



A protective method to reduce radiation exposure to the surgeon during endoscopic lumbar spine surgery

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Background: Endoscopic lumbar spine surgery is a minimally invasive technique that requires intraoperative fluoroscopic imaging. Fluoroscopy is a source of ionizing radiation, and exposure of the surgeon to this radiation has a risk for radiation-induced morbidities. To reduce this radiation exposure, we developed a protective method that can be used during endoscopic lumbar spine surgery. The purpose of the study was to determine the effectiveness of this method.

Methods: A prospective interventional study was performed, in which the primary outcome was radiation exposure to the surgeon [Sievert (Sv)] per case. This was measured using a radiation badge at the levels of the neck, chest, and abdomen on the surface of a protector for the surgeon in 18 endoscopic lumbar spine surgeries, including 9 each with the radiation protection method and the conventional method. Data were also collected for age, gender, body mass index, operative side, and total fluoroscopy time. Primary outcomes were compared in cases that used the radiation protection method and the conventional method.

Results: The mean radiation exposures to the surgeon at the neck, chest, and abdomen were 1.0, 0.8 and 0.7 μ Sv, respectively, using the radiation protection method, and 3.2, 10.8, and 10.2 μ Sv, respectively, using the conventional method. The differences in exposure at all three points were significant ($P=0.013$, $P<0.001$, $P<0.001$, respectively).

Conclusions: These results show the effectiveness of the radiation protection method developed to reduce exposure of the surgeon to radiation during endoscopic lumbar spine surgery.

Keywords: Endoscopic spine surgery; radiation exposure; radiation protection method

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Introduction

Endoscopic lumbar spine surgery is a minimally invasive surgery (MIS) that is less invasive than conventional open lumbar spine surgery (1,2). This surgery has emerged through refinement of surgical techniques, detailed understanding of local anatomy, and development of surgical instruments. However, MIS uses intraoperative fluoroscopy, which causes higher ionizing radiation exposure

to the surgeon during endoscopic lumbar spine surgery compared to open surgery (3). This exposure is much less than that in occupational guidelines of the National Council on Radiation Protection & Measurements, but the surgeon must be protected against radiation as much as possible, based on the linear no-threshold risk model (4). In this model, the stochastic effect of radiation exposure, which is different from the deterministic effect, has no threshold and

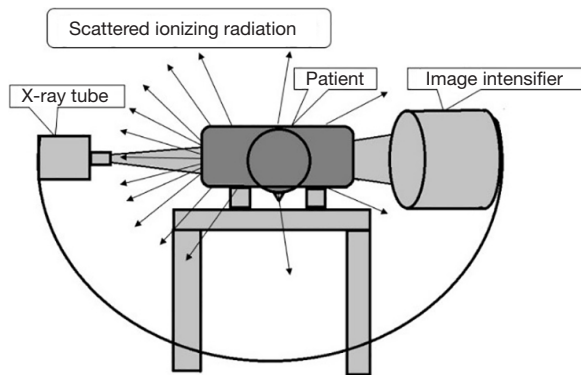


Figure 1 Schematic image of the procedure.



Figure 2 A special frame is covered with a lead radiation protector.

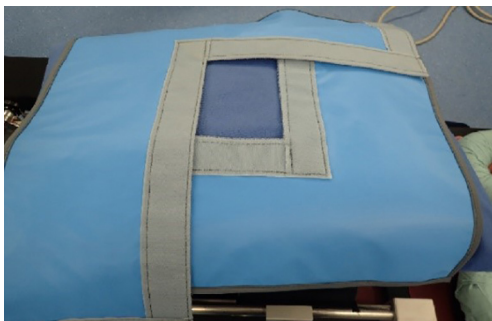


Figure 3 The patient is covered with a specially designed lead radiation protector. The operator performs the procedure through a hole in the protector. The width of the hole is changeable.

the risk of death increases with radiation dosage.

To reduce the risk of radiation-induced morbidities among surgeons, we developed a new protective method to reduce radiation exposure during endoscopic lumbar spine surgery. The hypothesis in this study is that radiation

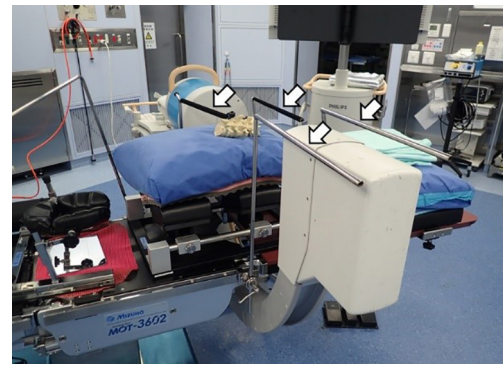


Figure 4 Arrows show the frame in the new radiation protection method.

exposure to the surgeon using the new method will be much less than that using the conventional method.

Methods

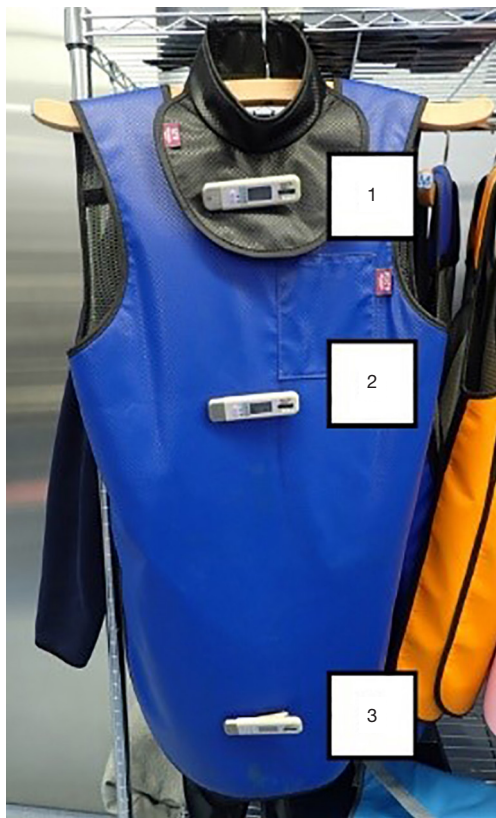
In using fluoroscopy during spine surgery, surgeons and other persons in the operating room are exposed to scattered ionizing radiation from the patient's body (*Figure 1*). The core concept of the protective method used in this study is to separate two spaces using a lead protector: one space contains the patient, operation table, X-ray tube and image intensifier, and the other space is the rest of the operation room. This separation allows the operator to perform the operative procedure through a hole in the lead radiation protector with little radiation exposure. Less scattered X-rays may reach the surgeon by covering the patient with a specially designed lead radiation protector and setting up a special frame to shield the X-ray tube and image intensifier with a lead radiation protector between the fluoroscope and the operating table (*Figures 2,3*). These lead radiation protectors were not anchored to the patients, but just placed on the patients. The frame was made of iron and set up not to interfere directly with the beam from the X-ray tube (*Figure 4*). This frame is patent pending (Application No./Patent No.15843463.9-1666 PCT/JP2015/004772). We named the radiation protection method, which includes the frame, as the Separation between Two Spaces (STS) method. The STS method is non-sterile; however, since the entire STS is completely covered with surgical sterile sheets, the surgical field is guaranteed to be aseptic.

We performed a prospective interventional study to determine the effectiveness of the new radiation protection method during endoscopic lumbar spine surgery. The primary

Table 1 Demographic data using the new and conventional methods

Characteristic	STS (n=9)	Conventional (n=9)	P value
Age (years)	64.3±17.6	68.4±15.3	0.625
Gender: male	5	5	1.000
Body mass index (kg/m ²)	23.1±2.1	24.2±2.3	0.321
Operative time (min)	35.4±13.0	55.7±28.6	0.086
Total fluoroscopic time (s)	35.4±21.8	30.9±14.0	0.626

STS, Separation between the Two Spaces.

**Figure 5** Positions of radiation measurement badges during endoscopic lumbar spine surgery: 1, neck; 2, chest; 3, abdomen.

outcome was radiation exposure to the surgeon [Sievert (Sv)] per case, while the intervention was use of the new method or the conventional method during surgery. After approval by the Institutional Review Board at our institution (Number of the Ethic Approval 20140213-1), 18 adult patients scheduled for single or two level endoscopic lumbar spine surgery, including microendoscopic discectomy (MED) and

microendoscopic laminectomy (MEL), were enrolled in the study. This was a prospective study and all surgeries were performed by one doctor between March 2014 and August 2015. The inclusion criterion was patients aged >18. The exclusion criterion was a history of previous surgery at the same level and side. Of the 18 patients, 9 each underwent surgery with the new method and the conventional method randomly at the discretion of the doctor.

Demographic data for patient age, gender, and body mass index (BMI) were collected, and the surgical time and total fluoroscopy time in each surgery were recorded. The patients treated with the new method were 5 males and 4 females of average age 64.3±17.6 years, and those treated with the conventional method were five males and four females of average age 68.4±15.3 years. The average BMIs in STS group was 23.1±2.1 kg/m² and those in conventional group was 24.2±2.3 kg/m², the operative times were 35.4±13.0 and 55.7±28.6 min, and the total fluoroscopy times were 35.4±21.8 and 30.9±14.0 s, respectively. The small differences in background between the two groups are unlikely to influence the radiation exposure results (Table 1). The surgeon always stood at the X-ray tube side but not at the image intensifier side in all 18 cases.

Exposure of the surgeon to radiation was measured using three radiation badges (MYDOSE mini x, Hitachi, Japan) placed outside the lead apron and thyroid shield of the surgeon (Figure 5) at the levels of the neck, chest, and abdomen. These badges displayed radiation exposure instantly and the value was recorded when the surgery was completed.

MED and MEL were typically performed as described previously (5,6). The patient was placed on a radiolucent operating table. The fluoroscope (BV Endura, Philips, The Netherlands), which is a single plane image intensifier, was used to confirm the surgical level and site in the lateral view during surgery. It was positioned in advance by a radiation technologist and was not moved during surgery. X-rays were beamed in the lateral direction of the patient from the side where the surgeon stood to the opposite side.

An independent statistician performed statistical analysis using SPSS (SPSS, Inc.). An unpaired Student t-test was used to compare differences between the two groups for demographic data, except for gender and surgical side, which were evaluated by Fisher exact test. A significant difference was accepted at P<0.05.

Results

Radiation exposures to the surgeon with STS and

Table 2 Radiation exposure (μSv) using the new and conventional methods

Case No.	Protection method	Disease	Level	Surgical procedure	Total fluoroscopy time (s)	Neck (H_a)	Chest (H_b)	Abdomen (H_c)	Effective dose (H_{EE})
1	New	LDH	L4-5	MED	18	1	3	3	2.84
2	New	LDH	L5-S1	MED	30	0	0	0	0
3	New	LSS	L5-S1	MEL	31	0	1	1	0.92
4	New	LSS	L5-S1	MEL	56	0	0	0	0
5	New	LSS	L5-S1	MEL	64	4	2	1	1.77
6	New	LDH	L5-S1	MED	7	1	0	0	0.11
7	New	LSS	L4-5	MEL	13	0	0	0	0
8	New	LDH	L4-5	MED	28	2	1	0	0.66
9	New	LDH	L3-4	MED	72	1	0	1	0.56
10	Conventional	LDH	L4-5, L5-S1	MED	8	2	8	1	4.37
11	Conventional	LDH	L4-5	MED	23	1	4	7	5.2
12	Conventional	LSS	L2-3, L4-5	MEL	40	2	8	8	7.52
13	Conventional	LSS	L4-5, L5-S1	MEL	45	2	8	7	7.07
14	Conventional	LDH	L4-5	MED	20	5	14	15	13.76
15	Conventional	LSS	L3-L4	MEL	24	3	10	10	9.44
16	Conventional	LDH	L4-L5	MED	26	7	23	22	21.27
17	Conventional	LSS	L3-L4, L4-5	MEL	35	2	8	12	9.44
18	Conventional	LSS	L3-L4, L4-5	MEL	57	5	14	10	11.48

H_{EE} is calculated by the formula, $H_{EE} = 0.08H_a + 0.44H_b + 0.45H_c + 0.03H_m$. H_m is maximum value among H_a , H_b , and H_c . LDH, lumbar disc herniation; LSS, lumbar spinal stenosis; MED, microendoscopic discectomy; MEL, microendoscopic laminectomy.

Table 3 The average value of radiation exposure (μSv) and H_{EE} (μSv) with the new and conventional methods

Characteristic	STS	Conventional	P value
Neck	1.0 \pm 1.2	3.2 \pm 1.8	0.013
Chest	0.8 \pm 1.0	10.8 \pm 5.2	<0.001
Abdomen	0.7 \pm 0.9	10.2 \pm 5.5	<0.001
H_{EE}	0.8 \pm 0.9	10.0 \pm 4.9	<0.001

STS, Separation between the Two Spaces; H_{EE} , effective dose.

conventional methods are shown in *Table 2*. The average radiation exposures to the neck, chest, and abdomen were 1.0, 0.8 and 0.7 μSv , respectively, with STS, and 3.2, 10.8, and 10.2 μSv , respectively, with the conventional method. The effective doses (H_{EE}) calculated by the formula, $H_{EE} = 0.08H_a + 0.44H_b + 0.45H_c + 0.03H_m$ (H_a : neck, H_b : chest, H_c : abdominal, H_m : maximum value among the

former 3 values) with STS and conventional methods were 0.8 and 10.0 μSv , respectively (*Table 3*) (7). The differences in radiation exposure at the neck, chest, and abdomen, and that in H_{EE} between the two groups were all significant ($P=0.013$, $P<0.001$, $P<0.001$, $P<0.001$, respectively).

Exposure of the surgeon to radiation using the conventional method was far lower than the limit of 20,000 μSv in the 1990 International Commission on Radiological Protection (ICRP) guidelines (7). This value is equivalent to 2,000 endoscopic surgeries using the conventional method in 1 year. However, STS reduced the exposure effective dose equivalent to approximately 8% of that with the conventional method.

Discussion

Minimally invasive (MI) endoscopic spine surgery was established in the 1990's and has developed through

improvements in technology and procedures. This surgery has advantages of reductions in surgical time, bleeding, postoperative pain medication, hospital stay, and return-to-work time, and has good outcomes compared to conventional open spine surgery (6,8-12). However, exposure of the surgeon to radiation during MI endoscopic spine surgery is greater than that during open surgery since ionizing radiation is generally used during MI endoscopic spine surgery to localize the surgical site. In MI lumbar microdiscectomy, Mariscalco *et al.* found that the surgeon is more exposed to radiation than in open microdiscectomy (13).

Ionizing radiation causes hazards to human health, including radiation-induced complications such as cataract, skin erythema, thyroid cancer, and other cancers (4). In procedures that use X-rays during surgery, surgeons should recognize the risk and try to reduce exposure of radiation for all operating room staff. A lead apron and lead collar can reduce exposure to radiation by 96.9% and 94.2%, respectively, compared to their non-use (14), and facing 90 degrees from the operating table during use of X-rays reduces radiation exposure to the surgeon's eyes (3). A surgeon positioned on the X-ray tube side is exposed to more scatter radiation from the patient, compared to the image intensifier side (3) (*Figure 1*). Therefore, the surgeon should not stand on the X-ray tube side, if possible. However, the positioning of the surgeon in this study was on the tube side, and this may have caused greater radiation exposure. The X-ray tube should be placed as close to the patient as possible because this reduces scatter radiation (3). One-shot radiation causes less exposure than continuous radiation (3), and surgeons should be aware of the location of the fluoroscope.

STS reduced the radiation exposure to 8% of the conventional exposure in this study. This method shields scattering radiation reflected on or passing through or near the patient so that the surgeon and all persons in the operation room have reduced radiation exposure. This is important because the surgeon is not entirely shielded by a lead apron or lead collar. Moreover, STS is available for full endoscopic lumbar discectomy (FELD) or percutaneous pedicle screw fixation (PPSF) because of the unique design.

The lead radiation protector in STS should not be placed in the X-ray field during surgery since this might increase X-ray beams due to the fluoroscopy automatic exposure control mode, which can then increase the scattered ionizing radiation. The limitations of this study are the small number of cases and selection bias due to non-random design. A further study in more cases and with

randomized controls is required to validate the results. The primary surgeon, Hirohiko Inanami has a patent for this system. However, possession of patents has no influence on the scientific nature of this study.

In this study, radiation exposure at the hand was not measured. Funao *et al.* measured the radiation dose to the unshielded finger, thyroid, chest, and genitals in minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF), and found that the finger was significantly more exposed than the other body regions (15). Although STS reduces exposure of scattered ionizing radiation, the finger might be exposed to direct ionizing radiation. Hence, care should be taken to avoid direct radiation exposure of the surgeon's finger.

We did not measure the radiation exposure of the patients. However, scattered X-rays reflected on the lead shield should be unlikely to increase patient exposure, because X-ray shielding by lead is mainly done by converting that energy into thermal energy.

In conclusion, STS developed to reduce exposure of the surgeon to ionizing radiation during MI endoscopic lumbar spine surgery was significantly more effective than the conventional approach. The protective method reduced the effective dose equivalent to approximately 8% of that with the conventional method.

Acknowledgments

None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Institutional Review Board approval (No. 20140213-1) and necessary patient consents were obtained for this study.

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