

How and Why do the Endurant Endograft for EVAR in France Differ from the Global Results

What are the implications

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Disclosure



Speaker name:

Becquemin JP

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
- Studies sponsored sy Medtronic

- I do not have any potential conflict of interest

Editor's Choice — Five Year Outcomes of the Endurant Stent Graft for Endovascular Abdominal Aortic Aneurysm Repair in the ENGAGE Registry

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WHAT THIS PAPER ADDS

Analysis of the performance of modern stent grafts is necessary as earlier generation stent grafts are associated with an increased need for secondary interventions. Five year follow up of patients treated with the Endurant stent graft in the ENGAGE registry demonstrates better survival and lower rates of endoleaks, stent migration, and re-intervention. Longer term follow up to 10 years will be necessary to compare fully the advantages of endovascular aneurysm repair against open repair. However, these mid-term results show the Endurant stent graft was successful in treating a large cohort of patients with a wide range of anatomies.

Objective/background: Endovascular abdominal aortic aneurysm repair (EVAR) is commonly used to treat abdominal aortic aneurysm (AAA). However, the incidence of long-term complications and the need for re-interventions after EVAR remain a concern. Newer generation stent grafts have encouraging short and mid-term outcomes, but thorough analysis of their long-term performance is necessary.

Methods: The ENGAGE registry includes a total of 1263 patients with AAA enrolled from March 2009 to April 2011 at 79 centres across 30 countries. The aim of this study is to present standard EVAR outcomes in the registry after five years.

Results: A significant proportion of the ENGAGE patients presented with challenging features, such as 15.2% with an AAA diameter >7 cm, 12.0% with proximal neck lengths <15 mm, and 10.2% with infrarenal neck angles >60°. Of the 1263 enrolled subjects, 17.8% were implanted outside of the instructions for use for the device. At the five year follow up, the Kaplan–Meier overall survival rate was 67.4% and the freedom from aneurysm related mortality was 97.8%. Freedom from aneurysm rupture, secondary procedures, and conversion to open repair at five years were 98.6%, 84.3%, and 97.9% respectively. The five year freedom from type IA endoleaks was 95.2% and for type III endoleaks 97.4%. Aneurysm sac diameter at five years was observed to have either decreased ≥ 5 mm in diameter or remained stable in 89.4% of the patients.

Conclusion: Five year follow up of patients in the ENGAGE registry demonstrates sustained safety, effectiveness, and durability in an international cohort that is reflective of real world experience. Additional follow up is expected through to 10 years.

Keywords: ENGAGE, Endurant, EVAR, Long term outcomes

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Five Year Patient Outcomes of Endovascular Abdominal Aortic Aneurysm Repair in the ENDURANT France Registry

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WHAT THIS PAPER ADDS

This analysis of the ENDURANT France registry provides five year outcomes from a French population treated under real life conditions. Patients experienced a $69.9\% \pm 3.5\%$ Kaplan–Meier overall survival, $97.6\% \pm 1.2\%$ freedom from aneurysm related mortality, low rates of type IA endoleaks, few secondary procedures, and showed positive signs of remodelling. These outcomes are similar to other recent global registries and better than the outcomes with earlier generation devices. With the current focus on managing costs and reimbursements, these five year outcomes of a French specific cohort provide further evidence of the long term durability and success with the Endurant stent graft system.

Objective: Endovascular repair is the preferred method of treatment for infrarenal abdominal aortic aneurysms with numerous publications from multiple geographic regions showing excellent patient outcomes. Since the original ACE (Anevrisme de l'aorte abdominale: Chirurgie versus Endoprothese) randomised control trial, studies of French specific population have also contributed significantly to the body of evidence in support of endovascular abdominal aortic repair.

Methods: In the ENDURANT France registry, 180 patients were consecutively enrolled from 20 French centres starting in 2012. Investigational sites included public and private practice and differing centre volumes to be as representative of real world French experience as possible. The aim of this study was to present the five year outcomes from this registry.

Results: Instructions for use (IFU) were respected in 97.8% (176/180) of patients. At five years, the Kaplan–Meier overall survival was $69.9\% \pm 3.5\%$ and the freedom from aneurysm related death was $97.6\% \pm 1.2\%$. The freedom from Type IA endoleaks was $94.5\% \pm 1.7\%$, freedom from endoleaks of any type was $70.1 \pm 3.4\%$, and freedom from secondary endovascular procedure $90.4\% \pm 2.6\%$. In addition, 61.6% (45/73) of patients exhibited sac shrinkage at five years.

Conclusion: In this five year report of the Endurant France registry, survival, re-intervention, and freedom from endoleak rates were comparable to recent EVAR registries and there was a high sac shrinkage rate. Secondary procedure and aneurysm rupture were lower than those of ACE, the French RCT which included older generation devices. This prospective registry demonstrates favourable five year outcomes of the Endurant stent graft used within IFU.

Keywords: Endurant stent graft, EVAR, France, Long term outcomes

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Editor's Choice — Five Year Outcomes of Endovascular Abdominal Aortic Aneurysm Repair

Real World patients and practice Liberal inclusion / exclusion criteria

Endovascular Abdominal Aortic Aneurysm Repair Registry

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WHAT THIS PAPER ADDS

Analysis of the performance of EVAR with an increased need for re-intervention and re-intervention. Longer follow-up and re-intervention. Longer follow-up and re-intervention.

100% Data Management Reviewed Independent End Point and Clinical Event Monitoring

French population treated with EVAR, overall survival, 97.6% ± 1.2% at five years, secondary procedures, and global registries and better outcomes in managing costs and re-intervention evidence of the long term

Objective/background: Endovascular abdominal aortic aneurysm repair (EVAR) is commonly used to treat abdominal aortic aneurysm (AAA). However, the incidence of long-term complications and the need for re-interventions after EVAR remain a concern. Newer generation stent grafts have encouraging short and mid-term outcomes, but thorough analysis of their long-term performance is necessary.

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Conclusion: In this five year report of the Endurant France registry, survival, re-intervention, and freedom from endoleak rates were comparable to recent EVAR registries and there was a high sac shrinkage rate. Secondary procedure and aneurysm rupture were lower than those of ACE, the French RCT which included older generation devices. This prospective registry demonstrates favourable five year outcomes of the Endurant stent graft used within IFU.

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High Quality Data

ENGAGE and Endurant France - DEMOGRAPHICS & RISK FACTORS

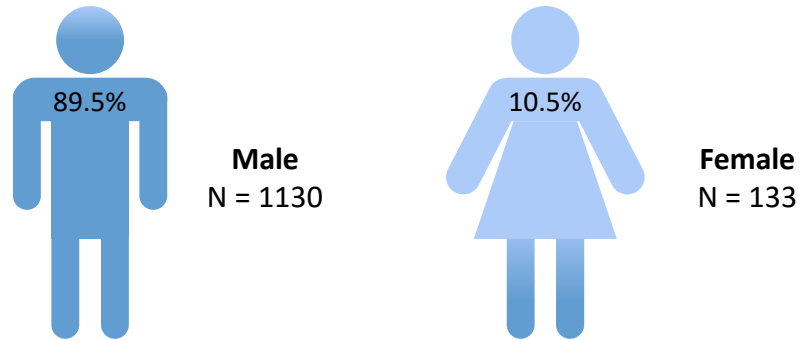
ENGAGE 1263 patients
30 countries, 79 sites



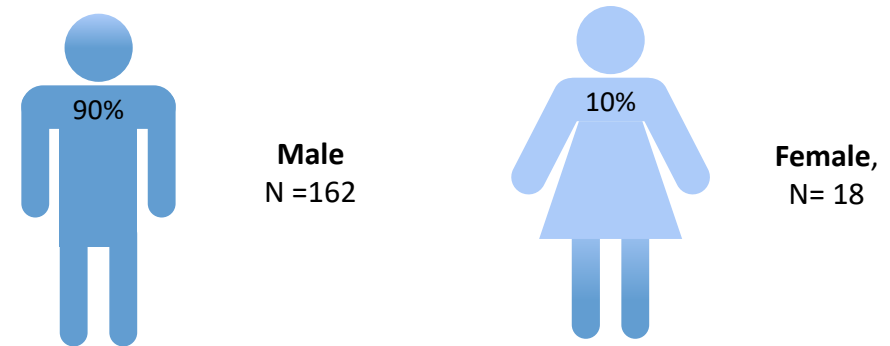
Endurant France 180 patients,
1 country, 20 sites



Mean age: 73.1 ± 8.1 years (min 43, max 93)



Mean age: 74.6 ± 8.7 years (min 46, max 91)



Tobacco use	49.3% (608/1233)
Hypertension	75.4% (940/1246)
Hyperlipidemia	60.6% (721/1190)
Diabetes	19.0% (237/1245)
Cancer	20.5% (254/1242)
Family History of Aneurysms	6.8% (86/1262)
Cardiac Disease	53.7% (678/1262)
▪ Myocardial Infarction (MI)	26.6% (321/1209)
▪ Arrhythmia	16.1% (199/1234)
▪ Angina	15.7% (194/1235)
▪ Congestive Heart Failure (CHF)	5.8% (71/1230)
▪ Coronary Artery Disease (CAD)	34.8% (424/1219)
▪ Cardiac Revascularization (including CABG or PTCA)	27.2% (339/1245)
▪ Valvular Heart Disease	6.1% (76/1236)

Tobacco use	43.3% (78/180)
Hypertension	73.3% (132/180)
Hyperlipidemia	63.3% (114/180)
Diabetes	17.2% (31/180)
PAD	20.6% (37/180)
Chronic Respiratory Insufficiency	6.1% (11/180)
Renal Failure	5.6% (10/180)
Heart Failure	3.9% (7/180)
Coronary artery disease (CAD)	26.1% (47/180)
Other relevant medical history	41.1% (74/180)

ASA CLASSIFICATION AT BASELINE

ENGAGE

N = 1262

Class I **6.0%** (76/1262)

Class II **41.8%** (528/1262)

Class III **41.5%** (524/1262)

Class IV **10.6%** (134/1262)

ENDURANT FRANCE

N = 180

Class I **6.7%** (12/180)

Class II **35.0%** (63/180)

Class III **52.8%** (95/180)

Class IV **5.6%** (10/180)

Both studies had Challenging/Real World Population: CLASS IV pts included

ANEURYSM FEATURES

	ENGAGE	French Registry	P-value
AAA Diameter (mm)	60.3 +/- 11.6	56,6 +/- 8,5	NS
Challenging Anatomy	22 %	21 %	NS
Symptomatic AAA	16 %	2 %	0.01
Outside IFU	17,8 %	2,2 %	0.001

PROCEDURE DETAILS

	ENGAGE	French Registry
General Anesthesia	62 %	90 %
Procedural Duration (min)	100 +/- 45	115 +/- 52
Fluoroscopic time (min)	21 +/- 12	18 +/-14
Contrast medium (ml)	131 +/-71	123 +/- 66
Blood loss (ml)	208 +/- 220	NA

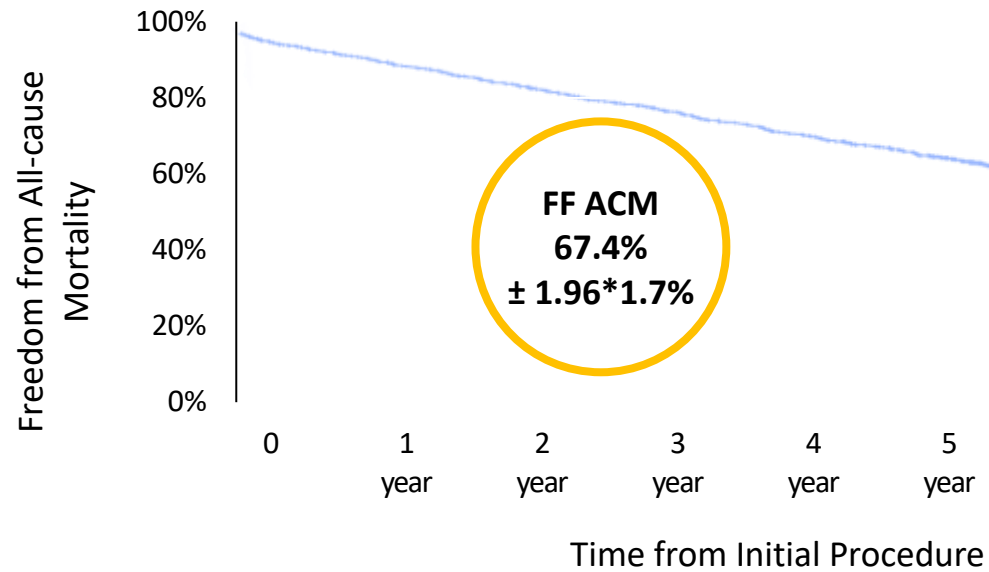
POST-OPERATIVE RESULTS

	ENGAGE	French registry
Successful Delivery	99 %	99 %
ICU or RCR stay > 24 h	6 %	5 %
In-hospital stay (days)	5 +/- 5	6 +/- 5

	ENGAGE	French registry
Mortality	1.3 %	1.8 %
Complications	1,8 %	2 %
Conversion	0.2 %	0 %
Additional Procedures	21 %	21.7 %

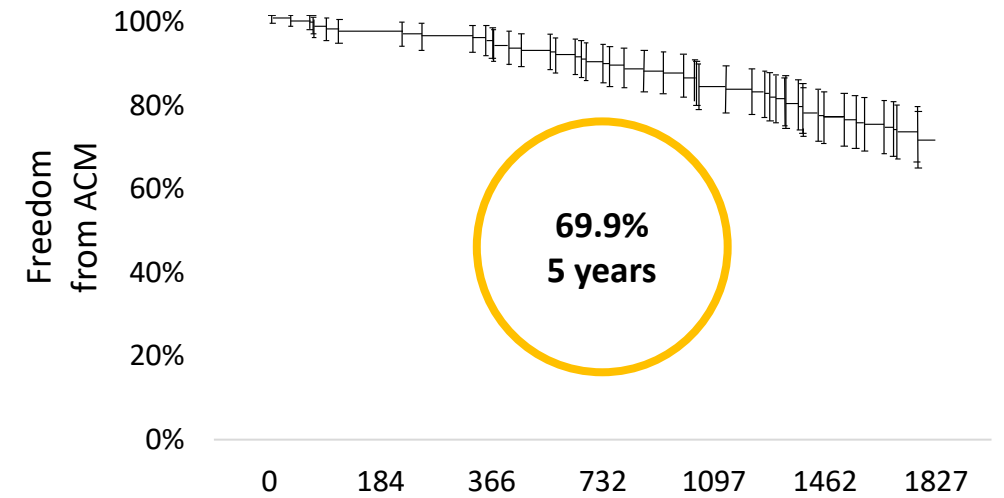
FREEDOM FROM ALL-CAUSE MORTALITY

ENGAGE



	Kaplan-Meier Estimates for All-cause Mortality					
	0–30 days	1 month–1 year	1–2 year	2–3 year	3–4 year	4–5 year
No. at Risk ¹	1263	1243	1150	998	893	779
No. of Events	16	79	80	76	70	54
No. Censored ²	4	14	72	29	44	262
Kaplan-Meier Estimate ³	0.987	0.924	0.859	0.793	0.729	0.674
Peto Standard Error	0.003	0.008	0.010	0.012	0.014	0.017

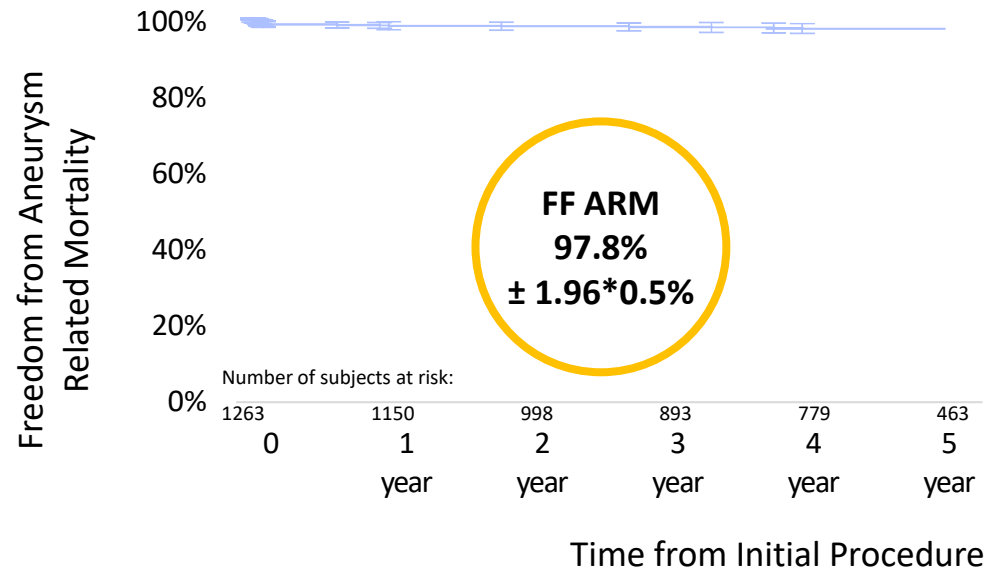
ENDURANT FRANCE



	Days after Endurant stent graft placement						
	0–30	31–183	184–365	366–731	732–1096	1097–1461	1462–1826
Days	0–30	31–183	184–365	366–731	732–1096	1097–1461	1462–1826
No. at Risk	180	179	173	169	158	147	134
Events	1	6	4	9	11	13	9
Censored	0	0	0	2	0	0	42

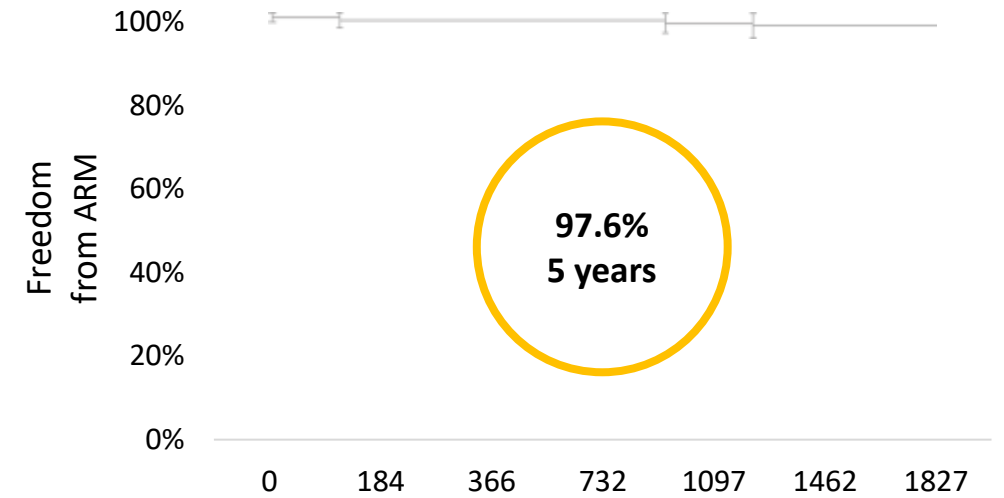
FREEDOM FROM ANEURYSM RELATED MORTALITY

ENGAGE



Kaplan-Meier Estimates for Aneurysm-related Mortality						
	0–30 days	1 month–1 year	1–2 year	2–3 year	3–4 year	4–5 year
No. at Risk ¹	1263	1243	1150	998	893	779
No. of Events	16	3	1	1	3	1
No. Censored ²	4	90	151	104	111	315
Kaplan-Meier Estimate ³	0.987	0.985	0.984	0.983	0.979	0.978
Peto Standard Error	0.003	0.004	0.004	0.004	0.005	0.005

ENDURANT FRANCE



Days after Endurant stent graft placement							
Days	0–30	31–183	184–365	366–731	732–1096	1097–1461	1462–1826
No. at Risk	180	179	173	169	158	147	134
Events	1	1	0	0	1	1	0
Censored	0	5	4	11	10	12	51

Aneurysm-Related Deaths

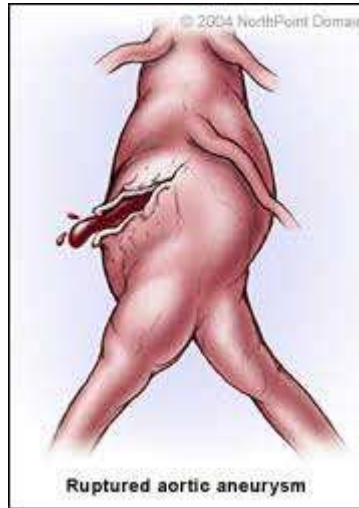
Day 4: Mesenteric Infarction, Day 114: Acute Pulmonary Edema,
Day 929: Aorto-Enteric Fistula, Day 1220: AAA Rupture

RUPTURE



ENGAGE Registry

13/1263 1 %



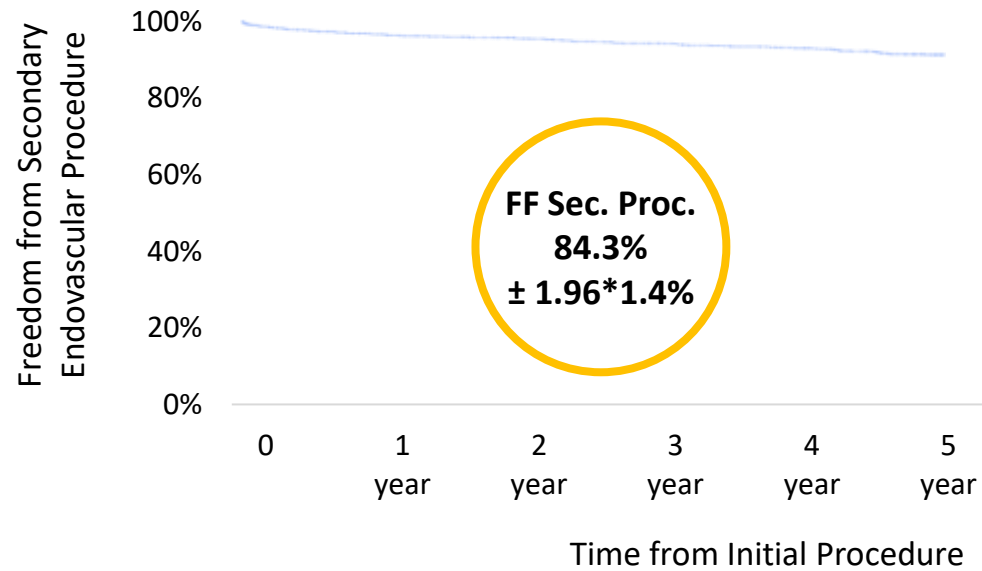
French Registry

1/180 0.5 %



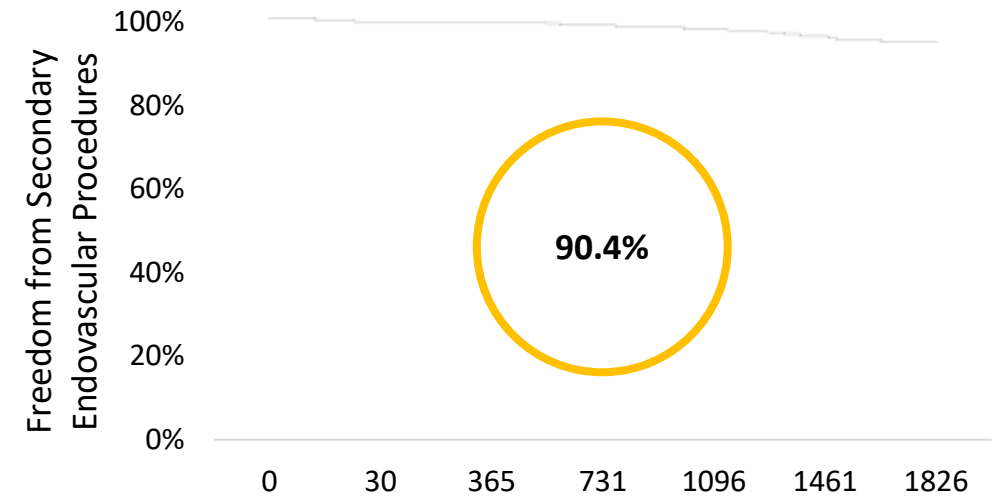
FREEDOM FROM SECONDARY PROCEDURE

ENGAGE



Kaplan-Meier Estimates for Secondary Endovascular Procedure						
	0-30 days	1 month-1 year	1-2 year	2-3 year	3-4 year	4-5 year
No. at Risk ¹	1257	1214	1081	921	804	685
No. of Events	25	51	21	22	19	22
No. Censored ²	18	82	139	95	100	258
Kaplan-Meier Estimate ³	0.98	0.938	0.919	0.896	0.874	0.843
Peto Standard Error	0.004	0.007	0.008	0.010	0.012	0.015

ENDURANT FRANCE



Days after Endurant stent graft placement						
Days	0-30	31-365	366-731	732-1096	1097-1461	1462-1826
No. at Risk	180	179	166	155	141	123
Events	0	3	0	3	5	3
Censored	1	10	11	11	13	46

Reinterventions for all type Endoleak (n = 10)

Type I endoleaks (n = 4), Type II endoleaks (n = 5), Type III endoleak (n = 1)

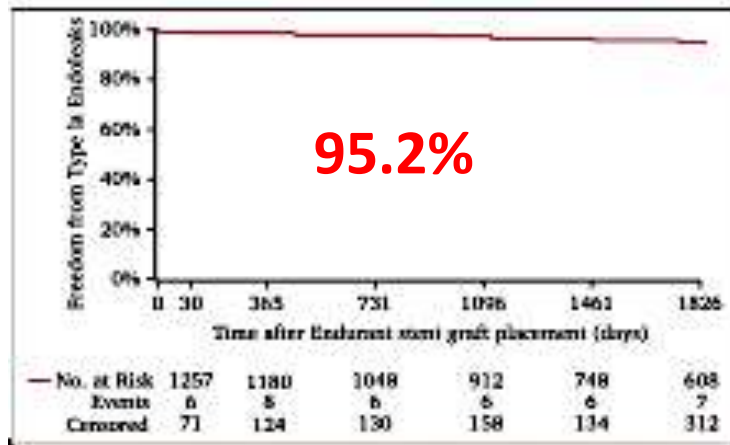
ENGAGE and Endurant France – Main Outcomes

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ENGAGE Freedom from type Ia endoleak

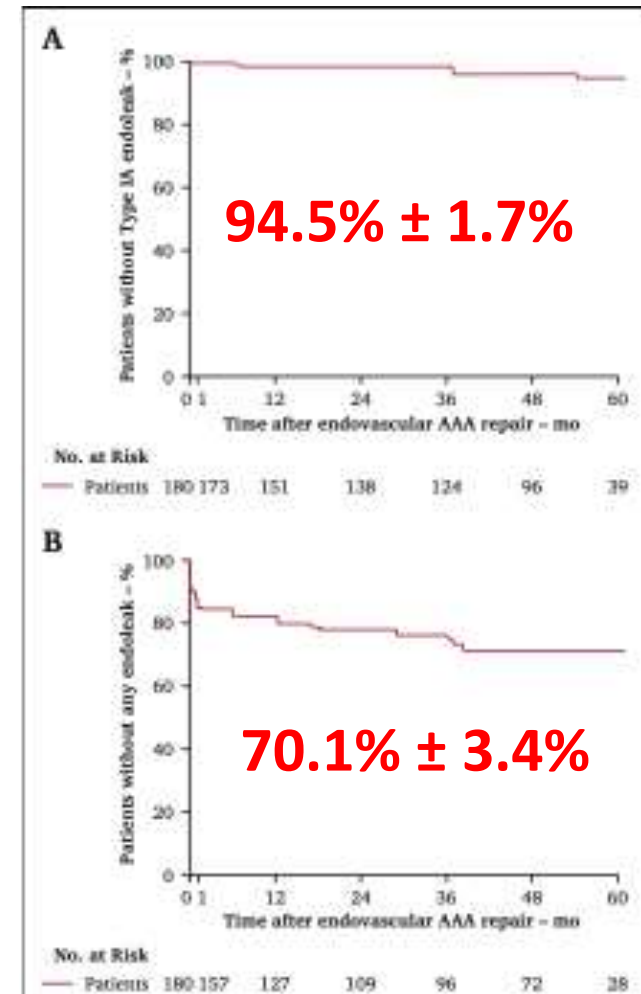


Freedom from	%
Any endoleak	68.6 %
Type Ib endoleak	95.9%
Type III endoleak	97.4%

Eur J Vasc Endovasc Surg (xxxx) xxx, xxx

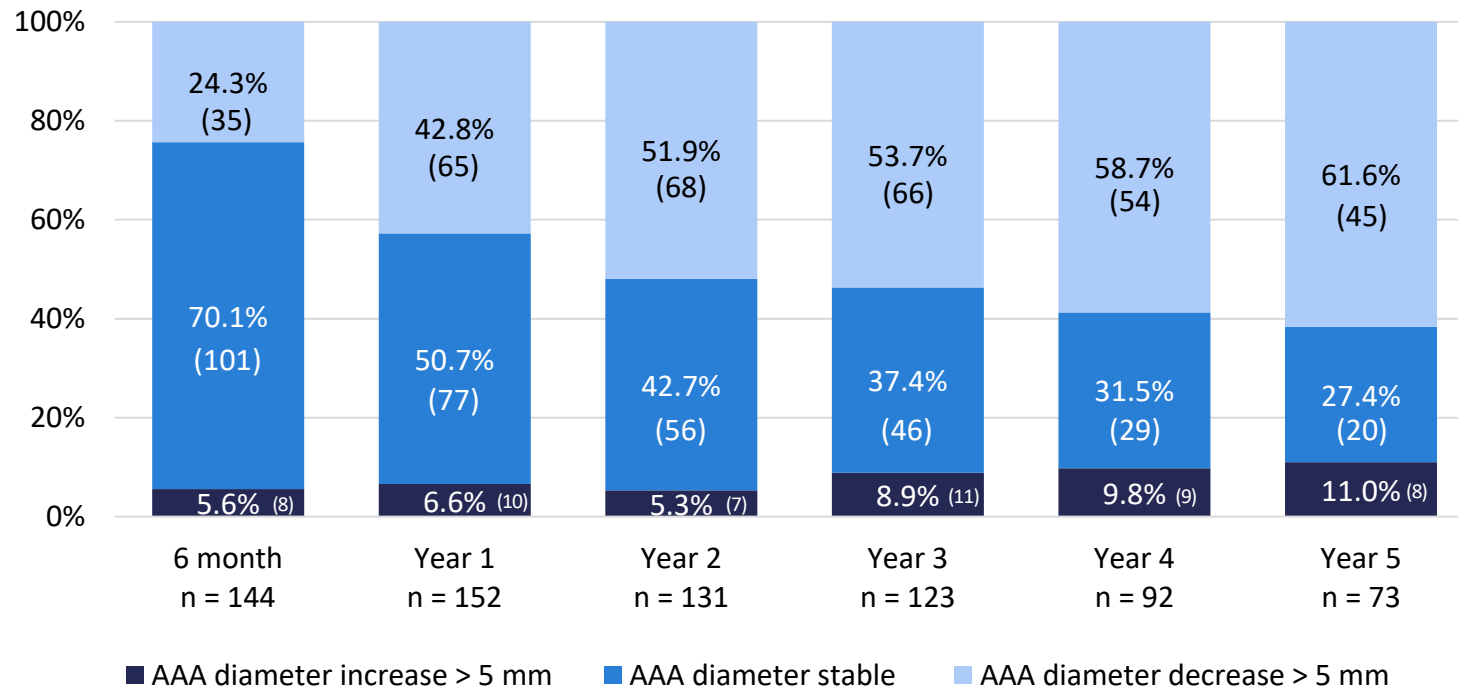
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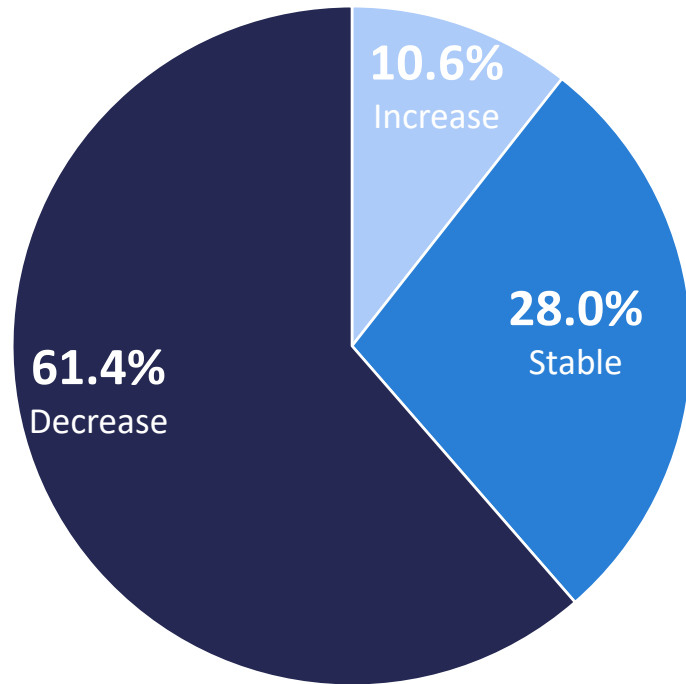
FRENCH ENDURANT REGISTRY

AAA SAC Dynamic



Majority of AAA show decrease/stable diameter at 5 years: **89%**

ENGAGE REGISTRY



Majority of AAA show decrease/
stable diameter
at 5 years: **89.4%**

In Summary

The ENGAGE and the French post Market registry show:

- 1) Comparable five year results in term of aneurysm related mortality and sac shrinkage
- 2) A slightly better five year all cause mortality and freedom from secondary procedures in the French post market registry
- 3) This difference may be related to a better respect of IFU and a more conservative approach of type 2 endoleak treatment
- 4) Both registries show improved EVAR results compared to the 15 year old RCTs
- 5) Longer term follow up remains necessary to ensure the durability of the device

Conclusions



- When used within the IFU, the 5 year results of the Endurant Graft are Outstanding
- In challenging cases, the results of the Endurant Graft remain quite acceptable



How and Why do the Endurant Endograft for EVAR in France Differ from the Global Results

What are the implications

Jean Pierre Becquemin
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