

The simple EVAR no longer exists: Everything that circulates is embolized and the prediction of failures is essential

Jean-Paul P.M. de Vries

Head of Department of Surgery
University Medical Centre Groningen, The Netherlands
j.p.p.m.de.vries@umcg.nl



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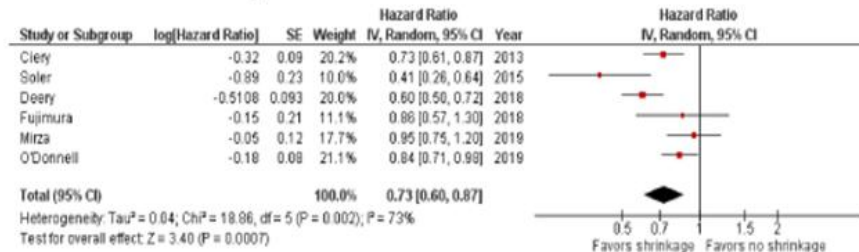
Flux Robotics

Is EVAR undergoing a paradigm shift?

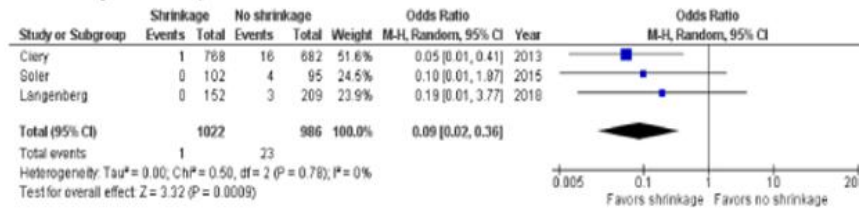
Evidence links sac shrinkage to better outcomes

17,096
 total subjects in 8 studies
 (8,518 patients with sac shrinkage & 8,578 patients without shrinkage)
 subjected to EVAR
 between 1997-2018²

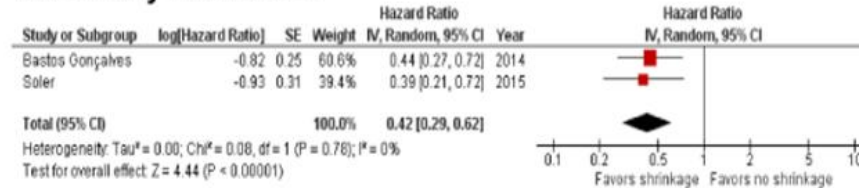
A All-Cause Mortality



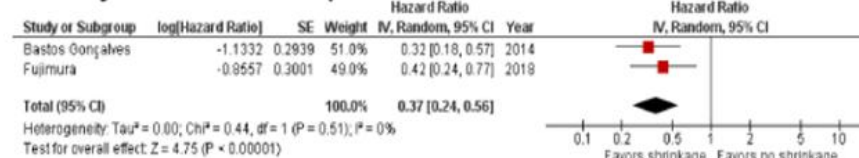
C Aneurysm Rupture



D Secondary Intervention



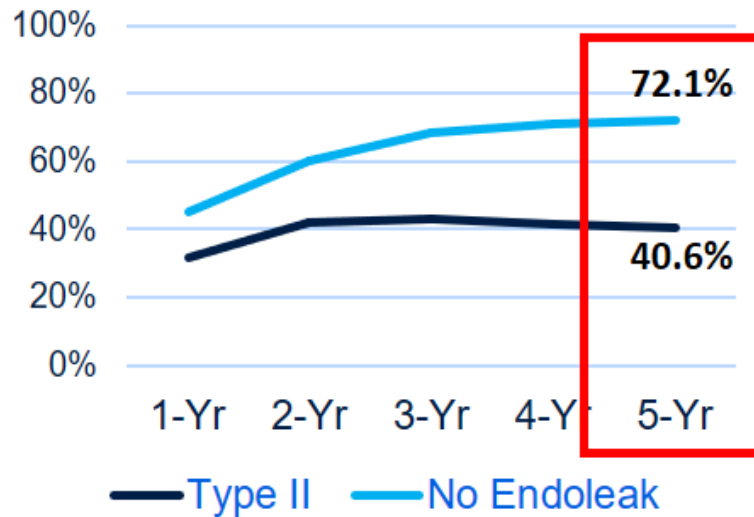
F Aneurysm-Related Complications



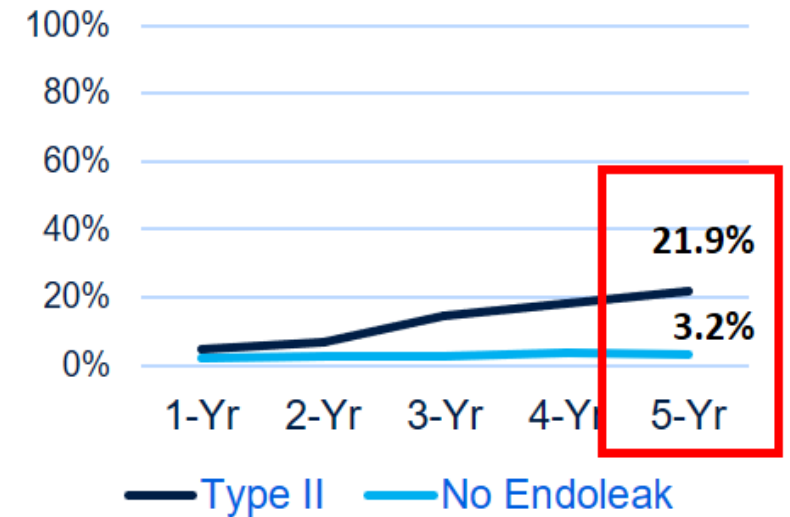
Isolated type II endoleaks

AAA sac dynamics

Shrinkage

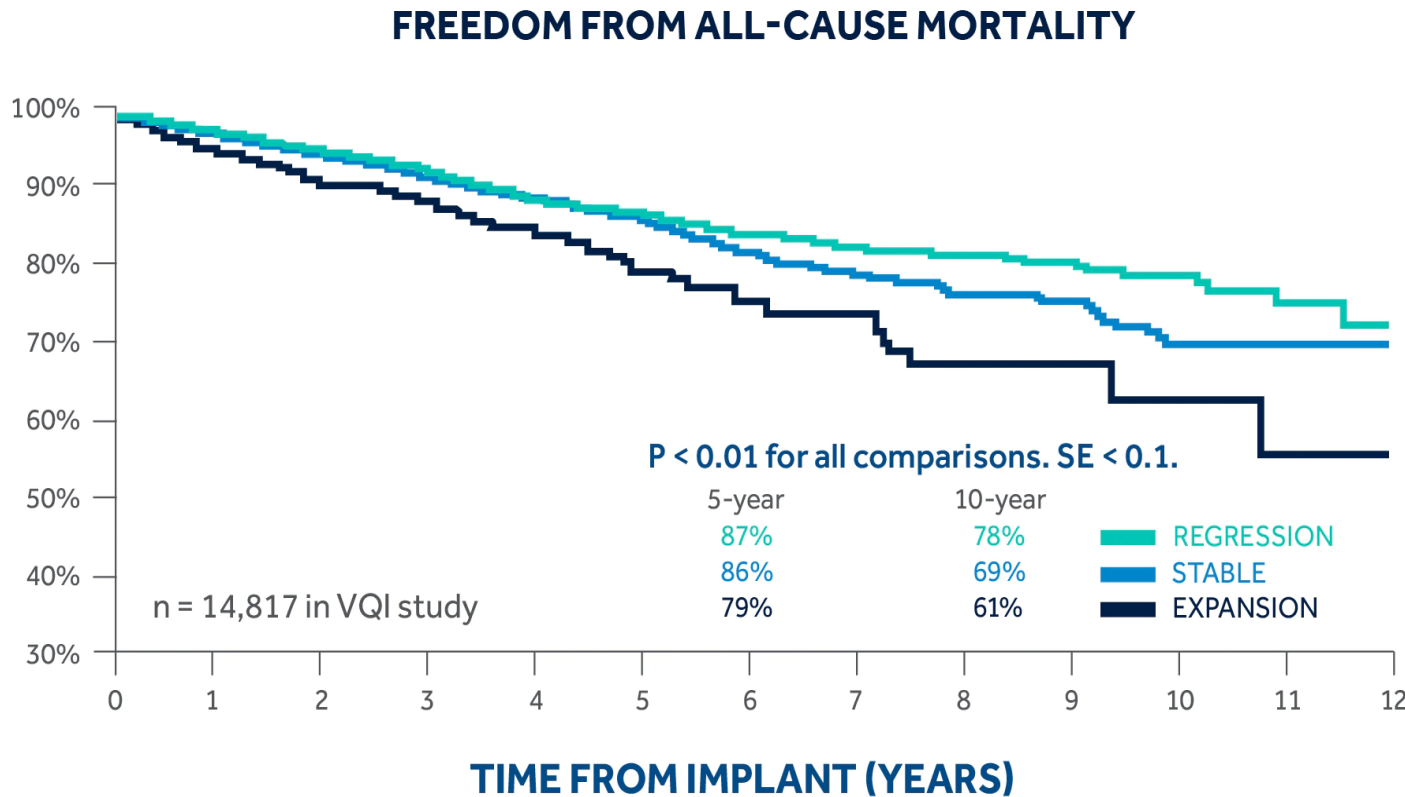


Growth



Isolated type II endoleak patients experienced *less AAA sac regression and greater AAA sac enlargement* compared to patients without any documented endoleaks

AAA sac expansion post-EVAR: increased mortality (VQI database)



**40%
Regress**

Survival
87% at 5y
78% at 10y

**35%
Stable**

Survival
86% at 5y
69% at 10y

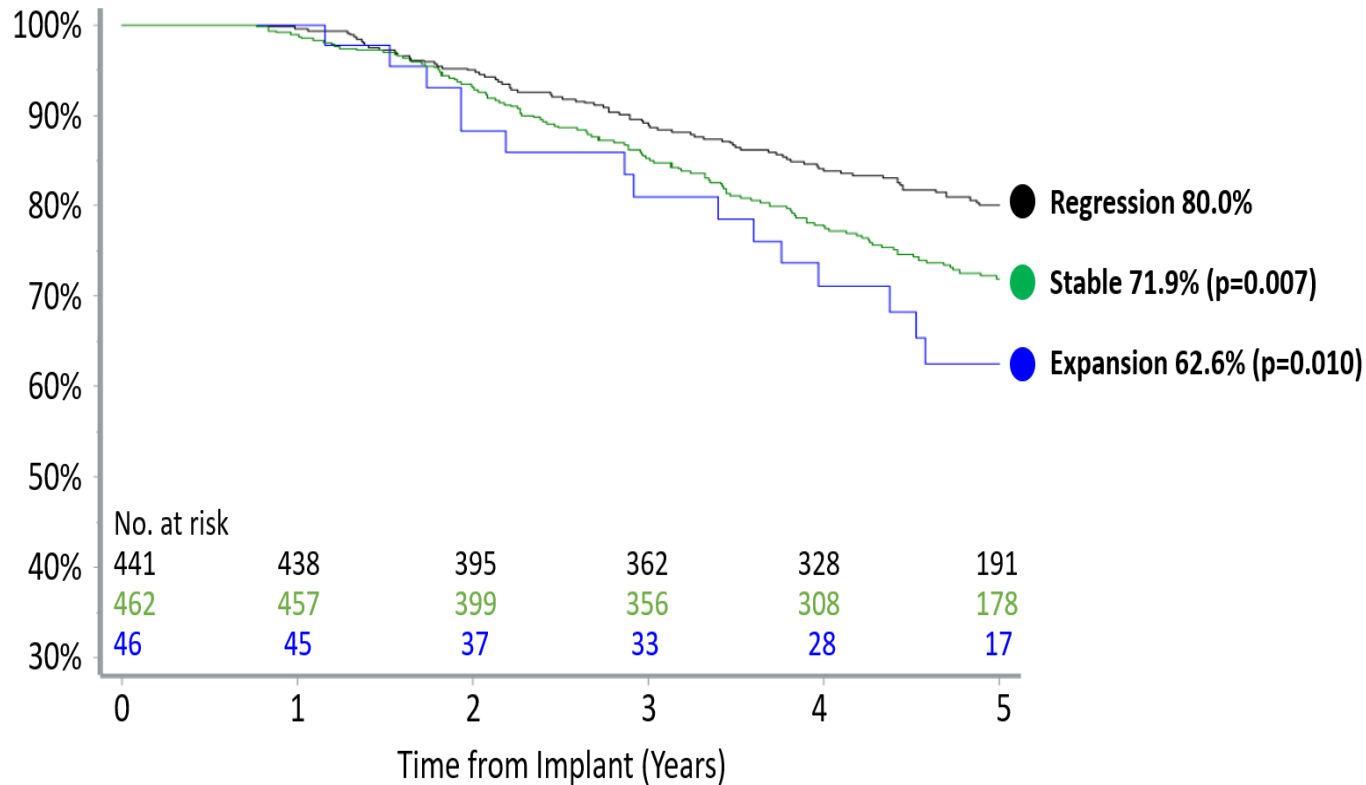
**25%
Expand**

Survival
79% at 5y
61% at 10y

*O'Donnell TFX, Deery SE, Boitano LA, Siracuse JJ, Schermerhorn ML, Scali ST, Schanzer A, Lancaster RT, Patel VI. Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival.

J Vasc Surg 2019;69(2):414-422.

AAA sac failure to regress post-EVAR: ENGAGE Registry



All patients (N=949) with 30-day and 1-year imaging following EVAR, 2009 - 2011

- **Sac expansion (>5 mm) and stable sac at 1 year were independently associated with increased mortality**

Largest Contemporary EVAR Registry with single manufacturer's stent graft: ENDURANT

1263 Patients
30 Countries
6 Continents

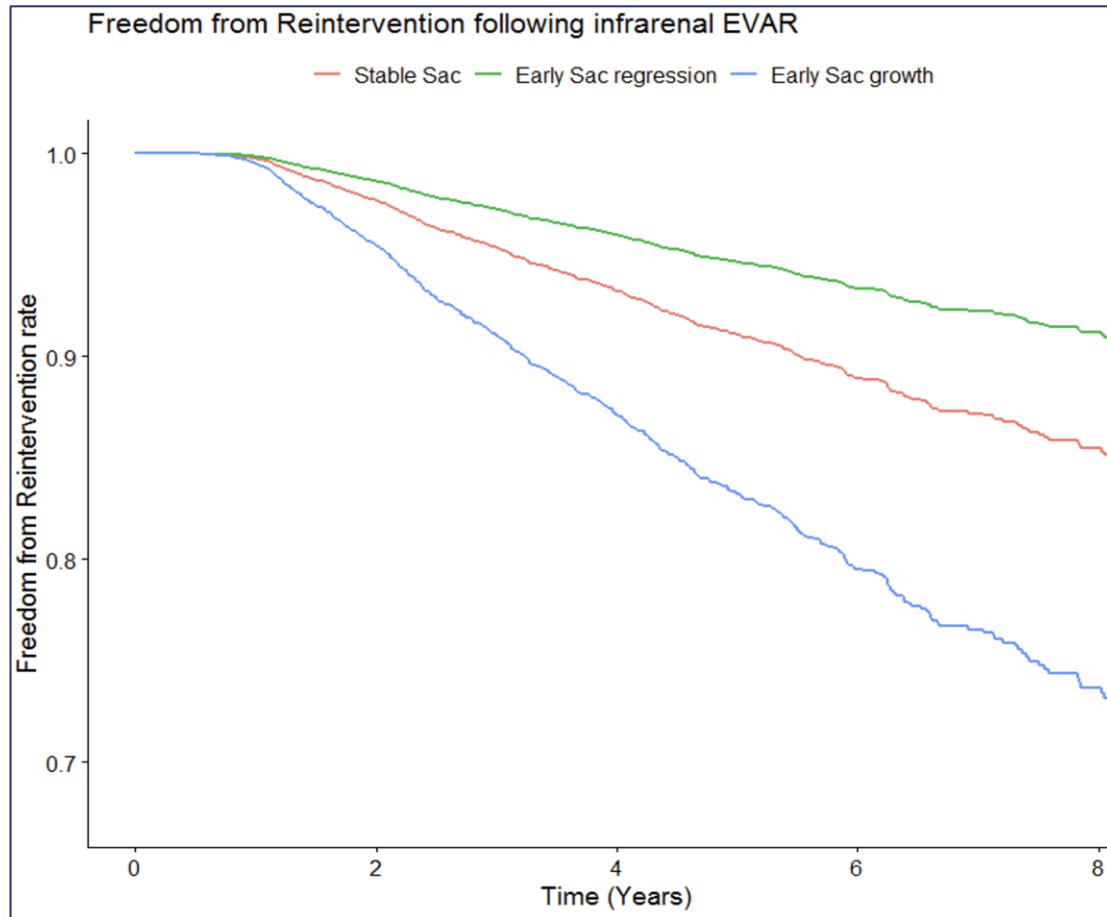
Real world patients:
Limited inclusion/exclusion criteria

Real world practice:
Limited procedural specifications
- Standard follow-up

14 publications and > 100 presentations at major International/National conferences characterizing ENDURANT clinical outcomes

Li et al. ENGAGE Registry. Accepted for publication.

8-Years freedom from reintervention (VQI database)

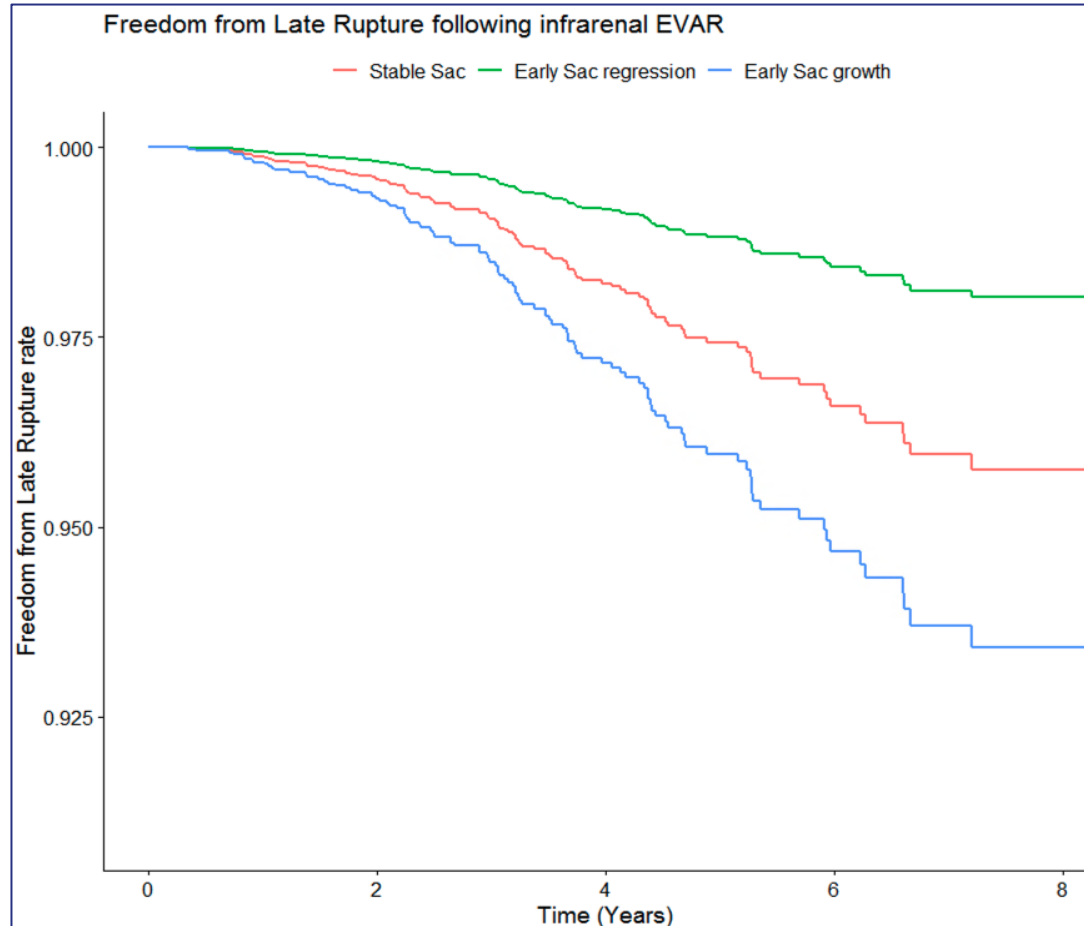


Sac Regression HR: 0.58 [95%CI: 0.50-0.68], p<.001

Ref: Stable Sac

Sac Expansion HR: 1.98 [95%CI: 1.57-2.51], p<.001

8-Years freedom from rupture (VQI database)

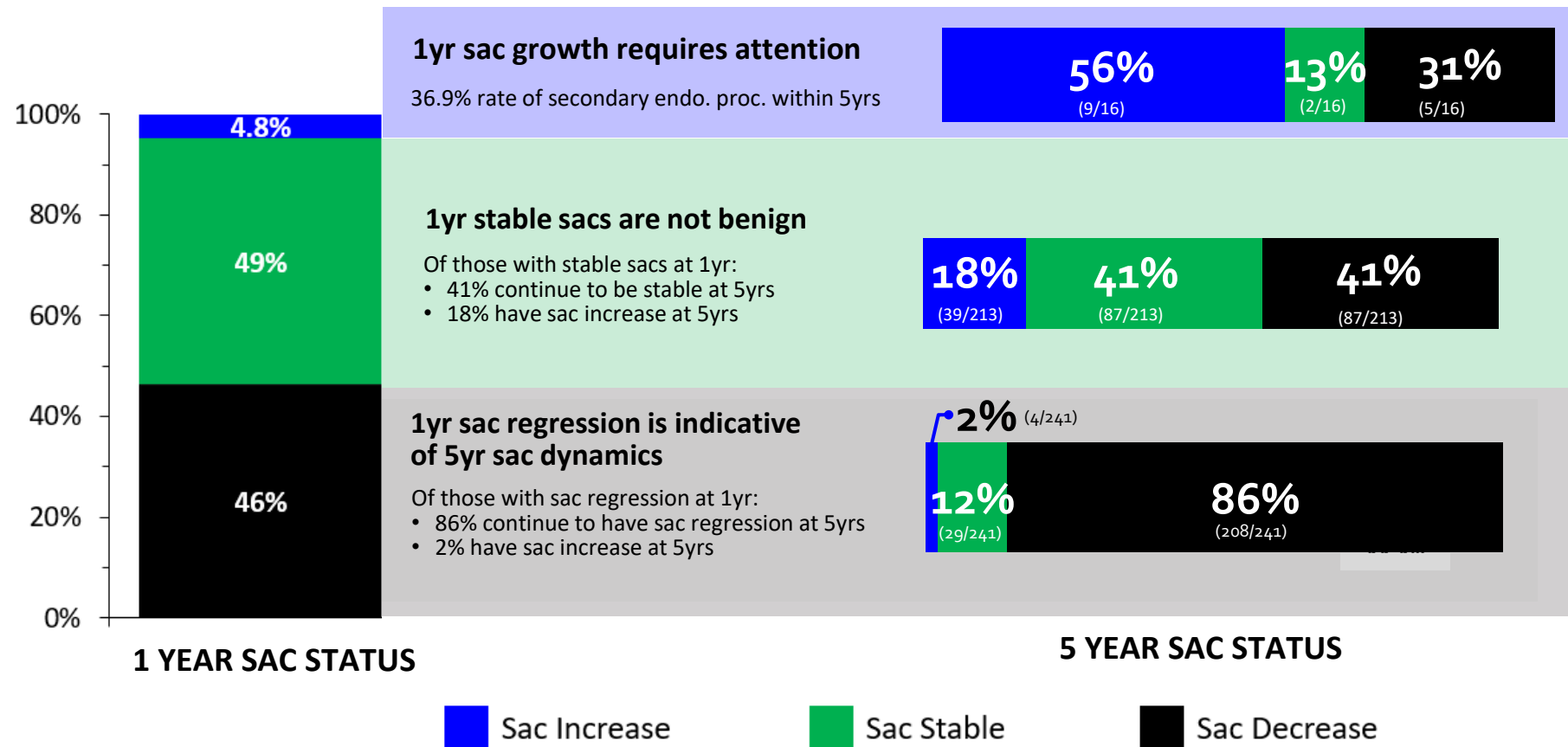


Sac Regression HR: 0.45 [95%CI: 0.29-0.69], p<.001

Ref: Stable Sac

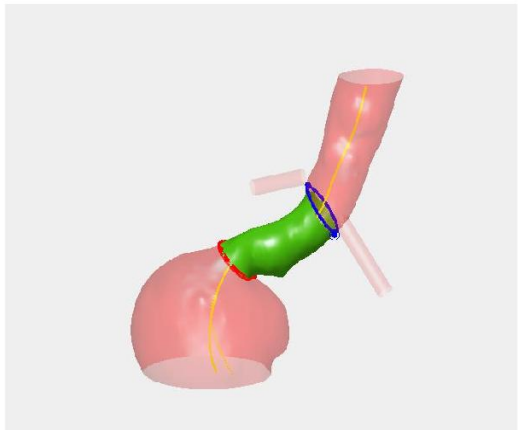
Sac Expansion HR: 1.61 [95%CI: 0.88-2.96], p=.12

One year-status of sac behavior is predictive of future sac behavior



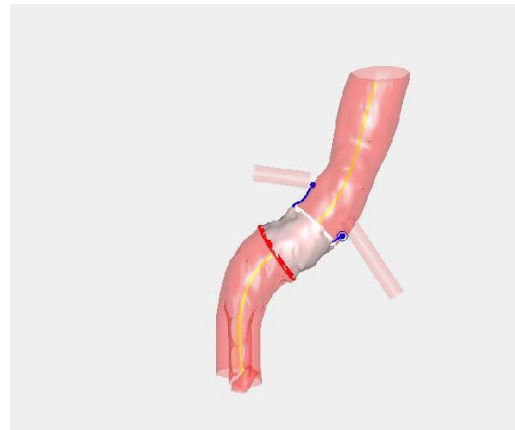
AAA growth leads to proximal seal loss (and risk of type IA endoleaks).

Preoperative CTA



Neck length: 34
mm

CTA 1 month



Apposition: 14 mm

CTA 13 months



Apposition: 4 mm

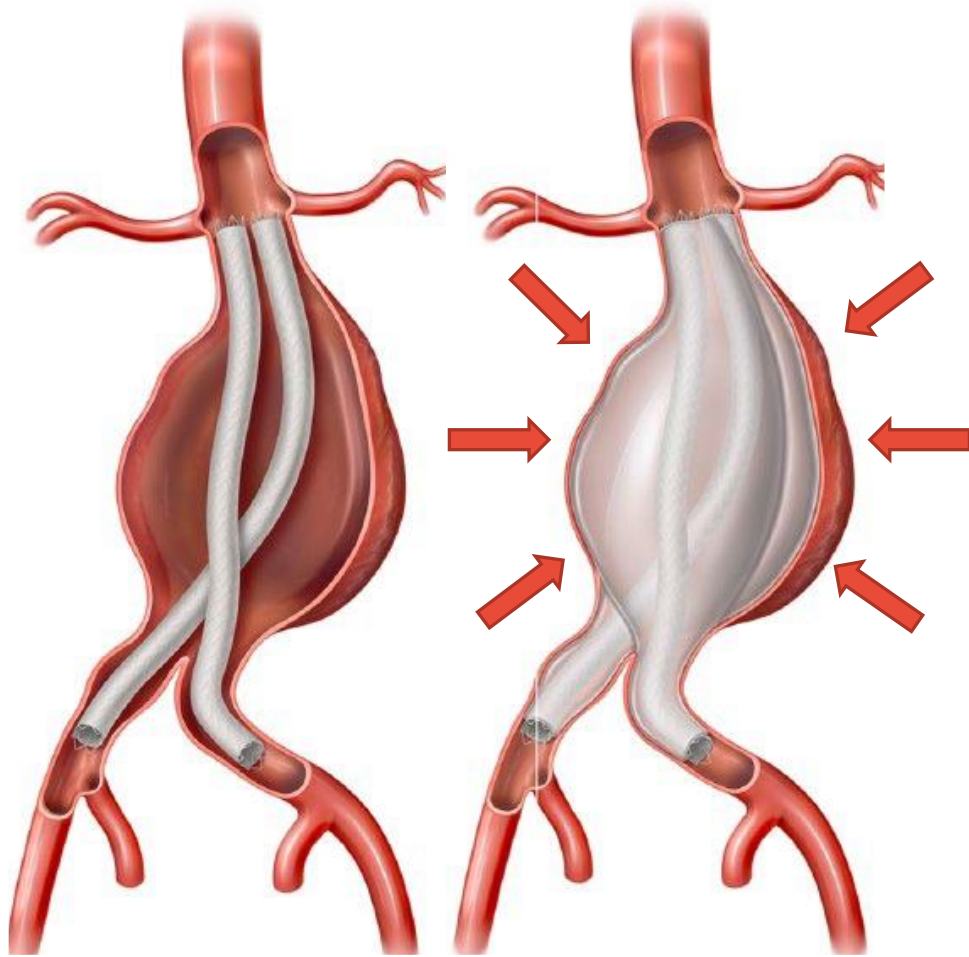
CTA 62 months



Apposition: 0 mm
(type IA endoleak)

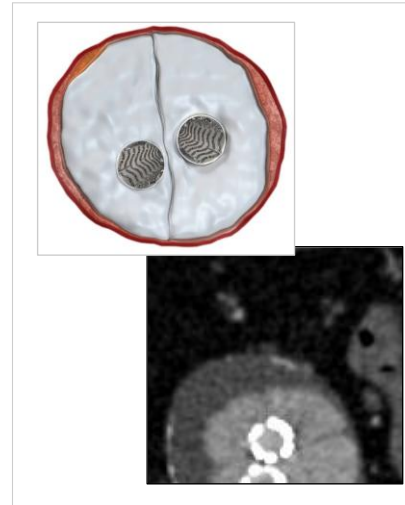
Past of active AAA sac management

Concept of EndoVascular Aneurysm Sealing (EVAS) = Nellix



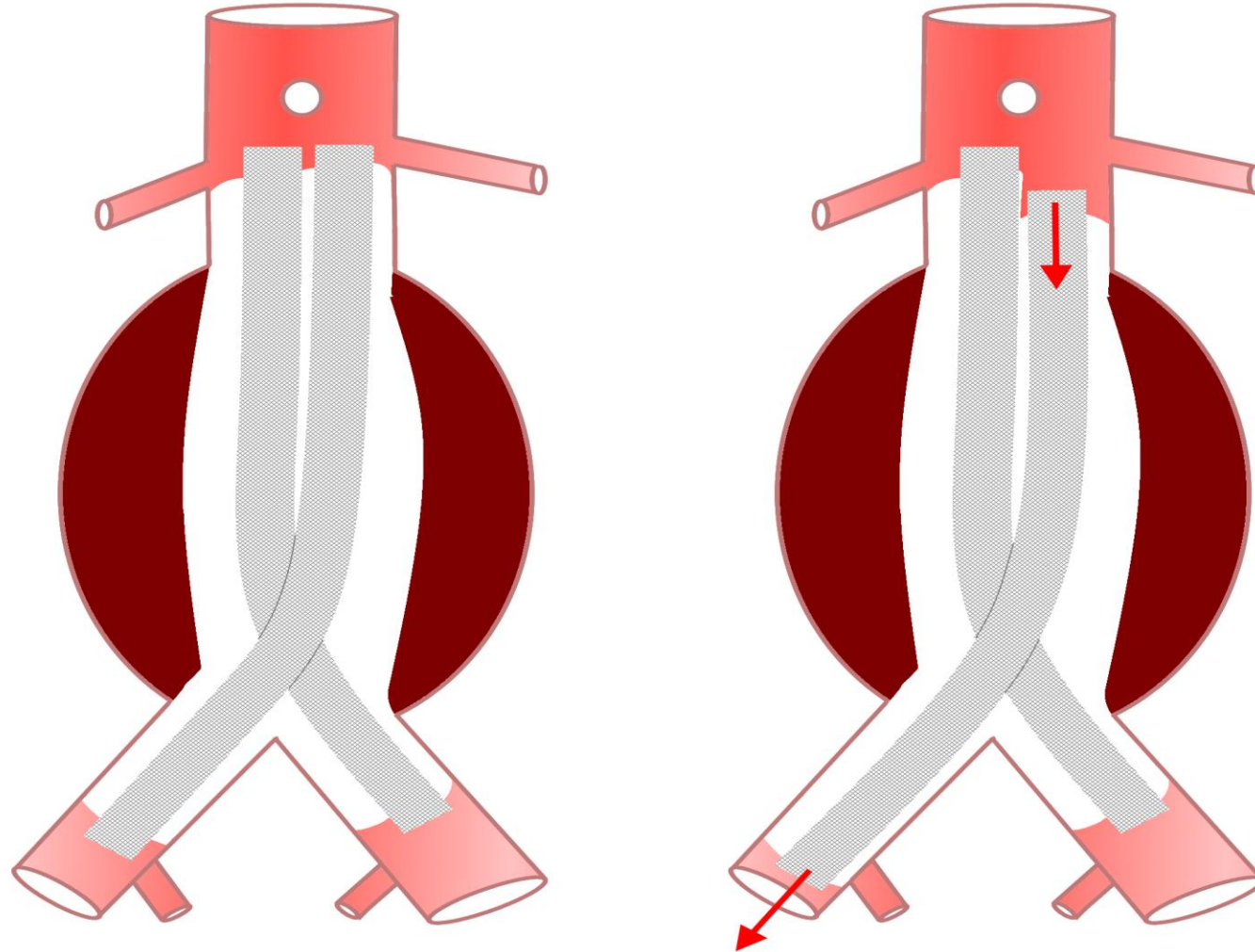
Active aneurysm sac management

- Designed to mitigate endoleak of any type
- Analogous to open surgical repair with sac ablation

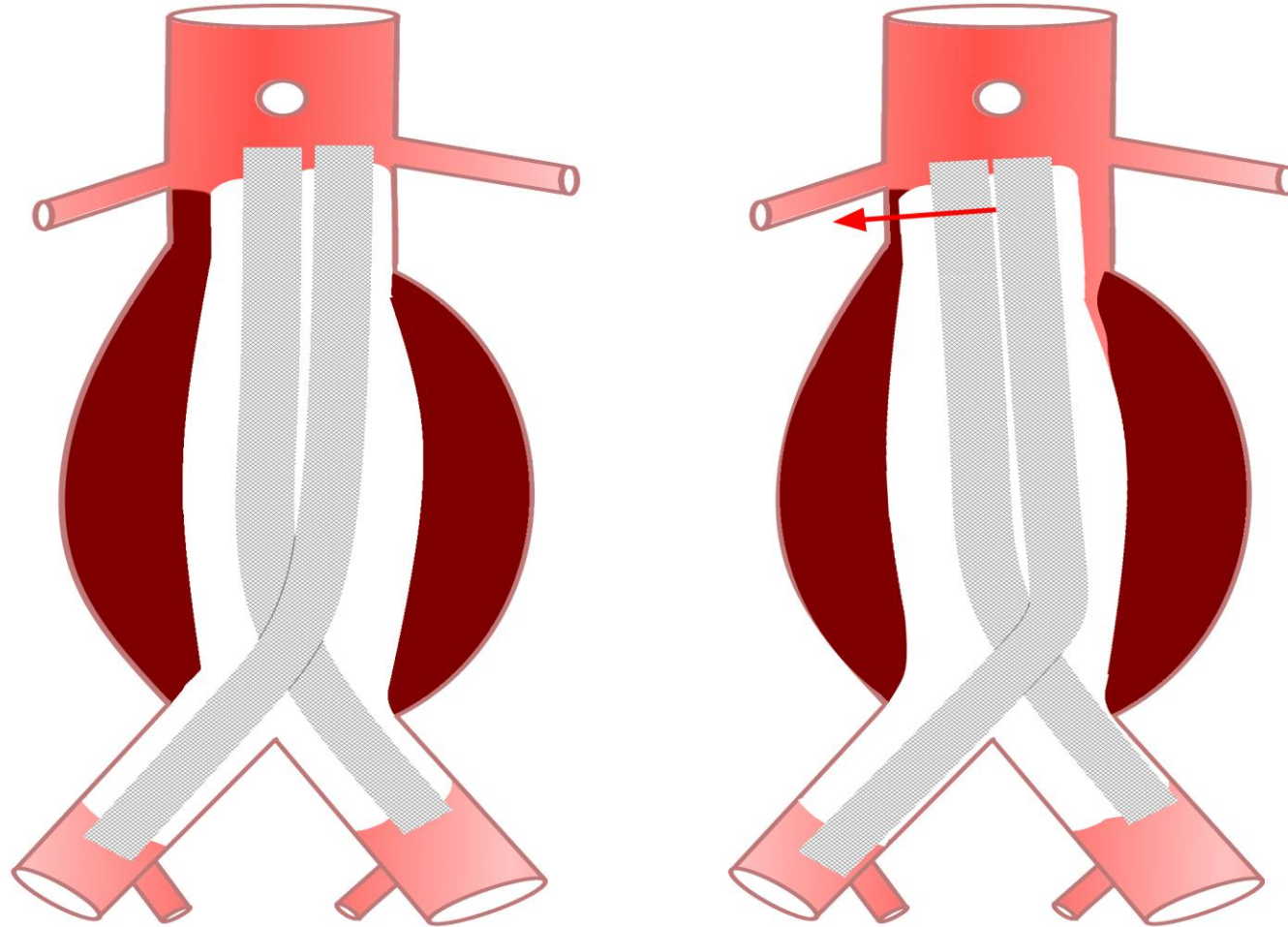


But

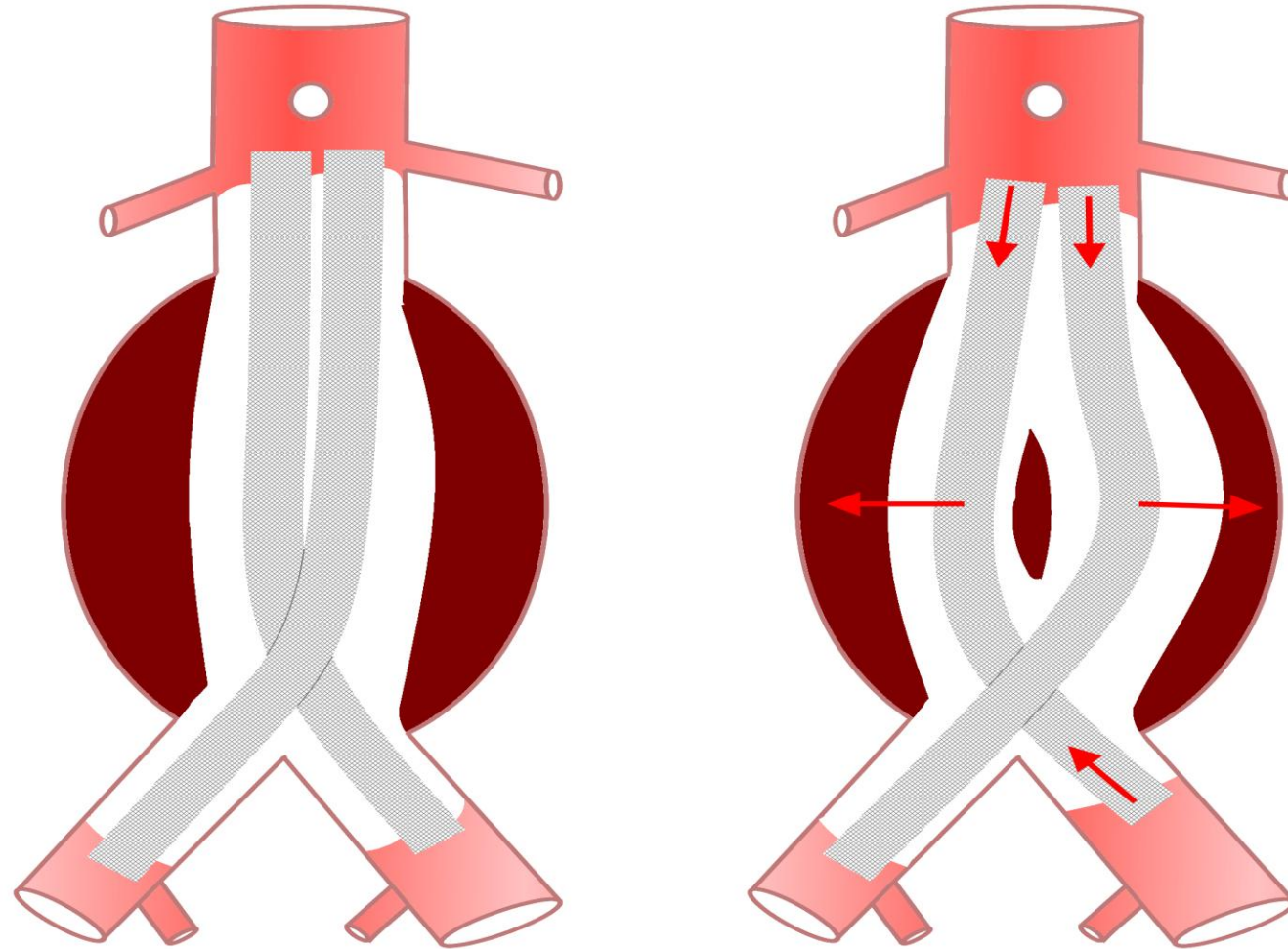
Different types of displacement (vertical)



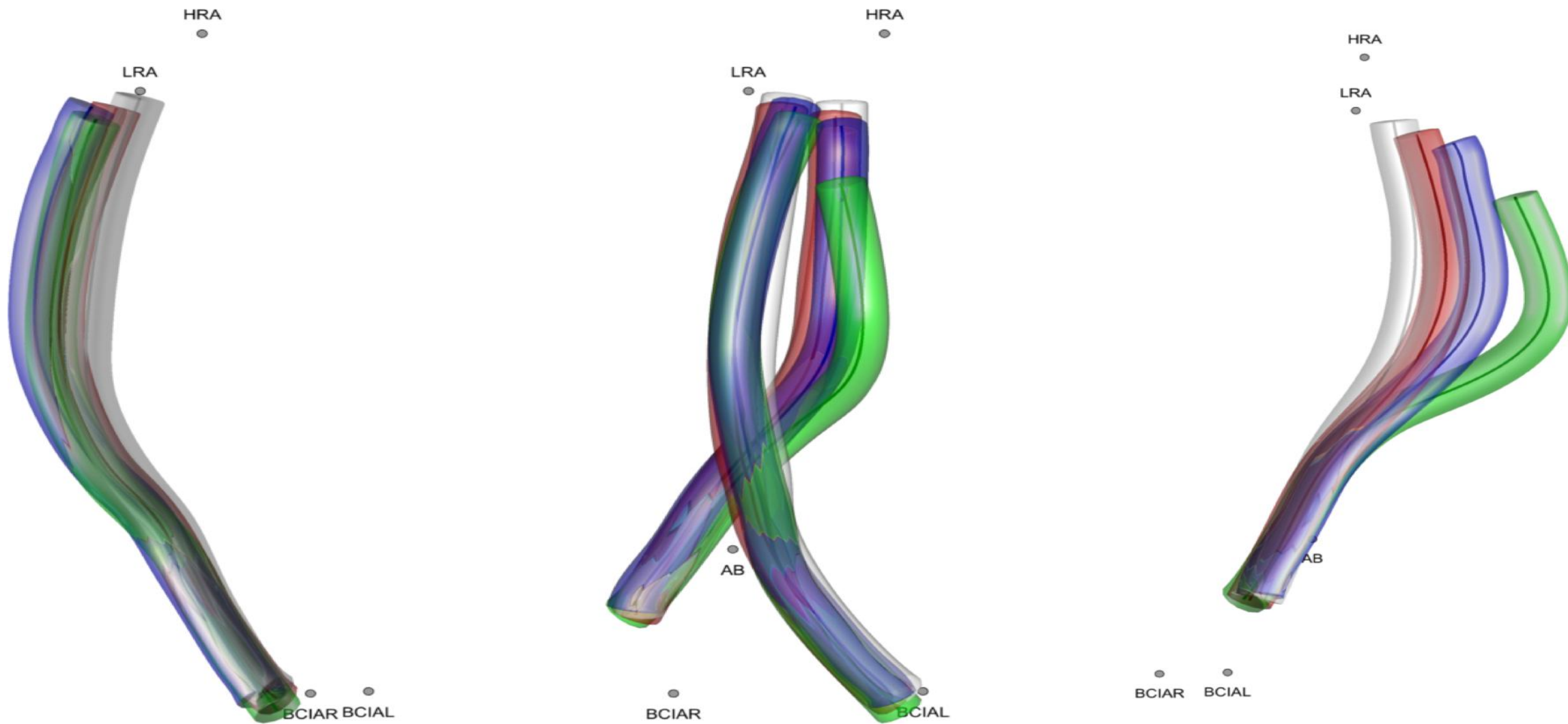
Different types of displacement (lateral)



Different types of displacement (buckling)



Case #1: Displacement, 18 months



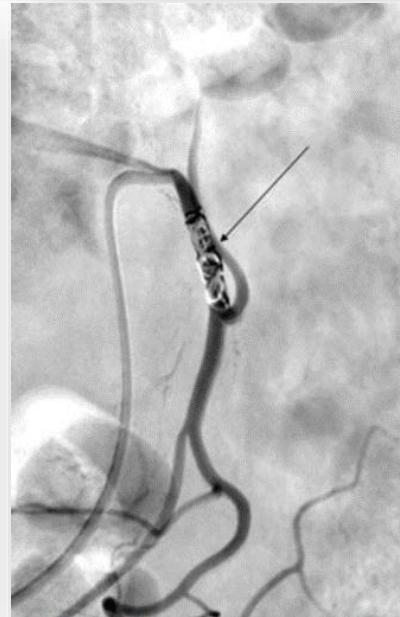
Present of active AAA sac management

Pre-emptive IMA Embolization

From the Society for Vascular Surgery

Prophylactic sac outflow vessel embolization is associated with improved sac regression in patients undergoing endovascular aortic aneurysm repair

Rae S. Rokosh, MD,^{a,b} Heepeel Chang, MD,^c Jonathan R. Butler, MS,^c Caron B. Rockman, MD,^a Virendra I. Patel, MD,^d Ross Milner, MD,^e Glenn R. Jacobowitz, MD,^a Neal S. Cayne, MD,^a Frank Veith, MD,^a and Karan Garg, MD,^a *New York and Valhalla, NY; Boston, Mass; and Chicago, Ill*



Outcome	emboEVAR (n = 272)	EVAR alone (n = 14,788)	P value
Mean clinical follow-up, months	15 ± 7.5	14.6 ± 6.2	.8749
Mean maximum aortic diameter, cm	4.8 ± 1.2	5 ± 1.2	.008
Mean decrease in aortic diameter, cm	0.69 ± 0.9	0.54 ± 0.9	.006
Aneurysm sac status			.082
Regression (≥5 mm)	146 (53.7)	7205 (48.7)	
Stable (<5 mm change)	116 (42.7)	6623 (44.8)	
Growth (≥5 mm)	10 (3.7)	960 (6.5)	
Type II endoleaks	36 (13)	1758 (11.9)	.481
Lumbar artery	29 (10.9)	1286 (8.8)	.23
IMA	7 (2.6)	588 (4)	.341
ARA	2 (0.8)	54 (0.4)	.258
Reintervention	17 (6.3)	621 (4.2)	.096
Mortality/reintervention composite ^a	22 (8.1)	1243 (8.4)	.852

Rokosh RA, et al. *J Vasc Surg* 2022;76:113-21.

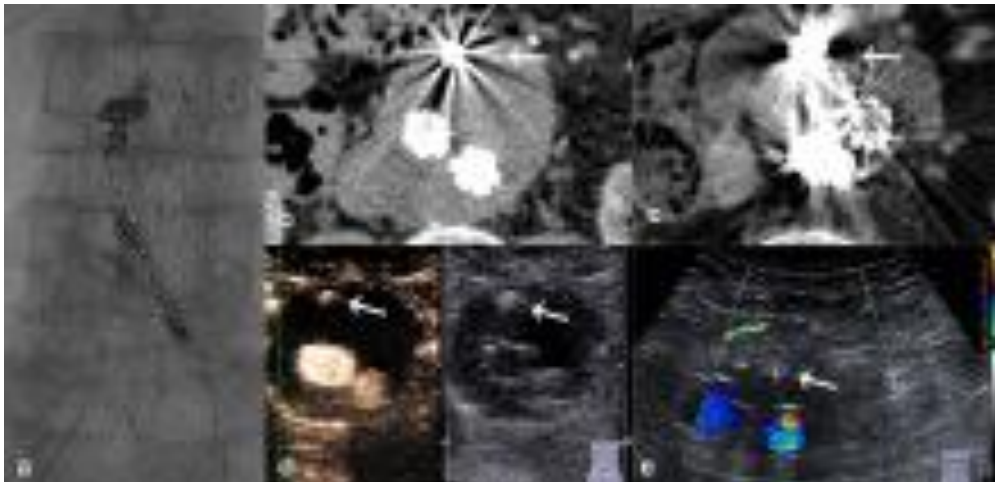
Sac embolization using coils

Sac embolization significantly reduces the incidence of type II endoleaks

- At discharge 8/26 vs. 33/44 ($p < .001$)
- At 12 months 5/25 vs. 32/44 ($p < .001$)

Failure of sac embolization is related to

- Higher endoluminal residual sac volume
- Lower concentration of coils implanted



Complete filling of the aneurysmal sac seems to be the key factor driving success

Coils cause significant scatter on follow-up imaging

Mascoli C, et al. Ann Vasc Surg. 2021 Oct;76:293-301..

Frenzel F, et al. Ultrasound Med Biol. 2021 Mar;47(3):488-498.

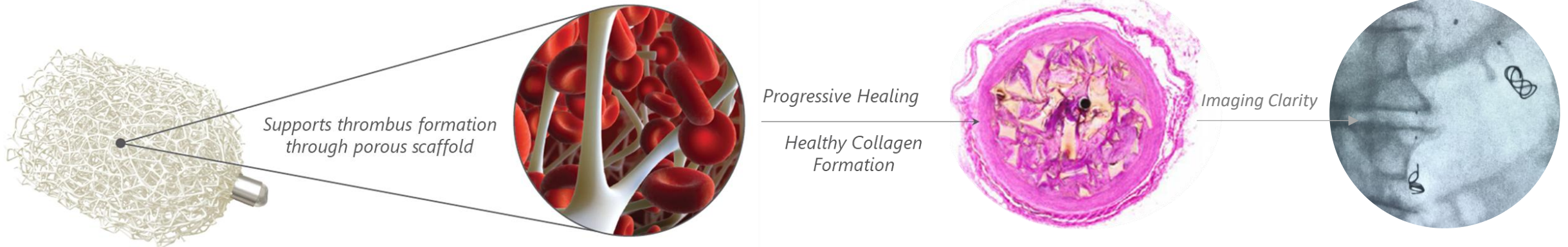
Shape Memory Polymer

High volume embolic material for **space filling**

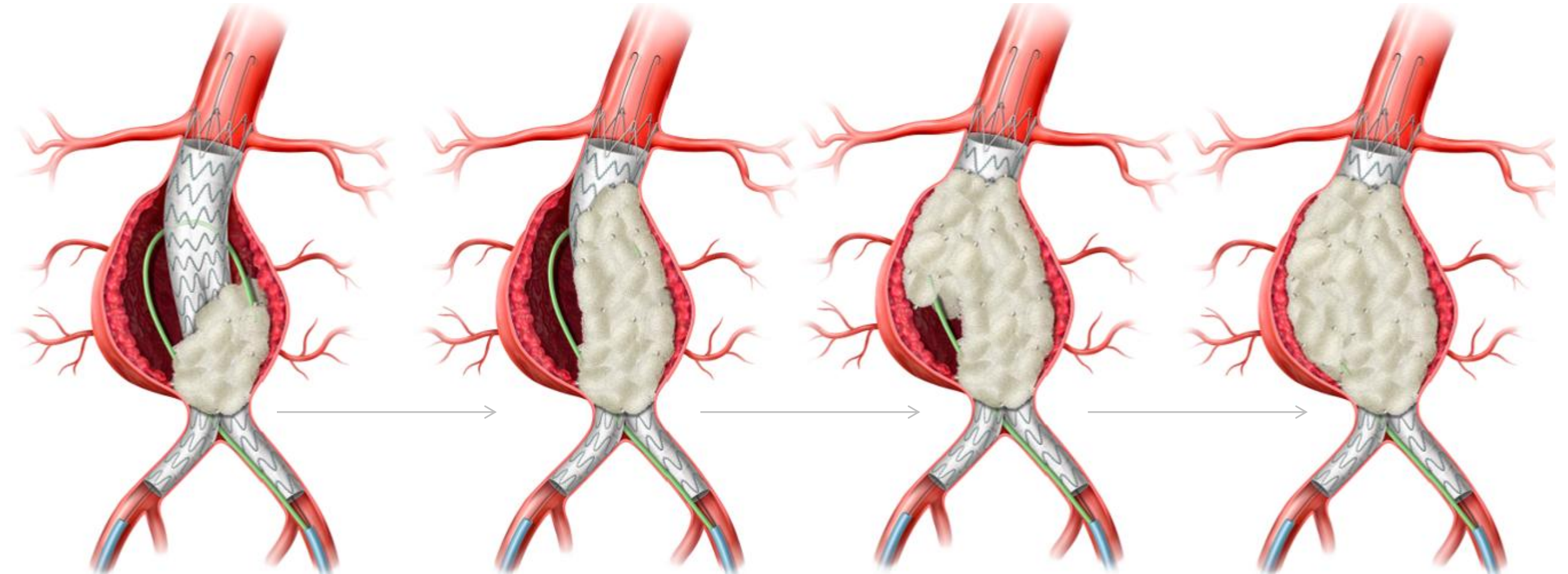
High surface area of porous scaffold induces long fluid residence times, low shear rates; Leads to **stasis** and **thrombus formation**

Progressive healing of thrombus to mature tissue

Radiolucent for **imaging clarity** and minimal imaging artifact



IMPEDE-FX RapidFill Device Delivery – Loop Approach



AAA-SHAPE Safety Trial



Active aortic aneurysm sac treatment with shape memory polymer during endovascular aneurysm repair

Andrew Holden, MBChB, EBIR,^a Andrew A. Hill, MD,^b Manar Khashram, MBChB, PhD,^c Jan M. M. Heyligers, MD, PhD,^d Arno M. Wiersema, MD, PhD,^e Paul D. Hayes, MD,^f and Michel M. P. J. Reijnen, MD, PhD,^{g,h} Auckland and Hamilton, New Zealand; Tilburg, Hoorn, Arnhem, and Enschede, The Netherlands; and Cambridge, United Kingdom

ABSTRACT

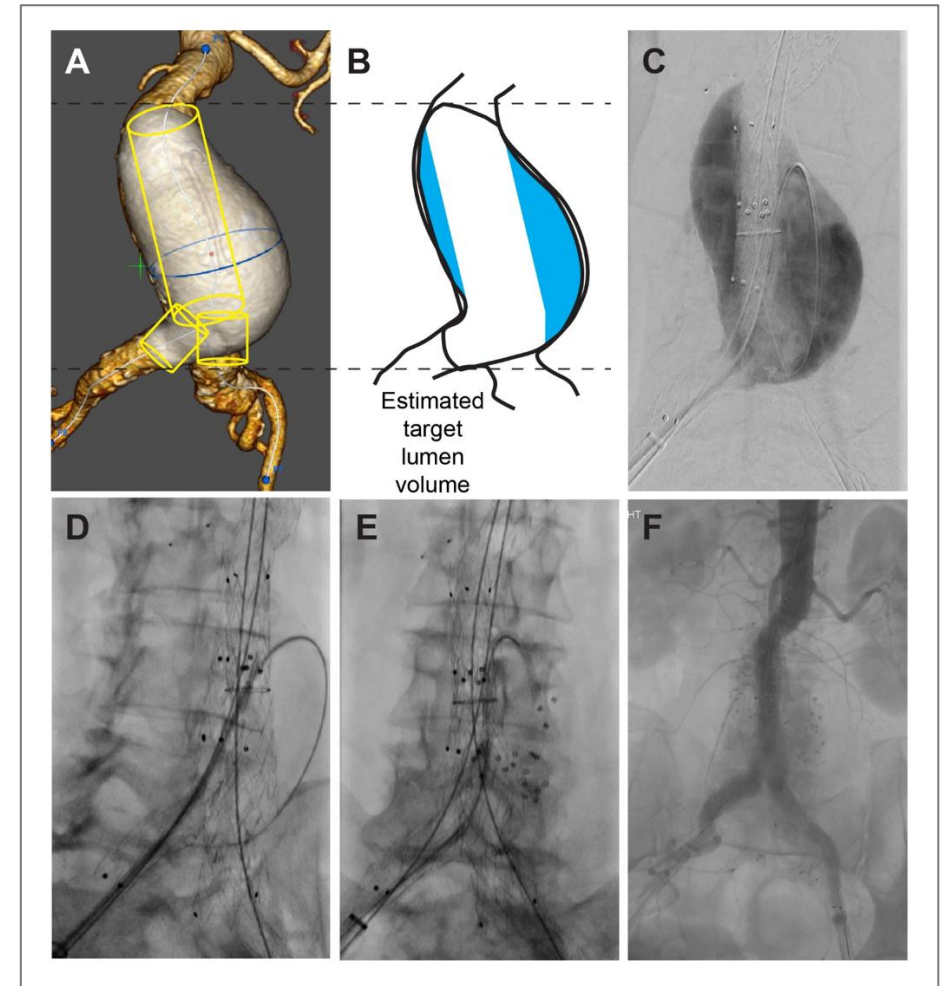
Preprocedural image analysis and intraprocedural techniques to fully treat infrarenal abdominal aortic aneurysm sacs outside of the endograft with shape memory polymer (SMP) devices during endovascular aneurysm repair were developed. Prospective, multicenter, single-arm studies were performed. SMP is a porous, self-expanding polyurethane polymer material. Target lumen volumes (aortic flow lumen volume minus endograft volume) were estimated from the preprocedural imaging studies and endograft dimensions. SMP was delivered immediately after endograft deployment via a 6F sheath jailed in a bowed position in the sac. Technical success was achieved in all cases, defined as implanting enough fully expanded SMP volume to treat the actual target lumen volume. (J Vasc Surg Cases Innov Tech 2023;9:101241.)

Keywords: Abdominal aortic aneurysm; Aneurysm regression; Aortic endograft; Endovascular aneurysm repair; Shape memory polymer

Abdominal aortic aneurysm (AAA) sac regression after endovascular aneurysm repair (EVAR) is associated with improved survival compared with stable or expanding sacs.¹ Preemptive coil or plug embolization of the inferior mesenteric artery and lumbar arteries has been shown to decrease the rate of persistent type II endoleaks.² Nonselective coil embolization of the AAA sac at the same time

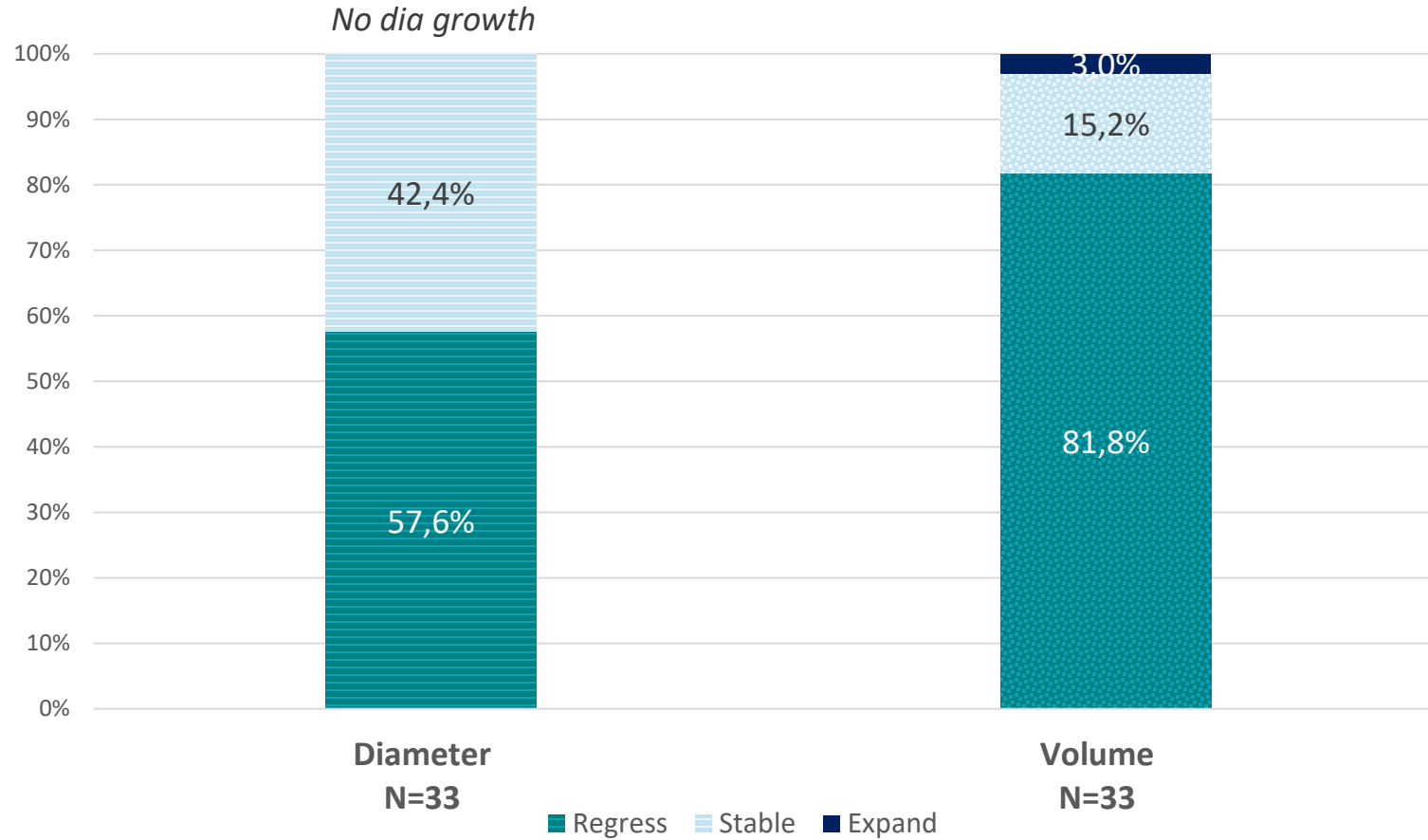
preclude imaging of endoleaks, and the procedure is difficult to standardize.

Shape memory polymer (SMP) is a novel radiolucent material that self-expands to a porous scaffold on delivery into a vessel and is designed to support thrombus formation throughout its structure. In animal studies, SMP formulations have been shown to stimulate the immune



Percent of Patients, Sac Change at One Year

% Patients, Sac Change at 1y (Compared to 30d Baseline)

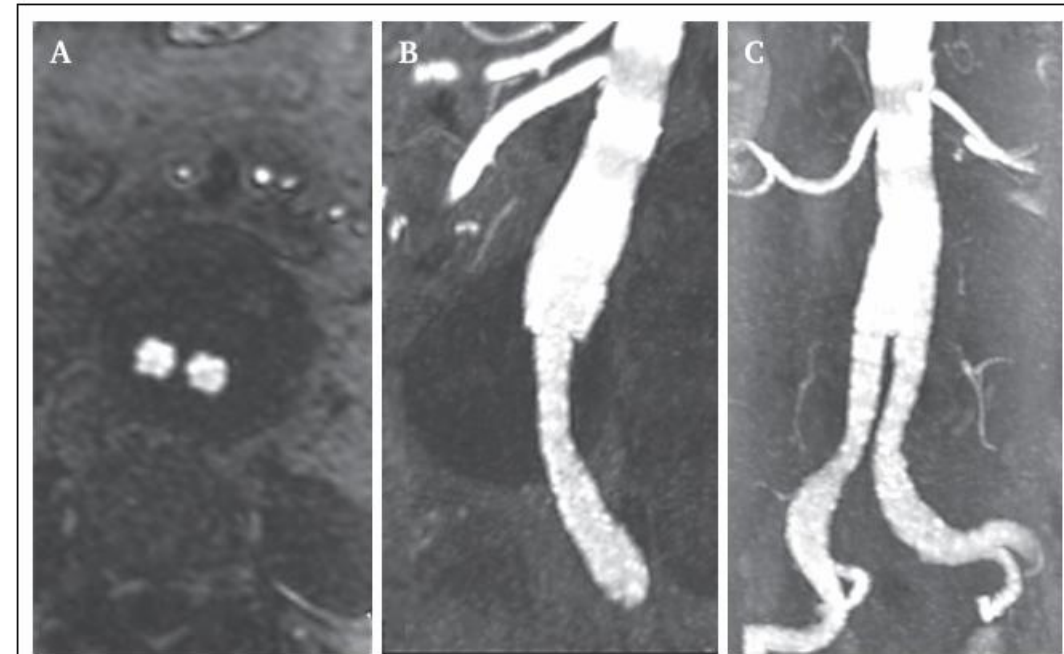
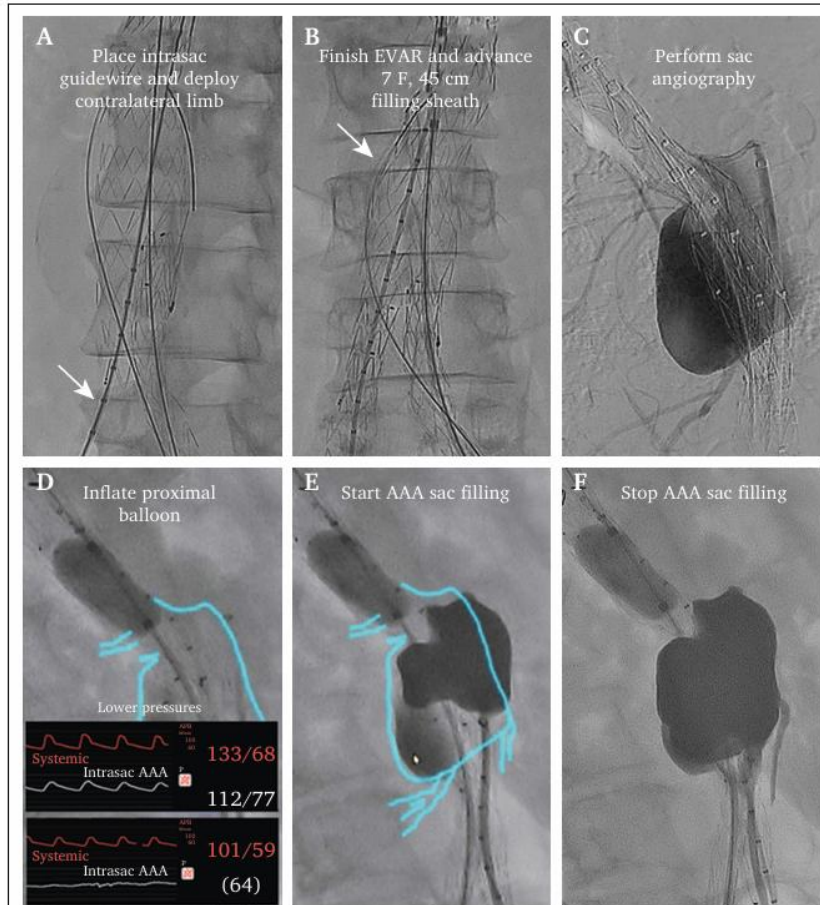


	Diameter	Volume
Expansion	≥5 mm	≥10%
Stable	>-5mm and <5 mm	>-10% and <10%
Regression	≤ -5 mm	≤-10%

Preliminary data from an ongoing clinical investigation, data subject to change.

First in Human Aortic Aneurysm Sac Filling with AneuFix Injectable Polymer during Endovascular Aneurysm Repair

Stefan P.M. Smorenburg ^{a,b,*}, Rutger J. Lely ^{b,c}, Vincent Jongkind ^{a,b}, Menno E. Groeneveld ^{a,b}, Alexander C. de Vries ^d, Henri.L.F. Brom ^d, Michael J. Jacobs ^{d,e}, Arjan W.J. Hoksbergen ^{a,b}



Conclusions

- Sac regression post-EVAR is associated with less mortality, less reinterventions and less AAA-ruptures compared to stable and progressive aneurysm sacs
- Sac progression post-EVAR may decline proximal sealing zone and increases the risk for type IA endoleaks
- Sac behavior post-EVAR is an important outcome parameter and we should strive for sac regression (with active sac management)

Open questions

- What drives sac behavior in the first year after EVAR: device, biologics?
- As the patients with AAA sac increase or stability don't massively die from ruptures, what drives their worse survival? Biologics, genetics ?
- Can we influence patient survival by changing endografts resulting in higher % of patients showing AAA sac shrinkage @ 1 year ?
- Can we influence patient survival by intervening and have the patient “jump” from one line to another in the survival curve ?

Active sac management comes with costs (and complications). Need for prospective (randomized?) trials.

The simple EVAR no longer exists: Everything that circulates is embolized and the prediction of failures is essential

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