The Cook Zenith Alpha AAA Endograft System: Advantages, Limitations and 1-Year Results

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Disclosures

• Cook: consultant, speaker, research grants, patents

Zenith Alpha™ Abdominal

• Three-piece modular system designed to accommodate varying patient anatomies
• Low-profile main body device:
  • 16F/17F
  • Active suprarenal fixation
  • Gold marker at the flow divider for increased visualization
• New Alpha-Legs
  • Enhanced kink resistance and flexibility

Improvements: Simplified Deployment

• Captor sleeve reduces deployment forces
• No top cap to retrieve
  • Improved trackability
• No trigger wires to manually remove
  • Trigger wires now remain contained within the new rotational handle

Intuitive Introduction System

• New rotational handle
  – Controlled, simple & precise deployment
• More intuitive system
STS1  
copied this one from below to visualize simplicity  
Stefan Schlueter, 3/6/2014

FT1  
Ray & Scott - please note that picture three below is currently being updated to show the gray knob on the black gripper. This will most likely not be caught by anyone but me (and, honestly, we could simply say that this user has already rotated 180 degrees putting the gray knob on the backside of the device thus being unable to be seen here). I would like to show the gray knob for AAA though. We can always add it later.  
Foley, Tim, 3/7/2014
**Cook Inc. Testing**

**Migration Resistance**

- Porcine aorta pull out
  - Greater force than Zenith Flex® AAA
  - Barbs do not fracture
  - Resists rotation

**Cook Inc. Testing**

**Alpha Sealing Stent**

- Seal Stent Radial Force Test Results
  - Equivalent radial force as Zenith Flex® AAA
  - Radial force at: minimum vessel diameter per IFU

**Cook Inc. Testing**

**Alpha Graft Fabric**

- Higher density graft fabric results in lower graft permeability
- Lower permeability results in reduced fluid leakage

**Zenith Alpha Experience**

- 39 Patients
  - Specific anatomy...
    - Need for longer body in angulated neck
    - Small and angulated iliac arteries

**Indication for Treatment**

- Elective 38
  - AAA 30
  - AAA+ iliac* 5
  - Iliac* 3
- Acute 1
* 7 EVAR + IBD

**AAA Characteristics**

- Dmax: 57.3 ± 11.1 mm
- Neck length: 29.4 ± 13 mm
Perioperative Outcome

- Technical Success: 97.4% (38/39)
  - 1 Early Type I Endoleak (disappeared at 1st CT)

- 30-d Mortality: N=1 (2.6%)
  - POD 5, Intracerebral bleeding

Follow-up

Range: 1-26 months

- No Type I Endoleak
- No Mortality

Follow-up

Range: 1-26 months

- Limb Occlusion: N=1 (1.3%, 1/78)*
  - No reason identified
    - Thrombectomy and stenting

* 10 limbs (12.8%) relined primarily, all open!

Follow-up

Range: 1-26 months

- Reinterventions: N=3 (7.7%)
  - Conversion with homograft due to Infection*
  - Iliac limb thrombectomy & stenting
  - Relining of IBD (Type III Endoleak)

* Salmonella Aortitis

Conversion with Homograft

- Salmonella Aortitis
  - “Exotic” travel history

Discussion & Conclusions

- Clear improvement
  - Low profile
  - Much easier and more controlled deployment
  - Flexibility/Conformability

- Points of attention
  - We are now used to Visibility/Position of markers
  - Advice to position two limbs at same level
  - Durability to be proven with time