The “New” Zenith Alpha Thoracic Endovascular Graft

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Disclosures
PI/Co-PI for several thoracic and abdominal aortic stent graft trials (Cook, Inc, Cordis® Corporation, Bolton Medical)
Proctor and lecturer at symposia hosted by Cook, Inc., Bolton, W.L. Gore and Associates, Jotec and Medtronic, Inc.

Features of thoracic aorta
1. Different diseases
2. Aortic diameter
3. Aortic length
4. Tortuosity
5. Proximity to crucial branches
6. Specific deployment problems
7. Late migration

Modular strategy
TX2
No migration / shortening during deployment

Device Overview
- Two-piece modular system
- Nitinol stents / Dacron fabric
- 16-20 Fr (ID) sheath
- For grafts Ø 18-46 mm
- Low profile (OD)
  6.0 mm, 7.1 mm, 7.7 mm
Differences TX2 → Alpha

1. Stainless steel → Nitinol
2. No top bare stent → bare stent
3. Dacron dense weave
4. Barbs location
5. Distal bare metal stent
6. Release trigger wires mechanism

1. Stainless steel → Nitinol

Gold markers positioned on each end of the proximal and distal components

2. No top bare stent → bare stent

Rounded, atraumatic design “Alignment” stent to assure proximal conformance

3. Polyester woven in denser yarn
4. Barbs location

The fixation barbs are located in a double row in the proximal sealing stent.

Barbs pointing downwards are aimed at avoiding distal migration of the proximal end.

5. Distal bare metal stent

Barbs pointing upwards are aimed at avoiding proximal migration of the distal end.

6. Wires keeping endograft attached to delivery system

6. Release trigger wires mechanism

Pull

Rotate
6. Deployment sequence

Three steps

1. Position device
2. Pull back sheath
3. Rotate handle

Similarities with TX2

1. General philosophy/ modular strategy
2. Internal sealing stent
3. Wires keeping end stents closed
4. Wires keeping endograft attached to delivery system
5. Deployment sequence

Initial clinical experience with a new low-profile thoracic endograft

Germanno Melissano, MD, Yumate Yotomba, MD, Fabrizio Rinaldi, MD, and Roberto Chessa, MD, Milan, Italy

• 42 patients (31 men; median age, 71 years; range, 54-83 years)
• 34 degenerative aneurysms, 4 aortic ulcers, 2 false aneurysms and 2 traumatic blunt injuries.
• Mean access vessel diameter of 6.7 mm (range, 6-11 mm). In 11 cases, aortoiliac occlusive disease (TASC B and C lesions)


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• The proximal landing was in zone 1 in 2 cases, in zone 2 in 25 cases, in zone 3 in 11 cases, and in zone 4 in 4 cases.
• 51 endografts (45 proximal components and 6 distal components) were deployed in 42 patients


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• Mean access vessel diameter of 6.7 mm (range, 6-11 mm)
• In 11 cases, aortoiliac occlusive disease (TASC B and C lesions) was present


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• In patients with associated aortoiliac disease, no adjunctive procedures were required, except for predilation with balloon angioplasty in 2 cases
• No device-related major complications, no perioperative mortality, paraparesis, or paraplegia
• 30 days, morbidity: one case of major stroke, two cases of transient acute renal failure, and one case of postimplantation syndrome.
No access-related complications were recorded
CT AT 6 months was obtained in 39 patients and confirmed 100% clinical success without device-related complications.
No type I endoleaks or bird’s beak effects were documented

Conclusions
– Extended indications for narrow access vessels
– Safer passage of calcified and tortuous vessels
– Minimized deployment / release force
– Improved stent graft adaptation

Conclusions
– Retains the precision and control of previous generation device
– Larger series and longer follow up required