Optical Topographic Imaging for Spinal Intraoperative 3-Dimensional Navigation in the Cervical Spine

Initial Preclinical and Clinical Feasibility

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Summary of Background Data: Computer-assisted 3-dimensional navigation may guide spinal instrumentation. Optical topographic imaging (OTI) is a novel navigation technique offering comparable accuracy and significantly faster registration workflow relative to current navigation systems. It has previously been validated in open posterior thoracolumbar exposures.

Objective: To validate the utility and accuracy of OTI in the cervical spine.

Study Design: This is a prospective preclinical cadaveric and clinical cohort study.

Methods: Standard midline open posterior cervical exposures were performed, with segmental OTI registration at each vertebral level. In cadaveric testing, OTI navigation guidance was used to track a drill guide for cannulating screw tracts in the lateral mass at C1, pars at C2, lateral mass at C3–6, and pedicle at C7. In clinical testing, translaminar screws at C2 were also analyzed in addition. Planned navigation trajectories were compared with screw positions on postoperative computed tomographic imaging, and quantitative navigation accuracies, in the form of absolute translational and angular deviations, were computed.

Results: In cadaveric testing (mean ± SD) axial and sagittal translational navigation errors were (1.66 ± 1.18 mm) and (2.08 ± 2.21 mm), whereas axial and sagittal angular errors were (4.11 ± 3.79 degrees) and (6.96 ± 5.40 degrees), respectively. In clinical validation (mean ± SD) axial and sagittal translational errors were (1.92 ± 1.37 mm) and (1.27 ± 0.97 mm), whereas axial and sagittal angular errors were (3.68 ± 2.59 degrees) and (3.47 ± 2.93 degrees), respectively. These results are comparable to those achieved with OTI in open thoracolumbar approaches, as well as using current spinal neuronavigation systems in similar applications. There was no radiographic facet, canal or foraminal violations, nor any neurovascular complications.

Conclusions: OTI is a novel navigation technique allowing efficient initial and repeat registration. Accuracy even in the more mobile cervical spine is comparable to current spinal neuronavigation systems.

Key Words: computer-assisted surgery, navigation, image guidance, cervical spine

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Intraoperative 3-dimensional computer-assisted navigation (CAN) has become standard-of-care in cranial neurosurgery for the localization of subsurface anatomy. CAN in spinal surgery may guide instrumentation placement as well as bony and soft tissue resection; however, adoption has been limited by cumbersome and lengthy registration protocols, spatial and temporal workflow hindrances, steep learning curves, and high costs.1–6

In current practice, the utility of CAN is most apparent in minimally invasive and deformity-correcting procedures in the thoracolumbar spine, where anatomic landmarks are not directly visible or are significantly distorted.1,5,7,8 Navigation may play an increasing role in the cervical spine, for the placement of minimally invasive instrumentation in the setting of acute trauma, for fixation of the atlantoaxial spine and craniocervical junction, and for the placement of cervical pedicle screws which are biomechanically superior to lateral mass fixation.9–11 However, the cervical spine is inherently more mobile than the thoracolumbar spine, with narrower pedicles and tighter tolerances, hence navigation inaccuracy due to intersegmental mobility is of significant concern with most current CAN systems. Unsurprisingly, the reported radiographic accuracy of current 3D-CAN systems is typically lower in the cervical than in the thoracolumbar spine.12,13
Optical topographic imaging (OTI) is a novel technique for 3D surface anatomy acquisition, patient-to-image registration and intraoperative navigation, developed by our research group. OTI registers significantly faster than current CAN systems, without intraoperative radiation exposure and with comparable accuracy in open thoracolumbar approaches. This technology obviates many of the limitations of current CAN techniques.

Here, we assess the ability of OTI to perform successful patient-to-image registration and accurate intraoperative navigation in the mobile cervical spine, in preclinical cadaveric models and in initial human clinical testing.

METHODS

Reporting of all methodology is performed in accordance with the criteria for STrengthening the Report- ing of OBservational studies in Epidemiology (STROBE —www.strobe-statement.org).

Specimen/Patient Selection

Preclinical validation was performed in 4 human cadavers. All cadavers underwent preoperative and postoperative helical computed tomography (CT) imaging at 0.5 mm slice thickness. Institutional ethics board approval was obtained (IRB# 16-0051-E).

In human in vivo clinical validation, 15 patients without history of prior spinal surgery were enrolled in an ongoing prospective trial of OTI navigation at Sunnybrook Health Sciences Centre (IRB# 309-2014 and 086-2015). All patients underwent preoperative and postoperative helical CT imaging, reformatted at 0.625 mm slice thickness.

Surgical Technique

Cadavers were positioned prone on a standard operating table, with head fixed in a Mayfield clamp. Standard midline posterior exposures were performed from occiput to the cervicothoracic junction, with exposure of the medial 1.5 cm of the posterior arch of C1, and the entire lateral masses of C3–7. All cadaveric procedures were performed by a single surgeon (D.G.).

In human in vivo testing, all patients underwent open posterior cervical instrumented fusion for traumatic or degenerative pathologies. All patients were positioned prone on a Wilson frame, with head fixed in a Mayfield clamp. Standard midline open posterior exposures were used for all cases. In vivo procedures were performed by a single surgeon (V.X.D.Y.), with trainee assistance.

Regression and Intraoperative Navigation

In cadaveric testing, the exposed anatomy at each level was individually registered to preoperative CT using OTI, with the dynamic reference frame (DRF) clamped to the spinous process of the registered level. Registration at C1 was performed segmentally, but with the DRF clamped on C2 due to the lack of a C1 spinous process. Technical details of OTI registration are described separately. Briefly, a structured-light pattern is projected onto the exposed anatomy and recorded by stereoscopic visible-band cameras to reconstruct a 3D surface point cloud. This is automatically aligned to preoperative CT imaging using a segmentation and registration algorithm in real time.

Registration accuracy was verified manually by placing an optically tracked awl on bony landmarks and assessing correlation to the navigation display. Registration was deemed successful if the OTI system captured sufficient anatomy for patient-to-image registration (≥100 surface points), and if manual verification by the operator demonstrated acceptable accuracy with visual and tactile feedback.

An optically tracked drill guide (Medtronic Sofamor Danek; Memphis, TN) was used with OTI navigation to fashion pilot holes for screw tracts in the C1 lateral mass, C2 pars, and C3–6 lateral mass (Fig. 1). A tracked awl and gearshift probe were used to fashion tracts for C7 pedicle screws. Appropriately sized titanium instrumentation was then placed using an untracked screwdriver. Screw holes were not tapped.

In human in vivo validation, segmental OTI registration, tract cannulation, and instrumentation placement were performed similar to cadaveric testing.
Evaluation of Navigation Accuracy

Absolute quantitative navigation accuracy was measured by comparing the final screw position, on postoperative CT, to a screenshot of the planned screw trajectory on the navigation system intraoperatively. Translational and angular deviations from the planned entry point and trajectory were quantified, in the axial and sagittal planes, using multiplanar reformatting of both preoperative and postoperative CT imaging. The method of absolute navigation error quantification has been described by our group previously (Fig. 2).15–17

Radiographic accuracy of all in vivo screws were graded using the 2 mm classification of Neo et al.18 Screws were dichotomized as acceptable (deviation ≤2 mm) or unacceptable (deviation >2 mm) per convention.

All image processing and measurements were performed using an OsiriX 64-bit workstation (version 10.9.5; PIXMEO SARL, Geneva, Switzerland).

Statistical Analyses

Differences in absolute navigation errors between spinal levels, and between the cervical cohort in this study and the thoracolumbar cohort from our prior trial of OTI, were quantified with 1-way ANOVA with the Tukey Honest-Significant-Difference test for post hoc comparisons. Correlation between radiographic cervical spondylosis, based on Kellgren grade (Table 1), and navigation errors were assessed using general linear modeling.19 Hierarchical mixed-effects general linear modeling was used to adjust for second-order differences between cadavers/patients, where required, on the basis of univariate analyses. In vivo cases were matched 1:1 based on age and sex, to patients who had undergone open thoracolumbar instrumentation using OTI guidance in our prior trial.20 Significance levels for all tests were set at α<0.05.

All statistical analyses were performed in SPSS Statistics (version 21; IBM, Chicago, IL).

RESULTS

For the 4 cadavers used in preclinical validation, mean age at death was 91.4 years (range, 83–96 y). No significant cervical deformity was evident in any cadaver; however, significant osteophyte bridging across the lateral masses was seen in 2 (Kellgren grade 3). In total, 53 screws from 4 cadavers were included in our analysis, encompassing C1 lateral mass, C2 pars, C3–6 lateral mass, and C7 pedicle screws (Table 2).
TABLE 1. Kellgren Classification for Radiographic Cervical Spondylosis

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
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<tbody>
<tr>
<td>0</td>
<td>No anterior osteophytes</td>
</tr>
<tr>
<td></td>
<td>0%–25% disk space narrowing</td>
</tr>
<tr>
<td></td>
<td>No endplate sclerosis</td>
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<tr>
<td></td>
<td>No olisthesis</td>
</tr>
<tr>
<td>1</td>
<td>Minimal anterior osteophyte formation (&lt; 2 mm)</td>
</tr>
<tr>
<td></td>
<td>25%–50% disk space narrowing</td>
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<td>Moderate anterior osteophyte formation (2–4 mm)</td>
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<td></td>
<td>Severe endplate sclerosis</td>
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<tr>
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<td>Olisthesis &gt; 5 mm</td>
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In vivo clinical feasibility was assessed in 15 patients, with mean age 61.1 years (range, 34–78 y). In total, 74 cervical screws placed with OTI guidance were analyzed, lateral mass at C1, pars and translaminar at C2, lateral mass at C3–6, and pedicle at C7 (Table 2).

Quantitative Navigation Accuracy

In preclinical cadaveric testing, overall (mean ± SD) axial and sagittal translational errors were (1.66 ± 1.18 mm) and (2.08 ± 2.21 mm), while axial and sagittal angular errors were (4.11 ± 3.79 degrees) and (6.96 ± 5.40 degrees), respectively (Fig. 3). There were no significant differences in errors between levels, nor any correlation between radiographic cervical degeneration, based on Kellgren classification, and any metric of absolute navigation error.

TABLE 2. Number of Screws in Cadaveric and Clinical Testing, Stratified by Level and Kellgren Grade

<table>
<thead>
<tr>
<th>Level</th>
<th>C1</th>
<th>C2</th>
<th>C2</th>
<th>C3–6</th>
<th>C7</th>
<th>Pedicle</th>
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<tr>
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<td>16</td>
<td>2</td>
<td>87</td>
<td>17</td>
<td>127</td>
<td>154</td>
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</table>

Italic values represent the subtotals in each of the ‘Cadaveric’ and ‘In vivo’ groupings. LM indicates lateral mass; TL, translaminar.

In clinical validation, overall (mean ± SD) axial and sagittal translational errors were (1.92 ± 1.37 mm) and (1.27 ± 0.97 mm), while axial and sagittal angular errors were (3.68 ± 2.59 degrees) and (3.47 ± 2.93 degrees), respectively (Fig. 4). There were no significant differences in errors between levels, nor correlation with radiographic cervical spondylosis. In univariate analyses, sagittal translational and angular error were significantly greater in cadaveric than in vivo testing ($P < 0.001$). There were no differences in any error metric between age-matched and sex-matched cervical cases and open thoracolumbar controls, showing equivalent quantitative accuracy for OTI navigation in open thoracolumbar and cervical approaches. The workflow benefits of OTI navigation continued to be realized in open cervical procedures, and have not been requantified here.

Radiographic Navigation Accuracy

No radiographic breach was observed in any cadaveric or in vivo C1, C2, or C7 screws (neo grade 0). There were no unintentional facet violations for any lateral mass screws placed at C3–6. There were no neurovascular or other clinical sequelae of any placed screws in clinical testing.

DISCUSSION

We demonstrate here that application accuracy in the cervical spine of OTI, a novel technique for image-to-patient registration and intraoperative navigation, is comparable to that in open thoracolumbar procedures and to currently available navigation devices. The workflow advantages associated with OTI in the thoracolumbar spine are maintained with comparable accuracy in the cervical spine.

The most frequently cited benefit of CAN for spinal procedures is improved instrumentation accuracy, and minimization of associated acute and long-term complications from misplaced hardware. CAN has been shown to reduce pedicle screw breach rates from 12% to 40%, under freehand or fluoroscopic guidance, to under 10% with 3D-CAN. Improved instrumentation accuracy is seen across all 3D-CAN techniques, registering to preoperative or intraoperative imaging. In one of the most recent meta-analyses on CAN-guided instrumentation accuracy, 3D-CAN was shown to result in pedicle screw accuracy of 96.7% in the lumbosacral spine, 93.2% in the thoracic spine, and 90.3% in the cervical spine, with the finding of reduced CAN accuracy in the cervical spine echoed in an earlier review.

The reduced accuracy of cervical CAN in the literature is likely due in part to the focus of previous publications on navigated subaxial pedicle screws specifically, rather than the more common lateral mass and C2 pars/translaminar implants. Radiographic accuracy has also been evaluated purely on ordinal classifications based on some variant of 2 mm gradients, which is not necessarily reflective of quantitative application accuracy. In addition, navigation for cervical procedures is often performed with nonsegmental registration. That is, the DRF is affixed to either a head clamp or to the cervicothoracic junction, distant from the level being instrumented to avoid the DRF obstructing the surgeon’s hands as may often occur with C1/2 instrumentation, where CAN guidance is most useful. As intersegmental mobility is
typically greater in the cervical spine, this practice may lead to increased navigation error.\textsuperscript{27} In a separate study, our own group has used OTI with real-time vertebral motion tracking to quantify intersegmental mobility across the spine from a variety of sources; we demonstrate in our analysis that instrumentation up to 2 levels from the level to which the DRF is affixed, may be safe using current optical tracking techniques.\textsuperscript{28} Therefore, while affixing the DRF to each individual level is a deviation from standard practice with current navigation systems, it does afford greater accuracy according to our experimental data once working >2 levels distant, and the workflow efficiency afforded by OTI render repeat registration at each level relatively seamless in the overall surgical workflow. In the current analysis, we demonstrate equivalent navigation accuracy with OTI in our cervical cohort and our prior open thoracolumbar cases. This is likely due largely to our practice of registering each instrumented level segmentally, a technique facilitated by the rapid registration workflow of OTI, which thereby eliminates error from intersegmental mobility.

Sagittal translational and angular errors in our clinical cohort were significantly lower than those observed in preclinical cadaveric testing. This is likely due in part to the significantly older age of the cadaveric specimens, with commensurately greater degenerative cervical spondylosis. Half of the cervical screws in cadaveric testing were placed in severely degenerated spines (Kellgren grade 3), whereas only 19 of 74 screws (25.6\%) in clinical testing were placed in Kellgren grade 3 spines. Facet arthrosis in the more severely degenerated cadaveric cervical spines, resulting in poorer vertebral segmentation with machine vision, is a likely contributor to the increased sagittal plane errors observed in cadaveric testing, however without ultimate radiographic misplacement. In the setting of severe facet arthrosis, therefore, clinicians should be

FIGURE 3. Standard boxplots showing the translational (A) and angular (B) absolute navigation errors, in cadaveric testing. Boxes represent the first, median, and third quantiles. Whiskers represent 1.5× the interquartile range.

FIGURE 4. Standard boxplots showing the translational (A) and angular (B) absolute navigation errors, in clinical in vivo testing. Boxes represent the first, median, and third quantiles. Whiskers represent 1.5× the interquartile range.
cognizant to carefully verify navigation accuracy manually based on correspondence to known anatomic landmarks.

There are multiple limitations to our analysis. In total, 87 of the 127 screws analyzed in combined cadaveric and clinical testing were lateral mass implants at C3–6. While it is well documented that freehand placement of C3–6 lateral mass instrumentation is safe, obviating the need for navigation, these screws were analyzed here to quantitatively assess OTI applicability. The accuracy of OTI navigation in the cervical spine is not directly compared with current navigation techniques in cervical approaches, as direct comparison has been made in our prior clinical trial of open thoracolumbar approaches with no significant differences in accuracy demonstrated, and with the present study showing no significant differences in accuracy for OTI between cervical and thoracolumbar approaches. The cumbersome workflow necessitated by registering 2 separate navigation devices in a single procedure precluded a direct comparison in this study, hence patients between this cervical and our earlier thoracolumbar cohort were age-matched and sex-matched to show non-inferiority. Future studies of OTI may include larger prospective cohorts of C1/2 instrumentation.

CONCLUSIONS

OTI is a novel navigation technique previously validated for open posterior thoracolumbar exposures. We show here that OTI is feasible and comparably accurate in open posterior cervical approaches. Accuracy is not dependent on the instrumented spinal level. Careful manual verification of navigation accuracy should be performed particularly with severe facet arthrosis, to minimize the likelihood of navigation error. This work extends the applicability of OTI to the cervical spine, allowing the workflow benefits of this technique to be realized and perhaps the adoption of navigation increased in these approaches, allowing safer and faster surgery for patients.

REFERENCES