TEVAR for the Ascending Aorta



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Disclosures—Himanshu J. Patel MD

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National Principal Investigator for WL Gore Thoracic Side Branch Endograft Trial



• THE PROBLEM



"Medicine, especially surgery,
is a conservative profession;
a physician departs only reluctantly
from established techniques and lessons.

And for good reason; the stakes, if you are wrong, are too high."

Atul Gawande"Desperate Measures"

- The New Yorker
- May 5, 2003



Fundamental Decision for Operation Performed for Life Expectancy Benefit

Probability of rupture and death



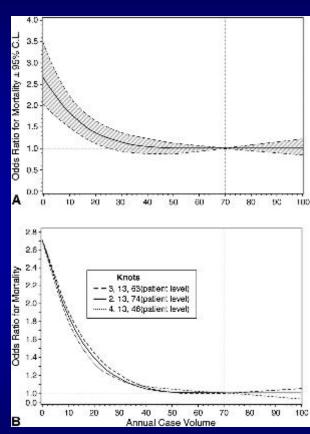
Probability of complication from intervention

$$P_{r/d} > P_c$$



Outcomes of Surgery Determinants

- Age
- Comorbidities
- Urgency of procedure
- Functional status
- Extent of needed operative procedure

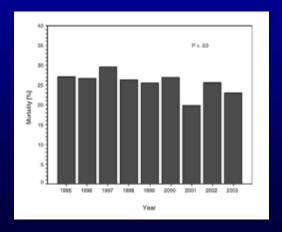


•Hughes GC, JTCVS 2013



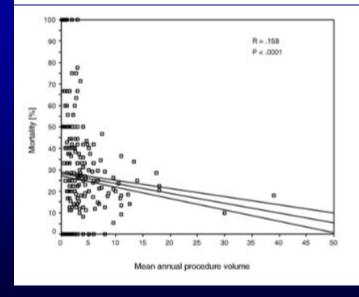
Mortality for Repair of Type A Dissection in US

- NIS administrative database study
- **1**995-2003



A contemporary analysis of outcomes for operative repair of type A aortic dissection in the United States

Brian S. Knipp, MD, G. Michael Deeb, MD, Richard L. Prager, MD, Candace Y. Williams, MD, Gilbert R. Upchurch, Jr., MD, and Himanshu J. Patel, MD, Ann Arbor, Mich





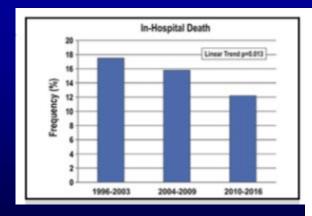
Mortality for Repair of Type A Dissection at "Experienced" Centers of Excellence

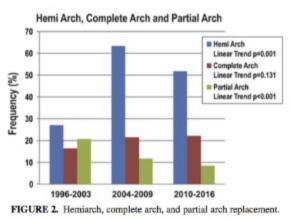
IRAD

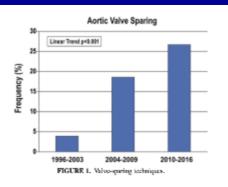
Changes in operative strategy for patients enrolled in the International Registry of Acute Aortic Dissection interventional cohort program



Neil Parikh, BS, a Santi Trimarchi, MD, PhD, Thomas G. Gleason, MD, Arnoud V. Kamman, MD, Marco di Eusanio, MD, PhD, Truls Myrmel, MD, PhD, Amit Korach, MD, Hersh Maniar, MD, Takeyoshi Ota, MD, PhD, Ali Khoynezhad, MD, PhD, Daniel G. Montgomery, BS, Nimesh D. Desai, MD, PhD, Kim A. Eagle, MD, A. Nienaber, MD, PhD, Eric M. Isselbacher, MD, Daseph Bavaria, MD, Thoralf M. Sundt, MD, and Himanshu J. Patel, MD









Conclusion---The Problem

- Operative results have and will continue to improve
- Perhaps an alternative option is reasonable

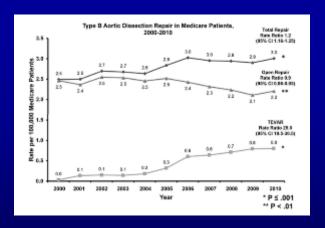


The Alternative Option

- TEVAR effects for type B dissection
- Medicare claims data 2000-2010
- Increase in aortic repair by 21%
- TEVAR 27% by 2010

National trends in utilization, mortality, and survival after repair of type B aortic dissection in the Medicare population

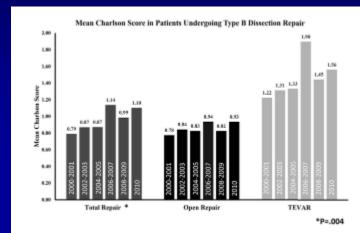
Douglas W. Jones, MD, ^a Philip P. Goodney, MD, MS, ^{b,c} Brian W. Nolan, MD, ^{b,c}
Benjamin S. Brooke, MD, PhD, ^b Mark F. Fillinger, MD, ^b Richard J. Powell, MD, ^b and
David H. Stone, MD, ^b New York, NT; and Lebanon and Hanover, NH

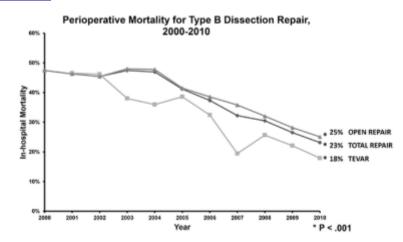




TEVAR Alternative

- TEVAR with higher rates of comorbidities
- Continued improvement in mortality rate
 - OSR 25%
 - TEVAR 18%





TEVAR for Ascending Aorta

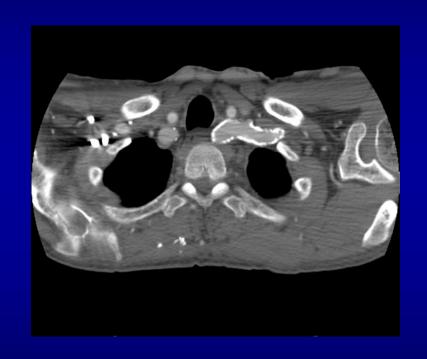
- 65 year old male
- Dialysis dependent
- Suspected IVDA
- Prior Bentall procedure
- Presented in 1999with aortocutaneousfistula





TEVAR for Ascending Aorta

- Lost to followup
- Re-presented now in 2003
- Expired shortly after admission during evaluation





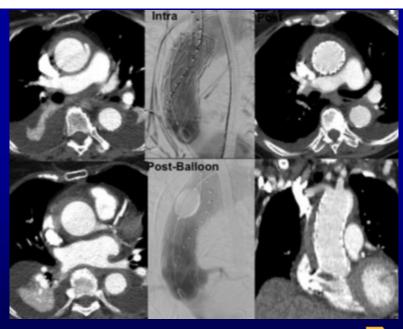
Experience with Ascending TEVAR

Endovascular stent grafting for ascending aorta repair in high-risk patients

22 patients

Eric E. Roselli, MD, Jahanzaib Idrees, MD, Roy K. Greenberg, MD, Douglas R. Johnston, MD, and Bruce W. Lytle, MD

- 9 with type A
- 86% 30-day survival
- 80% at 1 year





The Challenge of Ascending

TEVAR

Notice the difference











The Anatomical Challenge of Ascending TEVAR

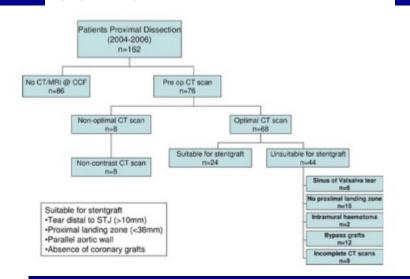
- 162 patients
- 77% suitable for review with centerline analysis
- Only 32% treatable by current paradigm

Table III. Criteria for suitability of an endovascular intervention

- Proximal landing zone (sinotubular junction ≤38 mm)
- Fenestration distal to sinotubular junction
- Minimum distance between intimal fenestration and sinotubular junction ≥10 mm
- Absence of coronary bypass grafts originating from ascending aorta

Computed tomography-based anatomic characterization of proximal aortic dissection with consideration for endovascular candidacy

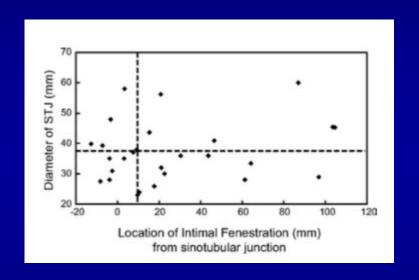
Michael C. Moon, MD,* Roy K. Greenberg, MD,** Jose P. Morales, MD,* Zenia Martin, MD,* Qingsheng Lu, MD,* Joseph F. Dowdall, MD,* and Adrian V. Hernandez, MD, PhD,* Cleveland, Ohio





The Anatomical Challenge of Ascending TEVAR

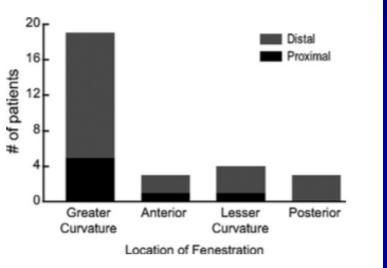
- The root and the entry tear
- Intimal tear itself
 identifed in 41%
- Of these 75% had tears originating distal to the root

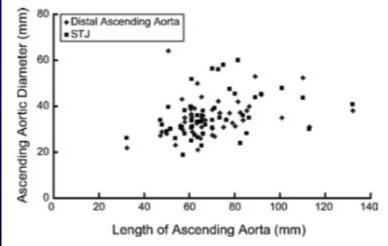




The Anatomical Challenge of Ascending TEVAR

- Length problem
- average 70.5 mm



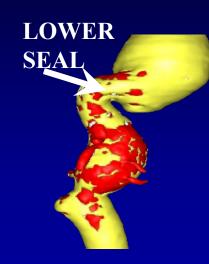




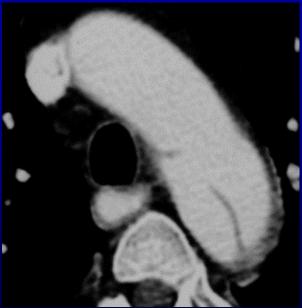
The Sizing Problem

• Differences between type A and type B dissection treatment











The Sizing Problem

 63 patients (non Marfan non bicuspid) type A with CT within 2 years and at time of type A Journal of the American College of Cardiology © 2014 by the American College of Cardiology Foundation Published by Elsevier Inc. Vol. 63, No. 11, 2014 135N 0733-1097/836.00 http://dx.doi.org/10.10165.ioc.2013.12.038

Discourse of the Aort

How Does the Ascending Aorta Geometry Change When It Dissects?



Bartosz Rylski, MD, † Philipp Blanke, MD,† Friedhelm Beyersdorf, MD, PhD,†
Nimesh D. Desai, MD, PhD,† Rita K. Milewski, MD, PhD,† Marthias Siepe, MD,†
Fabian A. Kari, MD,† Martin Czerny, MD,§ Thierry Carrel, MD,§ Christian Schlensak, MD,¶
Tobias Krüger, MD,∥ Michael J. Mack, MD,¶ William T. Brinkman, MD,¶
Friedrich W. Mohr, MD, PhD,# Christian D. Etz, MD, PhD,# Maximilian Luchr, MD,#
Joseph E. Bavaria, MD*

Philadelphia, Pennsylvania; Freiburg, Würzburg, Tübingen, and Leipzig, Germany; Berne, Switzerland; and Plano, Texas

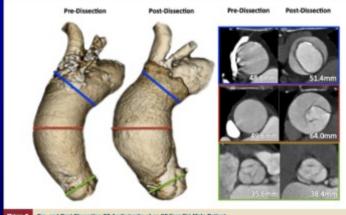


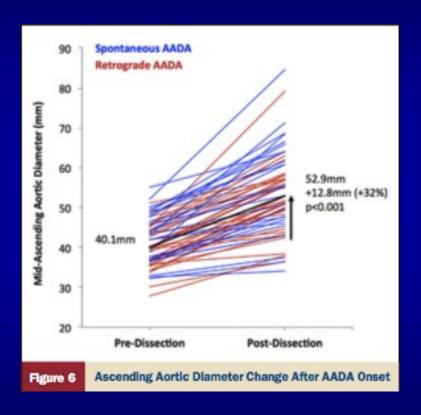
Figure 5 Pre- an

Pre- and Post-Dissection CT Anglography of an IIS-Year-Old Male Patient



The Sizing Problem

- Average increase greatest in ascending aorta
 - 32% ascending
 - 10% descending
- Increase in tortuosity
 by centerline analysis





Summary of Difficulties

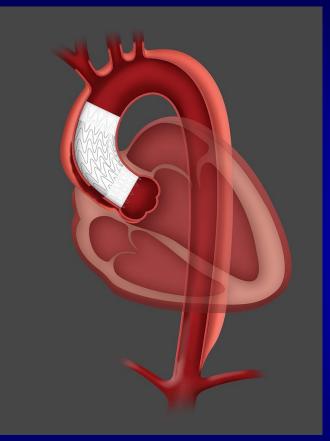
- No suitable landing zone
- Unclear sizing methods
- Not amenable to conventional stent graft length and design—need modified version and potentially new paradigm



Onward to an FDA Clinical Trial

- WL Gore Type A Early Feasibility Study
- Study population: DeBakey Type I/II
 Dissection
- Approved for up to 10 patients
 - 7/10 patients enrolled
- 6 investigational sites:

Houston Methodist Hospital	University of Michigan Hospital
St. Luke's Health Baylor	Cleveland Clinic
Memorial Hermann Heart & Vascular Institute	Hospital of the University of Pennsylvania



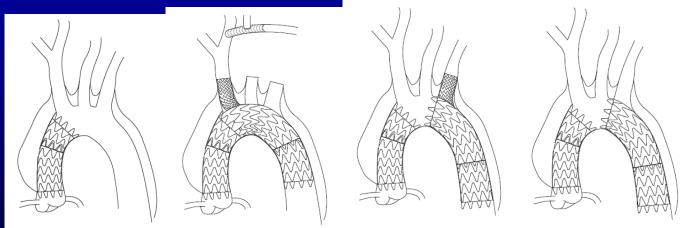
•Gore Investigational Device



Gore Type A EFS Original Study Device

- Extender cuff from Thoracic Branch Endoprosthesis
- Modified version now for ascending Ao

Remaining TBE system available for distal extension







First University of Michigan Procedure

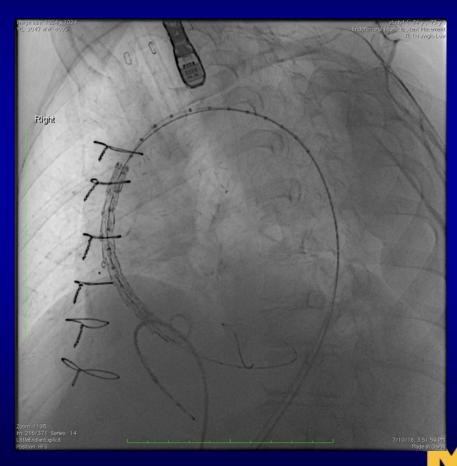
- 71 year old female
- Prior CABG
- Frail with poor ambulation
- Severe COPD
- TEE no AI, normal LVEF
- CT entry tear in arch



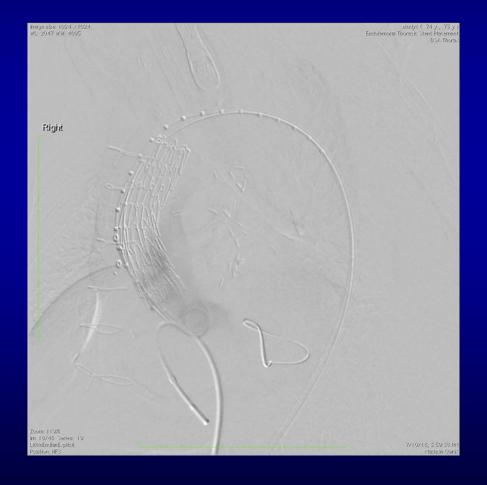


Partial ASG Component Deployment

- Cervical debranching first
- Size??
 - Total aortic diameter
- Deploy the TBE or the ASG component first
- What will happen to the aortic valve

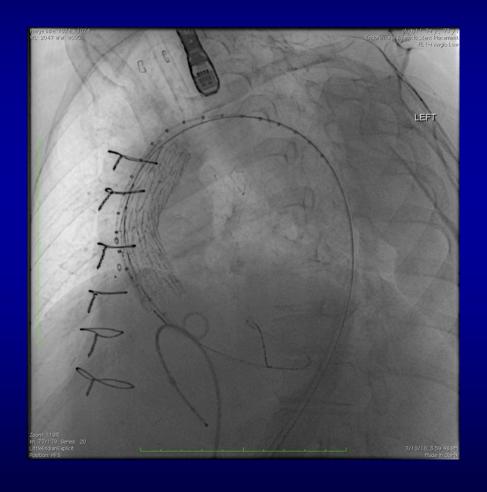


Angiogram and Adjustment of Lesser Curvature Length



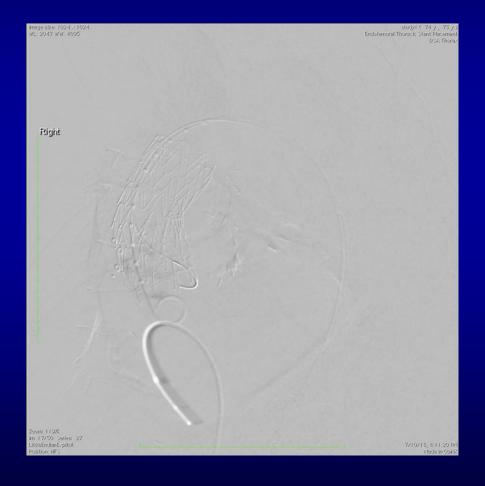


Complete ASG Deployment





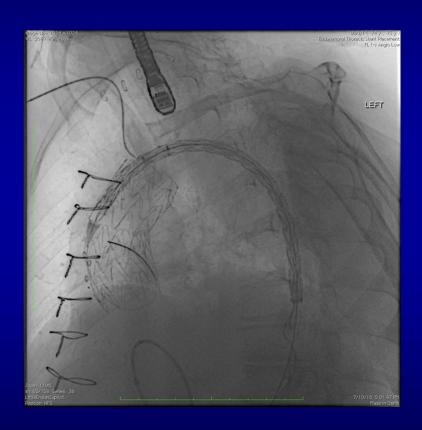
Angiogram after ASG Deployment





Deployment of TBE Component

- Size to total aortic diameter
- Concern of type III endoleak with limited overlap and subsequent balloon aortoplasty
- Deployment of single side branch endograft





Completion Angiogram





CT scan at 7 days







A Patient Came to Clinic....

- 80 year old female with past history of rheumatoid arthritis and lupus (prednisone, methotrexate for 20 years), hypertension and EVAR who presents with NYHA Class III from severe AS.
- STS Risk Score 7% mortality, 26% morbidity



Aortogram





Stent Graft Cook TX2 Distal Extension Piece



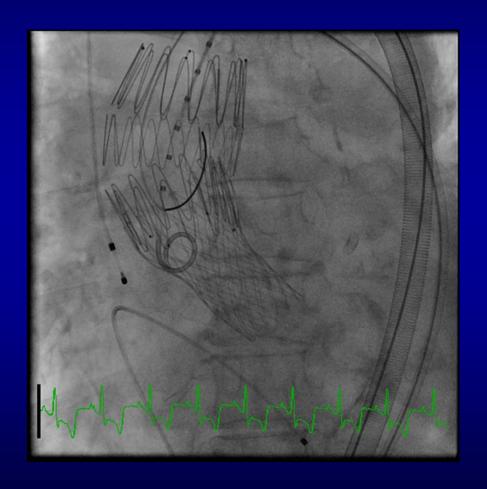


Thoracic Endograft Deployment





Aortography





Conclusion

- Endovascular repair of type A dissection is coming
- There are no brave surgeons but only brave patients

