# Technical considerations for the different commercially available arch devices

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# Conflicts of interest

**Honoraria for proctorship**:

Artivion, Medtronic

**Honoraria for lectures**:

COOK, W.L. GORE, Bentley, Artivion, Medtronic, BD, Cordis, Angiodroid, Phillips

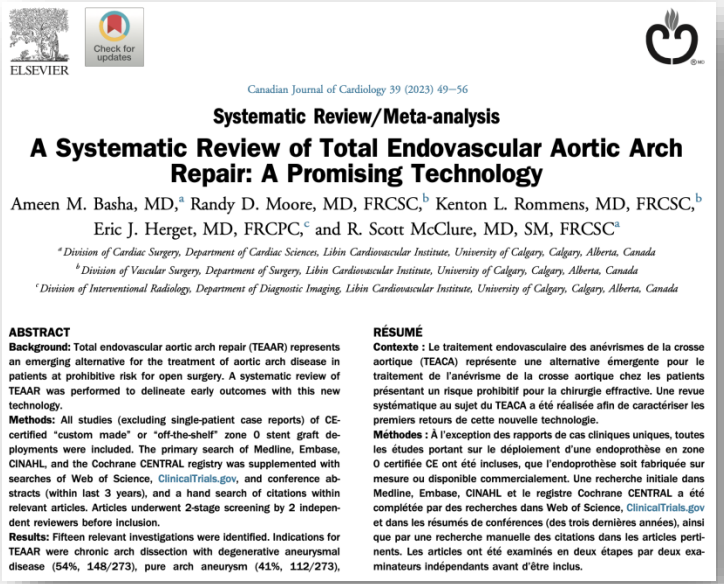
**Research grants:**

Medtronic, BD

# Endovascular aortic arch repair (EEAR)

Systematic review of CE- or CMD endografts

- 15 original investigations
  - 8 observational studies
  - 7 case reports/series
- **N=273 EAAR patients**
- PMEG or in-situ fenestrated arch grafts were excluded



Canadian Journal of Cardiology 39 (2023) 49–56

Systematic Review/Meta-analysis

## A Systematic Review of Total Endovascular Aortic Arch Repair: A Promising Technology

Ameen M. Basha, MD,[a] Randy D. Moore, MD, FRCSC,[b] Kenton L. Rommens, MD, FRCSC,[b] Eric J. Herget, MD, FRCPC,[c] and R. Scott McClure, MD, SM, FRCSC[a]

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**ABSTRACT**

**Background:** Total endovascular aortic arch repair (TEAAR) represents an emerging alternative for the treatment of aortic arch disease in patients at prohibitive risk for open surgery. A systematic review of TEAAR was performed to delineate early outcomes with this new technology.

**Methods:** All studies (excluding single-patient case reports) of CE-certified "custom made" or "off-the-shelf" zone 0 stent graft deployments were included. The primary search of Medline, Embase, CINAHL, and the Cochrane CENTRAL registry was supplemented with searches of Web of Science, ClinicalTrials.gov, and conference abstracts (within last 3 years), and a hand search of citations within relevant articles. Articles underwent 2-stage screening by 2 independent reviewers before inclusion.

**Results:** Fifteen relevant investigations were identified. Indications for TEAAR were chronic arch dissection with degenerative aneurysmal disease (54%, 148/273), pure arch aneurysm (41%, 112/273),

**RÉSUMÉ**

**Contexte :** Le traitement endovasculaire des anévrismes de la crosse aortique (TEACA) représente une alternative émergente pour le traitement de l'anévrisme de la crosse aortique chez les patients présentant un risque prohibitif pour la chirurgie effractive. Une revue systématique au sujet du TEACA a été réalisée afin de caractériser les premiers retours de cette nouvelle technologie.

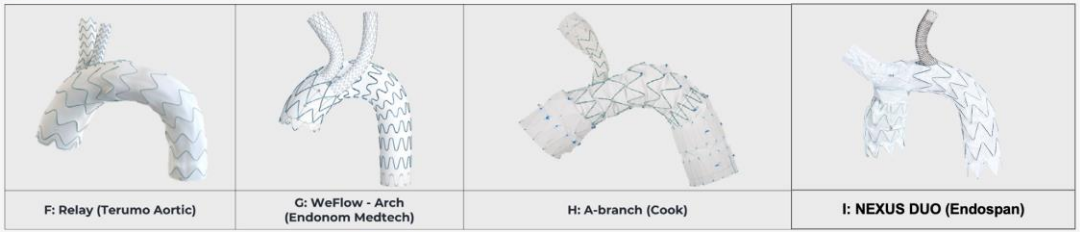
**Méthodes :** À l'exception des rapports de cas cliniques uniques, toutes les études portant sur le déploiement d'une endoprothèse en zone 0 certifiée CE ont été incluses, que l'endoprothèse soit fabriquée sur mesure ou disponible commercialement. Une recherche initiale dans Medline, Embase, CINAHL et le registre Cochrane CENTRAL a été complétée par des recherches dans Web of Science, ClinicalTrials.gov et dans les résumés de conférences (des trois dernières années), ainsi que par une recherche manuelle des citations dans les articles pertinents. Les articles ont été examinés en deux étapes par deux examinateurs indépendants avant d'être inclus.

# EAAR Devices Available

## Single Branch

A: Valiant Mona LSA (Medtronic) | B: TBE (Gore) | C: Relay (Terumo Aortic) | D: NEXUS (Endospan) | E: Castor (Microport)

## Dual Branch



F: Relay (Terumo Aortic) | G: WeFlow - Arch (Endonom Medtech) | H: A-branch (Cook) | I: NEXUS DUO (Endospan)

## Triple Branch

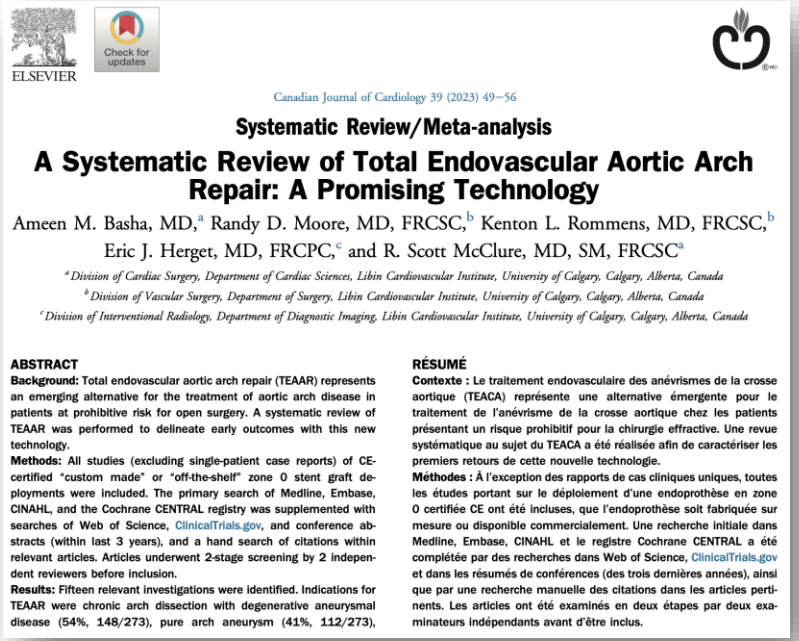
I: Relay (Terumo Aortic)

## Fenestrated Device

J: Najuta (Kawasumi Laboratories) | K: Customized Scalloped or Fenestrated (Zenith, Cook) | L: Customized Relay Proximal Scallop (Terumo Aortic)

# EAAR Key Therapy Outcomes

| Outcome | Meta-analysis (95% CI) |
|---|---|
| Mortality | **15.6%** |
| CVA | **14.0%** |
| MI | **3.7%** |
| PVE | **7.3%** |
| Endoleaks | **13.3%** |
| Dissection | **3.0%** |
| Procedure success | **92.5%** |



ELSEVIER

Check for updates

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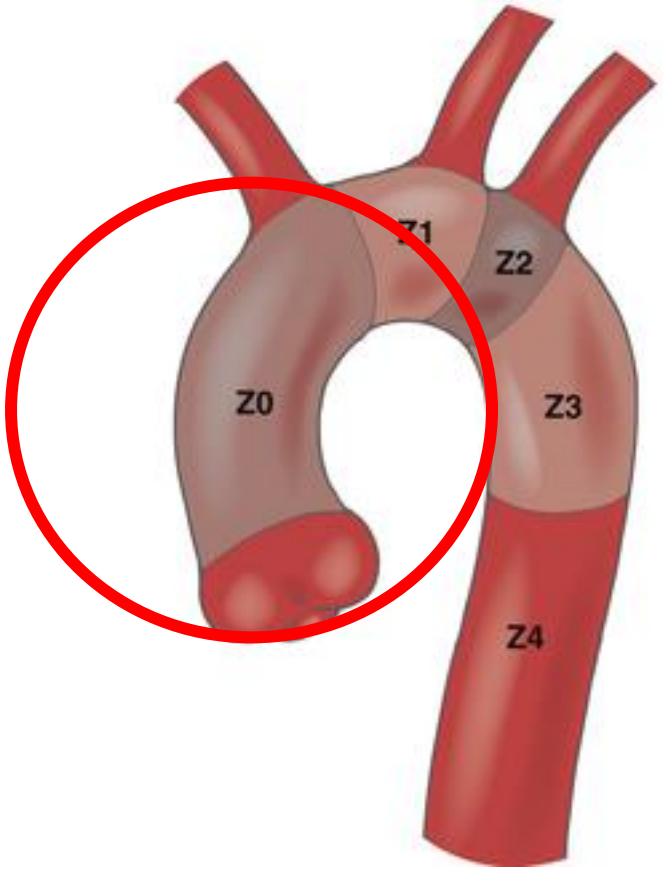

Z0
Z1
Z2
Z3
Z4

# Global Endovascular Aortic Arch Market

FDA and CE Marked

## Current Single and MultiBranch Devices for the Endovascular Aortic Arch Repair

| | Device | Make | Off the shelf? | Zone | #Branch | FDA | CE Mark |
|---|---|---|---|---|---|---|---|
| Single Branch | NEXUS | Endospan | Yes | 0 | 1 | **Ongoing** | **Yes** |
| | Gore TBE | Gore | Yes | 2 | 1 | **Approved** | **Yes** |
| | | | No | 0 | 1 | **Ongoing** | No |
| Multi Branch | NEXUS DUO | Endospan | No | 0 | 2 | **Start 2024** | Custom only |
| | RelayBranch | Terumo | No | 0 | 2 or 3 | **On Hold due to Stroke** | Custom only |
| | Zenith Arch Branch | Cook | No | 0 | 3 | No | Custom only |
| | Branched Inoue | PTMC | No | 0 | 3 | No | Custom only |

# Early post-op stroke

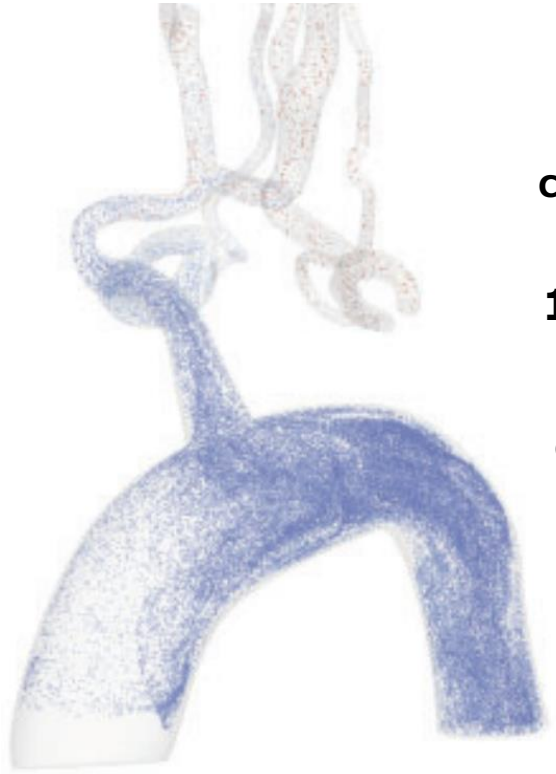
**Major Studies Reporting Early Postoperative Stroke Incidence With Branched Arch Endograft**

| First Author, Ref. # | Manufacturer | N | Proximal LZ | Stroke Incidence % |
|---|---|---|---|---|
| Dake[3] | TBE, Gore | 9 | 0 | 22.2 |
| Planer[4] | NEXUS, Endospan | 28 | 0 | 3.6 |
| Haulon[5] | A-branch, Cook | 38 | 0 | 15.8 |
| Spear[6] | A-branch, Cook | 27 | 0 | 11.1 |
| Ferrer[7] | RelayBranch, Terumo | 24 | 0 | 25.0 |
| Czerny [8] | RelayBranch, Terumo | 43 | 0 | 25.6 |


1 Roselli et al. J Vasc Surg. 2015;62:1465–1471.e3.
2 Dake et al J Vasc Surg. 2022;76:1141–1149.e3.
3 Dake et al JTCVS Tech. 2021;7:1–6.
4 Planer et al Ann Surg. 2023;277(2):e460–e466.
5 Haulon et al J Thorac Cardiovasc Surg. 2014;148:1709–1716.
6 Spear et al. Eur J Vasc Endovasc Surg. 2016;51:380–385.
7 Ferrer et al. J Vasc Surg. 2019;70:672–682 e1.
8 Czerny et al. Eur J Cardiothorac Surg. 2021;60: 662–668.

# Nexus standard arch device

## The impact of supraaortic debranching



**Cervical Blood Flow preop**

**1029 ml/min**

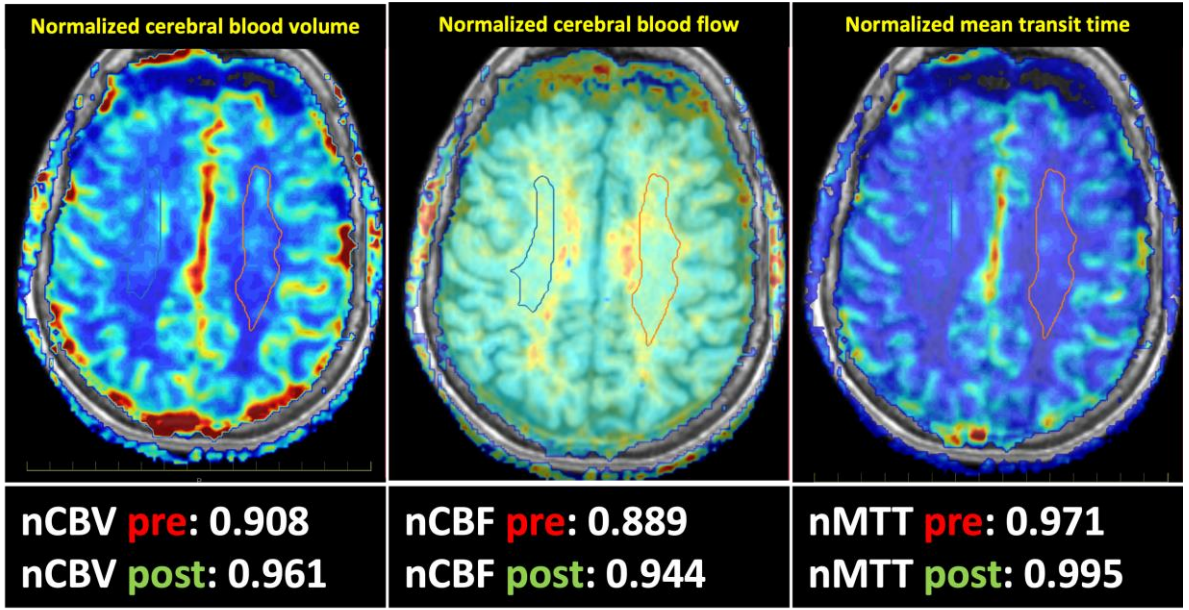
**Cervical Blood Flow Post Nexus**

**1041 ml/min**

Van Bakel et al. A computational analysis of different endograft designs for Zone 0 aortic arch repair. EJCTS 2018;58:389–396

# Perfusion MRI (3T)

## Pre VS post NEXUS




Courtesy: Dr. T. Bisdas

# Mechanisms of Early Stroke Risk During EAAR

## Solid Embolization

### High Atheromatous Burden

- Female
- Advanced age
- Prior cerebral disease
- Obesity
- Heart disease history
- Renal dysfunction
- Hypercholesterolemia
- Degenerative aneurysm

Image Evidence: "High Atheromatous Burden"

- ✓Aortic arch
- ✓Descending thoracic aorta
- ✓Supra-aortic arch branch vessels

### Procedural Complexity

- More proximal landing zone (zone 0 > 1 > 2)
- Unfavored aortic anatomy (high tortuosity)

## Air Embolization

- Air released during endograft deployment
  - Bubble

## Cerebral Perfusion Insufficiency

- Left subclavian artery coverage
- Incomplete Willis circle
- Retrograde access to common carotid artery
- Anemia
- Intraoperative hypotension
- Urgent procedure

*Cao L et al. J Am Coll Cardiol 2023;82:265–277*

# Neck access is proven to deliver higher risk of stroke compared to femoral access alone

## Association of upper extremity and neck access with stroke in endovascular aortic repair

Check for updates

Anastasia Plotkin, MD,[a] Li Ding, MD, MPH,[b] Sukgu M. Han, MD, MS,[a] Gustavo S. Oderich, MD,[c] Benjamin W. Starnes, MD,[d] Jason T. Lee, MD,[e] Mahmoud B. Malas, MD,[f] Fred A. Weaver, MD, MMM,[a] *and* Gregory A. Magee, MD, MSc,[a] *Los Angeles, Calif; Rochester, Minn; Seattle, Wash; and Palo Alto and San Diego, Calif*

**ABSTRACT**

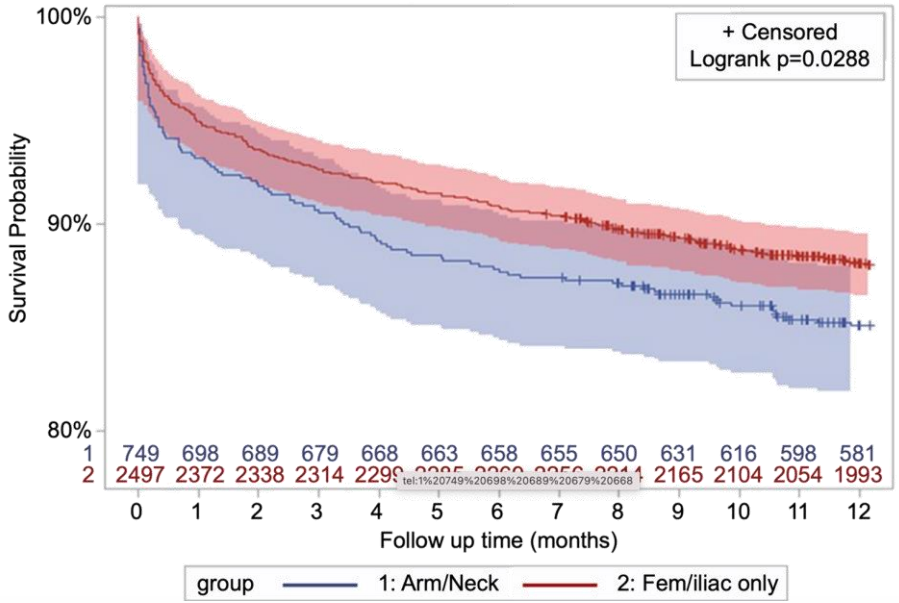
**Objective:** Upper extremity and neck access is commonly used for complex endovascular aortic repairs. We sought to compare perioperative stroke and other complications of (1) arm/neck (AN) and femoral or iliac access versus femoral/iliac (FI) access alone, (2) right- versus left-sided AN, and (3) specific arm versus neck access sites.

**Methods:** Patients entered in the thoracic endovascular aortic repair/complex endovascular aortic repair registry in the Vascular Quality Initiative from 2009 to 2018 were analyzed. Patients with a missing access variable and aortic arch proximal landing zone were excluded. The primary outcome was perioperative in-hospital stroke. Secondary outcomes were other postoperative complications and 1-year survival. Kaplan-Meier curves and log-rank test were used for survival analysis.

**Results:** Of 11,621 patients with 11,774 recorded operations, 6691 operations in 6602 patients met criteria for analysis (1418 AN, 5273 FI). AN patients had a higher rate of smoking history (83.6% vs 76.1%; $P < .0001$), and prior stroke (12.6% vs 10.1%; $P = .01$). Operative time (280 ± 124 minutes vs 157 ± 102 minutes; $P < .0001$), contrast load (141 ± 82 mL vs 103 ± 67 mL; $P < .0001$), and estimated blood loss (300 mL vs 100 mL; $P < .0001$) were larger in the AN group, indicative of greater complexity cases. Overall, AN had a higher rate of stroke (3.1% vs 1.8%; $P = .003$) compared with FI and on multivariable analysis AN access was found to be an independent risk factor for stroke (odds ratio, 1.97; $P = .0003$). There was no difference in stroke when comparing right- and left-sided AN access (2.8% vs 3.2%; $P = .71$). Stroke rates were similar between arm, axillary, and multiple access sites, but were significantly higher in patients with carotid access (2.6% vs 3.5% vs 13% vs 3.7%; $P = .04$). AN also had higher rates of puncture site hematoma, access site occlusion, arm ischemia, and in-hospital mortality (7.1% vs 4.2%; $P < .0001$). At 1 year, AN had a lower survival rate (85.1% vs 88.1%; $P = .03$).

**Conclusions:** Upper extremity and neck access for complex aortic repairs has a higher risk of stroke compared with femoral and iliac access alone. Right-sided access does not have a higher stroke rate than left-sided access. Carotid access has a higher stroke rate than axillary, arm, and multiple arm/neck access sites. (J Vasc Surg 2020;72:1602-9.)

**Keywords:** Tevar; Complex EVAR; Access; Arm; Neck; Stroke

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# Technical features to be highlighted

# COOK Alpha branch endograft

- Triple-branched device
- LCCA branch diameter compatible with commercially available covered stents
- Pre-cannulated LSA branch
- Diameter reducing sutures
- Wide sockets for the branches proximal

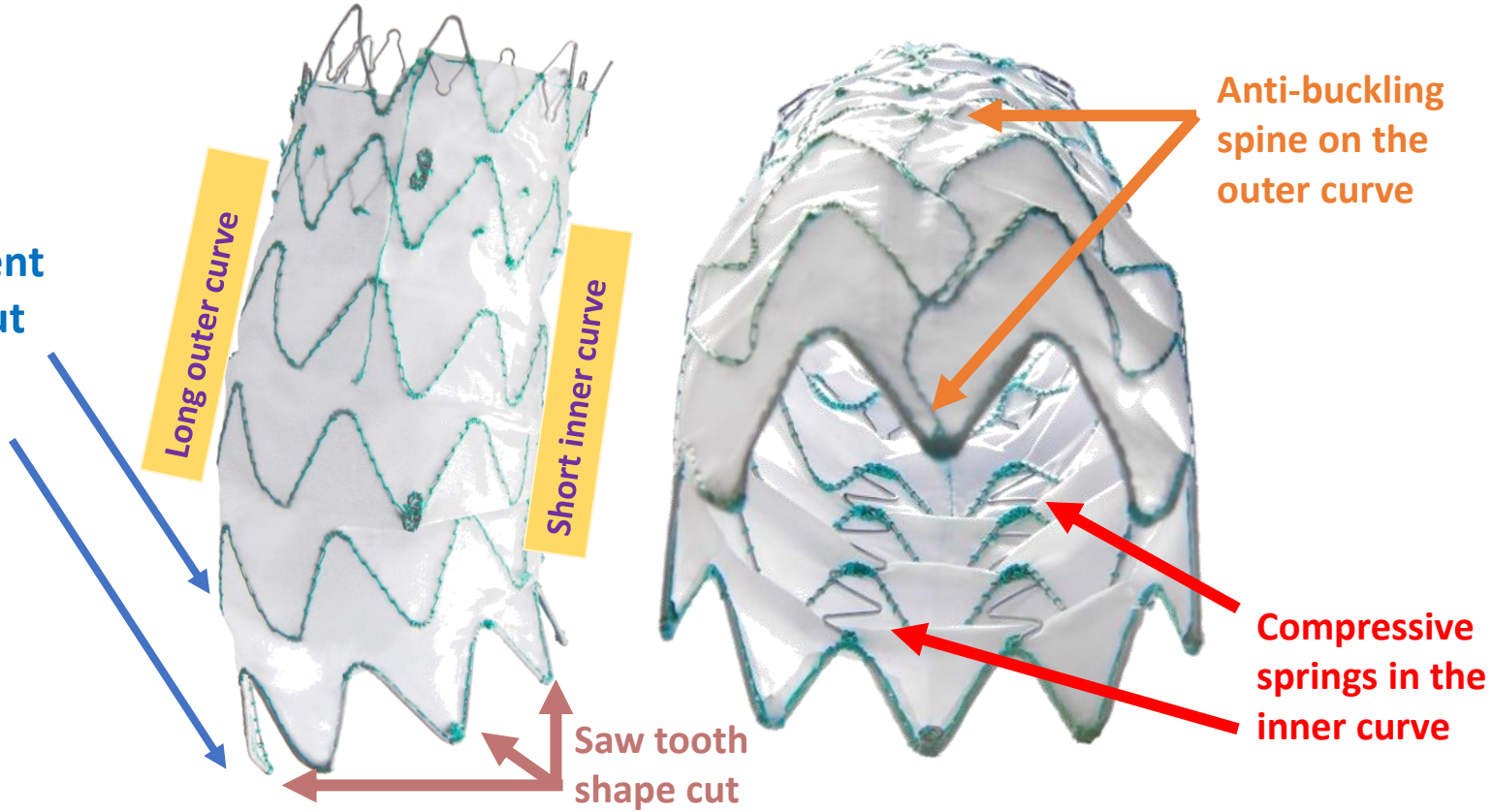
# Relay Arch Branch™

- Triple-branched device
- No need of ballooning
- Self-alignment
- Wide window allows big margin of radial misplacement
- Lock-stent technology **(?)**
- Three clasping points of the SG on the DS
- Big variety of dimensions and combinations available
- Dual sheath system

# Nexus™ and Nexus Duo™ endograft

- Off-the-shelf and CMD
- Pre-cannulated LSA or LCCA branch
- **Dual flushing ports**
- Stability of the system due to a suture anchoring the main branch
- Mimics the native anatomy of the aortic arch
- **Dedicated ascending graft**

# Nexus ascending graft



# Najuta stent-graft

- Semi-custom made design
- Avoids debranching
- 21 patterns of fenestration configuration, 7 positioning patterns, 3 size patterns
- Pre-shaped configuration
- Different shapes of distal end
- 21-23F

# What about aortic hemodynamics and myocardial stress?

# Postoperative remodeling in proximal to aortic valve branches

WeFlow stent-graft

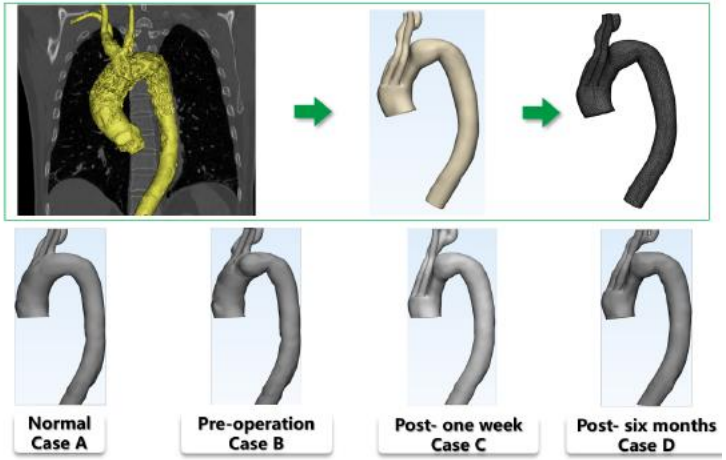
bioengineering

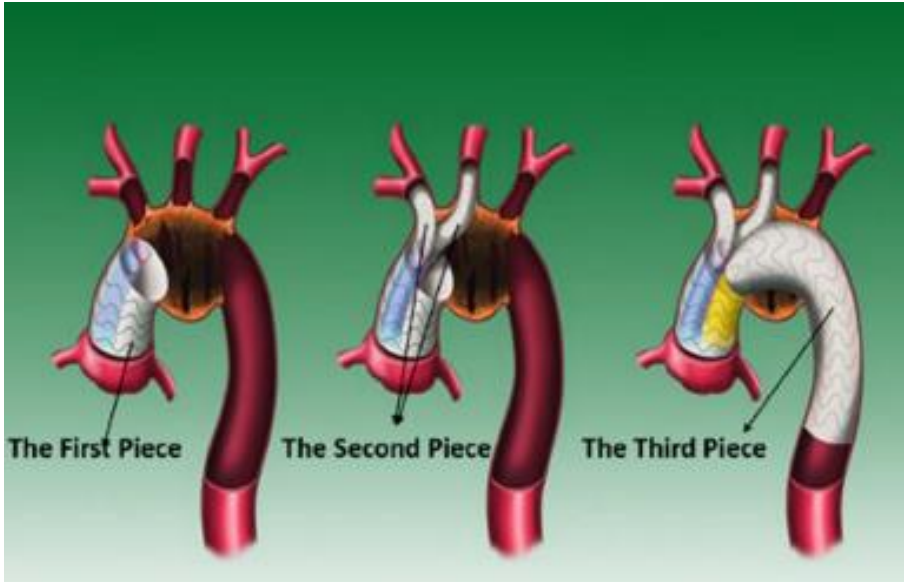
MDPI

Article

**Analysis of Postoperative Remodeling Characteristics after Modular Inner Branched Stent-Graft Treatment of Aortic Arch Pathologies Using Computational Fluid Dynamics**

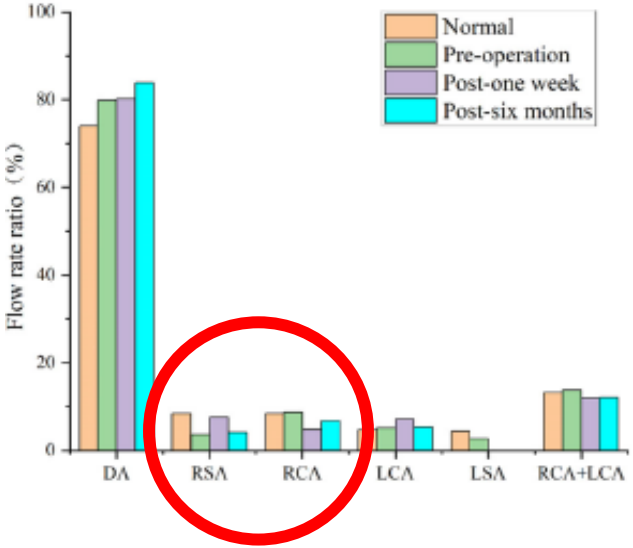
Fen Li [1,2], Yating Zhu [3], Hui Song [1,2], Hongpeng Zhang [3], Lingfeng Chen [4,*] and Wei Guo [3,*]



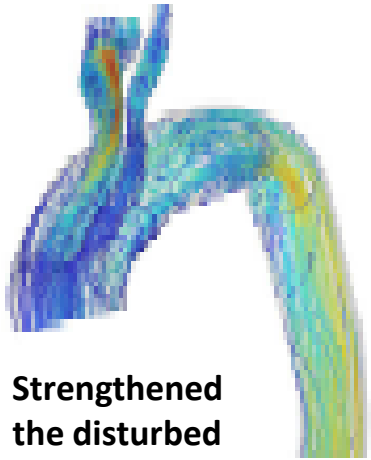



# Postoperative remodeling characteristics

## Blood perfusion rate of each outlet

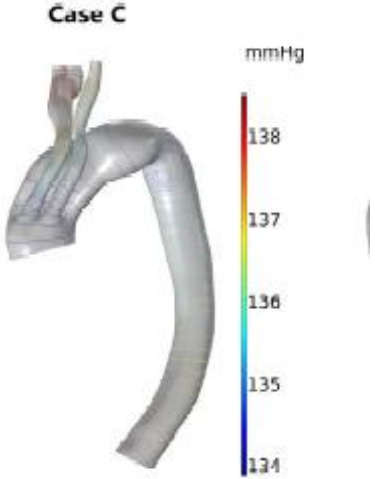



## Flow pattern



**Strengthened the disturbed blood flow** within the branches

## Pressure

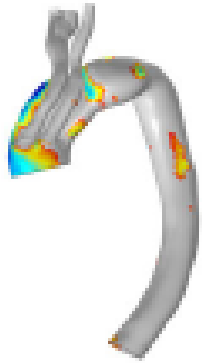



No significant differences

# Wall-shear-stress-based hemodynamics

**Time-averaged WSS**

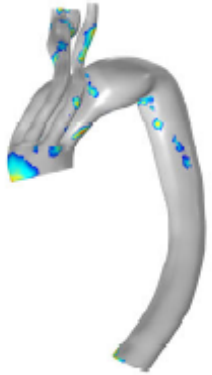
**Threshold: <0.4Pa**



**All branches**

**Oscillatory shear index**

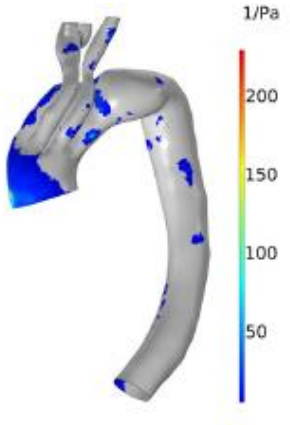
**Threshold: >0.25**



**Proximal part of the device and branches** as well as **lesser curvature of the descending aorta**

**Relative residence time**

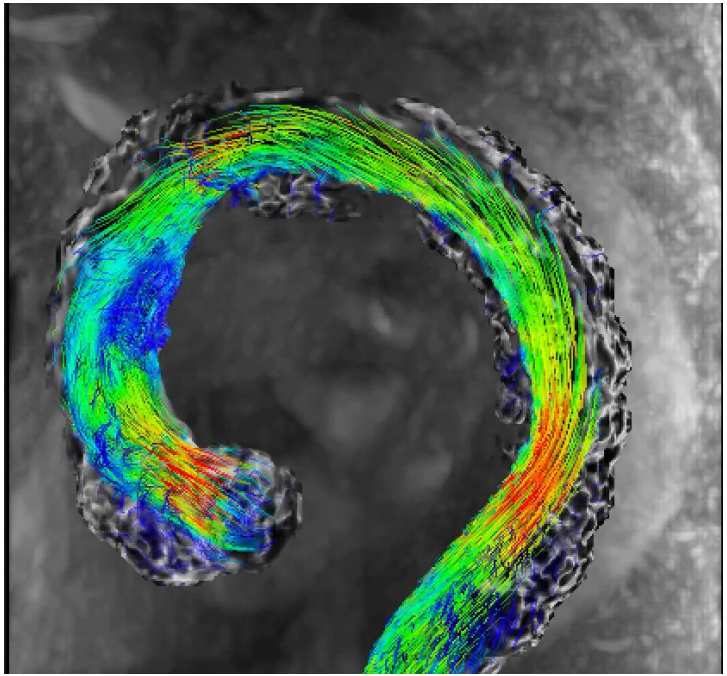
**Threshold: >5 $Pa^{-1}$**

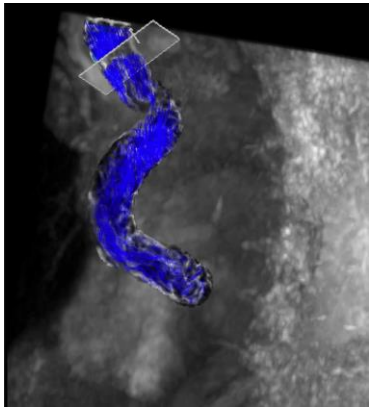


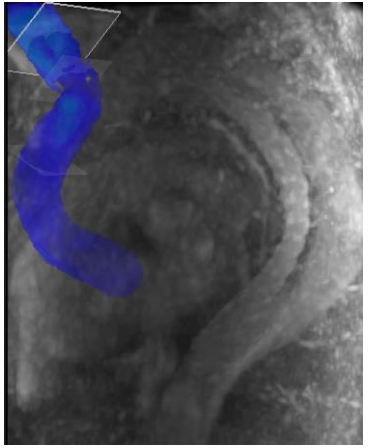

**All branches**

# Hemodynamics in devices mimicking the native aorta

Nexus stent-graft – **Flow pattern**





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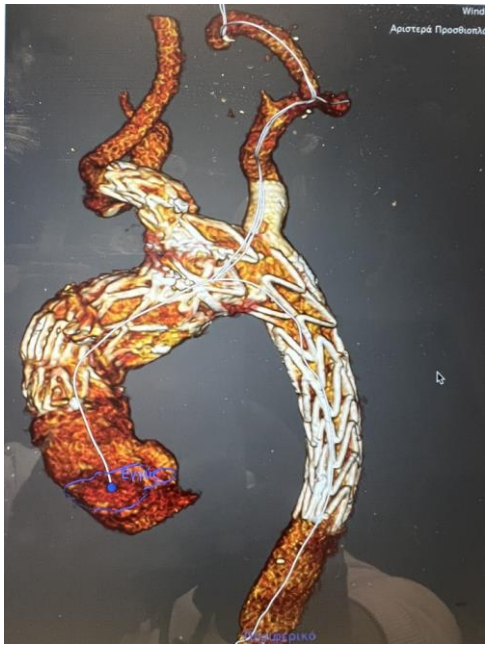
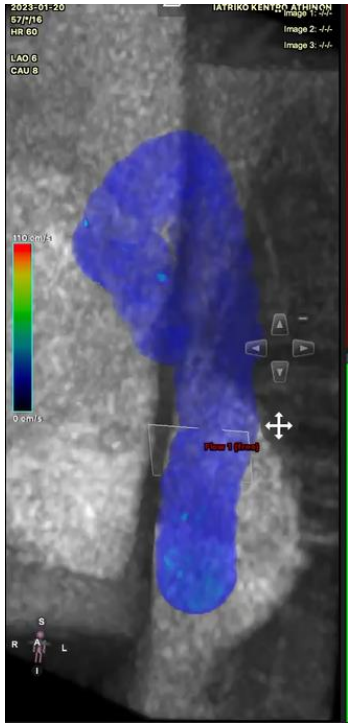
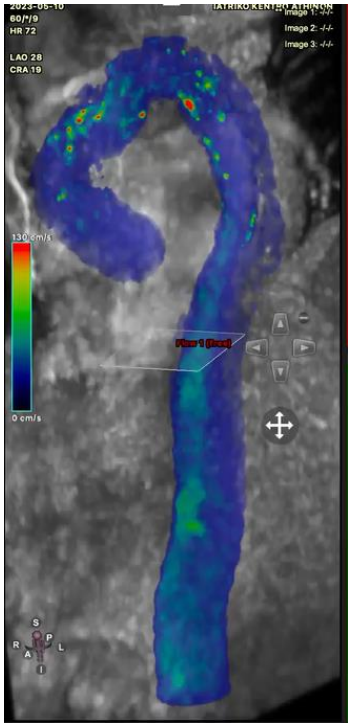
Nexus stent-graft - **Wall shear stress**



**PREOPERATIVE**



**POSTOPERATIVE**



# Conclusions

- There is no ideal arch device: several advantages and disadvantages in each device
- At present no comparison data between endografts
- Main aim must be to further reduce early post op stroke rate but…
- the long-term impact of the devices and branch design on **blood flow**, **late stroke**, **myocardial stress** and **branch patency** needs further assessment

# Technical considerations for the different commercially available arch devices

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Assoc. Professor of Vascular Surgery, Universitätsklinikum Münster

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