Attachable Radiation Reduction Extension Support Sheath (ARRESS) to Reduce Radiation Exposure for Endovascular Specialists

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Studies show that ionizing radiation exposure in the US rose 74% (per capita) from the early 1980s to 2006 and half of that exposure can be attributed to medical imaging[1]. Little attention has been paid to the safety and well-being of medical professionals who experience significant cumulative radiation exposure during their career. Professionals who are more consistently exposed to low-levels of radiation have reported increased rates of various medical issues like reports of malignant brain left-sided brain tumors in interventional cardiologists that have been shown to correlate to their proximity to the radiation source in the cath lab[2]. Other recent papers have gone on to show and summarize findings that sustained exposure to low-dose radiation is causing several other serious adverse health issues for interventional medical teams[3].

Percutaneous treatment of peripheral artery disease (PAD) and endovascular aneurysm repair (EVAR) rates have risen dramatically over the last decade even to the point where they outnumber open surgical procedures[4,5] and this is a trend that we will likely see continue in the future as newer, more sophisticated technologies are made available that increase the pool of patients amenable to such procedures. Studies of PAD estimate a 3-10% prevalence in the general population and as high as 20% in people older than 70 years[6]. Armed with the knowledge of the increasing health problems seen in other fields that have already spent years exposed to low-levels of ionizing radiation in the fluoroscopy suite and knowing that vascular surgeons will only be increasing their time spent in the fluoroscopy suite given disease prevalence and technological advancement, it is important for vascular surgeons to learn from those experiences and always be cognizant of these risks as their time in the endovascular suite will surely increase throughout their careers.

It is known that ionizing radiation can alter the structure of DNA and can cause serious adverse health effects like cancer, cataracts, benign tumors and cellular damage in reproductive organs[7,8]. These are considered stochastic adverse health effects, which are long-term and chronic health effects due to recurrent, low-doses of ionizing radiation like the type encountered by health professionals. The concerning part of this is that there is no safety threshold for long-term exposure to low levels of radiation[8]. The Environmental Protection Agency (EPA) has found that there is a linear dose-dependent response in terms of radiation exposure and stochastic health effects[8]. Others, like the Biological Effects of Ionizing Radiation Committee sponsored by the National Research Council, have come to the same conclusion that even very low-doses of ionizing radiation exposure present a risk of developing cancer[7]. Procedures using interventional fluoroscopy, like in EVAR and percutaneous treatment of PAD, are the leading source of occupational ionizing radiation exposure for medical personnel[8]. In contrast to medical personnel in other radiation-based diagnostic procedures, interventionalists and interventional staff are typically not able to exit the room to avoid radiation exposure. Interventional teams have the greatest risk of exposure to ionizing radiation[9] as they are typically located within four feet of the radiation source. Radiation exposure during individual procedures is usually below the threshold for acute radiation effects but our concern, as previously mentioned, is that there is no threshold for safe recurrent, low-level radiation exposure so that interventionalists may

receive enough radiation exposure over their entire career to be concerned over the possible long-term health effects. Studies have reported a link between low-level radiation exposure and a number of adverse health effects, like brain tumors[10], skin cancer[11], cataracts precursors[12], thyroid disease[13] and neuro-degenerative disease[14].

The Occupational Safety and Health Administration (OSHA) is authorized to regulate exposure to ionizing radiation from medical imaging devices during procedures performed in the hospital setting. OSHA's ionizing radiation exposure limits were set in 1971 and were based on limits set by the Atomic Energy Commission in the late 1960s, they have not been updated since then so do not take into account interventional procedures that were first conducted in the US in the late 1970s and weren't widely used until the 1990s. OSHA has established ionizing radiation limits for the whole body and specific anatomy, not including the eye lens, but in 2005 OSHA recognized that their guidelines may be antiquated and obsolete so they requested information regarding ionizing radiation exposure but no action has been taken since that request for information over 10 years ago. The United States Nuclear Regulatory Commission (NRC) has its own set of guidelines for ionizing radiation exposure which are a bit more stringent than OSHA's regulations and also include a limit for exposure to the eye lens. In recent years, the NRC has also requested new information to consider a revision to the eye limit but no formal change has been proposed. Outside of the US, many First World countries follow the recommendations set by international bodies like the International Council of Radiation Protection (ICRP). In contrast to OSHA and the NRC, the IRCP updates its guidelines regularly as new scientific information is discovered and currently its guidelines are much more stringent than OSHA and NRC (*Table 1*)[3].

Anatomy		**Annualized Exposure Limit (rems)**	
	NRC	**OSHA**	**ICRP**
Whole Body	5	5	2
Lens of Eyes	15	*Included in whole body*	2
Skin of whole body	50	30	--
Hands and forearms, feet and ankles	--	75	50

Table 1. Comparison of ionizing radiation exposure limits recommended by the Nuclear Regulatory Committee (**NRC**), the Occupational Safety and Health Administration (**OSHA**) and the International Council on Radiation Protection (**ICRP**).

Current safety measures for ionizing radiation exposure are based on a principle called ALARA, or "as low as reasonably achievable."[15] Ways to implement ALARA include the use of personal protection equipment (PPE), radiation shielding and dose optimization. Radiation shielding and dose optimization require a re-design of interventional suites and new technology to better protect medical professionals while still offering the immediate benefit to our patients. PPE is designed to shield medical professionals from ionizing radiation exposure in the interventional suite, but this relies on the willingness of the professionals to consistently and

correctly wear the equipment. This can be quite cumbersome when considering PPE includes lead-aprons, thyroid collars, face masks, eyewear and gloves. And the equipment a person uses must be properly fitted and maintained to ensure it remains effective. Even when worn correctly there is still concern over unprotected areas like the arms, sides of the eyes and the head and neck area. There is also concern that the long-term use of PPE can cause chronic pain and other severe musculoskeletal and orthopedic conditions affecting the spine, neck, hips, knees and ankles[16]. Due to the physical effects of PPE, practitioners may not always wear all of the recommended PPE and even when they do they are still exposed to the low levels of ionizing radiation that may cause the previously mentioned long-term health effects. Relying too heavily on PPE leaves medical professionals in a vulnerable position.

Due to the problems associated with PPE, reducing ionizing radiation exposure would do better to focus on non-PPE safety measures. This may include complete re-design of interventional suites, new technology with decreased radiation and in the future even newer technologies with non-radiation sources for imaging. An overhaul of this size and magnitude will take years of work and innovations and quite a hefty investment from regulatory committees. An easier and more readily-achievable way to reduce radiation exposure to medical professionals is with newer devices that serve to distance providers from the radiation energy source. If long-term health effects are the result of the accumulated radiation exposure experienced over an entire career, every measure that reduces radiation exposure even a small amount may add up to a large decrease of lifetime radiation exposure and may serve to decrease the likelihood of serious chronic health problems. Devices that are simple to implement that help distance the operator from the radiation source include extension sheaths that can be used with medical devices already on the market. One such device is the "Attachable Radiation Reduction Extension Support Sheath" or ARRESS, which we used in our study to assess and compare ionizing radiation exposure to operators when conducting a common procedure with a standard introducer sheath alone and with a standard introducer sheath with the ARRESS attached.

Endovascular procedures access patient vessels through a vascular sheath. Standard vascular sheaths are typically 4-10 centimeters in length with the hub of the sheath just external to the surface of the skin. This position puts the hands of the operator close to, or even within, the primary radiation beam throughout the duration of the procedure. The ARRESS incorporates a novel design with a malleable sheath attachment. The shape of the sheath extender may be configured in various orientations to facilitate an intervention in the optimal workflow in the operating room environment. As the operator's hand will be further away from the primary radiation field, use of ARRESS may reduce radiation exposure, in addition to improving posture and workflow during the procedures. The ARRESS is comprised of a universal distal connection hub, sheath intermediary, and proximal hemostasis valve having side--- arm tubing with a three---way stopcock (Figure1). It includes a securement clasp to position the ARRESS sheath in the desired shape. The securement clasp includes an adhesive back so that it may be attached to the sterile drape, patient, or other object associated with the patient (Figure 2). Examples of the ARRESS sheath placed in a variety of curvatures are shown in Figure 3.

Figure 1. ARRESS Sheath

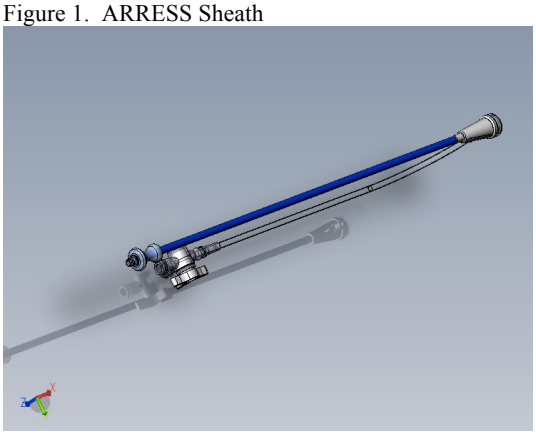


Figure 2. ARRESS Securement Clasp

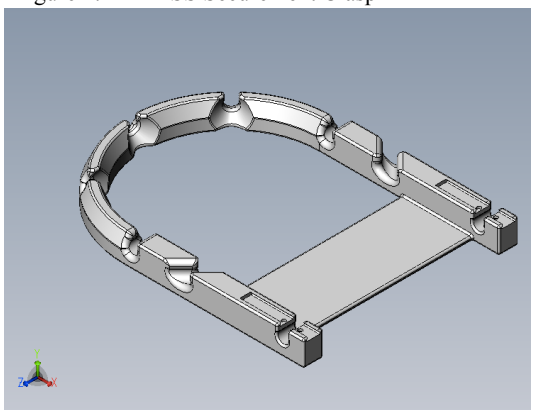
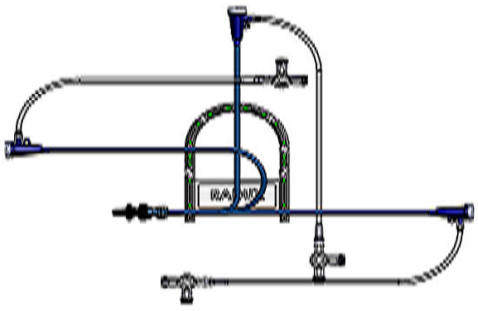


Figure 3. ARRESS Sheath Positioned in a Variety of Curvatures with Securement Clasp



METHODS

Animal Model Selection and Preparation:

Testing was conducted in domestic swine, which is generally the accepted model for studying this device type. The interventional testing procedure in porcine superficial femoral arteries correlates with similar procedures in humans. This specific interventional approach best mimics the technical problems encountered when treating human superficial femoral artery and arteriovenous fistula stenosis. Specifically, this model allows for antegrade arterial intervention of superficial femoral arteries in humans and treatment of an arterial anastomotic stenosis from an AV fistula during endovascular dilation.

When determining the numbers of animals to be tested, the following factors were considered:

- Femoral artery access would be obtained on both sides
- The test and control devices would be tested on each side (4 part procedure)
- During each of the 4 part procedure the arteries in the limb would undergo angioplasty and stenting

Upon considering the invasive nature of the procedure, including the potential for vasospasm, it was decided that one animal would be used for each participating operator. This was the minimum number of animals necessary to generate valid data to demonstrate reasonable performance.

Before entry into the study, all animals were certified healthy and free from disease using proper veterinary practice. Animals used had the following characteristics:

- Species: Domestic swine
- Weight: 50 kg (range: 45.9 – 58.2 kg)
- Gender: 4 Female; 3 Male

In preparation for the procedure, the swine were fasted overnight. The animals were anesthetized with an intramuscular (IM) injection followed by atropine give IM to dry oral-tracheal secretions and to prevent bradycardia during the procedure. Inhalation anesthesia (isoflurane) was administered. All animals were secured in a supine position with extremities extended. The four part procedure was performed and upon completion, all animals were euthanized by intravenous injection.

Operator Selection:

Seven physician operators were selected based on their various experience in endovascular and interventional procedures. Operators included two vascular surgeons, two interventional nephrologists and three interventional radiologists. Operators were exposed to radiation levels normally experienced during procedures, the study was reviewed and approved by the IRB.

Procedure:

1. A sterile field was prepared according to the animal facility's standard procedure.
2. Two video cameras were placed in the room at orthogonal (90 degree) angles for recording purposes.
3. Animals were anesthetized, intubated and ventilated per standard procedure. Heart rate and SpO2 were recorded at 10 minute intervals and there was continuous monitoring of ECG, heart rate and SpO2 throughout the procedure.
4. Operators wore radiation monitors as described in the following sections. They then gowned and gloved as normal.
5. A standard arterial sheath was placed percutaneously in an antegrade fashion into both femoral arteries using ultrasound guidance and micropuncture technique.
6. Start time was called.
7. Three-way stopcock of vascular access sheath was aspirated and flushed.

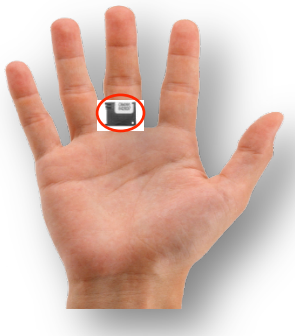
8. Digital subtraction angiography (DSA) of access sheath confirmation was performed at the right thigh and through runoff vessels.
    a. 2 separate runs
    b. 3 frames per second frame rate
    c. Automated dosing from GE 9800 fluoroscopy machine
9. A 0.035 inch x 180 cm angled glide wire was placed through a 4 Fr angled catheter, both of which were placed antegrade through the vascular access sheath.
10. The wire and catheter were then advanced past the popliteal artery and into runoff vasculature.
11. The wire was removed and confirmatory DSA was performed (3 fps, PVD dosing algorithm GE 9800 OEC).
12. The 4 Fr catheter was exchanged for a 0.014 inch x 300 cm stability wire.
13. DSA at the superficial femoral artery was performed.
14. Over the wire exchange for a 5-8 mm x 1-4 cm x 75-135 cm shaft angioplasty balloon. The balloon was inflated to 8 mmHg for 30 seconds, deflated and removed over the wire.
15. DSA was repeated.
16. 0.018 inch 508 mm x 15-40 mm self-expandable stent on 135 cm shaft was then placed over wire into the right SFA.
17. The self-expandable stent was deployed and removed over the wire while maintaining wire access.
18. The stent was post-dilated with the same angioplasty balloon that was used in Step 14 for 30 seconds at 8 atm.
19. The balloon was deflated and removed.
20. DSA was repeated and the sheath was flushed.
21. Stop time was called (**End of Part 1**).
22. Radiation monitors were removed from the operators.
23. The entire procedure (Steps 5-22) was repeated on the right using the ARRESS sheath connected to the previously placed sheath (**Part 2**) and included the following additional operations:
    a. The ARRESS sheath was prepared and attached to the sheath following the "Instructions for Use."
    b. The securement clasp was attached to the drape in the operator-selected position for workflow redirection with the ARRESS sheath.
24. Steps 6-22 were repeated on the left side (**Part 3 sheath alone**).
25. Steps 6-23 were repeated on the left side (**Part 4 sheath with ARRESS**).

Radiation Exposure Measurements:

Radiation dose to the physician's extremities (right and left hand) were monitored. In addition, whole body dose was measured as is standard in endovascular procedures. Extremity doses were measured placing a NanoDot^{TM} Optically Stimulated Luminescent dosimeter (Landauer, Inc., IL, USA) on the proximal side of the middle finger on both the right and left hands prior to gloving (Figure 4).

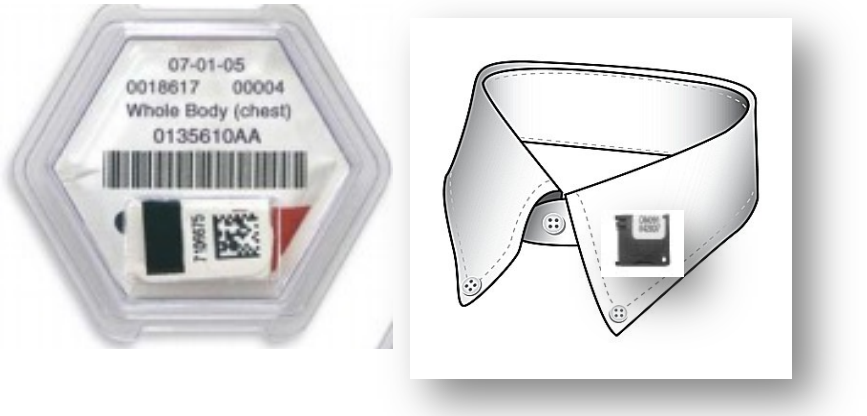
Figure 4. NanoDot^{TM} placed on the proximal

side of the middle finger prior to gloving.



The whole body dose was measured using both a NanoDot and a standard Luxel+ (Landauer, Inc., Glenwood, IL, USA) (Figure 5) on the outside of the lead apron on the collar area. After each part of the procedure, all dosimeters were removed and replaced with new dosimeters.

Figure 5. Luxel+ dosimeter badge worn on the apron and a NanoDot dosimeter worn on the collar.



The nanodots were measured for radiation dose using a microSTAR ii medical dosimetry system (Landauer, Inc., Glenwood, IL, USA) calibrated for diagnostic photon energies while the Luxel+ dosimeter badges were sent to Landauer for measurement. Readings from both the nanodots and dosimeters were used to derive the average whole body dose.

Radiation dose to the extremities and whole body are reported in radiation dose received (millirem or mrem) and the radiation dose normalized by the Dose Area Product (DAP) recorded for that part of the procedure the dosimeters were exposed. The DAP (rad-cm^2) is a measure of the amount of radiation imparted t the operator with essentially the same geometry and field of view used (e.g., twice the DAP reading implies twice the amount of radiation used). The normalized dose vale, mrem/(rad-cm^2), helps minimize the various confounding factors that could contribute to an increased dosimeter reading but that were not related to the use of a

particular device. For example, radiation exposure may be increased during the use of a device due to vasospasm that was present prior to use of the device leading to difficulties in device placement and need for increased fluoroscopic imaging.

RESULTS

Extremity Radiation Exposure

The extremity doses were measured bilaterally at the hand. The average measured dose was 15.2 mrem without the ARRESS device and 11.1 mrem using ARRESS resulting in a 27% average dose reduction when using ARRESS. In most cases, a dose reduction can be observed using the ARRESS device. This is to be expected since the use of ARRESS device places the physician's hands further away from the radiation source resulting in a lower radiation dose rate field.

However, the extremity doses for one physician were higher using the ARRESS device (Note: one of the radiation dosimeters was also lost for this particular physician). If this apparent outlier is excluded from analysis, the average dose is 15.1 mrem without ARRESS and 8.7 mrem with ARRESS, resulting in a 43% dose reduction.

Radiation dose was also normalized by the Dose Area Product (DAP). As discussed earlier, this normalized value was used to minimize the confounding factors that may have affected the radiation dose irrespective of use of the ARRESS device. The average normalized dose was 0.30 mrem/(rad-cm^2) without ARRESS and 0.23 mrem/(rad-cm^2) with ARRESS resulting in a 24% dose reduction. If the physician with higher extremity doses using the ARRESS with higher extremity doses using the ARRESS device is excluded, the average without ARRESS is 0.28 mrem/(rad-cm^2) and with ARRESS is 0.19 mrem/(rad-cm^2), resulting in a 32% reduction.

A summary of average extremity dose is provided in Table 2.

Table 2. Average Extremity Dose

	Average Nanodot Dosimeter Reading (mrem)	Average NanoDot Reading Normalized by DAP [mrem/(rad-cm2)]
Without ARRESS	15.2	0.3
With ARRESS	11.1	0.23
% Reduction	27%	24%
p-value	0.21	0.27

Whole Body Radiation Exposure

The average measured dose was 5.2 mrem without the ARRESS device and 4.4 mrem with the ARRESS device, resulting in a 14.5% dose reduction. The radiation doses to the whole body badges are lower than the extremity badge, as was the dose reduction. This was expected since the whole body badge is further away from the radiation source. In fact, a large reduction in radiation would be expected because operators remain standing in the same place. Excluding the whole body doses for the one physician with higher extremity doses using the ARRESS device minimally affected the dose reduction (14.2% versus 14.5%).

The whole body radiation dose normalized by DAP was 0.103 mrem/(rad-cm^2) without the ARRESS and 0.085 mrem/(rad-cm^2) with the ARRESS resulting in a 17.9% reduction. If the physician with higher extremity doses using the ARRESS device is excluded, the average without ARRESS is 0.091 mrem/(rad-cm^2) and with ARRESS is 0.081 mrem/(rad-cm^2) resulting in an 11% reduction.

A summary of average whole body dose is provided in Table 3.

Table 3. Average Whole Body Dose

	Average Nanodot Dosimeter Reading (mrem)	Average NanoDot Reading Normalized by DAP [mrem/(rad-cm2)]
Without ARRESS	5.2	0.103
With ARRESS	4.4	0.085
% Reduction	15%	18%
p-value	0.16	0.26

DISCUSSION

Given the recent increase in attention to health concerns related to long-term low-dose radiation exposure, our study was designed to assess the effects of a new device, the ARRESS sheath, on physician radiation exposure experienced during a common procedure. Medical device design, development and commercialization utilizes both quantitative and qualitative measure. Quantitative data is commonly used to assess procedure success and patient outcomes. Our study measured several reproducible quantitative data points to judge the radiation exposure reduction experienced when using the ARRESS. Results demonstrate the ARRESS yields occupational health benefits secondary to reducing ionizing radiation exposure when compared to procedures with standard equipment alone. The addition of a few simple steps to a procedure adds up to greatly decreased radiation exposure over the length of an entire career and possibly

greatly reduces the chances of serious long-term health problems caused by chronic radiation exposure.

During this study, operators were allowed to place the ARRESS device in the location and configuration of their choice. Radiation dose reduction was observed, but was variable, likely due to ARRESS placement and other confounding factors that led to the need for increased imaging. DAP analysis was used to minimize the effects of confounding factors. Using this method, radiation to the extremities was reduced up to 32% when using ARRESS. If ARRESS is placed in a straight configuration away from the radiation source, inferring from the inverse square law of radiation physics (dose reduction = 1/distance squared in feet), the radiation dose reduction expected with the 24 cm extension sheath will decrease the operators' extremity dose by 70% compared to operators using standard vascular access working 12 inches from the image intensifier beam; not uncommon with endovascular procedures.

Admittedly, the radiation exposure reduction per procedure is measured in very small values. Per procedure, the overall reduction is minimal so there may appear to be only minimal benefit from using an extension device to like the ARRESS. The reason that even these very small reductions are important and should matter to each physician practicing in the endovascular suite is that as previously-stated, there is no safe amount of low-dose radiation exposure. There is no way to say that any certain amount is safe and won't cause serious long-term health detriments. Experts agree that there is a linear dose-dependent response in terms of radiation exposure and stochastic health effects[8] so reducing radiation exposure during every procedure over the span of an entire career has the potential to seriously reduce the chances of negative health effects due to ionizing radiation. It is clear that the governing bodies looking out for the safety of medical staff are working with antiquated policies and have been unable to keep pace with medical innovations. This means that the onus is on medical professionals to protect themselves. Endovascular surgeons and interventionalists must push for more research into ways to improve safety in the endovascular and interventional suite and must be open to using new devices and methods that are steps on the right path for physician safety.

CONCLUSION

Quantitative analyses of extremity and whole body radiation exposure during standard endovascular procedures identify a beneficial trend of decreased physician radiation exposure when using ARRESS compared to standard practice. Although our study did not attain statistical significance, results are promising and indicate a need for further investigations.

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