Clinical Evidence for the Use of PediGuard in Spine Surgery
Pedicle screw challenges

Pedicle screw-based stabilization has become the gold standard for treating spine instabilities and deformities. Technological advancements such as minimally invasive surgery, bone substitutes, and thoracic screws further reiterate the importance of pedicle screw placement in spine surgery.

Accuracy of pedicle screw placement remains a critical issue in spine surgery

In recently published papers studying screw placement accuracy:
- Around 20% of pedicle screws using conventional techniques have been reported as misplaced.1,2,3
- 2-5% of patients have complications related to misplaced screws.2,3,4

Level of evidence

<table>
<thead>
<tr>
<th>Accurate screws</th>
<th># screw</th>
<th>Accuracy %</th>
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</thead>
<tbody>
<tr>
<td>TIAN (2011)</td>
<td>II</td>
<td>3096</td>
</tr>
<tr>
<td>GELALIS (2011)</td>
<td>II</td>
<td>3139</td>
</tr>
<tr>
<td>VERMA (2010)</td>
<td>IV</td>
<td>2064</td>
</tr>
<tr>
<td>Total Conventional techniques</td>
<td></td>
<td>8299</td>
</tr>
</tbody>
</table>

Conventional techniques

(Free-hand with or without fluoroscopy assistance)

A surprising number of patients emerge from surgery with screws of concern

- Up to 40% of patients have screws of concern (106 patients / 2,229 screws). Screws of concern are qualified as: adjacent to aorta, viscera or 2-4mm breach or impinging on aorta, viscera medial displacement greater than or equal to 4mm.5

Consequences of misplaced pedicle screws are not to be underestimated

Literature reviews and clinical studies recently published suggest that:
- 2.3% of patients (29/1,254) presented neurologic complications due to misplaced screws placed free hand with or without fluoroscopy.2,3
- 4.7% of patients (7/148) showed screw proximity to the aorta and revision surgery was recommended.4

Level of evidence

<table>
<thead>
<tr>
<th>Accurate screws</th>
<th># screw</th>
<th>Accuracy %</th>
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</thead>
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<tr>
<td>TIAN (2011)</td>
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<tr>
<td>GELALIS (2011)</td>
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<td>VERMA (2010)</td>
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<td>Total Conventional techniques*</td>
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</table>

Navigation techniques (CT, 2D or 3D nav)

Estimated level of evidence

<table>
<thead>
<tr>
<th>Gelalis literature review 2011</th>
<th>Verma literature review 2010</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Free-Hand</td>
<td>Fluoroscopy</td>
<td>Conventional techniques</td>
</tr>
<tr>
<td>Patients</td>
<td>362</td>
<td>323</td>
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<tr>
<td>Neurologic complications %</td>
<td>2.2%</td>
<td>2.5%</td>
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</table>

CT based navigation

| Patients                      | 313                           | 107   | 1139  | 1254 |
| Neurologic complications %    | 2.6%                          | 0%    | 0%    | 0.7%  |

Gelalis literature review 2011

Verma literature review 2010

Total

Rates of properly placed screws (%)
Dangers of radiation

Radiation exposure in spine surgery is excessive, protection is underutilized, and the long-term biological effects can be deadly. Fortunately, there is a growing concern among influential spine surgeons who are calling for the reduction of radiation vulnerability in the OR. A study published in Spine by the team at the University of Florida with Dr. Harry Shufflebarger found that the average spine surgeon will receive the maximum allowable lifetime exposure of radiation for classified workers within 10 years of practice. An article in Orthopedics This Week reported that a startling 95% of physicians grossly underestimate how much radiation both they, and their staff, are absorbing. Furthermore, this article states that only 14% of doctors have undergone any training on radiation susceptibility.

Surgeons’ greater reliance on fluoroscopy during procedures exposes the OR team to dangerous radiation:

- The average spine surgeon will receive the maximum allowable lifetime exposure of radiation for classified workers within 10 years of practice.
- The radiation exposure in spine surgery has been found to be 10 to 12 times greater than the radiation exposure during other fluoroscopically assisted non-spinal musculoskeletal procedures.
- The highest amount of fluoro intensity is needed for spinal procedures.

There are simple steps you can take to limit the amount of radiation you and your staff receive during spinal procedures:

- Wear your lead apron
- Cover your thyroid
- Invest in lead-lined glasses
- Protect your hands by removing it from the field when using fluoroscopy
- Contact us today to try the PediGuard, which demonstrates a 25% - 30% reduction in fluoroscopy shots during pedicle screw placement.

Our mission is to help you make spine surgery safer – for you, your patient and your staff.

How PediGuard Can Help

Studies show that PediGuard can significantly reduce the radiation exposure to you and your staff:

- 73% radiation time reduction
- 51% reduction in thyroid radiation exposure to the surgeon
- 25% - 30% reduction in fluoroscopy shots during pedicle screw placement.

<table>
<thead>
<tr>
<th>Decrease in Radiation Exposure CHAPUT 2011 &amp; BAI 2012</th>
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<tbody>
<tr>
<td>Fluor shots</td>
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<td>Chaput 2011</td>
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<td>Bai 2012</td>
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</table>

Mokbel Chedid, MD
Neurosurgeon
Henry Ford Hospital
Detroit, Michigan

“When not using PediGuard, we would regularly reach our facility mandated radiation level by October and not be permitted to operate for the rest of the year. With PediGuard, we have been able to keep our radiation exposure low and operate through the end of the year.”

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PediGuard is the first and only handheld, wireless device that can detect possible vertebral cortex perforation during pedicle preparation for screw placement. PediGuard can alert the surgeon prior to a breach by accurately analyzing the electrical conductivity of the surrounding tissues in real time.

The PediGuard technology has demonstrated strong results in a wide number of clinical studies.

In a recent cadaver study, PediGuard detected 100% (32/32) of the breaches while anticipating 87% of breaches.

Statistically significant decrease in neurophysiologic alarms: PediGuard demonstrates a 3-fold reduction.

• 97% screw placement accuracy
• 98% breach detection
• 87% breach anticipation
• 3-fold reduction in neuro-monitoring alarms
• 25% – 30% reduction in radiation exposure during pedicle screw placement
• 15% time saving during screw placement

PediGuard offers the most accurate technology today.

Rates of properly placed screws (%)

Conventional techniques

Navigation techniques

PediGuard

<table>
<thead>
<tr>
<th>Ref</th>
<th>Level of evidence</th>
<th>Number of Screws</th>
<th>Patients</th>
<th>Screws</th>
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<tbody>
<tr>
<td>TIAN 2011</td>
<td>PR-I</td>
<td>347</td>
<td>217</td>
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<tr>
<td>CHAPUT 2011</td>
<td>PR-II</td>
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<td>CHANG 2009</td>
<td>R-IV</td>
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<td>268</td>
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<td>BOCQUET 2007</td>
<td>P-IV</td>
<td>98</td>
<td>104</td>
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<tr>
<td>LUBANSU 2006</td>
<td>P-IV</td>
<td>261</td>
<td>271</td>
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<td>TOTAL</td>
<td></td>
<td>1044</td>
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<td>7307</td>
</tr>
</tbody>
</table>

Average=97%

With growing clinical evidence confirming its efficacy, PediGuard is emerging as the most compelling answer to the clinical needs associated with pedicle screw placement.

• 97% screw placement accuracy
• 98% breach detection
• 87% breach anticipation
• 3-fold reduction in neuro-monitoring alarms
• 25% – 30% reduction in radiation exposure during pedicle screw placement
• 15% time saving during screw placement

PediGuard has assisted orthopedic spine surgeons and neurosurgeons all over the world in over 20,000 surgeries – experience the difference today.
The bipolar sensor of PediGuard® emits an electrical current which flows locally through the bone from the inner electrode to the outer electrode, creating a circular electromagnetic detection field at the very tip of the instrument. The real time, local changes in electrical conductivity of the bone as measured by the sensor are translated into audio feedback that varies in pitch and cadence to inform the surgeon while advancing the pedicle about the changing nature of the bone encountered at its tip.

The result is that PediGuard can alert the surgeon about a possible perforation of the cortex, and furthermore may help the surgeon anticipate a breach by detecting the approaching cortical wall.

Learn more about the PediGuard family of products at www.spineguard.com

References


