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A novel removable shield attached to C-arm units against scattered X-rays from a patient's side

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## **Abstract**

We invented a drape-like shield against scattered X-rays that is safe to come into contact with medical equipment or people during fluoroscopically guided procedures. The shield can be easily removed by one hand from a C-arm unit. We evaluated the use of the novel removable shield under the endoscopic retrograde cholangiopancreatography (ERCP) procedure. We measured the dose rate of scattered X-rays around endoscopists with and without this removable shield, and surveyed the occupational doses to the ERCP staff. We also examined the endurance of the shield. The removable shield reduced the dose rate of scattered X-rays to one-tenth and reduced the monthly dose to an endoscopist by at least two-fifths. For 2.5 years, there was no damage to the shield and no loosening of the seam. The bonding of the hook-and-loop fasteners did not weaken, although the powerful double-sided tapes for plastic did weaken. The removable shield can reduce radiation exposure to the ERCP staff, and may contribute to reducing the exposure to the lens of the eyes of operators. It would also be possible to expand its use to other fluoroscopically guided procedures besides ERCP because it is a light, simple, and useful device.

**Keywords:** endoscopic retrograde cholangiopancreatography, interventional radiology, lens, radiation protection, shield

## **Key points**

- We invented a shield removable by 1 hand from C-arm units.
- The removable shield reduces the dose rate of X-rays to one-tenth.
- The removable shield reduces the exposure of the operator to two-fifths.
- The removable shield is endurable for several years.
- The drape-like removable shield is light, simple, and useful.

## **Abbreviations**

ERCP = endoscopic retrograde cholangiopancreatography

ICRP = International Commission on Radiological Protection

ICRU = International Commission on Radiation Units and Measurements

IR = interventional radiology

## **Introduction**

Abdominal interventional radiology (IR) techniques involve using a wider radiation field and being closer to the scatter regions, compared to interventional cardiology techniques. The operators are consequently exposed to a high level of scattered X-rays from a patient's side [1, 2]. Protective screens suspended from the ceiling or attached to the unit generally provide radiation protection during these procedures. However, heavy protective screens must be articulated with large furniture [3, 4]. The protective screens accordingly often interfere with the angulation of a C-arm unit.

C-arm units with a large field for the abdominal IR are often used for endoscopic interventional procedures and for IR because endoscopists verify from many directions the digestive tract, biliopancreatic duct, and the placement of catheters or the position of guide wires [4, 5, 6]. If board-like shields are positioned close to a patient's side, protective screens such as lead-glass shields [4, 5, 7, 8] would easily strike the detector of a C-arm unit and an endoscope. This protective measure consequently presents difficulties in performing procedures such as endoscopic retrograde cholangiopancreatography (ERCP).

Therefore, we invented a drape-like shield against scattered X-rays that is safe to come into contact with medical equipment or patients during fluoroscopically guided procedures. The shield can be easily removed by one hand from the C-arm unit. In this study, we evaluated the capability of our removable shield when used for the ERCP procedure. We report the results and discuss the effectiveness and usefulness of our removable shield.

## **Materials and methods**

### Structures and materials of the removable shield

The removable shield consists of rectangular drapes with the dimensions of  $58 \times 42 \times 0.3$  cm that can cover a patient's side from which the scattered X-rays arise (Fig. 1). The drape (RadPad; Worldwide Innovations and Technologies, Overland Park, KS) was composed of tin and bismuth to reduce the weight of the drape, and its nominal lead equivalent thickness ranged from 0.20 mm to 0.25 mm [9, 10]. The removable shield

was produced by laminating 2 drapes together, resulting in a shield of approximately 0.50 mm lead equivalent thickness. This removable shield weighs 1.4 kg.

To attach the removable shield to a C-arm unit, a hook-and-loop fastener was sewn at the top of the drapes (Fig. 1). The other fastener was attached to the top of the detector of a C-arm unit by powerful double-sided tapes for plastic. The hook-and-loop fasteners (Wide Fastener Tape White; CAN DO, Shinjuku, Tokyo, Japan) were 10-cm square nylon sheets. Figs. 2a and 2b show how the removable shield is attached to the C-arm unit. A lead under-curtain [11], which had a lead equivalent thickness of 0.35 mm, was placed by the vendor. We also applied a bismuth arm tray and a lead side-shield [3, 10], which had a lead equivalent thickness of 0.25 mm and 0.35 mm, respectively. The capability evaluation of the removable shield was performed by a C-arm unit with an under-couch X-ray tube (Infinix Celeve VC; TOSHIBA Medical Systems, Ohtawara, Tochigi, Japan).

## Experimental study

We measured the dose rate of scattered X-rays around endoscopists with and without the removable shield (Fig. 3). As defined by Report 51 of the International Commission on Radiation Units and Measurements (ICRU), the dose rate of the scattered X-rays is presented by the ambient dose equivalent in the ICRU sphere at a depth of 10 mm [12]. The water phantom used to simulate a patient was set at a height of 90 cm. This elliptic cylindrical phantom (i.e. X-ray water phantom for chest and abdomen) (Iken Engineering, Sumida, Tokyo, Japan) was standardized by the Japanese Industrial Standards Committee (JIS Z4915-1974) with a major axis of 30 cm, a minor axis of 20 cm, and a length of 45 cm. A standard dosimetry laboratory calibrated the survey meter (Ionization Chamber Survey Meter ICS-321; Hitachi Aloka Medical, Mitaka, Tokyo, Japan). The sensitivity was set at 1.04 for the energy response test. The primary X-ray was generated at 80 kVp, 2.0 mA, and continuous radiation, and filtered with a tantalum equivalent thickness of 0.06 mm. The radiation field was the square of 29.8 cm. The detector of the C-arm unit was set at 2 distances from the table: at 30 cm and at 40 cm.

## Clinical study

We surveyed the monthly occupational doses to the ERCP staff with and without the removable shield. We used the monthly data of individual monitoring. Their monthly occupational doses are presented with the personal dose equivalent in the ICRU tissue at a depth of 0.07 mm and 10 mm, as defined in the ICRU Report 51 [12]. The ERCP staff wore a dosimeter (Glass Badge; Chiyoda Technol, Chiyoda, Tokyo, Japan) at the collar level above the protective apron and at the body level beneath the protective apron. A lead side-shield was not used in this clinical study. Excepting 2 gastroenterologists who engaged in ERCP and vascular IR, the study participants were 1 endoscopist and 3 assistant nurses who engaged in only ERCP. The assistant nurses stayed at approximately 50 cm behind the endoscopist [4].

We also examined the endurance of the removable shield. Beginning on May 1, 2011, we daily checked the damage to the shield, the looseness of the seam, the bond power of hook-and-loop fasteners, and the durability of the double-sided tape for plastic. We compared the durability of 2 types of powerful double-sided tape for plastic: (1) Nicetack NW-UP15SF tape (Nichiban, Bunkyo, Tokyo, Japan) with a tensile shear strength of 1.74 N per 100 mm<sup>2</sup> and (2) Scotch KPP-19 tape (Sumitomo 3M, Setagaya, Tokyo, Japan) with a tensile shear strength of 2.71 N per 100 mm<sup>2</sup>.

## Results

### Experimental study

Figure 4 shows the dose rate of the scattered X-rays around the endoscopists with and without the removable shield. When the dose rate was measured at a height greater than 120 cm, the removable shield reduced the dose rate of the scattered X-rays to one-tenth. When the dose rate was measured at the height of 100 cm, the removable shield could not sufficiently reduce the dose rate of the scattered X-rays. However, by mounting a lead side-shield, the dose rate decreased to one-tenth. There were significant differences in the distribution of dose rates with and without the removable shield ( $p < 0.01$ ), although no significant differences were detected with the addition of a lead side-shield ( $p > 0.05$ ).

### Clinical study

Figure 5 shows the monthly occupational doses to the ERCP staff with and without the removable shield. By using the removable shield, the dose to an endoscopist significantly decreased to at least two-fifths ( $p < 0.05$ ). The dose to the assistant nurses did not decrease significantly ( $p > 0.05$ ). However, there was a downward tendency in the doses to which they were exposed. The staff engaged in 141 procedures without the removable shield and 154 procedures with the removable shield. These procedures were all therapeutic procedures such as biopsy, sphincterotomy, drainage, stone extraction, and stent placement.

As of October 31, 2013 (i.e. after 2.5 years), the removable shield had been used for 548 therapeutic procedures. There was no damage to the shield and no loosening of the seam. The bond power of the hook-and-loop fasteners also had not weakened. Both types of powerful double-sided tapes for plastic had come off the C-arm unit when the removable shield was detached from C-arm units. The tape with the tensile shear strength of 1.74 N per 100 mm<sup>2</sup> was peeling off on March 30, 2012 (Fig. 6 a)—this indicated that the tape withstood tearing 135 times for 11 months. The tape with the tensile shear strength of 2.71 N per 100 mm<sup>2</sup> was peeling off on December 29, 2012 (Fig. 6 b)—this indicated that the tape withstood tearing 240 times for 20 months.

## **Discussion**

The protective screens that were previously invented for ERCP decrease the dose rate of scattered X-rays to one-tenth [7, 8, 13, 14]. The removable shield that we invented in this study had the same effect (Fig. 4). At the height of 100 cm, the gap between the removable shield and a lead under-curtain sometimes allowed scattered X-rays from the collimator, the table, and the phantom (Fig. 3 a); however, the gap could be covered with a lead side-shield (Fig. 3 b and 4). We confirmed that the monthly occupational doses to an endoscopist decreased with the use of the removable shield, although the dose reduction to assistant nurses could not be sufficiently confirmed (Fig. 5).

In this clinical study, measurements with and without the removable shield were not performed under the same conditions, and the number of study participants was insufficient. To generalize these results in a clinical study, it would be necessary to increase the number of study participants and evaluate occupational doses and

exposure parameters such as entrance surface doses [2].

Figures 4 and 5 b demonstrate that the removable shield has a sufficient shield effect of reducing the exposure to operator's upper body. The current international guidelines in ERCP have pointed out that radiation exposure of the upper body may be significant [4, 5]. The International Commission on Radiological Protection (ICRP) recently recommended an equivalent dose limit of 20 mSv per year to the lens of the eye, averaged over defined periods of 5 years [15]. For ERCP operators, the annual personal dose equivalent around the collar (including the lens of the eye) has almost exceeded this 20 mSv limit, according to papers to date [2, 13, 16, 17].

On the basis of the dose exposure in this study, an endoscopist without the removable shield also received an excessive dose during 12 months. (Fig. 5 b). However, by using the removable shield, the annual personal dose equivalent at the collar level of an endoscopist could be reduced to 20 mSv or less (Fig. 5 b) because the removable shield can reduce the dose rate of scattered X-rays to one-tenth at a height of approximately 160 cm (Fig. 4). Therefore, the removable shield can contribute to reducing the exposure to the lens of operator's eyes.

The results of the clinical study suggest that the removable shield and its components should endure for several years, except for the powerful double-sided tapes that adhere the hook-and-loop fasteners onto the C-arm unit. The removable shield did not fall off during procedures, although the tapes were coming off the C-arm unit owing to tearing during the removal of the shield. In clinical use, it may be necessary to check the double-sided tapes annually. We also recommend using double-sided tape with a tensile shear strength greater than 1.74 N per 100 mm<sup>2</sup> because the tape with a tensile shear strength of 1.74 N per 100 mm<sup>2</sup> did not last past 1 year in this study.

Figures 1 and 2 clearly show that the removable shield is simpler and lighter to use, compared to existing protective screens [4, 5, 7, 8]. For image intensification fluoroscopy units with a built-in image detector or X-ray tube beneath the unit's table, add-on protective shields also exist that lessen the inconvenience and large furniture of protective screens [13, 14]. However, for C-arm units only, our removable shield is a new technical development. Furthermore, compared to these improved protective devices [13, 14], our removable shield has a compact shape, is light, and can be detached by one hand. Therefore, we believe that the removable shield is a very functional protective device.

The occupational exposure of scattered X-rays to endoscopists during the ERCP procedure is high and occurs chiefly at the upper body [16, 17]. Other researchers have recommended that the C-arm unit of an under-couch X-ray tube should be used in

ERCP for improving therapeutic procedures and reducing the exposure of the upper body [2, 4, 6]. We predict that the use of C-arm units in ERCP will increase. It appears that usable protective devices, regardless of the IR technique, are henceforth needed. For fluoroscopically-guided procedures such as endoscopic interventional procedures and nasoenteral tube insertion, the removable shield would be an effective and useful protective measure against scattered X-rays from a patient's side.

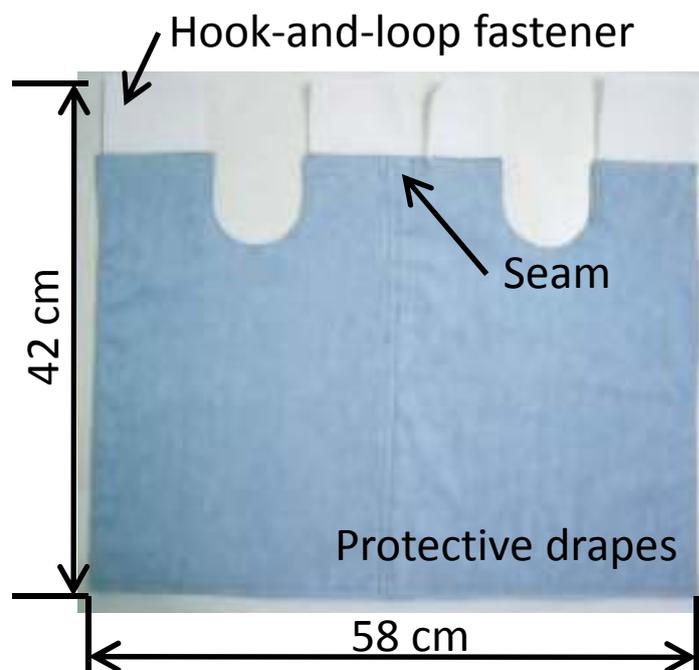
### **Conflict of interest**

The authors have no conflicts of interest to report.

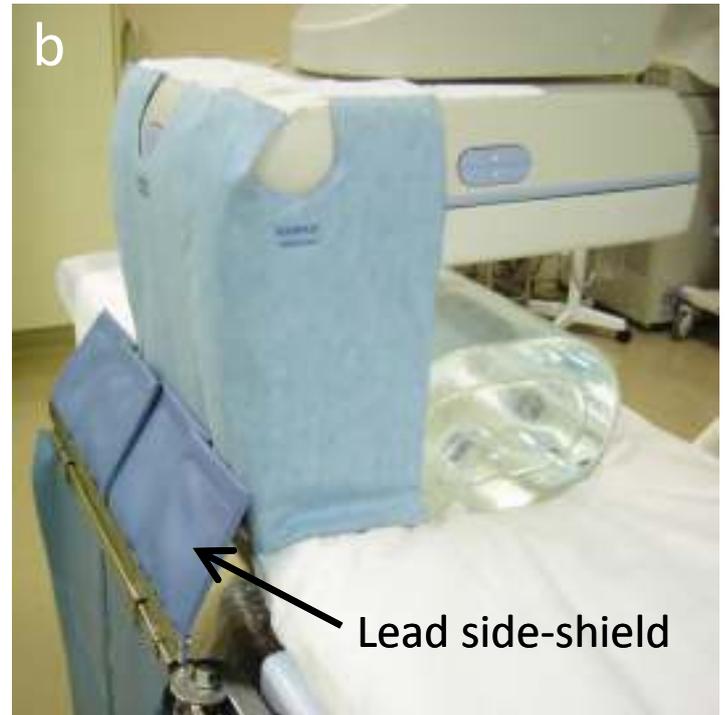
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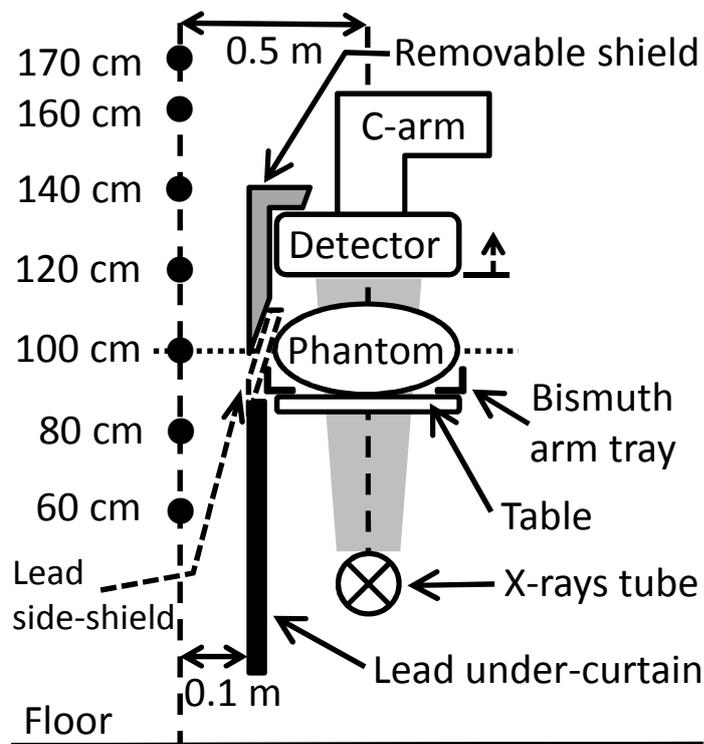
**Fig. 1.** Outside of the removable shield against scattered X-rays from a patient's side.



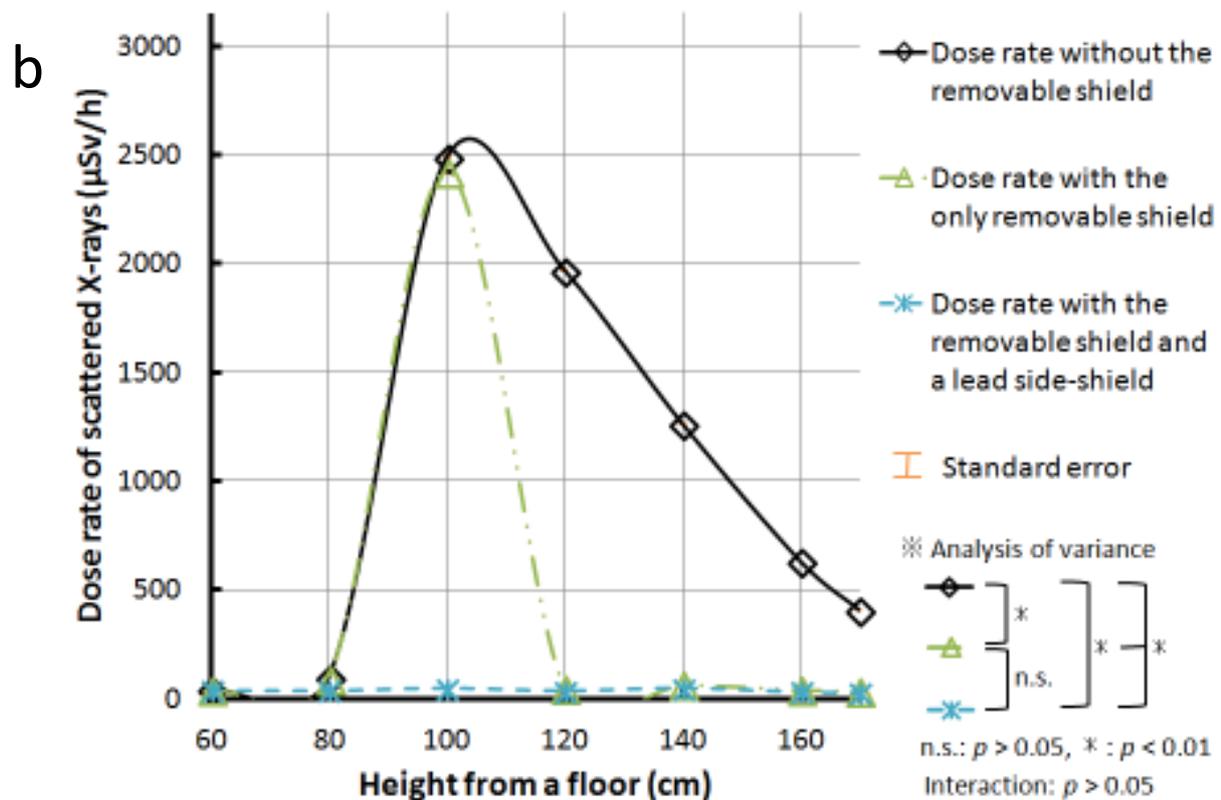
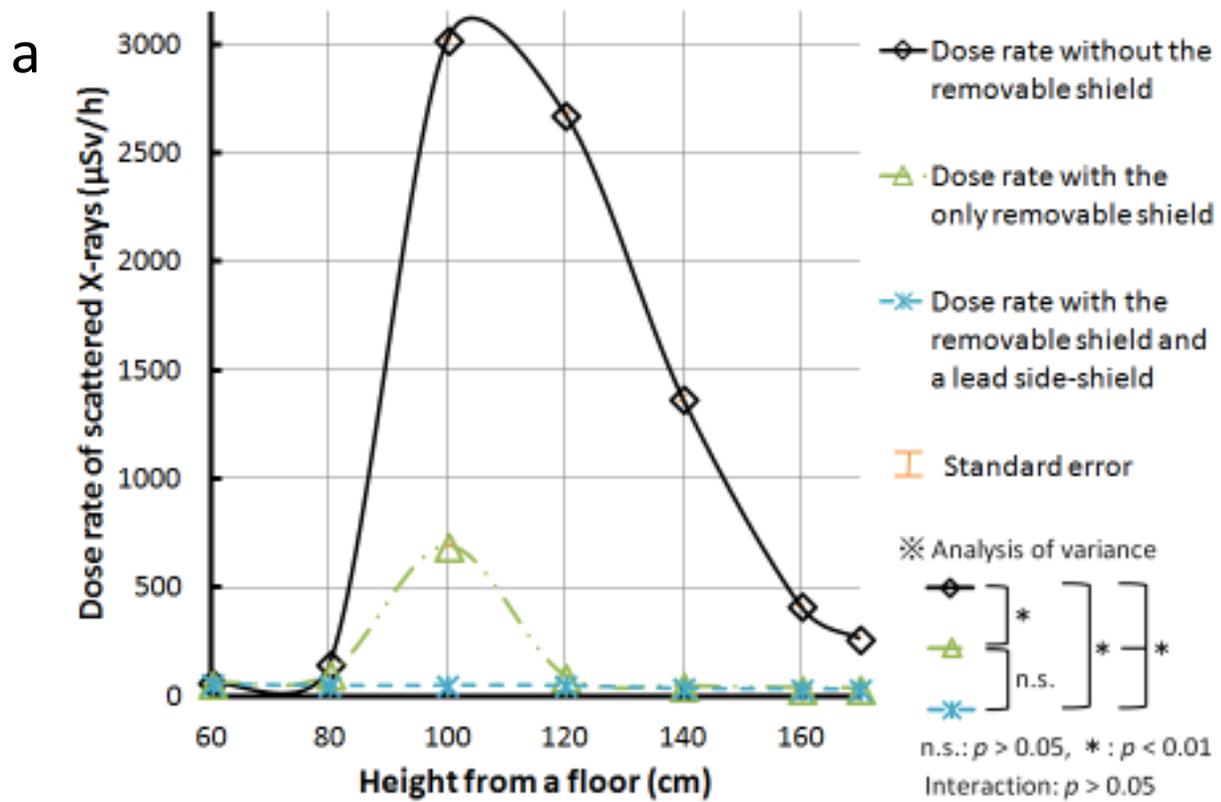
**Fig. 2a-b.** A removable shield attached to the top of a C-arm unit.

**a** Front image of a removable shield. When ERCP is performed at this unit, a patient makes the head of the right side and lies prone; besides, an endoscopist stands at the front of a removable shield.

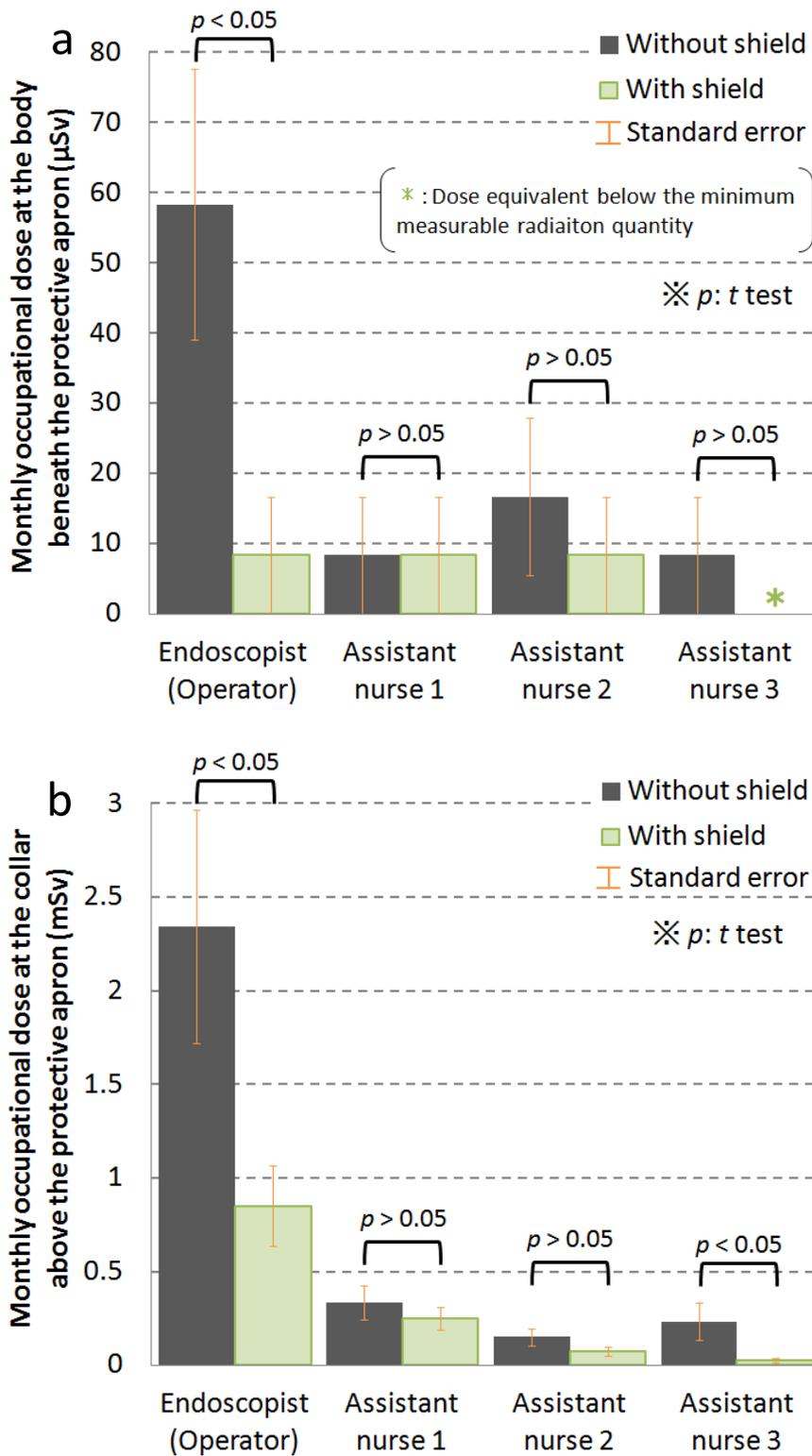
**b** Oblique image of a removable shield. This image is viewed from the head side of a patient, and a lead side-shield is mounted.



**Fig. 3.** Geometry measured the dose rate of scattered X-rays with and without the removable shield. The measured points (●) were at the heights of 60, 80, 100, 120, 140, 160, and 170 cm.



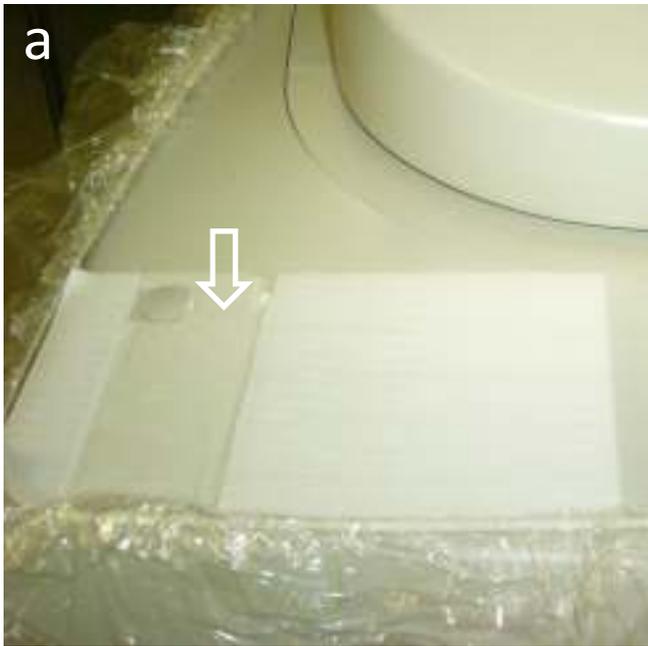
**Fig. 4a-b.** Dose rate of the scattered X-rays around the endoscopists with and without the removable shield. A lead under-curtain and a bismuth arm tray were mounted in all cases. The distance between the table and the detector of a C-arm unit was set at 30 cm (a) or 40 cm (b).



**Fig. 5a-b.** Monthly occupational doses to the ERCP staff with and without the removable shield.

**a** Personal dose equivalent at the body level in the ICRU tissue at a depth of 10 mm, as defined in the ICRU Report 51 [12].

**b** Personal dose equivalent at the collar level in the ICRU tissue at a depth of 0.07 mm, as defined in the ICRU Report 51 [12].



**Fig. 6a-b.** Traces of the exfoliation of hook-and-loop fasteners off powerful double-sided tapes for plastic.  
**a** Traces off the tapes with the tensile shear strength of 1.74 N per 100 mm<sup>2</sup>. The hook-and-loop fastener completely came off.  
**b** Traces off the tapes with the tensile shear strength of 2.71 N per 100 mm<sup>2</sup>. The hook-and-loop fastener partly came off.