Contact Force assessment in the arch during TEVAR; how do different graft designs perform?

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Disclosures

☑ Consultancy: Vascutek Terumo

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TEVAR
Silent Cerebral Ischemia After Thoracic Endovascular Aortic Repair: A Neuroimaging Study

Philipp Kahlert, MD, FESC, Holger Eggebrecht, MD, FESC, Rolf A. Jánosi, MD, Heike A. Hildebrandt, MD, Björn Plicht, MD, Konstantinos Tsagakis, MD, Christoph Moenninghoff, MD, Felix Nensa, MD, Petra Mummel, MD, Gerd Heusch, MD, FRCP, Heinz G. Jakob, MD, Michael Forsting, MD, Raimund Erbel, MD, FESC, and Marc Schlamann, MD

Management of the left subclavian artery and neurologic complications after thoracic endovascular aortic repair.

Patterson BO¹, Holt PJ², Nienaber C³, Fairman RM⁴, Heijmen RH⁵, Thompson MM².

A systematic review of spinal cord injury and cerebrospinal fluid drainage after thoracic aortic endografting.

Wong CS¹, Healy D, Canning C, Coffey JC, Boyle JR, Walsh SR.

Preoperative prediction of spinal cord ischemia after thoracic endovascular aortic repair.

Scali ST¹, Wang SK², Feezor RJ², Huber TS², Martin TD³, Klodell CT³, Beaver TM³, Beck AW².
Embolic risk

- Endovascular manipulation in the arch is associated with significant risk of cerebral (7-15%) and SC (4%) embolization

- DWI-MRI lesions 63%

- Significant risk factors identified as: atheroma grade, extent of coverage, LSA revascularization
Transcranial Doppler

Perera A et al, BJS 2018

EMBOLI number

Procedural Stage
Transcranial Doppler findings during thoracic endovascular aortic repair

Jean Bismuth, MD, Zsolt Garami, MD, Javier E. Anaya-Ayala, MD, Joseph J. Naoum, MD, Hosam F. El Sayed, MD, Eric K. Peden, MD, Alan B. Lumsden, MD, and Mark G. Davies, MD, PhD, MBA, Houston, Tex

![Graphs showing MES in Landing Zones 0-2 and 3-4 (Mean)](image)

- **MES in Landing Zones 0-2 (Mean)**
  - Right side: Diagnostic Phase (DP) is higher than Treatment Phase (TP)
  - Left side: DP is lower than TP

- **MES in Landing Zones 3-4 (Mean)**
  - Right side: DP is lower than TP
  - Left side: DP is lower than TP
TEVAR
RELY on experience of more than 4000 patients reached with RELAY and RELAY NBS Thoracic Stent-Graft

RELAY™ shows lower stroke rates compared to other series of Thoracic Aortic Endografting

- RELAY: 0.6%
- ZENITH TX1/TX2: 3.0%
- GORE TAG: 3.5%
- VALIANT: 3.8%
Dual Sheath Design

Designed to:

/// Minimize access vessel trauma
/// Navigate the thoracic aorta
/// Deploy precisely
/// Optimize conformability & seal
Dual Sheath Design

The Outer Primary Sheath is advanced until the Delivery System Tip is just below the intended distal landing zone.
**DElivery System**

A unique dual sheath system designed for optimal aortic navigation and predictable placement.

**1. Proximal Clasp**

Allows for precise and perpendicular deployment.

Allows repositioning
**Delivery System**

A unique dual sheath system designed for optimal aortic navigation and predictable placement.

**Inner Sheath**
Flexible inner sheath for optimal navigability to target landing site and allows for precise deployment.
**Delivery System**

A unique dual sheath system designed for optimal aortic navigation and predictable placement.

**Pre-Curved Inner Catheter**

Nitinol inner catheter guides the system through the thoracic aorta for optimal navigation.
Specifically designed for the Thoracic Aorta
Relay offers both types of proximal end configurations: Covered and Uncovered

- Covered stent-graft configuration
- Uncovered stent-graft configuration
- Force rig developed to measure contact forces on phantom (Type I arch)
- Phantom mounted and coupled onto a 6 DOF (F/T) sensor
  - Based on force modulus obtained from 3 orthogonal sensor readings
  - Circulated pulsatile pump, physiological conditions
  - Sheath decoupled from phantom
- Direct CF measurements (sensitivity 4mN, 25Hz)
- Sensor readings zeroed to omit the weight of the platform and setup
### Standard Sheath

<table>
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<th>mean force (N) (µ ± σ)</th>
<th>max force (N) (µ ± σ)</th>
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<tr>
<td>Insertion</td>
<td>2.96 ± 0.78</td>
<td>12.4 ± 6.17</td>
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<tr>
<td>Retraction</td>
<td>1.57 ± 0.51</td>
<td>3.82 ± 1.36</td>
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Standard vs Dual Sheath

- 10 conventional standard sheath devices
  n=50

- Relay Plus
  n=10

Landing Zone: 2-3
Standard vs Dual Sheath

Wilcoxon signed-rank test
CF in the Arch

Compared to Cardiac Ablation Forces
Successful ablation vs Perforation/tamponade

Max force TEVAR = 12 N = 1200 g
vs.
Perforation forces ablation procedures = 40 – 50 g
Force Time Integral TEVAR = 213Ns = 21300gs
vs.
FTI during ablation = 400gs

Summary

• Embolization principal risk during TEVAR & occurs in all procedural stages

• Contact forces in the aorta during stent placement & positioning significant

• Awareness for atheromatous/shaggy aortas; vessel trauma, embolization, inflammatory response

• Dual sheath design Relay Plus significantly reduces CF

• Explore further design & technology options for endovascular manipulation, device placement and delivery