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Original research

A novel self-expanding shape memory polymer coil for intracranial aneurysm embolization: 1 year follow-up in Chile

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► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/jnis-2022-018996).

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Received 8 April 2022
Accepted 21 June 2022

To cite: Echeverría D, Rivera R, Giacaman P, *et al*. *J NeuroIntervent Surg* Epub ahead of print: [*please include* Day Month Year]. doi:10.1136/neurintsurg-2022-018996

ABSTRACT

Background Aneurysm recurrence remains a challenge when coiling cerebral aneurysms. Development of next generation coils has focused on accelerating thrombus maturation and increasing coil packing density. Ultra low density shape memory polymer is a novel embolic material designed for this purpose. The polymer is crimped over a platinum–tungsten coil for catheter delivery and self-expands to a predefined volume on contact with blood.

Methods This prospective study in humans evaluated aneurysms 5–16 mm (inclusive) in diameter that were indicated for endovascular coil embolization. At least 70% coil volume was required to be shape memory polymer coils. Patients were followed-up according to standard of care for 12 months.

Results Nine patients (89% women, mean age 55.8±11.7 years) were treated with shape memory polymer coils and completed 12 months of follow-up. Aneurysms were all unruptured and were in the ophthalmic segment of the internal carotid artery (n=7), posterior communicating artery, and anterior cerebral artery A1–A2 segment. Aneurysms were a mean of 7.8±2.9 mm in diameter (range 5.2–14.9 mm). The mean packing density based on unexpanded polymer was 17±6%. Packing density based on expanded polymer was 43±13%. At 12 months, no recurrence had occurred, and a Raymond–Roy occlusion classification of 1 (n=5) or 2 (n=4) was observed. No serious adverse events related to the study device occurred over the 12 months after the procedure.

Conclusions Shape memory polymer coils were safe and effective in treating intracranial aneurysms over 12 months in this first study in human subjects.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Intracranial aneurysm recurrence/recanalization rates are inversely proportional to the packing density of implanted coils.

WHAT THIS STUDY ADDS

⇒ The study describes the first clinical experience in human subjects with a self-expanding shape memory polymer coil that offers a greater packing density of embolic material for intracranial aneurysm embolization. The porous polymer scaffold supports thrombus formation throughout its structure while the mass of the polymer itself in the aneurysm is low.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE, OR POLICY

⇒ This study is the first report on clinical experience with a novel material and device for intracranial aneurysm embolization.

INTRODUCTION

It is widely accepted that intracranial aneurysm recurrence/recanalization rates are inversely proportional to packing density,[1] where packing density is defined as the ratio of the volume of implanted coils and the volume of the aneurysm. Packing density thresholds of ~20–27% result in adequate outcomes with bare metal coils.[2–8] Increasing the packing density of intracranial aneurysms is an ongoing goal of the neurointerventionalist, given that~20% of the coiled aneurysms may recur/recanalize.[9 10] Shape memory polymer is a new material that allows greater packing density of embolic material during intracranial aneurysm embolization.

Shape memory polymer is a material that is stable in two different shapes. The properties of an ultra low density polyurethane shape memory polymer have been developed to support vessel and aneurysm embolization.[11 12] This material can be crimped for catheter delivery and self-expands in the vessel (warm aqueous conditions) to a predefined volume in the form of a porous structure. The expanded form has a high surface area and supports thrombus formation throughout its structure. The use of embolic devices based on shape memory polymer in the peripheral vasculature and aorta has been reported.[13–15] The shape memory polymer is bioabsorbable,[16] although the timeline for absorption is unknown in human clinical cases.

Shape memory polymer coils[17] are now available for intracranial aneurysm embolization. In a rabbit elastase model, aneurysms treated with these novel coils had more connective tissue and less debris than those treated with bare metal coils at 180 days after implantation.[16] In a porcine aneurysm model, the use of a similar shape memory polymer material (ie, a similar polymer and without a metal coil) resulted in a greater reduction in aneurysm cross sectional area compared with bare metal coils.[18] The volume of shape memory coils increases approximately

fourfold on complete polymer expansion. The expanded porous material of the device supports thrombus formation throughout its high surface area structure of embolic and biocompatible material. The porous structure means the packing density of the expanded coil is substantially increased on expansion of the polymer, while the mass of polymer itself in the aneurysm is low. Here, we describe the first clinical experience in human subjects on the use of shape memory polymer embolization coils for the treatment of intracranial aneurysms, with 12 month follow-up.

METHODS

Study

This was the first prospective study in human subjects, with enrollment and follow-up over 12 months at two centers in Chile. Written informed consent was obtained from all patients prior to study procedures. Key inclusion criteria were an aneurysm of 5–16 mm (inclusive) in diameter, an indication for endovascular treatment by coil embolization, and an intention to have ≥70% of the coil volume from shape memory polymer coils. Key exclusion criteria were prior treatment of the aneurysm, planned use of other modified coils or liquid embolics, and intended parent vessel occlusion. A complete list of eligibility criteria is available in online supplemental table 1. Patients were followed until 12 months after the procedure in the study, on a schedule consistent with institutional standard of care follow-up up to 3 years. All serious adverse events were reviewed by an independent medical monitor.

Device and procedure

The study device was the TrelliX 18 embolic coil (Shape Memory Medical Santa Clara, California, USA), as shown in figure 1. The TrelliX 18 embolic coil includes an outer layer of crimped shape memory polymer over a tungsten–platinum coil with a primary wind outer diameter of 0.008 inches, resulting in a composite primary coil diameter of approximately 0.015 inches (0.38 mm). The shape memory polymer coils are available in a standard range of lengths and secondary diameters. The coil system has a standard electrolytic detachment mechanism with a patient groin grounding needle. The coil is supplied in a dispenser hoop and vacuum packaged with desiccant to eliminate moisture induced expansion during storage. The coils were shipped with temperature management.

Shape memory polymer coils have a unique working time, defined as the maximum time between the coil entering the microcatheter and deployment into the target site. The primary coil diameter slowly increases to a maximum of 0.030 inches (0.76 mm) on exposure to an aqueous environment and body temperature. The coil is compatible with microcatheters with an inner lumen diameter of 0.021 inches (0.53 mm). The working time for this coil in a 0.021 inch inner diameter microcatheter is 10 min, according to the instructions for use.

Study embolization procedures were performed according to standard intracranial aneurysm embolization procedures at each institution. Stent assisted coiling was allowed at the interventionalist's discretion. Since study initiation, the TrelliX 18 embolic coil received CE marking. At the time of manuscript submission for publication, the device had not yet received marketing clearance from the United States Food and Drug Administration.

Endpoints and data analysis

The primary endpoint of the study was the angiographic occlusion rate using the Raymond–Roy occlusion classification (RROC)[19] on completion angiography and at 6 and 12 months. The safety endpoint was the rate of device/procedure related serious adverse events up to 30 days after the procedure. Secondary endpoints were rates of aneurysm bleeding, recurrence, and retreatment; clinical outcome assessed by the modified Rankin Scale (mRS) score; neurological mortality and morbidity; all cause death; and the number of coils and adjunctive devices used to treat the aneurysm. The study is ongoing, and the data presented here represent the data available at the time of submission for publication for patients with 12 month follow-up.

Aneurysm volumes, coil volumes, and packing densities were determined using the calculator at www.angiocalc.com (March 2022). Preprocedure aneurysm volumes were determined using the ellipsoid model calculator, where the width and depth were equal to the aneurysm width determined by fluoroscopy guided catheter angiography immediately before the procedure. Total packing densities were determined by entering all the coils used in each case into the angiocalc.com calculator, in which the total per cent packing density is calculated based on the fully

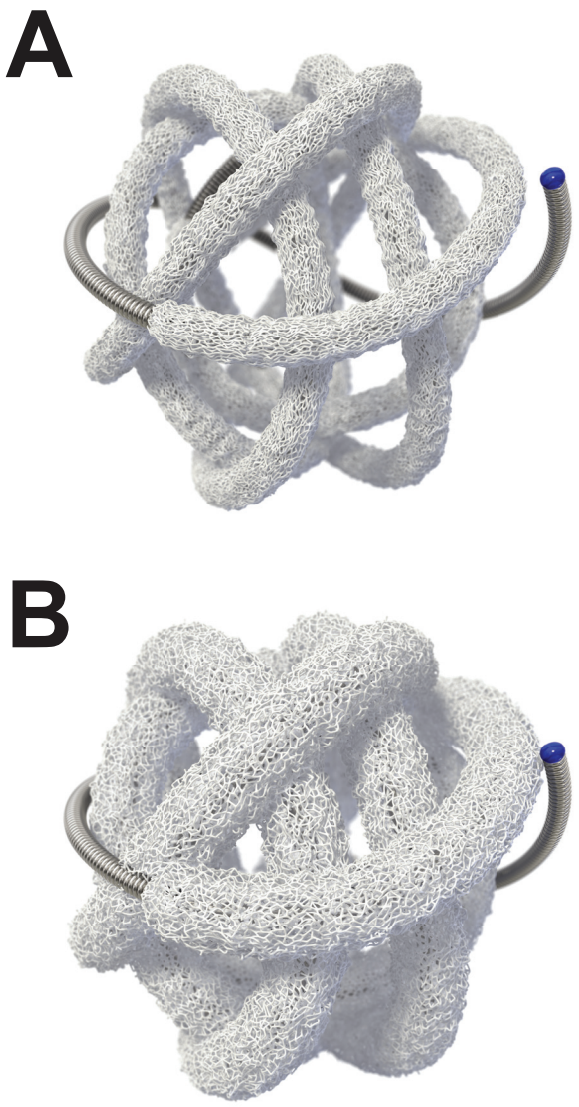

Figure 1 The shape memory polymer coil in its (A) crimped and (B) expanded forms. The polymer self-expands on contact with blood. The pores of the expanded form are ~200 µm in diameter and the polymer supports thrombus formation throughout its structure. The volume occupied by the coil with the fully expanded polymer structure is approximately fourfold larger than that occupied by the crimped form.

expanded shape memory polymer. The total per cent packing density based on the volume of study coils prior to expansion of the shape memory polymer was calculated independently, based on the pre-expanded volume reported at angiocalc.com. Continuous data are presented as mean±SD and categorical data as number (% of total).

RESULTS

Nine patients (89% women) with a mean age of 55.8±11.7 years were treated with shape memory polymer coils between November 2018 and January 2020. Patients underwent a 30 day clinical evaluation, and the majority underwent fluoroscopy guided catheter angiography at 6 and 12 months postprocedure; in three cases, 6 month follow-up imaging was unavoidably delayed because of COVID-19 pandemic restrictions to fluoroscopic evaluation and were therefore performed with MR angiography (table 1). In two cases, 12 month follow-up visits were delayed until ~19 months (table 1) because of the same restrictions.

The shape memory coils were delivered through a Headway 21, 2.5 F outer diameter, 150 cm or 156 cm length microcatheter (MicroVention, Aliso Viejo, California, USA), except in one case where a Headway 17, 2.4 F outer diameter, 150 cm length microcatheter was used based on case specific needs (ophthalmic segment of the internal carotid artery (ICA) aneurysm, neck width 3.4 mm). Stent assisted coiling was used in four cases (Leo Baby, Balt, Irvine, California, USA, n=3; Neuroform Atlas Stent System, Stryker, Fremont, California, USA, n=1).

Aneurysms were all unruptured and were in the ophthalmic segment (C6) of the ICA (n=4 left, n=3 right), right posterior communicating artery, and left anterior cerebral artery A1–A2 segment. Aneurysms had a mean diameter of 7.8±2.9 mm (range 5.2–14.9 mm) based on the largest measurement of width and height, with a mean neck width of 4.2±1.8 mm (range 2.0–8.2 mm) (table 1). The aneurysms had a mean volume of 305±498 mm^3 (range 63–1618 mm^3). Three patients (33%) were symptomatic.

Acute outcome based on the RROC was satisfactory in each case (table 1). The acute result of the largest aneurysm of the ophthalmic segment of the ICA (volume 1618 mm^3) was satisfactory considering its size. The treatment plan of this aneurysm included use of a flow diverter if 6 month assessment indicated further intervention, and this was the case. The flow diverter (FRED, MicroVention, Aliso Viejo, California, USA) was implanted immediately following the 6 month visit. The 12 month assessment showed an improvement, based on the RROC (table 1). At 6 months, all other aneurysms had either improved or remained stable, and at 12 months an RROC of 1 (n=5) or 2 (n=4) was observed in all patients. Neither aneurysm bleeding nor recurrence was observed in any patient after 12 months.

Figure 2 illustrates embolization of one of the smaller aneurysms of the ophthalmic segment of the ICA in the study, with a volume of 94 mm^3. Just one shape memory polymer coil was used in this case, but it constituted 75% of the total coil volume, based on the fully expanded shape memory polymer. On expansion of the shape memory polymer, packing density increased from 20% to 45%. The completion angiography RROC of 1 (figure 2B) was sustained at 12 months (figure 2C).

Figure 3 illustrates the treatment of one of the largest aneurysms of the ophthalmic segment of the ICA in the series, with a volume of 143 mm^3. Stent assisted coiling was used in this case. The shape memory polymer coils constituted 85% of the total coil volume, based on the fully expanded shape memory polymer. On expansion of the shape memory polymer, packing density increased from 12% to 31%. Although completion angiography showed an RROC of 3 (figure 3B), the result improved to an RROC of 1 at 6 months that was sustained at 12 months (figure 3C). The change from dual antiplatelet therapy to mono antiplatelet therapy during follow-up likely contributed to the improved outcome.

Figure 4 illustrates the treatment of the posterior communicating artery aneurysm, with a volume of 321 cm^3. The shape memory polymer coils constituted 82% of the total coil volume, based on the fully expanded shape memory polymer. On expansion of the shape memory polymer, the packing density increased from 10% to 25%. Figure 4B shows the aneurysm post coiling and prior to the stent. The aneurysm was RROC 2 at completion angiography (post stent) and at 12 months (figure 4C).

There were no safety concerns or serious adverse events related to the study device/procedure during the first 30 days. One serious adverse event related to a standard of care follow-up angiogram was recorded; the patient treated with the flow diverter exhibited hemiparesis after the 12 month angiogram. At this time, the patient acknowledged dual antiplatelet therapy non-compliance (prescribed after implantation of the flow diverter at 6 months after the index procedure) and episodes of hemiplegia, but had not sought medical attention. MRI showed signs of subacute and chronic infarctions, but no acute ones and it was concluded that the symptoms were exacerbations of the subacute infarctions due to brain edema in the context of contrast media use. The patient subsequently recovered following medical and physical therapy.

All patients had an mRS score of 0 at baseline, and mRS of 0 at the 6 month and 12 month follow-up clinic visits. The patient who exhibited hemiparesis after the 12 month angiogram recovered shortly thereafter.

The mean working time for the delivery of the shape memory coils was 4.5±2.3 min (range 1.3–10 min). All coils used in each case are listed in online supplemental table 2. The mean proportion of embolic material volume from shape memory polymer coils was 82±8% (range 75–100%, table 1), based on the volume of fully expanded shape memory polymer. Table 1 also includes the total volumes of embolic material from shape memory polymer coils (with the polymer in pre-expanded and fully expanded state) and other coils for each case. The total packing density increased more than 2.5 times on expansion of the porous shape memory polymer. The total packing density was a mean of 17±6% (range 7–26%) based on pre-expanded shape memory polymer and 43±13% (range 25–64%) based on fully expanded shape memory polymer (table 1).

DISCUSSION

The aneurysms treated in this study are representative of cases routinely encountered at our centers, and therefore the results of this first study in human subjects reflect those likely to be achieved in real world clinical practice. Although the study eligibility criteria accommodated ruptured aneurysms, occurrence rates are lower than unruptured aneurysms, and no otherwise suitable cases were consented into this study. The overall procedure, treatment plans for each patient, and follow-up schedule reflected our standard of care. Follow-up schedules were affected by patient and staff movement restrictions during the COVID-19 pandemic, but every effort was made to adhere to the protocol schedule as much as reasonably possible.

The TrelliX embolic coil is currently available as a complex filler coil, and therefore the first study protocol in human subjects was designed with the intention to apply a lower limit for the amount of shape memory polymer coil (≥70% by volume) to evaluate the technology, while at the same time not limit the ability to achieve the best possible result for the patient. In practice, a minimum of 75% shape memory polymer coil use by volume was used. In all except

Table 1 Baseline, procedural, and follow-up data

		Baseline aneurysm dimensions				Embolization coil volumes and packing densities									Raymond–Roy*		
		NW	W	H	V	TX-PE V	TX-E V	TX-PE pack	TX-E pack	Total V	Total pack TX-PE	Total pack TX-E	TX-E % total	Stent assisted coiling	PP	6 months	12 months
Aneurysm/side		mm	mm	mm	mm^3	mm^3	mm^3	%	%	mm^3	%	%	%				
C6 seg ICA	R	8.2	14.4	14.9	1618	120	460	28	0	460	7	28	100	Yes	3	3	2
C6 seg ICA	L	2.0	6.0	8.3	156	20	76	49	15	91	22	58	84	–	2	1†	1
C6 seg ICA‡	L	5.5	7.8	4.5	143	10	38	26	7	45	12	31	85	Yes	3	1	1
C6 seg ICA	R	2.7	6.2	5.7	115	12	47	41	13	60	22	53	78	–	1	1†	1
C6 seg ICA	L	4.1	6.1	6.0	117	10	36	31	12	48	19	41	75	–	2	1	2§
C6 seg ICA¶	R	3.1	6.1	4.8	94	8	31	34	10	42	20	45	75	–	1	1	1
C6 seg ICA	L	3.4	4.8	5.2	63	6	24	38	5	28	18	45	83	–	2	2	2§
PCom A**	R	4.7	8.7	8.1	321	17	65	20	15	80	10	25	82	Yes	2	2†	2
ACA A1–A2	L	4.0	6.8	5.0	121	16	62	51	15	77	26	64	80	Yes	2	1	1

Aneurysm volumes, coil volumes, and packing densities were determined using the calculator at www.angiocalc.com in March 2022. Online supplemental table 2 contains specifics on all the coils used in each case.
*Determined by fluoroscopy guided catheter angiography at the time points indicated, with some exceptions (see below).
†Determined by MR angiography at 10 months because of COVID-19 pandemic restrictions to clinical operations.
‡Illustrated in figure 3.
§Determined by catheter angiography at 19 months because of COVID-19 pandemic restrictions to clinical operations.
¶Illustrated in figure 2.
**Illustrated in figure 4.
ACA A1-A2, anterior cerebral artery A1–A2 segment; C6 seg ICA, ophthalmic segment of the internal carotid artery; H, height; NW, neck width; PCom A, posterior communicating artery; PP, at case completion angiography; Raymond–Roy, Raymond–Roy occlusion classification; Total pack TX-E, packing density based on the total volume of all coils used in the aneurysm with the TrelliX embolic coil volume with expanded shape memory polymer; Total pack TX-PE, packing density based on the total volume of all coils used in the aneurysm with the TrelliX embolic coil volume prior to expansion of the shape memory polymer; Total V, total coil volume, including coils other than TrelliX embolic coils; TX-E pack, packing density based on the TrelliX embolic coil volume with expanded shape memory polymer; TX-E % total, proportion of the total coil volume that is TrelliX embolic coil volume, based on expanded shape memory polymer; TX-E V, TrelliX embolic coil volume with expanded shape memory polymer; TX-PE pack, packing density based on the TrelliX embolic coil volume prior to the expansion of the shape memory polymer; TX-PE V, TrelliX embolic coil volume prior to the expansion of the shape memory polymer; V, volume; W, width.

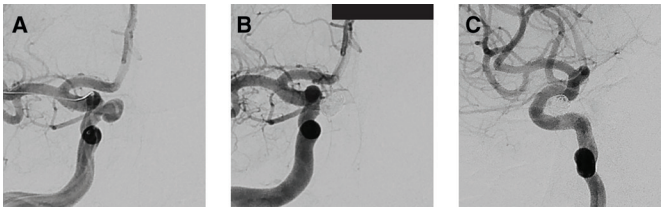

Figure 2 (A) Preprocedural angiogram illustrating a 6.1 mm (width) × 4.8 mm (height) aneurysm of the ophthalmic segment (C6) of the right internal carotid artery with a calculated volume of 94 mm^3. (B) Completion angiography with a Raymond–Roy occlusion classification of 1. Shape memory polymer coil constituted 75% of the total coil volume, based on expanded shape memory polymer. The packing density was 20% based on pre-expanded shape memory polymer and 45% based on fully expanded shape memory polymer. (C) 12 month follow-up angiography illustrating continued exclusion of the aneurysm (Raymond–Roy occlusion classification of 1).

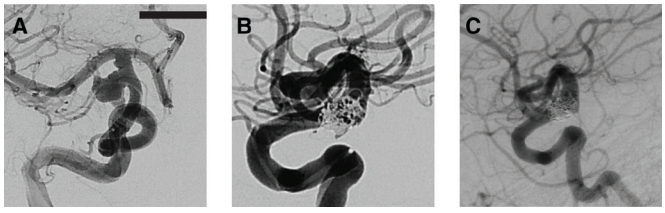

Figure 4 (A) Preprocedural angiogram illustrating a 8.7 mm (width) × 8.1 mm (height) aneurysm of the posterior communicating artery with a calculated volume of 321 mm^3. (B) Post coiling but prior to the stent that was used in this case. Shape memory polymer coil constituted 82% of the total coil volume, based on expanded shape memory polymer. The packing density was 10% based on pre-expanded shape memory polymer and 25% based on fully expanded shape memory polymer. Case completion angiography showed a Raymond–Roy occlusion classification of 2. (C) 12 month follow-up angiography illustrating a Raymond–Roy occlusion classification of 2.

the 14–15 mm aneurysm, we used a framing/larger bare metal coil, filled with shape memory polymer coil(s) and, if needed, finished with bare metal coils. In four cases, stent assisted coiling was used due to aneurysm neck size. Overall, we did not significantly adjust our treatment strategy based on the novel shape memory polymer coils.

There is a short learning curve associated with the shape memory polymer coil. As the microcatheter pushes back during initial deployment, the user should firmly hold position (and not continue applying further movement). The shape memory polymer will slowly plasticize and soften on contact with blood. This material softening along with the forward pressure/tension will cause the implant to coil within the aneurysm sac without having to apply additional pressure/tension.

The 10 min working time of shape memory polymer coils is a unique feature and is defined as the maximum time between the coil entering the microcatheter and deployment into the target site. This time begins when the coil's introducer comes into contact with the hemostasis valve. The shape memory polymer starts to expand after exposure to warmth and moisture, and if the working time is exceeded, friction with the delivery microcatheter may occur and/or it may be difficult to retract the coil into the microcatheter with the shape memory polymer in a partially expanded state. In our experience, 10 min was sufficient time to deliver the coils (68% of the shape memory coils were delivered in ≤5 min) and we did not encounter any working time based issues using a 0.021 inch inner diameter microcatheter. We performed a single case with a 0.017 inch inner diameter microcatheter and were mindful to minimize the working time (actual 8.1 min) as the 10 min working time in the instructions for use is based on a 0.021 inch inner diameter. We did not experience any delivery issues with the smaller diameter catheter.

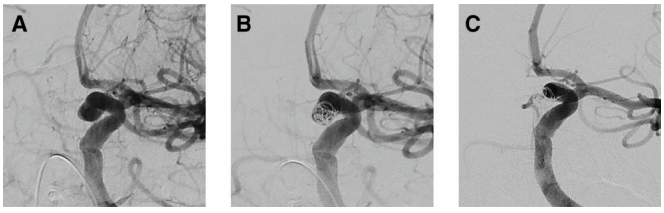

Figure 3 (A) Preprocedural angiogram illustrating a 7.8 mm (width) × 4.5 mm (height) aneurysm of the ophthalmic segment (C6) of the left internal carotid artery with a calculated volume of 143 mm^3. (B) Completion angiography post stent assisted coiling, with a Raymond–Roy occlusion classification of 3. Shape memory polymer coil constituted 85% of the total coil volume, based on expanded shape memory polymer. The packing density was 12% based on pre-expanded shape memory polymer and 31% based on fully expanded shape memory polymer. (C) 12 month follow-up angiography illustrating exclusion of the aneurysm (Raymond–Roy occlusion classification of 1).

The x-ray transparency of the polymer is extremely advantageous when performing intraprocedural angiography as it is easier to see through the aneurysm to verify complete exclusion of contrast from the sac (figure 3B). Furthermore, it may be important in follow-up imaging in cases where it is advantageous to visualize vessels behind the treated aneurysm. Figure 3C illustrates the visibility of the vessel behind the coils at the 12 month follow-up. The mean packing density of 43% achieved in this study (based on expanded polymer volume) is substantially higher than the threshold of 20–27% reported to result in adequate outcomes with bare metal coils.[2–6 8 20]

Other bioactive or coated neurovascular coils include hydrogel[21] and matrix coils. Hydrogel coated coils (second generation) have been shown to have high packing density and lower recurrence rate than bare metal coils (4.4% vs 15.4%) in a randomized controlled trial.[22] Hydrogel coils have also shown a lower recurrence rate than bare metal coils in a retrospective review of the treatment of anterior communicating artery aneurysms.[23] A systematic review of first and second generation hydrogel coils showed they had significantly higher packing density and significantly lower recurrence than bare metal coils, but no difference in initial occlusion rate.[24] Separately, hydrogel coils have shown evidence of progressive thrombosis and improvement of RROC up to 6 months and retreatment rates comparable with historical data up to 5 years.[25] Matrix coils showed non-inferiority in recurrence rate to bare metal coils (13.3% vs 14.6%) in a randomized controlled trial at ~1 year[26] and also non-inferiority at 5 years, but no benefit was demonstrated.[27]

The unique feature of the shape memory polymer coils is that the mass of polymer implanted in the aneurysm is low, but the expanded polymer substantially increases the packing density as the porous polymer supports thrombus formation throughout its structure (ie, the shape memory polymer does not displace significant blood volume). There was no evidence in this small study that any bioabsorption had a negative effect on outcomes. We envision that these polymer based devices will be effective in the treatment of dural arteriovenous fistulas or other disease processes where a significant volume of embolic material is required to occlude vessels.

The limitations of this study are those common to first studies in human subjects. The study was small and did not have a control arm. The aneurysms treated were all unruptured and were a range

of sizes and volumes, and radiological outcomes were not adjudicated by a core laboratory. Bare metal coils and stents/flow diverters were used in addition to shape memory polymer coils in some cases, which likely affected overall outcomes. However, these initial data provide a foundation for the design of larger controlled studies to further evaluate the utility of these shape memory polymer coils.

CONCLUSIONS

Shape memory polymer coils were safe and effective in treating intracranial aneurysms up to 12 months in this small case series. The porous nature of the shape memory polymer means that the packing density is substantially increased on expansion of the polymer and as thrombus forms throughout its structure, while the mass of implanted polymer is low. The expected learning curve with a new technology is short and the radiolucent shape memory polymer makes it easy to see through the aneurysm during filling. Further experience is required to fully evaluate the use of the device in a wider range of aneurysms.

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Acknowledgements The authors thank MT Fabían Bravo and Research Nurse Loreto Bravo from the Instituto de Neurocirugía, Dr Asenjo in Santiago, and Research Nurses Jessica Parra and María José Saldaña from the Hospital Clínico Regional Guillermo Grant Benavente in Concepción for their dedication and time spent on this endeavor. The authors also thank Aquilla S. Turk for acting as medical monitor of the study.

Contributors Conception and design: DE and RR. Acquisition of the data: all authors. Analysis and interpretation of the data: all authors. Drafting the manuscript: DE. Critically revising the manuscript: all authors. Reviewing submitted version of manuscript: all authors. DE accepts full responsibility for the work and/or the conduct of the study, had access to the data, controlled the decision to publish, and acts as guarantor.

Funding The study was sponsored by Shape Memory Medical.

Competing interests DE is a consultant for Shape Memory Medical.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Comité de Ética Científico del Servicio de Salud Metropolitano Oriente (Santiago, ID 20181120) and Comité de Ética Científico del Servicio de Salud Concepción (Concepción, ID 19-05-31). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available.

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