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Review Article

Evaluation of surgeon and patient radiation exposure by imaging technology in patients undergoing thoracolumbar fusion: systematic review of the literature

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Abstract

BACKGROUND CONTEXT: Minimally invasive spine techniques are becoming increasingly popular owing to their ability to reduce operative morbidity and recovery times. The downside to these new procedures is their need for intraoperative radiation guidance.

PURPOSE: To establish which technologies provide the lowest radiation exposure to both patient and surgeon.

STUDY DESIGN/SETTING: Systematic review

OUTCOME MEASURES: Average intraoperative radiation exposure (in mSv per screw placed) to surgeon and patient. Average fluoroscopy time per screw placed.

METHODS: We reviewed the available English medical literature to identify all articles reporting patient and/or surgeon radiation exposure in patients undergoing image-guided thoracolumbar instrumentation. Quantitative meta-analysis was performed for studies providing radiation exposure or fluoroscopy use per screw placed to determine which navigation modality was associated with the lowest intraoperative radiation exposure. Values on meta-analysis were reported as mean ± standard deviation.

RESULTS: We identified 4956 unique articles, of which 85 met inclusion/exclusion criteria. Forty-one articles were included in the meta-analysis. Patient radiation exposure per screw placed for each modality was: conventional fluoroscopy without navigation (0.26±0.38 mSv), conventional fluoroscopy with pre-operative CT-based navigation (0.027±0.010 mSv), intraoperative CT-based navigation (1.20±0.91 mSv), and robot-assisted instrumentation (0.04±0.30 mSv). Values for fluoroscopy used per screw were: conventional fluoroscopy without navigation (11.1±9.0 seconds), conventional fluoroscopy with navigation (7.20±3.93 s), 3D fluoroscopy (16.2±9.6 s), intraoperative CT-based navigation (19.96±17.09 s), and robot-assistance (20.07±17.22 s). Surgeon dose per screw: conventional fluoroscopy without navigation ($6.0\pm7.9\times10^{-3}$ mSv), conventional fluoroscopy with navigation ($1.8\pm2.5\times10^{-3}$ mSv), 3D Fluoroscopy ($0.3\pm1.9\times10^{-3}$ mSv), intraoperative CT-based navigation (0±0 mSv), and robot-assisted instrumentation ($2.0\pm4.0\times10^{-3}$ mSv).

CONCLUSION: All image guidance modalities are associated with surgeon radiation exposures well below current safety limits. Intraoperative CT-based (iCT) navigation produces the lowest

FDA device/drug status: Approved.

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radiation exposure to surgeon albeit at the cost of increased radiation exposure to the patient relative to conventional fluoroscopy-based methods.

Keywords: Fluoroscopy; Image-guided surgery; Instrumented fusion; Intraoperative CT; Minimally invasive surgery; Radiation exposure

Background

The steady increase in the use of minimally invasive techniques in spine surgery has seen a commensurate rise in the use of image-guided navigation. One of the major concerns with this trend is the increased radiation exposure to both patient and surgeon relative to open, freehand techniques. The oldest of the image-guided techniques, two-dimensional fluoroscopy, exposes both patient and surgeon to radiation in a fashion proportional to the length of time that the fluoroscopy unit is running. Other advanced intraoperative imaging technologies have now also been developed, aiding in the accuracy of intraoperative instrumentation checks while also increasing concern for radiation exposure. These include intraoperative computed tomography-based guidance (iCT, eg, O-arm [Medtronic Inc, Minneapolis, MN], AIRO [Brainlab, Munich, Germany]), three-dimensional fluoroscopy (3D fluoro, eg, Orbic 3D, Siemens, Erlangen, Germany), and IR-navigation using preoperatively acquired CT (eg, BrainLab, Munich, Germany). Some have argued that these newer technologies decrease both surgeon and operating room (OR) staff radiation exposure [1−4]. However, the evidence for this is based solely upon small to moderate-sized cohorts.

The National Council on Radiation Protection and Measurements and the International Commission on Radiological Protection have published “maximal limits” for exposure for those that work with radiation (eg, spine surgeons). These proposed safe limits take into account both yearly cumulative dose (ie, “deterministic” effects) and a lifetime cumulative dose (ie, “stochastic” effects). Currently, guidelines recommend no more than 20 millisievert (mSv) per year averaged over 5 years, or 50 mSv/year in any 1 year. For nonradiation workers, the recommended limit of exposure to radiation is 1 mSv/year [5]. However, it is critical to understand that this limit is *in addition* to natural background radiation (which itself is ≈3 mSv/year) and *in addition* to medical imaging [6]. Although many professionals quote these limits and apply them to patients, they often misinterpret how these were intended to be used.

Recently there has been more interest in medical radiation, particularly as it applies to the surgeon or technologist exposed to it on a daily basis [7]. For patients, seeking to minimize radiation exposure is important, although it should be noted that “safe lower limits” have been traditionally arrived at by extrapolating in a linear manner from known unsafe levels, despite little to no data that suggest an increased cancer risk for undergoing advanced medical imaging under 10 mSv (or even receiving radiation up to 100 mSv) [8]. For example, a chest radiograph imparts a radiation exposure of only 0.1 mSv, equivalent to the exposure routinely experienced on a round-trip flight from New York City to Los Angeles. Both exposures are roughly 30-fold lower than the amount of background radiation exposure from the environment in 1 year. [8] Nonetheless, minimizing exposure to the patient and particularly the OR staff remain priorities.

Some have suggested that attempts to decrease surgeon and OR staff radiation exposure come at the cost of increased patient radiation exposure. We therefore decided to conduct a systematic review of the available literature assessing radiation exposure to patient, surgeon, and OR personnel for the currently available imaging technologies, including conventional 2D fluoroscopy (with or without preoperative CT-based navigation), navigation using intraoperative CT-imaging, 3D fluoroscopy-based navigation, and robot-assisted navigation based upon preoperative CT imaging. To help guide our review, we asked three main questions: (1) what is the average radiation exposure to the patient during pedicle screw placement for each of the imaging technologies above? (2) What is the average surgeon and OR staff member radiation exposure? (3) For fluoroscopy-based instrumentation, does the addition of intraoperative navigation based upon preoperatively acquired CT reduce fluoroscopy use and patient radiation exposure? For those studies presenting results in terms of effective radiation dose per screw placed or that could be converted into these terms, a meta-analysis was performed to look for significant differences in radiation exposure per screw.

Methods

We conducted a review of the PubMed, Web of Science, CINAHL, Cochrane Reviews, and EMBASE medical databases for all articles published as of September 14, 2018 that reported patient and/or surgeon radiation exposure during thoracolumbar fusion operations using conventional fluoroscopy (2D fluoro), conventional fluoroscopy with intraoperative navigation based on preoperative CT (2D nav fluoro), 3D fluoroscopy (3D fluoro), intraoperative CT (iCT), or robot-assisted instrumentation based on preoperative CT (robot-assisted). An example search string for PubMed is presented in Supplementary Table 1. Inclusion and exclusion criteria are presented in Table 1. Endpoints considered were patient radiation exposure and surgeon radiation exposure (converted to millisieverts, mSv).

Table 1
Inclusion and exclusion criteria for the literature search

Inclusion	Exclusion
• Article presents results for fluoroscopy time or radiation exposure in patients instrumented with 2D fluoro, 2D nav fluoro, 3D fluoro, iCT-guidance, or robot-assisted procedure • Minimum of 5 patients in each category • Minimum of 20 screws placed under each imaging technique • Surgery is for any indication (osteomyelitis, tumor, degenerative disease) • Full-text availability in English • All patients in study are instrumented with open or percutaneous, or in studies presenting both, the results of open and percutaneous cohorts are reported separately	• Article is a review, opinion piece, perspective, meta-analysis • Article has fewer than 5 patients (20 screws) per condition • Article does not report fluoroscopy time or radiation dose to the patient or surgeon

All search results were uploaded into the Covidence systematic review application (Melbourne, Australia) and screened against title and abstract by two reviewers (ZP and EC). In cases where there was disagreement, a third reviewer (EW) was included to resolve discrepancies. Full texts of articles meeting inclusion/exclusion criteria based upon title and abstract were then screened by two reviewers (ZP and EC), with a third reviewer (EW) again being recruited to resolve discrepancies. Data extraction was performed using a standardized Microsoft Excel (Redmond, WA) datasheet. All radiation exposures were reported as exposure per patient and per screw placed. For articles reporting radiation exposure per procedure or per patient only, average exposure per screw placed was calculated by dividing the mean exposure by the mean number of screws placed (unless individual patient-level data were available). Mean values were reported along with the associated standard deviation, where available. Propagation of error technique [9] was used to assign estimates for these calculated values. For calculated radiation per screw placed, we assumed that all intraoperative radiations were assignable to pedicle screw placement.

All studies were evaluated for the level of evidence using the guidelines set forth by the North American Spine Society [10]. Insufficient evidence was found to exclude level III to V studies or to subdivide the meta-analysis based upon the level of evidence. Summary of the results was performed with a single meta-analysis comparing the mean radiation (in mSv) per screw placed for each of the imaging groups: 2D fluoro, 2D nav fluoro, 3D fluoro, iCT, and robot-assisted. For each group, the average value was calculated as the weighted mean of all values with associated uncertainties (standard deviation); the uncertainty estimate of the mean value was determined by calculating the pooled standard deviation. This was converted to a standard estimate of the mean. Differences in mean radiation across groups were evaluated using one-way ANOVA with post hoc Tukey Honest Significant Difference tests being used for individual comparisons. A quantitative assessment of bias was not performed. However, a qualitative assessment was performed based upon reviewer assessment.

Results

Search results

Using the search criteria specified, we identified 4,956 unique articles, of which 340 met the inclusion/exclusion criteria for full-text review. (Figure 1) Of these, 255 studies were excluded, with the most common reasons being: the study failed to report patient or surgeon radiation exposure, or fluoroscopy time (n=141), the study was published in abstract form only (n=63), or the study did not have a full English translation available (n=21). Of the 85 included studies, 57 reported results of conventional fluoroscopy without intraoperative guidance (Table 2) [1,3,11−65], 9 studies reported results of conventional fluoroscopy with intraoperative guidance based upon preoperative CT (Table 3) [11,19,26,31,33,42,45,58,66], 11 studies reported results of 3D fluoroscopy (Table 4) [3,41,47,55,67−73], 24 studies reported results of intraoperative CT-based navigation (Table 5) [1,3,4,40,43,50,53,65,74−89], and 10 studies reported results of robot-assisted instrumentation using preoperatively acquired CT (Table 6) [21,23,25,28,29,44,48,74,90,91].

Comment on study heterogeneity

The results of the data search were highly heterogeneous in terms of the exact procedure performed and indication for surgical intervention. Because most studies included a mix of patients undergoing interbody placement and those treated with pedicle screw fixation alone, it was impossible to assess the individual contribution of interbody placement to radiation exposure. We did however attempt to limit the heterogeneity of the studies included in the meta-analysis by restricting considered studies to only those reporting the results of thoracolumbar pedicle screw fixation performed via a posterior open approach.

Table 2
Studies reporting radiation exposure in patients instrumented using conventional fluoroscopy without navigation

Study	Screws (n)	Patient dose/screw	Surgeon dose/screw	Fluoro time/screw
Alaid et al., 2018 [21]	648	—	—	29.4±21 s
Atria et al., 2018 [32]	24	—	—	8.39 s
Bandela et al., 2013 [43]	7	0.004−0.965 mGy	0.001−0.323 mGy	—
Bindal et al., 2008 [54]	114	26.3±20.9 mGy	0.057±0.12 mSv	0.36±0.07 min
Bronsard et al., 2013 [62]	128	0.129±0.03 mSv	—	6.91±1.63 s
Chaput et al., 2012 [63]	78	—	—	7.51 shots
Clark et al., 2013 [64]	200	—	—	4.68 s
Dabaghi Richerand et al., 2016 [65]	647	0.0023±0.0024 mSv	—	—
Dusad et al., 2018 [11]	240	2.74±0.60 mGy	—	29.78±7.45 s
Ege et al., 2013 [12]	378	—	—	7.95 s
Erken et al., 2014 [13]	2,100	—	$3\pm1.2\times10^{-3}$ mSv	2.6±1.7 s
Fan et al., 2015 [14]	40	—	0.016±0.005 mSv	17.10±1.96 s
Fan et al., 2017a [16]	287	—	$8.55\pm2.8\times10^{-3}$ mSv	9.08±1.83 s
Fan et al., 2017b [92]	152	0.145±0.023 mSv	—	8.21±1.26 s
Fransen et al., 2011 [17]	158	—	—	8.4 s
Funao et al., 2014 [18]	154	—	0.012±0.004 mSv	8.88±4.2 s
Gebhard et al., 2006 [19]	32	273 mGy/pt	—	44.25 s
Gu et al., 2015 [20]	152	—	—	13.07±3.06 s
Harrison Farber et al., 2018 [22]	330	4.6±2.6 mGy	1.06±0.71 μSv	9.52±6.3 s
Hyun et al., 2017 [23]	140	0.27±0.29 mSv	—	13.3±11.8 s
Jones et al., 2000 [24]	626	0.51 mSv	—	0.33 min
Keric et al., 2017b [91]	121	—	—	0.19±0.21 min
Kim et al., 2008 [26]	40	—	0.031 mSv	36.8±18.3 s
Kouyoumdijan et al., 2018 [27]	515	—	0.33±0.54 μSv	19.81 s
Le et al., 2018 [28]	144	19.9±4.66 μSv	—	20.4±5.4 s
Lieberman et al., 2012 [29]	37	—	0.101±0.025 mSv	33.0 s
McArthur et al., 2015 [30]	348	21.8 μSv	0.099-0.112 μSv	—
Merloz et al., 2007 [31]	138	—	—	5.75±1.5 s
Mirza et al., 2003 [33]	94	0.073±0.012 mSv	0.0013±0 mSv	—
Mulconrey 2016 [34]	114	—	0.101 mSv	18.4±7.7 s
Nakahara et al., 2016 [35]	658	—	—	9.55 s
Nayar et al., 2018 [36]	48	15.75 mGy	—	—
Noriega et al., 2017 [1]	320	0.175±0.035 mGy	1.75 μGy	—
O'Donnell et al., 2014 [37]	598	0.014±0.012 mSv	—	1.87±1.30 s
Perisinakis et al., 2004 [38]	96	0.30±0.06 mSv	—	0.69±0.33 min
Rampersaud et al., 2000 [39]	72	—	—	9.3±1.5 s
Riis et al., 2017 [40]	—	3.7±2.69 mSv/pt	—	—
Ruatti et al., 2016 [41]	—	—	—	6.875 s
Sagi et al., 2003 [42]	48	—	—	5.9 s
Schizas et al., 2012 [44]	64	0.11 ± 0.11 mGy·m^{-2}	—	14.2±8.9 s
Schuetze et al., 2018 [45]	90	—	15.8±25 nSv	—
Slomczykowski et al., 1999 [46]	100	0.167 mSv	—	62.75±1.94 s
Smith et al., 2008 [47]	24	—	0.011±0.007 mSv	8.38±2.44 s
Solomiichuk et al., 2017 [48]	214	—	—	20.74±17.46 s
Spitz et al., 2015 [49]	90	1.63±1.09 mGy	—	22.73±12.02 s
Tabaraee et al., 2013 [50]	80	0.156 mSv	0.008 mSv	—
Tajsic et al., 2018 [3]	504	0.286 mSv	—	—
Tumialan et al., 2015 [51]	260	—	—	2.6−4.7 s
Ul Haque et al., 2006 [52]	319	—	0.005±0.002 mSv	7.36±3.46 s
Urbanski et al., 2018 [53]	387	0.11 mGy	—	—
Villard et al., 2014 [55]	73	—	0.033±0.044 mSv	—
Wang et al., 2017 [56]	48	35.8 mGy	0.0165 mSv	—
Winder et al., 2017 [57]	615	—	—	—
Yang et al., 2012 [108]	160	—	—	9.6±6.2 s
Yoshida et al., 2016 [59]	688	—	—	0.34 min
Yoshihara et al., 2018 [60]	696	0.001−0.005 mSv	0−0.007 mSv	—
Zhang et al., 2014 [61]	135	—	—	56.5±31.8 s

Table 3
Studies reporting radiation exposure in patients instrumented using conventional fluoroscopy with navigation

Study	Screws (n)	Patient dose/screw	Surgeon dose/screw	Fluoro time/screw
Dusad et al., 2018 [11]	108	0.42±0.10 mGy	—	11.6±2.95 s
Gebhard et al., 2006 [19]	40	108 mGy	—	18.8 s
Kim et al., 2008 [26]	40	—	0 mSv	14.28±9.34 s
Luo et al., 2012 [66]	68	—	—	7.9 s
Merloz et al., 2007 [31]	140	—	—	1.75±0.7 s
Mirza et al., 2003 [33]	169	0.027±0.0097 mSv	0.002±0.003 mSv	—
Sagi et al., 2003 [42]	48	—	—	3.6 s
Schuetze et al., 2018 [45]	—	—	93±123 nSv/pt	—
Yang et al., 2012 [108]	210	—	—	6.6±5.1 s

Table 4
Studies reporting radiation exposure in patients instrumented using 3D fluoroscopy

Study	Screws (n)	Patient dose/screw	Surgeon dose/screw	Fluoro time/screw
Bohoun et al., 2018 [68]	170	13.96 mGy	0.70 μSv	26.0 s
Fomekong et al., 2018 [69]	714	—	0 mSv	—
Fomekong et al., 2017 [70]	276	—	0 mSv	—
Kaminski et al., 2017 [71]	541	192 mGy/pt	—	6 s
Malham et al., 2018 [72]	204	54.5 mGy	—	31.1 s
Ruatti et al., 2016 [41]	—	0.115 mSv	—	20 s
Smith et al., 2008 [47]	24	—	0.0008±0.002 mSv	—
Tajsic et al., 2018 [3]	192	0.081 mSv	—	—
Villard et al., 2014 [55]	76	—	0.003±0.006 mSv	—
Villavicencio et al., 2005 [73]	220	—	—	46.2 s
Wendl et al., 2003 [67]	141	—	—	0.27±0.16 min

Table 5
Studies reporting radiation exposure in patients instrumented using intraoperative CT-guided navigation (iCT)

Study	Screws (n)	Patient dose/screw	Surgeon dose/screw	Fluoro time/screw
Balling et al., 2018a [88]	1,547	865.1±360.9 mGy·cm/pt	—	—
Balling et al., 2018b [109]	320	542.9±385.1 mGy·cm/pt	—	—
Bandela et al., 2013 [43]	7	0.279-2.99 mGy	0 mGy	—
Costa et al., 2015 [89]	6,590	0.448 mSv	0.004 μSv	—
Costa et al., 2016 [4]	—	5.15 mSv/pt	0.005 μSv/pt	—
Dabaghi Richerand et al., 2016 [65]	488	0.112±0.126 mSv	—	—
Fan et al., 2018 [75]	1,275	0.485±0.117 mSv	—	—
Farah et al., 2018 [76]	168	1.24 mSv	0.093 mSv	—
Kobayashi et al., 2018 [77]	836	18.23±8.83 mGy	—	—
Lee et al., 2015 [78]	315	1.35 mSv	—	—
Lian et al., 2016 [79]	144	1.25 mSv	0 mSv	—
Mendelsohn et al., 2016 [2]	—	6.88±1.52 mSv/pt	—	23.92±33.8 s/pt
Noriega et al., 2017 [1]	305	1.10±0.26 mSv	0 mSv	—
Nottmeier et al., 2013 [110]	—	3.73 mSv/pt	0.036 mSv/pt	—
Petersen et al., 2012 [82]	290	0.233±0.277 mSv	—	—
Rajasekaran et al., 2018 [83]	452	0.332±0.081 mSv	0 mSv	—
Riis et al., 2017 [40]	—	3.3±1.5 mSv/pt	—	—
Scarone et al., 2018 [84]	858	3.70±1.86 mSv	—	—
Su et al., 2016 [85]	36	0.77±0.45 mSv	—	—
Tabaraee et al., 2013 [50]	80	2.19−4.22 mSv	0 mSv	—
Tajsic et al., 2018 [3]	162	0.523 mSv	—	—
Urbanski et al., 2018 [53]	454	1071±447 mGy·cm	—	—
Van de Kelft et al., 2012 [86]	1,922	1.95±2.57 mGy	—	—
Zausinger et al., 2009 [87]	324	—	—	19.96±17.09 s

Table 6
Studies reporting radiation exposure in patients instrumented using robot-assistance

Study	Screws (n)	Patient dose/screw	Surgeon dose/screw	Fluoro time/screw
Alaid et al., 2018 [21]	451	—	—	21.09±23.25 s
Fan et al., 2018 [75]	1,013	0.0336±0.326 mSv	—	—
Hyun et al., 2017 [23]	130	0.13±0.10 mSv	—	3.5±2 s
Kantelhardt et al., 2014 [90]	138	—	—	18.7±3.3 s
Keric et al., 2017a [25]	2,071	—	—	22.4±16.7 s
Keric et al., 2017b [91]	341	—	—	0.40±0.16 min
Le et al., 2018 [28]	86	7.60±4.79 μSv	—	33.21±12.33 s
Lieberman et al., 2012 [29]	197	—	0.002±0.004 mSv	0.7 s
Schizas et al., 2012 [44]	64	0.18±0.18 $mGy \cdot m^{-2}$	—	16.7±7.8 s
Solomiichuk et al., 2017 [48]	203	—	—	25.1±16.4 s

Meta-analysis

The subset of studies reporting patient intraoperative radiation dose, total fluoroscopy time, or surgeon radiation dose along with an associated uncertainty were selected for meta-analysis. This included 41 total studies [1,11,13,16,18,20−23,26−29,31,33,34,37−39,43,44,47,48,50,52,54,55,62,65,67,69,75,79,82−85,87,90,92,93], of which 15 reported patient radiation dose [1,23,28,33,37−39,62,65,74,82−85,94], 28 reported fluoroscopy usage [11,13,16,18,20−23,26,28,31,34,37−39,44,47,48,52,54,62,67,82,83,85,87,90,91], and 20 reported surgeon radiation exposure [1,13,16,18,22,26,27,29,33,39,43,45,47,50,52,54,55,69,79,83].

Patient radiation exposure

Among those evaluating intraoperative patient radiation exposure, there were 9 studies reporting the placement of 2,063 total screws using conventional fluoroscopy without navigation [16,23,28,33,37−39,62,65], 1 study reporting 99 total screws placed using conventional fluoroscopy with preoperative CT-based intraoperative navigation [33], 7 studies reporting 3,705 total screws placed using intraoperative CT imaging [1,65,74,82−85], and 3 studies reporting 1,228 total screws placed with robot-assistance based upon preoperative CT imaging [23,28,75]. Average dose (mean±standard deviation) for each navigation modality was: conventional fluoroscopy without navigation (0.26±0.38 mSv/screw), conventional fluoroscopy with intraoperative navigation (0.027±0.010 mSv/screw), intraoperative CT-based navigation (1.20±0.91 mSv/screw), and robot-assisted navigation (0.042±0.30 mSv/screw). One-way ANOVA demonstrated a significant difference in intraoperative radiation dosage among the imaging modalities (F=1,284.56, p<.0001). Post hoc testing using the Tukey honest-significant difference test demonstrated significant differences (p<.01) between all groups except for between conventional fluoroscopy with intraoperative navigation and robot-assisted instrumentation (p>.99; Figure 2A). The highest intraoperative dosage was imparted by intraoperative CT-based imaging and the lowest was imparted by fluoroscopy with navigation and robot-assisted placement. The addition of preoperative CT-based intraoperative navigation to conventional fluoroscopy reduced intraoperative patient radiation exposure by nearly an order of magnitude. Overall exposure to the patient (including preoperative CT imaging) was beyond the scope of this review.

Fluoroscopy usage

Of the 27 studies reporting fluoroscopy usage, 22 described results for 6,266 total screws placed using conventional fluoroscopy without intraoperative navigation [11,13,16,18,20−23,26,28,31,34,37−39,44,47,48,52,54,62,91], 3 described results for 288 total screws placed using conventional fluoroscopy with preoperative CT-based

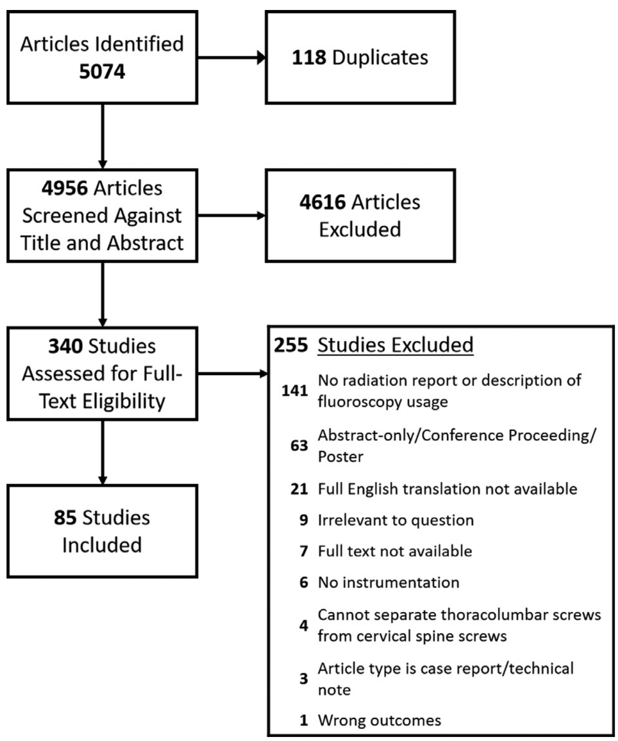
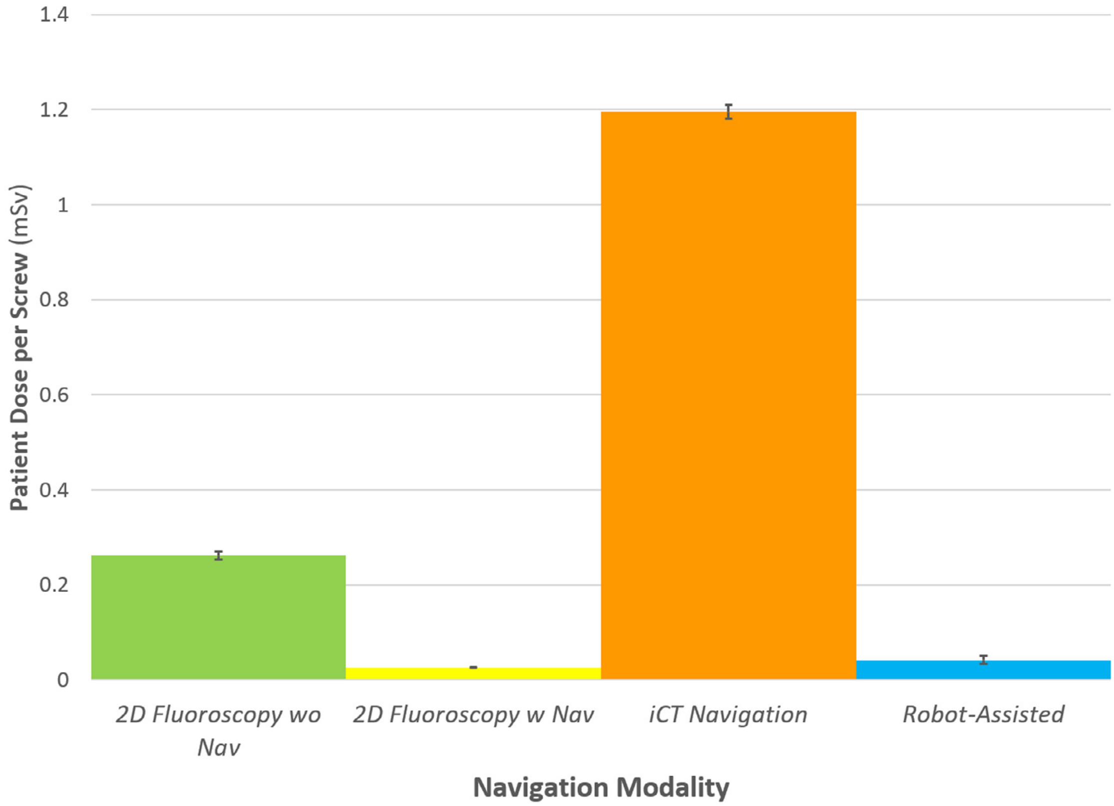


Fig. 1. PRISMA diagram for literature search.



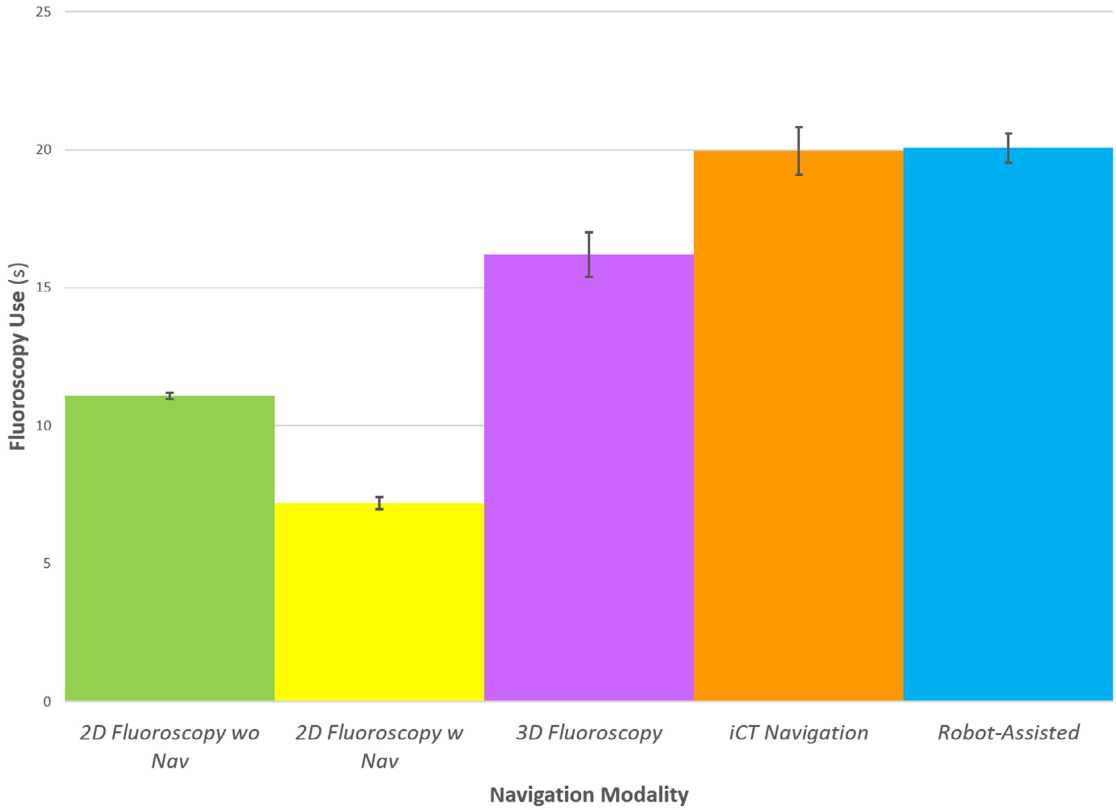
Post-hoc Comparisons Using Tukey Honestly Significant Difference				
	2D Fluoro wo Nav	*2D Fluoro w Nav*	*iCT Nav*	*Robot-Assisted*
2D Fluoro wo Nav	—	0.0058	0.0000	0.0000
2D Fluoro w Nav	—	—	0.0000	0.9966
iCT Nav	—	—	—	0.0000
Robot-Assisted	—	—	—	—

Fig. 2. Results of the quantitative meta-analysis of all included studies comparing (A) mean patient radiation exposure per screw placed, (B) mean fluoroscopy time per screw placed, and (C) mean surgeon radiation exposure per screw placed. For (A) mean patient dose, and (C) mean surgeon dose, the plotted values are mean ± standard error of the mean as expressed in millisieverts. All values are for open procedure. We also note that both the 2D fluoroscopy with preoperative CT-based guidance and robot-assisted instrumentation conditions required a preoperative CT scan, whereas the other three conditions did not.

intraoperative navigation [11,26,31], 1 described 141 screws placed using 3D-fluoroscopy [67], 1 described the results for 388 total screws placed using intraoperative CT-based navigation [87], and 6 studies described the results for 1,061 total screws placed using robot-assistance based upon preoperatively acquired CT imaging [21,23,28,44, 48,90]. Average fluoroscopy usage (mean±standard deviation) was reported for conventional fluoroscopy without navigation (11.08±8.96 s/screw), conventional fluoroscopy with intraoperative navigation (7.20±3.93 s/screw), 3D fluoroscopy (16.2±9.6 s/screw), intraoperative CT-based navigation (19.96±17.09 s/screw), and robot-assisted navigation (20.07±17.22 s/screw). One-way ANOVA demonstrated a significant difference between imaging modalities ($F=225.13$, $p<.0001$). Post hoc testing using the Tukey test demonstrated significant differences between all modalities (Figure 2B, $p<.001$) except for between intraoperative CT-based navigation and robot-assisted instrumentation ($p>.99$).

Surgeon radiation exposure

Of the 20 studies evaluating surgeon radiation exposure, 13 described results for 4,202 total screws placed using conventional fluoroscopy without intraoperative navigation [13,16,18,22,27,29,33,39,47,52,54,55,93], 2 described results for 209 total screws placed using conventional fluoroscopy with preoperative CT-based intraoperative navigation [26,33], 3 described results for 814 total screws using 3D fluoroscopy [47,55,69], 5 studies described results for 988 total screws using intraoperative CT-based navigation



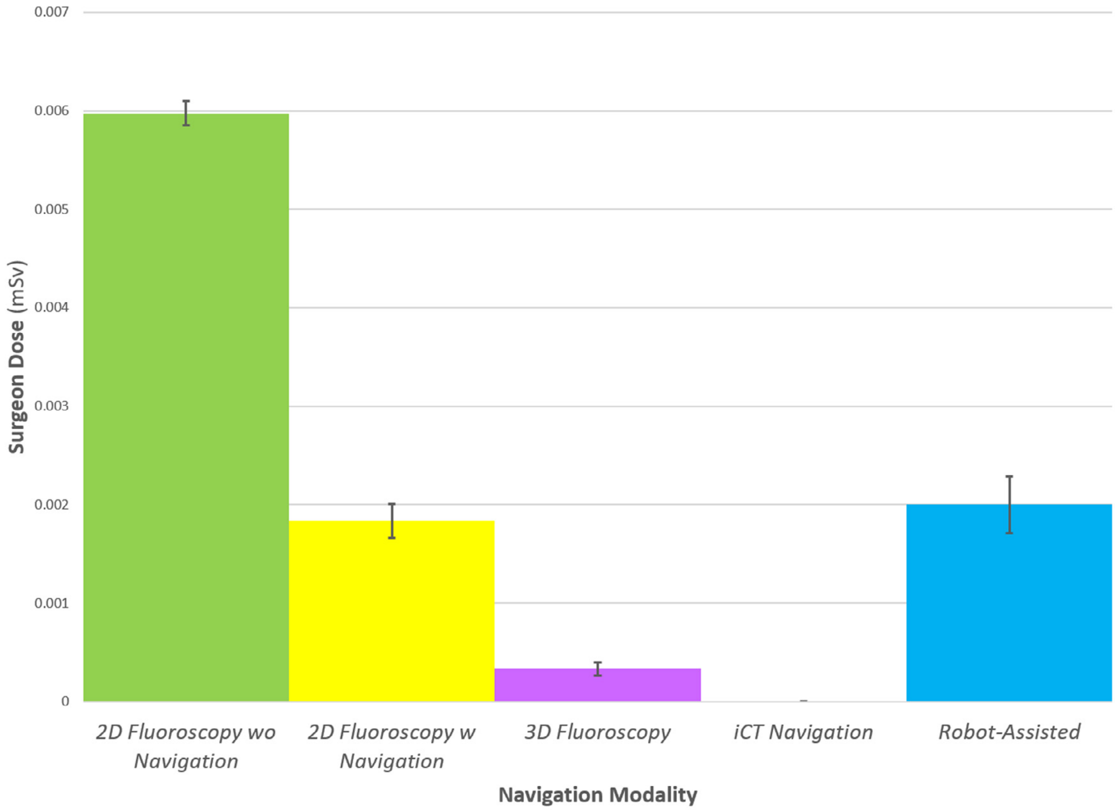
Post-hoc Comparisons Using Tukey Honestly Significant Difference					
	2D Fluoro wo Nav	*2D Fluoro w Nav*	*3D Fluoro*	*iCT Nav*	*Robot-Assisted*
2D Fluoro wo Nav	—	0.0000	0.0143	0.0000	0.0000
2D Fluoro w Nav	—	—	0.0000	0.0000	0.0000
3D Fluoro	—	—	—	0.0036	0.0006
iCT Nav	—	—	—	—	0.9996
Robot-Assisted	—	—	—	—	—

Fig. 2. (*Continued*)

[1,43,50,79,83], and 1 study described the results for 197 screws placed using robot assistance [29]. Average surgeon radiation dose (mean ± standard deviation) for the included studies by modality was: $6.0\pm7.9\times10^{-3}$ mSv/screw for conventional fluoroscopy without navigation, $1.8\pm2.5\times10^{-3}$ mSv/screw for conventional fluoroscopy with preoperative CT-based navigation, $0.33\pm1.86\times10^{-3}$ mSv/screw for 3D fluoroscopy, 0 ± 0 mSv/screw for intraoperative CT-based navigation, and $2.0\pm4.0\times10^{-3}$ mSv/screw for robot-assisted instrumentation. One-way ANOVA showed significant differences ($p<.001$) between all imaging modalities (Figure 2C, $F=263.56$, $p<.001$). Post hoc Tukey testing demonstrated significant differences between all groups ($p<.001$) except for between intraoperative CT-based navigation and 3D fluoroscopy-based navigation ($p=.82$), and between 2D fluoroscopy with navigation and robot-assisted instrumentation ($p>.99$). The addition of preoperative CT-based intraoperative navigation to conventional fluoroscopy decreased surgeon radiation exposure by roughly threefold.

Discussion

We found that, in terms of decreasing intraoperative patient radiation exposure, iCT-based navigation was associated with the greatest exposure, followed by conventional fluoroscopy without navigation. The lowest exposure was associated with conventional fluoroscopy with preoperative CT-based navigation, which provided similar exposure to robot-assisted placement using preoperative CT-based navigation. However, we note that both of these conditions require a preoperative CT examination, as compared to the



Post-hoc Comparisons Using Tukey Honestly Significant Difference					
	2D Fluoro wo Nav	*2D Fluoro w Nav*	*3D Fluoro*	*iCT Nav*	*Robot-Assisted*
2D Fluoro wo Nav	—	0.0000	0.0000	0.0000	0.0000
2D Fluoro w Nav	—	—	0.0244	0.0020	0.9991
3D Fluoro	—	—	—	0.8210	0.0111
iCT Nav	—	—	—	—	0.0008
Robot-Assisted	—	—	—	—	—

Fig. 2. (*Continued*)

other three, which do not. With respect to fluoroscopy use, we found that total fluoroscopy time decreased as follows: robot-assistance and intraoperative CT-based navigation were associated with the greatest use, followed by 3D fluoroscopy, which was greater than conventional fluoroscopy without navigation, which was greater than conventional fluoroscopy with preoperative CT-based navigation. Last, surgeon radiation exposure was greatest when using conventional fluoroscopy without preoperative CT-based navigation, followed by conventional fluoroscopy with navigation and robot-assisted instrumentation using preoperative CT-based navigation, and 3D-fluoroscopy-based navigation. Intraoperative CT imaging offered the lowest surgeon exposure to radiation, at 0 mSv per screw, as the surgeon steps outside of the room while the scan is run. Across all modalities, the use of preoperative CT-based navigation decreased intraoperative patient and surgeon radiation dose as well as fluoroscopy use.

Since the first description of fluoroscopy for thoracolumbar instrumentation by Benzel et al. [95], intraoperative imaging has promised to increase instrumentation accuracy and reduce operative time [96]. Additionally, with the advent of intraoperative navigation [97] and the adoption of percutaneous instrumentation [46,98], it has also promised to reduce surgical invasiveness, helping to speed patient recovery and improve the cosmetic results of surgery [96]. To this end, several systematic reviews and meta-analyses have been published demonstrating the superior instrumentation accuracy offered by both fluoroscopy and CT-based techniques relative to open freehand instrumentation [99−102]. However, the present study is the first meta-analysis to evaluate differences in both patient and surgeon intraoperative radiation exposure.

With the increased use of these navigation-based techniques, surgeon radiation exposure has become an increasing concern [96]. While many agencies govern radiation exposure in different fields, the two major advising bodies are the National Council on Radiation Protection and Measurements and the International Commission on Radiological Protection [103]. Current guidelines suggest a maximum annual radiation exposure of 50 mSv for radiation workers (with a recommended average maximum dose of 20 mSv per year over any 5-year period) and 1 mSv for nonradiation workers (eg, patients). The 20 mSv annual limit for radiation workers was derived from the assumption that 1 Sv of radiation exposure over a lifetime was tolerable and very low risk [8]. Based upon a 50-year career, the annual safe limit is 20 mSv. Effects are a problem once annual exposure exceeds 100 mSv, with a documented increase in cancer risk [8].

Based on the results in the present paper, a surgeon would not be expected to exceed any of these limits using intraoperative CT imaging, as it is standard practice for the surgeon to either protect themselves behind a lead-based shield or to exit the operative suite during acquisition of the CT scan. Even using the imaging modality conferring the greatest exposure to surgeons − conventional fluoroscopy without navigation − surgeons would need to place more than 8,375 screws annually to exceed the 50 mSv limit. This is outside the volume for even the most prolific deformity surgeons. However, for those surgeons seeking an additional safety margin, using either intraoperative CT imaging or conventional fluoroscopy with preoperative CT-based navigation may help reduce overall radiation exposures. Surgeons utilizing the latter would be expected to exceed safe limits only after placing over 27,000 screws in a given year and those using intraoperative CT imaging would never be expected to exceed safe limits. We favor using preoperative CT to measure and plan each screw which is then placed using a freehand technique. Trajectory is checked with a plain film and markers after cannulation and an intraoperative CT spin after placement of screws. In this manner, the procedure moves quickly, the surgeon is protected, and the hardware placement is optimized.

These increases in surgeon safety are not without costs though. Our results suggest that the decreases in surgeon radiation exposure are inversely correlated with increases in patient radiation exposure, as intraoperative CT-based navigation was associated with a nearly fourfold increase in exposure relative to conventional fluoroscopy without intraoperative navigation, and a more than fortyfold increase in exposure relative to patients instrumented using conventional fluoroscopy with preoperative CT-based navigation. However, even the dose associated with a large construct would still be well below 100 mSv (above which data exist linking radiation exposure to cancer risk). Further, these limits were not put in place for the medical patient, a point often forgotten in these arguments. In fact, the American College of Radiology, the governing body of radiologists in the United States, has published extensively on the relative risks and benefits of various imaging protocols, with the guiding principle that the “benefit should outweigh the risk” [104]. As an example, while whole body CTs in asymptomatic patients are obviously contraindicated (risk without clear benefit), any imaging ordered by a physician to aid in diagnosis or preoperative planning is likely to have benefit that far outweighs the small risk associated with the scan.

Finally, it should be noted that iCT imaging is acquired as a volume containing five to six vertebral levels with an average dose per scan as low as 2.4 mSv using standard imaging parameters [4,76,83,85,89]. This is markedly lower than the typical 6 to 7 mSv exposure from a standard lumbar CT [105], and use of one or more spins intraoperatively to correctly place hardware clearly outweighs risks. In practice, this dose is similar to that produced by conventional fluoroscopy for all but the shortest constructs. The size of the iCT radiation quantum for guidance-only is 2.4 mSv, whereas that for conventional fluoroscopy without navigation is 0.26 mSv per screw. We can see that the radiation exposure to the patient should be nearly equivalent for a construct of nine screws (four to five vertebral levels), with radiation from fluoroscopy being 2.34 Sv. A similar investigation can be performed for conventional fluoroscopy with preoperative CT-based intraoperative navigation using radiation quanta sizes of 0.03 mSv for the fluoroscopy group and 2.4 mSv for the iCT-navigation group. Using this, we see that the intraoperative CT-based navigation would never be expected to produce lower patient radiation exposure. These results can be contextualized by acknowledging that intraoperative radiation exposure is just one portion of the total radiation exposure experienced by a patient during spine surgery. Additionally, important are the preoperative and postoperative CT scans, which are essential for the navigated fluoroscopy technique. As discussed, these typically carry a radiation exposure roughly threefold higher than the radiation associated with an O-arm spin. The total episode-of-care exposure for the navigated fluoroscopy technique would then be estimated at 14 to 16 mSv, compared to 4.8 mSv for an intraoperative CT-guided case acquiring scans for both navigation and verification of instrumentation placement. It can then be seen that the use of O-arm navigation may actually reduce total patient radiation exposure during a given episode of care relative to other navigation modalities. Consequently, it may reduce the radiation risks for both patient and surgeon. A similar argument can be made for the comparison of O-arm based and robot-assisted instrumentation, as the latter requires a preoperative CT examination for registration to the patient’s anatomy.

Despite these differences, the total radiation exposure to the patient appears to be safe under all navigation technologies assessed. Even in the instance of maximal radiation exposure, namely one preoperative CT scan, two intraoperative O-arm scans, and one postoperative CT scan, the maximum dose experienced by a patient would be less than

20 mSv of radiation. This is far below the 100 mSv dosing where adverse effects have been noted [8]. New imaging protocols can reduce the exposure per CT volume to 1 mSv though, further reinforcing the safety of the associated radiation [106]. In direct contrast with this is the patient who receives no CT scans and leaves the OR with a symptomatic misplaced screw. This patient may require revision surgery or suffer a permanent deficit [107]. Thus, the relative risk-benefit analysis for the patient may even favor the acquisition of both preoperative CT for planning and intraoperative CT imaging for navigation and/or verification of hardware placement.

Limitations

As with all systematic reviews, the quality of the evidence presented here is determined by the strength of the included studies. The studies presented here were almost exclusively level III or IV evidence per the current guidelines of the North American Spine Society. Consequently, the present results are at best level III evidence. The fact that the majority of included studies were level IV evidence without comparison groups (eg, a group instrumented without any navigation) also precluded us from using conventional meta-analysis methods. The results are accordingly less able to account for heterogeneity within the data than conventional analyses, such as a random effects model of mean differences between treated groups. Second, we are limited by the heterogeneity of the mechanisms by which radiation dose was calculated. Most studies employed thermoluminescent dosimeters to estimate surgeon and OR staff radiation exposure, but used estimates based upon the output (dose area product or dose length product) of the C-Arm or iCT machine to estimate patient exposure. We were also forced to exclude several of the studies as their estimates did not have associated error ranges. Third, the indications for surgery were highly variable, including adolescent idiopathic scoliosis, lumbar spondylolisthesis, adult spinal deformity, and lumbar spondylosis. Fourth, many of the studies described surgeries that also involved the placement of a lumbar interbody device. Placement of these devices likely also employed fluoroscopic or image-based guidance that cannot be dissected from the amount of fluoroscopy required for screw placement. Fifth, the radiation numbers evaluated in the meta-analysis are strictly the intraoperative radiation number. What would be most valuable is to determine the effect of the differing imaging modalities on total episode-of-care radiation exposure. Several of the groups used a postinstrumentation iCT image acquisition or 3D-fluoroscopy spin in place of a postoperative CT to evaluate the accuracy of the hardware placement. The iCT image and 3D-fluoroscopy spin both deliver lower radiation to the patient than does a postoperative CT [4]. Therefore, it may be that while iCT and 3D-fluoroscopy technologies increase intraoperative patient radiation exposure, they decrease the radiation exposure for the overall care episode by eliminating the need for preoperative and/or postoperative CT studies. Last, several groups have established that adequate imaging placement under iCT guidance can be achieved with reduced radiation output (lower kVp and mAs values). So, although the standard iCT imaging sequences may elevate intraoperative radiation exposure relative to conventional fluoroscopy guidance for short-construct fusions, these modified dosing techniques may lead to comparable or lower intraoperative exposures for the patient.

Conclusions

Our results suggest that intraoperative CT decreases surgeon and OR staff radiation exposure, while increasing intraoperative patient radiation exposure relative to both conventional fluoroscopy and fluoroscopy with preoperative CT-based navigation. Despite this, whole episode-of-care radiation exposure may be lowered using intraoperative CT-based navigation as this eliminates the need for preoperative and postoperative CT scans. Regardless, the overall patient exposure remains well below pre-established safety levels for both intraoperative CT and fluoroscopy-based techniques. It may therefore be the case that these newer technologies improve instrumentation accuracy without noticeably affecting the patient's cancer risk relative to conventional techniques.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.spinee.2019.04.003.

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