Early Experience

Initial Experience with a New Device Used to Reduce Radiation Exposure for Patients and Healthcare Providers

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Although the field of electrophysiology has been transformed with the advent of intracardiac echocardiography and electroanatomical mapping, fluoroscopy is still the primary imaging modality used for our procedures.

With the increasing medical use and recognition of the untoward effects of x-ray, medical societies now recommend the principle of ALARA (As Low As Reasonably Achievable) to protect patients and providers from radiation exposure.

Optimal radiation dose is defined as no more or less than what is necessary to produce a high-quality image, minimizing radiation risk while maximizing clinical benefit.[1] There are a number of radiation dose reduction techniques that should be used in fluoro-guided procedures to limit radiation risks:

- Keep the table height as high as comfortably possible for the operator.
- Vary the imaging beam angle to minimize exposure to any specific skin area.
- Use intermittent fluoroscopy. Stay off the fluoroscopy pedal whenever possible.
- Minimize use of cine, magnification modes, and frame rate.
- Employ automatic adjustment of beam quality.
- Use collimation to the fullest extent possible.
- Utilize protective shielding equipment such as lead aprons, leaded glasses, thyroid collars and table skirts to blocking scatter radiation.

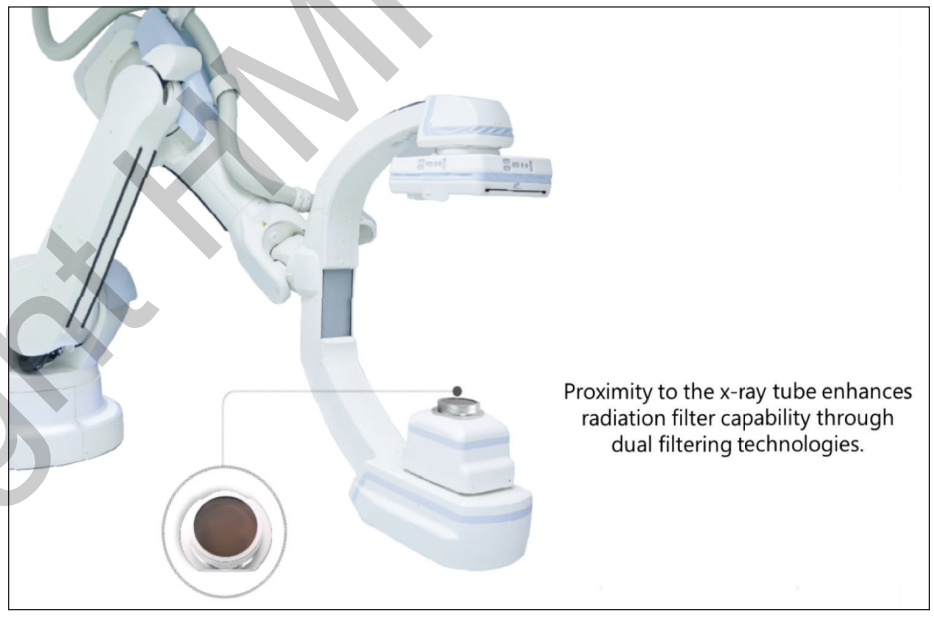
A NOVEL DEVICE FOR PROTECTING PATIENTS AND PROVIDERS

Apart from the radiation dose reduction techniques discussed above, there have been few radiation protection solutions that simultaneously protect both the patient and providers, until recently.

A new patented filter can be added to existing x-ray machines to reduce patient dose as well as radiation doses to occupational workers while preserving image quality. This radiation reduction filter, called the SELD X70 (Figure 1; CARESON Healthcare), is mounted on top of the collimator and utilizes a dual filtering technology to reduce both primary and secondary scatter radiation. Primary scatter radiation is defined as that which reflects off the patient or table, whereas secondary scatter is defined as that which reflects off the walls, other people, or other equipment.

According to the manufacturer, this device can lead to significant reductions in x-ray exposure. In their study, under

continued on page 32



Proximity to the x-ray tube enhances radiation filter capability through dual filtering technologies.

Figure 1: Installation of the SELD X70 Radiation Shielding System (CARESON Healthcare).

FIGURE 2. C-arm radiation exposure with and without the SELD X70.

	60 kV / 1.5 mA/s	70 kV / 1.5 mA/s	80 kV / 1.5 mA/s	90 kV / 1.5 mA/s	100 kV / 1.5 mA/s	110 kV / 1.5 mA/s	120 kV / 2.0 mA/s
No filter	2.55	3.814	5.307	6.941	8.725	10.68	17.90
With SELD X70	1.490	0.490	0.865	1.788	2.587	3.519	4.416
With SELD X70 (repeat)	1.380	0.490	0.857	1.793	2.583	3.535	4.393
% reduction*	**43.7%**	**87.2%**	**83.8%**	**74.2%**	**70.4%**	**67%**	**75.4%**

Radiation exposure measured in milliroentgens per second (mR/s). Results confirmed by the Central Technology Inspection Institute, South Korea. Provided by the manufacturer.
*Based on an average of both SELD X70 tests for each voltage.

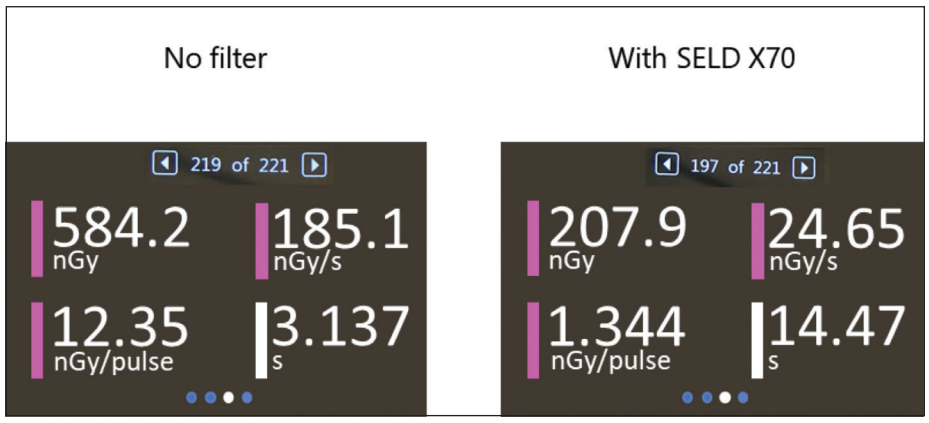


Figure 3: Sample of an ion chamber measurement of cine shot with and without the SELD X70 obtained in the same patient, using the same fluoroscopy settings and image beam angle.

FIGURE 4. Absorbed radiation dose with and without the SELD X70.

	Weight (kg)	BMI	Average nGy / sec	% Reduction
Patient 2	98	32.7		
No filter			179.9	**88%**
With SELD X70			20.72	
Patient 6	48	21.4		
No filter			34.71	**68%**
With SELD X70			11.23	
Patient 7	121	35.4		
No filter			36.25	**75%**
With SELD X70			8.141	

FIGURE 5. Pooled data on average absorbed radiation dose with and without the SELD X70.

	Weight (kg)	BMI	Pulses	nGy / sec	nGy / pulse
Average of 13 patients	98	34.1			
No filter			170	128.1	8.54
With SELD X70			119	41.62	2.776
% reduction				**67.5%**	**67.5%**

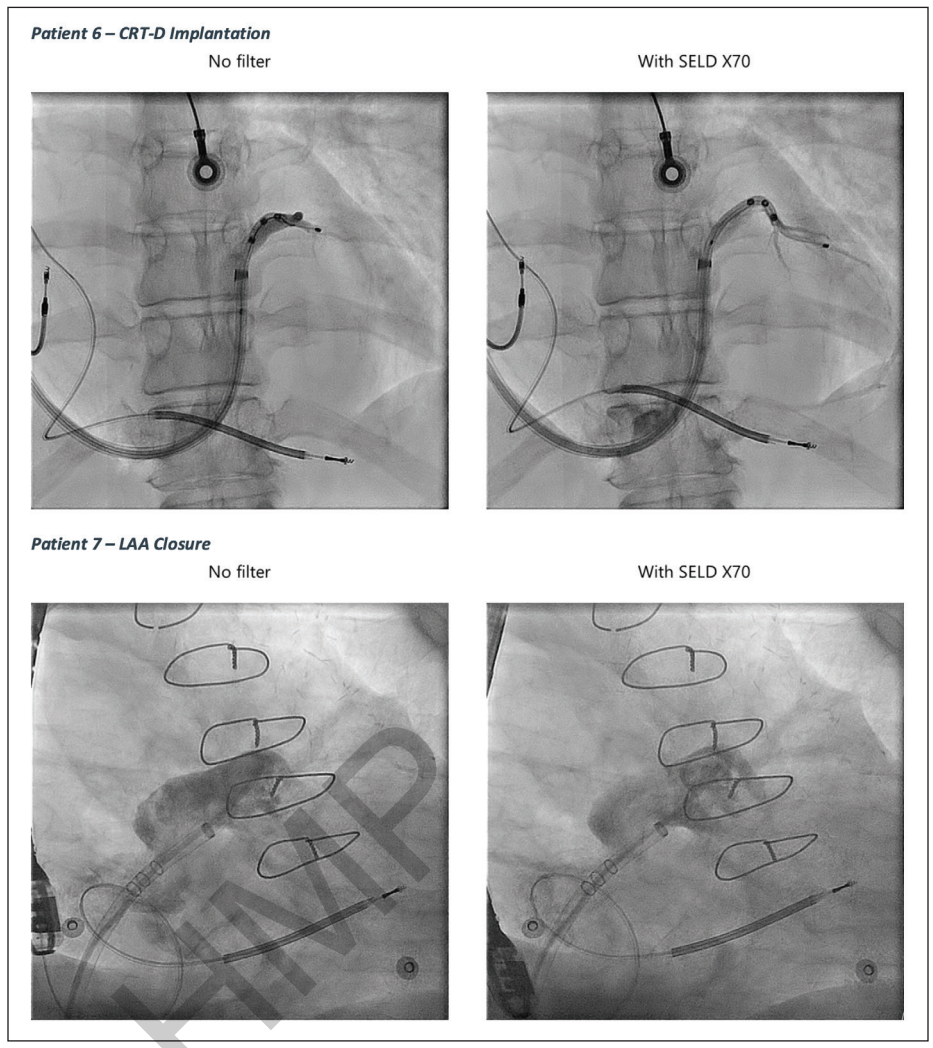


Figure 6: Examples of images obtained during different procedures with and without the use of the SELD X70 filter.

The device was initially tested in 13 patients undergoing interventional cardiology and EP procedures (*e.g.*, peripheral SFA stent, diagnostic heart cath, LAA closure, and CRT-D implantation).

Radiation Filter

Continued from page 30

controlled conditions with no patient on the table, use of the SELD X70 radiation reduction filter decreased radiation exposure by up to 87% (Figure 2).

INITIAL EXPERIENCE AT GRANDVIEW

We recently had the opportunity to test the SELD X70 at Grandview Medical Center. A device to measure radiation exposure was provided to us by Alterra Medical, the distributor of the SELD X70, for use during the initial test phase, assuring safety to all patients and staff. In real time, we analyzed snapshots of absorbed radiation dose (measured in nanograys, or nGy) (Figure 3). Radiation exposure was measured using an ion chamber (Radcal) positioned two and a half (2.5) feet from the x-ray at a static level below the table height. The ion chamber documented all runs of both fluoro and cine throughout each procedure. The SELD X70 filter was mounted and removed during each procedure, without notice to the operating physician, while we continuously analyzed image quality.

The device was initially tested in 13 patients undergoing interventional cardiology and electrophysiology procedures (e.g., peripheral SFA stent, diagnostic heart cath, left atrial appendage closure, and CRT-D implantation).

There was a substantial reduction in radiation exposure as measured by the ion chamber device during the procedure (Figures 4 and 5), and no meaningful reduction in image quality was observed (Figure 6).

Although this pilot study was neither randomized nor designed to statistically analyze differences in radiation exposure, our experience corroborates the manufacturer's claim of radiation reduction in the order of 60-80%, which is substantial. Controlled studies designed to analyze image quality and radiation exposure reduction are planned.

SUMMARY

Fluoroscopy is the primary image modality used in catheterization and electrophysiology laboratories. New fluoroscopy equipment, dose reduction techniques, and shielding personal protective devices are used to minimize exposure to patients and healthcare providers. The SELD X70 is a filter that can be easily installed to existing fluoroscopy equipment to reduce patient dose and exposure to providers. In our experience, the radiation reduction was substantial with no change in image quality. Further studies analyzing the impact of this protective device in the clinical setting for a wider array of electrophysiology, interventional, and structural heart procedures should be performed, as this could have a tremendous impact to patients and healthcare workers. ■

Disclosures: The authors have no conflicts of interest to report regarding the content herein.

Reference

1. White Paper: Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging. U.S. Food and Drug Administration. Published June 14, 2019. Available at https://bit.ly/2nbNUJQ. Accessed September 30, 2019.