Active AAA Sac Management With Polymer Plugs

How To Use Them To Improve Outcomes By Preventing Endoleaks After EVAR

Results From the AAA-SHAPE Trial From Shape Memory

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Disclosures

- Clinical Investigator for Cook Medical, Endologix, Gore Medical, Medtronic, Nectero, Shape Memory Medical
- Medical Advisory Board Member for Medtronic, Gore, Boston Scientific, Shape Memory Medical

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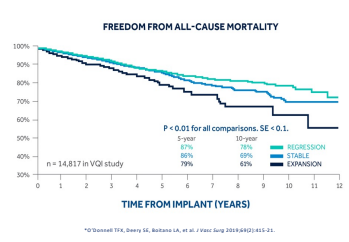
AAA sac failure to regress post-EVAR: A significant unmet need



40% Regress → Survival 87% at 5y 78% at10y

35% Stable → Survival 86% at 5y 69% at10y

25% Expand → Survival 79% at 5y 61% at10y

*O'Donnell TFX, Deery SE, Boitano LA, et al. J Vasc Surg 2019;69(2):415-21.

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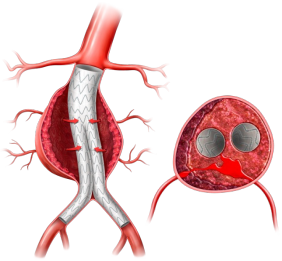
AAA Sac Exclusion with EVAR

Goals

- Depressurize aneurysm
- Prevent rupture
- Promote sac regression

Failure to Regress

- Endoleak perfuses/pressurizes sac
- Chronic inflammation
- Secondary interventions
- Morbidity and mortality



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AAA Sac Management with Shape Memory Polymer

Goals

- High volume filling of AAA sac
  - Compliant material, low radial force
- Stable clot formation and thrombosis
- Improve imaging visibility
- Improve sac shrinkage
- Reduce reintervention for T2 endoleak
- Avoid chronic inflammation

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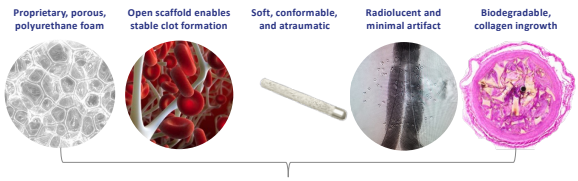
Shape Memory Polymer



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AAA-SHAPE Early Feasibility Studies

- **Prospective, multicenter**
  - New Zealand, 2 centers (NCT04227054)
  - The Netherlands, 3 centers (NCT04751578)
- **Up to 35 patients**
- **Primary outcomes: Technical success, 30d MAE**
- **Secondary outcomes (through 2 years)**
  - MAEs, SAEs
  - Endoleak, sac diameter/volume, AAA-related secondary intervention, conversion to open repair

AAA-SHAPE NZ

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Dijklander Hospital, Hoorn

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AAA-SHAPE Demographics

Demographics	Value, N=34
Age, years	75.5 ± 7.3
Male sex	29 (85.3)
ASA Grade	
I	0 (0)
II	6 (17.6)
III	27 (79.4)
IV	1 (2.9)

Aneurysm Characteristics	Value, N=34
Aneurysm Diameter, mm	60.8 (57.8 to 63.9)
Aneurysm Volume, mL	181.4 (150.7 to 212.1)
Blood Lumen Volume, mL	98.2 (88.4 to 108.1)
Thrombus Volume, %	41.7 (35.5 to 47.8)
Patent IMA ≥3 mm	10 (29.4)
Patent Renal Accessory Arteries	5 (14.3)
Patent Lumbar Arteries, ≥1	31 (91.2)

Data presented as mean ± standard deviation (95% confidence interval) for continuous variables unless stated otherwise or number (%) for categorical variables.

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AAA-SHAPE Procedure Data

Demographics	Value, N=34
Endografts	
Medtronic Endurant II/IIs	17 (50)
Gore Excluder	12 (35.3)
Gore Excluder Conformable	5 (14.7)
Sac Management Approach	
Ipsilateral	20 (50.8)
Contralateral	14 (41.2)

Aneurysm	Value
Target Lumen Volume, mL (Blood Lumen Vol – Endograft Vol)	56.3 (46.9 to 65.8)
Technical Success	100%
IMPEDE-FX RapidFill Devices	11 (7 to 15)
Shape Memory Polymer Volume / Target Lumen Volume Ratio	1.4 ± 0.3
Additional Procedure Time, min	27 ± 14
Additional Radiation Time, min	135 seconds (n=6)

Data presented as mean ± standard deviation (95% confidence interval) for continuous variables unless stated otherwise or number (%) for categorical variables.

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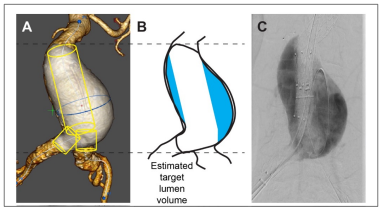
AAA-SHAPE Sac Management

JVS-CIT

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

Holden A, et al. J Vasc Surg Cases Innov Tech 2023;9:101241



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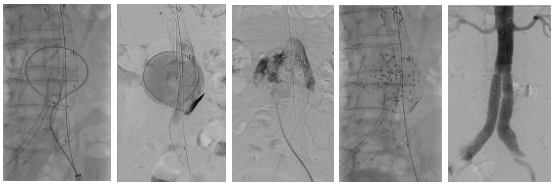
Case Example



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Two Year Clinical Results-to-Date

- **No device- or procedure-related MAEs**
  - Procedural blood loss >1000mL, 0d
    - Femoral access, resolved without sequalae
  - CHF, 177d: death
  - COVID-19, 185d, death
  - NSTEMI, 381d, resolved with sequelae
  - Suicide death, 400d
  - Death (cause unknown), 574d
- **One AAA perforation (iatrogenic)**
  - Guidewire perforated AAA during index procedure; **no clinical sequalae, sac decrease**
- **Seven device/study procedure-related SAEs**
  - Arrhythmia, 1d
  - Post implantation syndrome, 1d
  - Constipation, 2d
  - Abdominal pain, 5d
  - Endoleak T2 with sac growth, 806d
- **Six AAA-related reinterventions for:**
  - EVAR limb stenosis
  - EVAR limb occlusion
  - Partial coverage LRA with EVAR graft
  - Type 1a endoleak
  - **Type 2 endoleak (embolization)**
  - **Type 2 endoleak (sac repair)**

Device AEs refer to investigational device, IMPEDE-FX RapidFill
Data from an ongoing clinical investigation, data subject to change.

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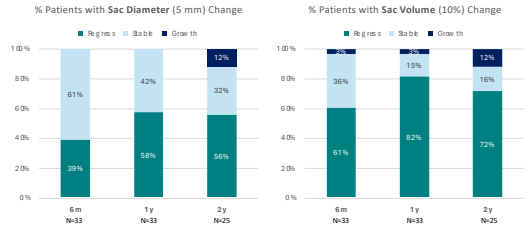
Percent of Patients, Sac Change (Compared to 30d Baseline, Core-Lab Adjudicated)



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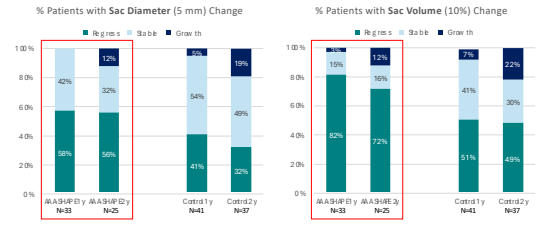
Sac Changes: Comparison to Standard EVAR (Retrospective Core Lab Control Group*)



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

*Cleveland Clinic (CCF) Control group selected from CCF standard EVAR cases from 2014 to 2019 that met AAA-SHAPE inclusion/exclusion criteria. 41 endografts consisted of 26 Gore, 9 Cook, 4 Terumo, and 2 Medtronic grafts.

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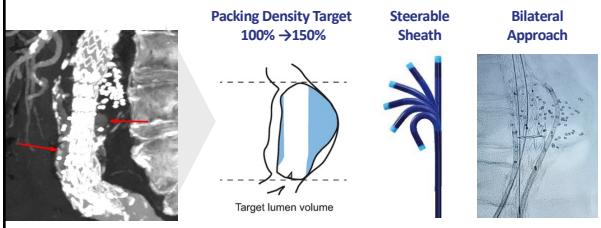
Evolving Procedure: Lessons Learned and Modified Best Practices



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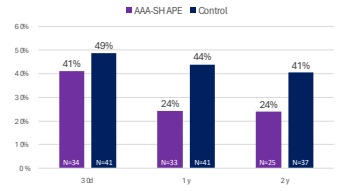
T2 Endoleak: Comparison to Standard EVAR (Retrospective Core Lab Control Group*)



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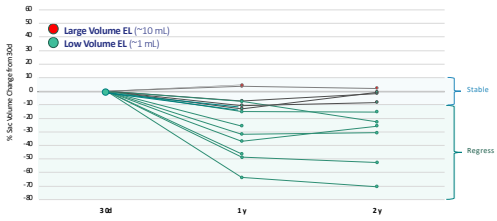
Sac Volume Changes in Presence of 30d Type 2 Endoleak (Core Lab)



AAA SHAPE

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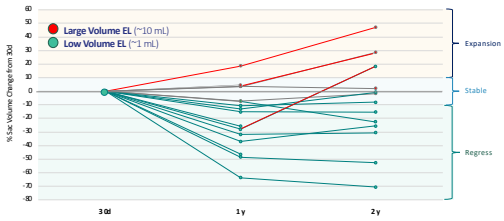
Sac Changes in Presence of 30d Type 2 Endoleak (Core Lab)



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

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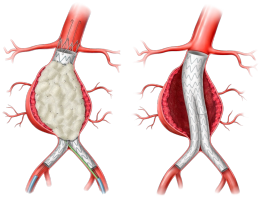
Abdominal Aortic Aneurysm Sac Healing and Prevention of Expansion

Randomized Controlled Pivotal Trial

FDA-Approved IDE

180 patients, up to **50 sites** (US, EU, NZ)
2:1 randomization
1y primary efficacy endpoint:
% Patients with ≥10% Volume Sac Regression and No AAA-Related Reintervention
5y follow-up: clinical, imaging, health economics



EVAR *plus* IMPEDE-FX RapidFill
120 patients

vs

Standard EVAR
60 patients

Infrarenal AAA, Thrombus <50%, Max Lumen Dia ≥40 mm

Conclusions

- **Aneurysm failure to regress increases complications, all cause mortality**
- **Shape memory polymer offers stable clot formation, healing**
- **AAA-SHAPE establishing safety and efficacy of AAA sac management**
  - **Validated procedure, key learnings (access; complete fill and distribution)**
  - **No device- or procedure-related MAEs**
  - **Early signs of significant reduction in aneurysm sac diameter and volume**
  - **Low incidence of secondary interventions for sac growth**
- **Active sac management with shape memory polymer may become an important addition to EVAR**
- **Larger series and longer-term follow-up needed**
  - **AAA-SHAPE prospective, global randomized controlled trial underway**