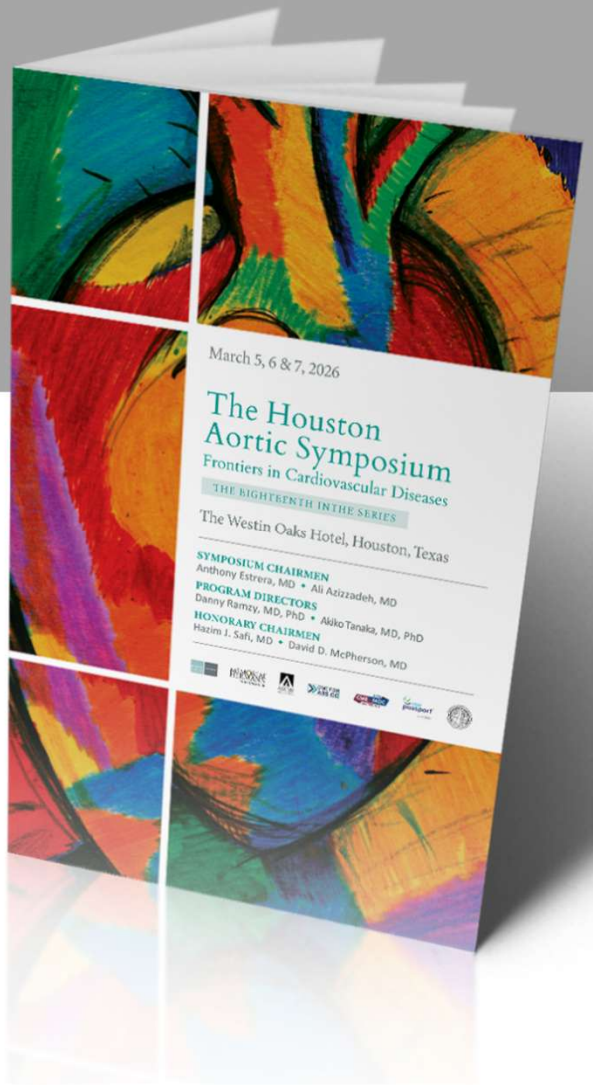
Update on Endovascular Management of Type A Aortic Dissection



Ali Azizzadeh, MD, FACS

Lee and Harold Kapelovitz Distinguished Chair in Cardiovascular Biology
Professor & Director, Division of Vascular Surgery
Vice Chair, Jim and Eleanor Randall Department of Surgery
Associate Director, Heart Institute
Associate Dean, Faculty Affairs

Cedars Sinai

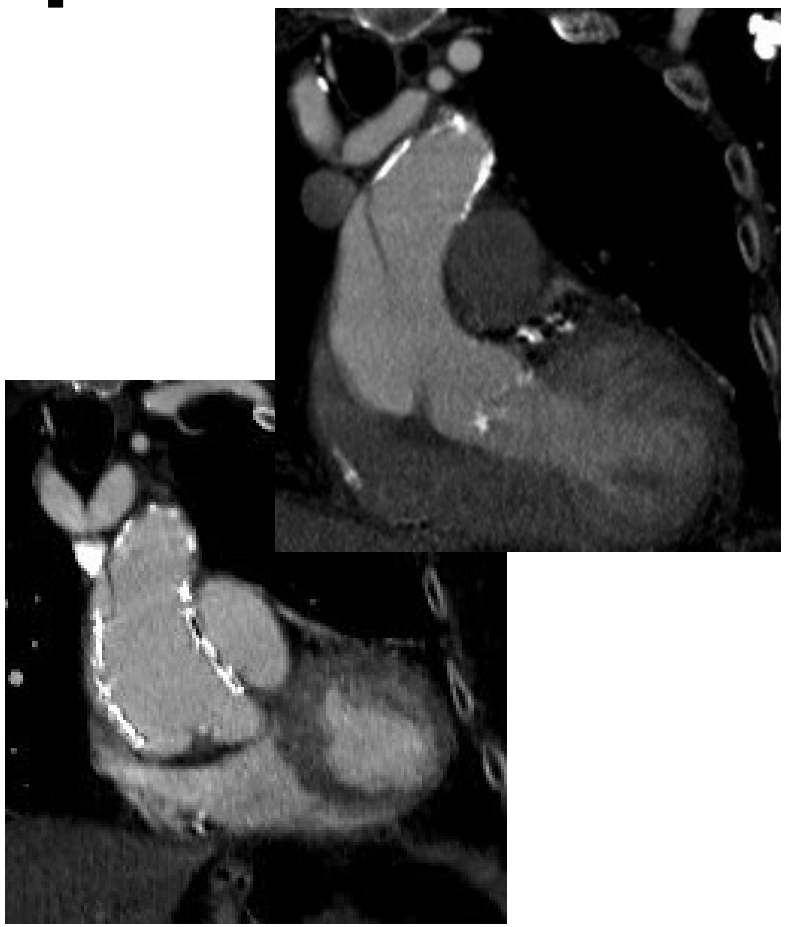
BEST HOSPITALS U.S.News & World Report HONOR ROLL 2024-2025

Financial Disclosures

- No conflicts

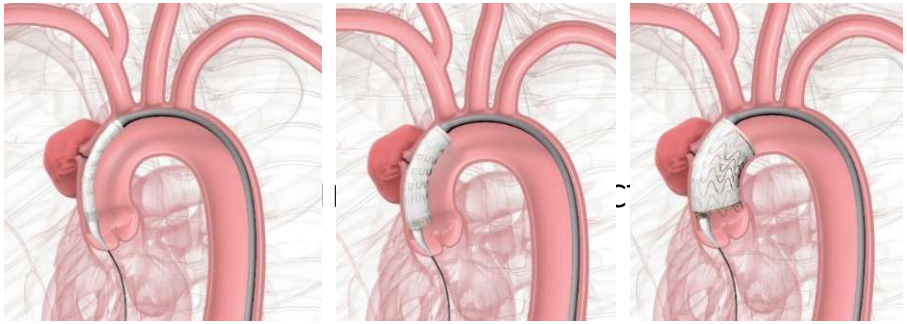
Ascending Aorta: Challenges To Endovascular Repair

- Open surgery gold standard
- 10-20% HR pts not candidates
- Anatomical challenges:
  - Short landing zone
  - Large diameter
  - Non-cylindrical lumen
  - Short radius of curvature
  - Increased compliance
- Dynamic cardiac and respiratory forces
- Complications: Stroke & Death



GORE® Ascending Stent Graft (ASG)

- Device sizes
  - 34mm to 53mm diameters
  - 7 or 8cm & 10cm lengths
- Using ACTIVE CONTROL technology
  - Staged Deployment
  - Angulation Control
- Avoid interference with the coronary arteries
  - Deployment sleeve pullback
  - Uncovers proximal stent apices
- Used in conjunction with TBE Device
  - Zone 0 arch repair



CAUTION — Investigational device. Limited by United States law to investigational use.

ARISE Clinical Program:

Early Feasibility Study
National PI: Michael Reardon, MD

ARISE EFS
Enrollment: 2016 – 2021

- **Type A Dissections**
- Emergency and compassionate use included isolated lesions

Enrollment concluded, 5-year follow up complete Spring 2026

NCT02380716

Pivotal Trial Studies
National PI: Eric Roselli, MD

ARISE II
Enrollment: 2023 – ongoing

- **Isolated lesions:**
  - Pseudoaneurysm, aneurysm, penetrating aortic ulcer (PAU)
- **Type A Dissections:**
  - Chronic with arch repair

Enrollment ongoing

NCT05800743

ARISE III
Enrollment: 2025 - ongoing

- **Acute Type A Dissections**

Enrollment ongoing

NCT06827990

ARISE Early Feasibility Study (EFS)

- Study Design
  - Prospective, multicenter, non-randomized, single-arm clinical trial across 9 US centers.
- Patient Profile
  - HR pts ineligible for open surgery, mean age 76, 58% female.
- Procedural Success
  - ASG successfully delivered and deployed in all 19 pts.
- Clinical Outcomes
  - 30-day MACCE included mortality (15.8%), disabling stroke (5.3%), and myocardial infarction (5.3%), comparable to surgery.

ARISE: First-In-Human Evaluation of a Novel Stent Graft to Treat Ascending Aortic Dissection

Journal of Endovascular Therapy
2023, Vol. 30(4) 550–560

DOI: 10.1177/15266028221095018
www.jevt.org
SAGE

Eric E. Roselli, MD[1], Marvin D. Atkins, MD[2], William Brinkman, MD[3], Joseph Coselli, MD[4], Nimesh Desai, MD[5], Anthony Estrera, MD[6], Douglas R. Johnston, MD[1], Himanshu Patel, MD[7], Ourania Preventza, MD[4], Patrick R. Vargo, MD[1], Fernando Fleischman, MD[8], Bradley S. Taylor, MD[9], and Michael J. Reardon, MD[2] On behalf of the ARISE Investigators

Abstract

Background: Operative mortality for type A aortic dissection is still 10–20% at centers of excellence. Additionally, 10–20% are not considered as viable candidates for open surgical repair and not offered life-saving emergency surgery. ARISE is a multicenter investigation evaluating the novel GORE® Ascending Stent Graft (ASG; Flagstaff, AZ). **Objective:** The purpose of this study is to assess early feasibility of using these investigational devices to treat ascending aortic dissection. **Methods:** This a prospective, multicenter, non-randomized, single-arm study that enrolls patients at high surgical risk with appropriate anatomical requirements based on computed tomography imaging at 7 of 9 US sites. Devices are delivered transfemorally under fluoroscopic guidance. Primary endpoint is all-cause mortality at 30 days. Secondary endpoints include major adverse cardiovascular and cerebrovascular events (MACCE) at 30 days, 6 months, and 12 months. **Results:** Nineteen patients were enrolled with a mean age of 75.7 years (range 47–91) and 11 (57.9%) were female. Ten (52.6%) had DeBakey type I disease, and the rest were type II. Sixteen (84.2%) of the patients were acute. Patients were treated with safe access, (7/19 (36.8%) percutaneous, 10/19 (52.6%) transfemoral, 2/19 (10.5%) iliac conduit), delivery, and deployment completed in all cases. Median procedure time was 154 mins (range 52–392) and median contrast used was 111 mL (range 75–200). MACCE at 30 days occurred in 5 patients including mortality 3/19 (15.8%), disabling stroke in 1/19 (5.3%), and myocardial infarction in 1/19 (5.3%). **Conclusion:** Results from the ARISE early feasibility study of a specific ascending stent graft device to treat ascending aortic dissection are promising.

Keywords
ascending aorta, aortic dissection, stent graft, TEVAR, ARISE

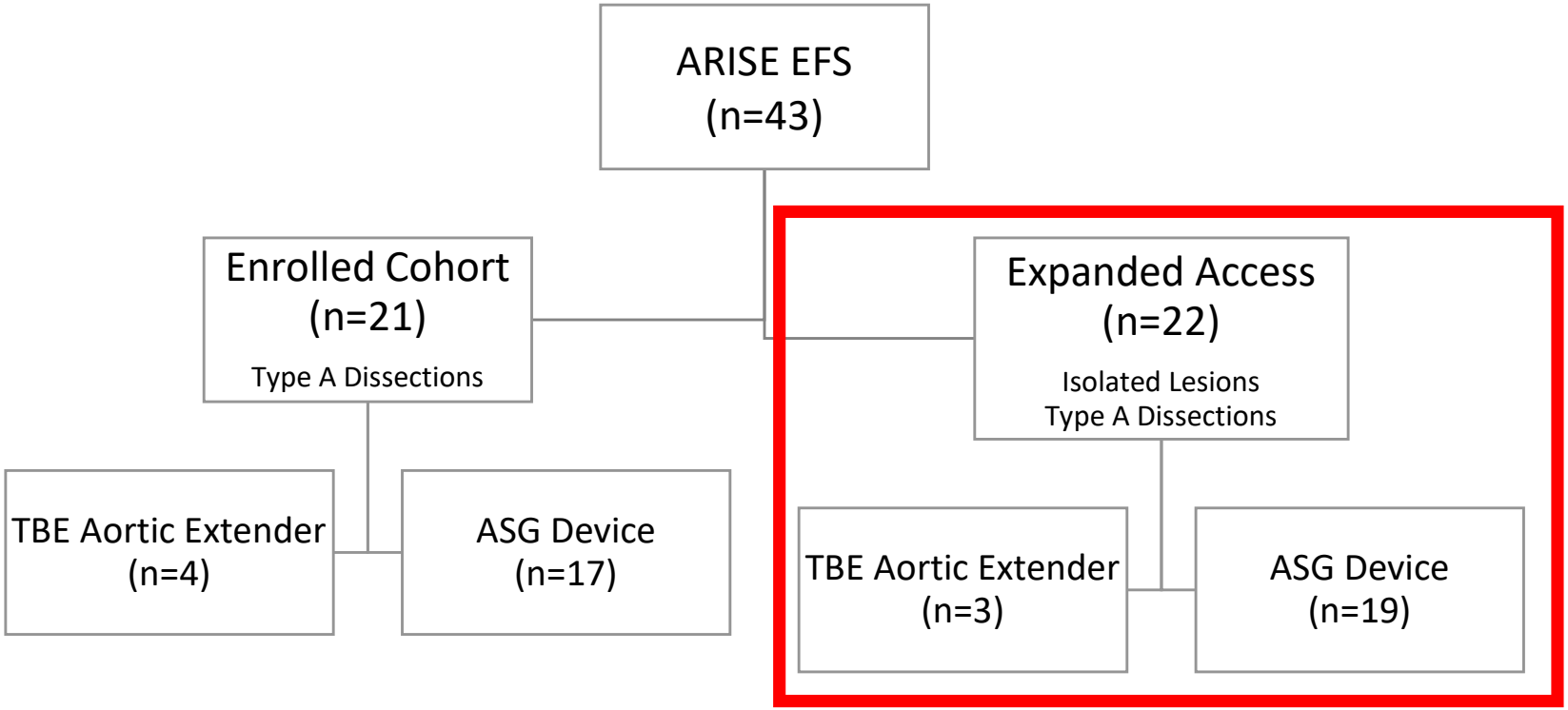
Roselli EE, Atkins MD, Brinkman W, et. Al ARISE: First-In-Human Evaluation of a Novel Stent Graft to Treat Ascending Aortic Dissection. J Endovasc Ther. 2023 Aug;30(4):550-560.

ARISE EFS: ASG Enrolled Cohort

Additional mid-term outcomes at 1 year with ASG Device

- Mortality
  - 1 additional late-mortality occurred within 1 year, non-aortic due to pneumonia
- Neurological events
  - 1 moderate severity at POD 61 with arch atheroma identified as a likely cause, no treatment and resolved with sequelae
- Endoleaks
  - 1 additional Type III endoleak documented within 1 year, unresolved with reintervention, open repair at 3.5 years

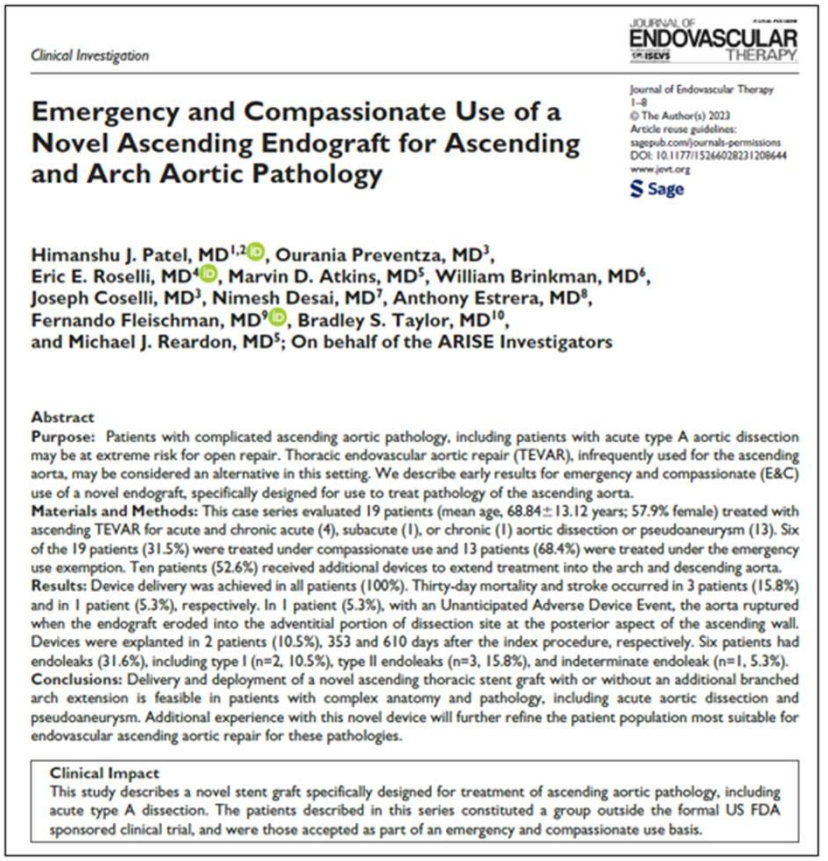
ARISE EFS: Expanded Access



ASG device: GORE® Ascending Stent Graft
TBE: GORE® TAG Thoracic Branch Endoprosthesis

ARISE Emergency & Compassionate Use and Non-Dissection Pathologies

- Expanded Emergency Use
  - The ASG device received E&C use for 22 pts.
- Non-Dissection Pathologies Treated
  - ASG for PSA's, aneurysms, and PAU's in the ascending aorta.
- Clinical Outcomes
  - 30-day mortality (15.8%) and stroke (5.3%)
- Device Versatility
  - ASG device shows potential to treat broad aortic pathologies using endovascular approaches alone or combined.



Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY

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1–8
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DOI: 10.1177/15266028231208644
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Sage

Emergency and Compassionate Use of a Novel Ascending Endograft for Ascending and Arch Aortic Pathology

Himanshu J. Patel, MD[1,2], Ourania Preventza, MD[3], Eric E. Roselli, MD[4], Marvin D. Atkins, MD[5], William Brinkman, MD[6], Joseph Coselli, MD[3], Nimesh Desai, MD[7], Anthony Estrera, MD[8], Fernando Fleischman, MD[9], Bradley S. Taylor, MD[10], and Michael J. Reardon, MD[5]; On behalf of the ARISE Investigators

Abstract

Purpose: Patients with complicated ascending aortic pathology, including patients with acute type A aortic dissection may be at extreme risk for open repair. Thoracic endovascular aortic repair (TEVAR), infrequently used for the ascending aorta, may be considered an alternative in this setting. We describe early results for emergency and compassionate (E&C) use of a novel endograft, specifically designed for use to treat pathology of the ascending aorta.

Materials and Methods: This case series evaluated 19 patients (mean age, 68.84±13.12 years; 57.9% female) treated with ascending TEVAR for acute and chronic acute (4), subacute (1), or chronic (1) aortic dissection or pseudoaneurysm (13). Six of the 19 patients (31.5%) were treated under compassionate use and 13 patients (68.4%) were treated under the emergency use exemption. Ten patients (52.6%) received additional devices to extend treatment into the arch and descending aorta.

Results: Device delivery was achieved in all patients (100%). Thirty-day mortality and stroke occurred in 3 patients (15.8%) and in 1 patient (5.3%), respectively. In 1 patient (5.3%), with an Unanticipated Adverse Device Event, the aorta ruptured when the endograft eroded into the adventitial portion of dissection site at the posterior aspect of the ascending wall. Devices were explanted in 2 patients (10.5%), 353 and 610 days after the index procedure, respectively. Six patients had endoleaks (31.6%), including type I (n=2, 10.5%), type II endoleaks (n=3, 15.8%), and indeterminate endoleak (n=1, 5.3%).

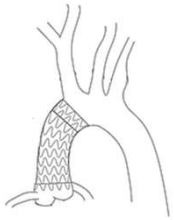
Conclusions: Delivery and deployment of a novel ascending thoracic stent graft with or without an additional branched arch extension is feasible in patients with complex anatomy and pathology, including acute aortic dissection and pseudoaneurysm. Additional experience with this novel device will further refine the patient population most suitable for endovascular ascending aortic repair for these pathologies.

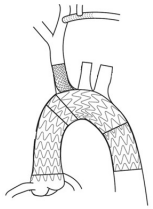
Clinical Impact

This study describes a novel stent graft specifically designed for treatment of ascending aortic pathology, including acute type A dissection. The patients described in this series constituted a group outside the formal US FDA sponsored clinical trial, and were those accepted as part of an emergency and compassionate use basis.

Patel HJ, Preventza O, Roselli EE, et. al. Emergency and Compassionate Use of a Novel Ascending Endograft for Ascending and Arch Aortic Pathology. J Endovasc Ther. 2023

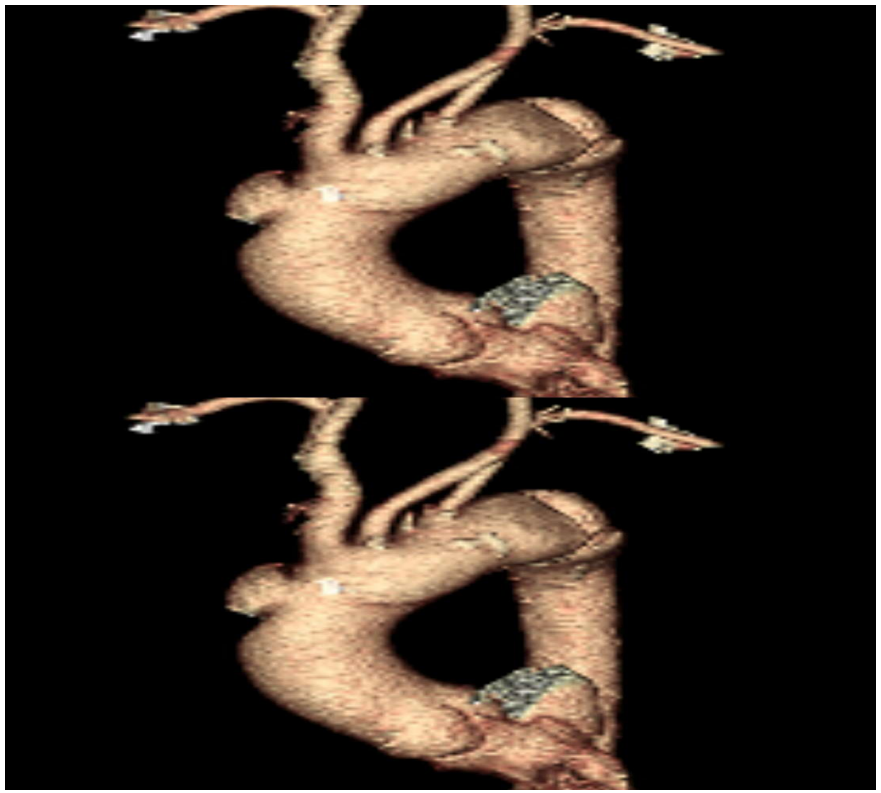
ARISE II Pivotal Study Design

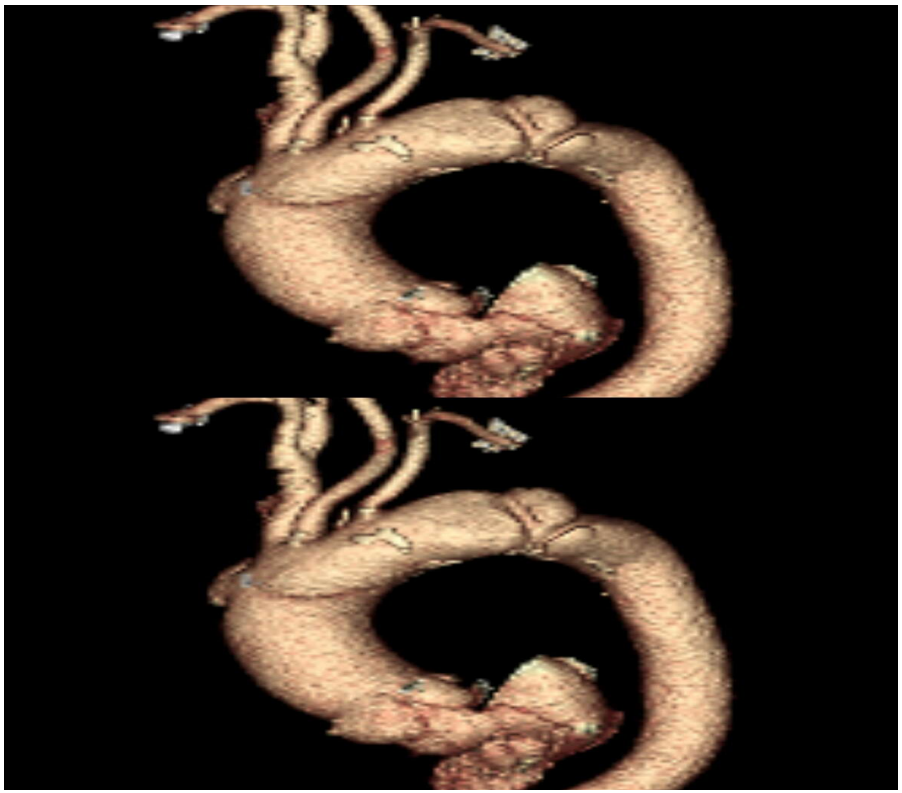




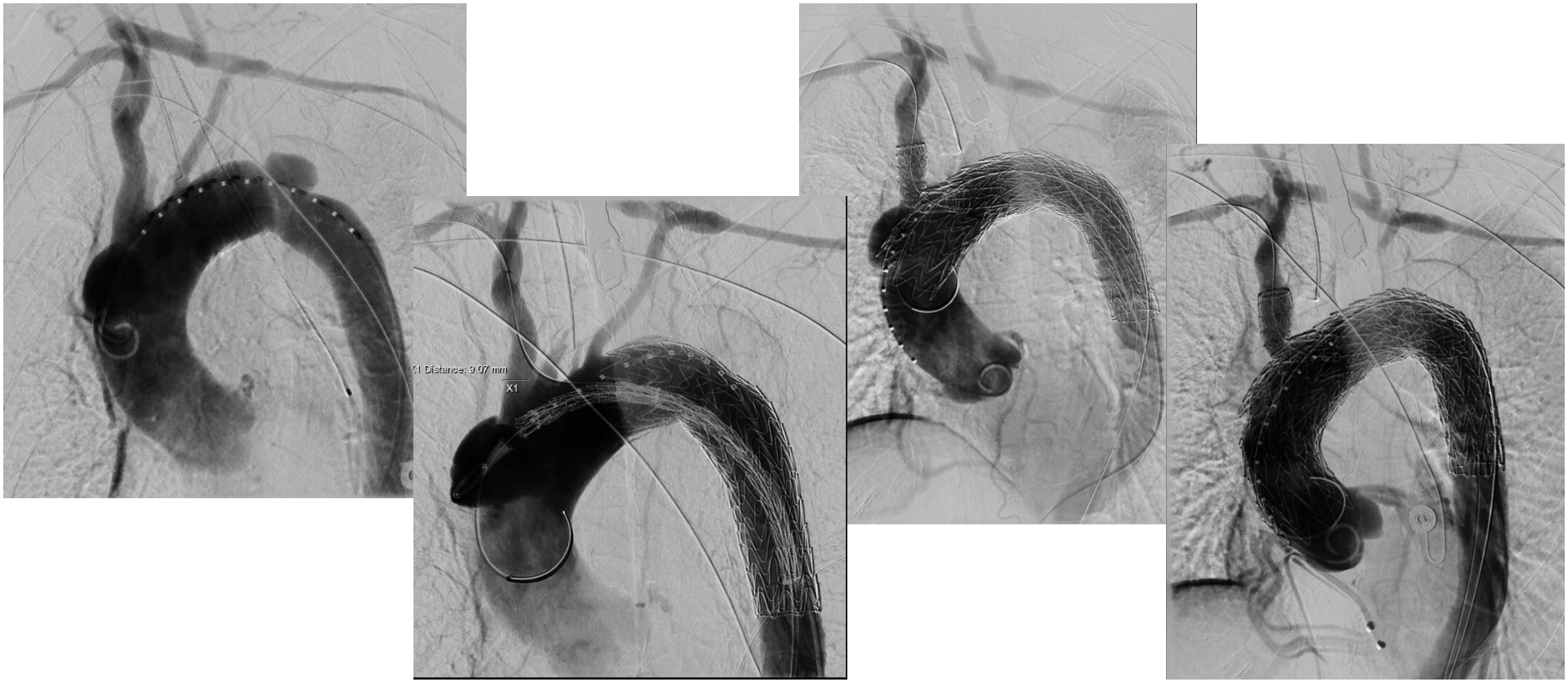
	Primary Arm (N=70)	**Secondary Arm** (N=50-150)	**Surgical Follow-up** (N=50-150)
Procedure/Devices	ASG device	ASG device + TBE device	Open surgical repair
Patient Characteristics	High-risk surgical patient	High-risk surgical patient	High-risk surgical patient not meeting requirements for enrollment in primary or secondary arm
Disease States	Isolated aortic lesion of ascending aorta (aneurysms, pseudo aneurysms, PAU)	Isolated aortic lesion or chronic dissection that requires arch treatment	Same as primary and secondary (Anatomic screen fail)

72 yo man with TAAD + IMH + DTAA

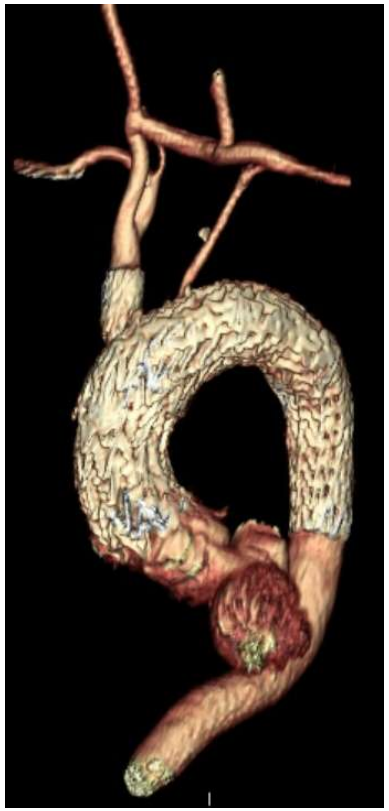


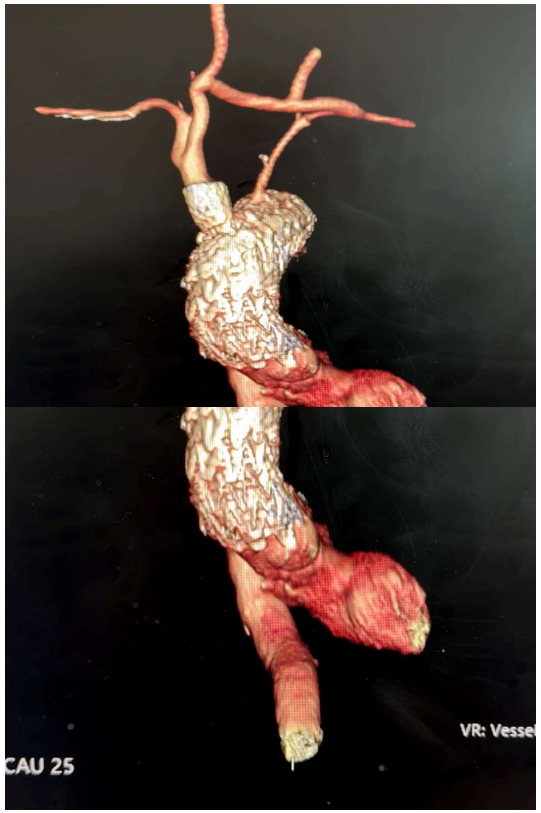


GORE Zone 0 TBE + ASG



Follow Up CTA at 1 year





ARISE II Activated Sites and Investigators

- Currently there are 34 activated sites
- We will be continuing to initiate the invited sites throughout the winter and spring.
- For additional information please visit clinicaltrials.gov (NCT05800743)

Site Name	Investigator	Location
Washington University - St Louis	Kachroo	St. Louis, MO
Hartford Hospital	Cheema	Hartford, CT
University of Pittsburgh Medical Center	Sultan	Pittsburgh, PA
Mayoclinic - Rochester	Shrestha	Rochester, MN
Medical University of South Carolina	Zeigler	Charleston, SC
University of Washington	Burke	Seattle, WA
Atrium Health	Frederick	Charlotte, NC
UAB Hospital	Eudaily	Birmingham, AL
Ohio Health Research Institute /Riverside Methodist	Lyons	Columbus, OH
Froedtert & Medical College of Wisconsin	Ali	Milwaukee, WI
Westchester Medical Center	Ohira	Valhalla, NY
Corewell Health	Leung	Grand Rapids, MI
Cedars-Sinai Medical Center	Menga	Los Angeles, CA
Hackensack University Hospital	Dudiy	Hackensack, NJ
West Virginia University	Wei	Morgantown, WV
MemorialCare Heart & Vascular Institute	Khoynezhad	Long Beach, CA

ARISE II Activated Sites and Investigators

- Currently there are 34 activated sites
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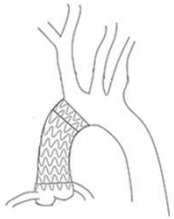
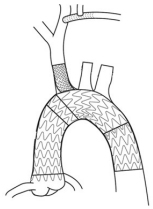
- For additional information please visit clinicaltrials.gov (NCT05800743)

Site Name	Investigator	Location
The Stanford Hospital	Watkins	Stanford, CA
Northwestern University	Mehta	Evanston, IL
Indianapolis University Hospital	Covera	Indianapolis, IN
Cleveland Clinic Foundation	Vargo	Cleveland, OH
Baylor Research Institute	Brinkman	Dallas, TX
Massachusetts General Hospital	Jassar	Boston, MA
Emory University Hospital	Leshnower	Atlanta, GA
University of Florida – Gainesville	Beaver	Gainesville, FL
University of Pennsylvania Hospital	Desai	Philadelphia, PA
University of Michigan	Patel	Ann Arbor, MI
University of Maryland	Taylor	Baltimore, MD
Duke University Medical Center	Hughes	Durham, NC
The Methodist Hospital – Houston	Atkins	Houston, TX
University of Southern California	Fleischman	Los Angeles, CA
Sentara Norfolk General Hospital	Barreiro	Norfolk, VA
MedStar Health Research Institute	Shults	Hyattsville, MD
Intermountain Medical Center	Doty	Salt Lake City, UT
Cardiothoracic & Vascular Surgeons	Felger	Austin, TX

ARISE III Pivotal Study Design





	Primary Arm (N=62)	**Secondary Arm** (N=50)
Devices	ASG device	ASG device OR ASG device + TBE device
Patient Characteristics	High-risk surgical patient	High-risk surgical patient
Dissection Characteristics	Type A dissection with ascending primary tear Within 30 days from onset	Type A dissection with arch primary tear, or ascending tear that does not qualify for primary arm Within 90 days from onset

ARISE III Activated Sites and Investigators

- Currently there are 8 activated sites
- We will be continuing to initiate the invited sites.
- For additional information please visit clinicaltrials.gov (NCT06827990)

Site Name	Investigator	Location
Cleveland Clinic Foundation	Vargo	Cleveland, OH
Emory University Hospital	Leshnower	Atlanta, GA
University of Florida – Gainesville	Beaver	Gainesville, FL
Baylor Research Institute	Brinkman	Dallas, TX
University of Michigan	Patel	Ann Arbor, MI
University of Alabama at Birmingham	Eudailey	Birmingham, AL
Duke University Medical Center	Hughes	Durham, NC
Northwestern University	Mehta	Evanston, IL
Ohio Health Research Institute /Riverside Methodist	Lyons	Columbus, OH
Massachusetts General Hospital	Jassar	Boston, MA
The Methodist Hospital – Houston	Atkins	Houston, TX

ARISE III and Long-Term Outlook

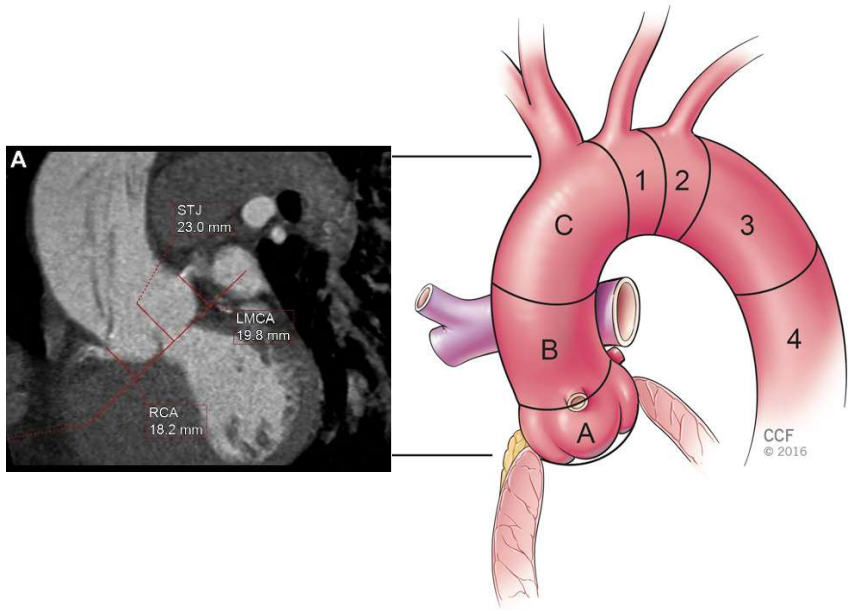
- ARISE III Trial Focus
  - The ARISE III trial targets acute TAADs in HR patients
- Current Treatment Standards
  - OSR remains the gold standard for TAAD treatment
- Endovascular Advancement
  - ASG devices and trials represent progress toward expanding endovascular treatment for TAAD patients.
- Future Treatment Potential
  - Ongoing research is expected to offer safer, effective alternatives for patients ineligible for open surgery.

Imaging characteristics of acute type A aortic dissection and candidacy for repair with ascending aortic endografts

Alexander P. Nissen, MD,[a,b] Laura Ocasio, MD,[c] Bruce L. Tjaden Jr, MD,[a,d] Harleen K. Sandhu, MD, MPH,[a] Roy F. Riascos, MD,[c,e] Hazim J. Safi, MD, FACS,[a,d] Anthony L. Estrera, MD, FACS,[a,d] *and* Kristofer M. Charlton-Ouw, MD, FACS,[a,d] *Houston and Fort Sam Houston, Tex*

Table V. Examination of individual exclusion criteria

Exclusion criteria	Patients excluded by this criterion alone
Static	
Stanford type A dissection	0
Proximal entry tear in ascending aorta	39
Native aortic valve without 3+ or worse insufficiency	30
Absence of any patent coronary artery bypass grafts from the ascending aorta	6
Adjustable	
Proximal entry tear	
≥20 mm distal to the most distal coronary ostia	56
≥15 mm	50
≥12 mm	40
≥10 mm	35
Landing zone diameter	
≤40 mm	88
≤42 mm	71
≤44 mm	65
≤46 mm	49
<48 mm	35

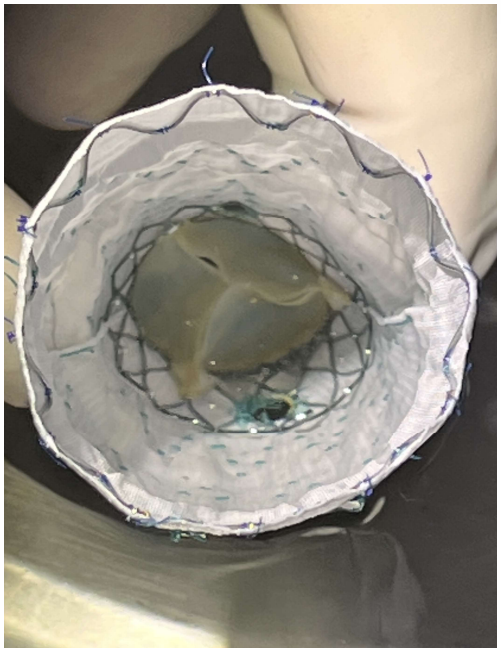


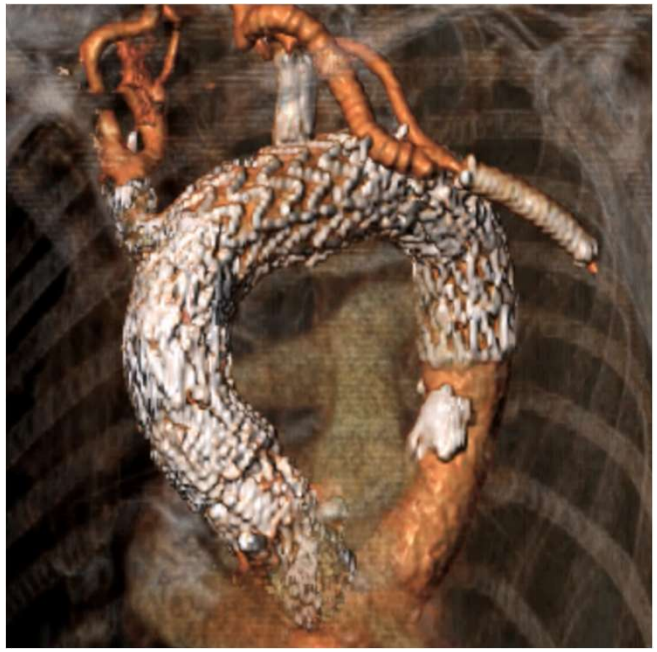
>30-60% of patients with TAAD require Z0A landing

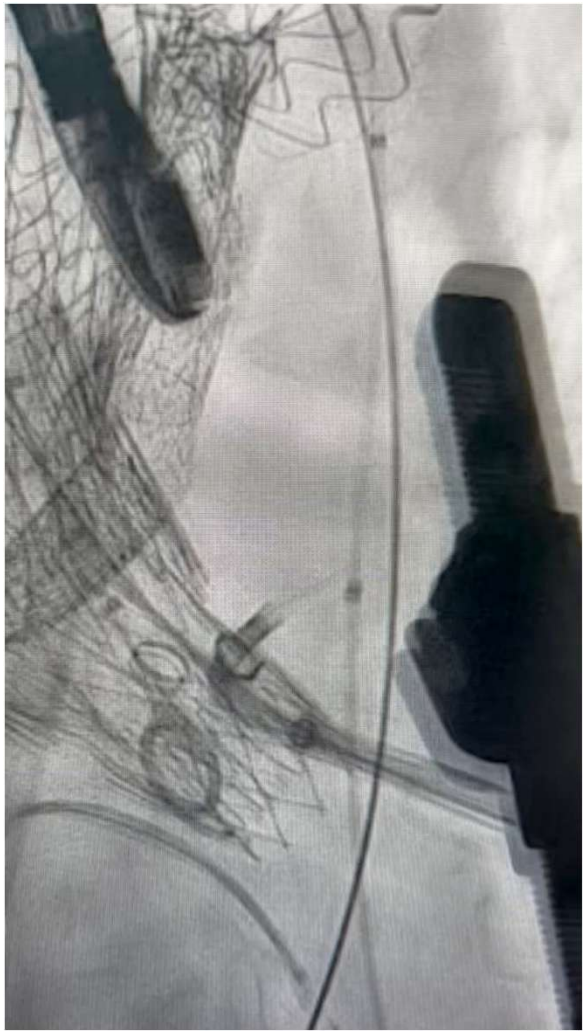
CASE REPORTS IN INTERVENTIONAL CARDIOLOGY

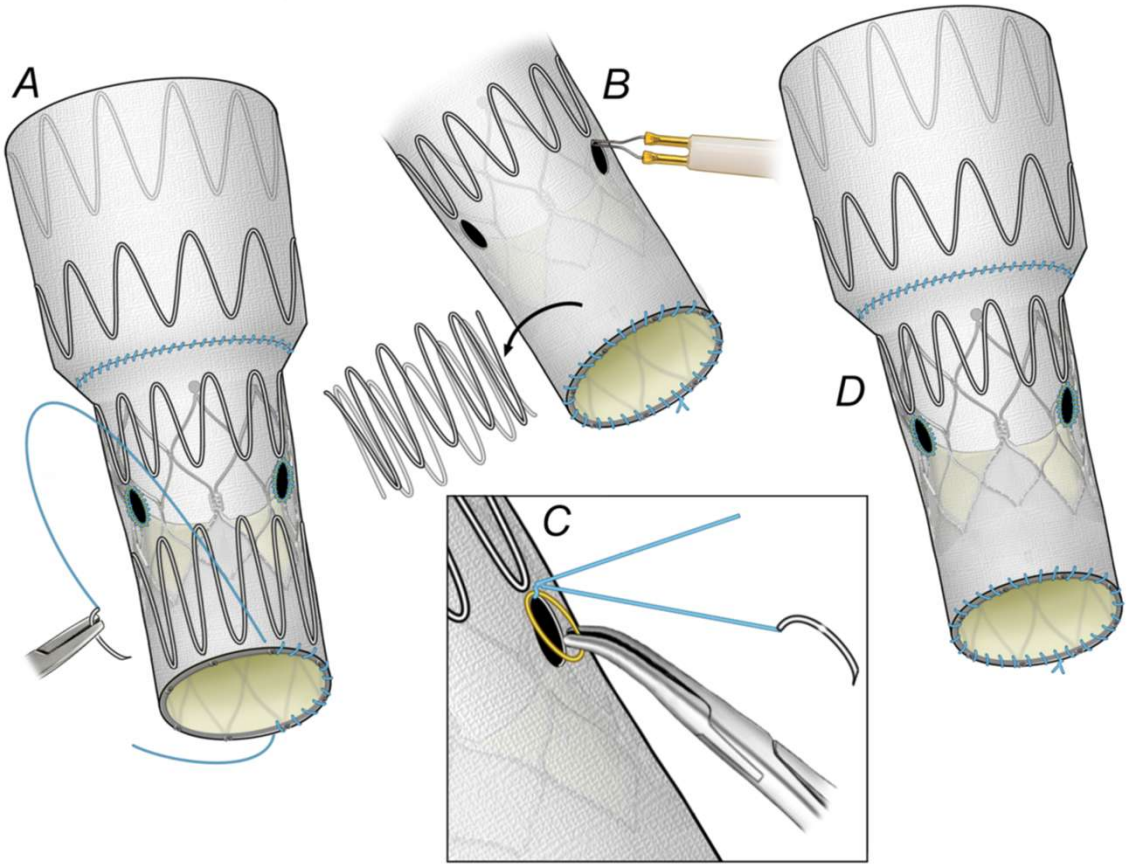
First-in-Human Endovascular Aortic Root Repair (Endo-Bentall) for Acute Type A Dissection

Mehrdad Ghoreishi, MD; Diljon Chahal, MD; Aakash Shah, MD; Jeanwan Kang, MD; Jeffrey Hirsch, MD; Douglas Tran, MD; Dana McCloskey, MD; Melsjan Shkullaku, MD; Anuj Gupta, MD; Erik R. Strauss, MD; Siamak Dahi, MD; Bradley S. Taylor, MD; Shahab Toursavadkohi, MD





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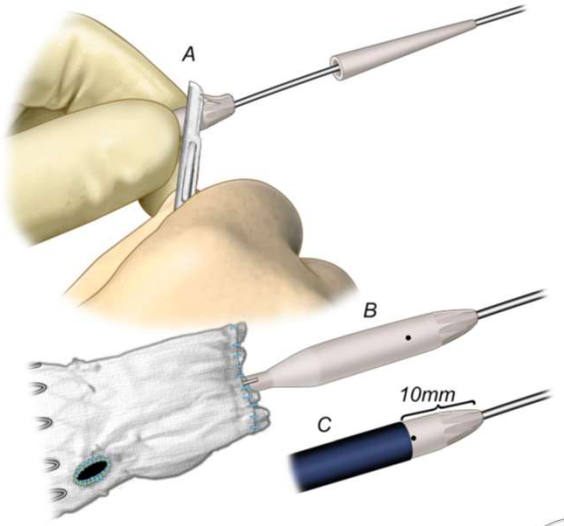
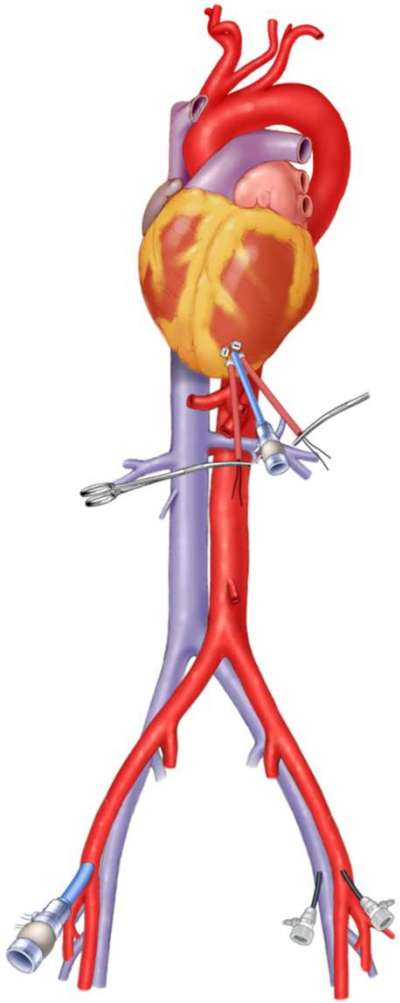
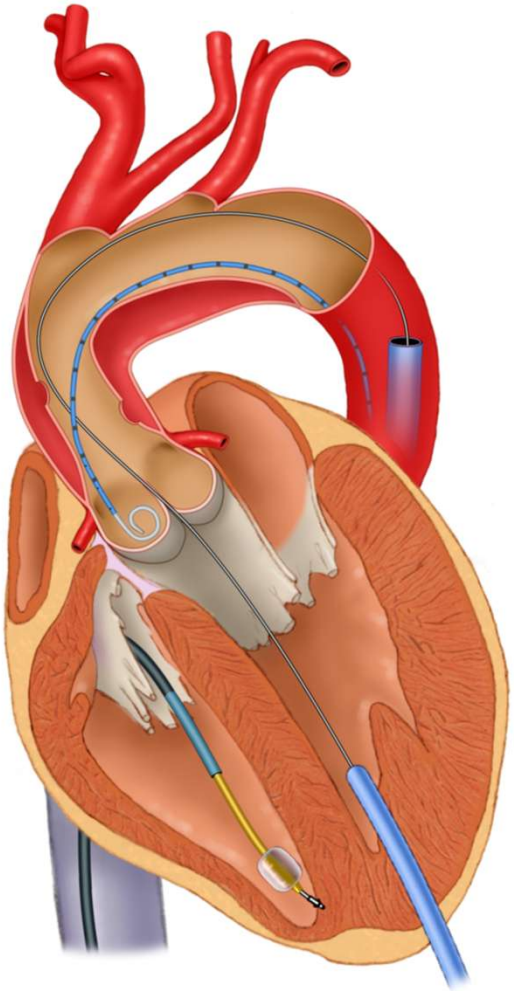
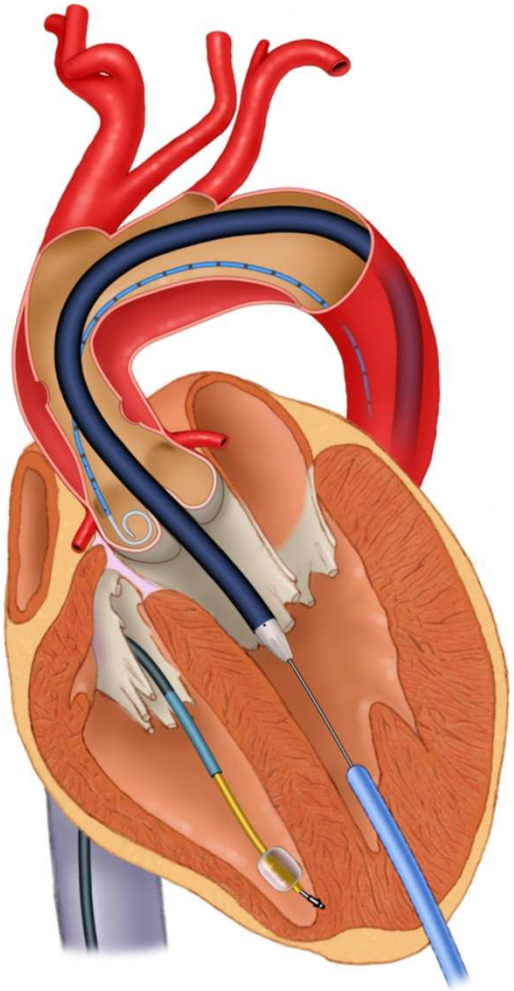
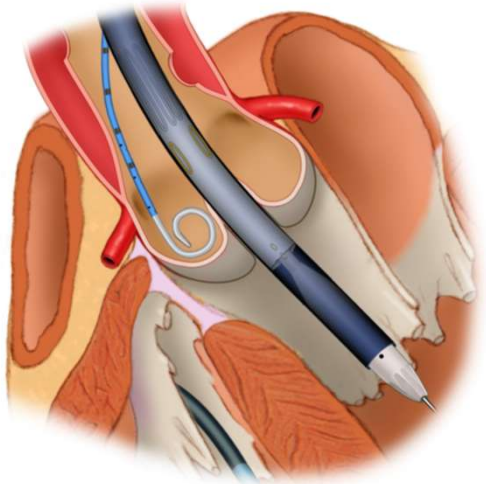
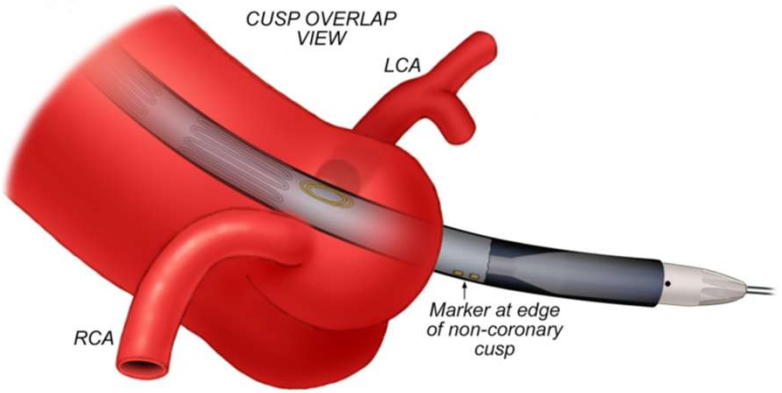

A
B
10mm
C










CUSP OVERLAP
VIEW
LCA
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of non-coronary
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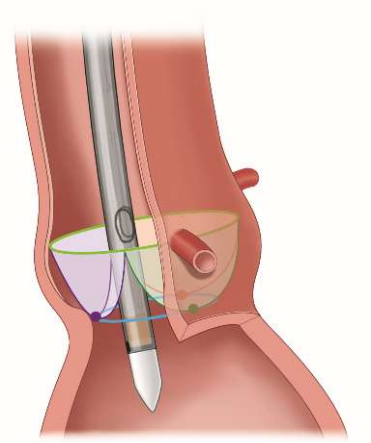
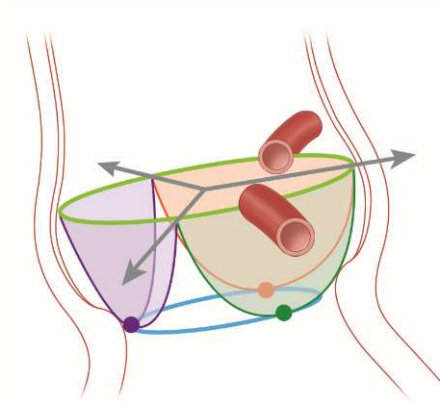
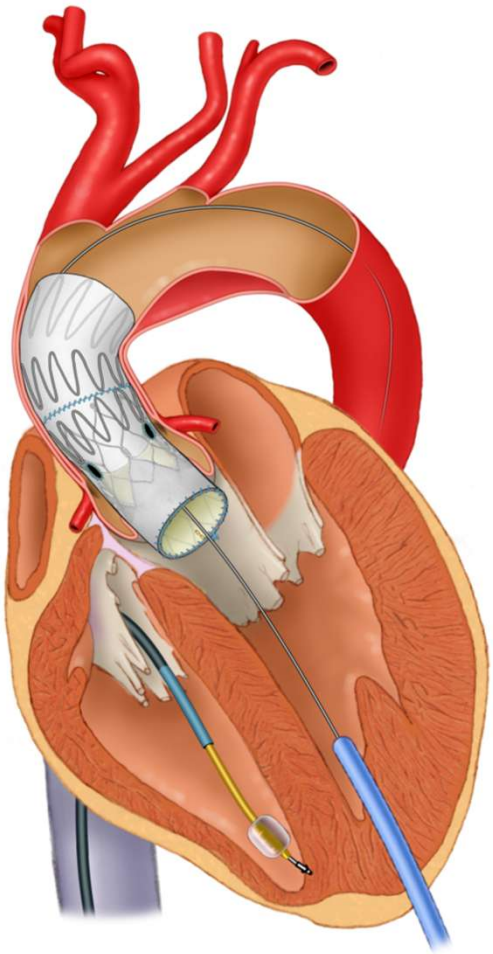
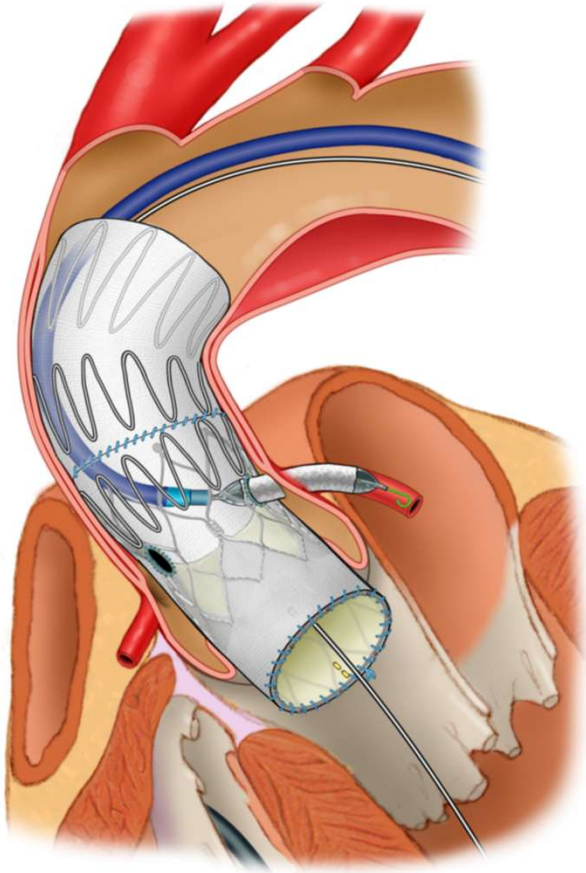
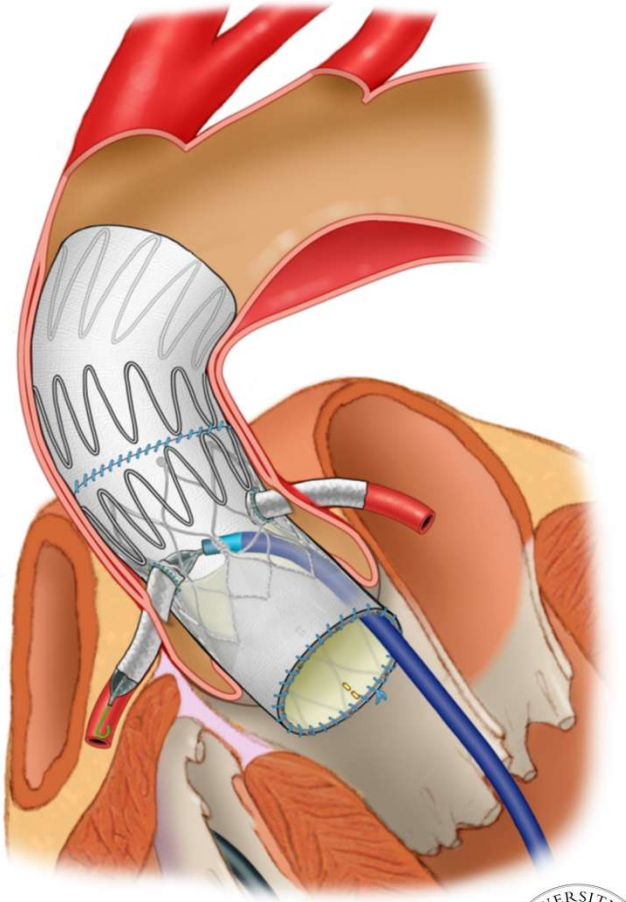
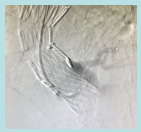
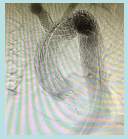
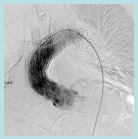
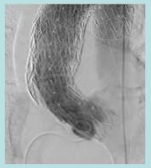
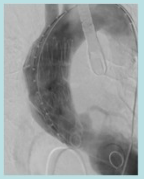




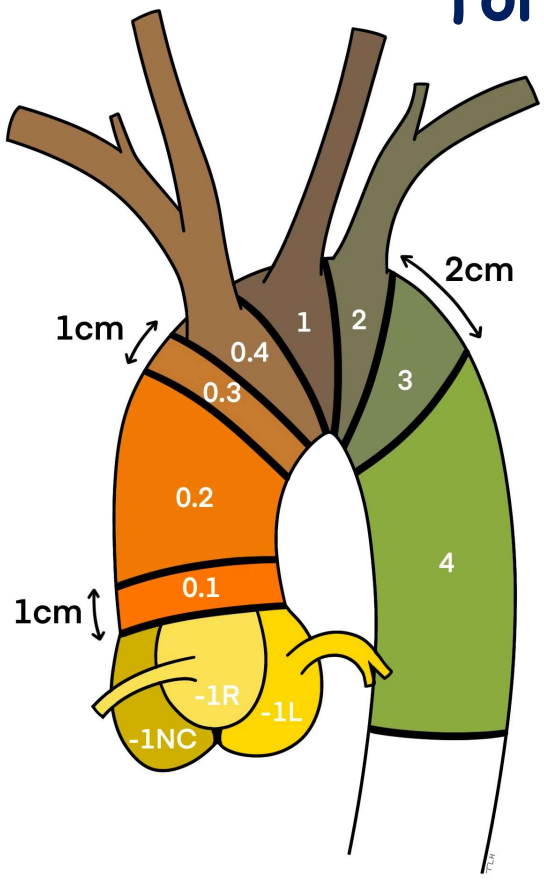






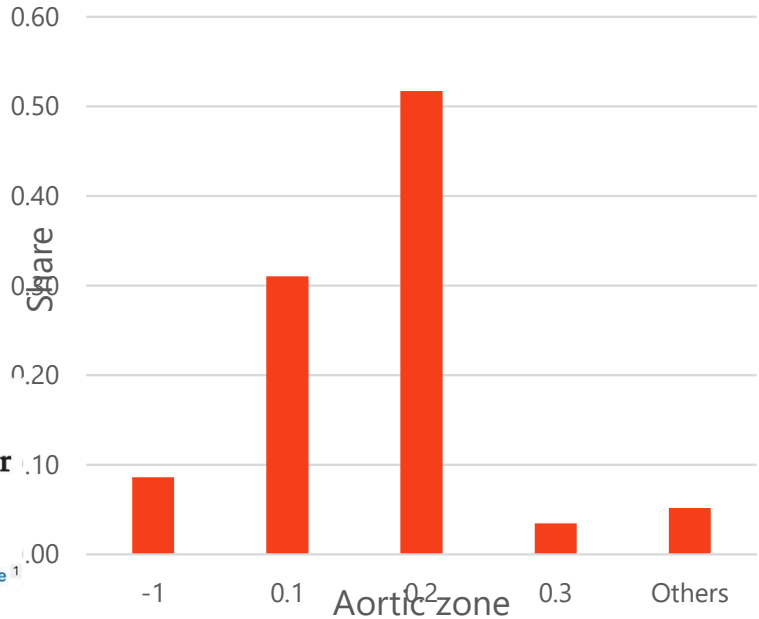
	Patient N#1	Patient N#2	Patient N#3	Patient N#4	Patient N#5	Patient N#6	Patient N#7	Patient N#8	Patient N#9	Patient N#10
										
Age-Gender	**63-yo female**	**85-yo female**	**58-yo female**	**85-yo female**	**66-yo male**	**77-yo male**	**88-yo female**	**78-yo female**	**86-yo female**	**86-yo female**
Etiology	**Acute Type A**	**Acute Type A**	**Acute Type A**	**Subacute Type A/Aneurysm**	**Acute Type A**	**Subacute Type A**	**Acute Type A Prior Ascending TEVAR**	**SINE Acute retrograde Type A**	**Acute Type A**	**Acute Type A**
Location of Tear	**Non-Coronary Cusp**	**Left Coronary Cusp**	**STJ**	**N/A**	**STJ/Innominate**	**STJ**	**STJ**	**Proximal Ascending**	**STJ**	**Ascending Aorta-STJ**
Repair	**Endo-Bentall**	**Endo-Bentall + Endo-Arch+ Coronary Stent**	**Endo-Bentall + Coronary Stent**	**Endo-Bentall + Coronary Stent**	**Endo-Bentall + Endo-Arch**	**Endo-Bentall + Endo-Arch**	**Endo-Bentall + Coronary Stent**	**Endo-Bentall + Endo-Arch**	**Endo-Bentall Open Conversion Ex-plantation**	**Endo-Bentall + Arch PETICOAT**

Anatomic feasibility of FBEVAR Endo-bentall treatment for acute type A aortic dissections



250 CT scans

Mean aortic annulus:
- diameter was 26.71mm (+/-3.71)
- perimeter was 87.7mm (+/- 17.7)
- surface was 571.2 mm²(+/-168.2)



> Ann Surg. 2024 Oct 1. doi: 10.1097/SLA.0000000000006548. Online ahead of print.

Anatomical Feasibility of Endobentall Strategies for Management of Acute type A Aortic Dissection

Aurelien Vallée [1 2], Guillaume Guimbretière [3], Julien Guihaire [1 2 4], Antoine Guery [5], Maira Gaillard [1], Le Houerou Thomas [1], Antoine Gaudin [1], Ramzi Ramadan [1], Deleuze Phillippe [1], Blandine Maurel [3], Jean Christian Roussel [3], Said Ghostine [6], André Vincentelli [7], Francis Juthier [7], Dominique Fabre [1 2], Jonathan Sobocinski [5], Stephan Haulon [1 2]

Affiliations + expand

PMID: 39351661 DOI: 10.1097/SLA.0000000000006548

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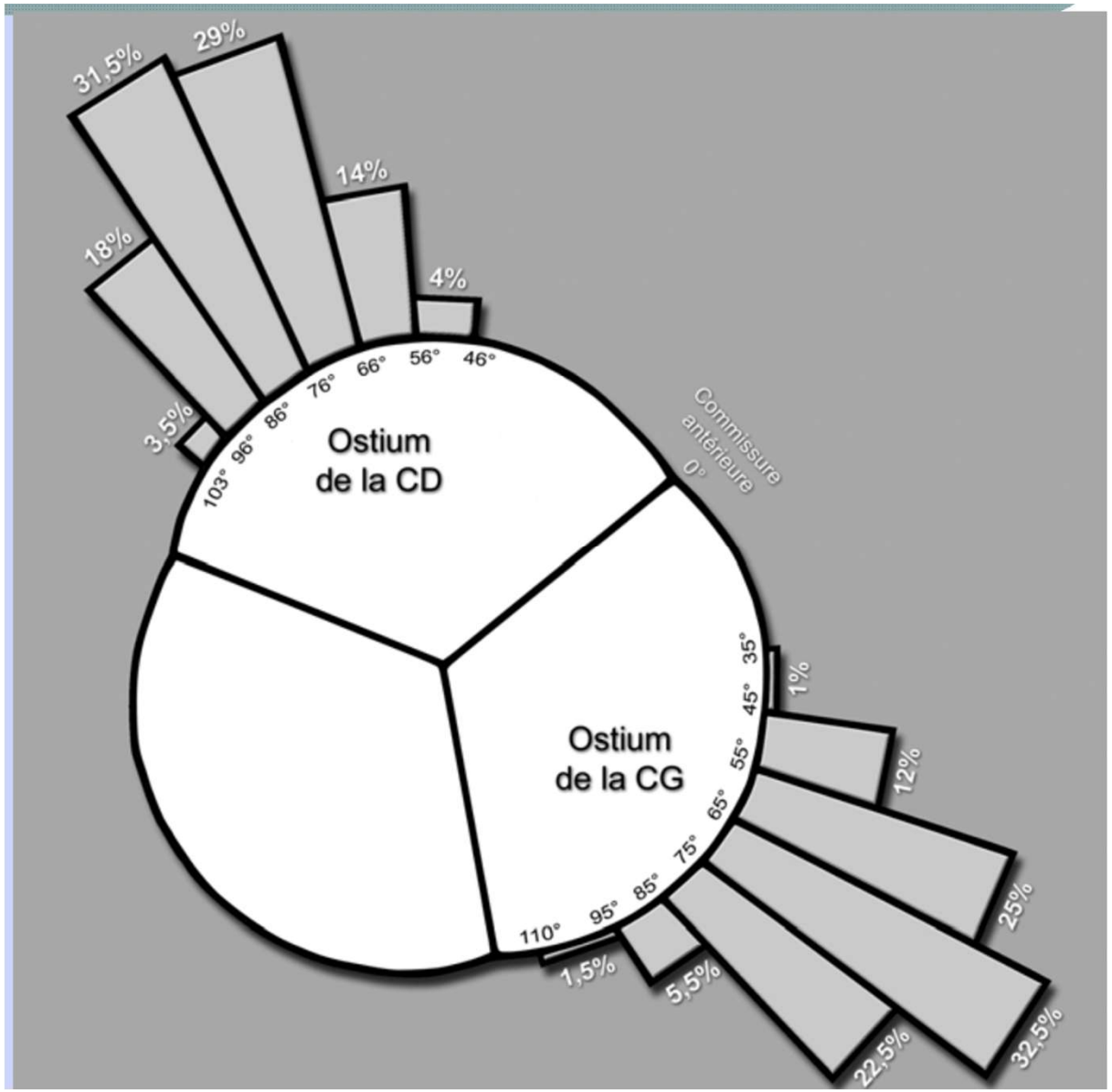

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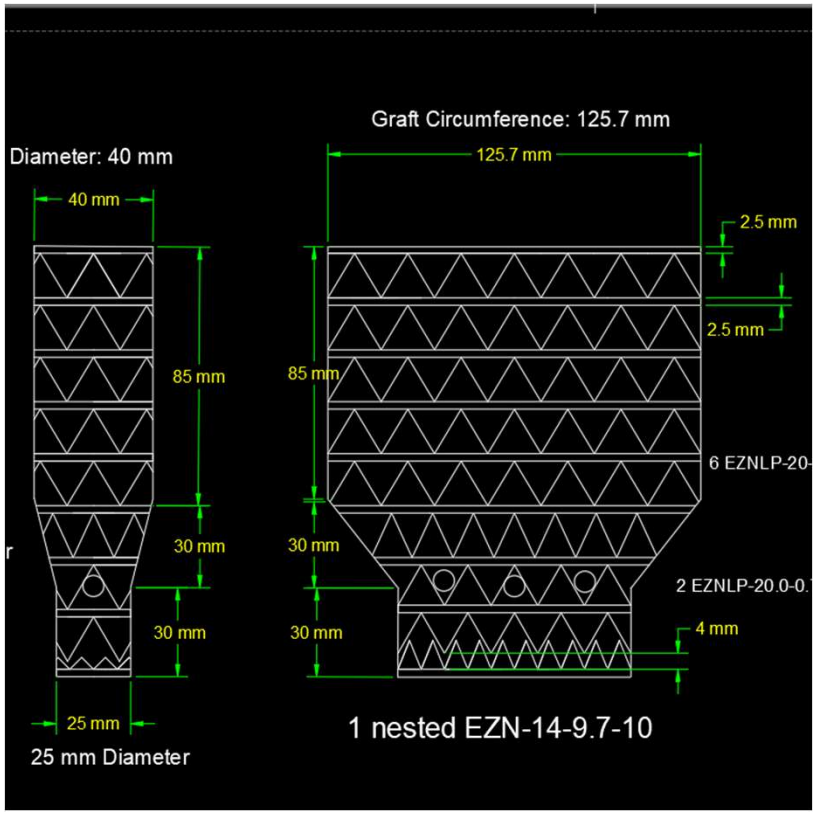

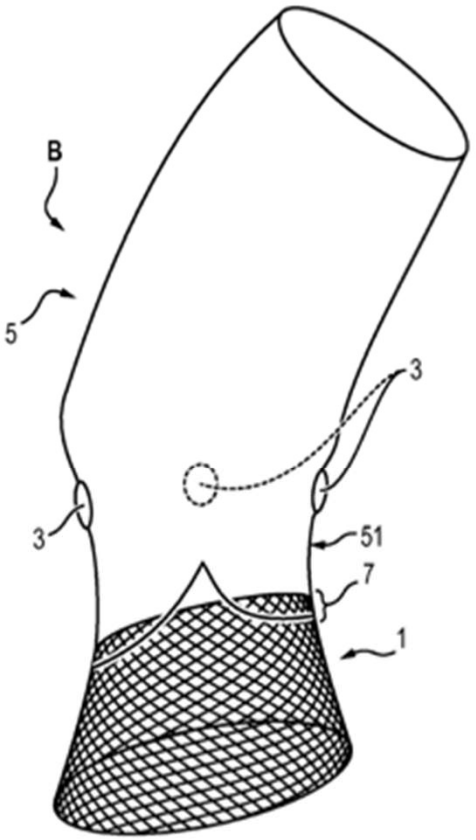

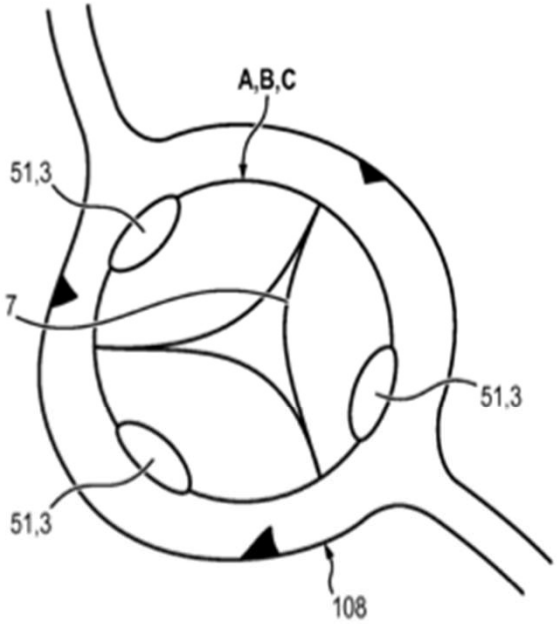

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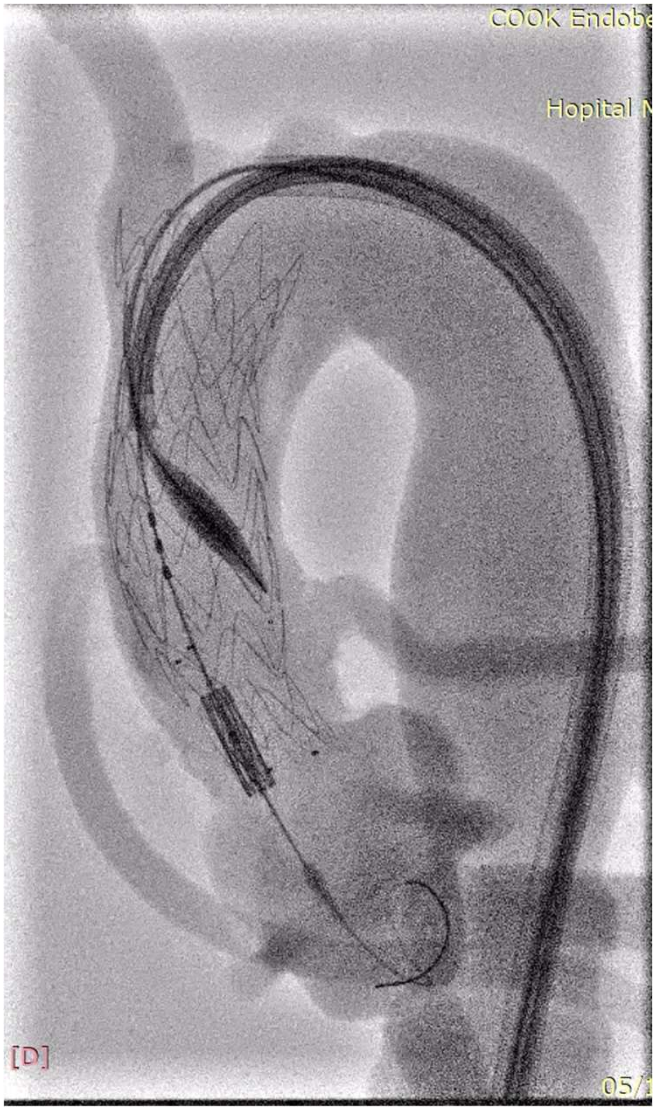

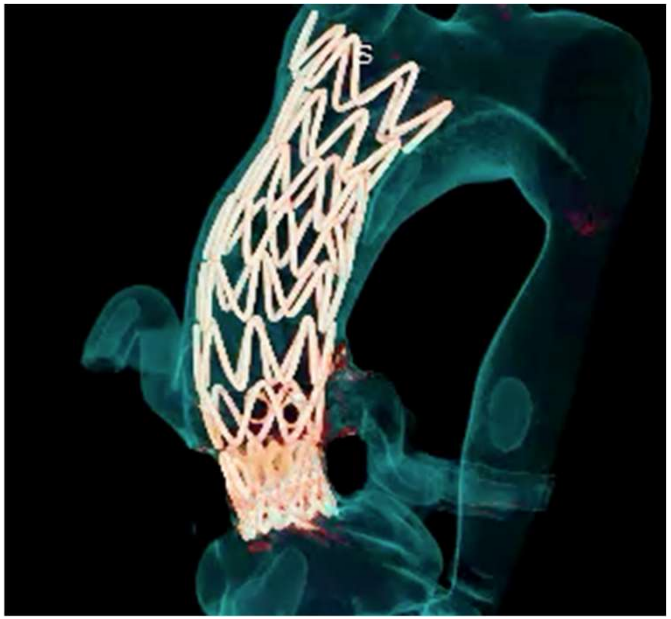

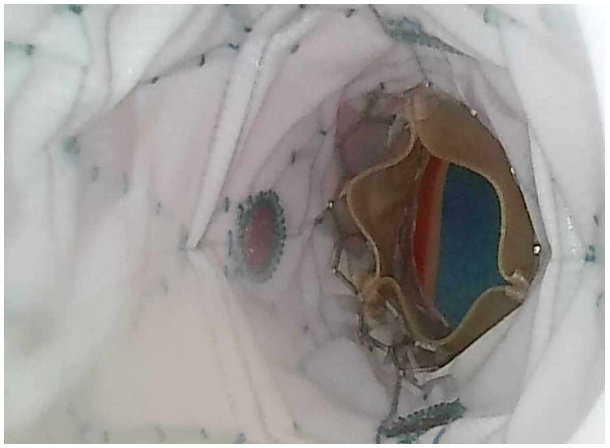

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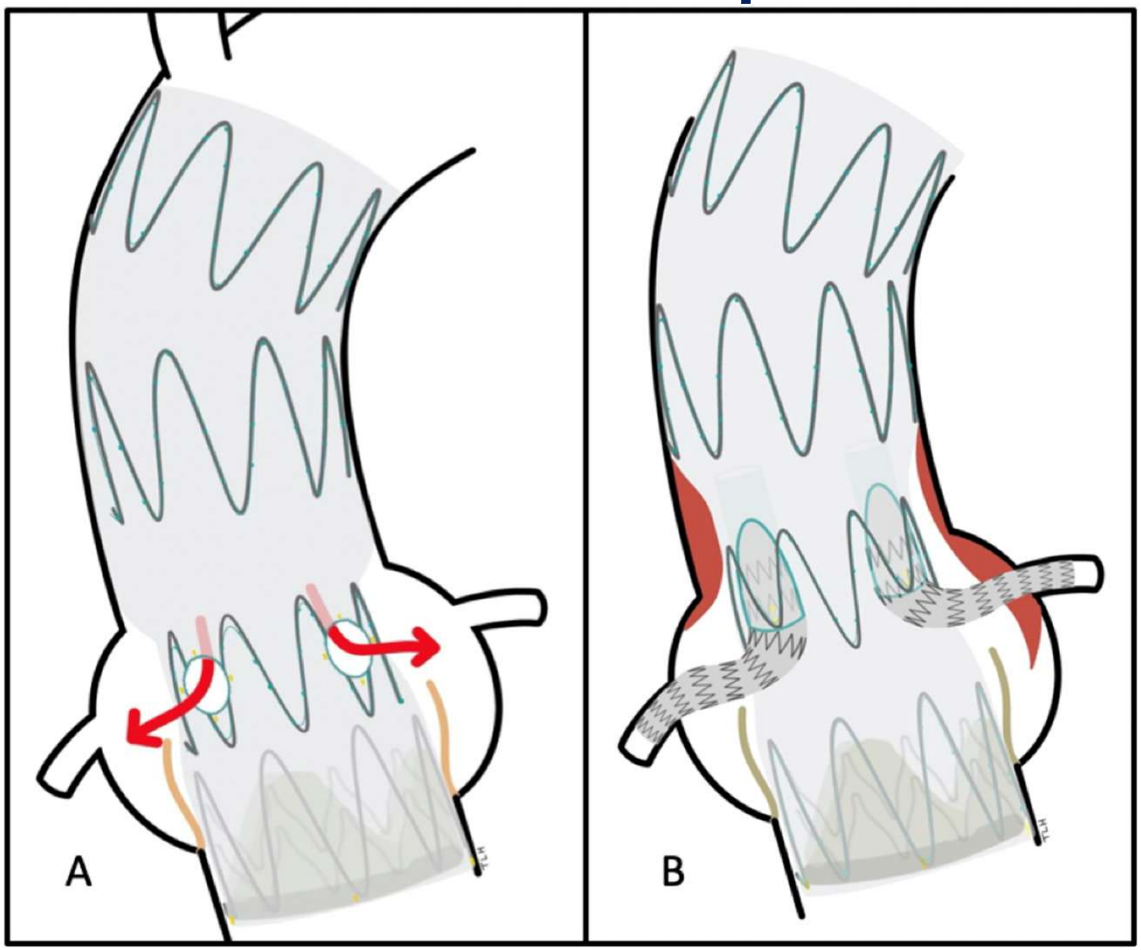
Acute Type A dissections / Ascending-Root Aneursyms
Two treatment options

Open Fenestrations
EndoWheat



Branched
Coronaries
EndoBentall

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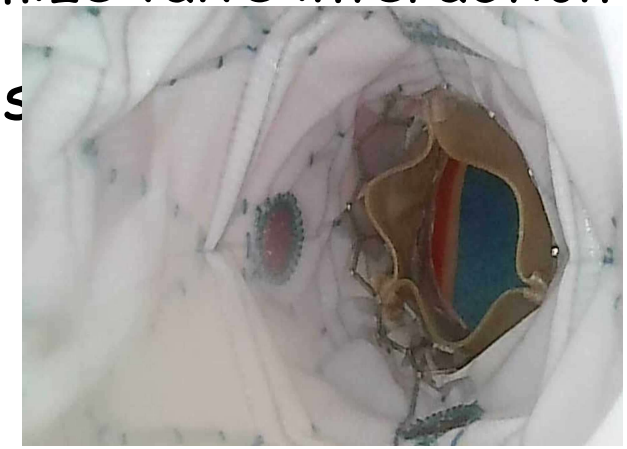
Key Design Updates
EndoGraft/Valve delivery system Compatibili

a. Fenestration locations – minimize potential valve interference

b. Proximal Graft seal – Exterior seal and fixation stent to anchor graft and minimize valve interaction

c. Distal Graft seal – Exterior to s
distal extension needed



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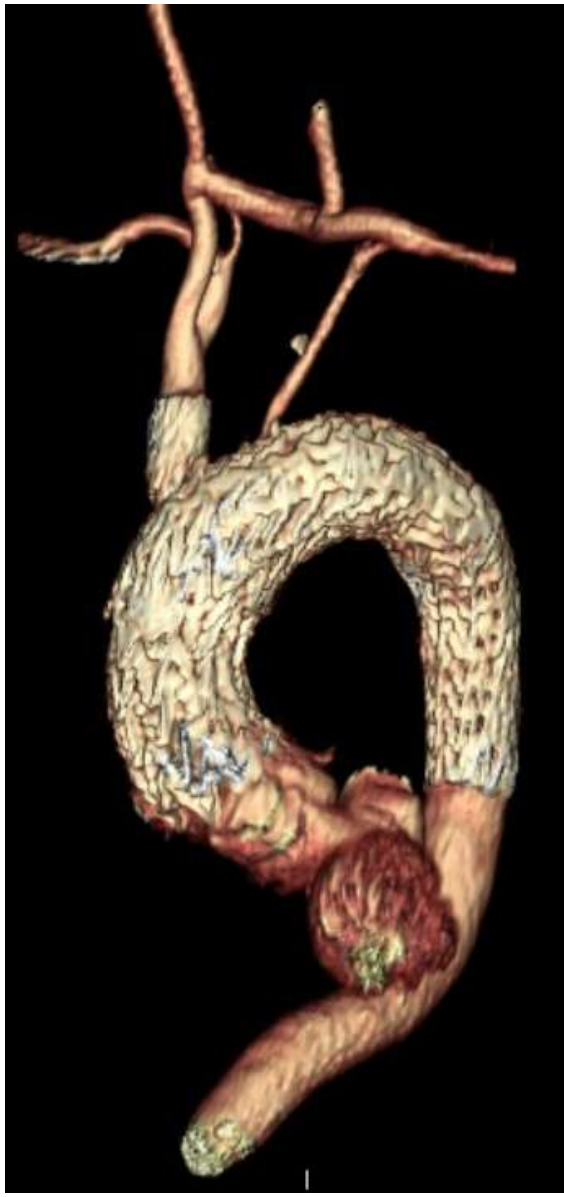
Endovascular Ascending Repair

- “The last frontier”
- Launch of ARISE III Pivotal trial for TAAD in the US
- EndoBentall & EndoWheat platforms in progress
- Tailor the therapy to the patient risk profile, anatomy, local expertise, and available technology
- Significant opportunities for innovation



Thank You

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