Current Status and Results With Manifold Branched Grafts for TAAA Repairs: What Are They: What Are Their Limitations And Why Haven't They Been Commercialized

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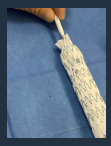
Disclosures

Cook Medical - Speaker
Gore – Consultant
Medtronic Valiant TAA Study Participant

Manifold/Off-The Shelf TAAA Systems

Limited Devices Available in USA
Newly released Gore TAMBE
Physician Innovation

- Snorkels and Chimneys
- PMEG
- PS-IDE (Aorta Consortium) CMD and off-the shelf



Limitations to Current TAAA Devices

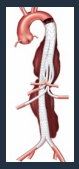
High rates of patient exclusions
Prior open repair or EVAR
Delay in building CMD
FDA – limits to IDE

Introduction

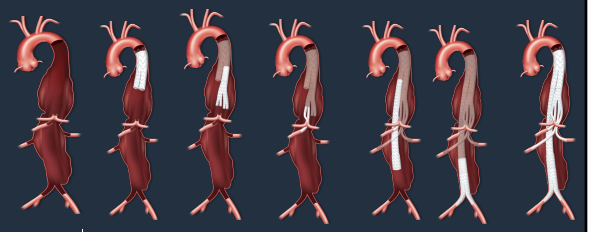
Valiant Multi-Branch Endograft "Pat Kelly device" received "Breakthrough Device Designation" from the FDA in October 2019

Study Group

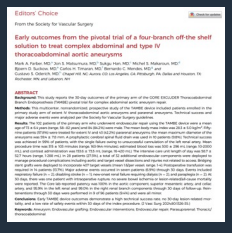
- Stanford –Pat Kelly
- Christ Hospital Cincinatti – Geoff Answini
- NYU – Tom Maldanado
- Vanderbilt – Tom Naslund
- USF – Murray Shames
- Johns Hopkins – Jim Black
- MGH – Matt Eagleton



Deployment



Gore- TAMBE


Editors' Choice

From the Society for Vascular Surgery

Early outcomes from the pivotal trial of a four-branch off-the shelf solution to treat complex abdominal and type IV thoracoabdominal aortic aneurysms

- 102 patients (75% screen fail), exclusion Type 1-3 TAAA
- 30-Day Outcomes:
  - 0 Mortalities
  - 7% MAE
  - 99% Primary Patency
- 12 Month Outcomes
  - 96% branch patency
  - 14 renal or visceral branch occlusions
  - 15% reintervention rate
  - 5% persistent SCI

Jotech E-Inside


From the Society for Vascular Surgery

Outcomes of off-the-shelf preloaded inner branch device for urgent endovascular thoraco-abdominal aortic repair in the ItaliaN Branched Registry of E-nside EnDograft

- 185 Patients INBREED
- (study only reports 64 urgent patients)
- Technical Success 92%
- 50% Type 1-3
- 30-Day Outcomes
  - 9.1% Mortality
  - 28% MAE
  - 97% Patency
  - 7% persistent SCI

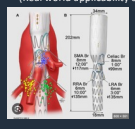
Cook T-Branch


From the Society for Vascular Surgery

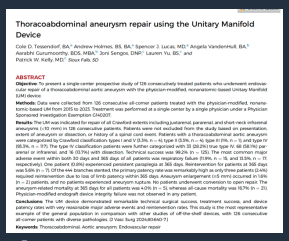
Urgent endovascular repair of juxtarenal/pararenal aneurysm by off-the-shelf multibranched endograft

- 197 Patients , 38 prior failed EVAR
- Technical Success 92%
- 30-Day Outcomes
  - 11% mortality
  - 35% MAE
  - 14% reintervention
  - 8% persistent SCI

(Real world applicability 50%)

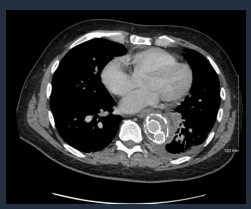


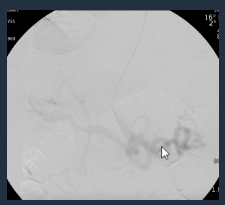
Unitary IDE (Pat Kelly)


Thoracoabdominal aneurysm repair using the Unitary Manifold Device

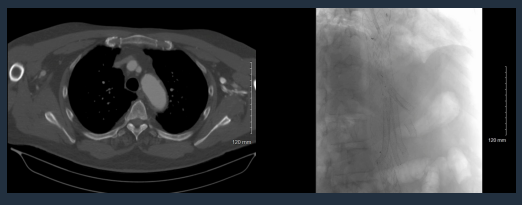
- 126 Consecutive Patients , 50% failed EVAR
- Includes all TAAA patients
- Technical Success: 99% (125/126)
- 30-Day Outcomes:
  - 3.2% mortality
  - 11.3% MAE
  - 98% primary patency
  - 5.6% reintervention rate
  - 1.3% Persistent SCI

Reinterventions Bridging Stent Fractures - RAAA

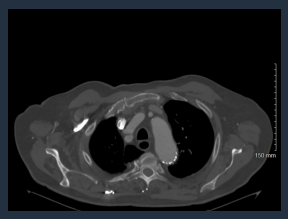


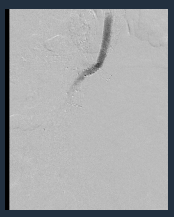


Reinterventions – Bridging Stent Dissociation

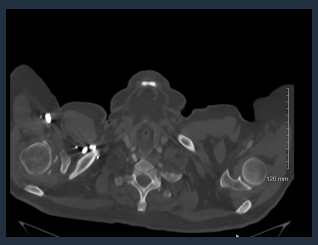


Reintervention – Type III Endoleak SMA





Type III Endoleak TEVAR



Gore TAMBE

Summary

- Endo TAAA possible with Modular Devices to include challenging anatomy
- Long bridging stents at risk for thrombosis, fracture, dissociation from target vessel, or separation
- Multiple components and extended length of coverage pose risk for device related failures
- Thoracic aorta at risk for dissection from multiple catheters, sheaths and manipulations in potentially tortuous aorta