Michigan STS Sir Magdi Yacoub 2016 Lecture: Future of Cardiovascular and Thoracic Surgery

Achievements, Innovation and Future Directions

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Roberts-Measy Professor and Vice Chief
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Director: Thoracic Aortic Surgery Program
University of Pennsylvania, Philadelphia USA

Boyne Michigan, 2016

Future lies in….

Big Picture Procedurally

- Reparative valve surgery (especially minimally invasive & robotic approaches)
- Small pumps – VADs/CHF
  - ECMO (Rescue, Bridge, etc)
- Thoracic Aortic (endovascular)
  - GenTAC concepts
- Transcatheter endo-cardiac surgery
  - TAVR … (The big concept)
  - Transcatheter mitral valve replacement
    - Transcatheter pulmonic valve replacement

Minimally invasive approach provides at least equivalent results for surgical correction of mitral regurgitation: A propensity-matched comparison

Andrew B. Goldstone, MD,[a] Pavan Atluri, MD,[a] Wilson Y. Szeto, MD,[a] Alen Trubelja, BS,[a] Jessica L. Howard, BS,[a] John W. MacArthur, Jr, MD,[a] Craig Newcomb, MS,[b] Joseph P. Donnelly, BS,[a] Dale M. Kobrin, BA,[a] Mary A. Sheridan, MPAS, PA-C,[a] Christiana Powers, MSN, CRNP,[a] Robert C. Gorman, MD,[a] Joseph H. Gorman III, MD,[a] Alberto Pochettino, MD,[a] Joseph E. Bavaria, MD,[a] Michael A. Acker, MD,[a] W. Clark Hargrove III, MD,[a] and Y. Joseph Woo, MD[a]

Objective: Minimally invasive approaches to mitral valve surgery are increasingly used, but the surgical approach must not compromise the clinical outcome for improved cosmesis. We examined the outcomes of mitral repair performed through right minithoracotomy or median sternotomy.

Methods: Between January 2002 and October 2011, 1011 isolated mitral valve repairs were performed in the University of Pennsylvania health system (455 sternotomies, 556 right minithoracotomies). To account for key differences in preoperative risk profiles, propensity scores identified 201 well-matched patient pairs with mitral regurgitation of any cause and 153 pairs with myxomatous disease.

Results: In-hospital mortality was similar between propensity-matched groups (0% vs 0% for the degenerative cohort; 0% vs 0.5%, $P = .5$ for the overall cohort; in minimally invasive and sternotomy groups, respectively). Incidence of stroke, infection, myocardial infarction, exploration for postoperative hemorrhage, renal failure, and atrial fibrillation also were comparable. Transfusion was less frequent in the minimally invasive groups (11.8% vs 20.3%, $P = .04$ for the degenerative cohort; 14.0% vs 22.9%, $P = .03$ for the overall cohort), but time to extubation and discharge was similar. A 99% repair rate was achieved in patients with myxomatous disease, and a minimally invasive approach did not significantly increase the likelihood of a failed repair resulting in mitral valve replacement. Patients undergoing minimally invasive mitral repair were more likely to have no residual post-repair mitral regurgitation (97.4% vs 92.1%, $P = .04$ for the degenerative cohort; 95.5% vs 89.6%, $P = .02$ for the overall cohort). In the overall matched cohort, early readmission rates were higher in patients undergoing sternotomies (12.6% vs 4.4%, $P = .01$). Over 9 years of follow-up, there was no significant difference in long-term survival between groups ($P = .8$).

Conclusions: In appropriate patients with isolated mitral valve disease of any cause, a right minithoracotomy approach may be used without compromising clinical outcome. (J Thorac Cardiovasc Surg 2013;145:748-56)

A Population-Based Analysis of Robotic-Assisted Mitral Valve Repair

Subroto Paul, MD, Abby J. Isaacs, MS, Jessica Jalbert, PhD, Nonso C. Osakwe, MD, MPH, Arash Salemi, MD, Leonard N. Girardi, MD, and Art Sedrakyan, MD, PhD

Departments of Health Policy and Research and Cardiothoracic Surgery, New York Presbyterian Hospital–Weill Cornell Medical College, New York, New York

Background. Robotic-assisted mitral valve repair is becoming more frequently performed in cardiac surgery. However, little is known about its utilization and safety at a national level.

Methods. Patients undergoing mitral valve repair in the United States from 2008 to 2012 were identified in the National Inpatient Sample. Inhospital mortality, complications, length of stay, and cost for patients undergoing robotic-assisted mitral valve repair were compared with patients undergoing nonrobotic procedures.

Results. We identified 50,408 isolated mitral valve repair surgeries, of which 3,145 were done with robotic assistance. In a propensity score matched analysis of 631 pairs of patients, we found no difference between patients undergoing robotic-assisted and nonrobotic-assisted mitral valve repair with respect to inhospital mortality, complications, or composite outcomes in unadjusted or multivariable analyses. Robotic-assisted mitral valve repair surgery was associated with a shorter median length of stay (4 versus 6 days, $p < 0.001$), and there was no difference in median total costs between the two procedures.

Conclusions. In our analysis of a large national database with its inherent limitations, robotic-assisted mitral valve repair was found to be safe, with an acceptable morbidity and mortality profile.

(Ann Thorac Surg 2015;99:1546–53)

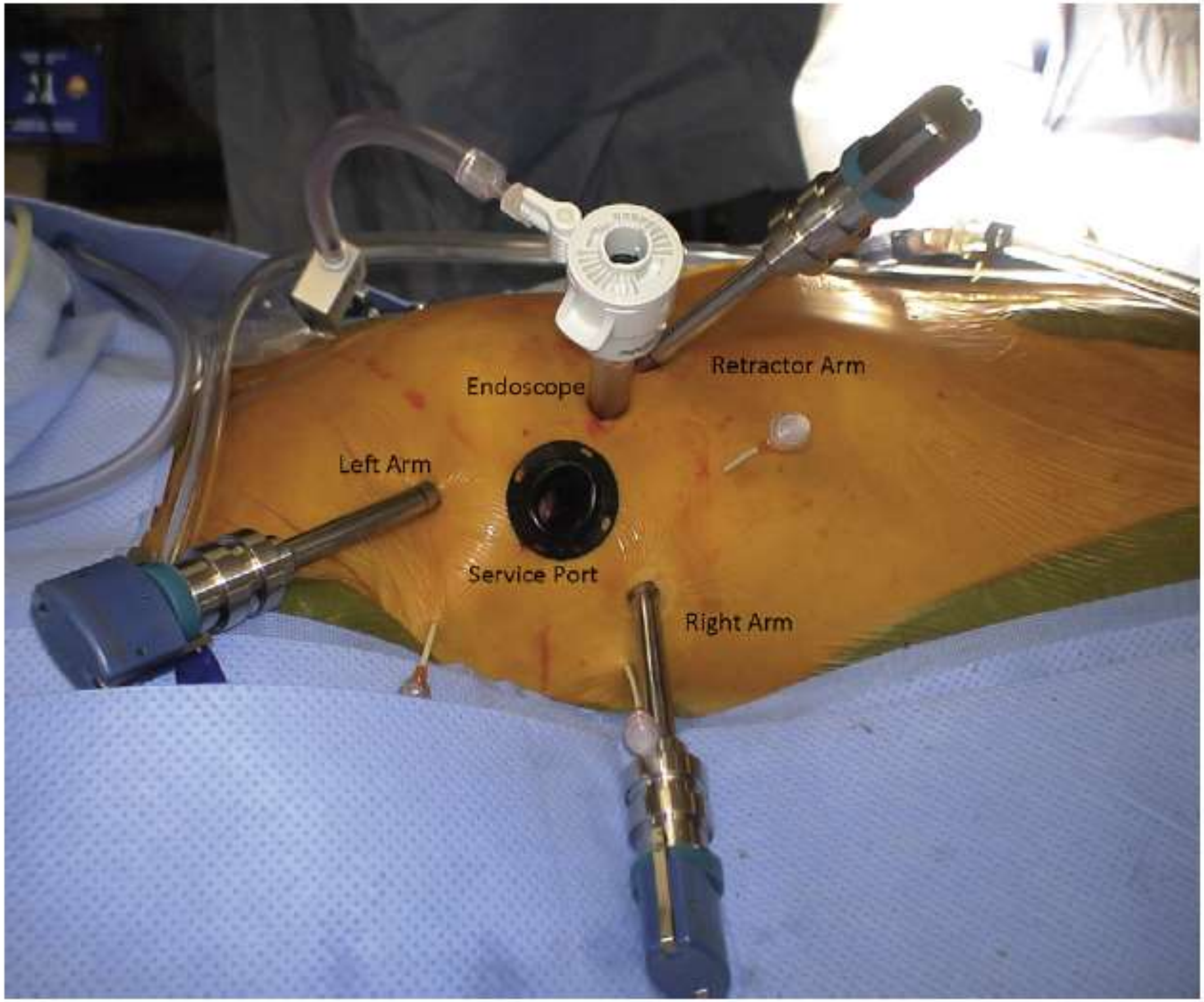

Fig 1. Port placement for lateral endoscopic approach using robotics (LEAR) surgery.

No Difference in Outcomes

Table 2. Inhospital Outcomes for National Sample and Propensity-Matched Cohort

	Unmatched Cohort			Propensity Matched Cohort		
Outcomes	Robotic MV Repair n = 3,145	MV Repair n = 47,263	*p* Value	Robotic MV Repair n = 631	MV Repair n = 631	*p* Value
Inhospital mortality[a]	40 (1.3)	1,039 (2.2)	0.048	*	*	0.78
Composite outcome[b]	141 (4.5)	2,863 (6.1)	0.07	27 (4.3)	20 (3.2)	0.31
Length of stay, days	4 (3–6)	7 (5–9)	0.004	4 (3–6)	6 (4–8)	<0.001
Morbidity						
Any complication	1,173 (37.3)	17,552 (37.1)	0.94	236 (37.4)	217 (34.4)	0.26
Cardiovascular complications	132 (4.2)	2,339 (4.9)	0.36	26 (4.1)	19 (3.0)	0.28
Stroke	112 (3.6)	1,926 (4.1)	0.51	22 (3.5)	15 (2.4)	0.25
Pulmonary complications	950 (30.2)	13,440 (28.4)	0.35	193 (30.6)	171 (27.1)	0.16
Infectious complications	115 (3.7)	2,818 (6.0)	0.004	22 (3.5)	21 (3.3)	0.88
Iatrogenic complications[c]	206 (6.5)	2,590 (5.5)	0.30	41 (6.5)	32 (5.1)	0.29
Discharge status[a]			<0.001			0.07
Routine	2,046 (65.1)	21,228 (44.9)		220 (34.9)	251 (39.8)	
Nonroutine[d]	1,097 (34.9)	26,013 (55.1)		411 (65.1)	380 (60.2)	
Cost[e]						
Total charges, USD	114,959 (92,036–161,358)	123,313 (85,840–186,758)	0.34	114,846 (92,036–161,358)	113,331 (81,237–166,835)	0.16
Estimated total costs, USD	33,720 (26,537–45,099)	34,509 (26,238–47,513)	0.44	33,638 (26,473–45,099)	31,756 (25,001–43,127)	0.06

* Less than 10. [a] Less than 1% missing data. [b] Composite outcome consists of death or stroke. [c] Accidental puncture or laceration complicating surgery, bleeding complicating procedure. [d] Including inhospital death. [e] Cost is estimated using National Inpatient Sample charge data, cost-to-charge ratio files, and a scaling factor by diagnosis-related group published by Healthcare Cost and Utilization Project in 2009; less than 10% missing cost/charge data.

Values are median (IQR) or n (%).

IQR = interquartile range; MV = mitral valve; USD = US dollars.

REMATCH

The New England Journal of Medicine

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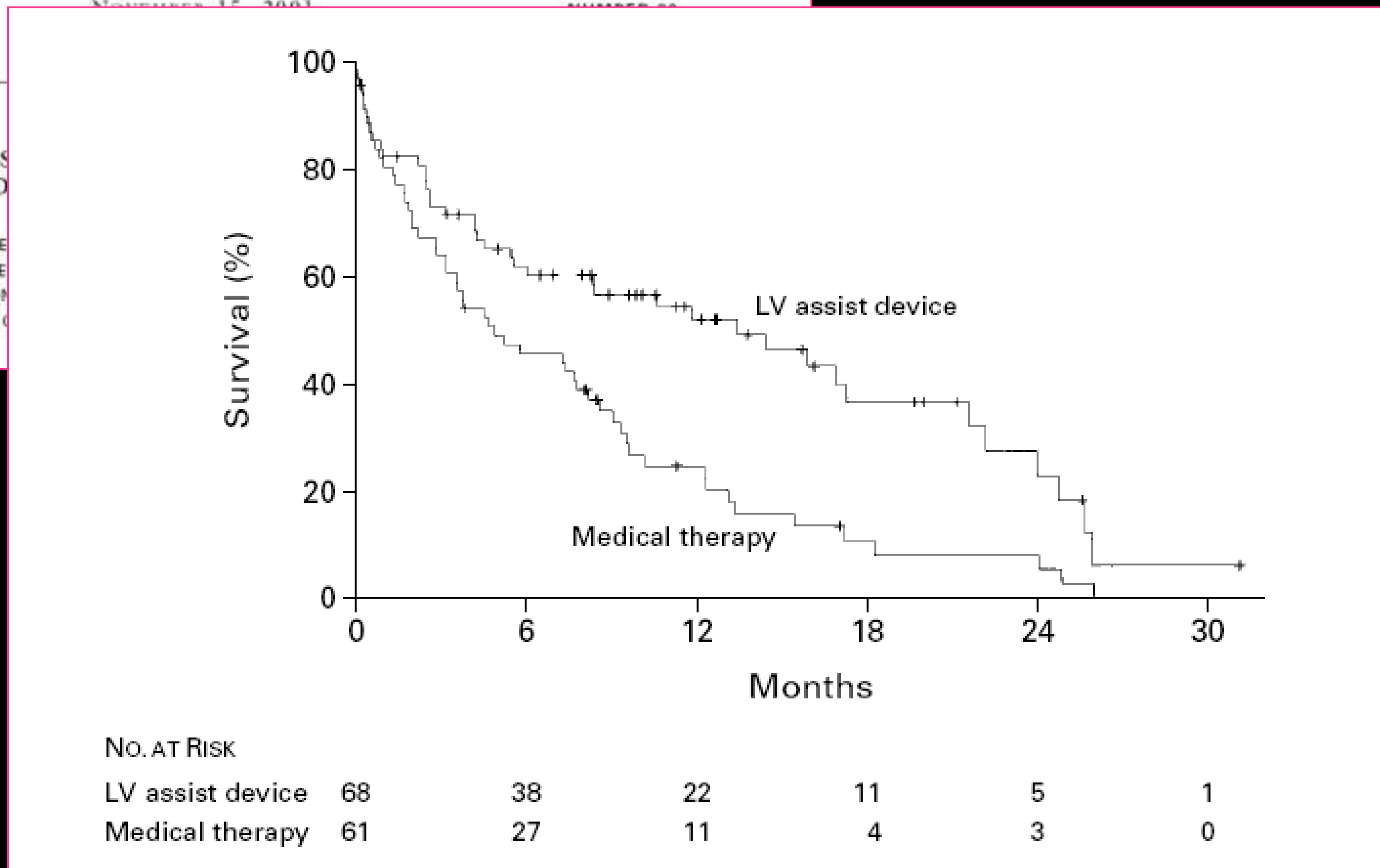
VOLUME 345

LONG-TERM US
FO

ERIC A. ROSE, M.D., ANNETINE
LYNNE W. STEVENSON, M.D., WALTE
ANITA R. TIERNEY, M.P.H., RON
FOR THE RANDOMIZED EVALUATION



HeartMate XVE: Things we can fix

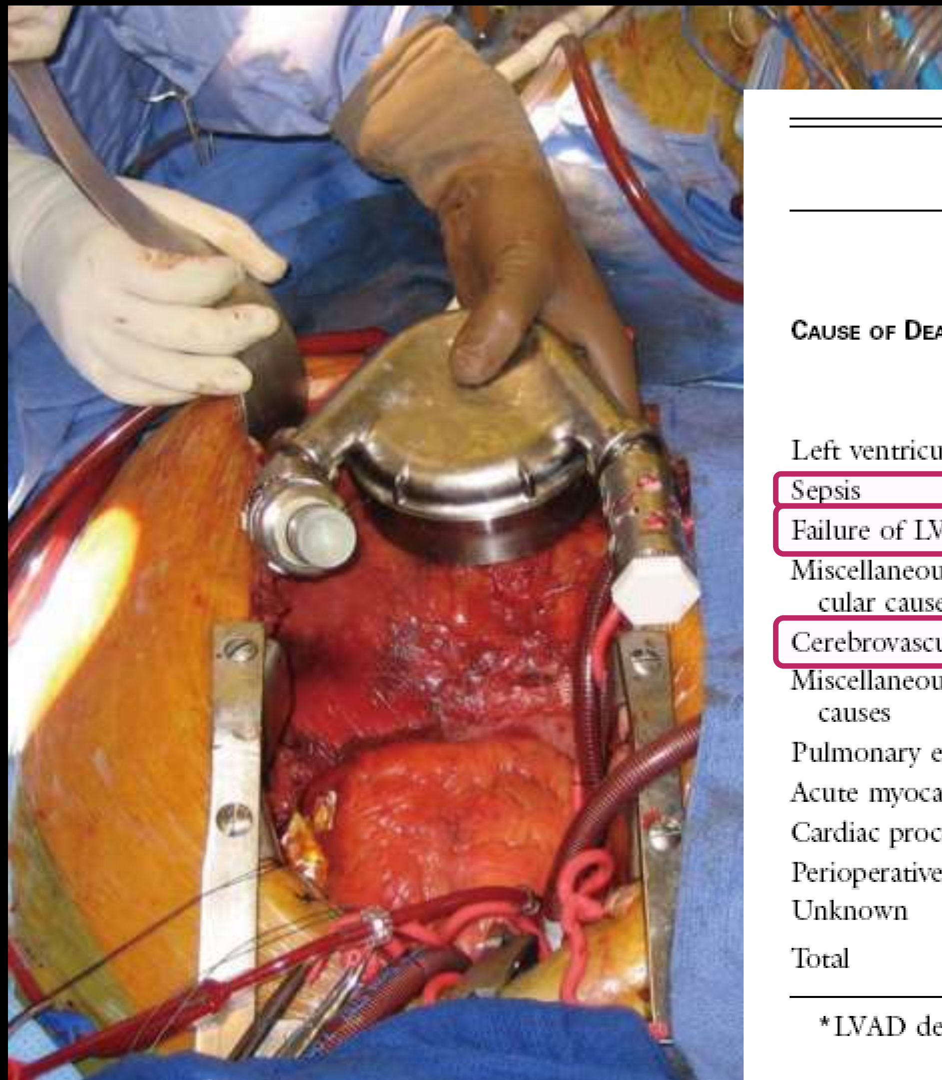


TABLE 2. CAUSES OF DEATH.*

CAUSE OF DEATH	MEDICAL-THERAPY GROUP	LVAD GROUP	TOTAL
	no. of patients		
Left ventricular dysfunction	50	1	51
Sepsis	1	17	18
Failure of LVAD	0	7	7
Miscellaneous noncardiovascular causes	0	5	5
Cerebrovascular disease	0	4	4
Miscellaneous cardiovascular causes	1	2	3
Pulmonary embolism	0	2	2
Acute myocardial infarction	1	0	1
Cardiac procedure	1	0	1
Perioperative bleeding	0	1	1
Unknown	0	2	2
Total	54	41	95

*LVAD denotes left ventricular assist device.

New ERA In VAD Therapy – CF LVAD

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Advanced H
Continuous-Flov

Mark S. Slaughter, M.D.,
Stuart D. Russell, M.D.,
Benjamin Sun, M.D., Anto
James W. Long,
Waqas Ghumman, M.D.,
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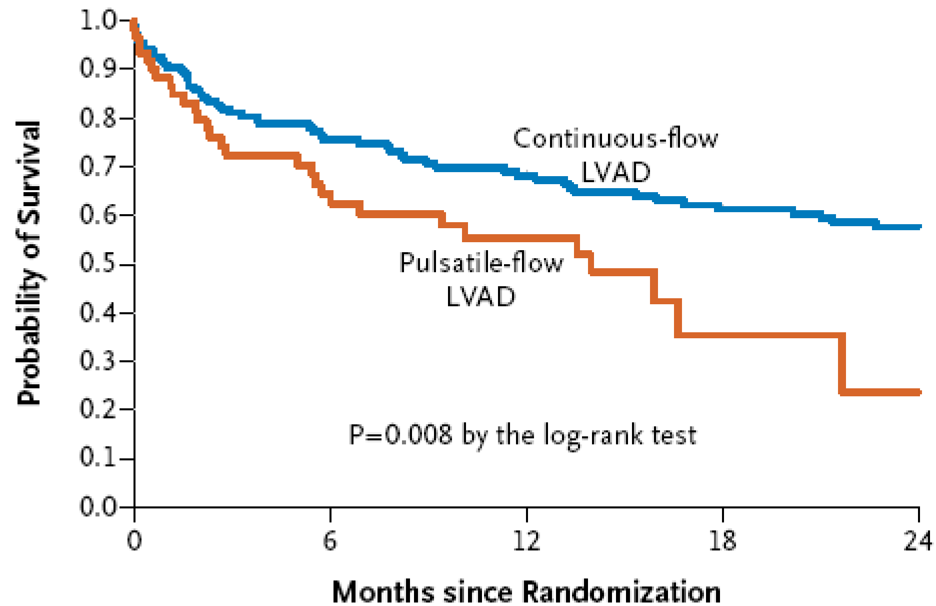


No. at Risk					
Continuous-flow LVAD	133	95	82	69	62
Pulsatile-flow LVAD	59	32	19	5	2

ELSEVIER

The Journal of
Heart and Lung
Transplantation

http://www.jhltonline.org

INTERMACS ANNUAL FEATURE

Sixth INTERMACS annual report: A 10,000-patient database

CrossMark

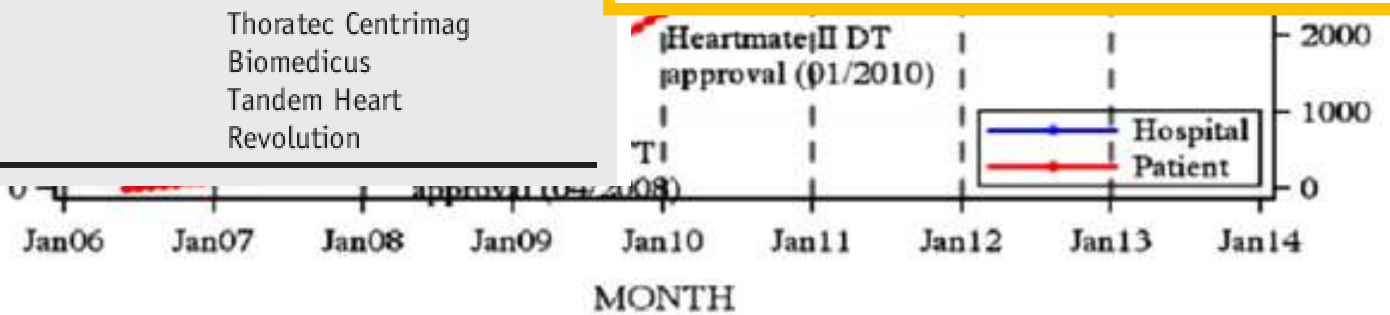
James K. Kirklin, MD,[a] David C. Naftel, PhD,[a] Francis D. Pagani, MD, PhD,[b] Robert L. Kormos, MD,[c] Lynne W. Stevenson, MD,[d] Elizabeth D. Blume, MD,[e] Marissa A. Miller, DVM, MPH,[f] J. Timothy Baldwin, PhD,[f] and James B. Young, MD[g]

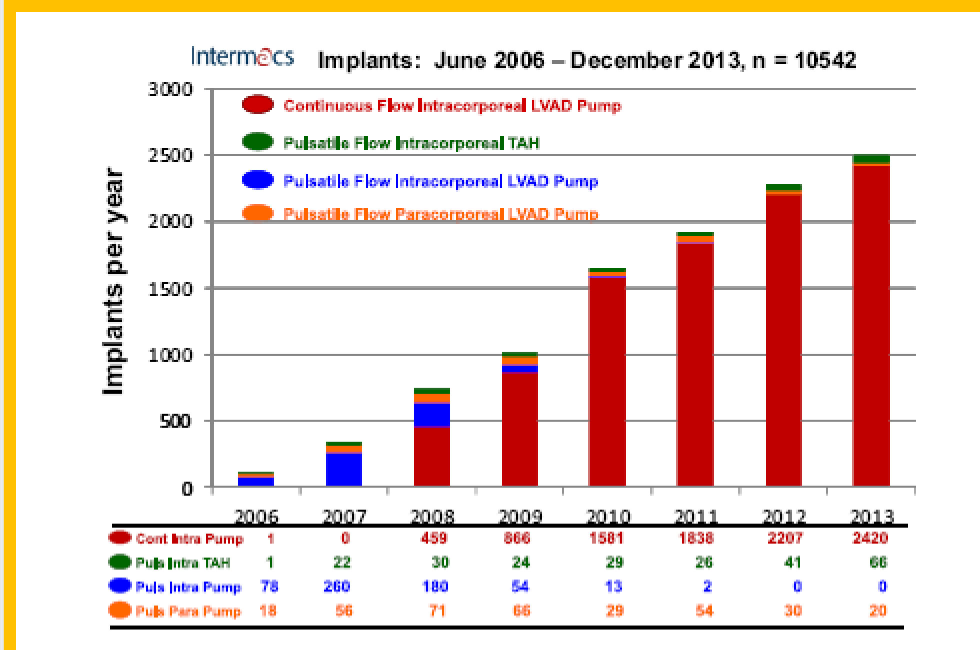
Intermacs

Implants: June 2006 – December 2013

Table 1 FDA-approved DevicesAdults

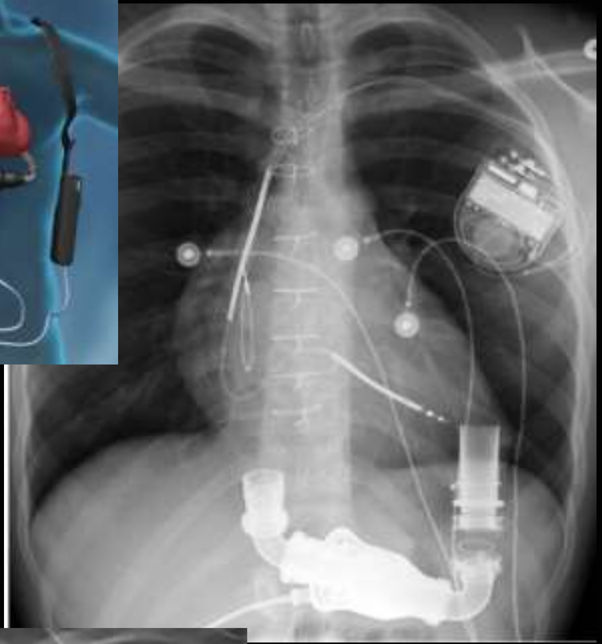
Type	Device
Durable devices	
Continuous flow	Thoratec HeartMate II
	HeartWare HVAD
	MicroMed DeBakey Child VAD
Pulsatile extracorporeal	Thoratec PVAD
	Berlin Heart EXCOR
Pulsatile intracorporeal	HeartMate IP
	HeartMate VE
	HeartMate XVE
	Thoratec IVAD
	Novacor PC
	Novacor PCq
Total artificial heart	SynCardia CardioWest
	AbioCor TAH
Temporary devices	
Short-term devices	Abiomed AB5000
	Abiomed BVS 5000
	Thoratec Centrimag
	Biomedicus
	Tandem Heart
	Revolution

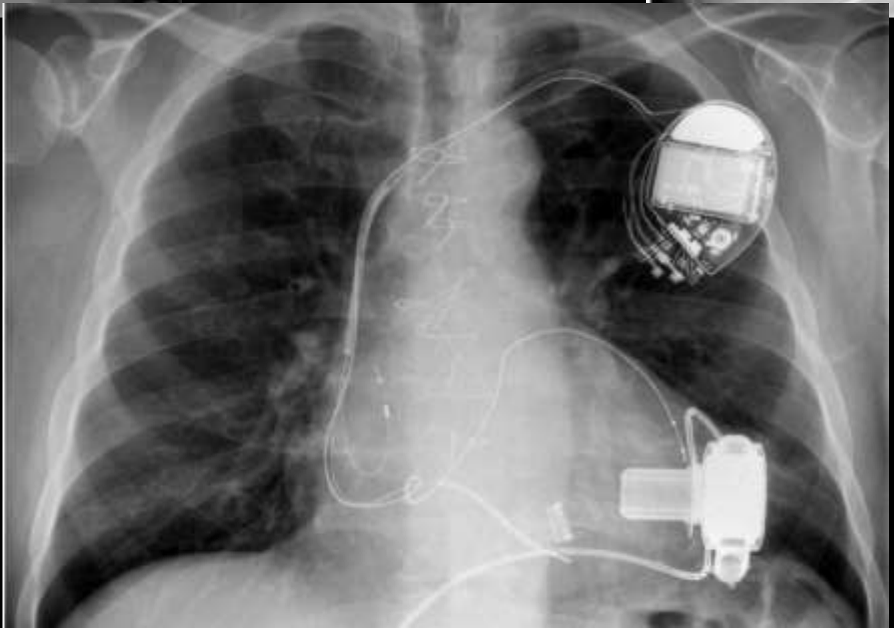




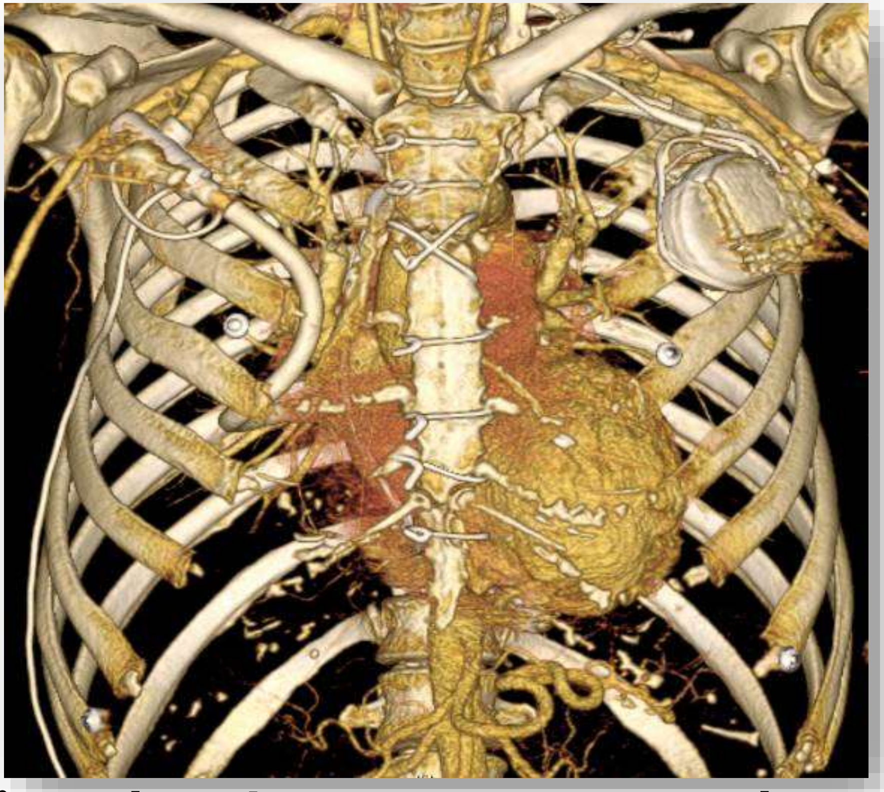
	2006	2007	2008	2009	2010	2011	2012	2013
Cont Intra Pump	1	0	459	866	1581	1838	2207	2420
Puls Intra TAH	1	22	30	24	29	26	41	66
Puls Intra Pump	78	260	180	54	13	2	0	0
Puls Para Pump	18	56	71	66	29	54	30	20

Perpetual Miniaturization



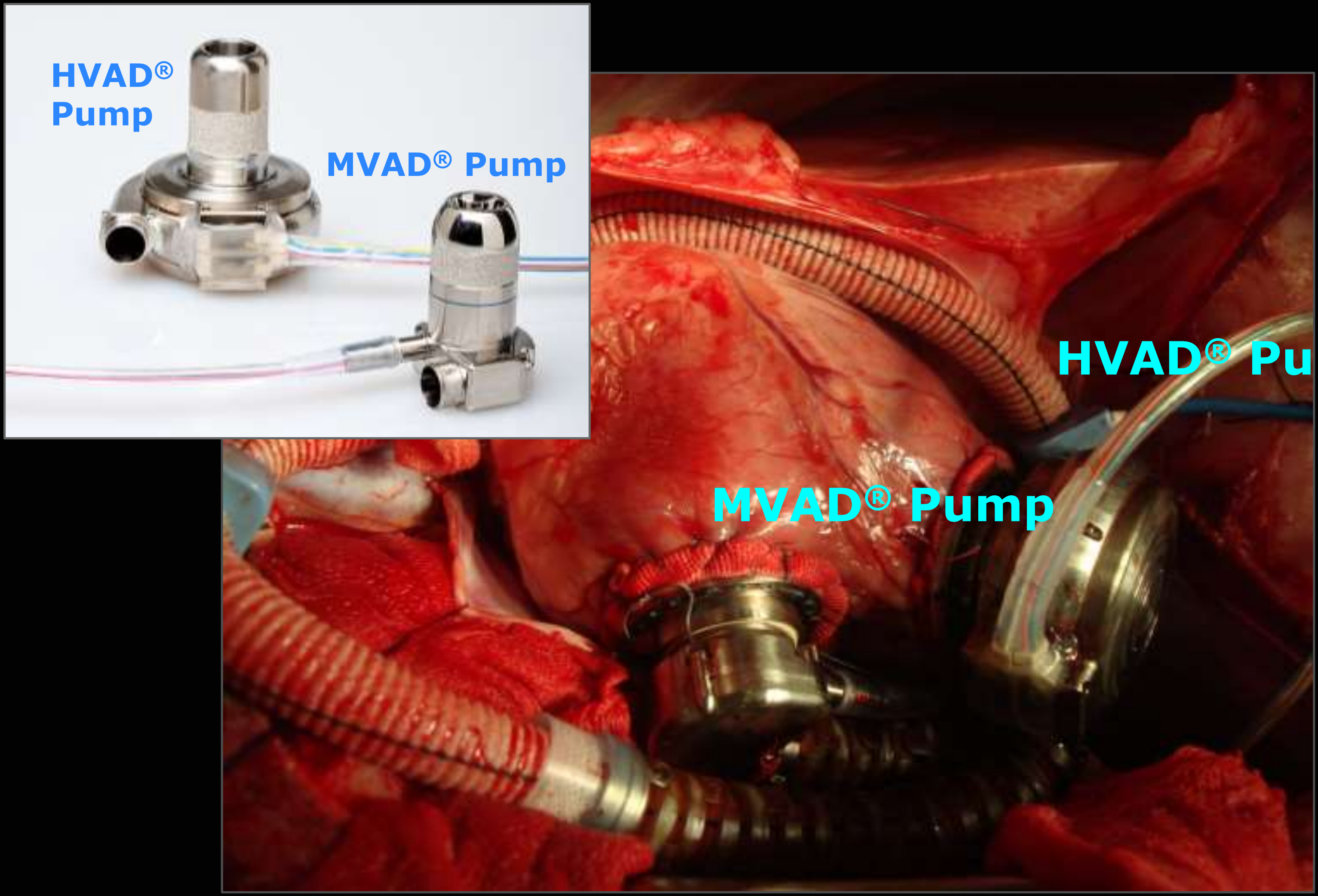


CircuLite Surgical System



Pump in subcutaneous pacemaker pocket
Right sided mini-thoracotomy
Extubation in OR possible
Off pump procedure

Possible Biventricular Support



Future lies in….

Big Picture Procedurally

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- Small pumps – VADs/CHF
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- Thoracic Aortic (endovascular)
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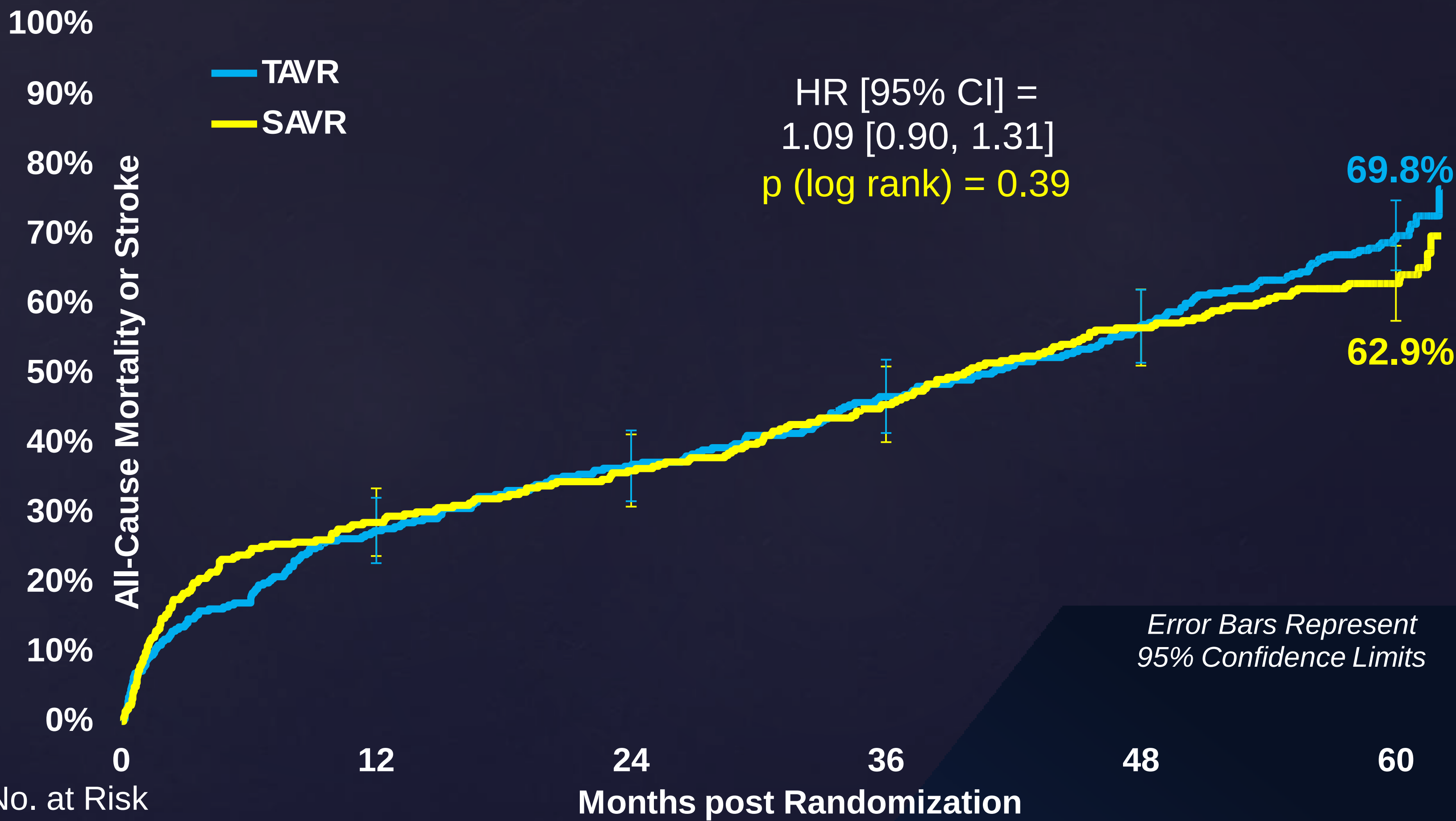
  - Transcatheter mitral valve replacement
    - Transcatheter pulmonic valve replacement

All-Cause Mortality or Stroke (ITT)
All Patients



No. at Risk

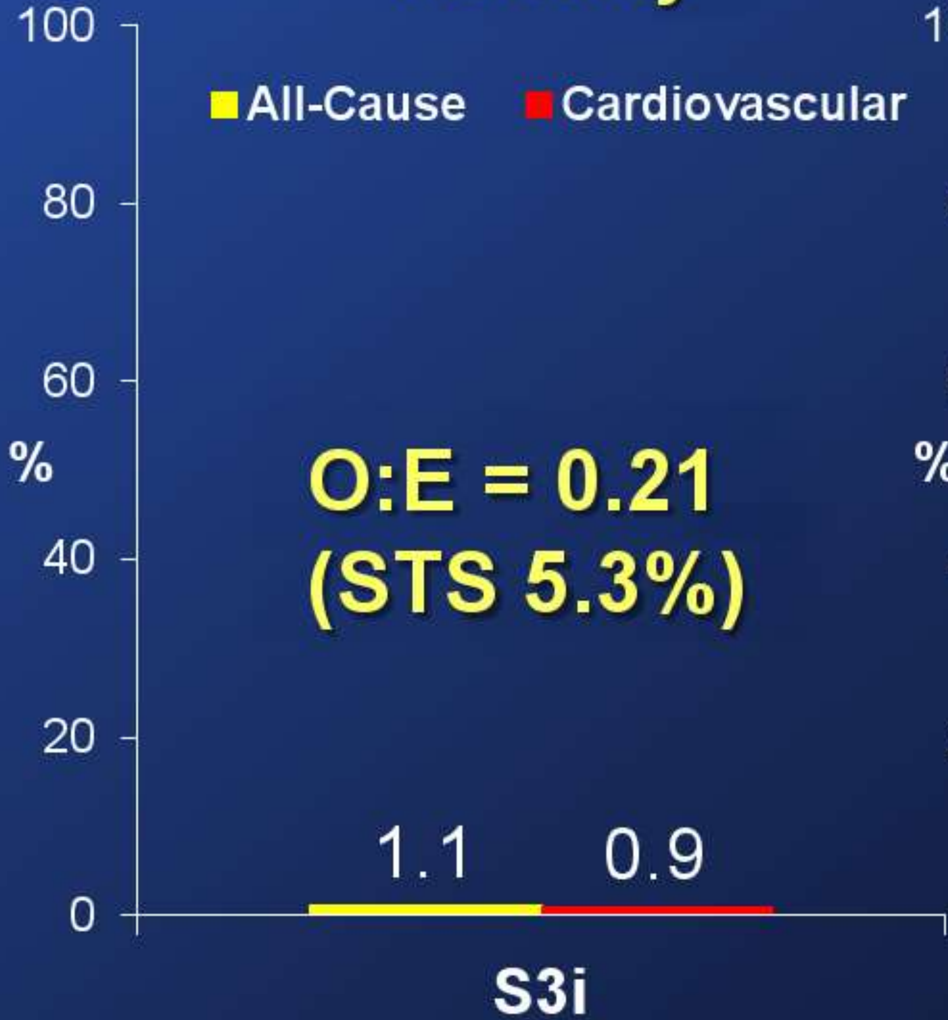
	0	12	24	36	48	60
TAVR	**348**	**251**	**217**	**181**	**144**	**57**
SAVR	**351**	**230**	**205**	**169**	**128**	**64**

Mortality and Stroke: S3i

At 30 Days (As Treated Patients)

THE PARTNER II TRIAL

Mortality



Stroke

PARTNER Manuscripts in NEJM (October, 2010 – May, 2012)

Very well studied/Data driven/RCT

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 21, 2010 VOL. 363 NO. 17

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D., John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JUNE 9, 2011 VOL. 364 NO. 23

Transcatheter and Surgical Aortic-Valve Replacement in High-Risk Patients

Craig R. Smith, M.D., Martin B. Leon, M.D., Michael J. Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., Mathew Williams, M.D., Todd Dewey, M.D., Samir Kapadia, M.D., Vasilis Babaliaros, M.D., Vinod H. Thourani, M.D., Paul Corso, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart J. Pocock, Ph.D., for the PARTNER Trial Investigators*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement for Inoperable Severe Aortic Stenosis

Raj R. Makkar, M.D., Gregory P. Fontana, M.D., Hasan Jilaihawi, M.D., Samir Kapadia, M.D., Augusto D. Pichard, M.D., Pamela S. Douglas, M.D., Vinod H. Thourani, M.D., Vasilis C. Babaliaros, M.D., John G. Webb, M.D., Howard C. Herrmann, M.D., Joseph E. Bavaria, M.D., Susheel Kodali, M.D., David L. Brown, M.D., Bruce Bowers, M.D., Todd M. Dewey, M.D., Lars G. Svensson, M.D., Ph.D., Murat Tuzcu, M.D., Jeffrey W. Moses, M.D., Matthew R. Williams, M.D., Robert J. Siegel, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Stuart Pocock, Ph.D., Craig R. Smith, M.D., and Martin B. Leon, M.D., for the PARTNER Trial Investigators*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement

Susheel K. Kodali, M.D., Mathew R. Williams, M.D., Craig R. Smith, M.D., Lars G. Svensson, M.D., Ph.D., John G. Webb, M.D., Raj R. Makkar, M.D., Gregory P. Fontana, M.D., Todd M. Dewey, M.D., Vinod H. Thourani, M.D., Augusto D. Pichard, M.D., Michael Fischbein, M.D., Wilson Y. Szeto, M.D., Scott Lim, M.D., Kevin L. Greason, M.D., Paul S. Teirstein, M.D., S. Chris Malaisrie, M.D., Pamela S. Douglas, M.D., Rebecca T. Hahn, M.D., Brian Whisenant, M.D., Alan Zajarias, M.D., Duolao Wang, Ph.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., and Martin B. Leon, M.D., for the PARTNER Trial Investigators*

So the Real Question is ……. Why **NOT** a New TAVI trial into **LOW and NTERMEDIATE RISK** patients??

THE PARTNER TRIAL

The Future will still include….

Incremental improvements in:

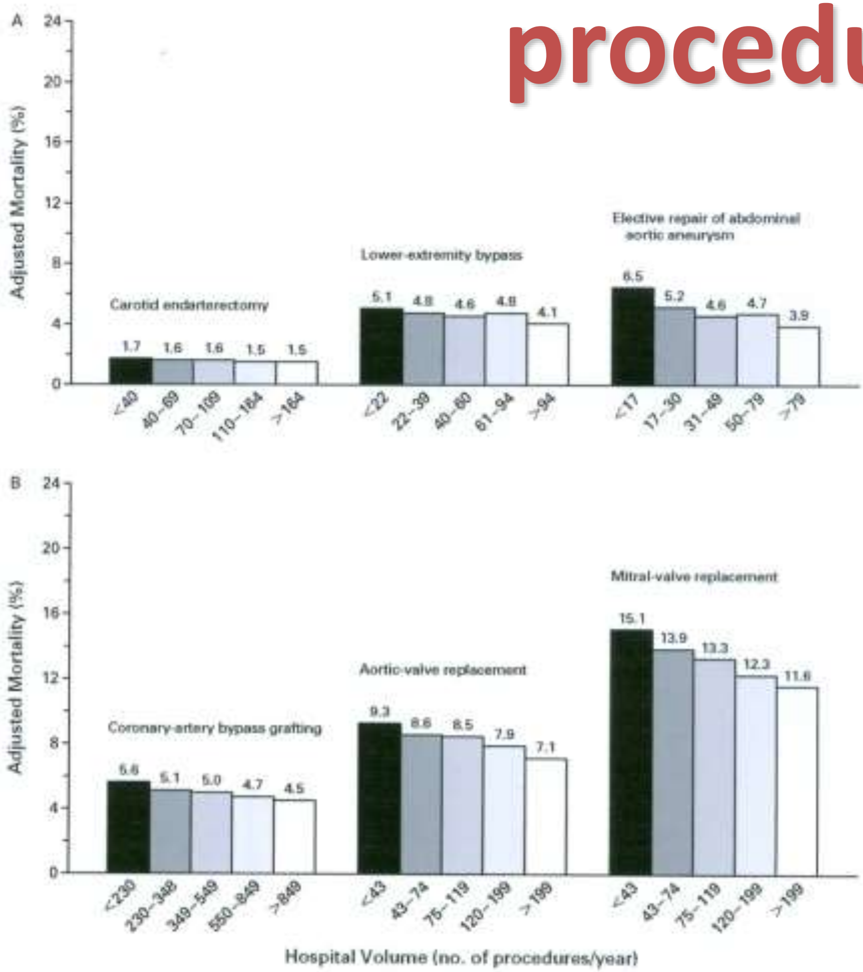
- Improved Perfusion Concepts
  - “improvements” to CPB machine
  - Sensors
- All-Arterial CABG
- EP Surgery (?)
- Pain management

Additionally, Future lies in…..

- Greater transparency
- Quality initiatives
- Public reporting of outcomes

- Of course, some of the main components of present cardiac surgery will remain, but with decreased growth
  - Congenital, CABG, standard valve replacement, complex operations, niche areas

Hospital volume of 12 procedures

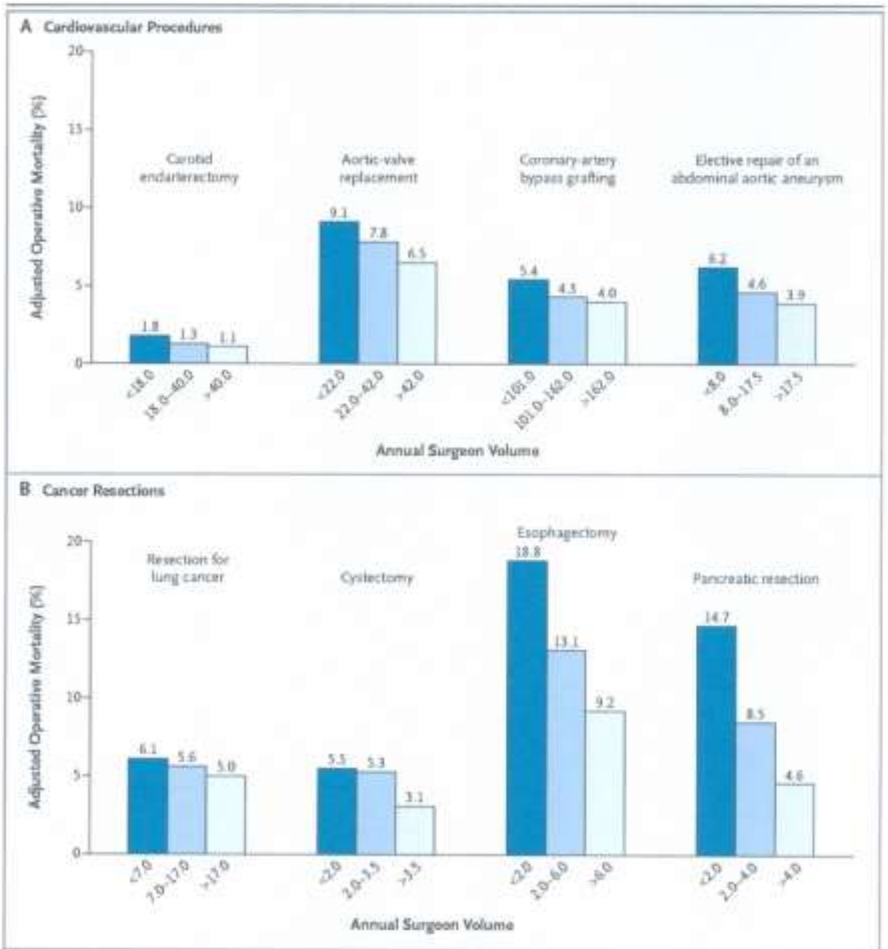


Medicare population:

- 1994-99
- > 65 yrs
- 2.5 mill pats
- 30 d mortality
- 11/12 inversely related
- Max diff. 16 vs 4 %
  pancreatic resection
- Min diff. 1.7 vs 1.5 %
  carotid TEA

Birkmeyer JD et al:
Hospital volume and surgical mortality in the United States
N Engl J Med 2002;346:346:1128-37

<u>Surgeon</u> volume of 8 procedures



Medicare population:

- 1998-99
- > 65 yrs
- 474 000 pats
- 30 d mortality

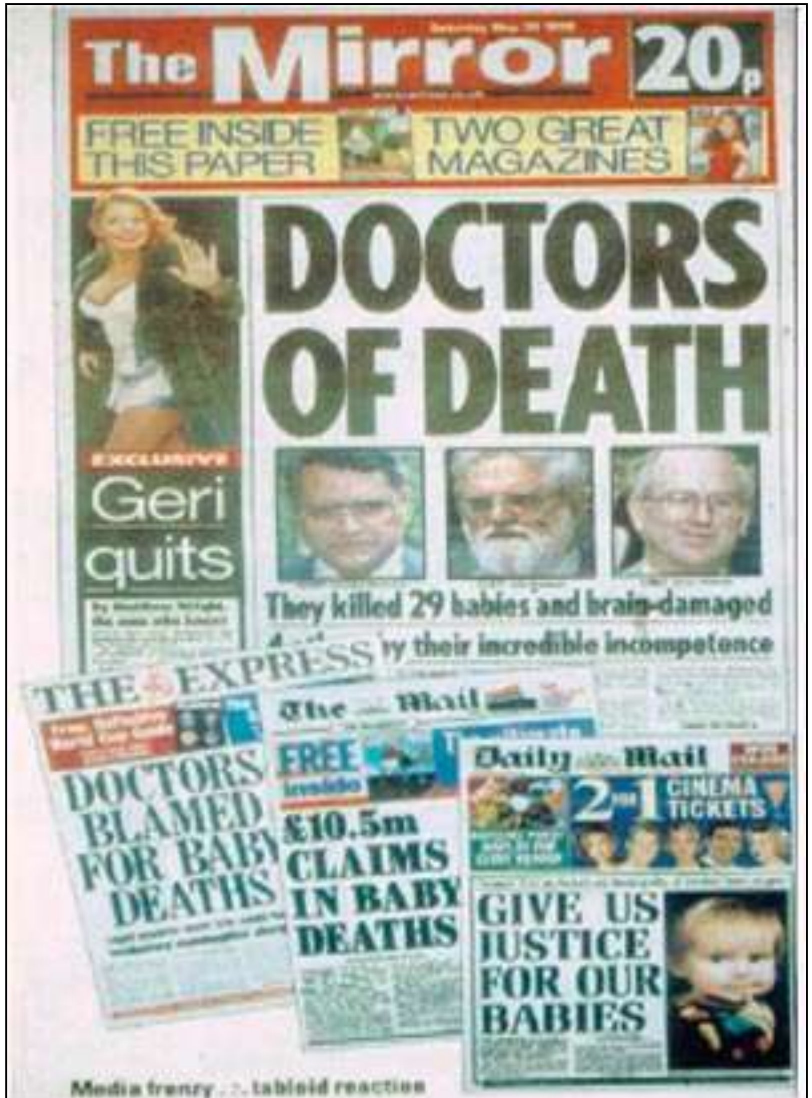
Conclusion:

"Surgeon volume was inversely related to operative mortality for <u>all</u> eight procedures"

Birkmeyer JD et al:
Surgeon volume and operative mortality in the United States
N Engl J Med 2003;349:346:2117-27

National Policy OUS based on Volume-Outcome Relationship: The UK NHS

The Bristol (UK) scandal (1988-95)



doi:10.1510/icvts.2004.102137

INTERACTIVE CARDIOVASCULAR AND THORACIC SURGERY

Interactive CardioVascular and Thoracic Surgery 4 (2005) 197-199

www.icvts.org

Brief communication - Congenital

Effects of 'Bristol' on surgical practice in the United Kingdom

Colin J. Hilton*, J.R. Leslie Hamilton, Nicola Vitale[1], Rune Haaverstad[2]

Department of Cardiothoracic Surgery, Cardiothoracic Centre, Freeman Hospital, Newcastle-upon-Tyne, NE7 7DN, UK

Received 5 November 2004; received in revised form 27 January 2005; accepted 16 February 2005

Abstract

In 1995 a child died following an arterial switch operation for complex transposition of the great arteries. There had been general concern regarding the outcomes for the arterial switch procedure in the unit in Bristol. A review, prompted by parents whose children had died, showed that 29 children had died and four others suffered from cerebral damage postoperatively. The General Medical Council (GMC) considered the conduct of three doctors from the unit. This hearing culminated in the suspension and subsequent removal from the Medical Register of the senior Cardiac Surgeon and the Chief Executive of the hospital. The second Cardiac Surgeon was banned from practising in the field of paediatric cardiac surgery for three years (his results in adult cardiac surgical practice were not called into question). Following this the Government set up a public Inquiry to investigate the causes behind the deaths. This Inquiry, which took three years, made recommendations that have affected the way all doctors in the UK practice.

-GMC inquiry: 15 millGBP and 600 page report

-198 recommendations: Only 31 related to children; only 7 pediatric

-Aim: Fewer pediatric cardiac units, volume >300 and >3 surgeons

-<u>Effects on ALL cardiac surgical practice:</u>

- -Communication
- -Competence
- -Performance monitoring
- -Release of mortality data (hospital and surgeon)

Interactive Cardiovasc and Thoracic Surgery 2005;4:197-199

Additionally, Future lies in…..

Organizational Dynamics

- HVC Concept
  - How and Why it works. When it's virtual
  - Relationship with Interventional Cardiology
- ?? Reorganization of Medical Care
  - MACRA, etc
- STS perch

- Interesting ….. Job Market is Robust!
  - Why? The "Shulkin" effect.?

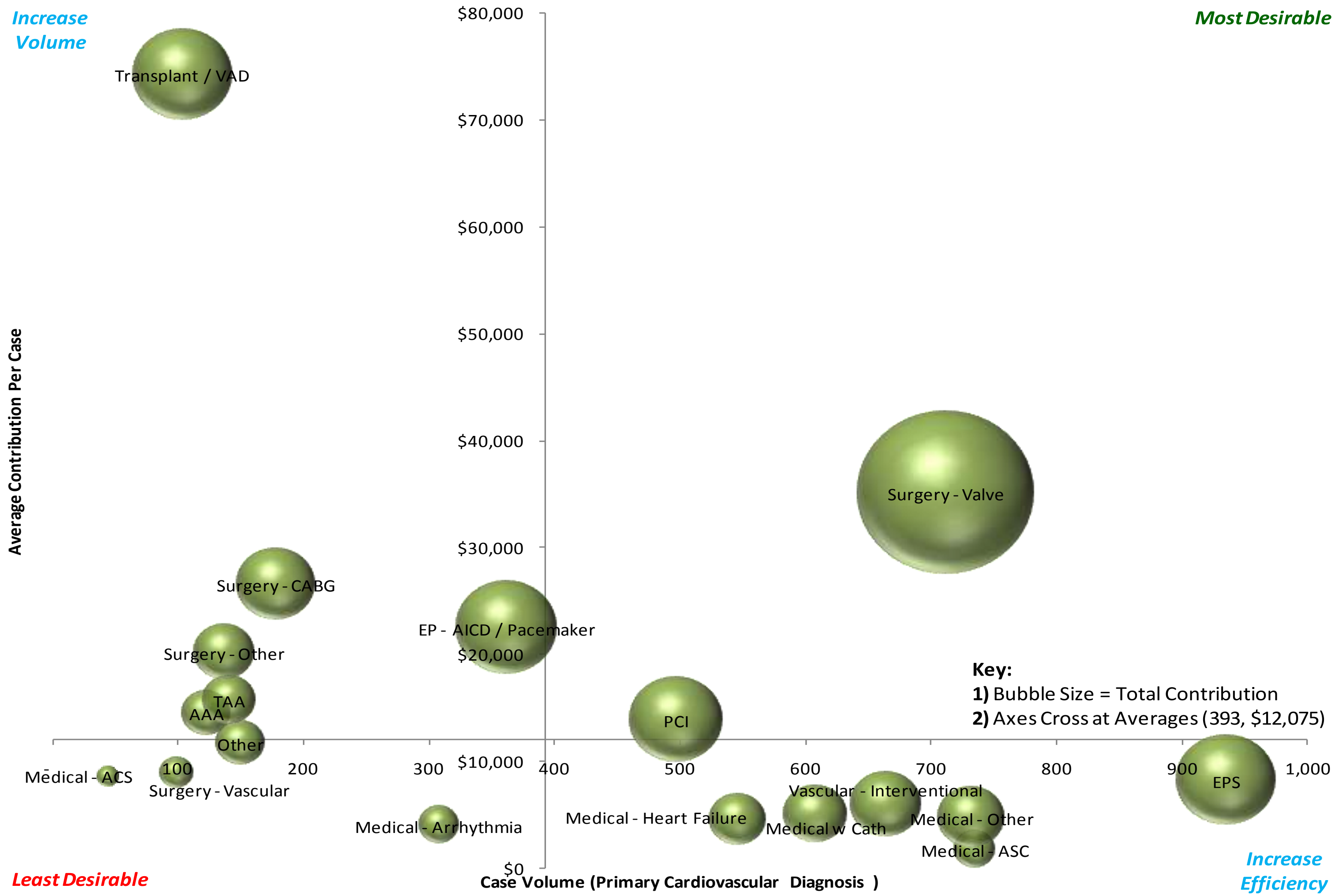
HVC Background

Is AVR (and the HVC) Important (Financially) to the Health System?

How Important?
Now?
Future?

Contribution Margin of Various Cardiac Treatments

Valve procedures are highly profitable; generating a healthy average contribution margin and per case gain

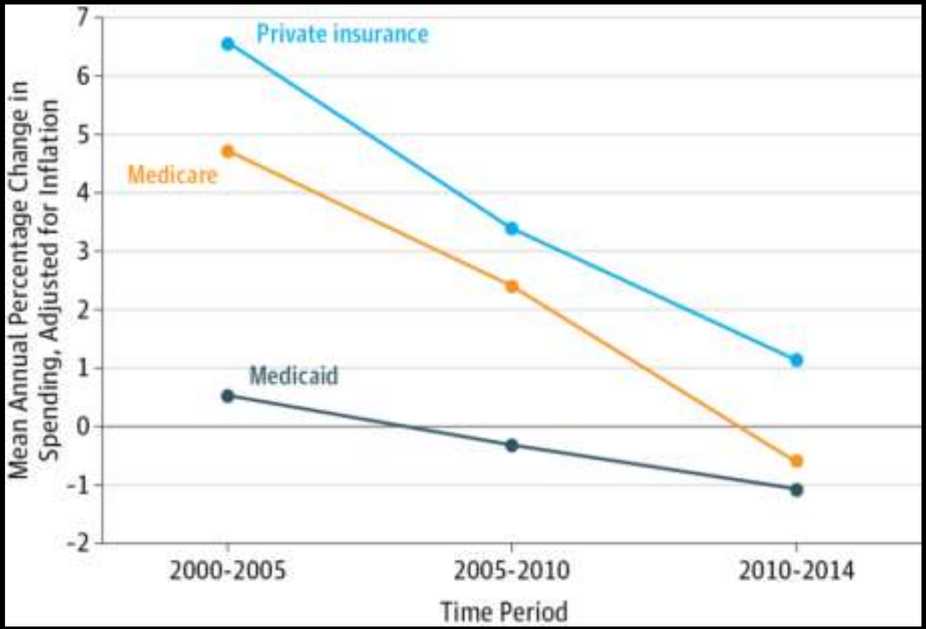


We're Actually doing quite well over 15 years!

From: **United States Health Care Reform: Progress to Date and Next Steps**

JAMA. 2016;316(5):525-532. doi:10.1001/jama.2016.9797

The JAMA Network



Rate of Change in Real per-Enrollee Spending by PayerData are derived from the National Health Expenditure Accounts. Inflation adjustments use the Gross Domestic Product Price Index reported in the National Income and Product Accounts. The mean growth rate for Medicare spending reported for 2005 through 2010 omits growth from 2005 to 2006 to exclude the effect of the creation of Medicare Part D.

Date of download: 8/9/2016

Additionally, Future lies in…..

Organizational Dynamics

- HVC Concept
  - How and Why it works. When it's virtual
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- STS perch

- Interesting ….. Job Market is Robust!
  - Why? The "Shulkin" effect.?

$2.5 Trillion total, $765 Billion in Waste
(>50% "Medical")

overtreatment

failures of delivery and coordination

undertreatment

Source: The Institute of Medicine: The Healthcare Imperative: Lowering Costs and Improving Outcomes.

A Pause ……

Example Patient

Name for Scrolling	CROUTHAMEL,PAUL; 000103917606
DRG	219
Entity	(All)

	-1	0	1	2	3	Grand Total	
000103917606	**$1,345**	**$39,552**	**$1,912**	**$1,100**	**$193**	**$44,101**	
OR SUPPLIES		**$32,825**				**$32,825**	
01304336 CATHETER ANGIOPLASTY NON LA		$325				$325	
VALVE		$32,500				$32,500	
O.R. YELLOW	**$173**	**$2,666**				**$2,839**	**6%**
01100346 OR 1ST HALF HR		$369				$369	
01100353 OR ADDTL HALF HR		$1,552				$1,552	
01100452 OR PROVIDER PER 1/2 HOUR		$138				$138	
01100460 CATH LAB PROVIDER PER 1/2 H		$608				$608	
06550008 ART. (THORAC. AORTA) S/I	$173					$173	
NUR-SILVERSTEIN 10	**$802**		**$802**	**$802**		**$2,405**	**5%**
NUR-SICU-CT/GS		**$1,606**				**$1,606**	**4%**
PHAR - IP CENTRAL ROBOT NARC	**$43**	**$467**	**$170**	**$96**	**$25**	**$802**	**2%**
BLOOD BANK	**$207**		**$496**	**$83**		**$786**	**2%**
PERFUSION SUPPLIES		**$667**				**$667**	**2%**
PERIOP ANES TECHS HUP		**$444**				**$444**	**1%**
AUTO LAB	**$71**	**$213**	**$126**	**$11**	**$14**	**$434**	**1%**
INTRAOPERATIVE MONITORING		**$400**				**$400**	**1%**
RESPIRATORY THERAPY-HUP		**$107**	**$138**			**$245**	**1%**
BONE/CHEST/ER SUPP	**$36**	**$26**	**$26**	**$26**	**$62**	**$176**	**0%**
INPATIENT PT-HUP				**$69**	**$84**	**$153**	**0%**
ECHO LAB			**$117**			**$117**	**0%**
PERFUSION HUP		**$95**				**$95**	**0%**
PHLEBOTOMY	**$4**	**$17**	**$21**	**$4**	**$4**	**$51**	**0%**
COAGULATION	**$7**		**$7**	**$7**		**$22**	**0%**
PREP & RECOVERY SC		**$16**				**$16**	**0%**
EKG LABORATORY	**$3**	**$3**	**$6**		**$3**	**$15**	**0%**
CLINICAL LAB		**$1**	**$2**	**$0**	**$0**	**$3**	**0%**
Grand Total	**$1,345**	**$39,552**	**$1,912**	**$1,100**	**$193**	**$44,101**	

OR Supplies, driven by valve 74% of direct cost

Final Thought …… You're the Hospital CFO

- **Cohort A (STS > 8; mean 10-11) shows clinical "equivalence" between TAVI and Open AVR, However, at $32,500 per Valve The CM is reduced by $20-25K PER CASE and throwing profitability to a LOSS, Basically showing massive financial superiority to open AVR. ….. This is bad enough.**

- **BUT …… Intermediate Risk (STS 4-8) TAVI (P2A and SURTAVI), where there is even LESS equipoise than Cohort A, …… Is this Financial irresponsibility??**

- **Obviously I feel it is more complicated than that but ….**

TAVR Experience at PENN

"Just the Facts Ma'am" …… Detective Joe Friday, Dragnet

"There is no Right or Wrong here, Just Decisions and Consequences

My CFO's response is: Do what you want but the consequences are this means less RESOURCES for your team

Additionally, Future lies in…..

Organizational Dynamics

- HVC Concept
  - How and Why it works. When it's virtual
  - Relationship with Interventional Cardiology
- ?? Reorganization of Medical Care
  - MACRA, etc
- STS perch

I have no real idea !!!

- Interesting ….. Job Market is Robust!
  - Why? The "Shulkin" effect.?

However, The Real Future of our Specialty Resides in Innovation

The Future Lies in .....

The “Emerging” and Innovative Approach to Treatment ?

CT Surgery has Achieved a lot!

……..However, The only Constant is Change

Circa 1993: Response of a Newly minted Cardiac Surgeon

301 CABG cases, Sir!

No Innovation here!!

Thoracic Aortic Surgery:
Emerging and Innovative Therapy and Future Landscape

1. Innovation occurs at a number of Levels:
    1. Conceptual
        1. New operations based on new and improved Knowledge
    2. Device Related
        1. New operations based on availability of New Theraputic Devices
    3. Conceptual and Device Related

2. All need a CULTURE of Innovation and Early Adoption **(with Audit)**

Thoracic Aortic Surgery:
Emerging and Innovative Therapy and Future Landscape

1. Increased Valve Sparing Root Surgery (ALWAYS for AI) David V (and BAV repair techniques) .. **(Conceptual)**
2. Ascending Aortic TEVAR for High Risk Type A Dissection +/- Endo-Bentall **(Device)**
    1. Distal Aortic TEVAR Adjunct in Type A Dissection **(Conceptual and Device)**
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4. Chronic Type B Dissecting Aneurysms **(Mostly Conceptual also Device)**

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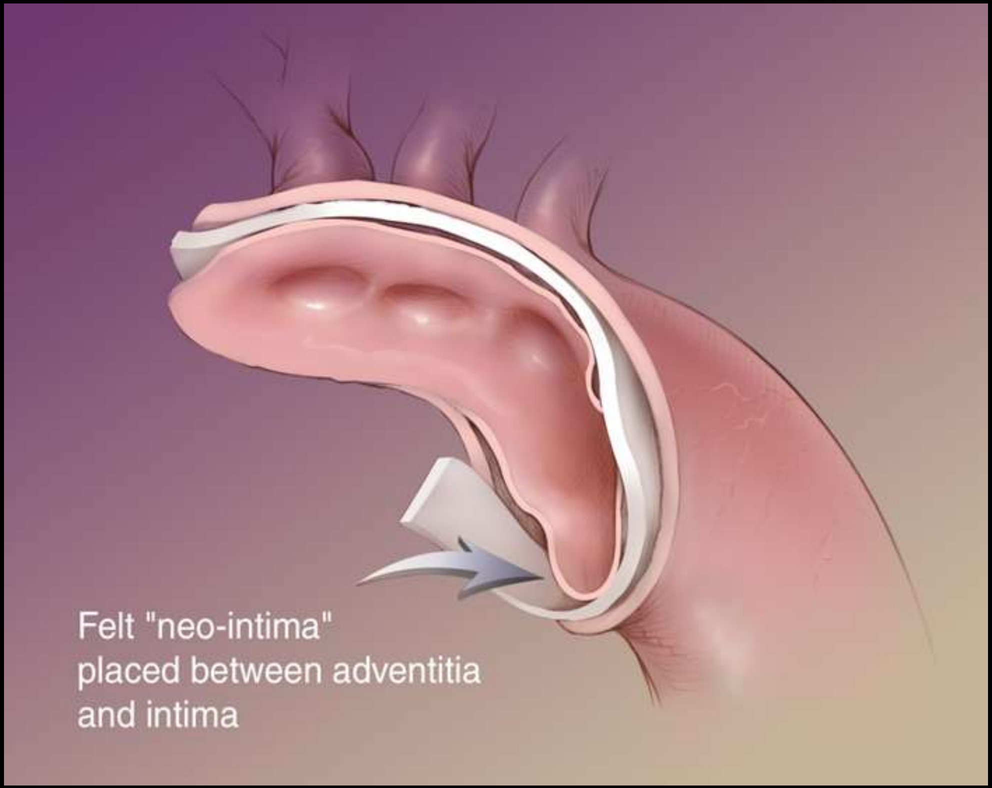
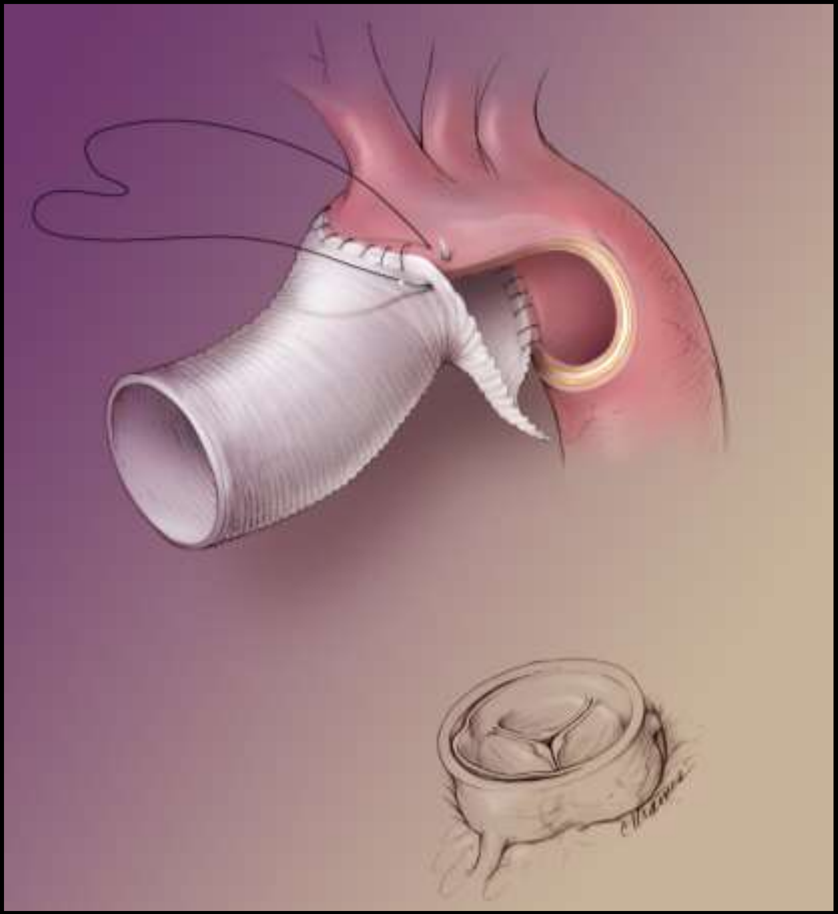
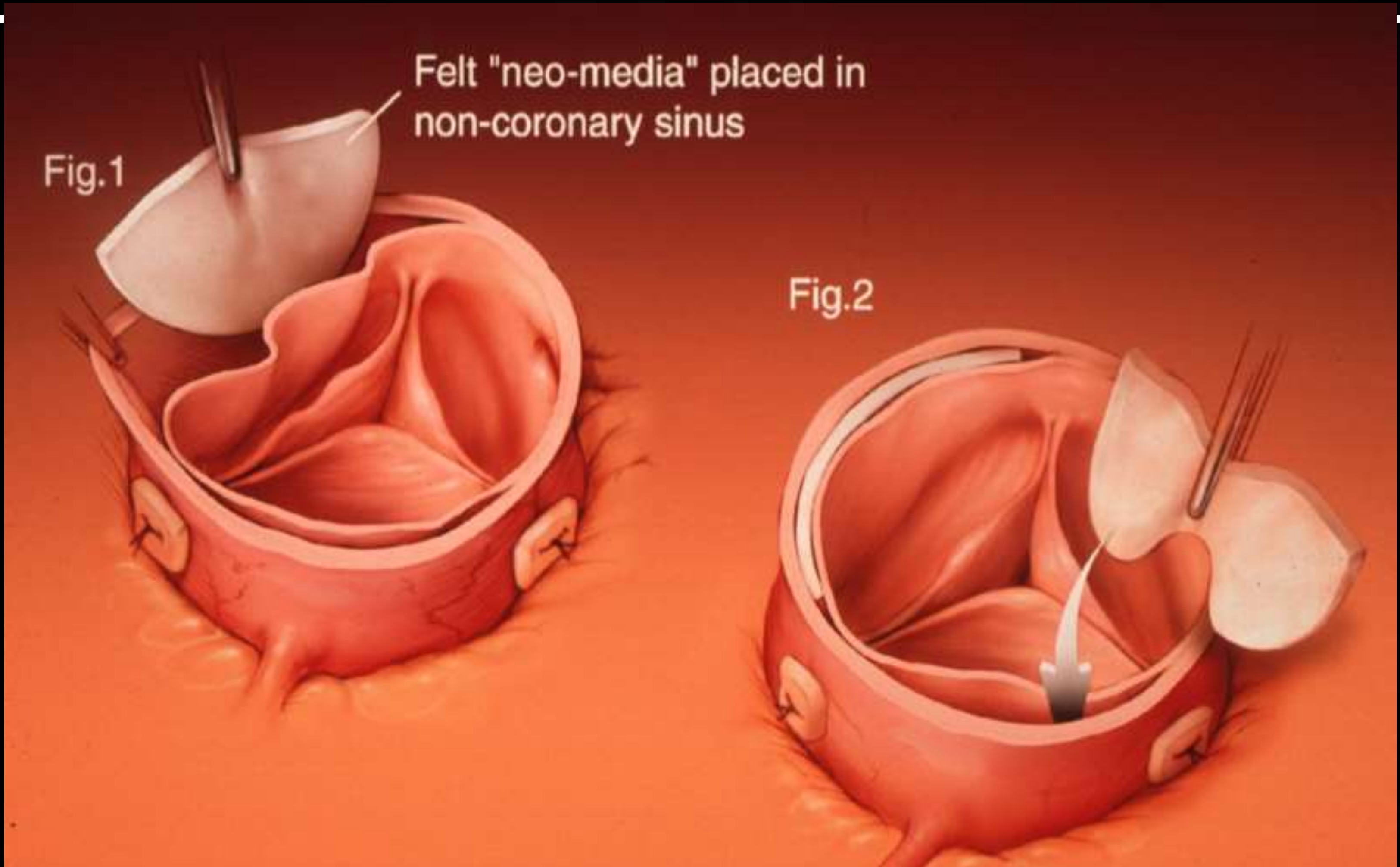
Obliteration of False Lumen and Creation of "Neo-Media" and Distal Graft Anastomosis: "Aggressive" Hemi-Arch





Aortic Root Reconstruction/Sinus of ValSalva Repair



Bavaria, Pochettino, Gleason, et al; Ann Thor Surg 2003

Type A Dissection with Valve Resuspension and Ascending & Hemi-Arch (+/- Bioglue)

Note: Efficient Conduct of operation

Acute Type A Dissection: Rational Design of an Operation (What is Missing?)

Cause of death	Treatment
Acute CHF due to AI	Aortic valve resuspension
Coronary malperfusion	Aortic root repair
Cerebral malperfusion	Arch replacement
Free Ascending rupture	Asc aortic replacement

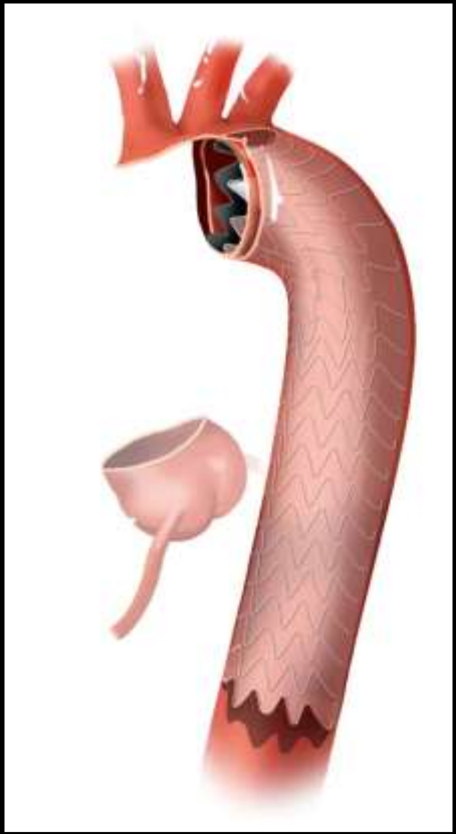
Acute Type A Dissection: Design of an Operation (What is Missing?)

Cause of death	ent
Acute CHF due to AI	alve resuspension
Coronary malperfusio	ot repair
Cerebral malperfusion	lacement
Free Ascending ruptur	ic replacement

Fate of Distal Descending Aorta!

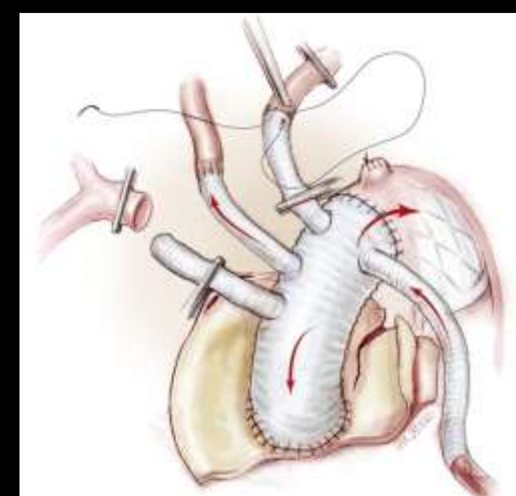
Solution (?): Surgical Innovation

Can We Build a Case for the use of an Antegrade delivered TEVAR in Modifying the Descending Aorta in Type A Dissection?



Technical: Conventional Total Arch with Frozen Elephant Trunk:

Standard Zone 3 Arch FET



Distal LZ: Zone 2 Arch +/- Distal TEVAR Solution

Presently in Early FDA Feasibility trials in US; J. Bavaria, PI

J.Bavaria et al; JTCVS 2016 In Press

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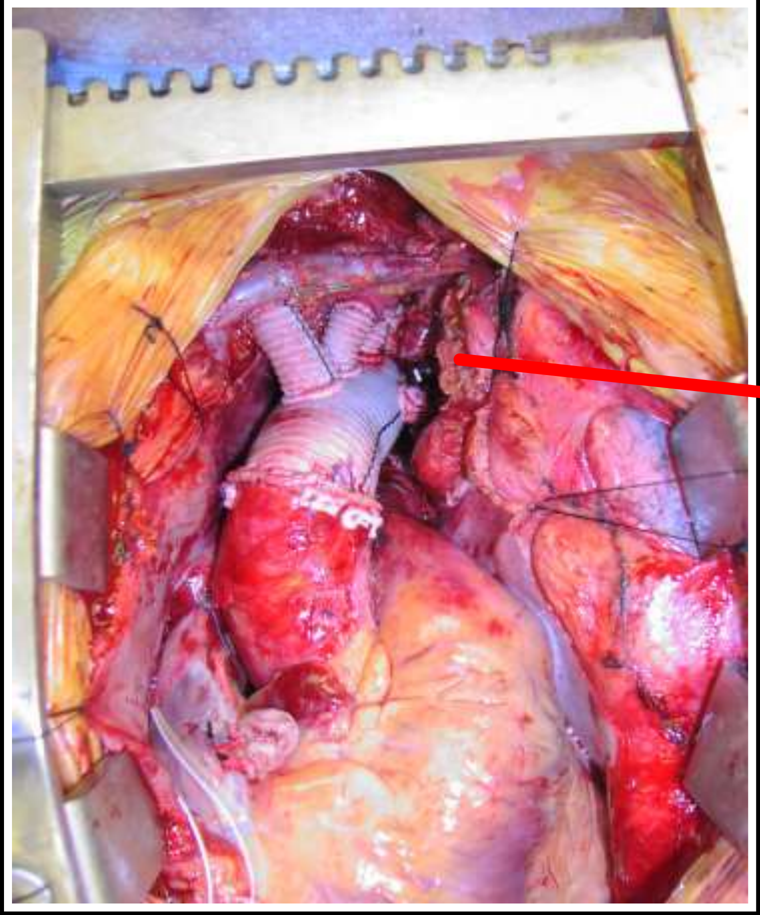
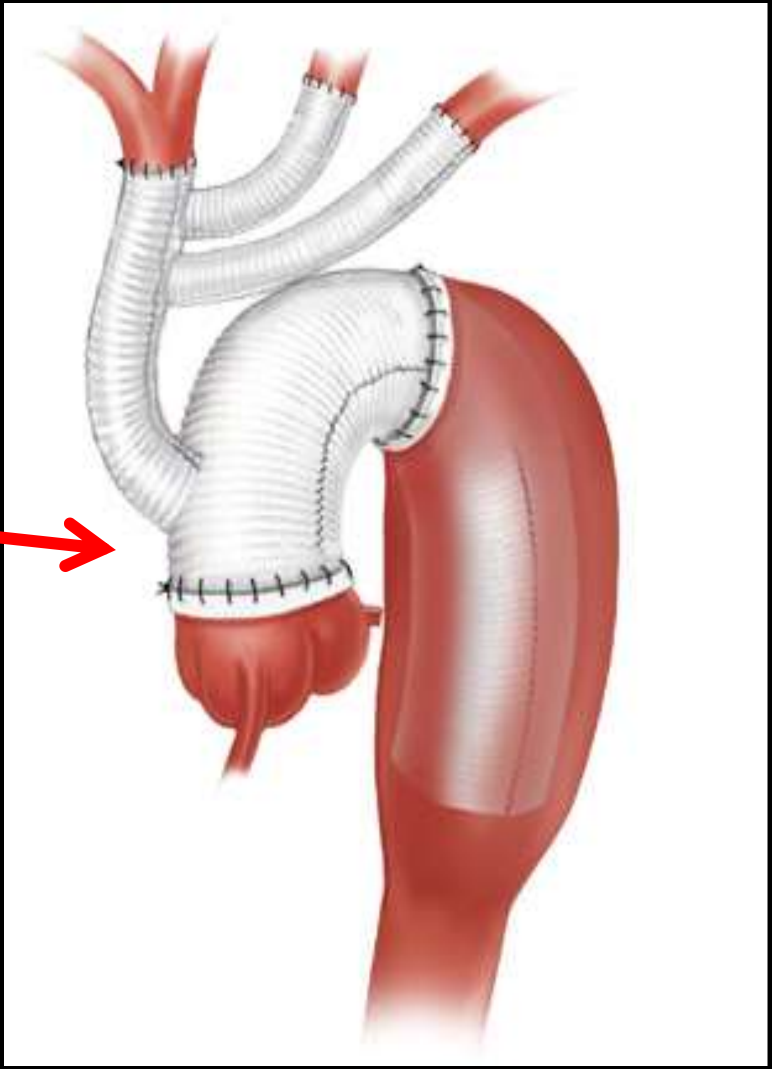
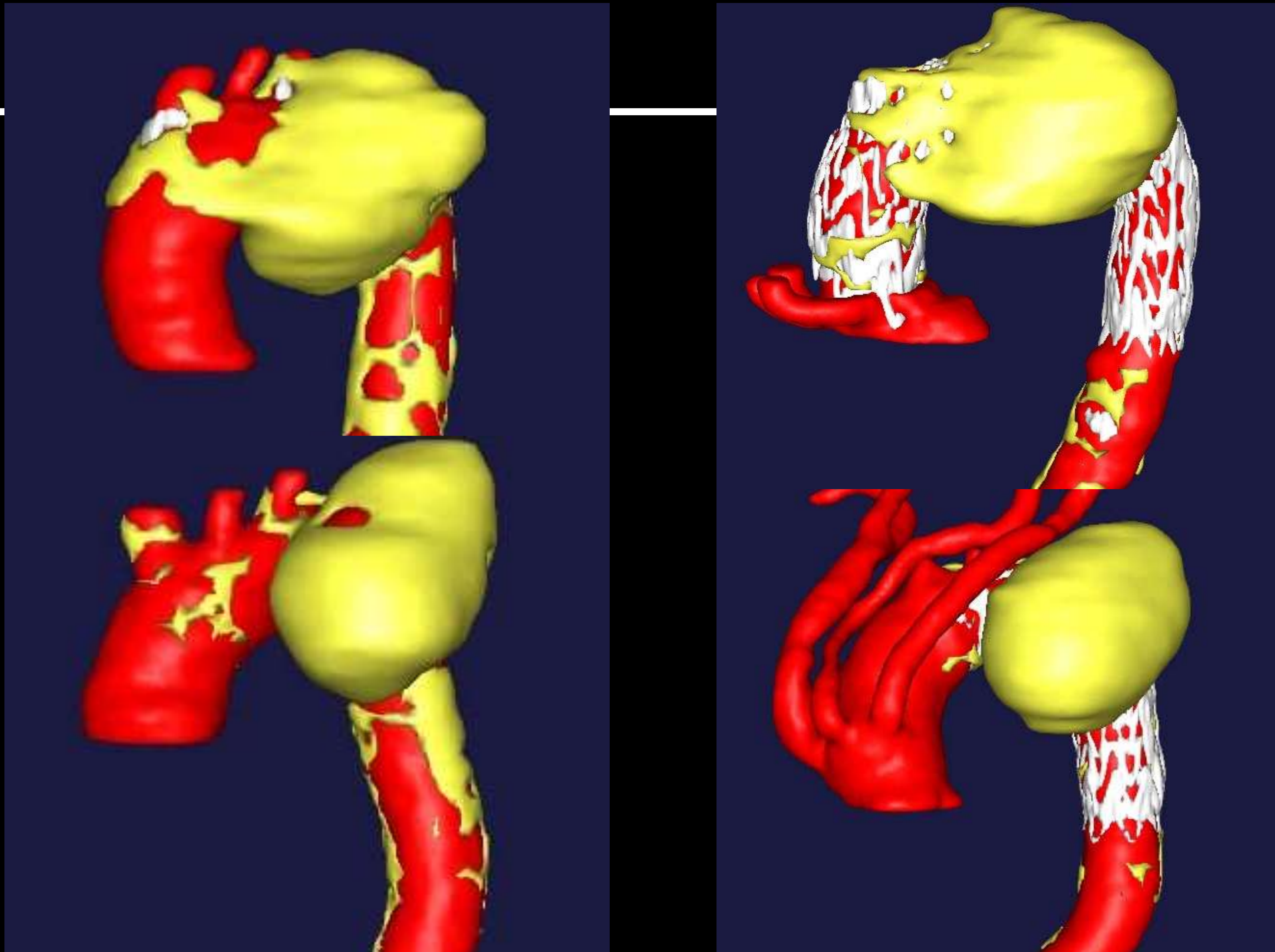
"More Proximal" Aortic Arch Surgery ENABLING later TEVAR if anatomy Suitable

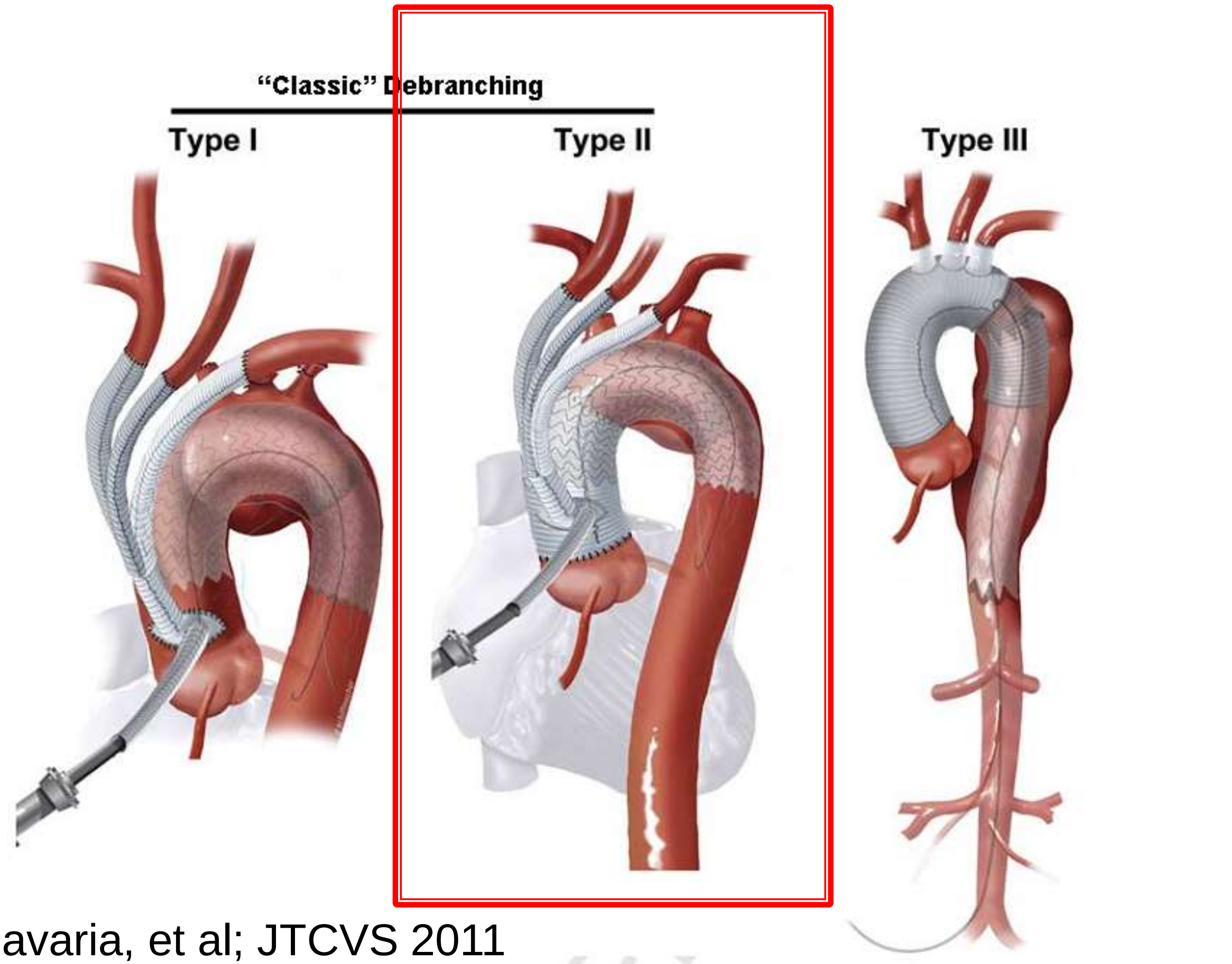




Saccular Distal/Mid Arch Aneurysm Repair .. Difficult!!!

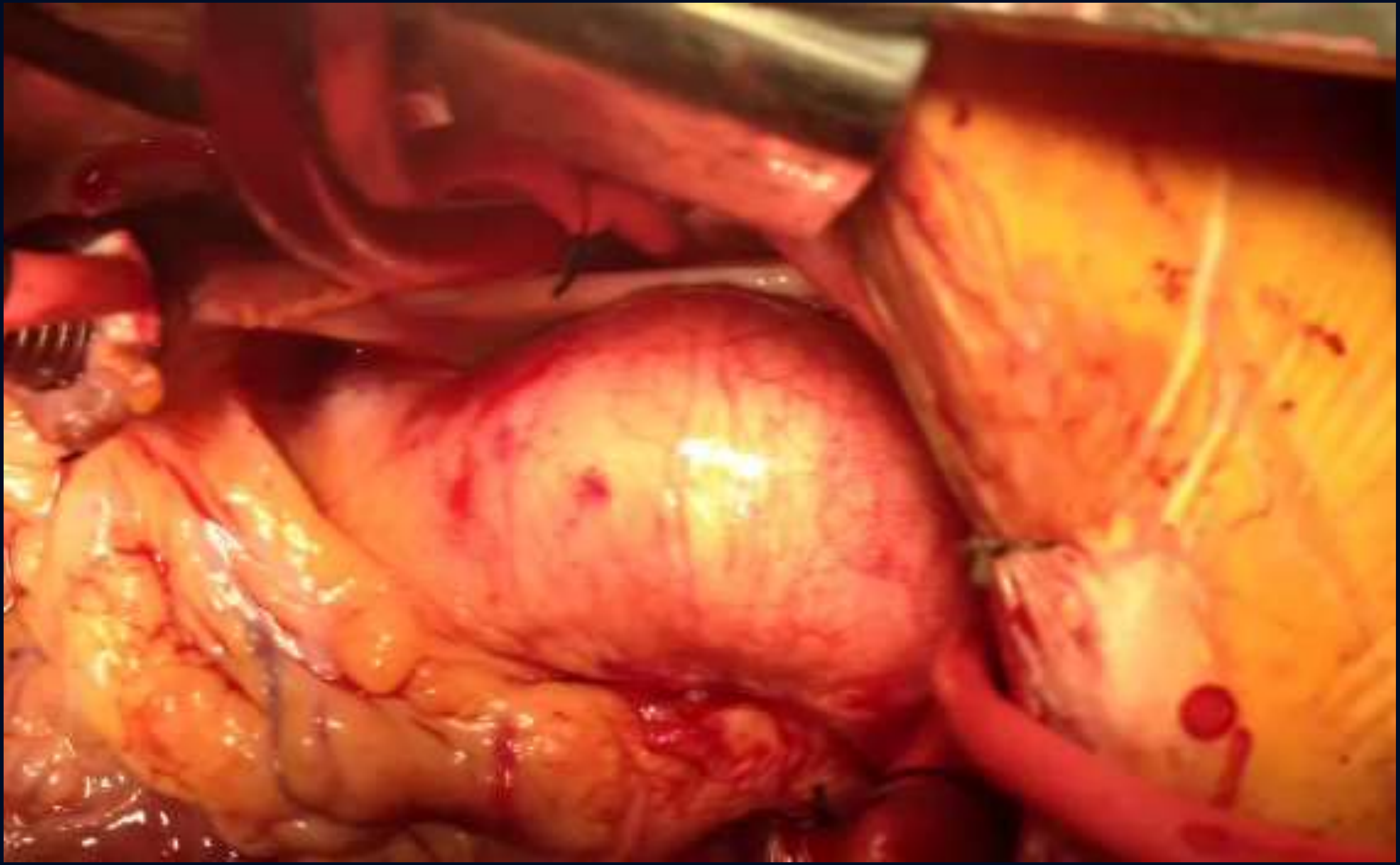


Hybrid Arch (Proximal Aortic) Procedure and Concept



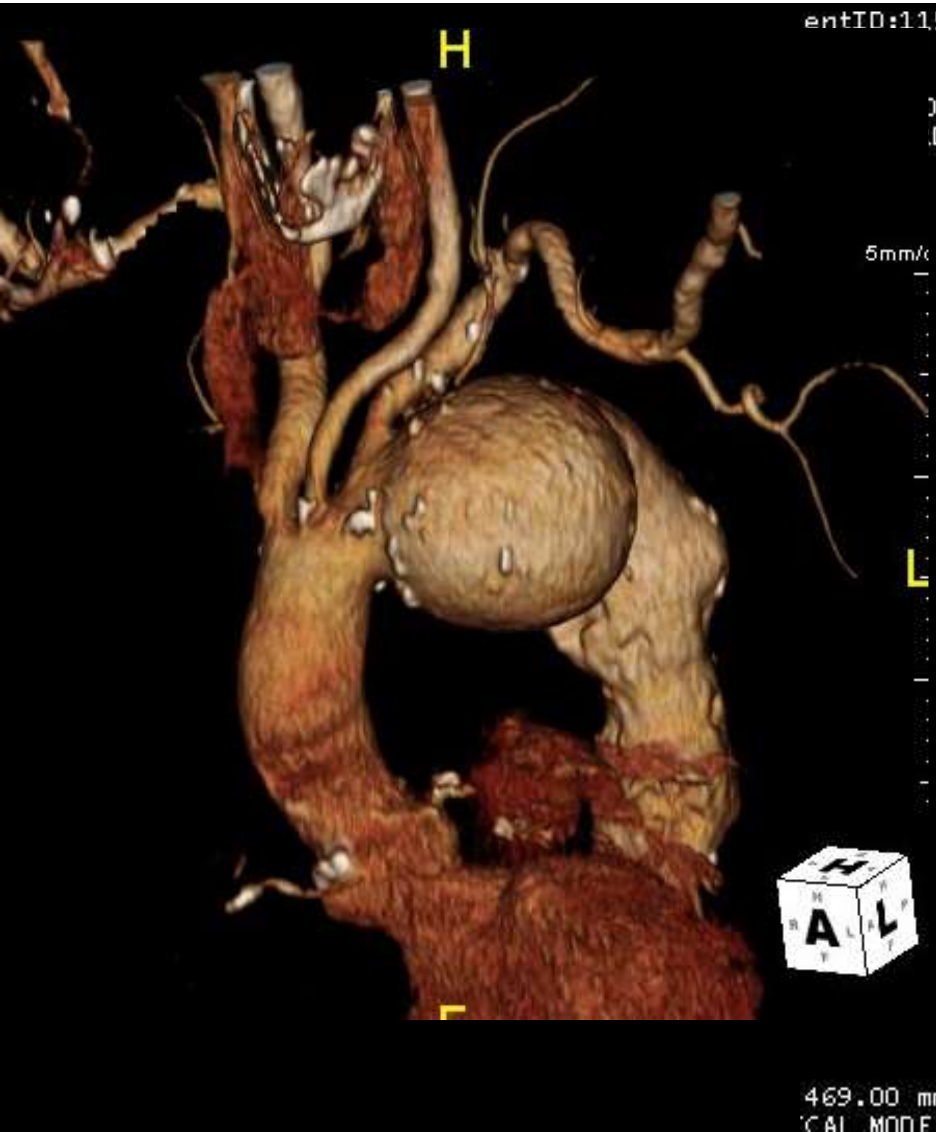
J. Bavaria, et al; JTCVS 2011

Water Hammer Pulse AI Aneurysm: Crazy!!!! Ascending application?



Total EndoVascular Arch Procedure

Courtesy of Cherrie Abraham, MD, Montreal, Canada



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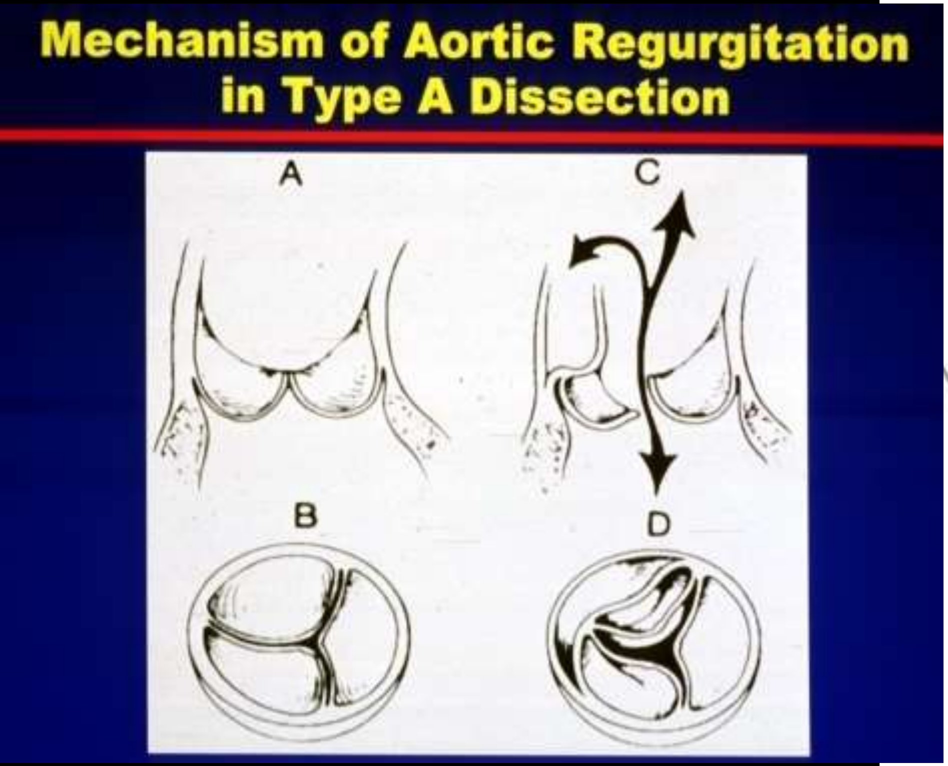
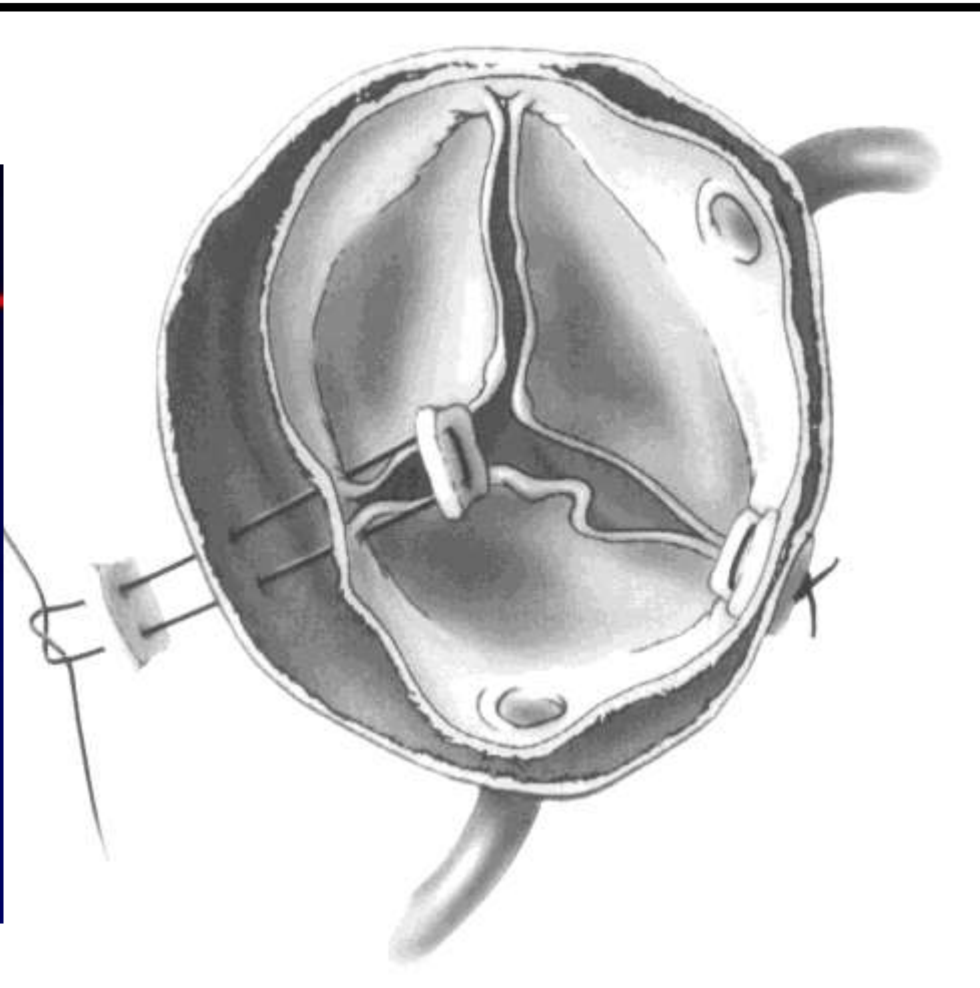
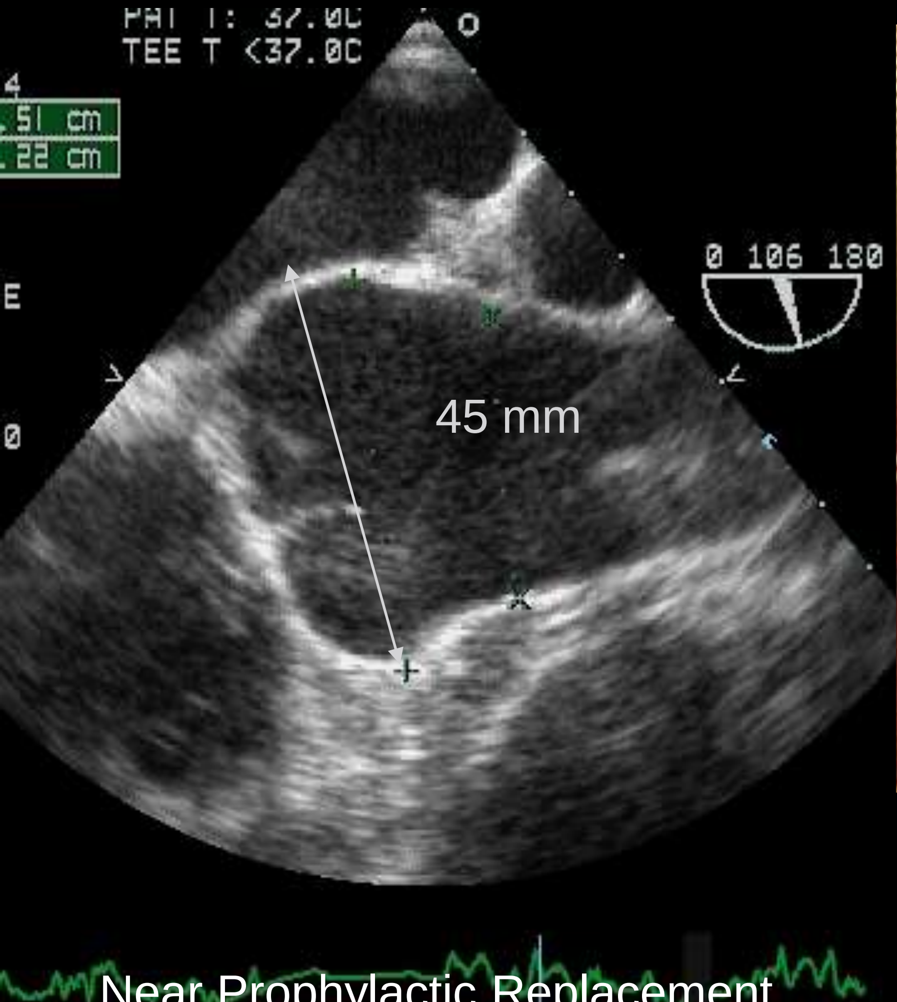
New Innovation: When do/can You Repair the Aortic Valve?

Aortic Valve Resuspension

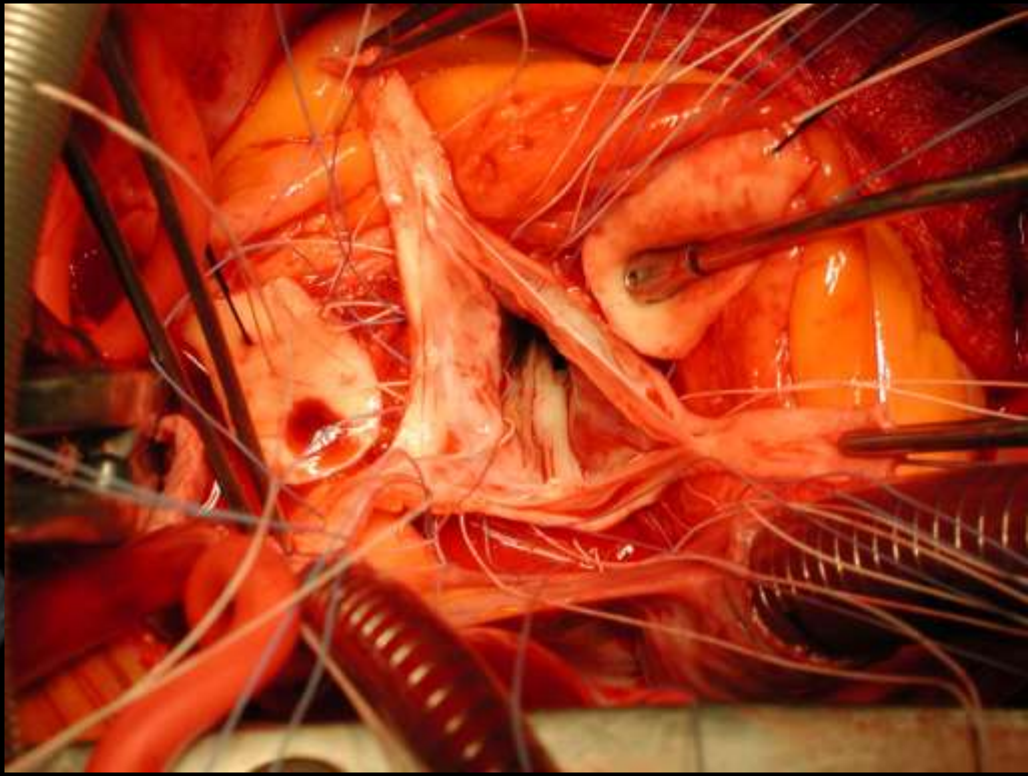




Marfan Root (41 yr. old Man) with 9 1st Order Relatives with either Dissection, Death from Rupture, or Replaced Roots !

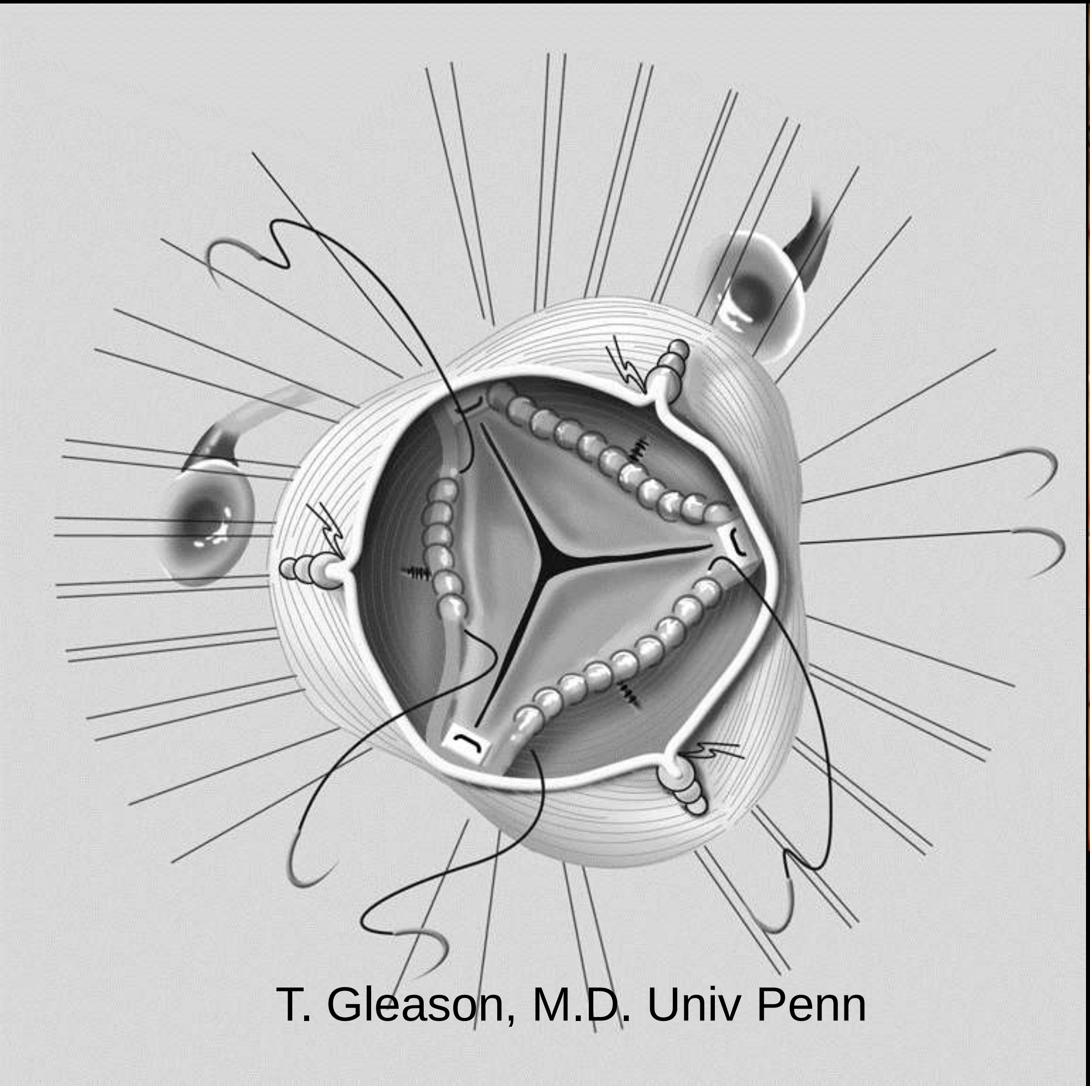


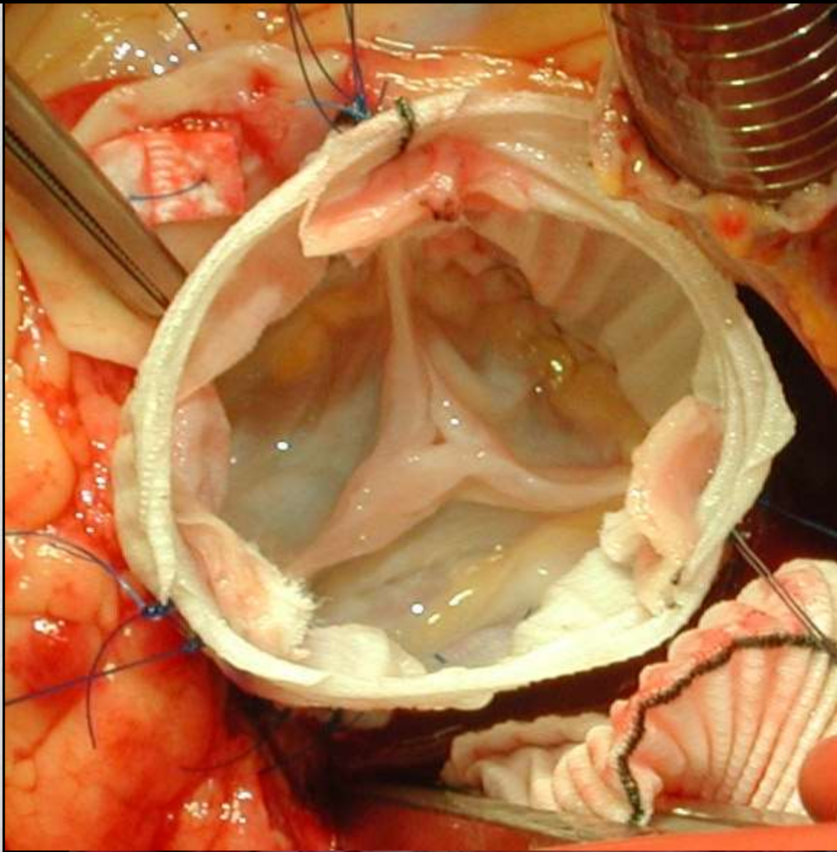
Near Prophylactic Replacement



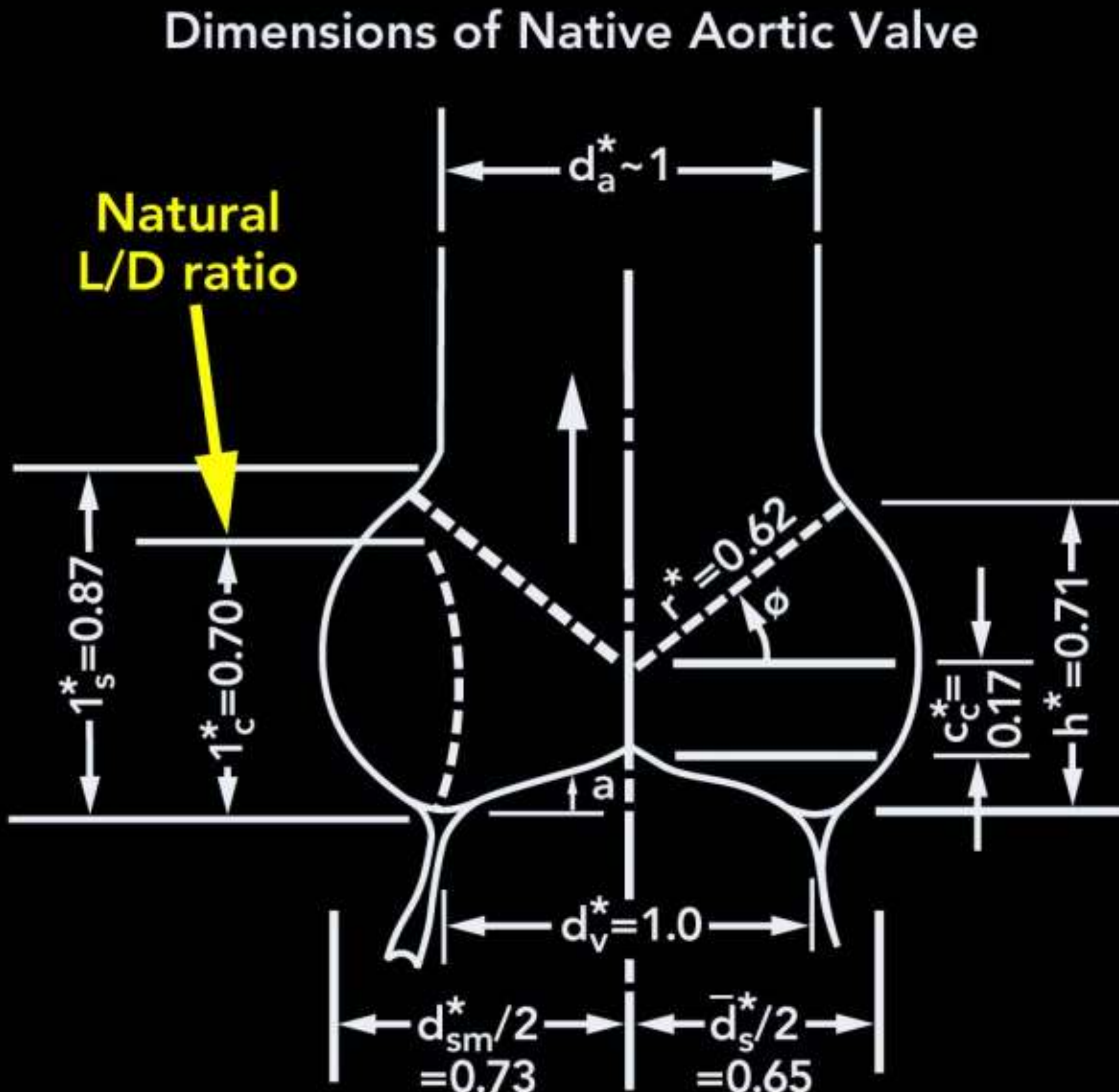
The Challange for Thoracic Aortic Surgeons is to Spare <u>RELATIVELY</u> normal aortic valves, even if they are regurgitant, when the fundamental disease process is primarily an Aortic issue

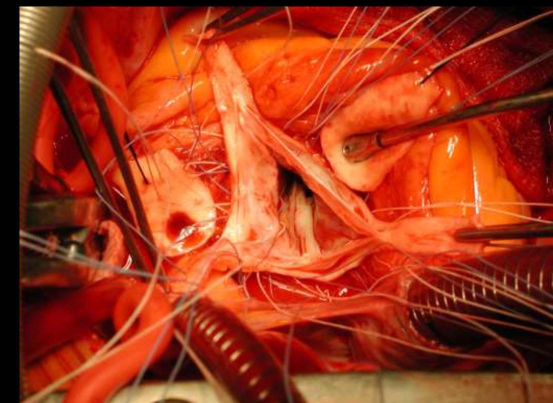
Goal: Restore (even fix) Geometry and Reduce Stress for long lasting repair

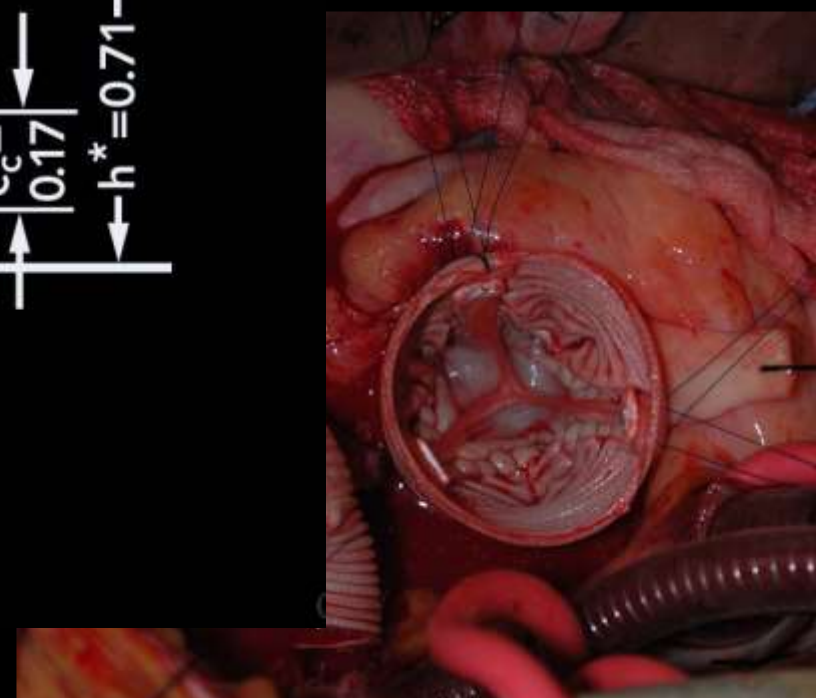




The Innovation is <u>Conceptual</u> and Improved Knowledge base







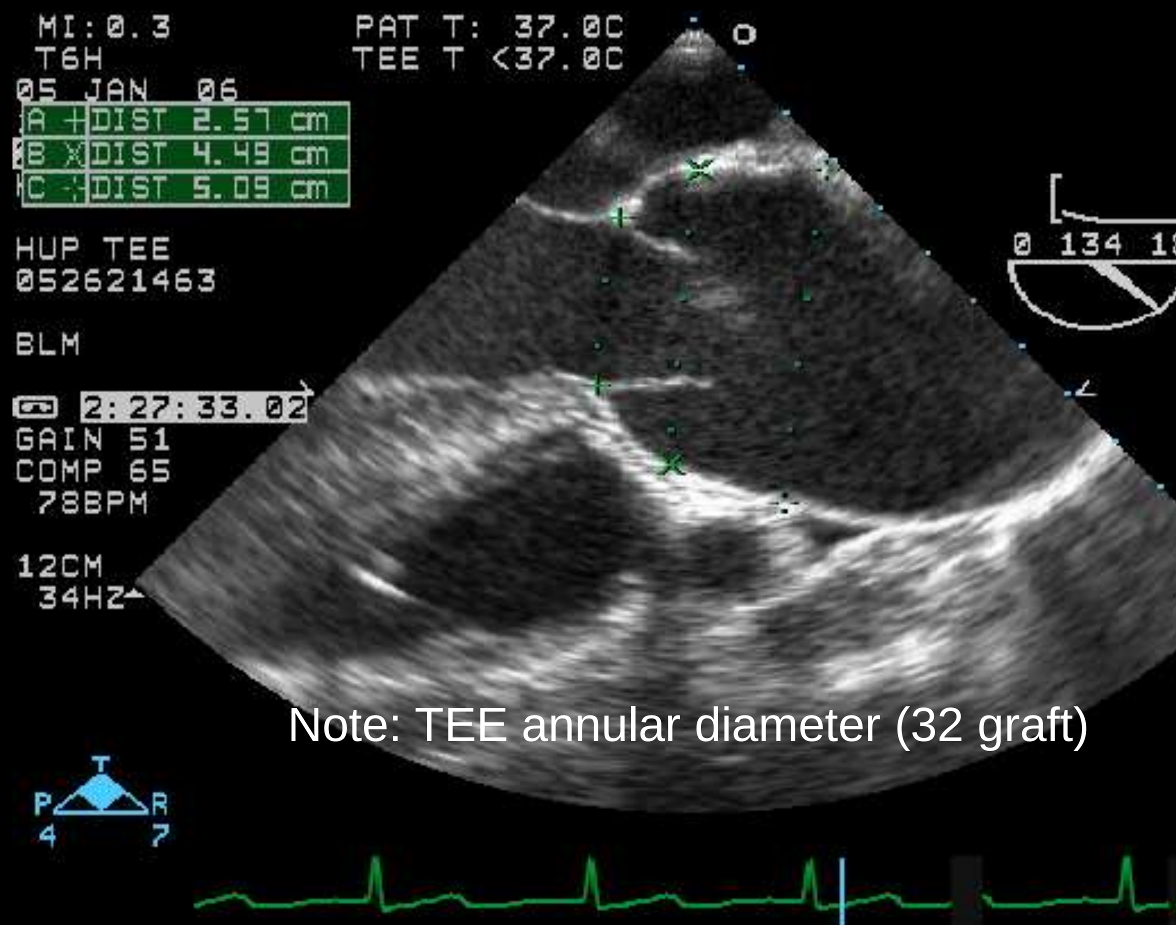
Swanson & Clark. *Circ Res* 1974;35:871-82.

Can We Spare more Complicated Clinical Aortic Valve Presentations?

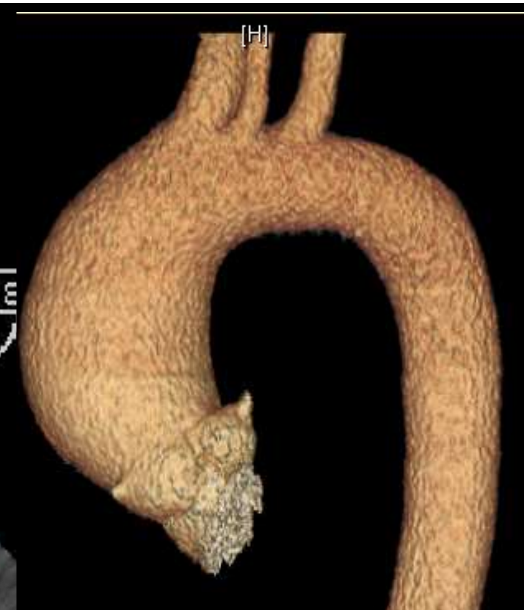
And Why is this so Important!

Bicuspid Valve and the Aorta: Effect of New guidelines?

1-2 Million people in USA !!!

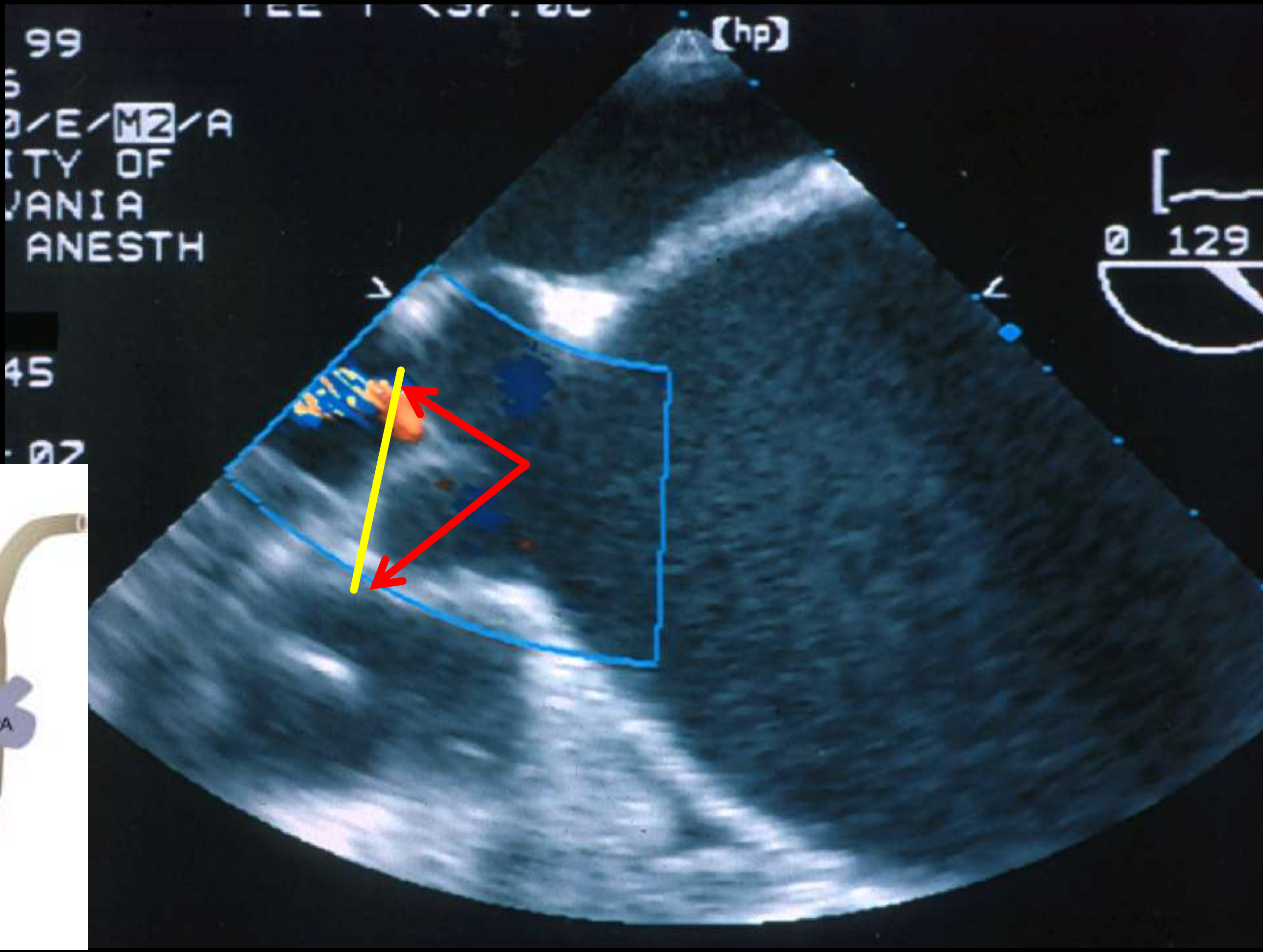


Note: TEE annular diameter (32 graft)

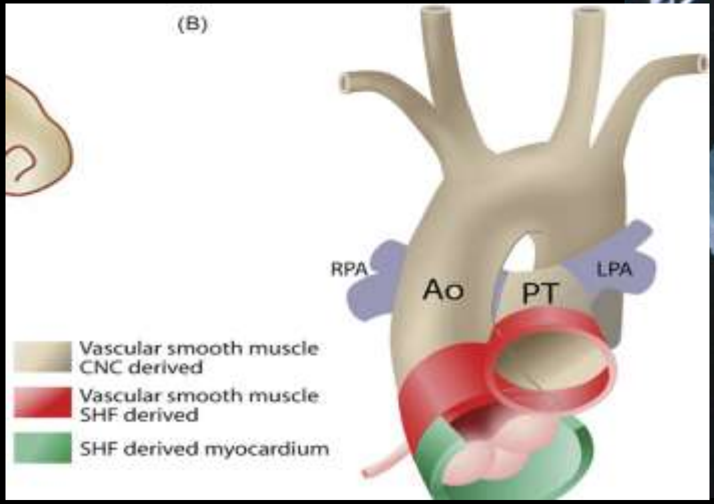


Young 32 yr. Woman with Bicuspid Aortic Valve with Mild-Moderate AI, Mild AS (leaflet restriction) and 8.0 cm Ascending Aneurysm

Concept of "Sino-Tubular Definition"

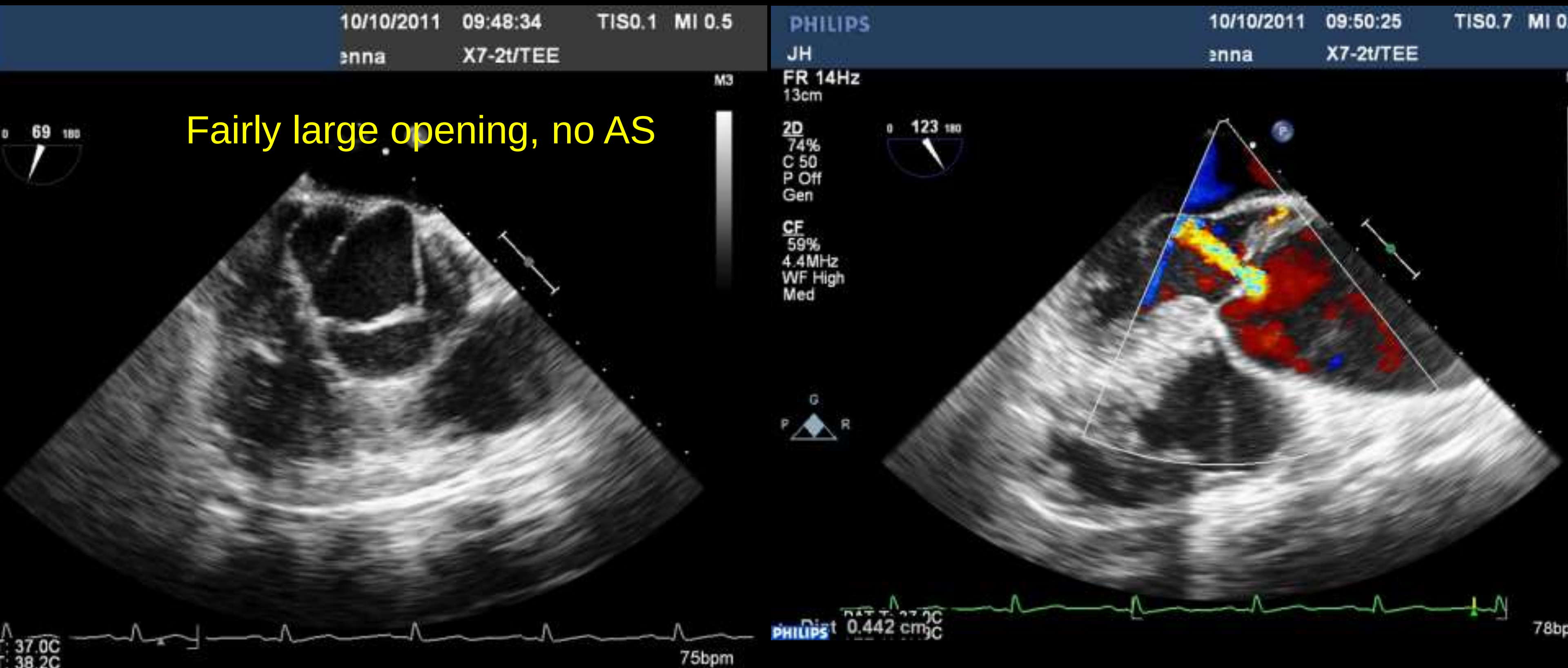


New Knowledge



The Pure AI BAV Patient with Dilated/Aneurysmal Proximal aorta

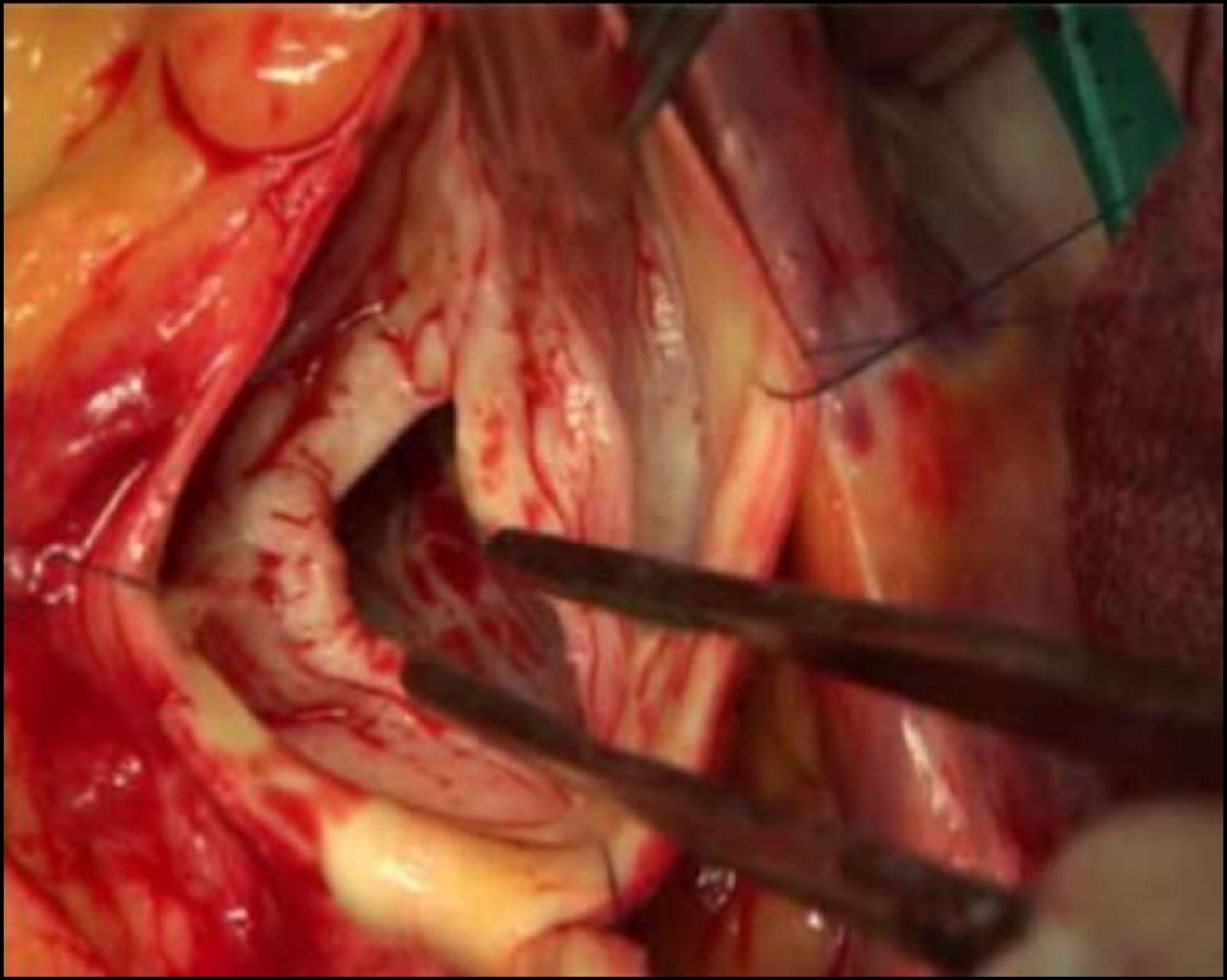
NOTE; Pure AI, No Calcified Leaflets



Still frames to depict anatomy

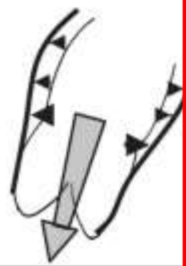
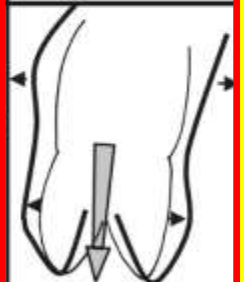
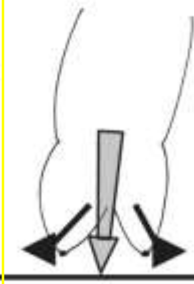
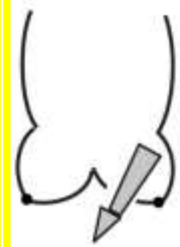
Can we really Repair something like this??

Bicuspid Valve Type 1? or 2?



Surgical Repair BAV AI Classification:
Fundamentally we are discussing Ib and c with II

Most Common combination

AI Class	Type I Normal cusp motion with FAA dilatation or cusp perforation				Type II Cusp Prolapse	Type III Cusp Restriction
	Ia	Ib	Ic	Id		
Mechanism						
Repair Techniques (Primary)	STJ remodeling *Ascending aortic graft*	Aortic Valve sparing: *Reimplantation or Remodeling with SCA*	SCA	Patch Repair *Autologous or bovine pericardium*	Prolapse Repair *Plication* *Triangular resection* *Free margin Resuspension* *Patch*	Leaflet Repair *Shaving* *Decalcificatio* *Patch*
(Secondary)	SCA		STJ Annuloplasty	SCA	SCA	SCA

BAV Ib + II usually associated with 15-25% larger annulus than standard for BSA

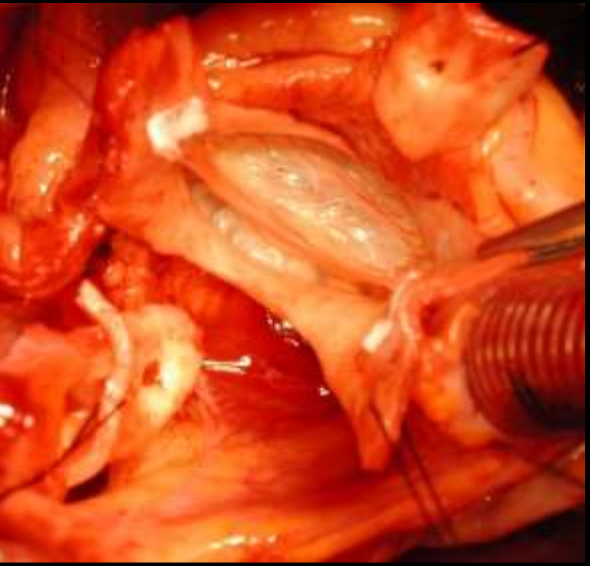
[1]Boodhwani et al. J Thorac Cardiovasc Surg. 2009;137:286-294

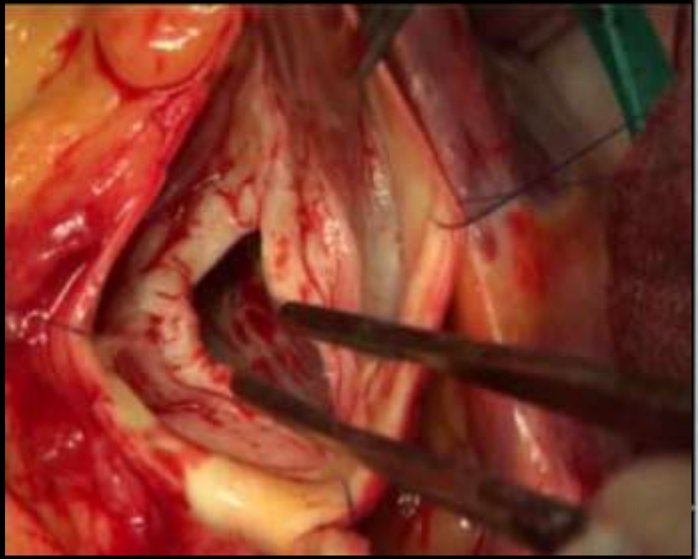
Problem in the World Wide Cardiac Surgery Community …… Are we Ready for "Prime Time" ……. No!

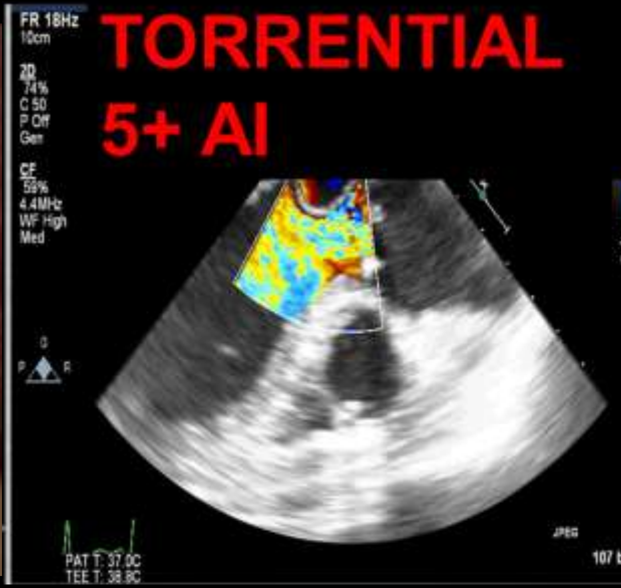
Einstein: Make everything as simple as possible …… But No Simpler!!

So ………….

What kind of Operation are we Talking about?





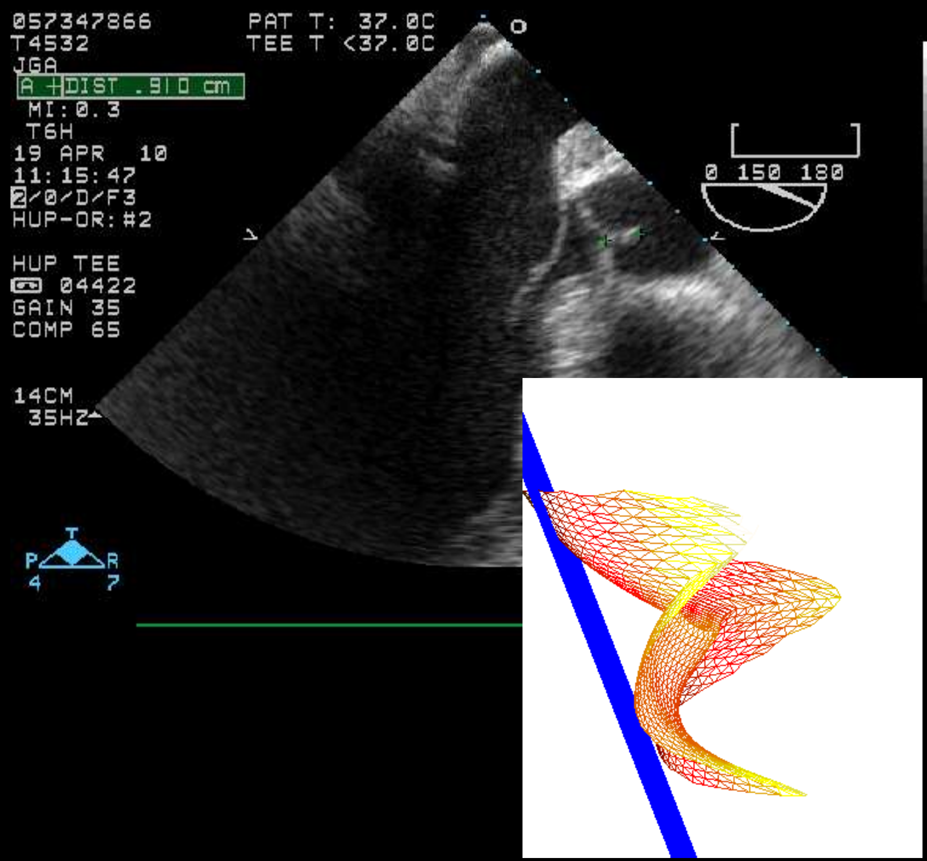


Bicuspid Aortic valve Reair Concepts (Direct Cusp or Leaflet)

- Even the free margin lengths: Plicate (or cut) the prolapsed cusp
- Annular Reduction (10-15%) and Stabilization with either Re-implantation (or Sub-Annular technique)
- Increase height (decrease length) of Free margin (gore-tex) ….if leaflet belly below annular plane.

- Bottom line: "Any purely insufficient valve with enough leaflet surface area can be repaired"

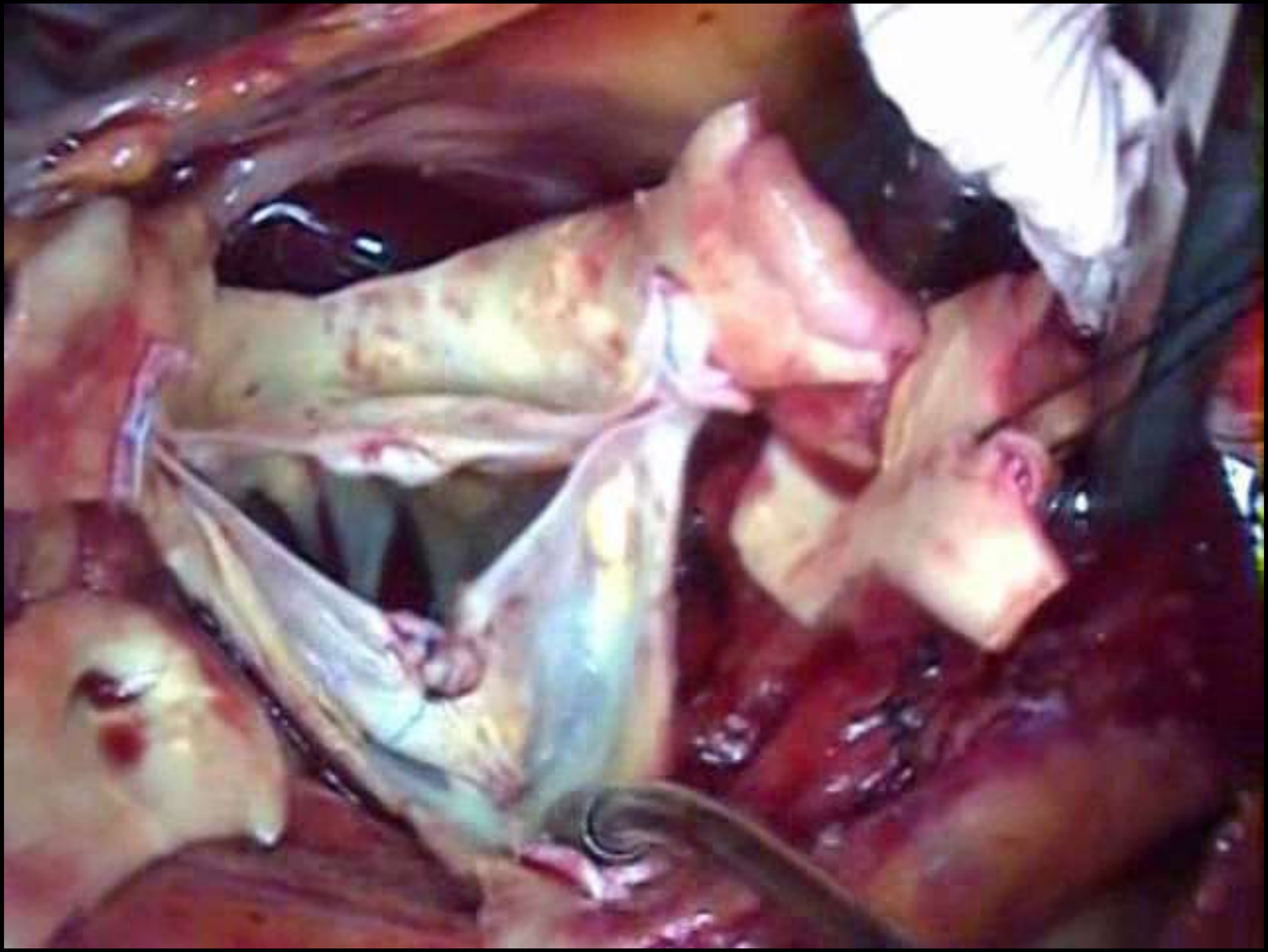
Goal: Great Coaptation Zone



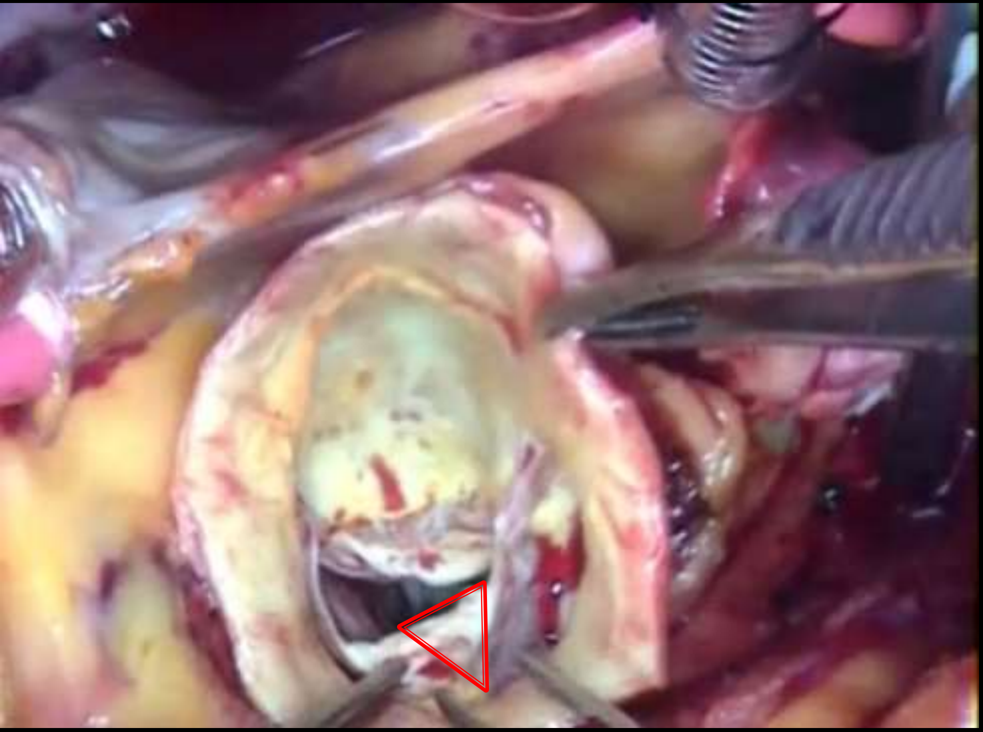
Measuring the Amount of excess leaflet to resect for Leaflet Free Margin Equality

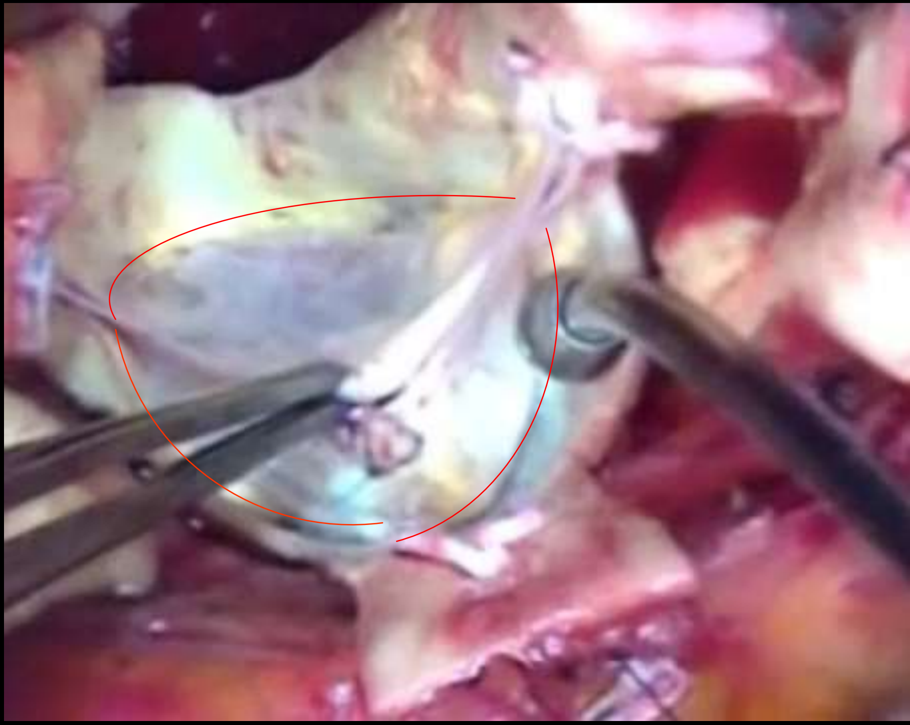
Treating the Prolapse

Post-Repair Evaluation: For Margin Equality, Perimeter assessment



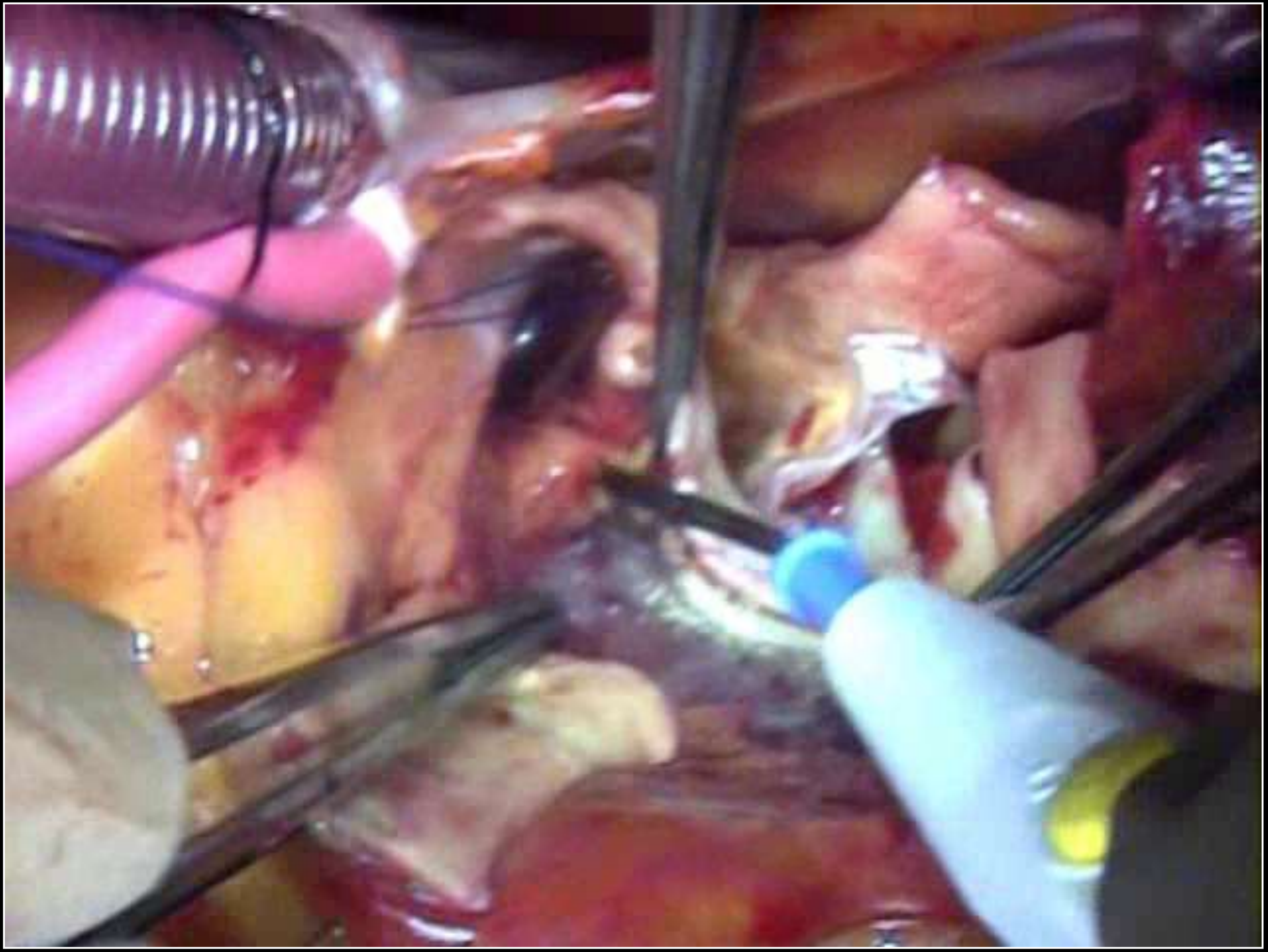
Raphe Release, Equalization of Free Margin, and Plication/Resection of Redundant leaflet



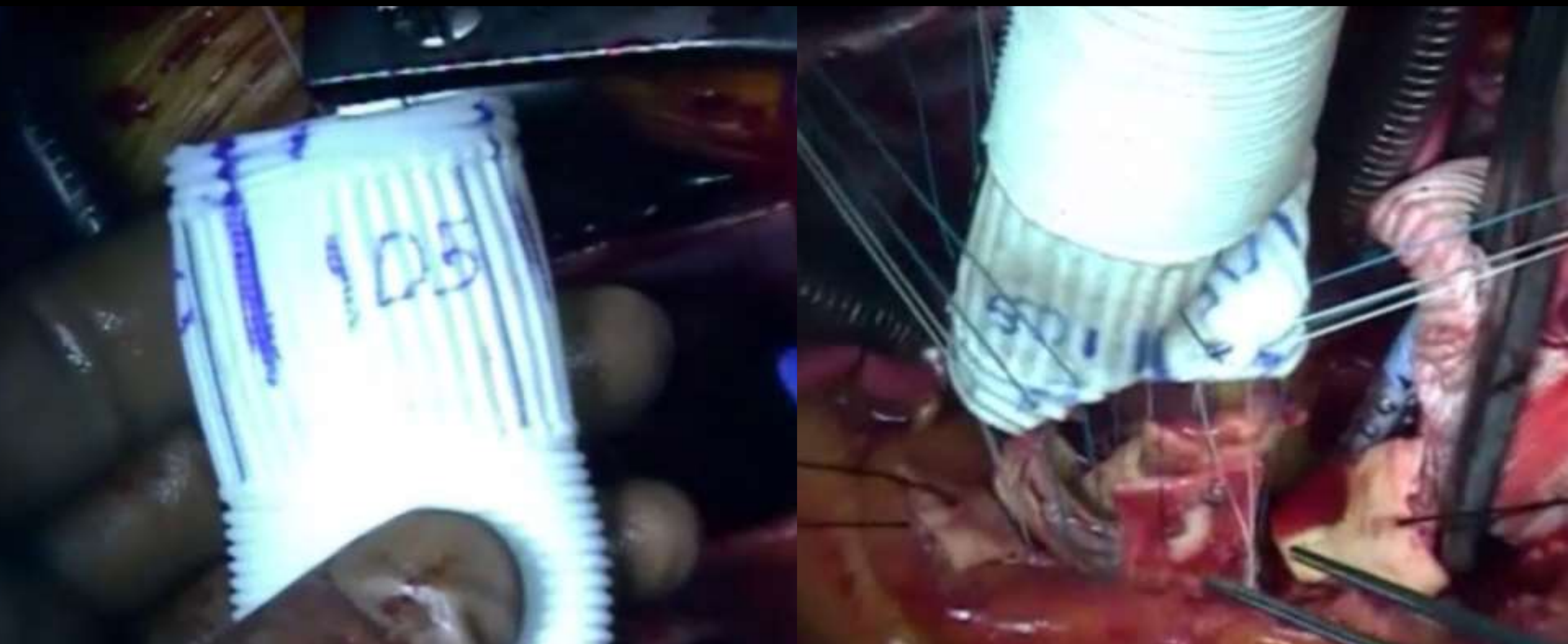


Coronary Buttons are cut.
210/150 peerimeter and Leaflet surface area ratios.

Preparation of the Root for Subannular Suture Placement and Re-Implanation Procedure



Construction of Stable (smaller) Annulus and Reimplantation of the “New Root” in 3 dimensions



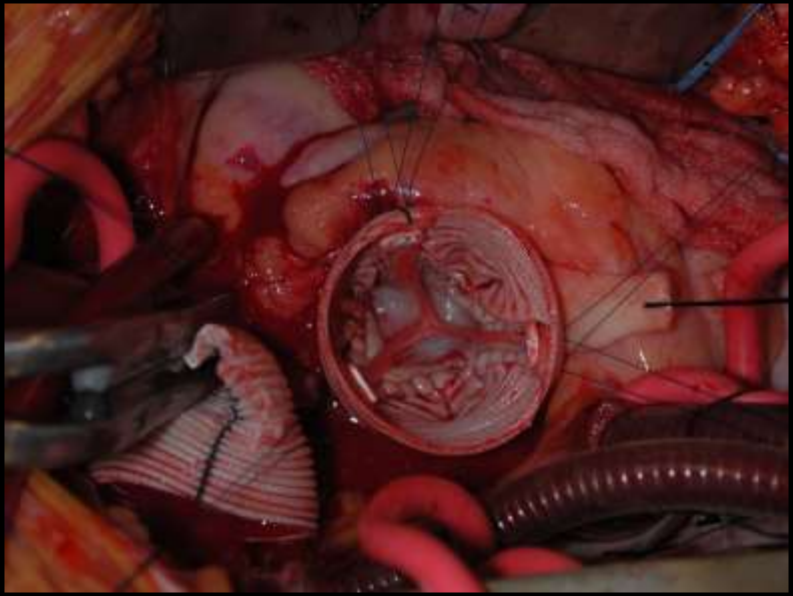
210/150 Neo ValSalva Root
(Raphed BAV)

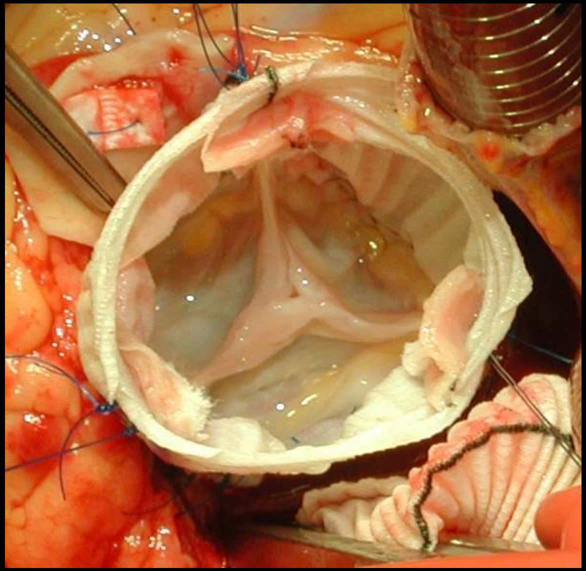
Bavaria, J; et al: EJCTS 2013 (presented at EACTS, Barcelona 2012)

So What's the data on Bicuspid Reimplantation Valve Sparing with Aneurysm and repaired AI?

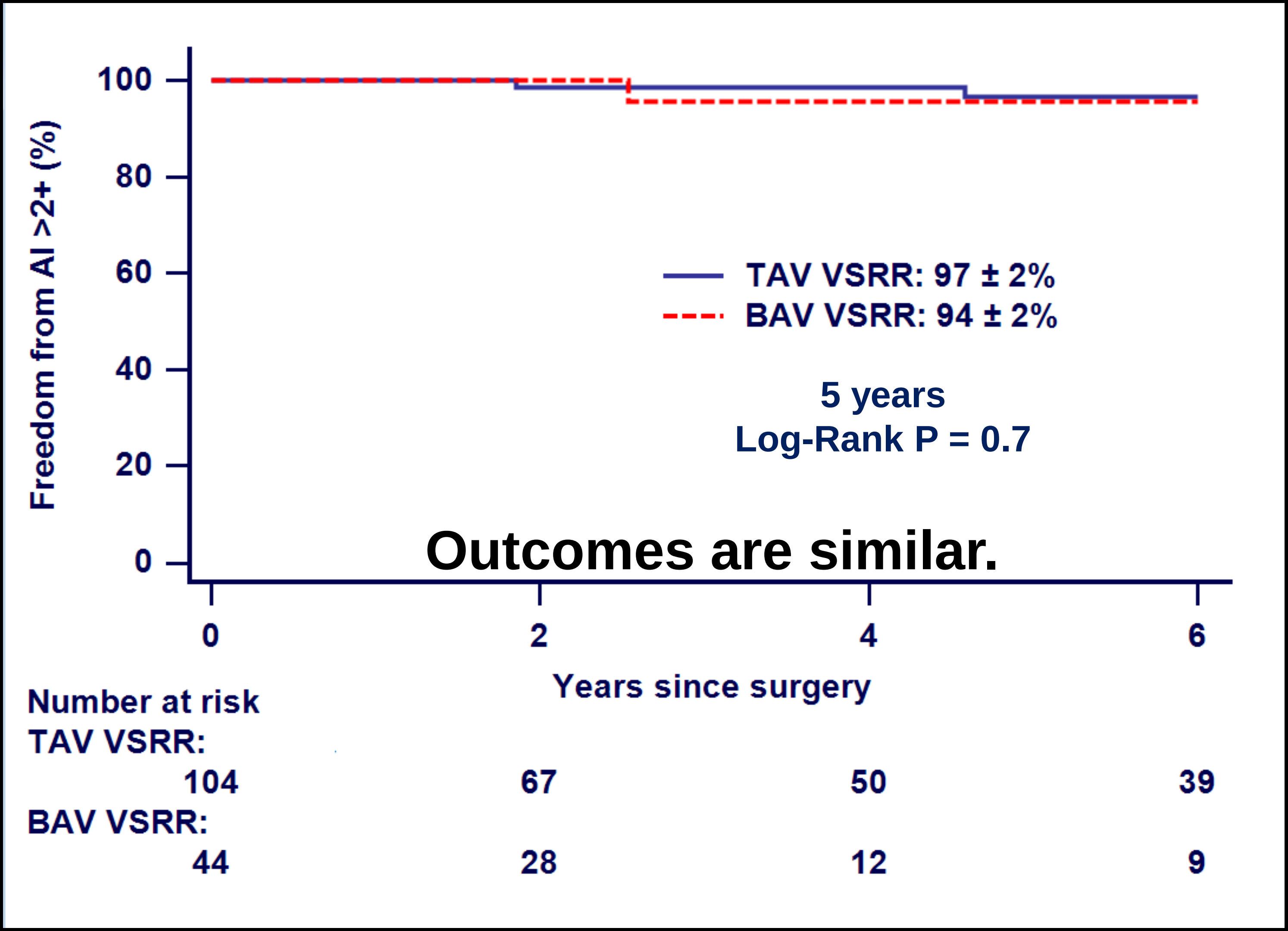
Outcomes with BAV Repair + Root Reimplantation:

How do they compare to our institutional tricuspid aortic valve root reimplantation?



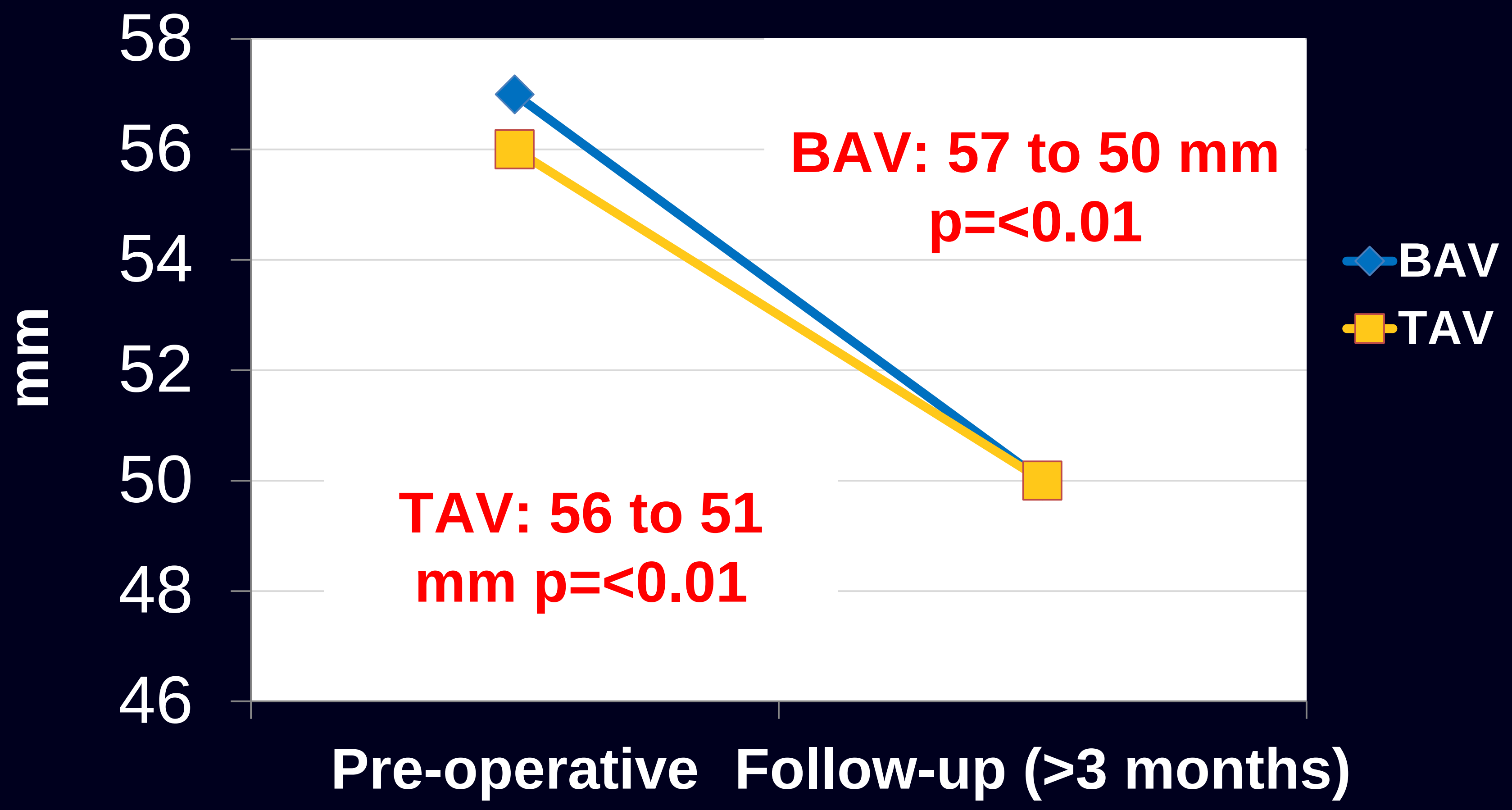


Freedom from AI >2+ (%)
100% of BAV VSRR had Leaflet Repair



Data thru 4/2014 Bavaria et al JTCVS 2015

LV Diastolic dimension change



VSRR achieved excellent left ventricular remodeling in both BAV and TAV patients over follow-up. (STS 2014)

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        1. New operations based on availability of New Theraputic Devices
    3. Conceptual and Device Related

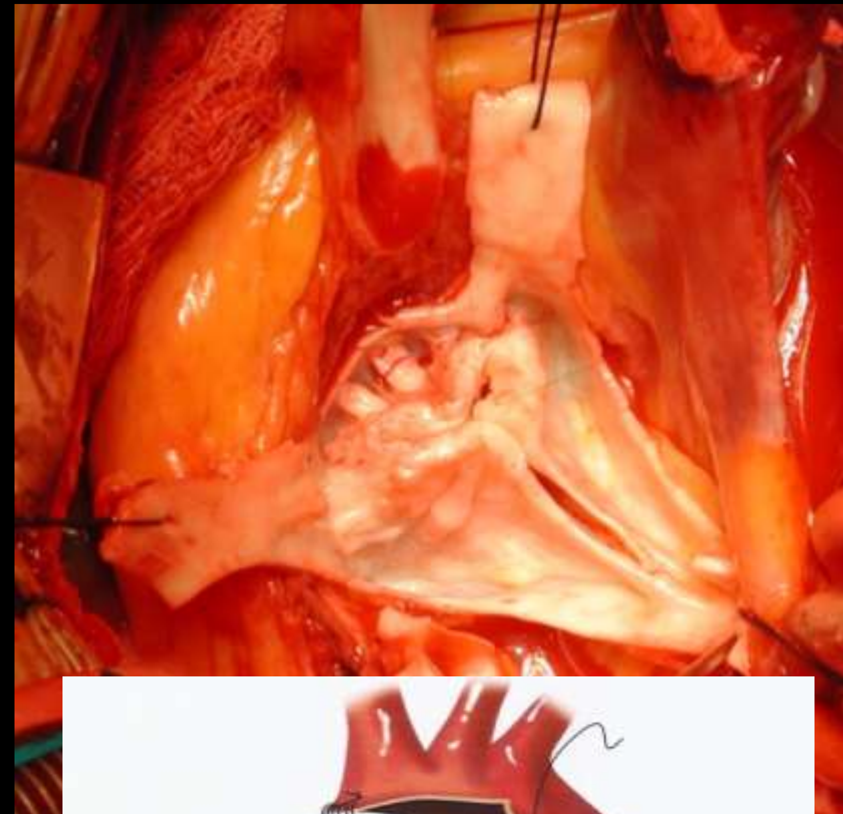
2. All need a CULTURE of Innovation and Early Adoption **(with Audit)**

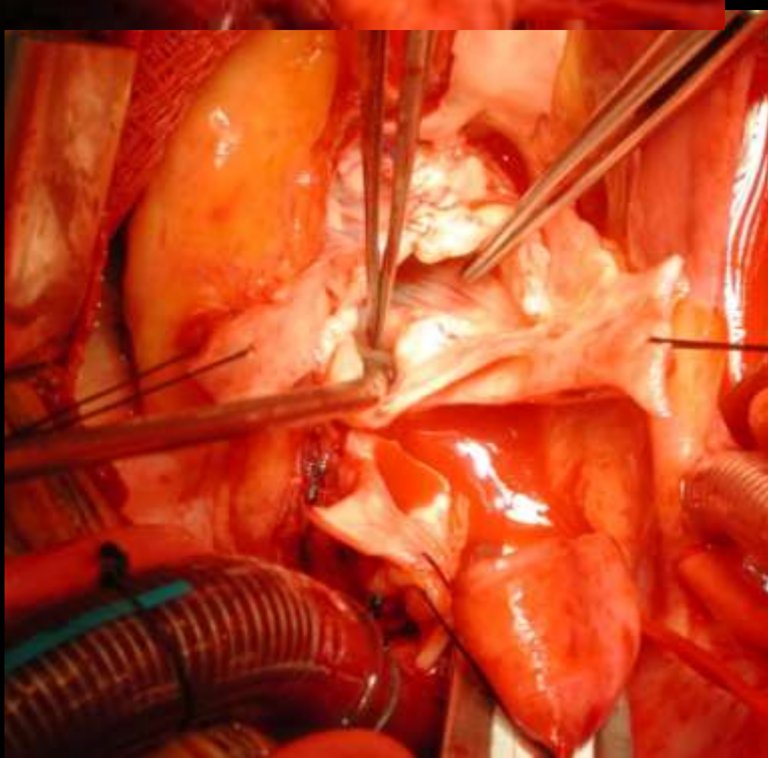
Why Audit?

Why Audit?

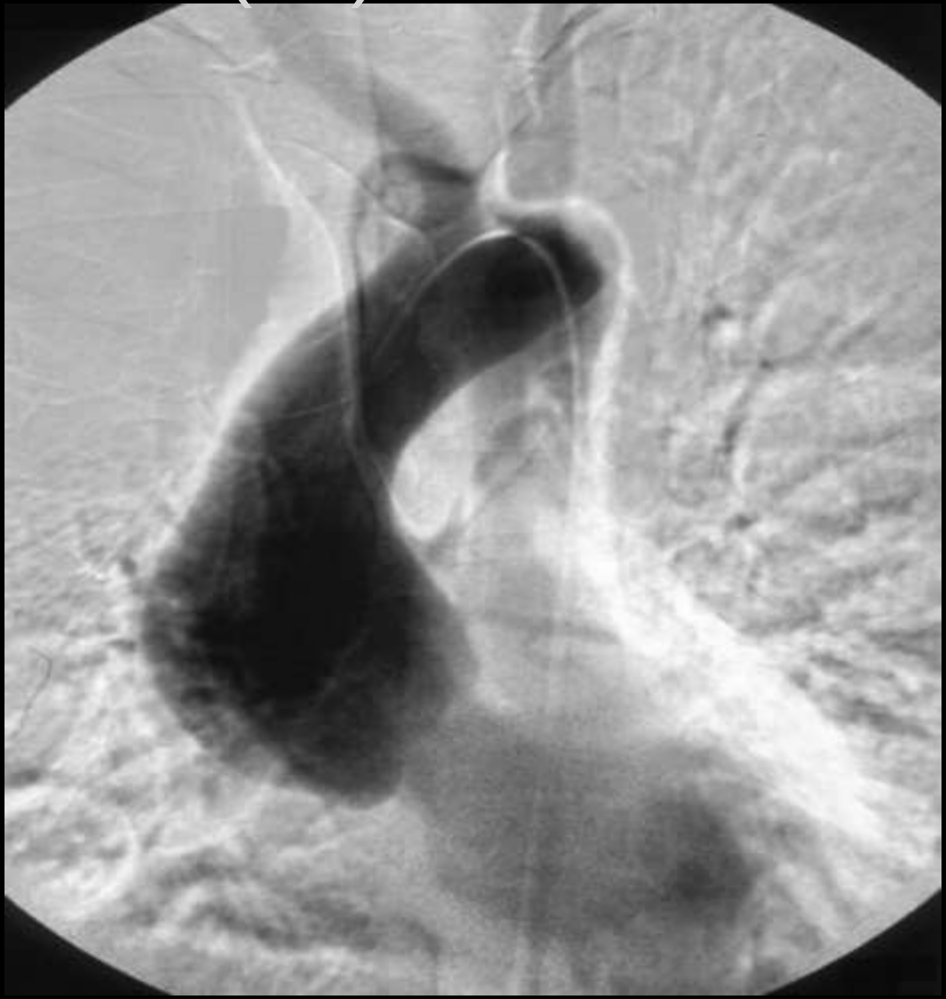
Because we’re human and can make mistakes

Mike „Choogs“ Machuga
Professional bowler
10 years on tour
4 PBA titles



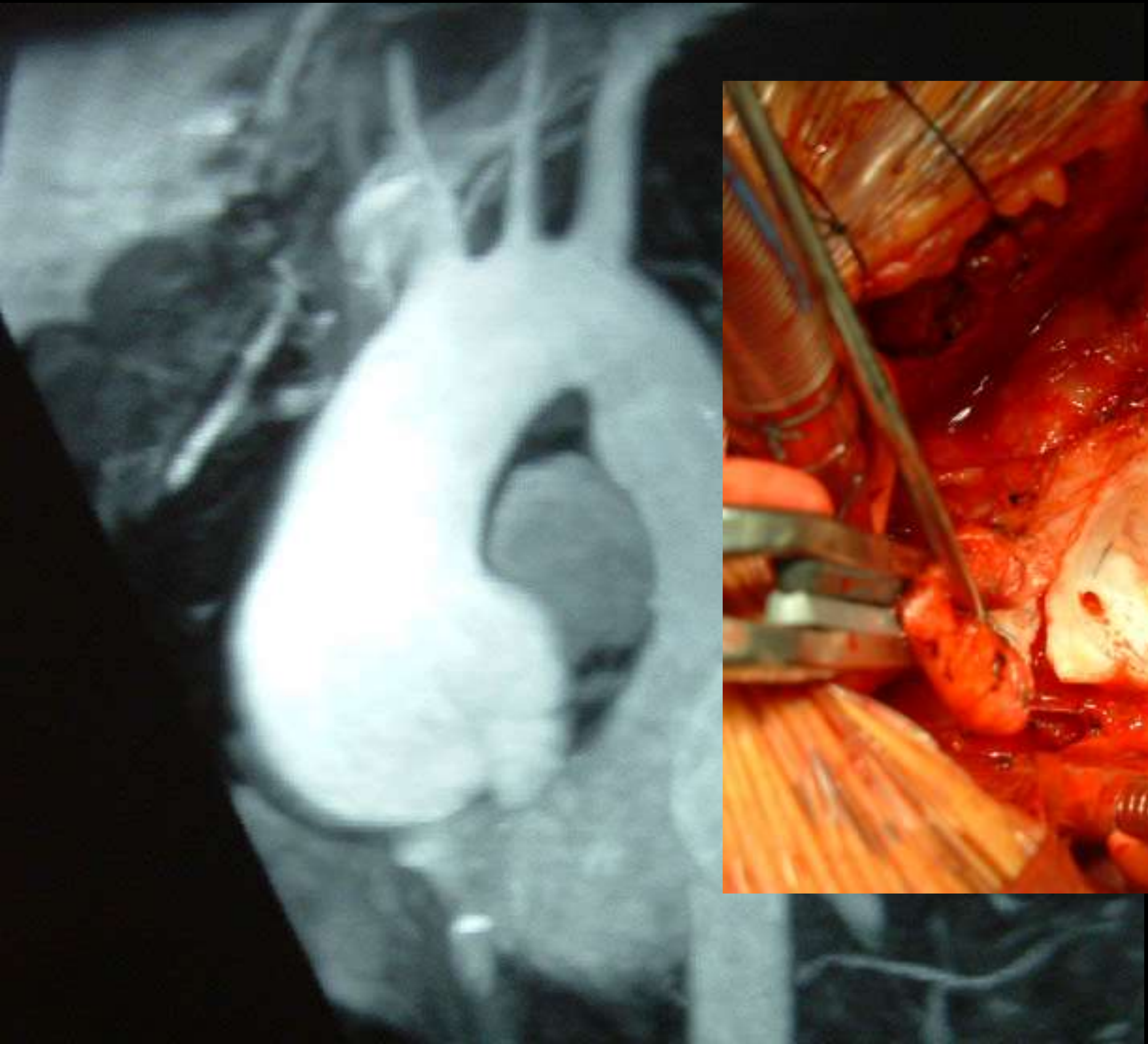


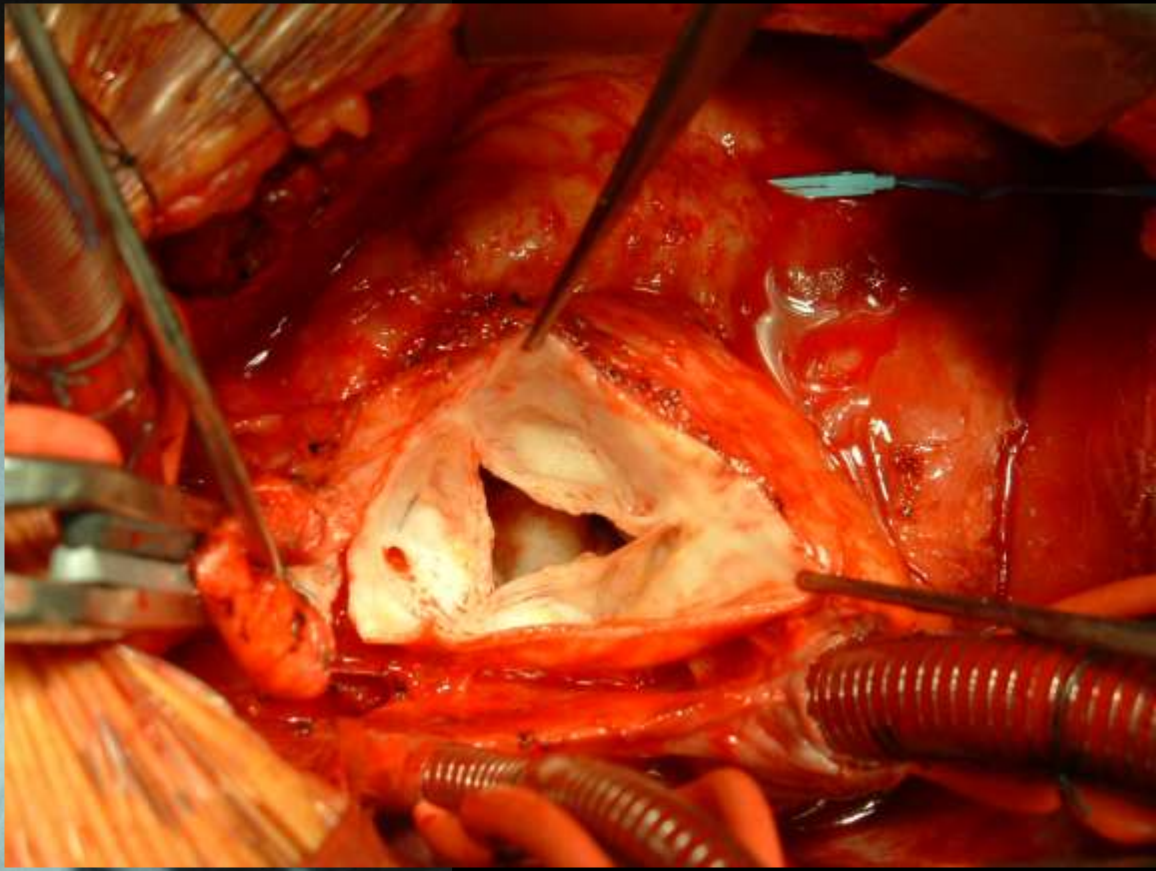
Marfan’s Sinus of ValSalva Aneurysm (7.0 cm.) with Severe (+4) AI



Valve Sparing ?? Too much AI, too much aneurysmal dilation, too much leaflet surface area,

Failed Ross in 30 Year Old Male (Redo Buttons): Concept of COMBINATION Root aneurysm and DECREASED Leaflet (Cusp) Surface Area





Thoracic Aortic Surgery: Emerging and Innovative Therapy and Future Landscape

1. Increased Valve Sparing Root Surgery (ALWAYS for AI) David V (and BAV repair techniques) .. **(Conceptual)**
2. Ascending Aortic TEVAR for High Risk Type A Dissection +/- Endo-Bentall **(Device)**
    1. Distal Aortic TEVAR Adjunct in Type A Dissection **(Conceptual and Device)**
3. Hybrid Arch +/- Endo-Arch (Mixture) …… The march towards "More Proximal" Reconstruction **(Conceptual and Device)**
4. Chronic Type B Dissecting Aneurysms **(Mostly Conceptual also Device)**

Chronic Dissection: Either Residual Type B after Type A Repair or simple Chronic Type B

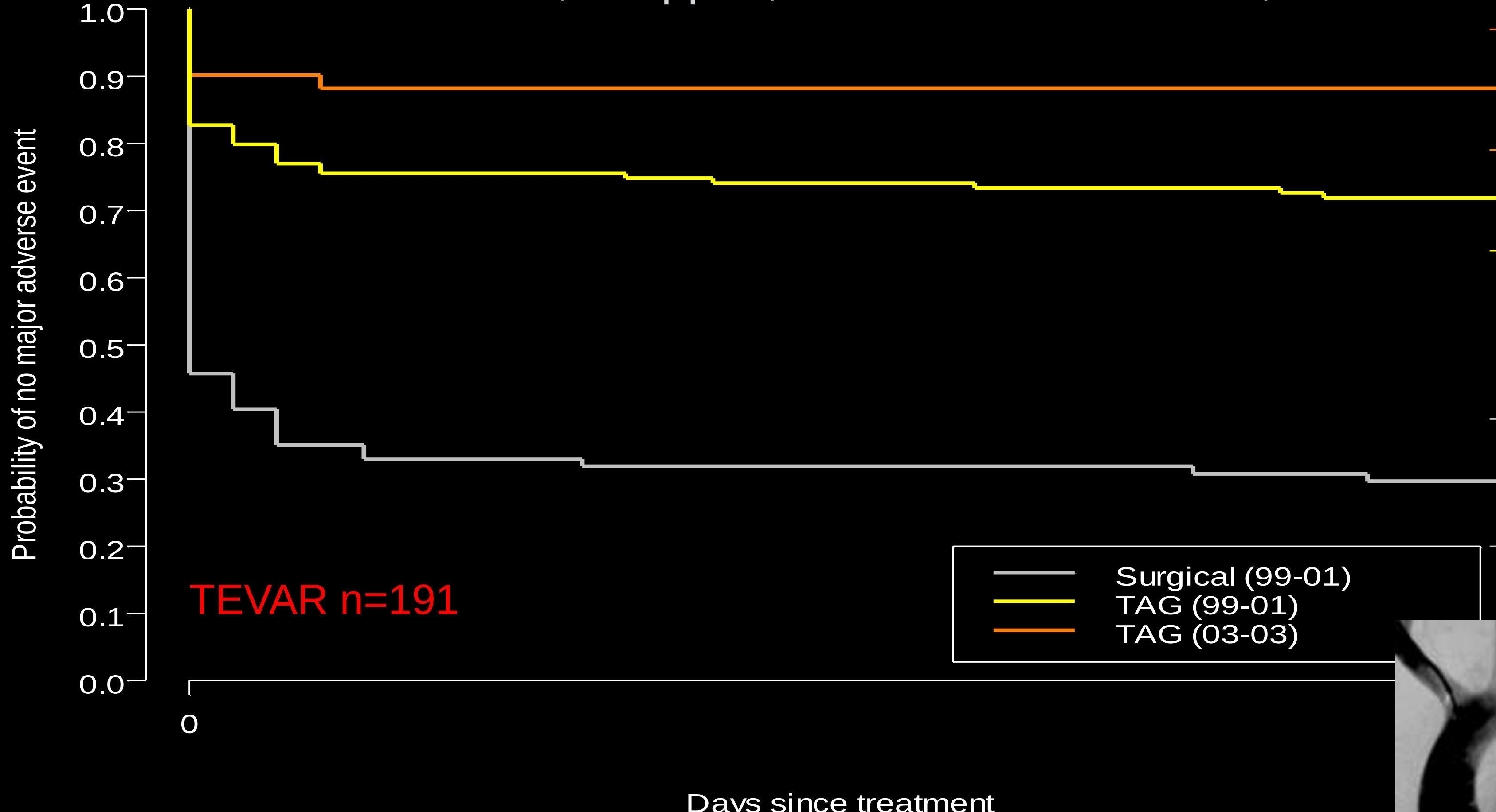
10 yrs out

Thick chronic Membrane/Flap

Pivotal Study (TAG 99-01) **Confirmatory Study (TAG 03-03)**

Freedom from a Major Adverse Event Through 30 Days

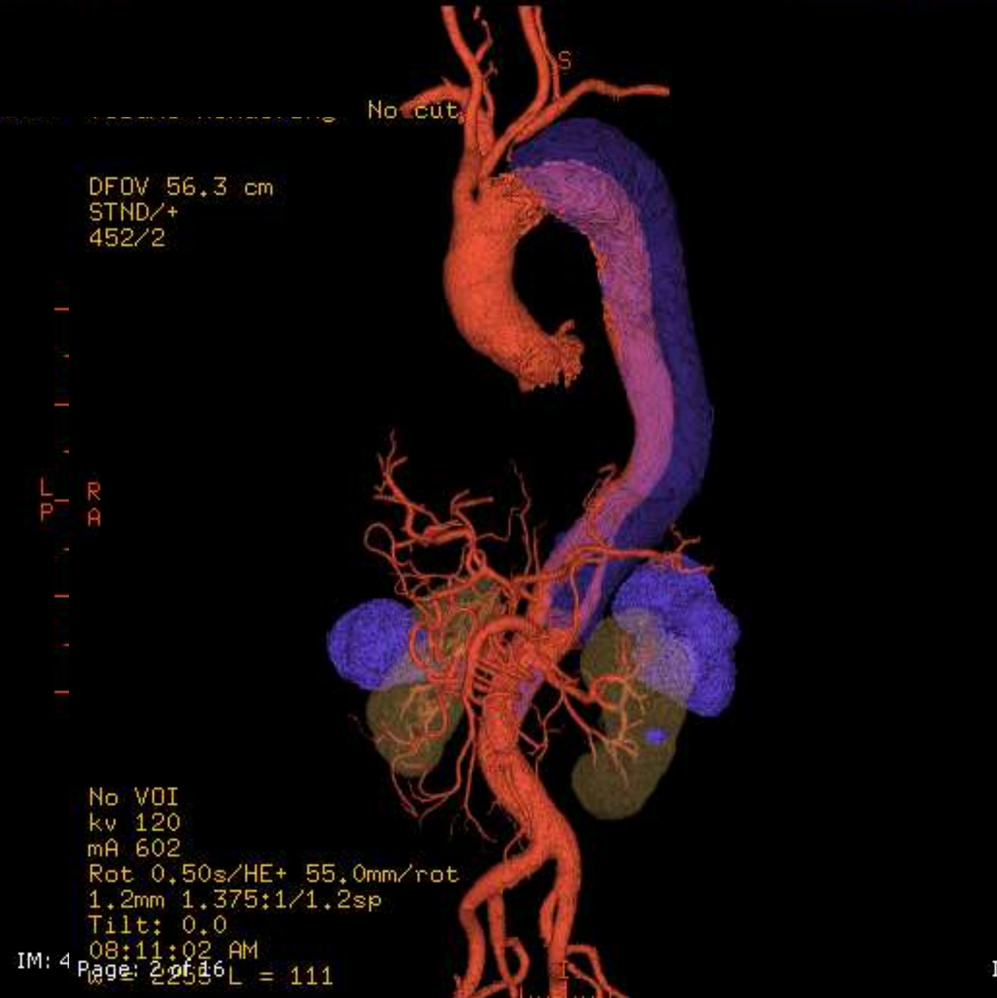
J.Bavaria, J. Appoo, S.Mitchell: AATS 2005, JTCVS 2007



Chronic Distal Aortic Dissection after previous Type A: TEVAR

Chronic Type B aortic dissection: Again all 4 vessels off true lumen

Pre-stenting



Post-stenting

Operative Candidate?
Must Be a Better Option!!!

Patient / Anatomy Selection

TEVAR

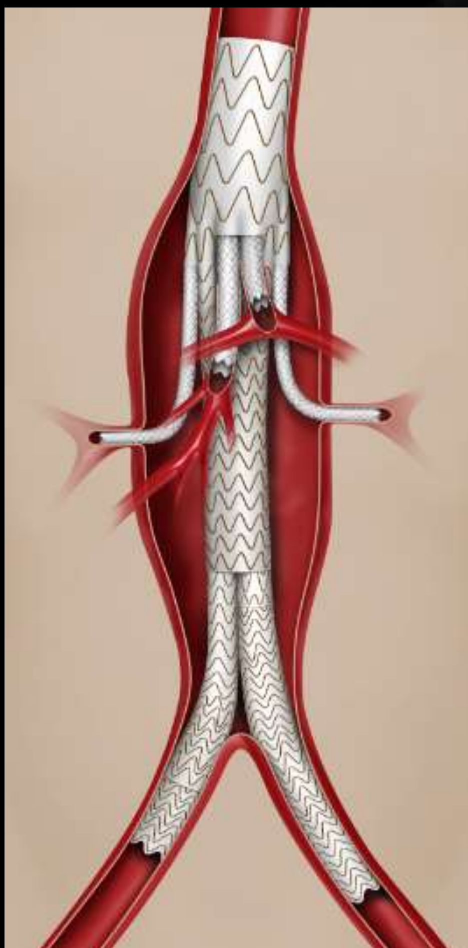
TEVAR

Most cases

Open

TEVAR vs Medical??

EndoVascular TAAA: Especially for Atherosclerotic Aneurysm



Courtesy of T. Mastrucci, CCF

Chronic Dissecting TAAA further in the future

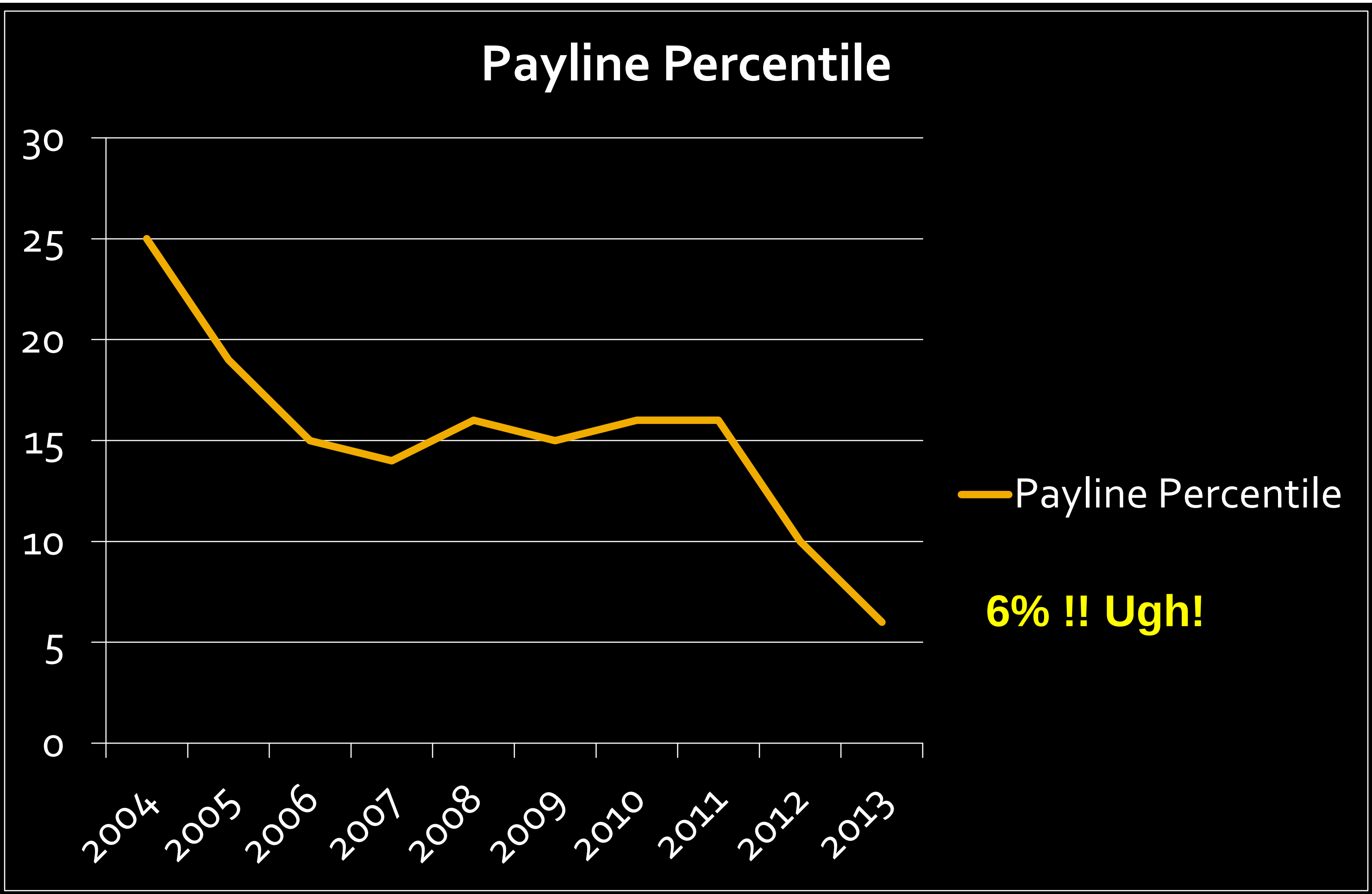
How does a Division of Cardiovascular Surgery (or a Department of Surgery) CREATE an environment of Innovation and Early Adoption?

None of the stuff we just talked about can happen in a sclerotic surgical environment!

Benefits of a Robust Clinical Research Program

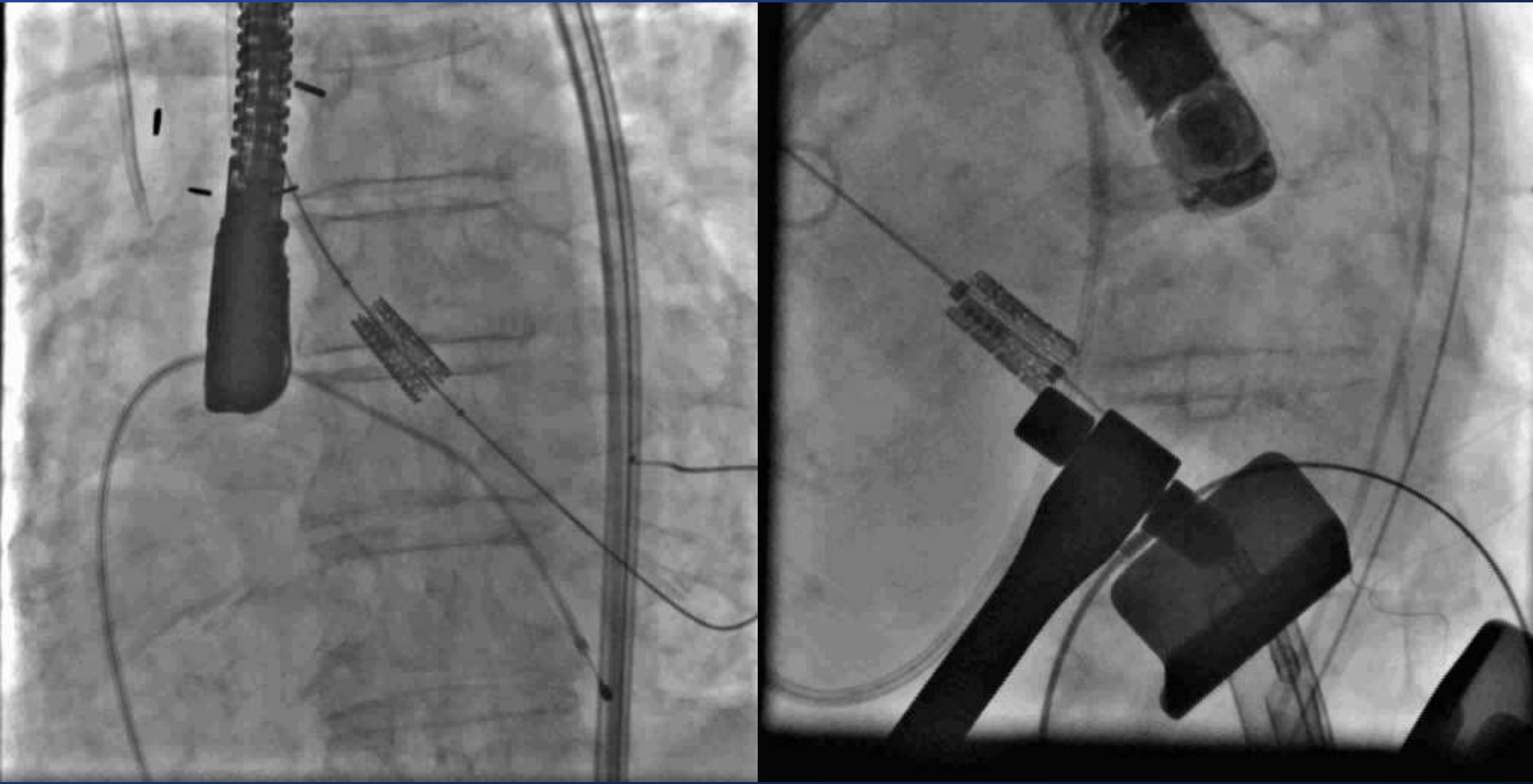
- Trials:
  - New Technology early
  - Attracts the best residents to your program
  - Marketing Budget (New Stuff!)
  - Academic Papers, publications
- Outcomes:
  - Academic Papers, publications, presentations
  - Quality improvement
  - Tie in with marketing (own the data ….. Superiority of clinical databases over administrative/billing databases.

NIH Year Payline Percentile



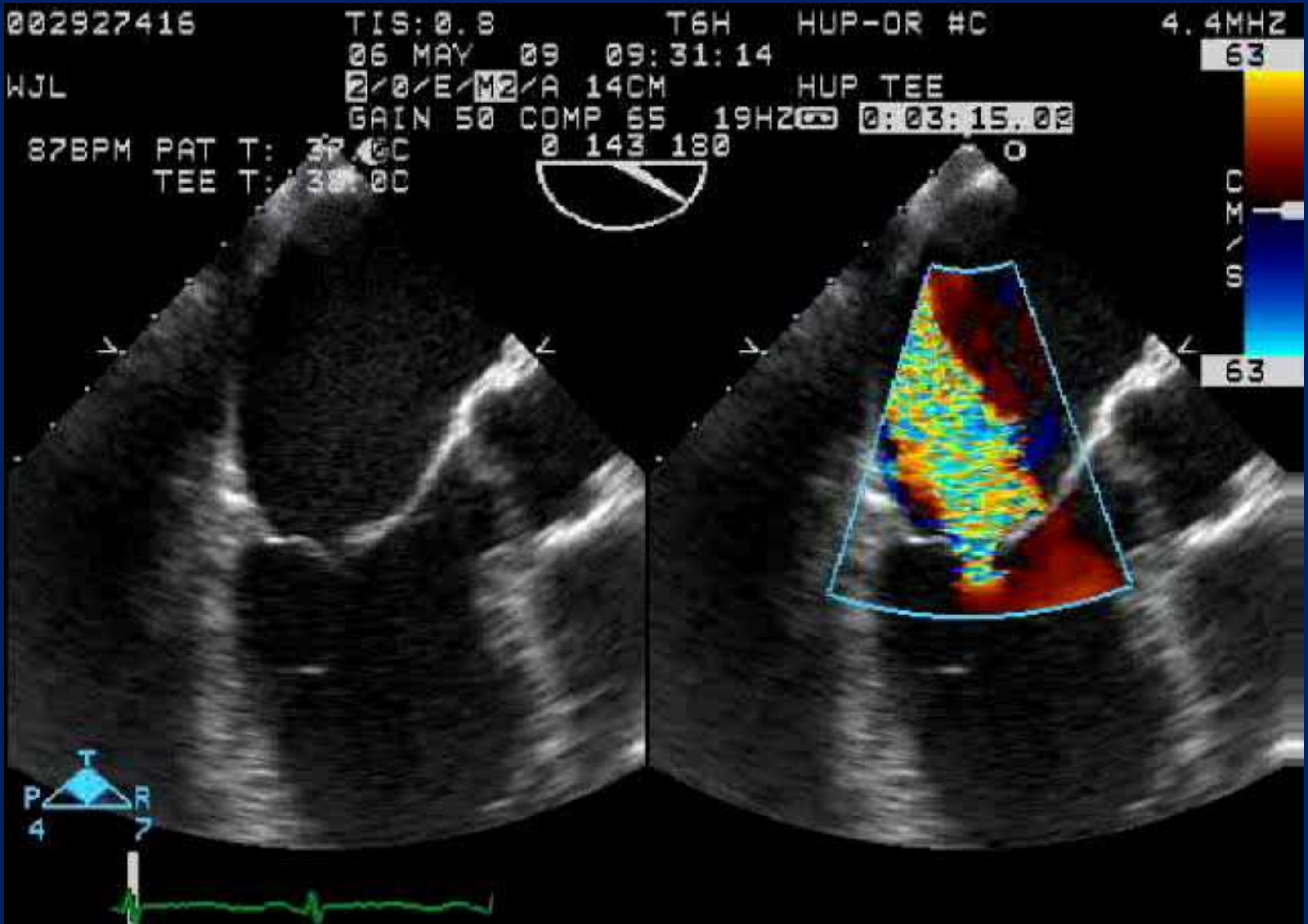
Examples

TAVI Deployment



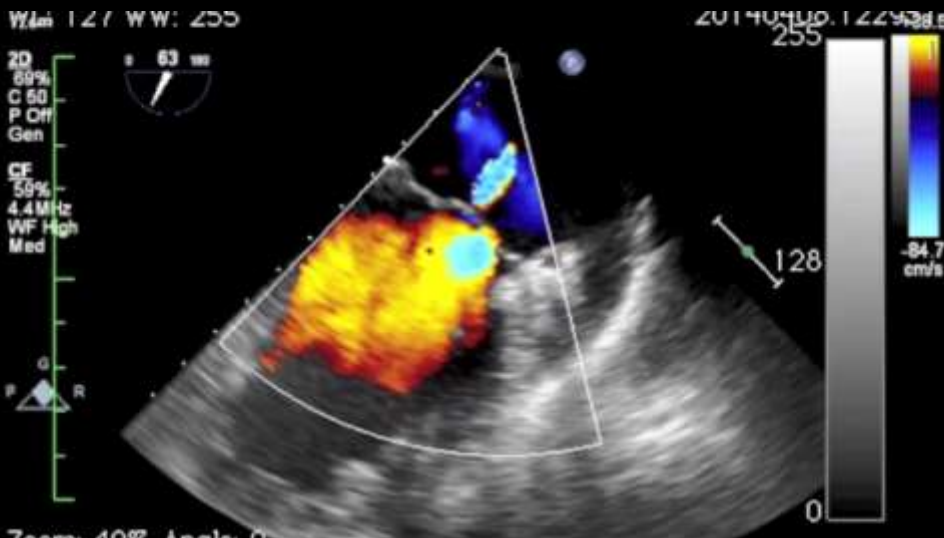
It all started in US with Partner Trial (Penn Nov 2007)

So ……The Four Key Criteria:
1. Delivery, 2. Fixation, 3. Residual MR, 4. No SAM

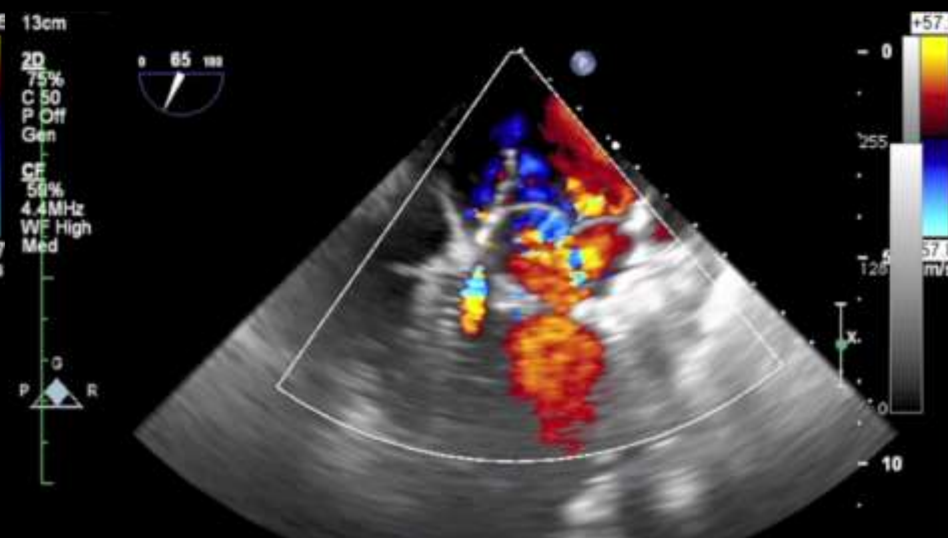


CardiAQ™ Gen2 TA FIH

- Performed by Lars Sondergaard and team at Rigshospitalet in Copenhagen
- 88yr old Female, MR 4+, prior CABG, not a candidate for Surgery or MitraClip
- CardiAQ Gen2 Transcatheter Mitral Valve
- New *Trans-Apical* Delivery System



Pre-Procedural: MR 4+



Post-Procedural: Trace

Disclosure: J. Bavaria; Holder of Founders Shares equity

Spectrum of Adult Cardiovascular Surgery

1. Cryolife Bioglue (Dissections/Aneurysms)
2. GenTAC Aorta (clinical NIH)
3. Toronto/Prima Biolgical Porcine Full Root
4. Gore Descending Aortic Stent Graft
   a. Dissection/Transection
5. Medtronic Descending Aortic Stent Graft Trial (Phase I, II , III, post market)
6. Bolton , Jotec IDE, TAAA and Arch
7. Cook post Market TEVAR

→ **Thoracic Aortic Surgery**

1. Cardeon Differential Cerebral perfusion trial
2. Terumo Monitor (TCD,EEG,NIRS)
3. CPB Inflammatory Mkrs
4. Neuro protection drugs

→ **Circulation Management**

1. Acorn Jacket
2. Gen Vec
3. Stitch
4. CTS Network Ischemic MR EF<35

→ **Heart Failure Surgery**

1 Heartmate I II LVAD
2. Heartware
3. syncardia; ventrcor
4. Thoratec

→ **Heart Lung Transplantation & Mechanical Assist**

1. Partner I and II, Sub studies,Corevalve surtavi
2. Artic Root Phase I
3. Trifecta/Mitroflow IDE
4. Sorin Solo; Perceval, Intuity
5. Myocor
6. CTS network: Mitral valve (NIH)

→ **Valvular Heart Disease**

1. Atricure (Bipolar Ablation)
2. Medtronic

→ **Arrhythmia Surgery**

1. PREVENT IV
2. FREEDOM Trial
3. Cormatrix

→ **Ischemic Heart Disease**

1. CABG Robotic Trial/ da Vinci

→ **Minimally Invasive Heart Surgery**

1 EASAI Drug Trial
2. XOMA Trial
3. Nesiritide
4. Clevidipine vs. Nipride
5. ESP Pharma
6. INOTEK-PARP inhibitor (TAAA)
7. Heart and Lung Transplant Drug studies.

→ **CT-ICU**

→ **Post-Op/Long term Clinical Research Disease Management Clinic**

Population: GenTAC Registries (IRAD, Marfans)

Innovation does need some Vision

Disclosures/Conflicts

- Medtronic: Co-Primary Investigator Talent Trial; Primary Investigator Valiant Valor II Trial, National CV PI Acute Type B Dissection trial; PI Surtavi Trial
- W.L. Gore: Primary Investigator TAG Trial; FDA PMA submission; PI Early Feasibility TBE, PI Dissection trial
- St Jude Medical: PI Trifecta FDA PMA trial; Portico Trial
- Cook Medical: Co-Primary Investigator TX2 Thoracic Aorta Trial, PI Post market TX2 trial
- Bolton Relay: sub-PI TEVAR trial
- Sorin: sub PI Perceval trial
- Jotec: Consultant; FDA E-Vita submission
- Vascutek: Aortic Symposium Director
- Edwards: PI, Partner Trial/ FDA PMA; PI Commence FDA Trial; PI Intuity FDA Trial
- CardiAQ/Edwards: Founding Team, Equity Holder

DisclosuresConflicts

- Medtronic: Consultant; Co-Primary Investigator Talent Trial; Primary Investigator Valiant Valor II Trial, National CV PI Acute Type B Dissection trial
- W.L. Gore: Consultant; Primary Investigator TAG Trial; FDA PMA submission; Primary Investigator High Risk Trial, Dissection trial and Large Diameter 45 trial
- Cook Medical: Co-Primary Investigator TX2 Thoracic Aorta Trial, PI Post market TX2 trial
- Bolton Relay: sub-PI TEVAR trial
- Jotec: Consultant; FDA E-Vita submission
- Vascutek: Aortic Symposium Director
- Edwards: PI, Partner Trial/ FDA PMA
- Etc, etc, etc.

This is Not a Bad Thing!!

Partner TAVI Trial High-Risk Enrollment by Site
NEJM 2010, NEJM 2011, NEJM 2012, etc, etc…..

Cedars-Sinai Medical Ctr **116**
Los Angeles, CA
G. Fontana, R. Makkar

Columbia University **97**
New York City, NY
M. Leon, C. Smith

Medical City Dallas **95**
Dallas, TX
D. Brown, T. Dewey

Emory University **67**
Atlanta, GA
P. Block, R. Guyton

University of Pennsylvania **52**
Philadelphia, PA
J. Bavaria, H. Herrmann

Cleveland Clinic Found **47**
Cleveland, OH
L. Svensson, M. Tuzcu

Washington Hospital Ctr **40**
District of Columbia
P. Corso, A. Pichard

University of Miami **25**
Miami, FL
W. O̓Neill, D. Williams

Barnes-Jewish Hospital **24**
St. Louis, MO
R. Damiano, J, Lasala

Stanford University **23**
Palo Alto, CA
C. Miller, A. Yeung

Northwestern University **20**
Chicago, IL
C. Davidson, P. McCarthy

St. Paul's Hospital **19**
Vancouver, BC, Canada
A. Cheung, J. Webb

Non-University programs

Epiphany …. (Vision):

Eventually, Every Aortic condition will be treated with TEVAR and Every Valvular Condition with Endo-Cardiac treatment and every Bad heart with a small pump !?!

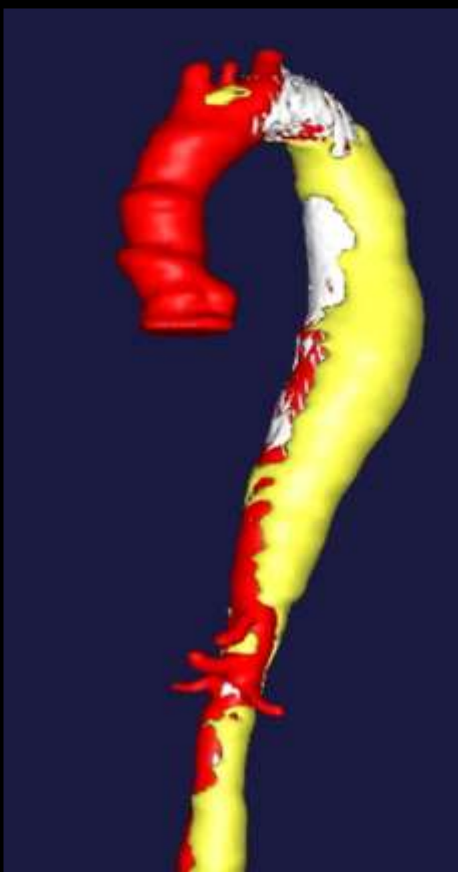
However:

We will Need Surgeons who can do BOTH Open Surgery and TEVAR/TAVI

….. Lots of Complications and the necessity for definitive treatment will remain …. And Reconstruction always wins

“The Treatment is best provided by specialists who are great open surgeons **AND** great endovascular surgeons”

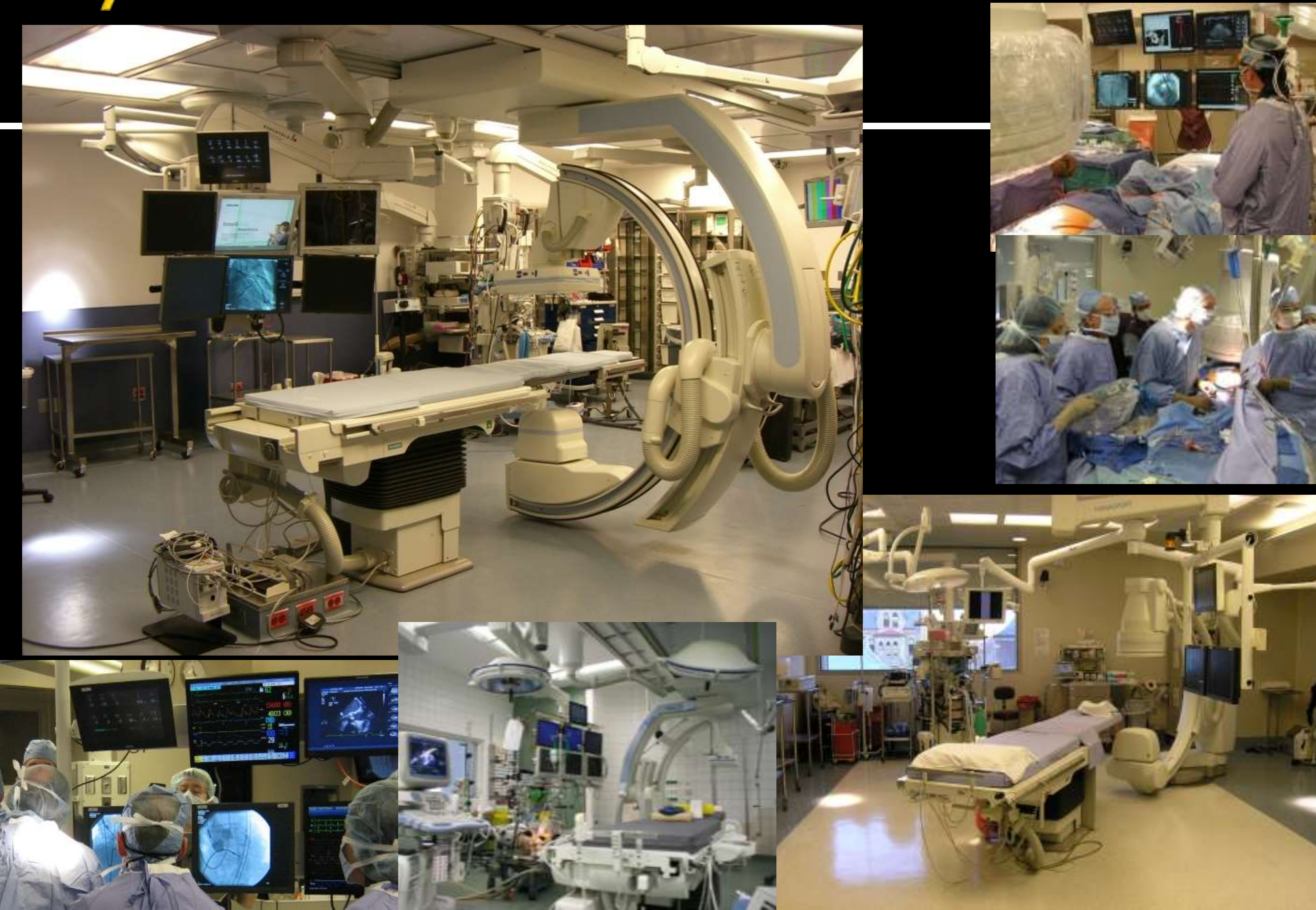
Juan Parodi, MD; STS 2006






Best Landscape for the Continuing Aortic, Valve and LVAD Treatment Revolution ?

Hybrid OR-Part of The Future



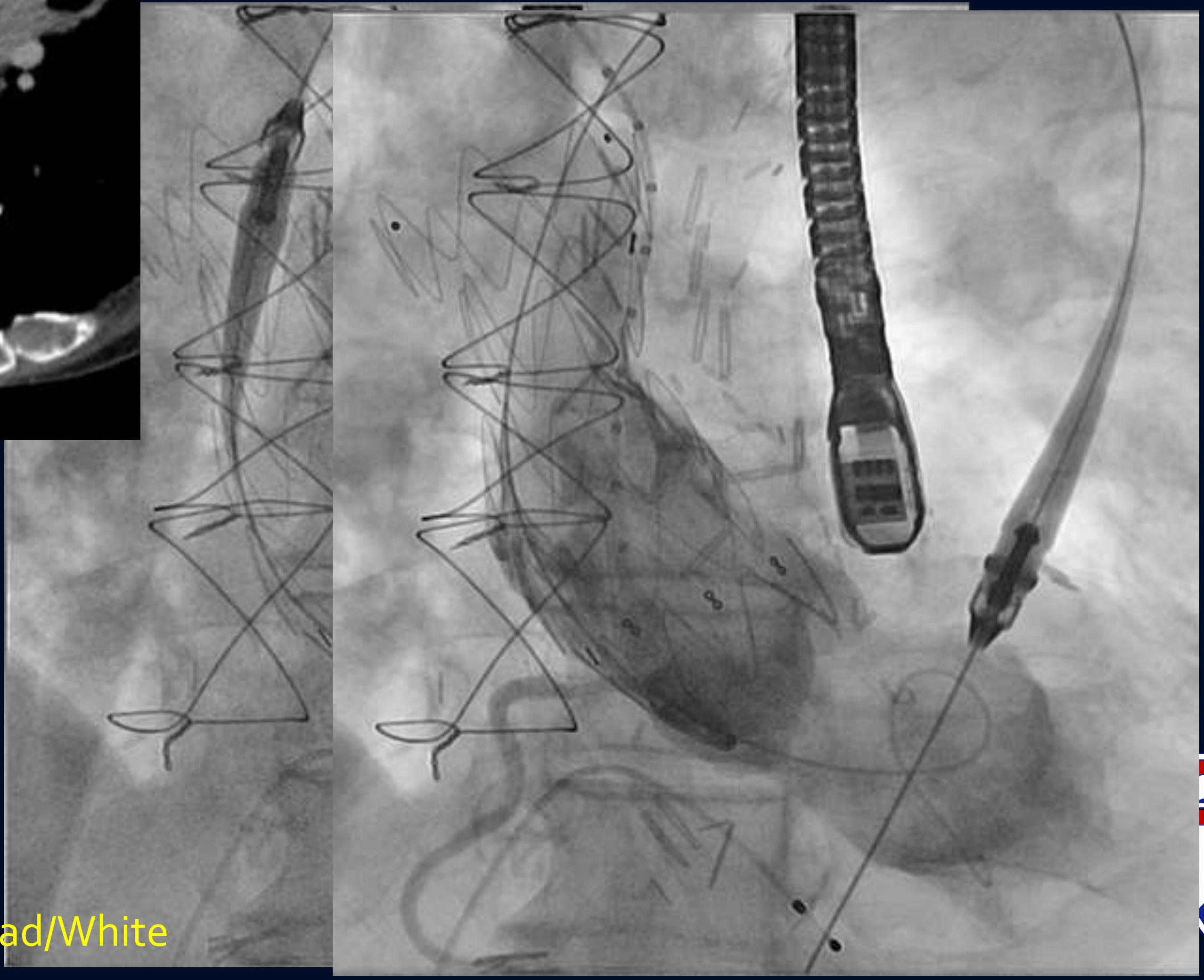
Thomas Eakins: Gross Clinic (1878@JEFF) and Agnew Clinic (1888@PENN)

Great Progress in 10 years!

Thank You

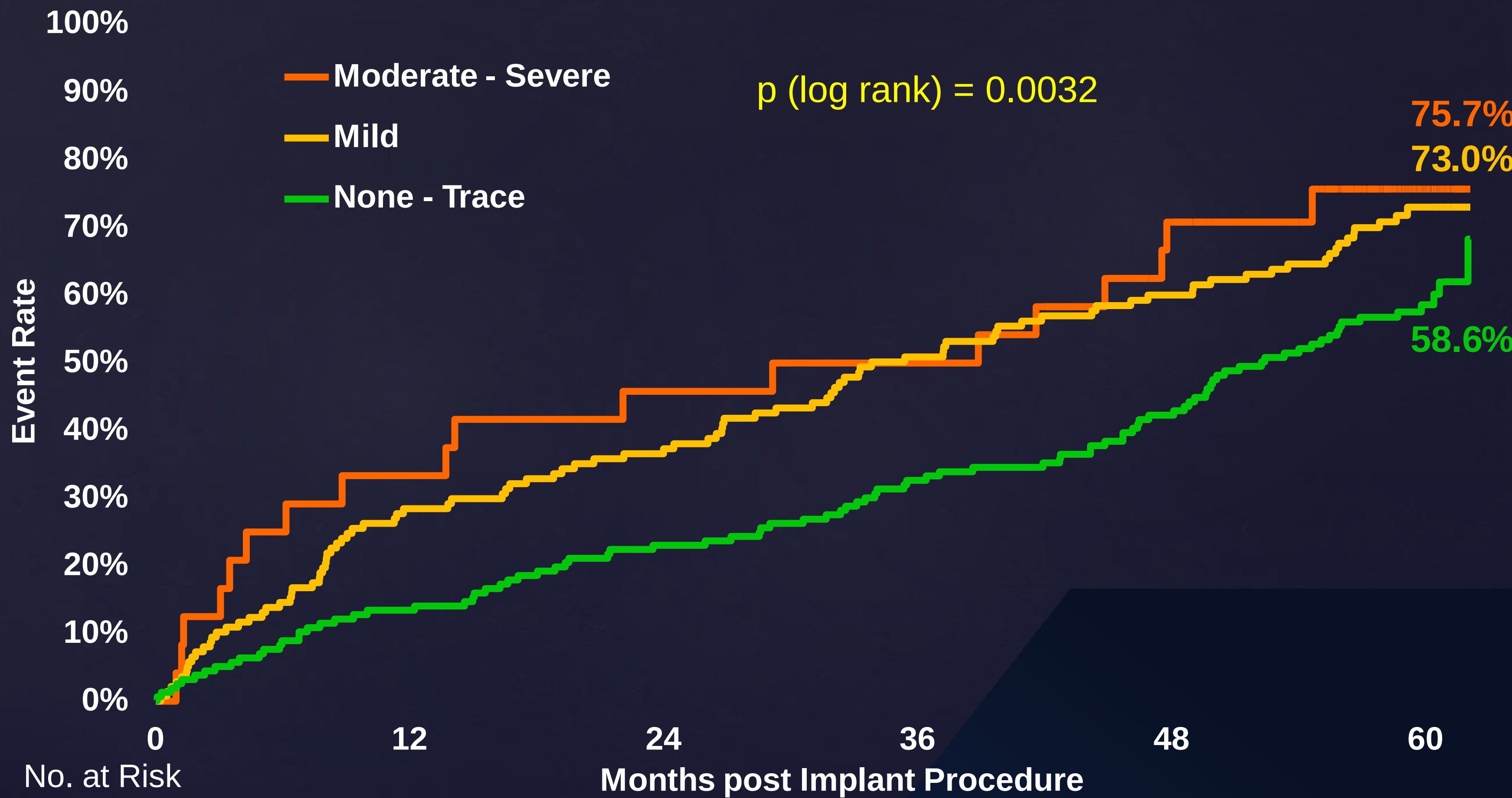
Medtronic Ascending Endograft

Valiant Captiva
46x46x80 mm



Courtesy of Khoynezhad/White

Mortality and Post Procedural PVL
TAVR Patients



No. at Risk

	0	12	24	36	48	60
M-S	24	16	13	12	7	2
Mild	137	98	84	65	52	11
N-T	158	135	120	105	88	34

Baseline Patient Characteristics
S3i Patients

THE PARTNER II TRIAL

Average STS =

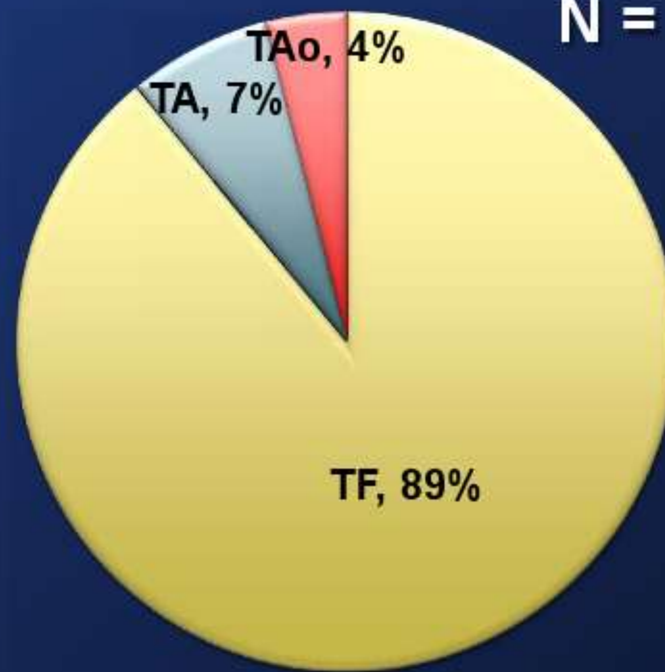
5.3%

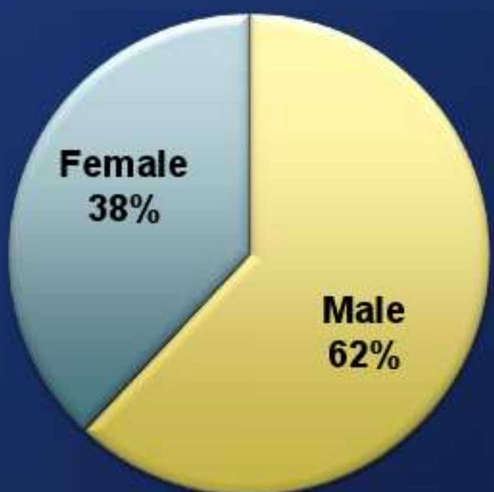
(Median 5.2%)

Average Age =

81.9yrs

N = 1076





Example Commercial Patient

Name for Scrolling	
DRG	219
Entity	(All)

	-1	0	1	2	3	4	Grand Total	
	$242	$37,269	$1,831	$1,206	$971	$127	$41,647	
OR SUPPLIES		**$32,500**					**$32,500**	78%
01305192 TAVIAORTIC VALVE		$32,500					$32,500	
NUR-SILVERSTEIN 10			**$802**	**$802**	**$802**		**$2,405**	6%
O.R. YELLOW		**$2,093**					**$2,093**	5%
01100346 OR 1ST HALF HR		$369					$369	
01100353 OR ADDTL HALF HR		$1,552					$1,552	
06550008 ART. (THORAC. AORTA) S/I		$173					$173	
NUR-SICU-CT/GS		**$1,606**					**$1,606**	4%
PHAR - IP CENTRAL ROBOT NARC		**$281**	**$605**	**$105**	**$86**	**$64**	**$1,140**	3%
PERIOP ANES TECHS HUP		**$444**					**$444**	1%
AUTO LAB		**$196**	**$119**	**$8**	**$14**	**$33**	**$371**	1%
BLOOD BANK	**$207**		**$83**				**$290**	1%
RESPIRATORY THERAPY-HUP		**$94**	**$164**				**$258**	1%
BONE/CHEST/ER SUPP		**$26**	**$26**	**$26**	**$62**	**$26**	**$167**	0%
ECHO LAB				**$117**			**$117**	0%
INPATIENT PT-HUP				**$69**			**$69**	0%
INPATIENT OT-HUP				**$67**			**$67**	0%
PHLEBOTOMY		**$9**	**$21**	**$4**	**$4**	**$4**	**$43**	0%
RAD DIAGNOSTIC CAM	**$33**						**$33**	0%
PREP & RECOVERY SC		**$16**					**$16**	0%
COAGULATION			**$7**	**$7**			**$14**	0%
EKG LABORATORY	**$3**	**$3**	**$3**		**$3**		**$12**	0%
CLINICAL LAB		**$0**	**$1**	**$0**			**$1**	0%
Grand Total	**$242**	**$37,269**	**$1,831**	**$1,206**	**$971**	**$127**	**$41,647**	100%

OR Supplies, driven by valve 78% of direct cost

Future Considerations and Conclusions

- Repairative Heart Valve surgery, Small Pumps, Aortic Endovascular, and Transcatheter "EndoCardiac" procedures will gain traction and grow along with other niche areas
- Traditional Cardiac Surgery will remain important and steady as will Congenital
- Cardiovascular Surgery may get a bit smaller (ABTS 135 vs 95) as a specialty
- Public Reporting of Outcomes and therefore the clinical STS National Database will become essential (also STS/ACC TVT database)

Present State of Thoracic Aortic Surgery: Achievements

1. Stunning Advances in Aortic Root Surgery
2. Extremely Low Morbidity/Mortality Ascending (Proximal Aortic) Treatment Outcomes
3. Advances in Aortic Arch Results
4. Acute Type A Dissection Series in High Volume Centers between 8-14% Mortality
5. Outstanding Descending Aortic Treatment Results
    1. Open and TEVAR (especially “on-Label”)

Present State of Thoracic Aortic Surgery II

6. Improving Technical Advances in TAAA Surgery, especially Dissection TAAA Aneurysm.

From: **United States Health Care Reform: Progress to Date and Next Steps**

JAMA. 2016;316(5):525-532. doi:10.1001/jama.2016.9797

The JAMA Network

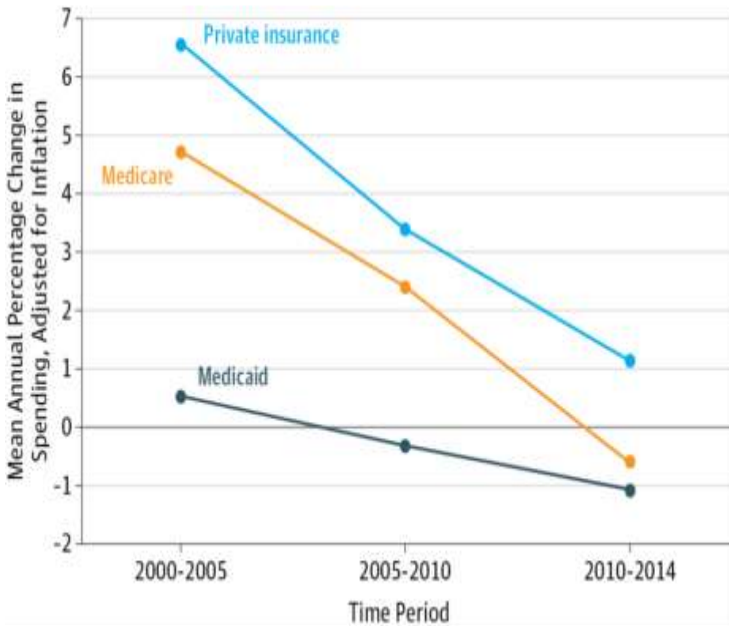


Figure Legend:

Rate of Change in Real per-Enrollee Spending by PayerData are derived from the National Health Expenditure Accounts. Inflation adjustments use the Gross Domestic Product Price Index reported in the National Income and Product Accounts. The mean growth rate for Medicare spending reported for 2005 through 2010 omits growth from 2005 to 2006 to exclude the effect of the creation of Medicare Part D.