Technical Note

INR INTERVENTIONAL NEURORADIOLOGY

Interventional Neuroradiology
1–7

DOI: 10.1177/15910199231187048
journals.sagepub.com/home/ine
Sage

Treatment of a ruptured shallow trilobed cerebral aneurysm with the novel saccular endovascular aneurysm lattice (SEAL) device: A case report with one year follow-up

Boris Pabon[1], Victor Torres[1], Keith Woodward[2], Margarita Cardozo[1], Benedict Tan[3], Varun Chaubal[3], Aamir Badruddin[4], Thomas Wolfe[4], Edgard Pereira[4], Brian Jankowitz[5], Vincent Costalat[6], David Altschul[7], Claire A Langerford[8] and Osama O Zaidat[4]

Abstract

Intrasaccular flow disruption is a viable alternative to other endovascular treatments for saccular or wide-necked bifurcation intracranial aneurysms; however, wide neck aneurysms with irregular shapes or shallow depth may not be amenable to treatment currently available intrasaccular devices. Here, we present the first ever case report of the novel Saccular Endovascular Aneurysm Lattice Embolization System (SEAL™). The versatile utility of the SEAL™ device is demonstrated in a patient with acute subarachnoid hemorrhage (SAH) from a ruptured, complex, left middle cerebral artery (MCA) trilobed shallow wide-necked bifurcation aneurysm. Deployment and implantation of the SEAL device were technically feasible, safe, and conformed well to the irregular shape of the complex, ruptured aneurysm. Immediate total aneurysm occlusion was observed after implantation. Importantly, 1-year angiographic follow-up demonstrated durable, complete occlusion with no safety concerns. The SEAL device is a promising new novel technology which has the potential to treat very shallow aneurysms with limited height and irregular, multilobulated aneurysms.

Keywords

Saccular, aneurysm, flow diversion, endovascular, rupture

Received 17 June 2023; accepted 20 June 2023

Introduction

Intrasaccular flow disruption is a viable alternative to other endovascular treatments for saccular or wide-necked bifurcation intracranial aneurysms and offers several advantages, such as eliminating the need for dual antiplatelet therapy.[1] Currently, the only FDA-approved intrasaccular device available in the US is the Woven EndoBridge (WEB) device; however, due to the WEB device's compact nature and size availability, wide aneurysms with irregular shapes or shallow depth may not be amenable to treatment with WEB.

The Saccular Endovascular Aneurysm Lattice Embolization System (SEAL™, Galaxy Therapeutics, Inc, Milpitas, CA, USA) is a new generation intrasaccular aneurysm flow disruptor, consisting of a self-expanding, dual layer, nitinol and with core platinum wire mesh braided implant, that is designed with three main attributes:

[1]Department of Neurosurgery, Universidad De Antioquia, Medellin, Colombia
[2]Department of Neurointerventional Radiology, Covenant Health, Knoxville, TN, USA
[3]Department of Neurosciences, St. Vincent Mercy Medical Center, Toledo, OH, USA
[4]Galaxy Therapeutics INC, Milpitas, CA, USA
[5]Department of Neurosurgery, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA, USA
[6]Department of Neuroradiology, Gui de Chauliac University Hospital of Montpellier, Montpellier, France
[7]Department of Neurosurgery, Montefiore Medical Center-Albert Einstein College of Medicine, Bronx, NY, USA
[8]MedX CRO, Toledo, OH, USA

Corresponding authors:
Osama O Zaidat, 2213 Cherry St, M200 Mercy Health Neuroscience, Toledo, OH 43608, USA.
Email: OOZaidat@mercy.com

Boris Pabon, Department of Neurosurgery, Universidad De Antioquia, Carrera 25A # 1A Sur 45 - Torre médica el Tesoro, Consultorio 1234, Medellín, Colombia.
Email: borispabon@hotmail.com

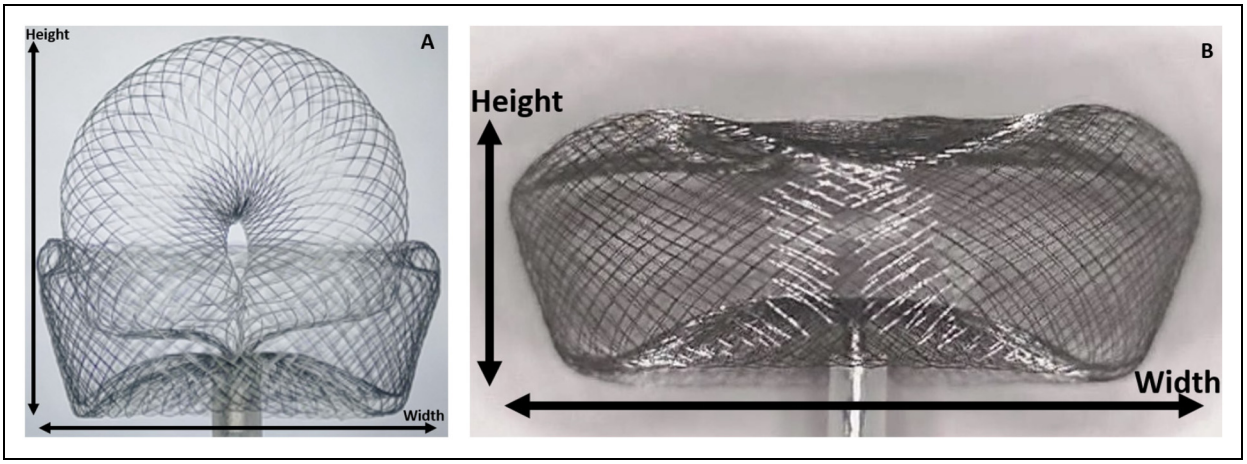

Figure 1. Saccular endovascular aneurysm lattice (SEAL) device. (a) SEAL™ Arc and (b) SEAL™ Base.

1. Ease of use for the operator: making the deployment safer with no lead in marker band with atraumatic distal part and increase device softness for better conformability to the aneurysm geometry without higher risk of compaction.
2. Dual layer design: approximated at the aneurysm neck and entry zone, to increase flow diversion and enhancement early thrombosis of the aneurysmal sac.
3. Durability: improved long-term occlusion of intracranial aneurysms.

The SEAL™ device merges the characteristics of flow diversion and coiling for ease of use to permanently seal an intracranial aneurysm. The SEAL™ has a dual layer architecture that is available in two configurations: one configuration has an ovoid upper loop with a base bridging component (SEAL™ Arc), and the second configuration includes only the base portion (SEAL™ Base) (Figure 1).

Here, we present the first ever case report of the SEAL device, the versatile utility of the SEAL™ device is demonstrated in a patient with acute subarachnoid hemorrhage (SAH) from a ruptured, complex, left middle cerebral artery (MCA) trilobed shallow wide-necked bifurcation aneurysm.

Case presentation

A 58-year-old Hispanic male without known significant past medical history presented to the emergency department (ED) with sudden onset of severe headache and mental status changes. On exam, he had right hemiplegia and responded to pain. The non-contrast head CT scan in the ED demonstrated diffuse subarachnoid hemorrhage (Figure 2). Both the exam and imaging were consistent with a Hunt and Hess Scale of 3 and a Fisher Grade of IV.

CT angiography of the head demonstrated a left MCA bifurcation shallow aneurysm with complex irregular trilobed shape configuration. The patient was enrolled in the PRE-SEAL™ IT: Saccular Endovascular Aneurysm Lattice System First In Human Interventional Trial (PRE-SEAL IT) clinical feasibility study after evaluation of the inclusion and exclusion criteria. The SEAL™ System is currently only had marketing approval in New Zealand. Informed consent was obtained from the patient's legally authorized representative, and the patient was taken immediately to the angiography suite for endovascular treatment with the SEAL™ device.

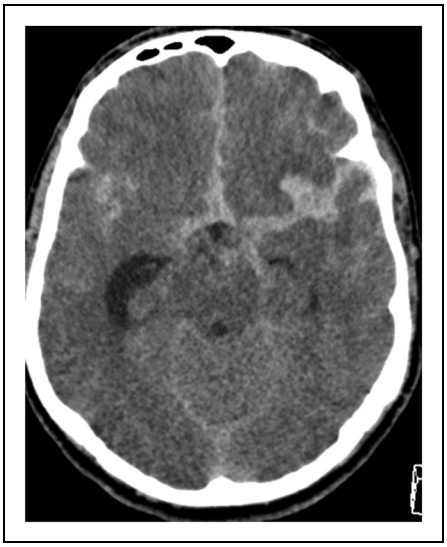

Figure 2. Diffuse subarachnoid hemorrhage, fisher grade IV (left sylvian fissure small hematoma), with hydrocephalus and enlarged right temporal horn.

Procedural and technical case description

Access and baseline images

Access was obtained via a transfemoral approach, and an introducer sheath was placed into the common femoral artery. After obtaining the arterial access, 5000 IU intravenous (IV) heparin was administered per the standard of care. Then, using a 90 cm sheath, an intermediate catheter SOFIA™ 5F (MicroVention, Irvine, CA, USA) was used for support and placed at the distal internal carotid

artery proximal to the bifurcation. The initial baseline digital subtraction angiogram (DSA) confirmed the presence of a complex, wide-necked, left MCA bifurcation, trilobed irregular, shallow, wide aneurysm with a height of 3.46 mm, an equatorial width of 6.25 mm, maximum width of 8.47 mm, and a neck size of 4.77 mm (Figure 3(a) and (b)).

SEAL™ device size choice

Sizing for the SEAL™ Device was determined using the following two-step process:

Step 1: Configuration choice: For the configuration choice (Base versus Arc), determine if the aneurysm is shallow or elongated.

1. For shallow, irregularly shaped aneurysms with the width being the largest diameter, the Base configuration is recommended.
2. For deep, elongated, and spherical shape aneurysm, the Arc configuration is recommended.

In this case, the aneurysm is a shallow wide aneurysm; therefore, the SEAL™ Base was chosen for treatment of the patient's aneurysm.

Step 2 Sizing choice: Determine the correct device width needed for the SEAL™ device.

The SEAL™ Base is available in increments of 3 mm width devices (up to 18 mm then to maximum of 20 mm in width), and the manufacturer's current recommendation in the PRE-SEAL IT early clinical feasibility study is to go to the next size up based on the equatorial width and neck size.

In this case, the aneurysm width is 6.25 mm and the neck is 4.27 mm; therefore, the 9 mm SEAL™ Base device was selected for treatment of the index aneurysm (Figure 1(b)). Oversizing to the width of the aneurysm for lateral compression against the aneurysm wall is critical to assuring total occlusion and good long-term outcomes.

SEAL™ device deployment steps

Following the selection of the SEAL™ Device configuration and size, the Headway™ 27 (Microvention, Irvine, CA, USA) microcatheter was placed into the aneurysm lumen via the SOFIA™ 5Fr and over the 0.14″ microguidewire (Figure 4(b)). The SEAL™ device was then advanced through the 0.027″ inner diameter microcatheter and deployed within the aneurysm lumen by a pushing and unsheathing approach without difficulty (Figure 4). The SEAL™ device has an atraumatic leading distal part without lead-in marker band, since it is radio-opaque within the microcatheter lumen and when deployed in the aneurysm sac under fluoroscopic guidance with very visible proximal marker band as seen in Figure 4(b)–(f) (white arrows and within the circle). The device was fully deployed and detached using an electrical detachment controller. When SEAL™ device is detached; the marker band may be no longer aligned with the microcatheter tip (Figure 4(f)).

The immediate post SEAL™ deployment DSA demonstrated complete instantaneous aneurysm occlusion (Roy Raymond (RR) Scale of 1 and Web Occlusion Scale (WOS) of A). No device herniation or parent artery thrombosis, or stenosis was noted on the final images (Figure 5(a)). Total fluoroscopic time was 53 min.

Post-Procedure antiplatelet therapy

No aspirin, clopidogrel, or other antiplatelet agents were administered. The patient was then transferred to the intensive care unit (ICU) for post SAH post-procedure standard care.

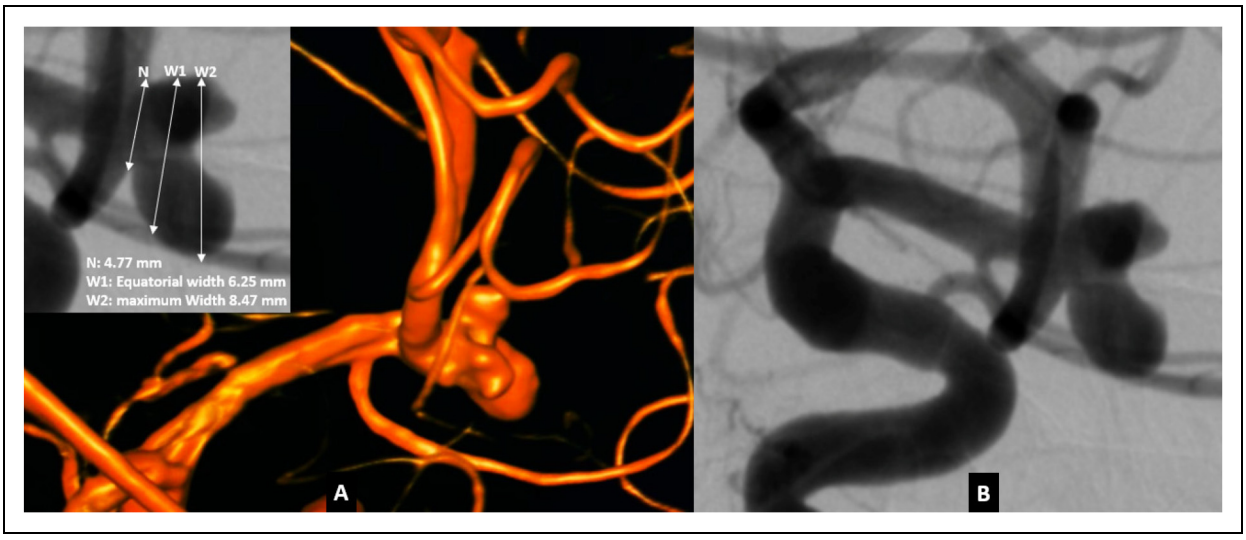

Figure 3. Baseline angiography of the index aneurysm. (a) 3D working projection baseline angiography. Upper left corner denotes the aneurysm dimensions: N: neck at 4.77 mm, W1: Equatorial width at 6.25 mm, and W2: Maximum width at 8.47 mm, (b) Angiography showing the index aneurysm in 2D.

Patient follow-up

24-h clinical and imaging follow-up and hospital course

At the 24-h follow-up, the patient's condition improved, and he regained consciousness and was extubated. On the 24-h follow-up exam, the patient's modified Rankin scale (mRS) score was 2. The 24-h post-procedure DSA follow-up demonstrated persistent complete occlusion of the ruptured aneurysm (Figure 5(b)). The patient was closely monitored and was discharged home on day 15 with residual right hemiplegia and mRS of 3.

Two-month vascular imaging and clinical follow-up

At two-month follow-up, the patient had improved significantly in his right arm and leg, with a mRS 2 for minor residual right hemiparesis. A repeat DSA demonstrated complete occlusion of the aneurysm and normal patency of the parent artery without evidence of luminal narrowing (Figure 5(c)).

6-Month vascular imaging and clinical follow-up

At six-month follow-up, the patient had completely recovered without sequelae (mRS 0). A repeat DSA again demonstrated total occlusion of the aneurysm and complete patency of the parent artery.

12-Month vascular imaging and clinical follow-up

The patient remained asymptomatic at the 12-month follow-up, with a mRS of 0. A repeat DSA continued to demonstrate complete occlusion of the aneurysm and normal caliber of the parent artery (Figure 5(d)).

Discussion

In this case report, we present the the first ever use of the novel SEAL™ intrasaccular device for the treatment of a ruptured, complex, wide-neck intracranial aneurysm. Deployment and implantation of the SEAL device were technically feasible, safe, and conformed well to the shape of the complex, ruptured aneurysm. Immediate total aneurysm occlusion was observed after implantation, which is a crucial factor when considering neuro-endovascular tools to effectively treat ruptured aneurysms and prevent rebleeding.[2] Importantly, 1-year angiographic follow-up demonstrated durable, complete occlusion with no safety concerns.

The achievement of instantaneous total occlusion in this case report suggests that the SEAL™ device compares favorably to competitor aneurysm flow disruptors, including LUNA™ aneurysm embolization system (Medtronic, Irvine, CA), Woven Endo Bridge (WEB™, MicroVention, Irvine, CA), and Contour™ device (Cerus Endovascular Ltd).[3–5] The LUNA system had a low post-operative rate of adequate occlusion (18%).[3] WEB has been used successfully to treat ruptured aneurysms, but the rate of complete occlusion was 53.4% in

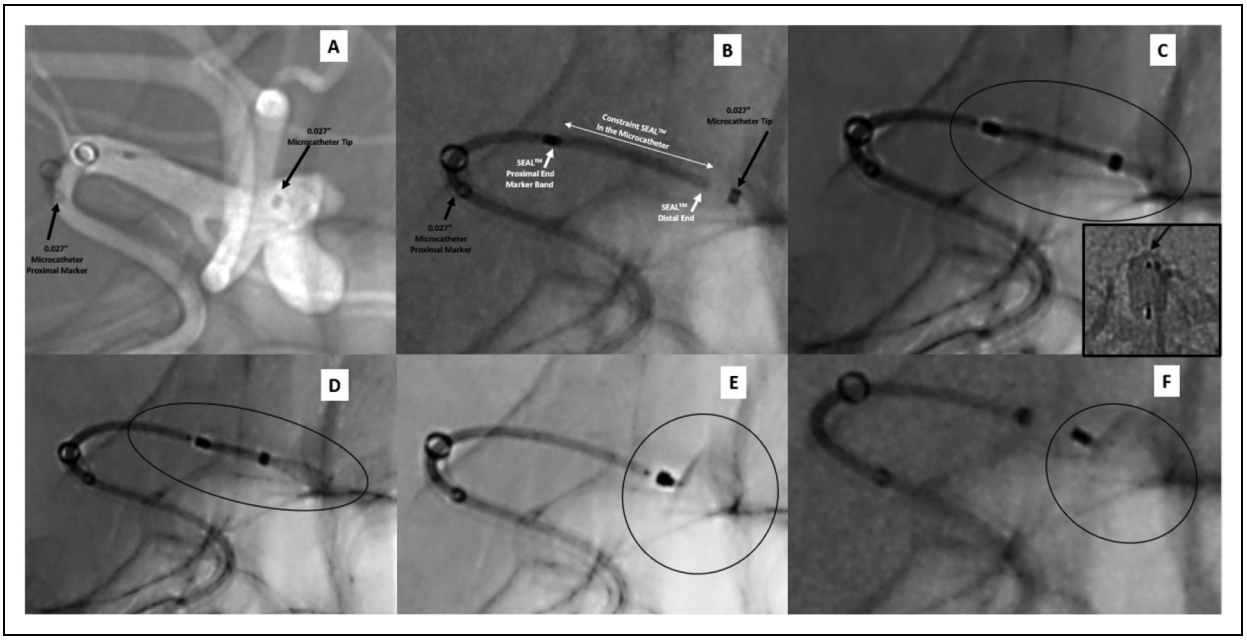

Figure 4. (a)–(f) SEAL™ device deployment steps from A to F. The standard technique is used to access the aneurysm lumen with commercially available neurovascular 0.027″ microcatheter. Subsequently, the constraint device is advanced inside the microcatheter. Black arrows (a and b) are showing the proximal and distal microcatheter tips, while the white arrows (b) are showing the constraint device within the microcatheter lumen. Subsequent panels are showing progressive deployment (a–f) of the device (in the circle) until fully detached in f. Notice that the SEAL™ device has no leading marker band; in contrary to the WEB™ device shown in the left lower corner of panel C.

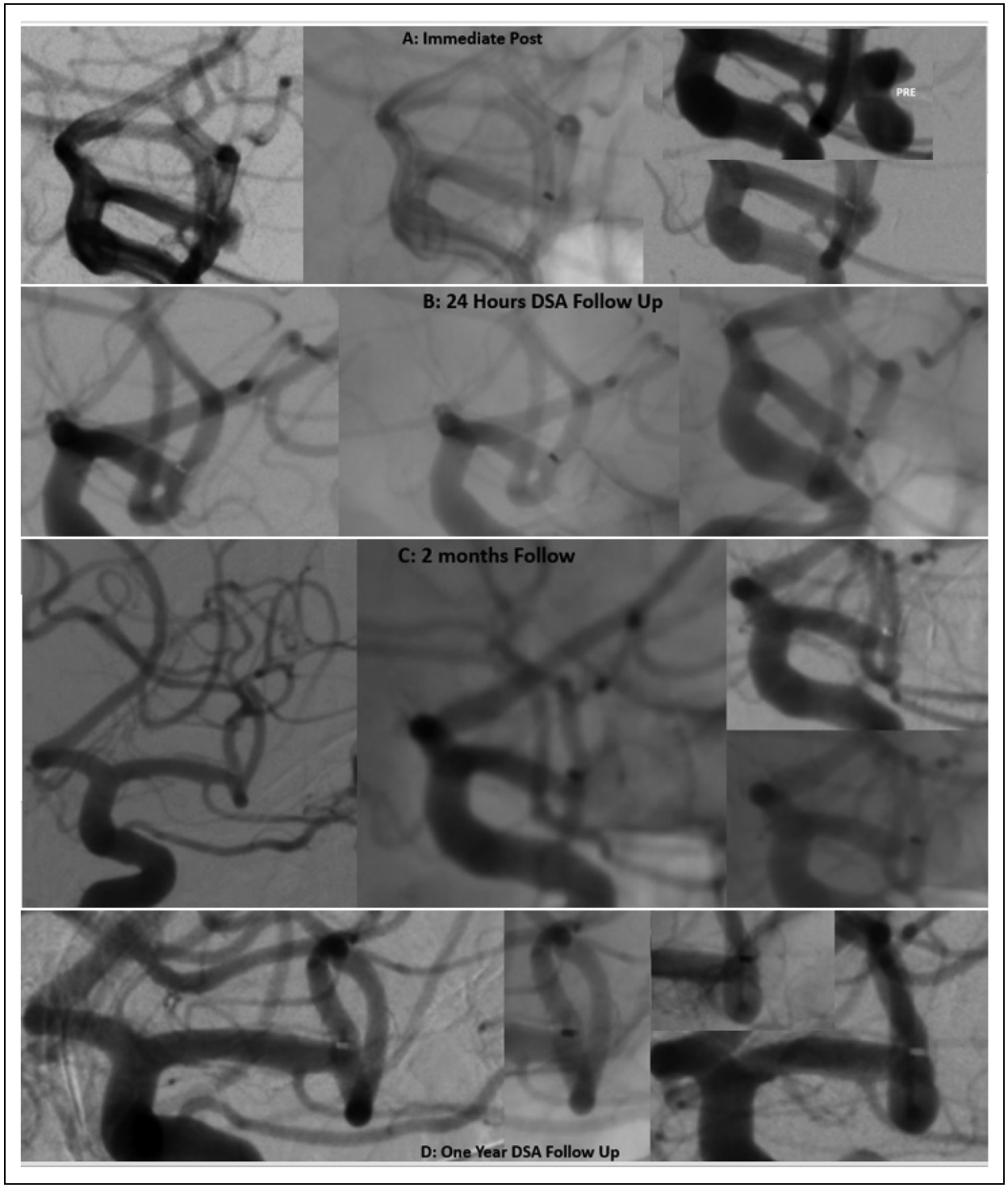

Figure 5. (a)–(d) Aneurysm occlusion using the SEAL™ device. (a) Immediate post deployment with complete occlusion that was durable on the 24 h (b), 2 months (c) and 1 year (d) Digital subtraction angiography as compared to pre-treatment angiogram (right upper corner).

the WEB IT pivotal trial and did not report data on instant or 24-h occlusion rate.[4] Future prospective clinical trials on the SEAL™ device will provide immediate and long-term aneurysm occlusion rates in a larger patient population.

The SEAL™ device has several unique features including an atraumatic leading tip (Figure 6), softness that allows conformability to various complex aneurysms shapes and versatility in having two configurations, a shallow double layer basket-like design with wavy perimeter to increase the healing surface area and anchorage (SEAL™ Base) and a deep loop design to allow extra endoluminal part for deeper aneurysm called SEAL™ Arc. The dual-layer architecture, with increased wire numbers (192 wires), allows for high flow diversion which leads to faster aneurysm occlusion (Table 1). In

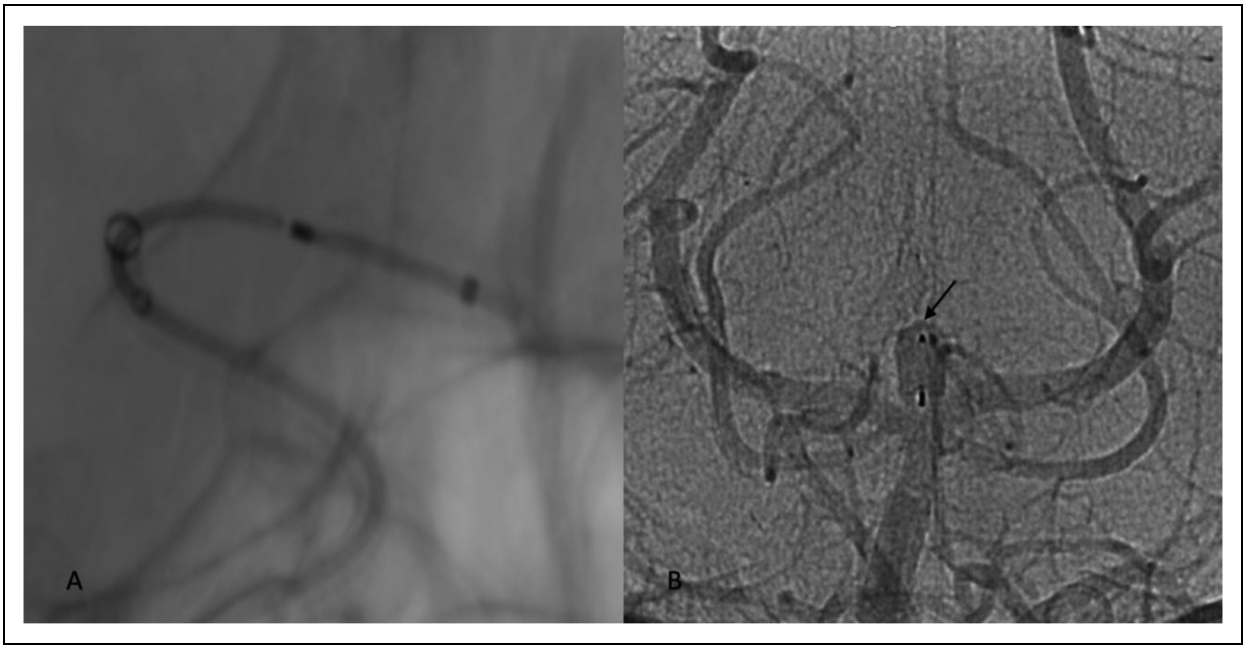

Figure 6. The distal tip of the SEAL™ device without a lead marker (a) and the distal tip of the WEB™ device with a lead marker (b).

Table 1. Comparison of intrasaccular devices: WEB™, Contour™ and SEAL™

	WEB™	Contour™	SEAL™
Configuration	Two: Cylindrical (SL) and Spherical (SLS)	One concave shape with no roof	Two: Wavy perimeter short (SEAL Base) and taller with anchoring loop (SEAL Arc)
Braid Layers	Single	Dual	Dual
Design	3D (Braids all around)	2D (Concave)	3D (Braids all around)
Dome Anchoring	Sizing dependent	No	Sizing dependent
Number of Wires for Device	144 for 4 mm to 216 for the 11 mm	2 × 64 wires for 5 mm to 2 × 81 wires for the 14 mm	SEAL Base: 96 wires for 3 mm to 288 wires for 20 mm SEAL Arc: 48 wires for 4 mm to 96 wires for 20 mm
Configuration Focused Design	Hard for shallow aneurysm	Focus on neck bridging	For shallow and deep aneurysms, focus on conformability
Design for Aneurysm Dome and Neck Shape	Unknown	Unknown, neck mainly?	Yes, wider at the dome than neck side, sloping to conform to the aneurysm shape
Microcatheter Compatibility	0.017″, 0.021″, 0.027″, 0.033″	0.021″, 0.027″, 0.033″	0.017″, 0.021″, 0.027″, 0.033″
Aneurysm Width	3 to 10 mm (average width on two planes)	2 to 10.5 mm (equatorial width)	Proposed 2.5 to 16.5 mm (equatorial width)
Available Sizes	3 to 11 mm	5 to 14 mm	3 to 20 mm
Distal Lead Marker	Yes	No	No
Detachment	Electro-thermal	Electrical	Electrical
Deployment	Unsheath then advance	Unsheath	User choice either approach
Sizing	Complex: Average of width and height	Neck and equatorial width	Neck and equatorial width
Stock Keeping Unit	29 in the SL configuration	5 up to 14 mm	4 per configuration up to 12 mm
Neck Bridging Part	Flat	V Shape	Flat
Conformability	Mild to moderate	At the neck	Both dome and neck conformability
Spatial Design (2D, 3D or 4D)	3D, device has neck braids and dome braids and sides braids	2D, device has neck braids no roof dome braids and side braids	3D, device has neck braids and dome braids and sides braids

the present report, we highlight the SEAL's ability to treat very shallow aneurysms with limited height and irregular, multilobulated aneurysms.

One potential limitation of all endovascular devices for the treatment of aneurysms is the possibility of the device becoming dislodged and compacted into the aneurysm

lumen and dome. This was illustrated in a recent case report using the Contour device in which the device became fully displaced into the aneurysm dome on follow-up angiography.[6] Devices can become dislodged for many reasons including improper sizing or enlargement of the aneurysm over time, which might occur in the setting of regular use of antiplatelets, inadequate control of comorbidities, such as hypertension or unchanged modifiable risk factors such as smoking. In the present report, no antiplatelets were used and no medical comorbidities were identified.

Conclusion

In this novel SEAL™ intrasaccular aneurysm device first ever case report, complete aneurysm occlusion was demonstrated from immediate post-procedure through one-year follow-up with no aneurysm recurrence or safety events. The conformable and soft SEAL system is a promising novel versatile technology that offers treatment options to patients with irregular and shallow aneurysms that may not be amenable to other intrasaccular devices. Larger studies are warranted to further clarify the role of this new intrasaccular flow disruptor.

Declaration of conflicting interests

Drs Zaidat, Wolfe, Pereira, and Badruddin are co–founders for Galaxy therapeutics, Inc and share holders. SEAL device is only approved for marketing and commercializing in New Zealand. This case report is part of the Pre–SEAL IT ethics committee approved early feasibility clinical study in Medellin Colombia.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article

ORCID iDs

Benedict Tan https://orcid.org/0000-0001-7485-7283
Varun Chaubal https://orcid.org/0009-0003-5354-1636
David Altschul https://orcid.org/0000-0002-5130-1378

References

1. Dmytriw AA, Salem ML, Yang V, et al. Endosaccular flow disruption: a new frontier in endovascular aneurysm management. *Neurosurgery* 2020; 86: 170–181.
2. Júnior S, Trivelato FP, Nakiri GS, et al. Endovascular treatment of residual or recurrent intracranial aneurysms after surgical clipping. *J Cerebrovasc Endovasc Neurosurg* 2021; 23: 221–232.
3. Piotin M, Biondi A, Sourour N, et al. The LUNA aneurysm embolization system for intracranial aneurysm treatment: short-term, mid-term and long-term clinical and angiographic results. *J Neurointerv Surg* 2018; 10: e34–e34.
4. Pagano P, Paiusan L, Soize S, et al. Intracranial aneurysm treatment with intrasaccular flow disruption: comparison of WEB-21 and WEB-17 systems. *J Neurointerv Surg* 2022; 14: 904–909.
5. Liebig T, Killer-Oberpfalzer M, Gal G, et al. The safety and effectiveness of the contour neurovascular system (Contour) for the treatment of bifurcation aneurysms: The CERUS study. *Neurosurgery* 2022; 90: 270–277. https://doi.org/10.1227/NEU.0000000000001783
6. Bellanger G, Darcourt J, Januel A, et al. The reversed umbrella: displacement of a Contour device into an MCA aneurysm 18 months after treatment. *J Neurointerv Surg* Published online March 20, 2023. https://doi.org/10.1136/jnis-2022-019814