

Salus Scientific

Clinical Insights Series

The AeroShield™ Clinical Evaluation at Tallahassee Memorial Healthcare

Early Clinical Experience and Establishing a Clinical Benchmark for Occupational Radiation Dose Per Case

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Executive Summary

Occupational scatter radiation exposure remains an unavoidable reality for physicians and staff performing fluoroscopically guided procedures. While traditional studies have focused primarily on percentage reductions of enhanced radiation protection devices (ERPDs) compared with conventional shielding, these comparisons do not fully answer the two questions that matter most to physicians, radiation safety teams, and healthcare organizations:

- What level of occupational radiation exposure (for everyone in the lab) should we expect during a typical procedure?
- Can an ERPD be used *consistently* throughout every procedure without disrupting workflow?

The AeroShield™ formative evaluation at Tallahassee Memorial Healthcare was designed to begin answering both questions. In addition to establishing **occupational dose per procedure** as a clinically meaningful endpoint, the study evaluated whether AeroShield could remain in use throughout the entire procedure across a broad range of case types while integrating naturally into routine clinical practice. This approach provides physicians, radiation safety officers, and hospital leaders with practical evidence that extends beyond radiation reduction alone and reflects how a protection system performs in the real world.

Key Clinical Findings

Low Occupational Dose Per Procedure:

Average occupational exposure with AeroShield was:

Primary Operator: **0.83 mrem per case** (p<0.001)

Scrub technologist: **0.23 mrem** (p<0.001)

Sedation nurse: **0.09 mrem** (p<0.001)

Circulator: **0.01 mrem** ($p < 0.26$, not statistically significant)

Occupational dose measurements were normalized to Dose Area Product (DAP) to account for differences in procedural radiation output and case complexity.

These findings demonstrate consistently low occupational radiation exposure across the procedural team while using AeroShield. Statistically significant reductions were observed for the primary operator, scrub technologist, and sedation nurse. Although the circulator experienced a very low average dose (**0.01 mrem** per case), the difference compared with conventional shielding was not statistically significant ($p = 0.26$). This was likely influenced by the already low baseline exposure at the circulating position and the limited sample size of this formative study.

For physicians performing 300 fluoroscopically guided procedures annually, the observed occupational exposure using AeroShield would total approximately **248 mrem per year**, representing only **5.0% of the current annual occupational dose limit of 5,000 mrem**. These findings demonstrate that low occupational dose per procedure can translate into meaningful reductions in cumulative annual radiation exposure while maintaining procedural versatility and seamless workflow integration.

Procedural Versatility:

AeroShield was successfully used in **100% of consecutive study procedures**, including diagnostic coronary angiography, PCI, right heart catheterization/structural procedures, and peripheral interventions. This demonstrates that the system can provide continuous protection across a diverse procedural mix rather than being limited to selected cases or procedural steps.

Workflow Integration

The clinical team reported minimal impact on patient preparation, room turnover, or patient access, while achieving proficiency after approximately **one to two procedures**.

Why This Evaluation Matters

Engineering controls should be evaluated by more than their ability to reduce radiation.

For meaningful clinical adoption, they must also:

- Deliver consistently low occupational dose
- Remain usable throughout virtually every procedure
- Integrate naturally into existing workflow

The Tallahassee experience demonstrates that these objectives can be achieved simultaneously, providing a practical framework for evaluating engineering controls in procedural medicine.

Background

Occupational scatter radiation continues to expose physicians, nurses, technologists, and imaging staff during every fluoroscopically guided procedure. Traditional shielding methods remain an important component of radiation protection; however, their effectiveness often depends on continual repositioning, staff compliance, and procedural ergonomics. At the same time, clinicians continue to experience cumulative radiation exposure over the course of their careers despite these protective measures.

AeroShield was developed as a passive ERPD designed to provide consistent protection while preserving procedural access and workflow. Rather than requiring continual adjustment during a case, AeroShield is intended to remain integrated into the procedural environment, allowing clinicians to focus on patient care while maintaining protection for the procedural team.

The Tallahassee Memorial Healthcare evaluation represents Salus Scientific's first prospective formative clinical experience with AeroShield and serves as the foundation for the company's expanding multicenter evidence-generation program.

Clinical Evaluation

Study Site: Tallahassee Memorial Healthcare

Principal Investigator: William Dixon, MD

Objectives

The formative evaluation sought to answer three fundamental questions:

1. What occupational radiation dose is experienced by physicians and staff during routine procedures using AeroShield?
2. Can AeroShield remain in use throughout a wide variety of procedures?
3. Can these benefits be achieved without disrupting procedural workflow?

Study Design

- Prospective observational evaluation
- 61 consecutive procedures
- Traditional shielding comparison
- Four monitored staff positions

- External dosimetry normalized to Dose Area Product (DAP)
- Coronary, PCI, right heart, and peripheral procedures

Importantly, procedural complexity was comparable between groups, with no significant difference in DAP between shielding configurations.

Clinical Results

Occupational Dose Per Procedure

One of the most important outcomes from the Tallahassee evaluation was establishing occupational dose benchmarks for routine clinical practice.

<u>Clinical Role</u>	<u>Mean Occupational Dose per Procedure</u>
Primary Operator	0.83 mrem (p<0.001)
Scrub Technologist	0.23 mrem (p<0.001)
Sedation Nurse	0.09 mrem (p<0.001)
Circulating Nurse	0.01 mrem (p<0.26, not statistically significant)

These values provide hospitals and physicians with practical expectations for occupational exposure while using AeroShield and establish reference points for future multicenter investigations.

Dose in Perspective*

- Flight New York to San Francisco: ~3.5 mrem
- Typical chest x-ray: ~10 mrem
- Average natural background radiation in the United States: ~360 mrem/year

**approximate context only, since occupational effective dose, cosmic-radiation exposure, and patient medical exposure are not directly equivalent*

For physicians performing **300 fluoroscopically guided procedures annually**, the observed occupational exposure using AeroShield would total approximately **248.4 mrem** per year, representing only **5.0% of the annual occupational dose limit of 5,000 mrem without personal lead protection.**

For the scrub tech position and sedation nurse positions, the observed annual occupational exposure with AeroShield in place at 300 procedures would total 69 and 28 mrem per year respectively, representing 1.2% and 0.6% of the annual occupational dose limit.

If a light lead option was chosen for all positions (0.25mm Pb equivalent), at 300 procedures per year, the exposure would be:

Primary Operator **97.3 mrem** (1.9% annual occupational dose)

Scrub Technologist **27.3 mrem** (0.5% annual occupational dose)

Sedation Nurse **10.4 mrem** (0.2% annual occupational dose)

These findings demonstrate that low occupational dose per procedure can translate into meaningful reductions in cumulative annual radiation exposure while maintaining procedural versatility and seamless workflow integration.

Procedural Versatility

Radiation protection only creates value when clinicians choose to use it consistently.

Throughout the Tallahassee evaluation, AeroShield remained in use during **100% of consecutive procedures**, demonstrating compatibility across:

- Diagnostic coronary angiography
- Percutaneous coronary intervention (PCI)
- Right heart catheterization
- Peripheral vascular interventions

This finding suggests that AeroShield can become a standard component of routine procedural workflow rather than a technology reserved for selected case types.

As Salus expands its evidence program, future studies will evaluate procedural versatility in electrophysiology, structural heart, neuro intervention, interventional radiology, vascular surgery, and mobile C-arm environments.

Workflow Integration

Successful engineering controls must support—not interrupt—the clinical workflow.

Staff surveys demonstrated:

- **94%** reported no additional pre-procedure preparation time.
- **94%** reported no impact on room turnover efficiency.
- **95%** reported no impact on patient access or communication.
- **100%** indicated they would continue using AeroShield in its current form.

Equally important, the learning curve was remarkably short. Most physicians and staff became comfortable using AeroShield after approximately **one to two procedures**, supporting rapid implementation into routine practice.

By shifting the focus from percentage reduction alone to **occupational dose per procedure, procedural versatility**, and **workflow integration**, Salus Scientific aims to establish a clinically relevant framework for evaluating ERPDs and advance the standard of occupational radiation protection across procedural medicine.

Investigator Perspective

Occupational radiation exposure has always been something we accepted as part of practicing interventional cardiology. As procedures become increasingly complex, we have a responsibility to find better ways to protect not only physicians, but the entire procedural team.

What impressed me most was how quickly AeroShield became part of our normal workflow. After the first couple of cases, the team wasn't thinking about the device, they were simply focused on the patient. That's important because the best safety technology is the technology clinicians will use.

Equally important was the System's versatility. We were able to use AeroShield across our routine procedural mix without feeling like it was only appropriate for certain cases or certain portions of a procedure. That consistency is essential if you're going to meaningfully reduce occupational exposure over the course of a career.

My advice to other hospitals is simple: approach the first few cases as a learning experience, involve the entire team, and commit to using the system consistently. Once everyone becomes familiar with the workflow, you'll have a much better appreciation for how naturally AeroShield fits into everyday clinical practice while providing meaningful protection for everyone in the room.

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