

The Surgical Approach Visualization and Navigation (SAVN) System reduces radiation dosage and surgical trauma due to accurate intraoperative guidance

Ying Jiang^{a,*}, Hong-Rui Wang^{b,1}, Pan-Feng Wang^b, Shuo-Gui Xu^b

^a Department of Neurosurgery, Shanghai Chang Zheng Hospital affiliated to China Second Military Medical University, 415 Feng Yang Rd, 200003, Shanghai, PR China

^b Department of Emergency Medicine, Shanghai Chang Hai Hospital affiliated to China Second Military Medical University, 168 Chang Hai Rd., 200433, Shanghai, PR China

ARTICLE INFO

Article history:

Accepted 16 March 2019

Keywords:

SAVN system
Radiation reduction
Fluoroscopy
C-arm

ABSTRACT

Object: The intraoperative fluoroscopy has been widely used in modern neuro-spinal surgery due to the overwhelming trend toward minimal-access surgery. However, both patients and surgical personnel were under ionizing-radiation exposure during fluoroscopy usage. Since the fluoroscopy constitutes the vast majority of radiation exposure for both surgeons and patients, the development and improvement of new interventional possibilities are of great importance and interests.

Patients and methods: A total of 20 patients were included in the current study, who received thoracic-spinal tumor resection via posterior midline approach. In comparison to the conventional C-Arm mobile fluoroscopy machine, the Surgical Approach Visualization and Navigation (SAVN) System was used to evaluate the effectiveness in reducing radiation.

Results: The pain intensity and Japanese Orthopedic Association Score were equally ameliorated in patients of two groups. However, compared to C-arm group, the SAVN significantly reduced the screening time from 26.8 + 12.4 to 17.1 + 9.2 s (36.2% radiation reduction, $P < 0.05$), which was mainly due to the significant reduction of radiation attempts (from 12.8 + 4.9 to 7.1 + 5.5 times, $P < 0.05$). For patients, the direct and scatter radiation dose dropped 30.4% ($P < 0.05$) in the surgical region and 47.6% ($P < 0.01$) in the non-surgical region by using the SAVN System. Additionally, the tumor diameter/skin incision ratio increased from 0.39 + 0.4 to 0.47 + 0.28 after SAVN usage. Meanwhile, the dosimeter showed that the radiation dose to the primary surgeon was also lower in the SAVN group (72.1% reduction, $P < 0.01$).

Conclusion: Comparing the conventional C-arm, the SAVN System based thoracic-spinal surgery significantly lowered radiation duration and dosage application towards both surgeons and patients.

© 2019 Elsevier Ltd. All rights reserved.

Introduction

The intraoperative fluoroscopy has been widely used in modern neuro-spinal surgery due to the overwhelming trend toward minimal-access surgery [1,2]. However, both patients and surgical personnel were under ionizing-radiation exposure during fluoroscopy usage, which can cause somatic effects (e.g. skin-related injuries and cataract) as well as stochastic effects (e.g. thyroid cancer and leukemia) [3]. For patients receiving fluoroscopy, these

risks are of particular concerns in those who are young, obese or requiring long, complex, or repeated procedures [4]. For all surgical personnel, they are not only affected by the acute exposure, but also by the protracted exposure. The International Commission on Radiological Protection (ICRP) recommends that the yearly maximum permissible dose is 50 mSv for the whole body, head, neck, trunk, eyes, bone marrow and gonads [5]. Multiple studies have indicated the increased risk for carcinogenesis for chronic doses above 50 mSv [6–9] while the dosimeter readings (outside lead gown) of surgeons averaged up to 0.22 mSv monthly [10]. As such, it is important for surgical personnel to understand the principles and risk of ionizing radiation and methods for minimizing exposure risk to themselves, patients, and the operating room team. Thus, the development and improvement of new interventional possibilities are still of great importance and interests.

* Corresponding author.

E-mail addresses: yjiang1@vt.edu (Y. Jiang), zhangdfgood@163.com (H.-R. Wang), xiaokaikai11@yeah.net (P.-F. Wang), poopo600@hotmail.com (S.-G. Xu).

¹ These authors contributed equally to this publication.

In the current study, we introduced a new imaging-guidance system named Surgical Approach Visualization and Navigation (SAVN) System. Among all fluoroscopy guided surgical procedures, we chose the surgical resection of thoracic spinal lesions since it requires multiple fluoroscopies during surgery. To evaluate radiation reduction difference between the SAVN system and conventional C-Arm mobile fluoroscopy machines, we undertook the measurement of both primary and scatter radiation doses that were delivered to both patients and primary surgeon during spine surgery.

Patients and methods

Patients

This study was performed in the Trauma Department of our hospital and a total of 60 patients were enrolled. All patients received reconstructed CT scan and MRI (Siemens TRIO; 3T) of the thoracic spine and were diagnosed with a small thoracic intra-spinal tumor (< 2 cm in diameter, including both intramedullary and extramedullary subdural tumors) located between T5 to T11 levels. Inclusion criteria were patients over 18-years-old for tumor resection. Exclusion criteria were the presence of any contraindication of surgery. An informed consent was obtained from all patients enrolled. Overall, a total of 20 patients met all criteria and were included in the current study. Randomization was carried out by block-randomization and allocation was concealed from the patient. Overall, 12 patients were enrolled into the control group, who were treated with the conventional C-Arm during surgery while the others were included in the test group, who received the SAVN during surgery. The age, gender, pain intensity and Japanese Orthopedic Association Score (JOAs) [11,12] of the patients were comparable between the two groups. The intensity of pain was assessed via a 10-point patient-reported numeric rating scale, which ranges from 0 (no pain) to 10 (worst possible pain).

Surgical treatment

Before surgery, an MRI imaging was used to identify the exact location of the tumor and its corresponding vertebrate. All patients were laid prone on the operation table and received the posterior midline approach under general anesthesia. The key surgery procedures were consisted of three steps, including laminectomy, microsurgical resection, and laminoplasty. The laminectomy was performed at the lesion level and extended if needed. The dura was opened in the midline and tacked up with 4.0 Nurolon (Ethicon, Inc., Somerville, New Jersey, USA) suture. A gross total tumor resection was performed using microsurgical techniques. Intra-operative spinal electrophysiological activity (including sensory and motor evoked potentials) were monitored in all cases. For the intramedullary tumor, either the posterior median sulcus approach or the posterolateral sulcus approach was picked for tumor resection. The principle for selecting the surgical approach is direct with the shortest distance to the tumor. The C-arm is intra-operatively used only to identify the correct vertebrae before the matching process. Localization of the lesion level was confirmed in both AP and lateral dimensions.

The Surgical Approach Visualization and Navigation (SAVN) System

The SAVN is a real-time image guidance system and does not require the preoperative acquisition of imaging data set or registration. Fig. 1 provides a demonstration of the SAVN system, which consists of a laser beam unit and a small computer unit. The laser beam unit was mounted onto the fluoroscopic tube of conventional C-Arm, while the computer unit was connected to the C-Arm monitor. The SAVN mounted C-arm configuration was used pre-operatively as standard. The fluoroscopic tube is located 50–60 cm above the patients and perpendicular towards the floor. After the computer is connected, a mouse shows up on the C-Arm screen and the user could move the mouse to select a target of interest in the image within a red circle range (Fig. 2). After the first click, the visible laser beam will be activated, which precisely

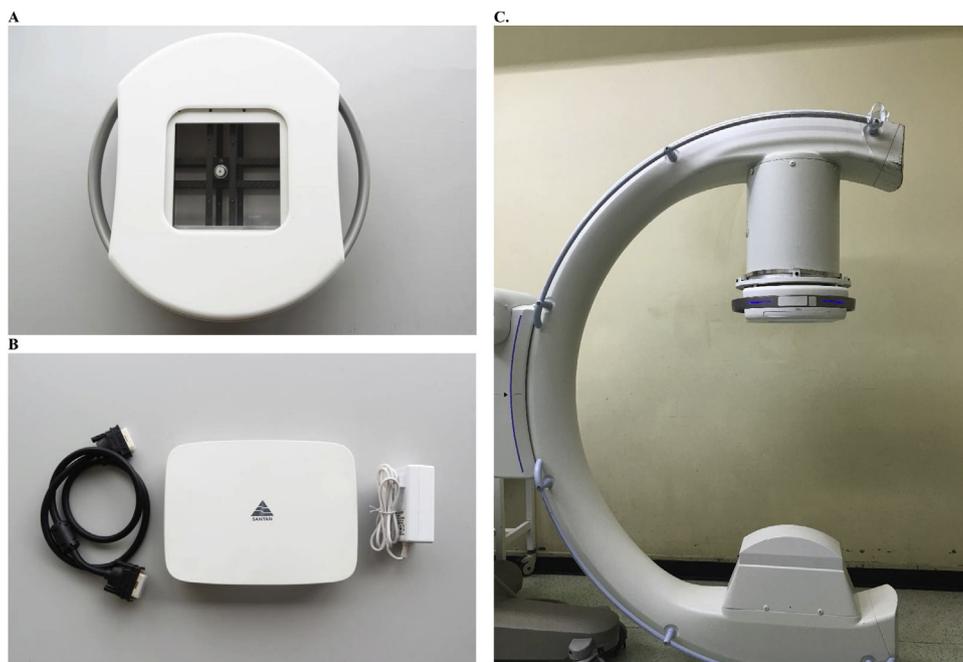


Fig. 1. A demonstration of the SAVN system, which consists of a laser beam unit (A) and a small computer unit (B). The laser beam unit was mounted onto the fluoroscopic tube of conventional C-Arm before usage (C).

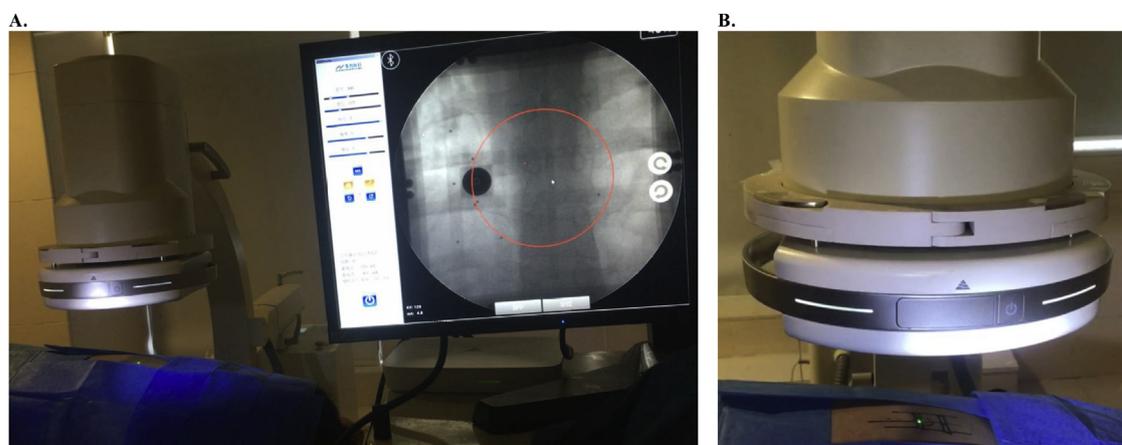


Fig. 2. A demonstration of the SAVN system usage. The SAVN was placed at the thoracic spine in posterior–anterior–view. The visible laser beam would target at exactly where the mouse clicked inside the red circle on the screen (A). The projection of a thoracic vertebral body on the skin is acquired according to the movement of the laser beam (B) (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article).

aligned with the mouse on the fluoroscopic image. Then, the visible laser beam follows each mouse click, which allows the surgeons to design optimum incision position and length.

Radiation time and dose

The OEC Brivo Plus C-Arm (General Electric Company, Boston, MA, USA) was used in the current study. The fluoroscopic tube was automatically adjusted by the C-Arm to determine its radiation dose, depending on the fluoroscopic area and depth. The primary and scatter radiation dose were recorded by using a thermoluminescent dosimeter attached to the patients' surgical regions and eye regions, respectively. For female patients, an extra dosimeter was placed close to the nipple of left breast tissue. For the primary surgeon, a thermoluminescent dosimeter was attached to the neck region. After the surgery, the total radiation dose, procedure time and a number of exposures were documented. Radiation time was automatically measured by the C-Arm in second while dose was measured in dose-area-product ($\text{cGy}\cdot\text{cm}^2$). The procedure time was recorded by an operating room nurse. The patients received multiple fluoroscopic screening by the same senior operator.

Data analysis and statistics

All data were analyzed by the SPSS version 17.0 (SPSS Inc., Chicago, IL). Differences between categorical variables were analyzed by either the *chi*-square test or Fisher's exact test, while those continuous variables were analyzed using the Student *t*-test.

Results

All patients received gross total thoracic-spinal tumor resection. No complication occurred. Before surgery, the mean Japanese Orthopedic Association Score (JOAs) in all patients was 8.2 ± 4.2 (range 0–17). Fourteen days after the surgery, the mean JOAs in all patients was 11.1 ± 3.4 . Additionally, there was a significant reduction of pain (from 5.5 ± 2.3 – 3.9 ± 2.5 , $P < 0.05$) after therapy. No significant difference was detected between the control group and the SAVN group ($P > 0.05$), indicating that two surgical therapy were equally effective.

Contrary to the similar results of the surgical therapy results between two groups, the SAVN group led in spine surgery in a clear reduction of both screening time and radiation dose in general (Table 1). Compared to the control group, the SAVN system

Table 1

A comparison of radiation reduction difference between the conventional C-arm fluoroscopy and SAVN system combined C-arm fluoroscopy.

	C-arm	SAVN
Total screening time (sec)	26.8 ± 12.4	$17.1 \pm 9.2^*$
Radiation attempts	12.8 ± 4.9	$7.1 \pm 5.5^*$
Radiation dose ($\text{cGy}\cdot\text{cm}^2$)		
Patients		
surgical region	2.93 ± 0.95	$2.04 \pm 0.77^*$
eye region	1.05 ± 0.48	$0.55 \pm 0.26^*$
breast region	0.79 ± 0.51	$0.52 \pm 0.36^*$
Caspar ratio	0.39 ± 0.4	$0.47 \pm 0.28^*$
Primary surgeon		
neck region	0.82 ± 0.82	$0.23 \pm 0.61^*$

significantly reduced the screening time from 26.8 ± 12.4 to 17.1 ± 9.2 s, which represented a 36.2% radiation reduction ($P < 0.05$). This result was mainly due to the significant reduction of radiation attempts ($P < 0.05$), which reduced from 12.8 ± 4.9 to 7.1 ± 5.5 times.

For patients, they were exposed to both direct (primary) and scattered (secondary) radiation. The thermoluminescent dosimeter showed that the direct radiation dose exposure to the surgical region were 2.93 ± 0.95 and 2.04 ± 0.77 $\text{cGy}\cdot\text{cm}^2$ in the control and SAVN group, respectively. On the other hand, the scattered radiation to the eye region was 1.05 ± 0.48 and 0.55 ± 0.26 $\text{cGy}\cdot\text{cm}^2$ in the control group and SAVN group, respectively. These data represented a 30.4% ($P < 0.05$) in the surgical region and 47.6% decrease ($P < 0.01$) in the non-surgical region by patients by using the SAVN System. For female patients, we also detected the direct radiation at the breast region, which were 0.79 ± 0.51 and 0.52 ± 0.36 $\text{cGy}\cdot\text{cm}^2$ in the control group and SAVN group ($P < 0.05$), respectively. Additionally, since the SAVN provided the accurate location of the tumor, the tumor diameter/skin incision ratio (also known as the Caspar ratio) of SAVN group patients (0.47 ± 0.28) was dramatically bigger than that of the control group (0.39 ± 0.4) ($P < 0.05$).

While the direct radiation from the C-arm was the main source of radiation exposure for patients, that to surgical personnel is from scattered radiation [13]. Moreover, The primary surgeon receives the greatest amount of radiation exposure among all surgical personnel [14]. Thus, we monitored the scattered radiation dose received by the primary surgeon in the neck area. The thermoluminescent dosimeter showed that the radiation dose

received by the neck region was 0.82 ± 0.82 cGy-cm² and 0.23 ± 0.61 cGy-cm² in the control group and SAVN group, respectively. This represented a 72.1% decrease of radiation received by the primary surgeons by using the SAVN System ($P < 0.05$).

Discussion

Intraoperative fluoroscopy acquires real-time moving images of skeletal structures, which provides surgical personnel with valuable information during minimal-access surgery. However, markedly increased use of intraoperative fluoroscopy exposes both surgical personnel and patients to non-trivial amounts of radiation. In the current study, we introduced a new imaging system named SAVN. Compare to the conventional C-arm, the SAVN system significantly lowered overall mean radiation exposure times as well as dosage for both patients and primary surgeon. In addition, the SAVN provides a guidance function, which significantly shortened the surgical incision.

Accumulated evidence has shown a tight association between increased risk of a myriad of morbidities and ionizing radiation among surgeon populations. For example, the previous study demonstrated a higher incidence of cancer among orthopedic surgeons in a hospital with poor radiation protection [15]. Additionally, female orthopedic surgeons had a higher prevalence of breast cancer than the general female population in the US due to radiation exposure [16]. Thus, the enthusiasm for reducing radiation exposure for surgical personnel, especially the primary surgeons, remains substantially high. In recent year, major improvement have been made to reduce ionizing radiation exposure for surgeons. Other than the introduction of protective shielding and ALARA principle practice, refined operative techniques [17], novel technology [14,15] and proper training program [18] have been introduced to surgical personnel. However, radiation exposure remains inevitable in most cases. Since the scattered radiation from the patient is the main source of radiation-exposure towards the surgeons during fluoroscopy [13], reducing scatter radiation could significantly lower the surgeons' radiation-exposure. In our current study, we detected the scatter radiation exposure to surgeons' neck region, as the thyroid in this area is a highly sensitive organ toward radiation [19]. We found the radiation-exposure was significantly reduced after the SAVN system usage, which is mainly due to reduced performance of fluoroscopy due to more accurately locating lesion regions.

For patients, the adverse effects of radiation exposure include both somatic effects and stochastic effects. The somatic effects are tightly associated with radiation dosage. The radiation-induced cataract is a typical example of the somatic effects, increased frequency of which has been found among radiation-exposed population [20]. On the other hand, the stochastic effects include various types of cancer, which, compared to the somatic effects, often has a longer latent period and less tight dose-response relationship. In the current study, we assessed the scatter radiation towards the eye of patients for observing the stochastic effects of radiation. The current dose thresholds for radiation-induced cataracts are 2 Gy for a single dose or 5 Gy for fractionated doses [20,21]. According to our data, the radiation dosage from the traditional C-arm is very close to that threshold, which increased risks of patients lens opacities. After the SAVN usage, we observed a statistically lowered radiation dosage towards the eye region. To the best of our belief, this is mainly due to the significantly reduced exposure numbers by using a laser to precisely positioning the spinous and vertebral body in the supine and prone position, respectively. Moreover, we also monitored the radiation exposure to female patients' breast tissue during surgery for observing the somatic effects of radiation. Breast is highly sensitive to radiation [19,22]. As an established human carcinogen [13], the ionizing

radiation has been well demonstrated to associate with an increased risk of breast cancer [23]. During thoracic intra-spinal tumor resection, the breast tissue of female patients were under direct radiation exposure from the C-arm, which may potentially cause damage or even cancer to the breast tissue. In the current study, the SAVN was shown to apparently lowered the radiation exposure towards the breast tissue of female patients. This phenomenon could potentially protect female patients from breast tissue damage and cancer.

The navigation feature of the SAVN allows the surgeons to pinpoint the tumor at the thoracic spine, which makes minimally invasive neuro-spinal surgery possible. During the laminectomy, disruption of the paraspinal musculature due to extensive surgical exposure cause endured years of pain and spinal deformity, which can compromise the subsequent surgical outcomes. Thus, Caspar [24] laid the conceptual foundation for minimally invasive spinal surgery by introducing the notion of a ratio between the surgical target and surgical exposure. Since exposure beyond the dimensions of the thoracic canal has little utility, current minimally invasive neuro-spinal surgery advocated a Caspar ratio (ratio of the surgical target to the surgical exposure) as close to 1 as possible [25]. In the current study, we found that although both group had good surgical outcomes, the SAVN group had a prominently bigger Caspar ratio than that of the control group. This result indicates that SAVN can precisely pinpoint the lesion in the thoracic spine, which allows surgeons to resect lesions using relatively smaller exposure. More tissues (e.g. posterior tension band and paraspinal musculature) are spared, which facilitates rapid recovery and preserves spinal stability. Since multiple studies had also introduced minimally invasive approaches for spinal lesion resection [26–28], we will focus on combining the SAVN with these approaches in future studies and tried to optimize the current spinal surgery as much as possible. In a future study, the radiation exposure to all surgical personnel will also be tested and surgery will be further investigated at various spine levels.

Conclusion

In conclusion, the fluoroscopy constitutes the vast majority of radiation exposure for both surgeons and patients. Comparing the conventional C-arm, the SAVN System based surgery significantly lowered radiation duration and dosage application towards both surgeons and patients.

Conflict of interest

The authors have no conflict of interests to documents concerning the materials used in this study or the study findings.

Funding

There is no funding source supporting the study in the current manuscript.

Acknowledgements

I want to express my sincere acknowledgment to all the participants and those helped in completing the current study.

References

- [1] Li Y, Hsu R, Cheng C, Huang T. Minimally invasive vertebroplasty managed by a two C-arm fluoroscopic technique. *Minim Invasive Ther Allied Technol* 2007;16:350–4.
- [2] Zwingmann J, Konrad G, Kotter E, Südkamp N, Oberst M. Computer-navigated iliosacral screw insertion reduces malposition rate and radiation exposure. *Clin Orthop Relat Res* 2009;467:1833–8.

- [3] Blakely E. Biological effects of cosmic radiation: deterministic and stochastic. *Health Phys* 2000;79:495–506.
- [4] Ector J, Dragusin O, Adriaenssens B, Huybrechts W, Willems R, Ector H, et al. Obesity is a major determinant of radiation dose in patients undergoing pulmonary vein isolation for atrial fibrillation. *J Am Coll Cardiol* 2007;50:234–42.
- [5] Green P. The response of the International Commission on Radiological Protection to calls for a reduction in the dose limits for radiation workers and members of the public. *Int J Radiat Biol Relat Stud Phys Chem Med* 1988;53:679–82.
- [6] Giordano B, Baumhauer J, Morgan T, Rehtine G. Cervical spine imaging using standard C-arm fluoroscopy: patient and surgeon exposure to ionizing radiation. *Spine (Phila Pa 1976)* 2008;33:1970–6.
- [7] Brenner D, Doll R, Goodhead D, Hall E, Land C, Little J, et al. Cancer risks attributable to low doses of ionizing radiation: assessing what we really know. *Proc Natl Acad Sci U S A*. 2003;100:13761–6.
- [8] Mehlman C, DiPasquale T. Radiation exposure to the orthopaedic surgical team during fluoroscopy: "how far away is far enough?". *J Orthop Trauma* 1997;11:392–8.
- [9] Rampersaud Y, Foley K, Shen A, Williams S, Solomito M. Radiation exposure to the spine surgeon during fluoroscopically assisted pedicle screw insertion. *Spine (Phila Pa 1986)* 1976;2000(25):2637–45.
- [10] Tasbas B, Yagmurlu M, Bayrakci K, Ucaner A, Heybeli M. Which one is at risk in intraoperative fluoroscopy? Assistant surgeon or orthopaedic surgeon?. *Arch Orthop Trauma Surg* 2003;123:242–4.
- [11] Kato S, Oshima Y, Oka H, Chikuda H, Takeshita Y, Miyoshi K, et al. Comparison of the Japanese Orthopaedic Association (JOA) score and modified JOA (mJOA) score for the assessment of cervical myelopathy: a multicenter observational study. *PLoS One* 2015;10:e0123022.
- [12] Yonenobu K, Abumi K, Nagata K, Taketomi E, Ueyama K. Interobserver and intraobserver reliability of the Japanese orthopaedic association scoring system for evaluation of cervical compression myelopathy. *Spine (Phila Pa 1976)* 2001;(26):1890–4.
- [13] Hak D. Radiation exposure during intramedullary nailing. *Injury* 2017; (Suppl. 1):S26–9.
- [14] Baumgartner R, Libuit K, Ren D, Bakr O, Singh N, Kandemir U, et al. Reduction of radiation exposure from C-Arm fluoroscopy during orthopaedic trauma operations with introduction of real-time dosimetry. *J Orthop Trauma* 2016;30:e53–8.
- [15] Giordano B, Ryder S, Baumhauer J, DiGiovanni B. Exposure to direct and scatter radiation with use of mini-c-arm fluoroscopy. *J Bone Joint Surg Am* 2007;89:948–52.
- [16] Chou L, Lerner L, Harris A, Brandon A, Girod S, Butler L. Cancer prevalence among a cross-sectional survey of female orthopedic, urology, and plastic surgeons in the United States. *Womens Health Issues* 2015;25:476–81.
- [17] Mariscalco M, Yamashita T, Steinmetz M, Krishnaney A, Lieberman I, Mroz T. Radiation exposure to the surgeon during open lumbar microdiscectomy and minimally invasive microdiscectomy: a prospective, controlled trial. *Spine (Phila Pa 1976)* 2011;(36):255–60.
- [18] Gendelberg D, Hennrikus W, Slough J, Armstrong D, King S. A radiation safety training program results in reduced radiation exposure for orthopaedic residents using the mini C-arm. *Clin Orthop Relat Res* 2016;474:580–4.
- [19] Biswas D, Bible J, Bohan M, Simpson A, Whang P, Grauer J. Radiation exposure from musculoskeletal computerized tomographic scans. *J Bone Joint Surg Am* 2009;91:1882–9.
- [20] Jacob S, Michel M, Spaulding C, Boveda S, Bar O, Brézin A, et al. Occupational cataracts and lens opacities in interventional cardiology (O'CLOC study): are X-Rays involved? Radiation-induced cataracts and lens opacities. *BMC Public Health* 2010;10:537.
- [21] Ainsbury E, Bouffler S, Dörr W, Graw J, Muirhead C, Edwards A, et al. Radiation cataractogenesis: a review of recent studies. *Radiat Res* 2009;172:1–9.
- [22] Yoshinaga S, Mabuchi K, Sigurdson A, Doody M, Ron E. Cancer risks among radiologists and radiologic technologists: review of epidemiologic studies. *Radiology* 2004;233:313–21.
- [23] Ma H, Hill C, Bernstein L, Ursin G. Low-dose medical radiation exposure and breast cancer risk in women under age 50 years overall and by estrogen and progesterone receptor status: results from a case-control and a case-case comparison. *Breast Cancer Res Treat* 2008;109:77–90.
- [24] Caspar W. A new surgical procedure for lumbar disc herniation causing less tissue damage through a microsurgical approach. Berlin, Germany: Springer-Verlag; 1977.
- [25] Tumiälán L, Theodore N, Narayanan M, Marciano F, Nakaji P. Anatomic basis for minimally invasive resection of intradural extramedullary lesions in thoracic spine. *World Neurosurg* 2018;109:e770–7.
- [26] Raygor K, Than K, Chou D, Mummaneni P. Comparison of minimally invasive transspinous and open approaches for thoracolumbar intradural-extramedullary spinal tumors. *Neurosurg Focus* 2015;39:E12.
- [27] Wong A, Lall R, Dahdaleh N, Lawton C, Smith Z, Wong R, et al. Comparison of open and minimally invasive surgery for intradural-extramedullary spine tumors. *Neurosurg Focus* 2015;39:E11.
- [28] Lu D, Chou D, Mummaneni P. A comparison of mini-open and open approaches for resection of thoracolumbar intradural spinal tumors. *J Neurosurg Spine* 2011;14:758–64.