

Microscopic Foreign Body Contamination During Interventional Procedures

NEW CARDIOVASCULAR HORIZONS 2012

Marsha Holton CCRN RCIS FSICP

Kelly W. Elliott RN MS

Nick Cavros MD

Robert Gallino MD

John Laird MD

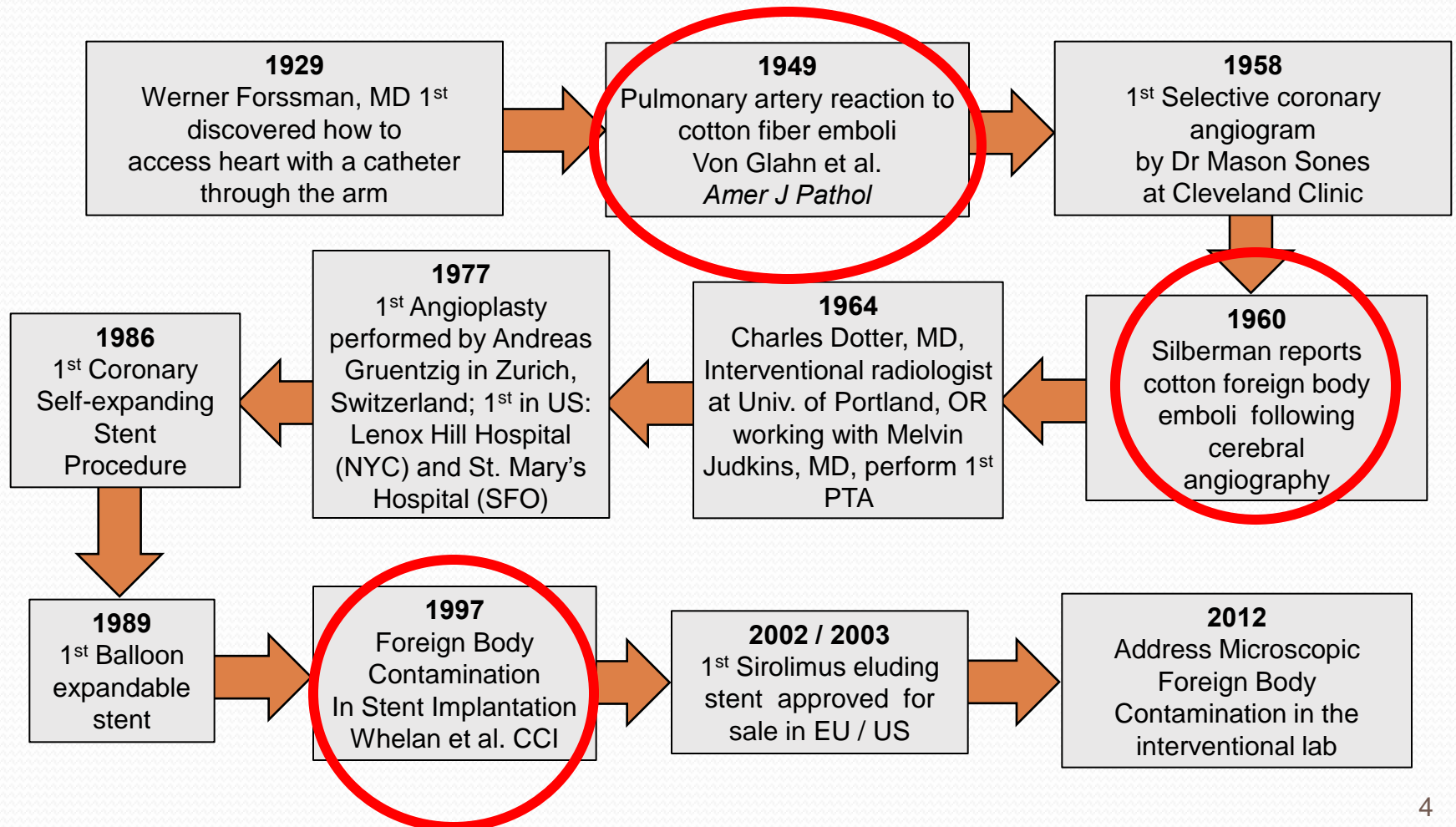
DISCLOSURES

- **SYNTERVENTION, INC.**
MEDICAL ADVISORY BOARD MEMBER

Microscopic Foreign Body Contamination in Interventional Procedures

- **The Problem:** Microscopic foreign body contamination is the entry of materials not intended to enter the body, that can result in benign changes to severe complications.
- **The Cause:** Commonly used cotton-based materials, such as gauze pads and sponges, deposit particles on interventional tools and in saline, thereby causing inadvertent introduction of the particles into the patient.

Microscopic Foreign Body Contamination in Interventional Procedures



Microscopic Foreign Body Contamination in Interventional Procedures

- **Impact on Clinical Outcomes:**

Embolization - Particulate embolizes and causes a thrombus to form at the site where the foreign body becomes lodged ultimately blocking flow;



Fischi and Narins (2005) reported coronary embolization of a gauze fragment in a coronary artery causing thrombus formation in the LAD after leaving the cath lab. A thrombectomy was performed and it revealed a gauze fragment from the coronary artery.

GRAPHIC REPRODUCED WITH PERMISSION for using in this presentation on WWW.SYINTERVENTION.COM FROM: Fischi M. and Narins CR. Coronary Embolization of a Gauze Fragment. Catheterization and Cardiovascular Intervention 2005. Vol 66; pp. 570-572.

THIS GRAPHIC WAS NOT INCLUDED IN THE PRESENTATION PRESENTED AT NCVH 2012.

Microscopic Foreign Body Contamination in Interventional Procedures

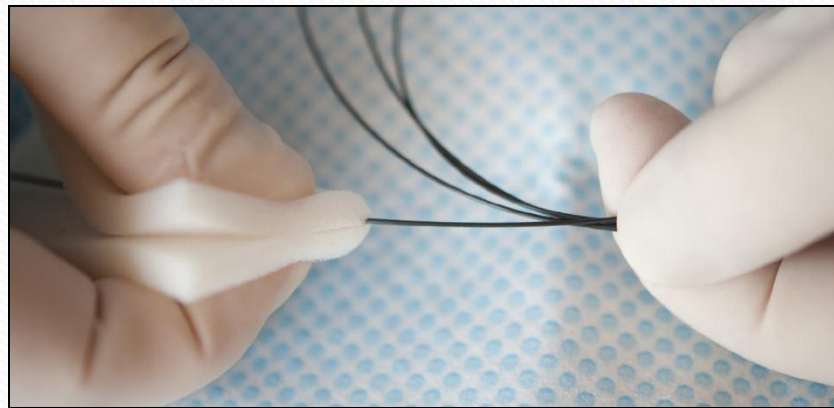
- **Impact on Clinical Outcomes:**

Infection - Foreign bodies, or particulate, carry bacteria that can cause infection.

Foreign Body (Granulomatous) Reaction - Studies have shown intravascular foreign bodies can cause inflammation, increased neointimal formation and granuloma formation; all contributors to the restenosis process.

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- **Hypothesis:** We hypothesized that a new fiber-free product, the Swiper™ (Syntervention Inc, Rocky Mount, NC) would shed less particulate than the currently used products, gauze (Covidien, Mansfield, MA) and Telfa™ (Covidien, Mansfield, MA).



The SWIPER™ is a sterile, biocompatible, fiber-free, foam wiper designed for the removal of blood, contrast and other contaminants from sterile instruments and medical devices.

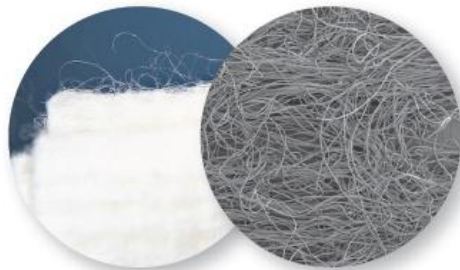
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- **Testing Methodology*:**

Individual samples were hydrated in filtered water (80ml) and squeezed under water 3 times.

The product remained in the water for 2 minutes, absorbed water was squeezed back into bowl, then the product was discarded.

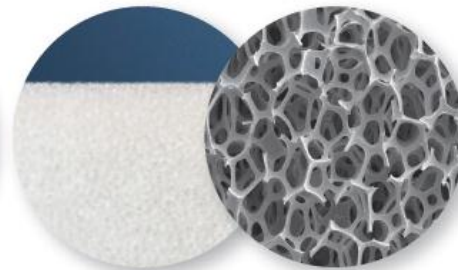
A sample of the water was aspirated and injected into a light obscuration particulate counter. Particles measuring ≥ 10 , ≥ 25 , ≥ 50 , and ≥ 100 microns (μm) in size were counted for each of the products.



Cotton Gauze
Magnification 30X



Telfa Pad
Magnification 30X



SWIPER
Magnification 30X

*Independent testing by: Nelson Laboratories, Salt Lake City, Utah

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- Results:**

Average Particle Count per 80 ml Fluid Volume				
Product	≥10 μm	≥25 μm	≥50 μm	≥100 μm
Gauze (n=5)	29809 [†]	937 [†]	8	0
Telfa (n=5)	27884 [†]	2401 [†]	111 [†]	15 [†]
Swiper (n=5)	6692	70	2	0

[†] Denotes particle count significantly greater than SWIPER (p< 0.05).

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Many medical devices are manufactured to strict requirements concerning cleanliness, particulate and fiber content.

- It should be noted that once the sterile medical devices are opened in the lab, they are exposed to a number of foreign bodies or contaminating elements.
- The manufacturing requirements no longer benefit the patient when the device is subjected to microscopic foreign body contaminants in the operating room or the interventional lab.

Conclusions:



Image provided by Robert Gallino, MD NCVH 2012

- Complications from microscopic foreign body contamination are under-reported and the cause may go unrecognized.
- Severe complications may occur even after achieving an optimal interventional result.
- A fiber-free material is a viable option to reduce microscopic foreign body contamination in the interventional lab.
- We reduced the ergonomic risks by developing better shielding and lead protection...so ...

Microscopic Foreign Body Contamination in Interventional Procedures

We MUST do ALL we can to prevent this!



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It is all about the patients... anyway and all ways we can reduce the risk... we need to do it.