By Dr S Balter & Dr J F Granada

In vivo demonstration of Significant Radiation Reduction in Interventional Fluoroscopy Using a Novel Eye - Controlled Movable Region of Interest

While the positive clinical impact of interventional fluoroscopy in the management of many pathologies is undeniable, the increased radiation exposure associated with the procedure and to which both patients and medical staff are exposed is of growing concern.

This article describes a recently developed innovative technology that has the potential to reduce radiation levels associated with fluoroscopic procedures by as much as 75% without compromising either workflow or image quality.

INTRODUCTION

Fluoroscopically Guided Imaging (FGI) procedures should ideally maximize patient benefit via the images provided without exposing either patients or staff to non-justifiable risk [1]. Radiation load as described by the total Kerma Area Product (KAP) delivered during a procedure is one measure of risk. (KAP is closely related to the Dose-Area Product (DAP) and for all practical radiation protection purposes can be considered as being equivalent to DAP).

From the patients' point of view, KAP provides an estimate of the nominal Effective Dose [2]; the intensity of scattered radiation to which medical staff members are exposed is proportional to KAP [3]. However, simply reducing KAP by reducing the dose-rate increases image noise and may thus interfere with the overall diagnostic accuracy and safety of the procedure. Reducing the field size limits anatomical coverage and may blind the operator to the occurrence of clinically important peripheral events.

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For a fixed aperture, it is necessary to move either the patient or the equipment to keep the clinical region of interest (CROI) in the unattenuated beam. Gross movements of the entire imaging system can be reduced by moving the CROI within the larger field.

THE HUMAN EYE/VISUAL SYSTEM

The human visual system enables simultaneous surveillance of a large field while being able to rapidly focus on a smaller and often moving target [4]. For most visual tasks such as reading, eye motion continuously moves the observer's gaze to bring an 'interesting' event into foveal vision. While this is happening, peripheral vision provides continuous surveillance of the rest of the scene.

Applying this principle to fluoroscopy, overall KAP could be reduced without adversely affecting anatomical coverage and peripheral surveillance by providing different local dose-rates in the immediate CROI and the remainder of the field [5]. This is accomplished by reducing X-ray beam intensity outside of the CROI [6-8]. Digital post-processing provides relatively uniform brightness across the image. Figure 1 is a simulation of this process.

A recent publication reported the first, promising results obtained with such an approach, using an innovative gaze-controlled system produced by ControlRad Systems [9]. The system minimizes KAP while both supporting peripheral vision and simultaneously maintaining image quality in the CROI.

The essential element of the new system is a unique

FIGURE 1. Processing Simulation
A) Fully "irradiated." The operator's interest is currently on the shed (Shed ROI), but simultaneously the operator needs to see if the sheep have moved.
B) Figure A with "reduced dose" overall and matched brightness
C) Collimated to shed with "full dose" in Shed ROI
D) Figure C with "reduced dose" and brightness outside of the Shed ROI
E) Shed ROI ("full dose") with brightness equalized "low dose" in the remainder of the image
F) Sheep ROI ("full dose") with brightness equalized "low dose" in the remainder of the image

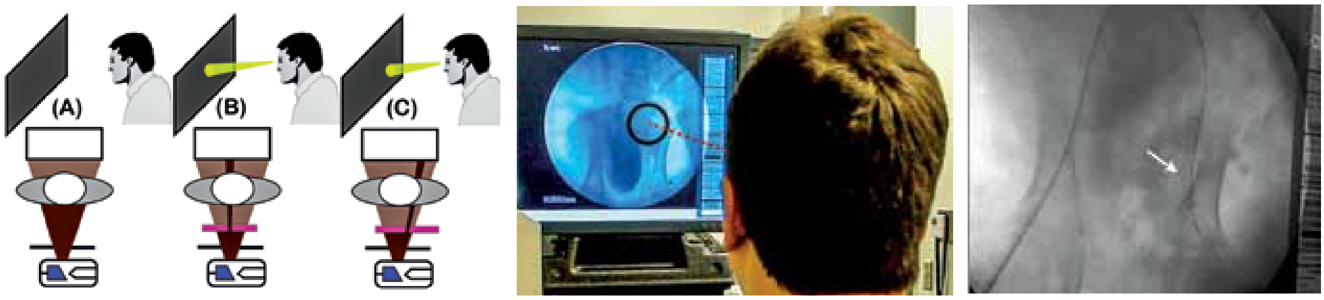

FIGURE 2. The Eye Controlled Region of Interest (ECR) Concept
A) Full field irradiation with the operator's gaze at the center of the image (Full KAP)
B) ECR engaged with full dose rate at center and reduced dose rate outside CROI
C) Operator's gaze and CROI directed toward lower right side of Image Area
D) Operator's view of "C" with brightness compensated image display (Reduced KAP)
E) In this close up photograph (captured by a video camera) of the display, the CROI containing a stent (arrow). The CROI is visible due to a residual brightness difference

real-time dynamic collimator that locates the CROI in response to the operator's gaze by positioning, in real time, the unattenuated portion of the beam. Overall image brightness is then digitally equalized across the field. The positioning of the aperture anywhere in the field by the eye tracker is automatic and consequently does not affect procedure workflow. This technology is known as Eye Controlled Region-of-Interest (ECR); its operation is depicted in Figure 2.

The aperture provides an image quality bonus. Reduced radiation intensity in the volume of the field outside of the CROI cone reduces the level of scatter and therefore the amount of scattered radiation reaching the image receptor. This improves the signal-to-noise ratio in the CROI [Figure 3].

MATERIALS AND METHODS

An animal model was used to measure objectively the radiation reduction during fluoroscopically guided stent placements using the Eye Controlled Region of Interest (ECR) system. Kerma Area Product and Kerma Area Product Rate were used to characterize the animal irradiation. Air Kerma Rate and integrated Air Kerma measurements outside the primary field were used to characterize operator irradiation. A subjective evaluation of the effect of applying ECR as measured by the visibility of guide-wires and stents was obtained by interviewing the operators after they had performed the procedures.

Technology

A conventional C-arm fluoroscope with a 30 cm image intensifier and a unique collimator was added. In this collimator, a circular aperture in an attenuating plate projects an unattenuated field within a portion of the image intensifier's active input area. This zone encompasses the operator's foveal vision and is the CROI. When ECR is engaged, the operator's gaze determines the location of the CROI within the imaged area (IA). When the attenuating plate is removed (i.e. ECR disengaged), the entire IA is uniformly irradiated. The eye tracker is calibrated to the operator prior to each procedure without radiation.

Procedures

Animal experiments were performed at the CRF Skirball Center for Innovation in Orangeburg, NY, USA. The study was approved by the Institutional Animal Care and Use Committee.
The experimental animals were five male swine, of body weight ranging from 46 kg to 51 kg. Three pairs of stent placements were performed in each animal (two pairs of iliac and one pair of renal arteries). Each pair of stent placements involved one placement procedure carried out on

one side of the animal and in which the ECR was engaged and an equivalent procedure on the opposite side with the ECR disengaged. Half of the pairs of procedures were performed with ECR engaged, the other half disengaged. Three Board-certified interventional physicians performed the procedures. The same operator performed each pair of stent placements (ECR engaged/disengaged). The catheters, guide-wires, and stents were all standard equipment.

Dosimetry Measurements

External Air Kerma and Air Kerma Rate were measured using a dosimeter placed at a fixed position near the animal. Dose rates near the operator's head were sampled using a survey meter. A KAP chamber was placed between the collimator and the animal.

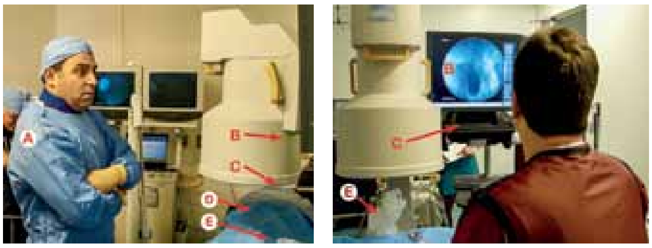

FIGURE 4 Experimental Arrangement
A) Operator gaze controlling position of CROI. In the left photo, the operator has stepped back from the working position.
B) Operator's monitor
C) Eye tracker
D) Animal
E) External dosimeter

RESULTS

Table 1 shows the values of several measured parameters, expressed as the ratio of the value with ECR Engaged compared to corresponding ECR Disengaged values, (so a value of less than 1.0 corresponds to a reduction of that measured parameter when the ECR is engaged). It can be seen that there were no significant differences in fluoroscopy duration. There were borderline differences in procedure time but, importantly a statistically significant reduction in radiation in all measurements. The overall effect was a radiation reduction of 75% relative to baseline, i.e. ECR disengaged.

Parameter	Stent Implant Region			p value
	Left	Renal	Right	
Procedure Time	1.00	1.25	1.00	0.068
Fluoroscopy Time	0.99	0.95	1.12	0.363
KAP Integrated	0.22	0.21	0.24	0.001
Dosimeter Integrated	0.31	0.23	0.31	0.001
Survey Meter Rate	0.29	0.31	0.31	0.002

TABLE 1. Experimental results. All data are expressed as the ratios of the median results obtained with the ECR system engaged to those with the ECR system disengaged. Thus, a value of less than 1.0 means a reduction in the value of the measured parameter with ECR engaged compared to that without ECR.

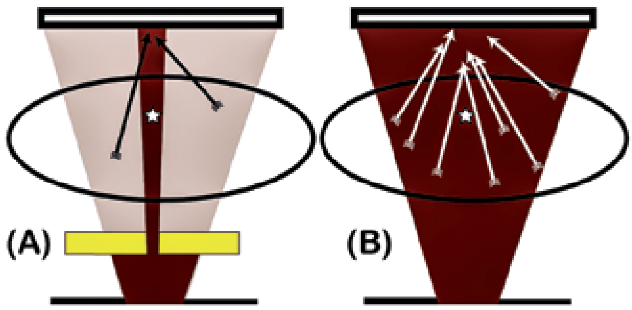

FIGURE 3 Effect of ECR on scatter production
The star represents a clinical object
A) ECR engaged. Less scatter produced outside the CROI, less scatter in the CROI.
B) ECR disengaged. Higher overall irradiation produces more scatter; more scatter is in the CROI.

Although formal evaluation of image quality was beyond the scope of these experiments, subjective opinions were solicited immediately after each experiment. In many instances, the operator stated that stent visibility was improved with ECR engaged. All three operators stated that the fluoroscopic images were acceptable, that stent visibility was improved, that stent placement had approximatelyabout the same difficulty with ECR engaged or disengaged, and that overall the practical experience of carrying out the procedures was equivalent.

CONCLUSION

This first *in vivo* evaluation of ECR demonstrated objectively that the eye-controlled technology can reduce KAP and operator irradiation by 75% without interfering with the performance of fluoroscopically guided interventional procedures. As expected from the literature, reduced scatter subjectively improved device visualization. These findings indicate the potential of the technology and the practicability of minimizing radiation dose in fluoroscopy.

Acknowledgment.

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REFERENCES

1. ICRP, Report 103: The 2007 Recommendations of the International Commission on Radiological Protection. 2007(103).
2. Compagnone G *et al.* Calculation of conversion factors for effective dose for various interventional radiology procedures. Med Phys. 2012; 39(5): 2491-8.
3. Sakamoto H *et al.* [Estimation of operator dose by dose area product meter]. Nihon Hoshasen Gijutsu Gakkai Zasshi 2006; 62(7): 951-60.
4. Wandell BA. Foundations of Vision. 1995, Sunderland, MA: Sinauer Associates Inc.
5. Kezerashvili M, Rudin S and Bednarek D. Automatic filter placement device for region of interest (ROI) fluoroscopy. Health Phys 1997; 72(1): 141-6.
6. Rudin S *et al.* Application of region-of-interest imaging techniques to neurointerventional radiology. Radiology. 1996; 199(3): 870-3.
7. Panse A S *et al.* Dose reduction by moving a region of interest (ROI) beam attenuator to follow a moving object of interest. Proc SPIE Int Soc Opt Eng 2012; 8313: 831355.
8. De Buck S *et al.* Asymmetric collimation can significantly reduce patient radiation dose during pulmonary vein isolation. Europace 2012; 14(3): 437-444.
9. Balter S *et al.* Significant radiation reduction in interventional fluoroscopy using a novel eye controlled movable region of interest. Med Phys. 2016; 43(3): 1531.