Clinical Experience With a Shape Memory Polymer Peripheral Vascular Embolisation Plug: A Case Series

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Research Article

Keywords: shape memory polymer, peripheral embolisation, vascular plug

DOI: https://doi.org/10.21203/rs.3.rs-193321/v1

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Abstract

**Background:** Shape memory polymers are materials that are manufactured in a certain shape, can be stored in a temporary deformed shape, and then return to – or remember – their original shape upon exposure to external stimuli such as temperature and moisture. This property lends itself to application in endovascular medical devices. Peripheral vasculature embolisation devices incorporating this novel technology have become commercially available and this case series, where the data were collected as part of a post market registry, outlines initial clinical experience with these novel devices.

**Results:** Eight cases are described in this series. The disease state/conditions for which embolisation was indicated were right common iliac artery aneurysms (n = 3), a type II endoleak into the thoracic aorta following thoracic endovascular aneurysm repair (n = 1), a left inferior gluteal artery aneurysm (n = 1), left internal iliac artery aneurysms (n = 2), and a case of splenomegaly, where splenectomy was planned after the embolisation procedure (n = 1). Target arteries were 5-10 mm in diameter. In each case, at least one IMPEDE Embolization Plug of an appropriate diameter was used. All procedures were technically successful and target vessel thrombosis was achieved in all cases. Follow-up imaging available during the 45-90-day data collection timeframe showed sustained vessel occlusion. This case series includes examples of situations commonly encountered when embolising the peripheral vasculature, namely, the use of one or multiple devices in a single vessel and in combination with the use of other embolic devices (e.g., microcoils, gelatin sponge, and PVA particles) in the same case. There were no adverse events related to the specific use of the device.

**Conclusions:** This small series illustrates the safety and efficacy of this novel sponge-based embolic device for the embolisation of small and medium sized arteries and further experience will demonstrate the utility of the shape memory polymer devices.

**Background**

Shape memory polymers can be deformed into a temporary shape and return to – or remember – an original shape upon exposure to external stimuli such as temperature and moisture. The shape memory polymer in the IMPEDE Embolization Plug family (Shape Memory Medical, Santa Clara, California, USA) has been developed with properties that support vessel embolisation. Fig. 1 illustrates the IMPEDE Embolization Plug and IMPEDE-FX Embolization Plug. The shape memory portion of the device is crimped for compatibility with catheter delivery and expands to its original space-lling shape once delivered into the warm and aqueous environment of a blood vessel. The expanded shape memory polymer is a porous scaffold that supports thrombus formation throughout the device as the blood penetrates the device upon initial contact. The polymer fabrication and physical properties have previously been described (Landsman et al., 2016). Preclinical work characterised cellular infiltration into the shape memory polymer scaffold and conversion of thrombus to mature collagenous connective tissue over time (Jessen et al., 2020). Furthermore, preclinical work suggests shape memory polymer-based devices support an advanced state of healing, within a designated timeframe, compared to other
commonly used vessel embolisation devices (Jessen et al., 2020). Following CE marking of the devices, the manufacturer established a post market study to collect data on their routine clinical use. This case series describes our clinical experience with the novel IMPEDE Embolization Plug in the registry study to date.

**Methods**

**Study structure, case series**

A prospective multicentre registry of the CE marked IMPEDE and IMPEDE-FX Embolization Plug devices, involving no change to standard of care, was approved by London-Hampstead Health Research Authority Research Ethics Committee (Reference IRAS 250759, REC 19/LO/0767). The study is also registered at clinicaltrials.gov (NCT04044443). Participants gave written consent on ethics committee-approved consent forms. Adults (≥18 years) that were candidates for arterial or venous embolisation of the peripheral vasculature were invited to join the study. Those that could not provide written informed consent or were vulnerable persons were excluded. If a patient or planned treatment was outside of the device instructions for use (IFU), the patient was also excluded from the study. The aim of the study is to enroll up to 50 participants and enrollment is ongoing, although hampered by the Covid pandemic. This case series represents the first 8 cases enrolled, all of which used the IMPEDE Embolization Plug. Participants were followed through 45 days post procedure to collect follow-up data (including adverse events) during that time. Case 7 was followed for 90 days after a protocol amendment to extend the follow-up period.

**Device use and usability hints and tips**

The device was used in accordance with its IFU. There are two aspects of use that operators should especially note when using these pushable devices, the second being specific to the IMPEDE Embolization Plug with the anchor coil. First, the IFU outlines a 1-minute working time, defined as the time between when the device enters the catheter and it being deployed into the vessel. Since the polymer begins to slowly expand once in the catheter (because it is in a warm fluidic environment), it may expand enough to cause friction during delivery or even not be able to exit the catheter if the working time is exceeded. The implant is provided in the introducer and it is important not to flush the introducer prior to use or to only flush immediately prior to introduction to the catheter for the same reason (i.e., the working time clock starts upon flushing). Second, the delivery of the anchor coil of the IMPEDE Embolization Plug is similar to other coils, however, delivery of the shape memory portion of the device is delivered into the vessel by unsheathing rather than pushing. In practice, this means holding the guidewire steady and retracting the delivery catheter to reveal the shape memory polymer plug. This process ensures the shape memory polymer portion of the device is not pushed into the anchor coil, which would limit its expansion.

**Case follow-up**
Cases were followed according to the standard of care throughout the study timeline of 45-90 days post procedure. Any standard of care follow-up imaging during this time was available for evaluation in the study.

Results

The disease state/conditions for which peripheral vascular embolisation was indicated in each case were right common iliac artery aneurysms (cases 1-3), a type II endoleak into the thoracic aorta following thoracic endovascular aneurysm repair (case 4), a left inferior gluteal artery aneurysm (case 5), left internal iliac artery aneurysms (cases 6-7), and splenomegaly (case 8), where a splenectomy was planned after the embolisation procedure. Table 1 summarises brief patient demographics, the target vessels for embolisation, the point of vascular access, the target vessel diameters and of the implanted devices, and any concurrent procedures.

Cases 1-3 – Right common iliac artery aneurysms

Fig. 2 illustrates embolisation of a right internal iliac artery to treat a large common iliac artery aneurysm (case 1). A 6 Fr 45 cm long Destination Sheath (Terumo, Tokyo, Japan) and a 180 cm long Amplatz Super Stiff guidewire (Boston Scientific, Marlborough, Massachusetts, USA) were used for device delivery. An IMP-07 device (diameters: expanded shape memory polymer 8 mm, anchor coil 9 mm) was deployed, followed by an IMP-10 device (diameters: expanded shape memory polymer 12 mm, anchor coil 13 mm), into the 10 mm diameter vessel. Additional embolic material in the form of an IMPEDE-FX Embolization Plug was considered. However, stasis occurred with the two devices, and therefore no further embolic material was necessary. An iliac artery stent was placed across the origin of the internal iliac artery, completing the procedure. Duplex ultrasound assessment prior to discharge of the patient confirmed cessation of flow into the aneurysm. Follow-up computed tomography angiography (CTA) at 5 weeks post procedure showed that the vessel remained occluded, although a very small feeding vessel above the plug was perfusing the aneurysm. No further procedures have been planned or undertaken due to the complexity of any further interventions and the aneurysm size is stable.

Fig. 3 shows further intraprocedural fluoroscopic images of right internal iliac artery embolisation (cases 2 and 3) to treat common iliac artery aneurysms. In case 2, the patient underwent endovascular aneurysm repair (EVAR) at the same time as vessel embolisation and in case 3, the patient underwent EVAR and right iliac stent placement at the same time as vessel embolisation. In both cases, a 6 Fr Destination Sheath and a 0.035 inch Amplatz Superstiff guidewire were used to deliver an IMP-10 device (diameters: expanded shape memory polymer 12 mm, anchor coil 13 mm) into each of the 8 mm diameter vessels. Acute vessel embolisation was achieved in both cases. No follow-up imaging to evaluate sustained occlusion was performed within the study timeline. In case 2, the patient experienced postoperative general abdominal pain and in case 3, the patient experienced postoperative buttock claudication and a small groin haematoma. The pain and buttock claudication were managed medically and resolved without sequelae. Buttock claudication is a recognized sequela of internal iliac artery
aneurysm embolisation, and can be caused by any embolic device used for this procedure. Furthermore, the patients underwent EVAR procedures at the same time as vessel embolisation with associated vascular access requirements.

**Case 4 – Type II endoleak into thoracic aorta**

Fig. 4 illustrates embolisation of a 10 mm diameter left subclavian artery to treat a type II endoleak into the thoracic aorta following TEVAR. An IMP-10 device (diameters: expanded shape memory polymer 12 mm, anchor coil 13 mm) was delivered using a 6 Fr Destination Sheath and Amplatz Superstiff guidewire as used in the prior procedures via a transbrachial access. Follow-up CTA at 6 weeks post procedure confirmed continued vessel occlusion and no further endoleak into the proximal sac of the descending thoracic aorta. The patient developed a self-limiting mild haematoma related to manual compression after withdrawal of sheath.

**Case 5 – Left inferior gluteal artery aneurysm**

Fig. 5 shows embolisation of a 5 mm diameter left inferior gluteal artery to treat one of the bilateral aneurysms of the participant. In this case, an IMP-05 device (diameters: expanded shape memory polymer 6 mm, anchor coil 7 mm) was delivered using a 4 Fr Glidecath Cobra 2 catheter (Terumo, Tokyo, Japan) and a 180 cm long Bentsen guidewire (W Cook Europe, Bjaeverskov, Denmark). Microcoils were deployed distal to the aneurysm sac and the IMPEDE Embolization Plug was used to embolise the vessel proximal to the aneurysm sac. Acute vessel embolisation was achieved. Six-week follow-up CTA showed a sustained vessel occlusion and a decrease in the aneurysm diameter from 26.5 mm to 24 mm.

**Cases 6-7 – Left internal iliac artery aneurysms**

Fig. 6 shows embolisation of a 9 mm diameter left internal iliac artery to treat an aneurysm (case 6). An IMP-10 device (diameter: expanded shape memory polymer 12 mm, anchor coil 13 mm) was delivered using a 6 Fr Destination Sheath and 180 cm long Amplatz Superstiff guidewire. Microcoils were used to embolise distal branches and the IMPEDE Embolization Plug was used to embolise the main IIA trunk. Follow-up CTA at 6 weeks post procedure revealed satisfactory occlusion of the aneurysm. In case 7, an IMP-10 device was delivered into a 10 mm diameter left internal iliac artery using a 5 Fr Rim catheter (Merit Medical, Salt Lake City, Utah, USA) and a 180 cm long angled tip Terumo guidewire (Terumo, Tokyo, Japan). The participant underwent EVAR during the same procedure. Follow-up imaging duplex ultrasound assessment at 2 weeks post procedure was satisfactory with no residual endoleak.

**Case 8 – Splenomegaly**

Fig. 7 shows embolisation of an 8 mm diameter splenic artery prior to a planned splenectomy. An IMP-07 device (diameter: expanded shape memory polymer 8 mm, anchor coil 9 mm) was delivered via a 5 Fr Headhunter I catheter (Cordis, Santa Clara, California, USA) and 0.035 Starter guidewire (Boston Scientific, Marlborough, Massachusetts, USA) via a brachial access. Equispon haemostatic gelatin sponge (Equimedical, Zwanenburg, The Netherlands) and Contour PVA particles (500-710 microns)
(Boston Scientific, Marlborough, Massachusetts, USA) were used to pack distal branches prior to vessel embolisation with the IMPEDE Embolization Plug. Six Complex Helical-18 coils (Boston Scientific, Marlborough, Massachusetts, USA) were used to embolise a different branch prior to case completion. The splenectomy was performed 2 days later, as planned. The patient developed a haematoma and small pseudoaneurysm, which significantly decreased in size upon manual compression. This is not an uncommon complication following transbrachial artery access.

**Discussion**

The shape memory polymer-based porous embolic scaffold in the IMPEDE Embolization Plug device family is a material new to medical devices, and its properties, particularly its porosity, mechanisms of healing, and lack of radio-opacity, are unique. Peripheral vasculature embolisation is a good initial clinical application of this novel material. As outlined above, the devices performed as expected in the embolisation of small and medium sized arteries. The follow-up imaging showed sustained occlusion of the treated vessels. The IFU states “[Shape memory polymer] undergoes slow degradation with the majority (>90%) of the SMP plug remaining at 30 days in a porcine intravascular model. Near complete degradation was observed in vivo in rat subcutaneous and rabbit intramuscular implants at 180 days.” Longer-term follow-up will show longer-term clinical results, however preclinical work demonstrated the conversion of thrombus to mature collagenous connective tissue as the polymeric scaffold degrades (Jessen et al., 2020).

In terms of practical operations, the 1-minute working time of the device is manageable, but catheter choice is an important aspect of case planning. The delivery catheter internal diameters should be in line with the device labeling to avoid potential friction during delivery. Furthermore, the devices are pushable and therefore the catheter internal diameter should not be so large as to allow feeding the guidewire down past the side of the device. The technique of unsheathing the shape memory polymer portion of the device, as outlined above, should be familiar to interventionalists. This is an important operational detail to avoid deploying the shape memory polymer into the anchor coil and thereby potentially limiting its expansion. The manufacturer recommends slightly oversizing the device based on the shape memory polymer plug diameter and since the radial force of the shape memory polymer is minimal, this appears reasonable. The anchor coil of the IMPEDE Embolization Plug does has a landing zone of 2-4.5 cm, depending on the size of the device, and this should be taken into consideration during case planning.

Although the IMPEDE-FX Embolization Plug has not been used in the cases to date, it was considered in case 1. The IMPEDE-FX device offers interventionalists the ability to add a large amount of embolic material without adding much artifact in follow-up imaging. The volume of the expanded 12 mm diameter IMPEDE-FX device is approximately 1.25 mL and the proximal radiopaque marker is the only radiopaque material. Case 4, the embolisation of the subclavian artery to treat a type II endoleak following TEVAR, is a reasonable example of how the radiolucency of the shape memory polymer contributes to the clarity of follow-up imaging. It is our understanding that the IMPEDE-FX devices are best used behind another device to avoid potential migration. This other device could be the IMPEDE
Embolization Plug or a microcoil, for example. Practical use in the ongoing study will result in future examples for evaluation.

The limitations of this study are the limited patients enrolled to date. However, data collection is ongoing and future lessons learned in terms of utility and application of shape memory polymer-based devices will follow.

**Conclusion**

All procedures were technically successful and target vessel thrombosis was achieved in all cases. This case series includes examples of situations commonly encountered when embolising the peripheral vasculature, namely the use of one or multiple devices in a single vessel and in combination with the use of other embolic devices (e.g., microcoils, gelatin sponge, and PVA particles) in the same case. Adverse events were few and were those commonly encountered when embolising the peripheral vasculature with any embolic device. Moreover, they were unrelated to the use of this specific device.

In summary, this small series illustrates the safety and efficacy of this novel sponge-based embolic device for the embolisation of small and medium sized arteries and further experience will demonstrate the utility and potential of the shape memory polymer devices.

**Abbreviations**

CTA: computed tomography angiography; EVAR: endovascular aneurysm repair; IFU: instructions for use; TEVAR: thoracic endovascular aneurysm repair.

**Declarations**

**Ethics approval and consent to participate**

The study was approved by London-Hampstead Health Research Authority Research Ethics Committee (Reference IRAS 250759, REC 19/LO/0767). Participants gave written consent on ethics committee-approved consent forms.

**Consent for publication**

Ethics committee-approved participant information sheets and consent forms for the study included publication.

**Availability of data and material**

Not applicable.
Competing interests
None.

Funding
The study was sponsored by Shape Memory Medical Inc.

Authors' contributions
RAM is a study site principal investigator, performed cases included in the manuscript, and was involved in data collection and writing the manuscript. IL performed cases included in the manuscript was involved in revising the manuscript. LR was involved in the study and revising the manuscript. RD was involved in the study and revising the manuscript. LM was involved in the study and revising the manuscript. MSH is a study site principal investigator, performed cases included in the manuscript, and was involved in revising the manuscript. KL is study chief investigator and was involved in revising the manuscript. All authors read and approved the final manuscript.

Acknowledgements
None.

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Tables
Table 1 Case series summary
| # | Sex | Age | Target artery   | Vascular access | Vessel diameter (mm) | Polymer diameter (mm) | Anchor coil diameter (mm) | Concurrent procedure                |
|---|-----|-----|-----------------|-----------------|---------------------|-----------------------|---------------------------|-----------------------------------|
| 1 | M   | 79  | R internal iliac | Femoral         | 10                  | 8 + 12                | 9 + 13                    | Iliac stent                      |
| 2 | M   | 78  | R internal iliac | Femoral         | 8                   | 12                    | 13                        | EVAR                              |
| 3 | M   | 69  | R internal iliac | Femoral         | 8                   | 12                    | 13                        | EVAR and iliac stent             |
| 4 | M   | 79  | L subclavian     | Brachial         | 10                  | 12                    | 13                        | -                                 |
| 5 | F   | 79  | L inferior gluteal | Femoral        | 5                   | 6                     | 7                         | -                                 |
| 6 | M   | 59  | L internal iliac | Femoral         | 9                   | 12                    | 13                        | -                                 |
| 7 | M   | 66  | L internal iliac | Femoral         | 10                  | 12                    | 13                        | EVAR                              |
| 8 | F   | 77  | Splenic          | Brachial         | 8                   | 8                     | 9                         | -                                 |