

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

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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



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Limitations to Current TAAA Devices

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

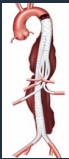
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Introduction

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

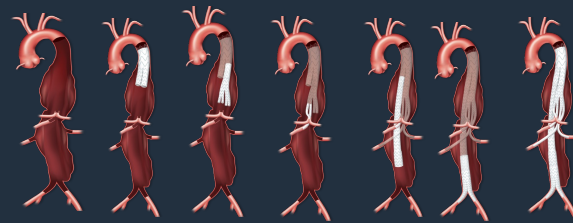
Study Group

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



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Deployment



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Gore- TAMBE

Abstract 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 aneurysms

Abstract
Objective: To evaluate the safety and efficacy of the Gore TAG Thoracoabdominal Branch Endoprosthesis (TAMBE) in the treatment of complex abdominal and type IV thoracoabdominal aneurysms. The TAMBE is a four-branch endoprosthesis designed to treat these aneurysms in a single operation. The study included 102 patients with complex abdominal and type IV thoracoabdominal aneurysms. The primary endpoint was 30-day mortality. Secondary endpoints included 30-day primary patency, 12-month mortality, and 12-month primary patency. The TAMBE was found to be safe and effective in the treatment of these aneurysms. The 30-day mortality was 0%. The 30-day primary patency was 99%. The 12-month mortality was 15%. The 12-month primary patency was 95%.

- 102 patients (75% screen fail), exclusion Type 1-3 TAAA
- 30-Day Outcomes:
 - 0 Mortalities
 - 7% MAE
 - 99% Primary Patency
- 12 Month Outcomes
 - 95% Branch patency
 - 14 renal or visceral branch occlusions
 - 15% reintervention rate
 - 5% persistent SCI



GORE TAG Thoracoabdominal Branch Endoprosthesis (TAMBE)

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Jotech E-Inside

Abstract Choice
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 Branches Study of E-inside Endograft

Abstract
Objective: To report the outcomes of endovascular repair of thoracoabdominal aortic aneurysms (TAAA) using the off-the-shelf preloaded inner branch device for urgent endovascular thoraco-abdominal aortic repair (E-inside Endograft). The study included 185 patients with TAAA. The primary endpoint was 30-day mortality. Secondary endpoints included 30-day primary patency, 12-month mortality, and 12-month primary patency. The E-inside Endograft was found to be safe and effective in the treatment of TAAA. The 30-day mortality was 9.1%. The 30-day primary patency was 97%. The 12-month mortality was 28%. The 12-month primary patency was 93%.

- 185 Patients INBRED (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



E-inside™
TAAA
Making the Branching Easier.

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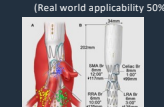
Cook T-Branch

Abstract Choice
From the Society for Vascular Surgery

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

Abstract
Objective: To evaluate the safety and efficacy of the Cook T-Branch endograft in the treatment of juxtarenal/pararenal aneurysms. The study included 197 patients with juxtarenal/pararenal aneurysms. The primary endpoint was 30-day mortality. Secondary endpoints included 30-day primary patency, 12-month mortality, and 12-month primary patency. The Cook T-Branch endograft was found to be safe and effective in the treatment of these aneurysms. The 30-day mortality was 13%. The 30-day primary patency was 92%. The 12-month mortality was 14%. The 12-month primary patency was 81%.

- 197 Patients, 38 prior failed EVAR
- Technical Success 92%
- 30-Day Outcomes
 - 13% mortality
 - 35% MAE
 - 14% reintervention
 - 8% persistent SCI (Real world applicability 50%)



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Unitary IDE (Pat Kelly)

Abstract Choice
From the Society for Vascular Surgery

Thoracoabdominal aneurysm repair using the Unitary Mansfold Device

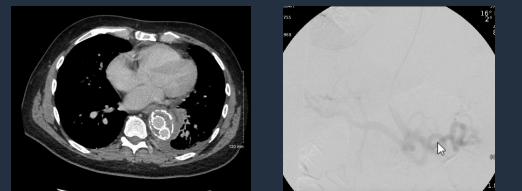
Abstract
Objective: To report the outcomes of thoracoabdominal aneurysm repair using the Unitary Mansfold Device. The study included 126 consecutive patients with thoracoabdominal aneurysms. The primary endpoint was 30-day mortality. Secondary endpoints included 30-day primary patency, 12-month mortality, and 12-month primary patency. The Unitary Mansfold Device was found to be safe and effective in the treatment of these aneurysms. The 30-day mortality was 3.2%. The 30-day primary patency was 98%. The 12-month mortality was 5.6%. The 12-month primary patency was 98%.

- 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



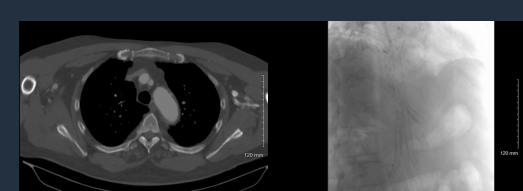
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Reinterventions Bridging Stent Fractures - RAAA

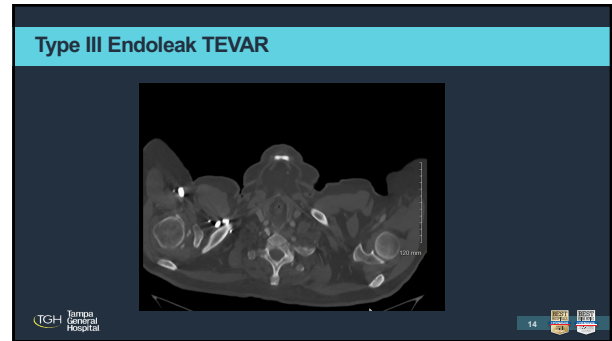
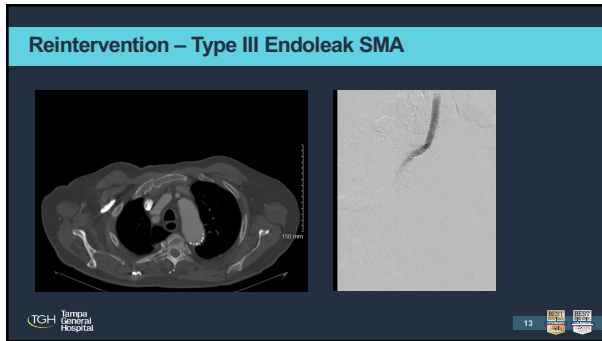


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Reinterventions – Bridging Stent Dissociation



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- 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
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