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## Aortic aneurysms Today's Novel Clinical Trials

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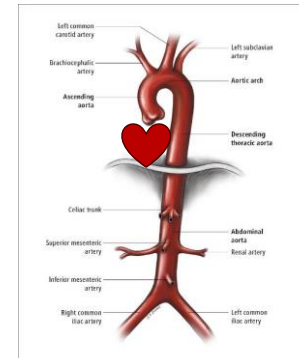
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### Disclosures

- Consultant: Vivex Vascular, Nectero Medical
- Site Primary Investigator: TAMBE (Gore), Panther (Terumo), AAA-SHAPE (Shape Memory Medical), stAAAbble (Nectero)

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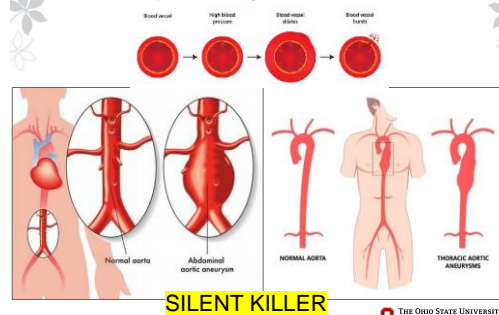
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## What is the difference between an ANEURYSM and a DISSECTION?

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### Aortic Aneurysm- enlarged Aorta

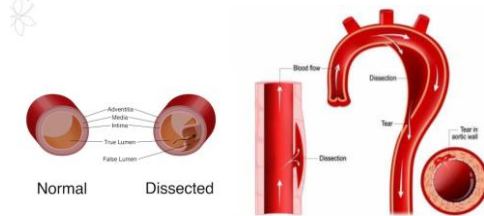


**SILENT KILLER**

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### Aortic Dissection- tear in between the layers



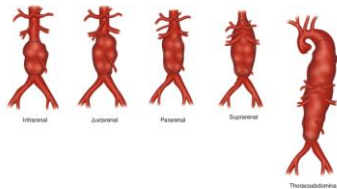
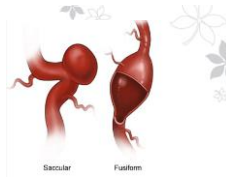
**AORTIC ATTACK**

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## Types of aneurysms

- Most are fusiform
- Tend to be more aggressive in treatment of saccular aneurysms



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## Risk factors for Aortic Aneurysms

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## Aortic Risk Factors

age.

1. Age
2. Family History
3. Male Sex
4. Tobacco
5. Hypertension
6. Connective Tissue Disorders
7. Obesity



Aneurysm in Detection and Management (ADAM)  
VA Cooperative Study (Annals 1997;126:441-449)

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## So, you have a patient with AAA

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## Treatment

- Risk factor modification
- Surveillance
- Surgery!
  - >5.5 cm for men
  - >5.0 cm for women

Size of Aneurysm	Risk of Rupture per year
< 4.0 cm	0.5%
4-4.9 cm	1-5%
5.0-5.9 cm	3-15%
6.0-6.9 cm	20%
7.0-7.9 cm	40%
>8.0 cm	50%



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## When to refer to Vascular Surgery?

- Aneurysm approaching 5 cm for men, 4 for women
- Fast growing aneurysms: >0.5 cm / year
- Described as a saccular aneurysm
- Any size AAA in the setting of PVD
- Anytime!

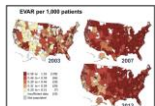
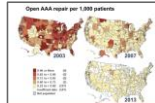
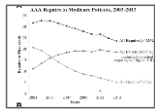


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### Surgical Repair of AAA



150,000 abdominal aortic aneurysms repaired/year

~70% amenable to simple endovascular repair (stent)

Cost of stent about \$9K and open graft \$800

Currently 6 commercially available endografts

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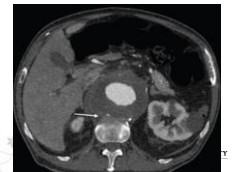
### OPEN AAA REPAIR

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### Case 1- Jimmy Ohio

- 49-year-old man steelworker with 2 months of back pain, worse in the past 7 days.
- He is avid smoker of 2 ppd since 15
- Does not see a doctor- no medications



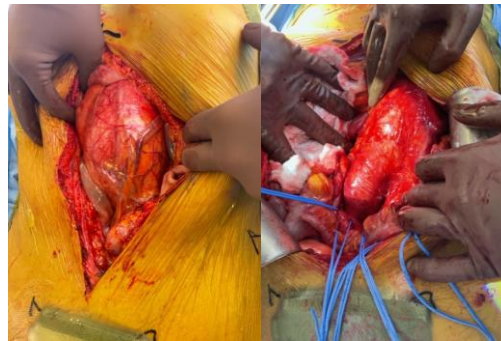
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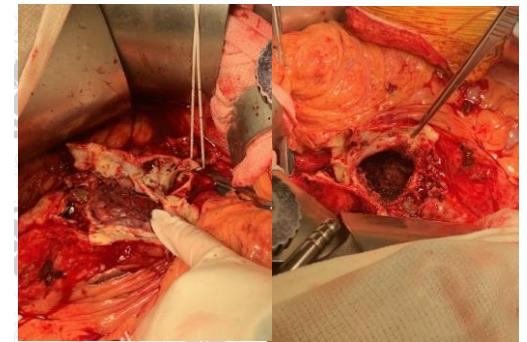
Graphic photos to follow

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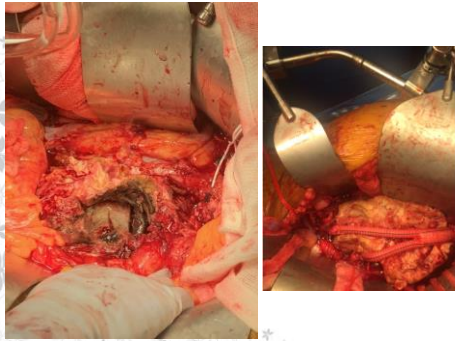
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### Case 1 - Jimmy Ohio



- Spends 23 days in the hospital
- Discharges to inpatient local rehab
- Follow up yearly with me
- QUIT SMOKING!

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## ENDOVASCULAR AAA REPAIR (EVAR)

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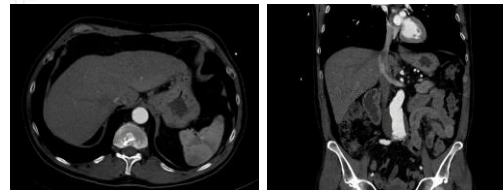
### Case 1 - Steven Jumper



- 67 yom presents to the ER with left abdominal pain and diagnosed with diverticulitis
- Takes vitamin supplements and smokes
- Some recreational drug use
- Has 11 brothers and sisters but no one with aneurysms

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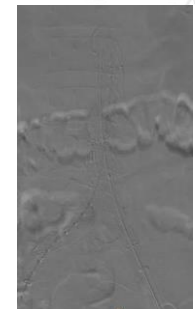
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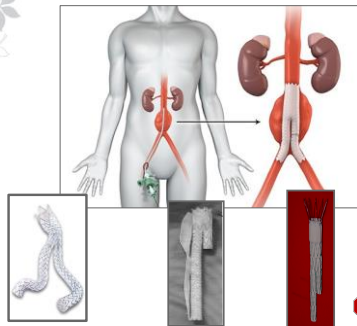
### EVAR



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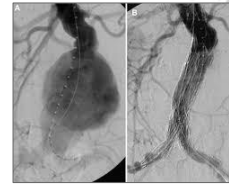
### Endovascular Repair



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### 2 hours- minimally invasive



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### Case 1 - Steven Jumper



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### Endoleaks



A medical condition created by medical advancement

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### Clinical Trials- Aortic Care

Ohio State University

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### AAA SHAPE Trial

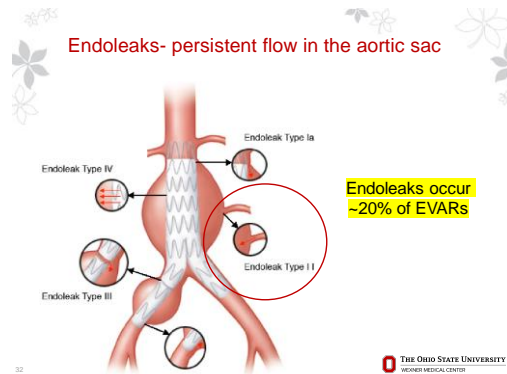
Novel Prevention of Type II Endoleaks

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**Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival**

Presented at the 10th World Congress Neurological Society for Clinical Neurological Sciences, San Diego, March 28-31, 2014, and received the Best Research Award.

Thomas F. X. O'Connell MD<sup>1</sup>, Sarah E. Dineley MD<sup>1</sup>, John A. Bortone MD<sup>2</sup>, Jeffrey J. Litwin MD<sup>3</sup>, Hans L. Schermer MD<sup>4</sup>, Subhojit K. Sin MD<sup>5</sup>, Andrew Schneider MD<sup>6</sup>, Robert T. Lancaster MD<sup>7</sup>, Vaseehra J. Venkatesh MD<sup>8</sup>, John A. Bortone MD<sup>9</sup>

<sup>1</sup>University of Maryland Medical Center, Baltimore, MD; <sup>2</sup>University of Maryland Medical Center, Baltimore, MD; <sup>3</sup>University of Maryland Medical Center, Baltimore, MD; <sup>4</sup>University of Maryland Medical Center, Baltimore, MD; <sup>5</sup>University of Maryland Medical Center, Baltimore, MD; <sup>6</sup>University of Maryland Medical Center, Baltimore, MD; <sup>7</sup>University of Maryland Medical Center, Baltimore, MD; <sup>8</sup>University of Maryland Medical Center, Baltimore, MD; <sup>9</sup>University of Maryland Medical Center, Baltimore, MD

**The Relevance of Abdominal Aneurysm Sac Shrinkage After Endovascular Repair**

Objectives: To determine the relationship between abdominal aortic aneurysm (AAA) sac shrinkage and long-term survival after endovascular repair.

Methods: A retrospective analysis of 100 patients who underwent endovascular repair of AAA. The relationship between sac shrinkage and long-term survival was assessed using Kaplan-Meier survival analysis.

Results: The mean follow-up time was 4.5 years. The mean sac diameter at baseline was 4.5 cm. The mean sac diameter at follow-up was 3.5 cm. The mean sac shrinkage was 22%. The mean survival time was 5.5 years. The mean survival time for patients with sac shrinkage was 6.5 years. The mean survival time for patients without sac shrinkage was 4.5 years.

Conclusions: Sac shrinkage after endovascular repair of AAA is associated with improved long-term survival.

**Biomechanics and early sac regression after endovascular aneurysm repair of abdominal aortic aneurysm**

Marko Björk MD<sup>1</sup>, Andrei Sila MD<sup>2</sup>, Monty Lindqvist Lijegård MD, PhD<sup>3,4</sup>, T. Christian Gasser MD, PhD<sup>5</sup>, Radebka Björk MD, PhD<sup>6</sup>, and Jay Rong MD, PhD<sup>7</sup> Stockholm, Sweden, and Odense, Denmark


**Predictors of Aneurysm Sac Shrinkage after a Global Registry**

The world-wide incidence and predictors of sac regression in patients with infrarenal abdominal aortic aneurysm after standard EVAR

Gregg H. Hult MD, PhD<sup>1</sup>, Ju Li<sup>2</sup>, Toshiro Kato, Shinya Dango, Sheng Yang, Zhongping Fan, Mingping He

<sup>1</sup>University of Maryland Medical Center, Baltimore, MD; <sup>2</sup>University of Maryland Medical Center, Baltimore, MD; <sup>3</sup>University of Maryland Medical Center, Baltimore, MD; <sup>4</sup>University of Maryland Medical Center, Baltimore, MD; <sup>5</sup>University of Maryland Medical Center, Baltimore, MD; <sup>6</sup>University of Maryland Medical Center, Baltimore, MD; <sup>7</sup>University of Maryland Medical Center, Baltimore, MD


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# AAA!SHAPE

Aortic Aneurysm Repair with the Next-Gen Endovascular Approach

**Study Purpose:** To determine the safety and effectiveness of IMPEDE-FX RapidFill to improve AAA sac behavior when used with EVAR stent graft treatment.




**EVAR plus  
IMPEDE-FX RapidFill**

**versus**

**EVAR**

Caution – INVESTIGATIONAL DEVICE, LIMITED BY FEDERAL (OR UNITED STATES) LAW TO INVESTIGATIONAL USE.



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## Procedure

The diagram illustrates the procedure for EVAR (Endovascular Aneurysm Repair) using a stent graft and Shape Memory Polymer (SMP) plugs. It shows two stages of the procedure:

- Initial Placement:** The EVAR stent graft is placed into the aorta, covering the aneurysm neck. The stent graft is shown as a red and white structure.
- Final Placement:** The Shape Memory Polymer (SMP) plugs (study device) are delivered into the aneurysm sac through the flexible sheath. The SMP plugs are shown as yellow, cone-shaped devices that expand to fill the aneurysm sac.

Labels in the diagram include:

- EVAR stent graft is placed
- Shape Memory polymer plugs (study device) are delivered into the aneurysm sac through the flexible sheath.

Logo: AAA&SHAPE  
Aortic Aneurysm & Shape Memory Polymer

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Complete filling of the aneurysm sac around the EVAR stent graft.

The embolization plugs are soft, like small sponges. Blood will form a stable clot as it flows into the holes of the plugs.

The intention is for the aneurysm sac to become smaller over time.

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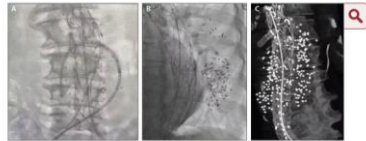


Figure 1. Intraoperative image of SMP deployment mid-fill (A). Intraoperative image of SMP deployment post fill (B). Postoperative CTA (C).



## stAAAbile Trial

Groundbreaking treatment for small to moderate sized aortic aneurysms

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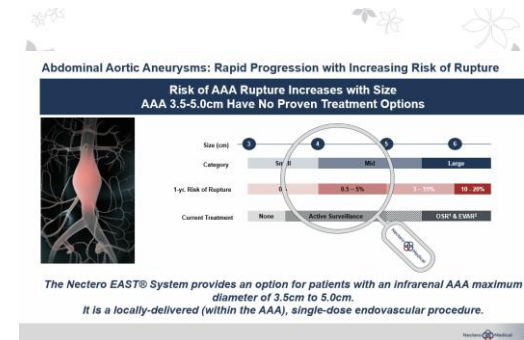
### Size criteria for surgery

- Men- AAA > 5.5 cm
- Women- AAA > 5.0 cm

Aneurysm Size	1-yr Incidence of Rupture %
<5.5 cm	≤1.0
5.5–5.9 cm	9.4
6.0–6.9 cm	10.2
≥7.0 cm	32.5

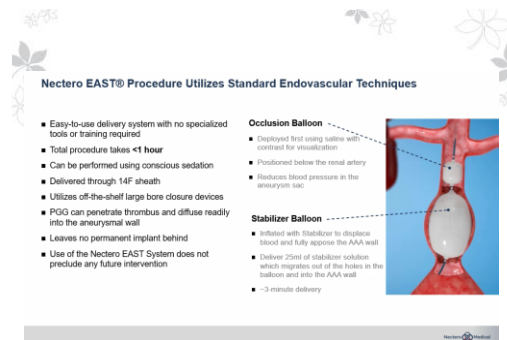
<sup>a</sup> Data are from Powell et al.,<sup>23</sup> Lederle et al.,<sup>24</sup> and Lederle et al.<sup>25</sup> The overwhelming majority of study participants were men.

### Nectero Medical

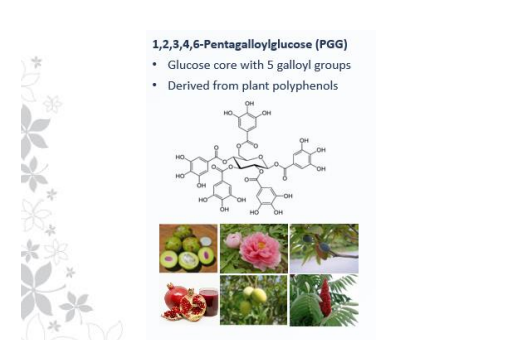




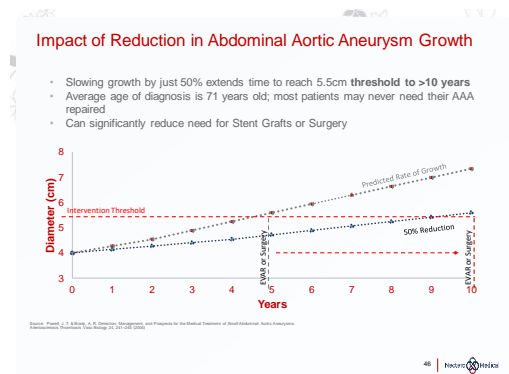
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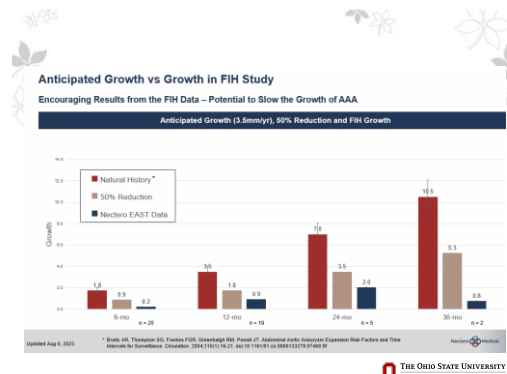
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First in the United States



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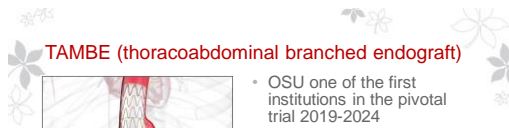
## TAMBE Trial

## Endovascular repair of thoracoabdominal aortic aneurysms



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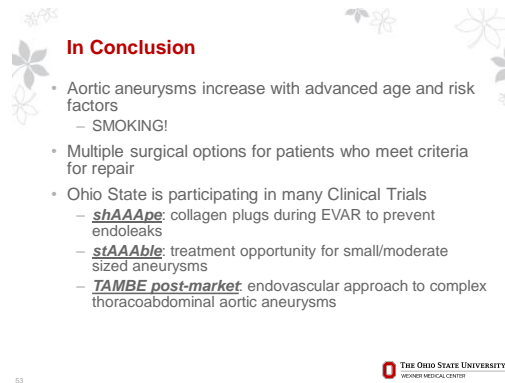
TAMBE (thoracoabdominal branched endograft)

- OSU one of the first institutions in the pivotal trial 2019-2024
- FDA approved device 2024



**First in the world!**

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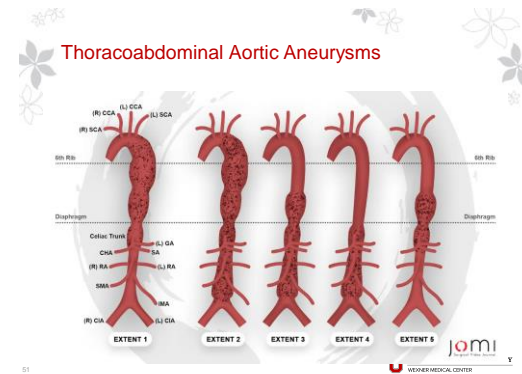
## In Conclusion

- Aortic aneurysms increase with advanced age and risk factors
  - SMOKING!
- Multiple surgical options for patients who meet criteria for repair
- Ohio State is participating in many Clinical Trials
  - **shAAApe**: collagen plugs during EVAR to prevent endoleaks
  - **sTAAAbLe**: treatment opportunity for small/moderate sized aneurysms
  - **TAMBE post-market**: endovascular approach to complex thoracoabdominal aortic aneurysms

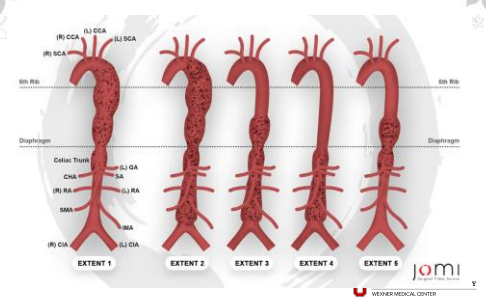


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## Thoracoabdominal Aortic Aneurysms



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Thank you.



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