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Accuracy of Stereovision-Updated Versus Preoperative CT-Based Image Guidance in Multilevel Lumbar Pedicle Screw Placement

A Cadaveric Swine Study

Xiaoyao Fan, PhD, Sohail K. Mirza, MD, MPH, Chen Li, PhD, Linton T. Evans, MD, Songbai Ji, DSc, and Keith D. Paulsen, PhD

Investigation performed at Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire

Background: Change in vertebral position between preoperative imaging and the surgical procedure reduces the accuracy of image-guided spinal surgery, requiring repeated imaging and surgical field registration, a process that takes time and exposes patients to additional radiation. We developed a handheld, camera-based, deformable registration system (intraoperative stereovision, iSV) to register the surgical field automatically and compensate for spinal motion during surgery without further radiation exposure.

Methods: We measured motion-induced errors in image-guided lumbar pedicle screw placement in 6 whole-pig cadavers using state-of-the-art commercial spine navigation (StealthStation; Medtronic) and iSV registration that compensates for intraoperative vertebral motion. We induced spinal motion by using preoperative computed tomography (pCT) of the lumbar spine performed in the supine position with accentuated lordosis and performing surgery with the animal in the prone position. StealthStation registration of pCT occurred using metallic fiducial markers implanted in each vertebra, and iSV data were acquired to perform a deformable registration between pCT and the surgical field. Sixty-eight pedicle screws were placed in 6 whole-pig cadavers using iSV and StealthStation registrations in random order of vertebral level, relying only on image guidance without invoking the surgeon's judgment. The position of each pedicle screw was assessed with post-procedure CT and confirmed via anatomical dissection. Registration errors were assessed on the basis of implanted fiducials.

Results: The frequency and severity of pedicle screw perforation were lower for iSV registration compared with StealthStation (97% versus 68% with Grade 0 medial perforation for iSV and StealthStation, respectively). Severe perforation occurred only with StealthStation (18% versus 0% for iSV). The overall time required for iSV registration (computational efficiency) was ~10 to 15 minutes and was comparable with StealthStation registration (~10 min). The mean target registration error was smaller for iSV relative to StealthStation (2.81 ± 0.91 versus 8.37 ± 1.76 mm).

Conclusions: Pedicle screw placement was more accurate with iSV registration compared with state-of-the-art commercial navigation based on preoperative CT when alignment of the spine changed during surgery.

Clinical Relevance: The iSV system compensated for intervertebral motion, which obviated the need for repeated vertebral registration while providing efficient, accurate, radiation-free navigation during open spinal surgery.

Image-guided surgery is poised to become an increasing part of standard operative care because it improves surgical precision and reduces trauma from surgical exposure[1,2]. In spinal surgery, it facilitates complex procedures, enables minimally invasive interventions, reduces radiation exposure, and increases the accuracy of pedicle screw placement[3,4]. Most spinal surgery still involves open exposure, and <15% of surgeons use navigation routinely[3,4], in part because it increases procedure duration and cost, provides unreliable accuracy in some cases, and involves complex equipment and additional training[3,4]. Image guidance must transform the surgical space to image space accurately; the process is compromised by any change in vertebral position during surgery[5]. Motion can be compensated for by registering each vertebra individually. Here, segmental

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registration and attaching the reference frame to the level of interest are common in cases in which accuracy becomes critical (e.g., small pedicles in the thoracic or cervical spine or L1). However, these processes take time and can be cumbersome for some surgeons. Intraoperative fluoroscopic computed tomography (CT), such as use of the O-arm (Medtronic), provides accurate mapping and automated registration[1], but it adds radiation exposure (to the patient and, potentially, the surgical team) and operative time[6,7]. The 7D Surgical image-guided technology registers the surgical field with preoperative CT (pCT) using anatomical landmarks, but it involves structured light equipment and manual selection in both pCT and the surgical field, and limits navigation to 1 vertebra at a time. The efficacy of intraoperative magnetic resonance imaging (MRI) is limited by availability, the lack of MR-compatible instruments and equipment[8], and imaging artifacts caused by instrumentation in the surgical field[9].

We developed a novel method of compensating for spinal motion between preoperative scans and intraoperative positioning, and registering the surgical field automatically on the basis of intraoperative photographs acquired with a handheld camera system rather than more expensive structured light equipment or repeated CT scans with ionizing radiation[10,11]. This optically tracked, radiation-free, handheld intraoperative stereovision (iSV) device acquires depth-of-field data of exposed vertebral surfaces[12]. It uses a validated deformable registration to align each vertebra with pCT automatically and without the manual identification of landmarks. The process modifies pCT data to reflect each vertebra's current position[10,11].

In this study, we measured the magnitudes of motion-induced errors using a state-of-the-art commercial spinal navigation system during in vitro pedicle screw placement in whole-pig cadavers and compared the results to those of iSV registration, which compensated for intraoperative vertebral motion.

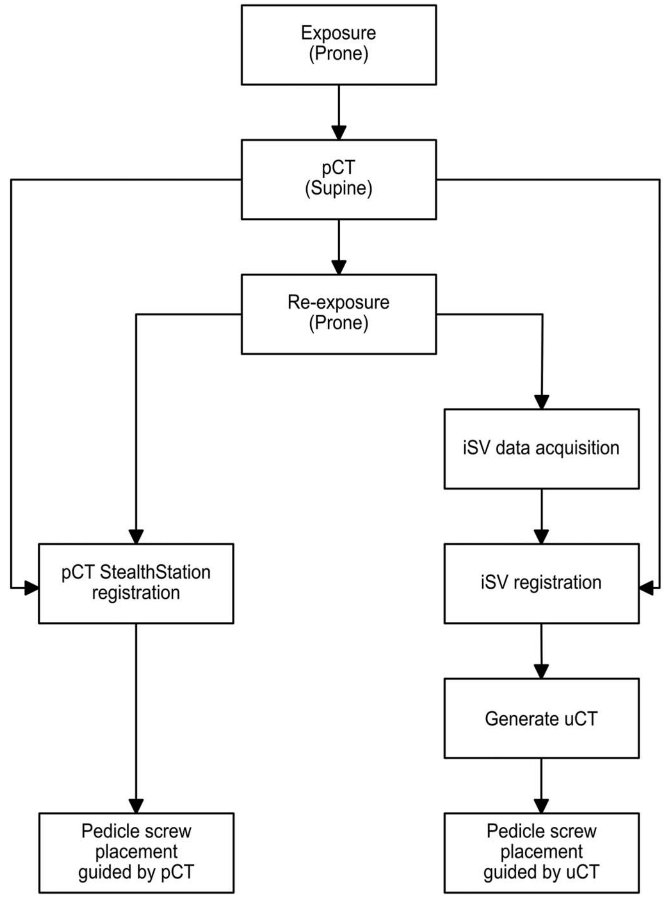

Fig. 1

Flowchart of surgical procedures involving StealthStation and iSV registrations. pCT = preoperative computed tomography, uCT = updated computed tomography, and iSV = intraoperative stereovision.

Materials and Methods

Study Design

We designed the study to compare registration performance with conventional image guidance (StealthStation i7; Medtronic) and our iSV system under conditions of accentuated vertebral motion to determine how large registration errors can become with standard methods and to assess the clinical need for updated images and whether our iSV approach can compensate for the induced misalignment. We recognize that the study was not comparing expected clinical performance of standard image guidance with our new technology per se because strategies to mitigate registration errors from vertebral motion with standard methods, for example vertebra-by-vertebra re-registration, were not evaluated. We used 6 cadaveric whole-pig specimens because of their anatomical similarities with human lumbar spines[13]. The sample size was based on variations observed in previous experiments. No inclusion/exclusion criteria for specimens were established. A surgical procedure flowchart is shown in Figure 1. Both StealthStation and iSV registrations were performed once at the beginning of the procedure. The guidance system used for each screw was randomly assigned, and the surgeon was blinded to the guidance system used for each screw. The same experienced spine surgeon placed pedicle screws in lumbar vertebrae and was instructed to suspend clinical judgment and place screws based solely on image guidance. We compared registration errors, the accuracy of screw position, and efficiency (the time required for registration) of the 2 approaches.

Surgical Setting

Standard midline posterior lumbar exposure was performed from L1 to L6. Eighteen mini-screws (1.5-mm diameter; Stryker) were implanted as fiducial markers in the spinous and transverse processes at each level. The incision was closed, the animal was positioned supine with accentuated lumbar lordosis at L3, and pCT was acquired (pixel spacing: 0.21×0.21 to 0.35×0.35 mm; slice thickness: 0.6 mm). The animal was repositioned prone and secured to the operating table to minimize intraoperative alignment change. The surgical site was reopened. A dynamic reference frame (Medtronic) was attached rigidly to the ilium. Ground-truth locations of 18 fiducials were digitized with a tracked stylus (Medtronic).

StealthStation Registration

Fiducial-based registration (FBR) was performed on the StealthStation with pCT using the same 10 (the maximum number of registration points allowed by StealthStation) of 18 fiducials to align the entire lumbar exposure. The 10 fiducial locations were distributed evenly across the lumbar spine following literature suggestions[14]. We used fiducials instead of anatomical landmarks typical of clinical cases to minimize localization errors.

Stereovision Registration

The handheld iSV[12,15] acquired 3 to 4 image pairs with tracking data to reconstruct a complete 3D profile of the exposed spine. Figure 2 shows a photograph of iSV acquisition in a typical experiment. The accuracy of iSV reconstruction was assessed as the distances between tracked fiducial locations and their counterparts localized on iSV surfaces. Preoperative CT was registered with iSV surfaces using a deformable registration (illustrated in Fig. 3, technical details published elsewhere[10,11]). An updated CT (uCT) image volume was generated by deforming the pCT, and uploaded to the StealthStation.

Pedicle Screw Insertion

Pedicle screws of the same size (Vertex Select; Medtronic) were inserted on each vertebra based on StealthStation image guidance using pCT or iSV-updated image guidance using uCT, respectively, although screw diameters varied between cases because of the limited availability of instruments for animal cadaveric studies. The sequence of screw insertions was randomized. A second randomization was employed to choose the registration method. For each insertion, a corresponding registration and scan were loaded into the StealthStation for image guidance: pCT for StealthStation registration (Fig. 4-A) and uCT for iSV registration (Fig. 4-B).

Assessment of Accuracy

We assessed the point-to-point registration error (ppRE) of 18 fiducials, calculated as the distances between tracked fiducial locations in physical space and their counterparts as transformed from image to physical space. With respect to StealthStation measurements, the fiducial registration error (FRE)[16] was calculated from the 10 fiducials involved in StealthStation registration, and the target registration error (TRE)[16] was calculated using the other 8 fiducials. In addition, the ppRE was calculated using the 3 fiducials on each level. The ppRE of iSV registration is equivalent to its TRE since the 18 fiducials were not involved in iSV registration, whereas the ppRE of StealthStation registration is a combination of its FRE and TRE.

Postoperative CT images (pixel spacing: 0.21 × 0.21 to 0.31 × 0.31 mm; slice thickness: 0.6 mm) were acquired to visualize screw positions. Subsequently, specimens were dissected at the instrumented levels, and perforation of each implanted pedicle screw was measured in medial-lateral and superior-inferior directions[6]. Anterior perforation was not measured because of the limited selection in pedicle-screw lengths. Perforation severity grades were assigned according to thresholds defined by Gertzbein and Robbins[17]: 0 mm (no breach) = Grade 0, a perforation distance of <2 mm = Grade 1, 2-4 mm = Grade 2, and >4 mm = Grade 3. If the perforation distance was not measurable with calipers but screw

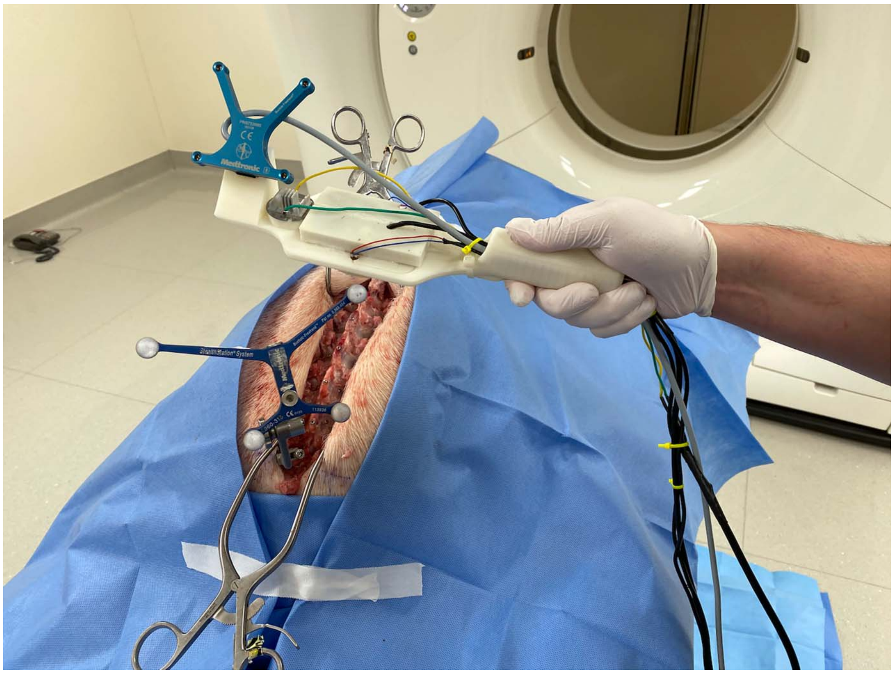

Fig. 2

A photograph of iSV (intraoperative stereovision) acquisition in a typical experiment.

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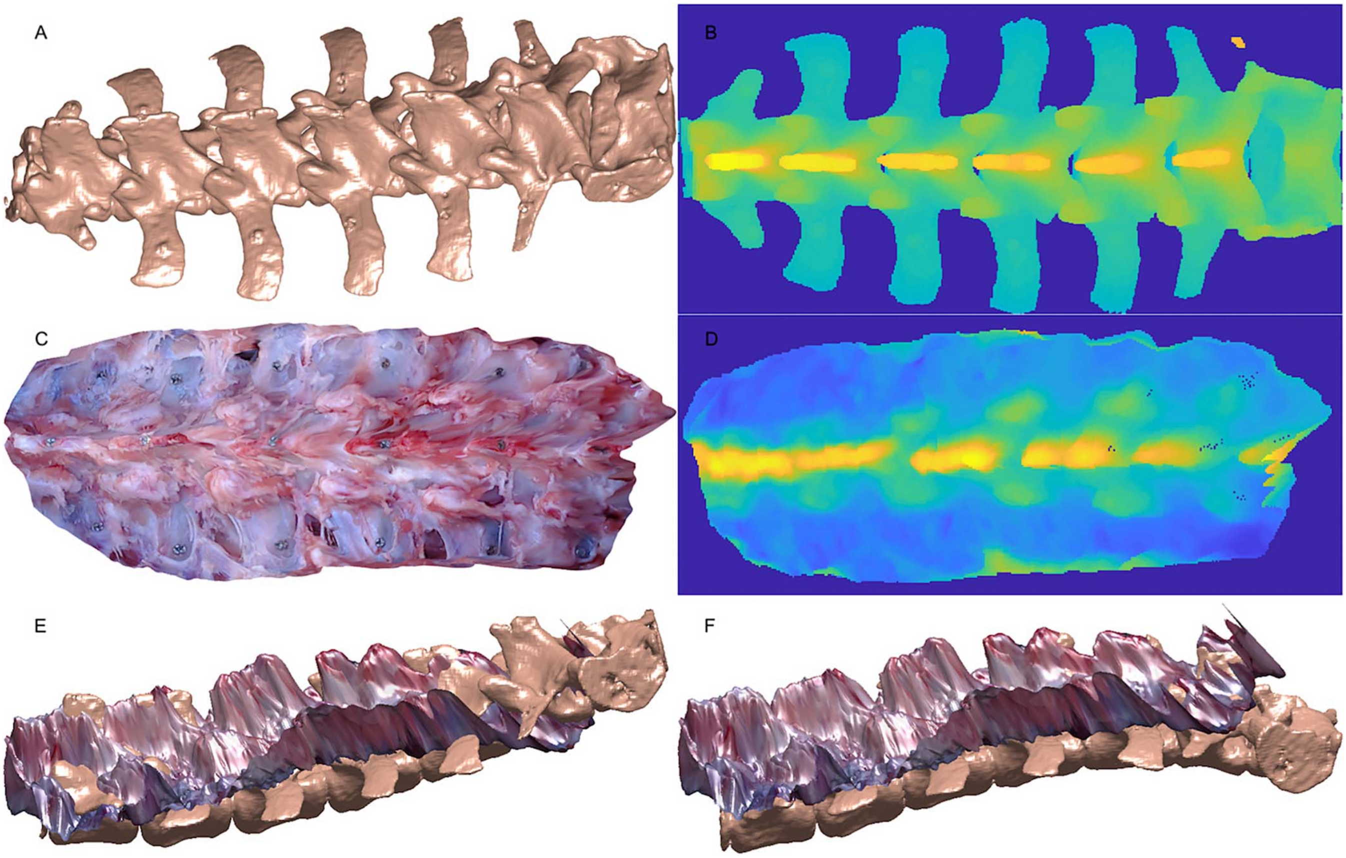

Fig. 3

Intraoperative stereovision (iSV) registration is illustrated. Preoperative CT (pCT, in supine orientation) was segmented (**Fig. 3-A**), and 3 iSV surfaces were combined to cover the entire surgical field (**Fig. 3-C**). Both pCT and iSV were rectified to a neutral position, and 2D projection images were generated (**Figs. 3-B and 3-D**, respectively). The 2D projection images were aligned through registration, which mapped iSV into the same coordinate system with pCT and enabled image guidance (**Fig. 3-E**). Misalignment between pCT and iSV indicates posture change. Level-wise registration was performed, and pCT was deformed level-by-level to generate updated CT (uCT) that matched with iSV (**Fig. 3-F**). Technical details of the registration method have been published elsewhere[10,11].

threads were visible upon dissection, Grade 0 was assigned. Figure 5 shows representative images of medial (Fig. 5-A) and lateral (Fig. 5-B) perforation, and Grade 0 perforation with no visible breach (Fig. 5-C) and with a visible but unmeasurable breach (Fig. 5-D). We also investigated relationships between perforation magnitude and (1) screw location (vertebral level), (2) sequence of insertion, and

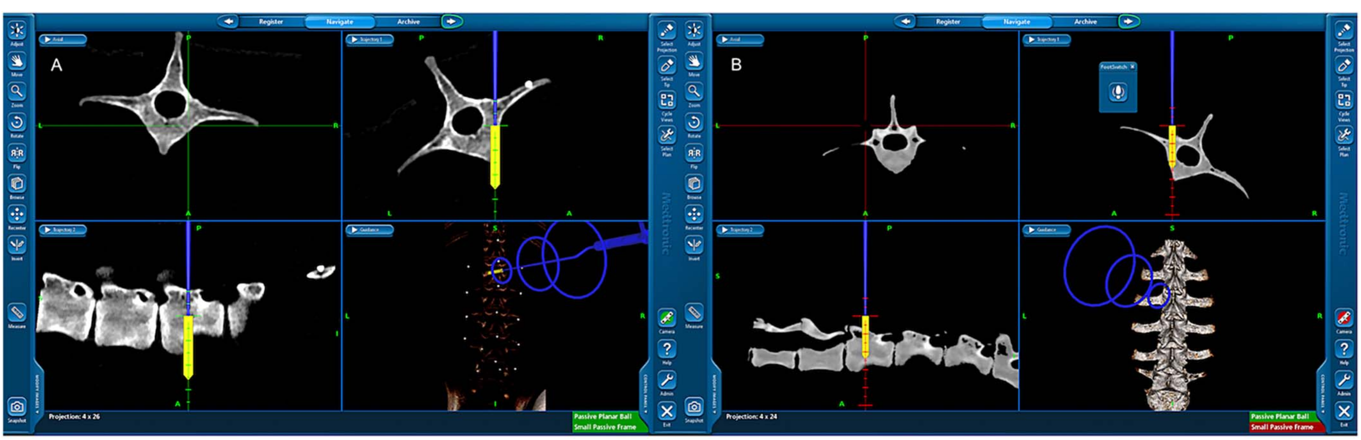

Fig. 4

Intraoperative navigation using StealthStation (**Fig. 4-A**) and intraoperative stereovision (iSV) (**Fig. 4-B**) registrations. A stylus was tracked, and its tip location and trajectory were shown on the display for image guidance.

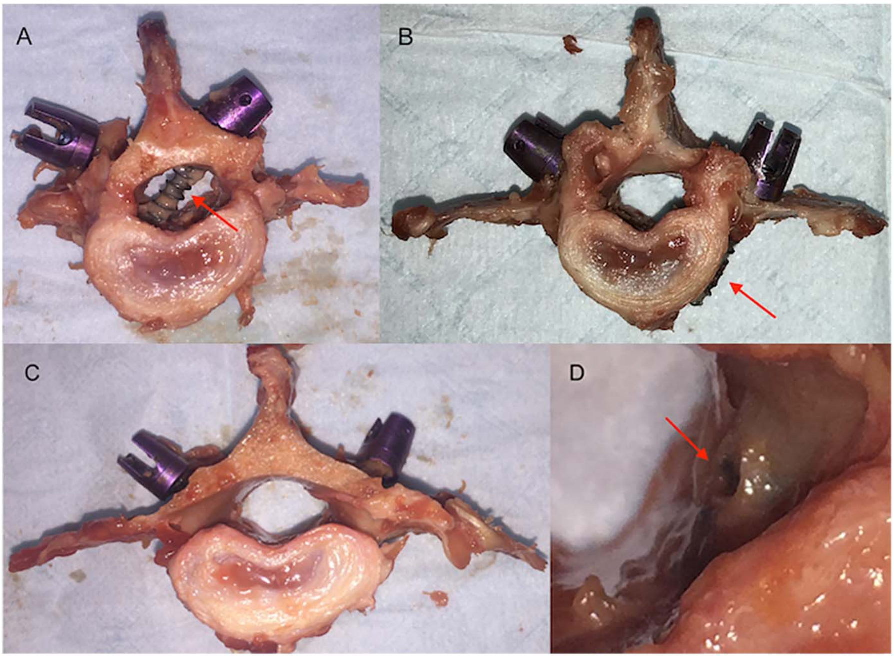

Fig. 5

Representative medial breach (**Fig. 5-A**), lateral breach (**Fig. 5-B**), and Grade 0 perforation with no visible breach (**Fig. 5-C**) and with a visible but unmeasurable breach (**Fig. 5-D**). Red arrows point to pedicle screws with visible perforation on dissected vertebrae. Our study protocol required the surgeon to suspend clinical judgement and place screws exactly as directed by image guidance. The profound medial perforation in the figure typically would be discerned by the surgeon on the basis of the screw track prior to its placement.

(3) the ppRE at the vertebral level. The Spearman rank correlation coefficient, ρ, was calculated to assess associations between these variables, and a p value was found in testing a no-correlation hypothesis. All data analyses were performed in MATLAB (MathWorks).

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Results

Case characteristics are summarized in Table I. Pedicle widths were measured on pCT (column 3: range, 2.7 to 8.5 mm) and were narrower than those of humans as reported in the literature (range, 6.4 to 17.5 mm[18]). Pedicle screw diameters are reported in column 4 of Table I.

Registration Accuracy

The accuracy of StealthStation and iSV registrations is reported in Table II. The FREs and TREs of StealthStation registration appear in columns 2 and 3, respectively. Points with large registration errors were excluded by the StealthStation in its FRE calculations (the number of excluded points is reported in parentheses in column 2). The TRE (average [and standard deviation], 8.37 ± 1.76 mm) was larger than the FRE (average, 4.40 ± 1.35 mm) in StealthStation registration. The TRE of iSV registration (column 4 in Table II) (average, 2.81 ± 0.91 mm) was smaller than both the FRE (column 2) and TRE (column 3) of StealthStation registration. The overall iSV reconstruction accuracy across the 6 cases (column 5) was 1.22 ± 0.19 mm, indicating that iSV data acquisition was accurate. The change in lumbar lordosis between preoperative imaging and the intraoperative surgical position was measured using the Cobb method[19] and is reported in column 6 of Table II.

TABLE I Spinal Levels Instrumented, Range of Pedicle Width, and Size of Inserted Screws

Case ID	Levels*	Pedicle Width *(mm)*	Screw Diameter *(mm)*
1	L1-L6 (6)	4.3-5.4	4.0, 4.5
2	L1-L6 (6)	2.7-4.7	4.0, 4.5
3	L1-L6 (6)	2.9-4.2	4.0, 4.5
4	L1-L5 (5)	7.4-8.5	3.5
5	L2-L6 (5)	6.9-7.8	3.5
6	L1-L6 (6)	4.4-6.5	4.0

*The number of levels instrumented for each case is reported in parentheses.

TABLE II Accuracy of StealthStation (FRE and TRE) and iSV (TRE) Registrations and Reconstructed iSV Surfaces, and Change in Lumbar Lordotic Angle Between Preoperative Supine Imaging and Intraoperative Prone Position*

Case ID	StealthStation FRE† *(mm)*	StealthStation TRE† *(mm)*	iSV TRE† *(mm)*	Reconstruction Accuracy of iSV† *(mm)*	Lumbar Lordotic Angle Change‡ *(°)*
1	6.32 (2)	7.38 ± 3.50	2.34 ± 0.81	1.55 ± 0.54	38
2	5.61 (1)	7.86 ± 4.22	3.93 ± 1.47	1.16 ± 0.31	39
3	2.97 (3)	7.38 ± 2.98	2.87 ± 1.16	0.96 ± 0.34	36
4	3.87 (3)	8.80 ± 4.49	2.51 ± 2.34	1.16 ± 0.48	65
5	3.12 (3)	7.06 ± 3.75	3.71 ± 0.77	1.22 ± 0.44	48
6	4.50 (3)	11.74 ± 6.02	1.48 ± 0.95	1.27 ± 0.43	62
Average†	4.40 ± 1.35	8.37 ± 1.76	2.81 ± 0.91	1.22 ± 0.19	48 ± 13

*iSV = intraoperative stereovision, FRE = fiducial registration error, and TRE = target registration error. †The values are given as the mean and standard deviation. The number of points excluded from StealthStation registration is reported in parentheses in column 2. ‡Change between preoperative imaging and intraoperative surgical position, as measured using the Cobb method[19].

We also compared the ppREs of StealthStation and iSV registrations at all 18 fiducial locations and at each vertebral level (Fig. 6-A and 6-B, respectively). The overall ppREs of iSV registration were smaller than those of StealthStation registration at all 18 fiducial locations as well as at all 6 levels. Furthermore, the ppREs of StealthStation registration were larger toward the ends of the exposed spine (L1 average, 16.45 ± 3.32 mm; L6 average, 12.19 ± 5.37 mm), whereas the ppREs from iSV registration were distributed evenly across all screws and all levels. The ppRE for L6 (average, 3.68 ± 0.85 mm) was larger than at other levels. The standard deviations show that the ppRE of StealthStation registration (range, 4.09 to 7.52 mm) was more variable than that of iSV registration (range, 0.81 to 2.50 mm).

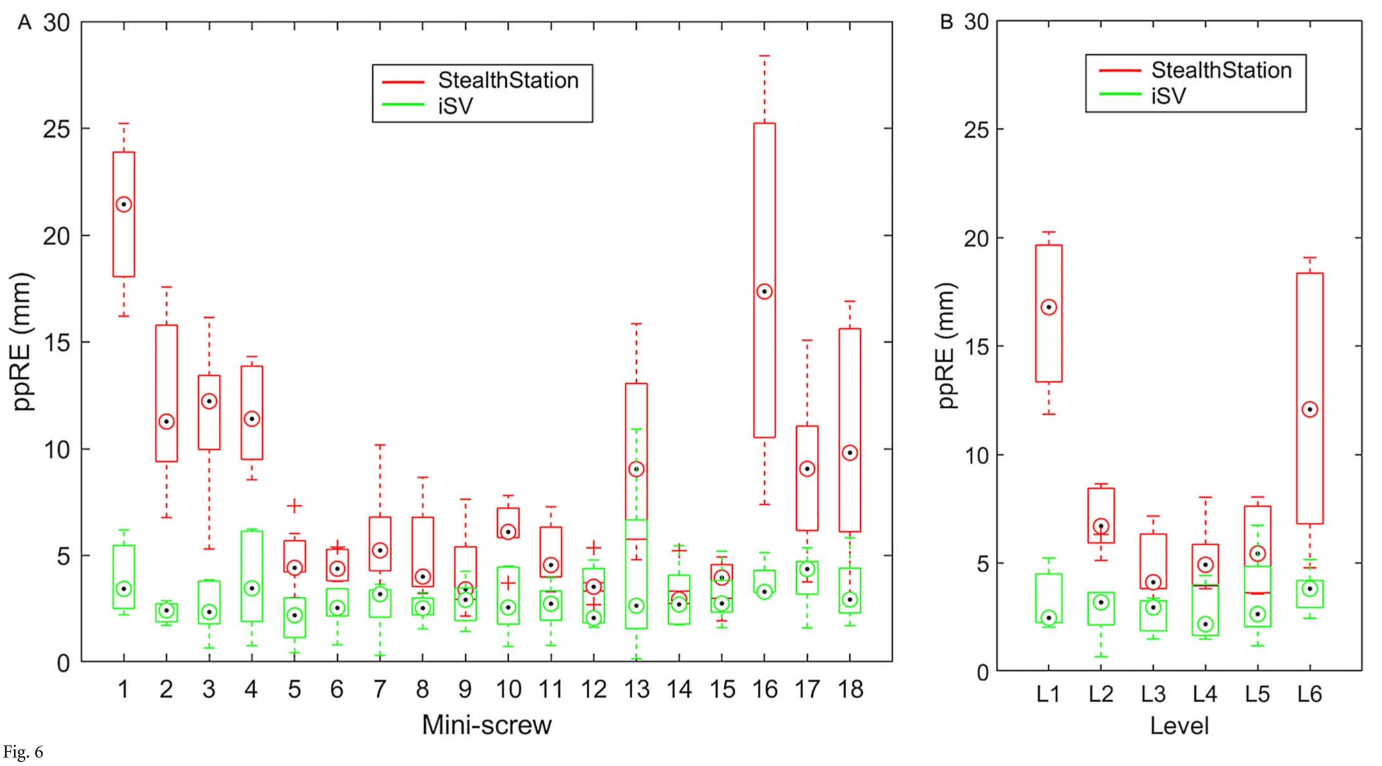

Fig. 6

Comparison of point-to-point registration errors (ppREs) for StealthStation (red) and intraoperative stereovision (iSV, green) registrations. Box plots of ppREs for the 2 registrations at each fiducial location (**Fig. 6-A**) and at each vertebral level (**Fig. 6-B**) are shown. In each box plot, the target symbol corresponds to the median value, edges of the box indicate the 25th and 75th percentiles, whiskers extend to the most extreme data points that are not considered outliers, and the plus symbol corresponds to outliers.

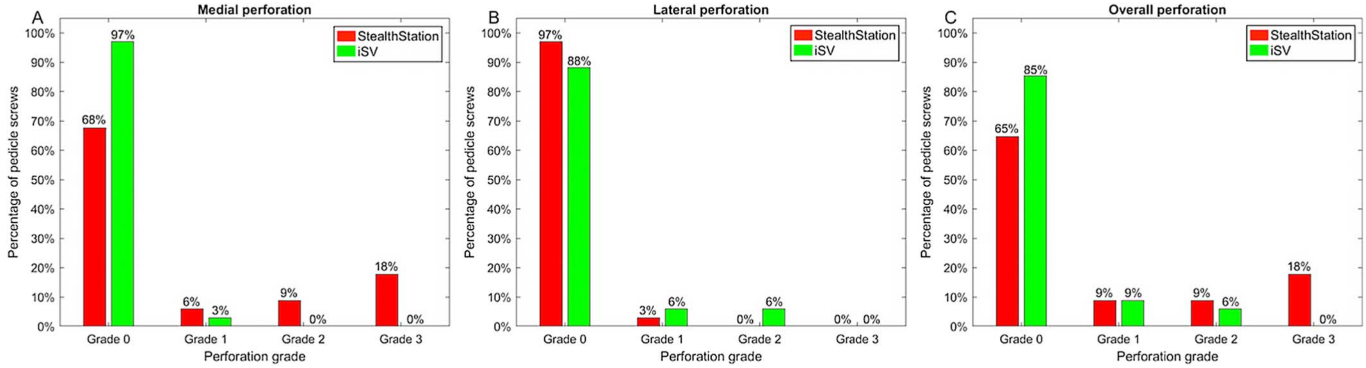

Fig. 7

The distribution of pedicle screws across perforation grades for StealthStation (red) and intraoperative stereovision (iSV, green) registrations in medial (**Fig. 7-A**), lateral (**Fig. 7-B**), and combined (**Fig. 7-C**) directions. Each bar represents the percentage of pedicle screws for each perforation grade listed on the horizontal axis.

Pedicle Screw Position

Sixty-eight pedicle screws were inserted (34 using each registration method). The distributions of pedicle screws across perforation severity grades are shown in Figure 7 for StealthStation and iSV registrations. The results show that iSV registration had a higher rate of Grade 0, similar rates of Grades 1 and 2, and a lower rate of Grade 3 perforations relative to StealthStation registration.

All screws from both registrations had Grade 0 perforation in superior-inferior directions. In the medial direction (Fig. 7-A), iSV registration had a higher rate of Grade 0 screws than StealthStation (97% versus 68%) and lower rates for all other grades. StealthStation registration had a high rate of Grade 3 perforation (1 screw in each case; range: 4.5 to 14.0 mm). In the lateral direction (Fig. 7-B), iSV registration had higher rates of Grades 1 and 2 perforation (6% and 2 screws in each grade). All Grade 1 and 2 screws resulted from Case 3, in which the pedicle width was smaller (2.9 to 4.2 mm). Neither registration had lateral Grade 3 perforation. Overall performance is shown in Figure 7-C.

Spearman correlation results show that perforation from iSV registration was associated with the sequence of insertion ($\rho = 0.37$; $p = 0.03$), whereas StealthStation registration was not correlated with the sequence of insertion ($\rho = -0.04$; $p = 0.79$). Figure 8 shows the relationships between perforation magnitude and screw location (Fig. 8-A), sequence of insertion (Fig. 8-B), and ppRE at the vertebral level (Fig. 8-C) for StealthStation and iSV registrations. Figure 8-A shows that StealthStation registration had larger perforation toward the ends (L1 and L6), whereas perforation from iSV registration was more evenly distributed across all levels. Figure 8-B shows perforation ordered by sequence of insertion (horizontal axis). Figure 8-C shows that perforation was severe with a large ppRE, and Spearman correlation shows a strong association ($\rho = 0.38$; $p = 0.001$) when all data points were analyzed.

Efficiency

The overall time required for iSV registration (computational efficiency) was ~10 to 15 minutes. The overall cost in time of FBR on the StealthStation was similar (~10 minutes), and

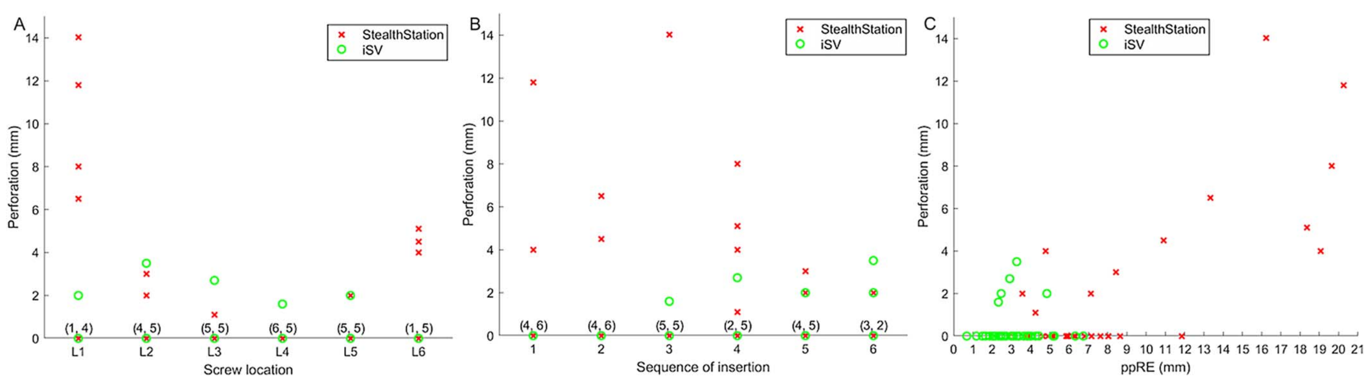

Fig. 8

Perforation of pedicle screws by screw location (**Fig. 8-A**), sequence of insertion (**Fig. 8-B**), and point-to-point registration error (ppRE) at the corresponding vertebral level (**Fig. 8-C**) for StealthStation (red Xs) and intraoperative stereovision (iSV, green circles) registrations. In **Figs. 8-A and 8-B**, points with Grade 0 perforation are clustered on the horizontal axis. Numbers above the horizontal axis in parentheses in **Figs. 8-A and 8-B** indicate the Grade 0 data points using StealthStation registration (first number) and iSV registration (second number), respectively.

involved manual selection of homologous points on CT scans and in the surgical field.

Discussion

Registration accuracy was assessed using fiducials, but errors at fiducials may not represent the accuracy at pedicles. We implanted pedicle screws on the basis of image guidance only and measured the perforation of pedicle screws to assess registration performance. The natural anatomy of the pedicle canal may have compensated for some errors, as the cortical margin of the pedicle may redirect the tap and screw during placement. If so, the correction would affect both iSV and StealthStation systems equally, and our results show that iSV registration outperformed StealthStation registration in terms of medial/lateral perforations under the experimental conditions in the study. Severe medial perforation (Grade 3) was observed in 6 of 8 pedicle screws with a large ppRE (>10 mm; all from StealthStation registration).

We also found that perforation was associated with the sequence of insertion in iSV registration (Fig. 8-B). One possible explanation is that additional alignment change was introduced during pedicle screw insertion. Compared with other techniques, iSV registration is low-cost and efficient, and can be repeated during surgery to account for recurring alignment changes without radiation exposure.

FRE and TRE depend on the severity of alignment change in FBR. For reference, we acquired intraoperative CT (iCT) in the operative prone position and performed FBR with iCT, which served as the "gold standard" because the image stack matched the intraoperative position exactly[20]. The accuracy of iCT-based registration was superb (0.49 ± 0.07 mm), and any remaining errors were mainly due to localization effects (e.g., tracking system errors and human errors in localizing fiducials in image and physical space). StealthStation registration using pCT was subject to similar localization effects, but TREs were caused largely by posture changes between supine imaging and prone positioning (average change in lumbar lordosis, 48° ± 13°). Here, we only investigated multilevel procedures, and observed that alignment change was larger and ppREs were larger toward the ends of spine exposures. Since fiducials were evenly distributed, registration points toward exposure ends were often excluded by the StealthStation because of their large errors. As a result, the TRE was larger than the FRE.

StealthStation accuracy was lower relative to published case series[6,21,22] and systematic reviews/meta-analyses[23,24] because we deliberately evaluated errors that resulted when vertebral motion between imaging and surgical position was not addressed with conventional registration systems. Discrepancies between the StealthStation and iSV would likely be reduced if individual vertebrae were registered on the StealthStation as suggested by others[5], or with shorter segments[25]. For example, ppRE can be improved to 1.92 ± 0.50 mm by registering only 3 levels and limiting navigation to 1 level at a time. However, for some surgeons, and perhaps those new to navigation, repeated segmental registration can be cumbersome and increase operative time, and the resulting accuracy is surgeon-dependent[26]. In this study, intervertebral motion caused a range of pedicle breaches with the StealthStation when the whole lumbar spine was registered. Intraoperative stereovision registration, on the other hand, was able to compensate for this motion to a large extent and navigate the entire surgical field. It avoided the repositioning of instruments, requiring multiple level-wise registrations, and the repeating of CT scans. We plan to compare the performance of iSV registration with segmental registration and iCT registration in a future study.

Several limitations must be acknowledged. First, iSV registration is only possible on exposed levels. Levels at exposure ends are more difficult to acquire due to line-of-sight restrictions, and errors can be higher. The issue is mitigated by positioning instruments away from the vertebrae. Second, soft-tissue and ligamentous structures remaining on the dorsal surface of the vertebrae, which were not present in CT-segmented spines, likely contributed to errors in iSV registration. Although injury could not be assessed here, a previous report[18] suggested that distances between the pedicle cortex and neural structures were 1.7 to 2.0 mm medially, and 2.4 (L5) to 9.6 (L1) mm laterally, in the lumbar section. We have since improved our algorithms and reduced the overall ppRE to <2.0 mm (average, 1.94 ± 0.37 mm; range, 1.26 to 2.24 mm) in the 6 cadavers to meet clinical acceptance criteria. Third, a long and wide exposure was made in this study to reveal the entire lumbar section, including partial transverse processes. Simulations show that registration accuracy is similar for various lengths of exposure[27]. Preliminary data indicate that a narrower exposure (up to the facet joints) with reduced muscle stripping and tissue damage may still be sufficient for iSV registration, but accuracy can be affected. Effort is underway to evaluate iSV image updating performance as a function of exposure size. Finally, the exposed spine was selected manually to remove irrelevant background from iSV images, but that required minimal expertise, and the reconstruction and registration processes were automatic. Effort is underway to develop machine learning-based algorithms to segment the spine automatically from iSV images to eliminate user input.

The iSV technique may be applicable to open exposure, the cervical spine, and uninstrumented revision surgery, where landmarks are not clearly available or posterior structures have been removed in the primary surgery. For instrumented revisions, further investigation would be needed to demonstrate the adequacy of using pCT imaging with hardware artifacts. The technique also has possible clinical applications for navigation in nonspinal surgery. ■

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Xiaoyao Fan, PhD[1]
Sohail K. Mirza, MD, MPH[1,2]
Chen Li, PhD[1]
Linton T. Evans, MD[3,4]

Songbai Ji, DSc[1,5]
Keith D. Paulsen, PhD[1,3,6]

[1]Thayer School of Engineering, Dartmouth College, Hanover, New Hampshire

[2]PEERClinic for Back Pain and Spine Surgery, Fairfax, Virginia

[3]Geisel School of Medicine, Dartmouth College, Hanover, New Hampshire

[4]Section of Neurosurgery, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire

[5]Department of Biomedical Engineering, Worcester Polytechnic Institute, Worcester, Massachusetts

[6]Norris Cotton Cancer Center, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire

Email for corresponding author: Keith.D.Paulsen@dartmouth.edu

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