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Clinical Study

Accurate placement of thoracolumbar pedicle screws using a handheld iOS-based navigation device: a prospective intra-patient agreement study

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Abstract

BACKGROUND: Accurate pedicle screw placement is a challenge with reported misplacement rates of 10% and higher. A handheld navigation device (HND) may provide accuracy equal to CT-based navigation (CT-Nav) but without the cost and complexity.

OBJECTIVE: To study the accuracy of a handheld navigation device for pedicle screw placement.

STUDY DESIGN: This prospective cross-sectional study with consistently applied reference standard enrolled 20 patients undergoing 92 pedicle screw placements.

PATIENTS: Patients who underwent pedicle screw placement between May 2022 and September 2022.

OUTCOME MEASURES: Pedicle screw placement accuracy per Gertzbein−Robbins.

METHODS: Once the screw pilot hole was established, the proposed trajectory of the HND was compared with that proposed by CT-Nav. Postoperatively, screw accuracy was graded according to Gertzbein−Robbins by a blinded radiologist based on CT scans. Accuracy was compared between the two systems and published control for fluoroscopy assisted and CT-Nav placement using Bayesian posterior distribution.

RESULTS: The trajectory proposed by the HND and CT-Nav were in agreement in 98.9% (95% Exact CI; 94.09%−99.97%). The HND accuracy was 98.9% with 91 screws rated “A” and 1 rated “C”.

Non-inferiority to fluoroscopic placement was achieved because the one-sided normal-approximation 95% CI Lower Bound (LB) of 95.3% is greater than the Performance Goal (PG) of 83.4%. Post-hoc analysis demonstrated that the probability of superiority of the HND relative to the historical accuracy rate of 91.5% for fluoroscopy assisted procedures is >0.999 and that the HND’s accuracy rate is within 4.5% of CT-Nav of 95.5% is >0.999.

No adverse events or intra-operative complications associated with HND were observed. There was 1 (1.1%) intra-operative repositioning and no re-operations for any reason.

CONCLUSIONS: The accuracy rate of the HND was 98.9%, and the proposed trajectory matched with CT-Nav in 98.9% of the time. This is superior to the historical published accuracy rate for fluoroscopy-assisted procedures and equivalent to the historical published accuracy rate for CT-Nav.

FDA device/drug status: Approved.

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Introduction

Pedicle screw placement has been widely used to reconstruct local stability in spine surgery [1−4]. However, conventional free-hand pedicle screw placement with fluoroscopic assistance is prone to pedicle violation. Although there is a low morbidity of clinically relevant complications, a misplaced screw can result in neurovascular damage, dural tearing, or visceral involvement because of the anatomical proximity of the vertebral pedicles to associated neurovascular structures [2,3,5−13]. Further, fluoroscopic guidance often requires the user to take multiple iterative intraoperative images to achieve accurate placement adding time to a procedure and increasing radiation exposure to the patient, surgeon, and staff [11].

Therefore, a variety of techniques have been introduced to assist screw insertion and to reduce the prevalence of pedicle violation. Despite the availability of intraoperative 3D imaging/CT-based image guided navigation systems (CT-Nav) or associated robotic-assisted systems that have demonstrated accuracy improvements, pedicle screw placement with fluoroscopic assistance is still the technique used most widely as it is practical and cost-effective [1,2,4,14,15]. The use of CT-Nav is limited by its complexity, operational inefficiency and high acquisition and maintenance costs.[16]

A navigation system that leverages limited use of standard C-arm X-rays, offers similar accuracy to CT-Nav and mitigates the associated limitations that could be of value to spine surgeons and their patients. A proprietary software that runs on a handheld iOS-based (Apple®) device has been developed which has the potential to achieve these objectives (Bolt® Navigation System, Circinus Medical Technology) (Fig. 1). The purpose of the clinical investigation was to assess the accuracy of this handheld navigation device (HND).

Methods

The data for this study is from the first phase of the study: "Handheld iOS-based spinal navigation versus O-arm image guided navigation in the placement of thoraco-lumbar pedicle screws." The study was performed following GCP, including approval by the local research ethics committee and registered at the Dutch trial register maintained by the Central Committee on Research involving human subject (CCMO) under NL74268.058.20. Written informed consent was obtained from the patients.

Study monitoring was performed by the Tapas Group (Laren, The Netherlands) and statistical analysis by Biomedical Statistical Consulting (Wynnewood, USA).

Study design

This prospective agreement study was designed to validate the pedicle screw placement accuracy of the HND intraoperatively by comparing the trajectory established by the HND in making the screw pilot hole to the trajectory proposed by CT-Nav (Medtronic, O-arm-StealthStation) for each screw. Postoperatively, a Gertzbein−Robbins classification was assigned to each screw by an independent radiologist based on a CT scan (O-arm) performed immediately after all implants were placed. The HND accuracy was then compared to historical published data of CT-Nav and fluoroscopy assisted placement. It was determined that, assuming a 92.0% success rate for the investigational device, a sample size of 100 screws was required.

Participants

This prospective agreement study included patients who were treated with thoraco-lumbar pedicle screw between May 2022 and September 2022 at the Departments of Neurosurgery of Haaglanden Medical Center (The Hague, The Netherlands). Patients older than 18 with the following indications for thoraco-lumbo-sacral pedicle screw placement for single or multilevel fusions (T12 to S1) were eligible for the study: degenerative spondylolisthesis with stenosis, spondylolytic spondylolisthesis, degenerative disc disease, and failed back surgery syndrome. Trauma, infection, and tumor cases were not eligible. Patients undergoing cortical trajectory screw fixation were excluded.

Study device

The HND is an iOS (Apple⍰) device with only the proprietary navigation app (software) on it. The device's built-in camera is used to capture images of the surgical levels to be operated on from standard pre-op CT/MRI (axial) imaging and a perioperative lateral X-ray. The unit is then placed into a sterile drape and entered into the surgical field where it is placed in a case that allows it to be precisely attached to any surgical instrument. Using the touchscreen the surgeon plans the ideal mediolateral position of the screw on the axial image and the sagittal position on the lateral X-ray. The system uses trigonometry to turn these two orthogonal angles into a three-dimensional construct of the planned angle. The system's gyroscope

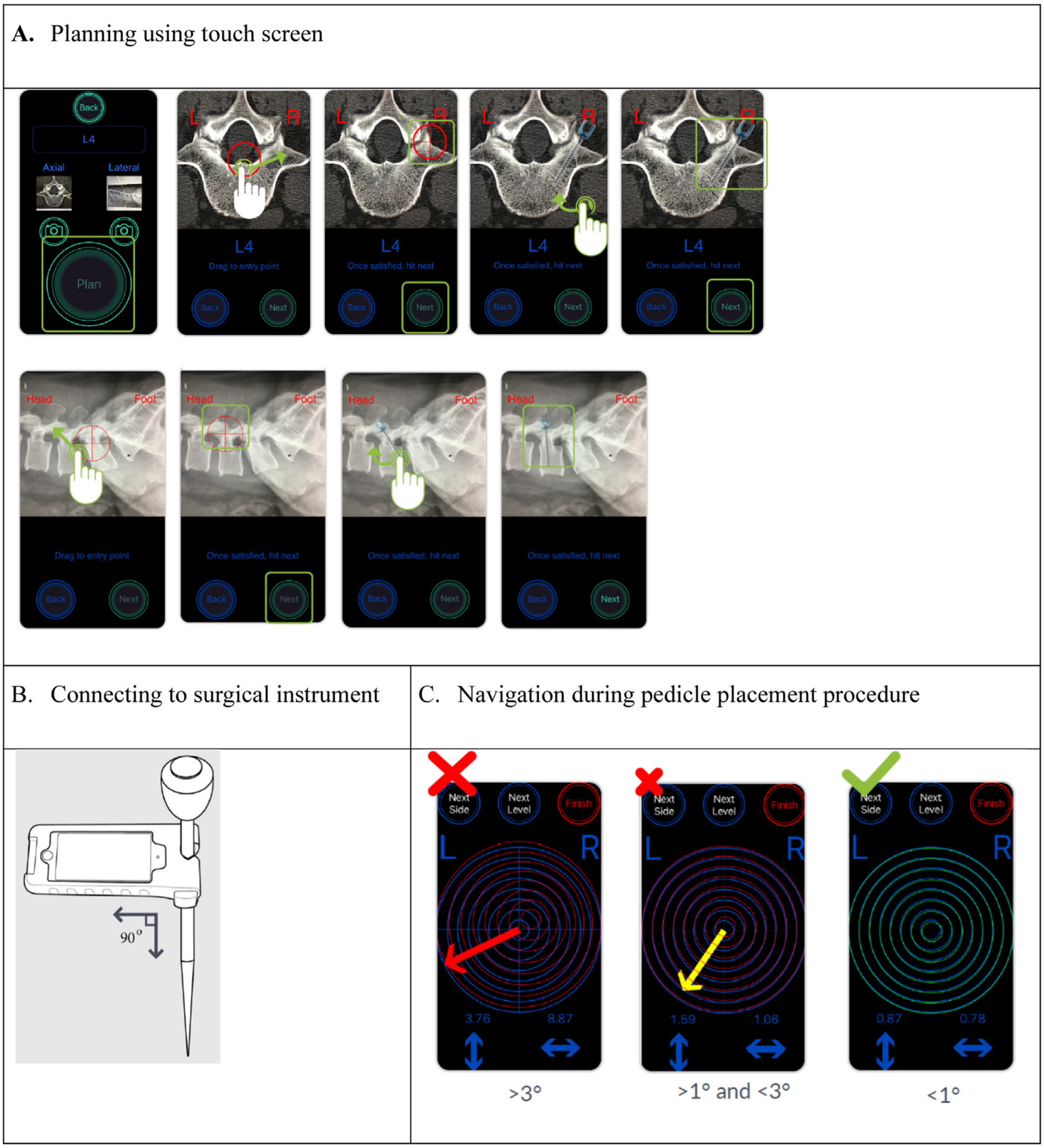

Fig. 1. Use of the HND system.

then communicates real-time navigation to the surgeon based on their plan (Fig. 1).

Intervention and outcomes

Surgeries were performed by either of two surgeons working at Haaglanden Medical Center. Both surgeons in this study were experienced with other guidance techniques, including fluoroscopy and CT-Nav, and were able to begin utilizing the HND system after a short training with cadavers and demonstration models. Posterior surgery was performed with the patient in the prone position. Spinal stabilization was provided based on local protocols, and the surgical procedure was performed by certified and experienced neurosurgeons. There were no study specific requirements with regard to type and brand of intervertebral body cages, pedicle screws and other implants used for spinal stabilization (Fig. 2).

Based on pre-operative diagnostic axial lumbar MR/CT and perioperative true-lateral X-ray, the ideal position of the entry point and trajectory for each pedicle screw was determined with the HND. During surgery, the holder for the HND was connected to the CT-Nav pedicle probe. This combined instrument was used to make the pilot hole for the screw according to the planning and trajectory provided by the HND.

The HND was attached to the CT-Nav probe in a manner that blocked the CT-Nav navigation marker array rendering

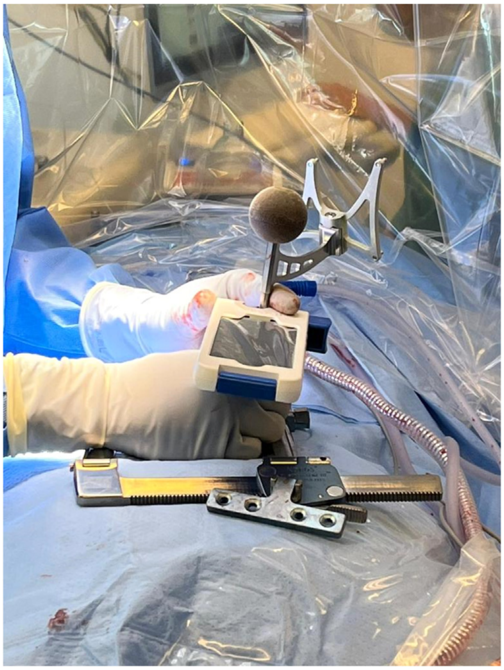

Fig. 2. HND combined with CT-Nav guided navigation system set-up for study purposes.

it non-functional ensuring that only the HND was used to make the pilot hole. The HND was then rotated out of the way allowing CT-Nav to provide its telemetry. This allowed the HND trajectory to be confirmed and compared to CT-Nav prior to pedicle screw placement.

If CT-Nav verified that the trajectory as established by the HND was inside the pedicle, it was defined as "acceptable," and the screw was placed via the HND. If the screw according to CT-Nav was not inside the pedicle, it was defined as "unacceptable." In the latter case, CT-Nav overruled the position as established by the HND, the pedicle screw was inserted by CT-Nav guidance, and a misplacement assigned to the HND.

A CT/O-arm run was performed on all patients at the end of the surgical procedure. Based on these images, a radiologist, blinded to whether the screw was placed based on the HND or CT-Nav, rated the position of the pedicle screw according to the Gertzbein−Robbins classification, in which Grade A and Grade B were determined as "clinically acceptable."

Statistics

Descriptive statistics were used, including mean, standard deviation, median, minimum, and maximum values for continuous variables and counts and percentages for categorical variables.

The trajectory presented by the HND was compared intraoperatively with that indicated by CT-Nav. The exact binominal 95% confidence interval was calculated for the agreement estimate.

The accuracy of the screws placed with the HND was determined by a blinded radiologist according to the Gertzbein−Robbins classification based on CT scans performed immediately post-operatively. A Gertzbein−Robbins classification of A or B was considered acceptable. The success rate and a one-sided normal-approximation 95% CI LB was calculated.

The primary data source for the historical published data of fluoroscopy assisted guided placement of thoracolumbar pedicle screws is the "Accuracy of Current Techniques for Placement of Pedicle Screws in the Spine: A Comprehensive Systematic Review and Meta-Analysis," Perdomo −Pantoja et al. [9] This meta-analysis published in 2019 looked at 5,378 patients and 51,161 pedicle screws placed by a variety of techniques. Based on this meta-analysis, the accuracy rate for fluoroscopy assisted pedicle screw placement is 91.5% (95% CI, 88.4%−93.8%) and the accuracy for CT-Nav is 95.5% (95% CI, 94.2%−96.5%.)

A non-inferiority margin of 5% has been deemed acceptable. This means that the lower bound of the 95% CI for the HND accuracy must exceed 83.5%. This equals the lower bound of the 95% CI for fluoroscopy assisted techniques minus the 5% non-inferiority margin. The performance goal was determined by subtracting the non-inferiority margin from the reference rate. Therefore, the performance goal is 83.4%.

The primary effectiveness hypothesis was tested using a normal approximation z-test at a one-sided type 1 error rate of α=0.05. Additionally, the lower bound (LB) of a normal approximation one-sided 95% confidence interval is provided. This lower bound is interpreted as the lowest accuracy rate of the HND that is consistent with the sample data.

Additional (post-hoc) analyses aim to determine the difference in accuracy probabilities between the HND, fluoroscopy assisted placement, and CT-Nav guided navigation. The Bayesian posterior distributions of the screw placement accuracy rates of the HND, fluoroscopy assisted and CT-Nav were calculated.

Source of funding

The study was sponsored by Circinus Medical Technology, LLC, the HND manufacturer. The sponsor provided the HNDs, paid for the electronic data capture system and data entry. The sponsor performed monitoring, source data verification and statistical analysis.

Results

Participants characteristics

Ninety-two pedicle screw placements in 20 patients were enrolled in the study after informed consent was obtained. All patients had complete follow-up with both radiographic evaluation immediately post pedicle screw placement and clinical evaluation at 3 months.

The study group included 14 women (70%) and 6 men (30%), with a mean age of 62.4 years (range, 49 to 82 years). Thirty-six screws (39%) were in patients with degenerative spondylolisthesis, thirty screws (33%) in patients with spondylolytic spondylolisthesis, fourteen screws (15%) in patients with degenerative disc disease, eight screws (9%) in failed back surgery syndrome patients and 4 (4%) for other indication (Table 1).

Primary outcomes

The protocol provided for a fully paired comparison between the screw trajectory shown by the HND to that of CT-Nav. The HND trajectory matched the CT-Nav trajectory in 91 of the 92 screws, resulting in an agreement of 98.9% (95% Exact CI; 94.09%−99.97%). In the one case (L3 left) that CT-Nav did not confirm the HND trajectory, based on his clinical judgement, the surgeon chose not to follow the CT-Nav guidance but to place the pedicle screw per the HND trajectory. The surgeon suspected that the reference frame (marker) of the CT-Nav system had moved intra-operatively. The radiologists assigned a Gertzbein −Robbins grade A confirming that the HND trajectory was correct.

The prospective effectiveness hypothesis of the study is that the accuracy success rate (percentage of pedicle screws rated as clinically acceptable) for the HND is higher than the performance goal of 83.4%. In the study 91 of the 92 pedicle screws inserted (98.9%) were placed accurately. Intra-operatively there was 1 (1.1%) pedicle screw repositioning for a Gertzbein−Robbins grade C screw. The screw mispositioning was caused by the surgeon not using the planned entry point, the surgeon rated the trajectory (vector) provided by the HND as correct for the planned entry point. It should be noted that CT-Nav confirmed the HND in this case. The one-sided normal-approximation 95% CI LB is 95.3%. Because this lower bound is greater than the PG of 83.4%, the primary endpoint has been established. The normal approximation and exact p-value testing of the primary endpoint based on the 83.4% PG are statistically significant at p=<.0001. Therefore, it can be concluded that the accuracy rate of the HND is non-inferior to the historical published accuracy rate for fluoroscopy assisted procedures.

Table 1
Demographics and operative data*

Characteristic	Patients (n=20)	Pedicle screws (n=92)
Age (years)	62.4±10.5	
BMI (kg/m^2)	27.6±5.1	
Sex		
Female	14 (70%)	
Male	6 (30%)	
Diagnosis		
Degenerative disc disease	3 (15%)	14 (15%)
Degenerative spondylolisthesis	7 (35%)	36 (39%)
Isthmic spondylolisthesis	7 (35%)	30 (33%)
Failed back surgery syndrome	2 (10%)	8 (9%
Other (foraminal stenosis)	1 (5%)	4 (4%)
Vertebral level		
L2		2 (2.2%)
L3		16 (17.4%)
L4		30 (32.6%)
L5		32 (34.8%)
S1		12 (13.0%)
Surgery		
Blood loss (ml)	427.5±295.8	
Blood loss per screw (ml)		93.5±66.7
Duration surgery (min)	104.8±48.8	
Duration surgery per screw (min)		22.6±8.6
Hospital stay (days)	2.4±0.9	

* The values are given as the count with the percentage in parentheses or the mean±standard deviation.

Secondary outcomes

Given that the accuracy success rate for the HND of 98.9% is higher than the performance goal of 83.4% (p=<.0001) an additional set of post-hoc analyses were performed to provide additional information about the data collected within the clinical trial. These analyses aim to compare the success probabilities of the HND to fluoroscopy assisted and CT-Nav guided literature-based historical accuracy rates. The primary source, identified through a systematic literature search, is the Meta-Analysis published by Perdomo−Pantoja [9] (Table 2).

The probability that the HND accuracy rate is within 5% of CT-Nav accuracy is >0.999 (Table 3). The Posterior Probability of superiority of the HND relative to fluoroscopy assisted accuracy is > 0.999. The probability the difference is >5.0% in favor of the HND is 0.992 (Table 4).

Because the HND provides a trajectory (vector) relative to an entry point on the pedicle and gravity, the ability of the surgeon to use the entry point selected on the HND is important. The used entry point matched exactly the selected entry point in 87 (94.6%) of the cases, in 4 (4.3%) of the cases approximately and in 1 (1.1%) case it was off. In the latter case, the screw was graded as Gertzbein−Robbins C, all other screws were Gertzbein−Robbins A. The

Table 2
Posterior probability accuracy rates

Device	Accuracy rate
HND	98.9% (91/92)
Fluoroscopy assisted	91.5%
CT-Nav guided	95.5%

Table 3
HND accuracy compared to CT-Nav guided accuracy

Accuracy delta	Probability
+/-5.0%	>0.999
+/-4.5%	>0.999

Table 4
HND accuracy compared to fluoroscopy assisted accuracy

Accuracy delta	Posterior probability
-0.075	>0.999
-0.050	>0.999
-0.025	>0.999
0.000	>0.999
0.025	>0.999
0.050	0.992
0.075	0.926

misplaced screw was the only intra-operative repositioning. No re-operation was required.

There were 5 intra-operatively complications, one intra-operative repositioning (1.1%) and 4 dural tears (4.3%). All dural tears occurred prior to pedicle screw placement and in subjects with all pedicle screws graded as Gertzbein−Robbins A. Therefore, the dural tears are considered unrelated to pedicle screw placement. The repositioned screw was for a pedicle screw graded Gertzbein−Robbins C and did not result in a dural tear or nerve root injury.

Four patients each experienced one adverse events during the first 30 days post-operative (2 constipations and 2 cage migrations). None of them were related to the pedicle screw placement procedure.

Discussion

The present study is the first study with a new handheld navigation device for the placement of thoracolumbar pedicle screws. In this study the accuracy of the device is 98.9%, non-inferior to published historical accuracy rate for CT-Nav and superior to published historical accuracy rate for fluoroscopy assisted placement.

Currently, most pedicle screw are placed with fluoroscopic assistance, a technique that has significant drawbacks, including radiation exposure to patients, surgeons, and other OR staff and sub-optimal accuracy. The HND provides superior accuracy compared to pedicle screw placed with fluoroscopic assistance, without the need for repetitive fluoroscopic imaging.

Several CT-Nav systems have been developed with demonstrated ability to efficiently increase screw placement accuracy. Unfortunately, these systems have not seen widespread adoption as they are complex systems, require fixation of a reference frame, expose the patient and the staff to radiation, are unable to compensate for positional changes, rely on reference frame stability throughout the procedure and are expensive in terms of capital investment, ongoing maintenance and navigated surgical instruments and markers. In addition, not every operating room can accommodate the large footprint of a CT-Nav. The HND provides non-inferior accuracy compared to CT-Nav without the limitations inherent to CT-Nav.

The sample size of 92 pedicle screw placements is not a limitation of this analysis. Instead, the ability to show such strong results based on the 92 screw trials attests to the strength of the observed data. The sample size was determined by a power calculation for non-inferiority to fluoroscopy assisted placement. It assumed a one-sided type 1 error of α=0.05 and was determined that the statistical power to reject the null hypothesis using a normal approximation z-test equals 82.1%, with a sample size of 100 screws assuming a 92.0% success rate for the HND.

The present study has the limitation that it was performed by two surgeons working at one institution. Therefore, a large (at least 528 pedicle screws) multi-center, multi-surgeon RCT is underway comparing the HND to CT-Nav to explore if these results can be extrapolated to the broader surgical community. However, two cadaveric studies with the HND device demonstrated minimal variability between users. A study that included thirteen surgeons with minimal training on the system demonstrated an average Gertzbein−Robbins score of 1.29 (A=1, B=2, etc.) with a mean deviation from midline placement of 0.66 mm and a standard deviation of 1.52 mm [17]. “A second study of 58 screw placements by three surgeons (one experienced user, one with familiarity of the system and one who had never used the system before) demonstrated an actual vs. planned placement accuracy of 1.59° and no statistical difference in accuracy between the users” (P. West, personal communication, November 14, 2023).

The study was a prospective agreement study and compared the accuracy rate to historical data. While this allows us to compare the HND accuracy with a large amount of real-world data, the study was not randomized. To compensate for this, the study also included a fully paired evaluation of the trajectory, allowing a direct comparison between the HND trajectory and the CT-Nav trajectory for the same pedicle screw. This evaluation demonstrated that both trajectory matches almost perfectly. The only mismatch was a failure of the CT-Nav system which was recognized by the surgeon and ascribed to movement of the system’s reference frame. This potential source of inaccuracy does not exist with the HND. The second phase of the study will randomize HND versus CT-Nav providing for a direct comparison.

A non-inferiority margin (delta) of 5% has been deemed acceptable. The non-inferiority margin is the largest reduction in the success rate allowable under the hypothesis of clinical noninferiority. There are many approaches to selecting appropriate delta values in noninferiority trials approaches to selecting the delta include those relying entirely on clinical criteria and those seeking a non-inferiority margin with good statistical properties for the decision rule. The approach chosen in the present study accomplishes both goals. One reasonable approach is to set the delta such that the test intervention preserves a certain fraction of the efficacy of the control, and this is the approach we took since it also results in good statistical properties for the statistical decision rule. Reasonable fractions may range from 0.80 to 0.95.

In conclusion, the HND was shown to have an accuracy of 98.9%, non-inferior to published historical CT-Nav accuracy rate and superior to published historical fluoroscopy assisted accuracy rate. This study provides a new option for pedicle screw navigation in the thoracolumbar spine at a lower cost but with the same accuracy as CT-Nav. A large ongoing multi-center RCT comparing the HND to CT-Nav will further validate the HND's efficacy.

CRediT authorship contribution statement

Mark P. Arts: Writing − review & editing, Supervision, Methodology, Investigation, Data curation, Conceptualization. **Geert Lycklama à Nijeholt:** Writing − review & editing, Investigation, Data curation. **Eddie Van Eeckhoven:** Writing − original draft, Validation, Supervision, Methodology, Investigation, Formal analysis, Conceptualization. **Jasper F.C. Wolfs:** Writing − review & editing, Investigation, Data curation.

Declaration of competing interest

One or more of the authors declare financial or professional relationships on ICMJE-TSJ disclosure forms.

Acknowledgment

The study was sponsored by Circinus Medical Technology, the device's manufacturer. The sponsor provided the Bolt Navigation System devices, paid for the electronic data capture system and data entry. The sponsor performed monitoring, source data verification and statistical analysis.

References

[1] Tian W, Liu YJ, Liu B, He D, Wu JY, Han XG, et al. Technical Committee on Medical Robot Engineering of Chinese Society of Biomedical Engineering; Technical Consulting Committee of National Robotic Orthopaedic Surgery Application Center. Guideline for Thoracolumbar Pedicle Screw Placement Assisted by Ortho. Orthop Surg 2019;11(2):153–9.

[2] Fan Y, Du JP, Liu JJ, Zhang JN, Qiao HH, Liu SC, et al. Accuracy of pedicle screw placement comparing robot-assisted technology and the free-hand with fluoroscopy-guided method in spine surgery: An updated meta-analysis. Medicine (Baltimore) 2018;97(22):e10970.

[3] Tarawneh AM, Salem KM. A Systematic Review and Meta-analysis of Randomized Controlled Trials Comparing the Accuracy and Clinical Outcome of Pedicle Screw Placement Using Robot-Assisted Technology and Conventional Freehand Technique. Global Spine J 2021;11(4):575–86.

[4] Matsuoka A, Toyone T, Okano I, Kudo Y, Ishikawa K, Maruyama H, et al. Comparison of pedicle screw placement accuracy between two types of imaging support (Artis Zeego versus two-dimensional fluoroscopy): a cross-sectional observational study. BMC Musculoskelet Disord 2022;23(1):644.

[5] Feng W, Wang W, Chen S, Wu K, Wang H. O-arm navigation versus C-arm guidance for pedicle screw placement in spine surgery: a systematic review and meta-analysis. Int Orthop 2020;44(5):919–26.

[6] Li C, Li W, Gao S, Cao C, Li C, He L, et al. Comparison of accuracy and safety between robot-assisted and conventional fluoroscope assisted placement of pedicle screws in thoracolumbar spine: A meta-analysis. Medicine (Baltimore) 2021;100(38):e27282.

[7] Gautschi OP, Schatlo B, Schaller K, Tessitore E. Clinically relevant complications related to pedicle screw placement in thoracolumbar surgery and their management: a literature review of 35,630 pedicle screws. Neurosurgical Focus FOC 2011;31(4):E8.

[8] Alqurashi A, Alomar SA, Bakhaidar M, Alfiky M, Baeesa SS. Accuracy of Pedicle Screw Placement Using Intraoperative CT-Guided Navigation and Conventional Fluoroscopy for Lumbar Spondylosis. Cureus 2021;13(8):e17431.

[9] Perdomo-Pantoja A, Ishida W, Zygourakis C, Holmes C, Iyer RR, Cottrill E, et al. Accuracy of Current Techniques for Placement of Pedicle Screws in the Spine: A Comprehensive Systematic Review and Meta-Analysis of 51,161 Screws. World Neurosurg. 2019;126:664–678.e3.

[10] Sielatycki JA, Mitchell K, Leung E, Lehman RA. State of the art review of new technologies in spine deformity surgery-robotics and navigation. Spine Deform 2022;10(1):5–17.

[11] Kalfas I H. Machine Vision Navigation in Spine Surgery. Front Surg 2021;8:640554.

[12] Naik A, MacInnis BR, Shaffer A, Krist DT, Smith AD, Garst JR, et al. Trends in Technology for Pedicle Screw Placement: A Temporal Meta-Analysis. Spine (Phila Pa 1976) 2023;48(11):791–9.

[13] Matur AV, Palmisciano P, Duah HO, Chilakapati SS, Cheng JS, Adogwa O. Robotic and navigated pedicle screws are safer and more accurate than fluoroscopic freehand screws: a systematic review and meta-analysis. Spine J 2023;233(2):197–208.

[14] Liu A, Jin Y, Cottrill E, Khan M, Westbroek E, Ehresman J, et al. Clinical accuracy and initial experience with augmented reality-assisted pedicle screw placement: the first 205 screws. J Neurosurg Spine 2021;36(3):351–7.

[15] Schütz L, Brendle C, Esteban J, Krieg SM, Eck U, Navab N. Usability of Graphical Visualizations on a Tool-Mounted Interface for Spine Surgery. J Imaging 2021;7(8):159.

[16] Guha D, Moghaddamjou A, Jiwani ZH, Alotaibi NM, Fehlings MG, Mainprize TG, et al. Utilization of Spinal Intra-operative Three-dimensional Navigation by Canadian Surgeons and Trainees: A Population-based Time Trend Study. Can J Neurol Sci 2019;46(1):87–95.

[17] Driver J, Dorman JK, Chi JH. A Novel Mobile Device-Based Navigation System for Placement of Posterior Spinal Fixation. Oper Neurosurg (Hagerstown) 2022;22(4):249–54.