Original research

Early angiographic response to Pipeline Vantage flow diverter embolization of intracranial carotid aneurysms

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ABSTRACT

Background The Pipeline Vantage 027 flow diverter became available a year ago in the United States. We report an observational study of its safety and early angiographic response in the treatment of internal carotid artery (ICA) aneurysms.

Methods All patients treated with the Vantage 027 for ICA aneurysms from April to November 2024 at a single center were included. Intraprocedural contrast-enhanced cone-beam CT was used to evaluate vessel wall apposition. A novel proximal ledge deformity is defined as delayed elevation of one stent edge into the lumen while the opposite edge remains wall-apposed.

Results Twenty-four aneurysms (mean size 4.2±2.7 mm) in 20 patients underwent Vantage 027 embolization. Clinical follow-up at 6 months revealed no major/minor stroke and a single reversible ischemic attack following dual anti-platelet therapy (DAPT) non-compliance. Follow-up angiography in all patients revealed complete occlusion in 19/24 aneurysms at a median of 3.5 months (79%). Severe ≥50% stenosis was noted in 7/20 (35%) with distal fishmouth deformity in 12/20 (60%); both fishmouthing (p=0.003) and severe stenosis (p=0.04) were associated with younger age. We also observed a proximal ledge in 5/20 (25%) with luminal caliber compromise.

Conclusions Although Vantage 027 ICA aneurysm embolization resulted in early robust aneurysm involution, it was associated with an age-dependent fishmouthing braid deformity and a proximal ledge deformity possibly requiring extended DAPT. These results encourage further analysis of the vascular response to Vantage 027 and similar stents.

WHAT IS KNOWN ON THIS TOPIC

⇒ Vantage, the newest generation Pipeline Embolization Device, has demonstrated promising results in European and Australian populations but remains relatively understudied in the United States. The devices use a new drawn-filled tube design, with 48- and 64-wire variants for smaller and larger (≥4 mm) stents; the latter is known as the Vantage 027.

WHAT THIS STUDY ADDS

⇒ Twenty patients were treated with Vantage 027 devices for 24 internal carotid artery (ICA) aneurysms. With a median angiographic follow-up of 3.5 months, 19/24 (79%) aneurysms achieved complete occlusion, but 7 patients developed severe (≥50%) stenosis and 12 exhibited a distal fishmouth deformity, both of which were more common in younger patients. There were five instances of a previously undescribed phenomenon, proximal stent ledge deformity, defined as one proximal edge of the stent raising away from its corresponding vessel wall and into the lumen in a delayed fashion (ie, not present at the conclusion of the stent deployment procedure) while the opposite proximal stent edge remains apposed.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE, OR POLICY

⇒ Our findings indicate that the Vantage 027 demonstrates excellent early occlusion rates after follow-up at 3.5 months but with high rates of in-stent stenosis, especially in younger patients. We also note a proximal ledge deformity not common in earlier generations of the Pipeline flow diverter. Further research is required to understand the vascular response to the Vantage 027 and similarly constructed devices.

INTRODUCTION

Flow-diverting stents have become a mainstay in the treatment of wide-necked sidewall intracranial aneurysms, with an associated high rate of occlusion and a favorable safety profile, although certain design variants may be prone to deformities such as fishmouthing, braid collapse, or in-stent stenosis.[1–3] The Pipeline Embolization Device (PED; Medtronic Neurovascular, Irvine, CA, USA) has undergone multiple refinements to its delivery mechanism and surface modification. The fourth generation of the stent, Pipeline Vantage flow-diverting stent with Shield Technology (Vantage FD), was studied in Europe and Australia with promising results in its safety and efficacy for endovascular aneurysm embolization.[4–10] The device was released in the United States (US) for use in endovascular procedures following the publication of these data.

Having similar phosphorylcholine-based surface modification to the Pipeline Shield, the Vantage FD comes in two variants, the Pipeline Vantage 027 and Pipeline Vantage 021. Both variants use a base design of 48 drawn-filled tube (DFT) wires; the Vantage 027 variant (stents of ≥ 4 mm diameters) utilizes a 64-wire model, consisting of an additional

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16 cobalt-chromium wires added to the 48 DFT wires to improve radial force and opening.[5 8] The smaller diameter DFT wires in the Vantage FD reduce the profile of the stent, and the platinum distributed more densely throughout the device increases its radiopacity to improve visualization on fluoroscopy.[8] The device had been given favorable ratings by operators for its resheathability, visibility, and wall apposition.[6 7 10] However, the Vantage 027 stent was recently recalled from the market a year after its US release due to concerns about incomplete stent apposition (ISA) and braid deformity.[11]

In this study, we describe early angiographic and clinical outcomes from a prospectively collected, retrospectively reviewed single-center cohort of US patients with internal carotid artery (ICA) aneurysms treated using the Vantage 027.

METHODS

Patients and study design

The current study is a Tufts Institutional Review Board (IRB)-approved retrospective analysis of a single-center, single-surgeon cohort of patients treated with the Vantage FD since its US release. Thirty patients underwent Vantage FD treatment between April and November 2024. Inclusion was predicated on the patient being treated with at least one Vantage 027 device for an aneurysm involving the intracranial ICA, while no aneurysm size exclusions were applied. All patients so treated with Vantage 027 were included in the study regardless of rupture status or prior treatments. Aneurysm location was defined according to the seven-segment classification of ICA segments.[12] Adverse events were considered neurologic (intracranial hemorrhage, ischemic stroke, cranial neuropathies, non-ischemic cerebral enhancing (NICE) lesions) or non-neurologic and were stratified as permanent (present at last follow-up) or not permanent (resolved since onset), as well as whether they were periprocedural (<30 days after procedure). Imaging data included angiographic aneurysm occlusion status according to the modified Raymond–Roy Classification (mRRC), and in-stent stenosis or braid deformity is reported according to the guidelines and nomenclature (F2B2) proposed by Fiehler *et al*[2 3 13] Specifically, fishmouth deformity was reported as defined in the F2B2 classification as a delayed braid narrowing beginning at the proximal or distal tines of the stent and extending up to one-third of the affected braid end without similar narrowing of the stent's mid-section. An additional stent deformity phenomenon, which has not previously been well-described, the proximal ledge deformity, is reported. This deformity is defined as one proximal edge of the stent raising away from its corresponding vessel wall and into the lumen in a delayed fashion (ie, not present at the conclusion of the stent deployment procedure) while the diametrically opposing proximal stent edge remains apposed to its corresponding side of the vessel wall. Luminal narrowing was computed using biplane high-magnification angiography as the ratio of the diameter at the narrowed lumen over the nearest segment of normal parent vessel as described in the aforementioned recommendations for imaging analyses in clinical studies (see online supplemental figure 1).[3]

Patients were observed in an intensive care unit overnight and discharged 2 days post-procedure with clinic follow-up visits and platelet function testing at 1 week, then at 3 and 6 months. All patients underwent 3 Tesla MRI and angiography (MRI/A) on post-procedure day 1, then at 3 and 6 months, with follow-up catheter digital subtraction angiography (DSA) being performed when MRA at one of the prespecified time points suspected aneurysm involution (generally around the 3-month time point to enable earlier dual antiplatelet therapy (DAPT) de-escalation, by confirming endothelialization and ruling out in-stent stenosis and/or braid deformity).

Procedure

DAPT with aspirin 81 mg daily and prasugrel 10 mg daily was initiated ~7 days before treatment, and same-day platelet function testing was performed using VerifyNow (Accumetrics, San Diego, CA, USA) P2Y12 reactivity units (PRUs) to ensure therapeutic effect prior to intervention. Embolization was performed using a transfemoral triaxial system consisting of a 6-French shuttle sheath (Cook Medical Inc., Bloomington, IN, USA), Phenom Plus intermediate catheter, and Phenom 27 microcatheter (Medtronic Neurovascular, Irvine, CA, USA) after intravenous heparin administration for a goal activated clotting time (ACT) of ≥220 s with intraprocedural monitoring every 15–30 min. Selection of the Vantage 027 size and length was based on proximal and distal target vessel diameter and length measurements performed using multiplanar reconstruction of rotational angiography and cone beam CT angiography (CBCT-A) volumetric datasets. ISA was treated with balloon angioplasty (4×7 mm HyperForm; Medtronic Neurovascular). The decision to perform angioplasty was based on either the presence of obvious areas of ISA on native-view post-deployment biplane angiography or, if such areas were noted on post-deployment, small field-of-view CBCT-A. The use of adjunctive stents to resolve ISA was introduced in cases where proximal stent tines were located around the carotid siphon in an area where angioplasty was felt to be minimally effective, or where angioplasty was previously attempted without resolution of ISA (one case each).

Statistical analysis

Standard mean, median, and standard deviation were calculated for patient demographic information. Statistical analysis with one-way analysis of variance (ANOVA) was completed using the JMP 17.2.0 statistical software package (SAS Institute, Cary, NC, USA) with statistical significance assumed for $p<0.05$.

RESULTS

Twenty patients, aged 54.5±13.4 years (range, 22–74 years; 17/20 female), underwent 20 embolization procedures using Vantage 027 to treat a total of 24 ICA aneurysms, with four procedures targeting two adjacent aneurysms with a single device. Of the 24 treated aneurysms, 1 (4.2%) was in the C4 segment, 5 (20.8%) were in the C5 segment, 12 (50%) were in the C6 segment, and 6 (25%) were in the C7 segment. Lesions measured 4.2±2.7 mm (range, 1.6–13.8 mm) in maximal dimension and were mostly saccular (19/24, 79.2%). Three aneurysms (12.5%) had undergone previous coiling of the target lesion, two of which had previously been ruptured. These clinical and demographic variables and anatomic and technical features are summarized in online supplemental table 1.

Mean procedural time from arterial puncture to closure was 70.2±21.2 min (range, 47–138 min) and all the Vantage 027 stents were successfully deployed. Ten (50%) cases required balloon angioplasty for ISA to the vessel wall, with two additional patients requiring proximal tandem concentric stent placement with an additional Vantage 027 in one and a Neuroform Atlas stent (Stryker Neurovascular, Fremont, CA, USA) in the other with ISA resolution.

Radiologic and clinical outcomes are summarized in table 1, and illustrative cases are shown in figure 1. All 20 patients were available for clinical follow-up at a median period of 6

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Table 1 Post-procedural outcomes

Variable	Cases (N=20)
Neurologic complications, n (%)	
Stroke or TIA	1 (5)
NICE lesions	1 (5)
Complications occurring within 30 days of procedure, n (%)	1 (5)
Non-neurologic complications, n (%)	
Bacteremia	1 (5)
Access-related femoral artery pseudoaneurysm	1 (5)
Flash pulmonary edema without respiratory distress	1 (5)
Severe headache requiring readmission for pain control	1 (5)
Persistent neurologic deficit at 7 days post-procedure, n (%)	0 (0)
Clinical follow-up, months (median, range) (N=20)	6 (2–9)
MRA or CTA follow-up, months (median, range) (N=20)	5.5 (2–9)
DSA follow-up, months (median, range) (N=20)	3.5 (2–7)
mRRC occlusion status of aneurysm on angiographic follow-up, n (%) (N=24)	
1	19 (79.2)
2	1 (4.2)
3a	3 (12.5)
3b	1 (4.2)
Adequate occlusion (mRRC 1 or 2) at follow-up angiogram, n (%) (N=24)	20 (83.3)
Presence of luminal narrowing from any cause, n (%)	15 (75)
Degree of luminal narrowing, n (%)	
≤25%	3 (15)
26–49%	5 (25)
≥50%	7 (35)
Hemodynamically significant narrowing, n (%)	6 (40)
Causes of luminal narrowing, n (%)	
Fishmouth deformity	12 (60)*
Proximal ledge deformity	5 (25)*
Intimal hyperplasia without braid deformity	1 (5)
Persistent, new neurologic deficit after stent placement, n (%)	0 (0)

*Patients developed both fishmouthing and proximal stent ledging.
CTA, computed tomography angiography; DSA, digital subtraction angiography; MRA, magnetic resonance angiography; MRI, magnetic resonance imaging; mRRC, modified Raymond–Roy Classification; NICE, non-ischemic cerebral enhancing; SD, standard deviation; TIA, transient ischemic attack.

months and noninvasive radiographic imaging at 5.5 months. At 3-month MRI/A follow-up (n=20), complete occlusion (mRRC 1) was seen in 13/20 (65%), while 7 patients (35%) had some residual central filling (mRRC 3a). At 6-month MRI/A follow-up (n=18), 15/18 (83.3%) had complete occlusion, 17/18 (94.4%) had adequate occlusion (mRRC 1+2), and 1 case (5.6%) had residual central filling. DSA was obtained in all cases at median 3.5 months postoperatively (range, 2–7 months), demonstrating complete occlusion in 19/24 (79.2%) and adequate occlusion in 20/24 (83.3%) treated aneurysms.

Vantage 027-associated luminal narrowing of any cause (intimal hyperplasia, braid deformity, or a combination of the two) was detected in 15/20 cases at angiographic follow-up (75%). All cases of braid deformity were also associated with at least some degree of intimal hyperplasia. Five of 20 cases (25%) demonstrated luminal narrowing due to proximal ledge deformity of the stent resulting in the device mesh protruding de novo into the vessel lumen, with intimal hyperplasia anchoring the ledge in a raised position and covering it (figure 1J–L). One of 20 cases (5%) exhibited intimal hyperplasia without stent deformity. Severe (≥50%) narrowing was present in 7/15 instances of luminal narrowing (46.7%), and 7/20 (35%) of the overall cohort. Twelve of 20 cases (60%) developed a fishmouth deformity at one or both ends (figure 2). The overall rate of any stent deformity, excluding isolated intimal hyperplasia without any associated stent deformity, was 14/20 (70%). Flow limitation leading to compensatory collateral flow via the anterior or posterior communicating arteries occurred in 6/20 (30%) patients (figure 3).

Patients with fishmouth deformity were significantly younger (48.2 vs 64 years, p=0.003; figure 2F); there was no age dependence in patients with proximal ledge deformity (53.8 vs 56.6 years in those without and with deformity, respectively, p=0.669; figure 2G). Evaluation of age stratified by degree of luminal narrowing revealed younger patients were more likely to develop severe ≥50% narrowing (p=0.004; figure 3E). Similarly, patients developing hemodynamically significant flow-limiting narrowing were significantly younger (42.2 vs 57.3 years, p=0.04; figure 3F).

One patient (5%) with a right ICA Vantage 027 presented 3 months post-procedure with transient left arm numbness following lapse in DAPT compliance with angiographic evidence of fishmouth deformity leading to severe luminal narrowing, as well as mild proximal ledge deformity. The patient was restarted on prasugrel and maintained on DAPT with resolution of the sensory symptoms. Non-neurologic complications included an instance of methicillin-susceptible *Staphylococcus aureus* bacteremia without identification of a clear source treated with intravenous antibiotics and associated with transient fever and confusion with detection of asymptomatic NICE lesions on MRI (single neurologic complication within 30 days). Other adverse events included an asymptomatic femoral arterial pseudoaneurysm associated with a Celt arterial closure device (Vasorum Ltd, Dublin, Ireland) discovered on follow-up angiography successfully treated surgically, a case of flash pulmonary edema at emergence from anesthesia, and one case of severe headache 1 week post-procedure requiring admission for pain control. At the most recent clinical follow-up at a median of 6 months, no patients had experienced new or permanent neurologic deficits.

DISCUSSION

Flow diversion stenting has emerged as a cornerstone therapeutic modality for the management of intracranial ICA aneurysms. Vantage FD represents an evolution from its antecedent, the third-generation Pipeline Shield, which has demonstrated robust efficacy and safety profiles. Complete aneurysm occlusion rates with Pipeline Shield have been reported to range from 75.7% at 12 months to 92.5% at 18 months, as substantiated by longitudinal studies.[14 15] Complications associated with flow diversion, though infrequent, generally are categorized as thromboembolic, hemorrhagic, and those relating to the procedure or device itself. Thromboembolism may occur with inadequate platelet inhibition leading to thrombosis, which can cause occlusion within the stent or form smaller thrombi which embolize distally; in-stent stenosis secondary to intimal hyperplasia; as well as morphologic stent alterations known as braid deformities. A recently proposed scheme describing these deformities includes foreshortening, fishmouthing, braid collapse, and braid hump deformation (F2B2).[2 3 14–17]

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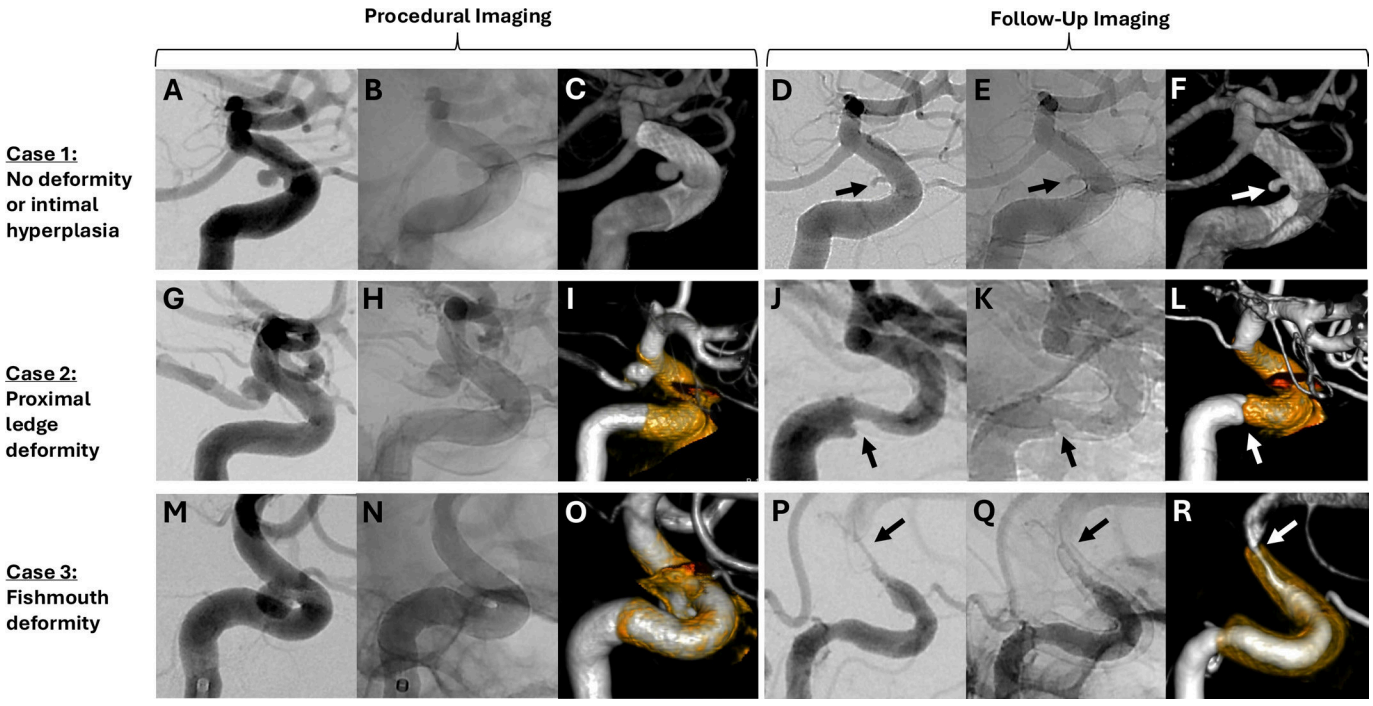


Figure 1 Angiographic comparison of Pipeline Vantage 027 at the time of placement and at follow-up digital subtraction angiography (DSA). Each row represents one patient. Case 1: C6 segment aneurysms with (A) lateral subtracted and (B) unsubtracted DSA post-deployment and (C) three-dimensional (3D) reconstruction showing the Vantage flow diverter stent's final position at the end of the procedure. (D) Lateral subtracted and (E) unsubtracted DSA, and (F) 3D reconstruction of the 3-month follow-up DSA of the same stent. No deformity is seen; the aneurysm has decreased in size with continued filling (arrow). Case 2: C7 segment aneurysm (G, H, and I) at the end of the procedure. Five-month follow-up imaging (J, K, and L) shows development of a proximal ledge deformity (arrows) with 65% stenosis. Case 3: C6 segment aneurysm (M, N, and O) with 3-month follow-up DSA (P, Q, and R) reveals a severe 85% flow-limiting narrowing associated with distal fishmouth deformity and superimposed intimal hyperplasia (arrows).

Data from earlier-generation PEDs reported a low incidence of severe luminal narrowing (≥50%), ranging from 0% to 3% at follow-up time points between 6 and 18 months.[7 14 15 17–19] Among non-Pipeline flow diverters, the incidence of ≥50% narrowing varied by device: p64 flow diverter (Phenox GmbH, Bochum, Germany) showed 11.2% at 9 months, while the FRED X stent (Terumo Neuro, Aliso Viejo, CA, USA) showed 13.1% at 6 months, and the uncoated FRED variant showed 0% at 6 months. Notably, in the FRED X group, all cases of ≥50% narrowing at 6 months showed improvement by 12 months at follow-up. Surpass Evolve (Stryker Neurovascular) demonstrated a≥50% narrowing rate of only 0.9% at 6 months.[19–21] Among causes of luminal narrowing, structural integrity of flow diverters has also been studied. A dedicated meta-analysis of braid stability and stent deformities within the unified F2B2 classification scheme reported pooled rates of 3% for fishmouthing, 1% for braid collapse, 7% for braid narrowing, and 1% for braid hump deformation.[2 3]

The current study suggests that these issues occur at a significantly higher rate with the Vantage 027 compared with both prior PED generations and other flow-diverting stent types. We observed an overall parent-vessel luminal narrowing rate of 15/20 (75%), including a 7/20 (35%) rate of severe ≥50% narrowing, with the majority of these being hemodynamically significant, a rate exceeding previous results from other flow diverters. Our data also exceed the rate reported in previous studies on the Vantage FD, which ranged from 0% to 9.9% with a pooled rate of 8.1%.[4 6–9] Younger patients were more prone to severe (≥50%) and hemodynamically significant narrowing in our cohort, likely resulting from a more robust vascular and intimal response to the stent as compared with older individuals.

A notable finding of the current series is that 25% of cases (5/20) showed a proximal ledge deformity at follow-up imaging (figure 1J–L). To our knowledge, this type of effect has not been well described and was not included as a distinct braid deformity subtype in the aforementioned F2B2 classification system.[2] Unlike the fishmouth deformity and severe flow-limiting stenoses also seen in this series, the proximal ledge deformity did not show age dependence. It is possible that the cases with in-stent stenosis may resolve, as has been seen with prior iterations of the PED and other stents with an intimal hyperplasia response.[22] However, the proximal ledge phenomenon has an as-yet undefined natural history and will need follow-up to assess the resolution.

A recent single-center study by Popica *et al* on braid deformity across multiple different types of flow-diverting stents found that both a DFT design, as well as devices with more than 48 wires, were associated with the development of braid deformity. Some 24/88 (27.3%) DFT stents developed braid deformity, while 16/60 (26.7%) devices with >48 wires developed deformity, relative to the cohort's overall deformity rate of 36/245 (14.7%).[23] In comparison, a retrospective analysis of the PREMIER trial's data from PED Classic and Flex devices using the F2B2 classification system reported a deformity rate of only 8/133 (6%). The overall deformity rate in our cohort between fishmouthing and/or proximal ledge deformity was 14/20 (70%), indicating a significant tendency of the Vantage 027 to develop some form of delayed deformity despite seemingly optimal positioning at

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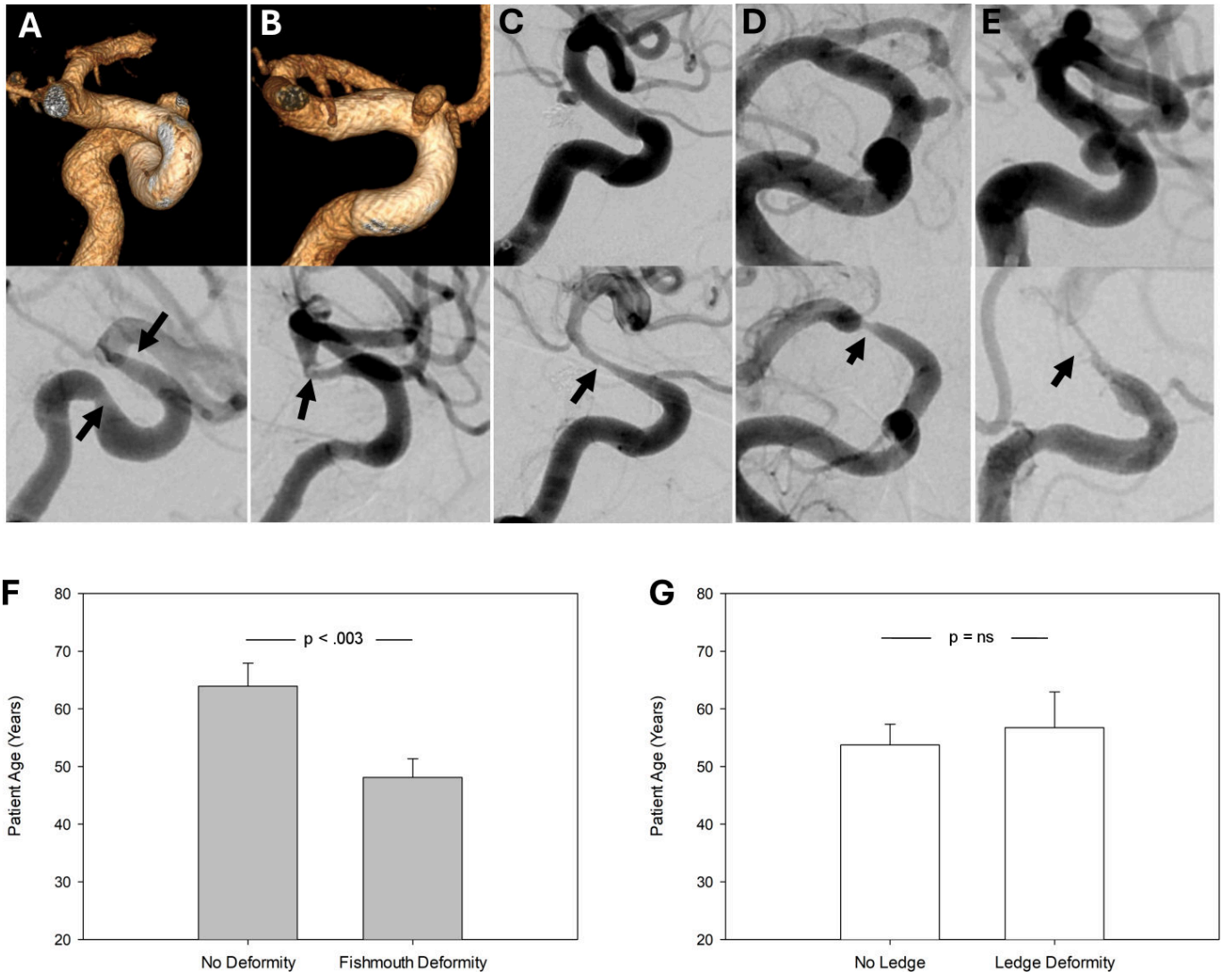


Figure 2 Illustrative cases of fishmouth stent deformity leading to significant stenosis in predominantly younger patients; the immediate post-deployment appearance is demonstrated in the top panel (subtracted runs or three-dimensional reconstructions were chosen to best capture both the stent and aneurysm); follow-up DSA is shown in the bottom panel. (A) Proximal and distal fishmouth, (B–E) distal fishmouth. Patients with fishmouth deformity were younger on average than those without any stent deformity (F), while those with proximal ledge deformities did not demonstrate a statistically significant age difference (G).

the end of the deployment procedure. Although the Vantage 027 itself has been recalled from the market and it is yet unknown how it may be modified for the future, our current data with the results of the Popica study raise questions about the role of specific braid design features in the vessel's response to the implant and subsequent braid deformity. This may be relevant to stents utilizing similar design features to the Vantage 027, which appears to provoke a strong response from the parent vessel, possibly contributing to braid deformity and intimal hyperplasia (in contrast to the preceding generations of PED which lack the DFT and 64-wire build).[24 25] This suggests that data examining the mechanisms between stent design specifics and the underlying vascular response could inform future optimizations in flow diversion technology, although subsequent studies must achieve greater control and larger sample sizes to examine these variables.

It remains unclear whether stent ledging and fishmouth-related luminal narrowing in the Vantage 027 will be clinically benign or whether DAPT prolongation will be needed to prevent delayed embolic/ischemic events. Prior literature suggests that ISA predisposes to clinical consequences, with poor apposition correlating to ischemic complications as well as suboptimal aneurysm involution.[26–28] The Vantage 027 had an excellent occlusion rate (mRRC 1 or 2) of 83.3% at a median angiographic follow-up of just 3.5 months, with better aneurysm involution rates than previous Vantage FD series despite a shorter follow-up period. This aneurysm occlusion rate was seen in the setting of persistent and significantly therapeutic antiplatelet effect as measured with VerifyNow testing showing an average PRU value of 56 at >3 months angiographic follow-up. Prior studies on Vantage FD demonstrated variable occlusion rates; a pooled analysis of occlusion rates between studies was 75.7% at a mean follow-up of 7 months.[4–9] The Vantage 027, in this small current series, outperformed the Surpass Evolve, another 64-wire counterpart, which demonstrated an occlusion rate of 73% at a median follow-up of 10.2 months.[29] We hypothesize that the same parent vascular response underlying the exuberant braid deformity and resulting in luminal narrowing described in the current series may be concomitantly increasing the speed of aneurysm involution.

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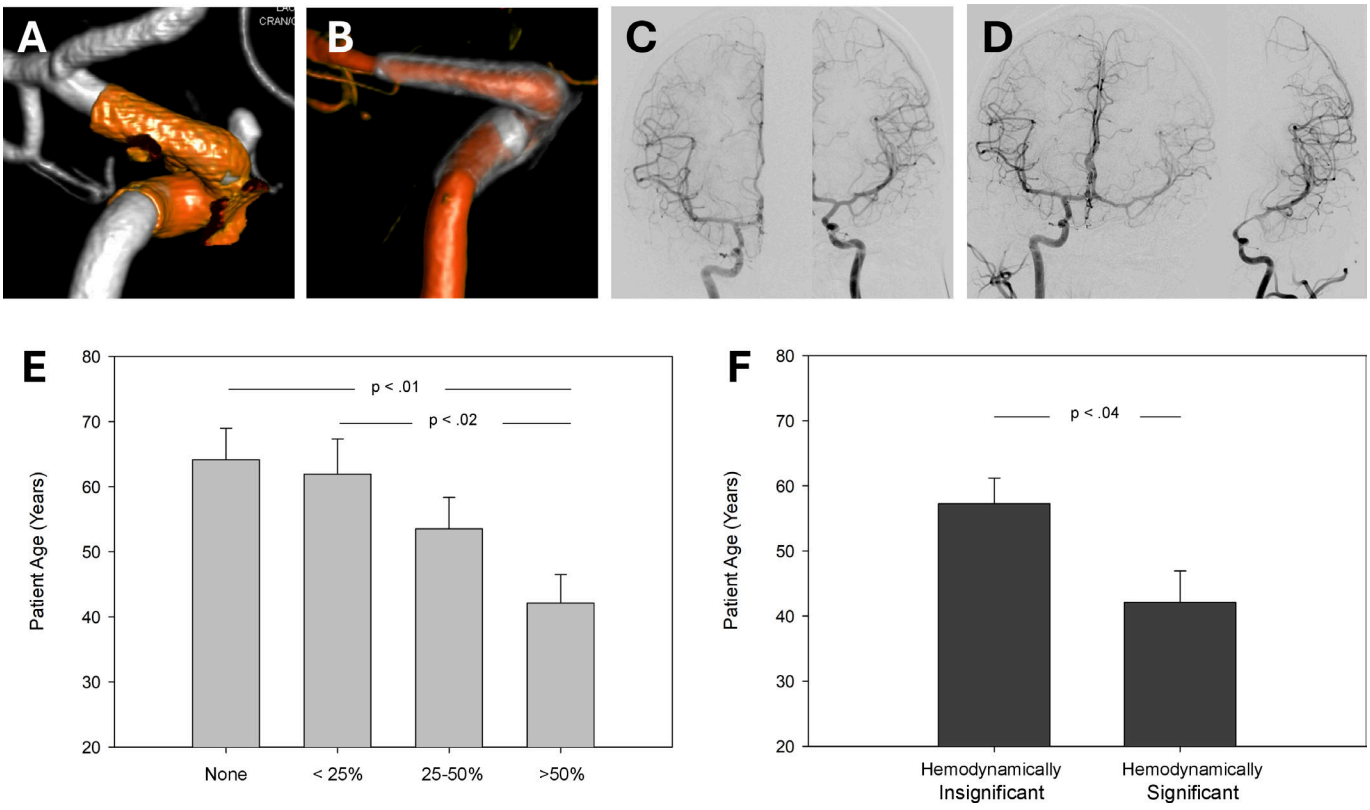


Figure 3 Flow-limiting stenosis secondary to distal fishmouth deformity in Vantage 027 treatment of a left C6 segment aneurysm showing good apposition at the end of the procedure (A). Follow-up at 4 months shows distal fishmouth deformity with 63% stenosis (B). Comparison of pre-procedural bilateral internal carotid artery (ICA) injections (C) and at follow-up (D) demonstrates hemodynamic effect of stenosis, with the left anterior cerebral artery (ACA) and some of the left middle cerebral artery (MCA) now filling from the contralateral right ICA. These severe stenoses were age dependent, with a younger average patient age in stents with ≥50% stenosis (E) and in stents with hemodynamically significant stenoses (F).

The current study is limited by its retrospective design and small sample size compared with the larger European and Australian cohorts. Luminal narrowing could be overestimated in this study compared with others, which tended to use follow-up time points >6 months; it is also possible that some cases of narrowing in this cohort could improve by the 6- to 12-month time points. Although the implications of our current data are significant for the relationship between braid deformity and stent construction, the specific model of stent studied here has been withdrawn from the market, limiting some direct clinical applicability in the future. However, the positive attributes of the current data include close clinical follow-up and 100% availability of DSA and non-invasive vascular imaging. Furthermore, procedures were performed by a single operator at one medical center, reducing variability in procedural techniques and standardizing follow-up and DAPT regimens, but also potentially introducing deterministic bias.

CONCLUSIONS

The PED Vantage 027 performed well as a flow-diverting stent with high rates of aneurysm occlusion at early follow-up, achieving excellent rates of ICA aneurysm involution. However, the Vantage 027 was associated with delayed braid deformity and luminal narrowing in a high proportion of younger patients, as well as development of a proximal ledge deformity, a new type of stent deformity requiring careful clinical and angiographic follow-up.

Contributors MHS: study conceptualization, data collection, statistical analysis, drafting the manuscript, critically revising the manuscript. AMM: study conceptualization, data collection, statistical analysis, critically revising the manuscript, guarantor, approved final version of the manuscript.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the Tufts Medical Center Institutional Review Board (IRB #9035).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information.

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