Clinical Value of Image Guided Surgery for Spinal Procedures
The purpose of this document is to assist in the education of the Spine Navigation industry on the value statement of Spinal Navigation, backed by peer reviewed papers.

Table of Contents

1. Introduction to Image-Guided Surgery
2. Current usage of Spinal Navigation and Intra-operative Imaging
3. Key spine procedures and challenges with traditional surgery
   - Outlines various types of spine procedures, challenges, and corresponding high-level value of image-guided surgery use to the patient, surgeon and provider.
   - Posterior Cervical Fusion – Page 8
   - Posterior Thoracic Fusion – Page 9
   - Posterior Lumbar Fusion – Page 11

4. Cross reference of peer reviewed papers to value statements
5. Abstract summary of peer reviewed papers
6. Appendix – Abstracts of peer reviewed papers

Less revision surgeries
Reduced radiation
Less operative time
Greater accuracy
1 Introduction to Image-Guided Surgery

Since the mid-1970’s, image-guided surgery has emerged as an accepted and clinically appropriate alternative to traditional surgery. Hundreds of articles in the form of case reports, retrospective reviews, clinical studies, and small-scale clinical trials have been published in the peer reviewed medical literature demonstrating collectively that surgical navigation has:

- Revolutionized operating room procedures
- Enhanced pre-operative planning
- Improved intra-operative effectiveness and efficiency
- Increased the speed of post-operative recovery, and
- Improved clinical outcomes

Modern image-guided surgery has been described in the clinical literature using a variety of terms such as "surgical navigation," “computer assisted surgery,” "surgical stimulation,” and “3-D computer surgery,” in this document “surgical navigation” is used to represent these concepts. Using surgical navigation methods, physicians may make more accurate diagnoses before and during surgery. Advanced technologies provide computerized, three-dimensional viewing so physicians and surgical teams can precisely locate and position surgical instruments in the anatomic field and view the results on their visual displays. As a result, procedures are shorter and protocols are improved. Surgical navigation may also be less invasive than traditional surgery as surgeons may be more accurate using technologically advanced devices in place of (or in addition to) the traditional hand-guided, mechanical devices during surgery. This allows for an increased level of patient safety and an overall reduction in patient morbidity. In addition, recent enhancements to surgical navigation technology have enabled new and more minimally invasive procedures to be possible.

Surgical navigation technology has been critical to the success of modern day brain surgery. Doctors from the Department of Neurological Surgery, Radiation Oncology, and Radiation at the University of Pittsburgh and the Center for Image-Guided Neurosurgery reviewed the pre-operative and intra-operative benefits of six surgical navigation technologies used in 7,388 brain operations performed at their institution over a 20-year period (Lee, et al., 2000). The surgical navigation devices surgeons used afforded them far-improved means to three-dimensionally view, navigate through and around, and accurately assess all aspects of anatomical fields in which they would and did work.

Today, the use of surgical navigation in brain surgery is considered to be standard of care. The seamless integration of surgical navigation technologies with other intra-operative technologies such as operating microscopes, neuroendoscopy and intra-operative imaging modalities such as fluoroscopy, CT and MRI, have further enhanced surgical capabilities and improved patient outcomes.

- MRI guided neuronavigation was effective for accurately placing the craniotomy, locating intra-axial lesions, defining the margin of resection involved, and avoiding critical
structures. It has become the standard of care for resection of many intra-axial tumors (Lee, et al., 2000)

The authors commented that decreased brain tumor revision rates and shorter length of stay (LOS) are beneficial to both patients and payers. Reducing the repeat resection rate and morbidity of brain tumor surgery is beneficial to patients as well as physicians, who can treat additional patients in the time normally treating recurrent disease.

Surgical navigation has also created major advances in ENT-related medicine, specifically in sinus and skull-based procedures. Peer-reviewed articles have described surgical navigation surgery as a beneficial technology for successful functional endoscopic sinus surgery (FESS), one of the most frequently performed procedures in otorhinolaryngology.

The risks of intra-operative and post-operative complications with FESS are well-established. The risks of serious injury, including intra-cranial penetration and vision loss, are increased when distorted anatomy, extensive disease, bleeding or previous surgery complicates the surgeon’s work. The narrow confines of the sinonasal area and its close relationship with orbital and intracranial structures leave little room for surgical error. Moreover, FESS has its own set of challenges, including lack of depth perception because of the monocular nature of the endoscope and the inability to visualize surrounding extranasal anatomy (Fred et al., 2002). Although FESS has been associated with a relatively low risk of major complications that ranges from 0.3-3% (Tabaee et al., 2003), a significant number occur every year given the large number of FESS procedures performed (Hemmerdinger et al., 2005). Consequently, surgical navigation surgery as an adjunct to FESS has rapidly become the standard of care in the otolaryngology community (Sindwani, 2005).
2. Current usage of Spinal Navigation and Intra-operative Imaging

Image-guided surgery has evolved from the previous standards of spinal intra-operative navigation – direct visualization, serial radiography, and C-arm fluoroscopy – to become a useful tool in the spine surgeon’s armamentarium. IGS provides simultaneous, multi-planar visualization of spinal anatomy and allows virtually any instrument to be tracked in relation to the displayed anatomy in real time. This can be particularly helpful during instrumentation procedures, when the surgeon places an implant into unexposed or partially exposed spinal structures, such as the vertebral body or pedicle. IGS has improved the accuracy and safety of many of these procedures and thus has become a widely accepted method of intra-operative navigation. Its beneficial effect on spine surgery outcomes is clear, and augments the surgeon’s decision making capability.

Minimal access technologies have become the gold standard in the treatment of pathologic conditions in many surgical disciplines and these principles are being applied increasingly to spine surgery. The goal of Minimal Invasive Surgery, or MIS, is to reduce tissue trauma and approach-related morbidity without compromising the effectiveness of the surgical procedure. The deleterious effects of the extensive muscle stripping and retraction that frequently occur during standard spine procedures have been well documented in the medical literature.[8-13] The potential benefits associated with a minimal access approach include diminished post-operative pain, earlier mobilization, shorter LOS and a faster return to work.

A Spinal Navigation system utilizes an image-guided surgery system coupled with varying imaging modalities. Pre-operative CT images may be used, or intra-operative images such as 2D fluoro images from a c-arm or conebeam CT (cbCT) images from rotational devices such as the O-arm. In all uses, the combined system provides real-time updates of instrument location and trajectory in reference to the operative images. In the use-case of pre-operative CT, the patient is registered (aligned) to the images through a manual method of picking common points on the image and on the patient. In the use-case of intra-operative imaging, the images obtained in the operating room are automatically registered to the patient without any surgeon intervention required.

To a trained, skilled surgeon, the use of pre-operative imaging can be just as efficient as the automatically registered intra-operative imaging, however, for minimally invasive surgery, the inability to touch points requires the use of intra-operative imaging.

Intra-operative imaging is comprised of two modalities, fluoro and cbCT. In fluoro imaging, the images are 2D pictures through the body, typically in the lateral and anterior-posterior (AP) plane, and do not provide an axial image of the vertebral body or pedicles. Newer intra-operative systems
rotate the imaging device around the patient and produce cbCT images which are similar to CT images, allowing visualization of the axial plane. Spine Navigation systems interface with all of the intra-operative system types with automatic registration to increase staff and surgeon efficiency.

MIS has provided game-changing advances in many surgical fields, but spine surgeries lag behind, mostly due to a natural reluctance to change by surgeons. Other resistance has come in the form of objections rising from a perceived limited field of view. Some surgeons are concerned they will lose their typical visual cues during MIS when compared with the anatomical landmarks open surgery provides. This is a valid apprehension for someone who has had limited experience with MIS. In practice, however, the advancements in intra-operative imaging and image-guided surgery (IGS), have virtually eliminated this issue.

Surgical navigation has been used for more than a decade in many surgical circles, and especially in cranial applications for removal of brain tumors. Surgical navigation, in fact, will continue to promote the growth of MIS because it allows surgeons to navigate to a target more accurately and safely. From a results perspective, surgeons need to put MIS on their radar; our goal as surgeons is to enable patients to get back to their normal activities as soon as possible, and MIS has shown its success in achieving this objective time after time.

MIS provides several clear advantages in a variety of procedures, not the least of which is pedicle screw placement. In surgeries correcting deformities like scoliosis, surgeons are able to automatically register patient anatomy and immediately navigate in the spine using proven tools that provide real-time cbCT images, such as the Medtronic O-ARM® Imaging System and StealthStation® Navigation System. Screw placement often requires millimeter-accuracy – a goal regularly achieved utilizing the spectacular images provided by the O-ARM® and StealthStation® System. After screws have been placed, surgeons can now look to the O-ARM® System to check their work while the patient is still in the OR – rather than waiting a day or two for a CT from radiology. The O-ARM® System allows surgeons to view intra-operative scans to verify that nerves have been thoroughly decompressed and pedicle screws have been accurately placed. By utilizing intra-operative imaging and navigation, surgeons may decrease the risk of mal-placed instrumentation, and may reduce radiation exposure to patients and staff – all while enabling MIS techniques.

In conclusion, as intra-operative imaging and navigation technologies continue to improve, minimally invasive surgeries will continue to become easier to perform. Employing modern tools and technology to complete MIS surgeries accurately and safely may lead to improved patient outcomes.
3. Key spine procedures, challenges with traditional surgery

There are several spine procedures where anatomical challenges and/or deficiencies in traditional procedure techniques render these procedures less effective or not possible. In this section, we outline the various types of spine procedures, including posterior cervical fusion, posterior thoracic fusion and posterior lumbar fusion (including revision surgery), challenges, and corresponding high-level value of image-guided surgery use during these procedures to the patient, surgeon and provider.

**Posterior Cervical Fusion** is generally divided into 2 procedures, C1-C2 fusion where the Magerl Technique is used, and posterior fusions of the lower cervical and upper thoracic spine, where pedicle screws are utilized.

- **C1-C2 fusion** is a difficult procedure where a screw is placed down the C2 pedicle, an area which is virtually surrounded by the spinal cord, nerves and the vertebral artery. A deviation by the screw of just a few millimeters can cause severe deficit, or death. Without image-guided surgery, this procedure is performed using 2 C-arms in the field, which guide the surgeon with only 2D fluoroscopic images. The addition of image-guidance and a pre-operative CT or an intra-operative CT (O-ARM), adds axial imaging to be able to view the C2 pedicle. This viewing ability provides value as follows:

  - **Pedicle screws** are typically used in fusion procedures of the high thoracic spine. The anatomy in this area is typically very small pedicles where the spinal cord is very close to the pedicle. Without image-guided surgery, these procedures are performed with C-arms and direct visualization. Without image-guided surgery, laminar hooks are often used instead of pedicle screws. Imaging in this anatomical region may be challenging as the mass of the shoulders in the lateral view can be quite poor due to the absorption of the x-rays. Image-guidance is typically used together with pre-operative CT or intra-operative cbCT in these procedures due to the need to view the fine spinal anatomy.

- In both C1-C2 fusion and high thoracic pedicle screw procedures, the use of image-guided surgery provides the following benefits:
  - **Patient**
    - Better visualization enables a safer, faster procedure and improved accuracy (therefore less revisions)
  - **Surgeon**
    - Better visualization enables a safer, faster procedure and improved accuracy (therefore less revisions)
    - Reduced radiation dose
  - **Provider**
    - Reduced intra-operative time
    - Improved accuracy (therefore less revisions) and higher quality of patient care
Posterior Thoracic Fusion typically utilizes image-guided surgery in two main procedures: trauma, where the vertebral body is fractured and posterior stabilization is required to bridge the fracture; and pediatric and adult deformity, where pedicle screw/rod constructs are utilized to correct the deformity (scoliosis).

- **Spinal trauma** typically results in a fractured vertebral body and a gross instability in the spinal column. The trauma is not isolated to the spine, and often includes other organs and structures. Typically this procedure is performed several days after the initial incident, after the patient is stabilized. During this time the patient must be immobilized to prevent injury (or further injury) to the spinal cord. Typically the adjacent vertebral bodies are not in a normal anatomical position, which makes this procedure demanding and time consuming. With the use of image-guided surgery, using either pre-operative CT (post trauma) or intra-operative cbCT, the surgeon has access to better information than fluoro or direct visualization provide. The additional software tools available via image-guidance allow the surgeon to define and execute his plan for placing pedicle screws in this anatomy.

- In addition to typical trauma procedures, there is a trend to perform **minimally invasive trauma** procedures, placing the screws and rods percutaneously. This technique enables the care center to perform the procedure earlier, with less procedure trauma and blood loss. By enabling surgery earlier, the risk to the patient is reduced. The use of image-guided surgery in minimally invasive trauma procedures helps to enable this emerging technique. The use of image-guided surgery in trauma procedures brings the following value:
  - **Patient**
    - Better visualization enables a safer, faster procedure and improved accuracy (therefore less revisions)
    - Earlier surgery utilizing minimally invasive techniques reduces risk of procedure trauma, blood loss and further spinal cord injury
  - **Surgeon**
    - Better visualization enables a safer, faster procedure and improved accuracy (therefore less revisions) and reduces stress
    - Image-guidance software tools enable easier planning and subsequent achievement of plan
    - Reduced radiation dose
  - **Provider**
    - Improved accuracy (therefore less revisions) and higher quality of patient care
    - Reduced intra-operative time
    - Less patient risk
• **Pediatric and adult deformity** surgery is typically performed when the spinal column is deformed to an extent that it is affecting patient health. Such deformity occurs typically in the thoracic spine, and often extends to the lumbar spine. To correct the deformity, pedicle screws are placed in multiple levels, each vertebral body is released from the adjacent body, the spinal column is straightened, and then held in place with rods while the spine fuses. In this procedure, the spine can be quite deformed from normal anatomy with pedicles at severe angles, distorted pedicles, and very small pedicles.

Image-guided surgery has typically been used with pre-operative CT, and more recently with the accessibility of cbCT. Image-guidance enables the surgeon to view through the pedicles, a view which cannot be obtained with fluoro or direct visualization. Similar to trauma, the value of image-guided surgery in deformity surgery (thoracic and lumbar) is:

- **Patient**
  - Better visualization enables a safer, faster procedure and improved accuracy (therefore less revisions)

- **Surgeon**
  - Better visualization enables a safer, faster procedure and improved accuracy (therefore less revisions) and reduces stress
  - Image-guidance software tools enable easier planning and subsequent achievement of plan

- **Provider**
  - Improved accuracy (therefore less revisions) and higher quality of patient care
  - Reduced intra-operative time
Posterior Lumbar Fusion procedures are the most common instrumented spinal procedure today. Typical procedures are performed as the result of the aging spine, which results in degenerative pathology. Often an active lifestyle can cause injury to the disk structure and also similar degeneration. Posterior lumbar fusions typically entail removing the injured disk, replacing the disk with an interbody fusion device to restore the spacing between the vertebral bodies, and adding a posterior tension band in the form of pedicle screws with connecting rods to add stability while the spine fuses. As in the cervical and thoracic spine, the pedicles are surrounded by the spinal cord and nerve roots, so great care must be taken to place the pedicle screw accurately.

- **Degeneration** of the lumbar spine is typically corrected with the use of interbody fusion devices and pedicle screw/rod constructs as described above. Image-guidance is not commonly used in open procedures as the majority of lumbar pedicles are large, and screws can be placed safely under direct visualization (although in a high percentage of the population, the pedicles of L1 and L2 can be much smaller and present the challenges discussed in the thoracic spine). To gain the visualization necessary, a large wound must be opened, which in itself can be traumatic, and increases the chances of infection. As a result, there is an emerging trend of minimally invasive lumbar fusion surgery to reduce or eliminate the wound.

- **Minimally invasive lumbar fusion** brings new challenges to the spine surgeon. To ensure reduced trauma and infection rates, the surgeon must use increased fluoroscopy for guidance, and has less information than in an open procedure. Increased fluoroscopy use can result in increased radiation exposure to the patient, surgeon and staff, along with higher risk of a misplaced screw. Depending on the mode of use, image-guided surgery provides the surgeon with additional information. When using image-guidance together with a C-arm, the surgeon can view up to four (4) pre-acquired fluoroscopic views of the anatomy simultaneously, rather than the one view which is available when the C-arm is used alone. These views are stored, and as such, radiation exposure is greatly reduced. Further, when using image-guidance with intra-operative imaging (O-ARM), the surgeon is presented with 3D axial information which is not available on a C-arm, and the clinical staff is exposed to minimal radiation. In both modes, the value of image-guidance use in these minimally invasive procedures is as follows:

  - **Patient**
    - Better visualization enables a safer, faster procedure and improved accuracy (therefore less revisions)
  - **Surgeon**
    - Better visualization enables a safer, faster procedure and better decision making
- Faster procedure due to less C-arm manipulation
- Reduced radiation dose
  - **Provider**
    - Improved accuracy (therefore less revisions) and higher quality of patient care
    - Reduced intra-operative time

**Revision** surgeries are the most demanding of the lumbar fusions. In these revision cases, the spine has been previously fused, the anatomy which surgeons use to identify the pedicle has been removed or modified, and a large fusion mass of bone has grown over the entire area. In these cases, as the surgeon has no landmarks, the procedures are much longer and more technically difficult. Image-guidance has facilitated these cases for the past decade. Using either preoperative CT or intra-operative CT, the surgeon has the ability to "see" through the fusion mass to locate the pedicles and anatomy of interest. Without image guidance, the surgeon must painstakingly remove the fusion mass to expose the critical anatomy. In revision cases, image-guidance adds the following value:

  - **Patient** – typically revision patients are having the additional procedure because their previous surgery has failed
    - Better visualization enables the surgeon to "see" more information, thus making the procedure safer
    - Faster procedure as the surgeon can be confident about what is below the fusion mass
    - Reduced radiation dose

  - **Surgeon**
    - Better visualization enables a safer, faster procedure and reduces stress
    - Reduced radiation dose
    - Image-guidance software tools enable easier planning and subsequent achievement of plan

  - **Provider**
    - Reduced intra-operative time
    - Less patient risk
4. Cross reference of 50 peer reviewed papers to value statements

Overall, use of image guidance across cervical, thoracic and lumbar spine procedures provides clinical value to each stakeholder.

- **Patient:**
  - With the use of image-guided surgery, the surgeon is presented with additional information through better visualization, either axial views of the anatomy with pre-operative CT or intra-operative CT (O-ARM), or in the case of fluoroscopic image guidance, multiple live views of the anatomy in up to four fluoroscopic images. This may yield:
    - Greater accuracy with overall better outcomes (less revisions)
      - Ref: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 36, 39, 41, 42, 43, 44, 45, 46, 49
    - Reduced intra-operative time, including less time under anesthesia, which brings better outcomes and lower infection rates.
      - Ref: 5, 21, 23, 40, 41, 43, 44, 45, 46, 47, 48, 49, 50
    - Reduced radiation exposure when compared to using live fluoroscopy to guide the surgeon
      - Ref: 7, 16, 25, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 49

- **Surgeon**
  - With the use of image-guided surgery, the surgeon is presented with additional information through better visualization, either axial views of the anatomy with pre-operative CT or intra-operative CT (O-ARM), or in the case of fluoroscopic image guidance, multiple live views of the anatomy in up to four fluoroscopic images. The additional information, or utilization of stored fluoroscopic views may yield:
    - Greater and more consistent accuracy, resulting in better pedicle screw positioning, less complications and overall better outcomes.
      - Ref: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 36, 39, 41, 42, 43, 44, 45, 46, 49
    - Reduced intra-operative time with a trained surgeon and staff. Time savings is proportional to the difficulty of the surgery - the more difficult the surgery, the more time may be saved by using image-guidance.
      - Ref: 5, 21, 23, 40, 41, 43, 44, 45, 46, 47, 48, 49, 50
    - Reduced radiation exposure when compared to using live fluoroscopy to guide the surgeon
      - Ref: 7, 16, 25, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 49

- **Clinical team**
  - Reduced radiation exposure when compared to using live fluoroscopy to guide the surgeon
    - Ref: 7, 16, 25, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 49

- **Provider**
  - Higher quality of patient care
    - Ref: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 36, 39, 41, 42, 43, 44, 45, 46, 49
  - Reduced intra-operative time, particularly in complex procedures
    - Ref: 5, 21, 23, 40, 41, 43, 44, 45, 46, 47, 48, 49, 50
  - Reduced radiation exposure to the staff when compared to using live fluoroscopy to guide the surgeon
    - Ref: 7, 16, 25, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 49
5. Peer reviewed support of clinical value statements

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 Spinal Navigation systems coupled with intra-operative imaging 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 can be provided as the data is published.

Three specific statements relating to the clinical value of image-guided surgery use in spine procedures are supported by peer-reviewed literature:
1) Greater accuracy, and thus reduced revision surgeries
2) Reduced operative time
3) Reduced radiation exposure

The following tables provide direct excerpts form 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
- **Reduced Operative Time** = Red

<table>
<thead>
<tr>
<th>Greater Accuracy/Reduced Revision</th>
<th>Reduced Radiation Exposure</th>
<th>Reduced Operative Time</th>
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<tr>
<td>Lumbar</td>
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<td>Total</td>
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**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>
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<tr>
<th><strong>Peer-Reviewed References</strong></th>
<th><strong>Objectives/Conclusions Excerpts</strong></th>
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| **Greater Accuracy - Lumbar** | **Clinical evaluation of a computer assisted spine surgical system is presented. For fractures, spondylolisthesis, or pseudarthrosis, comparison between the two groups showed that:**  
  - 4 screws in 52 (8%) vertebrae had incorrect placement with computer assisted technique whereas  
  - 22 screws in 52 (42%) vertebrae had incorrect placement with manual insertion.  
  In patients with scoliosis:  
  - 4 screws in 28(14%) vertebrae had incorrect placement.  
  In all of the patients (132 pedicle screws) there were no neurological complications. Conclusion: These results show that a computer assisted technique is much more accurate and safe than manual insertion. |
  Computer-assisted frameless stereotactic image guidance allows precise preoperative planning and intraoperative localisation of the image. This technique provides a safe and reliable guide for placement of transpedicular screws in the lumbar spine. |
  Three-dimensional (3D) fluoroscopy-based image guidance system using an isocentric C-arm (Iso-C) fluoroscope was shown to be as effective as computed tomography-based systems in guiding the accurate percutaneous placement of lumbar pedicle screws in cadavers. We report a case in which isocentric 3D fluoroscopic images, along with image-guidance software, were used to guide the placement of percutaneous pedicle screws for fusion in a patient with degenerative spondylolisthesis. Results: A postoperative computed tomography scan showed accurate placement of all pedicle screws. The patient experienced an improvement in leg pain with no new neurologic deficits. Conclusions: The present case is the first case to demonstrate the intraoperative use of a 3D fluoroscopy-based image-guidance system for accurate navigation during lumbar pedicle screw placement. |
  To determine the accuracy rate of computerized stereotactic image-guided pedicle screw placement in previously fused lumbar spines. CONCLUSIONS: The accuracy rate of stereotactic image-guided pedicle screw placement into previously fused lumbar spine levels is 96%. Computerized stereotactic image-guidance may have particular application in situations in which posterior element anatomy is altered, such as in the presence of a prior fusion mass. |
  To assess the accuracy of single-time multilevel registration for multilevel pedicle screw placement during image-guided, computer-assisted spine surgery, in the setting of degenerative disorders of the lumbar spine. Results: None |
of the patients involved in this study experienced clinical sequelae of improper pedicle screw placement. The postoperative CT scans showed in 10 patients accurate placement in 55 of the 57 pedicle screws with expansion of the medial wall in two screws. Conclusions: Single-time, multilevel registration may decrease operative time relative to repeated, single-level registrations, without compromising the increased accuracy of pedicle screw placement afforded by this technique in the setting of degenerative disorders of the lumbar spine.


We sought to study the intraoperative accuracy of VF over time and space during lumbar pedicle screw placement in human patients. CONCLUSIONS: Our results suggest that the use of VF is a reliable method of verifying the use of anatomic and/or radiographic landmarks for guidance during lumbar pedicle screw placement.


A surgical simulation study in human cadaver specimens was done to evaluate and compare the accuracy of standard fluoroscopy, computer-assisted fluoroscopic image guidance, and Iso-C3D image guidance in the placement of lumbar intervertebral disk replacements. RESULTS: Intervertebral disk replacements placed using the StealthStation with Iso-C3D were more accurately centered than those placed using the StealthStation with FluoroNav and standard fluoroscopy. Intervertebral disk replacements placed with Iso-C3D and FluoroNav had improved rotational divergence compared with standard fluoroscopy. Iso-C3D and FluoroNav had a smaller interprocedure variance than standard fluoroscopy. Relative to both virtual and standard fluoroscopy, use of the StealthStation with Iso-C3D resulted in improved accuracy in centering the lumbar disk prosthesis in the coronal midline. CONCLUSIONS: The StealthStation with FluoroNav appears to be at least equivalent to standard fluoroscopy and may offer improved accuracy with rotational alignment while minimizing radiation exposure to the surgeon. Surgical guidance systems may offer improved accuracy and less interprocedure variation in the placement of intervertebral disk replacements than standard fluoroscopy.


OBJECTIVES: To compare the accuracy of lumbar total disc arthroplasty placement using an image-guidance system (IGS) with conventional fluoroscopy. CONCLUSION: This is the first clinical study to demonstrate significantly improved accuracy of lumbar total disc arthroplasty placement on CT using IGS compared with conventional fluoroscopy. IGS should be considered for routine use with lumbar total disc arthroscopy insertion.

Greater Accuracy - Thoracic

9 Merloz, P. Tonetti J et al; Pedicle Screw Placement Using Image Guided Techniques; Clinical Orthopaedics &

Clinical evaluation of a computer assisted spine surgical system is presented. For fractures, spondylolisthesis, or pseudarthrosis, comparison between the two groups
### Related Research

**354:39-48, September 1998.**

- **4 screws in 52 (8%) vertebrae had incorrect placement with computer assisted technique whereas**
- **22 screws in 52 (42%) vertebrae had incorrect placement with manual insertion.**

In patients with scoliosis:
- **4 screws in 28(14%) vertebrae had incorrect placement.**

In all of the patients (132 pedicle screws) there were no neurological complications. **Conclusion:** These results show that a computer assisted technique is much more accurate and safe than manual insertion.

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<th>Title</th>
<th>Details</th>
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<tr>
<td>10</td>
<td>Youkilis AS, Quint DJ, et al; Stereotactic navigation for placement of pedicle screws in the thoracic spine. Neurosurgery. 2001: April.</td>
<td>The goal of this study is to evaluate the accuracy of thoracic pedicle screw placement by use of image-guided techniques. <strong>CONCLUSION:</strong> The low rate of cortical perforations (8.5%) and structurally significant violations (2.2%) in this retrospective series compares favorably with previously published results that used anatomic landmarks and intraoperative fluoroscopy. This study provides further evidence that stereotactic placement of pedicle screws can be performed safely and effectively at all levels of the thoracic spine.</td>
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<td>12</td>
<td>John PS, et al. A novel computer-assisted technique for pedicle screw insertion. The international journal of medical robotics + computer assisted surgery : MRCAS 2007; 3:59-63.</td>
<td>The advantage of the great accuracy of computer-assisted systems for pedicle screw insertion makes them highly desirable and essential for current spinal surgeries. <strong>CONCLUSIONS:</strong> The cadaveric study supports the view that computer-assisted pedicle screw fixation using the newly developed software is superior to the conventional fluoroscopic method, especially with regard to the thoracic spine, where a higher degree of accuracy is needed.</td>
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<tr>
<td>13</td>
<td>Kim JM, Bowers AL, Chin KR. Intraoperative Imaging Techniques in Spine Surgery. Seminars in Spine Surgery 2007; 19:78-86.</td>
<td>With recent advances in imaging technologies, such as computed tomography-based image guidance and isocentric C-arm fluoroscopy, surgeons are now able to visualize hidden pedicles and reduce screw misplacement. Using these various navigation systems, the rate of pedicle screw perforation can be decreased to less than 10% and potentially eliminate clinically significant complications and revision surgeries.</td>
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<td>14</td>
<td>Lekovic GP, et al. A comparison of two techniques in image-guided thoracic pedicle screw placement: A retrospective study of 37 patients and 277 pedicle screws. Journal of Neurosurgery: Spine 2007; 7:393-8.</td>
<td><strong>Objective:</strong> The goal of this study was to compare the accuracy of thoracic pedicle screw placement aided by two different image-guidance modalities. <strong>Conclusions.</strong> The authors have shown that either image-guidance system may be used with a high degree of accuracy and safety.</td>
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<td>15</td>
<td>Li Q, et al. Percutaneous pedicle screw</td>
<td><strong>Objective:</strong> To assess the therapeutic effects of thoracic-pedicle...</td>
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The aim of the current paper is to describe a computer-assisted surgical navigation system based on fluoroscopic X-ray image calibration and three-dimensional optical localizers in order to reduce radiation exposure while increasing accuracy and reliability of the surgical procedure for pedicle screw insertion. Evaluation of screw placement in every case was done by using plain X-rays and post-operative computer tomography scan. A 5 per cent cortex penetration (7 of 140 pedicle screws) occurred for the computer-assisted group. A 13 per cent penetration (18 of 138 pedicle screws) occurred for the non-computer-assisted group.


OBJECTIVE. To report on the efficacy of Iso-C 3-dimensional intraoperative spinal navigation in excising osteoid osteomas. CONCLUSION. Intraoperative Iso-C 3-dimensional navigation is useful in accurately localizing and guiding complete excision of spinal osteoid osteomas through a minimally invasive approach without compromising spinal stability.


OBJECTIVE. Assess the clinical accuracy of computer-assisted fluoroscopy for the placement of thoracolumbar pedicle screws through a mature posterolateral fusion mass. CONCLUSIONS. The use of computer-assisted fluoroscopy is safe and effective for the placement of thoracolumbar (T10-S1) pedicle screws through a posterolateral fusion mass without performing laminoforaminotomies.

Greater Accuracy - Cervical


She underwent pedicle screw fixation at C-6, C-7, and T-1 for stabilization of the spinal column. A neuronavigation system was used to obtain accurate placement of the pedicle screws. The patient recovered well without further neurological compromise.


Objectives: Also, to evaluate if accuracy and safety of [cervical] pedicle screw placement can be improved using a computer-assisted surgery (CAS) system. Conclusions: The CAS system leads to significantly reduced screw misplacement rates. Therefore, because of the potential risk of injury to the vertebral artery and neural elements, the use of a CAS system seems to be beneficial, especially for pedicle instrumentation C3-C6.


With recent advances in imaging technologies, such as computed tomography-based image guidance and isocentric C-arm fluoroscopy, surgeons are now able to
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<td>Surgery 2007; 19:78-86.</td>
<td>visualize hidden pedicles and reduce screw misplacement. Using these various navigation systems, the rate of pedicle screw perforation can be decreased to less than 10% and potentially eliminate clinically significant complications and revision surgeries.</td>
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<td>Nottmeier EW, Foy AB.; Placement of C2 laminar screws using three-dimensional fluoroscopy-based image guidance. Eur Spine J (2008) 17:610-615</td>
<td>Overall, fifteen C2 laminar screws were placed. There were no complications in any of the patients.</td>
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<td>Bostelmann R, Benini A. Computer-navigated pedicle screw insertion in the lumbar spine. Operative Orthopadie und Traumatologie 2005; 17:178-94.</td>
<td>Objective: Decrease of surgical risks in transpedicular, lumbar spondylodesis by insertion of screws into the pedicle under continuous visual control of the screw channel in the sagittal, axial, and orthogonal planes in relation to the direction of screw insertion. Results: No complications were observed and no revision became necessary.</td>
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<td>Ohnsorge JAK, et al. Minimally-invasive computer-assisted fluoroscopic navigation for kyphoplasty. Zeitschrift fur Orthopadie und Ihre Grenzgebiete 2005; 143:195-203.</td>
<td>Aim: The transpedicular placement of a hollow needle into vertebral bodies for kyphoplasty requires utmost accuracy and thereby permanent multiplanar X-ray control. Facing the increasing number of vertebral compression fractures, the aim of this work was the implementation of computer-assistance to optimise the issue. Results: Planning and navigation could be executed with high accuracy. Conclusion: In challenging cases of deteriorated anatomy and difficult radiomorphologic orientation, especially of the lower thoracic spine, the CAOS-procedure succeeds in finding the optimal pedicular approach to the vertebral body, helps to avoid collateral damage and minimises the overall risk of the procedure. High accuracy and reduced radiation exposure justify the clinical use of fluoroscopic navigation for transpedicular instrumentation.</td>
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<td>Sasso R et al. Percutaneous computer-assisted translaminar facet screw: an initial human cadaveric study. The Spine Journal 2005; 5:515-519.</td>
<td>OBJECTIVE: This study evaluates the percutaneous placement of translaminar facet screws with the use of virtual fluoroscopy as an image guidance technique. CONCLUSIONS: Virtual fluoroscopy provides significant assistance in percutaneous placement of translaminar facet screws and results in safe position of entry, lamina course, and terminus.</td>
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<td>Seller K, et al. Prospective screw misplacement analysis after conventional and navigated pedicle</td>
<td>BACKROUND: The aim of this prospective study was (1) to evaluate the accuracy of pedicle screw placement using Computer - Assisted Orthopedic - Surgery (CAOS) in</td>
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<td>Holly LT. Image-guided spinal surgery. International Journal of Medical Robotics and Computer Assisted Surgery 2006; 2:7-15.</td>
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<td>30</td>
<td>Day AC, Stott PM, Boden RA. The accuracy of computer-assisted percutaneous iliosacral screw placement. Clinical Orthopaedics and Related Research 2007; :179-86.</td>
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<td>31</td>
<td>Holly LT, Foley KT. Image Guidance in Spine Surgery. Orthopedic Clinics of North America 2007; 38:451-61.</td>
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<td>Kim JM, Bowers AL, Chin KR. Intraoperative Imaging Techniques in Spine Surgery. Seminars in Spine Surgery 2007; 19:78-86.</td>
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<td>Kotani Y, et al. Accuracy analysis of pedicle screw placement in posterior scoliosis surgery: Comparison between conventional fluoroscopic and computer-assisted technique. Spine 2007; 32:1543-50.</td>
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<td>34</td>
<td>Rajasekaran S, Kamath V, Shetty AP. Intraoperative Iso-C three-dimensional navigation in excision of spinal osteoid osteomas. Spine 2008; 33:E25-E29.</td>
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35 Tjardes T, et. al; Computer assisted percutaneous placement of augmented iliosacral screws: a reasonable alternative to sacroplasty. SPINE Volume 33

RESULTS: The procedure, especially fluoroscopic visualization and navigation of the osteoporotic sacrum is technically feasible. A total radiograph time of 7.4 minutes, including image acquisition for navigation and fluoroscopic control of cement injection, is acceptable and can be expected to be significantly reduced with repeated applications of the procedure.


OBJECT: The goal of this study was to compare the accuracy of thoracic pedicle screw placement aided by two different image-guidance modalities. RESULTS: The rate of unintended perforations was found to depend on pedicle diameter (p < 0.0001). There were no statistical differences between groups with regard to rate or grade of cortical perforations. Overall, the rate and grade of perforations was low, and there were no neurological or vascular complications. CONCLUSIONS: The authors have shown that either image-guidance system may be used with a high degree of accuracy and safety. Because both systems were found to be comparably safe


Study Design. Comparison of the radiation dose between the traditional fluoroscopic approach and computed tomography (CT)-based computer-assisted surgery for pedicle screw placement was determined. Objectives. To evaluate the radiation dose delivered by fluoroscopy-controlled pedicle screw placement versus insertion guided by computer. Conclusions. Percutaneous pedicle screw insertion in the lumbar region of the spine, performed using fluoroscopic control, requires a lower radiation dose than do CT scans necessary for computer-assisted surgery. The CT radiation dose can be significantly decreased by optimization of the scanner settings for computer-assisted surgery. The advantages of computer-assisted surgery justify CT scans, when based on correctly chosen indications.


Aim: Goal of the current study was to compare radiation dose and fluoroscopy time of fluoroscopic computer assisted pedicle screw implantation versus the conventional technique. Conclusion: We achieved significantly lower radiation dose and fluoroscopy time with fluoroscopic computer assisted pedicle screw implantation compared with the conventional technique. Concerning exposure to radiation for patients and personnels fluoroscopic navigated screw insertion is to favour.


Aim: The transpedicular placement of a hollow needle into vertebral bodies for kyphoplasty requires utmost accuracy and thereby permanent multiplanar X-ray control. Facing the increasing number of vertebral compression fractures, the aim of this work was the implementation of computer-assistance to optimise the issue. Results: Radiation exposure could be reduced through computer assistance
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<th>Authors</th>
<th>Title</th>
<th>Publication</th>
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<td>40</td>
<td>Gebhard FT, et al.</td>
<td>Does computer-assisted spine surgery reduce intraoperative radiation doses?</td>
<td>Spine 2006; 31:2024-7.</td>
<td>OBJECTIVE. The aim of the study was to quantify the radiation doses during spine surgery in different types of computer-assisted surgical procedures (i.e., computerized tomography [CT] based and C-arm) compared to standard methods and, as a new technique, the Iso-C C-arm (Siemens, GER). METHODS: Despite the small number of patients, the existing results up until now showed a clear reduction of the duration of radiation time using CAS compared to standard methods in spine surgery. RESULTS. The duration of radiation was reduced from 177 seconds in the standard spine procedure to 75 seconds in CT-based CAS spine intervention. Comparing the different types of CAS application at the spine, the Iso-C C-arm based surgery is the method with the lowest duration of radiation. The radiation doses at the C-arm tube (source) are reduced from a median of 1091 mGy in the standard procedure versus 432 mGy in CT-based and 664 mGy in C-arm based guided surgery. In this study, the median dose of an Iso-C C-arm was 152 mGy.</td>
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<td>41</td>
<td>Smith HE, et al.</td>
<td>The use of computerized image guidance in lumbar disk arthroplasty.</td>
<td>Journal of spinal disorders &amp; techniques 19[1], 22-7. 2006.</td>
<td>CONCLUSIONS: The StealthStation with FluoroNav appears to be at least equivalent to standard fluoroscopy and may offer improved accuracy with rotational alignment while minimizing radiation exposure to the surgeon.</td>
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<td>42</td>
<td>Merloz P, et al.</td>
<td>Fluoroscopy-based navigation system in spine surgery.</td>
<td>Proceedings of the Institution of Mechanical Engineers.Part H, Journal of engineering in medicine 2007; 221:813-20.</td>
<td>The aim of the current paper is to describe a computer-assisted surgical navigation system based on fluoroscopic X-ray image calibration and three-dimensional optical localizers in order to reduce radiation exposure while increasing accuracy and reliability of the surgical procedure for pedicle screw insertion. The radiation running time for each vertebra level (two screws) reached 3.5 s on average in the computer-assisted group and 11.5 s on average in the non computer-assisted group. The fluoroscopy-based (two-dimensional) navigation system for pedicle screw insertion is a safe and reliable procedure for surgery in the lower thoracic and lumbar spine.</td>
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<td>43</td>
<td>Rajasekaran S, Vidyadhara S, Shetty AP.</td>
<td>Iso-C3D fluoroscopy-based navigation in direct pedicle screw fixation of hangman fracture: A case report.</td>
<td>Journal of Spinal Disorders and Techniques 2007; 20:616-9.</td>
<td>The 2 groups were compared for accuracy of screw placement, time for screw insertion, and the number of times the C-arm had to be brought into the field. The C-arm had to be moved into the operation field on an average of 1.5 _ 0.25 times (range 1–3) per screw. With single screening data, an average of 11.4 pedicles (range 9–14) could be visualized without necessity to bring the C-arm into operating field again. Conclusions. Iso-C navigation increases accuracy, and reduces surgical time and radiation in thoracic deformity correction surgeries.</td>
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<td>44</td>
<td>Sasso RC, Garrido BJ.</td>
<td>Computer-assisted spinal navigation versus serial</td>
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<td>OBJECTIVE: To review the operative time differences between computer-assisted spinal navigation versus serial</td>
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<td>45 Kim C et al.</td>
<td>Use of Navigation-assisted Fluoroscopy to Decrease Radiation Exposure during Minimally Invasive Surgery</td>
<td>However, limited views of the surgical field require extensive use of intraoperative fluoroscopy that may expose the surgical team to higher levels of ionizing radiation. The total fluoroscopy time was higher for the FLUORO group compared with the NAV group (41.9 seconds vs. 28.7 seconds, p=0.042). Radiation exposure was undetectable when navigation-assisted fluoroscopy is used (NAV group). In contrast, an average 12.4 mRem of radiation exposure is delivered to the surgeon during unilateral MIS TLIF procedure without navigation (FLUORO group). No statistically significant differences are noted for operating time, estimated blood loss, or hospital stay. No inadvertent durotomies, postoperative weakness, or new radiculopathy were noted in the NAV group. CONCLUSION: The use of navigation-assisted fluoroscopy is feasible and safe for minimally invasive spine surgery. Radiation exposure is decreased to the patient as well as the surgical team.</td>
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**Reduced Operative Time**

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<td>46 Ohnsorge JAK, et al.</td>
<td>Minimally-invasive computer-assisted fluoroscopic navigation for kyphoplasty. Zeitschrift fur Orthopadie und Ihre Grenzgebiete 2005; 143:195-203.</td>
<td>Aim: The transpedicular placement of a hollow needle into vertebral bodies for kyphoplasty requires utmost accuracy and thereby permanent multiplanar X-ray control. Facing the increasing number of vertebral compression fractures, the aim of this work was the implementation of computer-assistance to optimise the issue. Results: … the pure operating time thereby decreased by 40%.</td>
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<td>48 Li Q, et al.</td>
<td>Percutaneous pedicle screw fixation in thoracic-lumbar fracture using mini-invasive pedicle screw system guided by navigation. National Medical Journal of China 2007; 87:1339-41.</td>
<td>The surgical time of the sextant group was 2.1 (plus or minus) 0.4 hr, significantly shorter than that of the conventional pedicle screw fixation group (2.7 (plus or minus) 0.7, P &lt; 0.05).</td>
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<td>49 Rajasekaran S, Vidyadhara S et al;</td>
<td>Randomized clinical study to compare the accuracy of navigated and non-navigated thoracic pedicle screws in deformity correction surgeries; SPINE 2007; Vol 32, No 2.</td>
<td>The 2 groups were compared for accuracy of screw placement, time for screw insertion, and the number of times the C-arm had to be brought into the field. Average screw insertion time in the non-navigation group was 4.61 ± 1.05 minutes (range 1.8–6.5) compared to 2.37 ± 0.72 minutes (range 1.16–4.5) in navigation group (P &lt; 0.01). Conclusions. Iso-C navigation increases accuracy, and reduces surgical time and radiation in thoracic deformity correction surgeries.</td>
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<td>50 Sasso RC, Garrido BJ.</td>
<td>Computer-</td>
<td>OBJECTIVE: To review the operative time differences</td>
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assisted spinal navigation versus serial radiography and operative time for posterior spinal fusion at L5-S1. Journal of Spinal Disorders and Techniques 2007; 20:118-22.

between computer-assisted spinal navigation versus serial radiography. RESULTS: Computer-assisted image-guided spine surgery has overall demonstrated shorter mean operative times when compared with intraoperative serial radiography technique; an average of 40 minutes less per case (P<0.001). There is also less variation in operative times using image guidance… Lastly, in an attempt to minimize such a confounding factor as a learning curve, the last 20 cases in each group were compared. There was an average difference of about 22 minutes less for the image guidance group. CONCLUSIONS: In the best scenario, image navigation saved a statistically significant (P<0.001) amount of time in the operating room.
5. Appendix – Abstracts Referenced in This Document

Note: The following citations are arranged alphabetically by citation author.

Abstract: Background context: Three-dimensional (3D) fluoroscopy-based image guidance system using an isocentric C-arm (Iso-C) fluoroscope was shown to be as effective as computed tomography-based systems in guiding the accurate percutaneous placement of lumbar pedicle screws in cadavers. To date, however, no description is available of the intraoperative use of 3D fluoroscopy to guide lumbar pedicle screw placement in an actual spinal fusion procedure. Purpose: We report a case in which isocentric 3D fluoroscopic images, along with image-guidance software, were used to guide the placement of percutaneous pedicle screws for fusion in a patient with degenerative spondylolisthesis. Study design/setting: Operating room of a large academic medical center during the placement of percutaneous pedicle screws in a patient with degenerative spondylolisthesis. Methods: A percutaneous dynamic reference array was attached to the L3 spinous process. A satisfactory image set was obtained and automatically registered. The L4 and L5 pedicles were localized, and pedicle holes were then cannulated, drilled and tapped. A screw was then inserted using the Sextant system for percutaneous pedicle screws. In this manner, bilateral pedicle screws were inserted into the L4-L5 pedicles. All steps of pedicle cannulation were performed under Iso-C 3D image guidance. Results: A postoperative computed tomography scan showed accurate placement of all pedicle screws. The patient experienced an improvement in leg pain with no new neurologic deficits. Conclusions: The present case is the first case to demonstrate the intraoperative use of a 3D fluoroscopy-based image-guidance system for accurate navigation during lumbar pedicle screw placement. (copyright) 2005 Elsevier Inc. All rights reserved.

Abstract: Objective: Decrease of surgical risks in transpedicular, lumbar spondylodesis by insertion of screws into the pedicle under continuous visual control of the screw channel in the sagittal, axial, and orthogonal planes in relation to the direction of screw insertion. Indications: All indications of a transpedicular lumbar spondylodesis performed for intervertebral instability, spinal stenosis, or displacement of vertebrae secondary to degenerative diseases. Contraindications: Previous surgery that does not permit the obligatory intraoperative matching. Usual contraindications for lumbar spondylodesis. Spondylolyses, as they rarely allow a satisfactory result of matching due to the mobility in the vertebral segment. Surgical Technique: Preoperative multi-slice computed tomography (CT). Intraoperative matching of real and virtual views. On the monitor the instruments are controlled visually in their relation to the lumbar spine in almost real time. Opening of pedicles and insertion of screws. Only thereafter, treatment of the pathologic conditions either by decompression or realignment of the spine. Results: Between July 2000 and February 2002 this system was selected for 109 patients. No complications were observed and no revision became necessary. The screw length varied between 35 and 50 mm; the length of the screws does not affect the procedure. Intra- and postoperative radiographs (anteroposterior and lateral) were done in every patient. The first 48 patients underwent CT control that confirmed the optimal intrapedicular and intravertebral screw position. Thereafter, these controls were omitted for cost-saving. (copyright) Urban & Vogel Muchen 2005

Abstract: The benchmark fluoroscopic technique of iliosacral screw insertion is disadvantaged by its reliance on ionizing radiation and presentation of dynamic information in only one plane. Multiplane targeting requires interpolation, which may be associated with inherent errors. Computer-assisted surgery enables surgeons to monitor their screw trajectory in 3-D space. The clinical application of computer-assisted surgery requires validation of its accuracy when tested against a benchmark technique. We simulated surgical implantation of cannulated screws in 10 embalmed human cadavers. Two specimens had sacral dysplasia. We inserted 20 screws into the S1 body, the left side by the benchmark fluoroscopic technique and the right side by a fluoroscopically registered computer-assisted surgery technique. All specimens were intact with no simulated injuries. A postoperative high-definition computed tomography scan showed the screw track. The actual track was compared with the intended screw track by a graphical technique. There was no deviation from the intended screw path in any of the simulated screw paths. With both techniques, two of the 10 tracks penetrated the sacral cortex in dysplastic pelvices. A fluoroscopic computer-assisted surgery technique appears as accurate as the standard fluoroscopic technique but no more so. Caution is recommended in dysplastic pelvices. (copyright) 2007 Lippincott Williams & Wilkins, Inc.


Abstract: STUDY DESIGN. Prospective clinical study. OBJECTIVE. Computer-assisted surgery (CAS) means improved accuracy in inserting screws. Usually the required time of the intraoperative use of a C-arm device is reduced. The aim of the study was to quantify the radiation doses during spine surgery in different types of computer-assisted surgical procedures (i.e., computerized tomography [CT] based and C-arm) compared to standard methods and, as a new technique, the Iso-C C-arm (Siemens, GER). SUMMARY OF BACKGROUND DATA. A total of 38 individuals were enrolled in the study, including 8 who underwent standard spine surgery, 10 with CT-based, 9 with C-arm based, and 11 with Iso-C C-arm based. The thermoluminescence dosimetry measurements were 2 at the radiation source, 2 at the patient, and 2 at the receiver. METHODS. This study is based on the thermoluminescence method. A total of 38 individuals were enrolled in the study. Despite the small number of patients, the existing results up until now showed a clear reduction of the duration of radiation time using CAS compared to standard methods in spine surgery. Much more important is the fact that the radiation doses were clearly reduced from a median of 1091 mGy using the standard procedure versus 432 mGy in CT-based and 664 mGy in C-arm based guided surgery. The Iso-C C-arm showed a median of 152 mGy. RESULTS. The duration of radiation was reduced from 177 seconds in the standard spine procedure to 75 seconds in CT-based CAS spine intervention. Comparing the different types of CAS application at the spine, the Iso-C C-arm based surgery is the method with the lowest duration of radiation. The radiation doses at the C-arm tube (source) are reduced from a median of 1091 mGy in the standard procedure versus 432 mGy in CT-based and 664 mGy in C-arm based guided surgery. In this study, the median dose of an Iso-C C-arm was 152 mGy. CONCLUSION. These findings are important for the operating room personnel, which is exposed daily to radiation intraoperatively, as well as the patients, when using CAS procedures. (copyright)2006, Lippincott Williams & Wilkins, Inc

Girardi FP, Cammisa FP Jr, et al; The placement of lumbar pedicle screws using computerised stereotactic guidance. J Bone Joint Surg Br. 1999 Sep; (PubMed) Computer-assisted frameless stereotactic image guidance allows precise preoperative planning and intraoperative localisation of the image. A total of 62 patients (28 men, 34 women) had lumbar decompression and spinal fusion with segmental pedicle screws. Postoperative CT scans were
taken of 35 patients to investigate the placement of 330 screws. None showed penetration of the medial or inferior wall of a pedicle. Registration was carried out 66 times. The number of standard points used on each registration averaged 5.8 (4 to 7) The mean registration error was 0.75 mm (0.32 to 1.72). This technique provides a safe and reliable guide for placement of transpedicular screws in the lumbar spine.


Abstract: **Background:** The purpose of this review is to present a comprehensive summary of commonly used methods of spinal image guidance, including the benefits and limitations of this novel technology. **Methods:** The relevant medical literature was examined, supplemented by the author's laboratory and clinical experience with image-guided spinal surgery. **Results:** Spinal image guidance has undergone significant evolution and rapid technological advancement in recent years. Image guidance provides three-dimensional visualization of the spine that can be used for preoperative planning and intraoperative navigation. There are three commonly used methods of spinal image guidance: preoperative CT-based, fluoroscopy-based, and 3D fluoroscopy. Each of these methods demonstrates lower rates of spinal implant misplacement than non-image-guided techniques. **Conclusions:** Image guidance provides highly accurate intraoperative navigation and the medical literature suggests that this technology increases the safety of a variety of routine and complex spinal procedures. Copyright (copyright) 2006 John Wiley & Sons, Ltd


Abstract: Computer image guidance is one of the most significant recent technologic advancements in the field of spine surgery, because preoperative or intraoperative images can be used for multiplanar, three-dimensional intraoperative navigation. Laboratory and clinical studies have demonstrated that image guidance increases the safety and accuracy of a variety of spinal procedures (see sub-references below). This article describes the application of intraoperative image guidance to spinal surgery, with a particular focus on minimal access procedures. Although commonly performed separately, these techniques can work in a complementary fashion. The apparent benefits and limitations of the various image-guided modalities are described. (copyright) 2007 Elsevier Inc. All rights reserved.

**Papers relating to increased accuracy of IGS as referenced by Holly et al:**


Abstract: BACKGROUND: Commercialey available systems for computer-assisted pedicle screw placement are prohibitively expensive, even in advanced countries. The advantage of the great accuracy of computer-assisted systems for pedicle screw insertion makes them highly desirable and essential for current spinal surgeries. METHODS: We have tried to develop a new software for pedicle screw placement, based on paired point matching. RESULTS: The newly developed software is much less expensive and is an excellent educational tool. Its accuracy has been established by a cadaveric study, described in this paper. CONCLUSIONS: The cadaveric study supports the view that computer-assisted pedicle screw fixation using the newly developed software is superior to the conventional fluoroscopic method, especially with regard to the thoracic spine, where a higher degree of accuracy is needed. Further clinical studies are planned and the software needs further refinement for complex clinical situations. Copyright 2006 John Wiley & Sons, Ltd

Abstract: STUDY DESIGN: Retrospective clinical and intraoperative navigational data review. OBJECTIVE: To evaluate quantitatively the application of frameless stereotactic image guidance in thoracoscopic discectomy procedures. SUMMARY OF BACKGROUND DATA: Thoracoscopic spinal surgery has technical and anatomic challenges that result in difficult orientation with a 2-dimensional imaging procedure in a complex 3-dimensional structure. METHODS: There were 16 patients who underwent image-guided thoracoscopic discectomy procedures that combine these 2 technologies. Accuracy was determined by the registration (calculated) error and actual navigation (intraoperative) error. The clinical outcomes and complications were reviewed. RESULTS: Accuracy determined by registration (calculated) and navigation (intraoperative) was 1.7 and 1.2 mm, respectively. The additional time required for the image guidance portion of the procedure was countered by the efficiency of the remaining procedure. Clinical outcomes and complication were comparable with previous experience. CONCLUSIONS: Image-guided thoracoscopic spinal surgery can provide 3-dimensional orientation to a 2-dimensional imaging procedure that ultimately improves accuracy, efficiency, and safety. Future developments in combining guidance technology with standard surgical procedures will likely continue

Abstract: The conventional method of inserting pedicle screws (ie, plain radiography, standard 2D fluoroscopy, direct palpation) was found to be less accurate with cortical violation ranging from 10 to 50%. Small and variable anatomy of the cervical and thoracic spine poses a particular challenge, and it can lead to a devastating neurovascular complication. With recent advances in imaging technologies, such as computed tomography-based image guidance and isocentric C-arm fluoroscopy, surgeons are now able to visualize hidden pedicles and reduce screw misplacement.
Using these various navigation systems, the rate of pedicle screw perforation can be decreased to less than 10% and potentially eliminate clinically significant complications and revision surgeries. (copyright) 2007 Elsevier Inc. All rights reserved.

Abstract: STUDY DESIGN. The accuracy of pedicle screw placement was evaluated in posterior scoliosis surgeries with or without the use of computer-assisted surgical techniques. OBJECTIVE. In this retrospective cohort study, the pedicle screw placement accuracy in posterior scoliosis surgery was compared between conventional fluoroscopic and computer-assisted surgical techniques. SUMMARY OF BACKGROUND DATA. There has been no study systematically analyzing the perforation pattern and comparative accuracy of pedicle screw placement in posterior scoliosis surgery. METHODS. The 45 patients who received posterior correction surgeries were divided into 2 groups: Group C, manual control (25 patients); and Group N, navigation surgery (20 patients). The average Cobb angles were 73.7(degrees) and 73.1(degrees) before surgery in Group C and Group N, respectively. Using CT images, vertebral rotation, pedicle axes as measured to anteroposterior sacral axis and vertebral axis, and insertion angle error were measured. In perforation cases, the angular tendency, insertion point, and length abnormality were evaluated. RESULTS. The perforation was observed in 11% of Group C and 1.8% in Group N. In Group C, medial perforations of left screws were demonstrated in 8 of 9 perforated screws and 55% were distributed either in L1 or T12. The perforation consistently occurred in pedicles in which those axes approached anteroposterior sacral axis within 5(degrees). The average insertion errors were 8.4(degrees) and 5.0(degrees) in Group C and Group N, respectively, which were significantly different (P < 0.02). CONCLUSION. The medial perforation in Group C occurred around L1, especially when pedicle axis approached anteroposterior sacral axis. This consistent tendency was considered as the limitation of fluoroscopic screw insertion in which horizontal vertebral image was not visible. The use of surgical navigation system successfully reduced the perforation rate and insertion angle errors, demonstrating the clear advantage in safe and accurate pedicle screw placement of scoliosis surgery. (copyright) 2007 Lippincott Williams & Wilkins, Inc.

Abstract: Objective: The goal of this study was to compare the accuracy of thoracic pedicle screw placement aided by two different image-guidance modalities. Methods. The charts of 40 consecutive patients who had undergone stabilization of the thoracic spine between January 2003 and January 2005 were retrospectively reviewed. Three patients were excluded from the study because, on the basis of preoperative findings, small pedicle diameter precluded the use of pedicle screws. Thus, a total of 37 patients had 277 screws placed with the aid of either virtual fluoroscopy or isocentric C-arm 3D navigation. The indications for surgery included trauma, degenerative disease, and tumor, and were similar in both groups. All 37 patients underwent postoperative computed tomography scanning, and an independent reviewer graded all screws based on axial, sagittal, and coronal projections for a full determination of the placement of the screw in the pedicle. Results. The rate of unintended perforations was found to depend on pedicle diameter (p < 0.0001). There were no statistical differences between groups with regard to rate or grade of cortical perforations. Overall, the rate and grade of perforations was low, and there were no neurological or vascular complications. Conclusions. The authors have shown that either image-guidance system may be used with a high degree of accuracy and safety. Because both systems were found to be
comparably safe and accurate, the choice of image-guidance modality may be determined by the level of surgeon comfort and/or availability of the system.

Abstract: Objective: To assess the therapeutic effects of thoracic-lumbar fracture fixation with percutaneous mini-invasive pedicle screw system guided by computer navigation. Method: Fifty-one thoracic-lumbar fracture patients were divided into two groups: Sextant group (n = 21) undergoing percutaneous screw fixation with a minimally invasive pedicle screw system, and conventional pedicle screw fixation group (n = 30). The differences in the incision size, average blood loss during operation, surgical time, time of resuming walking after operation, numerical analogous pain score, etc. were analyzed. Results: The incision length of the sextant group was 2.4 (plus or minus) 0.41 cm, significantly shorter than that of the conventional pedicle screw fixation group (17.4 (plus or minus) 3.4 cm, P < 0.001). The average blood loss during operation of the sextant group was 114 (plus or minus) 67.4 ml, significantly less than that of the conventional pedicle screw fixation group (317 (plus or minus) 113.2 ml,P <0.001). The surgical time of the sextant group was 2.1 (plus or minus) 0.4 hr, significantly shorter than that of the conventional pedicle screw fixation group (2.7 (plus or minus) 0.7, P < 0.05). The time of resuming walking after operation of the sextant group was 2.0 (plus or minus) 0.7 d, significantly shorter than that of the conventional pedicle screw fixation group (7.2 (plus or minus) 2.5 d, P < 0.001). The postoperative NAPS was significantly lower than that before operation in both groups, however, there was no significant difference in the improvement of NAPS between the two groups. Conclusion: Percutaneous pedicle screw fixation using mini-invasive pedicle screw system guided by computer navigation is a good surgical therapeutic choice in thoracic-lumbar fracture.

STUDY DESIGN: A retrospective chart and radiographic review of 122 pedicle screws placed with computerized stereotactic image-guidance into posterolateral fusion masses.
OBJECTIVES: To determine the accuracy rate of computerized stereotactic image-guided pedicle screw placement in previously fused lumbar spines. SUMMARY OF BACKGROUND DATA: Placement of pedicle screws into a previously fused lumbar spine is challenging. The normal anatomic landmarks used to determine the starting point and trajectory of the screws have either been removed or are obscured by the fusion mass. Computerized frameless stereotaxis provides precise intraoperative real time multiplanar image-guidance and may be valuable in this clinical situation. METHODS: Computerized frameless stereotactic image-guidance was used to place pedicle screws into 78 consecutive patients with prior lumbar spine fusions. Postoperative computed tomography was available on 35 patients (231 screws). One hundred and twenty-two screws were placed into fusion masses. Pedicle cortical perforations were characterized by the direction (medial, inferior, lateral, or superior) and magnitude (in 2-mm increments) of perforation. RESULTS: Five (4.1%) of the 122 pedicle screws placed into previously fused levels were found to have unintentional cortical violations. There were 1 superior (<2 mm), 1 medial (<2 mm), and 3 lateral perforations (<2, 4, and 6 mm). None of these perforations led to clinically apparent radicular pain or weakness. No pedicle screws required revision for malpositioning.
CONCLUSIONS: The accuracy rate of stereotactic image-guided pedicle screw placement into previously fused lumbar spine levels is 96%. Computerized stereotactic image-guidance may have particular application in situations in which posterior element anatomy is altered, such as in the presence of a prior fusion mass.

Abstract: Aim: Goal of the current study was to compare radiation dose and fluoroscopy time of fluoroscopic computer assisted pedicle screw implantation versus the conventional technique. Method: For each of 10 specimens two pedicle screws were placed using conventional technique (group 1) and two screws were inserted with fluoroscopic navigation system (group 2) contralateraly. Results: For implantation of two pedicle screws the mean radiation dose was 0.041 mSv in group 1 and 0.029 mSv in group 2. Fluoroscopy time was 34 seconds in group 1 and 25 seconds in group 2. The differences of radiation dose and fluoroscopy time for group 1 and 2 were statistically significant (radiation dose p = 0.00044, fluoroscopy time p = 0.00039). Conclusion: We achieved significantly lower radiation dose and fluoroscopy time with fluoroscopic computer assisted pedicle screw implantation compared with the conventional technique. Concerning exposure to radiation for patients and personnels fluoroscopic navigated screw insertion is to favour. (copyright) Georg Thieme Verlag KG Stuttgart


Abstract: A 51-year-old female presented with traumatic C6-7 subluxation associated with C-7 fracture due to an automobile accident. She underwent pedicle screw fixation at C-6, C-7, and T-1 for stabilization of the spinal column. A neuronavigation system was used to obtain accurate placement of the pedicle screws. The patient recovered well without further neurological compromise. Postoperative cervical radiography showed reasonable restoration of the vertebral column without delayed kyphotic deformity


Abstract: OBJECTIVES: To compare the accuracy of lumbar total disc arthroplasty placement using an image-guidance system (IGS) with conventional fluoroscopy. BACKGROUND: Most disc arthroplasties are inserted and analyzed using fluoroscopy. One previous cadaveric study demonstrated beneficial, but insignificant, effects of IGS on total disc arthroscopy placement compared with conventional fluoroscopy. METHODS: Patients were considered for lumbar total disc arthroplasty who had chronic discogenic low back pain unresponsive to nonoperative management for at least 6 months. Total disc arthroplasty was performed in n=6 with IGS and in n=14 without IGS. Implant placement was analyzed after surgery using computer software on high-resolution CT with respect to 3 parameters: 1) off-center mal-placement, 2) axial rotational mal-placement, and 3) coronal tilt. RESULTS: Arthroplasties inserted with IGS were positioned with significantly greater accuracy than non-IGS arthroplasties with respect to all 3 parameters measured (off-center: 1.1 ±0.3 vs. 2.3 ± 0.3 mm, P = 0.031; rotation: 88.8 degrees ± 0.2 degrees vs. 87.1 degrees ± 0.4 degrees; P = 0.0084; and tilt: 1.0 degrees ± 0.5 degrees vs. 2.6 degrees ± 0.3 degrees, P = 0.01). There was no significant difference in operating time between non-IGS controls (123 ± 5 minutes) and IGS (139 ± 10 minutes) groups (P = 0.129). CONCLUSION: This is the first clinical study to demonstrate significantly improved accuracy of lumbar total disc arthroplasty placement on CT using IGS compared with conventional fluoroscopy. IGS should be considered for routine use with lumbar total disc arthroscopy insertion.
Clinical evaluation of a computer assisted spine surgical system is presented. Eighty pedicle screws were inserted using computer assisted technology in thoracic and lumbar vertebrae for treatment of different types of disorders including fractures, spondylolisthesis, and scoliosis. Fifty-two patients with severe fractures, spondylolisthesis, or pseudoarthrosis of T10 to L5 were treated using a computer assisted technique on 1/2 the patients and performing the screw insertion manually for the other 1/2.

At the same time, 28 pedicle screws were inserted in T12 to L4 vertebrae for scoliosis with the help of the computer assisted technique. Surgery was followed in all cases by postoperative radiographs and computed tomographic examination, on which measurements of screw position relative to pedicle position could be done.

Results:
- For fractures, spondylolisthesis, or pseudarthrosis, comparison between the two groups showed that:
  - 4 screws in 52 (8%) vertebrae had incorrect placement with computer assisted technique whereas
  - 22 screws in 52 (42%) vertebrae had incorrect placement with manual insertion.

In patients with scoliosis:
- 4 screws in 28(14%) vertebrae had incorrect placement.

In all of the patients (132 pedicle screws) there were no neurological complications.

Conclusion: These results show that a computer assisted technique is much more accurate and safe than manual insertion.


Abstract: The variability in width, height, and spatial orientation of a spinal pedicle makes pedicle screw insertion a delicate operation. The aim of the current paper is to describe a computer-assisted surgical navigation system based on fluoroscopic X-ray image calibration and three-dimensional optical localizers in order to reduce radiation exposure while increasing accuracy and reliability of the surgical procedure for pedicle screw insertion. Instrumentation using transpedicular screw fixation was performed: in a first group, a conventional surgical procedure was carried out with 26 patients (138 screws); in a second group, a navigated surgical procedure (virtual fluoroscopy) was performed with 26 patients (140 screws). Evaluation of screw placement in every case was done by using plain X-rays and post-operative computer tomography scan. A 5 per cent cortex penetration (7 of 140 pedicle screws) occurred for the computer-assisted group. A 13 per cent penetration (18 of 138 pedicle screws) occurred for the non computer-assisted group. The radiation running time for each vertebra level (two screws) reached 3.5 s on average in the computer-assisted group and 11.5 s on average in the non computer-assisted group. The operative time for two screws on the same vertebra level reaches 10 min on average in the non computer-assisted group and 11.9 min on average in the computer-assisted group. The fluoroscopy-based (two-dimensional) navigation system for pedicle screw insertion is a safe and reliable procedure for surgery in the lower thoracic and lumbar spine.


Abstract: Aim: The transpedicular placement of a hollow needle into vertebral bodies for
kyphoplasty requires utmost accuracy and thereby permanent multiplanar X-ray control. Facing the increasing number of vertebral compression fractures, the aim of this work was the implementation of computer-assistance to optimise the issue. Prior to clinical implementation, experimental trials were undertaken to analyse the quality-improving options of the technique. Method: The virtual image of the planning and the puncture were correlated with the postoperative X-ray image of the needle. The real canal in the bone was then correlated with the preoperative planning in a CT-based 3D model and differences were calculated. As a measure of accuracy the deviation of the needle from the ideal intruding vector and the distance between its top and the centre of a predefined target were scrutinised and related to the indications of the navigation system. Operating time, radiation exposure and general applicability were additionally assessed. All data were compared with those of a conventional control group. Results: Planning and navigation could be executed with high accuracy. With an exactly transpedicular approach, neural structures were safely circum-navigated without once missing the target. In the control group the distance fault was up to 9 mm. The navigated drilling differed from the ideal trajectory by 1(degrees) to max. 4(degrees). Conventional C-arm control led to a divergence of 4(degrees) to 8(degrees). Radiation exposure could be reduced through computer assistance by 76% to a fourth of the conventionally resulting amount and the pure operating time thereby decreased by 40%. The inconvenient course of repeated positioning of the C-arm was overcome. Conclusion: In challenging cases of deteriorated anatomy and difficult radiomorphologic orientation, especially of the lower thoracic spine, the CAOS-procedure succeeds in finding the optimal pedicular approach to the vertebral body, helps to avoid collateral damage and minimises the overall risk of the procedure. High accuracy and reduced radiation exposure justify the clinical use of fluoroscopic navigation for transpedicular instrumentation. (copyright) Georg Thieme Verlag KG Stuttgart

Abstract: Background context: Computerized frameless stereotactic image-guidance has been used in recent years to improve the accuracy and safety of pedicle screw placement during spine surgery. Because the possibility of intervertebral motion exists, and because the patient is usually in a different position when preoperative imaging is performed compared with the operative position, it has been suggested that the imaging model of the complete lumbar spine and the surgically exposed lumbar spine may be significantly discordant. Consequently, current protocols suggest registering each spinal level (single-level registration) separately before pedicle screw placement at that level, a time-consuming process. Purpose: To assess the accuracy of single-time multilevel registration for multilevel pedicle screw placement during image-guided, computer-assisted spine surgery, in the setting of degenerative disorders of the lumbar spine. Study design/setting: This is a prospective clinical and radiological study of 45 patients with degenerative disorders of the lumbar spine who underwent instrumented fusion with the use of single-time multilevel registration computer-assisted, image-guided tomography. The accuracy of the pedicle screws placement was confirmed on the basis of a protocol that included intraoperative spontaneous electromyographic (EMG) recordings, direct pedicle visualization, and computer tomography (CT) scans when clinically indicated during the follow-up period. Patient sample: Forty-five consecutive patients who fulfilled the criteria of computer-assisted, image-guided tomography pedicle screw placement for degenerative lumbar spine disease without overt instability. Outcome measures: The principal outcome measure was the accuracy of pedicle screw placement with single-time multilevel registration for multilevel pedicle screw placement during image-guided, computer-assisted spine surgery; postoperative CT performed for clinical indications during the follow-up course was used for the assessment of pedicle screw placement. Methods: Patients were assessed clinically before and after the operation. Data from 45 consecutive cases of image-guided, computer-assisted lumbar spinal fusion were statistically analyzed to determine the relationship between the number of
levels registered during single-time registry and the mean registration error (MRE). Intraoperative spontaneous EMG, direct visualization, and postoperative CT scans were used to assess the accuracy of pedicle screw insertion. Results: None of the patients involved in this study experienced clinical sequelae of improper pedicle screw placement. MREs after surface mapping and after point merge were small (less than 1.00 mm and less than 3.00 mm, respectively). During the intraoperative assessment of the pedicle screws placement, no significant spontaneous EMG activity was recorded and the pedicular walls were found intact in direct visualization. The postoperative CT scans showed in 10 patients accurate placement in 55 of the 57 pedicle screws with expansion of the medial wall in two screws. Conclusions: Single-time, multilevel registration may decrease operative time relative to repeated, single-level registrations, without compromising the increased accuracy of pedicle screw placement afforded by this technique in the setting of degenerative disorders of the lumbar spine. Despite the advantages in computer-guided image surgery, cautious application in the individual patient is recommended until more comprehensive data can be gathered in specific degenerative pathology with overt instability; thus the knowledge of the anatomy remains crucial. (copyright) 2005 Elsevier Inc. All rights reserved

Abstract: OBJECTIVE: The integration of digital image-guided surgical navigation with C-arm fluoroscopy, known as virtual fluoroscopy (VF), has been shown to enhance the safety of spine surgery in vitro. Few clinical studies have assessed the accuracy of VF during actual spinal surgery, and no studies have investigated variations in accuracy over the course of a series of measurements obtained during operative cases. We sought to study the intraoperative accuracy of VF over time and space during lumbar pedicle screw placement in human patients. METHODS: Fluoroscopic images of the lumbar spine were obtained, calibrated, and saved to the Stealth Station (FluoroNav) on seven patients undergoing lumbar fusion surgery. The tracking arc was attached to an exposed lumbar spinous process, which was designated the index level. With use of anatomic surface irregularities in the laminae and spinous processes, several points were identified and registered on three different vertebrae directly adjacent to the index level vertebra. Every 15 minutes, throughout the operative case, the probe was brought to each point and the apparent distance from the original location recorded (as measured by the FluoroNav system). Measurements were collected from three vertebral levels adjacent to the index level over a time course of 120 minutes during the operation. RESULTS: At the index, index +1, index +2, and index +3 levels, 89%, 81%, 92%, and 64% of measurements were within <2 mm, whereas 97%, 96%, 97%, and 91% were within <3 mm, respectively. At 15, 30, 45, 60, 75, 90, 105, and 120 minutes, 96%, 89%, 85%, 61%, 85%, 90%, 93%, and 50% of measurements were within <2 mm, whereas 100%, 93%, 100%, 83%, 100%, 90%, 100%, and 100% of measurements were within <3 mm, respectively. The error in millimeters tended to increase as the distance from the index level increased (R=0.19, P<0.05) and as operative time increased (R=0.26, P<0.01). Calibration studies of intraoperative VF (IoVF) in the lumbar spine documented a reasonable degree of accuracy. The majority of sequential measurements obtained during IoVF in the lumbar spine were within an error range of <3 mm. CONCLUSIONS: Our results suggest that the use of VF is a reliable method of verifying the use of anatomic and/or radiographic landmarks for guidance during lumbar pedicle screw placement. Copyright (copyright) 2006 by Lippincott Williams & Wilkins.

Abstract: Direct pedicle screw fixation of the C2 is rarely performed in trauma owing to the risk of damage to the neurovascular structures. Computed tomography-based navigation has the problem of change in intersegmental anatomy after positioning for surgery. Iso-C-based computer navigation acquires the intraoperative real-time images after patient positioning and thus avoids registration errors and improves accuracy. A Hangman fracture treated by posterior direct pedicle screw fixation using Iso-C computer navigation guidance is reported. Postoperative computed tomographic images confirmed the accurate placement of pedicular screws. Intraoperative fluoroscopy-based computer navigation is advantageous especially in an unstable upper cervical spine injury where the likelihood of change in the intersegmental relationship is maximal before and after positioning for surgery. The Iso-C navigation has the advantages of clarity and accuracy, making safe pedicle fixation of C1 and C2 possible despite fractured posterior elements. To our knowledge, this is the first reported case of displaced Hangman fracture treated successfully using Iso-C fluoroscopic navigation assisted direct pedicle screw osteosynthesis in the literature. Intraoperative acquisition of fluoroscopic images avoids registration-related problems. Three-dimensional fluoroscopic navigation gives excellent accuracy and safety in screw instrumentation of Hangman fracture.

Rajasekaran S, Vidyadhara S et al; Randomized clinical study to compare the accuracy of navigated and non-navigated thoracic pedicle screws in deformity correction surgeries; SPINE 2007; Vol 32, No 2.

Study Design. Randomized clinical trial (level I evidence).

Objective. To compare the accuracy of non-navigation and Iso-C based navigation in pedicle screw fixation in thoracic spine deformities. Summary of Background Data. Thoracic pedicle screw insertion for spinal deformity correction can be associated with increased pedicle breaches. Iso-C based navigation has been reported to improve the accuracy of pedicle screw placement, but its use in the presence of deformity has not been reported. Methods. Twenty-seven patients with scoliosis and 6 patients with kyphosis had a total of 478 thoracic pedicle screws. The average Cobb angle was 58.4° ± 8° (range 50°–80°), and the mean kyphotic angle was 54.6° ± 4° (range 51°–76°). By random allocation, 17 patients had screw insertion under navigation (242 screws) and 16 under fluoroscopic control (236 screws). The 2 groups were compared for accuracy of screw placement, time for screw insertion, and the number of times the C-arm had to be brought into the field. Two independent blinded observers determined accuracy using postoperative computed tomography assessments. Results. There were 54 (23%) pedicle breaches in the non-navigation group as compared to only 5 (2%) in the navigation group (P < 0.001). Thirty-eight screws (16%) in the non-navigation group had penetrated the anterior or lateral cortex compared to 2 screws (0.8%) in the navigation group. Average screw insertion time in the non-navigation group was 4.61 ± 1.05 minutes (range 1.8–6.5) compared to 2.37 ± 0.72 minutes (range 1.16–4.5) in navigation group (P < 0.01). The C-arm had to be moved into the operation field on an average of 1.5 ± 0.25 times (range 1–3) per screw. With single screening data, an average of 11.4 pedicles (range 9–14) could be visualized without necessity to bring the C-arm into operating field again. Conclusions. Iso-C navigation increases accuracy, and reduces surgical time and radiation in thoracic deformity correction surgeries.


Abstract: STUDY DESIGN. A prospective observational study on the use of Iso-C 3-dimensional navigated surgery in treating 4 patients with spinal osteoid osteomas by a minimally invasive approach. OBJECTIVE. To report on the efficacy of Iso-C 3-dimensional intraoperative spinal navigation in excising osteoid osteomas. SUMMARY OF BACKGROUND DATA. Curative treatment
of osteoid osteomas entails complete intralesional excision of the nidus. However, intraoperative localization of the nidus can be difficult, and may involve wide resection of the surrounding normal bony structure resulting in instability requiring fusion or inadvertent neurovascular injury. Computer navigation provides real-time multiplanar images of the vertebral anatomy, and has been used extensively to increase the accuracy of pedicle screw placement. However, the efficacy of this technology in intraoperative localization and excision of spinal tumors is still largely unknown.

METHOD. Iso-C 3-dimensional intraoperative navigation was used to localize osteoid osteomas of the spine in 4 patients. A minimally invasive reflective array, tool navigator, and a registered burr were used for localization and deroofing of the lesion, followed by curettage and high-speed burring of the cavity. Complete removal of the nidus was confirmed intraoperatively by reacquisition of data.

RESULTS. In all 4 patients, Iso-C 3-dimensional computer navigation was successful in accurate localization of the osteoid osteomas. The tool navigator was helpful to localize and deroof the lesion. The ability to register the burr was useful to clear the lesion without removal of any excess bone. Reregistration allowed intraoperative confirmation of adequacy of excision. Conservation of bone allowed early mobilization and also removed the need for reconstruction. Postoperative computer tomography scan done in 2 patients confirmed complete extirpation of the nidus. Histopathology confirmed the clinical diagnosis in all cases. All patients had immediate relief of the characteristic pain after surgery and were asymptomatic at 2 years follow-up. CONCLUSION. Intraoperative Iso-C 3-dimensional navigation is useful in accurately localizing and guiding complete excision of spinal osteoid osteomas through a minimally invasive approach without compromising spinal stability. (copyright) 2008 Lippincott Williams & Wilkins, Inc

Abstract: STUDY DESIGN. Observational matched cohort study with computed tomography (CT) analysis of pedicle screw placement. OBJECTIVE. Assess the clinical accuracy of computer-assisted fluoroscopy for the placement of thoracolumbar pedicle screws through a mature posterolateral fusion mass. SUMMARY OF BACKGROUND DATA. Pedicle screw placement through an amorphous posterolateral fusion mass intuitively carries a higher risk of pedicle wall violation. METHODS. Postoperative CT scans of 102 pedicle screws placed through a mature posterolateral fusion mass (n = 10 [T10-T12]; n = 92 [L1-S1]) were independently assessed and compared with a matched control (nonobscured anatomy) group. All screws were placed before any decompression using the FluoroNav system. RESULTS. In the fusion mass group, overall 81.4% of screws were completely within the pedicle. Seven medial and 12 lateral pedicle breaches occurred. Relative to the total number of screws, pedicle breaches were graded II (<2 mm) in 13.5%, III (2-4 mm) in 2.9%, and IV (>4 mm) in 2.0% of screws. The number and direction of pedicle breaches were not significantly different when compared with the control group. There were no clinically significant screw misplacements in either group. CONCLUSIONS. The use of computer-assisted fluoroscopy is safe and effective for the placement of thoracolumbar (T10-S1) pedicle screws through a posterolateral fusion mass without performing laminoforaminotomies. (copyright) 2007 Lippincott Williams & Wilkins, Inc

Abstract: STUDY DESIGN: Prospective clinical study with postoperative radiologic control of pedicle screw placement in the cervical spine. OBJECTIVES: To evaluate whether cervical pedicle screws can be placed safely in a conventional technique when using cannulated screws and separate stab incisions. Also, to evaluate if accuracy and safety of [cervical] pedicle screw

Medtronic
placement can be improved using a computer-assisted surgery (CAS) system (VectorVision; BrainLAB AG, Heimstetten, Germany). SUMMARY OF BACKGROUND DATA: Pedicle screws are rarely used in the cervical spine compared to the use in lumbar and thoracic spine. The main reason is probably the potential risk of iatrogenic damage to the spinal cord, nerve roots, or vertebral artery caused by screw misplacement as well as the more demanding technique of pedicle screw placement in the cervical spine. METHODS: A total of 52 consecutive patients with posterior cervical or cervicothoracic instrumentations using pedicle screws were evaluated prospectively. For the first 20 patients, 93 pedicle screws were implanted using the conventional technique with the image intensifier in the lateral view, and for the next 32 patients (167 screws), a CAS system was additionally used. For registration of the vertebra, surface-matching algorithms were used. For evaluation of screw placement, postoperative computerized tomography with multiplanar reconstructions in the screw axis was performed for each screw. RESULTS: No implant-related complications were observed. No neurologic or vascular complications were found related to pedicle screws. The rate of pedicle perforations was 8.6% (8 screws) in the conventional group and 3.0% (5 screws) in the CAS group, and in all cases, less than 2-mm displacement. None of the screws with pedicle perforation had to be revised as a result of nonsufficient biomechanical stability or compression of neural/vascular structures. CONCLUSIONS: Transpedicular screws in the cervical spine and cervicothoracic junction can be applied safely and with high accuracy in a conventional technique. Cannulated screws and the use of separate stab incisions from C3-C6 with a trocar system allow for reduced screw misplacement rates. The CAS system leads to significantly reduced screw misplacement rates. Therefore, because of the potential risk of injury to the vertebral artery and neural elements, the use of a CAS system seems to be beneficial, especially for pedicle instrumentation C3-C6.

Abstract: BACKGROUND: Translaminar facet screws are a minimally invasive technique for posterior lumbar fixation with good success rates. Computer-assisted image guided navigation using virtual fluoroscopy allows multiple simultaneous screens in various planes to plan and drive spinal instrumentation. OBJECTIVE: This study evaluates the percutaneous placement of translaminar facet screws with the use of virtual fluoroscopy as an image guidance technique. STUDY DESIGN/SETTING: A human cadaveric study was performed with a percutaneous reference frame applied to the iliac crest. Ten translaminar facet screws were placed bilaterally at five levels. Anteroposterior and lateral images were used to navigate 4.0-mm screws through a percutaneous portal under virtual fluoroscopy. METHODS: An axial computed tomographic scan through the instrumented levels was obtained after the screws were placed. Screws were graded on entry, course through the lamina, and terminus. A grading system was devised to grade the course through the lamina. RESULTS: All 10 screw-entry points were judged optimal at the spinous process laminar junction. There were five Grade I breeches with less than ½ the screw through the lamina, and five Grade 0 screw placements with the screw contained completely within the lamina. The termination point was acceptable in five screws. The screws that began on the right and terminated on the left were all found to have grade II breakouts. No screws placed the spinal canal or exiting nerve root at risk. CONCLUSIONS: Virtual fluoroscopy provides significant assistance in percutaneous placement of translaminar facet screws and results in safe position of entry, lamina course, and terminus.

Abstract: OBJECTIVE: To review the operative time differences between computer-assisted spinal navigation versus serial radiography. SUMMARY OF BACKGROUND DATA: There have been multiple studies describing the use of computer-assisted image guided surgery (IGS) in the application of spinal instrumentation. Techniques have evolved to allow attainment of multilevel visualization intraoperatively both successfully and safely. These have proven to result in low screw misplacement rates, low incidence of radiation exposure and excellent operative field viewing. As a result, image guidance has become an increasingly accepted and practiced form of intraoperative spinal navigation. However, potential limitations to IGS have been described including longer operating times. Many studies have looked at the success of beneficial outcomes; however, none to our knowledge have reviewed such described operative time increments with IGS. METHODS: The authors performed a retrospective database analysis of 105 patients undergoing posterior L5-S1 spine fusion with pedicle screw instrumentation for isthmic spondylolisthesis with and without the use of fluoroscopy-based image guidance. This was followed by a chart review of anesthesia operative time documentation. Subsequent time calculations and statistical analysis were performed for comparison. RESULTS: Computer-assisted image-guided spine surgery has overall demonstrated shorter mean operative times when compared with intraoperative serial radiography technique; an average of 40 minutes less per case (P<0.001). There is also less variation in operative times using image guidance, with 13 of 43 (30%) cases using serial x-ray lasting more than 3.75 hours compared with none of the 57 done via image guidance (P<0.001). The operative duration for both procedures trended downward over time. For both procedural cohorts operating room time continued to decrease as of the most recent year being performed. Lastly, in an attempt to minimize such a confounding factor as a learning curve, the last 20 cases in each group were compared. There was an average difference of about 22 minutes less for the image guidance group but missed being statistically significant (P=0.0503). CONCLUSIONS: Image-guided spinal surgery did not cause an increase in operative time. In the best scenario, image navigation saved a statistically significant (P<0.001) amount of time in the operating room. At its worst, fluoroscopy-based image-guided navigation is not significantly different from standard serial radiography.


Abstract: BACKGROUND: The aim of this prospective study was (1) to evaluate the accuracy of pedicle screw placement using Computer-Assisted Orthopedic-Surgery (CAOS) in comparison to conventionally image intensifier controlled pedicle screw instrumentation, (2) to compare our results with data from literature and (3) report our experiences with this technique. PATIENTS AND METHODS: Between 11/00 and 11/01 sixteen patients planned for spine surgery were subsequently recruited. Pedicle screw instrumentation was done in each patient as well with computer aided surgery (CAOS, SurgiGate-System, Medivision, Stratec Medical, Swiss) as also with image intensifier control, allowing for intraindividual comparison. Evaluation of pedicle screw placement was carried out with postoperative computed tomography (CT) or magnetic resonance imaging (MRI). RESULTS: 33 of altogether 36 pedicle screws inserted with Computer-Assistance (CAOS) were correctly placed (91.7%), however only 17 of altogether 24 pedicle screws inserted under image intensifier control (70.8%). The difference of frequency of screw misplacement between Computer-aided and image intensifier controlled instrumentation was statistically significant (p<0.05; chi-square test). CONCLUSION: Computer assisted surgery reduces significantly the misplacement rate of pedicle screws and remains for experienced spine surgeons an important support in the operative treatment of complex spinal deformities in future. Additionally it can be expected that Computer-Navigation will also spread out in the field of minimal-invasive spinal surgery, e.g. the kyphoplasty. The use of this technique supports beside the medical-technical knowledge an improved three-dimensional orientation in the education of spine surgeons.

Abstract: Study Design. Comparison of the radiation dose between the traditional fluoroscopic approach and computed tomography (CT)-based computer-assisted surgery for pedicle screw placement was determined. Objectives. To evaluate the radiation dose delivered by fluoroscopy-controlled pedicle screw placement versus insertion guided by computer. To define the CT computer-assisted protocol, involving lower radiation exposure for the patient, that still provides acceptable image quality. Summary of Background Data. There are no published data describing the dose delivered in CT-based image-guided surgery, and there are few studies in which the organ dose and the effective dose delivered during pedicle screw insertion that is performed traditionally with fluoroscopic control are described. Methods. Dose measurements were performed on two types (REMAB and RANDO) of anthropomorphic phantoms. Thermoluminescent dosimeters were used to measure the organ dose. Both phantoms were exposed to the fluoroscopic x-ray beam. The representative intraoperative scenario was determined by observation of 20 consecutive surgical interventions featuring pedicle screw implantation. For the CT dose measurement only, the REMAB phantom was used with two types of CT scanners. Three scanning protocols were evaluated: sequential, spiral optimized, and sequential optimized. Optimization of the scanning protocol included changes of anode current. The CT images were subsequently processed to achieve three-dimensional reconstruction of the lumbar spine for the computer-assisted intervention. Results. Organ and effective doses were higher in any of the CT examinations than in the fluoroscopic procedure. There was a slight difference between doses registered during optimized spiral scanning and doses in the calculated optimized sequential CT protocol. Optimized sequential scanning was associated with an effective dose 40% lower than that in nonoptimized sequential scanning. The small anatomic structures of the spine could be easily recognized on each of the three-dimensional reconstructions, and all of them were suitable for use in computer-assisted surgery. Conclusions. Percutaneous pedicle screw insertion in the lumbar region of the spine, performed using fluoroscopic control, requires a lower radiation dose than do CT scans necessary for computer-assisted surgery. The CT radiation dose can be significantly decreased by optimization of the scanner settings for computer-assisted surgery. The advantages of computer-assisted surgery justify CT scans, when based on correctly chosen indications.


Abstract: OBJECTIVES: Surgical navigation systems have been increasingly studied and applied in the application of spinal instrumentation. Successful disk arthroplasty requires accurate midline and rotational positioning for optimal function and longevity. A surgical simulation study in human cadaver specimens was done to evaluate and compare the accuracy of standard fluoroscopy, computer-assisted fluoroscopic image guidance, and Iso-C3D image guidance in the placement of lumbar intervertebral disk replacements. METHODS: Lumbar intervertebral disk prostheses were placed using three different image guidance techniques in three human cadaver spine specimens at multiple levels. Postinstrumentation accuracy was assessed with thin-cut computed tomography scans. RESULTS: Intervertebral disk replacements placed using the StealthStation with Iso-C3D were more accurately centered than those placed using the StealthStation with FluoroNav and standard fluoroscopy. Intervertebral disk replacements placed with Iso-C3D and FluoroNav had improved rotational divergence compared with standard fluoroscopy. Iso-C3D and FluoroNav had a smaller interprocedure variance than standard fluoroscopy. These results did not approach statistical significance. Relative to both virtual and standard fluoroscopy, use of the StealthStation with Iso-C3D resulted in improved accuracy in centering the lumbar disk prosthesis in the coronal midline. CONCLUSIONS: The StealthStation with FluoroNav appears to be at least equivalent to
standard fluoroscopy and may offer improved accuracy with rotational alignment while minimizing radiation exposure to the surgeon. Surgical guidance systems may offer improved accuracy and less interprocedure variation in the placement of intervertebral disk replacements than standard fluoroscopy. Further study regarding surgical navigation systems for intervertebral disk replacement is warranted.

Papers relating to increased accuracy of IGS as referenced by Smith et al:


OBJECTIVE: Pedicle screw fixation in the lumbar spine has become the standard of care for various causes of spinal instability. However, because of the smaller size and more complex morphology of the thoracic pedicle, screw placement in the thoracic spine can be extremely challenging. In several published series, cortical violations have been reported in up to 50% of screws placed with standard fluoroscopic techniques. The goal of this study is to evaluate the accuracy of thoracic pedicle screw placement by use of image-guided techniques.

METHODS: During the past 4 years, 266 image-guided thoracic pedicle screws were placed in 65 patients at the University of Michigan Medical Center. Postoperative thin-cut computed tomographic scans were obtained in 52 of these patients who were available to enroll in the study. An impartial neuroradiologist evaluated 224 screws by use of a standardized grading scheme. All levels of the thoracic spine were included in the study.

RESULTS: Chart review revealed no incidence of neurological, cardiovascular, or pulmonary injury. Of the 224 screws reviewed, there were 19 cortical violations (8.5%). Eleven (4.9%) were Grade II (< or =2 mm), and eight (3.6%) were Grade III (>2 mm) violations. Only five screws (2.2%), however, were thought to exhibit unintentional, structurally significant violations. Statistical analysis revealed a significantly higher rate of cortical perforation in the midthoracic spine (T4-T8, 16.7%; T1-T4, 8.8%; and T9-T12, 5.6%). CONCLUSION: The low rate of cortical perforations (8.5%) and structurally significant violations (2.2%) in this retrospective series compares favorably with previously published results that used anatomic landmarks and intraoperative fluoroscopy. This
study provides further evidence that stereotactic placement of pedicle screws can be performed safely and effectively at all levels of the thoracic spine.

Tjardes T, et. al; Computer assisted percutaneous placement of augmented iliosacral screws: a reasonable alternative to sacroplasty. SPINE Volume 33

STUDY DESIGN: A technical report of fluoroscopy guided placement of augmented iliosacral screws in osteoporotic insufficiency fractures of the sacrum. OBJECTIVE: To describe a combined approach of navigated iliosacral screw placement and screw augmentation as an option for osteosynthesis of sacral insufficiency fractures in the elderly. SUMMARY OF BACKGROUND DATA: The incidence of sacral insufficiency fractures is increasing. Outcome of conservative treatment is inconsistent. Recently sacroplasty is propagated as an interventional therapy but the long-term outcome is still unknown. Evidence from finite element models suggests that stabilization of the sacrum achieved by sacroplasty is insufficient to restore the weight bearing capacity of the sacrum permanently. METHODS: We suggest a minimally invasive fluoroscopically navigated iliosacral screw osteosynthesis with cement augmentation of the screws for treatment of insufficiency fractures of the sacrum. RESULTS: The procedure, especially fluoroscopic visualization and navigation of the osteoporotic sacrum is technically feasible. A total radiograph time of 7.4 minutes, including image acquisition for navigation and fluoroscopic control of cement injection, is acceptable and can be expected to be significantly reduced with repeated applications of the procedure. The patient presented in the report was discharged to rehabilitation soon after the operation. An assistive device (delta wheel) is only needed for longer walking distances. Pain was reduced drastically immediately after surgery. CONCLUSION: In general, fractures are treated by reduction and fixation to restore the biomechanical function of the injured bone. These principles should be applied to elderly patients with osteoporotic fractures as well. The technique reported here is adapted to the special demands of the elderly patient, i.e., minimally invasive, support of the weakened bone by cement augmentation, bone protective screw positioning and safety due to navigation support.


OBJECT: The goal of this study was to compare the accuracy of thoracic pedicle screw placement aided by two different image-guidance modalities. METHODS: The charts of 40 consecutive patients who had undergone stabilization of the thoracic spine between January 2003 and January 2005 were retrospectively reviewed. Three patients were excluded from the study because, on the basis of preoperative findings, small pedicle diameter precluded the use of pedicle screws. Thus, a total of 37 patients had 277 screws placed with the aid of either virtual fluoroscopy or isocentric C-arm 3D navigation. The indications for surgery included trauma, degenerative disease, and tumor, and were similar in both groups. All 37 patients underwent postoperative computed tomography scanning, and an independent reviewer graded all screws based on axial, sagittal, and coronal projections for a full determination of the placement of the screw in the pedicle. RESULTS: The rate of unintended perforations was found to depend on pedicle diameter (p < 0.0001). There were no statistical differences between groups with regard to rate or grade of cortical perforations. Overall, the rate and grade of perforations was low, and there were no neurological or vascular complications. CONCLUSIONS: The authors have shown that either image-guidance system may be used with a high degree of accuracy and safety. Because both systems were found to be comparably safe and accurate, the choice of image-guidance modality may be determined by the level of surgeon comfort and/or availability of the system.

The use of C2 laminar screws in posterior cervical fusion is a relatively new technique that provides rigid fixation of the axis with minimal risk to the vertebral artery. The techniques of C2 laminar screw placement described in the literature rely solely on anatomical landmarks to guide screw insertion. The authors report on their experience with placement of C2 laminar screws using three-dimensional (3D) fluoroscopy-based image-guidance in eight patients undergoing posterior cervical fusion. Overall, fifteen C2 laminar screws were placed. There were no complications in any of the patients. Average follow-up was 10 months (range 3-14 months). Postoperative computed tomographic (CT) scanning was available for seven patients allowing evaluation of placement of thirteen C2 laminar screws, all of which were in good position with no spinal canal violation. The intraoperative planning function of the image-guided system allowed for 4-mm diameter screws to be placed in all cases. Using modified Odom’s criteria, excellent or good relief of preoperative symptoms was noted in all patients at final follow-up.

Kim CW, et. al; Use of navigation-assisted fluoroscopy to decrease radiation exposure during minimally invasive spine surgery. The Spine Journal 8 (2008) 584-590

BACKGROUND: Minimally invasive surgery decreases postoperative pain and disability. However, limited views of the surgical field require extensive use of intraoperative fluoroscopy that may expose the surgical team to higher levels of ionizing radiation. PURPOSE: To assess the feasibility and safety of navigation-assisted fluoroscopy during minimally invasive spine surgery. STUDY DESIGN: A combined cadaveric and human study comparing minimally invasive transforaminal lumbar interbody fusion (MIS TLIF) using navigation-assisted fluoroscopy with standard intraoperative fluoroscopy to determine differences in surgical times and radiation exposures. METHODS: Eighteen fresh cadaveric spines underwent unilateral MIS TLIF by using either navigation-assisted fluoroscopy or standard fluoroscopy. Times for specific surgical steps were compared. In addition, a prospective short-term evaluation of the intraoperative and perioperative results of 10 patients undergoing navigation-assisted MIS TLIF (NAV group) compared with a retrospective review of 8 patients undergoing MIS TLIF performed by using standard fluoroscopy (FLUORO group). RESULTS: In the cadaveric study, the times were similar between the NAV group and the FLUORO group for most key steps. No statistically significant differences were obtained for approach, exposure, screw insertion, facetectomy/decompression, or total surgical times. Statistically significant differences were obtained for the setup time and total fluoroscopy time. The setup time for the NAV group averaged 9.67 (standard deviation [SD], 3.74) minutes compared with 4.78 (SD, 2.11) minutes for the FLUORO group (p=.034). The total fluoroscopy time was higher for the FLUORO group compared with the NAV group (41.9 seconds vs. 28.7 seconds, p=.042). Radiation exposure was undetectable when navigation-assisted fluoroscopy is used (NAV group). In contrast, an average 12.4 milli-REM (mREM) of radiation exposure is delivered to the surgeon during unilateral MIS TLIF procedure without navigation (FLUORO group). In the clinical series, the total fluoro time for the NAV group was 57.1 seconds (SD, 37.3; range, 18-120) compared with 147.2 seconds (SD, 73.3; range, 73-295) for FLUORO group (p=.02). No statistically significant differences are noted for operating time, estimated blood loss, or hospital stay. No inadvertent durotomies, postoperative weakness, or new radiculopathy were noted in the NAV group. One inadvertent durotomy was encountered in the FLUORO group that was repaired intraoperatively without clinical sequelae. CONCLUSION: The use of navigation-assisted fluoroscopy is feasible and safe for minimally invasive spine surgery. Radiation exposure is decreased to the patient as well as the surgical team.