Cost-effectiveness of confirmatory techniques for the placement of lumbar pedicle screws

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Object. There is considerable variation in the use of adjunctive technologies to confirm pedicle screw placement. Although there is literature to support the use of both neurophysiological monitoring and isocentric fluoroscopy to confirm pedicle screw position, there are no studies examining the cost-effectiveness of these technologies. This study compares the cost-effectiveness and efficacy of isocentric O-arm fluoroscopy, neurophysiological monitoring, and postoperative CT scanning after multilevel instrumented fusion for degenerative lumbar disease.

Methods. Retrospective data were collected from 4 spine surgeons who used 3 different strategies for monitoring of pedicle screw placement in multilevel lumbar degenerative disease. A decision analysis model was developed to analyze costs and outcomes of the 3 different monitoring strategies. A total of 448 surgeries performed between 2005 and 2010 were included, with 4 cases requiring repeat operation for malpositioned screws. A sample of 64 of these patients was chosen for structured interviews in which the EuroQol-5D questionnaire was used. Expected costs and quality-adjusted life years were calculated based on the incidence of repeat operation and its negative effect on quality of life and costs.

Results. The decision analysis model demonstrated that the O-arm monitoring strategy is significantly (p < 0.001) less costly than the strategy of postoperative CT scanning following intraoperative uniplanar fluoroscopy, which in turn is significantly (p < 0.001) less costly than neurophysiological monitoring. The differences in effectiveness of the different monitoring strategies are not significant (p = 0.92).

Conclusions. Use of the O-arm for confirming pedicle screw placement is the least costly and therefore most cost-effective strategy of the 3 techniques analyzed.

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Key Words • quality of life • lumbar fusion • pedicle screw • EuroQol-5D health survey • O-arm monitoring • neurophysiological monitoring

The use of instrumented lumbar fusion for degenerative disease has risen dramatically over the past 2 decades, with 32,701 instrumented fusions performed in the US in 1990 compared with 122,316 in 2001.18 Despite widespread use of instrumented fusion for degenerative disease, there is still a dearth of data to support the cost-effectiveness of this procedure.8,12

Pedicle screw instrumentation offers theoretical advantages over noninstrumented fusion, including an immediately rigid construct to facilitate bone fusion. Although several studies have demonstrated an increased rate of fusion with instrumentation,15,32 this has not always correlated with improved clinical outcomes.21,27 In a prospective trial, Bjarke Christensen et al.7 demonstrated that functional outcome improved in both instrumented and noninstrumented groups, but only the subset of patients in whom primary degenerative instability was diagnosed benefited from the addition of pedicle screw fixation.

The reported complication rate for lumbar spine fusion varies widely. Whereas some series have rates as low as 3%, others have reported nearly 50%.23,24 Several adjuncts to confirm pedicle screw placement have been suggested in an effort to minimize complications stemming from pedicle screw malpositioning. Intraoperative neurophysiological monitoring allows for detection of
nerve root irritation and potentially early repositioning of malpositioned screws. Use of intraoperative image guidance, such as the O-arm (Medtronic, Inc.), improves accuracy of screw positioning. Considerable controversy exists regarding the optimal method of monitoring pedicle screw placement. It is unknown how these monitoring technologies influence patient outcomes or whether such adjunctive strategies are cost-effective. The purpose of this study is to evaluate the cost-effectiveness of 3 common strategies for monitoring placement of pedicle screws in the lumbar spine: intraoperative O-arm confirmation, intraoperative neuromonitoring, and postoperative CT scanning.

Methods

We developed a decision analytical model to evaluate costs and outcomes of 3 monitoring strategies for pedicle screw insertion (Fig. 1). We limited the population studied to patients undergoing pedicle screw fixation for at least 3-level lumbar fusions as part of their operative treatment for lumbar degenerative disease. Patients with single-segment fixation or those in whom pedicle screws were inserted for neoplasm, trauma, or other diseases were excluded. The 3 monitoring strategies generally used by spine neurosurgeons at our institution between July 2005 and June 2010 included the following: 1) screw placement by anatomical landmarks confirmed by uniplanar fluoroscopy, followed by secondary confirmation with postoperative CT scanning; 2) uniplanar fluoroscopic guidance, followed by fluoroscopic O-arm confirmation of placement; and 3) uniplanar fluoroscopy with neurophysiological monitoring. Neurophysiological monitoring consisted of a combination of evoked electromyography of appropriate muscles and electrical resistance to pedicle screw stimulation. Both uniplanar and isocentric fluoroscopy were used in determining the levels at which fusion would take place.

The decision analysis model predicts the costs and QALYs associated with each monitoring strategy. We considered direct health care costs from the perspective of society, and used as a proxy for these costs the means obtained from 2011 Medicare national average reimbursements, as shown in Table 1. All costs are expressed in 2011 US dollars. Since the surgical and hospital charges for the original screw placement are the same, regardless of monitoring strategy used, these costs are not included in the calculation. It should also be noted that Medicare reimbursement rules include intraoperative radiography performed to confirm screw position in the basic surgical fee. There is no additional reimbursement for the added time, equipment, and effort used to reposition screws found to be incorrectly placed at surgery. The additional time, use of equipment, and effort used in repositioning screws that were incorrectly placed amounted to morbidity, costs, and charges—but not reimbursement, as expected. Operative notes were reviewed for any patient who underwent a second lumbar surgical procedure to determine the incidence of removal and replacement of a malpositioned screw.

For data on effectiveness of monitoring strategies, we reviewed cases involving multiple-level pedicle screw fixation for lumbar degenerative disease performed by the spine surgeons in the department of neurosurgery at our institution. We limited our review to cases that fit the criteria above, and excluded procedures performed by members of the department of neurosurgery who were not primarily spine surgeons.

We recorded each patient's sex, age at surgery, and date of surgery. Because obtaining follow-up information on all patients exceeded our resources, we chose 64 cases from the group for structured interviews, using the EQ-5D questionnaire as a measure of postoperative QOL. Patient selection was random, with an attempt made to sample the range of patient ages and surgery dates and to

![Fig. 1](image-url)
Cost-effectiveness in pedicle screw monitoring

TABLE 1: Costs used in the decision analysis model for patients undergoing pedicle screw placement

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cost (2011 US$)</th>
</tr>
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<tbody>
<tr>
<td>pedicle screw fixation*</td>
<td>766.96</td>
</tr>
<tr>
<td>diagnosis-related group: initial fusion, posterior, lumbar/lumbosacral*</td>
<td>16,693.65</td>
</tr>
<tr>
<td>neuromonitoring</td>
<td>300.59</td>
</tr>
<tr>
<td>confirming screw position (radiography, fluoroscopy, O-arm)</td>
<td>0</td>
</tr>
<tr>
<td>postop CT scan</td>
<td>257.37</td>
</tr>
<tr>
<td>spinal fixation instrumentation removed &amp; replaced</td>
<td>1,268.80</td>
</tr>
<tr>
<td>diagnosis-related group: refusion, posterior, lumbar/lumbosacral</td>
<td>27,677.70</td>
</tr>
</tbody>
</table>

* These are the same for all patients, so they are omitted from the model.

include a representative proportion of patients from all 3 monitoring groups. In addition, we attempted to interview all patients requiring repeat operation. The questionnaire consists of 5 questions, each with 3 possible responses, relating to overall health-related QOL. Responses were converted to a global index score, using a standard algorithm. Global index scores range from 0 (dead) to 1 (perfect health). This score was converted to QALYs by multiplying by the average duration of follow-up in years.

In our primary analysis we evaluated the optimal monitoring strategy for a patient undergoing pedicle screw insertion. We calculated the direct costs and determined the QALYs associated with each strategy, based in part on the incidence of repeat operation and its negative effect on QOL and costs. Cost-effectiveness was calculated using standard principles. We performed sensitivity analysis for each parameter of the model by using beta distributions for probabilities, normal distributions for costs, and a 2D Monte Carlo simulation (expected value for 1000 simulated trials, each made up of 1000 microsimulations). If a particular strategy was found to be both more effective and less costly than the alternatives, it was said to dominate the other options, and we did not report a (negative) cost-effectiveness ratio. For analyses of the model we used TreeAge Pro 2009 (TreeAge Software, Inc.).

Assuming a difference of 15% in QALYs between any 2 groups, we calculated that 39 total cases would be needed to demonstrate significance within a 95% confidence interval. Statistical analyses involved Student t-test for comparisons between 2 groups and ANOVA for comparisons involving more than 2 groups. For the latter, the Bonferroni correction was used for post hoc pairwise comparisons. Examination of covariation involving continuous variables involved multiple variable regression. All statistical comparisons were done using Stata version 12 software (Stata Corp.). Differences in which the probability was less than 0.05 were considered significant.

Results

During the 5-year period between July 2005 and June 2010, 4 spine surgeons in this study performed 448 lumbar pedicle screw fixation procedures, involving at least 3 levels, for degenerative disease. Numbers of cases and percent of malpositioned screws with each monitoring technique are shown in Table 2. Four cases (0.9%) required a repeat operation for malpositioned screws. In 3 of these cases the patients underwent prior operation with neurophysiological monitoring, and in the remaining case intraoperative uniplanar fluoroscopy with postoperative CT scanning was used. There was a 73% response rate (47 of 64 patients) for completion of the EQ-5D. One individual refused to participate, 14 were lost to follow-up, and 2 died of unrelated causes.

Eighty-two percent of the respondents were women. Demographic characteristics and QOL results are summarized in Table 3. Patient age at surgery varied from 30 to 81 years, the time from surgery to interview varied from 4 to 70 months (mean 28.3 months), and the range of QOL scores was 0.21–1.0.

Although a malpositioned screw requiring a second operation was associated with a lower QOL, the difference was not significant (p = 0.679). There were no significant differences in QOL among the 3 monitoring strategies (F-statistic = 1.29, p = 0.285), nor were significant differences apparent between pairs of approaches. Although the QOL of patients treated with uniplanar fluoroscopy and postoperative CT scanning (0.63) was lower than that of monitored patients, this nonsignificant difference is mitigated by the longer follow-up period in these patients. As shown in Fig. 2, there is a trend toward decreasing QOL with longer follow-up ($r^2 = -0.03/year; p = 0.205$). Figure 3 shows that age at the time of surgery had no significant effect on QOL ($r^2 = -0.002/year; p = 0.522$).

Power calculations had demonstrated that 39 cases would be necessary to demonstrate significance within a 95% confidence interval, assuming a 15% difference in QALYs, and we had 47 responses. The largest difference

TABLE 2: Intraoperative monitoring for pedicle screw placement in 448 surgeries and repeat operations to reposition screws

<table>
<thead>
<tr>
<th>Monitoring Technique</th>
<th>No. of Cases</th>
<th>% Repositioning Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>postop CT</td>
<td>131</td>
<td>0.76</td>
</tr>
<tr>
<td>O-arm</td>
<td>105</td>
<td>0</td>
</tr>
<tr>
<td>neurophysiological</td>
<td>212</td>
<td>1.42</td>
</tr>
</tbody>
</table>

TABLE 3: Characteristics of patients undergoing pedicle screw fixation

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value; Mean ± SD</th>
</tr>
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<tbody>
<tr>
<td>age at op (yrs)</td>
<td>60.13 ± 10.55</td>
</tr>
<tr>
<td>time from op at time of interview (yrs)</td>
<td>2.36 ± 1.55</td>
</tr>
<tr>
<td>overall QOL (all 47 cases)</td>
<td>0.71 ± 0.23</td>
</tr>
<tr>
<td>QOL w/ no reop (44 cases)</td>
<td>0.71 ± 0.22</td>
</tr>
<tr>
<td>QOL w/ reop (4 cases)</td>
<td>0.60 ± 0.39</td>
</tr>
<tr>
<td>QOL w/ neurophysiological monitor (15 cases)</td>
<td>0.73 ± 0.25</td>
</tr>
<tr>
<td>QOL w/ postop CT scan (16 cases)</td>
<td>0.63 ± 0.22</td>
</tr>
<tr>
<td>QOL w/ O-arm monitor (16 cases)</td>
<td>0.76 ± 0.22</td>
</tr>
</tbody>
</table>
between groups was 0.2%, a value that would not be significant even if the entire population had been sampled. Furthermore, there were no significant differences among the groups with respect to sex, age, or time since surgery.

Inserting the costs (Table 1) and outcomes into the Monte Carlo simulation of the cost-effectiveness model yields the results illustrated in Table 4. Arranged in order of increasing cost, the O-arm monitoring strategy is significantly (p < 0.001) less costly than the strategy of postoperative CT scanning only, which in turn is significantly (p < 0.001) less costly than neurophysiological monitoring. Because the least costly alternative is also the most effective, O-arm monitoring dominates the other 2 strategies. The differences in effectiveness are not significant (p = 0.92).

**Discussion**

Placement of pedicle screws has traditionally been associated with increased operative risk compared with noninstrumented fusion. Whereas 5-year follow-up has demonstrated a role for pedicle screws in the subset of patients suffering from degenerative instability,² this was not evident in the same cohort at 2-year follow-up,² seven possibly because of the mitigating effects of operative complications associated with screw placement at the earlier time point.

Intraoperative monitoring has been used extensively as an adjunct to pedicle screw placement. In a recent meta-analysis of the literature, Fehlings et al.¹⁰ found that there is low evidence to support unimodal neuromonitoring as a valid diagnostic test, but there is strong evidence that multimodality intraoperative neuromonitoring is both sensitive and specific for detecting neurological injury during pedicle screw placement. There was low evidence, however, to suggest that neurophysiological monitoring reduces the rate of postoperative deficit or impacts outcome.

Of the 3 cases requiring repositioning in the group with neurophysiological monitoring, none demonstrated frank impingement of the nerve root on postoperative imaging. Based on operative notes, the subset of patients requiring repeat operation for malpositioned screws demonstrated no apparent changes on neuromonitoring during initial screw placement. This study was not designed to analyze the sensitivity of neuromonitoring for detecting nerve root impingement; repositioning or altering the trajectory of a pedicle screw in response to feedback from neuromonitoring is a relatively common occurrence and not always noted in the operative report. This may be mitigated by the finding that an intraoperative response to a neuromonitoring alert does not significantly reduce the rate of postoperative neurological deficit.

Intraoperative 3D fluoroscopy is a relatively new addition to the spine surgeon’s armamentarium. Several studies have demonstrated a role for 3D fluoroscopy in improving accuracy of pedicle screw placement.²⁶,²⁸,²⁹ Although there are data to support either the use of multimodality neurophysiological monitoring or the use of isocentric fluoroscopy to confirm pedicle screw placement, there are no studies that directly compare these 2 techniques or determine cost-effectiveness of each modality.

The O-arm may also be used for intraoperative frameless stereotactic navigation of pedicle screws. This technique is occasionally used at our institution in select patients, who are not represented in this cohort. Using isocentric fluoroscopy for intraoperative navigation is associated with an additional cost of $233.35 per case. Given the limited number of repeat surgeries for malpositioned pedicle screws in our cohort, it is unlikely that this would have proven more cost-effective than our strategy of using it for confirmation after the pedicle screws have been placed.

The differing practice patterns of surgeons within our group and the retrospective nature of our cohort allowed us to compare various confirmatory techniques for pedicle screw placement. Health-related QOL scores did not differ between patients in whom pedicle screws were placed using intraoperative monitoring, isocentric

### Table 4: Cost-effectiveness of the 3 monitoring techniques in patients undergoing pedicle screw placement

<table>
<thead>
<tr>
<th>Intraop Monitoring Technique</th>
<th>Cost (2011 US$)</th>
<th>Effectiveness (QALYs)</th>
</tr>
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<tbody>
<tr>
<td>O-arm</td>
<td>59.49 ± 24.93</td>
<td>1.6489 ± 0.4968</td>
</tr>
<tr>
<td>postop CT</td>
<td>483.26 ± 126.74</td>
<td>1.6473 ± 0.4939</td>
</tr>
<tr>
<td>neurophysiological</td>
<td>725.94 ± 158.96</td>
<td>1.6454 ± 0.4911</td>
</tr>
</tbody>
</table>

* Values are expressed as the mean ± SD.
Cost-effectiveness in pedicle screw monitoring

fluoroscopy, or postoperative CT scanning to confirm placement. There was a nonsignificant trend toward better health-related QOL outcomes in those patients who had some form of intraoperative confirmation, either O-arm or neurophysiological monitoring, compared with those in whom placement was guided by uniplanar fluoroscopy with a postoperative CT. Although this trend did not reach statistical significance, the current study is relatively small and may be underpowered to detect a difference.

In the setting of clinical uncertainty regarding the utility of monitoring pedicle screw placement, and the corresponding pressure from government funding agencies, insurers, and patients to demonstrate cost-effectiveness, it is particularly important for spine surgeons to quantify their results in a meaningful way. Although many scales have been invented and subsequently validated to measure outcomes, the majority of these scales are based purely on physical impairment.

Both the SF-36 and EQ-5D are widely used health-related QOL measures. The SF-36 questionnaire has been extensively used to assess global health-related QOL in patients undergoing spine surgery, including pedicle screw fixation for lumbar degenerative disease. The report- mean postoperative summary scores total from 70 to 91 in most series. However, some authorities have raised concerns regarding the use of the SF-36 in cost-effectiveness and related studies. The SF-36 cannot be reconciled with scales based on subject preference for various health states. Furthermore, the scoring varies with the population studied, and there are different standard SF-36 scores for different countries and years.

The EQ-5D is intended as a general measure of health for both clinical and economic assessment. A large sampling of the US population performed by the Agency for Healthcare Research and Quality, the Medical Expenditure Panel Survey found that the mean EQ-5D score for the US population is 0.871. By comparison, the EQ-5D score for our population of patients who have undergone multilevel fusion for degenerative disease is much lower, at 0.71. In a study of 230 patients undergoing surgery for lumbar spinal stenosis, including both simple decompression and decompression with fusion, Jansson et al. found an improvement from a mean EQ-5D score of 0.36 preoperatively to 0.64 postoperatively. Although we lack data on our patients preoperative EQ-5D scores, our postoperative scores are comparable to those of Jansson et al., although differences in patient population and surgical technique make comparison difficult. Taken together, these data suggest that although surgery may improve the QOL, it does not return it to levels comparable to the general population.

Interestingly, age did not significantly affect outcome scores in our patient cohort. This supports previously published data by Becker et al., who demonstrated an improvement in QOL measures in elderly patients following instrumented lumbar fusion. These data bolster the case for not considering age to be an inherent contraindication to instrumented fusion.

We made several simplifying assumptions in our model, any of which may impact our results. Medicare and Medicaid reimbursement were used as proxies for direct health care costs to society. Although commonly accepted, this practice may not represent true cost. We recognize that other cost perspectives, such as those of the patient, the hospital, and the insurance company exist, and these groups might very well reach different conclusions. Items such as capital expenses for equipment, length of a procedure, and so on contribute to hospital costs, but have no direct effect on cost to society (although they are often factored into federal reimbursement rates). Societal perspective is the standard in cost-effectiveness studies.

Because this trial is retrospective and because each monitoring group consists of different surgeons operating at different times, we cannot rule out the influence of surgical skill on our results. We lack preoperative EQ-5D scores and therefore cannot be certain of the number of QALYs gained by surgery. However, the incremental cost-effectiveness ratios we calculated were based on the differences in QALYs between pairs of treatments. If we can assume that there were no significant differences in QOL among groups prior to surgery, our conclusions remain valid. Again, although commonly accepted, this practice may not represent true cost. Other limitations include our inability to determine whether monitoring allowed intraoperative repositioning of misplaced screws, thus avoiding the need for later repeat operation.

Our conclusions are limited to degenerative lumbar conditions. The presence of cancer, trauma, or infection would have had too great an impact on QOL to permit analysis of monitoring effects. Although isocentric fluoroscopy allows for precise screw placement in all planes, this does not negate the value of neurophysiological monitoring as a sensitive and specific measure of irritation of the neural elements. It may be a valuable adjunct for pedicle screw placement in the thoracic and cervical spine, and under specific conditions in the lumbar spine.

Given the low rate of screw misplacement requiring repeat operation among all groups, one may wonder about the practical utility of postoperative CT scanning or using intraoperative monitoring. Keeping in mind that this study is not designed to answer this question, specifically related to the comparative efficacy and cost, further collection of data may help discern valuable differences between patients who have malpositioned screws and those who do not. For example, clinical signs and symptoms following a lumbar fusion operation may prompt CT scanning and a potential second operation. Given the small subset of patients requiring repeat operation, it may be a more cost-effective strategy to further investigate the integrity of screw placement in only those patients who remain symptomatic.

With these limitations in mind, intraoperative 3D fluoroscopy is more cost-effective than either neurophysiological monitoring or postoperative CT confirmation.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author contributions to the study and manuscript preparation include the following. Conception and design: Stein. Acquisition of data: Shmulevich, Hardy, Benedetto, Malhotra, Marcotte, Welch, Dante. Analysis and interpretation of data: Thawani, Stein. Drafting the article: Sanborn. Critically revising the article: Sanborn, Thawani,
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