Does Navigation Improve Pedicle Screw Placement Accuracy? Comparison Between Navigated and Non-navigated Percutaneous and Open Fixations

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Abstract

Background

The aim of our study was to assess how a preoperative computed tomography (CT)-based navigation system affected the correctness and safety of transpedicular screw insertion, compared with standard techniques.

Method

Between January 2012 and February 2014, 203 patients underwent thoracic and lumbar fixation, with open and percutaneous techniques; 218 screws were implanted through an open navigated technique (1.0 Spine & Trauma 3d ver. 2.0 BrainLab, Feldkirchen Germany) in 43 patients; 220 screws were inserted with an open free-hand technique in 45 patients; 230 screws were implanted in 56 patients using percutaneous CT-based navigation; and 236 screws were inserted in 59 patients using a percutaneous fluoroscopy-guided technique. To our knowledge, this is the first work comparing these four different techniques. The position of each screw was evaluated on CT scan reconstruction and classified according to a four-point grading scale (grade 0: no breach, grade 1: breach < 2 mm, grade 2: breach between 2 and 4 mm; grade 3: breach >4 mm). Statistical analysis was assessed by two-way analysis of variance (ANOVA) *t* test, while the Fisher least significant difference (LSD) method was employed to determine statistical significance.

Results

Statistical analysis showed a significant difference in accuracy between the open CT-based navigation and the percutaneous CT-based navigation techniques ($P= 0.0263$) and between the open CT-based navigation and the percutaneous fluoroscopy-guided techniques ($P=0.0258$): a particular difference was observed in anterior misplacement between open CT-based navigation and the percutaneous fluoroscopy-guided technique ($P= 0.0153$).

Conclusions

Our results confirm the advantages of the navigation technique, which ensures greater accuracy, in open as well as percutaneous procedures.

Keywords Percutaneous pedicular screw fixation • Free-hand pedicular screw fixation • Fluoroscopy-guided pedicle screw fixation • Spinal CT-based navigation system • Pedicle screw accuracy

Introduction

Pedicle screw fixation techniques are progressively improving in terms of less invasivity and greater safety and accuracy. Advances in percutaneous techniques allow a less traumatic approach, resulting in improved short- as well as long-term results. Safety in transpedicular screw fixation especially concerns violation of the cortical bone of the pedicles and vertebral bodies that can potentially lead to the damage of neurovascular structures. Misplacement of the screws can also threaten the grip of the implant [11].

Many attempts have been made in order to improve insertion accuracy. Among these, computed tomography (CT)-based navigation seems to be the most reliable, due to visualization of the precise anatomy, as well as reduced radiation exposure.

The aim of this study was to compare the efficacy and reliability of an open free-hand technique, an open navigated technique (BrainLab® System), a percutaneous CT-based navigation technique, and a percutaneous fluoroscopy-guided technique.. To our knowledge this is the first work comparing these four different techniques applied in the same period by the same surgical team.

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Materials and Methods

Between January 2012 and February 2014, 203 patients (115 females, 88 males) underwent thoracic and lumbar fusion with percutaneous (Viper 2 System, DePuy Synthes Spine, Raynham, MA) and open pedicle screw (Expedium 5.5 System, DePuy Synthes Spine, Raynham, MA) instrumentation carried out by the same neurosurgical team.

Indications for instrumentation were for degenerative pathologies (166 patients; spondylolisthesis with or without stenosis, post-laminectomy syndrome, twice-recurrent disc herniation), unstable fractures (25 patients), tumors (10 patients), aneurysmal cyst (1 patient), and inflammatory lesion (1 patient).

Two hundred and eighteen pedicle screws were implanted in 43 patients (21 females, 22 males) of average age 56.5 years (range 20–79 years) using open CT-based navigation (1.0 Spine & Trauma 3D ver. 2.0 BrainLab®) (ON group); 220 screws were implanted in 45 patients (21 females, 24 males) of average age 53.8 years (range 19–75 years) using an open free-hand technique (O group); 230 screws were implanted in 56 patients (35 female, 21 males) of average age 60.2 years (range 25–81 years) using percutaneous CT-based navigation (1.0 Spine & Trauma 3D ver. 2.0 BrainLab®) (PN group); and 236 screws were implanted in 59 patients (38 females, 21 males) of average age 59 years (range 16–78 years) using a percutaneous fluoroscopy-guided technique (P group).

Distribution of screws in all groups is shown in Table 1.

All patients were operated in the prone position on a carbon-top radiolucent table.

For patients in in the ON and PN groups a preoperative CT scan (CT scan 24-multislice GE Healthcare, Little Chalfont, UK) was performed in the prone position and transferred to the computer navigation platform which reconstructed data to provide real-time intraoperative three-dimensional images of the vertebra.

In the O and P groups, screws were implanted according to the Roy-Camille technique [28]. The procedure in the P group was assessed using the C-arm in a step-by-step fashion, while in the O group, we performed just a final check at the end of the procedure with the C-arm.

Postoperative CT scans with sagittal and coronal reconstruction were performed in each patient. The position of each screw was reviewed by a neurosurgeon and a radiologist uninvolved in the procedure and classified according to a four-point grading scale: grade 0 (screws fully contained in the pedicle); grade 1 (perforating screws, up to 2 mm misplacement); grade 2 (perforating screws, between 2 and 4 mm misplacement); and grade 3 (perforating screws, greater than 4 mm misplacement) [25] (Fig. 1).

Statistical relationships between various groups were assessed by two-way analysis of variance (ANOVA) *t*-test, while the Fisher least significant difference (LSD) method was employed for determining statistical significance. Significance was defined as $P < O = 0.05$.

Results

Thoracic pedicle screws were not included in the analysis, because the low number did not allow any statistical analysis.

Screw distribution, according to the Neo classification [24], is shown in Table 2.

Table 1 Distribution of screws

Level	Group ON	Group O	Group PN	Group P
D4				2
D5		2		
D6		2	2	2
D8			4	
D10	2		2	2
D11			2	4
D12	2	2	6	12
L1		2	2	12
L2	10	8	10	20
L3	28	18	26	16
L4	64	64	84	72
L5	80	78	82	78
S1	32	44	10	16
Total	218	220	230	236

ON open computed tomography (CT)-based navigation, *O* open free-hand, *PN* percutaneous CT-based navigation, *P* percutaneous fluoroscopy-guided

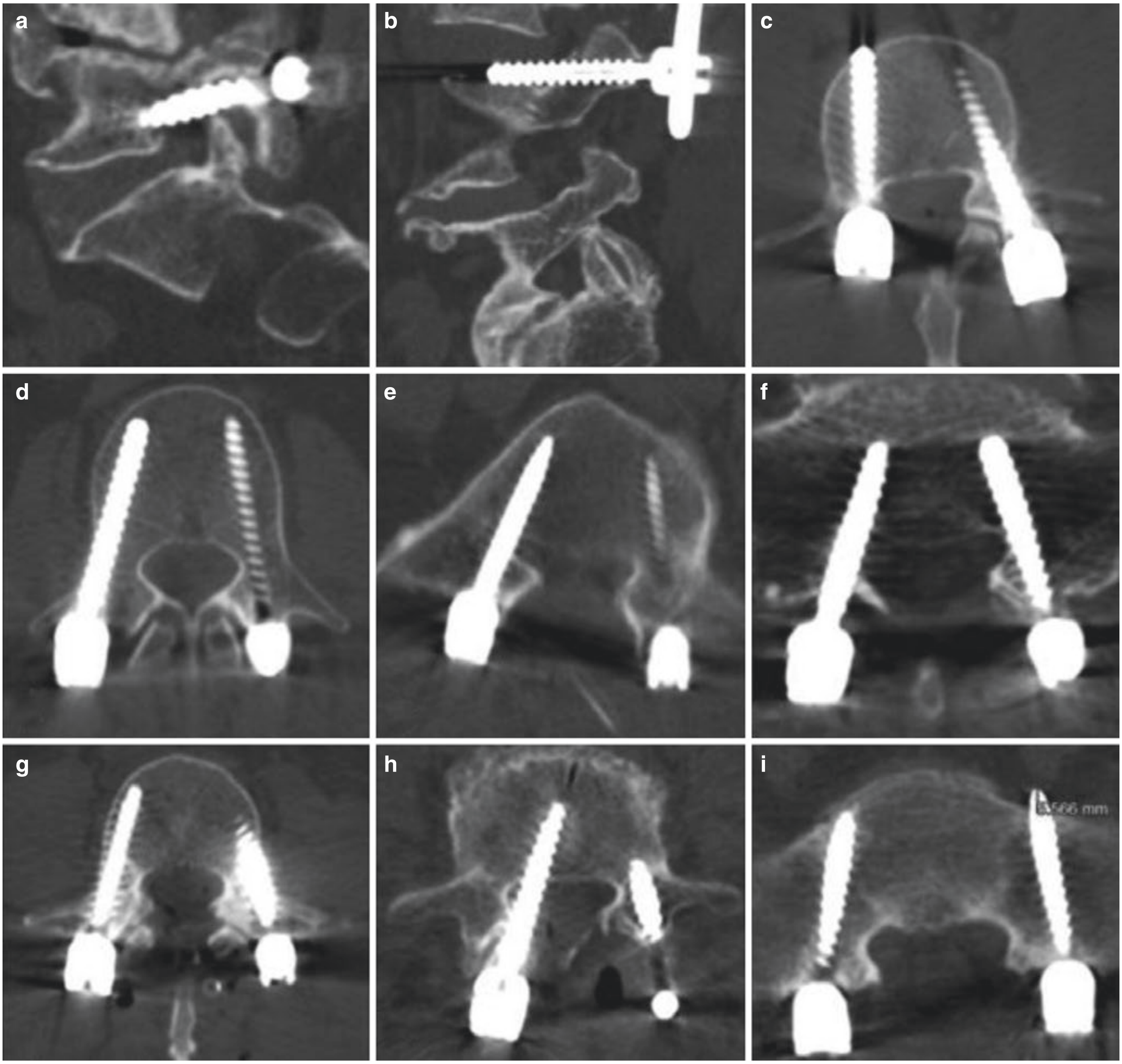

Fig. 1 Examples of grade 1 screw misplacement (**a** caudal, **b** cranial, **c** anterior, **d** lateral, **e** medial); grade 2 misplacement (**f** medial, **g** lateral); and grade 3 misplacement (**h** medial, anterior)

Statistical analysis of collected data showed a significant difference in accuracy between the ON and PN groups (*P*: 0.0263) and between the ON and *P* groups (*P*: 0.0258): a particular difference was observed in anterior misplacement between the ON and *P* groups (*P*: 0.0153) (Table 3).

We also considered each single vertebra, but we found no significant differences (Table 4).

Complications are shown in Table 5.

Discussion

Surgical landmarks and fluoroscopy have been used routinely for pedicle screw insertion, but a number of studies reveal inaccuracies in placement using these conventional techniques (inaccuracies range from 14 to 55 %, with as many as 7 % of these misplaced screws resulting in neurological injuries) [1, 21–23, 25, 38].

Table 2 Direction of breaches in lumbar vertebrae

Screw placement	Group ON	Group O	Group PN	Group P
Lateral axial/coronal				10 (4.7 %)
Grade 1			6 (2.8 %)	3 (1.4 %)
Grade 2	4 (1.9 %)	2 (0.9 %)	1 (0.5 %)	1 (0.5 %)
Grade 3	1 (0.5 %)	2 (0.9 %)	2 (0.9 %)	
Medial axial/coronal	1 (0.5 %)		8 (3.7 %)	7 (3.3 %)
Grade 1			5 (2.3 %)	3 (1.4 %)
Grade 2			2 (0.9 %)	8 (3.7 %)
Grade 3				
Anterior axial	4 (1.9 %)	11 (5.1 %)	8 (3.7 %)	10 (4.7 %)
Grade 1		1 (0.5 %)		4 (1.9 %)
Grade 2		2 (0.9 %)		6 (2.8 %)
Grade 3				
Caudal sagittal/coronal	5 (2.3 %)			2 (0.9 %)
Grade 1				1 (0.5 %)
Grade 2				
Grade 3				
Cranial sagittal/coronal	1 (0.5 %)			1 (0.5 %)
Grade 1				
Grade 2				
Grade 3				

ON open CT-based navigation, *O* open free-hand, *PN* percutaneous CT-based navigation, *P* percutaneous fluoroscopy-guided

Table 3 Statistical analysis of differences in lumbosacral screw misplacement according to placement method

	Total misplaced screws (p value)	Anterior misplacement (p value)	Lateral misplacement (p value)	Medial displacement (p value)	Caudal misplacement (p value)	Cranial misplacement (p value)
Group ON vs Group O	0.580	0.214	0.742	0.423	0.423	0.423
Group ON vs Group PN	**0.0263**	0.423	0.184	0.0848	0.423	0.423
Group ON vs Group P	**0.0258**	**0.0153**	0.188	0.0599	0.635	1
Group O vs Group PN	0.204	0.0742	0.370	0.102	—	—
Group O vs Group P	0.0641	0.321	0.289	0.0591	0.225	0.423
Group PN vs Group P	0.0742	0.0742	0.370	0.729	0.225	0.423

ON open CT-based navigation, *O* open free-hand, *PN* percutaneous CT-based navigation, *P* percutaneous fluoroscopy-guided, statistical significative P values in bold type

Table 4 Statistical analysis for each vertebra

	L2	L3	L4	L5	S1
Group ON vs Group O	0.182	0.229	1	0.769	0.291
Group ON vs Group PN	1	0.664	0.0917	0.839	0.340
Group ON vs Group P	0.127	0.508	0.252	0.948	0.426
Group O vs Group PN	0.182	0.0917	0.138	0.391	0.323
Group O vs Group P	0.124	0.860	0.201	1	0.373
Group PN vs Group P	0.206	0.495	0.435	0.866	0.0577

ON open CT-based navigation, *O* open free-hand, *PN* percutaneous CT-based navigation, *P* percutaneous fluoroscopy-guided

Table 5 Complications

	Group ON	Group O	Group PN	Group P
Transient neurological deficit	1	1		
Superficial wound infection (debridement and antibiotics)		2		
Superficial wound infection (antibiotics)	2			
Deep wound infection	1			
Prolongation of stabilization	1	2		1
Replacement because of pain			1 (after 1 week) L4 medial displacement grade 3	1 (intraoperative) D12 medial displacement grade 3 1 (after 1 week) L5 medial displacement grade 3 1 (after 2 months) L5 medial displacement grade 3 2 (after 2 days) L5 medial displacement grade 3 and L4 medial displacement grade 3

ON open CT-based navigation, *O* open free-hand, *PN* percutaneous CT-based navigation, *P* percutaneous fluoroscopy-guided

Spinal navigation was introduced in 1995 in order to improve the accuracy of pedicle screw insertion and thereby minimize the risk of neurovascular injuries [25]. In a number of published studies, the use of image guidance has been reported to consistently reduce pedicle breaches to less than 5 % [14, 15, 25, 26, 31, 37].

Our accuracy rate for lumbar and sacral vertebrae with the open free-hand technique was 91.1 %, which is comparable to the literature data (range from 69 to 94 %) [10]; we found no case of grade 3 medial misplacement; only 2 cases (0.9 %) showed an anterior breach of more than 4 mm, and this was not accompanied by neurological or vascular injury.

The open CT-based navigation technique showed an accuracy of 92.5 %, which is comparable to the literature data (range from 72.03 to 95.68 %) [32, 35]. We found no case of grade 3 misplacement. In only one case we observed a transient neurological deficit.

Our accuracy rate for lumbar and sacral vertebrae with the percutaneous fluoroscopy-guided technique was 73.8 %. Accurate minimally invasive pedicle screw placement is complicated, however, by the obscuring of normal anatomical landmarks [40]. Errors in placement are therefore a primary concern, with one study reporting almost 10 % of patients needing revision surgery [27]. We reported 16 cases (7.5 %) of grade 3 misplacement, of which 8 cases (3.7 %) showed medial breach, 6 cases (2.8 %) anterior breach, 1 case (0.5 %) lateral breach, and 1 case (0.5 %) inferior breach. Only four medial screws were replaced for irritative pain in the period from the first postoperative day to 2 months after surgery. We found no permanent neurological deficit or construction failure related to screw misplacement.

The percutaneous CT-based navigation technique showed an accuracy of 85 %. Jako et al. [40] reported an accuracy rate of 64.9 % for screws placed with electromagnetic field guidance vs. 40 % for screws placed with fluoroscopy. We reported four cases (1.9 %) of grade 3 misplacement, of which two cases (0.9 %) showed medial breach and two cases (0.9 %) lateral breach. Only one medial screw was relocated for irritative pain, after 1 week. We found no permanent neurological deficit or construction failure related to screw misplacement.

The potential for neurological risk is due to the intrinsic anatomy inherent to screw placement and anatomical variability among patients. Gertzbein et al. [11] postulated a 4-mm safe zone for medial misplaced screws in the lower back region, this being without neurological complications. Even in patients with medial and lateral grade 3 misplacement no neurological deficits were observed: this may be explained in the light of the degenerative spine, which has a different threshold for nerve root irritation.

In our series, the accuracy of placement over all lumbar and sacral segments was slightly better in the open CT-based navigation group than in the conventional open free-hand group, but this difference was not statistically significant (*P*: 0.580).

However, we noted an advantage with statistical significance for the open CT-based navigation technique compared with the percutaneous CT-based navigation (*P*: 0.0263) and percutaneous fluoroscopy-guided techniques (*P*: 0.0258).

One important finding of our study is that screws positioned with the open CT-based navigation technique compared with the percutaneous fluoroscopy-guided technique (*P*: 0.0153) tended to perforate the cortex anteriorly, especially for L5 (2/4 L5screws in group ON, 12/20 L5 screws in group *P*), probably due to difficult evaluation of fluoroscopic bidimensional images in the lateral view and due to the shape of L5, which is similar to S1 with a reduction of the lateral diameter of the body.

Gelalis et al. [10] found that screws placed with CT navigation guidance seemed to perforate the lateral cortex more often, differently from screws placed with a free-hand technique, which tended to perforate the cortex medially. Our data did not confirm such a statistically significant difference, but we noted a more medial trajectory in the percutaneous groups than in the open groups.

In comparison with the percutaneous technique, we found that the open technique showed five cases of wound infection, due to the significant exposure of the posterior bony elements of the spine and significant amounts of blood loss [16, 40].

These data confirm the superiority of the navigation technique, which ensures greater accuracy, above all for the percutaneous procedure, probably because of the poor quality of the fluoroscopy images (especially for obese patients); our data also reinforce the superiority of percutaneous vs. open techniques with regard to less damage to the surrounding muscles, less blood loss, less postoperative back pain, and shorter recovery time.

Although image-guided surgical techniques have resulted in lower perforation rates (ranging from 9.3 to 14.3 %), these technologies have their limitations [2–9].

Inaccuracies could also be associated with lack of correspondence between preoperative CT, acquired in the standard supine position, and the intraoperative prone position, especially in cases of severe instability and isthmic lysis. In order to reduce these inaccuracies, we started to perform preoperative CT scanning in the prone position, mimicking the position in the operation room. Although intraoperative CT scanning could be useful in screw placement, this device is not still available in every operation room, due to its high cost. Moreover, it is mandatory to consider the radiation exposure for operative staff, which is significantly higher with intraoperative CT scanning than with standard and neuronavigated techniques.

We also noted an inaccuracy in a patient with intraspinous devices from a previously implanted fixation system, due to anatomical distortion.

Intraoperative CT scanning has recently been introduced to bridge the gap between preoperative and intraoperative position-dependent changes [5, 12, 17–21, 23]. Moreover, this CT scanning offers the possibility of monitoring and visualizing pedicle screws immediately after their placement [26, 29, 30, 33–36, 39, 41]. Bydon et al. [5] maintain that the intraoperative CT scanner is much more sensitive for detecting unfavorably placed screws than conventional intraoperative fluoroscopy or radiography, and dramatically lowers the threshold for screw revision.

An advantage of a navigation system is the decreased radiation exposure for the patient, surgeon, and all the operating room staff, especially when compared with the percutaneous fluoroscopy-guided technique, where we usually perform at least five to six fluoroscopic scans for each pedicular screw. The average dose in a single scan is 0.10 mGy for patients weighing up to 75 kg and 0.21 mGy for those over 75 kg. The radiation exposure of the patient is obviously reduced with a navigation system, and also the radiation exposure of surgeons is greatly reduced, considering the addition of all such exposures during all the surgeries performed in their careers; and of course the reduced number of fluoroscopic scans is associated with a reduction in surgery time.

Another advantage of the Brainlab® system compared with fluoroscopy is that it allows simultaneous and multiplanar visualization of the spinal anatomy, which helps in virtually tracking surgical instruments in relation to the displayed anatomy in real time [13].

Conclusion

Our results confirm the superiority of the navigation technique, which ensures greater accuracy, above all for the percutaneous procedure. A significant reduction in radiation exposure was also noted in our percutaneous navigation group. The free-hand technique is safe and accurate when it is in the hands of an experienced surgeon. In our opinion the navigation system is a valuable tool for spine surgeons, especially for complex cases.

Conflict of Interest Statement We declare that we have no conflict of interest.

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