**Observational Study** 

# Radiation Exposure in Percutaneous Spinal Cord Stimulation Mapping: A Preliminary Report

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Free full manuscript: www.painphysicianjournal.com **Background:** The utilization of spinal cord stimulation (SCS) to treat intractable pain has increased substantially in recent years. Integral to this therapy, the fluoroscope assists with requisite mapping protocols during trialing procedures to identify topographical dermatomal representations of spinal segments, and its use demands measurements of radiation exposure. However, such data is not found in the literature.

**Purpose:** The aim of this study was to report on radiation exposure during percutaneous SCS trialing procedures.

Design: An observational study.

**Setting:** A non-university out-patient Interventional Pain Management practice in the United States.

**Methods:** Fluoroscopy time from 110 SCS trialing procedures performed in a non-university, outpatient setting was studied retrospectively. Summary statistics were reported for all procedures collectively, as well as for lead arrangement and location. The interventional spine team carried out all procedural cases with the same mobile C-arm fluoroscopy system. Incident air kerma was evaluated by simplistic modeling.

**Results:** Mean total fluoroscopy time was 133.4 s with a standard deviation of 84.8 s, and the mean percentage of time allocated to pulsed fluoroscopy was 31.9%. Fluoroscopy time for the most common lead arrangement/location, neural canal dual leads/low-thoracic (n=87), ranged from 28.5 s to 387.4 s. Incident air kerma was 1.8–43.7 mGy.

Limitations: A preliminary report with a sample size of 110.

**Conclusion:** Various lead placement options are available to the spinal interventionalist to treat pain with SCS. Our data set provides first steps to obtain benchmark reference estimates on fluoroscopy times and radiation exposure during SCS trialing procedures/spinal segment mapping. Fluoroscopy times for such interventions may be considerable when compared to more commonly performed pain medicine procedures; however, skin injury is improbable.

Key words: Neuromodulation, radiation safety, fluoroscopy, dosimetry, dose reduction, health physics

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pinal cord stimulation (SCS) crosses clinical and academic boundaries (1-9). Notably, this therapy is considered for the treatment of intractable pain (10-21). According to data from the

available literature from the Centers for Medicare and Medicaid Services there was a 518% increase in Medicare population of SCS from 1997 through 2006 for pain medicine (22-25). Moreover, the utilization



Fig. 1. Percutaneous SCS trialing procedure, case 26 (fluoroscopy time 329.3 s, with 4.8% pulsed fluoroscopy). Images are maintained counter-clockwise throughout the procedure in order to replicate patient positioning on the fluoroscopy table relative to the view of the interventionalist. Furthermore, the images are shown here, respectively, as seen on the left hand and right hand monitors during spinal segment mapping. (A.) Dual parallel lead alignment dorsomedially over the spinal cord. Mapping results indicated best placement of the lead tips at the interspace of the T7-T8 vertebral bodies. (Note: needle tip.) (B.) The left and right introducer needles enter the epidural space through the ligamentum flavum at the T12-L1 and T11-T12 interlaminar spaces, respectively. (Note scoliosis with rotated vertebral bodies and the tip of lumbar fusion hardware on the right.) Both images were subsequently used to help guide epidural entry and confirmatory mapping during the subsequent implant procedure.

of SCS offers opportunities to better understand the physiology and clinical management of pain phenomena (26-35). Spinal cord stimulation has been studied and significant evidence has been provided based on systematic review, randomized trials, and observational studies encompassing appropriate methodology of evidence-based medicine and comparative effectiveness research (12,16,17,36-41).

Under fluoroscopic guidance, multi-electrode percutaneous or paddle-style leads are aligned in the epidural fat dorsomedially to the spinal cord (Fig. 1). The electrodes may be assigned and reassigned as cathodes or anodes or remain neutral. Designated cathodes/anodes, electrode spacing, and programmable waveform parameters create a three-dimensional stimulation field to selectively influence neurons in the dorsal column (42-48). The resultant waveform stimulus primarily discriminates for large myelinated  $A\beta$ -type fibers (diameters larger than 10 µm), as these fibers are readily recruited due to an advantageous stimulus threshold (28-30). The primary effect is a change in the transmembrane potential, typically antidromic depolarization versus hyperpolarization, that ultimately activates biochemical systems (49,50).

Advantages of a percutaneous approach include minimal invasiveness with low infection risks (51). However, prior to implanting SCS systems, requisite mapping protocols are carried out during trialing procedures to identify topographical dermatomal representations of targeted spinal segments (28-30) (Fig. 2), with feedback provided by the awake patient. A trial period is then implemented to help predict treatment effectiveness (52), after which the percutaneous leads are easily removed. Subsequently, it is our practice to utilize fluoroscopic images from a trialing procedure as blueprints for lead placement and confirmatory dermatomal mapping during device implant, i.e., potentially minimizing the overall fluoroscopy time associated with both SCS trialing and implant- procedures.

Although concepts outlining radiation risks in the interventional laboratory are available (53-55), data on radiation exposure during SCS procedures has not been published. Fifteen studies examining exposure levels from 21 different types of interventional pain medicine procedures were reviewed (56-70). As reflected in these studies, fluoroscopy time remains the traditional metric used for clinical radiation management (71). The value in collecting data on this acquisition parameter serves to benchmark performance, and such practice is inherent to optimization strategies in health physics (72). Table 1 presents the fluoroscopy times reported for discography, kyphoplasty, and vertebroplasty (58-64), as these procedures carry potential for greater radiation exposure compared to the other reviewed procedures (56,57,65-70).

Furthermore, in recent years the assessment of radiation dose has received increased scrutiny; notably, the evaluation of deterministic effects, for which the severity of effects will vary according to the dose received and for which dose thresholds usually exist (e.g., radiation induced skin injuries) (71,73-80). Moreover, dose assessment has seemingly evolved from an academic enterprise to a clinical endeavour. Direct influence on clinical practice is appreciated by The Joint Commission's recent decision to add unexpectedly prolonged fluoroscopic exposure to its list of reviewable sentinel events, as well as their suggestion to followup qualifying events with a period of over 6 months to one-year to monitor cumulative skin dose (81). While fluoroscopy time alone provides inadequate skin dose estimates (71,73), the evaluation of incident air kerma (x-ray exposure to the skin, previously referred to as entrance skin exposure) is possible by simplistic modeling (73,79,80). The aim of this study is twofold: 1) to report mean fluoroscopy times for the introduction of percutaneous SCS leads and subsequent spinal segment mapping during trialing procedures, and 2) to provide incident air kerma estimates. These results may support future data collection efforts by investigators seeking to definitively classify dosimetric reference levels for SCS procedures.



# METHODS

During the retrospective one-year period, 110 patients (58 females and 52 males) underwent percutaneous SCS trialing procedures by the same spinal interventionalist upon informed consent as part of various non-surgical treatment plans for intractable pain. The procedures were performed at a non-university, outpatient setting in a dedicated interventional procedure suite by means of accepted practice for percutaneous placement of SCS leads (Boston Scientific Neuromodulation, Valencia, CA, USA; Medtronic Neuromodulation, Minneapolis, MN, USA).

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Table 1 Moan	fluorosconv	time in	seconds (	c )	and sta	ndar	d doi	intion	in	naronthosis	for	various	interne	ntional	enino	nracoduros
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	Discography	Kyphoplasty	Vertebroplasty
Botwin et al (58)	57.0 s (n/a)		
Boszczyk et al (59)		216.0 s (n/a) <sup>a</sup> 150.0 s (n/a) <sup>b</sup>	
Ortiz et al (60)		390.0 s (108.0 s)	480.0 s (132.0 s)
Perisinakis et al (61)		609.0 s (132.0 s)	
Kallmes et al (62)			522.0 s (n/a)
Fitousi et al (63)			1662.0 s (n/a)
Zhou et al (64)	146.8 s (25.1 s)		

aPer single level cases.

bPer level for multi-level cases.

Patients were positioned prone on a 6-way adjustable fluoroscopy table. Fluoroscopic guidance was achieved using a mobile C-arm fluoroscopy system with multifield image intensification (OEC 9800 Super-C with a HX class intensifier, OEC GE Healthcare, Salt Lake City, UT, USA). The same certified radiologic technologist utilized and operated the fluorosco pe. The fluoroscope was deemed to be in compliance with all federal and state rules/regulations, as well as manufacturer calibrations and physics acceptance testing. Continuous mode produced x-rays without interruption. Alternatively, pulsed mode created x-rays at 8-pulses per second. The applied constructs of the radiation safety program are described here.

Fluoroscopic imaging was judiciously used, in that the fluoroscope was only activated when localizing, adjusting, or advancing a needle/lead. The low dose and automatic brightness control features were used with a 23 cm field of view (FoV) (i.e., the normal magnification mode). The C-arm anti-scatter grid was not removed. If panning or moving the C-arm in continuous mode was required, then a "manual beam on/off" operator technique was employed versus "continuous beam on" imaging. However, pulsed mode was engaged as frequently as possible. The arm of the fluoroscope was designed with a fixed source-to-image intensifier distance of 97.5 cm, and a typical sourceto-skin distance was 43 cm for SCS procedures. In anteroposterior imaging, beam angulations were approximately 15 degrees caudal at the image intensifier to show the interlaminar space during needle placement. Lateral imaging was used on a case-by-case basis. Also, an electronic collimation feature governed a radiopaque octagonal iris and semitransparent beam equalizing shutters (paired leaves lung shutters). Pertinent images captured via "last image hold" were saved and constructively placed onto-or recalled tothe right hand monitor to limit unnecessary imaging and exposure. Finally, a counter-clockwise image orientation, viewed on the monitor, accurately replicated patient positioning on the fluoroscopy table from the perspective of the interventionalist. This display technique permitted imaging of the thoracolumbar region of interest, from the introducer needles (displayed on the right hand monitor) to the SCS leads inside the neural canal (shown on the left hand monitor), without the need for repeat exposure to more caudal regions and effectively "expanded" the FoV during spinal segment mapping (Fig. 1).

#### **Fluoroscopy Time**

The fluoroscopy system automatically tabulated and stored total fluoroscopy time (in seconds) per case, and in doing so, also partitioned the absolute time and the percentage of time allocated to — pulsed and continuous fluoroscopy. Accordingly, dose summaries were retrieved from an image archiving unit (Medical Digital Recorder Video, MDRvideo, NAI Tech Products, Auburn, California, USA) for the 110 SCS trialing/procedural cases from August 2007 to August 2008.

SCS lead placement categories and spinal segment mapping subsets:

- Category 1: neural canal dual leads (NCDL), subsets: parallel placement low thoracic (NCDL/T), longitudinal placement low thoracic and low cervical (NCDL/TC), and parallel placement low-cervical (NCDL/C);
- Category 2: neural canal single lead only (NCSL), subsets: low thoracic (NCSL/T) or low cervical (NCSL/ C); and
- Category 3: NCSL/T with subcutaneous-low-back, mid-back, or occipital nerve.

In addition, assigned intervals for fluoroscopy time, in seconds, across all categories were organized, as follows:

- Group A: 1–60 s
- Group B: 61–120 s
- Group C: 121–180 s
- Group D: 181–240 s
- Group E: ≥ 241 s

#### **Incident Air Kerma**

This section describes the modeling used to calculate exposure to the skin (79,80). Entrance skin exposure is the radiation exposure to the skin measured in Röentgen (R) or milliRöentgen (mR) at the point of skin entrance for the nominal patient (i.e., 30 cm from the image intensifier). The measurement is made without the contributions from scatter radiation. The model stipulates that, in compliance with physics acceptance testing, the fluoroscopic tube potentials (kVp) under automatic brightness control should operate at/or between 70 and 90 kVp with 3.8 cm of aluminum (~15 cm of water or acrylic plastic) attenuation material. This produces measured fluoroscopic exposure rates in the range of 1.0 to 4.0 R/minute for all FoVs (magnification modes) for continuous mode in the normal dose setting. The lower portion of the exposure range accounts for the largest FoV (least magnification), and the upper portion of the exposure range accounts for the smallest FoV (most magnification). The name of the quantity which corresponds to entrance skin exposure and which is recognized by the International Commission on Radiation Units and Measurements is incident air kerma (73), and the unit of measurement is millgray (mGy). (Note: 1 R = 1 Röentgen = 2.58 × 10-4 coulombs/ kg-m of air at standard temperature and pressure, and 1 R = 8.76 mGy [milligray].)

In accordance with the aforementioned valuations, we calculated the fluoroscopic beam intensity using a skin exposure rate of 1.333 R/min for the 23 cm FoV (least magnification) in continuous mode for the normal dose setting. However, because the low dose setting was used exclusively, resultant values were reduced by 40% (82,83). Exposure is further affected by the amount of time allocated to pulsed fluoroscopy, with published data showing up to 50% dose savings at 7.5-pulses per second (53,79). Consequently, for our valuations, a 50% reduction was applied to pulsed fluoroscopy time.

# **Statistical Methods**

Analysis of fluoroscopy time and incident air kerma was conducted by means of summary statistics (Microsoft Office Excel/Access 2007, Microsoft Vista, Microsoft Co., Seattle, WA).

# RESULTS

# **Fluoroscopy Time**

Mean total fluoroscopy time was 133.4 s with a standard deviation of 84.8 s. Table 2 shows fluoroscopy time summary statistics across all categories/subsets. The range in fluoroscopy time (28.5 s to 387.4 s) relative to the complete data set was derived from the NCDL/T subset, which also contained the greatest number of procedural cases (n = 87). Figure 3 depicts the number of cases delineated by grouped time intervals; with Group B (61 – 120 s) receiving the greatest number of cases (n = 53).

The mean percentage of time allocated to pulsed fluoroscopy was 31.9%. Whereas this imaging feature was applied in 109 of the 110 cases, the range in utilization fell between 0.0% and 83.0%, for cases with total fluoroscopy times of 263.3 s and 28.5 s, respectively. For the group with the highest fluoroscopy time, Group E (≥ 241 s), percentage values for pulsed imaging fell be-

0.4 (84.9)
0.4 (84.9)
71.8 (61.9 )
9.3 (101.8 )
64.0 (96.4 )
9.9 (31.0)
51.1 (131.0 )
7.3 (47.2 )
.6 (3.4 )

Table 2. SCS trialing procedures: fluoroscopy time (mean, and standard deviation).

n=number, F=temale, M=male



Fig. 3. Across all categories, number of SCS trialing procedures. In group D, fluoroscopy time was recorded at 198.9 s in 2 cases, with 4 cases  $\pm$  10 seconds of this amount. Thirteen procedures exceeded 241 s (group E), and 8 of these cases were greater than 300 s (including 3 cases greater than 360 s).

tween 0.0% and 28.5%, for the cases with 263.3 s and 246.1 s of fluoroscopy time, respectively.

# **Incident Air Kerma**

Across all procedural cases, the mean incident air kerma was 13.9 mGy. Minimum incident air kerma was 1.8 mGy for the case incurring 28.5 s of fluoroscopy time with 83.0% pulsed imaging. Maximum incident air kerma was 43.7 mGy for the case incurring 387.2 s of fluoroscopy time with 6.7% pulsed imaging. Table 3 shows incident air kerma for Group E.

# Discussion

All SCS trialing procedures were performed by an experienced interventional spine team, and based upon clinical judgment, introducer needles were placed at the thoracolumbar spine to gain epidural access during the retrospective time period. Also, fluoroscopic activation meant either "live" or "picture" imaging, utilized for both needle and lead placement. Although the mean total fluoroscopy time was 133.4 s with a standard deviation of 84.8 s, the most common placement for SCS leads was NCDL/T (n = 87), 79% of total cases, which occurred with a subset mean fluoroscopy time of 130.4 s with a standard deviation of 84.9 s. The high percentage of NCDL/T cases was expected since this subset includes the best placement (low-thoracic spine) for coverage of pain associated with failed back surgery

Procedural case	Incident air kerma	Total time	Pulsed Time	Continuous Time		
NCDL/T	25.7 mGy	246.1 s	53.0 s	193.2 s		
NCDL/T	30.8 mGy	263.3 s	0.0 s	263.3 s		
NCSL/T*	32.6 mGy	280.4 s	2.3 s	278.0 s		
NCDL/T	33.5 mGy	290.5 s	8.2 s	282.3 s		
NCDL/T	31.9 mGy	295.2 s	43.5 s	251.7 s		
NCSL/T and low-back sub-q	35.5 mGy	307.1 s	5.7 s	301.4 s		
NCDL/T	36.5 mGy	321.1 s	17.0 s	304.1 s		
NCDL/T	37.4 mGy	329.3 s	17.4 s	311.9 s		
NCDL/T	39.0 mGy	336.2 s	4.4 s	331.8 s		
NCDL/C	36.2 mGy	343.8 s	67.8 s	276.0 s		
NCDL/T	41.2 mGy	373.1 s	41.3 s	331.8 s		
NCDL/T	43.7 mGy	387.2 s	26.9 s	360.3 s		
NCDL/T	42.4 mGy	387.4 s	48.8 s	338.7 s		

Table 3. Incident air kerma for group E.

syndrome or lower extremity complex regional pain syndrome (15,17-19,25), as these 2 conditions represent a large number of the case referrals to our center.

In Group E, the group with procedural cases at or in excess of 241 s (Fig. 3), 8 cases were greater than 300 s including 3 cases greater than 360 s. Based on time values only, we note that this grouping exceeded the mean fluoroscopy time published for single level kyphoplasty by Boszczyk et al (59), as well as represented cases which approached the mean fluoroscopy time for kyphoplasty published by Ortiz et al (60). However, due to the high number of procedural cases for SCS which fell into Group B, on the basis of time intervals only, this subgroup represented cases which are comparable to the mean fluoroscopy times published for discography (Table 1) (58,64).

Notably, because we are presenting the first look at radiation exposure for SCS procedures (and doing so by eliminating inter-physician-implanter variability), data to compare fluoroscopy times between beginner and advanced physician-implanters are not available. However, the reader may reference the aforementioned discography citations (58,64), with special attention to the article by Zhou et al (64) to gain a general appreciation of the issues concerning "beginner-level" physicians and variability in fluoroscopy times. Note: One such factor alluded to, the need for image quality (64), will be discussed in detail below relative to SCS procedures.

\*Attempted dual lead placement.

Note: Bold text indicates fluoroscopy times greater than 300 s, including 3 cases over 360 s (bold text/italics).

Key: s=seconds, mGy=milligray.

#### Variables Pertaining to Fluoroscopy Time

Fluoroscopy times were noted to deviate rather largely from their mean valuations, both the mean total computation and the categorical/subset mean values (except for NCSL/T with occipital nerve stimulation). While statistical outliers may define a large variance among a distribution (84), our discussion on variance will encompass 5 factors we consider to have general clinical relevance, as follows:

- Differences in neural tract arrangement and epidural space geometry
- Aberrant bony/spinal alignment
- Proper introducer needle angle/placement
- Intra-epidural tissue obstructions and/or epidural scarring
- Attenuation physics/image quality

First, the inter- and intra-segmental course of the neural tracts in the dorsal column can manifest in atypical arrangements producing unexpected topographical dermatomal representations, and may, therefore, require "trolling" of the SCS lead under pulsed fluoroscopy (31). This technique is employed with "stimulation on" while pulling the lead rostrally in order to find the desired dermatomal representation for the appropriate paresthesia coverage. Similarly, the nature of the three-dimensional epidural space may require additional fluoroscopy time to locate geometric areas that promote favorable stimulation paresthesia thresholds (this is most notably related to the conductivity differences associated with cerebrospinal fluid layer thickness) (47,49,85).

Second, aberrant spinal alignment, such as scoliosis or prominent kyphosis, may require extra time to steer the lead within the curvature and keep it from "flipping" ventrally to the spinal cord or aligning laterally, near dorsal rootlets, which may produce undesirable stimulation effects.

Third, similar to the challenges encountered with aberrant spinal alignment, additional fluoroscopy time may be incurred due to offset angles at the introducer needles, as such angles may present challenges to advancing leads for dorsomedial positioning. Other factors concerning needle placement and fluoroscopy time include dermal and ligamentous scarring related to spinal surgical histories (whereas such extra-dural scars may result in more fluoroscopy time to place the introducer needles).

Fourth, other scar-related concerns include the presence of intra-epidural tissue obstructions concern-

ing epidural scarring (post-surgical, post-traumatic, and degenerative), and similarly, the presence of canal obstructions related to normal anatomy (globular epidural fat, vessels, supporting ligamentous structures, as well as the plica mediana dorsalis) (86). It is interesting to note, although it is commonly viewed that the morphometric variations inherent to the plica mediana dorsalis may effectively interfere with catheter/lead placement and alignment (87), there are various reports by authors who use this membrane in a beneficial way to reduce lead migration (i.e., "midline anchoring") (88,89). However, we find that when a challenging epidural environment exists, with respect to advancing the initial lead, attempts at navigating a second lead from the contralateral introducer needle-which results in successful advancement-may often provide the first lead with a "track" to follow. A second option includes re-setting an introducer needle at a different interlaminar level to ultimately "bypass" the epidural obstruction with the lead.

Finally, variances in fluoroscopy times may be attributed to attenuation physics and image quality. The 2 common challenges that we encountered are discussed here: 1) highly radiolucent vertebral bodies against the imaged lung field creating excess image brightness at the thoracic spine region of interest, and 2) large body habitus with resultant poor image quality. In the former, tight collimation with the paired leaves lung shutters drawn close to the spine and continuous mode imaging may help compensate for the poor contrast resolution due to the vertebral bodies lacking enough cortical bone density to effectively attenuate the beam (i.e., low beam attenuation) (90). Subsequently, overriding automatic brightness control by manually ramping down tube current (mA) during tightly collimated bony imaging can help improve image resolution, especially for extremely radiolucent vertebral bodies. Alternatively, a manual adjustment to monitor/display window contrast may effectively improve image quality.

To compensate for poor image quality secondary to large body habitus (i.e., a highly attenuated beam with resultant image granularity), it too may be necessary to operate the fluoroscope in continuous mode to increase the overall radiation at the image intensifier rather than disengaging the low dose feature. This strategy may improve image contrast while limiting patient exposure if a "manual beam on/off" operator technique is used, e.g., while panning or moving the C-arm to keep the leads in view on the workstation monitor. Note: High dose fluoroscopy, or "boost" mode, was not used.

# Radiation Risk Management and Incident Air Kerma

As discussed above, images with a grainy or mottled appearance due to insufficient x-ray "quanta" striking the image intensifier may be of particular concern (i.e., beam attenuation) during pulsed fluoroscopic imaging of patients with a large body habitus. The term-quantum mottle-is used to describe such phenomenon (91). Although all electromagnetic imaging modalities are, in theory, susceptible to image degradation due to quantum mottle (91), most fluoroscope manufacturers incorporate an increase in mA during pulsed mode in an attempt to maintain image uniformity (53), based on the understanding that increases in x-ray "quanta" improves the signal-to-noise ratio (91). Therefore, in practice, interventionalists should keep this aspect of imaging/radiophysics in mind when considering techniques to maximize image uniformity and minimize quantum mottle, as applied to the fluoroscopic imaging chain (from x-ray production to image acquisition).

Moreover, to better understand the effects of radiation dose—concerning image acquisition for image viewing—one study examined perceptual ("visual") comparisons between pulsed and continuous mode fluoroscopy. In this study, it was concluded that the average absolute difference in equivalent-perception dose was 3%, as determined by equating the signal-tonoise ratios between the 2 modes (92). In other words,

Procedural case	Case 3	Case 43
Date	8/24/2007	12/27/2007
Fluoroscopy time	198.9 s	198.9 s
-Continuous mode	75.1 s	182.6 s
-Pulsed mode	123.8 s	16.3 s
Incident Air Kerma		
-Low-dose / pulsed modes*	16.0 mGy	22.3 mGy
-Low-dose setting only**	23.2 mGy	23.2 mGy
-Pulsed setting only**	26.7 mGy	37.1 mGy
-Neither modes utilized**	38.7 mGv	38.7 mGv

Table 4. Differences in incident air kerma based upon simplistic modeling.

\*Actual incident air kerma for case 43 was 39.4% more than that incurred in case 3, due to less pulsed fluoroscopy time utilized during case 43.

\*\*Hypothetical incident air kerma: different dose and imaging settings for the actual time values (as shown) per procedural case.

Key: s=seconds, mGy=milligray.

equivalent-perception dose was defined as the necessary dose operating in pulsed mode to give the visual equivalence to that incurred while operating in continuous mode (92).

Notably, even with consideration given to the average 3% increase in mA to maintain equivalent image perception with pulsed mode engaged (92), pulsed fluoroscopy can reduce radiation exposure by about 20% to 50% (with the upper range achieved using 7.5-pulses per second) (53,79,92). It is important to note while our fluoroscope defaulted to 8-pulses per second in pulsed mode, some authors advocate that as little as 4-pulses per second will allow for sufficient image guidance during SCS procedures (93). However, to our knowledge, equivalent-perception dose comparisons have not been studied using 4-pulses per second.

As incorporated here, the dedicated use of the low dose setting (which has been found to provide a 40% or more dose reduction compared to the normal dose setting) (82,83), when paired with pulsed fluoroscopy, promoted optimal radiation risk management. This impact is best observed by a closer inspection of procedural cases 3 and 43. Although pulsed fluoroscopy was utilized differently during these cases, the fluoroscopy time for each case was recorded as 198.9 s. Table 4 shows analysis between actual settings used and hypothetical use variances for the low dose setting and the pulsed mode feature, based on simplistic modeling, and illustrates how fluoroscopy time alone may lead to inadequate skin dose assessments. In other words, analysis of incident air kerma derived from actual settings used reveals that case 43 incurred 39.4% more skin exposure than case 3. It is important to note that if neither the low dose feature nor pulsed fluoroscopy are utilized (as hypothetically calculated in Table 4), the resultant incident air kerma (38.7 mGy) will approximate the actual estimates derived for Group E (i.e., 25.7 – 43.7 mGy, Table 3) (those procedural cases with approximately twice the amount of fluoroscopy time). Moreover, because the earliest deterministic threshold is 2.0 Gy, the level associated with transient erythema (74), our estimates of incident air kerma suggest that induction of skin injuries is improbable within the presented fluoroscopy times - given the nominal patient's entrance skin location established in the model.

Radiation protection is based upon health optimization strategies to keep exposure to patients and personnel as low as reasonably achievable (72,94), thus all fluoroscopically guided procedures should be evaluated. This study not only provides the first report on radiation exposure during SCS procedures, but our data may be extrapolated to generalize the cumulative exposure from both trialing and implant procedures for percutaneous SCS applications. In this view, the fluoroscopy times reported here for trialing procedures can be conservatively doubled to attain estimated total exposure times. That is, provided of course, that the applied constructs of the radiation safety program described herein are also followed at implant.

# **Study Limitations**

The following assumptions were taken into account for the incident air kerma model: 1) generalization of exposure technique factors, i.e., automatic brightness control which produced 70 to 90 kVp with 3.8 cm of aluminum, or equivalent, attenuation material; 2) modifications to exposure technique factors determined by the effects of low-dose and pulsed mode features on beam intensity; 3) the distance from the image intensifier relative to the patient's entrance skin location; and 4) overlapping of fluoroscopic beam projections. Furthermore, although the broad utility of the model is advantageous, different fluoroscopy systems, or technological improvements which affect the fluoroscopic imaging chain, may require recomputation of valuations. Finally, information on patient size was not available.

Based on these limitations, future examinations of radiation exposure for SCS procedural cases may benefit from complex models which account for specific exposure technique factors and source-to-skin distance measurements, as well as patient body mass index values. In addition, such studies should not only investigate skin dose, but also consider inclusion of tissue weighting factors for breast dose and thyroid dose due to the prone positioning of the patient coupled with the anteroposterior projections and/or the proximity of the primary beam to these organs/tissues.

Patient radiation exposure was the primary focus for this study, and occupational radiation dose was not examined. However, a retrospective assessment of radiation exposure during SCS mapping on a new patient population (n = 106), and likewise involving trialing procedures, was recently concluded by the authors (KW, KD1). Data parameters included cumulative occupational radiation dose, acquired prospectively and re-

ported by optically stimulated luminescence dosimetry readings. The results of the study were made available by poster presentation at the 13th annual meeting of the North American Neuromodulation Society (95). We note while fluoroscopic utilization (i.e., the radiation safety program) was identical to that presented here, the mean fluoroscopy time averaged 35.8% less (with a "tighter" standard deviation). The study-specific personal dosimeter worn by the physician recorded a whole body cumulative dose of 73 mrem (milliRöentgen equivalent man, or dose equivalent) for the examination period (one-year). This readout was well under the annual occupational dose limit, 5 rem. Moreover, the study-specific dosimeters worn by the first assistant (scrub nurse) and radiologic technologist, each recorded whole body cumulative doses less than 10 mrem.

# CONCLUSION

In summary, the stimulus waveforms from SCS activate biochemical systems by artificially influencing neural circuits. The use of SCS to treat intractable pain has grown substantially in recent years, and practice standards incorporate spinal segment mapping for trial periods prior to implanting SCS systems. Moreover, information on radiation exposure through dose assessment has come under increased scrutiny.

As shown here, various SCS lead placement options are available to the spinal interventionalist when treating pain. Our data set provides first steps to obtain benchmark reference estimates for fluoroscopy times and skin dose during SCS procedures. Several factors contribute to variances in fluoroscopy time and radiation exposure; however, the inter-physician-implanter variability was eliminated by study design. We conclude that fluoroscopy time associated with requisite spinal segment mapping protocols in SCS trialing procedures may be considerable when compared to more commonly performed fluoroscopically guided pain medicine interventions; however, skin injuries are improbable.

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