

Editorial Manager(tm) for Spine Journal
Manuscript Draft

Manuscript Number:

Title: Percutaneous Lumbar Pedicle Screw Placement Aided by Computer-Assisted Fluoroscopy-Based Navigation: Perioperative Results of a Prospective, Comparative, Multicenter Study

Article Type: Surgery

Keywords: computer-aided surgery; fluoroscopy; navigation; guidance; minimally invasive; radiation

Corresponding Author: Benson P. Yang, MD

Corresponding Author's Institution: Northwestern Neurosurgical Associates

First Author: Benson P. Yang, MD

Order of Authors: Benson P. Yang, MD;Melvin M Wahl, MD;Cary S Idler, MD

Title: Percutaneous Lumbar Pedicle Screw Placement Aided by Computer-Assisted
Fluoroscopy-Based Navigation: Perioperative Results of a Prospective, Comparative,
Multicenter Study

Authors: Benson P. Yang, MD¹; Melvin M. Wahl, MD²; Cary S. Idler, MD³

¹Northwestern Neurosurgical Associates, Chicago, IL

²Kadlec Health System and Spine, Richland, WA

³Orthopaedic Specialists of NC, Wake Forest, NC

Corresponding/Reprint Request Author:

Benson P. Yang, MD

Northwestern Neurosurgical Associates

7447 W Talcott Ave, Suite 340

Chicago, IL 60631

Phone: (773) 594-0200

Fax: (773) 594-9083

Email: b-yang1@md.northwestern.edu

Conflicts of Interest and Source of Funding

This prospective, multicenter study was sponsored by NuVasive Inc., through research support at the participating sites. All authors were participants in the study, and received study funding. The authors received no financial support specific to the results of this study. Dr. Yang, Dr. Wahl, and Dr. Idler are educational consultants for NuVasive and receive limited compensation for teaching, training, and research.

Abstract

Study Design: IRB-approved, prospective, multicenter, comparative study.

Objective: To assess the accuracy and utility of a computer-assisted fluoroscopic navigation method for percutaneous placement of lumbar pedicle screws as compared to conventional fluoroscopic placement.

Summary of Background Data: Recent reports indicate that cortical breaches during percutaneous pedicle screw placement can exceed 15%. CT- and fluoroscopy-based navigation systems may facilitate increased placement accuracy with reduced radiation exposure and operative times.

Methods: Patients were alternately assigned to either the Guidance or Control group. The Guidance group underwent lumbar pedicle screw placement using the oblique visualization technique and computer-assisted fluoroscopic navigation. The Control group underwent lumbar pedicle screw placement per standard percutaneous technique aided by fluoroscopy alone. Baseline demographics, Visual Outcome Scores (VAS), and American Spinal Injury Assessment (ASIA) scores were obtained preoperatively and in the immediate postoperative period. Fluoroscopy times and guidewire insertion times were recorded intraoperatively. All postoperative CT scans were reviewed by an independent spine surgeon to grade screw placement accuracy.

Results: 42 patients (210 screws) were assigned to the Guidance group, 34 patients (152 screws) were assigned to the Control group. Use of Guidance resulted in reduced average fluoroscopy usage per pedicle (6.6 sec (SD 5.1) vs. 9.6 sec (SD 6.2), $p < 0.001$) and more expedient placement of guidewires per pedicle (3.65 min (SD 2.31) vs. 4.43 min (SD 2.56), $p = 0.003$). The Guidance group experienced less than half of the breach rate of the Control group (3.0% vs. 7.2%, $p = 0.055$) and reduced breach magnitudes. None of the breaches resulted in a corresponding neurological deficit or required revision. All patient-reported outcomes were significantly improved after surgery and there were no significant differences in average postoperative VAS scores between treatment groups.

Conclusions: Use of Guidance reduces fluoroscopy and insertion times with increased accuracy when compared to conventional fluoroscopic methods of percutaneous pedicle screw insertion.

- Key Points:**
1. The use of a fluoroscopy-based computer navigation system reduced fluoroscopy use during percutaneous pedicle screw insertion compared to screw insertion with fluoroscopy alone.
 2. The fluoroscopy-based pedicle screw navigation system presented in this manuscript resulted in a low percutaneous pedicle screw breach rate with small breach magnitude. None of the malpositioned screws in either study group resulted in neurologic deficits.
 3. The fluoroscopy-based navigation platform presented in this manuscript is not intended to be purchased by the hospital and can be used in most operating rooms without additional capital expenditures. As such, this system may serve as a low-cost alternative to CT-based navigation systems which are often only available in select hospitals with sufficient funding to purchase and house such platforms.

Mini Abstract/Précis: This prospective, multicenter, comparative study reports the placement accuracy, fluoroscopic exposure, procedure time, and perioperative clinical outcomes of patients treated with percutaneous pedicle screws using either a fluoroscopy-based computer navigation system for placement of pedicle screws or traditional pedicle screw placement using fluoroscopy alone.

1
2
3
4 **Introduction**

5
6 Percutaneous placement of pedicle screws is becoming routine in spine surgery with the advent and
7 maturity of minimally invasive techniques. The reported benefits of minimally invasive over open
8 procedures include reductions in blood loss, length of hospital stay, infection rates, postoperative pain,
9 and time to return to work.¹⁻³ Placement of percutaneous pedicle screws using the conventional
10 fluoroscopic technique with anteroposterior and lateral images is time-consuming and exposes the patient
11 and surgical team to considerable radiation.⁴ Recent reports indicate that cortical breaches during
12 percutaneous pedicle screw placement can exceed 15%,⁵⁻⁸ with neurologic injury as high as 15%.⁹ A
13 number of CT- and fluoroscopy-based navigation systems have been developed with demonstrated ability
14 to increase screw accuracy, decrease radiation exposure, and reduce operative times.^{10,11} Unfortunately,
15 these systems have not seen widespread adoption because they require time-consuming planning and
16 invasive fixation of a reference arm, they are unable to compensate for positional change, and are
17 expensive capital investments.^{5,12-20}

18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36 The purpose of this prospective, multicenter study is to compare a fluoroscopy-based navigation system
37 with conventional fluoroscopy alone for the percutaneous placement of lumbar pedicle screws. The
38 navigation technique described herein takes advantage of the oblique “owl’s eye” fluoroscopic pedicle
39 view and has been previously published with favorable placement accuracy and clinical outcomes in a
40 single-cohort, retrospective study.²¹

41
42
43
44
45
46
47
48 **Materials and Methods**

49
50
51 The NVM5™ Guidance System (NuVasive®, Inc, San Diego, CA) applied to a standard two-dimensional
52 C-arm forms the navigation platform in this study and has been previously described.²¹ A portable reticle
53 with integrated central laser beam is attached to the image-intensifier surface of the C-arm and tracks the
54 angular position of the fluoroscope in real time. A micro-accelerometer integrated into a clip-on
55
56
57
58
59
60
61
62
63
64
65

1
2
3
4 attachment enables real-time calculation of the angular position of the pedicle cannulation needle. The
5
6 pedicle cannulation needle is also continuously stimulated to enable evoked electromyography (EMG)
7
8 monitoring of potential cortical breaches. Preoperative CT or MRI images are used to calculate the
9
10 targeted medial-lateral angle of each pedicle trajectory. A single intraoperative lateral fluoroscopic image
11
12 is used to calculate the targeted cranial-caudal angle of each pedicle trajectory. With the medial-lateral
13
14 and cranial-caudal angles programmed, the reticle-equipped C-arm is then brought into an oblique view
15
16 down the central axis of the pedicle. After an incision is made, the micro-accelerometer-attached pedicle
17
18 cannulation needle is then brought into the programmed angles using feedback displayed on the Guidance
19
20 system (Figure 1.), as well as light emitting diodes (LED) on the cannulation needle (Figure 2.) to direct
21
22 impaction into the pedicle. A guidewire is placed and the remaining steps of screw insertion are identical
23
24 to conventional percutaneous methods.
25
26
27
28
29

30
31 Enrollment in this institutional review board-approved, multicenter, prospective, comparative study was
32
33 limited to patients between the ages of 20 and 79 with a preoperative diagnosis requiring treatment with
34
35 pedicle screw fixation in the lumbar spine. Patients were excluded from study participation if they had
36
37 previous instrumented surgery at the targeted lumbar level(s). At each study site, after obtaining written
38
39 informed consent, patients were assigned to alternating treatment groups according to the order of
40
41 enrollment. At each site, the first patient treated was assigned to the Guidance group. The Guidance group
42
43 underwent percutaneous pedicle screw placement aided by fluoroscopy-based navigation. The Control
44
45 group underwent percutaneous pedicle screw placement aided by conventional fluoroscopy alone.
46
47

48 Demographic data collected included age, sex, height, weight, and body mass index (BMI). Patient-
49
50 reported clinical outcomes were collected using the visual analog scale for back (VAS_{back}) and leg
51
52 (VAS_{leg}) pain at baseline and within 1 week after surgery. A neurological exam, including evaluation of
53
54 lower extremity motor strength and sensory function was performed at baseline and within 1 week after
55
56 surgery using the American Spinal Injury Association (ASIA) classification. If motor or sensory deficits
57
58
59
60
61
62
63
64
65

1
2
3
4 were identified at the first postoperative visit, patients were evaluated again 4-6 weeks postoperatively to
5
6 determine whether the deficit was transient.
7

8
9 Intraoperative data include levels treated, operative time, estimated blood loss, intraoperative
10 complications, number and location of screws, screw diameters and lengths, and time to guidewire
11 insertion in the pedicle. The EMG thresholds of the final position of each pedicle cannulation needle and
12 each pedicle screw were recorded. Total fluoroscopy time was collected as well as subset fluoroscopy
13 times for preincisional skin marking and guidewire placement for each pedicle. Additional data collected
14 in the Guidance group included Guidance system set-up time, preoperative measured pedicle angles, and
15 actual pedicle cannulation needle angles after impaction into the pedicle. Postoperative complications
16 and duration of hospital stay were noted.
17
18

19
20 Pedicle screw placement was assessed by a single, independent, blinded spine surgeon based on a
21 postoperative CT scan obtained within 1 week after surgery. The magnitude of pedicle perforation was
22 categorized as no breach, breach less than 2 mm, breach 2-4 mm, breach 4-6 mm, and breach greater than
23 6 mm. The direction of the perforation was categorized as lateral, medial, inferior, or superior.
24
25

26
27 Clinical and radiographic data were analyzed using PASW Statistics 18.0 (SPSS Inc., Chicago, IL). An
28 independent t-test was used to compare mean results between treatment groups, the paired t-test was used
29 to compare mean results in the same treatment group across different time points, and the Fischer's exact
30 test was used to compare categorical data between treatment groups. The significance level was defined
31 as $p < 0.05$.
32
33
34
35
36
37

38 **Results**

39
40
41
42
43
44
45
46
47
48
49
50
51

52
53
54
55
56 79 patients were consented for study participation at 5 sites. Three control patients from two different
57 sites withdrew consent prior to treatment. Ultimately, 76 patients were included in the study; 42 patients
58
59
60
61
62
63
64
65

1
2
3
4 were assigned to the Guidance group and 34 were assigned to the Control group. The difference in
5
6 patients per group can be attributed to enrollment of an odd number of patients at each site, and patients
7
8 who withdrew consent prior to treatment. The average age at surgery was 52 years (range 20-79) and the
9
10 average body mass index (BMI) was 31.0 kg/m² (range 19.1-45.9). Indications for surgery included
11
12 degenerative disc disease (85.5%), central or foraminal stenosis (69.7%), loss of disc height (55.3%),
13
14 spondylolisthesis (44.7%), herniated nucleus pulposus (17.1%), degenerative scoliosis (13.2%), and post-
15
16 laminectomy instability (5.3%). Baseline patient-reported pain scores were VAS_{back} 75.5 mm (SD 17.9),
17
18 VAS_{left_leg} 38.5 mm (SD 35.2), and VAS_{right_leg} 46.9 mm (SD 33.3). Prior to surgery 60 (78.9%) patients
19
20 had at least one lumbar motor or sensory deficit. Baseline variables including sex, age, BMI, and
21
22 indications for surgery were well matched between cohorts (p>0.05) and are reported in Table 1. Surgical
23
24 data are reported by group in Table 2.
25
26
27

28
29 A total of 362 screws were placed, (210 Guidance, 152 Control) from L2 to S1. Patients were treated with
30
31 an average of 4.8 screws (range 2-10) and screw diameters ranged from 5.5 to 7.5 mm. The average
32
33 screw diameter and number of screws placed per patient were not statistically different between treatment
34
35 groups (p=0.294 and p=0.083, respectively). On average the Guidance group used less fluoroscopy per
36
37 pedicle (6.6 sec (SD 5.1) vs. 9.6 sec (SD 6.2), p<0.001) (Figure 3.), and resulted in more expedient
38
39 placement of guidewires per pedicle (3.65 min (SD 2.31 vs. 4.43 min (SD 2.56), p=0.003) (Figure 4.).
40
41 The Guidance system set-up can be done without surgeon supervision and averaged 5.0 min (SD 5.6).
42
43 Pre-incision fluoroscopy included skin marking in both groups and an additional lateral registration image
44
45 in the Guidance group. Pre-incision fluoroscopy time was not significantly different between groups.
46
47
48

49
50 Estimated blood loss was less than 200 cc in 71.6% of patients, 200-300 cc in 18.9% and greater than 300
51
52 cc in 9.5%. There were no intraoperative complications and all screws were placed percutaneously
53
54 without transition to an open technique. Postoperative CT scans of 75 patients were available for review
55
56 by an independent spine surgeon. CT data was available for 354 screws (202 Guidance, 152 Control).
57
58 There were 17 pedicle breaches, including 6 (3.0%) in the Guidance group and 11 (7.2%) in the Control
59
60
61
62
63
64
65

1
2
3
4 group ($p=0.055$). All breaches in the Guidance group and 10 of 11 in the Control group were less than 2
5
6 mm. The remaining Control group breach was 2-4 mm. One Guidance group breach occurred at the
7
8 endplate and two Control group breaches occurred at the lateral cortex of the pedicle. All remaining
9
10 breaches occurred at the medial cortex of the pedicle. None of the breached pedicle screws required
11
12 revision. There was no significant association between treatment side or vertebral level and incidence of
13
14 breach.
15

16
17
18 No neurologic complication could be attributed to screw malposition. Complications included 7
19
20 postoperative motor deficits (5 Guidance, 2 Control) and 4 sensory deficits (3 Guidance, 1 Control). One
21
22 motor and 1 sensory deficit occurred together in a Guidance group patient with a breached pedicle screw;
23
24 however, the breach was remote from the symptomatic nerve roots and all deficits resolved within 4
25
26 weeks. It is suspected that the deficit was related to the patient's anterior surgery. All other deficits
27
28 occurred in patients without pedicle screw breaches. One sensory deficit in a Guidance group patient was
29
30 persistent at 8 weeks, and one motor deficit was not further assessed as the patient was lost to follow-up.
31
32 All other deficits resolved by the 8 week visit. Clinical outcomes are reported by group in Table 3.
33
34 Average postoperative patient-reported pain scores were not significantly different between treatment
35
36 groups and were significantly improved compared to baseline scores.
37
38
39
40
41
42

43 Discussion

44
45
46
47
48 Perhaps the most important attribute of any navigation system is that it facilitates safe and accurate screw
49
50 placement. In this study, 97% of navigated screws were entirely intrapedicular and 100% of navigated
51
52 screws were less than 2 mm breached, commonly considered to be within the 'safe zone' around the
53
54 pedicle.^{22,23} The breach rate was less than half of that using conventional fluoroscopy. According to a
55
56 recent meta-analysis, average pedicle screw placement accuracy was 92.1% in navigated and 87.3% in
57
58 unnavigated cases.²⁴ Although many clinical studies report a low incidence of neurologic injury
59
60
61
62
63
64
65

1
2
3
4 associated with misplaced screws, there is evidence that small cortical breaches can impact the
5
6 biomechanical strength of a construct.^{12,21,25-27} George et al. demonstrated the importance of cortical
7
8 containment of pedicle screws in their findings that the pull-out strength of pedicle screws with a cortical
9
10 breach was 11% less than that of screws contained wholly within the pedicle.²⁸ Similarly, Acikbas et al.
11
12 observed that patients with malpositioned screws had reductions in early correction, increased long-term
13
14 loss of correction, and greater non-union rates.²⁹
15
16
17
18
19

20 As long as fluoroscopy remains an integral part of percutaneous pedicle screw placement, radiation
21
22 exposure to the surgical team will remain a legitimate concern. Cumulative radiation dose can exceed
23
24 regulatory occupational limits.^{4,30} This study confirmed that the use of the Guidance system significantly
25
26 reduced fluoroscopy time per pedicle. Additionally, the central laser beam from the reticle denotes the
27
28 target in the oblique pedicle view and enables the surgeon to step back from the C-arm during skin
29
30 marking. In contrast, during conventional anteroposterior and lateral fluoroscopy, the surgeon typically
31
32 stands next to the patient and C-arm and holds a guidewire against the skin to localize anatomical
33
34 landmarks. With current CT- and three-dimensional fluoroscopy-based navigation systems, the patient is
35
36 exposed to significant amounts of radiation during image acquisition even if the surgeon is able to step
37
38 away.^{20,31} The Guidance system takes advantage of routine preoperative imaging without requiring
39
40 extensive reimaging of the patient intraoperatively.
41
42
43
44
45
46

47 Many surgeons have been hesitant to embrace navigation technologies because of early experience with
48
49 tedious matched-pair point registration of numerous anatomical landmarks, excessive operative set-up
50
51 times, and prolonged screw placement times.^{13,15,32} Some navigation platforms mandate the attachment of
52
53 a reference arc through a separate incision.^{12,18,20} With newer generation systems, more recent reports
54
55 describe image registration and set-up times between 14 and 18 minutes.^{5,11,20} Results from the current
56
57 study demonstrated a relatively short set-up time of approximately 5 minutes by ancillary staff as well as
58
59 reductions in screw placement time. Before starting the case, the surgeon need take only a few moments
60
61
62
63
64
65

1
2
3
4 to measure the medial-lateral pedicle angles on the patient's preoperative CT or MRI scan. With the
5
6 Guidance system, no reference arc is attached to the patient since no additional point registration or
7
8 calibration is necessary. This portable navigation system is designed to integrate with a standard C-arm
9
10 and does not require any additional capital expenditures by the hospital; this is critical when one considers
11
12 that CT-based navigation platforms require hospitals to purchase the platform. Once a CT-navigation
13
14 system is purchased, implementation the system may also require permanent modification of the operative
15
16 suite to integrate intraoperative CT scans for automated system registration. In the example of small
17
18 community hospitals with limited funding or operative suites that must be reconfigured frequently for
19
20 multipurpose use, a CT navigation system may not be a realistic option. The technology presented in this
21
22 manuscript represents an innovative step toward a simpler, more efficient, and more cost-effective
23
24 fluoroscopy-based navigation platform for percutaneous placement of pedicle screws.
25
26
27
28
29
30

31 **Conclusions**

32
33
34
35 Computer-assisted fluoroscopic navigation of percutaneous lumbar pedicle screws effectively reduces
36
37 fluoroscopy times and shortens screw insertion times without compromising accuracy when compared to
38
39 conventional fluoroscopic methods. Further study may show the utility of this technology in the
40
41 placement of thoracic pedicle screws where breach rates are typically elevated in the setting of lower
42
43 tolerance for error. As navigation technologies become more advanced, they will be increasingly
44
45 employed to aid in the placement of pedicle screws. Future studies directly comparing different systems
46
47 will need to be performed to evaluate the advantages of one over another.
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

References

1. Gepstein R, Shabat S, Reichel M, Pikarsky I, Folman Y. Treatment of postdiscectomy low back pain by percutaneous posterior lumbar interbody fusion versus open posterior lumbar fusion with pedicle screws. *Spine J* 2008;8:741-6.
2. Kim DY, Lee SH, Chung SK, Lee HY. Comparison of multifidus muscle atrophy and trunk extension muscle strength: percutaneous versus open pedicle screw fixation. *Spine (Phila Pa 1976)* 2005;30:123-9.
3. Isaacs RE, Hyde J, Goodrich JA, Rodgers WB, Phillips FM. A prospective, nonrandomized, multicenter evaluation of extreme lateral interbody fusion for the treatment of adult degenerative scoliosis: perioperative outcomes and complications. *Spine (Phila Pa 1976)* 2010;35:S322-S330.
4. Mroz TE, Abdullah KG, Steinmetz MP, Klineberg EO, Lieberman IH. Radiation Exposure to the Surgeon During Percutaneous Pedicle Screw Placement. *J Spinal Disord Tech* 2010.
5. Nakashima H, Sato K, Ando T, Inoh H, Nakamura H. Comparison of the percutaneous screw placement precision of isocentric C-arm 3-dimensional fluoroscopy-navigated pedicle screw implantation and conventional fluoroscopy method with minimally invasive surgery. *J Spinal Disord Tech* 2009;22:468-72.
6. Verma R, Krishan S, Haendlmayer K, Mohsen A. Functional outcome of computer-assisted spinal pedicle screw placement: a systematic review and meta-analysis of 23 studies including 5,992 pedicle screws. *Eur Spine J* 2010;19:370-5.

7. von JR, Finn MA, Yonemura KS, Araghi A, Khoo LT, Carrino JA et al. Minimally invasive percutaneous transpedicular screw fixation: increased accuracy and reduced radiation exposure by means of a novel electromagnetic navigation system. *Acta Neurochir (Wien)* 2011;153:589-96.
8. Ravi B, Zahrai A, Rampersaud R. Clinical accuracy of computer-assisted two-dimensional fluoroscopy for the percutaneous placement of lumbosacral pedicle screws. *Spine (Phila Pa 1976)* 2011;36:84-91.
9. Lotfinia I, Sayahmelli S, Gavami M. Postoperative computed tomography assessment of pedicle screw placement accuracy. *Turk Neurosurg* 2010;20:500-7.
10. von Jako RA, Carrino JA, Yonemura KS, Noda GA, Zhue W, Blaskiewicz D et al. Electromagnetic navigation for percutaneous guide-wire insertion: accuracy and efficiency compared to conventional fluoroscopic guidance. *Neuroimage* 2009;47 Suppl 2:T127-T132.
11. Kim CW, Lee YP, Taylor W, Oygur A, Kim WK. Use of navigation-assisted fluoroscopy to decrease radiation exposure during minimally invasive spine surgery. *Spine J* 2008;8:584-90.
12. Fu TS, Wong CB, Tsai TT, Liang YC, Chen LH, Chen WJ. Pedicle screw insertion: computed tomography versus fluoroscopic image guidance. *Int Orthop* 2008;32:517-21.
13. Kamimura M, Ebara S, Itoh H, Tateiwa Y, Kinoshita T, Takaoka K. Accurate pedicle screw insertion under the control of a computer-assisted image guiding system: laboratory test and clinical study. *J Orthop Sci* 1999;4:197-206.
14. Lekovic GP, Potts EA, Karahalios DG, Hall G. A comparison of two techniques in image-guided thoracic pedicle screw placement: a retrospective study of 37 patients and 277 pedicle screws. *J Neurosurg Spine* 2007;7:393-8.

15. Merloz P, Tonetti J, Pittet L, Coulomb M, Lavallee S, Troccaz J et al. Computer-assisted spine surgery. *Comput Aided Surg* 1998;3:297-305.
16. Park P, Foley KT, Cowan JA, Marca FL. Minimally invasive pedicle screw fixation utilizing O-arm fluoroscopy with computer-assisted navigation: Feasibility, technique, and preliminary results. *Surg Neurol Int* 2010;1:44.
17. Smith HE, Welsch MD, Sasso RC, Vaccaro AR. Comparison of radiation exposure in lumbar pedicle screw placement with fluoroscopy vs computer-assisted image guidance with intraoperative three-dimensional imaging. *J Spinal Cord Med* 2008;31:532-7.
18. Tormenti MJ, Kostov DB, Gardner PA, Kanter AS, Spiro RM, Okonkwo DO. Intraoperative computed tomography image-guided navigation for posterior thoracolumbar spinal instrumentation in spinal deformity surgery. *Neurosurg Focus* 2010;28:E11.
19. Wood MJ, Mannion RJ. Improving accuracy and reducing radiation exposure in minimally invasive lumbar interbody fusion. *J Neurosurg Spine* 2010;12:533-9.
20. Zausinger S, Scheder B, Uhl E, Heigl T, Morhard D, Tonn JC. Intraoperative computed tomography with integrated navigation system in spinal stabilizations. *Spine (Phila Pa 1976)* 2009;34:2919-26.
21. Idler C, Rolfe KW, Gorek JE. Accuracy of percutaneous lumbar pedicle screw placement using the oblique or "owl's-eye" view and novel guidance technology. *J Neurosurg Spine* 2010;13:509-15.
22. Gertzbein SD, Robbins SE. Accuracy of pedicular screw placement in vivo. *Spine (Phila Pa 1976)* 1990;15:11-4.
23. Modi HN, Suh SW, Fernandez H, Yang JH, Song HR. Accuracy and safety of pedicle screw placement in neuromuscular scoliosis with free-hand technique. *Eur Spine J* 2008;17:1686-96.

24. Kosmopoulos V, Schizas C. Pedicle screw placement accuracy: a meta-analysis. *Spine (Phila Pa 1976)* 2007;32:E111-E120.
25. Kim YJ, Lenke LG, Bridwell KH, Cho YS, Riew KD. Free hand pedicle screw placement in the thoracic spine: is it safe? *Spine (Phila Pa 1976)* 2004;29:333-42.
26. Isaacs RE, Podichetty VK, Sandhu FA, Santiago P, Spears JD, Aaronson O et al. Thoracic microendoscopic discectomy: a human cadaver study. *Spine (Phila Pa 1976)* 2005;30:1226-31.
27. Krag MH, Weaver DL, Beynonn BD, Haugh LD. Morphometry of the thoracic and lumbar spine related to transpedicular screw placement for surgical spinal fixation. *Spine (Phila Pa 1976)* 1988;13:27-32.
28. George DC, Krag MH, Johnson CC, Van Hal ME, Haugh LD, Grobler LJ. Hole preparation techniques for transpedicle screws. Effect on pull-out strength from human cadaveric vertebrae. *Spine (Phila Pa 1976)* 1991;16:181-4.
29. Acikbas SC, Arslan FY, Tuncer MR. The effect of transpedicular screw misplacement on late spinal stability. *Acta Neurochir (Wien)* 2003;145:949-54.
30. Rampersaud YR, Foley KT, Shen AC, Williams S, Solomito M. Radiation exposure to the spine surgeon during fluoroscopically assisted pedicle screw insertion. *Spine (Phila Pa 1976)* 2000;25:2637-45.
31. Scheufler KM, Cyron D, Dohmen H, Eckardt A. Less invasive surgical correction of adult degenerative scoliosis. Part II: Complications and clinical outcome. *Neurosurgery* 2010;67:1609-21.

32. Laine T, Lund T, Ylikoski M, Lohikoski J, Schlenzka D. Accuracy of pedicle screw insertion with and without computer assistance: a randomised controlled clinical study in 100 consecutive patients.
Eur Spine J 2000;9:235-40.

Tables

Table 1. Patient demographics.

	Guidance (SD)	Control (SD)	p
Patients	42	34	N/A
Age	52.7 (16.3)	51.9 (11.9)	0.804
BMI (kg/m ²)	30.7 (6.8)	31.4 (6.9)	0.685

Table 2. Surgical results.

	Guidance (SD)	Control (SD)	p
Total screws placed	210	152	N/A
Screws per patient placed	5.0 (1.3)	4.7 (1.3)	0.083
Fluoroscopy time before incision (sec)	13.8 (7.5)	16.5 (12.9)	0.277
Fluoroscopy time per pedicle (sec)	6.6 (5.1)	9.6 (6.2)	<0.001
Incision to guidewire placement time per pedicle (min)	3.65 (2.31)	4.43 (2.56)	0.003

Table 3. Baseline and postoperative Visual Analog Scale results. All results are in millimeters.

		Guidance (SD)	Control (SD)	p value
Back	<i>Baseline</i>	73.2 (18.8)	78.5 (16.7)	0.197
	<i>Postoperative</i>	57.2 (25.4)	56.0 (29.0)	0.857
Left Leg	<i>Baseline</i>	35.0 (33.1)	42.8 (37.8)	0.347
	<i>Postoperative</i>	21.8 (25.7)	21.1 (26.7)	0.907
Right Leg	<i>Baseline</i>	46.8 (32.6)	47.1 (34.7)	0.969
	<i>Postoperative</i>	23.1 (30.0)	29.9 (28.0)	0.308

Figure Legends

Figure 1. Graphical user interface of the Guidance System. By centering the pedicle an oblique “owl’s eye” fluoroscopic image, the C-arm reticle laser becomes co-linear with the pedicle axis. The laser projection on the patient aids skin marking and pedicle cannulation. Instrument and C-arm angles are continuously updated and displayed at the right of the screenshot. Evoked EMG thresholds are also reported.

Figure 2. Pedicle cannulation needle with micro-accelerometer attachment. LED arrows on the attachment direct angulation toward the pre-programmed cranial-caudal and medial-lateral angles.

Figure 3. Fluoroscopy use per pedicle. Error bars represent 95% confidence interval for the mean

Figure 4. Guidewire placement time per pedicle. Error bars represent 95% confidence interval for the mean.

Figure 1

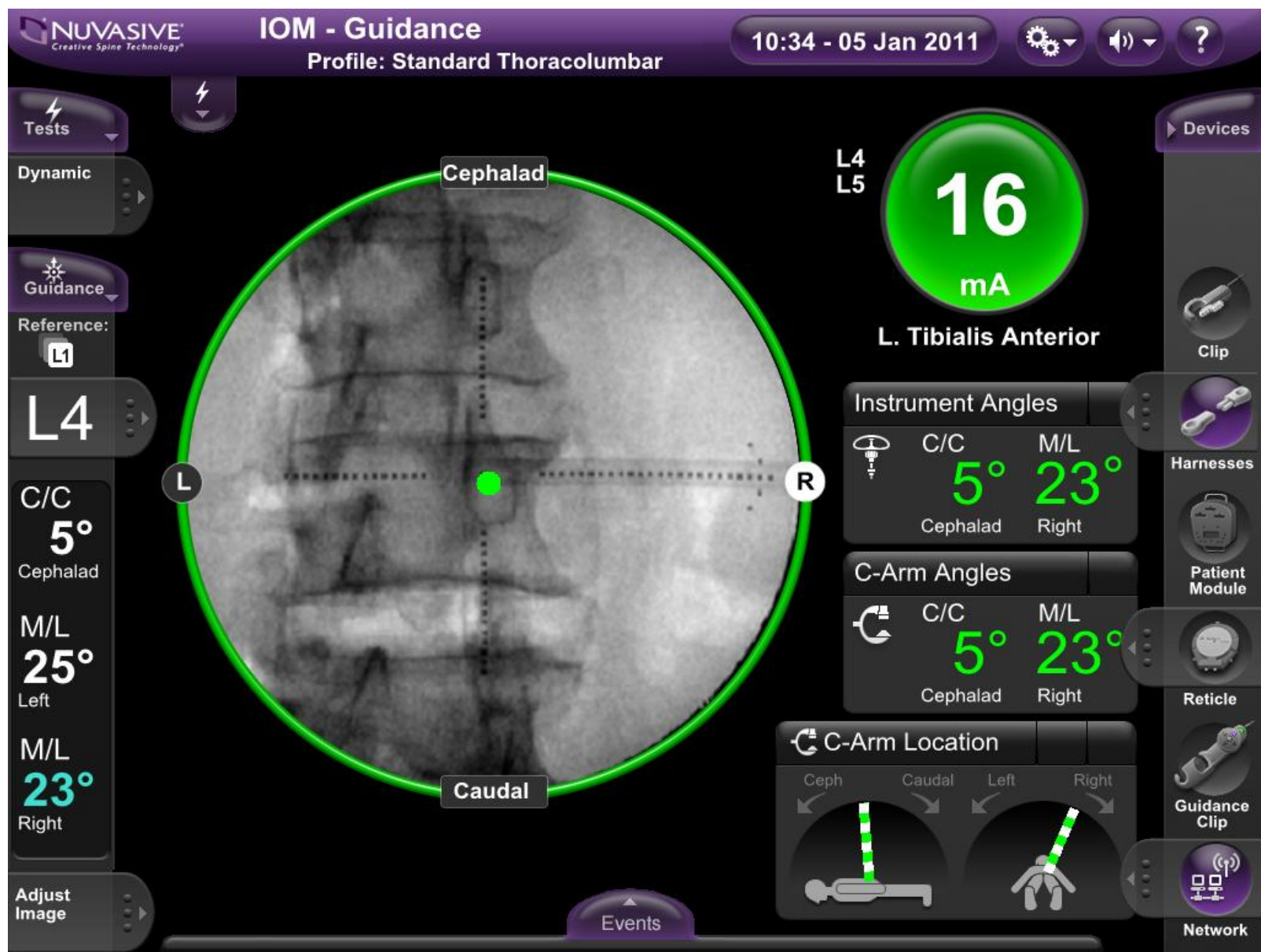


Figure 2



Figure 3

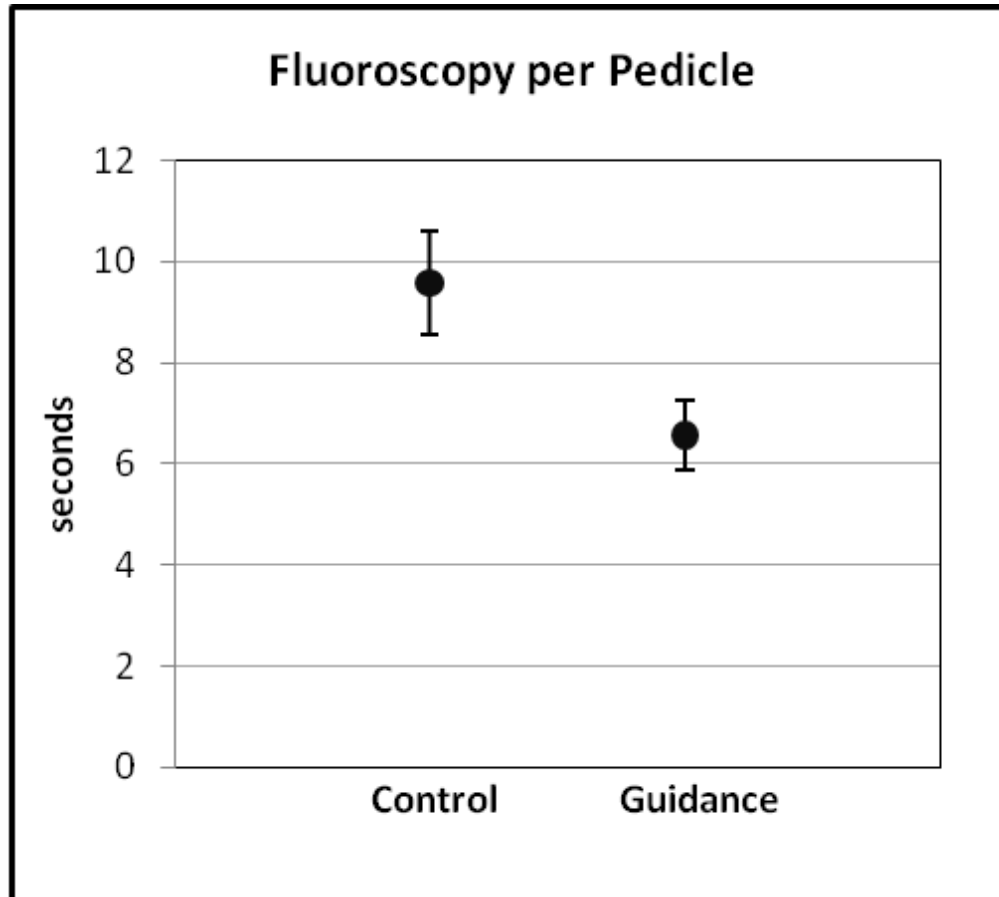
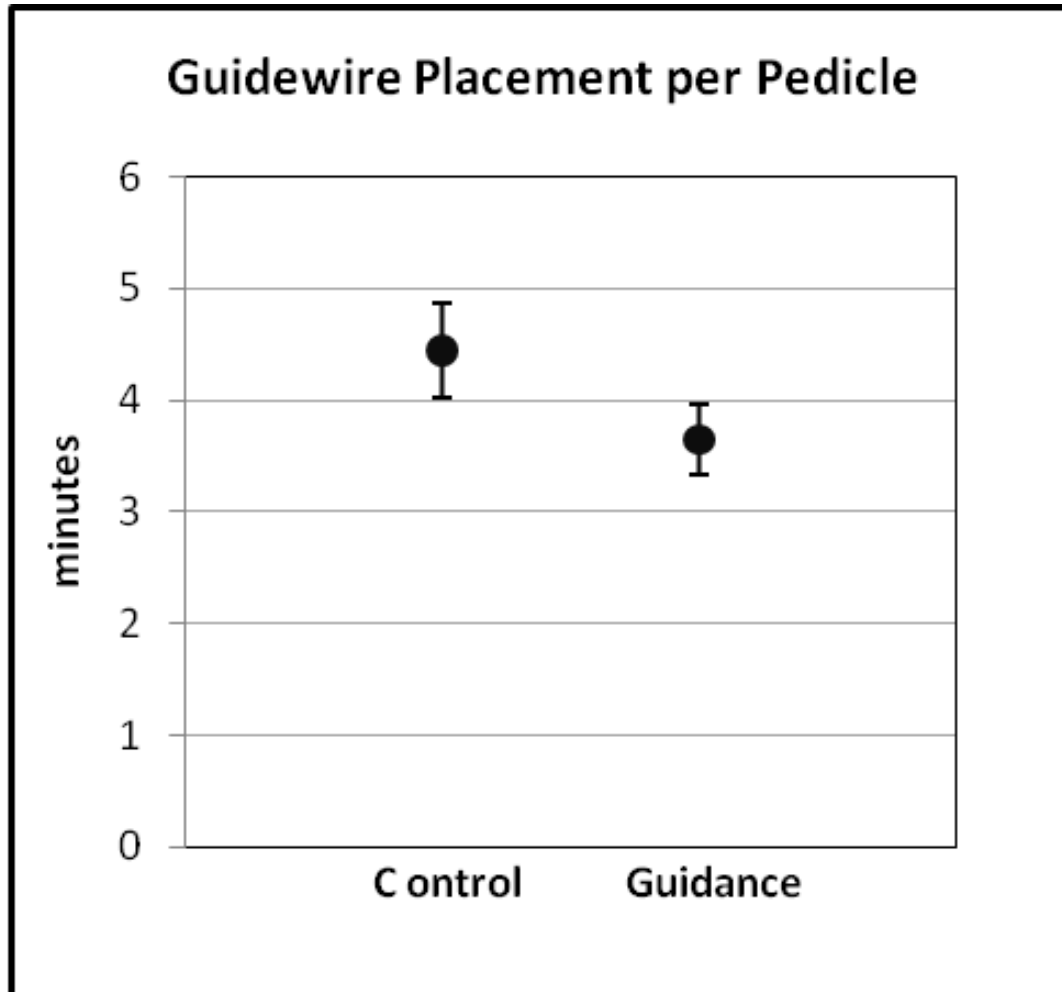


Figure 4



***LWW Copyright Transfer and Disclosure Form**

[Click here to download LWW Copyright Transfer and Disclosure Form: disclosure.IDLER.pdf](#)

***LWW Copyright Transfer and Disclosure Form**

[Click here to download LWW Copyright Transfer and Disclosure Form: disclosure.WAHL.pdf](#)

***LWW Copyright Transfer and Disclosure Form**

[Click here to download LWW Copyright Transfer and Disclosure Form: disclosure.YANG.pdf](#)