

Long-Term (5 Years) Good Results Of The Medtronic Valiant Captivia Endografts For TEVAR In TBAD Patients: Advantages And Disadvantages

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For the Medtronic Dissection Trial Investigators

Veith Meeting NYC, 2024

DISCLOSURES

- Investigator:
 - Gore
 - Medtronic
 - Cook
 - Edwards
 - Abbott
- Speaking Honoraria:
 - Gore
 - Medtronic
 - Terumo Aortic

Disclosure: Penn Cardiovascular and Vascular Surgery enrolled in all these Trials as Either National PI's, Leading Enrollers, or Trial Participants

VALIANT CAPTIVIA TYPE B AORTIC DISSECTION US IDE TRIAL

Medtronic Dissection US IDE Trial

Study purpose: Evaluate clinical performance of Valiant Captivia for Treatment of Acute, Complicated Type B Aortic Dissections.

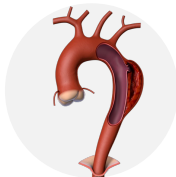
Study design: Prospective, non randomized, multicenter, single arm 6 sites in the US. 50 patients enrolled between 6/2010 – 5/2012

Primary Safety Endpoint: 30-day All-Cause Mortality.

Inclusion: malperfusion (visceral, renal, spinal cord, and/or lower limb ischemia), rupture.

Exclusion: history of known connective tissue disorder.

Follow-up: 30-day, 6 months, 12 months and annually through 5 years.



Beveris et al JTCVS 2020.

Clinical Status at Onset (N=50)

Very Sick group of Complicated Type B Patients

Back/Chest Pain	88%
Clinical Malperfusion	86%
Abdominal Pain	36%
Rupture	20%
Paraparesis	12%

Clinical Malperfusion in 86% of pts

- Visceral ischemia: 40%
- Renal ischemia: 42%
- Lower Limb: 40%
- Spinal Cord: 6%

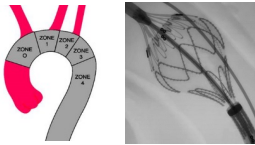
Antihypertensives administered to 84%
Inotropic support required in 16%

Procedural Data

- 100% Delivery and Deployment Success
- Proximal entry tear covered in 100% of subjects
- No misaligned deployment


Implant zones

- Zone 1: 2% (1/50)
- Zone 2: 58% (29/50)**
- Zone 3: 34% (17/50)
- Zone 4: 6% (3/50)

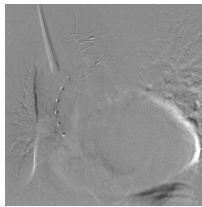


Valiant stent graft with the Captivia delivery system

Pre



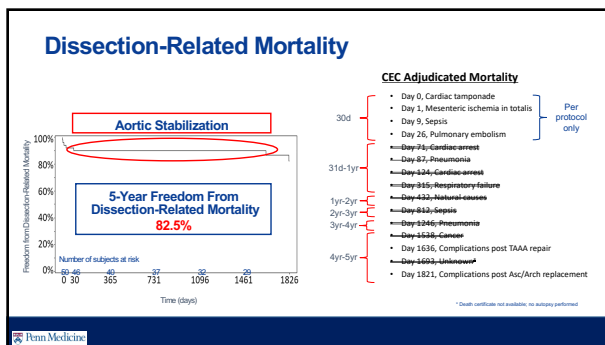
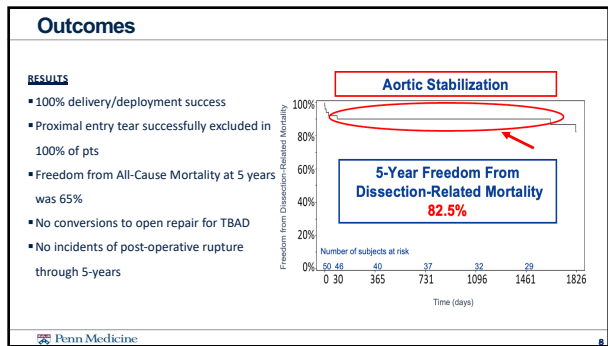
Post



Select Serious Adverse Events

	0-30 Days	31-365 Days	366-731 Days	732-1096 Days	1097-1461 Days	1462-1826 Days
Aortic Rupture	0.0% (0/50)	0.0% (0/46)	0.0% (0/40)	0.0% (0/37)	0.0% (0/32)	0.0% (0/29)
Conversion	0.0% (0/50)	0.0% (0/46)	0.0% (0/40)	0.0% (0/37)	0.0% (0/32)	0.0% (0/29)
Aortic Dissection (Retrograde Type A)	0.0% (0/50)	0.0% (0/46)	0.0% (0/40)	0.0% (0/37)	0.0% (0/32)	0.0% (0/29)
Cardiac Tamponade	0.0% (0/50)	0.0% (0/46)	0.0% (0/40)	0.0% (0/37)	0.0% (0/32)	0.0% (0/29)
Cerebral Ischaemia	0.0% (0/50)	0.0% (0/46)	0.0% (0/40)	0.0% (0/37)	0.0% (0/32)	0.0% (0/29)
Cerebrovascular Accident	0.0% (0/50)	0.0% (0/46)	0.0% (0/40)	0.0% (0/37)	0.0% (0/32)	0.0% (0/29)
Paraplegia	2.0% (1/50)	0.0% (0/46)	0.0% (0/40)	0.0% (0/37)	0.0% (0/32)	0.0% (0/29)
Paralysis	2.0% (1/50)	0.0% (0/46)	0.0% (0/40)	0.0% (0/37)	0.0% (0/32)	0.0% (0/29)
Spinal Cord Ischemia	2.0% (1/50)	0.0% (0/46)	0.0% (0/40)	0.0% (0/37)	0.0% (0/32)	0.0% (0/29)
Acute Renal Failure	6.0% (2/50)	2.2% (1/46)	0.0% (0/40)	0.0% (0/37)	0.0% (0/32)	0.0% (0/29)

4% (2/50) Retro Type A Dissection Rate - Zero SAE's after 1 year

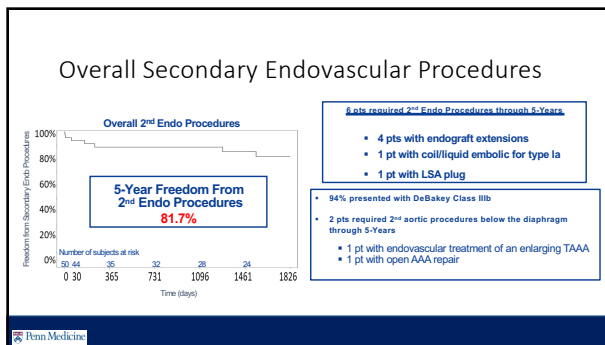


Aortic Remodeling through 5 Years (per Core Lab)

94% (46/49) had DeBakey Class IIIB dissections (extending to or past diaphragm)

100% Entry Tear Coverage

Core Lab	1-Year	2-Year	3-Year	4-Year	5-Year
Partial or Complete Thrombosis of the False Lumen - Stented Segment	93.9% (5/53)	100% (2/27)	95.7% (22/23)	96.0% (24/25)	100.0% (18/18)
Partial or Complete Thrombosis of the False Lumen - Distal Stent to Celiac	64.5% (23/37)	61.5% (16/28)	78.9% (19/25)	88.0% (22/25)	88.9% (16/18)
Partial or Complete Thrombosis of the False Lumen - Abdominal Aorta	48.3% (16/29)	65.2% (15/23)	59.1% (13/22)	78.9% (20/26)	68.8% (11/16)



Summary: Main Clinical Points

Long-term Evaluation of Valiant Captivia for Acute, Complicated TBAD

- SICK PATIENTS:**
 - 94% presented with DeBakey Class IIb dissections; 86% clinically malperfused; 20% with rupture
 - 100% delivery/deployment success
- Proximal entry tear successfully excluded in 100% of pts
- Freedom from All-Cause Mortality was 65%; Freedom from Dissection-Related Mortality was 83%
- Acceptable rate of SAEs given the patients' complex presentations
- No incidents of post-operative rupture through 5-years
- Excellent remodeling** was evident over the stented segment, with significant positive remodeling beyond the stented segment

Conclusion

Based on these 5-year results:

*The Valiant Captivia Thoracic Stent Graft System
is Effective in the Long-Term Management of
Acute Complicated Type B Aortic Dissection*



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