U.S. MEDTRONIC DISSECTION TRIAL 3 YEAR RESULTS

PROSPECTIVE, NON-RANDOMIZED, MULTI-CENTER TRIAL

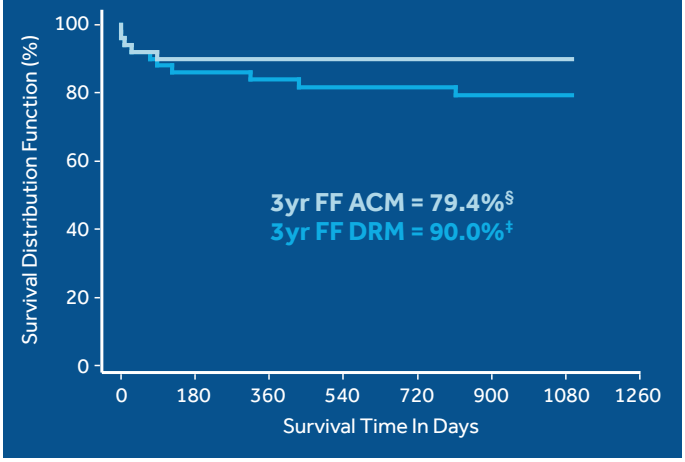
TEVAR in Acute, Complicated Type B Aortic Dissection: Results from the Valiant Captivia IDE Trial (n=50)†

CLINICAL STATUS AT ONSET

Malperfusion: 86%

Rupture: 20%

FREEDOM FROM MORTALITY



- The Valiant™ Captivia™ stent graft system demonstrates safety and effectiveness in the treatment of acute, complicated Type B aortic dissections
- The Valiant™ Captivia™ stent graft system is stabilizing the aorta

3 YEAR AORTIC REMODELING

92.3%	True Lumen diameter increase/stable
69.2%	False Lumen diameter decrease/stable
75.0%	Partial/complete False Lumen thrombosis

KEY OUTCOMES THROUGH 3 YEARS

0%	Ruptures or Conversions
3	Patients with Dissection-related Reinterventions

RETROGRADE TYPE A AORTIC DISSECTION

POST-TEVAR FOR TYPE B AORTIC DISSECTION:

- Based on the published IDE data in the chart below, Retrograde Type A Dissections (RTADs) can occur with any device.

STUDY	DEVICES STUDIED	PATIENTS	RETROGRADE TYPE A	1Y RTAD (%)
Medtronic Dissection IDE[1]	**Medtronic Valiant™ Captivia™**	50 acute	1 RTAD <30d 1 RTAD <1yr	**4%**
Gore Dissection IDE[2]	**GORE cTAG™***	50 acute	3 RTAD <30d	**6%**
Cook STABLE IDE[3]	**Cook Zenith™* TX2™***	24 acute 16 sub acute	2 RTAD <30d 1 RTAD <1yr	**7.5%**

NOTE: These trials are not powered to be compared directly.

- According to the Systematic Review by Canaud et al., **pathology, landing zone, and oversizing are significantly associated with a risk of RTAD development regardless of device,** whereas proximal device configuration is not.[4]

†Azizzadeh A. Endovascular Repair in Acute, Complicated Type B Aortic Dissection: 3-Year Results from the Valiant US-IDE Study, VIVA 2016
‡Dissection-related mortality
§All-cause mortality
¹Valiant Captivia IFU
²Gore cTAG IFU
³Lombardi JV, Cambria RP, Nienaber CA, et al. "Prospective multicenter clinical trial (STABLE) on the endovascular treatment of complicated Type B aortic dissection using a composite device design." J Vasc Surg. 2012 Mar; 55(3):629-640.e2. doi: 10.1016/j.jvs.2011.10.022. Epub 2011 Dec 9.
⁴Canaud, L, et al. "Retrograde Aortic Dissection After Thoracic Endovascular Aortic Repair." Annals of Surgery. 2014 Aug;260(2):389-95. doi: 10.1097/SLA.0000000000000585.

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OBJECTIVE[†]

Evaluate the clinical performance of the Valiant™ thoracic stent graft with the Captivia™ delivery system for the treatment of acute, complicated Type B aortic dissections.

STUDY DESIGN

- 16 U.S. centers; enrollment 2010–2012
- N = 50 patients with acute, complicated (malperfusion, rupture) Type B aortic dissection
- 1° endpoint: all-cause mortality within 30 days of index procedure

MAIN CLINICAL FINDINGS THROUGH 3 YEARS

Treatment of trial patients resulted in:

- Primary endpoint achieved with 8% all-cause mortality at 30 days
- No conversions to open repair and three patients with dissection-related reinterventions
- No incidents of post-operative rupture
- 100% delivery and deployment success
- 100% coverage of primary entry tear
- 3 CVA /1 CVI
- Favorable remodeling over stented segment

[†]Azizzadeh A. Endovascular Repair in Acute, Complicated Type B Aortic Dissection: 3-Year Results from the Valiant US-IDE Study, VIVA 2016

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