The accuracy of pedicle screw placement using intraoperative image guidance systems

A systematic review

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Object. Several retrospective studies have demonstrated higher accuracy rates and increased safety for navigated pedicle screw placement than for free-hand techniques; however, the accuracy differences between navigation systems has not been extensively studied. In some instances, 3D fluoroscopic navigation methods have been reported to not be more accurate than 2D navigation methods for pedicle screw placement. The authors of this study endeavored to identify if 3D fluoroscopic navigation methods resulted in a higher placement accuracy of pedicle screws.

Methods. A systematic analysis was conducted to examine pedicle screw insertion accuracy based on the use of 2D, 3D, and conventional fluoroscopic image guidance systems. A PubMed and MEDLINE database search was conducted to review the published literature that focused on the accuracy of pedicle screw placement using intraoperative, real-time fluoroscopic image guidance in spine fusion surgeries. The pedicle screw accuracy rates were segregated according to spinal level because each spinal region has individual anatomical and morphological variations. Descriptive statistics were used to compare the pedicle screw insertion accuracy rate differences among the navigation methods.

Results. A total of 30 studies were included in the analysis. The data were abstracted and analyzed for the following groups: 12 data sets that used conventional fluoroscopy, 8 data sets that used 2D fluoroscopic navigation, and 20 data sets that used 3D fluoroscopic navigation. These studies included 1973 patients in whom 9310 pedicle screws were inserted. With conventional fluoroscopy, 2532 of 3719 screws were inserted accurately (68.1% accuracy); with 2D fluoroscopic navigation, 1031 of 1223 screws were inserted accurately (84.3% accuracy); and with 3D fluoroscopic navigation, 4170 of 4368 screws were inserted accurately (95.5% accuracy). The accuracy rates when 3D was compared with 2D fluoroscopic navigation were also consistently higher throughout all individual spinal levels.

Conclusions. Three-dimensional fluoroscopic image guidance systems demonstrated a significantly higher pedicle screw placement accuracy than conventional fluoroscopy or 2D fluoroscopic image guidance methods.

Key Words • fluoroscopy • Iso-C • image-guided surgery • navigation • O-arm • pedicle screw • technique

Computer-assisted navigation for the placement of pedicle screws has been shown to result in increased placement accuracy, lower complication rates, and improved functional outcome.23,52,56 Intraoperative image guidance has undergone a substantial evolution in recent years, and surgical spinal procedures have been benefiting tremendously from the development of high-resolution imaging systems because of advancements in stereotactic navigation. This technology has evolved to allow surgeons to use real-time localization of surgical anatomy in multiple views. Recent work in the literature has suggested that lower rates of pedicle screw misplacement occur when 3D navigation is used compared with 2D fluoroscopic image guidance;52 however, other studies have also reported no differences between 2D and 3D fluoroscopic navigation methods in the rate of pedicle screw misplacement.26,27 The present study was undertaken to examine and compare the accuracy of pedicle screw placement using conventional, 2D, and 3D volumetric fluoroscopic guidance techniques in patients undergoing spinal fusion. The secondary objective was to compare the rates of medial pedicle screw perforations in 2D versus 3D fluoroscopic navigation-assisted surgeries.

Methods

Search Strategy and Inclusion Criteria

A PubMed and MEDLINE database search was conducted to explore published literature that focused on the accuracy of pedicle screw placement in spine surgeries. In the database, the term “pedicle screw” was combined with the following key words: fluoroscopy, virtual fluoroscopy, Iso-C fluoroscopy, O-arm, 2D fluoroscopy, 3D fluoroscopy, intraoperative image guidance, and intraoperative navigation. The search limits included human clinical
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studies, randomized controlled trials, comparative studies, and evaluation studies published from 2002 to 2012. Publications written in English were considered for analysis.

The abstracts from the relevant searches were examined to sort articles that could clearly be excluded. Subsequently, full-text articles were extensively reviewed to determine which publications were suitable for inclusion. The references within the selected publications were also manually searched to identify additional works for inclusion. To be included in the analysis, an article must have reported accuracy-based results for pedicle screw placement in the living human spine and used conventional fluoroscopy, 2D fluoroscopic navigation, or 3D fluoroscopic navigation to assist in pedicle screw placement. Only results pertaining to the placement of pedicle screws in the cervical, thoracic, or lumbar spine were included, excluding other screw types such as lateral mass, odontoid, and iliosacral screws. Studies that focused primarily on atypical placement of pedicle screws (for example, the in-and-out technique or parapedicular screw fixation) were excluded from the analysis.58-62 No restrictions were placed on the clinical conditions, age, revision surgeries, surgical approach, or techniques. Further revisions were made to exclude any papers that did not report the methods42 or grading system17,42,53 for assessing pedicle screw placement accuracy or repeatedly reported previously published results.9

The analysis of the selected papers was independently performed by 2 authors (A.M. and A.V.) who used the previously predetermined criteria. Disagreements among the reviewers were discussed until a consensus was reached. If a consensus could not be reached, a third reviewer was consulted. If an article investigated 2 or more fluoroscopic techniques, the individual data sets were assigned to their corresponding categories (that is, conventional fluoroscopy, 2D fluoroscopic navigation, or 3D fluoroscopic navigation).

Data Analysis

The accuracy of pedicle screw placement was examined according to the spinal levels that were treated, as each spinal region has individual anatomical and morphological variations. The outcome measure that we analyzed was the accuracy of pedicle screw placement, which was categorized as either correct placement or misplacement. For this analysis, a misplaced screw was defined as one perforating the pedicle cortex to any degree. Additional data extracted from the papers included the following parameters: number of patients, number of pedicle screws, instrumented vertebral levels, number of misplaced screws, location of the misplacement, and the imaging technique used for the assessment of screw placement accuracy.

Statistical Analysis

Accuracy was calculated as a percentage for non-missing data only. The differences in the accuracy rates of pedicle screw placement between the groups were analyzed using Fisher’s exact test. A p value < 0.05 was considered to be statistically significant.

Results

Search Results

The database search and review of references yielded a total of 30 studies that were included in our analysis. The data were abstracted and analyzed for the following groups: 12 data sets that used conventional fluoroscopy, 8 data sets that used 2D fluoroscopic navigation, and 20 data sets that used 3D fluoroscopic navigation (Table 1). The conventional fluoroscopy group contained studies that used real-time fluoroscopy imaging without the use of computer-aided navigation; the 2D navigation group included studies that used virtual fluoroscopy; and the 3D navigation group included studies that implemented Isoc-C fluoroscopy, O-arm fluoroscopy, or a combination of these 2 techniques. These studies included 1973 patients in whom 9310 pedicle screws were inserted in total.

Analyzing the quality of the published studies, we identified only 1 randomized, controlled clinical trial38 (Table 1). The rest of the studies represented either Level IV (observational studies) or Level III (observational studies with controls) data, based on the designation of levels of evidence according to the Agency for Healthcare Research and Quality criteria: Level I, conclusive; Level II, strong; Level III, moderate; Level IV, limited; and Level V, indeterminate. The observational studies with controls were classified as Level IV if their control group(s) was not included in this analysis (for example, CT-based image guidance).

Accuracy

With conventional fluoroscopy, a total of 2532 of 3719 screws were inserted accurately (68.1% accurate). The percentage of misplaced screws ranged from 8.3% to 50.3% (mean 23.6%). Considering the individual spinal levels, 188 of 271 cervical pedicle screws, 614 of 1209 thoracic pedicle screws, and 1544 of 2035 lumbosacral screws were placed accurately (69.4%, 50.8%, and 75.9% accuracy rates, respectively).

Using 2D fluoroscopic navigation, 1031 of 1223 screws were inserted accurately (84.3% accurate). The percentage of misplaced screws ranged from 5.0% to 26.3% (mean 16.1%). Considering the individual spinal levels, 22 of 30 cervical pedicle screws, 247 of 315 thoracic pedicle screws, and 762 of 878 lumbosacral screws were placed accurately (73.3%, 78.4%, and 86.8% accurate, respectively).

With 3D fluoroscopic navigation, 4170 of 4368 screws were inserted accurately (95.5% accurate). The percentage of misplaced screws ranged from 0.0% to 19.1% (mean 7.0%). Considering the individual spinal levels, 669 of 741 cervical pedicle screws, 509 of 546 thoracic pedicle screws, and 1020 of 1055 lumbosacral screws were placed accurately (90.3%, 93.2%, and 96.7% accurate, respectively).

Comparison of Conventional, 2D, and 3D Fluoroscopic Methods

In comparison with conventional fluoroscopy without the aid of computer navigation, both 2D and 3D fluoroscopic navigation had significantly greater pedicle screw placement accuracy (p = 4.00 × 10⁻³⁰ [2D] and p = 1.09 × 10⁻³⁰ [3D]) (Fig. 1). Both methods of navigation also
TABLE 1: Summary of studies involving pedicle screw insertion stratified by intraoperative placement technique *

<table>
<thead>
<tr>
<th>Authors &amp; Year</th>
<th>Pedicle Screws</th>
<th>Cervical Spine</th>
<th>Thoracic Spine</th>
<th>Lumbar Spine</th>
<th>Accuracy Assessment Tool</th>
<th>Study Design</th>
<th>Class of Evidence</th>
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</thead>
<tbody>
<tr>
<td></td>
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<td>Misplaced Screws</td>
<td>Total Screws</td>
<td>Misplaced Screws</td>
<td>Total Screws</td>
<td>Misplaced Screws</td>
<td>Total Screws</td>
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<td></td>
<td></td>
</tr>
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<td>51</td>
<td>14 (27.5)</td>
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<td>observational w/ controls (uni-planar fluoroscopy)</td>
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<td>141</td>
<td>18 (12.8)</td>
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<td>observational w/ controls</td>
<td>Level III</td>
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<td>49 (33.8)</td>
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<td>Level III</td>
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<td>8 (40)</td>
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<td>3D image guidance studies (Iso-C &amp; O-arm)</td>
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<td>66</td>
<td>6 (9.1)</td>
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(continued)
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<table>
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<tr>
<th>Study Design</th>
<th>Accuracy Assessment Tool</th>
<th>Authors &amp; Year</th>
<th>Class of Evidence</th>
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<td>Level III</td>
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<td></td>
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<td>Level IV</td>
<td>220</td>
<td>4 (1.8)</td>
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</tbody>
</table>

* Values in parentheses represent percentages. NR = not reported.

The differences in pedicle screw placement accuracy between 2D and 3D fluoroscopic navigation methods were also statistically significant for the individual spinal levels. With 3D navigation, 9.7% of cervical pedicle screws were incorrectly placed whereas 26.7% of the screws were misplaced using 2D navigation (p = 8.29 x 10⁻⁶). In the thoracic spine, 6.8% of pedicle screws were misplaced when using 3D navigation whereas 21.6% were misplaced when using 2D navigation (p = 5.09 x 10⁻⁶); in the lumbosacral spine, 3.3% and 13.2% of the pedicle screws were incorrectly placed when using 3D and 2D fluoroscopic navigation techniques, respectively (p = 3.39 x 10⁻⁴).

Interestingly, when the accuracy rates of the two 3D fluoroscopic navigation techniques, Iso-C 3D and O-arm fluoroscopy, were compared, significantly higher pedicle screw placement accuracy was observed when O-arm fluoroscopy was used (p = 3.94 x 10⁻³). Of 1606 screws placed using Iso-C 3D fluoroscopy, 1488 (92.7%) were placed accurately. With O-arm fluoroscopy, 2682 (97.1%) of 2762 pedicle screws were correctly placed.

Discussion

Pedicle screws have become the mainstay of fusion constructs and the proper placement of these structures is crucial. Gross pedicle screw misplacement can lead to neurological deficits, either on an immediate basis or, less frequently, a delayed basis. Some degree of disagreement exists within the literature in regard to the necessity of accurate pedicle screw placement within a given vertebral body. Many surgeons consider the majority of cortical violations to be clinically silent depending on the location and the length of penetration. However, even those initially silent violations may be responsible for instability of the biomechanical construct, reduced fusion rates, or accelerated adjacent-level degeneration (H.Y. Seo et al., unpublished data [presented at the Annual Meeting of the American Academy of Orthopaedic Surgeons, 2011]). In this retrospective long-term clinical study by Seo et al., the authors compared patients who underwent a subsequent lumbar fusion surgery for adjacent-level degeneration to control patients who did not require surgery. They found a significantly higher score of facet joint violations of the nonfused segment in the patient group that required surgery. Clearly, precision in pedicle screw placement is
of utmost importance; however, misplacement rates have been reported to range from 5% to 41% in the lumbar spine and from 3% to 55% in the thoracic spine when using conventional techniques.\textsuperscript{2,6,45,61}

In addition to higher pedicle screw placement accuracy, fluoroscopic navigation has also been reported to reduce radiation exposure and improve intraoperative scanning efficiency.\textsuperscript{50} Although, surgeons and patients receive a significant amount of ionizing radiation due to intraoperative scanning, experimental and clinical studies have reported that radiation exposure is reduced with navigation-assisted fluoroscopy compared with conventional fluoroscopy, especially if the doses received with confirmatory CT scans are taken into account.\textsuperscript{22} Furthermore, the use of 2D or 3D image-guided navigation provides advantages over other types of computer-guided surgical navigation such as CT-based navigation. While CT-based navigation requires extensive preoperative preparation, including CT scanning, data transfer, and patient registration steps, fluoroscopy-based navigation allows for real-time, intraoperative imaging of patients’ anatomy without time lost for data mapping.

Three-dimensional (and especially O-arm–based) intraoperative image guidance is perceived as the most expensive navigation method.\textsuperscript{35} However, a recent study by Sanborn et al.\textsuperscript{43} directly compared the cost effectiveness of O-arm intraoperative neuromonitoring and postoperative CT imaging for the pedicle screw accuracy assessment in patients undergoing at least 3-level lumbar fusions. The calculations were based on 2011 Medicare reimbursement rates, and because the surgical and hospital charges were constant, they were not included in the calculations. The cost for intraoperative navigation using O-arm imaging was $233.35 per case with an additional $59.49 ± $24.93 if the cost of confirmatory scans was added. According to the study, this was the most cost-effective method of intraoperative monitoring, and the cost was significantly less than performing postoperative CT scanning ($483.26 ± $126.74) or intraoperative neuromonitoring ($725.94 ± $158.96). The authors concluded that the least costly alternative was also the most effective.\textsuperscript{41} Furthermore, if according to Hodges et al., an estimated 1% of patients would require pedicle screw revision, the nationwide annual cost was approximated to reach $40,595,000, not considering the costs associated with morbidity.\textsuperscript{14} In another study, the cost for a 2-hour spinal revision surgery was $23,762 when costs to the surgery department, inpatient fees, and surgeon reimbursement were included.\textsuperscript{60}

We analyzed existing reports in the literature published on the accuracy of spinal pedicle screw placement with the assistance of conventional fluoroscopy or with image guidance systems. All of the included studies are recent publications, from 2004 to 2012, and the vast majority are either observational studies (Class IV evidence) or observational studies with controls (Class III evidence) with the exception of 1 randomized controlled clinical trial.\textsuperscript{38} The quality of the published studies is quite low; often the important information is not clear or is missing, which impedes the generalizability of the results. From a methodological standpoint, there is no uniformity in reporting on accuracy and much variability exists concerning what actually constitutes a misplaced screw. Different screw misplacement grading systems are used to assess the screw placement accuracy,\textsuperscript{24,25,32} but almost all of them included the following categories: Grade 0, no pedicle perforation; Grade 1, 0–2 mm; Grade 2, 2–4 mm; Grade 4, greater than 4 mm. In some of the reports, a breach of less than 2 mm is not considered to reflect an incorrectly positioned screw, and this type of screw position is commonly called Grade 1 and included within the number of accurately placed screws.\textsuperscript{2,28} Only a few studies stated whether inaccuracies in screw placement were clinically significant, caused any complications, or required an operation for repositioning. However, there is no clear evidence that any degree of pedicle breach is acceptable, especially if medial screw
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misplacements are considered. All of these factors make the analysis and reporting of pedicle screw placement data particularly difficult. Because the main objective of this paper was to evaluate the accuracy of the intraoperative guidance systems and not to analyze clinical implications of pedicle screw misplacements, we included any degree of unintentional pedicle cortex breach as misplacement. We hope this approach presented a more balanced view of the rates of accurate pedicle screw placement of the varying fluoroscopic techniques and reduced the effects of reporting variations.

In May 2005, the O-arm imaging system was granted Food and Drug Administration marketing clearance for intraoperative applications in surgical theaters and particularly for orthopedic applications based on the equivalency to the Iso-C system. The system is indicated for use whenever the physician benefits from intraoperatively generated 3D information of high-contrast objects and anatomical structures. The 2D image guidance system only offers navigation in coronal and sagittal planes, but clinically significant pedicle violations most often occur in the medial plane. We were hoping to demonstrate the advantage of the 3D navigational systems in this regard, but the majority of papers did not provide this information, and a meaningful statistical analysis could not be performed with the information that was available. This would be our most important recommendation for future reports: report not only the grading system describing misplacements but also the location of pedicle screw perforations.

The reported data are generally observational and the quality of reporting is quite low. The reports on the rates of misplaced screws are not only affected by the definition of misplacement but also by discrepancies in how screw placement accuracy is assessed. Assessing the accuracy of screw placement is best performed with CT scanning; however, not all of the literature reported uses this method or the imaging system used for screw accuracy assessment is not reported. Therefore, the papers that did not report the methods or grading systems for assessing pedicle screw placement accuracy were excluded from this analysis.

Our study design itself has limitations. Systematic analyses are inherently affected by multiple confounding factors that are difficult to control. However, due to the nature of the subject studied (different image guidance methods used in consecutive surgeries based on availability during the certain time periods), prospective, randomized studies are not always feasible. The strength of the analysis will always depend on the quality and credibility of the included studies, and systematic analysis studies could be placed in the same category of evidence as prospective, controlled studies. Prospective, controlled trials belong to the highest hierarchy of evidence, but observational studies could provide a complementary and true representation of what is achieved in everyday medical practice compared with the special settings of a controlled trial. The results of the study and conclusions with regard to the accuracy of pedicle screw insertion using different methods of image guidance were mainly based on observational studies. Although such evidence belongs to a lower category of recommendations, previous studies have found that observational studies and randomized controlled trials often agree. Systematic reviews of observational studies may help to reduce “a dangerous discrepancy between the experts and the evidence.” It was estimated that about a half of all meta-analyses are based on observational studies, and they are equally important because the sources of bias are minimized by performing systematic reviews with predetermined inclusion criteria. Our analysis is limited by the fact that only studies written in English were included. Several recent papers written in Chinese or Japanese could not be included in the analysis at the time, which could lead to a distorted effect. However, within our current data set, we clearly demonstrate that 3D fluoroscopic navigation techniques result in higher pedicle screw placement accuracy than 2D fluoroscopic navigation techniques, and both methods of computer-assisted navigation are superior to conventional fluoroscopy with free-hand screw placement, especially in the thoracic region. These results are in agreement with recent findings and in disagreement with the argument that 3D fluoroscopy does not provide clear advantages over 2D methods. Beyond expanding previous data sets, we also demonstrate that differences in accuracy also exist between 3D fluoroscopic navigation methods, as we found O-arm fluoroscopy to be cumulatively more accurate than Iso-C 3D fluoroscopy. Clearly as these systems are used in larger numbers of surgeries, the advantages of the different platforms will become even more apparent and allow a surgeon to weigh the advantages and disadvantages of each system for the best patient outcome.

Conclusions

The results of this analysis suggest a significantly greater rate of pedicle screw placement accuracy in the cervical, thoracic, and lumbosacral spine when intraoperative 3D fluoroscopic navigation is used instead of 2D fluoroscopic navigation. Additionally, both 2D and 3D methods of navigation produced superior pedicle screw insertion accuracy rates compared with traditional fluoroscopic techniques.

Disclosure

Dr. Nelson is a consultant for Medtronic Navigation. Dr. Rajpal is a consultant for Medtronic, LDR, and LANX.

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