Aorfix Endograft For EVAR: 3-Year Results Of PYTHAGORAS Pivotal PMA Trial In Standard And Angulated Neck AAAs

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Aorfix™ Device

- Designed and tested to treat highly angulated aortic necks
- Highly flexible, soft, conformable device
- Polyester fabric, Nitinol rings
- 4 pairs of hooks proximally
- 8 mm long primary seal zone
- Commonly placed in a trans-renal position

U.S. Pythagoras Clinical Trial: First EVAR Trial in aortic neck angles 60-90 degrees

- **EVAR Arms**
  - ‘Roll-in’ Group: 67 EVAR pts, neck angle <60°
  - Primary Study Group: 151 EVAR pts, neck angles 60-90° (and higher)
  - The US trial enrolled 218 patients on intent-to-treat
- **Control Arms**
  - SVS Registry meta-analysis of control patients from prior US EVAR clinical trials (n=323)
  - Concurrently enrolled Open Surgical controls (n=76) for neck angulation and other variables not in SVS registry

Demographics, Comorbidities, Anatomy

- EVAR and open control patients had similar AAA sac diameter (5.8 cm in each group, p=ns), but the high-angle group differed from open controls with regard to factors previously shown to adversely affect outcomes:
  - Age [EVAR 76 ± 7, vs 69 ± 7 years, p<0.001],
  - Female [EVAR 29%, high],
  - Neck angle [EVAR all 71 ± 22, EVAR high angle 83 ± 15, vs Open 48 ± 23 degrees, p<0.001] ; EVAR 69% > 60°, Open 27% > 60° (p<.05)

First trial with more severe neck angles in the test group

First trial with more female pts in the test group

Gender Distribution, EVAR Trials

US AAA population ~22% female

Disclosure

Speaker name: Mark Fillinger

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x I have the following potential conflicts of interest to report:
  x Consulting (WL Gore, Endologix, Cook)
Interaction between neck angle, gender

Effect of Neck Angle on Seal Zone

Mean Neck Lengths (±1SD) in IDE Studies

Results: 30 day + Hospital

- Aortic endografts were successfully implanted in 210/218 cases on intent-to-treat (all 8 were access-related, device not attempted in 4/8).
- Mortality was 1.8% for the entire cohort (4/218), 2.0% for the 60-131° angle group (3/153), and 2.8% for the open controls (9/323, p=ns)
- 30-day outcomes favored the test group for procedure duration, EBL, transfusion, and hospital length of stay (all p<0.05).

Freedom from SVS Major Adverse Events (MAEs): Aorfix EVAR Superior to Open Controls

EVAR-specific Results: 1-3 years
### Summary of sac expansion rates derived from literature and compared with Aorfix

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<th>Author</th>
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<th>Year 2</th>
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### 5 Year Freedom from All-cause Mortality: Intent to Treat Basis

- Lifeline 2005

### 5 Year Freedom from Aneurysm-Related Mortality: Intent to Treat Basis

- Lifeline 2005

### 5 Year Freedom from Secondary Interventions: Intent to Treat Basis

- Lifeline 2005

### 5 Year Freedom from Sac Rupture: Intention to Treat Basis

- Lifeline 2005

**DHMC Case #2:** Device straightens, short available seal zone remains sealed

- Pre-implant
- 1 Month post-implant
- 1 Year post-implant
Norfolk case: Adapts at neck and iliac limbs

Tips
- Read the IFU, learn the device deployment, start with normal anatomy
- Avoid severely irregular necks (≥5mm diameter change over 15mm length)
- Put the device at the renal arteries: that is where the neck is stable
- Watch the renals in angulated necks: use proper c-arm gantry angles based on CTA

Summary
- The Pythagoras Clinical Trial of the Aorfix endograft is the first EVAR Pivotal trial focusing on highly-angulated aortic necks (60-90 degrees).
- Despite predictors of worse short and long-term outcomes, MAEs are superior to open repair, and EVAR-specific outcomes are similar to trials with much less severe anatomy, even when followed to five years
- Based on Pythagoras results, Aorfix was FDA-approved for 0-90° neck angles, and remains the only on-label alternative to open repair for patients with highly angulated aortic necks.

Pythagoras Investigators