

An Internally Randomized Control Trial of Radiation Exposure from Ultra-Low Radiation Imaging (ULRI) Versus Traditional C-arm Fluoroscopy for Patients Undergoing Single-level Minimally Invasive Transforaminal Lumbar Interbody Fusion (MIS-TLIF)

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Introduction

- Radiation exposure during minimally invasive (MIS) spine fusion is one of the paramount concerns for surgeons. - There is a significant amount of radiation exposure to surgeon and operating room (OR) personnel.

- Our goal with this work was to see if by using ultra-low dose radiation settings coupled with image enhancement, this exposure could be minimized.

Methods

An IRB approved, prospective, internally randomized controlled trial was performed comparing ultra-low dose settings coupled with image enhancement software to conventional fluoroscopic imaging (Figure 2, 3). In this study, each patient served as their own control, randomly assigning one side of MIS-TLIF for cannulation and k-wire placement using each imaging modality (Figure 1). Further, the case was also randomly divided into screw placement and cage placement/final images to allow further comparisons amongst patients. Radiation production from the c-arm fluoroscope as well as radiation exposure to all operating room personnel were recorded.





Ultra-low radiation without image enhancement

Figure 3



Ultra-low radiation imaging with image enhancement

Results

24 patients were randomly assigned to undergo a single level MIS-TLIF. In no case was low radiation imaging abandoned, and no patient had a neurologic decline or required hardware repositioning. Ultra-low radiation imaging resulted in a 75.5% decrease in total radiation production by the c-arm fluoroscope. Everyone in the operating room: the physician, scrub nurse, circulator, and anesthesiologist, all benefited with 61.6-83.5% reduction in radiation exposure during cannulation and k-wire placement to screw insertion aided by ultra-low radiation imaging. In every case but the anesthesiologist dose, this was statistically significant (p<0.05). This benefit required no additional time (p=0.78 for k-wire placement).

		Standard-dose (mGy)	Using ULRI (mGy)	% Change	р
Interval 1 and 2 Average		39.15	10.23	-73.9%	< 0.0014
Interval 3		39.76	4.26	-89.3%	< 0.001
Interval 4		24.76	10.71	-56.7%	0.019*
Cumul	ative	143.20	35.02	-75.5%	
		Tetel	Heads	Taile	
able 1: Demographic da	ta for	patients unde	rgoing single-le	evel MIS TLIF	
		T-+-	Loode	Taile	
		Iotal	neaus	Talls	р
Age (mean ± SD)	59	.4 ± 16.0	61.7 ± 11.3	56.6 ± 20.4	0.45
Age (mean ± SD) Male (n)	59	.4 ± 16.0	61.7 ± 11.3 9	56.6 ± 20.4 8	0.45 0.65
Age (mean ± SD) Male (n) BMI (mean ± SD)	59 29	.4 ± 16.0 17 9.5 ± 4.1	61.7 ± 11.3 9 29.2 ± 4.5	56.6 ± 20.4 8 29.9 ± 3.7	0.45 0.65 0.68
Age (mean ± SD) Male (n) BMI (mean ± SD) Levels	59 29	.4 ± 16.0 17 9.5 ± 4.1 24	61.7 ± 11.3 9 29.2 ± 4.5 12	56.6 ± 20.4 8 29.9 ± 3.7 12	0.45 0.65 0.68 1.00
Age (mean ± SD) Male (n) BMI (mean ± SD) Levels L1-2	29	.4 ± 16.0 17 9.5 ± 4.1 24 0	61.7 ± 11.3 9 29.2 ± 4.5 12 0	56.6 ± 20.4 8 29.9 ± 3.7 12 0	0.45 0.65 0.68 1.00
Age (mean ± SD) Male (n) BMI (mean ± SD) Levels L1-2 L2-3	59 29	.4 ± 16.0 17 9.5 ± 4.1 24 0 0	61.7 ± 11.3 9 29.2 ± 4.5 12 0 0	56.6 ± 20.4 8 29.9 ± 3.7 12 0 0	0.45 0.65 0.68 1.00
Age (mean ± SD) Male (n) BMI (mean ± SD) Levels L1-2 L2-3 L3-4	29	.4 ± 16.0 17 9.5 ± 4.1 24 0 0 2	Heads 61.7 ± 11.3 9 29.2 ± 4.5 12 0 0 0 0	56.6 ± 20.4 8 29.9 ± 3.7 12 0 0 2	p 0.45 0.65 0.68 1.00
Age (mean ± SD) Male (n) BMI (mean ± SD) Levels L1-2 L2-3 L3-4 L3-4 L4-5	29	.4 ± 16.0 17 9.5 ± 4.1 24 0 24 10 17	Heads 61.7 ± 11.3 9 29.2 ± 4.5 12 0 0 0 11	56.6 ± 20.4 8 29.9 ± 3.7 12 0 0 0 2 6	p 0.45 0.65 0.68 1.00
Age (mean ± SD) Male (n) BMI (mean ± SD) Levels L1-2 L2-3 L3-4 L4-5 L5-51	29	101 14 ± 16.0 17 9.5 ± 4.1 24 0 0 2 17 5	neads 61.7 ± 11.3 9 29.2 ± 4.5 12 0 0 0 0 11 1	56.6 ± 20.4 8 29.9 ± 3.7 12 0 0 2 6 4	P 0.45 0.65 0.68 1.00

		Circulator			Anesthesia				
N	Standard-dose (mrem)	ULRI (mrem)	% Change	р	Standard-dose (mrem)	ULRI (mrem)	% Change	р	
Interval 1 and 2 Average	0.11	0.38	-66.7%	<0.001*	0.05	0.01	-84.6%	0.282	
Interval 3	0.00	0.01		0.287	0.03	0.001	>99.9%	0.046*	
Interval 4	0.13	0.04	-69.8%	0.047*	0.05	0.03	-32.3%	0.481	
Cumulative	0.35	0.12	-66.3%		0.19	0.05	-74.6%		
indicates statistically signature	nificant result wh	iere p < 0.05							
Table 3a: A comparison of	radiation exposi	are to surgeon	and scrub n	urse betw	een standard-de	se fluoroscopy a	and ULRI		
		Surgeon			Scrub Nurse				
	Standard-dose (mrem)	ULRI (mrem)	% Change	р	Standard-dose (mrem)	ULRI (mrem)	% Change	р	
Interval 1 and 2 Average	1.46	0.36	-75.2%	0.001*	0.20	0.03	-83.7%	<0.001	
Interval 3	3.16	0.16	-94.8%	0.002*	0.38	0.05	-88.2%	0.014*	
Interval 4	0.56	0.22	-61.8%	0.110	0.25	0.28	16.0%	0.830	
Cumulative	6.61	1.09	-83.5%		1.04	0.40	-61.6%		
		1000 - 0.00							
Table 3: Operati	on time he	twoon sta	ndard	lace f	horoscon	v and LILE	11		
Table 3: Operati	on time be	tween sta Stand do fluoro: (mi	indard- fard- se scopy in)	dose f	luoroscop (min) ?	y and ULF 6 change	ti P		
Table 3: Operati Interval 1 and	on time be d 2 Averag	tween sta Stand do fluoro: (mi ge 10	indard-i fard- se scopy in) .6	dose f ULRI	luoroscop ((min) ?	y and ULF 6 change 3.9%	ц р 0.7	81	
Table 3: Operati Interval 1 and	on time be d 2 Averag Interval	tween sta Stand do fluoros (mi ge 10 3 11	indard- fard- se scopy in) .6 .5	ULRI	luoroscop l (min) ? 1.0 3.8	y and ULF 6 change 3.9% 107.1%	U 0.7 0.0	81	
Table 3: Operati	on time be d 2 Averag Interval Interval	tween sta Stand do fluoros (mi ge 10 3 11 4 56	indard- fard- se scopy in) .6 .5 .4	ULRI	luoroscop (min) ? 1.0 3.8 1.4	y and ULF 6 change 3.9% 107.1% 8.8%	0.7 0.0 0.4	81 62 38	

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Conclusions

Ultra-low radiation imaging, when aided by image enhancement software, affords the ability for all parties in the operating room to substantially decrease their radiation exposure compared to standard-dose c-arm fluoroscopy without adding additional time or an increased complication rate.

Learning Objectives

 MIS-TLIF can be safely performed using ultra-low dose radiation imaging (ULRI)
Ultra-low dose radiation settings provide significant reduction in radiation exposure to all operating room personnel
Use of ultra-low dose radiation imaging does not significantly increase operation time

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