Advances in Vascular and Cardiac Hybrid Procedures

Eric E. Roselli, MD

Cleveland Clinic
<table>
<thead>
<tr>
<th>Company</th>
<th>Role</th>
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<tbody>
<tr>
<td>Medtronic</td>
<td>Investigator, consultant</td>
</tr>
<tr>
<td>Cook</td>
<td>&quot;</td>
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<td>Terumo</td>
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<td>Apica</td>
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<td>Edwards</td>
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Baby-Boomers now > 60

U.S. Population over Age 65 --1985 to 2050

% of Population

Year

1990 2000 2010 2020 2030 2040 2050
“Boomers” Expectations

• Conformity →
• Informed consumers
  • Internet – webMD, hospital-based
  • Print journalism – newspapers, periodicals
  • Television – commercials, Oprah, Oz

↑ Health Literacy

↑ Access
Highest Quality
Accountability
Minimally Invasive Revolution

Small Incisions

Intraluminal Approaches

Percutaneous

Robotics

Endovascular
MISurgical Techniques

- Parasternal thoracotomy
- Partial upper sternotomy
- Mini-thoracotomy
- Robotic totally endoscopic
- Transapical / Transfemoral

Safety must be maintained
High Hazard Industry

• Highly complex
• Technically demanding
• Mishaps occur
• Human factors can be ameliorated by system processes

Cardiovascular Care

• Last Resort
• Adapting to $\Delta$
• Advocates for Safety
Treatment Options for Complex CardioVascular Disease

• Make the patient amenable to the currently available devices
  • Hybrid Approach
• Apply current devices off-label
• Make new devices applicable to different disease patterns
TEVAR
n > 1500 at CCF
Disease Knows No Boundaries
Extensive Aneurysmal Disease

- Descending + Distal Arch
- Proximal Arch + Proximal Descending
- Proximal Arch + Thoracoabdominal

+ / - Dissection
Mesenteric Debranching
Roselli EE, Greenberg RK, et al. JTCVS 2007
Standard TAAA Device
Design # 1

Helical celiac branch trajectory

Helical SMA branch trajectory

Distribution of celiac junction points

Distribution of SMA junction points

? Plus in-situ fenestration?
Fenestrated Devices Entering Mainstream
Hybrid OR

Space / structure
Fixed imaging
Data visualization
Equipment
Chronic Dissection - Hybrid Solution

Debranching From: Ascending, Infrarenal or Iliacs

Hybrid Type 2 TAAA: Endo ET  n=22

Complex Arch Disease Requires a Tailored Approach
Endovascular Elephant Trunk Completion

1st stage

2nd stage

Arch Debranching Hybrid

2 stage

1 stage

Hybrid Arch Debranching Issues

- Emboli, Retrograde dissection
- Size disparity
- Partial/full sternotomy
- Proximal aortic disease
- Associated CV disease
- Endoleaks
# Results of Hybrid Arch Repairs

Stentgraft in Zone 0 or 1

<table>
<thead>
<tr>
<th>Study</th>
<th>Mortality</th>
<th>Stroke</th>
<th>SCI</th>
<th>IaEL</th>
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<td>Weigang,09</td>
<td>15.4%</td>
<td>0%</td>
<td>0%</td>
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<td>Melissano,07</td>
<td>7.7%</td>
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<td>Czerny,07</td>
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<td>15%</td>
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<td>Bergeron,06</td>
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<td>8%</td>
<td>4%</td>
<td>12%</td>
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<tr>
<td>Saleh,06</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Schumacher,06</td>
<td>20%</td>
<td>4%</td>
<td>0%</td>
<td>12%</td>
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**TOTAL**

15/144(10%) 5/144(3.5%) 1/144(.7%) 15(10%)

Up to 11% retrograde dissection


Frozen Elephant Trunk

Site for Arch Branch
Proximal Anastomosis

Old Proximal Graft

Arch Branch Graft & LtSC Bypass

FET Anastomosis
86y/o asc an, chronic dissx
Hypothermic Circ Arrest, Selective Brain Perfusion
Completion CT
Simplified FET for Acute Dissection
n = 40

- Hybrid OR
- Novel technique
- Safe and effective
- Promotes false lumen thrombosis
- Expedites tx of ischemia

Repairing Retrograde Dissection

- Circ Arrest, ‘Reverse Frozen Elephant Trunk’

Idrees J, Roselli EE, et al. JTCVS, 2014
Hybrid Repair Post-Coarct Aneurysm

Dedicated Devices Coming

Thoraflex Device is Investigational
Antegrade Device Delivery
Branch Arch Devices

Valiant Mona LSA

Gore branch

Presented at 2013 AATS, Minneapolis, MN
Mona LSA System
Total Arch Branched Devices
High Risk Ascending TEVAR

2006-2014
N = 22

- Acute Type A Dissection  9
- IMH with PAU          2
- Pseudoaneurysm        9
- Complicated Chronic Dissx  2

Roselli EE, et al. JTCVS, 2014
Transapical Repair
Acute Type A Dissection

Roselli EE, et al; JACC Int, 2013
Transaxillary Repair
Ascending Pseudoaneurysm
Acute Type A with Aneurysm

Tx are Complementary
NOT Competitive
Alternate Access: Transapical

1/3rd screened poor femoral access
Delivery and Positioning
Transapical TAVI

Currently requires mini-thoracotomy
Less Invasive Apical Access

- Automated suturing devices
- Implantable access and closure devices
- Potential for percutaneous/port access
- Re-accessible
Ongoing Aortic Valve Trials

- Intuity Edwards
- GLX Edwards
- XT Edwards
- S3 Edwards
- Perceval Sorin
- Solo Sorin
- Direct Flow
- Portico St Jude
Complex Mitral Procedures

Balloon occlusion device for MR

Artificial Chordae for MR

Direct approach for MV Replacement
Composite Valve and Ascending
Hybrid Procedures

• Aortic aneurysm and dissection
  • Optimizing sealing and fixation, coverage
• Coronary
  • ITA plus DES
• Valve
  • Transcather valves
• Coronary plus Valve
• Atrial fibrillation
  • Intra plus extracardiac ablation, LAA
• Thoracic
  • Endobronchial plus VATS

• Structural Heart options are growing quickly
Intraop Team: Personnel Intense

OR
- Surgeon(s) + fellow(s)
- Anesthesiologist + resident / CRNA
- OR Nurses, scrub techs
- RNFA/PA
- Perfusionist

Cath Lab
- Interventional Cardiologist + fellow(s)
- Cath Lab Nurses – OR and control room
- Radiology technologist

50% more staff
Staffing is Expensive

*Early Duplication of Teams / Roles → Potential for Improved Efficiency*

Cross-Training to achieve efficient staffing models

- Anesthesia and Cards Imaging
- Cath lab and OR nurse
- Radiology techs and nurses/PA
- Int Cards and Surgeon hybrid
- Residents, fellows
- Perfusionist
Preparedness Rescues

Hybrid OR Best Suited for TAVR
Simple Rescue Table Cannulas in reach

Pump Under Wraps
Expediency and Efficiency Requires A Team Approach

The Bull Pen

Pump in Action

RN

Perfusion

Tech

PA
Emergency Use of CPB in TAVR: Importance of Heart Team

n = 303; CPB n = 12 (9TA, 3TF)

• Reasons: severe AI 5
  embolization 3
  coronary occ 2
  bleeding 2

• Add procedures: PCI 2
  valve in valve 4
  SAVR 3

• Mortality: 2 / 12 (16%)

Roselli EE, et al. JTCVS 14
A familiar, experienced, Multi-skilled TEAM with the Proper EQUIPMENT for Imaging, performance and rescue in a Versatile LOCATION will Succeed and Can Continuously Improve!
We must ALL get better, TOGETHER!

• Quality
  • Requires measurement of outcomes
  • Enforced with pay for performance

• Improvement depends upon INNOVATION
  • Devices/procedures, Knowledge of dz
  • Health care delivery
  • Education
  • Data collection/analysis