3-dimensional virtual navigation versus conventional image guidance: a randomized controlled trial

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Level of evidence: NA

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Abstract

Background: Providing image guidance in a 3-dimensional (3D) format, visually more in keeping with the operative field, could potentially reduce workload and lead to faster and more accurate navigation. We wished to assess a 3D virtual view surgical navigation prototype in comparison to a traditional 2-dimensional system.

Methods: Thirty-seven otolaryngology surgeons and trainees completed a randomized crossover navigation exercise on a cadaver model. Each subject identified three sinonasal landmarks with 3D virtual image guidance and three landmarks with conventional cross-sectional computed tomography (CT) image guidance. Subjects were randomized in regard to which side and display type was tested initially. Accuracy, task completion time and task workload were recorded.

Results: Display type did not influence accuracy (p>0.2) or efficiency (p>0.3) for any of the six landmarks investigated. Pooled landmark data revealed a trend of improved accuracy in the 3DV group by 0.44mm (95%CI (0.00-0.88)). High-volume surgeons were significantly faster (p<0.01) and had reduced workload scores in all domains (p<0.01) but were no more accurate (p>0.28).

Conclusion: Real-time 3D image guidance did not influence accuracy, efficiency or task workload when compared to conventional tri-planar image guidance. The subtle pooled accuracy advantage for the 3DV view is unlikely to be of clinical significance. Experience level was strongly correlated to task completion time and workload but did not influence accuracy.

Level of evidence: NA

Introduction

Image guided surgery (IGS) systems provide valuable assistance during complex sinonasal and skull base operations.\(^1\)\(^2\) Spatial awareness is essential in this area to avoid intracranial or orbital complications. The rigid, bony framework of the skull allows for accurate registration of a surgical navigation system as there is little
anatomic deformation during surgery and a reference marker can be sufficiently fixed in relation to the head.\(^3\)

Computed tomography (CT) scans accurately display the bony contours of this region and have become an invaluable adjunct in both diagnosis and treatment of sinonasal diseases. Image-guided surgery systems allow surgeons to compare an intraoperative position with imaging by referencing CT based data in 3 planes (axial, coronal and parasagittal). Traditionally, this “tri-planar” display has been utilized for IGS systems with the tip of the tracked probe shown in each plane.

One weakness of this method is that the user must mentally correlate 2-dimensional (2D) CT based spatial data with an operative field that does not physically resemble the scans in any way.

There has been significant interest in providing 3D image guidance to help reduce the differences between the “real” operative view and 2D CT images.\(^4\)\(^6\) Visually matching the endoscopic view to a 3D virtual endoscopic image guidance system could in theory reduce the mental processing required for navigation.

At the Guided Therapeutics group at the University Health Network, Toronto, we have developed a prototype 3D virtual endoscopy system that tracks the endoscope and provides a real-time virtual view.\(^7\) (Figure 1a.) The system updates constantly inline with endoscope movement and displays a virtual image with spatial cues matched in appearance and scale to the “real” endoscopic image.\(^8\)\(^9\) This system may be quickly referenced and avoids the user having to mentally reconfigure the data to match the real-world surgical field. (Figure 1b.) This could potentially lead to greater precision and efficiency during surgical tasks. Reducing mental workload may also lead to better performance.\(^10\) Figure 1(c) demonstrates a standard, triplanar 2D image guidance display.

For 3D virtual endoscopy to provide useful information, you must be able to see through the “walls” to the pertinent anatomy. To do this the surface contour must be mapped and then made more transparent to allow structures behind to be seen. (Figure 1d.) In addition to this, the important structures you wish to see (or avoid) need to be
anatomically contoured (highlighted) so that they can be seen through the wall.\textsuperscript{3} Improvements in software and computer processing speeds mean that virtual views can be almost instantly updated so that the perceptible temporal delay is minimal.

We wished to test the hypothesis that real-time 3D surgical navigation would allow more efficient and accurate landmark identification whilst reducing task workload, when compared to a standard 2D triplanar CT display.

Methods

Thirty-seven otolaryngology surgeons (n=19) and surgeons-in-training (n=18) were enrolled as subjects after approval from the University Health Network Research Ethics Board (University of Toronto). A cadaver model was created to directly compare the two surgical navigation displays. A cadaver head underwent a CT scan after some pre-dissection of the sinuses to provide space for the exercises to be completed. This was followed by manual contouring of critical structures and significant anatomical landmarks using ITK-SNAP software.\textsuperscript{11} (Figure 2a.) A reference marker and fiduciary markers were then attached to the head to allow use of an optical IGS system. Optical markers were also attached to a 0-degree endoscope (Karl Storz Hopkins II 0° telescope and IMAGE1 camera, Karl Storz, Tuttingen, Germany) to enable endoscope tracking. Custom software could then provide a standard 2D cross-sectional CT image guidance display or a 3D virtual display.

A randomized crossover trial was designed to allow each subject to use both displays. Subjects were asked to localize 6 sinonasal landmarks with a tracked probe. For three of the landmarks 2D standard cross-sectional (2DS) image guidance was utilized, while the 3D virtual image guidance (3DV) was used for the other remaining target points. They were randomized as to which side/technology was used first. The landmarks were identified in the same order for each subject but the side and display type varied. The six targets were:
1a. the frontal recess
1b. the orbital apex (postero-lateral wall of the posterior ethmoids.)
1c. the carotid artery (parasellar segment)
2a. the anterior ethmoidal artery
2b. the sphenopalatine foramen
2c. optic nerve within the sphenoid sinus

Subjects placed the probe on the tip of the nose prior to completing each task. Individual times and a 3D data point were logged when the subject indicated they had identified the point to the best of their ability and confirmed with the available image guidance. Some of these landmarks are zones rather than a pinpoint location. The investigators were careful to ensure the reference point for accuracy analysis was located centrally within a correct volume for each landmark.

Each subject completed a NASA task load index (NASA-TLX) questionnaire midway through the exercise for one display and again at the completion for the second display.\textsuperscript{12}

**Statistical Analysis**

Analysis was performed using SPSS Statistics 19 (Chicago, Illinois, USA). Accuracy was measured by computing the distance, in millimeters, between the 3D position to a “gold standard” for each point determined by the investigators aided by image guidance. Time to complete each task was recorded to the nearest second. Linear regression analysis was used to assess the impact of display type, side, experience level and time on accuracy.

**Results**

Thirty-seven otolaryngology surgeons (n=18) and otolaryngology trainees (n=19) completed the trial. (Table 1.) The median (IQR) number of career endoscopic sinus cases performed by the group was 50 (10-500). Sixteen surgeons reported performing 5 or more sinonasal cases per month and were designated as high volume surgeons for sub-group analysis. This arbitrary cut-off was considered by the investigators to be an appropriate point to reasonably distinguish between low-volume surgeons and those who would be familiar with the anatomy, techniques and tasks examined in this trial.

**Accuracy**
Display type did not significantly affect accuracy for any of the six landmarks (p>0.2 for all target points). Table 1. Side (right versus left) did not influence accuracy (p>0.3 for all target points). 3D localization data collection is shown graphically in Figure 2b.

For high volume surgeons there was no significant difference in accuracy for any landmark, when compared with other participants (all p>0.28).

Data was pooled for landmarks 1(a,b & c) and 2 (a,b &c) with mean accuracy and task completion time calculated. No further significant findings were noted when data was pooled with display type still not influencing accuracy or efficiency. All 222 data points (37 subjects, 6 landmarks) were then individually pooled and divided into 3DV (n=111) and 2DS (n=111) groups. The mean (SD) accuracy for the 2DS group was in millimeters was 6.1(2.1) and 5.7(2.6) for the 3DV group. The accuracy difference between groups was 0.44mm with a 95% CI (0.00-0.88) suggesting better accuracy in the 3DV group. This difference fails to reach significance but borders the p=0.05 cut-off.

The side (left versus right) remained insignificant while high volume surgeons again showed faster task completion times (p<0.001) with no increase in accuracy.

**Efficiency**

Image guidance display type did not significantly affect the task completion time for any of the landmarks. The side (left or right) the landmark was identified on did not influence efficiency.

Experience did affect efficiency with high volume surgeons (5 or more endoscopic sinonasal cases per month) performing the task at a faster rate than low volume surgeons and trainees (p<0.01 for all landmarks).

**Task workload**

There was no significant difference in mean workload across all six NASA-TLX categories (mental demand, physical demand, temporal demand, performance, efficiency and frustration) when comparing the different display groups.
High volume surgeons reported significantly lower task workload in all domains (all p<0.01) when compared to the less experienced subjects. Table 2.

Discussion

This experiment failed to convincingly detect any of the theoretical advantages that real-time 3D image guidance may have over conventional image guidance. There were no clear performance gains in terms of efficiency or accuracy nor was task workload affected. Our previous studies assessing this technology suggested that such improvements might be achievable. It did, however, show that experienced subjects completed the tasks faster and with decreased perceived workload.

Pooled accuracy results for all 111 data points for each randomization group did show improved accuracy results for the 3DV group. The improvement (95% CI) of 0.44(0.00-0.88) millimeters is of questionable clinical relevance. Expected contouring and registration errors as well as the subjective placement of the “gold standard” landmark reference need to be taken in to account. In this context, a sub-millimeter difference is unlikely to translate into any real-world navigational advantage.

Our group has previously trialed similar technology in both navigation and operative pre-clinical experiments and shown significant reductions in task workload. A previous cadaver 3DV view navigation trial showed a significant reduction in mental demand, effort and frustration with an increase in perceived performance (p<0.05), while accuracy was increased. Subjects in this trial were less experienced (otolaryngology trainees) and the control group was not provided with any image guidance. This is likely to account for the differences in results when compared to the current study.

In a cadaveric preclinical study involving otolaryngology residents and fellows performing endoscopic sinus surgery, 3D image guidance once again showed a reduction in mental demand, effort and frustration (p<0.02). A highly trained cohort then trialed this real-time 3D system and compared it directly to a 2DS tri-planar IGS system. In this study, fellowship-trained skull base surgeons performed an endoscopic
clivus ablation and once again mental demand, effort and frustration were significantly reduced (p< 0.05) when using the 3DV system.\textsuperscript{3} During this trial the image guidance was provided with active feedback including critical structure proximity alerts and perhaps this additional feature partly explains the difference in findings compared with the current experiment. Additionally, enhanced 3D views might be more useful during operative dissection tasks compared to navigation alone.

Intuitive and more readily accessible navigation technology is shown in this study to be no substitute for experience and case volume. There was a strong association between high-volume surgeons and reduced task completion times while workload measures were reduced. This was consistent for every anatomic landmark as well as in every domain of the task workload score. We hypothesized that providing image guidance in a format more visually in keeping with the operative field would reduce the workload scores and mitigate some of the gap between novice and expert. This was not found to be the case with both efficiency and task workload dependent on experience, not the technology.

Various reports in surgical literature claim that the demands of minimally invasive surgery can be reduced through computer technology.\textsuperscript{14-16} Unfortunately there is very little assessable data published to support these claims. Liver resection studies suggest 3D visualization may aid in surgical planning through greater anatomical appreciation.\textsuperscript{17} Whether this will allow for a reduction in surgical mistakes is speculative and real-time navigation may in fact lead to distraction rather than safer surgery.\textsuperscript{17,18} Real-time navigation has been successfully used for neurosurgical procedures but a recent study found little benefit for cerebral arteriovenous malformations.\textsuperscript{19} While proof of concept studies in real-time surgical navigation are present for many surgical specialties including neurosurgery, otolaryngology, urology and hepatic surgery, actual benefits have not been quantifiably measured.\textsuperscript{17,20-23} We believe this is one of few experiments documenting quantitative measures comparing real-time image guidance to conventional techniques.\textsuperscript{24}

A number of factors may have contributed to a lack of difference between display groups. Only one prototype display was used during the study. Adjusting the design to incorporate alternative anatomical modeling or different surface contours may provide
a more realistic view and improve the system. Recent advances in automated segmentation techniques may help to provide more accurate and realistic virtual contours. Contrast enhanced scans as well as a number of magnetic resonance imaging techniques could be employed to further refine automated contouring. Unfortunately these methods could not be used in this cadaver-based experiment.

Increasing the number of subjects may help find a difference between displays, although, this small study was sufficiently powered to reliably identify a difference between experience levels, suggesting this was the main factor. Greater power would quite possibly reveal a statistically significant benefit in accuracy with a 3DV view but the sub-millimeter scale of improvement is unlikely to translate to greater real-world surgical precision. We also acknowledge, as a weakness of the study that some of the landmarks are not pinpoint locations and that 3D localization within a significant volume could be classified as “correct” placement. As such, analysis for sub-millimeter differences is unlikely to be valid.

One factor not measured in this experiment is distraction caused by real-time image guidance. Our recent studies in this field suggest this may be an issue.\textsuperscript{18,25} With this in mind, we believe that further pre-clinical investigation is required in order to refine displays to provide real-time assistance to surgeons while limiting distraction. Further attempts should be made to quantify and define the benefits of such displays prior to routine introduction into the operating room.

**Conclusion**

Real-time 3D image guidance did not influence accuracy, efficiency or task workload when compared to conventional tri-planar image guidance. The subtle pooled accuracy advantage for the 3DV view is unlikely to be of clinical significance. Experience level was strongly correlated to task completion time and workload but did not influence accuracy. Further pre-clinical investigation of real-time surgical displays should be undertaken to identify benefits while limiting distraction.

Captions
Figure 1. (a) Optical image guidance reference markers were placed on the endoscope, in addition to the tracked probe and head, to allow a 3D virtual view to be displayed. (b) Localization of the sphenopalatine artery. The navigation display system was placed on a sub-monitor adjacent to the endoscopic display. Image guidance aiding localization of the sphenopalatine artery is shown in (c) with a standard 2D image guided surgery system and (d) with a 3D virtual view displaying the location of the pterygopalatine fossa (PPF).

Figure 2. (a) Pertinent structures were contoured on CT scans. This 2D figure is for demonstration purposes showing relevant contours in addition to scope and probe placement. (b) Accuracy data points for the sphenopalatine artery were recorded relative to a gold standard. Localization points for the 2DS group are shown in pink and 3DV in blue. This method was used for accuracy measurements for all six landmarks.

Acknowledgements
Thank you to the 37 surgeons and trainees who gave up time to participate in this study. Thank you to Karl Storz Endoscopy Canada and Medtronic of Canada for providing wet lab dissection instruments and devices. This study could not have been performed without assistance from staff at the University of Toronto Surgical Skills Centre, Mount Sinai Hospital, Toronto. This work is supported by the Guided Therapeutics (GTx) Program at the University Health Network, including The Kevin and Sandra Sullivan Chair in Surgical Oncology, The Hatch Engineering Fellowship Fund, The RACH Fund, and the Princess Margaret Hospital Foundation.

References


Table 1: Comparison of task completion time, accuracy and workload between Display Groups

<table>
<thead>
<tr>
<th></th>
<th>3D Virtual View</th>
<th>2D Standard IGS</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>i) Mean (SD) task completion time in seconds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Landmark 1a</td>
<td>20.5 (18.4)</td>
<td>21.9 (12.8)</td>
<td>p = 0.79</td>
</tr>
<tr>
<td>1b</td>
<td>27.1 (15.3)</td>
<td>30.2 (25.5)</td>
<td>p = 0.65</td>
</tr>
<tr>
<td>1c</td>
<td>25.9 (22.9)</td>
<td>30.4 (30.2)</td>
<td>p = 0.61</td>
</tr>
<tr>
<td>2a</td>
<td>41.1 (28.1)</td>
<td>31.8 (26.6)</td>
<td>p = 0.31</td>
</tr>
<tr>
<td>2b</td>
<td>34.3 (26.4)</td>
<td>28.2 (22.1)</td>
<td>p = 0.44</td>
</tr>
<tr>
<td>2c</td>
<td>25.3 (15.6)</td>
<td>22.0 (16.2)</td>
<td>p = 0.53</td>
</tr>
<tr>
<td>Pooled time for all six landmarks</td>
<td>28.9 (17.4) n=111</td>
<td>27.4 (17.5) n=111</td>
<td>NS</td>
</tr>
<tr>
<td>ii) Mean (SD) accuracy in millimeters</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Landmark 1a</td>
<td>4.9 (2.3)</td>
<td>5.7 (3.3)</td>
<td>p = 0.40</td>
</tr>
<tr>
<td>1b</td>
<td>8.1 (4.9)</td>
<td>7.3 (3.4)</td>
<td>p = 0.57</td>
</tr>
<tr>
<td>1c</td>
<td>5.0 (2.5)</td>
<td>6.4 (2.3)</td>
<td>p = 0.09</td>
</tr>
<tr>
<td>2a</td>
<td>5.3 (3.8)</td>
<td>7.1 (4.3)</td>
<td>p = 0.20</td>
</tr>
<tr>
<td>2b</td>
<td>7.6 (6.1)</td>
<td>6.6 (3.6)</td>
<td>p = 0.53</td>
</tr>
<tr>
<td>2c</td>
<td>2.9 (1.7)</td>
<td>3.7 (2.2)</td>
<td>p = 0.24</td>
</tr>
<tr>
<td>Pooled accuracy for all six landmarks</td>
<td>5.66 (2.6) n=111</td>
<td>6.10 (2.1) n=111</td>
<td>Difference(mm)(95%CI) 0.44(0.00-0.88)</td>
</tr>
<tr>
<td>iii) Mean (SD) NASA-TLX workload score (n= 37 for all fields)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental Demand</td>
<td>6.8 (4.9)</td>
<td>6.7 (4.1)</td>
<td>p = 0.92</td>
</tr>
<tr>
<td>Physical Demand</td>
<td>5.7 (4.3)</td>
<td>5.8 (4.5)</td>
<td>p = 0.96</td>
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<tr>
<td>Temporal Demand</td>
<td>6.9 (4.5)</td>
<td>6.2 (4.3)</td>
<td>p = 0.48</td>
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<tr>
<td>Performance</td>
<td>6.1 (4.7)</td>
<td>6.8 (4.6)</td>
<td>p = 0.53</td>
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<tr>
<td>Effort</td>
<td>6.8 (4.2)</td>
<td>6.7 (4.0)</td>
<td>p = 0.89</td>
</tr>
<tr>
<td>Frustration</td>
<td>5.9 (4.5)</td>
<td>6.1 (4.3)</td>
<td>p = 0.83</td>
</tr>
</tbody>
</table>

Table 1. i) Task completion times were similar for each group with no trend towards faster completion times. ii) There were no significant differences in accuracy for individual landmarks, however, when pooled there was a trend towards improved accuracy with 3DV. iii) Workload scores were similar across the randomization groups.
Table 2: Comparison of task completion time, accuracy and workload between high volume surgeons and other subjects.

<table>
<thead>
<tr>
<th></th>
<th>High Volume Surgeons (n=16)</th>
<th>Other Subjects (n=21)</th>
<th>Significance</th>
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</thead>
<tbody>
<tr>
<td>i) Mean (SD) task completion time in seconds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Landmark 1a</td>
<td>11.6 (6.1)</td>
<td>28.6 (16.8)</td>
<td>p&lt;0.01</td>
</tr>
<tr>
<td>1b</td>
<td>17.7 (10.3)</td>
<td>36.9 (22.8)</td>
<td>p=0.01</td>
</tr>
<tr>
<td>1c</td>
<td>15.8 (6.9)</td>
<td>37.5 (31.8)</td>
<td>p=0.01</td>
</tr>
<tr>
<td>2a</td>
<td>18.4 (11.0)</td>
<td>50.0 (28.3)</td>
<td>p&lt;0.01</td>
</tr>
<tr>
<td>2b</td>
<td>15.7 (10.3)</td>
<td>42.9 (25.2)</td>
<td>p&lt;0.01</td>
</tr>
<tr>
<td>2c</td>
<td>16.5 (11.1)</td>
<td>29.0 (16.9)</td>
<td>p=0.01</td>
</tr>
<tr>
<td>ii) Mean (SD) accuracy in millimeters</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Landmark 1a</td>
<td>5.2 (2.2)</td>
<td>5.3 (3.2)</td>
<td>p=0.85</td>
</tr>
<tr>
<td>1b</td>
<td>7.9 (4.3)</td>
<td>7.6 (4.4)</td>
<td>p=0.80</td>
</tr>
<tr>
<td>1c</td>
<td>5.2 (2.6)</td>
<td>6.1 (2.3)</td>
<td>p=0.28</td>
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<tr>
<td>2a</td>
<td>6.1 (3.4)</td>
<td>6.4 (4.6)</td>
<td>p=0.82</td>
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<td>2b</td>
<td>6.3 (3.4)</td>
<td>7.7 (5.9)</td>
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<td>2c</td>
<td>3.2 (2.0)</td>
<td>3.5 (2.0)</td>
<td>p=0.72</td>
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<tr>
<td>iii) Mean (SD) NASA-TLX workload score</td>
<td></td>
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<tr>
<td>Mental Demand</td>
<td>4.4 (3.6)</td>
<td>8.5 (4.3)</td>
<td>p&lt;0.01</td>
</tr>
<tr>
<td>Physical Demand</td>
<td>3.4 (3.6)</td>
<td>7.6 (4.1)</td>
<td>p&lt;0.01</td>
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<tr>
<td>Temporal Demand</td>
<td>4.7 (4.1)</td>
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<td>Frustration</td>
<td>3.5 (2.8)</td>
<td>7.9 (4.4)</td>
<td>p&lt;0.01</td>
</tr>
</tbody>
</table>

Table 2. Surgeons performing 5 or more endoscopic sinonasal procedures per month (n=16) were classed as high volume. i) Task completion time was significantly reduced for all landmarks but ii) accuracy was similar between these groups. iii) All task workload domain scores were significantly lower for high volume surgeons.
Figure 1. (a) Optical image guidance reference markers were placed on the endoscope, in addition to the tracked probe and head, to allow a 3D virtual view to be displayed. (b) Localization of the sphenopalatine artery. The navigation display system was placed on a sub-monitor adjacent to the endoscopic display. Image guidance aiding localization of the sphenopalatine artery is shown in (c) with a standard 2D image guided surgery system and (d) with a 3D virtual view displaying the location of the pterygopalatine fossa (PPF).
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