



Alto[®]

CHALLENGING NECKS

Hostile Necks & Large Aortic Necks



TABLE OF CONTENTS



Alto[®]

Slide:
3

HOSTILE NECKS

Slide:
7

LARGE AORTIC NECKS

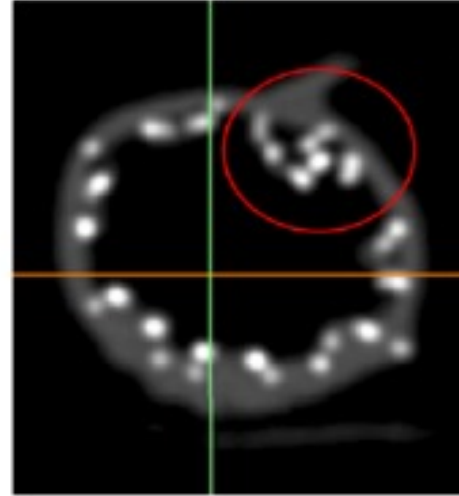
The background features a large, stylized graphic composed of several overlapping, semi-transparent rings. The rings are primarily light blue and light green, with some darker shades of blue and green. The rings are arranged in a way that they appear to be part of a larger, circular structure, possibly representing a neck or a similar anatomical feature. The overall effect is a clean, modern, and professional look.

HOSTILE NECKS

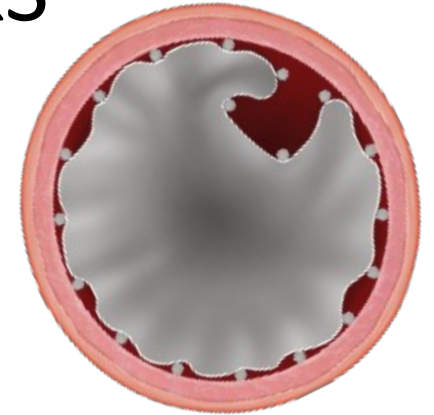
CHALLENGES OF EVAR IN HOSTILE AORTIC NECKS

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 enlargement²
- 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

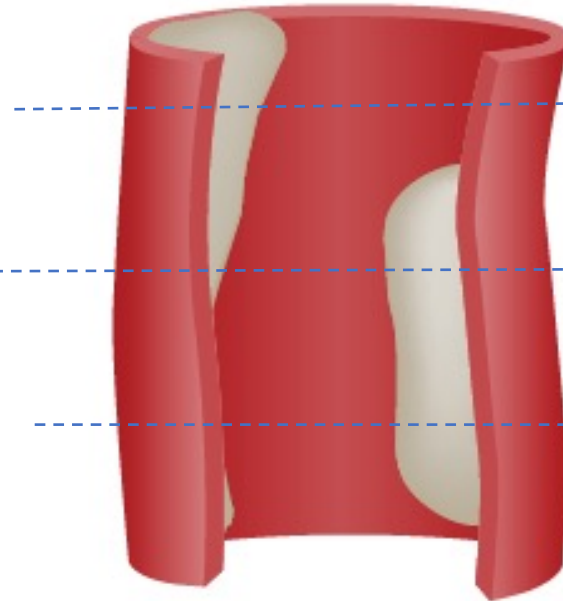
2 Schanzer A, et al. Circulation. 2011;123:2848-2855

CustomSeal™ Conforms: Customized treatment for each patient

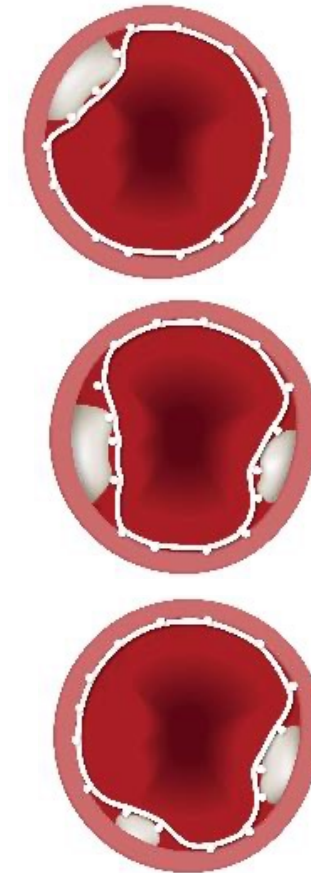
Polymer Seal



Irregular Aortic Neck Anatomy



Traditional Mechanical Seal



CUSTOMSEAL™ CONFORMABILITY CREATES PATIENT-SPECIFIC SEAL

CustomSeal sealing technology creates an adaptive seal customized for every patient

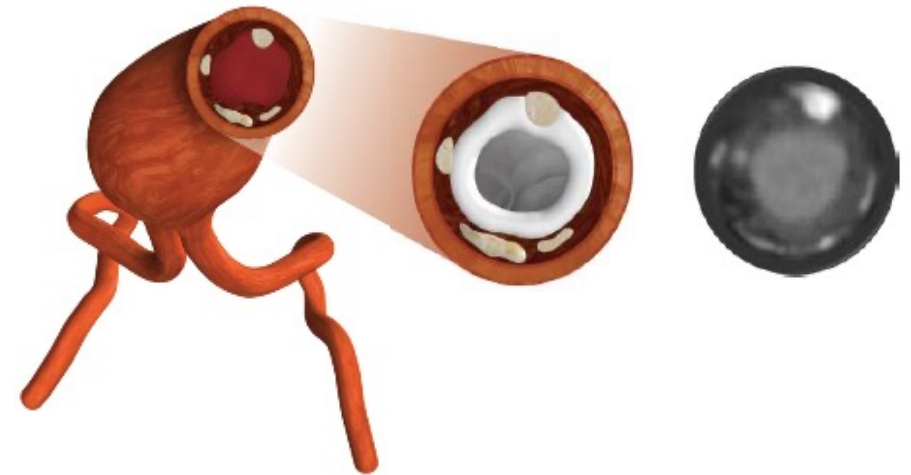
- Conforms to vessel wall
- Does not exert chronic radial force, resulting in stable neck diameters out to 5 years*¹

*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.



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



LARGE AORTIC NECKS

From the Eastern Vascular Society
Comparative study of clinical outcome of endovascular aortic aneurysm repair in large diameter aortic necks (>35 mm) versus smaller necks

OBJECTIVE: To compare the clinical outcome of endovascular aortic aneurysm repair (EVAR) in patients with large diameter aortic necks (>35 mm) versus smaller necks (≤35 mm).
DESIGN: Retrospective comparative study.
SETTING: Tertiary care center.
PATIENTS: 100 patients with large diameter aortic necks (>35 mm) and 100 patients with smaller necks (≤35 mm).
MEASUREMENTS AND MAIN RESULTS: Primary endpoint was freedom from type II endoleaks. Secondary endpoints were freedom from type I and III endoleaks, freedom from conversion to open repair, and freedom from mortality. Freedom from type II endoleaks was significantly higher in the large diameter group (p < 0.05). Freedom from type I and III endoleaks, conversion to open repair, and mortality were not significantly different between the two groups.
CONCLUSIONS: EVAR in patients with large diameter aortic necks (>35 mm) is associated with a higher rate of freedom from type II endoleaks compared to patients with smaller necks (≤35 mm). Freedom from type I and III endoleaks, conversion to open repair, and mortality were not significantly different between the two groups.

Patients with large neck diameter have a higher risk of type Ia endoleaks and aneurysm rupture after standard endovascular aneurysm repair

OBJECTIVE: To evaluate the risk of type Ia endoleaks and aneurysm rupture after standard endovascular aneurysm repair (EVAR) in patients with large neck diameter (>35 mm) versus smaller neck diameter (≤35 mm).
DESIGN: Retrospective comparative study.
SETTING: Tertiary care center.
PATIENTS: 100 patients with large neck diameter (>35 mm) and 100 patients with smaller neck diameter (≤35 mm).
MEASUREMENTS AND MAIN RESULTS: Primary endpoint was freedom from type Ia endoleaks. Secondary endpoints were freedom from aneurysm rupture, freedom from conversion to open repair, and freedom from mortality. Freedom from type Ia endoleaks was significantly higher in the large neck diameter group (p < 0.05). Freedom from aneurysm rupture, conversion to open repair, and mortality were not significantly different between the two groups.
CONCLUSIONS: Patients with large neck diameter (>35 mm) have a higher risk of type Ia endoleaks after EVAR compared to patients with smaller neck diameter (≤35 mm). Freedom from aneurysm rupture, conversion to open repair, and mortality were not significantly different between the two groups.

Endovascular Repair of Wide Neck AAA – Preliminary Report on Feasibility and Complications

OBJECTIVE: To evaluate the feasibility and complications of endovascular repair of wide neck abdominal aortic aneurysms (AAA).
DESIGN: Retrospective comparative study.
SETTING: Tertiary care center.
PATIENTS: 50 patients with wide neck AAA (>35 mm).
MEASUREMENTS AND MAIN RESULTS: Primary endpoint was technical success. Secondary endpoints were freedom from type Ia and II endoleaks, freedom from conversion to open repair, and freedom from mortality. Technical success was achieved in 90% of patients. Freedom from type Ia and II endoleaks was significantly higher in the wide neck group (p < 0.05). Freedom from conversion to open repair and mortality were not significantly different between the two groups.
CONCLUSIONS: Endovascular repair of wide neck AAA is feasible and associated with a higher rate of freedom from type Ia and II endoleaks compared to patients with smaller neck diameter (≤35 mm). Freedom from conversion to open repair and mortality were not significantly different between the two groups.

Long-Term Follow-up of Aneurysm Repair with L1-Graft Migration Follow-up of Aneurysms with Luminal Risk Factors and L1-Graft Migration

OBJECTIVE: To evaluate the long-term follow-up of aneurysm repair with L1-graft migration in patients with luminal risk factors and L1-graft migration.
DESIGN: Retrospective comparative study.
SETTING: Tertiary care center.
PATIENTS: 100 patients with luminal risk factors and L1-graft migration.
MEASUREMENTS AND MAIN RESULTS: Primary endpoint was freedom from aneurysm rupture. Secondary endpoints were freedom from conversion to open repair, freedom from mortality, and freedom from L1-graft migration. Freedom from aneurysm rupture was significantly higher in the luminal risk factors group (p < 0.05). Freedom from conversion to open repair, freedom from mortality, and freedom from L1-graft migration were not significantly different between the two groups.
CONCLUSIONS: Patients with luminal risk factors and L1-graft migration have a higher risk of aneurysm rupture after EVAR compared to patients without luminal risk factors and L1-graft migration. Freedom from conversion to open repair, freedom from mortality, and freedom from L1-graft migration were not significantly different between the two groups.

Outcomes of Using Endovascular Aneurysm Repair with Active Fixation in complex aneurysm morphology

OBJECTIVE: To evaluate the outcomes of using endovascular aneurysm repair (EVAR) with active fixation in patients with complex aneurysm morphology.
DESIGN: Retrospective comparative study.
SETTING: Tertiary care center.
PATIENTS: 100 patients with complex aneurysm morphology.
MEASUREMENTS AND MAIN RESULTS: Primary endpoint was freedom from type Ia and II endoleaks. Secondary endpoints were freedom from conversion to open repair, freedom from mortality, and freedom from L1-graft migration. Freedom from type Ia and II endoleaks was significantly higher in the active fixation group (p < 0.05). Freedom from conversion to open repair, freedom from mortality, and freedom from L1-graft migration were not significantly different between the two groups.
CONCLUSIONS: Using EVAR with active fixation in patients with complex aneurysm morphology is associated with a higher rate of freedom from type Ia and II endoleaks compared to patients without active fixation. Freedom from conversion to open repair, freedom from mortality, and freedom from L1-graft migration were not significantly different between the two groups.

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

Several clinical trials comparing modern open repair for abdominal aortic aneurysm repair (AAA) have confirmed the potential benefits of an endovascular repair.¹⁻³ Two randomized trials (EVAR I and EVAR II) have demonstrated favorable outcomes with the EVAR approach, reporting significantly reduced operative time, perioperative morbidity, duration of hospital stay, and time to return to normal diet.^{4,5}

However, patients with large aortic necks (>35 mm) may have a higher risk of type Ia endoleaks and aneurysm rupture after EVAR compared to patients with smaller neck diameter (≤35 mm).^{6,7}

Endovascular repair of wide neck AAA is feasible and associated with a higher rate of freedom from type Ia and II endoleaks compared to patients with smaller neck diameter (≤35 mm).⁸

Patients with luminal risk factors and L1-graft migration have a higher risk of aneurysm rupture after EVAR compared to patients without luminal risk factors and L1-graft migration.⁹

Using EVAR with active fixation in patients with complex aneurysm morphology is associated with a higher rate of freedom from type Ia and II endoleaks compared to patients without active fixation.¹⁰

Background: EVAR is an established treatment for abdominal aortic aneurysms (AAA). It is a minimally invasive approach that offers several advantages over open repair, including shorter hospital stays, reduced morbidity, and faster recovery. However, patients with large aortic necks (>35 mm) may have a higher risk of type Ia endoleaks and aneurysm rupture after EVAR compared to patients with smaller neck diameter (≤35 mm).^{6,7}

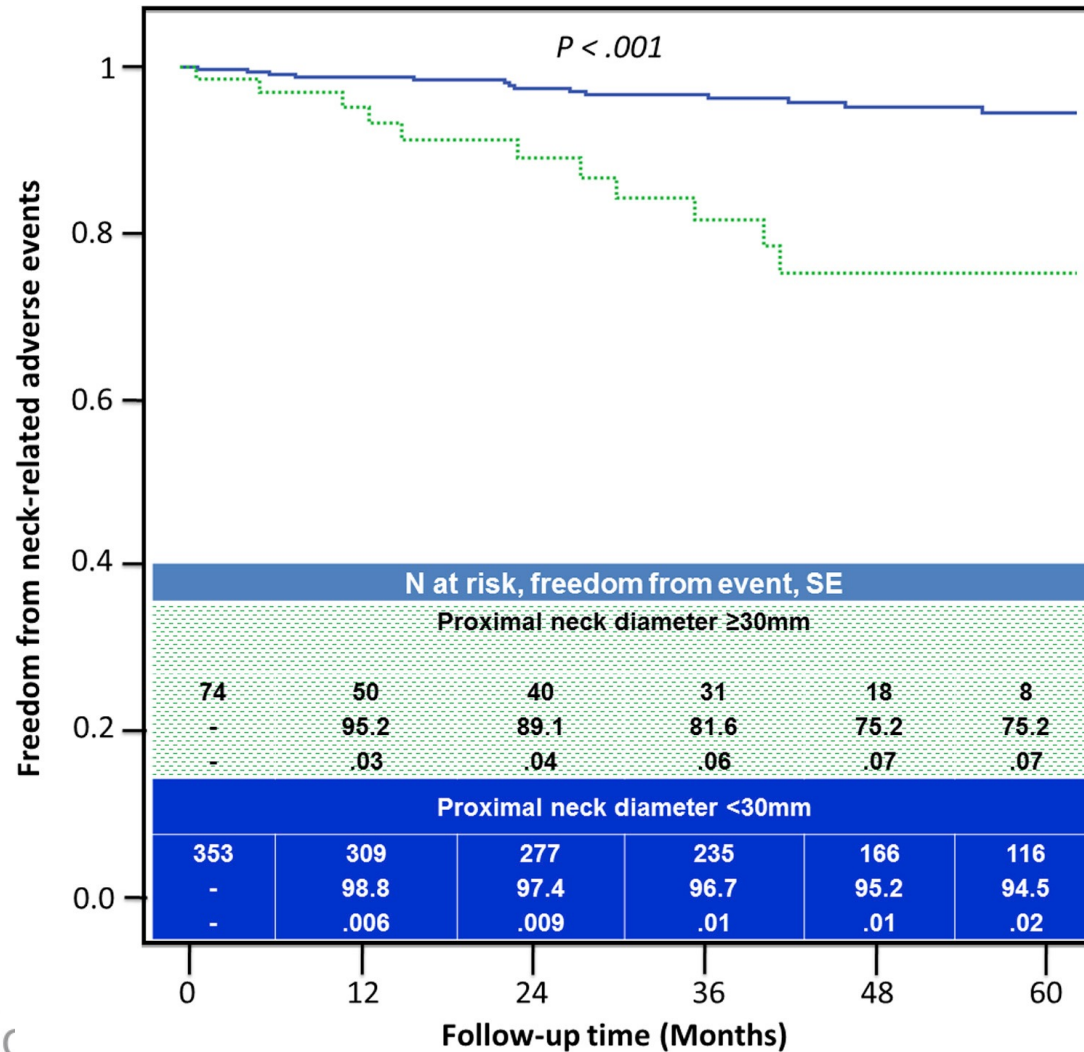
Objective: To evaluate the risk of type Ia endoleaks and aneurysm rupture after EVAR in patients with large neck diameter (>35 mm) versus smaller neck diameter (≤35 mm).
Design: Retrospective comparative study.
Setting: Tertiary care center.
Patients: 100 patients with large neck diameter (>35 mm) and 100 patients with smaller neck diameter (≤35 mm).
Measurements and Main Results: Primary endpoint was freedom from type Ia endoleaks. Secondary endpoints were freedom from aneurysm rupture, freedom from conversion to open repair, and freedom from mortality. Freedom from type Ia endoleaks was significantly higher in the large neck diameter group (p < 0.05). Freedom from aneurysm rupture, conversion to open repair, and mortality were not significantly different between the two groups.
Conclusions: Patients with large neck diameter (>35 mm) have a higher risk of type Ia endoleaks after EVAR compared to patients with smaller neck diameter (≤35 mm). Freedom from aneurysm rupture, conversion to open repair, and mortality were not significantly different between the two groups.

Objective: To evaluate the feasibility and complications of endovascular repair of wide neck abdominal aortic aneurysms (AAA).
Design: Retrospective comparative study.
Setting: Tertiary care center.
Patients: 50 patients with wide neck AAA (>35 mm).
Measurements and Main Results: Primary endpoint was technical success. Secondary endpoints were freedom from type Ia and II endoleaks, freedom from conversion to open repair, and freedom from mortality. Technical success was achieved in 90% of patients. Freedom from type Ia and II endoleaks was significantly higher in the wide neck group (p < 0.05). Freedom from conversion to open repair and mortality were not significantly different between the two groups.
Conclusions: Endovascular repair of wide neck AAA is feasible and associated with a higher rate of freedom from type Ia and II endoleaks compared to patients with smaller neck diameter (≤35 mm). Freedom from conversion to open repair and mortality were not significantly different between the two groups.

Objective: To evaluate the long-term follow-up of aneurysm repair with L1-graft migration in patients with luminal risk factors and L1-graft migration.
Design: Retrospective comparative study.
Setting: Tertiary care center.
Patients: 100 patients with luminal risk factors and L1-graft migration.
Measurements and Main Results: Primary endpoint was freedom from aneurysm rupture. Secondary endpoints were freedom from conversion to open repair, freedom from mortality, and freedom from L1-graft migration. Freedom from aneurysm rupture was significantly higher in the luminal risk factors group (p < 0.05). Freedom from conversion to open repair, freedom from mortality, and freedom from L1-graft migration were not significantly different between the two groups.
Conclusions: Patients with luminal risk factors and L1-graft migration have a higher risk of aneurysm rupture after EVAR compared to patients without luminal risk factors and L1-graft migration. Freedom from conversion to open repair, freedom from mortality, and freedom from L1-graft migration were not significantly different between the two groups.

Objective: To evaluate the outcomes of using endovascular aneurysm repair (EVAR) with active fixation in patients with complex aneurysm morphology.
Design: Retrospective comparative study.
Setting: Tertiary care center.
Patients: 100 patients with complex aneurysm morphology.
Measurements and Main Results: Primary endpoint was freedom from type Ia and II endoleaks. Secondary endpoints were freedom from conversion to open repair, freedom from mortality, and freedom from L1-graft migration. Freedom from type Ia and II endoleaks was significantly higher in the active fixation group (p < 0.05). Freedom from conversion to open repair, freedom from mortality, and freedom from L1-graft migration were not significantly different between the two groups.
Conclusions: Using EVAR with active fixation in patients with complex aneurysm morphology is associated with a higher rate of freedom from type Ia and II endoleaks compared to patients without active fixation. Freedom from conversion to open repair, freedom from mortality, and freedom from L1-graft migration were not significantly different between the two groups.

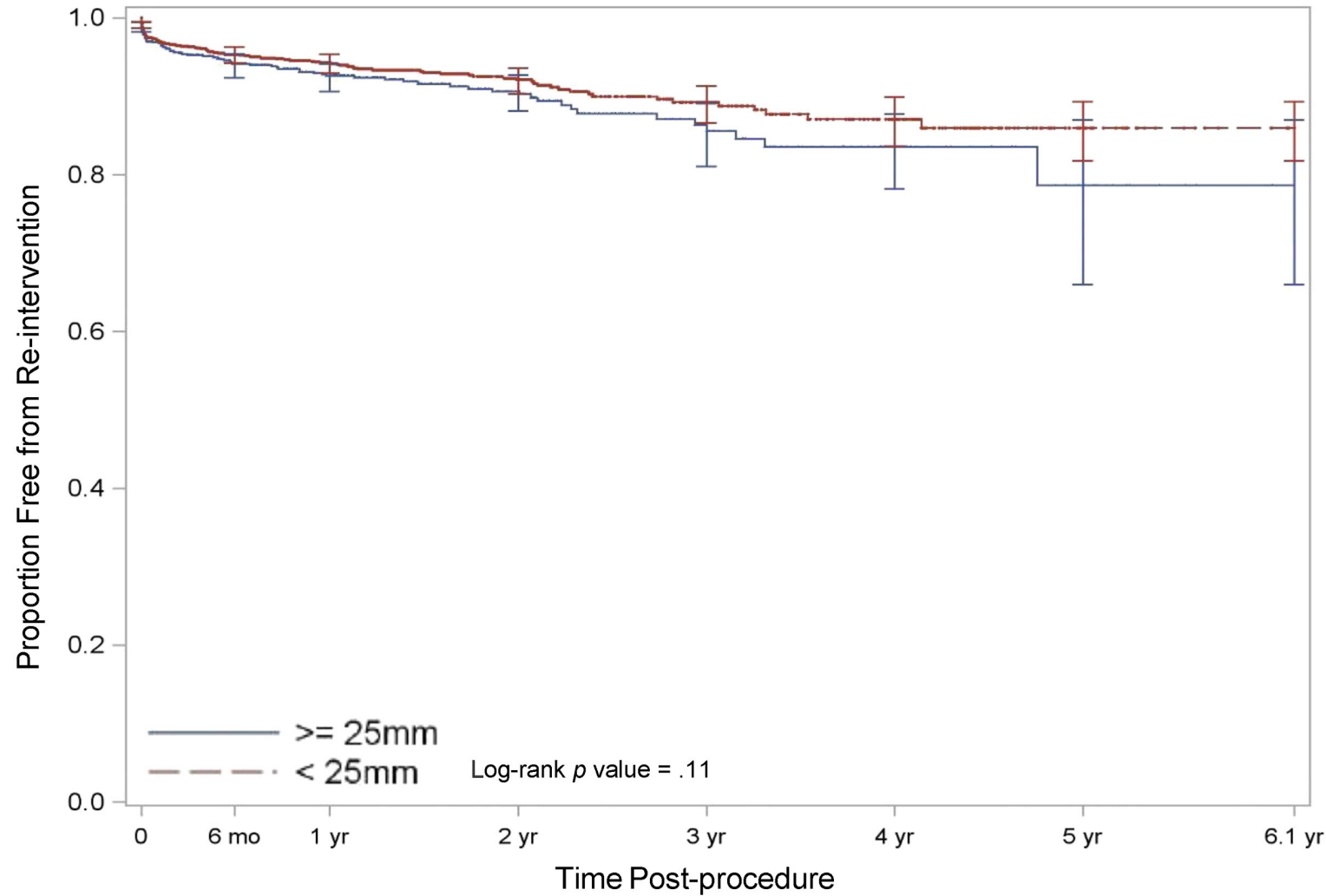
DIFFERENTIAL PERFORMANCE OF SELF EXPANDING ENDOGRAFTS IN LARGE AORTIC NECKS – KM



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 Ruiten, 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

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

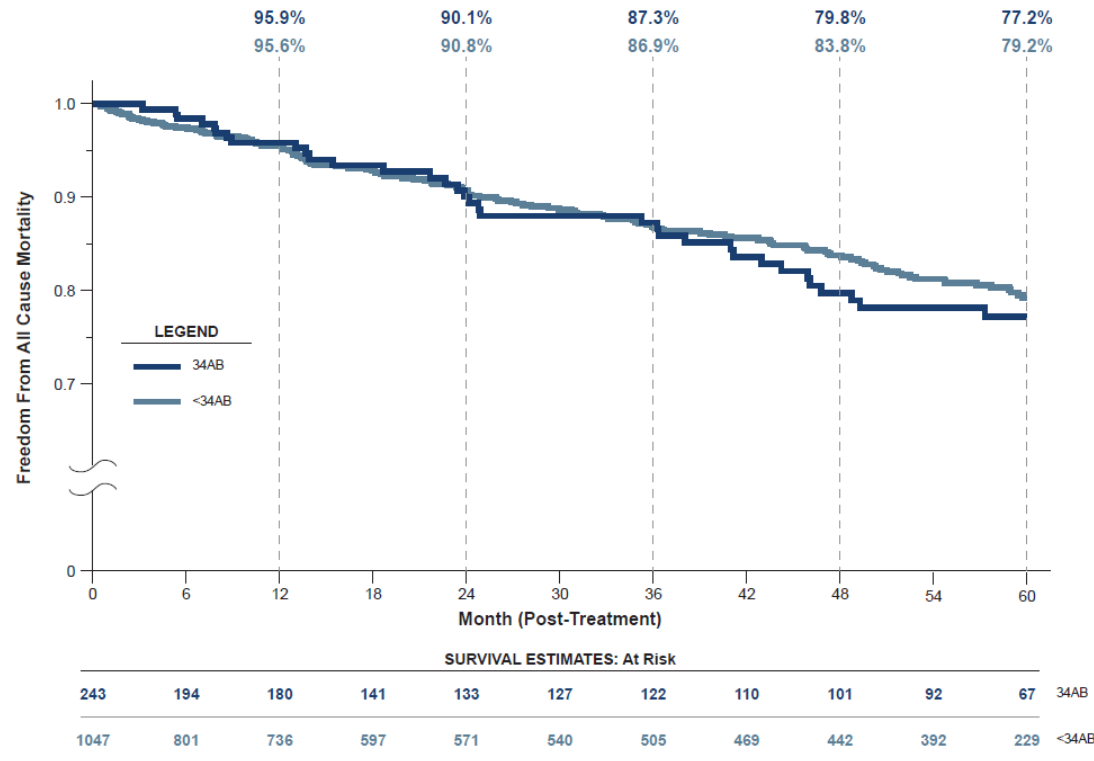


Howard EJVES 2018

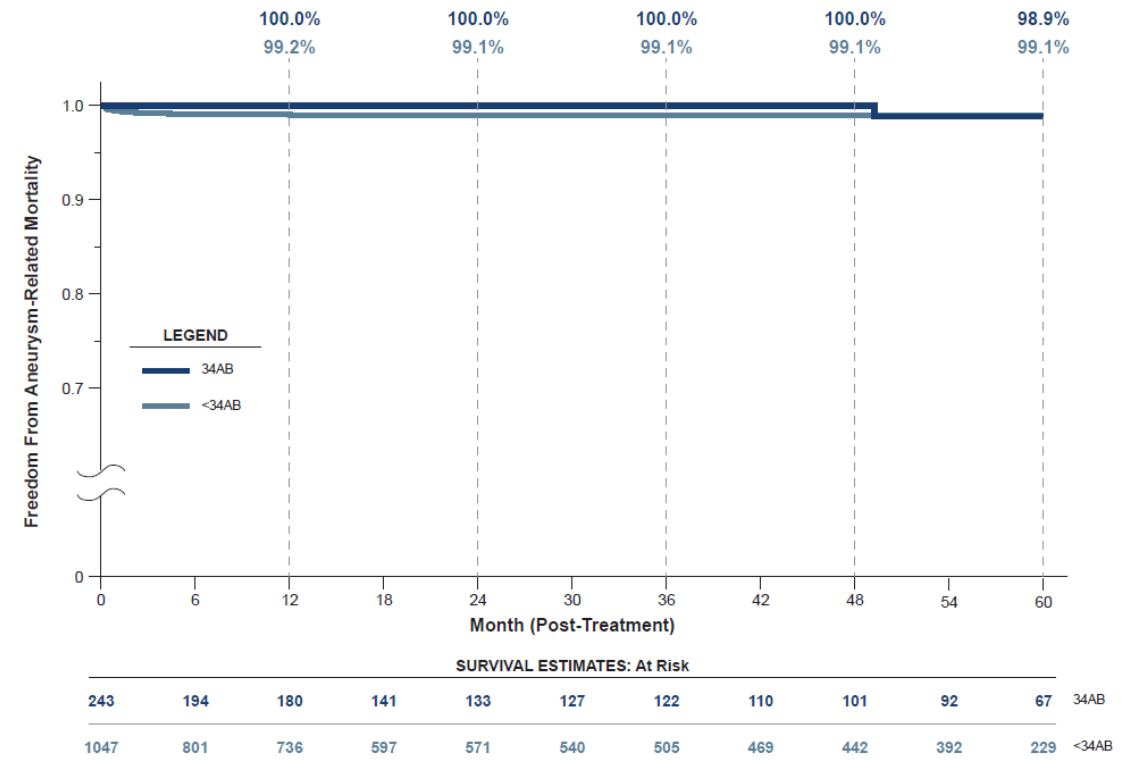
Reprinted from European Journal of Vascular and Endovascular Surgery, Vol 56, Dominic P.J. Howard, Conor D. Marron, Ediri Sideso, Phillip J. Puckridge, Eric L.G. Verhoeven, James I. Spark, Influence of Proximal Aortic Neck Diameter on Durability of Aneurysm Sealing and Overall Survival in Patients Undergoing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

ENCORE DEMONSTRATES DURABILITY REGARDLESS OF SIZE

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



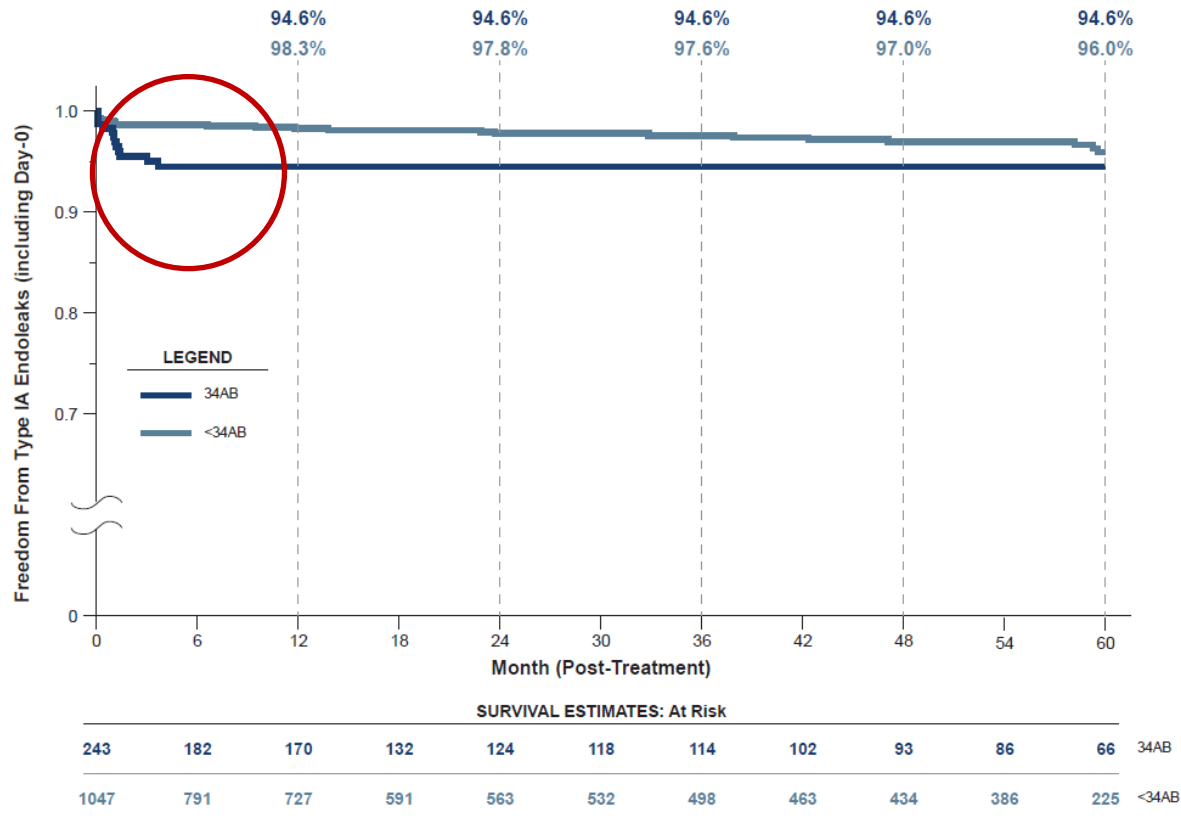
Freedom From AAA Related Mortality
(34mm AB vs. 20,23,26,29mm AB)



Verhagen CX Symposium 2019

ENCORE DEMONSTRATES DURABILITY REGARDLESS OF SIZE

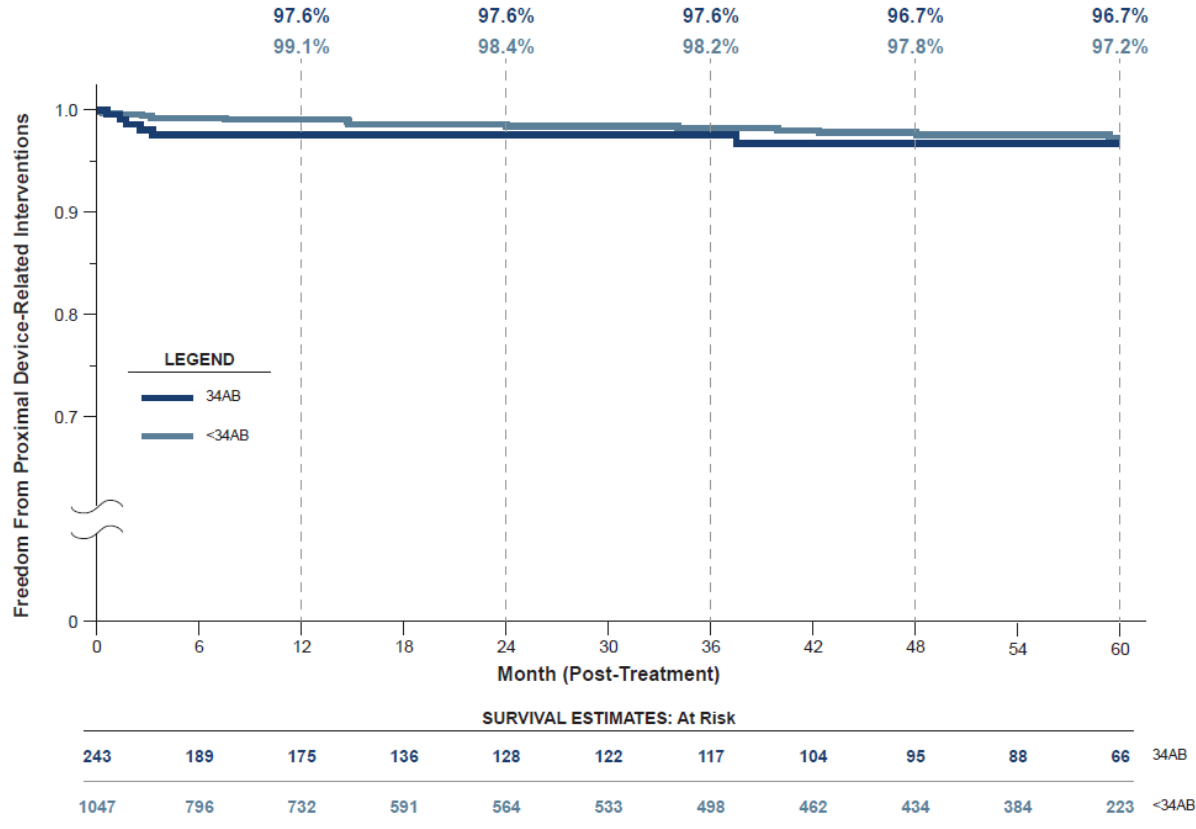
Freedom From Type 1A EL
(34mm AB vs. 20,23,26,29mm AB)



- 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

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.

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.