Surgeon-interpreted Intra-operative Electromyography (EMG) versus Conventional EMG Pedicle Screw Testing—A Prospective Comparison

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The reported incidence of lumbar pedicle screw malpositioning is between 5 and 40%.1–4 Post-operative neural deficits related to screw misplacement have been reported at rates between 3 and 11%.1–4 Radiography alone is an unreliable tool for determining pedicle wall violation due to malpositioned screws, whether by intra-operative fluoroscopy,1–10 plain X-ray,11–17 image-guided surgery based on radiographic registration,18–20 or even computed tomography,21 which is often considered to be the gold standard in instrumentation placement verification.

Intra-operative testing of pedicle integrity via electrically triggered electromyography (EMG) during pedicle-screw placement procedures is the standard of care where neurophysiological monitoring services are available. The test has been shown to be highly sensitive to screw misplacement10,15,22–33 and more accurate than radiography, direct visualization, or palpation in detecting pedicle breach due to misplaced screws.34,35

Properly implanted pedicle screws are electrically shielded from adjacent nerve tissue by surrounding bone such that electrical stimulation within a given current range will fail to depolarize the nerve. Conversely, a breach in the pedicle wall creates a low resistance path between the implant and nerve tissue, and applied current passes between them. Subsequent nerve depolarization and muscle contraction is recorded as a compound muscle action potential (CMAP) on the corresponding myotome. In the case of a pedicle breach, application of a low-amplitude stimulus (<7mA) to a pedicle-screw implant will elicit a CMAP from the corresponding innervated muscle group, whereas an intact pedicle will block the passage of stimulus to the nerve and depolarization will not occur at these low currents.

The purpose of this prospective single-site study was to evaluate the use of an automated EMG system for detecting pedicle-screw misplacement by determining its equivalence to current standard practices of nerve monitoring.

Materials and Methods

Following informed consent, 30 consecutive patients who underwent instrumented posterior lumbar fusion involving a total of 45 levels and 150 pedicle screws between L2 and S1 were enrolled into an Institutional Review Board (IRB)-approved study. Patients received stimulus-evoked EMG monitoring during placement of pedicle screws, using a conventional EMG system while the automated system was idle. Alternately, patients received EMG monitoring using an automated system to monitor pedicle-screw placement. Study end-points included comparison of intra-operative EMG stimulation threshold values from each system. A summary of the vertebral levels that were treated in this study is presented in Figure 1. Study subjects were administered a neuromuscular blocking agent in conjunction with standard anesthesia medications prior to surgery. The neuromuscular blocking effects were allowed to subside at the end of the surgical exposure, and neuromuscular status was reported as a score of total number of twitches out of a possible four, commonly referred to as the ‘train-of-four’ test (see ‘Discussion,’ below).

Automated Electromyography Monitoring

Automated EMG testing was performed using a surgeon-controlled eight-channel capacity neuromonitor that performs automated EMG analysis using proprietary algorithms (NeuroVision® JJB EMG System; NuVasive®, Inc., San Diego, CA). To prepare the patient for automated monitoring, myotome surface electrodes were placed on the skin overlying the four muscle groups (bilaterally, for a total of eight) to be monitored. In lumbar procedures, the quadriceps (vastus medialis), anterior tibialis, hamstrings (biceps femoris), and medial gastrocnemius provide the myotomes to monitor nerve root levels from L2 to S120. The skin was prepared by light abrasion and an adhesive reference electrode was placed on the patient’s upper lateral thigh to act as a common reference for each of the recording myotome electrodes. An anode return electrode was similarly adhered to the skin near the stimulation site, or on around the lower lateral trapezius.

This placement helps to mitigate the occurrence of stimulation artifact (see ‘Discussion,’ below).

To test the integrity of the pedicle subsequent to screw insertion, an insulated ball-tipped pedicle sound stimulator was placed on the screw head and held in this contact position throughout the stimulation sequence. The stimulation circuit was continuously monitored to ensure an appropriate stimulation return path. Similarly, the recording electrodes were continuously monitored to ensure good electrical contact with the skin. The surgeon initiated the automated screw test stimulation by depressing a stimulation button on a hand-held device. The stimulation delivered a ramped stimulus from 0mA to the default
Determination of Pedicle Cortex Integrity

Pedicle cortex integrity was tested by stimulating the positioned screw head and recording CMAPs. Based on the findings of Calancie et al., a stimulus threshold intensity below 7mA elicits CMAPs from the muscle group innervated by the adjacent spinal nerve root was indicative of a pedicle.

Discussion

Threshold Interpretation and Sensitivity/Specificity

The threshold value for the stimulation current that indicates a well-placed screw has been the subject of several publications, with a typical threshold range of 6 to 7mA. Several authors have suggested a threshold of 7mA, following the original suggestion by Calancie in 1994. The range of accepted values demonstrates variations in both normal physiological properties and testing sensitivity and specificity. A higher threshold criterion will lead to higher specificity but with more potential for false-negative results. Conversely, a lower threshold criterion will lead to higher specificity but with more potential for false-positive results.

Results

Pedicle Screw Tests

In 150 pedicle screw placements, 144 (96%) had no CMAP responses from either system following stimulation up to 17mA. In six screws (4%), CMAP responses were elicited following stimulus values less than 17mA, in five of the six only with the automated system. A summary of these findings is presented in Table 3. All screw test results (100%) were greater than 10mA. No significant EMG findings, defined by CMAP response to <7mA stimulus, were observed with either system following placement of any pedicle screws in any of the subjects in this study.

Pedicle Screw Placement Findings

All pedicle screw placements were satisfactory, based on the surgeon’s judgment of radiographic findings. There were no immediate post-operative symptoms correlated to any of the EMG findings in this study from either system. A summary of EMG findings by magnitude of response is shown in Table 4.

Agreement Between Systems

Overall, there was disagreement in the numerical value of the stimulation threshold required to elicit a CMAP between the conventional and the automated systems. 2% of the time (3/150), with an average threshold difference of about 1mA (range 0.5–2mA).
Surgeon-interpreted Intra-operative EMG versus Conventional EMG Pedicle Screw Testing

Table 2: Features of Conventional and Automated Electromyography Monitoring Systems

<table>
<thead>
<tr>
<th>Feature</th>
<th>Automated System</th>
<th>Conventional System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stimulation</td>
<td>Controlled by surgeon from the field; stimulation ramp and associated EMG recording are automatic</td>
<td>Neuromonitor controls stimulation from outside the field; neuromonitor ramps the amplitude and visually determines the EMG response</td>
</tr>
<tr>
<td>Pulse width</td>
<td>200µs</td>
<td>250µs</td>
</tr>
<tr>
<td>Frequency response range</td>
<td>30Hz to 4.8kHz</td>
<td>30Hz to 1.5kHz</td>
</tr>
<tr>
<td>Number of channels</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Minimum EMG amplitude value</td>
<td>100µV</td>
<td>25µV</td>
</tr>
<tr>
<td>Artifact rejection</td>
<td>Incorporates artifact rejection algorithms</td>
<td>Technician interprets waveforms for artifact responses</td>
</tr>
</tbody>
</table>

Electromyography (EMG) monitoring systems used in this study were technically comparable. s = seconds.

Table 3: Summary of Pedicle Screw Test Results

<table>
<thead>
<tr>
<th>Subject #</th>
<th>Screw Location</th>
<th>Automated Threshold (mA)</th>
<th>Conventional Threshold (mA)</th>
<th>Difference (mA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>S1 Right</td>
<td>14</td>
<td>14.5</td>
<td>0.5</td>
</tr>
<tr>
<td>15</td>
<td>S1 Right</td>
<td>10</td>
<td>17</td>
<td>7</td>
</tr>
<tr>
<td>23</td>
<td>S1 Left</td>
<td>16</td>
<td>17</td>
<td>1</td>
</tr>
<tr>
<td>24</td>
<td>S1 Right</td>
<td>10</td>
<td>17</td>
<td>7</td>
</tr>
<tr>
<td>26</td>
<td>L4 Left</td>
<td>16</td>
<td>17</td>
<td>1</td>
</tr>
<tr>
<td>26</td>
<td>L5 Left</td>
<td>15</td>
<td>17</td>
<td>2</td>
</tr>
<tr>
<td>Average difference</td>
<td>1.16</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Responses elicited following stimulation with less than 15mA are shown. Nerve roots are indicated by region, either lumbar (L) or sacral (S), and level (1–4). Responses from the automated system were recorded on a channel that was not monitored by the conventional system.

Table 4: Electromyography Finding by Magnitude of Response

<table>
<thead>
<tr>
<th>EMG Response</th>
<th>Fraction of Screw Tests (n=150)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None at any level with maximum stimulation</td>
<td>96%</td>
</tr>
<tr>
<td>Intermediate findings (&gt;7mA - &lt; max stimulation)</td>
<td>4%</td>
</tr>
<tr>
<td>Significant findings (CMAP with &lt;7mA stimulation)</td>
<td>0%</td>
</tr>
</tbody>
</table>

The majority of electromyography (EMG) findings in 150 screw tests from both systems were negative after maximum stimulation. CMAP = compound muscle action potential.

Understanding Potential Mitigating Factors

There are several physiological and/or peri-operative conditions that affect reliability of EMG testing regardless of what type of system is used. If an EMG contraction is generated by stimulation at a low level of current, there must exist a physiological pathway in order for the depolarization to occur (e.g. pedicle breach). However, the choice of acceptable current threshold may be dependent on bone quality. Osteoporotic or osteopenic patients may have insufficient bone density to mimic the insulation properties of a normal pedicle. Therefore, a screw that is well placed may appear to be breached because the current applied exceeds the intrinsic insulation properties of the compromised bone. While placement of instrumentation in very-low-density bone is a rare occurrence, in these circumstances acceptance of a slightly lower threshold as still indicative of a well-placed screw may be advisable. Similarly, there has been anecdotal evidence of screw placement testing at the S1 pedicle, where slightly lower thresholds may be acceptable due to lower bone density. Indeed, in this study 52% of EMG findings below the maximum stimulation levels in either system were observed at the S1 level (four out of six or 66% of screw tests). Nearly half (43%) of study subjects underwent fusion involving S1 in either one- or two-level fusions, so clarifying the threshold criterion at this pedicle level seems clinically important.

Stimulation artifact is a potential source for false-positive results due to non-physiological effects. The applied stimulation current is designed to be isolated to the operative field by incorporating a stimulation (lower sensitivity). The threshold criterion that was applied in this study was consistent with the literature findings for the highest sensitivity and specificity in subjects with normal nerve function and bone density.

Findings revealed response values that were consistently lower in the automated system than in the conventional system (see Table 2). These findings suggest that other factors may introduce systematic error between any two systems, be they automated or conventional, including stimulation parameter settings. The system settings were not standardized between these conventional and automated systems (but are detailed in Table 2), and therefore were not addressed in this study. The default settings employed by the automated system follow those from the original studies validating the clinical relevance of the numerical thresholds. All EMG findings less than 15mA were viewed by the surgeon in this particular study with a high index of suspicion for malpositioned instrumentation. Only three of 150 (2%) of the findings from either system fell into this group (see Table 3), and therefore the relative clinical utility of these systems in this range could not be rigorously analyzed.

Practical Considerations

Although they function similarly, automated and conventional EMG systems differ in the speed with which data are analyzed and displayed to the end-user. Conventional monitoring requires interpretation of waveforms to deduce a threshold number, which is then reported verbally. Automated systems provide the waveform analysis and visual/audio displays, which are provided to the end-user within visibility and/or audibility of the device. While the threshold number is critical to the decision-making process and both systems have direct accessibility to this information, verification of some CMAP waveforms may be necessary for further evaluation. With conventional monitoring, the technician may check the EMG waveforms for artifact responses. While the automated system incorporates artifact rejection algorithms, it is still in the best interests of the surgeon to understand the potential causes of artifact.
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return electrode near the site of stimulation (in this study, via a larger surface electrode just above the surgical site in the automated system; and, in the case of conventional monitoring, via an electrode within the surgical wound). It is this stimulation circuit that depolarizes the nearby nerve(s) and causes a physiological CMAP response. If the return electrode is absent or positioned in such a way that the stimulation current is instead returned via the recording myotome electrodes, the EMG recording system picks up that stimulation as a waveform that could be interpreted as a false CMAP response at very low stimulation current thresholds. In conventional monitoring, however, the monitoring technician can usually distinguish this type of waveform from a true physiological CMAP response. In automated monitoring, the system is designed to recognize this type of artifact and reject it from analysis. However, if the end-user is suspicious of the potential for stimulation artifact, the numeric results screen can be verified by visually discerning the nature of the waveform response, just as in conventional monitoring. Thus, a healthy understanding of what the typical CMAP response should look like is warranted by the end-user. In all cases where disagreement between conventional and automated EMG testing occurred in this study, stimulation artifact was ascertained by the attending neurophysiologist’s interpretation. In the five tests where there was disagreement in the EMG findings for final pedicle screw placement, there were no stimulation artifacts identified on the waveforms.

The potential for false-negative results is concerning because in EMG testing a negative result is desirable. A common mitigating factor in the accurate measurement of EMG is the level of muscle relaxant affecting the patient. Muscle relaxants act to interrupt the depolarization–muscle activation sequence. Therefore, a patient under the effects of muscle relaxants will not demonstrate electrically stimulated or free-run EMG. In effect, the level of muscle relaxant is typically monitored by the anesthesiologist by stimulating a peripheral nerve with a series of four pulses and monitoring for an associated myotome response of up to four twitches, commonly referred to as the train-of-four test.20,21 All subjects were tested under conditions of ‘four out of four twitches,’ thereby minimizing the chances for the occurrence of false-negatives in this series of EMG findings. False-negative results can also be observed in the presence of compromised nerve function, such as those that have been chronically irritated or compressed and thus may require higher levels of stimulation to incite the same CMAP response as that from a healthy nerve. If a nerve requires stimulus intensities outside the normal range for eliciting a CMAP response, the effective testing threshold will also shift. Findings from this study do not suggest that any of the subjects were outside the normal testing threshold range, particularly given that inclusion/exclusion criteria were designed to eliminate this variable.

The phenomenon of current shunting or dissipation is perhaps the most common source of false-negative results and was observed several times during this study. The stimulation–depolarization process occurs by amassing enough current density near the nerve to cause electrical potential changes across its membrane. However, if the current is not applied in such a way as to direct the current density in a localized area, but instead disperses the current through fluids and soft tissues, the result can be an artificially high threshold; that is, although the stimulation current is applied and ramped to a high value, there will be insufficient current density surrounding the nerve to depolarize it and no CMAP response will be generated (a negative test result), even in the presence of a breach (a false-negative result). Procedures for insulating stimulating instruments from fluid and soft tissues are effective barriers to current shunting.20,21

This study was conducted to evaluate the clinical utility of automated EMG testing compared with conventional testing in a series of study subjects undergoing instrumented lumbar fusion. The numerical values obtained from each testing system were directly compared to determine concordance between findings. Clinical and numerical agreement between the systems was high. Although low thresholds were rare in this study, and conclusions about the utility of EMG testing in general cannot therefore be rigorously evaluated, the screw-for-screw comparisons demonstrate that results from these two systems are equivalent. The differentiating feature between automated and conventional EMG systems is the manner in which the result is conveyed to the operating surgeon. Because mitigating surgical and physiological factors can potentially affect the interpretation of EMG results from any system, the end-user should become familiar with how to prevent, or at least identify and evaluate, these effects.

EMG testing has been shown in other studies to be a useful tool to help identify misplaced pedicle screws. Automated EMG systems may widen the availability of this technology.

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