Pedicle screw navigation

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In their paper, Mr. Shin and colleagues present a meta-analysis comparing the accuracy of computer-navigated pedicle screw insertions versus nonnavigated techniques. The authors only included studies in which both techniques were performed. A total of 18 cohort studies and 2 randomized controlled trials, performed between 2000 and 2011, were evaluated. Approximately similar numbers of pedicle screws were placed in the 2 groups evaluated.

The authors found that navigated screws violated the pedicle in 6% of instances, while nonnavigated screws had a 15% violation rate (p < 0.001). Despite this discrepancy, the revision surgery rates were not statistically different between the 2 groups. Additionally, the operative times and the blood loss were not significantly different between the groups.

While the numbers appear to favor superior accuracy in the navigation group, the details of some of these studies lead to some problematic issues. Bias cannot be excluded in this meta-analysis. Articles that compared the 2 methods are very likely written by advocates of navigation. In fact, the authors of this meta-analysis state, “...the published literature is likely to exhibit a publication bias.”

Issues that raise concern in these articles include the complication rates. With more than 8000 pedicle screws placed, the navigation group had a single wound infection, while nonnavigated screws had 3 wound infections in only 1 study in this group. These figures are at dramatic odds with the published wound infection rates for thoracic spinal surgery and cause the reader to be concerned that an underreporting of complications exists in these reports.

The well-described in-out-in technique, used predominantly in the thoracic spine for placing larger screws into smaller pedicles, is ignored in this meta-analysis. No attempt was made to assess screw size. The clinical significance of placing a screw entirely within a pedicle is not clear from the wealth of published data on this topic. If a navigation advocate places smaller screws to remain intrapedicular, will maneuvers such as deformity correction be helped or hindered? This topic is not covered, and it bears much clinical importance.

While the authors of the meta-analysis state that radiographic evidence was required, it is not clear whether plain films or CT scans (much more accurate for this type of analysis) were assessed. The quoted survey of more than 3000 spine surgeons, with a 10% response rate, is not adequate to make scientific statements regarding this topic. Furthermore, it is likely that advocates of navigation were more likely to respond to a survey on its usage than spine surgeons who do not use, or possibly do not believe in, navigation.

Additional information that would be useful for spine surgeons in determining the utility of navigation would be clinical outcomes, cost data, and radiation exposure. None of these was addressed in this meta-analysis.

Some highly experienced spine surgeons who do not use navigation have reported better screw placement accuracy, using CT scanning data, than either of the groups in this meta-analysis. As such, it is possible that this meta-analysis has inadvertently skewed the argument in favor of surgeons who utilize navigation and may not be reflective of the spine surgical community at large. While this meta-analysis clearly shows that navigation is able to improve the accuracy of pedicle screw placement in the hands of surgeons who perform both navigation and non-navigation techniques, this review is unable to determine whether there is a clinical advantage to the use of navigation for the reasons outlined above.

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Disclosure

The author reports no conflict of interest.

Reference


Response

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We appreciate the editorial by Dr. Robert Heary, which brings forth several important points and some limitations regarding our meta-analysis.
Publication bias, which occurs because positive studies in which treatments show significant effects are more likely to be published and cited, was assessed. Quantification of this bias attempts to account for the existence of unpublished or missing studies and is indicated by asymmetry in the funnel plot. The presence of publication bias was examined using the regression-based Egger test, which did not reveal significance. However, the Begg-Mazumdar test (another test for publication bias) trended toward significance ($p = 0.07$). Statistical tests for publication can be underpowered depending on the number of component studies pooled in the meta-analysis. Therefore, the existence of publication bias cannot be completely ruled out, and we recognize it as a limitation of our study.

A meta-analysis can only be as good as the published literature. Dr. Heary mentions that radiation exposure, cost data, and screw size should have been addressed, and we completely concur. In fact, we attempted to analyze these factors but found the number of studies to be lacking. We can, however, make some statements regarding screw size. There is no indication from the literature that proponents of navigation use smaller diameter screws to minimize pedicle breaches (which would indeed be concerning). The opposite seems to be true; we compared our experience with navigated versus nonnavigated pedicle screw placement in 260 patients and 1434 screws, looking at screw accuracy, screw size, and the complexity of surgery (Iorgulescu JB, Luther N, Geannette C, et al., presentation to the AANS Annual Meeting, 2012). Navigation was associated with the use of larger pedicle screws and a significantly higher screw-to–pedicle diameter ratio (0.71 vs 0.63, $p < 0.05$). This can be explained by the ability with navigation to plan and optimize the diameter and also the length of the screw used. Screw outer diameter, in association with inner diameter, pitch, and factors intrinsic to the pedicle itself (for example, bone quality) are important variables predicting and preventing screw pullout. In this regard navigation provides important advantages, especially when treating deformity and patients with poor bone quality. To our knowledge this is the only report looking at screw size and navigation.

The in-out-in technique for placement of thoracic pedicle screws was not ignored. We included 8 studies with thoracic pedicle screws, and the only study that used this technique was Rajasekaran et al. These authors reported using the in-out-in technique for the placement of 7 pedicle screws; each of the screws was placed using navigation, and each was found to have a greater than 4-mm lateral pedicle breach, thereby actually worsening the navigation performance in this study.

We agree that the type of radiographic evaluation of implants is especially important in this type of analysis. Of the 20 studies included, 2 used intraoperative CT scanning or fluoroscopy CT, 1 used MRI, and 1 used postoperative CT or MRI, while the remaining studies used the gold standard, which is postoperative CT imaging.

Of course, it is true that there are experienced surgeons who achieve very high pedicle screw accuracy rates even without navigation. What our meta-analysis implies, however, is that their success rate may be even higher with navigation (if the surgeons are familiar with and well trained on the equipment). A recent survey of 3348 spine surgeons showed the most frequent users of navigation are actually also the busiest surgeons in high-volume centers. The current limitations of navigation are mainly technical in nature: surgeons perceive that navigation increases operating room time (even though our meta-analysis does not support this). Current navigation systems do not meet the surgeon's expectations in terms of ease of use and integration into the surgical workflow. However, as with many other innovations in surgery, it is only a matter of time until these issues have been resolved.

Last, Dr. Heary states that this meta-analysis is unable to determine whether there is a clinical advantage to the use of navigation. Again, a meta-analysis cannot go beyond the published literature. There are no studies comparing clinical outcome in patients treated with navigation compared with those treated without navigation. The published literature focuses on screw accuracy, and the best we can do is extrapolate from accuracy to clinical outcome. Malpositioned screws, even on an order of millimeters, can cause morbidity; in addition, the presence of any breach usually implies deviation from planned or intended trajectory and therefore is an indication of inaccuracy. The question of whether neuronavigation can produce tangible and relevant clinical improvements needs to be addressed in further randomized studies.

We would like to thank Dr. Heary for writing this editorial to our meta-analysis. We hope that the reader carefully reads both our meta-analysis and this editorial to get a more complete picture. In addition, this editorial has provided helpful feedback to us in determining future directions in how we will move forward with our work. Neuronavigation is a rapidly evolving field, and we reviewed the state of the field as it presents itself at an early stage of the technology. Our meta-analysis included only studies from the first- and second-generation navigation systems. More advanced and user-friendly systems that work with true intraoperative CT scanners are becoming available, and it will be interesting to see how these systems will impact the use and acceptance of navigation. We have no doubt that navigation will at some point in the future become the standard of care for spinal instrumentation surgery.

References

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