

Background

The increase in exposure to low-dose radiation from the growing use of medical imaging has raised concerns about cumulative dose among the general population,¹⁻³ and accordingly, dose assessment has received increased scrutiny.⁴

Conversely, unique among implantable devices, some spinal cord stimulation (SCS) systems utilize integrated technology to perform “electronic fluoroscopy” to assess device orientation (i.e., the leads) without irradiation.⁵

We have, however, recently presented a first look at radiation exposure from SCS [trailing] procedures to help determine reference levels.⁶

- Although estimated exposure was negligible, data on patient size was unavailable and the source-to-skin distance (SSD) was not taken into account due to simplistic modeling.
- To address these limitations, we examined radiation exposure on a new patient population.
 - Estimates for incident air kerma were stratified according to body mass index (BMI) and SSD.

Methods

106 dual parallel lead SCS trailing procedures in the non-university, outpatient setting, from October 2008 to October 2009, were studied retrospectively.

- The *fluoroscopy system automatically tabulated total fluoro-time (in seconds) per case, and partitioned the absolute time and the percentage of time allocated to- pulsed and continuous mode imaging.

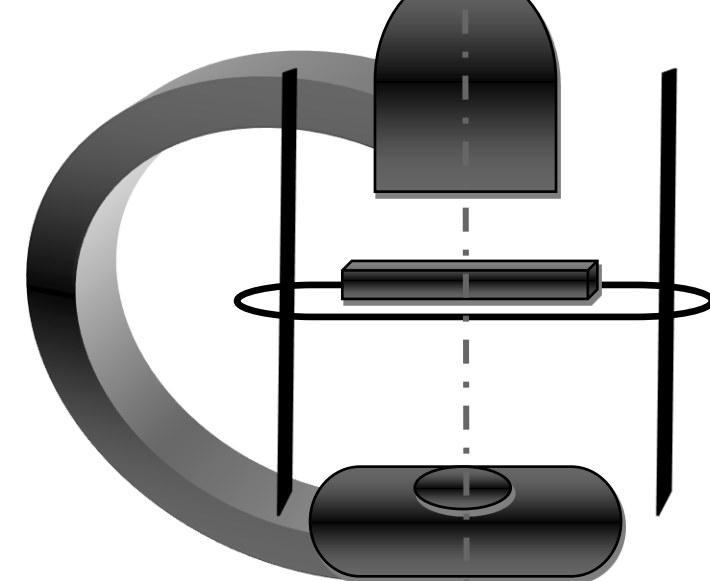
Dose Model

$$ESE_{pat} = ESE_{pha} \cdot \left[\frac{O_{pha}}{O_{pat}} \cdot \left(\frac{SSD_{pat}}{SSD_{pha}} \right)^2 \right] \cdot t_{flu}$$

Where ESE_{pat} and ESE_{pha} are skin exposure to the patient and phantom; O_{pha} and O_{pat} are radiation output for phantom and patient exposure (in Röntgens); SSD_{pat} and SSD_{pha} are the distances from the x-ray source to the skin for the patient and phantom; and t_{flu} is fluoro-time (converted to minutes).

Radiation output was measured with a ‡dosimeter located 30 cm from the image intensifier, along the central axis of an anteroposterior projected beam.

Incident air kerma is measured in milligray (mGy) and is converted from ESE_{pat} by applying a factor of 8.76 mGy to 1 Röntgen.

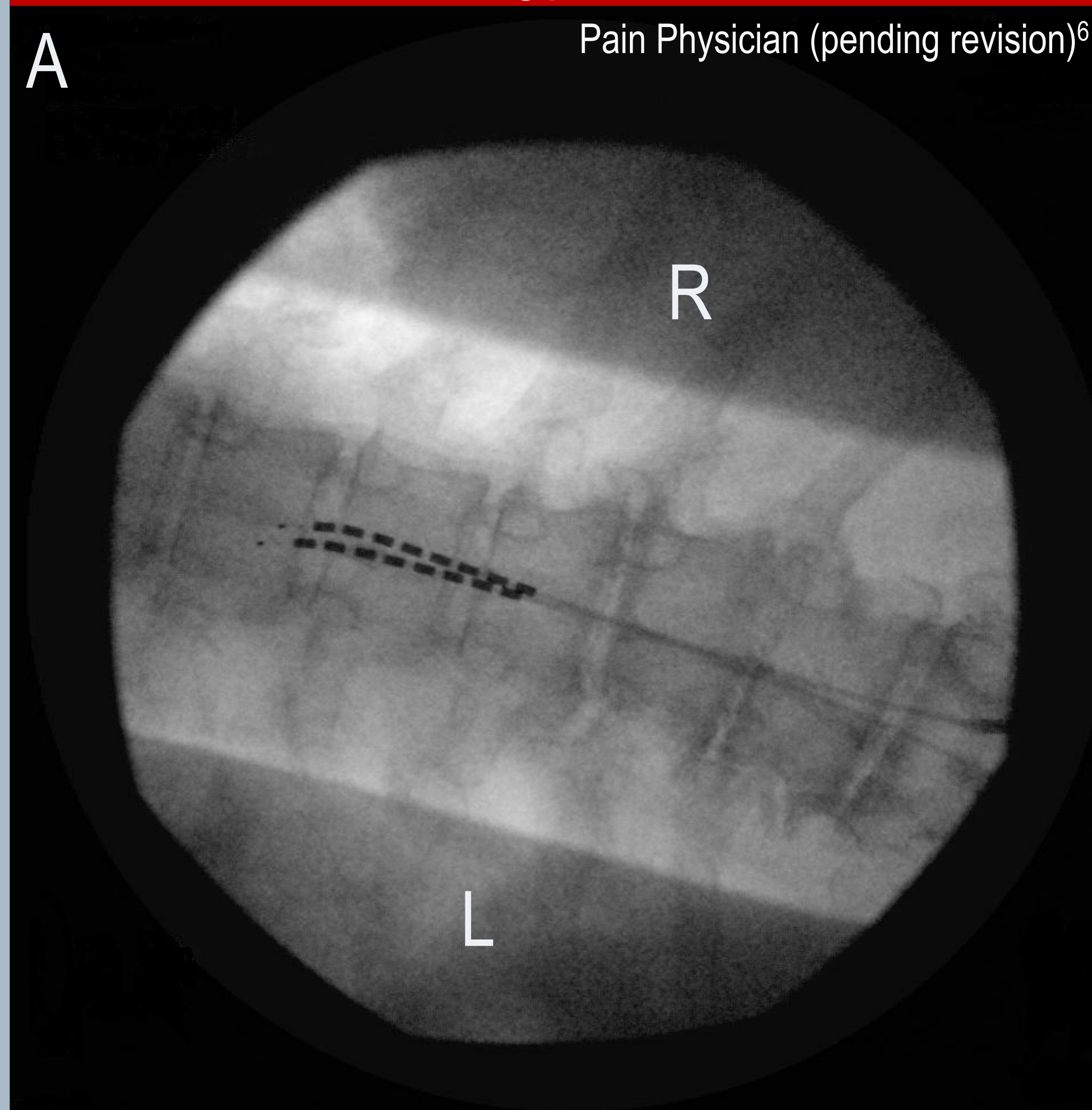


*OEC 9800 Super-C, GE Healthcare, Salt Lake City, UT, USA.

†Phantom: 3.8 cm of aluminum.

‡Radiation meter – model 1515 with converter model 1050U and ion chamber model 10X6-6M – Radcal Co., Monrovia, CA.

Trialing procedure



Dual parallel 1x8 Linear™ leads (T8 vertebral level)
Boston Scientific Neuromodulation,
Valencia, CA, USA

Results

Total fluoroscopy time:

Mean: 85.6 seconds; standard deviation: 57.2 seconds
Range: 19.5 seconds to 304.0 seconds

Percentage pulsed imaging:

Mean: 33.4%
Range: 1.80% to 75.2%
Mode: 55.4% (compiled percentage most frequent)

Source-to-skin distance:

Mean: not reported
Range: 43 cm to 50 cm

Body mass index:

n = 54 females
Mean: 31.54 kg/m²
Range: 18.46-53.32 kg/m²
n = 52 males
Mean: 29.65 kg/m²
Range: 17.03-42.45 kg/m²

Incident air kerma:

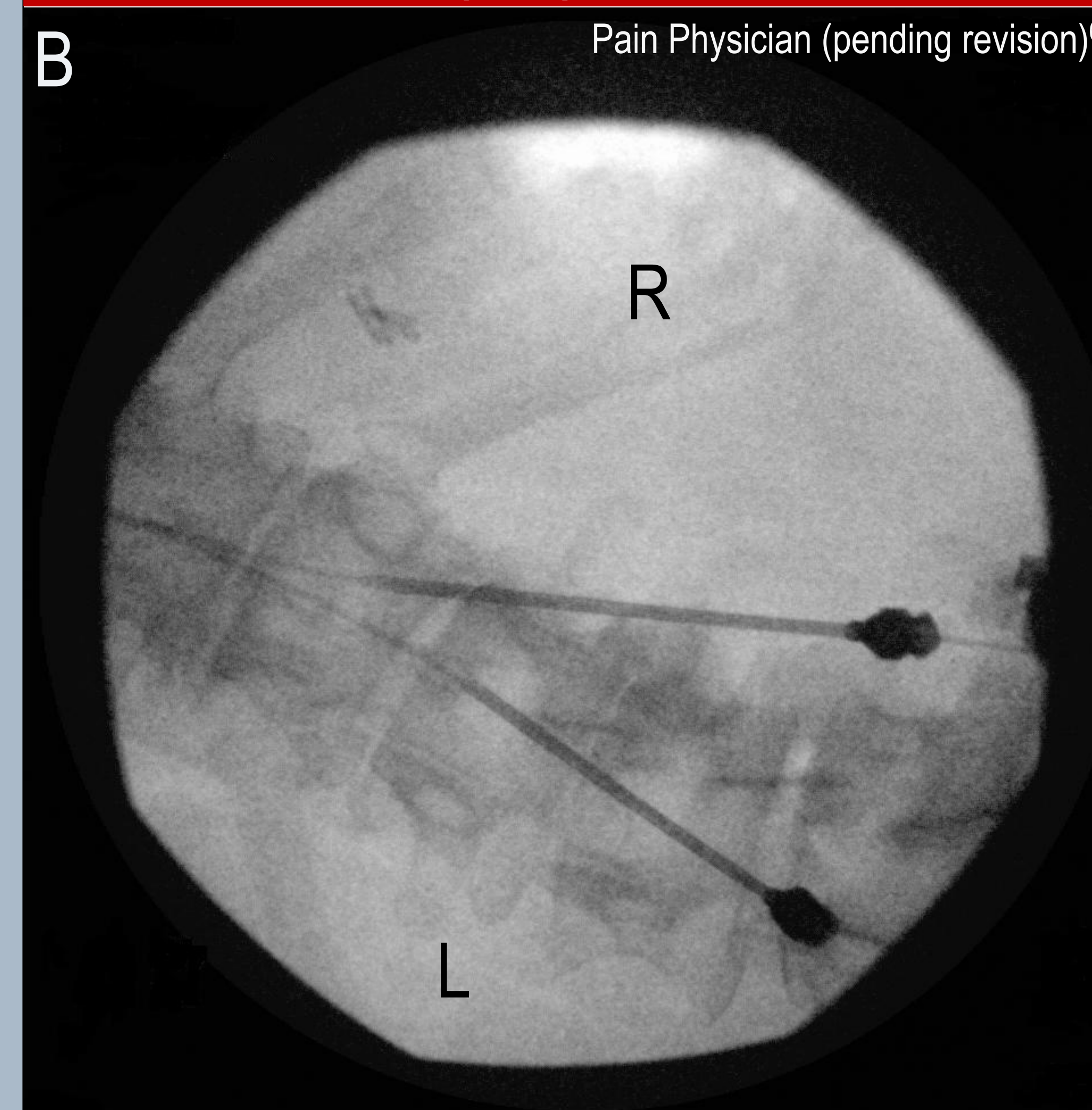
Mean: 8.33 mGy
Range: 1.53 mGy to 32.0 mGy

§Personal dosimeter: study-specific:

Physician: 73 mrem, whole body cumulative dose

§Badge report: LANDAUER: Luxel, optically stimulated luminescence dosimetry

Implant procedure



Images (A and B) appear as viewed on the monitor,
left- and right- hand screens respectively, effectively
expanding the field of view.

Discussion

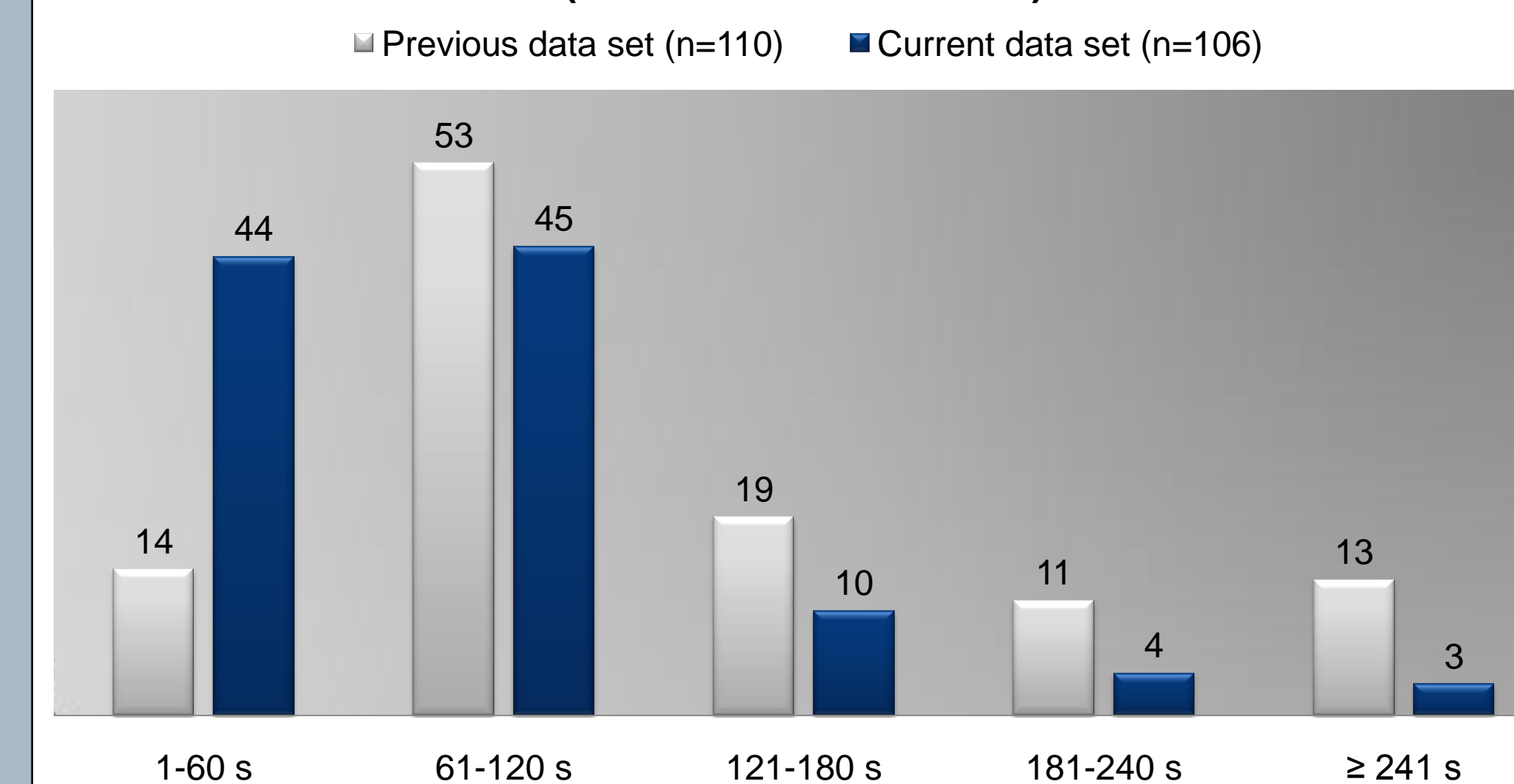
Compared to our previous data set:

- Mean total fluoroscopy time: 35.8% less.
- Percentage pulsed imaging: statistically equivalent.
- Patient radiation exposure: substantially less.

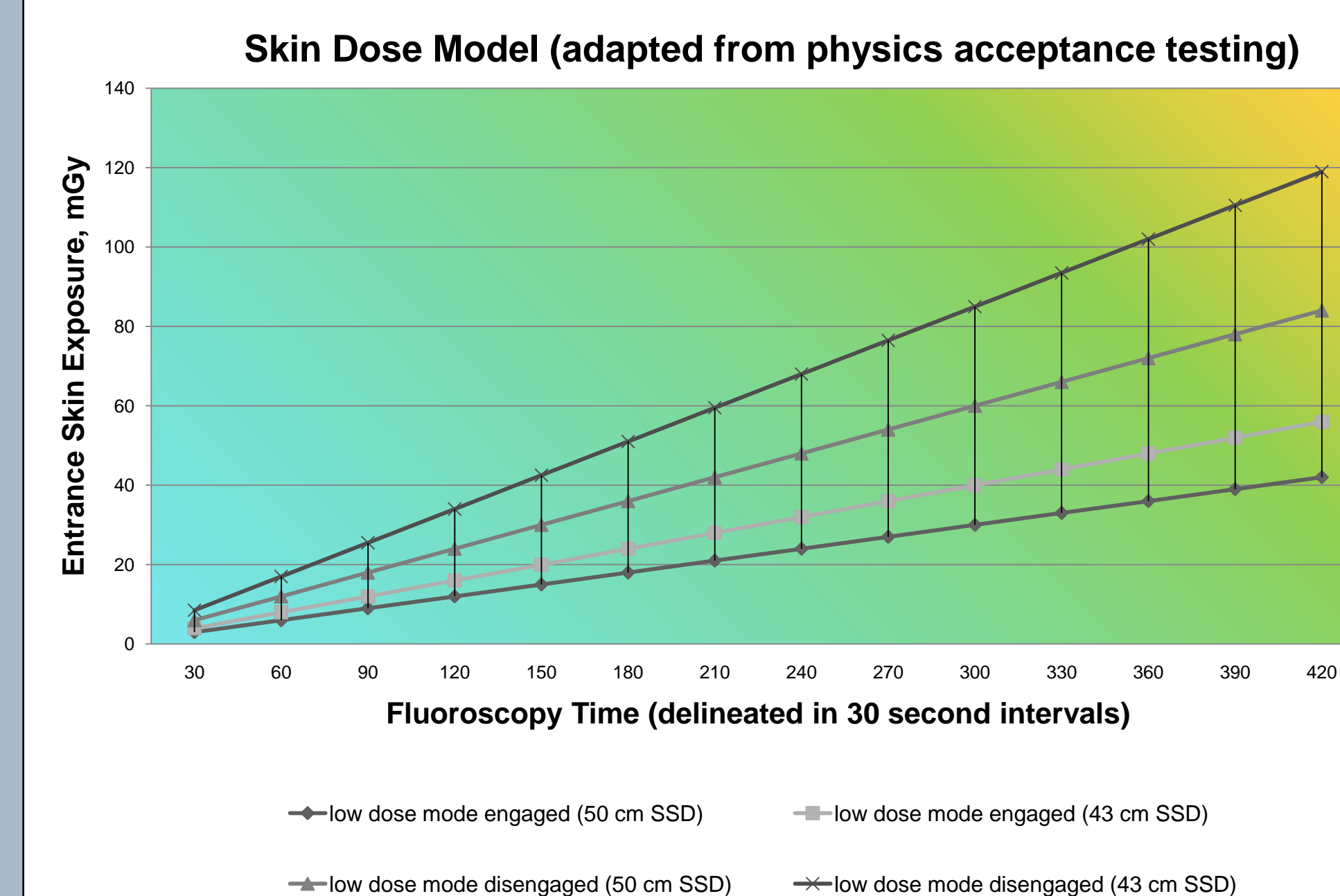
Patient size ranged from mildly underweight to morbidly obese according to BMI.⁷ The mean BMI, by gender, bordered pre-obese and obese.

- Note: trending increase in body weight among the U.S. population paired with concern about cumulative dose underscores the need to obtain accurate reference levels on radiation exposure, as such exposure will, in general, be higher for patients with greater body mass.^{1,8}

Number of SCS trialing procedures / time intervals (fluoro-time in seconds)



Entrance Skin Exposure



ESE_{pat} to anterior chest: 50 kg. adult patient: SCS mapping.
(Continuous mode imaging before beam collimation.)

Conclusion

Radiation exposure from SCS trialing procedures remains negligible despite the likelihood, as suggested here, for this therapy to be used in a patient population with a greater risk for increased irradiation based on BMI valuations.

Literature cited

1. Fazel R, Krumholz HM, Wang Y, et al. Exposure to low-dose ionizing radiation from medical imaging procedures. *N Eng J Med.* 2009;361:849-857.
2. U.S. National Academy of Sciences, National Research Council, Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation. Health Risks from Exposure to Low Levels of Ionizing Radiation. BEIR VII Phase 2. Washington, DC: National Academies Press, 2006.
3. Little MP, Wakeford R, Tawn EJ, Bouffler SD, Berrington de Gonzalez A. Risks associated with low doses and low dose rates of ionizing radiation: why linearity may be (almost) the best we can do. *Radiology.* 2009;251:6-12.
4. Balter S. Capturing patient doses from fluoroscopically based diagnostic and interventional systems. *Health Phys.* 2008;95:535-540.
5. Kosek P, Morgan D, Dunn J, et al. Electronically generated lead (EGL) scan: report of first clinical use. [abstract]. *North American Neuromodulation Society.* Dec. 7-9, 2006.
6. Winger KL, Deshpande KK, Deshpande KK. Radiation exposure in percutaneous spinal cord stimulation mapping: a preliminary report. *Pain Physician.* (pending revision).
7. World Health Organization. The WHO Global Database on Body Mass Index. BMI Classification website. http://apps.who.int/bmi/index.jsp?introPage=intro_3.html.
8. Yanch JC, Behrman RH, Hendricks MJ, McCall JH. Increased radiation dose to overweight and obese patients from radiographic examinations. *Radiology.* 2009;252:128-139.