

Techniques to estimate radiation dose to skin during fluoroscopically guided procedures^α.

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1. Introduction

Fluoroscopically guided *invasive* procedures are an essential part of medicine. Until the late 1980's, most of these were relatively low dose diagnostic procedures. Patient radiation safety issues focused on the risks of stochastic injury. Deterministic effects were rare and usually attributable to malfunctioning equipment.

The substantial use of fluoroscopy to guide *interventional* procedures began in the eighties with the widespread adoption of balloon angioplasty. By 1990, radiation induced skin injury became a concern (American College of Radiology 1993). Initially, attention was focused on malfunctioning equipment and high dose-rate techniques. By the mid 90's the most likely cause was seen to be long procedures conducted at 'normal' dose rates (Food and Drug Administration 1994 and 1995; Koenig, Mettler, and Wagner 2001; Lichtenstein et al. 1996; Huda 1994). Evidence for chronic skin injury began to emerge by the end of the second millennium (Vañó et al. 2001).

Dosimetric information is helpful at multiple levels. Equipment manufacturers can only build equipment within the limits of the laws of nature and available technology. The standards and regulatory systems place safety and performance baselines to assure at least minimum implementations. Fortunately, most modern interventional equipment exceeds these minimums. The physics acceptance testing and QA processes assure dose-rate limits on clinical equipment. Post-procedure tools provide valuable feedback both into the quality improvement process and in the supervision of individual patients. The latter can be important either if a patient returns for a follow-up procedure or for continuing management if the index procedure was high-dose. Finally, real-time monitoring allows the operating physician to appropriately balance the expected clinical benefits and radiation risks of continuing a procedure.

There can be no regulatory upper limits on the radiation dose delivered during a particular procedure. There are also non-radiation 'dose' considerations in interventional procedures: Iodinated contrast media is toxic. Too much will produce medical complications. A radiation, or pharmacological, injury may be tolerable if a consequence of stopping is death or premature acceptance of failure to improve the patient's condition. Appropriate feedback allows the responsible physician to balance benefits and risks.

The irradiation of any particular portion of skin depends on dose rate, irradiation time, and beam geometry. It is not surprising that more inclusive measuring means, in the sense of providing information about the spatial and temporal distribution of absorbed dose, give better dosimetric estimates than do simpler means.

2. Standards, and Regulations

2.1. International Standards

The International Electrotechnical Commission (IEC) has recently published a safety standard for interventional fluoroscopic equipment (IEC 60601-2-43 2000). Compliance with IEC standards is typically part of the design process for new models of equipment. This document includes items relating to biological, mechanical and thermal safety. It also deals with issues of staff and patient radiation safety. Major elements of this standard related to equipment performance features are currently under consideration for inclusion in the Federal performance standard. (FDA 1998a).

Equipment that complies with the IEC standard includes tools for estimating patient skin-dose. Because the requirements included in this document are implemented by equipment design, an interventional reference point (IRP) is defined by the manufacturer in relation to the mechanical construction of the system. Dose rate and cumulative dose at the interventional reference point are displayed where the operator can see them during the performance of the procedure.

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^Ω The opinions expressed herein are those of the authors and do not necessarily reflect those of the United States Navy, the Department of Defense, the Food and Drug

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2.2. United States Regulations

The proposed amendments to the Federal performance for fluoroscopic x-ray systems would also adopt a requirement that the fluoroscopic system provide a display of the irradiation time, dose rate at the interventional reference point during irradiation, and the cumulative dose for the procedure upon completion of irradiation (FDA 1998a, 1998b). The displayed dose would be the dose at the (IRP), defined as in the IEC standard. Note that the IEC standard only applies to fluoroscopic x-ray systems that are indicated by the manufacturer as being appropriate for use in interventional procedures. The proposed Federal standard amendments would be applicable to all fluoroscopic x-ray systems manufactured after the effective date of the amendments. The proposed amendments also address features of fluoroscopic system performance beyond display of dose information and the draft amendments have proposed, among others, changes to beam quality, x-ray field collimation, provision of additional beam filtration and a requirement that fluoroscopic systems provide a "last-image-hold" feature.

2.3. European Guidelines and Regulations

There was a diversity of national regulations when the European Community was first organized. A 'new directives' policy promotes uniform standards. This process, including the acceptance of IEC standards is called 'harmonization'. Items meeting the essential requirements of a directive receive a 'CE-mark'.

The basic requirement for equipment-based elements of medical radiation protection is found in the Medical Device Directive (European Directive 93/4 1993). Through the harmonization process, interventional equipment is acceptable if it meets the requirements of IEC 60601-2-43 discussed above. The CE mark is issued following an evaluation and test process.

Human exposure to ionizing radiation is based on the EURATOM Directive (European directives 96/29 1976 and 97/43 1997). There is less harmonization in this arena. The rules allow regional deviations for the purpose of increasing safety. Thus, there are different regulations in different European countries. Indeed, there are differences between different German 'States'.

In broad terms, these directives require procedural justification and optimization. There are additional requirements on equipment, training, special practices (including interventional fluoro) and other areas Portions of the document (abridged) follow

'All doses due to medical exposure shall be kept as low as reasonably achievable consistent with obtaining the required diagnostic information, taking into account economic and social factors.'

'The optimization process shall include the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcome as well as the practical aspects, quality assurance including quality control and the assessment and evaluation of patient doses or administered activities.'

'Member States shall promote the establishment and the use of diagnostic reference levels for radiodiagnostic examinations, and the availability of guidance for this purpose having regard to European diagnostic reference levels where available.'

'Diagnostic Reference Levels: dose levels in medical radiodiagnostic practices, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.'

The focus of regional regulations is on stochastic effects. This is why dose area product instruments are often installed. The reference level process is intended to limit stochastic risk by managing equipment performance. Interventional procedures are viewed as too dependent on individual patient situations to be managed by reference levels.

3. Direct Dose Measurement Methods

This section and the next briefly review methods used to assess patient dose during interventional procedures. We adopt the approach taken in the recent review by Geise and O'Dea and categorize the methods as either direct measurement methods, in which the dose is determined by a direct measurement at or very near the skin during the procedure, or as indirect or calculation methods, in which the dose at the skin inferred from dose measurements at other locations or from other equipment parameters (Geise and O'Dea 1999).

3.1. Post-Procedure Dose Results Methods

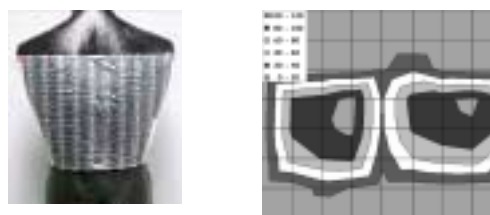
3.1.1. Thermoluminescent Dosimetry

TLDs have several limitations as a method for determining patient dose from fluoroscopy: Information is not provided during the procedure. The variable locations of the x-ray beam make it difficult to place TLDs so that they will appropriately record the doses of interest. This is especially difficult if the maximum dose to the skin is the quantity of interest. We will use the term peak skin dose (PSD) to refer to the highest dose delivered to any individual portion of the skin during a procedure. A point measurement with a TLD chip requires advance knowledge as to the location of PSD on the patient. This information is seldom available.

Techniques for using arrays of TLDs better characterize fluoroscopic dose distributions. The increased numbers of chips complicates logistics. Even when arrays are used, unless the separation between the TLDs is quite small, it is quite likely that the TLDs would not be placed so as to record the PSD. At least one dosemetry service provides arrays of TLDs intended for monitoring the dose distributions resulting from fluoroscopy¹ (figure 1). Such a service might be of interest to a facility wishing to assess initially or periodically the dose distributions typically resulting in their facility without investing in the equipment to do so in-house.

Figure 1: TLD array and an example of the data reported for a radiofrequency cardiac catheter ablation procedure.

Peak skin dose is indicated as 100 to 120 cGy.
Isodose contours are in increments of 20 cGy.
The grid is 4 x 4 cm.
(Figure courtesy of T. Slowey)



3.1.2. X-ray Film Dosimetry

Patient dosimetry for diagnostic and interventional x-ray procedures, using various types of film has been described by a number of investigators (Geise and Ansel 1990; Fajardo et al. 1995a; Fajardo, Geise, and Ritenour 1995b; Vañó, et al. 1997; Geise and O'Dea 1999; Vañó, et al. 2001). Dosimetry using film has the advantages of providing a detailed indication of the location of the skin dose, providing quantitative dose information with careful calibration and densitometry, and being used with any x-ray system.

Certain films have a working range from 0.01 Gy to about 2 Gy. This is sufficient for many procedures, but too sensitive for very complex interventional procedures. Even in these cases, the film can demonstrate the distribution of dose and qualitatively indicate those skin locations where the dose exceeded the upper limit of the useful range of the film sensitivity. These films reveal complex and quite different dose distributions as recorded on the film.

3.1.3. Radiochromic Film

A version of a radiochromic dosimetry film² can be used for quantitative mapping of patient skin dose during fluoroscopy. This is GAFCHROMIC® XR-Type R dosimetry media. This product's lower sensitivity makes it suitable for higher-dose fluoroscopy procedures. Giles and Murphy recently evaluated the characteristics of this material (Giles and Murphy 2002).

3.2. Real-time Direct Dose Measurement Methods

There are several approaches to measuring dose during fluoroscopic procedures using geometrically small radiation detectors that provide immediate dose information via an electronic display. Hence, they can provide real-time feedback about relative dose magnitudes to the physician during the procedure to influence the conduct of the procedure. These systems have the advantages of providing immediate dose information but must be positioned, *a priori*, at exactly the right location on the patient if they are to record the PSD, the quantity of most interest.

3.2.1. MOSFET Radiation Sensors and Scintillation Dosimeters

The evaluation or use of a MOSFET radiation sensor has been described in several reports (Bower and Hintenlang 1997; Peet and Pryor 1999). Bower and Hintenlang evaluated the sensitivity, linearity, angular response, post-exposure response, and physical characteristics. They anticipated that the system could find use in diagnostic radiology as a dosimetry tool if the directional sensitivity and post-exposure drift of response were accounted for.

¹ K& S Associates, Inc., Knoxville, TN

² Manufactured by International Specialty Products, Inc. of Wayne, NJ and distributed by Nuclear Associates, Hicksville NY

Peet and Pryor describe a lower limit on the sensitivity of the system as being 4 mGy for the standard dosimeter and 1.5 mGy for the high sensitivity version of the detector. They did not evaluate the system for fluoroscopic dose monitoring, but did note some concern due to the post-exposure drift of the response. This same drift could also be important for long, continuous exposures as might be encountered in interventional procedures.

Hwang et al. (1998) and Wagner and Pollock (1999) have described the use of a scintillation dosimeter for estimation of patient skin dose in fluoroscopy. This dosimeter uses a small zinc-cadmium scintillator having a 1mm by 0.1 mm active area, which is placed in the radiation field to be measured. The scintillator is bonded to a flexible optical fiber 1.5 m in length, which transmits the light produced in the scintillator to a battery powered detection/display unit.

Hwang, et al. used the skin dose monitor to measure dose to the skin of patients during cardiac catheterization procedures, both diagnostic and interventional cases. During the diagnostic procedures, the sensor was placed on the skin over the apex of the left scapula for the entire procedure. During the interventional procedures, the sensor was placed in the anticipated field of maximum x-ray exposure, referred to as the "working view." The measured doses for both diagnostic and interventional procedures showed great variation but it was concluded that the information allowed the physicians to be more cognizant of the skin dose during the procedures.

The scintillation detector was used in a quite different way by Wagner and Pollock, who placed the sensor at the exit port of the x-ray tube housing assembly directly in the x-ray beam. A calibration process was used to relate the reading from the sensor to the dose in air, as a function of distance from the x-ray source. The measurements they made for a number of procedures illustrated that the cumulative skin dose estimated in this manner did not track well with the fluoroscopic time or number of recorded image frames. They concluded that, with care to technique, skin dose estimates within 20% of the actual dose were attainable with this method, especially if recording was not initiated until the x-ray tube is positioned to irradiate the skin area that is expected to receive the major portion of irradiation during the procedure. They acknowledge, however, the difficulty of knowing the area to receive the most intense irradiation before hand and the uncertainty introduced in determining the actual maximum dose to the skin from the cumulative skin dose measurement. However, they found the real-time dose information useful in managing doses to the patients.

4. Indirect Dose Measurement Methods

By indirect dose measurement methods we mean those methods that provide an estimate of the dose at either the IRP or some defined location based on direct measurements at other locations. Indirect dose measurements can also be obtained from calculations based on equipment operating parameters and geometry combined with appropriate calibration data.

4.1. Measurement of Dose at the Collimator Port

4.1.1. Dose-Area-Product Meters

Dose-Area-Product (DAP) meters are large-area, transmission ionization chambers and associated electronics. In use, the ionization chamber is placed perpendicular to the beam central axis and in a location to completely intercept the entire area of the x-ray beam. The DAP, in combination with information on x-ray field size can be used to determine the average dose produced by the x-ray beam at any distance downstream in the x-ray beam from the location of the ionization chamber. The use of DAP is discussed further in Section 5.2.

A recent modification of the ionization chamber design used in a DAP meter has resulted in an instrument that measures both DAP and the dose delivered by the x-ray beam. This design effectively combines data from a small ionization chamber that is completely irradiated by the beam and independent of the collimator adjustments with the conventional DAP meter.

4.1.2. Beam Port Dosimeter

Measurements of dose obtained with a dosimeter placed in the beam at or on the beam port can provide data on the cumulative dose at a point further from the x-ray source such as the IRP or the patient's skin without a dosimeter having to be placed on or near the patient and without interfering with the procedure. The use of a scintillation detector in this manner was described in Section 3.2.2.

4.2. Patient Dose Derived from System Parameters

An alternate approach to direct measurement of dose is the use of data on the x-ray system technique factors, combined with data on the system and patient geometrical relationships, along with predetermined calibration information to calculate the dose rate and cumulative dose to a reference point.

4.2.1. The PEMNET[®] System

An example of an add-on dose measurement system providing real-time display of dose information, as well as a record of the dose, is the PEMNET[®] System³. This instrument is electrically connected to the fluoroscopy system to obtain information on system technique parameters. These data, combined with geometrical and patient position information, are combined with calibration data via a microprocessor to provide a display and record of dose rate and cumulative dose to the patient's skin. This system, however, does not differentiate the dose to different locations on the skin. The use of the PEMNET[®] system for patient dose monitoring has been described in a number of reports (Gkanatsios et al. 1997; Cusma et al. 1999).

4.2.2. The CareGraph[®] System

A system that uses a mathematical model to combine data from a DAP meter with geometrical information derived from the system parameters and information on patient size and location has been developed that provides a display of dose rate, cumulative dose and a graphical display of the estimated dose distribution on the skin of the patient. A prototype of this system has been described by den Boer, et al. (2001) and used to monitor patient skin dose in cardiac procedures. A version of this system has been marketed as the CareGraph[®] System⁴.

The dose mapping software uses the patient's height, weight, and position on the angiographic table to model the shape and location of the patient's skin surfaces as an array of 0.5 cm x 0.5 cm patches. Since the angiographic system retains information about table position, table height, gantry angle, x-ray output, and beam size and shape, the software can calculate which portions of the skin model are being radiated at any given time. Every 500 ms, the software calculates which of the skin patches are irradiated, and the corresponding dose rate at each patch. The dose received by each skin patch is obtained by integrating the dose rate over time. The results are graphically displayed to the operator in real time.

In this display (figure 5), the simulated patient's skin has been unwrapped and flattened. The patient's back is centered in the display. The approximate doses to the skin are depicted by various shades of color.. Current values for fluoroscopy time, cumulative dose ("Patient Entrance Dose"), DAP, peak skin dose ("max. Hot Spot") and the skin area receiving a dose \geq the 95th percentile of skin dose ("95% area load") are also shown.

5. Real-Time Parameters

5.1. Fluoroscopic Time

Modern fluoroscopes continue to include the five-minute timer. Improved electronics now permits tracking total fluoroscopic time as well as the interval from the last reset. The fluoroscopic timer provides an inadequate skin-dose estimate in the interventional lab for several reasons. The most obvious of these is the total lack of information regarding fluoroscopic dose rate. In addition fluorographic contributions are ignored. Finally, no account is taken of the beam's entrance ports.

Dose from a fluoroscopic procedure might be reconstructed with acceptable accuracy. This is a tedious procedure and was only done to obtain a retrospective dose analysis in rare cases (Suleiman et al. 1991; Stern et al. 1995a). This approach has been applied to estimate the dose to various tissues during cardiac imaging (Stern et al. 1995b).

5.2. Dose-Area-Product

Up to a decade ago, radiological patient safety concerns were focused on stochastic risk. Monitoring and managing stochastic risk requires estimates of the effective dose delivered to the patient. There is no need for real-time feedback.

DAP is defined as the integral of dose across the X-ray beam. Therefore DAP includes field non-uniformity effects such as anode-heel-effect, and the use of semi-transparent beam-equalizing shutters (lung shutter).

DAP is easy to measure. The simplest method is to place a transmission full-field ionization chamber in the beam between the final collimators and the patient. DAP may also be obtained by calculation. Data is accumulated during fluoroscopy, fluorography, and radiography. Assuming that the incident beam is totally confined to the patient, the recorded value essentially provides an upper limit on the X-ray energy absorbed by the patient (i.e. there is no transmission or scatter). DAP's ability to estimate stochastic risk is degraded because of the lack of dose distribution information within the patient. The best that one can do is to assume an average weighting factor for all the tissues at

³ Clinical Microsystems, Inc., of Arlington, VA

⁴ Siemens Medical Systems, Iselin, NJ.

risk. This may lead to an over or under estimate of risk in certain cases. As an example, it does not account for the differential risk of breast cancer from an AP or a PA projection.

DAP rate and cumulative DAP can easily be displayed in real-time. The primary utility of DAP rate is in a teaching situation. Scattered dose rate at any place in the lab is more or less proportional to DAP rate. The trainee can be shown that reducing DAP rate reduces his or her personal exposure rate. The effect of different control options (e.g., collimation, zoom mode) on DAP rate can be demonstrated.

Cumulative DAP does not provide a direct indication of the possibility of skin injury. The same DAP is observed with large fields and low skin doses as with small fields and high skin doses. Exceeding skin tolerance is more likely in the latter case. However, reasonable entrance field size estimates can be made for many procedures. These estimates are dependent on factors such as equipment configuration, patient size, and operator technique. Once known, the nominal field size can be used to obtain an estimate of skin dose. Rules-of-thumb can be established to make this conversion for typical procedures.

DAP provides no information regarding the spatial distribution of the entrance beam around the patient's skin. It produces an overestimate of the possibility of exceeding the deterministic threshold when there is significant beam movement during the procedure.

5.3. Dose at a Reference Point

As discussed previously, dose and dose rate delivered to a reference point can be estimated either by means of an upstream physical measurement or by calculation. It should be noted that in the context of this section, 'dose' usually means air kerma as measured in free air without influence of scatter from nearby objects (phantom or patient). Effects, such as backscatter and the conversion of air to tissue kerma need to be dealt with separately. These effects need to be considered when comparing instrument readings with measurements obtained on the patient using film or TLD. Instrumentation for dose measurements is available either as part of the fluoroscopic equipment or as an add-on accessory.

The definition of the reference point for interventional equipment is somewhat arbitrary. The FDA's definition of a measuring point for the purpose of limiting the maximum entrance air-kerma rate (exposure rate in the current Federal standard) is 30 cm in front of the image receptor at any Source to Image Receptor Distance (SID) for C-arm or isocentric systems. FDA measurements are usually made at minimum SID. The IEC's definition of the IRP is 15 cm from isocenter toward the x-ray tube for any SID. Both of these points are intended to represent the location where the beam enters the patient's skin surface. (figure 3). The points seldom coincide either with each other or with the patient's actual skin surface.

Figure 2 Locations of important points in a fluoroscopic system

- A – Isocenter of the system gantry
- B – Dose reference point
- C – Transmission dose measurement chamber (centered in beam)
- D – Dose-Area-Product measurement chamber (intercepts entire beam)
- E – Beam equalizing shutter (partially radiolucent)
- F – Beam defining collimator
- G- Area with lower dose rate (downstream from equalizing shutter)

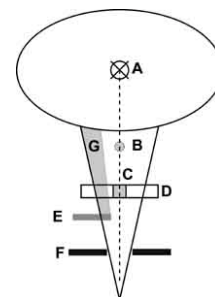
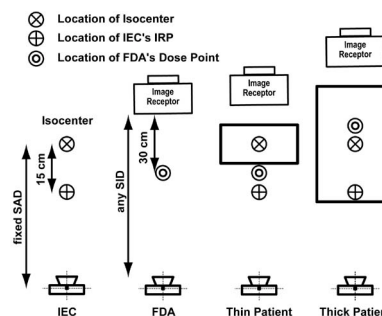


Figure 3 Dose Reference Points.

The IEC reference point is defined relative to the isocenter.
It is independent of SID

The FDA measurement point is defined relative to the image receptor at any SID.
This point moves away from the focal spot as SID increases.

These points are seldom congruent with each other or with the patient's skin. For the system shown in this figure, the IEC dose rate will always be higher than the FDA value. Depending on patient thickness, either number will over or under estimate the patient's actual skin dose.



Dose at a reference point also provides no information regarding the spatial distribution of the entrance beam over the patient's skin. Beam motion or variation in the location of the central beam axis and field size will cause the dose at a reference point to overestimate maximum skin dose.

6. Real-Time Skin-Dose Mapping

The dose delivered during a fluoroscopically-guided procedure differs at different points on the patient's skin due to many reasons (patient pathology, radiation field size and location, specifics of the procedure, etc). Since the risk of skin injury at a specific skin location is related to the radiation dose to that portion of the skin, (Shope 1995; Wagner 1994) the peak skin dose determines the risk of injury. Accurate measurement or estimation of PSD and skin dose distribution is desirable, but technically difficult. As shown previously, real-time dose monitoring procedures have been developed which are capable of continually calculating the delivered patient skin dose. (den Boer et al. 2001) This real-time quantification allows the operator to evaluate the PSD delivered to the skin and more effectively monitor the risk of skin injury.

The match between estimates of PSD and reality are dependent on the behavior of the sensors, congruence of the anatomical model to the patient, and the accuracy of the calculation algorithm. With real-time display of a skin dose map, the interventionalist can monitor the distribution of skin dose during the procedure. In many cases a slight modification to the position of the x-ray beam on the patient's skin, whether by angulation of the gantry, table movement, or collimation can dramatically reduce PSD. Final maps provide documentation of the irradiated skin, for patient management or for planning subsequent procedures. Such information can also contribute to a quality improvement program.

7. Comparison of Real-Time Methods

Some of the present authors (Fletcher et al. 2002) determined four dose metrics: Fluoroscopy time, DAP, Cumulative Dose (at a reference point), and PSD for two angiographic and one interventional radiology procedures (table 1; procedures 1-3). These procedures were chosen because they are usually performed in a relatively standardized way. The study was performed at a teaching hospital and residents were involved in all of the cases. The purpose was to determine PSD using a real-time computer monitoring system, and to evaluate whether commonly used measures of radiation delivery correlate with PSD. The ratio of PSD to the cumulative dose at the reference point (the dose index) for each of the same three procedures was also examined.

The procedures studied differ substantially in how radiation is used, both in terms of spatial distribution of the incident radiation field and in the ratio between fluoroscopy and fluorography. The relationship among fluoroscopy time, DAP, cumulative dose at the reference point and PSD is a function of the type of procedure and may be unique for a specific type of procedure. The nature of the procedure determines the proportion of dose from fluoroscopy versus digital imaging, the spatial distribution of dose and the amount of time the X-ray beam is directed at any particular tissue.

Table 1. Dose data for four procedures

Procedure	1. Carotid Arteriography	2. Chest Port Placement	3. Aortogram and Runoff	4. Cardiac Ablation
Number of Procedures	93, 35 with and 58 without PSD determination	57, 34 with and 23 without PSD determination	62, 36 with and 26 without PSD determination	150
Dose Area Product (Gycm ²)	64 ± 32 (13.6-229.6)	6 ± 6 (0.7-31.5)	104 ± 65 (5-346)	
Cumulative Dose (mGy)	862 ± 411 (170-2510)	89 ± 78 (12-347)	748 ± 585 (10-2609)	
Peak Skin Dose (mGy)	190 ± 78 (2-337)	30 ± 29 (3-149)	204 ± 189 (2-1015)	{film} 1300 (250 - >4000)
Ratio	0.25 ± 0.11	0.41 ± 0.13	0.27 ± 0.14 (0.004 – 0.70)	
Peak to Cumulative	(0.003 – 0.47)	(0.25 – 0.80)		

Data for the first three procedures are presented in the form of mean ± standard deviation (range)

Data for the fourth procedure were determined using film and is presented in the form of mean and (range).

Doses from fluoroscopy and digital film acquisition were not separated.

Derived from Fletcher et al. 2002 {procedures 1-3} and Kwan et al. 2000 {procedure 4}

Since both DAP and cumulative skin dose correlate well with PSD for the first three procedures, it seems reasonable that either of these dose analogues could be used as a basis for a qualitative estimate of patient risk for these procedures. Other studies have shown that calculation of skin dose based on DAP data may or may not be reliable in individual patients. (Vaño et al. 2001, van de Putte et al. 2000; McParland 1998) Analysis of our dose index data shows that there is also marked variability in the relationship between PSD and cumulative dose. For any individual case, PSD cannot be predicted or determined with confidence from cumulative dose data. Since mean cumulative skin dose is more than twice the mean PSD for each of the procedures (table 1), determinations of risk based on cumulative dose may markedly overestimate the risk of radiation injury. Thus, PSD appears to be the only dose analogue that provides a reliable quantitative estimate of patient risk for skin injury.

8. Experience at Another Facility in Investigating Dose Monitoring Methods

Kwan et al. (2000) separately investigated cardiac ablations (procedure 4) in his institution.

The first efforts were devoted to attempts to use small or point detectors on the eyelid, over the gonads, and at the locations anticipated, *a priori*, to receive the largest skin dose from the specific type of procedure. For cardiac procedures, the typical projections or entrance x-ray fields described by Stern et al. (1995b) guided the placement of the dosimeters. Peak skin doses up to a few thousand mGy were anticipated for coronary procedures.

Concern regarding the results obtained was raised when the measurements using the point dosimeters failed to register doses of the magnitudes anticipated. In order to investigate more carefully the dose distribution resulting on the skin of the patient, attention was turned to film dosimetry. It was determined that Kodak X-Omat V and EC films could be calibrated with diagnostic x-ray beams and used to record doses up to a maximum dose of about 500 and 1500 mGy respectively. Extensive use of these films, either singly or in combination in a single package, placed under the patient and referenced to the patient's anatomy established the range of fluoroscopic times and skin doses, along with the median peak skin dose, for a variety of procedures (Table 1).

A significant number of the interventional procedures requiring extended exposure times appeared to deliver PSDs beyond the effective range of the x-ray film used for dosimetry. Therefore, a method that could extend the working range of the film dosimetry to higher skin doses was sought. These led to the development of a form of radiochromic dosimetry film with a working range for diagnostic x-ray energies over the range of 100 to 10,000 mGy.

Figure 4 illustrates typical results for patient entrance dose distributions obtained with combinations of x-ray and radiochromic film. The PSD was estimated from the radiochromic film to be about 4000 mGy near the center of the darkest region. The EC film does not permit easy visualization of the PSD due to over exposure. After digitization for publication, the images were edge enhanced to better demonstrate the various x-ray beam positions during the procedure. The radiochromic film on the left had edge enhancement or "sharpening" applied after digitization for publication that highlights the edges of the x-ray fields for different portions of the procedure. Significant beam movement is evident. The less sensitive radiochromic film better delineates the PSD compared to the x-ray film.

Figure 4 Radiochromic film image (left) and Kodak EC x-ray film image (right) of the dose distribution resulting from a RF cardiac catheter ablation procedure

(obtained simultaneously during the procedure).

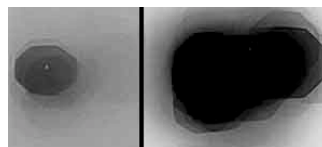
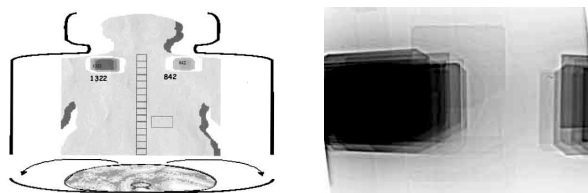


Figure 5 Dose distribution information from CareGraph® system and Kodak EC film for an RF cardiac catheter ablation procedure

50.8 min of fluoroscopy.

(both data sets were obtained simultaneously).



Over the last several years, extensive experience has been gained in using the film dosimetry in combination with either a DAP meter or, more recently, an x-ray system equipped with the CareGraph® system. Figure 5 presents typical results. The film image did not fully capture the beam entrance location on the right side of the patient's back. In addition, the film was positioned at a slight angle with the centerline of the patient and was placed on the film scanner for image digitization at a slight angle, accounting for the non-rectangular shape of the film image. The two primary locations for the x-ray beam are visible in each display. The film display provides detailed information on the dose distribution. The PSD (max. Hot Spot) from the CareGraph® was 1322 mGy, consistent with the maximum film density on the left side of the film.

After digitization for publication, the film image was edge enhanced to better demonstrate the various x-ray beam positions during the procedure. The CareGraph® provides dose distribution information in the sense of identifying and displaying the area of highest skin dose, but does not provide the exact distribution provided by the film. This combination of film and real-time display of information related to skin dose provides the physician with both immediate feedback regarding dose levels during the procedure and a detailed record of the patient dose distribution including the precise location of the PSD after the procedure. This facility, however, has not had occasion to stop or interrupt a procedure based on concern over PSD. The information on dose distribution has increased physician awareness regarding the need to change x-ray beam direction when the dose to one location or the DAP becomes large.

9. Dose Information and Patient Management

Most non-interventional procedures and many interventional procedures do not approach deterministic dose levels. There is little need to monitor individual patients undergoing such procedures. Determining 'typical' doses and assuring appropriate equipment performance achieves adequate radiation monitoring. Radiation risks are accepted when the procedure is ordered and agreed to.

Complex interventional procedures may be at the other end of the radiation dose spectrum for reasons including increased imaging time and, perhaps, the need for higher dose-rate imaging. One can anticipate exceeding deterministic injury levels in some of these procedures. In this arena, dosemetry instrumentation facilitates better patient dose management.

Clinical dosemetry in the fluoroscopic laboratory is a component of good patient management. One can anticipate continued improvements in technologies available for patient dose estimation. Were appropriate, direct and measurements document the radiological footprint of a procedure. As such, they provide useful information regarding the possible occurrence of an acute injury. Given, that many patients require multiple procedures, this documentation also aids in the planning of return visits. The nature of the measuring tool, and its required accuracy are procedure dependent. There is little need to install elaborate instrumentation on fluoroscopes used only for known low-dose procedures. Advanced techniques using more extensive evaluation tools are indicated for higher dose procedures and susceptible patients. As in most things, a reasonable balance is appropriate.

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