

RADIATION DOSES TO PATIENTS DURING PEDICLE SCREW FIXATION OF THE SPINE

M.V. Kubasov¹, M.N. Kravtsov^{1–3}, A.V. Golubin², V.N. Malakhovsky², D.V. Svistov²

¹North-Western State Medical University n.a. I.I. Mechnikov, St. Petersburg, Russia

²S.M. Kirov Military Medical Academy, St. Petersburg, Russia

⁵Research Institute of Emergency Medicine n.a. I.I. Dzhanelidze, St. Petersburg, Russia

Objective. To analyze the radiation doses to patients during spinal decompression and stabilization surgery under optical CT navigation and fluoroscopy.

Material and Methods. Study design: retrospective cohort study. The sample consisted of 164 patients who underwent transpedicular fixation of the spine performed by percutaneous or open techniques. In the O-arm group (n = 109), cone-beam CT combined with optical navigation was used; in the C-arm group, fluoroscopy (n = 55) was used. The effective dose equivalent (EDE) and the maximum absorbed dose (MAD) in the skin were evaluated.

Results. EDE in the O-arm group was Me 9.1 mSv, [IQR: 7.1–11.6], and in the C-arm group -Me 1.8 mSv [IQR: 1.8–5.6], p < 0.0001. Maximum absorbed dose in the skin in the O-arm group was Me 49.3 mGy [IQR: 27.0–96.9], and in the C-arm group - Me 36.1 mGy [IQR: 16.6–111.5], p = 0.424.

Conclusion. The use of CT navigation and fluoroscopy during pedicle screw fixation of the spine is not associated with the risk of developing deterministic effects. The use of intraoperative CT navigation during pedicle screw fixation is associated with a greater patient EDE compared with that of fluoroscopy (p < 0.05). Differences in EDE received by patients undergoing open and percutaneous techniques of pedicle screw fixation are statistically insignificant, regardless of the type of beam guidance and the number of fixation levels. The number of intraoperative CT scans is proportional to the patient EDE (p = 0.018).

Key Words: pedicle screw fixation, effective dose equivalent, cone-beam computed tomography, CT navigation.

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Patients and medical staff have been exposed to higher levels of ionizing radiation as a result of an upward trend in surgeries in recent years [1].

It is commonly known that radiation is associated with the development of both deterministic (local erythema, epilation, ulceration, necrosis) and stochastic effects (radiation-induced cancer, cataract, etc.). Reducing the exposure time and observing the principle of "as little as possible" is considered an imperative task for all healthcare professionals [2].

The disadvantages associated with traditional intraoperative fluoroscopy techniques in spine surgery led to increased interest in enhancing navigation methods. The use of two-dimensional fluoroscopy navigation reduced the frequency of pedicle screw malposition, and the introduction of intraoperative 3-dimensional CT navigation techniques minimized this indicator, making spine surgery safer and less invasive. Moreover, intraoperative navigation is associated

with such advantages as a reduction in radiation exposure and a reduction in the time of spine surgery [1].

Nowadays, no guidelines have been developed to control the exposure doses of patients and medical staff during spine surgeries using intraoperative cone-beam computed tomography (CBT) [3, 4].

There are substantial differences in the published data in the literature [1, 2, 5–8] regarding the exposure doses of patients and spine surgeons when using intraoperative cone-beam CT and conventional fluoroscopy. A surgeon's personal experience, the technical equipment of the operating room, and the technique of surgical intervention have a considerable influence on the measurement results [9–11].

The objective is to analyze the radiation dose to the patients during spinal decompression and stabilization surgery under optical CT navigation and fluoroscopy.

Study design: retrospective cohort study.

Material and Methods

The study included patients from the Department of Neurosurgery of S.M. Kirov Military Medical Academy (St. Petersburg) who underwent stabilization surgeries using transpedicular instrumentation in 2019–2021.

Inclusion criteria: degenerative diseases and injuries of the lower thoracic and lumbosacral spine (T10-S1) in patients who underwent surgery using transpedicular instrumentation; the number of fixed vertebrae was no more than four (3 segments), no more than 8 screws; procedures performed by surgeons who have done at least 100 similar surgical interventions.

Exclusion criteria: cases associated with a significant increase in the exposure dose (performing more than three intraoperative CT scans, a combination of various polymethylmethacrylate augmentation techniques, or the replacement of pedicle screws due to unac-

ceptable malposition detected during a staged radiography or CT).

Transpedicular fixation (TPF) was performed by open (O-TPF) or percutaneous (P-TPF) techniques. In some cases, TPF was combined with decompression and interbody stabilization using the TLIF technique (transforaminal lumbar interbody fusion).

The surgeries were performed under the monitoring of conventional fluoroscopy or intraoperative cone-beam CT. The Ziehm Vision RFD 3D mobile C-arm, which provides 2D images, and the O-arm-Medtronic intraoperative conebeam tomography (CBT), combined with the StealthStation S7-Medtronic navigation, which allows obtaining 3D CT images, were used.

The study of dose loads of patients during neurosurgical procedures on the spine was performed by retrospective analysis of effective doses equivalents (EDE) and maximum absorbed dose (MAD) in the skin of patients.

The EDE of the patients were determined by the calculation method according to the formulas given in methodical guidelines MU 2.6.1.2944-11 [3]. The index of the dose-area product (DAP) was used as a basis in fluoroscopy, and the dose-length product (DLP) was used in cone-beam CT. Kd = 0.2 mSv $(Gy \cdot cm^2)$ was used to determine the EDE of a patient according to the DAP data during the surgery as a whole, including various inclination angles of the C-arm axis. Kd = 0.015 [3, 4, 7, 10]was selected to calculate EDE in CT of the lower thoracic and lumbar vertebrae, according to MU 2.6.1.2944-11, the International Atomic Energy Agency (IAEA) material and a number of other worldwide publications.

Statistical data processing was performed using Microsoft Excel and IBM SPSS Statistics Version 23 software (IBM Corp., USA). The significance of differences in the mean values of quantitative and ordinal indicators in independent samples was evaluated using the Mann-Whitney U test; verification of hypotheses of homogeneity of more than two independent samples was assessed using the Kruskal-Wallis one-way analysis of

variance. The results were considered statistically significant at p < 0.05.

The exposure doses of patients during 164 surgeries were analyzed. According to the intraoperative radiation therapy, the patients were divided into two groups. In the O-arm group (n = 109), cone-beam CT combined with optical navigation was used; in the C-arm group, fluoroscopy (n = 55) was used.

The structure in the O-arm group was as follows: 23 cases of percutaneous TPF (n = 5: P-TPF + TLIF; n = 18: P-TPF); and 86 cases of open TPF (n = 82: O-TPF + TLIF; n = 4: O-TPF). In the group with the use of conventional fluoroscopy, 23 percutaneous TPF (n = 3: P-TPF + TLIF; n = 20: P-TPF) and 32 open TPF (n = 6: O-TPF + TLIF; n = 26: O-TPF) were performed.

In case of percutaneous TPF under the control of the O-arm navigation, the reference frame was fixed as standard: to the spinous process of the vertebra below the fixation level or to the iliac wing. Wires for cannulated screws were placed into the vertebral bodies using a pre-installed navigated biopsy needle (Fig. 1). In case of open TPF under the control of radiography in anteroposterior and lateral views, the hands-free technique was used with assessment of the point and direction of screw placement via wires.

The exposure parameters for the Ziehm Vision RFD 3D mobile C-arm were set automatically, depending on the patient's anthropometric measurements. The mean values of voltage and current at the roentgen tube anode were 88.1 kV and 15.3 mA. The mean exposure time was 303.4 seconds. The radiation parameters of the O-arm-Medtronic intraoperative CBT on the roentgen tube anode were standard: voltage 120.0 kV and current 125.12 mA.

Examples of protocols for intraoperative studies of the Ziehm Vision RFD 3D mobile C-arm and the O-arm-Medtronic intraoperative CBT are given in Fig. 2.

Results

The values of the EDE and MAD in the skin in the presented sample did not

comply with the normal distribution law (the Shapiro – Wilk test = 0.000).

The minimum and maximum EDE values of a patient in the O-arm group were 4.7 and 29.6 mSv, and 0.23 and 28.6 mSv in the C-arm group. The EDE median in the O-arm group was 5 times higher than the same indicator in the C-arm group.

The MAD in the skin of a patient was in a range of 6.9–453.4 mGy and 4.5–572.1 mGy in the O-arm and C-arm groups, respectively. The arithmetic mean of MAD in the skin was 1.4 and 2.7 times higher than the median values in the groups due to the presence of a small number of cases with a high exposure dose (Table 1, Fig. 3).

The EDE in the groups had statistically significant differences. No significant intergroup differences in the MAD in the skin were obtained (Fig. 3).

The revealed intergroup differences in the EDE of a patient required more detailed evaluation of this indicator in the groups. The dependence of the patient's total EDE on the type of surgical treatment (open TPF or percutaneous TPF) and on the number of operated segments was analyzed (Table 2). Additionally, the dependence of the EDE of a patient on the number of CT scans performed during one surgery was identified.

Regardless of the type of radiotherapy, intra-group differences in the total EDE in open and percutaneous TPF techniques were not statistically significant. There was only a slight upward trend in the EDE of a patient in the C-arm group if percutaneous TPF was used (Fig. 4).

The EDE median of a patient in open procedures with the use of cone-beam tomography and navigation was 6.2 times higher than the similar indicators of the conventional fluoroscopy group. In the subgroup of percutaneous TPF, the EDE of a patient in the use of cone-beam tomography with navigation was 3.2 times higher (Fig. 5).

The dependence of the EDE of a patient on the number of operated segments in both groups was not statistically significant (Table 3).

CT with the O-arm was performed 2 or 3 times during one surgery, which



Fig. 1

The main stages of percutaneous transpedicular fixation under O-arm control: \mathbf{a} – fixation of the reference frame; \mathbf{b} – insertion of a navigated biopsy needle into the vertebral body; \mathbf{c} – insertion of a cannulated screw along a wire; \mathbf{d} – completion of the navigated stage

depended on the sequence of stages of the decompression and stabilization procedure. A double scan was necessary to combine the CBT data with the navigation station and control the position of the screws in the vertebrae. The third scan was performed if necessary in order to evaluate the degree of decompression of the neural structures of the spinal canal. The dependence of the EDE of a patient on the number of CT scans is reflected in Table 4.

The differences in the number of intraoperative CT scans in the O-arm group turned out to be statistically significant (Fig. 6).

Discussion

The reduction of radiation exposure associated with traditional intraoperative imaging techniques in spine surgery is largely achieved by the use of navigation techniques, both optical and electromagnetic [2, 12]. CT navigation technologies have evolved considerably to date. The modern O-arm intraoperative conebeam computed tomography scanner, combined with the StealthStation (S7, S8) 3D optical navigation system, Medtronic Inc., offers several advantages in comparison with traditional techniques of intraoperative fluoroscopy, the most important of which is the reduction of the radiation exposure to the operating room staff. This fact is widely mentioned in the literature [5, 10, 13, 14].

We did not analyze the clinical outcomes of treatment or the accuracy of the position of the pedicle screws. Nevertheless, it is known that the use of O-arm CBT allows for more accurate implantation of screw structures and reduces the risk of injury to neural structures [13]. Silbermann et al. [7] reported that the navigation control using CBT is more accurate when placing screws compared to the "hands-free" technique, reaching 100 %. The accuracy of intraoperative CT navigation is combined with automatic registration and universal software that, in turn, minimizes the impact of the

human factor and reduces the total duration of the surgery. The ability to obtain control CT images considerably reduces the proportion of perioperative complications and has a positive effect on treatment outcomes [9, 14, 15].

Data on the exposure doses of patients and surgeons during spine surgery using techniques of intraoperative cone-beam computed tomography and traditional fluoroscopy are controversial [1, 9, 14–16]. In an experimental study of exposure doses in TPF under the C-arm [11], a surgeon received a considerably greater radiation load than when using

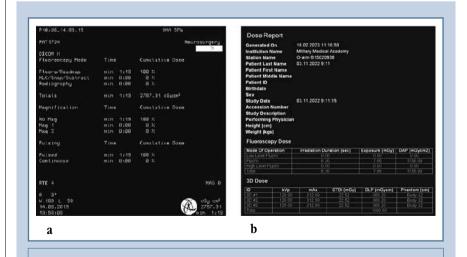


Fig. 2
Protocol of intraoperative studies of the Ziehm Vision RFD 3D mobile C-arm (a) and O-arm-Medtronic cone-beam tomography scanner (b)

Table 1

Effective dose equivalent and maximum absorbed dose in the skin of patients when performing transpedicular fixation of the spine under the control of optical CBT navigation and radiation guidance

Parameters	О	= 109)	C-arm group $(n = 55)$			p-value*	
	M	Me	Q1-Q3	M	Me	Q1-Q3	
Effective dose equivalent, mSv	10.1	9.1	7.1-11.6	4.9	1.8	1.8-5.6	0.000
Maximum absorbed dose in the skin	70.9	49.3	27.0-96.9	98.9	36.1	16.6-111.5	0.424
of patients, mGy							

^{*} Mann - Whitney U Test.

the O-arm, which may be clinically significant throughout his career (3.87×10) rad versus 0.32×10 ; p < 0.001). Moreover, the measurement of a patient's dose revealed the opposite dependence (0.03 vs. 2.76 rad; p < 0.001). Similarly, Pitteloud et al. [6] found out that the additional application of intraoperative navigation based on 3D fluoroscopy, compared with conventional fluoroscopy, showed an insignificant decrease in the radiation exposure to a surgeon with an increase in the radiation load on a patient. According to Wojdyn et al. [2], a statistically significant difference was observed between the values of the mean exposure dose emitted by the O-arm and C-arm systems when performing vertebroplasty under the control of neuronavigation. The O-arm system emitted 912 cGy/cm², compared to 1,722 cGy/cm² emitted by the C-arm.

The above data are very complicated to interpret due to the impact of a large number of factors on the results of the study [6, 11, 13]. An objective evaluation is prevented by the lack of generally accepted guidelines for radiation control during spine surgery using the CBT equipped with a navigation system.

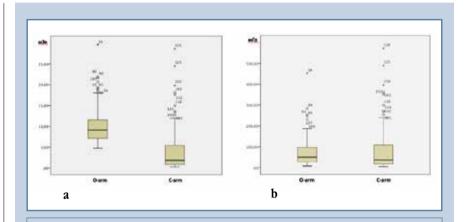


Fig. 3

Effective dose equivalent (a) and maximum absorbed dose in the skin of patients (b) during transpedicular fixation of the spine under CBT navigation and fluoroscopy

It is recommended to determine the MAD in the skin to identify the risks for the development of deterministic effects during surgical interventions [3]. For lumbar spine surgery, the recommended by MU control value of MAD in the skin, which ensures the lack of a cutaneous effect, is ~2000 mGy [3, 4]. We have found that TPF of the lower tho-

racic and lumbosacral spine, regardless of the intraoperative control technique (CT navigation or fluoroscopy), is not associated with the risk of developing deterministic effects in patients.

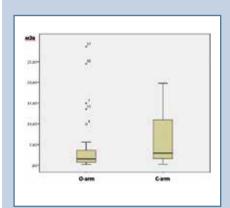
Despite the differences in the values of the total patient's EDE received by us, some features of decompression and stabilization surgery on the spine should

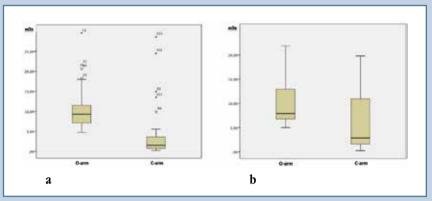
Table 2

Dependence of the patient's effective dose equivalent (mSv) on the type of transpedicular spinal fixation (TPF)

Groups	Groups Open TPF					Percutaneous TPF				
	n	M	Me	Q1-Q3	n	M	Me	Q1-Q3		
O-arm	86	9.9	9.3	7.0-11.5	23	10.4	9.3	6.4 - 14.4	0.861	
C-arm	32	4.2	1.5	0.7 - 3.6	23	6.0	2.9	0.7 - 3.6	0.109	
*p-value			0.000				0.003		-	

^{*} Mann – Whitney U Test.





Total effective dose equivalent (mSv) to a patient within CBT and fluoroscopy groups

Fig. 5
Effective dose equivalent (mSv) to a patient in the group of open surgery (a) and percutaneous transpedicular fixation (b)

be considered for the correct comparison and interpretation of the results of the study. For intraoperative monitoring, all patients operated on with the use of fluoroscopy were indicated to perform a CT scan of the spine in the postoperative period, which is associated with additional radiation exposure (approximately 3–4 mSv). It should also

be considered that intraoperative conebeam tomography with navigation is used both to evaluate the success of the surgical stage of metal osteosynthesis and to evaluate the completeness of the decompression of the spinal nerves. This, on the one hand, results in increased radiation exposure to a patient; on the other hand, it improves the quality of neurosurgical procedures and reduces the frequency of revision surgeries [14].

Conclusions

1. The values of the MAD in the skin of patients indicate that the use of CT navigation and fluoroscopy in TPF is not

Table 3

Dependence of the patient's effective dose equivalent (mSv) on the number of fixed spinal segments

Number of segments		O-arm	n group (n = 1)	109)	C-arm group $(n = 55)$			
	n	M	Me	Q1-Q3	n	M	Me	Q1-Q3
1	55	10.3	8.9	7.2 - 1.6	27	4.8	2.9	1.5-6.9
2	44	9.5	9.12	6.0 - 1.4	26	5.4	1.4	0.7 - 5.6
3	10	11.1	10.9	8.0 - 14.8	2	_	-	-
p-value	0.562*				0.147**			
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^{*} Kruskal — Wallis Test; ** Mann — Whitney U Test.

Table 4 Dependence of the patient's effective dose equivalent (mSv) on the number of CT scans during one surgery

Number of scans	O-arm group $(n = 109)$							
	n	M	Me	Q1-Q3				
2	63	8.9	7.7	5.7-10.9				
3	46	11.6	10.6	8.4-12.4				
p-value	0.000*							

^{*} Mann — Whitney U Test.

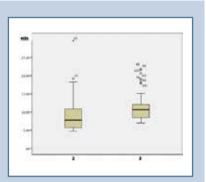


Fig. 6
Effective dose equivalent (mSv) to a patient when performing two and three intraoperative CT scans

associated with the risk of developing deterministic effects.

- 2. The use of intraoperative optical CT navigation in TPF is associated with higher EDE values in patients in comparison with the use of fluoroscopy (p < 0.05).
- 3. Differences in the patient EDE values when comparing open and percutaneous TPF techniques turned out to be statistically insignificant, regardless of the type of radiation guidance and the number of fixation levels.
- 4. Decompression and stabilization procedures on the spine performed under CT navigation require two or three intraoperative scans. The number of CT scans is relative to the value of the patient EDE value (p = 0.018).

The study had no sponsors. The authors declare that they have no conflict of interest.

The study was approved by the local ethics committees of the institutions. All authors contributed significantly to the research and preparation of the article, read and approved the final version before publication.

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Address correspondence to:

Kravtsov Maksim Nikolayevich S.M. Kirov Military Medical Academy, 6 Academika Lebedeva str., St. Petersburg, 194044, Russia, neuromax@mail.ru

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Maksim Valeryevich Kubasov, clinical resident of the Department of Neurosurgery n.a. Prof. A.L. Polenov, North-Western State Medical University n.a. I.I. Mechnikov, 41 Kirochnaya str., St. Petersburg, 191015, Russia, ORCID: 0009-0002-5101-1925, kubasov-maxim.kubasov@yandex.ru;

Maksim Nikolayevich Kravtsov, DMSc, senior lecturer of the Department of Neurosurgery, S.M. Kirov Military Medical Academy, 6 Academika Lebedeva str., St. Petersburg, 194044, Russia; Head of the Department of Neurosurgery, Research Institute of Emergency Medicine n.a. I.I. Dzbanelidze, 3 Budapeshtskaya str., St. Petersburg, 192242, Russia; Associate Professor of the Department of Neurosurgery n.a. Prof. A.L. Polenov, North-Western State Medical University n.a. I.I. Mechnikov, 41 Kirochnaya str., St. Petersburg, 191015, Russia, ORCID: 0000-0003-2486-6995, neuromax@mail.ru;

Anton Valeryevich Golubin, Head of the Department of Radiation Diagnostics of the Neurosurgery Clinic, S.M. Kirov Military Medical Academy, 6 Academika Lebedeva str., St. Petersburg, 194044, Russia, ORCID: 0000-0001-5842-623X, golubin_anton@mail.ru;

Vladimir Nikolayevich Malakhovsky, DMSc, Prof., Lecturer of the Department of Roentgenology and Radiology with a course of ultrasound diagnosis, S.M. Kirov Military Medical Academy, 6 Academika Lebedeva str., St. Petersburg, 194044, Russia, ORCID: 0000-0002-0663-9345, malakhovskyvova@gmail.com;

Dmitry Vladimirovich Svistov, MD, PhD, Associate professor, Head of the Department of Neurosurgery, S.M. Kirov Military Medical Academy, 6 Akademika Lebedeva str., St. Petersburg, 194044, Russia, ORCID: 0000-0002-3922-9887, dvsvistov@mail.ru.