How Can Shape Memory Plug Embolization Be Used To Improve Results After TEVAR For Degenerative Aneurysm And TBAD

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Vascular Surgery and
Endovascular Interventions

ColumbiaDoctors Aortic Center
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Disclosures

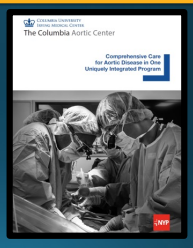
Speaker name:
Virendra I. Patel MD MPH

I have the following potential conflicts related to this presentation to report:

Speaker/Consultant
- COOK / Terumo / Artivion / GE / Shape Memory Medical

Principal Investigator
- SMART EVAR trial

Off-label use



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Sac Behavior following EVAR

From the Society for Clinical Vascular Surgery

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,[a] Boston and Worcester, Mass; Gainesville, Fla; and New York, NY

- Infrarenal AAA – VQI 2003 – 2017
- 14817 patients
- Pre-op and one year AAA diameter

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Results

- Sac behavior:
  - 40% regressed
  - 35% remained stable
  - 25% expanded

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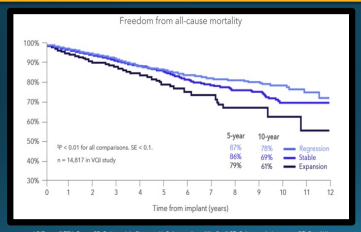
Long-Term Mortality – Impact of Sac Behavior



Stable sac:
HR 1.20
[1.03 – 1.39]
P = .02

Sac expansion:
HR 1.63
[1.28 – 2.07]
P < .001

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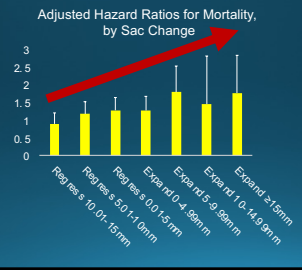
Long-Term Mortality Hazard



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VQI / VISION TEVAR and Sac Behavior

Retrospective / Multi-center VQI VISION - 2014 to 2018
- Vascular Implant Surveillance & Interventional Outcomes Network (VISION) VQI + Medicare

- Inclusion
  - All TEVAR of the descending thoracic aorta
    - Repair for aortic aneurysm, dissection, PAU, IMH
  - Data on 1-year postoperative imaging

- Exclusion
  - Ruptured repair
  - Missing preoperative or 1-year follow-up aortic diameter measurements

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Results

- TAA Sac behavior:
  - 39% Aortic regression
  - 38% remained stable
  - 23% expanded

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Predictors of Failure to Regress

	Odds Ratio	95% CI	P-value
Aortic diameter (per cm)	0.6	0.6 – 0.7	<.001
Completion Endoleak			
None	*Ref*	--	--
Type I or III	2.5	1.2 – 5.2	.019
Type II	1.3	0.5 – 3.2	.618
1 year Endoleak			
None	*Ref*	--	--
Type I or III	3.3	1.5 – 7.3	.003
Type II	3.2	1.3 – 7.8	.011

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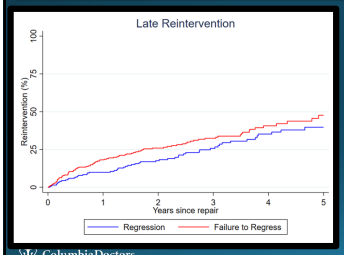
Decreased Re-intervention w. Regression



	aHR (95% CI)	P-value
Regression	*Ref*	--
Exp/Stable	1.5 (1.1 - 2.1)	.033

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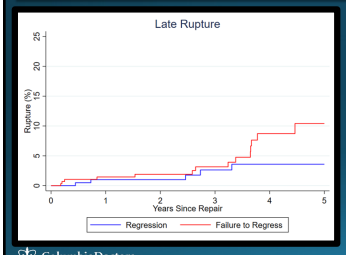
Decreased Late Rupture w. Regression



	aHR (95% CI)	P-value
Regression	*Ref*	--
Exp/Stable	4.6 (1.3 - 16)	.017

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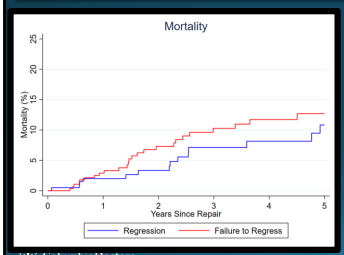
Survival not Associated with Sac Change



	aHR (95% CI)	P-value
Regression	*Ref*	--
Exp/Stable	1.4 (0.7-2.6)	.33

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Treatment of Sac during EVAR / TEVAR

Endograft excludes the sac

- Biologically active thrombus triggers acute and chronic inflammation
- Endoleak perfuses/pressurizes sac

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Pre-emptive IMA Embolization

Samura M, et al. Ann Surg 2020;271:238–244

RANDOMIZED CONTROLLED TRIAL

Endovascular Aneurysm Repair With Inferior Mesenteric Artery Embolization for Preventing Type II Endoleak

A Prospective Randomized Controlled Trial

Makoto Samura, MD, Noriyasu Morikage, MD, Ryo Otsuka, MD, Takahiro Mizoguchi, MD,

- **Randomized 106 patients at high risk of T2EL**
  - **IMA Embolization + EVAR (n=53) or standard EVAR (n=53)**

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Pre-emptive IMA Embolization

TABLE 5. Clinical Outcomes in the Per-protocol Analysis

Variables	Embolization (n = 46)	Nonembolization (n = 51)	*P*	ARR (95% CI)	NNT (95% CI)
Follow-up periods, mo	23.9 ± 10.9	23.2 ± 11.0	0.76		
Presence of T2EL	10 (21.7%)	24 (47.1%)	0.009	25.3% (6.4%–41.0%)	3.9 (2.4–15.6)
Source of T2EL (% in T2EL presence)					
IMA	0	3 (12.5%)			
LAs	11 (100%)	12 (50.0%)			
IMA + LAs	0	6 (25.0%)			
Others (MSA, LAs + MSA or ARA)	0	3 (12.5%)			
Aneurysmal diameter change, mm	−6.3 ± 7.5	−2.9 ± 6.7	0.021		
Aneurysmal growth ≥2 mm related to	1 (2.2%)	9 (17.6%)	0.017	15.5% (3.6%–18.9%)	6.5 (5.3–27.6)
Source of T2EL (% in related to T2EL)					
IMA, IMA + LAs	0	8 (88.9%)			
Others	1 (100%)	1 (22.2%)			
Secondary intervention	1 (2.2%)	1 (2.0%)	1.00		
Related to T2EL	0	0			

ARA indicates accessory renal artery; ARR, absolute risk reduction; CI, confidence interval; IMA, inferior mesenteric artery; LA, lumbar artery; MSA, medial sacral artery; NNT, number needed to treat; T2EL, type II endoleak.

Samura M, et al. Ann Surg 2020;271:238–244

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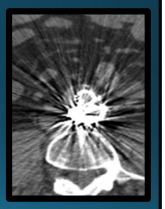
Pre-emptive Aneurysm Sac Embolization

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



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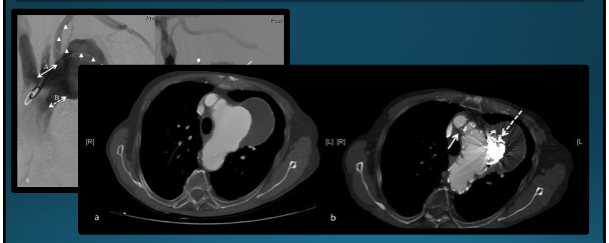
Pre-emptive Thoracic Aneurysm Embo.



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Pre-emptive Segmental Artery Embolization

From the Society for Vascular Surgery

Check for updates

Type II endoleak and aortic aneurysm sac shrinkage after preemptive embolization of aneurysm sac side branches

Daniela Branzan, MD,[a] Antonia Geisler,[a] Sabine Steiner, MD, PhD,[b] Markus Doss, MD,[a] Manuela Matschuck, MD,[b] Dierk Scheinert, MD, PhD,[b] *and* Andrej Schmidt, MD, PhD,[b] *Leipzig, Germany*

- **139 Patients 2014 – 2019 side branch embolization**
- **76% Branch vessel occlusion**
- **5% T2L**
- **87% sac shrinkage**

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Pre-emptive Segmental Artery Embo.

Minimally invasive staged segmental artery coil embolization (MIS²ACE) for spinal cord protection

Josephina Haunschild[1], Tilo Köbel[2], Martin Misfeld[1,3,4,5,6,7], Christian D. Etz[1]

[1]Department of Cardiac Surgery, University Heart Center, Rostock University Medical Center, Rostock, Germany; [2]German Aortic Center, Department of Vascular Medicine, University Heart and Vascular Center, Hamburg, Germany; [3]Department of Cardiothoracic Surgery, Royal Prince Alfred Hospital, Sydney, NSW, Australia; [4]University Department for Cardiac Surgery, Leipzig Heart Center, Leipzig, Germany; [5]Sydney Medical School, University of Sydney, Sydney, NSW, Australia; [6]Institute of Academic Surgery, RPAH, Sydney, Australia; [7]The Baird Institute of Applied Heart and Lung Surgical Research, Sydney, Australia

Correspondence to: Christian D. Etz, MD, PhD. Department of Cardiac Surgery, University Heart Center, Rostock University Medical Center, Schillingallee 35, 18057 Rostock, Germany. Email: Christian.etz@med.uni-rostock.de.

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Haunschild, et al. Ann CardioThorac Surg 2023;12:492-99.

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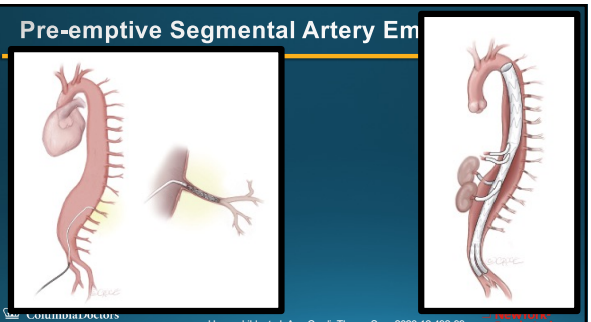
Pre-emptive Segmental Artery Em



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Haunschild, et al. Ann CardioThorac Surg 2023;12:492-99.

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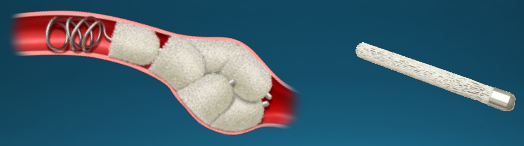
Sac Rx – foam plugs

- Soft and Conformable Shape Memory Polymer
- FDA approved for vascular embolization - 2018



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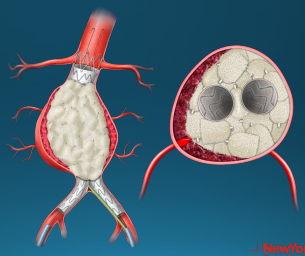
Sac Mgmt. with Shape Memory Polymer

Goal: Manage the Sac

- Stable clot formation
- Reduce T2 EL
- Prevent sac growth
- Aneurysm regression



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First Clinical Experience

- **FIH experience, prophylactic AAA sac management**
- 18 patients, 2 German centers, 2019-2021
- IMPEDE-FX, IMPEDE-FX RapidFIll
- 100% technical success
- Sac regression in all patients with ≥3m follow-up (mean 11m)
- Sac regression even in presence of small T2 endoleaks
- No morbidity or mortality related to treatment

Conclusion: Sac management with Shape Memory Polymer appears feasible and safe in small case series

Maximann A. European Radiology Experimental (2024)8:7

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AAA-SHAPE Early Feasibility Study

- **Prospective, multicenter safety trial**
- **35 patients**
- **100% technical success**
  - Endurant II/IIs (51%), Excluder/Conformable (49%)
  - Mean IMPEDE-FX RapidFill devices 12 (5-27)
- **No device- or procedure-related MAEs**
- **Four reinterventions related to EVAR procedure for:**
  - Type 1a endoleak
  - EVAR limb stenosis
  - EVAR limb occlusion
  - Partial coverage of left renal artery with EVAR graft

AAA-SHAPE NZ
Andrew Holden, Andrew Hill
Auckland City Hospital, Auckland
Manar Khashram
Waikato District Health Board, Hamilton

AAA-SHAPE NLD
Michel Reijnen
Rijnstate Hospital, Arnhem
Jan Heyligers
St. Elisabeth Hospital, Tilburg
Arno Wiersema
Dijklander Hospital, Hoorn

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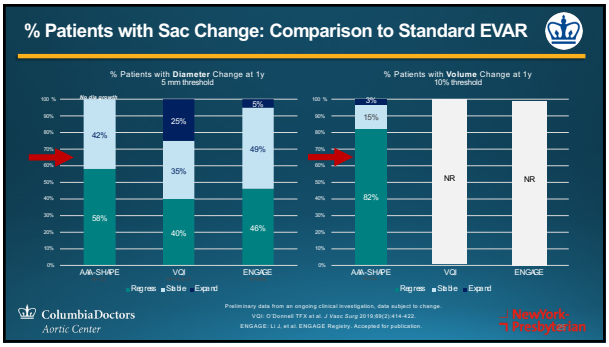
% Patients with Sac Change: Comparison to Standard EVAR
% Patients with Diameter Change at 1y
5 mm threshold
% Patients with Volume Change at 1y
10% threshold
42%
58%
25%
35%
40%
5%
49%
46%
3%
15%
82%
NR
NR
AAA-SHAPE
VQI
ENGAGE
Regress
Stable
Expand
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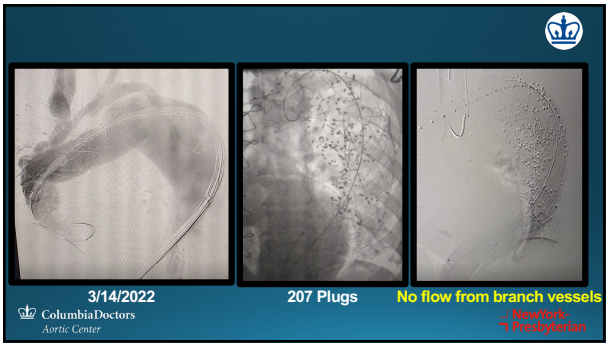
3/14/2022
207 Plugs
No flow from branch vessels
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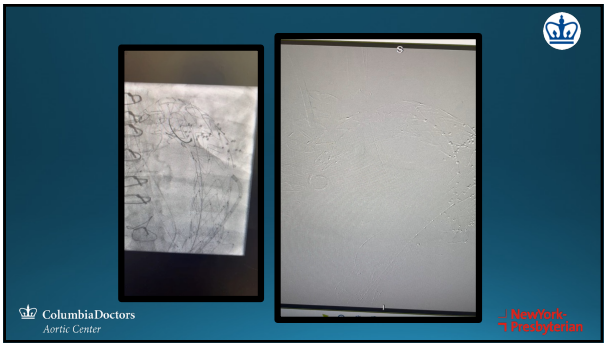
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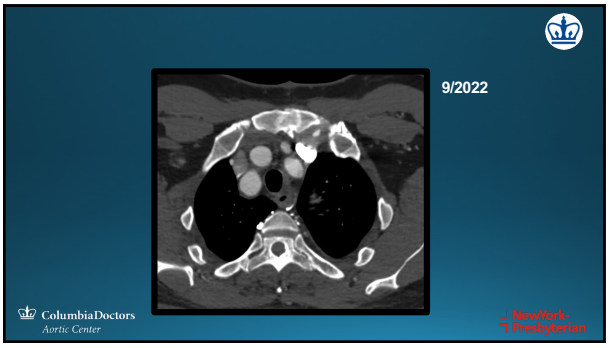
9/2022
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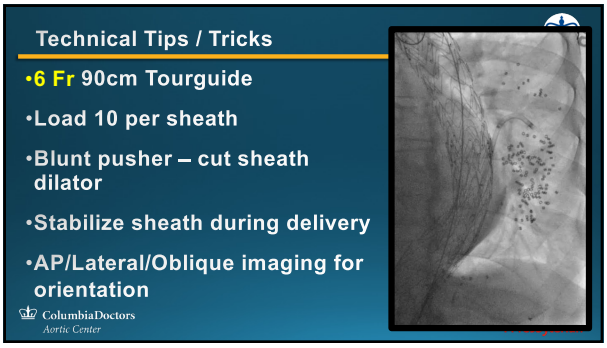
Technical Tips / Tricks
•6 Fr 90cm Tourguide
•Load 10 per sheath
•Blunt pusher – cut sheath dilator
•Stabilize sheath during delivery
•AP/Lateral/Oblique imaging for orientation
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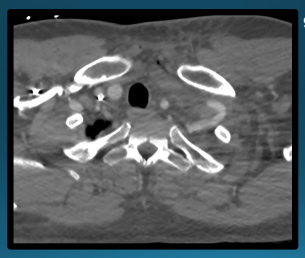
False Lumen Embolization



9/10/2020

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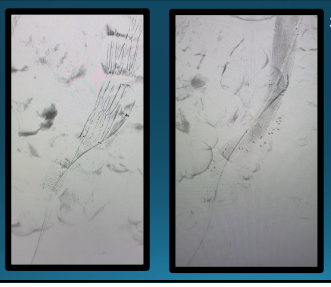
False Lumen Embolization



3/14/2022

23 plugs

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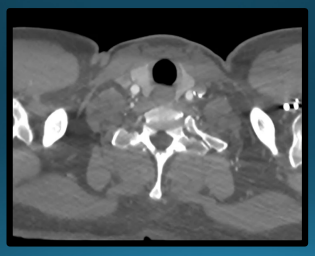
False Lumen Embolization



7/18/2022

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Columbia Experience

- Aneurysm sac embolization concomitant with
  - EVAR ~35
  - F-EVAR ~15
  - TEVAR ~10
- Median 94 plugs
- 0 SAE / 0 death
- 1 month – 1 endoleak <1cc
- 1-6mm diameter reduction (86%) / 10 – 18 % volume reduction (76%)
- 6 months: -3.4 mm / -21cc volume decrease
- 1 year: 80% with volume decrease >10%

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AAA SHAPE

Abdominal Aortic Aneurysm Sac Healing and Prevention of Endoleak

Safety and Early Feasibility Study

AAA SHAPE

Abdominal Aortic Aneurysm Sac Healing and Prevention of Expansion

Randomized Controlled Pivotal Trial

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AAA SHAPE

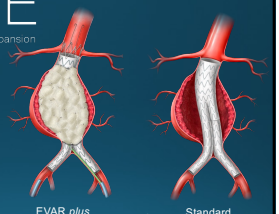
Abdominal Aortic Aneurysm Sac Healing and Prevention of Expansion

Randomized Controlled Pivotal Trial

IDE Approval Sept. 1, 2023

180 patients, up to **50 sites** (US, EU, NZ)
2:1 randomization
5y follow-up: clinical, imaging, health economics

IMPEDE-FX RapidFill



EVAR *plus* IMPEDE-FX RapidFill (Study Device)

vs

Standard EVAR

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