



Update on progress from Greenberg Stent Summit 2016

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MATADORS Dissection Collaboration Project:

Multidisciplinary study of **A**scending **T**issue characteristics **A**nd hemodynamics for the **D**evelopment of novel **aOR**tic **S**tentgrafts

Collaborators and Roles

Cleveland Clinic

- *Pt Enrollment, sample collection, epiaortic imaging, histologic assessment, proteomic/genetic analysis, protocol design, manuscript preparation*
 - Eric Roselli, MD – CT Surgery
 - Matthew Eagleton, MD –Vascular Surgery
 - Milind Desai, MD – Cardiovascular Medicine
 - Suneel Apte, M.B.B.S., D.Phil. –Biomedical Engineering
 - Kelly Emerton, PhD --Innovations
 - Jennifer Hargrave, DO – Anesthesiology
 - Frank Cikach – Lerner College of Medicine
 - Chris Koch – Biomedical Engineering
 - Zoran Popovic, MD --Cardiology
 - Wilson Tang, MD – Clinical Genomics/Cardiology

Medical Device Solutions

- *Mechanical testing and interpretation of results*
 - Karl West, MS
 - Robb Colbrunn, PhD

Industry

- *Industry partner, manuscript author, industry insight into project goals, statistics*
 - Michael Nilson—WL Gore
 - Tab Bonny – WL Gore
 - Scott Rush—Bolton
 - Sam Arbefeuille—Bolton
 - Blayne Roeder, PhD – Cook Medical
 - Jarin Kratzberg – Cook Medical
 - Justin Metcalf – MED Institute
 - Brandon Gulker – MED Institute
 - Julie Benton, PhD – Medtronic

FDA

- *Regulatory input, protocol design*
 - Valerie Merkle, PhD
 - Pablo Morales, MD
 - Dorothy Abel
 - Terry Woods, PhD



Clinical Importance

- ✓ No approved endovascular devices to treat ascending aorta
 - ✓ Significant morbidity associated with open repair, some inoperable
- ✓ Connective tissue disorder patients are excluded from endovascular studies
- ✓ Device design parameters important for aortic disease population
- ✓ Key vessel parameters required for endovascular graft design verification and validation testing

Study Objectives

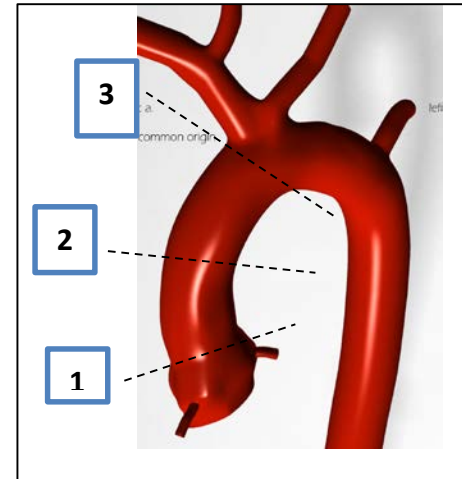
1. Create novel partnership: CCF (HVI + MDS) & FDA & Industry
2. Further understanding of ascending aortopathy (dissection and aneurysms).
3. Define boundary conditions for verification and validation testing
4. Determine tissue architecture and molecular changes to elucidate pathogenesis

Patients [CCF IRB Approval # 16-900]

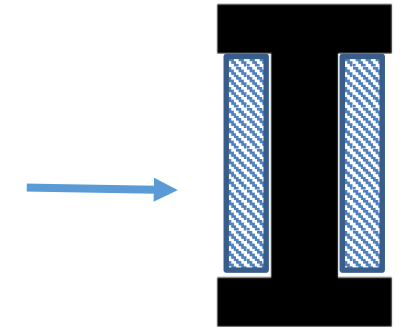
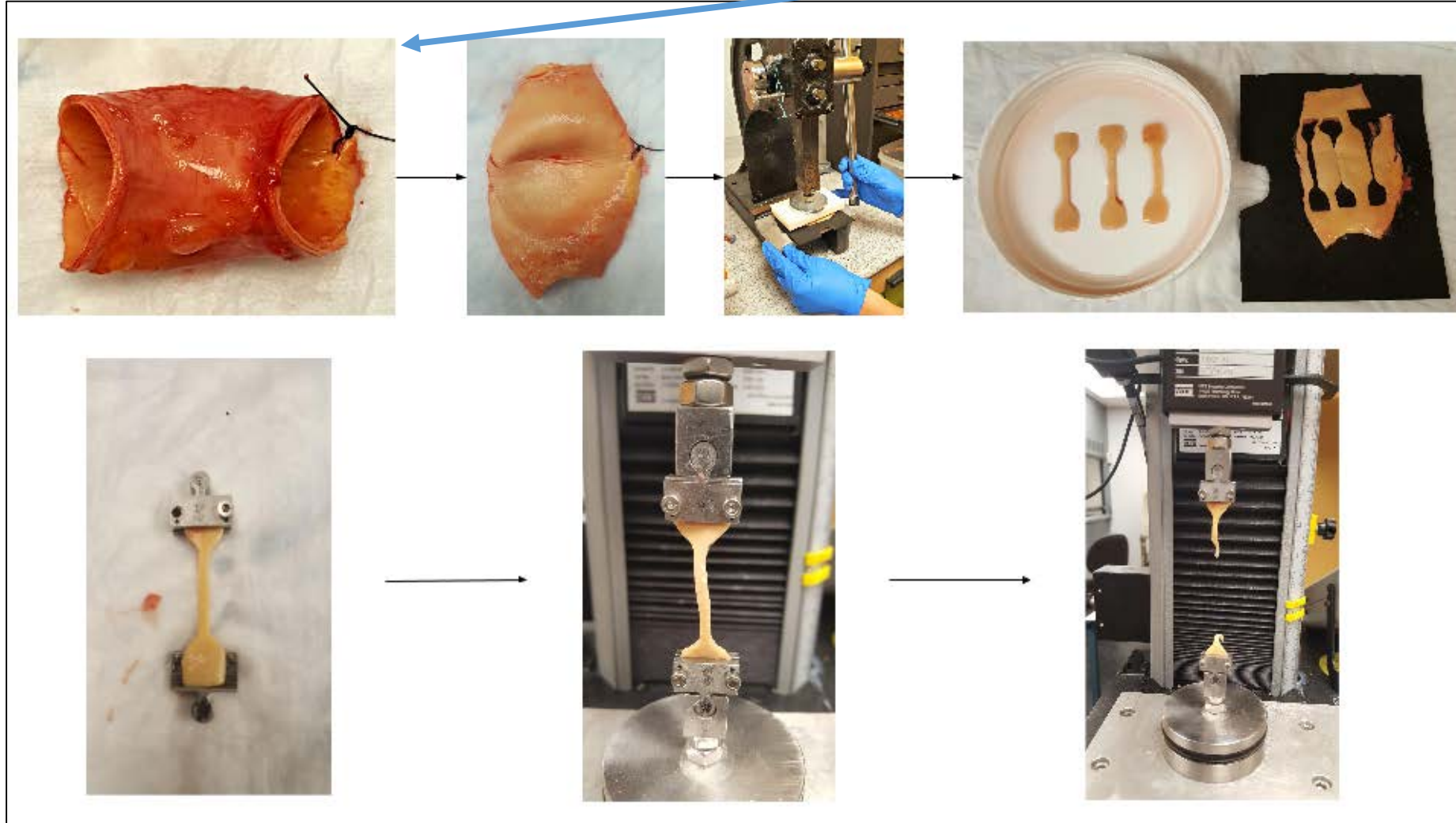
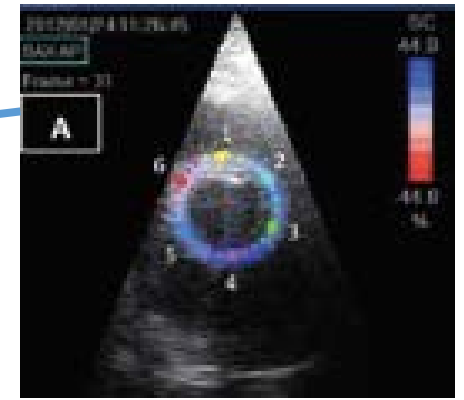
- Three arms (n=400 Total)
 1. Ascending dissection (study population)
 2. Ascending aneurysm (disease control)
 3. Transplant recipients and root replacements without aneurysm (non-disease control)

- Three regions of interest
 1. STJ
 2. Mid-ascending
 3. Distal ascending

- Preliminary patient count to date
 - Aneurysm -- **39**
 - Dissection -- **21**
 - Control/Reference--**5**



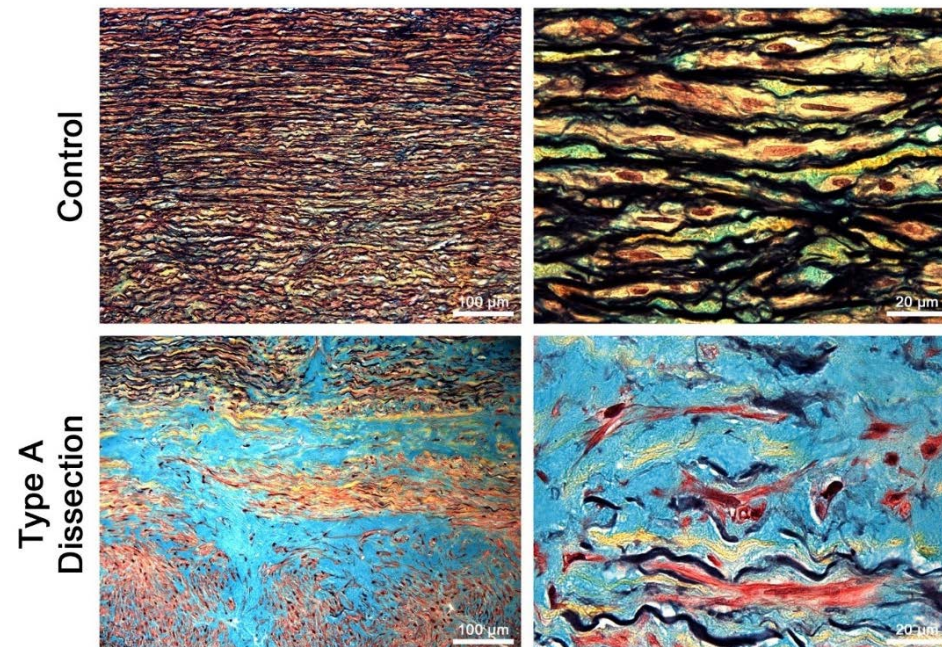
- Removed as standard of care
- Anterior, distal margin marked with suture/clip
- Tissue gathered fresh



Blue striped regions are for histology samples.

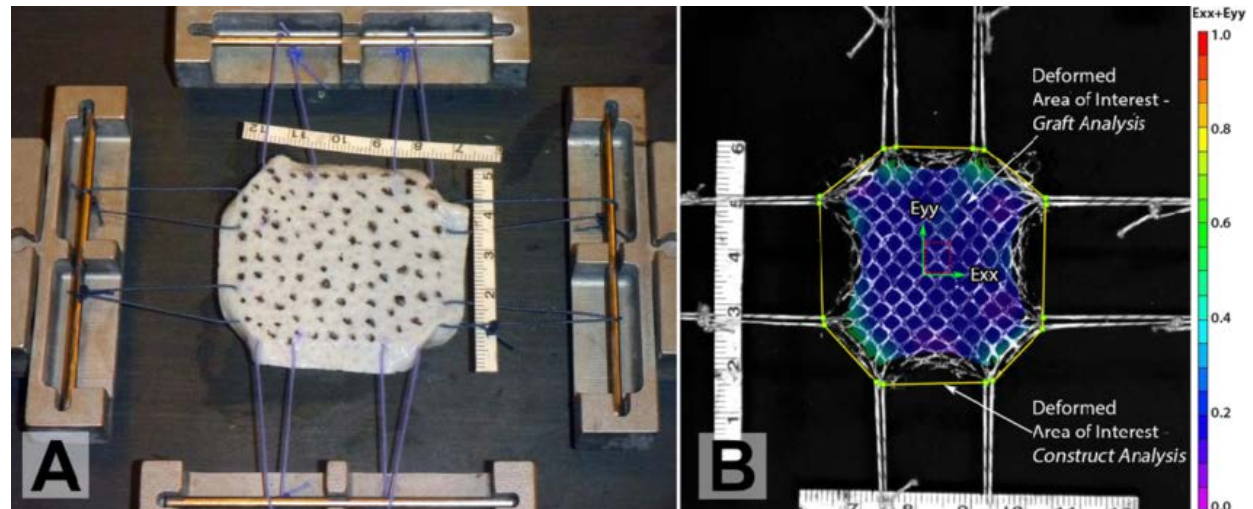
MATADORS Team Progress To Date

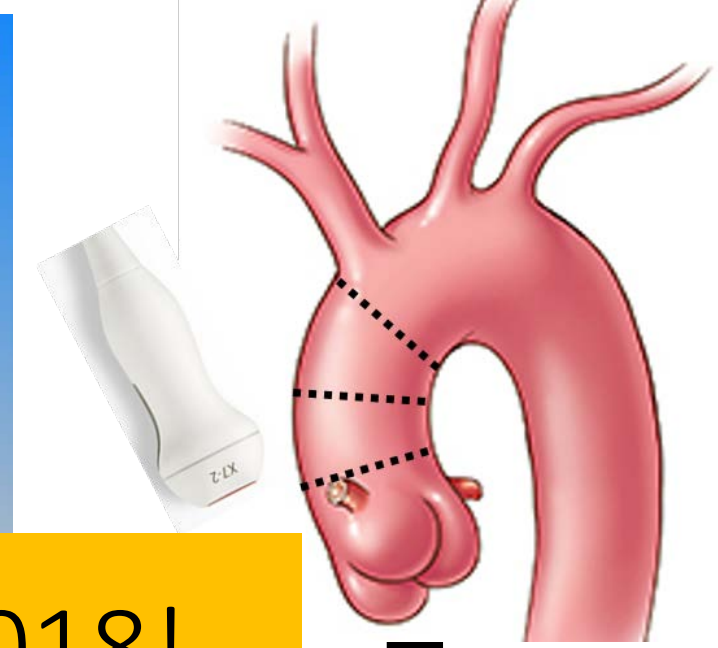
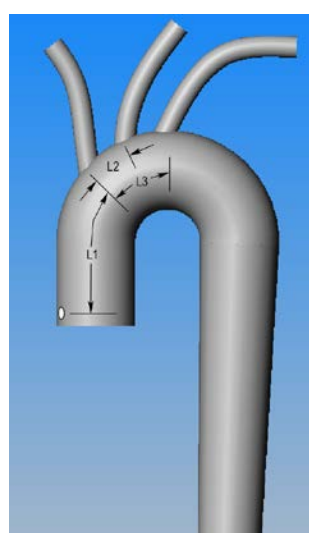
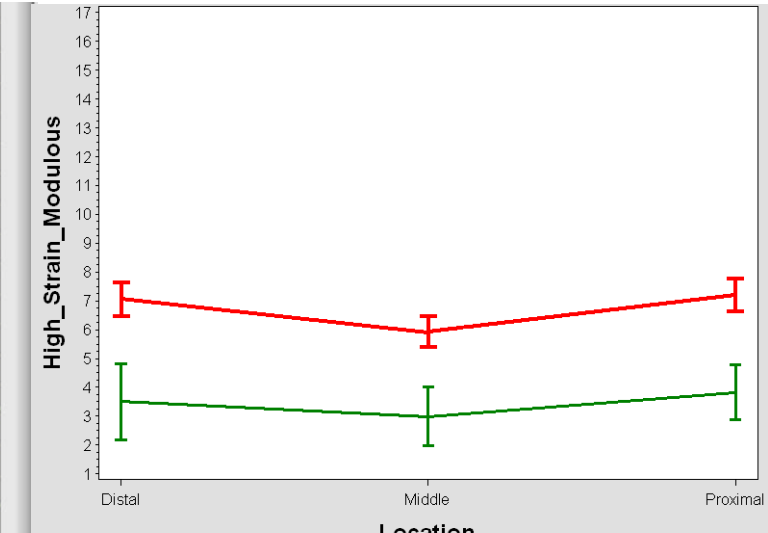
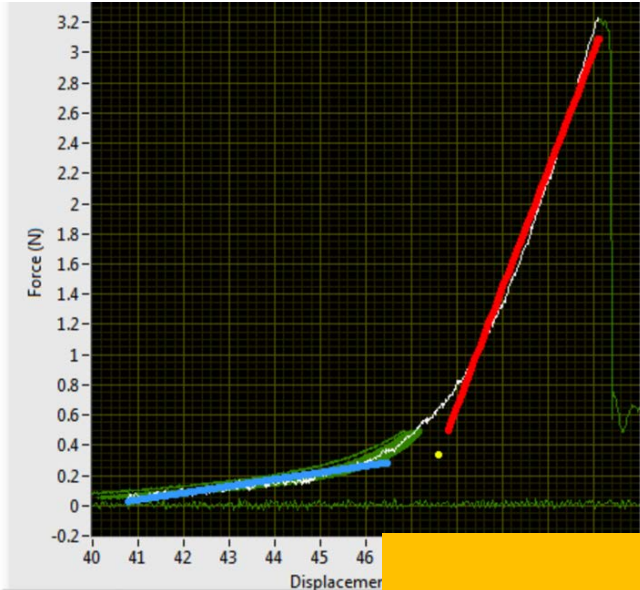
- ✓ Bi-monthly team progress meetings
- ✓ CC-HVI initial resource dedicated to project (Frank Cikach)
- ✓ Preliminary results of the 60+ patients
- ✓ Industry Consortium Meeting for discussion on preliminary results
 - Next steps charted, and data collection optimized
- ✓ Histology manuscript submitted based on recent findings



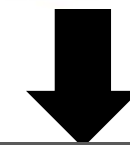
MATADORS Team Next Steps

- Expansion of initial IRB study (n= 100 → n = 400 total)
- Biomechanics to include bi-axial loading & testing
- CC-HVI headcount dedicated to project starting September
- Industry check-in meeting





Results to be presented in 2018!



Control
Sporadic aneurysm
Sporadic dissection

