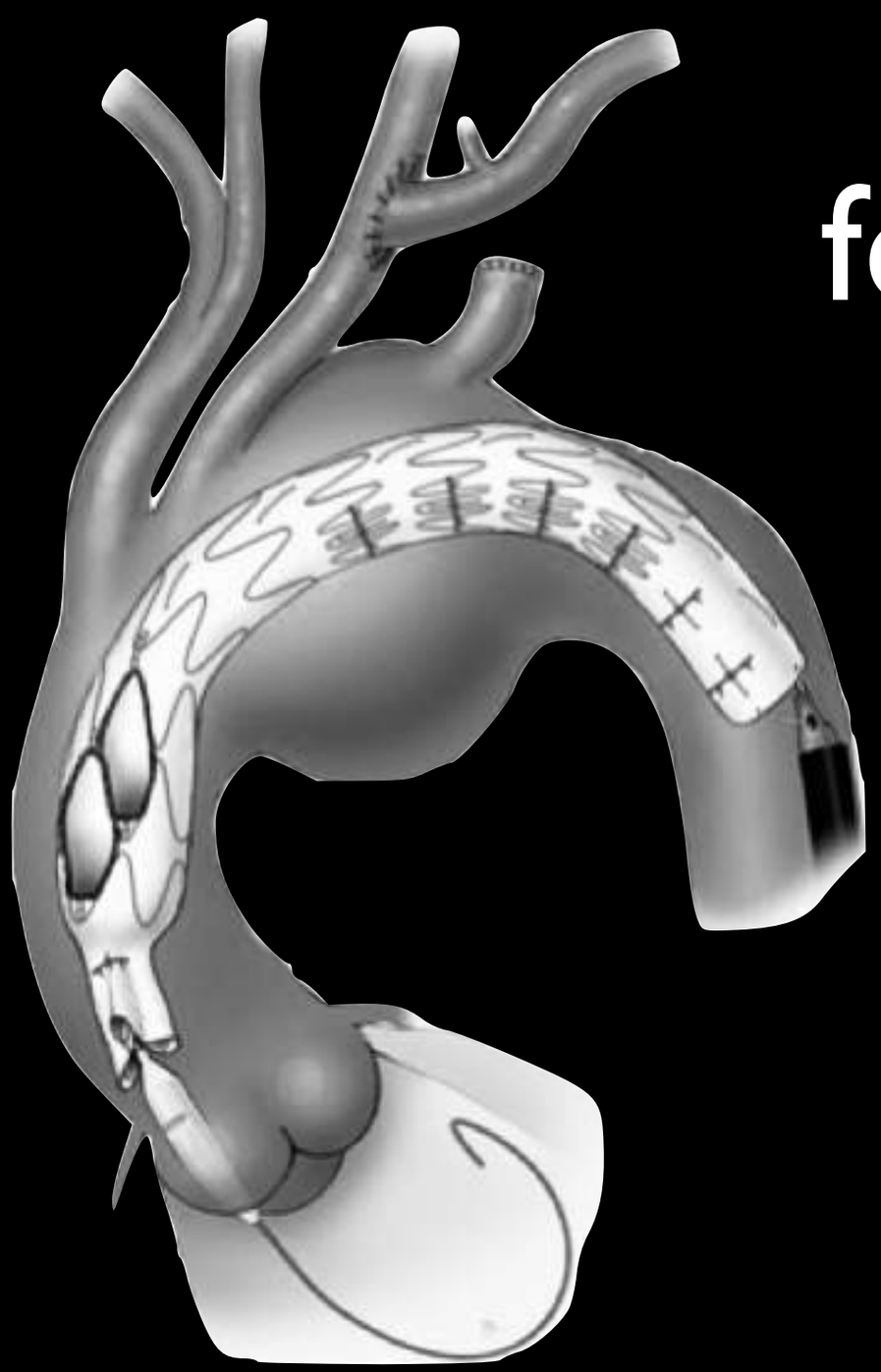
New branched and fenestrated devices for the aortic arch

Mark A. Farber
Professor of Surgery and Radiology
Director, UNC Aortic Network
University of North Carolina
Chapel Hill,NC



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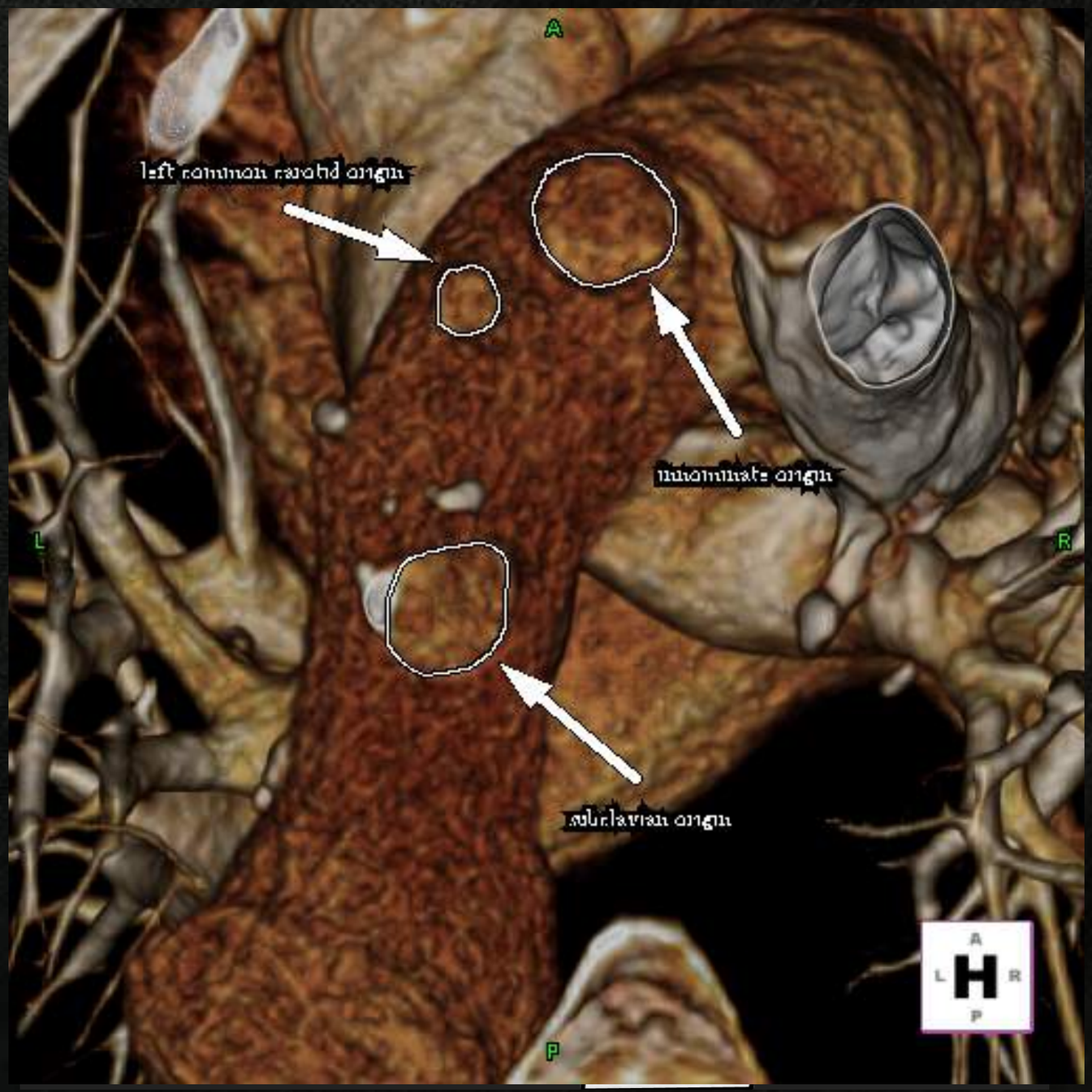
Disclosures

- Cook Medical:
  - Consulting, Clinical Trials Research Support
- WL Gore:
  - Clinical Trials, Consulting
- Medtronic
  - Clinical Trials, Consulting
- Endologix:
  - Clinical Trials, Consulting

Why Is Endo Repair of the Arch a Challenge



- Branch Involvement
  - Distance between branches and location of take off variable
  - Varies longitudinally and axially
- Arch angulation
- Ascending – descending aortic size discrepancy
  - Arch and descending aortic aneurysms

Other Problems Unique to the Arch

- Increased pressure and migration forces
- Coronary Arteries
- Imaging difficulty
- Dealing with the aortic valve and working in LV
- Monitor LV function
- Need for overdrive pacing for deployment
- Delivery system problems

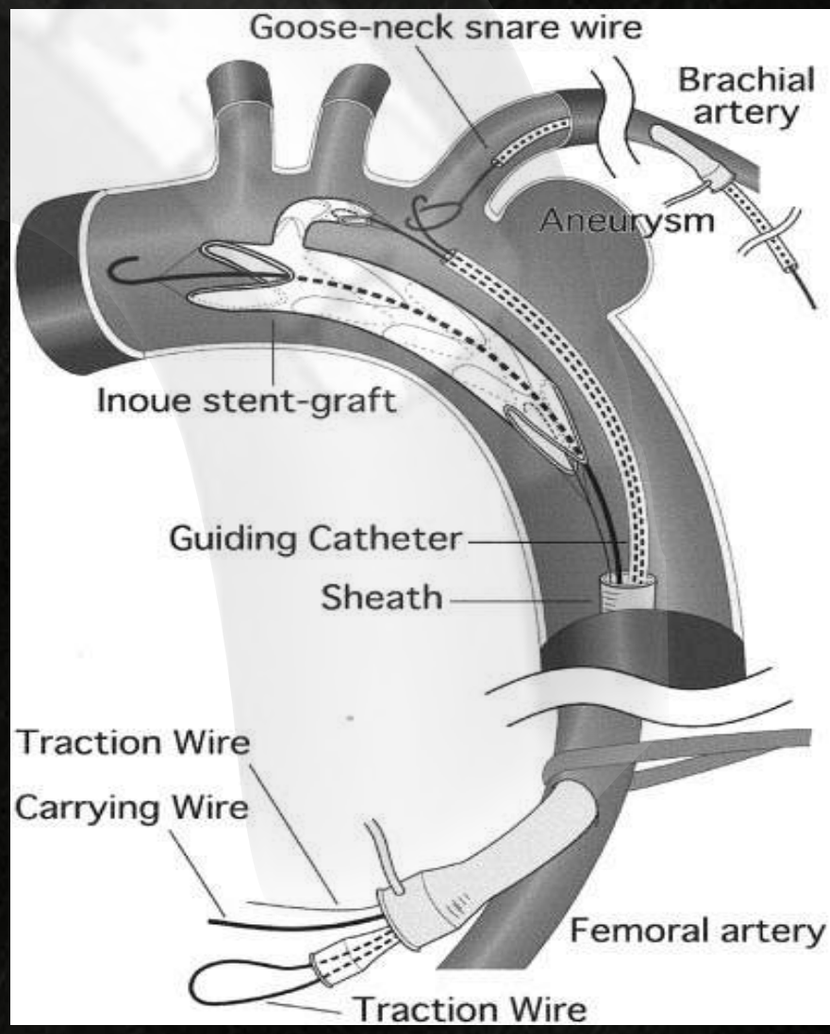
How do we achieve arch branch preservation?

- Fenestrations
  - Standard
  - Custom
  - In situ creation
- Branches
  - Standard
  - Custom

Single Fenestration/Branch: Zone 1 or 2 Left Subclavian or left Carotid

Cook Zenith
Prox Fenestration

Medtronic
Valiant
Mona LSA



Inoue Graft

Single fen

Early Outcomes – but data is old

- 15 Patients
  - 14 single branched cases
  - 1 triple branched case
- 60% Primary Success (exclusion of aneurysm at first procedure)
  - 2 had access issues
  - 4 endoleaks
    - 2 major – one treated with graft extentsion
    - 2 minor – one spontaneously occluded.
- Mean follow-up 12.6 months
- 73% achieved complete thrombosis of aneurysm

Insidon, Stat Circulation 1999; 100 (Suppl II): II-316

Current Devices

- Gore TBE
- Cook A-branch
- Cook CMD Fenestrated
- In-Situ Fenestration
- Medtronic Mona-LSA
- Bolton Medical
- Inoue
- Najuta
- Nexus

Currently no approved FDA devices

Gore TBE

Device Overview

TBE Device

- Aortic Component
- Side Branch (SB) Component
- Aortic Extender (Optional)

Additional TBE accessory

- GORE® DrySeal Side Branch Introducer Sheath (SBIS)

Procedural Steps

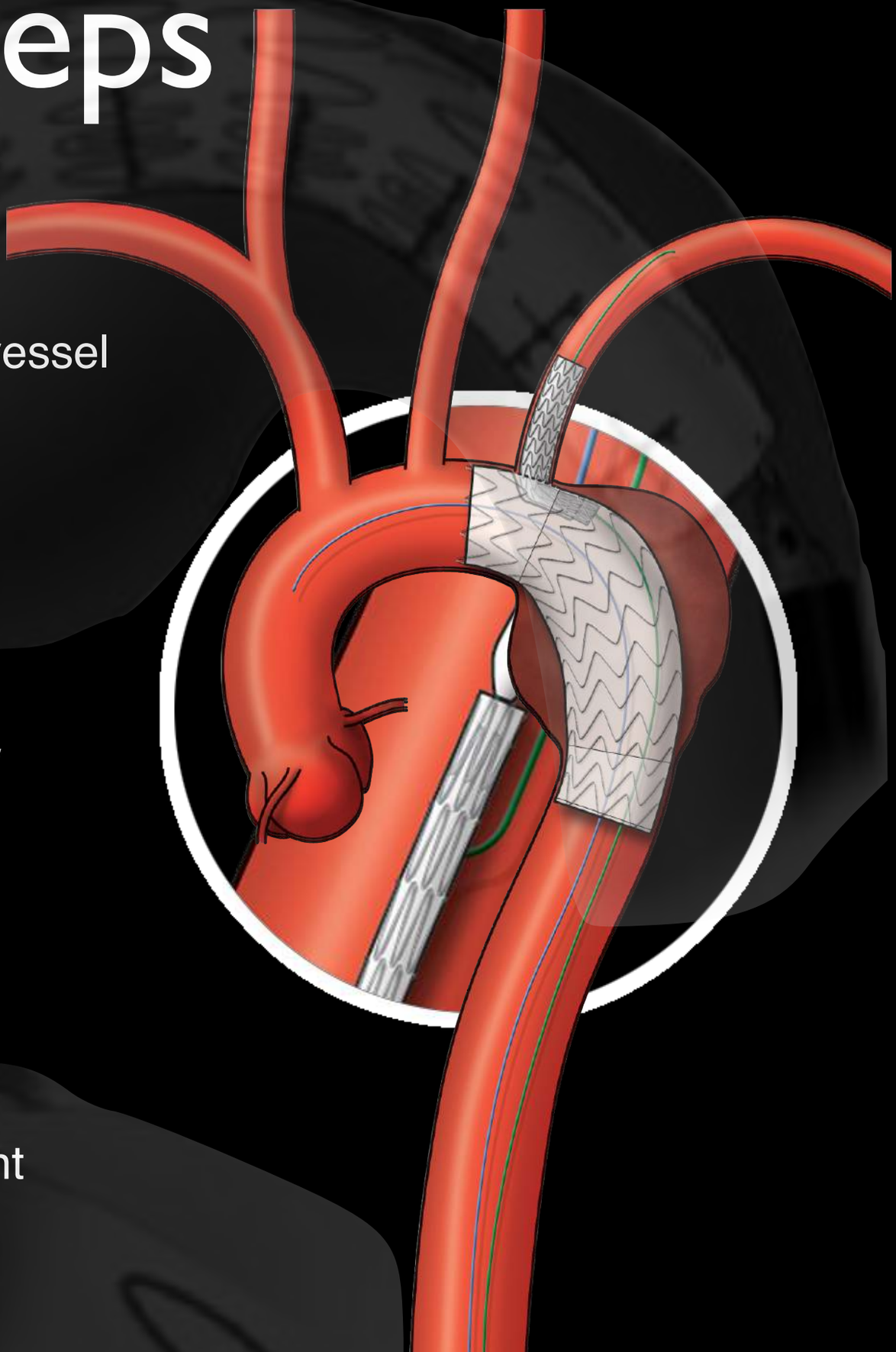
Step 1:
- Insert guidewires in aorta and branch vessel

Step 2:
- Introduce aortic component over both guidewires into position within the arch

Step 3:
- Deploy aortic component and withdraw catheter

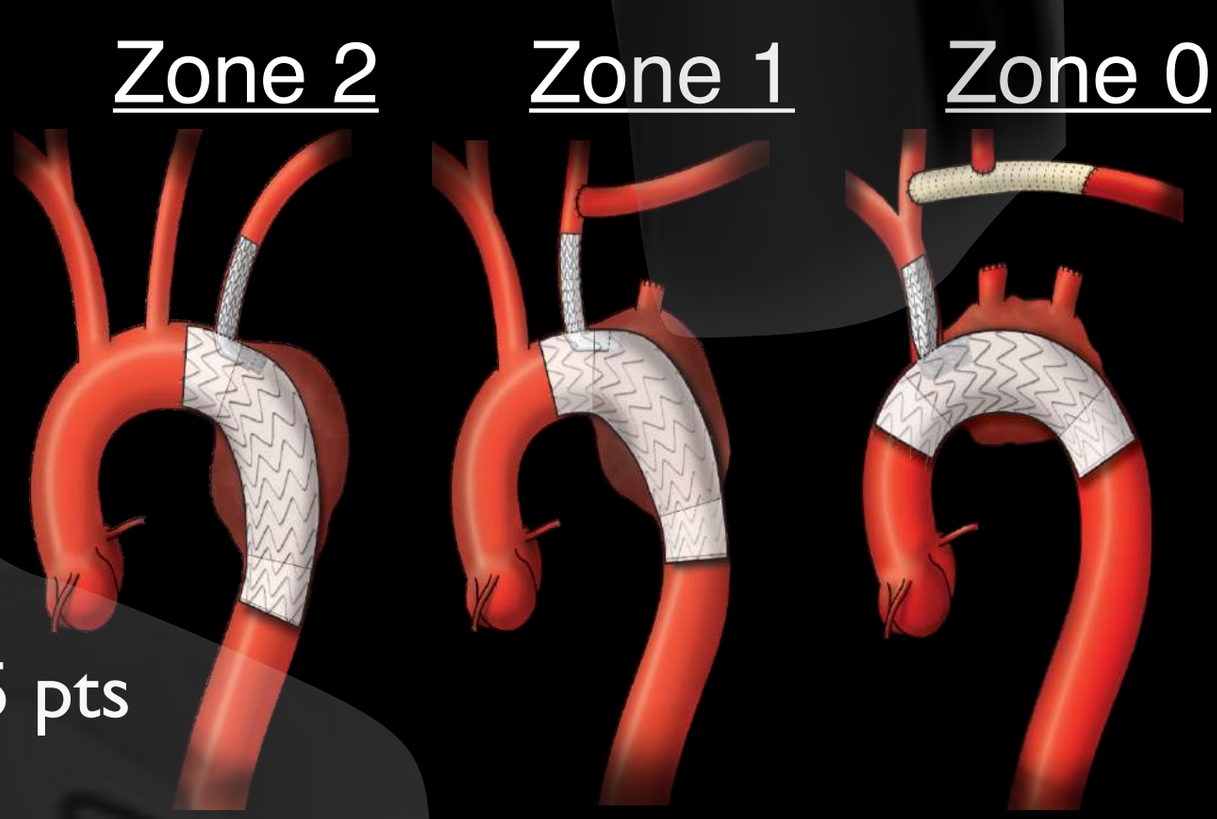
Step 4:
- Advance introducer sheath and dilator

Step 5:
- Advance and deploy branch component



Gore Side Branch Device

- Completed feasibility study
- PI: Michael Dake
- Enrollment:
  - Zone 2: 50 of 85 pts
  - Zone 0/1: ~20 pts
    - Phase I: Cervical debranching
    - Phase II: TSSB
- No strokes, death or SCI
- Pivotal Trial Enrolling Sept 2016: 175 pts



Preliminary Results from Multicenter Feasibility Trial

- N=22, Mean Age - 74.1
  - Fusiform (10)
  - Saccular (12)
  - Zone 2
- L SCA Patency: 100%
- Type I endoleaks
  - Intra-Op: 18%
  - 1 month: 0%
- Survival: 94.7% @ 6 months

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

Departments of Cardiac Surgery and Radiology, University of Michigan Frankel Cardiovascular Center, Ann Arbor, Michigan; Department of Cardiothoracic Surgery, Stanford University Hospitals, Palo Alto, California; Department of Surgery, Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania; Department of Surgery, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania; Department of Surgery, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire; Department of Surgery, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin; and Department of Surgery, Mayo Clinic, Rochester, Minnesota

Background. Endovascular treatment for aortic arch aneurysms often requires adjunctive use of hybrid debranching procedures to maintain branch vessel perfusion. This study describes early results with a novel branched arch endograft for total endovascular repair of distal arch aneurysms.

Methods. This US feasibility multicenter clinical trial evaluated 22 patients (mean age, 74.1 ± 10.5 years; 54.5% male) undergoing branched thoracic endovascular aortic repair in Ishimaru zone 2. This endograft was designed with a single side branch designed to facilitate aortic coverage proximal to the left subclavian artery while maintaining branch vessel patency. The pathologic features treated included fusiform (n = 10) and saccular (n = 12) aneurysms, with a mean aortic diameter of 5.7 ± 1.1 cm. The mean preoperative left-to-right brachial index was 1.0 ± 0.1.

Results. The mean total treatment length was 17.6 ± 8.9 cm; 8 patients were treated with a single 10-cm graft for isolated arch disease. The primary endpoint of device delivery and branch vessel patency was achieved in 100% of patients, without 30-day death, stroke, or permanent paraplegia. The median duration of hospitalization was 4.0 days. Type I endoleaks at completion angiography were observed in 4 patients, and all resolved by 1 month without reintervention. All side branches were patent at 1 month. The Kaplan-Meier survival rate at 6 months was 94.7%.

Conclusions. Total endovascular repair of distal zone 2 arch aortic aneurysms can be achieved with a novel branched arch endograft. Future studies will evaluate the feasibility of this approach for aneurysms encompassing the brachiocephalic trunk and left carotid artery.

(Ann Thorac Surg 2016;102:1190–8)

The seminal work by Dake and colleagues [1] introduced the concept of endovascular repair of the thoracic aorta. Since the initial approval of the Gore TAG device (WL Gore, Flagstaff, AZ) by the US Food and Drug Administration (FDA) in 2005, endovascular repair has been rapidly adopted in the treatment of thoracic aortic disease [2–4]. Three additional devices have obtained FDA approval on the basis of industry-sponsored clinical trials. However, pure "on-label" endovascular repair for all available devices is currently limited to treatment of aortic segments where no critical branch vessels exist. When treating the arch of the aorta in the region of the left subclavian artery (LSA), the strategy most frequently used is adjunctive extraanatomic revascularization. Although the merits of LSA revascularization continue to be debated, the ideal solution would be endoprosthetic device development to allow for endovascular branch vessel reconstruction [5–8]. We present the early results of the US feasibility multicenter trial evaluating the Gore Thoracic Branch Endoprosthesis (TBE) in the treatment

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Drs Patel, Dake, and Bavaria disclose a financial relationship with WL Gore; Dr Filinger with WL Gore and Endologix; Dr Matsumura with WL Gore, Cook, Covidien, NIH, Abbott, and Endologix.

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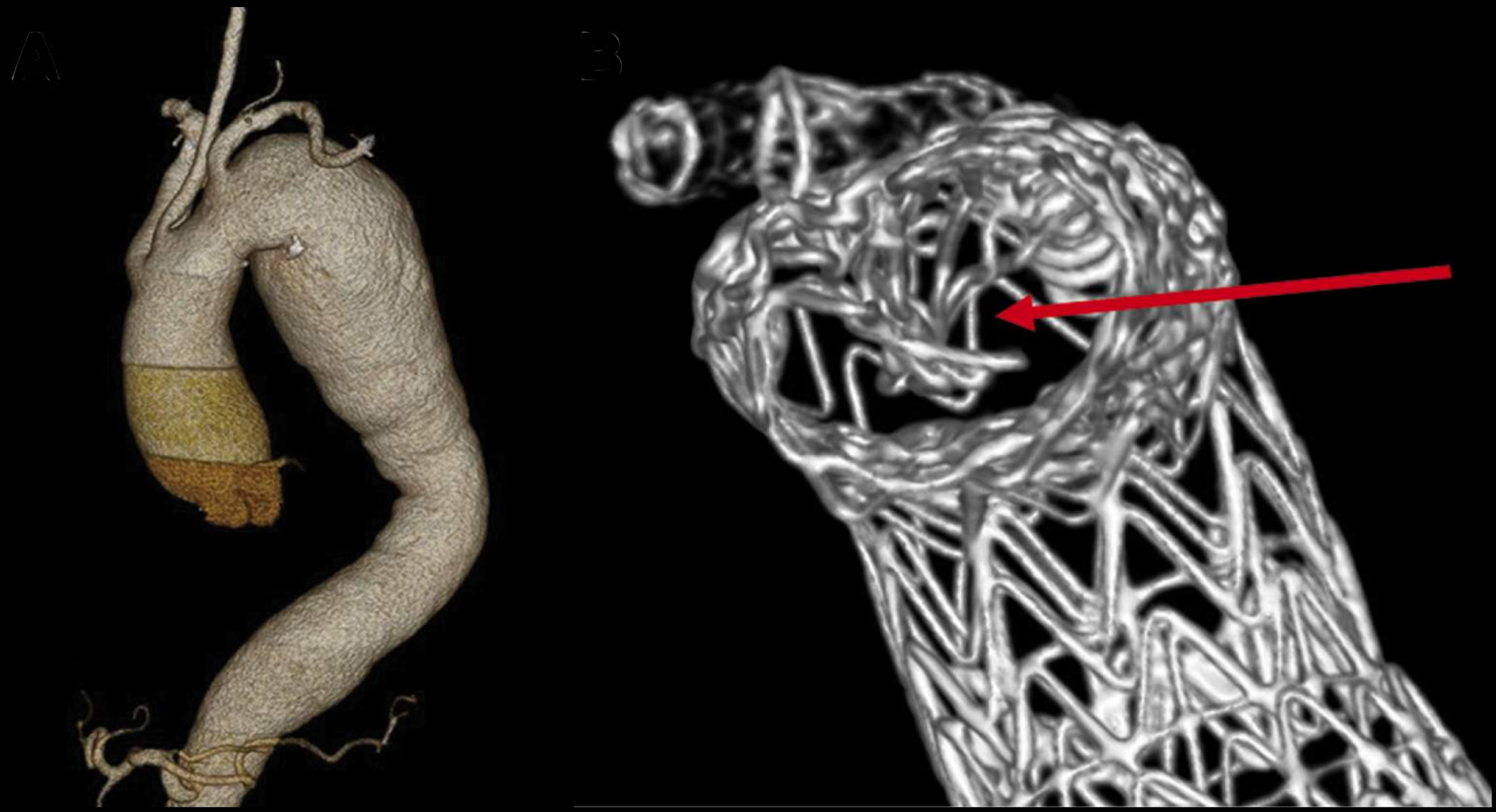
0003-4975/$36.00

Ann Thorac Surg 2016;102:1190–8

Preliminary Results from Multicenter Feasibility Trial

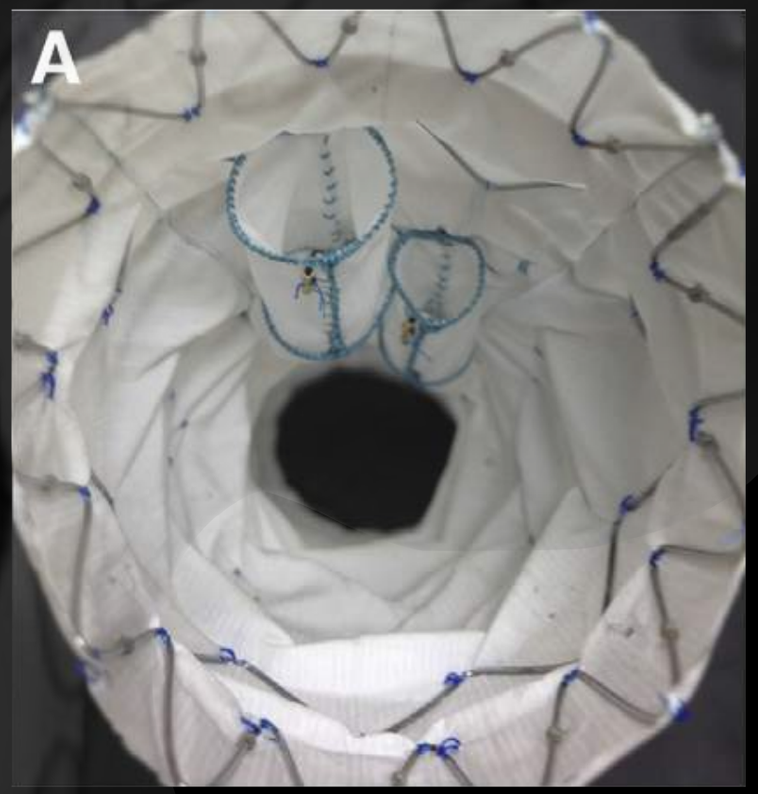


Ann Thorac Surg 2016;102:1190–8

Branched Arch Endograft – Cook Medical

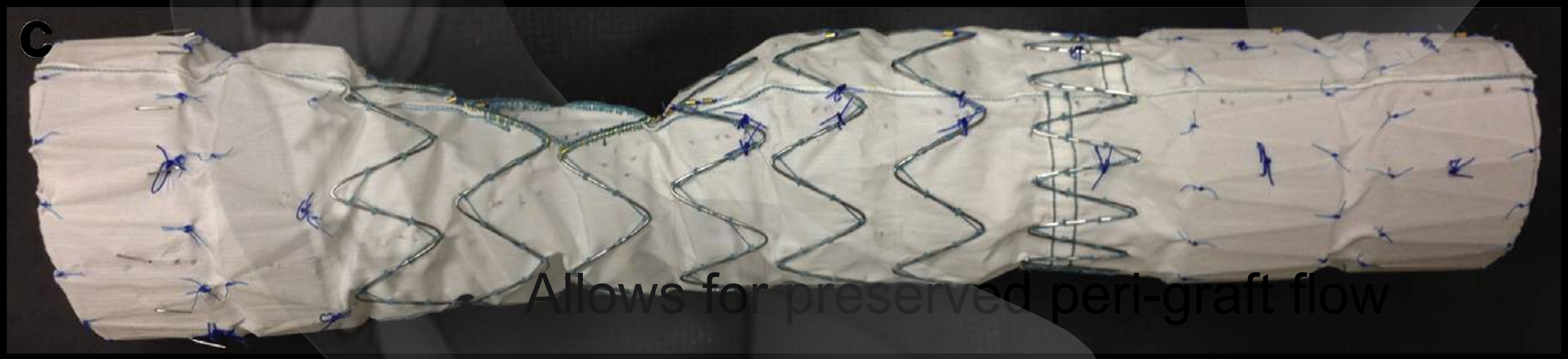
Custom graft

Pre-curved



Two Internal Branches

-Carotid Artery
  +Fluency
  +Vaibahn
-Innominate
  +Custom limb
  +14 Fr sheath



Allows for preserved peri-graft flow

Haulon S et al., JTCVS 2014; epub

Anatomic Criteria (Generalized)

- Arch aneurysms and chronic dissections
- No prior aortic valve replacement
- Ascending aortic length ≥50mm (STJ to IA)
- Sealing zone in Asc. Aorta ≤38 mm in diameter
- IA: ≥20 mm sealing length, ≤20 mm diameter
- Iliac able to accommodate 22-24 Fr sheath

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]

- Pts: 38 with a mean age of 71
- Technical Success: 84.1%
- Mortality: 13.2%
- Cerebrovascular Complications: 15.8%

Haulon S, Greenberg RK, Spear R, Eagleton M, Abraham C, Lioupis C, et al. Global experience with an inner branched arch endograft. J Thorac Cardiovasc Surg. 2014 Oct;148(4):1709–16.

Subsequent Results with Inner Branch

	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.

Spear, R., et al. (2016). Editor's Choice - Subsequent Results for Arch Aneurysm Repair with Inner Branched Endografts. *EJVES*, *51*(3), 380–385.

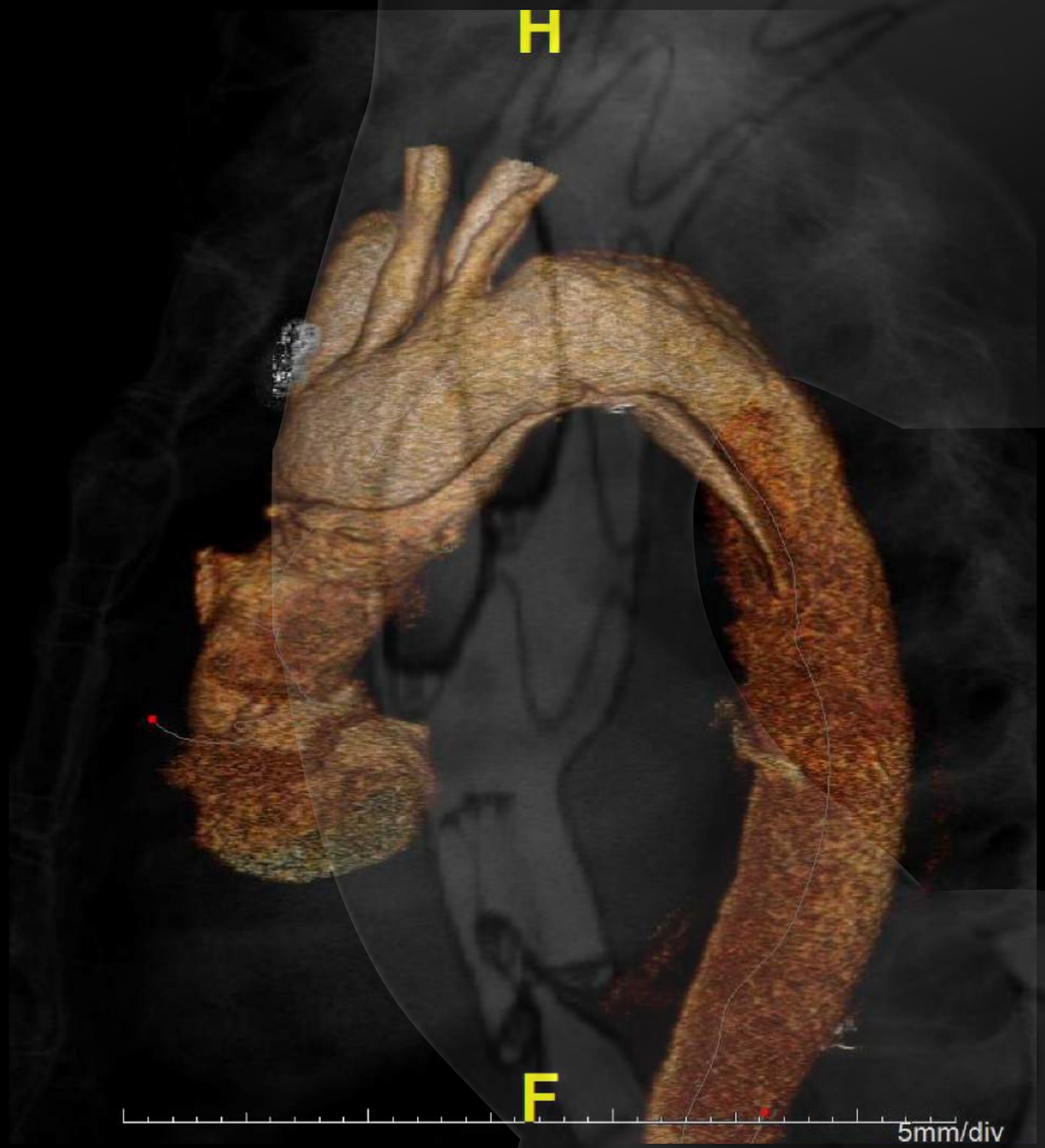
Learning Curve

- Compared first 10 patients to last 28 patients
  - Similar demographics
  - Improved outcomes
    - Intraoperative complications: 40% v. 10.7%
    - All secondary procedures: 40% v. 10.7%
    - Early secondary procedures for endoleak: 20% v. 0%
    - All secondary procedures for endoleak: 30% v. 0%
    - Operative time (min): 320 v. 248
    - Radiograph duration (min): 120 v. 39

Haulon S et al., JTCVS 2014; epub

Cook Zenith Fenestrated CMD

Bilateral Ca-SCA Bypass
Cook Arch Branch and VBX



Total Endovascular Arch Repair

Cook Arch Device

- Third retrograde portal
  - Pre-catheterized
- Post-dissection Aneurysms
- N=3
- Patency 6 months: 100%

Case Report

JOURNAL OF ENDOVASCULAR THERAPY

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

Journal of Endovascular Therapy
2017, Vol. 24(4) 534–538
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DOI: 10.1177/1526602817714569
www.jevt.org

SAGE

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]

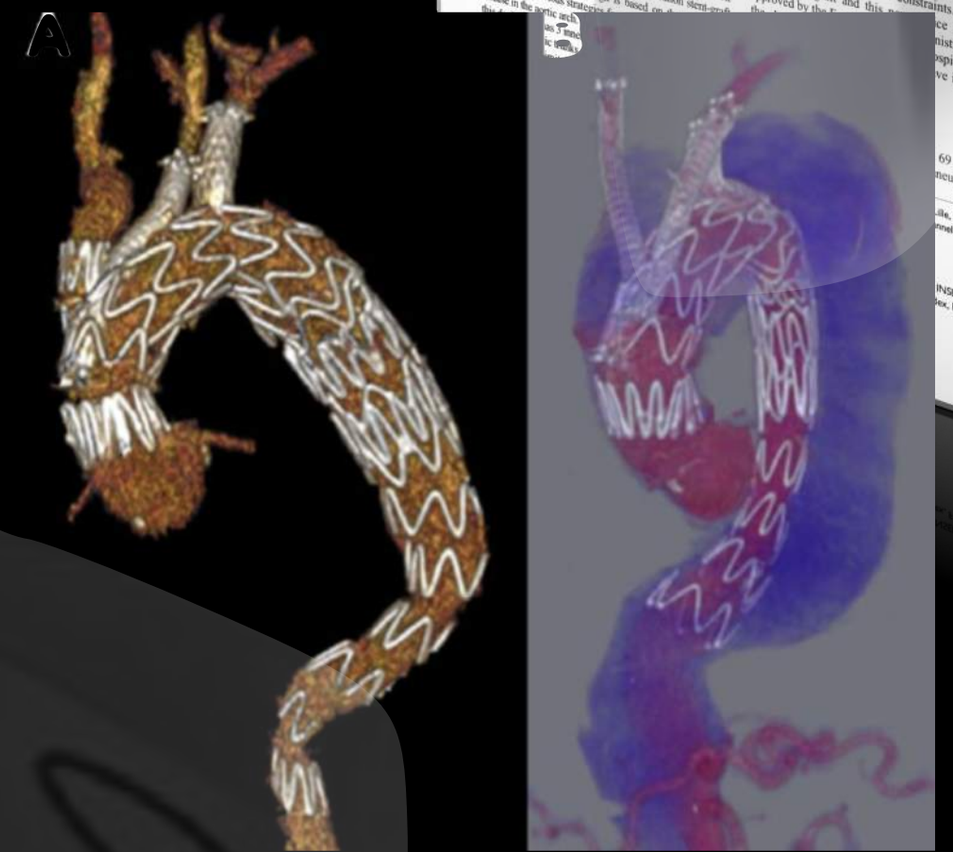
Abstract

Purpose: To report early experience with a new endovascular graft developed for aortic arch aneurysm repair in patients unfit for open surgery. **Case Report:** Three consecutive men (62, 74, and 69 years old) at high risk for open repair were treated for postdissection aortic arch aneurysms using a custom-made 3 inner branched endovascular graft. The 2 proximal branches are antegrade and perfuse the innominate artery and the left common carotid artery; the third branch is retrograde and perfuses the left subclavian artery. The latter is preloaded with a catheter and wire to aid cannulation. Technical success was achieved in each case. The mean procedure time, fluoroscopy duration, and contrast volume were 180 minutes, 35 minutes, and 145 mL, respectively. The perioperative period was uneventful. All branches were patent on 6-month computed tomography and duplex ultrasound imaging. **Conclusion:** This new patient-specific device allows total endovascular revascularization of the supra-aortic trunks during arch repair. These encouraging results support its more widespread use.

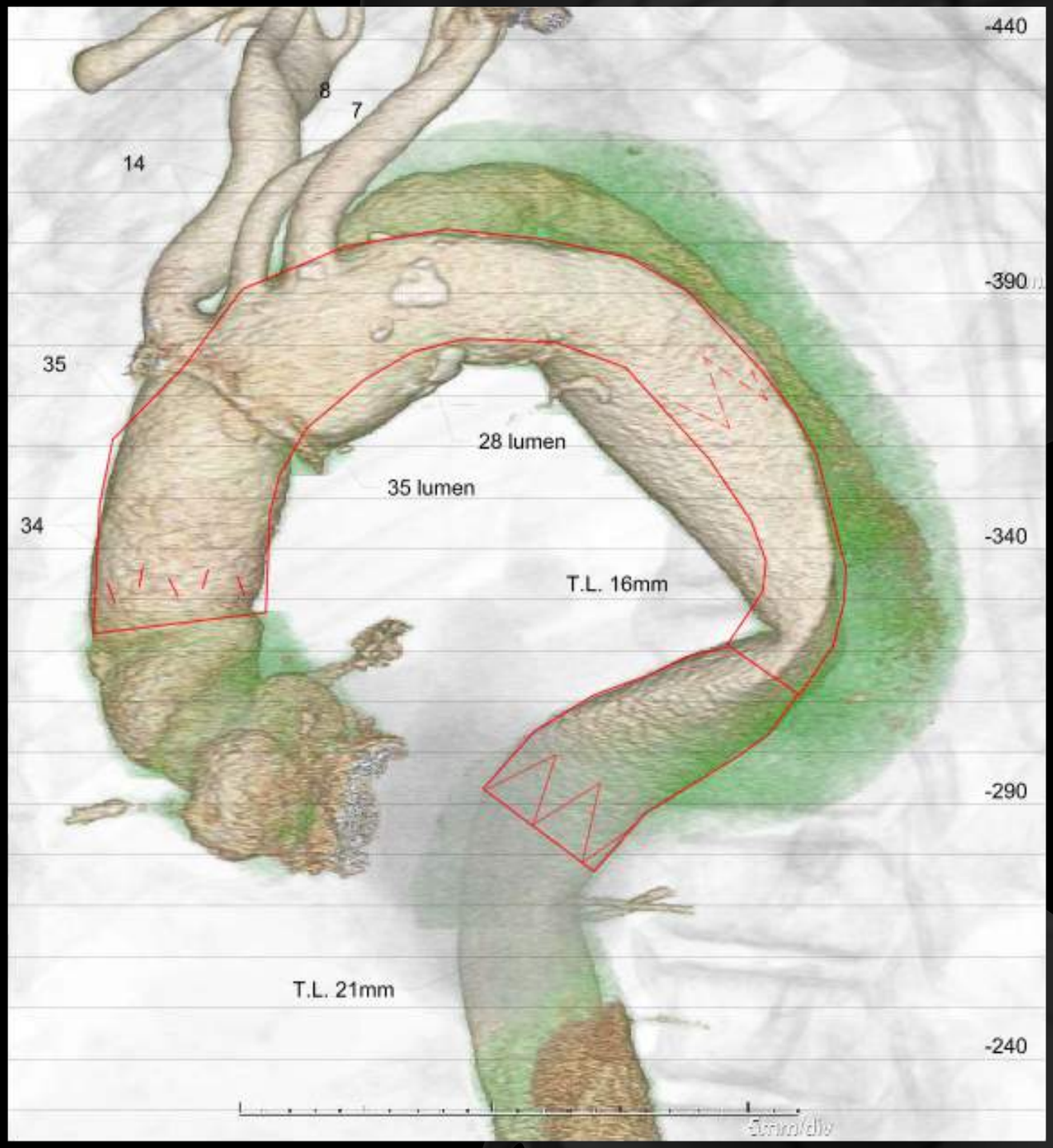
Keywords

aneurysm, aortic arch, arch branched stent-graft, dissection, endograft, thoracic endovascular aortic repair

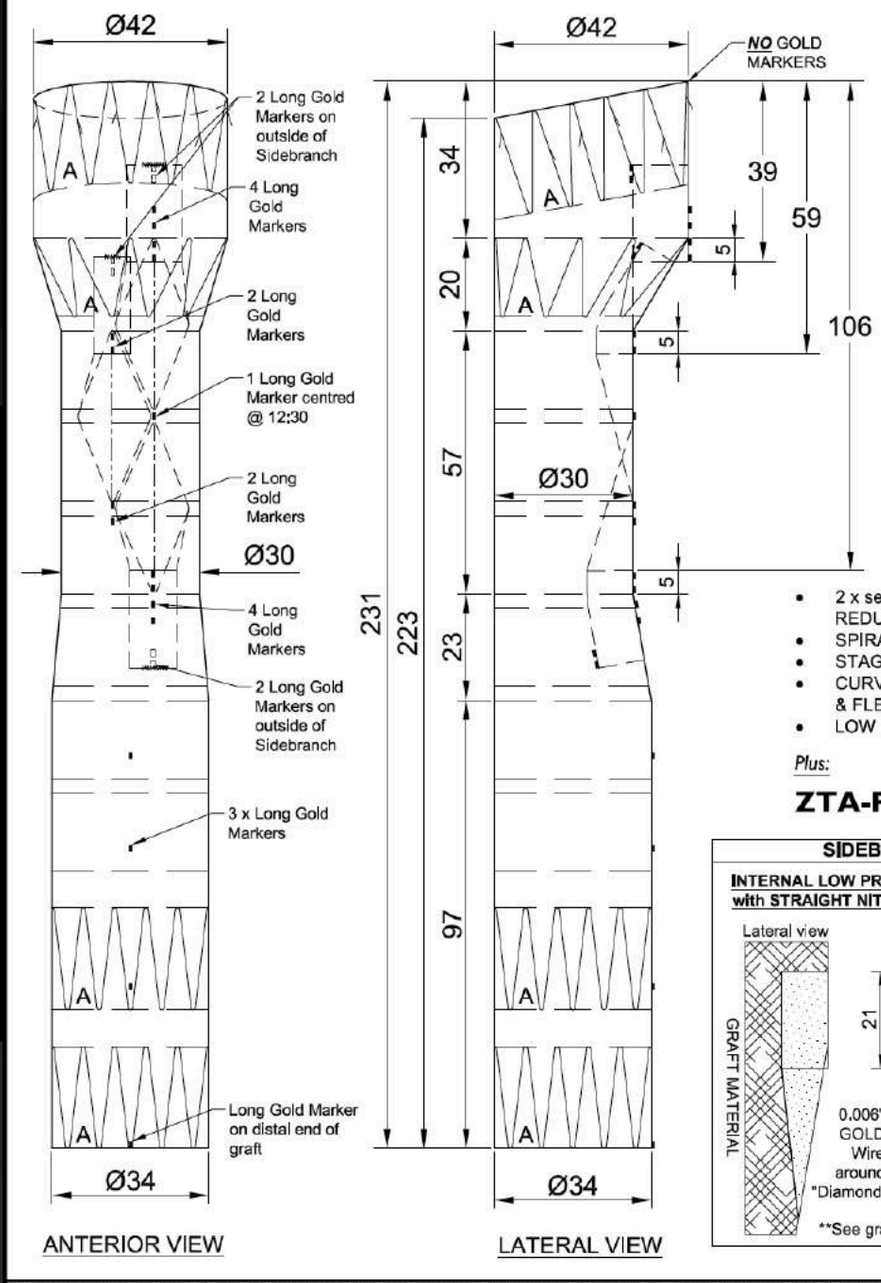
Introduction



Device Design



REA34245_v2	NON STANDARD DEVICE REQUEST - PROPRIETARY COOK MEDICAL	VERSION 2
Device: BRANCH-ASCENDING-ARCH-DEVICE Component: THORACIC-ASCENDING-BRANCH		PAGE 2 of 4



INTERNAL LOW PROFILE SIDEBRANCH #1
DIAMETER: 12mm
LENGTH: 21mm
DIST FROM PROX EDGE: 39mm
CLOCK: 12:30

INTERNAL LOW PROFILE SIDEBRANCH #2
DIAMETER: 8mm
LENGTH: 21mm
DIST FROM PROX EDGE: 59mm
CLOCK: 11:30

INTERNAL LOW PROFILE SIDEBRANCH #3
Upwards Facing
Preloaded Catheter & Guidewire
DIAMETER: 10mm
LENGTH: 21mm
DIST FROM PROX EDGE: 106mm
CLOCK: 12:30

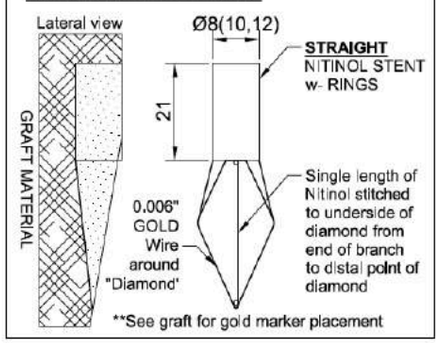
- 2 x sets of DIAMETER REDUCING TIES
- SPIRAL STABILISING WIRE
- STAGED RELEASE
- CURVED NITINOL CANNULA & FLEXOR SHEATH
- LOW PROFILE FABRIC

Plus:

ZTA-PT-36-32-161-W

SIDEBRANCH 1, 2 & 3

INTERNAL LOW PROFILE SIDEBRANCH with STRAIGHT NITINOL WIRE

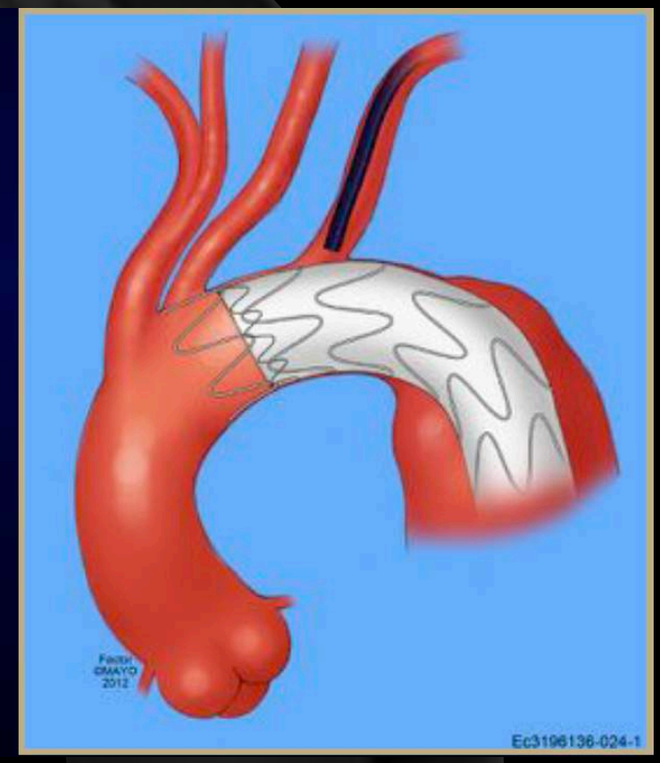


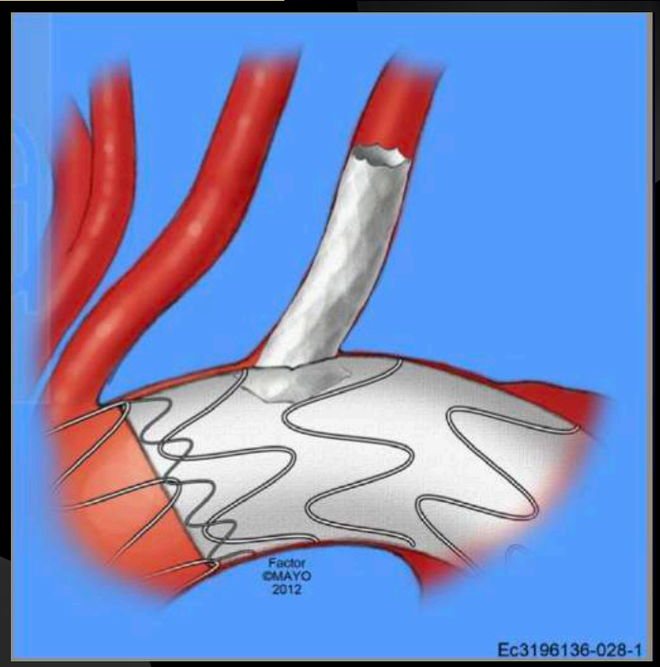
**See graft for gold marker placement

Please note the following: 1. By signing this graft plan you are confirming that the patient has consented to the provision of their personal information to Cook Medical. The patient understands that in order to plan and manufacture the requested device, Cook Medical may share his/her personal information with other Cook Group companies in the United States, Australia, Denmark, United Kingdom and Ireland and has consented to his/her personal information being so shared. **2.** You are confirming that all clinically important features (eg. fenestration size / orientation, gold marker placement, sealing stents) are included in this graft design prior to your

In-Situ Laser Fenestration

- N=41 (39 LSCA, 2 LCCA)
- Operative Mortality: 7.3%
- Neurologic Complications:
  - Stroke: 2 (4.9%)
  - SCI: 3 (7.3%, 2 permanent, 1 transient)
- No Type III endoleaks
- Type Ic: 3 7.3%
- All stents patent
  - 2 asymptomatic stenosis

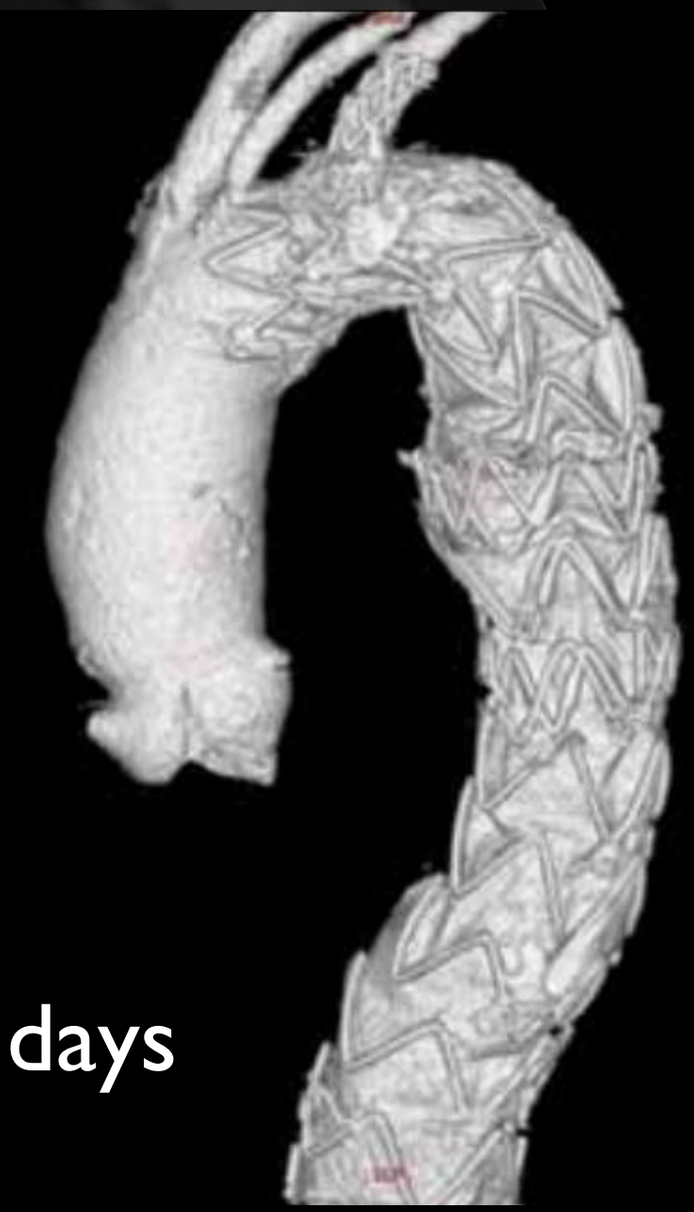




Redlinger, R.et al (2013). *Journal of Vascular Surgery : (58)* 1171–1177.

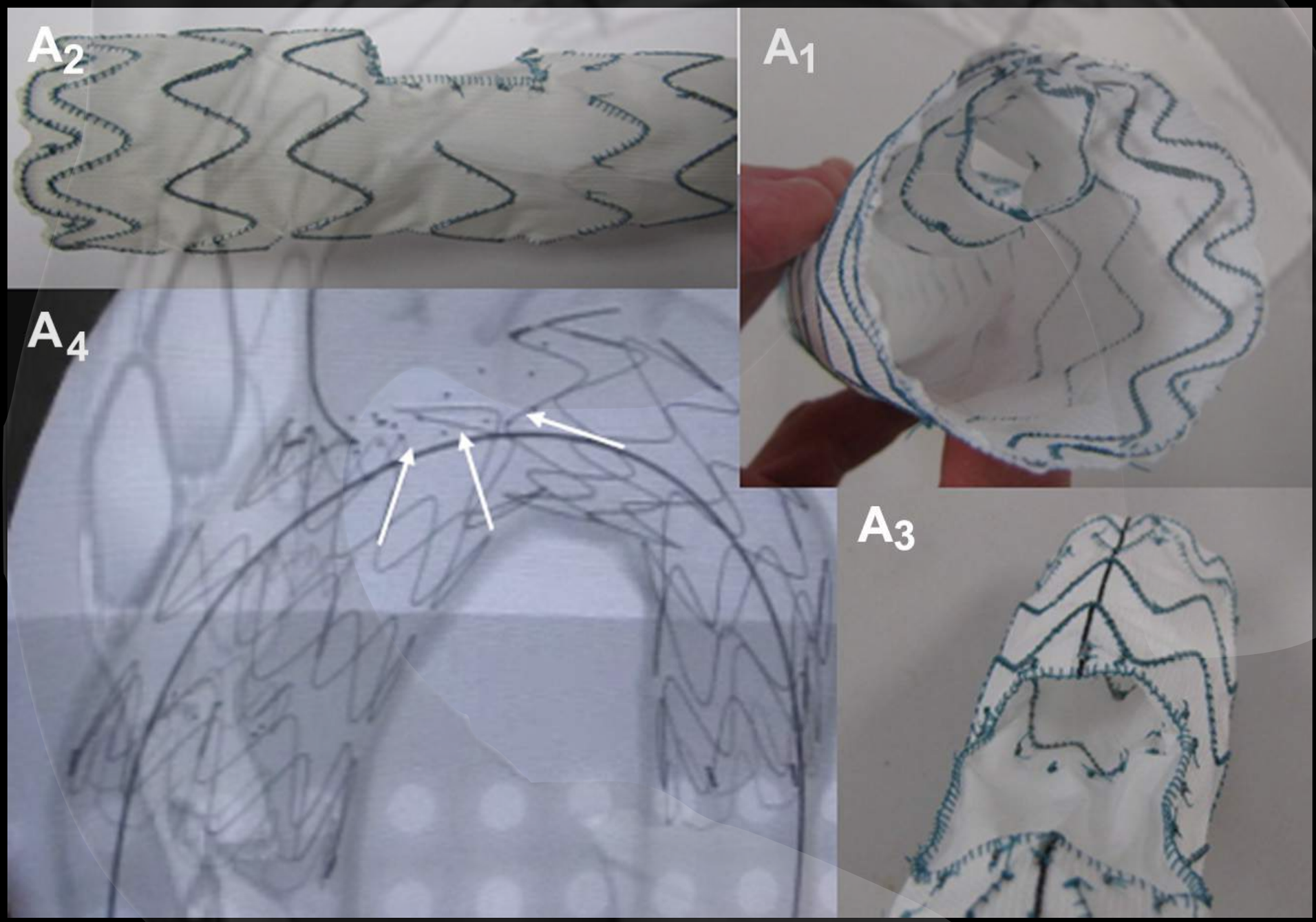
Medtronic Mona-LSA

- 9 subjects enrolled
- Four (50%) endoleaks in 8 pts
  - Type II - 2
  - Undetermined - 2
- Major strokes: 0
- Minor strokes: 4 (3 pts - 33%)
- No L arm ischemia or deaths @ 30 days



http://dx.doi.org/10.1016/j.jvs.2015.07.078

Branched Arch Endograft
Bolton Medical



Piffarreti G et al., J Vasc Surg 2013; 57: 1664

Thoracic Branch Technology with Relay®Branch

- Based on Relay NBS (Non-Bare Stent) Plus platform

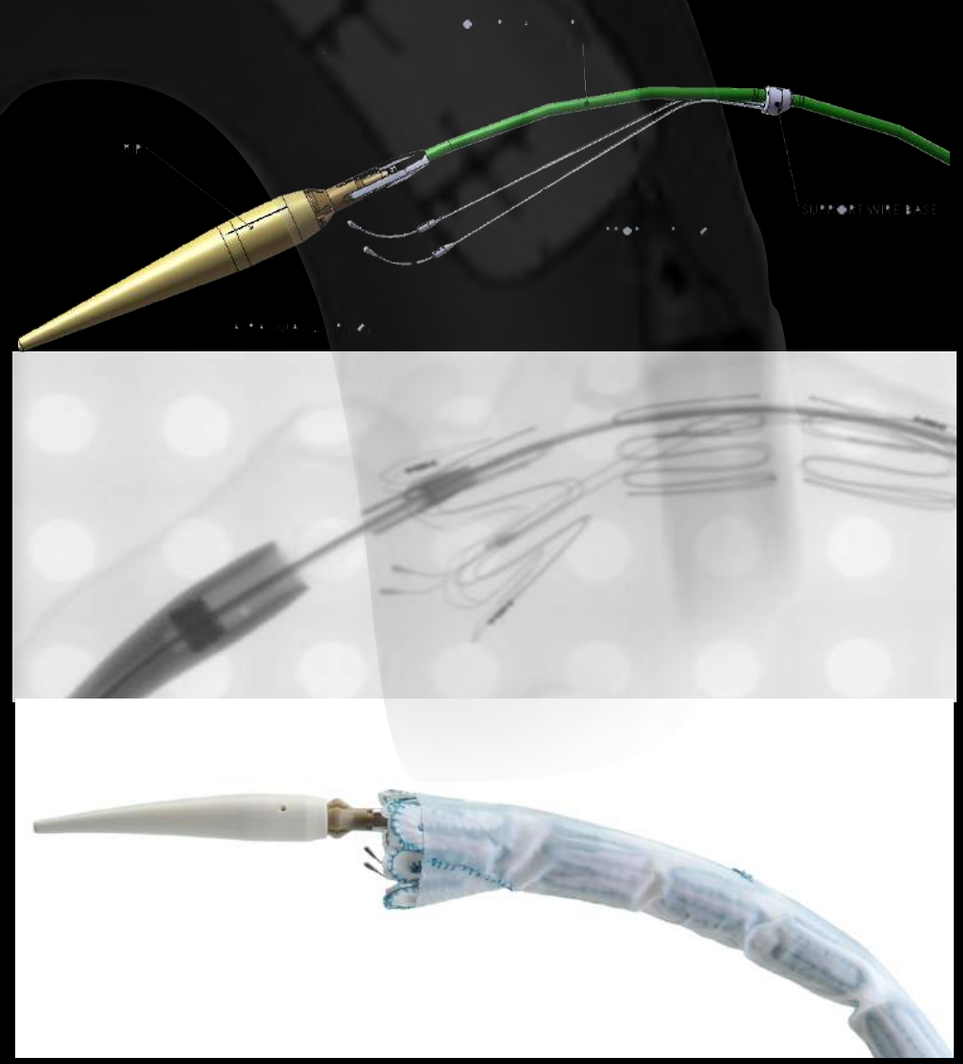
- “Off-the-shelf” (various proximal diameters, standard branch position and endograft length)

- Large single window for ease of cannulation of 2 internal tunnel(s)
  - Innominate and LCCA

- Intended for Zone 0 deployment combined with extra-anatomic arch branch bypass as required

Relay NBS Plus Platform Technology has Allowed for Development and Clinical Use of Thoracic Branch Technology

- Patented proximal capture technology
- Improved arch conformation and prevention of retroflex deployment
- Self-orienting pre-curved NiTi guidewire lumen
- Dual sheath design facilitates advancement into Zone 0



Worldwide Clinical Experience

Single Branch (n-5):

- Patients treated via Custom Made Program
- 5 patients from initial feasibility experience (5 centers)
- Limited experience since the initiation of the Double Branch phase

Double Branch (n=101*):

- Patients treated via Custom Made Program (20 centers)

* Experience as of 10/1/2017

Inoue Arch Graft

- N=89
  - Single-64
  - Double-18
  - Triple-7
- Mortality (30d): 4.5%
- Stroke: 16%
- Branch Occlusion: LSCA-1
- ACM @ 1 and 5 yrs: 85%/59%


ARTICLE IN PRESS

Thoracic endovascular aortic repair with branched Inoue Stent Graft for arch aortic aneurysms

Junichi Tazaki, MD,[a] Kanji Inoue, MD,[b] Hirooki Higami, MD,[c] Nobuya Higashitani, MD,[c] Masanao Toma, MD,[d] Naritatsu Saito, MD,[e] Masahide Kawatou, MD,[e] *and* Takeshi Kimura, MD,[a] *Kyoto, Otsu, and Amagasaki, Japan*

ABSTRACT

Background: Thoracic endovascular aortic repair (TEVAR) for thoracic aortic aneurysms (TAAs) is in rapid expansion due to its minimal invasiveness. However, TEVAR for an arch aneurysm with a straight stent graft needs surgical reconstruction for supra-aortic vessels. A branched stent graft pioneered by Inoue (branched Inoue Stent Graft [ISG]) has been expected to resolve this problem, but its utility remains to be established in the real clinical setting. This study evaluated the long-term clinical outcome of branched ISGs for TAAs.

Methods: Among 217 consecutive patients who underwent TEVAR with ISGs between March 2003 and September 2013, 89 patients with TAAs were treated with implantation of the branched ISG (single branch: n = 64; double branch: n = 18; triple branch: n = 7). The primary end point was freedom from aneurysm-related death. Secondary end points included periprocedural adverse events, freedom from all-cause death and major adverse events (composite of aneurysm-related death, surgical conversion, aneurysm rupture, persistent type I or III endoleak, graft infection, graft occlusion, graft migration, and aneurysm expansion), changes of aneurysm diameter, stroke, and any endovascular reintervention during follow-up.

Results: All deployments of branched ISGs were successful. The 30-day mortality was 4.5% (single branch, 3.1%; double branch, 0%; triple branch, 29%), and periprocedural stroke was 16% (single branch, 7.8%; double branch, 33%; triple branch, 42%). At 1 and 5 years, freedom from aneurysm-related death was 93% and 93%, respectively, and freedom from all-cause death was 85% and 59%, respectively. Survival free of major adverse events was 76% at 5 years. The cumulative incidence of stroke was 11% at 5 years. Three patients underwent surgical conversion because of persistent type I endoleak. One branch graft occlusion was observed at the left subclavian artery in a patient who received a double-branched graft.

Conclusions: Periprocedural outcome of the single-branched ISG was acceptable, and long-term safety and efficacy were demonstrated. However, the procedural complications of the multibranched ISG leave room for improvement. (J Vasc Surg 2017;■:1-9.)

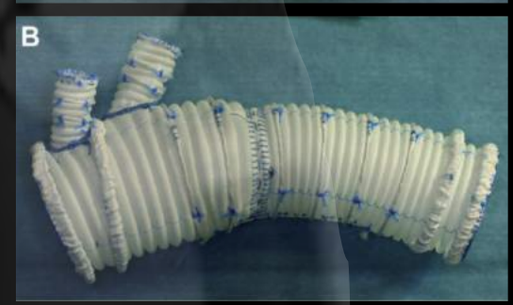
Thoracic endovascular aortic repair (TEVAR) for thoracic aortic aneurysms (TAAs) is in rapid expansion because it is less invasive. Recent reports indicate the feasibility of TEVAR for TAA in various clinical conditions.[1-7] TAA of the descending aorta is a good indication for TEVAR with the straight stent grafts that are now commercially available. However, patients with an arch aneurysm that involves the supra-aortic vessels need conventional open repair. Extra-anatomical surgical bypass for those vessels, which is called debranched-TEVAR (dTEVAR),[8-11] or complex endovascular procedures, such as chimney technique[12,13] or in situ fenestration,[14] are needed to preserve neck vessels for TEVAR with a straight stent graft. Although dTEVAR is less invasive than conventional open arch replacement, mortality and morbidity are higher,[8,9,11] and sometimes it is difficult to perform for complicated patients because of old age or severe comorbidities.

To resolve these problems straightforwardly, Inoue devised a branched stent graft of unibody construction, the branched Inoue Stent Graft (ISG), that allows repair of arch aneurysm without extra-anatomical surgical reconstruction or a complex endovascular procedure.[15-18] Saito et al[17] have reported short- to midterm feasibility of TEVAR with the single-branched ISG.[17] However, long-term clinical follow-up with larger numbers of patients is still unclear. This study evaluated the long-term clinical outcomes of TEVAR with the branched ISG for arch aneurysms.

METHODS

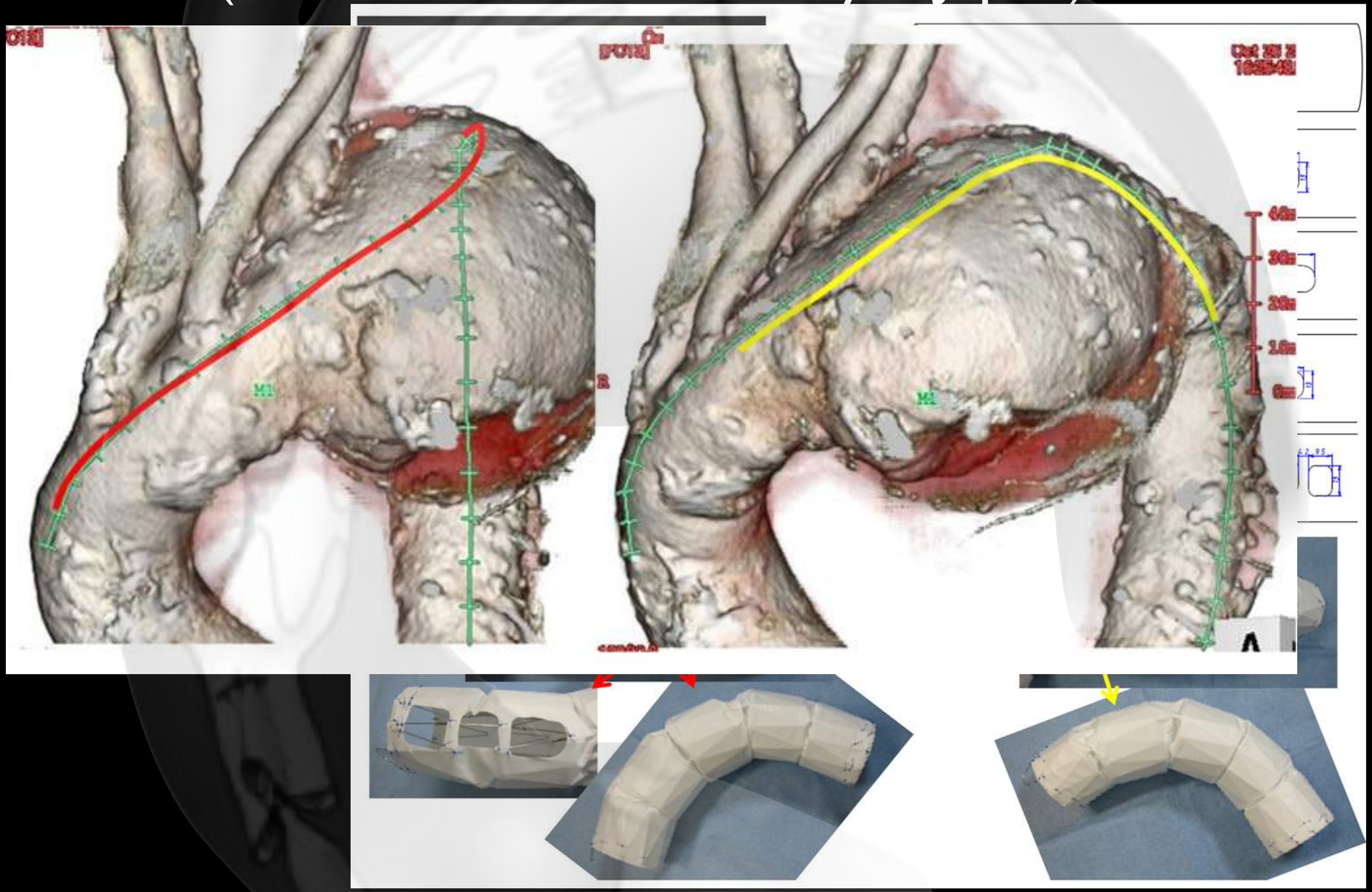
Study population

This study was a physician-initiated, noncompany sponsored, prospective registry of the ISG in Kyoto University



Tazaki, J., I et al. (2017). Thoracic endovascular aortic repair with branched Inoue Stent Graft for arch aortic aneurysms. *JVS*. http://doi.org/10.1016/j.

Najuta Next-gen Fenestrated TEVAR (Kawasumi Lab, Inc. Tokyo, Japan)



Yokoi Y et al., JTCVS 2013; 145: S103

Najuta Results

- N=54 (Jan 2008 - May 2016)
- Operative Mortality: 3.7%
  (embolic, resp failure)
- Stroke: 5.5%
- Survival 75% @ 41.4 months
- Endoleak: 7.4% (I, II, III, V)
- Secondary Interventions: 5.5%

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A Challenging Treatment for Aortic Arch Aneurysm With Fenestrated Stent Graft

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Background. The endovascular stent graft is a novel therapeutic technique that is used in the treatment of aortic aneurysms. However, the aortic arch is a still an area that requires endovascular repair. Since 2008, the authors have treated aortic arch aneurysms (AAA) in patients without an extraanatomical bypass using a fenestrated stent graft (FSG). This study aimed to evaluate the early outcomes of FSG treatment.

Methods. The authors retrospectively investigated the early outcomes of 54 AAA cases that were performed in their department from January 2008 to May 2016. The early results were analyzed retrospectively.

Results. The primary technical success rate was 100%. There were 2 operative deaths due to shower embolism and respiratory failure (2 of 54, 3.7%). Two patients suffered central nervous system injury (2 of 54, 3.7%) without remaining sequelae. At a mean follow-up period of 41.4 months, the survival rate was 75.0% and there were no aortic-related deaths. On follow-up, secondary intervention was necessary in 3 cases. The rate of freedom from secondary reintervention was 92.5%.

Conclusions. Although further observation and prospective studies involving larger numbers of patients will be needed to validate this process, the outcomes of FSG treatment and our procedures were acceptable. This procedure has the potential to expand the indications for treatment in patients with AAA that are deemed to be suitable for this treatment.

(Ann Thorac Surg 2017;■:■–■)

The endovascular stent graft (SG) is a less invasive technique for treating aortic aneurysms, especially descending aortic aneurysms. However, in Japan, the aortic arch is the most common site of thoracic aortic aneurysm (TAA) [1]. Generally, using an SG in the repair of these sites necessitates an extraanatomical bypass or an extra technique to preserve the arch branches [2].

In 2008, a clinical trial of this device was launched at Najuta FSG (Kawasumi Laboratory, Inc, Tokyo, Japan) (Fig 1). Thus, this device has been commercially available in Japan since 2013. We herein describe the early results regarding the outcomes of cases in which an FSG was used, and discuss the usefulness and the remaining issues associated with FSG.

Patients and Methods

The records of 234 patients who underwent single AAA repair in our institute from January 2008 to May 2016 were reviewed. Among 70 cases in which an FSG was used, 54 patients without aortic dissection underwent single elective FSG treatment. Regarding the proximal end of the SG, 51 cases involved Zone 0, whereas the remaining 3 involved Zone 1. The landing zones were classified according to Ishimaru's classification [3]. The primary endpoint of this study was the technical success and the initial success rate of procedures. Technical success was defined by the deployment of the SG in planned position without the collapse of the SG. Initial success was defined by the absence of type 1 or 3 endoleaks and the absence of major complications necessitating an extended hospital stay.

The secondary endpoint was the incidence of remaining type 1 and 3 endoleaks, the rates of mortality and morbidity and the rate of aneurysm-related complications. All of the early and midterm results were analyzed retrospectively.

This study is simply evaluation of the outcomes of FSG treatment. Therefore, cases treated with other methods such as individual branched graft, chimney [illegible] other arch vessel-preserving [illegible] from this study.

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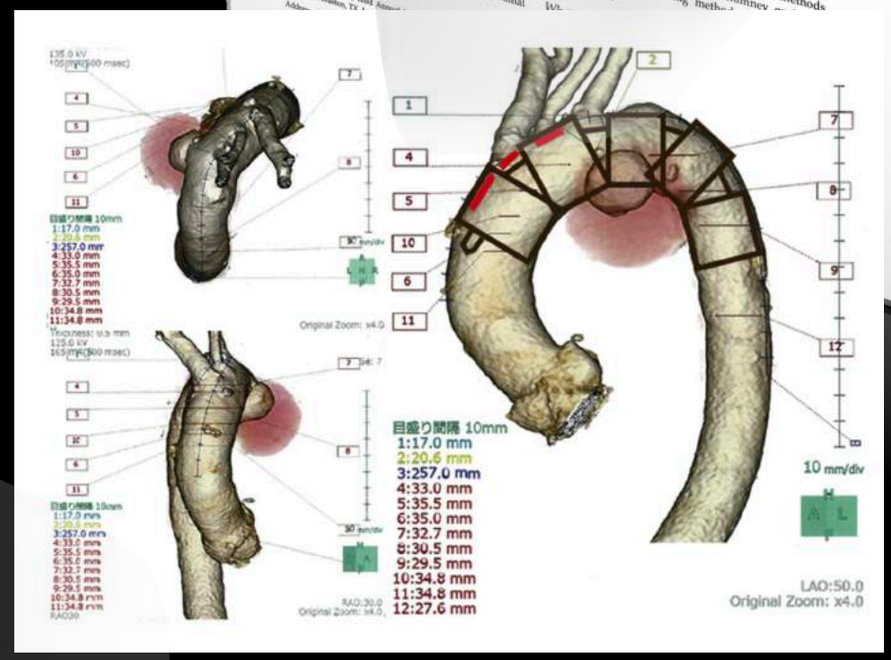
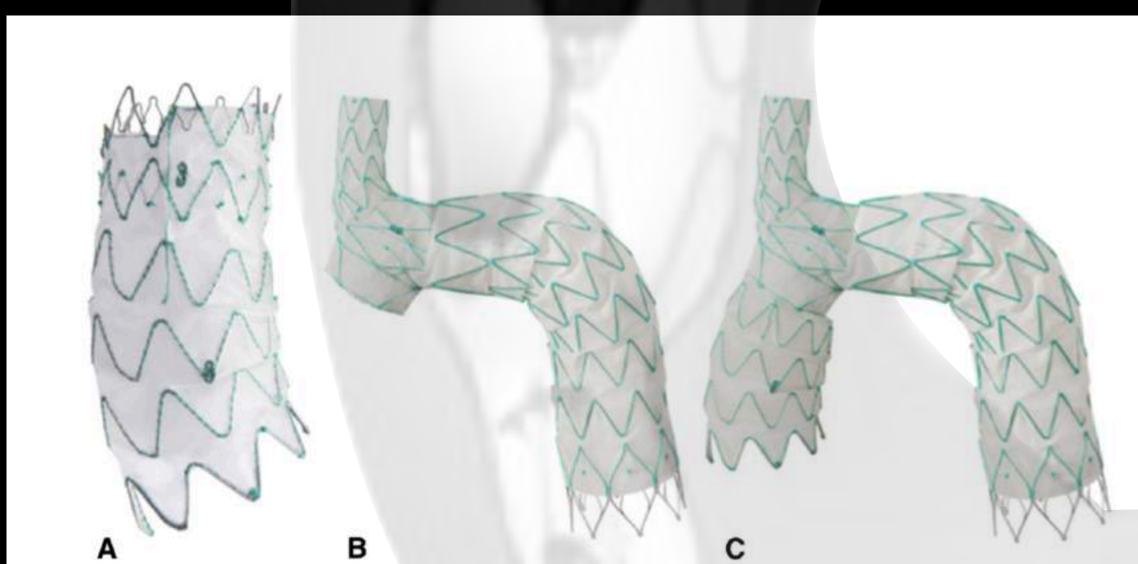
Presented at the Fifty-third Annual Meeting of the Society of Thoracic Surgeons, Houston, TX, [illegible]



Yuri, K., et al. (2017). A Challenging Treatment for Aortic Arch Aneurysm With Fenestrated Stent Graft. *The Annals of Thoracic Surgery*. http://doi.org/10.1016/j.athoracsur.2017.05.062

Nexus Endospan Aortic Branched Graft Graft



CASE REPORT

Endovascular treatment of aortic arch aneurysm with a single-branched double-stage stent graft

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0022-5223/$36.00

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A, The ascending module, (B) the main module with its side branch for the brachiocephalic artery, and (C) the final assembled device.

Central Message

Endovascular stent grafting of the aortic arch is a new promising emerging technology that allows the exclusion of aortic arch aneurysms through a micro-invasive procedure.

See Editorial Commentary page xxx.

Video clip is available online.

Stent grafting for the treatment of aortic arch pathologies is the new frontier of endovascular aortic surgery because it allows the exclusion of aortic arch aneurysm through a microinvasive procedure[1,2] with no cardiopulmonary bypass, aortic crossclamping, and circulatory arrest, which commonly are needed during conventional surgery. We hereby describe for the first time the use of a new endovascular system, Nexus (Endospan, Herzlia, Israel), for the treatment of aortic arch lesions. Nexus is made of 2 components: (1) a main module, for the aortic arch and the descending aorta with a side-branch for the brachiocephalic artery (BCA) and (2) a curved module for the ascending aorta that connects to the main module through a side-facing self-protecting sleeve and lands into the sinotubular junction (Figure 1). Before Nexus positioning, an extraanatomic surgical debranching of supra-aortic vessels, with the use of the BCA as the main source of blood, is required to provide adequate cerebral blood flow.

CASE REPORT

A 74-year-old patient was referred to our center with diagnosis of aortic arch aneurysm. The preoperative computed tomography (CT) reconstruction showed a 6.5-cm × 6-cm aneurysm on the anterior portion of the aortic arch (Figure 2, A). Surgery was indicated and proposed to the patient but, since he was a Jehovah's witness, he denied it because of the high risk of blood transfusions. Therefore, hybrid correction of the aortic arch aneurysm was planned.

The patient underwent extra-anatomic supra-aortic reconstruction with right carotid to left subclavian bypass (both end-to-side) with an 8-mm polytetrafluoroethylene vascular graft and end-to-side reimplantation of the right carotid artery on the graft. After 1 week, the endovascular stent-grafting procedure was performed. Under general anesthesia and with bilateral percutaneous femoral access, the main module was introduced via right brachiofemoral through-and-through guidewire landing with the side-branch in the BCA and covering the arch and the descending aorta. Subsequently, via a guidewire placed in the left ventricle and during rapid pacing the ascending aorta module was implanted, taking care of positioning the "B"-shaped radiopaque marker of the ascending module at the level of the tantalum ring of the main module in order to achieve perfect sealing and to avoid coverage of the BCA branch.

Figure 2, *B* shows the final result with complete exclusion of the aneurysm, good sealing between the 2 components, and good perfusion of all supra-aortic vessels with blood flow originating from the stented BCA. Video 1 shows the procedural steps of Nexus implantation. Total procedural time was 120 minutes, overall fluoroscopy time was

- Comprised of a curved aortic component
- Ascending Component

D'Onofrio,A, et al. (2017). Endovascular treatment of aortic arch aneurysm with a single-branched double-stage stent graft. J*TCVS*. 2017.06.030

Anatomic Criteria

- Exclusion
  - Prox and Dist landing zone >42 mm
  - All supra-aortic branches involved in aneurysm wall
  - Prohibitive occlusive disease
- Required
  - Adequate proximal seal zone between supra-aortic branches and lesion on aortic wall
  - Minimal length depends on arch pathology
  - Proximal landing zone ≥10 mm
- 19 types of curved stent skeletons
- 8 types of graft fenestrations

Azuma T et al., Eur J Cardiothor Surg 2013; 44: e156

Outcomes

	Najuta Graft	Cook Graft
Time of Study	2010-2011	2009-2013
No. Patients	393	38
No. Centers	35	10
Patient Demographics	NR	As expected
ASA Class of 3 or 4	NR	89.5%
Proximal Aortic Diameter (mm)	33.7±3.7	34 (32-38)
Proximal Graft Diameter (mm)	NR	40 (38-46)
Mean Prox. Seal Length (mm)	14.2±5.1	NR
Location Proximal Landing Zone - Zone 0 - Zone 1 - Zone 2	 376 (95.5%) 15 (3.8%) 2 (0.5%)	 38 (100%)
Card Output Modulation	0	38 (100%)

Azuma T et al., Eur J Cardiothor Surg 2013; 44: e156
Haulon S et al., J Thorac Cardiovasc Surg 2014; epub

Outcomes

	Najuta Graft	Cook Graft
Left Subclavian Artery		
- Covered and occluded	281 (71.5%)	0
- Bypassed	17 (4.3%)	30 (79%)
- T		8 (21%)
- S		33 (87%)
		13 (34%)
		8 (21%)
-		5 (13%)
Duration of Procedure (min)	NR	250 (210-330)
Technical Success	99.2%*	84.2%
Initial Success	95.4%**	84.2%
ICU LOS (days)	NR	2 (1.5-4)
Hospital LOS (days)	NR	10 (7.5-15.5)

3 deaths within 24 hours
1 type 1 endoleak
1 failure to catheterize IA branch
1 conversion to chimney technique

*Able to deliver and deploy the graft; ** No initial type 1 or 3 endoleaks

Azuma T et al., Eur J Cardiothor Surg 2013; 44: e156
Haulon S et al., J Thorac Cardiovasc Surg 2014; epub

Outcomes

Najuta Graft

- 1.5% 30-day mortality
  - Multiple embolisms
  - Stroke
  - Ascending dissection
  - Respiratory failure
  - Aneurysm rupture (type 1 EL)
  - Unknown
- 1.7% Neurologic Event
- 0.76% Paraplegia

Cook Graft

- 13.5% 30-day mortality
  - Cardiac arrest at induction
  - Hemorrhagic shock
  - MI
  - Pulmonary infection
  - Unknown etiology
- 13.5% Neurologic Event
  - 4 TIA
  - 1 Stroke
  - 1 Meningeal hemorrhage
- 0 Paraplegia

Azuma T et al., Eur J Cardiothor Surg 2013; 44: e156
Haulon S et al., J Thorac Cardiovasc Surg 2014; epub

Early Endoleaks

Najuta Graft

- 4.6% type 1 or 3 endoleak
  - Larger proximal aortic diameter
  - Longer length of aneurysm treated
- No other information provided

Cook Graft

- 11 (29%) on pre-discharge CT
  - 5 proximal type 1
  - 3 type 2
  - 1 type 3
  - 2 unknown etiology
- 2 Early interventions for EL
  - PTA of type 3 leak
  - Plug in origin of IA
- At 6 months
  - 1 type 1 spontaneously resolved
  - None with type 2 had sac growth
  - Indeterminants resolved

Azuma T et al., Eur J Cardiothor Surg 2013; 44: e156
Haulon S et al., J Thorac Cardiovasc Surg 2014; epub

Follow Up

- No follow up is provided for the Najuta Graft
- Cook Graft
  - Median FU = 12 mos. (6-12)
  - 9.1% secondary procedures
    - 1 conversion to open surgery – kink in ascending aortic graft causing coarctation
    - 1 PTA/stent of LCC branch partially obstructed
    - 1 coil embolization and gluing of type 1 endoleak
  - 12.1% Late Mortality
    - Pneumonia
    - Sepsis
    - Ruptured AAA
    - Hemorrhagic stroke
    - No aortic arch-related mortality

Azuma T et al., Eur J Cardiothor Surg 2013; 44: e156
Haulon S et al., J Thorac Cardiovasc Surg 2014; epub

Conclusions

- Promising early results
- Designs are consolidating, and likely amenable to a broadly applicable standard design
- Techniques require proficiency with cardiac based interventions, as well as endovascular aortic interventions
- High volume aortic centers with open cardiac surgical programs are optimal for assessing and further development of these technologies
- Procedural stroke remains a significant issue
- Require longer-term outcomes to assess durability