Flow diverter neuroendovascular stents – Reconstructive endovascular treatment of intracranial aneurysms – Single centre experience

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ABSTRACT

Objectives: Flow diverter stents (FDS) are new neuroendovascular tools able to achieve the complete and curative treatment of aneurysm by reconstruction of the parent arteries from which the aneurysm arises. We present our initial experience with flow diverter embolization devices and follow-up results. **Materials and Methods:** Patients with large, giant and wide necked aneurysms, saccular, fusiform and recurrent aneurysms were selected for the treatment. All patients were pretreated with dual antiplatelet agents at least for 7 days before procedure and continued taking both agents for 3 months after treatment. A MRI was done after 3 months of treatment and digital subtraction angiogram was performed at 4 months of treatment. After 1 year both MRI and digital subtraction angiogram was performed. **Results:** 11 patients (age range 37 year to 79 year, mean 51.1) with 11 intracranial aneurysms were treated with 15 flow diverter stents. 9 aneurysm were located on the anterior circulation and 2 on posterior circulation. 8 aneurysms were large (10-25 mm), 2 were small (<10 mm) and 1 was giant (>25 mm) with mean largest diameter of 13.22 mm. 9 were saccular aneurysm and 2 were fusiform, out of these 3 were remnant of the previously treated aneurysm. Treatment was achieved with 10 Silk stents in 7 patients and 5 Pipeline embolization devices in 4 patients. The mean time between treatment and follow up was 9.6 months (range 4-12 months). One mortality was noted due to rebleed after 3 weeks of treatment. Complete angiographic occlusion was achieved in 9 (90%) patients after 4 months and 1 (10%) patient had near complete occlusion at 12 months. All the patients were stable clinically during follow up period. **Conclusion:** Endovascular treatment with FDS is safe, easy, and permanent treatment for the selected group of aneurysms. The complete occlusion rate in follow-up study approaches 100% with no angiographic recurrence in this study.

Key words: Aneurysm, flow diverter stents, neuro-endovascular, pipeline embolization device, silk stent

INTRODUCTION

Much has been changed in the field of interventional neuroradiology after the landmark randomized trial, International Study of Subarachnoid Aneurysm Treatment.[1] With the help of coils, endosaccular packing of "good neck" aneurysms is being the treatment of choice. But for large and giant or fusiform aneurysm or aneurysm with wide neck the endosaccular coil packing is not effective, because of certain difficulties and limitations and complete occlusion is almost not possible even after stent (available till date) remodeling and even if achieved, there is always the chance of recurrence due to coil compaction and recanalization and may require more than one sitting for treatment.[1-3]

As compared to "endosaccular" treatment of "focal defects" in the parent artery from which arises most good neck aneurysm, the flow diverter stents (FDS) addresses the "endoluminal" treatment for more diffuse "segmental" defects large, wide necked, and fusiform aneurysms.[4] Although this "endoluminal" treatment is partially possible with available stents, but their ability to reconstruct "segmental" defect is limited due to their less metal surface area coverage, and in almost all cases along with "endoluminal" treatment, "endosaccular" treatment with coils is needed.

FDSs are endovascular stents which can be used alone to reconstruct the segmentally diseased artery by disrupting the inflow dynamics of blood into the aneurysm sac to the extent that progressive thrombosis can be induced and subsequent exclusion of aneurysm is possible.

Access this article online	
Quick Response Code:	Website: www.ijns.in
	DOI: 10.4103/2277-9167.118122

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Although long-term results are still awaited but initial experience and certain studies[4-7] have shown good and promising results. We present our preliminary series of 11 patients treated with silk (Balt, Montmorency, France) and pipeline embolization device (PED) (ev3, Irvine, California, USA) and their follow-up.

MATERIALS AND METHODS

Patient population

Between January 2009 and October 2010, 11 patients were treated with 15 FDSs after obtaining proper consent from the patient and prior intradepartmental discussion. Eight patients had un-ruptured aneurysm diagnosed following symptoms related to mass effect, two patients had remnant after their initial treatment with endosaccular packing with coils, and 1 patient had ruptured fusiform aneurysm. All the patients included in this study had either large or giant saccular aneurysms and wide neck defined as neck size >4 mm or dome neck ratio <2, and fusiform aneurysms. After discussing we considered these aneurysms to have high chance of recurrence or failure with endosaccular packing with coils alone either because of their size or unfavorable dome neck ratio.

Antiplatelet medication regimen

Patients were pretreated with 250 mg of aspirin and 75 mg clopidogrel at least 5-7 days before intervention and continued for 3 months after the procedure. After 3 months, only aspirin 250 mg was continued for 1 year. Activated clotting time was maintained between 250 and 300 seconds by intravenous heparin and heparinization was not reversed after the procedure.

Microcatheter selection

The navigation of stents was done with Vasco (Balt, Montmorency, France) microcatheter (supplied with stent) in the case of silk stent and Marksman (ev3, Irvine, California, USA) microcatheter for PED.

Peri-procedural angiographic evaluation and follow up

Anatomical characteristics of aneurysm and parent vessel were measured after performing 3D rotational angiography and reconstruction. The parameters chosen for selecting the correct FDS were neck size of the aneurysm along with the proximal and distal diameter of the parent artery. Flow modification in the aneurysm, after the deployment of the FDS was taken as either complete stasis (if no contrast material entered in the aneurysmal sac after deployment of FDS) or stagnation of contrast (if contrast filling of aneurysm was seen in venous phase also). Patency of the parent artery is also assessed as no change in the parent artery diameter, narrowing of the parent artery and parent artery occlusion. Correct deployment of FDS was taken as when it covers the complete aneurysm neck and patency of parent artery and perforators were preserved along with no deterioration in clinical status.

Follow up of patients were monitored clinically and radiologically. MRI was done after 48 hours if there was no clinical deterioration. Repeat MRI was performed after 3 months and clopidogrel was stopped. Angiographic follow up was performed after 1 month of stopping clopidogrel, i.e., 4 months after the intervention. Clinical follow up was performed regularly. After 12 months of intervention, both MRI and angiographic studies were performed. Angiography was performed in the standard position as well as in the working position along with 3D rotational angiography and reconstruction.

RESULTS

Demographic profile

Between January 2009 and January 2011, 11 patients were treated with FDSs. Their average age was 51.1 years with a minimum age of 37 year and maximum 79 year. Out of 11 patients, 7 were females and 4 were male patients. One patient presented with ruptured aneurysm had WFNS grade 4, remaining 10 patients presented with various clinical presentations [Table 1].

Aneurysm characteristics

9 (81.8%) aneurysm were located on the anterior circulation and 2 (18.1%) on posterior circulation [Table 2]. 8 (72.7%) aneurysms were large (10-25 mm), 2 (18.1%) were small (<10 mm), and 1 (9.0%) was giant (>25 mm) according to the International Study of Unruptured Intracranial Aneurysms[8] size classification with a mean largest diameter of 13.22 millimeter. 9 (81.8%)

Table 1: Clinical presentation

Presentation (*n*=11)	No.	%
Incidental	4	36.3
Remnant	3	27.2
Visual symptoms	2	18.1
Cranial nerve symptoms	1	9.9
Ruptured	1	9.9

Table 2: Location

Location (*n*=11)	No.	%
Cavernous	6	54.4
Ophthalmic	1	9.0
Termination	1	9.0
A1-2 junction	1	9.0
Vertebral	1	9.0
Basilar	1	9.0

were saccular aneurysm and 2 (18.1%) were fusiform aneurysms. Out of 9 saccular aneurysm, 7 (77.7%) had a dome neck ratio of <2, and 2 (33.3%) had a dome neck ratio of >2 but these two aneurysm had absolute neck size of 4 millimeter. Two fusiform aneurysms had parent artery defect of >10 mm. Of the three remnant aneurysms, one was fusiform aneurysm of vertebral artery treated previously with coils and two were cavernous aneurysms, one treated with coils only and one with coils and commercially available non-FDS [Table 3].

Flow diverter stent treatment

Out of 11 patients, 7 (63.6%) patients were treated with 10 silk stents and 4 (36.3%) patients with 5 PEDs, so total of 15 FDSs were deployed for 11 aneurysms. Out of 11 patients, 1 patient was treated with two silk stents, 1 with three silk stents, and 1 patient with two PED. All the aneurysms were treated with FDS only without coils.

Difficulty in deploying stent occurred in four (36%) of patient, exclusively with silk stent. In one case, we were unable to advance silk stent due to defect in delivery wire, in one case silk stent fail to open and in two cases stent narrowing was noticed, when fully deployed, in one such case stent was fully expanded by a hyperglide balloon. In rest of seven (64%) patients, there was no technical difficulty and deployment was successful. In one patient, we predeployed the stent so we had to use second PED to cover the neck of the aneurysm.

One patient of ruptured fusiform aneurysm died after 3 weeks due to re-bleeding. One (9%) patient developed hemiparesis which improved in follow-up.

Angiographic results

After the completion of the procedure, only 2 (18.1%) aneurysm showed complete angiographic occlusion. Both aneurysms were of large size, one was treated with silk stent located at A1-2 junction and the other was with PED and located at carotid termination. Remaining aneurysms showed stagnation of contrast inside the aneurysm sac.

Radiological follow up was available of 12 months for seven (70%) patients and of 4 months for three (30%) patients. The average radiological period was 9.6 months [Figures 1 and 2]. Two aneurysms which showed complete occlusion at the end of procedure continued to have total occlusion in follow-up angiogram. By 4 months,

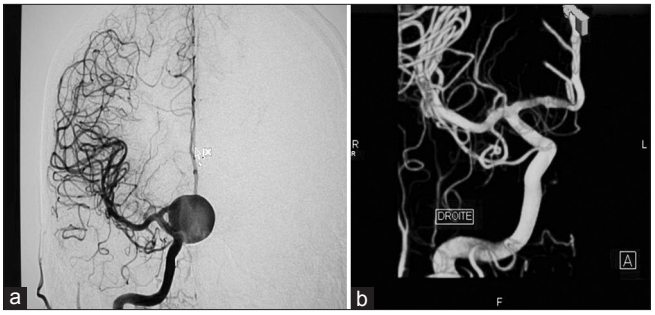

Figure 1: (a) Acom aneuyrsm pre-stenting. (b) After 4 months follow-up DSA

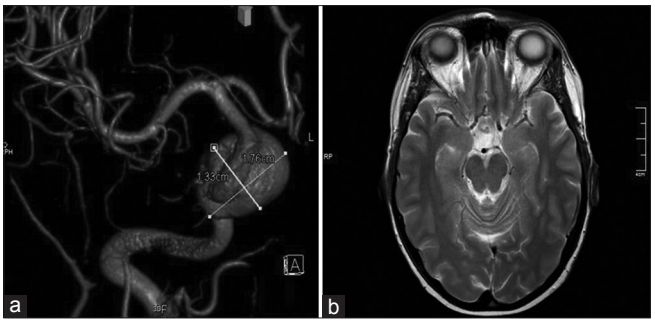

Figure 2: (a) Cavernous segment aneurysm pre-stenting. (b) Follow-up MRI after 1 year

Table 3: Summary of cases in which stent was deployed

Age	Sex	Site	Aneurysm characteristic	Type of aneurysm	Symptoms	Type of stent	Size of stent (mm)	Technical difficulties
37	F	Acom	Large	Saccular	Hemianopsia	Silk	2×15	No
54	M	VA	Large	Fusiform	Remnant	Silk	3.5×35	Yes
40	F	C4	Large	Saccular	Right hemifacial pain	Silk	4×35	Yes
58	M	Basilar trunk	Giant	Fusiform	Ruptured	Silk (3)	4×25 4×35 4.5×40	No
79	F	C4	Large	Saccular	Right eye visual loss	Silk (2)	3.5 × 35 4 × 20	Yes
65	F	C4	Large	Saccular	Remnant	Silk	4.5×40	Yes
53	F	C4	Large	Saccular	Incidental	Silk	4×25	No
45	F	C4	Blister	Saccular	Remnant	Pipeline	3.25×16	No
39	M	C4	Large	Saccular	Right eye visual loss	Pipeline	4.25×16	No
43	M	C7	Large	Saccular	Incidental	Pipeline	4.5×20	No
50	F	C5	Small	Saccular	Incidental	Pipeline (2)	3.5 × 18 3.25 × 16	No

seven (87.5%) patients had total occlusion and one (12.5%) had near total occlusion which was there at 12 months also. Of the seven patients which showed complete occlusion at the end of 4 months, four had silk stents and three had PED. One patient who had near total occlusion had silk stent.

Three patients showed in-stent stenosis during follow-up angiogram, all the patients had silk stent. Out of this, two had mild stenosis and one had severe stenosis, this was the same patient who had developed hemiparesis after the procedure.

Clinical results

One patient of giant fusiform aneurysm died because of rebleed after 3 weeks of treatment and post-mortem findings showed in-stent thrombosis and absent aneurysm wall. This was the same patient where we had to use three silk stents. Seven patients have the clinical follow up of 12 months and three patients have had the follow up of 8 months. No patient had experienced clinical deterioration or fresh clinical symptoms after during this period. One patient who had hemiparesis after the procedure started having improvement in hemiparesis.

DISCUSSION

Advances in techniques and newer innovations at various points of time had tried to solve the problem of coiling complex aneurysms or aneurysms traditionally not considered for coiling. In around 2002, first dedicated intracranial stent was introduced and with it the use of stents to support the coil embolization of complex aneurysms.

Since then experimental work and *in-vitro* studies in silicon models were being conducted to study the effect of placement of stents on flow dynamics of parent vessels and aneurysms.[9] These and earlier experimental studies suggest that following placement of stents there is improvement in the anatomic reconstruction of the segment of parent artery, physiological flow modification across the origin of the aneurysm, and neointimal growth causing repair of the aneurysm neck.[10] But these effects were extremely less *in-vivo* for the traditionally and commercially available non flow-diverter stents which provides only 6.5% to 9.5% metal surface area coverage.[5] To overcome this problem and to maximize the effect of stent placement of flow dynamics on parent vessel and aneurysm, FDSs are constructed. Two such commercially available stents are silk stent (Balt, Montmorency, France) and PED (ev3, Irvine, California, USA) which has the metal surface area coverage of 35-55%[11] and 30-35%,[5] respectively.

The silk stent[11] is a flexible, self-expanding device made of 48-braided nitinol strands with platinum microfilaments. It forms 35% to 55% metal coverage mesh after expansion and produce a hemodynamic flow diversion, reconstructing a laminar flow in the parent artery. Many diameters (2 to 5 mm) and lengths are available (15 to 40 mm). Silk stent has very good visibility and has a sinusoidal system of markers. To increase the stability of the stent, it is recommended to choose a stent length at least three times the diameter of the parent vessel plus the neck size. Silk stent can be resheathed, removed, and repositioned even when up to 80% of the stent was deployed.

PED[5] is a woven wire mesh tube made of 25% platinum and 75% cobalt-nickel alloy. It provides 30% to 35% metal coverage after expansion and has a pore size of 0.02-0.05 mm^2 at nominal diameter. PED has poor visibility so there is some problem during deployment [Figure 3]. It comes in three sizes with a maximum length of 20 mm. It is recommended to choose a stent length at least 2.5 times the neck size because of its shortening after deploying. PED has limited repositioning capability once deployed even when partially deployed and cannot be resheathed.

Kallames *et al.*[12] in their experimental rabbit model demonstrated that these FDSs acts as a scaffolding for endothelial and neointimal proliferation with the covering of neck of aneurysm from one end to the other and ultimately excluding the aneurysm from the circulation. As such the FDSs acts like "endo-clip" when placed in lumen of parent vessel, and virtually excluding the aneurysm sac from the circulation.

Although all the PEDs were deployed successfully with mild effort, deployment of silk stent took moderate effort

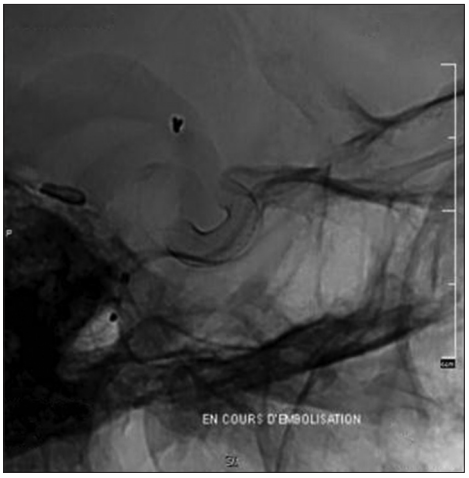

Figure 3: Pipeline flouro image opened

along with some technical problems. Like in one case, there was failure of advancement of silk stent due to defect in the delivery wire [Figure 4], in one case silk stent failed to open and we replaced it with new stent and in two cases we noticed stent narrowing at the curvature of the parent vessel and we performed the balloon dilatation of stent in one of these cases [Figure 5]. In all these cases, we had not encountered any clinical consequences. However, follow-up angiogram of the other patient with stent narrowing even after 12 months showed some residual filling.

Multiple FDSs were used in giant or large aneurysm with prior approval from the institutional ethical committee [Figure 6], where there was difficulty in achieving significant flow reduction after deployment of single stent. But no major branch or perforators were compromised after deployment of either single or multiple stents despite more metal surface coverage area than non-FDSs. The same findings of preservation of branches were noted by other authors.[11,13,14] The mechanism of this phenomenon may be attributed to either the negative pressure gradient formed in perforators to maintain flow[14] or to the size of perforators to be too small to be occluded by even these overlapping stents[11] or to both of these. Still there are chances of late infarcts due to migration of microthrombus which need to be studied by long-term follow up.

FDSs after been deployed redirects the flow to the parent vessel thus promoting stasis of blood inside the aneurysmal sac and thrombus thus formed is rich is red blood cells and few fibrin network and platelets. This red thrombus thus formed is more fragile that white thrombus formed in the case of endosaccular coiling, increasing the risk of rupture of aneurysm during initial days after embolization till the thrombus is being organized.[15] This may be the reason that Balt started recommending to use coils along with silk stents. This may be precisely what had happened to the only mortality we encountered of giant fusiform aneurysm which was later confirmed by post mortem findings of absent aneurysm wall because of lysis. Similar hypothesis and mortality have been reported by other authors also.[16,17] There was one case of delayed rupture of cavernous aneurysm treated with silk stent, presented later on with carotid cavernous fistula.[18] Delayed aneurysm rupture after flow diversion treatment has been reported by other authors also.[19,20]

One of the main advantages of using these stents is reduction in mass effect and subsequent improvement in symptoms associated with mass effect like headache and cranial neuropathies [Figure 7]. This is confirmed by follow-up MRI at 4 months and 1 year in our study.

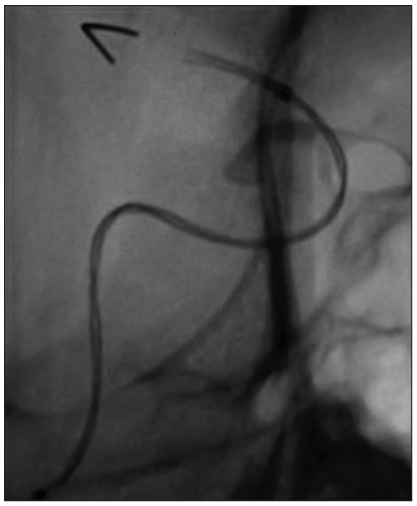

Figure 4: Silk stent fail to open

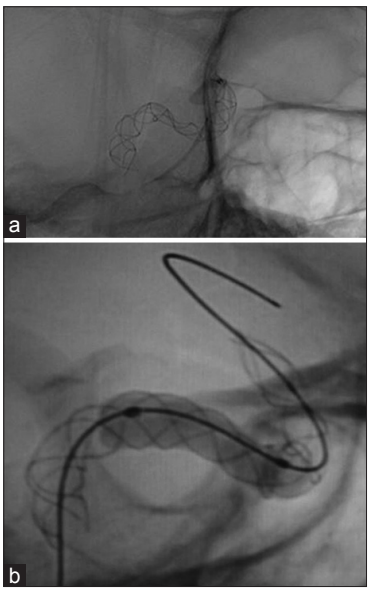

Figure 5: (a) Narrowing of silk stent. (b) Balloon dilatation of narrowed segment

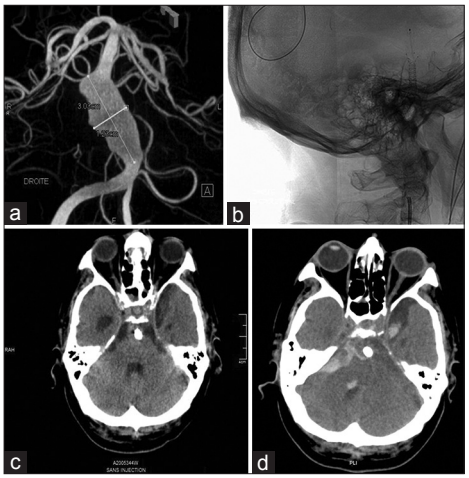

Figure 6: (a) Fusiform aneurysm. (b) Stent *in situ*. (c) NCCT 1 week after treatment. (d) NCCT after 3 weeks of treatment

Similar findings were also confirmed in other large series also.[13]

The main disadvantage of using such type of stents is there tendency to form thrombus and in stent thrombosis. We encountered one such patient of giant fusiform aneurysm in which multiple silk stents were placed and he died of rebleed after 3 weeks of treatment. Postmortem findings showed in-stent thrombosis even after the patient was on double anti-platelet agents. This findings suggest that we still do not know the exact dose of anti-aggregation agents at least where the multiple devices were deployed. However, the complication rate of in-stent thrombosis is rare in some series having deployed PED[13,21] to as high as 18% at 3 months.[4] But we have not seen any in-stent thrombosis in our patient having PED.

The small or blister aneurysms are always difficult to treat either by endovascular saccular coiling or surgery. In our series we placed a PED in one patient with recurrent small aneurysm previously treated with coiling and non-FDS. Angiogram at 4 months and 1 year confirmed the complete occlusion of this aneurysm. The same results were achieved in small series of three patients with blister aneurysms by Zsolt *et al*.[22]

During our radiological follow up, two patients had immediate aneurysm occlusion, six patients had angiographic occlusion on repeat DSA after 4 months, and one patient had occlusion on DSA after 1 year. One patient had residual filling on DSA after 1 year.

Most of the studies[4,13,23] including ours had the maximum angiographic and clinical result of up to 6 months to 1 year. For the device to have its efficacy established we need to have studies with much longer follow ups.

Along with the need for long-term follow up, there are some other technical limitations also like future difficulty to coil recurrent aneurysm treated previously with FDSs, use of antiplatelet agents limits deploying FDS in recent subarachnoid hemorrhage, and difficulty in placing FDSs in bifurcation aneurysm.[5] However, Cruz *et al*. used the PED in acute SAH with acceptable results.[24] In addition there is a recent study showing increased intra-aneurysmal pressure, increasing risk of rupture of rupture of aneurysm following FDS.[25]

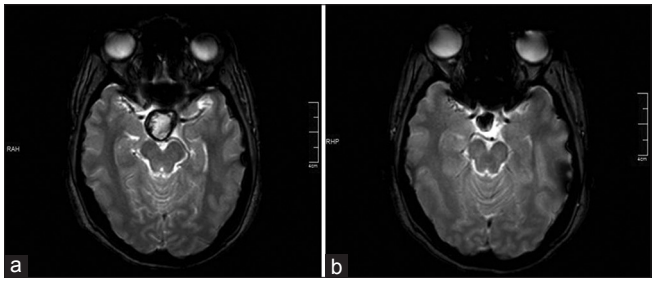

Figure 7: (a) Mass effect at 3 months. (b) Mass effect at 1 year

There are about a number of case series[4,5,13,23,24] regarding PED in the literature and all of them concluded that these are safe, durable with good short-term results. Literature regarding silk stent also showed it to be feasible, safe, and cost effective alternative.[7,16,26,27] Rather long-term follow up of silk stent is up to 3 years[28] which showed that the complication rate is much higher in these stents.

There is one study[23] by Piano *et al*. which showed the results of both PED and silk stent at single center but the as such no comparisons were drawn regarding where to use which stent.

Based on our institutional experience, we have observed that silk stent has low radial force than the PED so we had noticed narrowing of silk stents at the acute curvature of the vessels so we personally started using PED for cavernous segment aneurysm or for curved parent vessels and reserved the silk stents for relatively straight vessels or fusiform aneurysm because of the large stent size.

Currently, the best indication to use FDSs are for the recurrent aneurysm following treatment with coils and stents or aneurysms difficult to treat with surgery or endosaccular coiling and giant and fusiform aneurysms.

CONCLUSION

Treatment of large, giant, fusiform aneurysms has come a long way from parent artery occlusion, EC-IC bypass through balloon, and stent-assisted coiling to flow diversion in the parent artery, altering the flow dynamics in aneurysm sac and subsequent occlusion. Although flow diverter stents are still in the evolving stage, but the short-term results and follow-ups look promising and conclusive.

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How to cite this article: Rajpal G, Kadzioloka K, Estrade L, Pierot L. Flow diverter neuroendovascular stents - Reconstructive endovascular treatment of intracranial aneurysms - Single centre experience. Indian J Neurosurg 2013;2:182-8.
Source of Support: Nil, **Conflict of Interest:** None declared.