CLINICAL OUTCOMES THAT MEET YOUR DEMANDS

Meeting the unmet needs of complex female patients with challenging anatomies

Conventional EVAR and females – disparities by the numbers

The data is compelling. Significant disparities exist between the eligibility, treatment and outcomes in females and males with conventional EVAR. Females continue to be underserved, and need an exceptional EVAR treatment to meet their complex anatomical needs.

LOWER ELIGIBILITY

20% More females are **ineligible and declined** for intervention – driven by small access and short necks[1, 2]

HIGHER AAA GROWTH RATES

While females have a lower prevalence of AAA, their **baseline AAA diameter growth rate is higher than males**[3]

4X AAA RUPTURE RATE

Female AAAs rupture with a greater frequency than males at all size intervals and have a fourfold increased frequency at < 5.5cm[4]

LoS, COMPLICATIONS, AND MORTALITY HIGHER

Length of stay is higher in females – 5 days v. 4 days[8]

Females are **more prone to access-related injuries**, including arterial injury and iliac access[5, 6]

30 day mortality: 2.5% v. 1.6% – female to male

1 year: 9.3% v. 7.3% – female to male[8]

Females Males

For every woman. For life. We remain focused.

Read on to understand the clinical evidence demonstrating outcome equivalency to males when females are treated to exceptional EVAR...

References

1. Ulug P, Sweeting MJ, von Allmen RS, Thompson ST, Powell JT. Lancet 2017; 389(10089):2482-2491.
2. Sweet et al. J Vasc Surg Oct 2011;54(4):931-937
3. Solberg et al. Eur J Vasc Endovasc Surg 2005; 29:145-149
4. Skibba et al. J Vasc Surg 2015; 62(6): 1429-1436
5. Lo et al. J Vasc Surg 2016; 63(3): 839-44
6. Lo et al. j Vasc Surg 2013; 57: 1261-8
7. V.N. Tedjawirja, M.C.J. de Wit, R. Balm, M.J.W. Koelemay, Annals of Vascular Surgery, 2021: 76: 330-341
8. Lowry et al. Eur J Vasc Endovasc Surg 2016;52(4):518–525

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Proven to meet the needs of female EVAR patients

The data in the LUCY and ENCORE studies demonstrate improved outcomes throughout the treatment continuum as compared to conventional EVAR.

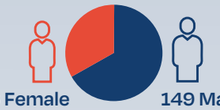
"There are disparities in outcomes in EVAR between females and males. Historically, females have been underserved by conventional EVAR. The management of AAA in females needs improvement".[1] –Lo

LUCY study: Evaluation of females who are underrepresented for AAA repair –J. Ash et al J Vasc Surg 2020

FIRST study to evaluate EVAR outcomes in females

Conclusion: Females have equivalent outcomes to males following AAA despite more complex aortic morphology

225 EVAR Patients



76 Female 149 Male

LUCY 1 year

Elibility for EVAR	Delivery & Deployment	Endoleaks Type IA	Secondary Interventiions	AAA Mortality
28% more females were eligible***	100% technical success rate	FF Type IA 98.6% v. 95.2%	FF 97.2% in both females and males	FF AAA mortality 1-year 100% v. 98.6%

NOTE: No difference in procedure or recovery variable between females and males.

***Analysis based on available data from the LUCY Study female cohort (72 out of 76) and on comparisons with grafts ranging from 18F – 21F OD manufactured by global market leaders. Data extracted on May 1, 2017. The Ovation Abdominal Stent Graft System has not been studied in a head-to-head clinical study against other EVAR devices for outcomes in women.

Females Males

Exceptional EVAR Therapy

"Females continue to suffer higher complication rates, a problem that may be expected to improve with the development of newer, lower-profile devices that can better navigate challenging aortoiliac anatomy." – Lo [5]

ENCORE study: Similar 5-year repair outcomes between female and male patients undergoing elective EVAR

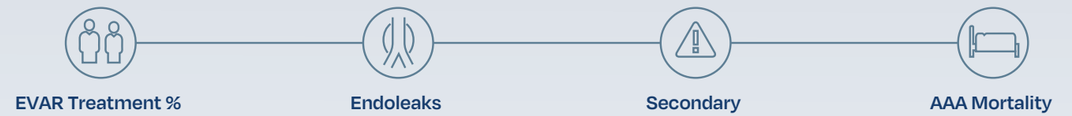
–Varkevisser et. al. J Vasc Surg 2019.

Data from the ENCORE gender sub-analysis compares outcomes in EVAR in females and males over five years. Not all studies within ENCORE followed patients to year 5.

1,296 EVAR Patients

251 Female 1,045 Male

ENCORE 5 year



EVAR Treatment % Female v. Male	Endoleaks Type IA	Secondary Interventiions	AAA Mortality
19% v. 81%	FF Type I or III 91.0% v. 94.4% Type IA 93.9% v. 96.0%	FF reinterventions/ complications 91.0% v. 92.8%	FF AAA 5-year mortality 99.6% v. 99.2%

Females Males

ONLY FROM ENDOLOGIX

The Alto Stent Graft

Choose an EVAR treatment designed to meet the unique needs of the complex female anatomy.

ALTO's exclusive technology is optimized for specialized anatomies, including short necks, accessing smaller vessels and tortuous iliacs due to the 7mm neck indication and highly conformable limbs.

Challenge	Solution	
Extreme Aortic Neck Angulation	Exclusive adaptable sealing technology creates an effective seal around the vessel wall conforming to the patient's native anatomy[9]	
Short Proximal Neck Length	Separation of fixation and seal allows you to fixate graft in healthy tissue of the aorta and seal closest to renals[9]	
Smaller External Iliac Artery Diameter	Lowest profile device on the market – 13F inner diameter and 15F outer diameter[7]	

Why Choose Endologix?

Endologix is committed to the steadfast pursuit of focused innovation, guided by data. Approach challenging anatomies with confidence and meet the unique needs of your complex patients.

We strive to ally with physicians for procedural success and proficiency, including:

- Immersive procedural training with virtual reality (VR)
- Detailed training plans for each product and therapy
- Dedicated in-procedure support from expert field team (in every case with you)
- Strong Peer to peer network and support including: PTAB and EVAR communities, roundtables, and more

Choose to treat your female patients with an exceptional EVAR stent graft designed with their exceptional and complex anatomy in mind.

Explore the evidence or talk with a peer today. Endologix.com/AAA/Alto/ForWomen

References:
9. Varkevisser et al. J Vasc Surg 2019
10. Sampaio et al. Annal Vasc Surg 2004; 18(6):653-660

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 7 mm 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: Not all product components are available in every country. Please consult with your Endologix representative to confirm product availability.

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