Stroke: Vascular and Interventional Neurology

ORIGINAL RESEARCH

Safety and Clinical Effectiveness of Pipeline Shield Device for Intracranial Aneurysms in an Australian Cohort (SCOPE-AUS)

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BACKGROUND: The Pipeline Flex Embolization Device (PED) with Shield Technology (PED-Shield) is a third-generation flow diverting stents with surface modification designed to reduce platelet adhesion and thrombogenicity. We report the long-term safety and effectiveness of the PED-Shield in the treatment of unruptured intracranial aneurysms in an Australian cohort.

METHODS: SCOPE-AUS (Safety and Clinical Effectiveness Of Pipeline Shield Embolization Device for Treatment of Intracranial Aneurysms in Australia) is a multicenter, single-arm, retrospective study of patients with unruptured intracranial aneurysms treated with the PED-Shield flow diverting stents at 3 high-volume neurointervention centers in Australia between May 1, 2015, and June 30, 2018, evaluating safety and efficacy. The primary outcome was neurologic adverse event or neurologic-related death at 1 year, and the secondary outcome was long-term complete aneurysm occlusion.

RESULTS: A total of 238 patients (mean age 55.8±11.0 years, 73.1% [174/238] female) and 278 aneurysms were treated via 247 procedures. Two (0.7%) aneurysms were retreated during the 18-month follow-up. Overall occlusion rates at 18 months or at last follow-up imaging were 92.5% (233/252). There were 35 (14.7%) total primary end point events. The 12-month neurologic morbidity and mortality rates were 3.8% (9/238) and 1.3% (3/238), respectively. For the subgroup of internal carotid artery aneurysms, mortality (0.7%) and morbidity (2.0%) rates were low, and the complete occlusion rate was 92.5% (147/155).

CONCLUSIONS: In this multicenter study, which includes a wide variety of both distal bifurcation and proximal unruptured intracranial aneurysms, the occlusion rates and safety outcomes of the PED-Shield flow diverting stent demonstrate a high proportion of complete aneurysm occlusion, extremely low retreatment rates, and low complication rates.

Key Words: aneurysm ■ endovascular procedures ■ flow diverter ■ Pipeline Embolization Device

Flow diverting stents (FDs) have fundamentally altered the endovascular treatment of intracranial aneurysms, particularly wide-necked aneurysms, resulting in high rates of durable occlusion and an acceptable safety profile.[1–6] In recent years, the use of FDs has expanded to treat distal aneurysms beyond the

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internal carotid artery (ICA), including intracranial bifurcation aneurysms, posterior circulation aneurysms, as well as ruptured intracranial aneurysms. Meta-analyses have shown that the use of FDs in these anatomical and clinical situations confers a higher risk of neurologic morbidity.[7–9] Surface modification may improve the safety profile during FDs treatment of these and other intracranial aneurysms by reducing stent thrombogenicity and potentially also reducing the need for prolonged dual antiplatelet therapy.[10]

Since the introduction of the first-generation Pipeline Embolization Device (PED Classic, Medtronic Neurovascular, Irvine, California, USA) more than 10 years ago, thromboembolic complications remain a significant contributor to neurologic morbidity in FD treatment.[11] The Pipeline Flex Embolization Device with Shield Technology (PED-Shield), introduced in 2015, represents the third generation of the PED. PED-Shield technology features a surface modification of the braid wires with covalently bonded phosphorylcholine, which has demonstrated reduced thrombus formation on the surface of the device in in vitro and animal models compared with other FDs.[12–14]

SCOPE-AUS (The Safety and Clinical Effectiveness Of Pipeline Shield Embolization Device for Treatment of Intracranial Aneurysms in Australia) is a retrospective study conducted to evaluate the long-term clinical safety and efficacy outcomes in patients treated with the PED-Shield FDs in a real-world setting in Australia for an array of unruptured intracranial aneurysms including distal bifurcation intracranial aneurysms of the anterior and posterior circulations.

Nonstandard Abbreviations and Acronyms

FDs	flow diverting stents
ICA	internal carotid artery
IPH	intraparenchymal hemorrhage
PED	Pipeline Embolization Device

CLINICAL PERSPECTIVE

- The third-generation Pipeline Embolization Device with Shield surface modification technology has the potential to reduce stent thrombogenicity and improve the safety profile of the treatment.
- In this multicenter study, a wide spectrum of unruptured aneurysms including distal bifurcation and posterior circulation aneurysms was treated, achieving high complete aneurysm occlusion rates and low complication rates.

METHODS

Additional data supporting the findings of this study may be available from the corresponding author upon reasonable request. The corresponding author had full access to all the data in the study and takes responsibility for their integrity and the data analysis. SCOPE-AUS is a multicenter, single-arm, prospectively enrolled, retrospective study conducted at 3 high-volume neurointervention centers in Australia. The study was approved by the institutional review board for all participating centers. Eligible patients were sequentially selected patients with unruptured intracranial aneurysms treated with the PED-Shield embolization device between May 1, 2015, and June 30, 2018. The institutional review boards waived the need for written informed consent to join the study. Comprehensive clinical and imaging data were collected from the hospital electronic medical records at each center and collated in the Research Path Basecamp database; all data collection procedures were in accordance with institutional guidelines. Multiple data points were collected in the analysis, including patient demographics, comorbidities, aneurysm characteristics, number of devices implanted per aneurysm, failed deployment attempts, antiplatelet medication and anticoagulation regime, procedural and periprocedural complications, morbidity and mortality, and aneurysm occlusion status on progress imaging. The data collection template used at the 3 enrolling centers allowed for variability in routine standard of care, including antiplatelet therapy and follow-up imaging protocols.

Antiplatelet and Anticoagulant Therapy

At the largest enrolling center (Gold Coast University Hospital), the antiplatelet standard of care for elective unruptured aneurysms during the enrolment was 300 mg aspirin and 300 mg clopidogrel administered 12 and 2 hours before the procedure as a loading dose. Platelet function testing with VerifyNow P2Y12 Assay (Accumetrics) was performed at this center at the commencement of the procedure. Thresholds of platelet reactivity unit >200 or platelet inhibition <40% were used to define clopidogrel hyporesponders, and for these patients, additional loading of 500 mg intravenous aspirin was administered intraprocedurally with ticagrelor commenced post procedure with a loading dose of 180 mg followed by 90 mg twice daily as

the alternative to clopidogrel therapy. At the 2 other enrolling centers (Prince of Wales and Liverpool Hospital), patients were administered 100 mg aspirin and 10 mg prasugrel for 5 to 7 days prior to the procedure. No P2Y12 assay testing was performed at these centers. All 3 centers administered intravenous heparin during the procedure to maintain an activated clotting time of more than twice the baseline value.

Following routine elective PED-Shield implantation at all centers, patients were continued on dual antiplatelet therapy daily for 3 months and 100 mg aspirin daily for 12 months.

Flow Diverting Stent Procedure

All procedures were performed by interventional neuroradiologists, at high-volume centers, experienced in FD treatment of intracranial aneurysms. All were performed under general anesthesia. Arterial access was performed under ultrasound guidance. At 1 center (Gold Coast University Hospital), operators typically use a biaxial system using a 6-F vascular sheath, whereas the other 2 centers (Liverpool Hospital/PLOW) typically prefer a triaxial system using an 8-F vascular sheath with the use of an intermediate support catheter. Adjunctive coiling of the aneurysm was performed at the neurointerventionists' discretion, usually for aneurysms with irregular morphology, presence of daughter sacs, or large size.

Follow-Up

As the routine standard of care at each center, daily clinical and neurological examination was performed and documented on all patients following PED Shield implantation by the attending neurointerventional and neurosurgical treating teams before discharge from the hospital.

Any clinical adverse events were documented in the hospital medical records during the initial treatment admission, at follow-up clinical review, or on representation with any adverse event.

Routine imaging and clinical follow-up were performed at 1 month (computed tomography angiography), 3 months (magnetic resonance imaging [MRI]/magnetic resonance angiography), 6 months (digital subtraction angiography), 18 months (MRI/magnetic resonance angiography) post treatment at Gold Coast University Hospital and was performed at 6 months (digital subtraction angiography), 12 months (digital subtraction angiography or MRI/magnetic resonance angiography), and 18 months (MRI/magnetic resonance angiography) at Prince of Wales and Liverpool Hospital.

Outcome Assessment

The primary outcome was neurologic death or adverse neurologic event occurring within 1 year of aneurysm treatment. Neurologic adverse events included neurologic death, ischemic stroke, intracranial hemorrhage, transient ischemic attack, visual deficits, cranial neuropathy, and seizure.

Neurologic adverse events not resulting in death but causing residual or persistent clinical deficit were classified as neurologic morbidities. The primary outcome was calculated per patient. Nonneurologic intraprocedural or periprocedural complications, such as iatrogenic vessel dissection, access site pseudoaneurysm, or retroperitoneal hematoma, were also recorded.

The secondary outcome was complete aneurysm occlusion on angiographic follow-up as defined by the O'Kelly Marotta grading scale,[15] up to 18 months from treatment.

Image assessed aneurysm occlusion rates were determined by independent neuroradiologist review.

Statistical Analysis

Discrete variables are presented as counts (n/N) and percentages. Continuous data are presented as means with SD and/or range, as indicated. No statistical comparisons were performed on this retrospective review.

RESULTS

Patient Demographics and Aneurysm Characteristics

A total of 278 aneurysms were treated in 238 patients over 247 procedures during the study period. The mean patient age was 55.8±11.0 years, and 73.1% (174/238) patients were female. A total of 41.4% (89/238) patients had 2 or more aneurysms at the time of treatment, and 29.4% (63/238) had a history of prior aneurysm rupture that was previously treated. Patient demographic data are summarized in Table 1.

Characteristics of the treated aneurysms are presented in Table 2. The majority of treated aneurysms were in the anterior circulation (91.7% [255/278]) and saccular (93.9% [261/278]) in morphology. Intracranial ICA sidewall aneurysms constituted 65.8% (183/278) of aneurysms, and 15.8% (44/278) were distal bifurcation aneurysms. A total of 58.6% (160/278) of aneurysms were small, 28.2% (77/278) were medium, 12.5% (34/278) were large (≥10 mm), and 0.7% (2/278) were giant. The mean aneurysm neck diameter was 4.2 mm, and the mean aneurysm sac diameter was 7.3 mm. Forty-six (16.5%) aneurysms were previously treated, of

Table 1. Baseline Patient Characteristics

Characteristic	Frequency (N=238)
Age (y)	55.8±11.0 (15–82)
Female	174 (73.1%)
Family history of aneurysms	24 (10.1%)
Family history of hemorrhagic stroke/SAH	25 (10.5%)
Multiple aneurysms (≥2)	89 (41.4%)
Cigarette smoking	
Previous	77 (32.4%)
Current	68 (28.6%)
Alcohol consumption	122 (51.3%)
Comorbidities	
Hypertension	127 (52.3%)
Diabetes	23 (9.5%)
Hyperlipidemia	56 (23.0%)
Atrial fibrillation	8 (3.3%)
Ischemic heart disease	16 (7.5%)
History of Aneurysm Rupture	63 (29.4%)

SAH indicates subarachnoid hemorrhage.
Data are mean±SD (range) or n (%).

Table 2. Baseline Target Aneurysm and Procedure Characteristics

Characteristic	Frequency (N=278)
Aneurysm morphology	
Saccular	261 (93.9%)
Fusiform	11 (4.0%)
Dissecting	4 (1.4%)
Blister	2 (0.7%)
Aneurysm location, total (%)	
Cavernous ICA	11 (4.0%)
Persistent trigeminal artery	1 (0.4%)
Paraophthalmic ICA	42 (15.1%)
Supraclinoid ICA	78 (28.1%)
Communicating ICA	47 (16.9%)
ICA T-Junction	4 (1.4%)
M1, M2, M3 MCA	12 (4.3%)
MCA bifurcation	28 (10.1%)
Anterior communicating artery	25 (9.0%)
Pericallosal ACA	7 (2.5%)
V4 vertebral artery/PICA	9 (3.2%)
Basilar artery/SCA	11 (4.0%)
Sidewall	234 (84.2%)
Bifurcation	44 (15.8%)
Aneurysm size	
Small (<7 mm)	160 (58.6%)
Medium (7–<13 mm)	77 (28.2%)
Large (13–<25 mm)	34 (12.5%)
Giant (≥25 mm)	2 (0.7%)
Maximum diameter (mm)	7.3±4.8
Aneurysm neck	
Wide-necked (≥4 mm)	136 (48.9%)
Neck diameter (mm)	4.2±2.5
Previous treatment	46 (16.5%)
Coiled for staged PED	37 (13.3%)
Recurrence (coiled or clipped)	9 (3.2%)
Number of procedures	247
Adjunctive coiling	72 (25.9%)
Number of PED implanted	293
Devices per aneurysm (mean)	1.05
Devices per patient (mean)	1.23
Technical success	285 (97.3%)
Retreatment	2 (0.7%)

ACA indicates anterior communicating artery; ICA, internal carotid artery; MCA, middle cerebral artery; PED, Pipeline Embolization Device; PICA, posterior inferior cerebellar artery; and SCA, superior cerebellar artery.
Data are mean±SD, n, or n (%).

which 37 (13.3%) had been acutely ruptured and coiled as an initial emergency procedure to safely secure the aneurysm with the planned delayed intention for staged PED Shield FDs treatment of the parent artery following clinical recovery from the initial acute hemorrhage.

Treatment Details

Within the study period, 247 total procedures were performed. A total of 293 PED Shield devices were implanted in 278 aneurysms, with an average of 1.05 devices per aneurysm and 1.23 devices per patient. In 37/247 (15.0%) of procedures, 2 or more devices were implanted for treatment of the target aneurysm. Two separate PED-Shield procedures were performed in 9/238 (3.2%) patients. Of these, 7 patients had a second PED Shield procedure for a separate intracranial aneurysm during the study period. The remaining 2 patients required a repeat treatment of the initial target aneurysm, 1 due to distal stent shortening, and 1 for persistent aneurysm filling after a single device.

Stent deployment was technically successful in 97.3% (285/293) of the implanted devices. Eight stents had initial deployment difficulties for the following reasons: 3 faulty devices, 1 unable to open due to device twisting, the distal end of 1 device did not open adequately, 1 device delivery failure, and 2 devices not deployed due to access instability. All 8 stents were removed with the subsequent successful deployment of a new PED Shield device during the same treatment session. Adjunctive coiling was performed in 25.9% (72/278) of the treated aneurysms. A biaxial access system was used in 67.1% of treated aneurysms, with the remainder triaxial.

There were 3/247 (1.2%) intraprocedural adverse events with no long-term neurologic sequelae: 2 iatrogenic cervical ICA dissections and an intraprocedural M2/3 thromboembolic occlusion requiring successful mechanical thrombectomy.

Table 3. Neurologic Adverse Events <12 Months

	Resolved	Neurologic morbidity	Neurologic death
Cerebral hemorrhage			
Target aneurysm rupture	0 (0%)	0 (0.0%)	1 (0.4%)
Intraparenchymal hemorrhage	0 (0%)	2 (0.8%)	2 (0.8%)
New SAH	1 (0.4%)	1 (0.4%)	0 (0%)
Cerebral infarction	4 (1.7%)	4 (1.7%)	0 (0.0%)
Neurologic deficit	9 (3.8%)	0 (0.0%)	0 (0.0%)
Transient ischemic attack	5 (2.1%)	0 (0.0%)	0 (0.0%)
Visual defect	2 (0.8%)	1 (0.4%)	0 (0.0%)
Visual disturbance/scintillation	2 (0.8%)	1 (0.4%)	0 (0.0%)

Data are n (%). ICA indicates internal carotid artery; and SAH, subarachnoid hemorrhage.

Safety Outcome

Over a 1-year posttreatment period, there were a total of 35/238 (14.7%) recorded neurologic adverse events, of which 23 (65.7%) completely resolved and did not result in long-term clinical sequelae (Table 3). Combined long-term neurologic morbidity and mortality occurred in 5.0% (12/238) patients, with 9 (3.8%) neurologic morbidities and 3 (1.3%) neurologic mortalities.

Of the 12 patients with permanent neurologic morbidity and mortality, 4 (1.7%) were the result of cerebral infarction in the treated territory, and 6 (2.4%) were the result of intracranial hemorrhage.

The 3 neurologic-related mortalities in the study all occurred within 30 days of aneurysm treatment. Two delayed aneurysm ruptures occurred post treatment, both resulting in neurologic mortality; 1 patient was symptomatic on presentation with acute left-sided weakness secondary to mass effect from a large, partially thrombosed left posterior inferior cerebellar artery origin aneurysm and recent foci of acute left cerebellar infarction. There was a progression of the presentation infarcts in the periprocedural period and development of extensive subarachnoid hemorrhage on postoperative day 26, likely secondary to delayed aneurysm rupture resulting in death the following day. The second patient developed delayed intraparenchymal hemorrhage (IPH) and subarachnoid hemorrhage distal to the treated unruptured left middle cerebral artery bifurcation aneurysm less than 24 hours after treatment. The third neurologic mortality occurred because of acute infarction of the left basal ganglia followed by hemorrhagic conversion (IPH) after treatment of a left paraclinoid ICA aneurysm. These latter 2 deaths occurred 4 days after the procedure.

There were 2 (0.8%) additional delayed IPHs, which were anatomically remote from the aneurysm, resulting in 2 documented neurologic morbidities.

Additionally, there was 1 nonneurologic death secondary to coronary artery disease within 1 year of treatment with an overall all-cause mortality rate of 1.7% (4/238).

Ischemic lesions in the treated arterial territory were present on progress MRI in 17 patients (7.1%); 10 (4.2%) patients were symptomatic, and 7 (2.9%) were clinically silent.

Four patients developed access site pseudoaneurysms, and 1 patient developed retroperitoneal hemorrhage. Five (2.1%) additional adverse events were related to access site complications. No subsequent long-term clinical sequelae were observed in this cohort.

The neurologic events correlated to aneurysm location and size are presented in Table 4. For the subgroup of ICA aneurysms proximal to the carotid terminus (62.2% of this cohort), the neurologic morbidity and mortality rates were 2.0% (3/148) and 0.7% (1/148), respectively.

Effectiveness Outcome

Angiographic imaging follow-up data were available for 252 (90.6%) aneurysms extending up to 18 months following treatment. At 6 months, complete aneurysm occlusion was present in 78.5% (193/246) of aneurysms. At 18 months or last imaging follow-up, complete aneurysm occlusion was present in 92.5% (233/252) of aneurysms. There were 19 incompletely occluded aneurysms, of which 3.2% (8/252) had a residual neck, and 4.4% (11/252) had residual but reduced aneurysm size, with no aneurysms increasing in size. A total of 2 (0.7%) aneurysms required retreatment with a second PED Shield device. There were 3 (1.2%) cases of in-stent stenosis/intimal hyperplasia of >50% present on digital subtraction angiography at either 6-month or last follow-up. All were asymptomatic. Imaging outcomes are summarized in Table 5. For the subgroup of ICA aneurysms imaged (n=155), the rate of complete occlusion at 6 months was 75.5% (117), at 12 months was 90.8% (129), and at 18 months/last

Table 4. Neurologic Adverse Events <12 Months by Aneurysm Characteristics

	Neurologic morbidity	Neurologic death	Total neurologic SAEs
Aneurysm location (% of total)			
Supraclinoid ICA (28.1%)	3/238 (1.3%)	1/238 (0.4%)	4/238 (1.7%)
MCA bifurcation (10.1%)	3/238 (1.3%)	1/238 (0.4%)	4/238 (1.7%)
Anterior communicating artery (9.0%)	2/238 (0.8%)	0 (0.0%)	2/238 (0.8%)
V4 vertebral artery/PICA (3.2%)	1/238 (0.4%)	1/238 (0.4%)	2/238 (0.8%)
Aneurysm size			
Small (<7 mm)	5/238 (2.1%)	2/238 (0.8%)	7/238 (2.9%)
Medium (7–<13 mm)	2/238 (0.8%)	0 (0.0%)	2/238 (0.8%)
Large (13–<25 mm)	2/238 (0.8%)	1/238 (0.4%)	3/238 (1.2%)
Giant (≥25 mm)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Data are n (%).ICA indicates internal carotid artery; MCA, middle cerebral artery; PICA = posterior inferior cerebellar artery; and SAE, serious adverse event.

Table 5. Effectiveness Outcomes

	6 months	12 months	18 months/last follow-up
Total aneurysms imaged	246	224	252
Complete occlusion (OKM-D)	193 (78.5%)	207 (92.4%)	233 (92.5%)
ICA Aneurysms imaged	155	142	159
ICA Complete occlusion	117 (75.5%)	129 (90.8%)	147 (92.5%)
Residual neck (OKM-C)*	–	–	8 (3.2%)
Residual aneurysm (OKM-B)*	–	–	11 (4.4%)
In-stent stenosis/intimal hyperplasia >50%*	–	–	3 (1.2%)

Data are n or n (%). ICA indicates internal carotid artery; and OKM, O'Kelly Marotta grading scale.
*No interim 6- or 12-month data available.

follow-up was 92.5% (147). These rates were similar to the overall occlusion rates.

DISCUSSION

SCOPE-AUS is the largest multicenter clinical study reported to date describing the safety, clinical outcomes, and effectiveness of the PED-Shield FDs. The study cohort included unruptured aneurysms in the anterior and posterior circulation, including a large proportion of distal bifurcation aneurysms.

The results of this study are corroborated by the previously published studies of PED-Shield,[16] PFLEX,[17,18] PEDSU,[19] and SHIELD,[20] demonstrating both high aneurysm occlusion rates and safety of the PED-Shield device. In vitro and animal studies of the PED-Shield FDs demonstrate lower intrinsic thrombogenicity.[12–14] Ischemic complication rates of 3.3% (PED-Shield),[16] 6.6% (SHIELD),[20] and in 2 studies of earlier generation PED 4.7% (IntrePED)[11] and 2.1% (PREMIER)[21] were reported.

Symptomatic ischemic events in this study (2.5%) are comparable to the previously reported studies despite the inclusion of posterior circulation and distal bifurcation aneurysms, which intrinsically carries a higher overall thromboembolic risk that may be reduced by the PED FDs surface modification.[7–9]

Three cases of delayed IPH in this study occurred between 1 and 8 days of treatment, 2 of which had large-volume IPH distal to the treated aneurysm resulting in neurologic mortality. The pathogenesis of IPH is poorly understood and usually carries a high risk of morbidity and mortality.[22,23] Rates of IPH after FD treatment have been reported to be between 1% and 8.5%.[23] Proposed mechanisms include hemorrhagic conversion of thromboembolic infarcts, foreign body inflammatory reaction, dual antiplatelet use, and increased flow diversion effect into poorly autoregulated distal territory resulting in posttreatment normal pressure cerebral hyperperfusion.[23]

The 12-month total neurologic morbidity (3.8%) and mortality (1.3%) rates in this study compare favorably with the IntrePED study, which reported long-term neurologic morbidity and mortality rates of 7.5% and 3.8%, respectively.[11] IntrePED assessed a total of 793 patients with 906 aneurysms and is one of the largest retrospective international multicenter studies of the first-generation PED FDs in the treatment of intracranial aneurysms in a real-world setting.

Complete aneurysm occlusion rates at 6 and 18 months or at last follow-up (92.5%) imaging were superior to complete occlusion rates in PFLEX (76.3% at 6 months, 81.8% at 1 year), SHIELD (70.8% at 6 months and 77.2% at 1 year), and PEDSU (69.2% at 6 months, 82.7% at 18 months) studies. This study

also demonstrated high rates of successful device deployment and a low average number of devices per aneurysm (1.05 devices per aneurysm and 1.23 devices per patient), comparable to the PED-Shield studies,[17–20] as well as the second generation PED Flex studies.[24] These favorable rates, as compared with the average of 3 PED stents per aneurysm in the first-generation PED Classic,[22] may be attributed to the reliable updated PED-Shield delivery system, allowing precise device deployment and increased operator experience.

There were 5 (1.8%) severe adverse events arising from groin complications with 4 pseudoaneurysms and 1 retroperitoneal hemorrhage. Adopting a radial first approach for FDs treatment can significantly reduce access site complication rates, as shown in a recent study by Li et al,[23] who reported no access site complications in 134 transradial approaches for placement of FDs.

The major limitation of this study is the single-arm retrospective design. There was heterogeneity in the dual antiplatelet regimen and platelet reactivity testing across treatment centers, as well as variation of follow-up time intervals and imaging methods. However, this reflects the standard of practice at each high-volume center and demonstrates real-world variability in the enrolled cohort of consecutive cases.

CONCLUSIONS

The SCOPE-AUS multicenter study evaluating the use of the Pipeline Shield Embolization device in a real-world setting in Australia demonstrates excellent prolonged aneurysm occlusion rates (92.5%), low retreatment rates (0.7%), and robust safety outcomes. Of interest, the mortality (0.7%) and morbidity (2.0%) rates of unruptured ICA aneurysms treated in this study are lower than previously reported studies and suggest a potential benefit of the Shield technology in current practice. This study also included complex aneurysms, such as posterior circulation, distal small vessel, and bifurcation aneurysms. Despite this the overall neurologic morbidity (3.8%) and mortality (1.3%) results are comparable to prior published PED FDs studies. Future prospective studies evaluating the clinical benefit of PED Shield technology in contemporary practice are warranted.

ARTICLE INFORMATION

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Author Contributions

All authors contributed to the design of the work and the acquisition, analysis, or interpretation of data; drafted the manuscript or made critical revisions; approved of the final version to be published; and agree to be accountable for all aspects of the work.

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