EVOLVING EVAR

The durability of adaptive sealing technology in specialized anatomies

Mathlouthi, A. et al., Annals of Vascular Surgery 2021

Study Design

A total of 238 patients underwent EVAR with adaptive sealing technology and a median follow-up of 58 months

238 patients
at 36 sites in

- US
- Germany
- Chile

Inclusion criteria:

- AAA diameter ≥ 5 cm
- Proximal neck length ≥ 7 mm
- Inner wall diameter 16 mm–30.5 mm @ 13 mm below interior renal artery
- Neck angulation ≤ 60°
- Bilateral iliac fixation length ≥ 10 mm

Patient Demographics

Patients were predominantly male with a mean age of 73 years

Baseline characteristics	Study cohort (N=238)
Age (years)	73.3 ± 8
Male sex	193 (81.1%)
BMI (kg,m^2)	28.5 ± 6

46.2% with challenging anatomy*

17.2% of patients had a neck length < 10 mm

39% had a minimum access vessel diameter < 6 mm

Anatomic Demographics

Nearly half of patients had short neck or small access vessel diameter

Aneurysm characteristics	Study cohort (N=238)
AAA diameter (mm)	54 ± 8
Proximal neck diameter (mm)	
At the level of the renal arteries	22.4 ± 3
7 mm infrarenal	22.1 ± 3
13 mm infrarenal	22.7 ± 3
Proximal neck length (mm)	22 ± 12
Proximal neck length < 10 mm	41 (17.2%)
Proximal neck length < 15 mm	79 (33.2%)
Right minimum iliac access diameter (mm)	6.7 ± 1.7
Left minimum iliac access diameter (mm)	6.7 ± 1.6
Minimum access diameter < 6 mm	93 (39%)
Anatomy outside IFU with other stent grafts	110 (46.2%)
Infrarenal neck angulation (degrees)	19.9 + 14

*Defined as outside the instructions for use (IFU) with other commercially available stent grafts.

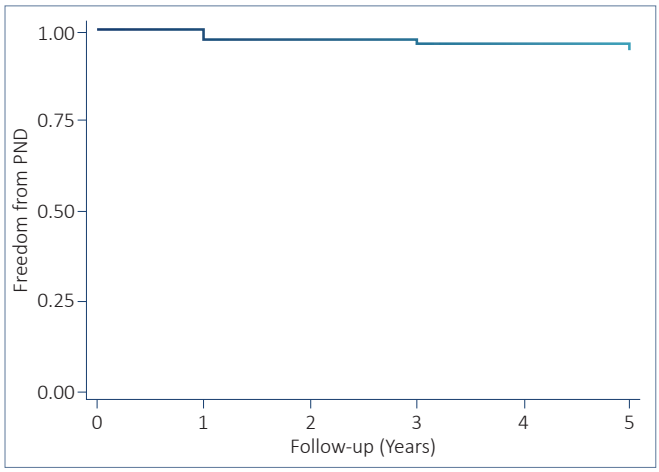
Results and Main Outcomes

5-year results demonstrate excellent durability for adaptive sealing technology, despite:

- 41% of patients had anatomies unfit for other stent grafts
- 73.9% of patients were considered to be at high operative risk

5-year outcomes	Study cohort (N=238)
Freedom from PND	93.6%
Freedom from type IA EL	96.3%
Freedom from reintervention	78.2%
Freedom from ACM	74.9%
Freedom from ARM	99.3%

Freedom from proximal neck dilatation



The adaptive sealing technology featured in the ALTO stent graft contributes to the durability of the device as demonstrated by low rates of neck dilatation and migration, even in patients with specialized anatomies.

Reference
Mathlouthi A, Yei K, Barleben A, Al-Nouri O, Malas MB. Polymer based endografts have improved rates of proximal aortic neck dilatation and migration. Ann Vasc Surg. 2021

Diclaimer
The Ovation platform product family includes a series of device iterations using adaptive neck sealing technology such as Ovation, Ovation Prime, Ovation iX, and ALTO. The devices included in the studies used in the analysis all include adaptive sealing technology. ALTO was not included in this data set.

The ALTO® Abdominal Stent Graft System
INDICATIONS FOR USE: The ALTO® Abdominal Stent Graft System is indicated for treatment of patients with infrarenal abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair with the device, which includes the following:

- Adequate iliac/femoral access compatible with vascular access techniques (femoral cutdown or percutaneous), devices, and/or accessories,
- A proximal aortic landing zone for the sealing ring 7 mm below the inferior renal artery.
- An aortic sealing zone comprised of healthy aorta defined as:
  - Lack of significant thrombus > 8 mm in thickness; at any point along the aortic circumference at the level of 7mm below the inferior renal artery,
  - Lack of significant calcification at the level of 7 mm below the inferior renal artery,
  - Conicity < 10% as measured from the inferior renal artery to the aorta 7 mm below the inferior renal artery,
  - An inner wall diameter of no less than 16 mm and no greater than 30 mm at 7 mm below the inferior renal artery, and
  - An aortic angle of ≤ 60 degrees
- A distal iliac landing zone:
  - With a length of at least 10 mm, and
  - With an inner wall diameter of no less than 8 mm and no greater than 25 mm.

CONTRAINDICATIONS: The system is contraindicated for use in patients who have a condition that threatens to infect the graft and in patients with known sensitivities or allergies to the device materials including polytetrafluoroethylene [PTFE], polyethylene glycol [PEG]-based polymers, contrast agents, fluorinated ethylene propylene [FEP], titanium, nickel, platinum, or iridium.

Refer to Instructions for Use for more information concerning Indications, Contraindications, Specific Anatomic Considerations, Warnings, Precautions, and Adverse Events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Note: Endologix products and associated components are not available in all countries or regions. Please consult with your Endologix representative regarding product availability.

Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the "Instructions for Use" for complete and specific indications, contraindications, all warnings and precautions. Rx only.