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Original article

Prospective analysis of intraoperative radiation dose in foot and ankle surgery using mini-C-arm fluoroscopy. Continuous series of 1,064 procedures

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ABSTRACT

Introduction: Foot and ankle surgeons make daily use of mini-C-arm fluoroscopes. The present study aimed to quantify associated radiation doses.

Hypothesis: X-ray exposure for foot and ankle surgeons using a mini-C-arm fluoroscope is below the nuclear safety authority authorized doses of 20 mSv/year for the whole body and crystalline lens, 150 mSv/year for the thyroid and 500 mSv/year for the skin and limbs.

Material and methods: A single-center, single-surgeon prospective series was treated between February 2014 and December 2017. Doses emitted by the mini-C-arm (15 cm field) were recorded during 1,064 operations. Doses received by the surgeon were recorded by 3 passive dosimeters (thorax, eyes and hands) and 1 active dosimeter. The significance threshold was set at $p < 0.05$.

Results: 64.4% of procedures concerned the forefoot, 35.3% the hindfoot and ankle, and 0.3% were strictly percutaneous. Mean dose-area product (DAP) per procedure was $3.9 \text{ cGy/cm}^2 \pm 7$: in forefoot surgery, $1.1 \text{ cGy/cm}^2 \pm 0.9$, and in hindfoot and ankle surgery $8.7 \text{ cGy/cm}^2 \pm 9.7$ ($p < 0.05$), for mean irradiation times of $7.6 \text{ sec} \pm 5.3$ and $36.7 \text{ sec} \pm 35.5$ respectively and image numbers 4.1 ± 2.7 and 18.7 ± 20.5 . Total ankle replacement was associated with the highest doses: $20.1 \text{ cGy/cm}^2 \pm 14.7$. Mean daily active dosimetry was $2.2 \text{ } \mu\text{Sv} \pm 1.4$. Mean annual dose to the hand, crystalline lens and deep (Hp(10)) and shallow (Hp(0.07)) whole body was respectively 1.28 mSv, 0.6 mSv, 0.31 mSv and 0.19 mSv. The highest annual exposure was recorded for the hands: 2.68 mSv in 2015. There was a significant linear relationship between daily active dosimetry and daily emission: daily active dosimetry = $(\text{DAP} \times 0.11) + 0.54$, for a correlation coefficient of 0.77.

Discussion/conclusion: The exposure of foot and ankle surgeons using mini-C-arms was well below threshold, and also lower than in the literature.

Level of evidence: IV

Key-words: foot, ankle, radiation, mini-C-arm fluoroscope

Abbreviations: Dose-area product: DAP; Sievert: Sv; Gray: Gy; total ankle replacement: TAR

I) INTRODUCTION

Foot and ankle surgery increasingly involves intraoperative radioscopy and, more recently, less irradiating and more manageable mini-C-arm fluoroscopy [1,2]. With the development of minimally invasive and percutaneous orthopedic surgery, fluoroscopy is more and more widely used. Patient irradiation is non-negligible and radioprotection measures ensure safety [3,4]. Surgeon irradiation has been assessed [5–7], notably finding elevated breast-cancer rates [8,9]. Risk at organism level, however, remains undetermined [10].

Emitted dose or dose-area product (DAP) is the dose delivered by the fluoroscope, measured in centigray per square centimeter (cGy/cm²). Sievert (Sv) is the unit measuring human radiation impact. The recommendations of the International Commission on Radiological Protection specify thresholds of 20 millisieverts per year (mSv/year) for the whole body, 150 mSv/year for the thyroid and 500 mSv/year for the hands [11]. In France, the Decree of June 4, 2018 concerning worker radioprotection moreover stipulates that the limit is 20 mSv/year for the crystalline lens, and 500mSv/year for the skin and limbs [12]. Received dose is measured on individual dosimeters.

The main aim of the present study was to quantify delivered and received dose during foot and ankle surgery using a mini-C-arm, according to type of surgery. The study hypothesis was that received dose for foot and ankle surgeons using a mini-C-arm is below official thresholds.

II) MATERIAL AND METHODS

1- Inclusion and exclusion criteria

A single-center single-surgeon prospective study performed between February 2014 and December 2017 included all patients, regardless of age, undergoing foot and/or ankle surgery involving fluoroscopy by a surgeon (JLB) exclusively specializing in foot and ankle surgery. Intraoperative radioscopy used a single mini-fluoroscope (Fluoroscan InSight mini-C-arm Hologic®) with 15 cm field (compared to 22 or 30 cm for a traditional fluoroscope).

2- Radiation assessment and other study parameters

Procedures were classified in 3 main categories according to number of images (Table 1). For each operation, the following were recorded directly from the mini-C-arm: DAP in cGy/cm², radiation time, and image number. Passive dosimetry was recorded quarterly, in mSv; 3 sensors (Dosilab®) were worn each surgery day: thorax for whole-body dose, frontal for crystalline lens, and a ring for the limbs (hands) and skin. The aim was to detect any excessive dose. The detection threshold was 0.1mSv. A value of 0 corresponded to negligible rather than zero dose for a given period. Results were reported as dose equivalent, noted Hp(10) and Hp(0.07), where “10” and “0.07” refer to the depth in the body (10mm or 0.07mm) at which exposure was assessed; dose equivalent Hp(10) assessed dose to deep organs and tissue, including the thyroid (thoracic sensor), and Hp(0.07) assessed superficial organs and tissue (skin, limbs, crystalline lens).

As well as the passive dosimeter, the surgeon wore an active device (Dosilab®), recording received dose in real time, with an alarm set for a predefined threshold of Hp (10) 250 µSv, rest at the end of the surgery day; daily active or operational dose was recorded at end of day in µSv.

So as to optimize relevance, the passive and active devices were worn over any radioprotective equipment (not worn systematically for all operations). All intraoperative activity (images and dose reports) was entered in the PACS database and surgery report. For forefoot surgery, there were no postoperative images.

3- Statistics

Statistical analyses used Stata software, v12 (Stata-Corp, Texas, USA). Descriptive data were reported as numbers and percentages for categoric variables and as means for continuous variables. Comparison between surgical categories used chi² test or Fisher exact test as appropriate for categoric variables and Student test (or Mann-Whitney test for non-normal

distributions) for continuous variables; normal distribution was checked graphically and on Shapiro-Wilk test. Dose concordance was assessed on Pearson correlation coefficient (or Spearman for non-normal distribution) and by Bland-Altman plots with systematic error check on Student test for matched data, or Wilcoxon signed rank test for non-normal distribution. All tests were 2-tailed, with the significance threshold set at $p < 5\%$.

III) RESULTS

1- General population data

Between February 2014 and December 2017, 1,092 operations were performed, 1,064 of which involved a mini-C-arm:

- A: forefoot: 64.4% (685 patients)
- B: hindfoot and ankle: 35.3% (376 patients)
- C: exclusively percutaneous: 0.3% (3 patients).

Due to the small number of category C procedures, only A and B were compared (Table 2). Percutaneous surgery, notably for the lateral rays of the forefoot, was included under categories A2 and A3 (not that category C was thus subsumed, but that most percutaneous surgery was type A2 or A3).

2- General radiation data

Mean DAP was $3.9 \text{ cGy/cm}^2 \pm 7$ (range, 0.1 – 52.4), mean number of images 9.3 ± 1.2 (1 - 211), radiation time $17.9 \text{ sec} \pm 25.6$ (1 - 192) and daily active dose $2.2 \text{ } \mu\text{Sv} \pm 1.4$ (0.1 – 9.6). Table 3 shows annual passive and active dosimetry findings. The hands were the most exposed region (up to 2.68 mSv in 2015 and a mean 1.28 mSv overall), followed by the eyes (mean, 0.6 mSv) (Table 3). In 2015, one “crystalline” passive dosimeter was mislaid and not immediately replaced, leading to 3 months’ missing data; the results for 9 months were extrapolated over 12.

3- Radiation according to type of surgery

Isolated forefoot surgery was the least irradiating (Table 2); Mean dose was low in A2: mean 0.8 cGy/cm^2 per operation, with a mean 3.6 images. Total Ankle Replacement (TAR) was the

most irradiating: $20.1 \text{ cGy/cm}^2 \pm 14.7$ (1.3 – 52.4), with 39.7 ± 26.2 images (3 – 90) (Table 4).

4- Concordance

There was a significant linear relation between daily active dose to the surgeon and daily emitted dose: daily active dose = (DAP x 0.11) + 0.54 (Figure 1), giving a correlation coefficient of 0.77: i.e., 77% of variation in daily active dose was explained by the dose emitted by the C-arm.

A significant correlation was also found between DAP and operative time (Table 5).

There was no significant correlation between passive and active dosimetry (Table 5).

IV) DISCUSSION

The present study demonstrated that radiation dose to the surgeon during foot and/or ankle procedures is well below International Commission on Radiological Protection thresholds and those of the French June 4, 2018 Decree. Hindfoot surgery and above all TAR were more irradiating than forefoot surgery, but still did not exceed threshold. Dose increased with surgery time. The non-correlation of active to passive dosimetry was surprising, but is explicable: passive dosimetry had a regulatory detection threshold at 100 μSv , which active dosimetry did not, and the active and passive thoracic sensors were not in the same position on the thorax; orientation and distance with respect to the source differed, accounting for the lack of correlation.

To avoid confusion, it should be borne in mind that dose to the surgeon (in mSv) is not the same thing as emitted dose (DAP, in cGy/cm^2). As active and passive dosimetry did not correlate, we focused on the latter, as it was the focus of most studies and is used in the international radioprotection guidelines.

Few studies [13–17] assessed radiation in foot and ankle surgery. Singh [14] reported 2.4 mSv/year to the surgeon's hand, greater than the present mean 1.28 mSv/year, with far fewer procedures (80, versus a mean 266 in the present study) (Table 6).

In hand surgery, Wang [24] reported a monthly 0.46 mSv to the hand with mini-C-arm, for an annual 5.52 mSv/year (vs 1.28 mSv/year in the present series). Van Rappard [25], reporting 94 hand and wrist procedures with mini-C-arm over a 5 month period, found cumulative

doses to the main operator of 0.029 mSv, 0.012 mSv and 1.28 mSv to the whole body, thyroid and hand; extrapolated to 12 months, the 3.1 mSv to the hand was higher than in the present study (1.28 mSv/year); other regions received less than in the present study, but for fewer procedures. Tuohy [23] also found higher radiation levels in hand surgery: mean DAP, 19.3 cGy/cm², versus 3.9 cGy/cm² in the present study (Table 6).

In spine surgery, doses again were higher than in the present study. In scoliosis surgery, McArthur [21] reported a mean DAP per procedure of 91.3 cGy/cm², versus 3.9 cGy/cm² in the present series. In percutaneous spinal screwing, Kouyoumdjian [22] reported even higher doses, with 30.5 μ Sv to the crystalline lens per procedure, compared to 1.3 μ Sv for McArthur (Table 6).

In 13 months' general orthopedic-traumatologic surgery, Loisel [18], using 2 types of fluoroscope, reported a cumulative dose to the hand of 4.75 mSv, well above the present average of 1.28 mSv/year. Gausden [19] demonstrated wide variation in received dose according to activity, from 0.002 to 0.79 mSv/month, with the highest levels found in traumatology [20] (Table 6).

Several studies (Table 6) reported lower exposure with mini-fluoroscopes, with doses halved in orthopedics-traumatology [1]. Thus Dawe [16], in foot and ankle surgery, found significantly lower DAP in all procedures taken together: 3.46 Gy/cm² vs. 7.43 Gy/cm² ($p = 0.0013$); the same held true for the hindfoot in particular. This was confirmed in foot and ankle traumatology [15]. Standard fluoroscopes also seem less efficient in terms of time and money [16,26,27]. This was shown in foot and ankle surgery by Angthong [17] in a series of 55 total ankle replacements: radiation time was much longer than in the present study: 77 ± 34 sec vs. 35.5 ± 25.6 sec. Dawe [16] showed that cost savings with a mini versus standard device in foot and ankle surgery could amount to £9,391 a year.

Compared to open surgery, percutaneous surgery is reputed to entail greater exposure due to greater use of fluoroscopy. This was confirmed in spine surgery, with high doses for percutaneous procedures: 30.5 μ Sv vs. 1.3 μ Sv to the crystalline lens [21,22,28], although irradiation is non-negligible in such open procedures too [29].

Such findings were not confirmed in hand and wrist surgery by Zyluk [30]: dose per internal fixation procedure in the wrist or metacarpals was 0.34 mSv in open surgery and not significantly different, at 0.37 mSv, in percutaneous surgery.

There have been no assessments of radiation in percutaneous foot and ankle surgery, and the present series had too few strictly percutaneous forefoot surgeries for any conclusion to be drawn.

To reduce exposure in foot and ankle surgery, certain measures can be taken: a 15 cm field should be systematically used without possibility of diaphragm (the 10 cm field proposed on the device being too small and better suited to hand surgery); and the continuous mode should be avoided, with acquisition of simple images only, using a foot-pedal for shorter exposure time than triggering at the source. Staff training is also essential [31]. The very low radiation level found in the present study can be explained by the above measures, the surgeon's experience (reducing image number and exposure time) and, of course, the use of a mini-C-arm with 15 cm field rather than a traditional fluoroscope with 22 or 30 cm field.

The strong points of the present study lie in its design: prospective, exhaustive, with a single senior surgeon exclusively practicing foot and ankle surgery and systematically using the same fluoroscopic device. The 4-year study period, with 1,064 procedures and inclusion of all patients managed using the same mini-C-arm ensured a true vision of radiation in foot and ankle surgery, providing strong statistical power.

Category A patients were significantly older, more often female (with actual female predominance in forefoot surgery), and had shorter tourniquet times; categories A and B did not differ in operated side. Thus, the 2 groups were not identical, but could be compared inasmuch as age and gender do not affect operative time or fluoroscopy time. The series did not cover all foot and ankle procedures, as there were very few cases of exclusively percutaneous surgery: the surgeon did not use percutaneous approaches to the first ray, but sometimes for the lateral rays and/or hallux, but in association to open surgery.

V) CONCLUSION

In foot and ankle surgery, received doses are well below international occupational radioprotection thresholds. Logically, the lowest levels are in isolated forefoot surgery. However, we lacked data for exclusively percutaneous surgery, which is probably more irradiating, with longer exposure times per procedure.

The present doses in foot and ankle surgery were lower than reported in other types of orthopedic-traumatologic surgery using fluoroscopy.

The mini-C-arm should be used for limb surgery, to minimize radiation dose to the surgical team and patient.

Depending on the type of surgery and expected exposure time, the traditional systematic use of a lead apron may be unnecessary, given the very low doses received per procedure and per year.

Disclosure of interest:

C. Guyonnet: none

A. Mulliez: none

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Authors contributions:

C. Guyonnet: data collection, article writing

A. Mulliez: statistical analysis

M-H. Fessy: study director

J-L. Besse: surgeon, study investigator and supervisor, re-editing

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VII) Figure legend

Figure 1: Correlation between daily emitted dose (cGy) and daily active dose (μSv) with regression slope

VII) TABLES

Table 1: classification of foot and ankle surgery procedures according to radiation level

A: Forefoot

- **A1:** Isolated lateral ray, claw-foot, hardware removal
- **A2:** M1 osteotomy \pm lateral rays
- **A3:** MTP1 fusion \pm lateral rays

B: Hindfoot, ankle

- **B1:** Ligament reconstruction, Achilles tendon, hardware removal, minor surgery
- **B2:** Osteotomy, fusion
- **B3:** Ankle replacement
- **B4:** Reconstructions or fusion after ankle replacement

C: Exclusively percutaneous forefoot surgery
(Lateral metatarsal DMMO or hallux osteotomy)

Table 2: Comparison of general characteristics between categories A and B

	A Forefoot	B Hindfoot-ankle	p-value
Surgery time (min)	52.9 ± 20.7 (5 - 140)	95.5 ± 46.8 (5 - 265)	<0.05
Tourniquet time (min)	42.8 ± 19.4 (0 - 125)	75 ± 32.7 (0 - 150)	<0.05
DAP (cGy/cm²)	1.1 ± 0.9 (0.1 - 8.7)	8.7 ± 9.7 (0.1 - 52.4)	<0.05
Radiation time (sec)	7.6 ± 5.3 (1 - 41)	36.7 ± 35.5 (2 - 192)	<0.05
Number of images	4.1 ± 2.7 (1 - 23)	18.7 ± 20.5 (1 - 211)	<0.05

Table 3: Annual passive dosimetry (mSv) according to type of sensor and annual active dosimetry (mSv)

	2014	2015	2016	2017	Mean
Whole body Hp(10)	0.38 mSv	0.33 mSv	0.13 mSv	0.43 mSv	0.31 mSv
Whole body Hp(0.07)	0.3 mSv	0.25 mSv	0.1 mSv	0.1 mSv	0.19 mSv
Ring	1.03 mSv	2.68 mSv	0.85 mSv	0.55 mSv	1.28 mSv
Crystalline lens	0.85 mSv	0.38 mSv	0.6 mSv	0.58 mSv	0.6 mSv
Active dosimetry	0.12 mSv	0.18 mSv	0.14 mSv	0.12 mSv	0.14 mSv

Table 4: Detailed comparison of general radiation characteristics according to surgical category

Surgical category	Subcategory	DAP (cGy/cm ²)	Radiation time (sec)	Number of images
A: Forefoot	A1 (isolated lateral rays, hardware removal, etc.)	0.9 ± 1.1 (0.1 - 8.7)	6.3 ± 5.4 (1 - 34)	3.3 ± 2.7 (1 - 17)
	A2 (M1 osteotomy +/- lateral rays)	0.8 ± 0.6 (0.1 - 4.5)	6.4 ± 3.7 (2 - 33)	3.6 ± 2 (1 - 18)
	A3 (MTP1 fusion +/- lateral rays)	1.6 ± 1.1 (0.3 - 7.5)	10.8 ± 6.4 (3 - 41)	5.6 ± 3.3 (2 - 23)
B: Hindfoot-ankle	B1 (ligament reconstruction, Achilles, hardware removal, etc.)	3.1 ± 3.8 (0.3 - 21.8)	13.1 ± 14.5 (2 - 85)	6.2 ± 7.1 (1 - 34)
	B2 (fusion, osteotomy)	11.6 ± 9.7 (0.3 - 47.7)	46.7 ± 33.7 (2 - 163)	24.4 ± 24.3 (1 - 211)
	B3 (ankle replacement)	8.7 ± 7.2 (0.8 - 51)	35.4 ± 25.6 (6 - 174)	18.1 ± 12.9 (3 - 86)
	B4 (reconstructions or fusion after replacement)	20.1 ± 14.7 (1.3 - 52.4)	78.9 ± 52.6 (7 - 192)	39.7 ± 26.2 (3 - 90)

Table 5: Correlation between surgery or tourniquet time and DAP according to surgical category

	Correlation coefficient	p-value
Surgery time/DAP Category A (forefoot)	0.45	< 0.05
Surgery time/DAP Category B (hindfoot-ankle)	0.71	< 0.05
Passive dosimetry (whole body Hp(10)) vs. active	0.23	0.41
Passive dosimetry (whole body Hp(0.07)) vs. active	0.31	0.27
Passive dosimetry (ring) vs. active	0.46	0.07
Passive dosimetry (crystalline lens) vs. active	0.03	0.92

Table 6: Comparison with the literature

Type of surgery	Author	Type of fluoroscope	Number of patients	Conclusion(s)
General orthopedic-traumatology	Loisel 2017 [18]	Mini and standard	182	Hand: 4.75 mSv in 13 months
	Gausden 2017 [19]	Standard	No data	Traumatology: 9.48 mSv/year
	Rashid 2018 [20]	Standard	849	Femoral nail (DAP): 172 cGy/cm²
Spine	McArthur 2015 [21]	Standard	30	DAP: 91.3 cGy/cm²
	Kouyoumdjian 2018 [22]	Standard	100	Crystalline lens: 30.5 µSv/procedure
Hand	Tuohy 2011 [23]	Mini	198	DAP: 19.3 cGy/cm²
	Wang 2017 [24]	Mini	25	Hand: 5.52 mSv/year Crystalline lens: < 0.3 mSv/month
	Van Rappard 2019 [25]	Mini	94	Hand: 3.1mSv/year
Foot and ankle	Singh 2007 [14]	Standard	80	Hand: 2.4mSv/year
	Dawe 2011 [16]	Mini and standard	127	Mini: less radiation in hindfoot surgery
	Angthong 2014 [17]	Standard	55	Radiation time: 77 sec/case
	Greffier 2019 [15]	Mini and standard	300	Mini: less radiation

	Present series	Mini	1064	Hand: 1.28 mSv/year Crystalline lens: 0.6 mSv/year DAP: 3.9 cGy/cm² Radiation TAR: 35.4 sec/case
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TAR: total ankle replacement

DAP: mean dose-area product per procedure

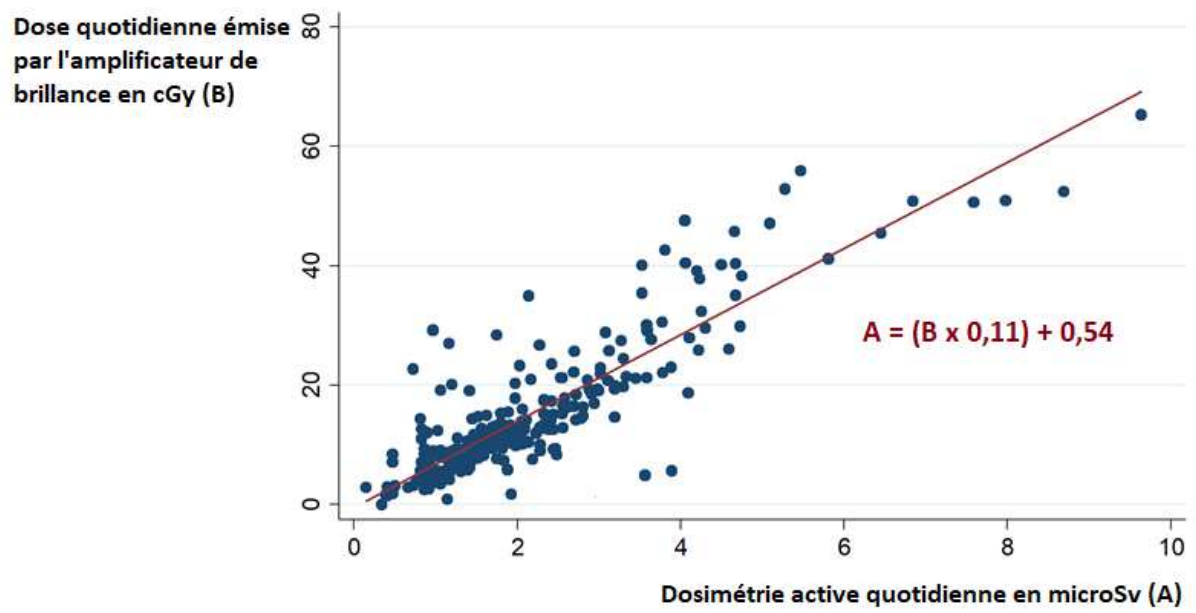


Figure 1 :

Daily dose emitted by the fluoroscope (cGy): B

$$A = (B \times 0.11) + 0.54$$

Daily active dose (μ Sv): A