

Are your MRI contrast agents cost-effective?

Learn more about generic Gadolinium-Based Contrast Agents.



FRESENIUS
KABI

caring for life

AJNR

**PulseRider Stent-Assisted Coiling of
Wide-Neck Bifurcation Aneurysms:
Periprocedural Results in an International
Series**

B. Gory, A.M. Spiotta, S. Mangiafico, A. Consoli, A.
Biondi, E. Pomero, M. Killer-Oberpfalzer, W. Weber, R.
Riva, P.E. Labeyrie and F. Turjman






This information is current as
of April 16, 2024.

AJNR Am J Neuroradiol 2016, 37 (1) 130-135

doi: <https://doi.org/10.3174/ajnr.A4506>

<http://www.ajnr.org/content/37/1/130>

PulseRider Stent-Assisted Coiling of Wide-Neck Bifurcation Aneurysms: Periprocedural Results in an International Series

 B. Gory,  A.M. Spiotta,  S. Mangiafico,  A. Consoli,  A. Biondi,  E. Pomerio,  M. Killer-Oberpfalzer,  W. Weber,  R. Riva,  P.E. Labeyrie, and  F. Turjman

ABSTRACT

SUMMARY: The PulseRider is a novel endovascular device specifically designed to treat bifurcation intracranial aneurysms with wide necks. In an international series, we report the results of PulseRider stent-assisted coiling of 15 patients (9 women and 6 men; mean age, 62.6 years) with 15 unruptured wide-neck (median dome size, 8 mm; median neck size, 5 mm) bifurcation aneurysms. Failure of PulseRider treatment occurred in 1 case, and 1 intraprocedural thromboembolic complication was observed. There was no mortality or neurologic permanent morbidity at discharge and at 1 month. Immediate angiographic outcome showed 12 complete occlusions and 2 neck remnants. Follow-up at 6 months was available for 3 aneurysms and demonstrated 2 complete aneurysm occlusions and 1 growing neck remnant. In this small series of selected patients, PulseRider stent-assisted coiling of wide-neck bifurcation aneurysms was feasible with low procedural complication rates. Angiographic follow-up will be required to evaluate the efficacy of the PulseRider device.

ABBREVIATION: IA = intracranial aneurysm

Endovascular treatment with coils is the reference therapy for ruptured intracranial aneurysms (IAs).¹⁻³ Although no randomized study demonstrated the superiority of endovascular treatment compared with clipping for unruptured IAs, endovascular treatment is also often the preferred therapeutic option.³ However, endovascular treatment with coils of IAs with wide necks is difficult or simply not feasible. In this specific situation, balloon-assisted and stent-assisted techniques have widened the indications for endovascular treatment.⁴⁻⁷ Endovascular treatment of bifurcation IAs often requires stent placement with double stents in “Y” or “X” configurations, which could increase the risk of clinical complications,^{7,8} whereas some authors reported low rates of complications compared with the balloon-remodeling technique.^{9,10}

Recently, 3 devices have been specifically developed for the

endovascular treatment of such aneurysms arising at bifurcations: the WEB (Sequent Medical, Aliso Viejo, California), the pCONus (phenox, Bochum, Germany), and the PulseRider device (Pulsar Vascular, San Jose, California). The WEB is an intrasaccular braided-wire flow disruptor,^{11,12} and the pCONus is a new stent-like self-expanding nitinol implant with 4 distal petals allowing coiling of the aneurysmal sac.¹³ The PulseRider has a unique frame configuration that opens to conform to the vessel walls. It is specifically designed to preserve luminal patency and hemodynamic flow through the parent vessel bifurcation, while minimizing exposed metal to encourage early endothelialization while securely retaining coils within the aneurysm sac. It received a CE mark for intracranial aneurysms but has not been approved by the FDA. To date, a single published article on aneurysms treated with the PulseRider reported a series including 3 IAs.¹⁴ The aim of this study was to evaluate the results of the treatment of wide-neck bifurcation IAs with the PulseRider in an international series.

Case Series

The PulseRider is a self-expanding nitinol implant (Fig 1) that is delivered via a standard microcatheter with an inner diameter of 0.021 inches. The device is retrievable and may be repositioned by retracting it into the microcatheter at any time during or after deployment. It is deployed at the parent vessel bifurcation and across the aneurysm neck to provide a supporting framework, bridging the aneurysm neck while retaining coils within the aneurysm. The PulseRider is electrolytically detached from the delivery wire. The T or Y configurations are available according to

Received April 10, 2015; accepted after revision June 8.

From the DHU IRIS, Department of Interventional Neuroradiology (B.G., R.R., P.E.L., F.T.), Hôpital Neurologique Pierre Wertheimer, Hospices Civils de Lyon, Lyon, France; Department of Neurosciences (A.M.S.), Division of Neurosurgery, Medical University of South Carolina, Charleston, South Carolina; Department of Neuroradiology (S.M., A.C.), Careggi University Hospital, Florence, Italy; Department of Neuroradiology and Endovascular Therapy (A.B., E.P.), Jean-Minjoz Hospital, Franche-Comté University, Besançon, France; Neuroscience Institute/Department of Neurology (M.K.-O.), Paracelsus Medical University, Christian Doppler Clinic, Salzburg, Austria; and Department of Neuroradiology (W.W.), Knappschaftskrankenhaus, Recklinghausen, Germany.

Please address correspondence to Benjamin Gory, MD, MSc, DHU IRIS, Department of Interventional Neuroradiology, Hôpital Neurologique Pierre Wertheimer, Hospices Civils de Lyon, 59 Blvd, 69677 Bron, France; e-mail: benjamin.gory@chu-lyon.fr

<http://dx.doi.org/10.3174/ajnr.A4506>

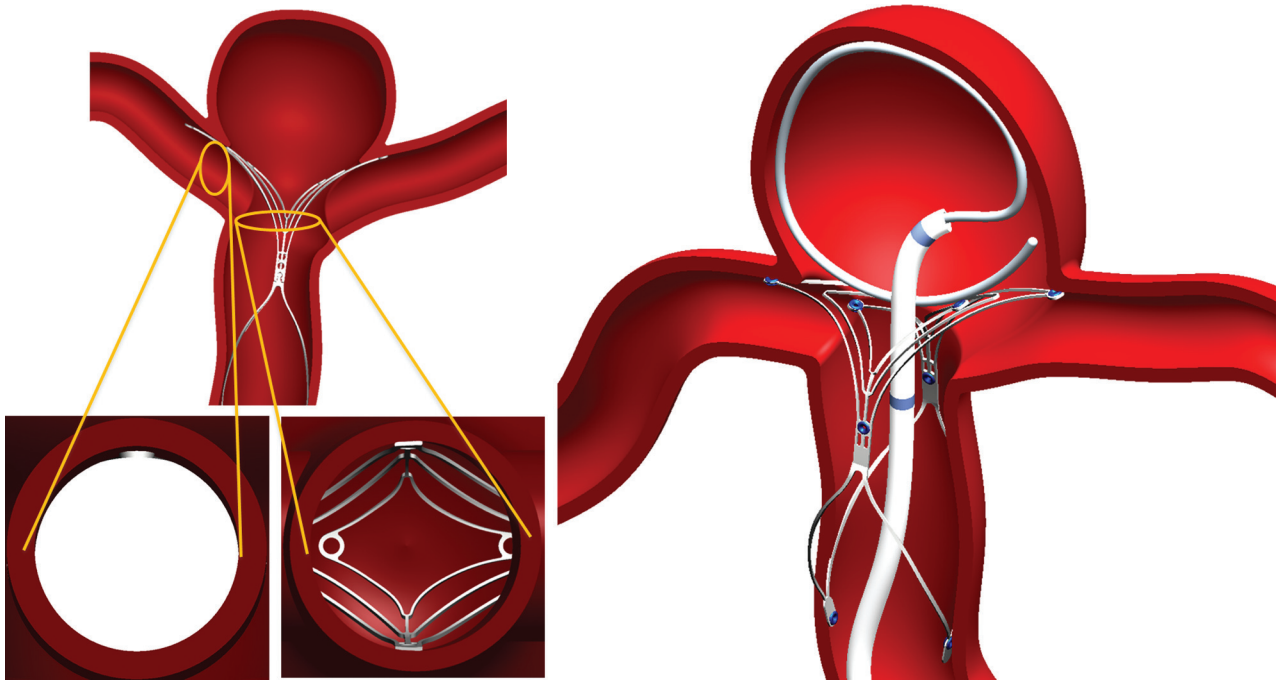


FIG 1. The PulseRider device is intended for use with embolic coils for the treatment of unruptured wide-neck intracranial aneurysms originating on or near a vessel bifurcation. The PulseRider has a unique arch design with concentrated coverage at the neck allowing attenuated coil packing, and open architecture in the branch vessels eliminates struts crossing through the lumen of the branch vessels. Reproduced with permission from PulsarVascular.

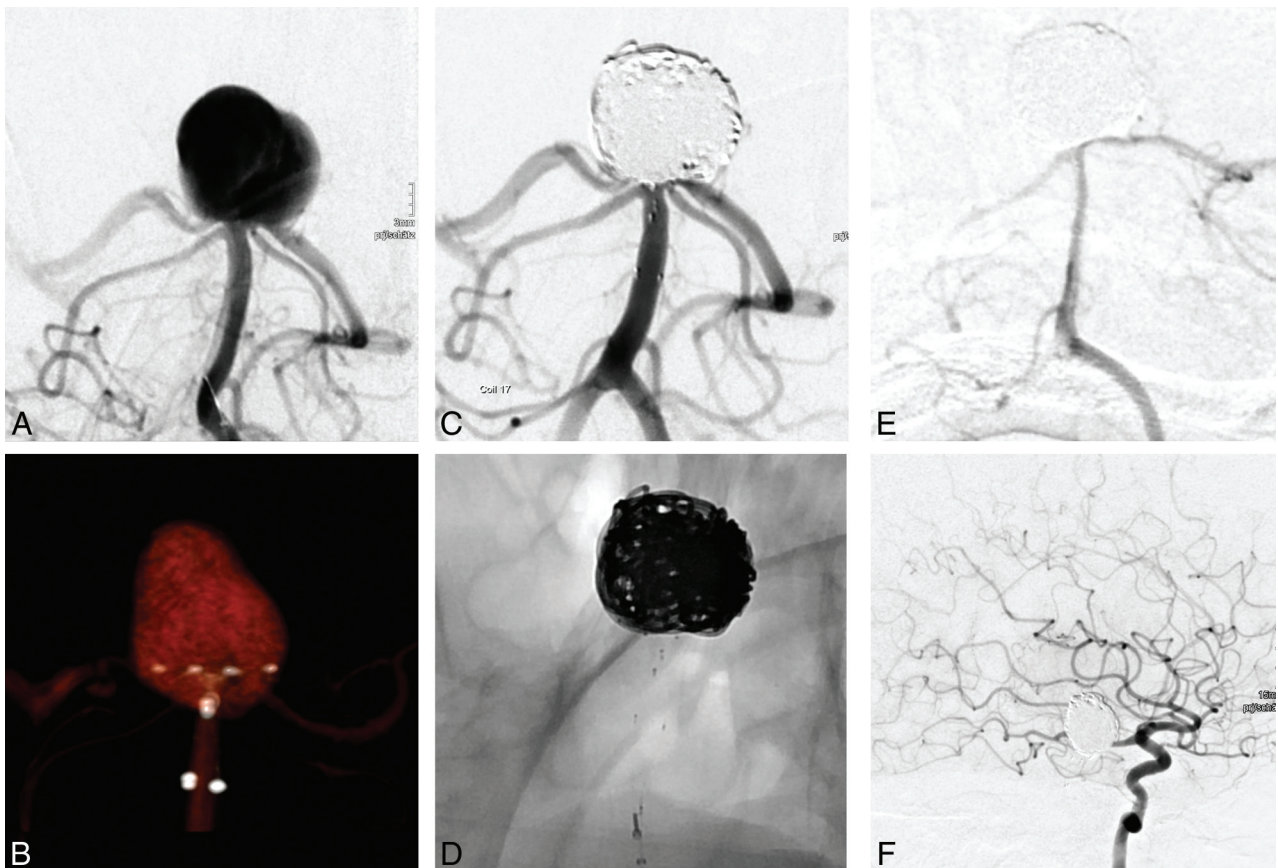


FIG 2. Incidental large basilar artery aneurysm in a 60-year-old woman (case 1). *A*, The angiogram shows a 17-mm aneurysm with an 8-mm neck. *B*, 3D reconstruction after rotational angiography shows the PulseRider device placement before coiling. *C* and *D*, An angiogram at the end of the procedure shows final complete aneurysm occlusion. *E*, Angiographic follow-up at 6 months reveals complete aneurysm occlusion with an occlusion of the P1 segment of the posterior cerebral artery, which was supplied by the internal carotid artery via the posterior communicating artery (*F*). The patient was asymptomatic.

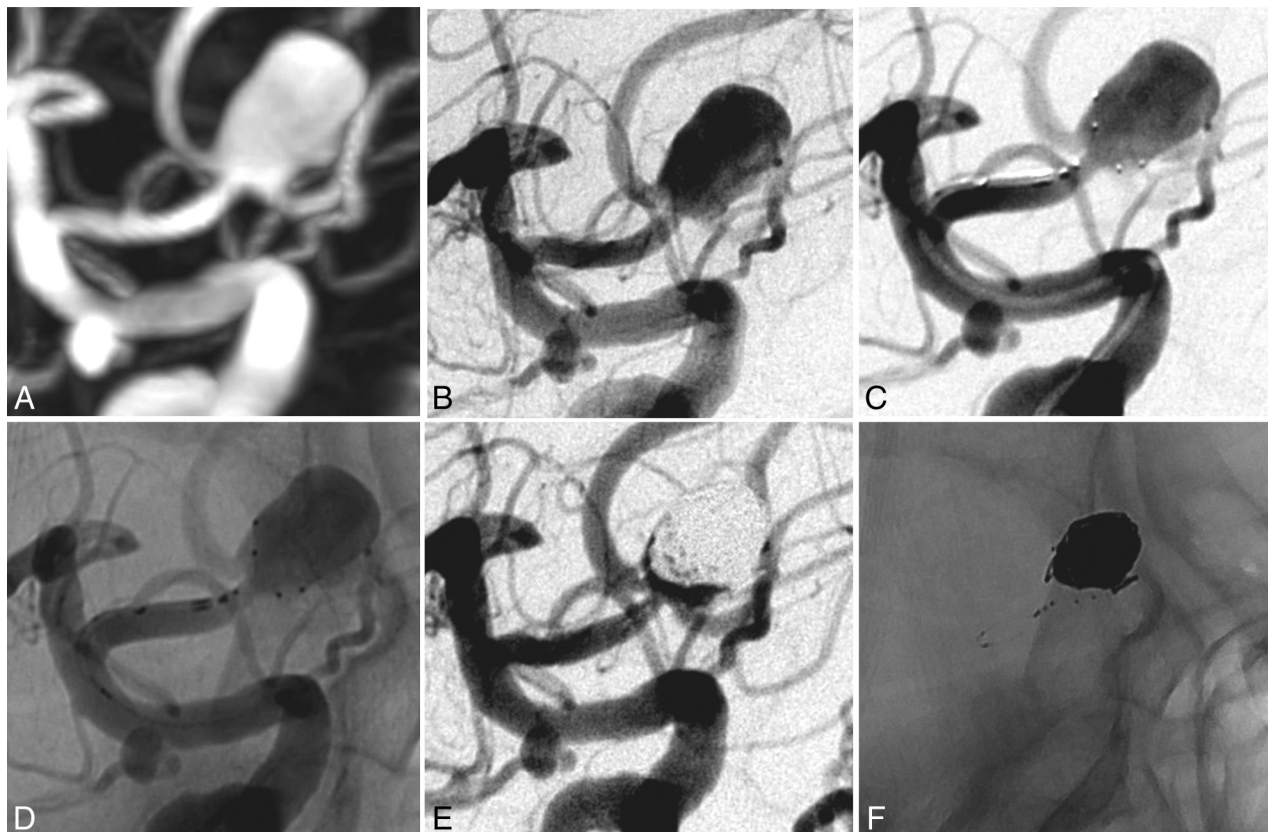


FIG 3. A wide-neck anterior communicating artery aneurysm in a 50-year-old woman (case 2). *A*, 3D reconstruction after rotational angiography shows a large anterior communicating artery with a 4.2-mm neck. *B*, Subtracted angiography shows a large anterior communicating artery. *C* and *D*, PulseRider stent-assisted coiling was performed. *E* and *F*, Subtracted angiographies at the end of the procedure show a neck remnant. The PulseRider device retained coils within the aneurysm sac.

the geometry of the daughter vessels arising at the bifurcation with 8- or 10-mm diameters.

From June 2014 to February 2015, 15 consecutive patients (9 women and 6 men; mean age, 62.6 years) with 15 unruptured bifurcation IAs (median dome size, 8 mm; median neck size, 5 mm) at 1 US center (Charleston, South Carolina) and 5 European institutions (Lyon and Besançon, France; Florence, Italy; Recklinghausen, Germany; Salzburg, Austria) who were treated with the PulseRider device for IAs were retrospectively analyzed (under institutional review board approved protocol in United States and without approved ethics committee protocols in the European Union). The decision to assist coiling by a PulseRider device was made at the discretion of the senior author. All patients were treated under general anesthesia and full anticoagulation. In addition, double antiplatelet therapy was administered preoperatively according to the operator's protocol.

Endovascular Procedure

A Prowler Select Plus 0.021-inch microcatheter (Codman & Shurtleff, Raynham, Massachusetts) was navigated over a 0.014-inch microwire and positioned at the neck of the aneurysm. In a suitable working projection, the appropriately sized PulseRider was then deployed across the neck of the aneurysm with limbs in the daughter vessels arising at the bifurcation or in the aneurysm, or in a hybrid fashion with one limb in the branch vessel and the other limb in the aneurysm. Thereafter, a second microcatheter

was inserted through the shaft into the aneurysm fundus, and coiling was performed. The PulseRider was detached either at or near the final coiling.

Treatment Failure

Treatment failure with the PulseRider occurred in 1 patient (patient 11) with a wide-neck carotid terminus aneurysm and a 4.5-mm dome. The deployment of the PulseRider was achieved, but on control angiograms, suboptimal positioning of the device was seen with incomplete protection of the neck. The PulseRider was replaced several times without success, and the aneurysm was then treated with stent-assisted coiling (Y-stent placement).

Procedural Complications

One thromboembolic event after detachment of the device occurred. After successful PulseRider-assisted coiling of a right MCA aneurysm, a thrombus formation occurred at the limbs of the device and caused a stenosis of the distal M1 segment. After immediate administration of glycoprotein IIb/IIIa inhibitors, the stenosis remained but the patient woke up without neurologic deficits and remained in this status at 1 month follow-up. No intraoperative rupture was observed.

Outcome

Among the 14 patients treated with the PulseRider, no neurologic impairment was observed at discharge and at 1-month follow-up

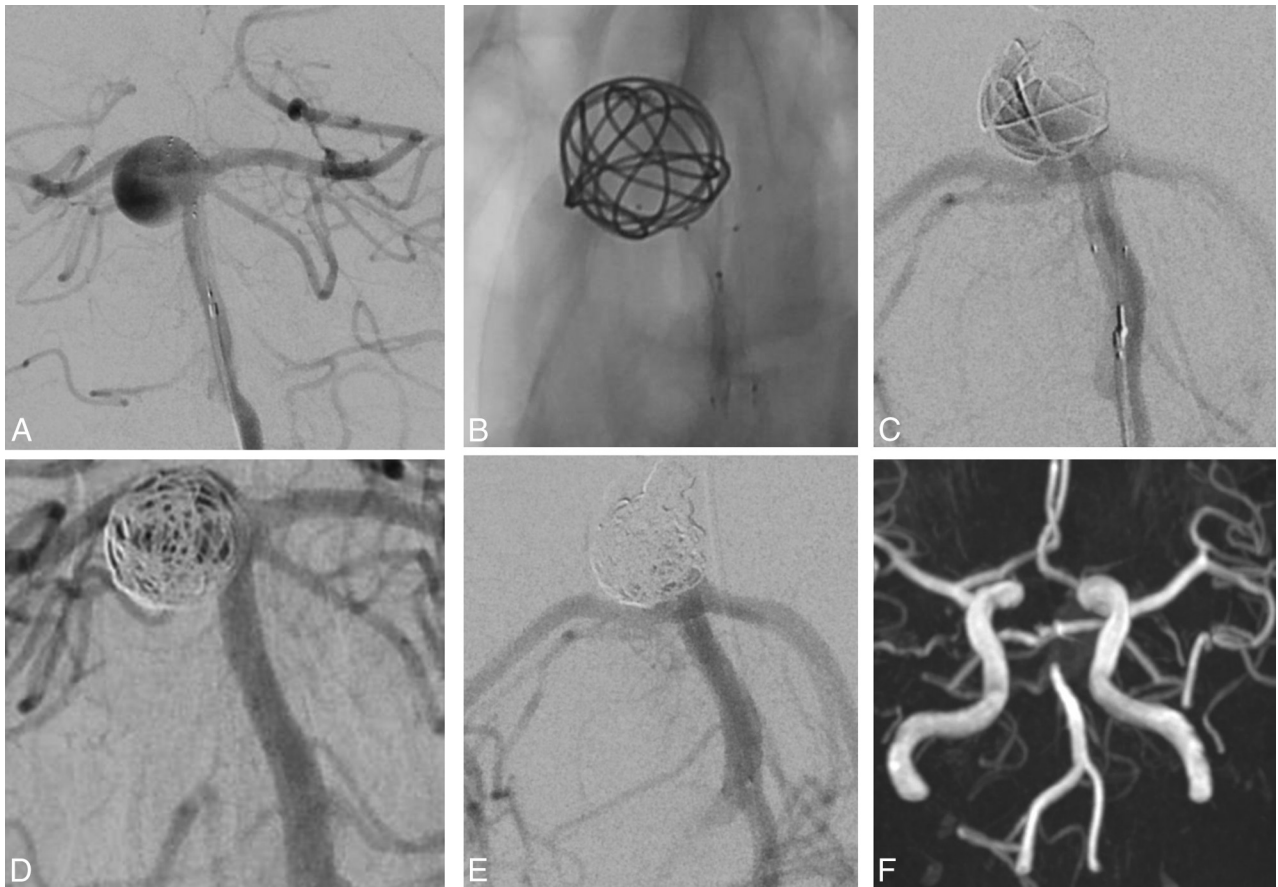


FIG 4. An unruptured basilar tip aneurysm in a 60-year-old man (case 3). *A*, Subtracted angiography shows a large basilar tip aneurysm with a 4-mm-wide neck. *B–D*, Endovascular treatment was performed by using a PulseRider device. *E*, Subtracted angiography at the end of the procedure shows complete aneurysm occlusion. *F*, MRA at 1 day shows complete occlusion.

(11 patients). There were no delayed neurologic deficits or deaths at follow-up.

One reader (B.G.) independently evaluated all the angiograms by using a simplified 3-point scale (total occlusion, neck remnant, aneurysm remnant).¹⁵ Immediate angiograms showed complete occlusion in 12 patients and neck remnant in 2 patients. Angiographic follow-up at 6 months was available for 3 patients and demonstrated 2 complete aneurysm occlusions and 1 growing neck remnant. During follow-up, retreatment was performed in 1 case due to a significant increase in the size of the neck remnant, with complete occlusion at the end of procedure. No in-stent stenosis and 1 jailed branch occlusion were observed.

Illustrative Cases

Case 1. A 60-year-old woman (Fig 2, patient 9) presented with an incidental large basilar artery aneurysm. Angiography revealed a 17-mm aneurysm with an 8-mm neck. Endovascular treatment was performed by using a PulseRider device with final complete aneurysm occlusion. Angiographic follow-up at 6 months revealed complete aneurysm occlusion with an occlusion of the P1 segment of the posterior cerebral artery, which was supplied by the internal carotid artery via the posterior communicating artery. The patient was asymptomatic.

Case 2. A 50-year-old woman (Fig 3, patient 6) presented with an

incidental finding of a 4.2-mm wide-neck anterior communicating artery aneurysm. Endovascular PulseRider deployment and then coiling was performed. The final angiogram showed a neck remnant.

Case 3. A 60-year-old woman (Fig 4, patient 14) presented with an unruptured basilar tip aneurysm. Angiography showed a large basilar tip aneurysm with a 4-mm-wide neck. Endovascular treatment was performed by using a PulseRider. The final angiogram showed complete aneurysm occlusion, and MRA at 1 day showed complete aneurysm occlusion.

DISCUSSION

This initial study reports a series of patients with unruptured bifurcation IAs with wide necks treated by PulseRider stent-assisted coiling.

Feasibility and Patient Selection

This report suggests that PulseRider-assisted coiling of IAs with wide necks is feasible; however, the selection of patients should be well-considered before deciding on a PulseRider treatment. In fact, in this small series of 15 patients, the rate of failure was 6.7% (patient 11). This patient presented with a wide-neck terminus carotid aneurysm with a small-size dome. The PulseRider deployment was feasible, but it did not provide protection of the aneu-

Clinical and angiographic outcomes

No.	Age (yr), Sex	Location	D (mm)	N (mm)	Failure	PulseRider Diameter (mm)	Immediate Angiographic Outcome	6-Month Angiographic Outcome	Modified Rankin Scale		
									Initial	Discharge	1 Month
1	74, F	Basilar tip	16.3	10.9	No	10	Complete		1	1	3
2	69, M	Carotid terminus	4.2	3.5	No	8	Complete		0	0	1
3	69, F	Basilar tip	7.9	4.1	No	8	Complete		0	0	0
4	57, F	Carotid terminus	4.1	2.3	No	8	Complete		1	0	
5	65, F	Basilar tip	9.5	5.7	No	10	Complete		0	1	
6	50, F	AcomA	8.4	4.2	No	8	Neck remnant		0	0	0
7	82, M	MCA	5.6	3.9	No	8	Complete		1	1	1
8	54, F	Basilar tip	4.5	11	No	8	Neck remnant	Neck remnant (w)	0	0	0
9	60, F	Basilar tip	17	8	No	10	Complete	Complete	0	0	0
10	51, F	MCA	5.5	4	No	8	Complete	Complete	0	0	0
11	64, M	Carotid terminus	4.5	4	Yes	8	—	—	—	—	—
12	67, M	MCA	8	5	No	8	Complete		0	0	0
13	56, M	AcomA	15	5	No	10	Complete		0	0	0
14	60, M	Basilar tip	7	4	No	8	Complete	Complete ^a	0	0	
15	74, F	MCA	6	5	No	8	Complete		0	0	0

Note:—AcomA indicates anterior communicating artery; D, dome; N, neck; w, worsening; —, not applicable because the treatment failed with PulseRider.

^aMRA at 1 day.

rysmal neck even after several attempted placements. The pCONus device was placed and not detached due to the same problem occurring repeatedly; the aneurysm was then successfully treated with Y-stent-assisted coiling without complications.

Selection of patients is also important when using a WEB device. In the recent series of Gherasim et al¹¹ dealing with 10 patients with unruptured anterior communicating artery aneurysms (mean dome size, 5.8 mm; range, 3.8–8.2 mm; mean neck size, 5.4 mm; range, 3.6–8 mm), WEB deployment failed in 3 of 10 patients because of unfavorable anatomy and the use of a much larger and stiffer microcatheter for the WEB device than usually used for coiling.¹¹

Periprocedural Complications

Our results show that endovascular treatment of IAs with the PulseRider is safe despite the very specific population with a median neck size of 5 mm. There was neither device-related mortality nor permanent morbidity. Similar results have also been reported in the first published series.¹⁴ The safety of the PulseRider was also highlighted because no clinically evident complications were associated with its use in 3 wide-neck aneurysms.¹⁴ Contrary to sidewall IAs, bifurcation IAs with wide necks are difficult or impossible to treat with simple coiling and often need double stent placement in “Y” and “X” configurations. However, the risk of procedure-related morbidity and mortality is not negligible. The rate of procedure-related permanent neurologic deficits was 10% in 97 patients with complex and wide-neck bifurcation aneurysms.⁸ Compared with regular intracranial stent placement, PulseRider treatment also needed dual antiplatelet therapy during the perioperative period despite a very low amount of metal. The safety of this device seems very good in our small series. However, the safety of PulseRider stent-assisted coiling remains to be assessed in larger series.

Anatomic Results

As previously reported in the small series of Spiotta et al,¹⁴ complete initial aneurysm occlusion was achieved in most cases (84.6%). These immediate anatomic results are encouraging, given the unfavorable angiographic aspects of IAs included in our

series. In this series of Spiotta et al with 3 wide-neck bifurcations aneurysms, complete aneurysm occlusion was observed in all cases.¹⁴ In fact, large or giant IAs treated with coils presented low initial angiographic occlusion rates and high rates of recanalization.^{3,15,16} However, in our series, angiographic control at follow-up was obtained in only 3/13 patients (23%). A follow-up is mandatory to evaluate the efficacy of this treatment. Although angiography remains the criterion standard, there is a role for MRA in following up these patients because small artifacts were introduced by metal as illustrated in Fig 4 (patient 14).¹⁷ Much more data with the PulseRider device are clearly required to evaluate the mid- and long-term results of this new endovascular approach.

The limitations of our study were a small number of patients with a relatively short follow-up period to evaluate the efficacy of the PulseRider device. In addition, a small percentage of patients were followed in our series. However, we believe it is important to have a preliminary evaluation for this new endovascular treatment device dedicated to challenging IAs with wide necks and/or complex anatomy. So far, the preliminary results are encouraging.

Disclosures: Alejandro M. Spiotta—UNRELATED: Consultancy: Penumbra, Pulsar, MicroVention, Stryker; Grants/Grants Pending: MicroVention (research grant)*; Travel/Accommodations/Meeting Expenses Unrelated to Activities Listed: Penumbra, Pulsar, MicroVention, Stryker. *Money paid to the institution.

REFERENCES

- Molyneux A, Kerr R, Stratton I, et al; International Subarachnoid Aneurysm Trial (ISAT) Collaborative Group. **International Subarachnoid Aneurysm Trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms: a randomised trial.** *Lancet* 2002;360:1267–74 CrossRef Medline
- Molyneux AJ, Birks J, Clarke A, et al. **The durability of endovascular coiling versus neurosurgical clipping of ruptured cerebral aneurysms: 18 year follow-up of the UK cohort of the International Subarachnoid Aneurysm Trial (ISAT).** *Lancet* 2015;385:691–97 CrossRef Medline
- Gory B, Turjman F. **Endovascular treatment of 404 intracranial aneurysms treated with Nexus detachable coils: short-term and mid-term results from a prospective, consecutive, European multicenter study.** *Acta Neurochir* 2014;156:831–37 CrossRef Medline

4. Gory B, Kessler I, Seizem Nakiri G, et al. **Initial experience of intracranial aneurysm embolization using the balloon remodeling technique with Scepter C, a new double-lumen balloon.** *Interv Neuroradiol* 2012;18:284–87 CrossRef Medline
5. Gory B, Klisch J, Bonafé A, et al. **Solitaire AB stent-assisted coiling of wide-necked intracranial aneurysms: short-term results from a prospective, consecutive, European multicentric study.** *Neuroradiology* 2013;55:1373–78 CrossRef Medline
6. Gory B, Klisch J, Bonafé A, et al. **Solitaire AB stent-assisted coiling of wide-necked intracranial aneurysms: mid-term results from the SOLARE study.** *Neurosurgery* 2014;75:215–19; discussion 219 CrossRef Medline
7. Gory B, Rouchaud A, Saleme S, et al. **Endovascular treatment of middle cerebral artery aneurysms for 120 nonselected patients: a prospective cohort study.** *AJNR Am J Neuroradiol* 2014;35:715–20 CrossRef Medline
8. Bartolini B, Blanc R, Pistocchi S, et al. **“Y” and “X” stent-assisted coiling of complex and wide-neck intracranial bifurcation aneurysms.** *AJNR Am J Neuroradiol* 2014;35:2153–58 CrossRef Medline
9. Consoli A, Vignoli C, Renieri L, et al. **Assisted coiling of saccular wide-necked unruptured intracranial aneurysms: stent versus balloon.** *J Neurointerv Surg* 2014 Nov 26. [Epub ahead of print] CrossRef Medline
10. Limbucci N, Renieri L, Nappini S, et al. **Y-stent assisted coiling of bifurcation aneurysms with Enterprise stent: long-term follow-up.** *J Neurointerv Surg* 2014 Dec 11. [Epub ahead of print] CrossRef Medline
11. Gherasim DN, Gory B, Sivan-Hoffmann R, et al. **Endovascular treatment of wide-neck anterior communicating artery aneurysms using WEB-DL and WEB-SL: short-term results in a multicenter study.** *AJNR Am J Neuroradiol* 2015;36:1150–54 CrossRef Medline
12. Bozzetto Ambrosi P, Gory B, Sivan-Hoffman R, et al. **Endovascular treatment of bifurcation intracranial aneurysms with the WEB SL/SLS: 6-month clinical and angiographic results.** *Interv Neuroradiol* 2015;21:462–69 CrossRef Medline
13. Gory B, Aguilar-Pérez M, Pomero E, et al. **pCONus device for the endovascular treatment of wide-neck middle cerebral artery aneurysms.** *AJNR Am J Neuroradiol* 2015 Jul 23. [Epub ahead of print] CrossRef Medline
14. Spiotta AM, Chaudry MI, Turk AS, et al. **Initial experience with the PulseRider for the treatment of bifurcation aneurysms: report of first three cases in the USA.** *J Neurointerv Surg* 2015 Jan 5. [Epub ahead of print] CrossRef Medline
15. Raymond J, Guilbert F, Weill A, et al. **Long-term angiographic recurrences after selective endovascular treatment of aneurysms with detachable coils.** *Stroke* 2003;34:1398–403 CrossRef Medline
16. Campi A, Ramzi N, Molyneux AJ, et al. **Retreatment of ruptured cerebral aneurysms in patients randomized by coiling or clipping in the International Subarachnoid Aneurysm Trial (ISAT).** *Stroke* 2007;38:1538–44 CrossRef Medline
17. Choi JW, Roh HG, Moon WJ, et al. **Optimization of MR parameters of 3D TOF-MRA for various intracranial stents at 3.0T MRI.** *Neurointervention* 2011;6:71–77 CrossRef Medline