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The Pipeline Endovascular Device versus the Flow Re-Direction Endoluminal Device for Cerebral Aneurysm. A One-Year Follow-up in a Single-Center Experience

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Abstract

Background: The Flow Diverters are devices derived from brain stents, made up of a network of microfilaments of various materials that allow the vessel remodeling. The Pipeline Embolization Device and The Flow Re-Direction Endoluminal Device are the two devices with more global clinical experience. Our objective is to compare the 1-year results using these devices in a cohort of patients assessing their occlusion rate and their clinical outcome as by the modified Rankin Score (mRS).

Methods: In this retrospective nested case-control cohort study, we reviewed the medical records of patients undergoing treatment with a Flow Diverter stent for brain aneurysms with a 1-year follow up. We considered the following inclusion criteria: patients between 18 and 80 years of age, with at least one cerebral aneurysm and aneurysms in the segments of the internal carotid artery and vertebral arteries. We recorded the clinical presentation as subarachnoid hemorrhage, headache, mass effect, transient ischemic attack, family history, and incidentals. Demographic data, topography, quantity, and lateralization of all aneurysms were collected.

Results: A total of 91 patients were included in the final analysis. The 6-month occlusion rate was 91.5% for PED and 95.7% for FRED 95.7% (*p* 0.597); and at 12 months it was 95.7% for PED and 97.7 for FRED (*p* 0.555). In pairing the propensity score (PPS) the complete occlusion rate was 90% for PED and 100% for FRED, without statistical significance in the difference at 12 months (*p* 0.631).

Conclusion: Flow diversion devices PED and FRED are an efficient treatment for aneurysms of the anterior circulation and some of the posterior circulation (vertebral arteries), showing similar occlusion rates and clinical outcomes.

Visual Abstract

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VISUAL ABSTRACT

The Pipeline Endovascular Device Versus the Flow Re-direction Endoluminal Device for Cerebral Aneurysm. A One-year Follow-up in a Single-center Experience, Pichardo O. et al, *Archives of Neurosurgery*, 2021, Issue I, Volume I, Pag 53-60.

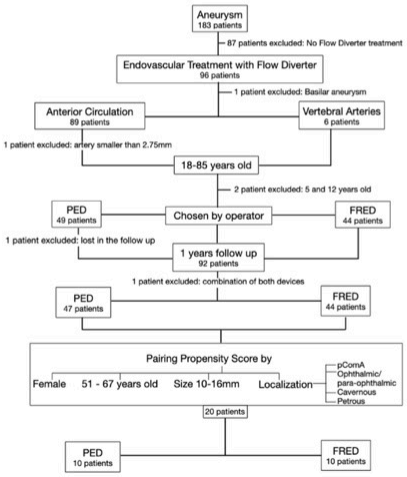

Table 3. Propensity score matching results.

	PED = 10		FRED = 10		
Gender					
Female	10		10		
Age	59 (8)		56 (11)		0.835
Num. Aneurysms	10		10		
Size. Aneurysms	12 (3)		13 (3)		0.190
Clinical Presentation					0.095
Incidental	5	50	5	50	
Headache	4	40	5	50	
Familiar History	1	10	0	0	
Parent Vessel Localization					0.278
pComA	1	10	4	40	
Ophthalmic/para-ophthalmic	3	30	3	30	
Cavernous	3	30	2	20	
Petrous	3	30	1	10	
Side					0.404
Left	7	70	6	60	
Right	3	30	4	40	
Occlusion (12 months)	9	90	10	100	1
Complications		0		0	
Neurological	1	10	0	0	0.331
Non-neurological					0.335
mRS (90 days)					
0	9	90	10	100	
1	0	0	0	0	
2	0	0	0	0	
6	1	10	0	0	

The Pipeline Embolization Device and The Flow Re-Direction Endoluminal Device are the two devices with more global clinical experience, this report compares their occlusion rate and the clinical outcome (mRS) in 1-year follow-up in 91 patients. Flow diversion devices PED and FRED are an efficient treatment for aneurysms of the anterior circulation and some of the posterior circulation (vertebral arteries), showing similar occlusion rates and clinical outcomes between them.

Keywords

Aneurysm, Endovascular therapy, occlusion rate, Flow Diverter, PED, FRED, embolization

Cover Page Footnote

Our thanks to Dr. Edgardo Ruiz, Head of Department, for always supporting us and allowing us to keep reaching the state-of-the-art.

Authors

Omar Pichardo, Alan Picazo, Omar Castillon, Jonathan Zuniga, and Gustavo Alan Juarez Jimenez

The Pipeline Endovascular Device Versus the Flow Re-direction Endoluminal Device for Cerebral Aneurysm. A One-year Follow-up in a Single-center Experience

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Abstract

Background: **The Flow Diverters are devices derived from brain stents, made up of a network of microfilaments of various materials that allow the vessel remodeling. The Pipeline Embolization Device and The Flow Re-Direction Endoluminal Device are the two devices with more global clinical experience. Our objective is to compare the 1-year results using these devices in a cohort of patients assessing their occlusion rate and their clinical outcome as by the modified Rankin Score (mRS).**

Methods: **In this retrospective nested case-control cohort study, we reviewed the medical records of patients undergoing treatment with a Flow Diverter stent for brain aneurysms with a 1-year follow up. We considered the following inclusion criteria: patients between 18 and 80 years of age, with at least one cerebral aneurysm and aneurysms in the segments of the internal carotid artery and vertebral arteries. We recorded the clinical presentation as subarachnoid hemorrhage, headache, mass effect, transient ischemic attack, family history, and incidentals. Demographic data, topography, quantity, and lateralization of all aneurysms were collected.**

Results: **A total of 91 patients were included in the final analysis. The 6-month occlusion rate was 91.5% for PED and 95.7% for FRED 95.7% (p 0.597); and at 12 months it was 95.7% for PED and 97.7 for FRED (p 0.555). In pairing the propensity score (PPS) the complete occlusion rate was 90% for PED and 100% for FRED, without statistical significance in the difference at 12 months (p 0.631).**

Conclusion: **Flow diversion devices PED and FRED are an efficient treatment for aneurysms of the anterior circulation and some of the posterior circulation (vertebral arteries), showing similar occlusion rates and clinical outcomes.**

Keywords: Aneurysm, Occlusion rate, Flow diverter, PED, FRED, Embolization

1. Background

Cerebral aneurysms surgery has been one of the most challenging procedures since the beginning of modern neurosurgery. The incorporation of the surgical microscope - by Theodore Kurze in 1957 - and the subsequent development of microsurgical techniques (by outstanding exponents such as M.G. Yasargil) made great strides in the neurovascular fields [1]. Simultaneously, medical devices achieved a significant leap forward in blood vessel navigation to solve cerebral

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ORIGINAL RESEARCH

aneurysms by creating a system that allowed the introduction of platinum coils into the aneurysm dome sufficiently safe to be even released by electrolysis [2]. G. Gugliemi's publication about the use of these new coils reported morbidity and mortality as low (for cerebral aneurysms) as 4.8 and 2.4%, respectively [3]. With proper time and effort, neuroendovascular techniques gained an essential role in the cerebrovascular diseases' armamentarium by their results, which ended up currently, in the design of Flow Diverters [4].

Flow Diverters (FDs) are devices derived from brain stents that take advantage of the principle of vascular remodeling to reconstruct the parent vessel carrying the aneurysm. A network of distinct microfilaments constitutes the structure of a Flow Diverter that enables the creation of a new arterial wall by interrupting the blood flow within the aneurysmal sac, permitting vessel remodeling over the stent's full length [5].

The PipelineTM Embolization Device (PED, Medtronic, Dublin, Ireland) consists of a braided mesh flexible tube of 48 interwoven microfilaments, 25% platinum-tungsten, and 75% cobalt-chromium-nickel alloy [6]. In 2008 Nelson P. reported the use of the Pipeline device for the first time.; later published in the PITA trial in 2011. This device consisted of 48 individual cobalt chrome microfilaments in their initial version [7]. In 2009, Lylyk P. et al. reported its use in 53 patients, concluding that PED reconstruction was durable, safe, and curative [8].

The Flow Re-Direction Endoluminal Device (FREDTM; MicroVention, Tustin, California) is a self-expanding nickel-titanium paired stent. It comprises an integrated dual-layer coverage provided by a low-porosity inner mesh of higher pore attenuation (48 nitinol wires) and an outer stent with high porosity (16 nitinol wires with four interwoven marker strands), that has proximal and distal markers [9]. The global clinical experience with this device is minor than that of PED, provided that the FDA approval process started after 2018; therefore, it developed mainly in Europe [10].

This report compares the results of patients implanted with these devices, assessing their occlusion rate and their clinical outcomes (mRS) at 1-year follow-up.

2. Methods

In this nested case–control retrospective cohort study, we reviewed the medical records of patients undergoing treatment with a Flow Diverter stent for cerebral aneurysms within a Mexican hospital at one year-follow-up. The selection began in October 2016 and ended in December 2019; all cases had at least one control, Digital Subtraction Angiography (DSA), by December 2019. We included patients between 18 and 85 years of age, at least one cerebral aneurysm, aneurysm located in segments of the internal carotid artery and vertebral arteries regardless of lateralization. Pediatric patients, aneurysms located at the middle cerebral artery bifurcation, anterior communicating artery, basilar artery, and distal arteries less than 2.75 mm, and those with combined use of devices were excluded. We recorded clinical presentation as follows: subarachnoid hemorrhage, headache, mass effect, transient ischemic attack, family history, and incidentals. Demographic data, topography, quantity, and lateralization of all aneurysms were collected.

All procedures were done under general anesthesia with one of the two FDs available at our center: the Pipeline Embolization Device version Flex (PED) or the Flow Redirection Endoluminal Device (FRED). We did not consider the use of additional coils for the analysis, mainly because our resources were often limited, impeding the use of assisted coils with flow diverter, even though it was a reasonable option. The selection of the FD depended exclusively on the treating physician; the patients signed informed consent before the procedure in every case. All the patients received dual antiplatelet therapy for seven days before the procedure with 100 mg aspirin and 75 mg clopidogrel daily. If any patient was unable to complete this protocol for any reason, we administered a short scheme consisting of 100 mg aspirin and a clopidogrel loading dose of 150 mg every 2hrs until reaching a total 450 mg at least 12hrs before the procedure. We used the VerifyNowTM device (Accumetrics, Bedford, MA, USA) in all the patients to verify the antiplatelet effect. We used clopidogrel

Abbreviation list

AVA	Advanced Vessel Analysis
COFEPRIS	Federal Commission for the Protection Against Health Risks (name in Spanish)
DSA	Digital subtraction angiography
FD	Flow Diverter
FDA	Food and Drug Administration
FRED	Flow Redirection Endoluminal Device
PED	Pipeline Embolization Device version Flex
PITA	The pipeline embolization device for the intracranial treatment of aneurysms trial
PPS	Pairing propensity score
mRS	Modify Rankin Score
SPSS	Statistical Package for the Social Sciences

for six months and acetylsalicylic acid for at least one year after the procedure in every case. The procedures were performed through a puncture in the right or left common femoral artery, using a 6 Fr access system as a standard; however, an 8 Fr was used in some cases. A 5000 IU bolus of heparin was administered at the beginning of the catheter's intracranial access, followed by hourly bolus doses of 1000 IU to maintain activated clotting time between 2 and 2.5 times the basal value. In no case, more than 7500 IU were used in total.

In all the cases, the Angio-SealTM (Terumo Corporation, Tokyo, Japan) vascular closure device was used. The complete deployment of the device used, its permeability and apposition in the parent vessel, and the aneurysm sac contrast retention was reviewed at the end of the procedure. In some cases, the first follow-up was performed at three months, based on specific circumstances; however, for the data analysis, the first follow-up was considered at six months and the last one at 12 months. Standard angiographic projections were used in addition to other projections used as required during treatment. Aneurysm occlusion was graded using the Raymond–Roy (CRR) classification [11], and the functional result was evaluated using the modified Rankin Scale (mRS) at 90 days and on each follow-up (6 and 12 months) by complete neurological examination. Standard techniques were used to measure the height and width of the aneurysm dome and the width of the aneurysmal neck. The Advanced Vessel Analysis (AVA®) software (Philips, Best, The Netherlands) was used to calculate the length of the affected artery and the length between the proximal and distal edge of the aneurysm.

2.1. Statistical analysis

We used standard techniques to measure the height and width of the aneurysm dome and the width of the aneurysmal neck. Even more, we used the Advanced Vessel Analysis (AVA®) software (Philips, Best, The Netherlands) to calculate the length of the affected artery and the length between the proximal and distal edge of the aneurysm. We collected and coded data related to the patients' profile, the aneurysm characteristics, and the device used in every procedure as appropriate. We divided the patient's sample into two groups based on the implanted device for the analysis. We reported categorical variables as proportions and continuous variables as means, standard deviations, or median interquartile-ranges as appropriate according to the data's distribution. We compared categorical variables using the chi-square test in each group, whereas continuous variables with the Mann–Whitney U test. Additionally, we performed a sub-analysis based on the propensity score matching for age, sex, aneurysm size, and location. We performed these statistical analyses using IBM's Statistical Package for the Social Sciences (SPSS Statistics®) Version 23.

3. Results

Data were collected from 96 patients; two were excluded because of being pediatric patients (5 and 12 years old), one by having a basilar aneurysm, an additional one by losing follow-up at six months, and one more derived from the combined use of devices (telescoped). A total of 91 patients were analyzed, 41 (45.1%) were men and 50 (54.9%) women. The average age of the patients was 61

Table 1. Global baseline data.

Gender	n	%
Male	41	45.1
Female	50	54.9
Age	61 (+10.7)	
Num. Aneurysms	127	
Size. Aneurysms	11 (+5)	
Clinical Presentation		
Incidental	38	41.8
Headache	37	40.7
Family History	8	8.8
SAH	5	5.5
Mass Effect	2	2.2
TIA	1	1.1
Parent Vessel Localization		
pComA	28	30.8
Ophthalmic/para-ophthalmic	18	19.8
Cavernous	15	16.5
Ant. Choroidal	9	9.9
Hypohyseal	8	8.8
Petrous	6	6.6
Vertebral	5	5.5
Posterior Cerebral Artery	1	1.1
Middle Cerebral Artery	1	1.1
Side		
Left	48	52.7
Right	43	47.3
Device		
PED	47	51.6
FRED	44	48.4
Occlusion (12 months)	83	91.2
Complications		
Neurological	4	4.4
Non-neurological	6	6.6
mRS		
0	87	95.6
1	1	1.1
2	2	2.2
6	1	1.1

PED: Pipeline Embolization Device; FRED: Flow Re-Direction Endoluminal Device.
SAH, subarachnoid hemorrhage; mRS: modified Rankin scale.

years (range 18–85 years). The most frequent clinical presentation was the category of incidental aneurysms (n = 38, 41.8%), followed by the patients who presented headache (n = 37, 40.7%), the rest were divided between SAH (subarachnoid hemorrhage), mass effect, TIA (transient ischemic attack) and, family history (Table 1). A total of 127 (mean 1.2) aneurysms were found, most of them were found on the right side (n = 48, 52.7%), the rest on the left side. The most frequent locations were pComA (n = 28, 30.8%), ophthalmic/para-ophthalmic (n = 18, 19.8%) and cavernous (n = 15, 16.5%). The mean major axis of the aneurysms was 11.6 mm (+5); 45 aneurysms were <10 mm (52.7%) were found; 43 (47.3%) > 10 but <25 mm and 3 (3.3%) >25 mm. The Pipeline device (PED) was used in 48 (52.7%) cases and FRED in 43 (47.3%). A total of 10 cases had complications; six were minor and non-neurological such as epistaxis, minor local hematoma, or groin pain. Three neurological complications (3.3%) occurred in the FRED group, including two events of thromboembolism (2.2%) and one intra-stent thrombosis (1.1%); two of those patients had an mRS of 2 at 90 days completely improving at 12 months. One death occurred in the PED group occurred, while none in the FRED group (Table 2). The 6-month occlusion rate was 91.5% for PED and 95.7% for FRED 95.7% (p 0.597); and at 12 months it was 95.7% for PED and 97.7 for FRED (p 0.555).

In pairing the propensity score (PPS) controlling for age, sex, and size and location of the aneurysms, 20 aneurysms were obtained, 10 for each group. With PPS, the complete occlusion rate was 90% for PED and 100% for FRED, without statistical significance in the difference at 12 months (p 0.631). The functional result and complications were not different (Table 3).

Table 2. Comparison between PED and FRED patients.

	PED = 47		FRED = 43		*p*
Gender	n	%	n	%	0.942
Male	21	44.7	20	45.5	
Female	26	55.3	24	54.5	
Age	61 (11)		61 (10.6)		0.842
Num. Aneurysms	65		59		
Size. Aneurysms	10 (4.8)		11 (5.4)		0.438
Clinical Presentation					0.005
Incidental	17	36.2	21	47.7	
Headache	20	42.6	17	38.6	
Family History	3	6.4	5	11.4	
SAH	5	10.6	0	0.0	
Mass Effect	1	2.1	1	2.3	
TIA	1	2.1	0	0.0	
Parent Vessel Localization					0.086
pComA	15	31.9	13	29.5	
Ophthalmic/para-ophthalmic	7	14.9	11	25.0	
Cavernous	6	12.8	9	20.5	
Ant. Choroidal	5	10.6	4	9.1	
Hypohyseal	3	6.4	5	11.4	
Petrous	4	8.5	2	4.5	
Vertebral	5	10.6	0	0.0	
Posterior Cerebral Artery	1	2.1	0	0.0	
Middle Cerebral Artery	1	2.1	0	0.0	
Side					0.353
Left	27	57.4	21	47.7	
Right	20	42.6	23	52.3	
Occlusion (6 months)	43	91.5	40	95.7	0.597
Occlusion (12 months)	45	90.9	43	97.7	0.555
Complications					
Neurological	1	2.1	3	6.8	0.280
Non-neurological	3	6.4	3	6.8	0.198
mRS (90 days)					
0	46	97.9	41	93.2	
1	0	0.0	1	2.3	
2	0	0.0	2	4.5	
6	1	2.1			

PED: Pipeline Embolization Device; FRED: Flow Re-Direction Endoluminal Device.
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Table 3. Propensity score matching results.

	PED = 10		FRED = 10		
Gender					
Female	10		10		
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Clinical Presentation					0.095
Incidental	5	50	5	50	
Headache	4	40	5	50	
Familiar History	1	10	0	0	
Parent Vessel Localization					0.278
pComA	1	10	4	40	
Ophthalmic/para-ophthalmic	3	30	3	30	
Cavernous	3	30	2	20	
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Side					0.404
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Occlusion (12 months)	9	90	10	100	1
Complications		0		0	
Neurological	1	10	0	0	0.331
Non-neurological					0.335
mRS (90 days)					
0	9	90	10	100	
1	0	0	0	0	
2	0	0	0	0	
6	1	10	0	0	

4. Discussion

This study was carried out in a single center in northern Mexico City. During the data collection and until the redaction of this paper, solely, these two devices remain available at our center. The Cofepris (Federal Commission for the Protection Against Health Risks) is the regulatory office that approves medical devices in Mexico. Until April 2020, the devices authorized for clinical use by this authority include the PED, FRED, FRED JrTM, Surpass StreamlineTM (Stryker Neurovascular, Kalamazoo, Michigan), and Silk VistaTM (Balt Extrusion, Montmorency, France). As by personal communication with the authors, local providers refer that authorization for intra-saccular and various other flow devices are in process. In our country, the use of these devices began in 2014, with isolated cases in different centers; in our hospital, the first FD implanted dates to December 2015.

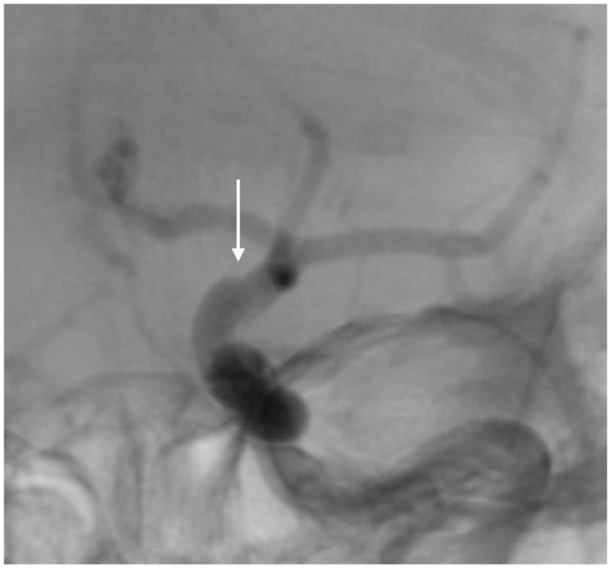

Fig. 1. Flow Diverter prolapsed into the aneurysm. The arrow shows the "watermelon seed effect".

Several authors reported occlusion rates close to 87.2% for FRED, with joint morbidity and mortality rates of 4.1%; nevertheless, no 5-year follow-up reports exist to our knowledge [10,12,13]. Regarding PED over ten years have passed since the device began to be used, and several authors have reported occlusion rates of 95.2% and combined morbidity and mortality of 3.7% at five years follow-up [14–16].

There are structural differences between these two devices to assume or at least suspect that range of occlusion and outcomes could be not similar. For example, the FRED composition has a more rigid and stable structure, with a pore density of <70% and porosity of at least 20 pores/mm2 [17,18]. The

PED has a 70% density; nevertheless, it has a predictable parabolic variability according to the parameters of the device, the size of the parent artery, and the curvature of the device; for example, a modest oversizing can increase porosity and compromise the aneurysm occlusion [14,19].

Regarding the patient with outcome mRS of 6 (the patient's death in the PED group), the procedure was performed without complications, and the patient was discharged 36hrs post-procedure. The patient returned 48hrs after hospital discharge due to sudden loss of consciousness and SAH Fisher IV on Head CT. In a retrospective analysis, we identified that the distal landing zone was too short and was not enough to resist aneurysm inflow; hence, the device did a "watermelon seed effect," causing a rupture and massive hemorrhage [20] (Fig. 1).

The two distal thromboembolic complications in the FRED group were resolved by direct thromboaspiration with the SofiaTM catheter (Microvention Inc., Aliso Viejo, CA), part of the triaxial system for implantation. The intra-stent thrombosis case in the FRED group was also managed by aspiration, achieving recanalization in less than 10 min with a subsequent infusion of Tirofiban [21]. After Tirofiban's bolus, the team waited 30 min in the angiosuit before taking off the endovascular systems; no new clot was observed. Except for epistaxis and slight hematuria, the patient had a normal postoperative exam (NIHSS 0). Even though he received the full dual anti-aggregation scheme, demonstrated optimal PRU levels (200) in the pretreatment test (VerifyNow), he developed thrombosis, which has been reported to occur in this scenario [22,23]. We do not change the anti-aggregation scheme because our health system does not allow it; nevertheless, no additional problems occurred.

The 12-month analysis by propensity score matching indicated no significant difference between both devices (PED 90% vs. FRED 100%), although results are slightly in favor of FRED (p 0.550).

It is important to note that the mean aneurysmal size for the entire cohort was 11 mm (±5 mm); therefore, even when some cases were indeed large or giant, most of the treated aneurysms were not, which could favor a higher occlusion rate.

Our findings coincide with those reported by Griessenauer et al. in their comparative study of both devices [24]. Our results may have been limited as a matter of insufficient sample size, given that differences among groups almost reached the preseated cutoff point (0.05) for statistical significance, but even so still non-significant; this is a matter of future research.

The decision to choose one device over another will probably depend on other factors (availability, price, approval by local authorities, the experience of the operator) and not exclusively on the clinical outcomes. From our perspective, the parental vessel's tortuosity and the anatomical disposition of the aneurysm are factors to consider when choosing one of these two devices.

5. Conclusion

Flow diversion devices PED and FRED are efficient means of treatment for aneurysms of the anterior circulation and some of the posterior circulation (vertebral arteries), showing occlusion rates and similar clinical outcomes between both of them. Further studies are needed to determine if there are substantial differences between these two devices and others available around the world.

Conflicts of interest

The authors declare that they have no conflict of interest.

Publication comment

In this publication, a single-center, single-surgeon experience is provided using two endovascular devices widely available. Both of them are accepted by the major health systems worldwide, having the FDA and CE-Mark as well as the Mexican COFEPRIS authorization. Each of these devices has pros and cons, comparing their rigidity, self-expanding ability, and delivery systems as well as the surgeon's preference. (1,2) Each case should be tailored to the patient considering the surgeon's ability to choose between any of these devices and the other Flow Diverters that are already approved and available in different regions based on their profiles. In the future, the decision will depend on defining: Which one has the earliest success rate of occlusion with the longest follow-up and the least complications. Undoubtedly it has been tried to compare both devices previously, even in multicenter studies (2), with a similar mean follow-up. Due to the lack of long-term follow-up in this comparison and the lack of prospective trials, every effort in this direction is to be considered useful for decision-making. Provided that these devices continue to show their efficacy and more Flow Diverters are available, the comparison process of these devices will be more specific to each type and location of the aneurysm. Therefore, this experience should not be misleading or mistaken as

a suggestion, to use one device over the other, since in other trails and this publication itself shows there are no statistical differences between the devices.

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