to the degree of cortex violation. For the same reason, the term safe zone was imported, but there is not scientific proof that any extent of perforation is acceptable. The different techniques exhibit various results regarding the grade of perforation. In addition, the percentage of screws that had a perforation of 2 mm was not higher than 7 and 5% for the CT and fluoroscopic navigation, respectively. In contrast, the same percentage in studies using fluoroscopy is 28% and when free-hand technique is used this percentage is up to 19%. Our findings confirm that navigation systems provide higher accuracy for pedicle screw placement, since the percentage of screws graded as C (more than 4 mm violation) was also considerably lower in both CT and fluoroscopy-based navigation compared to the other techniques.

The neurological complication rate was found to be similar in the studies using CT navigation, free-hand technique and fluoroscopy. In the studies using fluoroscopy-based navigation, there were no neurological complications reported. Although the number of complications was relatively small to obtain safe results regarding the correlation between the technique used and the neurological complications observed, there was no significant difference between the technique used and the complication rate. This is in accordance to the literature that the use of navigation systems has not proved yet to decrease the neurological complication rate [44]. Some studies suggest an association between the degree of spinal canal penetration and the frequency of neurological symptoms [45]. Our results did not show any correlation between the degree of screw malposition and neurological complications, as reported by similar studies in the field [15].

Some limitations of the present study should be acknowledged. Mainly, we had to deal with remarkable heterogeneity regarding the arms of comparison between the available evidence. This heterogeneity precluded statistical analyses in our systematic review and resulted to the descriptive format of our study. Other limitations include the heterogeneity of the study population, the indication of surgery and the different spine levels instrumented. Heterogeneity may also be a result of surgeon's skills and assessment of pedicle screw length and diameter. However, we tried to eliminate this issue by including only in vivo prospective studies and as many as possible randomized studies, as they provide the strongest evidence for meta-analysis. The small number of pedicles inserted with fluoro-based navigation method could also be a factor of heterogeneity in our different groups.

In conclusion, navigation does indeed exhibit higher accuracy in pedicle screw placement than free-hand technique and use of fluoroscopy. The results of the present study are in alliance with the literature. Our study confirms the improved accuracy in screw positioning when navigation assistance is used. The increased safety due to the usage of the navigation systems is attributed not only to the aforementioned more accurate screw positioning, but also to lateral cortex violation, that is related with less neurological complications.

Conflict of interest The authors have no conflict of interest to declare.

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