

The Woven EndoBridge Cerebral Aneurysm Embolization Device (WEB II): initial clinical experience

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Abstract

Introduction The Woven Endobridge (WEB II) device (Sequent Medical, Inc., Aliso Viejo, CA, USA) is an intra-saccular, oblate, braided-wire embolization device designed to provide flow disruption at the aneurysm neck–parent artery interface. The purpose of this study was to evaluate the acute and short-term performance of the WEB II device regarding the immediacy, degree, and durability of aneurysm occlusion in two patients.

Methods The WEB II device was implanted in one patient with an unruptured MCA trifurcation aneurysm and one patient with an unruptured basilar tip aneurysm. The degree of intra-aneurysmal flow disruption was graded based on serial digital subtraction aneurysm angiography performed over 30 min immediately following device implantation and at 8 weeks. Immediate and 8-week post-treatment CT and 3-T MRI studies were also performed.

Results Delivery and deployment of the WEB II device was technically straightforward and achieved without complications. Neither device required retrieval or repositioning after full deployment. There were no peri-procedural thrombembolic or hemorrhagic complications. In both

cases, complete aneurysm occlusion was observed within minutes of device deployment. Short-term angiographic follow-up confirmed stable complete occlusion at 8 weeks. **Conclusion** Early technical and clinical results from the first WEB II cases have been encouraging and suggest that the intra-saccular deployment of self-expanding, compliant, cylindrical, high-density, braided metallic mesh constructs may represent a feasible approach for the endovascular treatment of cerebral aneurysms.

Keywords WEB II device · Endovascular treatment · Aneurysm

Introduction

Modern endovascular techniques incorporating parent artery remodeling devices and intraluminal flow diverters have made the treatment of complex cerebral aneurysms more feasible [1–4]. The preliminary clinical experiences with flow diverters have demonstrated largely excellent occlusion rates even in the most challenging subtypes of cerebral aneurysms [5–10]. These new devices have refocused the attention toward the aneurysm neck as the point of relevance in aneurysm treatment [11]. Specifically, achieving a stable construct across the aneurysm neck, irrespective of aneurysm size or configuration, appears to be of primary importance in achieving complete and durable occlusion.

The WEB II embolization device (Sequent Medical Inc., Aliso Viejo, CA, USA) is a self-expanding, metallic mesh device that is designed for intra-aneurysmal deployment. The endosaccular implant conforms to the aneurysm wall and spans the aneurysm neck to essentially function as a two-layer “intra-saccular flow diverter”, providing uniform,

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high-density mesh coverage at the aneurysm neck–parent artery interface. The WEB II replaces an earlier version, the WEB I, which comprised only a single layer of nitinol mesh. Ding et al. reported on a preclinical study of the WEB I in the rabbit elastase aneurysm model [11]. Animal data indicate a higher occlusion rate by the use of the WEB II (C. Strother, personal communication). The WEB II device has recently been granted full CE Mark clearance for commercialization within the European Union as a stand-alone therapy for cerebral aneurysm treatment. In this report, we present first-in-man experiences with the WEB II device for the treatment of unruptured cerebral aneurysms. The two cases presented in this study allow the opportunity to discuss new procedural details and to anticipate potential limitations of intra-saccular flow diversion.

Methods

Device description

The self-expanding WEB II device (Sequent Medical) is an oblate, compliant, braided nitinol mesh (Fig. 1a). An oblate spheroid is a rotationally symmetric ellipsoid having a polar axis shorter than the equatorial diameter. The device is composed of an inner and outer braid held together by proximal, middle, and distal radio-opaque markers. The wire mesh presents a variable pore structure with a maximum inter-wire distance of $100 \times 150 \mu\text{m}$ across the aneurysm ostium, resulting in between 100% metal surface area coverage in the center of a device to a minimum of 22% coverage at the edge of a device. The device is delivered through a $\geq 0.027''$ microcatheter and is fully resheathable after delivery. The detachment system is electrothermal and provides instantaneous detachment. The highly conformable mesh structure of the WEBII expands to oppose to the aneurysm wall which in turn stabilizes the device mesh at the aneurysm neck. The device is designed with a concave base to avoid the formation of thrombus on the device.

Additionally, the oblate structure of the WEBII was designed for large neck aneurysms. The device is indicated for the treatment of saccular aneurysms with a neck-to-dome ratio of ≤ 1 and a neck length-to-width ratio of < 2 , where the neck length-to-width ratio is the ratio of the longest neck diameter divided by the shortest neck diameter. Devices are currently available in sizes suitable to treat aneurysms between 5 and 11 mm in diameter.

Device handling and placement

The WEB II device is attached to a delivery wire and compressed within a delivery sheath which allows it to be

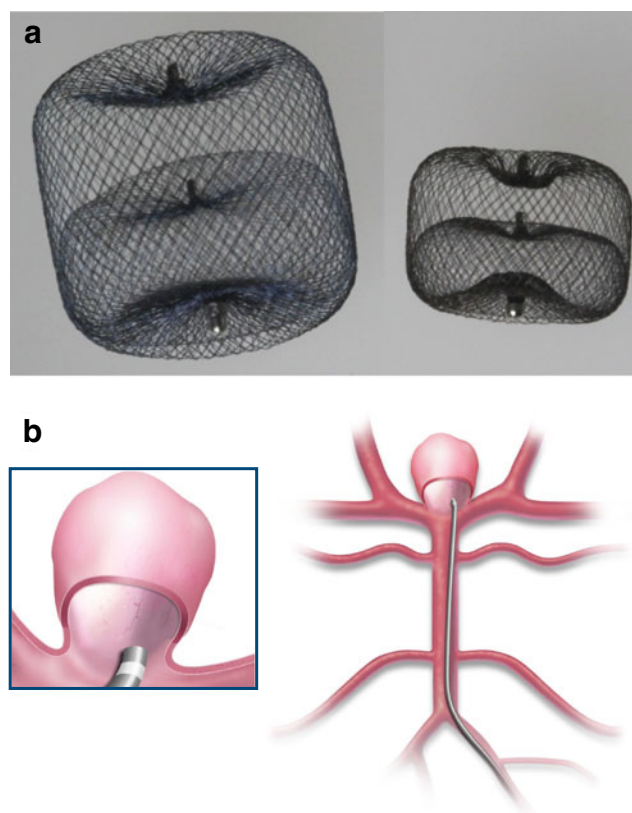


Fig. 1 **a** Photograph (with permission from Sequent, CA, USA) of the Woven EndoBridge II device. The proximal and distal ends of the device have radio-opaque markers attached. **b** The 0.027 microcatheter should be positioned within the base of the aneurysm

loaded into a $\geq 0.027''$ -internal-diameter microcatheter [e.g., Rebar (ev3/Covidien, Irvine, CA, USA)]. The microcatheter is optimally positioned within the proximal aspect of the aneurysm fundus (Fig. 1b). The device is advanced through the microcatheter and positioned within the aneurysm. The deployment is analogous to a stent deployment and is a combination of microcatheter retraction with gentle forward pressure to stabilize and advance the device. The device deploys more easily when it is not initially in contact with the aneurysm wall and when the angle between the microcatheter and the major axis of the aneurysm is straight. The distal radio-opaque marker should be positioned in the distal aspect of the dome. The proximal radio-opaque marker should be positioned in alignment with the aneurysm neck. Off-axis deployment may result in a poor seal of the neck and persistent neck remnant.

Immediately after deployment within the aneurysm, a control angiogram should be performed to assess the conformation of the device within the aneurysm fundus and at the aneurysm neck. If the sizing and orientation of the device is acceptable, it can be detached within the aneurysm. If the operator decides that the sizing or orientation is not favorable, the device should be immedi-

ately resheathed and either removed or repositioned. After detachment, control angiography was performed at 30 min to provide an assessment of the degree of intra-procedural occlusion.

Case reports

After discussion within our interdisciplinary neurovascular team, patients were selected for endovascular treatment with the WEB II device. The patients were informed that only limited experimental data were available for the WEB II device. We discussed the risks, benefits, alternatives, and potential complications involved with the WEB II embolization procedure. We also discussed the alternative endovascular treatments such as coiling with or without balloon remodeling or stent protection and indicated that these treatments would be available in the same session if treatment with the WEBII device appeared to be unsatisfactory or not feasible. Both cases were performed after the device had received CE Mark clearance within the European Union. Both patients provided full informed consent to proceed. All procedures were performed in a dedicated biplane neuro-angiography suite (Siemens Axiom Artis, Siemens, Erlangen, Germany). All control MR examinations were performed with the Philips Achieva 3.0 T X-Series MRI system (Philips Healthcare, Best, Netherlands).

Anti-platelet therapy

When optimally implanted, the endosaccular WEBII creates a high-density, uniform metallic mesh barrier at the parent artery–aneurysm neck interface. In comparison to endosaccular coils, this barrier at the aneurysm neck is of a much higher and more uniform density. As such, we did not expect that the surface interface of the WEB II would be any more thrombogenic than standard mass of randomly distributed embolization coils. Preclinical data in both canine and rabbit models have supported this contention, as the WEB exhibited thrombogenicity comparable to an endosaccular coil mass [11]. Therefore, patients were heparinized to a targeted activated clotting time of 250 to 300 s during the procedure and treated with a single dose of 500 mg of aspirin immediately before placement of the WEB II. Patients were continued on aspirin 100 mg daily for 6 months as well as low molecular weight heparin for 3 days after the procedure.

Patient 1

Presentation An adult patient presented with five aneurysms as demonstrated by cross-sectional brain imaging with

CT, CTA, and MR imaging. Two were surgically clipped, one is being observed, one is scheduled for treatment with a flow diverter, and the fifth, a basilar apex aneurysm, was selected for treatment with the WEB II.

Treatment The basilar aneurysm (Fig. 2a, b) measured 4.6 × 5.5 mm with a 2.1-mm neck. After conventional angiography and 3D rotational analysis was performed through a diagnostic catheter, a 6F guide catheter (Cordis Neurovascular, Miami Lakes, FL, USA, now Codman Neurovascular, Raynham, MA, USA) was navigated into the distal cervical segment of the left vertebral artery. Under high magnification fluoroscopic roadmap control, a co-axial system consisting of 0.041 Penumbra reperfusion catheter (Penumbra Inc., Alameda, CA, USA) with an internal Rebar-27 microcatheter (ev3, Irvine, CA, USA) was navigated into the mid-basilar trunk. The Rebar-27 was then carefully navigated into the proximal aspect of the aneurysm fundus. The 6 × 3 mm WEB II device was then gently delivered into the aneurysm and deployed (Fig. 2b). The total time required between catheter placement within the aneurysm and device deployment was 3 min. Serial control angiograms performed for 30 min after treatment demonstrated a progressive rapid cessation of flow within the aneurysm, starting distally and progressing toward the aneurysm neck. Contrast stasis was observed within the remaining aneurysm 10 min after detachment (Fig. 2c, d). There was a slight narrowing of the left P1 segment after deployment of the WEB II device without any change over time.

The post-procedure hospital course was uneventful and the patient remained at neurological baseline. CT scanning and MR imaging with diffusion and long TR-weighted sequences showed no evidence of acute parenchymal infarction (Fig. 2e). Follow-up catheter angiography and MR imaging with MRA were performed 8 weeks after the initial treatment demonstrating complete occlusion of the aneurysm (Fig. 2f). The narrowing of the left P1 segment was constant.

Patient 2

Presentation An adult patient presented with three aneurysms as demonstrated by cross-sectional brain imaging with CT, CTA, and MR imaging. Two of the aneurysms measured less than 4 mm and are being followed with serial imaging. A larger MCA aneurysm was selected for possible treatment with the WEB II.

Treatment The MCA aneurysm (Fig. 3a) measured 7 × 4.6 mm with a 3.35-mm neck. After a complete delineation of the aneurysm anatomy with both conventional and

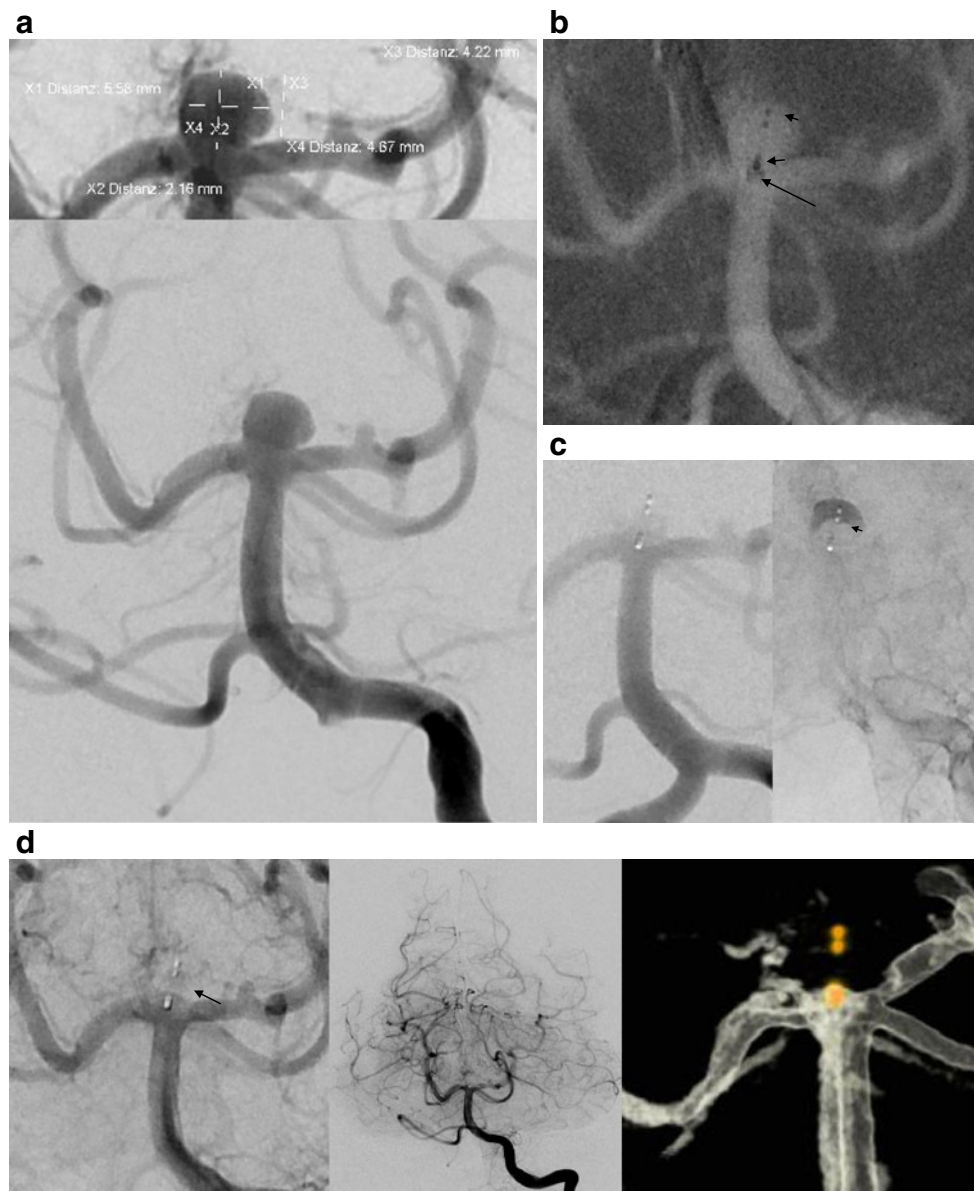


Fig. 2 **a** Arteriogram of the left vertebral artery p.a. view and angulated projection showing a broad-based aneurysm of the basilar tip. **b** Road map view of the basilar artery. Note that the distal and proximal WEB II markers (*arrowheads*) are located within the aneurysm. The position was stable enough to perform the deployment of the implant. The marker of the tip of the microcatheter is located at the base of the aneurysm (*arrow*). **c** Arteriogram of the left vertebral artery p.a. view: 3 min after deployment, there is a significant (80–90%) cessation of blood flow within the distal part of the WEB II device indicating progressive thrombosis. **d** Arteriogram of the left vertebral artery p.a. 10 min after deployment—there is a significant cessation of blood flow within the proximal part of the WEB II device indicating progressive thrombosis. At the end, the aneurysm is

completely occluded by the WEB II treatment. 3D angio confirmed complete occlusion and the typical aspect of the neck reconstruction. Note that there is a slight narrowing of the left P1 segment. The small aneurysm coming off the left P1 is being observed. **e** The T2-weighted imaging and the DWI sequence revealed no thrombotic complication. Note that there are the typical artifacts arising from the aneurysmal clips of the MCA aneurysm left. There are only a few artifacts arising from the WEB II device within the basilar tip aneurysm. **f** Arteriogram of the left vertebral artery p.a. view 8 weeks after treatment. Note that the narrowing of the left P1 segment is constant over time and that the bulge at the aneurysm base fits to the WEB II configuration as shown

rotational angiography, a 6F guide catheter (Cordis Neurovascular) was navigated into the distal cervical segment of the left internal carotid artery. Under high-magnification roadmap control, a Rebar-27 microcatheter (ev3) was navigated into the aneurysm. The 6×4 mm WEB II device

was gently delivered into the aneurysm and deployed (Fig. 3b). The total time between catheterization of the aneurysm and completion of the intervention was 13 min. Serial control angiography performed over a period of 30 min demonstrated a progressive rapid cessation of flow within the aneurysm,



Fig. 2 (continued)

starting at the distal fundus (100% distal lobe occlusion after 3 min) and progressing proximally. Ten minutes after deployment, complete stasis of contrast was observed within the aneurysm (Fig. 3c, d). The post-procedure hospital course was uneventful. CT scanning and MR imaging with diffusion and long TR-weighted sequences showed no evidence of acute parenchymal infarction (Fig. 3e, f).

Follow-up angiography and MR imaging with MRA were performed 8 weeks after the initial treatment and demonstrated complete occlusion of the aneurysm (Fig. 3g).

Discussion

Multiple flow disrupting devices have been tested in pre-clinical models and have been applied in small clinical series [6–12]. In this study, we describe the *in vivo* performance of the WEB II device, a new intra-saccular aneurysm embolization device designed to selectively create a mechanically stable, uniform, high-density metallic mesh across the aneurysm neck at the parent artery–aneurysm interface. The goal of this treatment strategy is to achieve robust flow diversion at the aneurysm neck without a requirement to reconstruct the entire parent artery segment with an endoluminal construct.

To this point, existing data for the intra-saccular, self-expanding, braided mesh implants had been derived exclusively from the treatment of *in vivo* experimental aneurysms created in animals [11, 13]. The present first-in-man cases demonstrate that this treatment strategy is technically feasible in humans. The device was readily delivered into saccular aneurysms through a standard 0.027 microcatheter and in both cases expanded to fill the aneurysm sac completely. Complete cessation of intra-aneurysmal flow was noted within minutes of placement. Complete occlusion of the aneurysms was confirmed at 8-week angiographic follow-up.

Intra-saccular flow diversion versus coil embolization

Intra-saccular flow diversion offers several potential advantages over traditional intra-saccular coiling. First, the homogeneous, high-density neck coverage would be expected to provide a much more homogeneous and continuous scaffolding to support the endoluminal overgrowth of neointimal–neoendothelium at the aneurysm–parent artery interface. This effect theoretically could provide greater rates of complete occlusion with lower rates of delayed re-canalization following treatment. Second, the amount of device manipulation within the aneurysm sac is reduced, particularly for large aneurysms. With an intra-saccular mesh flow diverter, the endovascular treatment requires the placement of only a single device, versus coil embolization, which typically requires the placement of multiple embolization coils, sometimes in addition to repeated manipulations of the microcatheter within the aneurysm sac. This limitation on the manipulation of devices and the number of devices to be introduced into the aneurysm may result in a greater level of procedural safety, shorter procedural times, and lower levels of radiation exposure. Third, once the intra-saccular mesh flow diverter is in place, the operator can directly and accurately visualize any residual blood flow within the aneurysm neck and aneurysm fundus with X-ray-based imaging techniques (i.e., DSA and CTA). This is in distinction to platinum coils that are typically radiopaque to the point of obscuring residual contrast flow within the aneurysm neck and fundus on these modalities [14]. On the other hand, although digital subtraction angiography (DSA) is considered the gold standard for aneurysm follow-up, additional imaging modalities may be useful for WEB II control. In addition to DSA, we suggest that intravenous CT angiography may be useful in detecting small inflow zones similar to those observed in type II endoleaks.

If an aneurysm does not occlude after placement of the WEB II device, additional coiling of a remnant or placement of an additional intravascular flow diverter could be a bailout option.

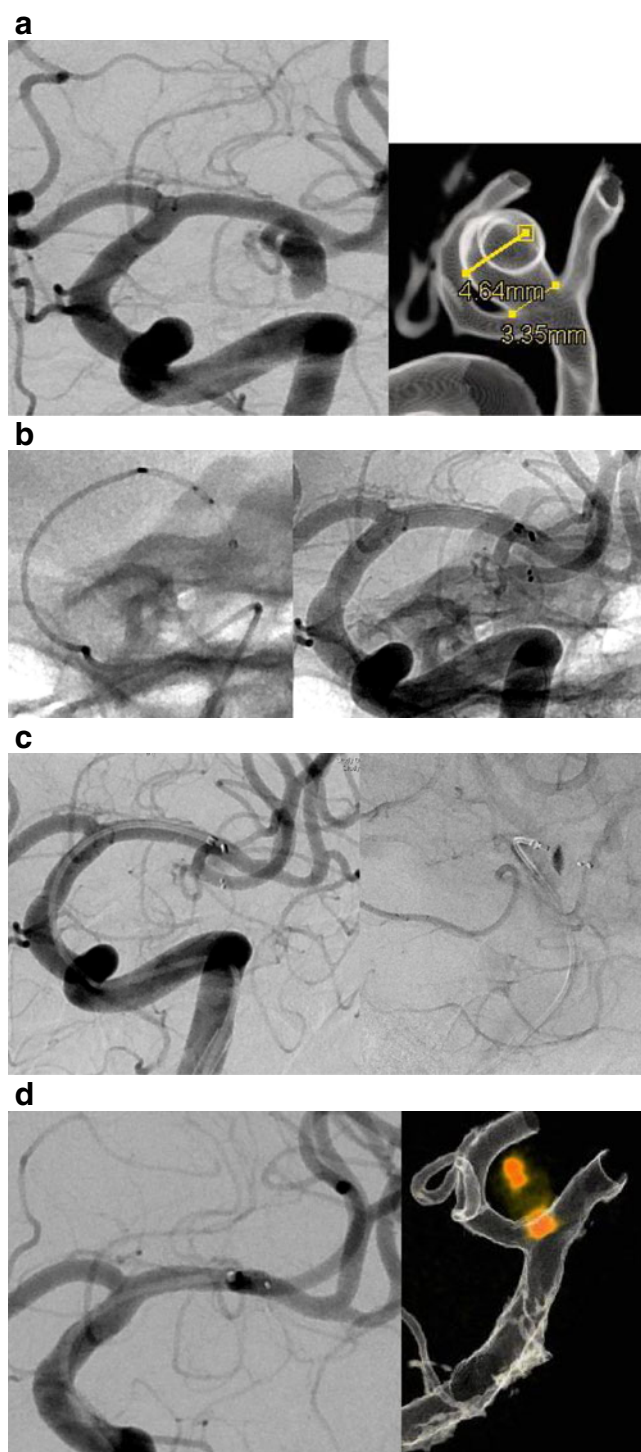


Fig. 3 **a** Arteriogram of the left internal carotid artery p.a. view showing a MCA aneurysm with a diameter of max. 7×4.6 mm. The diameter of the neck was estimated to be 3.4 mm. The 3D reconstruction demonstrates the broad base of the bifurcation aneurysm in relation to the parent vessel. **b** Arteriogram of the left internal carotid artery (unsubtracted view). The WEB II device is passed through the 0.027 microcatheter. Note that the WEB II device has three markers. **c** Arteriogram of the left internal carotid artery p.a. and lateral view immediately after deployment showing immediate cessation of flow within the implant. **d** Arteriogram of the left internal carotid artery p.a. view and 3D reconstruction showing complete occlusion of the aneurysm within 10 min after deployment. Note that **d** and **g** are differently angulated to **a** which is suboptimal as it does not allow a 1:1 comparison pre- and post-emo to detect a possible neck remnant. Therefore, we added 3D reconstructions prior and immediately after treatment. **e** Post-interventional CT scan demonstrating a regular situation without the typical artifacts seen after conventional coil occlusion. **f** Post-interventional axial FLAIR, T2, T1, DWI, GRE, and TOF MR scan at 3 T demonstrating no thrombotic complication and only a few artifacts arise from the WEB II device. **g** Control arteriogram of the left internal carotid artery p.a. view 8 weeks after treatment showing a persisting complete occlusion of the WEB II-treated MCA aneurysm. Note that the angulation is comparable to **d**. The 3D reconstruction (not shown) revealed no difference to **d**

treatment of fusiform, large and giant, and very wide-necked aneurysms, their application is limited in cases of bifurcation anatomy and possibly suboptimal in vascular segments which carry regional eloquent perforating arteries. The WEB II device, as an exclusively intra-saccular implant, is optimally suited for the treatment of both of these subtypes of cerebral aneurysms. Moreover, given the lack of endoluminal extension, the thrombogenicity of the implant is very likely similar to that of an intra-saccular coil mass, and as such, long-term dual anti-platelet therapy is probably not necessary in the majority of patients. In preclinical animal studies, the WEB II exhibited no more thrombotic potential than intra-saccular embolization coils. In our initial two patients, no peri-procedural thrombotic complications were noted and both patients were treated with peri-procedural aspirin therapy alone. Finally, the intra-saccular mesh implants are designed to produce aneurysm occlusion during the interventional procedure. This is in distinction to the endoluminal flow diverters, which induce aneurysm occlusion over a period of days to months. Thus, since the intra-saccular flow diverters do not require dual anti-platelet medications and are capable of producing prompt intra-procedural aneurysm occlusion, they are likely to be applicable to the treatment of ruptured aneurysms (in addition to unruptured aneurysms).

Intra-saccular versus endoluminal flow diversion

The self-expanding endosaccular mesh implants essentially provide a means by which to employ a “flow-diversion strategy” to treat aneurysms that are not amenable to (or optimal for) predicate endoluminal flow diverters. While endoluminal flow diverters have great utility for the

Technical aspects of WEB II handling properties, delivery, and deployment

Precise device sizing and positioning are the most important factors to achieve technical success with these intra-saccular, self-expanding mesh devices. A variety of diam-

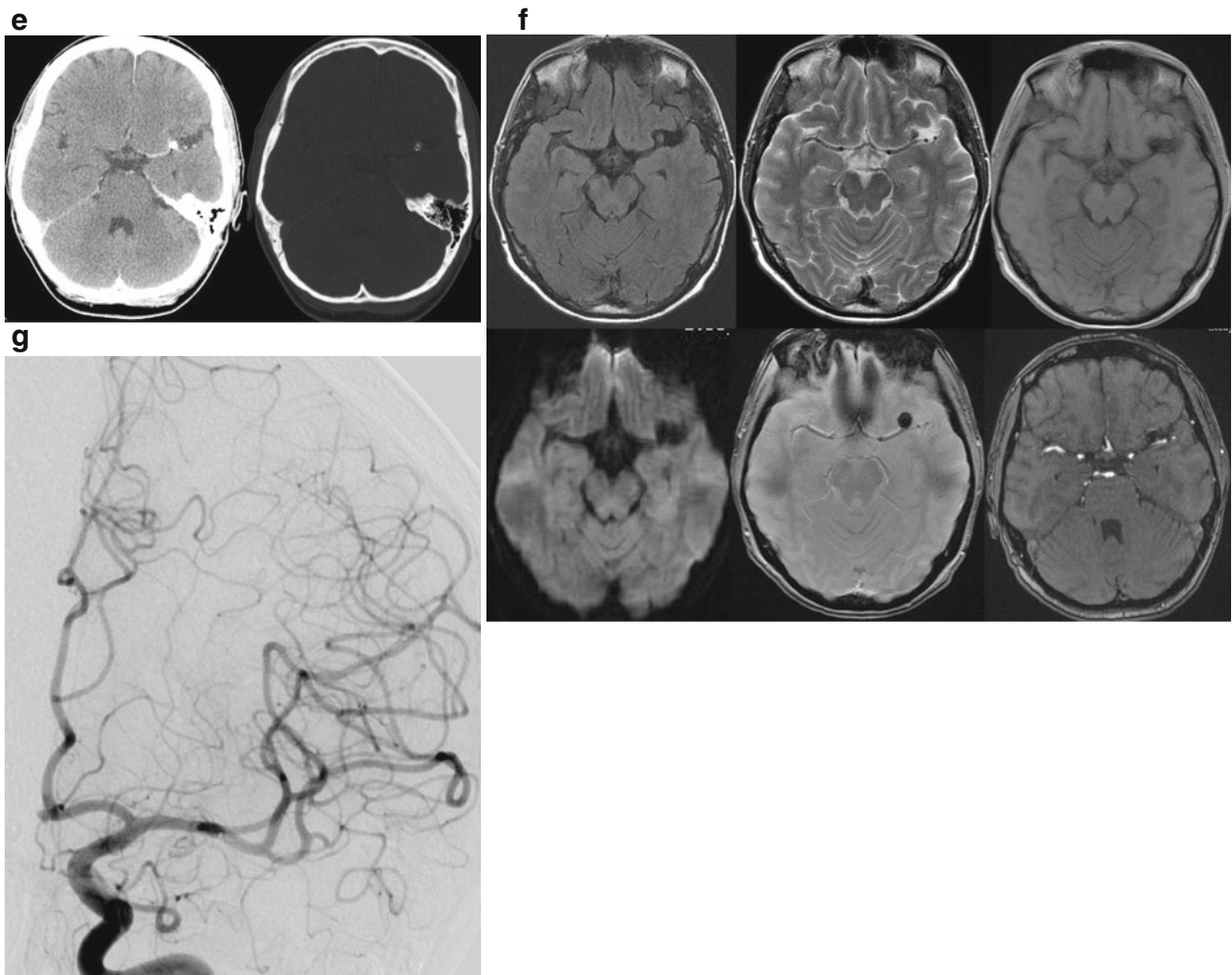


Fig. 3 (continued)

eters and lengths of the WEB II device are available so that the physician can select the device that will best fit the aneurysm and especially the neck of the aneurysm. The device's radial resistive force is comparable to that of a coil mass. Since coils recanalize due to compaction and the WEB II device cannot compact, we assume that the risk is much lower for recanalization after WEB II treatment. The device is of essentially constant volume over a range of expanded diameters, thus, if the device is over-sized relative to the aneurysm diameter, it will elongate along the path of least resistance and herniate through the aneurysm neck, rather than expand and pressurize the aneurysm fundus.

Size selection is critical to ensure sufficient wall apposition to allow for device stability and to create a complete “seal” along the entire circumference of the aneurysm neck–parent artery interface. If possible, 3D angiography should be performed to optimize the precision

of the measurement of the aneurysm dimensions and neck-to-dome (N/D) ratio. For generally spherical or elliptical narrow-necked ($N/D < 0.8$) aneurysms, the WEB II should be sized to match (or slightly exceed—by no more than 10%) the largest two-dimensional aneurysm diameter measurement. Selected wide-necked aneurysms may also be amenable to treatment with the device; however, the largest neck dimension should not exceed the device diameter. In addition to the aneurysm diameter measurement, the other perpendicular measurements of the fundus are useful to estimate the amount of device elongation (and potential herniation) that may occur after deployment. Therefore, sizing of the WEB II is an important part of case planning. For example, in the presented MCA case, the WEB was sized according to the proximal lobe of the aneurysm; the distal lobe was not implanted with WEB II or any other adjunctive devices. In this case, we used a slight (<10%) over-sizing of the proximal aneurysm width

and chose the WEB II height with the knowledge that the WEB II elongates in length when compressed in width (e. g., if a WEB II is compressed ~ 0.5 mm in width, the length will increase ~ 0.5 – 1.5 mm depending on the curvature of the aneurysm). The same sizing algorithm was used for the Basilar Tip case. We believe that this level of over-sizing is conservative and represents a reasonable safety margin in terms of preventing WEB II parent artery protrusion.

During placement of the device, it is critical to efficiently evaluate the configuration and adequacy of the seal created at the aneurysm neck–parent artery interface. If the device is left in place during a prolonged period of angiographic assessment, it may accumulate thrombus that could make it technically difficult, or even hazardous, to resheath and remove. The WEB II showed rapid contrast stasis in each case. Accordingly, this stasis may promote rapid thrombosis, depending on the patient’s hemostasis medication. This might be advantageous in case of aneurysm rupture. If an operator elects to withdraw a deployed WEB II device in favor of a different size, we recommend that this be performed within the time window of the patient’s ACT (e.g., most heparinization protocols produce ACTs ~ 250 s). This recommendation would be of particular importance for ruptured cases. To withdraw a WEB II beyond the ACT time window or if excessive thrombus is angiographically evident within or around a device that is not optimally sized to the aneurysm, it might be necessary to infuse intravenous glycoprotein IIb/IIIa receptor inhibitor to reduce the risk for a thrombembolic complication during resheathing and removal. Assessments of the adequacy of fit should be made on the basis of high frame rate angiography with optimized visualization of the aneurysm neck under high magnification with collimation around the aneurysm neck–parent artery interface.

Limitations

Notwithstanding the promising results from the current cases, there remain substantial uncertainties about the optimal application of the WEB II.

First, the WEB II delivery system was designed for the relatively straightforward vascular access of the posterior circulation. However, as shown in this paper’s MCA case, the WEB II system may be delivered through more challenging anterior vascular anatomy, but, increased friction, similar to clot retrieval devices, may be observed. “Telescoping” catheters (e.g., Rebar-27 inside a >0.41 inner lumen catheter) enhanced maneuverability of the WEB II system and are recommended for tortuous access. A more flexible, navigable delivery system may broaden use of the WEBII.

Second, the device is not suitable for complex irregularly shaped or fusiform aneurysms. In fact, since

the meshwork has a pre-shaped round geometry, it may seal only aneurysms with similarly regular anatomy and may more often produce doggy ears and neck remnants than is seen with coils that more easily fit into small and irregular spaces. On the other hand, Y-stenting is certainly not the only alternative to this new device. Simple coiling with or without balloon remodeling may do the job as well. Therefore, future cases, including multi-center clinical studies, are required to verify these performance features.

Third, more experience with a new device to increase its safety should not be gained by just using it in more patients. Strategies for addressing incomplete aneurysm occlusion, either immediate or delayed, may be problematic because coil placement into the lumen of the indwelling WEB II device will not be feasible. This is of particular concern if this treatment strategy is to be extended to ruptured aneurysms. Therefore, the expected effects of increased over-sizing etc. should be studied in more extensive experimental (in vitro and in vivo) work instead. The same is true for retreatment techniques if neck remnants occur and grow.

Fourth, the present patients were followed for only 8 weeks and the long-term outcome of this treatment strategy will not be evident until a larger population of patients have been treated and followed for a longer period to time.

Fifth, the safety of this technique for the treatment of ruptured aneurysms, while technically feasible and theoretically possible, remains unknown.

Conclusion

Preliminary results with the WEB II device in two patients with bifurcation aneurysms demonstrate the feasibility of this technique to achieve the endovascular occlusion of unruptured cerebral bifurcation aneurysms. However, there are only two cases done yet and such results are not at all to be generalized at this point in time. Further follow-up is needed to confirm several aspects of the WEB II as an intra-saccular flow diverter. The WEB II has the highest wire count of any intra-saccular flow diverter, and its oblate shape appears to allow stable deployment in wide-necked aneurysms. Furthermore, the inner and outer braid design appears to provide rapid contrast stasis.

This technique has potential advantages over other endovascular approaches and warrants continued investigation.

Conflict of interest J. Klisch consults to Sequent Medical, which manufactures the WEB II device.

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