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ORIGINAL ARTICLE

Accuracy and revision rate of intraoperative computed tomography point-to-point navigation for lateral mass and pedicle screw placement: 11-year single-center experience in 1054 patients

Basem Ishak[1] · Alexander Younsi[1] · Carola Wieckhusen[1] · Paula Slonczewski[1] · Andreas W. Unterberg[1] · Karl L. Kiening[1]

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Abstract
High accuracy in intraoperative computed tomography (iCT) navigation utilizing an intraoperatively acquired dataset for screw placement in the spine has been reported in the literature. To further improve the accuracy and counteract any intraoperative movement of predefined registration points, we introduce an iCT point-to-point navigation, where marker screws are inserted intraoperatively to increase patient safety. In all, 1054 patients who underwent iCT point-to-point navigation for lateral mass and pedicle screw placement were retrospectively analyzed between 09/2005 and 09/2016. Implant-related complications such as screw misplacement, screw loosening, and revision rate were determined. Furthermore, we investigated the rate of complications and the clinical outcome. In total, 6059 screws were inserted in 1054 patients. There were 553 (52.5%) female and 501 (47.5%) male patients. Average age was 63.5 years, mean BMI 27.5 (SD 13.9). Here, 1427 (23.5%) screws were inserted in the cervical, 995 (16.4%) in the thoracic, 3167 (52.3%) in the lumbar, and 470 (7.8%) in the sacral spine. Eight patients required a revision procedure for screw misplacement (0.8%). Total screw misplacement rate was 0.3% (16/6059). With the use of reference markers in iCT-based, spinal, point-to-point navigation, we achieved a high accuracy of screw placement with a low revision rate (0.8%) and a total screw misplacement rate of 0.3%.

Keywords Intraoperative CT · Computer-assisted spinal surgery · Point-to-point navigation · Spinal instrumentation

Introduction

Spinal instrumentation by using screws was first introduced by Roy-Camille and has become a standard procedure in spinal surgery over the last few decades [13, 37]. When performed freehandedly as originally described, the major drawbacks of the procedure are its complexity and technical demand due to limited visibility of spinal anatomical landmarks during surgery, especially in revision surgery, rheumatoid diseases, or complex spinal deformities [15, 25, 42, 45].

✉ Basem Ishak
basem.ishak@hotmail.com

[1] Department of Neurosurgery, Heidelberg University Hospital, Heidelberg, Germany

Accurate and safe screw placement is of utmost importance in spinal instrumentation surgery but it can be challenging due to the close proximity of neural and vascular structures as well as the variability in bone morphology [39]. Several studies have reported high rates of cortical perforation and screw misplacement [4, 6, 42]. Misplaced screws can also affect the biomechanical stability of the construct, thus increasing both the rate of revision surgery and costs [26]. Although the use of spinal navigation for routine insertion of screws is still being debated, it has become the gold standard in many hospitals and there is a consensus concerning the higher accuracy rate, improved clinical outcome, and decreased complication rate in spinal deformity [22, 28, 42, 45].

The learning curve for freehanded screw fixation is steep and the surgeon's experience, therefore, has become a key factor, with senior and more experienced surgeons being the most promising candidates to achieve a favorable outcome [5, 48]. These safety concerns have encouraged surgeons to improve the accuracy of pedicle screw placement by trying various approaches, which also include enhancements in education and training of residents [10, 24, 29, 35] and employing image-assisted guidance techniques [2, 18]. Multiple studies have shown that computer-assisted spinal surgery (CASS) improves the accuracy of pedicle screw placement and thereby the patient's outcome in comparison to conventional methods [2, 43].

Many options for CASS are available, ranging from intraoperative computed tomography (iCT) navigation, three-dimensional (3D) fluoroscopy, and robot-assisted systems, among which iCT navigation has proven to be superior to other CASS systems, with higher accuracy rates especially in multi-level instrumentation and obese patients [38, 45].

Despite the advantages of iCT navigation, such as precise screw placement by providing real-time feedback, anatomical details of a thin-slice, acquired dataset, and no need to expose the entry points completely, it has major drawbacks, too [33]. One of them is the fact that before scanning, a reference array must be placed, which should not be manipulated during surgery. In case of instability, especially in the cervical region, repositioning maneuvers, or unintentional movement, screw placement can become inaccurate, making it necessary to perform a further scan and therefore increase radiation exposure and operating time [12, 33].

In an attempt to reduce complications, likely associated with movement of the reference array, we introduce an iCT point-to-point navigation, where marker screws are inserted intraoperatively into the bony structures to increase accuracy using spinal navigation. The aim of this study was to assess the feasibility and safety of this technique after an 11-year single-center experience in 1054 patients with regard to screw misplacement, revision surgery, and overall complications.

Material and methods

Patient demographics

After receiving approval from the Ethics Committee of the Heidelberg University Medical School (No. S-723/2017), we retrospectively reviewed the medical chart findings of all consecutive patients who underwent pedicle screw (PS) and/or lateral mass screw (LMS) placement using iCT point-to-point navigation by inserting reference markers during a period of 11 years from September 2005 to September 2016 at our institution for either degenerative, traumatic, or infectious diseases. In all, 1054 consecutive patients (mean age 63.5 years + 13.9 years; range 18–96 years) were included.

Although spinal navigation is generally not necessary for inserting cervical LMS, we nevertheless used this technique frequently because the LMS were part of the constructs for C1/2- or cervicothoracic stabilization and their additional planning did not consume much time.

Comorbidities such as diabetes mellitus and hypertension as well as smoking status and BMI were recorded on admission. Prior to surgery, the American Society of Anesthesiologists (ASA) Physical Status Classification System was additionally assessed. All patients had signed a patient consent on admission. All surgical procedures were performed by board-certified neurosurgeons at the same institution.

Surgical procedure and navigated instrumentation

For the posterior instrumentation, polyaxial titanium alloy screw systems (Expedium®, Mountaineer®, Depuy Synthes Company, Raynham, MA, USA and Oasys®, XIA®, Stryker Corporation, Kalamazoo, MI, USA) were used, varying in length and diameter according to each patient's anatomy. After general anesthesia was induced and a single shot of cefazolin was given as perioperative antibiotic, each patient was set in a prone position with appropriate bolsters. A standard midline posterior approach was used with subperiosteal exposure of the entry points in the standard fashion. Self-drilling screws (4 mm long, 1.5 mm thick, Zimmer Biomet Holdings, Inc., Warsaw, IN, USA), which are usually used for cranial plating, were used as navigation reference markers and attached to the laminae and the spinous process at the surgeon's discretion (Fig. 1). At least four reference markers were inserted. An intraoperative CT scan (Siemens, CT Emotion®, Sliding Gantry, Siemens Company, Erlangen, Germany) was then performed under sterile conditions (Fig. 2). The CT data were transferred to the navigation system (Stryker Navigation System II with SpineMap™ 3D-Navigation, Stryker Corporation, Kalamazoo, MI, USA). Screw position,

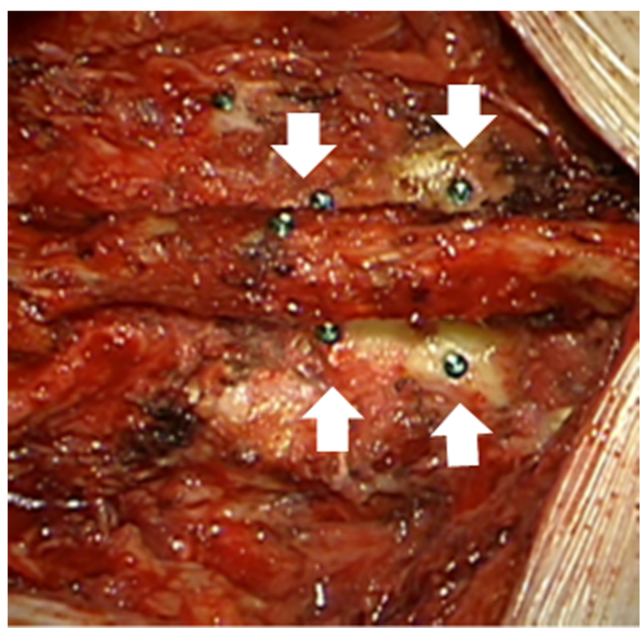

Fig. 1 Reference marker screws were inserted into the laminae and the spinous process (arrows)

Fig. 2 Intraoperative CT scan under sterile conditions

trajectory, length, and diameter were determined virtually after 3D reconstructing the intraoperatively acquired image datasets. A reference clamp was positioned at the spinous process and the reference markers were merged with the CT scan and defined as reference points (Fig. 3). The inserted reference markers were registered in the navigation system by touching them with a tracked pointer (Fig. 4). A point-to-point navigation was calculated. Correct location and mean deviation were validated by a navigated awl and anatomical landmarks. A calculated navigation accuracy of 0.3–0.8 mm

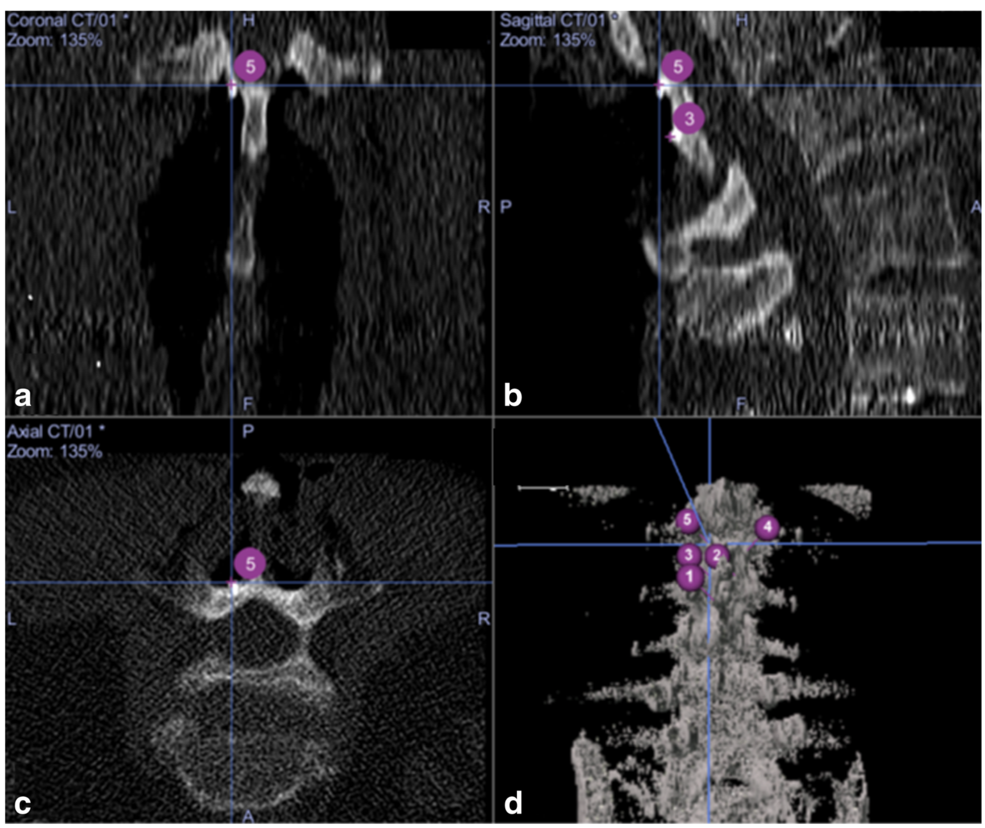

Fig. 3 Reference marker screws are merged and defined with the CT scan in coronal (**a**), sagittal (**b**), and axial (**c**) view. The 3D reconstruction shows the exact position of all marker screws (**d**)

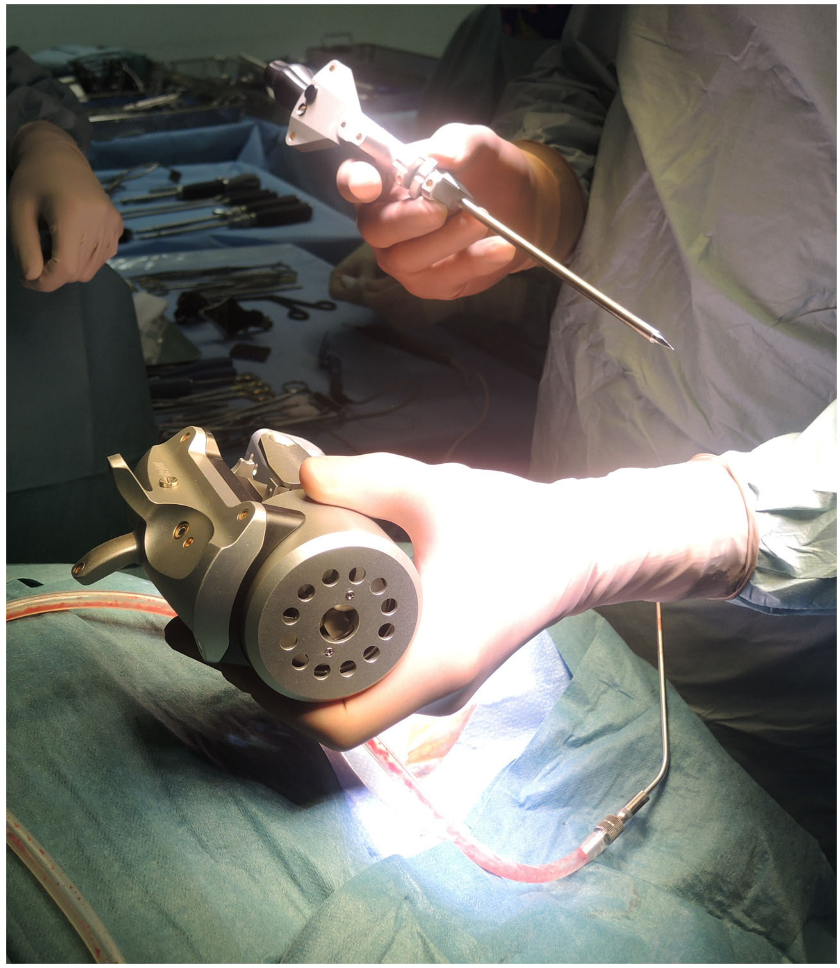

Fig. 4 A tracked pointer is visible to the navigation system

was deemed appropriate and was given in all cases (Fig. 5). Virtual drill paths were generated and adjusted to optimize the screw placement. We used a manual navigated 2.4-mm twist drill for the cervical spine which is fitted with a navigation tracker to guide drilling along the preselected trajectory up to the predetermined insertion depth. For the thoracolumbar spine, we used a pedicle awl, which was visible to the navigation system, to prepare the PS trajectory (Fig. 6). A pedicle

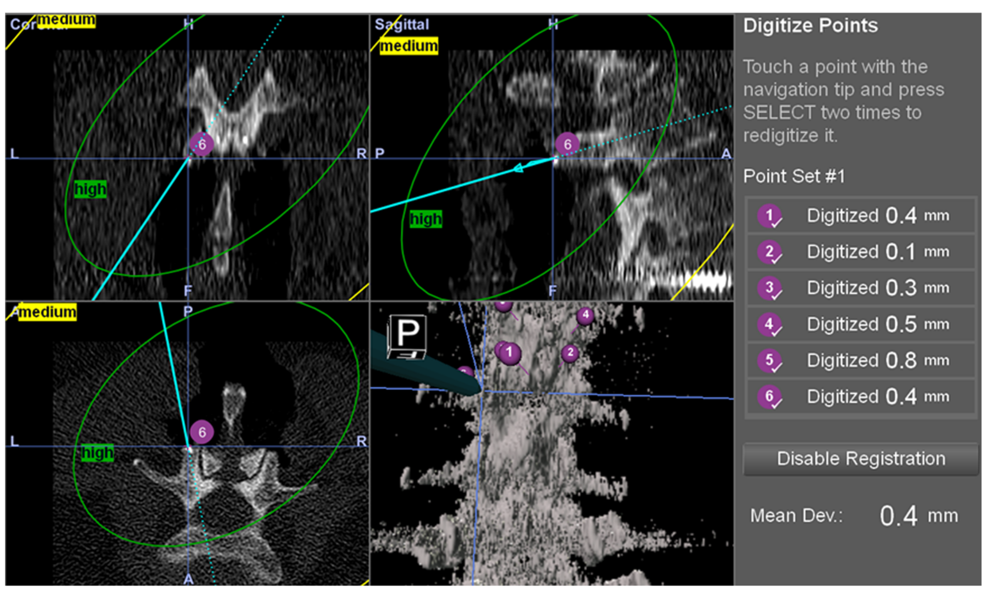

Fig. 5 This example shows that a navigation accuracy of 0.4 mm has been calculated

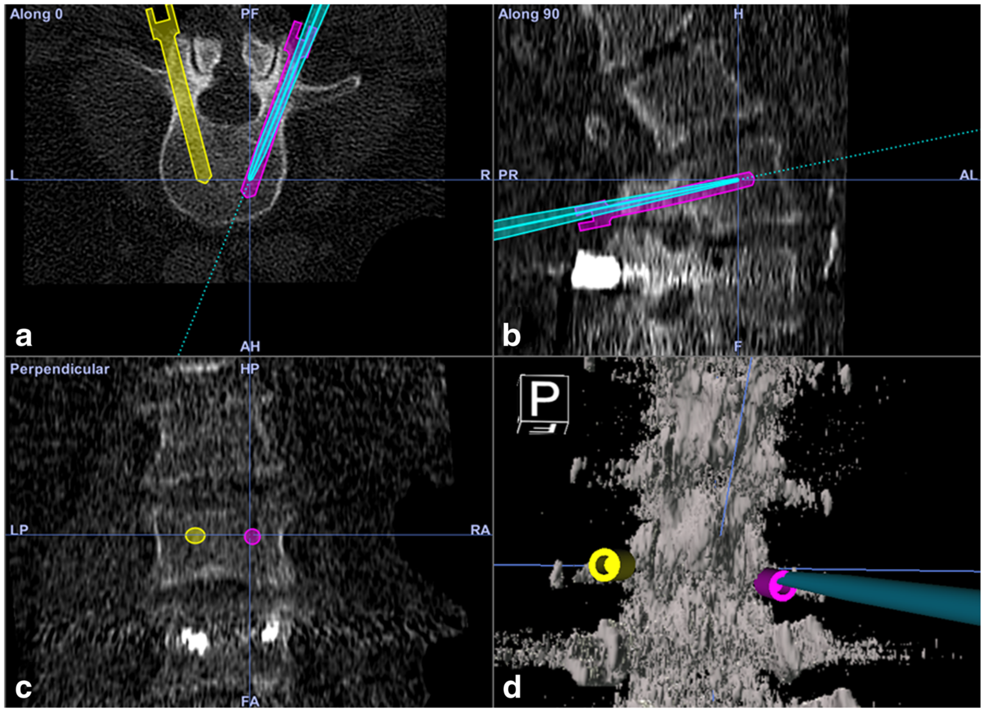

Fig. 6 Axial (**a**), sagittal (**b**), and coronal (**c**) scan and 3D reconstruction (**d**) demonstrating the virtually planned screws and intraoperative preparation of the pedicle using an awl, which is visible to the navigation system

feeler was always used to check the integrity of the screw hole. Then, screws were placed into the vertebral body and controlled via fluoroscopy. After that, the navigation reference markers have been removed.

If there was any concern about screw malpositioning on the intraoperative radiographs, an intraoperative CT was performed to verify screw position and to identify cortical perforation or neurovascular injuries.

Study documentation and radiological parameters

Routine clinical and radiological follow-ups with x-ray imaging of the spinal instrumentations were conducted before hospital discharge and at least 3 months postoperatively. The 3-month follow-up was regarded as the primary endpoint. Implant-related complications such as screw misplacement and screw loosening rate were assessed on postoperative imaging. If available, imaging data outside routine follow-ups were additionally analyzed. These included postoperative CT scans, which were used to classify the exact screw position within the pedicle of the thoracic and lumbar spine according to Gertzbein and Robbins [16].

Statistical methods

Data were reviewed for consistency, outliers, and normality and then analyzed using linear regression. Means and standard deviations were computed for descriptive analysis. The chi-squared test was used to determine complications within the same group. SPSS 22 (SPSS Munich, Germany) was used for all statistical analyses and a p value of $p < 0.05$ was considered significant. All data were analyzed by an independent external statistician.

Results

Patient population

In all, 1054 patients with PS and/or LMS placement using iCT point-to-point navigation were included in this study. Of those, 553 were female (52.5%) and 501 male (47.5%). Median age at the time of surgery was 63.5 years (range 18–96 years). Mean BMI was 27.5 (SD 13.9), indicating an overweight status in most of the patients. Moderate to severe obesity was present in 29% of cases. Comorbidities included arterial hypertension in 62% of cases and diabetes mellitus in 19%. Nicotine abuse was reported in 308 patients (31%). The ASA score prior to surgery was ≥ 3 in 48% of cases, indicating severe systemic disease. Table 1 depicts these findings in more detail.

Screw placement and perioperative course

A total of 6059 screws were inserted (4996 PS and 1063 LMS). Of those, 52.3% were placed in the lumbar, 23.4% in the cervical, 16.4% in the thoracic, and 7.7% in the sacral spine. Table 2 depicts the total number of screws implanted per vertebral body. In the lumbar spine, screw placement into the vertebral bodies L4 and L5 accounted for 61.8% of all cases. After surgery, no patient showed any new neurological deficits.

Table 1 Patient population

Characteristic	Value
No. of patients	1054
Age	
Median	63.5 years
Range	18–96 years
Sex (%)	
M	501 (47.5)
F	553 (52.5)
BMI	
Mean	27.5
SD	13.9
Comorbidities (%)	
Arterial hypertonus	616 (62.2)
Diabetes mellitus type 2	185 (18.7)
Nicotine abuse	308 (31.4)
ASA score (%)	
1	32 (3.4)
2	460 (48.4)
3	422 (44.4)
4	36 (3.8)

SD, standard deviation; *ASA*, American Society of Anesthesiologists

Implant-related complications and revision surgeries

Postoperative x-ray imaging was performed before discharge as well as minimum 3 months postoperatively in all patients. Median clinical and radiological follow-up was 76 months (range 3–114 months). A total of 16 misplaced screws (screw misplacement rate 0.3%) were discovered in the early postoperative phase in eight patients, who all required revision surgery (0.8%). The eight patients who underwent screw revision surgery did not have any neurological or vascular injury. Revision surgery was performed due to concerns regarding long-term biomechanical stability. In seven other patients, a total of 13 screws had loosened (screw loosening rate 0.2%) and revision surgery was performed (0.7%). In two additional patients, cage migration was observed and revision surgery was also indicated (0.2%). The overall rate of revision surgeries therefore was 1.7%. Details are depicted in Table 3. A total of 401 postoperative CT scans of the thoracic and lumbar spine were available to determine the exact screw position according to Gertzbein and Robins [16]. A total of 1490 PS were placed from T1 to the sacrum (Table 4). There were 106 PS in the thoracic spine and 1384 PS in the lumbosacral spine. Twenty PS screws were found to have a critical pedicle breach of > 4 mm and revision surgery was required due to screw misplacement or loosening (1.3%). There were 43 PS with a noncritical perforation of 2–4 mm, including 35 lateral wall breaches (2.3%) and 8 anterior body penetrations in S1 (0.05%). Out of the 35 lateral wall breaches, only 9 PS needed surgical revision (0.3%). No patient

Table 2 Total no. of screws implanted per vertebral body

		No. of screws implanted per vertebral body (%)												
		Total	1	2	3	4	5	6	7	8	9	10	11	12
Spinal segment	Cervical spine	1427 (23.6)	172 (2.8)	227 (3.7)	217 (3.6)	255 (4.2)	227 (3.7)	198 (3.3)	131 (2.2)					
	Thoracic spine	995 (16.4)	122 (2.0)	45 (0.7)	66 (1.0)	57 (1.0)	64 (1.1)	83 (1.4)	72 (1.2)	69 (1.1)	74 (1.2)	100 (1.7)	115 (1.9)	134 (2.2)
	Lumbar spine	3167 (52.3)	142 (2.3)	342 (5.6)	623 (10.3)	1004 (16.6)	1048 (17.3)	8 (0.1)						
	Sacral spine	470 (7.8)	470 (7.8)											

Table 3 Details on surgery and implant-related complications

Characteristic	Value
Total no. of screws implanted	6059
Type of screws (%)	
PS	4996 (82.5)
LMS	1063 (17.5)
Total no. of misplaced screws (%)	16 (0.3)
Total no. of loosened screws (%)	13 (0.2)
Total no. revision surgeries (%)	17 (1.7)
Indication for revision surgeries (%)	
Screw misplacement	8 (0.8)
Screw loosening	7 (0.7)
Cage migration	2 (0.2)

PS, pedicle screw; *LMS*, lateral mass screw

presented with clinical symptoms of malpositioned PS. Minor penetration (< 2 mm) occurred in 85 PS, which may be considered as insignificant. A total of 1375 PS did not show any penetration. In sum, placement of 1.9% of the screws had to be revised (29 PS/ 1490 PS); therefore, 98% of the screws were well placed according to Gertzbein and Robins [16].

Statistical analysis

In linear regression analysis of the number of screws placed per patient, we found significant correlations with the ASA score prior to surgery ($R = 0.139$; $p < 0.01$) and the BMI at admission ($R = 0.087$; $p < 0.01$). No other significant correlations could be observed. Comparison of patients with and without revision surgery with the chi-squared test did not reveal any significant results.

Discussion

Although screw placement in the spine using a freehanded technique is well established, the misplacement rate can be high [15]. Screw misplacement rates of 20 to 40% in thoracolumbar and up to 87% in the cervical spine have been described [23, 30, 32, 36]. CASS was introduced to improve the accuracy of screw placement and thus to reduce neurovascular complications [14]. Furthermore, it has been shown that radiation exposure of surgeons could be reduced to 1/10 and to 1/2 of the patient in comparison to the freehanded technique when using spinal navigation [47].

Table 4 Pedicle screw accuracy classified by Gertzbein and Robins

Level	Total screws	No perforation	Minor perforation < 2 mm	Perforation		
				2–4 mm	4–6 mm	> 6 mm
Total thoracic screws	106	93	5	3	2	3
Th 1	4	3	0	0	0	1
Th 2	0	0	0	0	0	0
Th 3	2	0	0	0	1	1
Th 4	0	0	0	0	0	0
Th 5	4	2	0	2	0	0
Th 6	2	2	0	0	0	0
Th 7	2	2	0	0	0	0
Th 8	2	2	0	0	0	0
Th 9	4	4	0	0	0	0
Th 10	6	6	0	0	0	0
Th 11	28	23	4	0	1	0
Th 12	52	49	1	1	0	1
Total lumbosacral screws	1384	1282	80	20	6	9
L 1	52	46	3	3	0	0
L 2	142	132	7	1	0	2
L 3	240	232	4	0	2	2
L 4	366	343	18	2	1	2
L 5	394	341	23	10	3	3
L 6	4	2	2	0	0	0
S 1	186	186	23	4	0	0
Total screws	1490	1375	85	23	8	12

The necessity of accurate screw placement is still being debated in the literature by many surgeons, as cortical screw perforation is clinically silent in the majority of cases, depending on the length and location of the penetration [14, 19]. However, even those clinically silent perforations may lead to biomechanical instability of the construct in the long-term [1, 17]. There is also an increasing concern that facet joint violation after suboptimally placed screws could cause adjacent level degeneration (ALD) [3, 34].

Currently, the use of 3D fluoroscopy-based navigation has become the most frequently used technique for spinal navigation worldwide [17, 44]. However, 3D fluoroscopy navigation remains limited due to the reduced image quality in multilevel instrumentation and in obese patients, as well as difficulties in the craniocervical and cervicothoracic region in comparison to iCT-based navigation [38, 45].

Advantages and disadvantages of iCT point-to-point navigation

ICT navigation seems to have the highest accuracy among the various navigation guidance methods [7, 45]. The accuracy of our iCT point-to-point navigation is maximized because the images were obtained in the same position as that during spinal instrumentation.

ICT point-to-point navigation was first introduced in 2017 in octo- and nonagenarians undergoing posterior intraoperative spinal navigation-based C1/2 fusion for type II odontoid process fractures [21]. In this study, 35 patients were successfully treated via posterior C1/2 fusion in a modified C1 lateral mass technique with 0% screw malposition rate. It was shown that iCT point-to-point navigation is a feasible and effective procedure, especially in critical and technically demanding areas of the spinal column.

In comparison to other iCT-based navigation solutions for screw placement, we demonstrated that by inserting reference markers in the surgical field, quick registration is possible by touching clearly defined landmarks, which can be repeated within an extremely short period of time in cases of uncertainty, movement of the reference clamp, or instability and therefore eliminates a further CT scan, which is an essential advantage over the previously described CT-based navigation techniques published in the literature [8, 17, 27, 36, 40, 49]. Anatomical landmarks or prolonged surface matching are not needed. Even in inexperienced hands, this technique can be considered a safe procedure. One major disadvantage of iCT point-to-point navigation is the need for CT-qualified medical technical assistants for this procedure.

Cost-benefit of iCT

In comparison to 3D navigation, the installation and use of an iCT is associated with higher costs. However, it has been shown that these higher costs can be easily offset against the higher screw malposition rate which is associated with the secondary screw revision surgery rate when using 3D navigation [46, 49, 51]. In 2012, Hoges et al. reported that a 1% rate of patients who would require pedicle screw revision could lead to costs of approximately $40,595,000 nationwide, without considering the costs associated with morbidity [20]. In another study, Watkins IV et al. have showed that the average cost of pedicle screw revision surgery was $23,762 [50]. Dea et al. recently analyzed the cost-effectiveness of iCT-based spinal navigation systems [9]. The authors calculated a cost-effectiveness ratio of $15,962 per reoperation that could be prevented in patients who underwent spinal instrumentation. However, the authors concluded that iCT-based spinal navigation is only cost-effective in high-volume centers with more than 254 spinal instrumentations per year. In addition to the higher accuracy of screw placement, intraoperative neuromonitoring and a postoperative CT control were not necessary when using iCT navigation and less surgical time was needed [9].

Comparison with the literature

Many studies have been published to evaluate the accuracy of PS placement using different guidance techniques [2, 6, 30, 31, 41]. In a review by Gelalis et al., 26 prospective studies for all available navigation guidance systems for PS placement in the thoracic and lumbar spine (freehanded technique, fluoroscopy-guided, 3D fluoroscopy, CT-based) were included [15], in total 1105 patients with 6617 screws. The authors concluded that CT-based navigation has the highest accuracy among those techniques evaluated, with an accuracy ranging from 89 to 100%.

A further review, in which 26 studies were included, compared the accuracy of PS placement between different CT-based navigation systems [33]. Here, 6716 PS were placed using StealthStation®, Medtronic PLC, Minneapolis, MN, USA, and 2.573 PS by using VectorVision®, BrainLab AG, Munich, Germany. In total, 9289 PS were placed with a total pedicle breech rate of 9.2% (853 screws). Of these, 34.2% (292 screws) were more than 2 mm. The mean accuracy of PS placement by using StealthStation® was 98.7% and for Vectorvision® 95.8%.

In 2018, Hecht et al. demonstrated a higher accuracy and safer PS placement by using iCT-based spinal navigation in comparison to 3D fluoroscopy-based navigation for spinal instrumentation [17]. A total of 1527 screws in 260 patients were implanted, of which 1219 screws were inserted using iCT (Airo®, BrainLab AG, Munich, Germany) and 308 using 3D fluoroscopy (Arcadis®, Siemens Company, Erlangen, Germany). An immediate intraoperative CT control or 3D fluoroscopy scan was performed in the OR to determine the intraoperative accuracy and to correct misplaced screws. The iCT group revealed an intraoperative accuracy rate of 94.7% and the 3D fluoroscopy group 89.4%, with no significant difference between the two groups. A significantly higher accuracy of iCT-based navigation could be found for the cervical and thoracic spine, whereas no difference was seen for the lumbosacral spine. After intraoperative revision of misplaced screws, the postoperative CT control for both groups showed an accuracy of 95.4% in the iCT group and 91.6% in the 3D fluoroscopy group [17].

One of the largest single-center studies comparing 3D fluoroscopy-based navigation to freehand pedicle screw placement has been published by Fichtner et al. in 2018. [11] A total of 13,703 PS in 2232 patients were implanted, of which 7548 PS were inserted using 3D fluoroscopy (Arcadis®, Siemens Company, Erlangen, Germany) and 6155 in a freehand technique [11]. A postoperative CT scan was available in all patients. The authors demonstrated significantly lower revision surgeries for misplaced screws in the 3D fluoroscopy group (1.35%) compared to the freehand group (4.38%). Of all PS in the 3D fluoroscopy group, only 0.4% (30/7548 PS) needed revision surgery compared to 1.14% (70/6155 PS) in the freehand group [11].

Limitations

This study has several limitations. The primary limitation is the retrospective design and the lack of an internal control group. The population is very heterogeneous. Surgery was performed by different spine surgeons, not by one surgeon only. Nevertheless, a cost-effectiveness analysis was not done. Surgeons who start performing this procedure with navigation must get through a learning curve. Out of 1054 patients, only 401 postoperative CT scans were available to determine the exact screw position. A routine follow-up CT scan for all patients could not be obtained because of concerns of the local ethics committee (Ethics Committee of the Heidelberg University Medical School) that this may not represent the standard of care. Large, prospective, randomized, controlled studies are needed to support our findings.

Conclusions

When introducing new computer-assisted techniques, it is of the utmost importance to assess patient safety and complication and revision rates. The data from this study show that using iCT point-to-point navigation not only avoids neurovascular complications but also minimizes implant-related complications and, therefore, revision rates. As a result, this reproducible technique can be regarded as a feasible and safe alternative to previously published iCT navigation procedures, with high precision in different regions of the spine. Navigation technology should be used frequently and not in selected cases. Further prospective comparative studies are needed to support our findings.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the local ethical committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This retrospective study was approved by the Ethics Committee of the Heidelberg University Medical School (No. S-723/2017).

Informed consent Informed consent was obtained from all individual participants included in the study.

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