shape memory medical

Expanding embolization solutions

Presented at CIRSE Summit
September 21, 2021

Shape Memory Polymer Vascular Plugs

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Disclosures. Andrew Holden is a consultant to Shape Memory Medical. Brendan Buckley and Andrew Hill have no relevant disclosures.
Funding. The study was sponsored by Shape Memory Medical, Santa Clara, California, USA.

Purpose

To determine the initial safety and efficacy of a novel shape memory polymer vascular plug

Methods

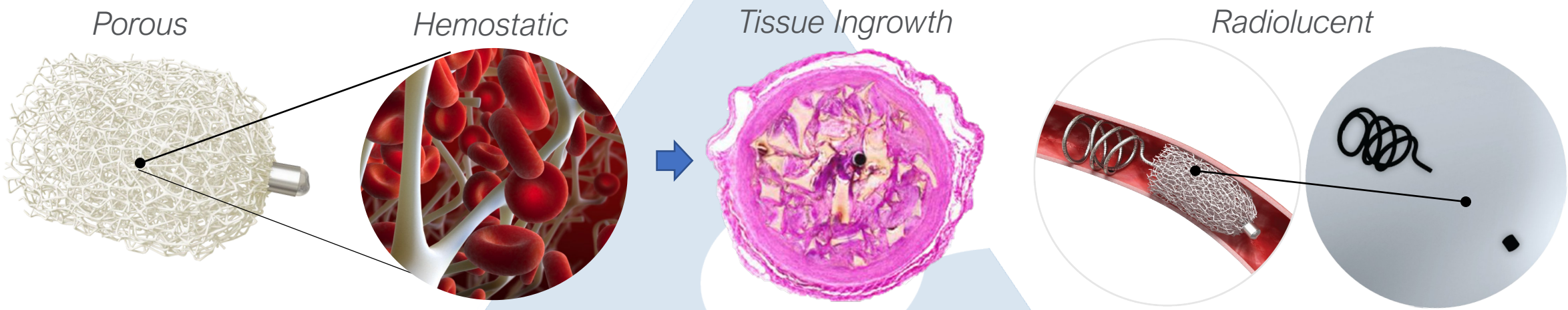
- First in human study at a single center in New Zealand
- Adult candidates for peripheral vasculature embolization
- 30-day follow-up
- 10 male patients (mean age 59.1 ± 18.6 years) implanted with the device
- Safety endpoint: Related serious adverse event rate
- Efficacy endpoint: Acute technical success of vessel embolization
- Efficacy endpoint: Recurrence of clinical symptoms indicating re-embolization or recanalization

Ethics

- Approved by the local Health and Disability Ethics Committee (reference 17/NTA/83)
- Listed at ANZCTR ACTRN12617000906358

Shape Memory Polymer

- Ultra-low-density polyurethane polymer[1]
- Porous expanded structure; Pore sizes ~1000-2000 µm, depending on formulation
- Radiolucent
- Hemostatic
- Supports tissue ingrowth based on animal studies[2]
- Bioabsorbable based on animal studies[3]



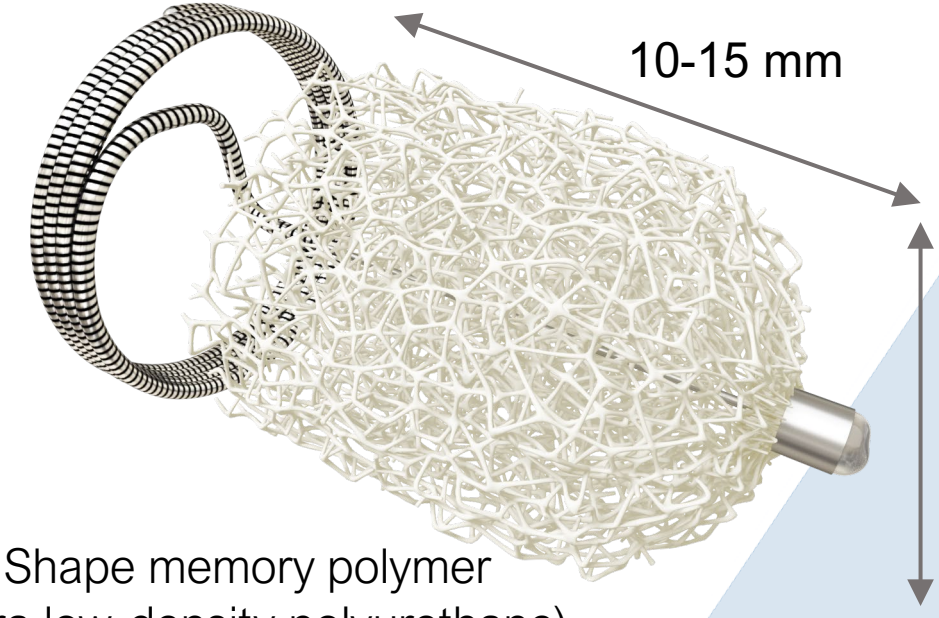
Study Device

Crimped for
catheter delivery

Proximal marker
(platinum/iridium)
0.032 - 0.065"

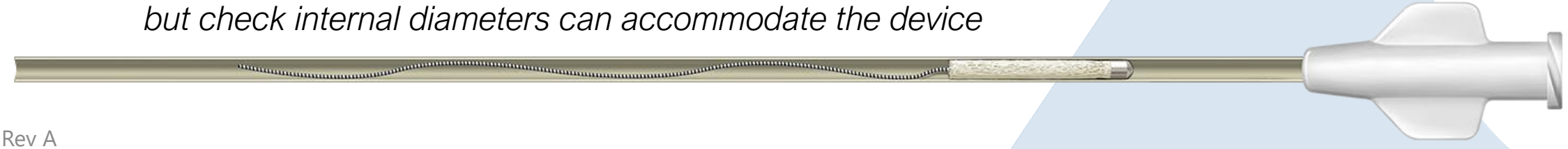
Anchor coil (nitinol)
7-13 mm diameter

Low radial force,
device can be oversized



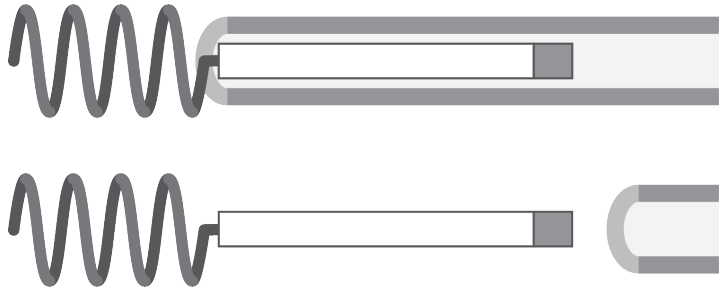
Shape memory polymer
(ultra low-density polyurethane)

Compatible with 5-6 Fr catheters
but check internal diameters can accommodate the device



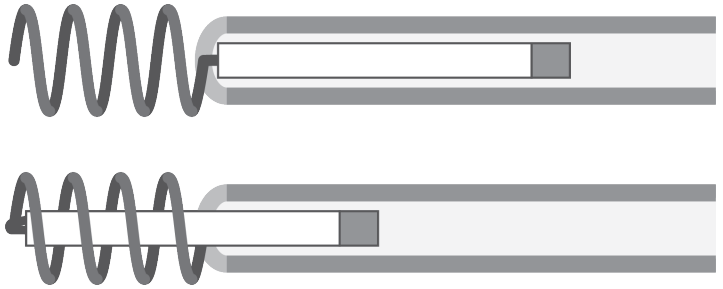
Study Device Use Tips

- The device is provided loaded in an introducer and no preparation is required
- Wetting should be avoided if possible as it starts the 1-minute working time clock
- Push with a 0.035 guidewire to position the anchor coil in the target vessel (2.5-4.0 cm landing zone)



✓ Unsheath the shape memory polymer by holding the guidewire and withdrawing the catheter

✗ **DO NOT** push the shape memory polymer coil into the anchor coil

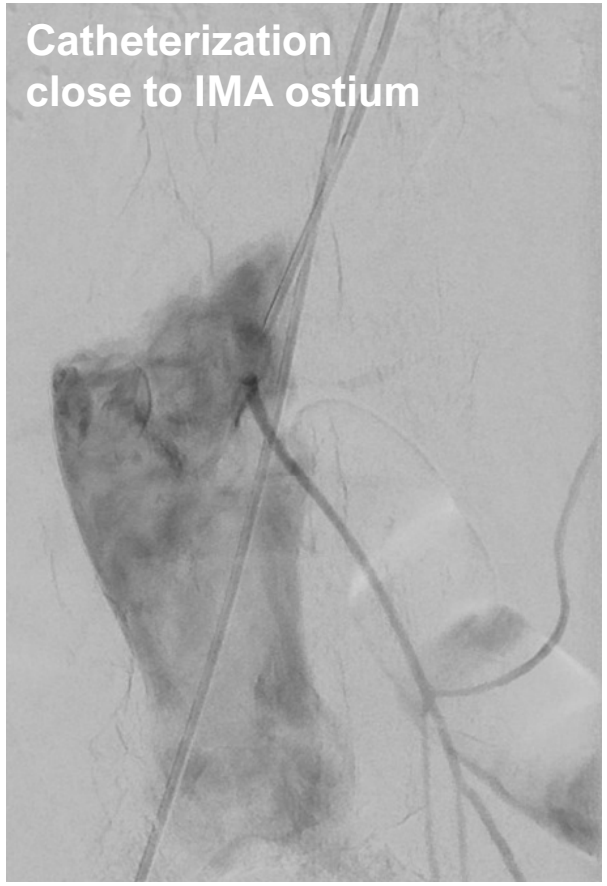


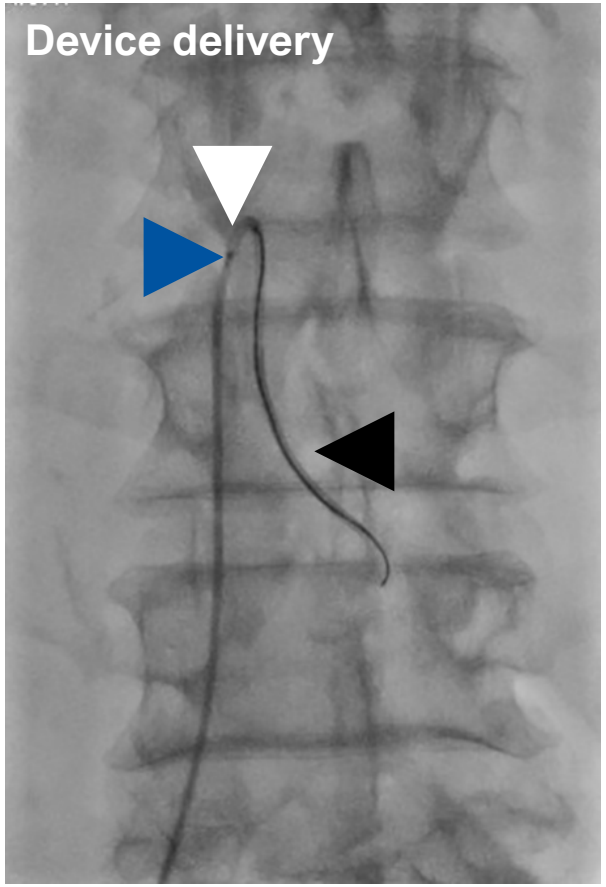
✗ **DO NOT** push the catheter into the anchor coil

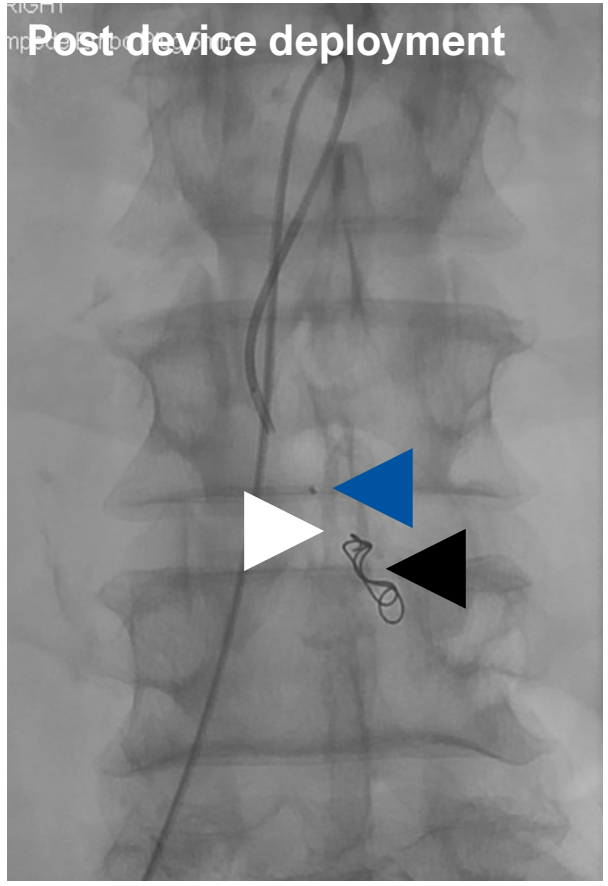
Incorrect delivery will limit the self-expansion of the polymer

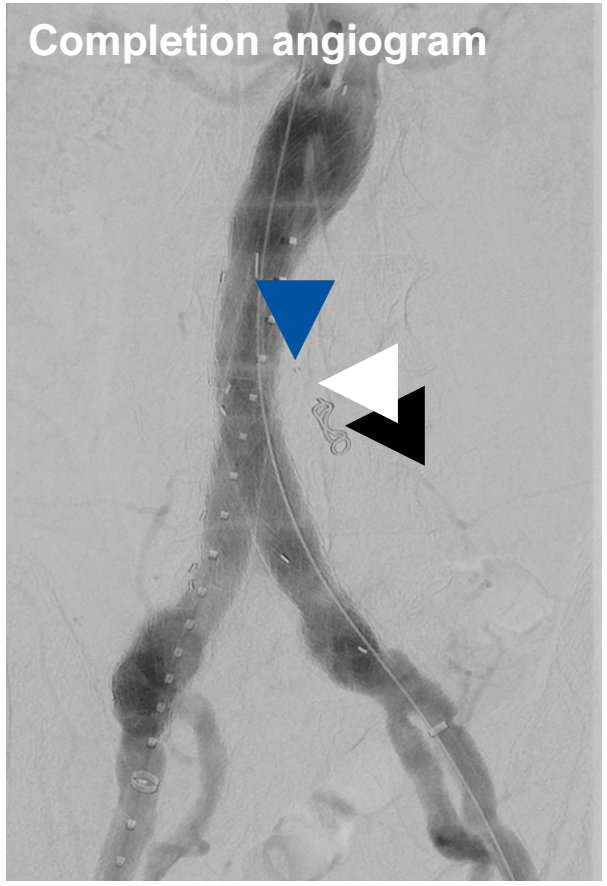
Study Cases – AAA Repair, Vessel Embolization

Inferior mesenteric artery (prior to EVAR) – 4-mm diameter vessel, 6-mm diameter device





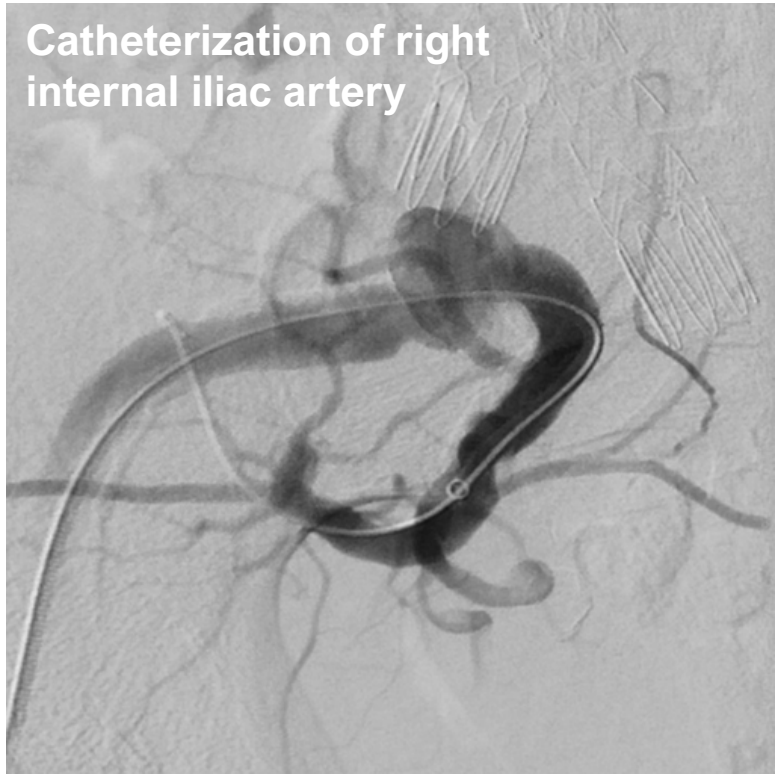


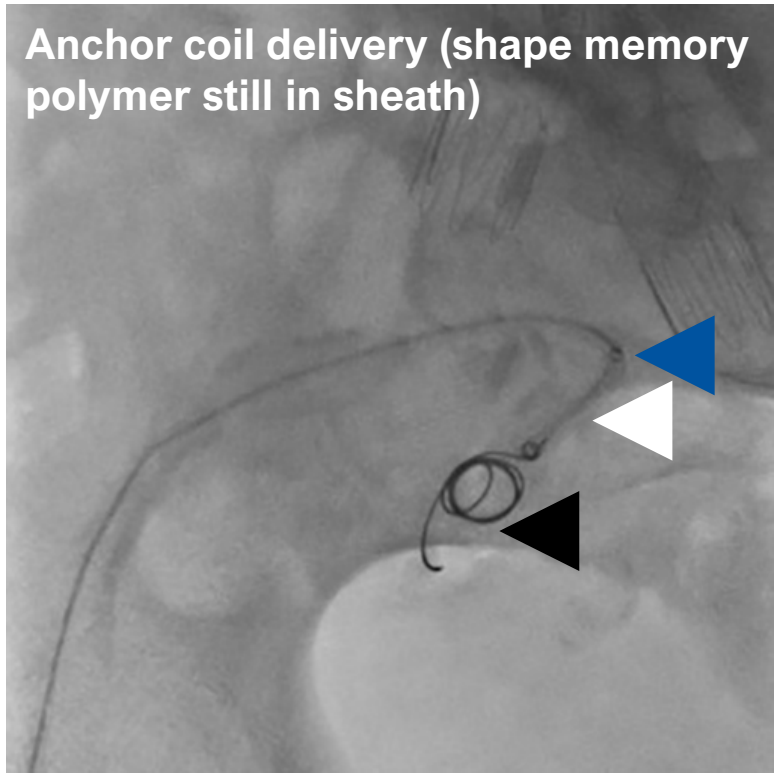


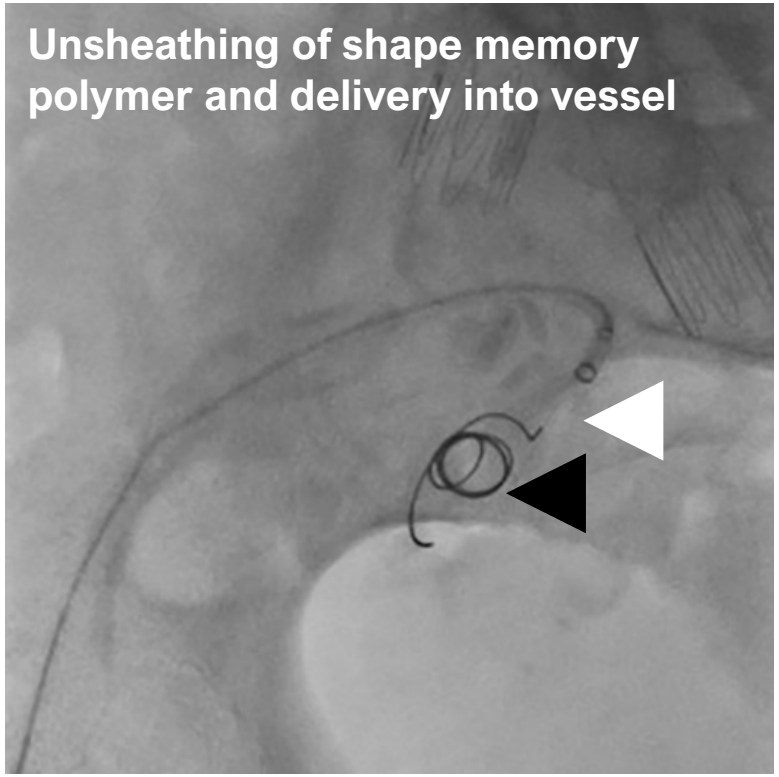
Anchor coil Shape memory polymer (radiolucent) Proximal marker

Study Cases – AAA Repair, Endoleak Treatment

Internal iliac artery, right (type Ib endoleak treatment) – 7-mm diameter vessel, 12-mm diameter device







Anchor coil | Shape memory polymer (radiolucent) | Proximal marker

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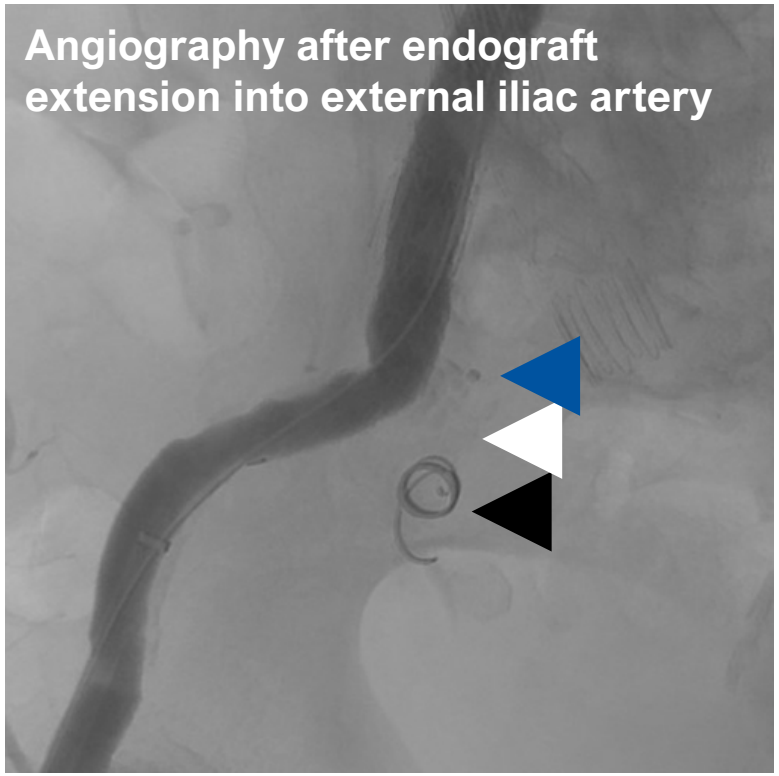
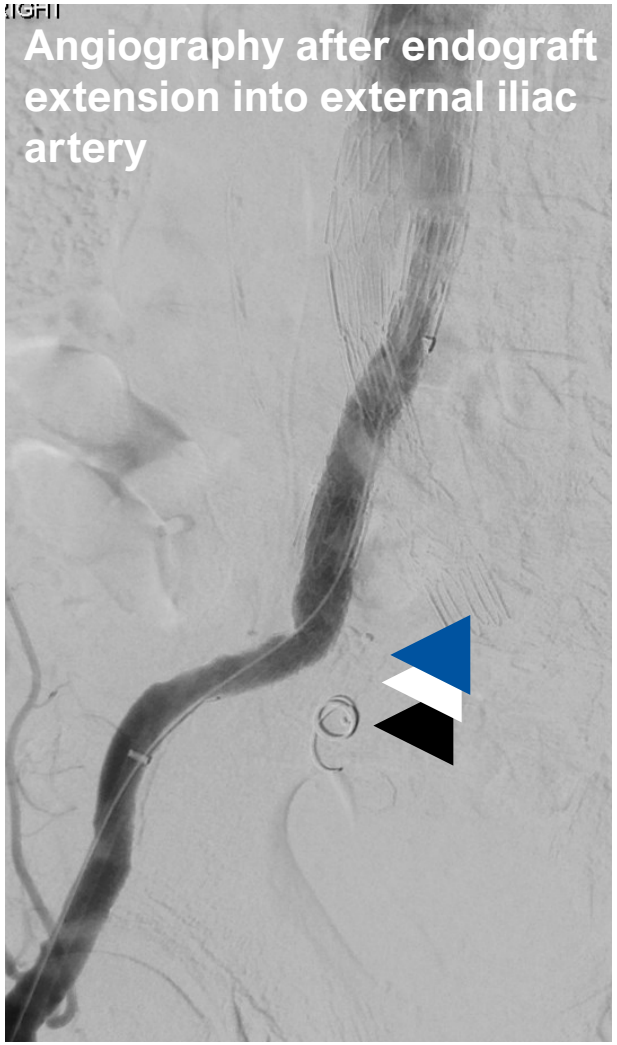
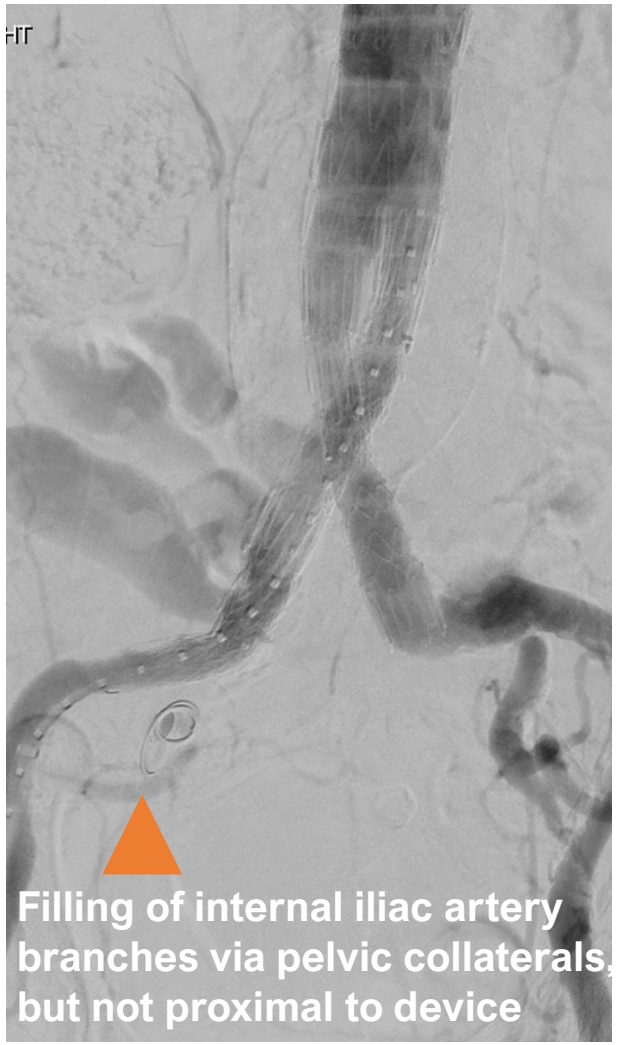


Anchor coil

Shape memory polymer (radiolucent)

Proximal marker

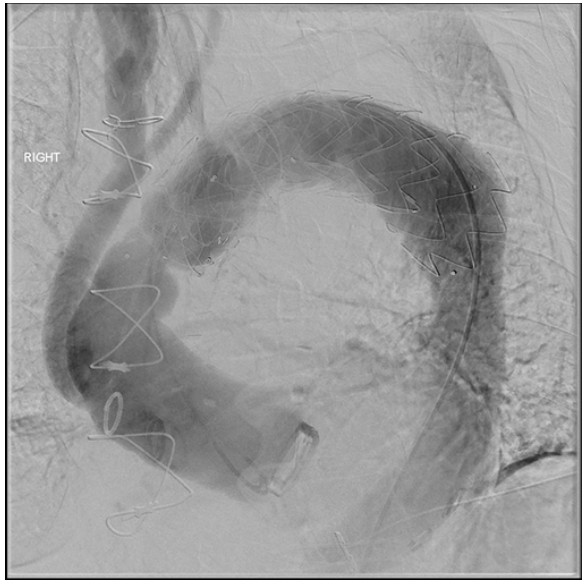




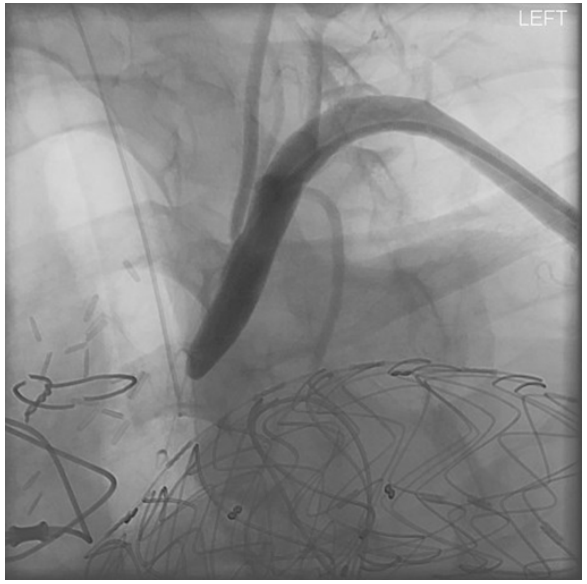
Study Cases –Endoleak Prevention Post TEVAR

Subclavian artery ostium, left (type II endoleak prevention) – 7-8-mm diameter vessel, 12-mm diameter device

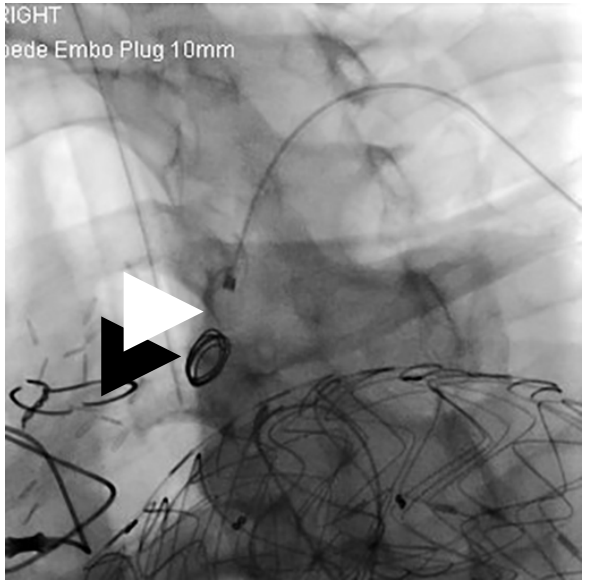
Completion angiogram showing patent TEVAR endograft and de-branching to head and neck arteries



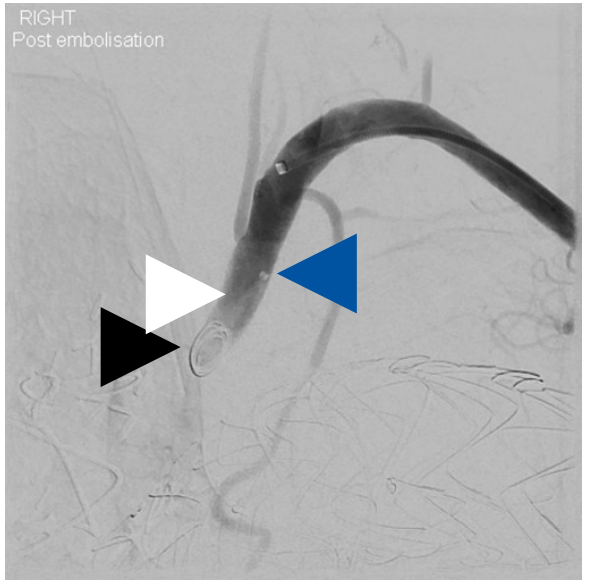
Left subclavian angiogram after TEVAR. Note the stenosis at the origin of the left subclavian artery



Shape memory polymer device deployment



Left subclavian artery angiogram after deployment of the shape memory polymer device

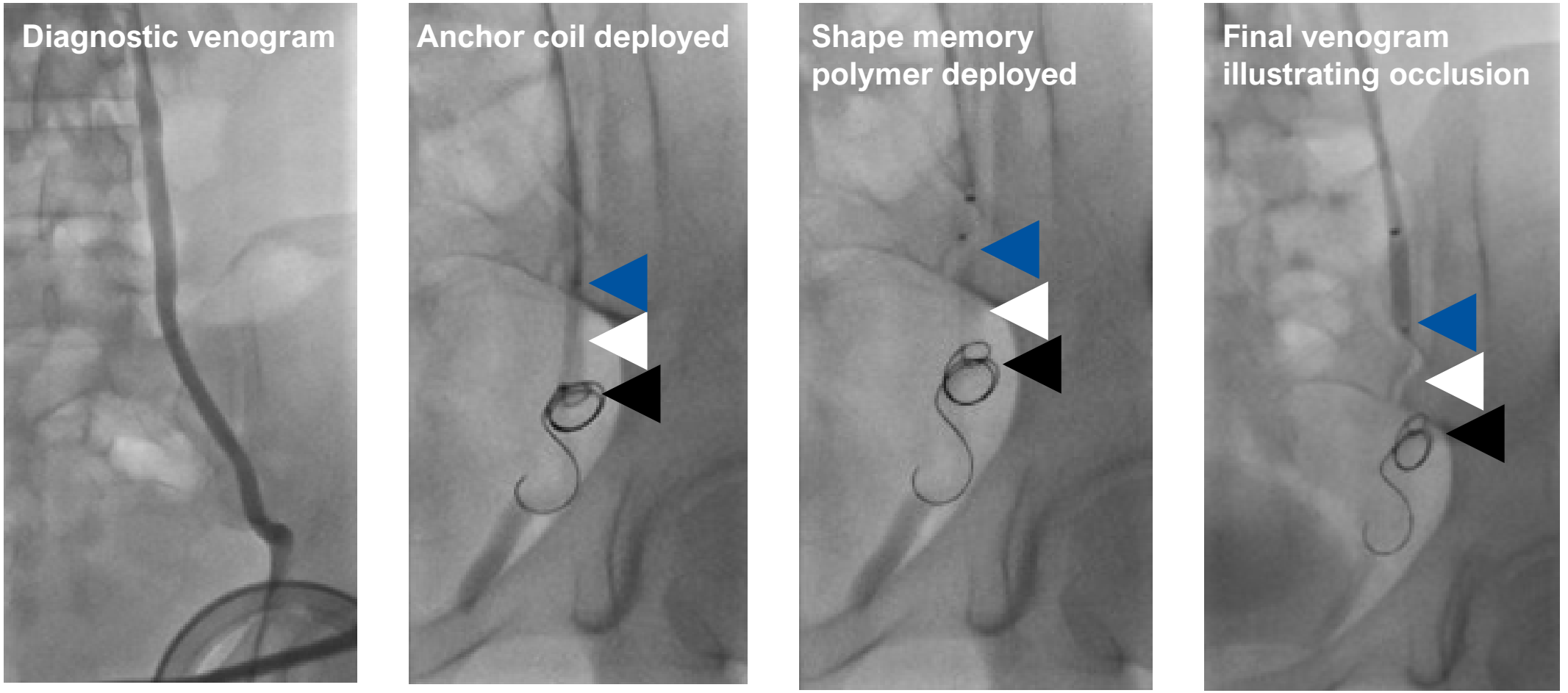


Anchor coil Shape memory polymer (radiolucent) Proximal marker

Study Cases – Varicoceles Treatment

Testicular vein, left – 6-7-mm diameter vessel, 12-mm diameter device

Sodium tetradecyl sulfate (STS) foam sclerosant used prior to vessel embolization



Study Results Summary

- 10 male patients (mean age 59.1 ± 18.6 years) implanted with the device
  - 3 inferior mesenteric arteries prior to EVAR
  - 1 accessory renal artery prior to EVAR
  - 1 internal iliac artery prior to open AAA repair
  - 1 internal iliac artery to treat type Ib endoleak
  - 1 subclavian artery to prevent type II endoleak
  - 1 profunda branch prior to tumor resection
  - 2 testicular veins to treat varicoceles
- Patients followed for 30 days
- No adverse events attributable to the use of the device occurred during that time
- Acute technical success of target vessel embolization achieved in all cases
- No recurrent clinical symptoms attributable to treated vessel embolization or recanalization documented
- Shape memory polymer devices used in combination with other commonly used embolic devices (sclerosant, particles)

Study Conclusions

- Porous shape memory polymer vascular embolization devices were safe and effective in this first in human clinical experience
- Further experience and longer-term follow-up will determine further applicability of the novel shape memory polymer material

References & Acknowledgements

1. Singhal P, Rodriguez JN, Small W, Eagleston S, Van de Water J, Maitland DJ, et al. Ultra Low Density and Highly Crosslinked Biocompatible Shape Memory Polyurethane Foams. J Polym Sci B Polym Phys. 2012;50:724-37.

2. Jessen SL, Friedemann MC, Ginn-Hedman A, Graul LM, Jokerst S, Robinson CB, et al. Microscopic Assessment of Healing and Effectiveness of a Foam-based Peripheral Occlusion Device. ACS Biomat Sci Eng. 2020;11:2588-99.

3. Device instructions for use, available from www.shapemem.com. Last accessed August 2021.

The authors thank Shape Memory Medical for device images and specifics, and for assistance with poster preparation.

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IMPEDE Embolization Plug Family

- In countries recognizing CE marking, the IMPEDE and **IMPEDE-FX Embolization Plugs** are indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature. Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device.
- In the U.S., the **IMPEDE Embolization Plug** is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature, and the **IMPEDE-FX Embolization Plug** is indicated for use with the **IMPEDE Embolization Plug** to obstruct or reduce the rate of blood flow in the peripheral vasculature.
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