Endo-Bentall: Fact or Fiction?

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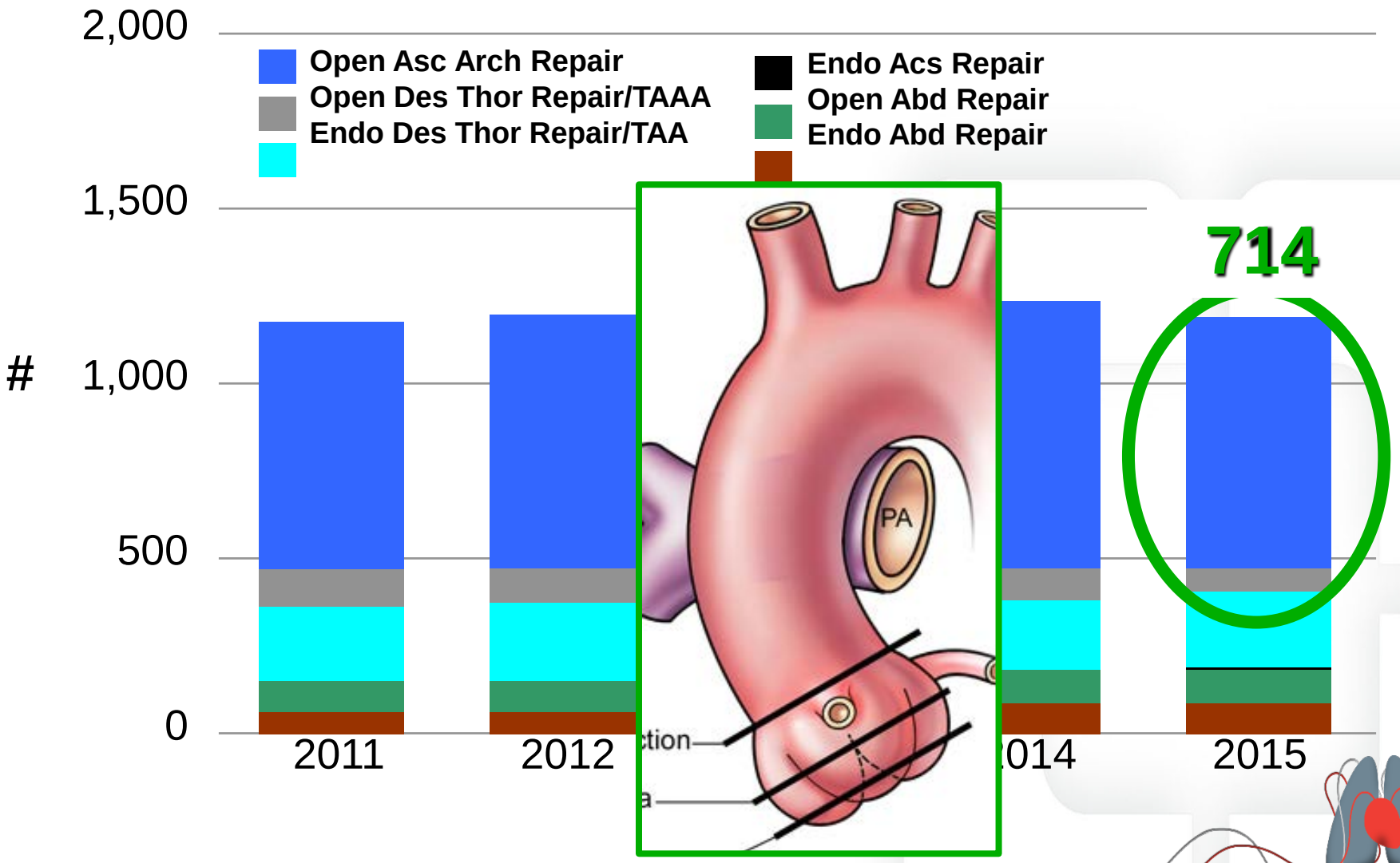
Chief, Adult Cardiac Surgery
Surgical Director, Aorta Center
Heart and Vascular Institute, Cleveland Clinic

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

Cleveland Clinic

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.

Root Replacement in North America: Valve Preserving vs Composite

- 2000 thru 2011, STS Database
- N = 31,747; 11% AVSp, 89% CVG
  - High Risk (~20K)

    >75, endocarditis, AStenosis, Dialysis, Multi-valve, Reop, or Emergency
  - Low Risk (~11K)
  - Overall Mortality 8.4%
    - AVSp 4.5%; 1.4% LR, **10.5% HR**
    - CVG 8.9%; 3.1% LR, **11.7% HR**
  - **AS with CVG** **5.1%**
  - **Emergency with CVG** **22.5%**

Caceres M, et al. EurJCTS, ‘14.

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

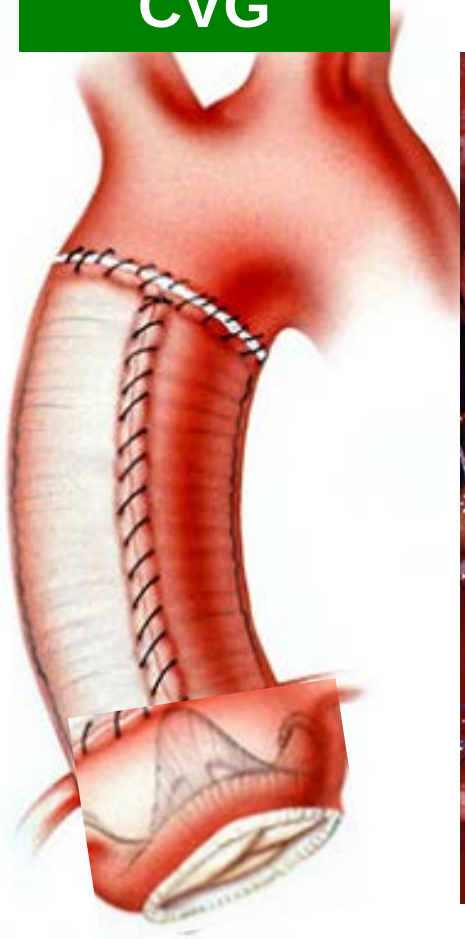
Annals of thoracic surgery, 2016

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

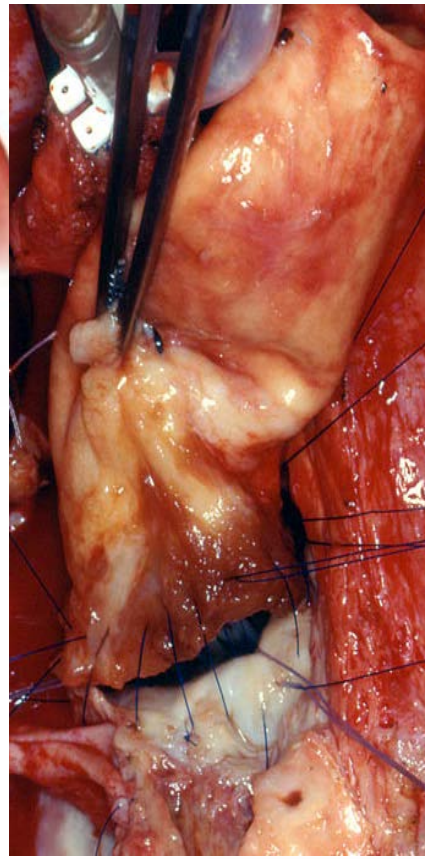
Four Root Procedures

Mechanical CVG

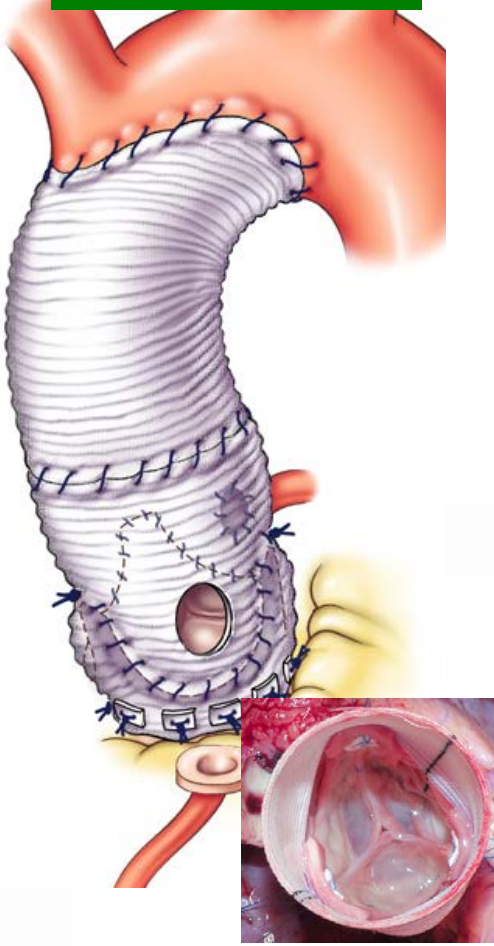
Biologic CVG



Homograft



Valve-Preserving Root



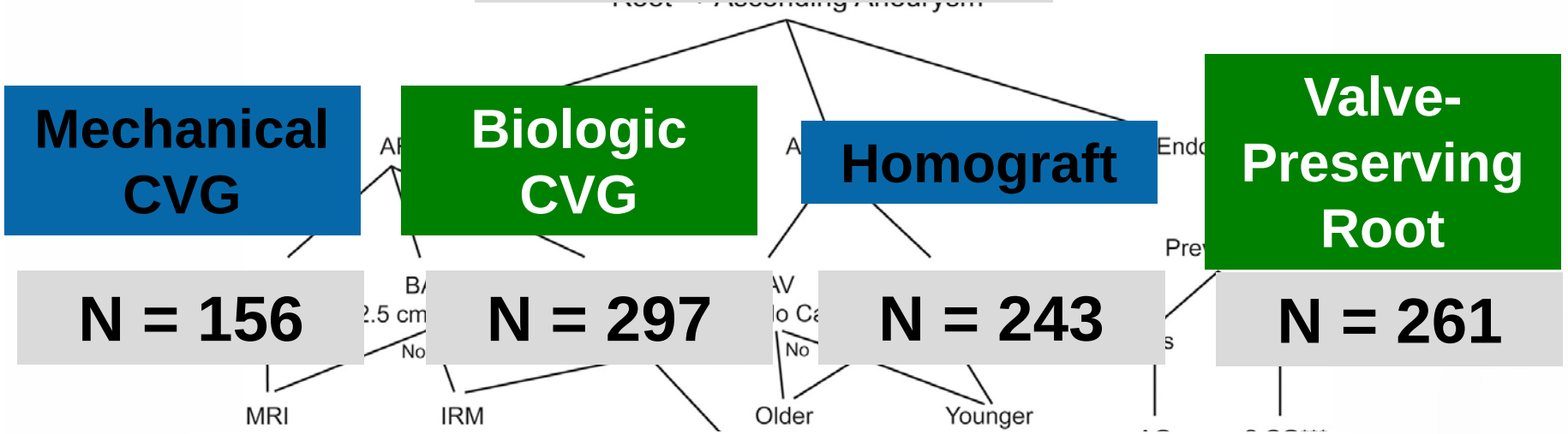
Svensson LG, et al. JTCVS, ‘16.

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]

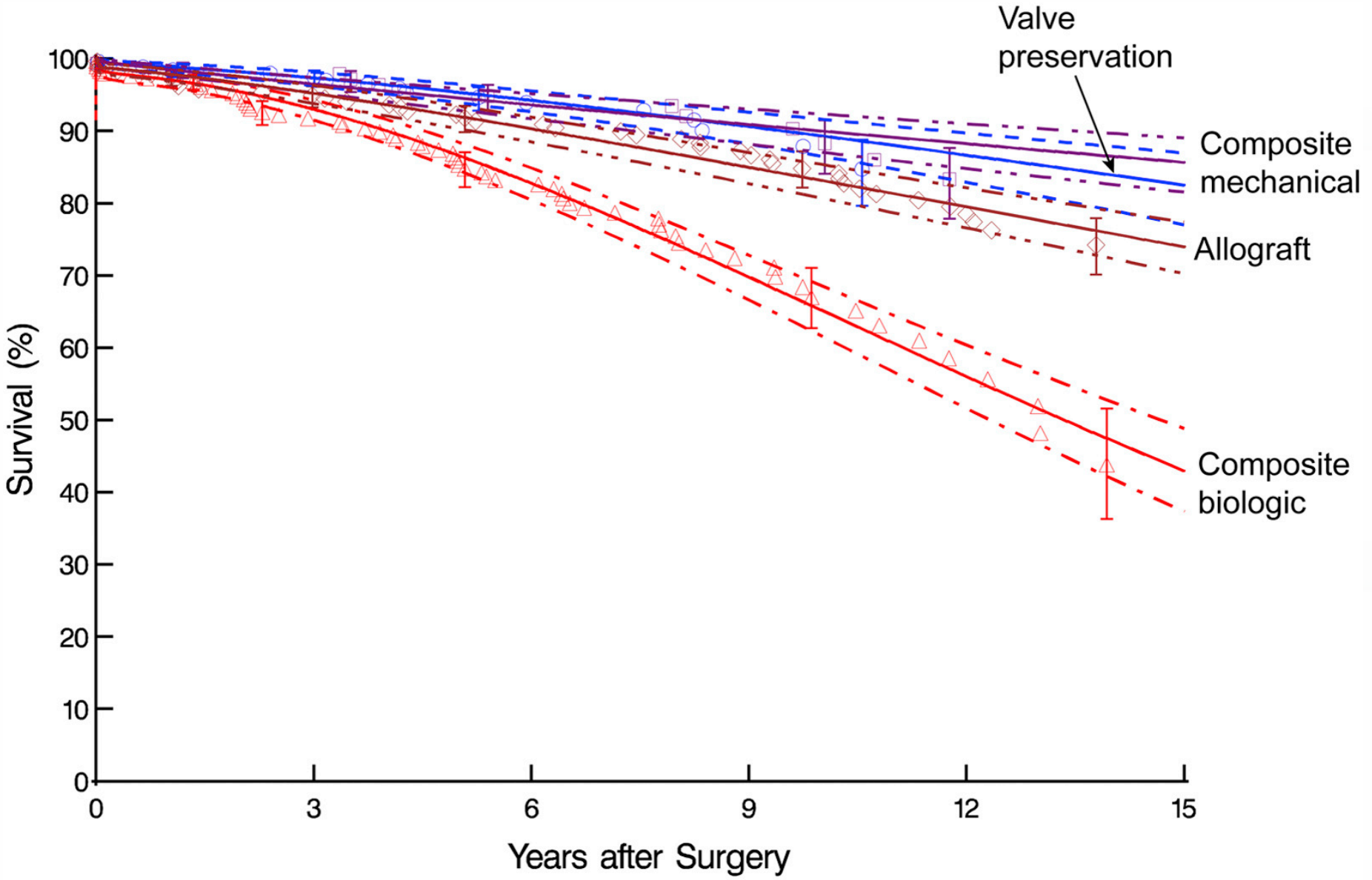
Cardiovasc Surg 2016;151:764-74)

1995 - 2011
N = 957

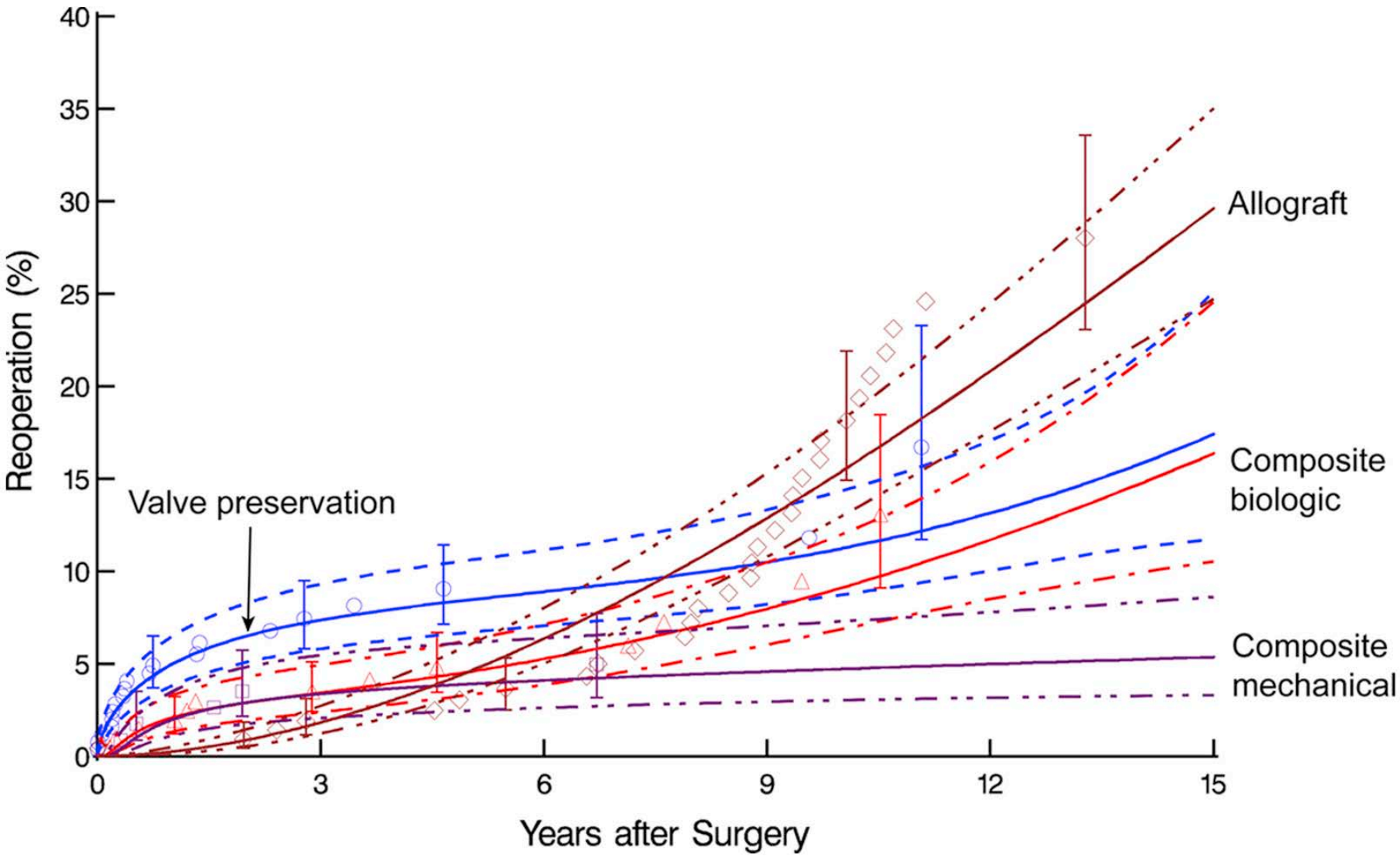


- **Mortality** **0.73%**
- **Stroke** **1.4%**

Survival Post Root Replacement



Reoperations Post Root Replacement



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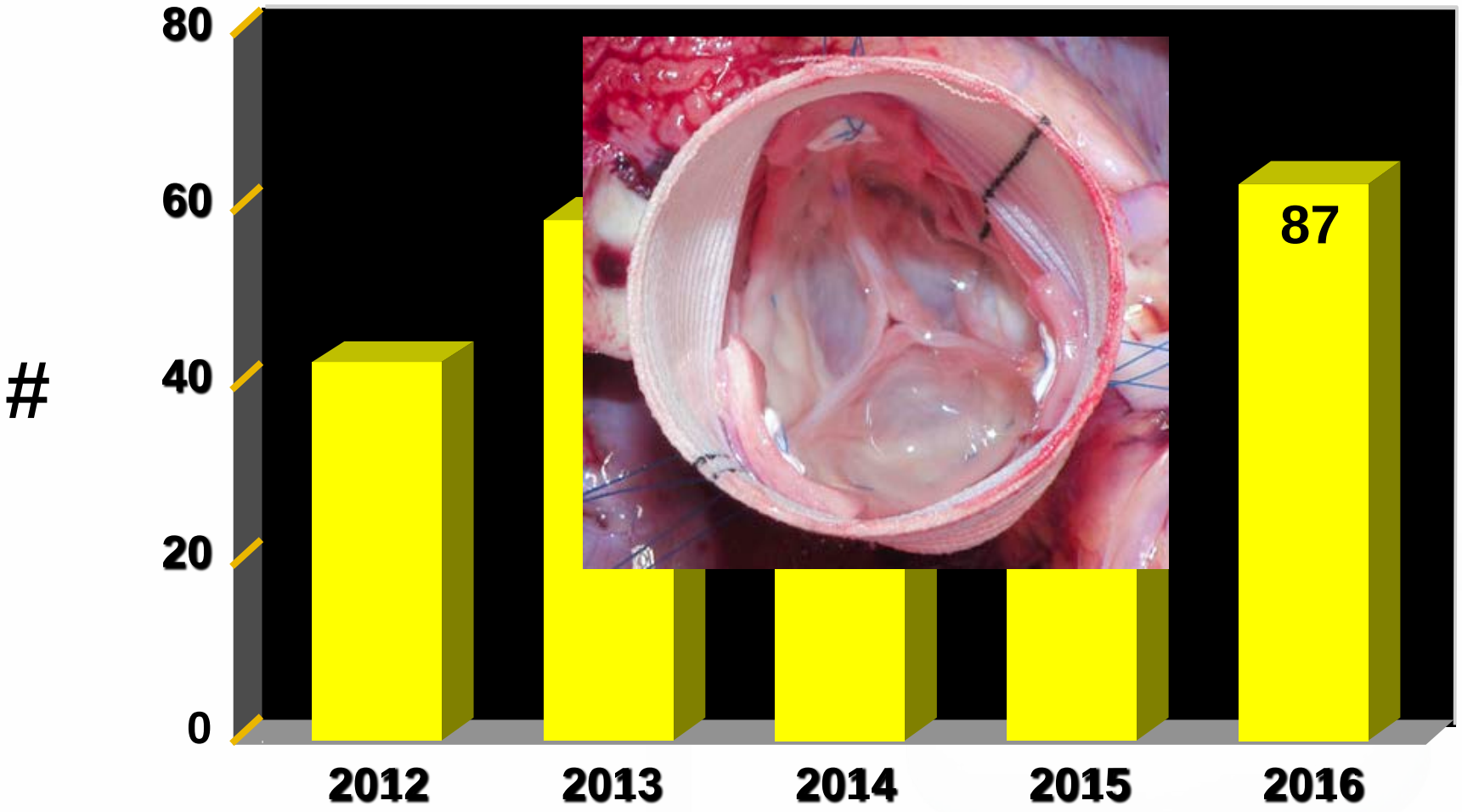
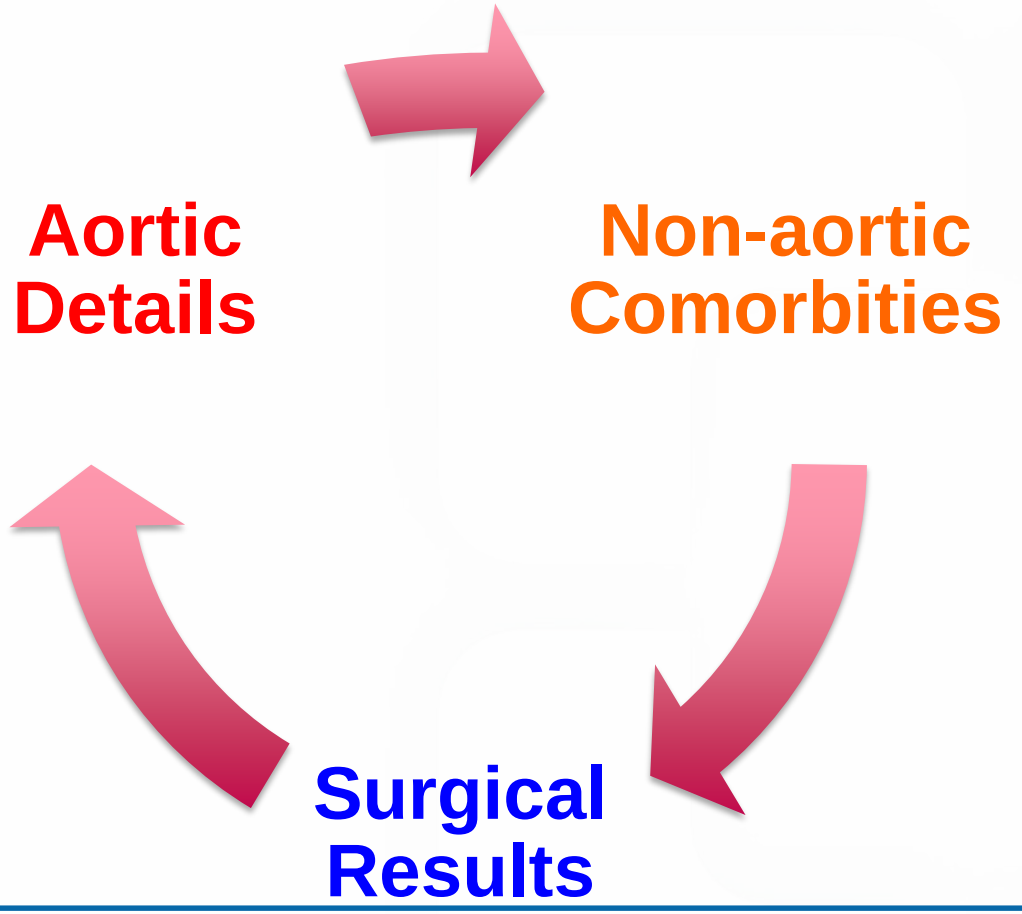
Saving the Living Valve

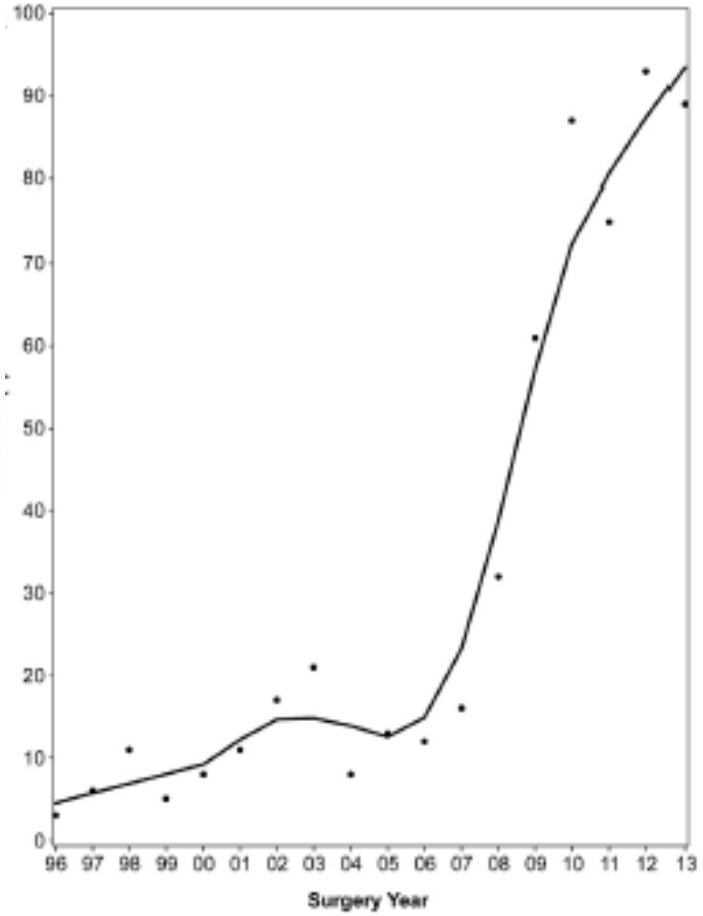


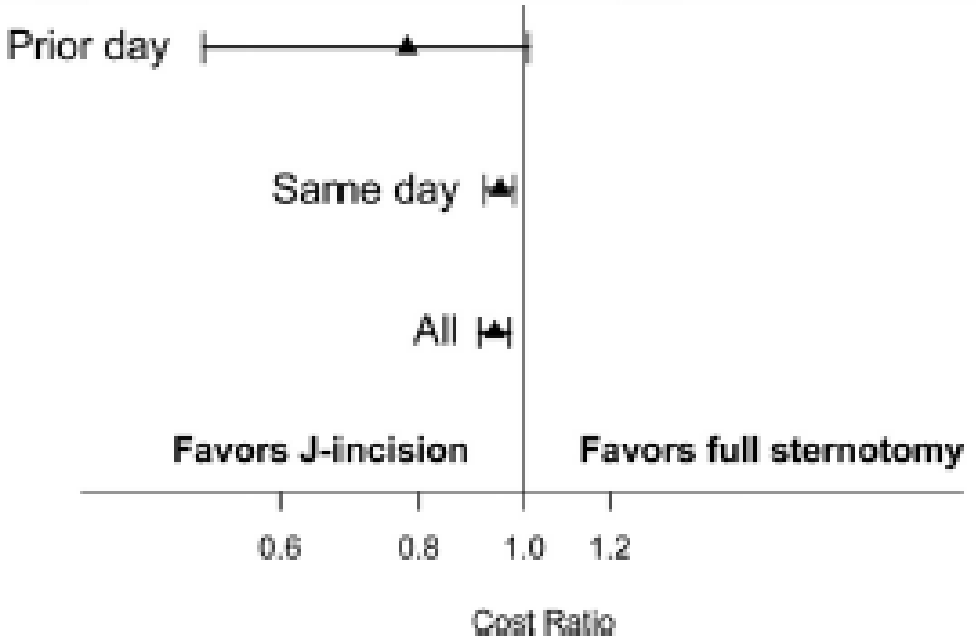
Risks and Benefits Must be Tailored to the Patient



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

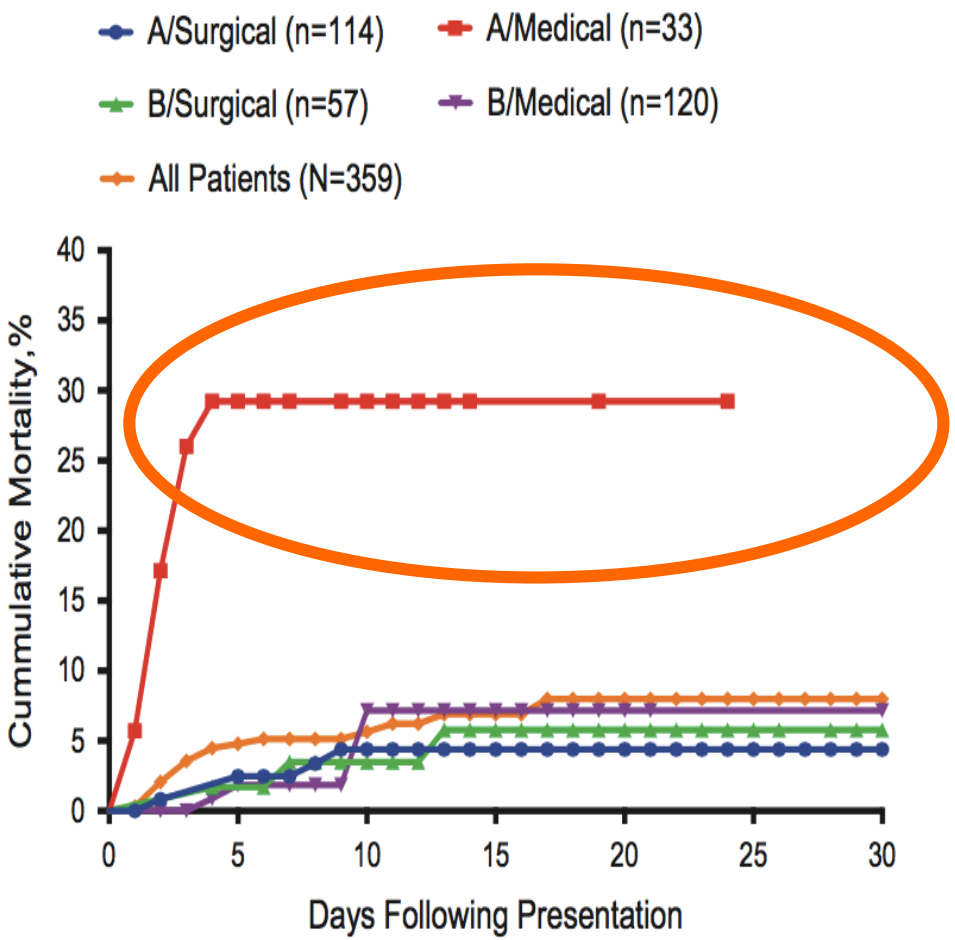




Levack M, et al. JTCVS, ’16.

Unmet Need in Aortic Dissection

4% Type A Op; 4.5% Type B



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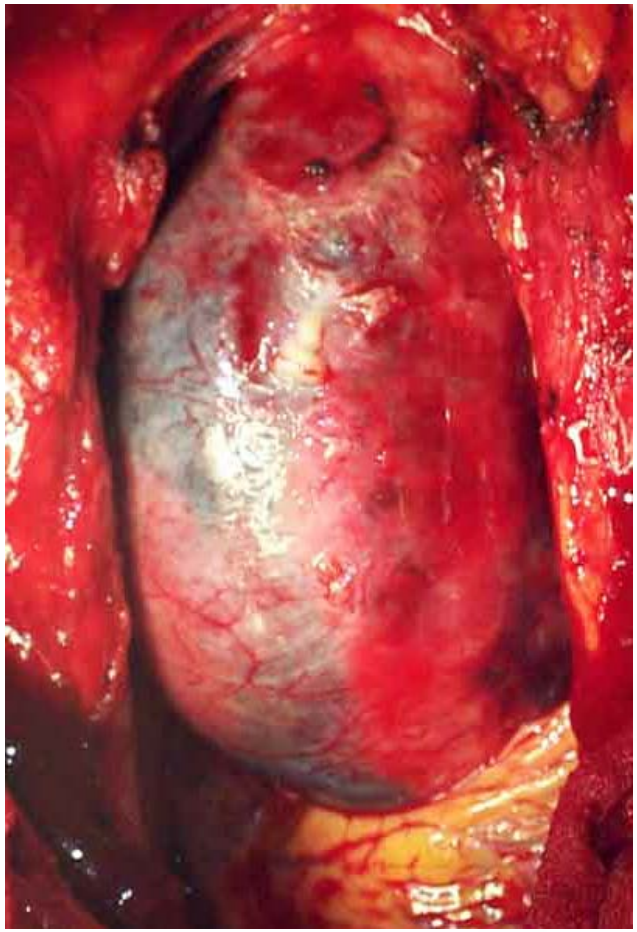
Hagan, et al. IRAD, JAMA 2000.
Aggarwal B, Roselli EE, et al. Circ CVQual Out, 2014.

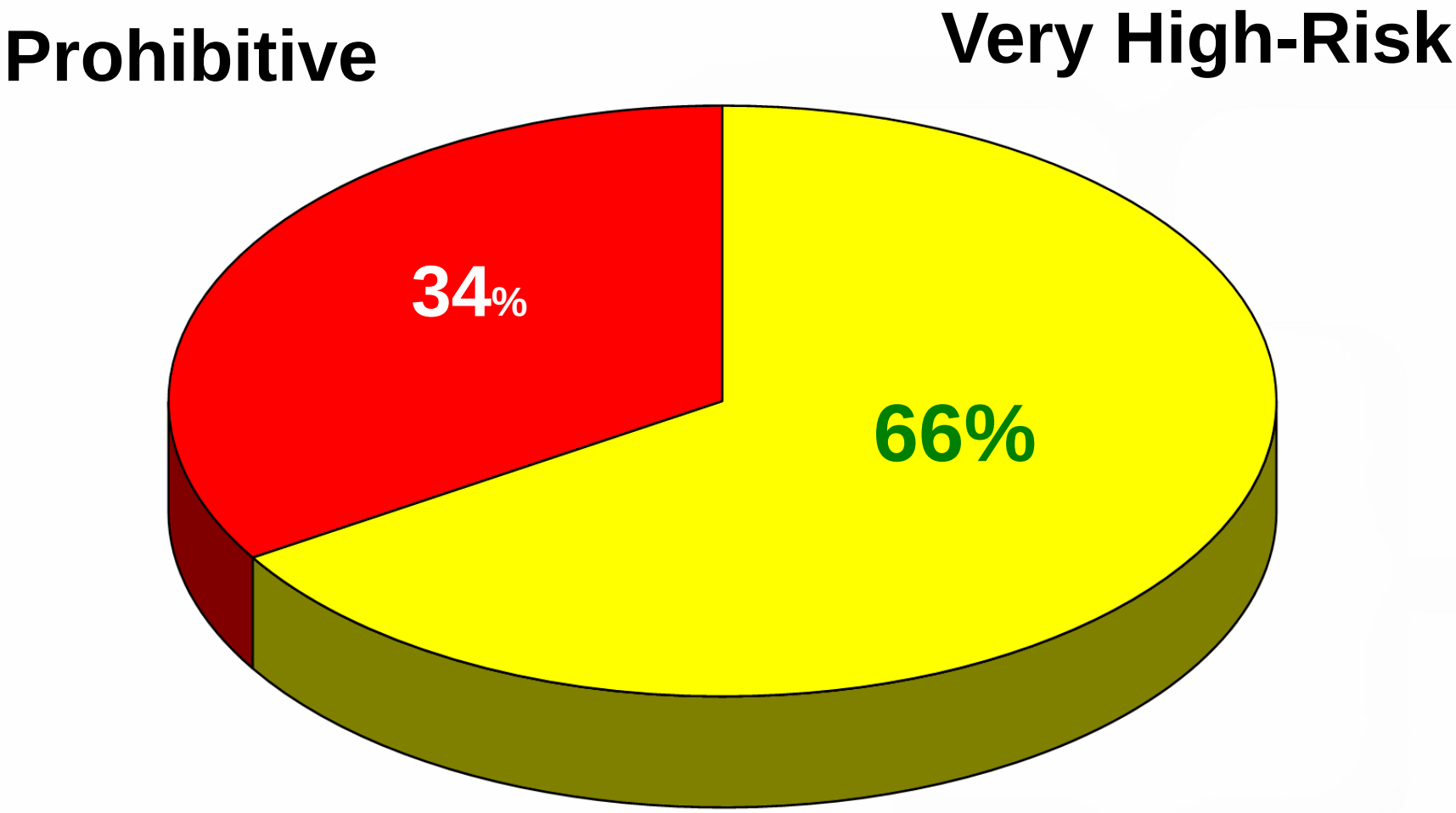
Inoperable Patients (2005-2015)

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



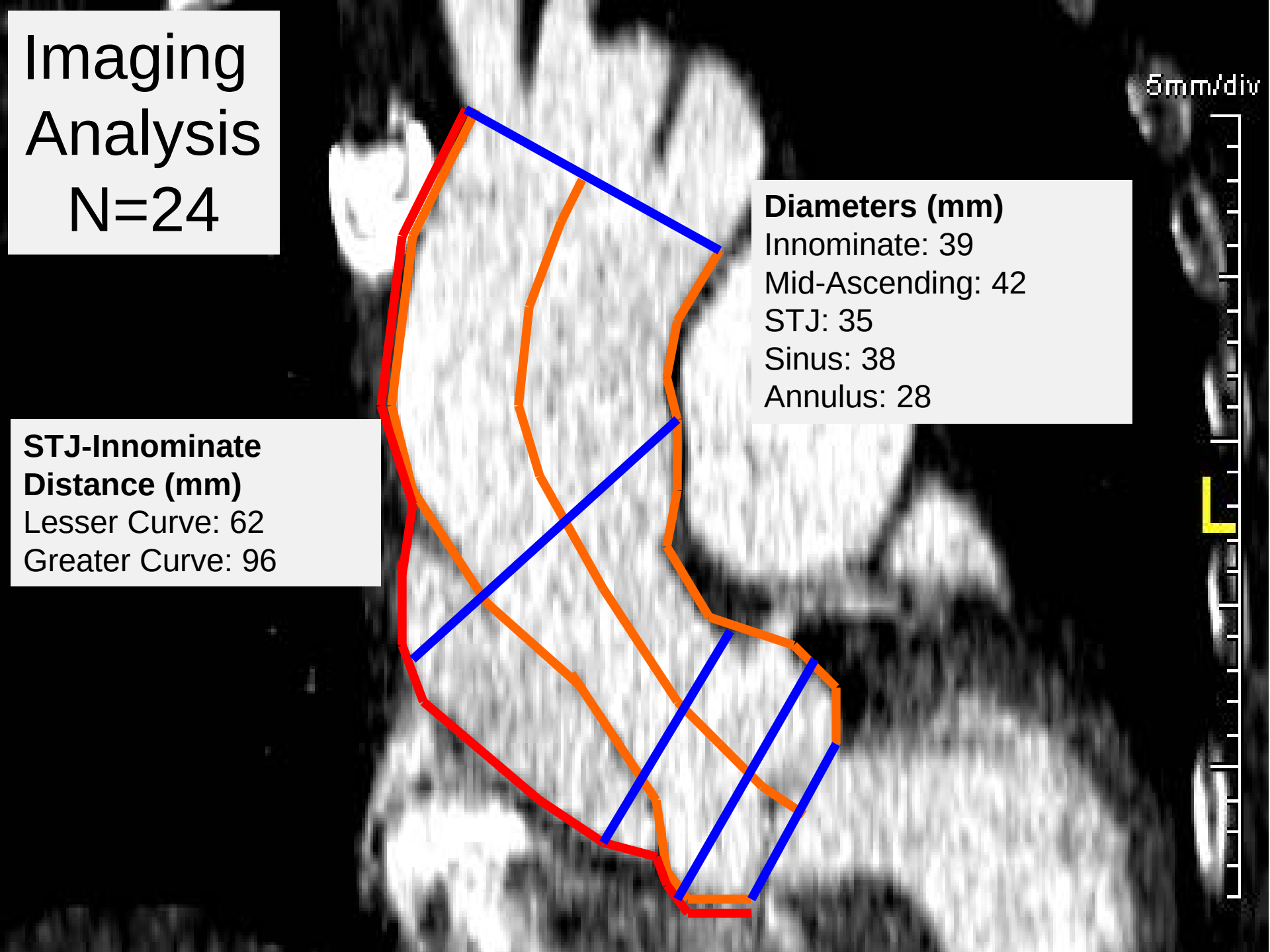
Roselli EE, Hasan S, et al. Int EurJCTS, ’17.

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

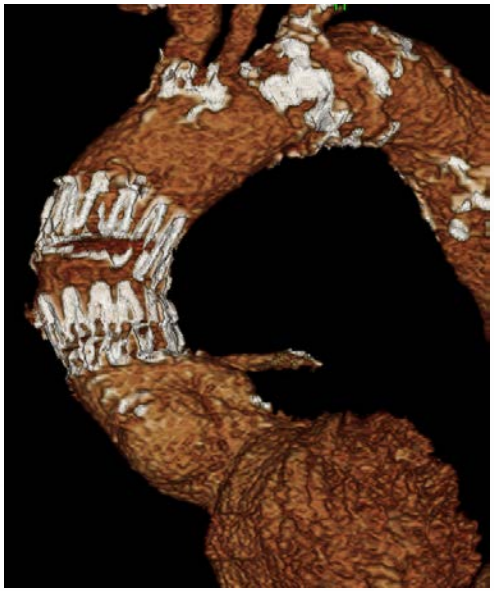
Can We Stentgraft Them ?

- 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 4 with contained rupture	9	23
• Complicated Chronic Dissx	2	2

Cleveland Clinic

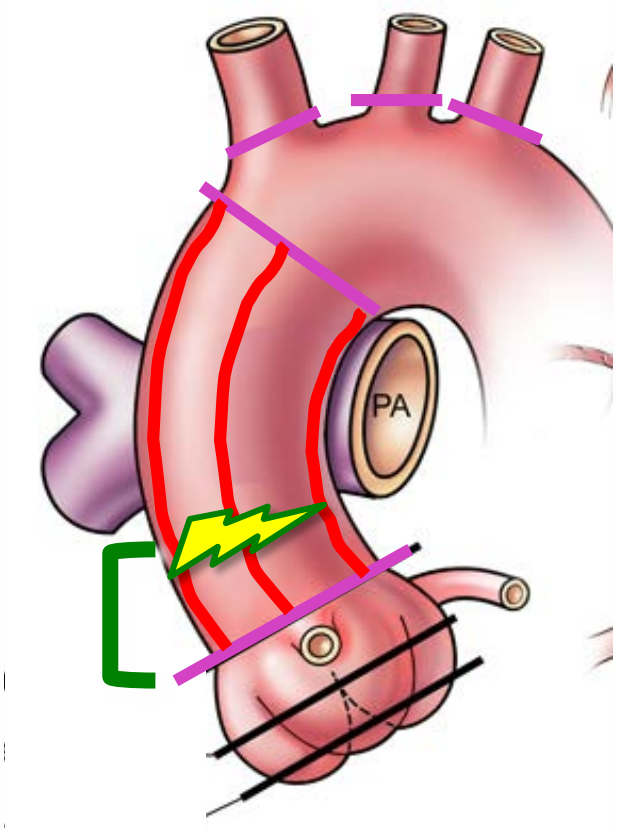
Roselli EE, et al. JTCVS, ‘15.

Challenges to Proximal TEVAR

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

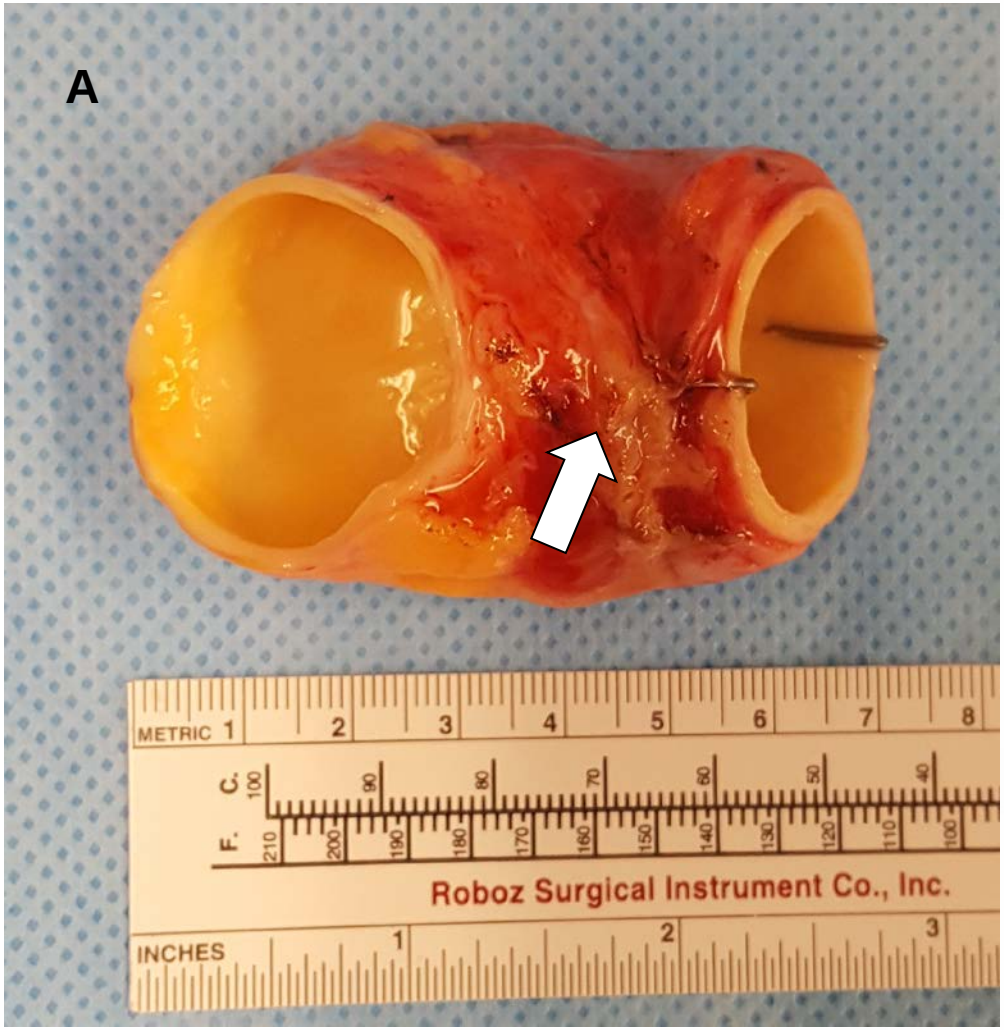
Pt Related: Anatomy / Morphology

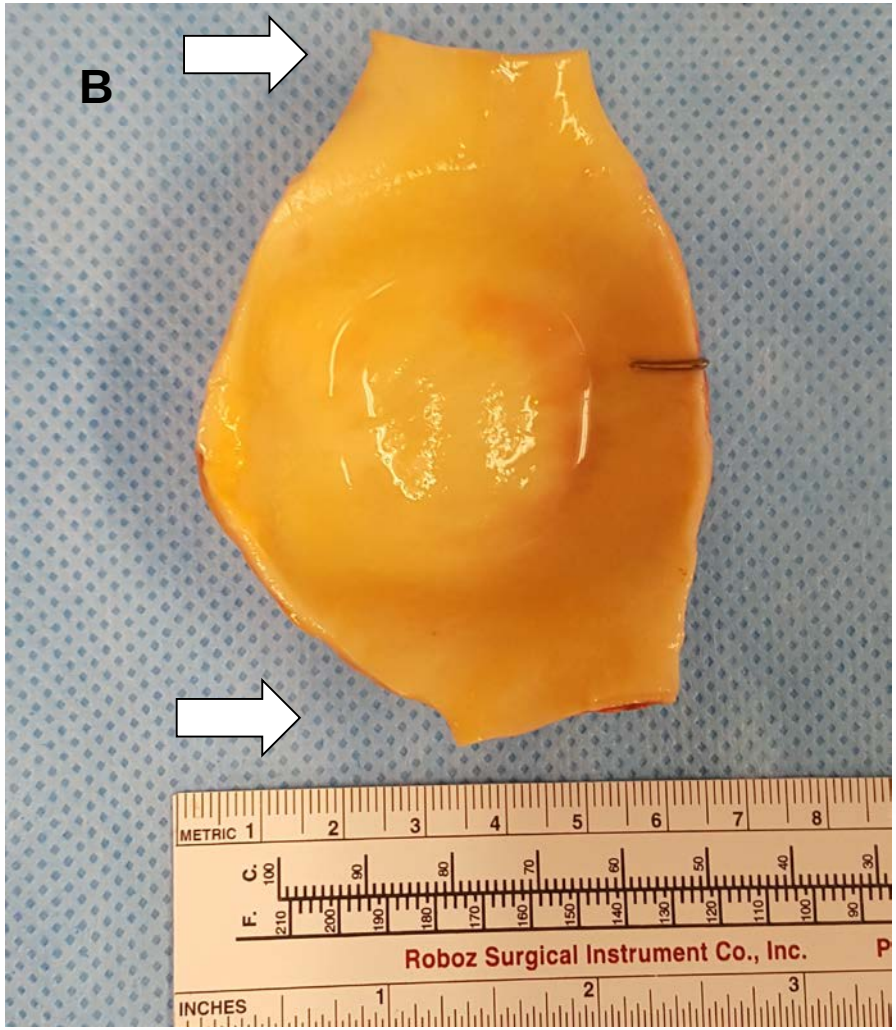
Greater	Center	Lesser
9.6	7.8	6.4



- 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

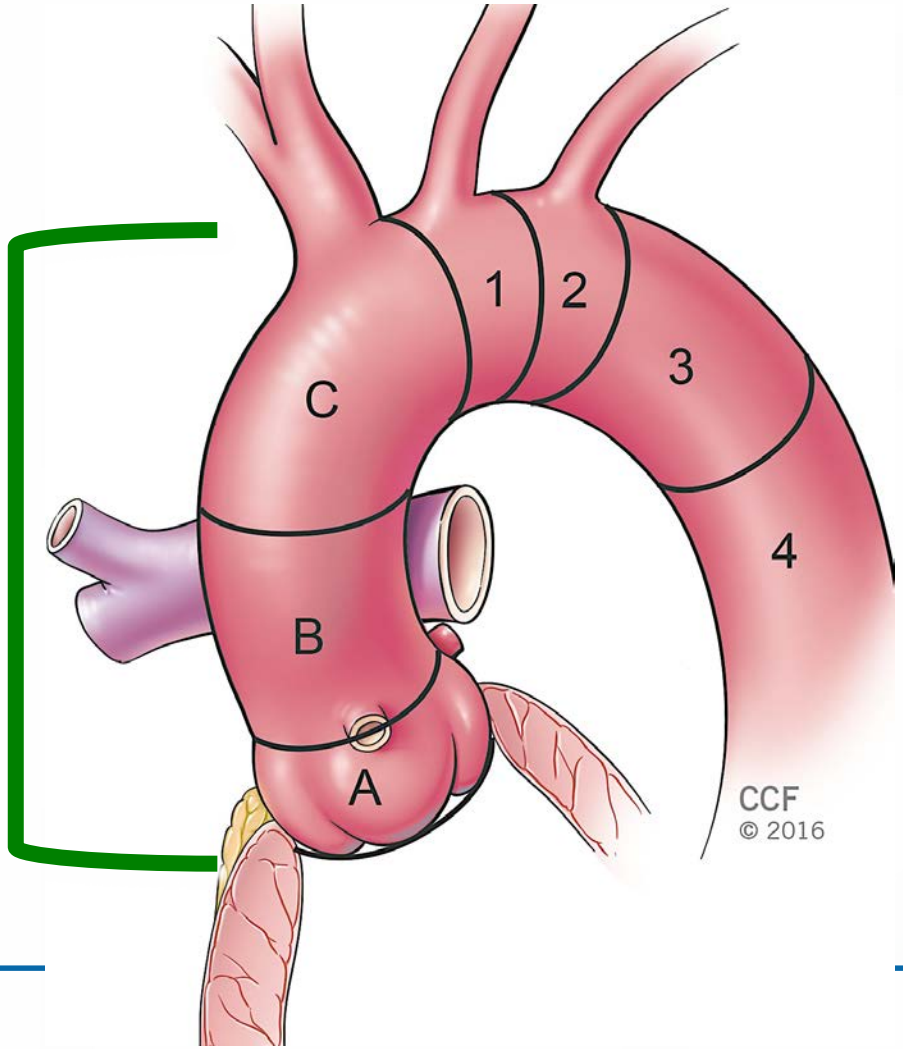
Modified Landing Zone Classification System

Zone 0

C: RtPA to Innom

B: cors to RtPA

A: annulus to cors



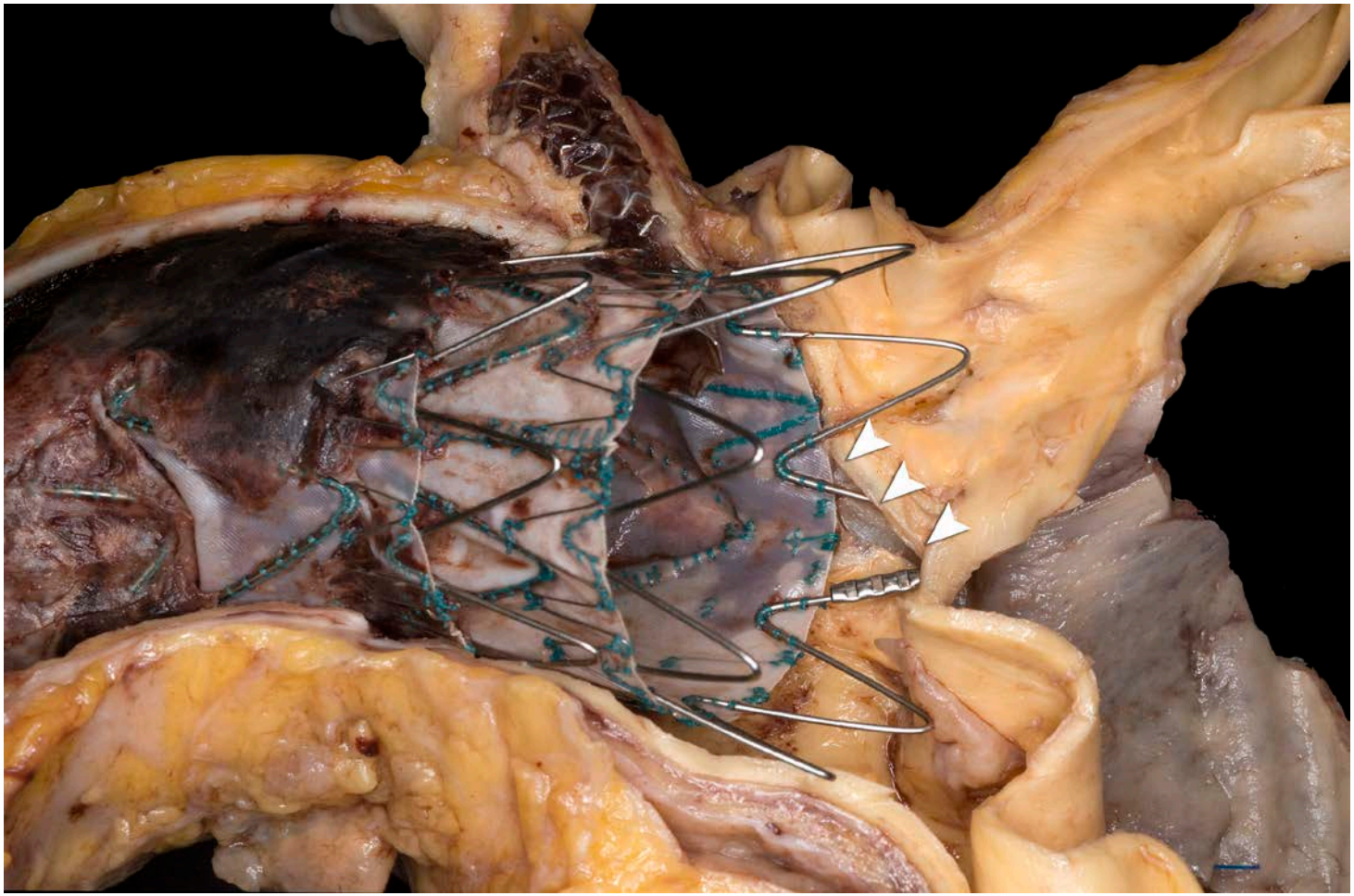
Mechanisms of Aortic Dissection

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

Normal

Aortic

Important Device Characteristics



Procedure Related: Device

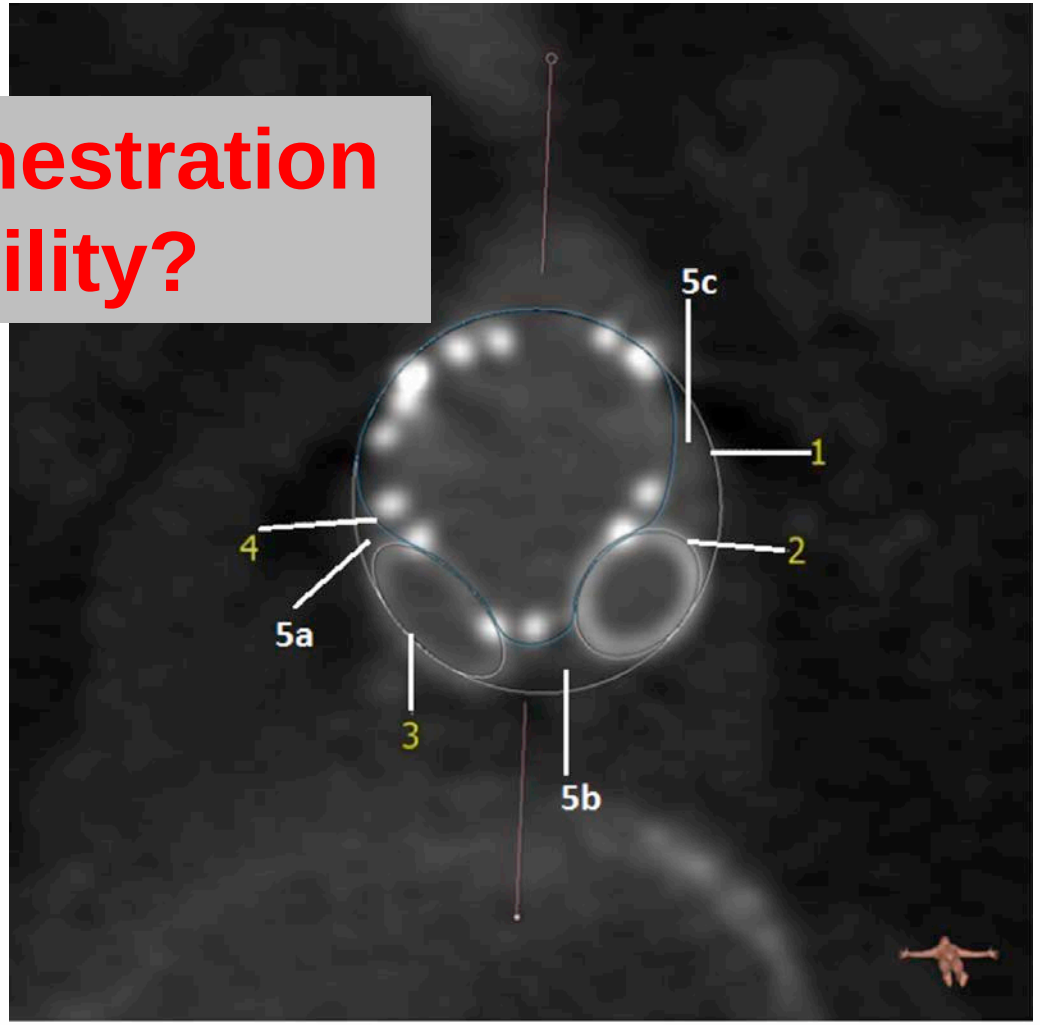
- Stentgraft
  - Highly conformable, Elastic
  - Strong fixation in hostile environment
    - Radial force
    - Active fixation
      - Internal or external?
  - Flush edge vs root component
  - Curved shape
  - ? Branch / branches for **distal and proximal** seal

? Arch Branches ?

- Proximal Seal Zone Length

Branch Challenge: Endoleaks, Patency ?

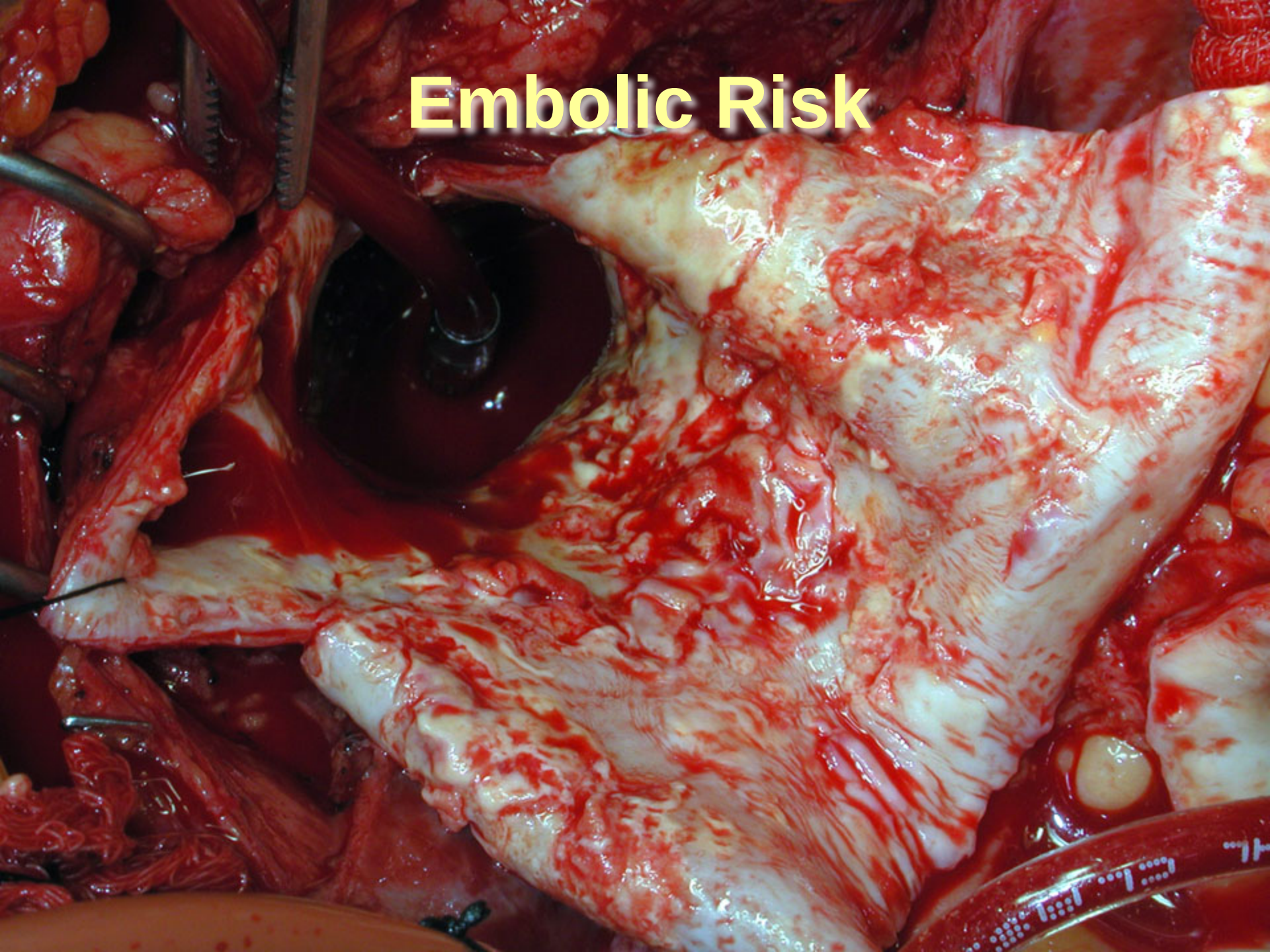
In-Situ Fenestration and Durability?



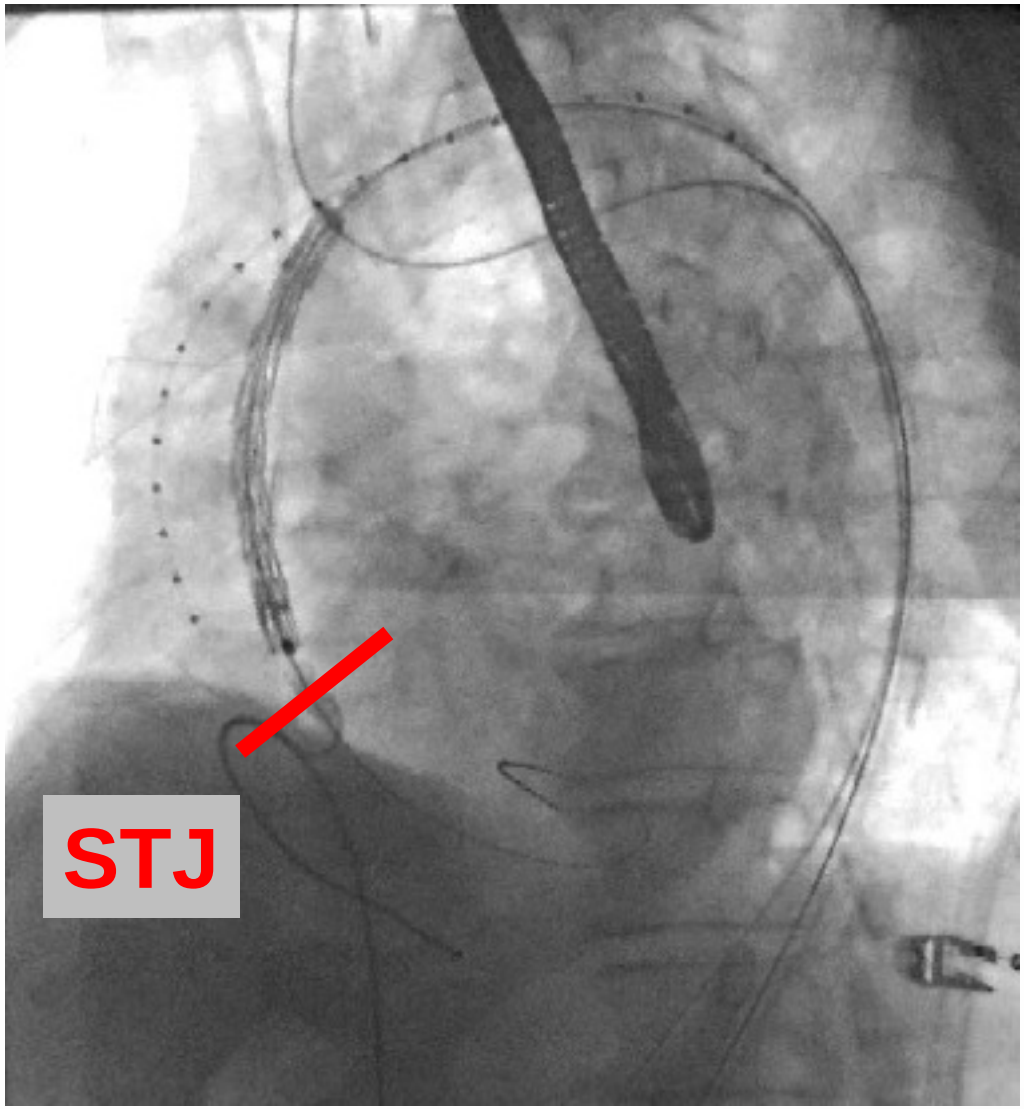
Beaufort H, et al. JVS, ‘17.

Procedure Related: Delivery & Deploy

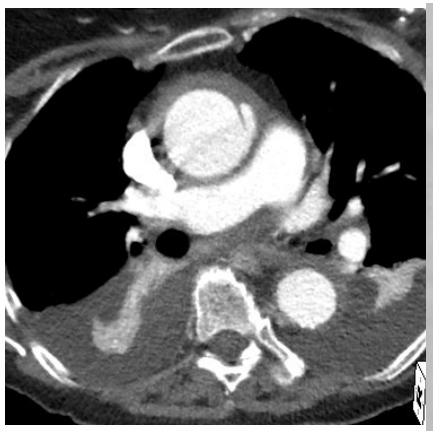
- Delivery Technique
  - Transfemoral vs alternate access
  - Disease dependent
  - Pre-curved – self orienting
  - Crossing the valve
  - Branch Access
- Deployment System
  - Exceedingly precise, controlled
  - Staged deployment
  - Repositionable
  - Flexible / steerable for coaxiality

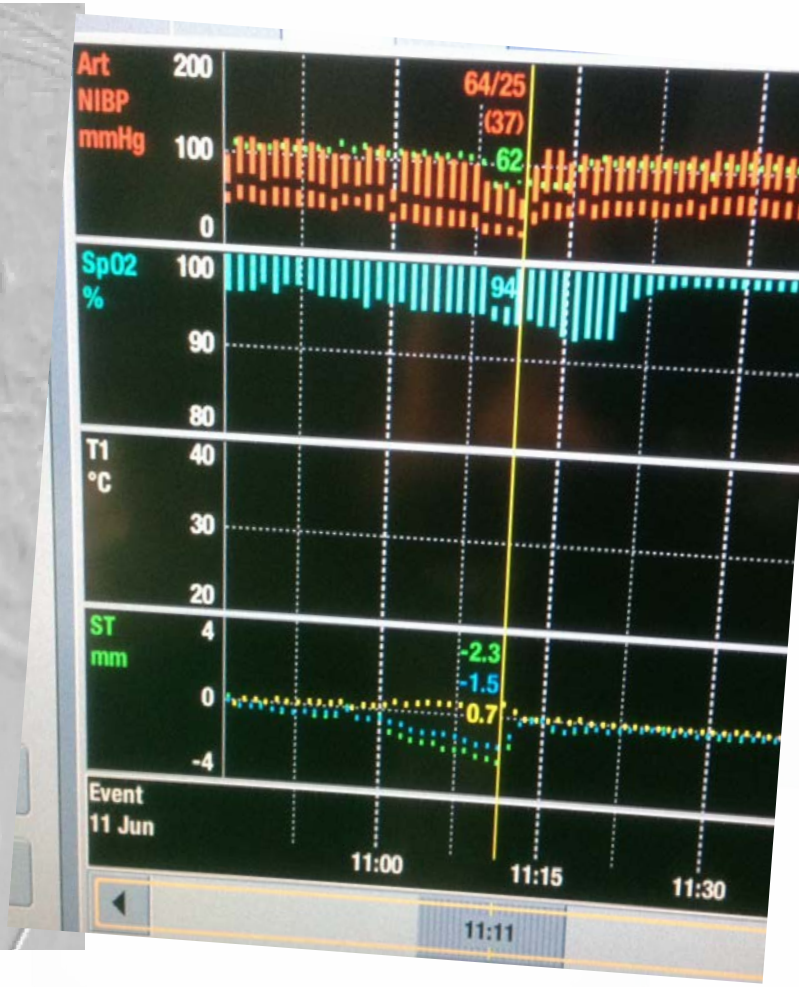

Embolic Risk

Transfemoral Deployment

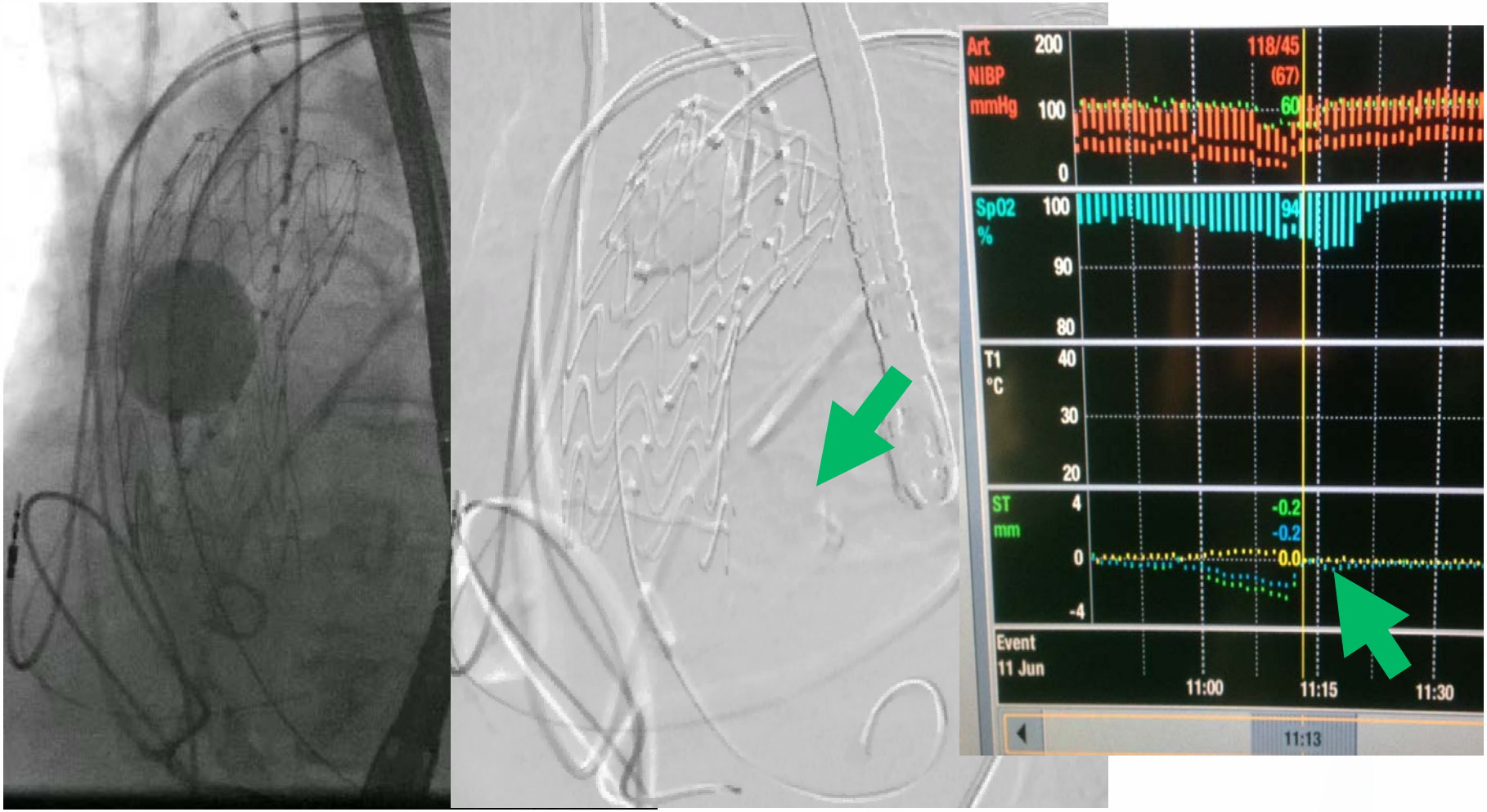


Coronary Occlusion





Balloon Repositioning



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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

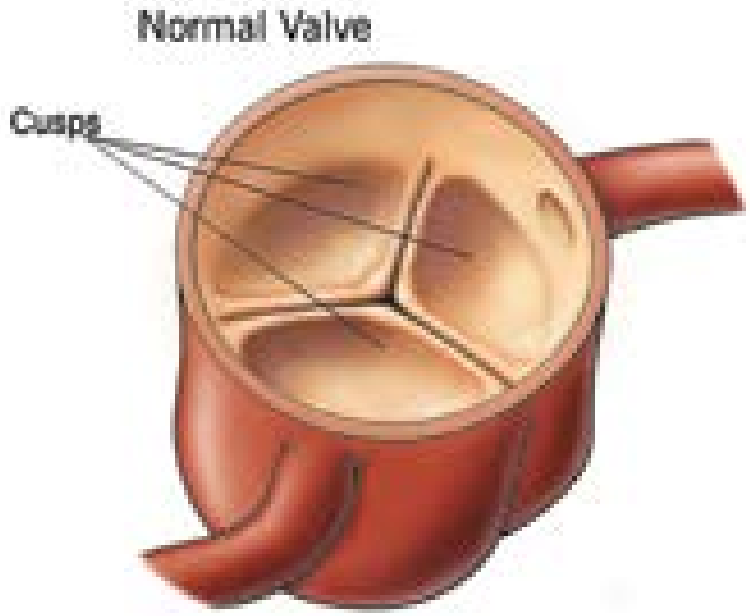
es with type A dissection, Li et al. (13) have succeeded in moving the discussion beyond the novelty level of "look, it can be done" to the next developmental stage, poised on the threshold of a prospective clinical trial. This is a valuable contribution. I wonder, however, if the current TEVAR technology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

Endo CVG Issues

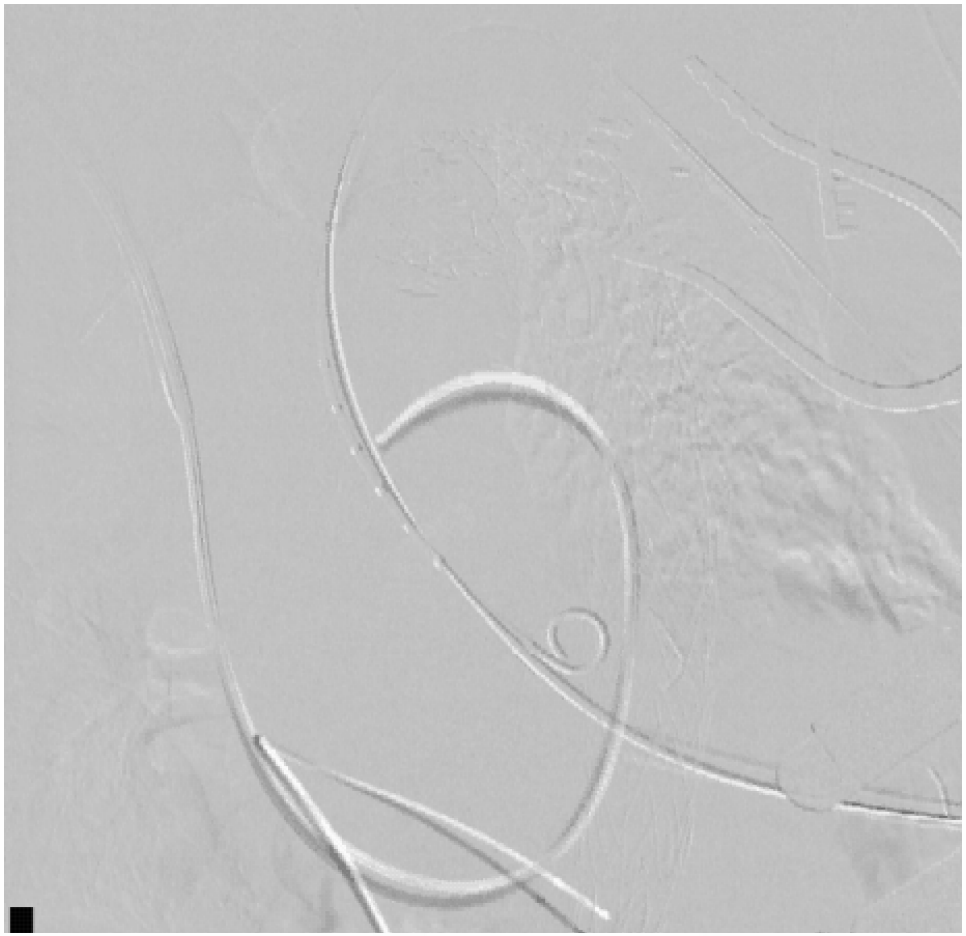
1) Proximal Fixation

AND SEAL

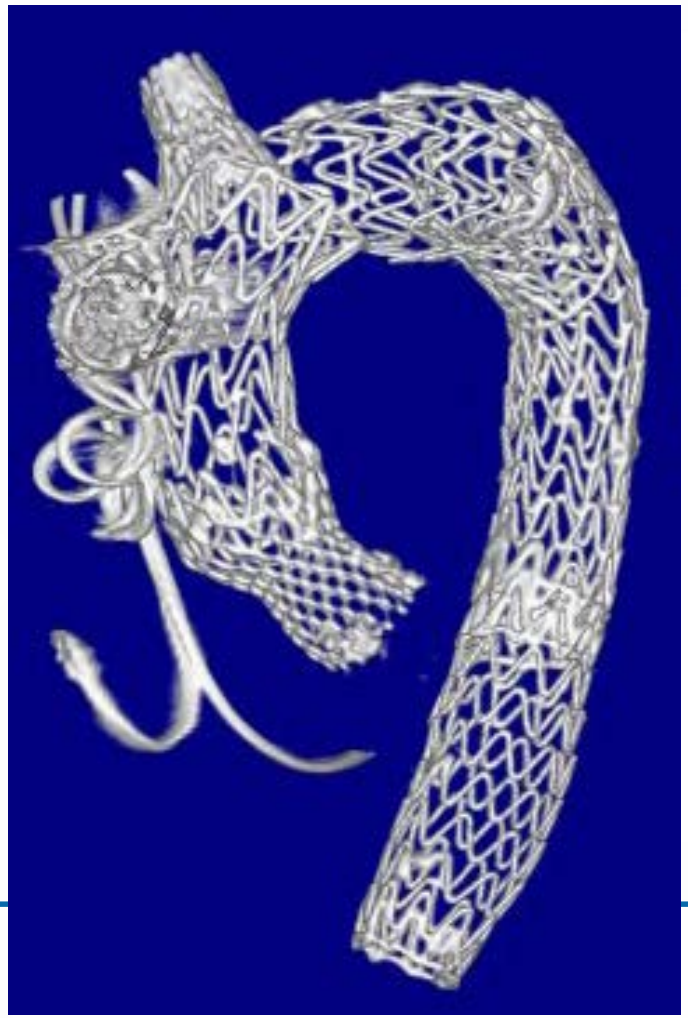
2) Coronary Patency



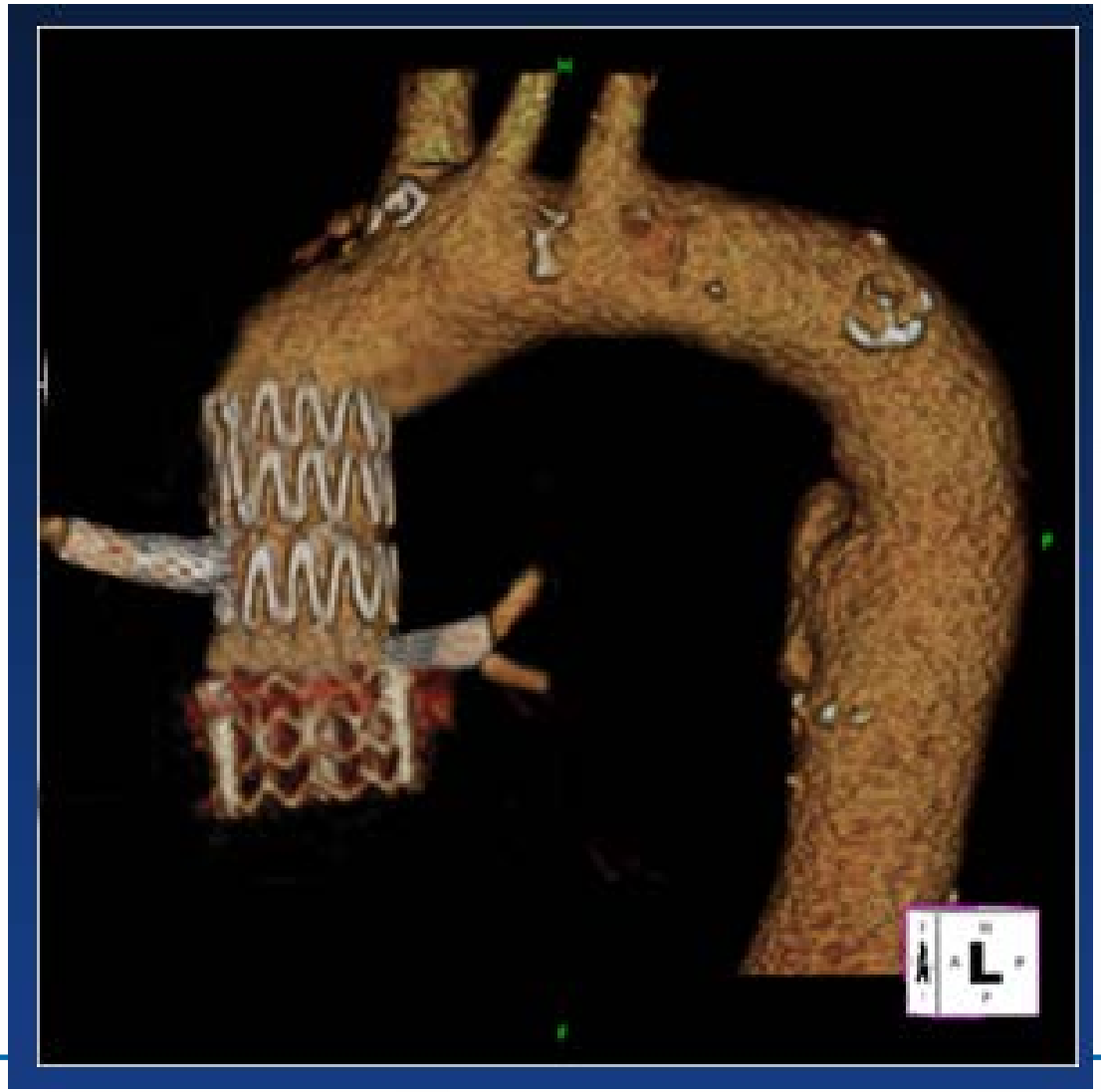
52 y/o s/p esophagectomy and colon interposition, new Type A



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

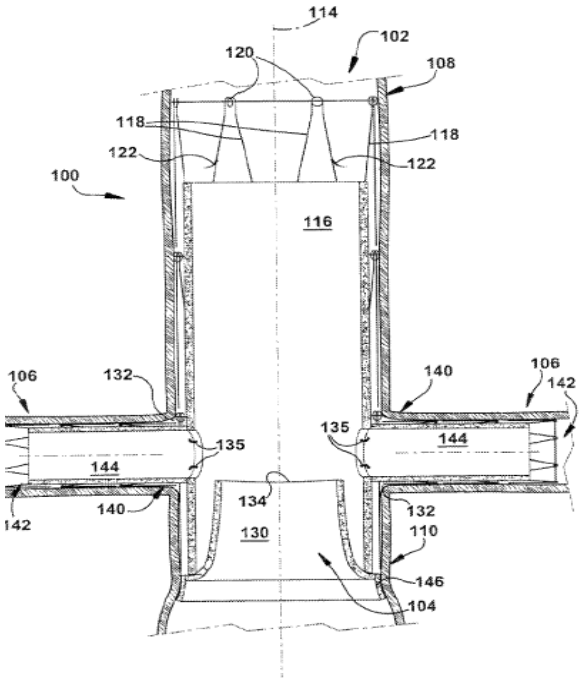


Endo Composite Valve Graft



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



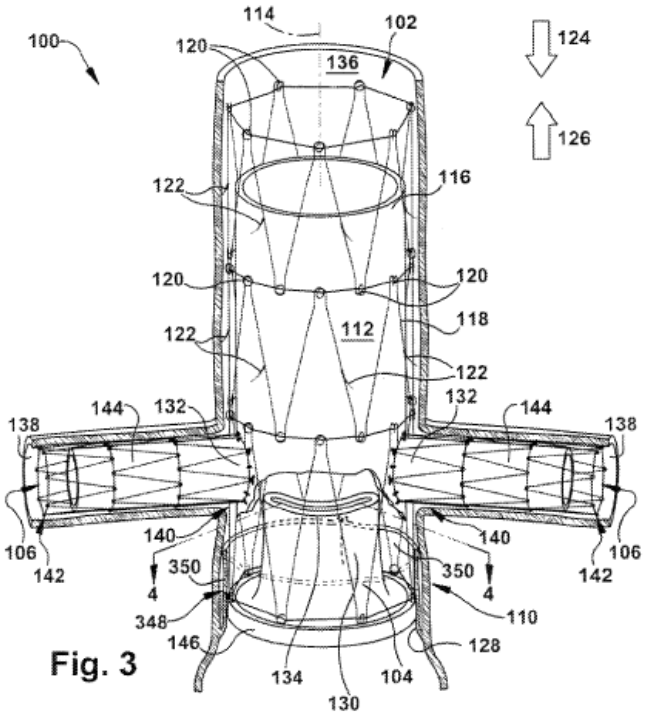


Fig. 3

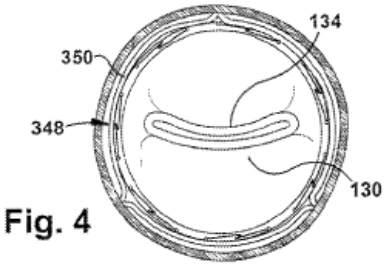
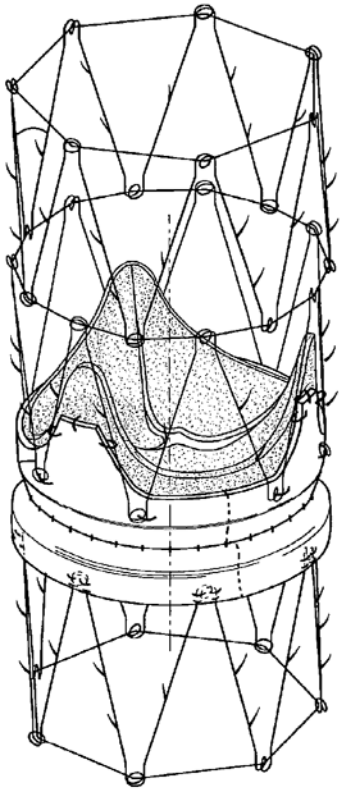
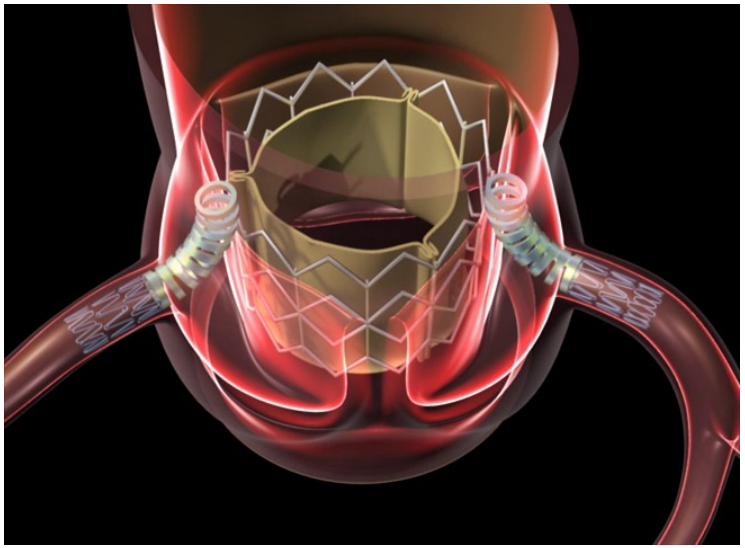


Fig. 4

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

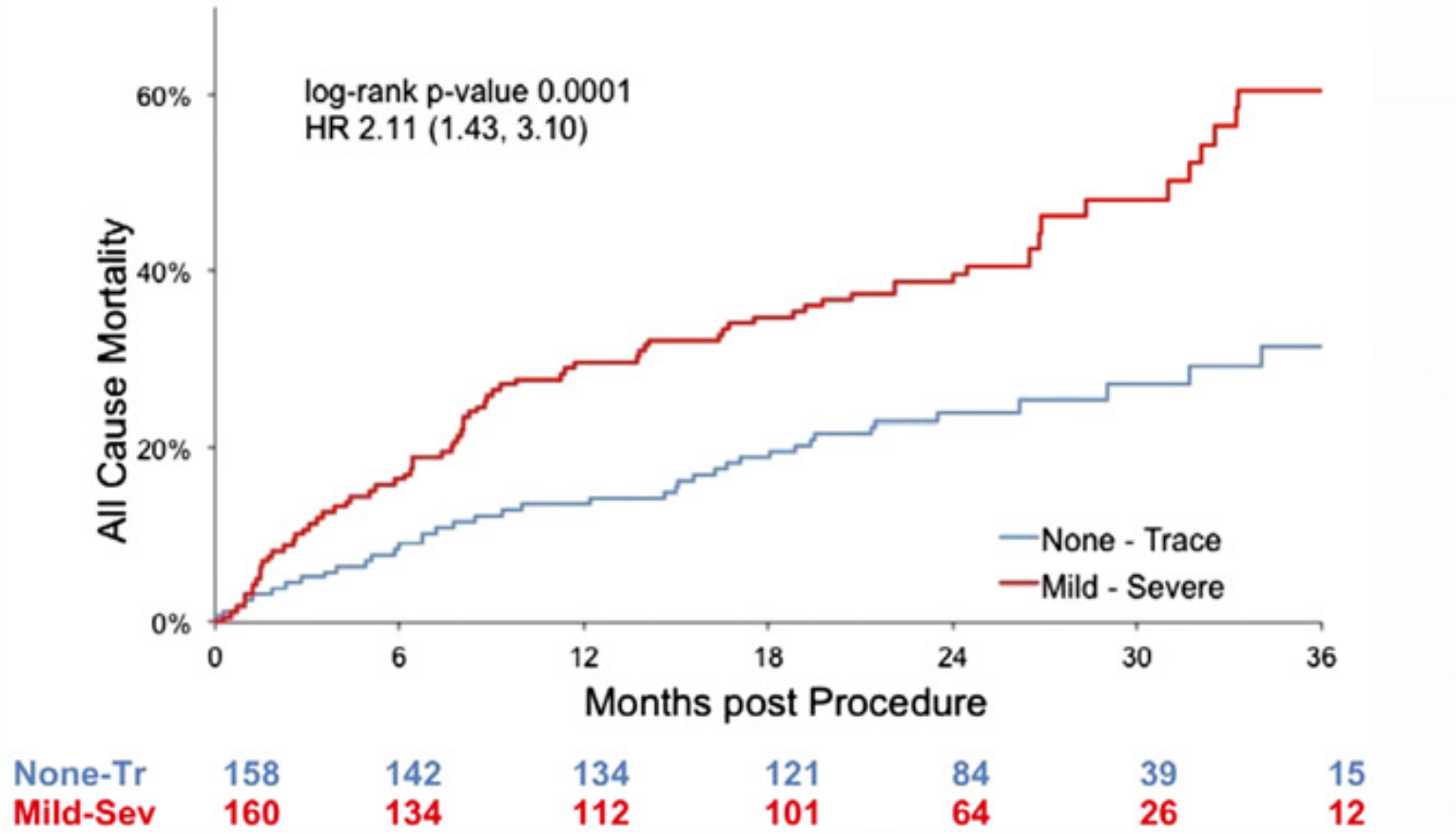
Paravalvular Leak After Transcatheter Aortic Valve Replacement

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

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

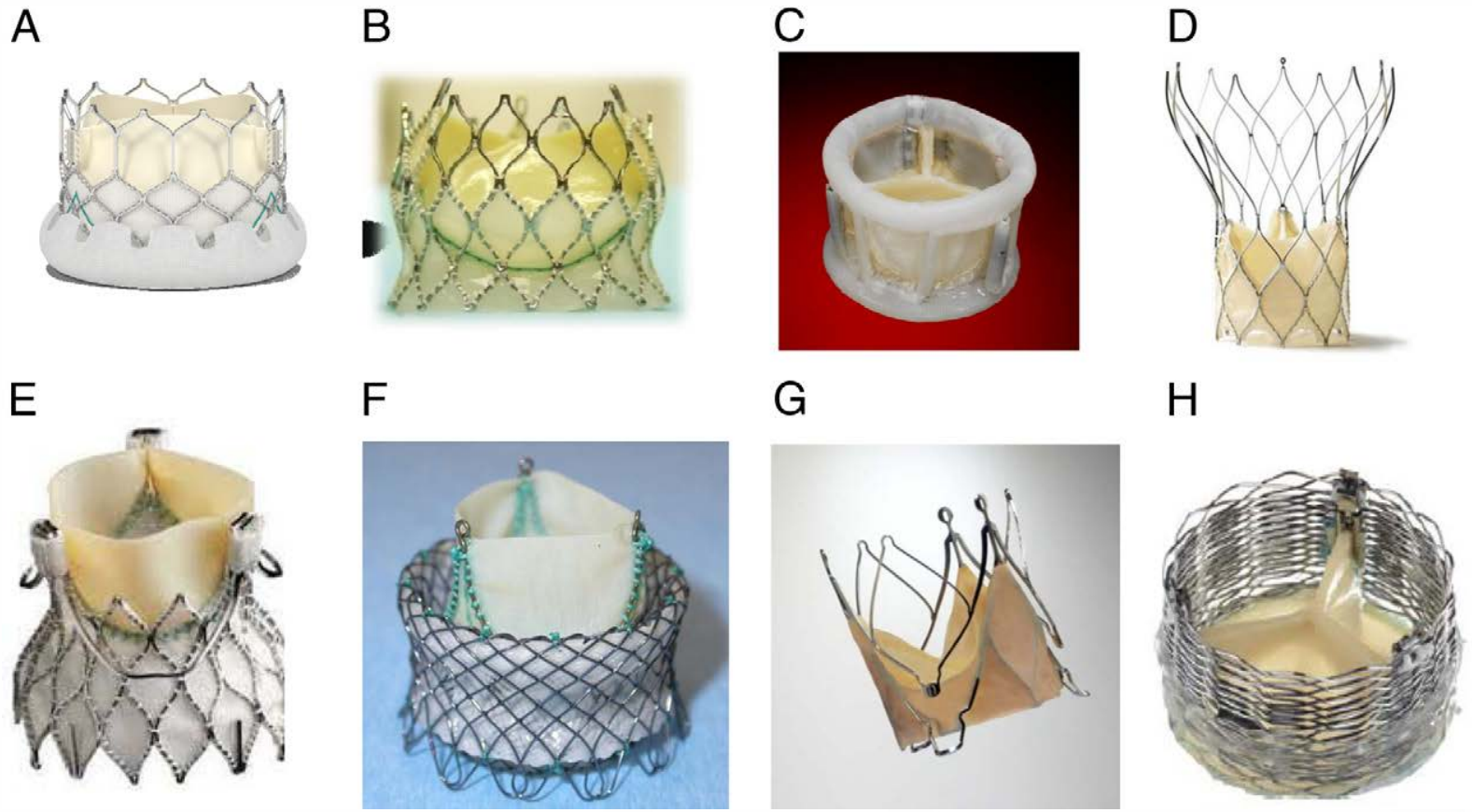
- Mild PVL is routine
- Moderate or worse PVL is common
  - Balloon expandable 6-14%
  - Self expanding 9-21%

PVL Associated with Mortality



Kodali S, et al. NEJM, ‘12.

New Valves to Reduce PVL



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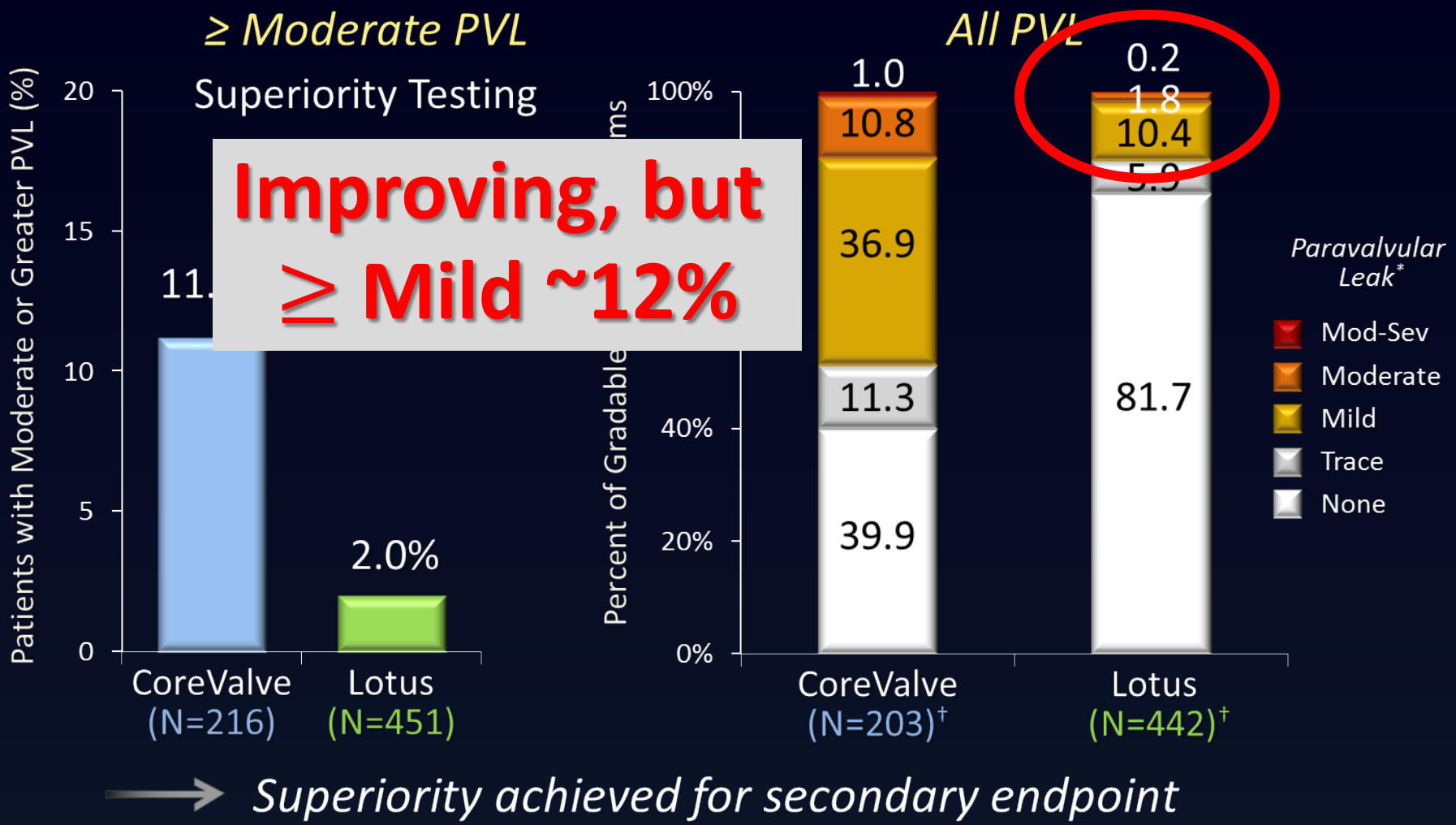
Genereaux P, et al. JACC, ‘13.

Paravalvular Leak at 1 Year

Core Lab Assessment – Intent-to-Treat

REPRISE III
Lotus™ Valve System

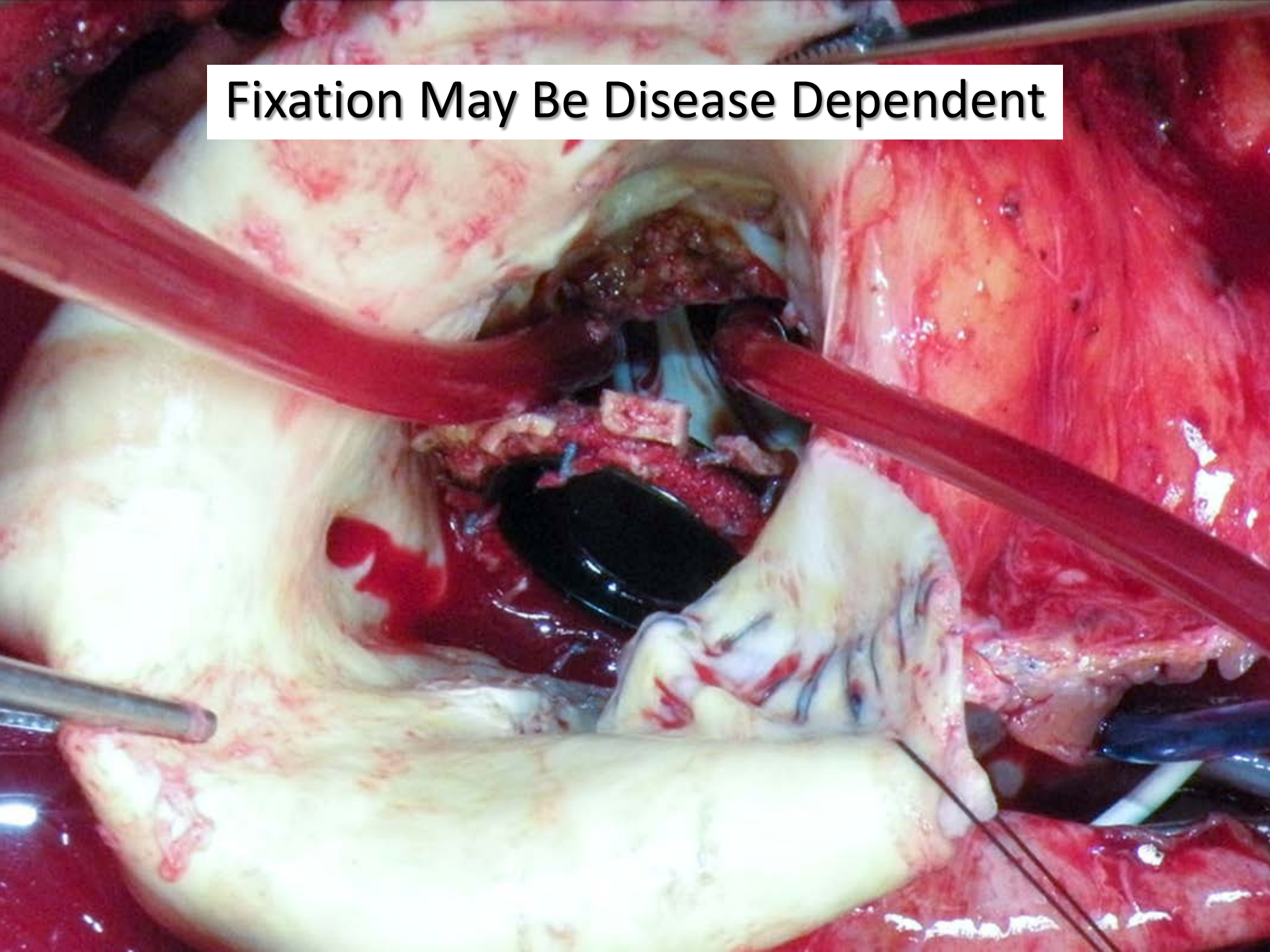


Improving, but ≥ Mild ~12%

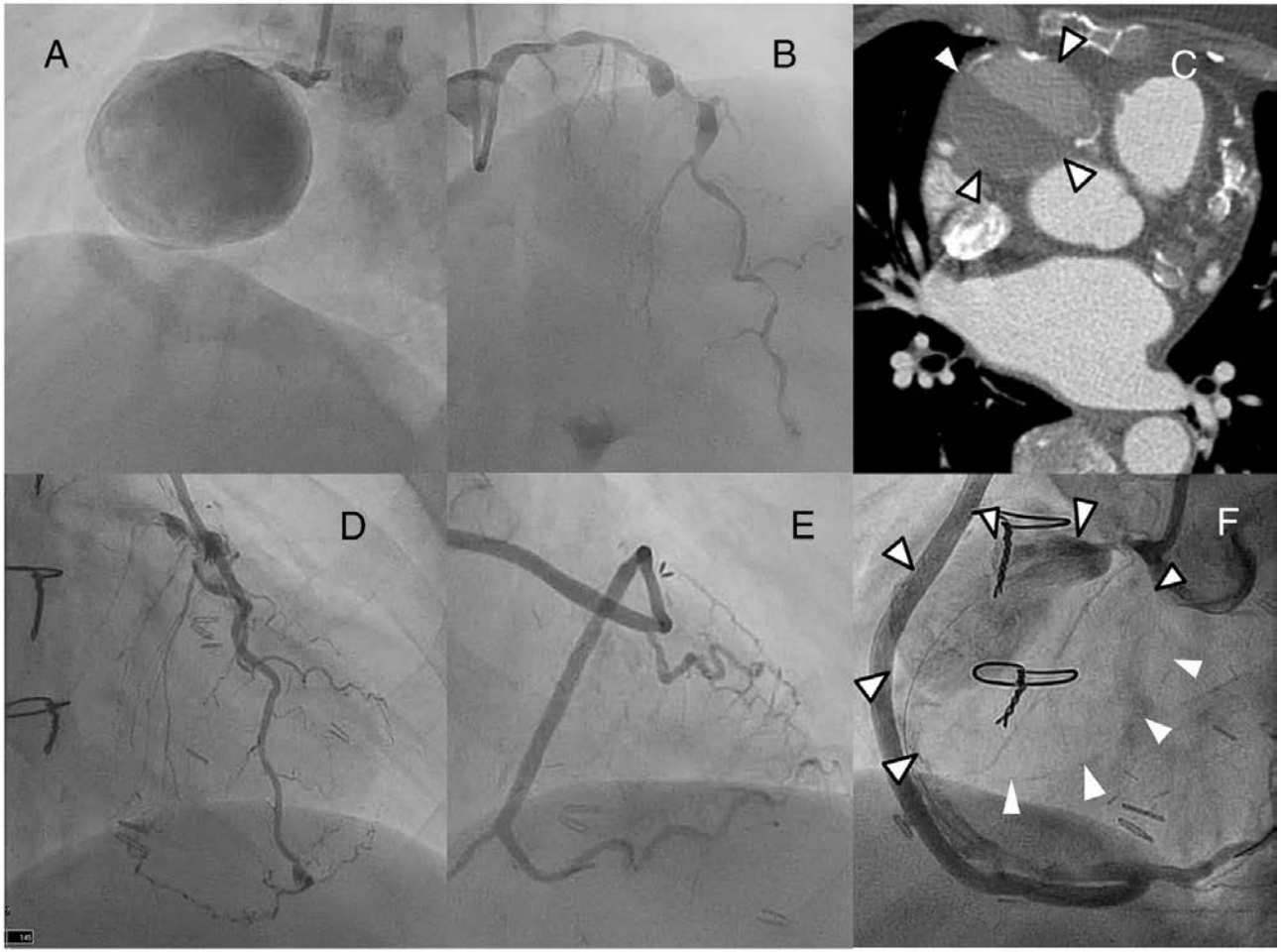
→ *Superiority achieved for secondary endpoint*

* There were no case
† For superiority testi
the group with less
d in

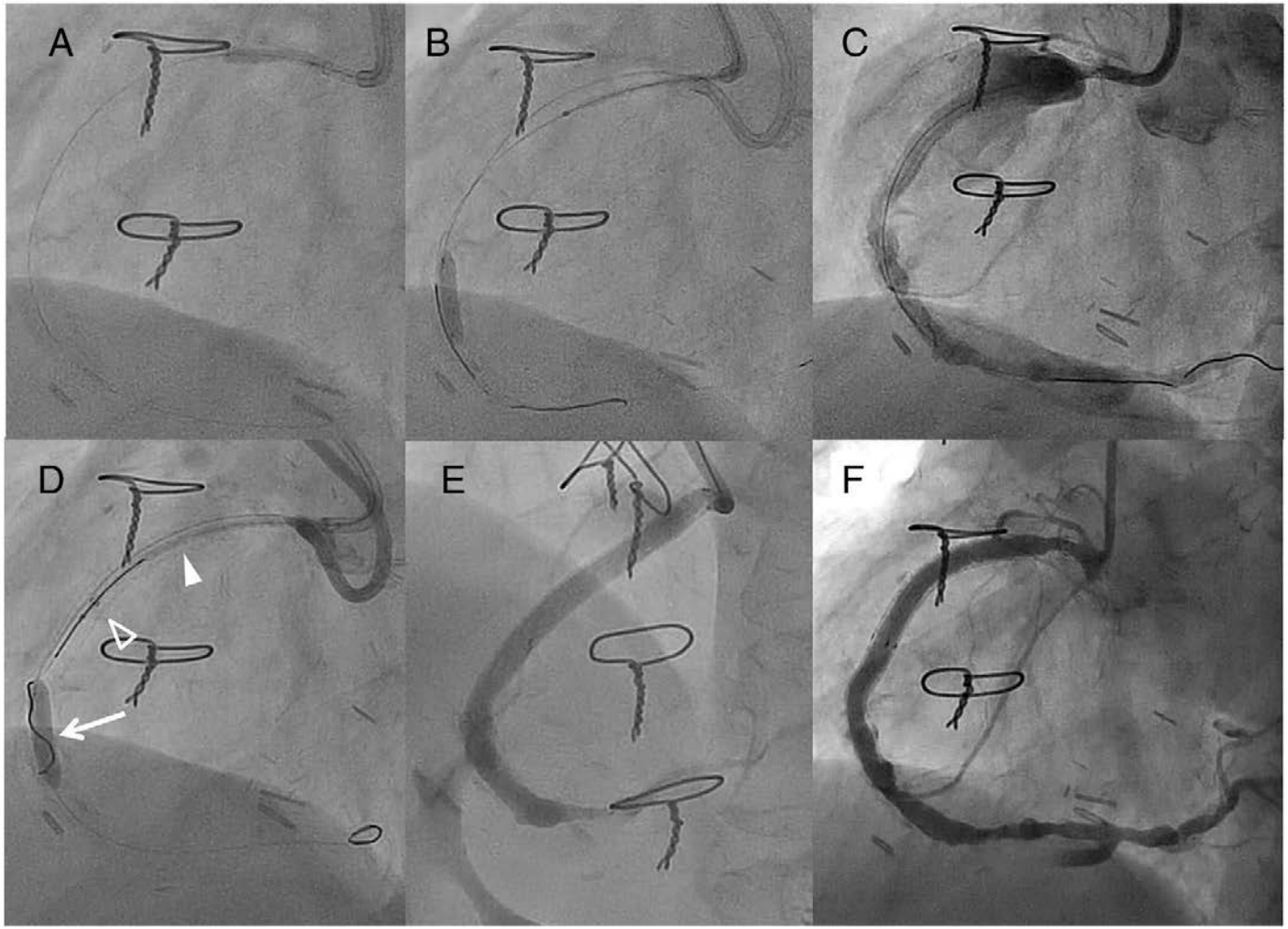
Presented at Euro PCR 2017


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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