

Improved Radiation Protection With The PROTEGO SYSTEM: How does it work and results


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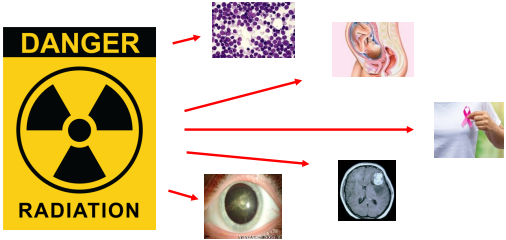



Disclosures



- I have no relevant disclosures



The Lead Apron Is Less Than a Pure Cure






The Lead Apron Is Less Than a Pure Cure

The Exposure Data Is Cause for Concern

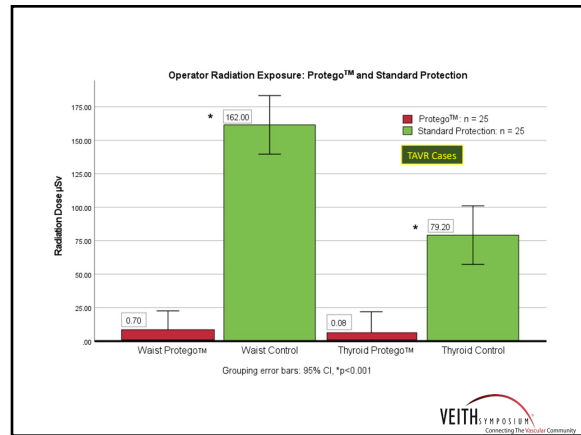
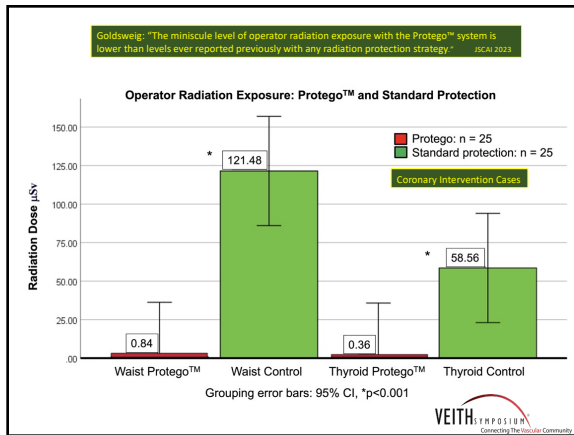
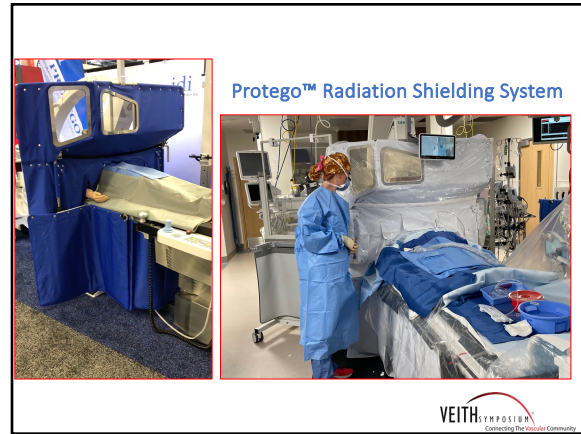
- 1) An interventional cardiologist is exposed to an estimated 50 mSv-200 mSv of ionizing radiation over the course of a career.
- 2) This equates to a lifetime "whole body exposure" of 2,500-10,000 chest X-rays.
- 3) The **brain** has the greatest exposure to the radiation beam.
- 4) The career exposure to the head has been estimated at an equivalent of 25,000 to 50,000 chest X-rays.
- 5) TAVR and structural heart cases have the highest exposure.
- 6) Complex PCI now accounts for ≈ 40% of all PCIs.
- 7) Radial access grew 13-fold last 5 years.

1. Picano. Brain and eye effects of chronic low-dose ionizing radiation exposure. BMC Cancer. 2012.
2. National Cardiovascular Data Registry (2007-2012). Circulation. 2013;127:2295-2306.
3. Andreassi et al. Occupational Health Risks in Cardiac Cath Lab Workers. Circ Interventions 2018.

Novel Radiation Barrier Systems





Original Research
Comprehensive Radiation Shield Minimizes Operator Radiation Exposure and Distraction for Lead Aprons
David G. Rusk, MD¹, Robert D. Wiley, MD², Robert F. Burke, MD³, Sabrina R. Kasan⁴, Ariana M. Nigoghossian⁵, Kevin F. Gosselin, PhD⁶, James A. Goldstein, MD⁷

ABSTRACT
Coronary Intervention Cases

Background: The comprehensive radiation shielding system (Protego™) has been shown to reduce operator radiation exposure and distraction for lead aprons. The purpose of this study was to evaluate the efficacy of the Protego™ system in reducing operator radiation exposure and distraction for lead aprons during coronary intervention cases. The primary endpoint was the mean operator radiation exposure (µSv) during coronary intervention cases. The secondary endpoint was the mean operator radiation exposure (µSv) during TAVR cases. The tertiary endpoint was the mean operator radiation exposure (µSv) during structural heart procedures. The results of this study will be presented at the JSCAI 2023 meeting.

Two Publications in JSCAI on
Coronary and Structural Interventions

Original Research
Comprehensive Shielding System Enhances Radiation Protection for Structural Heart Procedures
David G. Rusk, MD¹, Robert F. Burke, MD, Sabrina R. Kasan, Ariana M. Nigoghossian, Robert D. Wiley, MD, Kevin F. Gosselin, PhD, James A. Goldstein, MD

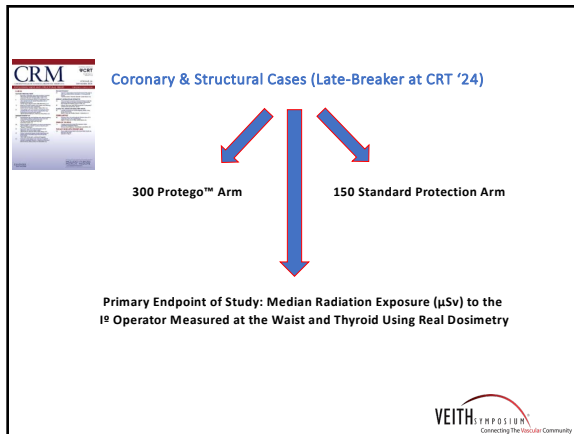
ABSTRACT
TAVR Cases

Background: The comprehensive radiation shielding system (Protego™) has been shown to reduce operator radiation exposure and distraction for lead aprons. The purpose of this study was to evaluate the efficacy of the Protego™ system in reducing operator radiation exposure and distraction for lead aprons during TAVR cases. The primary endpoint was the mean operator radiation exposure (µSv) during TAVR cases. The secondary endpoint was the mean operator radiation exposure (µSv) during coronary intervention cases. The tertiary endpoint was the mean operator radiation exposure (µSv) during structural heart procedures. The results of this study will be presented at the JSCAI 2023 meeting.

450 Patient Trial: Protego® vs Standard Protection

Largest Comparative Trial Published to Date

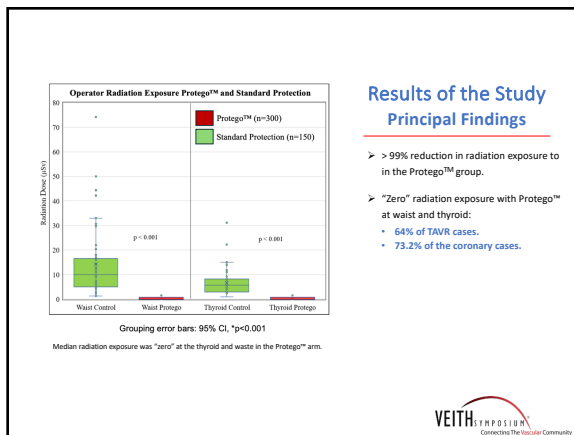
- This study evaluated the efficacy of a novel comprehensive shield system (Protego™) designed to minimize radiation exposure to physicians performing coronary and structural heart procedures.



Protego™ Median Exposure at the Waist and Thyroid

Aggregate Coronary & Structural Cases (LHC/PCI/TAVR)	Waist		Thyroid	
	Protego™	Standard Protection	Protego™	Standard Protection.
Number	300	150	300	150
Median	0.00	10.00	0.00	5.70
Percentiles	25	0.00	0.00	2.90
	50	0.00	0.00	5.70
	75	0.00	16.60	0.00

operator radiation dose with multiple comparison tests on the case participants resulting in an adjusted alpha of 0.001 (0.001/1000). Data were screened for parametric distribution. Histograms and normality tests were conducted for waist (Protego™: 0.99, p < 0.001 and Standard Protection: 0.99, p < 0.001) and thyroid (Protego™: 0.99, p < 0.001 and Standard Protection: 0.99, p < 0.001). Results of the Shapiro-Wilk test indicated significant non-normality for the Protego™ group compared to the Standard Protection group at the waist ($p = 0.001$) and thyroid ($p = 0.001$). Median levels of measured radiation exposure were zero in both the Coronary only and Structural only cases, with adjusted p-values for both comparisons at less than 0.001.



Implications of These Data

OSHA Federal Standards Set the Maximum Annual Allowable Occupational Radiation Exposure at 5 rem/annum (5,000 mrem/annum).

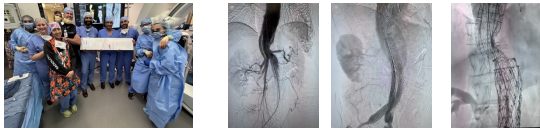
- Extrapolating from the present mean waist/case RE data (employing the standard mathematical conversion of μ Sv to mrem/case), a "Busy" Interventionist could perform 400 cases/year and be exposed to approximately only 0.5% of the allowable limit.
- A "high volume" Interventionist performing 1,000 cases/annum would receive 1.26% of the recommended annual allowable.

- Parting Shots...**
- Based on these two smaller published series, Protego™ system provides exceptional total body RE protection allowing operators to perform procedures without the need for personal protective equipment (PPE).
 - Protego™ has the potential to reduce catheterization laboratory occupational health hazards.
 - Further study is needed to assess its role in electrophysiologic and vascular procedures.
 - Further device iteration will be required to afford protection for collaborating members of the Heart Team (anesthesiologist and echocardiographer).
 - The larger series of nearly 500 patients will be presented as a "Late Breaker" at CRT in Washington DC next month.

Challenges in Endovascular Repair of Complex Abdominal Aortic Aneurysms

FDA Approved Endografts for Complex Abdominal Aneurysm

- Cook Zenith Customized Fenestrated Graft
- TAMBE



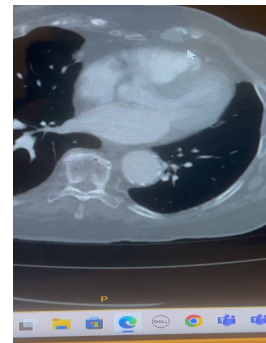
Case 1:

First Ever case using FORS and EGG Medical

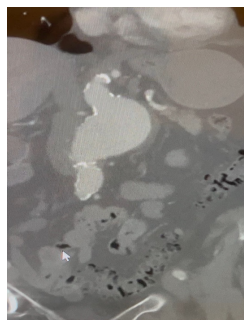
- 81yr old female with abdominal pain/epigastric tenderness
- Symptomatic 5.4 cm pararenal abdominal aortic aneurysm
- Severe COPD on home oxygen
- CAD : Coronary stents , EF 42%
- Prohibitive risk for open surgery
- Complex AND Technically Challenging Endovascular Option



Pre op CT



Pre op CT

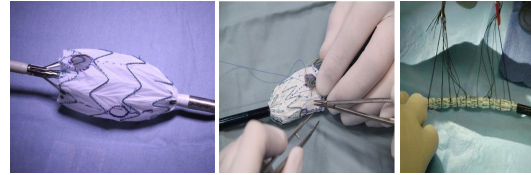


Plan

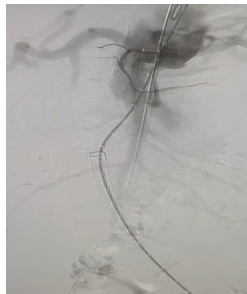
- High Risk
- Conservative Treatment Discussed/Leave well alone
- Not a candidate for FDA approved Devices
- PMEG....TERUMO TREO GRAFT
- FORS...(Image Guided Therapy)
- EGG MEDICAL....(Radiation Protection System)



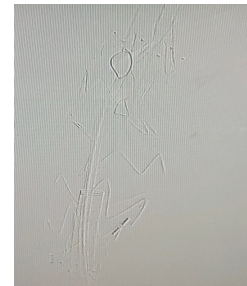
Back Table GRAFT Modification



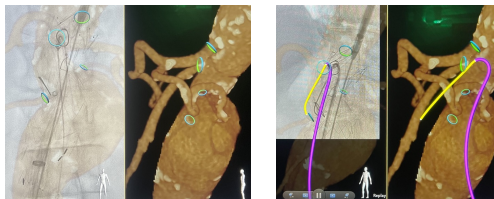
AORTOGRAM



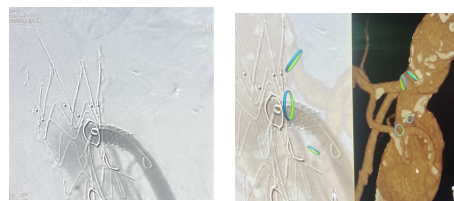
GRAFT DEPLOYMENT



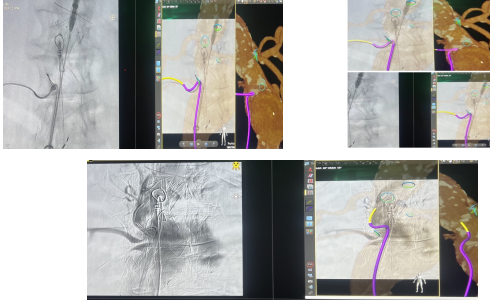
Cannulation of SMA with FORS



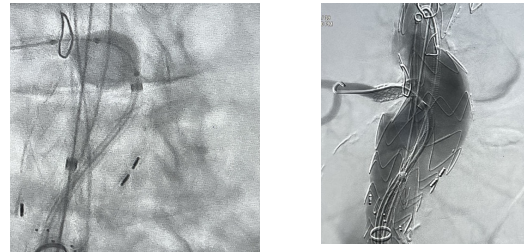
Stenting of SMA



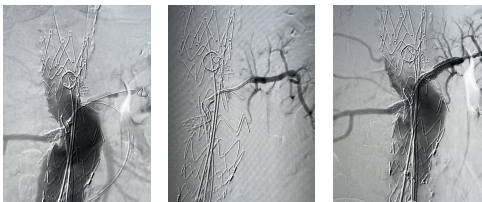
Cannulation of Right renal with FORS



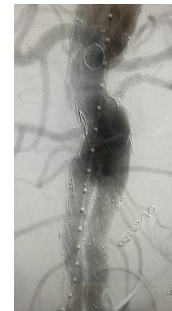
Stenting of Right Renal



Cannulation of Left Renal with FORS



Final Aortogram



DATA USING EGG WITH AAA CASES

