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

3yr FF ACM = 79.4%§
3yr FF DRM = 90.0%§

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.

<table>
<thead>
<tr>
<th>STUDY</th>
<th>DEVICES STUDIED</th>
<th>PATIENTS</th>
<th>RETROGRADE TYPE A</th>
<th>1Y RTAD (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic Dissection IDE¹</td>
<td>Medtronic Valiant™ Captivia™</td>
<td>50 acute</td>
<td>1 RTAD &lt;30d</td>
<td>4%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 RTAD &lt;1yr</td>
<td></td>
</tr>
<tr>
<td>Gore Dissection IDE²</td>
<td>GORE cTAG™</td>
<td>50 acute</td>
<td>3 RTAD &lt;30d</td>
<td>6%</td>
</tr>
<tr>
<td>Cook STABLE IDE³</td>
<td>Cook Zenith™ TX2™</td>
<td>24 acute, 16 sub acute</td>
<td>2 RTAD &lt;30d</td>
<td>7.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 RTAD &lt;1yr</td>
<td></td>
</tr>
</tbody>
</table>

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

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1Azizzadeh A. Endovascular Repair in Acute, Complicated Type B Aortic Dissection: 3-Year Results from the Valiant US-IDE Study. VIVA 2016
2Dissection-related mortality
3Valiant Captivia IFU
4Gore cTAG IFU
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