Scientific and epidemiological background for radiation risk to the lens of the eye

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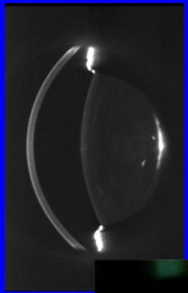

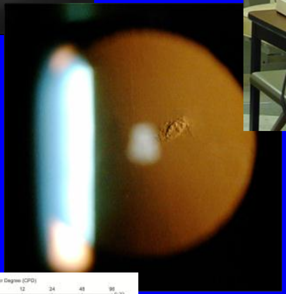
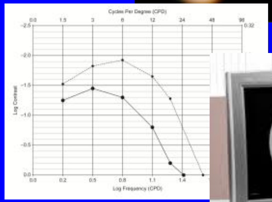


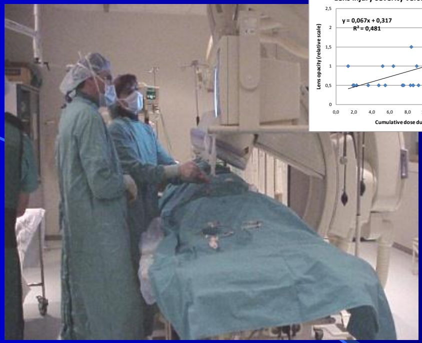
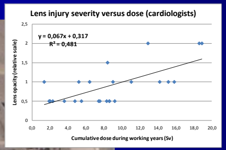

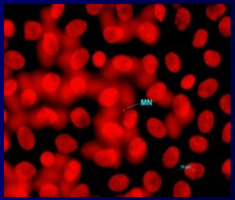

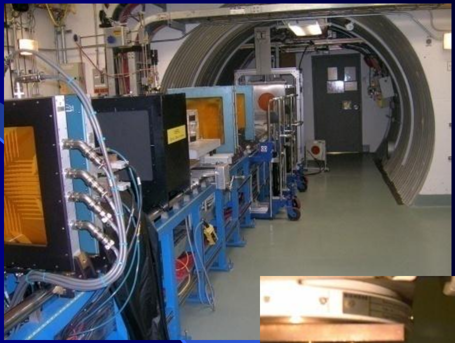
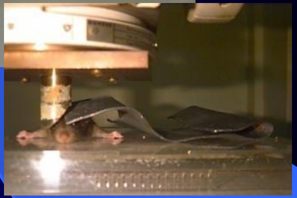

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Eye Radiation and Environmental Research Laboratory





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INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

ICRP ref 4825-3093-1464

Statement on Tissue Reactions

Approved by the Commission on April 21, 2011

(1) The Commission issued new recommendations on radiological protection in 2007 (ICRP, 2007), which formally replaced the Commission's 1990 Recommendations (ICRP, 1991a). The revised recommendations included consideration of the detriment arising from non-cancer effects of radiation on health. These effects, previously called deterministic effects, are now referred to as tissue reactions because it is increasingly recognised that some of these effects are not determined solely at the time of irradiation but can be modified after radiation exposure.

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INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

ICRP ref 4825-3093-1464

(2) The Commission has now reviewed recent epidemiological evidence suggesting that there are some tissue reaction effects, particularly those with very late manifestation, where threshold doses are or might be lower than previously considered. For the lens of the eye, the threshold in absorbed dose is now considered to be **0.5 Gy**.

(3) For occupational exposure in planned exposure situations the Commission now recommends an equivalent dose limit for the lens of the eye of **20 mSv** in a year, averaged over defined periods of 5 years, with no single year exceeding **50 mSv**.

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SOLACI
SOCIEDAD LATINOAMERICANA DE CARDIOLOGIA INTERVENCIONISTA


ICRP Publication 85

Avoidance of Radiation Injuries from Medical Interventional Procedures

Above: Photograph of the patient's back after a coronary angiography and two angioplasty procedures within three days, assessed cumulative dose 15,000 to 20,000 mGy. The patient has consistently refused skin grafting after excision of necrotic tissue. (Photograph courtesy of F. Mettler).

Below: Cataract in the eye of an interventionist after repeated use of old x-ray systems and improper working conditions related to high levels of scattered radiation. (Photograph courtesy of E. Vañó).

An information publication for the medical profession from the

ICRP
INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

IAEA.org
International Atomic Energy Agency

NATIONAL HEART ASSOCIATION OF MALAYSIA

Retrospective Evaluation of Lens Injuries and Dose: "RELID"

The British Journal of Radiology, 71 (1998), 728–733 © 1998 The British Institute of Radiology

Lens injuries induced by occupational exposure in non-optimized interventional radiology laboratories

[1]E VAÑÓ, PhD, [1]L GONZÁLEZ, PhD, [2]F BENEYTEZ, MD and [3]F MORENO, MD

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Chernobyl “Liquidators”

Interventional cardiologists

Residents of contaminated buildings

Infants treated for facial hemangiomas

Radiological technologists

A-bomb survivors

Astronauts

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IRPA

INTERNATIONAL RADIATION PROTECTION ASSOCIATION

Report of Task Group on the Implications of the Implementation of the ICRP Recommendations for a Revised Dose Limit to the Lens of the Eye

Summary

This report was commissioned by the IRPA President to provide an assessment of the impact on members of IRPA Associate Societies of the introduction of ICRP recommendations for a reduced dose limit for the lens of the eye.

The report summarises current practice and considers possible changes that may be required.

Recommendations for further collaboration, clarification and changes to working practices are suggested.

May 2013

NCRP
National Council on Radiation Protection & Measurements

Immediate Release
February 14, 2011

NCRP Releases Report No. 168, *Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures*

NCRP Report No. 168, *Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures*, provides recommendations and supporting information on radiation dose management for patients and medical staff during the use of fluoroscopic systems for guiding diagnostic and therapeutic medical procedures.

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Radiation Exposure of the Anesthesiologist in the Neurointerventional Suite

Zirka H. Anastasian, M.D.,* Dorothea Strozyk, M.D.,† Philip M. Meyers, M.D.,‡ Shuang Wang, Ph.D.,§ Mitchell F. Berman, M.D., M.P.H.‖

Anesthesiology **114**, 512-520, 2011

Catheterization and Cardiovascular Interventions 81:562–567 (2013)

Core Curriculum

A Summary of Recommendations for Occupational Radiation Protection in Interventional Cardiology

Ariel Durán,[1] MD, FACC, Sim Kui Hian,[2] MBBS, FRACP, Donald L. Miller,[3] MD, John Le Heron,[4*] BSc(Hons), FACPSEM, Renato Padovani,[5] PhD, and Eliseo Vano,[6] PhD

Journal of Radiation Research, 2013, 54, 315–321
doi: 10.1093/jrr/rrs104 Advance Access Publication 9 November 2012

Quantitative evaluation of light scattering intensities of the crystalline lens for radiation related minimal change in interventional radiologists: a cross-sectional pilot study

Toshi ABE[1,*], Shigeru FURUI[2], Hiroshi SASAKI[3], Yasuo SAKAMOTO[3], Shigeru SUZUKI[4], Tatsuya ISHITAKE[5], Kinuyo TERASAKI[1], Hiroshi KOHTAKE[2], Alexander M. NORBASH[6], Richard H. BEHRMAN[7] and Naofumi HAYABUCHI[1]

Radiation-associated Lens Opacities in Catheterization Personnel: Results of a Survey and Direct Assessments

Eliseo Vano, PhD, Norman J. Kleiman, PhD, Ariel Duran, MD, Mariana Romano-Miller, MD, and Madan M. Rehani, PhD

J Vasc Interv Radiol 2013; 24:197–204

Radiation Protection Dosimetry (2011), pp. 1–5 doi:10.1093/rpd/ncr010

PRINCIPLES FOR THE DESIGN AND CALIBRATION OF RADIATION PROTECTION DOSEMETERS FOR OPERATIONAL AND PROTECTION QUANTITIES FOR EYE LENS DOSIMETRY

J. M. Bordy[1,*], G. Gualdrini[2], J. Daures[1] and F. Mariotti[2]
[1]CEA, LIST, Laboratoire National Henri Becquerel (LNE LNHB), F91191 Gif sur Yvette Cedex, France
[2]ENEA-BAS-ION IRP Radiation Protection Institute, Via dei Colli 16, 40136 Bologna (BO), Italy

Radiation Protection Dosimetry (2011), pp. 1–5 doi:10.1093/rpd/ncr299

RADIATION AND CATARACT

Madan M. Rehani[1,*], Eliseo Vano[2], Olivera Ciraj-Bjelac[3] and Norman J. Kleiman[4]
[1]International Atomic Energy Agency, Vienna, Austria
[2]Radiology Department, Complutense University, Madrid, Spain
[3]Vinca Institute of Nuclear Sciences, Belgrade, Serbia
[4]Mailman School of Public Health, Columbia University, New York, NY, USA

Catheterization and Cardiovascular Interventions 78:770–776 (2011)

VALVULAR AND STRUCTURAL HEART DISEASES

Original Studies

Occupational Radiation Dose During Transcatheter Aortic Valve Implantation

Loes D. Sauren,[1*] PhD, Leen van Garsse,[2] MD, Vincent van Ommen,[3] MD, PhD, and Gerrit J. Kemerink,[4] PhD

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CATARACT

A change in transparency of the lens

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Why study the lens?

Why do we still care about cataract?

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Cataract and World Blindness

- 25 million blind people globally due to cataract
- 119 million individuals visually impaired by lens opacification
- Cataract is still the leading cause of blindness in the 3rd world
- Lens opacities can be found in 96% of all individuals older than 60 yrs
- With an increasingly healthy, aging population, the societal and economic burden of cataract surgery is expected to greatly increase
  - Cataract surgery represents 12% of the U.S. Medicare budget and 60% of all Medicare visual costs

WHO, 2002, Eye Diseases Research Prevalance Group, 2004

Hans Bethke

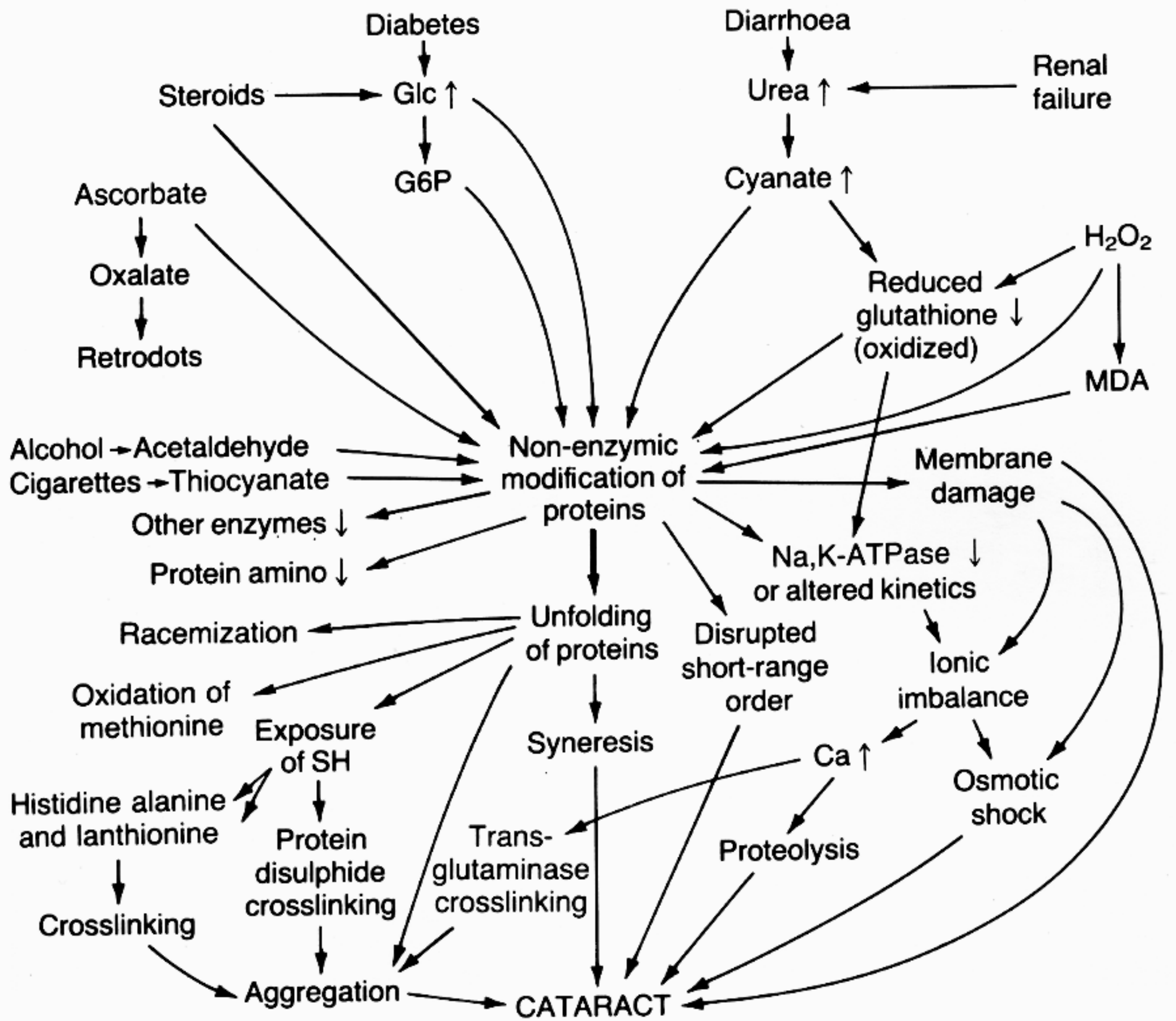

Figure 9.22 The pathways leading to lens protein degradation and cataract. (From Harding 1991 with permission.)

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RADIATION CATARACT

a specific subset of lens opacities

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Classical Radiation Cataract

A lens opacity most often originating near the visual axis, first appearing in the posterior subcapsular region of the lens

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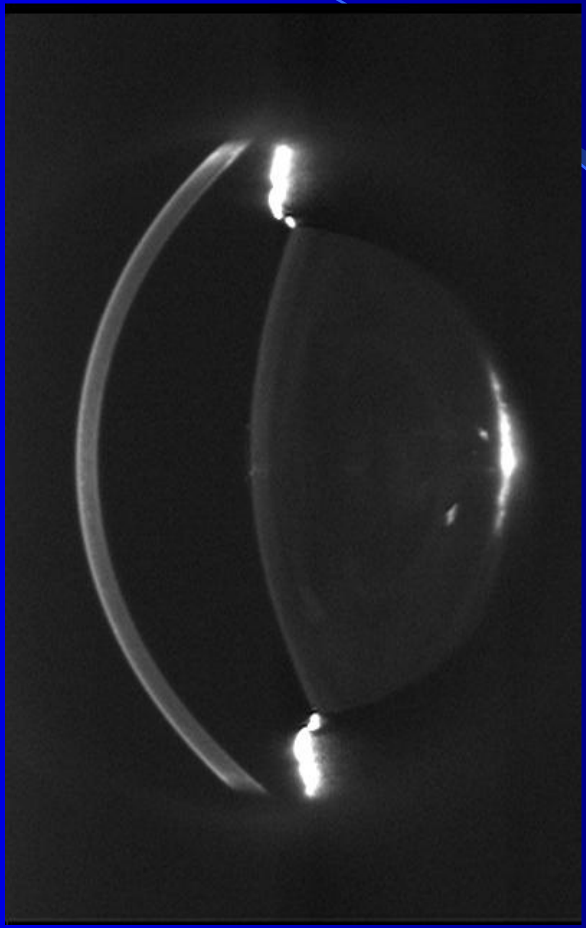
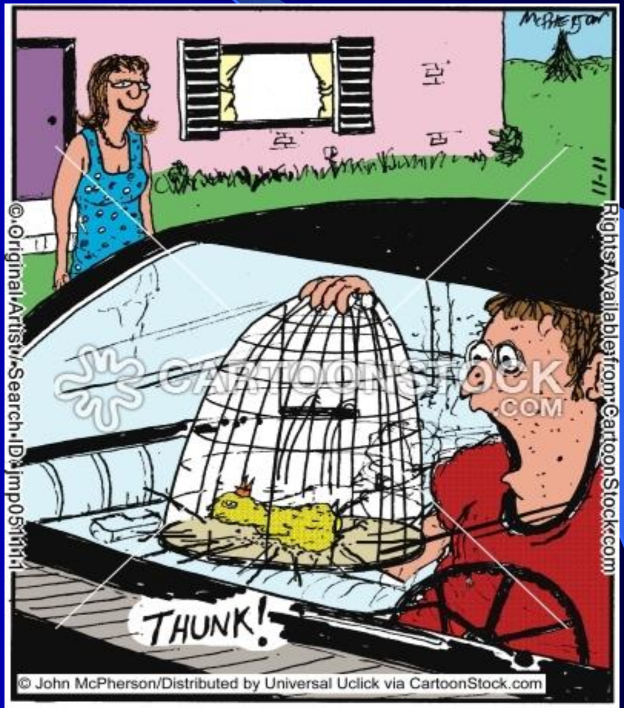


radiation cataract

(Scheimpflug image)

Why do we care about radiation cataract?

- Impact on workers
- May be preventable
- Canary in a coal mine?



Before picking up a date, Doug always tested his breath on a canary that he kept in the car.

The lens is one of the most radiosensitive of all tissues

Radiation cataract provides a model for studying long-term biological effects following low-dose ionizing radiation exposures in environmental or occupational settings.

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Potential visual disability and morbidity resulting from radiation cataract and/or its treatment is greatly underappreciated.

Potential Low-Dose Radiation Exposures

- Accidental
  - Chernobyl, Fukushima, future??
  - contaminated buildings (*e.g. Taiwan*)
  - terrorism
- **Occupational**
  - **interventional physicians**
  - **associated nurses and technicians**
  - **nuclear medicine personnel**
  - **nuclear plant workers**
  - **industrial workers**
  - **astronauts**
  - **uranium miners**
- Medical
  - Diagnostic procedures
  - Therapeutic treatments
- Environmental
  - indoor radon
  - geography (Denver, USA; Kerala, India; Ramsar, Iran**)**

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Occupational exposure to the lens

increasing usage

Radiologists

Cardiologists

Gastroenterologists

Orthopedists

Urologists

Vascular medicine

Neurologists

Anesthesiologists

Nurses and technicians

Other workers

…limited study

How much exposure?

- 17 million interventional fluoroscopic procedures (USA) (NCRP-2009)
  - *4.6 million cardiac*
  - *3.4 million vascular*
  - *8.6 million non-vascular*

- 8.6% annual increases

Health Physics ***103****: 80-99, 2012*

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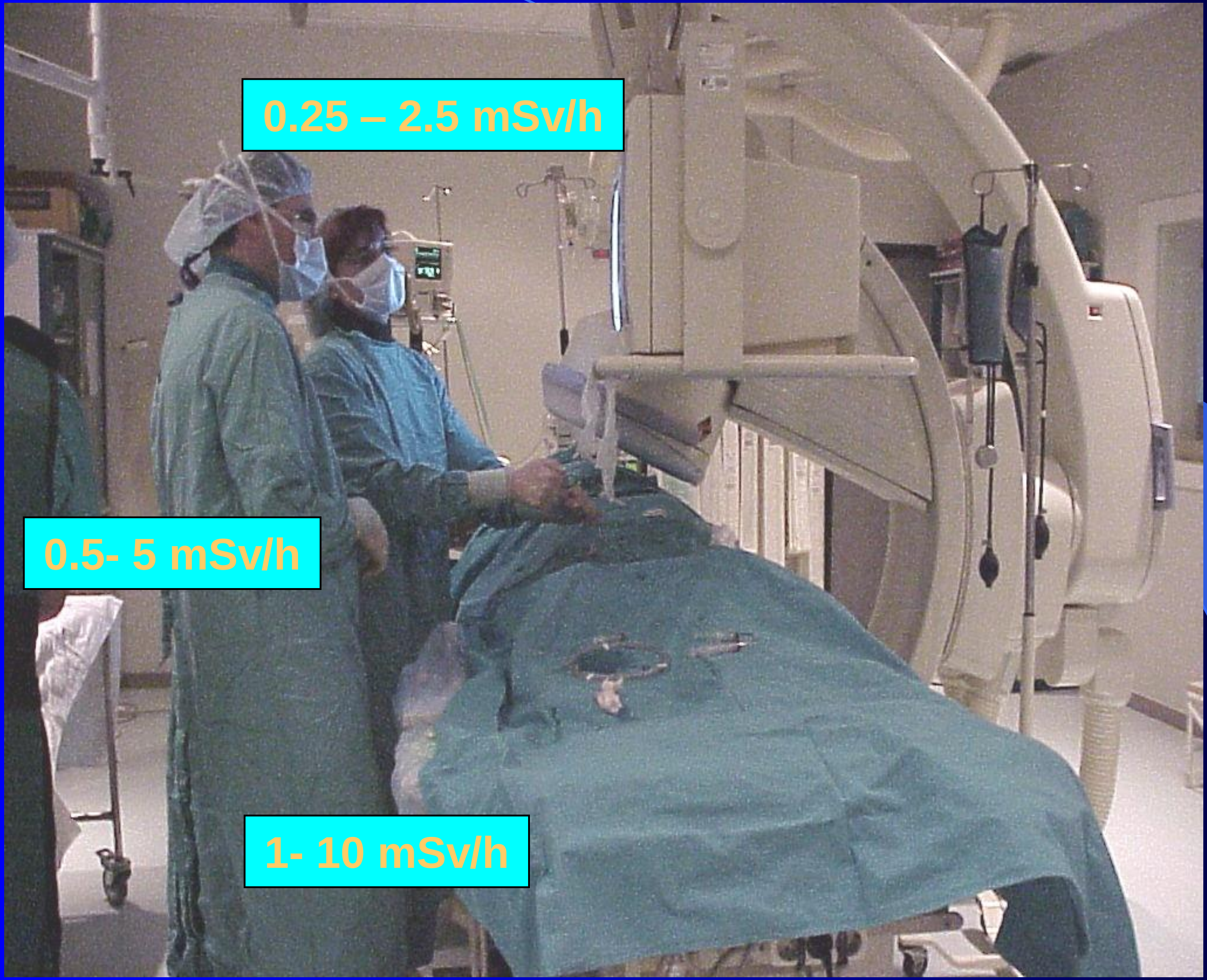
Interventional Medicine



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- *Is there new data on human radiation cataract risk? Are proposed new eye dose limits appropriate?*
- *What is the relevance of radiation cataract to human radiobiology?*
  - *-Can we utilize radiation cataract as a "biomarker" of radiation exposure?*
  - *-Can we model radiation sensitivity and /or population heterogeneity effects using this approach*
    - *-i.e., can we identify specific genes that confer sensitivity or resistance to radiation cataract?*
- *Can we find alternative methodologies for quantitating lens opacities for that better estimate any visual disability caused by radiation exposure?*

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Additional data regarding the dose threshold, if any, for visual disability is <u>essential</u> for better occupational risk assessment and further refinement of suggested exposure guidelines.

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Prior to 2012, eye exposure guidelines were based on the view that radiation cataract is a "deterministic" event with a relatively high threshold radiation dose

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ICRP ref 4825-3093-1464

(2) The Commission has now reviewed recent epidemiological evidence suggesting that there are some tissue reaction effects, particularly those with very late manifestation, where threshold doses are or might be lower than previously considered. For the lens of the eye, the threshold in absorbed dose is now considered to be **0.5 Gy**.

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Establishing an accurate dose threshold, if any, for radiation cataractogenesis is critical for risk assessment and exposure guidelines.

How did we derive the guidelines for lens exposure limits?

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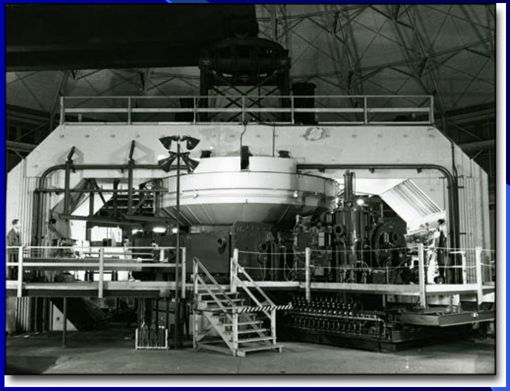
Early Radiation Cataract Studies

"Ophthalmological survey of atomic bomb survivors in Japan in 1949"
Trans. Am. Ophthalmol. Soc. **48**, 1950



"Cyclotron-induced radiation cataracts" *Science* **110**, 1949

- **Chalupecky, 1897**
- **Rohrschneider, 1932**
- **Hiroshima, Nagasaki, 1945**
- **Cyclotron , 1940's**
- **Poppe, Cogan, 1950's**
- **Merriam & Focht, 1957, 1962**
- **Merriam & Worgul, 1976**

Early Radiation Cataract Studies

- Important historical studies that helped define the nature of radiation cataract and establish initial guidelines for safe exposures to the lens.

- Failed to take into account increasing latency period as dose decreases.

- Did not have sufficient sensitivity to detect early lens changes.

- Relatively few subjects with doses below a few Gy.

Historical
Threshold Estimates (Sv)

threshold dose	reference	# subjects
5 - 15	*anecdotal*, pre-1950	100
2 - 5.5	*Merriam and Focht*, 1957	276
0.7 - 1.4	*Otake*, 1982	2,124
0.4 – 0.7	*Worgul, 2007*	8,600

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Additional data regarding the dose threshold, if any, for visual disability is essential for better occupational and environmental risk assessment and further refinement of suggested exposure guidelines.

The lens

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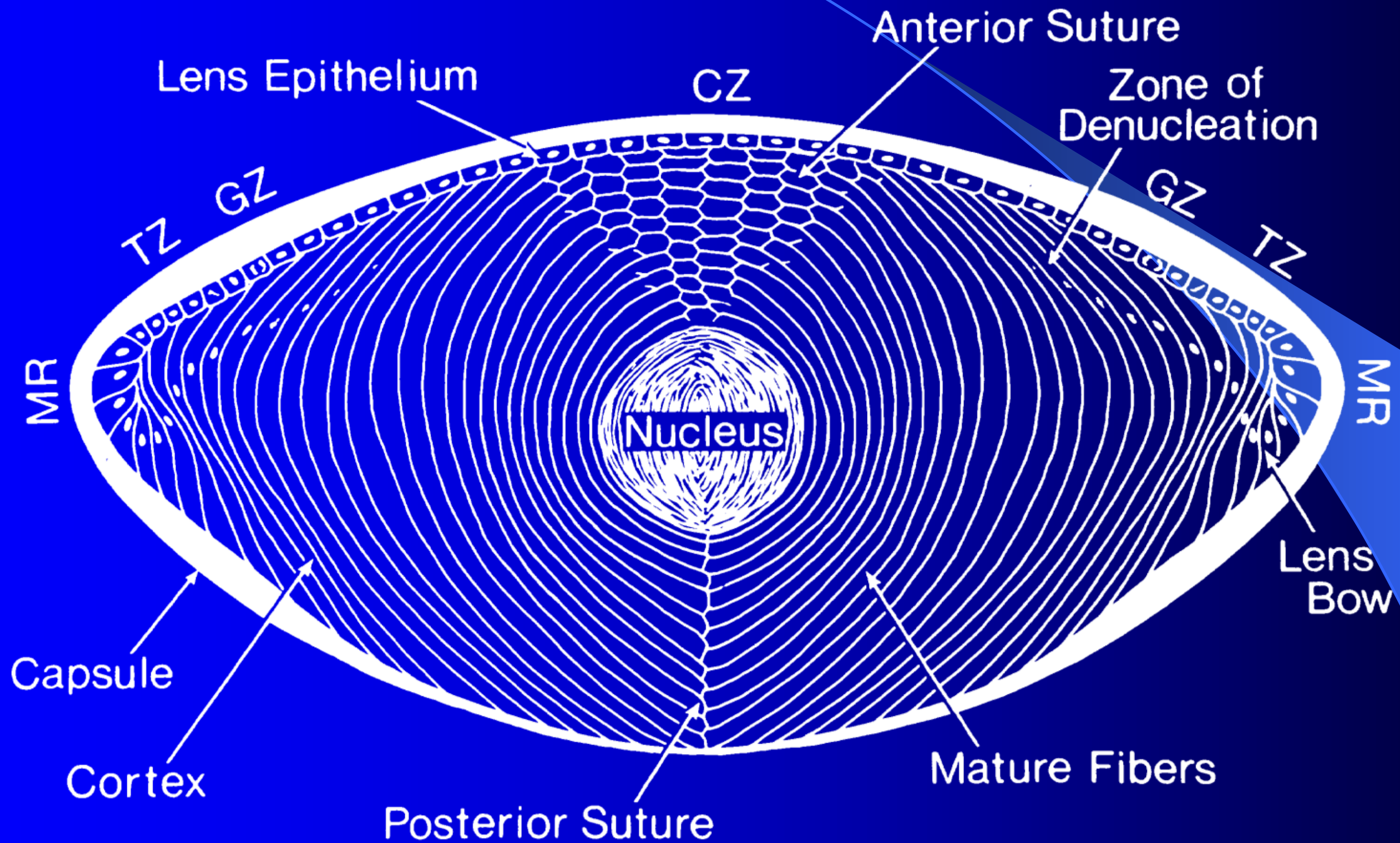

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Three things to remember about the lens

The lens grows throughout life

The source of that growth is a proliferating subset of the anterior epithelial cell monolayer

Transparency is dependent on proper division and differentiation of the progeny of this proliferative population

Radiation Cataract Pathomechanism

Genotoxic damage to the lens epithelium

Lens shielding studies
Mitotic inhibition studies
Irradiation of posterior 2/3 lens

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IONIZING RADIATION

Damage to Lens Epithelial DNA

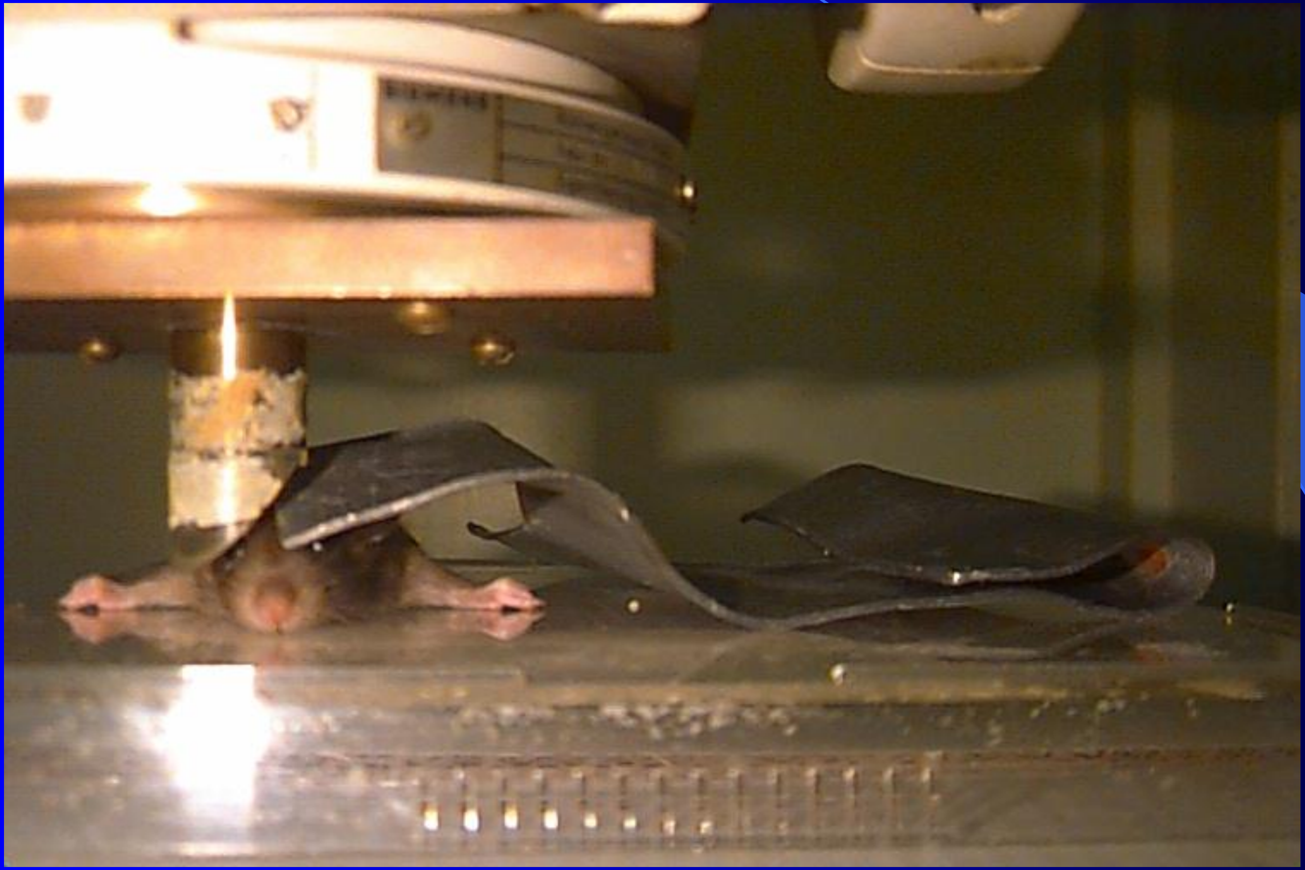
[*dividing cells*] → [*differentiating cells*]

Abnormal Lens Fibers

Loss of Transparancy

CATARACT

ANIMAL STUDIES



Irradiation of the mouse lens by 500 mGy X-ray
(Contralateral eye shielded)

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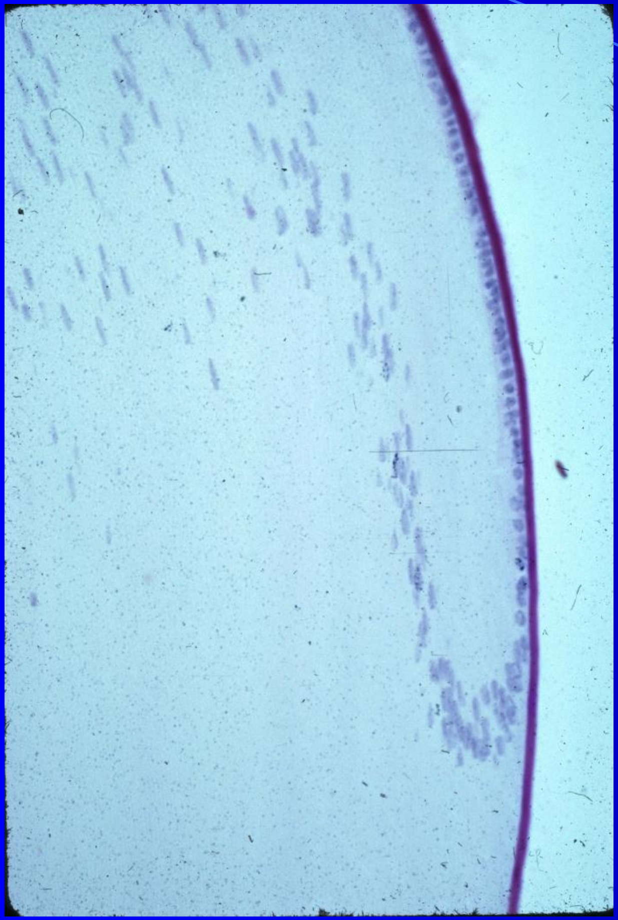
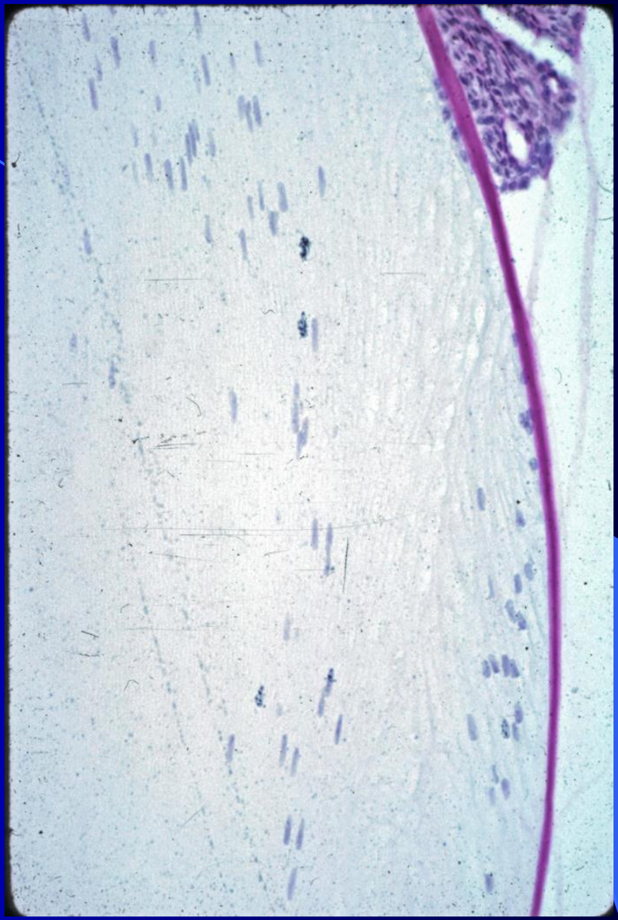


normal

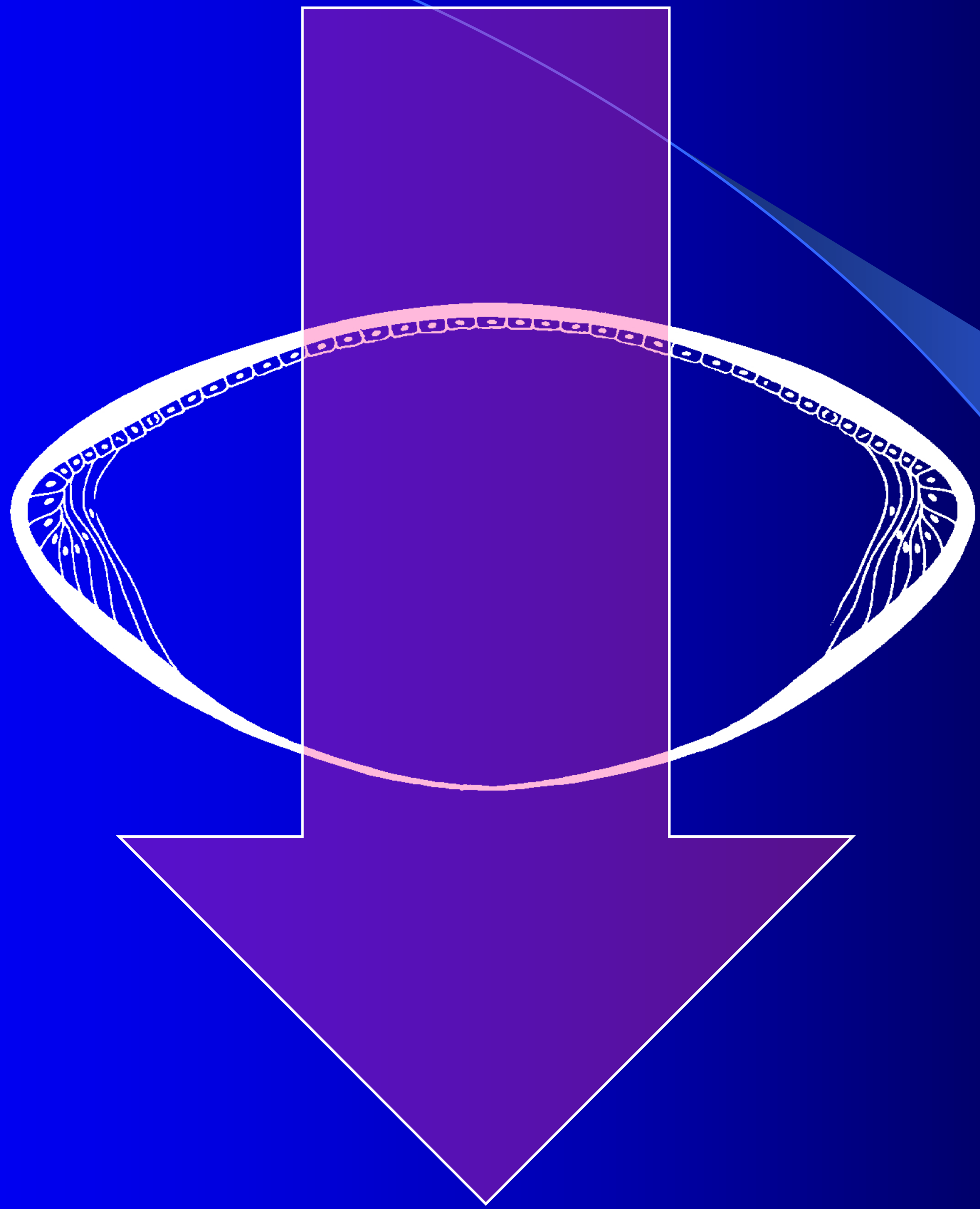


irradiated

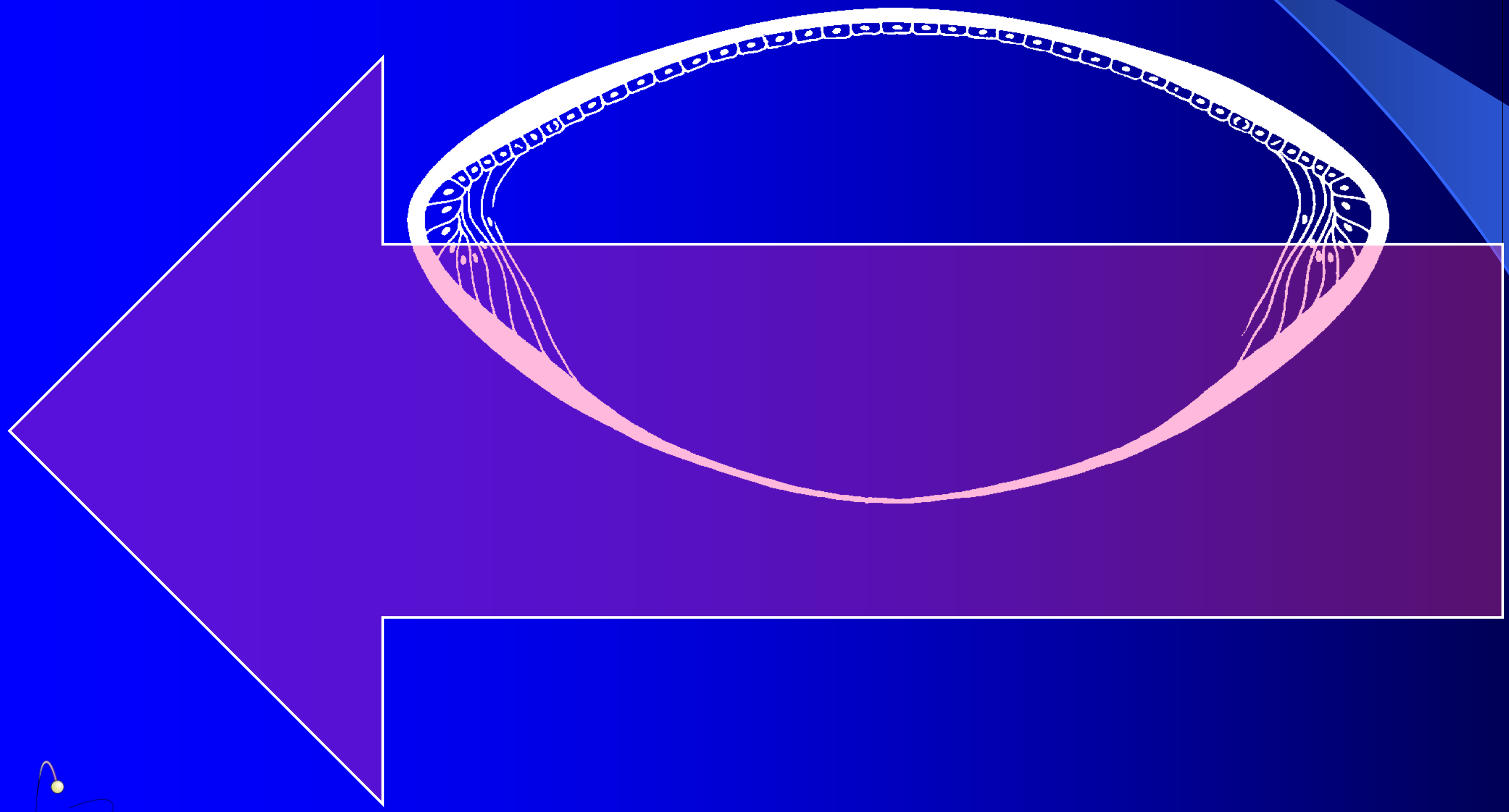
Transparency is dependent on proper differentiation of maturing lens fiber cells

X-ray

X



X



X-ray

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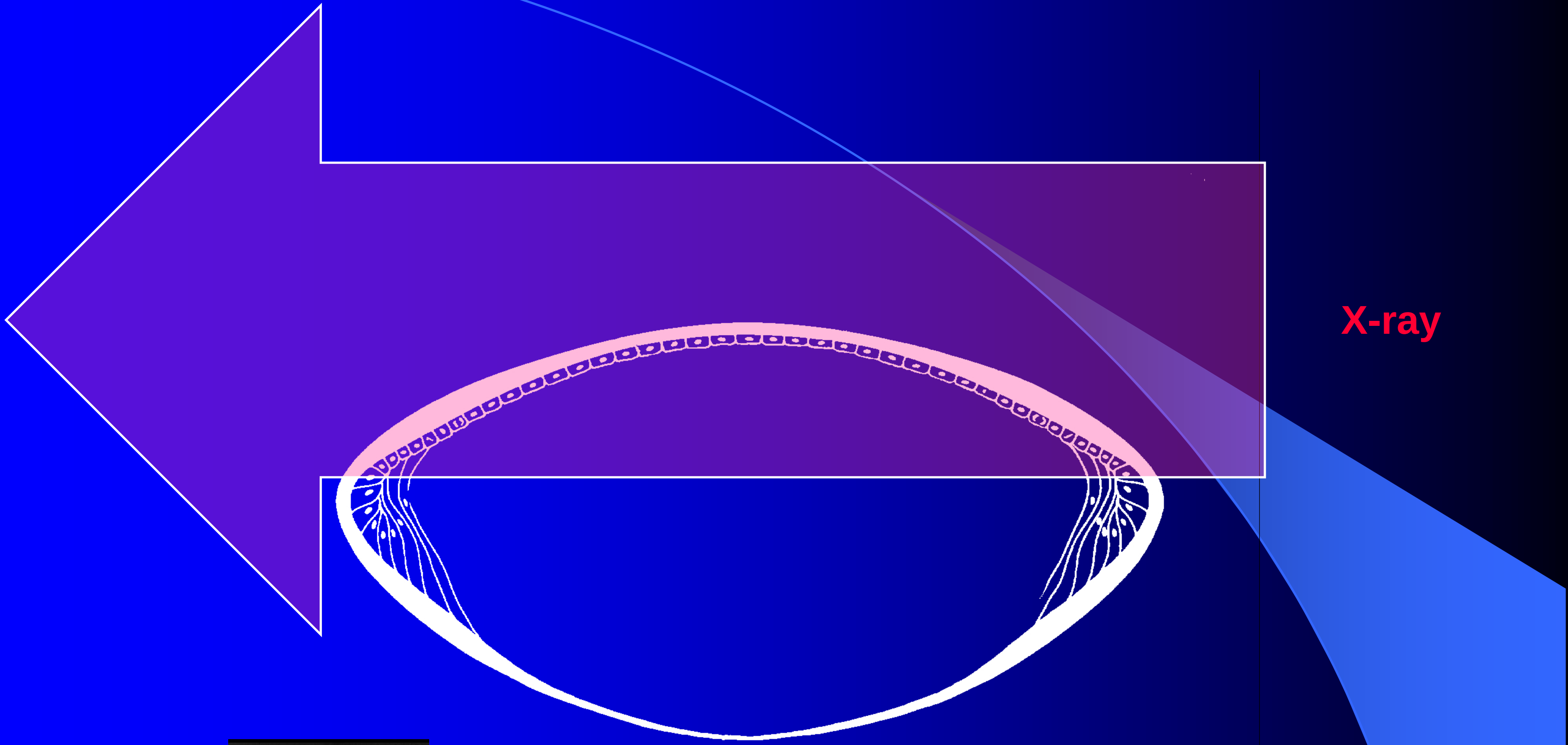

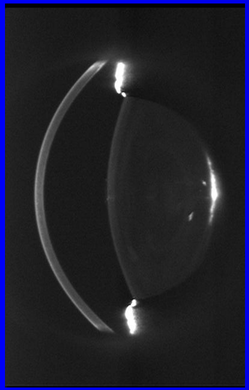

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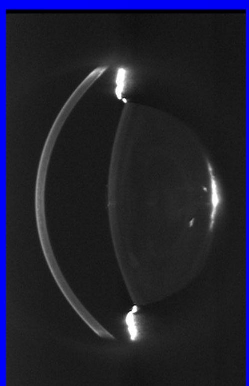
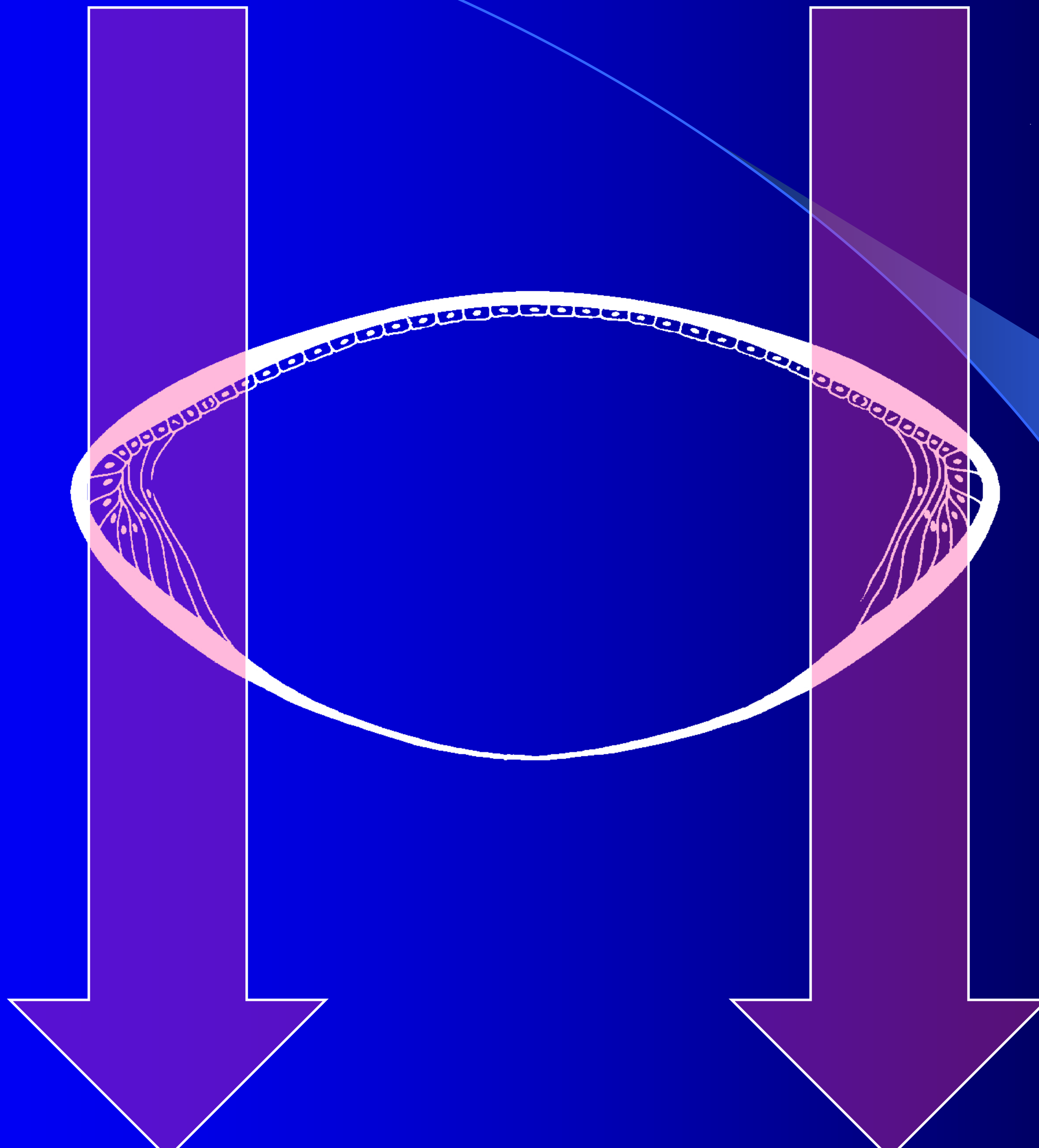
X-ray





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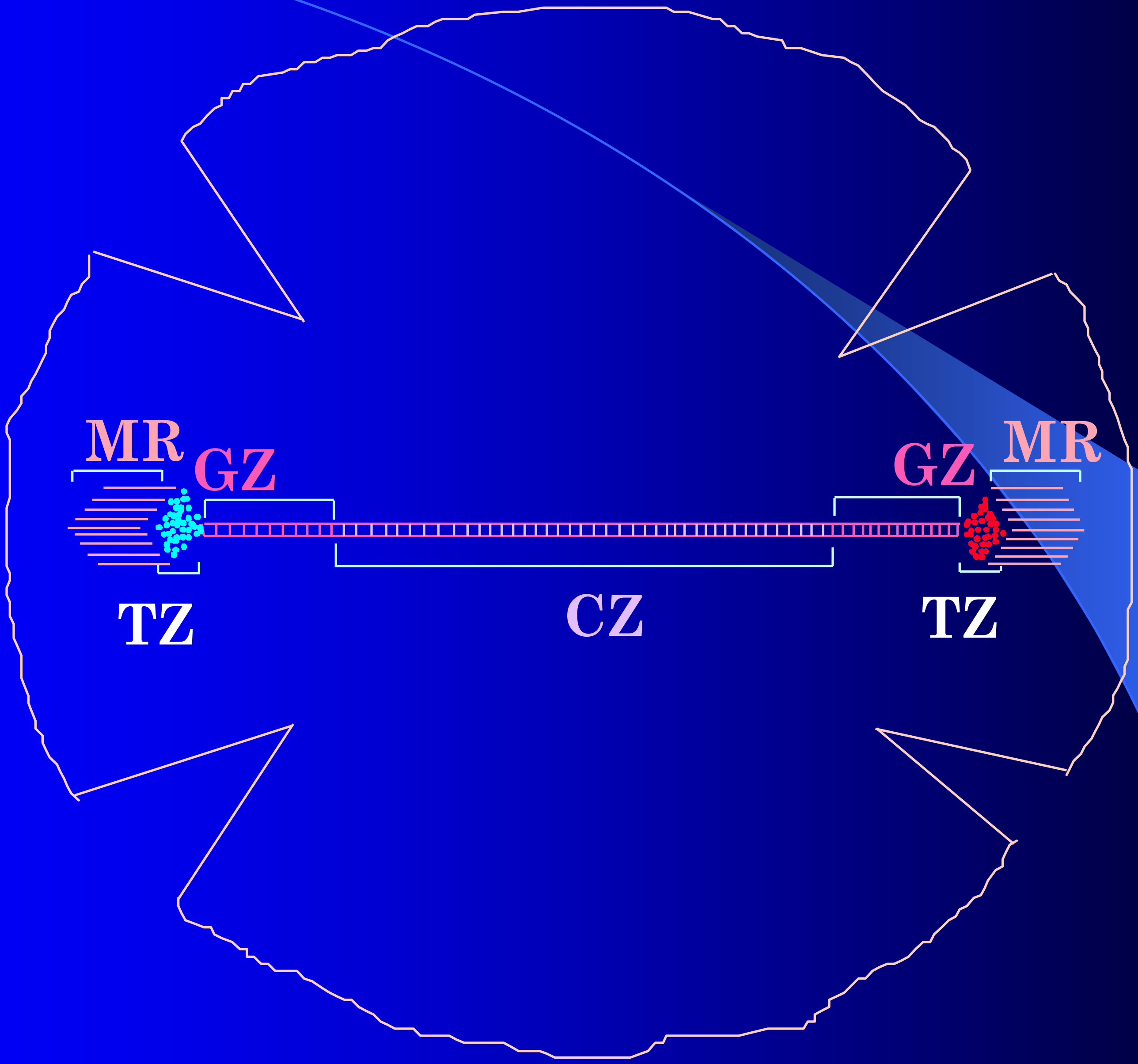
The radiation target is a small proliferating subset of the lens epithelial population



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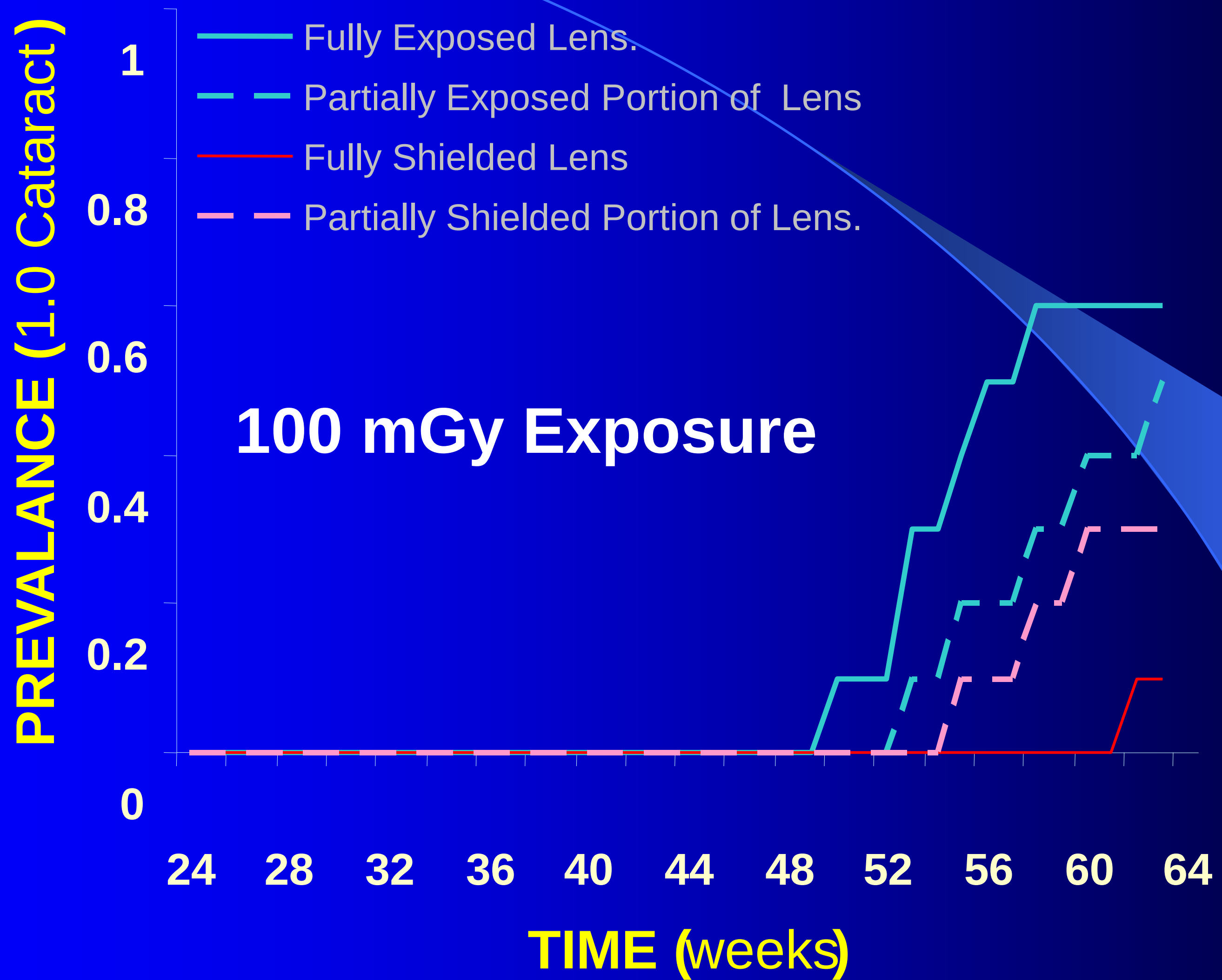
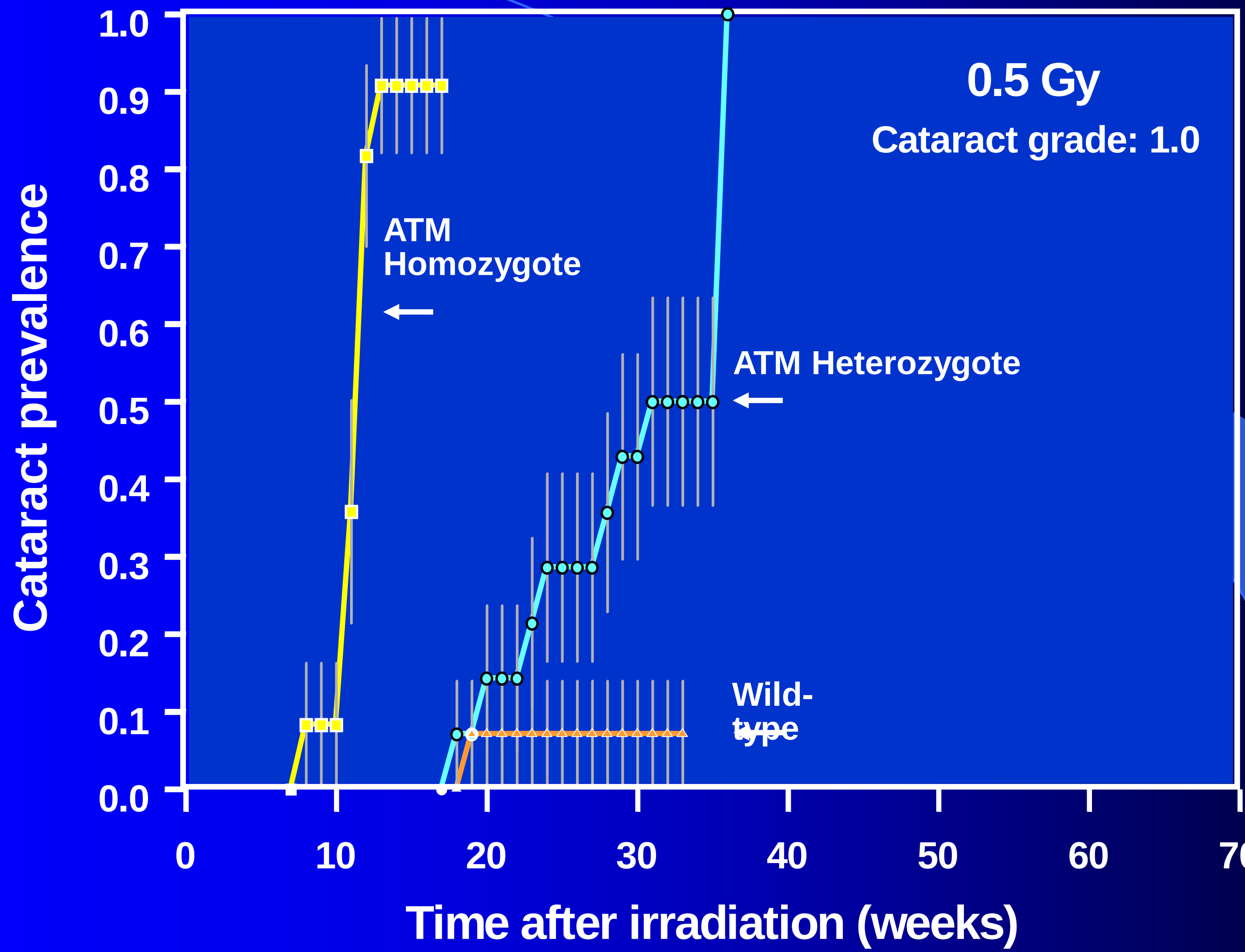
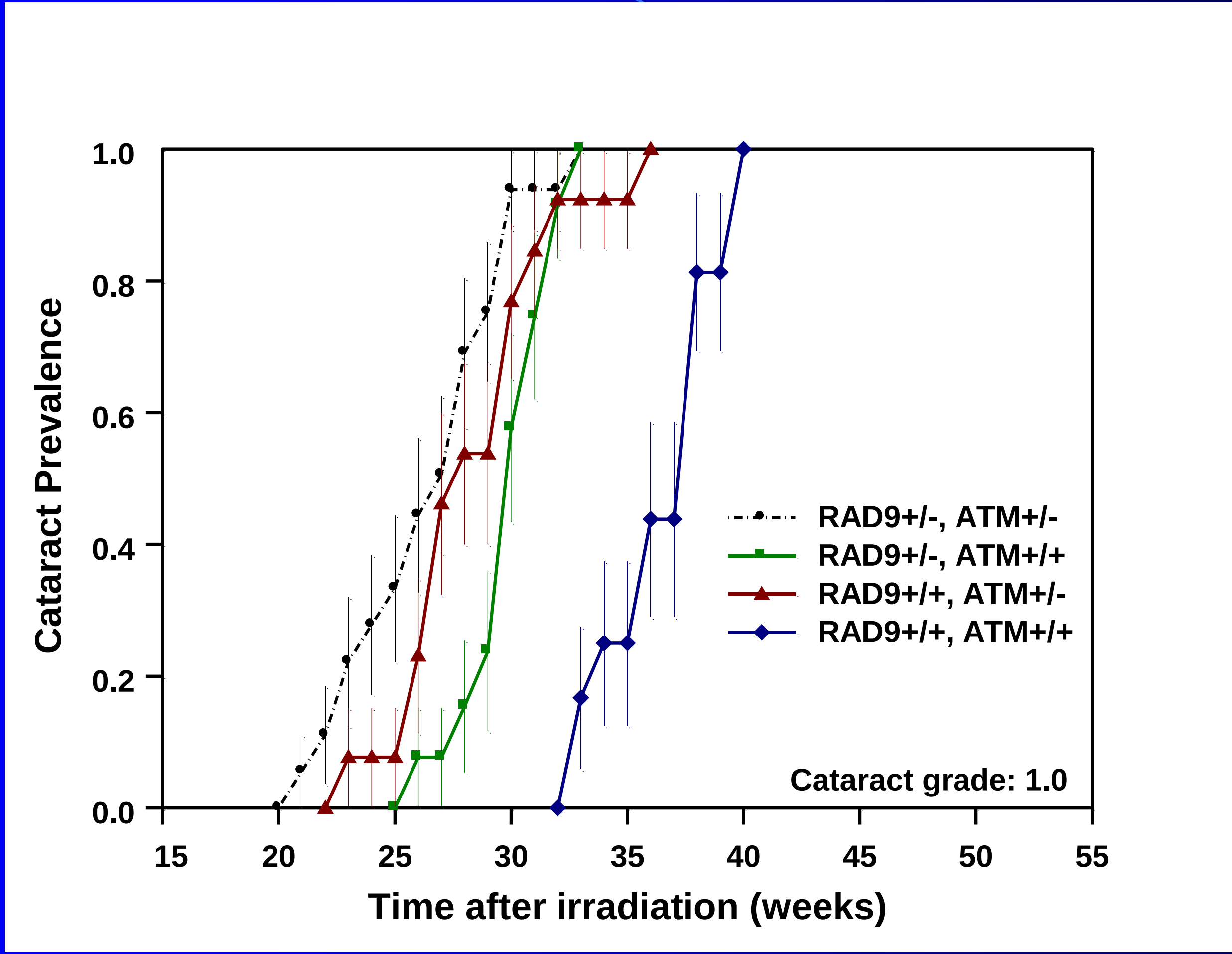


Invest. Ophthalmol. Vis. Sci. **46**, 2005



Rad Environ Biophys **45**, 2006



Radiat. Res **168**, 2007

HUMAN STUDIES

More recent studies of occupational risk: Epidemiological findings

More recent studies are consistent with a very low or even zero threshold model for radiation cataract

Diagnostic procedures	Klein, 1993
Radiotherapy	Wilde, 1997 Hall, 1999
Astronaut core	Cucinotta, 2001 Rastegar, 2002
Atomic bomb survivors	Nakashima, 2006 Neriishi, 2007, 2012
Contaminated buildings	Chen, 2001
Chernobyl	Day, 1995 Worgul, 2007
Occupational Risk	Worgul, 2004 Chodick, 2008

B.V. Worgul, Z.J. Haskal and A.K. Junk (2004)
RSNA News **14**, 5-6, 2004

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- Pilot study involving eye exams of 59 interventional radiologists 29-62 years old

- Frequency and severity of posterior subcapsular cataract increased with age and years in practice

- Nearly half of those examined had early lens changes associated with radiation cataract

- 5/59 had clinically significant posterior subcapsular cataracts (psc)

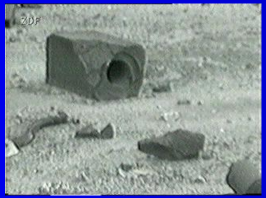
- 22/59 had posterior dots and vacuoles characteristic of early psc development

Cataracts among Chernobyl clean-up worker: Implications regarding permissible eye exposures

B.V. Worgul, Y.I. Kundiyev, N.M. Sergiyenko, V.V. Chumak, P.M. Vitte, C.P Medvedovsky, E.V. Bakhanova, A.K. Junk, O.Y. Kyrychenko, N.V. Musijachencko, S.A. Shylo, O.P. Vitte, S. Xu, X. Xue and R.E. Shore

Radiat. Res. 167, 233-243 (2007)

The Ukrainian American Chernobyl Ocular Study (UACOS)



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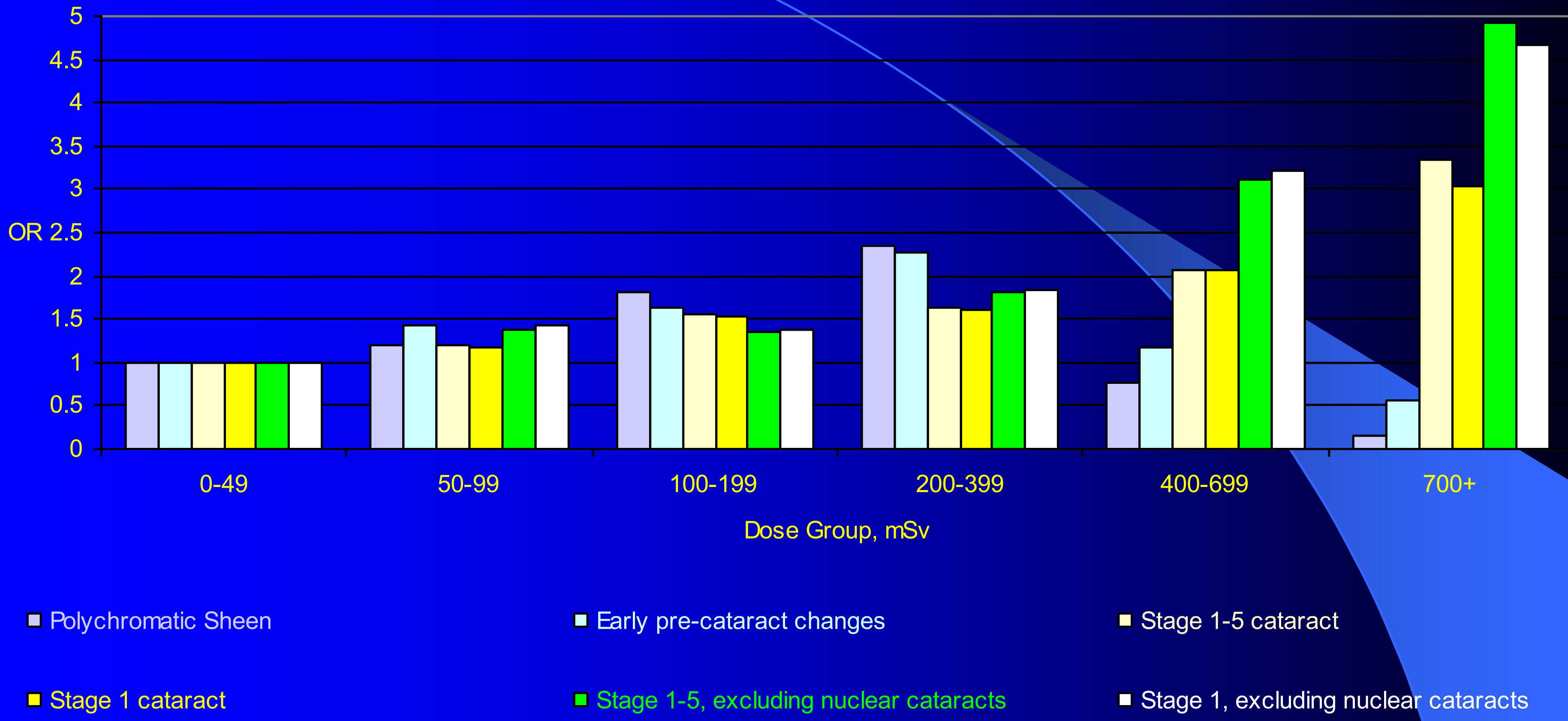
Adjusted Odds Ratios for Cataract Outcome Variables (Incidence Data) Among the Chernobyl Liquidators



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Neriishi, Nakashima, et al. (2007) Postoperative cataract cases among atomic bomb survivors: radiation dose response and threshold. *Rad Res* **168**:404-408.

Neriishi, Nakashima, *et al.* (2012) Radiation dose and cataract surgery incidence in atomic bomb survivors, 1986-2005. *Radiology* **265**:167-174.

first documentation of clinically relevant visual disability (cataract extraction) following low dose exposure

threshold dose estimate of 0.45 Gy
95% confidence interval of 0.1-1.0Gy

At the time of the study (2005), the youngest survivors were only 57 years old, suggesting that additional cases may occur in future years.

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Risk of Cataract after Exposure to Low Doses of Ionizing Radiation: A 20-Year Prospective Cohort Study among US Radiologic Technologists

G. Chodick, N. Bekiroglu, M. Hauptmann, B.H. Alexander, D.M. Freedman, M.M. Doody, L.C. Cheung, S.L. Simon, R.M. Weinstock, A. Bouville and A.J. Sigurdson

Am. J. Epidemiol. **168,** 620-631 (2008)

- long term, prospective analysis of self-reported cataract diagnosis in 35,700 individuals 22-44 years old at study onset

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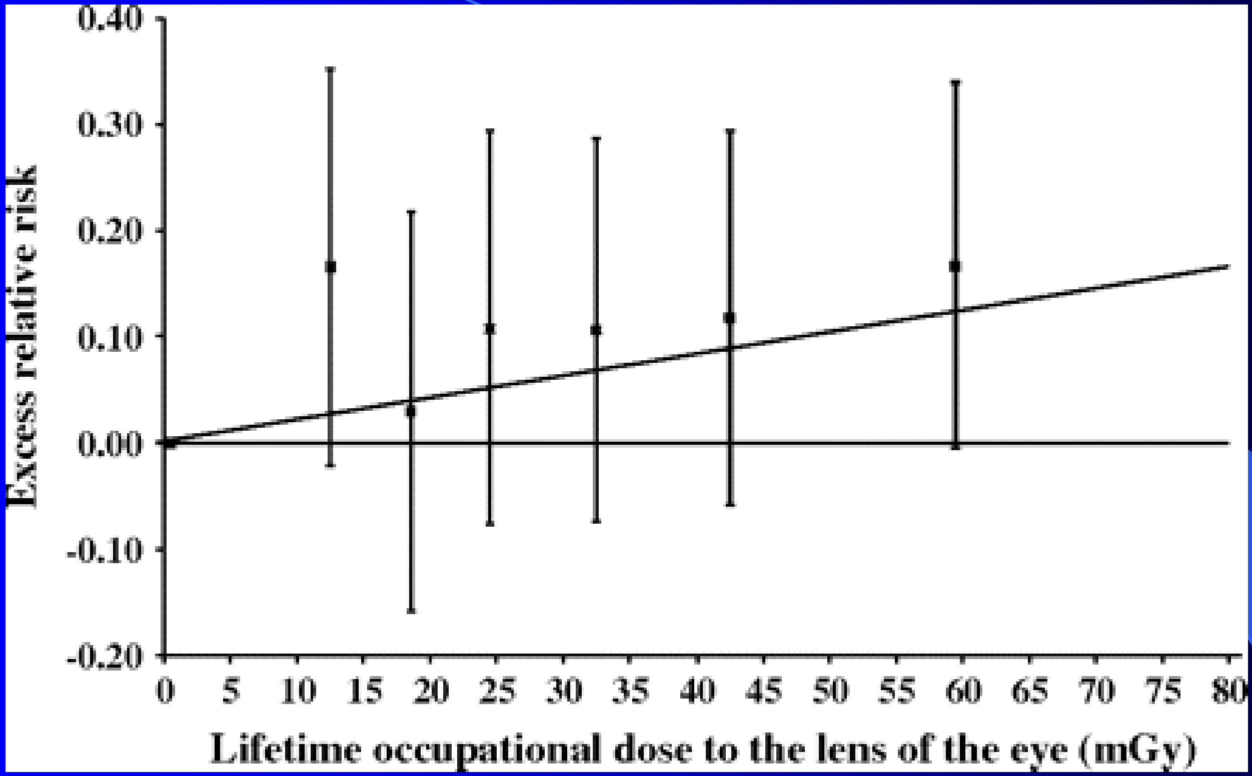

- adjusted cataract hazard ratio of 1.18 for those in the highest exposure range (60 mGy) as compared to those in the lowest (5 mGy)
- the median occupational ionizing radiation dose to the lens was estimated to be 28.1 mGy for the entire cohort

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Retrospective Evaluation of Lens Injuries and Dose

- Conducted at regional meetings of cardiologists and medical workers in Bogotá, Colombia, Montevideo, Uruguay, Bulgaria and Malaysia.
- Detailed questionnaire about medical, ocular and occupational history
- Dilated, comprehensive slit lamp of the lens
- Correlate occupational radiation exposure with radiation cataract risk

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Catheterization and Cardiovascular Interventions 76:826–834 (2010)

Risk for Radiation-Induced Cataract for Staff in Interventional Cardiology: Is There Reason for Concern?

Olivera Ciraj-Bjelac,[1] PhD, Madan M. Rehani,[2*] PhD, Kui Hian Sim,[3] MBBS, FRACP, Houng Bang Liew,[3] MBBS, FRCP, Eliseo Vano,[4] PhD, and Norman J. Kleiman,[5] PhD

Objectives: To examine the prevalence of radiation-associated lens opacities among interventional cardiologists and nurses and correlate with occupational radiation exposure. Background: Interventional cardiology personnel are exposed to relatively high levels of X-rays and based on recent findings of radiation-associated lens opacities in other cohorts, they may be at risk for cataract without use of ocular radiation protection. Methods: Eyes of interventional cardiologists, nurses, and age- and sex-matched unexposed controls were screened by dilated slit lamp examination and posterior lens changes graded using a modified Merriam-Focht technique. Individual cumulative lens X-ray exposure was calculated from responses to a questionnaire and personal interview. Results: The prevalence of radiation-associated posterior lens opacities was 52% (29/56, 95% CI: 35–73) for interventional cardiologists, 45% (5/11, 95% CI: 15–100) for nurses, and 9% (2/22, 95% CI: 1–33) for controls. Relative risks of lens opacity was 5.7 (95% CI: 1.5–22) for interventional cardiologists and 5.0 (95% CI: 1.2–21) for nurses. Estimated cumulative ocular doses ranged from 0.01 to 43 Gy with mean and median values of 3.4 and 1.0 Gy, respectively. A strong dose–response relationship was found between occupational exposure and the prevalence of radiation-associated posterior lens changes. Conclusions: These findings demonstrate a dose dependent increased risk of posterior lens opacities for interventional cardiologists and nurses when radiation protection tools are not used. While study of a larger cohort is needed to confirm these findings, the results suggest ocular radio-protection should be utilized.

Key words: cardiac catheterization; fluoroscopy; occupational exposure; posterior subcapsular cataract (psc); lens op...

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Radiation Cataract Risk in Interventional Cardiology Personnel

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Vano, E., Kleiman, N. J., Duran, A., Rehani, M. M., Echeverri, D. and Cabrera, M. Radiation Cataract Risk in Interventional Cardiology Personnel. *Radiat. Res.* 174, 490–495 (2010).

of such changes increases progressively with dose until vision is impaired and cataract extraction surgery is required (*5, 6, 8*). The latency of such changes is inversely related to dose. During typical fluoroscopy working conditions, and if radiation protection tools are routinely used, X-ray exposure to the eyes of ...rventional cardiologists, other physicians and/or ...medical personnel working in catheterization labo...ries can be high (*9–14*). These individuals often ...ain close to patients and may therefore be within a ...-scatter X-radiation field for several hours a day ...ng cardiac interventional procedures.

Radiation-associated Lens Opacities in Catheterization Personnel: Results of a Survey and Direct Assessments

Eliseo Vano, PhD, Norman J. Kleiman, PhD, Ariel Duran, MD, Mariana Romano-Miller, MD, and Madan M. Rehani, PhD

ABSTRACT

Purpose: To estimate ocular radiation doses and prevalence of lens opacities in a group of interventional catheterization professionals and offer practical recommendations based on these findings to avoid future lens damage.

Materials and Methods: Subjects included 58 physicians and 69 nurses and technicians attending an interventional cardiology congress and appropriate unexposed age-matched controls. Lens dose estimates were derived from combining experimental measurements in catheterization laboratories with questionnaire responses regarding workload, types of procedures, and use of eye protection. Lens opacities were observed by dilated slit lamp examination using indirect illumination and retroillumination. The frequency and severity of posterior lens changes were compared between the exposed and unexposed groups. The severity of posterior lens changes was correlated with cumulative eye dose.

Results: Posterior subcapsular lens changes characteristic of ionizing radiation exposure were found in 50% of interventional cardiologists and 41% of nurses and technicians compared with findings of similar lens changes in < 10% of controls. Estimated cumulative eye doses ranged from 0.1–18.9 Sv. Most lens injuries result after several years of work without eye protection.

Conclusions: A high prevalence of lens changes likely induced by radiation exposure in the study population suggests an urgent need for improved radiation safety and training, use of eye protection during catheterization procedures, and improved occupational dosimetry.

J Vasc Interv Radiol ***24***:*197-204, 2013*

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Prevalence

Subjects (n)	Posterior subcapsular opacities in one or both eyes	*P* value
Interventional cardiologists (58)	22 (37.9%)	< 0.005
Nurses and technicians (58)	12 (20.7%)	0.13
Unexposed controls (93)	11 (11.8%)	

Subject characteristics and prevalence of posterior lens changes in interventional cardiologists, nurses and technicians (Bogotá/Montivideo cohort

Subjects	Mean age (yrs)	Range (yrs)	Mean working time (yrs)	Cumulative occupational lens dose (Sv)	Range (Sv)
Interventional Cardiologists	46 ± 8	30-69	14 ± 8	6.0 ± 6.6	0.1-27
Nurses and Technicians	38 ± 7	22-60	7 ± 5	1.5 ± 1.4	0.2-4.5
Controls	41±10	20-66	n/a	n/a	

Vano, Rad Res ***174****:490-495, 2010*

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Dose Response

Dose (Sv)	Number of subjects	Number of subjects with posterior lens changes*	OR	95% CI
0 (Control)	22	2 (9%)	1.0	n/a
0.5-1	8	2 (25%)	3.8	0.36-39
1-2	11	5 (45%)	8.2	1.4-47
2-3	9	5 (55%)	13	2.1-81
>3	16	12 (75%)	16	4.2-58
	Total: 67	34 (51%)	5.4	2.0-14

Grade 0.5 or higher in either eye

The number of interventional cardiology workers (cardiologists or nurses) with posterior lens changes characteristic of ionizing radiation exposure as a function of total cumulative ocular occupational exposure. (Malaysian cohort)

*Ciraj-Bjelac, Cathet Cardio Interv **76**:826-834,2010*

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- Most cardiologists with early lens changes reported never or infrequently utilizing eye protection

- Frequency and severity of posterior lens changes increase with age and years in practice

Interventional cardiologists and risk of radiation-induced cataract: Results of a French multicenter observational study ☆

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ABSTRACT

Background: Interventional cardiologists (ICs) are exposed to X-rays and may be at risk to develop cataract earlier than common senile cataract. Excess risk of posterior subcapsular cataract, known as radiation-induced, was previously observed in samples of ICs from Malaysia, and Latin America. The O'CLOC study (Occupational Cataracts and Lens Opacities in interventional Cardiology) was performed to quantify the risk at the scale of France.
Methods: This cross-sectional multicenter study included an exposed group of ICs from different French centers and an unexposed control group of non-medical workers. Individual information was collected about cataract risk factors and past and present workload in catheterization laboratory. All participants had a clinical eye examination to classify the lens opacities (nuclear, cortical, or posterior subcapsular) with the international standard classification LOCS III.
Results: The study included 106 ICs (mean age = 51 ± 7 years) and 99 unexposed control subjects (mean age = 50 ± 7 years). The groups did not differ significantly in the prevalence of either nuclear or cortical lens opacities (61% vs. 69% and 23% vs. 29%, respectively). However, posterior subcapsular lens opacities, were significantly more frequent among ICs (17% vs. 5%, p = 0.006), for an OR = 3.9 [1.3–11.4]. The risk increased with duration of activity but no clear relationship with workload was observed. However, the risk appeared lower for regular users of protective lead glasses (OR = 2.2 [0.4–12.8]).
Conclusions: ICs, in France as elsewhere, are at high risk of posterior subcapsular cataracts. Use of protective equipment against X-rays, in particular lead glasses, is strongly recommended to limit this risk.

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The rate of progression of such radiation associated lens changes is slow.

Nevertheless, eye protection is recommended to delay progression and limit future cumulative dose to the lens.

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RADIATION AND CATARACT

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When this paper was about to go to press, the International Commission on Radiological Protection released a statement recommending a change in the threshold dose for the eye lens and dose limits for eye for occupationally exposed persons. It is clear that the earlier published threshold for radiation cataract is no longer valid. Epidemiological studies among Chernobyl clean-up workers, A bomb survivors, astronauts, residents of contaminated buildings, radiological technicians and recent surveys of staff in interventional rooms indicate that there is an increased incidence of lens opacities at doses below 1 Gy. Nevertheless, eye lens dosimetry is at a primitive stage and needs to be developed further. Despite uncertainties concerning dose threshold and dosimetry, it is possible to significantly reduce the risk of radiation cataract through the use of appropriate eye protection. By increasing awareness among those at risk and better adoption and increased usage of protective measures, radiation cataract can become preventable despite lowering of dose limits.

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These new studies provide additional support for the hypothesis that the threshold radiation cataract dose in human populations may be significantly lower than currently accepted.

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Additional studies, for example in other interventional physician cohorts and associated medical workers, may help further refine appropriate risk guidelines and the radiation cataract "threshold" for occupational exposure

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Future Interventional Medicine Studies

- **Large cohort size**
- **Broad representation age, gender, procedure**
- **Well documented exposure history**
- **Appropriate controls (*eg*; SocioEconomicStatus)**
- **Real –time eye dose measurements**
- **Careful dilated slit lamp exam**
- **Contrast Sensitivity Testing**
- **Long-term follow-up to study progression rate**

Potential visual disability and morbidity resulting from radiation cataract and/or its treatment is underappreciated.

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Potential surgical/post-surgical complications of cataract extraction

- Endophthalmitis
- Uveitis
- Hyphema
- Corneal edema
- Choroidal hemmorrhage
- Lens dislocation
- Rupture of the posterior capsule
- Retinal detachment
- Glaucoma
- Posterior subcapsular opacification

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Potential post-operative visual complications of cataract surgery

- Glare and flare
- Decreased acuity
- Decreased contrast sensitivity
- Photophobia
- Stereopsis

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Cataract surgery risk estimates

- Posterior Sub-Capsular Opacification
  - 10%
- Cystoid Macular Edema
  - 1-10%
- Retinal Detachment
  - 0.5%
- Permanent Vision Loss
  - 0.1%
- Death
  - 0.01%

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HEALTH PHYSICS SOCIETY
Comments on ANPR, 10 CFR 20
November 10, 2014
Docket ID No. NRC-2009-0279

Issue 2: Occupational Dose Limit for the Lens of the Eye

Q2–2: How should the impact of a radiation-induced cataract be viewed in comparison with other potential radiation effects?

Response: The Society wishes to bring the following information to the attention of the Commission:

"…available data suggests mortality following cataract surgery is on the order of 0.1%, and that morbidity, defined both from an ophthalmological as well as medical standpoint, is consider-ably higher. Of equal import, prior to a documented clinical need for cataract surgery, there may be accompanying progressive decreases in visual acuity, contrast sensitivity and visual function that may negatively impact worker performance"

"In conclusion, the combined morbidity and mortality risks of surgical correction of radiation-induced cataracts (1% or more) and the, as yet unquantified, risk of a physician misdiagnosing or mistreating a patient because of loss of visual acuity due to the presence of an undiagnosed cataract, greatly outweighs the risk of cancer in affected individuals. "

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LOW DOSE RADIATION RESEARCH PROGRAM

ICRP INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

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