Cook Zenith Alpha Low Profile Endograft System for TEVAR: Advantages, Limitations and Clinical Results in Europe and the US

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Contents of Interest

- Access issues: 20-30%

Size of introduction system for current thoracic devices is 20-25 French

<table>
<thead>
<tr>
<th>Company</th>
<th>Device</th>
<th>Metal</th>
<th>Covering</th>
<th>Tapered</th>
<th>Free flow</th>
<th>Outer diameter of delivery system (Fr)</th>
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<tr>
<td>Medtronic</td>
<td>Valiant</td>
<td>Nitinol</td>
<td>Yes</td>
<td>Proximal</td>
<td>20 – 25</td>
<td></td>
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<tr>
<td>Gore</td>
<td>TAG</td>
<td>Nitinol</td>
<td>ePTFE</td>
<td>No</td>
<td>No</td>
<td>22 – 24</td>
</tr>
<tr>
<td>Cook</td>
<td>Zenith TX2</td>
<td>Stainless steel</td>
<td>Yes</td>
<td>Proximal</td>
<td>23 – 25</td>
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<tr>
<td>Duke Vascular</td>
<td>TAGart</td>
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<td>22 – 24</td>
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<tr>
<td>Jotec</td>
<td>Evita</td>
<td>Nitinol</td>
<td>Polyester</td>
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<td>20 – 24</td>
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<tr>
<td>Bolton Relay</td>
<td>Nitinol</td>
<td>Polyester</td>
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<td>Proximal</td>
<td>22 – 24</td>
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</tr>
</tbody>
</table>

*18 – 24 ID; Sheath required

Comparison between Zenith® TX2 and Zenith Alpha

Zenith TX2® TAA Endovascular Graft
- Stainless steel Z-stents
- Standard Dacron
- Covered proximal stent
- 20-24 Fr Z-Trak Plus® Introduction System
- 22-42 mm diameter devices
- MR compatible

Zenith® TX2® Low Profile TAA Endovascular Graft
- Nitinol Z-stents
- Thinner, more tightly woven Dacron
- Bare rounded proximal stent
- 16-20 Fr Z-Trak Plus® Introduction System
- 18-46 mm diameter devices
- -

Published experience in US

One-year outcome from the international multicenter study of the Zenith Alpha Thoracic Endovascular Graft for thoracic endovascular repair

Endovascular repair for blunt thoracic aortic injury using the Zenith Alpha low-profile device


Conclusion: Early results indicate that the Zenith Alpha thoracic endovascular graft improves patient outcomes, reduces operative mortality, and is effective in the repair of blunt thoracic aortic injury. Further studies are needed to confirm these findings.
Published experience in Europe

- In six patients prior endovascular attempts to treat the aneurysm with a different device failed due to challenging vascular access.
- These patients were then treated successfully with a Zenith Alpha device.

Zenith alpha increased applicability of TEVAR

Key points:

- Published experience in Europe
- Zenith alpha increased applicability of TEVAR

Is there a trade-off with low profile stentgrafts?

- Will lighter fabrics and stent material decrease TEVAR durability?
- Will the rate of type III/IV endoleak increase in the future?
- Will the need for secondary procedures increase in the future?

“all comers” treated with Zenith Alpha

- (“real world” experience: 8/2010-10/2015; n:112)
  - 58% males, mean age 70.4 y.
  - Typical aneurysm population:
    - 90% hypertensive
    - 34.8% coronary artery disease
    - 52% “off-label”
    - 23.2% emergent/urgent

CTA and angiography after TEVAR and PTA of the right iliac artery

75-year old man with TAA and aortic tortuosity
CTA after implantation of Zenith Alpha

Procedure details and iliac morphology

- Percutaneous access used in 87.5% of patients (2.5% in TX-2 Pivotal study). 3.6% conduits.
- Technical success 98%
- Mean minimal iliac diameter: 5.8 mm
- Mean iliac tortuosity index: 1.27

Mid-term outcomes (follow-up: 6-62 m.)

- Deaths 11 (2 aneurysm-related)
- Ruptures 0
- Conversion 0
- Renal failure none related
- Stroke none related

Secondary procedures and morphology changes

- Three secondary interventions
  - One coil embolization and thrombus removal
  - One proximal and distal extension
  - One for type II endoleak (LSA)
- No retrograde dissection
- No device migration

Conclusions

- The Zenith Alpha performs equally well as the Zenith TX-2, while overcoming more difficult access morphologies
- The Zenith Alpha can be utilized in patients with demanding access vessel morphology, further extending its applicability
- More studies are needed to provide long-term durability and performance results

Thank you!

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