ORIGINAL ARTICLE

Evaluating a cutting-edge augmented reality-supported navigation system for spinal instrumentation

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Abstract

Objective Dorsal instrumentation using pedicle screws is a standard treatment for multiple spinal pathologies, such as trauma, infection, or degenerative indications. Intraoperative three-dimensional (3D) imaging and navigated pedicle screw placement are used at multiple centers. For the present study, we evaluated a new navigation system enabling augmented reality (AR)-supported pedicle screw placement while integrating navigation cameras into the reference array and drill guide. The present study aimed to evaluate its clinical application regarding safety, efficacy, and accuracy.

Methods A total of 20 patients were operated on between 06/2021 and 01/2022 using the new technique for intraoperative navigation. Intraoperative data with a focus on accuracy and patient safety, including patient outcome, were analyzed. The accuracy of pedicle screw placement was evaluated by intraoperative CT imaging.

Results A median of 8 (4–18) pedicle screws were placed in each case. Percutaneous instrumentation was performed in 14 patients (70%). The duration of pedicle screw placement (duration scan–scan) was 56 ± 26 (30–107) min. Intraoperative screw revision was necessary for 3 of 180 pedicle screws (1.7%). Intraoperatively, no major complications occurred—one case of delay due to software issues and one case of difficult screw placement were reported.

Conclusion The current study's results could confirm the use of the present AR-supported system for navigated pedicle screw placement for dorsal instrumentation in clinical routine. It provides a reliable and safe tool for 3D imaging-based pedicle screw placement, only requires a minimal intraoperative setup, and provides new opportunities by integrating AR.

Keywords Augmented reality · Dorsal instrumentation · Spinal navigation · Pedicle screw

Abbreviations

3D	Three dimensional
AR	Augmented reality
ASA	American Society of Anaesthesiologists
CT	Computed tomography
GRS	Gertzbein and Robbins classification system
LEDs	Light emitting diodes
ORCT	Operation room-based sliding gantry computed tomography
PS	Pedicle screw

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Introduction

In spine surgery, dorsal instrumentation using pedicle screws is a standard treatment for multiple spinal pathologies, such as trauma, infection, or degenerative indications, especially of the thoracolumbar spine [1–5]. Numerous studies, including systematic reviews and meta-analyses, have shown that intraoperative computed tomography (CT)—navigated screw placement is superior to screw placement using free-hand technique or 2-D fluoroscopy regarding screw positioning and patient safety [6–10].

Multiple imaging solutions, especially for mobile cone beam CT-based approaches but also for portable CT scanners, exist mainly differing regarding imaging quality, the field of view (FOV), acquisition and running costs, and not at least, their compatibility with navigation platforms [11]. Recently, a comprehensive review of assistive active and passive technologies summarizing current tools for spine surgery recommended the acquisition of devices with maximum compatibility and universal registration mechanisms [12]. As development has proceeded for intraoperative imaging, the same has occurred for intraoperative navigation, including augmented reality for spinal instrumentation [13–20].

For the present study, we evaluated a new navigation system enabling augmented reality (AR)-supported pedicle screw placement while integrating navigation cameras into the surgical instruments. Similarly to other systems, this system for spinal navigation is based on intraoperative 3D imaging. However, the setup is reduced by integrating navigation targets into the reference array and infrared camera into surgical instruments, establishing a flexible platform, including preoperative planning.

This study aimed to analyze the clinical application of this navigation system regarding safety, efficacy, and accuracy.

Methods

Ethics

The local ethics board approved the study (registration number: 2022-306-S-NP). The study was performed in accordance with the Declaration of Helsinki and in accordance to the STROBE statement.

Patients

Patients scheduled for dorsal instrumentation between June 2021 and January 2022 were considered eligible for this pilot study. Inclusion criteria were patients undergoing navigated pedicle screw placement of the thoracic and lumbar spine at our institution using the new navigation system (NextAR TS [Tracking System], Medacta, Castel San Pietro, Switzerland) enabling AR-supported pedicle screw placement.

Intraoperative procedures

An open midline approach or percutaneous pedicle screw implantation was performed depending on the additional need for decompression, construct length, and instrumentation levels. For spinal navigation, a reference array equipped with navigation targets incorporating multiple light emitting diodes (LEDs) in a certain spatial configuration was attached to a spinous process close to the levels planned for instrumentation, and an infrared camera was firmly attached to surgical instruments such as the drill guide (Fig. 1). Next, a navigation scan was performed using either a 3D C-arm scanner (Vision, Ziehm Imaging, Nuremberg, Germany) or an operation room-based CT scanner (ORCT) (Brilliance CT Big Bore, Philips, Amsterdam, Netherlands). During image acquisition, the surgery staff was outside the operation room to reduce radiation exposure. After uploading the navigation data set to the navigation software, the image quality, as well as the accuracy of the registration in correlation with anatomical structures, were reviewed. Under the use of the AR-supported navigation system, skin incisions for percutaneous instrumentation, screw entry points, and screw trajectories were planned using a navigated drill guide (Figs. 1, 2). The planned trajectory was drilled using a battery-powered drill, and a Kirschner wire was inserted via the drill guide to mark the screw trajectory. In the next step, cannulated pedicle screws (Medacta Universal Screw Technology [MUST], Medacta, Castel San Pietro, Switzerland) were implanted by passing them over the Kirschner wires. After implantation of all pedicle screws, a final control scan was acquired. Pedicle screw placement was then reviewed on 3D imaging. In case of screw revision, another final scan was performed. Afterward, rods were fitted regarding curvature and length and installed by fixating the pedicle screw nuts. Additional decompression was performed, depending on the indication of surgery.

Data acquisition

Surgical data, including perioperative data, accuracy of screw placement on 3D intraoperative imaging, and screw
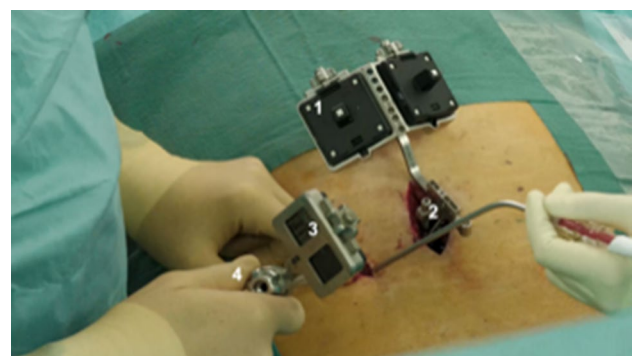
Fig. 1 Intraoperative Setup. Figure 1 represents the setup of the system during navigated pedicle screw placement. The navigation system consists of targets (1), which are battery-powered devices incorporating multiple LEDs in a known spatial configuration allowing for three-dimensional navigation and attached to the reference array (2) and infrared cameras (3) firmly attached to surgical instruments, such as the navigated drill guide (4) shown in this figure
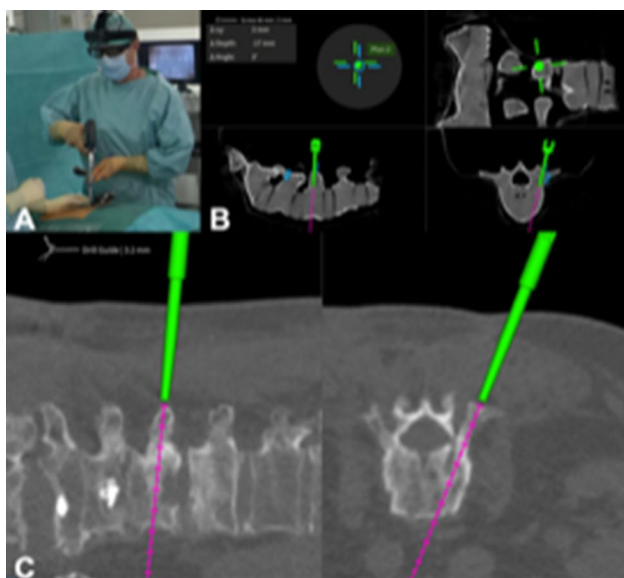
Fig. 2 Intraoperative visualization for navigated pedicle screw placement. Figure 2 illustrates the visualization of intraoperative neuronavigation as displayed through the surgeons (**A**) AR-goggle (**B**) and on the main screen (**C**) as used for K-wire placement. The navigated drill guide is represented in green color, and the planned trajectory is shown in pink. The fact that the surgeons' view has not been averted from the situs has been rated advantageously

revision rates were acquired for all patients undergoing AR-supported pedicle screw placement during the analyzed period. Furthermore, we analyzed data on intra- and postoperative complication rates and additional surgeries.

Radiation dose analysis

Intraoperatively, 3D radiographs were acquired before and after pedicle screw placement. The accuracy was rated on intraoperative imaging according to the Gertzbein and Robbins classification system (GRS) (Grade $A = 0$ mm breach distance, $B = <2$ mm, $C = <4$ mm, $D = <6$ mm, $E > 6$ mm) [21]. In addition, screw placement was evaluated intraoperatively into sufficient ($=$ intraoperative evaluation as solid $+$ no neurological compression suspected—usually GRS grade $A + B + C$) and insufficient ($=$ requiring screw revision) [11].

Data analysis

Statistical analyses were performed using Prism (version 8.4.1; GraphPad Software, La Jolla, CA, USA). Descriptive statistics, including mean, median, minimum, maximum, and standard deviation, were calculated for patient- and

Table 1 Patient data. This table shows patient-related data of all 20 patients included in the study

n (%)	
Number of patients	20
Female gender (%)	10 (50.0)
Age at surgery (y; mean $\pm$ SD; range)	69.4 $\pm$ 12.0 (32.1– 88.0)
Indication of surgery (%)	
Trauma	12 (60.0)
Degenerative spine disease	6 (30.0)
Infection	1 (5.0)
Tumor (pathological fracture)	1 (5.0)

surgery-related characteristics including radiation dose analysis.

Results

Patient characteristics

Twenty consecutive patients (10 women, 10 men) aged 69.4 $\pm$ 12.0 (32.1–88.0) years were included in this study and analyzed (Table 1). A median of 4 (1–11) segments were instrumented. Indications for surgical treatment were trauma, including ankylosing spondylitis and osteoporotic fractures in 12 cases (60%), degenerative spinal disease in 6 cases (30%), and infection and pathological fractures in one case each (5.0%) (Table 1).

Surgical data

Preoperative scans had to be repeated in three (15.0%) cases due to insufficient imaging quality and inaccuracies. One case (5.0%) of delay during surgery related to intraoperative software issues was reported. Overall, a median (range) of 8 (4–18) pedicle screws were implanted in each patient, summed up to a total of 180 (Table 2). The duration of surgery was 186 $\pm$ 68 (106–324) minutes. The time span between skin incision and first intraoperative imaging was 19 $\pm$ 11 (9–40) min, with durations of 16 $\pm$ 9 (9–40) min for intraoperative CT imaging and 28 $\pm$ 11 (13–37) min for 3D C-arm imaging ($p = 0.0169$). The estimated duration of pedicle screw placement as measured by the difference between the time of the first scan and the time of the final scan (including undraping of the situs and uploading data to the navigation system) was 57 $\pm$ 24 (30–107) min, resulting in an estimated duration per screw of 6.5 $\pm$ 1.9 (4.0–11.5) min (Table 2). Intraoperatively, three screws (1.7%) had to be revised. In 14 (70.0%) surgeries, pedicle screw placement

Table 2 Surgical data. This table outlines surgical data regarding pedicle screw placement. The number of pedicle screws and instrumented levels are lined up. Three-dimensional (3D) imaging was acquired intraoperatively using a 3D C-Arm or an operating room sliding gantry computed tomography scanner (ORCT)

Number of pedicle screws	
Total	180
Median (Min–Max)	8 (4–18)
Number of instrumented levels (%)	
1	3 (15.0)
2	1 (5.0)
3	1 (5.0)
4	10 50.0)
5	2 (10.0)
8	1 (5.0)
9	1 (5.0)
11	1 (5.0)
Duration of surgery (min) Mean (Min–Max)	186 ± 68 (106–324)
Duration of screw placement (min) Mean (Min–Max)	
Overall	57 ± 24 (30–107)
Per pedicle screw	6.5 ± 1.9 (4.0–11.5)
Intraoperative image acquisition	
ORCT (%)	14 (70.0)
3D C-arm (%)	6 (30.0)
Intraoperative radiation dose (mGy) Mean (Min–Max)	
3D C-Arm total dose	2195 ± 881 (1099–3617)
3D C-Arm dose per pedicle screw	370 ± 165 (193–595)
ORCT total dose	1418 ± 464 (838–2164)
ORCT dose per pedicle screw	150 ± 61 (92–271)

was performed percutaneously (Table 2). Cement augmentation of screws was performed in ten cases (50.0%) (Table 2). Revision surgery was necessary in one (5.0%) case due to a dislocation of two pedicle screw nuts. Lateral instrumentation was additionally performed in ten (50.0%) cases, with nine cases of vertebral body replacement and one case of implantation of intervertebral cages.

Clinical outcome

Navigated pedicle screw placement was successfully performed in all cases. No patient developed new neurological deficits postoperatively. Regarding pedicle screw placement, postoperative surgery-related complications were reported in three cases (15.0%) (Suppl. Table 1). Apart from the loosening of pedicle screw nuts in one patient, one patient developed a wound seroma postoperatively, and one patient showed cement embolism after cementation of pedicle screws (Suppl. Table 1). Non-surgical postoperative complications are further listed in Suppl. Table 1.

Radiological outcome

The initial pedicle screw placement, as analyzed in accordance with the GRS was Grade *A* for 116 PS (64.4%), *B* for 47 PS (26.1%), *C* for 14 PS (7.8%), *D* for two PS (1.1%), and *E* for one PS (0.6%) (Fig. 3).

Furthermore, rates of pedicle screw placements rated GRS *C–E* were analyzed regarding the distance from the index vertebral body the spinal navigation was registered to. A trend towards more GRS C-E for vertebral bodies distant more than three levels from the index level was found (Fig. 4).

ORCT was used for imaging in 14 cases (70%) and a 3D C-arm in 6 cases (30%), depending on its availability at the time of surgery.

Mean ± SD (Min–Max) radiation dose for ORCT was 1418 ± 464 (838–2164) mGy and 150 ± 61 (92–271) mGy per pedicle screw. For 3D C-arm imaging, the dose was 2195 ± 881 (1099–3617) mGy and 370 ± 165 (193–595) mGy per pedicle screw (Table 2).

Discussion

Assessment of safety, efficacy, and accuracy

For the present study, we evaluated a new navigation system enabling augmented AR-supported pedicle screw placement while integrating navigation cameras into the reference array and drill guide. The clinical application of the image-guided navigation system was feasible in multiple indications, such as trauma, degeneration, infection, and tumor. Pedicle screw placement was performed in open and in percutaneous technique, and navigation was precise in both techniques. Additional cement augmentation of the cannulated pedicle screws was performed in 50% of cases.

In all cases, navigated pedicle screw placement could be performed successfully, while intraoperative imaging had to be repeated in 15% of the cases due to insufficient imaging data, and in one case, a delay related to software issues (5.0%) was reported. With a focus on accuracy and patient safety, 90.5% of pedicle screws were rated GRS Grade *A* or *B* (Fig. 3), with a rate of screw revisions of 1.7% in this study. No new neurological deficits postoperatively. In a large study performed by Ille et al. [11] analyzing the accuracy of navigated pedicle screw placement in 6733 pedicle screws of the whole spine, an overall rate of screw revision of 3.4% was observed. Another study conducted by Ryang et al. [9] in 2011 and 2012 on navigated pedicle screw placement reported a screw revision rate of 4.7% for lumbar pedicle screw placement. These results match with studies performed by Waschke et al. reporting accuracy rates of 96.4% in CT-navigated pedicle screw placement, and Tkatschenko
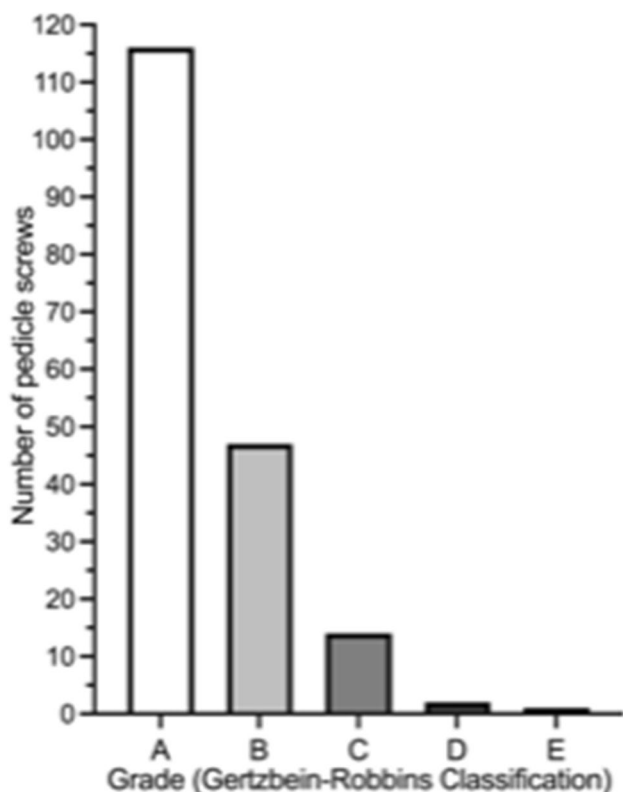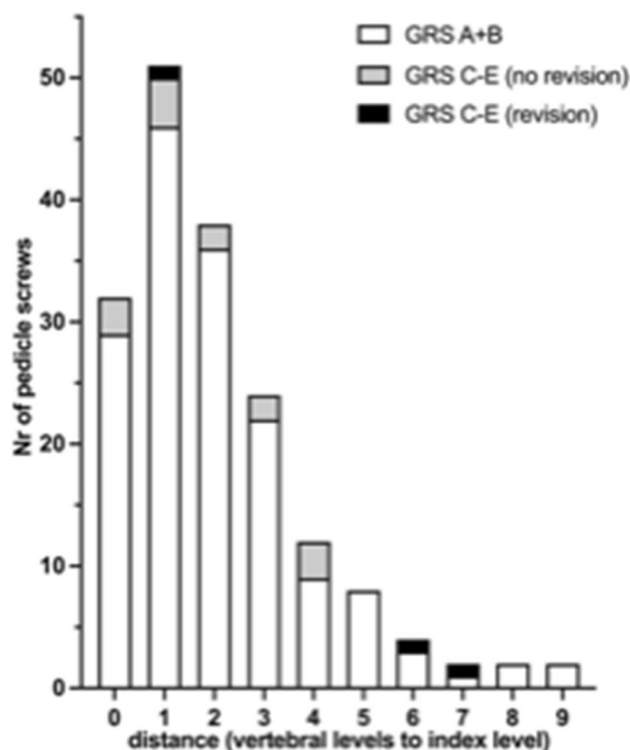
Fig. 3 Radiographic evaluation of pedicle screw placement. This figure lines up the rating of all 180 pedicle screw placements on intraoperative imaging according to the Gertzbein–Robbins classification scale (Grade $A=0$ mm breach distance, $B=<2$ mm, $C=<4$ mm, $D=<6$ mm, $E>6$ mm) before screw revision

Fig. 4 System accuracy. In Fig. 4, the accuracy of pedicle screw placement according to the Gertzbein and Robbins classification system (GRS) is illustrated in relation to the position of the reference array. The distance was measured as the number of vertebral levels between the instrumented and index levels

et al. showing accuracy rates of 96.6% for navigated percutaneous pedicle screw implantation [7, 22].

In this study, the duration between skin incision and first intraoperative imaging was 19 ± 11 (9–40) min, and the estimated duration per screw was 6.5 ± 1.9 (4.0–11.5) minutes. A comparable study by Ding et al. on navigated pedicle screw placement measured a time of skin incision to reference frame attachment of 28.3 ± 20.4 min and a time of 7.8 ± 2.7 min for a single pedicle screw placement [23]. The average time required from skin incision to reference frame attachment was 28.3 ± 20.4 min, and the average time required for insertion of a single pedicle screw was 7.8 ± 2.7 min [23]. Durations of pedicle screw placement on the thoracolumbar spine as low as 3.9 ± 2.5 (1–22) min were reported by Ryang et al. [9]. However, this report measured the time from placement of the navigated drill guide on the supposed/ planned pedicle entry point to final pedicle screw insertion [9].

Regarding radiation dose, comparable settings for ORCT or 3D C-Arm imaging were applied compared to spinal navigation systems routinely applied at our

institution. This results in a similar radiation dose, in total as well as per pedicle screw.

Canulated pedicle screws of titanium, as well as titanium rods, were used in this study. No intraoperative case of hardware failure was reported. One implant failure (loosened pedicle screw nuts) occurred in a long-segment construct.

Intraoperative set-up

Conventional CT-based spinal navigation systems applied in clinical routine mostly require a setup consisting of a central computing unit, display units and an external adjustable infrared camera [9, 11]. In many cases, the system is permanently installed in the operation room. Furthermore, a device for intraoperative 3D imaging, including software integration to the navigation system, is required. To provide intraoperative navigation, a reference array has to be attached to the patient, and all surgical instruments have to be equipped with reflective marker spheres.

In contrast, the system applied in this study offers excellent versatility. As the reference array is equipped with

targets incorporating LEDs and any navigated instrument is equipped with a camera, there is no need for an external infrared camera constantly being placed in the field of vision of reflective markers (Fig. 1). This enables improved visibility of the reference array without the necessity to adapt camera positioning due to line-of-sight issues [24]. Furthermore, only one main computing unit compact in size and equipped with a single screen is required (Fig. 5). Overall, the setup is reduced to a minimum by integrating the cameras into the surgical instruments and establishing a flexible platform, including preoperative planning. No specific modifications of the operating room or the 3D-imaging device, such as installing a reference frame, are required. This results in great flexibility and enables a versatile application of the system in multiple operation rooms as well as for several indications reaching beyond the instrumentation of the spine. However, the targets incorporating LEDs and cameras are single-use materials and are required for every surgery.

Intraoperative addition of augmented reality

The system offers the option to apply AR intraoperatively. Intraoperatively, the 3D imaging is integrated into the navigation software enabling real-time planning of the pedicle screw positioning on an external screen or integrated into an augmented reality view. The view can be chosen by the surgeon individually and changed intraoperatively. AR goggles (NextAR Smart Glasses, Medacta, Castel San Pietro, Switzerland) present the 3D-imaging and neuronavigation data combined with the view of the operation situs (Fig. 2). Subjectively perceived, the fact that the surgeons' view has not been averted from the situs has been rated advantageously. In general, AR is constantly gaining increasing importance in surgery. Augmented reality in pedicle screw placement has
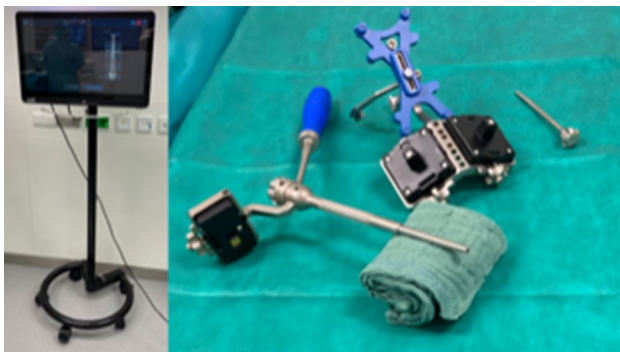
Fig. 5 Complete setup. Figure 5 represents the complete setup of the system required for spinal navigation. The mobile main computing unit (left) is equipped with a single screen. Furthermore, the sterile system (right) consists of two targets attached to the reference array and a camera attached to the surgical instruments, such as the navigated drill guide shown in this figure

become technically feasible over the last few years [13–20]. Recent studies in models and first clinical applications have shown promising results, especially regarding improved visualization of the situs, reduced time of surgery, and precise screw positioning [16, 25, 26].

Limitations

As this study aimed to evaluate the feasibility of this novel navigation system enabling AR, this study was limited to 20 patients at one single high-volume spine center. As a result, no specific analysis regarding instrumentation using only AR was performed.

Conclusion

Navigated pedicle screw placement using a system with integrated cameras for spinal navigation is feasible and appears safe in clinical use. The compact setup enables a versatile use of the system. In addition, the integration of AR and flexible screen application offer new opportunities when compared to an OR room-based navigation system. However, more extensive studies must be conducted in the future to assess the benefits of AR in detail.

Declarations

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