
July 2009
The purpose of this document is to assist in the education of the Spine Industry on the value statement of intra-operative imaging and Spinal Navigation, backed by peer reviewed papers. This document is a supplement to the “Clinical Value of Image Guided Surgery for Spinal Procedures”.

**Table of Contents**

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introduction to the O-arm® Imaging System</td>
<td>3</td>
</tr>
<tr>
<td>2. Brief Overview of Spinal Procedural Solutions</td>
<td>5</td>
</tr>
<tr>
<td>3. Synopsis O-arm System Papers</td>
<td>6</td>
</tr>
<tr>
<td>4. Citation Table - Clinical Value Statement Support</td>
<td>8</td>
</tr>
<tr>
<td>5. Abstracts of Peer Reviewed Papers</td>
<td>11</td>
</tr>
</tbody>
</table>
1. Introduction to the O-arm® Imaging System

The O-arm® System is a complete multi-dimensional mobile surgical imaging platform combining high precision robotics with unparalleled imaging capability. It improves intra-operative decision making through time effective automated 2D and 3D imaging providing a very large field of view, superior image quality and seamless integration with navigation.

- Mobile imaging platform optimized for neuro and orthopaedic surgeons
- Differentiator in the healthcare market
- May assist in complication avoidance & revisions
- Standard fluoroscopy (2D) and high resolution 3D Imaging in the OR
- Patented “Breakable Gantry” for lateral patient access which closes to a fixed “O” imaging position
- Reduction in radiation exposure to surgeon & staff
- Multiple imaging positions saved and recalled anytime
Patient Benefits

- Improved patient outcomes, less revision surgeries.
  - Use of the O-arm® System with StealthStation® Navigation, provides the surgeon with additional information at the time it’s needed. Through better visualization, such as real time axial views of the anatomy not available in standard fluoro imaging, the surgeon can make informed decisions during a procedure.
  - Potential to eliminate post-operative CT reducing dose to patient.

Surgeon & Staff Benefits

- Improved Safety for the Surgeon and Staff through Radiation Dose Reduction:
  - Large field of view (FOV) and pre-set positions eliminate the need to continuously re-scout to find a working image.
  - In 2D imaging mode, the fixed gantry allows for streamlined image acquisition in any plane without compromising sterility or workflow.

- Confidence in the achievement of surgical goals:
  - The O-arm® System allows for a pre-closure scan allowing the surgeon to ensure adequate hardware placement

Healthcare Services Provider Benefits

- Provide better patient care.
- Grow Spine Program - Enable unique and complex surgeries.
- Differentiate hospital offering – e.g. Neuroscience Center of Excellence
- Address OSHA and JCAHO imperatives on the National Council on Radiation Protection's radiation exposure guidelines to staff and surgeons.
2. Brief Overview of Spinal Procedural Solutions

**Computer-Assisted Spine Surgery:** Medtronic Navigation offers a broad array of computer-assisted surgery systems, accessories, and software applications for spine surgery. Our computer-assisted surgery software solutions are complemented by hardware made by the world leader in spine instrumentation, Medtronic Spine & Biologics. This unique relationship means that Medtronic can deliver a full spectrum of products to facilitate your computer-assisted spine surgery program.

**Degenerative Diseases** of the spine will affect many people as they age. Both open and percutaneous procedures are an important part of surgical treatment of patients with degenerative disease of the spine, and Medtronic Navigation offers computer-assisted solutions for both.

**Spinal Deformities** and scoliosis are three-dimensional in nature; so the images you use to assess and make your surgical plan should also be in three dimensions. Medtronic Navigation offers the tools you need for visualizing spinal deformities in three dimensions and allows you to place the most suitable implants with pinpoint precision.

**For Trauma,** in fractures of the spine, or pelvis, three-dimensional imaging is critical to any surgical plan. Equally critical is the ability to navigate through bone while staying clear of eloquent neural structures. Medtronic Navigation Spinal Solutions are designed to address these issues.

**Cervical Spine** anatomy demands imaging accuracy when utilizing cervical spine instrumentation. Medtronic Navigation offers the tools you need for trans-articular screw and anterior cervical plating screw implantation.

**Benefits of spinal surgery and navigation solutions:**
- 3D modeling of patient pathology
- Navigation using two-dimensional or three-dimensional images (fluoroscopy, CT, 3D fluoroscopy)
- Ability to create and visualize trajectories for pedicle screw implantation
- Ability to determine ideal screw selection before implantation
- Reduce exposure to radiation by eliminating the need for continuous fluoroscopy
- Enables minimal access spine technology
3. Synopsis O-arm® System Papers

Overall, use of the O-arm® System, with and without surgical navigation in clinical procedures provides clinical value to each stakeholder.

- **Patient:**
  - With the use of the O-arm® System and surgical navigation, the surgeon is presented with additional information through better visualization, such as real time axial views of the anatomy not available in standard fluoro imaging. This may yield:
    - Greater accuracy with overall better outcomes (less revisions)
      - Ref: 1, 2, 3, 4, 5.

- **Surgeon**
  - With the use the O-arm® System and surgical navigation, the surgeon is presented with additional information through better visualization, such as real time axial views of the anatomy not available in standard fluoro imaging, and the ability to navigate on images which are obtained when the surgeon is outside of the operative field. This may yield:
    - Greater and more consistent accuracy, resulting in better implant positioning, less complications and overall better outcomes.
      - Ref: 1, 2, 3, 4, 5.
    - Reduced radiation exposure when compared to using live fluoroscopy to guide the surgeon
      - Ref: 3, 4.

- **Clinical team**
  - Reduced radiation exposure when compared to using live fluoroscopy to guide the surgeon
    - Ref: 3, 4.

- **Healthcare Services Provider**
  - Higher quality of patient care
    - Ref: 1, 2, 3, 4, 5.
  - Reduced radiation exposure to the staff when compared to using live fluoroscopy to guide the surgeon
    - Ref: Ref: 3, 4.

As peer reviewed publication typically lags the actual adoption of a procedure by two years, even the most up to date publications are somewhat behind in our fast moving medical technology world. Clinical data collected over the past year at several sites utilizing O-arm® Systems, sometimes coupled with StealthStation navigation systems has been submitted for publication and is expected to publish this calendar year. The results are focused on the reduction of revision surgeries and the elimination of radiation exposure to the surgeon. In multiple cases the surgeons utilizing Spinal Navigation and intra-operative imaging have realized a zero revision rate. In the studies focused on radiation reduction, the surgeons have realized a reduction of radiation to nil, when utilizing Spinal Navigation and intra-operative imaging for their thoracic/lumbar fusion procedures.

While this data is not yet peer reviewed, the results are rather compelling and updates will be provided as the data is published.
Two specific statements relating to the clinical value of O-arm® Systems in surgery are supported by peer-reviewed literature:

1) Greater accuracy, and thus reduced revision surgeries
2) Reduced radiation exposure

The following tables provide direct excerpts from peer-reviewed citations to support these statements.

Summary Citation Table – Clinical Value Statement Support

Note: The following color conventions are applied through the remainder of this document:

- Greater Accuracy/Reduced Revision Surgeries = Blue
- Reduced Radiation Exposure = Green

<table>
<thead>
<tr>
<th>Greater Accuracy/ Reduced Revision</th>
<th>Reduced Radiation Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>2</td>
</tr>
</tbody>
</table>
4. Citation Table - Clinical Value Statement Support

Note: The following table is arranged by 1) clinical value statement, 2) citation published date, and 3) citation author name.

<table>
<thead>
<tr>
<th>Peer-Reviewed References</th>
<th>Objectives / Conclusion Excerpts</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Brennan, RP, et al: Minimally invasive image-guided direct repair of bilateral L-5 pars interarticularis defects. Neurosurgery Focus 25(2):E13, 2008</td>
<td><strong>Objective:</strong> Lower back pain from spondylolysis historically has been treated with a variety of options ranging from conservative care to open fusion. The authors describe the novel technique of minimally invasive bilateral pars interarticularis screw placement by utilizing intraoperative 3D imaging and frameless navigation in a 17-year-old male athlete. <strong>Conclusions:</strong> We described a modified form of the Buck screw procedure with a minimally invasive, image-guided method of pars interarticularis fixation. The utilization of image guidance simplifies the otherwise difficult visualization required for pars interarticularis screw placement and allows minimal skin and muscle dissection, which may translate into a more rapid postoperative recovery. Future applications of frameless navigation in the spine may allow such uncommon hardware applications to be both successful and less invasive.</td>
</tr>
<tr>
<td>2 Metz, L, Burch, S; Computer-Assisted Surgical Planning and Image-Guided Navigation in Refractory Adult Scoliosis Surgery. Spine 33(9):E287-E292, 2008</td>
<td><strong>Objective:</strong> In this case report, we present the utility of computer-assisted surgical planning and image-guided surgical navigation in the planning and execution of a major osteotomy to correct severe kyphoscoliosis. <strong>Results:</strong> The osteotomy was safely performed resulting in improved sagittal and coronal alignments, as well as, correction of the sharp kyphoscoliotic deformity at the thoracolumbar junction. At 6-month follow-up, the patient's myelopathy and pain had largely resolved and she expressed high satisfaction with the procedure. <strong>Conclusion:</strong> We advocate this novel application of virtual surgical planning and intraoperative surgical navigation to improve the safety and efficacy of complex spinal deformity corrections.</td>
</tr>
<tr>
<td></td>
<td>Authors</td>
</tr>
<tr>
<td>---</td>
<td>---------</td>
</tr>
<tr>
<td>3</td>
<td>Smith, HE., et al.</td>
</tr>
<tr>
<td>4</td>
<td>Nottmeier, EW. et al.</td>
</tr>
<tr>
<td>5</td>
<td>Bloom, JD, Rizzi, MD, &amp; Germiller, JA.</td>
</tr>
</tbody>
</table>
**Other Radiation Dose Abstracts**  
**Non O-arm® Imaging System, Non Navigation**

<table>
<thead>
<tr>
<th>Peer Reviewed Reference</th>
<th>Objectives / Conclusion Excerpts</th>
</tr>
</thead>
</table>
| Haque BA, Shufflebarger H et al.  
Radiation exposure during pedicle screw placement in adolescent idiopathic scoliosis: Is fluoroscopy safe? Spine 2006 31,(21) 2516-2520 | This article states that the observed radiation exposure levels are higher than the relevant protection standards. It also states that image-guided virtual fluoroscopy has been shown to reduce Fluoro time by approximately 40%. Use this article to demonstrate that by using the O-arm® System and navigation, surgeons can obtain 2D and 3D images which may reduce fluoroscopy time and therefore operative time. |

**Objective:** Lower back pain from spondylolysis historically has been treated with a variety of options ranging from conservative care to open fusion. The authors describe the novel technique of minimally invasive bilateral pars interarticularis screw placement by utilizing intraoperative 3D imaging and frameless navigation in a 17-year-old male athlete. This technique is a modification of the open technique first described in 1970 by Buck and has the advantages of minimal dissection requirements with improved screw trajectory visualization. The patient’s postoperative course is discussed, followed by a brief literature review of pars interarticularis defect treatment. **Conclusions:** We described a modified form of the Buck screw procedure with a minimally invasive, image-guided method of pars interarticularis fixation. The utilization of image guidance simplifies the otherwise difficult visualization required for pars interarticularis screw placement and allows minimal skin and muscle dissection, which may translate into a more rapid postoperative recovery. Future applications of frameless navigation in the spine may allow such uncommon hardware applications to be both successful and less invasive. (copyright) Lippcott & Williams. All rights reserved.


**Objective:** In this case report, we present the utility of computer-assisted surgical planning and image-guided surgical navigation in the planning and execution of a major osteotomy to correct severe kyphoscoliosis. **Summary of Background Data.** Computer-assisted surgical planning is useful to appreciate the three-dimensional nature of scoliotic deformities and allows for operative maneuvers to be simulated on a computer before their implementation in the operating room. Image-guided surgical navigation improves surgical accuracy and can help translate a virtual surgical plan to the operative setting. **Methods:** We report the case of a 38-year-old woman with severe, congenital kyphoscoliosis refractory to many previous surgeries, who presents with moderate progressive myelopathy and severe pain attributable to a sharp angular deformity at T12. Three-dimensional computed tomography reconstruction and computer-assisted surgical planning were used to determine the optimal corrective osteotomy. The surgical plan was translated to the operating room where a posterior vertebrectomy and instrumented correction were executed with the aid of image-guided surgical navigation. **Results:** The osteotomy was safely performed resulting in improved sagittal and coronal alignments, as well as, correction of the sharp kyphoscoliotic deformity at the thoracolumbar junction. At 6-month follow-up, the patient’s myelopathy and pain had largely resolved and she expressed high satisfaction with the procedure. **Conclusion:** We advocate this novel application of virtual surgical planning and intraoperative surgical navigation to improve the safety and efficacy of complex spinal deformity corrections. (copyright) Lippcott & Williams. All rights reserved.

Background/Objective: Little is known about the long-term effects of chronic exposure to ionizing radiation. Studies have shown that spine surgeons may be exposed to significantly more radiation than that observed in surgery on the appendicular skeleton. Computer-assisted image guidance systems have been shown in preliminary studies to enable accurate instrumentation of the spine. Computer-assisted image guidance systems may have significant application to the surgical management of spinal trauma and deformity. The objective of this study was to compare C-arm fluoroscopy and computer-assisted image guidance in terms of radiation exposure to the operative surgeon when placing pedicle screw-rod constructs in cadaver specimens. Methods: Twelve single-level (2 contiguous vertebral bodies) lumbar pedicle screw-rod constructs (48 screws) in 4 fresh cadavers were placed using standard C-arm fluoroscopy and computer-assisted image guidance (Stealth Station with Iso-C3D). Pedicle screw-rod constructs were placed at L1–L2, L3–L4, and L5–S1 in 4 fresh cadaver specimens. Imaging was alternated between C-arm fluoroscopy and computer-assisted image guidance with StealthStation Iso-C3D. Radiation exposure was measured using ring and badge dosimeters to monitor the thyroid, torso, and index finger. Postprocedure CT scans were obtained to judge accuracy of screw placement. Results: Mean radiation exposure to the torso was 4.33 ± 2.66 mRem for procedures performed with standard fluoroscopy and 0.33 ± 0.82 mRem for procedures performed with computer-assisted image guidance. This difference was statistically significant (P = 0.012). Radiation exposure to the index finger and thyroid was negligible for all procedures. The accuracy of screw placement was similar for both techniques. Conclusions: Computer-assisted image guidance systems allow for the safe and accurate placement of pedicle screw-rod constructs with a significant reduction in exposure to ionizing radiation to the torso of the operating surgeon. (copyright) American Paraplegia Society. All rights reserved.


Object.: The goal of this study was to analyze the placement accuracy and complications of thoracolumbar pedicle screws (PSs) inserted using 3D image guidance in a large patient cohort. Methods: The authors reviewed the charts of 220 consecutive patients undergoing posterior spinal fusion using 3D image guidance for instrumentation placement. A total of 1084 thoracolumbar PSs were placed using either the BrainLAB Vector Vision (BrainLAB, Inc.) or Medtronic StealthStation Treon (Medtronic, Inc.) image guidance systems. Postoperative CT scanning was performed in 184 patients, allowing for 951 screws to be graded by an independent radiologist for bone breach. All complications resulting from instrumentation placement were noted. Using the intraoperative planning function of the image-guided system, the largest diameter screw possible in each particular case was placed. The screw diameter of instrumentation placed into the L3–S1 levels was noted. Results: No vascular or visceral complications occurred as a result of screw placement. Two nerve root injuries occurred in 1084 screws placed, resulting in a 0.2% per screw incidence and a 0.9% patient incidence of nerve root injury. Neither nerve root injury was associated with a motor deficit. The breach rate was 7.5%. Grade 1 and minor anterolateral “tip out” breaches accounted for 90% of the total
breaches. Patients undergoing revision surgery accounted for 46% of the patients in this study. Accordingly, 154 screws placed through previous fusion mass could be evaluated using postoperative CT scanning. The breach rate in this specific cohort was 7.8%. A total of 765 PSs were placed into the L3–S1 levels in this study; 546 (71%) of these screws were ≥ 7.5 mm in diameter. No statistical difference in breach rate was noted in PSs placed through revision spinal levels versus nonrevision spinal levels (p =0.499). Additionally, no increase in breach rate was noted with placement of 7.5-mm-diameter screws. Conclusions: Three-dimensional image guidance is a useful adjunct to placement of spinal instrumentation. The complication rate in this study was low, and accurate placement of instrumentation was achieved despite the high percentage of revision surgery cases in our patient population. Additionally, because active fluoroscopy was not used for instrumentation placement, there was minimal to no radiation exposure to the surgeon or operating room staff. (copyright) Lippcott & Williams. All rights reserved.


Objective: Cochlear implantation is increasingly being performed in children with inner ear malformations. In severe cochleovestibular anomalies, such as severe partitioning defects and common cavity dysplasia, positioning of the electrode array can be hazardous, with inadvertent placement into the internal auditory canal (IAC) or carotid canal being well known. We describe a case in which real-time intraoperative computed tomographic scanning was used to help achieve proper electrode positioning in a child with a severe malformation. Patient: Child with common cavity malformations undergoing cochlear implantation. Intervention: Intraoperative computed tomography used during implantation procedure. Main Outcome Measure: Use of technique in determining electrode position. Results: A 10-year-old patient with bilateral common cavity malformations presented with declining performance in a functioning implant placed 7 years earlier. The family elected implantation of the contralateral ear. Via a posterior labyrinthotomy approach, a straight array was placed into the common cavity. Intraoperative computed tomographic scanning was immediately performed on the operating room table, showing that the array was in the IAC. A second attempt with a different insertion angle also resulted in IAC placement. In a third attempt, the electrode was advanced as a loop, grasping the tip through an adjacent second labyrinthotomy. Computed tomography confirmed good position against the outer wall of the cavity. Conclusion: Real-time intraoperative computed tomography is a new technology with many potential applications in surgery. In our patient, it allowed rapid and accurate determination of electrode position and helped achieve ideal placement in a severely malformed inner ear. (copyright) Lippcott & Williams. All rights reserved.
Other Radiation Dose Abstracts
Non-O-arm, Non-navigation

Haque M, Shufflebarger H et al. Radiation exposure during pedicle screw placement in adolescent idiopathic scoliosis: Is fluoroscopy safe? Spine 2006; 31(21); 2516-2520

Study Design. With institutional review board approval, prospective data were collected during fluoroscopically guided pedicle screw placement. Objective. To estimate a surgeon's radiation exposure with all screw constructs during surgery to repair idiopathic scoliosis. Summary of Background Data. To our knowledge, there is no established consensus regarding the safety of radiation exposure during fluoroscopically guided procedures. Methods. A surgeon was outfitted intraoperatively with a thermoluminescent dosimeter to estimate radiation exposure to his whole body and thyroid gland. Results. The index surgeon is projected to receive 13.49 mSv of whole body ionizing radiation and 4.31 mSv of thyroid gland irradiation annually. The National Council on Radiation Protection's current recommendations set lifetime dose equivalent limits for classified workers (radiologists) at 10 mSv per year of life and at 3 mSv for nonclassified workers (spinal surgeons). At the levels estimated, a surgeon beginning his/her career at age 30 years would exceed the lifetime limit for nonclassified workers in less than 10 years. The National Council on Radiation Protection limits the single-year maximum safe dosage to the thyroid to 500 mSv; the yearly exposure estimated here is significantly less. Conclusions. The spinal surgeon's intraoperative radiation exposure may be unacceptable. Spinal surgeons should be considered classified workers and monitored accordingly. Methods to lower radiation dosage seem strongly indicated. (copyright) Lippcott & Williams. All rights reserved.