How stent graft design influences overall AAA sac dynamics and overall therapy success

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Disclosure

Speaker name:

.....Ross Milner, MD.....

I have the following potential conflicts of interest to report:

- ■ Consulting: Endospan, Medtronic, Silk Road, and WL Gore
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any potential conflict of interest

Key Factors Determining EVAR Therapy Success

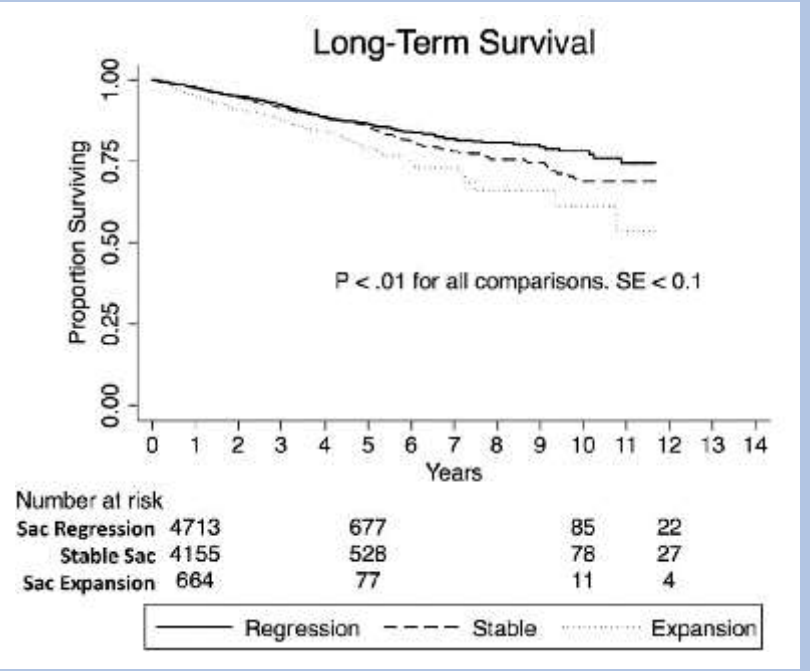
- Freedom From Aneurysm Related Mortality
- No/low incidence of endoleaks
- Freedom from Secondary Procedures
- AAA Sac Regression

New Insight into AAA Sac Dynamics

Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival

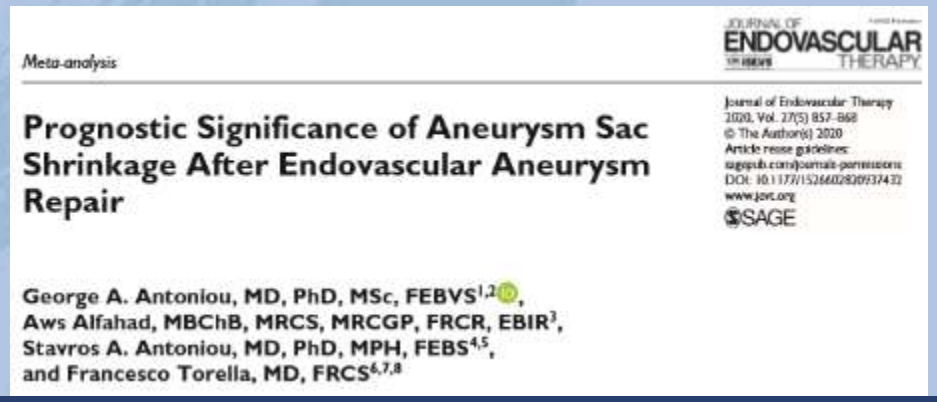
Thomas F. X. O'Donnell, MD,[a] Sarah E. Deery, MD, MPH,[a] Laura T. Boitano, MD,[a] Jeffrey J. Siracuse, MD,[b] Marc L. Schermerhorn, MD,[c] Salvatore T. Scali, MD,[d] Andres Schanzer, MD,[e] Robert T. Lancaster, MD, MPH,[a] and Virendra I. Patel, MD, MPH,[f] *Boston and Worcester, Mass; Gainesville, Fla; and New York, NY*

Not only sac expansion but any failure of the sac to regress is associated w/ higher long-term mortality, independent of reinterventions or endoleaks



O'Donnell et al. J Vasc Surg 2019;69:414-422

Additional Factors Associated with AAA regression



Meta-analysis

JOURNAL OF ENDOVASCULAR THERAPY

Prognostic Significance of Aneurysm Sac Shrinkage After Endovascular Aneurysm Repair

George A. Antoniou, MD, PhD, MSc, FEBVS[1,2], Aws Alfahad, MBChB, MRCS, MRCGP, FRCR, EBIR[3], Stavros A. Antoniou, MD, PhD, MPH, FEBS[4,5], and Francesco Torella, MD, FRCS[6,7,8]

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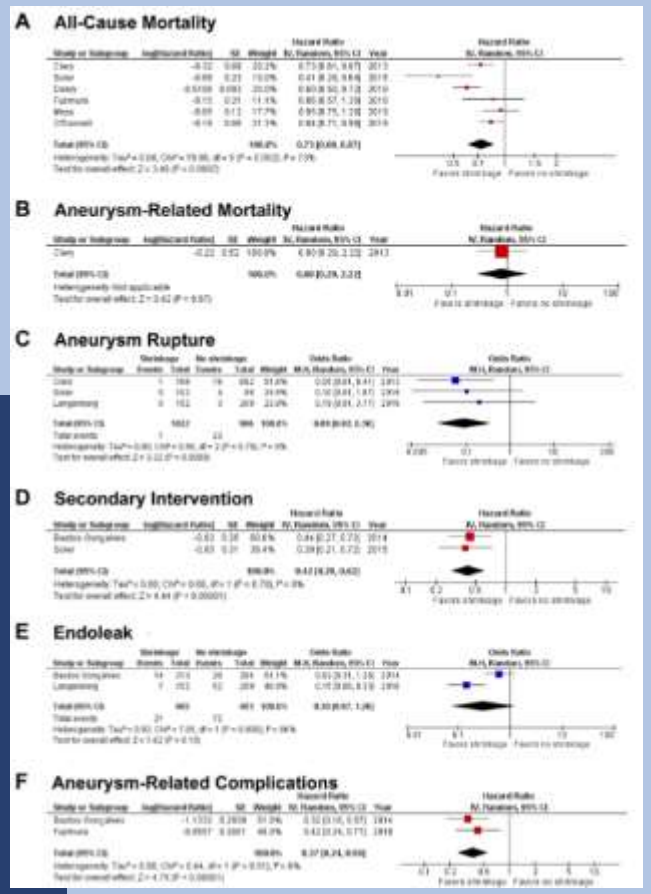
DOI: 10.1177/1526602820913743
www.jevt.org
SAGE

Meta-analysis encompassing 8 studies and 17,096 patients

Compared to patients with non-regressing aneurysms, patients with aneurysm regression experienced

1. Significantly lower hazard of death
2. Significantly lower odds of rupture
3. Significantly lower hazard of secondary interventions and late complications



Antoniou GA et al. J Endovasc Ther. 2020 Jun 26

Endurant Stent-Graft: Clinical Results

Study	Geo	Publication	N	5 year FF ARM	AAA sac decreased or stable at 5 yrs	Type Ia Endoleaks at 5 yrs	5 Year FF 2nd procedures
US IDE		Singh et al. J Vasc Surg 2016	150 pts	99.2%	94.0%	0.0% (0/73)	89.0%
ENGAGE Registry		Teijink et al. Eur J Vasc Endovasc Surg 2019	1263 pts	97.8%	89.4%	1.6% (8/501)	84.3%

Final results of the Endurant Stent Graft System in the United States regulatory trial

Michael J. Singh, MD,[a] Ronald Fairman, MD,[b] Paul Anain, MD,[c] William D. Jordan, MD,[d] Thomas Maldonaldo, MD,[e] Russell Samson, MD,[f] and Michel S. Makaroun, MD,[g] for the Endurant U.S. Pivotal Trial Investigators, *Pittsburgh and Philadelphia, Pa; Buffalo and New York, NY; Birmingham, Ala; and Sarasota, Fla*

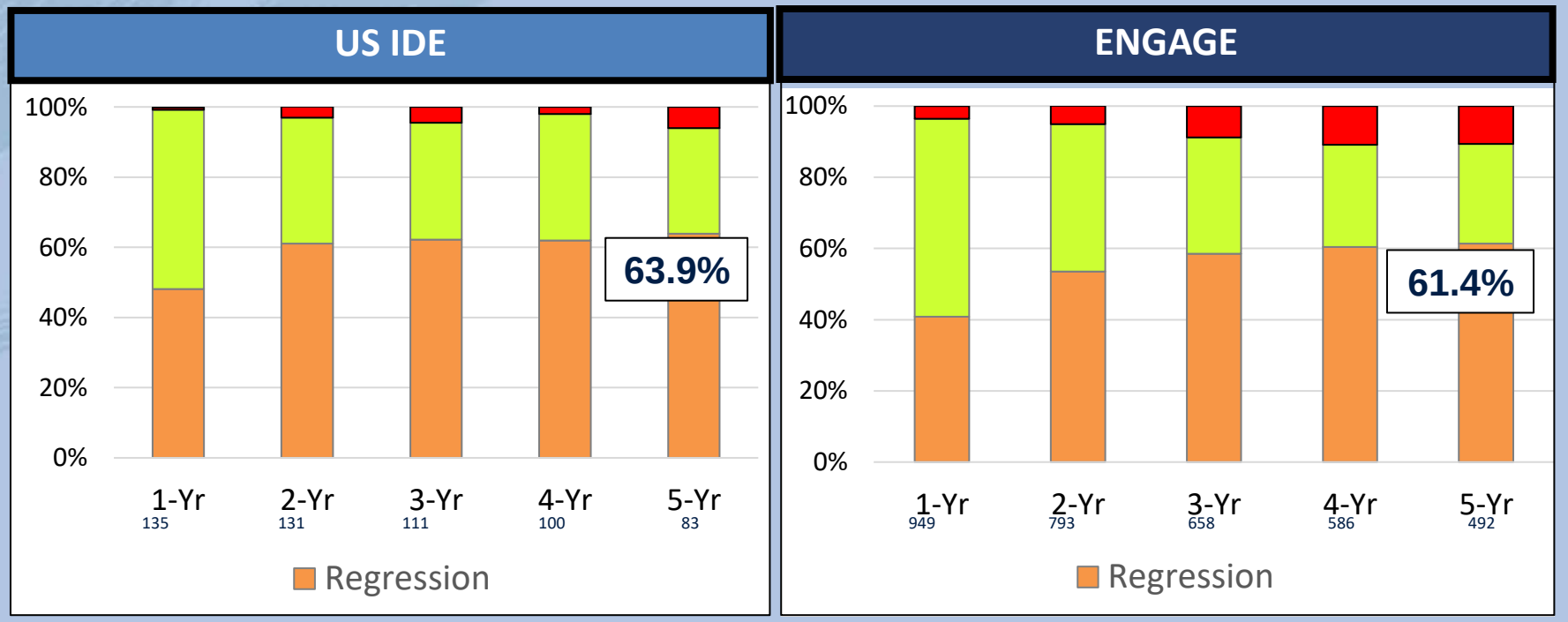
Five Year Outcomes of the Endurant Stent Graft for Endovascular Abdominal Aortic Aneurysm Repair in the ENGAGE Registry

Joep A.W. Teijink [a,*], Adam H. Power [b], Dittmar Böckler [c], Patrick Peeters [d], Steven van Sterkenburg [e], Lee H. Bouwman [f], Hence J. Verhagen [g], Marc Bosiers [h], Vincente Riambau [i], Jean-Pierre Becquemin [j], Philippe Guypers [k], Marc van Sambeek [l]

Singh et al. J Vasc Surg 2016;64:55-62
Teijink et al. Eur J Vasc Endovasc Surg 2019;58:175-181

Endurant US IDE and ENGAGE Sac Regression

Max AAA diameter decreasing by >5 mm



Singh et al. J Vasc Surg 2016;64:55-62
Teijink et al. Eur J Vasc Endovasc Surg 2019;58:175-181

Endurant Design Features that Influence Therapy Success

Tip Capture → Accurately deploy the proximal edge of the stent-graft → Maximize seal length and secure fixation

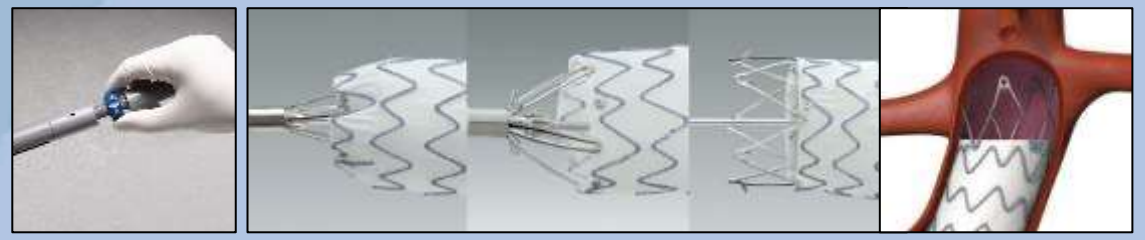
M Sealing Stent → Maximize the support within the seal region → Continuous wall apposition and seal durability

Endurant Fabric → Woven high-density multifilament polyester graft fabric → Durable hemostatic barrier

Arko et al. J Endovasc Ther 2011;18:779-85

Endurant Design Features that Influence Therapy Success

Tip Capture



- **Controlled delivery at the intended target zone to maximize seal length**
- **Controlled release of the suprarenal stent and anchor pins to provide secure fixation and prevent migration**

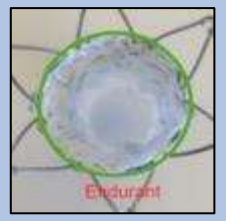
	US IDE
Successful Implantation	99.3% (149/150)
Use of Prox Extension	2.0% (3/150)
Main Body Migrations at 5 years	0%

	ENGAGE
Successfully Delivered and Deployed	99.4% (1255/1262)
Main Body Migration at 5 Years	0.3% (1/291)

Makaroun et al. J Vasc Surg 2011;54:601-8
Stokmans et al. Eur J Vasc Endovasc Surg 2012;44:369-75

Endurant Design Features that Influence Therapy Success

M Sealing Stent



- **M-stent design optimizes seal zone contact with uniform apposition against the vessel wall**
- **Self-expanding nitinol stent maximizes circumferential conformability and maintains a dynamic, continuous seal resulting in low type I endoleak rates**

	1 year	2 year	3 year	4 year	5 year
US IDE Type Ia (core lab)	0.0% (0/132)	0.8% (1/121)	0.0% (0/93)	0.0% (0/2)	0.0% (0/73)
ENGAGE Type Ia	0.3% (3/1034)	0.5% (4/856)	0.7% (5/705)	0.7% (4/614)	1.6% (8/501)

Singh et al. J Vasc Surg 2016;64:55-62
Teijink et al. Eur J Vasc Endovasc Surg 2019;58:175-181

Endurant Design Features that Influence Therapy Success

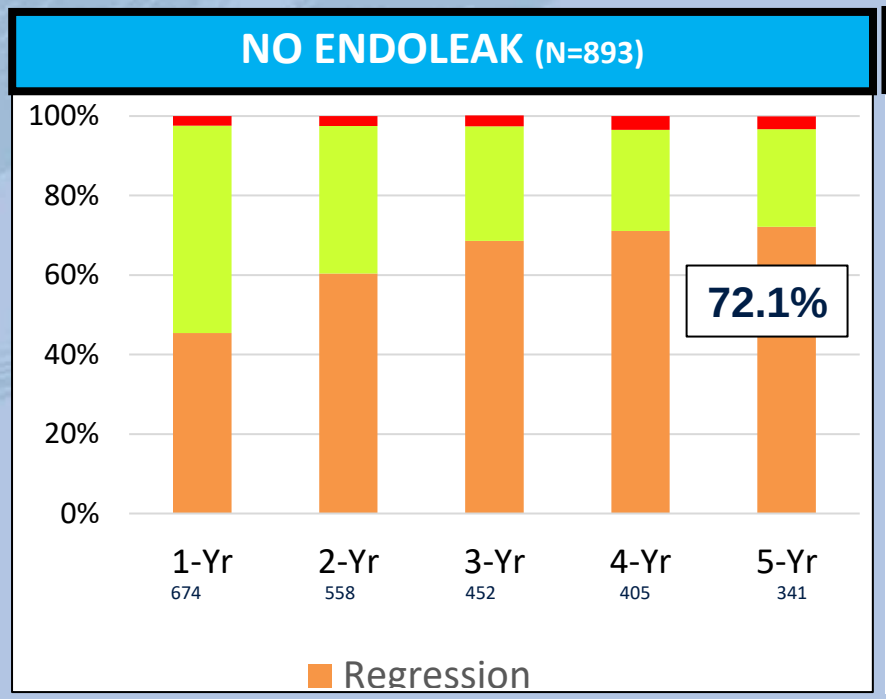
Endurant Fabric → Woven high-density multifilament polyester graft fabric → Durable hemostatic barrier that prevents endoleaks

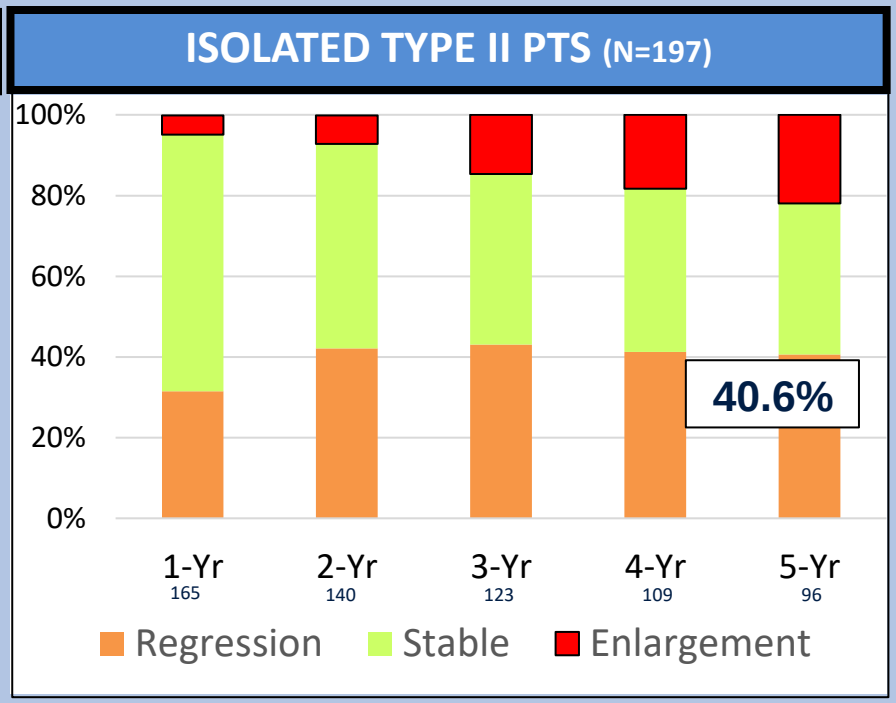
- **Designed to minimize blood permeability while optimizing flexibility and durability**

ENGAGE	1 year	2 year	3 year	4 year	5 year
Type II Endoleaks	9.2% (95/1034)	8.4% (72/856)	8.5% (60/705)	7.7% (47/614)	7.2% (36/501)
Type III Endoleaks	0.2% (2/1034)	0.6% (5/856)	0.1% (1/705)	0.2% (1/614)	0.4% (2/501)
Type IV Endoleaks	0.1% (1/1034)	0.0% (0/856)	0.0% (0/705)	0.0% (0/614)	0.0% (0/501)

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

ENGAGE: Type II Endoleaks and Sac Dynamics





Dijkstra et al. J Vasc Surg 2020;71:780-9

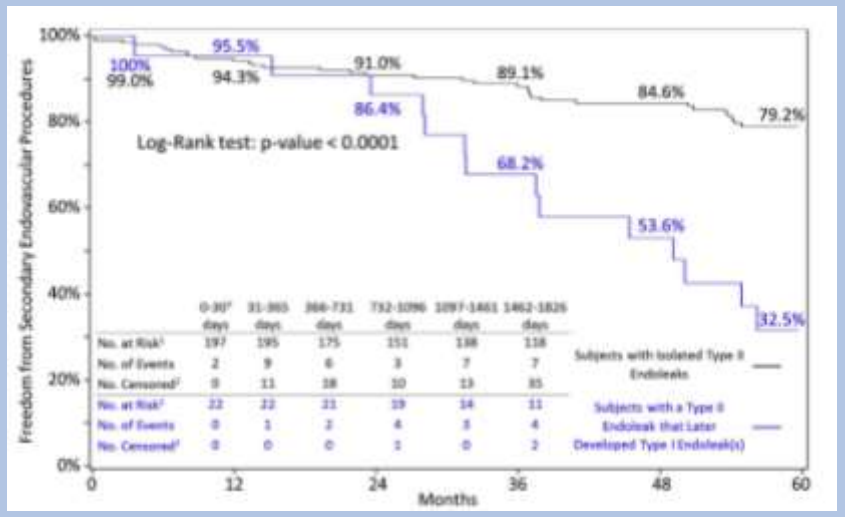
Endograft Fabric Material and Type II Endoleaks

Published US IDE Results*		
	1-Year Type II Endoleak Rate	5-Year Type II Endoleak Rate
Polyester Graft #1	4.9%	3.0%
Polyester Graft #2	9.1%	4.1%
ePTFE Graft #3	20.2%	12.3%
ePTFE Graft #4	35.7%	14.3%

*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.

Rates of type II Endoleaks may vary by graft material*

Type II Endoleaks are associated with higher rates of secondary procedures[1]



1- Dijkstra et al. J Vasc Surg 2020;71:780-9

Summary/Conclusion

- Successful AAA therapy w/stent grafts traditionally determined by freedom from mortality, no endoleaks/need for secondary intervention
  - Importance of sac regression highlight in studies showing patients with non-shrinking aneurysm sacs have an increased mortality
  - Endoleaks, including type II, have a negative impact on sac regression
- Endurant design features influence AAA sac dynamics and therapy success
  - Accurate deployment mechanism
  - Robust seal stent
  - Low permeability polyester graft material
- Endograft design plays important role in success of endovascular AAA therapy