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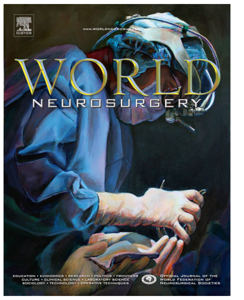

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Total navigation in spine surgery; a concise guide to eliminate fluoroscopy using a portable intraoperative-CT 3D navigation system

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Abbreviations

ELIF: Extreme Lateral Interbody Fusion
EMG: Electromyography
iCT NAV: Intraoperative Computer Tomography Navigation
MIS-TLIF: Minimally Invasive – Trans Foraminal Interbody Fusion
MISS: Minimally Invasive Spine Surgery
NAV: Image Guided Navigation
OR: Operating/Operating Room
RA: Reference Array

Keywords: Spine, navigation, minimally invasive spine surgery, CT, fusion, neural decompression

Abstract

Background: Portable intraoperative computed tomography (iCT) with integrated 3D navigation offers new opportunities for more precise navigation in spinal surgery, eliminates radiation exposure for the surgical team and accelerates surgical workflows. We present the concept of "total navigation" using iCT NAV in spinal surgery. Therefore, we propose a step-by-step guideline demonstrating how total navigation can eliminate fluoroscopy with time efficient workflows integrating iCT NAV into daily practice.

Methods: A prospective study was conducted on collected data from patients undergoing iCT NAV-guided spine surgery. Number of scans, radiation exposure and workflow of iCT NAV (instrumentation, cage placement, localization, etc.) were documented. Finally, the accuracy of pedicle screws as well as time for instrumentation was determined.

Results: iCT NAV was successfully performed in 117 cases for various indications and in all regions of the spine. 61% of cases were performed in a minimally invasive manner. Navigation was utilized for skin incision, localization of index level and verification of implant position. iCT NAV was used to evaluate neural decompression achieved in spinal fusion surgeries. Total navigation eliminates fluoroscopy in 75%, thus reducing staff radiation exposure entirely. The average time for iCT NAV setup and pedicle screw insertion was 12.1 and 3.1 minutes, respectively achieving a pedicle screw accuracy of 99%.

Conclusions: Total navigation makes spine surgery safer, more accurate and enhances efficient and reproducible workflows. Fluoroscopy and radiation exposure for the surgical staff can be eliminated in the majority of cases.

Keywords: navigation, CT, minimally invasive spine surgery, neural decompression, spine, degenerative

Introduction

As minimally invasive spine surgery (MISS) constantly progresses, spine surgeons increasingly rely on advanced image guided navigation (NAV). However, NAV systems still seem to decelerate surgical workflow, which limits its versatility and applicability in the broad field (1). Recent studies suggest intraoperative CT-guided (iCT) NAV provides benefits that outweigh these drawbacks, including reducing radiation exposure, saving operative (OR) time and improving the accuracy of instrumentation (2-4). The portable iCT AIRO NAV (Brainlab AG, Feldkirchen, Germany) is a state-of the-art iCT which offers new opportunities for more precise navigation in spinal surgery, while at the same time accelerating surgical workflow particularly in MISS when the anatomy is altered and orientation may be difficult (5-7).

Recently, we have introduced the concept of *total navigation* in MIS-TLIF (8). Total navigation employs intraoperative 3D navigation combined with the latest-generation portable iCT in all steps of spine surgery. Application of total navigation results in complete elimination of radiation exposure for the surgical staff, elimination of K-wires for instrumentation and elimination of the pedicle probe.

Here we propose a “step-by-step” guide for the application of total navigation in spine surgery which can be used to successfully implement this technique into daily spine surgery practice. Additionally, this manuscript can be considered as a complimentary part to our recently published MISS guide, if “total navigation through tubular retractors” is intended (9).

The aim of the present study was to prospectively review our first 117 cases using iCT NAV for total navigation, and to summarize our experiences regarding surgical workflow, pedicle screw accuracy and complications into a sufficient guideline. Case examples demonstrating the versatility of this technology are provided in the supplemental digital content. Additionally, an instructional step-by-step illustrative material on how to perform a totally navigated MIS-TLIF is provided.

Material and Methods

Indications for total navigation

A prospective single-center study of patients undergoing iCT NAV-guided spine surgery with single- or multilevel spinal disorders (occipital-cervical to lumbar-sacral), between November 2014 and January 2016 was conducted, including diverse pathologies (degenerative, trauma, neoplasm, deformity, etc.) as demonstrated in Table 1. Demographic data including patient history, age, sex, and comorbidities were documented.

Operating room setup

The iCT-guided NAV included the Airo® CT scanner, an image-guidance system, an infrared tracking camera navigation system (Brainlab CurveTM, Brainlab AG, Feldkirchen, Germany) and a patient reference array (RA) (Brainlab AG, Feldkirchen, Germany). The design of the Airo® CT scanner combined a large gantry opening (107cm) with a slim gantry (30.5cm x 38cm) and a small footprint ($1.5m^2$). The suspension-controlled electrical drive system allowed the machinery to be moved around the operating room (OR). A mobile, radiolucent carbon fiber table (Trumpf TruSystem 7500, TRUMPF Inc., Farmington, Connecticut, USA) was attached to the gantry during surgery. Airo® and CurveTM systems were connected to an automatic image-transfer device and an image-patient co-registration that assisted in navigation. Pre- or manually calibrated instruments could be used with navigation for enhanced workflow.

Setup of the iCT NAV for total navigation:

1. Before surgery, the iCT NAV is positioned parallel with the rail system and the gantry, facing anesthesia (Figure 1A).
2. After the patient is anesthetized on a transport bed parallel to the gantry, the gantry of the portable iCT system is rotated perpendicular to the rails into the scan position (Figure 1B).
3. Hereafter, a Trumpf carbon fiber tabletop with a T3 frame is connected to the Trumpf column on the integrated rail system.
4. Intubation and insertion of the needle electrodes for EMG monitoring is conducted, followed by flipping the patient onto the T3 frame.

5. Next, the patient is positioned on and taped to the table. Adequate taping is important since it minimizes anatomical displacement, especially in obese patients. Care has to be taken not to tape too tightly in order to avoid skin necrosis or pressure points (Figure 1B Supplemental Figure 1S).
6. The gantry is located on the cranial side of the patient and all cables (Bovie, suction and electromyography (EMG) monitoring, etc.) is let through the gantry (Figure 1B).
7. While the iCT-scanner is running, the surgical staff leaves the room, and thus avoid unnecessary radiation exposure (Figure 1C).

Workflow for lumbar/lower thoracic spinal surgery with pedicle screw instrumentation:

1. For lumbar/lower thoracic cases, a 2-pin fixator is attached to the patient's pelvis using two 3mm Schanz pins. The RA is connected to the 2-pin fixator and tightened (Figure 2 and Supplemental Video).
2. For identification of the index level, the RA is attached to the iliac crest with the patient secured safely to the table (Figure 2). The RA may also be clamped to the spinous process (one or two levels cranially or caudally to the index level).
3. For the preoperative scan, two half sheets are draped around the incision site and the region of interest was marked on the drape (Supplemental Video).
4. An infrared camera is positioned towards the RA and the reflective markers on the gantry.
5. All personnel leave the OR before a radiology technician initializes the scan via a remote control. This eliminates the X-ray exposure for the surgical staff.
6. After the scan, the images are automatically transferred to the NAV.
7. The site of incision and its proper trajectory are identified with a pointer. In open cases, accuracy is confirmed by palpation of anatomical landmarks (i.e. spinous transverse process at several levels). In MISS, the tip of a transverse process is used to verify accuracy (Supplemental Video).
8. For MISS cases, a drill guide tube is calibrated and connected above the desired entry point through a small skin and fascial incision (Figure 3A-B) (10). The use of a navigated guide tube streamlines the workflow by eliminating K-wires and the need to navigate multiple instruments (Point-Drill-Tap-Screw) (11). The navigated guide tube is used for drilling, tapping, and screw placement (10) (Supplemental Video).

9. A power drill with a 3.2mm fluted drill bit was then used to prepare the entry point, followed by tapping the pedicle (Figure 3B) (10).

11. The desired screw is now inserted through the navigated guide tube. The screw is then stimulated; we use at threshold above 9 mA for acceptance of the screw position.

12. In cases where the case requires additional decompression and placement of a cage the following steps are followed: Bone graft can be harvested from the iliac crest and the pointer can be used for best localization of appropriate iliac crest bone. In cases where a tubular retractor is placed for decompression and facetectomy the fascial incision for the tubular retractor is determined with navigation. The fascial incision is typically 2 to 3 cm medially to the fascial incision required for screw placement. The pointer identifies the inferior edge of the lamina and the facet joint. Over a series of tubular dilators, the retractor is then placed and adequate exposure of the anatomy is again confirmed with the navigated pointer. The decompression and facetectomy is performed under the microscope and can also be done with the assistance of navigation. Navigation at this point will also be helpful to determine, for example, the localization of the pedicle, the disk space and the trajectory of the disk space. We then use navigation also to determine the trajectory of the discectomy and cage placement.

13. After placement of the cage a control CT scan is obtained. Based on this CT scan the length of the rods can be determined either with navigation or directly off the computer screen.

Workflow for localization of spinal pathology:

This is useful for spine tumors and cervical instrumentation cases please refer to our supplemental digital content.

1. The patient is placed either prone or supine and secured to the table using cloth tape as described in the lumbar total navigation workflow.
2. The RA is placed and secured either to the table or to a Mayfield head-holder depending on the anatomical region of interest (Figure 2).
3. For the preoperative scan, two half sheets are draped around the incision site and the region of interest was marked on the drape (Supplemental Video).
4. An infrared camera is positioned towards the RA and the reflective markers on the gantry.
5. All personnel left the OR before a radiology technician initialized the scan via a remote control. This eliminated the X-ray exposure for the surgical staff.

6. After the scan, the images are automatically transferred to the NAV.
7. The site of incision and its proper trajectory are identified with a pointer. In open cases, accuracy could be confirmed by palpation of anatomical landmarks (i.e. spinous transverse process at several levels). In MISS, the tip of a transverse process is used to verify accuracy (Supplemental Video).
8. Displacement of anatomical structures must be taken into consideration and re-scanning or anatomical landmark confirmation may be necessary especially treating intra-dural spine tumors.
9. A final CT is obtained in those cases where permanent hardware is implanted specially in occipito-cervical instrumentations (Supplemental Video)

Radiographic and clinical assessment

iCT screw accuracy was measured by independent review by evaluation of the immediate pre- and postoperative iCT scans according to Costa et al. (11). Accuracy of iCT-guided NAV was assessed by summing the screw grades (graded as 0 or 1) according to Laine et al. (12).

Radiation dose assessment

The radiation exposure received by the patient was assessed by extracting the amount of radiation from the NAV system.

Results

Baseline characteristics

iCT NAV has been successfully employed in 117 cases (115 patients), without complications (mean age: 62.5 ± 15.4 years; 57% female and 43% male) as illustrated in Table 1. Major indications included degenerative disease (65%), trauma (3.4%), neoplasm (8.5%), deformity (6%), and adjacent segment disease (10.2%). 69% of spine surgeries addressed the lumbar spine, whereas 21% addressed the cervical spine, and 10% addressed the thoracic spine (Table 1).

Utilization of iCT

iCT-guided NAV was utilized for the measurement of instrumentation (screws, rod and cage size), localization (incision planning, tubular retractor placement, extent of laminectomy, index level, spinal tumor, thoracic disc herniation), and assessment of neural decompression in ELIF and TLIF. Within all cases involving instrumentation, a second intraoperative scan was conducted to verify the implant position.

Radiation exposure

Our standard protocol included a preoperative and postoperative scan before wound closure. In the first two surgeries more than 2 scans per patient were required; hereafter, the mean number of scans per patient was 2.1. The effective dose per scan for normal, overweight, and obese patients was 5.5, 6.5, and 7.4 mSv respectively, with a mean dose of 13.4mSv as shown in Table 1 (4).

Pedicle screw accuracy

The average time from “pointing” (pedicle identification through the navigated guide tube) to pedicle screw stimulation was 3.1 minutes. 390 pedicle screws (41 patients) were inserted in the lower cervical, thoracic and lumbar-sacral spine. 25 screws (6.4%) were identified with minor perforations (≤ 2mm), and four screws (1.0%) were misplaced with perforations (> 2-4mm) (Table 1). Misplacement of > 4 mm was not detected. As there is no clinical or structural difference between screws with a cortical violation (≤ 2mm) and screws without perforation (11), the accuracy of the iCT NAV was assessed by the number of screws evaluated as “misplaced” (12). All of the cortical breaches were lateral. One malpositioned screw (1/390, 0.3%) was replaced after the second scan during the same surgery. No patient required a revision after leaving the OR.

Discussion

Over the past years, we have expanded the utilization of iCT NAV in order to make MISS safer, eliminate radiation exposure to the surgical staff and create more efficient workflows (Table 2). Here we summarize our initial experiences with total navigation in spine surgery (6).

Utility of iCT NAV

Total navigation can be applied in daily practice for various spinal procedures (Table 3). Specifically, in MISS, iCT-guided NAV is helpful in anatomic regions where conventional imaging techniques fail (i.e. cervico-thoracic junction), and therefore helps to eliminate, for example, wrong-level surgeries. Although wrong level surgery is a rare adverse event it nevertheless may have devastating consequences for the patient as well as for the surgeon (13). Data of The Joint Commission between 2004 and 2012 propose, wrong-site, or wrong-procedure events to be the most common sentinel events, accounting for 928 of 6994 events (13.3%) (14). Wrong-level and/or wrong site surgery still occur occasionally, especially when the anatomy is altered in severely degenerative cases, revision surgeries, spinal deformity, and/or variant vertebral morphology. In a recent report, 50% of spine surgeons stated that they have performed at least one or more wrong-level operation throughout their careers; in general, numbers for wrong-level lumbar surgery range from 0.04% to 5.3% (15-21). Furthermore, accurate radiographic identification of the index level can be challenging even for highly experienced surgeons. Misinterpretation of conventional intraoperative radiographs and subsequent failure in localization have been found to be a risk factor for wrong-level spine surgery (18, 22, 23). The portable system described here significantly supports localization of the index region. Additionally, iCT NAV can be used in multiple ORs, which increases versatility and flexibility and provides better cost efficiency compared to cheaper alternatives although it requires a higher initial cost (24).

Another condition in which iCT NAV truly supports the implementation of MISS principles are spinal tumors. In the past, spinal tumor cases were traditionally approached via maximal access surgery in order to obtain best-possible visualization to achieve R0 resection (whenever possible) according to the Union for International Cancer Control. As MISS constantly progresses, spine surgeons increasingly rely on advanced image guided navigation. Spinal tumor resection in a minimally invasive manner requests the knowledge about the exact localization in situ. Therefore, at our institution iCT NAV is used for precise localization of the pathology before tumor removal as well as subsequent planning of the skin incision in order to minimize soft tissue disruption, specifically in radiologically suggestive benign tumors and/or in the thoracic or cervico-thoracic transitional levels, where radiological orientation can be impaired by surrounding anatomical structures i.e shoulders (i.e. Schwannoma, Supplementary Case 1). Furthermore, utilization of the iCT NAV provides the opportunity to evaluate the resection / decompression immediately after tumor resection, especially due to the relatively high soft tissue resolution the iCT is able to provide. Though, a second scan is necessary due to the interventional anatomical alteration due to tumor removal.

Effect of iCT on screw accuracy

Use of iCT NAV and alternative technologies has demonstrated significant improvements in pedicle screw placement accuracy, as well as reduced complication risks and fewer reoperations (7, 25-34). Noriega et al. showed a reduction in the number of malpositioned screws from 10.3% to 3.6% when using iCT NAV instead of fluoroscopy (30, 35).

In the present study, we achieved an accuracy of 99% (5, 36-39). Our average time for screw placement was 3.1 minutes (from pedicle identification to position confirmation), which was shorter than in the literature (40-42). In summary, iCT-guided NAV for pedicle screw placement provides superior accuracy compared to conventional techniques, and reduces the risk of malposition (43-45).

Total Navigation in MISS

Total navigation in MISS has become feasible with the implementation of navigation guide tubes, resulting in the elimination of K-wires for screw placement (8, 9). At our institution, MIS-TLIF cases are now routinely performed with total navigation, and 75% of all cases are conducted using total navigation. iCT NAV provides the opportunity to immediately assess the surgical outcome intraoperatively. The authors of the present study and others corroborate that iCT-guided NAV enhances the accuracy and safety of spinal procedures and improves surgical workflow, especially in complex cases (4). For example, Sembrano et al. assessed neural decompression by an intraoperative CT myelogram (34). The iCT was able to intraoperatively detect inadequate decompression, suboptimal pedicle screw position, suboptimal interbody spacer position and malposition of a kyphoplasty trocar. Compared to the iCT used by Santos et al., the iCT used in the present study has a higher image quality (especially in terms of soft tissue). iCT NAV provides immediate feedback, thus allowing for repositioning of implants while the patient is still under anesthesia which helps to prevent reoperations, morbidity and additional expenditures.

Total navigation and radiation exposure

As illustrated in Table 1, the mean number of iCT scans was 2.1±0.76 per surgery resulting in a mean radiation exposure of 13.44 mSv. iCT-guided spine surgery was able to reduce radiation exposure received by both the surgical staff and the patient when compared to conventional fluoroscopy (46, 47). The need for fluoroscopy was eliminated in 75% of the cases presented in this study, which was in line with previous reports (5). Employment of total navigation allowed the entire OR staff to avoid radiation exposure as the iCT could be activated remotely, and wearing lead-shielded vests during surgery was no longer necessary (48, 49). Patient radiation exposure was dependent on whether full soft tissue capacity resolution was required or not. In the present work, usually 50% iCT intensity was used. Our standard protocol included a second postoperative iCT scan in order to verify implant position, sufficient decompression, screw size etc. before wound closure. As with all new techniques, becoming comfortable with iCT NAV requires practice and high frequency (50, 51). Previous studies and our results display that with time and practice, obtaining successful results with fewer CT scans was feasible (4). Many authors did not perform more than one iCT, which reduced OR time accordingly (4). In the present study, intraoperative radiation exposure for patients was lower than in other studies, but still higher than conventional fluoroscopy in some cases; however, varying results have been reported including some with contradictory data (i.e. Dabaghi et al.: 1.48±1.66 mSv (CT) vs. 0.34±0.36 mSv (C-arm) (P=0.0012); Smith et al.: 4.33 ± 2.66 mRem (fluoroscopy) vs. 0.33 ± 0.82 mRem (computer-assisted image guidance); (P = 0.012), (42, 52-55)).

Total navigation and workflow

Several authors have described a learning curve in using iCT NAV (4, 50, 51). However, the time investment required to gain sufficient experience with NAV may be ameliorated over time. Hecht et al. outlined an additional time for setup and navigation between 30 and 50 minutes with an additional surgical time of 18 to 34 minutes for their first three surgeries. For the following 20 procedures, less time was needed, which was in line with previous reports (5, 56). We believe that it takes practice to become proficient and efficient in using this new technology, and agree with previous reports which propose that a routine use of spinal navigation is critical to establishing a routine workflow (5, 50, 51, 56, 57). For this reason, we want to share our 8 step surgical workflow for total navigation (Table 4 and Supplemental Video).

Limitations, pitfalls and common errors

The present work contains experiences from a single-institution of highly dedicated staff, which may positively bias accuracy. Additionally, the initial accuracy of a surgeon with less experience using iCT NAV might be lower than reported here. Similarly, a less experienced user may require a higher number of scans when implementing total navigation due to re-calibration of the RA, which might lead to increased radiation exposure to patients. When performing benign tumor cases as demonstrated in the supplementary, a second scan is necessary due to the interventional anatomical shift after tumor removal. For novice operators, ensuring that all mandatory equipment is in order before the operation begins is suggested to avoid unnecessary time consumption. A list of required equipment can be found in Table 5.

iCT NAV presents its own limitations due to technical complications. However, inaccuracies detected from the tracking system were usually due to bloodstains on the reflective markers, which could easily have been corrected but would have required additional time. Also, the instrument attachments and navigation markers may have become loose during surgery and required retightening or re-calibration. Use of hammer or mallet can also cause some shift we recommend to use a navigated guide-tube and a power-drill instead. However, the iCT scan did not have to be repeated unless the RA attached to the spine had loosened. Furthermore, soft tissue movements as well as instrumentation at a large distance from the tracking device may have caused inaccuracy. Increasing the distance from the RA may also have contributed to reduced accuracy.

Finally, the iCT NAV was higher in initial cost than conventional NAV systems, and The iCT NAV is associated with costs which are currently not considered in the reimbursement (58). Despite the huge advancement of iCT-guided navigation, a careful and repeated control of accuracy during all steps of surgery is mandatory. Utilizing easy accessible anatomic points to verify a proper registration and function of the system is highly recommended (59). Whenever in doubt, fluoroscopy should be used to verify correct anatomical position as it can be easily integrated at any time during the surgery.

Future perspectives

As long as patient radiation can be maintained within the safety limits, total navigation should be further implemented and developed. Although clinical benefits are not obvious during the short-term postoperative period, we believe that long term studies will further elucidate the huge benefits of iCT-guided NAV. Total navigation using iCT NAV is relatively easy to learn and makes spine surgery, especially MISS, safer and more efficient.

Total navigation ensures frequent and routine utilization of image-guidance, which facilitates and optimizes the workflow and potentially leads to improved clinical and radiologic outcome. Total navigation does not substitute surgical experience, skill or knowledge, but can improve on the training of young surgeons by allowing rapid feedback at all steps during surgery. The advancement of MISS techniques that aim to further reduce approach-related morbidity will be dependent on accurate 3D visualization.

Finally, as radiation exposure remains a major concern for the patient and surgical staff, minimization or elimination of radiation should be attained whenever possible. Future research must further describe the cost-benefit-ratio of iCT NAV, especially the implications of clinical outcome, complications (i.e. wrong level surgery), and reoperation rates as well as the potential combination with robotic surgery.

Conclusions

In conclusion, the latest generation of mobile iCT expands the role of navigation from a tool that was only used for placement of screws to a technology that is now used throughout the entire procedure. Using iCT NAV in conjunction with navigated guide tubes eliminates the need for fluoroscopy in 75% of cases and optimizes outcomes in spinal surgery (40). We predict that going forward, navigation will increasingly replace fluoroscopy in spinal surgery.

Declaration of interest

The authors declare that they have no conflict of interest.

Roger Härtl, M.D. has the following financial disclosures:

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The authors of this manuscript declare that there is no conflict of interest.

Ethical standards

The study was approved by our local institutional review board and informed consent was obtained from all patients before surgery. All human studies have been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

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Figure captions

Figure 1. iCT OR Setup

From left to right: **A)** Before surgery, the iCT is parallel with the rail system. **B)** Intraoperative OR suite setup. The patient is face-down with arms up for a lumbar procedure (note: arms should be placed down at the side for cervical surgery). It is important to lead all anesthesia, EMG, Bovie, and suction cords through the gantry of the iCT. Cloth tape is applied across the chest and hips and laterally from the patient's side downwards in order to minimize tissue movement and shifting during surgery. **C)** OR suite setup when taking iCT scans of the patient. All personnel leave the room while the iCT is in use.

Figure 2. Reference array

A) For pathology of T12-pelvic, the reference array (RA) is placed in posterior iliac crest via a 2-pin fixator (lower right) **B.** For pathology of C3-T11, the RA is placed on a spinous process (mid right) **C.** For pathology of C0-C3, the RA is docked in the Mayfield head clamp (top right) **D.** For localization only (i.e. intraraquideal tumor, thoracic disc herniation etc.) from occiput to pelvic, the RA is attached to the table with the patient adequately immobilized with tape (not shown).

Figure 3. Total navigation workflow (8 step guide)

From top to bottom and left to right. **A)** Skin incision is planned with the pointer. **B)** Screw trajectory planning and power-drill tap. **C) "Hands-off" test** for screw placement controlled via screen display. **D)** Tubular retractor placement **E)** Microsurgical decompression. **F)** Cage size prediction is performed and controlled under image guidance. **E)** Rod length is measured by image guidance. **F)** iCT scan is performed before wound closure to evaluate morphological outcome.

References

1. Hartl R, Lam KS, Wang J, Korge A, Kandziora F, Audige L. Worldwide survey on the use of navigation in spine surgery. World neurosurgery. 2013;79(1):162-72.
2. Slomczykowski M, Roberto M, Schneeberger P, Ozdoba C, Vock P. Radiation dose for pedicle screw insertion. Fluoroscopic method versus computer-assisted surgery. Spine. 1999;24(10):975-82; discussion 83.
3. Van de Kelft E, Costa F, Van der Planken D, Schils F. A prospective multicenter registry on the accuracy of pedicle screw placement in the thoracic, lumbar, and sacral levels with the use of the O-arm imaging system and StealthStation Navigation. Spine. 1976;37(25).
4. Khanna AR, Yanamadala V, Coumans JV. Effect of intraoperative navigation on operative time in 1-level lumbar fusion surgery. Journal of clinical neuroscience : official journal of the Neurosurgical Society of Australasia. 2016;32:72-6.
5. Hecht N, Kamphuis M, Czabanka M, Hamm B, Konig S, Woitzik J, et al. Accuracy and workflow of navigated spinal instrumentation with the mobile AIRO((R)) CT scanner. European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society. 2016;25(3):716-23.
6. Joseph JR, Smith BW, Patel RD, Park P. Use of 3D CT-based navigation in minimally invasive lateral lumbar interbody fusion. Journal of neurosurgery Spine. 2016;22:1-6.
7. Kim TT, Drazin D, Shweikeh F, Pashman R, Johnson JP. Clinical and radiographic outcomes of minimally invasive percutaneous pedicle screw placement with intraoperative CT (O-arm) image guidance navigation. Neurosurgical focus. 2014;36(3):E1.
8. Lian X, Navarro-Ramirez R, Berlin C, Jada A, Moriguchi Y, Zhang Q, et al. Total 3D Airo(R) Navigation for Minimally Invasive Transforaminal Lumbar Interbody Fusion. BioMed research international. 2016;2016:5027340.
9. Boukebir MA, Berlin CD, Navarro-Ramirez R, Heiland T, Schöller K, Rawanduzy C, et al. Ten-Step Minimally Invasive Spine Lumbar Decompression and Dural Repair Through Tubular Retractors. Operative Neurosurgery. 9000;Publish Ahead of Print.
10. Shin BJ, Njoku IU, Tsiouris AJ, Hartl R. Navigated guide tube for the placement of mini-open pedicle screws using stereotactic 3D navigation without the use of K-wires: technical note. Journal of neurosurgery Spine. 2013;18(2):178-83.
11. Costa F, Villa T, Anasetti F, Tomei M, Ortolina A, Cardia A, et al. Primary stability of pedicle screws depends on the screw positioning and alignment. The spine journal : official journal of the North American Spine Society. 2013;13(12):1934-9.
12. Costa F, Dorelli G, Ortolina A, Cardia A, Attuati L, Tomei M, et al. Computed tomography-based image-guided system in spinal surgery: state of the art through 10 years of experience. Neurosurgery. 2015;11 Suppl 2:59-67; discussion -8.
13. Vachhani JA, Klopfenstein JD. Incidence of neurosurgical wrong-site surgery before and after implementation of the universal protocol. Neurosurgery. 2013;72(4):590-5; discussion 5.
14. Commission TJ. Summary data of sentinel events reviewed by the Joint Commission
2012 [Available from: https://www.jointcommission.org/.
15. Ammerman JM, Ammerman MD. Wrong-sided surgery. Journal of neurosurgery Spine. 2008;9(1):105-6; author reply 6.
16. Devine J, Chutkan N, Norvell DC, Dettori JR. Avoiding wrong site surgery: a systematic review. Spine (Phila Pa 1976). 2010;35(9 Suppl):S28-36.
17. Mody MG, Nourbakhsh A, Stahl DL, Gibbs M, Alfawareh M, Garges KJ. The prevalence of wrong level surgery among spine surgeons. Spine (Phila Pa 1976). 2008;33(2):194-8.
18. James MA, Seiler JG, 3rd, Harrast JJ, Emery SE, Hurwitz S. The occurrence of wrong-site surgery self-reported by candidates for certification by the American Board of Orthopaedic Surgery. The Journal of bone and joint surgery American volume. 2012;94(1):e2(1-12).
19. Barrios C, Ahmed M, Arrotegui J, Bjornsson A, Gillstrom P. Microsurgery versus standard removal of the herniated lumbar disc. A 3-year comparison in 150 cases. Acta orthopaedica Scandinavica. 1990;61(5):399-403.

20. Jhawar BS, Mitsis D, Duggal N. Wrong-sided and wrong-level neurosurgery: a national survey. Journal of neurosurgery Spine. 2007;7(5):467-72.
21. Matsumoto M, Hasegawa T, Ito M, Aizawa T, Konno S, Yamagata M, et al. Incidence of complications associated with spinal endoscopic surgery: nationwide survey in 2007 by the Committee on Spinal Endoscopic Surgical Skill Qualification of Japanese Orthopaedic Association. Journal of orthopaedic science : official journal of the Japanese Orthopaedic Association. 2010;15(1):92-6.
22. Fager CA. Malpractice issues in neurological surgery. Surgical neurology. 2006;65(4):416-21.
23. Goodkin R, Laska LL. Wrong disc space level surgery: medicolegal implications. Surgical neurology. 2004;61(4):323-41; discussion 41-2.
24. Costa F, Cardia A, Ortolina A, Fabio G, Zerbi A, Fornari M. Spinal navigation: standard preoperative versus intraoperative computed tomography data set acquisition for computer-guidance system: radiological and clinical study in 100 consecutive patients. Spine. 2011;36(24):2094-8.
25. Baaj AA, Beckman J, Smith DA. O-Arm-based image guidance in minimally invasive spine surgery: technical note. Clinical neurology and neurosurgery. 2013;115(3):342-5.
26. Houten JK, Nasser R, Baxi N. Clinical assessment of percutaneous lumbar pedicle screw placement using theO-arm multidimensional surgical imaging system. Neurosurgery. 2012;70(4):990-5.
27. Di Silvestre M, Parisini P, Lolli F, Bakaloudis G. Complications of thoracic pedicle screws in scoliosis treatment. Spine. 2007;32(15):1655-61.
28. Şarlak AY, Tosun B, Atmaca H, Sarisoy HT, Buluç L. Evaluation of thoracic pedicle screw placement in adolescent idiopathic scoliosis. European Spine Journal. 2009;18(12):1892-7.
29. Upendra BN, Meena D, Chowdhury B, Ahmad A, Jayaswal A. Outcome-based classification for assessment of thoracic pedicular screw placement. Spine. 2008;33(4):384-90.
30. Noriega DC, Hernandez-Ramajo R, Rodriguez-Monsalve Milano F, Sanchez-Lite I, Toribio B, Ardura F, et al. Risk-benefit analysis of navigation techniques for vertebral transpedicular instrumentation: a prospective study. The spine journal : official journal of the North American Spine Society. 2016.
31. Tang J, Zhu Z, Sui T, Kong D, Cao X. Position and complications of pedicle screw insertion with or without image-navigation techniques in the thoracolumbar spine: a meta-analysis of comparative studies. Journal of Biomedical Research. 2014;28(3):228-39.
32. Hicks JM, Singla A, Shen FH, Arlet V. Complications of pedicle screw fixation in scoliosis surgery: a systematic review. Spine. 2010;35(11):E465-70.
33. Waschke A, Walter J, Duenisch P, Reichart R, Kalff R, Ewald C. CT-navigation versus fluoroscopy-guided placement of pedicle screws at the thoracolumbar spine: single center experience of 4,500 screws. European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society. 2013;22(3):654-60.
34. Santos ER, Sembrano JN, Yson SC, Polly DW, Jr. Comparison of open and percutaneous lumbar pedicle screw revision rate using 3-D image guidance and intraoperative CT. Orthopedics. 2015;38(2):e129-34.
35. Luther N, Iorgulescu JB, Geannette C, Gebhard H, Saleh T, Tsiouris AJ, et al. Comparison of navigated versus non-navigated pedicle screw placement in 260 patients and 1434 screws: screw accuracy, screw size, and the complexity of surgery. Journal of spinal disorders & techniques. 2015;28(5):E298-303.
36. Lee GY, Massicotte EM, Rampersaud YR. Clinical accuracy of cervicothoracic pedicle screw placement: a comparison of the "open" lamino-foraminotomy and computer-assisted techniques. Journal of spinal disorders & techniques. 2007;20(1):25-32.
37. Sugimoto Y, Ito Y, Tomioka M, Shimokawa T, Shiozaki Y, Mazaki T, et al. Clinical accuracy of three-dimensional fluoroscopy (IsoC-3D)-assisted upper thoracic pedicle screw insertion. Acta medica Okayama. 2010;64(3):209-12.
38. Bledsoe JM, Fenton D, Fogelson JL, Nottmeier EW. Accuracy of upper thoracic pedicle screw placement using three-dimensional image guidance. The spine journal : official journal of the North American Spine Society. 2009;9(10):817-21.
39. Barsa P, Frohlich R, Sercl M, Buchvald P, Suchomel P. The intraoperative portable CT scanner-based spinal navigation: a viable option for instrumentation in the region of cervico-thoracic junction. European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society. 2016;25(6):1643-50.
40. Laine T, Lund T, Ylikoski M, Lohikoski J, Schlenzka D. Accuracy of pedicle screw insertion with and without computer assistance: a randomised controlled clinical study in 100 consecutive patients. European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society. 2000;9(3):235-40.

41. Girardi FP, Cammisa FP, Jr., Sandhu HS, Alvarez L. The placement of lumbar pedicle screws using computerised stereotactic guidance. The Journal of bone and joint surgery British volume. 1999;81(5):825-9.
42. Tabaraee E, Gibson AG, Karahalios DG, Potts EA, Mobasser JP, Burch S. Intraoperative cone beam-computed tomography with navigation (O-ARM) versus conventional fluoroscopy (C-ARM): a cadaveric study comparing accuracy, efficiency, and safety for spinal instrumentation. Spine. 2013;38(22):1953-8.
43. Tian N-F, Xu H-Z. Image-guided pedicle screw insertion accuracy: a meta-analysis. International Orthopaedics. 2009;33(4):895-903.
44. Zausinger S, Scheder B, Uhl E, Heigl T, Morhard D, Tonn JC. Intraoperative computed tomography with integrated navigation system in spinal stabilizations. Spine. 2009;34(26):2919-26.
45. Kosmopoulos V, Schizas C. Pedicle screw placement accuracy: a meta-analysis. Spine. 2007;32(3):E111-20.
46. Gebhard F, Kraus M, Schneider E, Arand M, Kinzl L, Hebecker A, et al. [Radiation dosage in orthopedics -- a comparison of computer-assisted procedures]. Der Unfallchirurg. 2003;106(6):492-7.
47. Nelson EM, Monazzam SM, Kim KD, Seibert JA, Klineberg EO. Intraoperative fluoroscopy, portable X-ray, and CT: patient and operating room personnel radiation exposure in spinal surgery. The spine journal : official journal of the North American Spine Society. 2014;14(12):2985-91.
48. Verma SK, Singh PK, Agrawal D, Sinha S, Gupta D, Satyarthee GD, et al. O-arm with navigation versus C-arm: a review of screw placement over 3 years at a major trauma center. British journal of neurosurgery. 2016:1-4.
49. Nottmeier EW, Bowman C, Nelson KL. Surgeon radiation exposure in cone beam computed tomography-based, image-guided spinal surgery. The international journal of medical robotics + computer assisted surgery : MRCAS. 2012;8(2):196-200.
50. Bai YS, Zhang Y, Chen ZQ, Wang CF, Zhao YC, Shi ZC, et al. Learning curve of computer-assisted navigation system in spine surgery. Chinese medical journal. 2010;123(21):2989-94.
51. Ryang YM, Villard J, Obermuller T, Friedrich B, Wolf P, Gempt J, et al. Learning curve of 3D fluoroscopy image-guided pedicle screw placement in the thoracolumbar spine. The spine journal : official journal of the North American Spine Society. 2015;15(3):467-76.
52. Dabaghi Richerand A, Christodoulou E, Li Y, Caird MS, Jong N, Farley FA. Comparison of Effective Dose of Radiation During Pedicle Screw Placement Using Intraoperative Computed Tomography Navigation Versus Fluoroscopy in Children With Spinal Deformities. Journal of pediatric orthopedics. 2015.
53. Weir V, Zhang J, Bruner A. SU-E-I-21: Dosimetric Characterization and Image Quality Evaluation of the AIRO Mobile CT Scanner. Medical physics. 2015;42(6):3246.
54. Mohapatra A, Greenberg RK, Mastracci TM, Eagleton MJ, Thornsberry B. Radiation exposure to operating room personnel and patients during endovascular procedures. Journal of vascular surgery. 2013;58(3):702-9.
55. Smith HE, Welsch MD, Sasso RC, Vaccaro AR. Comparison of radiation exposure in lumbar pedicle screw placement with fluoroscopy vs computer-assisted image guidance with intraoperative three-dimensional imaging. The journal of spinal cord medicine. 2008;31(5):532-7.
56. Nottmeier EW, Crosby TL. Timing of paired points and surface matching registration in three-dimensional (3D) image-guided spinal surgery. Journal of spinal disorders & techniques. 2007;20(4):268-70.
57. Sasso RC, Garrido BJ. Computer-assisted spinal navigation versus serial radiography and operative time for posterior spinal fusion at L5-S1. Journal of spinal disorders & techniques. 2007;20(2):118-22.
58. Kapoor S, Sharma R, Garg S, Jindal R, Gupta R, Goe A. Navigated pedicle screw placement using computed tomographic data in dorsolumbar fractures. Indian Journal of Orthopaedics. 2014;48(6):555-61.
59. Rahmathulla G, Nottmeier EW, Pirris SM, Deen HG, Pichelmann MA. Intraoperative image-guided spinal navigation: technical pitfalls and their avoidance. Neurosurgical focus. 2014;36(3):E3.

Table 1. Patient demographics of 115 patients undergoing spinal surgery (117 cases)

Parameter		**N**	**%**
Sex	Male	50	43.4
	Female	65	56.5
	Total	115	100
Age in years	Mean ± SD	62.5 ± 15.4	
Spinal region	Cervical Thoracic Lumbar	24 12 81	20.5 10.3 69.2
Pathology	Degeneration Trauma Neoplasm Deformity Adjacent segment disease Revision Surgery	76 4 10 7 12 8	64.9 3.4 8.5 5.9 10.2 6.8
Type of Surgery	MISS Conventional	71 46	60.7 39.3
Navigation Modality	Total Navigation C-Arm assisted	88 29	75.2 24.8
Utilization of navigation	Localization Localization + Implant Placement	11 106	9.41 90.6
IONM		114	97.4
iCT scans and dose	Number of Scans (m) Dose mSv (m)	2.1 ± 0.76 ≈13.44 mSv	
Screw accuracy	Number of Cases	41	
	Number of Screws	309	
	Time per screw in minutes	3.1	
	Minor Breach < 2mm	25	6.4
	Misplaced > 2-4mm	4	1
	Misplaced > 4mm	0	0

N: absolute number; **%:** relative number in percent; **IONM:** Intraoperative neurophysiologic monitoring; **iCT**: intraoperative CT; **SD**: standard deviation; **MISS**: Minimally invasive spine surgery

Table 2. Tips to improve accuracy in iCT-guided navigation

Draping	• Securing the patient with tape to the OR table minimizes tissue movement • Tape across the chest and hips and laterally from the patient's side downwards
Intraoperative scan	• Include anatomical landmarks allowing accurate determination of the index level /pathology. • Obtain introp CT immediately before it is actually needed (some times after the anatomical structures have been exposed e.g. posterior cervical cases, this minimizes the chances of shift and inaccuracies caused by surgical manipulation
Verification of accuracy	• Point out the tip of the transverse process after skin incision (in MISS) • Constantly compare position and tactile feedback of the navigated instrument during surgery • Reflective markers should not be contaminated
Throughout the procedure	• Confirm stable placement and avoid hitting the array during surgery • Avoid pressure, mechanical impact (with hammers or mallet) or movements • Use a battery driven drill to prepare screw holes and avoid Jamshidi needles
"Hands-off test"	• After full insertion of the tap into the pedicle, let go of the instrument • If the screw simulation on the navigation screen demonstrates an adequately positioned screw in the pedicle without breach, this is usually a confirmation of a well-placed screw trajectory (not in osteoporotic patients)
Neuromonitoring	• Intraoperative neuromonitoring and screw stimulation with a cut-off of approximately 9 mAmp
Verification of position	• iCT scan after implantation of instrumentation / implants to verify desired position and accuracy

Table 3. Utilization of iCT-guided navigation for the most common spinal procedures

Procedure	Position	Reference Array	Additional Fluoroscopy	TOTAL NAVIGATION					K-Wire	IONM
				Incision	Retractor Placement	Decompress.	Localization	Rod/cage Size prediction		
CERVICAL										
O-C fusion*	Prone	Mayfield HH	☐	YES					☐	☑
Anterior cervical corpectomy	Supine	Mayfield HH	☐	YES					☐	☑
Posterior/cervico-thoracic instrumentation C2-T10	Prone	Spinous process	☐	YES					☐	☑
THORACIC										
Thoracic Tumor Removal	Prone	Spinous process/Table	☐	YES					☐	☑
Thoracic Discectomy	Prone / lateral	Spinous process /Iliac Crest (lat. Approach)	☐	YES					☐	☑
LUMBAR										
Direct repair of pars defect	Prone	Iliac Crest	☑	YES					☑	☑
Far lateral discectomy	Prone	Iliac Crest/Table	☐	YES					☐	☐
MIS-TLIF	Prone	Iliac Crest	☐	YES					☐	☑
ELIF± Posterior Decompression/Fusion	Lateral	Iliac Crest	☑	NO (Fluroscopy aided)					☐	☑

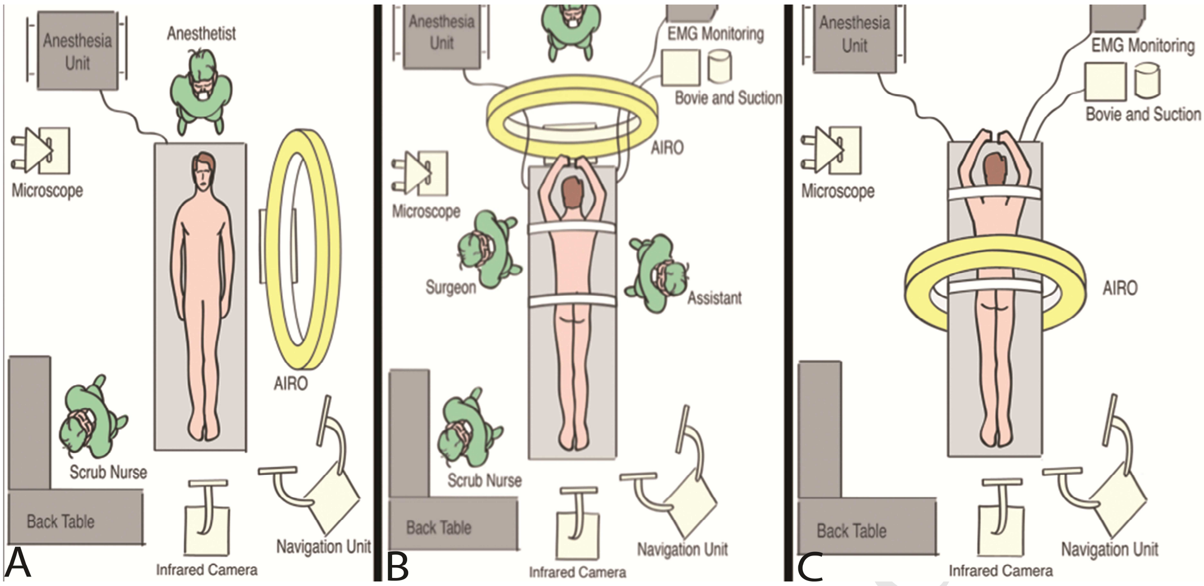
☐ Absence, ☑ Presence, O-C; occipitocervical; **HH**: head holder, **ELIF**; Extreme Lateral Interbody Fusion; **MISS:** Minimally Invasive Spine Surgery; **TLIF:** Transforaminal interbody fusion, **IONM:** Intraoperative neurophysiologic monitoring; **Decompress**.: decompression; **lat:** lateral; * İn general the CT is obtained immediately before needed, that means after anatomical exposure and before screw insertion.

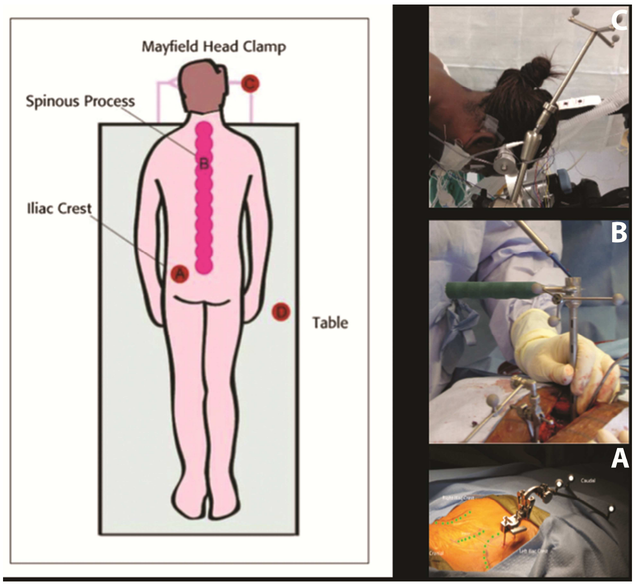
Table 4. 8 step workflow for total navigation (Refer to Supplemental Digital Content).

8 Step workflow for total navigation (Supplemental Digital Content)	
1	Skin incision planning
2	Screw size prediction
3	Screw placement (Point-Drill-Tap-Screw)
4	Tubular retractor placement
5	Decompression
6	Cage placement
7	Rod measurement
8	Final CT check

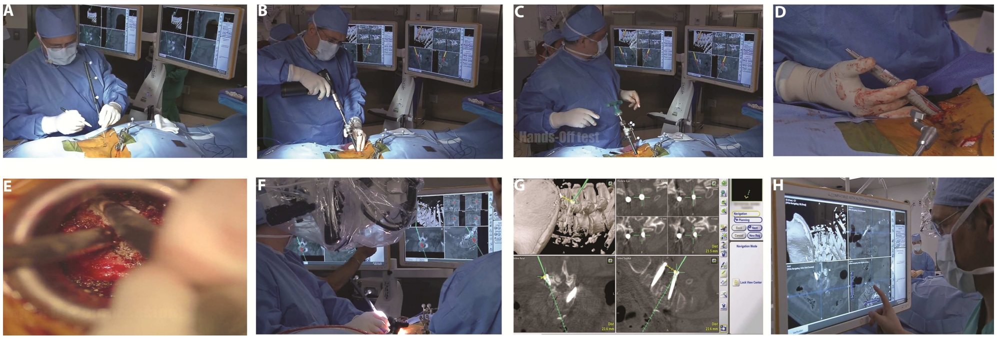
Table 5. Equipment needed for total navigation

Mandatory
Intraoperative CT scanner
Infrared tracking camera navigation system
Image-guidance system (navigation unit)
Patient reference array + 2-pin fixator (or spinous process clamp)
Navigated pointer
Navigated guide tube (Power Drill, Tap, Headless screws)
Microscope or surgical loupes
EMG monitoring
Optional
Mayfield head clamp (cervical)


Anesthesia Unit
Anesthetist
Microscope
AIRO
Scrub Nurse
Back Table
Infrared Camera
Navigation Unit
A
Anesthesia Unit
EMG Monitoring
Bovie and Suction
AIRO
Microscope
Surgeon
Assistant
Scrub Nurse
Back Table
Infrared Camera
Navigation Unit
B
Anesthesia Unit
EMG Monitoring
Bovie and Suction
Microscope
AIRO
Back Table
Infrared Camera
Navigation Unit
C



Mayfield Head Clamp
Spinous Process
Iliac Crest
Table
C
B
A


A
B
C
Hands-Off test
D
E
F
G
H

Highlights

- We introduce a concept of "total" navigation in spine surgery
- We are able to incorporate the use of total navigation into our daily practice and eliminate the use of fluoroscopy in ~70% of our spine cases
- We can decrease to 0 the radiation exposure for the surgical staff in ~70% of our spine cases
- Modifications to our concise and step by step technique can be applied to replicate our workflow in other sites around the world

Abbreviations

ELIF: Extreme Lateral Interbody Fusion

EMG: Electromyography

iCT NAV: Intraoperative Computer Tomography Navigation

MIS-TLIF: Minimally Invasive – Trans Foraminal Interbody Fusion

MISS: Minimally Invasive Spine Surgery

NAV: Image Guided Navigation

OR: Operating/Operating Room

RA: Reference Array