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Are orthopedic surgeons exposed to excessive eye irradiation? A prospective study of lens irradiation in orthopedics and traumatology.

Céline Cuenca¹; Pierre-Jean Mention²; Guillaume Vergnenegre¹; Pierre-Alain Matthieu¹; Jean-Louis Charissoux¹; Pierre-Sylvain Marcheix¹.

- Service de Chirurgie Orthopédique et Traumatologique, Centre Hospitalier Universitaire de Limoges, 2 Avenue Martin Luther King, 87042 Limoges Cedex, France.
- 2- Service de Médecine Nucléaire, Centre Hospitalier Universitaire de Angers, 4 Rue Larrey, 49933 Angers cedex 9, France.

Corresponding author: Céline Cuenca, celine.cuenca@hotmail.fr

<u>Abstract</u>

Introduction: Numerous studies in recent years highlighted an increased risk of pathologies related to ionizing radiation in caregivers. A new French decree was adopted on June 4, 2018, dividing by 7.5 the radiation dose authorized in the lens for exposed workers.

Hypothesis: The hypothesis of the present study was that ocular irradiation in orthopedic surgeons was below the new legal threshold.

Method: The equivalent dose (mSv) received by the lens was prospectively assessed in 10 orthopedic surgeons (5 senior, 5 residents), using 3 passive dosimeters placed at the forehead and either temple. Each intervention of each operator was recorded, with dose per area in the operating room at each use of the fluoroscope.

Results: All equivalent doses to the lens at the end of the 4 month study period were well below threshold. Doses were not significantly different between forehead and either temple (p = 0.7, p = 0.6 for the 2 temples). There was no difference according to side of the head (p = 0.3). The dose received in the lens correlated with the dose delivered in the room (p = 0.004). There were no significant differences in irradiation according to the surgeon's experience (p = 0.2) or trauma activity rate (p = 0.4).

Discussion: No studies have reported equivalent doses to the lens exceeding the authorized limit. But none previously measured equivalent dose to the lens according to the axis of irradiation in the eyes. The present study showed that orthopedic surgeons received as much eye radiation laterally as frontally. Ocular radiation protection needs therefore to be as effective laterally as frontally. The surgeon's experience did not emerge as a protective factor against ocular irradiation.

Key-words: Radiation, lens, orthopedics, traumatology; radioprotection

1. Introduction

Caregiver irradiation during medical and surgical procedures is increasingly controlled and monitored [1]. Many recent studies showed increased risk of pathologies related to ionizing radiation in caregivers [1-5].

The literature shows increasing concern for radiation risk in theater, and orthopedics is now among the most severely exposed specialties [6-11]. Many studies reported increased risk of radiation-induced cataract in exposed populations [4, 5, 11]. Irradiation of the lens was studied in particular in interventional radiologists; cataract risk correlated with prolonged low-dose exposure [2]. The relative risk of developing cataract was also 3-fold higher in interventional cardiologists than in a comparable non-exposed population [12].

The present study hypothesis was that radiation doses to the lens in orthopedic surgeons are below the thresholds specified in the European Commission Euratom Directive of May 30, 2013 which led to the French Decree n° 2018-437 of June 4, 2018 concerning employee protection against ionizing radiation risk 13].

The main study objective was to assess radiation dose in the lens received by orthopedic surgeons over a 4-month period of mixed orthopedic and traumatologic activity, compared to the Euratom Directive norms.

The main endpoint was therefore the equivalent dose per operator in mSv detected by passive dosimeters over the 4-month period.

Secondary endpoints comprised:

- comparison of total doses in the operating room in cGy/cm² and received by the lens;
- comparison of dose to the lens according to operator experience;
- and comparison of dose to the lens according to the surgeon's orthopedic/traumatologic activity ratio.

2. Material and Method

2.1. Study population

The study was conducted over 4 months from December 2017 to April 2018, within our orthopedics-traumatology department. Participants were informed of the study procedure and provided oral and written consent. Age, gender and handedness were recorded. All participants had mixed orthopedic and traumatologic activity.

2.2. Lens irradiation assessment

At each procedure involving intraoperative imaging, an ocular passive dosimetry device was worn, with 1 sensor between the eyes and 1 at either temple; the 3 thus lay in different axes, enabling frontal and right and left lateral measurement. The Hp(0.07) dosimeters were provided by DOSILAB, with 3 per surgeon (**Figures 1 and 2**). They were stored away at the end of the day in a radiation-free space controlled by a dosimeter.

Three types of fluoroscope were used during the 4-month period:

- 1 small XiScan® fluoroscope (FM Control), with mGy.cm² doses;
- 2 large fluoroscopes: 1 Siremobil Compact L® (Siemens), 1 Endura® (Philips BV), with respectively Gy.cm² and cGy.cm² doses.

The large models were handled and set off by a nurse, and the XiScan by the surgeon.

Radiation doses were recorded at end of procedure in the patient's file. Missing data were listed; as these were few, they were simply excluded from analysis.

To obtain 1-year data for comparison with the legal annual thresholds, results were multiplied by 3 to give 4x3=12 months.

2.3. Statistics

Quantitative variables were reported as mean \pm standard deviation, range and median, and qualitative variables as numbers and percentages. Normal distribution of quantitative variables was checked on Shapiro-Wilk test. Quantitative variables (gender, handedness, etc.) were compared between groups on chi² or Fisher exact test as appropriate. Quantitative variable distributions for equivalent doses were compared on Wilcoxon tests for matched series, or the Mann-Whitney test (Monte-Carlo method) for non-matched series in case of non-normal distribution. The significance threshold was set throughout at 0.05. SAS 9.1.3 software (SAS Institute, Cary, NC) was used.

3. Results

3.1. Overall epidemiological data

Ten orthopedic surgeons were included: 5 senior (50%) and 5 residents able to operate independently (50%).

Mean age was 31.7 years (range, 26-40 years). Eight of the 10 participants were male (80%). Eight were right-handed (80%).

One participant was excluded after theft of the measurement equipment (10%).

During the 4-month period, 1,227 procedures were performed: 655 orthopedic (53.38%), 572 traumatologic (46.62%). Participants performed a mean 136 procedures each (range, 91-205). Traumatology constituted a mean 44.9% of activity (range, 28.9-65.5%), for a mean 64 procedures (**Table 1**).

Fluoroscopes were used in a mean 37.9% of procedures (range, 26.8-48%).

3.2. Radiation measurement

Table 2 shows radiation levels per surgeon. The "missing data" column corresponds to measurements not taken, ranging from 0 to 9 doses, for a mean 7 missing doses out of 136 per operator: i.e., mean 3% missing data (range, 0-5%). Mean total dose in the operating room over the study period was 1,955.7 cGy.cm² (range, 511.8-3,496.2 cGy.cm²) (**Table 2**). **Table 3** shows doses according to dosimeter location; multiplying these by 3 gives the equivalent dose received by the lens for a period of 12 months (**Table 3**). It can be seen that, in all cases, doses were well below the new regulatory threshold of 20 mSv/year in equivalent dose to the lens.

There was thus a significant relation between dose in the operating room and dose in the lens on all 3 axes (p=0.004).

Statistical analysis found no significant differences in dose between right and left eyes, or between frontally and laterally received doses for any surgeon (p = 0.3, p=0.7, p=0.6, respectively). There would thus not seem to be any predominant axis of irradiation when using a fluoroscope in orthopedic and traumatologic surgery. Nor were there any significant differences according to the surgeon's experience, in dose in the operating room (p=0.2) or in frontally received dose (p=0.48). Likewise there were no significant differences according to the proportion of traumatologic activity in total operating room dose over 4 months (p=0.43) or in dose received by the lens (p=0.6).

4. Discussion

The present study confirmed that radiation doses to the lens of orthopedic surgeons are below the threshold set out in the Euratom Directive and French legislation. The new Euratom Directive sets the equivalent dose threshold in the lens at 20 mSv per year: i.e., 7.5-fold lower than previously for exposed medical personnel [13]. These results agree with the literature, which consistently reports sub-threshold doses.

Cheriachan et al., analyzing 131 orthopedic procedures using fluoroscopy, reported a mean dose to the lens of 0.02 mSv per procedure [10]. Wang et al. reported 12-month cumulative ocular doses in orthopedic surgeons, and found a mean dose to the lens of less than 30 millirem, or 0.3 mSv, per month [12]. Attigah et al., studying vascular surgeons, found equivalent doses to the lens well below the legal threshold; to reach the 20 mSv threshold would require an area dose of 932,000 mGy.cm² [14].

The present study had the particularity of measuring equivalent does to the lens along 3 spatial axes. This should better correspond to the real dose received, as it takes account of head movements during surgery, unlike previously published studies. In the study by Cheriachan et al., the dosimeter was placed either on the thyroid protection or on the lead apron [10]. In the study by Wang et al., there was a single dosimeter, attached to one arm of the surgeon's glasses [12], while Attigah et al. had a single dosimeter positioned on the forehead [14]. The present method was able to show that there was no significant difference between frontal, left lateral and right lateral irradiation to the lens, regardless of the position of the surgeon's head with respect to the source. Thus, any lead goggles should cover the sides so as to provide optimal bilateral protection.

Like Cheriachan, the present study found no correlation between the surgeon's experience and theater area dose or dose equivalent dose to the lens [10]. Only one study reported a significant correlation between the surgeon's experience and the dose in the operating room [8]. More experienced surgeons probably perform more complex traumatology procedures, which are often long and involve greater irradiation, while less experienced surgeons perform "routine" traumatology, but with a greater number of procedures.

Likewise, we found no significant correlation between dose to the lens and orthopedic/traumatology activity ratio. Gausden et al. reported much higher overall exposure levels in residents and senior surgeons specializing in traumatology, although still well below the regulatory threshold [11]. This discrepancy is probably due to how our department is organized, with no dedicated traumatologists but each surgeon alternating between orthopedics and traumatology in their schedule; moreover, we do not manage spinal trauma, which constitutes a major source of radiation [7, 11].

Radiation-induced cataract is a recognized entity with known pathophysiology and consequences. Although orthopedic surgeons remain well below the theoretic pathogenic exposure level, the "precautionary principle" should still be applied. Protective googles are

recommended, but are rarely used as they are expensive and impractical [1, 5, 7, 15]. They should be used not systematically but only in case of high prolonged radiation.

Awareness and education in practitioners using ionizing radiation are a major issue in avoiding at-risk behavior and harmful consequences [1, 9, 10].

Study limitations

The passive dosimeters used in this study were the Hp(0.07) model, whereas Hp(3) models are recommended to assess dose to the lens, as they measure the dose received under 3 mm of tissue. In photon radiation (X- or gamma-ray), however, which is what is used in surgery, the difference between Hp(3) and Hp(0.07) is slight: <6% beyond 24keV.

The present study reported results at 4 months, extrapolated to 1 year for purposes of comparison with regulatory thresholds. Variation in activity according to time of year was thus not taken into account.

Moreover, studies of radiation doses and equivalent doses are difficult to compare. A range of factors would need to be taken into account to achieve strict comparability [7, 8, 11]: type of radiation, make and type of fluoroscope, distance of patient and of surgeon from fluoroscope, surgeon's position in the operating room and position of the different components of the fluoroscope and of the operative area, etc.

Finally, due to these factors affecting irradiation, it was not possible to correlate total level in the operating room to the dose to the surgeon's lens.

5. Conclusion

Equivalent dioses received by the lenses of orthopedic and traumatology surgeons are well below the 20 mSv/year threshold set by the European Directive.

The surgeon's experience and orthopedic/traumatology activity ratio do not affect the received dose.

The only protective factor is individual, with adapted controlled radioprotective equipment including at least a circular apron and thyroid protection. Protective goggles need to have lateral cover; use should not be systematic but reserved to high-risk situations.

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Disclosure of interest

The authors have no conflicts of interest to disclose.

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Author contributions

Céline Cuenca: study design, article writing, study participation Pierre-Jean Mention: participation in study design, article writing Guillaume Vergnenègre: participation in study design, and in study Pierre-Alain Matthieu: participation in study Jean-Louis Charissoux : participation in article writing Pierre-Sylvain Marcheix: participation in study and article writing

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Figure and Table legends

Table 1: Epidemiology data

Table 2: Irradiation per operator.

Table 3: Equivalent doses assessed by passive dosimeters for 4 and for 12 months, according to device positioning.

Figure 1: Frontal view of passive dosimeters positioned on goggles (3 per operator: frontal, left and right lateral)

Figure 2: Lateral view of passive dosimeters positioned on goggles (3 per operator: frontal, left and right lateral)

Table 1: Epidemiological data

Participants	Number of procedures	Number of scheduled procedures (%)	Number of traumatology procedures (%)	Number of procedures with fluoroscopy (%)	Number of traumatology procedures with fluoroscopy (%)
1	91	54 (59)	37 (41)	28 (30.8)	26 (70.3)
2	97	69 (71.1)	28 (28.9)	26 (26.8)	21 (75)
3	117	61 (52.1)	56 (47.9)	55 (47)	42 (75)
4	124	85 (68.5)	39 (31.4)	36 (29)	24 (61.5)
5	145	92 (63.4)	53 (36.5)	54 (37.2)	32 (60.4)
6	177	61 (34.5)	116 (65.5)	85 (48)	78 (67.2)
7	154	57 (37)	97 (63)	67 (43.5)	55 (56.7)
8	117	66 (56.4)	51 (43.6)	51 (43.6)	37 (72.5)
9	205	110 (53.7)	95 (46.3)	72 (35.1)	56 (58.9)

Table 2: Irradiation per operator.

Participants	Total operating room dose (cGy.cm ²)	Missing data (T/S)
1	563.6	0-0%
2	511.9	4 (3T/1S)- 4.1 %
3	1592.4	1 (1T)- 0.9 %
4	1290	5 (2S/3T)- 4 %
5	2459.4	7 (6T/1S)- 4.8 %
6	3496.2	9 (9T)- 5 %
7	2334.2	7 (7T)- 4.5 %
8	2364.9	3(2T/ 1S)- 2.6 %
9	2988.6	2 (2T)- 1 %

T= in traumatology

P= in scheduled surgery

Table 3: Equivalent doses measured by passive dosimeters for 4 and for 12 months, according to positioning.

Participants	Equivalent dose, frontal 4/12 months	Equivalent dose, right lateral 4/12 months	Equivalent dose, left lateral 4/12 months
1	0.2/0.6 mSv	0.15/0.45 mSv	0/0 mSv
2	0.25/0.75 mSv	0/0 mSv	0.1/0.3 mSv
3	0/0 mSv	0/0 mSv	0.15/0.45 mSv
4	0/0 mSv	0/0 mSv	0.175/0.525 mSv
5	0.225/0.675 mSv	0/0 mSv	0.125/0.375 mSv
6	0.2/0.6 mSv	0.375/1.125 mSv	0.475/1.425 mSv
7	0.25/0.75mSv	0.1/0.975 mSv	0.2/0.6 mSv
8	0.225/0.75mSv	0.325/0.975 mSv	0.25/0.75 mSv
9	0.2/0.6 mSv	0.425/1.275 mSv	0.375/1.125 mSv





Figure 2 :

