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## Endovascular Treatment of Anterior Circulation Aneurysms With the p64 Flow Modulation Device: Mid- and Long-Term Results in 617 Aneurysms From a Single Center

**BACKGROUND:** Flow diverters have become an important tool in the treatment of intracranial aneurysms, especially when dealing with difficult-to-treat or complex aneurysms. The p64 is the only fully resheathable and mechanically detachable flow diverter available for clinical use.

**OBJECTIVE:** To evaluate the safety and effectiveness of p64 for the treatment of intracranial saccular unruptured aneurysms arising from the anterior circulation over a long-term follow-up period.

**METHODS:** We retrospectively reviewed our prospectively maintained database to identify all patients who underwent treatment for an intracranial saccular (unruptured or beyond the acute hemorrhage phase) aneurysm arising from the anterior circulation with  $\geq 1$  p64 between December 2011 and December 2019. Fusiform aneurysms and dissections were excluded. Aneurysms with prior or concomitant saccular treatment (eg, coiling and clipping) were included. Aneurysms with parent vessel implants other than p64 were excluded. Anatomic features, intraprocedural complications, clinical outcome, as well as clinical and angiographic follow-ups were all recorded.

**RESULTS:** In total, 530 patients (388 females; median age 55.9 yr) with 617 intracranial aneurysms met the inclusion criteria. The average number of devices used per aneurysm was 1.1 (range 1-3). Mean aneurysm dome size was 4.8 mm (range 1-27 mm). Treatment-related morbimortality was 2.4%. Early, mid-term, and long-term angiographic follow-up showed complete or near-complete aneurysm occlusion in 76.8%, 89.7%, and 94.5%, respectively.

**CONCLUSION:** Treatment of intracranial saccular unruptured aneurysms of the anterior circulation using p64 is a safe and effective treatment option with high rate of occlusion at long-term follow-up and low morbimortality.

**KEY WORDS:** Intracranial aneurysms, Flow diversion, Flow diverter stent, p64 Flow Modulation Device, Anterior circulation aneurysm, Endovascular treatment

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**F**low diverter stents (FDS) have gained acceptance as a valid treatment option for intracranial aneurysms (IAs). Aneurysm

occlusion results from the redirection of blood flow along the longitudinal axis of the parent vessel with flow stasis in the aneurysm fundus

**ABBREVIATIONS:** **ACA**, anterior cerebral artery; **AchoA**, anterior choroidal artery; **AcomA**, anterior communicating artery; **ASA**, acetylsalicylic acid; **CT**, computed tomography; **DAPT**, dual antiplatelet therapy; **DSA**, digital subtraction angiography; **EVT**, endovascular treatment; **FDS**, flow diverter stents; **FRED**, Flow-Redirection Endoluminal Device; **IAs**, intracranial aneurysms; **ICA**, internal carotid artery; **ICH**, intracerebral hematoma; **MCA**, middle cerebral artery; **MRI**, magnetic resonance imaging; **mRS**, modified Rankin Scale; **PcomA**, posterior communicating artery; **PED**, Pipeline Embolization Device; **pHPC**, phenox hydrophilic coating; **PTA**, percutaneous transluminal angioplasty; **PO**, per os; **RRC**, Raymond Roy Classification; **SAH**, subarachnoid hemorrhage

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**TABLE 1. Inclusion and Exclusion Criteria for the Presented Series of Patients Treated With the p64 Flow Modulation Device**

Criteria for the p64 treatment and analysis in this series	
<b>Inclusion</b>	
	Patient age $\geq$ 18-yr old.
	Intracranial saccular aneurysms of the anterior circulation.
	Unruptured aneurysms or beyond 30 d from the hemorrhage.
	Extra- or intradural aneurysms.
	Sidewall or bifurcation aneurysms.
	Aneurysms with prior or concomitant saccular treatment without complete occlusion of the aneurysm from the cerebral circulation.
	No previous treatment to the parent vessel.
<b>Exclusion</b>	
	Fusiform, blister-like or dissecting aneurysms.
	Aneurysm rupture within 30 d prior to the p64 treatment.
	Previous implantation of stents or flow diverters to the parent vessel.

and progressive thrombosis.<sup>1</sup> Neoendothelialization along the surface of the FDS occurs, which reconstructs the parent vessel.<sup>2</sup>

The following FDS are currently approved for clinical use in Europe: Silk and Silk Vista Baby (Balt Extrusion), Pipeline Embolization Device (PED) (Medtronic), Surpass Streamline and Surpass Evolve (Stryker Neurovascular), Flow-Redirection Endoluminal Device (FRED) and FRED jr (MicroVention), Derivo (Acandis), and p64/p48MW (phenox). All of them share similarities in design including high metal surface coverage.

We report on the single center experience of using p64 for the endovascular treatment (EVT) of intracranial saccular unruptured aneurysms arising from the anterior circulation. This is the largest study to date reporting data for IAs treated with the p64.

## METHODS

### Patient Selection

This is a single center retrospective series analysis of consecutive patients with IAs treated with at least 1 p64 between December 2011 and December 2019. From our prospectively maintained database, we identified all patients according to the inclusion and exclusion criteria as summarized in Table 1. For each patient, we recorded demographic data, anatomic features, procedural and general complications, and clinical and angiographic outcomes according to the latest available follow-up (Figure 1).

### Endovascular Treatment

All procedures were performed according to the established clinical routine.<sup>3-6</sup> All patients received dual antiplatelet therapy (DAPT) with 1  $\times$  100 mg acetylsalicylic acid (ASA) per os (PO) daily and 1  $\times$  75 mg clopidogrel during the first years or 2  $\times$  90 mg ticagrelor or 1  $\times$  10 mg prasugrel PO daily for at least 5 d before treatment, or a loading dose of 500 mg ASA and either 600 mg clopidogrel or 180 mg ticagrelor or 30 mg prasugrel 24 h prior to the treatment. The effectiveness of

the antiplatelet therapy was verified before and after all treatments with the Multiplate analyzer (Roche Diagnostics, Mannheim, Germany) and later also with the VerifyNow (Accriva, San Diego, California). In case of low response the medication was increased to the double of the standard dosage and in case of nonresponse the medication was changed to prasugrel in the majority of the cases. Postprocedural medication consisted of a daily lifetime dose of 100 mg ASA PO and either 1  $\times$  75 mg clopidogrel or 2  $\times$  90 mg ticagrelor or 1  $\times$  10 mg prasugrel PO daily for at least 1 yr. Postmedication in large and giant aneurysms included low molecular weight heparin, steroids, and nonsteroidal anti-inflammatory treatment as a measure to prevent aneurysm hemorrhage induced by excessive intrasaccular thrombus formation after flow diversion.<sup>7,8</sup>

### Data Collection and Follow-up

Patency and flow characteristics within the FDS, distal branches, as well as inside the aneurysm were angiographically assessed immediately after deploying the p64 as well as during follow-ups.

Patients were scheduled for clinical and angiographic follow-up examinations as follows: early follow-up (3 mo), mid-term follow-up (9 mo), and long-term follow-up (>24 mo). Assessment of the aneurysm occlusion was recorded as either "complete" (Raymond Roy Classification; RRC I), "neck remnant" (RRC II), or "aneurysm perfusion" (RRC III).<sup>9</sup> Neurological examinations were performed in the periprocedural period ( $\leq$ 24 h), postprocedural (>24 h and  $\leq$ 30 d), and during the follow-up (>30 d) by a neurologist or a certified stroke nurse, using the modified Rankin Scale (mRS).<sup>10</sup> Morbidity was defined as any permanent worsening in the baseline mRS.

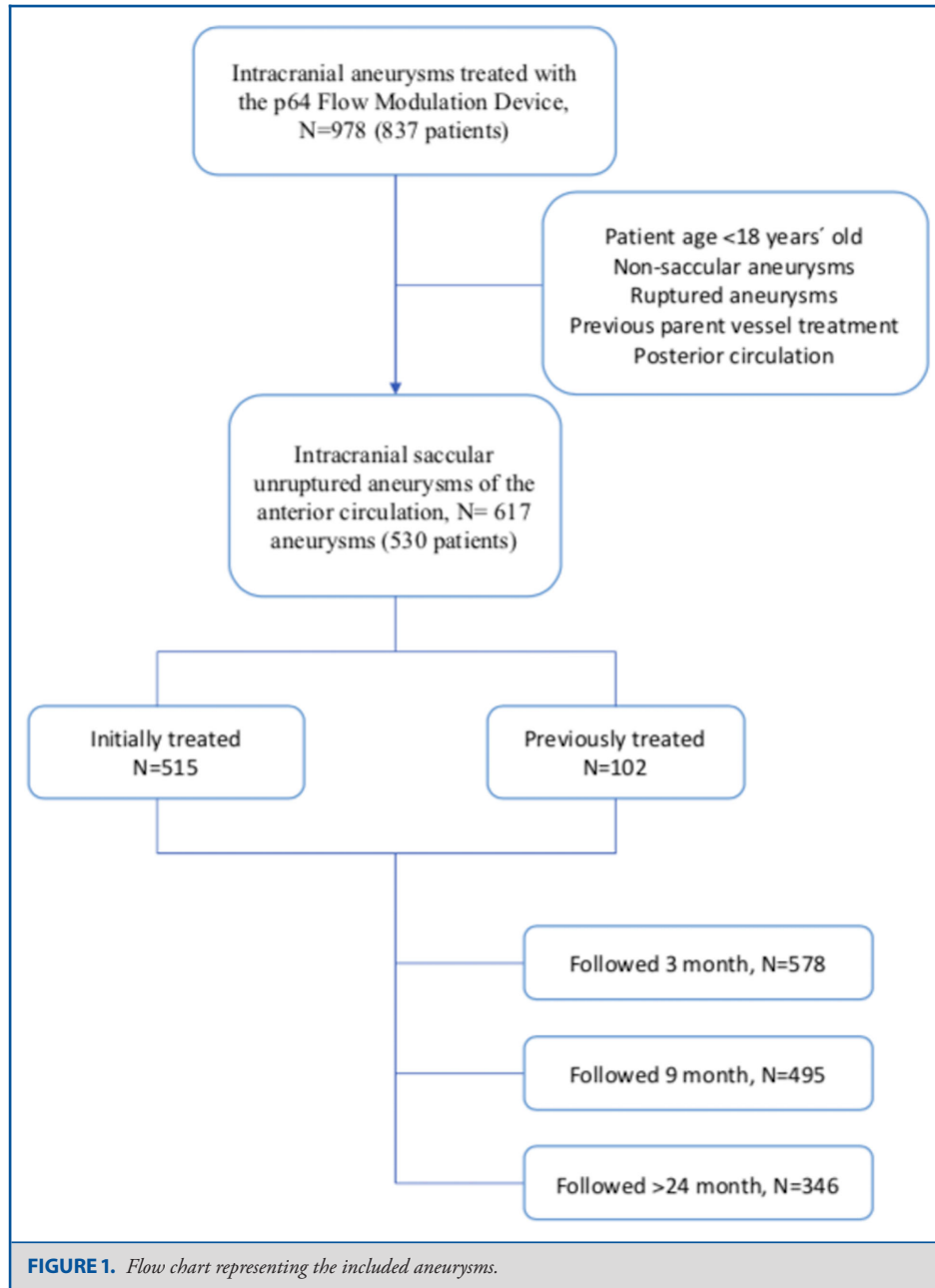
### Adherence to Ethical Standards

Informed consent was obtained from all individual participants included in the study at least 24 h before the procedure. Enrolled patients or legal representatives agreed to the data collection, analysis, and anonymous publication. The responsible ethics committee was consulted and approval was granted (Reference: F-2018-110).

## RESULTS

### Patients and Aneurysm Characteristics

Between December 2011 and December 2019, a total of 837 patients with 978 IAs underwent EVT with at least 1 p64 in our institution. Out of those patients, we identified 530 patients with 617 aneurysms who met the inclusion criteria. Multiple aneurysms were treated in 104 (19.6%) patients. There were 388 female patients (73.2%) and the average age of the patients was 55.9 yr (range 14-83). Mean aneurysm dome size was 4.8 mm (range 1-27 mm). Of the 617 aneurysms treated, 562 (91.1%) were small (<10 mm), 54 (8.7%) were large (10-25 mm), and 1 (0.2%) was giant (>25 mm). On average, 1.1 devices were implanted per aneurysm (range 1-3). The p64 procedure was the first treatment for 515 aneurysms (83.5%), whereas the remaining 102 (16.5%) were remnants or recurrences after the previous EVT (coiling, n = 70; Medina, n = 12; coils + Medina, n = 1; coils + Woven EndoBridge, n = 1), microsurgical clipping (n = 16), or both surgery and coils (n = 2).



A previous subarachnoid hemorrhage (SAH) (from the target aneurysm, from another aneurysm, or without identified cause) was confirmed for 46 aneurysms.

Aneurysm locations were: paraophthalmic internal carotid artery (ICA) (n = 156), superior hypophyseal artery (n = 108), posterior communicating artery (PcomA) (n = 98), anterior cerebral artery (ACA) (n = 63), MCA/M1 (n = 39), AchoA (n = 37), middle cerebral artery (MCA) bifurcation (n = 33), cavernous ICA (n = 32), supraclinoid ICA (n = 29), and ICA bifurcation (n = 22).

Table 2 shows a breakdown of occlusion and complication rates for each location.

### Angiographic Follow-up

Early follow-up (3 mo) was performed after a median of 96 d in 578/617 aneurysms (93.7%). Complete occlusion was confirmed in 337 (58.3%) aneurysms and a neck remnant was found in 107 (18.5%). In 134 (23.2%) aneurysms, a sac remnant was still visible.

Mid-term follow-up (9 mo) was available in 495 (80.2%) aneurysms after a median of 287 d, showing a complete occlusion in 379 (76.6%), neck remnant in 65 (13.1%), and a sac remnant in 51 (10.3%) aneurysms.

Long-term follow-up (>24 mo) was performed after a median of 863 d for 346 aneurysms (56.1%), revealing complete occlusion in 299 (86.4%), neck remnant in 28 (8.1%), and aneurysm remnant in the remaining 19 (5.5%), respectively. An adequate occlusion (RRC I/II) was seen in 94.5% of aneurysms during the follow-up period.

Retreatment of the target lesion was performed for 22 patients for whom the effect of the first implant was considered insufficient. Retreatment involved deploying another FDS.

## Complications

Thrombus formation was observed during the treatment of 4 aneurysms (0.6%). In 3 cases, the thrombus was related to an improper expansion of the p64 or detachment difficulties. In all cases, the thrombus resolved after administering a bolus of eptifibatid (Integrilin, GlaxoSmithKline), either alone or in combination with percutaneous transluminal angioplasty (PTA) (in cases of improper expansion) and/or proximal deployment of a second FDS (in cases of proximal collapse). There were no clinical or radiological consequences from these thrombus formations. Additionally, during the periprocedural period ( $\leq 24$  h), another 9 ischemic events and a total of 6 hemorrhagic complications occurred. None of the thromboembolic events produced permanent clinical deterioration. Regarding the hemorrhagic events, permanent clinical deterioration was reported in 2 of them, including 1 death. This patient died due to a wire perforation of the pericallosal artery causing a massive intracerebral hematoma (ICH), revealed only after successful implantation of the p64. The vessel was occluded by glue. The second patient presented deterioration from mRS 0 to 3 secondary to an ICH after mechanical thrombectomy of a migrated coil in the superior branch of the left MCA during the treatment of an anterior communicating artery (AcomA) aneurysm. One of the remaining hemorrhages was related to the delayed rupture of a supraclinoid ICA aneurysm treated with p64- symptomatic with severe headache. Both headache and SAH completely resolved within the following days. Angiographic follow-up 3 mo after treatment showed complete occlusion of the aneurysm. The remaining 3 cases consisted of minor cortical SAH probably related to hyper-response to DAPT.

Further adverse events: femoral access (6 patients), transient symptoms related to increased mass effect, and allergic reactions (2 patients).

Some kind of adverse events were observed in 18/617 aneurysms (2.9%) during the postprocedural period (>24 h and  $\leq 30$  d). Thromboembolic events occurred in 10 treatments (1.6%), including 6 in-stent-thrombosis, of which 2 resulted in permanent worsening of the mRS from 0 to 4 despite successful recanalization. One patient developed a minor

SAH due to hyper-response to DAPT. Therefore, a dose of ticagrelor was skipped leading to an acute in-stent-thrombosis that was successfully recanalized. The patient returned to her baseline neurological status within the following days (Figure 2). Hemorrhagic events were observed in 4/617 aneurysms (0.6%): 1 large ICH after treatment of a pericallosal aneurysm most likely due to transformation of an ischemic lesion, 1 minor cortical SAH, and 2 small subdural hematomas after previous craniotomy. Other adverse events were observed in 5 patients: 1 femoral artery occlusion, 2 acute diverticulitis, 1 pulmonary artery embolism, and 1 foreign body reaction, which resolved after steroids.

During the long-term follow-up period (>30 d), a total of 7 in-stent-thromboses occurred. In 6 of them, DAPT was interrupted against medical advice, and 1 patient admitted a massive intake of metazolone, which probably undermined the action of ASA.<sup>11</sup> Of those patients, 1 developed a major left MCA infarct which eventually caused death, while another presented with a worsening of the basal mRS from 0 to 2 despite recanalization. The other 5 thromboses occurred at some point between treatment and follow-up, with 4 patients remaining asymptomatic and 1 presenting ipsilateral tinnitus. During this period, no treatment-related hemorrhagic events were observed. One patient presented diplopia secondary to cranial nerve palsy due to the mass effect of a large ICA aneurysm.

A breakdown of the complications according to each period is shown in Table 3.

## DISCUSSION

EVT of IAs with complex morphologies remains challenging. The concept of redirecting the blood flow away from the aneurysm along the parent artery with progressive intra-aneurysmal stasis and subsequent thrombosis resulted in FDS being developed. They became a safe and effective treatment modality for many aneurysms.

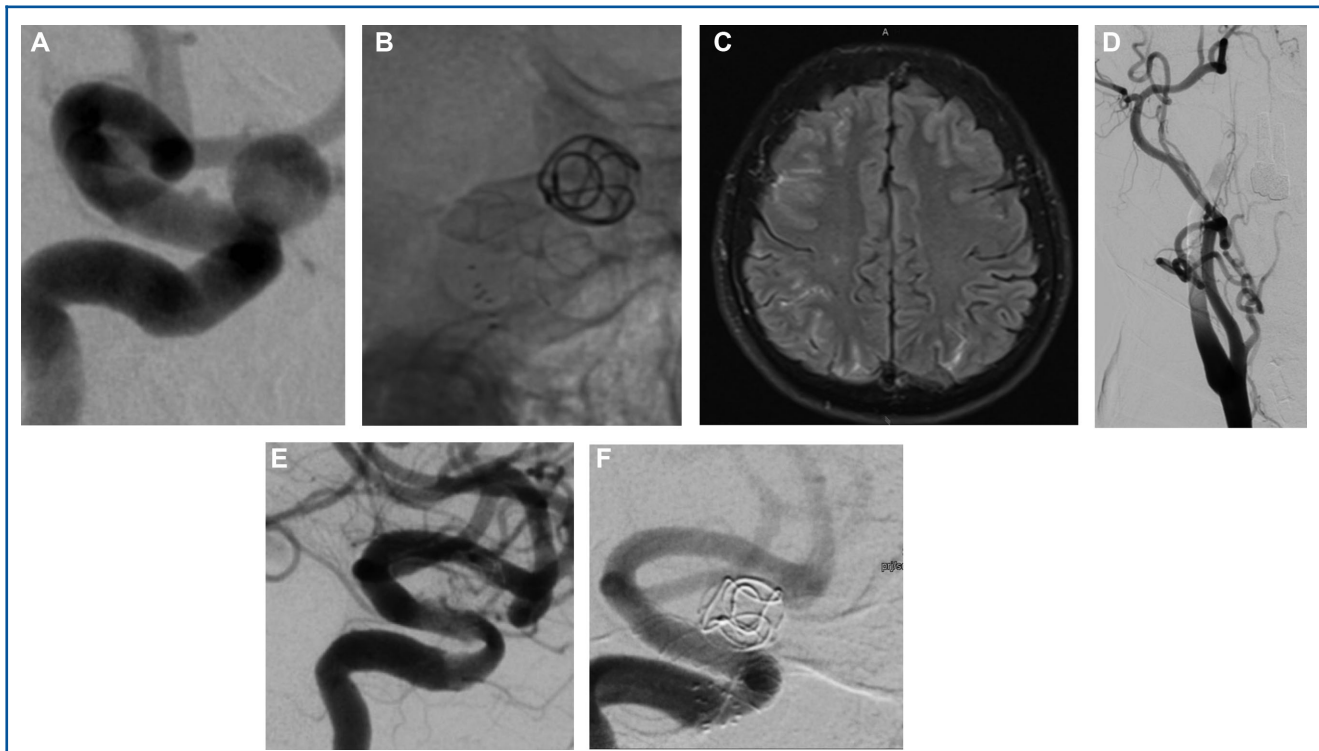
The extent of flow reduction depends on the porosity (the percentage of metal-free surface area relative to the entire surface area) and the pore density (the number of pores per unit of surface area) of the FDS. Most of the FDS are designed with a porosity of approximately 70% at nominal diameter, which was shown to be ideal for an adequate hemodynamic effect, while maintaining flow to normal vasculature.<sup>12,13</sup>

The p64 is a mesh-like tube of 64 interwoven nitinol wires, which results in denser coverage (the proportion of the surface area with metal coverage over the total surface area) across the aneurysm neck. This may lead to better occlusion rates. Several retrospective studies have shown mid-term occlusion rates of at least 85% when using the p64.<sup>3-5</sup> Sirakov et al<sup>6</sup> reported the longest period of follow-up outcome data for 72 aneurysms treated with this device. A 36-mo angiographic follow-up was available for 61 aneurysms (84.4%) by which point all aneurysms had been completely occluded (100%).

**TABLE 2. Thromboembolic and Hemorrhagic Complications (N = 617 Aneurysms)**

N = 617 aneurysms	Perioperative period	Postoperative period	Delayed period	Overall
Thromboembolic complications	13 (2.1%)	10 (1.6%)	7 (1.1%)	30 (4.8%)
*Morbimortality	*0	*5 (0.8%)	*3 (0.5%)	*8 (1.3%)
Hemorrhagic complications	6 (1%)	4 (0.6%)	0	10 (1.6%)
*Morbimortality	*2 (0.3%)	*1 (0.1%)	*0	*3 (0.5%)
Other complications	8 (1.3%)	4 (0.6%)	1 (0.1%)	13 (2.1%)
*Morbimortality	*0	*3 (0.5%)	*1 (0.1%)	*4 (0.6%)

\*Means inside the section above.



**FIGURE 2.** Unruptured right paraophthalmic aneurysm in a 65 yr-old female treated initially with a single Medina device and a single p64 FDS, both deployed during the same procedure **A** and **B**. Three days after treatment, the patient presented headache. Subsequent magnetic resonance imaging (MRI) showed bilateral cortical subarachnoid hemorrhage **C** due to hyper-response to the DAPT (ASA and ticagrelor), which was confirmed by Multiplate (ADP 7 U, ASPI 6 U) and VerifyNow (P2Y12 45, ARU 369). The afternoon dose of ticagrelor was skipped. The following morning, the patient presented acute onset of left hemiparesis. Both Multiplate and VerifyNow showed then an insufficient inhibition for ticagrelor. Subsequent digital subtraction angiography (DSA) confirmed occlusion of the right ICA due to acute thrombosis of the previous implanted FDS **D**, which was successfully recanalized by mechanical thrombectomy and aspiration **E**. The patient returned to baseline neurology (mRS 0). Angiography performed 3 mo after treatment demonstrated complete exclusion of the aneurysm from the circulation **F**.

### Occlusion Rate

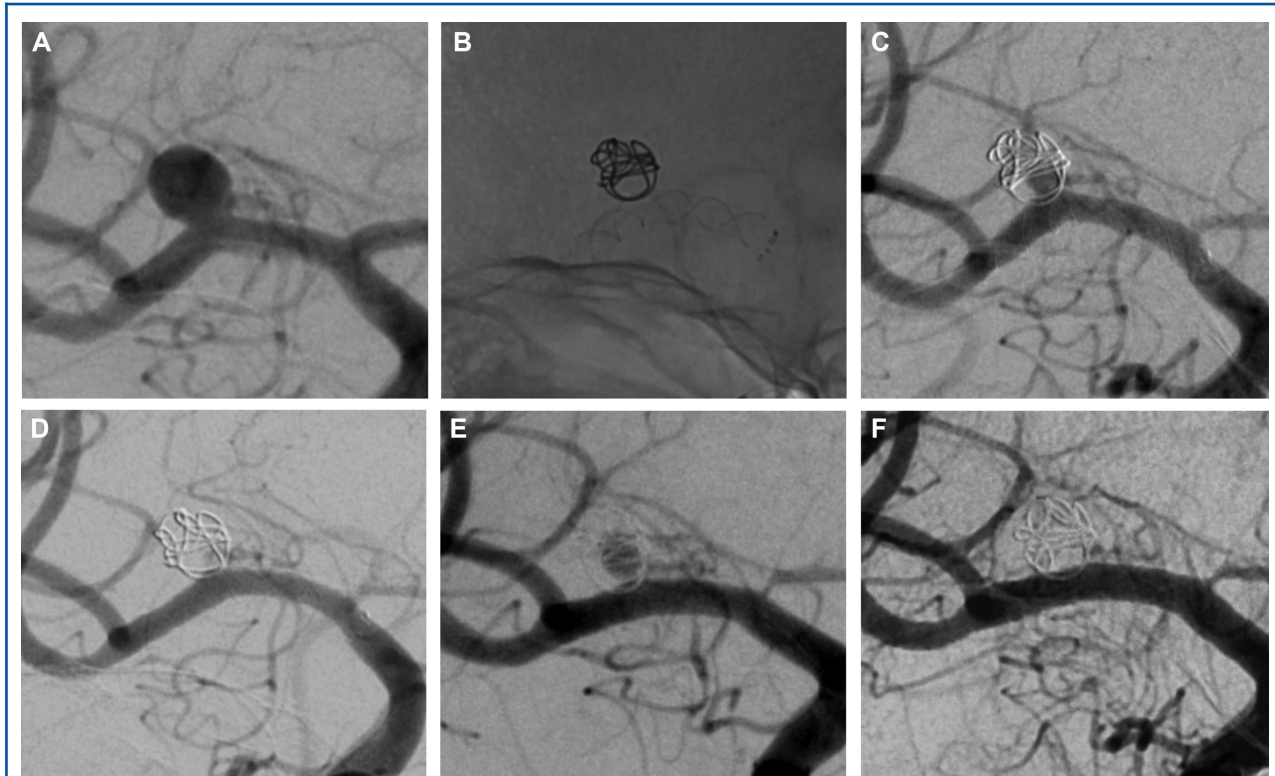
We observed a progressive occlusion rate over time with a (near-) complete obliteration of 76.8% at 3 mo, 89.7% at 9 mo, and 94.5% at >24 mo, which is in line with prior studies.<sup>14</sup> We also noted that the results for certain locations (eg, cavernous, ophthalmic, and ICA bifurcation) were particularly encouraging. On the other hand, it is noteworthy that M1 and PcomA aneurysms showed lower occlusion rates. These results are in

line with the study by Briganti et al<sup>15</sup> reporting their experience in the treatment of 39 aneurysms with the PED, where at the 24-mo follow-up only 3 aneurysms showed partial occlusion; 2 of them located on the M1 segment and 1 at the PcomA. PcomA aneurysms associated with dominant (“fetal”) PcomA have been shown to be particularly refractory to flow diversion. Chun On Tsang et al<sup>16</sup> reported their experience in the treatment of “fetal” PcomA aneurysms with FDS, where all 4 aneurysms

**TABLE 3. Complication Rates and Angiographic Results Depending on Each Location**

N = 617 aneurysms	ICA—cavernous segment		ICA—superior hypophyseal artery		ICA—ophthalmic segment		ICA—PcomA		ICA—anterior choroidal artery		ICA—supracaloid segment		ICA—bifurcation		ACA-complex (A1/AcomA/A2)		MCA—M1 bifurcation			
	Number	(%)	Number	(%)	Number	(%)	Number	(%)	Number	(%)	Number	(%)	Number	(%)	Number	(%)	Number	(%)		
Number of aneurysms treated	32	(5.2%)	108	(17.5%)	156	(25.3%)	98	(15.9%)	37	(6%)	29	(4.7%)	22	(3.6%)	63	(10.2%)	39	(6.3%)	33	(5.3%)
Mean aneurysm size (mm)	12.5		3.7		5.3		4.5		3.2		6.3		5.5		3.7		3.4		3.4	
Periprocedural complications	1	(3.1%)	3	(2.8%)	6	(3.8%)	1	(1%)	2	(5.4%)	1	(3.4%)	1	(4.5%)	4	(6.3%)	3	(7.7%)	5	(15.1%)
Postprocedural complications	1	(3.1%)	0		8	(5.1%)	2	(2%)	0		0		2	(9.1%)	3	(4.8%)	1	(2.6%)	1	(3%)
Delayed complications	1	(3.1%)	0		2	(1.3%)	3	(3%)	0		0		0		1	(1.6%)	0		1	(3%)
Overall complication rate	3	(9.4%)	3	(2.8%)	16	(10.2%)	6	(6%)	2	(5.4%)	1	(3.4%)	3	(13.6%)	8	(12.7%)	4	(10.2%)	7	(21.2%)
Morbimortality rate	2	(6.2%)	0		4	(2.6%)	2	(2%)	0		0		0		5	(8%)	0		2	(6%)
Available FUs at 3 mo	28	(88%)	102	(94%)	151	(97%)	90	(92%)	36	(97%)	28	(97%)	21	(95%)	58	(92%)	36	(92%)	31	(94%)
Occlusion rate at 3 mo	24	(86%)	85	(83%)	122	(81%)	59	(66%)	27	(75%)	20	(71%)	17	(81%)	45	(78%)	24	(67%)	20	(65%)
Available FUs at 9 mo	22	(69%)	92	(85%)	121	(78%)	71	(72%)	30	(81%)	25	(86%)	19	(86%)	55	(87%)	31	(79%)	29	(88%)
Occlusion rate at 9 mo	21	(95%)	85	(92%)	109	(90%)	59	(83%)	26	(87%)	24	(96%)	18	(95%)	51	(93%)	22	(71%)	24	(83%)
Available FUs ≥ 2 yr	19	(59%)	59	(55%)	79	(51%)	48	(49%)	24	(65%)	19	(66%)	14	(64%)	42	(67%)	25	(64%)	20	(61%)
Occlusion rate ≥ 2 yr	19	(100%)	56	(95%)	78	(99%)	41	(85%)	23	(96%)	18	(95%)	14	(100%)	40	(95%)	22	(88%)	19	(95%)

ICA: internal carotid artery; PcomA: posterior communicating artery; ACA: anterior cerebral artery; AcomA: anterior communicating artery; MCA: middle cerebral artery; FUs: follow-ups.



**FIGURE 3.** Unruptured M1 aneurysm in a 46 yr-old female treated with a single coil and a single p64 FDS **A** and **B**. The 3-mo follow-up angiography **C** showed a near occlusion of the aneurysms with a small neck remnant. The small lenticulostriate artery covered by the FDS was still patent. The 9-mo follow-up **D** showed complete occlusion of the aneurysm. The covered branch was reduced in filling but still patent. At 34-mo angiographic follow-up **E** showed partial recanalization of the aneurysm sac. The first follow-up angiography after retreatment with a second p64 device **F** showed again complete occlusion of the aneurysm.

showed persistent perfusion despite several treatments. Surprisingly, the occlusion rate of M1 aneurysms in our series was lower than in those located at the MCA bifurcation (88% and 95%, respectively). These results are contrary to other studies, where it has been suggested that the occlusion effect is less when branching vessels are larger, as in case of MCA bifurcation, and the occlusion would be more rapid for M1 aneurysms associated with smaller early cortical branches or lenticulostriate arteries.<sup>17-19</sup> One possible explanation for this lower occlusion rate in M1 aneurysms in our series is the rare case of an asymptomatic reperfusion of a previously completely occluded M1 aneurysm at long-term follow-up (Figure 3). Recurrence of a totally occluded aneurysm after FDS is a rare but possible finding.<sup>20</sup> In our case, a lenticulostriate artery was running off the aneurysm, which could explain the recurrent filling, as suggested by Trivelato et al.<sup>21</sup>

The overall occlusion rate found in our series is similar to previous reports dealing with different FDS. In a retrospective, multicenter series analyzing Silk in the treatment of 180 aneurysms, complete occlusion was observed in 78.1% at 1-yr follow-up.<sup>22</sup> Kallmes et al<sup>14</sup> analyzed 3 studies dealing with aneurysms treated with the PED, which includes 1221 aneurysms. In this pooled series, the occlusion rate at 1 yr was

85.5%. In a prospective, multicenter series, dealing with the treatment of 190 aneurysms with the Surpass, the rate of complete occlusion was 78.6% for anterior circulation aneurysms.<sup>23</sup> In the European retrospective series dealing with the treatment of IAs with the FRED device (EuFRED) in 579 aneurysms, the FRED showed an overall occlusion rate of 91.3% at 1 yr.<sup>24</sup> Finally, Kraus et al reported the German experience using the Derivo for the treatment of 42 unruptured aneurysms, where total aneurysm occlusion at 6 mo was observed in 72.7% of the aneurysms.<sup>25</sup>

### Clinical Complications and Related Morbimortality

Regarding complications, it has been suggested that the denser coverage of p64 may lead to an increased rate of ischemic complications. The overall rate of thromboembolic complications in our series (4.8%) is in line with previous studies reporting an incidence ranging from 4.1% to 4.5%.<sup>26,27</sup> Overall morbimortality rate in our series is also low (permanent morbidity of 2.1%, mortality of 0.3%), which is in line with other studies reporting on p64 such as Fischer et al<sup>3</sup> (morbidity 1.7% and mortality 0.8%), Briganti et al<sup>4</sup> (morbidity 2.5% and mortality 0%), Morais et al<sup>5</sup> (transient morbidity 5.7%, permanent morbidity and mortality 0%), and Sirakov et al<sup>6</sup> (morbidity 1.38% and

mortality 0%). These numbers are slightly lower than rates reported in series dealing with other FDS, such as with Silk (morbidity and mortality at 6 mo of 9.6% and 3.2%, respectively), PED (major morbidity 5.7% and mortality 3.3%), Surpass (permanent morbidity and procedure-related mortality observed in 6.0% and 2.7%, respectively), FRED (transient and permanent morbidity of 3.2% and 0.8%, respectively; overall mortality rate of 1.5%), and Derivo (morbidity 2.4% and no mortality).<sup>14,22-25</sup> One possible reason is that we did not include aneurysms located in the posterior circulation, which are known to be associated with higher complication rates.<sup>28,29</sup>

In our series, ACA-complex and MCA bifurcation aneurysms were associated with higher morbimortality (8% and 6%, respectively). This has been reported by other authors.<sup>30,31</sup> The recent development of low-profile FDS, which are compatible with smaller delivery systems (0.0172 or 0.021; Silk Vista Baby, FRED Jr, and p48MW (phenox)), might resolve this issue.<sup>32-34</sup> Likewise, the development of FDS with reduced thrombogenicity (Shield technology (Medtronic)<sup>35</sup> and the pHPC (phenox)).<sup>36</sup>

## Limitations

This study has several limitations, first, the retrospective data collection and a single center as a data source. Therefore, the applicability of our results to other FDS is unknown. Second, we have dealt solely with unruptured, saccular aneurysms of the anterior circulation and therefore it is not clear whether the results could be extrapolated to fusiform aneurysms or to the posterior circulation.

## CONCLUSION

The p64 offers a safe and effective treatment option when used to treat intracranial saccular unruptured aneurysms arising from the anterior circulation. The use of p64 achieved high occlusion rate on mid- and long-term follow-ups and it is associated with low morbimortality.

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## Disclosures

Dr Aguilar Pérez serves as proctor and consultant for phenox. Dr E Henkes and Dr Hellstern are consultants for phenox. Dr H Henkes is a co-founder and shareholder of phenox. The other authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

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## COMMENT

**A**s the field of flow diversion continues to evolve we are seeing the development within different companies of new flow diverters. There are now 7 approved devices in Europe and 3 in the United States. In the current publication the authors detailed their mid and long-term results in 617 aneurysms treated at a single institution. A total of 530 patients were treated in the average number of devices per aneurysm was 1.1. Overall morbidity and mortality was 2.4%. Long-term angiographic follow-up in 346 aneurysms (56.1%) revealed a 94.5% complete or near complete aneurysm obliteration.

As one surveys the literature of flow diversion, the overall obliteration rates of the different devices are approaching similar numbers. Devices with increased porosity will have lower cure rates unless an increased number of devices are utilized. The fear of using devices with decreased porosity which would favor obliteration is an increased thromboembolic complication rate. The authors found 7 in-stent thrombosis that occurred in the longer term follow-up interval. In 6 of the patients, dual antiplatelet therapy was interrupted against medical advice and in 1 patient utilization of Metamizole was thought to inhibit the activity of aspirin.

As future reports emerge utilizing different flow diverting devices it may indeed be the case that certain devices will have properties favorable for certain locations or anatomic features of aneurysms. The authors provide us with a well detailed report utilizing p64 flow modulation and should be commended for their work.

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