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Original article

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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ABSTRACT

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 $1.7 \pm 2.8 \,\mu$ Sv, $204.7 \pm 260.9 \,\mu$ Sv and $30.5 \pm 25.9 \,\mu$ Sv, 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.

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1. Introduction

Minimally invasive procedures using Percutaneous Pedicle Screw Fixation (PPSF) have gained popularity [1–5]. Necessity for

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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

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P. Kouyoumdjïan et al. / Orthopaedics & Traumatology: Surgery & Research xxx (2018) xxx-xxx



Fig. 1. Passive thermoluminescent dosimeters (TLD) locations: evaluation of surgeon equivalent doses (Hps) to the lens (Dosiris Cristallin; IRSN, Croisy-sur-Seine, France) and extremities (Bagues; IRSN, Croisy-sur-Seine, France).

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 ($cGy \cdot cm^2$) 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 (Math-Works, 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 PPPSS 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)

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2

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