CHALLENGING NECKS

Hostile Necks & Large Aortic Necks

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TABLE OF CONTENTS

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Select a topic to advance to that section.

HOSTILE NECKS

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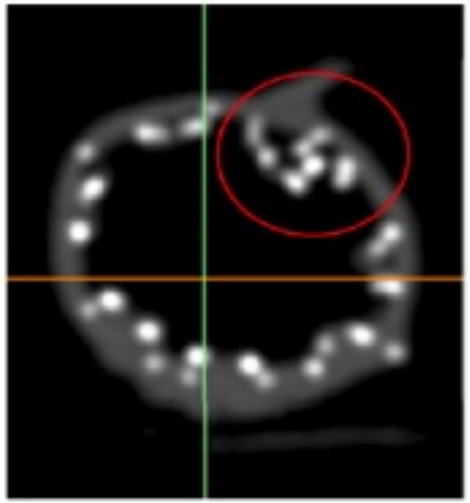
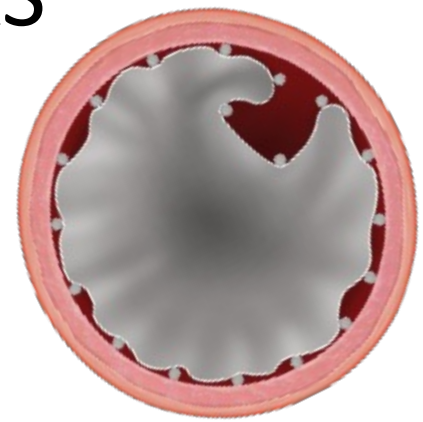
CHALLENGES OF EVAR IN HOSTILE AORTIC NECKS

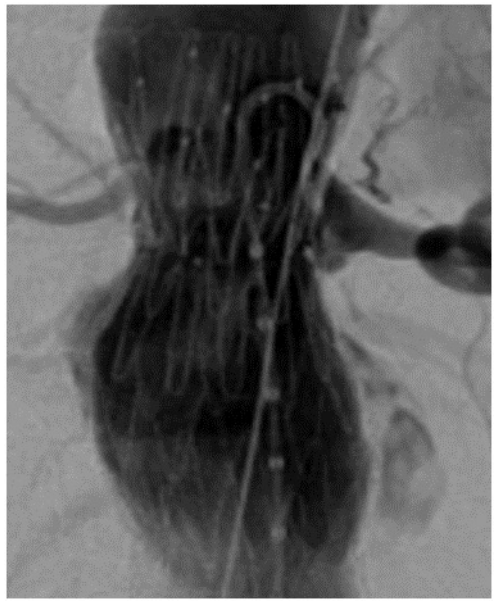
Commonly reported complications:

- Device Infolding
- Early Type 1A endoleak (P<.0001)[1]
- Need for adjunctive proximal components (P = .0146)[1]
- Increased risk for AAA sac enlargement [2]
  Malposition from inadequate fixation



Folding behavior of stent grafts
Lin, KK. Univ. of Iowa, 2012.
http://ir.uiowa.edu/etd/2929





1 AbuRahma et al. J Vasc Surg 2011;54:13-21

2 Schanzer A, et al. Circulation. 2011;123:2848-2855

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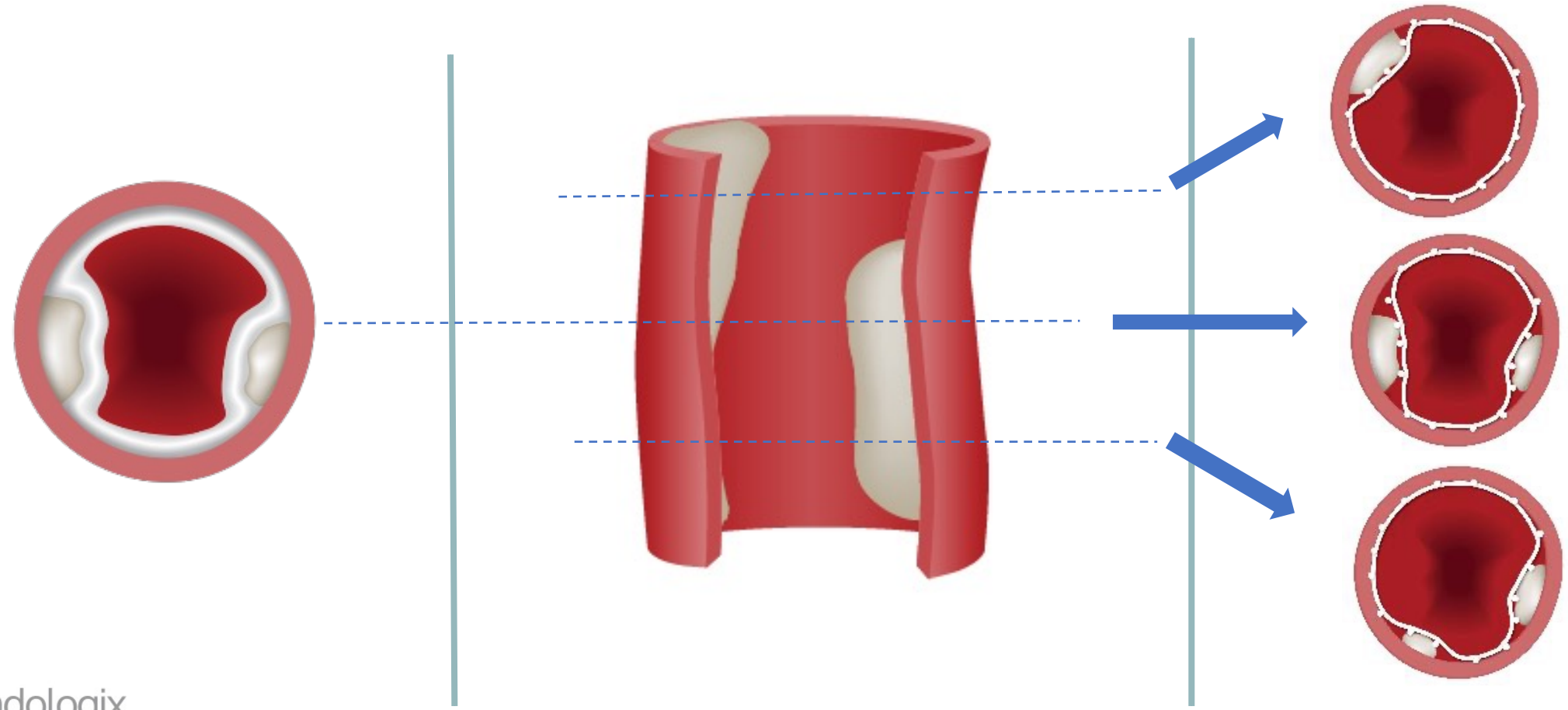
CustomSeal™ Conforms: Customized treatment for each patient

Polymer Seal

Irregular Aortic Neck Anatomy

Traditional Mechanical Seal



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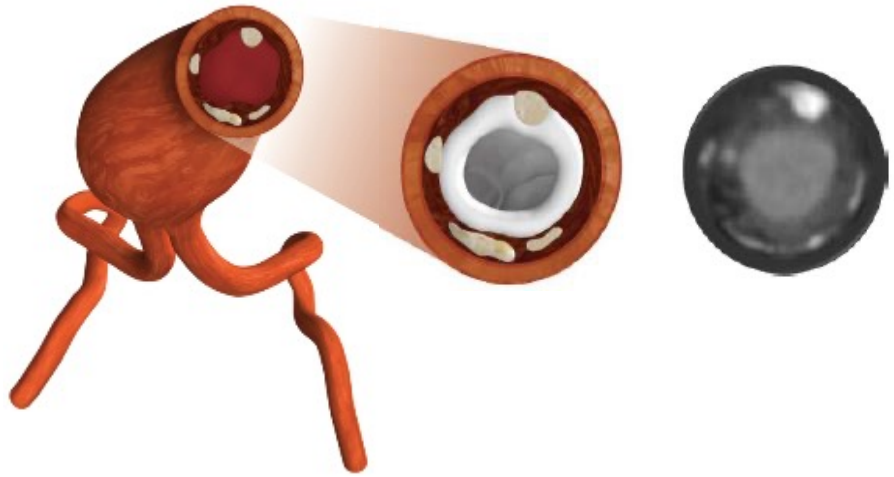
CUSTOMSEAL™ CONFORMABILITY CREATES PATIENT-SPECIFIC SEAL

CustomSeal sealing technology creates an adaptive seal customized for every patient

- Conforms to vessel wall
- Does not exert chronic radial force, resulting in stable neck diameters out to 5 years*[1]

Pre-operative illustration and CT image of an aortic neck with significant calcium and thrombus



17-month follow-up illustration and CT image of an aortic neck with sealing ring conforming to irregular surface, creating a custom seal with no Type Ia endoleak

Images courtesy of Jennifer Ash, MD, Christie Clinic, Champaign, Illinois

*ENCORE includes results from a real-world patient population. 4% of patients had vascular characteristics outside of approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established. The ENCORE analysis pools data using an April 12, 2018 data cut. ALTO was not included in the ENCORE data set.

1. Swerdlow, et al, JVS. 2020; 71:1528-37.

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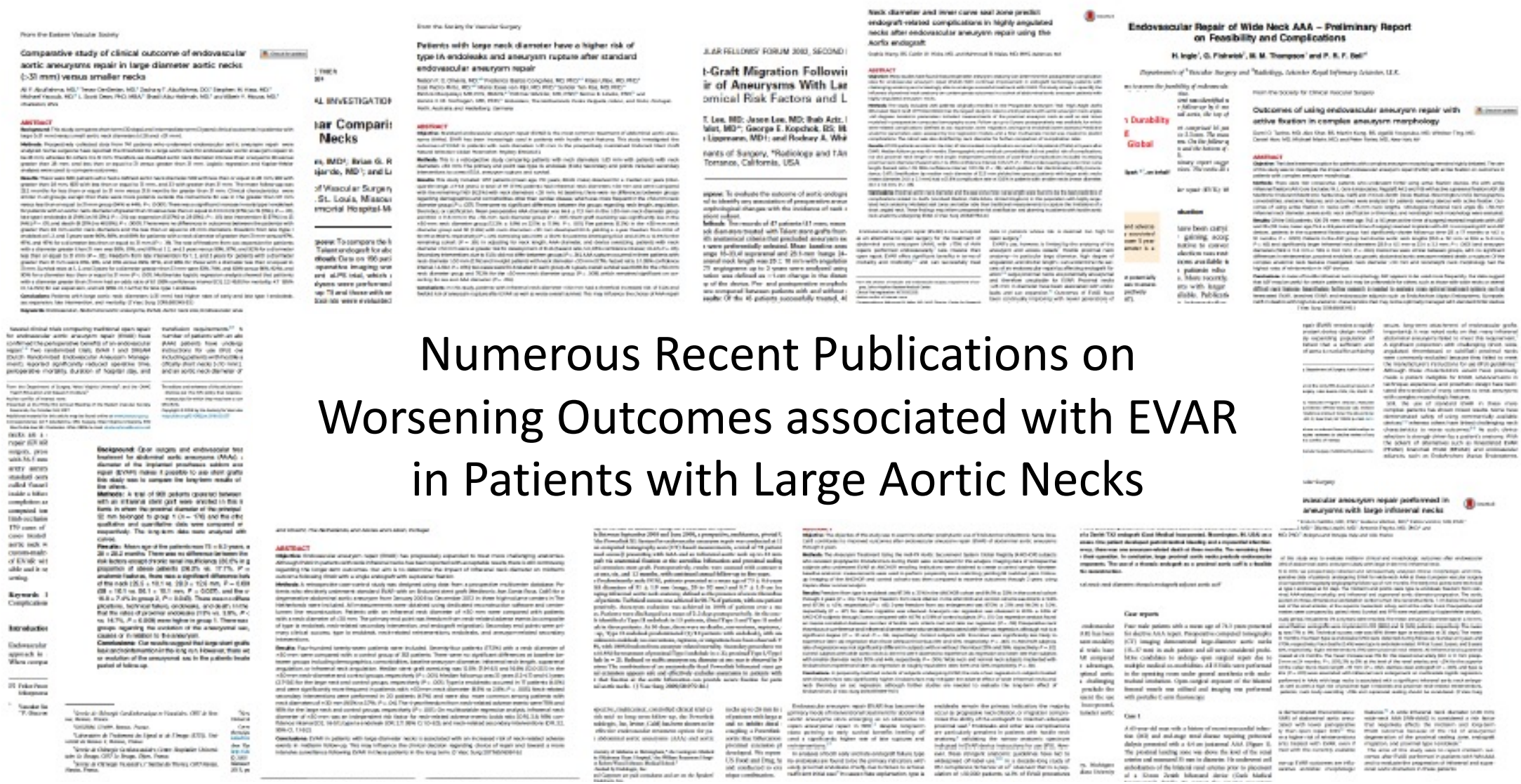
LARGE AORTIC NECKS



Numerous Recent Publications on Worsening Outcomes associated with EVAR in Patients with Large Aortic Necks

DIFFERENTIAL PERFORMANCE OF SELF EXPANDING ENDOGRAFTS IN LARGE AORTIC NECKS – KM

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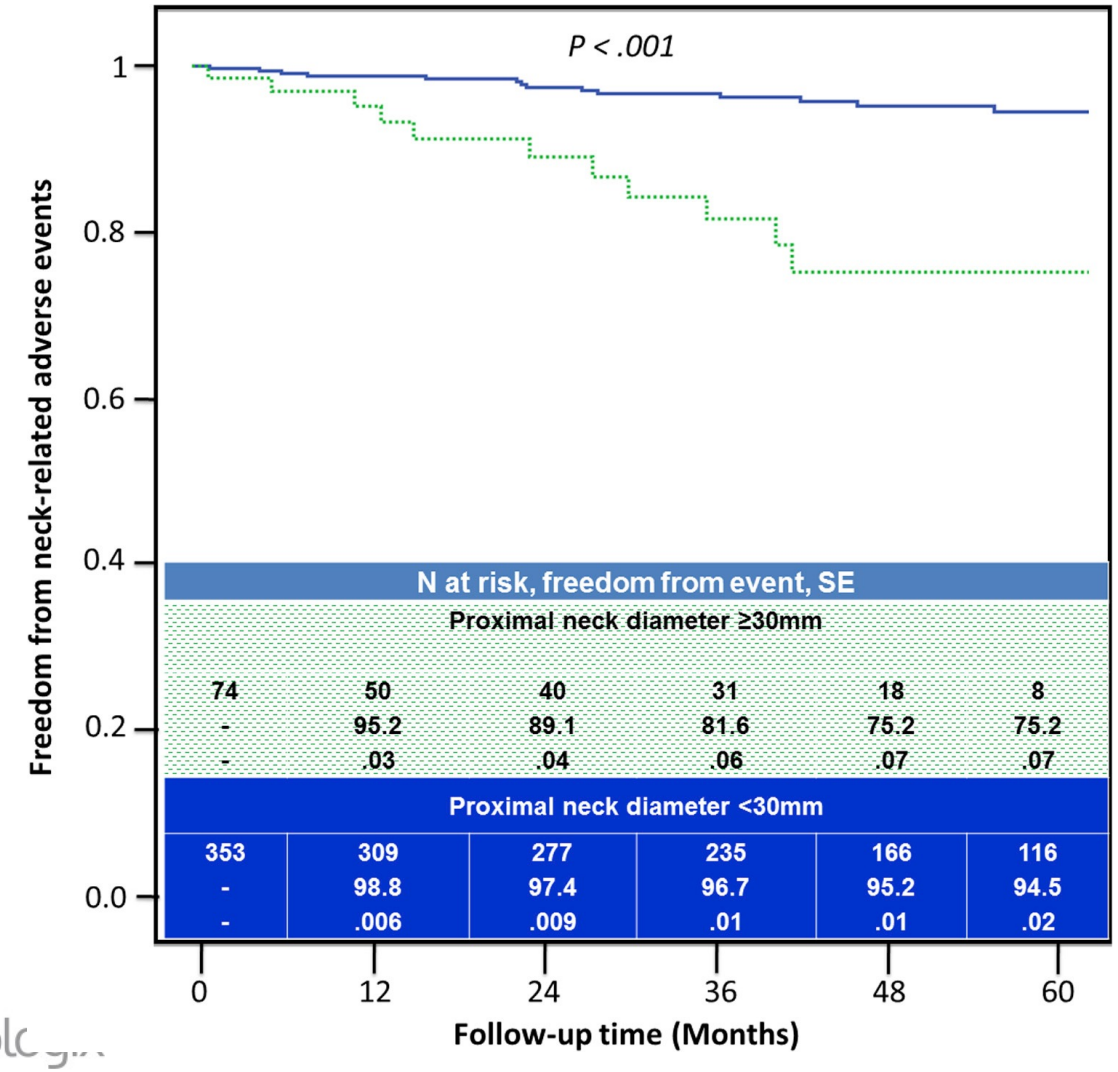

Oliveira JVS 2017

Reprinted from Journal of Vascular Surgery, Vol. 65, Nelson F.G. Oliveira, Frederico M. Bastos Gonçalves, Marie Josee Van Rijn, Quirina de Ruiter, Sanne Hoeks, Jean-Paul P.M. de Vries, Joost A. van Herwaarden, Hence J.M. Verhagen, Standard endovascular aneurysm repair in patients with wide infrarenal aneurysm necks is associated with increased risk of adverse events, Fig 2, Copyright 2016, with permission from Elsevier

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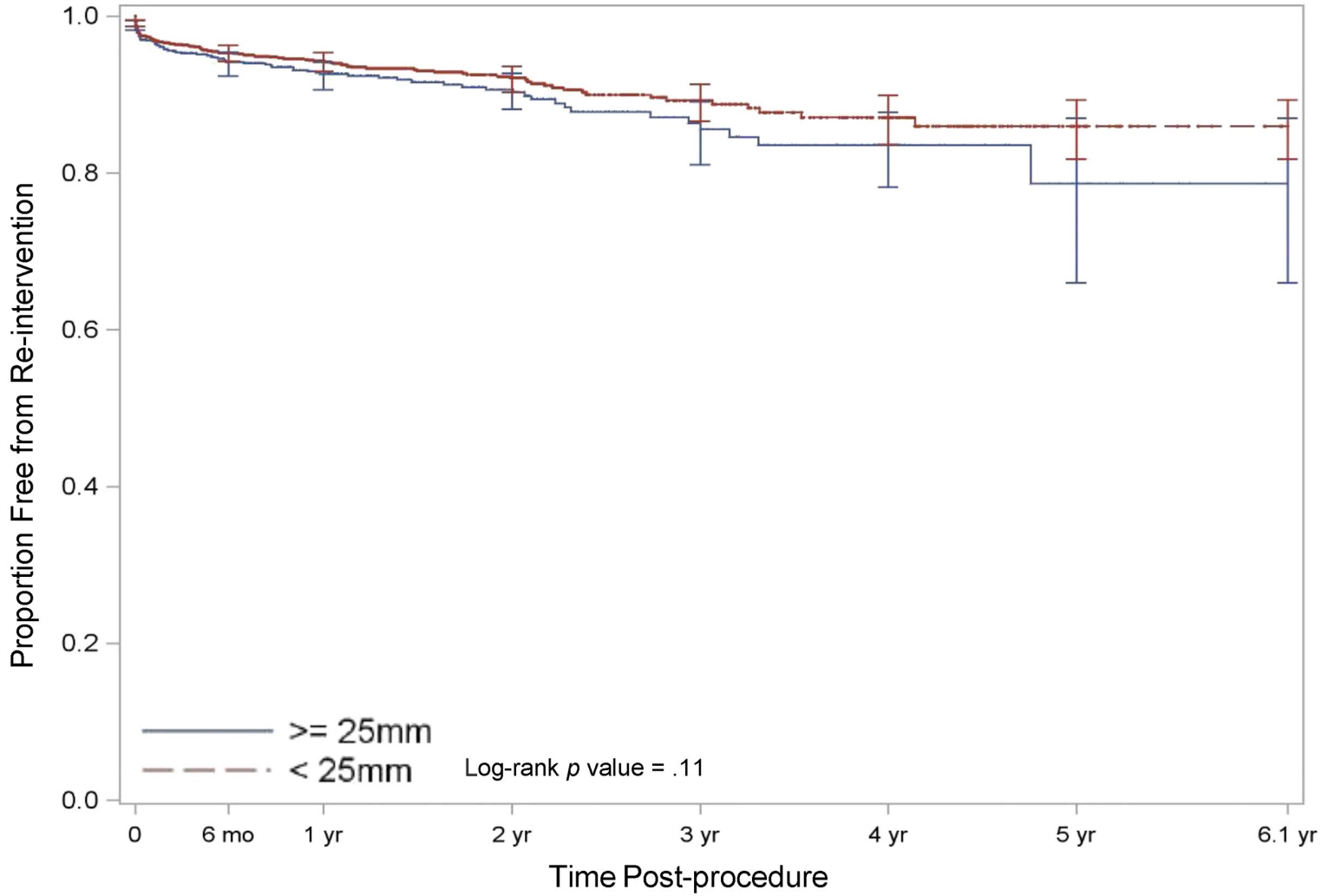
DIFFERENTIAL PERFORMANCE OF SELF EXPANDING ENDOGRAFTS IN LARGE AORTIC NECKS – KM



Howard EJVES 2018

Reprinted from European Journal of Vascular and Endovascular Surgery, Vol 56, Dominic P.J. Howard, Conor D. Marron, Ediri Sideso, Phillip J. Puckridge, Eric L.G. Verhoeven, James I. Spark, Influence of Proximal Aortic Neck Diameter on Durability of Aneurysm Sealing and Overall Survival in Patients Undergoing Endovascular Aneurysm Repair. Real World Data from the Gore Global Registry for Endovascular Aortic Treatment (GREAT), Fig 1, Copyright 2018, with permission from Elsevier

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ENCORE DEMONSTRATES DURABILITY REGARDLESS OF SIZE

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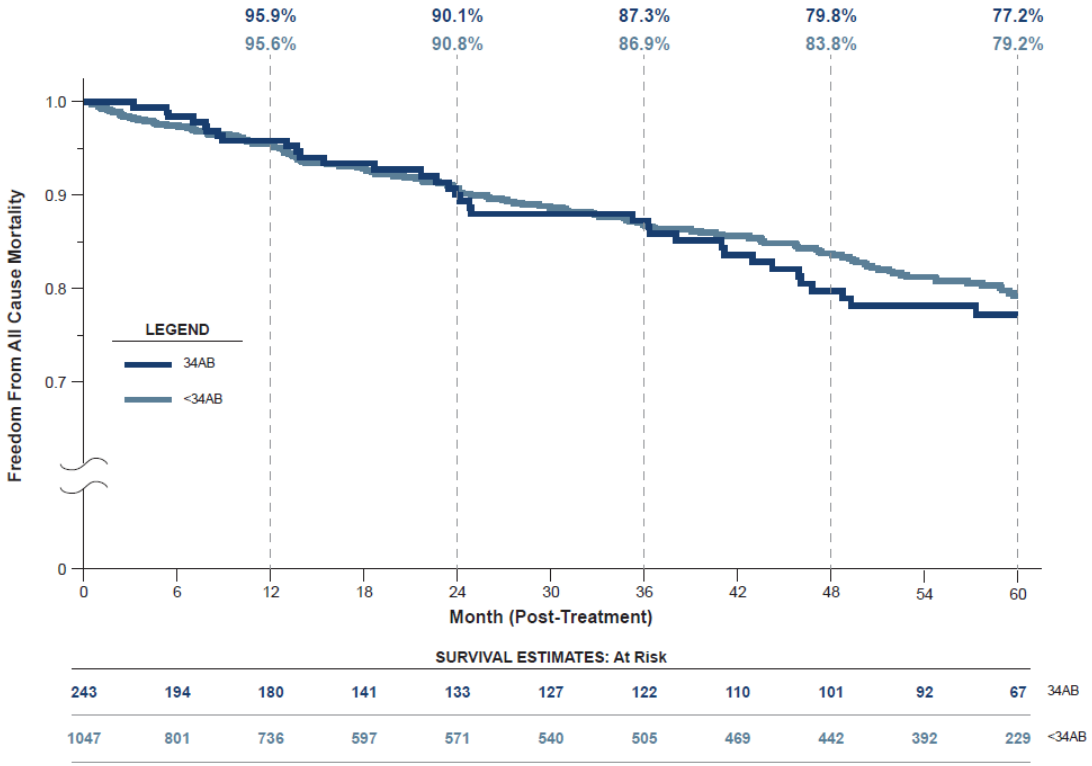
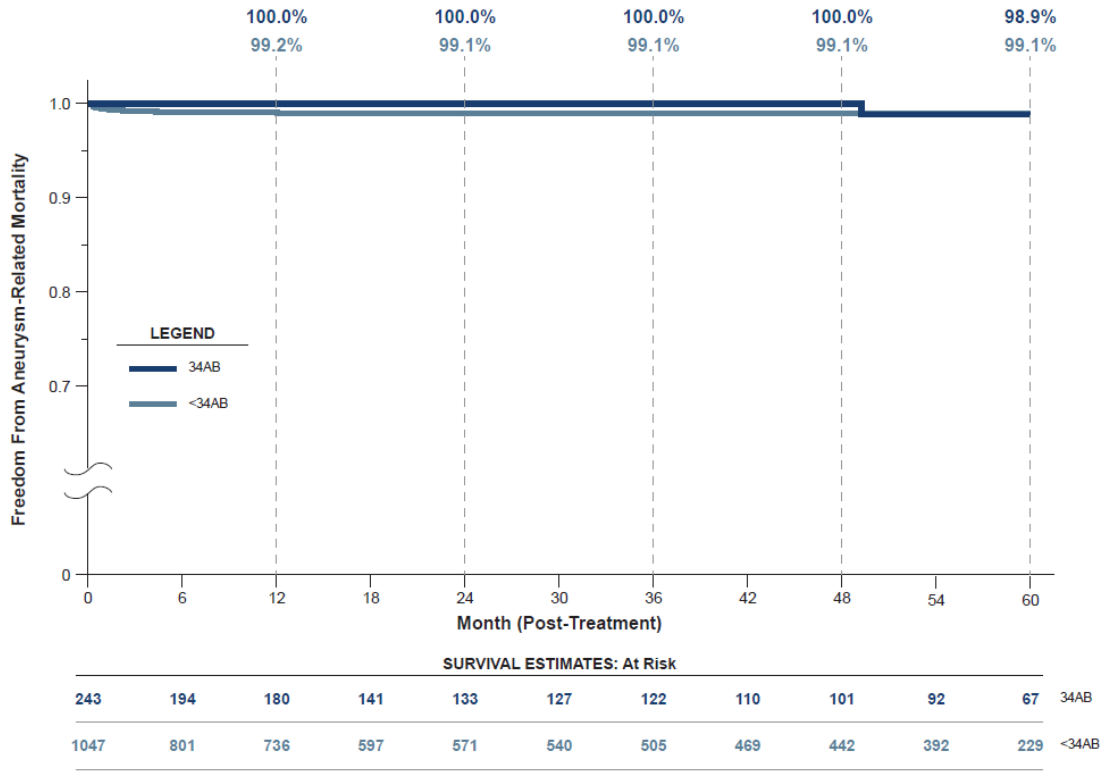
Freedom From All Cause Mortality (34mm AB vs. 20,23,26,29mm AB)



Freedom From AAA Related Mortality (34mm AB vs. 20,23,26,29mm AB)



Verhagen CX Symposium 2019

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ENCORE DEMONSTRATES DURABILITY REGARDLESS OF SIZE

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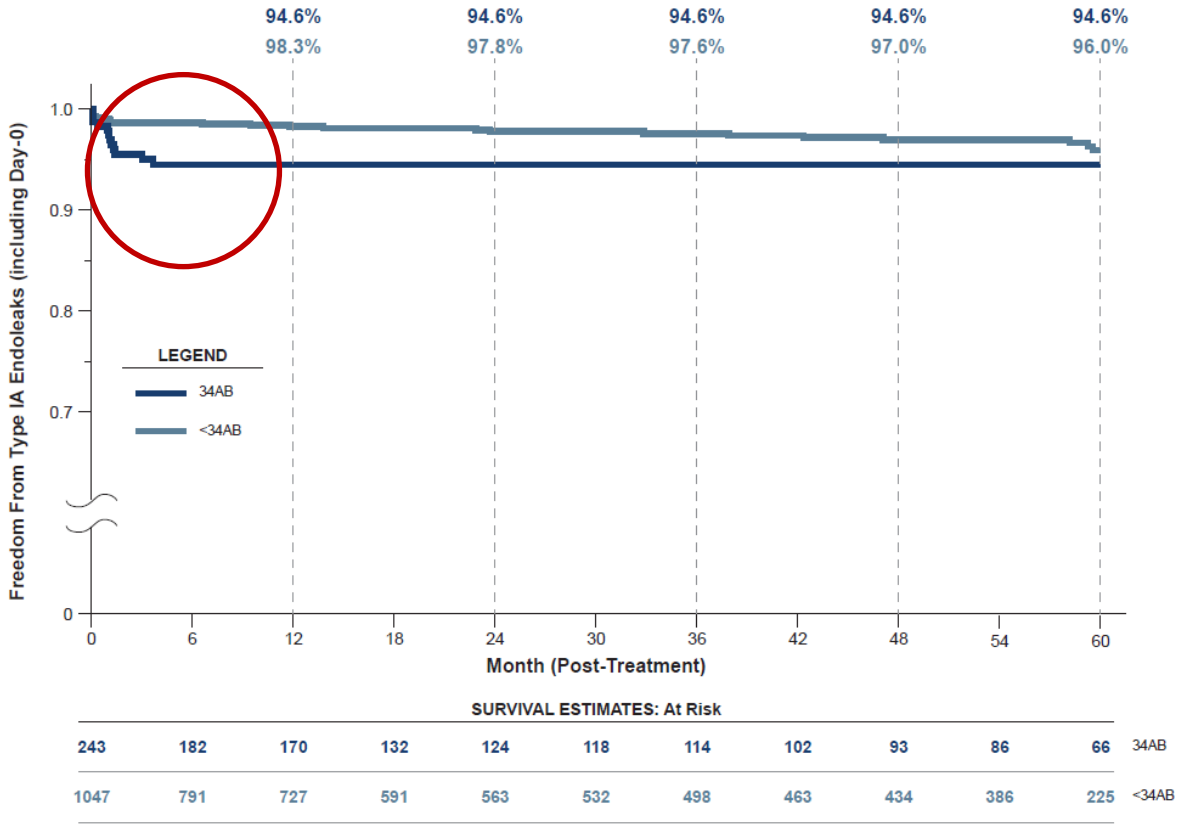
Freedom From Type 1A EL (34mm AB vs. 20,23,26,29mm AB)



- Pattern of Type 1A EL different to conventional endografts with most occurring in the perioperative period as opposed to later
- After 6 months, no Type 1A EL in 34mm AB
- Early Type 1A EL can be addressed through improved sizing, case selection and implantation
- Lack of late Type 1A EL signals differentiated longer term durability

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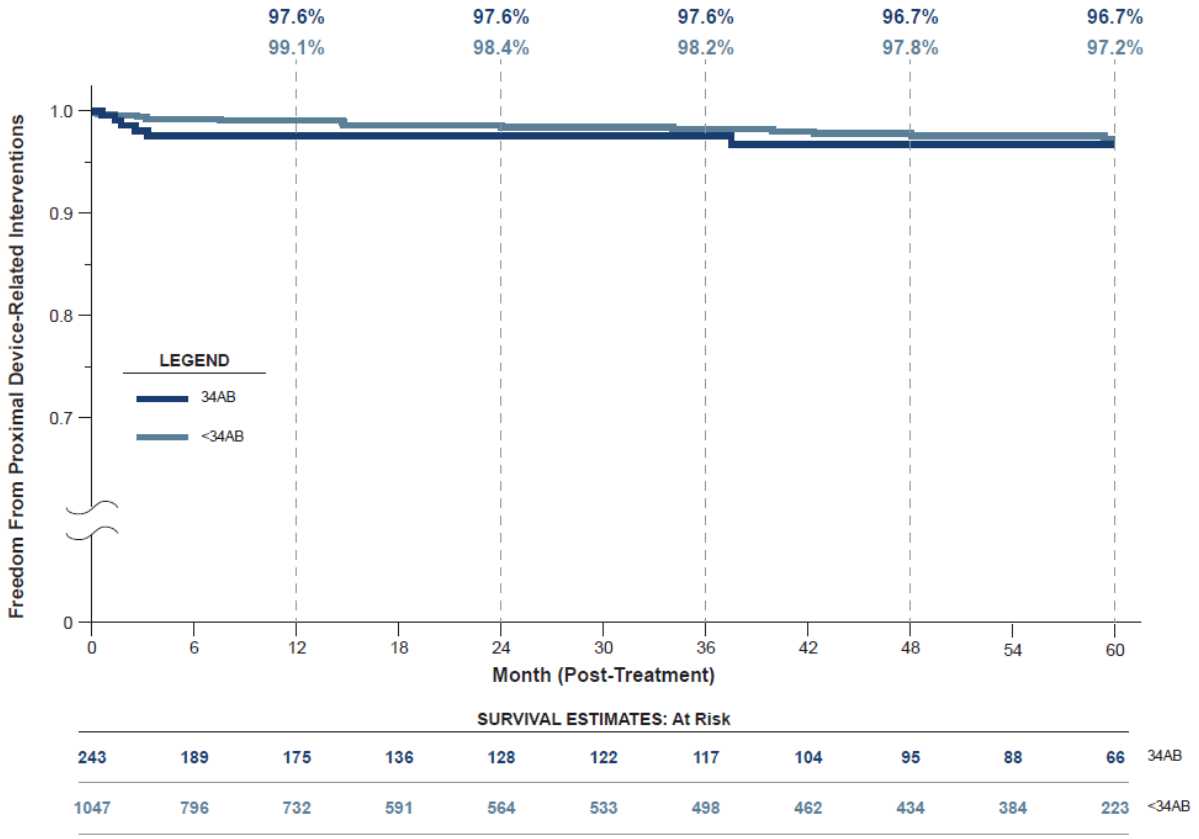
ENCORE DEMONSTRATES DURABILITY REGARDLESS OF SIZE

Freedom From Device Related Intervention (34mm AB vs. 20,23,26,29mm AB)



No increase in adverse outcomes, with the exception of Type 1A EL, in patients treated with largest size aortic body when using Ovation platform (34mm AB) compared to the smaller sizes.

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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.
- 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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