

VEITH SYMPOSIUM
 Tuesday - Saturday, November 19-23, 2018

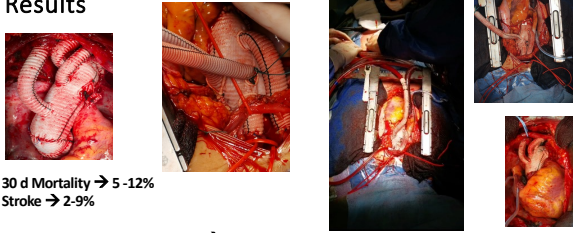
How Best To Treat Aortic Arch Lesions: Is There Still Ever An Indication For Chimney Endografting With OTS Devices For Aortic Arch Lesions, And How To Make Them Work Without Gutter Endoleaks: What Are Other Options For Emergent Patients

Symposium Chairman: David J. Stovroff, MD
 Executive Co-Chairman: James A. Brown, MD
 Symposium Co-Chairman: Kenneth W. Kim, MD, MBA
 Steve P. Lyden, MD

Cleveland Clinic
 Hilton

Prof Nicola Mangialardi, MD

Open Surgery for the Arch Immediate Results



**30 d Mortality → 5 -12%
 Stroke → 2-9%**

Redo Sternotomy 30 d Mortality →14%

Iafrancesco - Eur J Cardiothorac Surg 2015
 Shrestha - J Thorac Cardiovasc Surg 2016
 Urbanski - Eur J Cardiothorac Surg 2016
 Gaudino - Eur J Vasc Endovasc Surg 2018

2022 ACC/AHA CLINICAL PRACTICE GUIDELINE
 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines

6.6.2 Aortic Arch Aneurysms
 Recommended studies that support the recommendations are summarized in the table.

| Class | Level | Reference |
|-------|-------|-----------|
| I | C-E0 | 1 |
| IIa | B-NR | 2 |
| IIa | C-E0 | 3 |
| IIb | C-E0 | 4 |
| IIb | C-E0 | 5 |

1. In patients with an aortic arch aneurysm who have symptoms attributable to the aneurysm and are at low or intermediate operative risk, open surgical replacement is recommended.

2. In patients with an isolated aortic arch aneurysm who are asymptomatic and have a low operative risk, open surgical replacement or endovascular repair of the aortic arch, if it is reasonable to intend the repair with a hybrid approach, is reasonable.

3. In patients undergoing open surgical repair of an ascending aortic aneurysm, if the aneurysmal disease extends into the proximal descending aorta, it is reasonable to intend the repair with a hybrid approach.

4. In patients undergoing open surgical repair of an aortic arch aneurysm, if the aneurysmal disease extends into the proximal descending aorta, it is reasonable to intend the repair with a hybrid approach.

5. In patients with an aortic arch aneurysm who are asymptomatic but meet criteria for intervention, but have high risk from open surgery or need a hybrid or endovascular approach, endovascular repair may be reasonable.

EV Options to Treat Aortic Arch Lesions

- Arch dedicated devices (CMD/Semi CMD/OTS)
- PMD
- Chimney TEVAR
- Hybrid Surgery

Arch dedicated devices

Unruptured Aneurysms
 Chronic TBAD
 Favourable Anatomy
 Lesions in IFU
 (i.e. lesser curve lesions for Najata)

Neurologic Complications: 0-33%
 Short-term mortality: 0-13%
 Technical Barriers: 0-66%
 Technical Success: 100-66%
 Devices Profile: Misalignment (vessels loss)
 Migration
 Inadvertent Coverage

Endovascular repair of the aortic arch: State of the art
 James A. Brown, MD, MS¹ | George J. Anagnostis, MD² | Wilson Y. Szeto, MD³ | Derek Serna-Gallegos, MD⁴ | Braden Sultan, MD⁵

Outcomes of Fenestrated and Branched Endografts for Partial and Total Endovascular Repair of the Aortic Arch – A Systematic Review and Meta-Analysis

| Outcome | Studies | n | Patients | n | Events | n | Effect size | 95% CI | P | n | p | 95% CI |
|-----------------------------------|---------|-----|----------|-----|--------|------|-------------|--------|-------|---|------|--------|
| Technical success | 11 | 365 | 207 | 348 | 0.92 | 0.97 | 0.91 | 0.93 | <.001 | 0 | 0.91 | 0.93 |
| Death | 11 | 365 | 17 | 7.9 | 0.02 | 0.12 | 0 | 0.05 | 0.001 | 0 | 0.05 | 0.05 |
| Major or disabling stroke | 8 | 240 | 16 | 7.2 | 0.06 | 0.12 | 0.09 | 0.07 | 0.001 | 0 | 0.07 | 0.07 |
| Major endoleak | 6 | 202 | 0 | 0 | 0 | 0 | 0 | 0 | 0.001 | 0 | 0 | 0 |
| Minor endoleak | 6 | 202 | 10 | 5.4 | 0.03 | 0.09 | 0.03 | 0.02 | 0.001 | 0 | 0.02 | 0.02 |
| Endoleak reoperation | 7 | 220 | 10 | 4.5 | 0.02 | 0.08 | 0.02 | 0.01 | 0.001 | 0 | 0.01 | 0.01 |
| Conversion to open | 7 | 220 | 10 | 4.5 | 0.02 | 0.08 | 0.02 | 0.01 | 0.001 | 0 | 0.01 | 0.01 |
| Reoperation for aortic dissection | 8 | 144 | 0 | 0 | 0 | 0 | 0 | 0 | 0.001 | 0 | 0 | 0 |
| Type III endoleak | 6 | 202 | 0 | 0 | 0 | 0 | 0 | 0 | 0.001 | 0 | 0 | 0 |
| Reoperation | 6 | 202 | 0 | 0 | 0 | 0 | 0 | 0 | 0.001 | 0 | 0 | 0 |

CONCLUSIONS
 Endovascular repair of the aortic arch with fenestrated, branched, and/or hybrid devices seems to carry a comparable level of technical success to open surgery, together with a significantly reduced risk of stroke and death. However, endovascular repair carries the risk of endoleak, which may be treated by covered endografts, hybrid devices with covered covered stents, longer term follow-up, and hybrid repair, or possibly may need to reach clinical resolution.

Eur J Vasc Endovasc Surg 2023

Mono-Branch Devices

ARTIVION
 Formerly CryoLife | Lifestar

Device Description
 3 cm OI between modules
 Separation forces of the modules: 100-150 N (SD 3) (per ION)

Fixation sites

Nexus
 Innominate branch
 Nexus Main Module
 Ascending Module
 «Oriented»

NEXUS® ANATOMICAL INDICATIONS

- Ascending Aorta**
 - Diameter of 30-39 mm
 - Landing zone length of at least 30 mm
- Descending Aorta**
 - Diameter of 25-40 mm
 - Landing zone length of at least 30 mm
 - Perpendicular aorta to be a 10°
- Brachiocephalic trunk**
 - Diameter of 15-18 mm
 - Landing zone length of at least 20 mm
 - Take of angle between the brachiocephalic artery and the aortic arch perpendicular should be < 10°

REMARK: The only CE marked endovascular branch system for the aortic arch.
 Ready when you're ready.

Ascending Banding to gain total EV feasibility

Commenti
 Posizionamento di Relay Branch 42-12x270 mm
 Estensione RCT: 20x100 mm, 20x100 mm, 20x110 mm
 Estensione LCCA: 1x100 mm
 Estensione di stent Relay NES Pro 34-10x200 mm

Commenti
 Distensione aorta ascendente tramite graft per il ripristino con Relay EB

Planning after Asc Banding

Kawasumi Lab Najuta

- ✓ Semi-custom made stent graft for TEVAR
- ✓ 3D pre-curved endoskeleton stainless steel stents
- ✓ Covered with PTFE film sutured at both ends
- ✓ Selected fenestrations depend on vessel morphology
- ✓ CE mark in July 2017 and use in Italy started IN 2018

Clinical outcomes of thoracic endovascular aneurysm repair using commercially available fenestrated stent graft (Najuta endograft)

Shinichi Inokubo, MD¹, Shigeo Ishihashi, MD¹, Hirofumi Inoh, MD¹, Nobuhiko Takayoshi, MD¹, Shoji Nakaguchi, MD¹, Takashi Yoshida, MD¹, Yoshihiro Nakano, MD¹, and Kazuhiko Bunkaiwa, MD¹, Naoki Mizushima, and Taro Yano¹ (J Vasc Surg 2018;62:1473-8.)

32 patients – 2007-2013

- 71 supra-aortic vessels planned to be preserved
- 91% technical success rate
- No perioperative death
- No device migration

Mean follow-up 2.5 years

- Overall survival rate: 67%
- Freedom from aneurysm-related death: 97%
- Freedom from secondary intervention: 84%

Clinical impact of proximal fixation augmentation using the Najuta thoracic fenestrated stent graft during endovascular treatment for distal aortic arch aneurysm

Conclusions: Proximal fixation augmentation using the Najuta fenestrated stent graft during TEVAR for distal arch aneurysm is effective in preventing the postoperative late type Ia endoleaks.

T1EL → Comparison between

| standard TEVAR (41pts) | vs | Najuta + standard TEVAR (30pts) |
|-------------------------|----|---------------------------------|
| Reintervention for T1EL | | |
| 20,8% @ 36 months | | 0% |
| 34,8% @ 60 months | | 0% |

Preliminary results from an Italian National Registry on the outcomes of the Najuta fenestrated aortic arch endograft

PI Prof N Mangialardi

194 patients enrolled to date in EUROPE

| 3D D Technical success | % | Vascular center | Number of cases |
|--------------------------|------|--|-----------------|
| Type I endoleak | 97,4 | TOTAL | 76 |
| Type II endoleak | 2,6 | San Camillo Forlanini Hospital (Rome) | 16 |
| Type III endoleak | 5,2 | Santa Maria della Misericordia Hospital (Perugia) | 12 |
| Endograft migration | 1% | Civile Bagnascara Hospital (Modena) | 8 |
| Stroke (2 minor strokes) | 2,6 | Mauriziiano Umberto Hospital (Turin) | 8 |
| Retrograde dissection | 0 | Del Cuore G. Paganucci Hospital (Massa) | 5 |
| | | Civile SS Annunziata Hospital (Sassari) | 4 |
| | | Città della Salute e della Scienza Hospital (Turin) | 3 |
| | | Di Summa-Petrino Hospital (Brescia) | 2 |
| | | San Martino Hospital (Genova) | 2 |
| | | Giuseppe Mozzoni Hospital (Ferrara) | 2 |
| | | San Giovanni Bosco Hospital (Turin) | 2 |
| | | Santa Chiara Hospital (Trento) | 2 |
| | | Santa Croce e Carle Hospital (Cuneo) | 2 |
| | | Policlinico Umberto I Hospital (Rome) | 1 |
| | | San Giovanni di Dio Hospital (Florence) | 1 |
| | | Spiridi Cruli Hospital (Bari) | 1 |
| | | Istituto Hospital (Cagliari) | 1 |
| | | Annunziata Hospital (Cosenza) | 1 |
| | | Policlinico Hospital (Bari) | 1 |
| | | Careggi Hospital (Florence) | 1 |
| | | Azienda Ospedaliero-Universitaria Pisana Hospital (Pisa) | 1 |

Clinical outcomes of thoracic endovascular aneurysm repair using commercially available fenestrated stent graft (Najuta endograft)

9% under local anesthesia

ARCH SACCULAR ANEURYSM

17-Aug-2018 1:10 pm

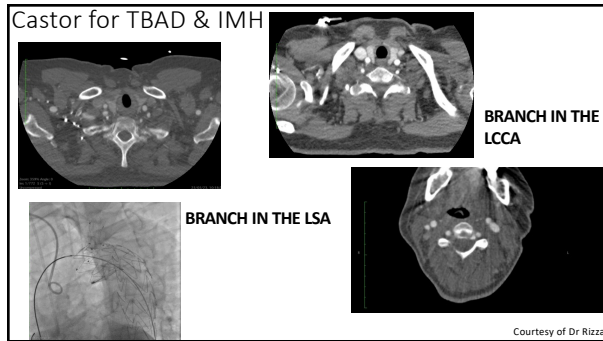
Microport Castor

Long-Term Outcomes of Thoracic Endovascular Repair for Aortic Arch Dissection Using Customized Single-Branched Fenestrated Stent-Graft

16 Subacute TBAD

51 Chronic Patients

- 7 TAAD
- 22 retrograde TAAD
- 22 TBAD



Clinical And Anatomical Setting Drive the choice

Symptomatic Cases
Healthy Zone 0/1
Favourable Anatomy
Emergent cases (big diameter Aneurysms/
Complicated TBAD)

➔ Physician-Modified Devices

Double homemade fenestrated stent graft for total endovascular aortic arch repair

Midterm Follow-up of Fenestrated and Scalloped Physician-Modified Endovascular Grafts for Zone 2 TEVAR

Journal of Vascular Medicine and Biology

Authors: Lucien Chassin-Trubert, MD, Marcello Mandelli, MD, Baris Ata Ozdemir, FRCS, PhD, Pierre Ahric, MD, PhD, Thomas Gander, MD, and Ludovic Canaud, MD, PhD

Journal of Vascular Medicine and Biology, Volume 35, Number 1, February 2023

Arch Repair with HM Fenestrated Graft for Symptomatic arch Aneurysm

Vallant 42 → 10% OS
VBX 10 → 1mm OS

0.42 mm (10% OS), 1.150 mm + Distal Ext

1. Fenestrations for the subclavian and vertebral arteries

2. Fenestrations for the common carotid arteries

3. Fenestrations for the common iliac arteries

Home Made Fenestrated TEVAR (Single/Double Fenestrations)

IN SITU Fenestrated TEVAR (Single Fenestrations)

12 mm
17 mm
22 mm

Ch-TEVAR Emergent/Bailout Repair

Physician-modified endografts are associated with a survival benefit over parallel grafting in thoracoabdominal aneurysms J Vasc Surg 2022;76:318-25)

Justin A. Smith, MD¹, Anuja L. Sarode, MPH¹, Jordan R. Stern, MD¹, Jae S. Cho, MD¹, Kaem Harth, MD², Virginia Wong, MD¹, Norman Kumins, MD¹, Vikram Kashyap, MD¹, and Benjamin Colvard, MD¹, Cleveland, OH, and Stanford, CA

| | | | |
|----------|---------|--------------------|---------|
| Ch-TEVAR | EL 1.0% | Fenestrated (PMEG) | EL 2.2% |
|----------|---------|--------------------|---------|

Review
Type 1A Endoleak after TEVAR in the Aortic Arch: A Review of the Literature J. Pers. Med. 2022, 12, 1279.

Lucia Scatola^{1,2}, Nicola Pizzoni¹, Federico Pascucci¹, Simona Nica^{1,3}, Francesca De Nigro¹, Maria Filippini¹, Fabrizio Minelli^{1,4}, Tommaso Donati¹, Giovanni Tinelli^{1,5} and Youssef Tahaoui^{1,6}

| | | | |
|--------------------|-------------------|---------------------|------------|
| Ch-TEVAR | EL 7.4-32% | Branched | EL 0-18.1% |
| Fenestrated (PMEG) | EL 0-23.4 (32.4)% | In Situ fenestrated | EL 0-4.7% |

#1st «O»→ OVERSIZING **Ch-TEVAR: CTAG with active control system**

European Multicenter Registry for the Performance of the Chimney/Snoekel Technique in the Treatment of Aortic Arch Pathologic Conditions

"Over-SIRIX": A New Method for Stenting Aortic Endografts in Combination with the Chimney Grafts: Early Experience with Aortic Arch Disease

#2nd «O»→ ONENESS

Single Ch-TEVAR: CTAG with active control system + Gore Graft Limb

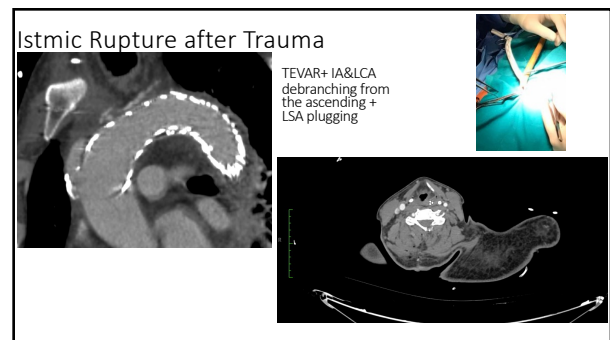
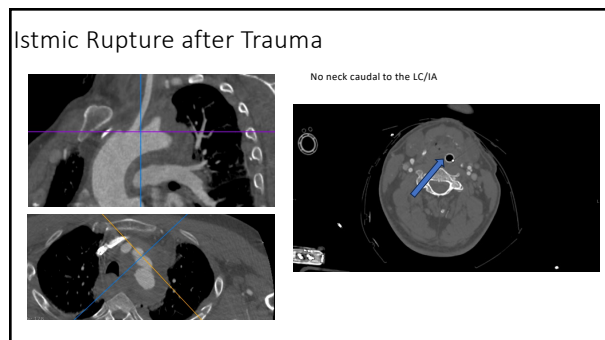
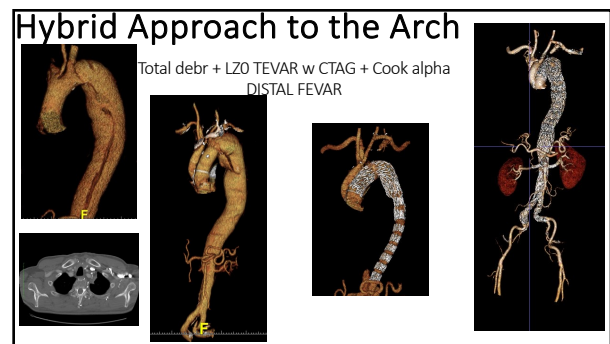
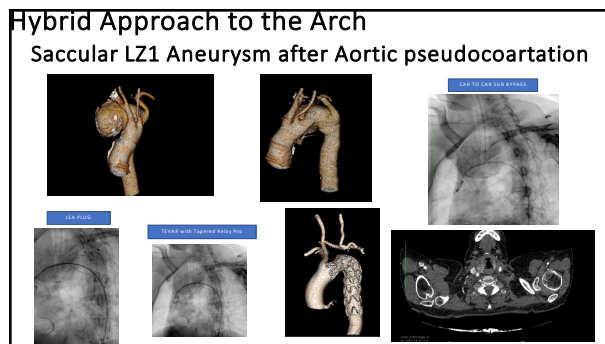
#3rd «O»→ OVERLAPPING **Longer overlapping to reduce gutters +/- reinforced**

#4th «O»→ ORIENTATION

Ch-TEVAR: different orientation to reduce gutters (for multiple PG)

Courtesy of M Lachat

Hybrid Approach to the Arch
Double Car-Subc BP & TEVAR for Kommerel Aneurysm



Conclusions

- Clinical and Anatomical setting drive the choice
- Custom devices → gold standard
- PME & ISF → selected/emergent cases
- Chimney → bailout/no option patients
- **Mastering several techniques is of utmost importance**

