

The Identification and Evaluation of Likely High-Dose Electrophysiology (EP) Procedures at a Large Teaching Hospital

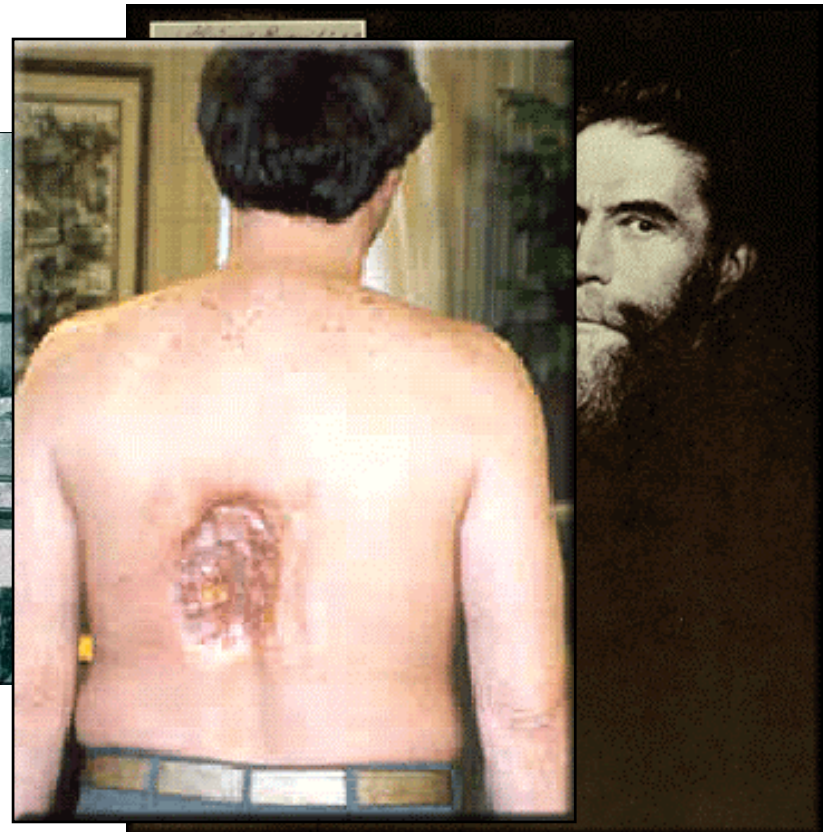
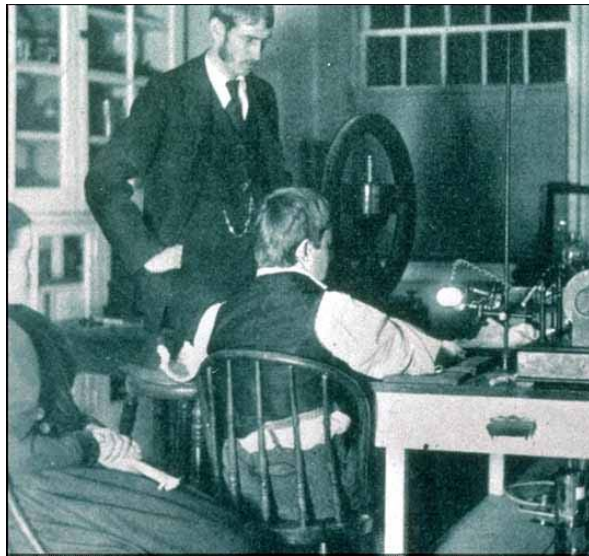
Bradford Taylor, MS, RT(R)
Associate RSO, UNC-Chapel Hill

October 18, 2007

NCHPS

Agenda

- Introduction



Introduction

- **Rationale**

- **Fluoroscopy procedures**
- **Interventional procedures**
- **FDA September 1994 Advisory**
- **1995 Advisory**
- **December 2005 JCAHO action**



Introduction

- **Study Purpose**
 - Evaluate radiation dose to adult patients undergoing EP procedures

Agenda

- **Specific Goals**
- **Background**
- **Review of EP Fluoroscopy Log**
- **Dose Monitoring**
- **Results**
- **Conclusions and Future Direction**

Introduction

- **Specific goals**
 - Retrospective evaluation of fluoroscopy time
 - Identify lengthy/high-dose procedures
 - Measure peak skin dose using film
 - Evaluate the relationship between dose, time, weight, BMI
 - Which variables are best predictors of dose?

Background

- **Biological effects of radiation exposure**
 - **Sufficiently high doses**
 - Cannot repair
 - Cellular death
 - Tissue breakdown

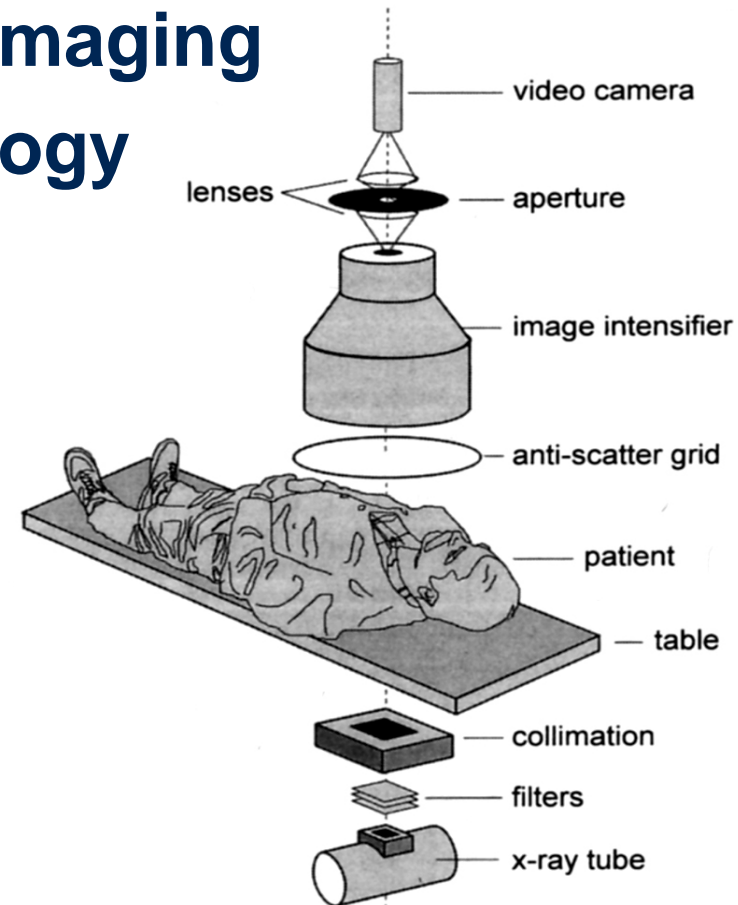
Background

- Biological effects of radiation exposure (Wagner 1996)

Effect	Single-dose Threshold (rad)	Onset	Peak
Early Transient Erythema	200	Hours	~24 hours
Main Erythema	600	~10 days	~2 weeks
Temporary Epilation	300	~3 weeks	NA
Permanent Epilation	700	~3 weeks	NA
Dry Desquamation	1000	~4 weeks	~5 weeks
Moist Desquamation	1500	~4 weeks	~5 weeks
Secondary Ulceration	2000	>6 weeks	--
Late Erythema	1500	~6-10 weeks	--
Dermal Necrosis (1st phase)	1800	>10 weeks	--
Dermal Atrophy (1st phase)	1000	>14 weeks	--
Dermal Atrophy (2nd phase)	1000	>1 year	--

Background

- Physics of fluoroscopic imaging
- Image-intensifier technology

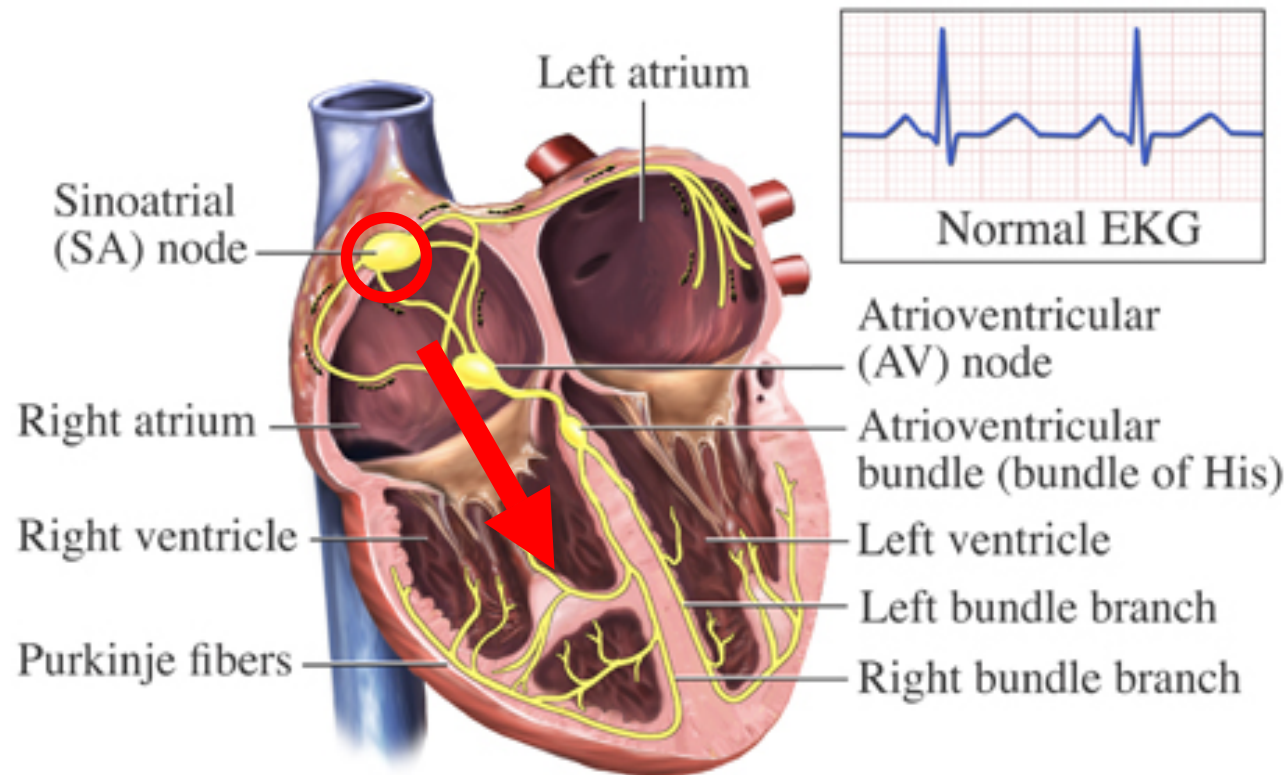


Background

- **Physics of fluoroscopic imaging**
 - **Typical ESE rates = 0.5 – 20 R/minute (Giles 2002)**
 - **Automatic Brightness System (ABS)**
 - **Equipment configuration**
 - **Continuous vs. pulsed**
 - **Magnification**
 - **Patient size/pathology**

Background

- How the heart works



Background

- **Diagnose and treat arrhythmia**
- **Overview of EP procedures**
 - Electrophysiology study (ESP)
 - **Catheter ablation (ABL)**
 - Implantable cardioverter defibrillator (ICD)
 - Pacemaker (PM)
 - **Biventricular devices (BIV)**
 - Change out (CO)

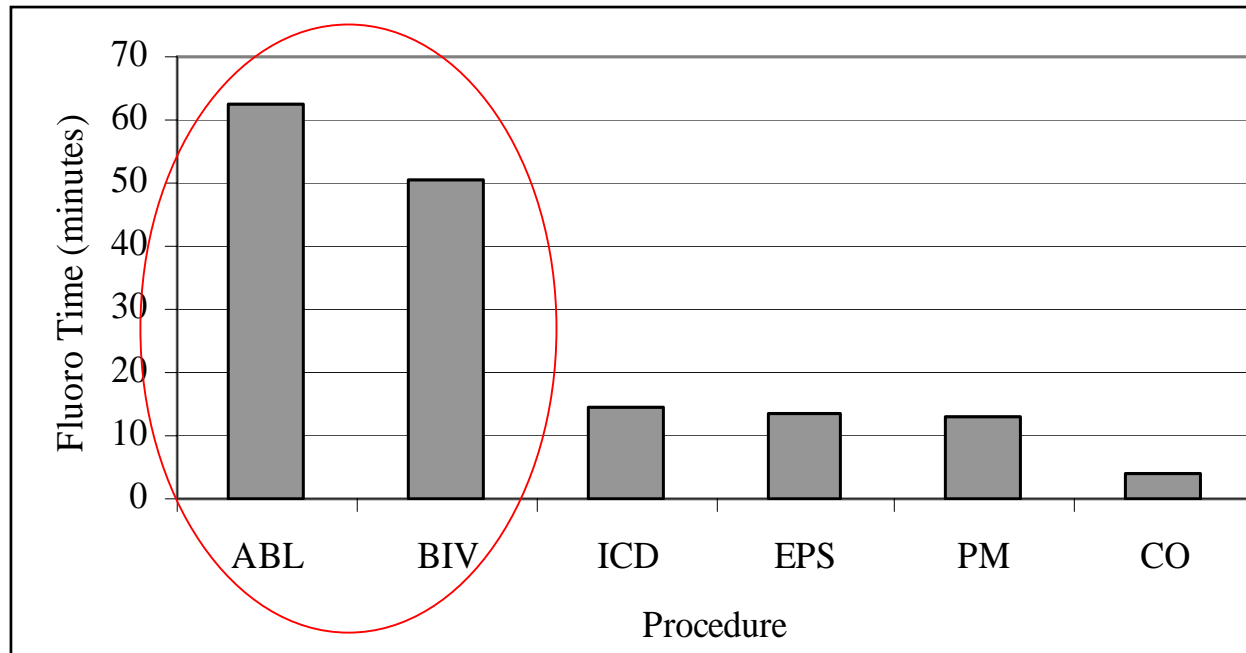
Review of EP Fluoroscopy Log

- Procedure date
- Procedure type
- Physician
- Total fluoroscopy time

- 247 properly documented adult EP procedures
 - March 27, 2003 – March 30, 2005

Review of EP Fluoroscopy Log

- Ablation 62 ± 48 min BIV Implant 51 ± 28 min



Review of EP Fluoroscopy Log

Type of Procedure	Total Procedures	# Procedures >60 min. (%)	# Procedures >90 min. (%)	# Procedures >120 min. (%)
ABL	33	12 (36)	8 (24)	5 (15)
BIV	28	7 (25)	2 (7)	2 (7)
EPS	13	1 (2)	0 (0)	0 (0)
PM	71	0 (0)	0 (0)	0 (0)
CO	46	0 (0)	0 (0)	0 (0)

Dose Monitoring for ABL and BIV

- Radiochromic dosimetry film
 - Gafchromic XR Type R
 - Manufactured by ISP
 - Designed for fluoroscopy-guided procedures

Dose Monitoring for ABL and BIV

- Characteristics:
 - Diacetylene - Solid state polymerization
 - Self-developing (simple color change)
 - Measures low-energy photons (<200 keV)
 - Energy independent in the diagnostic range
 - Dose rate and dose fractionation independent
 - Dynamic range of 10 – 1500 rad
 - Large format (14"x17")
 - Unaffected by light and water
 - Relatively inexpensive (\$20/sheet)

Dose Monitoring for ABL and BIV

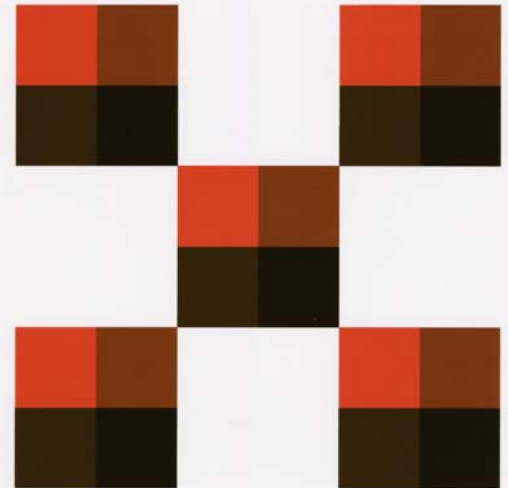
- Determining dose
 - Ordinary flatbed scanner (Epson Model 1680)
 - Coefficient of variation reported ~1.8% (Thomas 2005)
 - Photoshop software with RGB capability
 - Analyze mean red channel pixel values (C)
 - Film response = C_{ni}/C_i
 - Response of film increases over time (Dini et al 2003)
 - ~16% in 24 hours, ~4% in next 24 hours, ~2% over next 300 hours (12.5 days)

Dose Monitoring for ABL and BIV

- Determining dose
 - Create a calibration tablet
 - Scanning protocols

Dose Monitoring for ABL and BIV

- Scanner performance
 - Developed daily test pattern
 - Evaluate scanner operation
 - Coefficient of variation 2.1%
 - Dye sublimation process
 - Lab-quality printing
 - Very stable
 - Less vulnerable to fading



Dose Monitoring for ABL and BIV

- Needed to generate a calibration tablet and calibration curve
 - Necessary for each lot
 - Expose film to known dose rate for known time
 - Dose rate determined with a Rad Cal MDH Model 1515
 - Electronic dosimeter with a 6 cc ionization chamber

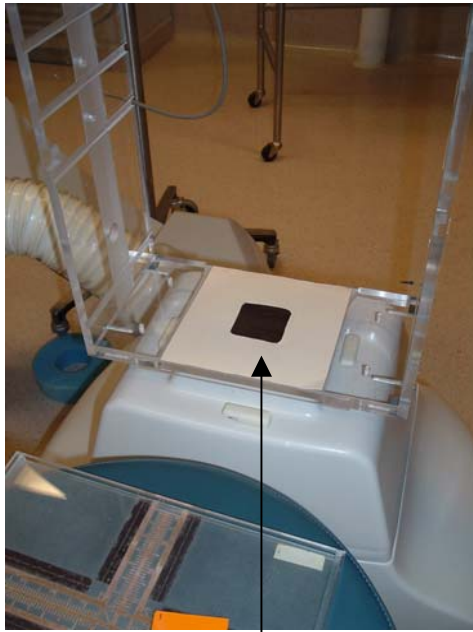
Dose Monitoring for ABL and BIV

- MDH and x-ray tube orientation
 - 90 kVp, 100 mA, 10 ms, 15 p/s
 - Mean exposure rate of 47.2 R/minute (Tablet 1)



Dose Monitoring for ABL and BIV

- Expose a 2"x2" piece of film
- Expose up to three films at once



Film Supporting Device



Radiochromic Film

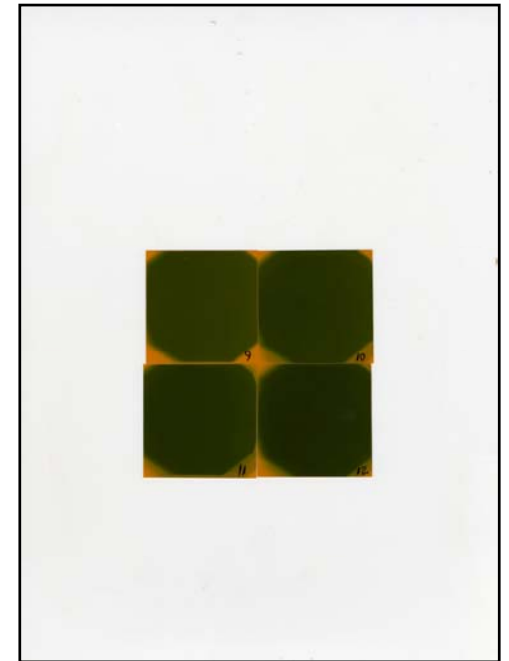
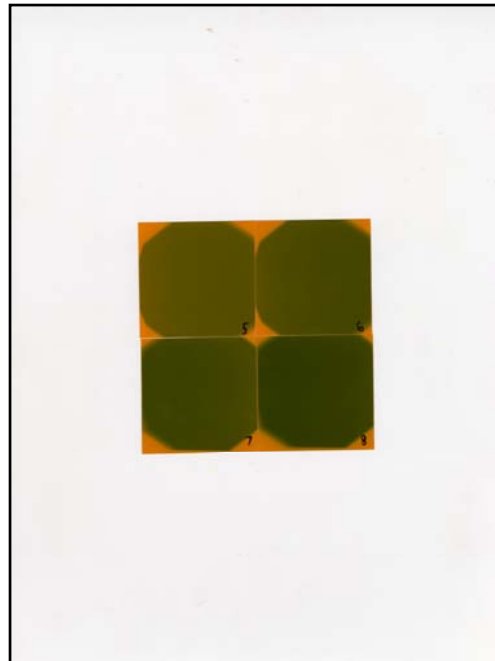
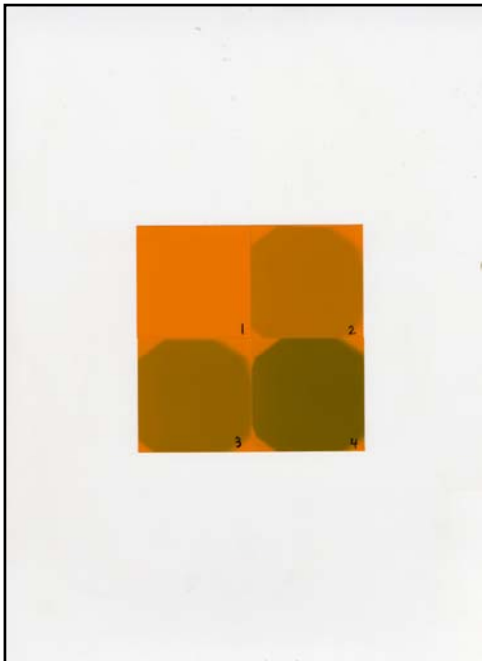
Dose Monitoring for ABL and BIV

Calibration Tablet 1

Film Number	Date of Exposure	Minutes Exposed	Total Dose (rad)
1	N/A	0.0	0.0
2	09/02/2005	1.1	51.0
3	09/02/2005	2.2	102.0
4	09/02/2005	4.3	199.3
5	09/02/2005	6.5	301.3
6	09/02/2005	8.7	403.2
7	09/02/2005	10.7	495.9
8	09/02/2005	12.9	597.9
9	09/02/2005	15.0	695.3
10	08/25/2005	17.8	825.0
11	08/25/2005	20.0	927.0
12	08/25/2005	22.5	1042.9

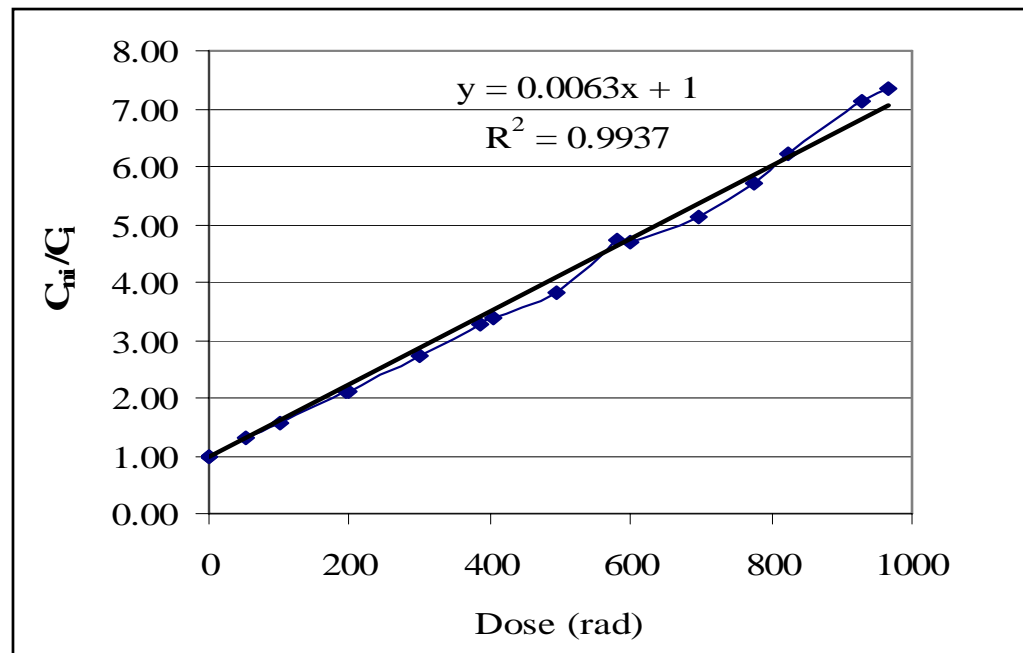
Dose Monitoring for ABL and BIV

- Calibration tablet 1 (final scan)



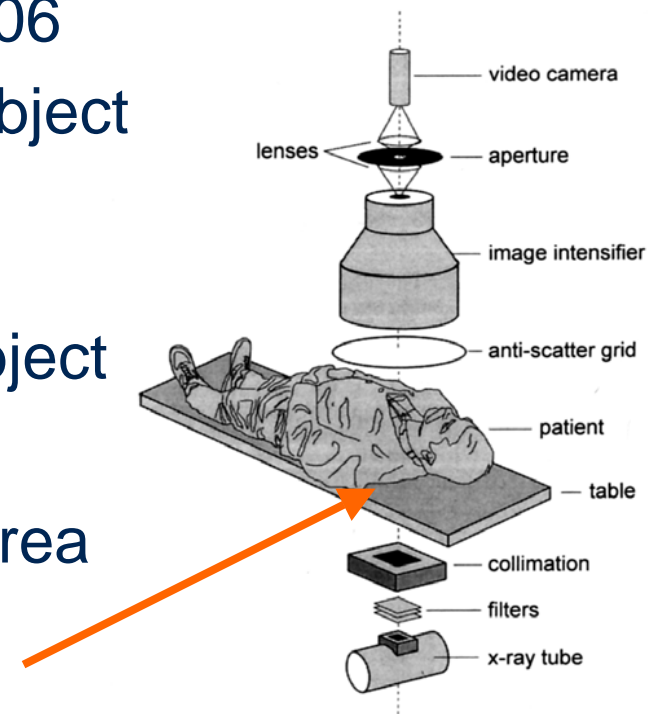
Dose Monitoring for ABL and BIV

- Combined calibration curve for tablets 1 and 2



Dose Monitoring for ABL and BIV

- Dose monitoring
 - September 9, 2005–June 8, 2006
 - Research described to each subject
 - Subject Information Sheet
 - Oral approval
 - Film placed underneath the subject
 - Protective plastic sleeve
 - Centered roughly to the heart area

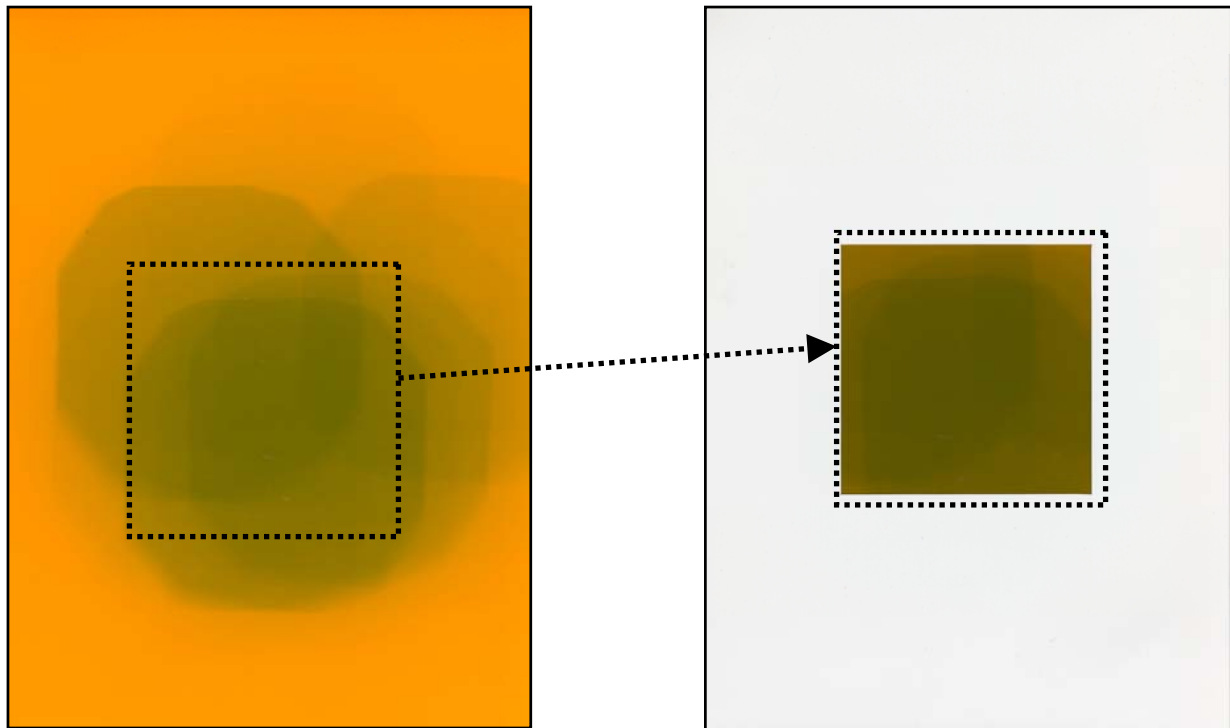


Dose Monitoring for ABL and BIV

- Dose determination
 - Subject films scanned at same post-irradiation time as calibration tablet
 - Visually identify darkest area
 - Scan in centering template
 - Lowest pixel value used to determine dose
 - Equation of line for calibration curve
 - $y=0.0063x+1$
 - x =dose
 - y =film response (C_{ri}/C_i)

Dose Monitoring for ABL and BIV

- Subject 27 with and without centering template



Results

- 33 subjects
 - 30 with accurate time and measurable dose
 - Determined mean, SD, maximum, minimum values for patient weight, BMI, fluoro time, peak skin dose

Results

- Descriptive statistics for all procedures

All Procedures	Mean	Standard Deviation	Maximum	Minimum
Weight (lbs)	204.0	57.7	331.0	116.0
Body Mass Index (BMI)	30.0	7.0	43.7	19.3
Fluoroscopy time (min)	46.2	24.5	94.0	12.5
Peak skin dose (rad)	149.9	142.1	764.4	31.8
Number of Procedures	30			

Results

- Descriptive statistics by procedure type

Ablation Only	Mean	Standard Deviation	Maximum	Minimum
Weight (lbs)	181.4	40.2	240.0	116.0
Body Mass Index (BMI)	27.4	5.3	37.8	19.3
Fluoroscopy time (min)	57.4	27.8	94.0	12.5
Peak skin dose (rad)	133.2	94.0	366.9	31.8
Number of Procedures	14			
BIV Only	Mean	Standard Deviation	Maximum	Minimum
Weight (lbs)	223.8	64.4	331.0	146.0
Body Mass Index (BMI)	32.4	7.6	43.7	21.1
Fluoroscopy time (min)	36.4	16.5	71.4	19.3
Peak skin dose (rad)	164.5	175.8	764.4	38.6
Number of Procedures	16			

Results

- Descriptive statistics of dose by BMI weight class

	Normal BMI of 18.5-24.9	Overweight BMI of 25-29.9	Obese BMI of 30 and greater
Number of Subjects	9	9	12
% of Total Subjects	30%	30%	40%
Mean Dose (rad)	72.4	119.1	231.1
Standard Deviation	30.3	75.4	188.6
Minimum	31.8	38.6	71.6
Maximum	111.0	264.7	764.4
Subjects (%) in BMI Class > 200 rad	0 (0)	2 (25)	5 (38)

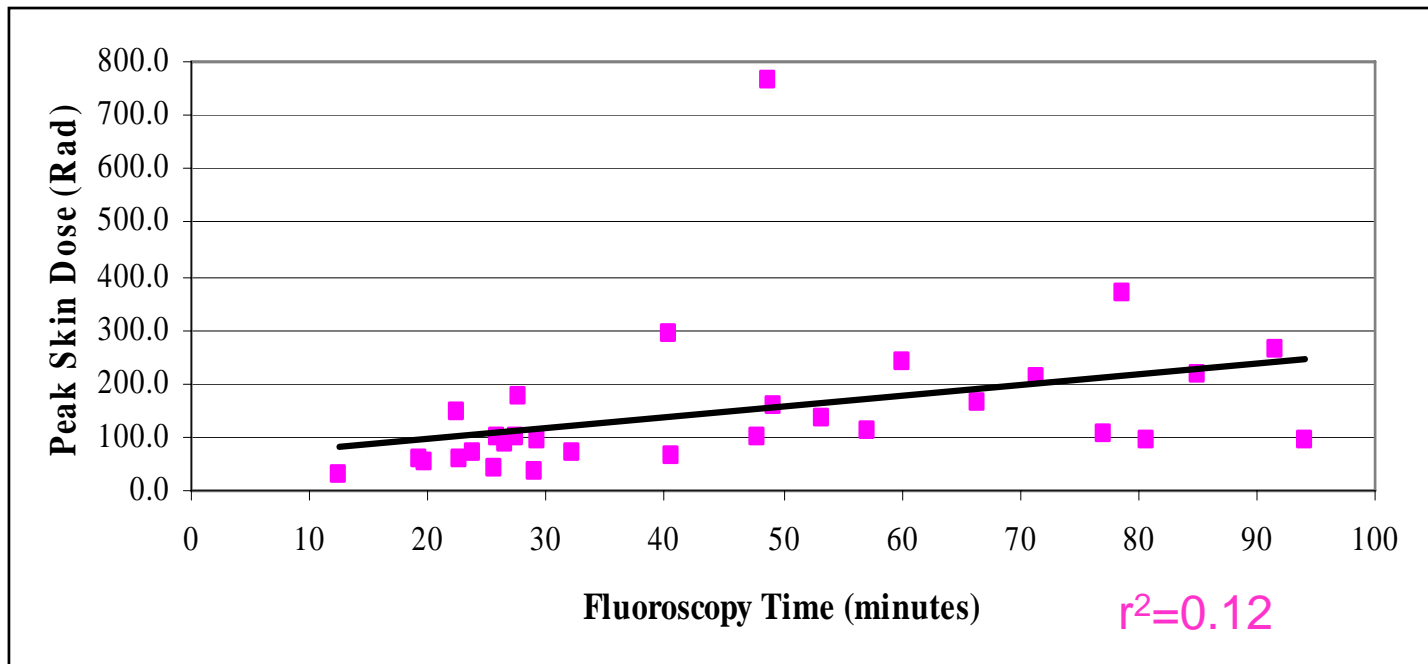
Results

- Differences between the sexes
 - Males received mean skin doses double that of women
 - No female subjects exceeded 200 rad
- Overall mean entrance skin dose rate was 3.4 rad/minute
 - Consistent with IAEA and Wall-1996

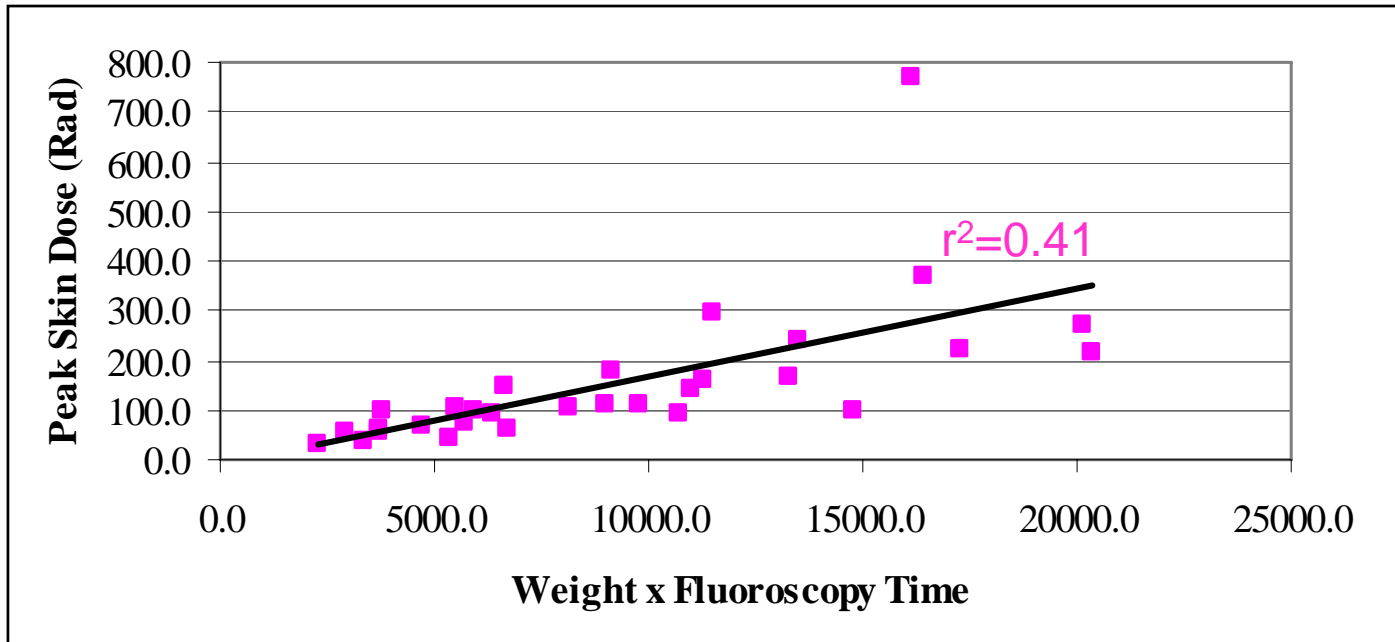
Results

- Scatter plots
- Linear regression analysis
- r^2 values determined
 - Describe the linear least squares fit

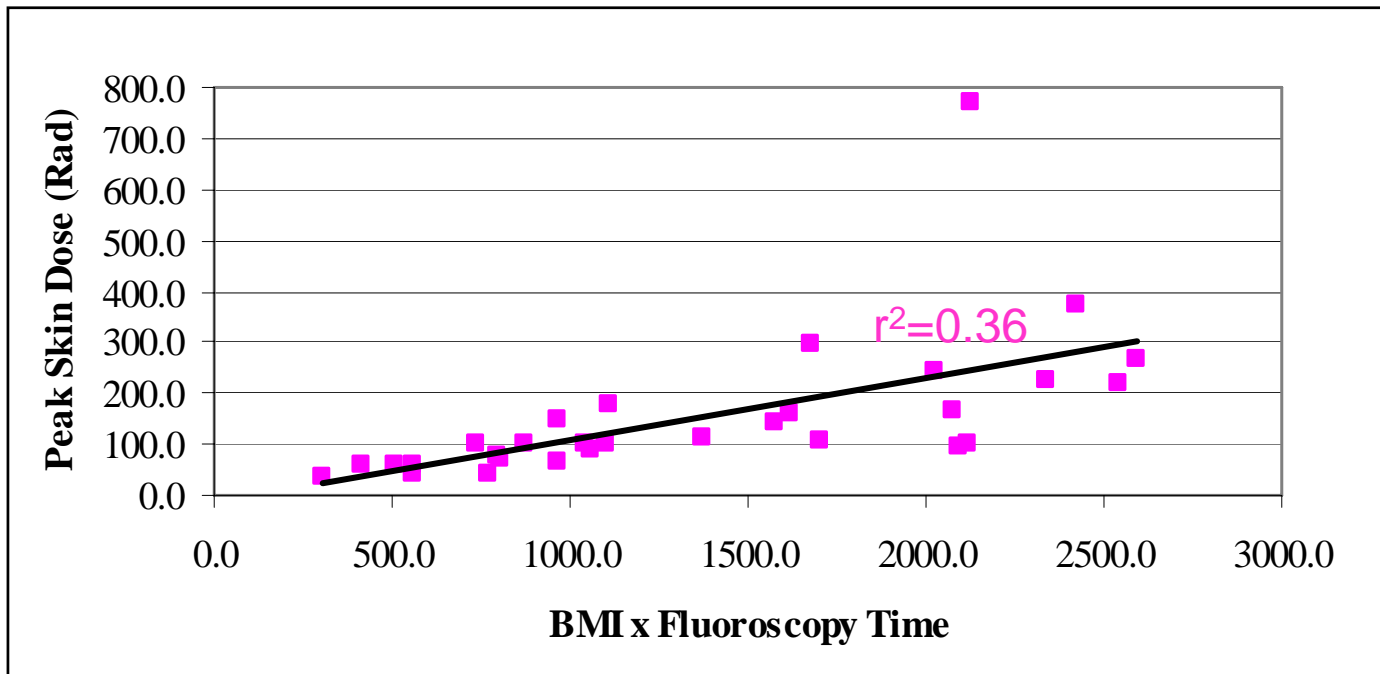
Results



Results



Results



Results

- Subject 1 as an outlier

Results

- Discussion
 - Developed simple, accurate and reproducible procedures
 - Positive correlation between variables compared
 - Strength of linear correlation consistent with literature
 - Mean fluoroscopy times are consistent with literature

Results

- Discussion
 - Fluoroscopy time is a poor predictor
 - **Weight x time** and BMI x time correlated best
 - Overall individual predictive strength
 - Sentinel event from single procedure not likely

Conclusions and Future Direction

- Concerns with overweight and obese patients
- Concerns with additional/repeat procedures
- Routine monitoring
 - Complicated but important consideration
 - Overweight and obese at greatest risk

Acknowledgements

- Dr. Don Fox
- Drs. Ivanovic and Watson
- Drs. Sanders and Selzman and the staff of the EP Lab
- Environment, Health and Safety

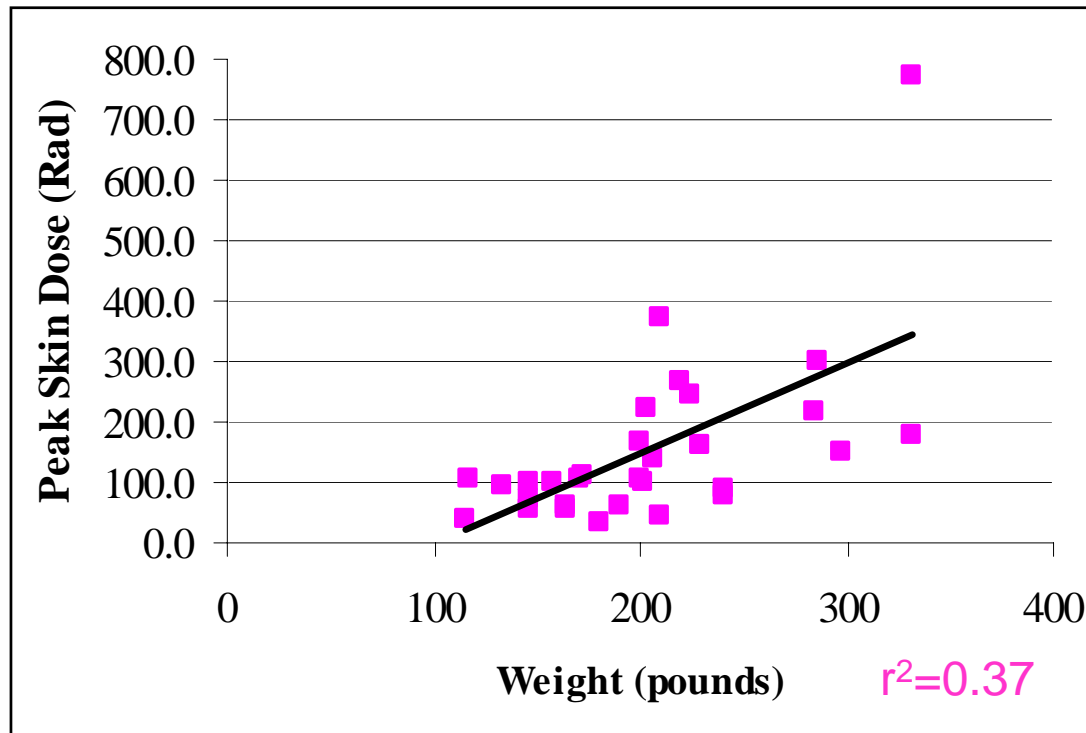
The End...Thank You



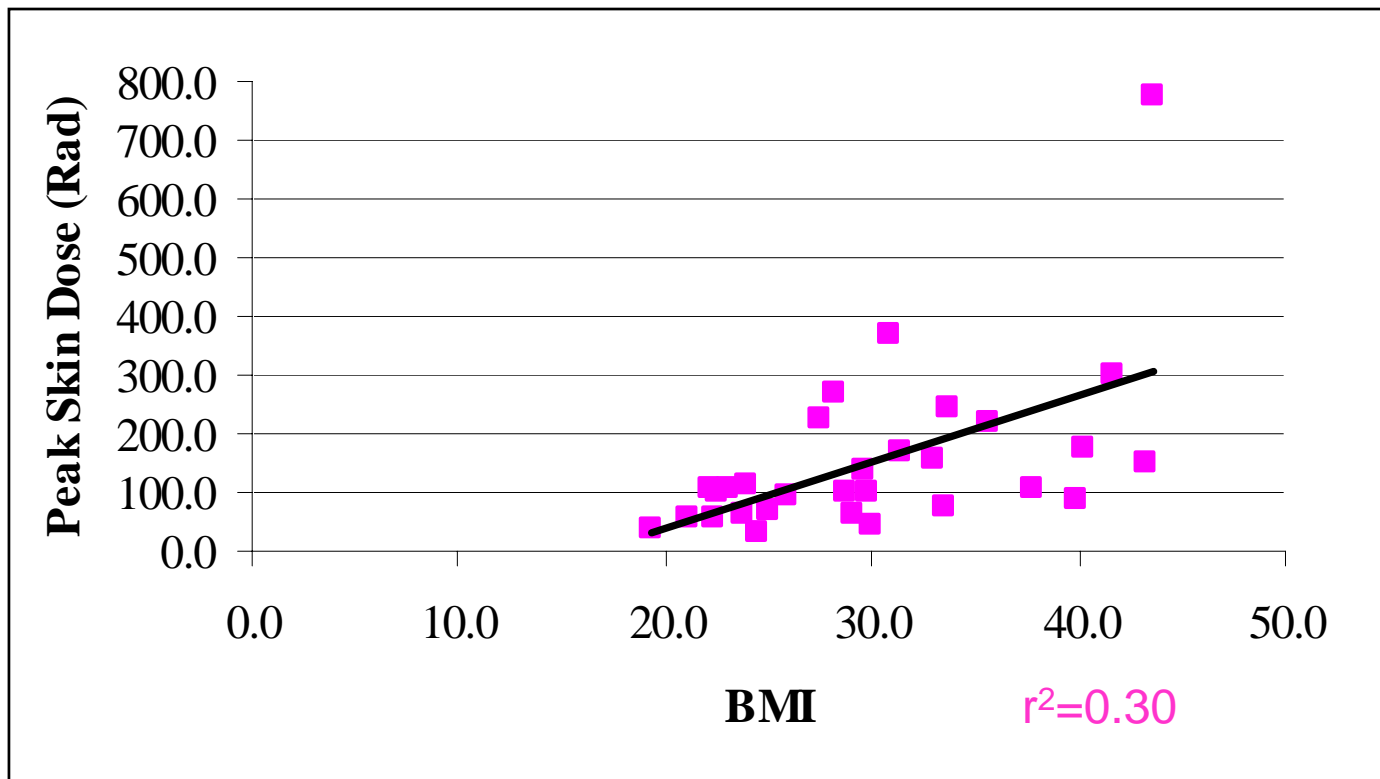
Results

r⁻² values	Dose vs. Weight	Dose vs. Weight x Time	Dose vs. BMI	Dose vs. BMI x Time	Dose vs. Time
Ablation Only	0.23	0.68	0.13	0.61	0.37
BIV Only	0.43	0.44	0.37	0.44	0.18
BIV (No Subject 1)	0.45	0.60	0.42	0.65	0.37
All Procedures	0.37	0.41	0.30	0.36	0.12
All Procedures (No Subject 1)	0.26	0.63	0.21	0.59	0.32

Results

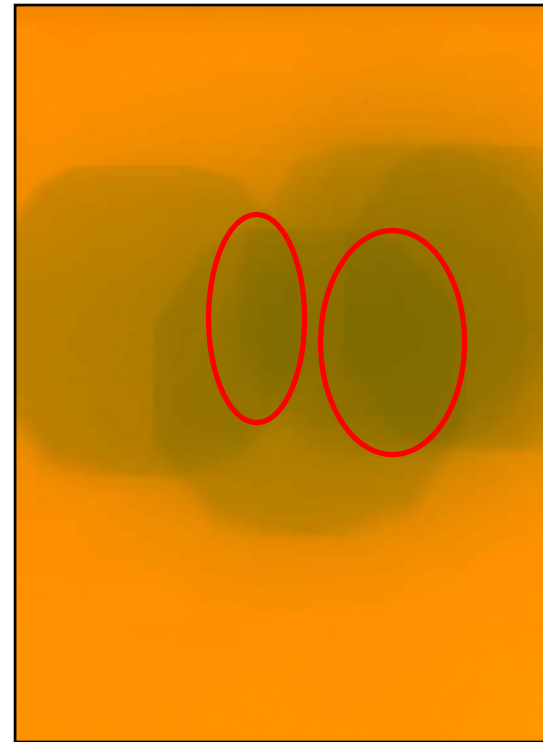
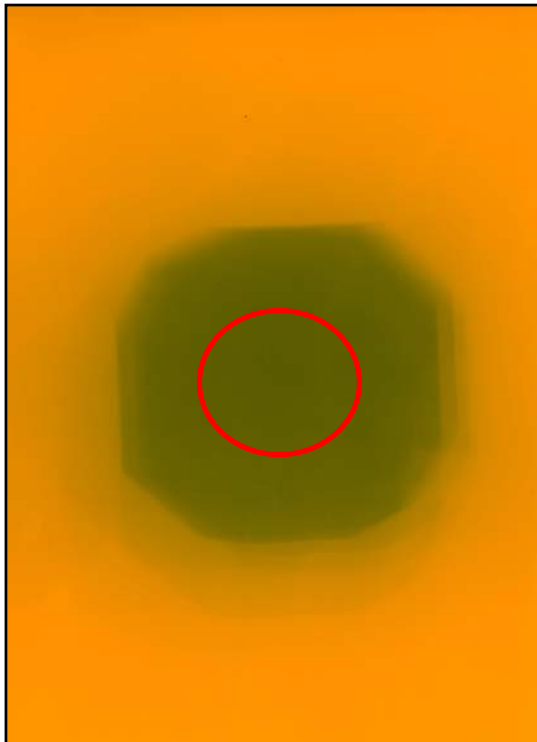


Results



Dose Monitoring for ABL and BIV

- Subject 2 (Ablation) and Subject 27 (BIV)



Literature Review - Ablation 62 ± 48 min

Author	Study Size	Procedure	Diagnosis	Fluoroscopy Time (minutes)	Skin Dose (rad)
Manolis	132	Ablation	Multiple Accessory Pathways	Mean of 89 ± 54	Not Reported
Rosenthal	799	Ablation	Not Specified	Mean of 58 ± 55	130 (estimate)
Macle	43	Ablation	Paroxysmal Atrial Fibrillation	Mean of 57 ± 30	Not Reported
Lindsay	108	Ablation	Supraventricular Tachycardia	Mean of 50 ± 31	Not Reported
Park	500	Ablation	Not Specified	Mean of 47 ± 31	93 ± 62 (estimate)
Manolis	24	Ablation	Atrial Tachycardia	Mean of 46 ± 35	Not Reported
Manolis	29	Ablation	Ventricular Tachycardia	Mean of 45 ± 28	Not Reported
Manolis	119	Ablation	AV Nodal Pathway	Mean of 27 ± 24	Not Reported

Literature Review - BIV Implant 51 ± 28 min

Author	Study Size	Procedure	Diagnosis	Fluoroscopy Time (minutes)	Skin Dose (rad)
Paisey	10	Biventricular	Not Specified	4.9-40.1 Median of 21.5	5-93 Median of 23
Kostas	14	Biventricular	Not Specified	Mean of 35 ± 22	Not Reported
Romeyer	103	Biventricular	Not Specified	Mean of 23 ± 19	Not Reported
AAPM	13	Biventricular	Not Specified	30-200 Median of 90	80-600 Median of 250

Background

- **Backscatter radiation**
 - **Significant contribution to skin dose**
 - **20-40%**
 - **X-ray energy**
 - **Field size**
 - **Patient thickness**
 - **Typical ESE 2.5-3 R/min (Mahesh/IAEA)**
 - **Backscatter factor**
 - **Observable effects after less than 1 hour**

Background

- **Body Mass Index (CDC 2005)**

- **BMI =** $\left(\frac{\text{Weight in Pounds}}{(\text{Height in inches}) \times (\text{Height in inches})} \right) \times 703$

- **18.5-24.9 is normal**
 - **25-29.9 is overweight**
 - **30 and above is obese**

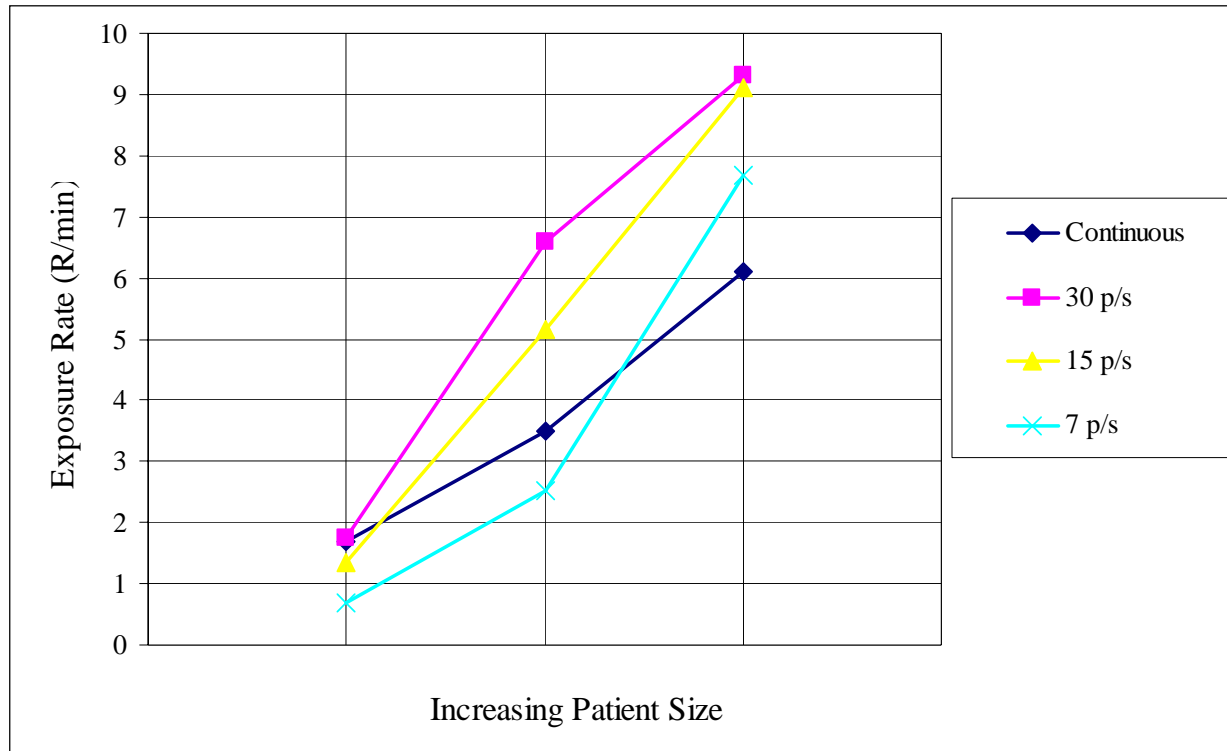
Dose Monitoring for ABL and BIV

- Dose monitoring
 - Procedure information sheet completed
 - Film and fluoroscopy time collected upon completion of the procedure

University of North Carolina-Chapel Hill Procedure Information Sheet
Medical IRB Study #: 05-RAD-358 Title of Study: The Use of a Radiochromic Film for the Evaluation of Skin Dose during Extended Fluoroscopy Procedures in an Electrophysiology Lab Principal Investigator: James Bradford Taylor UNC-CH Department: Environment, Health and Safety Phone Number: 919-962-5727
Subject Number (Corresponding to Number on Film) _____
Procedure Date _____
Subject Date of Birth _____ Subject Sex (circle one) <u>M</u> <u>F</u>
Patient Height (include units) _____ Patient Weight (include units) _____ Patient BMI (if available) _____
Procedure (circle one) <u>ABL</u> <u>BIV</u>
Nature of Ablation Procedure (i.e.: atrial flutter) _____
Attending Physician _____
Assisting Fellow (if applicable) _____
Total Fluoroscopy Time (minutes) _____
Optional Comments: kVp range during procedure _____ mA/ms range during procedure _____ SID range during procedure _____ Phosphor Size Used (circle one) <u>5</u> <u>7</u> <u>9</u> Mode of Operation (i.e.: continuous, pulsed) _____
FILM SCANNED ON _____ USING SCANNER STATION _____
CALIBRATION CURVE USED: _____ RED CHANNEL VALUE _____
DOSE (RAD) _____ (1Gy = 100 RAD)
ATTENDING PHYSICIAN NOTIFIED OF DOSE ON _____

Background

- **Toshiba Model XTP-8100 G**
 - **ESE depending upon patient size and mode**



Dose Monitoring for ABL and BIV

Calibration Tablet 2

Film Number	Date of Exposure	Minutes Exposed	Total Dose (R)
1	N/A	0.0	0.0
2	02/13/2006	6.0	193.4
3	02/13/2006	12.0	386.8
4	02/13/2006	18.0	580.2
5	02/13/2006	24.0	773.6
6	02/13/2006	30.0	967.0
7	02/13/2006	38.0	1224.9

Project Approval Process

- Office of Human Research Ethics
 - Institutional Review Board
 - Phase 1
 - 5 page application
 - Retrospective review of the fluoroscopy log



THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
Office of Human Research Ethics

Biomedical Institutional Review Board (IRB)
(919) 966-1344 FAX (919) 966-7879
www.med.unc.edu/irb/

School of Medicine Bldg. 52, CB 7097
University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-7097

September 8 2004

TO: Bradford Taylor

Your proposal entitled: Identification of Likely High Radiation Dose Procedures Through the Evaluation of Fluoroscopic Times in an Electrophysiology Lab


is exempt from review by The Committee on the Protection of the Rights of Human Subjects (the IRB for the University of North Carolina School of Medicine and the University of North Carolina Hospitals). Exemption is claimed on Number(s) 4 of the criteria for exemption outlined in 45 CFR Part 46 Section 101:

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly, or through identifiers linked to subjects.

Since the data, records and specimens referred to (in the regulations) are virtually never publicly available, the second requirement - anonymity - must be met. This precludes the recording of the research data (on worksheets as well as in final form) with a subject's name, initials, social security number, hospital record number, or code that can be used to link the information to the subject.

This exemption should be noted on the Department of Health and Human Services grant application form, and must include the exemption number(s) 4.

NOTE: If the project is changed, it should be re-submitted to the IRB office for a determination of whether it still satisfies exemption criteria.


Stephen A. Bernard, M.D.
Chairman, Committee on the Protection
of the Rights of Human Subjects

Project Approval Process

- Office of Human Research Ethics
 - Institutional Review Board
 - Phase 2
 - 14 page application
 - Use of radiochromic film to evaluate skin dose



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

OFFICE OF HUMAN
RESEARCH ETHICS

BIOMEDICAL INSTITUTIONAL
REVIEW BOARD (IRB)

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CHAPEL HILL, NC 27599-7097

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TO: Bradford Taylor
C/O Marija Ivanovic, PhD
Radiology CB# 7510
Carolina Campus

FROM: The Biomedical Institutional Review Board (IRB)

DATE: June 10 2005

SUBJECT: Research Application Review

STUDY: IRB# 05-RAD-358 Title: The Use of a Radiochromic Film for the
Evaluation of Skin Dose During Extended Fluoroscopy Procedures in
an Electrophysiology Lab

This research proposal has been considered by the Committee and
it has been approved until June 10 2006.

(1) Review Type: Expedited

(2) This Committee complies with the requirements found in Part 56 of the 21
Code of Federal Regulations and Part 46 of the 45 Code of Federal
Regulations. The assurance of compliance with DHHS regulations is on file
in the Committee office for your perusal. Federalwide Assurance: FWA-4801.

(3) Re-review of this proposal is necessary before:
(a) making any significant alterations or additions to the
proposal, except when necessary to eliminate apparent
immediate hazards to the subject, or
(b) continuing beyond the approval date.


Authorized Signature on behalf of the Committees

Project Approval Process

- Office of Human Research Ethics
 - Successfully complete Collaborative IRB Training Initiative



THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
Office of the Vice Chancellor for Research and Economic Development

Camper Box 4100, 301 Byram Hall
Chapel Hill, NC 27599-4100
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<http://research.unc.edu>

August 22, 2006

To Whom It May Concern:

In accordance with the National Institutes of Health (NIH) notices OD-00-039 of August 25, 2000 and OD-01-061 of September 5, 2001, The University of North Carolina at Chapel Hill submits the following information concerning the education in the protection of human research participants undertaken by the key personnel involved with this project. The following persons have been trained in the ethical and regulatory requirements for protection of human research participants in compliance with NIH requirements and The University of North Carolina at Chapel Hill "Policy on Education and Certification of Investigators Involved in Human Subjects Research." <http://ohre.unc.edu/irbtraining/>

Name	Dept	Training
James Taylor	Environment, Health & Safety	CITI- Biomedical
Marija Ivanovic	Radiology	CITI- Data only

Should any additional persons come to work on this project and meet the definition of key personnel, they will be trained similarly; their names and certification of their training in the protection of human research participants will be forwarded.

Sincerely,

James E. Peterson, Ph.D.
Associate Vice Chancellor and Director,
Office of Sponsored Research

Future Directions

- **Measure subject height/weight**
- **Measure chest thickness at landmark**
- **Record mode of operation (cont. vs. pulsed)**