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High-Profile Flow Diverter (Silk) Implantation in the Basilar Artery

Efficacy in the Treatment of Aneurysms and the Role of the Perforators

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Background and Purpose—The introduction of flow diverters (FDs) has expanded the possibilities for reconstructive treatment of difficult intracranial aneurysms. Concern remains as to the long-term patency of the perforating arteries and side branches covered during stent placement. Our purpose was to evaluate the performance of and early effect on covered branches after implantation of the Silk FD in the treatment of basilar artery aneurysms.

Methods—Twelve patients with an aneurysm of the basilar artery that was treated by implantation of the Silk FD were included in our retrospective study. Both unruptured and previously ruptured, formerly untreated, and recurrent aneurysms were treated. During follow-up, patients were monitored for clinical evolution, patency of the covered vessels, and aneurysmal obliteration.

Results—Of the 2 ruptured aneurysms, 1 was initially treated by FD implantation. The FD covered the basilar bifurcation and the origin of a P1 segment of the posterior cerebral artery in 9 cases, the origin of the superior cerebellar artery in 9, and of the anterior inferior cerebellar artery in 3. There was 1 acute basilar artery occlusion a few hours after FD implantation. During a mean follow-up of 16 weeks, 3 patients experienced a symptomatic neurologic event.

Conclusions—Implantation of the Silk FD in the basilar artery was feasible and well tolerated in most cases to date. However, late ischemic events affecting perforating arteries may occur after FD implantation, suggesting that the indication should be restricted to otherwise untreatable aneurysms in this location. (*Stroke*. 2010;41:1690-1696.)

Key Words: cerebral aneurysm ■ basilar artery ■ flow diversion ■ remodeling ■ perforators

The advent of flow diverter (FD) implants has provided an opportunity to treat intracranial aneurysms by vascular remodeling. FDs can alter aneurysmal inflow to the degree that progressive thrombosis and exclusion of the aneurysm from the circulation can be induced. Although long-term follow-up data are not yet available, there is accumulating experience in the treatment of aneurysms that have presented treatment difficulties or risk for recurrence when treated with currently recognized methods.¹⁻⁴

The use of such high-structural-profile implants raises the question of safety for perforators and side-wall branches covered by the device, especially because the mesh of available and approved FDs is much denser than that of conventional stents. Although data from animal experiments and preliminary human experience have shown that side branches covered by the FD remain open,^{1,5} this finding has not yet been verified in the basilar artery.

The aim of this study was to report the results from the first cases treated with an FD (Silk, Balt, Montmorency, France) for basilar artery aneurysms (Figure 1). The focus of the study was the patency of perforators and “jailed” arterial branches after deployment of the FD, as well as the efficacy of flow-diverting stents to cause persistent aneurysmal thrombosis.

Patients and Methods

Patients and Aneurysm Characteristics

This retrospective analysis includes the first 12 consecutive patients from 5 neurovascular centers treated for an aneurysm at the basilar artery with an FD during an 18-month period (Table). We excluded 2 patients with fusiform aneurysms involving the whole vessel circumference. The mean±SD age of the patients was 49±19 years and there were 9 women. The indication for Silk implantation was as follows: aneurysm regrowth after previous endovascular treatment(s) with stent and coils (n=3); broad-based aneurysms that were

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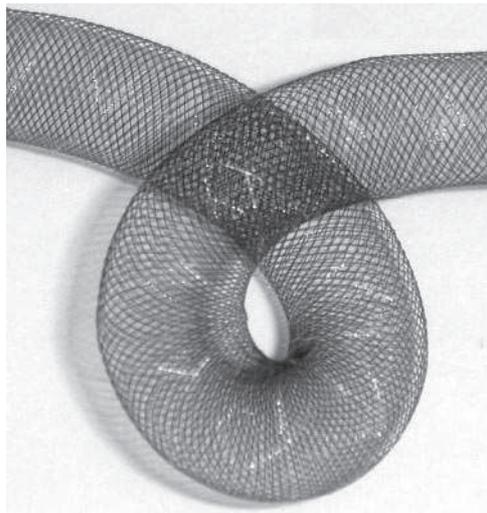


Figure 1. The Silk device.

symptomatic or considered at risk of rupture ($n=8$); and 1 very small (<2 mm), subacutely ruptured uncoilable aneurysm. All aneurysms were located at the basilar artery (basilar tip, $n=4$; basilar trunk, $n=6$; superior cerebellar artery, $n=2$). All aneurysms were recurring after previous treatments (Figure 2); were considered difficult to treat with currently accepted methods, like open neurosurgical clipping, and endovascular methods, like selective coiling or stent- and/or balloon-assisted coiling (Figure 3); or were considered as having a very high recurrence rate if treated with conventional endovascular modalities. To perform a reconstructive treatment, FD implantation was considered the best available option (Figure 4).

Aneurysm size ranged from 1.5 to 26 mm, with a median value of 10 mm. The aneurysms were symptomatic in 6 patients, in whom 2 presented with subarachnoid hemorrhage: in 1 patient subarachnoid hemorrhage occurred 20 days before treatment; the other patient was treated with conventional stent implantation and coil occlusion 14 months before Silk treatment and had a recurrence during follow-up. The remaining 4 patients presented with progressive compressive or ischemic brainstem or cranial nerve symptoms. In all other patients, the aneurysm was an incidental finding with an estimated high risk of future bleeding.

Device Description

The Silk FD is a flexible, self-expanding device specifically designed to produce a hemodynamic flow diversion and to reconstruct laminar flow in the parent artery. The device is a braided mesh cylinder with flared ends, composed of 48 nickel-titanium (nitinol) alloy and platinum microfilaments of $\approx 35 \mu\text{m}$. It is designed to provide 35% to 55% metal coverage of the target vessel's inner surface with a pore size of 110 to 250 μm at nominal diameter (Figure 1). Silk received CE mark in January 2008.

Patient Preparation

Patients were prescribed 75 mg clopidogrel QD together with 100 to 200 mg aspirin QD, both of which were administered at least 7 days before the procedure. When this was not possible, a loading dose of 600 mg clopidogrel was given.

Interventional Procedure

In this series, all patients were premedicated with a dual antiplatelet regimen 6 hours to 3 weeks before treatment. All procedures were done under general anesthesia, and heparin was given after insertion of the femoral sheath (intravenous bolus of 2000 to 5000 IU [International Units]). Before insertion into the hemostatic valve, the Silk delivery system was flushed at the distal end by using a 1-mL syringe containing pure heparin. The device was delivered to cover the whole length of the aneurysm and aligned to the normal

parent-vessel curvature. Additional coiling was performed in 6 aneurysms. In 2 cases, the microcatheter was jailed in the aneurysm by the FD, and aneurysm coiling was performed after FD placement. In 2 aneurysms, coils were implanted before FD placement, and in 2 additional cases, both before and after Silk deployment. In the 3 recurrent aneurysms pretreated with coils and a Neuroform (Boston Scientific, Natick, Mass) stent, the Silk FD was implanted through this preexisting stent. For further details of the materials used, see the Table.

Postprocedure Management

Clopidogrel (75 mg/d) and aspirin (100 mg/d) were administered for 3 months in the case of normal responders to these substances. In our practice, clopidogrel is then stopped and aspirin (100 mg/d) continued. All patients underwent brain imaging by magnetic resonance imaging (MRI)/magnetic resonance angiography (MRA) or computed tomography (CT)/computed tomography angiography (CTA) during their hospital stay.

Results

Silk Deployment Feasibility

The FD could be placed in a proper position across the whole length of the aneurysm in all patients. Only 1 device was implanted in all patients except in 1. In this case, after suboptimal opening of the first I was achieved, a second Silk and later, an Enterprise (Codman & Shurtleff Inc, Raynham, Mass) stent, was placed in a telescopic fashion in an attempt to achieve better remodeling.

Patency of Side Branches, Perforating Arteries, and Jailed Vessels

In all cases, the Silk FD covered at least one third of the basilar artery. The device was placed in the basilar trunk without reaching the basilar bifurcation or the vertebrobasilar junction in 4 patients. The basilar bifurcation was covered with the FD placed from the P1 segment of the posterior cerebral artery (PCA) to the basilar trunk in 9 cases. The origin of the anterior inferior cerebellar arteries was covered by the stent in 4 cases and of the superior cerebellar arteries (SCAs) in 9. At the end of the procedure, all angiographically visible vessels covered by the device were patent in all but 1 patient. In this patient, the P1 segment jailed by the device was no longer opacified from the vertebral artery injection immediately after device implantation; the PCA was immediately supplied by the carotid artery through the posterior communicating artery.

Aneurysm Occlusion Rate

One of the basilar bifurcation aneurysms and 1 aneurysm at the origin of the SCA treated with additional coil packing were completely excluded from contrast material inflow at the end of procedure. All remaining aneurysms showed some degree of filling after Silk FD implantation: immediate contrast material stagnation was observed inside the aneurysm in all cases except for 1 tiny aneurysm. Brain imaging by MRI/MRA and/or CT/CTA performed before discharge showed complete aneurysm occlusion in 5 of the 12 (42%) cases, 2 of whom received additional coil packing at the same session.

After discharge, during a mean follow-up of 16 weeks (range, 3 to 36 weeks), control imaging studies were available for 7 of 12 patients at different time intervals. In 2 of these

Table. Patient Demographics, Aneurysm Characteristics, and Treatment Details

Patient No.	Age, y (Sex)	Symptoms	mRS Before Treatment	Aneurysm Characteristics			Previous Treatment
				R/NR	Location	Maximum Diameter, mm	
1	51 (F)	Progressive brainstem compression syndrome	4	NR	Basilar trunk	20	
2	69 (F)	Recurrence after previous treatment	0	NR	Basilar tip	18	Neuroform and coils
3	17 (M)	Headaches	0	NR	Basilar trunk	8	
4	50 (F)	Recurrence after previous treatment, with progressive brainstem compression syndrome	4	NR	Basilar trunk	26	Neuroform and coils (twice)
5	42 (F)	Incidental finding after ischemic stroke	2	NR	Basilar trunk	10	
6	75 (F)	Right oculomotor nerve palsy	1	NR	SCA right	5	
7	8 (M)	Incidental finding with a history of tuberous sclerosis	0	NR	Basilar trunk	7	
8	49 (F)	Incidental finding after ischemic stroke of the medulla	0	NR	Basilar tip	5.5	
9	64 (F)	Subarachnoid hemorrhage	1	R	Basilar tip	1.5	
10	51 (F)	Previously ruptured aneurysm, with recurrence after former treatment, asymptomatic	0	R	Basilar trunk	19	Neuroform and coils
11	50 (M)	Incidental finding	0	NR	Basilar tip	14	
12	59 (F)	Incidental finding	0	NR	Basilar trunk–SCA left	3.5	

mRS indicates Modified Rankin Scale Score; R/NR, ruptured/nonruptured; AICA, anterior inferior cerebellar artery. Other abbreviations are as defined in text.

patients, the aneurysm was observed to be still filling at the 12- and 30-week follow-up CTA or digital subtraction angiography (DSA), respectively, and in another 2, there was a persistent neck remnant on the 6-week and 6-month follow-up MRI. In the remaining 3 cases, the aneurysm was occluded as proven by MRI or DSA. Two of these 3 patients had left the hospital with their aneurysm still not excluded, meaning that altogether, 7 of the 12 patients (58%) had had their aneurysm occluded in the short-term follow-up. In 5 patients, however, no follow-up imaging is yet available.

Complications

Thromboembolic complications during the Silk FD implantation procedure occurred in 1 patient who presented with a ruptured, uncoilable tiny aneurysm. In this patient, a loading dose of only 300 mg clopidogrel and 300 mg aspirin was given only 6 hours before aneurysm treatment. The reason for administering a relatively low loading dose only a few hours before treatment was that this aneurysm was ruptured and still unprotected. The Silk FD was then placed by reaching from the P1 segment of the right PCA to the midbasilar artery. Shortly after uneventful delivery of the device, a thrombotic occlusion of the left P1, right distal P1 segment, and left SCA was noted. Immediate local administration of the glycopro-

tein IIb/IIIa antagonist tirofiban via microcatheter led to rapid and complete recanalization of the vessel. The patient left the hospital in good clinical condition and without neurologic deficits.

In another patient, who had a basilar trunk aneurysm causing severe neurologic symptoms due to brainstem compression and ischemia, a Silk FD was placed in the basilar trunk to cover the aneurysm orifice. The device did not fully open at its proximal end during deployment; hence, balloon angioplasty was performed. Owing to enhanced proximal inflow into the aneurysm after percutaneous transluminal angioplasty, it was decided to insert another Silk and 1 Enterprise stent to reduce proximal aneurysmal inflow. Control angiography showed immediate reduction of blood flow into the aneurysm with almost complete contrast stasis. Twelve hours after the procedure, the patient became comatose and CT/CTA and MRI/MRA were performed, showing a previously known pontine infarct on the right and an additional small, thalamic ischemic lesion. Because luminal patency could not be evaluated, DSA was performed, which revealed complete occlusion of the basilar artery. Reperfusion was achieved with percutaneous transluminal angioplasty. The CT performed 15 hours later did not show any new infarcts. The patient remained intubated. MRI 5 days later

Table. Continued

Treatment Details			mRS at Latest Follow-Up	Aneurysm Occlusion During Follow-Up		
Additional Devices Applied	Jailed Major Branches	Complications		Modality	Occlusion Grade	Timing
Enterprise stent	AICA, SCA, and PCA	Stent thrombosis 12 hours after treatment	5	MRA	Occluded	At discharge
Coils	SCA and PCA	No	0	MRA	Neck remnant	At 23 weeks
None	None	No	0	MRA	Occluded	At discharge
Coils	AICA, SCA, and PCA	Thalamic infarct 7 months after treatment	4	MRA	Occluded	At 32 weeks
None	None	No	2	CTA, MRA	Occluded	At discharge
None	SCA and PCA	No	1	CTA, MRA	Sac filling	At 12 weeks
None	SCA and PCA	No	0	CTA	Sac filling	At 12 weeks
Coils	AICA, SCA, and PCA	Tiny thalamic infarct 4 weeks after intervention	0	MRA	Occluded	At discharge and at 4 weeks
None	SCA and PCA	In-stent thrombosis during treatment, resolving after thrombolysis	0	DSA	Occluded	At 12 weeks
Coils	AICA	No	0	CTA, MRA	Neck remnant	At discharge
Coils	SCA and PCA	Pontine infarct 5 weeks after treatment	3	DSA	Neck remnant	At 6 weeks
Coils	SCA and PCA	No	0	MRA	Occluded	At discharge

demonstrated no aneurysmal filling but extensive edema around the aneurysm in the brain stem. The patient’s clinical symptoms did not improve, and she was discharged to rehabilitation.

During the mean follow-up of 16 weeks (range, 3 to 36 weeks), 2 other patients had a thalamic ischemic lesion and 1 patient, a pontine ischemic lesion visible on MRI, accompanied by neurologic worsening. At the time of the event, 2 of

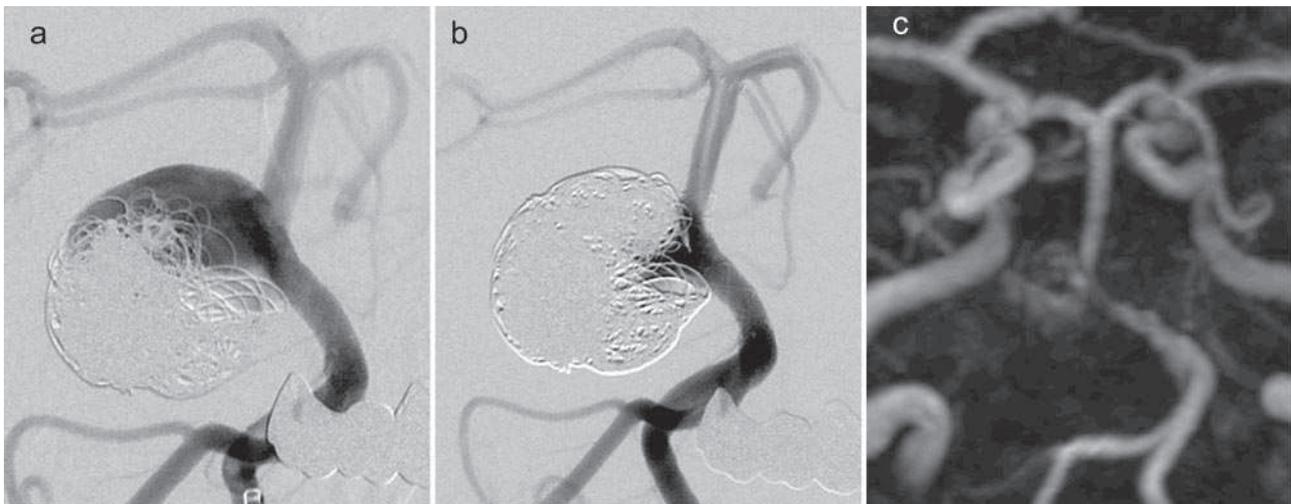


Figure 2. Patient 10. a, Slight posteroanterior-oblique view digital subtraction angiogram of a large basilar trunk aneurysm with a history of rupture, recurring after a previous treatment with Neuroform stent–assisted coiling. b, Immediate angiographic result after complementary coiling of the aneurysm followed by placement of Silk FD inside the formerly implanted Neuroform stent. c, Time-of-flight angiography performed before hospital discharge, demonstrating signs of residual filling of the neck remnant.

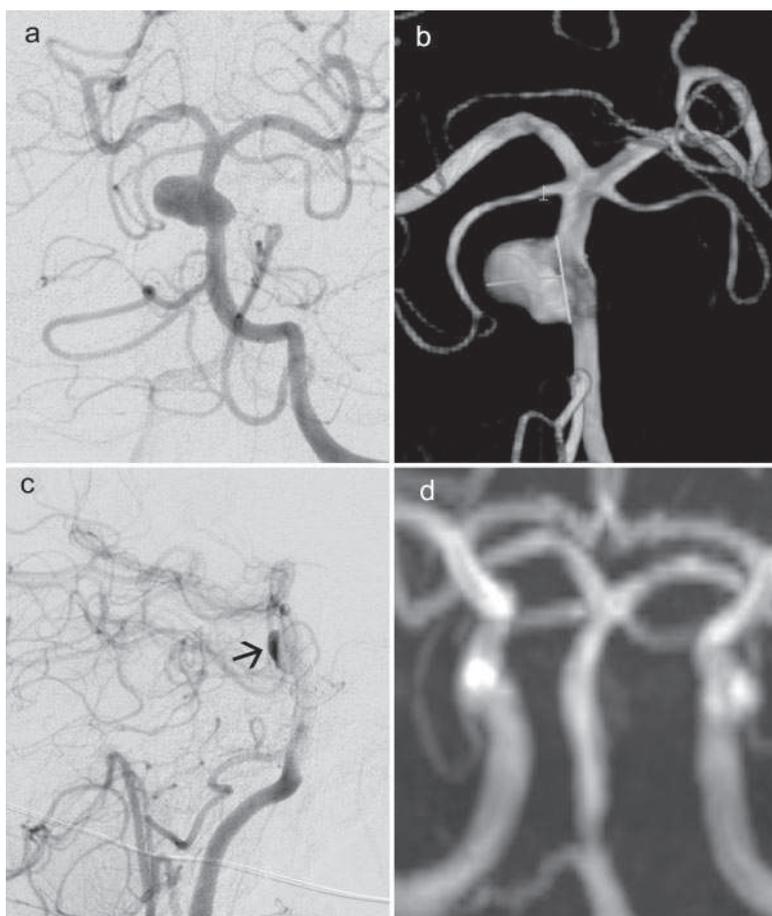


Figure 3. Patient 5. Broad-based aneurysm affecting the middle portion and major circumference of the basilar artery, posteroanterior view digital subtraction angiogram (a) and 3D reconstruction angiography. b, Treatment with an FD alone resulted in immediate contrast material stagnation in the aneurysm sac (arrow). Before discharge, time-of-flight MRA demonstrated complete occlusion of the aneurysm (d).

the patients were still receiving double antiplatelet therapy, and 1 was being treated with aspirin only. In 1 of them, the lesion causing transient diplopia was detected on MRI as being 2 mm in size in the left anteromedial part of the posterior thalamus 4 weeks after the procedure. The second patient developed a pontine infarct at the level of the proximal end of the stent 5 weeks after the procedure, resulting in swallowing disturbances. Laboratory tests showed a lack of response to aspirin in this case. In the third patient, a larger right lateral thalamic infarct developed 7 months after intervention, causing a transient worsening of her already severely disabled neurologic status caused by brainstem compression. This latter patient was taking 200 mg aspirin QD at the time of the thalamic infarct.

Discussion

The results of this small series of patients with basilar artery aneurysms treated with the Silk FD show that implanting a high-structural-profile stent in the posterior circulation is technically feasible.

With the advent of FDs, a very important endovascular tool became available to provide a step forward in the treatment of difficult intracranial aneurysms for which reconstructive treatment would otherwise be either difficult or even impossible, or the chance of recurrence after conventional therapeutic methods would be significantly high. A recent series of such treatment has shown that broad-based, nonsaccular, and

giant aneurysms were effectively treated with complete cure and vessel wall remodeling.¹⁻⁴ The vast majority of these aneurysms were located at the internal carotid artery. There are only a few reported cases of basilar artery aneurysms treated with the pipeline endovascular device,^{1,2,4} and to our knowledge, there are no publications dealing with the Silk FD in this location. Patients participating in this series (1) had already undergone a previous ineffective reconstructive treatment with conventional stents and coil occlusion and showed recurrence; (2) presented with severe compression and/or ischemic brainstem symptoms caused by a giant aneurysm; (3) had an aneurysm location and morphology that were predisposed to a high risk for recurrence; or (4) were judged that to achieve reconstructive treatment, an FD implantation was considered the best available option.

Jailed Branching Vessels and Perforators

The first and major concern of using a high-structural-profile device for vessel reconstruction in the basilar artery is the patency of the perforators. Although in a rabbit model it has been shown that branching vessels (the vertebral artery and lumbar arteries) covered by a high-mesh-density implant were patent on follow-up imaging and by histology,⁵ one should raise 2 obvious questions. First, were these covered branches patent all the time, or is there a possibility that they underwent transient occlusion and recanalization between the imaging periods, and how can one exclude the possibility of

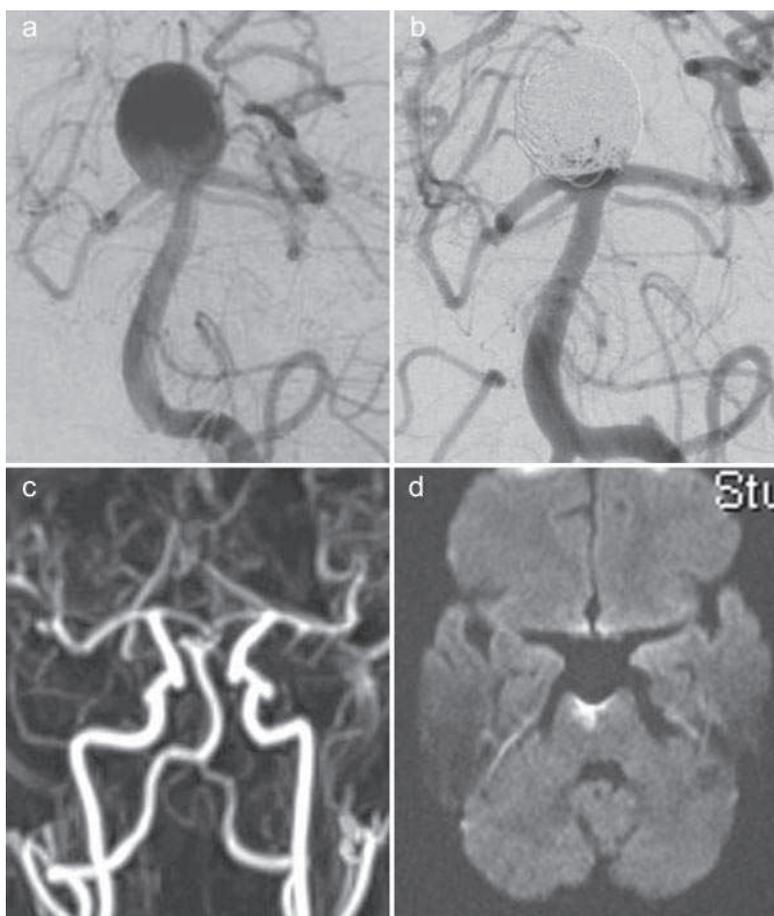


Figure 4. Patient 11. Posteroanterior digital subtraction angiogram of a broad-based aneurysm of the basilar bifurcation (a) treated with FD implantation and coil occlusion (b). c, Contrast-enhanced MRA performed before discharge, demonstrating a small residual neck. d, Diffusion-weighted MRI performed 5 weeks after treatment, showing an ischemic lesion of the pons, causing swallowing disturbances.

tiny emboli migrating from the surface of the device covering the orifice? In both cases, resulting infarcts might not be detectable in an animal model but might pose a severe clinical deficit in the human basilar artery. Second, although these branching vessels in the animal model may correspond in size to the larger branches of the basilar artery, the perforators are obviously much smaller and even barely visible on DSA. Therefore, assessment of permeability during and immediately after stent implantation might be impaired or impossible.

The FD covered at least one third of the basilar trunk in all cases in this series. One of the PCAs was jailed in 9, both SCAs in 9, and the anterior inferior cerebellar artery in 4. All of these branches remained patent throughout the follow-up period except for 1 jailed P1 segment that was no longer opacified on vertebral injection immediately after Silk FD implantation. One patient had a pontine infarct; in this case, the entire basilar artery was occluded, most probably as a result of maldeployment and incomplete opening of the FD. The lack of brainstem and cerebellar lesions and corresponding symptoms in the remaining patients suggests that the branches of the basilar artery, that is, the cerebellar branches, long pontine arteries, and perforating arteries, remained open immediately after FD implantation. Two patients presented during follow-up with small, symptomatic ischemic lesion of the thalamus, and 1 patient had a pontine infarct. In both patients with thalamic lesions, the FD was implanted starting

from the P1 segment down to the basilar trunk, and the infarcts developed on the side of the P1 harboring the FD. In 1 of these patients, the FD device was placed inside 2 previously implanted Neuroform stents.

Having a side branch of the parent artery occluded shortly after a high-profile FD implantation may occur by 2 mechanisms: the profile of the device either mechanically blocks the orifice of the side branch or narrows it to an insufficient size; or tiny thrombi form on the surface of the FD, which are then carried downstream by flowing blood. To assess the first possibility, we need to address the structural properties of the FD and the dimensions of the branching vessels. The Silk FD is composed of microfilaments of $\approx 35 \mu\text{m}$, and the pore size varies between 110 and 250 μm , very much depending on the final FD morphology and selection of the proper size adapted to the vessel diameter. The smallest branching arteries of the basilar trunk are the perforators, which tend to have a diameter in the range of 80 to 940 μm , with a mean value of $\approx 400 \mu\text{m}$.⁶ The interpeduncular perforating branches of the P1 segment of the PCA have a diameter in the range of 100 to 750 μm , with a mean value of 320 μm .⁷ These data suggest that in the worst case, when 2 filaments cross in front of a perforator with a diameter of 100 μm , this small artery will lose $\approx 55\%$ of its orifice area. Either this size may still be enough to provide sufficient blood flow to the affected areas, or the fact that these perforators have anastomotic connections in 50% of cases could also contribute to avoiding infarctions by occlusion.^{6,7}

Concerning late infarcts, as happened in 3 of our patients, neointimal overgrowth and progressive narrowing of the perforator's orifice, thus inducing insufficient perfusion, should also be considered as a potential causative factor. This process may have been enhanced in 1 of the cases by the 2 formerly implanted Neuroform stents. Because neointimal overgrowth is not yet controllable, our data suggest that both the effectiveness of and the patient's compliance with antiplatelet therapy need to be surveyed before treatment and during follow-up to minimize the risk of ischemic complications.

Aneurysm Occlusion Rates

The main objective of this work was to assess the role of branching vessels and perforators of the basilar artery when covered by a high-structural-profile FD device. Not all patients have yet undergone brain vascular imaging to assess aneurysm occlusion rates. From the available data, however, we conclude that 7 of 12 patients had their aneurysm occluded during short-term follow-up. To assess occlusion rates and the persistence of occlusion in the long term, continuation of follow-up is needed.

Conclusions

This series of patients who were treated with flow-diverting stents presented with aneurysms of the basilar artery that were either difficult to treat by conventional endovascular methods, had recurred after previous endovascular treatments, or were candidates for high recurrence rates and disease progression. Treatment of these aneurysms by FD implantation in the basilar artery was feasible and well tolerated in the vast majority of cases. Ischemic events affecting perforating arteries, however, may occur after FD implantation. This suggests that at this time, FD treatment of aneurysms of the basilar artery should be restricted to those patients who have lesions that are otherwise not amenable to standard reconstructive treatment or who have progressive

recurrence after previous treatments with current endovascular methods. Striking a balance between adequate antiplatelet treatment and the risk of bleeding remains problematic. Regarding aneurysm occlusion and vessel remodeling, the early follow-up results are encouraging, but long-term data are needed to assess occlusion and recurrence rates, the risk of bleeding, and intimal reactions.

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Disclosures

I. Wanke, Z. Kulcsar, and D.A. Rufenacht are contractual proctors for SILK FD implantation. The other authors report no conflicts of interest.

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