Segmental Surface Referencing during Intraoperative Three-dimensional Image-Guided Spine Navigation: An Early Validation with Comparison to Automated Referencing

Amro F. Al-Habib[1] Salah Al-Akkad[2]

[1] Division of Neurosurgery, Department of Surgery, King Saud University, Riyadh, Saudi Arabia
[2] Neurospinal Unit, Department of Surgery, Johns Hopkins Aramco Healthcare, Dhahran, Saudi Arabia

Address for correspondence Amro F. Al-Habib, MD, FRCSC, MPH, Division of Neurosurgery, Department of Surgery, College of Medicine, King Saud University, PO Box 59220, Riyadh 11525, Saudi Arabia (e-mail: amro.alhabib@gmail.com).

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Abstract

Study Design Interventional human cadaver study.

Objective Intraoperative three-dimensional (3-D)-guided navigation improves spine instrumentation accuracy. However, image acquisition may need to be repeated with segment hypermobility or distant target from reference frame (RF). The current study evaluates the usefulness of internal metal fiducials (IMFs) as surface references in enhancing registration accuracy and avoiding repeating imaging.

Methods Six fresh-frozen cadaveric human torsos were utilized. Posterior C1–T2 exposure was done, and three IMFs were inserted per level; intraoperative 3-D images were then acquired. Two registration methods were utilized: autoregistration (AR, group 1) and point registration using IMF (IMFR, group 2). Registration accuracy was checked by identifying IMFs in both groups. Pedicle screws inserted into C2, C4, C5, and C7 based on the two registration methods (three cadavers each) with RF on C7 and then on C2.

Results The mean registration error was lower with IMFR compared with AR (0.35 ± 0.5 mm versus 2.02 ± 0.85 mm, $p = 0.0001$). Overall, 34 pedicle screws were inserted (AR, 18; IMFR, 16). Final screw placement was comparable using both techniques ($p = 0.58$). Lateral screws violations were observed in four IMFR screws (1 to 2 mm) as compared with five in AR group (2 to 3 mm). Reregistration after moving RF to C2 was possible using surface screws in IMFR group, thus avoiding new 3-D image acquisition.

Conclusion During intraoperative 3-D navigation in spine procedures, surface fiducial registration using IMF provided superior accuracy over automated registration. It allowed repeat registration without repeating radiation during long spine segment instrumentations. More studies are needed to clarify both practical and clinical application of this method.

Keywords
- spine instrumentation
- pedicle screws
- spine navigation
- cervical spine
- fiducial markers
- O-arm

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Introduction

In recent times, imaging technology has improved greatly, with subsequent improvements in intraoperative visualization that provide enhanced accuracy for spinal instrumentation. When combined with spine navigation, such intraoperative visualization affords better accuracy and safety of spine instrumentation.[1] In a study including placement of 4,500 screws, pedicle screw insertion utilizing computed tomography (CT)-guided navigation was shown to be superior to the fluoroscopy-guided approach in the lumbar spine (accuracy of 96.4 versus 93.9%, respectively, $p = 0.001$) as well as the thoracic spine (accuracy of 95.5 versus 79%, respectively, $p < 0.001$).[2] Intraoperative CT navigation has also been judged superior to the freehand technique in thoracic pedicle screw placement (accuracy of 98 versus 89.8%, respectively).[3] Similar success rates (97%) for pedicle screw placement have been demonstrated in other studies with the use of three-dimensional (3-D) or CT-based navigation with a low rate of screw revision (1.2%).[4,5]

Intraoperative 3-D-guided navigation leads to lower radiation exposure for the surgeon and operating room staff as compared with other methods.[6,7] Smith et al found that the surgeon's exposure to radiation is lower with navigation-guided lumbar pedicle screw insertion compared than with C-arm fluoroscopy.[8] For the patient, the administered radiation dose by intraoperative 3-D imaging is approximately one-third of the dose for an abdominal CT scan.[9] In their study of 1,922 pedicle screw insertions using intraoperative CT-guided navigation, Van de Kelft et al showed that the mean radiation dose was half that of a 64-multislice CT scan.[5]

However, despite these advantages, several challenges involved in intraoperative spine navigation may limit its use. Instrumentation levels far from the reference frame (RF) render the technique less accurate. Additionally, any changes in the anatomy of the spine (traumatic instability, correction of deformity, or laminectomy) render the patient's original images (i.e., baseline registration) inaccurate. Both situations may necessitate acquiring another imaging sequence, which increases intraoperative radiation, interrupts the surgical procedure, and may not be possible in the absence of an intraoperative 3-D imaging device.

The use of anatomical landmarks for segmental surface referencing during navigation has been shown to increase registration accuracy.[10,11] Given the difficulty in matching exact anatomical landmarks with intraoperative images in the spine, we propose the use of surface marker screws that serve as internal metal fiducials (IMFs) to overcome many of the challenges. In this study, we hypothesize that segmental surface referencing (using IMFs) would provide improved registration accuracy, offer the ability to adjust for changes in registration without taking another intraoperative radiation image, and may allow instrumentation at levels far from the RF. Subsequently, instrumentation with IMF could be clinically tested for better accuracy and less radiation compared with other CT-guided navigation techniques.

Materials and Methods

Basic Design

Six adult, fresh-frozen human cadavers were used in this study. None of the cadavers had been previously utilized for any dissection purpose. Institutional ethical board approval was obtained before the start of the study.

The O-arm (Medtronic PLC, Littleton, Massachusetts, United States) was the 3-D intraoperative imaging device used for the current study. It has a mobile cone beam that allows taking two-dimensional and 3-D images and produces images similar to CT scans. The images are sent to the StealthStation navigation system (Medtronic PLC, Louisville, Colorado, United States). Automatic registration (AR) then follows, based on the acquired images and the RF. One can also use manual registration based on fixed surface anatomic points and register these into the system.

Exposure of the dorsal surface of C1 to T2 was performed, then 3-D imaging was performed. Cadavers were divided into two groups based on the method of registration: group 1 with AR and group 2 with IMF registration (IMFR). The accuracies of registration and pedicle screw insertion were compared between the two groups.

The IMFs used in this study were titanium screws (Marquardt, Medizintechnik, Germany) used as surface markers. Each screw has a small depression on the top for the navigation instrument and a cross-shaped head for the screwdriver. Each screw measured 3 mm in length and 2 mm in width, and three screws were inserted per level, at a midline position on the spinous process and one on each lamina (►Fig. 1).

Study Variables

Registration

Following 3-D image acquisition, AR registration was performed in all the cadavers with the RF fixed to the C7 spinous process. The RF was placed on the spinous process of C7 to test the accuracy when going further up in the cervical spine toward C2, where the spine tends to be more mobile.

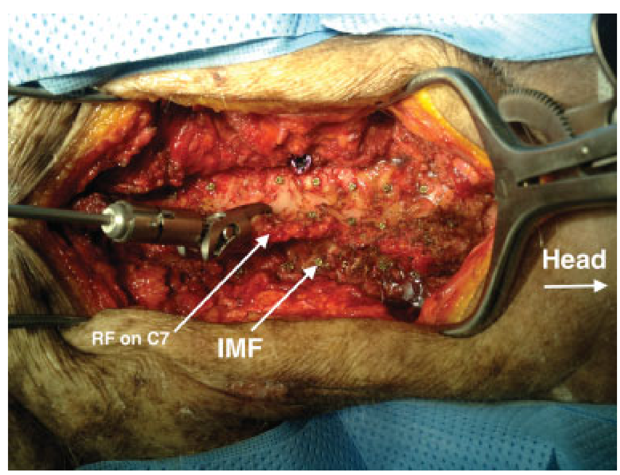

Fig. 1 IMFs on the posterior cervical spine surface. Reference frame was placed on the C7 spinous process. Abbreviations: IMF, internal metal fiducials; RF, reference frame.

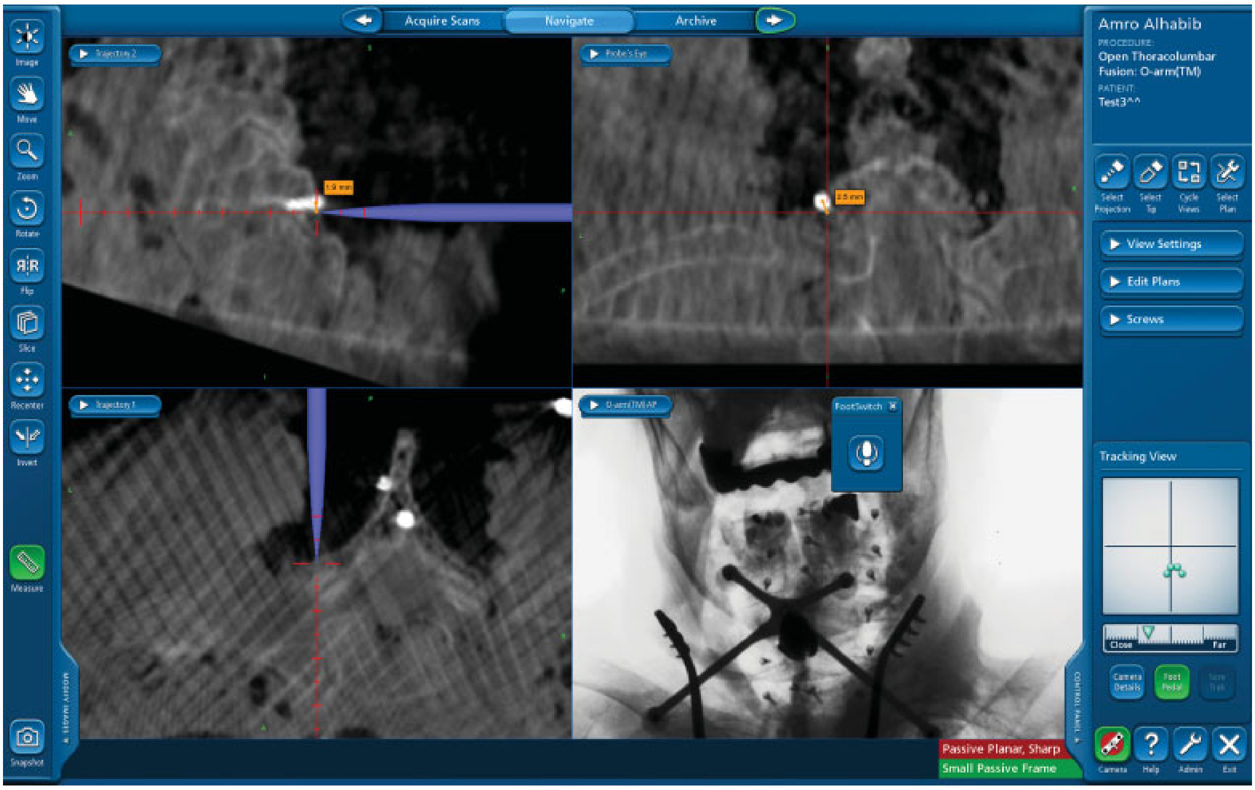

Fig. 2 The method used for measuring registration accuracy on the screen of the StealthStation software (Medtronic PLC, Louisville, Colorado, United States).

The registration was repeated for the IMFR group based on IMF screws placed from C2 to T1. Registration errors, in both groups, were measured in millimeters on the StealthStation navigation screen. The area between the tip of the registration probe and the center of the IMF surface screw head was measured on two of three clear planes (axial, sagittal, or coronal; ►**Fig. 2**). The comparison was performed between automatic AR and IMFR on the left side for standardization.

Instrumentation

All the screws were inserted using navigation by two spine surgeons (with a minimum of 5 years in clinical practice). The pedicle screws were inserted in both groups at C4, C5, and C7 along with pars screws at C2. Within group 1, instrumentation was based on intraoperative 3-D reconstructed images and navigation with AR. Within group 2, instrumentation was performed after IMFR. When the C4, C5, and C7 pedicle screws were inserted, the RF was placed on the C7 spinous process. However, when the C2 pars screws were inserted, the RF was moved to the C2 spinous process for better accuracy. For group 1, another 3-D image acquisition was performed including a new AR due to the movement of the RF. On the other hand, for group 2, reregistration was performed using the original 3-D acquired images and IMFs. No reimaging was performed for the C2 screws in group 2. Following instrumentation, a 3-D scan was performed to check screw placement in both groups. The precision of the screw placement was assessed by describing the measurement (in millimeters) and direction (medial, lateral, cranial, or caudal) of any cortical breach. The accuracy of screw placement was assessed according to Gertzbein and Robbins based on the measurement of their cortical breaches: group A for screws located within the pedicles, group B for screws with cortical breaches < 2 mm, group C when the cortical breach is 2 to 4 mm, group D for screws with >4 mm of cortical breach, and group E for screws with cortical breach > 6 mm.[12]

Outcome Measures

The primary outcome was to compare registration errors between the two methods of registration, AR and point registration (IMFR). The secondary outcomes were to compare the accuracy of cervical spine instrumentations using both techniques of registration and the number of 3-D images acquired during the procedure.

Statistical Analysis

Statistical analysis was performed using the Statistical Package for Social Science software (IBM SPSS Statistics for Windows, Version 19.0; IBM Corp, Armonk, New York, United States). Descriptive statistics (mean, standard deviation) were used. Continuous variables were analyzed using the Mann-Whitney test. A p value of <0.05 was considered to be statistically significant.

Results

Registration Accuracy Comparing Automatic Registration and Point Registration Using Internal Metal Fiducials

In group 2, IMFR had smaller registration errors as compared with intraoperative 3-D AR (0.35 ± 0.5 mm and

Table 1 Error of registration (mm) comparison between autoregistration and IMFR

	Cadaver 1		Cadaver 2		Cadaver 3		Mean	
	AR	IMFR	AR	IMFR	AR	IMFR	AR	IMFR
C2	1.5	0	3.95	0.75	2.75	0	2.73	0.25
C3	2	0	2.35	1.45	2.10	0	2.15	0.48
C4	2.5	0	2.25	1.10	1.70	0	2.15	0.367
C5	1	0	1.2	1.10	1.65	0	1.28	0.367
C6	3.5	0	2.3	0.65	0	0	1.93	0.217
C7	2.65	0	2	1.20	1.30	0	1.98	0.40
T1	1.5	0	2.05	1.10	2.20	0	1.917	0.367

Abbreviations: AR, automatic registration; IMFR, internal metal fiducial-based registration.
Note: Registration was performed twice within group 2 with reference frame on the C7 spinous process. The first technique with AR was followed by IMFR. Accuracy was checked on the left side from C2 to C7 for all 3 cadavers by pointing the navigation probe to the IMF. This was performed twice: after AR and then after IMFR. The distance between the pointer's tip and the IMF on the three-dimensional image was measured on two of three views (axial, sagittal, and coronal). The greater of these values is presented above for comparison.

2.02 ± 0.85 mm, respectively; $p = 0.0001$; ►**Table 1** and ►**Fig. 3**). The range of registration error was smaller in IMFR compared with AR (0 to 1.45 mm and 0 to 3.95 mm, respectively). The AR accuracy was lower when the target level was further from the RF. However, IMFR registration showed a consistent mean registration error even at levels away from the RF (►**Fig. 3**). In the manual registration group, five IMF registration points were required to achieve the minimum registration error. The other IMF screws were used to confirm accuracy and for reregistration.

Cervical Pedicle Screws in Both Groups and Radiation Exposure

Thirty-four cervical pedicle screws were inserted (AR, 18; IMFR, 16). Final screw placement was comparable using both techniques ($p = 0.58$). There were no medial screw violations through the pedicle wall. As shown in ►**Table 2**, lateral violations were observed in 4 IMFR screws (1 to 2 mm) compared with 5 violations in the AR group (2 to 3 mm). According to Gertzbein and Robbins classification, 2 screws were group C (2.9%, within 2 and 4 mm breach category) and 7 screws were group B (20.6%, <2 mm breach). The rest were group A (76.5%, within the pedicles).

Following repositioning of the RF on to the C2 spinous process, another image had to be obtained in the AR group. On the other hand, the use of IMFR (group 2) achieved good accuracy. Therefore, repeat intraoperative 3-D imaging was avoided in group 2.

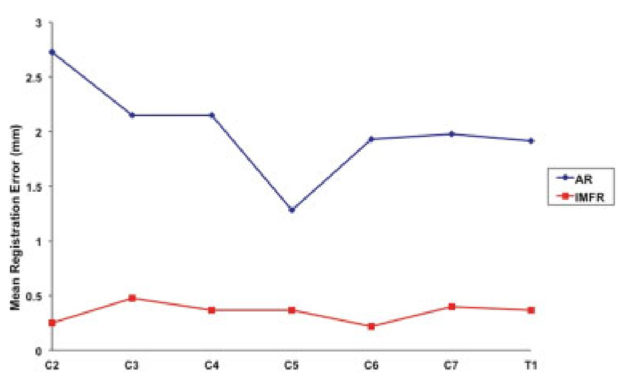

Fig. 3 The mean registration error when comparing autoregistration (AR) versus internal metal fiducial registration (IMFR). Reference frame is fixed on the C7 spinous process in both methods.

Discussion

The registration process in navigation is a critical step for ensuring the accuracy of the procedure.[13,14] The goal is the identification of the real patient's anatomy on the navigator screen.[15] Subsequently, the intraoperative anatomy identified on the surface of the patient's spine should correspond exactly to what is seen on the navigator screen.

Spine navigation using the intraoperative 3-D imaging devices allows the surgeon to use either automatic or manual registration.[11,15,16] In AR, images are calibrated to the navigator

Table 2 Cervical pedicle screw encroachment into the foramen transversarium using both registration techniques

	C2		C5[a]		C7	
	Right	Left	Right	Left	Right	Left
IMF						
Cadaver 1	0	0	–	0	–	0
Cadaver 2	0	0	0	2[b]	0	0
Cadaver 3	1[c]	1[c]	0	1[c]	0	0
Autoregistration						
Cadaver 4	0	1[c]	1[c]	1[c]	0	0
Cadaver 5	3[d]	0	0	0	0	0
Cadaver 6	0	0	0[e]	0[e]	1[c]	0

Abbreviation: IMF, internal metal fiducial-based registration.
[a]Except in cadaver 5 where the level was C4 (not C5).
[b]Encroachment into the left foramen transversarium by 2 mm.
[c]Encroachment into the left foramen transversarium by 1 mm.
[d]Encroachment into the left foramen transversarium by 3 mm.
[e]Short screw; did not reach the pedicle.

system and structures are identified in relation to the RF. This method does not require the identification of points on the patient's anatomy and can be beneficial in minimally invasive spine surgery procedures because it can be used before skin incision. It also localizes levels automatically, omitting the chance of registration at the wrong level, which may occur in difficult cases of trauma and deformities. However, AR completely controls the registration process and the surgeon has minimal input. When the RF has to be moved for any reason or there is a change in the relationship of the vertebrae, such as in cases of spine instability, then the registration process has to be repeated, which can be time-consuming and is associated with a higher radiation exposure.

Manual registration (or point-matching registration) involves feeding the system with chosen points from the patient's anatomy.[15] Subsequently, the system will connect the patient's radiologic image (CT or magnetic resonance imaging) with the structures seen intraoperatively. The process is operator-dependent and relies on identifying and feeding the correct information. Without intraoperative imaging, accuracy could be challenging given the changes in the patient's position from supine (while imaging) to prone (in surgery). It is therefore advisable to take several points at different planes for such manual registration.[11]

Previous reports have showed an enhanced accuracy of instrumentation using point-matching registration with fixed landmarks in combination with the preoperative CT scan.[15,17,18] Glossop et al reported a reduction in registration errors when using implanted metal fiducial markers on a human cadaveric lumbar spine, which were imaged using CT.[15] Winkler et al implanted fiducial markers percutaneously in a patient with spondylolisthesis before surgery, and they were identified using CT.[17] These fixed landmarks helped improve the accuracy of intraoperative registration. The technique of intraoperative CT with marker screws was first used by Haberland et al.[18] The use of marker screws helped achieve high accuracy of pedicle screw placement.[18]

The current study demonstrated the usefulness of marker screws (IMFs) in association with intraoperative 3-D imaging technology. Cervical spine pedicle screws were selected to test the new method, based on the difficulty of their insertion as well as the hypermobility of the cervical spine segments that makes navigation more challenging. The RF was placed initially on the C7 spinous process. It could have been placed on the spinous process of any other vertebra. However, we would have had to move a sufficient distance away to test the hypothesis of navigation accuracy in long-segment spine instrumentation. Also, the C7 spinous process is big and provides an easy attachment to the RF, which is closer to reality during cervical spine navigation.

Cervical pedicle screws remain a challenge. In the recent review of 207 screws implanted using 3-D navigation from C1 to C7 in 64 patients, Bredow et al reported perforation of <2 mm in 78.51% of C3–C7 screws and 93.9% of C1–C2 screws.[19] Their report included three cases of vertebral artery injury and one death.[19] In another study by Bydon et al, the use of intraoperative CT led to the revision of more cervical pedicle screws than other spine regions.[20] The current study included 34 screws inserted in the cervical spine with results consistent with published data. Although most of the screws (76.5%) were entirely within the pedicles, cortical breach was <2 mm in 20.6% and within 2 to 4 mm in 2.9%. It appears from the current study that using either of the registration methods does not produce safe results for cervical pedicle screw instrumentation in clinical practice.

The IMF navigation technique provided better registration accuracy for long-segment fusion, offered the ability to double-check the accuracy during the procedure, and allowed reregistration if necessary. However, when short-segment instrumentation is performed, AR is probably sufficient, particularly when the segment is mechanically stable. This technique also avoids the time necessary to implant the IMF screws required for manual registration.

Intraoperative radiation exposure poses significant risks to patients, spine surgeons, and operating room personnel.[21–23] It can result in DNA damage and be carcinogenic.[21,24] Intraoperative CT has shown a reduction in the radiation dose during spine procedures.[25] However, in long-segment fusions or in cases with increased spine mobility due to fractures or tumors, a second intraoperative 3-D image may be necessary. The current article demonstrates that using the IMFR method prevents the need for repeat intraoperative imaging, resulting in lower radiation exposure for the patient. The original image can be used with reregistration using the IMF surface markers.

The current study has certain limitations. Although superior results for registration accuracy was demonstrated using six cadavers, a larger number would be better to further test the hypothesis. Additionally, cadaveric tissues may be stiffer in consistency compared with live surgery. However, the use of fresh cadavers may lessen this effect. Furthermore, additional time is required to place the fiducials. This time may not have been wasted considering the surgical time that could be saved if reregistration is required or an additional intraoperative 3-D radiation image is necessary. The IMFR technique is also limited to open spine procedures. Future modification could be added for minimally invasive spine procedures.

Although three IMF screws were used per level in the current study, only five were sufficient to achieve the minimum registration error in navigation. Extra IMF screws could be inserted further from RF when repeat registration is necessary. The current study compared radiation exposure based on the number of intraoperative 3-D spins required. However, future studies could provide more details with quantification of radiation exposure.

Conclusions

The current study should be considered an early validation of the usefulness of surface markers during 3-D navigation of long-segment spine instrumentations. The RF could be moved when necessary to a different spine level, and repeat registration could then be performed based on the original image, avoiding repeat imaging. Although better registration for surface markers is demonstrated for long and mobile spine segment, its advantages over AR for a short and stable segment are questionable.

Disclosures
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