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RESEARCH

Evaluation of a Novel Enhanced Radiation Protection Device in Interventional Neuroradiology: a Phantom Study

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Abstract

Introduction Scatter radiation during interventional neuroradiological (INR) procedures is potentially harmful to the operator and cath-lab staff. Enhanced radiation protection devices (ERPDs) aim to improve safety by minimizing scatter radiation in addition to standard and personal protective equipment (PPE). This study evaluated the efficacy of a novel ERPD in INR.

Methods Radiation exposure of the main operator was estimated by measuring the local dose rate at the examination position. An anthropomorphic patient whole body phantom was used simulating a standard INR procedure. The relative dose reductions were determined for the following settings: a) MasterPeace (Texray AB, Sweden) combined with ceiling-suspended lead screen (Mavig, Germany) compared to no shielding. b) MasterPeace combined with ceiling-suspended lead screen, compared to standard radiation protection consisting of a table-side curtain for lower body protection (Kenex, UK) and ceiling-suspended lead screen.

Scatter radiation was measured at various operator heights (70, 130 and 160 cm) across seven routine projection angles using a biplane angio-suite (Artis zee, Siemens Healthineers, Germany).

Results (a) The mean scatter radiation shielding effect was 98.5% compared to no shielding across all measured heights and angular projections when used in combination with a ceiling-suspended lead screen. (b) The mean scatter radiation shielding effect was 79.7% compared to standard radiation protection for all measured heights and angular projections. The shielding efficacy ranged from 93.1% for the PA projection to 31.8% for LAO30/CAU30; and from 87.0% at 70 cm to 39.5% at 160 cm.

Conclusions This phantom study demonstrates that the MasterPeace is highly effective and provides relevant radiation protection in addition to existing standard and personal protection equipment. Clinical evaluation in INR procedures is underway.

Keywords Enhanced Radiation Protection Devices · Occupational Hazard · Radiation Safety · Occupational Health

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Abbreviations

AEC Automatic Exposure Control
AVM Arteriovenous Malformation
ERPDs Enhanced Radiation Protection Devices
ERPS Enhanced Radiation Protection System
FGI Fluoroscopically Guided Intervention
ICRP International Commission on Radiological Protection
INR Interventional Neuroradiology
KAP Kerma Area Product
MDR Medical Device Regulation
MV Mean Value
PPE Personal Protective Equipment
SD Standard Deviation

Introduction

During fluoroscopically guided endovascular procedures, interventionalists and staff are exposed to high scatter radiation doses, emanating from the patient and equipment [1]. Scatter radiation exposure increases the susceptibility to adverse health outcomes and is associated with stochastic and deterministic effects such as cataracts, skin damage, DNA damage, and cancer [2]. Staff radiation protection is therefore crucial, especially in long-lasting INR procedures. Several studies have reported scatter radiation doses to personnel during endovascular stroke and intracranial aneurysm treatment [3, 4], highlighting the need for dose optimization and enhanced radiation protection.

To address this significant occupational health hazard, various shielding systems have been developed aiming to reduce operator radiation exposure. The typical radiation protection shields are made of lead or non-lead composite materials and include both personal protective equipment (PPE) worn by clinical staff and additional shields mounted alongside the table to reduce occupational radiation exposure. PPE is susceptible to fractures and should not be folded as pinholes can easily develop, which can rapidly evolve into major tears and cracks, compromising the safety of exposed staff [5–7]. In a study evaluating the integrity of 1011 radiation protective products, 6% were found to have tears within the first year of use [8].

To reduce the risk of musculoskeletal strain and potential injury caused by wearing heavy PPE, significant advancements have been made in movable/portable radiation protection shields. These enhanced radiation protection devices (ERPD) are entering clinical practice and may allow for the use of lighter aprons or even eliminate the need for aprons altogether [9, 10]. These ERPDs typically consist of large, floor-mounted movable shields positioned laterally and superiorly to the patient, designed to create a physical barrier between the most important source of scatter radiation, the patient, and the medical staff. While these solutions can offer substantial protection in certain configurations, their integration with existing ceiling-suspended shields may be challenging and potentially lead to redundancy in some scenarios.

The MasterPeace ERPD (Texray AB, Sweden) comprises, table-side radiation protective shields and drapes placed directly on the patient to minimize scatter radiation emitted from the patient. The pliable textile drapes can be easily connected to the table-side shielding, creating a continuous protective barrier that minimizes radiation leakage and closes any gaps between the shields and the patient table. The aim of this study was to evaluate the efficacy of MasterPeace measured in a patient phantom study simulating a standard INR setup under laboratory conditions in order to identify weaknesses in the system. Questions regarding the handling of MasterPeace in practical use were not part of the study.

Materials and Methods

Radiation Protection Devices

MasterPeace (Texray AB, Sweden) incorporates a proprietary pliable radiation-protecting textile with two main subcomponents (Fig. 1).

These are

1. the foldable over-table shields, a comprehensive patient-draped solution designed to reduce scatter radiation emitted from the patient, and
2. the table-side shielding components allowing unimpeded C-arm angulations while reducing scatter radiation below the table.

MasterPeace is registered as approved medical device by the U.S. Food and Drug Administration and complies with MDR 2017/745 (EU). The attenuating material of the patient-draped shields combine 0.25 and 0.50 mm lead equivalence, and the table-side shields have a protection level of 0.50 mm lead equivalence. The attenuation of 0.50 mm lead equivalence was determined using inverse broad beam geometry at 60–150 kV, in accordance with the IEC 61331-1:2014 standard.

The modular MasterPeace device is designed to be used in conjunction with an existing ceiling-suspended lead screen. The modularity also allows for easy removal of the shields after use, for cleaning, and contributes to a seamless turnover between patients. The product's first version, evaluated in this study, supports bilateral femoral, radial, and brachial vascular access, allowing the interventionalist to choose the appropriate access site. The components of the MasterPeace are fully reusable.

Fig. 1 The ERPD, MasterPeace (Texray AB, Sweden), displaying the foldable over-table shields designed to reduce scatter radiation emitted from the patient; and the table-side shielding components allowing unimpeded C-arm angulations while reducing scatter radiation below the table

Standard shielding consisted of table-mounted shields (Kenex, UK) and a ceiling-mounted lead shield (Mavig, Germany). Both with a lead equivalence of 0.5 mm. The table shield and the ceiling-mounted lead screen was positioned to protect the primary operator.

Design of the INR Phantom Study

The study was conducted using an anthropomorphic whole-body phantom consisting of tissue-equivalent hard foam rubber and human bone material placed on the patient table of an Artis zee biplane (Siemens Healthineers, Germany) angiography system to replicate INR procedures using a femoral vascular access (Fig. 2).

Key aspects of the experimental setup are defined in Table 1. The tube voltage was automatically set to 66–80 kV, DSA runs with a frame rate of 4 images/second; 0.3–0.6 mm Cu filters were employed. A Raysafe 452 real-time dosimeter (Unfors Raysafe AB, Sweden) was used to measure the local dose rate at the position of the physician. A tripod was used to adjust the position of the dosimeter relative to the radiation source and the phantom. The real-time dosimeter was positioned at 70 cm, 130 cm and 160 cm to measure the radiation exposure at three different heights. To increase the measurement statistics and improve reproducibility, only DSA series were performed as the resulting overestimation of the examiner dose is irrelevant when considering the relative dose reduction.

Depending on the relevant literature [7, 8, 11], the phantom rail was designed to evaluate seven routine IN C-arm projection angles, as listed in Table 1. Measurements were taken for each angular projection: posterior anterior (pa); left anterior oblique 30° (LAO30); left anterior oblique 30°/cranial 30° (LAO30/CRA30); left anterior oblique 30°/caudal 30° (LAO30/CAU30); right anterior oblique 30°/cranial 30° (RAO30/CRA30); right anterior oblique 30°/caudal 30° (RAO30/CAU30) and lateral (LAT90 resp. RAO90). The aim was to identify weaknesses in MasterPeace and determine potential for improvement. To avoid possible interference from superpositions, only monoplanar measurements were taken.

The measurements were repeated in the three different scenarios:

1. No shielding
2. Table-side curtain for lower body protection (Kenex, UK) and a ceiling-suspended lead screen (Mavig, Germany), representing the Standard.
3. MasterPeace combined with a ceiling-suspended lead screen (Mavig, Germany) representing the Intervention.

Data Collection and Statistical Analysis

Dose rates measured as the personal dose equivalent rate $\dot{H}_{\mathrm{P}}(10)$ in mSv/h. To ensure comparability of the measurements, the measured dose rates were normalized to the irradiation time and the accumulated kerma area product of each datapoint. The normalized dose rates were used to determine the relative dose reduction in the following settings

Table 1 Exposure parameters for the phantom study, simulating neuroradiology procedures.

Parameter	Setting/Device
Modality	Artis Zee biplane[1]
Table height (cm)	100 cm
Position of isocenter	Central in the head
Dosimeter	RaySafe 452[2]
Reference dosimeter	KAP-Chamber
Dose quantity	Personal dose equivalent rate $\dot{H}^*(10)$
Exposure, DSA sequence mode	Cerebral
Source to isocenter distance	75 cm
Source to flatpanel distance	120 cm
Field of view	$(22.62 \times 22.62)\ \mathrm{cm}^2$
Frame rate	4 1/s
Tube voltage (kV)	66–80 kV
Additional filtering	0.3–0.6 mm Cu
C-Arm Projection angles	PA
	LAO30
	LAO30/CRA30
	LAO30/CAU30
	RAO30/CRA30
	RAO30/CAU30
	LAT90 resp. RAO90

[1] Artis zee angiography system (Siemens Healthineers GmbH, Germany)
[2] Raysafe 452 dosimeter (Fluke Biomedical Inc, USA)

Fig. 2 The configuration of the ERPD set-up for intervention using femoral access, having the Raysafe 452 dosimeter at a height of 160 cm

as a function of the beam angulation and the measurement height:

a) MasterPeace combined with ceiling-suspended lead shield screen compared to standard radiation protection comprising a table side curtain and ceiling-suspended lead screen.
b) MasterPeace combined with ceiling-suspended lead screen compared to No shielding.

The dose reduction R is given in percent. The calculation of the dose reduction of configuration 1 compared to configuration 2 for each data point was done as follows:

$$R = \left(\frac{\dot{H}_P\,(10)_1 \cdot t_1 / KAP_1}{\dot{H}_P\,(10)_2 \cdot t_2 / KAP_2} - 1 \right) \cdot 100$$

$\dot{H}_P(10)$ = measured dose rate in mSv/h; t = exposure time in s; KAP = kerma area product.

The relative measurement uncertainties were 7.5% for the KAP measurement and 5.0% for the $\dot{H}_P(10)$ measurement (coverage factor $k = 1$). The resulting uncertainty for the determined dose reductions was calculated using Gauss's law of error propagation.

The given mean dose reduction is weighted in terms of the dose contributions of the corresponding angles and measurement heights to the total dose. The average dose reduction of configuration 1 compared to configuration 2 is calculated as follows:

$$R = \left(\frac{\sum_{k=1}^{n} \dot{H}_P\,(10)_{1;k} \cdot t_{1;k} / KAP_{1;k}}{\sum_{k=1}^{n} \dot{H}_P\,(10)_{2;k} \cdot t_{2;i} / KAP_{2;k}} - 1 \right) \cdot 100$$

$\dot{H}_P(10)$ = measured dose rate in mSv/h; t = exposure time in s; KAP = kerma area product.

It is assumed that all angles are used with equal frequency and intensity. It should be noted at this point that the measurements were taken under laboratory conditions to test the effectiveness of the protective equipment. Therefore, no conclusions can be drawn about the actual dose reduction for the examiner in a clinical practice setting.

The given standard deviation foe the mean reduction is of a descriptive nature. It is not the standard error of the mean but only describes the spread of the sample around the mean.

Results

MasterPeace combined with a ceiling-mounted lead screen demonstrated an average scatter radiation shielding effect of 98.5 ± 3.7% (MV ± SD) compared to no shielding (a) and of 79.7 ± 29.2% compared to standard radiation protection (b) for all measured configurations (b). The resulting reduction factors are summarized in Tables 2 and 3 and shown in Figures 3 and 4

Discussion

This is the first patient phantom-based study demonstrating the MasterPeace efficacy for INR procedures. The overall relative dose reduction for the MasterPeace used in combination with a ceiling-suspended screen was 98.5 ± 3.7% compared to no shielding and 79.7 ± 29.2% compared to standard shielding. The shielding effect varied by heights and projection angulations. From a radiation protection standpoint, the RAO30/CAU30 projection at 160 cm height posed the greatest challenge for effective shielding. Even for this angle, the dose could be reduced by almost 40% on average compared to standard protection through the use of MasterPeace. But further improvement of the product is desirable, especially for taller individuals. In addition, the ceiling-suspended lead shield screen used in this study did not have lead lamellae, which means that a gap

Table 2 Results of the shielding efficacy of MasterPeace and ceiling-suspended screen compared to no shielding at different heights.

Detector height	C-Arm Angle	Normalized dose rate at point of measurement/µSv/(3,600 µGy·m^2)		Relative dose (compared to no shielding)	Mean reduction
		No shielding	MasterPeace + Screen		
70 cm	Pa	114.0 ± 10.3	0.4 ± 0.1	(–99.6 ± 0.1) %	(99.6 ± 0.2) %
	LAO30	109.3 ± 9.9	0.3 ± 0.1	(–99.8 ± 0.1) %	
	LAO30/CRA30	119.6 ± 10.8	0.3 ± 0.1	(–99.7 ± 0.1) %	
	LAO30/CAU30	112.6 ± 10.2	0.5 ± 0.1	(–99.6 ± 0.1) %	
	RAO30/CRA30	135.0 ± 12.2	0.6 ± 0.1	(–99.6 ± 0.1) %	
	RAO30/CAU30	114.2 ± 10.3	0.6 ± 0.1	(–99.5 ± 0.1) %	
	LAT90	51.6 ± 4.7	0.3 ± 0.1	(–99.4 ± 0.1) %	
130 cm	Pa	226.8 ± 20.5	1.6 ± 0.2	(–99.3 ± 0.1) %	(98.5 ± 0.9) %
	LAO30	137.0 ± 12.4	1.1 ± 0.1	(–99.2 ± 0.2) %	
	LAO30/CRA30	139.2 ± 12.6	1.8 ± 0.2	(–98.7 ± 0.2) %	
	LAO30/CAU30	150.2 ± 13.6	3.4 ± 0.4	(–97.7 ± 0.3) %	
	RAO30/CRA30	63.1 ± 5.7	2.0 ± 0.2	(–96.8 ± 0.5) %	
	RAO30/CAU30	89.0 ± 8.1	2.1 ± 0.2	(–97.7 ± 0.3) %	
	LAT90	131.3 ± 11.9	1.8 ± 0.2	(–98.6 ± 0.2) %	
160 cm	Pa	129.8 ± 11.7	2.4 ± 0.3	(–98.2 ± 0.3) %	(97.4 ± 5.9) %
	LAO30	114.7 ± 10.4	2.1 ± 0.2	(–98.2 ± 0.3) %	
	LAO30/CRA30	100.2 ± 9.1	2.1 ± 0.2	(–97.9 ± 0.3) %	
	LAO30/CAU30	145.9 ± 13.2	3.5 ± 0.4	(–97.6 ± 0.4) %	
	RAO30/CRA30	76.2 ± 6.9	2.6 ± 0.3	(–96.6 ± 0.5) %	
	RAO30/CAU30	15.7 ± 1.5	2.8 ± 0.3	(–82.2 ± 2.3) %	
	LAT90	84.6 ± 7.7	2.1 ± 0.2	(–97.6 ± 0.4) %	
Total average reduction:					(98.5 ± 3.7) %

Table 3 Results of the shielding efficacy of MasterPeace and ceiling-suspended screen compared to standard shielding at different heights.

Detector height	C-Arm Angle	Normalized dose rate at point of measurement/µSv/(3,600 µGy·m^2)		Relative dose (compared to standard shielding)	Mean reduction
		Standard shielding	MasterPeace + Screen		
70 cm	Pa	6.8 ± 0.7	0.4 ± 0.1	(−93.7 ± 0.9) %	(87.0 ± 13.8) %
	LAO30	8.2 ± 0.8	0.3 ± 0.1	(−96.8 ± 0.5) %	
	LAO30/CRA30	1.3 ± 0.2	0.3 ± 0.1	(−73.4 ± 3.4) %	
	LAO30/CAU30	1.3 ± 0.2	0.5 ± 0.1	(−61.6 ± 4.9) %	
	RAO30/CRA30	1.6 ± 0.2	0.6 ± 0.1	(−65.5 ± 4.4) %	
	RAO30/CAU30	1.9 ± 0.2	0.6 ± 0.1	(−69.0 ± 4.0) %	
	LAT90	1.8 ± 0.2	0.3 ± 0.1	(−82.1 ± 2.3) %	
130 cm	Pa	50.8 ± 4.6	1.6 ± 0.2	(−96.9 ± 0.4) %	(88.2 ± 25.9) %
	LAO30	6.2 ± 0.6	1.1 ± 0.1	(−82.3 ± 2.3) %	
	LAO30/CRA30	31.1 ± 2.8	1.8 ± 0.2	(−94.2 ± 0.8) %	
	LAO30/CAU30	5.4 ± 0.5	3.4 ± 0.4	(−37.1 ± 8.1) %	
	RAO30/CRA30	16.3 ± 1.5	2.0 ± 0.2	(−87.6 ± 1.6) %	
	RAO30/CAU30	4.2 ± 0.4	2.1 ± 0.2	(−50.3 ± 6.4) %	
	LAT90	3.1 ± 0.3	1.8 ± 0.2	(−41.8 ± 7.5) %	
160 cm	Pa	5.5 ± 0.5	2.4 ± 0.3	(−56.9 ± 5.5) %	(39.5 ± 25.6) %
	LAO30	3.3 ± 0.3	2.1 ± 0.2	(−37.7 ± 8.0) %	
	LAO30/CRA30	4.8 ± 0.5	2.1 ± 0.2	(−55.3 ± 5.7) %	
	LAO30/CAU30	4.1 ± 0.4	3.5 ± 0.4	(−15.4 ± 10.8) %	
	RAO30/CRA30	6.2 ± 0.6	2.6 ± 0.3	(−57.9 ± 5.4) %	
	RAO30/CAU30	2.6 ± 0.3	2.8 ± 0.3	(+7.0 ± 13.7) %	
	LAT90	2.5 ± 0.3	2.1 ± 0.2	(−15.6 ± 10.8) %	
Total average reduction:					(79.7 ± 29.2) %

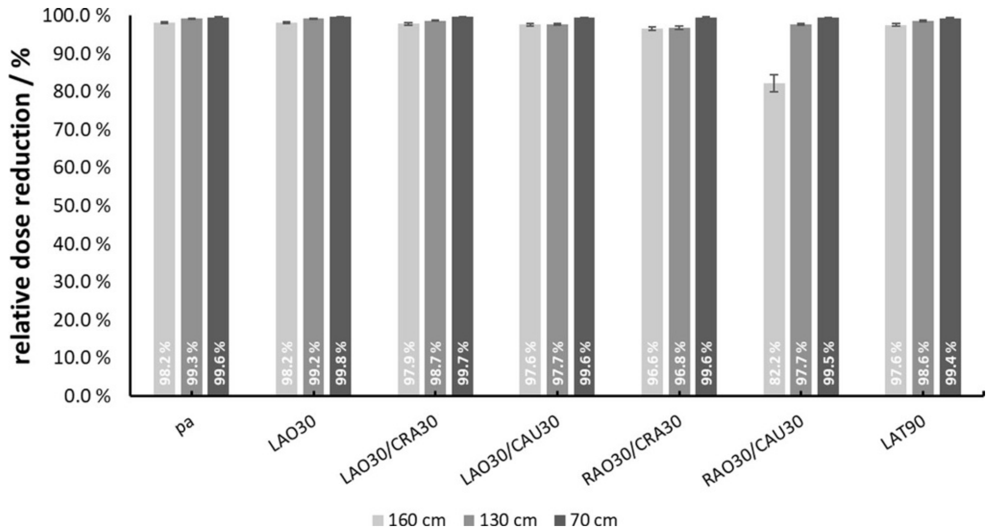

Fig. 3 Reduction factors of the MasterPeace relative to the measurement without radiation protection equipment as a function of the projection angle and the measurement height

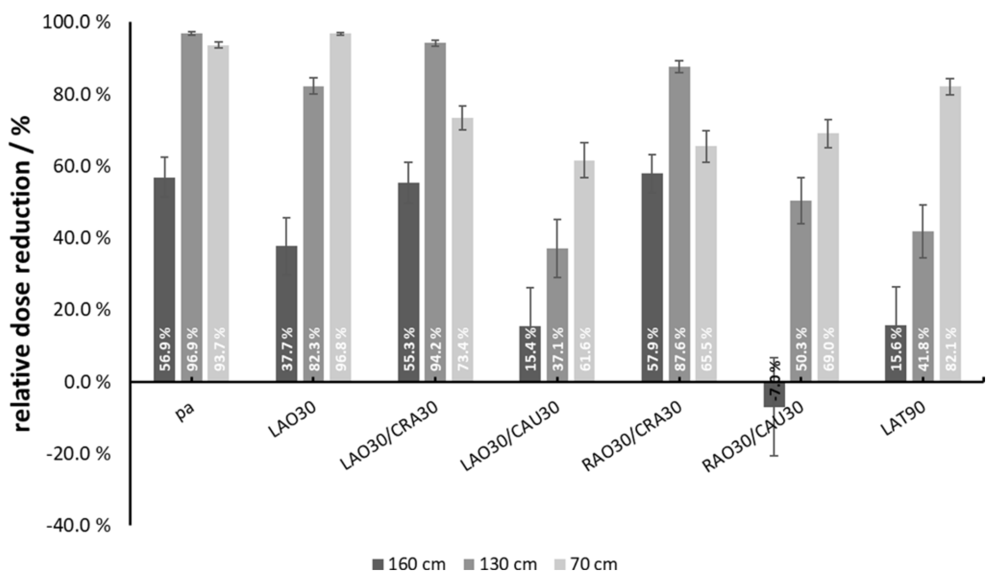

Fig. 4 Reduction factors of the MasterPeace relative to the measurement with standard shielding as a function of the projection angle and the measurement height

can form between the patient and the shield, possibly contributing to the increased exposure at projection angles toward the examiner.

Hence, the overall shielding effect of MasterPeace, used in combination with a ceiling-suspended screen, demonstrates high radiation protection at all heights and in nearly all C-arm angulations. Dedicated neck, face, and head protectors may be used to complement the shielding effect at 160 cm height and especially during complex procedures when the ceiling-suspended lead screen may not be able to be positioned optimally [12, 13]. The shielding was never placed in the beam path. Any influence of the material on the automatic exposure control (AEC) and a corresponding increase of the dose to the patient can therefore be ruled out.

Our findings confirm the findings of recent interventional cardiology studies on ERPD.

Crowhurst et al. [10] compared the Rampart IC to conventional shielding. Radiation exposure was measured with real time dosimeters on head, collar, waist and ankle. The median primary operator radiation dose was significantly lower for all locations with the Rampart IC system when compared to conventional shielding, being reduced by 86%, 80%, 100%, and 50% for the head, collar, waist, and leg respectively.

While many interventional cardiology procedures are highly standardized, INR procedures often require extended fluoroscopy times and use of high dose runs, especially during the treatment of AVM, fistulae or complex aneurysms, leading to potentially high radiation exposure to the interventionalist and staff. Moreover, with extreme angulations of the biplane tubes, operators are frequently standing close to the X-ray source with higher scatter radiation exposure. However, there is limited data about the burden of radiation exposure in INR. Bor et al. [14] examined the kerma area product and skin dose in 57 neurointerventions. Mean staff doses for eye, finger and thyroid were 80.6, 77.6 and 28.8 µGy per procedure. The mean effective dose per procedure for the radiologists was 32 µSv. More recently, Punikhom et al. [15] evaluated the patient and scatter radiation doses at INR staff during coil-embolization in a phantom study. Comparable to our own findings, they measured the highest radiation doses at the position of the interventionist at a height of 100 cm.

Regarding the most frequent INR, thrombectomy in stroke patients, published data on radiation exposure to staff remains scarce: Zucca et al. [16] assessed the radiation exposure of 670 ischemic stroke patients, reporting a median Kerma Area Product of 115 Gycm^2. However, the authors did not provide data on staff radiation exposure. Weyland et al. [3] found that neurointerventionalists experience generally low but highly variable radiation exposure during endovascular stroke treatment, with the highest doses observed on the left arm and temporal bone [3]. The median radiation dose was 7 µSv for both the left arm (IQR: 3.1–16.9 µSv) and the left temporal bone (IQR: 3.2–17.4 µSv). Radiation exposure correlated significantly with fluoroscopy time, KAP, and the number of thrombectomy attempts, but showed no significant association with vessel occlusion location or operator height.

Thus, in INR settings, ERPDs offer an entirely new approach to operator radiation protection, aiming to achieve near-zero radiation exposure not only to operators, but also to entire cath-lab staff. The use of comprehensive ERPDs is expected to significantly reduce radiation exposure to staff, potentially enabling operators to wear lightweight protective garments. There are challenges in achieving low scatter radiation without leaks, as evidenced by the Rabah 2023 study in which there was a need to convert to aprons in 8% of the cases, due to scatter radiation [9]. Hence, the need for PPE remains of importance to provide sufficient protection for the staff. Moreover, dedicated radiation protection training of the staff is required to ensure proper use of the system.

The presented ERPD is not designed for interventions with vascular access points around the head area and thus the radiation protection for anesthesiologists, echocardiographers and nurses at this position is limited. Further studies are required to evaluate the shielding efficacy for more clinical situations and to determine the routine use of this ERPD.

Limitations

Although this study is based on pre-clinical data using a phantom in an INR setting, the study provides data using seven typical C-Arm projections and does not consider the operator's normal movement and the technical settings actually used, such as c-arm angle, field size, pulse rate, etc. during INR procedures. It is therefore not possible to draw conclusions about the actual dose reduction for the examiner during clinical conditions. To establish the data in clinical practice, clinical validation studies should be conducted and pre-clinical phantom-based data for other medical fields, such as interventional cardiology are required.

In the test setup of this phantom study, routine parameters were not used. For example, a field of view of 32 cm is unusual and DSA was used rather than choosing fluoroscopy which is routine practice. It can be argued that this may be an extreme situation which makes radiation protection more difficult and hence an ERPD threshold performance test. Further studies with more routine settings should be performed thus to be comparable to daily work in the clinical setting.

No conclusions can be drawn about usability and handling from this study. MasterPeace is a portable system that does not require any installation, more than hanging the table shields to the rails of the table and placing the drapes on the patient. The turnover time between interventions could be affected with the MasterPeace system compared to the standard radiation protection set-up. Clinical trials are required to investigate the impact on workflow.

Conclusions

The measurements show that the ERPD tested here has the potential to further reduce the examiner dose compared to standard protection.

Given these encouraging results, clinical evaluation is justified to determine the extent to which the system reduces radiation to the medical staff under clinical conditions. Furthermore, such studies may also provide insight into whether lighter PPE can be used in conjunction with the ERPDs, potentially improving the working environment for interventionalists performing fluoroscopically guided interventions.

Conflict of interest P. Hidefjäll, F. Gellerstedt and P. Apell are Texray employees. F. Bärenfänger, G. Bartal, and S. Rohde declare that there are no competing interests.

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