Percutaneous thoraco-lumbar-sacral pedicle screw placement accuracy results from a multi-center, prospective clinical study using a skin marker-based optical navigation system

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Abstract

Study design  Prospective multi-center study.

Objective  The study aimed to evaluate the accuracy of pedicle screw placement using a skin marker-based optical surgical navigation system for minimal invasive thoraco-lumbar-sacral pedicle screw placement.

Methods  The study was performed in a hybrid Operating Room with a video camera-based navigation system integrated in the imaging hardware. The patient was tracked with non-invasive skin markers while the instrument tracking was via an on-shaft optical marker pattern. The screw placement accuracy assessment was performed by three independent reviewers, using the Gertzbein grading. The screw placement time as well as the staff and patient radiation doses was also measured.

Results  In total, 211 screws in 39 patients were analyzed for screw placement accuracy. Of these 32.7% were in the thoracic region, 59.7% were in the lumbar region, and 7.6% were in the sacral region. An overall accuracy of 98.1% was achieved. No screws were deemed severely misplaced (Gertzbein grading 3). The average time for screw placement was 6 min and 25 secs (± 3 min 33 secs). The average operator radiation dose per subject was 40.3 µSv. The mean patient effective dose (ED) was 11.94 mSv.

Conclusion  Skin marker-based ON can be used to achieve very accurate thoracolumbarsacral pedicle screw placements.

Keywords  Minimally invasive spine · Thoracolumbarsacral pedicle screw placement · Screw accuracy · Computer-assisted navigation · Image-guided surgery

Introduction

In minimally invasive spine surgery (MISS), the use of intra-operative fluoroscopy can mitigate issues associated with the loss of direct visualization of anatomic landmarks. However, only relying on fluoroscopy in MISS [1] is associated with pedicle perforation rates in the range of 12.5–13.5%. Computer-assisted navigation (CAN) offers the promise of improving screw placement accuracy [2–4, 6, 7], reducing radiation exposure, and reducing complications during MISS procedures [2, 30].

Currently available CAN platforms rely on infra-red camera-based tracking and bone-anchored dynamic reference frames (DRF) [8]. The infra-red cameras have the disadvantage of requiring a clear line-of-sight. Any movement of the DRF and the distance of the operating level from the DRF may influence accuracy [9].
A video camera-based optical navigation system (ClarifEye, Philips) was recently developed. Optical Navigation (ON) relies on skin markers in place of invasive DRFs for patient tacking and on-shaft optical markers for live instrument tracking. This system was previously shown to have high accuracy in complex open deformity cases [10] and a pre-clinical study reported on the accuracy of the system for percutaneous pedicle screw placements in the thoracolumbar-sacral spine compared with fluoroscopy [11].

The study aimed to evaluate the accuracy of pedicle screw placement using a skin marker-based optical surgical navigation system for minimal invasive thoraco-lumbar-sacral pedicle screw placement. Here, we present the first clinical results on screw placement accuracy using this system. Secondary objectives include procedure time and the patient and staff radiation dose.

**Materials and methods**

This was a prospective study with a primary objective of collecting accuracy data on pedicle screw placements when using the ON system. The study was approved by the ethics committee and competent authorities in the involved countries (Germany: Medizinische Fakultat Der Christian-Albrechts-Universitat Zu Kiel ethic committee (00,011,811) and BfArM (00,011,828) and Switzerland: Comitato Etico del Cantone Ticino (2019–00,378) and Swissmedic (10,000,492)). Only subjects older than 18 years and undergoing percutaneous spine surgery in the thoracolumbar sacral spine in a maximum of 4 levels, were enrolled. All enrolled patients provided the informed consent.

The study was performed in a hybrid Operating Room equipped with a radiolucent, motorized, carbon fiber surgical table. 3D Cone Beam-Computed Tomography (CBCT) (XperCT, Philips, Best, the Netherlands) scans were done intra-operatively using a robotic ceiling-mounted C-arm system (AlluraClarity Flexmove, Philips, Best, The Netherlands). Navigation guidance was provided by ON (ClarifEye, Philips), based on video inputs from four optical cameras, rigidly integrated on each side of the detector frame (Fig. 1).

Surgery was performed under general anesthesia with patient in prone position. Approximately 8–10 optical skin markers (Philips, The Netherlands) were attached to the patient’s back, in a random pattern, around the surgical site (Fig. 2). A 10 s 3D CBCT was performed by robotic rotation of the C-arm through 180° and an automatic 3D segmentation was obtained. The segmented view of the spinal volume with

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**Fig. 1** Devices and software used as a part of the study. Imaging was provided by the Allura angiographic system. The cameras in the detector (marked with a blue circle) provided the video input of the surgical site. The augmented reality surgical navigation (ARSN) system software was used to provide navigational guidance. The adhesive skin markers are used to track the patient movements. The Jamshidi needle had an optical pattern engraved on the shaft, which was used by the video cameras to provide 3D tracking of the needle in relation to the 3D scan.
the vertebra labeled and pedicles highlighted, together with the multiplanar slice display was shown on a medical grade monitor (Fig. 2). The surgeon selected the desired pedicles and manually adjusted the trajectory, and dimensions of the virtually placed screw. A choice of four C-arm positions was provided to the surgeon, based on which of the four cameras was aligned to the planned trajectory. The surgeon chose the C-arm position which provided the best working position.

Intraoperative CBCT and planned paths for screw placement were augmented to the video images showing the surgical field (Fig. 2). In case of patient movement, the planned paths were automatically corrected, without need for re-registration, owing to the continuous patient tracking by the optical skin markers. The surgeon placed the tip of the tracked Jamshidi needle (ClarifEye Needle, Philips) at the skin entry point and advanced it through the skin, and soft tissue until it reached the entry point on the vertebral body. As the optical marker on the shaft of the needle was at a pre-calibrated distance from the tip of the needle, tracking the on-shaft optical marker (Fig. 1) enabled depth tracking of the needle.

Based on the pathology being treated, screw placements and fusion procedures were either performed on their own or combined with decompression procedures, biopsy, cage placement and/or cement augmentation. When all screws were placed, intra-operative CBCT was performed to verify the screw positions. A screw was revised if the surgeon judged its position to be unsatisfactory. After revision, another CBCT was performed. At the end of the study, the final CBCT scans were collected, anonymized, and graded by three independent reviewers not involved in the procedure for accuracy according to the Gertzbein scale: grade 0 (screw within the pedicle without cortical breach), grade 1 (0–2 mm breach, minor perforation including cortical encroachment), grade 2 (2–4 mm breach, moderate breach, and grade 3 (> 4 mm breach, severe displacement) [12]. Neurophysiological monitoring was not performed during the procedure. Post-screw and rod placement, fascia and skin were closed in a standard fashion.

Post-operative CT was not performed because CBCT was considered sufficient for clinical evaluation [31].

The duration of different workflow steps and screw placement time were recorded. Staff dose was recorded using personalized dosimeters (DoseAware, Philips, Netherlands) and patient dose was recorded by the imaging system as Dose Area Product (DAP). The patient dose was calculated as the sum of the 2D and 3D component of the procedure and a post-instrumentation verification scan. Monte Carlo software (PCXMC v2.0, STUK, Helsinki, Finland) was used to estimate effective dose (ED) associated with given DAP [13].

SAS® Software Version 9.4 was used to calculate the sample size. Sample size calculation for the primary objective was based on a previous cadaver study [11] with 94%
percutaneous pedicle screw placements accuracy in the thoracolumbarsacral spine. Assuming a similar accuracy as a previous cadaver study\textsuperscript{11} with an 8% margin of error and 85% power to detect a two-sided 95% confidence interval, using the Exact Clopper–Pearson test, we obtained a sample size of 200 screws. We further estimated a patient dropout rate of 10% which resulted in a final sample size of 220 screws.

The Gertzbein Grade of the placed screws was summarized using frequency counts and percentages for the overall analysis set, by anatomical region (lumbar, sacral or thoracic), and by spinal level of the pedicles. For the overall analysis set, the proportion of accurately placed screws was summarized along with the 95% CI as calculated using Exact Clopper–Pearson (ignoring the clustering by subject or location of the pedicles) and Cochran method described by Zhou \textsuperscript{[14]} accounting for the patient level clustering of the pedicles. Procedure time, staff and patient radiation dose were expressed as mean (± standard deviation), median (min–max range), or frequency (percentage), as appropriate.

**Results**

Forty patients were enrolled between July 2019 and March 2021. In total, 220 pedicle screws were placed. Thirty percent of the patients had previous spine surgeries and 15.4% were obese according to the WHO criteria. Of the 40 patients, one patient was excluded (four screws) as the navigation system could not be used because the sterile drape was stuck in the metal casing of the C-arm, blocking all C-arm movements. In one patient (with four screws), no verification scan was performed; therefore, the screws could not be rated for accuracy. Finally, one screw was not navigated because of local power outage. As a result, of the 220 screws, 211 screws were included in the final analysis of the study results. Of these, 32.7% were in the thoracic region 59.7% in the lumbar region, and 7.6% in the sacral region. Table 1 summarizes patient demographics and surgical indications. The distribution of screws at each vertebral level is shown in Fig. 3.

All surgeries were performed by two surgeons in Lugano and three surgeons in Germany. None of these surgeons had previous experience with the ON system, except during cadaver or phantom training sessions. However, all the surgeons had some experience with other navigation systems. Every patient received a minimum of 4 screws and a maximum of 8 screws (average of 5.5 screws per subject). Twenty-three patients had two-level fusion, four patients had three-level fusion, and 13 patients had four-level fusion.

No device related adverse events were observed during this study.

**Accuracy**

The screw placement accuracy (grade 0 and 1) was 98.1% (95% CI: 95.2%, 99.5%) using the exact method, corresponding to 207/211 successfully placed ((and 98.1% (95%CI:95.9%, 100%) using the cluster method. A total of 196, 11 and 4 screws were rated grades 0 (93%), 1 (5%), and 2 (2%), respectively. No screws were rated as severely misplaced (Grade 3). Figure 4 shows a breakdown of the screw accuracy for each Gertzbein grade for each anatomical region. All four misplaced screws had grade 2 medial breach. Two breaches were at T6, one at T7 and one at L4. All misplaced screws were in patients with unstable fractures.

In the lumbar, thoracic, and sacral regions, 99.2, 95.7 and 100% of the screws, respectively, were accurately placed. Of the 211 screws placed, 6 were revised intraoperatively. None of the patients required postoperative screw revision prior to hospital discharge.

**Screw navigation time**

The average time from skin incision to skin closure was 2 h 50 min 28 s (± 1 h 9 min and 59 s) and included 27 cases in which the fusion was combined with discectomy, cage placement, laminectomy, biopsy and/or screw cementing. Because no invasive frame was used, the first skin incision was made at the start of the treatment step. Therefore, the skin incision to skin closure time, does not consider the time for preparation, acquisition, and planning steps, but includes the treatment duration which includes the time for all associated procedures, time for all verification scans, rod placement, and skin closure time. The average time out to skin closure time (including the preparation, acquisition, and planning in addition to time included as part of skin incision to skin closure) was 3 h 19 min 57 s (± 1 h 14 min and 41 s). The average time required to align the tracked Jamshidi needle, place K-wire, place the screw over the K-wire and tighten it in place was 6 min and 25 secs (± 3 min 33 secs). The time required for each individual workflow step and its relative proportion to the time out to skin closure time is provided in Tables 2, 3 and in Fig. 5.

An exploratory analysis divided patients in Lugano, where 31 of the 40 cases were performed, into three groups of consecutive 10 patients, based on their date of surgery. There was a tendency toward a shorter screw placement time (6 min 32 s to 3 min 59 s) when comparing the first and last 10 cases, suggesting that there may be reduced time required with increased physician experience with ON (Table 4).

**Patient and staff radiation dose**

The mean operator radiation dose per subject was 40.3 μSv. The mean patient effective dose (ED) was 11.94 mSv. The
patient dose included the dose required for the planning and verification scans as well as the fluoroscopy dose. The overall mean relative contributions of fluoroscopy, planning, and verification scans to the total patient ED were 8.58%, 32.46% and 53.90%, respectively. Fluoroscopy was needed, despite the use of navigation, as in majority of cases, screw placement was combined with procedures such as cage placement, decompression, biopsy, and cement augmentation.

### Discussion

This was the first clinical study in which ON was used for MISS pedicle screw placement. The obtained accuracy of 98.1% from 211 screws of which 32.7% were in thoracic region, in 39 patients with varying spine pathologies, 15.4% of those in the obese category and 30% had

| Variable                          | Statistic         | All subjects (N = 40) |
|-----------------------------------|-------------------|-----------------------|
| Age (years)                       | n (%)             | 40 (100%)             |
| Mean (SD)                         | 60.8 (15.3)       |                       |
| 95% CI                            | (55.9, 65.7)      |                       |
| Median                            | 60                |                       |
| Min, Max                          | 20, 87            |                       |
| Gender, n (%)                     |                   |                       |
| Female                            | 17 (42.5%)        |                       |
| Male                              | 23 (57.5%)        |                       |
| Height (cm)                       | n (%)             | 40 (100%)             |
| Mean (SD)                         | 169.7 (10.6)      |                       |
| 95% CI                            | (166.3, 173.1)    |                       |
| Median                            | 170               |                       |
| Min, Max                          | 147, 197          |                       |
| Weight (kg)                       | n (%)             | 40 (100%)             |
| Mean (SD)                         | 79.5 (18.5)       |                       |
| 95% CI                            | (73.6, 85.4)      |                       |
| Median                            | 78.5              |                       |
| Min, Max                          | 52, 160           |                       |
| Body mass index (kg/m²)           | n (%)             | 40 (100%)             |
| Mean (SD)                         | 27.8 (7.3)        |                       |
| 95% CI                            | (25.5, 30.1)      |                       |
| Median                            | 26.9              |                       |
| Min, Max                          | 18.3, 62.5        |                       |
| Primary reason for procedure, n (%)| Adjacent segment disease | 0 (0.0%) |
|                                    | Disk herniations  | 2 (5.0%)              |
|                                    | Fracture and spondylolysis | 18 (45.0%) |
|                                    | Instability       | 5 (12.5%)             |
|                                    | Spinal deformity: kyphosis | 0 (0.0%) |
|                                    | Spinal deformity: scoliosis | 0 (0.0%) |
|                                    | Spinal stenosis   | 8 (20.0%)             |
|                                    | Spinal tumors     | 1 (2.5%)              |
|                                    | Spondylolisthesis | 1 (2.5%)              |
|                                    | Revision surgery  | 1 (2.5%)              |
|                                    | Vertical collapse secondary to osteoporosis | 0 (0.0%) |
|                                    | Other             | 4 (10.0%)             |

*BMI* Body Mass Index, *CI* Confidence Interval, *SD* Standard Deviation
Fig. 3 Distribution of number of screws at each level. Screws were placed at all levels from T2 to S1 level. Most of the screws in the thoracic region were at the T6 level while L4 and L5 had the maximum number of lumbar screws.

Fig. 4 Combined accuracy of screw placement for all regions and individual accuracies for thoracic, lumbar and sacral regions. In all regions of the spine, majority of the screws were perfectly placed (grade 0). There were no grade 3 screw placements. Majority (3) of the grade 2 screws were in the small pedicles in the thoracic region and 1 was observed in the lumbar spine.
previous spine surgeries, with five different surgeons operating out of two separate hospitals in two different countries, strongly confirmed the safety and efficacy of this system.

Despite the continued rise in the adoption rates of MISS, very few clinical studies have specifically addressed the accuracy and clinical safety of such procedures with CAN, especially in the more challenging thoracic regions. Table 5 provides an overview of the accuracies of 3D navigation for MISS as reported in literature and the 98.1% accuracy obtained with the ON in this study, is in line with these published reports. The accuracy results of ON were also comparable to the pedicle screw placement accuracies of robotic systems [15–17].

In all the published reports, 3D navigation systems rely on bone-anchored reference frames to register the navigation system with the acquired 3D image data [18]. Attaching the DRF can be challenging in obese patients and there is the possibility of inadvertent motion of the reference frame [18]. This may lead to registration errors and the need for re-registration, which may add to the procedure time. In addition, the inaccuracy increases with increasing distance from the reference frame [19]. ON relies on skin markers, which mitigate the issues described for bone-based reference frames.
frames. Global movements of the markers with respect to the underlying spine, such as during breathing, have no impact on accuracy. In cases where there is a local deformation due to stretching of the skin, ON focuses on tracking the remaining rigid part of the skin marker model to maintain tracking accuracy.

Skin-based tracking can be a cause for concern in obese patients who have larger amounts of adipose tissue and subsequently larger subcutaneous mobility [20]. In our study, we had 42 screws placed in 7 patients with a BMI > 30, which is the WHO cut-off for obesity, and 1 patient with a BMI > 60. All screws were placed accurately in these patients. The only other system relying on a non-invasive patient tracker in the form of a fixed form (unlike random skin marker placement with ON), an adhesive frame fitted with light emitting diodes (LED), which is applied to the patient’s back during spine surgery is the SpineMask (Stryker). However, to ensure the visibility of a sufficient number of LEDs for tracking via

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**Table 4** Average time for screw placement in first 10, middle 10 and last 10 patients performed in Lugano

| Variable | Statistic | Subjects LUG-001 to LUG-010 (N=10) | Subjects LUG-011 to LUG-020 (N=10) | Subjects LUG-021 to LUG-031 (N=10) |
|----------|-----------|-----------------------------------|-----------------------------------|-----------------------------------|
| Average screw placement time (hh:mm:ss) | Number of screws | 50 | 52 | 62 |
|          | Mean (SD)  | 0:06:32 (0:03:01) | 0:05:40 (0:02:27) | 0:03:59 (0:01:46) |
|          | Median     | 0:05:48 | 0:05:24 | 0:03:24 |
|          | Min, Max   | 0:01:44, 0:14:33 | 0:02:20, 0:12:44 | 0:01:55, 0:12:03 |
infra-red cameras, this noninvasive patient tracker mask requires a larger intraoperative 3D image dataset which has been shown to result in a higher radiation exposure to the patient [21].

One of the issues associated with the use of navigation systems is the time required to set it up. The mean setting up time for ON (which included time for placing skin markers, obtaining 3D scan and segmenting the vertebrae to create a 3D model) was 15 min 26 s. This was lower than the 30 min preparation time reported by Shin et al. [22] and 33.6 min recorded by Ille et al. [23] for the O-arm. The reduced preparation time could be explained by following factors: (i) As a skin marker-based system, no additional time is needed to attach the DRF (ii) combining imaging and navigation into one system eliminates time needed to register and transfer the data between systems. In addition, no extra time is spent in re-registration (iii) tracked needle was pre-calibrated and so no time was needed for registering and calibrating the instrument (iv) there was no additional time required to position the cameras to ensure a clear line of sight as the cameras were integrated in the C-arm detector.

The longest part of the procedure time was devoted to the treatment time which included the time required to navigate the pedicle screw in the optimum position as well as the time required to carry out non-fusion related steps such as decompression, biopsy, cement augmentation and placement of rods. On average, the treatment time contributed 45% of the total procedure time. The mean time required to place screws in optimum position was lower than or comparable to values reported in the literature for open and MIS lumbosacral pedicle screw placements [5, 23, 25]. However, there was a large variation in the screw placement times which could be a consequence of the learning curve effect.

The hazards of increased radiation exposure to staff are well known [23]. The average operator radiation dose was 40.3 µSv in the present study. In a study where 2D fluoroscopy was used to place pedicle screws in 24 patients via a minimally invasive TLIF procedure, surgeons received several times higher radiation doses averaging 270 µSv, which is significantly higher than what was observed in our study and even underestimates the exposure to the staff, since the dosimeter was placed under the lead apron at the waist level [26].

Patient radiation dose is another aspect of concern when using CAN. The reported effective average radiation dose to the patient when using the Airo CT (Stryker) is 5.5 to 7.4 mSv per scan based on patient weight [27]. Corresponding average radiation dose for O-arm (Medtronic) is reported to be between 8 and 9 mSv per scan when using the High Dose scan [28, 29]. In the current study, the average ED for making planning scans was 3.65 mSv and the mean ED for the whole procedure was 11.94 mSv, based on an average of 2.4 scans per patient as well as the dose for fluoroscopy used during the remaining procedure (cage placement, cementing, etc.). Other studies have reported doses up to 31 mSv when maximum of three scans are performed during a procedure. [30] While indicative of the lower radiation dose of ON, an accurate comparison between different systems will require a study with the available CAN systems on phantoms or cadavers of similar BMI.

Moreover, publications indicate that the image quality of the intra-operative CBCT with the ON is as reliable as the image quality of a conventional CT scan for pedicle screw assessments. [31] Therefore, the post-op CT scan was replaced with an intra-operative verification CBCT which resulted in dose savings [31] and potentially avoiding repeat surgeries to reposition misplaced screws.

The main limitation of this study is that it does not compare ON to fluoroscopy or other navigation technologies. Also, due to limited cohort size, no definitive conclusion on learning curve associated with ON could be made.

### Table 5

| Author, year | Study design | Obtained accuracy | Spinal levels | CAN technique | Patients/screws |
|--------------|--------------|-------------------|---------------|---------------|-----------------|
| Innocenzi et al., 2017 [13] | Retrospective | 86.1% | Thoracic, Lumbar | CT-based navigation | 56/230 |
| Jorge Torres et al., 2012 [10] | Retrospective | 94.2% | Lumbar, S1 | 3D fluoro with navigation | 50/172 |
| Fraser et al., 2010 [15] | Retrospective | 100% | Lumbar, S1 | 3D fluoro with navigation | 29/66 |
| Bourgeis AC et al. [9] | Retrospective | 98.85% | Lumbar, S1 | 3D fluoro with navigation | 518/2132 |
| Holly et al., 2003 [14] | Cadaver | 97% | Thoracic, lumbar | 3D fluoro with navigation | 3/94 |
| Houten et al., 2012 [16] | Retrospective | 97% | lumbar | O-arm with navigation | 52/205 |
| Kim et al., 2014 [17] | Retrospective | 99% | Lumbar, sacral | O-arm with navigation | 48/290 |

**Conclusion**

ON with non-invasive skin markers can be used to achieve high accuracy (98.1%) for screw placement during MISS in thoracolumbarsacral with acceptable screw placement times and patient radiation.
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Declarations

Conflict of interest Authors declare that they do not have relationships/conditions/circumstances that present potential conflict of interest.

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