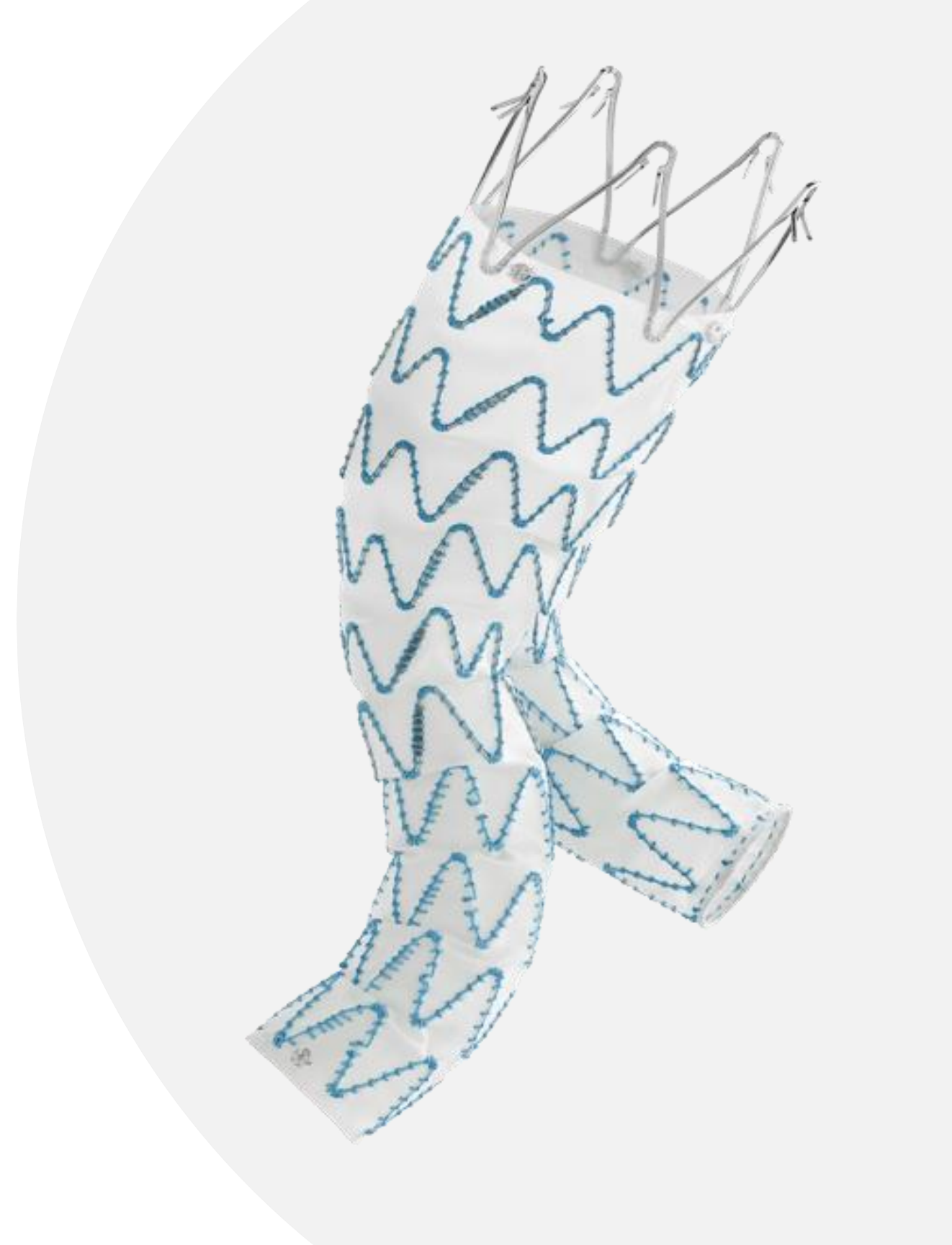


Medtronic

Engineering the extraordinary


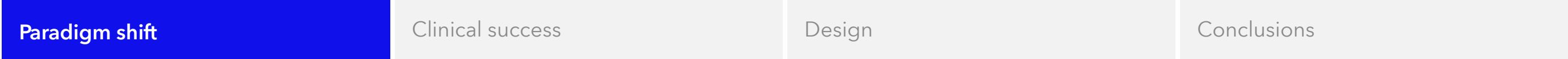
Endurant™ delivers sac regression with long-term outcomes

The New Standard of EVAR Durability

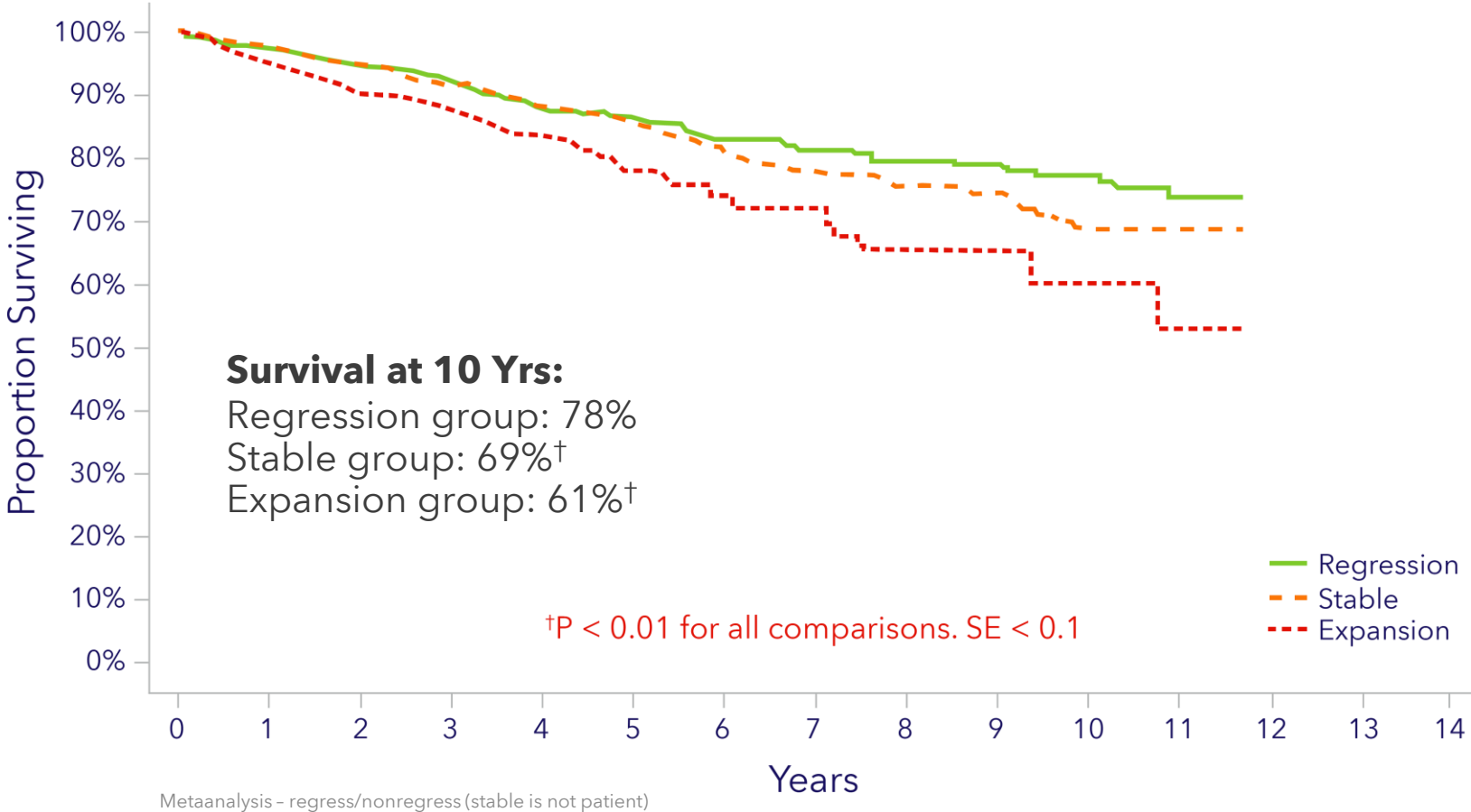


Evidence¹ links sac regression to better long-term survival

Endurant patients survival at 10 years from intervention¹



14,817
total subjects in VQI
(Vascular Quality Initiative)
subjected to EVAR
between 2003-2017¹



1. O'Donnell TFX, Deery SE, Boitano LT, et al. Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival. J Vasc Surg. 2019;69(2):414-422

ENGAGE OUS Registry confirms sac regression link to improved outcomes¹

Endurant patients survival and freedom from secondary re-intervention at 5 years¹

Paradigm shift

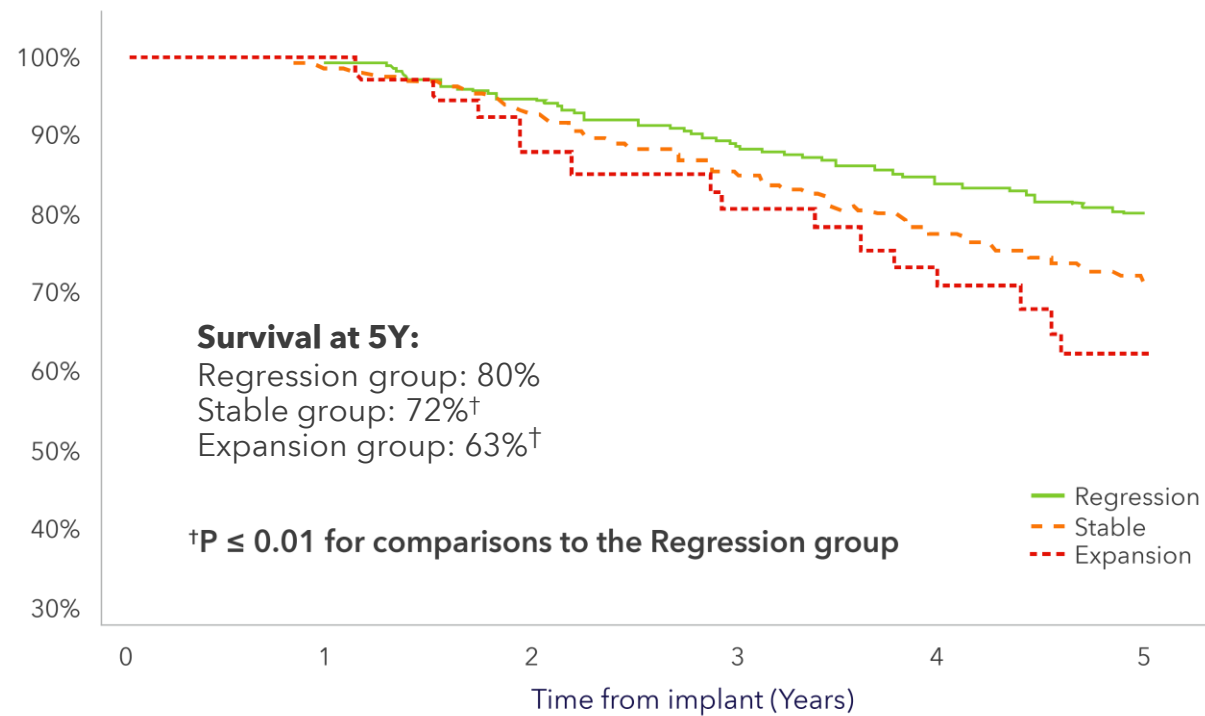
Clinical success

Design

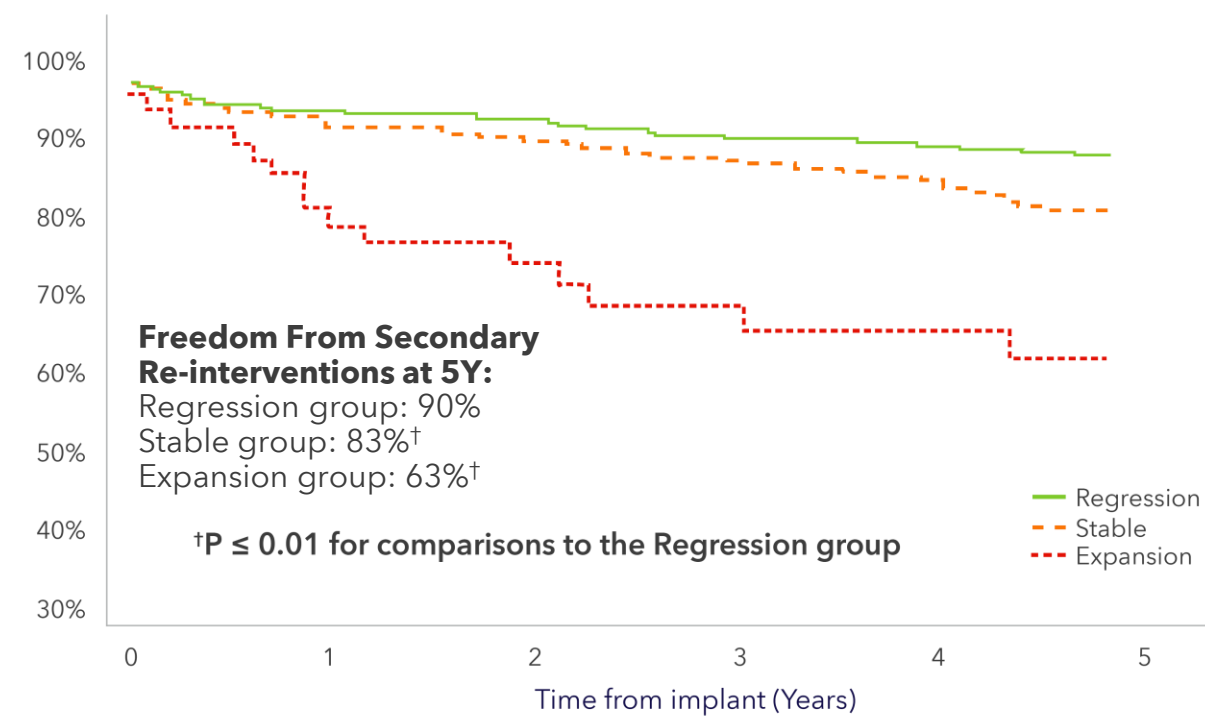
Conclusions

949 Patients with 1mo and 1yr imaging (ENGAGE OUS Registry)

Freedom from all cause mortality



Freedom from secondary endovascular re-interventions

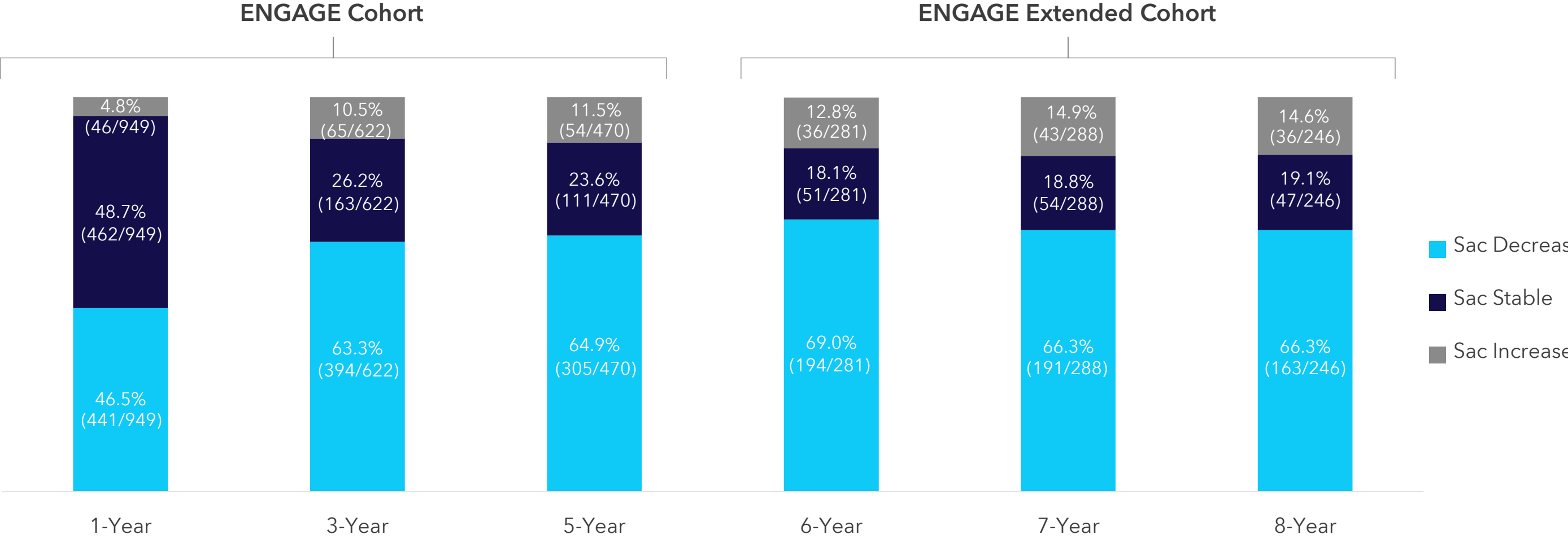


1. Böckler D, Li C, Dansey K, et al. Sac regression is associated with lower all-cause mortality after contemporary endovascular aneurysm repair - a new paradigm for success. Presentation presented online at: ESVS 34th Annual Meeting. October 6, 2020.

Endurant™ stent graft system delivers durability with sac regression

Endurant patients show consistent and high sac regression from 3 - 8 years in Real-World ENGAGE OUS Registry¹

Paradigm shift **Clinical success** Design Conclusions



1. Hence J.M Vehagen, Dittmar Bockler, Ian M. Loftus, Michel M.P.J. Reijnen, Frank R. Arko III, Joep Teijink, Brett Peterson, Marc L. Schermerhorn. How Sac Regression at 1Y affects All-Cause Mortality at Extended Timepoints: Key Insights from the ENGAGE Registry Charing Cross International Symposium, 26-28 April 2022, London UK. First to Podium., UC202301235 EN ©2022 Medtronic | 05/2022

Endurant™ demonstrates continued durable outcomes

Endurant™ patients with sac regression demonstrate significantly lower all-cause mortality¹



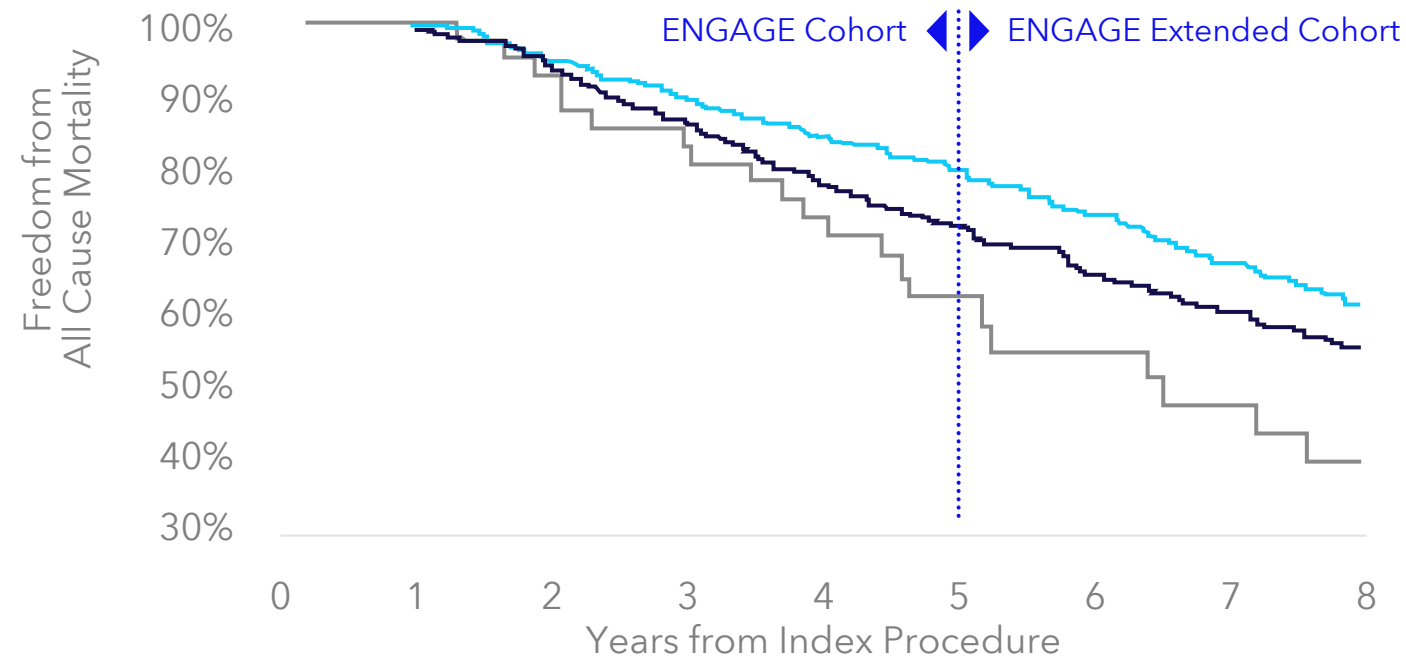
FF ACM through 8 years

Decrease 61.9±3.1% reference

Stable 56.4±3.1% p=.035

Increase 40.7±9.4% p=.005

p-values are comparisons to sac decrease group



No. at risk

	0	1	2	3	4	5	6	7	8
Decrease	441	438	395	362	331	272	191	172	155
Stable	462	457	401	358	316	254	174	161	142
Increase	46	45	37	33	28	21	15	13	11

1mo post op imaging used as baseline for determination of 1yr sac status group. Of the 1263 enrolled in ENGAGE, 949 had 1mo and 1yr imaging. Of the 390 patients who consented to the extended FU, 352 had 1mo and 1yr imaging

1. Hence J.M Vehagen, Dittmar Bockler, Ian M. Loftus, Michel M.P.J. Reijnen, Frank R. Arko III, Joep Teijink, Brett Peterson, Marc L. Schermerhorn. How Sac Regression at IY affects All-Cause Mortality at Extended Timepoints: Key Insights from the ENGAGE Registry Charing Cross International Symposium, 26-28 April 2022, London UK. First to Podium., UC202301235 EN ©2022 Medtronic 05/2022

Endurant™ demonstrates continued durable outcomes

Patients with sac regression demonstrate significantly lower secondary procedures¹



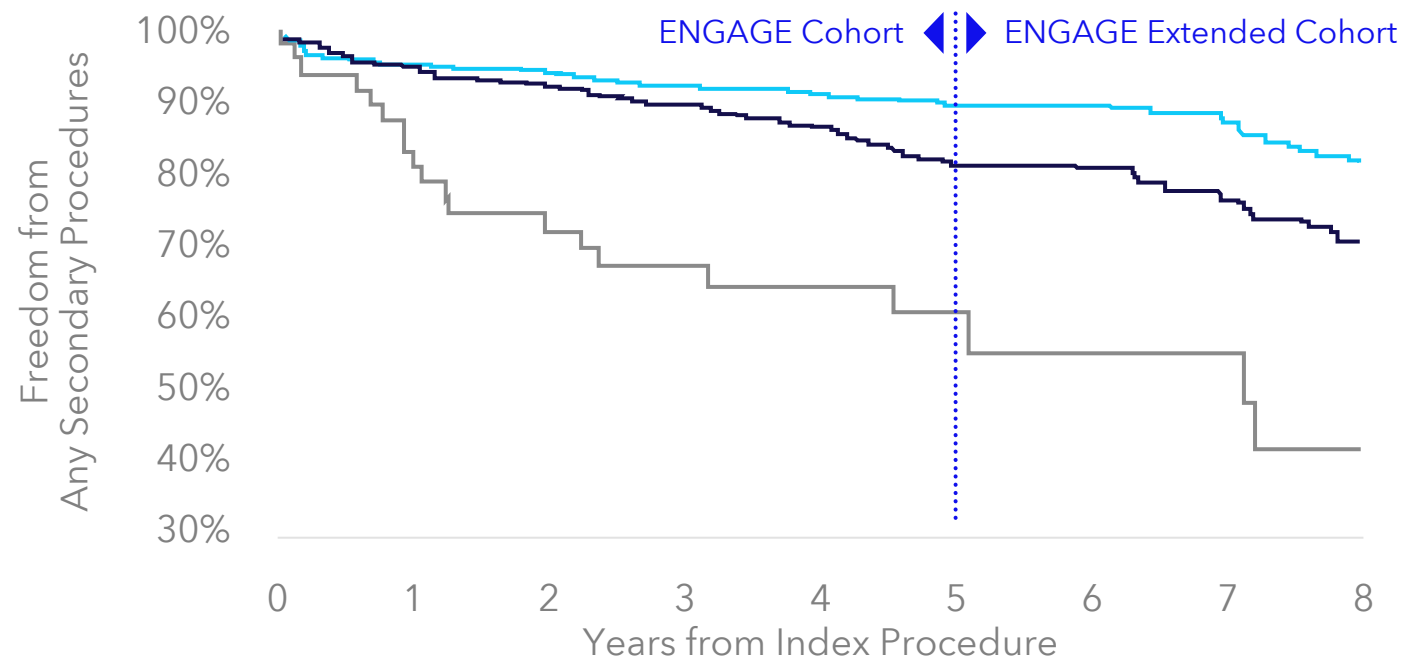
FF Secondary Procedures through 8 years

Decrease 80.7±3.1% reference

Stable 69.6±3.8% p=.002

Increase 40.2±12.7% p<.0001

p-values are comparisons to sac decrease group

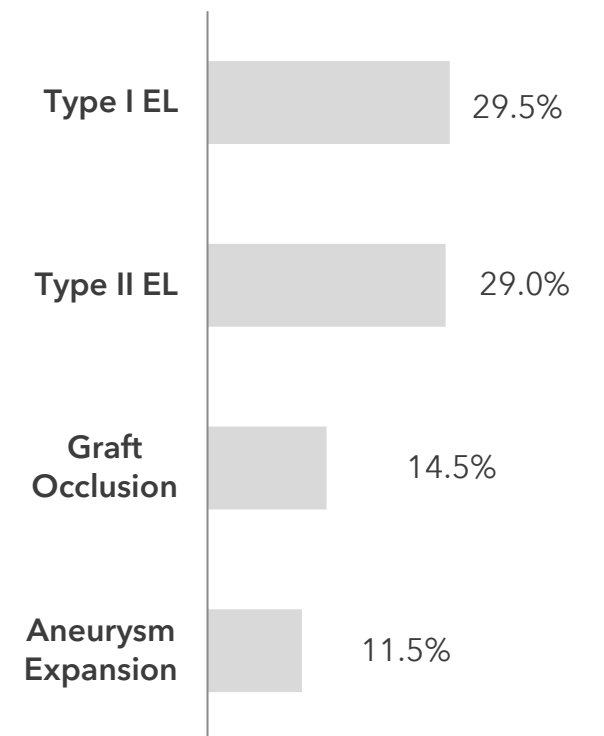


No. at risk

Decrease	441	416	377	340	303	236	155	149	127
Stable	462	431	365	316	270	200	130	121	102
Increase	46	37	29	23	19	14	9	8	5

1mo post op imaging used as baseline for determination of 1yr sac status group. Of the 1263 enrolled in ENGAGE, 949 had 1mo and 1yr imaging. Of the 390 patients who consented to the extended FU, 352 had 1mo and 1yr imaging

Reasons* for secondary endovascular procedures through 8 years



* A subject may have multiple reasons for the same secondary endovascular procedure

1. Hence J.M Vehagen, Dittmar Bockler, Ian M. Loftus, Michel M.P.J. Reijnen, Frank R. Arko III, Joep Teijink, Brett Peterson, Marc L. Schermerhorn. How Sac Regression at IY affects All-Cause Mortality at Extended Timepoints: Key Insights from the ENGAGE Registry Charing Cross International Symposium, 26-28 April 2022, London UK. First to Podium., UC202301235 EN ©2022 Medtronic 05/2022

Endurant™ demonstrates continued durable outcomes

Patients with sac regression demonstrate significantly lower endoleaks¹

Paradigm shift

Clinical success

Design

Conclusions

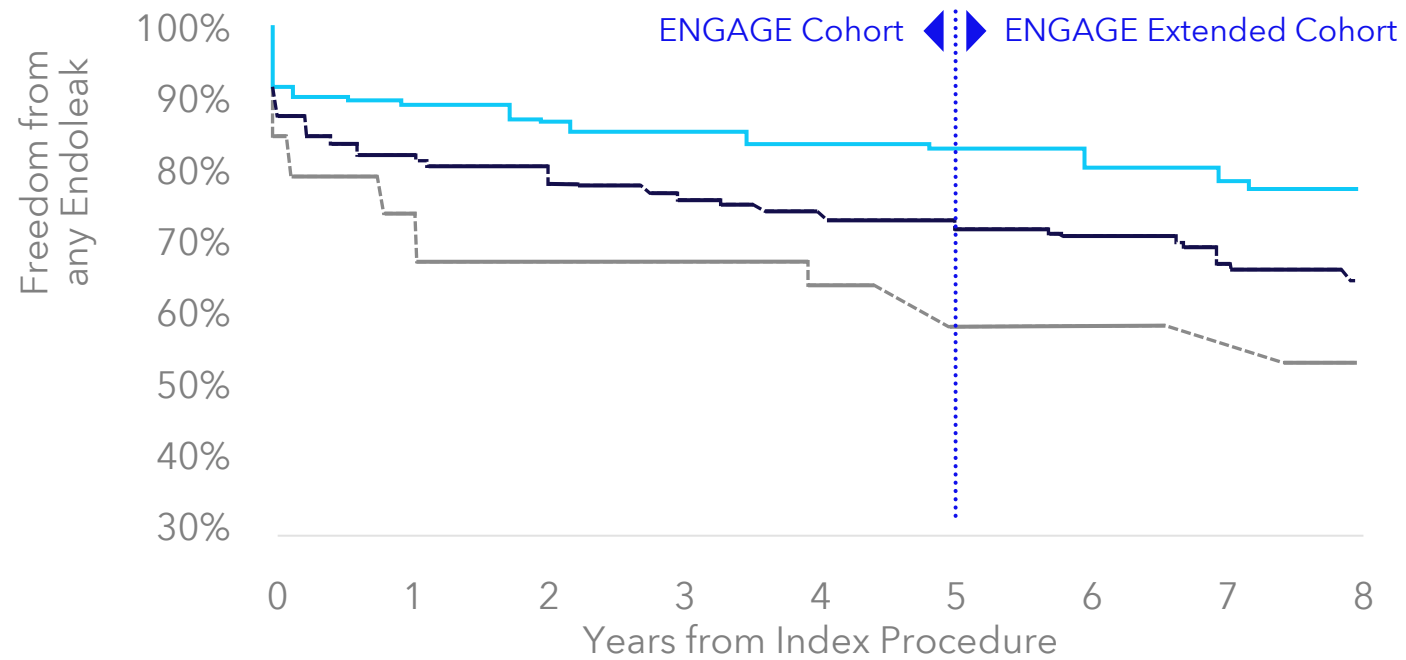
FF Any Endoleak through 8 years

Decrease 68.4±2.3% reference

Stable 52.9±2.4% p<.0001

Increase 35.4±7.1% p<.0001

p-values are comparisons to sac decrease group



No. at risk

	0	1	2	3	4	5	6	7	8
Decrease	441	365	319	255	218	134	129	115	96
Stable	462	333	278	215	175	104	98	89	74
Increase	46	29	22	18	16	11	9	6	4

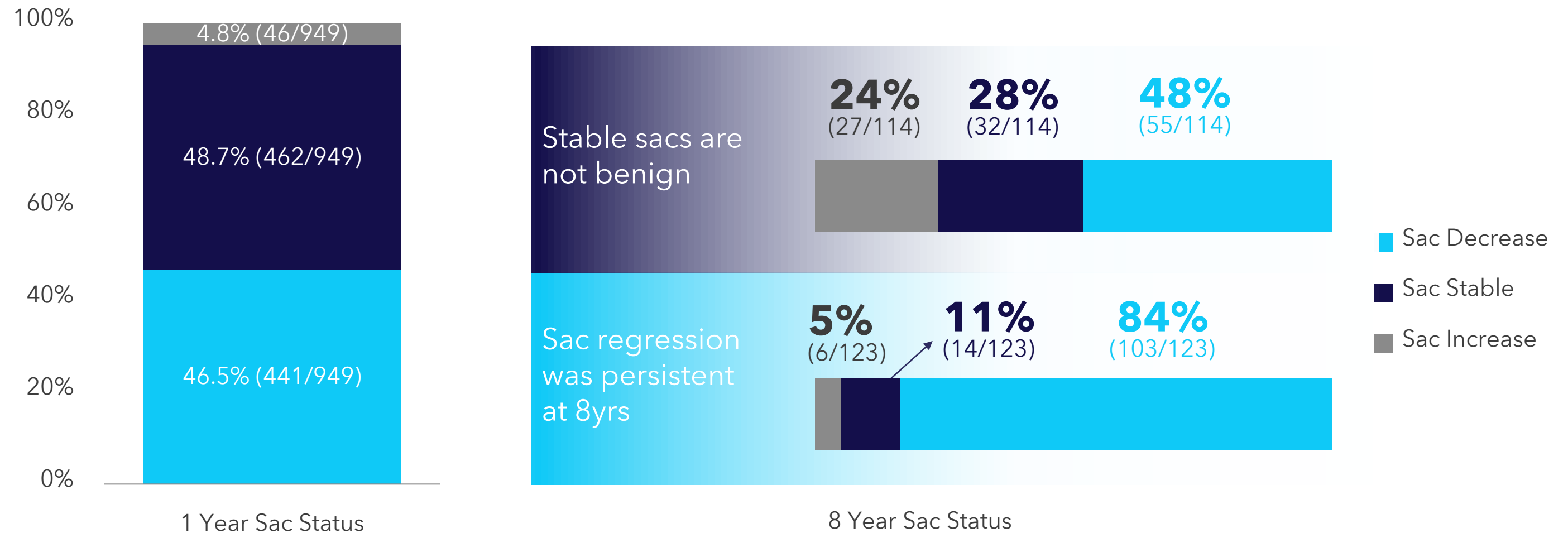
1mo post op imaging used as baseline for determination of 1yr sac status group. Of the 1263 enrolled in ENGAGE, 949 had 1mo and 1yr imaging. Of the 390 patients who consented to the extended FU, 352 had 1mo and 1yr imaging

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Sac regression with Endurant™ at 1Y is an indicator for high sac regression at 8Y

84% of Endurant patients who had sac regression at one year and had available images at 8Y demonstrated persistent sac regression¹

Paradigm shift	Clinical success	Design	Conclusions
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1. Hence J.M Vehagen, Dittmar Bockler, Ian M. Loftus, Michel M.P.J. Reijnen, Frank R. Arko III, Joep Tejjink, Brett Peterson, Marc L. Schermerhorn. How Sac Regression at 1Y affects All-Cause Mortality at Extended Timepoints: Key Insights from the ENGAGE Registry Charing Cross International Symposium, 26-28 April 2022, London UK. First to Podium., UC202301235 EN ©2022 Medtronic 05/2022

The drivers of sac regression are multifactorial.²

Case study

Paradigm shift

Clinical success

Design

Conclusions

Stent graft design affects sac regression²

⊕ Patient factors

⊕ Procedural & post-operative factors

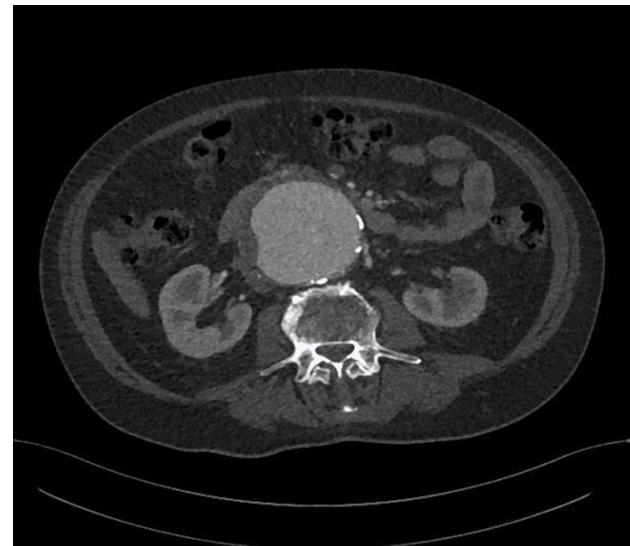
⊕ Stent graft design factors

70+-year-old male; 86 mm AAA¹

- Proximal neck length: 20mm
- Proximal neck diameter: 26mm
- Long tortuous Iliacs
- Iliacs diameter: 14-15mm

Implant: Endurant™ 32-16mm

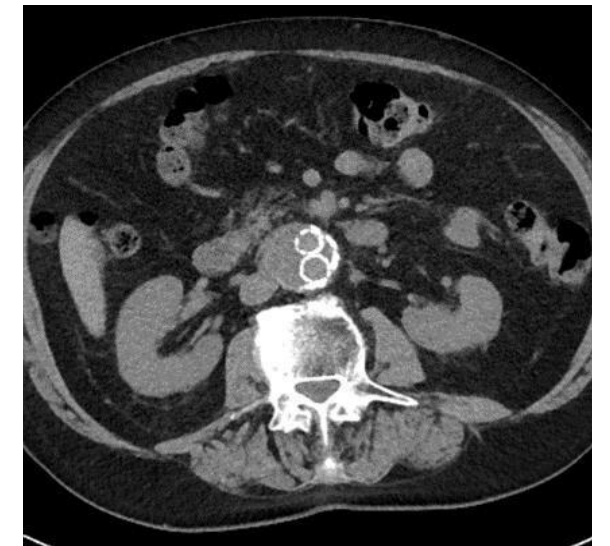
Pre op (86mm)



1-year post op (49mm)



5-years post op (39mm)



1. Case study and images courtesy of Dr. Hence Verhagen

2. Florent Lalys PhD et al. Influence factors of sac shrinkage after endovascular aneurysm repair. J of Vasc Surg. Jun 2017; 65 (6) :1830-38

The drivers of sac regression are multifactorial.²

Case study

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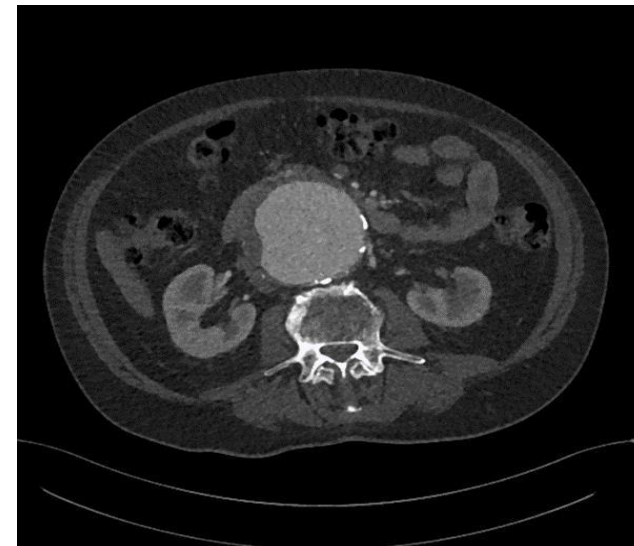
⊕ Patient factors

- Demographics
- Treatment medications
- Co-morbidities
- Aneurysm morphology

⊕ Procedural & post-operative factors

⊕ Stent graft design factors

Pre op (86mm)



1-year post op (49mm)



5-years post op (39mm)



1. Case study and images courtesy of Dr. Hence Verhagen

2. Florent Lalys PhD et al. Influence factors of sac shrinkage after endovascular aneurysm repair. J of Vasc Surg. Jun 2017; 65 (6) :1830-38

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Case study

Paradigm shift

Clinical success

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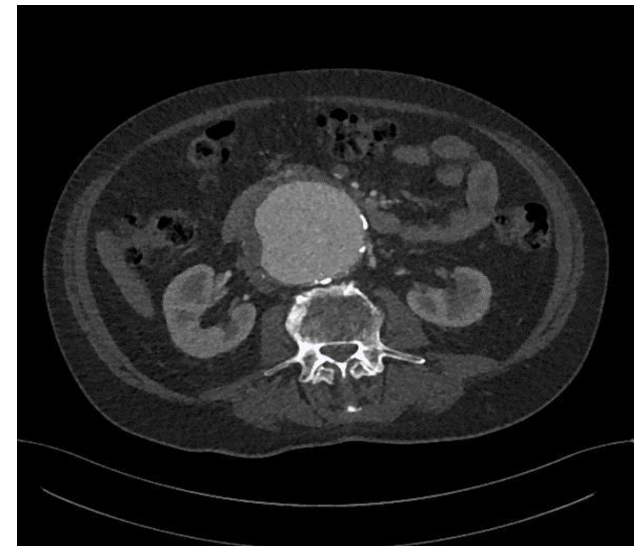
- Imaging quality
- Complications
- Re-interventions
- Endoleaks

70+-year-old male; 86 mm AAA¹

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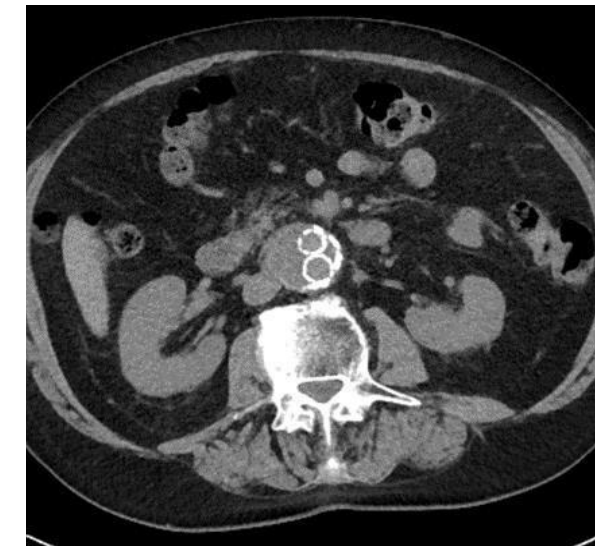
Pre op (86mm)



1-year post op (49mm)



5-years post op (39mm)



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The drivers of sac regression are multifactorial.²

Case study

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Stent graft design affects sac regression²

⊕ Patient factors

⊕ Procedural & post-operative factors

⊕ Stent graft design factors

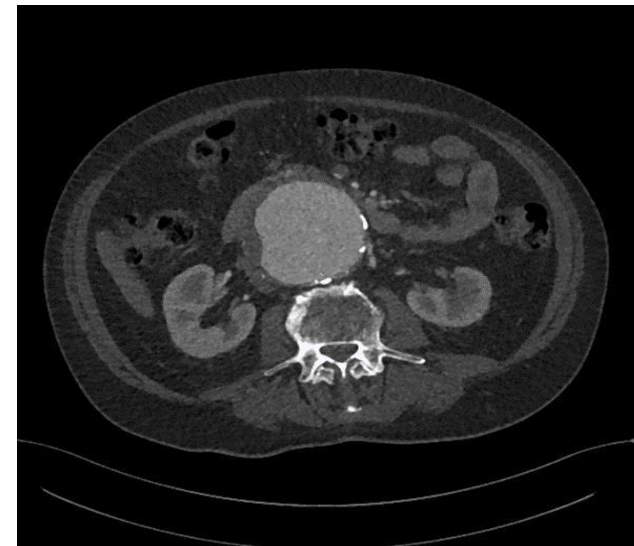
- Pre-case planning
- Graft of choice
 - Graft design

70+-year-old male; 86 mm AAA¹

- Proximal neck length: 20mm
- Proximal neck diameter: 26mm
- Long tortuous Iliacs
- Iliacs diameter: 14-15mm

Implant: Endurant™ 32-16mm

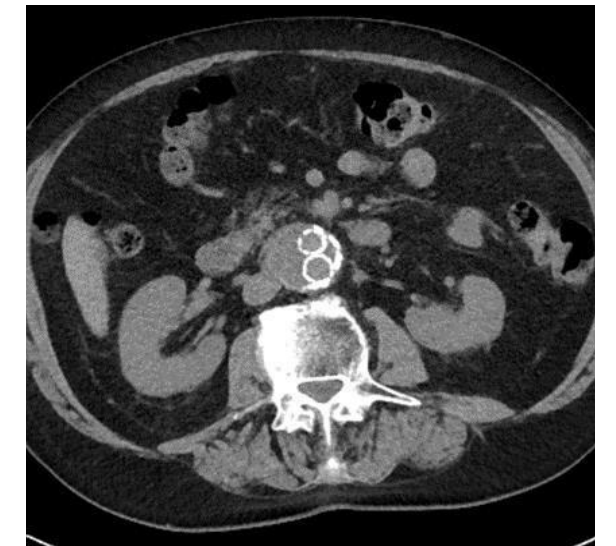
Pre op (86mm)



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1. Case study and images courtesy of Dr. Hence Verhagen

2. Florent Lalys PhD et al. Influence factors of sac shrinkage after endovascular aneurysm repair. J of Vasc Surg. Jun 2017; 65 (6) :1830-38

You're invested. So are we.

Aortic support where and when it matters | Technical expertise | Robust aortic clinical evidence

Paradigm shift

Clinical success

Design

Conclusions



ADVANCE Trial

EndurAnt Stent Graft system vs ExcluDer endoprosthesis:
a global, prospectiVe, rANdomized Clinical trial in sac rEgression

Principal Investigators

Prof. Hencé Verhagen
Professor & Head of Vascular Surgery
Erasmus MC

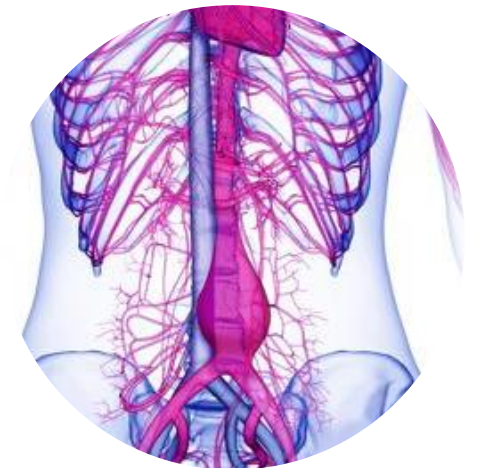
Dr. Marc Schermerhorn
Chief of Vascular and Endovascular Surgery
Beth Israel Deaconess

- Consistent patient population based on overlapping IFU and evaluated by core lab
- Standard EVAR - no planned use of Endoanchors, IBE, AUI or embolization

~275 Endurant
Patients*

1:1 Randomization, 5Y follow-up,
CT images (1M, annually)
Core Lab Adjudicated

~275 Excluder/
Conformable Patients



Primary endpoint

Comparison of **sac regression at 1 year**
based on CT image as analyzed by a core lab

Secondary endpoints

- Sac diameter & volume changes
- Risk factors for sac regression; Type I/II EL
- Sac dynamics as an indicator of long-term outcomes:
Secondary interventions and ACM

Additional outcomes

- Effectiveness and safety outcome comparison
- Systemic inflammation

The Effect of EndoAnchors on Aneurysm Sac Regression for Patients Treated With Infrarenal Endovascular Repair With Hostile Neck Anatomies: A Propensity Scored Analysis

Paradigm shift

Clinical success

Design

Conclusions

[Read the paper](#)

Study purpose

To analyze sac evolution patterns in matched patients with hostile seal zone anatomy (HNA) treated with standard endovascular aneurysm repair (sEVAR) and endosutured aneurysm repair (ESAR)

Study design

Observational retrospective study using prospectively collected data:

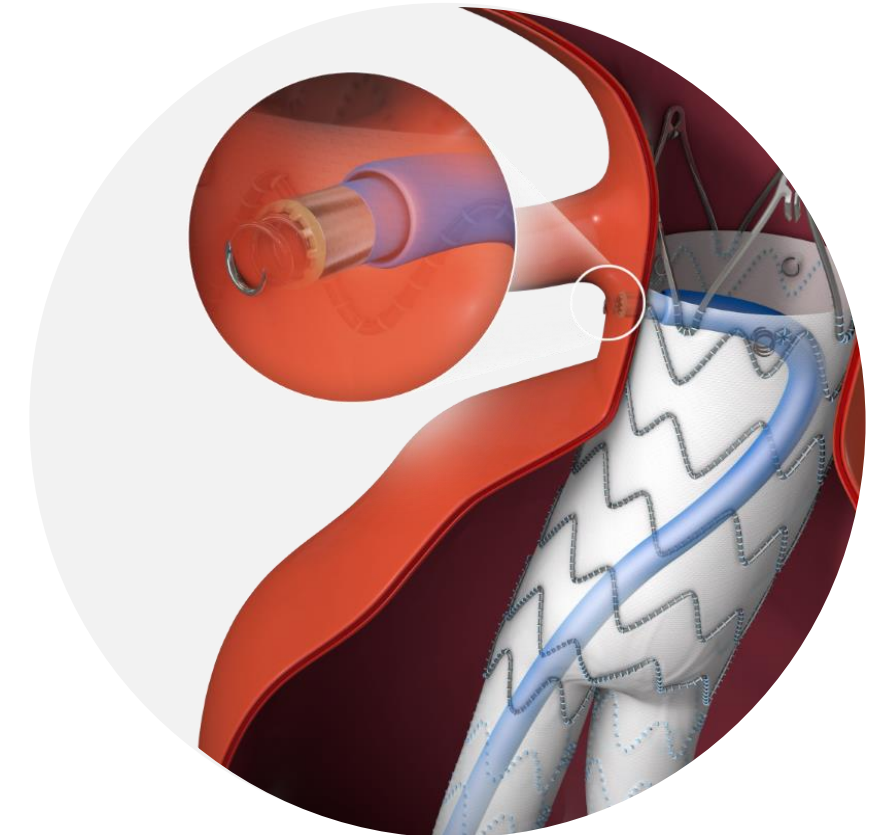
- ESAR: 8 centers (from 1st arm of PERU registry)
- sEVAR: 4 centers

Enrollment

N= 192 patients (96 ESAR, 96 sEVAR)

Suitability for inclusion required:

- no proximal endograft adjuncts
- ≤ 15 mm neck length
- min 12-months follow-up imaging



The Effect of EndoAnchors on Aneurysm Sac Regression for Patients Treated With Infrarenal Endovascular Repair With Hostile Neck Anatomies: A Propensity Scored Analysis

Paradigm shift

Clinical success

Design

Conclusions

[Read the paper](#)

Outcomes	ESAR group	sEVAR group
Sac regression achievement (> 5mm)	n=57, 59.4% (p<.001)	n=31, 32.3%
Cumulative Sac regression at 5 years	65% (p=.003)	38%
Type IA endoleak	3-3.1	5-5.2
Any overall and cumulative 5-ys endoleaks	25-26.0 (p=.747)	28-29.2
AAA related mortality	8.3% (p=.081)	16.7%

ESAR provided improved rates of sac regression for patients with AAA and hostile seal zone anatomies compared to **sEVAR**, at midterm and up to 5 years in this study.

Andrés Reyes Valdivia, MD, PhD, FEBVS, FACS, Kyriakos Oikonomou, MD, PhD, Ross Milner, MD, Piotr Kasprzak, MD, PhD, Michel M. P. J. Reijnen, MD, PhD, Georgios Pitoulis, MD, PhD, Giovanni B. Torsello, MD, PhD, Karin Pfister, MD, PhD, Jean-Paul P. M. de Vries, MD, PhD and Arindam Chaudhuri, MB, MS, FRCSEd, MSc, FRCS

A design that addresses sac regression

Latest insights: Significance of Sac regression and drivers for EVAR outcomes

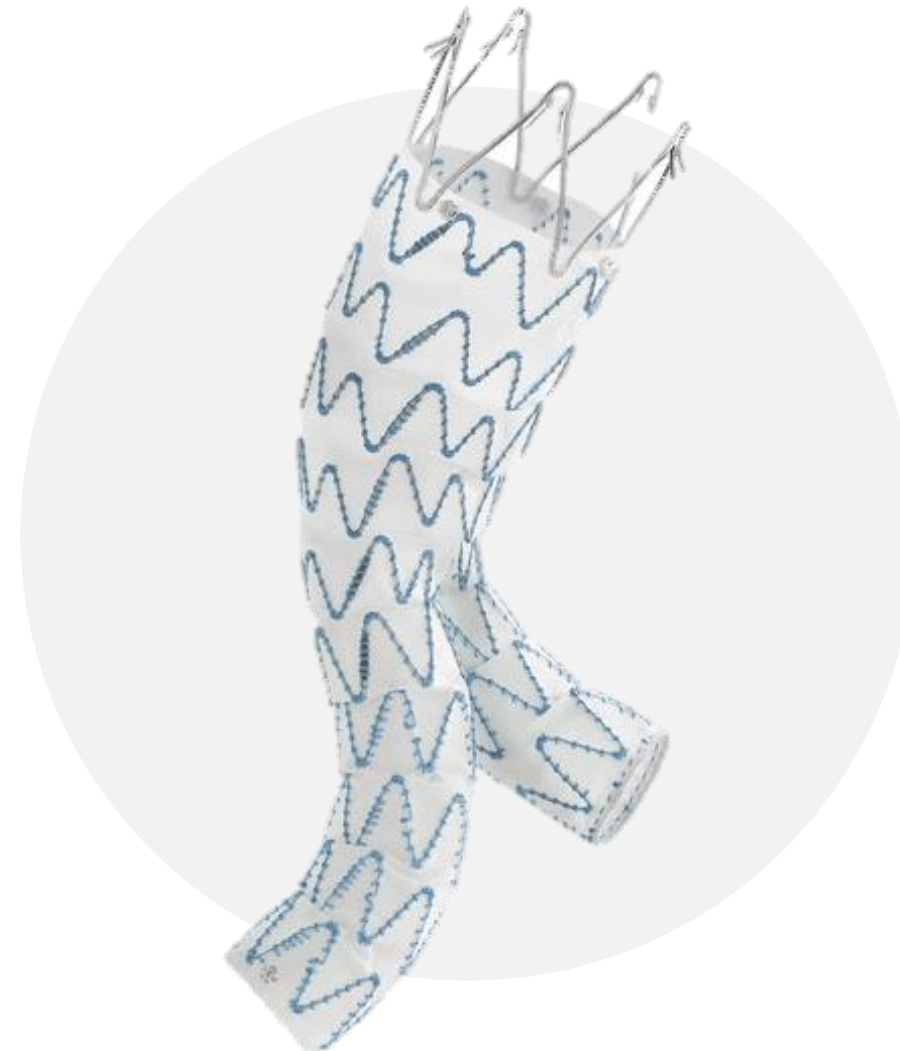
Paradigm shift

Clinical success

Design

Conclusions

Endurant II/II_s Stent graft system



A design that addresses sac regression

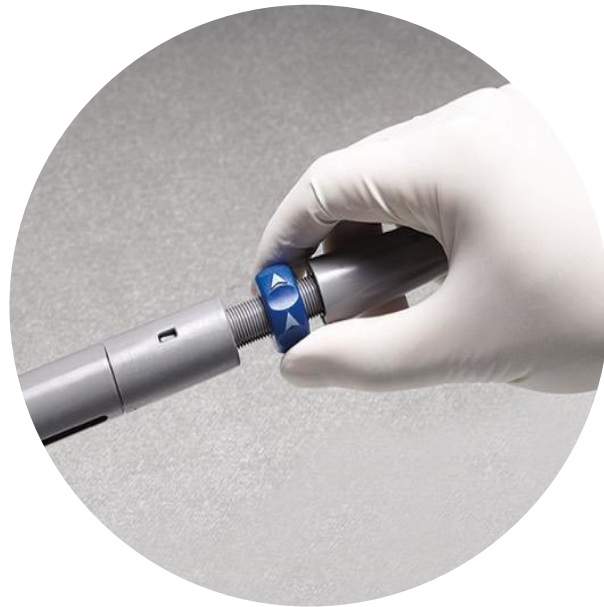
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Paradigm shift

Clinical success


Design

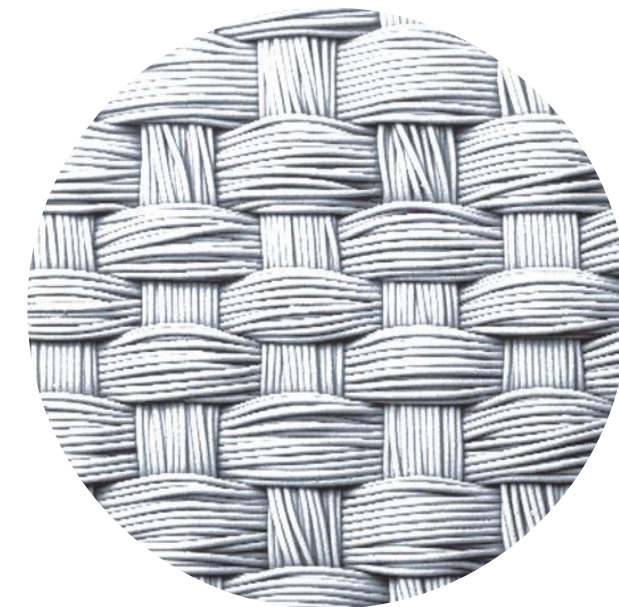
Conclusions



 Accurate placement & controlled deployment



 Continuous seal, fixation & graft conformability



 Resistance against type II EIs and durable hemostatic barrier

Endurant™ has a design that achieves durable sac regression^{1,2}

Latest insights: Significance of Sac regression and drivers for EVAR outcomes

Paradigm shift

Clinical success

Design

Conclusions



Tip capture

Endurant™ IDE study
N=150

Accurate deployment

- Maximize seal length
- Secure fixation

99.3%
deployment
success³



Accurate placement & controlled deployment

1. Böckler D, Li C, Dansey K, et al. Sac regression is associated with lower all-cause mortality after contemporary endovascular aneurysm repair - a new paradigm for success. Presentation presented online at: ESVS 34th Annual Meeting. October 6, 2020.
2. Teijink et al., Eur J Vasc Endovasc Surg. 2019;58(2):175-181.
3. FS156 Acute Evaluation of Medtronic Vascular Endurant Stent Graft System in an Ovine Model: Device Performance Rating Summary - Deployment, Accuracy of Placement of stent graft. DVR7245 Endurant Design Verification Report - Sec. 9.34 Introduction to Simulated Use Protocols. 10018188DOC Endurant II Simulated Use Test Report. Controlled delivery at the intended target zone. 99.3% delivery and deployment success. Data on file from the De Novo patients from the ENGAGE Post Approval Study (PAS) Percutaneous bilateral introduction of the device was performed in 31% (52/170) of patients enrolled in the ENGAGE Post Approval Study, achieving 100% delivery success and 100% deployment success.

A design that addresses sac regression

Latest insights: Significance of Sac regression and drivers for EVAR outcomes

Paradigm shift

Clinical success

Design

Conclusions

Continuous seal, fixation and graft conformability

Design

- + M-shaped proximal stents
 - See the benchtop data +
- + Suprarenal stent and fixation



- Continuous seal, fixation & graft conformability



Bench test data on file at Medtronic with reference Design Verification Report DVR7245 Rev. AA. Bench test data may not be indicative of clinical performance.

A design that addresses sac regression

Latest insights: Significance of Sac regression and drivers for EVAR outcomes

Paradigm shift

Clinical success

Design

Conclusions



Continuous seal, fixation and graft conformability

Design

- + M-shaped proximal stents
 - See the benchtop data +
- + Suprarenal stent and fixation

Benefit

Maximizes wall apposition and circumferential conformability with continuous seal

Minimizes in-folding resulting in low Type Ia endoleak rates

- 1.6% Type Ia endoleaks at 5 years (ENGAGE OUS Registry)
- 0% Type Ia endoleak at 5 years (Endurant IDE bifur study)



Continuous seal, fixation & graft conformability



Bench test data on file at Medtronic with reference Design Verification Report DVR7245 Rev. AA. Bench test data may not be indicative of clinical performance.

Proximal seal is critical to decreasing aneurysm sac pressure¹

The decreased pressure on the aneurysm reduces the risk of rupture¹

Paradigm shift

Clinical success

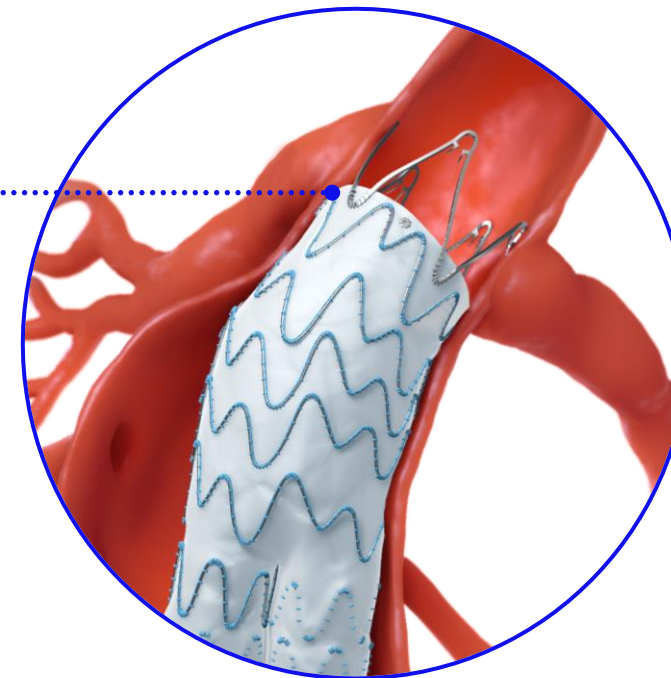
Design

Conclusions

What is the critical factor for depressurizing the aneurysm?

Proximal seal

Type Ia endoleak transmits the highest pressures into the sac, compared to other types of endoleaks¹



1. Li J, Tian X, Wang Z, et al. Influence of endoleak positions on the pressure shielding ability of stent-graft after endovascular aneurysm repair (EVAR) of abdominal aortic aneurysm (AAA). Biomed Eng Online. Dec 28, 2016;15(Suppl 2):135.

Endurant™ design addresses sac regression with durable outcomes

Latest insights: Significance of Sac regression and drivers for EVAR outcomes

Paradigm shift

Clinical success

Design

Conclusions

M-shaped proximal stent

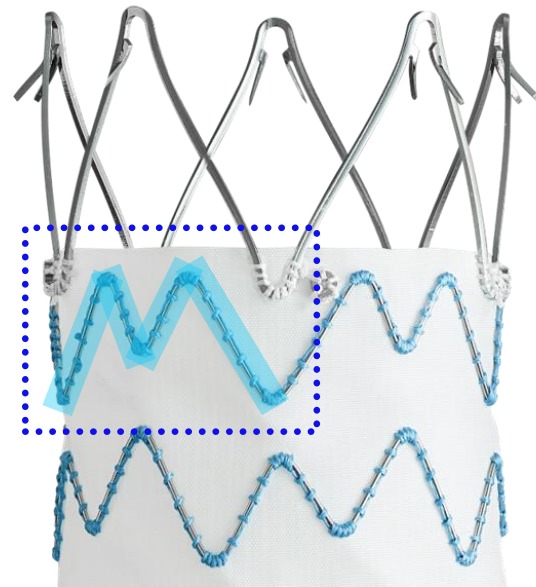
Continuous seal, fixation and graft conformability

- Maximum wall apposition
- Even contact pressure
- Minimizes in-folding

- Low type Ia endoleak rate



Continuous seal, fixation & graft conformability



Endurant™ IDE
bifur study
N=150
5Y Type Ia EL

0%
(0/73)

ENGAGE OUS
Registry
N=1263
5Y Type Ia EL

1.6%
(8/501)

ENGAGE OUS
Registry
Extension
N=390
8Y Type Ia EL

3.4%
(9/261)



M-shaped proximal stent enables continuous seal, fixation and graft conformability

Bench test conducted to understand how proximal seal zone with Endurant™ performs in a dynamic environment

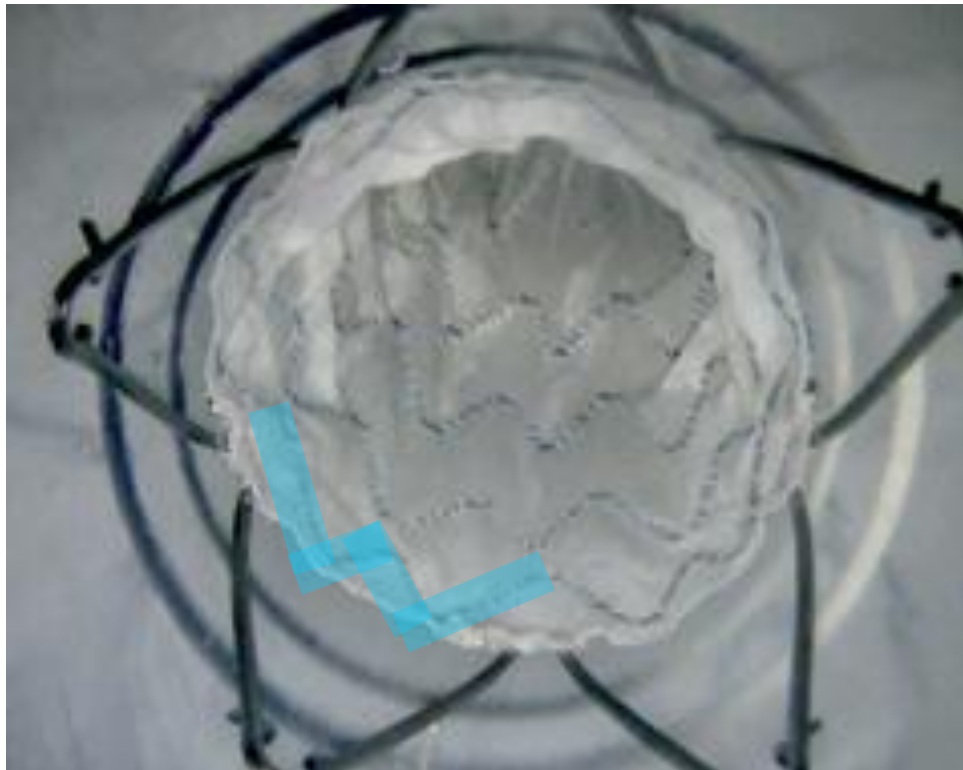
Paradigm shift

Clinical success

Design

Conclusions

M-shaped proximal stent



Methodology

- Independent lab
- Three devices tested each: 25mm Endurant™ II bifurs, 26mm Excluder™* bifurs
- Measured in a 22mm vessel, on-label for both devices
- Micro-CT used to map stent geometry
- Contact pressure modeled in seal zone (20mm) using finite element analysis (FEA)
- Modeled through the entire cardiac cycle (80mmHg - 120mmHg), subsequent slides are at 120mmHg (worst case scenario)

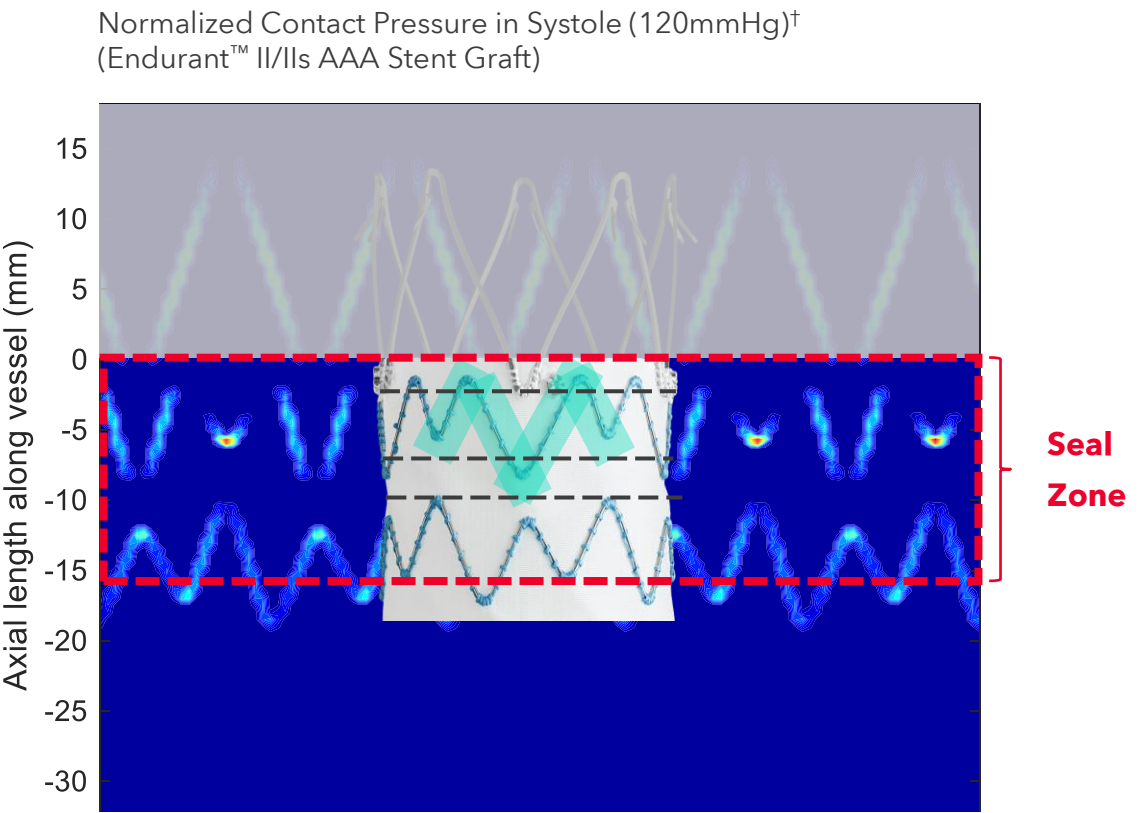
Endurant™ has a design that achieves durable sac regression ^{1,2}

Continuous seal, fixation and graft conformability

Paradigm shift	Clinical success	Design	Conclusions
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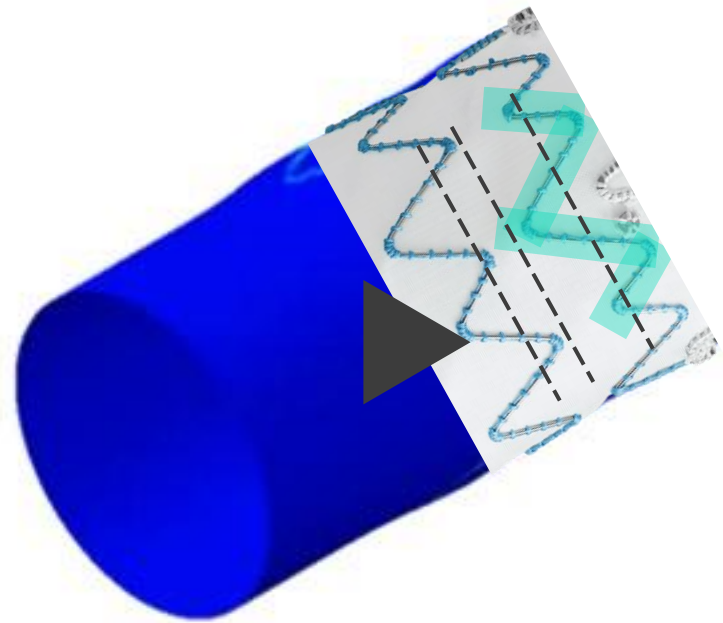
Results: M-stent maintains even distribution of contact pressure in a pulsatile environment

VIEW
M-STENT



[†]Represents worst-case scenario for a continuous seal.

VIEW
M-STENT



Bench test data may not be indicative of clinical performance. Performance may vary upon use. Medtronic data on file.

1. Böckler D, Li C, Dansey K, et al. Sac regression is associated with lower all-cause mortality after contemporary endovascular aneurysm repair – a new paradigm for success. Presentation presented online at: ESVS 34th Annual Meeting. October 6, 2020.
2. Teijink et al., Eur J Vasc Endovasc Surg. 2019;58(2):175-181.

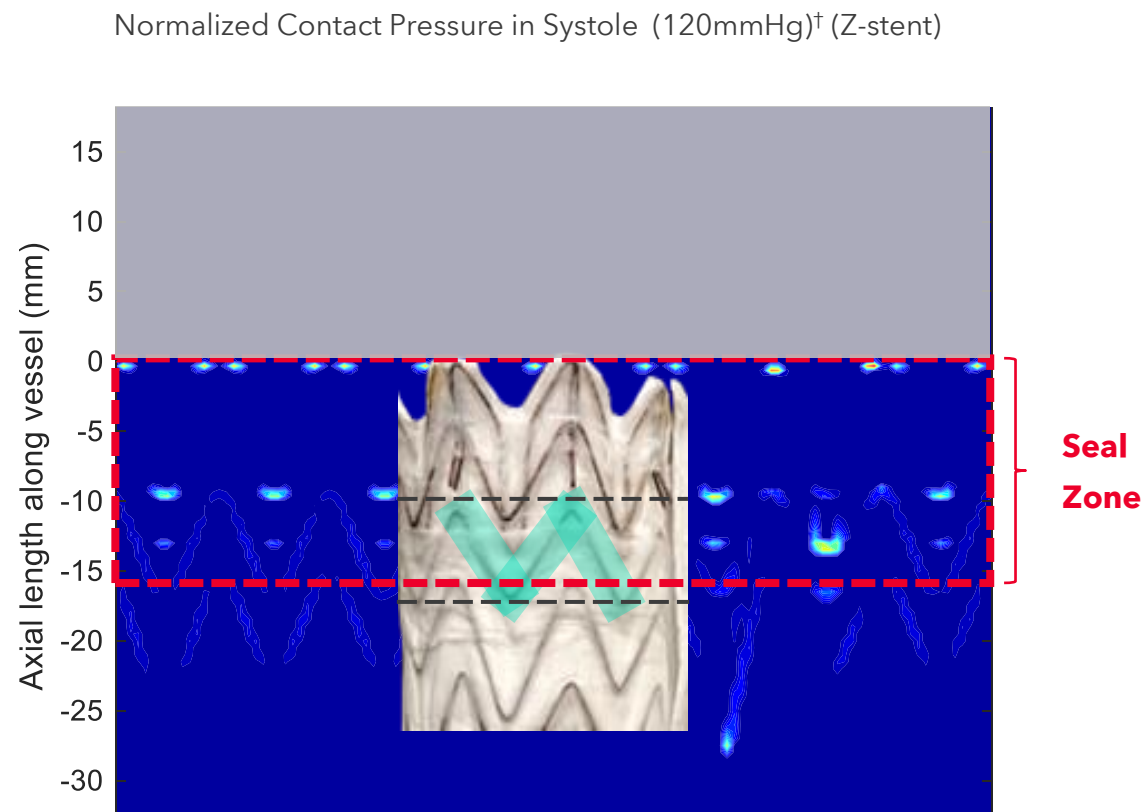
Latest insights

Significance of Sac regression and drivers for EVAR outcomes

Paradigm shift	Clinical success	Design	Conclusions
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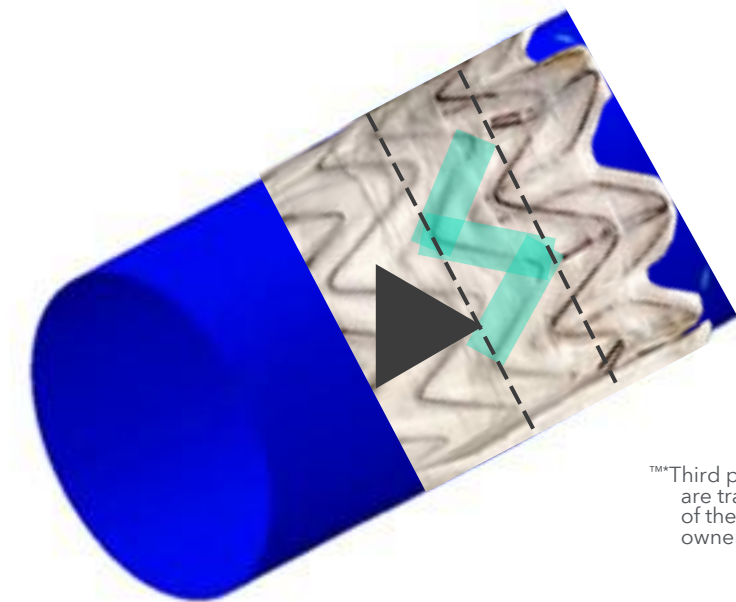
Results: Z-stent unevenly distributes contact pressure across the seal zone

VIEW
Z-STENT



[†]Represents worst-case scenario for a continuous seal.

VIEW
Z-STENT



[™]*Third party brands are trademarks of their respective owners.

Based on internal assessment of Endurant[™] II/IIIs and Gore Excluder[™]* under equal physiological and anatomical conditions. Bench test data may not be indicative of clinical performance. Performance may vary upon use. Medtronic data on file.

Based on internal assessment of Endurant[™] II/IIIs and Gore Excluder[™]* under equal physiological and anatomical conditions. Bench test data may not be indicative of clinical performance. Performance may vary upon use. Medtronic data on file with reference UC201909791aEN Claims matrix.

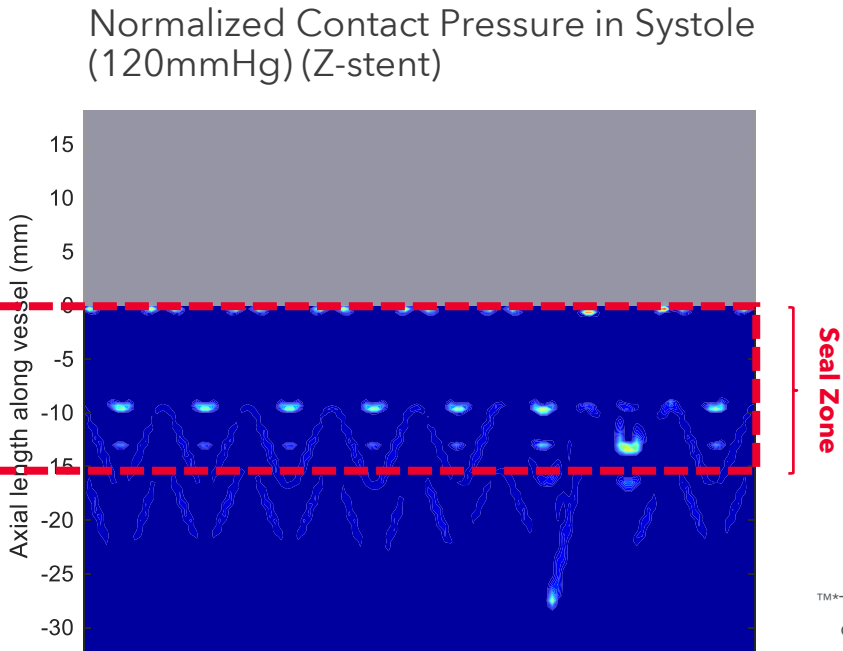
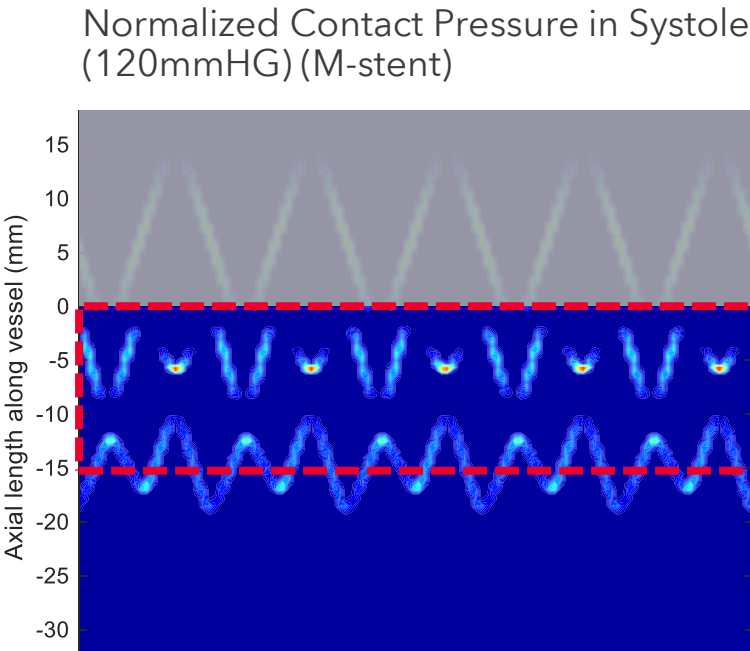
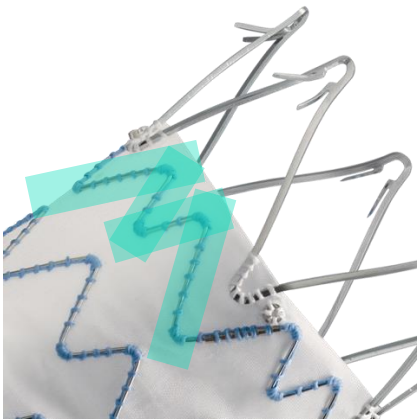
Latest insights

Significance of Sac regression and drivers for EVAR outcomes

Paradigm shift	Clinical success	Design	Conclusions
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Bench test results A design that addresses sac regression
Continuous seal, fixation and graft conformability

Results: M-stent evenly distributes contact pressure across the seal zone
Endurant™ II/II Stent Graft System has **18%** more stent-to-vessel surface area **contact** in seal zone (15mm) than Gore Excluder™*



™*Third party brands are trademarks of their respective owners.

Based on internal assessment of Endurant™ II/II and Gore Excluder™* under equal physiological and anatomical conditions. Bench test data may not be indicative of clinical performance. Performance may vary upon use. Medtronic data on file with reference UC201909791aEN Claims matrix.

Latest insights

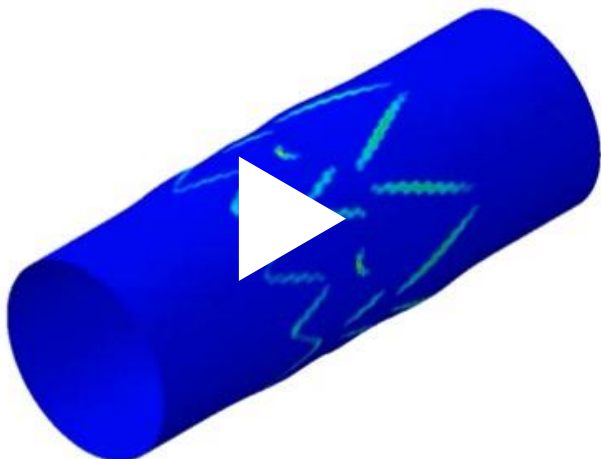
Significance of Sac regression and drivers for EVAR outcomes

Paradigm shift	Clinical success	Design	Conclusions
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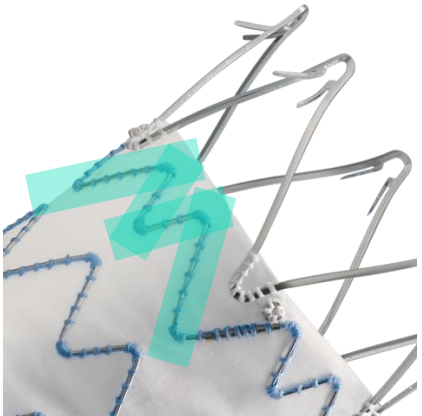
Bench test results A design that addresses sac regression
Continuous seal, fixation and graft conformability

Results: M-stent maintains even distribution of contact pressure in a pulsatile environment

M-stent



Z-stent



™*Third party brands are trademarks of their respective owners.

Based on internal assessment of Endurant™ II/IIIs and Gore Excluder™* under equal physiological and anatomical conditions. Bench test data may not be indicative of clinical performance. Performance may vary upon use. Medtronic data on file with reference UC201909791aEN Claims matrix.

What about the endoleaks we can't see or definitively diagnose?

Significance of Sac regression and drivers for EVAR outcomes

Paradigm shift

Clinical success

Design

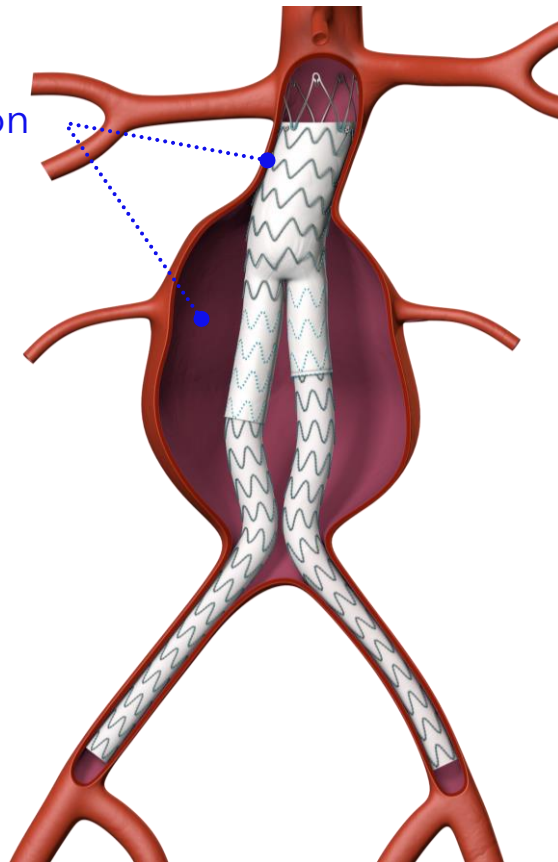
Conclusions

Dynamic aorta demands continuous seal

Cardiac cycle and posture can cause subtle interruption in the aorta-graft seal that may not be detected by standard CT

Depressurization

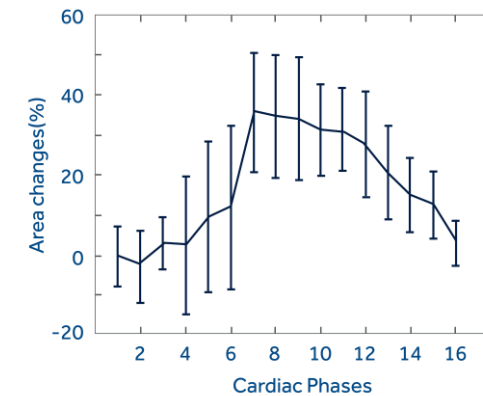
No endoleak
Hemostatic barrier



Dynamic intermittent endoleak^{1,2}

Cardiac cycle causes aorta to pulse asymmetrically, which can cause intermittent separation between aorta and graft

- 35% greater area in systole vs diastole
- 3x greater anterior wall motion vs posterior



Posture-dependent endoleak³

Imaging may not reveal endoleaks when patient is in supine position

- Study found that for patients with endotension, the endoleak was visible only after changing patient's position



Continuous proximal seal in dynamic aorta is mandatory for depressurization

A design that addresses sac regression

Latest insights: Significance of Sac regression and drivers for EVAR outcomes

Paradigm shift

Clinical success

Design

Conclusions



Continuous seal, fixation and graft conformability

Design

- + M-shaped proximal stents
 - See the benchtop data +
- + Suprarenal stent and fixation

Benefit

Enhances graft conformability in angulated anatomy

Separates fixation from seal

- Unlike with infrarenal fixation where sealing is dependent on infrarenal pins penetrating tissue, suprarenal fixation allows sealing to occur independently

Reduces main body migration risk and device movement

- 0% main body migration at 5 years (Endurant IDE study)
- 0.3% main body migration at 5 years (ENGAGE OUS Registry)

- Continuous seal, fixation & graft conformability

Bench test data on file at Medtronic with reference Design Verification Report DVR7245 Rev. AA. Bench test data may not be indicative of clinical performance.

Endurant™ has a design that achieves durable sac regression^{1,2}

Latest insights: Significance of Sac regression and drivers for EVAR outcomes

Paradigm shift

Clinical success

Design


Conclusions

Suprarenal fixation

- Enhances graft conformability in angulated anatomy
- Separates fixation from seal
- Reduces main body migration risk and device movement



Low main body migration rates

 Continuous seal, fixation & graft conformability



Endurant™ IDE
bifur study
N=150
5Y low main body
migration rate

0%
(0/83)

ENGAGE OUS
Registry
N=1263
5Y low main body
migration rate

0.3%
(1/291)

ENGAGE OUS
Registry
Extension
N=390
8Y low main body
migration rate

0.8%
(1/127)

1. Böckler D, Li C, Dansey K, et al. Sac regression is associated with lower all-cause mortality after contemporary endovascular aneurysm repair - a new paradigm for success. Presentation presented online at: ESVS 34th Annual Meeting. October 6, 2020.

2. Teijink et al., Eur J Vasc Endovasc Surg. 2019;58(2):175-181.

A design that addresses sac regression

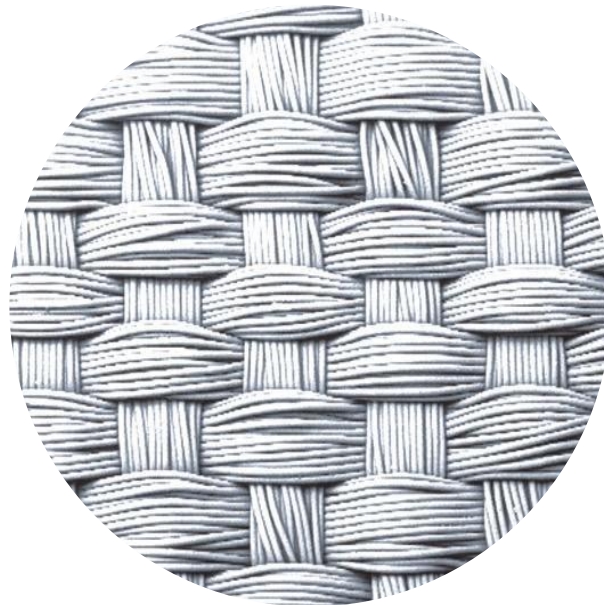
Latest insights: Significance of Sac regression and drivers for EVAR outcomes

Paradigm shift

Clinical success

Design

Conclusions



Resistance against type II Els & Durable hemostatic barrier

Design

Multifilament polyester material

Benefit

Provides resistance against type II endoleaks and a durable hemostatic barrier



Durable hemostatic barrier



A design that addresses sac regression

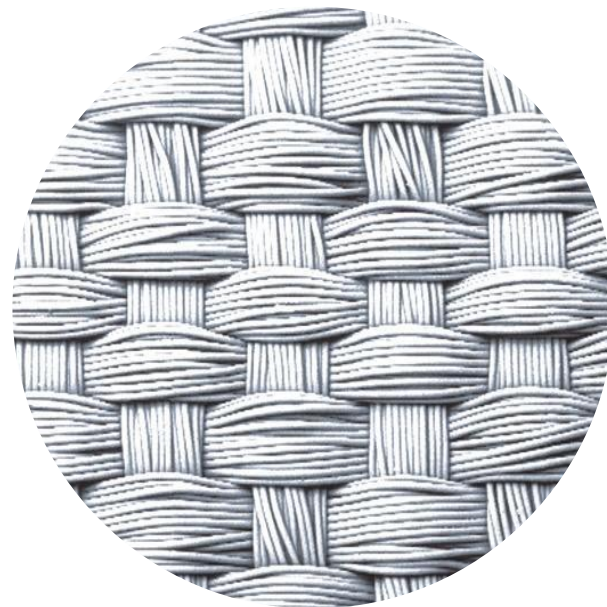
Latest insights: Significance of Sac regression and drivers for EVAR outcomes

Paradigm shift

Clinical success

Design

Conclusions



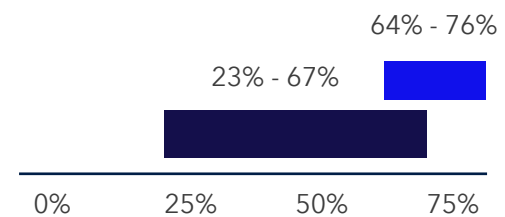
Resistance against type II Els & Durable hemostatic barrier

Graft material choice impacts sac dynamics and Type II endoleak rates. Published IDE data from 2 polyester grafts and 3 PTFE grafts show clear difference in outcomes between material types.



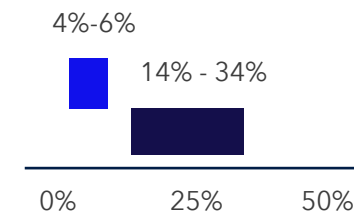
Sac regression

Lowest and Highest Reported Results per 5 Yr IDE Data



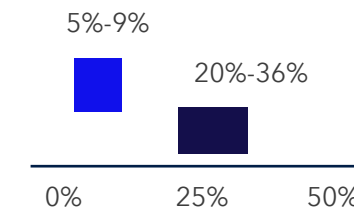
Sac expansion

Lowest and Highest Reported Results per 5 Yr IDE Data



Type II

Lowest and Highest Reported Results per 1 Yr IDE Data



■ Polyester
■ PTFE



Durable hemostatic barrier

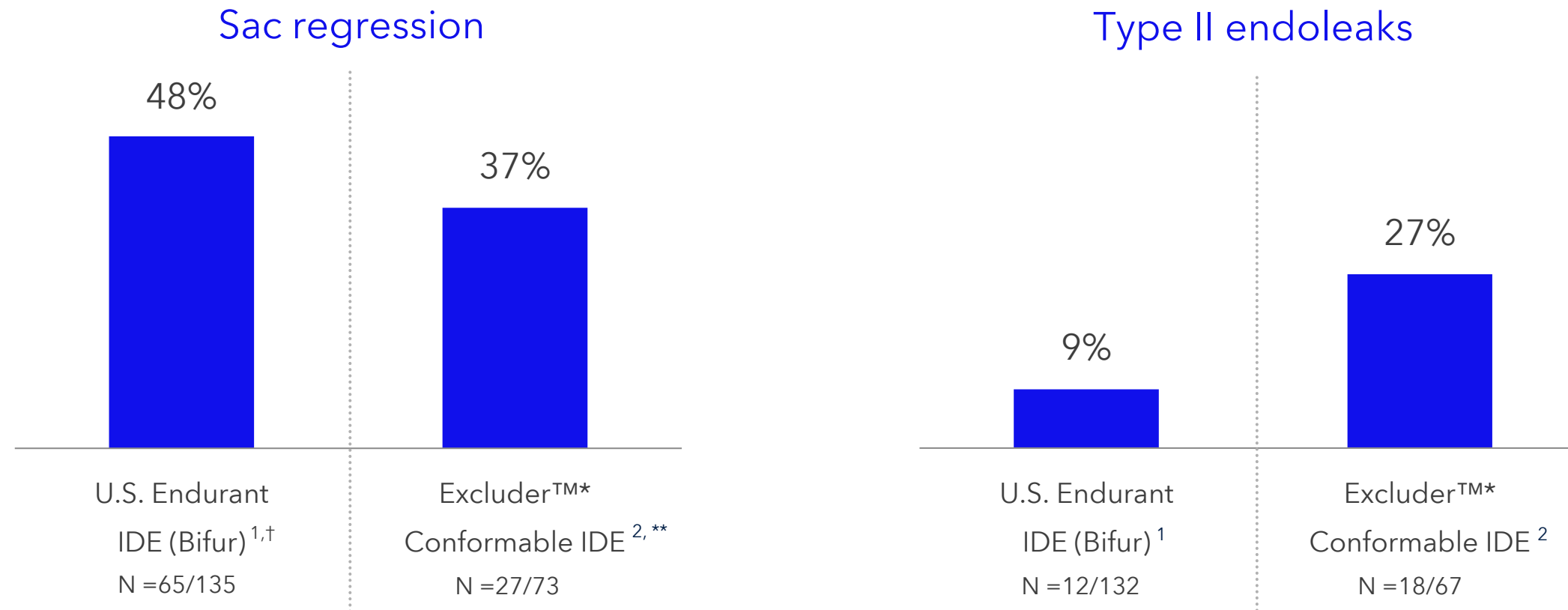
Results are taken from independent clinical studies for illustration purpose only and are not based on statistical analysis. Results may differ in a head-to-head study.



Bench test data on file at Medtronic with reference Design Verification Report DVR7245 Rev. AA. Bench test data may not be indicative of clinical performance.

Do type II endoleaks influence sac regression?

Endurant™ delivers durability with sac regression and reduced type II endoleaks at 1 year¹



Results are taken from independent clinical studies for illustration purposes only and are not based on statistical analysis. Results may differ in a head-to-head comparison; multiple factors contribute to clinical study outcomes and need to be considered in making assessments across different studies.

TM* Third party brands are trademarks of their respective owners.

†Sac regression > 5 mm, by core lab.

**Sac regression ≥ 5mm, by core lab.

1. Singh MJ, Fairman R, Anain P, et al. Final Results of the Endurant Stent Graft System in the United States Regulatory Trial. J Vasc Surg. July 2016;64(1):55-62.

2. IFU - GORE™* EXCLUDER™* Conformable US – P200030C January 2021.

3. Endurant US IDE Report, Core Laboratory reported data. Medtronic data on file.

Subset of type II endoleaks indicate occult type I endoleaks^{1,2,3}

Occult endoleaks diagnosed as type II can lead to treatment failure^{1,2,3}

Paradigm shift

Clinical success

Design

Conclusions

**Type II endoleaks
may be a risk factor
for sac increase**

- **Outcomes of percutaneous endovascular intervention for type II endoleak with aneurysm expansion**

Abdulhameed Aziz¹, Christine O Menias, Luis A Sanchez, Daniel Picus, Nael Saad, Brian G Rubin, John A Curci, Patrick J Geraghty

- **Incidence, natural course, and outcome of type II endoleaks in infrarenal endovascular aneurysm repair based on the ENGAGE registry data**

Martijn L Dijkstra¹, Clark J Zeebregts², Hence J M Verhagen³, Joep A W Tejjink⁴, Adam H Power⁵, Dittmar Bockler⁶, Patrick Peeters⁷, Vicente Riambau⁸, Jean-Pierre Becquemin⁹, Michel M P J Reijnen¹⁰, ENGAGE investigators

- **Occult type I or III endoleaks are a common cause of failure of type II endoleak treatment after endovascular aortic repair**

Michael C Madigan¹, Michael J Singh², Rabih A Chaer², Georges E Al-Khoury², Michel S Makaroun²

1. Abdulhameed Aziz, MD, et al. Outcomes of percutaneous endovascular intervention for type II endoleak with aneurysm expansion. J Vasc Surg. 2012 May;55(5):1263-7.

2. Martin L. Dijkstra, MD, PhD, et al. Incidence, natural course, and outcome of type II endoleaks in infrarenal aneurysm repair based on the ENGAGE registry data. J Vasc Surg. 2020 Mar;71(3):780-789

3. Michael C. Madigan, MD, et al. Occult type I and III endoleaks are a common cause of failure of type II endoleak treatment after endovascular aortic repair. J Vasc Surg 2019 Feb;69 (2): 432-439

Endurant™
delivers durability
with sac regression
and long-term
outcomes

Conclusions

1

The real-world ENGAGE OUS Registry data confirms VQI data and shows sac regression is associated with improved long-term survival and EVAR durability in both simple and complex anatomies.

2

The stent-graft design is one of many factors that may affect sac regression.

3

ENGAGE OUS Registry and Endurant Bifur US IDE study show Endurant™ stent design leads to low type 1a endoleak rates, low main body migrations, and successful stent graft deployment.

4

Endurant™ delivers durability with sac regression and reduced type II endoleaks.

5

Some type II endoleaks may be intermittent occult type 1a endoleaks that can lead to treatment failure

1. Michael C. Madigan, MD, et.al. Occult type I and III endoleaks are a common cause of failure of type II endoleak treatment after endovascular aortic repair. J Vasc Surg. 2019 Feb;69 (2):432-439.

Is EVAR undergoing a Paradigm Shift?

Latest insights: **Significance of Sac regression and drivers for EVAR outcomes**

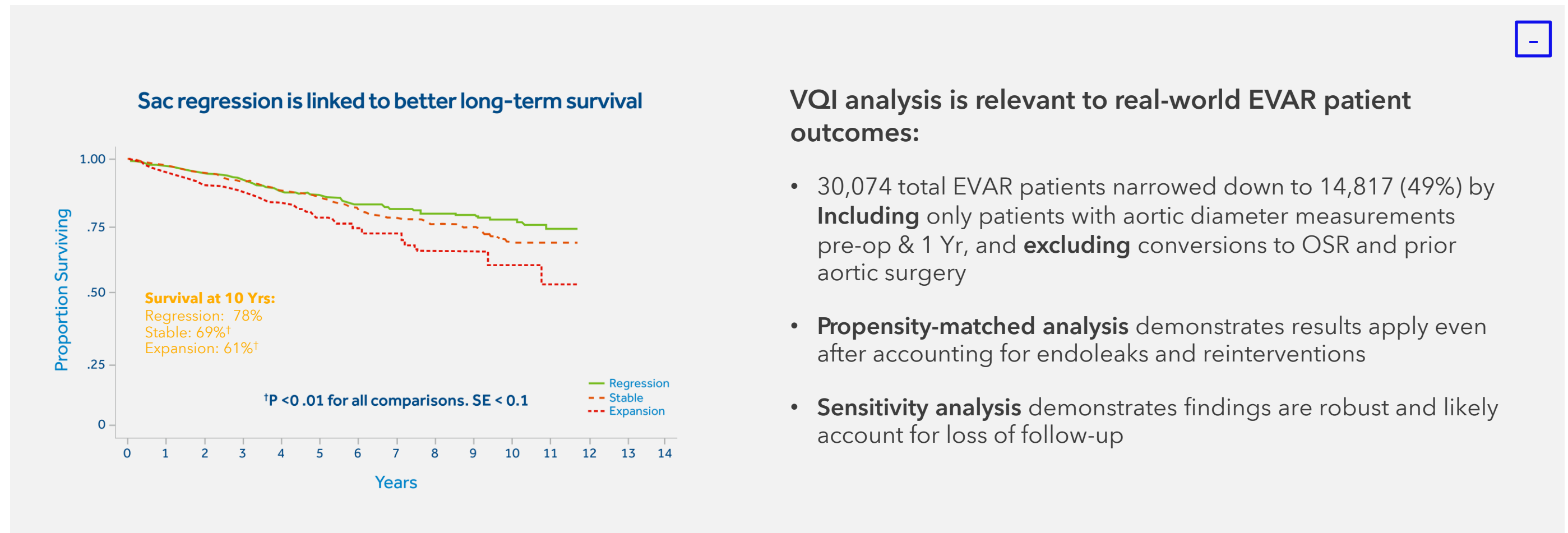
Paradigm shift

Clinical success

Design

Conclusions

New evidence¹ links sac regression to better long-term survival



Is EVAR undergoing a Paradigm Shift?

Latest insights: **Significance of Sac regression and drivers for EVAR outcomes**

Paradigm shift

Clinical success

Design

Conclusions

New evidence¹ links sac regression to better long-term survival

Sac dynamics have always been a robust indicator of EVAR durability but without distinction between stable and regressing aneurysms



1. O'Donnell TFX, Deery SE, Boitano LT, et al. Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival. J Vasc Surg. 2019;69(2):414-422.
2. Deery SE, Ergul EA, Schermerhorn ML, et al. Aneurysm sac expansion is independently associated with late mortality in patients treated with endovascular aneurysm repair. J Vasc Surg. 2018 Jan;67(1):157-164.

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New evidence¹ links sac regression to better long-term survival

1. O'Donnell TFX, Deery SE, Boitano LT, et al. Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival. *J Vasc Surg.* 2019;69(2):414-422.



How is Link confirmed with other data sets?

Latest insights: **Significance of Sac regression and drivers for EVAR outcomes**

Paradigm shift

Clinical success

Design

Conclusions

Engage ous registry confirms sac regression link to long-term outcomes¹

1. Böckler D, Li C, Dansey K, et al. Sac regression is associated with lower all-cause mortality after contemporary endovascular aneurysm repair - a new paradigm for success. Presentation presented online at: ESVS 34th Annual Meeting. October 6, 2020.



How do patients with sac regression at 1 year progress?

Latest insights: **Significance of Sac regression and drivers for EVAR outcomes**

Paradigm shift

Clinical success

Design

Conclusions

86% of patients with sac regression at 1Y are still regressing at 5y¹

1. Böckler D, Li C, Dansey K, et al. Sac regression is associated with lower all-cause mortality after contemporary endovascular aneurysm repair - a new paradigm for success. Presentation presented online at: ESVS 34th Annual Meeting. October 6, 2020.



Intentional Design drives clinical success in sac regression

Latest insights: **Significance of Sac regression and drivers for EVAR outcomes**

Paradigm shift

Clinical success

Design

Conclusions

Excellent outcomes in straight forward and complex patients



† Sac regression defined as the reduction in maximum diameter of the aneurysm sac by ≥ 5 mm for the ENGAGE OUS Registry Full Cohort.

Other studies cited use a threshold of > 5 mm.

* Medtronic data on file with reference UC201909791EN Claims Matrix.

1. Böckler D, Li C, Dansey K, et al. Sac regression is associated with lower all-cause mortality after contemporary endovascular aneurysm repair – a new paradigm for success. Presented online at ESVS 34th Annual Meeting, October 6, 2020.
2. Medtronic data on file (PASR 2020).

Technology can FURTHER optimize EVAR outcomes – including sac regression

Latest insights: **Significance of Sac regression and drivers for EVAR outcomes**

Paradigm shift

Clinical success

Design

Conclusions

The Endurant™ II/IIIs STENT GRAFT system with ESAR elevates EVAR design elements to be more like OSR

Provides benefits of both OSR and EVAR



1. Melas N, Perdikides T, Saratzis A, et al. Helical EndoStaples enhance endograft fixation in an experimental model using human cadaveric aortas. J Vasc Surg. 2012 Jun;55(6):1726-33.
2. Kester RC. The thrombogenicity of Dacron arterial grafts and its modification by platelet inhibitory drugs. Ann R Coll Surg Engl. 1984 Jul;66(4):241-6.
3. Wakefield TW, Shulkin BL, Fellows EP, Petry NA, Spaulding SA, Stanley JC. Platelet reactivity in human aortic grafts: a prospective, randomized midterm study of platelet adherence and release products in Dacron and polytetrafluoroethylene conduits. J Vasc Surg. February 1989;9(2):234-243.

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Is EVAR undergoing a Paradigm Shift?

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1. O'Donnell TFX, Deery SE, Boitano LT, et al. Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival. J Vasc Surg. 2019;69(2):414-422.
2. Deery SE, Ergul EA, Schermerhorn ML, et al. Aneurysm sac expansion is independently associated with late mortality in patients treated with endovascular aneurysm repair. J Vasc Surg. 2018 Jan;67(1):157-164
3. IDE TRIAL: Singh MJ, Fairman R, Anain P, et al. Final Results of the Endurant Stent Graft System in the United States Regulatory Trial. J Vasc Surg. 2016;64:55-62.
4. 4. Women-Medtronic data on file. Schermerhorn, VIVA 2017. Five-year EVAR Outcomes Are Equivalent Between Genders: Results From the ENGAGE Registry.
5. .Wide neck -Medtronic data on file (snapshot 4 nov 2016, created 7 Feb 2018). ENGAGE wide neck analysis table.
6. .ENGAGE 5-year data: Teijink, Joep A.W. et al. Editor's Choice—Five Year Outcomes of the Endurant Stent Graft for Endovascular Abdominal Aortic Aneurysm Repair in the ENGAGE Registry. European Journal of Vascular and Endovascular Surgery. 2019. 58:175 -181.

A design that addresses sac regression

Latest insights: **Significance of Sac regression and drivers for EVAR outcomes**

Paradigm shift

Clinical success

Design

Conclusions

Accurate placement & controlled deployment

FS156 Acute Evaluation of Medtronic Vascular's Endurant Stent Graft System in an Ovine Model: Device Performance Rating Summary - Deployment, Accuracy of Placement of stent graft.

DVR7245 Endurant Design Verification Report - Sec. 9.34 Introduction to Simulated Use Protocols.

10018188DOC Endurant II Simulated Use Test Report.

Controlled delivery at the intended target zone. 99.3% delivery and deployment success.

Data on file from the De Novo patients from the ENGAGE Post Approval Study (PAS) Percutaneous bilateral introduction of the device was performed in 31% (52/170) of patients enrolled in the ENGAGE Post Approval Study, achieving 100% delivery success and 100% deployment success.



A design that addresses sac regression

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Conclusions

Accurate placement & controlled deployment



Delivery success = successful vascular access and delivery of the device to the intended anatomical treatment site.

Deployment success = successful deployment of the device in the intended site and the successful removal of the delivery system.

Makaroun MS, Tuchek M, Massop D, et al. One year outcomes of the United States regulatory trial of the Endurant Stent Graft System. J Vasc Surg. 2011 Sep;54(3):601-8.

A design that addresses sac regression

Latest insights: **Significance of Sac regression and drivers for EVAR outcomes**

Paradigm shift

Clinical success

Design

Conclusions

Continuous seal, fixation and graft conformability



Stokmans RA, Teijink JA, Forbes TL, et al. Early results from the ENGAGE registry: real-world performance of the Endurant Stent Graft for endovascular AAA repair in 1262 patients. Eur J Vasc Endovasc Surg. 2012 Oct;44(4):369-75.

Endurant US IDE Report, Core Laboratory reported data. Medtronic data on file.

A design that addresses sac regression

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Design

Conclusions

Continuous seal, fixation and graft conformability

'M-shaped proximal stent provides wall apposition and minimize in-folding. Suprarenal stent with anchor pins provides secure fixation. Limb stents and optimal stent spacing reduce kinking.

Seal

- DVR 7245 Endurant Design Verification Report - Sec. 9.7 Stent Graft Seal Evaluation
- 10545143DOC Design Verification Seal Integrity Test Report for the Endurant II/IIIs Aptus Heli-FX Short Neck Indication Expansion

Secure fixation

- DVR 7245 Endurant Design Verification Report - Sec. 9.4 Stent Graft Migration Force

Conformability

- Stent design - short stent length, super elastic Nitinol
- DVR 7245 Endurant Design Verification Report - Sec. 9.11 Aortic Body and Limb Flexibility-
- DVR 7245 Endurant Design Verification Report - Sec. 9.7 Stent Graft Seal Evaluation

A design that addresses sac regression

Latest insights: **Significance of Sac regression and drivers for EVAR outcomes**

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Clinical success

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ENGAGE OUS Registry: Medtronic data on file. R.A. Stokmans, et al. European Journal of Vascular and Endovascular Surgery 44 (2012) 369-375.

Endurant US IDE Report, Core Laboratory reported data. Medtronic data on file.

A design that addresses sac regression

Latest insights: **Significance of Sac regression and drivers for EVAR outcomes**

Paradigm shift

Clinical success

Design

Conclusions

Continuous seal, fixation and graft conformability

D00339012 - Infrarenal Seal Zone Characterization Test Report.



A design that addresses sac regression

Latest insights: Significance of Sac regression and drivers for EVAR outcomes

Paradigm shift

Clinical success

Design

Conclusions

Resistance against type II ELS & durable hemostatic barrier



DVR 7245 Endurant Design Verification Report - Sec. 9.10 Stent Graft Permeability.

Resistance to Type II ELS:

Hemostatic barrier: Polyester / Dacron has proven durability and thrombogenicity:

- The thrombogenicity of Dacron arterial grafts and its modification by platelet inhibitory drugs. Kester et al. Annals of the Royal College of Surgeons of England (1984) vol. 66
- Platelet reactivity in human aortic grafts: A prospective, randomized midterm study of platelet adherence and release products in Dacron and polytetrafluoroethylene conduits. Wakefield et al. J Vasc Surg. 1989 Feb;9(2):234-43

Grafts with polyester material (Cook Zenith and Medtronic Endurant) have lower type II endoleak rates than grafts with PTFE material (AFX, Excluder, Ovation).

- Singh, Michael SVS 2015; Woo, Ed Charing Cross 2015; Endurant US IDE Report, Core Laboratory reported data. Medtronic data on file.
- Gore Excluder IFU Jan 2017
- Cook Zenith IFU; Zenith Annual Clinical Update 2012
- Endologix Powerlink and AFX Systems Annual Clinical Update 2015
- Trivascular Ovation IFU; Mehta et al J Vasc Surg 2014, Ovation Clinical Update 2015

A design that addresses sac regression

Latest insights: Significance of Sac regression and drivers for EVAR outcomes

Paradigm shift

Clinical success

Design

Conclusions

Resistance against type II ELS & durable hemostatic barrier



Published IDE data show clinical outcomes that differ between those that are polyester grafts (Endurant and Zenith) vs those that are PTFE grafts (Excluder, AFX, Ovation).

- Singh, Michael SVS 2015; Woo, Ed Charing Cross 2015; Endurant US IDE Report, Core Laboratory reported data. Medtronic data on file.
- Gore Excluder IFU Jan 2017
- Cook Zenith IFU; Zenith Annual Clinical Update 2012
- Endologix Powerlink and AFX Systems Annual Clinical Update 2015
- Trivascular Ovation IFU; Mehta et al J Vasc Surg 2014, Ovation Clinical Update 2015
- Cook Zenith IFU; Zenith Flex subjects with a 36mm neck (5/26 patients) - Zenith Annual Clinical Update 2012

The thrombogenicity of Dacron arterial grafts and its modification by platelet inhibitory drugs. Kester et al. Annals of the Royal College of Surgeons of England (1984) vol. 66.

Platelet reactivity in human aortic grafts: A prospective, randomized midterm study of platelet adherence and release products in Dacron and polytetrafluoroethylene conduits. Wakefield et al. J Vasc Surg. 1989 Feb;9(2):234-43.

A design that addresses sac regression

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Conclusions

Resistance against type II ELS & durable hemostatic barrier

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

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