



Exoskeleton System for Radiation Protection in Interventional Radiology

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ABSTRACT

Background: As the quantity and complexity of radiological interventions are constantly increasing, gear that offers optimal protection while maintaining mobility and a low weight burden is becoming more important. A newly developed exoskeleton radiation protection system (ERPS) (StemRad MD; StemRad Ltd.) can carry the weight of the shielding. The aim of our study was to analyze initial experience, especially in terms of advantages and disadvantages, with this new ERPS in interventional radiology.

Materials and Methods: Forty-six interventions utilizing the ERPS were analyzed. The interventional radiologists completed a 15-question survey evaluating various aspects of the protective system, including weight, mobility, comfort, and radiation protection adequacy.

Results and Discussion: In 98% of procedures, interventionalists reported being very satisfied (89%) or slightly satisfied (9%) and would recommend the system to colleagues. The exoskeleton system was rated as 100% comfortable, not too heavy, and did not restrict mobility in 98% of cases.

Conclusion: The ERPS is a recommendable alternative to standard lead aprons, providing flexibility, comfort, and effective weight distribution without restricting mobility.

Keywords: Radiation Protection, Interventional Radiology, Radiation Safety

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Introduction

Radiation safety is a significant concern for physicians, especially in departments where fluoroscopic procedures are common. These procedures contribute the highest radiation dose to medical staff, necessitating optimal radiation protection measures [1]. With the growing number of interventional radiology procedures, protective gear must ensure both adequate radiation shielding and user comfort [2–5], including unrestricted mobility [6]. While patient safety is a priority for interventional radiologists [7], most interventionalists neglect basic ergonomic principles for their own bodies during procedures, as also observed in surgical procedures [8–11]. Traditional lead aprons have notable ergonomic drawbacks, underscoring the need for alternative protection systems that account for the physical limitations, fitness levels, and age of the operators. Traditional lead aprons weigh about 2–3 kg and impose significant ergonomic stress

on medical personnel, causing musculoskeletal strain in the neck, shoulders, and lower back. Prolonged use is linked to chronic conditions like neck and back pain, with studies showing up to 60% of interventional radiologists experience weekly pain due to heavy protective gear. Additionally, lead aprons restrict healthcare workers' mobility during procedures. Their rigidity and weight hinder the range of motion needed for complex and prolonged interventions, potentially impacting efficiency and outcomes, especially in emergencies. Repeatedly wearing lead aprons throughout the day causes cumulative fatigue, leading to early fatigue during shifts, reducing the stamina and effectiveness of medical personnel, and affecting care quality and safety. Moreover, the physical strain and discomfort from lead aprons can cause psychological stress and anxiety, affecting mental well-being and job satisfaction. This can lead to burnout and higher attrition rates in high-stress medical fields like interventional radiology. Therefore, testing alternative protection systems is important in the context of possible physical limitations, individual fitness, and the age of the interventionalists [12].

The exoskeleton radiation protection system (ERPS) has been created to offer full operator mobility and maximum radiation shielding while supporting the weight of the pro-

TECTIVE APPAREL (StemRad MD; StemRad Ltd.). It weighs approximately 5 kg, but the wearer does not perceive the weight. The lead apron reduces radiation exposure-induced death such as cancer while eliminating the possibility of acute radiation due to solar particle events. The protective components for physicians include a visor for circular head protection while also enabling users to wear their own glasses beneath (Fig. 1A). In interventional radiology laboratories, safeguarding ocular health through effective radiation protection measures is critically important [13–15]. The visor covers a greater area than lead glasses for improved protection of the face, head, eyes, and brain. The visor weight, as well as the protective gear in total, is supported by the exoskeletal system. Furthermore, there is a protective envelope with an integrated thyroid collar, dispensing with the need for extra-protective apparel. Finally, the ERPS is the component that channels all the weight to the floor while maintaining maximum freedom of movement and comfort. It allows walking (even stairs or kneeling) while still supporting the load. A sterile use of the exoskeleton is easily possible (Fig. 1B). Patented knee and hip joints allow the user to turn and bend. For storage of the ERPS, a movable hanger system with wheels is provided (Fig. 1C). The ERPS is Conformité Européenne-certified for



Fig. 1. The new exoskeleton radiation protection system (StemRad MD; StemRad Ltd.). (A) The exoskeleton with visor. (B) Sterile using of the exoskeleton. (C) The hanger kit.

personal protective equipment in Europe.

This study evaluates the advantages and disadvantages of the ERPS based on initial site experiences in interventional radiology.

Materials and Methods

1. Study Design

The custom-designed ERPS was intended for evaluation of its clinical utility at a major university hospital in Germany. Given its bespoke design, the system was tailored for use by a single individual. From December 2022 to February 2023, a total of 140 interventional procedures were performed by a seasoned interventional radiologist with 15 years of experience at a major German university hospital. The ERPS was utilized in 46 of these procedures. The study was approved by the Institutional Review Board (Ethikkommission der Charité – Universitätsmedizin Berlin, registration number EA2/246/23). The ethics committee waived the need to obtain patient consent because of the retrospective study design. These procedures were conducted in an angiography suite equipped with either a monoplanar or biplanar X-ray system (Artis Icono Monoplane Ceiling and Biplane IR Pro; Siemens Healthineers). Following each intervention, the radiologist completed a digital questionnaire detailing the specifics of the procedure as well as evaluating the weight, movability, comfort, and overall satisfaction with the new protective gear.

2. Questionnaire

To ensure accurate data collection, decision questions were incorporated into the questionnaire. Developed using SurveyMonkey (<https://www.surveymonkey.de>), the questionnaire comprised 15 questions, including multiple-choice op-

tions and queries requiring numerical or text responses. In addition, further comments were possible. The full questionnaire is provided in Appendix 1.

3. Statistical Analysis

Statistical analysis and figure generation were conducted using SPSS version 27 Statistics for Mac OSX (IBM Co.). Results are presented as absolute numbers and percentages.

Results

1. Procedural Characteristics

A total of 46 interventions were performed. The majority of interventions were port implantations (30%); followed by percutaneous transluminal angioplasty/stent procedures (22%); embolizations (16%); peripherally inserted central catheter implantations (14%); tunneled catheter system implantations (7%); and angiographies (11%); computed tomography guided interventions accounted for 0% (Fig. 2).

Procedure durations (from local anesthesia to final image validation) varied, with 24% lasting over 60 minutes. The majority of procedures lasted between 15 minutes and 60 minutes (Table 1).

In 85% of cases, the physician performed the procedure himself; otherwise, procedures were supervised as a proctor. In all interventions, the questionnaire was completed.

Table 1. Distribution of Procedure Durations

How long did the intervention last? (min)	Percentage (%)
1–15	0
15–30	44
30–45	32
More than 60	24

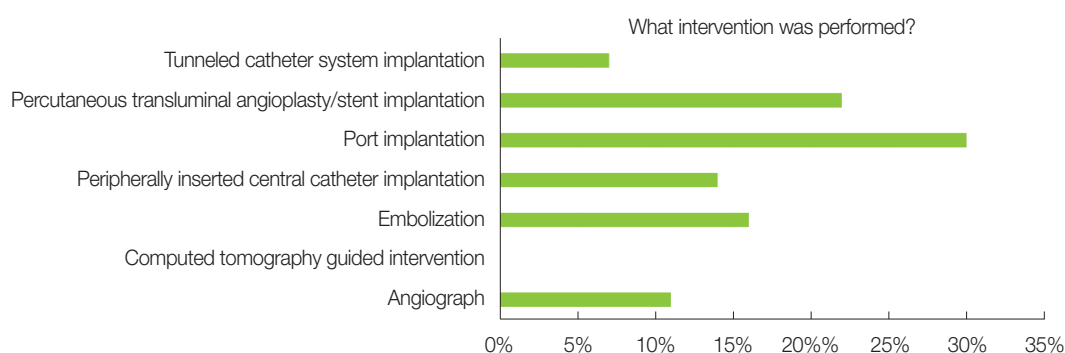


Fig. 2. Distribution of the interventions performed.

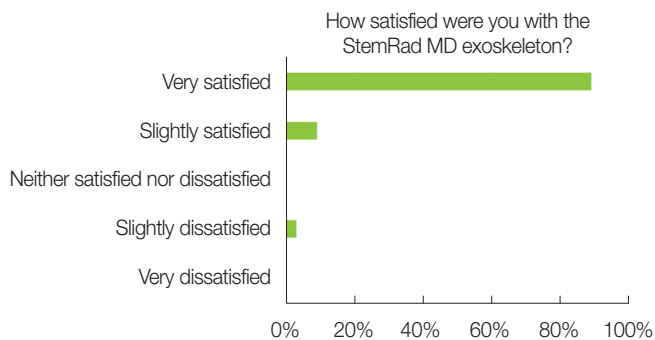


Fig. 3. Interventionalist's subjective satisfaction with the exoskeleton radiation protection system in 46 interventions.

2. Evaluation of the Exoskeleton Radiation Protection System

Satisfaction with the ERPS was rated on a 5-point scale. Satisfaction with the ERPS was high, with 98% of interventions resulting in very satisfied (89%) or slightly satisfied (9%) ratings. Only one intervention reported slight dissatisfaction (Fig. 3).

In 98% of procedures, the interventionalist would recommend the system to colleagues; there was only one intervention in which “maybe” was selected. The ERPS was rated 100% comfortable, the weight was scored 100% as not too heavy, and in 98% of interventions, mobility was not perceived to be restricted.

There were only two procedures in which there were problems encountered with the exoskeleton during the intervention: in one case, the waist belt became loose during the procedure, which could easily be solved, and in the other case, there were challenges with the shin profile and knee holder due to a three-dimensional (3D)-printed part of the initial prototype, which has now been exchanged for a serial production part.

In almost all cases (98%), the interventionalist could quickly put on or take off the ERPS. Initially, it took less than 1 minute, but with more experience over time, it was effortlessly possible to put on the suit (or take it off) from the hanger kit in 10–20 seconds without any assistance from extra-personnel. There was only one case (2%) in which some possible spatial constriction for the accompanying nurse was stated, caused by the exoskeleton during a procedure. The visor, used in 85% of cases, was consistently rated as providing good visibility. The visual experience provided by the curved shield seemed to be comparable and non-inferior to that of conventional radiation protection goggles, which also frequently feature a curved design.

Discussion

With advancements in technology, complex and long-term angiographic procedures are becoming increasingly significant and prevalent in interventional radiology, often necessitating extended fluoroscopy times [3, 4].

The ERPS was evaluated across various radiological procedures conducted in angiography suites. Neither the type nor the duration of the intervention impacted the interventionalist's satisfaction with the ERPS. In a minority of cases (two out of 46 procedures), minor challenges were encountered with the apron due to an inability to fully close all buckles. Despite these issues, the subsequent use of the ERPS was not hindered, and the interventions could be conducted without any limitations. This issue is likely attributed to the prototype's 3D-printed construction, which resulted in suboptimal mechanical tolerances. However, the serial product will be precision-machined and manufactured to avoid such issues.

Based on our observations, the ERPS could facilitate interventions for many interventionalists with diverse physical characteristics. Enhanced and comfortable exoskeleton radiation protection may mitigate the discomfort associated with increased procedure lengths, which is often exacerbated by the weight of conventional radiation protection gear.

Studies have indicated a correlation between occupational radiation exposure and malignancies, including left-sided brain tumors [16, 17]. The ERPS visor offers comprehensive head protection without impairing the wearer's visual field.

In the initial evaluation, the ERPS demonstrated 100% comfort with only minor restrictions in mobility (2%). Conventional lead aprons weigh 2–3 kg; the ERPS weighs around 5 kg. Nevertheless, the interventional radiologist hardly notices the ERPS. The weight transfer of the protective suit to the floor could enhance the wearer's endurance and enable longer interventions, potentially reducing physical complaints associated with conventional heavy protective gear. This is particularly relevant considering the high prevalence of neck and back pain among interventional radiologists, with 50% to 60% experiencing such pain weekly due to standard lead aprons. The results suggest that the ERPS may help prevent musculoskeletal health problems in interventionalists. Preliminary studies confirm that exoskeleton-based radiation protection reduces ergonomic posture risk [18].

A major limitation of this study is the small sample size and the fact that only one interventionalist evaluated the new

protection system. This was primarily due to the need for the ERPS exoskeleton to be custom-fitted to the individual interventional radiologist. Involving additional interventionalists would enhance data reliability, as individual physique may influence perceived comfort and mobility when using the ERPS. This, however, requires custom-fit gears for each colleague, which were not available and could not be provided for this initial feasibility study.

Future studies directly comparing the ERPS with standard lead aprons could provide insights into the new system's suitability for routine clinical use. Such comparisons could also help determine if the ERPS reduces the incidence of complications associated with traditional radiation protection gear.

Conclusion

The ERPS is a recommendable alternative to standard lead aprons, providing flexibility, comfort, and effective weight distribution without restricting mobility.

Conflict of Interest

The authors claim no conflicts of interest. StemRad MD did not pay any of the authors money for the study; they only lent the suit for the duration of the study.

Ethical Statement

This study was approved by the Institutional Review Board of Charité – Universitätsklinikum Berlin (registration number EA2/246/23). The ethics committee waived the need to obtain patient consent.

Author Contribution

Conceptualization: Hosse C, de Bucourt M. Data curation: Hosse C, Kolck J, de Bucourt M. Formal analysis: Hosse C, Fehrenbach U, Can E. Methodology: Hosse C, Pivetta F, de Bucourt M. Visualization: Hosse C, Kolck J, Auer TA. Writing - original draft: Hosse C. Writing - review & editing: Hosse C, Kolck J, Can E, Fehrenbach U, Auer TA, Pivetta F, Collettini F, Gebauer B, de Bucourt M. Investigation: de Bucourt M. Resources: Hosse C. Software: Hosse C, Can E, Fehrenbach U. Supervision: de Bucourt M.

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Appendix 1. Exoskeleton Survey

1. What intervention was performed?
 - Tunneled catheter system implantation
 - Percutaneous transluminal angioplasty stent implantation
 - Port implantation
 - Peripherally inserted central catheter implantation
 - Embolization
 - Computed tomography guided intervention
 - Angiography
2. How long did the procedure take (from local anesthesia to pressure dressing)?
 - 1–15 minutes
 - 15–30 minutes
 - 30–45 minutes
 - 45–60 minutes
 - More than 60 minutes
3. Did you perform the operation yourself or were you the proctor?
 - Performed by myself
 - Proctor
4. How satisfied were you with the StemRad MD Exoskelektion?
 - Very satisfied
 - Slightly satisfied
 - Neither satisfied nor dissatisfied
 - Slightly dissatisfied
 - Very dissatisfied
5. How likely is it that you will recommend the exoskeleton system to a friend or colleague?
 - Unlikely in any case
 - Unlikely
 - Maybe
 - Very likely
 - In any case
6. How comfortable was the Exoskelett system during the procedure?
 - Comfortable
 - Not comfortable
7. What was the weight of the exoskeleton system during surgery?
 - Too heavy
 - Not too heavy
8. Has your range of motion been limited by the exoskeleton system?
 - Yes
 - No
9. Did you have any problems with the exoskeleton system during the procedure?
 - Yes
 - No
10. Did it take long to put on/take off the exoskeleton?
 - Yes
 - No
11. Did other colleagues have enough space at the intervention table?
 - Yes
 - No
12. Did you use the Visor?
 - Yes
 - No
13. Did you have problems with the components you used?
14. Did you have problems with the movement of the components used?
15. Additional comments