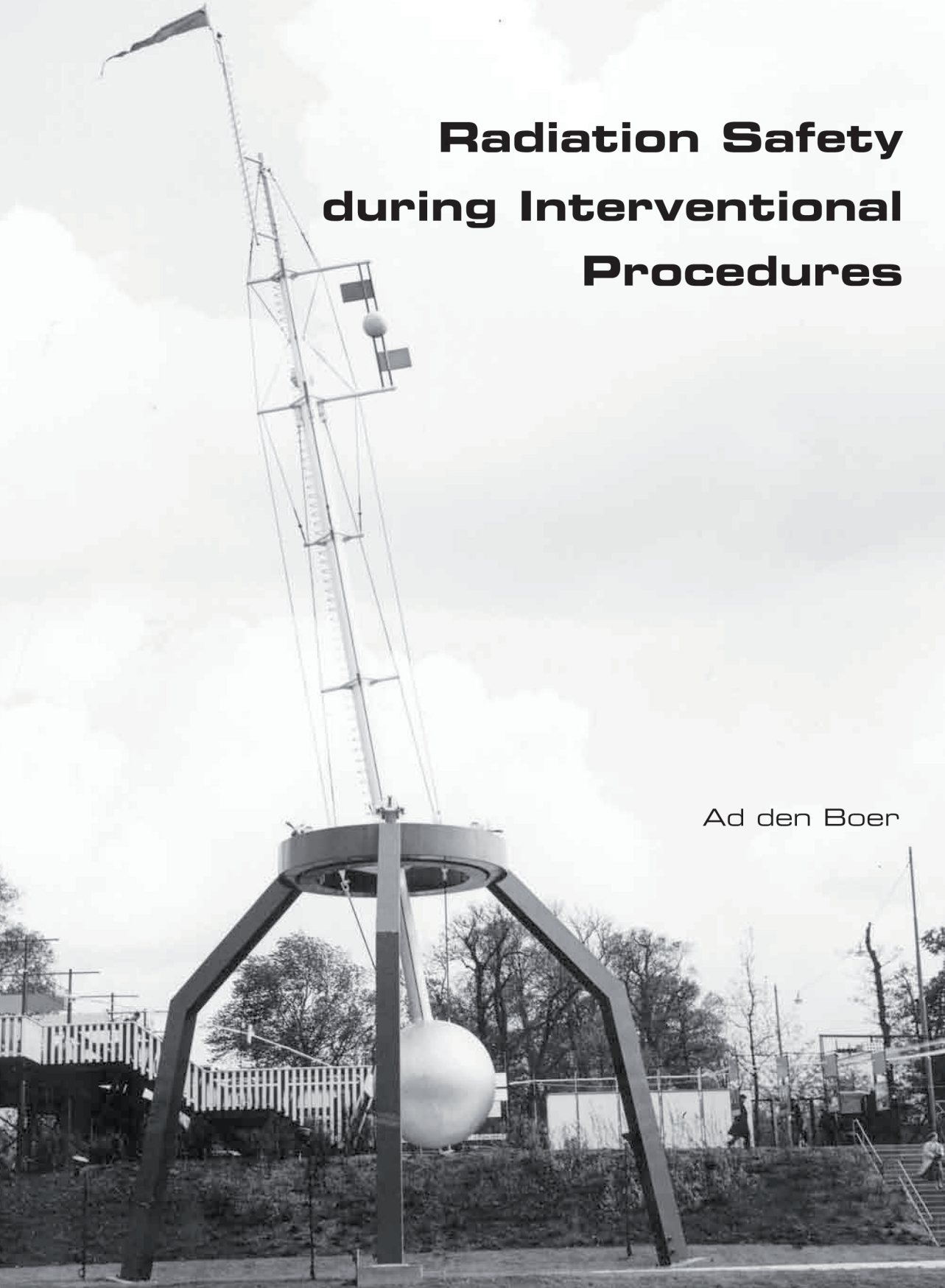
Radiation Safety during Interventional Procedures



Ad den Boer

Radiation Safety during Interventional Procedures

Stralingsveiligheid tijdens interventionele ingrepen

The front cover photograph was taken in 1955 by J.F.H. Roovers © and shows the Aeolus tower.

This moving monument, built by Arie Jansma, symbolizing the rebuilding of Rotterdam, was erected as an eye catcher for the E55 industrial exhibition in 1955.
The inscription on the counterweight ball was “Willen is Kunnen” (if there’s a will, there’s a way).
This monument was demolished in 1967 to make room for the Thoraxcenter building.

De foto op de voorkant is gemaakt in 1955 door J.F.H. Roovers © en toont deAeolus toren.

Dit bewegende monument, gebouwd door Arie Jansma, symboliseerde de herbouw van Rotterdam en werd geplaatst als blikvanger voor de E55 industriële tentoonstelling in 1955.
De inscriptie op de bol als contragewicht was “Willen is Kunnen”.
Dit monument is gesloopt in 1967 om plaats te maken voor het Thoraxcentrum.

The photograph on the back cover was taken in 1955 and shows the location where the Thoraxcenter was built in 1967. It will remain functional until 2020.

The bridge crossing the Westzeedijk was called “The bridge of knowledge” and ended exactly at the current entrance of the Thoraxcenter.
On the picture this bridge leads to the Aeolus tower.

De foto op de achterkant is gemaakt in 1955 en toont de locatie waar het Thoraxcentrum werd gebouwd in 1967. Dit zal tot 2020 functioneel blijven.

De brug over de Westzeedijk, genoemd “De Brug van de Wetenschap” eindigde precies op de plaats waar zich nu de ingang bevindt van het Thoraxcentrum.
Op de foto eindigt deze brug bij de Aeolus toren.

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Radiation Safety during Interventional Procedures

Stralingsveiligheid tijdens interventionele ingrepen

Proefschrift

**ter verkrijging van de graad van doctor aan de
Erasmus Universiteit Rotterdam
op gezag van de
Rector Magnificus**

Prof.dr. S.W.J. Lamberts

**volgens besluit van het College voor Promoties.
De openbare verdediging zal plaatsvinden op**

vrijdag 13 februari 2004 om 16:00 uur

door

Adrianus den Boer

**Geboren te Rotterdam
13 februari 1944**

Promotiecommissie

Promotor:	Prof.dr. J.R.T.C. Roelandt
Overige leden:	Prof.dr. P.J. de Feijter
	Prof.dr. H.A.M. Neumann
	Prof.dr. Th.H. van der Kwast
Copromotor:	Dr. W.J. van der Giessen

Financial support by the Netherlands Heart Foundation for the publication of this thesis is gratefully acknowledged.

Het verschijnen van dit proefschrift werd mede mogelijk gemaakt door steun van de Nederlandse Hartstichting.

This book is dedicated to my wife and children and all those interested in radiation physics and safety.

Dit boek is opgedragen aan mijn vrouw en kinderen en tot allen die stralen fysica en veiligheid spannend vinden.

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Radiation Safety during Interventional Procedures

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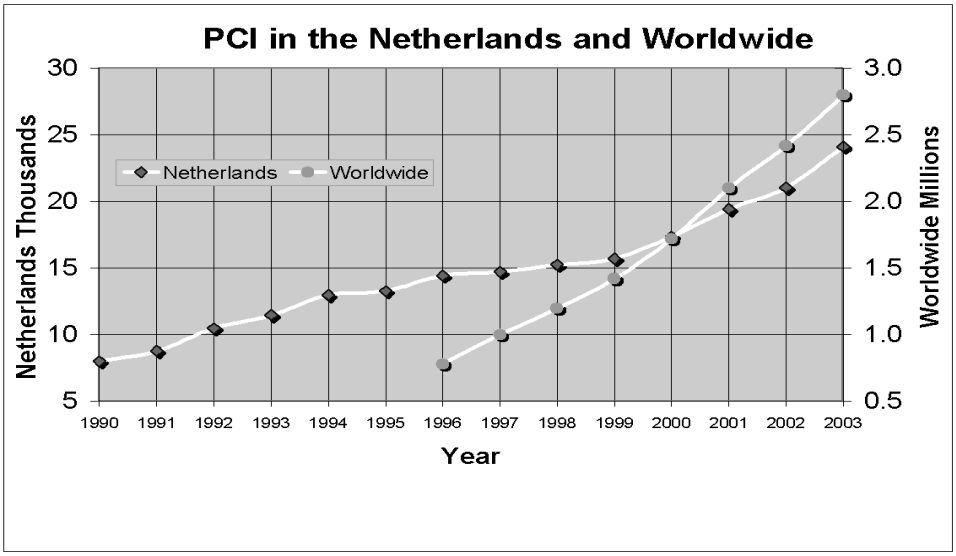
Introduction and Overview

Introduction and overview

Coronary arteriography and x-ray guided catheter-based interventions are increasingly being performed. This growth of percutaneous coronary interventions (PCI's) in the Netherlands from 1990 until 2003 is displayed in the following graph.



The increase in PCI's worldwide; in 1997 one million, growing to 2.8 million in 2003, on a linear scale this leads to a mean increase of 8 % per annum.

During these interventions both, patient and investigators are exposed to radiation.

The patient radiation dose is considered to be high since he/she falls under the direct x-ray beam, whereas the investigator is exposed to scattered radiation, which is considerably less in magnitude. However, the investigator absorbs a cumulative radiation dose from the various cardiac procedures, which he conducts over the years.

X-ray may produce adverse effects and the incidence of radiation induced skin injuries has increasingly been reported during the last 10 years.

In fact, Scott, had reported the first radiation induced skin injury as early as 1897 (1), the previous year Thomas A. Edison wrote a warning article (2), only one year after the invention of x-rays!

Although with modern x-ray equipment one may use lower radiation doses, complicated procedures require longer procedure times and therefore the risk of skin injury increases.

The use of interventional techniques and the treatment of patients with multi vessel diseases, earlier considered to be the sole domain of the surgeon, involve longer treatment times.

It is therefore important to reduce the radiation dose and the exposure time to a minimum. **[Chapter 1]**

Recent developments in x-ray technology have resulted in increased image quality and a reduction in x-ray dose to patient and personnel. **[Chapter 2 and 3]**

By significantly reducing the x–radiation exposure while maintaining good image quality, the introduction of pulsed fluoroscopy became a milestone making lengthy complex interventional procedures possible. **[Chapter 4]**

The latest x-ray units have an integrated ionization chamber which allows monitoring of the dose area product (DAP). However neither the skin entrance dose nor its distribution on the skin is indicated. In order to measure the patient skin burden during a procedure a monitoring system, which quantifies the skin radiation dose, is required. This would alert the investigator to take measures to avoid skin injury as a deterministic effect of radiation exposure.

Therefore we developed an entrance dose skin mapping monitoring system (3) in the Thoraxcenter. **[Chapter 5]**

This system calculates the dose administered to the skin measured in square centimeters. It became clear that the values provided by the DAP meters did not have any relationship to the local skin dose during an interventional procedure.

We subsequently investigated whether injuries could be prevented on the basis of this information by taking appropriate measures during the procedure.

We followed patients who received a radiation dose above 2 Gray on a part of the skin. It appeared that they did not have any deterministic skin effects. This is contrary to the effects described in literature and recent publications on skin defects caused during extensive interventions. Results with the dose mapping system are shown in **Chapter 6**, followed by a discussion on the reasons why deterministic skin effects were not observed by patients treated in the Thoraxcenter Rotterdam.

Does the use of pulsed fluoroscopy and this monitoring result in fewer complications to the skin?

We started, using diagnostical x-ray qualities, to determine which dose is required to see dermal effects on a Yorkshire pig's skin. This porcine model is comparable to Caucasian skin. (4)

The results of dermal sensitivity using continuous fluoroscopy and low frequency, pulsed technology with extra beam filtering are shown in **Chapter 7.**

It appeared that, with the same dose, the skin damage is less if lower pulse frequencies are used. The question is whether the dermis is capable to recover from radiation damage between the pulses, which involves an effective repair mechanism in milliseconds.

Testing this hypothesis on human or animal skin is unethical. However we subsequently tested this on human epidermal keratinocyte cells using continuously and pulsed fluoroscopy with different pulse rates. The results are described in **Chapter 8**.

In **Chapter 9** general radiation safety considerations are presented and issues are discussed which may indicate the direction for the development of a technique which could automatically select the lowest radiation dose for both patient and operator and provide satisfactory image quality.

Satisfactory image quality should however not be perceived or accepted to be the same as the optimal image quality.

Hopefully the manufacturers of x-ray equipment will consider some of the data presented in this thesis, in their development processes in this direction, for the benefit of both, the patient and the operator.

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Chapter 1

How to control dose limits to patients and personnel?

Patient Dose Limitation

Personnel Dose Limits

References

Patient Dose Limitation

More and more percutaneous coronary interventional (PCI) procedures and electrophysiological (EP) investigations will be performed in future. The growth of PCI's is shown in the introduction. Graph 1 in chapter 3 shows the increase of PCI's and EP's, performed in the Thoraxcenter Rotterdam.

With the introduction of newer and safer devices, such as the drug eluting stents, it is possible to treat more complex and multi vessel lesions, and the treatment of obese and/or diabetic patients may become routine.

Consequently, longer procedure times and an increased radiation dose both to the patient and the personnel are to be expected.

This means there is a need for the investigator to know the potential damage to the skin by these prolonged radiation exposures and that there is a need for an entrance dose skin mapping monitoring system. Such a system has been developed in the Thoraxcenter Rotterdam, however the production of these monitoring systems was discontinued as there was not enough demand. (1)

Safety costs money and hospitals, involved in PCI's must invest in protective issues and not only in responsibility claims.

Skin lesions caused by extensive fluoroscopy can be categorized into 3 groups.

1. Due to a too short distance to the focal spot (see photo1)

This is due to not properly trained practitioners and must be considered as malpractice.

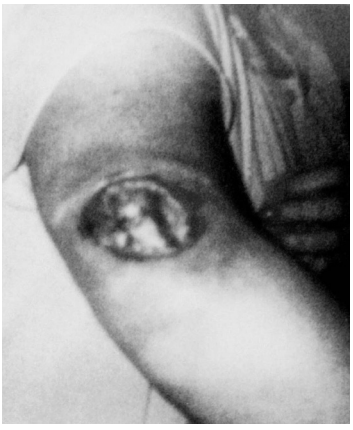

Photo 1.
Elbow positioned against the tube during a lengthy fluoroscopic procedure. (reproduced with permission from 2.)

2. Due to the use of aged equipment

The use of continuous fluoroscopy and aged x-ray tubes with insufficient tube output to create a reasonable image quality and where extra filtering is not an option are causing problems. This is an economical problem. One should not use outdated x-ray equipment for procedures, like PCI and EP.

This problem is partly solved by international radiation regulations enforced since the beginning of the third millennium.

Hospital management must be appealed to their responsibility to invest in safety.

3. Due to using modern equipment with incorrect programming

Using a high pulse rate (50/25 frames per second) and/or not using an extra beam filter causes problems.

Removing the extra beam filter when there is a lack of tube output should be forbidden as well as the possibility to select a high doserate (>140 mGy/min at 75 cm distance from focal spot) technique during fluoroscopy.

This is also an educational problem. In Europe it is partly solved by the obligation of training investigators and operators who are involved in interventional procedures. Photo 2 shows a patient 18 months after ablation, during the procedure, obviously a wrong technique was used.

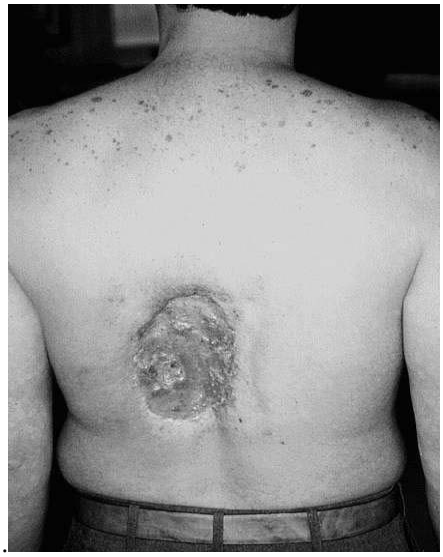

Photo 2.
Using a high doserate and a non extra filtered x-ray technique resulted in a radiation ulcus.
Picture taken 18 months after an ablation procedure, this is not a comfortable way of live.

PubMed archives contain over 250 papers, published in the last decennium, concerning severe skin damage caused by x-ray guided interventions.
In this thesis the author hopes to demonstrate how this can be avoided, even with the longest and/or repeated procedures.
If the precautions to be taken to avoid skin damage are automated, the result can be a system which delivers the lowest possible radiation dose to patient and personnel while maintaining an optimal image quality.

Personnel Dose Limits

Due to the expected increase in the number of interventional procedures and their duration not only the dose received by patients, but also by the investigators will significantly increase, unless extra measures are taken.
In Europe every government has accepted the basic safety standards for radiation for personnel dose limits of EURATOM. Every government has these incorporated into the national laws as of May 2000.
It also implied that the maximal effective dose limits to personnel was lowered from 50 milli Sievert per year to 20 milli Sievert per year (mSv/yr), more specific for the workers; eyes 150 mSv/yr; hands, feet and skin 500 mSv/yr.
For the general public these data are smaller; 1 mSv/yr, more specific for the eyes 15 mSv/yr; hands, feet and skin 50 mSv/yr.
This necessitates the need for an adequate theoretical and practical training of personnel and investigators.

In the Thoraxcenter and other institutes (3, 4) the investigator dose per extensive intervention is approximately 0.1 mSv per procedure. An enthusiastic cardiac investigator performing PCI's shall receive more than 20 mSv/yr outside the lead apron, meaning additional measures must be taken to avoid a too high personnel dose, as for the law, this is the effective dose.

Since 2000 there are uniform European regulations.

The history of dose limitation to professionals is interesting; there were reports of injuries as early as 1896. For example, Thomas Edison, Tesla and Grubbe noted eye and skin injuries and the former even cautioned about excessive exposure to x-rays. (5)

Unfortunately, this was too late for Edison's assistant, Clarence Dally, who suffered from severe radio dermatitis resulting in the amputation of his arm and his subsequent death in 1904. (see chapter 6)

By the late 1890's there were numerous reports of radiation skin burns and loss of hair (epilation) in the scientific literature, bearing testimony to the apparent cavalier attitudes and the size of the doses which were being experienced. One of the more absurd actions was that of the well known American physicist Elihu Thomson, who purposely exposed the little finger of his left hand over a period of several days to the direct beam of an x-ray tube.

The inevitable severe damage to his finger made him caution for over exposure,

"or there may be cause for regret when too late". (6)

Ironically, because of the increasing number of reports of radiation injury, some physicians recognized the possible therapeutic value of the rays and the first 'treatment' was reported in 1896, when a woman with advanced carcinoma of the left breast was treated in Chicago.

At about this time there was some pressure in the media. John Dennis, a New York journalist, who could possibly be considered the first radiation 'whistle blower', campaigned for controls on radiologists and radiographers by license issued by the state, and suggested that injury to a patient was a criminal act. (7)

The history of the maximal allowable dose limits for radiological workers is shown in detail in chapter 6 table 3.

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   St Bartholomew's and the Royal London School of Medicine Charterhouse Square London EC1M 6BQ United Kingdom

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Chapter 2

Fluoroscopy during cardiac interventional procedures

An overview of radiological developments in the last decennium

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Fluoroscopy during cardiac interventional procedures

An overview of radiological developments in the last decennium

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Radiation exposure is an important issue for the general public and for those involved in diagnostic and therapeutic procedures. New catheter-based therapeutic procedures require fluoroscopy for road mapping and angiography for the assessment of results. They are associated with increased radiation exposure, not only to the patient but also to medical personnel.

Awareness of the adverse effects of x-ray radiation has been an important stimulus to reduce radiation exposure to "As Low As Reasonably Achievable" (ALARA principle). Therefore continuing efforts are made to minimize the dose to patients and personnel and to maximize the image quality.

This article gives an overview of the latest developments in radiological fluoroscopy. Fluoroscopy which was initially used for patient and catheter positioning has become more important than (cine) angiography since the introduction of interventional procedures. In the last decade a dramatic improvement in image quality, a patient entrance dose reduction of >70% and an occupational dose reduction of 50% have been realized and improvements continue to be made.

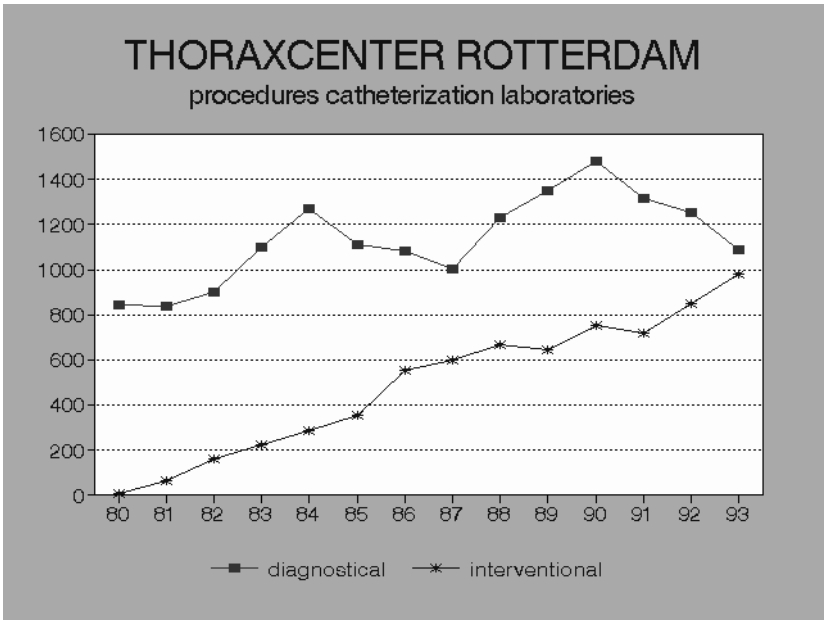


Figure 1. *Diagnostic and interventional procedures performed at the Thoraxcenter Rotterdam between 1980 and 1994.*

INTRODUCTION OF NEW TECHNIQUES

The first Digital Pulsed Fluoroscopy unit (DPF) from Siemens Erlangen was installed at the Thoraxcenter in 1987. The basis of this new technology was to give a series of short radiation pulses with high intensity instead of continuous radiation.

PULSED FLUOROSCOPY

During continuous fluoroscopy the maximal X-ray tube current is 6 milli-Amperes (mA) with a maximal high voltage level of 125 kilo-Volt peak (kVp), resulting in a tube load of 125 kVp x 6 mA = 750 Watt (W). With the pulsed technique the maximal high voltage level is 110 kVp and the tube current is 100 mA. Twelve point five pulses per second are given with a pulse time of 6 milli-seconds (ms), resulting in a mean current of 100x12.5x0.006 = 7.5 mA (figure 8.).

The tube load with pulsed technique is 750 W, which is the same as the continuous technique.

The short "X-ray flashes" eliminate the reduction in sharpness caused by movement of the heart and electronic gap filling ensures that the image on the monitor is visible without flickering.

For this new short pulse technique an X-ray tube with an integrated high voltage switch (grid switch) had to be developed to avoid the influence of the parasitical electrical capacity from the high voltage cables needed to link the generator and the tube. The striking image quality improvement is illustrated by a rotating bar, which simulates a moving object, with test patterns (figures 2 to 4).

Image enhancement by spatial filtering further improves the quality of the image (fig. 5).

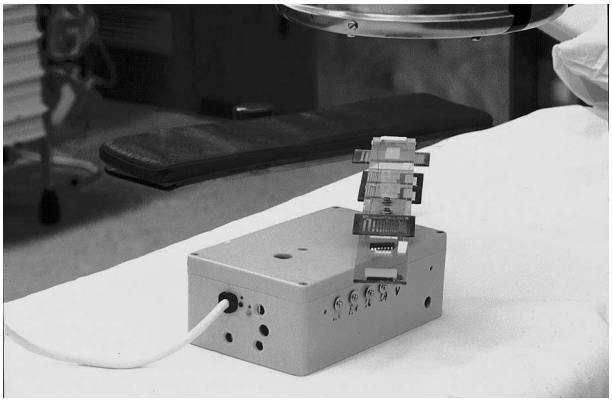


Figure 2.

A rotating bar with test patterns under the image intensifier to simulate a moving object.

Figure 3.

A frozen picture from a moving object during continuous fluoroscopy.

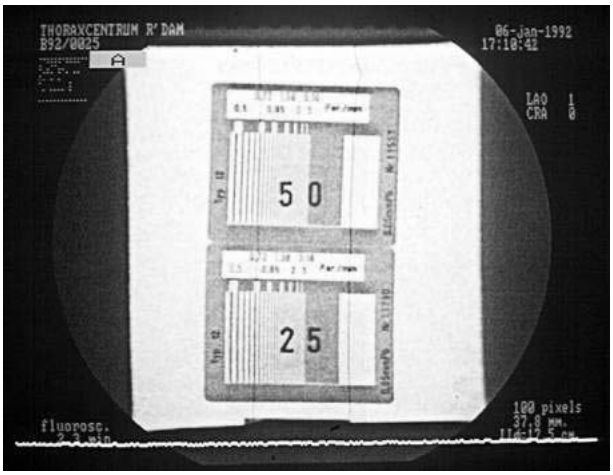


Figure 4.

A frozen picture from a moving object during pulsed fluoroscopy,
the "frozen moment effect".

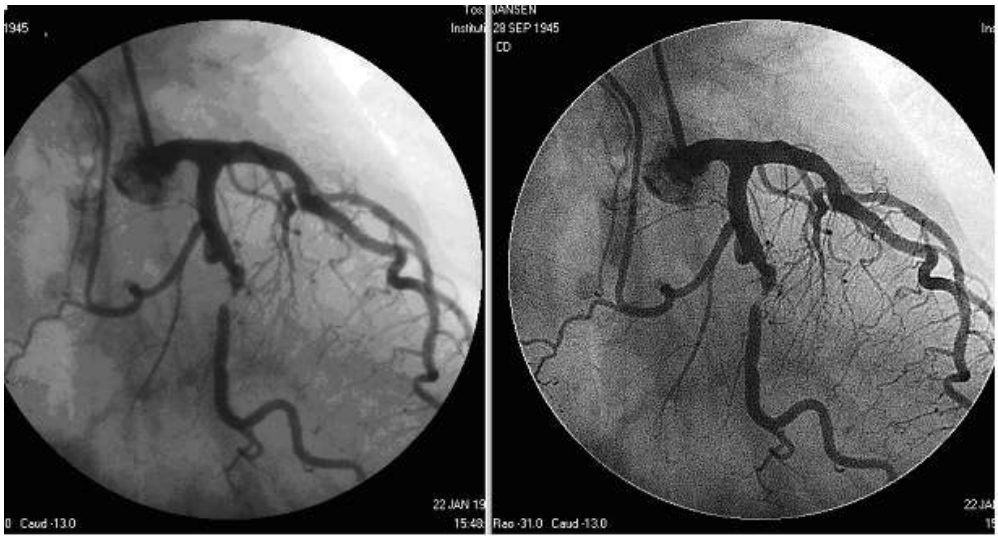


Figure 5. *A frozen picture of a moving object during pulsed fluoroscopy without and with image enhancement.*

RADIATION DOSERATES

During continuous fluoroscopy the X-ray dose for a 17.5/12.5 cm image intensifier entrance field is adjusted to 0.35/0.7 micro Gray per second (µ Gy/s) or 40/80 micro Röntgen per second (µR/s).

During continuous fluoroscopy 25 full video images are created by the video system and are visible on the monitor. Thus for each image an X-ray dose of 0.014/0.028 µ Gy or 1.6/3.2 µR is used.

During Digital Pulsed Fluoroscopy the system creates 12.5 images per second and the video system uses gap filling to insure that 25 full images are visible on the monitor. With 12.5 pulses per second and the same X-ray dose per image a doserate of .17/.35 μ Gy/s (20/40 μ R/s) is needed, resulting in a 50% reduction in radiation compared with "normal" continuous fluoroscopy. Additionally the (scattered) occupational dose is reduced. With introduction of the Digital Pulsed Fluoroscopy technique in the Thoraxcenter, we were able to perform high fidelity biplane fluoroscopy, one of the tools required to evaluate new catheter techniques.

The X-ray report system, developed in the Thoraxcenter, (figure 6) provided us with the ability to enhance this new technique and showed us that, because of nature of the interventional procedures, the fluoroscopic time increased and the number of cinematographic frames decreased, mainly because the lower frame frequency (12.5 images per second) used. Since the introduction of interventional catheterization procedures in the early nineteen eighties, the cine/fluoroscopy X-ray dose ratio changed from 70/30% to 50/50% and the mean fluoroscopic time increased from 6.2 minutes in 1980 to 13.4 minutes in 1993.

Dosimetrical Entrance Dose Report Room 1 THORAXCENTER R'dam

#94-1234 28 May 1994 09:45 12:34:12 procedure time 174 min
Demopat A. van 16-03-'38 mail 56yr 168cm 76kg hospital number: 1.234.5676
Diagnostical procedure Indication: A.P. after infarct
Crew: cardiologist ADB/JR nurse NV technician GJT

Fluoroscopy 10.6 min 45 runs 7950 pulses ~14.1s / 177p
KAP(source) 174.34 Gy*cm^2 ~23.0 cm^2 Dose 7.58 Gy
KAP(image) 24.67 mGy*cm^2 (175 μGy*141cm^2) 0.0247/174=Transmission 0.014%
Area saving through collimation 38%
Applied extra filter 0.2 mm Cu

Documentary 76.1 sec 12 runs 952 images ~6.3 s / 79i
KAP(source) 217.93 Gy*cm^2 ~25.4 cm^2 Dose 8.58 Gy
KAP(image) 17.13 mGy*cm^2 (126 μGy*136cm^2) 0.017/218=Transmission 0.007%
Area saving through collimation 18%
Applied extra filter 0.2 mm Cu

TOTAL ENTRANCE DOSE
KAP(source) 392.27 Gy*cm^2 Dose 16.16 Gy fluo/docu 47/53%
KAP(image) 41.82 mGy*cm^2 0.0418/392 Transmission 0.011%
Highest local entrance dose (95%) 7.24 Gy area 15.5 cm^2
Skinparts received >1 Gy: 23.4 cm^2

Figure 6. *Röntgen summary used in the Thoraxcenter.*

RECENT TECHNOLOGICAL DEVELOPMENTS

High output;

In 1990 Philips, Eindhoven, introduced a new X-ray tube with a spiral-groove bearing and liquid metal lubrication of the anode, the Maximus Rotalix Ceramic (MRC) tube, which was combined with an integrated high voltage switch (grid switch) in 1992. The Thoraxcenter tested the prototype of this tube, together with the research department of Philips. These tests resulted in a new type of fluoroscopy, the High Output Pulsed fluoroscopy with additional beam filtering. Again there was a dramatic improvement in fluoroscopic image quality and both the patient dose as well as the operator dose decreased further. The MRC tube has an enormous cooling capacity of about 3500 W, far greater than the capacity of the "old" tubes. This provided the opportunity of working with a higher radiation output during fluoroscopy. To reduce the patient entrance dose we changed the X-ray spectrum by using extra beam filtering. Earlier application of extra filters had not been used clinically as the extra filtration material absorbed much radiation, leaving insufficient output to provide an adequate fluoroscopic image.

COMPARISON OF FLUOROSCOPIC TECHNIQUES

Methods;

In 1992 we compared three fluoroscopic techniques: continuous fluoroscopy, pulsed fluoroscopy and the newly developed High Output Pulsed fluoroscopy with extra filtering. To assess differences in the quality of images we tested these three techniques during patient investigations. To determine differences in patient entrance dose and investigator radiation exposure we developed a reference fluoroscopic procedure with a "dummy" patient and a "dummy" investigator. These "dummies" or phantoms were developed together with the Department of Radiation Protection at the University of Technology in Eindhoven, who also performed all the dosimetrical measurements, allowing us to record the radiation effects of these new techniques. The X-ray report system gave us the opportunity of collecting and amalgamating the fluoroscopic data of >100 consecutive interventional patient procedures. The data was analyzed for radiographic projections, image intensifier field size and X-ray tube kilo voltage levels.

Based on this analysis a reference procedure was constructed.
This was tested on the phantoms, using all three fluoroscopic modes. The "dummy" patient was designed such that the kilo voltage requirement for each projection was comparable to those needed for the average patient. Radiation exposures to the operator and patient were measured during each mode. The patient entrance dose was measured in air and the operator dose was measured by 18 dosimeters on a dummy operator.

DUMMY OPERATOR

A dummy was placed in the usual investigator position, to the right side of the patient at 75 cm from the mechanical gantry isocenter. Eighteen thermo luminescence dosimeters (TLD) were placed on the dummy to measure the occupational exposure and the dose distribution over the body. The TLD's positions corresponded with the anatomical region of eyes, collar, thorax, groin, femur and tibia.

DUMMY PATIENT or PHANTOM

To measure the radiation dose to personnel during each of the three fluoroscopic modes, a phantom was created to simulate a patient and to produce the scattered radiation. Our X-ray report system provided the opportunity of constructing a phantom in such a way that comparable projections in patients required equal kilovoltage levels during fluoroscopy.
The phantom was made of polymethylmethacrylate (PMMA) also known as plexiglas or perspex and was 22.5 cm high, 40 cm long and 30 cm wide. The phantom was constructed in three segments: a solid abdominal part (22.5x15x30 cm), a thoracic component with mediastinal, cardiac and pulmonary sections and a thoracic cage with different thicknesses. The mediastinal and cardiac sections were composed of solid PMMA (15x25x9.5 cm) while the pulmonary section was simulated by wet sponges. The thoracic cage was made of PMMA plates, the lateral, anterior and posterior parts of which were 1.5, 4.5 and 2.0 cm thick respectively.

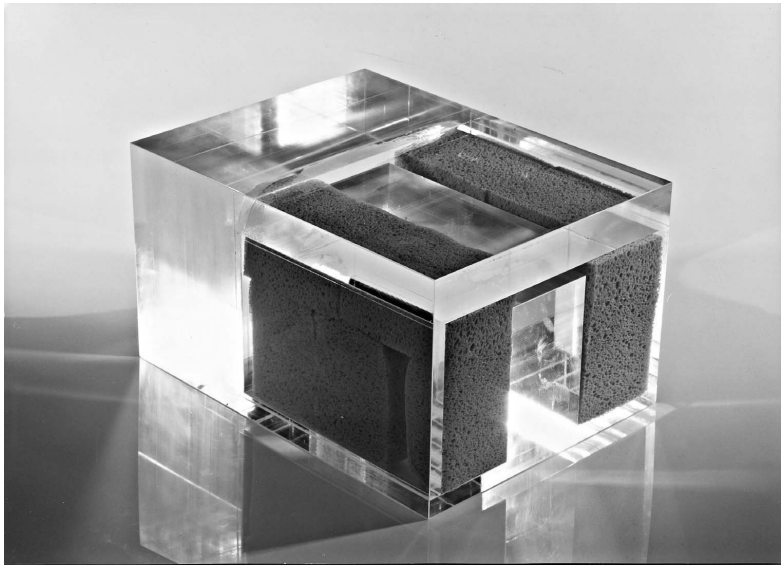
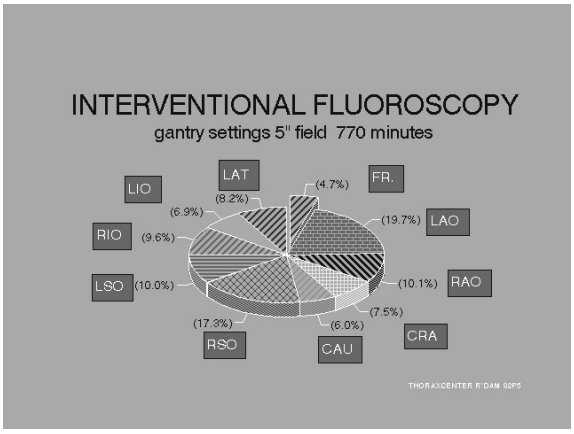


Figure 7. *The dummy patient used for the dose measurements.*

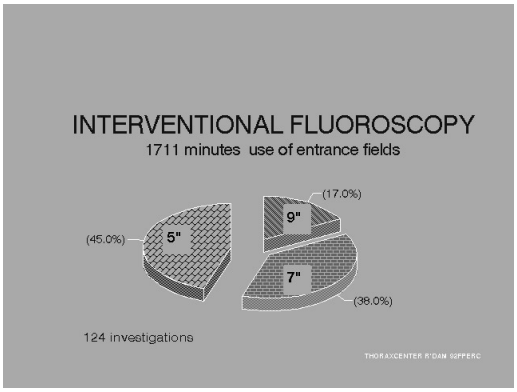
PATIENT PROCEDURE

The fluoroscopic data from 124 consecutive interventional patient procedures performed in one cardiac catheterization laboratory were collected prospectively and amalgamated. The data were analyzed for the geometric gantry settings, image intensifier field size (pie 1-4) and X-ray tube kilovoltage levels. Based on this analysis, a reference procedure was constructed.



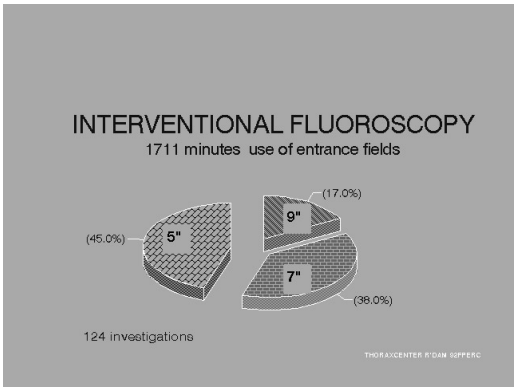
Pie 1.

Shows the fluoroscopic time used at the 5 inch image intensifier field per gantry position.



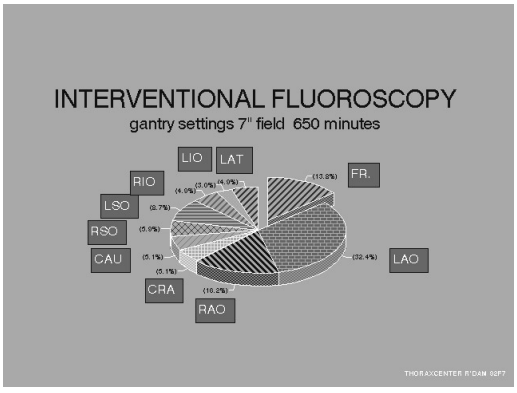
Pie 2.

Shows the fluoroscopic time used at the 9 inch image intensifier field per gantry position.



Pie 3.

Shows the fluoroscopic time used per image intensifier field.



Pie 4.

Shows the fluoroscopic time used at the 7 inch image intensifier field per gantry position.

REFERENCE PROCEDURE

A reference procedure was performed on the dummy patient. The gantry positioning was isocentrically, with the isocenter 14 cm above the tabletop, 10 cm cranial to the abdominal component of the phantom and 4 cm left from the centre (figure 7).

The tube loads for the three fluoroscopic techniques were as follows: 660 W for the conventional continuous and the grid switched pulsed techniques and 1320 W for the newly developed, high output pulsed technique, combined with extra beam filtering.

These studies were performed with the Philips MRC grid switched X-ray tube and an Optimus CP generator. The generator, which delivered the energy to the X-ray tube, had a clearly defined voltage to current (kV/mA) relationship for each fluoroscopic mode, shown in figure 8.

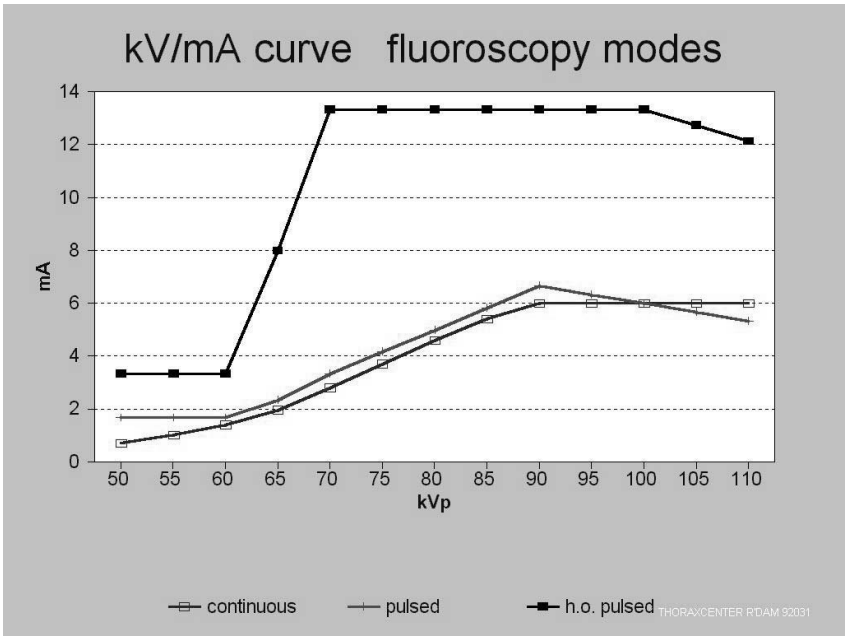


Figure 8. *Voltage to current relationship for the different techniques.*

During pulsed fluoroscopy the maximal tube current was 200 mA, the pulse frequency 8.3 frames per second (50/6 Hz) and the pulse width 4 ms, resulting in a tube current of 6.64 mA per second, (8.3 x 4 ms x 200 mA). During the high output modes the pulse width was doubled and the kV/mA relationship was altered in such a way that at the 70 kVp level, a maximum tube current of 13.6 mA per second (8.3 x 8 ms x 200 mA) was reached.

The x-ray doserate settings at the 7 inch entrance field of the image intensifier were for the continuous mode 0.53 μ Gy/s (60 μ R/s) and for both pulsed modes 0.019 μ Gy (2.1 μ R) per image, which, at 8.3 images per second, is equivalent to 0.157 μ Gy/s (17.5 μ R/s).

EXTRA FILTRATION

During the high output technique various extra filters were tested; of these the extra filter with the combination of 1 mm Aluminium (Al) and 0.4 mm Copper (Cu) is described in this report. The influence of extra filters on the radiation spectrum can be seen in figure 9.

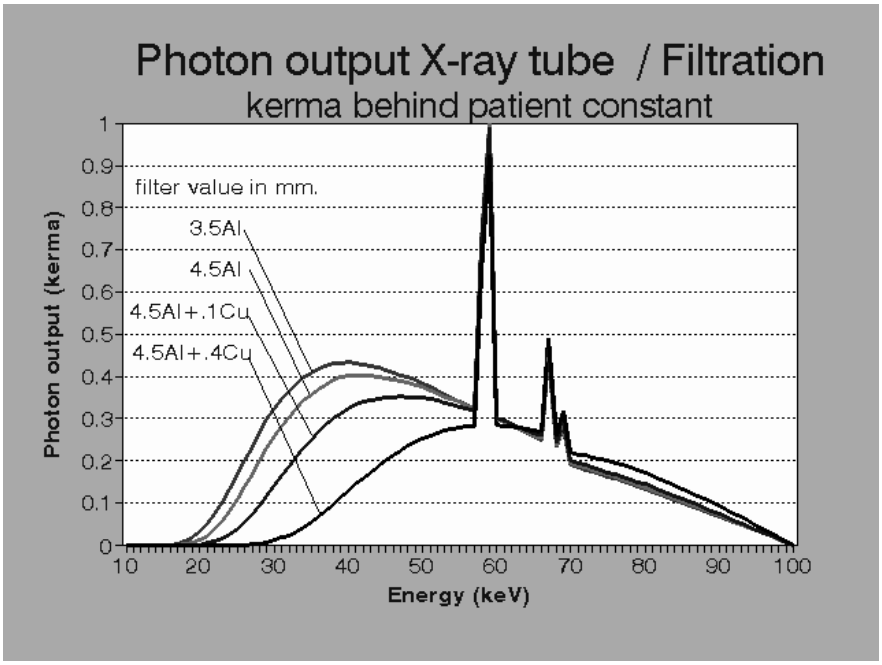


Figure 9. *X-ray spectrum with standard filtration of 3.5 mm Al and with extra filters of 1 mm Al, 1 mm Al+0.1 mm Cu. and 1 mm AL+0.4 mm Cu.*

We can clearly see that the low energy photons are filtered. This part of the spectrum does not contribute to the image forming process and contains the most absorbent radiation.

HIGH VOLTAGE LEVEL

The high voltage level required by an X-ray tube depends on the fluoroscopic technique used, the object size, the selected image intensifier field and the gantry settings.

Pulsed techniques permitted the performance of fluoroscopy with lower kVp and the with the 9 inch field with a focal spot to image intensifier distance (FFD) of 100 cm.

During each fluoroscopic mode, different object sizes were measured to determine the radiation volume curves.

Figure 10 shows the transmission using a 7 inch image intensifier field.

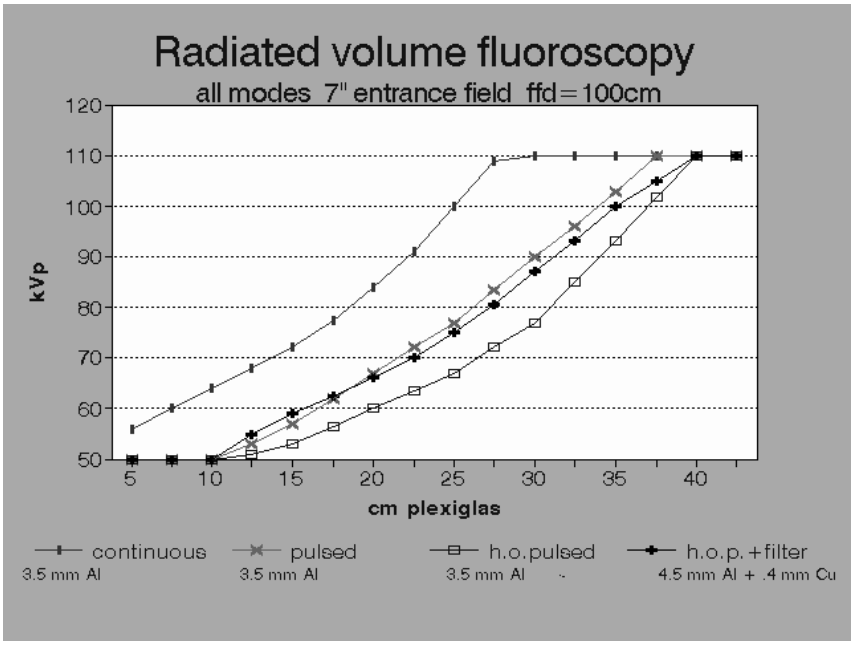


Figure 10. *Radiated volume and the required kVp levels for each fluoroscopic technique.*

ASSESSMENT OF IMAGE QUALITY

Over a 6 month period, the image quality of the 3 fluoroscopic techniques was compared by several senior cardiologists, using a double foot switch. During the first 3 month period, the foot switch provided the cardiologist with continuous or pulsed fluoroscopy. During the second period pulsed or high output pulsed fluoroscopy could be selected.

The functions of the foot switch were randomly alternated to avoid the routine use of either the right or left foot switch. The cardiologist was unaware of which fluoroscopic mode was connected to which switch, and the switch that they thought provided the optimal image quality was selected. The quality of the images during pulsed fluoroscopy was superior to those during continuous fluoroscopy as a result of a higher dose per image, a shorter pulsewidth and image enhancement. The quality of the images during high output pulsed fluoroscopy was better than the quality obtained during the continuous and pulsed technique on every occasion. The high output pulsed technique, combined with extra beam filtering, was routinely used because of its superior image quality during all investigations.

PULSE FREQUENCY

Patient radiation exposure was further reduced during the second evaluation period, when a pulse frequency of 8.3 (50/6) images per second was used instead of the usual pulse frequency of 12.5 (50/4) images per second. It appeared that the reduction of the pulse frequency to 8.3 images per second provided satisfactory fluoroscopic images in almost all the procedures. Only in a few instances during a two year evaluation period (>1000 patient procedures) was the time difference between the images too long, primarily when imaging fast targets such as a guide wire in the distal right coronary artery with a small image field. In these instances resetting to 12.5 images per second was felt to provide better imaging.

PATIENT ENTRANCE DOSE

The maximal doserate measured during continuous fluoroscopy was 110 mGy/min and during pulsed fluoroscopy (8.3 images per second) 87 mGy/min. During high output pulsed fluoroscopy, the application of an extra filter of 1 mm Al plus .4 mm Cu significantly reduced the maximal doserate (170 to 53 mGy/min). The total beam filtration during the high output mode consisted of 4.5 mm Al plus 0.4 mm Cu. Conventional continuous fluoroscopy compared with pulsed fluoroscopy showed a dose reduction in the higher energy ranges. Comparing continuous to the new, high output fluoroscopy with extra filtering reduced the maximal output dose by 54 %. The pulsed technique compared with the high output pulsed technique and extra filtering showed a reduction in the maximal output of 42%. The comparison of continuous with high output pulsed technique on patient obesity (a typical radiated volume of 25 cm.) showed an entrance dose reduction >70%.

Figure 11 shows that the high output mode without extra filtration is able to produce a maximal skin dose of 170 mGy per minute (19.7 R/min), which is unacceptably high for fluoroscopy. In the United States, FDA regulations do not allow a doserate higher than 87 mGy/min. (10 R/min.) at a focal spot distance of 70 cm.

In the rest of the world the maximum permittable dose is 174 mGy/min (20 R/min). There are no limitations to the duration of the investigation time.

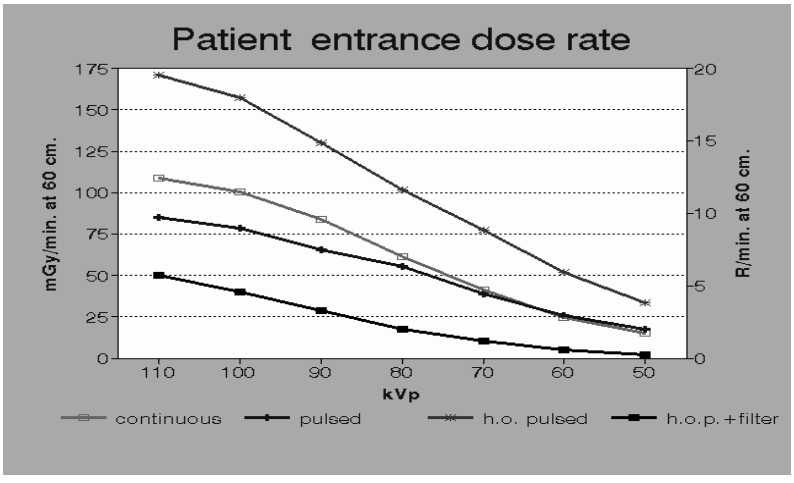


Figure 11. *Patient entrance dose for each investigated fluoroscopic technique.*

PHYSICIAN DOSE

A. Corneal dose

During the reference procedure on the phantom, the scattered radiation dose in air was measured at the eye level of the dummy physician, using a Babyline 61A monitor. The results are shown in figure 12. The pulsed technique, compared with continuous fluoroscopy, reduced the corneal radiation exposure by 46%. When the high output pulsed technique with extra filtration was compared with continuous fluoroscopy, the reduction in corneal radiation exposure was >69%.

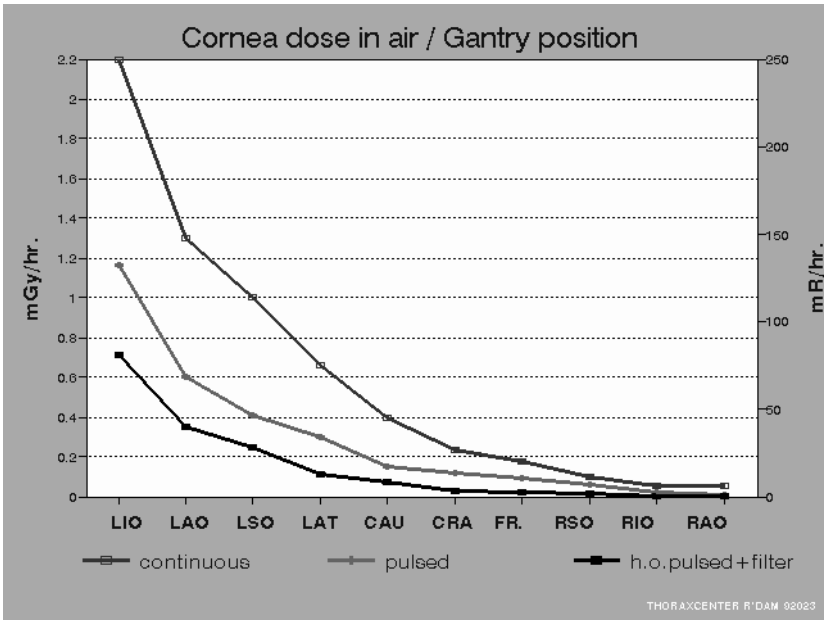


Figure 12. *Corneal dose measured per fluoroscopic technique. LIO indicates left inferior oblique; LAO, left anterior oblique; LSO, left superior oblique; LAT, lateral; CAU, caudal; CRA, cranial; FR., frontal; RSO, right superior oblique; RIO, right inferior oblique; and RAO, right anterior oblique.*

B. Body dose

Eighteen thermoluminescence dosimeters were placed on a dummy investigator to quantify the physician dose and the body distribution.

The results of measurements at six different positions are shown in figure 13.

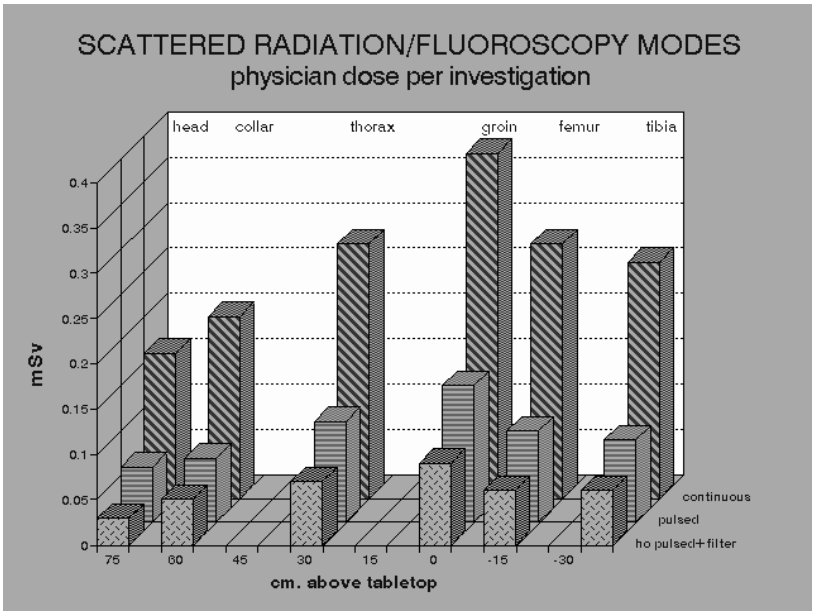


Figure 13. *Physician dose measured for each fluoroscopic technique.*

The body dose shows a significant difference among the three fluoroscopic techniques. Because scattering is energy dependant, the lower tube voltages used during the pulsed techniques were the primary reason for the lower personnel dose. Body exposure rate during pulsed fluoroscopy was 60% less than with continuous fluoroscopy. During the high output technique with extra filtration, the body exposure was reduced by >70% when compared to the continuous mode.

EXTRA SHIELDING OF X-RAY TUBE

Dosimetric measurements have clearly demonstrated that using the new high output pulsed technique, the X-ray tube and collimator must be additionally shielded, so that the X-ray exposure is maximally reduced. The results of our measurements agree with previous publications, which have reported a similar pattern of scattered radiation about the patient, except for the tibia dose which was lower in this study. This was felt to be due to the extra shielding of the X-ray tube and collimator with lead, so the only exposure to the tibia was scattered radiation from the patient. Also, the X-ray tube was covered with extra lead because the proximity of the lower extremities of the operator is close to the tube and because the increased production of leakage radiation in the high output modes.

The maximal allowable leakage radiation is defined by the industry at 87 μ Gy/hr (100 mR/hr) at a distance of one meter. It should be realized that almost every X-ray tube has less leakage radiation at this distance; however during interventional work, the investigator stands with his tibia near the tube and because of the inverse square law the leakage radiation is a factor of 100 higher at a distance of 10 centimeters than at one meter.

RADIATION EXPOSURE ACCORDING TO GANTRY SETTINGS

Of particular interest, our measurements revealed that >75% of the cardiologist radiation dose is received during fluoroscopy in the left projections (figure 14).

This finding has potential consequences for the practice of fluoroscopy during coronary interventional procedures. The use of shields between the patient and the physician would substantially reduce radiation exposure to the head and neck area.

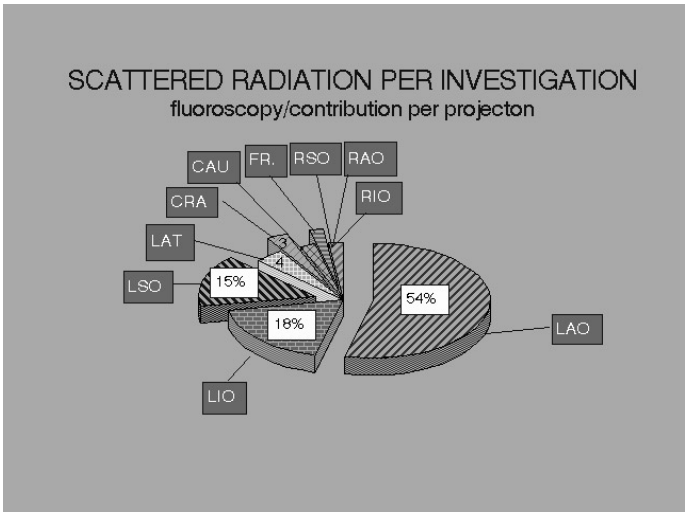


Figure 14. *Scattered radiation per investigation, contribution per projection, more than 75% is created by the left sided projections*

A radiation shield is shown in figure 15.

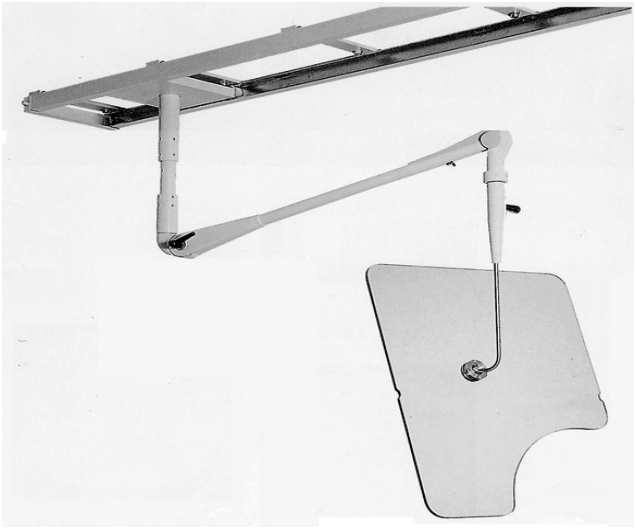


Figure 15. *A shield reduces the scattered radiation dose.*

Results of measurements showed that the use of a 0.5 mm leaded glass screen (or an equivalent) reduced the head and neck area dose by >80% and the abdominal area dose by >50% (figure 16).

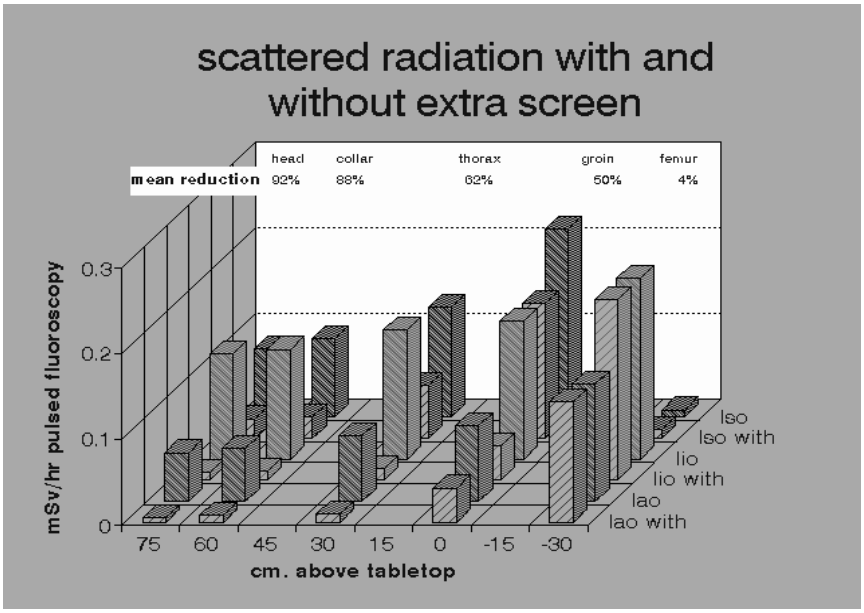


***Figure 16**. The influence of an extra screen between operator and patient.*

CONCLUSION

The combination of high output pulsed fluoroscopy and extra filtering produces superior image quality when compared to current established fluoroscopic modes. Pulsed fluoroscopy allows a lower image intensifier entrance doserate compared with continuous fluoroscopy (because of its lower frame rate). The image quality is superior and the required X-ray tube kilo voltage is lower during both pulsed modes, as well as obtaining improved images in more obese patients. The high output, low pulse rate, extra filtered fluoroscopic technique produces excellent image quality and dramatically reduces both patient entrance and occupational radiation dosages.

FUTURE DEVELOPMENTS

Smaller focal spot sizes will result in sharper fluoroscopic images. With better beam management and reference image mixing techniques even lower patient and operator doses can be expected the next few years.

Digital matrices of 1024 or more pixels and semi conductor video technology will improve the image quality.

High intensity and high resolution monitors and other display techniques will produce images that better match our visual perception. Further dose reduction may be expected with the use of other beam filters and intelligent collimating. The use of non mechanical frame rates (object movement dependent imaging) will further decrease tube load and required radiation per investigation.

Careful attention to and administration of the geometric positioning and X-ray dose parameters should be obligatory for every investigation in order to maintain and enhance image quality and to register the used skin- and absorbed dose. With the modern technologies described in this overview, complications of excessive radiation, such as dermatitis, will belong to the past.

Generator and tube technology is lagging behind. Ten years after the introduction of interventional procedures the majority of hardware is still equipped by cinematographic rather than fluoroscopic programs.

The introduction of digital imaging and display techniques in order to enhance images for our visual perception has just begun. We believe that further improvement of image quality and dose reduction for patient and operator may be expected. We may conclude that many small stepwise improvements have resulted in a leap forward in the science of fluoroscopy during cardiac interventional procedures.

ACKNOWLEDGMENT

The Thoraxcenter in Rotterdam could not have played such an important role in these new technological developments without the technological support of the Siemens organization in the Netherlands, Germany and Sweden, the Philips organization in Eindhoven and Best and the technicians in our department.

We are especially grateful to the radiation safety department of the University of Technology in Eindhoven, for the sharing of their knowledge and for the performing the dose measurements.

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Chapter 3

Coronary imaging in the 21st century

Introduction

Cardiac x-ray quantification celebrates one century

Coronary imaging in the 21st century

- Two dimensional x-ray techniques
- Fluoroscopy
- X-ray tube
- Absorption and scattering
- X-ray spectrum and extra filtering
- Focal spot size and image sharpness
- Image enhancement
- Flat panel technology

References

This chapter is submitted for publishing in Education in Heart 2003, in a briefer format.

Ad den Boer

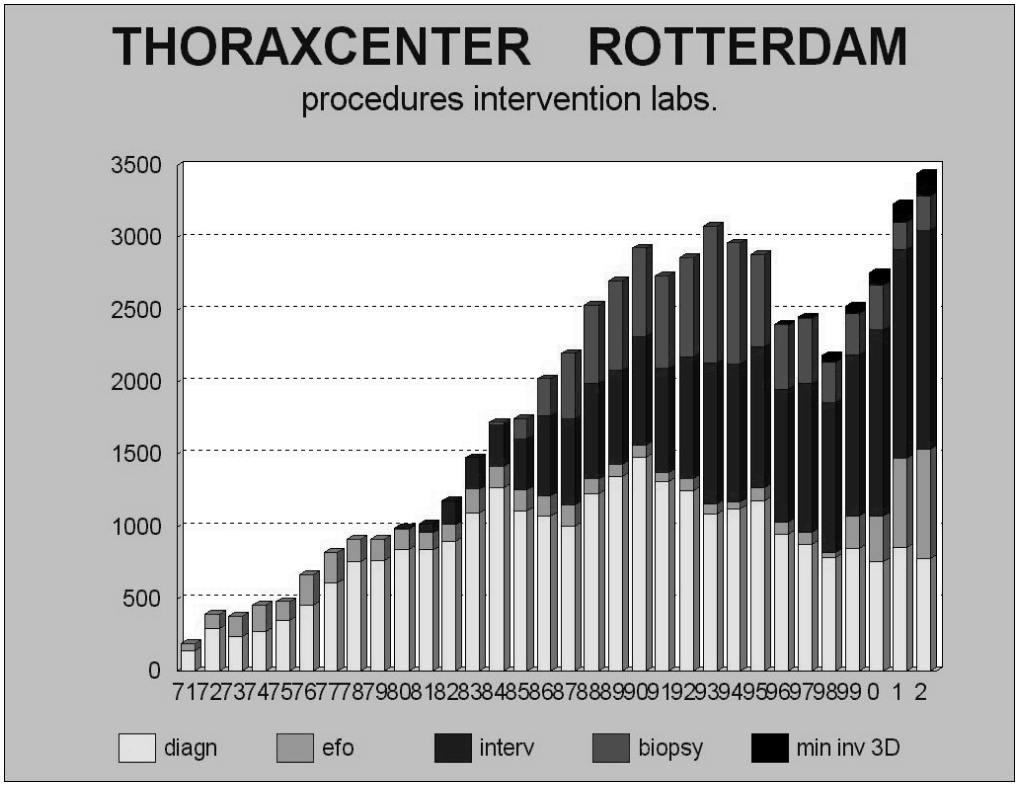
Introduction

The overview in chapter 2 covers up to and including 1994.

The number of procedures, performed in the interventional laboratories of the Thoraxcenter up to 2003 is shown in graph 1.

New in the graph is the introduction of minimal invasive 3 D technology, these are the Magnetic Resonance Imaging (MRI) and the Multi Slice Computer Tomography (MSCT) technologies.

In this chapter, a very short overview is given of the developments in coronary imaging, the 2D technology, up to the year 2003.



Graph 1. *The procedures, performed in the interventional laboratories in the Thoraxcenter.*

In the year 2003, cardiac X-ray quantification celebrates one century.

Orthodiagraphy of the heart in the Albers Schönberg Röntgenkabinet, Hamburg Germany.
Picture made in 1903. Moving with a mechanical parallelogram, a coupled tube and fluoroscopic screen, to find with the central x-ray beam the exact hart contour and mark the result on the chest.
Albers Schönberg produced in 1903 a set of rules for the use of radiologists in protecting themselves; he suggested that the regularly used technique of testing the "hardness" of the x-ray tube by placing the hand between the tube and the fluorescent screen was dangerous.

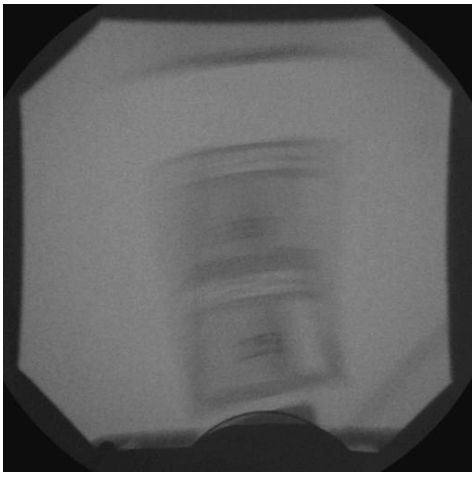
Coronary imaging in the 21st century

Two dimensional x-ray techniques

Last decennium techniques have been developed, provided for major advancements in image quality, making complex interventions possible.

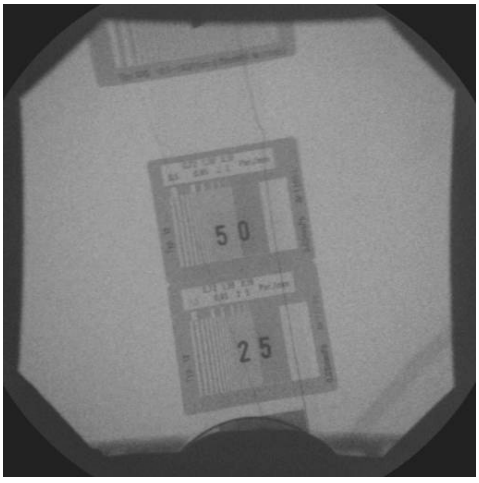
Fluoroscopy

From continuous to pulsed fluoroscopy; the movement is frozen when short pulses are used, as can be seen in picture 1 and 2.



Picture 1.

A fast moving object seen with continuous fluoroscopy.



Picture 2.

The same fast moving object seen with pulsed fluoroscopy, the movement is frozen.

Another advantage of pulsed fluoroscopy is the possibility to lower the x-ray dose to patient and personnel by selecting a low pulse frequency. (1)

X-ray tube

X-ray tubes are developed with forced and external cooling and liquid metal bearings, leading to thermal capacities as high as 3600 Watt/s. These tubes can deliver a high x-ray output; therefore lower x-ray qualities can be used, which means less scattered radiation to the personnel. The high output also makes it possible to use extra beam filtering, resulting in a lower patient dose (2) and the use of smaller focal spots, creating sharper images.

Absorption and scattering

Absorption and scattering are dependent of the radiated material and the used x-ray quality, see figures 1 and 2.

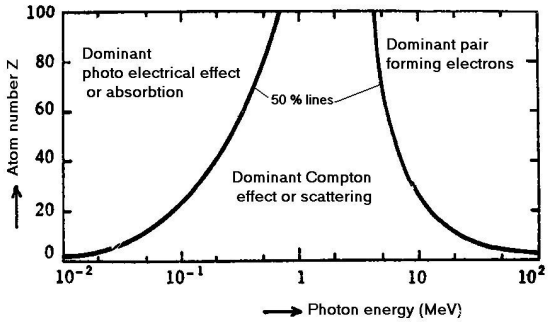


Figure 1.

Absorption and scattering versus photon energy. As shown, 70 keV is for Z=20 (calcium) the 50% line, scattering and absorption are equal.
Calcium is the highest atom weighted material in the human body.

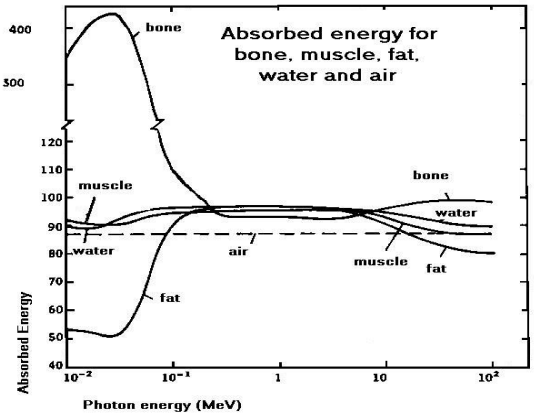


Figure 2.

Differences of photo energy absorption versus human tissue type.
Radio-diagnostics (<100KeV) use the absorption differences for imaging.
In radio-therapy (>0.25 MeV) absorption differences are not desired for a homogenic dosimetry.

While scattering is x-ray quality (kV) dependent, using high output tubes implicates that the personnel dose becomes lower due to the lower used kV values. (1)

X-ray spectrum and extra filtering

High output tubes have the possibility to be fitted with extra filtering. Non image forming elements of the spectrum can be filtered, reducing the entrance dose to the patient. X-ray tubes have an obligatory beam filtering of 2.5 mm Aluminium (Al), and are by law, permitted to produce a maximum doserate during fluoroscopy of 0.1 Gray (Gy) per minute at 75 cm focal spot distance. (0.1 Gy=10 R)

Novel high output tubes allow for the use of extra beam filters, while maintaining sufficient output to perform fluoroscopy on large objects. The entrance doserate, using an extra filter of 2 mm Al and 0.2 mm Cu, may be again reduced by one third (0.03Gy/m), simply by removing the non image forming elements from the spectrum, lowering the patient entrance dose while hardly influencing the image quality.

Figures 3 and 4 shows the object entrance radiation spectrum and the outgoing photons and their quality after radiating a volume of 20 cm water.

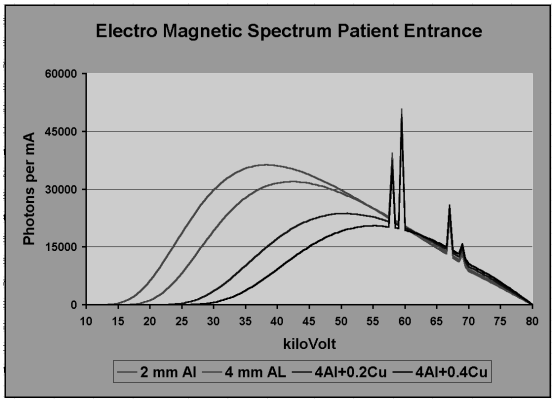


Figure 3.

X-ray spectra, using four different filters, showing the photon energies which are entering the patient.

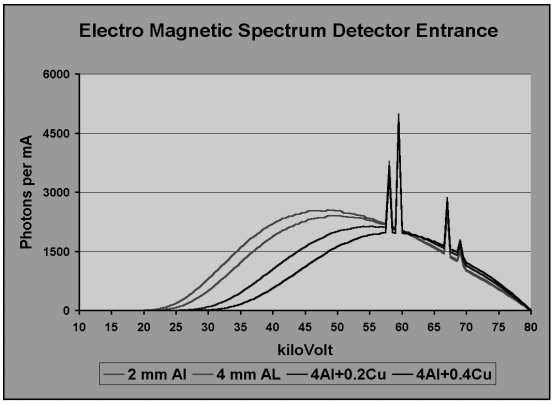


Figure 4.

Image forming photons from the 4 entrance beams in figure 3, entering the detector after irradiating 20 cm water, shows that photons <25 kV do not contribute to form the image, but only contribute to the patient dose. Note that only a few percents of the photons are entering the detector, >95% is absorbed.

Focal spot size and image sharpness

With normal geometrical settings, a focal spot of 0.7 mm gives a penumbra or half shadow of 0.2 mm; this equals one pixel or one video line on the detector, using 512 pixels or 625 lines video systems. The formula to calculate the penumbra is showed in figure 5.
A focal spot of 0.4 mm shows a penumbra of 0.11 mm; this justifies the use of high resolution (1024 pixels or 1250 lines) image systems, showing better image resolution and a better image quality. The (un)sharpness is dependent of the used detector to object distance, the formula to calculate this is shown in figure 5.

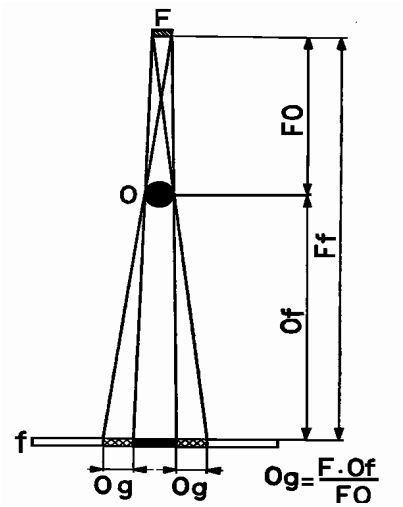


Figure 5.

Formula to calculate the penumbra or half shadow.

f = film or detector
Og = penumbra size at the detector
O = object
F = Focal spot in mm
Of = Object to film distance in mm
FO = Focus to Object distance in mm
Ff = Focus to film distance in mm

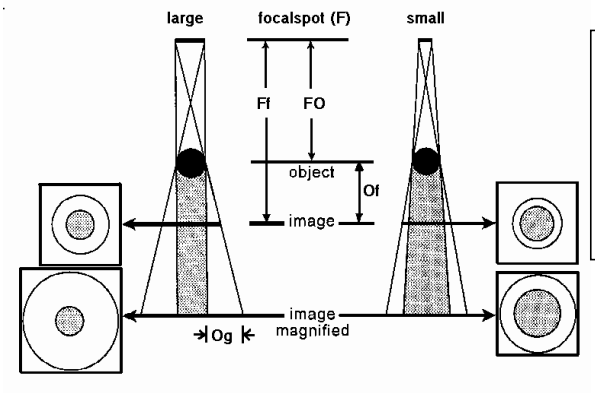


Figure 6.

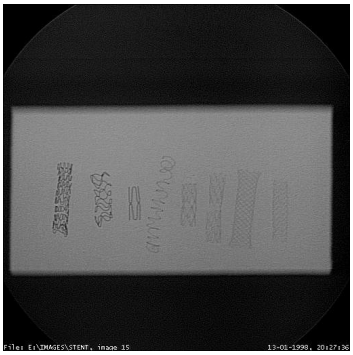
A smaller focal spot size creates sharper images, the closer the detector to the object, the sharper the image due to fewer penumbras.

Image enhancement

Electronical image enhancement, edge enhancement or spatial or high pass filtering, renders that the image is seen more sharply by our retina, see examples in pictures 3 and 4, picture 5 shows an auto windowing technique.

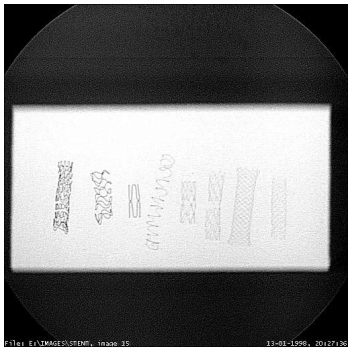
Picture 3.

Stents; the original x-ray picture.



Picture 4.

Stents; digital documented and enhanced with a spatial- or a high pass filter.



Picture 5.

Stents; digitally enhanced and the intensity levels stretched or auto windowed.

Auto windowing techniques adjust the intensity levels at the monitor, the image becomes more optimal for the human perception. This stretching technique provides that the whitest area of the image becomes a 100 percent signal (255 intensity steps with an 8 bits digital signal) and that the darkest area is black (intensity step 1), this digital technique simulates an optimally used darkroom.

Flat panel technology

Recently digital flat panel technology has been introduced. Converting x-ray photons to a digital video signal with vacuum image intensifiers is a process of many steps;

1st from photon to light in the Cesium Iodine intensifier entrance screen,

2nd from light to electrons in the photo cathode,

3rd an electron acceleration to the secondary screen and here,

4th an electron to light conversion,

5th light through glass of a plan parallel optic to the television tube and here the

6th step, light is converted in the photo cathode to electrons which are used to produce the video signal

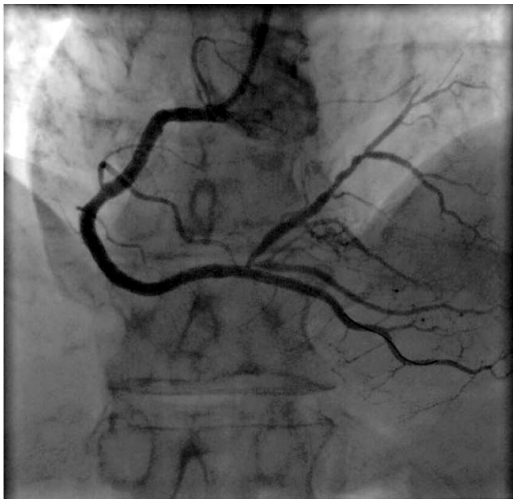
7th, this signal can be digitized the last step.

Flat panel technology is a much more efficient process; from photon to light to electrons which can be digitized directly.

The image quality of the flat panel is improved to a large extent, due to fewer transformation steps. The information depth of these systems (12 or 14 bits, 4098 or 16384 intensity steps) allows partial intensity enhancement and a combination of high and low pass filtering which brings intensity differences (diaphragm and lung tissue) closer together. This is easier for the human eye interpretation, but suboptimal for densitometrical image analysis, see picture 6 and 7.

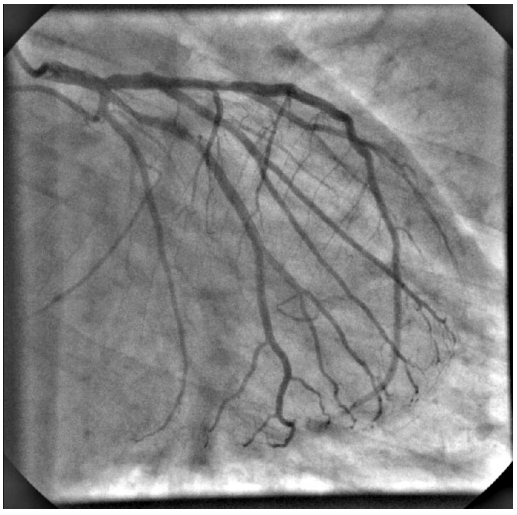
At this moment the sensitivity of flat panel technology is lower than the currently used vacuum intensifier systems, for fluoroscopy this can be compensated by using lower pulse frequencies.

It is expected that in a few years the digital flat technology shall be more sensitive than vacuum intensifiers, if ”low” resolution fluoroscopy is used (1024 pixel matrix). Higher resolution systems, used to replace x-ray plate film, shall demand higher dosages.



Picture 6.

Digital created images, enhancement techniques can bring intensity differences (diaphragm and lung tissue) closer together, which is easier for human eye interpretation.



Picture 7.

Digital enhancement is easier for interpretation, but suboptimal for densitometrical analysis while the radiated volumes can no longer be calculated.

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Reduction of radiation exposure while maintaining high-quality fluoroscopic images During interventional cardiology using novel x-ray tube technology with extra beam filtering.
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Chapter 4

Reduction of Radiation Exposure While Maintaining High-Quality Fluoroscopic Images During Interventional Cardiology Using Novel X-ray Tube Technology With Extra Beam Filtering

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David Keane, MB, MRCPI; J.R.T.C. Roelandt, MD, FESC

Circulation. 1994:89;2710-2714.

Reduction of Radiation Exposure While Maintaining High-Quality Fluoroscopic Images During Interventional Cardiology Using Novel X-ray Tube Technology With Extra Beam Filtering

Ad den Boer, BS; Pim de Feijter, MD; Willy A.Hummel, MS;
David Keane, MB, MRCPI; J.R.T.C. Roelandt, MD, FESC.

Background Radiographic technology plays an integral role in interventional cardiology. The number of interventions continues to increase, and the associated radiation exposure to patients and personnel is of major concern. This study was undertaken to determine whether a newly developed x-ray tube deploying grid-switched pulsed fluoroscopy and extra beam filtering can achieve a reduction in radiation exposure while maintaining fluoroscopy images of high quality.

Methods and Results Three fluoroscopic techniques were compared: continuous fluoroscopy, pulsed fluoroscopy, and a newly development high-output pulsed fluoroscopy with extra filtering. To ascertain differences in the quality of images and to determine differences in patient entrance and investigator radiation exposure, the radiated volume curve was measured to determine the required high voltage levels (kVpeak) for different object sizes for each procedure were combined.

The data were analyzed for radiographic projections, image intensifier field sizes, and x-ray tube kilovoltages levels (kVpeak). On the basis of this analysis, a reference procedure was constructed.

The reference procedure was tested on a phantom or a dummy patient by all three fluoroscopic modes. The phantom was so designed that the kilovoltage requirements for each projection were comparable to those needed for the average patient.

Radiation exposure of the operator and patient was measured during each mode. The patient entrance dose was measured in air, and the operator dose was measured by 18 dosimeters on a dummy operator. Pulsed compared with continuous fluoroscopy could be performed with improved image quality at lower kilovoltages.

The patient entrance dose was reduced by 21% and the operator dose by 54%. High-output pulsed fluoroscopy with extra beam filtering compared with continuous fluoroscopy improved the image quality, lowered the kilovoltage requirements, and reduced the patient entrance dose 55% and the operator dose by 69%.

Conclusions High-output pulsed fluoroscopy with a grid switched tube and extra filtering improves the image quality and significantly reduces both the operator dose and patient dose. **(Circulation. 1994:89:2710-2714.)**

Key Words ● radiation ● fluoroscopy

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Radiation exposure is of major concern to both the public and those involved in diagnostic and therapeutic procedures. Newer catheter-based therapeutic procedures require fluoroscopy for road mapping and angiography for assessment of results and are associated with increase radiation exposure, not only to the patient but also to medical personnel. Since the number of intervention procedures continues to rise and the magnitude of the radiation exposure is increasing, efforts should be made to reduce patient and personnel doses by developing new fluoroscopy techniques.

A trade-off between image quality and radiation exposure is inevitable; ideally, however, new techniques should be developed to provide optimal image quality while reducing radiation exposure to a level ”as low as reasonably achievable”, the ALARA principle. In this study, we investigated the difference between conventional continuous fluoroscopy, grid-switched pulsed fluoroscopy, and a recently developed high-output grid-switched pulsed fluoroscopic technique combined with extra beam filtering to establish which modality provided the best image quality with the lowest radiation exposure to both the patient and the investigator.

Methods

Patient Procedure

The fluoroscopic data of 124 consecutive intervention patient procedures performed in one cardiac catheterization laboratory were analyzed for the geometric gantry settings, image intensifier field size, and x-ray tube kilovoltage levels (kVpeak).

On the basis of this analysis, a reference procedure was constructed.

Assessment of Image Quality

Image qualities of the three fluoroscopic techniques were compared over a 6-month period by five senior cardiologists by the use of a double foot switch. During the first 3 months, the foot switch provides the cardiologist with continuous or pulsed fluoroscopy during the second 3 months; pulsed or high-output pulsed fluoroscopy could be selected. The functions of the foot switch were randomly alternated to avoid the routine use of either the right or left foot switch.

The cardiologists were blinded to the fluoroscopic mode on each switch and were asked to select the switch that they found to provide the optimal image quality.

The cumulative time in each fluoroscopic mode selected by the five cardiologists over the 6-month period was used to evaluate the image quality provide by each fluoroscopic technique.

Phantom

To measure the personnel dose during each of the three fluoroscopic modes, a phantom was created to stimulate a patient and to produce the scattered radiation.

The phantom was constructed in such a way that comparable projections in-patients required equal kilovoltage levels (kVpeak) during fluoroscopy. The phantom was made of polymethylmethacrylate (PMMA), known as Plexiglas or Perspex, and was 22.5 cm high, 40 cm long and 30 cm wide. The phantom was constructed in three segments: a solid abdominal part (22.5x15x30 cm); a thoracic component with mediastinal, cardiac, and pulmonary sections; and a thoracic cage with different thickness. The mediastinal and cardiac sections were composed of solid PMMA (15x25x9.5 cm), and the pulmonary section was simulated by wet sponges. The thoracic cage was made of PMMA plates; the lateral parts were 1.5 cm thick, the anterior plate was 4.5 cm thick, and the posterior plate was 2.0 cm thick.

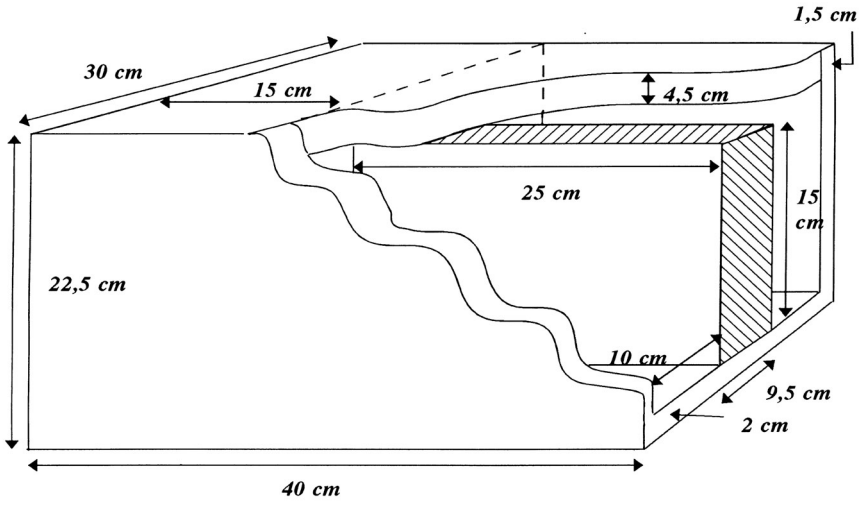

Figure 1. *Diagram showing phantom and dimensions.*

Reference Procedure

A reference procedure was performed at the isocenter of the phantom. The isocenter was positioned 14 cm above the tabletop, 10 cm cranial to the abdominal component of the phantom and 4 cm left from the centre (figure 1).

Three fluoroscopic techniques were compared: (1) conventional continuous technique, with a tube load of 660 W; (2) Grid-switch pulsed technique with an identical tube load; and (3) a newly developed, high-output pulsed technique with a tube load of 1320 W combined with extra beam filtering. All techniques were performed with the Philips MRC grid-switch x-ray tube and an Optimus CP generator. The generator delivering the energy to the x-ray tube has a clearly defined voltage-to-current (kV/mA) relation for each fluoroscopic mode shown in figure 2.

During continuous fluoroscopy, the maximal tube current was 6 mA. During pulsed fluoroscopy, the maximal tube current was 200 mA and the pulse frequency was 8.3 frames per second (50/60Hz); the pulse width was 4 milli seconds (ms), resulting in a tube current per second of 6.64 mA (8.3 x 4 ms x 200 mA), as shown in the pulsed milliampere curve. During the high-output modes, the pulse width was doubled and the kV/mA relation was altered in such a way that at the 70 kVpeak level, a maximum tube current was reached of 13.6 mA per second (8.3 x 8 ms x 200 mA).

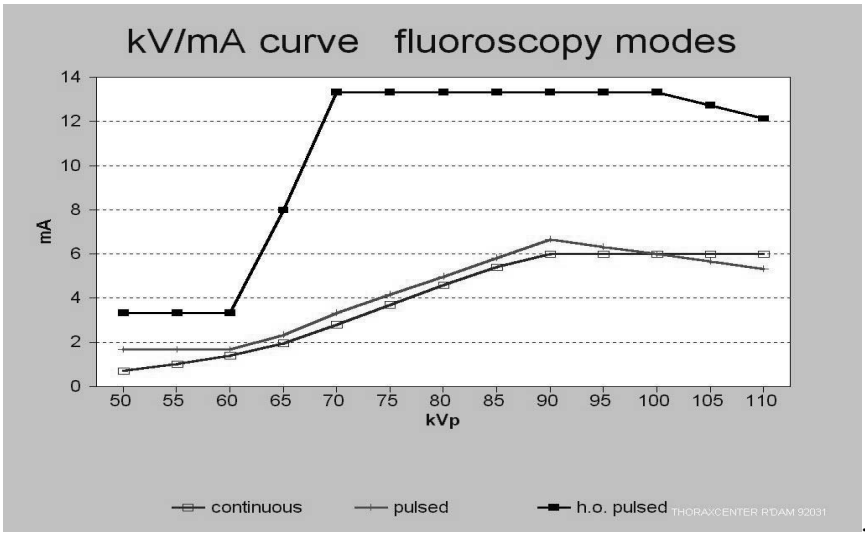

Figure 2. *Graph showing kV/mA curve fluoroscopy modes.*

The x-ray doserate settings at the 7-inch entrance field of the image intensifier were for the continuous mode, 0.53 μGy/s (60 μR/s) and for both pulsed modes, 0.019 μGy (2.1μR) per image, which, at 8.3 images per second, is equivalent to 0.157 μGy/s (17.5 μR/s).
During each fluoroscopic mode, different object sizes were measured to determine the radiation volume curves.

Patient Entrance Assessment

Since the patient's skin normally located 60 cm from the focal spot, the patient entrance doserate was measured in air during the three fluoroscopic techniques with a Radcal dose tempo meter at this distance.

Physician Dose: Corneal

During the reference procedure on the phantom the scattered radiation dose in air was measured at the eye level of the dummy physician by a Babyline 61A monitor.

Physician Dose: Body

Eighteen thermoluminescence dosimeters (TLD's) were placed on a dummy investigator to quantify the physician dose and distribution over the body.
The dummy investigator was positioned at the usual work position of the physician; on the right side of the patient, the nearest part positioned 75 cm from the isocenter.
The TLD's on the dummy investigator were located at six different positions: the eye, collar, thorax, groin, femur, and tibia.

Statistical Analysis

To study differences between the fluoroscopic techniques, Friedman's test were carried out. Significant was stated at the .05 probability level. Wilcoxon's rank sign tests were used when two techniques were compared. Analogous to Bonferroni's correction for repeated t tests, a more precise value of P=.02 was required for significance.

Results

Results of Patient Procedure

Gantry Settings

The total fluoroscopic time was 1711 minutes (average, 13.8 minutes): the 9 inch field was uses for 291 minutes (17%), the 7-inch field, 650 minutes (38%), and the 5-ich field, 770 minutes (45%). The 9-inch field size was selected most frequently for frontal and right anterior oblique projections, whereas the 5-inch mode was selected most frequently for left anterior oblique projection. The amalgamated gantry setting data for all 124 patient procedures are presented in the table.

Gantry Settings Used Per Image Intensifier Field in Percent

Projection	9 Inch	7 Inch	5 Inch
Frontal	45	14	5
Left Anterior Oblique (LAO)	17	32	20
Right Anterior Oblique (RAO)	34	16	10
Cranial		5	7
Caudal		5	6
Right Superior Oblique (RAO with cranial angulation)		6	17
Left Superior Oblique (LAO with cranial angulation)		9	10
Right Inferior Oblique (RAO with caudal angulation)		5	10
Left Inferior Oblique (LAO with caudal angulation)		3	7
Others	4		

Image Quality

The quality of the image during pulsed fluoroscopy was superior to those during continuous fluoroscopy as a result of a higher dose per image, a shorter pulse width, and image enhancement. The quality of images during high-output pulsed technique, combined with extra beam filtering, was used routinely because of its superior image quality.

Results of Reference Procedure

High Voltage Level

The voltage (kVpeak) level required on an x-ray tube is dependent on the technique deployed, the object size, the selected image intensifier field, and the gantry settings. The pulsed techniques permitted the performance of fluoroscopy with lower kilovoltages and the penetration of larger objects (more obese subjects). Even a transmission of 50 cm was possible at the 9-inch field. Figure 3 shows the transmission with a 7-inch image intensifier field. ANOVA shows significant difference between the three techniques. It can be seen from figure 4 that the high-output mode without extra filtration was able to produce a maximal skindose of 170 mGy/min (19.7 R/min), which is unacceptably high for fluoroscopy.

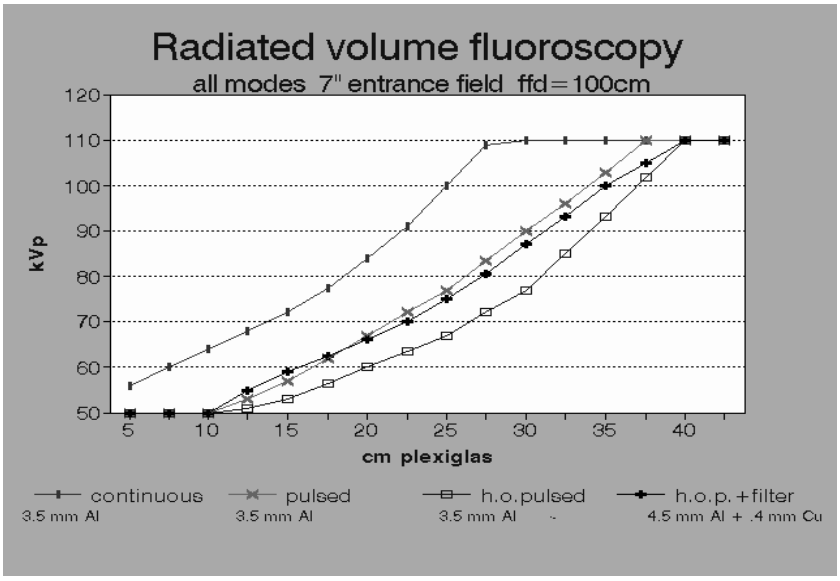

Figure 3. *Graph showing radiation volume fluoroscopy. All modes 7-inch entrance field; far-field depth, 100 cm, h.o.p. indicates high-output pulsed.*

Patient Entrance Dose

The maximal doserate measured during continuous fluoroscopy was 110 mGy/min. The maximal doserate during pulsed fluoroscopy (8.3 images per second) was 87 mGy/min. During the high-output pulsed fluoroscopy, the application of an extra filter of 1.0 mm aluminium plus 0.4 mm copper significantly reduced the doserate (from 170 to 53 mGy/min). The total beam filtration during the high-output mode consisted of 4.5 mm aluminium and 0.4 mm copper. Conventional continuous fluoroscopy compared with pulsed fluoroscopy (P=.016) reduced the dose by 54%.

Pulsed compared with the high-output pulsed technique and extra filtering (P=.016) showed a reduction of 42%.

Physician Dose: Corneal

For each fluoroscopic mode, the scattered radiation doserates were measured at the eye level of the dummy physician, with the described phantom as a patient. The dose measured in air is shown in figure 5. Comparison of the three techniques showed a significant difference. The pulsed technique, compared with continuous fluoroscopy, reduced the corneal radiation exposure by 46%. When the high-output pulsed techniques with extra filtration was compared continuous fluoroscopy, the reduction in corneal radiation exposure was >69%.

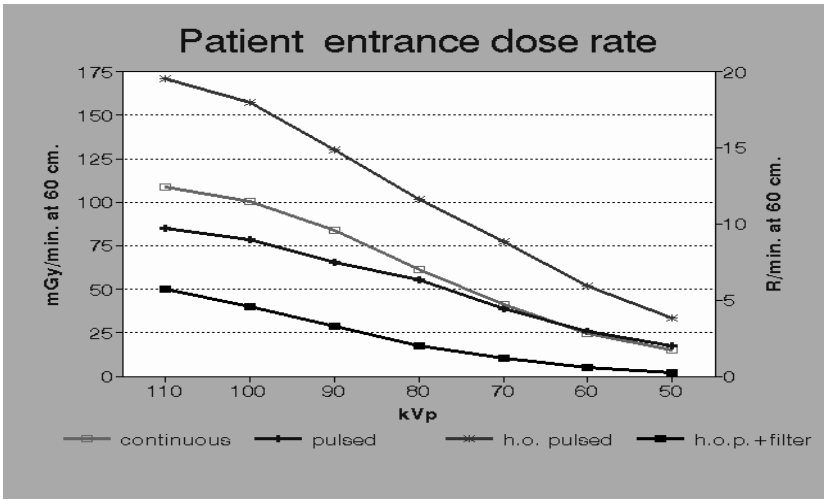

Figure 4. *Graph of patient entrance doserate, h.o.p. indicates high-output pulsed.*

Physician Dose: Body

TLD's on the dummy investigator revealed the same dose pattern for all fluoroscopic modes (figure 6). There is a significant difference between the three techniques. Because scattering is energy dependent, the lower tube voltages used during the pulsed techniques were the primary reason of the lower personnel dose.

The exposure rate to the body during pulsed fluoroscopy was 60% less than with continuous fluoroscopy. During the high-output technique with extra filtration the body exposure was reduced by >70% compared with the continuous mode.

Radiation Exposure According to Gantry Settings

Measuring the scattered radiation as dose per procedure, it was found that >75% of personnel dose is received during fluoroscopy of left projections. Figure 7 illustrates the total scattered radiation dose per investigation and the influence of the gantry position.

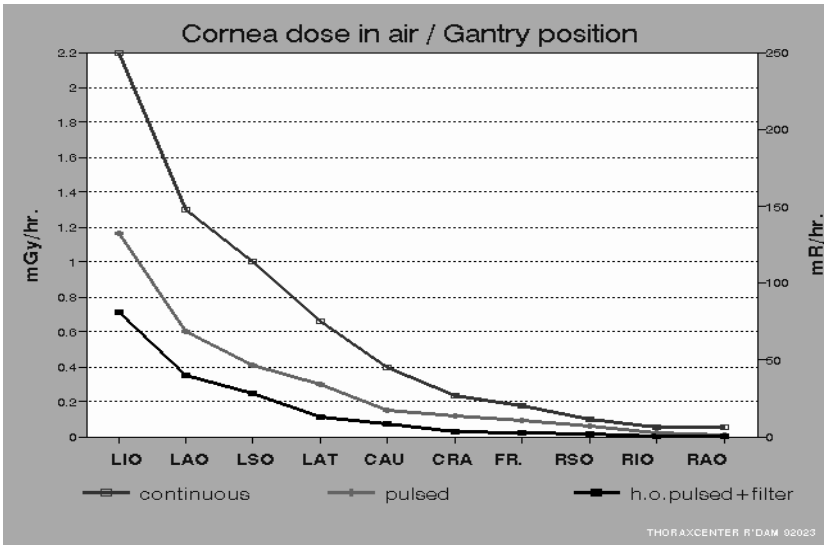

Figure 5 *.Graph showing cornea dose in air per gantry position. LIO indicates left inferior oblique; LAO, left anterior oblique; LSO, left superior oblique; LAT, lateral; CAU, caudal; CRA, cranial; FR., frontal; RSO, right superior oblique and RAO, right anterior oblique.*

Discussion

Awareness of the adverse effects of x-ray radiation exposure has been an important stimulus to reduce radiation exposure as low as reasonably achievable (ALARA).

The pulsed-mode version is a newly developed technique that, primarily because of its lower pulse frequency, is associated with a much lower patient radiation exposure compared with conventional continuous fluoroscopy. The most modern version of fluoroscopy, the high-output pulse mode, cause an even greater decrease in patient and occupational exposure compared with continuous-mode fluoroscopy because of its low pulse frequency and hardening of the x-ray beam by the use of extra filters. Patient radiation exposure was further reduced when a pulse frequency of 8.3 (50/6) images per second was used instead of the usual pulse frequency of 12.5 (50/4) images per second. It appeared in a large majority of the procedures.

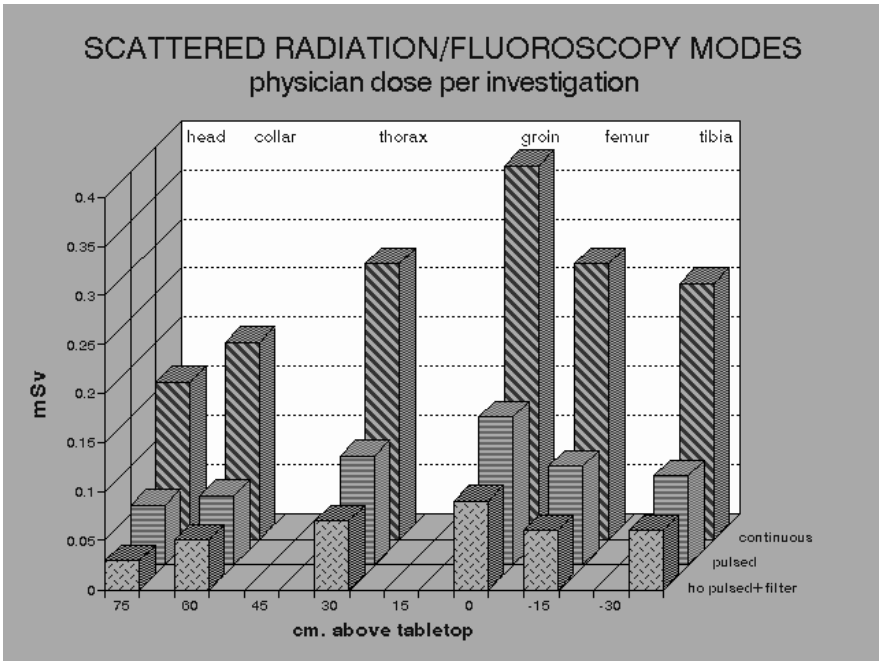

Figure 6. *Bar graph showing scattered radiation/fluoroscopy modes, physician doses per investigation. ho indicates high-output.*

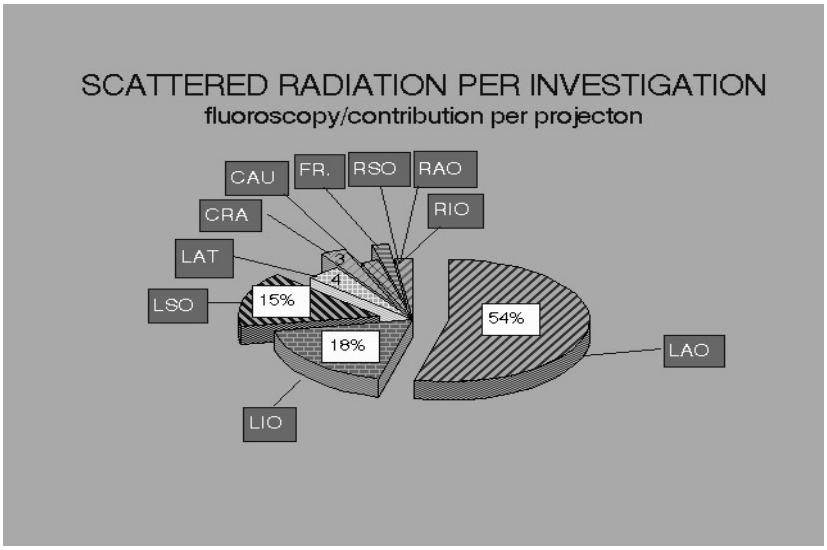

Figure 7. *Circle chart showing scattered radiation per investigation; Fluoroscopy / Contribution per projection. LIO indicates left inferior oblique; LAO, left anterior oblique; LSO, left superior oblique; LAT, lateral; CAU, caudal; CRA, cranial; FR., frontal; RSO, right superior oblique; RIO, right inferior oblique; and RAO, right anterior oblique.*

During an audit of 124 patient procedures, only in a few instances, primarily during imaging of last targets such as a guide wire in the distal right coronary artery with a small image field, was the time difference between the images too long and resetting to 12.5 images per second was required. The phantom that we used to measure the radiation dose during different fluoroscopic modes was a special custom-made construction. The square configuration of the phantom was different from that used in many other studies,[1-7] in which a round phantom was deployed.

Also, we added an abdominal component to the phantom, because the upper abdominal organs have a significant effect on x-ray scattering and therefore must be taken into account. This was not performed in previous studies,[1-3,8-10] in which only anterior oblique projections were used. From previous studies in patients we obtained radiation levels

The phantom was constructed especially so that it accurately stimulated the actual patient radiation levels during similar projections.

In our study, we clearly demonstrated that with the new high-output pulsed technique, the x-ray tube must be additionally shielded so that the x-ray exposure is maximally reduced. Our results are in agreement with previous publications[1-3,11,12] that have reported a similar scattered radiation pattern around the patient with the exception of the tibial dose, which was lower in this study. The lower tibia dose was a result of the extra shielding of the tibia was scattered radiation from the patient. In addition, the x-ray tube was covered with extra lead, because the position of the lower extremities of the operator is close to the tube and the high-output modes produce more radiation leakage. Of particular interest this study revealed that > 75% of the cardiologist radiation dose is received during fluoroscopy in left projections. This point has potential consequences for the practice of fluoroscopy during coronary interventional procedures. The use of shields between the patient and the physician would substantially prevent radiation exposure to the head and neck area. Results of measurement not shown in this study indicated that the use of a 0.5-mm leaded glass screen reduced the head and neck area dose by 80% and the abdominal area dose by 50%.

Conclusions

The combination of high-output pulsed fluoroscopy and extra filtration produces images, superior to those with current established fluoroscopy modes.

Pulsed fluoroscopy allows a lower image intensifier entrance doserate compared with continuous fluoroscopy (because of the lower frame rate).

The image quality is superior and the required kilovoltages (kVpeak) on the X-ray tube are lower during both pulsed modes, and the technique allows the performance of fluoroscopy on more obese patients. The high-output, low-pulse, extra-filtering a fluoroscopic technique procedure excellent image qualities and reduces both patient entrance and occupational radiation dose.

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Chapter 5

Real-Time Quantification and Display of Skin Radiation During Coronary Angiography and Intervention

Ad den Boer, BS; Pim J. de Feijter, MD; Patrick W. Serruys, MD; Jos R.T.C. Roelandt, MD

Circulation. 2001;104:1779-1784.

Real-Time Quantification and Display of Skin Radiation During Coronary Angiography and Intervention

Ad den Boer, BS; Pim J. de Feijter, MD; Patrick W. Serruys, MD; Jos R.T.C. Roelandt, MD

Background—Radiographically guided investigations may be associated with excessive radiation exposure, which may cause skin injuries.

The purpose of this study was to develop and test a system that measures in real time the dose applied to each 1-cm^2 area of skin, taking into account the movement of the X-ray source and changes in the beam characteristics.

The goal of such a system is to help prevent high doses that might cause skin injury.

Methods and Results—The entrance point, beam size, and dose at the skin of the patient were calculated by use of the geometrical settings of gantry, investigation table, and X-ray beam and an ionization chamber. The data are displayed graphically. Three hundred twenty-two sequential cardiac investigations in adult patients were analyzed. The mean peak entrance dose per investigation was 0.475 Gy to a mean skin area of 8.2 cm^2.

The cumulative KERMA-area product per investigation was 52.2 Gy/cm^2 (25.4 to 99.2 Gy/cm^2), and the mean entrance beam size at the skin was 49.2 cm^2.Twenty-eight percent of the patients (90/322) received a maximum dose of 1 Gy to a small skin area (6 cm^2), and 13.5% of the patients (42/322) received a maximum dose of 2 Gy.

Conclusions—Monitoring of the dose distribution at the skin will alert the operator to the development of high-dose areas; by use of other gantry settings with nonoverlapping entrance fields, different generator settings, and extra collimation, skin lesion can be avoided. **(*Circulation*. 2001;104:1779-1784.)**

Key Words: radiography catheterization dosage

Coronary arteriography and x-ray guided catheter-based interventions are increasingly used. X-ray exposure may be associated with adverse effects, however, as described as early as 1897.[1]

Numerous incidents of radiation-induced skin injuries have recently been reported. [2–14]

Doses from the prolonged use of fluoroscopy can be very high and place the skin at risk for injury.

Even though some modern x-ray equipment uses dose-saving measures, such as added filtration and dose-reducing variable-pulsed fluoroscopy, complicated procedures can still result in high-risk skin doses.

It is therefore important to reduce radiation exposure as much as possible. [15–20]

Newer x-ray units have an integrated ionization chamber that allows monitoring of the kinetic energy released in matter (KERMA); the absorbed dose in air, but the entrance dose and dose distribution at the skin are not indicated.

Therefore, there is a need to monitor and to quantify the skin radiation dose.[21–30]

We have developed a system that automatically measures and monitors the accumulated skin radiation dose and allows detection of high-dose areas in real time. In this study, the feasibility and usefulness of this technique have been investigated by analysis of the frequency distribution of high-dose areas in consecutive patients undergoing percutaneous intracoronary procedures.

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Methods

Study Patients

The radiation monitoring system was installed in 2 of our interventional laboratories. We were able to collect and analyze complete data from 322 consecutive adult patients (235 men, 87 women; mean age 59 years, range 50 to 69 years). Patient height was 174 cm (range 168 to 180 cm), weight 79 kg (range 70 to 87 kg), and obesity (Quetelet) index 26 (range 24 to 28).

Of these, 134 patients underwent a diagnostic procedure and 188 patients an intracoronary intervention (60 patients with a right coronary artery, 75 a left circumflex, and 39 a left anterior descending [LAD] stenosis, 9 patients had bypass grafts, and 5 had a total occlusion).

Procedures

We developed a mathematical model to calculate the x-ray entrance field and the location of the irradiated areas of the skin. To be able to measure the x-ray dose for each 1 cm^2 of irradiated surface, the following assumptions are made:

1. The patient position (skin position) is defined by the location of the floating tabletop, and it is further assumed that the patient does not change position during the investigation.
2. Patients are considered to have a circular thorax with a circumference of 90 cm (only adult patients are examined).

The following parameters for radiation monitoring are measured:

1. Table: Patient position and the tabletop (measured in a 3D plane in millimeters, with the floor as reference).
2. Gantry: Rotation and angulation in degrees and source-image distance and isocentric elevation from the floor in millimeters.
3. Collimator: x-ray beam size, horizontal and vertical, in millimeters and the KERMA-area product (KAP; sometimes called dose-area product) value in Grays per square centimeter.
4. Generator: x-ray mode and fluoroscopy time (continuous or pulsed) or (digital) cine pulses.

The entrance beam location at the skin was derived from the distance from the x-ray focal spot to the patient in the transverse plane by use of the gantry rotation, focal spot position, and patient position. This distance was corrected for the gantry angulation in the longitudinal plane. The entrance beam size was calculated from the collimator beam dimensions.

The radiation dose at the skin was calculated in grays by use of the entrance beam dimensions and the KAP, measured with an ionization chamber in the collimator.

The theoretical mathematical model is not presented in this article but is available from the authors. The model is used in a monitor system developed by the Siemens Co, the prototype of which is used to retrieve the data.

Graphical Display

Figure 1 shows a 3D graph with the dose distribution at a 50x50-cm^2 dorsal aspect of the skin after an interventional procedure involving the LAD, including implantation of 2 stents. This graph was generated with our prototype system during a pilot study. The graphical display of the system used for data accumulation during our study shows a skin area of 90x90 cm^2. Figure 2 is a plot of skin dose depicted in a 2D plane centered over the backbone; the skin surface is virtually split at the sternum and shown laid flat. This graph is automatically displayed on the x-ray monitor after radiation of any part of the skin exceeds a level of 1 Gy. The irradiated skin area is continuously displayed and updated, even when fluoroscopy is not used. This enables the physician to change gantry settings or use extra collimating to avoid possible overlapping with previously irradiated skin parts without using radiation.

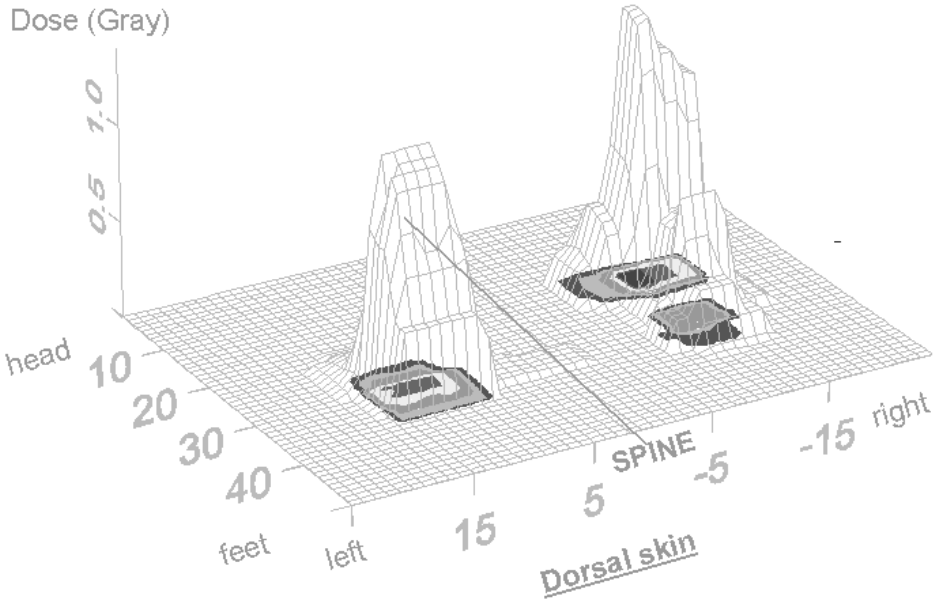

Figure 1. *Dose distribution at 50x50 cm^2 dorsal skin part after interventional procedure from LAD, followed by implantation of 2 stents. Peak, located at right side, is due to left superior oblique projection, the most radiation absorbent projection.*
Size of high-dose area >1 Gy was 19 cm^2.

Entrance Beam Dimensions

Both units have automated collimation that limits the beam areas to the selected field of view of the image intensifier, independent of changes in the source-to-image distance (SID tracking). The area of the beam at the skin, however, does change with the source-to image-intensifier distance.

The maximum possible beam areas are given in Table 1.

TABLE 1.

Maximal Possible Beam Size per Image-Intensifier Screen at the Skin

Used image-intensifier field, cm	23	17	13
Maximal size at entrance screen, cm	17.9x17.9	13.6x13.6	10.5x10.5
Maximal beam size at skin, cm	9.8x9.8	7.7x7.7	5.9x5.9
Maximal radiated skin area, cm^2	~100	~60	~35

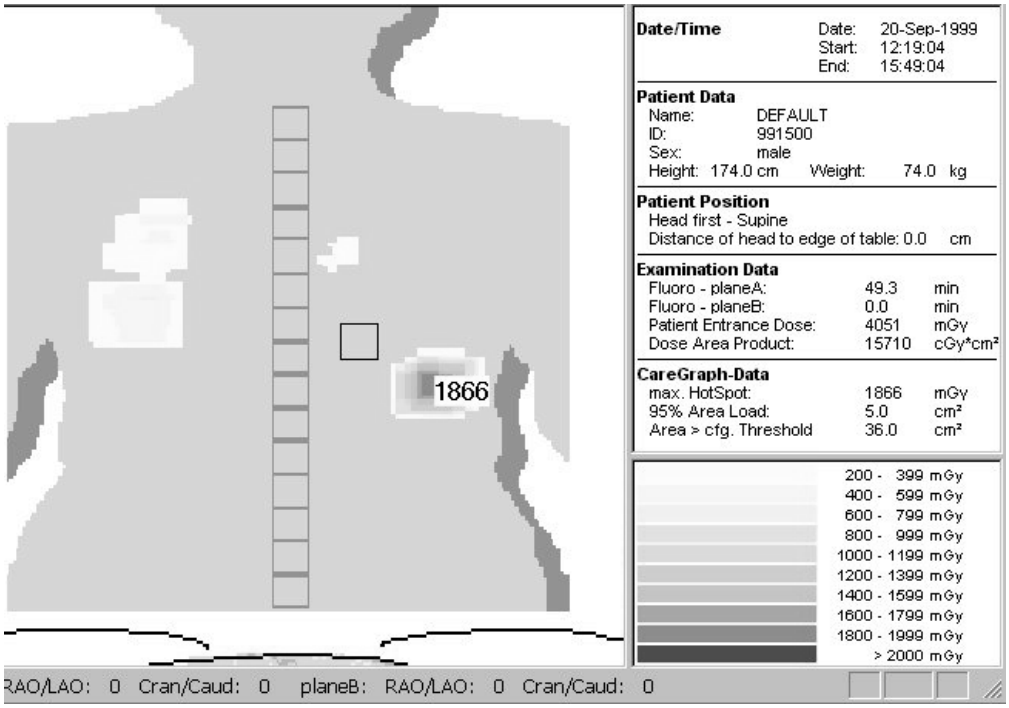

Figure 2. *Graphical display of prototype system shows skin area of 90x90 cm^2. Graph is automatically displayed on x-ray monitor after radiation at any part of skin exceeds a level of 1 Gy. Dose report is integrated into this display. Actual irradiated skin area is marked as a square on display (even without fluoroscopy), enabling physician to avoid possible overlap with previously irradiated skin parts by extra collimating or changing gantry settings. Example shows dose distribution at skin after a procedure with 49.3 minutes of radiation time, a PTCA of LAD. Peak entrance dose (hot spot) received by skin was 1.86 Gy to an area of 5.0 cm2.*

Dose Settings of the X-Ray Equipment

The dose settings for the x-ray equipment for the pulsed fluoroscopy mode (PFM) and the digital cine mode (DCM) during the study period are shown in Table 2. The highest possible kilovoltage peak (kVp) during PFM was 110 kVp, and during DCM, 125 kVp. The frequency of PFM was adjusted to 12.5 pulses per second, and the extra beam filter used was 0.2 mm Cu.

The scattered radiation grid had a ratio of 11 and 40 line pairs per centimeter and a focal spot distance of 950 mm and was carbon fiber filled and covered.

The radiation measurement was performed with an ionization chamber built into the collimator, and the KAP is shown.

TABLE 2.

Dose Settings of the X-Ray Equipment

Image-intensifier entrance field size, cm	23	17	13
PFM intensifier dose per image, nGy	10	16	28
PFM intensifier dose per second, mGy/s	0.12	0.20	0.35
DCM intensifier dose per image, nGy	63	104	174

Statistics

Unless otherwise stated, numerical data are presented as median with interquartile range.

Results

Total Radiation Dose per Investigation

The mean cumulative KAP per investigation was 52.2 Gy/cm2 (range 25.4 to 99.2 Gy/cm^2). The mean entrance beam size at the skin was 49.2 cm2, giving an absolute value of 1.06 Gy (Figure 3).

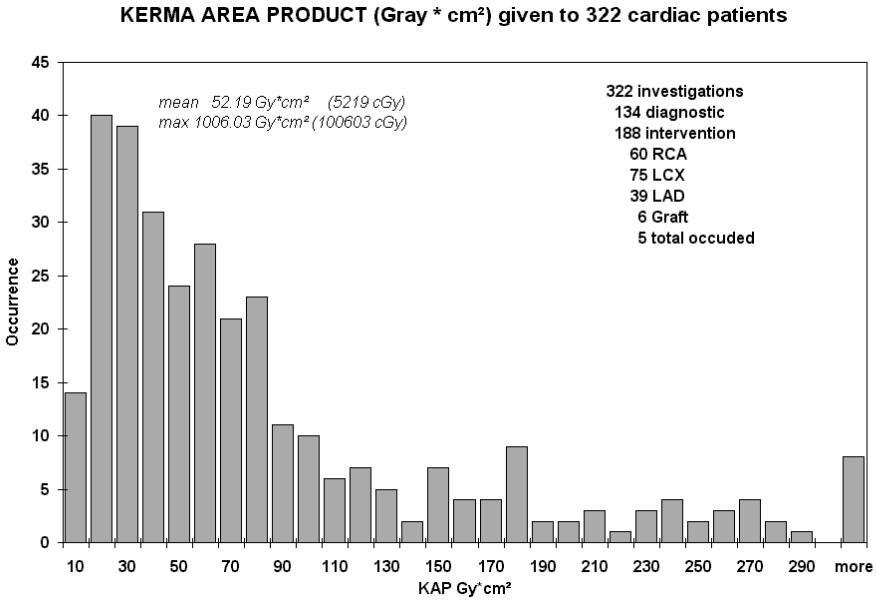

Figure 3. *KAP measured in 322 patients. Mean value was 52.19 Gy/cm^2 (range 25.4 to 99.2 Gy/cm^2). Mean size of entrance beam was 49.2 cm^2.*

Radiation Time

The mean fluoroscopy time was 17.8 seconds (range 8.8 to 33.1 minutes), with pulsed fluoroscopy of 12.5 pulses per second. The mean DCM time was 97.9 seconds (range 69.4 to 151.1 seconds), with a frequency of 12.5 frames per second.

Irradiated Skin Surface

The radiation-exposed skin area in 95% of all investigations was restricted to a size of 50x50 cm^2, including the irradiated area at the groin for catheter introduction and left lateral gantry positioning. This is shown in figure 1. In the remaining 5% of the cases, the exposed skin area could be visualized by showing a 90x90-cm^2 area.

Peak Entrance Dose

The distribution of peak entrance skin doses to the patients in our series is shown in figure 4. The mean value was 0.475 Gy, with a mean area of 8.2 cm^2 exposed. Dose values < 1 Gy occurred in the majority of the patients (52%), whereas parts receiving a dose > 4 Gy occurred in only 1.2%. Because our system alerted us in real time when a high-dose area was developing, we were able to avoid excessive dose to that area by changing the gantry settings. It was not necessary to interrupt any procedure as a result of a high-dose "hot spot."

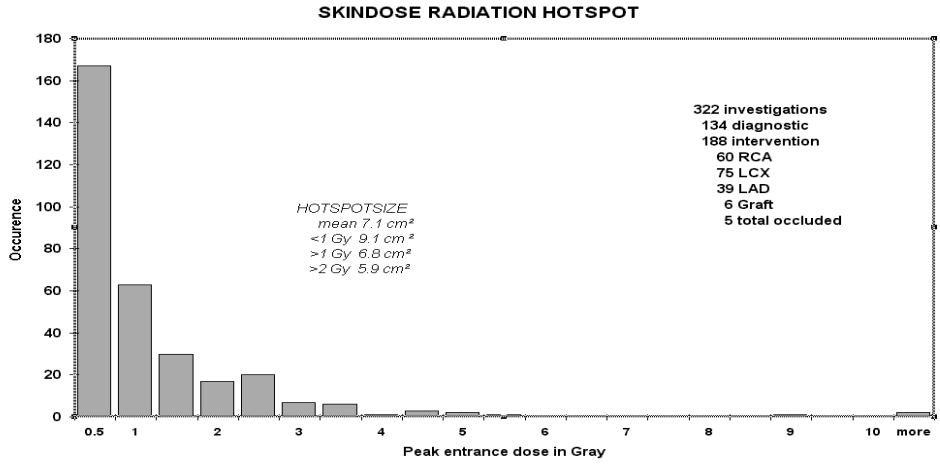

Figure 4. *Peak entrance dose measured in 322 patients; mean value was 0.475 Gy. Mean size of high-dose area was 8.2 cm^2.*

Correlation between the measured KAP, patient obesity, and fluoroscopy time

The correlation between the measured KAP and the obesity of the patient, the Quetelet index (kg/m^2), was low (*R*50.15). Higher doses were correlated with gantry projections that required penetration of thick, highly absorbent body masses. There was a strong relationship between the KAP and fluoroscopy time (*R*50.78) (Figure 5).

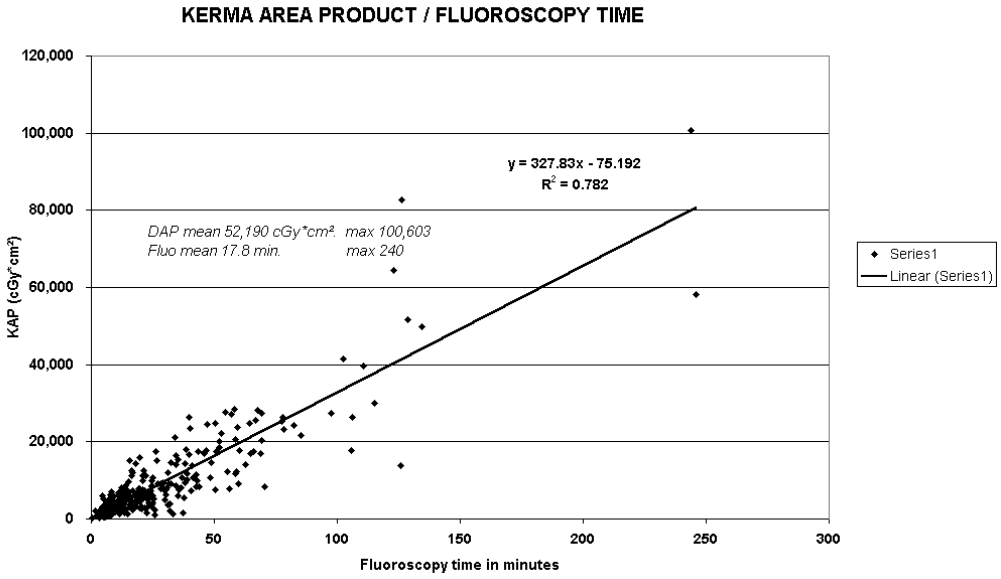

Figure 5. *Correlation between measured KAP and fluoroscopy time for complete patient group: R50.78, x5275.19, y5327.83. With extreme values taken out, fluoroscopy times 100 minutes showed R50.70, x5537.42, y5296.15. Mean KAP was 52.19; mean fluoroscopy time used was 17.8 minutes.*

Correlation between measured KAP and peak entrance dose

There was a high correlation between measured KAP and peak entrance dose (*R*50.89) (Figure 6). We also compared the correlation between KAP and the high-dose areas in the 134 diagnostic and the 188 interventional procedures. The correlation between the interventional procedures (*R*50.90) was higher than the correlation between diagnostic procedures (*R*50.35) because of more frequent changing of gantry settings and less overlapping of entrance fields in diagnostic cases.

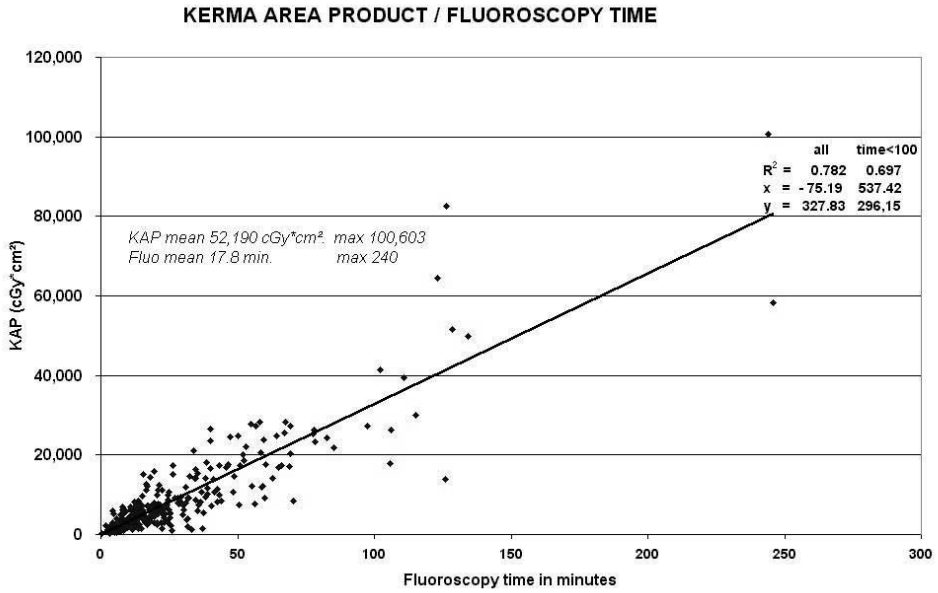

Figure 6. *Correlation between high-dose area (hot spot) at skin and measured KAP for whole patient group was high: R50.89, x51292.1, y57.947.*
Mean KAP was 52.19; mean high-dose area value was 0.475 Gy.
With extreme values taken out (hot spot .>4 Gy), R50.81, x51299.9, y57.835.

Validation of the Measured KAP

The ionization chamber readings were verified regularly with other measuring devices; the accuracy of the KAP readings was within a 5% range. The values that appear on the monitor reflect the free-in-air KERMA, measured in grays. The dose to the tissue is actually 30% to 40% greater than the value displayed during monitoring, because of backscattered radiation and the KERMA-to–tissue-dose conversion factor.

Table 3.

Reported Radiobiological Effects of Radiation [26–30]

Effect	Threshold	Onset	Peak	Comments
Epilation				
Temporary	~3 Gy	~2 weeks		New hair thinner
Permanent	~7 Gy	~2 weeks		Protracted threshold ~50 Gy
Erythema				
Early & Transient	~2 Gy	hours	~24 hrs	Not an indication for later response
Main effect	~6 Gy	~10 days	~2 wks	Reddening ⇒ pigmentation
	>10 Gy			pigment may last for months
Desquamation & Ulceration				
Dry desquamation	~10 Gy	~4 weeks	~5wks	Healing 2 wks to mths, late atrophy
Moist desquamation	~15 Gy	~4 weeks	~5wks	Dermal effect; ulceration
Secondary	~20 Gy	<6 weeks		Secondary to sterilized basal cells Scarring

Discussion

Skin injury as a result of radiation exposure was reported as early as 1897.[1]

The number of radiologically guided interventions is increasing, as well as the amount of radiation used per procedure. Recent publications show an increasing number of skin injuries during cardiac, abdominal, and neurological interventions.[2–14]

High entrance-dose values cannot be avoided in complex investigations, because they often require long exposure times.

Our method allows for skin dose management and makes it possible to keep the dose at a certain skin area as low as reasonable for the procedure. This is important because many patients have more than one procedure, and skin dose accumulates.

It should be kept in mind that a high dose may produce unacceptable skin damage and should be avoided [26–30] (Table 3).

Real-time dose monitoring can prevent these adverse effects because it allows selection of other x-ray techniques, such as extra beam filtering, selection of lower frame rates, and if available, documenting of low-dose fluoroscopic runs during the procedure.[15–18] Extra beam collimation is not often used but is a highly effective way to decrease both patient and operator radiation exposure without loss in image quality.

Finally, the use of other gantry settings allows distribution of the radiation dose over different skin areas and prevents development of a high dose. In our study, only 1.2% of the patients received a dose .4 Gy at some parts of the skin. It should be noted, however, that when equipment without dose-saving measures is used, levels are much higher (up to 7 times).[15]

Limitations

The monitoring system used in this study assumed a patient with a thorax circumference of 90 cm. Obviously, this does not apply to all patients, and ideally, a monitoring system should be tailored to the size of the patient. The actual size and location of irradiated skin parts may vary from one individual to another; future refinements to model the dimensions of individual patients more accurately would improve the accuracy of the skin dose distribution.

Clinical Recommendations

Our data show that the likelihood of high-dose areas may occur in the following circumstances: fluoroscopy time .0 minutes; gantry positioning unchanged throughout the procedure; and the irradiation occurring through a highly attenuating (eg, bone), thick body mass, requiring a high radiation quality during fluoroscopy and cinematography (110 kVp).

High-dose areas most likely occur when the left superior oblique projection is used.

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Chapter 6

Skin damages, when do they manifest?

Theoretical considerations

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Doserate
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Introduction

As already discussed in chapter 1, in literature several cases are reported of skin injuries caused by x-rays during Percutaneous Coronary Intervention (PCI).
In the Thoraxcenter to our knowledge we have not found comparable injuries in patients.
In this chapter I will discuss several parameters which influence the skin dose of the patients.

Continuous versus pulsed fluoroscopy

Continuous fluoroscopy was introduced for visualization of the heart almost immediately after the discovery of x-rays by Röntgen.
Film exposure was too long and the motion of the heart caused blurring of the images.
Pulsed fluoroscopy has been developed to freeze motion.
The introduction of high capacity x-ray tubes in 1994 made it possible to produce short, high intensity flashes of x-rays.
The thermal capacity for fluoroscopy gradually increased from 100 Watts per second [W/s], (110 kiloVolt peak [kVp] with 1 milli Ampere [mA]) in 1910 to 1600 W/s (110 kVp, 16 mA) in 1990 and later to 3600 W/s with the grid switched pulsed technique (110 kVp, 200 mA, 25 pulses per second [p/s] and an 8 milli seconds [ms] pulse width).
This was possible with the use of metal casing tubes, liquid metal bearings and external cooling. If low pulse frequencies (12.5 p/s or less) are used, pulsed fluoroscopy shows lower doserates per second than the continuous technique and the image quality of moving structures improves. Consequently, the fluoroscopic technique (unintentionally) changed from a low dose continuous technique to a high dose fractionated technique.
Is pulsed fluoroscopy the reason why we noticed less or even no skin injury in our patients?

Extra filtering

At the Thoraxcenter we use extra beam filtering (1).

This is certainly one of the reasons, why less skin injuries are noticed. However, the deterministic skin effects, reported in literature during the last years, occurred also in units using extra filtering and pulsed fluoroscopy.

The influence of extra filtering on high capacity tubes is shown in figure 1.

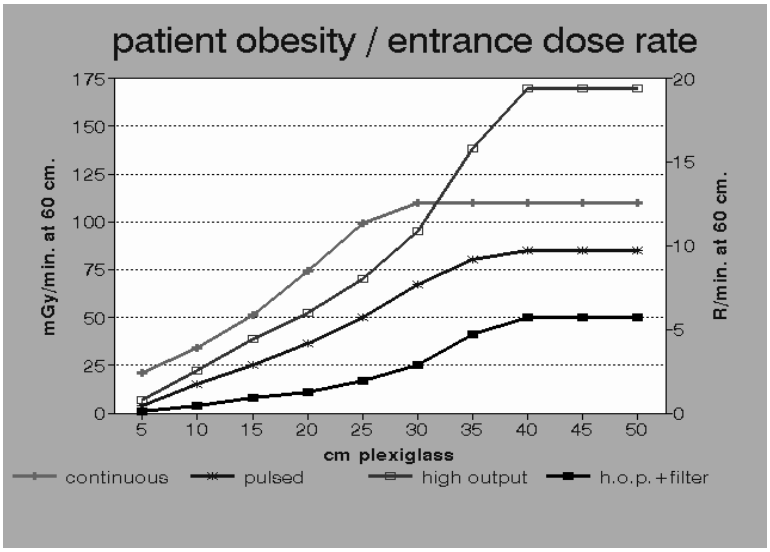

Figure 1. *Doserates, using different techniques, the larger the radiated volume, the higher the entrance dose.*

The thermal tube capacity used during continuous fluoroscopy and pulsed technique is 600 W/s. During the high output pulsed technique (metal bearing tubes) using an extra filter of 0.4 mm Cu, the thermal capacity was 1800 W/s. The pulse frequency for this technique was 8.3 fr/s. It should be noted, that the entrance doserate, radiating a volume with a thickness of 25 cm, for continuously fluoroscopy can be up to 7 times higher compared to the high output pulsed fluoroscopy with extra filtering.

This extra filtering helps to reduce the skin dose significantly.

Doserate

Is the dose (rate) necessary to create an image on the detector an important contributor to the entrance dose?

Yes, it is very important when the x-ray tube is used within the normal range during fluoroscopy.

With automatic exposure systems one can expect a lesser skin dose if a lower doserate is selected.

If there is sufficient image quality, try to keep the dose as low as possible and select a low pulse frequency.

When thick or highly absorbent body masses (steep angulations and/or obese patients) are investigated with small image fields, the tube output may be insufficient to generate a good quality image.

In these situations a low fluoroscopy detector entrance doserate has no influence on the skin dose. However, when using automatic exposure systems, the generator regulates the tube to the maximum possible output, giving the highest entrance dose.

It is then beneficial to select the lowest dose, which automatically tunes the imaging chain to the highest sensibility.

Limitation tube output

Governmental regulations in the United States and Europe permit during fluoroscopy a maximum x-ray tube output of 87 mGy/min (10 R/min) at a the focal spot distance of 75 cm (4).

When an acoustic alarm is used, or the procedure demands for “HIGH” fluoroscopy, the maximal output may be 174 mGy/min (20 R/min).

While most gantry isocenters are located at 70 or 75 cm from the focal spot, the skin to focal spot distance is approximately 60 cm.

The maximum allowed doserate at this distance is 136 mGy/min. (15.6 R/min) and using “HIGH”, even >270 mGy/min (31 R/min.). In the interventional laboratories in the Thoraxcenter, the maximal doserate during fluoroscopy at 60 cm focal spot, using a tube filter of 2.5 mm Al and an extra filter of 0.2 mm Cu, is 70 mGy/min.

Figure 1 shows that the high output mode without extra filtering can produce a maximum skin doserate of 170 mGy/min (19.7 R/min), which is unacceptably high for fluoroscopy.

Yet there are systems which have these dose settings, and when the maximal tube output is reached, the extra filter is automatically switched off to increase the tube output. This kind of automation should be prohibited as there is no benefit to image quality while the entrance or skin dose becomes unnecessarily high.

It must be noted that extra filtration weakens the photon output and only high output tubes with forced external cooling can be used. Using outdated technology, the output after extra filtering is so greatly weakened that there is insufficient photon output for large volume fluoroscopy on small fields.

Field size regulation

Small fields are less likely to cause skin injuries and when there is an injury, small fields heal better. Therefore the industry should not automatically increase the beam as large as possible when switching from a small to a larger detector field.

The following principle should be adhered to: when a user collimates the beam wider; he does it until the needed size is reached.

If the maximum size automatically regulated, steps to reduce the beam size are seldom undertaken, there are few operators who routinely do so.

In fact, I think these operators should be extra rewarded.

Regulatory requirements for collimating the x-ray beam currently exist. (4)

The aim of these regulations is to limit the x-ray beam to the image receptor and to keep the amount of patient tissue exposed to x-rays equal to the region which is imaged. If the collimator blades are too widely set for the used field of view (FOV), additional patient tissue will be radiated unnecessarily.

The regulations state that the x-ray beam must be restricted to (not larger than) the image intensifier phosphor size or detector size when the collimator is fully opened. These conditions are met if the collimator blades are visible on the monitor during fluoroscopy.

Changing to a smaller FOV on the image intensifier implicates that the beam size automatically becomes smaller.

Changing to a larger FOV shall automatically result in a wider beam size. Disabling this function is dose saving, consequently, one has to widen the beam size manually, which results in a beam as large as deemed necessary and not as large as possible.

A smaller beam size or extra collimation is not only dose saving for the patient, but also for the operator as less tissue is radiated, less x-ray scattering will occur.

The patient is the first absorber for the scattered radiation and more tissue around the radiated part will absorb more scattering. While scattered radiation is image forming, extra collimation also increases the image quality because less scattering creates less “grey fog” on the detector.

Distance to focal spot and detector

Skin injuries located on arms, elbows and skin parts, placed at a short distance to the focal spot are published. A good illustration can be found in chapter 1, photo 1, which shows the outcome of placement of the elbow in the x-ray beam at a distance of 35 cm from the focal spot. At this relative short distance the maximum doserate is, using the highest possible setting, about 1 Gy/min.

With this doserate, only a brief period of fluoroscopy is enough to create severe skin defects to the patient.

This explains the compulsory nature of radiological training for operators and investigators in the European community.

A short skin to tube distance is actually considered to be a form of malpractice.

In practice the distance from focal spot to the skin is 60 cm or higher and for lateral projections approximately 50 cm. Using lateral projections, one has to be aware of the pitfalls with the easiness to use short distances.

The distance from the detector to the patient should be as small as possible, not only for dosimetry reasons, but also for the image quality, the closer the detector to the body, the sharper the images due to the smaller penumbra or half shadow, see the figures 5 and 6 in chapter 3.

Fluoroscopy time and used frame rate

The amount of radiation used is linear to the fluoroscopy time and the frame rate used. While a PCI can be a life saving procedure, there are and never shall be legal limitations for the investigation time.

If non moving objects are investigated, a low pulse frequency should be chosen.

The dose, received during 15 minutes of fluoroscopy with 25 pulses per second (p/s), equals the dose, received during one hour fluoroscopy when a pulse rate of 6¼ p/s. Using electronically gap filling, no flickering on the monitor or “slapstick” effect is observed with the human eye and no differences in image quality will be noticed.

Also, the operator will notice on his/her personal dosimeter that the scattered radiation dose is much less, when low pulse rates are used.

Which x-ray energy should be used?

Different radiation qualities on the same object show various transmission patterns.

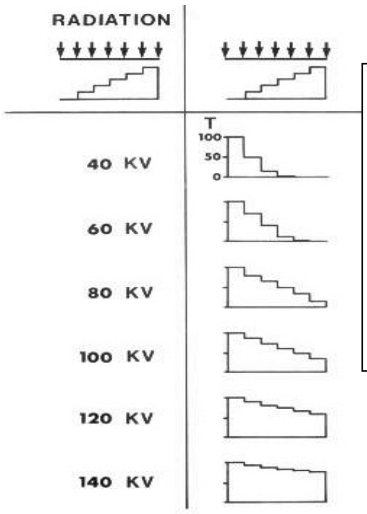

Diagram showing a test object irradiated with different x-ray qualities. T=100 is no object, 100 % transmission. Obviously the transmission pattern with 40 kV is not optimal, there is no transmission of the highest object part and the radiation contrast is too high. Using 140 kV, the transmission of the highest part is too much; the radiation contrast is too low.
A quality of 80 kV represents a correct transmission pattern.

Diagram 1. *Radiation transmission patterns*

During the last decennia automated exposure systems have been developed, starting with a central measuring field at the image intensifier output screen.
This system regulates the x-ray generator such that the amount of energy or light represents a predefined intensity level on cine film or video signal on the monitor.
The thorax is the part of the body where the highest absorption differences occur for x-rays.
If all parts of the imaging chain are correctly regulated (developing machine and projector for cine film, video chain and monitor for fluoroscopy with stable quality), this central dominant measurement regulation results in a well functioning automatic exposure system.

If the central field was placed at the heart, representing the mean absorption in the thorax, the image quality is good. However when this field is placed on the lung field or the vertebra, the result is suboptimal, this is illustrated in diagram 2.

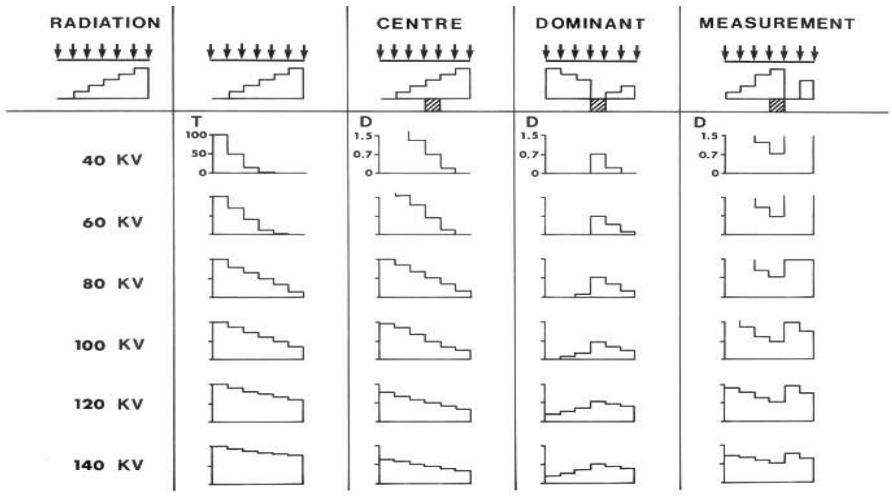

Diagram 2. *A central measuring field placed on other shaped objects and quantity regulation, all measurements show a density (D) on cinefilm of 0.7.*

For the thorax the radiation quality (kV level) has been selected by experience, the quantity regulation, beam current in mA and pulse width in msec, is used to keep the amount of energy or light constant (D=0.7).

The place of the central measuring field, used for the thorax region was selected by trial and error.

In practice a radiation quality between 100 and 120 kV was needed to present an image with readable density variations.

Placing the measuring field on lung tissue showed underexposure and measurement of the vertebra showed overexposed images, as shown in the two right rows in diagram 2.

To overcome the problem of underexposed and oversaturated images, one can measure the maximal signal or density and maintain this constant (D=1.5) by quantity regulation (mA and msec). Changing the x-ray quality, influencing the absorption differences, can be done up to a minimum density level (D=0.2).

This maximal and minimal exposure regulation system is illustrated in diagram 3.

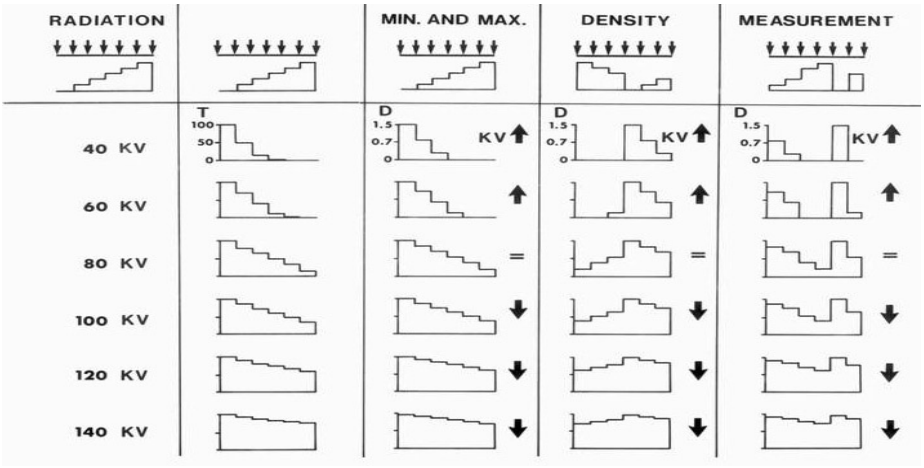

Diagram 3. *Measuring the maximal signal and keep this constant by quantity regulation (D=1.5). The arrow indicates the kV regulation. Changing the quality until a minimum (D=0.2)shows an optimal radiation contrast with 80 kV.*

X-ray quality or kilo voltage (kV) regulation is a powerful tool, while one takes advantage of changing the absorption differences. Independent of the object shape, 80 kV portrayed the best image.

However, the photon output of the older x-ray tubes was too low in most situations for adult thorax documentation and one had to select a higher kilo voltage than optimal.

Diagram 4 shows the results of the two exposure systems, the energy values per quality are translated via the S-shaped curve to density or video signal.

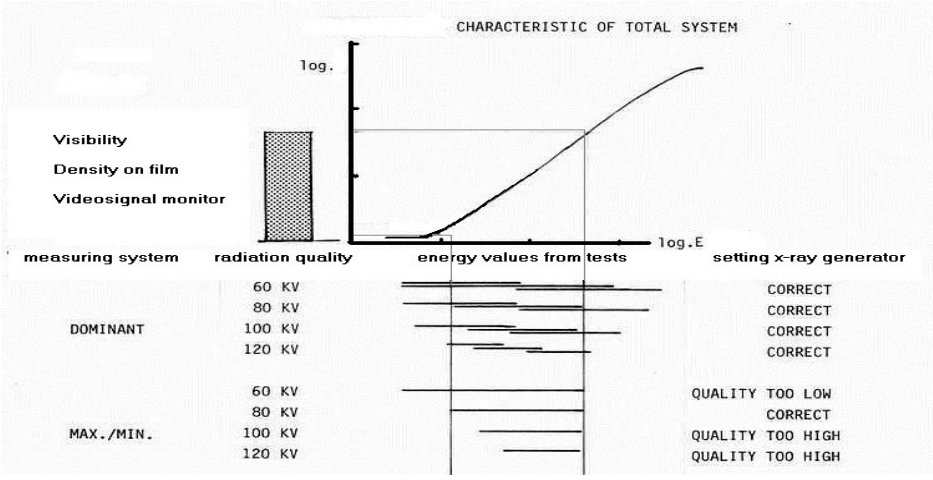

Diagram 4. *Regulation of a central dominant and a maximal/minimal exposure system.*

The result of the central-dominant and maximal-minimal regulation showed an optimal image quality. Each object demanded an optimal kV setting, giving a radiation contrast which matched optimal with the used imaging system.
The maximal- minimal exposure system has never been used on large scale. At the time it was developed, the photon output from the x-ray tubes was insufficient for adult patients, making this idea, which was tested and proposed in the 80's an academic one. (5)
The industry developed a dominant measuring field which was almost as large as the total image, half transparent wedge filters were used to overcome saturated images.
Digitization made chemical processing unnecessary, the darkroom is replaced by a workstation and the projector by a monitor.

Since the introduction of high output x-ray tubes (delivering a factor 20 more photon output during fluoroscopy) one is able to select the optimal radiation contrast by kV regulation, which matches the best with the detector.
A correct radiation contrast, best matching with the detector, remains the basis for good imaging
Novel x-ray tube technology provides an enormous improvement in quality.
Short (a few milli seconds) high intensity (in mA) pulses can freeze the motion of fast moving objects, creating much sharper images and by using smaller focal spot sizes, further improvement is possible.
Low pulse frequencies for cine and pulsed fluoroscopy have lowered the radiation dose to patient and personnel and permits longer radiation time in the interventional laboratory without harm to the patient skin.

Tube output and photon usage for imaging

During the last decennium, high output grid switched tubes were developed.

These x-ray tubes with beryllium windows are capable of delivering a high photon flux or output. These tubes have the possibility to optimize the x-ray spectrum in such a way that the patient entrance radiation dose mainly contains image forming elements.

The non image forming elements can be filtered from the electro magnetic spectrum with photo electric filtering, filters of aluminium and copper are often used, which weakens the photon output. Novel high output tubes can easily compensate for the extra required output and more, the pulse time or focal spot can be optimized as well, creating a better image and the entrance or skin radiation dose is, due to the use of an extra filter, lowered by a few factors. In figure 2 the amount of photons are shown, measured at 75 cm distance from the focal spot, using two x-ray qualities (100 and 80 kV), the weakening, caused by the obligated 2.5 mm Al filter and the weakening with an extra filter of 0.2 mm Cu, respectively 0.4 mm Cu.

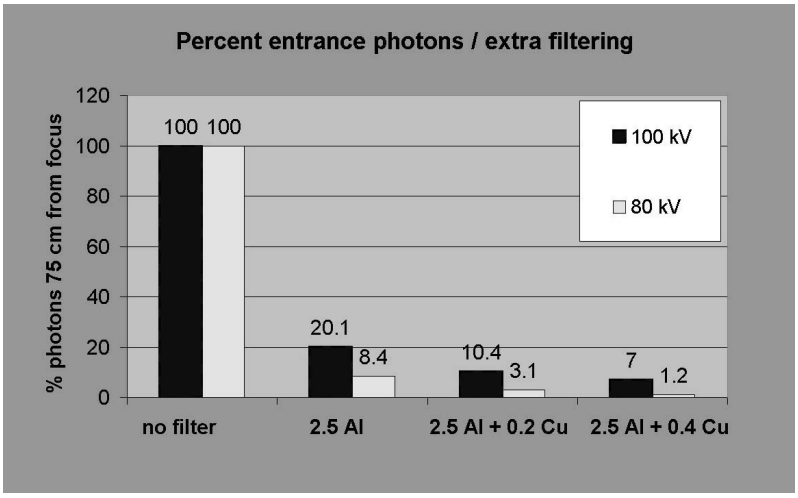

Figure 2. *The amount of skin entering photons, without and with beam filtering.*

Figure 2 illustrates the necessity of the obligatory 2.5 mm Al filter, using 100 kV, without this filter the entrance dose is a factor 5 higher (20.1/100). An extra filter of 0.2 mm Cu halves the entrance dose, using 0.4 mm Cu as extra filter, the entrance dose is one third. Looking to the amount of photons or flux, removal of the extra 0.4 mm Cu filter gives a 287 % (20.1/7.0) increase of photons.

In figure 3 the amount of photons leaving an object with a thickness comparable to 20 cm of water and entering the image detector are illustrated.

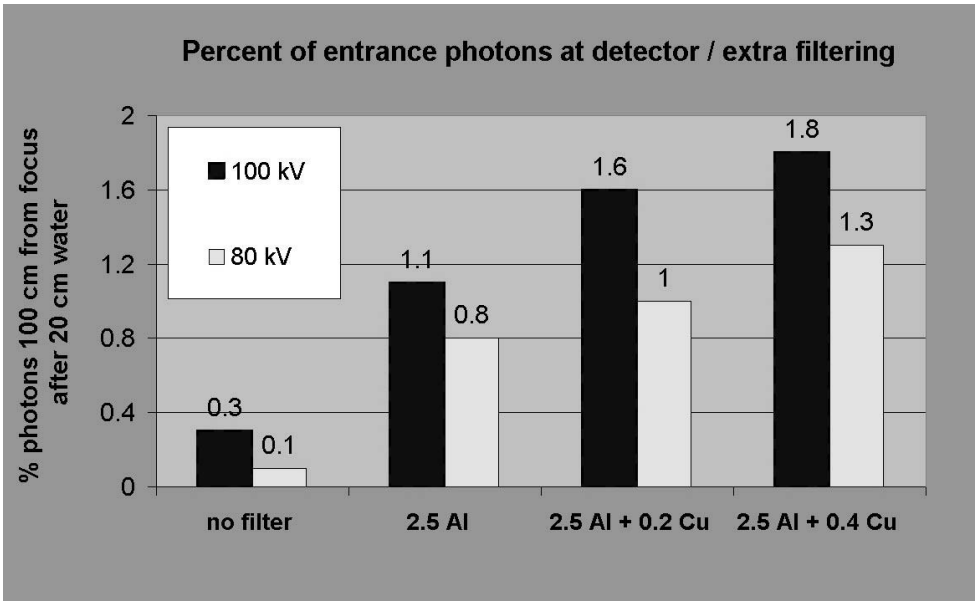

Figure 3. *Percentage of image detector entering photons behind an object of 20 cm water.*

It appeared that, when using x-rays with a maximum quality of 100 kV, only 0.3 % of the photons are left for imaging; 99.7 % of the photons are absorbed by the object.

Using the obligatory 2.5 mm Al filter results in x-rays with a higher mean quality (the photons with a low quality are more absorbed in the filter) and gives that 98.9 % of these photons are absorbed in the object and 1.1 % is left for imaging.

When additional copper filters are used (0.2 and 0.4 mm) the quantity of absorbed photons in the object decreases (98.4 and 98.2%) and the amount of photons left for imaging increases (1.6 and 1.8%).

As shown in figure 3 the same yields for x-rays with a maximum quality of 80 kV.

Figure 2 shows that extra filtering is very effective for diminishing the entrance dose, and figure 3 shows that only a few tens of a percent of the photons, useful for imaging are lost.

The shape of the electro magnetic spectrum, accompanied by these four beam qualities with different filters is shown in figure 4.

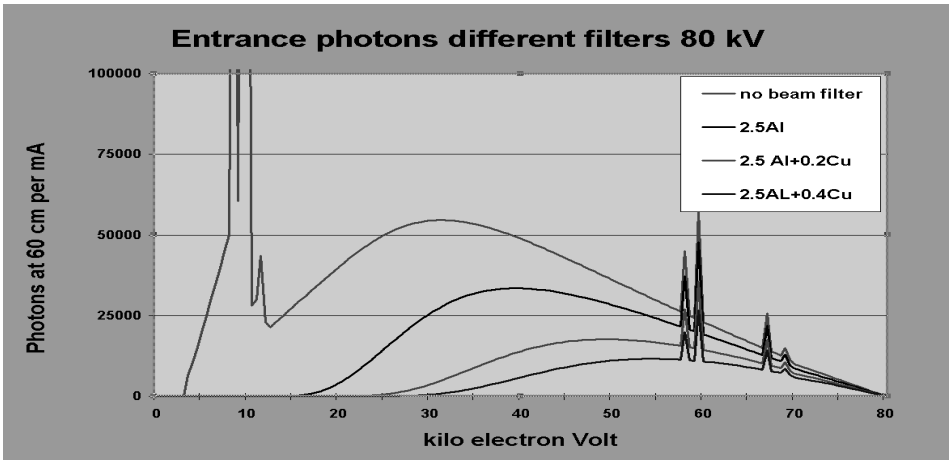

Figure 4. *Four different spectra, unfiltered and filtered with 2.5 mm aluminium and an extra filter of 0.2 and 0.4 mm copper. The extra copper weakens the lower energy photons very effective, the higher the energy, the least the weakening.*

Especially during fluoroscopy of obese patients, using small fields and projections which represent large tissue volumes, there is sometimes insufficient photon output or flux available for proper imaging.

In these situations some apparatus have an automatic mode to remove the extra filter. The manufacturer prefers to use the maximal tube output with the rational that the higher the tube output or flux is, the better the image quality shall be, without considering that the extra flux also contains a great amount of non image forming photons.

Due to the density of copper, 30 kV energy photons shall be absorbed for >90% in the extra filter, photons of 100 kV shall lose < 1 % of their imaging capacity.

Removal of the 0.4 Cu mm filter gives a triple entrance dose, removal of the 0.2 mm Cu filter a double entrance dose, while the amount of image forming photons at the detector only increase with a few percent.

In the Thoraxcenter we use a non removable 0.2 mm Cu extra filter in the tubes.

Using a high output tube, removing the extra filter should be prohibited; it is unjustifiable as it does not contribute to the quality of the image and it raises the entrance or skin dose to the patient and thus the chance of possible skin injuries.

Which x-ray spectrum is appropriate?

Four x-ray beam spectra, created in a tube with a beryllium window, one unfiltered and three spectra with different beam filters, the obligatory 2.5 mm Al and additional filters of 0.2 and 0.4 mm Cu, are illustrated in figure 5.

The surface of the curves represents the amount of energy entering the patient's skin.

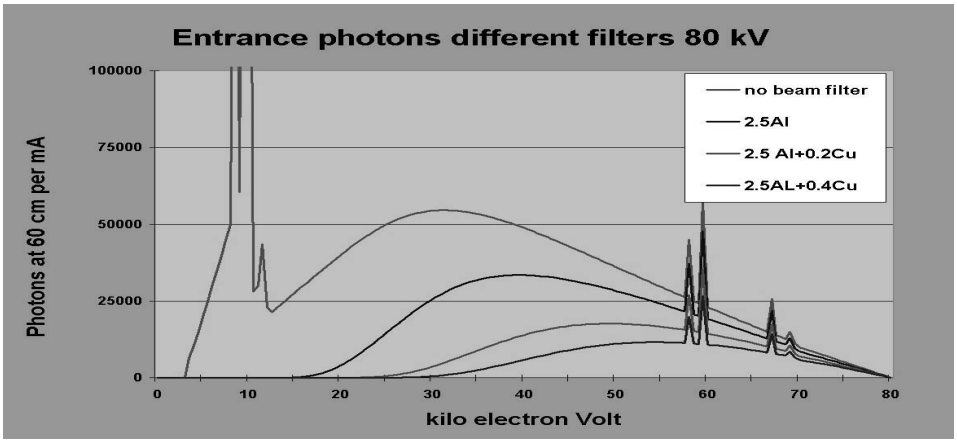

Figure 5. *The spectra of 4 entrance beams, using 80 kV peak radiation with different filters.*

Figure 6 shows the spectra of the same four x-ray beams, entering the detector after radiating an object comparable to 20 cm water.

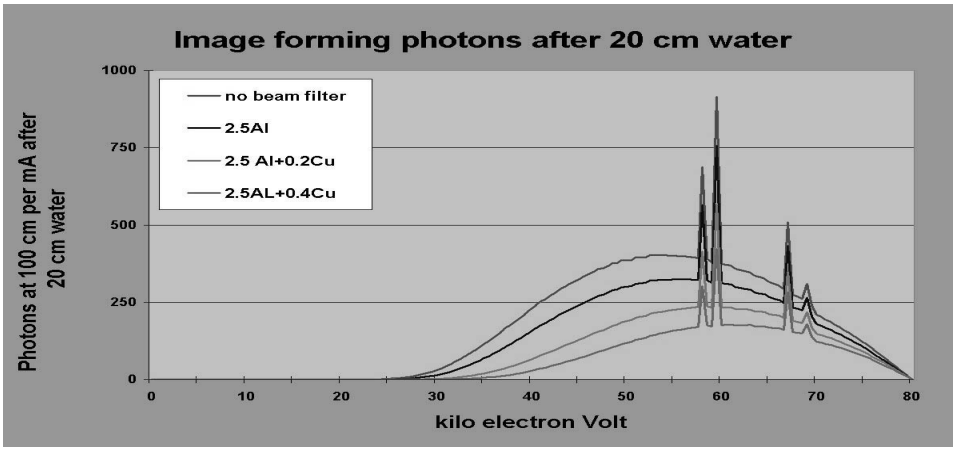

Figure 6. *The spectra of the same 4 beams, after radiating an object of 20 cm water*

Combination of the results shown in both figures 5 and 6 indicates that photons <30 kV do not contribute to the image and are absorbed in the object.

Low energy photons only contribute to the patient dose and they should not be used.
A filter that prohibits photons with energies lower than 30 kV would be ideal for imaging this object, but is not available.
The effect of extra filtering can be clearly noticed if one indicates not only the kV peak value, but also the kV mean.
In table 1 the influence of filtering using 80 and 110 kilo Volt peak is shown.

kV peak	filter	kV mean	ratio peak/mean
80/110	none	31.9 / 45.8	2.51 / 2.40
80/110	2.5 mm Al	45.6 / 55.6	1.75 / 1.98
80/110	3.5 mm Al	47.0 / 56.9	1.70 / 1.93
80/110	4.5 mm Al	48.1 / 58.0	1.66 / 1.90
80/110	2.5 Al+0.2 Cu	52.1 / 62.2	1.54 / 1.77
80/110	3.5 Al+0.2 Cu	53.6 / 62.8	1.49 / 1.75
80/110	2.5 Al+0.4 Cu	55.4 / 66.0	1.48 / 1.67
80/110	3.5 Al+0.4 Cu	55.7 / 66.4	1.44 / 1.66
80/110	2.5 Al+0.8 Cu	59.3 / 70.8	1.35 / 1.55
80/110	3.5 Al+0.8 Cu	59.5 / 71.1	1.34 / 1.55

***Table 1**. Filtering and the influence on the mean radiation quality, the higher the ratio, the higher the relative entrance- or skin dose.*

Filters, prohibiting higher energies do exist, they are attenuating photon energies above the K-electron shell binding energy, as shown in figure 7 for a 50 micron Tungsten filter.
This phenomenon is practiced in the development of light weight protective aprons.
Making use of different K absorption energies, multiple-attenuating elements are combined to create protective materials which improved attenuation in a well defined range of x-ray spectra. This improves radiation safety and provides a more realistic rating for lighter garments and reduces back strain to the wearer.

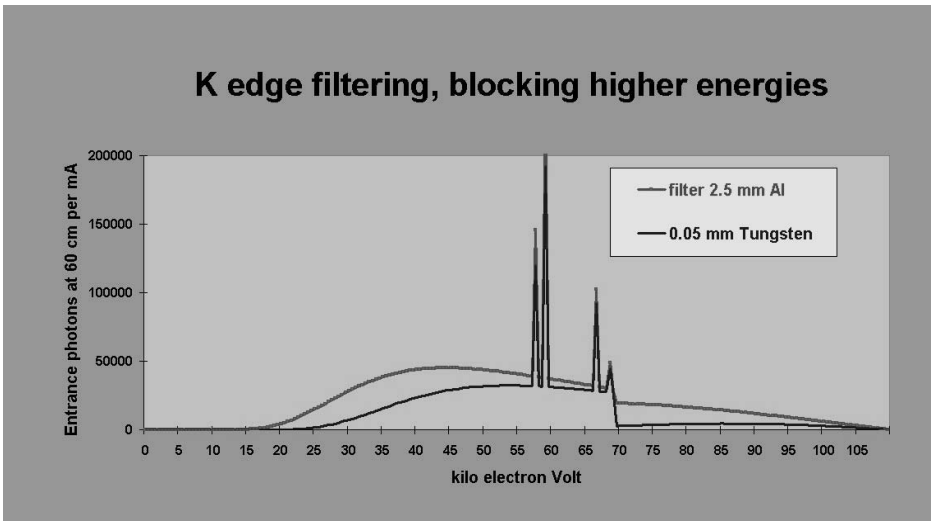

Figure 7. *K edge filtering with a 0.05 mm Tungsten filter.*

If filters, prohibiting energies below a certain value (turn around K-edge) were available, the use of the photo electric filters to reduce skin dose would be unnecessary and thus making the amount of image forming photons or flux, leaving the x-ray tube, higher, enabling shorter pulse times or the use of smaller focal spots.

All x-ray spectra and calculations, presented in this chapter, are simulated using software programs. (6,7)

Digital techniques

Since digital systems have the possibility to enhance certain parts of the information, such as spatial filtering, the investigator can perform complex procedures much easier.
However, one has to take care not to create non existing information by interpolation, partial enhancement, time middling (noise reduction) and equalizing.
One can change the information depth per pixel to fill structures, voids which help interpretation, but one must be aware that in this situation the densitometrical relation and calculation does not reflect the reality.
By level and window adjustment, digital systems allow the signal to optimally match with the display systems. With good perception circumstances (placement of the monitor and light level in the examination room) the images are optimally seen by the human eye.
The idea of changing the digital signal into a perfect image is tempting, however, the information can match optimal to our perception, but the basic signal must first be optimized. If only a part of the digitized signal is used, it implicates that there was an abundance of information, and that the radiation dose could be reduced.

If digital imaging techniques can change the information and provide optimal images to our eye, why should we not use a high x-ray quality with an extra filter? After all, the patient entrance or skin dose is than low and the image quality good.
This could be done. However, the scattered radiation is then high. While this is image forming, the optimal image is not created and the investigator dose is higher than necessary.
Therefore extra beam filtering and other dose saving techniques are needed, combined with automated exposure systems.

Digital systems are changing the world of medical imaging, but the basic information must be kept at an optimum.

Digital flat panel

This technology for the first time provides the possibility to measure x-ray energy behind the detector, and to determine the energy of the photons which create the image.
The spectral shape and the energy of photons, entering the detector are highly influenced by the object.
By comparing the object entrance spectral shape with the object output spectral shape, one has the opportunity to optimize the entrance spectrum.

Automatic exposure systems with in- and output spectrum comparison could create an optimal image quality, while giving the lowest skin burden for all objects, from children to adults, and the lowest personnel scattering dose.

Are x-rays and ultra violet rays (UVR) synergistic?

In the ICRP publication (2) concerning skin damage and radiation induced skin cancer it is stated that "UVR and x-rays are synergistic".

From an energetic point of view this is true. If the x-ray radiation is created in tubes with glass housing without extra filtering, non-ionizing radiation, like UVR leaves the tube as well.

Modern tubes have metal casings and the obligatory 2.5 mm Al filter which provides for the UVR and the low, non image forming spectra do not leave the x-ray tube.

This is a skin sparing effect as shown in figure 8.

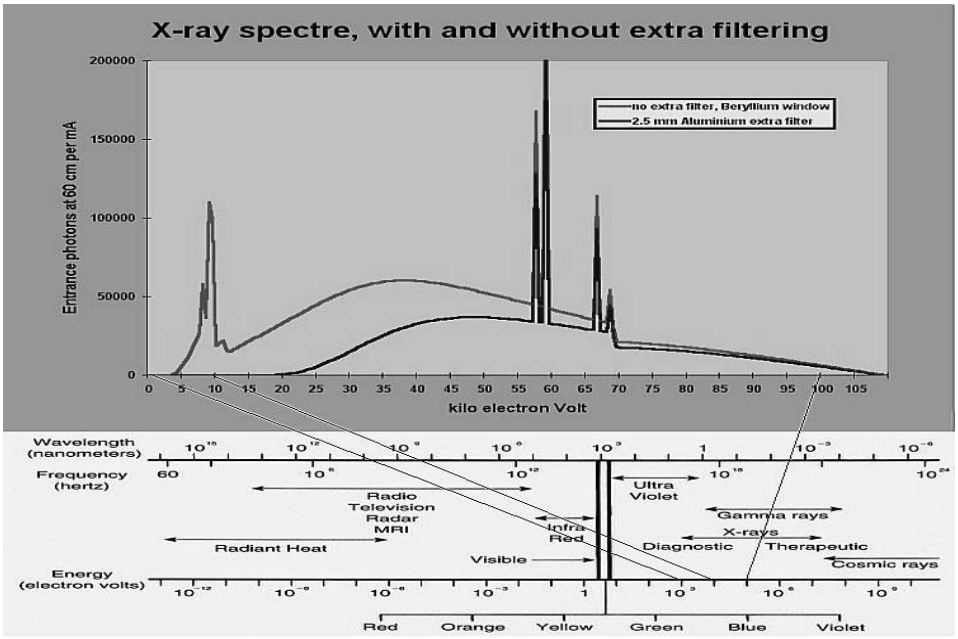

Figure 8. *The position in the EM spectrum of x-rays, ultra violet and visible light. Shown is an x-ray spectrum delivered by a tube with a Beryllium window with and without a filter of 2.5 mm Al.*

If a glass tube housing is used, the radiation spectrum, leaving the tube without a filter, contains visible and UV light. The photon energies (<3 kV) are non-ionizing and cannot be measured with x-ray spectra technology. Everyone who has looked (true a mirror or true lead glass) into a functional glass x-ray tube knows that the focal spot is visualized as a flashing white spot and one can also see the red hot anode.

Bohr described in his atom model (3) that one must, creating breaking radiation or "bremstrahlung", count on the creation of photons in the energy range from infrared to x-rays. (diagram 5)

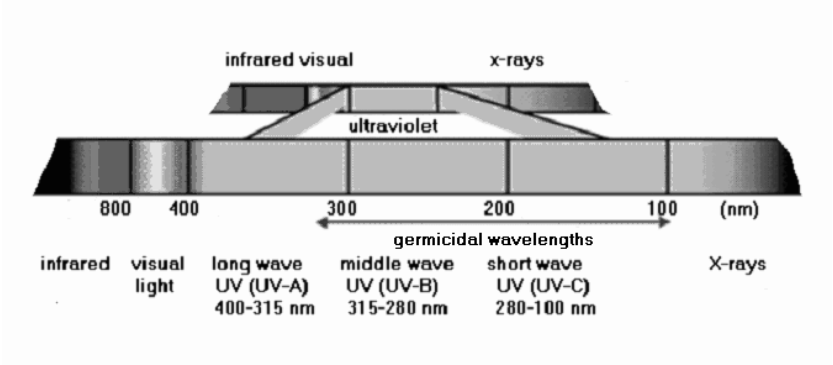

Diagram 5. *The quality of photons created in an x-ray tube, from infrared, visual light, ultraviolet to x-rays.*

Nowadays we know the region which is called ultra violet radiation can be subdivided into three parts, the UV-A, UV-B and UV-C regions. Each region has its own physical characteristics and will harm the skin in a different way.

For the Caucasian skin, UV-A (400-315 nm) causes pigmentation, UV-B (315-200 nm) causes sunburn and erythema, UV-C (280-100 nm) and x-rays have germicidal power and are most damaging to the skin.

In cardiology the x-ray tubes do have an obligatory filter of at least 2.5 mm Al, blocking all UV radiation. Photo 1 shows a skin defect caused by fluoroscopy with a radiation time of one hour; this is only possible if a glass tube is used without filtering, so UV radiation can reach the skin and/or if a very short distance to the focal spot is used.

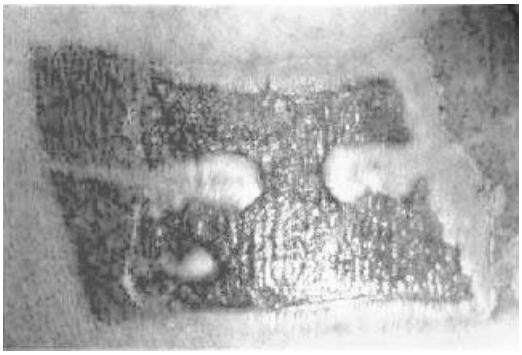

Photo 1. *Skin burn after one hour fluoroscopy*

Skin types

Concerning Ultra Violet Radiation, there is great variation in the human skin to tan, as a result a classification of sun skin types has been developed, see table 2.

Type 1	Fair hair and skin. Never tan, always burn (highest risk of damage). Severe sunburn within minutes (high radio sensitivity). Prevalence to premature aging.
Type 2	Fair skinned, not as sensitive as type 1. Always burn, sometimes tan.
Type 3	Darker, sallow skin. Sometimes burn, always tan.
Type 4	Never burn, always tan.
Type 5	Pigmented skin (Asiatic).
Type 6	Black African and Caribbean peoples.

Table 2. *Classification of skin types concerning sun burn.*

Concerning x-rays and skin sensitivity there are fewer differences in the skin types. This is explained by the ionizing character of the radiation.

In the studies, mentioned on next page, the described skin type is predominately the caucasian skin, type 2. (One of 10.000 Caucasians has a skin classified as type 1)

What is the maximal dose to the skin?

The first skin injury due to x-ray radiation was reported in 1896.

In the same year, Edison's assistant, Clarence Dally, described hair loss and inflammation and ulceration of his scalp. He suffered from severe radio dermatitis, resulting in the amputation of his arm and his subsequent death in 1904.

Elihu Thomson, a well-known American physicist, deliberately exposed his finger and described burning, Scott reported this, together with another 69 patients with skin injuries, in 1897 (8). Early radiologists did not realize the danger of daily exposure to the x-rays. They daily gauged the strength of tubes, testing the "hardness" of the x-ray tube by placing a hand between the tube and the fluorescent screen, performed demonstrations, positioned and studied patients during therapy and they even calculated an "erythema dose" on their own hands.

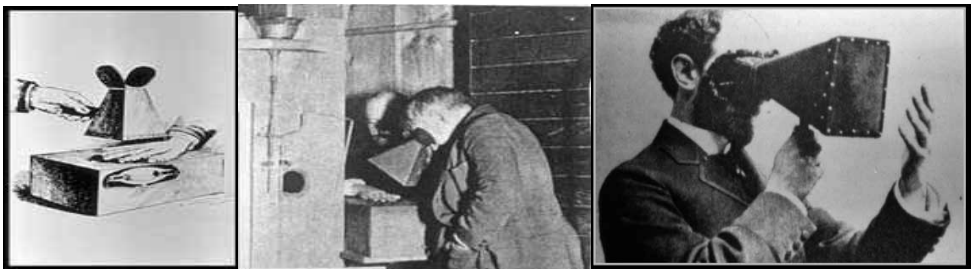

Photo 2. *Hand-held fluoroscopy was a common source of exposure in the 1890's.*

When it became obvious that x-ray radiation was harmful for the skin and possibly for more body parts, one came to the conclusion that the time spend in radiation should be maximized. A college of wise men produced a set of rules for radiologists to protect themselves; suggesting that the regulatory placing of the hand between the tube and the fluorescent screen was dangerous.

In the 1920's the maximal allowable dose for professionals was indicated in Skin Erythema Dose units (SED).

A SED was a dose strong enough to produce reddening of the skin 10 to 14 days after exposure. The erythema dose was thought to be about 600 R, or 6 Sievert.

In 1925 the maximal allowable personnel dose limit was reduced from 1/10 SED to 1/100 SED per day and 5 R per day on hands, see table 3.

In 1928 the limits were lowered to 1/1000 SED per month. At this moment, the year 2003, the maximal personnel dose is 20 mSv/yr, the extremities are allowed to receive 200mSv/yr, which is a factor 2500 lower than the 1925 norm.

Table 3 shows the history of the maximal dose limits to professionals. (9)

History maximum dose limits

	1/10th of the skin erythematic dose (SED) per day 1 SED=200R	20 R/day
1925	1/10th of the SED per year, Mutcheller, Sievert	0.2 R/day
1926	1 SED in 90.000 working hours, Dutch Board of Health	0.04 R/day
1928	1/1000th SED per month and 5 R/day on hands, Kaye	0.15 R/day
1928	0.00028 of an SED/day, Barclay and Cox	0.175 R/day
1931	Limit exposure 0.2R/day, X-ray and Radium prot. comm. USA	0.2 R/day
1936	0.1 R/day, X-ray and Radium prot. comm. Advisory USA	0.1 R/day
1941	0.02 R/day, Taylor	20 mR/day
1943	0.2 R/day is acceptable, Patterson	200mR/day
1959	5 rem/year, 5(n-18) rem accumulated, NCRP	20 mR/day
1987	50 mSv/year, NCRP (1 Sv=100R)	0.2 mSv/day
1991	20 mSv/year, NCRP	0.08 mSv/day
2000	20 mSv/year, Euratom	0.08 mSv/day

Table 3. *In the year 2003 the maximum dose limit is 1/2500 of the 1925 value.*

Photo 3 shows the hands of Mihran Krikor Kassabian, an x-ray pioneer.

He published Röntgen rays and electro-therapeutics, with chapters on radium and phototherapy by J.B. Lippincott in Philadelphia, 1907. He was a charter member of the American Roentgen Society, later becoming its vice president, he meticulously noted and photographed his hands during progressive necroses and serial amputations, hoping the data collected might prove useful after his death at the age of 40.

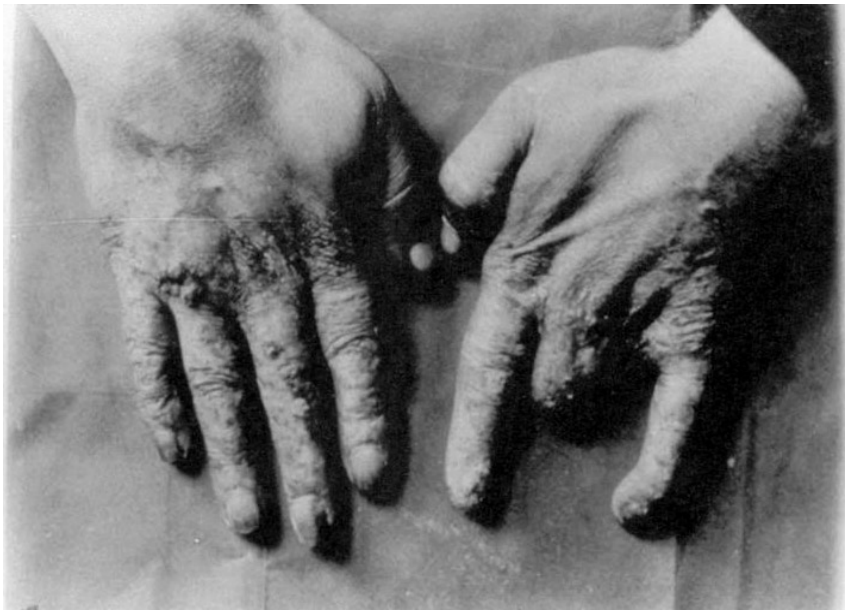

Photo 3. *Hands of Mihran Krikor Kassabian (1870-1910), an x-ray martyr. (Courtesy of American College of Radiology)*

In experiments performed in Paris in the 1920s and 1930s, rams could not be sterilized with a single dose of x-rays without extensive skin damages. When radiation was delivered in daily fractions over a period of time, sterilization was possible without skin damage, see photo 4. Multifraction radiotherapy was introduced. (10)

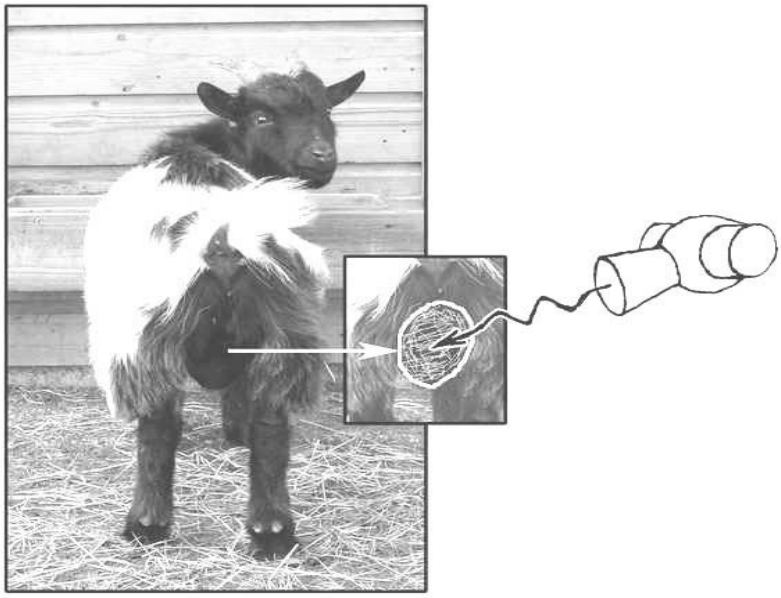

Photo 4. *Finding the maximum dose to the skin, the testis of rams were regarded as a model of a growing tumor. The skin was regarded as normal tissue for finding the dose limiting factor. (Photo by Paula C Delfos ©)*

In these experiments a radiation quality of 120 kV was used and filtering showed less damage to the skin (Thoraeus filtering).

They proposed a maximum of about 2 to 3 Gray per fraction.

Nowadays, the ortho-voltage x-ray radiotherapy is no longer applied and high energy electrons are used. With some added build-up material at the skin, the highest dose to the skin of 2 to 3 Gy per fraction is still valid.

The skin erythema dose of 6 Gy, used in the 1920s, could be found within a day when open tubes were used, this indicates the ultra violet components, the vacuum UV, created in the glass tubes played an important role in the skin reddening.

Radiobiology

Whatever the biological reaction to radiation may be, minimizing the radiation dose will always minimize the reaction and less damage will be the result.

If the cellular metabolism is lower the induced damage shall be less, probably by the formation of fewer free radicals or oxygen radicals.

Recently it was proven that patients who had undergone radiotherapy with a hypothermic skin at the radiated area had significant less hair loss at the skull. Less skin damage was also seen at the breast in a study of 220 women. (11, 12)

Free radical production

X-ray photons have the capability to “shoot” electrons out of an atom; this ionization causes free electrons and atoms with unpaired electrons which causes an instable electron configuration. This induces a high reactivity with the surrounding molecules, especially with oxygen radicals; this reacts in making super oxide, known as free oxygen radicals or reactive oxygen species (ROS).

The cellular metabolism of oxygen generates potentially deleterious reactive oxygen species, including super oxide anion, hydrogen peroxide and hydroxyl radical. Under normal physiologic conditions, the rate and magnitude of oxidant formation is balanced by the rate of oxidant elimination. (13, 14)

An imbalance between pro- and anti oxidants results in oxidative stress and pathogenic outcome.

There is growing evidence that increased oxidative stress and associated oxidative damage are mediators of cellular injury (15), so this must be valid for the skin as well.

The lower the oxidative stress, the less cell damage that should be expected. This is of considerable interest as therapies targeted against reactive oxygen may be useful in minimizing injury.

During pulsed fluoroscopy fewer free radicals are produced than during continuous fluoroscopy, while the dose is lower and the time of radiation is shorter.

This could be an explanation for less skin injury using pulsed fluoroscopy; the radio biological efficiency of the dermis is lower.

This is another reason for not exposing the patient to non image forming photons.

Clearly the cells in the skin will benefit most from a reduction in the generation of reactive oxygen.

Various skin types, Caucasian, Asiatic and African show other sun and ultra violet radiation sensitivity, but almost identical x-ray radiation sensitivity during radiotherapy.

The production of free radicals caused by x-rays is skin type and color independent.

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Chapter 7

Dermal Sensitivity Measurements

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Dermal Sensitivity Measurements

Introduction

Searching for radiation injury and intervention or for radio dermatitis in PubMed-Medline of the National Library of Medicine and the National Center of Biotechnology Information, more than 250 reports related to skin damage due to lengthy fluoroscopy were published during the last decennium.

An overview of deterministic skin effects caused by radiation, according to the literature (1-14) is given in table 1. A detailed sequence of epidermal and dermal skin lesions in time after ionizing radiation is published by Hopewell. (15)

Effect	Threshold	Onset	Peak	Comments
Epilation				
Temporary	~3 Gy	~2 wks		New hair thinner
Permanent	~7 Gy	~2 wks		Protracted threshold ~50 Gy
Erythema				
Early & Transient	~2 Gy	hours	~24 hrs	Not an indication for later response
Main effect	~6 Gy	~10 days	~2 wks	Reddening ⇒ pigmentation
	>10 Gy			pigment may last for months
Desquamation & Ulceration				
Dry desquamation	~10 Gy	~4wks	~5wks	Healing 2 wks to mths, late atrophy
Moist desquamation	~15 Gy	~4wks	~5wks	Ulceration
Secondary	~20 Gy	<6wks		Secondary to sterilized basal cells Scarring

Table 1. *Summary of published radiobiological effects.*

Using an x-ray skin dose mapping monitoring system, as described in chapter 5 (15), we collected the data of 2284 patients. 620 diagnostic cardiac catheterizations, 1393 coronary interventions and 271 electro physiologic procedures, all performed in 2002/2003. One hundred and six (4.6 %) of these patients, all PCI procedures, received a local skin dose > 2 Gy. The highest dose was 6.1 Gy, shown in figure 1.

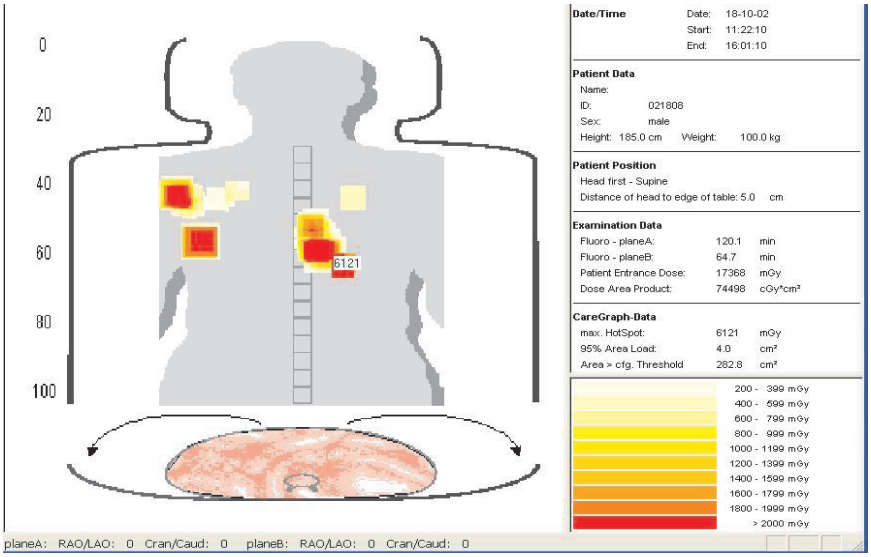

Figure 1. *The graphical result of a skin mapping dose system, showing the highest dose of 2284 studied patients. The procedure was a PCI. The patient, a male, 185 cm and 100 kg. Recanalisation and dilatations of LAD7, LCX12, and RCA4 including the placement of 5 stents. A procedure time of 4.5 hours, total 185 minutes fluoroscopy and 61 digital biplane cine runs (554 sec), both with pulse rates of 12.5 per second.*

The peak entrance dose distribution of the 2284 procedures is shown in table 2.

local skin dose in Gy	**0-0.5**	**0.5-1.0**	**1-2**	**2-3**	**3-4**	**4-5**	**5-6**	**6-7**	**>7**
number of patients	1252	642	284	71	16	11	5	3	0

Table 2. *Peak skin dose distribution.*

This distribution shows the same pattern as found in 2001 with a group of 322 patients which we published during the introduction of our dose mapping monitoring system, see chapter 5. We followed most of the patients in the >2 Gy group for a period of 6 months, none of those patients showed any deterministic skin effects as presented in table 1.

Radiation with x-rays using modern technologies can deliver lower doses to the patient and maintain sufficient time for the required procedures (17). Even so, our inventory displays that approximately 5 % of the patients still receive > 2 Gy.

Are modern technologies less harmful to the skin or do we use an other x-ray technique than the institutes who reported skin injuries?

The skin damages, as reported in Pubmed, are mostly incident reports, lacking questioning if this can be avoided with the use of better technology.

Studies concerning cosmetic effects are mainly performed to diminish these effects during radiotherapy. Skin sensitivity studies using diagnostic x-ray qualities and pulsed fluoroscopy are seldom performed. Could it be that we are referring to data, which have not been verified using diagnostical radiation quality?

To answer these questions we simulated a PCI on Yorkshire pigs to determine the radiation skin effects. To simplify this study we exclusively performed fluoroscopy and not the digital cine mode (DCM), as over 75 percent of the dose during PCI is caused by fluoroscopy. In our institute, we use extra filters; 0.2 mm copper (Cu) during pulsed fluoroscopy and 0.4 mm Cu filter during the DCM. The DCM skin dose (rate) in our institute is double, compared to pulsed fluoroscopy. (17)

Material and methods

Experiments were performed with Yorkshire pigs. According to radiobiological and dermatological criteria, a pig skin matches best with the Caucasian skin. (18)

In order to perform the experiments and to obtain approval from the Animal Ethical Commission, protocols were designed for the simulation of PCI procedures.

To prevent spontaneous movement of the animal during the radiation protocol, it was kept in a constant depth of anesthesia and was regularly monitored for corneal and pain reflexes. Using a gas mixture of isoflurane (2%), oxygen (70%) and nitrogen oxide (30%) no halothane was used as an anesthesia to avoid dermal vasoconstriction (19) and for the physical well-being of the pigs, the normal body and dermal temperature was maintained constant during the investigations.

The high skin doses, observed in our patients were correlated with long procedure times and the obesity of the patient and/or gantry projections that are required for penetration of thick or highly absorbent body masses.

Small image fields were consistently used and the maximal tube output was often used, similar to the high dose patient group. Therefore we performed fluoroscopy on the animals with an x-ray technique using the maximal tube output, quality 110 kilovolt peak (kVp), quantity 100 milli Ampere (mA), a pulse frequency of 12.5 per second (p/sec) and a pulse width of 14 milli seconds (ms).

By adding absorbent material between the pig and the detector, the maximal tube load was accomplished, thereby avoiding the discussion of which dose levels are needed at the detector for this experiment.

Skin reactions were studied independently by a dermatologist and a radiobiologist; the criteria were erythema, desquamation, hair density and necrosis, using standard classifications. (15)

At the end of the experiment the skin fields were biopsied and stored in 4 % buffered formalin for at least 24 hours, embedded in paraffin, for histology and examination. The specimens were stained with hematoxylin eosine as a routine stain and resorcine fuchsine for an elastin staining. The sections were reviewed blind and in a random order.

First measurement

We performed fluoroscopy on a Yorkshire pig (female, 32 kg and 10 weeks old). The distance from the skin to the focal spot was 70 cm.

Two fields were radiated, both sized 3 * 21 cm, one with a 2.5 mm Aluminium beam filter (skin doserate 121 mGy/min.) and the second with an extra copper filter, total value 2.5 mm Al + 0.2 mm Cu, giving a skin doserate of 52 mGy/min.

The ventral field was the extra filtered one. The two fields were separated by a 3 cm zone and used as control. The entrance beam size had a dimension of 9 * 9 cm^2, covering three fields of 3*3 cm^2 both in the dorsal and ventral area.

The animal was repositioned four times over a distance of 3 cm to divide the total length of the field in 7 blocks with different dosages. To simulate the reality of a PCI procedure, we performed fluoroscopy for 30 seconds and paused for 30 seconds, thus the overall time was double the fluoroscopy time, as shown in table 3.

Position	3	6	9	12	15	18	21	cm field length Y1a
Start	36	36	36					min investigation time
First reposition		36	36	36				min investigation time
Second reposition			72	72	72			min investigation time
Third reposition				72	72	72		min investigation time
Fourth reposition					144	144	144	min investigation time
Total investigation time	36	72	144	180	288	216	144	min
Total fluoroscopy time	18	36	72	90	144	108	72	min
Dose (121 mGy/min)	2.8	5.8	9.3	17.1	14.3	11.2	7.9	Gy (filter 2.5 mm Al)
Dose (52 mGy/min)	1.1	2.2	4.3	7.2	6.1	4.9	2.8	Gy (filter 2.5Al+0.2 Cu)

Table 3. *Summary of the investigation time, fluoroscopy time and the dose and distribution over the skin fields during the execution of the first measurement.*

The dose was measured with thermo luminescence dosimeters. This showed that, due to instability of the generator and the timer, the third and fourth position had some dose variations.

Results of the first measurement

During the first 2 weeks after exposure, the pig experienced irritation in the high dose fields; this was noticed as the animal tried to rub these skin parts against anything she could find. However this may also be due to the shaving and/or the tattooing we preformed to mark the fields. In a 12 weeks follow-up period no erythema or other deterministic effects were noticed.

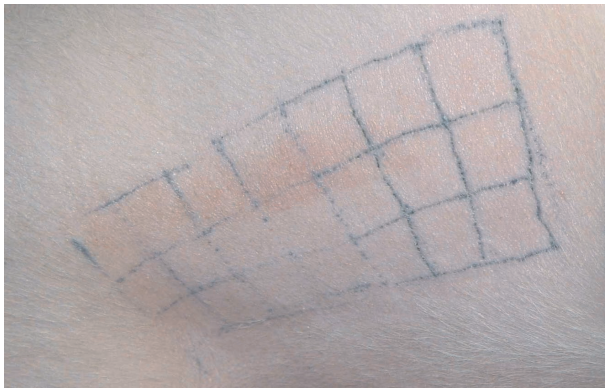

Photo 1. *Yorkshire pig's skin 2 weeks after radiation, showing 3 rows of 7 fields. Dorsal fields with the highest dose, up to 17.1 Gy, the ventral fields with extra filtering, max.7.2 Gy. Parts of the skin are red, due to rubbing.*

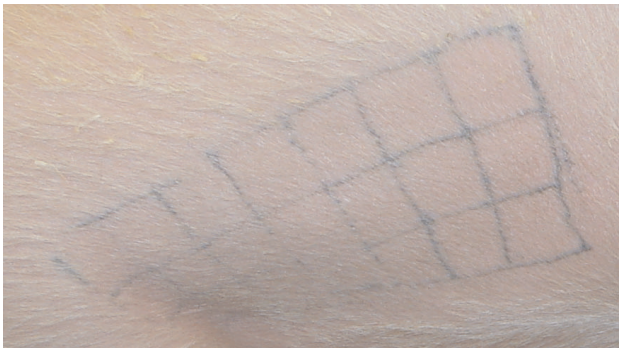

Photo 2. *Yorkshire pig skin 12 weeks after radiation, no skin effects visible.*

When no radiation effects in the irradiated fields were noticed after 8 weeks, we decided to perform a second, higher dose experiment on the same animal.

Second measurement

Anesthetic procedures were identical as described for the first experiment. To avoid discussion of a radio sensitized skin, the radiated skin fields were chosen at the same, left flank on the abdominal side. To enable skin effects, we extended the investigation time, although a total procedure time of 6 hours and 3 hours fluoroscopy on the same skin area with the maximal tube load is extreme.

We changed the focal spot to skin distance to 50 cm. This doubled the doserate (240 mGy/min and at the extra filtered part 105 mGy/min). We changed the pulse frequency to 25 p/sec, as this is used in centers who reported skin damage. As the tube current, switching from 12.5 to 25 p/sec. was halved; the higher pulse frequency did not mean a higher doserate. The entrance beam size was 7.5 * 10 cm^2.

A similar protocol as used for the first measurement was followed; we moved the pig 2.5 cm caudal four times, as shown in table 4.

Position	**2.5**	**5**	**7.5**	**10**	**12.5**	**15**	**17.5**	**20**	**cm field length**Y1b
Start	**36**	**36**	**36**	**36**					**min. investigation time**
First reposition		**36**	**36**	**36**	**36**				**min. investigation time**
Second reposition			**72**	**72**	**72**	**72**			**min. investigation time**
Third reposition				**72**	**72**	**72**	**72**		**min. investigation time**
Fourth reposition					**144**	**144**	**144**	**144**	**min. investigation time**
Total investigation time	**36**	**72**	**144**	**216**	**324**	**288**	**216**	**144**	**min.**
Total fluoroscopy time	**18**	**36**	**72**	**108**	**162**	**144**	**108**	**72**	**min.**
Dose (240 mGy/min)	**4.2**	**8.7**	**17.5**	**27.2**	**42.1**	**33.8**	**26.9**	**16.9**	**Gy (filter 3.0 mm Al)**
Dose (105 mGy/min)	**2.2**	**4.5**	**8.9**	**13.4**	**21.4**	**17.5**	**13.2**	**8.6**	**Gy (filter 3Al+0.2 Cu)**

Table 4. *The dose distribution at 16 skin areas during a 5.5 hours investigation.*

See photo 3 for the positioning of the fields

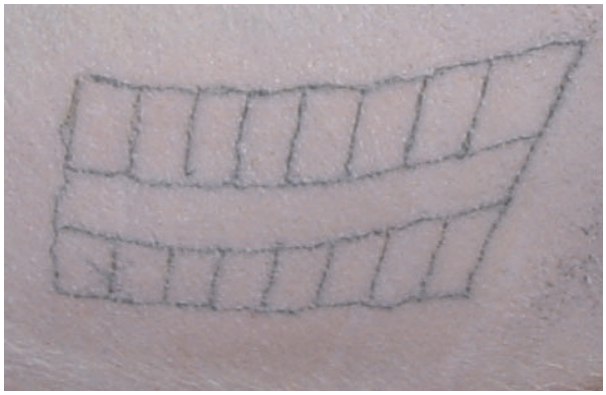

Photo 3. *Yorkshire pig skin, showing the 2 rows of 8 fields. Dorsal row with the highest dose 4-9-17-27-42-34-27and 17 Gy, beneath the unirradiated control stroke the extra filtered beam gave doses of 2-4-9-13-21-17-13 and 9 Gy.*

Skin effects second measurement

During the first 2 weeks after radiation there was irritation, the pig wanted to rub her skin, especially there where a dose >30 Gy was received. After 4 weeks the fields radiated with a dose higher than 30 Gy of the non-extra filtered beam showed some light erythema. Compared to the shaved but non radiated area of the skin, the control area, the skin felt more rugged, see photo 4. Eight weeks after radiation, the fields which received a dose >30 Gy, showed desquamation, see photo 4.

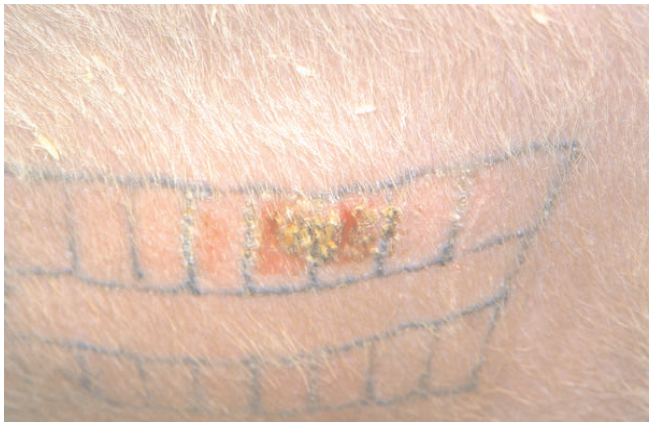

Photo 4. *Eight weeks after radiation, the fields >30 Gy (without extra filter) showed dry desquamation.*

This desquamation was healed two weeks later and a light erythema remained visible, see photo 5 and 6.

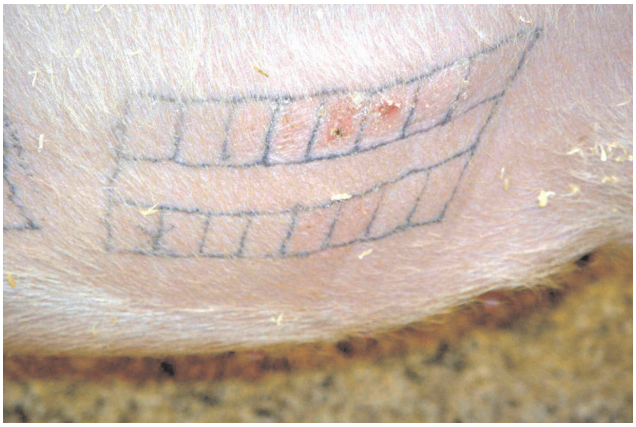

Photo 5. *Nine weeks after radiation, the desquamation shows healing, a light erythema at the highest doses (>20 Gy) and new hair growth was thinner in the fields which received >20Gy.*

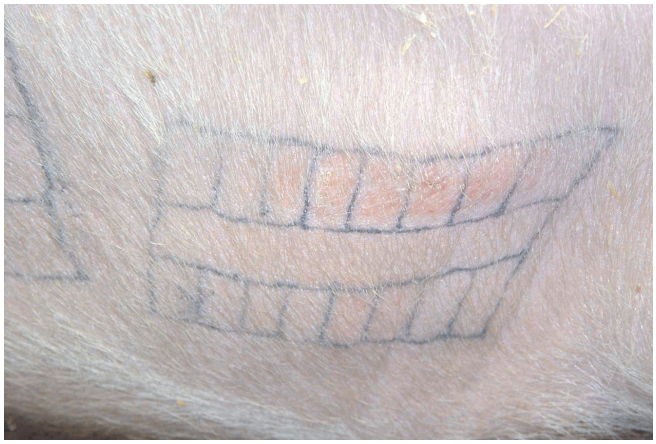

Photo 6. *Ten weeks after radiation, the desquamation has healed, thehair grow was less in the highest dose fields. he lower, extra filtered, field showed no reaction.*

We shaved the skin before the radiation. New hair growth at the areas which received a dose > 20 Gy in upper fields without extra beam filtering was thinner.

The skin fields radiated with the extra filtered beam did not show any erythema nor did they differ to touch in roughness from the control area.

Results of the fist and second measurement

The effects do not match with the expectations as given in table 1, skin subjected to >20 Gy should have shown an ulceration after 8 weeks.

Would we have seen these effects if we had used larger fields?

The measurement was done with pulsed fluoroscopy, 25 p/sec. Will the skin be more susceptible when higher pulse rates or continuously fluoroscopy is used?

Third measurement

We performed a third experiment with a second pure Yorkshire pig (female, 28 kg, 8 weeks old) in one of our interventional labs and compared pulsed and continuous fluoroscopy. Both techniques were used with the maximal tube output, 110 kV.

Realistic investigation times, based on clinical experience, were used (15, 15, 30, 30 and 60 min.). Two fields were radiated, one with the standard (2.5 mm Al) filter and one with an extra (2.5 mm Al + 0.2 mm Cu) filter, separated by a control area.

Fluoroscopy was performed in blocks of 30 seconds, followed by a 10 second pause.
The entrance beam size was 9 * 9 cm^2 and the focal spot to skin distance 60 cm.
Due to the small size of the animal, we had to use both flanks of the animal, realizing the outgoing radiation could radio sensitize the contra lateral flank.
The left flank was radiated with the continuous technique, the right flank with a grid switched pulse technique, both with the standard and extra filtering.
The same protocol was used as during the first two experiments, giving an effect in 7 fields in 2 rows, as presented in table 5.

Position	**3**	**6**	**9**	**12**	**15**	**18**	**21**	**cm field length** Y 2
Start	**15**	**15**	**15**					**min. investigation time**
First reposition		**15**	**15**	**15**				**min. investigation time**
Second reposition			**30**	**30**	**30**			**min. investigation time**
Third reposition				**30**	**30**	**30**		**min. investigation time**
Fourth reposition					**60**	**60**	**60**	**min. investigation time**
Total investigation time	**15**	**30**	**60**	**75**	**120**	**90**	**60**	**min.**
Total fluoroscopy time	**11.2**	**22.5**	**45**	**56.2**	**90**	**67.5**	**45**	**min.**
Continuous (0.23 Gy/min)	**2.8**	**5.4**	**10.8**	**13.3**	**21.3**	**16.0**	**10.6**	**Gy (filter 2.5 mm Al)**
Continuous (0.11 Gy/min)	**1.4**	**2.7**	**5.4**	**6.6**	**10.6**	**8.0**	**5.3**	**Gy (filter 2.5Al+0.2 Cu)**
Pulsed (12.5 p/s 0.23 Gy/min)	**2.7**	**4.8**	**10.4**	**13.0**	**20.9**	**16.3**	**11.0**	**Gy (filter 2.5 mm Al)**
Pulsed (12.5 p/s 0.11 Gy/min)	**1.3**	**2.4**	**5.7**	**6.5**	**10.4**	**8.1**	**5.5**	**Gy (filter 2.5Al+0.2 Cu)**

Table 5. *Protocol and dose comparison pulsed and continuously fluoroscopy***.**

Skin effects after continuous fluoroscopy

The upper fields at the left flank were radiated with the continuous technique and a 2.5 mm Al filter. This gave erythema after 20 days in the areas where the investigation time was >60 min, dose >10 Gy. After 90 days there was still erythema in the fields which were treated with >75 min, dose >13 Gy. After 29 days a wound, due to rubbing around the tattoo appeared in the highest dose fields. There was desquamation at 35 days, which healed after 1 week (16 Gy), but did not heal after 21.3 Gy and continued into dermal necrosis. Hair loss (>50%) appeared at week 4 after doses >10.8 Gy and was permanent. The continuous technique with extra beam filtering at the ventral fields, showed milder reactions; erythema at areas which were treated >75 min (>6 Gy).
There was less than 50% hair growth in the >60 min. treated area (>5.3 Gy), and there was no desquamation. The peak effect appeared after 35 days in the non extra filtered, dorsal fields, see photo 7.
Due to encrustation the optical peak effect seems to be later in this photo.

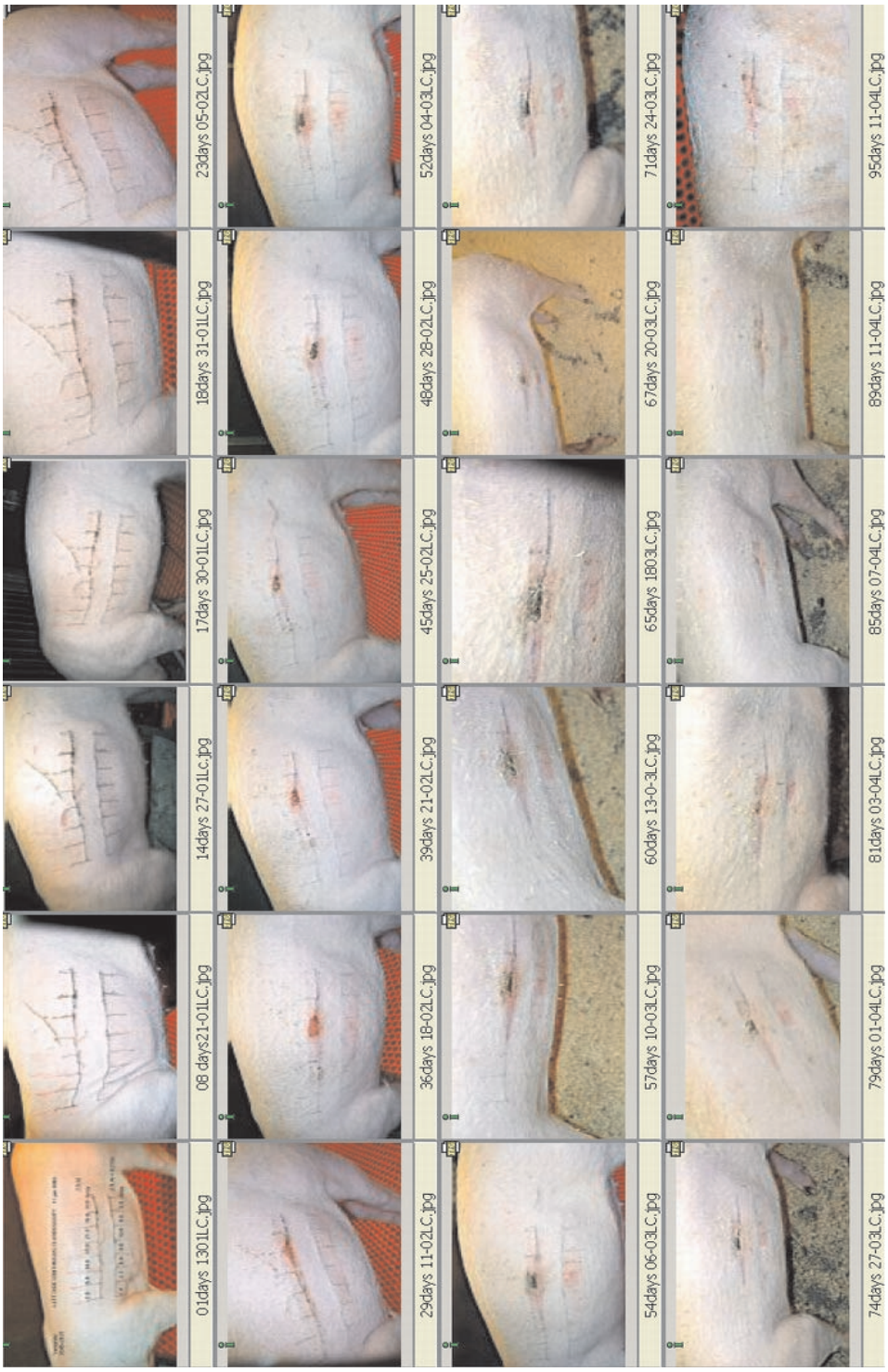

Photo 7. *Skin responses over a period of 13 weeks after continuous fluoroscopy*

Skin effect after pulsed fluoroscopy

The right flank of the animal, with the pulsed technique radiated skin fields and without extra beam filtering, developed erythema 50 days after treatment in areas which were investigated for 75 min. with higher doses (>13 Gy).

Diminished hair growth was seen in the fields, treated >60 min (> 10.4 Gy). Only after the highest dose of 20.9 Gy did desquamation develop. Due to rubbing, the skin was damaged at the tattoo on the maximal treated area after 60 days.

The pulsed technique with extra beam filtration showed the mildest reaction, transient erythema at areas which we treated >120 minutes (~10 Gy) and diminished hair growth (<50%) was seen after doses of 5.5 Gy. Dosages <8 Gy did not show any skin effect, apart from a reduced hair growth. Using pulsed fluoroscopy, the peak reaction appeared after 50 days for those fields treated without extra beam filtering, see photo 8.on next page.

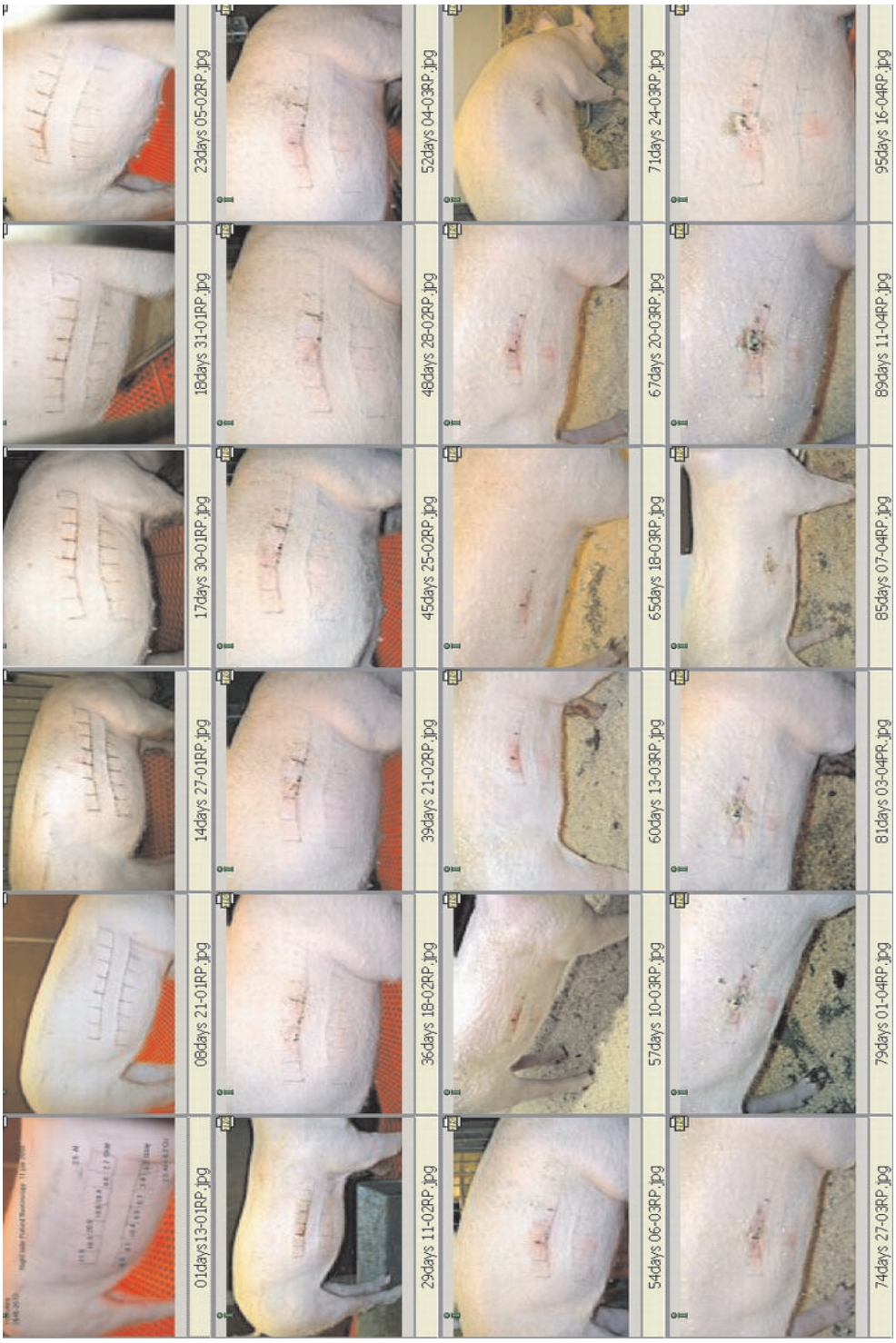

Photo 8. *Skin effects over a period of 13 weeks after pulsed fluoroscopy.*

Results of the third and forth measurement

The effects do not match the expectations as given in table 1.

Keeping in mind that the doserate at the skin during patient treatment is normally less than half used during this animal experiment, this experiment could explain why we did not see any deterministic effects in the high dose patients.

Using the pulsed technique and extra beam filtering, the damage to the skin is milder, the threshold is higher and peak onset time seems to be later than the effects mentioned in table 2. The measurements indicated that some effects could be initiated by inflammation of a tattoo and shaving of the skin apparently caused some itching and subsequently some rubbing of the skin causing some additional damage.

For this reason the protocol was slightly changed.

Fifth measurement with changed protocol

To exclude the possible effects of shaving and tattooing a third Yorkshire pig (a female, 20 kg, 6 weeks old) was treated. The tattoos were placed outside the radiated area and the skin was not shaved. Anesthesia was identical to the description of the first animal. We only performed pulsed fluoroscopy with extra filtering, the standard technique as used for patients, on the left flank of the animal.

The beam size at a skin was 9*12 cm and the focal spot to skin distance 60 cm.

The animal was repositioned 4 times 3 cm caudally and once 6 cm abdominally, resulting in 18 radiated skin fields of 3*3 cm, ten fields with different fluoroscopy times, ranging from 11 to 146 minutes.

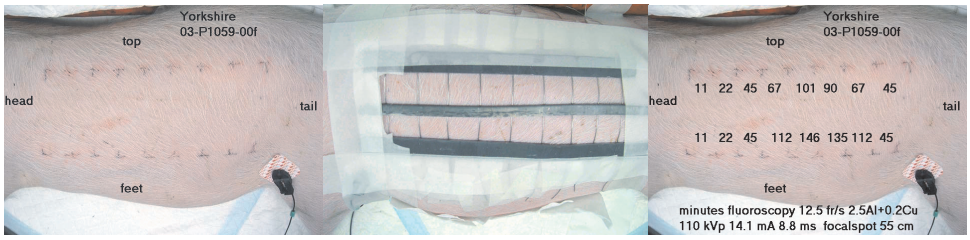

Photo 9. *Tattoos placed outside the radiated field, tattoos and control area extra shielded with lead, the skin was not shaved.*

The investigation time was more than 4 hours; the total fluoroscopy time was 146 minutes, using the maximal x-ray tube output, 110 kV, 14.1 mA, 8.8 ms, 12.5 p/s.

Again a PCI was simulated, fluoroscopy sequences of 30 seconds, followed by a pause of 10 seconds, the doserate at the skin was 83 mGy/min. giving a dose of 12.1 Gy at the longest radiated skin field, as can be seen in table 6 and photo 10.

Position	**3**	**6**	**9**	**12**	**15**	**18**	**21**	**24**	**cm field length** Y3
Start	**15**	**15**	**15**	**15**					**min. investigation time**
First reposition		**15**	**15**	**15**	**15**				**min. investigation time**
Second reposition			**30**	**30**	**30**	**30**			**min. investigation time**
Third reposition				**30**	**30**	**30**	**30**		**min. investigation time**
Fourth reposition					**60**	**60**	**60**	**60**	**min. investigation time**
Total investigation time	**15**	**30**	**60**	**90**	**135**	**120**	**90**	**60**	**min. upper field**
Total fluoroscopy time	**11.2**	**22.5**	**45**	**67.5**	**101**	**90**	**67.5**	**45**	**min. upper field**
Fifth reposition 12*3 cm only at lower field				**60**	**60**	**60**	**60**		**min. investigation time**
Total investigation time	**15**	**30**	**60**	**150**	**195**	**180**	**150**	**60**	**min. lower field**
Total fluoroscopy time	**11.2**	**22.5**	**45**	**112**	**146**	**135**	**112**	**45**	**min. lower field**
Dose pulsed upper field	**0.9**	**1.9**	**3.7**	**5.6**	**8.4**	**7.5**	**5.6**	**3.7**	**Gy (filter 2.5Al+0.2Cu)**
Dose pulsed lower field	**0.9**	**1,9**	**3.7**	**9.3**	**12.1**	**11.2**	**9.3**	**3.7**	**Gy (filter 2.5Al+0.2Cu)**

Table 6. *Protocol simulating pulsed fluoroscopy during an extensive PCI, dose over 18 skin fields divided, 10 fields received different dosages and had different investigation times.*

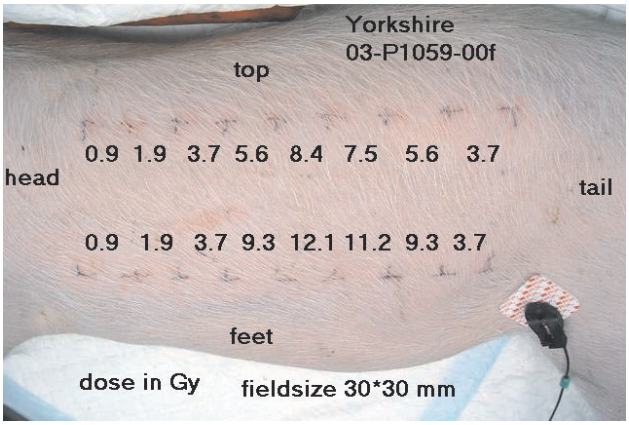

Photo 10. *The dose at the skin, using extra filtered beam quality with a doserate of 83 mGy/min.*

Using the maximal tube output during 146 minutes fluoroscopy on the same skin field is very unlikely during a PCI in the clinic, the treatment time needed to do so is too long for both the patient and investigator.

Skin effects of the fifth measurement

After 6 weeks a mild transient erythema and a <50% hairloss was found at the areas which were exposed to fluoroscopy of greater than 67.5 minutes (>12.3 Gy). (photo 11)

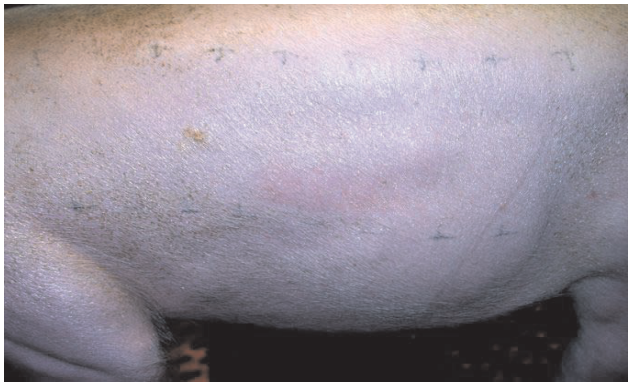

Photo 11. *After 6 weeks, light mild erythema at area's, >67.5 min. fluoroscopy, these area's received a dose >9.3 Gray.*

After 8 weeks the erythema was no longer visible, however the 50% hairloss remained, see photo 12.

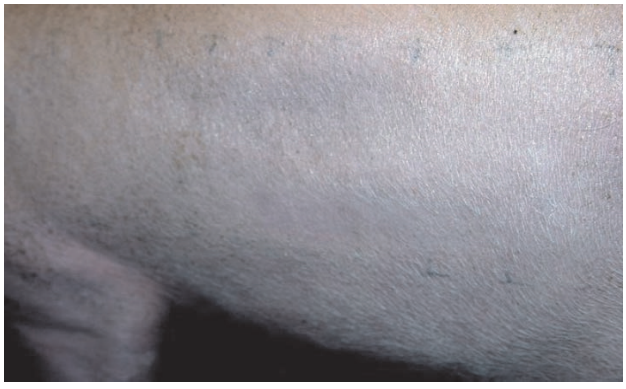

Photo 12. *Eight weeks after fluoroscopy 50 % hairloss was the remaining effect at the>100 minutes fluoroscopy area's.*

Histopathology

Once assessment of the skin responses was finished all irradiated fields were biopsied for histological investigation.

The results showed no changes in the epidermis and dermis, nor oedema, particularly no vascular changes, in all fields radiated with pulsed fluoroscopy and extra beam filtering, the technique used in our clinic.

Discussion

Pig skin is comparable to human skin, but we have to keep in mind that the skin of juvenile pigs was used in this study

The skin of our patients is older and it could be assumed that repair mechanisms are less efficient with age.

In this experimental study we described the effects of continuous and pulsed fluoroscopy using small entrance fields.

However, during a PCI, in the clinic the entrance fields are larger. The entrance field sizes used in these measurements match the size of the "hotspots", caused by overlapping fields, as measured in our patient's skin with a dose mapping system.

With electro physiologic investigations of patients, larger fields with fixed gantry settings are being used, thus this type of treatment does not spread the dose over a large skin area and, moreover, the patient population is older, therefore more severe effects and less or a slower healing could be expected.

However, due to the larger entrance fields, using image intensifiers, the entrance dose (rate) is lower. Not a single electro physiologic procedure performed in the group of 271 procedures, showing skin dosages >2 Gy. It is very unlikely that the reported incidents of severe skin lesions are due to high radio sensitivity of the patients.

Therefore the most probably explanation for the injuries reported in table 3 is the use of outdated technology without extra beam filtering, which can be changed by using modern equipment.

Some injuries, seen in patients, are caused by using very short focal spot to skin distances; which can be classified as malpractice and is one of the reasons why, at least in the European Community, additional training is obligatory for clinicians working with radiation.

Some manufacturers of fluoroscopic equipment have made provisional arrangements for automatically removal of the extra filter, provided there is a lack of tube output.

This should be prohibited, as it mainly contributes to a higher entrance dose and does little to better the image, as described in chapter 6, the section tube output and photon usage for imaging.

Conclusion

The measurements clearly demonstrated that the combination of high output x-ray tubes with extra beam filtering and pulsed (high doserate) fluoroscopy, with low pulse frequencies is less harmful to the (epi)dermis than the previously used continuous (low doserate) fluoroscopy.
Comparing identical examination times and a technique with and without extra beam filtering, indicated that with the extra filtering fewer less skin effects developed.

Extra beam filtering prevents that x-ray energies in the lower energy range, which do not contribute to imaging, are entering the skin, and is therefore an (entrance)dose saving and a skin-sparing technique.
Most of the skin damages, as described in the literature (5-8) are caused by the use of continuous fluoroscopy and fluoroscopy without extra beam filtering and/or are due to short skin to focus distances.
The deterministic skin effects after radiation, as published in the last decennium (2-15) and summarized in table 1, are not seen if one uses grid switched pulsed fluoroscopy with a high output tube, combined with a beam filter (2.5 mm Al and 0.2 mm Cu) and if the patient's skin is positioned at a distance of more than 55 cm from the focal spot.
During PCI long fluoroscopy times are sometimes unavoidable.
In our setting it is very unlikely that a patient's skin will be harmed, even with very long procedure times and with repeated PCI it is practically impossible to deliver a dose to the skin above 10 Gray.
Based on the animal study and our findings with patients, we expect no macroscopic skin damage when the total dose delivered is lower than 8 Gray.
In our clinical settings, it is practically impossible to deliver to our patients a dose > 8 Gy, using the highest tube output during three hours fluoroscopy at the same skin area.
In table 6 the findings are summarized.

Main findings

Effect	Threshold Fluoroscopy - Dose time	Peak	Comments Pulsed fluoroscopy, 12.5 pulses per sec. Filtering 2.5 mm Al + 0.2 mm Cu. Focal spot to skin distance >=55cm. Maximum doserate at skin 0.15 Gy/min. Maximum kilovoltage 110.
Erythema			
Transient	150 min - ~ 8 Gy	50 days	Healing in a few days
Main effect	>150 min - ~10 Gy	50 days	
Epilation			
Temporary	150 min - ~ 8 Gy	50 days	Density new hair is lower
MORE SEVERE EFFECTS ONLY POSSIBLE WITHOUT EXTRA BEAM FILTER			
Permanent	*>150 min - ~10 Gy*	*50 days*	
Desquamation			
Moist	*>160 min - >30 Gy*	*60 days*	
Necrosis Fluoroscopy time and dose needed to induce this are not realistic, while only found in presented experiments after doses >16 Gy, an estimation of >4 hours fluoroscopy without extra beam filtering			

Table 6. *Summary of deterministic effects versus fluoroscopy time and dose. Using maximal tube output and the entrance beam at the same skin area. Dosages in italic are not likely to be reached with the pulsed and extra filtered beam techniques currently used.*

It must be said, that removing the extra filter shall double the dose, using higher pulse frequencies can also double the dose(rate) as well as short distances from skin to the tube. With the same fluoroscopy time, the combination of these three factors can take care of a dose(rate) which can be increased by a factor ten or even higher.

Follow-up

In order to optimize the fluoroscopic technique, further research is needed.

Is the epidermis capable to recover from radiation damage during the time in between the pulses? Is cell recovery from radiation damage better if low frequency pulsed fluoroscopy is used?

If so, this is an extra reason to use low pulse frequencies, and an argument to use non mechanical, ECG driven, pulse timed fluoroscopy.

Recommendation

X-ray guided interventions should only be performed using modern, high output, x-ray tubes with extra filtering and grid switched fluoroscopy using low pulse frequencies and a focalspot to skin distance > 55 cm.

Especially when performing interventional procedures, requiring long fluoroscopy times, extra beam filtering and pulsed fluoroscopy are recommended.

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Chapter 8

Radio sensitivity of Human Keratinocytes

Introduction
Pilot experiment
Materials and methods
Preliminary findings
Discussion
References

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department of cardiology of the Erasmus Medical Centre Rotterdam.

Introduction

Writing this chapter was a dilemma for the author. Setting up a cell line took about one year, when the cell cultures were usable, a few experiments failed due to infection. At the moment I had to deliver the final text for this thesis we had too few data for a scientific presentation.
What to do? Forget this item or write down an incomplete study?
We decided, taking in to account the amount of work that was performed, to present the preliminary and far from complete data as a pilot study. Research is continuing; the author estimates that an other year is needed to complete the study. Readers with great interest are always welcome to ask us about the progress

In this chapter the attempt is discussed to find a correlation between cell radio sensitivity and the use of fluoroscopic techniques with different pulse to pause ratio (PPR). In order to measure whether the cell behavior is different when the same dose is given during pulsed fluoroscopy with other pulse frequencies, we started a pilot study testing adult normal human keratinocytes.
Is less damage to the skin caused by the influence of the effectiveness of cell repair?
Is there a possible preconditioning mechanism in the cell with regard to radio sensibility? Is there cell repair within milliseconds?
If so, a more efficient fluoroscopic pulse technique could be developed.
This is the argument to measure under identical physiological conditions with the same radiation qualities, dosages and fluoroscopy times, but with different pulse frequencies, the surviving curves of human keratinocytes.

From numerous studies (1), using the Linear Quadratic (LQ) model it is known that cell survival is better if less dose or less dose tempo is given, see figures 1 and 2.

It is also proven also that changing the oxygen level, the temperature or other metabolism variations influence the survival rate (figure 3).

Fractionated radio therapy shows a dramatic skin saving effect; this effect is confirmed in cell survival studies (figure 4).

In the previous chapters it is shown that not only the dose, but also the quality of the x-ray radiation plays a role in the entrance dose to the patient. Different qualities of radiation or differences in Linear Energy Transfer (LET), in kilo electron Volt per micro meter (keV/µm) given to cell cultures proved to give a non linear Relative Biological Effect (RBE), (figure 5).

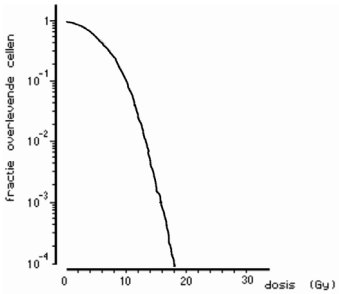

Fig. 1 the LQ model

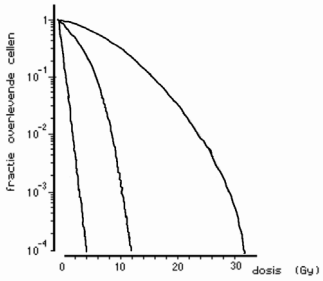

Fig. 2 Tempo variations

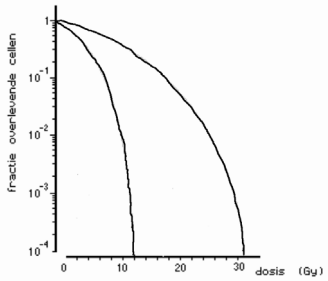

Fig. 3 Oxygen variation

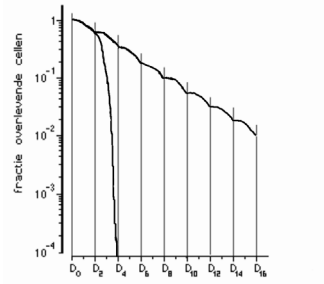

Fig. 4 Fractionating

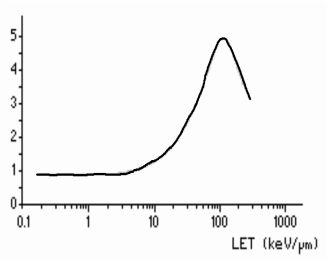

Fig. 5 Radiation quality

Materials and Method

Relevant cell line

Adult normal human epidermal keratinocytes (Cambrex, Bio Whittaker) were seeded, left to adhere and cultured in Keratinocyte Growth Medium KGM-2 (Cambrex, Bio Whittaker) in a density between 2,500 and 5,000 cells/cm^2. Flasks were placed in a routine cell culture incubator at 37^oC, 95% air humidity and 5% CO_2 in air. Fresh medium was supplied every 3rd days after initial cell adherence.

When cultures reach 70% confluence they were washed twice with HEPES buffered saline solution and subsequently detached from the substrate with 0.25mg/ml trypsin/EDTA (Cambrex, Bio Whittaker).

The cell suspension was harvested and washed by centrifugation. The amount of cells in the resulting pellet was counted (CDA-500 particle-counter, Sysmex) and a cell dilution prepared of 4000 cells/ml in KGM-2 medium.

All wells in two 24 well multi plates were each accurately filled with 0.5 ml of this suspension resulting in 2000 cells/well. Cells were left in the incubator adhered and spread were ready for experimenting.

Transport to the radiation laboratory

As a control group, cells of the identical parental cell-line and age was treated in an identical manner behold the radiation element.

Radiation setup

During fluoroscopy the cells were kept in their initial 24 multi well plate at 37^{o} C indirectly warmed by a temperature controlled water bath placed on top of the investigation table. The gantry was turned up side down, placing the x-ray tube overhead, and the focal spot to the cells distance was 60 cm see, photo 1.

Photo 1. The setup during fluoroscopy

The used x-ray technique was the maximal tube output, reached by adding absorbent material between the image intensifier and the radiated object (pieces of an old protective lead apron in the white envelope). The x-ray quality was 110 kilo Volt (kV), quantity 14.3 milli Ampere (mA) during continuous fluoroscopy. The used beam filter was 2.5 mm Aluminium (Al) and 0.2 mm Copper (Cu).

The dose tempo at the cell cultures was 106 milli Gray per minute (mGy/min). By placing 4 mm thick lead strokes between the beam and the cultures and by shifting the tabletop, different dosages were given per row of four wells of the 24 well plate.

At the right side in the water bath, the non radiated control group is visible.

Keratinocyte cell counting

Post experimental phase cultures remained in routine cell culture conditions thereafter and media were refreshed every 3rd day. Once the control group has become totally confluent both the latter and the experimental groups were subjected to total cell harvest counting. All wells were washed twice with HEPES buffered saline solution and subsequently loosened from the well with 0.5ml 0.25mg/ml trypsin/EDTA (Cambrex, Bio Whittaker). Each individual disaggregated cell suspension was collected, the well rinsed with 4.5ml cell pack counting solution (Sysmex) and both pooled resulting in a 5ml counting sample enough for a triple measurement. Countings were performed (CDA-500 particle-counter, Sysmex) with aperture 100 μm and range 3.0-12.0 μm in vacuum mode.

Pilot findings

Three experiments were needed for dose finding and to get an indication which time was best for counting the cells. (AB00, AB01 and AB02)

The forth experiment (AB03) we measured the LQ curve for continuous fluoroscopy, followed by pulsed fluoroscopy (AB04). During the 3 weeks period after radiation, the AB04 cell group showed infection, the data was lost. The sixth experiment (AB05) we measured again continuous fluoroscopy to see if the results were repeatable, see figure 6.

To measure the LQ curve for pulsed fluoroscopy we performed the seventh experiment (AB06), using 12.5 pulses per second (p/s) with a pulse time of 8.8 milli second (ms). Again we lost this last measurement due to infection and no data were usable. To measure differences between different pulsed fluoroscopy techniques, we used three techniques, 25, 12.5 and 6.25 p/s. Using the pulsed fluoroscopy technique with 12.5 p/s, the time between the pulses is 80 ms, with a radiation pulse time of 8.8 ms, the pulse to pause ratio (PPR) is 8.8 to 71.2 (1 to 8.09).

The PPR using 25 p/s is 8.8 to 31.2 (1 to 3.55). Using 6.25 p/s the time between the pulses is 160 ms, with a pulse time of 8.8 ms the PPR is 151.2 to 8.8 (1 to 17). However, selecting 6.25 p/s the x-ray generator automatically halved the beam current and doubled the pulse time to 17.8 ms, giving a PPR of 1 to 8.09.

To obtain the same dose per second, the radiation intensity was doubled with the 25 p/s technique and halved with the 6.25 p/s technique by changing the distance from the x-ray tube to the cells. Using 6.25 p/s the distance was 42 cm, 12.5 p/s this was 60 cm and with 25p/s, 84 cm. The dose tempo at the cells was for each technique 106 mGy/min.

From a paired comparison, the values for the cell fraction surviving 5.0 Gy (SF5) of the keratinocytes were measured.

Using 25.0 p/s, a PPR of 1 to 3.55, the SF5 was 0.55 (AB07), using 12.5 p/s, a PPR of 1 to 8.09 the SF5 was 0.70 (AB07b) and using 6.25 p/s. a PPR of 1 to 8.09 the SF5 was 0.73 (AB07a).

The result of this pilot experiment is graphically shown in figure 6.

The variation from both continuous LQ curves can be explained by the weeks between the experiments and the use of different cell families.

The three SF5 measurements were performed with the same cell family and under identical physiological conditions.

The expectation of the LQ curve from pulsed fluoroscopy (who both failed) is to be less sensitive, a curve to the right, crossing the SF5 points.

Seeing the first results from the SF5 fraction, we did get exited about the variation.

The radio sensitivity of human keratinocytes seems to follow the PPR of the fluoroscopic technique; the radiation induced damage decreased slightly using larger PPR's.

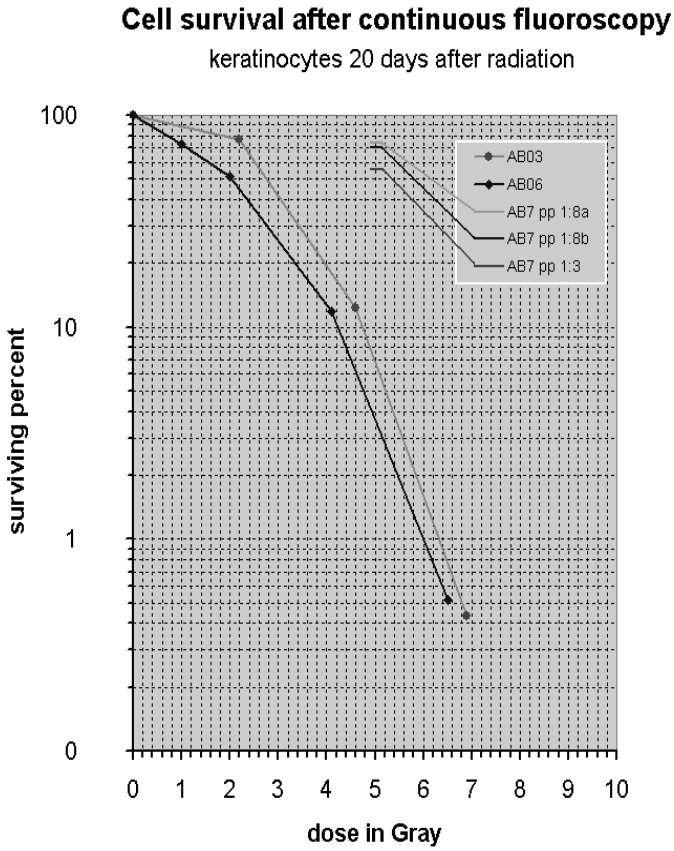

Fig 6. Cell survival findings of the pilot study.

.Exp AB03 continuous fluoroscopy
110 kV, 14.3 mA at 60 cm, filter 2.5 mm Al.
Twenty four wells batch with 2000 cells per well.
Plating efficiency (PE) 50%.
Counting cells after 20 days.
Thousand cells in the control group, after 20 days 656.666, the 9th doubling; 2.2 day doubling time.
Cell number composed after a triple count.
Control 656.666 +/-24.8889 cells (24 wells)
0 Gy 657.666 +/- 9.778 cell counts (3 wells)
2.5 Gy 321.999 +/- 17.332 cell counts (6 wells)
4.6 Gy 79.316 +/- 4.322 cell counts (6 wells)
6.9 Gy 2.853 +/- 382 cell counts (3 wells)
Equals a SV of 100%, 48.8%, 12.0% and 0.43%

Exp AB06 continuous fluoroscopy
110 kV, 14.3 mA at 60 cm, filter 2.5 mm Al.
Twenty four wells batch with 2000 cells per well.
Plating efficiency (PE) 50%.
Counting cells after 20 days.
Thousand cells in the control group, after 20 days 590.000, the 9th doubling; 2.2 day doubling time.
Cell number composed after a triple count.
Control 590.000 +/- 20.624 cells (24 wells)
0 Gy 582.000 +/- 21.228 cell counts (3 wells)
1.0 Gy 426.333 +/- 18.855 cell counts (3 wells)
2.0 Gy 297.667 +/- 38.856 cell counts (3 wells)
4.1 Gy 67.670 +/- 1.966 cell counts (3 wells)
6.5 Gy 3.006 +/- 366 cell counts (3 wells)
Equals a SV of 100%, 73%, 51%, 11% and 0.4%

Exp AB07 survival fraction 5 Gy
Control 404.833 +/- 17.653 100 %
PPR 1:8a 298.500 +/- 16.039 SV=73.7%
PPR 1:8b 284.500 +/- 19.792 SV=70.3%
PPR 1:3 223.667 +/- 7.695 SV=55.2%

Further studies are needed to determine the relationship between the radio sensitivity of keratinocytes and the used x-ray technique in order to estimate the relative biological efficiency and different PPR's.

Discussion

In chapter 4 and 5 a discussion is given about patient skin injuries caused during PCI.
In chapter 6 it is suggested the reason was not enough schooling, some investigators performed malpractice, that wrong x-ray techniques and/or outdated machinery was used.
In chapter 7 the results are given of animal experiments. From these experiments it is proven t hat pulsed fluoroscopy with extra filtering leads to less skin injuries than continuous fluoroscopy.
From these cell experiments, although real conclusions cannot be drawn, it seems to be that cells are able to repair themselves within short time periods.
Further cell experiments are necessary to come to the real conclusion that cells have a repair mechanism that reacts in milliseconds.
When data are available about repair times, then the PPR's of x-ray machines for intervention procedures can be derived, using the ECG as a trigger, mechanical pulse frequencies, based on the cine camera speed should be extinct anyway, and the industry can develop machines using techniques which are less harmful for the skin.

Suggestions for further research

X-ray generator software changes to enable us to measure larger PPR differences and the possibility to adjustment the beam current for identical doserates, with normal focal spot to cell distances.

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Chapter 9

Radiation Safety Considerations

Introduction

Room Shielding

Sources and Limits

Personnel Dose Reduction

Scattered radiation

Tube leakage radiation

X-ray beam collimation

Protection

Patient Dose Reduction

Registration and Monitoring

Detector Dose Settings

Biological Risks, Risk Perception

Cancer risks and risk perception

Heart and lungs

Breasts

Haematopoietics and gonads

Thyroid

Eyes

Skin

Pregnancy

Summary

Ergonomics and Perception

Expertise, Competency and ALARA

References, Reports, Organizations and Nomenclature

Ad den Boer Thoraxcenter Rotterdam.

Chapter in book Cardiac Catheterization and Percutaneous Intervention by I.P. Kay, M. Sabate and M.A. Costa by Martin Dunitz 2004. (in press)

Radiation Safety Considerations

Introduction

Radiation safety in an interventional laboratory starts with the planning and building of the department.

During the construction protection measures must be build in.

People working in the investigation room will receive radiation from 2 sources, the patient (scattering) and the x-ray tube (leakage and scattering).

Using modern equipment, the x-ray beam can not be larger then the used detector size, the personnel can not be in contact with the primarily radiation.

Personnel dose reduction can be achieved by lengthening the distance to the x-ray beam, shortening the radiation time, using shielding and protection devices and by extra collimation.

Patient dose reduction can be achieved by the use of modern techniques, pulsed fluoroscopy with extra beam filtering and extra collimation.

Entrance radiation monitoring can be used to avoid patient skin damage; registration of used radiation to optimize the procedure and the detector dose settings can be adjusted, keeping in mind the ALARA principle.

The biological risk for investigators and patients, as well as the ergonomics, perception and level of expertise are described in following sections.

Room Shielding

In cardiological X-ray equipment the beam is restricted to the intensifier or detector size even when the collimator is fully opened, direct radiation is unable to enter the room. This is why the investigation room needs only to be shielded for secondary, scattered, radiation.
Depending on the distance to the wall, a 0.25 mm shielding of lead should be adequate to meet the regulations, however 2 mm shielding is advised by most suppliers, while the costs are not much higher and the possibility to change the room into a standard diagnostical x-ray unit, shielded for primary radiation, remains.
In most lintervention rooms the location of the patient on the examination table is determined by the isocenter; the place of the (scattering) radiation source is known.
This enables the room to be built such that lead shielding in doors may not be necessary, provided they do see the source.
Taken into consideration that there is no secondary backscatter in the diagnostical range, shielding may end 210 cm above the floor.
Windows between the investigation- and control room may be fitted with lead glass; however this is manufactured in limited sizes and is expensive.
In the Thoraxcenter we have 18 mm float glass between the investigation- and control room up to a height of 210 cm, creating an opening between the ceiling and wall to facilitate better acoustical communication. (1)
The amount of room shielding depends on the quality of the radiation, the absorption of used material and the distance to the source.
Most published data concerning shielding are calculated with the assumption that direct radiation with a radiation quality of 125 kV enters the room.
The half-value layer (HVL) from material for direct radiation depends on the radiation quality. For two qualities (125-70 kVp) this is, in mm, for Lead 0.31-0.13, Concrete 20-14, Steel 3.3-1.0, Gypsum wallboard 58-30, Plate glass 19-12, Brick 24-14 and Barium plaster 4.1-1.1. (1)

In practice, for the scattered radiation qualities in the intervention room, one might use as a rule of thumb the density of material, to compare the shielding effect. (table 1)

Material	kg/dm^3	Material	kg/dm^3	Material	kg/dm^3
Mercury	13.5	Water	0.998	Aluminum	2.70
Copper	8.96	Iron	7.87	Lead	11.36
Concrete	1.5-2.4	Brownstone	3.4	Plaster	2.32
Glass normal	2.6	Glass flint	3.1-3.9	Granite	2.6-2.7
Sand	1.6	Street stone	1.5-2.0	PMMA	1.2

Table 1. Density of different building materials

The radiation safety department can perform calculations about the needed shielding, the calculations must take into account the workload in the room.

Sources and Limits

The primarily x-ray beam is restricted to the detector size; direct radiation cannot enter the room. If the personnel in the room receive radiation, this is exclusively caused by scattered radiation.

In our intervention rooms we performed several measurements. One can see the patient as a scattering radiation source with a doserate of 100 μSv/hr at one meter distance from the isocenter, as a standard for cardio logical investigations.

Using this source and the total working load in a year the total doserate per year can be calculated. Based on these calculations shielding can be designed as according to law there are prescribed limits for those in the surroundings of the intervention rooms. The maximal dose outside the room may not exceed 1 mSv/yr, outside the building 0.1 mSv/yr.

Any member of the population may not receive a dose >0.1 mSv/yr, this dose limit is unlawful for patients during investigation; he/she has at that moment an exceptional position and is not seen as a member of the population. For personnel inside the room the dose limit is 20 mSv/yr.

Additional shielding between the patient and the investigator is for personnel protection reasons, a must in interventional laboratories; see the section on protection further on in this chapter.

Personnel Dose Reduction

Scattered radiation.

The radiation levels, using digital cine mode (DCM) are approximately 5 times higher than during fluoroscopic imaging. The use of flat panel technology shall show comparable radiation levels with DCM and fluoroscopy, at this moment the flat panel technology requires high dose levels for fluoroscopy compared with vacuum image intensifiers with video chains.

A small Source to Image Distance (SID) requires the smallest dose.

The larger the Field of View (FOV) image size, the lower the dose, however the patient's own absorption of scattered radiation using large fields is less, giving a higher occupational dose.

Using flat panel technology, the FOV is not adjustable.

Extra collimating always reduces doses for patient and operator.

Scattered radiation levels from 0.2 to 4 mGy/hr at investigators place are reported. (2)

Per diagnostic procedure the investigator may receive a dose of 0.1 to 1.5 mGy, depending on the distance to the patient and the gantry angulations.

The use of an extra screen between the investigator and patient may reduce the head/neck dose by a factor 10. (3)

In practice in the Thoraxcenter in Rotterdam the scattered radiation levels at the investigators cornea are <1 mSv/hr (using 12.5 fr/sec. pulsed fluoroscopy, standing at the right side of the patient), see the figure 1 on next page, in which three fluoroscopic techniques are compared.

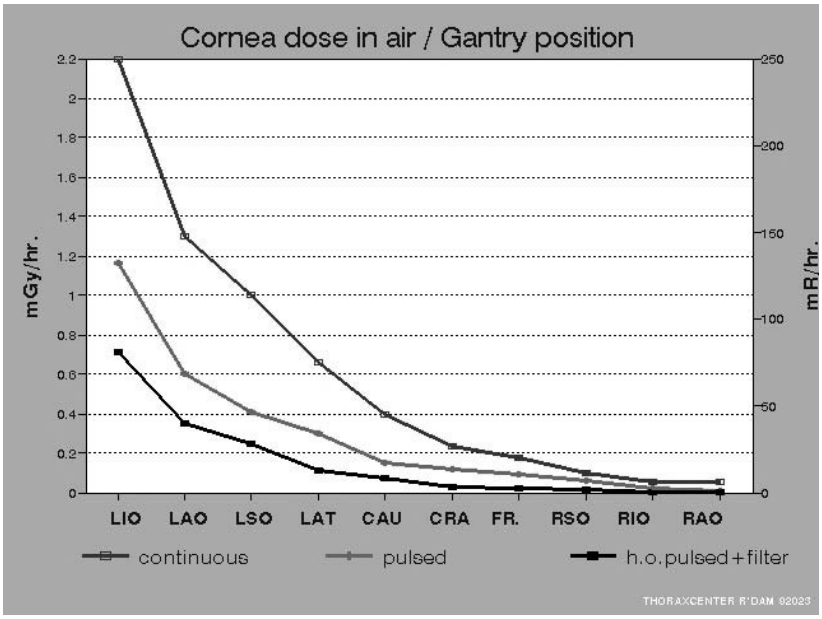


Figure 1. *Scattered radiation levels measured during continuous fluoroscopy with a 300 W/s tube, pulsed fluoroscopy with a 660 W/s tube and high output (3600W/s) grid switched tube with pulsed fluoroscopy and extra beam filtration.*
LIO indicates left inferior oblique; LAO, left anterior oblique;
LSO, left superior oblique; LAT, lateral; CAU, caudal; CRA, cranial;
FR., frontal; RSO, right superior oblique and RAO, right anterior oblique.

Using the maximal dosages indicated on the personal dosimeters (years 1996 to 2000) in the Thoraxcenter Rotterdam, the calculated dose received by an interventional cardiologist, based on 150 working days per year and 4 interventions per day is maximum 60 mSv/yr.
The effective dose, wearing a special procedure apron (0.25 mm Pb. equivalent), a thyroid protector and regularly using an extra screen between the patient and investigator is < 5 mSv/yr.

Tube leakage radiation

By law and regulation (4) the x-ray tube leakage radiation level of 1 mSv/hr may be measured at 1 meter distance from the focal spot during fluoroscopy with the maximal tube voltage and the maximal allowed continuous current.
Modern tubes are capable to work with a continuous current >30 mA (3600 Watt/s).
All tubes used in cardiology meet these specifications and have much lower values than "allowed", however during intervention the physician often stands only 10 cm from the tube. At this distance the radiation level may theoretically be 0.1 Sv/hr, everyone will agree that this is too high. Radiation levels >0.2 mSv/hr measured close to the tube (in the same order as scattering from the patient), are not exceptional.
The allowable leakage radiation norms should be much less for tubes used in a room where personnel need to stand adjacent to the tube during the investigation.
While modern tubes are externally cooled, there is (from a heat capacity point of view) no reason not to add extra shielding and there is no objection for the extra weight of shielding from a mechanical point of view as well, as mechanically balanced gantries without motorized movement do not exist anymore.
In my opinion the industry should take care that at the surface of the tube and collimator the maximal leakage level is <10 μSv/hr.
Extra shielding (diagram 1) with lead flaps mounted under the table to avoid extra dosage from tube leakage radiation is not necessary if the tube leakage is <10 μSv/hr.

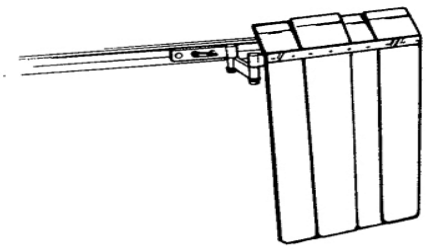


Diagram 1. *An extra shielding mounted on the table.*

A simple test can be performed to verify if there is noticeable tube leakage radiation.
Place a film against the tube (photo 1), perform 10 minutes of fluoroscopy with maximal tube load (place an amount of material between tube and intensifier until maximal output is reached) and have the film processed. (photo 2).
If there is leakage radiation visible on the film, ask the radiation safety department to quantify the radiation level and add extra lead. (photo 3)

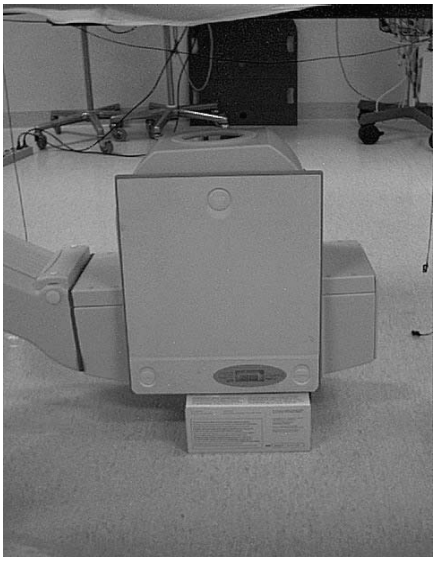


Photo 1. *Placement of a film cassette against the tube*

Photo 2. *Radiation visible on film*

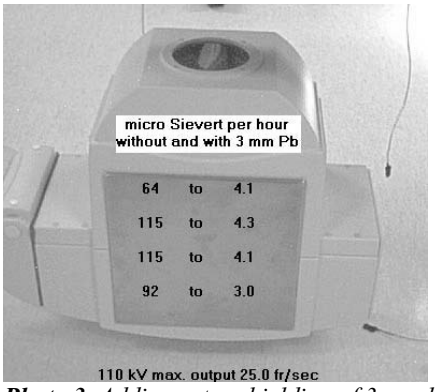


Photo 3. *Adding extra shielding of 3 mm lead shows >95% leakage radiation reduction.*

X-ray beam collimation

There are requirements regarding regulations for the collimator of the x-ray beam. (5)
The purpose of these requirements is to limit the x-ray beam to the image intensifier, thus for safety reasons, and to keep the amount of patient tissue being exposed to x-rays equal to the region being imaged.
If the collimator blades are set too wide for each FOV, additional patient tissue will be unnecessarily irradiated. The requirements state that the x-ray beam must be restricted to (not larger than) the image intensifier phosphor size or detector size when the collimator is fully opened.
The conditions are met if the collimator blades are visible on the monitor during fluoroscopy.
Changing to a smaller FOV on the image intensifier must implicate that the beam size automatically becomes smaller.
Changing to a larger FOV shall automatically result in a wider beam size. Disabling of this function is dose saving. In case one has to widen the beam size manually, this will result in a beam as large as necessary and not as large as possible.
Extra collimation is not only dose saving for patient, but also for the operator as less tissue is radiated and less scattering shall occur. The patient is the first absorber of the scattered radiation and more tissue around the radiated part shall absorb scattering.
Extra collimation increases the image quality while decreasing scattered radiation that creates grey fog on the detector.
Modern collimators are provided with a built in ionization chamber, measuring the Kerma[1] Area Product (KAP), the amount of radiation delivered during investigation. Due to different gantry settings the KAP value is not an indicator of the patient entrance dose.
With the use of this dosimeter, the geometrical gantry- and patient position a system is developed which can monitor the actual entrance dose to avoid possible skin damage due to radiation, see also chapter 5. (6)

[1] Kerma = Kinetic Energy Released in MAtter.

Protection

Lead aprons, used in the interventional rooms, must provide circumferential shielding. Special procedure aprons wrapped around the person in order to provide 360 degrees protection are advised.

For an optimal protection a correct fit is essential, oversized armholes and a low collar decreases the efficiency of protection.

Using special procedure aprons, an equivalency of 0.25 mm lead is sufficient; the front is double, giving a 0.5 mm protection at the sternum and gonads.

Careful handling of the aprons is important; the best way to achieve this is to provide personnel with their own apron (stitch on names), tailored for a correct fit. The added hygienic advantage is obvious; nobody likes to work with somebody else's sweaty wet apron. An apron needs cleaning, it may be cleaned in the shower and the in and outside brushed.

New composite materials such as Xenolite, Ergolite etc. are lighter in weight, lessening the weight on shoulders and back. The use of a lumbar support belt can reduce 50 percent of the weight on the shoulders, as does the use of two-piece aprons.

Lead equivalency and attenuation of scattered radiation. (1,7)

0.25 mm-70 kV= 97%, 105 kV= 90%
0.35 mm-70 kV= 98%, 105 kV= 94%
0.50 mm-70 kV= 99%, 105 kV= 97%

To calculate the effective dose one has to know which body parts are protected and the tissue-weighing factor, see the next table.

Gonads 20	Bone Marrow 12	Lung 12	Colon 12	Stomach 12
Liver 5	Breast 5	Bladder 5	Oesophagus 5	Thyroid 5
Bone Surface 1	Skin 1	Remainder 5	All together 100 %	

From this list the first 9 parts (read horizontally, the gonads up to the oesophagus) are protected using a special procedure apron, the effective dose is 100-88 or 12%.

If a thyroid protector is used as well; the effective dose is 5 percent lower; 100-93 or 7 %.

To protect the eyes, leadglass spectacles and helmets can be used; however in normal circumstances this is not needed.

Further protection can be obtained by using an extra screen between the patient and the investigator, a very efficient way to protect the head and neck area.This screen (photo 4), can dramatically reduce the investigators head/neck dose.(2)

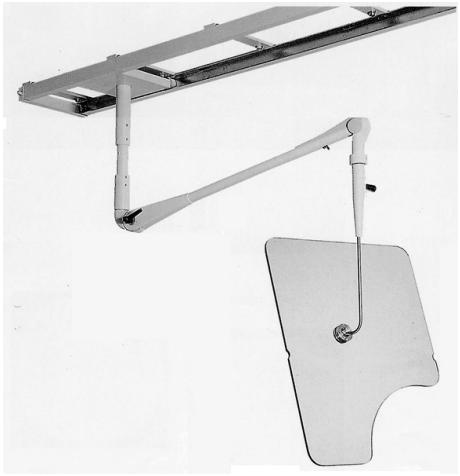


Photo 4. *An extra screen to be placed between the investigator and patient.*

Measuring the scattered radiation dose per procedure, we found that >75% of the investigator dose is received from the left projections, see figure 2.

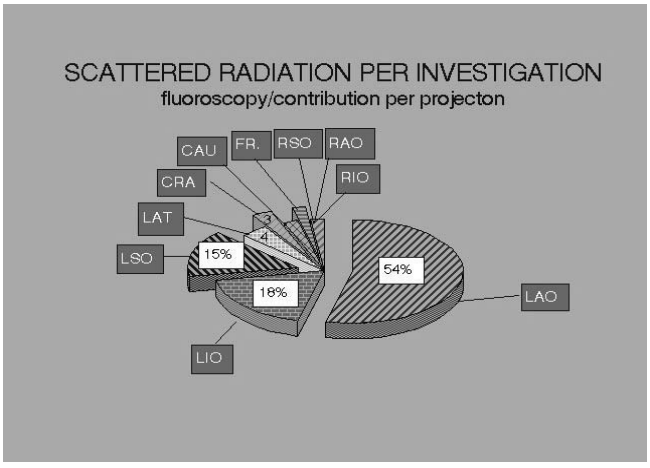


Figure 2. *Scatter diagram, used projections.*

Using left gantry settings an extra screen can be placed between the investigator (standing on the right side of the table) and the patient, resulting in dramatical dose reduction to the head and neck area (figure 3).

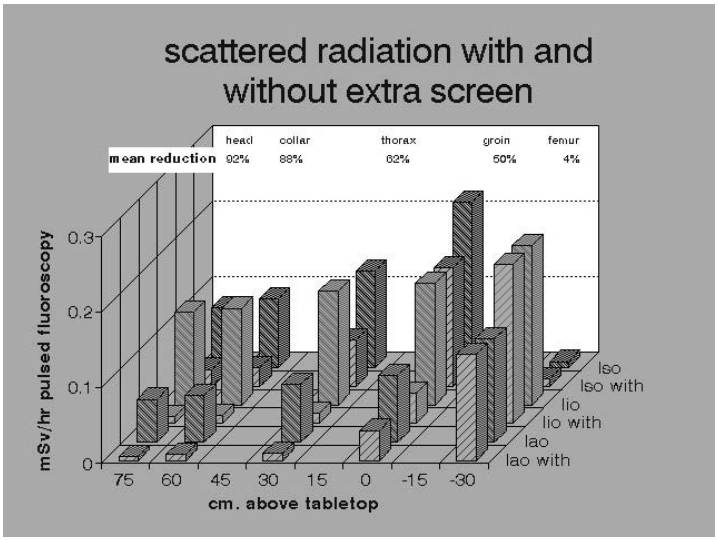
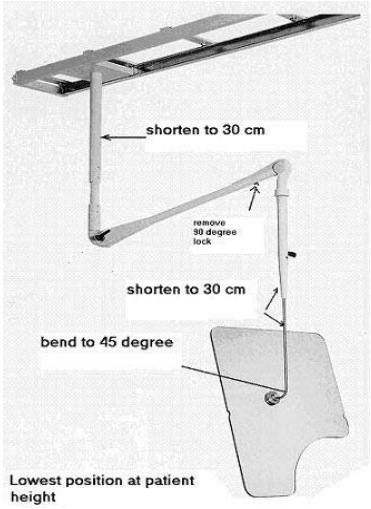
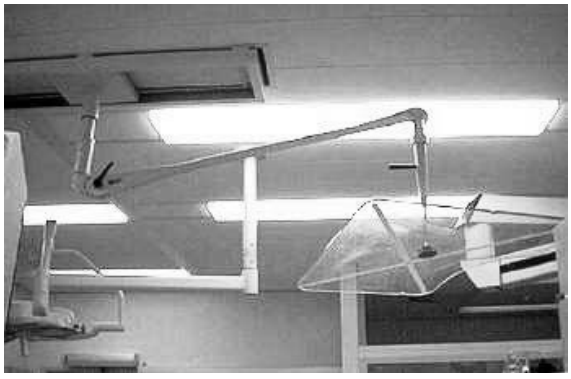


Figure 3. *Scattered radiation levels without and with the use of an extra screen, a major dose reduction.*

Some times the extra screen is not used, the reason; it is stored at a remote area, which is difficult to reach. We modified the screen in such a way that it can be parked overhead and it is still easily accessible, see next two photos.





Patient Dose Reduction

By governmental requirement the maximum x-ray tube output during fluoroscopy is 87 mGy/min. (10 R/min) at 75 cm distance from the focal spot. (8)
In practice the patient skin is placed at 60 cm distance, the maximal doserate is here 136 mGy/min. (15.6 R/min).
The shorter the distance to the focal spot, the higher the doserate. The industry placed distance holders at the tube while it happened that the arm of the patient was placed against the tube. At 35 cm the doserate is >43 Gy/min, in only a short time it is possible to give a patient a very high dose and a deterministic skin effect.
This is one of the reasons why radiological training is obligatory for investigators administrating radiation, such short skin to tube placement should be entitled as malpractice.
At 75 cm distance an x-ray tube with a cooling capacity of 300 watt/s (100 kV, 3 mA) delivers an output during fluoroscopy much more than 87 mGy/min.
The industry is obligated to use a tube filtration of at least 2.5 mm aluminium (Al) to limit the output by filtering the low energy components of the spectrum.
Recently x-ray tubes have been developed with an enormous cooling capacity, >3 kilowatt/s, equivalent with a heat radiator.

Pulsed fluoroscopy, short (high intensity) pulses to freeze the motion, could be developed due to these high output tubes, but skin damage is easy to accomplish.
The radiation created by an x-ray tube, using 80 kV and three types of extra filtering is shown in figure 4.

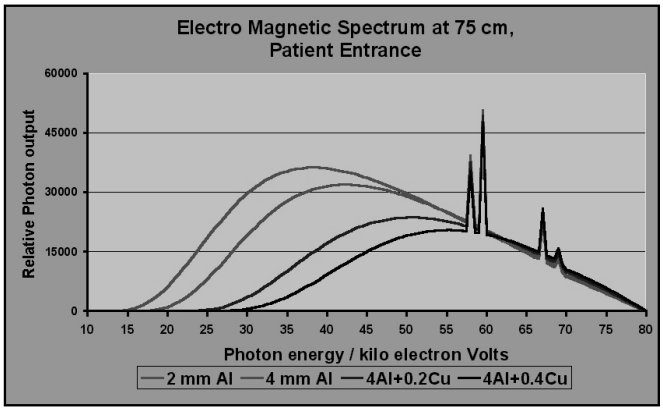


Figure 4. *The energy spectrum entering the patient skin.*

The energy spectrum, leaving the patient (20 cm water eq.) is shown in figure 5.

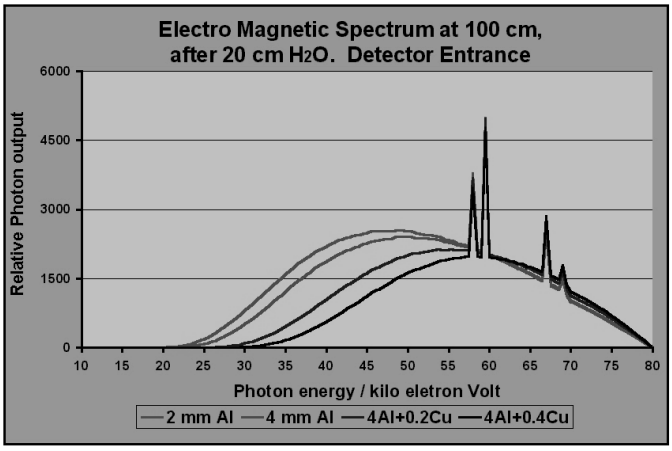


Figure 5. *The energy spectrum entering the detector.*

The difference between figures 4 and 5 is the number of photons, >90% are absorbed by the patient, it also illustrates that almost all photos with an energy < 30 kV are absorbed, they don't contribute to image forming.

The lowest curve of figure 4 is best matched for imaging. Low energy photons (<30 kVp) only contribute to absorption. Extra filtering is very efficient in decreasing the entrance dose of the patient, while maintaining high quality imaging. (2)

Extra filtering is only possible with high output tubes while the filters also weaken the complete tube output.

This is why extra filtering is not possible with “old” (300 to 600 watt/s) x-ray tubes; there remains insufficient output to perform fluoroscopy on adult patients.

The patient entrance dose, using different fluoroscopic techniques is shown in figure 6.

The entrance dose using high output tubes with extra filtering may be a factor 5 lower.

This figure also indicates that removing the extra filters in modern installations with high output tubes shall give an unacceptable, dangerously high doserate.

In the Thoraxcenter fluoroscopy is performed with an extra filter of 1.0 mm Al + 0.2 mm Cu and 1.0 Al + 0.4 Cu for DCM, above the obligated 2.5 mm Al filter.

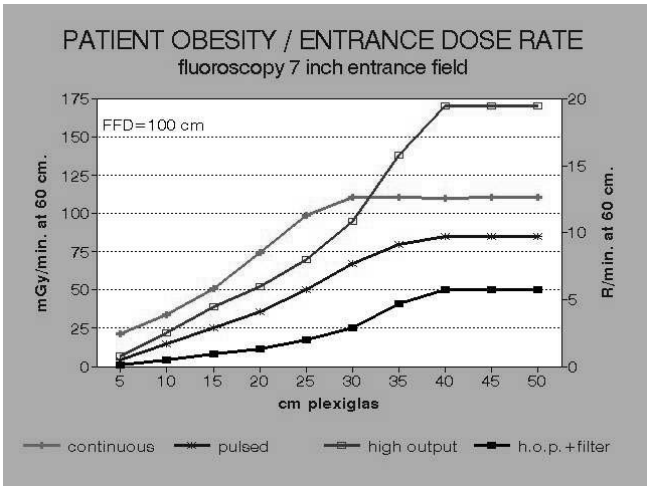


Figure 6. *Entrance dose reduction using different techniques and extra filters.*

Extensive x-ray guided interventions are increasingly performed. Even with low entrance doserates the patient’s skin can be harmed.

This is why modern units are equipped with x-ray tubes with a build-in ionization chamber in order to measure the amount of radiation used.

Considering the patient entrance dose, the usage of x-ray units without pulsed fluoroscopy and x-ray tubes without extra filtering should be forbidden for interventional, electro physiologic and other lengthy fluoroscopic investigations.

More detailed information about filtering is given in chapter 2 and 4.

Registration and Monitoring

There is an obligation to record the dose during patient handlings where radiation is used. Modern units can create an x-ray report during and at the end of an investigation.

The dose measured in the x-ray tube, the Kerma Area Product is an indicator, especially useful during interventions.

A recently developed patient entrance dose monitoring system uses the geometrical settings of the gantry and table to calculate the skin dose per square centimeter, enabling an investigator to prevent skin damage, see chapter 5. (6)

In figure 7 the graphical display of this system is shown.

The actual radiated skin area is marked as a square (even without fluoroscopy) enabling the physician to avoid overlap with previously radiated skin parts by extra collimating or changing gantry settings.

A dose report is integrated in the display and the system warns the investigator if at any part of the skin the dose exceeds 1 Gy.

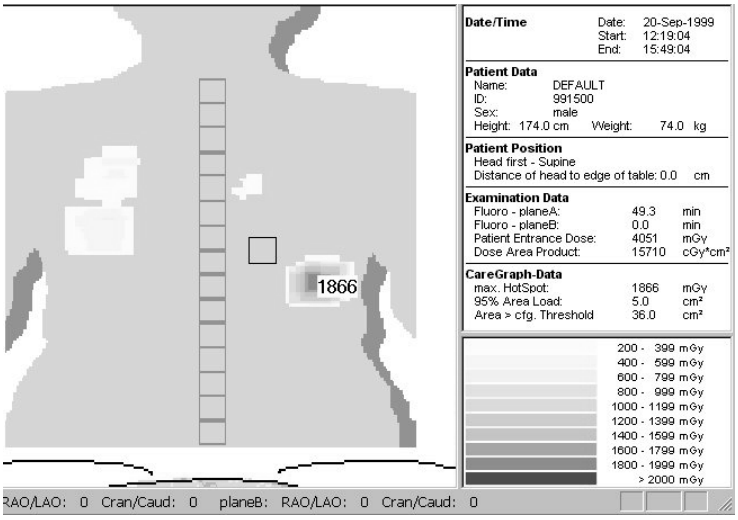


***Figure** 7. Skin dose monitoring can prevent injuries by taking measures, f.i. change gantry settings if the local dose reach a certain level.*

Detector Dose Settings

In different parts in the world various types of machinery use different dose settings, as every manufacturer uses her own standard settings.
The higher the dose is, the better the image quality is, might physically be true, however consideration has to be taken whether there is a need for the best image quality.

The higher the dose settings, the larger the dose that shall be given to the patient and operator and the sooner an x-ray tube shall deliver the maximum output.
With low dose settings the x-ray machine is able to penetrate larger objects and the more obese patient.
Modern equipment must be able to penetrate 40 cm of water with 110 kV during fluoroscopy before reaching the maximal tube output.
Last decennium x-ray tubes were developed with a heat capacity of 3600 watt/s, whereas 20 years ago tubes had a cooling capacity of 300 watt/s.
In cardiology continuous fluoroscopy should no longer be used, this technique shows a blurred image with moving objects and gives higher personnel dosages.
Grid switched pulsed fluoroscopy is developed to freeze motion, with low pulse rates (15-12.5, 7.5-6.25 fr/s) and with electronic gap filling good quality fluoroscopy is daily practice, using lower doserates compared with previously used continuous fluoroscopy.
In interventional cardiology, fluoroscopy is the most used modus. Using the ALARA principle (As Low As Reasonably Achievable) one has to optimize the x-ray unit in order to create useful images with a minimal amount of radiation. This can be obtained by using low pulse frequencies and by accepting a certain amount of noise.
Of course the signal noise ratio must not be so high that it results in longer investigation times and the investigator tires.
When non- or slow moving objects are investigated, some electronic recursive of time filtering can be used to diminish noise, fast moving objects shall show ghost imaging.

In the Thoraxcenter Rotterdam we perform pulsed fluoroscopy with dose levels of 10/16/28 nGy per pulse on a 23/17/13 cm detector field size using standard image intensifiers and video chains.

With a pulse frequency of 12.5 per second (normally used) the doserates during fluoroscopy are 0.13/0.20/0.70 µGy/s.

For the Digital Cine Mode (DCM) the detector dose per image is factors higher, 63/104/174 nGy/image. Due to higher extra filtering during DCM, the patient entrance doserate relation between fluoroscopy and DCM is 1 to 3.

The DCM mode is only used if quantification of images is desired. If the DCM mode is used for documentation (balloon and stent inflation) and no quantification is needed, ask the manufacturer for the possibility to store fluoroscopic runs, lessening dose for patient and operator.

The use of outdated scattered radiation grids which are Aluminium (Al) covered and filled should be forbidden, renewal of those grids with a carbon fiber (CF) covered and filled type shall save 20 percent of the needed intensifier dose, due to less absorption, see fig. 8.

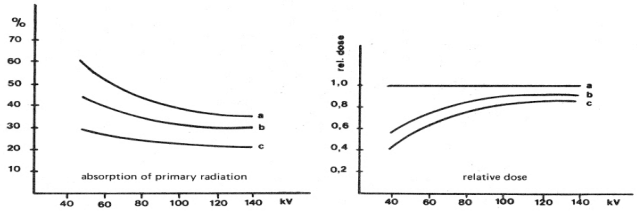


Figure 8. *Scattered radiation grids and absorption.*
a = Al filled and covered (4 mm Al)
b = Al covered, CF filled (2 mm Al)
c = CF filled and covered (0.2 mm Al)

Measurement of scattered radiation at the detector and outside the collimated beam, can give information of which scattering grid should be used. Changing or removal of the grid can optimize the patient and personnel dose as well as the image quality. For small objects and pediatrics one does not have to use a grid. The grid should be removable.

Modern equipment should be installed and fitted such that it is possible to work with very low dose settings for pulsed fluoroscopy; the user can increase the dose if necessary.

A detector dose of 10 nGy per image is technically possible using vacuum image intensifiers and modern imaging systems. The upcoming flat panel detectors show superior digital images but, while the detective quantum efficiency (DQE) is lower; one needs higher doserates for fluoroscopy, future systems shall have a higher DQE.

With low dose settings and modern tubes one should be able to penetrate 40 cm water or Polymethylmethacrylate (PMMA), also known as Plexiglas or Perspex, during fluoroscopy, using a 17 cm (7 inch) detector field size.

The higher the doserate, the higher the used kilovoltage and the less volume that can be penetrated, see figures 9 and 10.

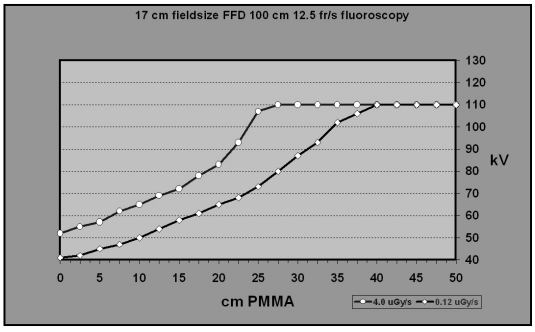


Figure 9. *Fluoroscopy, penetration and used kilo voltage using different doserates and an automatic exposure system with a fixed pulse width and coupled kV/mA values.*

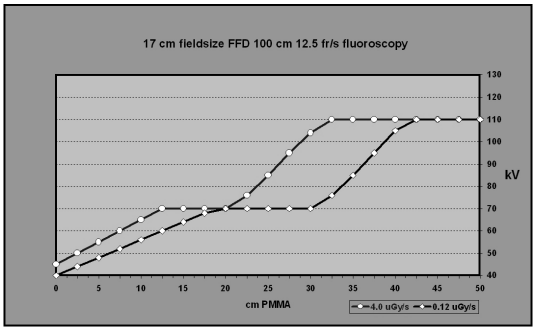


Figure 10. *Fluoroscopy, penetration and used kilovoltage using different doserates and an automatic exposure system with a kV plateau and mA, kV and pulse width regulation.*

With low dose settings and the use of a 23 cm (9 inch) field of view even 50 cm can be penetrated.

The higher the kilo voltage given, the more scattering that will occur.

A limitation of the highest x-ray quality at 110 kilovolt during fluoroscopy is advisable.

The scattered radiation coming from a large object is about 30 percent less, compared with a 125 kV limitation, see figure 11.

If, when radiating large objects, there is insufficient tube output at 110 kV, modern imaging chains shall increase the detector signal gain, resulting in a noisy but clear image.

If no limitation (125 kV) is used one shall see a less noisy, but grey picture, due to more scattering.

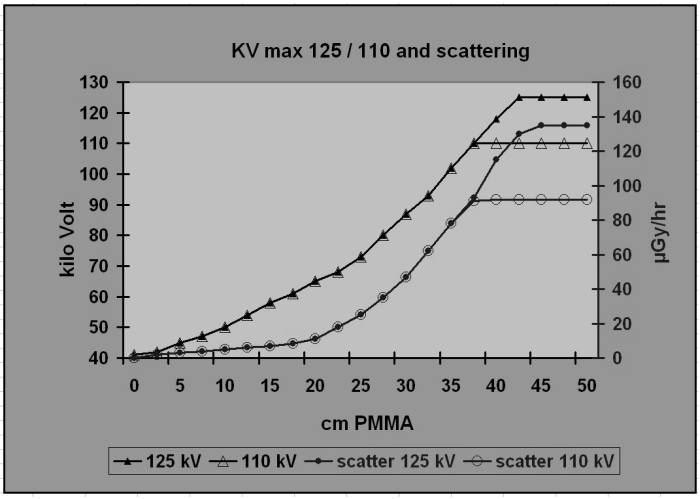


Figure 11. *Fluoroscopy without and with kV limitation a field size of 13*13 cm, shows >30% less scattering*

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Biological Risks

Both patient and personnel staff are exposed to radiation during cardiac studies and interventions.

The patient radiation dose is considerably higher since he/she is in the direct x-ray beam whereas the personnel is exposed to the scattered radiation, which is less in magnitude.

The personnel is exposed to the cumulative radiation dose from many different cardiac procedures, which are conducted over many years.

Hence, both types of radiation exposure must be assessed for biological risks.

Deterministic effects can be seen during life time, mainly affected by cell killing.

Stochastic effects are genetic effects and tumor induction.

Briefly next items are described:

- Cancer risks and risk perception
- Heart and lungs
- Breasts
- Haematopoietics and gonads
- Thyroid
- Eyes
- Skin
- Pregnancy
- Summary biological risks

Cancer risks and risk perception

The patient skin entrance exposure can be readily determined or measured with various types of radiation measurement equipment attached directly to the x-ray equipment. (6)

To assess the potential cancer risks, the radiation doses to various organs in the patient's body must be obtained.

The Center for Devices and Radiation Health (CDRH) of the FDA has published a "Handbook of Selected Tissue Doses for Fluoroscopic and Cine angiographic Examinations of the Coronary Arteries". (9)

This Handbook outlines procedures for estimating patient organ doses based on the skin entrance radiation levels.

The data were obtained from Monte Carlo calculations of a standard size and composition mathematical model of a person.

Data are provided for 11 angiographic views and 6 different beam qualities.

From this information, one can utilize National Council on Radiation Protection and Measurements, NCRP Report 116, 1993.

Limitation of Exposure to Ionizing Radiation for clinical staff, NCRP Report No. 122, 1995 can be utilized to calculate an Effective Dose Equivalent (or Effective Dose) from the readings of the radiation badges.

From these values, the **Cancer risks** can be estimated

The probability of fatal cancer from exposure to ionizing radiation depends upon the organ dose involved, the type of radiation, and the fractionation of the radiation dose.

The fatal cancer risks are quoted as:

0.005 per Sievert for bone marrow.

0.002 per Sievert for the breast.

0.0085 per Sievert for lung tissue.

0.0008 per Sievert for the thyroid gland.

0.0002 per Sievert for the skin.

The most sensitive organs are the gastrointestinal tract, the lung, the bone marrow and the bladder.

For radiation workers, the detriment for fatal and non-fatal cancers has been estimated to be 0.048 per Sievert Effective Dose. NCRP Report 116, 1993, Limitation Of Exposure To Ionizing Radiation and NCRP Report 115, 1993, Risk Estimates For Radiation Protection.

Interventional laboratory physician

The calculated maximal dose received by an interventional cardiologist in the Thoraxcenter Rotterdam is 60 mSv per year. This (worst case) calculation is based on maximum dose measurements in the years 1996 to 2000, 150 working days per year and 4 interventions per day. (3)

The effective dose, wearing a special procedure lead apron (0.25 mm Pb. equivalent), a thyroid protector and regularly using an extra screen, is < 5 mSv/yr.

The maximal allowed dose is 20 mSv/yr, the received dosages shall not show any deterministic or stochastic effect.

The probability of fatal cancer from exposure is acceptably small in respect to other daily risks, see also table 2 on next page.

Patient

Giving one Sv extra per 100 persons, 5 persons shall develop cancer within the next 40 years.

This means the chance is approximately 0.025 % up to 0.033 % for the next 40 years.

This is neglectable compared to the clinical risk and the disease itself, the quality of live after an intervention is higher and the chance of developing fatal cancer due to the intervention is very small, especially in older patients.

Cosmetic effects on the skin are possible, but can be corrected.

The benefit/risk analysis justifies cardiological interventions.

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Risk perception

Cancer risks perception; factors causing cancer, see table 2.

Carcinogen	Exposure or circumstance				Cancer site(s)
	Occupational	Medical	Social	Environmental	
Benzene	+				Bone Marrow
Asbestos	+			+/-	Lung, pleura, peritoneum
Arsenic	+				Lung, skin
Ionizing radiation	+	+			Marrow, bone. Lung, others
Ultra Violet Radiation	+		+		Lip, skin
Polycyc.hydrocarbon.	+	+		+/-	Skin, scrotum, lung
Alkyliting agents		+			Marrow, bladder
Steroids		+			Liver
Alcohol			+		Mouth, pharynx, oesophagus, liver
Tabacco smoking			+		As above and the bladder
Over nutrition				+	Endometrium, gall, bladder
Hepatitis B	+/-		+	+	Liver
Aflatoxin				+	Liver
Air pollution				+/-	Various
Sexual behavior (virus)			+		Cervix, uteri
Population mixing (virus)			+		Marrow, Burkitt's lymphoma

Table 2. Factors causing cancer, + Definite carcinogenic activity or circumstance,
+/- Probable carcinogenic activity or circumstance.

Heart and Lungs

As the object of study, the heart receives the largest radiation dose of any internal organ, approximately 0.02 Gy for adult males undergoing a typical fluoroscopic and cine angiographic examination and above 0.08 Gy with PCI. (10)

Although the myocardium may be capable of enduring fractionated radiotherapy doses as high as 100 Gy without obvious clinical changes, pericarditis has been reported in 7% of the patients who were treated for Hodgkin's disease and received a total dose less than 6 Gy.

Changes seen in the pericardium include pericardial effusion, fibroses, and possibly subsequent constrictive pericarditis.

Changes in small arteries, arterioles and capillaries are most likely responsible for delayed radiation injury in the heart. Injuries of capillaries have been demonstrated after a single dose to the skin as low as 4 Gy. Injuries to the microvasculature, and specific damage to endothelium cells, are apparently the most important factor in the delayed non-stochastic effects of radiation. (10)

However, the extent of radiation-induced damage from intervention is not known, and would be difficult to assess, as the myocardium is often already damaged prior to its radiation exposure in the interventional laboratory.

The lung is a relatively radiosensitive organ, which will typically receive a dose of 0.01 to 0.02 Gy during PTCA. (10)

A single dose of 6 to 7 Gy has been suggested as a clinical threshold for the development of radiation pneumonitis (inflammation of the lungs).

A single dose of 10 Gy to both lungs will cause acute pneumonitis in 84% of patients (11).

Breasts

Typical breast doses in adults undergoing cardiological intervention procedure are in the order of 0.05 Gy, but in children undergoing live saving repairs for congenital abnormalities, the chest dose may vary from 0.01 to 0.025 Gy. (12)

Radiation exposure of the infant breast in excess of 3 Gy may produce breast hypoplasia and later deformities. (13)

In pre puberty, patient doses 15 to 20 Gy delivered over a week, as part of a radiation therapy course will impair development.

The cancer mortality risk rate for breast cancer in adult women is 0.0024 per Sv.

Note; Overtable tube gives much more doses to the breasts.
Extra x-ray beam filtering during investigation is possible and worthwhile.

Haematopoietics and gonads

Radiation sensitivity is more pronounced in tissues undergoing rapid reproduction thus, haematopoietic bone marrow is highly sensitive to ionizing radiation.

Bone marrow doses in the order of 0.02 Gy may be received during angioplasty procedures. Animal studies have shown that radiation doses as low as 0.5 Gy can affect the haematopoietic system; however, the response is depending on the amount of tissue irradiated. (11)

With the small imaging fields used in catheterization laboratories, haematopoietic radiation syndrome is not usually a concern.

In young boys, 24 Gy has been suggested as the critical dose for severe impairment of Leydig cell function in the testes. However, menstrual irregularities may occur in females due to radiation exposure as little as 3 Gy. (14)

Temporary sterility in males could occur with radiation doses to the gonads in the range of 1 to 5 Gy.

Thyroid

Typical thyroid doses are about 0.01 Gy for adults undergoing angioplasty and are usually less in adults than in pediatric procedures. (15)

The individual response to external radiation of the thyroid may be quite variable.

Hyperthyroidism response may be seen at doses as low as 10 Gy. (13)

In adults, the thyroid cancer mortality risk rate is about 0.0008 per Gy. (16)

Although exposure to radiation in childhood has been associated with the introduction of thyroid tumors and hypothyroidism, most of this data pertains to children who receive doses for treatment of Hodgkin's disease.

Eyes

Cataracts are the most frequent delayed reaction to irradiation of the eyes.

The lens of the eye is an avascular structure cover by a capsule.

Single doses of 2 Gy or fractioned doses of 4 Gy may result in opacification.

The latent period for the production of cataracts from the time of the radiation exposure may range from 6 months to as long as 35 years.

The typical latent period is about 3 to 7 years.

Higher absorbed doses to the lens of the eyes exceeding 12 Gy have an almost certain risk for the development of cataracts.

Skin

For complicated cardiac procedures, like coronary intervention and electro physiology studies, the patient skin entrance radiation dose can range up to 5 Gy or more. (6, 9)

Radiation doses in this range may result in loss of hair (epilation) and skin reddening (erythema). These effects may occur with exposures as low as 2 to 3 Gy. (11, 14, 16)

The sequence of radiation induced skin burns can be described in three stages:

Stage 1 (within a week after exposure) is marked by a relatively prompt and transient erythema. This reddening is due to the release of histamine-like substances and proteolytic enzymes, which increase the permeability of the capillaries. This effect occurs within 1 to 2 days and than fades.

The higher radiation doses result in a more rapid identification of the erythema.

The second stage of erythema is due to vessel damage and may become apparent just after exposure. Reddening of the skin is followed by an increase in pigmentation due to the activation of melanocytes (threshold ~ 5 Gy).

This effect is an inflammatory reaction to depletion of basal cells in the epidermis.

A dusky or mauve erythema develops to define stage 3 in about 6 to 10 weeks following large radiation doses to the skin.

Healing can occur through repopulation from the edge of the burn if all clonogenic cells are sterilized. With doses to the skin above 18 Gy, vascular damage in the deep dermal plexus is thought to result in rapid increase of dermal necrosis.

As doses are fractionated, the threshold for skin erythema rises.

The individual response to external radiation of the skin may be quite variable.

Using modern equipment, pulsed fluoroscopy with low (15 p/s or less) pulse frequency with extra beam filtering and focal spot to skin distances more than 55 cm, no dermal effects are to be expected, even after a lengthy fluoroscopic intervention, see also chapters 6 and 7.

Pregnancy

The fetal dose is about 0.05 mSv if pregnant women undergo an angioplasty.

Fluoroscopy in the groin area should be kept as low as possible.

Fetal dose and x-ray investigation (NCRP report 100)

Investigation	***Fetus dose (mSv)***	
	mean	*max.*
Abdomen	1.4	4.2
Colon	6.8	24
Thorax	<0.01	<0.01
CT Thorax	0.06	0.96
CT Abdominal	8	49
CT Pelvis	25	79
PTCA	0.02	0.1

Almost all x-ray investigations are <30 mSv for the unborn child, most <10mSv.

Patient information

Patients should be applied with written information, if questions arise, remember to answer in layman terms, and don't tell the patient what she/he cannot remember.

Compare the risks to a fetus with natural incidence of deformation.

Compare dose variations with the natural background, UV radiation and skin burn.

State the probability that no adverse effects are seen, place risks in perspective, use a positive approach; don't communicate by phone, but in person.

Normal incidents of deformation of the fetus are with prenatal radiation

Up to 8 days	spontaneous abortion	50-75%	rejection all or nothing
9 days up to 8 weeks	deformation of organs	6%	small chance relatively high dose needed
8 weeks up to 15 weeks	mental retardation	0.5%	between 0.5 and 1 Sv brain damage, from < IQ until severe incompletion.
after 15 weeks	juvenile cancer	0.1%	0.5 Sv delayed grow, mental retar dation. (3 IQ point per 100 mSv)

The 8 to 15 week period is the most sensitive time for the fetus.

The (stochastic) effect of juvenile cancer, the chance of no incidence:
To 13 weeks after conception; 0 mSv=99,93% 10 mSv=99.75% 50 mSv=99.12%.
After 13 weeks, 0 mSv=99,93% 10 mSv=99.88% 50 mSv=99.70%.

A dose of 30 mSv from week 4; an extra chance of 0.5% of fatal tumor induction
(An airplane flight from Atlanta to Amsterdam + return gives a dose of 0.04 mSv.)

Calculation of dose to fetus

If necessary the radiation safety department can calculate the fetal dose.

The following data is essential; fluoroscopy- and cine time, the beam size and projections, the kilo voltage, the entrance dose ($Gy*cm^2$), filtration and focal spot to skin distance.

These data are available in x-ray and dosimetry reports from modern installations.

Conclusion

By regulation, the unborn child may not receive a dose >1 mSv.

Pregnant nurses and technicians may do their "normal" work in the intervention room and in radiology departments. Pregnant physicians may perform their duties normally in both interventional labs and radiology departments.

It is however advisable to consult the previously received dose levels, if >1 mSv/yr effective dose can be expected, it is recommended that she is not the first investigator and when possible take extra distance.

Local radiation protection regimes can tighten the regulations and may advise physicians not to perform interventions during pregnancy.

Under normal circumstances, radiological investigation shall NOT exceed the deterministic threshold values.

The chance of stochastic effects occurring is small.

Summary biological risks

The radiation doses from cardiac catheterization studies to patient and clinical staff is generally much lower than levels thought to be necessary to produce significant biological effects in tissue exposed to radiation.

However, sub optimal procedures, equipment malfunctions, frequently repeated studies and/or difficult interventional procedures could easily drive the patient radiation doses into the clinical relevant range.

Incidents with severe skin erythema in cardiac catheterization laboratories have been reported. (6,13,15,17-30)

Moreover, radiation induced cancer risk is a stochastic process in which the relative magnitude of the risk increases with the cumulative radiation exposure.

Therefore, it is important to provide good Quality Assurance Procedures in cardiac interventional and interventional laboratories in order to optimize the image quality while minimizing the levels of radiation to which patients and laboratory staff are exposed.

Ergonomics and Perception

Physician comfort

The physician should adjust the investigating table to the optimal working height and the gantry position should be adapted to the correct isocenter.

Unfortunately fewer gantries are produced with the possibility to elevate the C or U arm. Using biplane units the isocenter is fixed, meaning the table position has to be adjusted more than necessary.

Placing the patient in a fixed isocenter means in general the working height is suboptimal.

Both situations are bad from an ergonomic point of view; the spinal column already has the burden of a lead apron and moving the tabletop is an extra burden.

It may result in back problems for the investigator and is definitely tiring.

The first manufacturer, of a gantry which can elevate the isocenter, shall have an advantage. Ease of use; operating systems, using joysticks and switches, these functions are generally developed by engineers, better ergonomics are possible, the physician has to give attention to the patient must not experience difficulties using the system.

Patient comfort

Due to standardization there are only a few types of investigation tables produced; and they are not designed for patient comfort.

Where does the patient place his arms? Good armrests are seldom seen.

Probably the best improvement for patient comfort in the last decennium is the use of temper foam mattresses. If your investigation rooms don't use them, buy them now.

Better tables should be developed; sedation of patients while they cannot last long during treatment should seldom be necessary.

Especially for extended percutaneous coronary interventions, the industry should pay more attention to patient- and physician comfort, and the ease of use of equipment.

Perception

Video screens used in the intervention rooms should be placed in one line with the working field, so that by a simple glance one can see the x-ray image.

The lighting of the room must be adjustable; set the background light level around the monitors about the same as the mean intensity of the image for optimal perception.

The monitor screens should be cleaned regularly and a test image should routinely be checked to assure that one works in optimal conditions.

Expertise, Competency and ALARA

While radiation can be harmful, a medical treatment may only be performed by a radiological trained and qualified physician, **"no expertise is no performance"**.

Medical x-ray exposure is the responsibility of a qualified physician.
Justification, optimization, good medical practice and medical investigation according to the ICRP 62 norms are items, which must be known to all qualified physicians.
Training in radiation protection is a basic aspect of the optimization of medical exposures.

Safety considerations

In general it can be said, that every European country has its own basic nuclear laws. These basic laws differ in various countries.
Out of the European Council two basic directives (31, 32) are derived in which recommendations are specified for the protection of patients, health workers and the public against exposure to radiation.
The governments of the European countries accepted these recommendations and they were to be incorporated into the respective national laws by May 2000.
Council Directive 97/43/EURATOM establishes the need for an adequate theoretical and practical training of the staff working in radiological practices, and competence in radiation, for which Member States shall ensure the establishment of appropriate curricula.
International organizations that published directives are the ICRP and UNSCEAR.
In the USA the NCRP and the USFDA and in Canada the RPB-HC organizations published directives, a similar type of radiation protection regime. (33)
Radiation protection is basically determined by two principles, exposure must be justified by showing that it is more beneficial then detrimental and exposure should be as low as reasonable achievable, the ALARA principle.

In order to fully understand the overall philosophy of the radiation protection standards it is important to be aware of the three major general principles underlying radiation protection.

The principle of justification of practices implies that the detriment from exposure should be justified by the benefit resulting from the practice and thus requires that no frivolous applications of ionizing radiation be permitted.
However; the cornerstone of radiation philosophy is the principle of optimization of protection which is translated into the principle that doses should be as low as reasonably achievable taking social and economic considerations into account. Finally, the principle of dose limitation ensures an equitable distribution of individual benefits and detriments.

So there is no safe level of radiation and this is reflected by the strict regulatory control of practices involving ionizing radiation.

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Organizations

AAPM American Association of Physicists in Medicine
www.aapm.org

ARPS Australian Radiation Protection Society
www.arps.org.au

CDRH Center for Devices and Radiation Health of the Food and Drug Administration
www.fda.gov/cdrh/

EURATOM European Economic Community and the European Atomic Energy Community
http://europa.eu.int/abc/treaties_en.htm

IAEA International Atomic Energy Agency
www.iaea.org

IRPA International Radiation Protection Association
www.irpa.net

ICRP International Committee Radiological Protection
www.icrp.org

IEC International Electronical Commission
www.iec.ch

NCRP National Committee of Radiological Protection
www.ncrp.org

RPB-HC Radiation Protection Bureau-Health Canada
www.hc-sc.gc.ca/ehp/ehd/rpb

UNSCEAR United Nations Scientific Committee on the Effects of Atomic Radiation
www.unscear.org

USEU The United States Mission to the European Union
www.useu.be

Nomenclature

Standard International (SI) units:

Exposure; 1 Sievert (Sv) = 1 Gray (Gy) = 1 Joule/kg = 100 Röntgen (R).

Absorbed Dose = Gray (earlier called Rad, Radiation absorbed dose)

Equivalent Dose = Sievert (earlier called Rem, Radiation equivalent man)

Effective dose = Sievert

Collective effective dose = Man Sievert

Activity = Becquerel (Bq) (earlier called Curie)

Conversion Factors;

1 R = 0.258 mC/kg in air.

1R = 8.73 mGy in air and 9.2 mGy in muscle tissue.

100R = 1 Gy.

1 Curie (Ci) = 37 Giga Becquerel (GBq), 1 mCi = 37 MBq.

1Bq = $2.7*10^{-11}$ Ci.

1 Joule (J) = 1 Coulomb (C).

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Summary and Conclusions

Summary

In interventional cardiology revascularization procedures are on the increase and as such the x-ray radiation dose, used per procedure.
The recent introduction of new technologies, e.g. the drug eluting stent, has led to a treatment shift. An increasing number of patients with multi-vessel disease, smaller coronary arteries and diabetes, who previously underwent surgery, now undergo a percutaneous coronary intervention.

The worldwide increase in percutaneous coronary interventions is described in **Chapter 1.**
While a coronary intervention can be lifesaving, there is no limit to either the investigation or the radiation time. Therefore this result in an increase in the x-ray radiation dose to the patient, and a higher scattered radiation dose to the operator.
Thus increasing both the possibility of skin damage to the patient and consequences to the operator.

In **Chapter 2** the importance of dose reduction for patients and personnel as well as the importance of adequate training/education of physicians working with x-rays is presented.
Worldwide dose limit standard has been introduced in 2000.
It appears that it is imperative to use modern equipment to meet these standards.

Recent technological developments have resulted to a dramatic improvement of the image quality, enabling the investigator to treat smaller vessels, see **Chapter 3.**

The introduction of x-ray tubes with metal bearings, silent fluoroscopy and angiography became possible in the interventional laboratory.
This has provided a better work environment. In **Chapter 4** a detailed description is given of the possibility to reduce the radiation exposure for both the investigator and the patient while acquiring high quality fluoroscopic images with these new x-ray tubes.

A high entrance dose can harm patient skin. Therefore the investigator should have on-line information on the x-ray dose given to the patient.
In **Chapter 5** the development of a skin dose mapping monitoring system is described, which gives the investigator on-line information on x-ray dose and helps to avoid skin lesions.

A chain is as strong as its weakest link. In **Chapter 6** several aspects of the x-ray system are described and discussion on how to optimize these for a lower radiation burden to patient and operator. The skin effects of x-rays are also described.

We studied the dose and the dose distribution on the skin in 2283 consecutive intracoronary investigations. One hundred and six (4.6 %) of the patients received a skin dose which, according to the current standards, should caused some dermal effect.
However, none of the patients had any complaints pertaining to or showed any dermal effect. Is the reason a different application of x-ray technology applied in the Thoraxcenter?

In **Chapter 7** we report the results of an experimental study on the dermal effect of x-ray technology used in the Thoraxcenter. Yorkshire pigs were used. The dermal radiation sensitivity was measured by continuous and pulsed fluoroscopy, using different filtered x-ray beams.
We demonstrated that pulsed fluoroscopy with extra beam filtering is less harmful to the skin than the previously used continuous fluoroscopy. The lower the pulse rate used by pulsed fluoroscopy, the lesser the skin damage.
The question is whether this is caused by the lower dose or by a longer cell recovery time between the pulses during fluoroscopy?

Since it is unethical to evaluate this in patients or animals; we therefore initiated and performed a study using cell cultures.
We measured cell survival using different fluoroscopic techniques and determined the relative biological affectivity with identical dosages and varying pulse-pause time relationships.
The preliminarily results on human Keratinocyte cells are presented in **Chapter 8.**

Radiation safety considerations, such as room shielding, personnel and patient dose reduction, dose registration and monitoring are discussed in **Chapter 9,** as well as measures to produce the best image with the lowest x-ray dose, focusing on the as low as reasonably achievable, the ALARA, principle.
A short overview is given on radiation received in the interventional laboratories and the biological effects for patient and operator.

Conclusions

Extensive Percutaneous Coronary Interventions (PCI) and reinvestigations without skin injury to the patient are possible, provided modern technology with grid switched pulsed fluoroscopy, a low pulse frequency and an extra filter are used and one provides for a focal spot to skin distances greater than 55 cm.
Deterministic skin effects, caused by diagnostic x-ray radiation have been hardly investigated. Our investigations show that, the skin is less sensitive to x-ray exposure than was thought before.
Using modern equipment, and with proper training, one can prevent that skin damage will occur even after extensive PCI procedures.

Further technological improvement is possible. Comparison of the patient entrance x-ray spectrum and the image forming x-ray spectrum at the detector can indicate the optimal filtering. This selected gives the least x-ray entrance burden to the individual patient.

Digital enhancement techniques during fluoroscopy have optimized the image quality for human perception. However these techniques must not add non existing information to avoid misinterpretation!

New techniques make it possible to create electrocardiogram triggered images of the heart. This method permits us to study the heart with a minimum amount of images compared to the mechanical shutter frequencies that are currently used. This also provides dose reduction.

Properly used, digital image processing is a further aid to optimize the image quality, but one should realize that it is always dependent on the basic signal quality, as the saying goes, rubbish in is rubbish out. The current applied technology can still be optimized to improve the basic signal quality.

It is clear that the use of old and outdated x-ray equipment should be prohibited for interventional procedures.
Investigators and hospital administrators must give high priority to radiation safety for personnel and patient. With a downturn in the economy, the first victim is often safety.
.
We developed a real-time skin dose mapping monitoring system so that the investigator sees what he is administering to the patient and take appropriate action to prevent possible injury.
Nevertheless the industry has stopped production of this monitoring system as there was not enough demand!
Safety improvement and dose reduction to operator and patient is a task for the x-ray imaging industry, but they will only continue development in this field if users are ultimately willing to pay the price.
In this light, one could ask some ethical questions.

It is the author's belief, that our studies, described in this thesis, may lead to the development of an automated system which optimizes the patient entrance dose, and shows the least worse (or perhaps in the vision of the industry an optimal) image quality and lowers the scattering dose to personnel.

Samenvatting en Conclusies

Samenvatting

In de interventiecardiologie neemt het gebruik van röntgenstraling tijdens onderzoek en revascularisatie procedures toe.
Recent ontwikkelde technieken, o.a. de stent die medicijnen afgeeft, hebben ervoor gezorgd dat patiënten met meertaks coronaire afwijkingen, kleine vaten en patiënten met suikerziekte, die vroeger alleen door chirurgie geholpen werden, nu als kandidaten gezien worden voor een percutane transluminale coronaire angioplastiek (PTCA) behandeling.

In **Hoofdstuk 1** wordt de wereldwijde toename in PTCA's beschreven.
Omdat PTCA levensreddend kan zijn, is er geen beperking in onderzoekstijd en het gebruik van straling, waardoor de mogelijkheid van huidschade voor de patiënt en een hoge strooistralendosis voor de onderzoeker toeneemt.

In **Hoofdstuk 2** wordt het belang beschreven van dosis vermindering voor patiënt en personeel en het belang van een goede opleiding voor de onderzoekers, die röntgen straling gebruiken.
Sinds 2000 zijn wereldwijd voor het personeel de dosis limieten gestandaardiseerd.
Als men zich aan deze standaard wil houden, is het onontkoombaar dat er met moderne apparatuur gewerkt wordt.
Recente technische ontwikkelingen hebben voor een dramatische verbetering van de beeldkwaliteit gezorgd, die de onderzoeker in staat stelt om gemakkelijker kleinere vaten te behandelen. De aanwending van deze nieuwe technieken wordt beschreven in **Hoofdstuk3**.

Met de introductie van röntgenbuizen met vloeibare metaal lagering werd geruisloze doorlichting en angiografie in het interventielaboratorium mogelijk . Dit heeft voor betere werkomstandigheden gezorgd. In **hoofdstuk 4** wordt een gedetailleerde beschrijving gegeven hoe met deze buizen de stralingsdosis voor zowel de onderzoeker als de patiënt te verminderen is, met behoud van een hoge beeldkwaliteit.

Een hoge ingangsdosis kan de patiëntenhuid beschadigen. Als de onderzoeker niet weet welke dosis aan de patiënt wordt gegeven, kan hij ook niet weten of hij de huid van de patiënt schade aandoet.
In **Hoodstuk 5** wordt de ontwikkeling van een huiddosis bewakingsysteem beschreven, dat de onderzoeker in staat stelt maatregelen te nemen om huidschade te voorkomen.

Een ketting is zo sterk als zijn zwakste schakel, in **Hoofdstuk 6** worden verschillende gedeelten van het röntgensysteem beschreven en van gedachten gewisseld over de wijze waarop deze een lagere stralenbelasting kunnen geven voor de patiënt en de onderzoeker.
De huid effecten, veroorzaakt door röntgenstraling, worden besproken.

Met de gegevens van 2283 opeenvolgende onderzoekingen bestudeerden wij de dosis en de dosisverdeling op de huid. Honderd en zes (4.6 %) van de patiënten ontving een huiddosis die, volgens de huidige normen, een stralingseffect of schade zou moeten laten zien.
Geen enkele patiënt klaagde echter over de huid of vertoonde afwijkingen.
Wordt dat veroorzaakt door de afwijkende doorlichtings techniek die wij in het Thoraxcentrum toepassen?

In **Hoofdstuk** 7 wordt een studie beschreven die de huideffect laat zien, veroorzaakt door de in het Thoraxcentrum gebruikte röntgentechniek. Als model zijn Yorkshire biggen onderzocht. Huideffecten, veroorzaakt door continue en gepulste doorlichting met gebruik van verschillend gefilterde röntgenbundels werden bestudeerd.
Bevindingen laten zien dat gepulste doorlichting met extra bundelfiltering minder huidschade geeft, dan de voorheen gebruikte continue doorlichting.
Gepulste doorlichting met lagere pulsfrequenties laat minder huidschade zien.
Is dat veroorzaakt door de lagere dosis of komt dat omdat er een langere reparatietijd is tussen de pulsen tijdens doorlichting?

Omdat het is niet ethisch verantwoord is dit te meten bij patiënten of biggen, zijn we een studie met celculturen gestart.
Wij maten de celoverleving onder gebruikmaking van verschillende doorlichttechnieken en bepaalden de relatieve radiobiologische effectiviteit bij identieke doseringen en andere puls-pauze tijdrelaties.
De voorlopige resultaten van doorlichting op menselijke keratinocyten celculturen worden beschreven in **Hoofdstuk 8.**

Een korte beschouwing over stralenveiligheid, van kamerafscherming, personele en patiënten dosisreductie tot de registratie van dosis gegevens en bewaking is de inhoud van **Hoofdstuk 9**.
Met het oog gericht op het zo laag als redelijk bereikbaar, het ALARA principe, worden enige suggesties gedaan om de dosis te optimaliseren door extra technische maatregelen. Een kort overzicht wordt gegeven ten aanzien van straling, opgelopen in het interventielaboratorium, en de radiobiologische effecten voor patiënt en onderzoeker.

Conclusies

Uitgebreide Percutane Transluminale Coronaire Angioplastiek (PTCA) procedures en heronderzoek zonder de patiëntenhuid te beschadigen is mogelijk, indien gebruikt gemaakt wordt van moderne apparatuur, rooster gestuurde gepulste doorlichting met extra bundel filtering en er daarbij wordt voor gezorgd dat de focus tot huid afstand groter is dan 55 cm. Deterministische huideffecten, veroorzaakt door diagnostische kwaliteit röntgenstraling zijn nauwelijks onderzocht. Ons onderzoek laat zien dat, met gebruik van de juiste techniek, de huid minder gevoelig is dan eerder werd gedacht.
Het gebruik van moderne apparatuur, samen met een goede opleiding, voorkomt beschadigen van de patiëntenhuid, zelfs na gedurende PTCA procedures.

Verdere technologische verbeteringen zijn mogelijk. Vergelijking van het patiënt ingang röntgenstraling spectrum en het beeldvormende spectrum op de opnemer kan de optimale filtering aangeven.. Deze ingesteld geeft de laagste huidbelasting voor de individuele patiënt.

Digitale beeldverbeteringstechnieken om het beeld voor het menselijke oog te optimaliseren, hebben het gebruik verbeterd. Maar deze technieken mogen geen niet bestaande informatie toevoegen om misinterpretatie te voorkomen.

Nieuwe technieken maken het mogelijk om elektrocardiogram gestuurde beelden van het hart op te nemen. Dit is een manier om het hart en kransvaten te bestuderen met gebruik van zo min mogelijk beelden; in vergelijking met de mechanische sluiterfrequenties tot nu toe gebruikt en dit is dosisbesparend.

Digitale beeldbewerking is, mits goed gebruikt, een manier om de beeldkwaliteit te verbeteren, maar we moeten ons realiseren dat de kwaliteit altijd afhankelijk is van het begin beeld en, zoals het gezegde luidt “rommel in is rommel uit”.
De huidig gebruikte techniek heeft nog mogelijkheden het beginbeeld te optimaliseren.

Het is duidelijk gebleken dat het gebruik van oudere röntgenapparatuur voor interventiewerk verboden zou moeten worden.
Onderzoekers en ziekenhuis management moeten een hoge prioriteit geven aan stralingsveiligheid voor personeel en patiënt.
Bij economische teruggang is veiligheid een van de eerste sluitposten op de bezuiniging, dat zou later wel eens een verkeerde kunnen blijken.

Wij ontwikkelden een huiddosis bewaking systeem zodat de onderzoeker de hoeveelheid röntgen dosis ziet, die de patiënt ontvangt, zodat hij maatregelen kan nemen om huidschade te voorkomen.
De industrie heeft de productie van dit systeem gestopt omdat er onvoldoende vraag naar was. Veiligheidsverbetering en dosisverlaging voor personeel en patiënt is een taak van de röntgen industrie, maar deze zal dit alleen ontwikkelen en produceren als ervoor betaald wordt.
Men kan in dit verband wel ethische vragen stellen.

De auteur gelooft dat onze studies, beschreven in dit proefschrift, een basis kan zijn voor de ontwikkeling van een geautomatiseerd systeem om de patiëntdosis te optimaliseren en de minst slechte (wellicht in de visie van de industrie, de optimale) beeldkwaliteit laat zien en de strooistralingsdosis voor het personeel verlaagt.

Curriculum Vitae

Curriculum Vitae

Adrianus (Ad) den Boer was born 13 February 1944 in Rotterdam, the Netherlands.

After finishing secondary school he went to the Poly Technical High school in Rotterdam with electronics as field of interest.

In 1963 he started working at the radiology department in Dijkzigt Hospital, Rotterdam and in 1967 at the radiotherapy department of the Rotterdams Radio Therapeutic Institute, where he finished his trainings in 1966 and 1968.

In 1968 he joined the Erasmus University, the Medical Faculty, department of Cardiology, in the Thoraxcenter in Rotterdam.

He became head of clinical and experimental technology in 1972 and started that year trainings for cardiologists in radiology.

In 1978 he finished the course Ionizating Radiation Safety at the Technical High School in Rotterdam and became the radiation safety officer.

Promoted to technical research coordinator he started several industrial projects and in 1995 the project brachytherapy for prevention of restenosis.

For the Dutch society of cardiology he was a member of the Dutch ministry of health working group to prevent skin injury during long x-ray guided investigations in 1997 and in 2002 he began to write his thesis under the supervision of Prof. dr. JRTC Roelandt.

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The first years in the Thoraxcenter were elementary; we developed the first cardiological computer software for patient monitoring and heamodynamical analysis.

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Ad den Boer.

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Dankwoorden

Dankwoorden

De eerste cardioloog in Rotterdam, Joris Verheij, bracht mij naar het Thoraxcentrum, waar ik begon als bouwcoördinator onder leiding van Paul Hugenholz, hij was en is nog steeds een stimulator en motivator, ik ben hen beiden veel dank verschuldigd

De eerste jaren in het Thoraxcentrum waren een erg fundamentele periode, we ontwikkelden de eerste cardiologische computersoftware voor patiënten bewaking en heamodynamische analyse. Ik wil Geert Meester bedanken, die de basis heeft gelegd voor de catheterisatie laboratoria en de analyse, hij leerde mij hoe wetenschappelijke problemen op te lossen, en Klaas Bom, zijn technisch leiderschap heeft voor veel inventiviteit in cardiologie gezorgd.

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Terugkijkend was het werkelijke een voorrecht om met al deze clinici te mogen werken, hun naam staat voor een unieke en fascinerende ontwikkeling in cardiologie, zij hebben de industrie voor ontwikkeling aangetrokken en cardiologen over heel de wereld opgeleid en maakten van het Thoraxcentrum een topinstituut.

Discussies met de "technici"van het Thoraxcentrum waren altijd stimulerend; ik wil mijn speciale dank uiten aan Kees Slager, Hans Reiber, Kees Zeelenberg en Ruud Vinke voor hun inspanning, en, wat betreft radiologisch advies en discussie, Frits van der Meer van de afdeling Radiologie. Betere toepassing van de techniek kan niet gedaan worden zonder de industrie, samenwerking met fabrikanten heeft zeker een belangrijke rol gespeeld in het vormen van mijn wetenschappelijke gedachten.

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Ad den Boer

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The address;	PO Box 1738, 3000 DR Rotterdam	is old and changed to
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