CATARACT RISK

According to recent studies, the initial stages of radiation-induced lens opacities may already occur from a radiation exposure of 0.5 Gy.

(from [15/17])

The concept of X-ray protective eyewear for radiologists is to protect against scattered radiation. This scattered, secondary radiation emanates from the patient subjected to the primary beam or from components of the X-ray equipment. The angle of incidence at which these radiation sources hit the eye lens of the operating personnel must be taken into account when assessing the effectiveness of eyewear in protecting the individual at their workplace. (from [18])

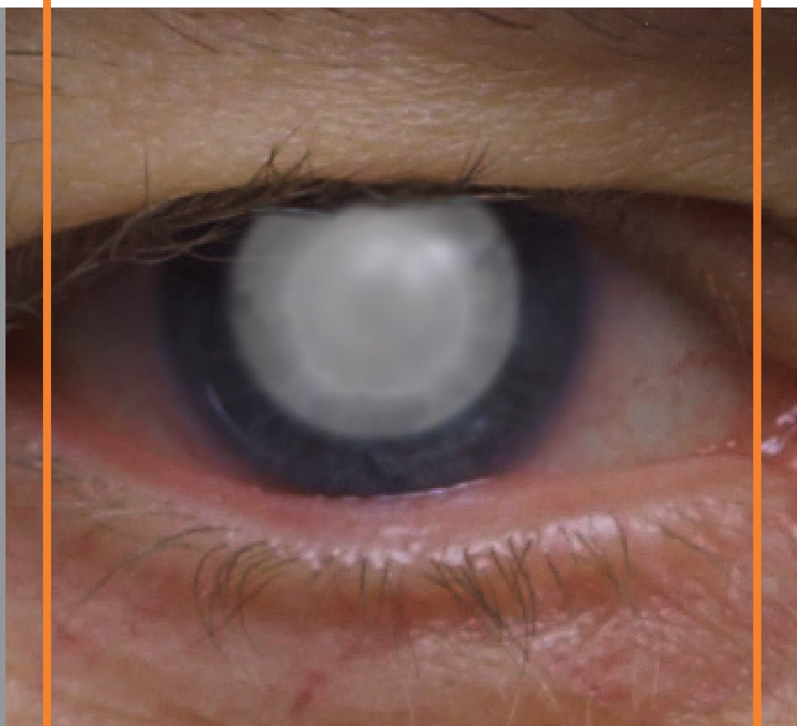
Depending on the position and head movements of the individuals exposed to the radiation, the angle of incidence varies during the procedure. Looking at the patient, the puncture/wound field, or monitors are all standard actions during a procedure and change the angle at which the radiation hits the eye lens. Typically, the secondary radiation emanating from a lying patient does not only hit the eye lens from the front, but at an angle either from below or laterally. (from [2])

The recommendations of the International Commission on Radiological Protection from 2009 state that during activities with potential significant eye lense exposure suitable protective measures such as protective eyewear must be used. (from [15])

In DIN 6815:2005-05 Annex A, X-ray protective eyewear is listed among the recommended protective measures for Angio/DSA, cardiac catheter, neuroradiological, interventional CT and urological examinations. (from [1])

Conclusion

- **It is highly probable that there is no dosage threshold safely avoiding a radiation-induced cataract**
- **The ALARA principle applies: The dosage on the eye lens must be minimized as much as possible within reasonable means**
- **Anatomically well-fitting protective eye wear provide a high level of protection against radiation cataracts (e.g. 98.8 % radiation reduction at 80 kV with a lead equivalent of Pb 0.50 mm)**



Regardless of the dose being acute or spread out over time, it's effect is cumulative and the individual doses are accumulated.

(from [15])

1 Deutsches Institut für Normung DIN 6815:2005-05: *Medizinische Röntgenanlagen bis 300 kV – Regeln für die Prüfung des Strahlenschutzes nach Errichtung, Instandhaltung und wesentlicher Änderung* [Norm]. - Berlin: Beuth Verlag GmbH, Mai 2005 - S. 28

2 Bartal G.: *How to Optimize Radiation Protection During Complex Peripheral* [Online] // The Leipzig Interventional Course - 2011 - 15.09.2011 *http://www.leipzig-interventional-course.com/index.php?option=com_docman&task=doc_download&gid=742*

3 Bundesamt für Strahlenschutz [Online] // *Grenzwerte im beruflichen Strahlenschutz - 2011* - 04. April 2011 - *http://www.bfs.de/ion/beruf_schutz/grenzwerte.html*

4 Bundesministerium der Justitz Röntgenverordnung - RöV: *Verordnung über den Schutz vor Schäden durch Röntgenstrahlen* [Verordnung]. - Oktober 2011. - S. 29, 30, 32. - 4.10.2011 I 2000

5 Chodick Gabriel [et al.] American Journal of Epidemiology: *Risk of Cataract after Exposure to Low Dose of Ionizing Radiation: A 20-Year Prospective Cohort Study among US Radiologic Technologists* [Buch]. - Bethesda: Am J Epidemiol, 29 July 2008. - S. 620, 621, 623, 628. - 168(6):620-31

6 Dr. Eder Heinrich Prüfbericht N-2011, *Messungen der Strahlenschwächung an 2 Schutzbrillen* [Prüfbericht]. - München: 31.01.2011

7 Jacob Sophie [et al.]: *Occupational cataracts and lens opacities in interventional cardiology (O´CLOC study): are X-Rays involved?* [Studie] : BMC Public Health, 2010 - S. 1, 7 - 10:537

8 Klinder Evi Kapselsack - *Zonulamodell zur Darstellung einer neuen Akkommodationstheorie* // Dissertation. - 2007

9 Körner Markus Der Radiologe: *Vorsicht vor Strahlenschäden der Linse durch die Arbeit in der interventionellen Radiologie* [Buch] : Springer Medizin Verlag, Oktober 2008. - Bd. 48, Ausgabe 10 : S. 930. - DOI: 10.1007/s00117-008-1777-8

10 Martin Colin J. Correspondence: *What are the implications of the proposed revision of the eye dose limit for interventional operators?* [Bericht]. - Glasgow: The British Journal of Radiology, October 2011 - S. 961, 962

11 Radiological Society of North America: *Cataract Risk Points to Need for Better Safety Measures* [Online] // Radiological Society of North America - 2011 - 06. Februar 2012 *http://www.rsna.org/Publications/rsnanews/December-2010/cataract_risk_feature.cfm*

12 Schmitz-Feuerhake Inge: *Strahleninduzierte Katarakte als Folge berufsmäßiger Exposition* [Konferenz]. - Universtität Bremen , 9.-10. Juni 2000 - S. 1-3

13 Spornitz Udo M.: *Anatomie und Physiologie: Lehrbuch und Atlas für Pflege- und Gesundheits-berufe* [Buch]. - Heidelberg: Springer Medizin Verlag, 2012. - Bd. 5. Auflage : S. 463

14 SSK Interventionelle Radiologie: *Empfehlung der Strahlenschutzkommission* [Konferenz]. - Bonn: SSK, 20./21. September 2007. - Bd. 217. Sitzung - S. 9

15 SSK: *Strahleninduzierte Katarakte, Empfehlung der Strahlenschutzkommission mit wissenschaftlicher Begründung* [Konferenz]. - Bonn, 14 Mai 2009. - Bd. 234. Situng der Strahlenkommission am 14. Mai 2009. - S. 9, 18, 21

16 SSK: *Überwachung der Augenlinsendosis, Stellungnahme der Strahlenschutzkommission mit wissenschaftlicher Begründung* [Konferenz]. - Bonn: SSK, 02. Feb. 2010 - Bd. 240. Sitzung. - S. 17

17 Strahlenschutzverordnung: *Verordnung über den Schutz vor Schäden durch ionisierende Strahlen* [Verordnung]. - Oktober 2011 - S. 31, 32, 34

18 Vano Eliseo [et al.] Radiology: *Eye lens Exposure to Radiation in Interventional Studies: Caution Is Warranted* [Buch]. - Madrid: RSNA, Sept. 2008. - Bd. Volume 248: Number 3 : S. 946, 947, 952

CF-en0512-1 / Printed in Germany

MAVIG

The human eye is regarded as very sensitive to radiation exposure, and the eye lens itself carries a high risk of damage. Normally a healthy eye lens is a transparent and translucent body that bundles the light coming in through the pupil, so that a focused image is created in the back of the eye on the retina. (from [8/13/15])

But in the case of a pathological change of the eye lens due to ionising radiation, very often clouding or irregularities in the refractive power of the originally clear eye lens occur. (from [8/15])

This change constitutes a so-called radiological cataract. The radiation damages the cells of the eye lens, causing cellular changes that produce disruption of the fibrous cell structure, liquid accumulation in the epithelial and fibrous cells, increased protein aggregation and gradual separation of the lens cytoplasm. In radiological lens clouding, sub-capsular as well as cortical cataracts are localized. (from [8/13/15])

The symptoms of the cataract are a progressive visual deterioration leading up to the complete loss of vision. The process can start with a clinically undetectable clouding, and develope to the final stage of complete lens opacity and blindness. In many cases, a simultaneous sensitivity against glaring light is observed. Blurred and double vision, as well as perceived halos around light sources can also be associated with stages of the disease. (from [8/15])

It is long known that the exposure to radiation when working with ionising radiation can lead to a radiation-induced lens clouding. Originally though, radiological cataracts were regarded as a predetermined effect, with an assured damage after exceeding a threshold level. (from [5/15])

However, more recent scientific research papers increasingly doubt the existence of a threshold dosage. (from [12/14/16])

In a 2009 recommendation from the Commission on Radiological Protection, the commision reported that the existence of a threshold dosage, below which damage to the eye lens can be clearly excluded, can not be assumed. (from [15])

It is probable that damage from radiation already occurs at small dosages. (from [5/7])

Epidemiological research, including examinations on personnel exposed to occupational radiation in interventional radiology, could not determine a threshold level at which damage to the eye lens due to exposure to ionising radiation could be excluded. A conclusion from this research is that it is highly probable that a dose of less than 0.8 Gy will already induce measurable clouding of the eye lens. (from [15])

The special vulnerability of the eye was taken into account by the International Commission on Radiological Protection (ICRP) with the first step of reducing the organ dosis for the eye lens from 500 mSv/year to 150 mSv/year for professionals subjected to radiation exposure, and of 15 mSv/year for people under 18. (from [3/4/15])

In several studies evidence has been provided that the exposure of the eye lens to ionising radiation in the region of only 0.5 Gy increases the cataract rate. The relative risk amounts to approx. 150 % after a radiological exposure of 1.0 Gy. (from [11/15/17])

These effects occurred not only after short-term exposures, but also after dosages accumulated over longer periods. (from [5/15])

The Commission on Radiological Protection therefore recommends:
„ ... the cataract risk is to be assessed on the basis of the professional life dosage received by the lens instead of an annual limit dosage." (from [15])

In consideration of the current findings regarding the non-existence of a threshold dose, suitable protective measures for the eye lens have become indispensable according to §21 RöV (German X-ray Ordinance). This follows the theory of minimizing all radiation risks where possible. (from [4])

In april 2011 the IRCP recommends a further, more drastic lowering of the limit values. The annual eye lense dosage shall not exceed 20 mSv, as an average value over 5 years. However, per year a dosage of 50 mSv shall not be exceeded. (from [15])

If one adds the exposure limit of 150 mSv/year over 20 years, this corresponds to a cummulative dose of 3.0 Gy. (from [15])

This dose is six times higher than the dosage determined to be sufficiently responsible for an increase in the cataract rate. The Commission on Radiological Protection describes a twofold increase in the spontaneous cataract risk according to the current research. (from [15])

In order to be able to relate limit and threshold values to one's personal risk profile, it is relevant to assess the dose one is actually subjected to as a radiology operator in interventional radiology or surgery. Simply through partial body dosimetry, the daily strain on the eye lens in the work environment can not be adequately determined. (from [18])

Various studies have taken up the controversial issue of the hazard of radiation-induced cataracts and have provided evidence of cataract-significant dosages at respective workplaces. (from [5/16/18])

Results of the research show that the eye lenses of radiology operators, especially in interventional and similar procedures, can be exposed to cataract-significant dosage levels after only a few years. (from [18])

In worst case scenarios, the annual dosage limit of 150 mSv for the eye lens could be reached after approx. 30 to 50 interventions. In extreme cases, it is already reached after only 15 interventions. The number of interventions depend strongly on the individual applications. (from [9/10])