Different arch branched devices are available, is morphology the main criteria of choice?

Ciro Ferrer, MD

Vascular Surgery Unit

''Sapienza'' University of Rome

Disclosure

Speaker name:

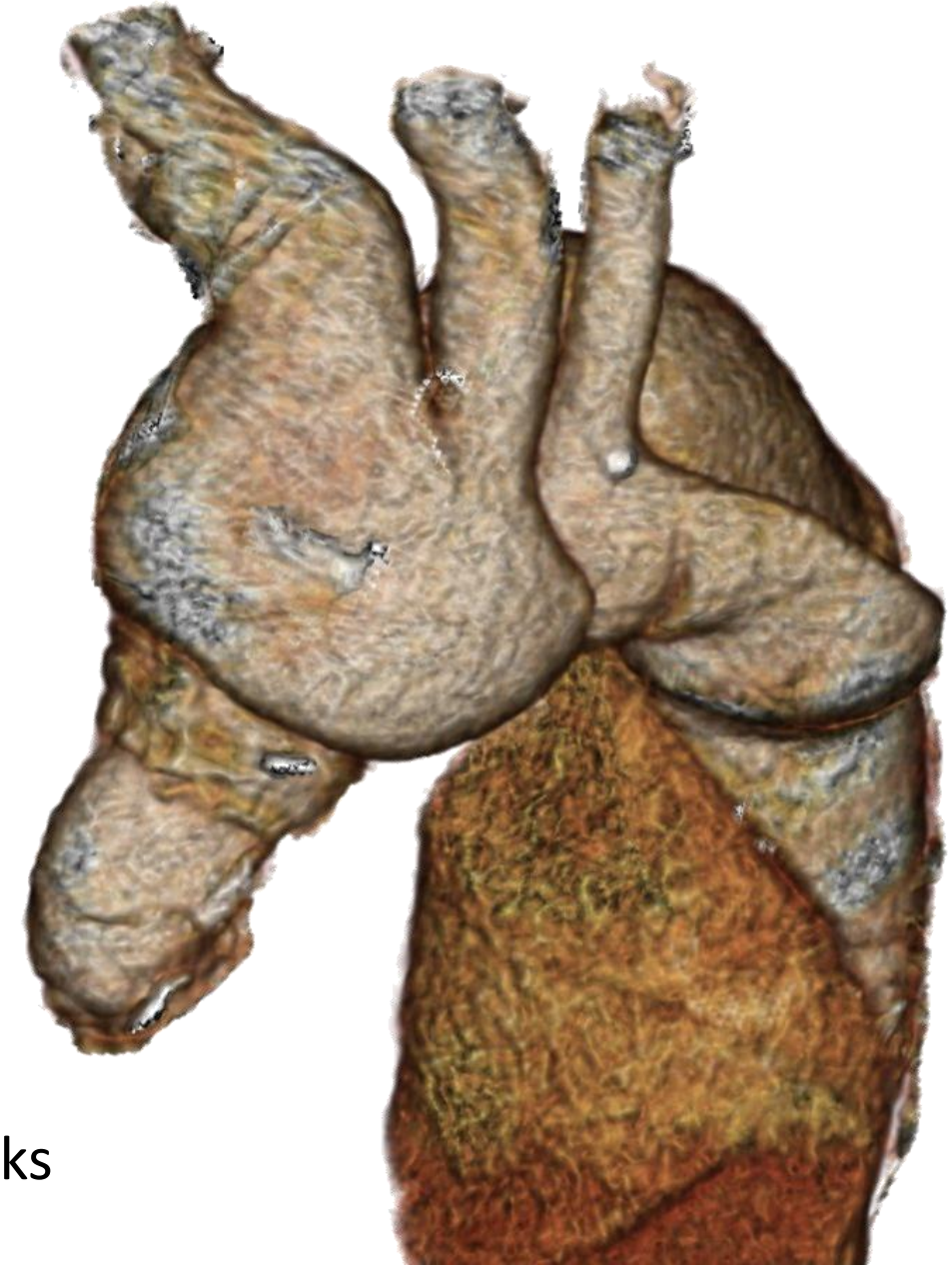
Ciro Ferrer

❑ Proctoring/speaking fee: Bolton Medical

Critical issues in endovascular arch repair

- ✓ **Proximal landing zone**
  - Lenght
  - Size
  - Angulation
  - Discrepancy with distal landing zone

- ✓ **Arch variability**
  - Anatomical variations
  - Variable branch vessels take off
  - Dissected arch
  - Dissected supra-aortic trunks



Critical issues in endovascular arch repair

- ✓ Proximity to coronary ostia and aortic valve
- ✓ LV catheterization
- ✓ Rapid pacing deployment
- ✓ Hybrid adjunct
- ✓ Large caliber access vessels

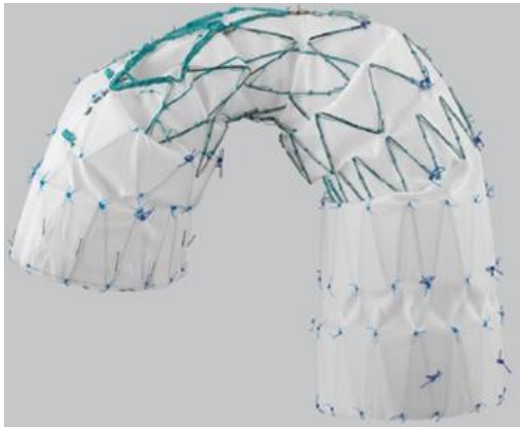
Dedicated devices to preserve supra-aortic trunks perfusion

- ✓ **Off-the-shelf**
  - Branched
  - Fenestrated
- ✓ **Custom-made**
  - Branched
  - Fenestrated
  - Combination of both
  - Scalloped

Current dedicated devices

- ✓ **Off-the-shelf**
  - Gore TBE
  - Medtronic Mona-LSA
  - Endospan Nexus

- ✓ **Custom-made**
  - Cook
  - Bolton
  - Najuta



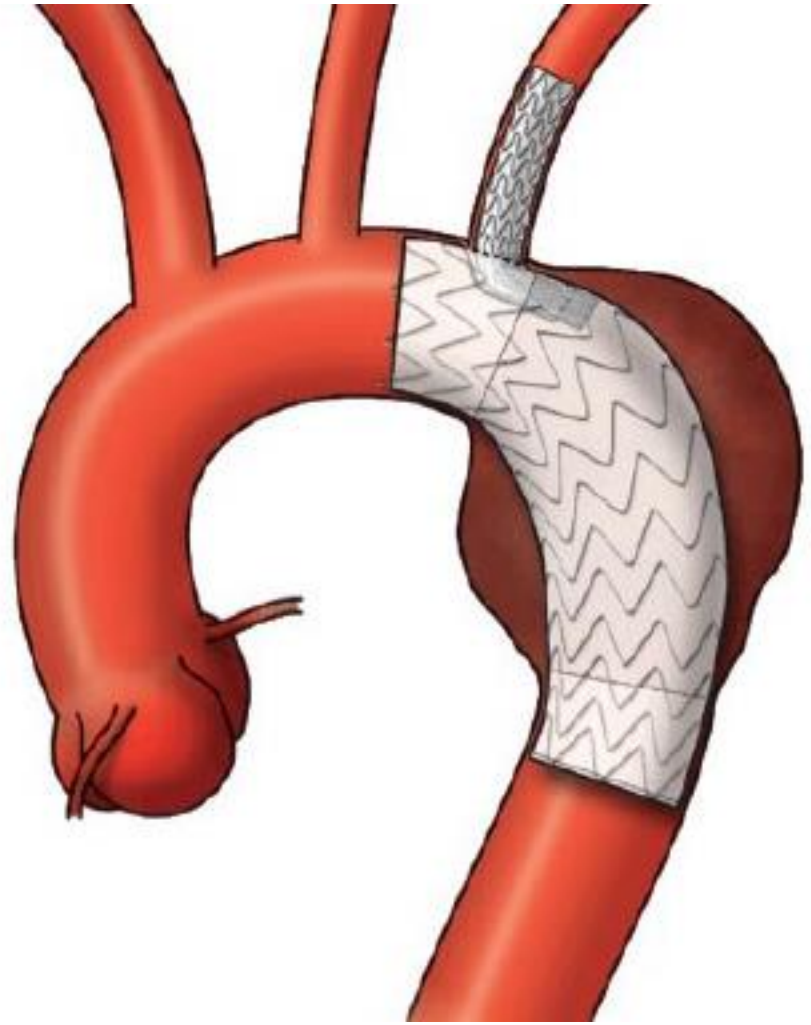
Gore TBE

Device Overview

- Aortic main body
- Single inner retrograde branch
- Dedicated side branch component
- Aortic extender (optional)

Gore TBE

Procedural steps



Step 1:
- Catheterization of ascending aorta and branch vessel from below

Step 2:
- Introduction of aortic main body over both guidewires

Step 3:
- Deployment of aortic main body

Step 4:
- Introduction of sheath into branch vessel

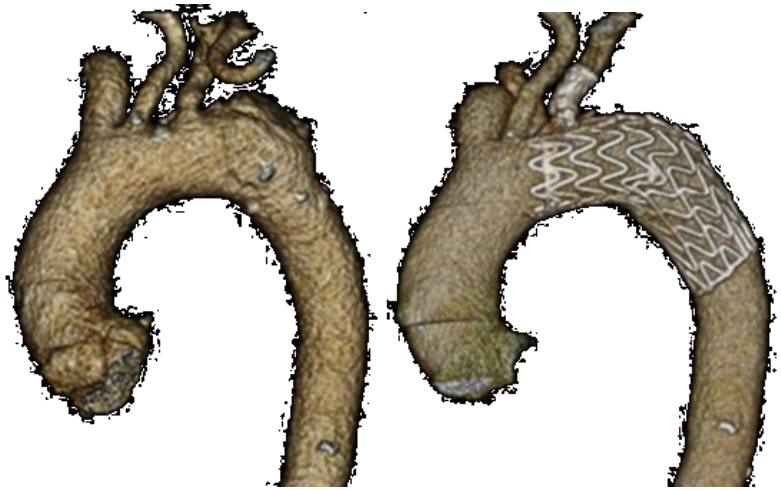
Step 5:
- Deployment of side branch component

Gore TBE

Results

Branched Endovascular Therapy of the Distal Aortic Arch: Preliminary Results of the Feasibility Multicenter Trial of the Gore Thoracic Branch Endoprosthesis

Himanshu J. Patel, MD, Michael D. Dake, MD, Joseph E. Bavaria, MD, Michael J. Singh, MD, Mark Filinger, MD, Michael P. Fischbein, MD, PhD, David M. Williams, MD, Jon S. Matsumura, MD, and Gustavo Oderich, MD



- 22 patients with distal arch aneurysm (landing zone 2)
- Fusiform (10)
- Saccular (12)

- LSA Patency: 100%

- Stroke: 0%

- Type I endoleaks
- Intraprocedural: 18%
- 1-month: 0%

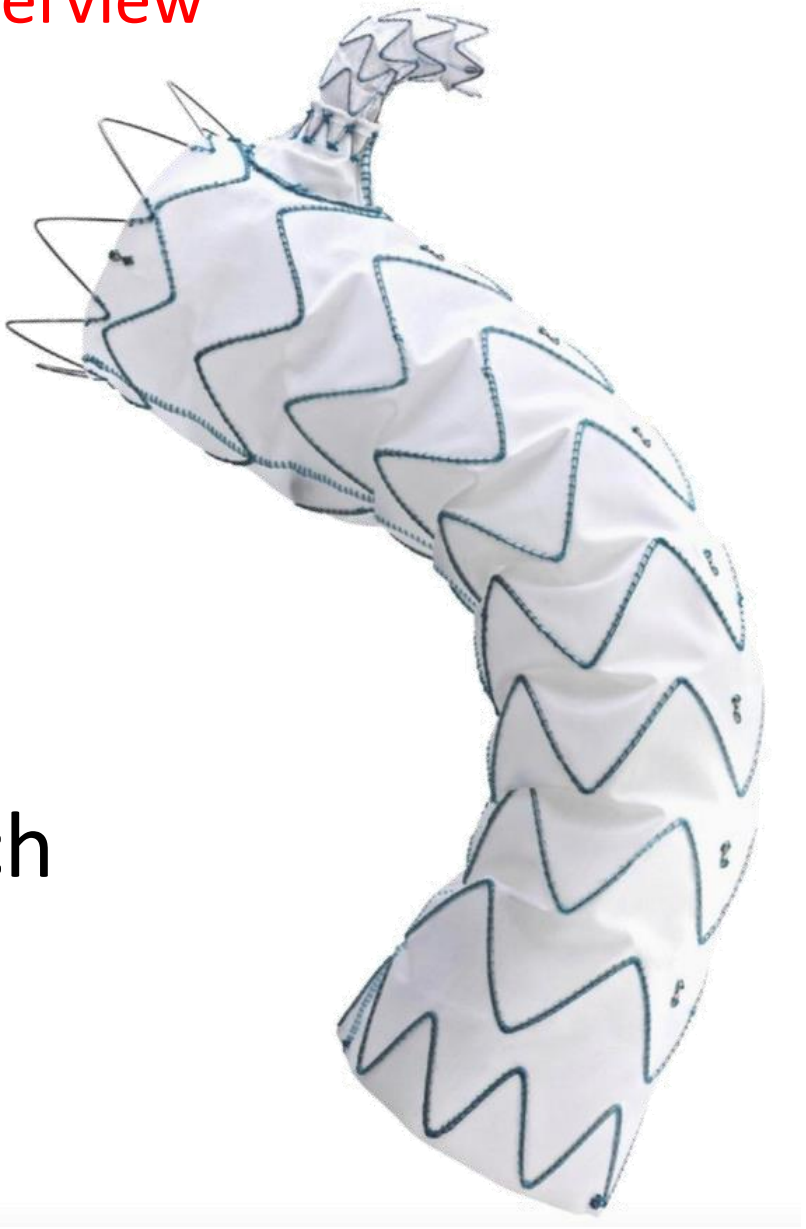
- Survival: 94.7% @ 6 months (1 death for ascending aorta aneurysm rupture in a patient scheduled for elective repair)

Ann Thorac Surg 2016

Medtronic Valiant Mona LSA

Device Overview

- Aortic main body
- Single volcano docking zone
- Dedicated side branch component

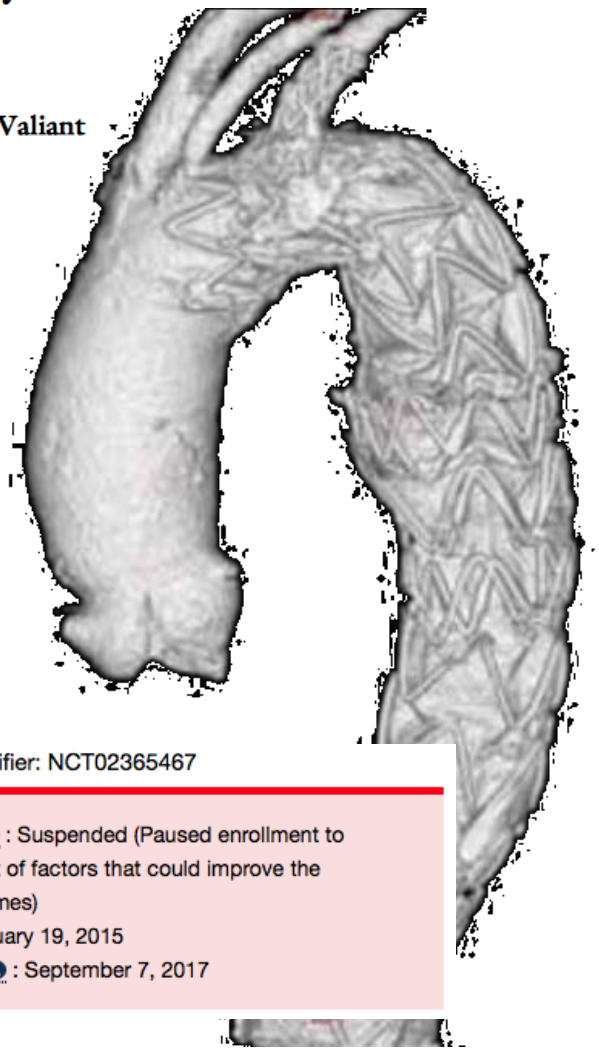


Medtronic Valiant Mona LSA

Results

Results of the Valiant Mona LSA early feasibility study for descending thoracic aneurysms

Eric E. Roselli, MD,[a] Frank R. Arko III, MD,[b] and Matthew M. Thompson, MD,[c] on behalf of the Valiant Mona LSA Trial Investigators, *Cleveland, Ohio; Charlotte, NC; and London, United Kingdom*



- 9 subjects enrolled
- No 30-day death
- 4 (50%) endoleaks in 8 pts
  - ➢2 Type II
  - ➢2 Undetermined
- No Major strokes
- 4 minor strokes in 3 pts (33%)
- No L arm ischemia

ClinicalTrials.gov Identifier: NCT02365467

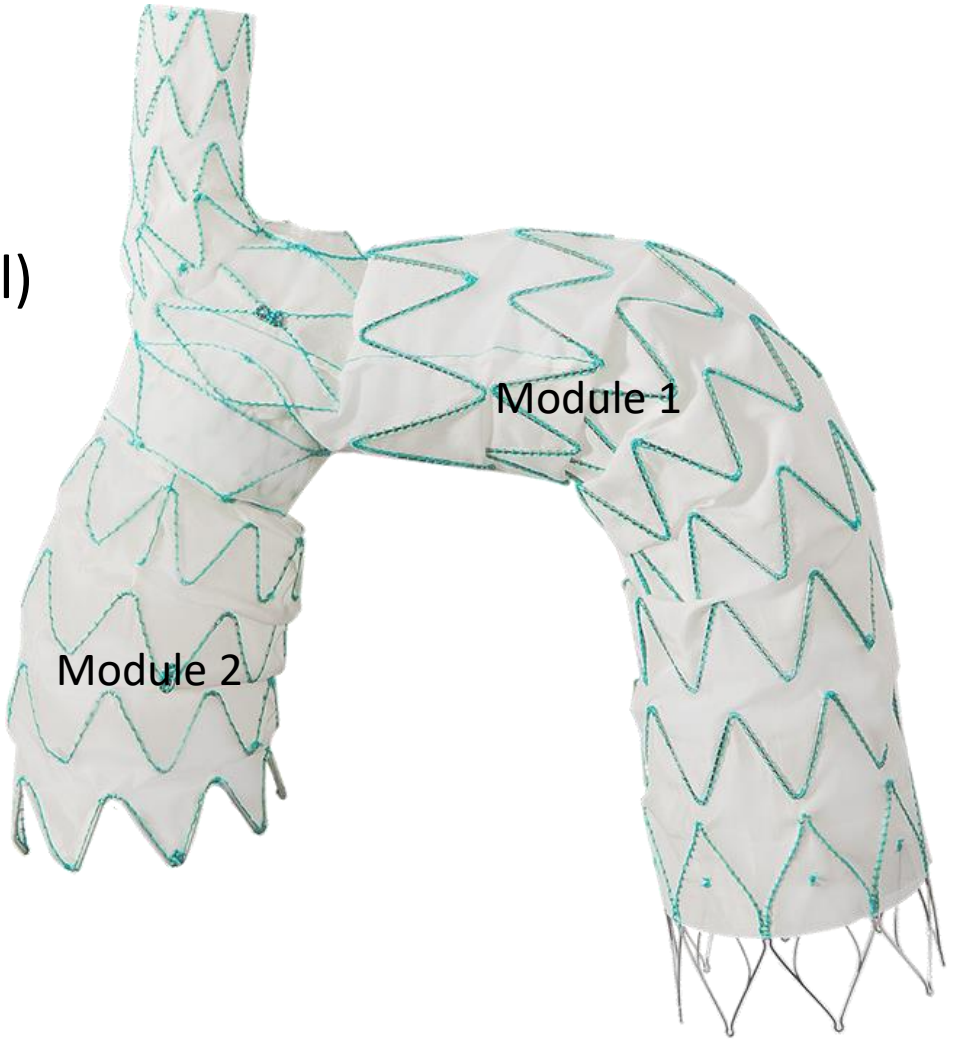
Recruitment Status : Suspended (Paused enrollment to complete assessment of factors that could improve the procedure and outcomes)
First Posted : February 19, 2015
Last Update Posted : September 7, 2017

J Vasc Surg 2015

Endospan Nexus

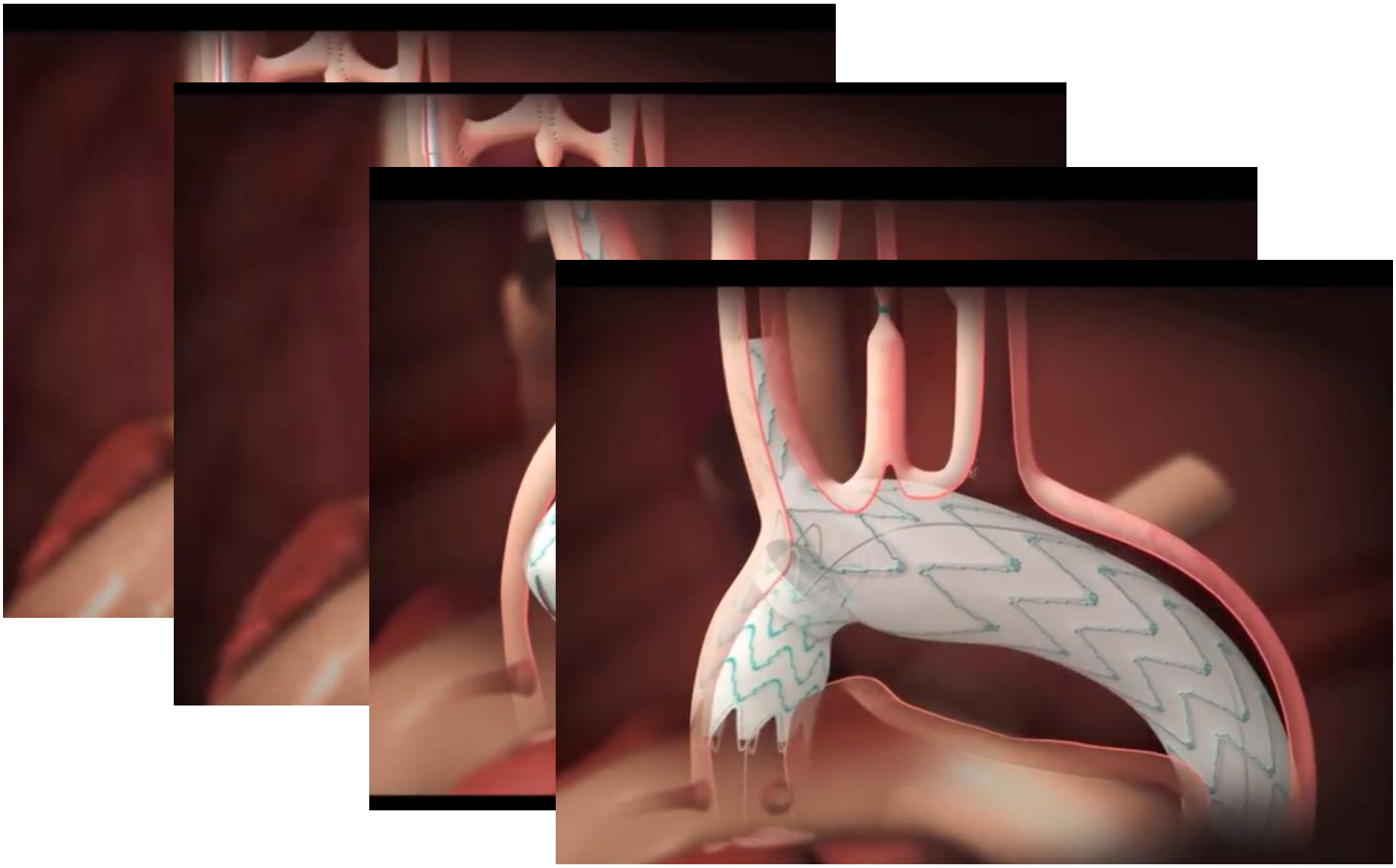
Device Overview

- Two-component system
- Pre-curved ascending module
- Elliptic tantalum docking ring
- Fenestration for LCCA (optional)
- 20 Fr delivery system



Endospan Nexus

Procedural steps



Endospan Nexus

Results

First-in-man (FIM) study + compasionate cases

Event	# of Patients	Details
Technical success	13/13	
Death	2/13	FIM #1: 11 days post implantation, due to Respiratory failure
		Compassionate #3: 2 days post implantation, due to MI
Stroke	Stroke 4/13 Permanent deficits 0/13	FIM #1: left side hemiparesis
		FIM #5: right arm paresis
		Compassionate #1: right side hemi-syndrome
		Compassionate #4: right arm paresis
Spinal Cord Ischemia	1/13	Compassionate #4: arch and descending aneurysms CSFD post implantation, patient recovered
Endoleak type Ia or III (> 30-day)	1/11	Compassionate #2: Type III Endoleak at 3 month follow up *In addition 2/11 Type Ib (gutters of PG)*

Presented by David Planer, MD
@ ICI 2015, Tel-Aviv

Endospan Nexus

Results

First-in-man (FIM) study + compasionate cases

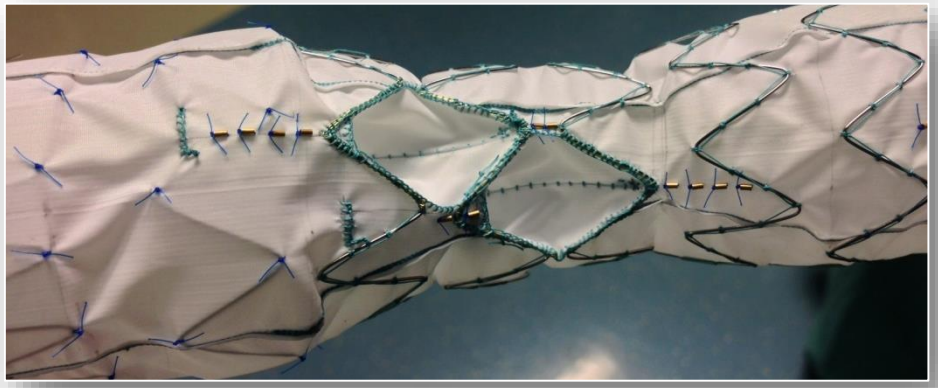
6/13 periscope grafts for LSA

Presented by David Planer, MD
@ ICI 2015, Tel-Aviv

Cook Arch branched device

Device Overview

- Aortic main body (custom-made)



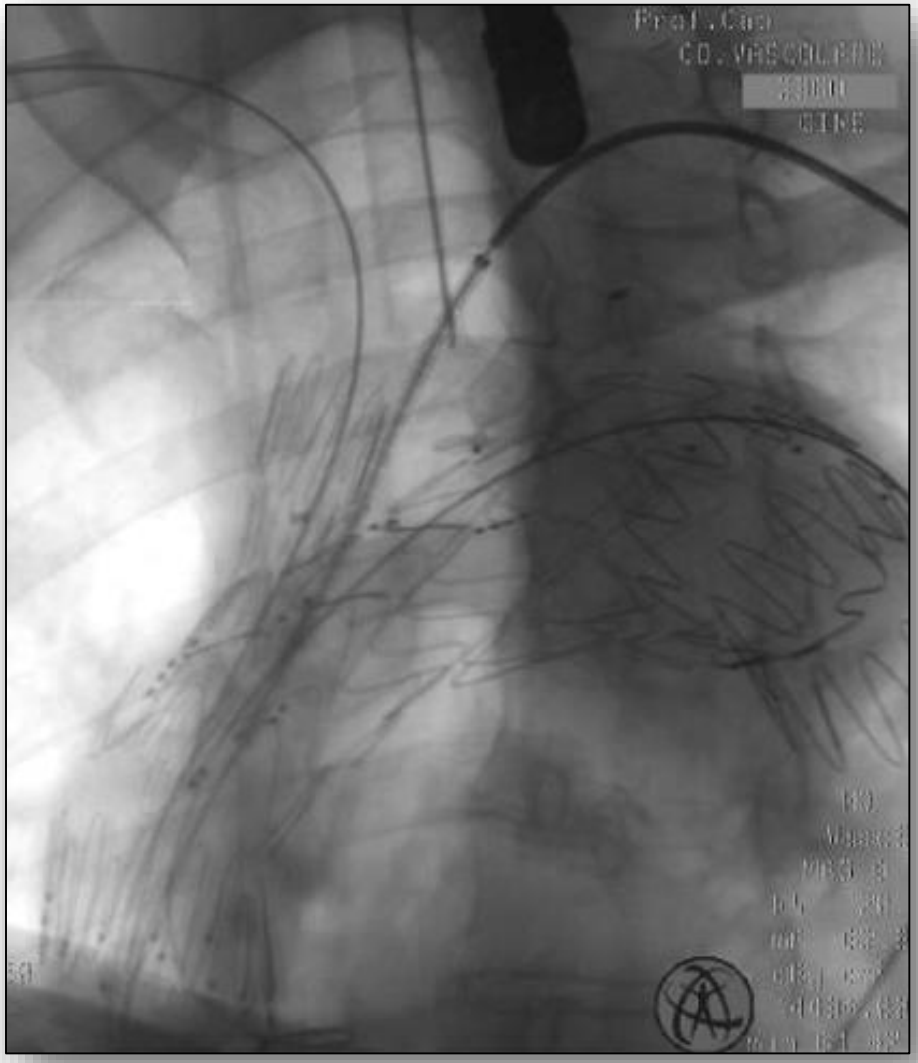
- Two inner antegrade branches

- Custom-made limb for IA – covered stent for LCCA

- Pre-curved system

Cook Arch branched device

Procedural steps



Cook Arch branched device

Results

Global experience with an inner branched arch endograft

Stéphan Haulon, MD, PhD,[a] Roy K. Greenberg, MD,[b] Rafaëlle Spear, MD,[a] Matt Eagleton, MD,[b] Cherrie Abraham, MD,[c] Christos Lioupis, MD,[c] Eric Verhoeven, MD, PhD,[d] Krassi Ivancev, MD,[e] Tilo Kölbel, MD, PhD,[f] Brendan Stanley, MD,[g] Timothy Resch, MD,[h] Pascal Desgranges, MD, PhD,[i] Blandine Maurel, MD,[a] Blayne Roeder, PhD,[j] Timothy Chuter, MD,[k] and Tara Mastracci, MD[b]

38 patients

30-day mortality	**13.2%** (7.1% in the last 28 cases)
Technical success	84.2%
Secondary procedures	10.5%
Neurologic complications	**15.8%** (Stroke 5.2%)

J Thorac Cardiovasc Surg 2014

Cook Arch branched device

Subsequent Results

Editor's Choice — Subsequent Results for Arch Aneurysm Repair with Inner Branched Endografts,☆

R. Spear [a], S. Haulon [a,*], T. Ohki [b], N. Tsilimparis [c], Y. Kanaoka [b], C.P.E. Milne [a], S. Debus [c], R. Takizawa [b], T. Kölbel [c]

	Group 1 ($n = 38$)	Group 2 ($n = 27$)	p
Procedure			
Length (min)	250 (210–330)	295 (232–360)	.35
X-ray time (min)	46 (32–84)	39.3 (34–61)	.07
Volume of contrast (mL)	150 (95–207)	183 (120–290)	.03
Early post-operative			
Endoleaks	11 (28.9%)	3 (11.1%)	.08
Secondary procedures	4 (10.5%)	4 (14.8%)	.61
Cerebrovascular events	6 (15.8%)	3 (11.1%)	.60
Systemic complications	17 (44.7%)	13 (43.3%)	.79
Mortality	5 (13.2%)	0 (0%)	.05
Follow up ($n = 33$)			
Endoleaks	3 (9.1%)	2 (7.4%)	.82
Secondary procedures	3 (9.1%)	2 (7.4%)	.82
Mortality	4 (12.1%)	1 (3.7%)	.24
Overall mortality	9 (23.6%)	1 (3.7%)	.02

Group 1: early experience study.[4]
Group 2: current study.

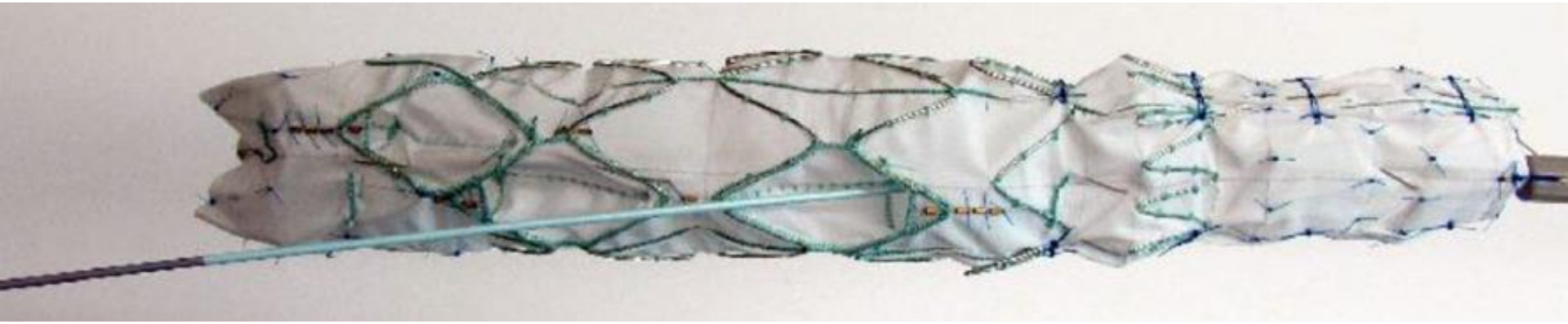
Eur J Vasc Endovasc Surg 2016

Cook Arch branched device

Total endovascular arch repair with **triple branch stent graft**

Device Overview

- Custom-made stent graft
- Third branch for LSA (retrograde and pre-catheterized)



Cook Arch branched device

Total endovascular arch repair with **triple branch stent graft**

Results

Total Endovascular Treatment of Aortic Arch Disease Using an Arch Endograft With 3 Inner Branches

Rafaëlle Spear, MD, PhD[1], Rachel E. Clough, MD, PhD[1], Dominique Fabre, MD, PhD[2], Blayne Roeder, PhD[3], Adrien Hertault, MD[1], Teresa Martin Gonzalez, MD, PhD[1], Richard Azzaoui, MD[1], Jonathan Sobocinski, MD, PHD[1], and Stéphan Haulon, MD, PhD[1]

3 post-dissection aneurysms

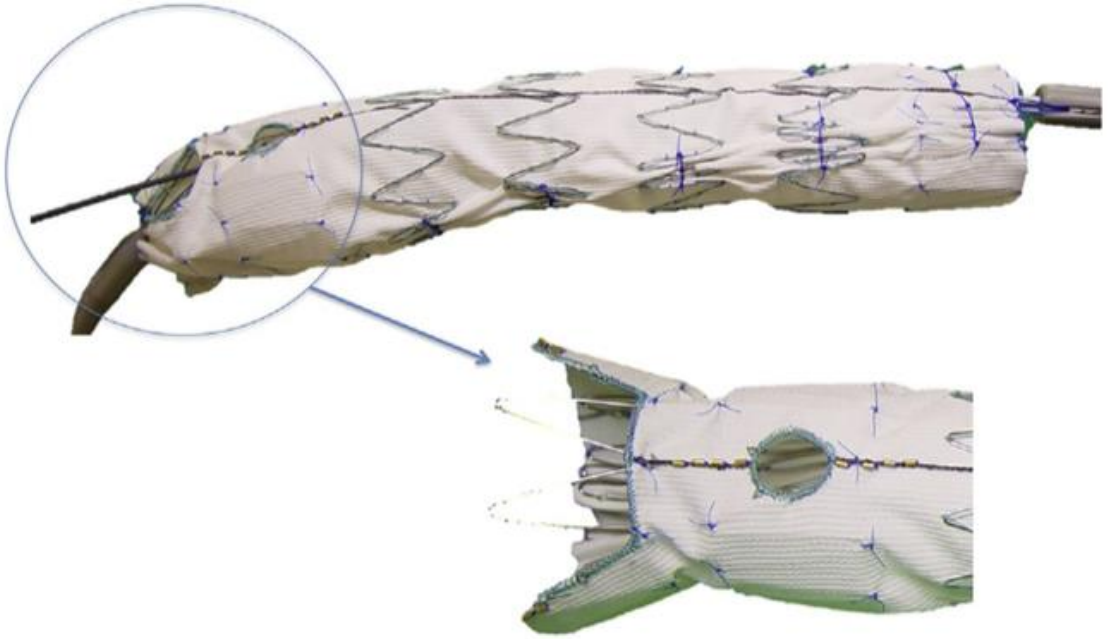
No death or branch vessel loss of patency at 6m

J Endovasc Ther 2017

Cook Arch fenestrated device

Device Overview

- Custom-made stent graft
- Proximal scallop (optional)



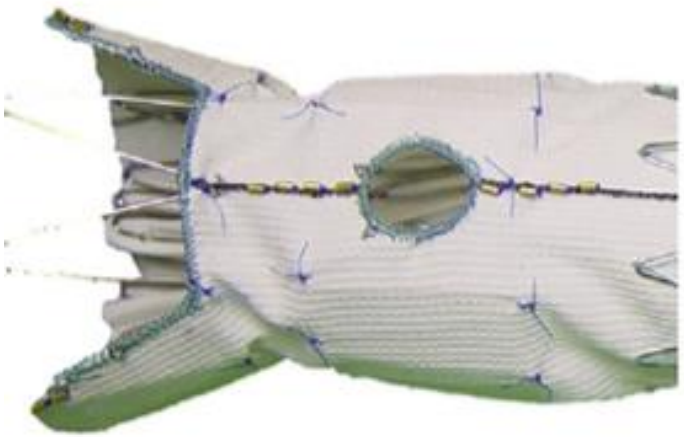
Cook Arch fenestrated device

Results

Branched versus fenestrated endografts for endovascular repair of aortic arch lesions

Nikolaos Tsilimparis, MD, PhD,[a] E. Sebastian Debus, MD, PhD,[a] Yskert von Kodolitsch, MD, PhD,[b] Sabine Wipper, MD, PhD,[a] Fiona Rohlffs, MD,[a] Christian Detter, MD, PhD,[c] Blayne Roeder, PhD,[d] and Tilo Kölbel, MD, PhD,[a] *Hamburg, Germany; and Bloomington, Ind*

	fTEVAR (n = 15)	*bTEVAR (n = 14)*	P
Procedure time, minutes	153 ± 23	270 ± 26	.02
Fluoroscopy time, minutes	36 ± 8	47 ± 8	NS
Intensive care unit stay, days	3.3 ± 1.2	3.8 ± 0.6	NS
Hospital stay, days	7 ± 5	14 ± 8	.02
Thirty-day mortality	3 (20)	0	NS
Myocardial infarction	0	1 (7)	NS
Relevant respiratory complications	2 (14)	0	NS
Major stroke	2 (14)	1 (7)	NS
Retrograde type A dissection	0	0	NS
Cardiac infarction	1	0	NS
Acute kidney injury (no dialysis)	2 (14)	1 (7)	NS
Acute kidney injury (dialysis)	0	0	NS
Pancreatitis	0	1 (7)	NS
Access site complications (minor and major)	3 (20)	1 (7)	NS



J Vasc Surg 2016

Bolton Arch branched device

Device Overview

- Aortic main body (custom-made)
- Wide window for two inner antegrade branches
- Custom-made limbs for IA and LCCA
- Dual Sheath and Pre-curved system

Bolton Arch branched device

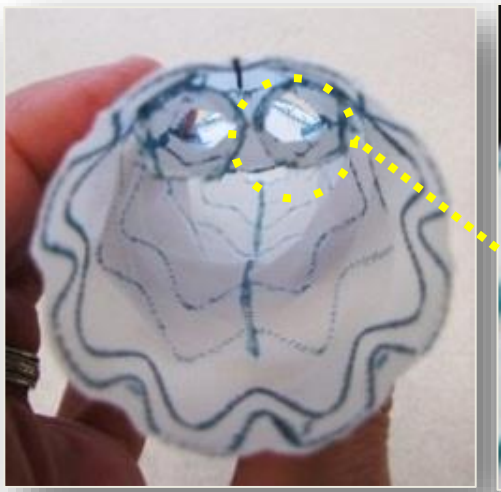
Procedural steps

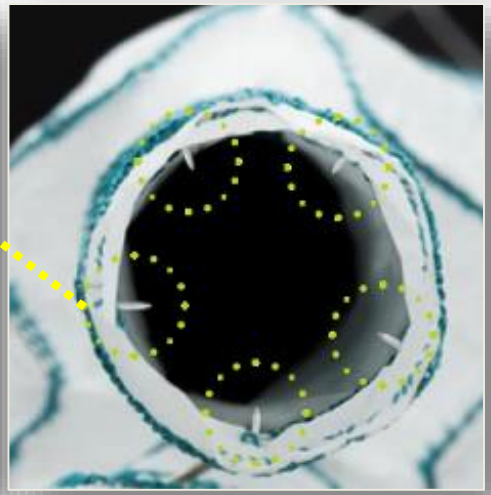
LCCA - LSA Bypass

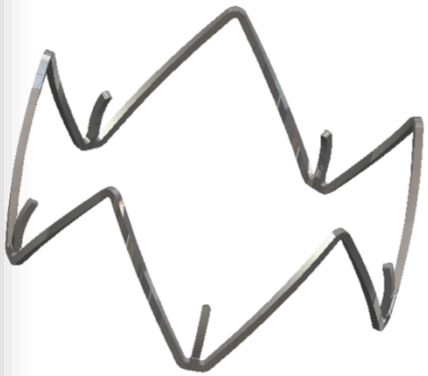
Main Body Deployment

BCT Branch Deployment

LCCA Branch Deployment







Bolton Arch branched device

Results

Orthotopic branched endovascular aortic arch repair in patients who cannot undergo classical surgery

Martin Czerny[a], Bartosz Rylski[a], Julia Morlock[a], Holger Schröfel[a], Friedhelm Beyersdorf[a], Bertrand Saint Lebes[b], Olivier Meyrignac[b], Fatima Mokrane[b], Mario Lescan[c], Christian Schlensak[c], Constatijn Hazenberg[d], Trijntje Bloemert-Tuin[d], Sue Braithwaite[d,e], Joost van Herwaarden[d,*] and Herve Rousseau[b]

Parameters	$n = 15$
Early endoleaks	
Type I and III	1 (7)
Type II	1 (7)
Late endoleaks	
Type I and III	0 (0)
Type II	1 (7)
Follow-up period	
Follow-up time (days)	263 (84; 564)
Intensive care unit stay (days)	4 (1; 8)
In-hospital stay (days)	14 (9; 18)
In-hospital mortality rate	1 (7)
Disabling stroke	1 (7)
Aortic-related deaths during the follow-up period	0
All-cause deaths at follow-up	4 (27)

Eur J Cardiothorac Surg 2018

Bolton Arch scallop device

Device Overview

- Custom-made stent graft
- Fenestration (optional)

Bolton Arch scallop device

Results

J Endovasc Ther. 2017 Feb;24(1):97-106. doi: 10.1177/1526602816674942. Epub 2016 Nov 4.

Results From a Nationwide Registry on Scalloped Thoracic Stent-Grafts for Short Landing Zones.

van der Weijde E[1], Bakker OJ[1,2], Tielliu IF[3], Zeebregts CJ[3], Heijmen RH[1].

- **23 pts with PROX SCALLOP TEVAR**
- Scallop used for LSA (17); LCCA (5); IA (1)
- CAR-CAR/CAR-LSA (4)

In-hospital mortality	3%
Peri-op stroke	3%
Vessel patency @meanFU9.7m	29/30

J Endovasc Ther 2017

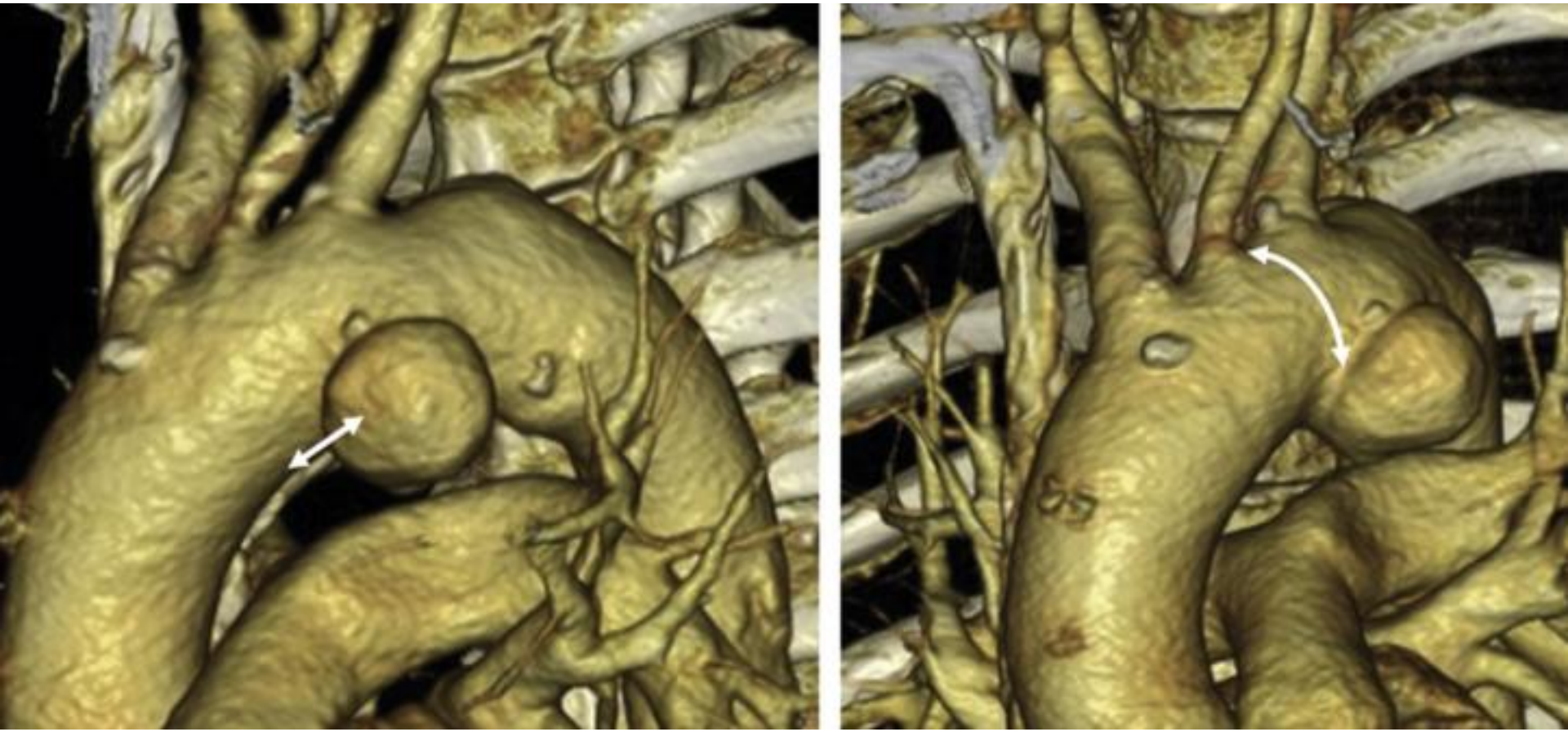
Najuta Arch fenestrated device

Device Overview

- Aortic main body
  (semi custom-made)
- Single piece system
- Up to 3 fenestrations
- No stent required for arch branches
- Only proximal and distal suture

Najuta Arch fenestrated device

Assessment of proximal landing zone



Yuri et al. Ann Thorac Surg 2017

Najuta Arch fenestrated device

Results

A Challenging Treatment for Aortic Arch Aneurysm With Fenestrated Stent Graft

Koichi Yuri, MD, PhD, Naoyuki Kimura, MD, PhD, Daijiro Hori, MD, Atsushi Yamaguchi, MD, PhD, and Hideo Adachi, MD, PhD

Department of Cardiovascular Surgery, Saitama Medical Center of Jichi Medical University, Saitama, Japan

54 arch aneurysms (mainly saccular)

- Operative Mortality: 3.7%
- Stroke: 5.5%
- Survival 75% @ 41.4 months
- Endoleak: 7,4%
- Secondary Interventions: 5.5%

Ann Thorac Surg 2017

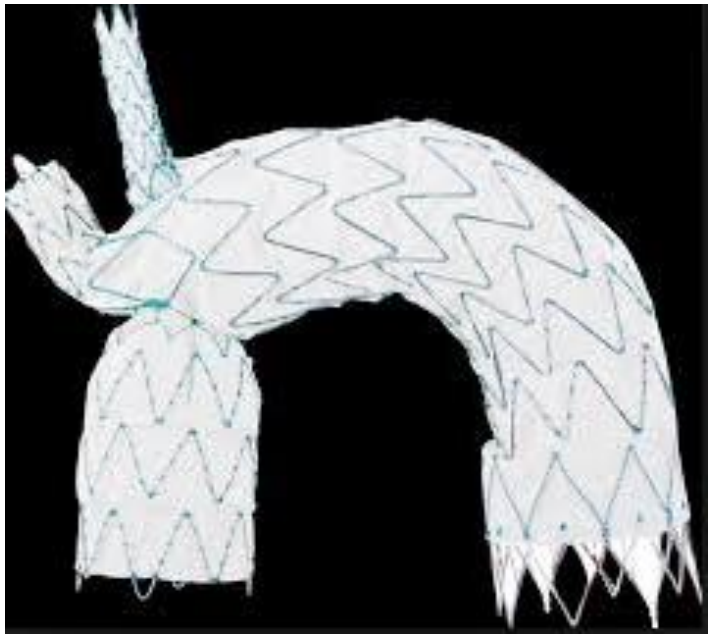
Summary

- Off-the-shelf single branch arch devices **(Gore TBE and Medtronic Mona LSA)** were born for treatment of distal arch disease

- *All patients included in the Trials were treated in landing zone 2*
- *10-15 mm between LCCA and LSA + ≥ 5 mm distally to LSA required*

Summary

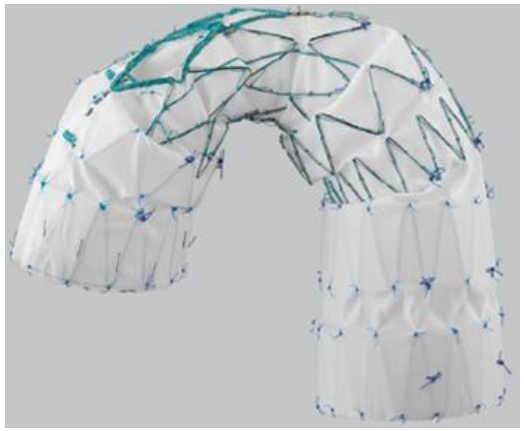
- **Endospan Nexus** is the only off-the-shelf arch device intended for use in landing zone 0



- *Single branch for IA and optional fenestration for LCCA*
- *More data and longer follow-up needed to test this modular system (disconnection resistance???)*

Summary

- **Cook and Bolton double branch** custom-made devices are the most investigated in the treatment of extensive arch disease (landing zone 0)



- *Strict adherence to inclusion and exclusion criteria (especially size and length of proximal sealing zone)*
- *Effect of learning curve*
- *Toward total endovascular approach (3 branches)*

Summary

- **Fenestrated and Scalloped** custom-made stent grafts provided by **Cook and Bolton** and **Najuta Fenestrated** device are preferable for…

- distal arch disease

- extending proximal landing zone

- **saccular aneurysm**

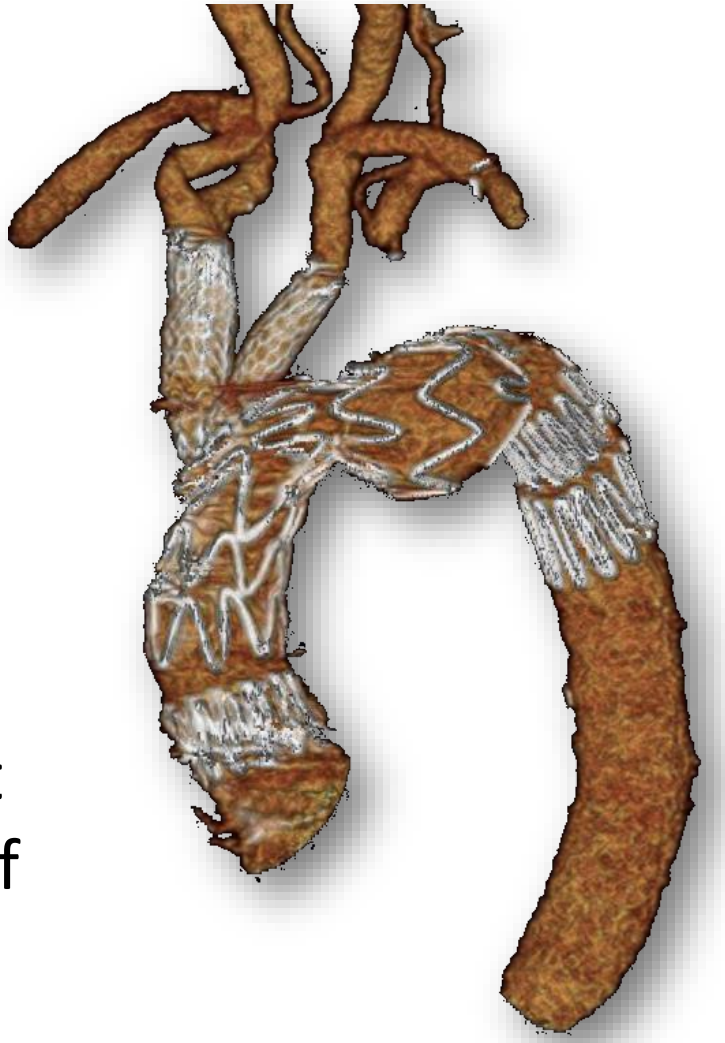
- **aneurysm of the inner curvature**

Conclusion (I)

- Choice of different models of arch stent grafts are stricly related to the extension of the disease

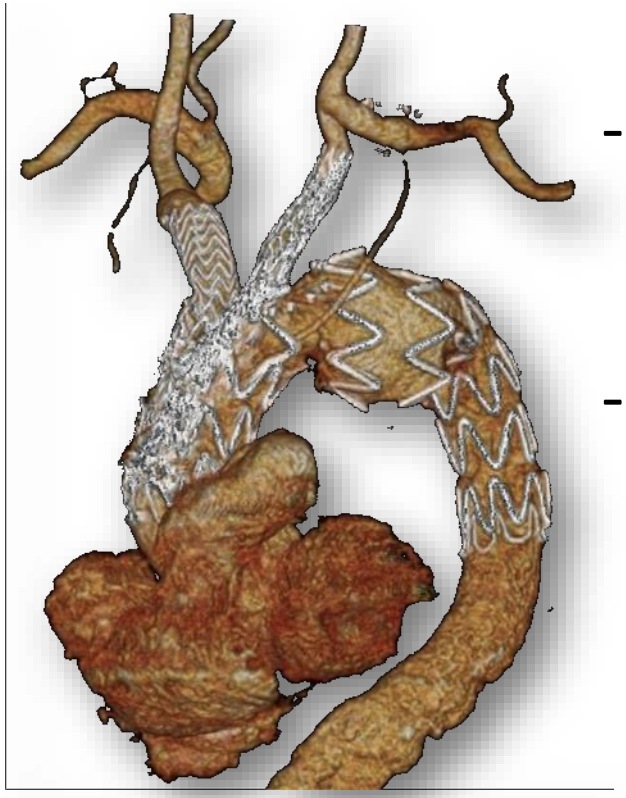
- Shift to a more proximal landing zone (from 1 to 0) can assure a longer durability but should be balanced with the complexity of the procedure

- Fenestrated or scalloped devices may be effective in the treatment of saccular aneurysm, especially if located in the inner curvature



Conclusion (II)

- Inner antegrade branched devices should be preferred for more extensive and fusiform aneurysms



- Off-the-shelf single branch devices will be usefull in emergencies

- Custom-made inner branched stent grafts should be developed to limit as much as possible hybrid adjuncts (3 branches)

- Current arch stent grafts are now limited to an investigational use and more data are needed to test their efficacy especially in the long-term