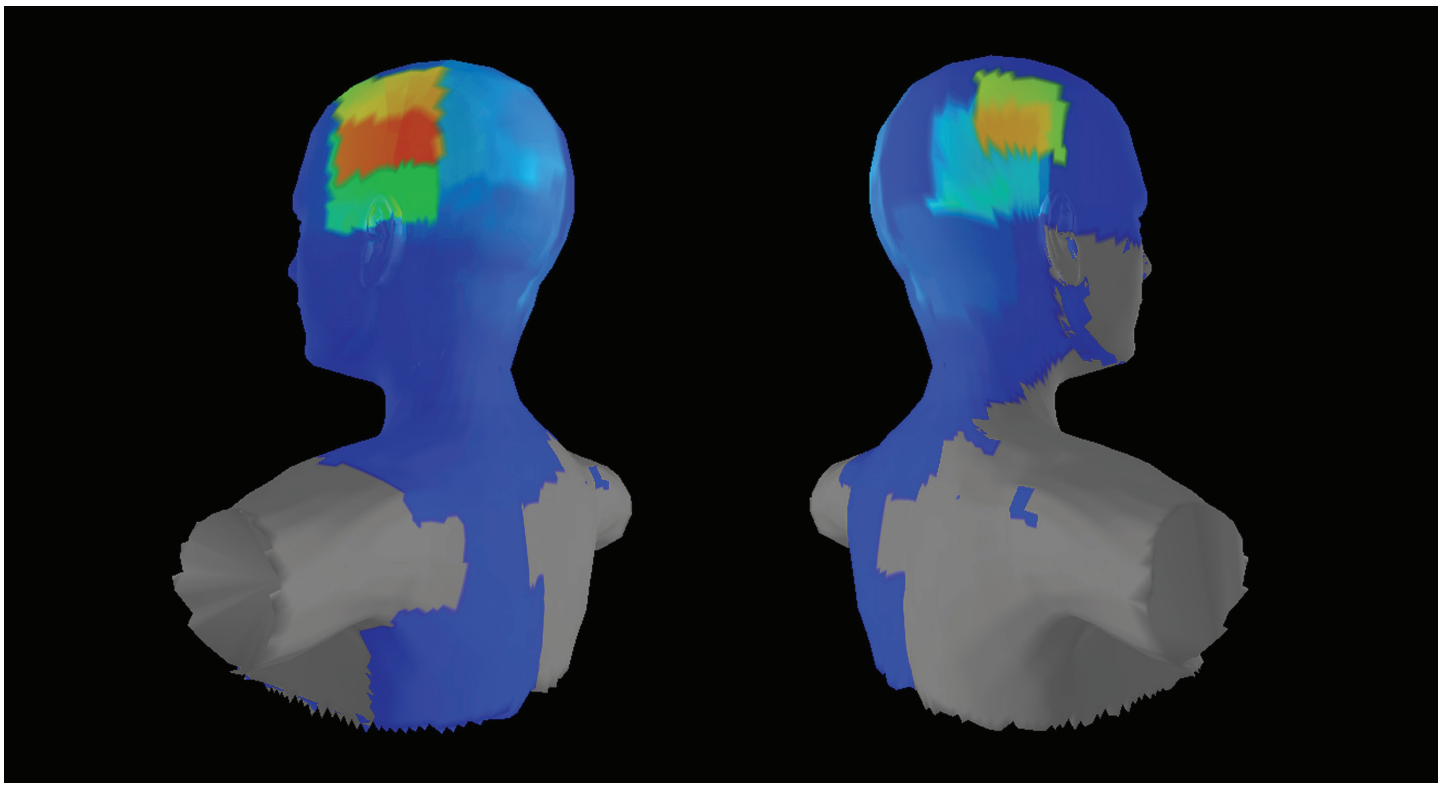
Canon

White Paper

Infinix™-i

Dose Tracking System

Patient Skin Dose Estimates in Real Time



DoseRite™

INTRODUCTION

In an era of increased utilization of ionizing radiation for medical diagnostic and interventional procedures and with the development of reference radiation dose levels, radiation dose monitoring and recording is of particular importance. This holds especially true with the use of fluoroscopic guidance during diagnostic and interventional procedures where radiation dose levels may be higher than other procedures. In this paper, we will explore the factors affecting radiation exposure, methods of measurement, and will discuss how the unique Infinix™-i Dose Tracking System (DTS) provides real-time peak skin dose estimates, empowering clinicians to track skin dose and modify their procedure to minimize radiation risks, if appropriate. In support of the aforementioned investigations, results from hundreds of interventional fluoroscopic procedures are presented.

BACKGROUND

Radiation Risk and When to Take Action

The National Council on Radiation Protection and Measurements (NCRP) suggests a substantial radiation dose level (SRDL) be defined at a peak skin dose of 3 Gy or a reference air kerma of 5 Gy, recommended to trigger additional dose management and patient follow-up actions to monitor for possible deterministic skin injury.[1] Table 1 shows the recommendations for peak skin dose, air kerma, dose area product and fluoroscopy time. In order to minimize these potential risks as much as practicable, the As Low As Reasonably Achievable (ALARA) principle should be followed whenever possible.

Dose Monitoring Techniques

Today's interventional fluoroscopy equipment provides a multitude of dosimetric indications, monitoring and reporting capabilities.

Fluoroscopy Time [unit: minutes (min)] is the total amount of time that fluoroscopy is utilized during an imaging or interventional procedure. Fluoroscopy time is a poor indicator of patient dose and is considered an inadequate indication of skin-dose estimation for many reasons, including the lack of information regarding fluoroscopic dose rate, exclusion of cine radiographic recording contributions, patient size, field-of-view (FOV) size or beam positions.

Cumulative Air Kerma (CAK) [unit: milligray (mGy)] is the total amount of radiation dose absorbed by air at a specific point in space relative to the X-ray source, measured free-in-air, during an imaging or interventional procedure. The most commonly utilized reference point is located 15 cm from the isocenter toward the X-ray source. Although CAK is an improved indicator of skin dose when compared to fluoroscopy time, it is still a poor indicator of peak skin dose. One of the reasons is that CAK sums all of the radiation dose as if it occurred at a single point in space without taking into consideration spatial distribution of the dose across the patient skin surface. Further, air kerma depends upon the reference point location, which may not correspond to the actual position of the patient's skin, which introduces further uncertainty. Lastly, CAK is measured free in air, meaning it does not take into account attenuation and scattering effects of the patient table and mattress nor tissue absorption and backscatter characteristics.

Dose Area Product (DAP), a.k.a., Kerma Area Product (KAP) [unit: gray centimeter squared (Gy.cm^2)] is the product of the area irradiated and the air kerma. Unlike air kerma, DAP is constant regardless of the distance from the X-ray source. DAP is generally considered a poor indicator of patient skin dose as compared to CAK.[2] In addition, DAP suffers from the inability to distinguish between large fields with low skin doses and small fields with high skin doses, which could result in the same dose area product.

Skin Dose [unit: milligray (mGy)] is the absorbed dose to soft tissue, including the contribution from any backscattering, at a specified point of the skin. *Peak Skin Dose (PSD)* refers to the highest skin dose occurring at any point on the skin surface, while *FOV Skin Dose* refers to the highest skin dose occurring at any point on the skin surface that is within the area of irradiation of the present FOV. Because skin dose depends upon a large number of

Dose Metric	Substantial Radiation Dose Level
Peak Skin Dose	3 Gy
Cumulative Air Kerma	5 Gy
Dose Area Product	500 Gy cm^2
Fluoroscopy Time	60 minutes

Table 1. NCRP recommendations.

factors, including gantry angle and position, field size and shape, and patient size and position, it cannot be calculated directly from overall measures of dose described previously, such as CAK and DAP.[3] The International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), and professional societies have emphasized the importance of estimating skin dose during and after fluoroscopically guided interventional (FGI) procedures.[1,4] Furthermore, the Joint Commission considers a skin dose that exceeds 15 Gy to be a sentinel event.[5] Hence, accurate estimation of peak skin dose and the skin dose distribution is important both during and after FGI procedures in order to efficiently and effectively manage deterministic radiation risk. The Infinix-i DTS is the first comprehensive real-time display of estimated skin dose on a realistic patient model.

METHODS

In this section we will describe how the DTS works. The revolutionary DTS (Figure 1) offers a transition from machine output measurements of CAK and DAP to patient-specific estimates of peak skin dose. The DTS goes beyond traditional dosimetric indications by offering the following advancements:

- Tracking and incorporating movement of the X-ray beam relative to a patient representation.
- Inclusion of realistic patient models that can be selected to closely match the actual patient for source-to-skin distance corrections.
- Addition of other real-world influences, such as the patient support and backscatter characteristics.

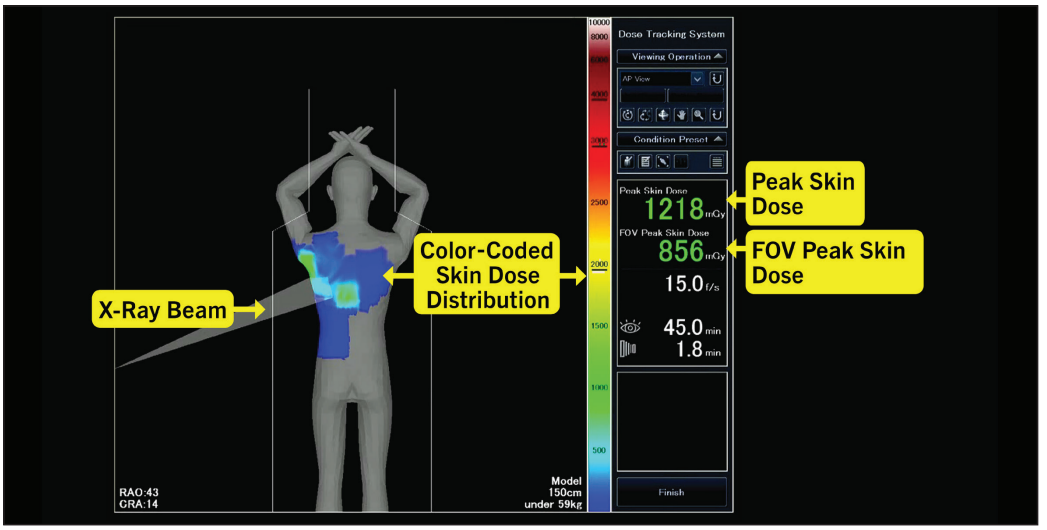


Figure 1. Dose Tracking System

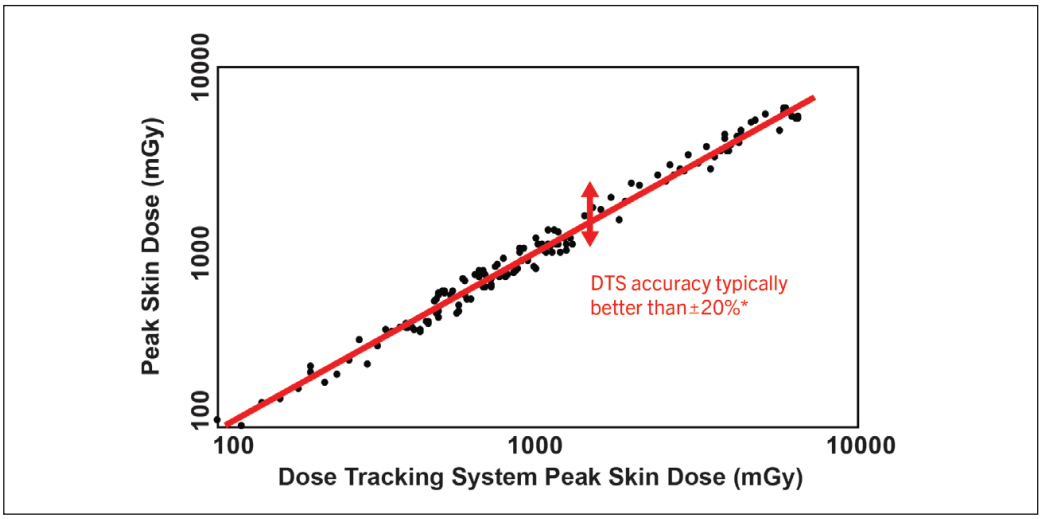


Figure 2. Illustrative example of PSD as a function of estimated DTS PSD.

The DTS skin dose values, under typical clinical conditions, are estimated to be within a range of plus or minus 20 percent (Figure 2) with careful matching of the patient graphic to that of the actual patient being imaged. Validation tests have shown that the dose distributions displayed by the DTS compared to the actual distribution of dose to various phantoms were within approximately 10 percent under test conditions.[6-9] Real-time dose management with DTS has been reported to provide 15 to 46 percent reduction in PSD.[10,11]

CLINICAL RESULTS

In this section we will present analysis of different radiation dose metrics acquired during clinical procedures.

Data Collection

Dose metrics and procedural information were collected from two Infinix-i Biplane systems (Tochigi, Japan) at the Gates Vascular Institute (GVI) in Buffalo, NY. A total of 348 clinical cases that included both DICOM Radiation Dose Structured Reports (RDSRs) and DTS reports were used in the analysis. To comply with the Health Insurance Portability and Accountability Act (HIPAA), the RDSR and DTS reports were completely anonymized and no specific clinical information was retained.

System Utilization

The collected data was acquired during neuro diagnostic and therapeutic interventional procedures.

The relative contribution for primary modes of operation is depicted in Figure 3. The total CAK for all cases resulted from the following contributions: 63 percent from stationary acquisitions (95 percent of which resulted from digital subtraction angiography), 33 percent from fluoroscopy and four percent from Low Contrast Imaging (LCI), the cone beam CT (CBCT) protocol. All cases utilized both the frontal and lateral planes with the frontal plane contributing 68 percent of the total CAK.

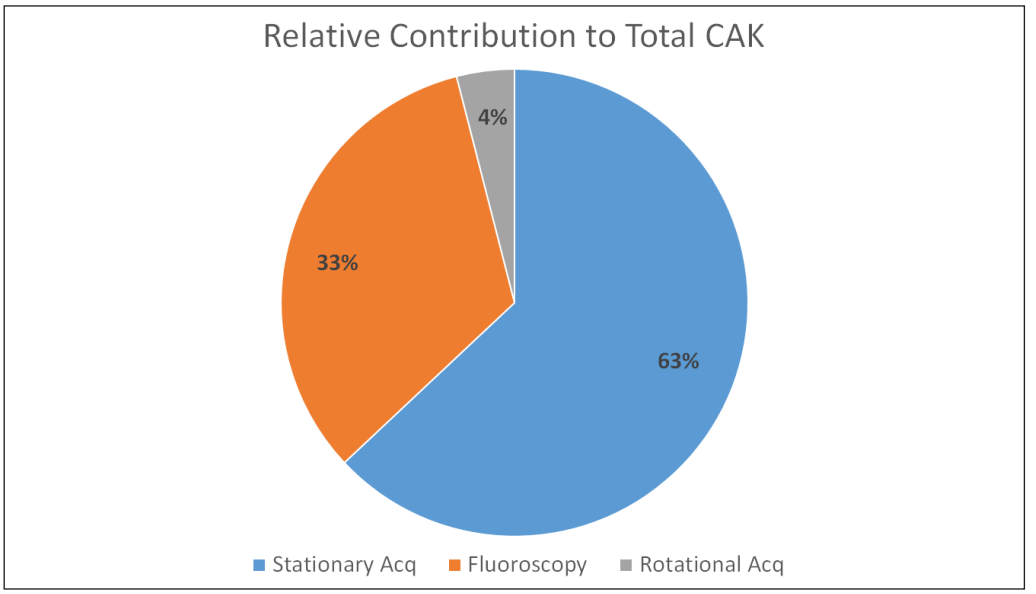


Figure 3. Distribution of CAK from different types of acquisitions.

System Parameter	Unit	Mean (95% C.I.)	Min	Max
Field of View	cm	23.3 (23.0-23.6)	14.8	29.5
Source to Image Distance	cm	103.9 (103.4-104.3)	93.6	128
Added Beam Filter (Fluoro)	mm Cu	0.44 (0.43-0.45)	0.25	0.5
Cumulative Air Kerma	mGy	1305 (1145-1465)	79.3	12,311
Dose Area Product	Gy cm^2	118 (108-127)	11.0	550
Peak Skin Dose	mGy	508 (452-564)	46.2	3,705

Table 2. Descriptive statistics on additional system parameters.

The mean fluoroscopy time was 20.4 min (95 percent Confidence Interval: 17.9 – 22.8; min: 1.1; max: 166.9). Fifteen frames per second fluoroscopy was used for all instances and the mean fluoroscopy air kerma rate at the patient entrance reference point was 15.2 mGy/min (95 percent Confidence Interval: 14.2 – 16.1; min: 1.9; max: 48). The mean number of non-fluoroscopy images (DA, DSA, 3D, LCI) was 397 (95 percent Confidence Interval: 375 – 419; min: 8; max: 1329). The primary non-fluoroscopy mode utilized was three frames per second DSA and the mean non-fluoroscopy air kerma rate at the patient entrance reference point was 2.1 mGy/frame (95 percent Confidence Interval: 2.0 – 2.2; min: 0.5; max 9.1). Other system recorded parameters relating to the facility-specific dose profile are listed in Table 2.

PSD was plotted as a function of CAK measured on the frontal (blue), lateral (orange) and combined frontal and lateral (gray) planes (Figure 4) on a log-log scale. CAK from the frontal and the combined data had higher correlation with PSD values than the lateral plane (R^2 values equal to 0.85 and 0.88 respectively). However, the lateral CAK most closely represented the PSD with a slope of 0.88 and the combined frontal and lateral CAK most deviating from the PSD with a slope of 0.35. The dose index, described as a convenient measure of the various operator, procedure, and patient factors (e.g. operator, technique, procedure complexity, patient anatomy) that affect PSD, was also measured by taking a ratio of the PSD to the CAK.[11] The mean dose index was 0.42 with a standard deviation of 0.12. This indicates that the CAK overestimated PSD by a factor of 2.4 (1/0.42) on average. Only one procedure resulted in a dose index greater than one.

As shown in Table 3, the substantial radiation dose level, as defined in terms of peak skin dose, was exceeded in only

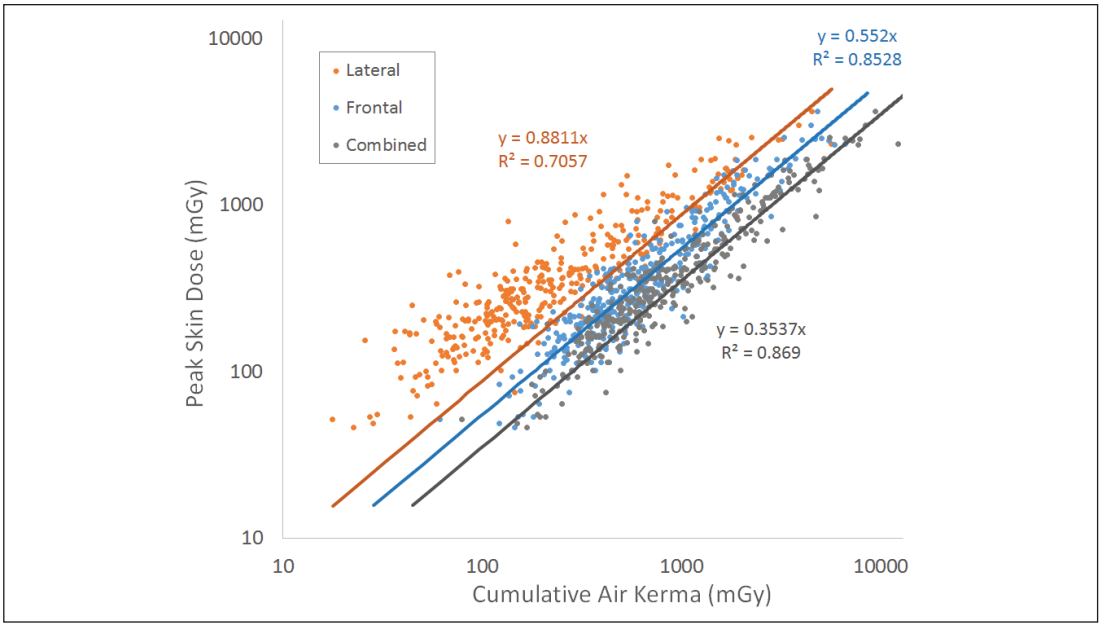


Figure 4. DTS PSD plotted as a function of CAK.

	Number of Cases			
CAK/PSD Range (mGy)	**Frontal**	**Lateral**	**Combined**	**PSD**
< 1000	256	311	214	303
1000 - 2000	64	29	75	36
2000 - 3000	13	3	27	7
3000 - 4000	7	3	11	2
4000 - 5000	4	1	10	0
> 5000	3	1	11	0

Table 3. Number of cases exceeding various thresholds. Frontal, lateral and combined represent CAK values in mGy, whereas PSD represents peak skin dose in mGy.

two of 348 cases (0.6 percent) with a maximum value of 3705 mGy. In contrast, there were 11 and 23 cases (3.2 percent and 6.6 percent) exceeding the substantial radiation dose level, as defined in terms of CAK and fluoroscopy time with a maximum value of 12312 mGy and 167 minutes, respectively. This suggests that reliance on alternative measures (i.e. CAK or fluoroscopy time) may have resulted in additional follow-up of 11 to 23 patients, or nine to 21 more patients than indicated when utilizing PSD estimates (a factor of 4.5 to 10.5 increase). Hence, utilization of the DTS can help clinicians minimize instances of unnecessary patient follow-up resulting from incorrect representation of patient dose when using CAK and/or fluoroscopy time.

PSD distribution as depicted by the DTS for the highest CAK procedure is shown in Figure 5. Different colors correspond to different levels of PSD, as indicated in the color bar to the right of the images. Imaging smaller areas, avoiding overlapping fields, and distribution over multiple areas can result in reductions of PSD.

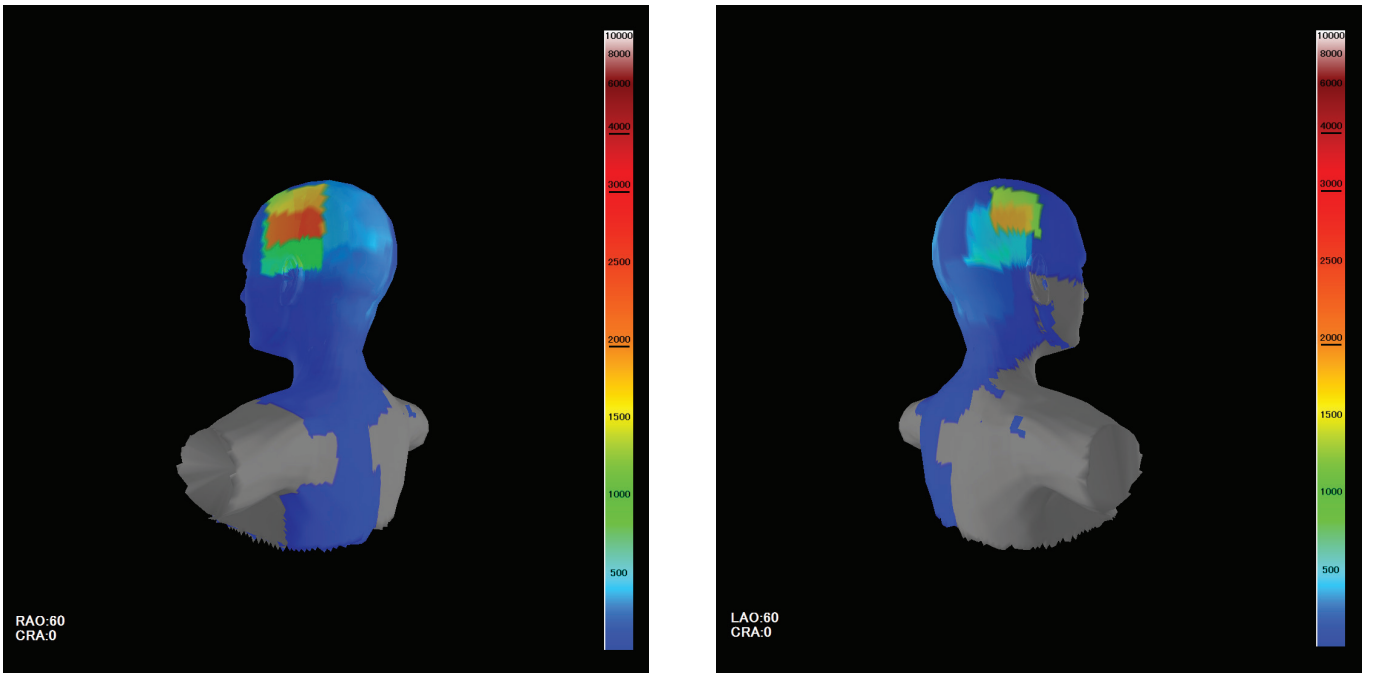


Figure 5. PSD distribution as depicted by the DTS for the highest CAK procedure.

Frequency with which Interventional Radiology Procedures Resulted in Peak Skin Dose Greater Than 1 Gy, 2 Gy, or 3 Gy								
Data Source	**Procedure Description**	**Total Cases**	**> 1 Gy**		**> 2 Gy**		**> 3 Gy**	
			n	**%**	**n**	**%**	**n**	**%**
RAD-IR	Neuroembolization-head (all)	356	286	80%	136	48%	60	17%
	Neuroembolization-spine (all)	18	17	94%	16	89%	10	56%
	Stroke therapy	5	3	60%	0	0%	0	0%
	Carotid Stent	17	3	18%	1	6%	0	0%
RAD-IR	All Related Procedures	396	309	78%	153	39%	70	18%
GVI	All Related Procedures	348	45	13%	9	2.6%	2	0.6%

Table 4. Comparison of PSD with RAD-IR study.

Comparison to Advisory Data Sets

The Society of Interventional Radiology Radiation Dose in Interventional Radiology Study (RAD-IR Study) represents one of the most comprehensive snap shots of "state-of-practice" radiation dose levels for interventional radiology and neuroradiology procedures. The RAD-IR Study collected data on more than 2,000 procedures from seven institutions over a three-year period, including nearly 400 neuroembolization, stroke and carotid stent cases.[12]

Comparing all related procedures from the RAD-IR study to the procedures performed in this study, there is a dramatic decrease in instances exceeding 3 Gy from nearly one in five procedures to one in 174 procedures (Table 4). While the procedure mix may not be exactly equivalent and there are many confounding variables to consider, including differences in clinical practice and other clinical variables, this provides an indication that exceeding even the lowest of deterministic thresholds can be a rare occurrence.

CONCLUSION

Dose management continues to be an important focus, assuring that fluoroscopically guided interventional procedures are providing the maximum benefit under the safest of conditions for both patients and staff. An appropriate understanding of the administration of radiation exposure, in terms of skin dose, during the course of an intervention is a crucial element in effectively managing risks while maximizing benefits. The DTS represents a unique real-time solution that facilitates effective management of PSD and subsequently enables clinicians to achieve further reduction and mitigation of radiation risks. The DTS, in combination with an industry-leading set of dose management and reduction technologies, such as Spot Fluoroscopy, Spot ROI Fluoroscopy, Virtual ROI, Fifth Generation Advanced Image Processing, variable isocenter, C-arm flip and other exclusive technologies, provides clinicians with the necessary tools to succeed in today's healthcare environment and achieve their highest safety standards.

REFERENCES

1. *NCRP, Report 168: Radiation dose management for fluoroscopically-guided interventional procedures, NCRP Report No.168 (2010)*
2. *D.L. Miller et al, Radiation Doses in Interventional Radiology Procedures: The RAD-IR Study Part I – Overall Measures of Dose, J Vasc Interv Radiol, 14:711-727 (2003)*
3. *D. Kwon et al, Reference air kerma and kerma-area product as estimators of peak skin dose for fluoroscopically guided interventions, Med Phys 38(7): 4196-4204 (2011)*
4. *ICRP, Avoidance of radiation injuries from medical interventional procedures, ICRP Publication 85, Ann ICRP 30: 7-67 (2000)*
5. *The Joint Commission, Radiation Overdose as a Reviewable Sentinel Event, Update March 7, 2006*
6. *V.K. Rana et al, Updates in the real-time Dose Tracking System (DTS) to improve the accuracy in calculating the radiation dose to the patients skin during fluoroscopic procedures, Proc of SPIE, 8668:86683Z-1-13 (2013)*
7. *D.R. Bednarek et al, Verification of the performance accuracy of a real-time skin-dose tracking system for interventional fluoroscopic procedures, Proc of SPIE, 7961: 796127-1-8 (2011)*
8. *K. Chugh et al, A computer-graphic display for real-time operator feedback during interventional X-ray procedures, Proc of SPIE, 5367 (2004)*
9. *V.K. Rana et al, Comparison of skin-dose distributions calculated by a real-time dose-tracking system with that measured by gafchromic film for a fluoroscopic c-arm unit, Med Phys 38:3702 (2011)*
10. *S.M. Wilson et al, Real-time colour pictorial radiation monitoring during coronary angiography: effect on patient peak skin and total dose during coronary angiography, EuroIntervention 12(8):e939-e947 (2016)*
11. *E. Ichimoto et al, Efficacy of radiation dose reduction due to real-time monitoring and visualization of peak skin dose during coronary angiography and percutaneous coronary intervention, Catheter Cardiovasc Interv. 1-6 (2017)*
12. *D.L. Miller et al, Radiation Doses in Interventional Radiology Procedures: The RAD-IR Study Part II – Skin Dose, J Vasc Interv Radiol, 14:977-990 (2003)*

Follow us: https://us.medical.canon @CanonMedicalUS +CanonMedicalUS Canon Medical Systems USA, Inc. +CanonMedicalUS

CANON MEDICAL SYSTEMS USA, INC.
https://us.medical.canon

2441 Michelle Drive, Tustin CA 92780 | 800.421.1968

VLWP12857US MCAXR0264EBA

Made For life