

# Computer-Assisted Instrument Navigation Versus Conventional C-Arm Fluoroscopy for Surgical Instrumentation: Accuracy, Radiation Time, and Radiation Exposure

Timothy Y. Wang<sup>1</sup>  
 Farah Hamouda  
 Eric W. Sankey  
 Vikram A. Mehta  
 Chester K. Yarbrough  
 Muhammad M. Abd-El-Barr

**OBJECTIVE.** Compared with open procedures, minimally invasive surgical procedures are associated with increased radiation exposure and long-term health risks. Ultralow radiation imaging coupled with image enhancement and instrument tracking (ULRI-IE/IT) is a new image modifier that allows a computer to show real-time movement of an instrument as it is adjusted, mimicking live fluoroscopy but without continuous radiation production. The purpose of this study was to determine the accuracy and radiation output of ULRI-IE/IT compared with unassisted conventional fluoroscopy in a variety of surgical procedures.

**MATERIALS AND METHODS.** Physicians of various specialties were asked to identify the ideal location for instrumentation in various spinal, orthopedic, pain, and physiatric procedures and then place an instrument in this location in a cadaver both with and without ULRI-IE/IT assistance. Whether ULRI-IE/IT was used was randomly assigned to reduce the impact of learning. Radiation exposure, time to place the instrument, and the number of images required to achieve accurate positioning were recorded for each procedure. These were compared for unassisted and ULRI-IE/IT-assisted fluoroscopy to determine the utility of ULRI-IE/IT in minimally invasive instrumentation.

**RESULTS.** Twenty-three trials of nine procedures by five physicians were completed both with and without assistance of ULRI-IE/IT. The procedures ranged from percutaneous pedicle screw insertion to foramen ovale ablation. Total time to localize the instrument for all 23 cases was 31.2% longer without assistance. Use of ULRI-IE/IT reduced the total number of images per case by 74.8% and radiation exposure by 91.8%. With ULRI-IE/IT, physicians were able to successfully place the instrument in the correct location on the first attempt in 82.6% of trials and in the second attempt in all trials versus a mean of 4.65 images needed for unassisted fluoroscopy.

**CONCLUSION.** Use of ULRI-IE/IT can dramatically reduce radiation output and the number of images acquired and time required to perform fluoroscopic procedures.

**Keywords:** accuracy, C-arm, fluoroscopy, instrument tracking, navigation, radiation

doi.org/10.2214/AJR.18.20788

Received October 14, 2018; accepted after revision March 15, 2019.

Based on presentations at the Southern Neurosurgical Society 2018 annual meeting, Marco Island, FL; American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons Spine Section 2018 annual meeting, Orlando, FL; and the AANS 2018 annual meeting, New Orleans, LA.

<sup>1</sup>All authors: Department of Neurological Surgery, Box 3087, Duke University Medical Center, Durham, NC 27710. Address correspondence to T. Y. Wang (timothy.wang@duke.edu).

AJR 2019; 213:1–8

0361–803X/19/2133–1

© American Roentgen Ray Society

The introduction of minimally invasive surgery provides patients with new surgical alternatives that avoid the morbidity of open dissection. In spine surgery specifically, minimally invasive approaches have been found to reduce blood loss, reduce use of postoperative opioid analgesics, and shorten hospital stays and recovery times, all while having fusion rates and long-term functional outcomes similar to those of open procedures [1–6]. Inherent to minimally invasive procedures, however, is the lack of direct anatomic visualization. Therefore, surgeons must rely on intraoperative imaging, generally accomplished with C-arm fluoroscopy, to assess patient anatomy and instrument positioning. This

reliance has increased radiation exposure to both surgeon and patient.

The increase in radiation exposure is substantial. Rampersaud et al. [7] found in an in vitro study that fluoroscopically assisted pedicle screw insertion was associated with a 12-fold increase in radiation exposure to the hand compared with pedicle screw insertion under direct visualization, in which the starting position of the pedicle screw could be directly seen. Likewise, in a prospective study, Mariscalco et al. [8] found up to a 20-fold increase in radiation exposure to the thyroid, eye, chest, or hand during minimally invasive lumbar discectomy compared with open lumbar discectomy [8]. In a study of 40 patients undergoing either minimally invasive or open posterior lumbar inter-

body fusion, Ntoukas and Müller [9] found a greater than twofold increase in radiation time using minimally invasive surgical technique compared with open technique.

Most of the radiation exposure in a variety of fluoroscopy-dependent procedures occurs during instrumentation, in which a staggering number of fluoroscopic images can be required to localize and relocalize instrument positioning. Instrument tracking and fluoroscopic image enhancement would help proceduralists understand the location of their surgical instrumentation in relation to the patient's anatomy. The intent is to reduce the number of fluoroscopic images and radiation required to safely perform a given procedure. To our knowledge, however, no such technology has been described. We conducted a single-institution randomized nonblinded multisurgeon

multiprocedure cadaveric study of the use of a novel optical instrument tracking and image enhancement package to determine whether its use would be associated with reduction in radiation output and accuracy compared with use of standard C-arm fluoroscopy.

### Materials and Methods

Five physicians—an orthopedic surgeon, general neurosurgeon, spine fellowship-trained neurosurgeon, pain management specialist, and physiatrist, all with more than 5 years of postresidency experience—participated in this randomized cadaveric study to compare conventional fluoroscopy and ultralow radiation imaging with image enhancement and image tracking (ULRI-IE/IT). The technology used combined two elements: TrackX (TrackX Technology) for instrument tracking and LessRay (NuVasive) for ULRI image enhancement.

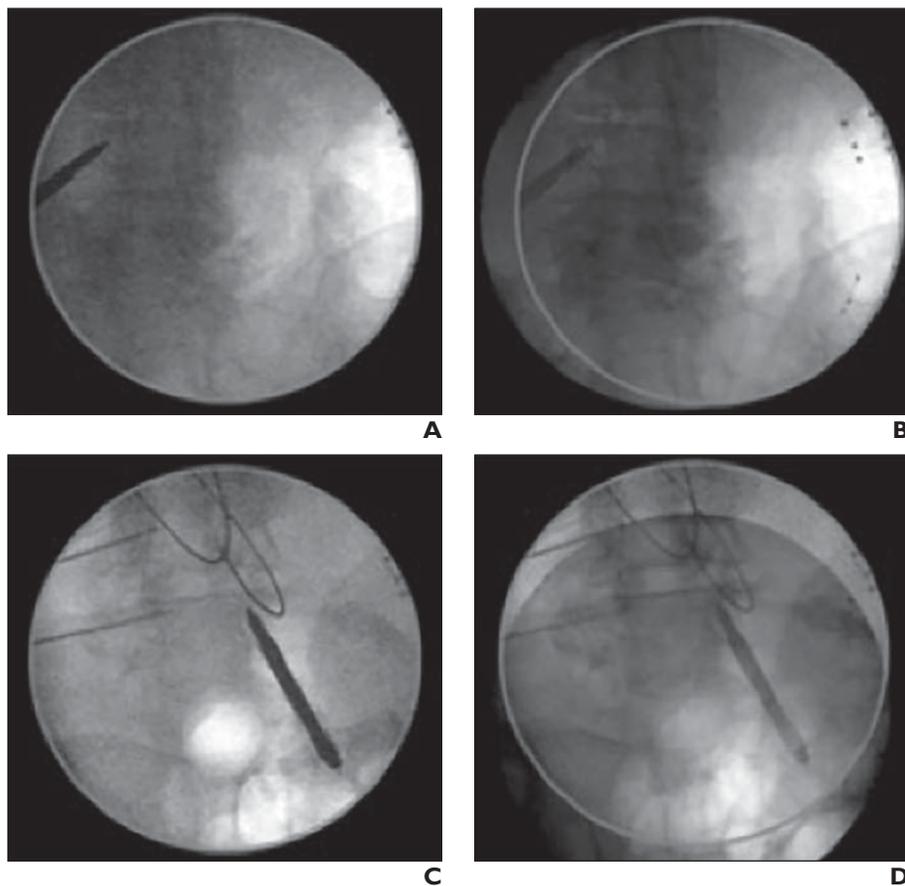
### Image Enhancement

The image enhancement package serves as the backbone of the standard C-arm fluoroscope and functions to enhance low-quality low-radiation images and provide the user with real-time instrument location tracking. Image enhancement of ultralow-radiation images has been described by Wang et al. [10] and Nayar et al. [11]. Briefly, full-dose fluoroscopic localizing images (with the C-arm autoregulating pulse width and dose with the assistance of automatic brightness control) are acquired at the beginning of the procedure. A navigation array placed on the C-arm camera and the radiation source allows registration of the position of the C-arm in relation to the immobilized patient.

The location of the C-arm in relation to the patient is displayed on a live viewfinder. As the C-arm is moved, the live viewfinder displays the relation of the C-arm to any one of the previously acquired and registered images, which aids the technologist in repositioning the C-arm back to its desired position without additional fluoroscopic images. This is particularly useful for procedures that require fluoroscopic images in different positions (i.e., multiple spinal levels) or in multiple planes (anteroposterior vs lateral) that require significant C-arm adjustment. The return of the C-arm to the desired position also allows any further images to be acquired with ultralow radiation (automatic brightness control off, 1 pulse/s). These lower-quality images are enhanced by fusing the low-radiation image to the original localizing images (Fig. 1).

### Instrument Tracking

The instrument tracking component of ULRI-IE/IT is performed in a manner similar to that of the image enhancement components. When an initial full-dose fluoroscopic image is acquired, the location of the associated instrument is registered in relation to the C-arm fluoroscope. This is achieved by means of a tracking clip, which is placed at a standardized location on each instrument. The clip contains two optic gray markers, which are captured by a mobile camera placed in view of both the instrument and the fluoroscope. The fluoroscope is also fitted with optic tracers around the camera and the radiation source (Fig. 2). As the instrument is moved, its position in relation to the fluoroscope is tracked, and this is reflected on the onscreen viewfinder, which displays relative instrument positioning based on a previously acquired fluoroscopic image without the need for additional fluoroscopic images (Figs. 3 and 4). In a combination of these two technologies, after the systems have acquired one standard-dose fluoroscopic image (which is used for anatomic relocalization and image enhancement), new images



**Fig. 1**—Cadaver of 55-year-old woman. Comparison of ultralow radiation imaging with and without image enhancement.

**A**, Ultralow-radiation anteroposterior (AP) radiograph of L2–L3 does not clearly show bony anatomy.

**B**, Ultralow-dose AP radiograph shows image quality after enhancement of **A**. Bony anatomy is clarified, and instrument tip projecting over left pedicle is evident.

**C**, Ultralow-radiation AP radiograph of L4–L5 does not clearly show bony anatomy.

**D**, Ultralow-radiation AP radiograph shows image quality after enhancement of **C**. Bony anatomy is clarified and instrument tip projecting over right L5 pedicle is evident.

## Computer-Assisted Instrument Navigation



**Fig. 2**—Instrument tracking.

**A**, Photographs show instrument tracking clip (asterisk) in comparison with dilator (left) for placement of lateral interbody spacer and pedicle cannulator (right) for T9 kyphoplasty.

**B**, Photograph shows optical tracer for C-arm (X) in direct view of ultralow radiation imaging coupled with image enhancement and instrument tracking camera. When tracking clip is placed on known and standardized surgical instrument, its position in relation to C-arm can be tracked by capturing spatial relation between it and C-arm, which is translated to screen and previously acquired fluoroscopic image. Proceduralist can view this process in real time.

**C**, Photograph shows camera (Y) used to image gray circular tracers on tracking clip. Z represents the radiation source for the C-arm fluoroscope.

can be obtained by means of ULRI. The anatomic features are enhanced, and the radiograph of the instrument is merged onto the enhanced image. Any additional movements of the instrument are mimicked on the computer screen, simulating live fluoroscopy, by display of the moving instrument image on the anatomic enhanced image.

### Study Design

In this study, nine varying surgical procedures were performed. A minimum of three pro-

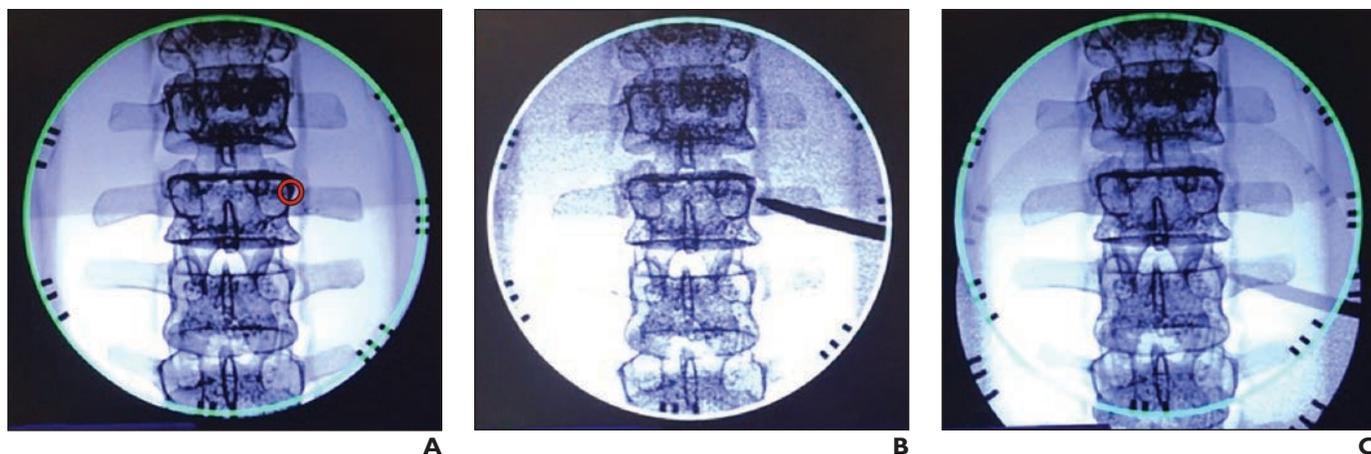
cedures relevant to the surgeon's field were assigned to each physician for a total of 23 cases. Procedures included entry at trochanteric starting point of a dynamic hip screw, tibial nail placement, cannulation of the ilium, sacral stimulator placement, foramen ovale ablation, pedicle cannulation for T9 kyphoplasty, initial dilator placement for a posterior decompression at C4–C5, needle placement for hip injection and initial dilator placement for a lateral interbody fusion to L3–L4. By means of coin flip, each of

the 23 cases was randomly assigned to start with or without the use of ULRI-IE/IT. Randomization is shown in Table 1.

All procedures were performed with the same 9-inch (23 cm) C-arm (OEC 9900, GE Healthcare) as the base fluoroscopic unit. Before the start of each trial, a full-dose fluoroscopic image of cadaver anatomy with the correctly placed instrument was obtained and served as the target for relocalization. To prevent any shifting that might occur within procedures, we secured each cadaver specimen to a radiographically translucent table with silk tape in a method similar to traditional operating room practice. The physicians were allowed to acquire as many fluoroscopic images and make as many positional adjustments as necessary until they were satisfied with the final instrument position. The instrument was then returned to the tray. The ULRI-IE/IT monitor was then revealed to the physician or remained covered, as decided by a coin toss. Relocalization was then attempted by bringing the instrument back to the desired position while time and radiation were tracked. Each trial in each case started upon the physician's lifting a surgical instrument from the surgical tray and ended upon verbal confirmation of the physician's satisfaction with instrument relocalization. To compare operative time and radiation exposure between ULRI-IE/IT and conventional fluoroscopy, this process was repeated: with ULRI-IE/IT if the initial trial had been randomized to conventional fluoroscopy and with conventional fluoroscopy if the initial trial had been randomized to ULRI-IE/IT.

The total time, number of images acquired, and amount of radiation emitted by the C-arm were recorded for each trial. Time was measured with a stopwatch. The number of images obtained was recorded from saved image directories, and radiation emission was assessed by recording the difference between the final and starting radiation doses as referenced by the cumulative air kerma value as displayed on the native C-arm.

To determine whether instrument tracking allows more accurate repositioning of the instrument to the desired location, images from each trial were compared. Because the C-arm was not moved during each trial, the absolute pixel location of the tip of the instrument could be compared between any two images. Images saved within the fluoroscope were imported into an image editing application file (Photoshop CC 2017, Adobe), and the tip location of the instrument in each image was determined with a pixel measurement tool. Data were collected and analyzed with a spreadsheet application (Excel 2016, Microsoft). Accuracy was calculated as the root-square distance between the pixel positions of the tip of the instrument on the ideal, initial, and fi-



**Fig. 3**—Plaster spine model.

**A**, Screen shot shows full-dose fluoroscopic image registered within instrument tracking system. Trephine needle with optical tracer is introduced to field with goal of placing tip of instrument on right lumbar pedicle. Red circle indicates estimated position of instrument tip based on positioning of instrument in relation to patient's anatomy.

**B**, Ultralow-dose image shows exact location of instrument tip, which is then registered within instrument tracking system. Because of density of trephine needle, it is clearly delineated even at ultralow radiation dose.

**C**, Screen shot obtained as instrument is repositioned shows exact location of instrument tip, allowing proceduralist to know exact position of instrument before acquiring additional image.

nal images. The ideal image was the image that the physician was trying to recreate from localization. The initial image was the first image of a relocalization trial. The final image was the final image of the relocalization.

#### Statistical Analysis

ANOVA was conducted with the ANOVA program within Matlab (version R2016b, MathWorks). The level of significance was set at  $p < 0.05$ .

#### Results

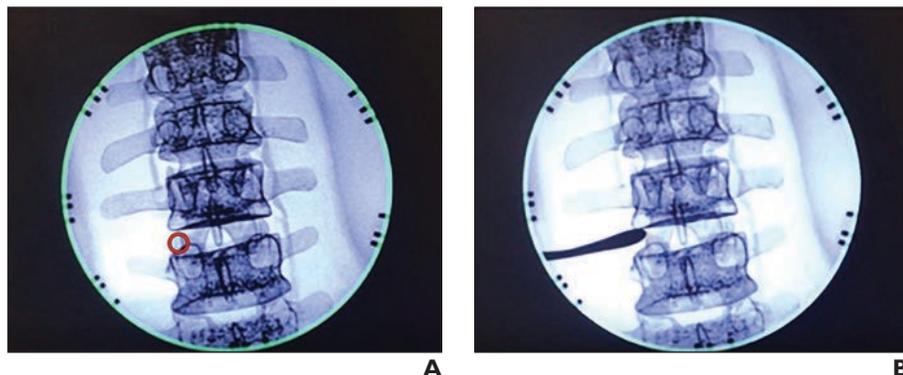
Board-certified physicians from each of the following five specialties were included in this study (five total physicians): orthopedic surgery ( $n = 1$ ), neurosurgery ( $n = 2$ ), pain management ( $n = 1$ ), and physiatry ( $n = 1$ ). The included procedures spanned six regions of the body: head, neck, thorax, abdomen, pelvis, and extremities. The following procedures were included in this study:

trochanteric hip screw placement, tibial nail placement, cannulation of ilium through an obturator oblique view, sacral stimulator placement, foramen ovale ablation, pedicle cannulation, posterior cervical dilator placement, needle placement for hip injection, and lateral lumbar dilator placement. The procedures and image enhancement modalities are summarized in Table 1. At least three procedures (range, 3–6) were performed per anatomic region. Each medical specialty performed a minimum of three procedures each (range, 3–6). The procedures were randomly assigned to start with or without ULRI-IE/IT to eliminate any impact of learning. Twenty-three total cases were performed directly comparing conventional and ULRI-IE/IT instrument positioning to discern overall improvement in operating time, number of radiographs obtained, and emission of radiation. The results by procedure are shown

in Table 2 for all recorded metrics, along with mean and SD for procedures performed more than once.

The total time to relocalize a surgical instrument was reduced by 31.2% with use of ULRI-IE/IT. The mean conventional relocalization time was 13.8 seconds compared with a mean ULRI-IE/IT time of 9.48 seconds ( $p = 0.00368$ ). The total number of images acquired per case was 74.8% less with the use of ULRI-IE/IT. A mean of 4.65 images was obtained conventionally, and a mean of 1.17 images was obtained with ULRI-IR/IT ( $p < 0.0001$ ).

A 91.8% reduction in radiation from conventional fluoroscopy was achieved, from a mean of 1.59 mGy for conventional fluoroscopy to a mean of 0.13 mGy for ULRI-IR/IT mean instrument relocalization ( $p < 0.0001$ ). We found a wide range of radiation reduction, depending on which image was being



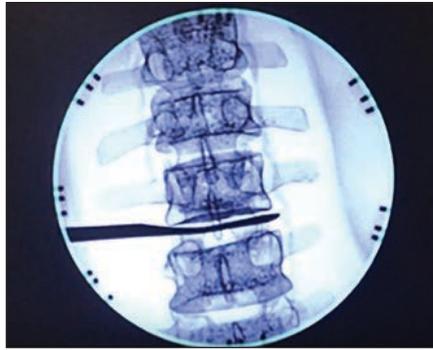
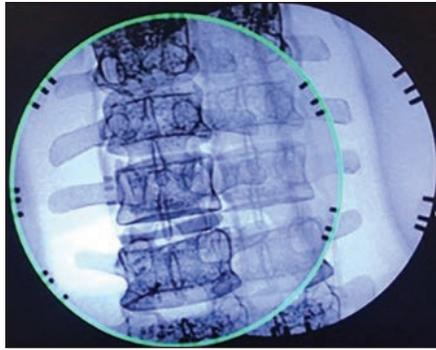
**Fig. 4**—Plaster spine model.

**A**, Screen shot shows full-dose image registered within instrument tracking system. Extreme lateral interbody fusion spacer with optical tracer is introduced into field with goal of placing tip of instrument at lateral border of disk space. Red circle indicates estimated position of instrument tip based on positioning of instrument in relation to patient's anatomy.

**B**, Ultralow-dose image shows exact location of instrument tip, which is then registered within instrument tracking system. Because of density of spacer, it is clearly delineated even at ultralow radiation dose.

(Fig. 4 continues on next page)

## Computer-Assisted Instrument Navigation



**Fig. 4 (continued)**—Plaster spine model.

**C**, Screen shot shows exact location of instrument as it is advanced into disk space, allowing proceduralist to know exact position of instrument before acquiring additional images. Spacer is being advanced to contralateral border of disk space.

**D**, Final low-dose image shows placement of spacer across entirety of disk space, matching estimated position in **C**.

acquired and the skill of the physician, owing to the varying difficulty of acquiring procedure-specific images of the patient's anatomy. The minimum dose reduction was 16.7%, and the maximum was 99.1%. Statistically significant radiation reduction was experienced for every specialty ( $p < 0.01$ ).

The physician was able to relocalize with ULRI-IE/IT on the first attempt in 82.6% of trials and on the second attempt in all trials. Without use of the tracking system, the physician was never able to relocalize on the first attempt and needed a mean of 4.65 images, with a minimum of two and maximum of eight images. The final relocalization position was off by a mean of 8.19 pixels without tracking versus 5.57 pixels (30% better) with the use of ULRI-IE/IT. The C-arm unit we used sizes each pixel at the image intensifier at approximately 0.50 mm, and thus the reported pixel improvement of 2.62 units approximately correlates with a distance of 1.25 mm at the level of the image intensifier and 0.95 mm at the level of

the patient. Physicians were also 12.9 times as accurate in relocalizing the instrument on the first radiograph (5.73 vs 72.09 pixel difference,  $p < 0.0001$ ) when using ULRI-IE/IT as they were without it. In 82.6% of cases, using ULRI-IE/IT the physician achieved the desired adjustment on the first attempt, compared with only once in the 23 trials (4.3%) without ULRI-IE/IT. Without ULRI-IE/IT, it took a mean of 4.9 images to accomplish this minor movement compared with 1.5 images with ULRI-IE/IT.

### Discussion

Ionizing radiation can pose considerable health risks to both surgeons and patients. Although there are dose-dependent rates of malignancy and side-effects at different levels of radiation, it is widely agreed that maximum reduction and avoidance of radiation while preserving procedural safety is the health care standard [12–18]. In fields such as orthopedic and neurologic surgery, in which radiation exposure is not regulated or monitored by a na-

tional governing body, daily radiation reduction is even more salient. Despite the known advantages of minimally invasive spine surgery and other minimally invasive procedures, reliance on intraoperative fluoroscopy inevitably increases radiation exposure for surgeons and patients. This increase is not without consequence. In a retrospective study, Mastrangelo et al. [19] found a fivefold increase in cancer rates among orthopedic surgeons compared with nonorthopedic surgeons. In a similar study, Jones et al. [20] found increased rates of thyroid cancers among physicians in radiation-intensive specialties.

Patients are also negatively affected by increased exposure. Compared with surgeons, they experience much higher doses of intraoperative radiation, which in some populations elevates the lifetime risk of solid malignancies 1.4–2.4% [21]. This increase is due to the patients' unmodifiable inability to wear intraoperative lead shielding and their proximity to the radiation source.

Reduction in radiation exposure should

**TABLE I: Procedure, Body Region on Which It Was Performed, and Randomization in Each Case**

Procedure	Region of Body	Randomization <sup>a</sup>				
		Orthopedics	Neurosurgery	Spine	Pain	Physiatry
Trochanteric hip screw placement	Extremities	Conventional				
Tibial nail placement	Extremities	ULRI-IE/IT				
Cannulation of the ilium by obturator oblique view (teardrop view)	Pelvis	ULRI-IE/IT	Conventional			
Sacral stimulator placement	Pelvis		Conventional	ULRI-IE/IT	Conventional	Conventional
Foramen ovale ablation	Head		ULRI-IE/IT		ULRI-IE/IT	ULRI-IE/IT
Pedicle cannulation for T9 kyphoplasty	Chest	Conventional	ULRI-IE/IT	Conventional	ULRI-IE/IT	ULRI-IE/IT
Initial dilator placement for posterior decompression at C4–C5	Neck	ULRI-IE/IT	ULRI-IE/IT	ULRI-IE/IT		
Needle placement for hip injection	Extremities				Conventional	
Initial dilator placement for a lateral interbody fusion to L3–L4	Abdomen	Conventional	Conventional	Conventional		

<sup>a</sup>Conventional = initial trial randomized to being performed with conventional fluoroscopy, ULRI-IE/IT = initial trial randomized to being performed with ultralow radiation imaging coupled with image enhancement and instrument tracking.

**TABLE 2: Procedure Comparison of Conventional and Ultralow Radiation Imaging Coupled With Image Enhancement and Instrument Tracking**

Procedure	No. of Trial Pairs	Operating Time (s)		Total No. of Images		Total Radiation Dose (mGy)	
		Conventional	ULRI-IE/IT	Conventional	ULRI-IE/IT	Conventional	ULRI-IE/IT
Trochanteric hip screw placement	1	17	9	5	1	1.02	0.01
Tibial nail placement	1	17	12	7	2	0.48	0.01
Cannulation of the ilium by obturator oblique view (teardrop view)	2	24 (12 ± 1.4)	10 (5 ± 0)	7 (3.5 ± 0.7)	2 (1 ± 0)	5.03 (2.5 ± 0.9)	0.41 (0.2 ± 0.2)
Sacral stimulator placement	3	53 (13.3 ± 6.8)	24 (6 ± 2.2)	14 (3.5 ± 1.3)	4 (1 ± 0)	5.35 (1.3 ± 0.5)	0.34 (0.9 ± 0.06)
Foramen ovale ablation	3	53 (17.7 ± 4.7)	30 (10 ± 5.2)	18 (6 ± 1)	4 (1.3 ± 0.6)	2.65 (0.9 ± 0.1)	0.12 (0.4 ± 0.05)
Pedicle cannulation for T9 kyphoplasty	4	74 (14.8 ± 3.0)	78 (15.6 ± 5.5)	30 (6 ± 1.9)	7 (1.4 ± 0.5)	9.4 (1.9 ± 0.6)	0.44 (0.09 ± 0.1)
Initial dilator placement for posterior decompression at C4–C5	4	30 (10 ± 5.3)	25 (8.3 ± 3.8)	9 (3 ± 1.7)	3 (1 ± 0)	1.13 (0.4 ± 0.3)	0.33 (0.1 ± 0.1)
Needle placement for hip injection	1	17	17	7	2	1.54	0.07
Initial dilator placement for a lateral interbody fusion to L3–L4	4	39 (13 ± 5.2)	22 (7.3 ± 0.6)	14 (4.7 ± 0.6)	3 (1 ± 0)	10.92 (3.63 ± 0.8)	1.31 (0.4 ± 0.2)
Total		324	227	111	28	37.52	3.04
Mean		14.09	9.87	4.83	1.22	1.63	0.13
SD		20.29	21.09	7.91	1.76	3.83	0.40
<i>p</i>		0.00368		< 0.0001		< 0.0001	

Note—Values are totals with mean ± SD in parentheses. Conventional = conventional fluoroscopy, ULRI-IE/IT = ultralow radiation imaging coupled with image enhancement and instrument tracking.

provide clear short- and long-term benefit to both patients and hospital staff. The Joint Commission and U.S. Food and Drug Administration (FDA) extend this concern to all operating room personnel [22]. It is clear that there is an acute need to reduce intraoperative radiation use during all minimally invasive procedures, especially in spine surgery. To our knowledge, ours is the first randomized trial to characterize radiation exposure, time, and accuracy using ULRI with instrument tracking.

Although other instrument tracking technology, including CT-guided instrument tracking and robot-assisted instrumentation, exists, these are not adaptable to intraoperative changes in spinal alignment or positioning without substantial additional radiation exposure. These technologies are also limited in application to only spinal procedures. ULRI with image enhancement can be adjusted to changes in patient positioning or alignment by simply storing a full-dose fluoroscopic image in the new orientation and, as we found, can be applied to many procedures in a variety of surgical and procedural subspecialties.

The current study was a randomized cadaveric study conducted to assess radiation exposure, time, accuracy, and number of images required to perform key steps in a

variety of multidisciplinary surgical procedures. This study showed that ULRI-IE/IT was associated with a significant reduction in radiation exposure (91.8%,  $p = 0.00368$ ) compared with conventional C-arm fluoroscopy. This new method was also associated with a significant reduction in the time (31.2%,  $p < 0.0001$ ) and number of images required to achieve acceptable instrument relocalization (74.8%,  $p < 0.0001$ ). Finally, there was a 25% increase in accuracy of relocalization of instruments by use of ULRI-IE/IT compared with conventional fluoroscopy. All comparative measures in these regards reached statistical significance ( $p < 0.05$ ). Significant absolute reductions were found in radiation exposure, procedure time, and number of images needed to localize instrumentation.

Although it can be argued that the total dose reductions are on a scale of milligrays, it is important to recognize that these individual tasks are only a single step in multi-step radiation-intensive procedures. For example, one such task evaluated in this study was placement of a dilator for lateral lumbar interbody fusion. Although placement of the initial dilator with ULRI-IE/IT assistance resulted in approximately 9 mGy of radiation reduction compared with that asso-

ciated with conventional fluoroscopy over multiple trials, it is only one component of the procedure. Placements of sequential dilators, rasps, trial spacers, pedicle screws, and lateral plates and screws are additional components of the lateral lumbar fusion that culminate in higher absolute reductions in radiation, operative time, and number of fluoroscopic images required. To show the broader impact of the instrument tracking and image enhancement system, we tested ULRI-IE/IT in individual portions of various procedures rather than in a single procedure. Future studies will focus on comparing radiation output, operative time, and number of localizing images between ULRI-IE/IT and conventional fluoroscopy for entire procedures within individual specialties.

Although accuracy improvements on the scale of 0.50–1.00 mm may seem inconsequential for large-scale fluoroscopy-dependent procedures, such as tibial nailing and hip injections, it can be quite important for other surgical procedures, such as pedicle cannulation for kyphoplasty or foramen ovale ablation, in which the instrument target may be on the scale of 3–5 mm wide. The initial results of this study show that ULRI-IE/IT can yield high-resolution millimeter-to-millimeter improvements applicable

to the widest range of fluoroscopy-intensive procedures and will not be limited by spatial resolution or spatial accuracy.

To our knowledge, this is the first human study quantifying the reduction of radiation, time, and image number for ULRI-IE/IT. This study included physicians from five specialties performing a total of 23 procedures, making the process we studied the single most widely applicable ultralow radiation instrument tracking technology currently available.

#### Limitations

There are several important limitations to consider in this study. The first centers on the lack of controlled randomization. Although the procedures were randomized to either ULRI-IE/IT or conventional C-arm fluoroscopy, there were no intraphysician controls. Thus, each physician's radiation data could not be compared between conventional C-arm fluoroscopy and ULRI-IE/IT. However, the substantial decrease in radiation exposure, time, and images acquired and the increase in accuracy suggest that these results would be reproduced in a study with the appropriate controls.

The accuracy of radiation production by the C-arm was recorded as the cumulative air kerma value on the unit's monitor. The accuracy of this measurement is known to have possible deviation from the norm. According to FDA regulation 21CFR1020.23 the cumulative air kerma displayed on the monitor should be within 35% of the true value for doses between 6 and 100 mGy/min. For the ultralow radiation segments of the procedure, accuracy would be expected to deviate further, calling into question the accuracy of our reported data. Although this measurement of radiation production has its inaccuracies, the relation between radiation production of conventional fluoroscopic imaging and ULRI-IE/IT persists. Although the absolute radiation difference between methods could vary between identical trials (on the basis of this assumption), the overall drastic reduction in radiation production is expected to be unchanged.

In an internally randomized study [10] in which the ULRI settings were identical to those in this study, our group previously studied the use of the cumulative air kerma value displayed on the C-arm as a surrogate and found it to be highly correlated with personal dosimetry readings. In this context, it is important to recognize the overarching goal of ULRI-IE/IT, which is to acquire clin-

ically safe fluoroscopic images with instrument guidance while substantially reducing radiation production. To better quantify radiation exposure, future studies of ULRI-IE/IT and the methods in this study will incorporate high-fidelity radiation dosimeters at standardized locations on the patient's body.

This study would have benefited from additional operative data from additional surgeons for similar procedures. Again, given the convincing nature of the preliminary data, we believe that additional procedures performed with ULRI-IE/IT would reproduce and strengthen the power of ULRI-IE/IT to reduce radiation exposure, time, and images acquired while increasing accuracy. Future work should be directed at providing intrasurgeon randomized controls for ULRI-IE/IT. In addition, radiation exposure, time, and accuracy should be compared between the ULRI-IE/IT software used in this study and other existing navigational systems, including CT-based and computerized isocentric fluoroscopy navigational systems.

The proceduralist was not blinded to the imaging modality used for each trial (ULRI-IE/IT vs conventional fluoroscopy), and hence the Hawthorne effect cannot be completely excluded. The technologic interface for ULRI-IE/IT precludes effectively blinding the proceduralist to the imaging modality being used, and given the strength of radiation reduction, it is likely that if blinding were possible, the results of this study would be similar. One limitation of the ULRI-IE/IT system is the learning curve associated with its implementation; however, as seen with the overall reduction in time and images required seen even with few trials, this limitation is rapidly and easily overcome.

#### Conclusion

Compared with conventional C-arm fluoroscopy, ULRI-IE/IT is effective at reducing radiation exposure, time, and number of images required while increasing the accuracy of instrumentation for multiple procedures across multiple specialties. Given the known harmful effects of radiation exposure, the use of the ULRI-IE/IT technology should be considered for minimally invasive spinal procedures and other fluoroscopy-intensive interventional procedures.

#### References

- Lee KH, Yue WM, Yeo W, Soeharno H, Tan SB. Clinical and radiological outcomes of open versus minimally invasive transforaminal lumbar inter-

- body fusion. *Eur Spine J* 2012; 21:2265–2270
- Peng CW, Yue WM, Poh SY, Yeo W, Tan SB. Clinical and radiological outcomes of minimally invasive versus open transforaminal lumbar interbody fusion. *Spine* 2009; 34:1385–1389
- Park Y, Ha JW. Comparison of one-level posterior lumbar interbody fusion performed with a minimally invasive approach or a traditional open approach. *Spine* 2007; 32:537–543
- Park P, Foley KT. Minimally invasive transforaminal lumbar interbody fusion with reduction of spondylolisthesis: technique and outcomes after a minimum of 2 years' follow-up. *Neurosurg Focus* 2008; 25:E16
- Youssef JA, McAfee PC, Patty CA, et al. Minimally invasive surgery: lateral approach interbody fusion: results and review. *Spine* 2010; 35(suppl):S302–S311
- Thongtrangan I, Le H, Park J, Kim DH. Minimally invasive spinal surgery: a historical perspective. *Neurosurg Focus* 2004; 16:E13
- Rampersaud YR, Foley KT, Shen AC, Williams S, Solomito M. Radiation exposure to the spine surgeon during fluoroscopically assisted pedicle screw insertion. *Spine* 2000; 25:2637–2645
- Mariscalco MW, Yamashita T, Steinmetz MP, Krishnaney AA, Lieberman IH, Mroz TE. Radiation exposure to the surgeon during open lumbar microdiscectomy and minimally invasive microdiscectomy: a prospective, controlled trial. *Spine* 2011; 36:255–260
- Ntoukas V, Müller A. Minimally invasive approach versus traditional open approach for one level posterior lumbar interbody fusion. *Minim Invasive Neurosurg* 2010; 53:21–24
- Wang TY, Farber SH, Perkins SS, et al. Internally randomized control trial of radiation exposure using ultra-low radiation imaging versus traditional C-arm fluoroscopy for patients undergoing single-level minimally invasive transforaminal lumbar interbody fusion. *Spine* 2017; 42:217–223
- Nayar G, Blizzard DJ, Wang TY, et al. Pedicle screw placement accuracy using ultra-low radiation imaging with image enhancement versus conventional fluoroscopy in minimally invasive transforaminal lumbar interbody fusion: an internally randomized controlled trial. *J Neurosurg Spine* 2018; 28:186–193
- Yoshinaga S, Mabuchi K, Sigurdson AJ, Doody MM, Ron E. Cancer risks among radiologists and radiologic technologists: review of epidemiologic studies. *Radiology* 2004; 233:313–321
- Mohan AK, Hauptmann M, Freedman DM, et al. Cancer and other causes of mortality among radiologic technologists in the United States. *Int J Cancer* 2003; 103:259–267
- Hoffman DA, Lonstein JE, Morin MM, Visscher W, Harris BS 3rd, Boice JD Jr. Breast cancer in

- women with scoliosis exposed to multiple diagnostic x rays. *J Natl Cancer Inst* 1989; 81:1307–1312
15. Hayes BP, Fisher RF. Influence of a prolonged period of low-dosage x-rays on the optic and ultrastructural appearances of cataract of the human lens. *Br J Ophthalmol* 1979; 63:457–464
  16. Freedman DM, Sigurdson A, Rao RS, et al. Risk of melanoma among radiologic technologists in the United States. *Int J Cancer* 2003; 103:556–562
  17. Chou LB, Chandran S, Harris AH, Tung J, Butler LM. Increased breast cancer prevalence among female orthopedic surgeons. *J Womens Health (Larchmt)* 2012; 21:683–689
  18. Adams MJ, Lipshultz SE, Schwartz C, Fajardo LF, Coen V, Constine LS. Radiation-associated cardiovascular disease: manifestations and management. *Semin Radiat Oncol* 2003; 13:346–356
  19. Mastrangelo G, Fedeli U, Fadda E, Giovanazzi A, Scozzato L, Saia B. Increased cancer risk among surgeons in an orthopaedic hospital. *Occup Med (Lond)* 2005; 55:498–500
  20. Jones DP, Robertson PA, Lunt B, Jackson SA. Radiation exposure during fluoroscopically assisted pedicle screw insertion in the lumbar spine. *Spine* 2000; 25:1538–1541
  21. Presciutti SM, Karukanda T, Lee M. Management decisions for adolescent idiopathic scoliosis significantly affect patient radiation exposure. *Spine J* 2014; 14:1984–1990
  22. US Food and Drug Administration website. White paper: initiative to reduce unnecessary radiation exposure from medical imaging. center for devices and radiological health. [www.fda.gov/radiation-emitting-products/radiation-safety/initiative-reduce-unnecessary-radiation-exposure-medical-imaging](http://www.fda.gov/radiation-emitting-products/radiation-safety/initiative-reduce-unnecessary-radiation-exposure-medical-imaging). Accessed April 30, 2019