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Title: Use of Navigation-assisted Fluoroscopy to Decrease Radiation Exposure during Minimally Invasive Spine Surgery

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Abstract: BACKGROUND: Minimally invasive surgery decreases post-operative pain and disability. However, limited views of the surgical field require extensive use of intra-operative fluoroscopy which 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 using either navigation-assisted fluoroscopy or standard fluoroscopy. Times for specific surgical steps were compared. In addition, a prospective short-term evaluation of the intra-operative and peri-operative results of 10 patients undergoing navigation-assisted MIS TLIF (NAV group) compared with a retrospective review of 8 patients undergoing MIS TLIF performed 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 set-up time and total fluoro time. The set-up time for the NAV group averaged 9.67 (SD 3.74) minutes compared to 4.78 (SD 2.11) minutes for the FLUORO group ($p=0.034$). The total fluoro time was higher for the FLUORO group compared to 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). In the clinical series, the total fluoro time for the NAV group was 57.1 seconds (SD 37.3, range 18-120) compared to 147.2 sec (73.3 SD, range 73-295) for FLUORO group ($p=0.02$). No statistically significant differences are noted for OR time, EBL or hospital stay. No inadvertent durotomies, post-operative weakness, or new radiculopathy were noted in the NAV group. One inadvertent durotomy was encountered in the FLUORO group which was repaired intraoperatively without clinical sequelae.

CONCLUSION: 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.

Use of Navigation-assisted Fluoroscopy to Decrease Radiation Exposure during Minimally Invasive Spine Surgery

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1 **ABSTRACT**

2 **BACKGROUND:** Minimally invasive surgery decreases post-operative pain and disability.

3 However, limited views of the surgical field require extensive use of intra-operative fluoroscopy
4 which may expose the surgical team to higher levels of ionizing radiation.

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6 minimally invasive spine surgery.

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8 transforaminal lumbar interbody fusion (MIS TLIF) using navigation-assisted fluoroscopy with
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13 compared. In addition, a prospective short-term evaluation of the intra-operative and peri-
14 operative results of 10 patients undergoing navigation-assisted MIS TLIF (NAV group)
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16 standard fluoroscopy (FLUORO group).

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18 FLUORO group for most key steps. No statistically significant differences were obtained for:
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21 set-up time for the NAV group averaged 9.67 (SD 3.74) minutes compared to 4.78 (SD 2.11)

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24 exposure was undetectable when navigation-assisted fluoroscopy is used (NAV group). In
25 contrast, an average 12.4 mREM of radiation exposure is delivered to the surgeon during
26 unilateral MIS TLIF procedure without navigation (FLUORO group). In the clinical series, the
27 total fluoro time for the NAV group was 57.1 seconds (SD 37.3, range 18-120) compared to
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29 differences are noted for OR time, EBL or hospital stay. No inadvertent durotomies, post-
30 operative weakness, or new radiculopathy were noted in the NAV group. One inadvertent
31 durotomy was encountered in the FLUORO group which was repaired intraoperatively without
32 clinical sequelae.

33 **CONCLUSION:** Use of navigation-assisted fluoroscopy is feasible and safe for minimally
34 invasive spine surgery. Radiation exposure is decreased to the patient as well as the surgical
35 team.

36

37 **Keywords:** Image guidance, Ionizing radiation, occupational safety, Interbody fusion

38 INTRODUCTION

39 The concept of minimally invasive spine (MIS) surgery rests on the tenet of minimizing soft
40 tissue disruption by limiting exposure to the necessary surgical corridor and employing
41 specialized retractors that distribute pressures evenly. This is best accomplished with the use of
42 intraoperative fluoroscopy to aim retractors directly over the surgical target, guide accurate
43 insertion of implants, and assist with various key steps of the surgical procedure such as
44 decompression and discectomy. Unfortunately, the use of intraoperative fluoroscopy has
45 significant drawbacks. First, the entire surgical team (surgeon, assistant surgeon, and scrub
46 nurse) must remain at the surgical field, directly adjacent to the image intensifier. Rampersaud
47 et al. reported fluoroscopically assisted pedicle screw placement exposes the spine surgeon to
48 significantly greater radiation levels than other non-spinal procedures [1]. In fact, dose rates are
49 up to 10-12 times greater [2]. Second, the use of intraoperative fluoroscopy can be cumbersome
50 and inconvenient. The surgical team must don protective equipment such as lead aprons and
51 thyroid shields. This gear is extremely uncomfortable, especially when the C-arm encroaches
52 upon the surgical field and forces the surgical team to work in awkward positions. Image-guided
53 spine surgery using computer-assisted navigation is a promising technique that addresses many
54 of these concerns [3-7]. We describe the use of navigation-assisted fluoroscopy to perform
55 minimally invasive transforaminal lumbar interbody fusion (MIS TLIF). A cadaveric model is
56 used to compare various surgical parameters between MIS TLIF performed with standard
57 fluoroscopy vs. MIS TLIF performed with navigation-assistance (NAV-MIS TLIF). Radiation
58 exposure to the surgeon for each technique was determined. In addition, a prospective analysis
59 of 10 consecutive patients is used to show safety and feasibility, along with surgical times, and
60 total fluoroscopy times using the NAV-MIS TLIF technique. This is compared with a

61 retrospective review of 8 patients undergoing MIS TLIF using standard fluoroscopy.

62 **MATERIALS AND METHODS**

63 **Cadaveric Study of NAV-MIS TLIF**

64 Eighteen unilateral TLIFs were performed on 4 cadaveric specimens from L1-2 through L5-S1
65 as described previously [8,9]. Randomization of each level and side was determined using a
66 Latin-square design prior to examination of the cadavers. Two disk space levels were omitted
67 due to severe disk space collapse. A navigation-assisted fluoroscopy system (FluoroNav,
68 Medtronic Navigation, Louisville, CO) was used to perform 9 separate TLIF procedures as
69 described below (NAV group). The comparison group underwent MIS TLIF using standard
70 fluoroscopic techniques (FLUORO group). Specified steps in the procedure were timed by a
71 separate observer. The set-up time begins at the completion of draping and ends with the start of
72 the skin incision. This includes insertion of the patient reference tracker into the posterior
73 superior iliac spine (PSIS), manipulation of the C-arm, acquisition of the C-arm images, and
74 registration of the navigation instruments. The total fluoro time is determined automatically by
75 the internal timer of the C-arm unit measured in seconds. In the NAV group, the C-arm is used
76 mostly during set-up since all the images are obtained at the beginning of the procedure. For the
77 FLUORO group, the C-arm remains in the surgical field and is used intermittently throughout
78 the procedure, particularly during pedicle screw insertion and cage placement.

79 Approach time is at skin incision until the retractor is fully deployed. Exposure time begins
80 once the retractor is deployed and ends after the facet, hemilamina and pedicle entry points are
81 exposed. Screw insertion time is averaged for 2 screws. Facetectomy time begins immediately
82 after the last screw is inserted until the start of diskectomy. Diskectomy time begins from the
83 annulotomy to insertion of the interbody cage. Surgery time is the total time for the procedure

84 and begins when draping is complete until the locking nuts are tightened with the torque wrench.
85 Radiation detection badges were worn by the surgeon on the outside of the lead protective gear,
86 directly anterior to the thyroid. A separate badge was worn for each procedure and analyzed by
87 an independent lab (Landauer, Glenwood, IL). No measurement was performed for the patient
88 or cadaver specimen. All procedures were performed by a single surgeon (CWK).

89 **NAV-MIS TLIF Technique**

90 The patient reference tracker is placed into the PSIS using a 5mm fluted pin (Fig. 1A). A
91 standard 9-inch C-arm (OEC 9800, GE) is fitted with the navigation tracker to allow image
92 capture by the navigation computer. Multiple images of the lumbar spine are obtained and
93 stored in the navigation system. During image acquisition, the surgical team can step away from
94 the surgical field and behind lead shielding. No lead aprons are worn by the surgical team. Once
95 the desired images are obtained, the C-arm is taken out of the surgical field. The navigation
96 computer imports the fluoroscopic virtual images from the C-arm and relates them to patient
97 reference tracker, which in turn orients the navigation instruments and fluoroscopic images in 3-
98 dimensional space. The navigation pointer is used to plan the incision. The entry point to a path
99 directly in line with the disk space on the lateral image and down the lateral aspect of the facet
100 joint on the AP and oblique images is marked (Fig. 1). The skin and dorsal fascia are incised and
101 blunt finger dissection is performed between the multifidus and longissimus muscles. The
102 pedicles are entered using the navigation awl (or drill with a universal navigation attachment),
103 blunt pedicle probe and tap (Fig. 1). Using a split-screen monitor, 4 separate images can be view
104 simultaneously (Fig. 2). The pedicle screw of the appropriate size is inserted with the navigation
105 screw driver (Fig. 3). All screws are placed prior to the discectomy since the motion segment
106 becomes hypermobile and thus may decrease the accuracy of the navigation images.

107 A complete facetectomy and contralateral decompression is performed as described
108 McCulloch and colleagues [10-13]. If necessary, a navigation osteotome is used to remove the
109 overhanging rim of the posterior vertebral endplate during diskectomy (Fig. 3C). Navigated,
110 angled curettes are used to remove disk from the contralateral side (Fig. 3D). The navigation
111 pointer can be used to determine the extent of the diskectomy anteriorly (Fig. 3E) and the
112 position of the spacer in the AP plane (Fig. 3F). Final C-arm images are obtained to confirm
113 satisfactory implant position and spinal alignment. Again, the surgical team steps away from the
114 operative field during image acquisition.

115 **Review of Clinical Series**

116 Ten patients underwent treatment of grade 1 spondylolisthesis via NAV-MIS TLIF.
117 Intraoperative and perioperative parameters were obtained prospectively. Times for specific
118 steps of the procedure, including time for each screw insertion, were measured by an
119 independent observer (Table 1). Surgery time, estimated blood loss (EBL), intraoperative and
120 perioperative complications, and hospital stay were assessed. The total fluoroscopy time was
121 determined from the internal timer of the C-arm. In addition, eight patients undergoing MIS
122 TLIF using standard fluoroscopic technique without navigation were retrospectively studied.
123 Chart review obtained information on total OR time, estimated blood loss, hospital stay, and
124 complications. Total fluoro time was obtained from a radiation log sheet used to monitor c-arm
125 use. These values are also obtained from the internal timer of the C-arm.

126 **Statistical Analysis**

127 All comparisons were statistically analyzed using a 1-way analysis of variance and a Fisher
128 comparison *t*-test. Significance level was $p < 0.05$.

129 **RESULTS**

130 **Cadaveric Study of NAV-MIS TLIF**

131 Times for various steps during the surgical procedure are shown in Figure 4. For most key
132 steps, the times were similar between the NAV group and the FLUORO group. No statistically
133 significant differences were obtained for: approach, exposure, screw insertion,
134 facetectomy/decompression, or total surgical times. Statistically significant differences were
135 obtained for the set-up time and total fluoro time. The set-up time for the NAV group averaged
136 9.67 (SD 3.74) minutes compared to 4.78 (SD 2.11) minutes for the FLUORO group (p=0.034).
137 The total fluoro time was higher for the FLUORO group compared to the NAV group (41.9
138 seconds vs. 28.7 seconds, p=0.042). Total surgery time for the NAV and FLUORO groups were
139 50.2 (SD 10.2) minutes and 46.8 (SD 4.8) minutes, respectively (p=0.39). Radiation exposure is
140 undetectable when navigation-assisted fluoroscopy is used (NAV group). In contrast, an average
141 12.4 mREM of radiation exposure is delivered to the surgeon during unilateral MIS TLIF
142 procedure without navigation (FLUORO group).

143 **Clinical Series**

144 The clinical results of 10 patients undergoing the NAV-MIS TLIF procedure were assessed
145 prospectively. Table 1 shows specific times for set-up, exposure, screw insertion time,
146 facetectomy/decompression, diskectomy/cage insertion, and total surgery time. All procedures
147 were performed by a single surgeon (CWK) using the same C-arm. The set-up time was 18.0
148 minutes (SD 6.8, range 5-26). The approach time was 22 minutes (SD 11.9, range 6-45). The
149 average time for screw insertion was 10.3 minutes per screw (SD 5.7, range 2-24). All screws
150 were in satisfactory position using post-operative radiographs independently evaluated by a

151 musculoskeletal radiologist. The time for facetectomy and contralateral decompression using the
152 MIS laminoplasty technique was 54.9 minutes (SD 22.7, range 27-94). The time for diskectomy
153 was 28.5 minutes (SD 7.9, range 17-39).

154 Table 1 compares NAV-MIS TLIF with MIS TLIF without navigation for total fluoroscopy
155 time, total OR time and hospital stay. No statistically significant differences are noted for OR
156 time, EBL or hospital stay. There is a statistically significant decrease in total fluoro time with
157 navigation. The total fluoro time for NAV group was 57.1 seconds (SD 37.3, range 18-120)
158 compared to 147.2 sec (73.3 SD, range 73-295) for FLUORO group (p=0.02). No inadvertent
159 durotomies, post-operative weakness, nor new radiculopathy were noted in the NAV group. One
160 inadvertent durotomy was encountered in the FLUORO group which was repaired
161 intraoperatively without clinical sequelae. In one case in the NAV group, the patient tracker was
162 inadvertently bumped out of position. Acquisition of new images used an additional 32 seconds
163 of fluoro time.

164 **DISCUSSION**

165 Minimally invasive spinal fusion using the MIS TLIF technique is efficacious and safe [8,9].
166 However, the need for intraoperative fluoroscopy poses significant disadvantages. In terms of
167 relative risk, a spine surgeon performing MIS procedures such as kyphoplasty will be at 50 times
168 greater risk of fatal cancer compared to a hip surgeon [14]. With the use of navigation-assisted
169 fluoroscopy, the surgical team can step away from the surgical field and thus eliminate direct
170 radiation exposure. Navigation-assisted fluoroscopy will not prevent exposure to the patient
171 since they must remain in the radiation field during image acquisition. Fortunately, radiation
172 exposure to patients is limited to the procedure itself. Unless they are undergoing multiple
173 procedures involving fluoroscopy, their risk has been negligible. In a recent experimental study

174 of radiation exposure to the fetus, it was estimated that at least 35 minutes of fluoroscopy would
175 be needed for the induction of radiation-related effects [15]. Most studies show that exposure to
176 the patient during various fluoroscopy-intensive procedures such as angioplasty and hepatic
177 neoplasm chemoembolization is low [16].

178 This study shows that navigation-assisted fluoroscopy is a promising method to decrease
179 radiation exposure during MIS surgery. The method is simple and straightforward, with an
180 acceptable clinical safety profile. This particular technique addresses many of the previous
181 drawbacks of navigation. No additional preoperative images are necessary and thus there is no
182 need for fiducial readings to “match up” the navigation image with a CT scan. Familiar
183 fluoroscopic techniques are enhanced with four simultaneous images of the spine in
184 anteroposterior, lateral and oblique views. Furthermore, since all navigation images are obtained
185 at the beginning of surgery, there is less repositioning of the C-arm. This is illustrated in the
186 clinical series where C-arm usage (as measured by the total fluoro time) for navigation-assisted
187 surgery is less than that for standard fluoroscopic surgery. However, it is important to point out
188 that in the clinical series the data for the NAV group was obtained prospectively and the
189 FLUORO group retrospectively. This may lead to certain biases since the surgeon was aware
190 that he was being timed and may be more proficient in MIS techniques. The cadaveric studies
191 may be more representative of the true difference in C-arm usage since the NAV and FLUORO
192 groups were randomized and the procedures were performed by a single surgeon during the same
193 study period. The cadaveric study also shows that the C-arm usage is decreased with navigation-
194 assisted MIS surgery. This can be advantageous when the fluoroscope technician is
195 inexperienced and/or uninterested.

196 The navigation-assisted fluoroscopic MIS surgery offers several other advantages. Desired
197 screw sizes and rod lengths can be determined. The extent of the diskectomy and the position of
198 the interbody graft can be assessed. Operating room ergonomics is improved by clearing the
199 surgical field. The operating microscope can be brought in without interference from the C-arm.
200 The need for heavy, restrictive protective gear is eliminated since all navigation images are
201 obtained while the surgical team steps away from the path of radiation scatter.

202 While there is a preconception that use of navigation-assisted fluoroscopy adds time-
203 consuming tasks to the procedure, our cadaveric studies show that overall surgical times are not
204 affected. There is additional time needed at the beginning of the procedure to acquire and
205 download all the images into the navigation computer. This step can be perceived as excessively
206 long, particularly to the expeditious spine surgeon. However, overall fluoroscopy time is
207 decreased with navigation by eliminating the time-consuming task of bringing the C-arm in and
208 out of the surgical field and obtaining additional scout images to re-establish the desired views.
209 By avoiding these steps, the time spent for navigation set-up is offset by the time needed to take
210 additional images and for the fluoroscope technician to reposition the C-arm.

211 **CONCLUSION**

212 The technique of navigation-assisted fluoroscopy for single level transforaminal lumbar
213 interbody fusion (NAV-MIS TLIF) is simple and readily applicable for most spine surgeons.
214 The technique described eliminates cumbersome preoperative imaging as well as intraoperative
215 image registration using fiducial points. It retains fluoroscopic techniques familiar to most spine
216 surgeons. Initial, short-term clinical results support its feasibility and safety. The surgical team
217 benefits from reduced exposure to ionizing radiation and improved operating room ergonomics.

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256 **FIGURES**

257

258 **Figure 1.** Use of navigation probe to plan incision and exposure. All images are captured in the
259 navigation system at the beginning of the procedure and the C-arm is taken out of the surgical
260 field during surgery. The navigation computer stores all images as virtual images. Various
261 navigation instruments can now be used with the virtual images which are overlaid onto the
262 image of the navigation tracking device. The navigation probe (white arrow) is placed on the
263 skin to plan center of the incision and the trajectory of the approach (A, C, D). A universal
264 tracking handle can accommodate various additional tools needed for pedicle screw insertion,
265 including awls, pedicle probes, and taps (B). In the anteroposterior (AP) plane, the tip of the
266 probe is docked lateral to the pedicles as shown in purple (C). In the lateral image, the probe is
267 directly in line with the disk space. An extension (shown in red) is placed at the tip of the probe
268 using the navigation software to aid in alignment (D). The tip can be extended by the navigation
269 system to aid in alignment. The probe is pictured in purple and the extension in red (C, D).

270

271 **Figure 2.** Use of simultaneous, multi-planar views during surgery. Using a 4-panel split screen
272 format, AP, lateral and obliques views of the spine can be visualized simultaneously.

273 Trajectories in the AP (A) and lateral (B) plane can ensure optimum screw position. Oblique
274 views provide additional information to prevent pedicle breaches (C). The contralateral oblique
275 (D) is not necessary for screw insertion and thus alternate images can be used, such as another
276 lateral image at a distant surgical level.

277

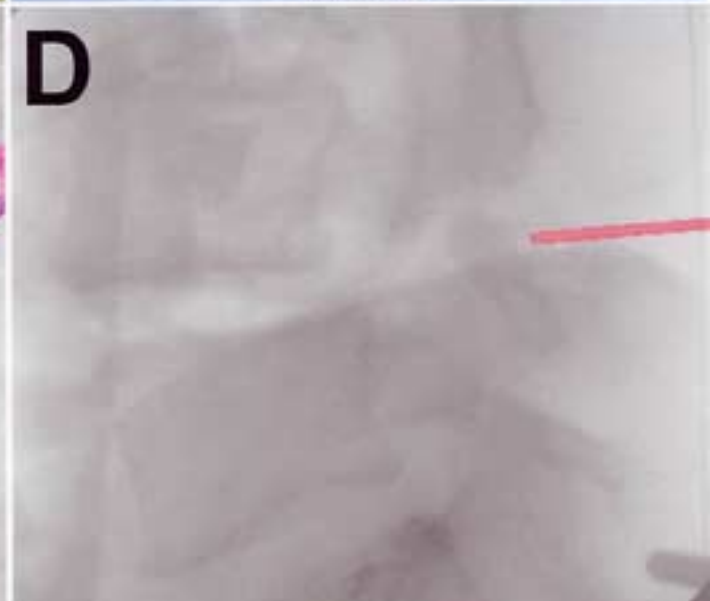
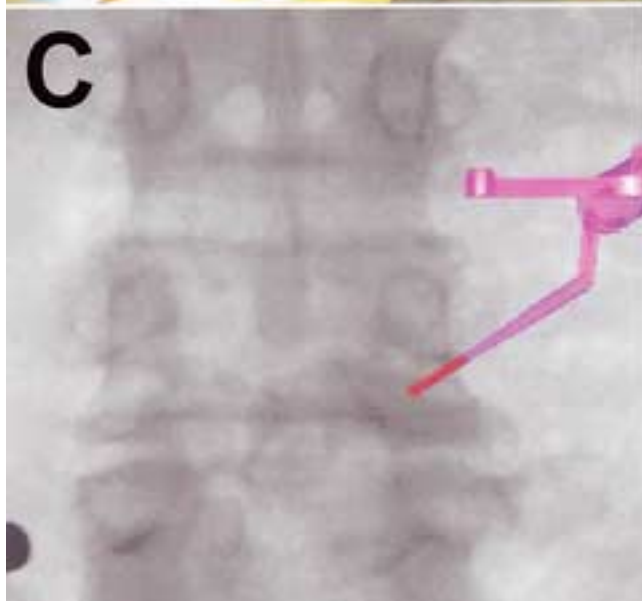
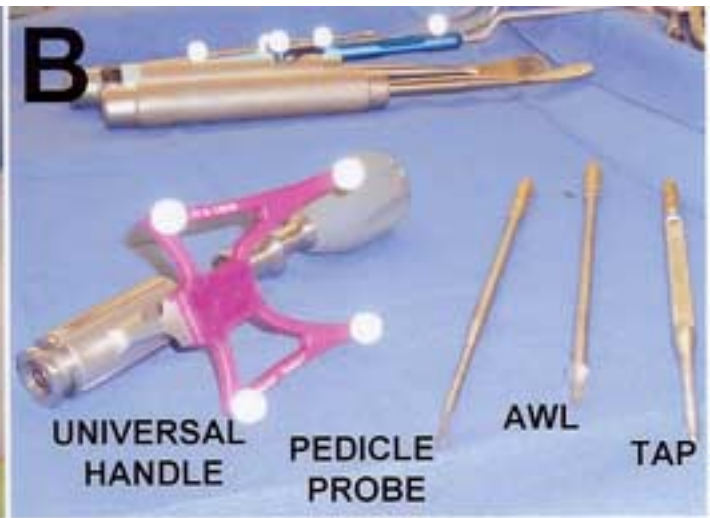
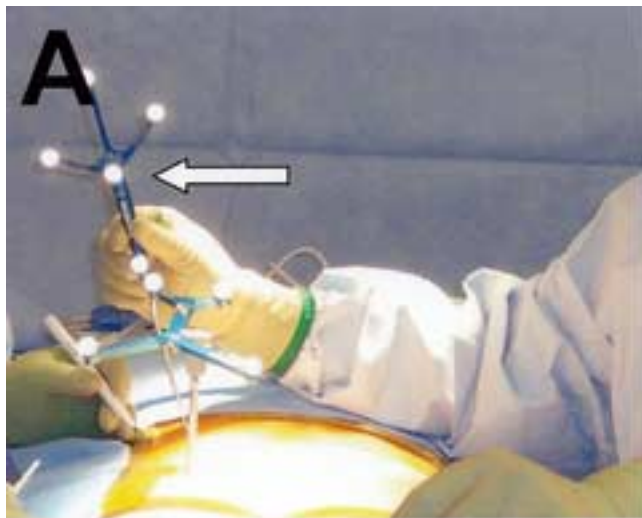
278 **Figure 3.** Use of navigation for pedicle screw insertion and diskectomy. Once all pedicle
279 screws are inserted (A, B), subtotal diskectomy is performed using various navigation
280 instruments such as osteotomes (C) and angled curettes (D). The navigation pointer is used to
281 determine the extent of diskectomy anteriorly (E) and location of the interbody spacer relative to
282 the midline (F).

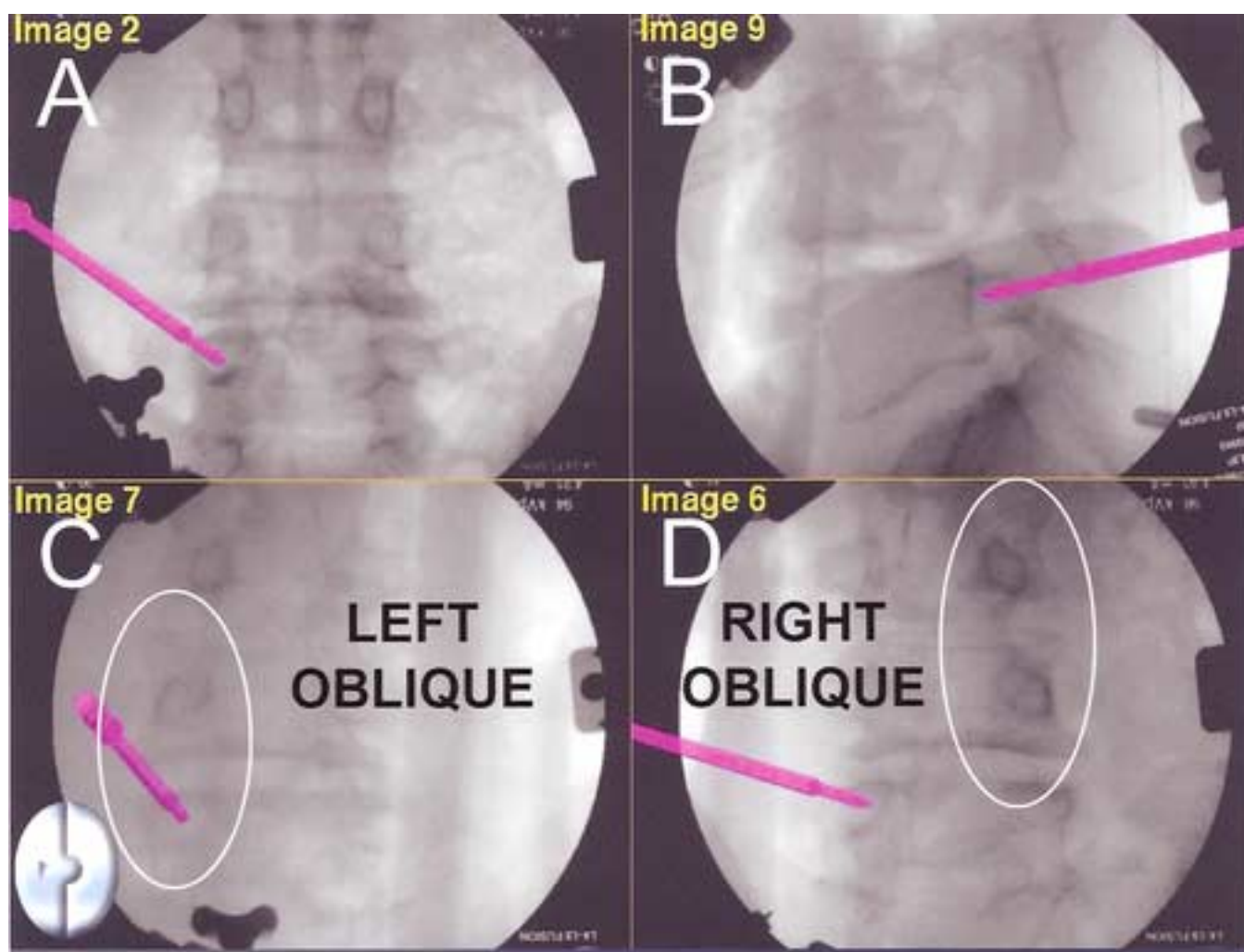
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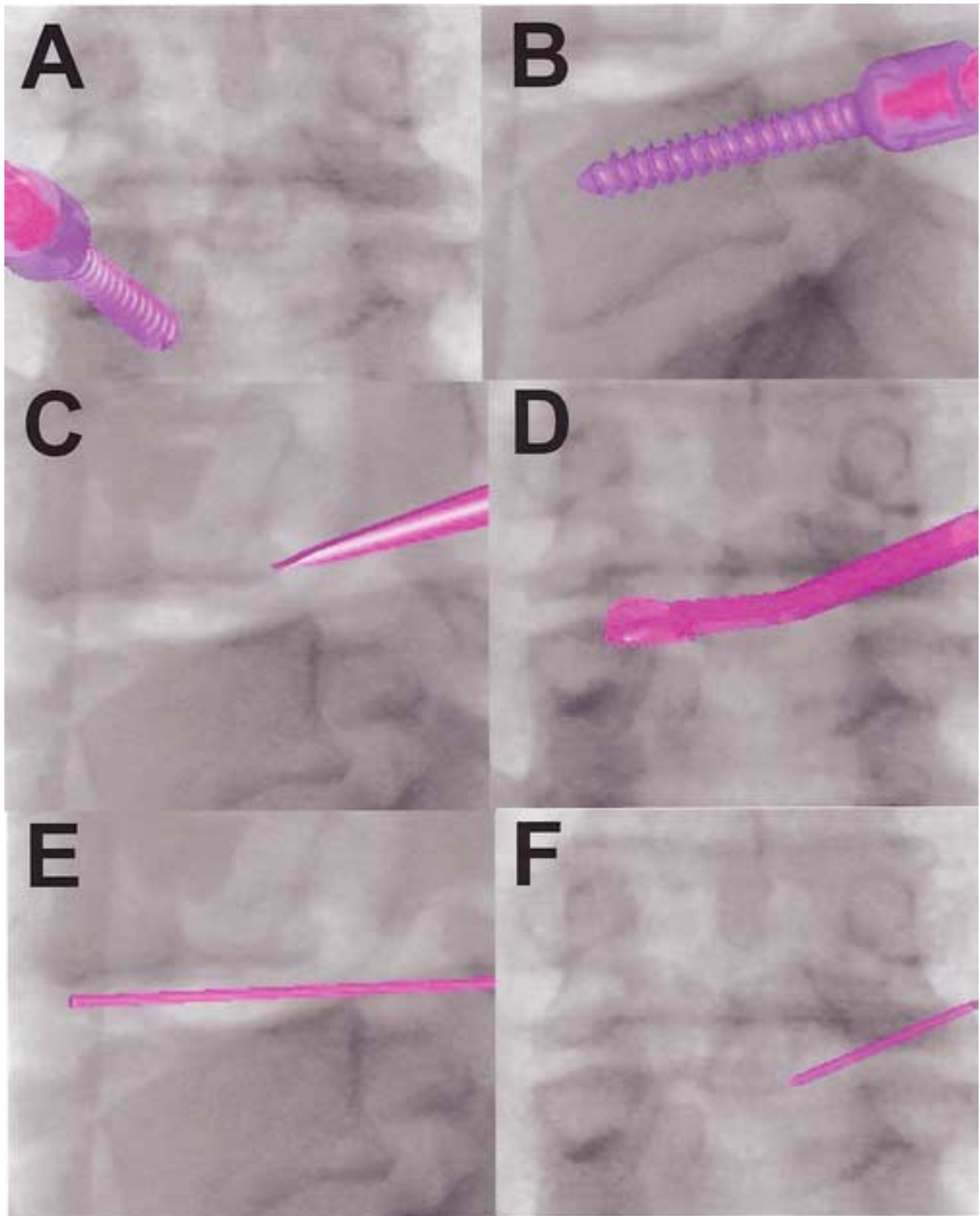
284 **Figure 4.** Cadaveric study comparing MIS TLIF using navigation assisted fluoroscopy (NAV,
285 black bars) vs. standard fluoroscopy (FLUORO, white bars). Statistical analysis was performed
286 using 1-way ANOVA with $p < 0.05$. Standard deviations are shown with vertical lines.
287 Statistically significant differences were found for the SET-UP time (minutes) and C-ARM time
288 (seconds). The remaining parameters showed no statistically significant differences.

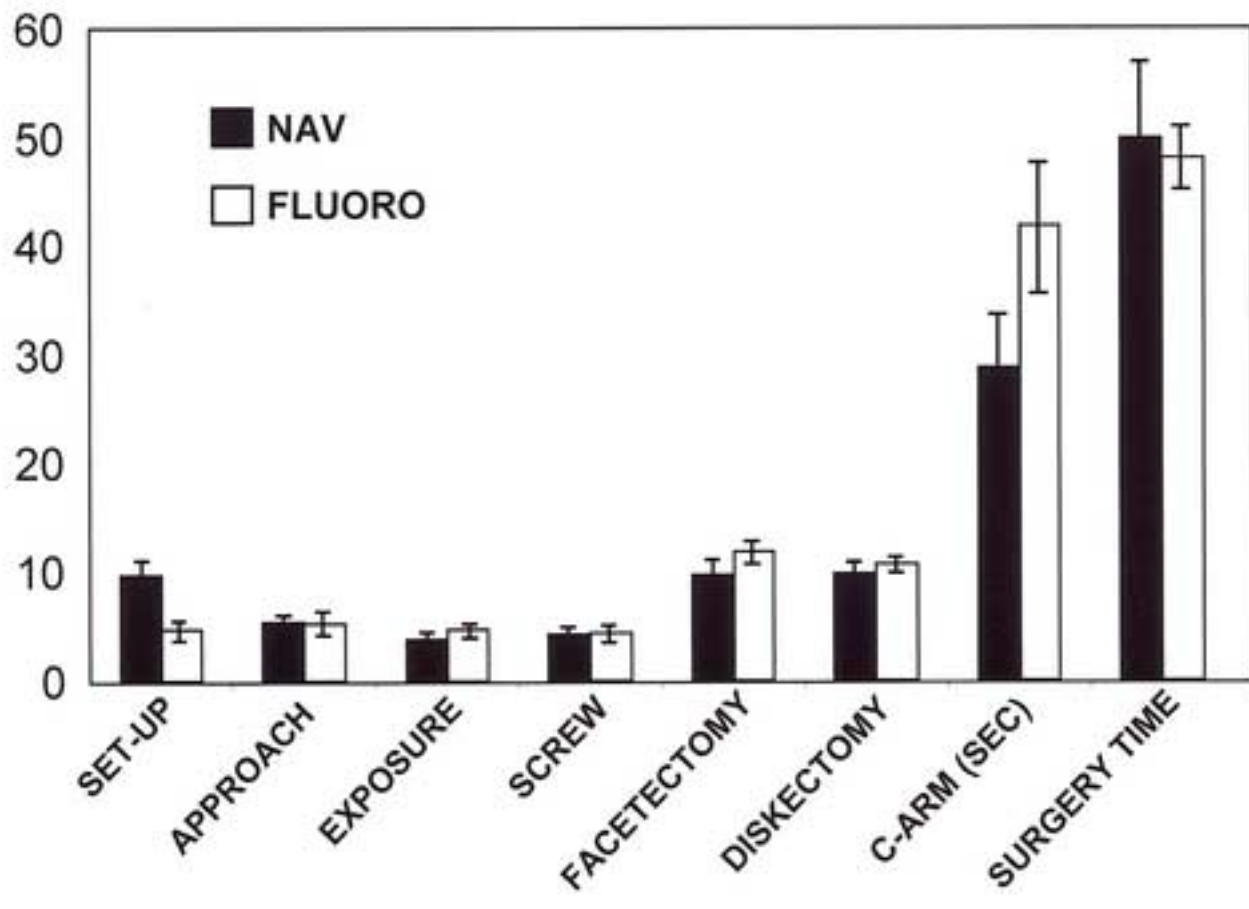
TABLE 1. Summary of Intraoperative and Perioperative Clinical Results

	NAVIGATION-ASSISTED	FLUORO
Set-up Time	18 (± 6.8 SD)	
Approach	24.3 (± 10.8 SD)	
Facetectomy	55.0 (± 24.5 SD)	
Diskectomy	27.6 (± 8.1 SD)	
Cage Insertion	14.0 (± 8.2 SD)	
Screw Insertion	10.3 (± 5.7 SD)	
Total OR Time	267.9 (± 37.4 SD)	293.4 (± 62.9 SD)
Fluoro Time (sec)	57.1 (± 34.5 SD)	147.0 (± 73.3 SD)
EBL (ml)	200 (± 77.7 SD)	206.2 (± 78.8 SD)
Hospital Stay (days)	3.6 (± 0.7 SD)	3.4 (± 0.5 SD)
Complications	NONE	CSF Leak (n=1)









THE SPINE JOURNAL

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NAME OF AUTHOR Choll W. Kim

December 20, 2006

Dear Dr. Branch,

Thank you for considering our manuscript for publication in the Spine Journal. We appreciate the thoughtful comments by the reviewers. I have addressed each concern as described below.

Reviewer #1: This manuscript is an interesting and excellent paper and worth publishing when minor revisions were done.

-We appreciate the supportive remarks and have addressed the issues below.

1) P-6, 14th line: "PCIS" should be "PSIS". –DONE

2) P-7, 8th line: "longismus" should be "longissimus". –DONE

3) P-18, References, 12. "Limitation of ---" is a duplicate phrase.

–THIS REFERENCE WAS DELETED IN THE COURSE OF SHORTENING THE MANUSCRIPT, AS REQUESTED BY REVIEWER #3.

4) P-20, Figure 1, 8-9th lines: "in the anteroposterior(AP) plane, the tip of the probe is docked lateral to the pedicles (C). This sentence is somewhat different from Fig.I-C picture.

-THE FIGURE LEGEND HAS BEEN CLARIFIED TO DESCRIBE THE PURPLE PORTION OF THE IMAGE AS THE PROBE AND THE RED LINE AS AN EXTENSION ON THE PROBE GENERATED BY THE NAVIGATION COMPUTER. IT LEGEN NOW READS:

“An extension (shown in red) is placed at the tip of the probe using the navigation software to aid in alignment (D). The tip can be extended by the navigation system to aid in alignment. The probe is pictured in purple and the extension in red (C, D).”

5) P-21, Figure 3, 2-3rd line: "location of the interbody spacer relative to the midline (E)"

Is this sentence appropriate description for Fig. 3-F?

-THANK FOR FINDING THIS ERROR. IT IS IN FACT 3F. THE TEXT HAS BEEN CHANGED ACCORDINGLY.

Reviewer #2: Abstract

1. Results, lines 17 through 26 - Please make clear that these results are for the cadaver group.

- THE TEXT HAS BEEN CHANGED TO: “In the cadaveric study, the times were similar between the NAV group and the FLUORO group for most key steps.”

Introduction

2. The authors mention in the introduction that one of the reasons for using computer assisted navigation is to decrease radiation exposure to the surgeon. However, nowhere in their manuscript do they report exposure to the patient using this system. Was this parameter measured in either the cadaver or clinical portions? If not, is there any published information that the authors can discuss in the discussion?

THIS IMPORTANT POINT IS ADDRESSED BY ADDING THE FOLLOWING DISCUSSION TEXT:

“Navigation-assisted fluoroscopy will not prevent exposure to the patient since they must remain in the radiation field during image acquisition. Fortunately, radiation exposure to patients is limited to the procedure itself. Unless they are undergoing multiple procedures involving fluoroscopy, their risk has been negligible. In a recent experimental study of radiation exposure to the fetus, it was estimated that at least 35 minutes of fluoroscopy would be needed for the induction of radiation-related effects [Theocharopoulos et al. 2006]. Most studies show that exposure to the patient during various fluoroscopy-intensive procedures such as angioplasty and hepatic neoplasm chemoembolization is low [Efstathopoulos et al. 2006].”

Materials and method

3. Do the authors have any financial relationship with the FluoroNav company? They should state whether they do or not.

-MY RELATIONSHIP AS MEMBER OF THE SPEAKER’S BUREAU FOR MEDTRONIC SOFAMOR DANEK IS LISTED IN THE CONFLICT OF QUESTIONNAIRE

4. Please describe exactly how the navigation system works (it is better to do so in the text than in the caption of the figure). How does the patient tracker and universal handle actually work?

THE FURTHER CLARIFICATION OF THIS TECHNIQUE IS GIVEN IN THE MATERIALS AND METHODS SECTION. THE FOLLOWING TEXT HAS BEEN ADDED:

“The navigation computer imports the fluoroscopic virtual images from the C-arm and relates them to patient reference tracker, which in turn orients the navigation instruments and fluoroscopic images in 3-dimensional space. The navigation pointer is used to plan the incision. “

Results

5. The set up time for the Nav group averaged almost 10 minutes in the cadaveric study and averaged approximately 18 minutes in the clinical study. Even though total OR time was not different between the Nav and the fluoro groups, isn't this increased set up time down-time for the surgeon? YES, THIS DOES REPRESENT INCREASED DOWN TIME FOR THE SURGEON AT THE BEGINNING OF THE PROCEDURE. HOWEVER, THIS TIME IS LIKELY OFFSET BY ELIMINATING THE TIME THAT THE C-ARM IS BROUGHT IN AND OUT OF THE SURGICAL FIELD WHEN STANDARD FLUOROSCOPIC TECHNIQUES ARE USED. SEE ALSO ANSWER FOR ITEM 7.

6. How much time is actually spent acquiring the Nav images during set up? i.e, how much x-ray time? THE FLUORO TIME AND XRAY TIME ARE SIMILARLY DEFINED. IT IS THE TIME THE C-ARM MACHINE IS ACTIVATED. AND INTERNAL COUNTER ON THE C-ARM MONITORS THIS PARAMENTS IN SECONDS. THE AVERAGE TIME SPENT ACQUIRING NAV IMAGES DURING SET-UP WAS NOT DETERMINED. OF THE AVERAGE 18 MINUTES OF SET-U TIME IN THE CLINICAL STUDY, HAVE OF THE SET-UP TIME IS OCCUPIED BY IMAGE ACQUISITION. OTHER STEPS INCLUDE INSERTION OF THE PATIENT REFERENCE TRACKER INTO THE PSIS AND REGISTRATION OF THE NAVIGATION INSTRUMENTS. THIS IS DESCRIBED IN THE MATERIALS AND METHODS SECTION WITH THE FOLLOWING TEXT:

“The set-up time begins at the completion of draping and ends with the start of the skin incision. This includes insertion of the patient reference tracker into the PSIS, manipulation of the C-arm, acquisition of the C-arm images, and registration of the navigation instruments. The total fluoro time is determined automatically by the internal timer of the C-arm unit measured in seconds. In the NAV group, the C-arm is used mostly during set-up since all the images are obtained at the beginning of the procedure. For the FLUORO group, the C-arm remains in the surgical field and is used intermittently throughout the procedure, particularly during pedicle screw insertion and cage placement.”

SEE ALSO ANSWER FOR ITEM 7.

7. Page 10, line 215 - Is the total fluoro time inclusive or exclusive of that used during set up? If it is exclusive of set up time, then how much x-ray time is used during the setup, and is that total x-ray time longer than the fluoro group?

-A CLARIFICATION OF THE SET-UP TIME AND FLUORO TIME IS ADDED TO THE MATERIALS AND METHODS SECTION WITH THE FOLLOWING TEXT:

“The set-up time begins at the completion of draping and ends with the start of the skin incision. This includes insertion of the patient reference tracker into the PSIS, manipulation of the C-arm, acquisition of the C-arm images, and registration of the navigation instruments. The total fluoro time is determined automatically by the internal timer of the C-arm unit measured in seconds. In the NAV group, the C-arm is used mostly during set-up since all the images are obtained at the beginning of the procedure. For the FLUORO group, the C-arm remains in the surgical field and is used intermittently throughout the procedure, particularly during pedicle screw insertion and cage placement. “

8. It is not a fair comparison to compare the method of time keeping for the clinical series to the retrospective review of the conventional fluoro guided procedures; one is prospective and the surgeon knew he was being timed, while the other is retrospective and the person keeping the time logs may not have been as precise as the prospective time keeper.

-THIS IS AN IMPORTANT LIMITATION IN THE STUDY THAT NEEDS CLARIFICATION. THE FOLLOWING TEXT HAS BEEN ADDED TO THE DISCUSSION.

“It is important to point out that in the clinical series the data for the NAV group was obtained prospectively and the FLUORO group retrospectively. This may lead to certain biases since the surgeon was aware that he was being timed and may be more proficient in MIS techniques. The cadaveric studies may be more representative of the true difference in C-arm usage since the NAV and FLUORO groups were randomized and the procedures were performed by a single surgeon during the same study period. The cadaveric study also shows that the C-arm usage is decreased with navigation-assisted MIS surgery. “

9. Page 11 lines 241 to 243 - Were there any cases in which the navigation image did not coincide with the expected anatomic landmarks and for which the C arm had to be brought back into the field and a new set of navigation images obtained? If so, how many cases did this happen in and how did it affect time?

-YES, THERE WAS ONE CASE WHEN THE PATIENT TRACKER WAS BUMPED AND NEW IMAGES NEEDED TO BE OBTAINED. THIS IS REFERENCED IN THE RESULTS SECTION WITH THE FOLLOWING TEXT:

“In one case in the NAV group, the patient tracker was inadvertently bumped out of position. Acquisition of new images used an additional 32 seconds of fluoro time.”

Conclusion

10. Omit the last two sentences since they are speculative and not a conclusion based directly on the presented data.

-DONE

Reviewer #3: This paper is pertinent to the interests of the readership of The Spine Journal. It needs major revision to be of publishable quality but with the rewrite, I believe it should be published. The text is far too long. The introduction, for example, lists indications for fusion, advantages of MIS, and downside of open operations. The Spine Journal is a publication read by spine specialists. Talking down to our audience is unbecoming. The intro could begin with line 47 (The use of...) and the remainder could be, at most, perhaps four sentences. The text of the entire paper should be shortened by fifty to sixty percent and I really believe that will make a more effective presentation of the information intended by these authors.

My other criticism had to do with the emphasis on "the learning curve". With current generation instruments and technology, MIS is very easy to adopt and it's very doable for a surgeon of more advanced career standing to enter the realm. There is a tone to this paper that emphasizes the difficulties of these techniques that to me sounds like "don't try this at home kids". These authors believe in MIS; (unless they believe they are gods and only they can do

this) they therefore are positioned to educate and promote the techniques. Emphasizing that courses and additional training are important is appropriate. Spine surgeons need this information and they need to hear it from those who take the position of peer educators. To the authors I simply say, this is a decent study, please rewrite it with a focus on concise, tightly worded information presented with the reader in mind.

-WE THANK THE REVIEWER FOR COMMENTS TO IMPROVE THE MANUSCRIPT. WE ARE ENCOURAGED THAT WITH A REVISION THIS MANUSCRIPT CAN BE PUBLISHED IN THE SPINE JOURNAL.

THE INTRODUCTION HAS BEEN REWRITTEN FOR AN AUDIENCE OF EXPERIENCED SPINE SURGEONS. IT SHORTENED TO A SINGLE PARAGRAPH WITH ONLY 22 LINES. ALSO, THE ENTIRE MANUSCRIPT IS NOW 184 LINES (COMPARED TO 309 LINES IN THE PREVIOUS SUBMISSION).

THE DISCUSSION OF THE “LEARNING CURVE” HAS BEEN DE-EMPHASIZED. THE SECTION ON “TIPS AND PEARLS” HAS BEEN ELIMINATED, WITH SOME SPECIFIC PERTINENT INFORMATION PLACED INTO THE MATERIALS AND METHODS SECTION. THE DISCUSSION OF RADIATION TOLERANCE LIMITS HAS BEEN CONSOLIDATED.

WE HOPE THAT THIS REVISION SATISFIES THE REQUEST TO MAKE THIS MANUSCRIPT MORE CONCISE AND TIGHTLY WORDED. WE SINCERELY APOLOGIZE FOR THE UNDESIRABLE TONE OF OUR MANUSCRIPT. IT WAS VERY MUCH UNINTENTIONAL. WE LOOK FORWARD TO YOUR RE-REVIEW OF THIS MANUSCRIPT.

Sincerely yours,

The Authors