# LONG-TERM OUTCOME OF THE ENTERPRISE STENT IN THE TREATMENT OF WIDE-NECKED CEREBRAL ANEURYSMS

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## ABSTRACT

Introduction: The long-term results of intracranial aneurysms treated with the Enterprise stent is not known. This study was to investigate the safety and long-term outcome of the Enterprise stent in the treatment of wide-necked intracranial aneurysms.

Materials and methods: Sixty-eight patients harboring 78 intracranial aneurysms were treated with the Enterprise stent-assisted embolization with or without coiling. Angiographic data and clinical outcomes before and after stenting and at follow-up were retrospectively evaluated.

**Results:** Seventy-seven Enterprise stents were successfully deployed in the desired position (100%). Seven procedure-related complications (10.3%) occurred including thrombosis formation in two patients, coil protrusion in two and stent dislocation in three. Twelve aneurysms were treated with stent deployment alone. Sixty-six aneurysms were treated with stent-assisted coiling, resulting in complete occlusion in 46 aneurysms (69.7%), near complete in 15 (22.7%) and incomplete in 5 (7.6%). At follow-up of 12-55 months (mean 38), progressive thrombosis occurred in 23 (71.9%) aneurysms, and aneurysm regrowth in 11 cases (18.0%). Stenting significantly (P<0.05) increased the parent artery diameters to  $3.72\pm0.09$  mm at point B and  $3.43\pm0.1$ mm at D. At the last angiographic follow-up, the artery diameter was significantly (P<0.05) decreased to  $3.45\pm0.2$  mm at point B and  $3.03\pm0.14$  mm at D, with a medium asymptomatic in-stent stenosis in six patients (8.8%).

**Conclusion**: The Enterprise stent reconstruction of the parent artery for treating intracranial aneurysms is safe and effective with long-term asymptomatic instent stenosis.

Keywords: Intracranial stenting, Wide-necked aneurysm, Vascular reconstruction device, Endovascular treatment.

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# Introduction

The Enterprise (EP) stent (Cordis Neurovascular, Miami, FL, USA) is a highly flexible nitinol stent designed specifically for endovascular treatment of wide-necked, irregular and complex intracranial aneurysms<sup>(1-3)</sup>. The stent has a fixed closed-cell design and is delivered through a standard microcatheter. Clinical studies have demonstrated good results in treating saccular and broadnecked intracranial aneurysms<sup>(4, 5)</sup>. An experimental study investigating the effect of vascular reconstruction device-assisted coiling with the EP stent on packing density, effective neck coverage and angiographic outcomes revealed significantly increased packing density and effective neck coverage of aneurysms using the EP stent compared with coiling alone<sup>(6)</sup>. Moreover, aneurysms treated with coiling alone were more likely to have a dome remnant and coil prolapse into the parent artery. Stent-assisted coiling is indeed better than coiling alone in embolizing intracranial broadnecked aneurysms especially in terms of using a closed-cell design stent because the closed cell will form a fixed-opening scaffold covering the neck of aneurysms to promote dense packing and prevent coil protrusion into the parent vessel<sup>(6,7)</sup>, thus creating fewer procedural complications and good outcomes. In this study, we investigated the safety and long-term results of intracranial aneurysms treated with the EP stent reconstruction of the parent artery with or without subsequent coiling.

#### Materials and methods

The EP stent implantation was administered in normal clinical care of patients in a university tertiary hospital, according to standard-of-care procedures warranted by the patients' clinical symptoms. Outcomes were evaluated retrospectively from medical chart data to assess the safety and efficacy of the procedure. All patients provided signed informed consent to the medical treatment and to future use of their medical data in research after the Ethics Committee of our hospital had approved this study. From March 2008 to July 2014, medical chart review revealed 68 patients with 78 widenecked intracranial aneurysms who were treated with the EP stent reconstruction of the parent artery. These patients were retrospectively studied for the efficacy and adverse effects of the EP stenting procedure. There were 46 female and 22 male patients with an age range of 25-88 years (mean 56). Aneurysm location involved the petrous (3), the cavernous (6), the paraclinoid (28) and the ophthalmic (11) segments of the internal carotid artery (ICA), the anterior communicating artery (5), the superior cerebella artery (3), the vertebral artery (5), the posterior cerebral artery (3), the middle cerebral artery (4), the posterior communicating artery (6) and the basal apex (4). No patients had acute subarachnoid hemorrhage.

The stenting procedure was performed with all patients under general anesthesia after oral administration of a loading dose of clopidogrel and aspirin (300 mg each) for 3 days before the procedure. At the procedure, an initial heparin bolus (70-100 UI/kg) was administered followed by a continuous infusion to achieve an activated clotting time of 250-300 s. Aneurysm occlusion at the end of the procedure and at follow-up angiography was considered to be complete when the aneurysm sac and

neck were packed with no filling of contrast material, near complete when the sac was occluded but a neck remnant was present, and incomplete when there was persistent opacification of a sac remnant. Two authors assessed the results of aneurysm occlusion, and if discrepancy arose, a third author would be involved to decide the occlusion degree of aneurysm. The patients were followed up 3-6 months, one year, and once every year thereafter.

Three-dimensional (3D) rotational angiography were performed in each patient for diagnosis, stent-coiling, and follow-up for assessment of any branch occlusion, thrombus formation, degree of aneurysmal occlusion, and stent position. The data were processed for measurement of the aneurysm dome height, width and neck and the parent artery diameter using the software of Amira 5.2.2 (Konrad-Zuse-Zentrum Berlin (ZIB), Germany) which is a 3D visualization and modeling system. The parent artery diameter was measured at points B and D on the stented segment, with point B at 2 mm distal to the proximal end of the stent and point D at 2 mm proximal to the distal end of the stent (Fig.1).



**Fig. 1**: Measurement of the parent artery diameter at points B and D is shown on the stented segment before and after stenting.

The mean aneurysm neck size was 4.5mm (range 1.1-8.4mm), and the mean aneurysm dome height and width was 7.4 mm (range 1.7-21.7 mm) and 7.1 mm (range 1.3-22 mm), respectively, with a mean dome(height)-to-neck ratio of 1.7. The mean diameter of the parent artery was 3.5 mm (range 1.85-4.65 mm) at point B and 3.1 mm (range 1.9-4.2 mm) at point D (Table 1).

	Prestenting (mm)	Poststenting (mm)	Last follow-up (mm)
В	1.85-4.65 (3.51±0.11)	1.96-5.2 (3.72±0.09)*	1.73-4.71(3.45±0.2)
D	1.9-4.2 (3.12±0.12)	2.1-4.6 (3.43±0.1)*	1.78-3.95 (3.03±0.14)

 Table 1: Parent artery diameter changes with time.

Note: \* significant difference (P < 0.05) compared with prestenting

#### Results

Seventy-seven EP stents were successfully deployed in the 68 patients for treating the 78 intracranial wide-necked aneurysms, with the technical success rate of 100%. Sixty six aneurysms were treated with stenting and subsequent coiling while 12 aneurysms with stent reconstruction of the parent artery alone. Among the 66 aneurysms with both stenting and coiling, complete occlusion was achieved in 46 (69.7%) aneurysms, near complete in 15 (22.7%) and incomplete in 5 (7.6%) immediately after the procedure. One EP stent was used to cover 2-4 adjacent aneurysms in 7 patients, with the largest aneurysm coiled and the other smaller ones uncoiled. Two stents were applied to cover an aneurysm in 7 patients for induction of thrombosis.

Seven procedure-related complications (9/68, 10.3%) occurred including thrombosis formation within the stent in two patients which was managed with intracatheter infusion of antithrombotic agents, coil protrusion in two which was managed with a second stent deployment for compressing the coil onto the vascular wall, and stent dislocation in three patients managed with a second stent deployed. Stenting and coiling were performed in the same session for most of the patients, with stenting firstly and coiling immediately afterwards. In four patients, stenting and coiling were performed in different sessions for the deployed stents to be embedded in the vascular wall because the maneuver of the micro-catheter might result in distal migration of the stents, and the coiling procedure was done after 1-3.5 months following stenting.

All the patients had one or more angiographic follow-up studies 12-55 months (mean 38) after embolization. During follow-up of 32 aneurysms with no complete occlusion (15 near complete occlusion + 5 incomplete occlusion + 12 stenting alone), progressive thrombosis occurred in 23 instances (71.9%), including 8 aneurysms with near complete occlusion progressing to complete occlusion, and 3 incomplete occlusion to complete occlusion. Twelve aneurysms with stent alone progressed to complete occlusion in 6 and decreased size in the other 6 (Table 2). Aneurysm regrowth took place in 11 patients (18.0%) of all the aneurysms with near complete or complete occlusion (61), with four patients retreated to complete occlusion and continuous surveillance for the remaining ones.

Immediately after stenting, the parent artery diameter was significantly (P<0.05) increased to a

mean value of  $3.72\pm0.09$  (range 1.96-5.2) mm at point B and  $3.43\pm0.1$ (range 2.1-4.6) mm at point D (Fig. 2 and Table 1). At the last angiographic follow-up, the diameter of the parent artery was decreased to  $3.45\pm0.2$  (1.73-4.71) mm at point B and  $3.03\pm0.14$  (1.78-3.95) mm at point D, which was not significantly different (P>0.05) from before stenting but significantly (P<0.05) from poststenting. At follow-up, six patients (8.8%) were noted to have a medium asymptomatic stenosis within the stented segment of the parent artery. No instent stenosis was noted in any other patients from the follow-up angiograms.

Occlusion	Postembolization (n, %)	Occlusion at follow-up (n, %)			
Occlusion		Complete	Near complete	Incomplete	Total
Complete	46 (59.0%)	40 (87%)	0	6 (13%, 4 retreated)	46 (100%)
Near complete	15 (17.0%)	8	2	5	15
Incomplete	5 (6.4%)	3	1	1	5
Stenting alone	12 (15.4%)	6	0	6	12
Total	78 (100%)	57	3	18	78

 Table 2: Results of aneurysms treated with stent reconstruction at postembolization and follow-up.



**Fig. 2**: The parent artery diameter at points B and D changes with time. \* significant difference (P<0.05) compared with before stenting and at follow-up at either point B or D.

#### Discussion

In this study investigating the EP stent reconstruction of the parent artery for the treatment of intracranial aneurysms, the success rate of the EP stent deployment is 100%, and most of the aneurysms (69.7% + 22.7%) achieve complete or near complete occlusion at the end of the procedure, with a comparable procedure-related complication rate of 10.3%. At long-term follow-up (3-55months), progressive thrombosis occurred in 71.9% aneurysms with near complete or incomplete occlusion, and aneurysm regrowth in 18.0% of aneurysms with near complete or complete occlusion. The parent artery diameter experiences an initial increase but later decrease trend, with no symptomatic stenosis of the parent artery.

The EP stent has a closed-cell design which is advantageous over open-cell designed stents when placed at curved vessels. At a vascular curvature, a stent with a closed-cell design will keep a constant opening, and prominence of the stent struts outside the parent arterial lumen or into the neck of an aneurysm is unlikely to happen, thus help preventing the protrusion of coils into the arterial lumen. However, a stent with an open-cell design may demonstrate elevated cell openings and outward protrusion of stent struts into the aneurysm neck at the curve convexity of arteries. However, at the concavity of an arterial curvature, the stent struts may prolapse inward<sup>(8,9)</sup>.

These adverse phenomena of an open-cell stent may cause some bad effects including thrombosis and stenosis within the stent, coil protusion into the parent artery, and entanglement with the endovascular devices including coils, guidewires, and microcatheters, subsequently resulting in severe consequences. At a curved artery, a closedcell stent may turn flattened at the midsection, but kinking of the stent will take place only at 30° or less of curvature of the artery<sup>(9)</sup>. For the majority of cerebral arteries which are not curved at a sharp angle, the above mentioned kinking phenomenon will not happen when the EP stent is implanted in these arteries to treat cerebral aneurysms.

In our study, the EP stent delivery system could be negotiated successfully to and beyond the targeted stent landing zone and deployed easily to cover the aneurysm orifice, with the technical success rate of stent deployment reaching 100%. The procedure-related complication rate was 10.3% which is comparable to that of the Neuroform stent procedure  $(4\%-13\%)^{(10-13, 14)}$ . Thrombus may be formed frequently in the endovascular procedure and may be caused by all devices put in the blood vessels including catheters, guidewires, coils and stents with severe results despite the use of anticoagulation.

Thrombi may probably result from flow stasis or interference in the aneurysm sac and may also be cause by electrothrombosis if electrically detachable coils are used. Thrombus may form on coils before or after the coils have been sent into the aneurysmal sac and may cause distal thromboembolic events with the ischemic incidence varying widely<sup>(15-17)</sup>. Immediate medical treatment may save the distal thromboembolic tissues if the thrombus is recognized earlier. Coil protrusion is another complication which can be managed with a stent to compress the protruded coil onto the vessel wall.

Stent dislodgement and misplacement may be another intraprocedural complication. In our study, three patients had distal migration of the deployed stent caused by maneuver of the microcatheter. Distal or proximal migration also occurred in other stents like the Neuroform stent<sup>(18)</sup>. Because the stents used for treating intracranial aneurysms usually have minimal radial force, it is natural that they cannot lodge firmly onto the vascular wall and that the maneuver of a microcatheter or microguidewire may cause the stent to move. If the radial force is great enough for the stent to fix onto the wall, the stent may lack longitudinal flexibility to pass through the tortuous cerebral vasculature especially the siphon of the ICA. In case of stent dislodgement and misplacement, the deployment of a second stent will usually be sufficient to support further coiling. In order to reduce the incidence of stent migration, one option may be to delay the coiling in another session one or two months later so that the deployed stent can be embedded into the vascular wall. Another option is to use the "jailed technique" to avoid stent migration.

Stent deployment alone was performed in 12 aneurysms and all these uncoiled aneurysms were noted to decrease in size or disappear at angiographic follow-up. Experimental and clinical data have demonstrated that the placement of stent alone across the neck of side-wall or fusiform aneurysms could change the intra-aneurysmal dynamics, leading to thrombosis and finally obliterating the aneurysm from blood circulation, which has been confirmed by our study with the EP stent reconstruction of the parent artery<sup>(11, 19-22)</sup>. Lee et al<sup>(23)</sup> reported 8 cerebral aneurysms treated with sole stenting and 4 of 6 aneurysms with follow-up achieved complete occlusion at a mean follow-up duration of 9 months. The progressive thrombosis rate was 71.9% in our study at long-term follow-up including aneurysms which became completely occluded and aneurysms which became smaller compared with immediately after stenting. Peng et al<sup>(3)</sup> also reported a high progressive occlusion rate of 69.7% (115/165) in 165 patients with cerebral aneurysms treated with the EP stent-assisted coiling

at a mean follow-up of 8.2 months. Weber et al<sup>(7)</sup> was the first to report the progressive occlusion rate of 40% with 10 of 25 aneurysms with initial incomplete occlusion aneurysms progressing to complete occlusion. However, the progressive occlusion rate of the Neuroform stent varied widely ranging from 14% to 57.1%<sup>(24-27)</sup>. This difference from the EP stent probably results from the closed-cell design which may provide a better scaffolding for reconstruction of the parent artery at the aneurysm neck, flow redirection, reduced flow into the aneurysm sac and better vessel wall healing<sup>(3)</sup>.

Aneurysm recurrence is common not only in coil embolization alone but also in Neuroform stent-assisted coiling of aneurysms<sup>(11, 28)</sup>. Some studies comparing coiling alone with stent-assisted coiling have demonstrated significant superiority of stent-assistance in terms of avoiding recurrence and even providing further occlusion<sup>(29-32)</sup>. At angiographic follow-ups, we noted medium asymptomatic stenosis within the stented segment of the parent artery in three patients. Late instent stenosis had also been noted in the Neuroform stent when it was used to assist coil embolization in wide-necked intracranial aneurysms<sup>(11, 33, 34)</sup>.

Hoit et al<sup>(34)</sup> performed 3D rotational angiographic detection of stenosis in the Neuroform stent for treating wide-necked aneurysms in 14 patients, and a 0.31-0.41mm reduction in the average diameter of the stented segment of vessel was found significant. However, the instent stenosis caused no clinical symptoms. Stenosis or restenosis is the arterial wall's healing response to mechanical forces of stenting<sup>(35,36)</sup>, and negative vascular remodeling is virtually absent after stenting<sup>(37, 38)</sup>. The diameter of the parent artery demonstrated a trend of increase at poststenting but decrease at follow-up of 3-55 months (mean 38), however, the diameter at follow-up was not significantly different from before stenting.

Our previous study had revealed that the EP stent can induce dynamic and reversible age-dependent stenosis in cerebral arteries when reconstructing the parent artery for intracranial aneurysm treatment<sup>(3940)</sup>. The initial diameter decrease was initiated within the first 4-6 months after stenting, whereas the reverse diameter increase was started 4-6 months poststenting until the diameter resumed almost to the original size before stenting. The current study did not have a detailed follow-up of the parent diameter and missed some details of the diameter changing trend with time.

At long-term follow-up, the vessel diameter had actually resumed almost to the original size before stenting, and the long-term follow-up diameter actually recorded the diameter value which had already resumed to the original size before stenting. That is why at long-term follow-up no significant stenosis was noted in the parent artery.

Limitations of this study included non-control, retrospective nature, a small cohort of patients and a single center enrolment. In the future, a randomized, prospective study with a large number of patients and multiple centers involved may need to better reflect the real results of the EP stent reconstruction of the parent artery in treating cerebral aneurysms.

In conclusion, the parent artery reconstruction with the EP stent is safe and effective in the treatment of wide-necked cerebral aneurysms with asymptomatic instent stenosis in long-term followup in some patients.

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