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INTERVENTIONAL NEURORADIOLOGY

Endovascular treatment of intracranial aneurysms with the p64 flow diverter stent: mid-term results in 35 patients with 41 intracranial aneurysms

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Abstract
Introduction The p64 flow diverter (FD) device is a fully resheathable and detachable stent dedicated for endovascular treatment (EVT) of intracranial aneurysms (IAs). We report our mid-term experience with this device.
Methods Between January 2015 and February 2016, we retrospectively identified, in our prospectively maintained database, all patients treated with p64 FDs in two institutions. Independent clinical follow-up was performed by a vascular neurologist. Imaging follow-up included a digitalized subtraction angiography (DSA) at 3, 6, and 12 months and a magnetic resonance angiography (MRA) at 12 months.
Results Thirty-nine patients (22 women/17 men; median age 54 years) with 48 IAs (median aneurysm size 6.2 mm; mean neck size 3.4 mm) were identified. All IAs were saccular and unruptured. Failure of safe stent delivery occurred in 15% of cases (7/48 IAs) which were excluded. Transient neurological morbidity occurred in 2/35 patients (5.7%) including one delayed thromboembolic complication. No permanent morbidity or mortality was encountered. Complete aneurysmal occlusion at 3, 6, and 12 months was 20/30 (66.6%), 18/27 (66.6%), and 24/28 (85.7%), respectively. Intra-stent stenosis was observed in 9/29 patients (31%) and classified as moderate in 4/29 (13.7%) and mild in 5/29 patients (17.2%). These stenoses gradually improved over time, with only mild stenoses being identified at 6 months and at 12 months.
Conclusion In our small case series, the p64 FD stent appears safe and effective for EVT of IAs. A high occlusion rate and a low morbidity rate were observed.

Keywords p64 · Flow diverter · Intracranial aneurysm · Neuroradiology

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Introduction

Flow diverter stents (FDSs) are now an accepted therapeutic option for the endovascular treatment (EVT) of selected complex intracranial aneurysms (IAs) such as wide neck, fusiform, large, and giant aneurysms [1–4]. Their use and indications are expanding, leading to the development of new devices [5–7]. The p64 FD stent has recently been released and approved for clinical use in Europe. Only two series [8, 9] have been published with only one providing short- and mid-term outcomes [9]. The aim of our study is to report our experience with this device in 35 patients with 41 IAs.

Methods

Patient population

The study protocol was approved by our institutional ethical committees. Between January 2015 and February 2016, we retrospectively identified in our prospectively maintained database all patients treated with p64 FDs in two institutions by

the same physicians. The inclusion criteria were as follows: (1) unruptured aneurysm or previously ruptured aneurysm with a minimum delay of 10 days from the acute phase and (2) aneurysms judged difficult for a coil treatment (e.g., branch arising from the sac, complex aneurysm morphology, wide neck) or recanalization of previously treated aneurysms.

p64 flow diverter

The p64 FD stent has received the CE mark approval in 2012 but it is not yet FDA-approved. It is a braided mesh tube composed of nickel-titanium alloy (nitinol), consisting of eight bundles of eight individual wires. They are proximally attached to a crown, resulting in a 64-mesh flow diverter. Under x-ray fluoroscopy, two platinum wires wrapped around the braided mesh tube are visible as well as the proximal markers. Available diameters range from 2.5 to 5 mm with 0.5-mm increments and the length ranges from 9 to 30 mm with 3-mm increments. It is delivered with a 0.027″ microcatheter [9].

The deployment technique requires pushing the device to reach the delivery microcatheter tip, which must be distal to the aneurysm neck, and then a combination of pushing the delivery wire and retrieving the microcatheter to allow full expansion of the stent (Fig. 1a). During deployment, the distal smooth wire tip must be able to advance distally and its progression must carefully be controlled to avoid any vessel perforation.

Detachment of the p64 stent starts with the repositioning of a torque device approximately 15 mm proximal to the end of the hypotube and then pulling this hypotube towards the torque device. This will result in releasing the eight markers from the slotted crown. The p64 stent can be retrieved even if fully deployed (Fig. 1b), by advancing the microcatheter while pulling back on the delivery wire. After detachment, recovery of the stent is no longer possible (Fig. 1c).

Endovascular procedures

All procedures were performed under general anesthesia by three senior interventional neuroradiologists with more than 8 years of experience in EVT of IAs. A telescopic access system was used consisting in the following: (1) a long introducer (IVA 6F, Balt, Montmorency, France) and (2) an intermediate access catheter (Neuron, Penumbra Inc., Alameda, USA). Then, an Excelsior XT27 (Stryker, Fremont, CA, USA) or a Marksman (Covidien Vascular Therapies, Mansfield, MA, USA) microcatheter was used for stent placement under roadmap guidance. In all cases, the p64 was first half-deployed and an angiographic control was performed to evaluate the vessel patency and stent wall apposition. If the control was satisfactory (no slowing of the flow within the parent artery, no clot formation), the stent was fully deployed. For stent detachment, we prefer to use a different torque device (from a 0.014 microguidewire, the Synchro guidewire, Stryker, Fremont, CA, USA) in order to properly secure the torquer on the wire and avoid kinking of the wire.

During the procedure, all patients received systemic heparin after femoral sheath placement. The activated clotting time (ACT) was maintained at two times the baseline throughout the procedure. The adequacy of systemic anticoagulation was

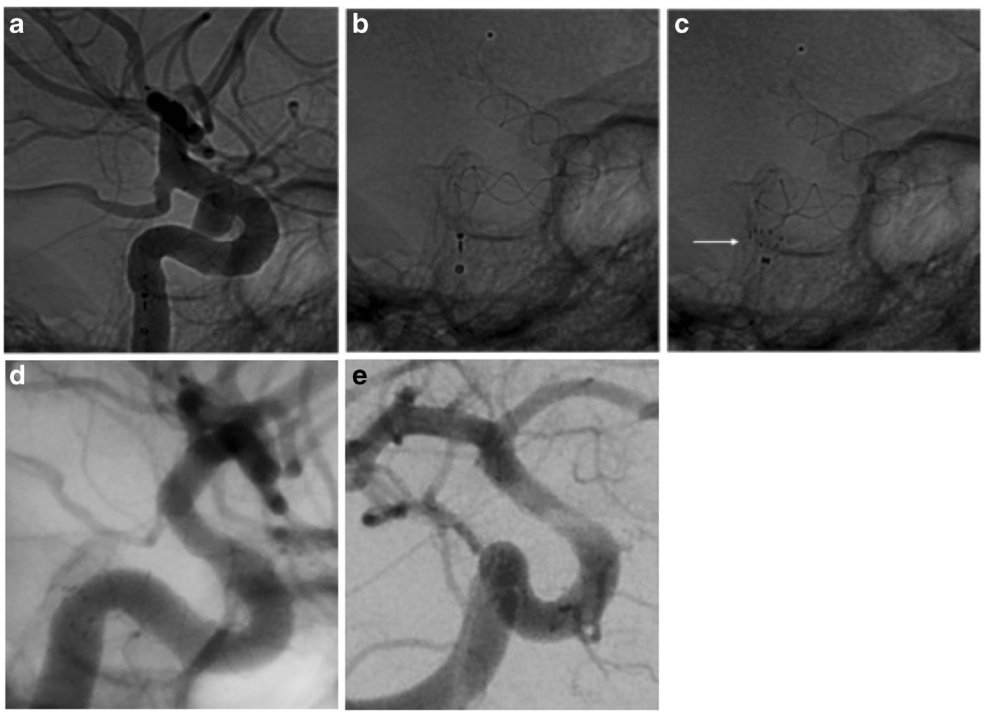

Fig. 1 Full deployment of the p64 for the treatment of a cavernous aneurysm is illustrated in (**a**) and (**b**). p64 FD after detachment is seen in (**c**); the *white arrow* points to the proximal markers released from the slotted crown (the FD is no longer resheathable). Follow-up angiogram at 12 months, showing occlusion of the aneurysm and slight reduction in the posterior communication artery, is seen in (**d**) and (**e**)

monitored by repeated ACT measurements. At the end of EVT, systemic heparinization was maintained for 24 h in most patients. For all procedures, a loading dose of 300 mg of clopidogrel and 320 mg of aspirin was administered 1 day before and on the day of EVT. At the end of procedure, patients were transferred to the intensive care unit for 24 h.

In all patients, clopidogrel (75 mg/day) and aspirin (160 mg/day) were maintained for 12 months and thereafter, only aspirin (160 mg/day) was administered.

Patient follow-up

Clinical outcome

Procedural and early post-procedural (within 48 h) complications were recorded in an independent manner by intensive care specialists and vascular neurologists. Independent clinical follow-up was performed by a vascular neurologist. The modified Rankin scale (mRS) and the National Institutes of Health Stroke Scale (NIHSS) were used to evaluate patients with neurological deterioration.

Anatomical outcome

Our imaging follow-up protocol includes a digitalized subtraction angiography (DSA) at 3, 6 and 12 months as well as magnetic resonance angiography (MRA) at 12 months and then every 2 years. Additional MRI/A was performed if the patient experienced symptoms suspected to be related to the EVT. All imaging exams were evaluated by two senior neuroradiologists for vessel patency, stent wall apposition, and aneurysm occlusion in an independent manner; discrepancies were settled by consensus. The degree of aneurysm occlusion was graded as follows: (1) complete occlusion, (2) neck remnant, (3) incomplete occlusion with residual sac filling, and (4) unchanged aneurysm perfusion (includes contrast medium stasis).

Parent artery stenosis was graded as mild (<50%), moderate (50–70%), or severe (>70%) when compared with the initial artery diameter before EVT. Significant stenosis of branches covered by the p64 FD stent was noted as well as significant flow modification (size reduction, occlusion, and refill by collateral circulation).

Illustrative cases

Case 1

Patient with a small, evolving, unruptured side-wall M1 aneurysm is shown in Fig. 2a. The aneurysm is wide-necked and a branch arises from the sac. The patient was annually followed by MRA since 2009. In 2014, an increase of the aneurysm size was identified with a bleb formation (Fig. 2b). Treatment with a p64 FD was performed because the patient refused surgery. Follow-up DSA at 12 months showed a complete aneurysm occlusion and permeability of the branch arising from the sac (Fig. 2c, d).

Case 2

Unruptured middle cerebral artery (MCA) bifurcation aneurysm in a patient with multiple IA is shown in Fig. 3a, b. Endovascular therapeutic options were discussed (Y-stenting + coils or FD placement) and treatment with a p64 stent was finally performed. DSA follow-up at 12 months showed a complete aneurysm occlusion (Fig. 3c). DSA also showed a significant stenosis of the lower M2 division and missing lateral lenticulostriates. The patient remained asymptomatic and follow-up MRI was unremarkable (Fig. 3d).

Case 3

Symptomatic giant cavernous ICA aneurysm in a 50-year-old male is show in Fig. 4a. Treatment by p64 stent placement and adjunctive coiling was performed. DSA follow-up at 6 (Fig. 4b) and 12 months (Fig. 4c) showed a complete aneurysm occlusion.

Case 4

Patient with a history of *s*ubarachnoid hemorrhage (SAH) and an evolving unruptured and wide-necked anterior choroidal aneurysm is shown in Fig. 5a. Treatment with a p64 FD was performed (Fig. 5b). DSA follow-up at 3 months showed a moderate stenosis at proximal and distal ends of the stent (Fig. 5c—white arrows). At 12 months, DSA showed a complete regression of the stenosis (Fig. 5d).

Results

Population

Thirty-nine patients with 48 IAs were identified. The mean aneurysm size was 6.2 mm (median 4.9 mm; range 1–24.7 mm) with a mean neck size of 3.4 mm (median 3.4 mm; range 1.5–11 mm). The descriptive analysis of the demographics, clinical findings, and aneurysm location and sizes are summarized in Tables 1 and 2.

Procedures

Table 3 summarizes intra-procedural complications and the success rate.

Failure of stent delivery occurred in 4 patients with 7 IAs (failure rate = 7/48 = 15%) who were excluded from the analysis. In 3 patients with tortuous cervical and intracranial

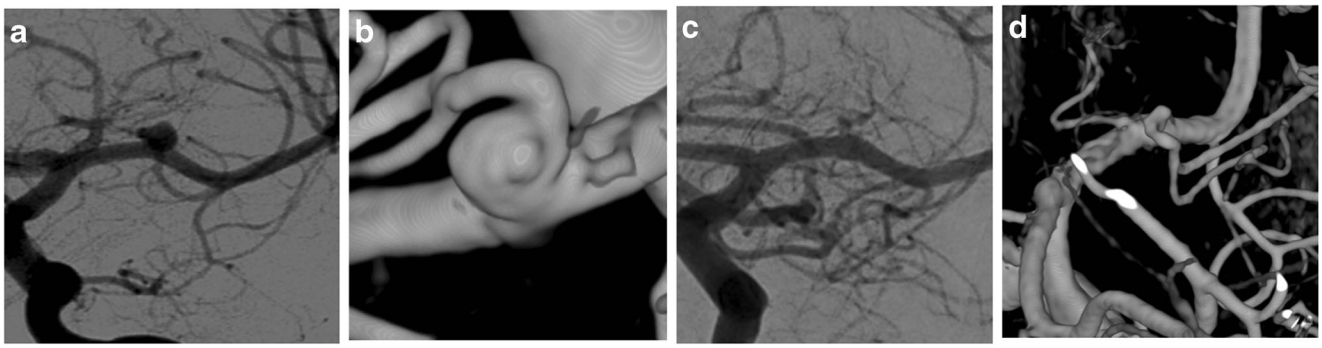

Fig. 2 Unruptured side-wall M1 aneurysm with a branch arising from the sac (**a**). Aneurysmal morphology changes with development of a bleb formation were depicted (**b**). Follow-up DSA at 12 months (**c** and **d**) shows complete aneurysm occlusion and permeability of the branch arising from the sac

arteries, the stent could not be delivered because of the stiffer delivery system of the first p64 stent generation. In the fourth case, the angiographic control, after half-deployment of the stent, showed an absence of flow in the parent vessel, precluding its full deployment. These 4 patients remained clinically unchanged after the failed intervention. Thus, successful FD deployment was achieved in 35 patients with 41 IAs, which represent our study population, resulting in a technical success rate of 85% (Table 2). All aneurysms were treated with a single FD. Patients with a ruptured aneurysm (2 patients/5.1%) were treated after initial coiling and in a sub-acute stage at least 10 days following SAH.

Stent shortening after detachment was identified in 8/35 cases (23%). Upon detachment, a slight stent displacement has been noticed in 3/35 cases (9%). All these cases were seen in patients with tortuous cervical and/or intracranial circulation. Additional coils were placed in the aneurysmal sac in 2 patients with IAs ≥ 15 mm in diameter. In one case, the jailing technique was used whereas coiling followed by p64 placement was performed in the second patient.

Intra-procedural complications occurred in 2/35 patients (5.7%) are the following:

- Clot formation within the stent was observed in one patient and it was successfully treated with intra-arterial administration of abciximab through the delivery microcatheter.
- In one patient, the proximal part of the stent did not fully open, even after manipulation with the microcatheter and different microguidewires. Numerous angiographic controls showed no slowing of the parent artery or clot formation. The 3-month DSA follow-up showed the complete opening of the proximal part and no thromboembolic lesions were identified on follow-up MRI.

Clinical outcome

Clinical follow-up was available in all 35 patients. There was no procedure-related mortality.

Immediately after EVT, the mRS score remained unchanged in all patients but one (1/35 = 2.8%). A 75-year-old woman treated for a 7-mm wide neck basilar aneurysm experienced an episode of bradycardia with 1-minute cardiac arrest. CT and MRI scan showed an inter-peduncular hemorrhage. Neurological evaluation identified a left central facial palsy (mRS = 1, NIHSS = 1). MRI at 3 months showed mesencephalic ischemic lesions. At 6 months follow-up, both mRS and NIHSS were 0.

At follow-up, one patient experienced a delayed thromboembolic complication (1/35 = 2.8%). An 89-year-old woman, treated for a left 15-mm and irregular carotid-ophtalmic aneurysm, experienced a right central facial palsy and a mild

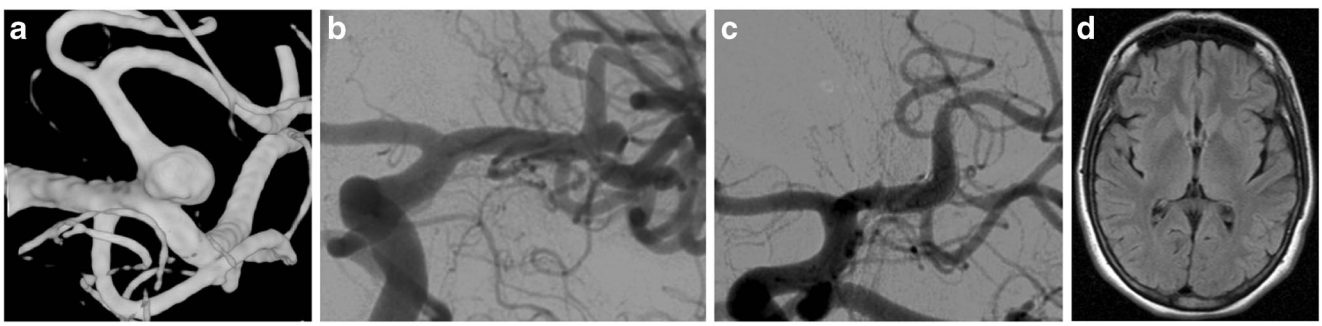

Fig. 3 Wide-necked MCA bifurcation aneurysm (**a** and **b**). DSA follow-up at 12 months (**c**) shows a complete aneurysm occlusion with lower M2 division stenosis and missing lateral lenticulostriates. Control MRI was unremarkable and patient remained asymptomatic (**d**)

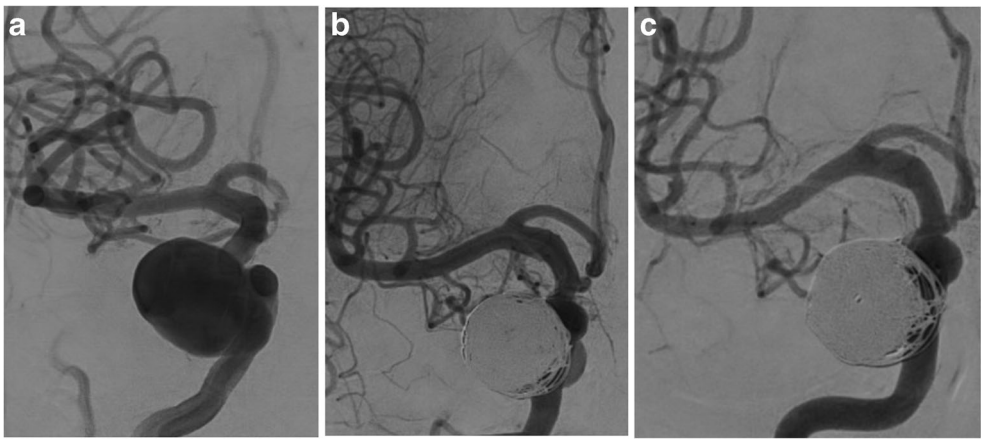

Fig. 4 Symptomatic giant cavernous aneurysm (**a**). Treatment by p64 stent placement and adjunctive coiling was performed. DSA follow-up at 6 (**b**) and 12 months (**c**) show complete aneurysm occlusion

dysarthria at day seven (mRS = 1, NIHSS = 4). MRI confirmed left small fronto-parietal cortical ischemic lesions. At 6 months, full recovery was documented by the referring neurologist (mRS = 0; NIHSS score of 0).

Thus, there was no permanent neurological morbidity.

Anatomical outcome

Successful FD deployment was achieved in 35 patients to treat 41 aneurysms. In the immediate post-procedural control, complete aneurysm occlusion was identified in 2/41 aneurysms (4.8%); neck remnant was found in 3/41 aneurysms (7.3%) and incomplete occlusion with residual sac filling in 13/41 aneurysms (31.7%); no changes or contrast medium stasis of the aneurysm sac was identified in 23/41 aneurysms (56%). Occlusion grades at 3, 6 and 12 months are summarized in Table 4.

Imaging follow-up was available for 34/35 patients (40/41 aneurysms). Mean follow-up was 283 days or 9.5 months (the range is immediate post-procedure DSA to 12 months).

During follow-up, all aneurysms showed improvement of the aneurysmal occlusion. At 3 months, improvement in aneurysmal occlusion grade (of at least one degree) was noted in 26/30 aneurysms (86.6%). At 6-month follow-up, 19/27 aneurysms (70.3%) showed improvement in the grade of occlusion. At 12-month follow-up, 9/28 aneurysms (32.1%) showed progression in the occlusion.

No recanalization or worsening in the degree of the aneurysmal occlusion was observed.

Overall, at the latest available follow-up, 35/41 aneurysms (85%) were completely occluded; neck remnant was identified in 4/41 aneurysms (9.7%) and sac remnant in 2/41 aneurysms (4.8%).

No parent artery (PA) occlusion was identified among the 35 patients with follow-up. At immediate post-procedural control, there was one mild stenosis (1/35 or 2.8%). At 3 months, stenosis of the PA was present in 9/29 patients (31%) and classified as moderate in 4/29 patients (13.7%) and mild in 5/29 (17.2%) patients. At 6 months, mild stenoses were present in 4/21 patients (19%) and at 12 months, mild stenoses were identified in 4/23 (17.3%) patients.

Significant stenoses of covered branches were seen in five MCA aneurysms and one basilar artery aneurysm. None of these patients experienced a clinical complication and these stenoses improved during imaging follow-up. Flow changes in the posterior communicating artery were noted in four cases, in the ophthalmic artery in five cases, and in the anterior cerebral artery (ACA) in one case. In all these cases, filling through collateral circulation was seen: the vertebral artery (Figs. 1 and 4), external carotid artery, and contra-lateral A1 from the ACA. No patient had symptoms related to these flow changes during the follow-up period. However, one patient experienced an asymptomatic basilar trunk perforator occlusion that was seen on a MR follow-up.

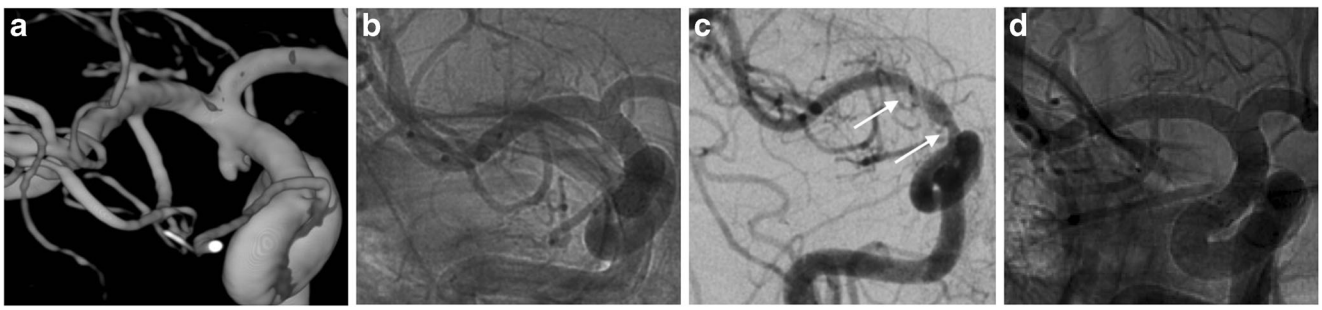

Fig. 5 Wide-necked anterior choroidal aneurysm (**a**). Treatment with a p64 FD was performed (**b**). DSA follow-up at 3 months (**c**) shows a moderate stenosis at proximal and distal ends of the stent (*white arrows*). DSA follow-up at 12 months (**d**) shows complete regression of the stenosis

Table 1 Descriptive analysis of the demographics and clinical presentation of the study population

Patients (*n*)	39
Women	56%
Mean age (years) (range)	54 (27–89 years)
Clinical presentation	
Incidental finding	41%
Headache	23%
Recanalization after coiling	12.8%
History subarachnoid hemorrhage	12.8%
Cranial nerve deficit	7.6%
Transient ischemic attack	2.5%

Discussion

Procedures

The stiffness of the first p64 FD generation was the main cause of technical failure in our series, due to excessive friction within the delivery catheter. We achieved an 85% success rate of device placement, inferior to the previous series from Fisher et al. (97.6%) [9]. Some technical issues were also encountered even if they did not prevent a safe and a satisfying stent delivery. In case of tortuous anatomy, we found that the detachment of the p64 stent was associated with some shortening and even small proximal displacement (23% and 9%, respectively). This phenomenon should be taken into account when planning p64 placement, since shortening of the device will imply a change in the proximal landing zone. In our series, this was not a problem because the mean neck size was 3.4 mm but in wider neck aneurysms, this aspect could be a significant limitation.

Clinical outcome

Our low rate of procedural complications may be explained by the extensive experience of our team with FD stents and also by the advantage that the p64 offers which is the full retrievability [8, 9]. Despite having experienced a 5.7% morbidity in the early period after EVT, none of our patients kept a neurological deficit. Only one ischemic lesion was depicted secondary to stent placement. It occurred in a patient treated for a basilar artery aneurysm which is located in a territory rich in perforators. These cases illustrate once again the need to be cautious when using a flow diverter in the basilar trunk or other vessels rich in perforators [10]. MCA stenting, in our series, was not associated with ischemic lesions even if branch occlusions were depicted at follow-up (Fig. 3). Our final mortality and morbidity rates are 0%. These results are in line with other published series, reporting a transient morbidity of 5%, a permanent morbidity of 1.7%, and a mortality of 0.8% [9]. In Briganti et al. [8] study, 5 patients with 6 aneurysms were treated with a p64 FD; no periprocedural complications, permanent morbidity, or mortality occurred. Similar rates with other FD stents have been reported [1–4, 11, 12].

Table 2 Mean sizes and number of aneurysms according to location

Anterior Circulation *n*	size/neck	37 (77%)
Cavernous	12.5/5.6 mm	8 (16.6%)
Carotid cave	5.3/3.2 mm	4 (8.3%)
Carotid-ophthalmic	5.8/3.4 mm	13 (27%)
Supraclinoid ICA	24.7/4.1 mm	1 (2%)
Anterior choroidal artery	3.1/1.8 mm	3 (6.2%)
Middle cerebral artery	5.8/3.6 mm	8 (16.6%)
Posterior circulation *n*		11 (23%)
Basilar trunk	7.5/4.8 mm	2 (4%)
Posterior communicating artery	7.6/4.2 mm	8 (16.6%)
Vertebral artery (V4 segment)	6.8/5.4 mm	1 (2%)

Table 3 p64 success rate implantation and complications

FD implantation	*n* (%)
Attempted treatment	48
FD implantation at target site	41 (85)
Intra-procedural complications	2 (5)
Thrombus formation	1
Incomplete opening of the stent	1
Permanent morbidity	0
Procedure-related mortality	0

Anatomical outcome

Occlusion rates in our study are in line with the previous series from Fischer et al. [9]. Both series are showing the progressive nature of the aneurysmal occlusion, leading to a high grade of total occlusion at 12 months. In our series, the occlusion rate at 3, 6, and 12 months were 66.6, 66.6, and 85.7%, respectively. In Fisher et al. [9], occlusion rates were 58.5% at 3 months, 87.7% at 9 months, and 85.7% at 16.5 months.

In our series, a careful anatomical evaluation of the intrastent stenosis and side branch occlusion was performed. Interestingly, the highest grade of the parent artery stenosis

Table 4 Occlusion grades at 3, 6 and 12 months

Occlusion	3 months *n* = 30 (%)	6 months *n* = 27 (%)	12 months *n* = 28 (%)
Complete occlusion	20 (66.6)	18 (66.6.)	24 (85.7)
Neck remnant	4 (13.3)	6 (22.2)	2 (7.1)
Sac remnant	4 (13.3)	2 (7.4)	2 (7.1)
Unchanged (includes stasis)	2 (6.6)	1 (3.7)	0

was found at 3 months, with a moderate stenosis of the parent artery in 13.7% (4/29) of cases. These stenoses gradually improved over time, with only mild stenoses being noted at 6 months and at 12 months. This phenomenon has previously been reported with other FD stent and even conventional stents [2, 3, 13]. Although the pathophysiological phenomenon and histological findings associated with these stenoses are still incompletely understood, our series brings additional data to highlight their regressive nature.

Last but not least, other significant modifications of arterial branches covered by the p64 stent were seen in this study including perforator occlusion, side branch stenosis, and flow reversal. These issues have already been described by several authors [14–16]. Fortunately, all of our patients remained asymptomatic but it highlights once again the need for a careful and long-term imaging follow-up in patients treated by FD stents placement.

Limitations

The major limitations of this work reside in its non-randomized nature, the relatively small patient population, and the absence of long-term follow-up.

Conclusion

The p64 FD seems to be an effective device for EVT of IAs. In our small case series, we observed a high occlusion rate with a low morbidity. The possibility to fully retrieve and redeploy the p64 FD is an advantage. Clinical and angiographic evaluations in a large multicentric prospective trial with long-term follow-up are encouraged.

Compliance with ethical standards We declare that all human and animal studies have been approved by the Erasme University Ethics Committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. We declare that due to the retrospective nature of this study, informed consent was waived.

Conflict of interest Hôpital Erasme received a Phenox educational grant.

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