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Initial Experience with Surpass Evolve Flow Diverter in the Treatment of Intracranial Aneurysms

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Abstract

Background and Purpose The principle of flow diversion has revolutionized the treatment of brain aneurysms. In this study, we report our experience of the new Surpass Evolve (SE) flow diverter in the treatment of intracranial aneurysms.

Material and Methods Patients were treated with the SE as first-line therapy between May 2019 and June 2020 at 2 experienced institutions. Inclusion criteria were wide-necked, blister-like, or fusiform/dissecting aneurysms in the anterior and posterior circulation. Primary endpoint was technical success defined as favorable navigation to the target vessel and successful deployment of the SE. Secondary endpoints were favorable aneurysm occlusion defined as O'Kelly Marotta (OKM) scale C1-3 + D on follow-up, procedure-related complications and retreatment.

Results A total of 46 aneurysms in 42 patients were treated with 57 SE flow diverters. Median aneurysm size was 6.6 mm (IQR 4.0–12.2 mm) with a median neck width of 4 mm (IQR 2.2–5.4 mm). On admission, 6 (13%) aneurysms were ruptured and 41 (89%) were located in the anterior circulation. The primary endpoint was reached in 96%. Median follow-up was 116 days (IQR 92–134 days) and available for 36/46 (78%) aneurysms. Favorable aneurysm occlusion was seen in 31/36 (86%) aneurysms and 27/36 (75%) were occluded completely. Parent artery occlusion appeared in 3 (3%) patients on follow-up and 2 aneurysms (6%) required additional treatment due to insufficient closure.

Conclusion The new SE flow diverter is safe and seems to be effective with promising occlusion rates at short-term follow-up.

Abbreviations

AOR	Aneurysm occlusion rate
CT	Computed tomography
ICA	Internal carotid artery
IQR	Interquartile range
MRI	Magnet resonance imaging
mRS	Modified Rankin scale
OKM	O'Kelly Marotta
SAH	Subarachnoid hemorrhage
SE	Surpass Evolve
SS	Surpass Streamline

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Introduction

The use of flow diverters for intracranial aneurysms has introduced a new era of endovascular treatment. As the initial treatment approach was deployment of coils within the aneurysm sac, flow diversion enables exclusion of the aneurysm from blood circulation without intrasaccular manipulation. The blood flow is redirected in the parent artery away from the aneurysm and thereby inducing aneurysm thrombosis and reconstruction of the diseased artery segment [1]. Especially in patients with wide-necked and large aneurysms of the internal carotid artery (ICA), the efficacy of flow diversion was demonstrated with a sufficient safety profile [2–6]. Due to the promising results the use of

flow diverters is nowadays expanding to distal, non-saccular, ruptured, and posterior circulation aneurysms [7–9].

The Surpass Evolve (SE, Stryker Neurovascular, Kalamazoo, MI, USA) received CE mark approval in March 2019 and represents the next generation of flow diverters. It is based on the Surpass Streamline (SS), which received Food and Drug Administration approval in July 2018 due to the promising results of the Surpass intracranial aneurysm embolization system pivotal trial to treat large or giant wide neck aneurysms (SCENT) trial [5]. In comparison to the previous SS, the main characteristic of the SE is a lower profile consisting of 64 wires, which enables navigation through a 0.027″ microcatheter, while the high mesh density remains constant with a rhomboid cell shape. Based on a flow model the fine mesh design can be expected to engender a sufficient intra-aneurysmal flow stasis [10]. A preliminary in vivo experience with the SE was recently described by Orru et al. with a successful deployment in all 29 patients with a complete aneurysm occlusion rate of 57% after a follow-up of 4 months [11].

In this study, we present our two center experience of patients with intracranial aneurysms and report feasibility, efficacy, and safety profile of the new SE.

Methods

Settings, Participants and Design

In this two center study (each tertiary care centers treating >100 aneurysms per year during the last 5 years with a minimum experience of 50 flow diverter cases) 42 patients treated with SE flow diverter due to intracranial aneurysms were reviewed. The inclusion period was from May 2019 through June 2020. Aneurysmal characteristics, antiplatelet regimen, technical issues, complications, and clinical outcome were noted. The institutional databases were anonymized and analyzed retrospectively on an intention-to-treat basis. The major criterion was the use of SE flow diverter as first-line therapy in a wide necked aneurysm with neck ≥4 mm or a dome/neck ratio ≤2, blister-like, or fusiform/dissecting aneurysms. Non-ruptured and ruptured aneurysms located in the anterior and posterior circulation, pretreated aneurysms and cases with adjunctive treatment were included. Cases with additional use of other types of flow diverters during the procedure were excluded ($n = 1$). All indications were based on an interdisciplinary decision-making between neurosurgeons and interventional neuroradiologists. The choice of SE flow diverter for aneurysm treatment was left to the discretion of the operator. In both centers the SE was not exclusively used for endovascular aneurysm treatment during the whole study period. The additional use of coils was decided by each operator and dependent of aneurysm size. In patients with evidence of hydrocephalus, an external ventricular drainage was inserted before endovascular treatment. Technical success was the primary endpoint of the study and defined as favorable navigation to the target vessel and successful deployment of the flow diverter. Secondary endpoints were a favorable aneurysm occlusion defined as O'Kelly Marotta (OKM) scale C1-3 + D on follow-up series [12] and occurrence of procedure-related complications and retreatment. An incomplete occlusion was defined as OKM A1–B3 on patient's final follow-up angiogram. All procedural complications were reported regardless of their clinical significance. Cross-sectional imaging using computed tomography (CT) or magnet resonance imaging (MRI) was regularly performed within the first 24 hours. According to the guidelines of the respective local ethics committees, no approval was necessary for this anonymous retrospective study, which was conducted in accordance with the Declaration of Helsinki. All patients signed an informed consent at least 24 hours prior to the procedure except from procedures in the acute setting of a subarachnoid hemorrhage (SAH).

Surpass Evolve Flow Diverter

The characteristics of the SE device are described previously [11]. Briefly, the SE flow diverter is the successor model of the SS and differs in some points from the first iteration. Available SE sizes range from 2.5 mm to 5 mm diameter with lengths between 10 mm and 40 mm. The SE sizes between 3.25 mm and 5 mm diameter consist of 64 wires and exhibit higher braid angles with a rhomboid cell shape, which enables the maintenance of the mesh density of 15–30 pores/mm^2 although thickness of each wire is decreased. A lower profile enables advancement of the device through a dedicated 0.027″ microcatheter with easier navigation and deployment avoiding the need for distal navigation of an intermediate catheter than with its predecessor.

Procedure

Patients undergoing elective SE flow diverter therapy received double antiplatelet medication (75 mg/day clopidogrel, 100 mg/day aspirin) starting 5 days prior to the intervention and maintained for 3 months after treatment, followed by continuous aspirin therapy for life. Platelet function tests were routinely performed using aspirin and P2Y12 assays (Multiplate Analyzer, Roche, Basel, Switzerland). A platelet inhibition level between 30–90% for clopidogrel and 350–550 response units for aspirin was defined as acceptable. Poor response to clopidogrel was either counteracted by dose escalation (e.g. clopidogrel 150 mg/day)

or switched to prasugrel (40 mg loading dose, 5 mg/day). Weight-adjusted administration of eptifibatide was given intraoperatively in patients with ruptured aneurysms before flow diverter placement for 24 hours followed by double antiplatelet medication. A bolus of heparin (5000 IU) was administered after groin puncture in all cases.

All procedures were performed with the patient under general anesthesia. Femoral access was obtained with a short 8F femoral sheath. Three-dimensional rotational angiography was executed in all patients for the determination of the ideal working projection. All SE flow diverters were deployed through a dedicated 0.027″ microcatheter (Excelsior XT, Stryker Neurovascular) using a triaxial guide-catheter system applying a push-pull technique and aiming a maximum mesh density across the aneurysm neck with a proper wall adaptation of the SE. The number of flow diverter deployed was left to the operator's discretion. Overlapping multiple SE flow diverter implantation was typically conducted in fusiform aneurysms.

Follow-up was performed regularly by digital subtraction angiography at 3 and 12 months after treatment. If the patient declined angiography, cross-sectional imaging was performed instead. An occlusion of the aneurysm on computed tomography (CT) angiography or magnet resonance imaging (MRI) was graded as OKM D. Occurrence of intimal hyperplasia during follow-up was defined as any lumen loss within the implanted SE. Angiographically, this appeared as a gap between the contrast filled vessel lumen and the inner contour of the SE. When there was no such appearance, there was no evidence of angiographic intimal hyperplasia. Intimal hyperplasia was graded as mild (<50%), moderate (50–75%), or severe (>75%) [13]. The clinical outcome was established by a consultant neurosurgeon at the time of discharge and the follow-up angiography using modified Rankin scale (mRS).

Results

Patient Demographics and Aneurysm Characteristics

A total of 42 patients harboring 46 intracranial aneurysms were treated in both institutions during the study period of 14 months. Median patient age was 58 years (range 28–84 years). Median aneurysm size was 6.6 mm (IQR 4.0–12.2 mm) with a median neck width of 4 mm (IQR 2.2–5.4 mm), 12 aneurysms were ≥10 mm (26%) and 39 (85%) aneurysms exhibited a dome/neck ratio ≤2. Mor-

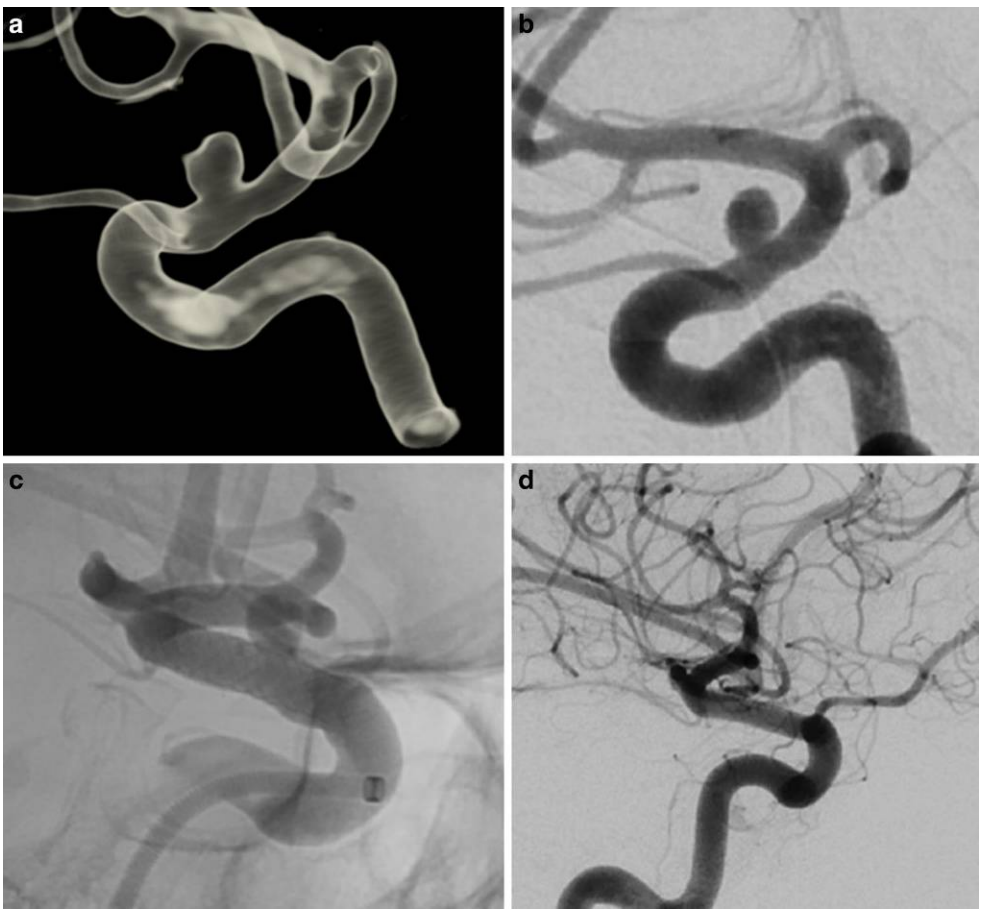

Fig. 1 **a**, **b** A 39-year-old patient with an incidental paraophthalmic internal carotid artery aneurysm on 3D rotational angiography (**a**) and on oblique view (**b**). **c** A Surpass Evolve flow diverter (3.25 × 15 mm) is placed over the aneurysm neck with adequate wall apposition without the use of a compliant balloon. **d** In the follow-up angiography after 3 months the aneurysm is completely occluded

Table 1 Individual overview of patient's baseline, aneurysm, procedural, and follow-up characteristics

Sex	Age (years)	Location	SAH	Aneurysm type	Dome/ neck ratio	Technical success	SE size (mm)	Adjunctive treatment	Angiographic follow-up (days)	Follow-up OKM	Last mRS	Parent artery occlusion	Retreatment
F	63	Terminal ICA Paraophthalmic ICA	*N*	Saccular Saccular	1.3 1.1	Y N	4 × 17 4.5 × 20	Stent –	– –	– –	0	– –	*N* –
F	60	Paraophthalmic ICA	*N*	Saccular	1.9	Y	4.5 × 30	–	–	–	0	–	*N*
F	49	Cavernous ICA	*N*	Saccular	1.38	Y	4.5 × 20	–	106	D	0	*N*	*N*
M	28	Paraophthalmic ICA	*N*	Fusiform	–	Y	5 × 40	–	96	C2	0	*N*	*N*
F	61	Paraophthalmic ICA	*N*	Saccular	2.13	Y	4.5 × 20	Coils	–	–	0	–	*N*
F	72	Paraophthalmic ICA	*N*	Saccular	1.43	Y	4 × 17 4 × 20	–	96	D	0	*N*	*N*
M	61	Paraophthalmic ICA	*N*	Saccular	2.65	Y	5 × 30	–	138	C3	0	*N*	*N*
F	56	Paraophthalmic ICA	*N*	Saccular	2.00	Y	4 × 17	Coils	155	D	0	*N*	*N*
F	60	Paraophthalmic ICA	*N*	Saccular	1.82	Y	4 × 30	Coils	90	D	0	*N*	*N*
F	69	Paraophthalmic ICA	*N*	Saccular	1.65	Y	4.5 × 30	Coils	–	–	0	–	*N*
M	42	Cavernous ICA	*N*	Saccular	1.17	Y	4 × 20	Coils	117	D	0	*N*	*N*
F	71	Paraophthalmic ICA	*N*	Blister	–	Y	4.5 × 20	–	92	D	0	*N*	*N*
F	80	Cavernous ICA	*N*	Fusiform	–	Y	5 × 25 5 × 15	–	66	B3	0	*N*	*N*
F	81	Cavernous ICA	*N*	Saccular	1.35	Y	5 × 25	–	92	B3	0	*N*	*N*
F	45	Cavernous ICA	*N*	Saccular	1.13	Y	4 × 20	–	90	D	0	*N*	*N*
F	71	Paraophthalmic ICA	*N*	Saccular	1.8	Y	5 × 25	–	92	D	0	*N*	*N*
F	51	Paraophthalmic ICA	*N*	Saccular	3.23	Y	4.5 × 17	Coils	105	D	0	Y	*N*
M	39	Paraophthalmic ICA	*N*	Saccular	1.03	Y	3.5 × 15	–	99	D	0	*N*	*N*
F	51	Communicating ICA	*N*	Saccular	1.73	Y	4 × 17	Coils	77	D	0	*N*	*N*
F	63	Paraophthalmic ICA	Y	Blister	2.6	Y	4 × 20	–	–	–	1	–	*N*
F	63	Paraophthalmic ICA	*N*	Saccular	2.27	Y	4 × 20	–	120	D	0	Y	*N*

Table 1 (Continued)

Sex	Age (years)	Location	SAH	Aneurysm type	Dome/neck ratio	Technical success	SE size (mm)	Adjunctive treatment	Angiographic follow-up (days)	Follow-up OKM	Last mRS	Parent artery occlusion	Retreatment
F	46	Paraophthalmic ICA	*N*	Saccular	1.72	Y	4 × 20	–	115	D	0	*N*	*N*
M	35	Paraophthalmic ICA	*N*	Saccular	1.00	Y	5 × 20	Coils	385	D	0	*N*	*N*
F	44	VA	*N*	Fusiform	–	Y	5 × 20, 4 × 15	–	101	B1	0	*N*	N
		VA		Fusiform	–	Y	3.25 × 20	–		D			N
F	84	Paraophthalmic ICA	*N*	Saccular	1.38	Y	5 × 25	Coils	180	D	0	Y	*N*
M	55	Paraophthalmic ICA	Y	Saccular	2.14	Y	5 × 25, 5 × 25	Coils	8	D	6	N	N
		Paraophthalmic ICA		Saccular	0.92	Y	5 × 20	Coils		C2		N	N
F	71	Paraophthalmic ICA	Y	Blister	1.00	Y	4 × 20	–	240	A2	1	*N*	Additional FD
M	63	Paraophthalmic ICA	*N*	Saccular	0.98	Y	4.5 × 20	–	120	D	0	*N*	*N*
F	76	BA	Y	Fusiform	–	Y	5 × 25, 5 × 25, 5 × 20, 5 × 20	–	–	–	1	–	*N*
F	54	VA	Y	Fusiform	–	Y	3.25 × 15	–	120	D	0	*N*	*N*
F	78	Paraophthalmic ICA	*N*	Saccular	3.74	Y	3.25 × 15	Coils	90	D	0	*N*	*N*
M	57	Paraophthalmic ICA	*N*	Fusiform	–	Y	5 × 20, 5 × 20, 5 × 25, 5 × 25	–	135	A2	0	*N*	Additional FD
F	51	Petrosal ICA	*N*	Dissecting	–	Y	5 × 30, 5 × 25	Coils	80	D	0	*N*	N
		Paraophthalmic ICA		Dissecting	–	Y	5 × 40	Coils	–	–		–	N
F	62	MCA	*N*	Saccular	0.53	Y	2.5 × 15	–	140	C2	0	*N*	*N*
F	37	Paraophthalmic ICA	Y	Blister	1.00	Y	4 × 20	–	150	D	2	*N*	*N*
F	70	Paraophthalmic ICA	*N*	Saccular	1.89	*N*	4.5 × 20	Coils, stent	130	D	0	*N*	*N*
F	63	Cavernous ICA	*N*	Saccular	1.53	Y	5 × 30, 5 × 25	–	130	D	0	*N*	*N*
M	52	VA	*N*	Fusiform	–	Y	5 × 40, 5 × 20	Coils	120	D	0	*N*	*N*
F	30	Paraophthalmic ICA	*N*	Saccular	1.00	Y	4 × 15	–	100	D	0	*N*	Angioplasty
F	58	Cavernous ICA	*N*	Fusiform	1.36	Y	5 × 20	–	–	–	0	–	*N*
F	58	Paraophthalmic ICA	*N*	Fusiform	–	Y	4.5 × 40, 5 × 30	Coils	–	–	1	–	*N*
M	37	Paraophthalmic ICA	*N*	Saccular	1.04	Y	5 × 20	–	180	D	0	*N*	*N*

BA Basilar artery, *FD* Flow diverter, *ICA* Internal carotid artery, *mRS* Modified Ranik Scale, *OKM* O'Kelly Marotta Scale, *SAH* Subarachnoid hemorrhage, *SE* Surpass evolve, *VA* Vertebral artery

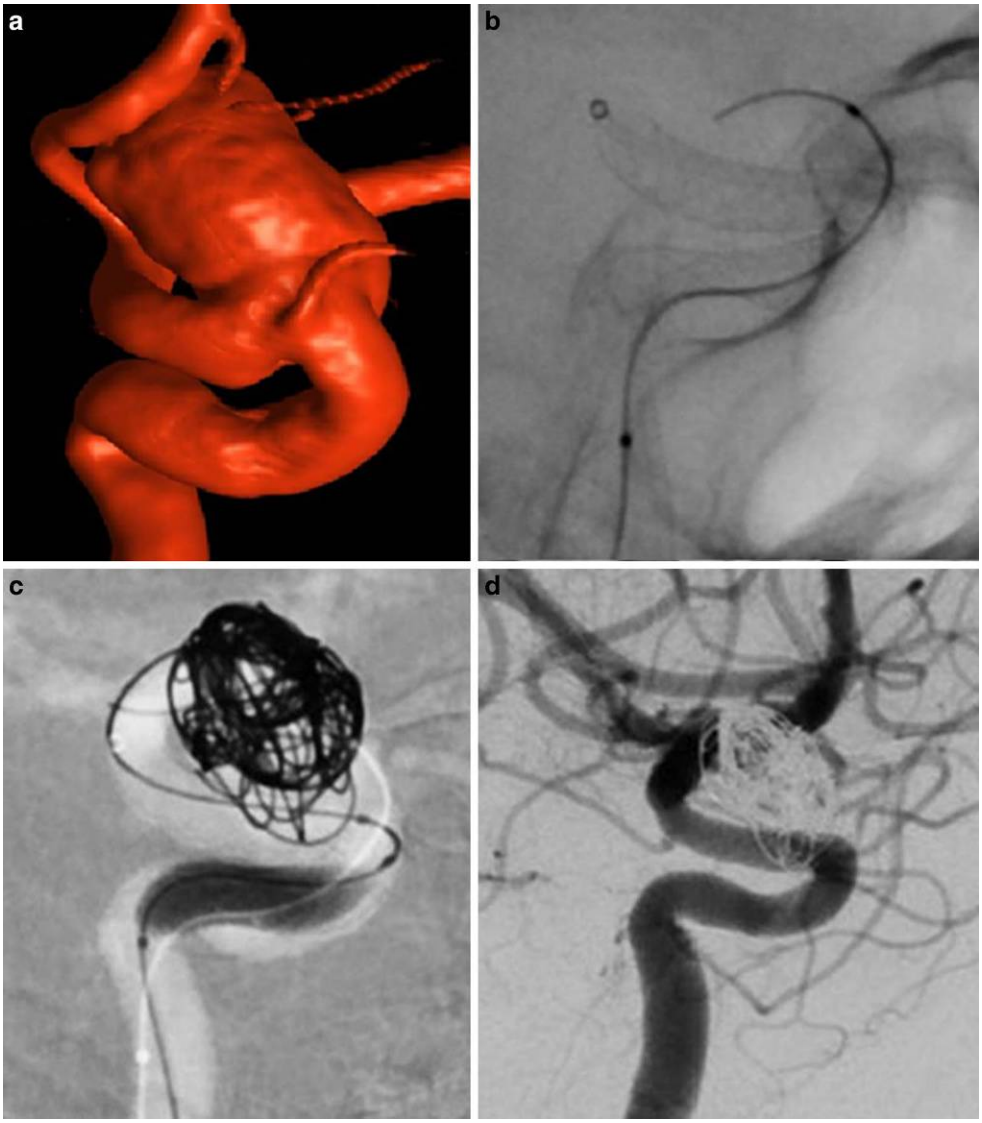

Fig. 2 **a** Three-dimensional rotational angiography presenting a paraophthalmic internal carotid artery aneurysm in a 61-year-old patient causing blurred vision. **b** Placement of a 4.0 × 30 mm Surpass Evolve flow diverter after jailing of an Excelsior SL 10 microcatheter, lateral view. **c** Loose coiling of the aneurysm followed by a wall adaption of the Surpass Evolve flow diverter at the proximal segment with a Scepter C balloon, lateral view. **d** 3-month follow-up angiography with complete occlusion of the paraophthalmic aneurysm and a regular reconstruction of the internal carotid artery, lateral view

phologically, 30 (65%) aneurysms were saccular, 10 (22%) were fusiform, 4 (9%) were blister, and 2 (4%) were dissecting aneurysms. Most of the aneurysms (41/46, 89%) were located in the anterior circulation and 6 (13%) patients presented with baseline SAH. The Hunt and Hess scale on admission was 4 in 1 (17%) patient, 3 in 1 (17%) patient, 2 in the remaining 4 (66%) individuals and 7 (17%) patients suffered from cranial nerve palsy with visual disturbances. The individual overview about baseline, aneurysm and procedural characteristics is shown in Table 1.

Procedural Results

The primary endpoint was reached in 96% (Fig. 1). A total of 57 SE flow diverters were implanted, of those 35 (76%) aneurysms were treated with a single SE. Average number of SE used was 1.2 ± 0.6. In 12 (26%) aneurysms, a mild wall adaptation was done by the use of a compliant balloon and 27 (59%) aneurysms underwent endovascular treatment using the SE flow diverter exclusively, meaning no adjunctive techniques were applied. In 17 (37%) aneurysms, an additional coil placement was executed (Fig. 2). In one (2%) patient with a terminal ICA aneurysm, the deployment of SE was successful, but the operator decided to implant an additional braided stent (LVIS EVO, Microvention, Aliso Viejo, CA, USA) at the distal portion to be assured to cover the aneurysm neck completely. In two (5%) patients, deployment of SE was unsuccessful; one patient suffered from a non-ruptured aneurysm at the ophthalmic segment of the internal carotid artery (ICA). The SE was navigated successfully to the target lesion, but during the deployment process the flow diverter foreshortened and the proximal part dislocated into the aneurysm sac. By implantation of a self-expanding laser cut nitinol stent (Neuroform Atlas, Stryker) the SE was stabilized and the aneurysm was occluded completely in follow-up angiography. In another pa-

tient with a paraophthalmic ICA aneurysm the deployment of the SE was unsatisfactory within the carotid siphon due to tortuous vessel anatomy, so the operator decided to remove the SE and implanted an intrasaccular flow diverter.

Procedure-related complications occurred in one (2%) patient. In this case, two SE flow diverter were implanted due to a huge, non-ruptured fusiform paraophthalmic ICA aneurysm. Although platelet inhibition was sufficient on baseline testing, an acute in-stent thrombosis was detected on final angiogram, which was successfully treated by thromboaspiration. Tirofiban was given intraoperatively and the medicinal regimen was switched to ticagrelor. The patient was discharged without neurological symptoms. The patient presented again 2 weeks later with an acute in-stent thrombosis, which made a further thrombectomy procedure necessary. The patient was discharged with an mRS of 1 and the medication was switched to prasugrel.

Clinical Outcome

In-hospital mortality was 2%. One patient presented with SAH on admission due to bilateral, intradural ICA aneurysms. As the bleeding source could not be clearly determined both aneurysms were successfully treated with SE in one procedure. No rebleeding occurred, but the patient died 10 days later as a consequence of SAH and vasospasms. All other patients (including five patients with ruptured aneurysms) were discharged with an excellent clinical outcome (mRS <2). Device-related mortality was 0%. Minor and transient neurological complications were observed in four (10%) patients: three individuals showed punctuate infarctions on postinterventional MRI without neurological symptoms and one patient with a huge aneurysm of the paraophthalmic ICA suffered from headache for 3 weeks after the intervention.

Angiographic and Clinical Follow-up

The median follow-up was 116 days (IQR 92–134 days). Angiographic and clinical follow-up was available for 34/42 (81%) patients and 36/46 (78%) aneurysms, respectively. Digital angiography was done in 27 (79%) patients, 4 (12%) patients received MRI and 3 (9%) CT angiography. Complete occlusion (OKM D) was achieved in 27 (75%) aneurysms and 31 (86%) aneurysms showed a favorable occlusion result (OKM C1-3 + D). No delayed aneurysm rupture occurred. Aneurysm retreatment was necessary in two (6%) patients due to insufficient closure with implantation of an additional flow diverter. One patient suffered from ongoing cranial nerve (III) palsy due to a fusiform paraophthalmic ICA aneurysm, which was treated initially with four SE flow diverters. An additional SE was implanted and the patient reported slight improvement of the visual symptoms at discharge. The other patient was treated in the acute phase of a ruptured blister-like ICA aneurysm with a single SE flow diverter and was successfully retreated due to insufficient closure with another flow diverter type (p64, Phenox, Bochum, Germany). In 4/34 (12%) patients, intimal hyperplasia within the SE was detected, which was treated with a drug-eluting balloon and an additional Neuroform Atlas stent in one case. This 30-year-old patient did not show any neurological deficits during follow-up, but due to the filiform narrowing at the distal end of the SE (>75%) with hemodynamic significance and the young age the operators decided on treatment. The other three patients showed mild stenosis and were left on dual antiplatelet therapy and are still under further observation. Three (9%) patients showed an occlusion of the parent ICA during follow-up without any neurological sequelae. All of them exhibited sufficient platelet inhibition on admission, but one patient meanwhile had discontinued dual antiplatelet medication independently. Visual symptoms had improved in two out of three (67%) patients on follow-up.

Discussion

In this study we examined the feasibility, efficacy, and safety profile of the new SE flow diverter in the treatment of intracranial wide-necked aneurysms. The high technical success rate of 96% in our study reflects the described optimization of the SE profile with easier navigation and deployment through a redesigned delivery system. This is comparable to the Pipeline flow diverter in the Prospective Study on Embolization of Intracranial Aneurysms with the Pipeline Device (PREMIER) study (99%) and to FRED in the Safety and efficacy Analysis of FRED Embolic device in aneurysm treatment (SAFE) study (95%) [4, 6]. In all cases except one the SE could be successfully deployed without occurrence of twisting, which might be due an increased radial pressure. As with the predecessor a distal-to-aneurysm navigation with an intermediate catheter was often necessary to ensure a smooth navigation of the stiff SS delivery system, the SE can mostly be delivered gently through a 2.7F microcatheter to the desired site. The improvement of navigability can be attributed to a lower flow diverter profile, which is based on a reduced number of wires than with the predecessor and a redesigned delivery wire.

The use of a compliant balloon for additional SE adaptation in 26% can be explained by a regular step in this situation as assessment of wall adaption with intraprocedural Dyna-CT is often not performed routinely in the participating institutions. This is slightly higher to the post-dilatation rate of 19% due to insufficient SS deployment in the multicenter study of Wakhloo et al. [14]. As previ-

ously mentioned [11], the implant foreshortens more than the predecessor, which led to dislocation of the SE into the aneurysm sac in one case with the need of a further Neuroform Atlas stent implantation.

The aneurysm occlusion rate (AOR) at approximately 3-month follow-up is promising in our cohort with complete occlusion in 75% of cases. This is comparable to the described AOR of 78% in the meta-analysis of Ye et al. after 6 months, who included various types of flow diverters [15]. In direct comparison to the predecessor SS, it can be assumed that the performance of the SE will be a similarly promising as the rate of complete AOR was 75% after 6 months in the multicenter study of Wakhloo et al. [14] and 62.8% after 12 months in the SCENT trial [5]. In comparison to the 4-month AOR of 57% in the first SE experience study of Orru et al. our rate is higher [11]. This has to be interpreted with caution as both cohorts were small and the rate of adjunctive treatment in their study was lower (16% vs. 39%); however, our rate of digital angiography on follow-up was considerably higher with 79% vs. 27%, which enables a more accurate assessment. Furthermore, our occlusion rate is almost identical to the 12 months complete AOR of 2 prospective studies: in the PREMIER study, the AOR was 76.8% using the Pipeline flow diverter, but use of adjunctive coiling was lower with 4% [6]. In the SAFE study, the AOR was 73.3% by using FRED and FRED Jr. flow diverters with an adjunctive use of coils and intrasaccular flow diverter in 25% of cases [4]. Characteristics of the treated wide-necked aneurysms in our study were comparable to the aforementioned studies with a median aneurysm target size of 4.6 mm (PREMIER) and a rate of small aneurysms (<10 mm) in 69% (SAFE). A promising flow diverting effect of the SE was recently shown in an in vitro study that demonstrated superior flow diversion effect of SE over the Pipeline Flex stent [16]. This might be due to the greater pore density and higher braid angles with a higher number of wires (64 vs. 48) compared to Pipeline Flex; however, it should be highlighted that so far no any human data exist that support this hypothesis.

Similar to the experience of Orru et al. [11], one patient suffered from an acute in-stent thrombosis despite sufficient platelet inhibition. As the patient presented again with an acute in-stent thrombosis after switch to ticagrelor, the presence of a coagulation disorder is conceivable. Furthermore, it is to mention that two patients (6%) with sufficient platelet inhibition testing and ongoing medication intake after the procedure showed parent artery occlusion at follow-up. This is comparable to the 6-month parent artery occlusion rate in the SAFE study (4.3%) [4]; however, other flow diverter studies did not report any parent artery occlusion during follow-up [2, 17]. If this is based on the flow diverter properties (including the number of used wires) needs to be evaluated in further studies. Further source of local thrombotic complications might be found in the duration and monitoring of the antiplatelet medication. Factors influencing the responsiveness to clopidogrel and aspirin, such as drug interactions, bioavailability, diabetes, smoking, and age might be inconsistent among patients and change during the follow-up interval. The rate of severe intimal hyperplasia in our study (3%) was comparable to other flow diverter stent studies reported in the literature that ranged from 3% to 5% [4–6, 13, 14]. In direct comparison to the initial SE experience of Orru et al. the rate of minor neurological complications was slightly lower with 10% vs. 20% and no device-related, major neurological complications were noticed (vs. 4% in Orru et al.) [11]; however, it is to mention again that the cohorts were too small and heterogeneous to allow a distinct comparison between both studies.

A limitation of our study is the retrospective design with the expected selection bias. Furthermore, the relatively small sample size, heterogeneity and the absence of a control group limits the validity of the data. Occlusion rates were self-assessed and results might be less favorable after core laboratory adjudication. Nevertheless, this study included the largest number of SE cases so far.

Conclusion

The new Surpass Evolve flow diverter seems to be effective with a favorable navigability and deployment profile. The short-term occlusion rate is promising; however, the efficacy of aneurysm occlusion has to be validated on long-term follow-up studies.

Conflict of interest V. Maus, W. Weber, A. Berlis, C. Maurer and S. Fischer declare that they have no competing interests.

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