Surgeon’s and patient’s radiation exposure during percutaneous thoraco-lumbar pedicle screw fixation: A prospective multicenter study of 100 cases

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A B S T R A C T

Hypothesis: Percutaneous pedicle screw fixations (PPSF) are increasingly used in spine surgery, minimizing morbidity through less muscle breakdown but at the cost of intraoperative fluoroscopic guidance that generates high radiation exposure. Few studies have been conducted to measure them accurately. Material and methods: The objective of our study is to quantify, during a PPSF carried out in different experimented centers respecting current radiation protection recommendations, this irradiation at the level of the surgeon and the patient. We have prospectively included 100 FPVP procedures for which we have collected radiation doses from the main operator. For each procedure, the doses of whole-body radiation, lens and extremities were measured.

Results: Our results show a mean whole body, extremity and lens exposure dose per procedure reaching 1.7 ± 2.8 μSv, 204.7 ± 260.9 μSv and 30.5 ± 25.9 μSv, respectively. According to these values, the exposure of the surgeon’s extremities and lens will exceed the annual limit allowed by the International Commission on Radiological Protection (ICRP) after 2440 and 4840 procedures respectively. Conclusion: Recent European guidelines will reduce the maximum annual exposure dose from 150 to 20 mSv. The number of surgical procedures to not reach the eye threshold, according to our results, should not exceed 645 procedures per year. Pending the democratization of neuronavigation systems, the use of conventional fluoroscopy exposes the eyes in the first place. Therefore they must be protected by leaded glasses.

Level of proof: IV, case series.

Keywords:
Minimally invasive surgery
Percutaneous pedicle screw fixation
Fluoroscopy
C-arm
Radiation exposure
Spine surgeon

1. Introduction

Minimally invasive procedures using Percutaneous Pedicle Screw Fixation (PPSF) have gained popularity [1–5]. Necessity for fluoroscopic guidance results in high radiation exposure for both the patient and the surgical team. Excessive X-ray exposure has been raised as a concern for surgeon and patient health when using minimally invasive techniques on the spine [6,7]. It depends on various factors such as the patient’s body mass index (BMI), the level of instrumentation, the surgeon’s experience, and the technical setting of the C-arm during surgery. Recent studies have outlined methods to reduce X-ray exposure during spinal procedures [7–14]. Other studies have highlighted the advantages of...
various imaging support systems, such as intraoperative computed tomography (CT) combined with navigation [15–17], however these systems are expensive and are only available in a minority of centers.

Intraoperative fluoroscopic control of Jamshidi needle placement and screw setting is performed using one or two C-arms in most institutions. Nevertheless, little data showing fluoroscopy time during surgery and radiation exposure to both the patient and the surgeon is available for PPSF to date [6,10,14,18,19]. This prospective clinical multicenter trial aims to quantify the radiation exposure of the surgeon and the patient during routine use of PPSF in seven different spine centers accustomed to percutaneous technique.

2. Materials and methods

2.1. Study design

One hundred consecutive patients were prospectively enrolled in this study from November 2014 to April 2015 in 7 different spine centers. Patients were treated by a routine PPSF procedure for various indications. In each center, the surgeon’s experience exceeded 5 years of practice with PPSF (other than 30 per year). In total, 14 experienced surgeons (2 per center) performed the surgeries. One C-arm was used in 69 procedures, and 2 C-arms were used in 31 cases. Standard posterior percutaneous devices were used (Longitude Medtronic®, Mantis Stryker®, Pathfinder Zimmer®, Viper 2 Depuy®), although different pedicle screw and rod systems were used. All surgeons wore a leaded apron and leaded thyroid protection during the procedures, but did not use any specific lead glasses.

2.2. Radiation measurement

The radiation measurement was performed as previously described [20,21]. Two different dosimeters were used in this study (Fig. 1):

- passive thermoluminescent dosimeters (TLD) were used to evaluate personal equivalent doses (Hp) of the lens (Dosiris Cristallin; IRSN, Croisy-sur-Seine, France); and Hp of extremities was measured at the palmar surface of the ring finger of the dominant hand (Bagues; IRSN, Croisy-sur-Seine, France). Surface doses of extremities were given at a tissue equivalent depth of 0.07 mm (Hp(0.07)) and equivalent lens doses at a tissue depth of 3 mm (Hp(3));

- an electronic personal dosimeter (EPD) was worn on the chest, under the lead apron, which corresponded to a direct reading dosimeter. This dosimeter displayed the Hp at a 10 mm equivalent depth (Hp(10)) and this value was considered a conservative estimate of the effective dose, indicating whole-body irradiation of the surgeon.

2.3. Data analysis

Data were collected immediately after each procedure. Data were retrieved concerning the center (location), the patient (age, BMI), the surgery (indication, spinal levels, operative time, C-arm(s) used, number of instrumented levels, number of screws used), and the patient’s radiation dose. Patient dose was recorded as the direct measurement of dose area product (DAP) based on the intraoperative radiation exposure (cGy·cm²) and the fluoroscopic time (FT, seconds) read on the C-arm. The surgeon’s whole-body irradiation was recorded from the EPD at the end of each procedure. For each center, TLD exposure doses were cumulated over the period of inclusion. At the end of the study, the cumulative dose was measured for each TLD in a nuclear department (IRSN, Croisy-sur-Seine, France).

2.4. Statistical analysis

Statistical analyses were carried out using the Matlab (MathWorks, Natick, MA USA) and BiostaTGV software. A Pearson correlation test was used to assess whether the operative time was correlated to DAP, FT, and Hp(10). A p-value < 0.05 was considered statistically significant. Comparisons (DAP, FT, Hp(10)) and dosimetric radiations between each fixation devices procedure were performed using a paired Mann-Whitney Wilcoxon test. Comparisons with the p-values < 0.05 were considered as significant differences. In order to verify the sample distribution within each level and within each center, we performed the ANOVA test.

3. Results

3.1. Patient population

One hundred patients underwent PPSF as the only treatment procedure. Clinical data, including patient demographics, spine anatomical levels are listed in Table 1. In the majority of cases, the reason for surgery was traumatic (78 patients), followed by degenerative spinal diseases or isthmic spondylolisthesis to complement prior anterior interbody fusion (17), metastasis lesion (3)
Table 1
Patient characteristics and number of patients per center and per level.

<table>
<thead>
<tr>
<th>BMI (kg/m²)</th>
<th>Thoracic</th>
<th>Thoraco-lumbar</th>
<th>Lumbar</th>
<th>Lumbo-sacral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>100</td>
<td>9</td>
<td>45</td>
<td>31</td>
</tr>
<tr>
<td>Age (19–96)</td>
<td>55.1</td>
<td>25.8 ± 4.6</td>
<td>53.7 ± 9.6</td>
<td>26.0 ± 4.9</td>
</tr>
<tr>
<td>Sex (f/m)</td>
<td>48/52</td>
<td>3/6</td>
<td>21/24</td>
<td>17/14</td>
</tr>
</tbody>
</table>

BMI are presented as average ± standard deviation; age presented as average with range in brackets. BMI: body mass index; f: female; m: male.

Table 2
Patient data, operative time and dosimetric indicator per center.

<table>
<thead>
<tr>
<th>BMI (kg/m²)</th>
<th>Operative time (min)</th>
<th>DAP (cGy·cm²)</th>
<th>FT (seconds)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Center 1</td>
<td>25.5 ± 5.0</td>
<td>107 ± 30</td>
<td>1604 (1260; 1860)</td>
</tr>
<tr>
<td>Center 2</td>
<td>24.6 ± 3.5</td>
<td>59 ± 25</td>
<td>277 (227; 693)</td>
</tr>
<tr>
<td>Center 3</td>
<td>25.4 ± 4.5</td>
<td>48 ± 16</td>
<td>834 (512; 2230)</td>
</tr>
<tr>
<td>Center 4</td>
<td>26.5 ± 5.4</td>
<td>58 ± 26</td>
<td>842 (564; 1140)</td>
</tr>
<tr>
<td>Center 5</td>
<td>23.5 ± 3.7</td>
<td>90 ± 37</td>
<td>1150 (542; 1732)</td>
</tr>
<tr>
<td>Center 6</td>
<td>26.0 ± 7.8</td>
<td>56 ± 27</td>
<td>425 (261; 467)</td>
</tr>
<tr>
<td>Center 7</td>
<td>24.2 ± 2.3</td>
<td>108 ± 26</td>
<td>625 (420; 732)</td>
</tr>
</tbody>
</table>

BMI and operative time are presented as average ± standard deviation. DAP and FT presented as median (first quartile; third quartile). BMI: body mass index; DAP: dose area product; FT: fluoroscopic time.

Table 3
Patient data, operative time and dosimetric indicator by anatomic level of the procedure.

<table>
<thead>
<tr>
<th>BMI (kg/m²)</th>
<th>Operative time (min)</th>
<th>DAP (cGy·cm²)</th>
<th>FT (seconds)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thoracic</td>
<td>25.8 ± 4.5</td>
<td>84 ± 29</td>
<td>760 (437; 1200)</td>
</tr>
<tr>
<td>Thoraco-lumbar</td>
<td>24.3 ± 4.9</td>
<td>77 ± 39</td>
<td>627 (256; 1060)</td>
</tr>
<tr>
<td>Lumbar</td>
<td>26.0 ± 4.9</td>
<td>63 ± 32</td>
<td>834 (464; 1265)</td>
</tr>
<tr>
<td>Lumbo-sacral</td>
<td>25.7 ± 3.2</td>
<td>70 ± 30</td>
<td>1545 (825; 2075)</td>
</tr>
</tbody>
</table>

BMI and operative time are presented as average ± standard deviation. DAP and FT presented as median (first quartile; third quartile). BMI: body mass index; DAP: dose area product; FT: fluoroscopic time.

Table 4
DAP per C-arm number.

<table>
<thead>
<tr>
<th>Number of patient</th>
<th>DAP (mGy·cm²)</th>
<th>Procedure time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 C-arm</td>
<td>2 C-arm</td>
<td>1 C-arm</td>
</tr>
<tr>
<td>Thoracic</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Thoraco-lumbar</td>
<td>27</td>
<td>18</td>
</tr>
<tr>
<td>Lumbar</td>
<td>23</td>
<td>8</td>
</tr>
<tr>
<td>Lumbo-sacral</td>
<td>12</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>69</td>
<td>31</td>
</tr>
</tbody>
</table>

Data are related as average and standard deviation.

3.2. Patient radiation dose

The mean operative time was 72 ± 35 minutes and the mean BMI was 25.2 ± 4.7 kg/m², without statistical difference between the different centers (Table 2). Across the different centers, the median (first quartile; third quartile) DAP and FT was 763 (418; 1315) cGy·cm² and 102 (63; 187) seconds, respectively. Data are detailed in Table 3. The median (first quartile; third quartile) FT and DAP per screw were 19.2 (14.3; 38.8) s and 142 (74; 286) cGy·cm², respectively.

Patient attenuation was significantly higher (p < 0.05) at the lumbo-sacral level than at the thoracic level (760 (437; 1200) and 1545 (825; 2075) cGy·cm²).

The correlations between the operative time and the DAP (r = 0.5454; p = 5.32 × 10⁻¹⁶), and the DAP and the fluoroscopic time (r = 0.5006; p = 1.32 × 10⁻¹⁷) were moderate. The correlation between the operative time and the fluoroscopic time (r = 0.2537; p = 0.011) was poor. DAP per C-arm number are related in Table 4. No statistical difference was found considering number of C-arm used during the procedure. DAPs per screw considering the anatomical level and the center of the procedure are related in Table 5.
Table 5
DAP (mGy cm²) per screw according to the level and the center.

<table>
<thead>
<tr>
<th>Center</th>
<th>Thoracic</th>
<th>Thoraco-lumbar</th>
<th>Lumbar</th>
<th>Lumbo-sacral</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Center 1</td>
<td>–</td>
<td>270 ± 87</td>
<td>451 ± 198</td>
<td>–</td>
<td>335 ± 157</td>
</tr>
<tr>
<td>Center 2</td>
<td>95</td>
<td>55 ± 26</td>
<td>91 ± 28</td>
<td>321 ± 131</td>
<td>108 ± 111</td>
</tr>
<tr>
<td>Center 3</td>
<td>–</td>
<td>141 ± 95</td>
<td>172 ± 73</td>
<td>655 ± 89</td>
<td>271 ± 221</td>
</tr>
<tr>
<td>Center 4</td>
<td>92 ± 69</td>
<td>210.5</td>
<td>195 ± 84</td>
<td>183 ± 157</td>
<td>166 ± 109</td>
</tr>
<tr>
<td>Center 5</td>
<td>300 ± 264</td>
<td>282 ± 355</td>
<td>218 ± 228</td>
<td>479.8</td>
<td>292 ± 281</td>
</tr>
<tr>
<td>Center 6</td>
<td>48 ± 7</td>
<td>90 ± 55</td>
<td>54 ± 33</td>
<td>–</td>
<td>74 ± 47</td>
</tr>
<tr>
<td>Center 7</td>
<td>–</td>
<td>103 ± 63</td>
<td>68.7</td>
<td>–</td>
<td>97 ± 58</td>
</tr>
<tr>
<td>Total</td>
<td>146 ± 169</td>
<td>157 ± 169</td>
<td>209 ± 161</td>
<td>360 ± 231</td>
<td>199 ± 186</td>
</tr>
</tbody>
</table>

Data are related as average and standard deviation.

Correlation between the BMI and the PDS is poor ($R^2 < 0.17$) globally and whatever the level (Fig. 2).

3.3. Surgeon’s exposure

Surgeon’s average whole-body radiation dose per procedure was $1.7 ± 2.8 \mu Sv$ and median (first quartile; third quartile) was $0.490 (0.163; 1.505) \mu Sv$. Average equivalent dose for lens was $30.5 ± 25.9 \mu Sv$ and $204.7 ± 260.9 \mu Sv$ for extremities. The mean $H_p(3)$ of each center ranged between 0.6 and 16.8 $\mu Sv$ and the average $H_p(0.07)$ between 28.1 and 751.3 $\mu Sv$ (Table 6).

The average effective dose received by surgeons per procedure varied with spine level, tending to increase in lumbar and lumbo-sacral area (1.920 [0.690; 3.113] $\mu Sv$ for lumbo-sacral vs 0.805 $\mu Sv$).

Fig. 2. DAP (dose area product) according to the BMI (body mass index) for each anatomical (thoracic/lumbar/thoraco-lumbar/lumbo-sacral) level and all levels.
of radiation (kilovolt and milliampere) at the output of the tube and DAP for each screw [6,14,18]. Lumbo-sacral exposure is higher.

### Table 6

<table>
<thead>
<tr>
<th>Center</th>
<th>Whole-body Hp(10) (µSv)</th>
<th>Personal dosimeter (TLD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Operational dosimeter (EPD)</td>
<td>Lens Hp(3) (µSv)</td>
</tr>
<tr>
<td>Center 1</td>
<td>0.310 (0.170; 0.530)</td>
<td>75.6</td>
</tr>
<tr>
<td>Center 2</td>
<td>0.660 (0.380; 1.190)</td>
<td>14.4</td>
</tr>
<tr>
<td>Center 3</td>
<td>0.001 (0.001; 0.002)</td>
<td>53.5</td>
</tr>
<tr>
<td>Center 4</td>
<td>0.845 (0.245; 3.855)</td>
<td>25.6</td>
</tr>
<tr>
<td>Center 5</td>
<td>1.000 (0.310; 7.300)</td>
<td>32.0</td>
</tr>
<tr>
<td>Center 6</td>
<td>0.001 (0.001; 0.002)</td>
<td>7.7</td>
</tr>
<tr>
<td>Center 7</td>
<td>0.530 (0.298; 1.385)</td>
<td>5.5</td>
</tr>
<tr>
<td>All centers</td>
<td>0.490 (0.163; 1.505)</td>
<td>30.5 ± 25.9</td>
</tr>
</tbody>
</table>

Whole-body personal equivalent dose (Hp(10)) per procedure are presented as median (first quartile; third quartile). Cumulated lens and extremities equivalent dose (Hp(3) and Hp(0.07)) per center are expressed as mean. EPD: electronic personal dosimeter; TLD: thermoluminescent dosimeter; Hp: personal equivalent dose.

Table 7

<table>
<thead>
<tr>
<th>Level</th>
<th>Operational dosimeter (EPD)</th>
<th>Whole-body Hp(10) (µSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thoracic</td>
<td>0.805 (0.103; 1.063)</td>
<td>868.15 (191.6–2885.18) cGy cm² and 139.67 ± 0.261 mSv respectively</td>
</tr>
<tr>
<td>Thoraco-lumbar</td>
<td>0.380 (0.165; 0.090)</td>
<td>0.026 mSv and 0.205 ± 0.261 mSv respectively</td>
</tr>
<tr>
<td>Lumbar</td>
<td>0.530 (0.140; 3.090)</td>
<td>0.0181</td>
</tr>
<tr>
<td>Lumbo-sacral</td>
<td>1.920 (0.690; 3.113)</td>
<td>0.006</td>
</tr>
<tr>
<td>All centers</td>
<td>0.490 (0.163; 1.505)</td>
<td>0.026 mSv and 0.205 ± 0.261 mSv respectively</td>
</tr>
</tbody>
</table>

Data are presented as median (first quartile; third quartile). Hp: personal equivalent dose.

[0.103; 1.063] µSv for thoracic) (Table 7). The correlation between the operative time and Hp(10) (r = 0.1583; p = 0.0181) was poor.

### 4. Discussion

The percutaneous procedures are reliable [22] but expose patients and surgeons to higher radiation compared to open surgeries.

Very few studies have investigated the radiation exposure during PPSF [6]. Adverse effects of ionizing radiation with deterministic or late stochastic effects [18] and underestimation of them can lead to potential risks of cancer over 5 times higher among exposed surgeons [1,23]. Spine surgeons were exposed to a 10-fold greater radiation level than orthopedic surgeons [24] especially with mini-invasive percutaneous procedures [6,14]. Bronsard et al. compared lumbar classical open fixation with closed fixation [6], showing that the DAP and time of fluoroscopy were respectively 267.72 (58.3–2054) cGy·cm² and 29.49 (13.2–83.1) seconds in open surgery versus 868.15 (191.6–2885.18) cGy·cm² and 139.67 (36–388.1) seconds in percutaneous procedure. However poor data are published.

Except in the lumbo-sacral area, fluoroscopic time and DAP, and thus effective dose to patients, was lower compared to previous studies [25–27] or similar considering the mean fluoroscopic time and DAP for each screw [6,14,18]. Lumbo-sacral exposure is higher. The thickness of the scattering volume in the low part of the spine is higher than the thoracic spine, leading to an increase in the amount of radiation (kilovolt and milliamperes) at the output of the tube and therefore the dose rate, which increases the DAP.

Experienced surgeons performed all the procedures eliminating the learning curve effect. We did not find any statistically significant center effect but the range is rather wide.

This study provides a great heterogeneity of irradiation depending on the centers and levels operated. Its origin is multifactorial (type of fluoroscopy, rigor of the respect of the rules of radioprotection, localization of the surgery, surgeon, difficulty of the surgery, type of instrumentation etc.). This work has the merit to globalize them and to give an order of magnitude of the actual irradiation exposure of the surgeon and the patient during this type of procedure.

Theoretically, the following technical aspects influence occupational radiation exposure [28–36].

The surgeon exposure annual dose limit recommended by the International Commission on Radiological Protection (ICRP) Guidance, is 500 mSv for the extremities and 150 mSv for the eye. In our study, the average radiation dose to lens and extremities per procedure was 0.031 ± 0.026 mSv and 0.205 ± 0.261 mSv respectively and lower than previous study on percutaneous vertebroplasty procedure [37]. Compared with kyphoplasty procedures, lens and extremities radiation surgeon exposure is lower in our study [30]. According to our results, the exposure dose to the extremity and the eye will exceed the annual limit after respectively 4840 and 2440 procedures.

Interventional cardiologists are also exposed to ionizing radiation (X-rays), Jacob et al. [38] reported in their series that posterior subcapsular lens opacities were significantly more frequent among these specialist (17% vs. 5%, p = 0.006), corresponding to a crude OR = 3.89. In part related to that risk, and also to keep in line with the ICRP Guidance, a recent European directive (2013/59/EURATOM) lowered the annual limit to 20 mSv. Using this cut-off, the exposure dose to the eye will exceed the annual limit after 645 procedures.

In addition to routine individual safety precautions, use of pulsed fluoroscopy, tight collimation, manual reduction of the dose rate, use of saved images instead of doing additional radiography, and optimized source-to-detector distance are also recommended and have been forwarded. Many studies have highlighted the potential of fluoronavigation or new experimental devices [9,39] to minimize radiation exposure. As fluoronavigation delivers less radiation in percutaneous procedures for many studies [16,40–44] especially at the sacral area [12], it seems best adapted to percutaneous procedures with less misplacement of screws compared to open surgery. However, these systems are expensive and only available in some institutions. Conventional 2D fluoroscopy is currently the most widely used image guidance method in all our centers.

Our study had several limitations. Statistical analysis was therefore lacking in power due to the low number of patients per procedure and center, and cross influences between the center and location of the surgery. In addition, procedures were heterogeneous in terms of percutaneous devices and type C-arm system, but also in terms of surgeon’s technique. Even experience of surgeon had to be considered. This study did not include junior surgeons potentially the most radiation providers.

### 5. Conclusion

With minimal invasive procedures becoming increasingly popular, there is a growing concern among surgeons about radiation exposure and the need for solutions. Here, we report the results of surgeon and patient radiation exposure in 7 centers. The surgeon...
radiation exposure procedure is low. However, the recent ICRP Guidance and the European directive limits the annual dose to the eye to below 20 mSv limiting the number of surgical procedures according to our data to 645 procedures per year. Whilst current radiation precautions appear to be adequate based on the low dose recorded for surgeons and patients, these have to be strictly observed and monitored in the future.

Disclosure of interest

The authors declare that they have no competing interest.

Funding

We received for this research study some funds from an academic support (Société française de chirurgie rachidienne [SFCR]). These funds allowed us to buy all the measuring equipment (Thermoluminescent dosimeters).

Authors' contributions

N.L. and P.K. designed the model and the computational framework and wrote the paper.

N.L. and P.K. directed the project and wrote the paper.

J.G. and J.L.R. analyzed the data, contributed to the design of the research, to the analysis of the results and to the writing of the manuscript.

G.C.G., M.S.F., B.B., P.T., F.Z., J.B., Y.P.C., A.D., H.E. processed the experimental data, aided in interpreting the results, carried out the manuscript.

We are grateful to Sarah Kabani for valuable editing assistance.

References