reduce material thrombogenicity, the PED Flex device underwent surface modification with covalently bonded phosphorylcholine to the surface of the implant, so called Shield Technology™. This technology has been shown to reduce thrombogenicity and promote endothelialization with earlier and thicker neointima formation but less hyperplasia.

Materials and Methods Prospectively maintained neurointerventional databases at 7 high-volume U.S. medical centers were retrospectively reviewed between April 2021 (corresponding with the FDA approval of the PED Shield) and October 2021. Additionally, compassionate use cases between 2016 and 2020 were also included. All patients who underwent placement of a PED Shield for treatment of a ruptured or unruptured intracranial aneurysm were identified. Patients who underwent re-treatment of an intracranial aneurysm due to failed primary treatment method were also included. Patient demographics, information on aneurysm size, morphology, and location as well as procedural data including device(s) used, adjunctive coiling and/or balloon angioplasty performed, intra-procedural complications, patient early angiographic and clinical outcome was collected.

Results One hundred thirty-eight patients were included (111 women) with 147 aneurysms. Eight aneurysms were ruptured. The patient’s mean age was 58 years. Most aneurysms were located along the ICA (n=120), specifically along the ophthalmic segment (n=53), wide-necked (n=121) and saccular in shape (n=110). Mean aneurysm size was 4.3 mm (1.5 – 22 mm). PED Shield deployment was technically successful in 136 cases (98.6%). Balloon angioplasty was performed in 22 cases (15.9%). Aneurysm stasis after device deployment was seen in 86 aneurysms (58.5%). No major ischemic stroke or neurological death occurred. Transient ischemic attack was seen in 2 patients (1.4%). One patient suffered an intraparenchymal bleed on post-op day 11 and 1 patient had a minor stroke leading to overall permanent neurological morbidity of 1.4%.

Conclusion Our study is the first to report the early experience with the newly FDA-approved PED Flex with Shield technology amongst US centers. Our results are comparable with non-US, international studies showing a high technical success rate and safe peri-procedural angiographic and patient outcome. Long-term follow-up will be needed to provide more robust data on angiographic and patient outcomes.

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The Contour is a novel intra-aneurysmal flow disrupting device to treat intracranial aneurysms. To evaluate the safety and effectiveness of the Contour in nonruptured intracranial bifurcation aneurysms, we conducted a prospective, multicenter, single-arm study on thirty-four patients.

The primary end points were occlusion status at 6 and 12 months as well as major stroke within 6 mo. Secondary end points were retreatment rate, procedure time, and procedure-related adverse events. An independent core lab reviewed all the images. Adverse events were reviewed by a clinical events committee.

32 of 34 aneurysms were successfully implanted. Two patients in the intention-to-treat group did not receive the Contour and were excluded from follow-up. Two were lost to angiographic follow-up and regarded as treatment failure. The primary safety end point was met in 2 patients in the ITT group.

Complete occlusion was seen in 14/32 (44%) at 6 mo and 22/32(69%) at 12 mo. Adequate occlusion (Raymond-Roy [RR] 1 and 2) was reached in 84% at a last available follow-up. One patient from the ITT group and 1 from the PP group received additional treatment during follow-up.

We conclude that the Contour appears to be both safe and effective in the treatment of intracranial bifurcation aneurysms. These results warrant further studies in the future.

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