E·N·C·O·R·E

ENCORE: A Study to Investigate the Durability of Polymer EVAR

A Contemporary Review of 1,296 Patients

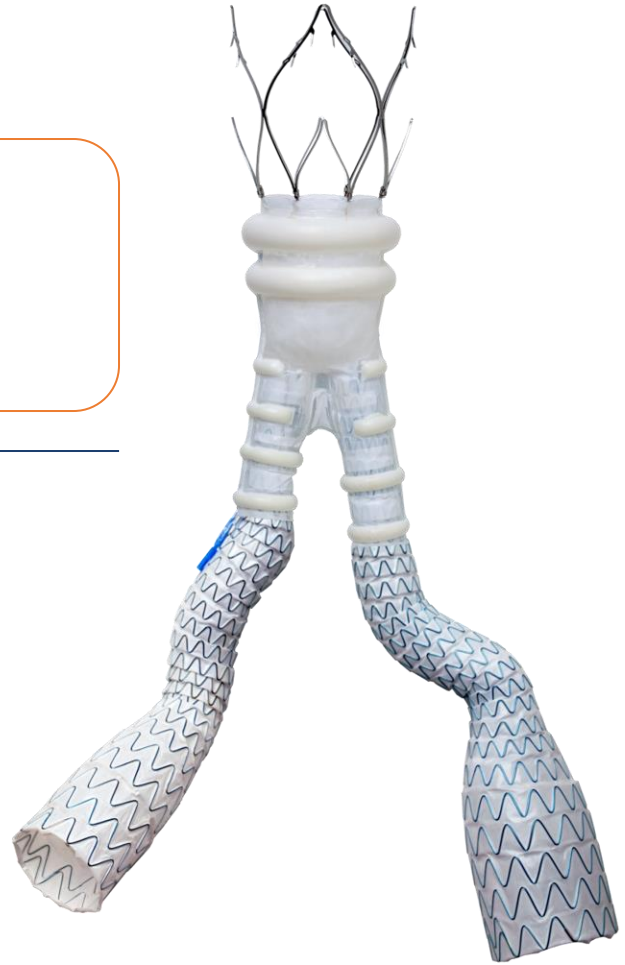
Endologix

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established. MM1918 Rev 03.

Agenda

01 ENCORE Results: Demonstrated favorable midterm durability* at 5 years

02 ENCORE: 5-year wide neck analysis



Endologix

*Evidenced by successful aneurysm exclusion and 5-year freedom from aneurysm-related mortality. (Swerdlow et al. J Vasc Surg. 2020; 71: 1528-1537)

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established. MM1918 Rev 03.

E·N·C·O·R·E

EffectiveNess of Custom Seal with Ovation: Review of the Evidence

The Ovation platform product family includes a series of device iterations using adaptive neck sealing technology such as Ova tion, Ovation Prime, Ovation iX, and Alto. The devices included in the studies used in the ENCORE Analysis all include adaptive sealing technology.

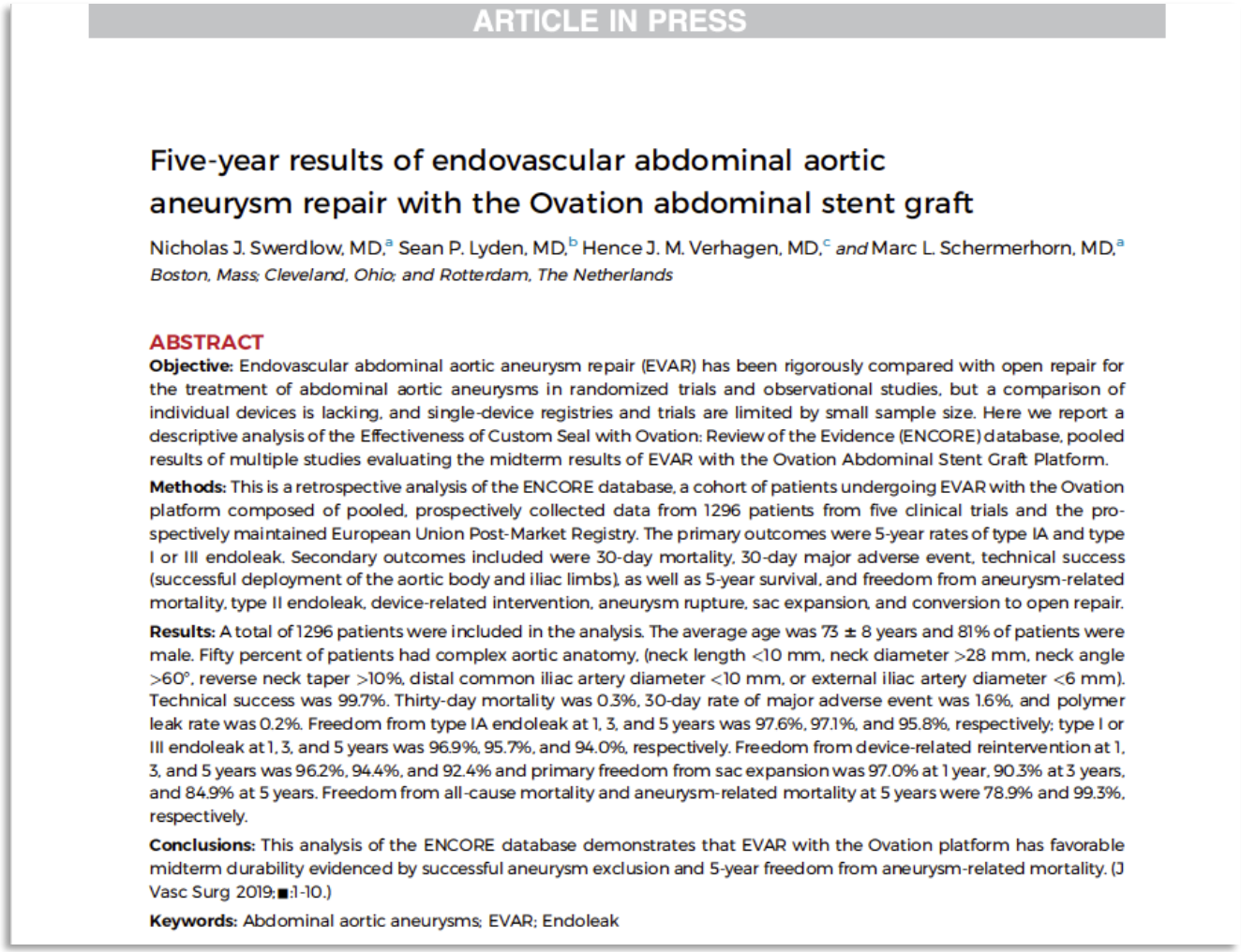
Endologix

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established. MM1918 Rev 03.

5-Year Results from JVS Publication

ENCORE ***demonstrates favorable midterm durability*** *at 5 years evidenced by successful aneurysm exclusion and low aneurysm-related mortality.*

Journal of Vascular Surgery 2019



ARTICLE IN PRESS

Five-year results of endovascular abdominal aortic aneurysm repair with the Ovation abdominal stent graft

Nicholas J. Swerdlow, MD,[a] Sean P. Lyden, MD,[b] Hence J. M. Verhagen, MD,[c] *and* Marc L. Schermerhorn, MD,[a]
Boston, Mass; Cleveland, Ohio; and Rotterdam, The Netherlands

ABSTRACT

Objective: Endovascular abdominal aortic aneurysm repair (EVAR) has been rigorously compared with open repair for the treatment of abdominal aortic aneurysms in randomized trials and observational studies, but a comparison of individual devices is lacking, and single-device registries and trials are limited by small sample size. Here we report a descriptive analysis of the Effectiveness of Custom Seal with Ovation: Review of the Evidence (ENCORE) database, pooled results of multiple studies evaluating the midterm results of EVAR with the Ovation Abdominal Stent Graft Platform.

Methods: This is a retrospective analysis of the ENCORE database, a cohort of patients undergoing EVAR with the Ovation platform composed of pooled, prospectively collected data from 1296 patients from five clinical trials and the prospectively maintained European Union Post-Market Registry. The primary outcomes were 5-year rates of type IA and type I or III endoleak. Secondary outcomes included were 30-day mortality, 30-day major adverse event, technical success (successful deployment of the aortic body and iliac limbs), as well as 5-year survival, and freedom from aneurysm-related mortality, type II endoleak, device-related intervention, aneurysm rupture, sac expansion, and conversion to open repair.

Results: A total of 1296 patients were included in the analysis. The average age was 73 ± 8 years and 81% of patients were male. Fifty percent of patients had complex aortic anatomy, (neck length <10 mm, neck diameter >28 mm, neck angle >60°, reverse neck taper >10%, distal common iliac artery diameter <10 mm, or external iliac artery diameter <6 mm). Technical success was 99.7%. Thirty-day mortality was 0.3%, 30-day rate of major adverse event was 1.6%, and polymer leak rate was 0.2%. Freedom from type IA endoleak at 1, 3, and 5 years was 97.6%, 97.1%, and 95.8%, respectively; type I or III endoleak at 1, 3, and 5 years was 96.9%, 95.7%, and 94.0%, respectively. Freedom from device-related reintervention at 1, 3, and 5 years was 96.2%, 94.4%, and 92.4% and primary freedom from sac expansion was 97.0% at 1 year, 90.3% at 3 years, and 84.9% at 5 years. Freedom from all-cause mortality and aneurysm-related mortality at 5 years were 78.9% and 99.3%, respectively.

Conclusions: This analysis of the ENCORE database demonstrates that EVAR with the Ovation platform has favorable midterm durability evidenced by successful aneurysm exclusion and 5-year freedom from aneurysm-related mortality. (J Vasc Surg 2019;■:1-10.)

Keywords: Abdominal aortic aneurysms; EVAR; Endoleak

Endologix

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established. MM1918 Rev 03.

Patient Demographics

Demographic	ENCORE Cohort
Age (yrs)	73 ± 8
Female sex	19 %
Body mass index (kg/m^2)	28 ± 5
Hypertension	18 %
Congestive heart failure	6.0 %
COPD	33 %
Diabetes	22 %
History of myocardial infarction	21 %
History of stroke	9.3 %
Family history	12 %
Smoking history	71 %

Characteristic	ENCORE Cohort
Maximum AAA diameter (mm)	54 ± 9
<50 mm	27 %
≥50 mm and <60 mm	55 %
≥60 mm and <70 mm	13 %
≥70 mm	6.0%
Neck diameter (IR, mm)	22 ± 3
>28 mm	4.4 %
Neck diameter (IR + 13, mm)	23 ± 3
Neck reverse taper ≥10%	28 %
Distal CIA (mm)	14 ± 4
<10 mm	11 %
Minimum EIA (mm)	8 ± 2
<6 mm	14 %
Aortic neck angulation	19 ± 19
Complex anatomy*	53%

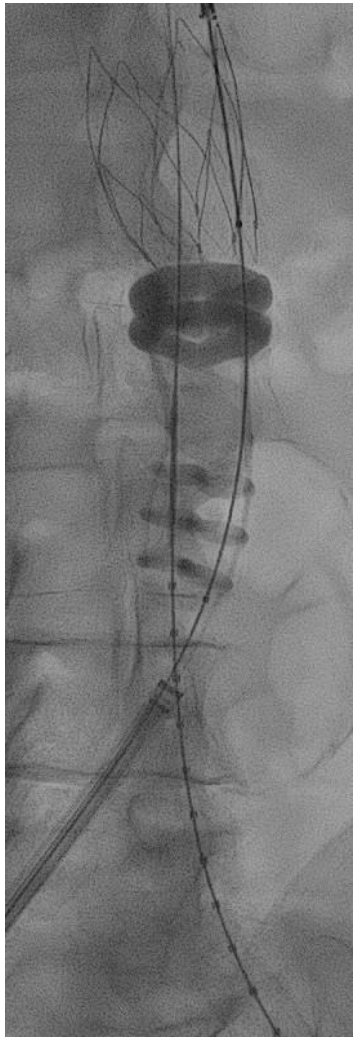
*Complex anatomy (neck length < 10, or neck diameter >28, or taper >10%, or neck angle >60, or sac diameter>70mm, or distal common iliac diameter <10mm, or external iliac diameter <6mm). Result excludes subjects who had missing info from any of these variables.

Endologix

ENCORE Data Cut March 20, 2019.

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established. MM1918 Rev 03.

Acute Procedural Outcomes



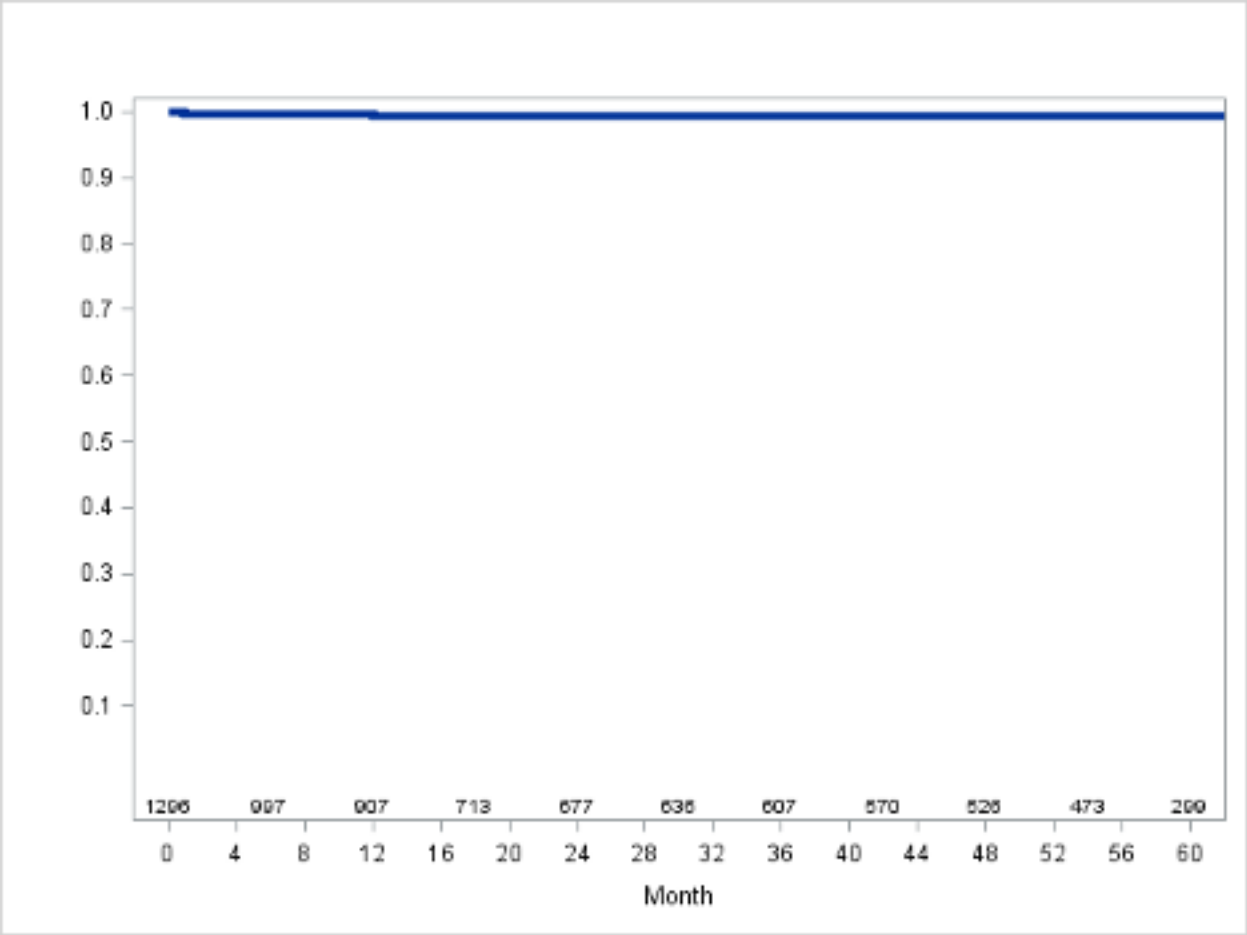
Procedure time (min)[1]	94
Fluoroscopy time (min)[1]	19
Contrast volume (mL)[1]	105
General Anesthesia (%)[2]	55
Technical Success (%)[2]	99.7
MAE (%)[2]	1.6
30d Mortality (%)[2]	0.3
Polymer Leak (%)[3]	0.9

1. ENCORE Data Cut March 20, 2019.
2. Swerdlow et al. J Vasc Surg. 2020; 71: 1528-1537
3. May 4, 2020, Ovation iX Medical Device Correction https://endologix.com/wp-content/uploads/2020/05/ENDO-Ovation-FSN-FS-0012-US-Letter-Final-5-6-20.pdf. (Assessed Feb 3, 2021)

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established.

Endologix

Freedom from AAA-Related Mortality



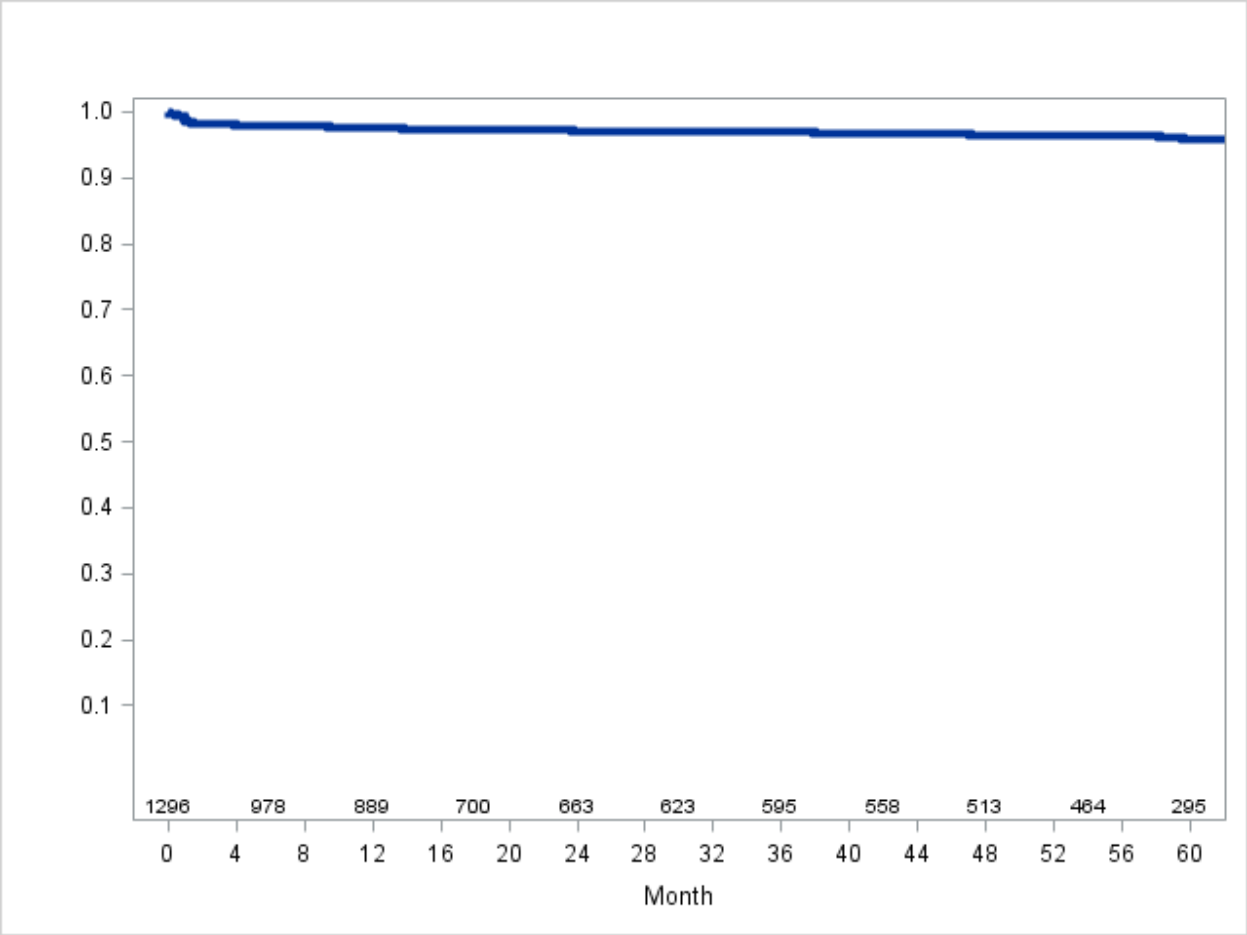
	Year 1	Year 3	Year 5
FF ARM (%)	99.6	99.5	99.3

Endologix

ENCORE Data Cut March 20, 2019.

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established. MM1918 Rev 03.

Freedom from Type IA Endoleak



	Year 1	Year 3	Year 5
FF Type IA EL (%)	97.6	97.0	95.7

ENCORE Data Cut March 20, 2019.

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established.

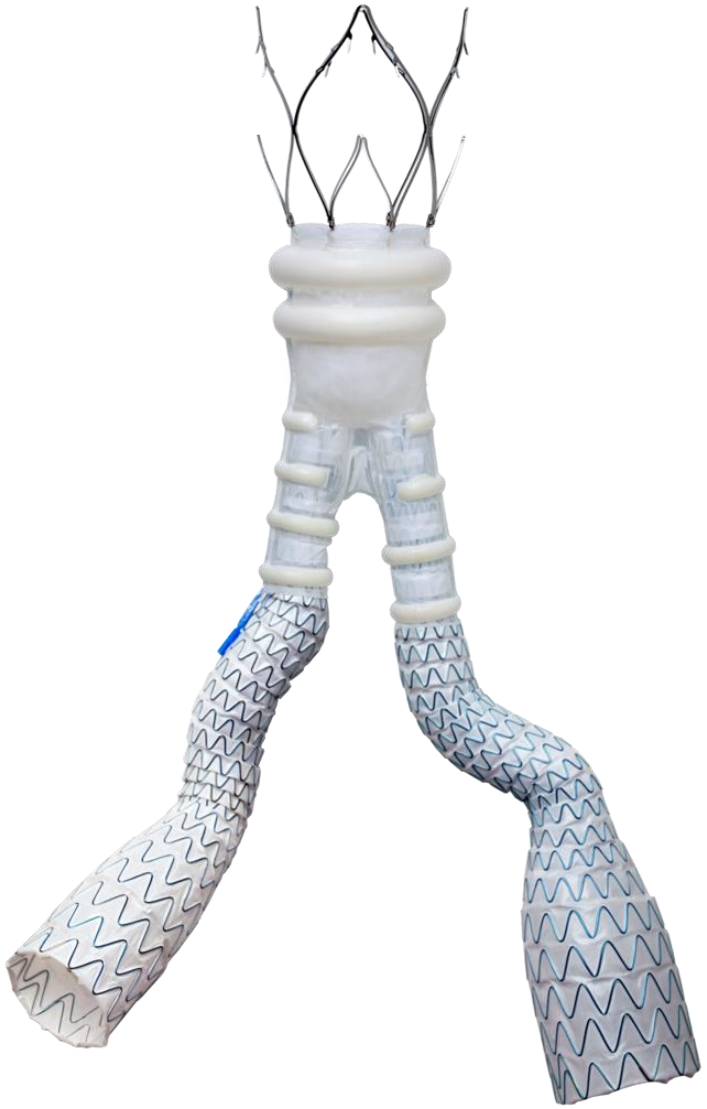
Outcomes

ENCORE Freedom From (%)[1]	Year 1	Year 3	Year 5
AAA-Related Mortality	99.6	99.5	99.3
Type IA Endoleak	97.6	97.0	95.7
Sac Expansion[2]	97.0	90.3	84.9
Rupture	99.8	99.8	99.5
Conversion	99.9	99.5	98.6
Device-Related Reintervention	95.9	93.8	90.2

1. All values come from ENCORE Data Cut: March 20, 2019 except for sac expansion which comes from ENCORE Data Cut: April 12, 2018.
2. ENCORE data cut: April 12, 2018

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established.

Endologix



E·N·C·O·R·E

POLYMER EVAR-OVATION®

Modern, Systematic Evidence Base of 1,296 patients

Pooled, retrospective analysis of six trials demonstrate favorable midterm durability at five-years

- 99.3% FF AAA-Related Mortality
- 95.7% FF Type IA Endoleak
- 99.5% FF Rupture
- 98.6% FF Conversion
- 90.2% FF Device-Related Reintervention

The ENCORE analysis pools data using a March 20, 2019 data cut.

Endologix

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established. MM1918 Rev 03.

Agenda

01 ENCORE Results: Demonstrated favorable midterm durability* at 5 years

02 ENCORE: 5-year wide neck analysis

*Evidenced by successful aneurysm exclusion and 5-year freedom from aneurysm-related mortality. (Swerdlow et al. J Vasc Surg. 2020; 71: 1528-1537)

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established. MM1918 Rev 03.

E·N·C·O·R·E

Numerous recent publications on worsening outcomes associated with EVAR in patients with wide aortic necks


From the Eastern Vascular Society

Comparative study of clinical outcome of endovascular aortic aneurysms repair in large diameter aortic necks (>31 mm) versus smaller necks

Ali F. AbuRahma, MD,* Trevor DerDerian, MD,* Zachary T. AbuRahma, DO,* Stephen M. Hass, MD,* Michael Yacoub, MD,* L. Scott Dean, PhD, MBA,* Shadi Abu-Halimah, MD,* and Albert Y. Mousa, MD,* Charleston, WVa

ABSTRACT

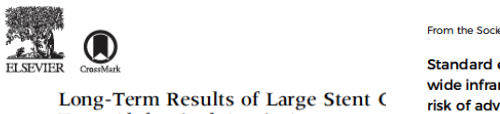
Background: This study compares short-term (30 days) and intermediate term (3 years) clinical outcomes in patients with large (≥31 mm) versus small aortic neck diameters (≤28 and ≤31 mm).

Methods: Prospectively collected data from 741 patients who underwent endovascular aortic aneurysm repair were analyzed. Some surgeons have reported the threshold for a large aortic neck for endovascular aortic aneurysm repair to be 28 mm, whereas for others it is 31 mm. Therefore, we classified aortic neck diameter into less than or equal to 28 versus greater than 28 mm; and less than or equal to 31 versus greater than 31 mm. Logistic regression and Kaplan-Meier analyses were used to compare outcomes.

Results: There were 688 patients who had a defined aortic neck diameter: 592 with less than or equal to 28 mm, 96 with greater than 28 mm, 655 with less than or equal to 31 mm, and 33 with greater than 31 mm. The mean follow-up was 25.2 months for less than or equal to 31 mm versus 31.8 months for greater than 31 mm. Clinica similar in all groups, except that there were more patients outside the instructions for use in th versus less than or equal to 31 mm group (94% ± 4.4%; P < .0001). There was a significant increase ir for patients with an aortic neck diameter of greater than 31 versus less than or equal to 31 mm (9 [27 late type I endoleaks (4 [14%] vs 18 [3%]; P = .01), sac expansion (5 [17%] vs 28 [5%]; P = .01), late inte (4%], P = .01), and death (9 [31%] vs 48 [8%]; P < .0001). There were no differences in outcomes betw greater than 28 mm aortic neck diameters and the less than or equal to 28 mm diameters. Free endoleak at 1, 2, and 3 years were 96%, 88%, and 88% for patients with a neck diameter of greater th 97%, and 97% for a diameter less than or equal to 31 mm (P = .19). The rate of freedom from sac with a diameter greater than 31 mm was 88%, 81%, and 81% at 1, 2, and 3 years versus 99%, 97%, ar less than or equal to 31 mm (P = .02). Freedom from late intervention for 1, 2, and 3 years for pat greater than 31 mm were 91%, 91%, and 91% versus 99%, 97%, and 96% for those with a diameter 31 mm. Survival rates at 1, 2, and 3 years for a diameter greater than 31 mm were 83%, 74%, and 68% 90% for a diameter less than or equal to 31 mm (P < .001). Multivariate logistic regression analysis with a diameter greater than 31 mm had an odds ratio of 6.1 (95% confidence interval [CI], 2.2-16.8) CI, 1.4-15.5) for sac expansion, and 4.9 (95% CI, 1.4-17.4) for late type I endoleak.

Conclusions: Patients with large aortic neck diameters (>31 mm) had higher rates of early and sac expansion, late intervention, and mortality. (J Vasc Surg 2018;68:1345-53.)

Keywords: Endovascular; Abdominal aortic aneurysms; EVAR; Aortic neck size; Endovascular anea


Several clinical trials comparing traditional open repair for endovascular aortic aneurysm repair (EVAR) have confirmed the perioperative benefits of an endovascular repair.[1-3] Two randomized trials, EVAR 1 and DREAM (Dutch Randomized Endovascular Aneurysm Management), reported significantly reduced operative time, perioperative mortality, duration of hospital stay, and transfusion requirements.[4-7] N number of patients with an ab (AAA) patients have undergo instructions for use (IFU) ov including patients with hostile a cifically short necks [<10 mm], and an aortic neck diameter of

From the Department of Surgery, West Virginia University*; and the CAMC Health Education and Research Institute.[b]
Author conflict of interest: none.
Presented at the Thirty-first Annual Meeting of the Eastern Vascular Society, Savannah, Ga, October 5-8, 2017.
Additional material for this article may be found online at www.jvascsurg.org.
Correspondence: Ali F. AbuRahma, MD, Surgery, West Virginia University, 3110 MacCorkle Ave SE, Charleston, WVa 25304 (e-mail: ali.aburahma@camc.org).

The editors and reviewers of this article have no disclose per the JVS policy that requires manuscript for which they may have a con (2141-5214)
Copyright © 2018 by the Society for Vascular https://doi.org/10.1016/j.jvs.2018.02.037

From the Society for Vascular Surgery

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

Nelson F. G. Oliveira, MD,[a,b] Frederico Bastos Gonçalves, MD, PhD,[b,c] Klaas Ultee, MD, PhD,[b] José Pedro Pinto, MD,[a,d] Marie Josee van Rijn, MD, PhD,[a] Sander Ten Raa, MD, PhD,[a] Patrice Mwipatayi, MD, FCS, FRACS,[a,e] Dittmar Böckler, MD, PhD,[b] Sanne E. Hoeks, PhD,[b] and Hence J. M. Verhagen, MD, PhD,[a] Rotterdam, The Netherlands; Ponta Delgada, Lisbon, and Porto, Portugal; Perth, Australia; and Heidelberg, Germany

ABSTRACT

Objective: Standard endovascular aneurysm repair (EVAR) is the most common treatment of abdominal aortic aneurysms (AAAs). EVAR has been increasingly used in patients with hostile neck features. This study investigated the outcomes of EVAR in patients with neck diameters ≥30 mm in the prospectively maintained Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE).

Methods: This is a retrospective study comparing patients with neck diameters ≥30 mm with patients with neck diameters <30 mm. The primary end point was type IA endoleak (ELA). Secondary end points included secondary interventions to correct ELIA, aneurysm rupture, and survival.

SCULAR FELLOWS' FORUM 2002, SECOND

nt-Graft Migration Followi
pair of Aneurysms With La
atomical Risk Factors and

es T. Lee, MD; Jason Lee, MD; Ihab Aziz,
Walot, MD*; George E. Kopchok, BS; M
rice Lippmann, MD†; and Rodney A. Wh
irtments of Surgery, *Radiology and †A
er, Torrance, California, USA

Neck diameter and inner curve seal zone predict endograft-related complications in highly angulated necks after endovascular aneurysm repair using the Aorfix endograft

Sophie Wang, BS, Caitlin W. Hicks, MD, and Mahmoud B. Malas, MD, MHS, Baltimore, Md

ABSTRACT

Objective: Many studies have found that preoperative aneurysm anatomy can determine the postoperative complication rates for endovascular aneurysm repair (EVAR). With continual improvement in endograft technology, patients with challenging anatomy are increasingly able to undergo successful treatment with EVAR. This study aimed to quantify the influence of proximal neck anatomy on contemporary outcomes in a cohort of abdominal aortic aneurysm patients with highly angulated aneurysm necks.

Methods: The study included 205 patients originally enrolled in the Prospective Aneurysm Trial: High Angle Aorfix Bifurcated Stent Graft (PYTHAGORAS) trial, the largest study to date to enroll patients with aortic aneurysm neck angles >60 degrees. Anatomic parameters included measurements of the proximal aneurysm neck as well as seal zones modeled in preoperative computed tomography scans. Follow-up up to 5 years postoperatively was available for which stent-related complications (defined as sac expansion, stent migration, and type Ia endoleak) were assessed. Predictive anatomic parameters were assessed by Cox regression models, and a final multivariate model was created to predict complications. The cohort was also stratified by neck diameter for further comparison of complication rates.

Results: Of 205 patients enrolled in the trial, 67 stent-related complications occurred in 36 patients (17.6%) at 5 years after EVAR. Median follow-up was 48 months. Demographic and medical comorbidities did not predict risk of complications, nor did proximal neck length or neck angle. Independent predictors of post-EVAR complications included increasing proximal neck diameter (hazard ratio, 1.74; 95% confidence interval, 1.05-1.27; P < .05) and decreasing seal zone inner curve

Endovascular Repair of Wide Neck AAA – Preliminary Report on Feasi

Ingle[1], G. Fishw

Durability

Global

Spark[4*], on behalf

From the Society for Clinical Vascular Surgery

Outcomes of using endovascular aneurysm repair with active fixation in complex aneurysm morphology

Rami O. Tadros, MD, Alex Sher, BS, Martin Kang, BS, Agelliki Vouyouka, MD, Windsor Ting, MD, Daniel Han, MD, Michael Marin, MD, and Peter Faries, MD, New York, NY

ABSTRACT

Objective: The ideal treatment option for patients with complex aneurysm morphology remains highly debated. The aim of this study was to investigate the impact of endovascular aneurysm repair (EVAR) with active fixation on outcomes in patients with complex aneurysm morphology.

Methods: There were 340 consecutive patients who underwent EVAR using active fixation devices, 234 with active infrarenal fixation (AIF; Core Excluder, W. L. Gore & Associates, Flagstaff, Ariz) and 106 with active suprarenal fixation (ASF; 85 Medtronic Endurant [Medtronic, Santa Rosa, Calif] and 21 Cook Zenith [Cook Medical, Bloomington, Ind]). Demographics, comorbidities, anatomic features, and outcomes were analyzed for patients receiving devices with active fixation. Outcomes of using active fixation in necks with <15-mm neck lengths, >60-degree infrarenal neck angle (β), >30-mm infrarenal neck diameter, severe aortic neck calcification or thrombus, and nonstraight neck morphology were evaluated.

Results: Of the 340 patients, 106 (78 men; mean age, 74.5 ± 9.3 years at the time of surgery) received implants with ASF and 234 (178 men; mean age, 74.6 ± 8.9 years at the time of surgery) received implants with AIF. In comparing AIF and ASF
the suprarenal fixation group had significantly shorter follow-up time (25 ± 17 months vs 44.3 ± 31). Patients in the ASF group had shorter aortic neck lengths (25.5 ± 15.1 mm vs 28.6 ± 14.9 mm; ently larger infrarenal neck diameters (25.9 ± 6.5 mm vs 23.4 ± 3.2 mm; P < .0001) and aneurysm .6 mm v. 55.9 ± 10.0 mm; P = .002). Outcomes were similar between groups, with no significant vention, proximal endoleak, sac growth, abdominal aortic aneurysm–related death, or rupture. Of the neck features investigated, neck diameter >30 mm and nonstraight neck morphology had the servention in ASF devices.

s of hostile infrarenal neck morphology, ASF appears to be used more frequently. Our data suggest ful for certain patients but may be unfavorable for others, such as those with wide necks or several es. Nevertheless, further research is needed to evaluate more optimal treatment options, such as ranched EVAR, and endovascular adjuncts such as EndoAnchors (Aptus Endosystems, Sunnyvale, high-risk anatomic characteristics that may not be optimally managed with standard EVAR devices

J Vasc Surg 2018;68:683-92.)

n repair (EVAR) remains a rapidly
n constant device design modifi-
ously expanding population of
ablished that a sufficient and
nt of aorta is crucial for achieving

ngery, Department of Surgery, Icahn School of

forum at the Forty-fifth Annual Symposium of
ar Surgery, Lake Buena Vista, Fla, March 18-

s, MD, Associate Program Director, Associate
ology Director, Off-site Vascular Lab, Division
of Medicine at Mount Sinai, The Mount Sinai
Ave, 4th Fl, New York, NY 10029 (e-mail: rami.

ticle have no relevant financial relationships to
e requires reviewers to decline review of any
have a conflict of interest.

for Vascular Surgery. Published by Elsevier Inc.

https://doi.org/10.1016/j.jvs.2017.12.089

e Society for Vascular Surgery

secure, long-term attachment of endovascular grafts. Importantly, it was noted early on that many infrarenal abdominal aortic aneurysms failed to meet this requirement.[1] A significant proportion with challenging (short, wide, angulated, thrombosed, or calcified) proximal necks were commonly excluded because they failed to meet the manufacturer's instructions for use (IFU) guidelines.[2] Although these characteristics would have previously made a patient ineligible for EVAR, advancements in technique, experience, and prosthetic design have facilitated the transition of many centers to treat aneurysms with complex morphologic features.

Still, the use of standard EVAR in these more complex patients has shown mixed results. Some have demonstrated safety of using commercially available devices,[2-6] whereas others have linked challenging neck characteristics to worse outcomes.[6-9] As such, device selection is strongly driven by a patient's anatomy. With the advent of alternatives such as fenestrated EVAR (FEVAR), branched EVAR (BEVAR), and endovascular adjuncts, such as EndoAnchors (Aptus Endosystems,

ımes of endovascular aneurysm repair performed in
minal aortic aneurysms with large infrarenal necks

rgüilo, MD, PhD,[a] Enrico Gallitto, MD, PhD,[a] Helene Wattez, MD,[b] Fabio Verzini, MD, PhD,[c] Gianchini Massoni, MD,[a] Diletta Loschi, MD,[c] Antonio Freyrie, MD, PhD,[c] and Haulon, MD, PhD,[b] Bologna and Perugia, Italy; and Lille, France

CT

The aim of this study was to evaluate midterm clinical and morphologic outcomes after endovascular repair (EVAR) of abdominal aortic aneurysm (AAA) with large (≥28 mm) infrarenal neck.

From 2009 to 2012, we prospectively collected and retrospectively analyzed clinical, morphologic, and intra- and postoperative data of patients undergoing EVAR for wide-neck AAA at three European vascular surgery centers that had computed tomography angiography follow-up of >24 months. The early end points were technical, proximal type I endoleak at 30 days. The midterm end points were type Ia endoleak, freedom from reintervention (FFR), survival, AAA-related mortality, and infrarenal and suprarenal aortic diameter progression. The aortic diameters were measured on three-dimensional workstation on center lumen line reconstructions, 1 cm below the lowest renal artery, at the level of the renal arteries, at the superior mesenteric artery, and at the celiac trunk. Preoperative and aortic diameters were compared by paired t-test. Survival and FFR were evaluated by Kaplan-Meier analysis.

During the study period, 118 patients (74 ± 8 years) were enrolled. The mean aneurysm diameter was 61 ± 10 mm. Type I and III endoleaks at completion angiography were implanted in 102 (86%) and 16 (14%) patients, respectively. The mean aortic diameter oversizing was 17% ± 9%. Technical success rate was 98% (three type Ia endoleaks at 30 days). The mean follow-up was 38 ± 12 months. Fourteen type Ia endoleaks (12%) were detected during follow-up. Survival at 3 years and 5 years was 89% and 70%, respectively. Four deaths (3.4%) were type Ia endoleak related. FFR at 1 year, 3 years, and 5 years was 85%, and 82%, respectively. Eight reinterventions (7%) were proximal neck related. All infrarenal and suprarenal aortic diameters increased at 24 months. The mean increase was 11% for the lowest renal artery (2.9 ± 1.1 mm preoperative vs 3.2 ± 1.5 mm at 24 months; P < .001), 5% to 5% at the level of the renal arteries, and <3% for the superior mesenteric artery and the celiac trunk. Neck length <15 mm (P = .032), stainless steel endograft (P = .003), and type Ia endoleak at 24 months (P = .001) were associated with infrarenal neck enlargement on multivariate logistic regression analysis. Type Ia EVAR performed in AAAs with large necks is associated with a significant infrarenal aortic neck enlargement at 24 months as well as with a high risk of proximal type I endoleak and proximal neck-related reinterventions. A large group of patients, main body oversizing >15% and suprarenal sealing should be considered. (J Vasc Surg 2018;67:1-12.)

trials have demonstrated that endovascu-
repair (EVAR) of abdominal aortic aneu-
is associated with lower perioperative
mortality than open repair (OR).[1-3] The
underline a higher risk of reinventions
for patients treated with EVAR, even if
are reported with the currently available

late follow-up EVAR outcomes are influ-
e preoperative aortoiliac morphologic

features.[3,4] A wide infrarenal neck diameter (≥28 mm; wide-neck AAA [WN-AAA]) is considered a risk factor that negatively affects the midterm and long-term EVAR outcomes because of the risk of aneurysmal degeneration of the proximal sealing zone, endograft migration, and proximal type I endoleak.[2]

The aims of this study were to report midterm outcomes after EVAR performed in patients with WN-AAA and to evaluate the progression of infrarenal and suprarenal aortic diameters in these patients.

Surgery, Department of Experimental, Diagnostic and
s, University of Bologna, Policlinico Sant'Orsola-Malpighi,
partment of Vascular Surgery, Aortic Centre, CHRU
Vascular Surgery Unit, University of Perugia, Hospital S.
orda, Perugia.[c]
lated: none.
International Fast Talk at the 2015 Vascular
of the Society for Vascular Surgery, Chicago, Ill., June

Correspondence: Enrico Gallitto, MD, PhD, Vascular Surgery, University of Bologna, Azienda Policlinico S. Orsola-Malpighi, Via Massarenti 9, Bologna 40138, Italy (e-mail: enrico.gallitto@gmail.com).
The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.
0741-5214
Copyright © 2017 by the Society for Vascular Surgery. Published by Elsevier Inc.

ELSEVIER CrossMark

Long-Term Results of Large Stent G
Treat Abdominal Aortic Aneurysms

Adrien Kaladji,[1,2,3] Eric Steintmetz,[4] Yann Gouëffic,[5] Michel Bartoli,[4] an
the Academic Association for Surgical Research (AURC), Rennes, Dijon, N
France

Background: Open surgery and endovascular treatment are currently treatment for abdominal aortic aneurysms (AAAs). Although the open s diameter of the implanted prostheses seldom exceeds 24 mm, and repair (EVAR) makes it possible to use stent grafts up to 36 mm in d this study was to compare the long-term results of these large stent g the others.

Methods: A total of 908 patients operated between 1998 and 2012 for with an infrarenal stent graft were enrolled in this multicentric retrospe tients in whom the proximal diameter of the principal component of the s 32 mm belonged to group 1 (n = 170) and the others belonged to grou qualitative and quantitative data were compared with the chi-squared respectively. The long-term data were analyzed with the log-rank test curves.

Results: Mean age of the patients was 75 ± 8.3 years, and the average fo 38 ± 28.2 months. There was no difference between the 2 groups regardin risk factors except chronic renal insufficiency (30.6% in group 1 vs. 21.2%, proportion of obese patients (26.2% vs. 17.7%, P = 0.02). Concerni anatomic features, there was a significant difference between the groups c of the neck (25.5 ± 10.1 vs. 28.3 ± 12.6 mm, P = 0.008), the maximum (58 ± 10.1 vs. 56.1 ± 10.1 mm, P = 0.027), and the oversizing (18.1 ± 16.8 ± 7.4% in group 2, P = 0.043). There was no difference of the postop plications, technical failure, endoleaks, and death. In the long run, analyse that the rates of proximal endoleaks (13% vs. 3.9%, P < 0.0001) and of r vs. 14.7%, P = 0.009) were higher in group 1. There was no significant diffe

Standard endovascular aneurysm repair in patients with wide infrarenal aneurysm necks is associated with increased risk of adverse events

Nelson F. G. Oliveira, MD,[a,b] Frederico M. Bastos Gonçalves, MD, PhD,[b,c] Marie Josee Van Rijn, MD, PhD,[a] Quirina de Ruiter, MSc,[d] Sanne Hoeks, PhD,[b] Jean-Paul P. M. de Vries, MD, PhD,[c] Joost A. van Herwaarden, MD, PhD,[c] and Hence J. M. Verhagen, MD, PhD,[a] Rotterdam, Nieuwegein, and Utrecht, The Netherlands; and Azores and Lisbon, Portugal

ABSTRACT

Objective: Endovascular aneurysm repair (EVAR) has progressively expanded to treat more challenging anatomies. Although EVAR in patients with wide infrarenal necks has been reported with acceptable results, there is still controversy regarding the longer-term outcomes. Our aim is to determine the impact of infrarenal neck diameter on midterm outcome following EVAR with a single endograft with suprarenal fixation.

Methods: A retrospective case-control study was designed using data from a prospective multicenter database. Patients who electively underwent standard EVAR with an Endurant stent graft (Medtronic Ave, Santa Rosa, Calif) for a degenerative abdominal aortic aneurysm from January 2008 to December 2012 in three high-volume centers in The Netherlands were included. All measurements were obtained using dedicated reconstruction software and center-lumen line reconstruction. Patients with an infrarenal neck diameter of ≥30 mm were compared with patients with a neck diameter of <30 mm. The primary end point was freedom from neck-related adverse events (a composite of type Ia endoleak, neck-related secondary intervention, and endograft migration). Secondary end points were primary clinical success, type Ia endoleak, neck-related reinterventions, endoleaks, and aneurysm-related secondary interventions.

Results: Four-hundred twenty-seven patients were included. Seventy-four patients (17.3%) with a neck diameter of ≥30 mm were compared with a control group of 353 patients. There were no significant differences at baseline between groups including demographics, comorbidities, baseline aneurysm diameter, infrarenal neck length, suprarenal angulation, or infrarenal neck angulation. Median stent graft oversizing was 12.5% (7.9-16.1) and 16.6% (12.0-23.1) in the ≥30-mm neck-diameter and control groups, respectively (P < .001). Median follow-up was 3.1 years (1.2-4.7) and 4.1 years (2.7-5.6) for the large neck and control groups, respectively (P < .001). Type Ia endoleaks occurred in 17 patients (4.0%) and were significantly more frequent in patients with ≥30-mm neck diameter (9.5% vs 2.8%; P = .005). Neck-related secondary interventions were performed in 20 patients (4.7%) and were also more common among patients with neck diameters of ≥30 mm (9.5% vs 3.7%; P = .04). The 4-year freedom from neck-related adverse events were 75% and 95% for the large-neck and control groups, respectively (P < .001). On multivariable regression analysis, infrarenal neck diameter of ≥30 mm was an independent risk factor for neck-related adverse events (odds ratio [OR], 3.8; 95% confidence interval [CI], 1.6-9.1), type Ia endoleak (OR, 2.7; 95% CI, 1.0-8.3), and neck-related secondary interventions (OR, 3.2; 95% CI, 1.1-9.2).

Conclusions: EVAR in patients with large diameter necks is associated with an increased risk of neck-related adverse events in midterm follow-up. This may influence the clinical decision regarding choice of repair and toward a more intensive surveillance following EVAR in these patients in the long term. (J Vasc Surg 2017;65:1608-16.)

ig-term results in this p

Getinge, S.R.H. has received an educational research grant from the Ujf en

https://doi.org/10.1016/j.jvs.2018.07.021

J Endovasc Ther. 2010;17:575–584

Key words: abdominal aortic aneurysm, endovascular aneurysm repair, stent-graft,

From the Society for Vascular Surgery

CLINICAL RESEARCH STUDIES

fixation following EVAR with the
ink XL System in wide aortic necks
ospective, multicenter trial

dian Jr, MD,[a] William M. Moore Jr, MD,[b] Jim G. Melton, DO,[c]
wn, MD, JD,[d] and Jeffrey P. Carpenter, MD,[e] for the Endologix Investigati
ia: West Columbia, SC; Oklahoma City, Okla; Royal Oak, Mich; and Camden, NJ

ecular stent graft repair of abdominal aortic aneurysms (AAA) with the Endolog
Irvine, Calif) has been shown to be a safe and effective alternative to open surgery
ter of up to 26 mm. We assessed the safety and effectiveness of AAA repair in pati
mm in diameter) using the Powerlink XL System.
n September 2005 and June 2008, a prospective, multicenter, pivotal US Food and
rlink XL System for endovascular aneurysm repair was conducted at 13 centers. Usi
ted tomography scan (CT)-based measurements, a total of 78 patients (N = 60 [
a]) presenting with AAA and an infrarenal aortic neck up to 32 mm in diameter
natomical fixation at the aortoiliac bifurcation and proximal sealing with a Pow
on stent graft. Postoperatively, results were assessed with contrast-enhanced CT
s, and 12 months, with continued annual follow-up to five years.
nantly male (91%), patients presented at a mean age of 73 ± 8.6 years with mean
ters of 31 ± 1.9 mm (range, 25 to 32 mm) and 5.7 ± 1.0 cm (range, 4.3 to
arenal aortic neck anatomy, defined as the presence of severe thrombus and/or severe
s. Technical success was achieved in 98.7% of patients, with one patient requiring fe
Aneurysm exclusion was achieved in 100% of patients over a mean procedur
ts were discharged at a mean of 2.2 days postoperatively. At the one-month CT s
ed a Type II endoleak in 1.3 patients, distal Type I and Type II endoleak in one pa
e patients. At 30 days, there were no deaths, conversions, ruptures, or migration
II endoleak predominated (9/10 patients with endoleak), with one proximal Ty
endoleak; no conversions, ruptures, or migrations have been observed. The one-year a
90% freedom from aneurysm-related mortality. Secondary procedures were performed
e treatment of proximal Type I endoleak (n = 2), proximal Type I/Type II endoleak (n
2). Reduced or stable aneurysm sac diameter at one year is observed in 96% of patient
combination of an anatomically-fixed Powerlink bifurcated stent graft and a Pow
ion appears safe and effectively excludes aneurysms in patients with wide aortic
rtion at the aortic bifurcation can provide secure fixation for patients with lar
necks. (J Vasc Surg 2009;50:979-86.)

multicenter, controlled clinical trial ex-
to long-term follow-up, the Powerlink
Inc, Irvine, Calif) has been shown to be

necks up to 26 mm in diameter.[1-5]
of patients with large aortic necks u
and to inhibit distal migration,

From The Vascular Experts, Middletown*, the Division of Vascular Surgery and Endovascular Therapy, Emory University, Atlanta†, Syntactx, New York‡,

INTRODUCTION

Endovascular abdominal aortic aneurysm repair (EVAR) has become the primary mode of interventional treatment for abdominal aortic aneurysms since emerging as an alternative to open aneurysmal repair in 1991,[1,2] despite long-term data pointing to early survival benefits leveling off and a significantly higher rate of late ruptures and reinterventions.[3-7]

In analyses of both early and late endograft failure, type Ia endoleaks are found to be the primary indication, with early proximal endoleaks chiefly due to failure to achieve sufficient initial seal.[8] In cases of late explantation, type Ia endoleaks remain the primary indication, the majority occur as progressive neck dilation, or migration compromises the ability of the endograft to maintain adequate proximal seal.[9] Endoleaks and other late complications are particularly prevalent in patients with hostile neck anatomy,[10] validating the narrow anatomic spectrum indicated in EVAR device instructions for use (IFU). However, these stringent anatomic guidelines have led to widespread off-label use.[10,11] In a decade-long study of IFU compliance, Schanzer et al[11] observed that in a population of >10,000 patients, 44.1% of EVAR procedures

of the work), JP-dV. discloses clinical research grants from Endologix and consulting fees from Medtronic and Endologix.

CASE REPORT

Use of Zenith TX2 endografts in endovascular abdominal
repair for large-diameter aortic necks

Patrick J Geraghty* and Luis A Sanchez*

to describe the use of thoracic endografts in endovascular repair of abdominal aortic aneurysms necks. We present four patients who underwent elective repair of AAAs. Preoperative imaging tic necks (35–37 mm) precluding treatment with standard abdominal aortic devices. All underwent luded the use of a Zenith TX2 endograft (Cook Medical Incorporated, Bloomington, IN, USA) as a 0% technical success. One patient developed gastrointestinal bleeding and a myocardial infarction. home. On follow-up, there was one aneurysm-related death at three months. The remaining three 7 months after their operation. In conclusion, large proximal aortic necks preclude endovascular al endograft components. The use of a thoracic endograft as a proximal aortic cuff is a feasible ternate open aortic reconstruction.

n repair; proximal neck; neck diameter; thoracic endograft; adjunct aortic cuff

decades ago, endovascular
A) repair (EVAR) has been
effective treatment modality
merous clinical trials have
nefits of EVAR compared
Despite these advantages,
tients with optimal aortic
cs such as a challenging
iameter) may preclude the
report, we present the use
Cook Medical Incorporated,
R with large-diameter aortic

Case reports

Four male patients with a mean age of 74.3 years presented for elective AAA repair. Preoperative computed tomography (CT) imaging demonstrated large-diameter aortic necks (35–37 mm) in each patient and all were considered prohibitive candidates to undergo open surgical repair due to multiple medical co-morbidities. All EVARs were performed in the operating room under general anesthesia with endotracheal intubation. Open-surgical exposure of the bilateral femoral vessels was utilized and imaging was performed with portable C-arm fluoroscopy.

Case 1

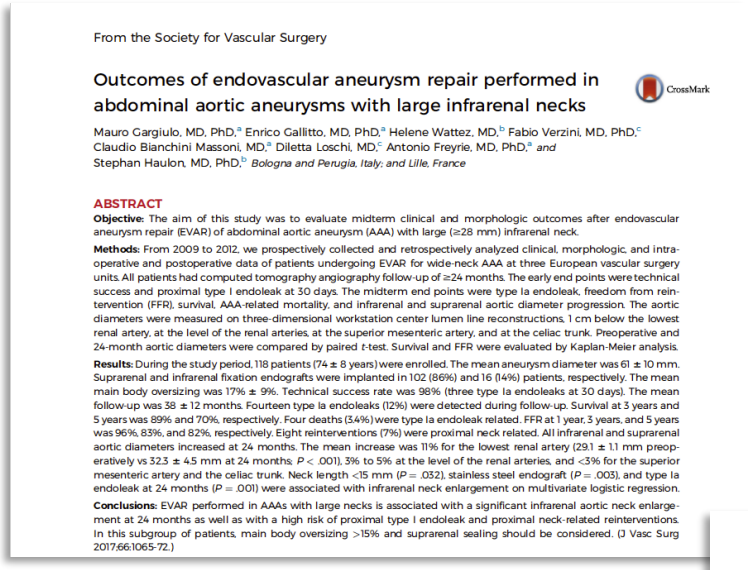
A 65-year-old man with a history of recent myocardial infarction (MI) and end-stage renal disease requiring peritoneal dialysis presented with a 6.4 cm juxtarenal AAA (Figure 1). The proximal landing zone was above the level of the renal arteries and measured 35 mm in diameter. He underwent coil embolization of the bilateral renal arteries prior to placement of a 32 mm Zenith bifurcated device (Cook Medical Incorporated) distally. To protect the superior mesenteric artery (SMA) during proximal endograft deployment, a wire

rtment of Surgery, Washington
s, MO, USA; †Indiana University
USA

Washington University School of
8108, St Louis, MO 63110, USA;

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established. ©2021 Endologix LLC. All rights reserved. MM1918 Rev 03.

EVAR durability: developing information on wide aortic necks



From the Society for Vascular Surgery

Outcomes of endovascular aneurysm repair performed in abdominal aortic aneurysms with large infrarenal necks

Mauro Gargiulo, MD, PhD,[a] Enrico Gallitto, MD, PhD,[a] Helene Wattez, MD,[b] Fabio Verzini, MD, PhD,[c] Claudio Bianchini Massoni, MD,[a] Diletta Loschi, MD,[c] Antonio Freyrie, MD, PhD,[a] *and* Stephan Haulon, MD, PhD,[b] *Bologna and Perugia, Italy; and Lille, France*

ABSTRACT

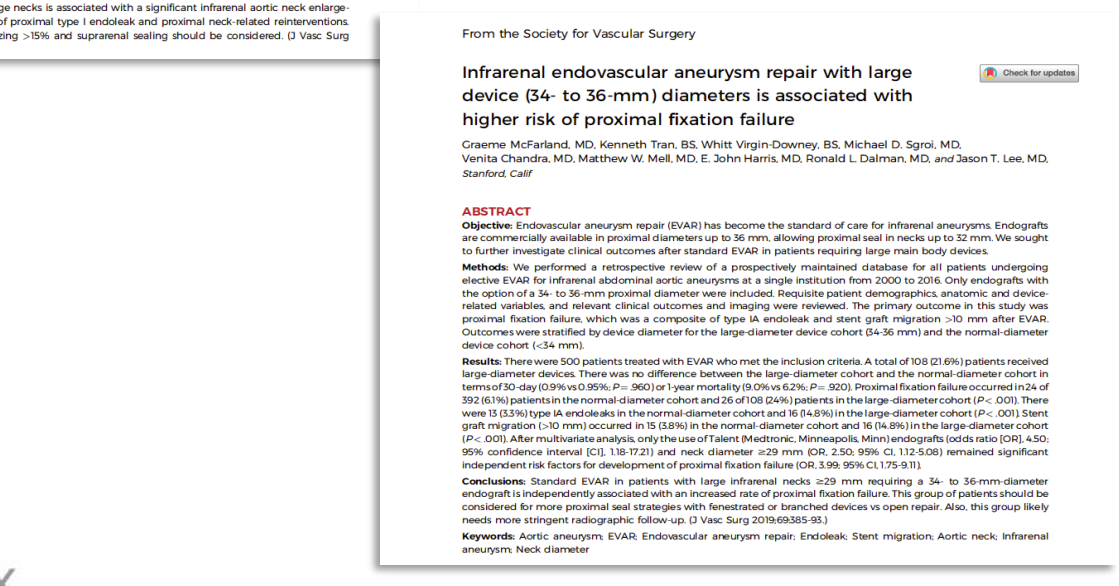
Objective: The aim of this study was to evaluate midterm clinical and morphologic outcomes after endovascular aneurysm repair (EVAR) of abdominal aortic aneurysm (AAA) with large (≥28 mm) infrarenal neck.

Methods: From 2009 to 2012, we prospectively collected and retrospectively analyzed clinical, morphologic, and intraoperative and postoperative data of patients undergoing EVAR for wide-neck AAA at three European vascular surgery units. All patients had computed tomography angiography follow-up of ≥24 months. The early end points were technical success and proximal type I endoleak at 30 days. The midterm end points were type Ia endoleak, freedom from reintervention (FFR), survival, AAA-related mortality, and infrarenal and suprarenal aortic diameter progression. The aortic diameters were measured on three-dimensional workstation center lumen line reconstructions, 1 cm below the lowest renal artery, at the level of the renal arteries, at the superior mesenteric artery, and at the celiac trunk. Preoperative and 24-month aortic diameters were compared by paired *t*-test. Survival and FFR were evaluated by Kaplan-Meier analysis.

Results: During the study period, 118 patients (74 ± 8 years) were enrolled. The mean aneurysm diameter was 61 ± 10 mm. Suprarenal and infrarenal fixation endografts were implanted in 102 (86%) and 16 (14%) patients, respectively. The mean main body oversizing was 17% ± 9%. Technical success rate was 98% (three type Ia endoleaks at 30 days). The mean follow-up was 38 ± 12 months. Fourteen type Ia endoleaks (12%) were detected during follow-up. Survival at 3 years and 5 years was 89% and 70%, respectively. Four deaths (3.4%) were type Ia endoleak related. FFR at 1 year, 3 years, and 5 years was 96%, 83%, and 82%, respectively. Eight reinterventions (7%) were proximal neck related. All infrarenal and suprarenal aortic diameters increased at 24 months. The mean increase was 11% for the lowest renal artery (29.1 ± 1.1 mm preoperatively vs 32.3 ± 4.5 mm at 24 months; $P < .001$), 3% to 5% at the level of the renal arteries, and <3% for the superior mesenteric artery and the celiac trunk. Neck length <15 mm ($P = .032$), stainless steel endograft ($P = .003$), and type Ia endoleak at 24 months ($P = .001$) were associated with infrarenal neck enlargement on multivariate logistic regression.

Conclusions: EVAR performed in AAAs with large necks is associated with a significant infrarenal aortic neck enlargement at 24 months as well as with a high risk of proximal type I endoleak and proximal neck-related reinterventions. In this subgroup of patients, main body oversizing >15% and suprarenal sealing should be considered. (J Vasc Surg 2017;66:1065-72.)

- >28mm neck
- 38 month mean follow up
- 12% Type IA endoleak, 3.4% endoleak related death
- 7% proximal neck reintervention



From the Society for Vascular Surgery

Infrarenal endovascular aneurysm repair with large device (34- to 36-mm) diameters is associated with higher risk of proximal fixation failure

Graeme McFarland, MD, Kenneth Tran, BS, Whitt Virgin-Downey, BS, Michael D. Sgroi, MD, Venita Chandra, MD, Matthew W. Mell, MD, E. John Harris, MD, Ronald L. Dalman, MD, *and* Jason T. Lee, MD, *Stanford, Calif*

ABSTRACT

Objective: Endovascular aneurysm repair (EVAR) has become the standard of care for infrarenal aneurysms. Endografts are commercially available in proximal diameters up to 36 mm, allowing proximal seal in necks up to 32 mm. We sought to further investigate clinical outcomes after standard EVAR in patients requiring large main body devices.

Methods: We performed a retrospective review of a prospectively maintained database for all patients undergoing elective EVAR for infrarenal abdominal aortic aneurysms at a single institution from 2000 to 2016. Only endografts with the option of a 34- to 36-mm proximal diameter were included. Requisite patient demographics, anatomic and device-related variables, and relevant clinical outcomes and imaging were reviewed. The primary outcome in this study was proximal fixation failure, which was a composite of type IA endoleak and stent graft migration >10 mm after EVAR. Outcomes were stratified by device diameter for the large-diameter device cohort (34-36 mm) and the normal-diameter device cohort (<34 mm).

Results: There were 500 patients treated with EVAR who met the inclusion criteria. A total of 108 (21.6%) patients received large-diameter devices. There was no difference between the large-diameter cohort and the normal-diameter cohort in terms of 30-day (0.9% vs 0.95%; $P = .960$) or 1-year mortality (9.0% vs 6.2%; $P = .920$). Proximal fixation failure occurred in 24 of 392 (6.1%) patients in the normal-diameter cohort and 26 of 108 (24%) patients in the large-diameter cohort ($P < .001$). There were 13 (3.3%) type IA endoleaks in the normal-diameter cohort and 16 (14.8%) in the large-diameter cohort ($P < .001$). Stent graft migration (>10 mm) occurred in 15 (3.8%) in the normal-diameter cohort and 16 (14.8%) in the large-diameter cohort ($P < .001$). After multivariate analysis, only the use of Talent (Medtronic, Minneapolis, Minn) endografts (odds ratio [OR], 4.50; 95% confidence interval [CI], 1.18-17.21) and neck diameter ≥29 mm (OR, 2.50; 95% CI, 1.12-5.08) remained significant independent risk factors for development of proximal fixation failure (OR, 3.99; 95% CI, 1.75-9.11).

Conclusions: Standard EVAR in patients with large infrarenal necks ≥29 mm requiring a 34- to 36-mm-diameter endograft is independently associated with an increased rate of proximal fixation failure. This group of patients should be considered for more proximal seal strategies with fenestrated or branched devices vs open repair. Also, this group likely needs more stringent radiographic follow-up. (J Vasc Surg 2019;69:385-93.)

Keywords: Aortic aneurysm; EVAR; Endovascular aneurysm repair; Endoleak; Stent migration; Aortic neck; Infrarenal aneurysm; Neck diameter

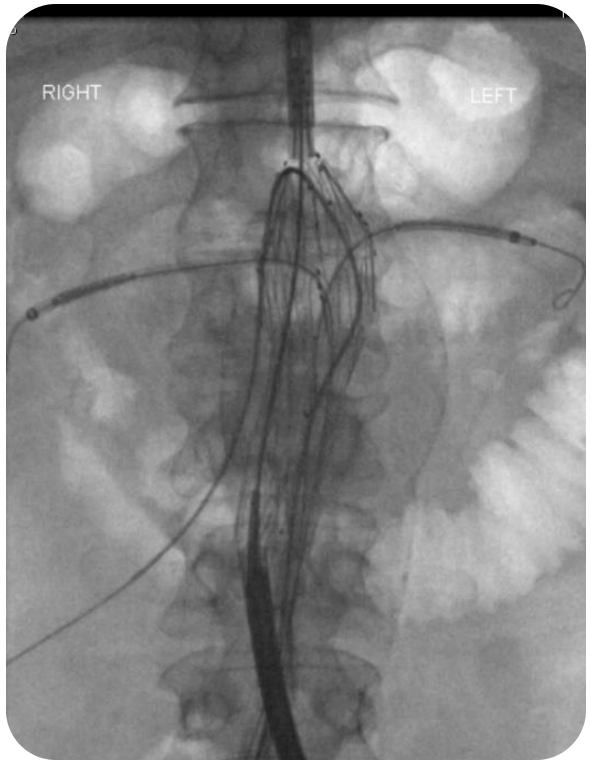
- >34mm vs <34mm devices
- Proximal fixation failure 6.1% vs 24%
- Type IA endoleak 3.3% vs 14.8%
- Migration 3.8% vs 14.8%

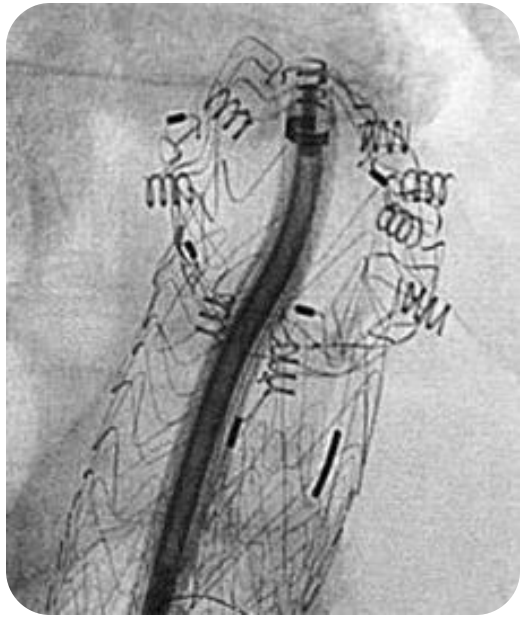
Endologix

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established. MM1918 Rev 03.

Wide neck analysis – why now?

- Validation that aortic neck dilation is common after EVAR
- Associated with wide proximal neck and degree of oversizing
- Suggestion that the use of endoanchors reduces aortic neck dilatation and increases sac regression
- Contention that fenestrated grafts increase the length of seal zone and are opposed to healthy aorta resistant to dilation

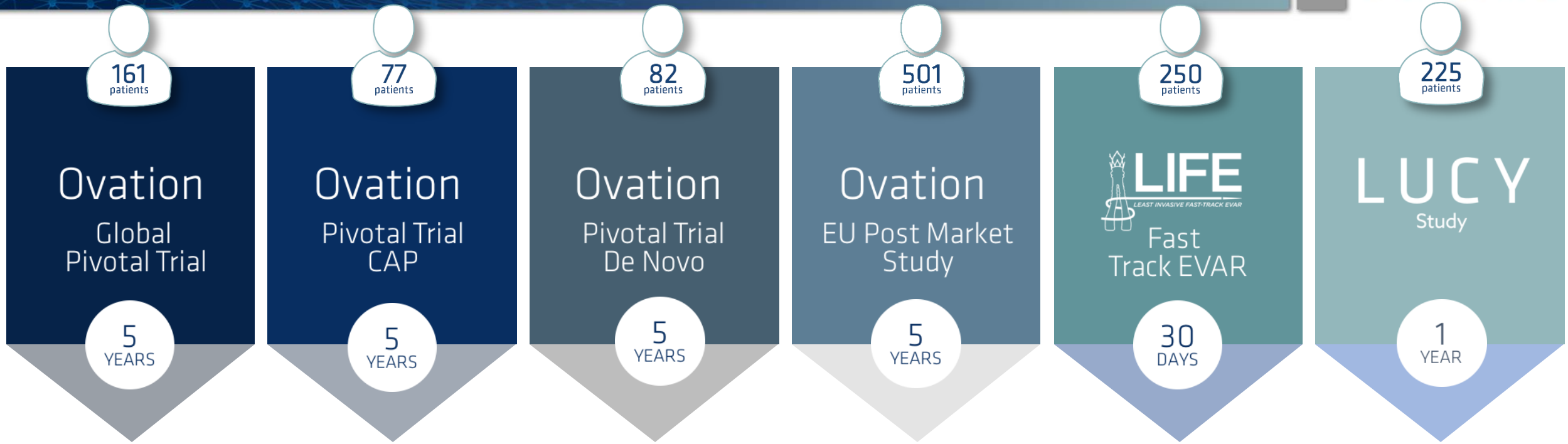




Tassipoulos et al JVS 2017; 66: 45
Muhs et al JVS 2018; 67: 1699

Endologix

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established. MM1918 Rev 03.



E·N·C·O·R·E

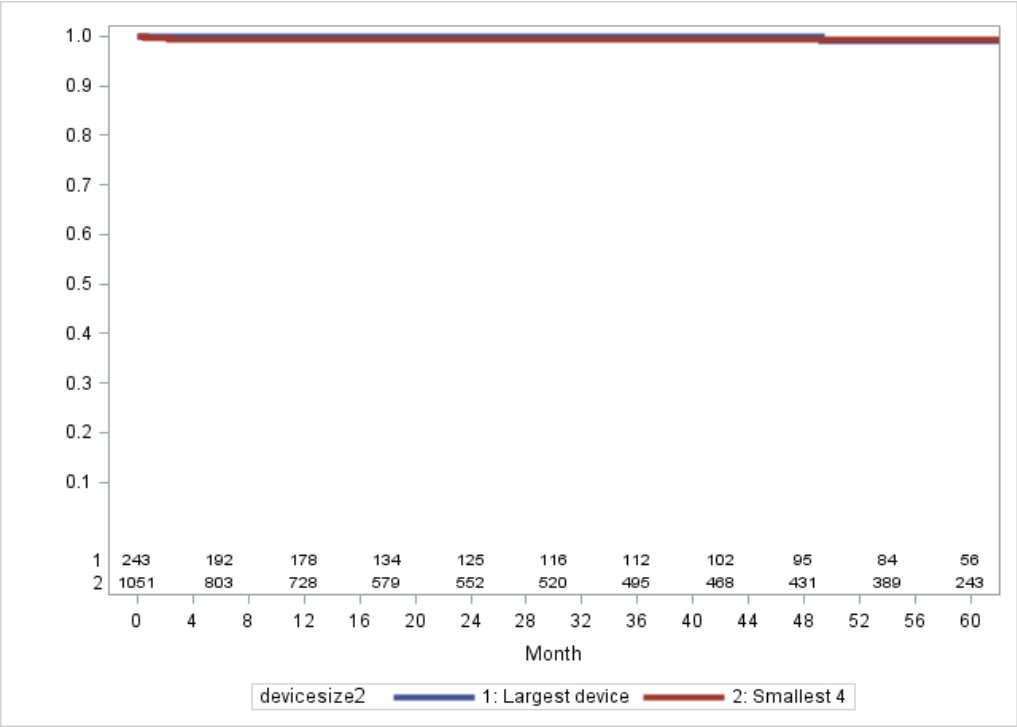
EffectiveNess of Custom Seal with Ovation: Review of the Evidence

The Ovation platform product family includes a series of device iterations using adaptive neck sealing technology such as Ova tion, Ovation Prime, Ovation iX, and Alto. The devices included in the studies used in the ENCORE Analysis all include adaptive sealing technology.

Endologix

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established. MM1918 Rev 03.

Freedom from AAA-Related Mortality



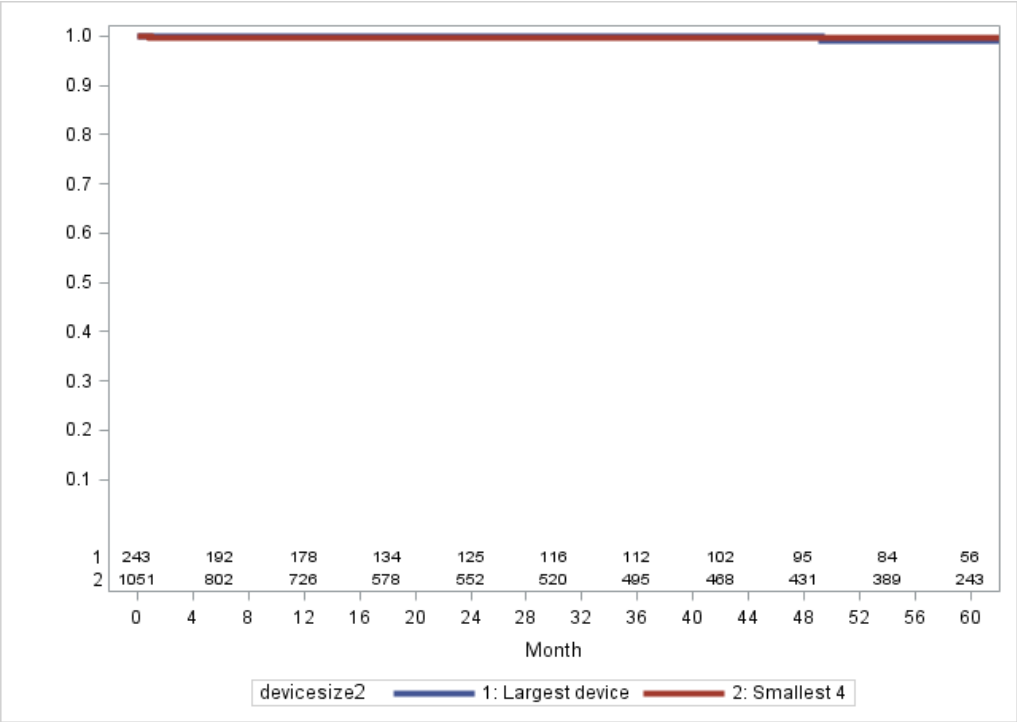
Durability remains consistent regardless of size

Device Diameter (mm)	5 years
34	98.9%
20, 23, 26, 29	99.4%

ENCORE Data Cut: March 20, 2019

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established. MM1918 Rev 03.

Freedom from Rupture



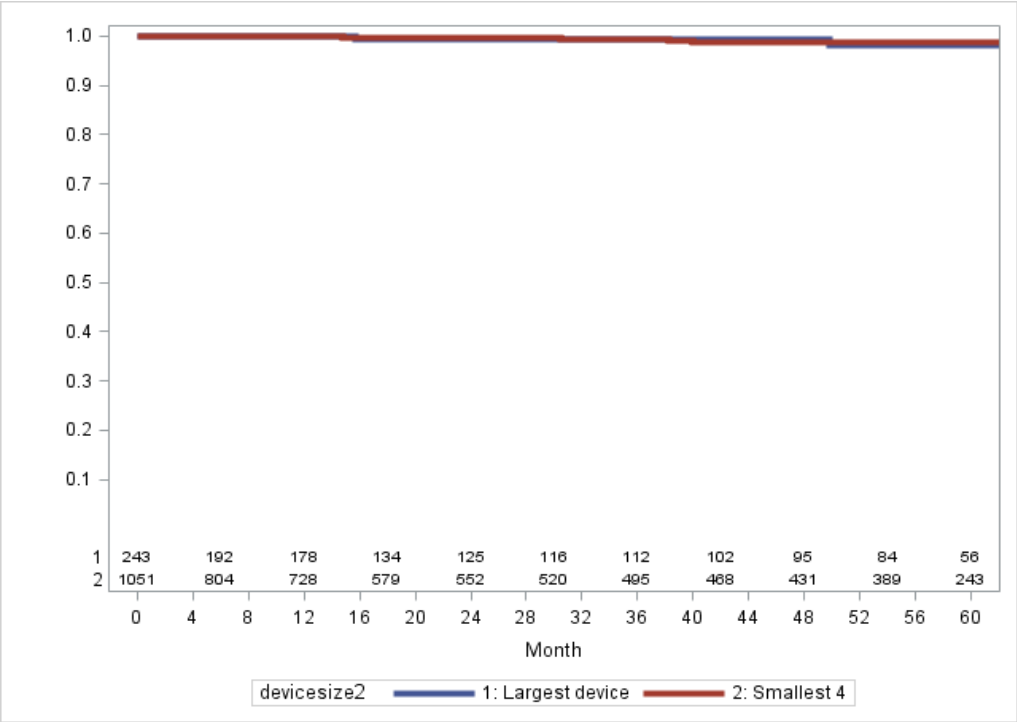
Durability remains consistent regardless of size

Device Diameter (mm)	5 years
34	98.9%
20, 23, 26, 29	99.6%

ENCORE Data Cut: March 20, 2019

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established.

Freedom from Conversion



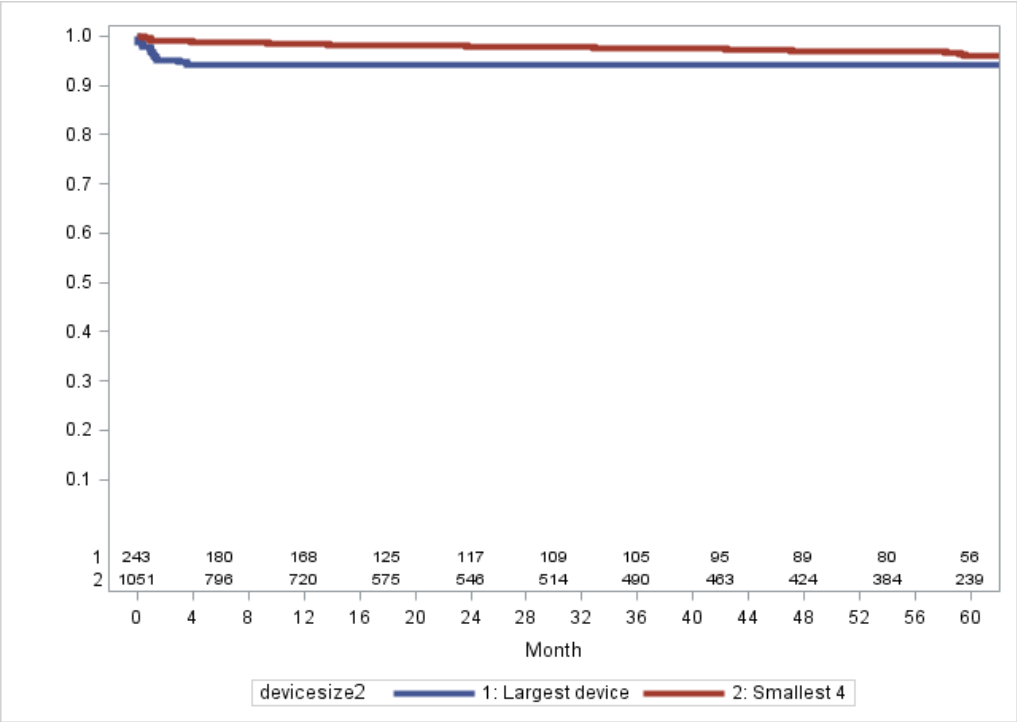
Durability remains consistent regardless of size

Device Diameter (mm)	5 years
34	98.2%
20, 23, 26, 29	98.6%

ENCORE Data Cut: March 20, 2019

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established.

Freedom from Type IA Endoleak



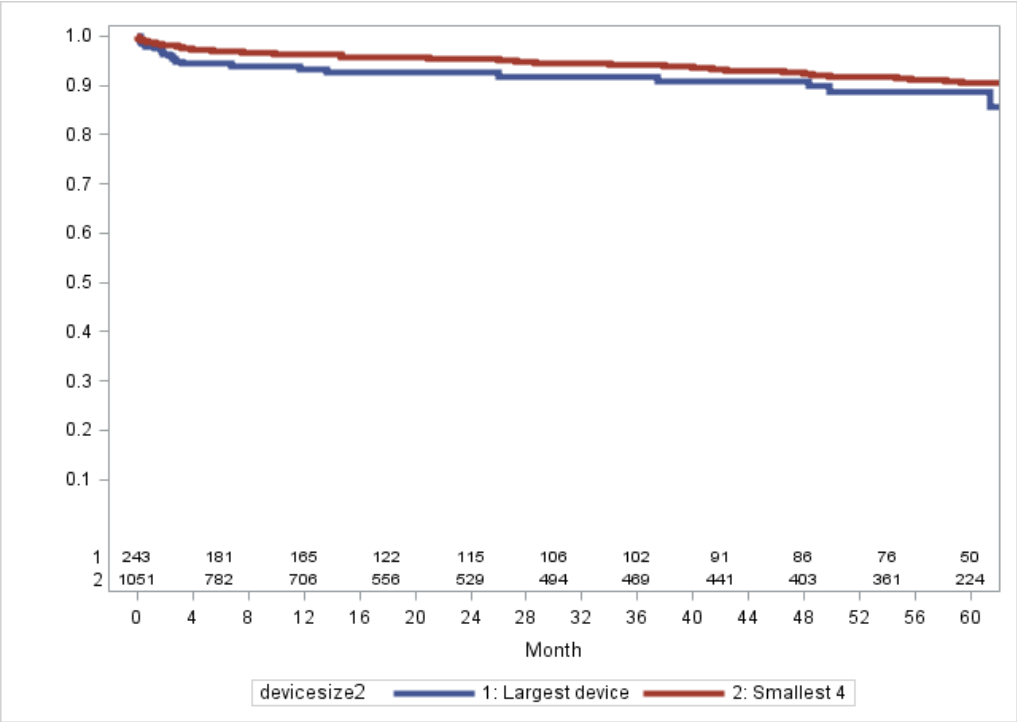
No degradation of performance over time

Device Diameter (mm)	5 years
34	94.2%
20, 23, 26, 29	96.1%

ENCORE Data Cut: March 20, 2019

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established.

Freedom from Device-Related Reintervention



Durability remains consistent regardless of size

Device Diameter (mm)	5 years
34	88.7%
20, 23, 26, 29	90.6%

ENCORE Data Cut: March 20, 2019

ENCORE includes results from a real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation when used outside the IFU have not been established. MM1918 Rev 03.


Endologix

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