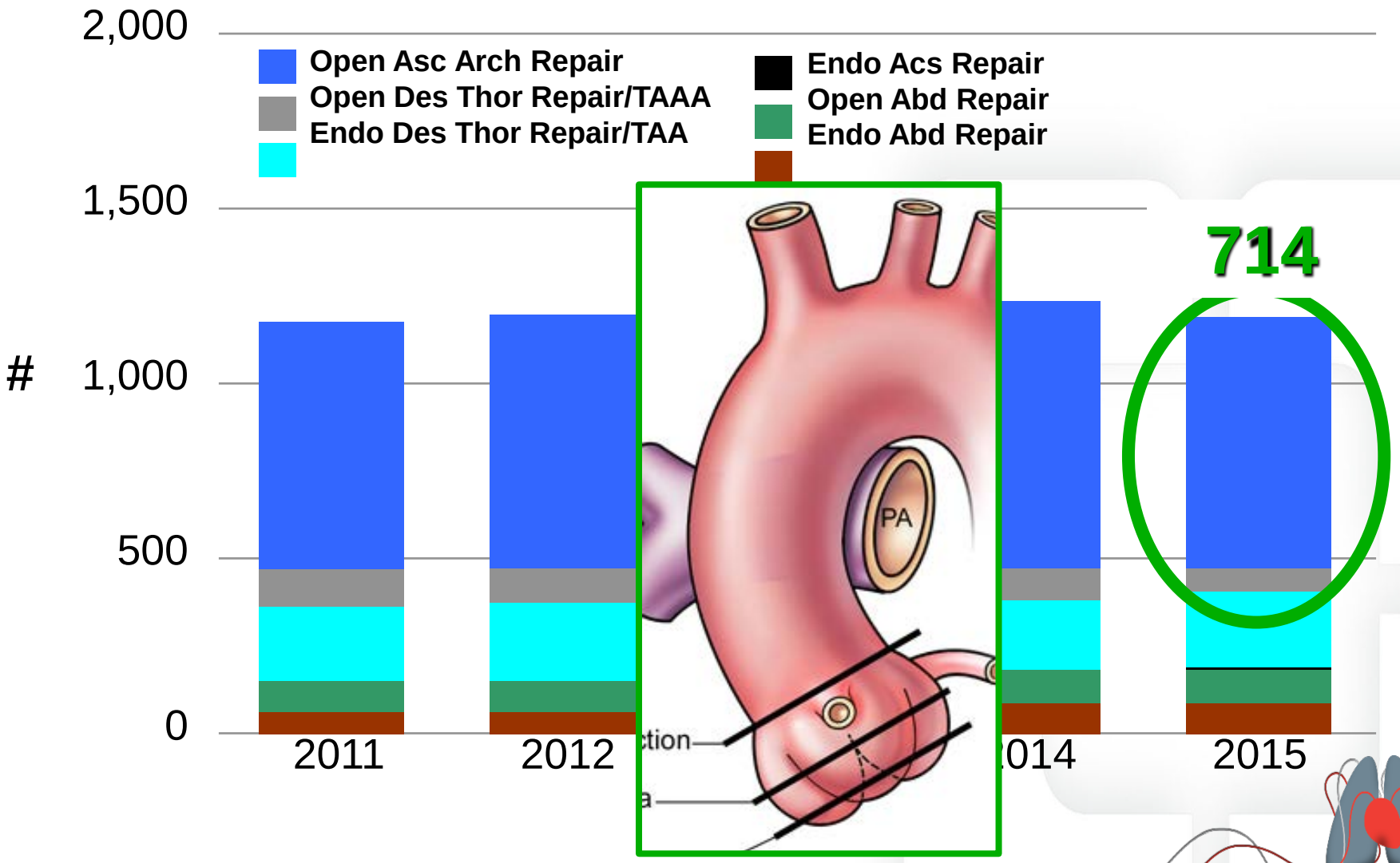
# Ascending and Arch Challenges: State of the Union

Eric E. Roselli, MD
Chief, Adult Cardiac Surgery
Surgical Director, Aorta Center
Heart and Vascular Institute, Cleveland Clinic

# Disclosures

| | |
|---|---|
| Bolton | Consultant, Investigator |
| Cook | Speaker, Investigator |
| Cryolife | Consultant |
| Edwards | Consultant, Investigator |
| Gore | Consultant, Investigator |
| LivaNova | Speaker, Investigator |
| Medtronic | Consultant, Investigator |
| St Jude | Speaker, Investigator |
| Vascutek | Speaker, Investigator |

# Aortic Surgery: Cleveland Clinic



The first endovas
dissection using a
ascending aorta

Matthew J. Metcalfe, MD, MRCS,
Ian M. Loftus, MD, FRCS, Robert
*London, United Kingdom*

apical Thoracic
air for Acute
l

Reiter, MD,
pina Wipper, MD,

**Endovascular repair**
**for open repair**

igh risk

ovascular
Hospital

Prashanth Vallabhajosyula, MD,
Nimesh D. Desai, MD, PhD, and

**Objective:** Although endovasc
g thoracic aortic

**Endovascular Stent**
**in Patients at High**

A Aortic Dissections

S. Ronchey [a], E. Serrao [a], V. Alb
rdi [a,*]

[a]Department of Vascular Surgery, San Fi
[b]Thoracic Aortic Research Center, Policlin


HELLO AGAIN, EVERYONE.
THIS IS HOWARD COSELL...
I'M LOOKING INTO THE FUTURE
AND YOU'RE NOT GOING TO BELIEVE
WHAT I'M ABOUT TO TELL YOU.

# Endovascular Proximal Aortic Repair

Two Critical Questions:

1) Should we?

2) Can we?

# Thoracic Aortic Surgery: Japanese Database

- 2000 thru 2005; JADSD 180 Hospitals
- N = 4,707 from 97 hospitals
- Root 10%, Asc 47%, Arch 44%, Desc 27%, TAA 8%
- OpMortality 8.6%; 7% Root, 8% Asc, 9% Arch; MajorMorb 30%
- Risks:

| | OR |
|---|---|
| – Emergency (25%) | 3.7 |
| – Cr >3.0 | 3.0 |
| – Unexpected CABG | 2.64 |



Motomura N, et al. Circ, '08.

# Volume to Outcome Relationship in North America

- 2004 – 2007, STS Database, 741 Centers
- N = 13,358; all elective, total roots AND AVR+Ascending
- 25% of operations performed at 3% centers
  - Quartiles: <6, 6-13, 13-30, >30 cases
  - Endocarditis and reops common at high volume center
- Mortality 4.5%
  - Quartiles: 6%, 5%, 4%, 3%



Hughes C, et al. JTCVS, '13.

# Elective Aortic Replacement is Safe and Effective

## Outcomes After Elective Proximal Aortic Replacement: A Matched Comparison of Isolated Versus Multicomponent Operations

Jay J. Idrees, MD, Eric E. Roselli, MD, Ashley M. Lowry, MS, Joshua M. Reside, BS, Hoda Javadikasgari, MD, Daniel J. Johnson, BS, Edward G. Soltesz, MD, Douglas R. Johnston, MD, Cósta R. Patterson, MD, PhD, Eugene H. Blackstone, MD

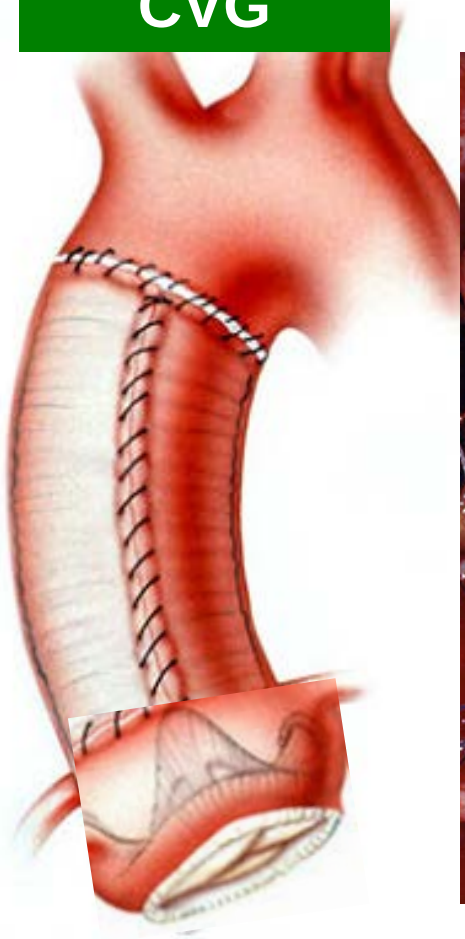
*Annals of thoracic surgery, 2016*

| | Operative Mortality | Stroke |
|---|---|---|
| **Isolated** | **0.5%** | **4%** |
| **Multi-component** | **2%** | **2%** |

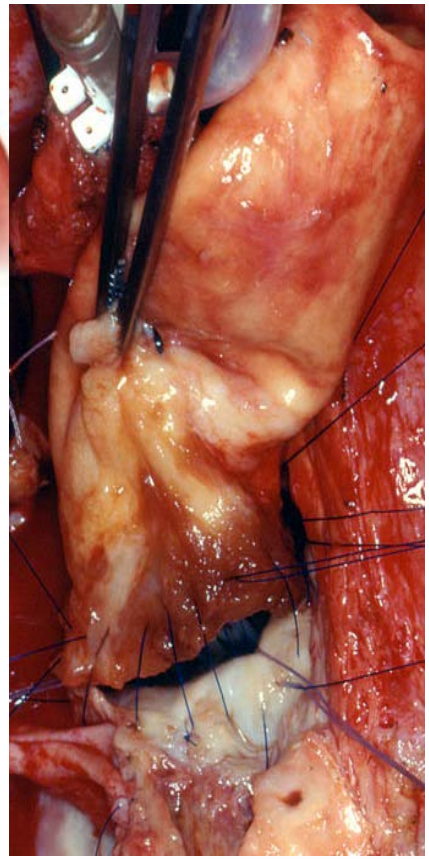
# Four Root Procedures

**Mechanical CVG**

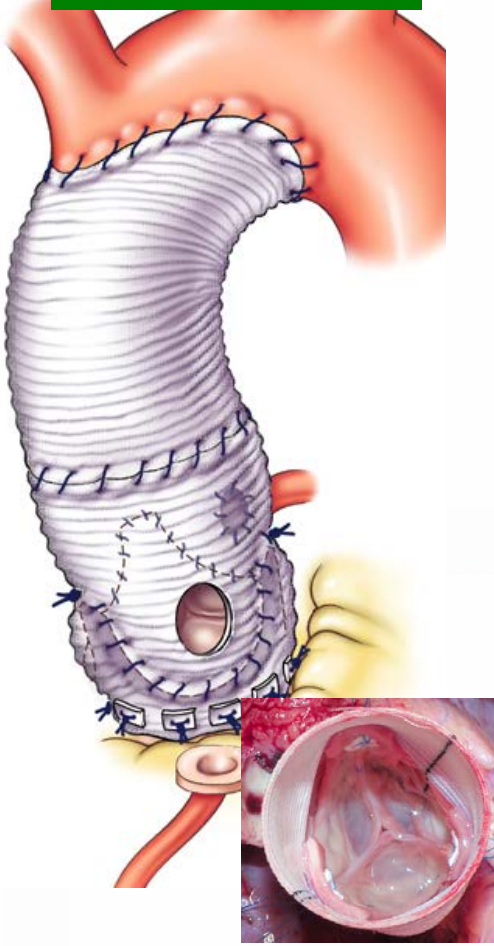
**Biologic CVG**



**Homograft**



**Valve-Preserving Root**



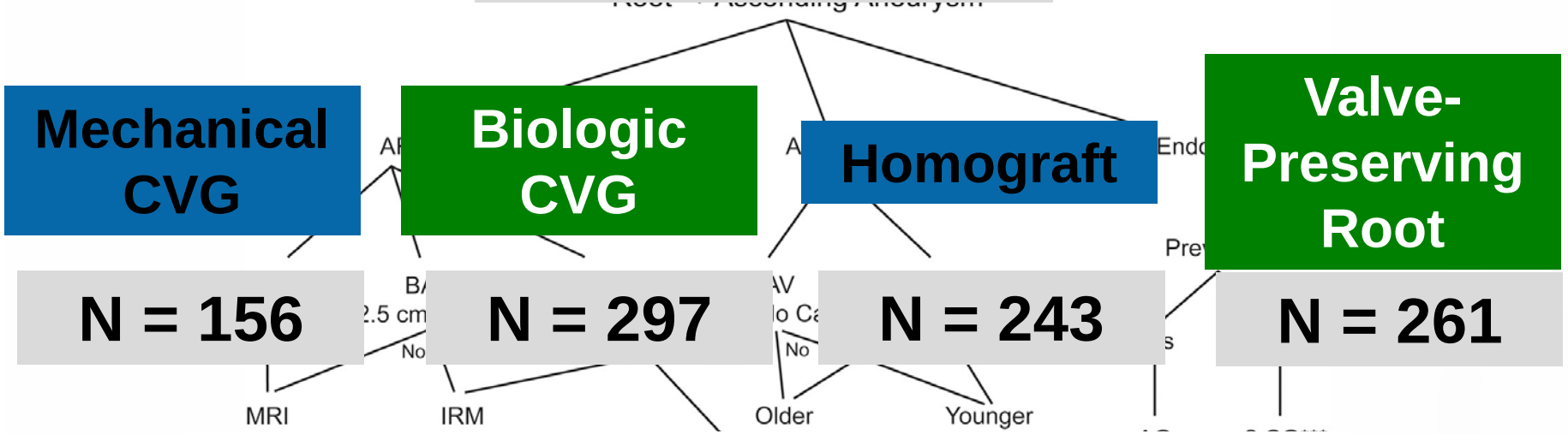
Svensson LG, et al. JTCVS, ‘16.

# Long-term survival, valve durability, and reoperation for 4 aortic root procedures combined with ascending aorta replacement

Lars G. Svensson, MD, PhD,[a,b] Saila T. Pillai, MD, MPH,[a] Jeevanantham Rajeswaran, PhD,[c] Milind Y. Desai, MD,[b,d] Brian Griffin, MD,[b,d] Richard Grimm, DO,[b,d] Donald F. Hammer, MD,[b,d] Maran Thamilarasan, MD,[b,d] Eric E. Roselli, MD,[a,b] Gösta B. Pettersson, MD, PhD,[a,b] A. Marc Gillinov, MD,[a,b] Jose L[illegible], MD,[a,b] Joseph F. Sabik III, MD,[a,b] Bruce W. Lytle, MD,[a,b] and Eug[illegible]

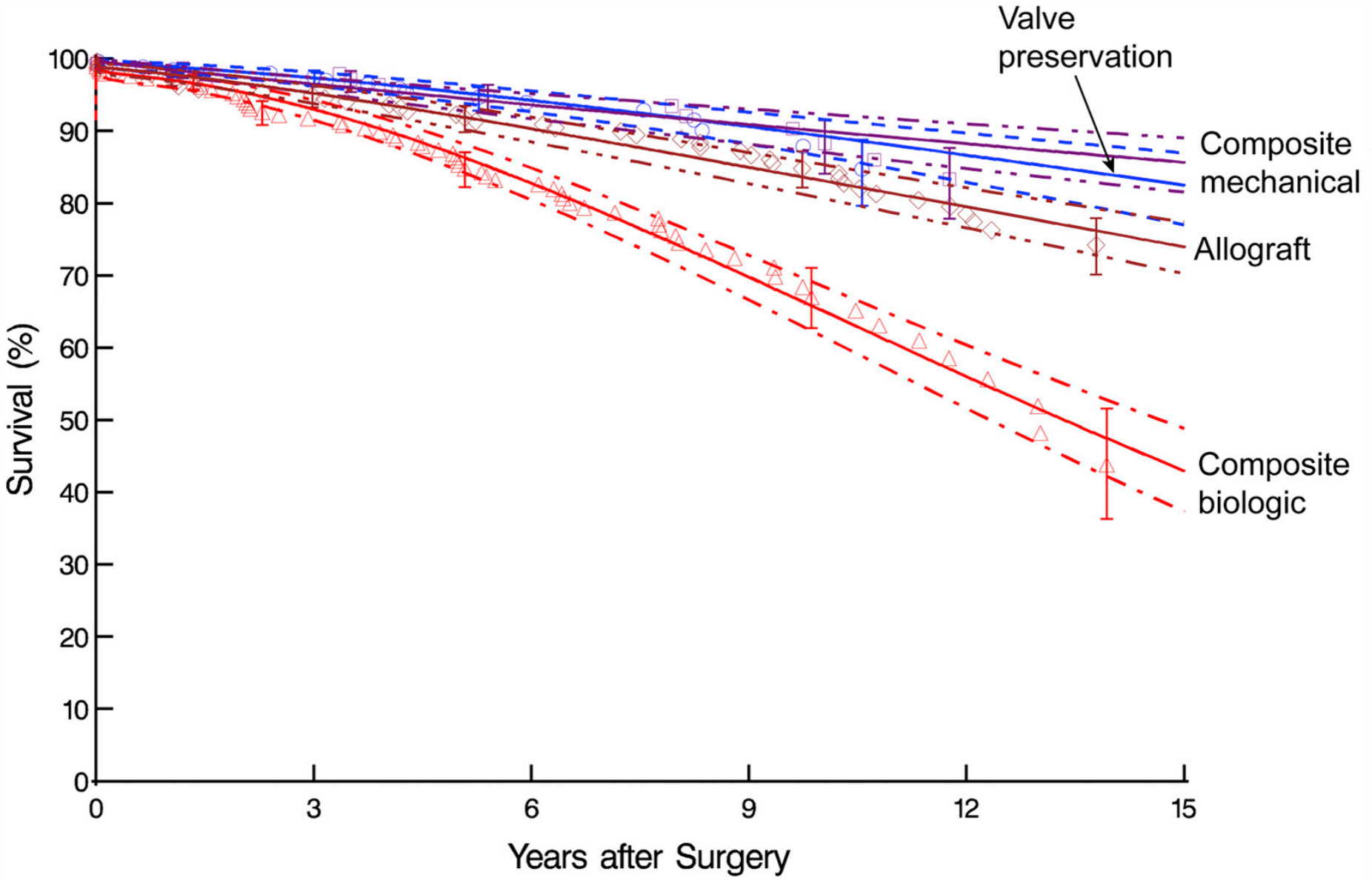
Cardiovasc Surg 2016;151:764-74)

**1995 - 2011**
**N = 957**

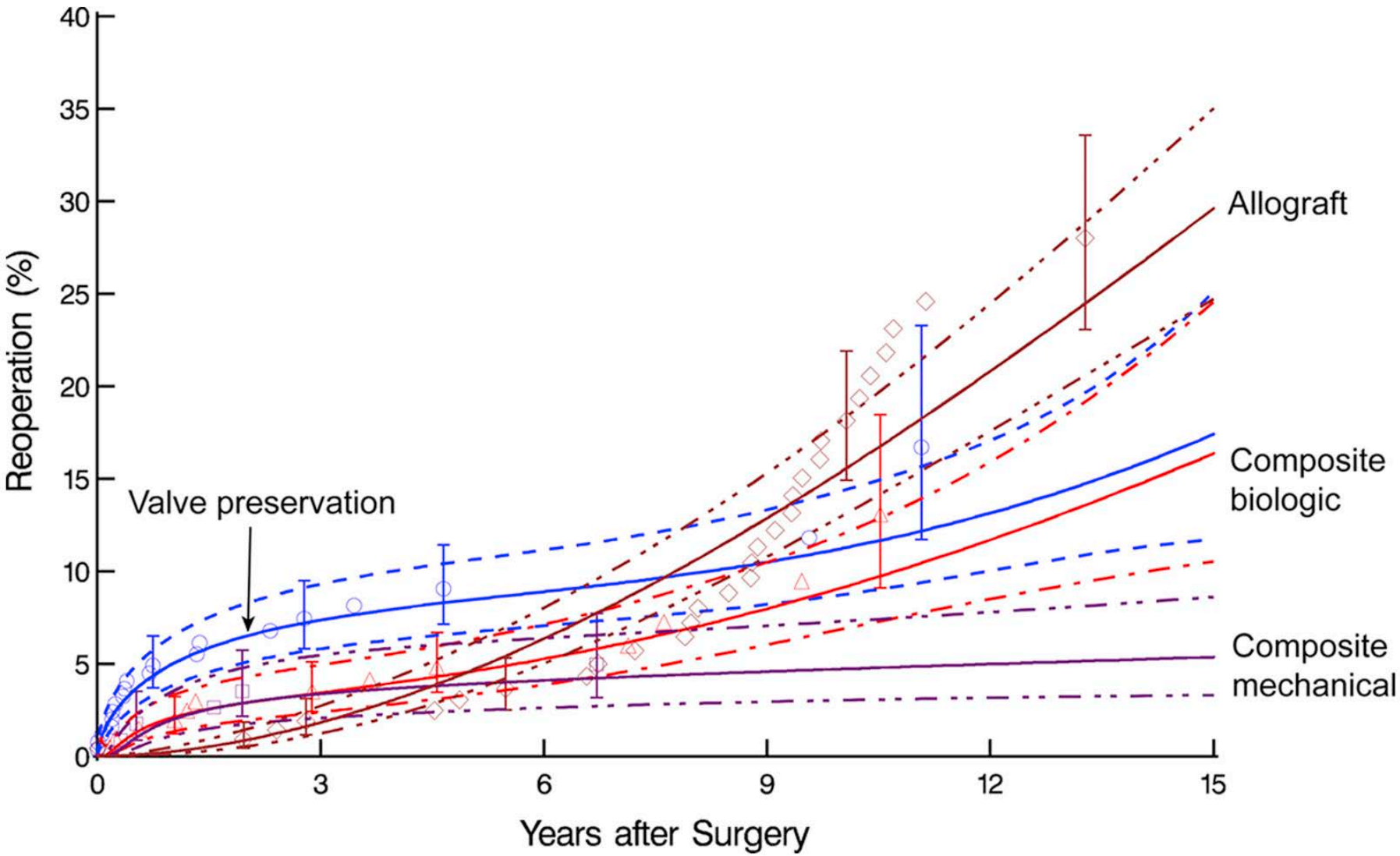



- **Mortality** **0.73%**
- **Stroke** **1.4%**

# Survival Post Root Replacement



# Reoperations Post Root Replacement

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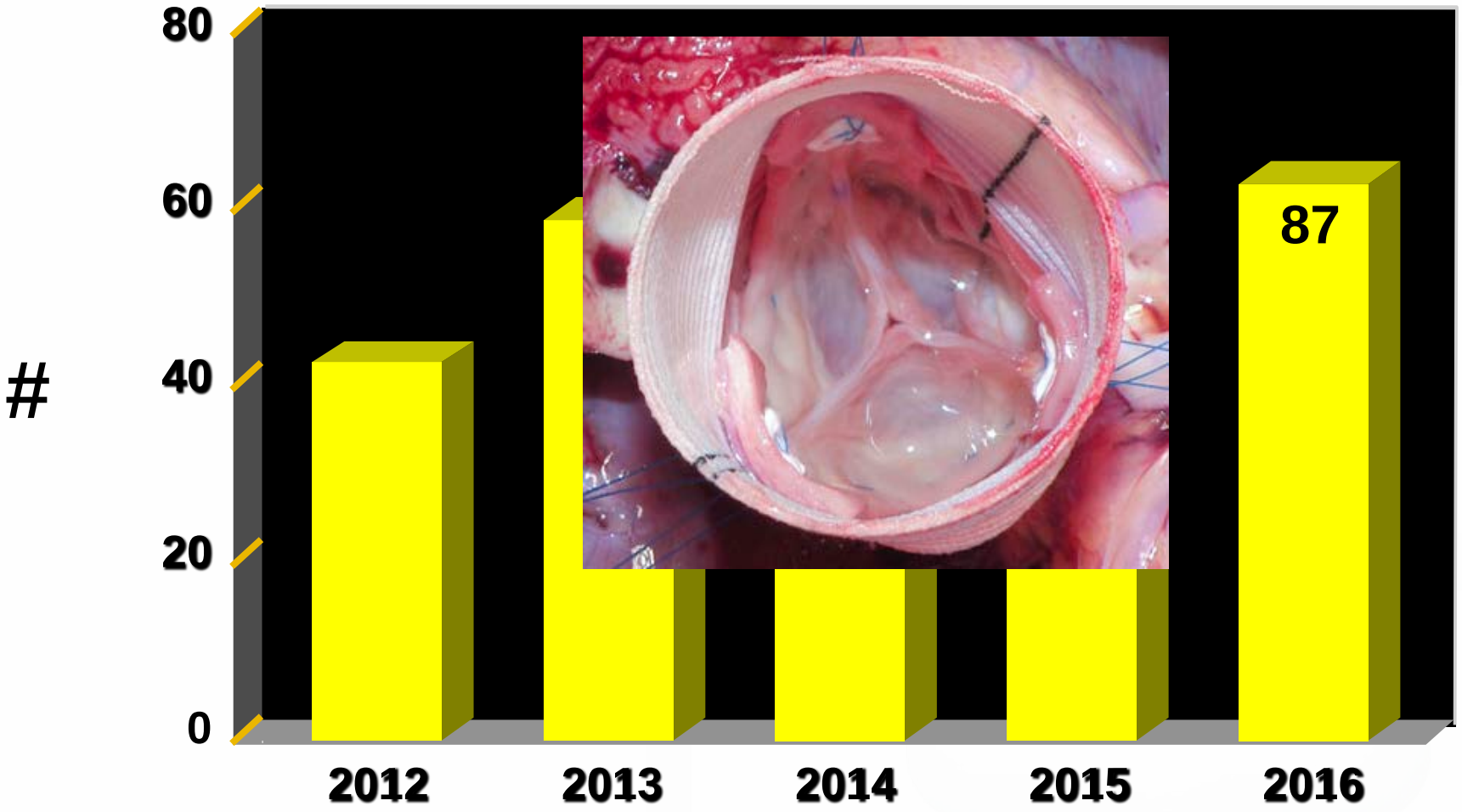
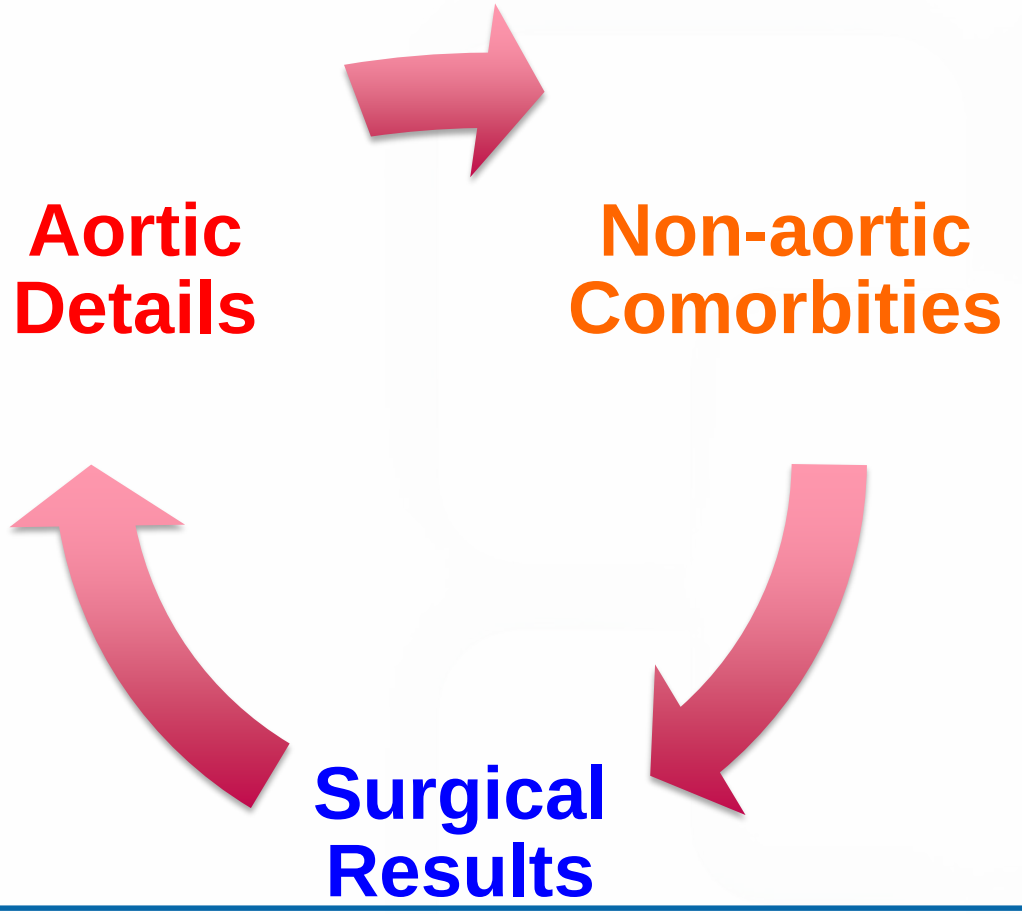
# Saving the Living Valve

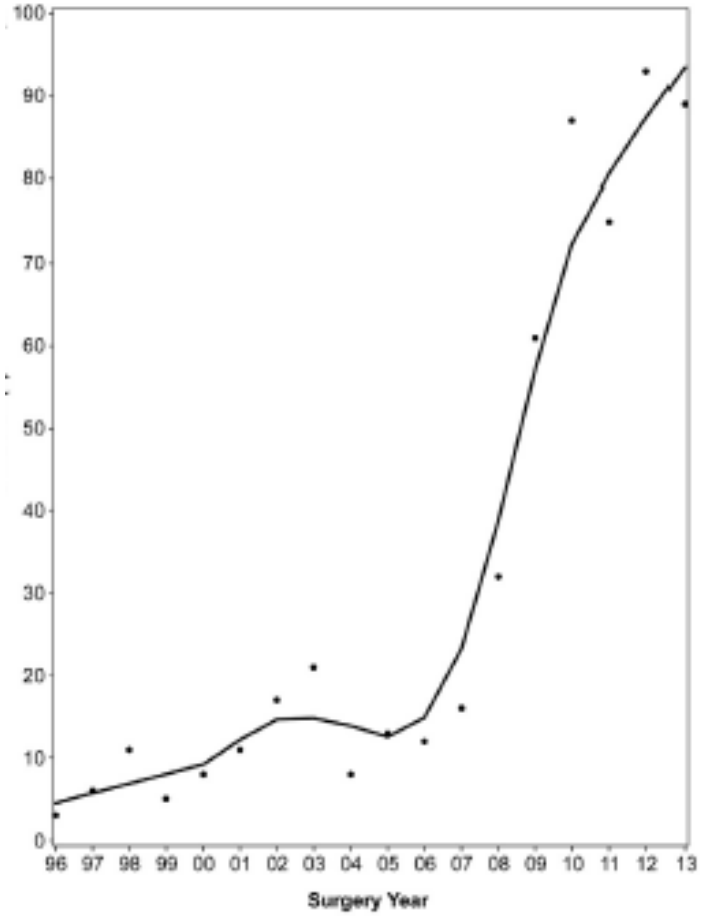


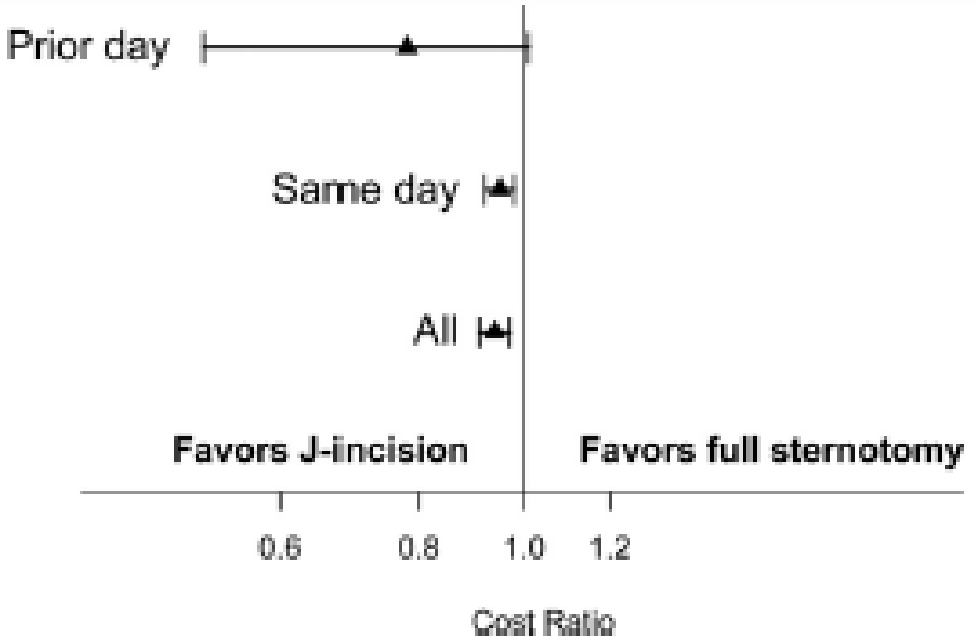
# Risks and Benefits Must be Tailored to the Patient



# Outcomes of a Less-Invasive Approach for Proximal Aortic Operations

Melissa M. Levack, MD, Muhammad Aftab, MD, Eric E. Roselli, MD, Douglas R. Johnston, MD, Edward G. Soltesz, MD, MPH, A. Marc Gillinov, MD, Gösta B. Pettersson, MD, PhD, Brian Griffin, MD, Richard Grimm, DO, Donald F. Hammer, MD, Adil H. Al Kindi, MD, MS, Turki B. Albacker, MD, MS, y Thuita, MS, Eugene H. Blackstone, MD, Lars G. Svensson, MD, PhD

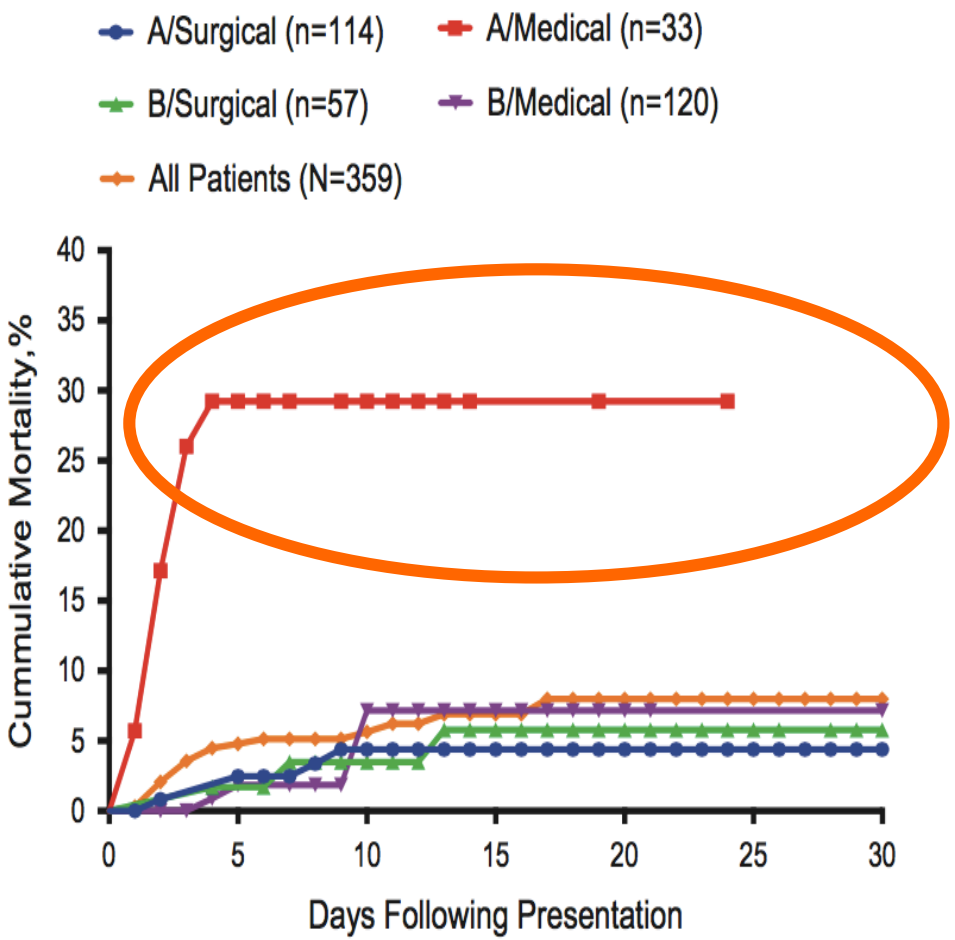



Levack M, et al. JTCVS, ’16.

# Unmet Need in Aortic Dissection

***4% Type A Op; 4.5% Type B***

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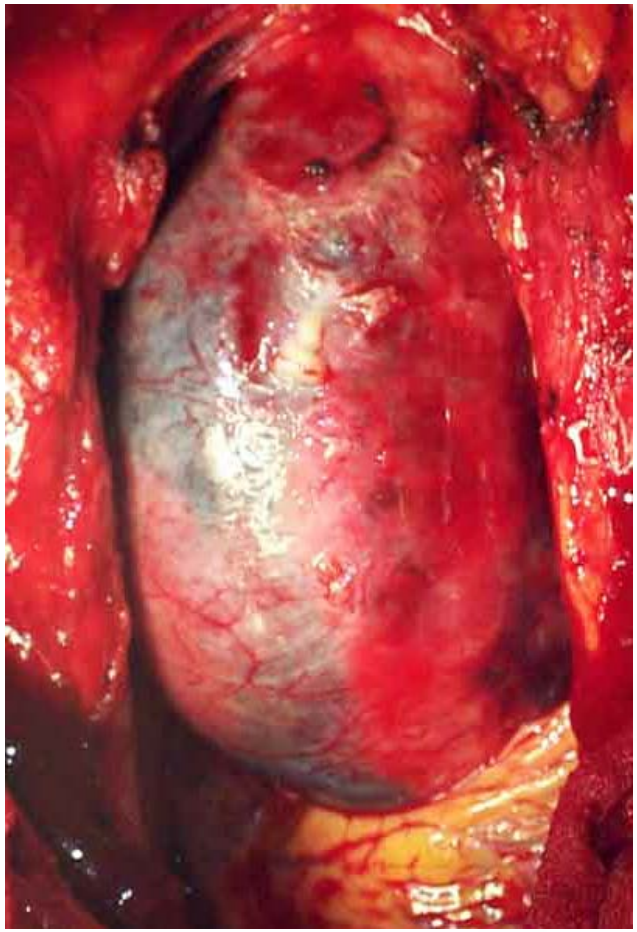
*Hagan, et al. IRAD, JAMA 2000.*
*Aggarwal B, Roselli EE, et al. Circ CVQual Out, 2014.*

# Inoperable Patients (2005-2015)

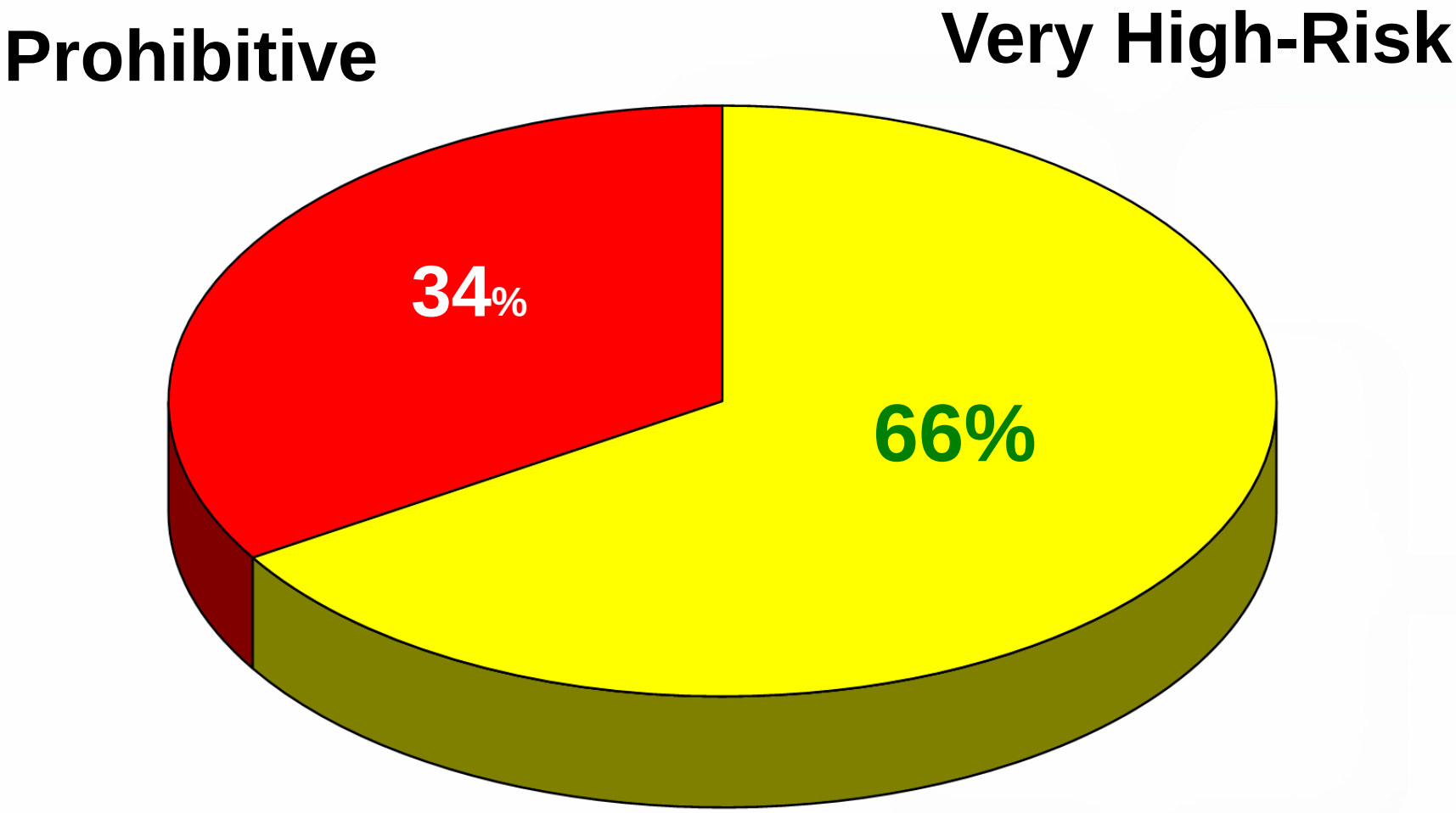
- 53 of 686 (7.7%)
- Mean 78y/o; 62% > 80y/o
- 53% female
- 81% from other hospitals
- 63% DeBakey Type I





Roselli EE, Hasan S, et al. Int EurJCTS, ’17.

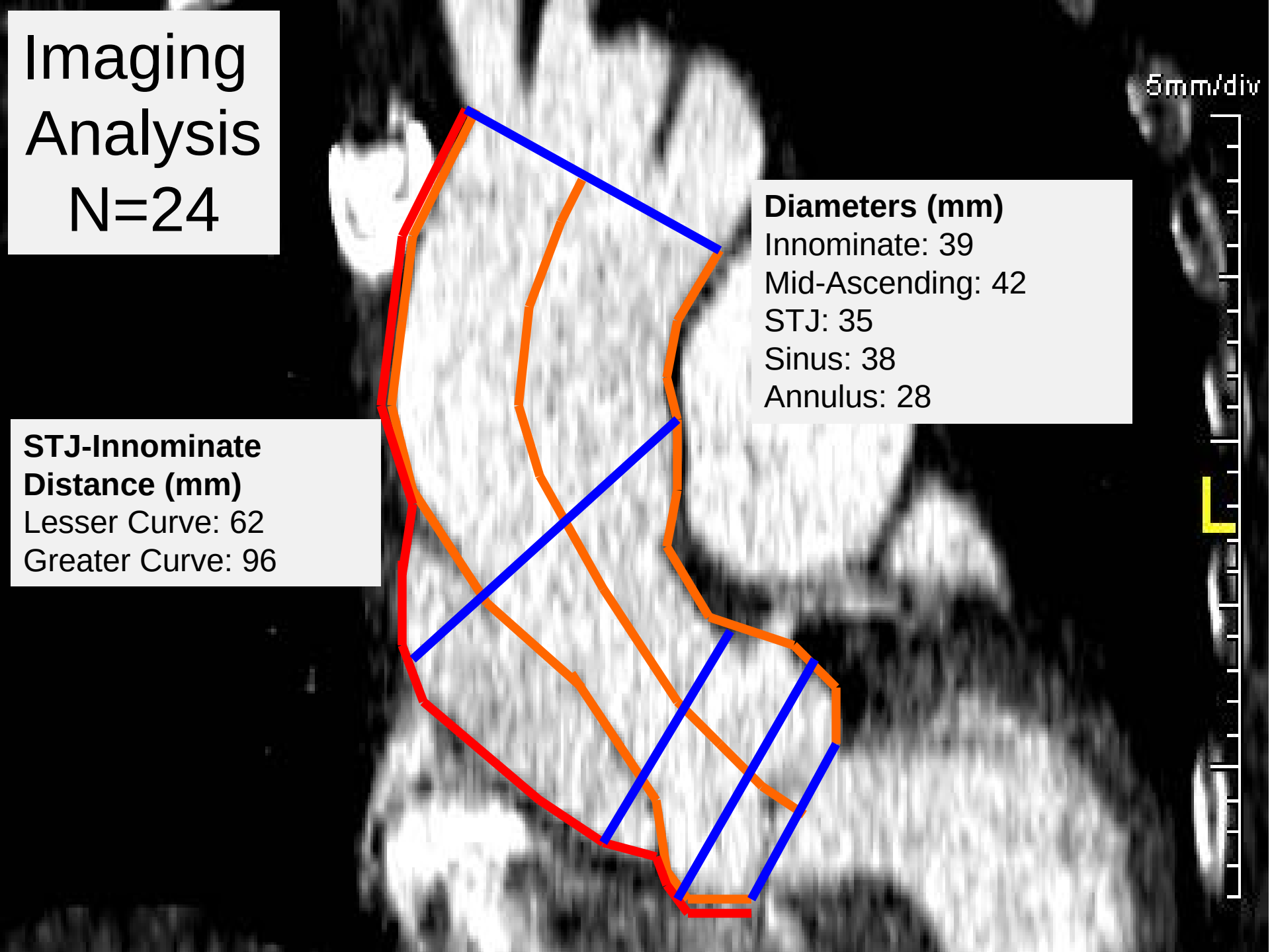
# Reasons for Inoperability






Roselli EE, Hasan S, et al. Int EurJCTS, ’17.

# Imaging Analysis N=24




**Diameters (mm)**
Innominate: 39
Mid-Ascending: 42
STJ: 35
Sinus: 38
Annulus: 28

**STJ-Innominate Distance (mm)**
Lesser Curve: 62
Greater Curve: 96

# Can We Stentgraft Them ?

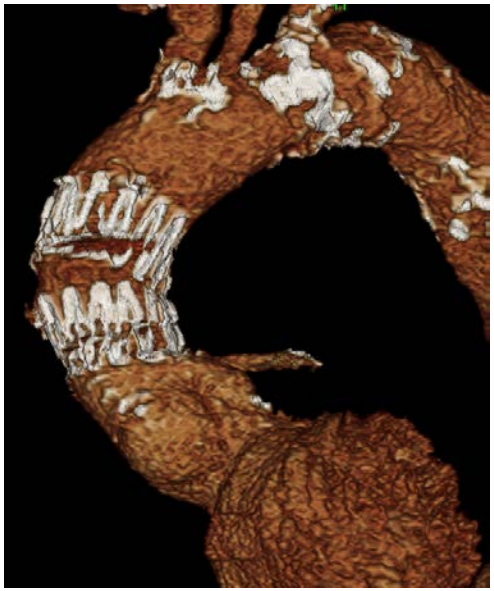
- STJ to entry tear distance: 21mm
- **Entry tear coverable in 19 (79%)**
  - 18 between STJ and innominate
  - 1 distal to left subclavian
- Other 5
  - 1 each in aortic root and arch
  - 3 not identifiable



Roselli EE, Hasan S, et al. Int EurJCTS, ’17.

# High Risk Ascending TEVAR

**2006-2014**
**N = 22**
**Thru 2017**
**N = 42**



| | | |
|---|---|---|
| • Acute Type A Dissection | 9 | 14 |
| • IMH with PAU | 2 | 3 |
| • Pseudoaneurysm<br>4 with contained rupture | 9 | 23 |
| • Complicated Chronic Dissx | 2 | 2 |

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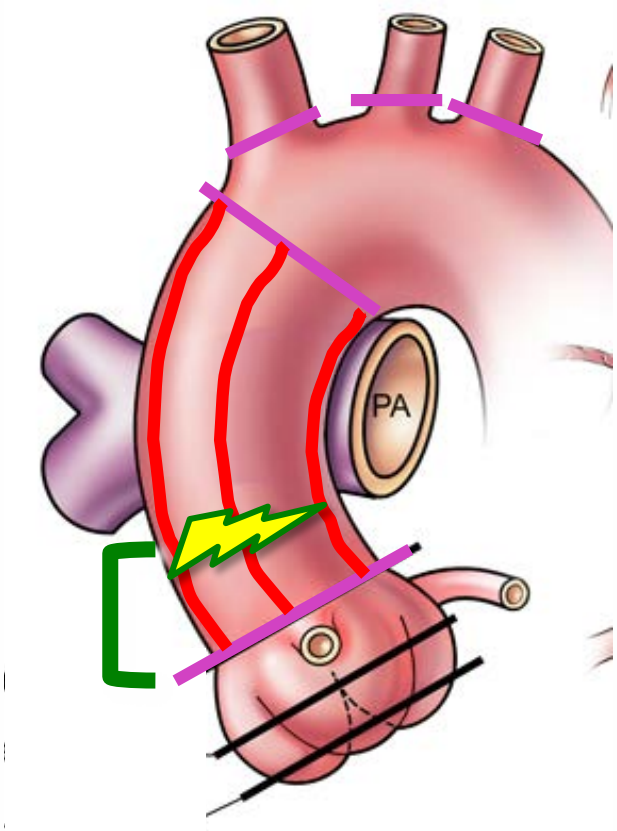
Roselli EE, et al. JTCVS, ‘15.

# Challenges to Proximal TEVAR

- Aorta/Patient Related
  - Anatomy, Morphology, Physiology, Pathology
- Procedure Related
  - Stentgraft Device
  - Delivery System

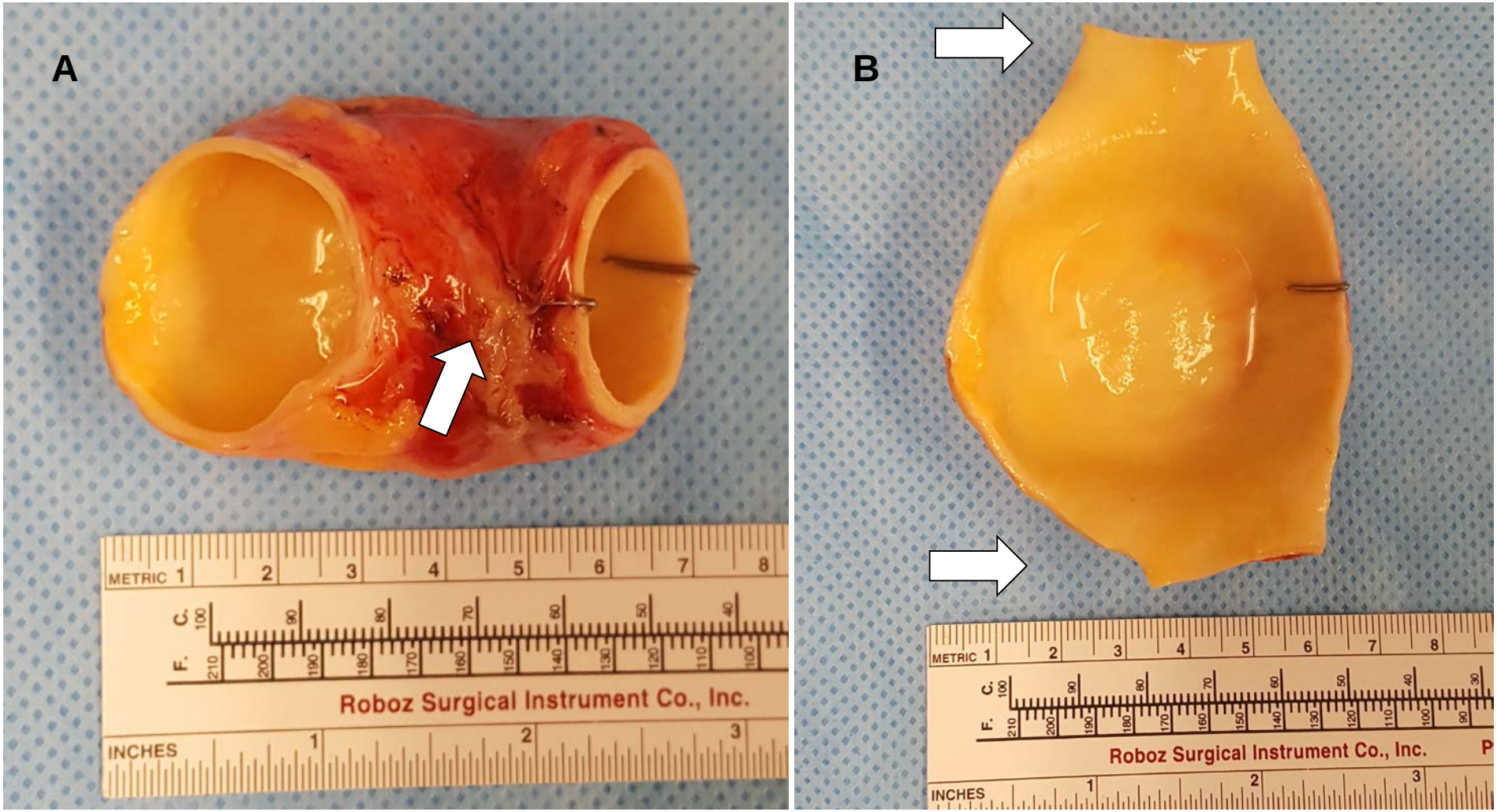
# Pt Related: Anatomy / Morphology

| Greater | Center | Lesser |
|---|---|---|
| 9.6 | 7.8 | 6.4 |




- Diameter
  - Usually dilated:
    - mean 3.5 cm
    - commonly 4.5cm
    - esp. dissx
- ? Length of a curve
- Entry tears difficult to characterize

# Ascending Aorta is Curved



# Outcomes Based on Modified Zone Zero

| Outcome | Disease | Device |
|---|---|---|
| • Operative M | | |
| –Root | | 2 |
| –Proximal As | | 3 |
| –Distal Asc | | 0 |
| • Late Death | | |
| –Root | | 2 |
| –Proximal As | | 8 |
| –Distal Asc | | 1 |

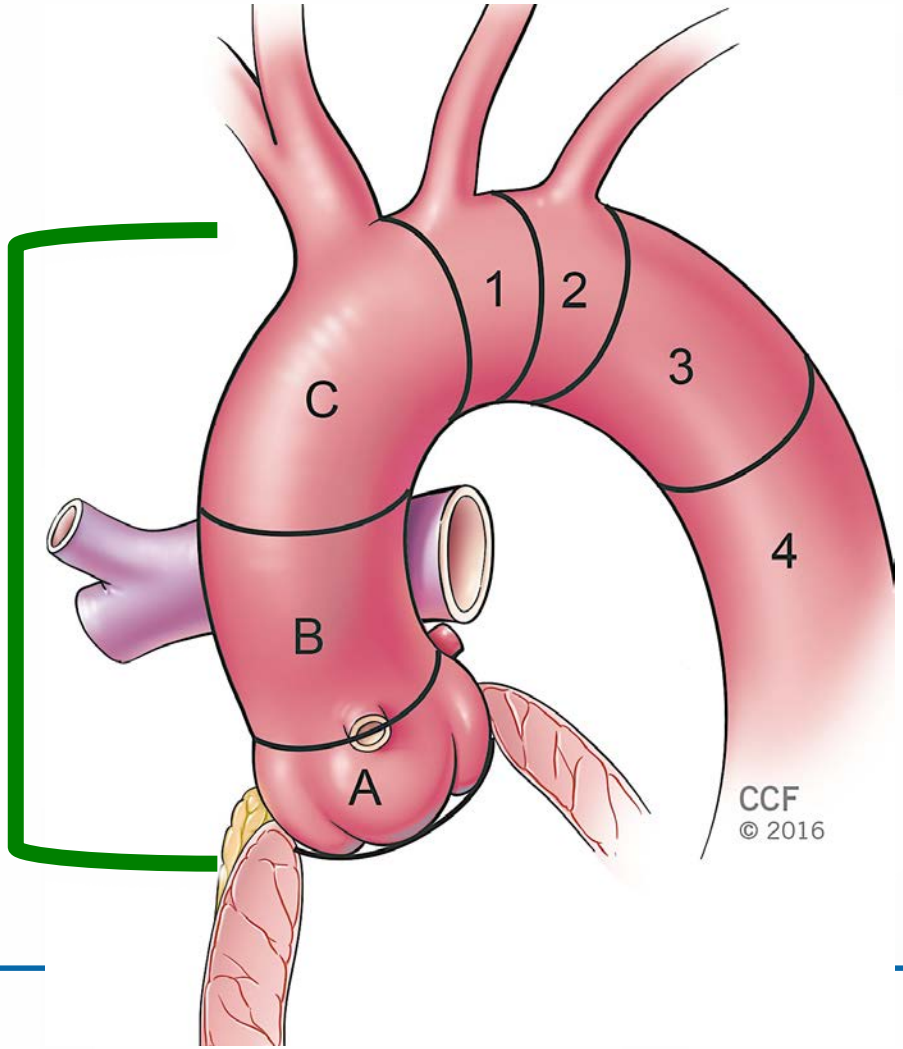
# Modified Landing Zone Classification System

## Zone 0

**C: RtPA to Innom**

**B: cors to RtPA**

**A: annulus to cors**



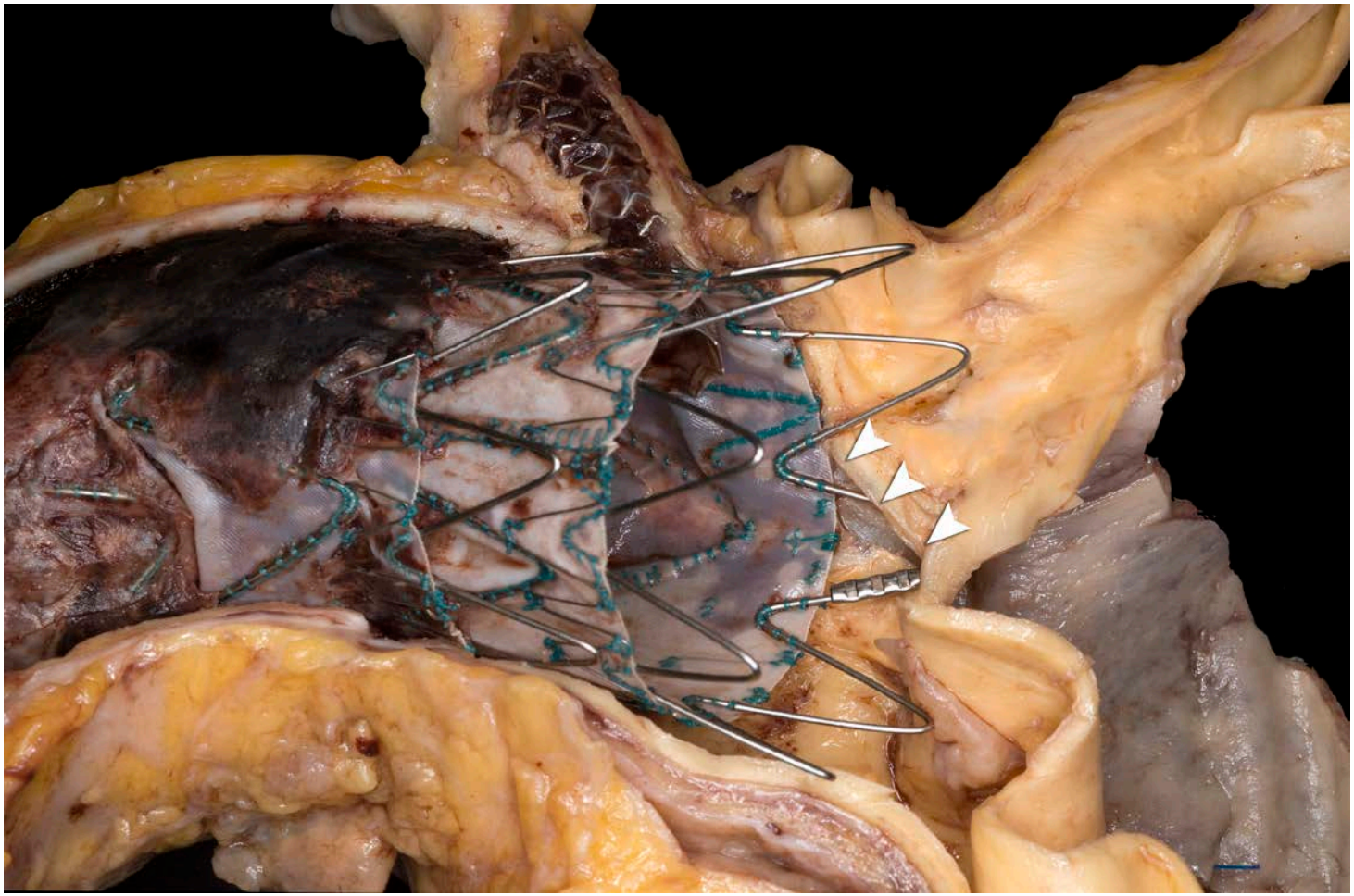
# Mechanisms of Aortic Dissection

- Altered cell-matrix mechanosensing
- Protease imbalance
  - Structural vulnerability
- Proteoglycan accumulation understudied

**Normal**

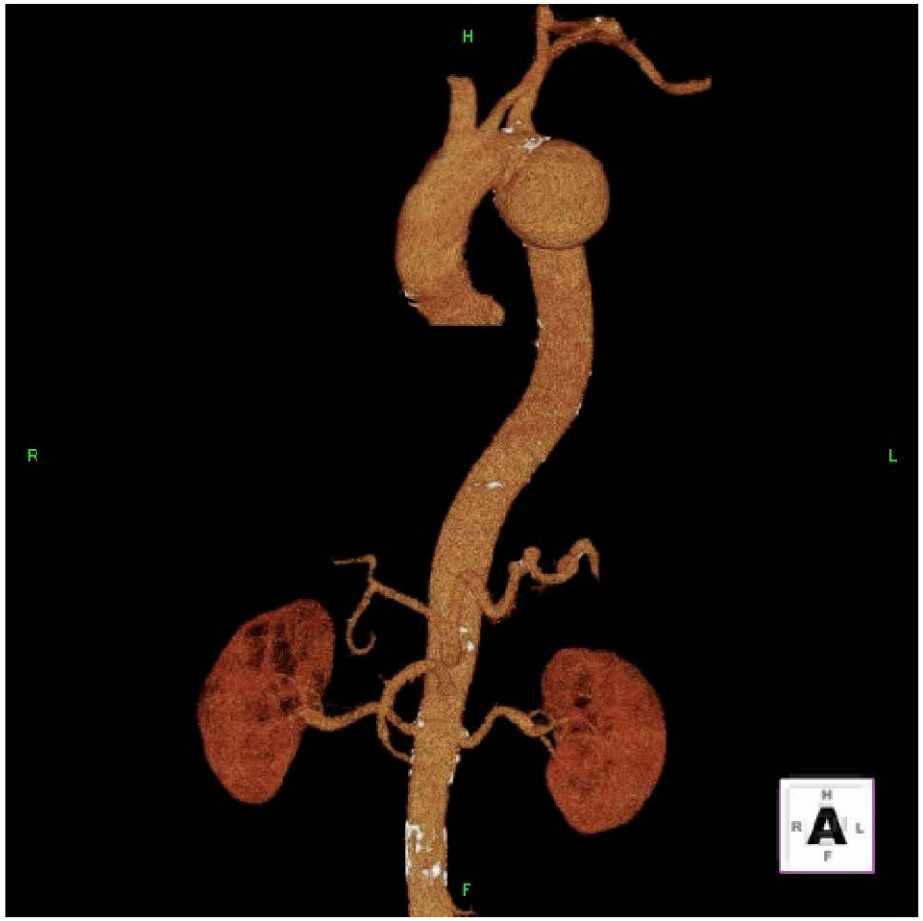
**Aortic**

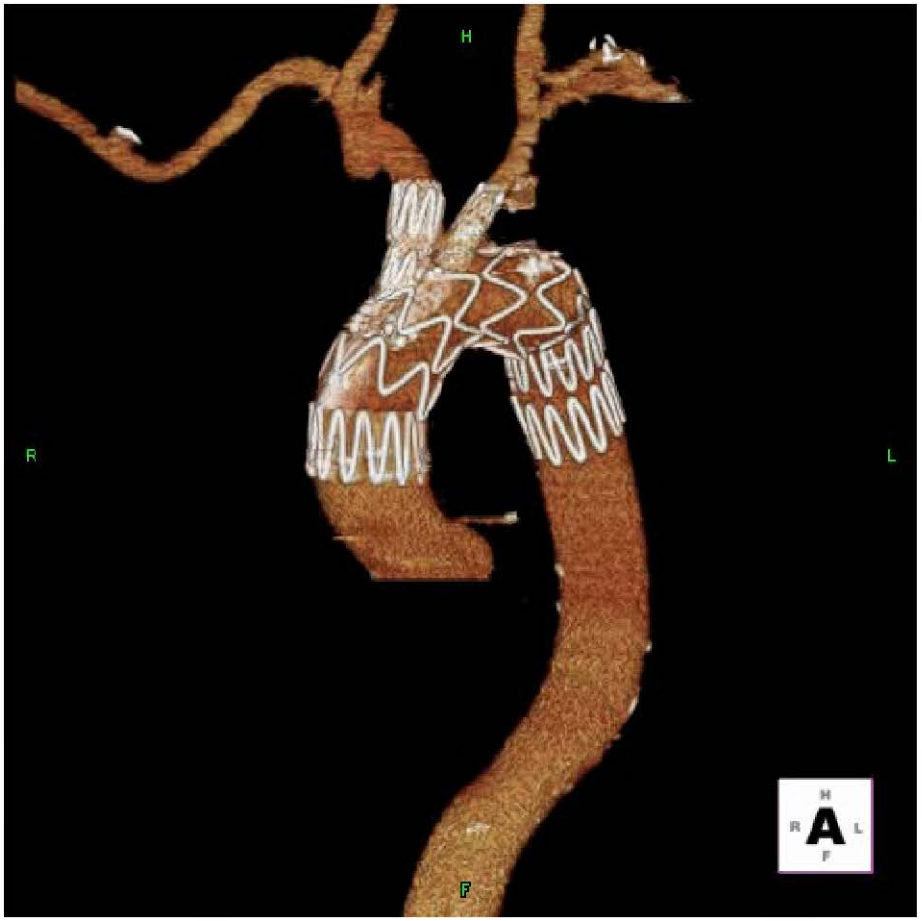
# Important Device Characteristics



# Procedure Related: Device

- Stentgraft
  - Highly conformable, Elastic
  - Strong fixation in hostile environment
    - Radial force
    - Active fixation
      - Internal or external?
  - Flush edge vs root component
  - Curved shape
  - ? Branch / branches for **distal and proximal** seal


H
R
L
F
A


H
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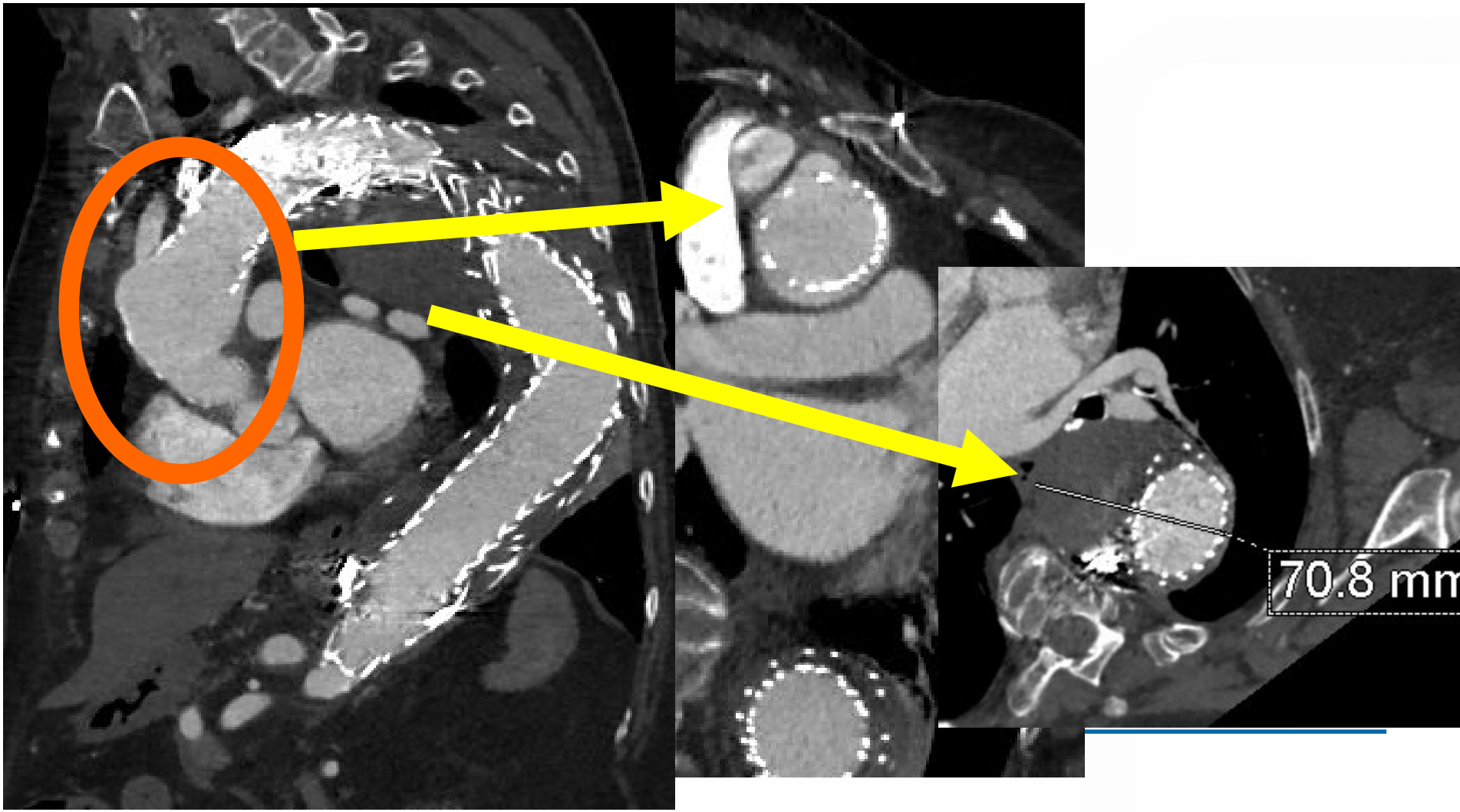
# Ascending Often Dilated / ing

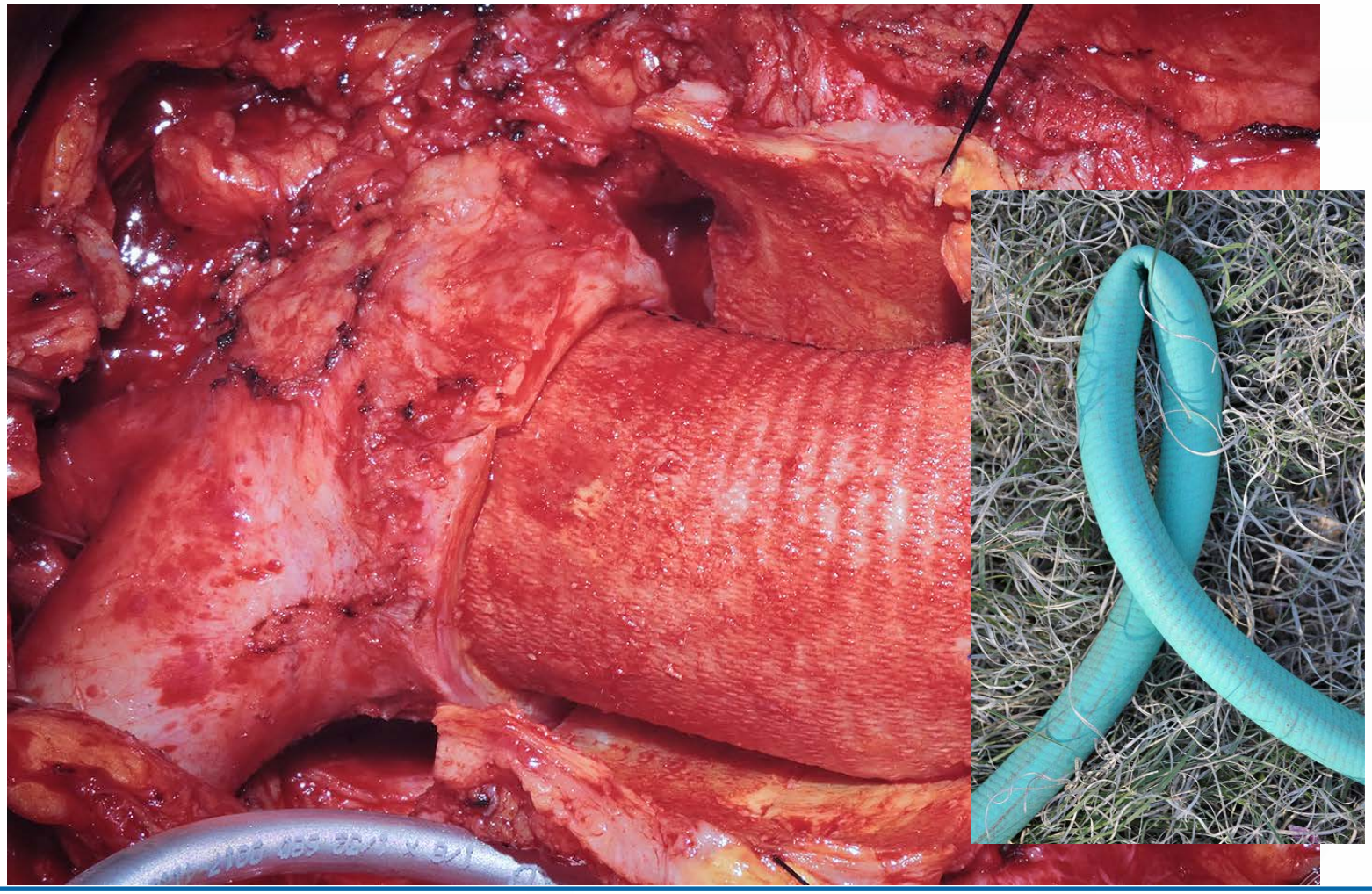
- Type 1 Endoleak ~ 10% (up to 19%)



# Type A after previous Type B

**Retrograde Dissection or Disease Progression ?**

# Grafts Often Short



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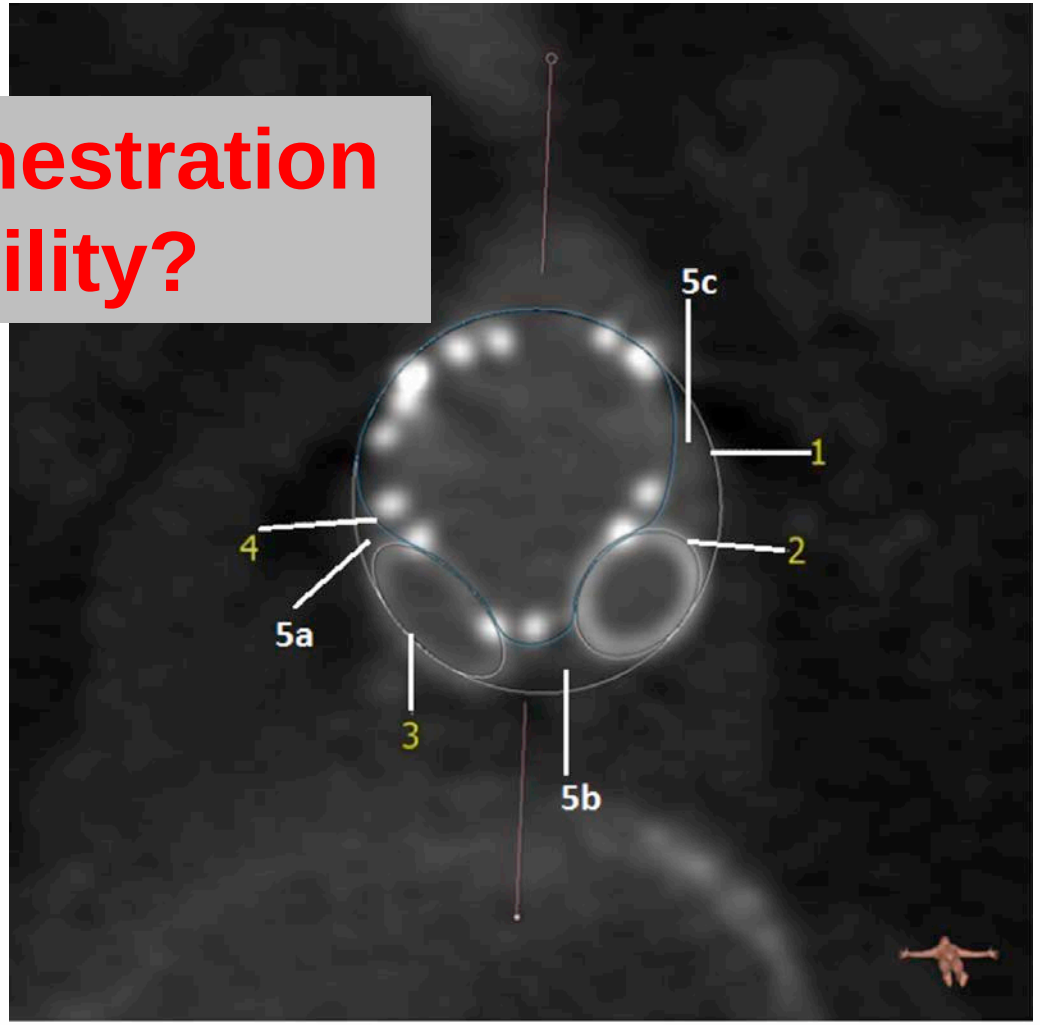
Or Kinked

# Procedure Related: Delivery & Deploy

- Delivery Technique
  - Transfemoral vs alternate access
  - Disease dependent
  - Pre-curved – self orienting
  - Crossing the valve
  - Branch Access
- Deployment System
  - Exceedingly precise, controlled
  - Staged deployment
  - Repositionable
  - Flexible / steerable for coaxiality

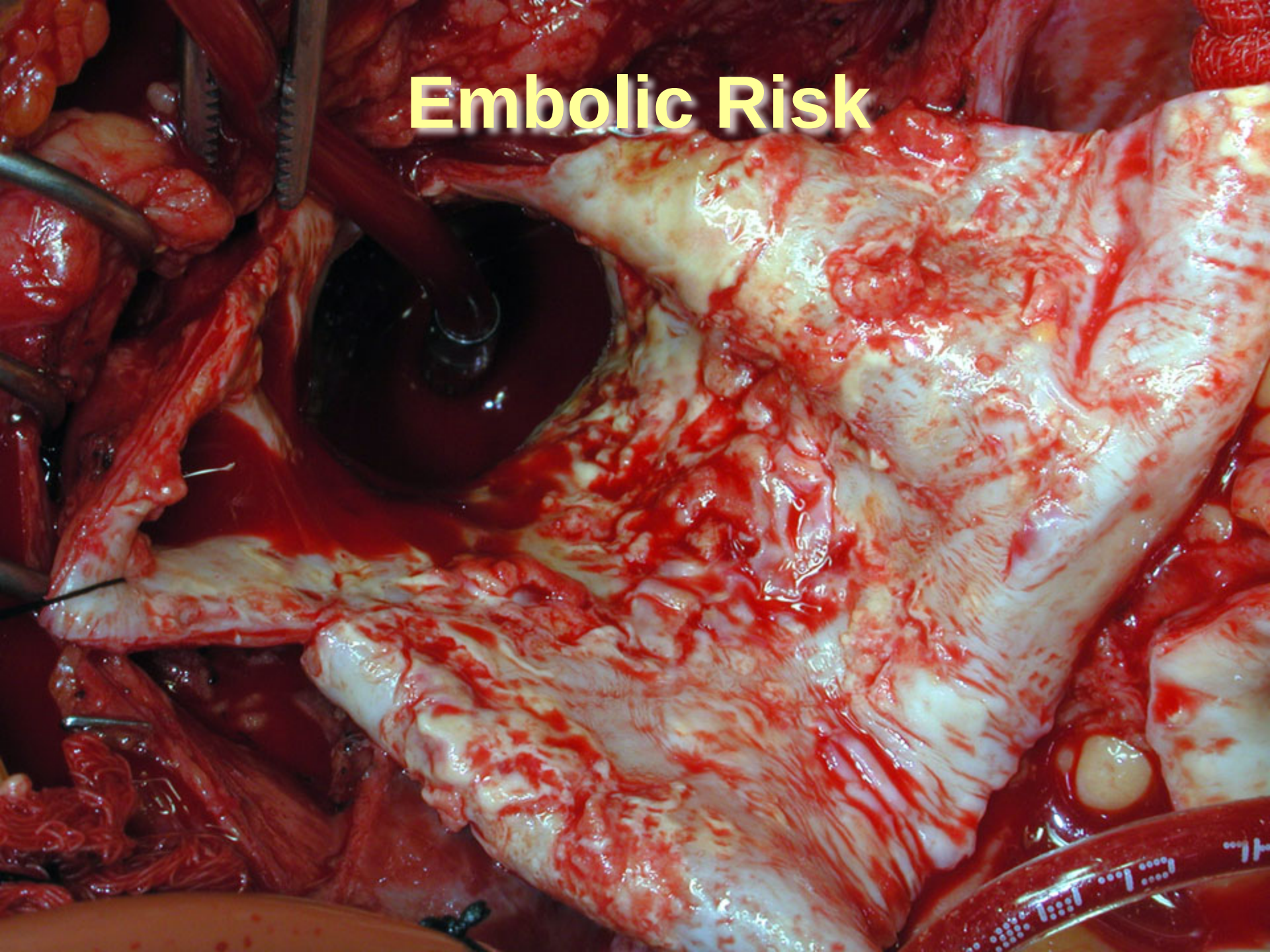
# Branch Challenge: Endoleaks, Patency ?

**In-Situ Fenestration and Durability?**

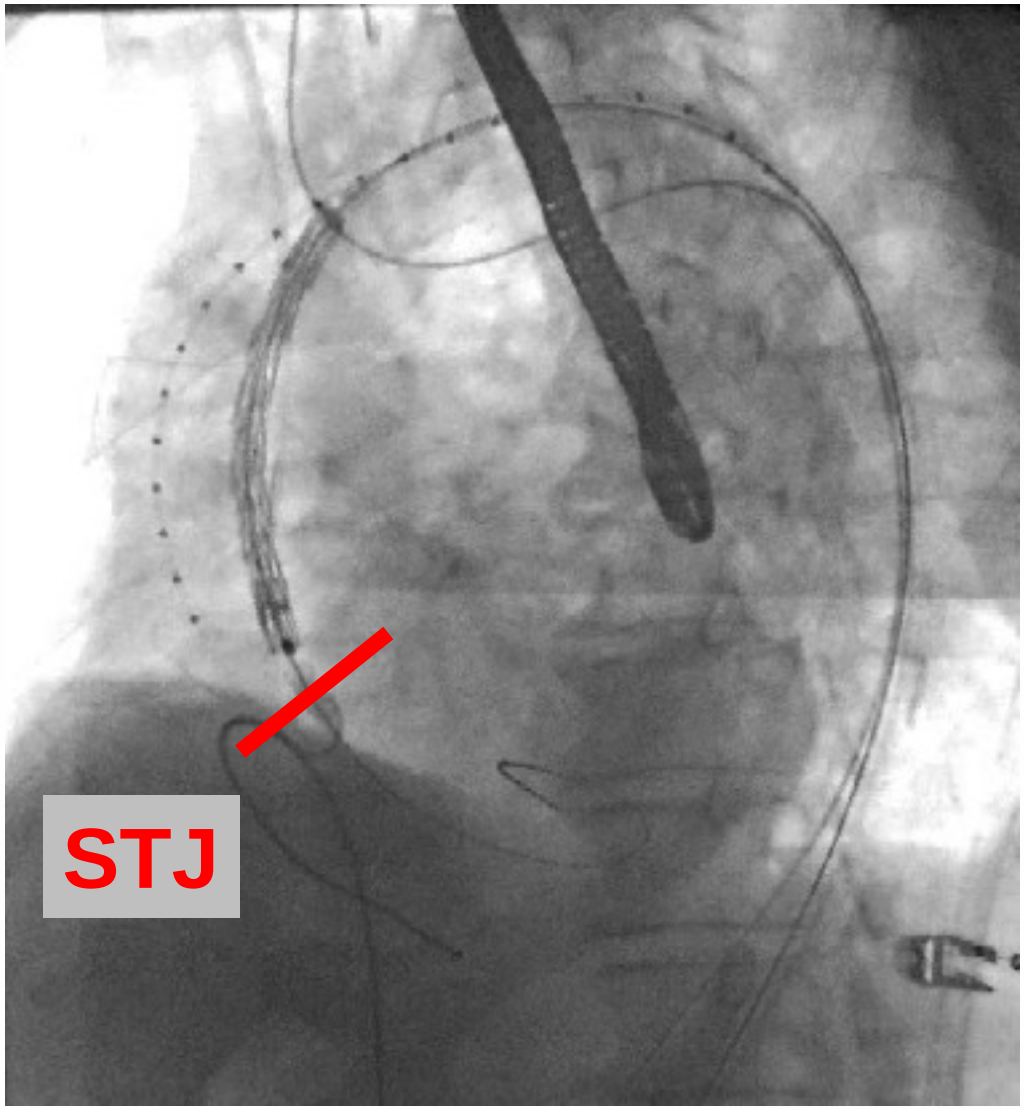





Beaufort H, et al. JVS, ‘17.


Embolic Risk

# Transfemoral Deployment



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EDITORIAL COMMENT

# On the Endovascular Climb to the Type A Dissection Summit, Reaching a New Base Camp*

Michael D. Dake, MD

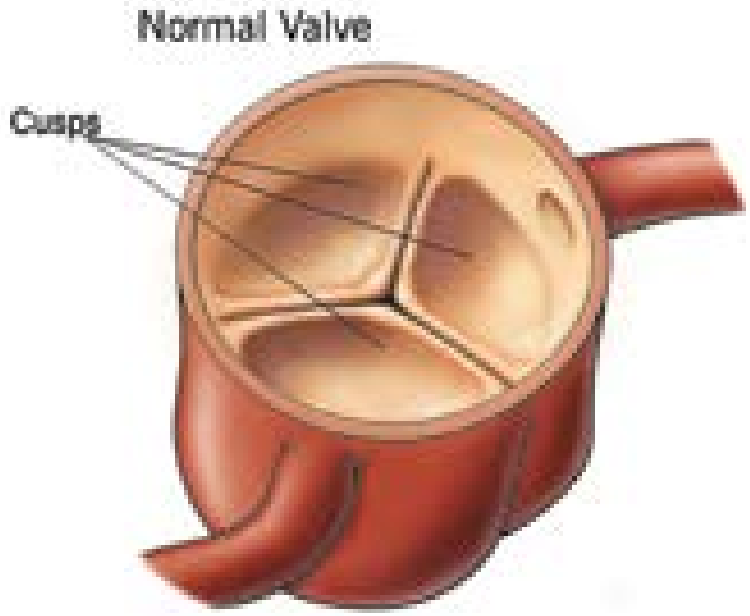
es with type A dissection, Li et al. (13) have succeeded in
c- moving the discussion beyond the novelty level of
as "look, it can be done" to the next developmental
R. stage, poised on the threshold of a prospective clin-
rd ical trial. This is a valuable contribution. I wonder,
of however, if the current TEVAR technology is ready to
st withstand the rigors it will face when we enter the

# Endo CVG Issues

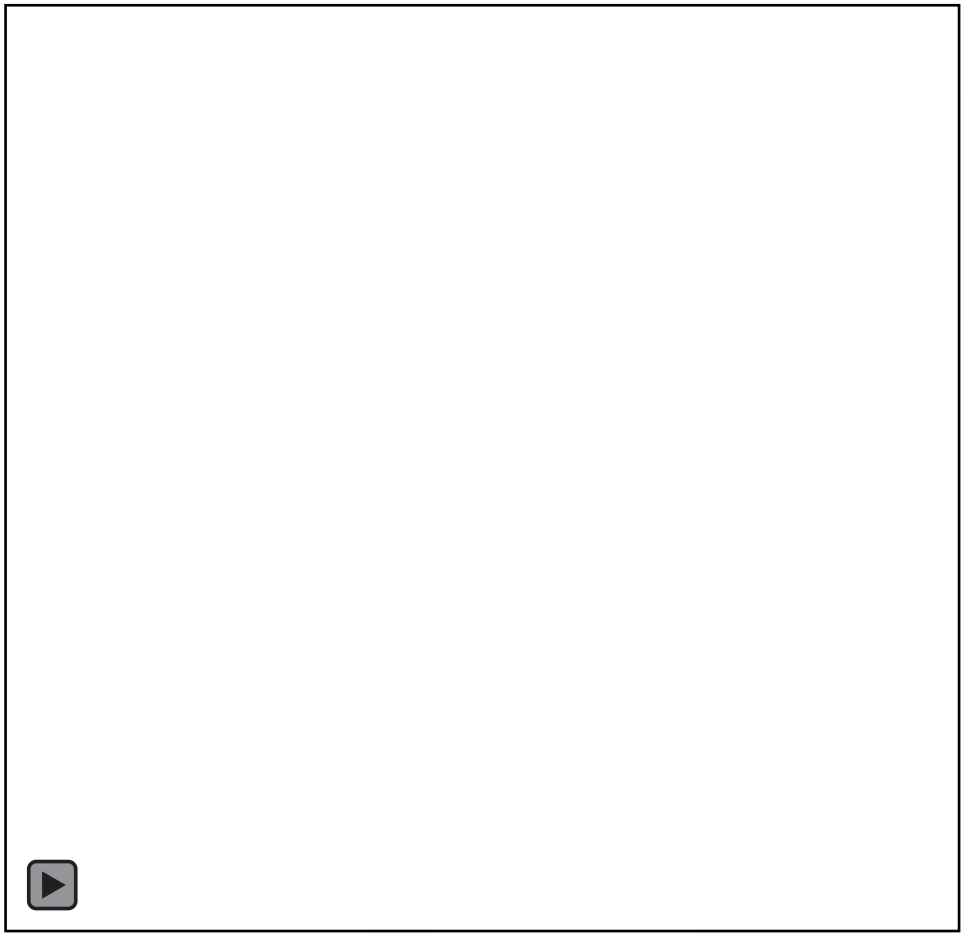
1) Proximal Fixation

AND SEAL

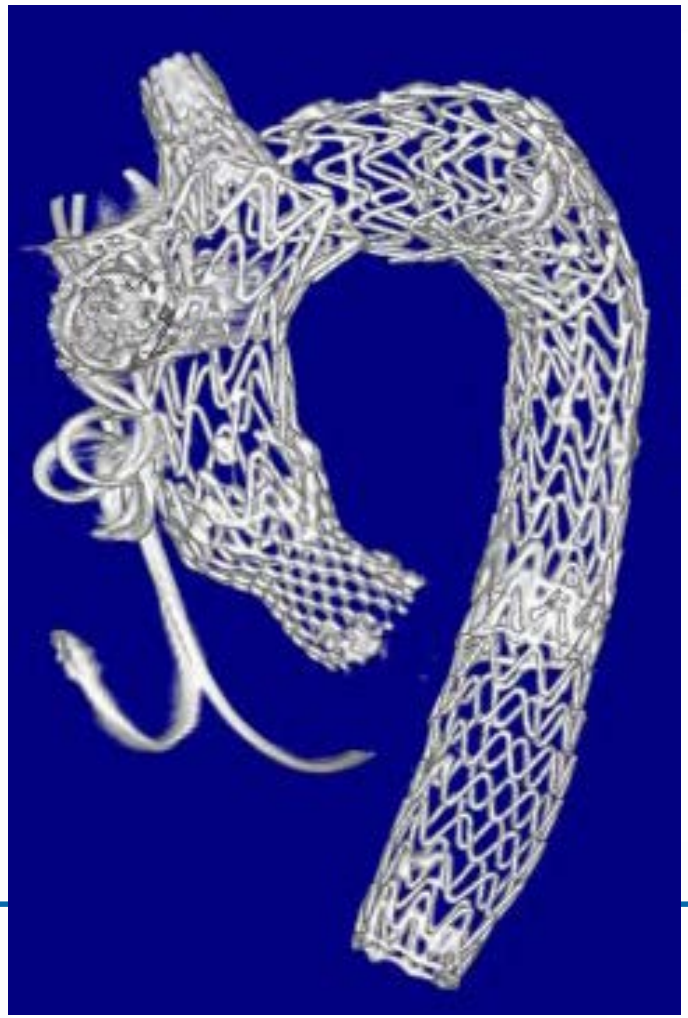
2) Coronary Patency



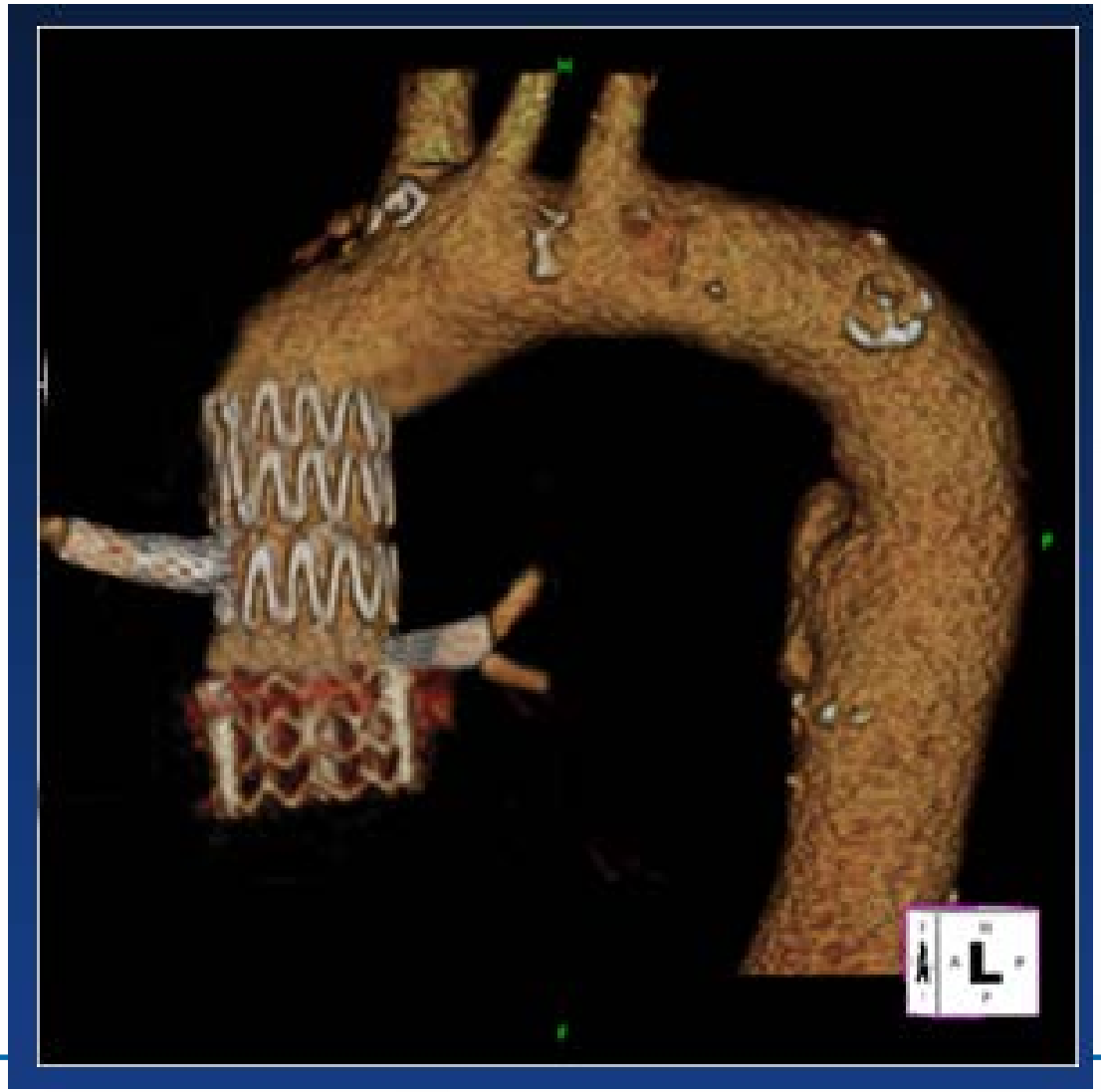
# 52 y/o s/p esophagectomy and colon interposition, new Type A



# 84 y/o, s/p TF TAVR 6 mos prior, recovered well, new Type A with asc and desc tears

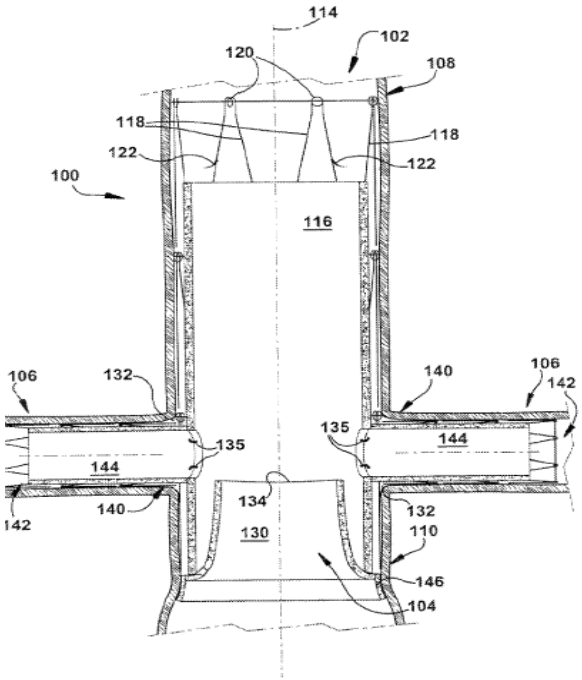


# Endo Composite Valve Graft



# Patent Issued

- ✓ US Issued patent 2007 (US 7,771,467 B2) *Apparatus for repairing the function of a native aortic valve*
- ✓ Prosthetic valve with ascending
- ✓ Coronary artery openings
- ✓ Method of deployment coverage



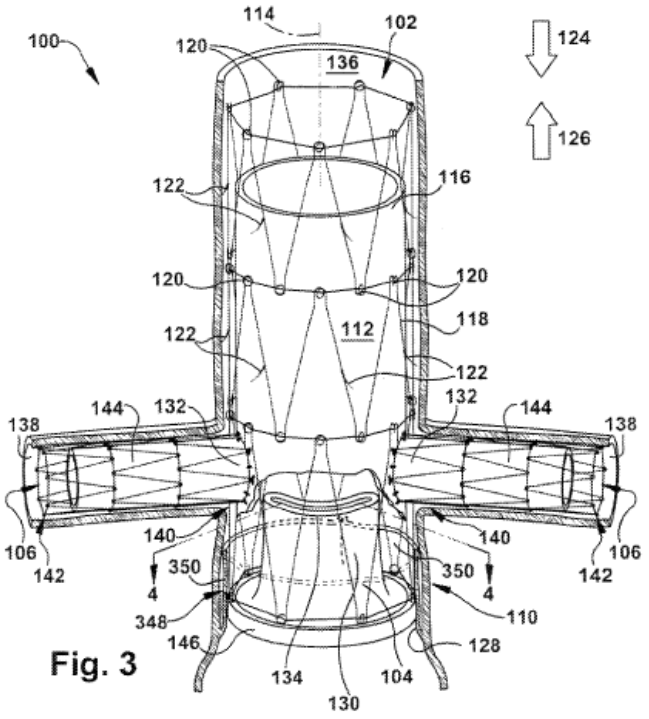




Fig. 3

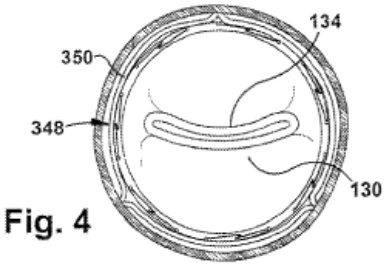
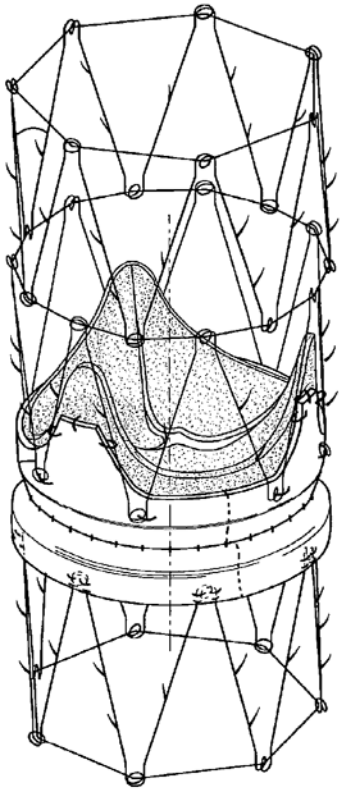
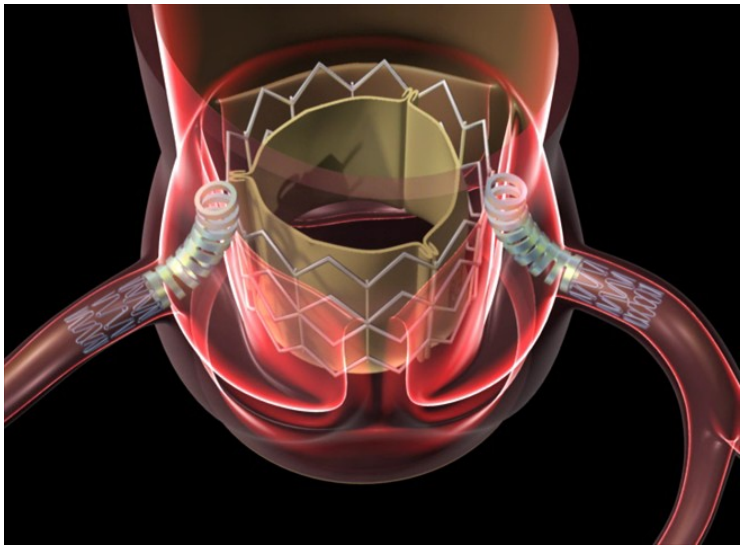



Fig. 4

# Invention: Greenberg Valve + COOL Stent

- ✓ *US, PCT and Non-PCT(Australia, Canada) patents issued (7,799,072 and 8,979,924)*
- ✓ US Issued patent (**US 8,968,386**) *Stent and method for maintaining the area of a body lumen*





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STATE-OF-THE-ART PAPER

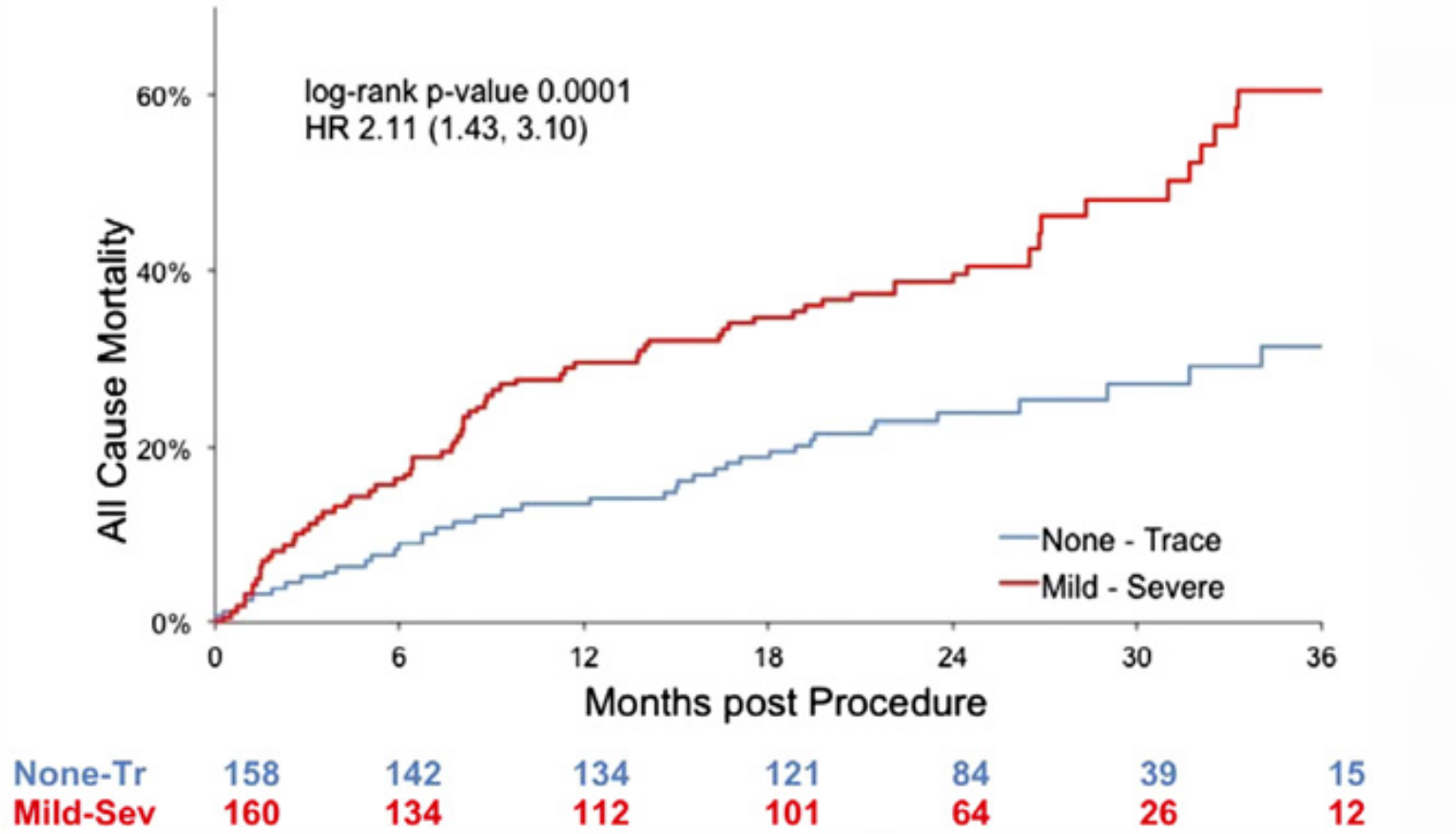
# Paravalvular Leak After Transcatheter Aortic Valve Replacement

## The New Achilles' Heel? A Comprehensive Review of the Literature

Philippe Généreux, MD,*†‡ Stuart J. Head, MSc,§ Rebecca Hahn, MD,*† Benoit Daneault, MD,*†

- Mild PVL is routine
- Moderate or worse PVL is common
  - Balloon expandable 6-14%
  - Self expanding 9-21%

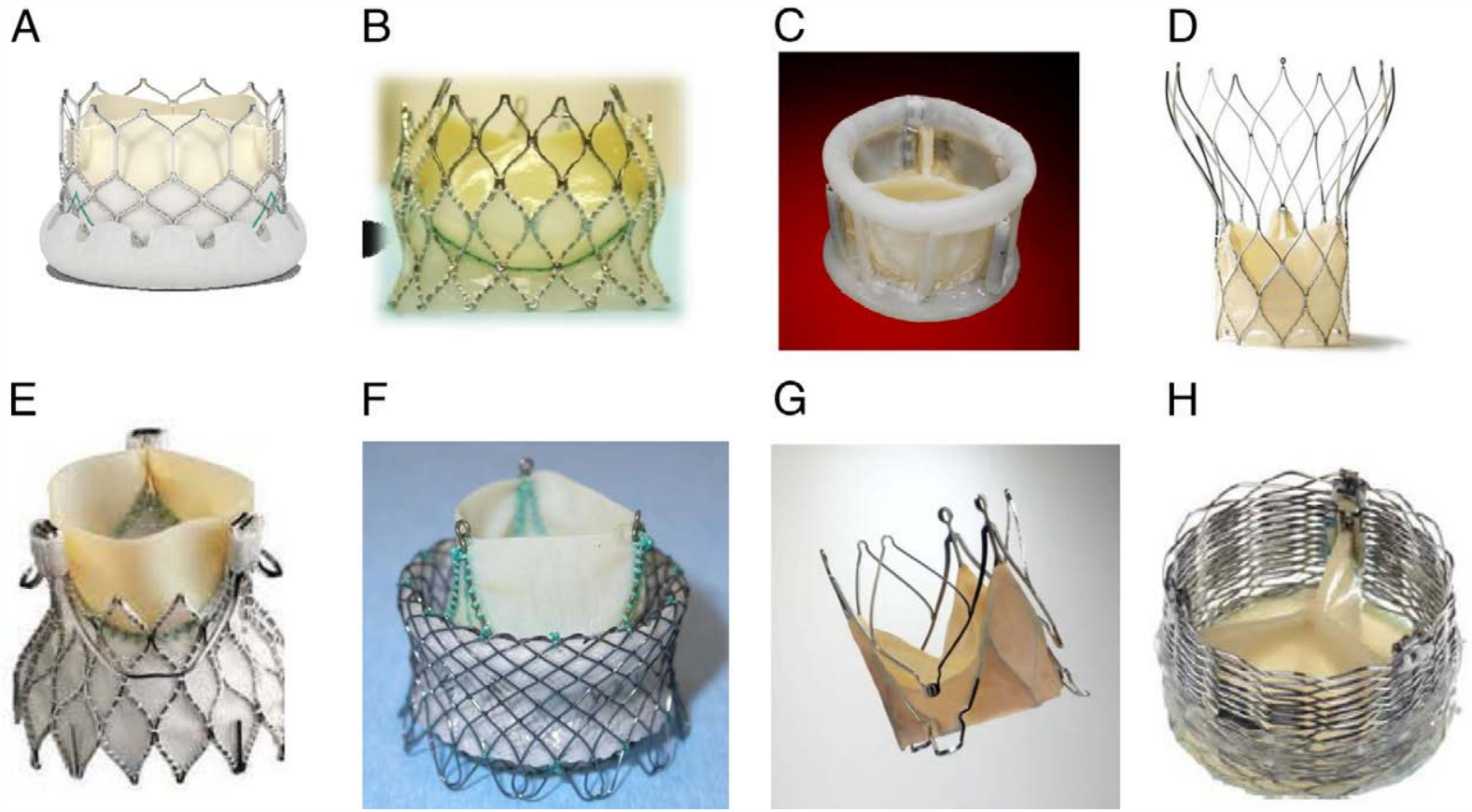
# PVL Associated with Mortality






Kodali S, et al. NEJM, ‘12.

# New Valves to Reduce PVL

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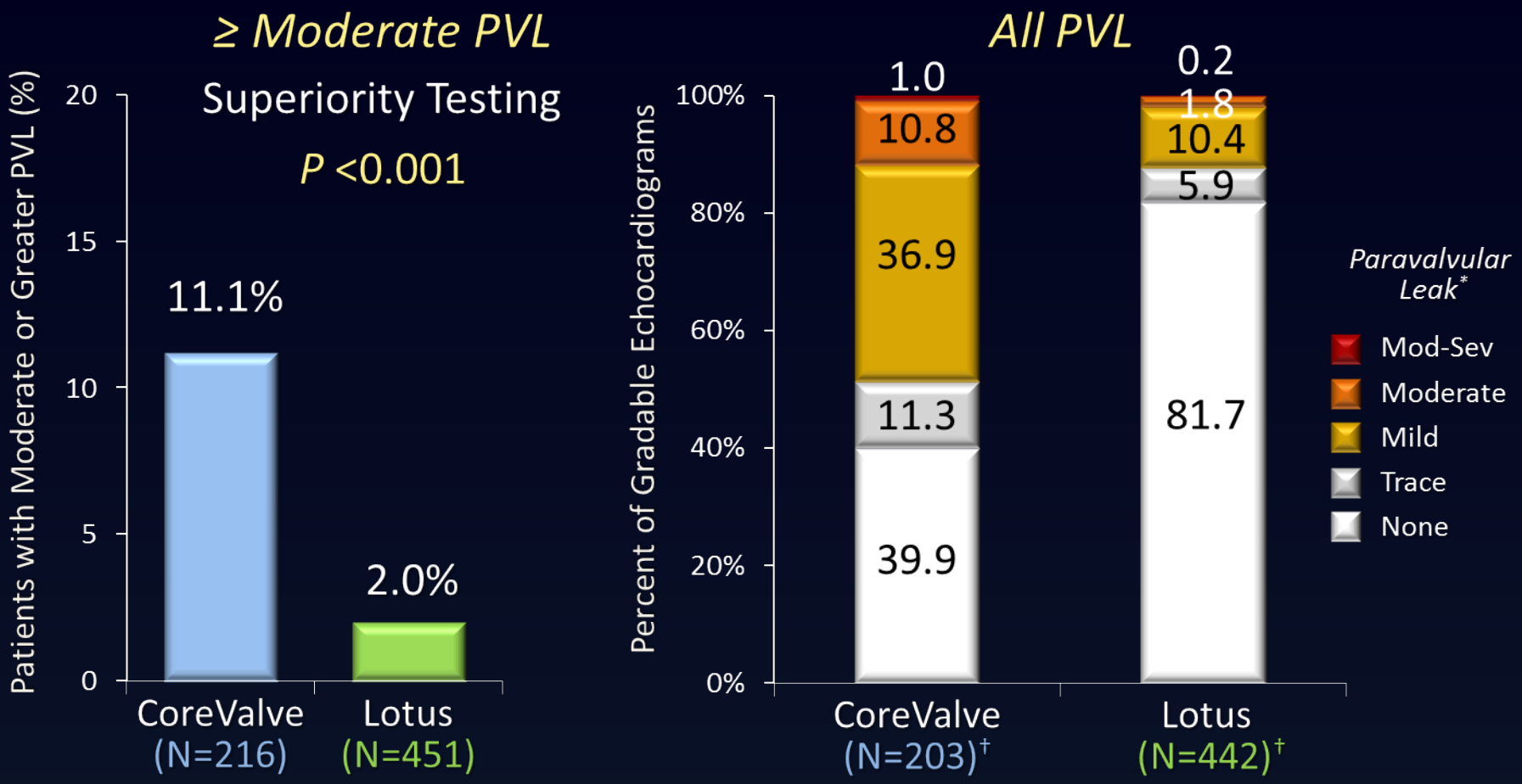
Genereaux P, et al. JACC, ‘13.

# Paravalvular Leak at 1 Year

## *Core Lab Assessment – Intent-to-Treat*

REPRISE III
Lotus™ Valve System




→ *Superiority achieved for secondary endpoint*

* There were no case

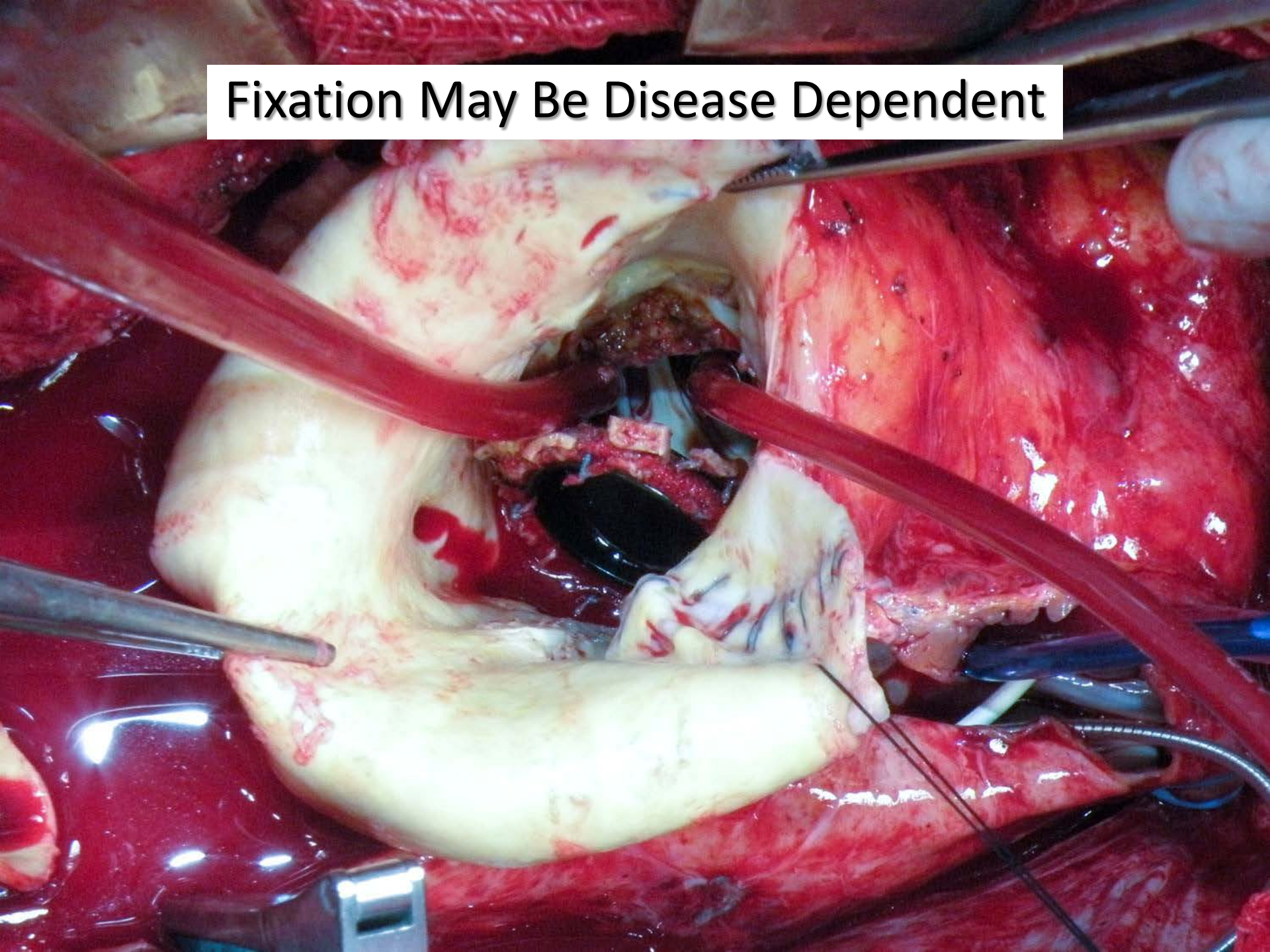
† For superiority testi

the group with less

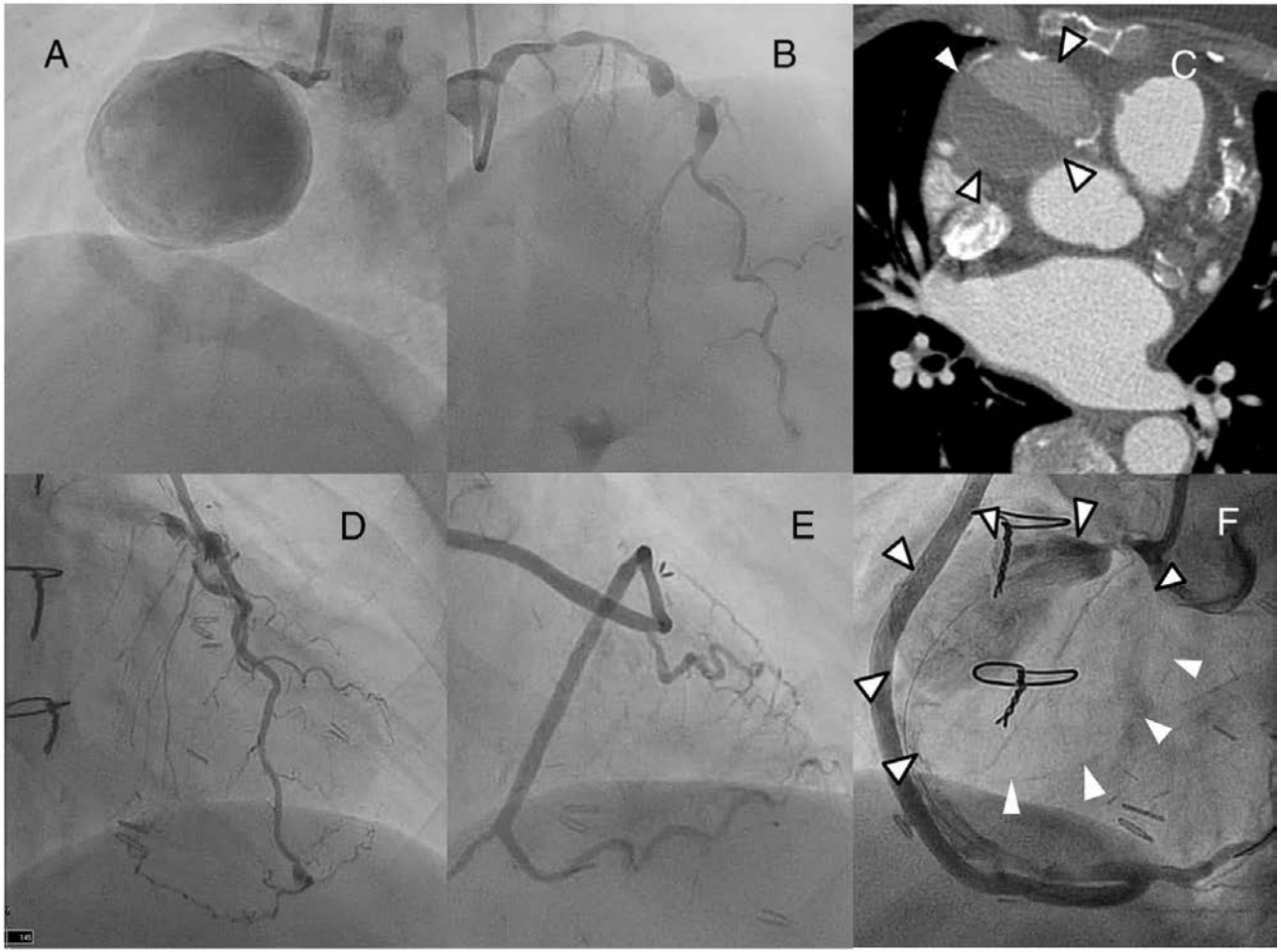
d in

Presented at Euro PCR 2017

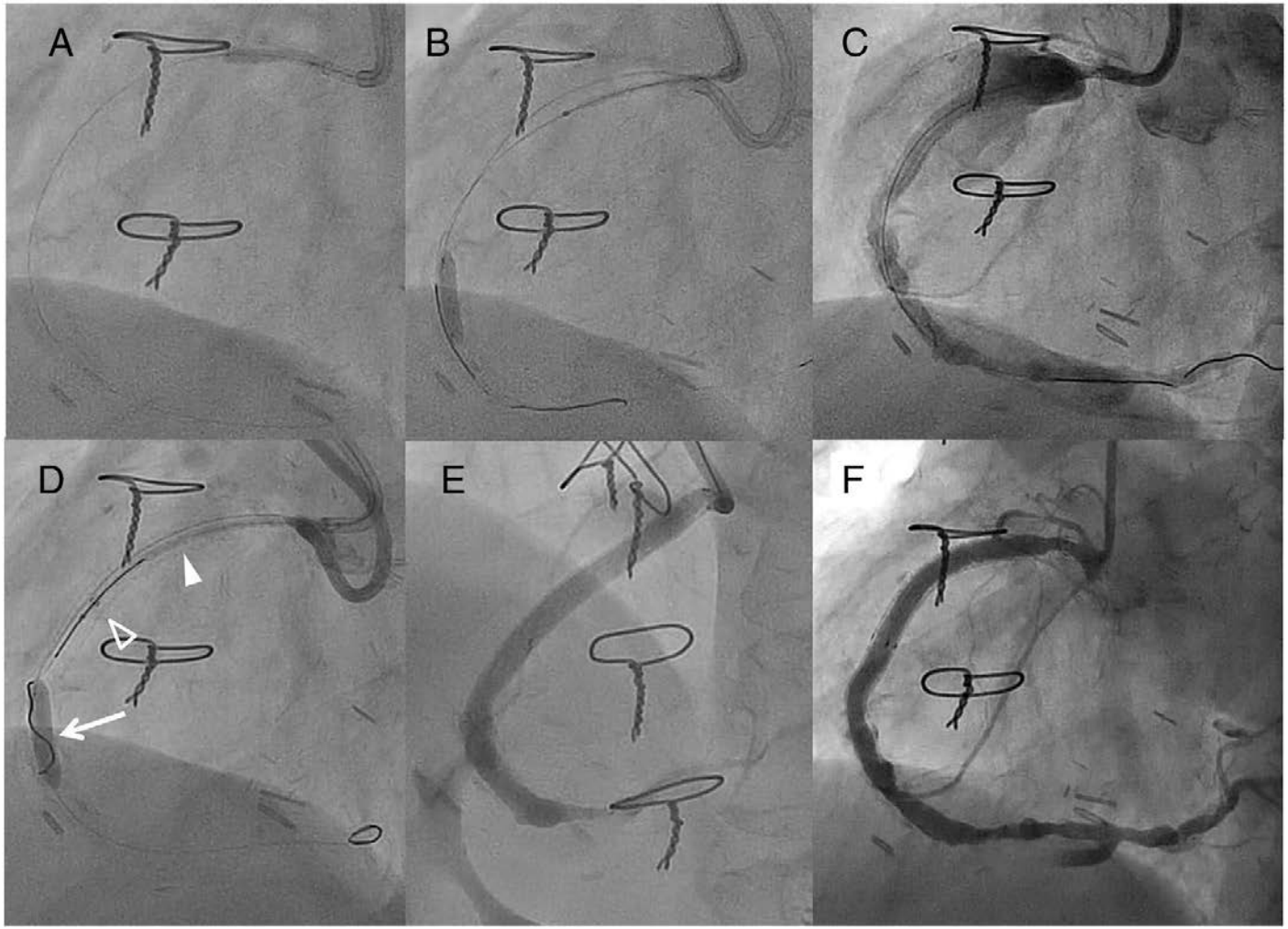
# Fixation May Be Disease Dependent



# Coronaries Can be Treated with Covered Stents



# Coronaries Can be Treated with Covered Stents



# Covered Coronary Stents For Perfs

**TABLE I. Graftmaster Rx Coronary Stent Graft System (Abbott Vascular)**

| Stent graft diameter (mm) | Stent graft length (mm) | Minimum deployment (nominal) and rated burst pressure | Guide catheter |
|---|---|---|---|
| 2.8 | 16, 19, 26 | 15/16 ATM | 6 Fr |
| 3.5 | 16, 19, 26 | 15/16 ATM | 6 Fr |
| 4.0 | 16, 19, 26 | 15/16 ATM | 6 Fr |
| 4.5 | 16, 19, 26 | 15/16 ATM | 7 Fr |
| 4.8 | 16, 19, 26 | 15/16 ATM | 7 Fr |

**Indication**: for use in the treatment of free perforations, defined as free contrast extravasation into the pericardium, in native coronary vessels or saphenous vein bypass grafts ≥2.75 mm in diameter. Requires IRB approval for use.

**Stent material**: Stainless steel 316 L.

**Graft material**: expandable polytetrafluoroethylene (ePFTE) sandwiched between two identical stents.



Sandoval Y, et al. CorCathInt, '17.

# What about Cost?

- Endografts $10-45K
- TAVR $25K +
- Surgical Grafts $200 - $2000

(Plus other direct hospital costs…)

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