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Original research

Vanguard Study: Initial experience with the new fourth generation Pipeline Vantage Flow Diverter (PVFD): 6-month results, technical and clinical considerations

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Received 27 October 2023
Accepted 15 December 2023

To cite: de Villiers L, Carraro do Nascimento V, Domitrovic L, *et al*. *J NeuroIntervent Surg* Epub ahead of print: [*please include* Day Month Year]. doi:10.1136/jnis-2023-021182

ABSTRACT

Background The Pipeline Embolization Device has proven to be a safe and effective device for the treatment of intracranial aneurysms. The Pipeline Vantage Flow Diverter (PVFD) with Shield Technology is the new fourth generation of this implant, with modifications made compared to previous iterations. We aimed to evaluate the mechanical properties and clinical safety and efficacy of this device.

Methods Vanguard is a single arm, single center, prospective study. Between April 2021 and April 2023, all consecutive patients with an unruptured aneurysm treated with Pipeline Vantage flow-diverting stents were included. There were no aneurysm size or location exclusion criteria. Safety (neurological serious adverse events) and efficacy (device deployment and aneurysm occlusion) were independently reviewed. Imaging follow-up data, and immediate, early (<30 days), and delayed (>30 days) neurological serious adverse events were independently assessed.

Results 101 consecutive patients with a total of 115 aneurysms were included. The aneurysms were situated in the anterior (90.4%) or posterior (9.6%) circulations. A total of 124 devices were implanted. The deployment success rate was 100%. In four (4.0%) cases post-deployment angioplasty was required to optimize device wall apposition. Occlusion rates at 1 month were 54.7%, at 3 months 72.1%, and at 6 months 81.7%. Morbidity and mortality were 4.9% and 0%, respectively, at 6 months. Eight cases (6.9%) demonstrated in-stent stenosis, four of which had 'fish mouth' deformity.

Conclusion Initial results of the new generation PVFD for unruptured intracranial aneurysm treatment demonstrate overall satisfactory device performance, safety profile, and effectiveness.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The Pipeline Embolization Device has proven to be a safe and effective device for the treatment of intracranial aneurysms.

WHAT THIS STUDY ADDS

⇒ The Pipeline Vantage Flow Diverter (PVFD) with Shield Technology is the new fourth generation of this implant with modifications made compared to previous iterations. At 6 months, the aneurysm occlusion rate was 81.7%, while the morbidity and mortality rates were 4.9% and 0%, respectively.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The PVFD demonstrates overall satisfactory device performance, safety profile, and effectiveness.

INTRODUCTION

Flow diversion is an increasingly used technology for the treatment of intra- or extracranial aneurysms.[1–7] The Pipeline Embolization Device (PED; Medtronic Neurovascular, Irvine, CA) is a braided, multi-alloy cylindrical mesh woven from platinum/tungsten (25%) and cobalt-chromium-nickel alloy (35-NLT) wires. The PED is one of the most frequently implanted flow-diverting stents (FDS) worldwide.[8–10] It has been extensively studied and proven to be a safe and effective device for treatment of intracranial aneurysms.[11 12]

The first-generation PED (Classic) was a flexible microcatheter-delivered self-expanding cylindric construct composed of 48 braided strands of cobalt-chromium and platinum. The individual strands measure between 28 and 33 nm in diameter (0.0011–0.0013 inches). When fully expanded to nominal diameter, the construct provides approximately 30–35% metal surface area coverage.[13]

The second-generation PED (Flex) was first introduced in Europe, receiving CE (Conformité Européenne) approval in 2014, and US Food and Drug Administration approval in 2015. Although the stent itself did not have any differences from its predecessor, the upgraded version incorporated a resheathing mechanism to allow repositioning and redeployment of the stent. These features allowed for a decrease in technical complications and malposition rates as observed in a multicenter US study compared with previous trials using first generation PED.[14]

The third generation of the device, PED (Flex) with Shield Technology, received CE clearance in 2015. The device structure remained identical to the PED (Flex), but in this modification, a synthetic phosphorylcholine biocompatible polymer is

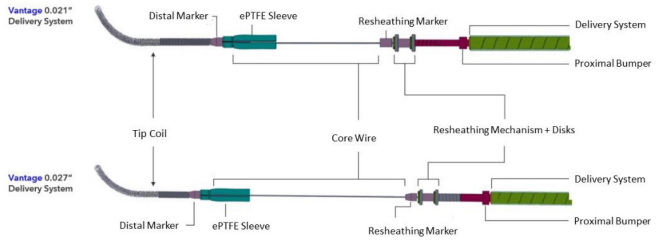

Figure 1 Fourth generation Pipeline Vantage Flow Diverter (PVFD) with Shield Technology. Schematic drawing of the PVFD 021 and 027 delivery system and its components. ePTFE, expanded polytetrafluoroethylene.

covalently bonded to the strands of the device proven to reduce thrombogenicity.[5 11 15]

Pipeline Vantage Flow Diverter (PVFD) with Shield Technology

The recently released fourth generation of the device, PVFD, features several modifications in comparison to its precursor, designed to improve device delivery, visibility, distal opening, deployment, and ease of recapture (figure 1). It is a single-layer, self-expanding, braided device that has two platforms with a 64-wire PVFD that is delivered through a 0.027 inch microcatheter and a smaller diameter 48-wire PVFD delivered through a 0.021 inch microcatheter. The 48-wire system consists of 48 drawn-filled tube (DFT) wires with an inner platinum core and an outer cobalt-chromium wire. The extra 16 wires of the 64 system are composed of cobalt-chromium, which provides increased radial force and improved opening of its distal end. In comparison to the PED Shield, the wires of the PVFD are smaller in diameter, with reduced device wall thickness. The density of the pores between the DFT wires is higher for the 64-wire PVFD device while maintaining similar metal coverage.[7]

The recommended delivery systems for the PVFD are the Phenom 21 for devices ≤3.5 mm and the Phenom 27 microcatheter for devices ≥3.5 mm (Medtronic Neurovascular, Irvine, CA) (figure 1). The PVFD consists of 48 braided wires for its 2.5, 2.75, 3.0, 3.25, and 3.5 mm diameters, and 64 wires for its 3.5, 4.0, 4.5, 5.0, 5.5, and 6 mm diameters, respectively. Specifically for the 3.5 mm stent diameter, there are options of both 48 and 64 braided-wire PVFD, which are compatible with the 021 and 027 delivery systems, respectively. The implant lengths vary from 10 mm to 50 mm. There is a soft, radio-opaque 15 mm platinum distal tip wire.

This single-center study describes the periprocedural safety and efficacy in consecutive patients treated with PVFD, as well as the technical considerations and perceived differences of the new implant in the treatment of unruptured intracranial aneurysms.

METHODS

Data source and study design

We performed a retrospective analysis of prospectively collected data according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines. Vanguard is a single-arm prospective study at a single center. Inclusion criteria were all patients in whom elective treatment with a flow diverter (FD) stent was considered best clinical practice. Patients were allocated for FD treatment by a multidisciplinary team of interventional neuroradiologists and neurosurgeons. There were no aneurysm size or location exclusion criteria. Safety (neurological serious adverse event) and efficacy (device deployment and aneurysm occlusion) were independently reviewed and analyzed.

All treated patients (18 years old and older) with anterior or posterior circulation unruptured or previously treated aneurysms were included in the study, irrespective of prior treatments (previous aneurysm coiling or other endosaccular device treatment or clipping). Acutely ruptured aneurysms were not included in this study.

Clinical and demographic data, aneurysm characteristics and location, number and size of implants used, technical aspects of each stent deployment, as well adjuvant or previous coil embolization and post-deployment balloon angioplasty were recorded. Aneurysms were morphologically classified as saccular, irregular, fusiform, and according to their maximum diameter, as in the SCENT study into small (<10 mm), large (10–25 mm), or giant (>25 mm).[16]

Safety outcomes were recorded as serious adverse neurological events and adverse neurological events. Neurological adverse events were categorized as intraprocedural, early (up to 30 days following procedure), and delayed (>30 days post-procedure). These events were considered minor if they were silent (noticed only on imaging) or transient, and major if they resulted in a permanent neurological deficit.

Clinical status was evaluated during the hospital admission for the procedure and at discharge using both the National Institutes of Health Stroke Scale (NIHSS) and the modified Rankin scale (mRS). Follow-up imaging was obtained with CT angiography (CTA) at 1 month, contrast-enhanced MR angiography (MRA) at 3 months, and digital subtraction angiography (DSA) at 6 months. Angiographic follow-up images were independently evaluated by an interventional neuroradiologist (PD) unrelated to the institution, treating interventionalists or procedures during the study period. Clinical follow-up after discharge from hospital was performed at 45 days and 6 months. Neurological serious adverse events were evaluated during the follow-up period by two local neurosurgeons (GS and WJ), who were unrelated to the procedures or treating interventionalists.

Procedures

Procedures were performed under general anaesthesia by three experienced neurointerventionalists, (between 3 and 24 years of neurointervention experience). A standardized dual antiplatelet therapy (DAPT) regimen was applied for all patients. A loading dose of 300 mg aspirin and 300 mg clopidogrel was administered 1 day before and on the morning of the procedure. All patients routinely underwent platelet function testing (P2Y12 inhibition) with VerifyNow (Werfen, Spain). In cases of resistance to clopidogrel, ticagrelor 180 mg loading dose was administered immediately before the procedure and clopidogrel was replaced by ticagrelor 90 mg twice daily for 3 months.

Intravenous heparin was administered intraoperatively and titrated against measured activated clotting time (ACT) to maintain an ACT >2× baseline. Following the procedure, intravenous heparin was maintained for 12 hours targeting an activated partial thromboplastin time (aPTT) of 65–90 s. DAPT was continued for 3 months post-procedure, followed by single antiplatelet therapy with aspirin 100 mg daily for a further 9 months.

Procedures were performed via femoral, radial or ulnar arterial access. The majority of procedures (89%) were performed with a biaxial access system, consisting of a Benchmark 071 catheter (Penumbra Inc, Alameda, CA) and a Phenom 21 or 27 catheter. The remainder were performed with a triaxial system, consisting of a long sheath 0.088, 0.091 or 0.096 inch, with an

intermediate catheter 0.055, 0.070, 0.071 or 0.074 inch, whenever vessel tortuosity or distal aneurysm location was a consideration. The decision for selecting the devices' specifications, such as length and diameter, was made based on three-dimensional angiography measurements and through a consensus among two experienced operators. In the majority of cases (92%) a single implant was deployed. In the remaining cases, up to three devices were used. Adjunctive coils (19%) were placed with a microcatheter jailing technique for larger or irregular aneurysms according to operator preference. Implant wall apposition was confirmed by SmartCT Vaso (Philips, Netherlands). Patients with no complications were discharged 48 hours post-procedure.

RESULTS

This study included 101 subjects with 115 aneurysms treated electively, between April 2021 and April 2023. Eighty-one (80.1%) were female and the median age was 59 years (IQR 52–69 years). At the time of analysis, all patients had been followed up for at least 6 months, clinically and with CTA, MRA and/or DSA. Two patients elected not to undergo a DSA at 6 months, and instead an MRA was performed.

One hundred and four (90.4%) aneurysms were located in the anterior circulation and 11 (9.6%) aneurysms in the posterior circulation. Of the anterior circulation aneurysms, 44 (38.2%) aneurysms had the 48-wire PVFD (up to 3.5 mm) implanted distal to the circle of Willis: four (3.4%) in the A2/A3 anterior cerebral artery segment, 16 (14.0) in the anterior communicating artery segment, six (5.2%) in the M1 middle cerebral artery (MCA) segment, and 19 (16.5%) in the MCA bifurcation or trifurcation.

The median aneurysm size was 5 mm (range 2–30 mm). Ninety-six (83.4%) aneurysms were small, 18 (15.6%) large, and one aneurysm (0.8%) was giant. The median aneurysm neck measurement was 3.0 mm (range 1.7–8 mm). Eighteen (15.6%) aneurysms had been previously coiled in the acute/emergency setting when ruptured, returning for planned FDS to treat a neck residual and obtain definitive artery reconstruction. Additional coil embolization was performed in 18 aneurysms (15.6%).

Robotic-assisted technique (CorPath GRX, Corindus, Inc, Waltham, MA, USA) was used in 15 cases exclusively to deploy coils in the aneurysm before PVFD manual deployment.

Post-deployment balloon angioplasty was performed in four cases (4.0%), to improve device opening and proximal device wall apposition. Baseline patient and aneurysm characteristics are detailed in table 1.

The median procedure time, from arteriotomy to closure, was 102 min (range 27–216 mins). The PVFD was easily advanced through the Phenom microcatheters in all cases, including the longest device of 6 mm × 50 mm. A total of 124 devices were inserted (mean 1.2 stents/case) and the success rate of device deployment was 100% (table 1). In one case, three PVFDs were implanted to treat a giant (30 mm) anterior cerebral artery dissecting aneurysm (figure 2).

Aneurysm occlusion rates at 1 month were 54.7%, at 3 months 72.1%, and at 6 months 81.7% (table 2). Of the 21 aneurysms (19%) that remained patent at 6 months, all demonstrated a reduction in size. The majority (n=16) of the incompletely occluded aneurysms were located distal to the circle of Willis, namely at the anterior communicating artery (ACOM) (nine aneurysms) with a median aneurysm size of 7 mm (range 4–13 mm), or middle cerebral artery (MCA) bifurcation/trifurcation (seven aneurysms) with a median aneurysm size of 6 mm (range 3–13 mm). Five para-ophthalmic aneurysms with a median aneurysm size of 7 mm (range 4–15 mm) also demonstrated

Table 1 Baseline patient and aneurysm characteristics

Characteristic	Frequency
Demographics, n=101	
Age, median (IQR)	59 (52–69)
Female, n (%)	81 (80.1)
Baseline mRS (median, IQR)	0 (0–0)
Medical history, n (%),	
Hypertension	44 (43.5)
Hyperlipidemia	21 (20.8)
Diabetes mellitus	6 (6.0)
Smoking history	43 (43.5)
Aneurysms treated	115
Previously coiled	18 (15.6)
Aneurysm characteristics, median (range)	
Aneurysm size (mm)	5.0 (2–30)
Neck width (mm)	3.0 (1.7–8)
Aneurysm size (n, %)	
Small (<10 mm)	96 (83.4%)
Large (10–25 mm)	18 (15.6%)
Giant (>25 mm)	1 (0.8%)
Aneurysm location, n (%)	
Anterior circulation	104 (90.4)
Posterior circulation	11 (9.6)
Aneurysm specific location, n (%)	
ICA – cervical segment	4 (3.5)
ICA – cavernous segment	7 (6.1)
ICA – paraophthalmic	26 (22.6)
ICA – posterior communicating	10 (8.7)
ICA – anterior choroidal	2 (1.7)
ICA – supraclinoid	9 (7.8)
ICA – terminus	1 (1.0)
Middle cerebral artery – M1	6 (5.2)
Middle cerebral artery – bifurcation	19 (16.5)
Anterior cerebral artery – A2/A3 segment	4 (3.4)
Anterior communicating artery (A1 and A2)	16 (14.0)
BA and P1 PCA segment	9 (7.8)
Vertebral artery at PICA origin	2 (1.7)
Vascular access, n (%)	
Right transfemoral*	52 (51.4)
Right distal radial	30 (29.7)
Right transradial	14 (13.8)
Right transulnar	4 (4.0)
Left transradial	1 (1.0)
Conversion radial to femoral	6 (6.0)
Access system, n (%)	
Biaxial access system	90 (89.1)
Triaxial access system	11 (10.9)
Pipeline Vantage Flow Diverter used, n	124
Successful device deployment (without angioplasty), n (%)	97 (96)
Successful device deployment (with angioplasty), n (%)	4 (4)
Median procedure time, range (min)	102 (27–216)
Number of Pipeline devices per patient	1.2

Continued

Table 1 Continued

Characteristic	Frequency
Adjunctive devices used, n (%)	
Coil embolization	22 (19.1)
Robotic assisted coiling	15 (13.0)
In-stent balloon angioplasty	4 (4.0)

*Inclusive of 6 transradial approach conversion to transfemoral approach.
BA, basilar artery; ICA, internal carotid artery; mRS, modified Rankin Scale; PCA, posterior cerebral artery; PICA, posterior inferior cerebellar artery.

incomplete occlusion. All patients, including those with the 19% of aneurysms that have remained patent at 6 months, will be subject to further angiographic follow-up at 12 months to assess the occlusion rate, before any potential further treatment.

Two patients developed transient contralateral hand weakness during the immediate postoperative period, which resolved 24 hours post-procedure and was thought to be contrast-related encephalopathy. All patients were discharged post-procedure without any permanent neurological deficit.

At 6 months following the procedure, the morbidity rate was 4.9% and mortality was 0% (table 2). Five patients, all with PVFD implanted in the middle cerebral artery (MCA) bifurcation, developed ischemic symptoms, with facial droop, dysphasia, and/or upper limb weakness corresponding to the ipsilateral treated side (these events occurred within 30 days in three patients and beyond 30 days in two patients). Of note, these patients were compliant with the DAPT regimen. Three patients (3%) recorded an mRS of 1 at 6 months due to minor permanent disability deficits, while the rest of the patients were deemed to have an mRS of 0.

Table 2 Clinical outcomes

Characteristic	Frequency, n (%)
Immediate neurological adverse events (<24 hours)	2 (2.0)
Early neurological adverse events (<30 days)	3 (3.0)
Late neurological adverse events (>30 days)	2 (2.0)
Modified Rankin Scale at 6 months:	
0	98 (97%)
1	3 (3%)
2–6	0 (0%)
Mortality	0 (0)
Complete occlusion	
1 month	63 (54.7)
3 months	83 (72.1)
6 months	94 (81.7)
In-stent stenosis at 6 months >50%	6 (5.9)
Stent occlusion	1 (1.0)

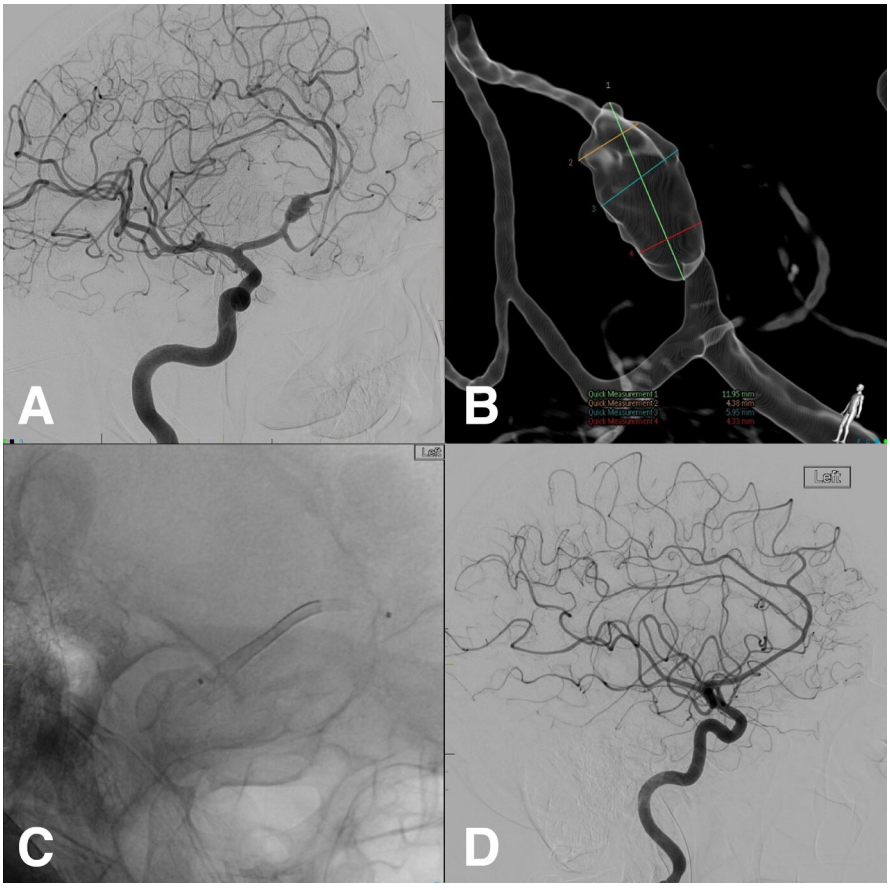

Figure 2 PVFD treatment of a dissecting, unruptured anterior cerebral artery. Digital subtraction angiography (A) and three-dimensional reconstruction of rotational angiography (B) show a giant aneurysm with a maximal diameter of 30 mm. (C) Deployment of three PVFDs across the aneurysm neck. (D) Angiography 6 months after the treatment demonstrates complete aneurysm occlusion and no intimal hyperplasia. Note symptomatic occlusion of covered proximal frontal branch. PVFD, Pipeline Vantage Flow Diverter.

At 6 months, on DSA post-procedure, there were eight cases of in-stent stenosis/intimal hyperplasia. Of these, six cases demonstrated >50% stenosis and two <50% stenosis. All but three patients were asymptomatic. In four of the six cases of >50% stenosis, there was significant narrowing 'fish mouth' deformity involving the distal end of the stent. In these patients, DAPT was continued for a further 3 months. A single patient developed asymptomatic implant occlusion (inferior M2 MCA division), encountered incidentally on a routine follow-up CT head angiogram at 30 days.

A single non-device-related complication of a femoral access site abscess occurred 4 days post-procedure.

Technical characteristics and nuances

The operators noted improved pushability and stability of the device with the more robust stainless-steel single-core pusher wire. The significantly thinner shortened polytetrafluoroethylene (ePTFE) sleeves offer faster distal braid release during deployment and more rapid distal device opening. The operators found the device easier to recapture/resheath and reposition, in comparison to the previous generations. The initial deployment technique is similar to PED Flex and Shield, with unsheathing the stent while maintaining position with forward loading on the pusher wire. The distal end of the device opened sooner, compared with the previous device iterations, allowing for more confident and precise distal device placement. The mid-portion of the stent was deployed with the conventional technique of predominantly pushing the wire delivery system to enable optimal opening and device wall apposition.

Successful deployment of the proximal aspect of the 64-wire PVFD device required a modified technique with predominant unsheathing of the device and reduced pusher wire loading, compared to previous PED iterations. If the proximal end of the device is deployed with too much forward loading and pushed out rather than unsheathed, this may result in device deformation and suboptimal opening of the proximal end. Four of our earliest cases required rescue in-stent balloon angioplasty to open the proximal device with no clinical sequelae.

DISCUSSION

To our knowledge, we report the largest experience with the new Pipeline Vantage embolization device with Shield Technology. The device demonstrated excellent technical success rates, safety, and efficacy. Occlusion rates at 1 month were 54.7%, at 3 months 72.1%, and at 6 months 81.7%.

Early preclinical studies demonstrated improved aneurysm occlusion, implant endothelialization, and lower thrombogenicity with the PVFD, compared with the Pipeline Flex with Shield Technology, while preserving the biocompatibility safety profile of its predecessor.[17] Our early clinical experience with the PVFD reveals high FDS implantation success and occlusion rates that are comparable to the previous generations of PED. The morbidity (4.9%) and mortality (0%) rates in our study were also comparable to those reported in prior studies which used earlier generations of PED. The SCOPE-AUS study, which investigated the use of the PED device with Shield technology, reported complete aneurysm occlusion rates of 78.5% at 6 months and 92.5% (233/252) at 18 months or at last follow-up imaging, while the combined long-term neurologic morbidity and mortality occurred in 5% (12/238) of patients, with nine (3.8%) neurologic morbidities and three (1.3%) neurologic mortalities.[11] The authors also reported successful stent deployment in 97.3% (285/293) without the need for adjuvant balloon angioplasty.[11] In a separate study, Rice *et al* demonstrated high rates of complete occlusion (70.8% and 77.2% at 6 months and 1 year, respectively) and low rates of retreatment (0.05%) among subjects treated with the PED-Shield in the SHIELD study, while the morbidity and mortality rates were 3% and 1%, respectively.[5] In addition, Trivelato *et al* reported 79.7% aneurysm occlusion at 6 months and 85.3% at 12 months, with a periprocedural complication rate of 7.3% among 151 patients with a total of 182 aneurysms treated with the PED-Shield.[18] The PUFS study demonstrated a 6-month aneurysm occlusion rate of 73.6% with a combined morbidity and mortality rate of 5.6%.[19]

In our cohort, lower occlusion rates of the ACOM and MCA bifurcation/trifurcation aneurysms at the 6-month follow-up DSA were noted. This is likely due to our intentional diameter oversizing of the PVFD (by a minimum of 0.5 mm) placed at these bifurcation locations to decrease the pore density and increase the stent porosity. This results in intentional slower aneurysm occlusion while facilitating arterial remodelling and collateral supply adaptation over time, mitigating the potential ischemic consequences of a jailed branch or perforating artery. Despite this, five of the 24 treated MCA aneurysm cases developed ischemic complications in our study, through a combination of either intimal hyperplasia and/or delay in the ante-grade perfusion in the jailed arterial branch. This relatively high rate of ischemic complications has also been described in previous studies involving FDS treatment of MCA bifurcation aneurysms.[20] A recent study demonstrated a significant delay in the MR brain perfusion values was detected in the vascularized territory of a jailed arterial branch following flow diversion when compared with the contralateral MCA territory.[21] Although these changes in arterial flow were rarely accompanied by clinical findings in the aforementioned study,[21] further interpretation was limited by its modest sample size of 18 patients.

In ACOM aneurysms, a further likely cause for delayed occlusion rates, seen in aneurysms treated with ipsilateral A1-A2 segment anterior cerebral artery (ACA) PVFD placement, is the contralateral A1 ACA supply to the aneurysm which may hypertrophy following PVFD placement.

Our study demonstrated a relatively high rate of neointimal hyperplasia among eight patients, with six patients developing >50% in-stent stenosis, mostly associated with a 'fish mouth' deformity at the distal end of the stent. A potential mechanism for this appearance may be due to a degree of discrepancy in the vessel diameters incorporating the distal and proximal ends of the implant, which has a smaller wire diameter and thinner device wall thickness. The oversizing of the FDS has also been shown to increase the wall shear stress, which may in turn induce a greater inflammatory response.[22] Furthermore, the use of the FDS with high strut density in smaller diameter vessels beyond the circle of Willis may have also been a contributing factor.

In terms of the metal coverage required for effective aneurysm treatment, our study had a low mean device utilization of 1.2, similar to the SCENT (1.1), SCOPE-AUS (1.1), and PREMIER (1.05) trials, compared with the PUFS trial that utilized a mean of 3.1 devices.[11 16 19 23]

Based on our experience, the new PVFD demonstrates improved device visibility (DFT technology), pushability (more robust stainless steel pusher wire), trackability, ease of resheathing, and precise distal opening, likely due to the modified ePTFE sleeves which result in faster distal braid release. The deliverability of the system was demonstrated, with 85% of our cases requiring only a biaxial system for deployment, not requiring an intermediate catheter. Furthermore, both Phenom 27 and 21 could be easily advanced over the implant's

delivery wire post-stent deployment. Another advantage of the PVFD is the smaller diameter of DFT wires, providing a lower overall thickness of the device compared with its predecessor, and allowing the 48-wire PVFD to be delivered through a 021 microcatheter. In addition, the smaller diameter of wires could theoretically decrease the risk of perforator infarction.

Although the overall deployment of the PVFD is similar when compared with the previous generation, the change in the deployment technique of the proximal end of the 64 system is necessary with predominantly an unsheathing rather than pushing technique. We reported a 4% rate of post-deployment rescue angioplasty, in this series, for suboptimal proximal device opening experienced in our early cases, before modifying our proximal device deployment technique.

Strengths and limitations

To our knowledge, this is the largest reported cohort of consecutive patients with unruptured intracranial aneurysms treated with the new generation PVFD with clinical and imaging follow-up. All the reported angiographic follow-up images were independently adjudicated.

Due to the PVFD only being recently available for clinical use, no extended long-term follow-up data are available at the time of publication. Long-term follow-up data are, however, continuing to be collected. Second, a standardized questionnaire (as opposed to a binary consensus) to measure the operators' experience of the PVFD deployment was not utilized. Third, although the PVFD was used as the FDS of choice for all eligible cases during the study period, challenging navigation with a 21 or 27 microcatheter system for aneurysms distal to the circle of Willis, for example in the distal anterior, middle or posterior cerebral artery segments, may have necessitated the use of alternative FDS compatible with a smaller delivery 17 microcatheter system. This may have introduced a potential source of bias in case selection.

CONCLUSION

Initial results of the new generation PVFD for unruptured intracranial aneurysm treatment demonstrate overall satisfactory device performance, safety profile, and effectiveness. Larger studies with long-term follow-up assessment are required.

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Acknowledgements We thank Gian Sparti and William James for their involvement in reporting any safety adverse events during the study period.

Contributors Conception and design: LDV, VCN, HAR. Acquisition of the data: VCN, LD, PSD. Analysis and interpretation of the data: All authors. Guarantor: LDV. Critical revision of the manuscript: All authors. All authors approved the final version of the manuscript.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests HR and LV: consultants for Medtronic, Stryker, Microvention, Philips, Corindus. No disclosures or competing interests were declared by the remaining authors.

Patient consent for publication Not applicable.

Ethics approval This study was registered with and approved by the local institutional board review (EX/2023/QGC/98011). Retrospective patient consent was not required for this study which was conducted in a de-identified manner.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Data are available upon reasonable scientific request.

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