


Alto Endograft For Standard EVAR: Results From The ELEVATE Trial and JAGUAR RCT

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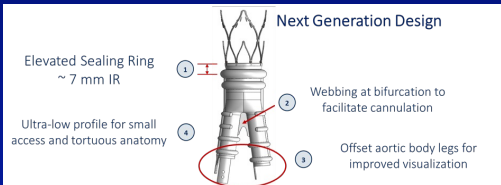



Disclosures

- Consultant: BD, Boston Scientific, Contego Medical, Cordis, Endologix, Inspire MD, Medtronic, Rapid Medical, Shockwave, Penumbra, Vivasure, Nectero
- Stock: Inspire MD and Centerline Biomedical
- VIVA Physicians, Board Member
- Research Studies: Abbott, Endologix, Surmodics, W.L. Gore, Terumo Aortic, NIH, Boston Scientific, Merit, Contego Medical, Inspire MD, Reva Medical, Penumbra, Medalliance, Nectero






Ovation Alto





Next Generation Design

- Elevated Sealing Ring ~ 7 mm IR
- Ultra-low profile for small access and tortuous anatomy
- Webbing at bifurcation to facilitate cannulation
- Offset aortic body legs for improved visualization

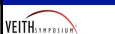

Alto Trial Inclusion Criteria

- Age ≥ 18 years
- AAA ≥ 5.0 cm
 - Or increased by 0.5 cm w/in 6 mos
 - Max AAA diameter $> 1.5 \times$ adjacent normal aortic
- Adequate iliac/femoral access
- Neck diameter $\geq 16\text{mm}$ and $\leq 30\text{mm}$
 - At 7mm below renal artery
- Aortic angle
 - ≤ 60 degrees neck was ≥ 7 mm
 - ≤ 45 degrees if proximal neck was < 7 mm
- Iliac landing zone 8-25 mm and > 10 mm long



Baseline Characteristics

• Age	73 \pm 7	
• Male	70	(93%)
• ASA 3-4	70	(93%)
• HTN	62	(83%)
• COPD	27	(36%)
• Hyperlipidemia	57	(76%)
• CKD	5	(5%)
• Current/Former Smoker	71	(95%)
• CAD	35	(47%)

Baseline Characteristics

- AAA diameter 51.7mm \pm 6.6
- Neck length 27.9mm \pm 13.7 (5.0, 66)
- Neck diameter 22.4mm \pm 2.4

Treatment Success

- Technical success &
- 12 month Freedom from type I & III endoleaks
- Freedom from stent graft migration > 10 mm
- Freedom from AAA enlargement > 5mm
- Freedom from AAA rupture
- Freedom from conversion to open repair
- Freedom from stent graft stenosis, occlusion or kink, thromboembolic event or stent fracture requiring secondary intervention



Results

- The EVAR procedure lasted 90 mins (median)
- EBL Minimal (52.5mL)
- 73 (97%) patients were discharged to home
- LOS (median: 1.3 day)



30-day Outcomes

- | | |
|-----------------------------|------|
| • AAA-related mortality | 0% |
| • All cause mortality | 0% |
| • Major adverse events rate | 5.3% |
| • Technical success | 100% |
| • Type Ia endoleak rate | 1.4% |
| • Type III endoleak rate | 0% |
| • AAA rupture | 0% |



12 Month Outcomes

- Treatment success was 96.7% (59 / 61; 95% CI)
- All-cause mortality was 4.0% (n = 3)
 - Lung Ca, blunt trauma and unknown
- KM freedom from mortality 95.9%
- KM freedom from AAA-related mortality 100%
- MAE rate at 1 year was 10.7%
- AAA expansion was 1 patient 1.6%
- 13 patients (21.3%) decreasing sac diameter



12 Month Outcomes

- No type I or III endoleaks*
 - One type Ia endoleak at completion Rx with BES prior to day 48
- No Migration
- One graft infection Rx explant





CCF trial experience

- 6 patients enrolled all out 5 years
- One late type Ia at year 5 with AAA growth
 - Eliminated with embolization and Palmaz stent
- No type III endoleaks
- No migration
- No fracture
- No conversion




5 Year follow up Trial Case




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Jaguar Trial

Objective Analysis to GaUge EVAR Outcomes Through Randomization 

- RCT 2:1 Alto vs Device of choice
- 450 participants followed for 5 years
- Treatable in real world anatomy by both devices (non IFU)

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Jaguar Trial


Objective Analysis to GaUge EVAR Outcomes Through Randomization 

Inclusion Criteria:


- Adult age 21 and older
- Subjects with minimum of 2 year life expectancy
- Subjects have signed the informed consent document
- Subjects with unruptured infrarenal AAA who are assessed by the Investigator to be eligible for endovascular Abdominal Aortic Aneurysm Repair with the trial devices.
- Patient must be able and willing to comply with all required follow-up exams.

Exclusion Criteria:


- Currently participating in another trial where the primary endpoint has not been reached yet.
- Known allergy to any of the device components
- Pregnant (females of childbearing potential only)
- Known connective tissue disorders
- Known active infection
- Subjects with pre-existing EVAR, i.e., in need of repair/intervention of a previously failed EVAR.
- Patient has other medical, social, or psychological conditions that, in the opinion of the investigator, preclude them from receiving the pre-treatment, required treatment, and post-treatment procedures and evaluations.

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Jaguar Trial

Objective Analysis to GaUge EVAR Outcomes Through Randomization 


- Primary Outcome
 - 5 Year Freedom from Aneurysm-Related Complication
 - Composite endpoint consisting of aneurysm-related death, aneurysm rupture, conversion to open surgery, type I and III endoleaks, device migration (>10mm), aneurysm sac enlargement (>5mm), occlusion, and freedom from device-related interventions
 - 5 Year Neck Dilatation in mm

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Jaguar Trial

Objective Analysis to GaUge EVAR Outcomes Through Randomization 

- Secondary Outcomes
 - Major Adverse Events 30 D and 12 M
 - All-cause mortality, Bowel ischemia, Myocardial infarction, Paraplegia, Renal Failure, Respiratory Failure, Stroke, Index Procedural Blood Loss \geq 1000mL
 - All Cause Mortality and AAA Mortality 30 D and 12-60 M
 - Endoleaks Type Ia, Ib, II, III, IV and unknown 30 D and 12-60 M
 - Secondary interventions, device integrity issues, patency, AAA ruptures, conversion, AAA enlargement, and migration at 30 D and 12-60 M

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Conclusions

- Ovation Alto is safe and effective in Rx AAA
 - Necks 16-30mm at IR 7 at 12 months
- Technical success 100% Treatment success 96.7%
- Low Rate of AAA expansion 1.6%
- No Migration
- One type Ia endoleak 1 month
 - Rx with BES without recurrence
- Durable in f/u at CCF
- Randomized Jaguar Trial Under way

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