



The Woven EndoBridge Device for Treatment of Bifurcation Aneurysms: Image-Based Computational Hemodynamic Analysis

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Abstract

Background: Woven EndoBridge (WEB) is an innovative device for the treatment of intracranial aneurysms, especially wide-necked bifurcation aneurysms. This study aims to assess the safety and efficacy of WEB devices and analyze aneurysmal hemodynamic modifications caused by WEB deployment.

Materials and Methods: We retrospectively studied 12 WEB-treated aneurysm cases (six Middle Cerebral Arteries (MCA) bifurcations, six anterior communicating Arteries (AcomA)). Clinical and imaging evaluation, aneurysm occlusion status, modified Rankin Scale (mRS) score were analyzed in the 6 months and 12 months follow-up periods. Pre-treatment and post-treatment hemodynamics based on Computational Fluid Dynamics (CFD) simulations was performed for 2 cases. Changes in wall shear stress (WSS), aneurysmal flow velocity (Velocity), and Residual Flow Volumes (RFVs) were calculated and analyzed.

Results: At 12-month follow-up, 66.7% of the aneurysms had complete occlusion, 16.7% had residual neck and 16.7% had residual aneurysm. A good clinical outcome (mRS score: 0–2) was obtained in all patients without any severe treatment-related morbidity or mortality. In Case 1, the aneurysm was completely occluded, while in Case 2 the aneurysm remained residual neck after treatment. The normalized sac-averaged WSS, sac-averaged velocity, and RFVs (0.2 m/s, 0.3 m/s) were decreased by 84.9%, 70.8%, 85.9%, 98.0%, and 72.7%, 54.3%, 75.9%, and 81.1%, respectively. The reduction of the hemodynamics was more substantial in Case 1 than that in Case 2.

Conclusion: The treatment of wide-neck bifurcation aneurysms with WEB devices is feasible with an acceptable safety and efficacy rate. Hemodynamic changes may predict the occlusion outcome of wide-necked bifurcation aneurysms treated by WEB.

Keywords: Computational fluid dynamics; Interventional neurosurgery; Intracranial aneurysm; Woven EndoBridge

Introduction

The overall prevalence of unruptured Intracranial Aneurysms (IAs) was 7.0 % in Chinese adults aged 35 to 75 years [1]. Treatment modalities for aneurysm obliteration include clipping, coil embolization, stent or balloon-assisted coiling, and flow diversion. There has been a shift from surgical clipping to endovascular treatment since the International Subarachnoid Aneurysm Trial results [2]. However, endovascular treatment of some aneurysms, e.g., wide-necked bifurcation aneurysms, can be challenging. Standard coiling of these aneurysms is associated with higher thromboembolic complications and lower occlusion rates [3]. The Woven EndoBridge (WEB; Sequent/Microvention, Aliso Viejo, California, USA) was developed specifically to treat wide-neck bifurcation aneurysms. The WEB device has been available for clinical use in Europe since 2011 and was approved by the US Food and Drug Administration in 2019. It offers an alternative to traditional endovascular approaches for treating wide-neck bifurcation aneurysms, as demonstrated by prospective studies showing low rates of complications and high rates of adequate occlusion [4,5]. Hemodynamic changes induced by intraluminal flow diverters have been widely investigated by Computational Fluid Dynamics (CFD), e.g. [6]. However, the hemodynamic studies on WEB treatment are very few [7,8]. Also, the association between the clinical outcome of WEB treatment and the hemodynamic alternations is not well understood. The Finite Element Method (FEM) is feasible to simulate the stent and coils deployment in vessels and aneurysms [9,10]. The FEM technique provides a higher-fidelity model

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for accurate post-treatment CFD analysis. The study aimed to report our clinical experience with the WEB for endovascular treatment of unruptured wide-neck bifurcation aneurysms and explore the possible mechanism for aneurysm prognosis *via* hemodynamic analysis based on high-fidelity FEM and CFD.

Materials and Methods

Patient population

We retrospectively studied 12 patients (7 females and 5 males) with unruptured wide-necked IAs admitted to our hospital and treated with WEB devices between September 2017 and August 2019. Note that one patient had multiple aneurysms, and one of the aneurysms was small and needed no treatment. The average age was 65 ± 6 years old. Six aneurysms (50%) were located at the bifurcation of the Middle Cerebral Artery (MCA), and six (50%) were located at the Anterior communicating Artery (AcomA). In this study, the diameters of the aneurysms were between 4 and 10 mm, which is the manufacturer's recommended size for WEB devices. Wide-necked morphology was defined as neck width ≥ 4 mm or dome-to-neck ratio < 2 . The average aneurysm diameter, neck, and dome-to-neck ratio were 5.6 ± 1.8 mm, 4.6 ± 1.1 mm, and 1.3 ± 0.3 , respectively. The detailed information is summarized in Table 1. All patients were assessed by Digital Subtraction Angiography (DSA) before surgery, and three interventional neuroradiologists independently determined the type of WEB devices to be used based on specific aneurysm characteristics. This study was approved by the ethical committee, and all patients had signed an informed consent form.

Clinical data were collected for each patient, including age, sex, history of hypertension, family history of subarachnoid hemorrhage, aneurysm location, aneurysm size (height and width), neck size, type and size of the device used, complications during and after the procedure, additional devices used during the procedure, and the mRS score both at discharge and the last follow-up. Two aneurysm cases were selected for hemodynamic analysis. Case 1 was completely occluded at the last follow-up, and Case 2 remained residual aneurysm at the last follow-up.

Device and antiplatelet therapy

The WEB (Sequent/Microvention, Aliso Viejo, CA, USA) device is a self-expanding flow disruption device that treats wide-necked and bifurcated IAs. The original WEB device, WEB-DL, is a two-layer nitinol braided intravascular device containing two components. After 2013, with the advent of WEB Single Layer (WEB-SL) and WEB Single Layer Sphere (WEB-SLS), WEB-DL was gradually replaced. All patients in this study were treated with WEB-SL devices.

We performed pre-operative anti-platelet therapy for the enrolled patients. Before the treatment, patients took 100 mg aspirin (Bayer) and 75 mg clopidogrel (SPC) every day for more than three days. The systemic heparinization was adjusted to 2 to 3 times the standard activated coagulation time during the treatment. According to the treatment results, most patients stopped clopidogrel. However, aspirin lasted at least until the first angiographic control.

Clinical data analysis

Clinical and imaging evaluations were performed at the time after treatment and during the 6-month and 12-month follow-ups. DSA was used to evaluate the anatomical results of each follow-up period in all aneurysms. The occlusion status was assessed by the Raymond Roy occlusion classification (complete occlusion, residual neck and

residual aneurysm) [11]. Good clinical outcome was defined as the mRS score of 0 to 2. Treatment-related morbidity at the last follow-up was defined as the mRS score > 2 or a more than 1 point increase compared with pre-treatment status.

Finite element method modeling of WEB deployment

WEB device was generated virtually using solid works (Dassault Systems, SolidWorks Corp., MA, USA) and transferred into the FEM software ABAQUS v6.14 (SIMULIA, Providence, RI, USA) to conduct the release of the device into the aneurysm. The FEM-based workflow for device deployment modeling was performed in ABAQUS/Explicit v6.14. The device was modeled by using nitinol alloy and the material properties were obtained from the literature [12,13]. The whole process is divided into three steps. The first step is the crimping of the device. The surface of the crimping tube is subjected to a radial displacement boundary condition to make it shrink in the radial direction. The second step is the forming stage: Device expansion and contact with the marker at the ends of the wall. After adding circle tubular auxiliary molding equipment in the middle of the device, the displacement boundary conditions were applied on the two reference points and the device was eventually forming. The third step was the release stage: A small space was opened at the aneurysm tip to expose the distal marker and distal device outside the aneurysm and round tubes were added to the aneurysm as auxiliary equipment. The displacement boundary conditions along the axial direction were applied at the distal reference point until the marker at the distal end is concave. The auxiliary equipment of the round pipe was removed, and the reference point at the far end was fixed. The reference point at the near end was subjected to displacement boundary conditions along the axial direction until the marker at the near end was concavity. The complex interaction in pushing and releasing the bracket was set as a general contact algorithm in ABAQUS, and the friction coefficient was set as 0.15.

Computational fluid dynamics modeling

Models were imported to ICEM CFD (ANSYS Inc, Canonsburg, PA, USA) to create finite volume tetrahedral element grids. The cases before and after WEB deployment have approximately 0.5 million and 21 million element grids, respectively. We solved the steady-state incompressible Navier-Stokes equations using the CFD software ANSYS CFX (ANSYS Inc). The blood was modeled as a Newtonian fluid material with a density of 1056 kg/m^3 and a viscosity of $0.0035 \text{ N}\cdot\text{s/m}^2$, and the vessel walls were modeled as the rigid wall with no-slip boundary conditions [14,15]. The inlet boundary condition was set to 4.6 ml/s , the mean flow rate for the internal carotid artery [16]. The mass flow rate of each vessel outlet was set to be proportional to the cube of its diameter according to the minimum energy principle [17].

To evaluate the hemodynamics, we visualized the flow streamlines and Wall Shear Stress (WSS). Also, we measured the average WSS on the aneurysm-sac wall (WSS-sac), the impacted area (the area where $\text{WSS} > 2 \text{ Pa}$) on the aneurysm-sac wall, the average velocity in the aneurysm-sac (Velocity-sac), and the Residual Flow Volumes (RFV, the space where the flow velocity $> 0.2 \text{ m/s}$ and 0.3 m/s , respectively). To account for the different aneurysm sizes and parent vessels, WSS-sac, the impacted area, Velocity-sac, and RFV were normalized by WSS of the parent vessel, aneurysm surface area, the average velocity of the parent vessel, and aneurysm volume, respectively.

Results

Clinical outcome

WEB-SL equipment treated all cases (100%). Technical success was achieved in all cases (100%). Every patient underwent a 12-month follow-up. No patients needed retreatment at the follow-up. All enrolled patients were evaluated before treatment and during the last angiographic follow-up. Overall, a good clinical outcome (mRS score: 0 to 2) was observed in 12/12 patients (100%) and no complications related to surgery occurred. The details are summarized in Table 1.

All patients used DSA, except for one patient who used Magnetic Resonance Angiography (MRA) at the 12-month follow-up. The angiographic results are summarized in figure. Angiograms immediately after WEB deployment showed complete occlusion in 4/12 aneurysms (33.3%), neck remnants in 6/12 (50%), and aneurysm remnants in 2/12 (16.7%). The 6-month follow-up angiograms suggested complete occlusion in 7/12 aneurysms (58.3%), neck remnants in 3/12 (25%), and aneurysm remnants in 2/12 (16.7%). The 12-month follow-up angiograms showed complete occlusion in 8/12 aneurysms (66.7%), neck remnants in 2/12 (16.7%), and aneurysm remnants in 2/12 (16.7%). One case (MRA at the 12-month follow-up) of residual neck at the 6-month follow-up had changed to complete occlusion at the 12-month follow-up. Four aneurysms with residual neck immediately after treatment had completely occluded at the 12-month follow-up.

Hemodynamic analysis

We conducted hemodynamic analysis on two cases. Figures show the angiographic results for the two cases. Case 1 was an aneurysm at the bifurcation of MCA. After treatment, the aneurysm was completely embolism. On the 12-month follow-up image, the aneurysm was completely occluded. Case 2 was an aneurysm at AcomA. After treatment, the angiographic image in figure indicates residual aneurysm. At the 12-month follow-up, Figure suggests the aneurysm residual was remained.

Figure show the hemodynamic results of the two cases. Figures demonstrate the pre-treatment 3D streamlines color-coded by velocity magnitude for Case1 and 2, respectively. Case 1 had a large impingement jet region in the distal end of the aneurysm. In Case 2, the flow from the A1 segment of the Anterior Cerebral Artery (ACA)

entered the sac and impinged on the sac dome. The flow then left the sac and entered the A2 segment of left and right ACAs. Multiple vortices existed in both aneurysms. After treatment, Figures show fewer streamlines entering the aneurysm and the reduction of velocity magnitude, indicating reduced aneurysmal inflow in both cases. In addition, the averaged hemodynamic parameters summarized in Table 2 suggest more significant aneurysmal flow reduction in Case 1 than in Case 2. The reduction of the normalized impacted area, Velocity-sac, and RFVs (0.2 m/s, 0.3 m/s) is 0.93, 0.34, 0.55, and 0.49 in Case 1 vs. 0.66, 0.19, 0.41, and 0.30 in Case 2. Also, the percentage of hemodynamic changes suggests a larger reduction rate in Case 1.

Figures present the pre-treatment WSS distributions for Case 1 and 2, respectively, showing high WSS regions on the aneurysm wall. The highest WSS was observed near the regions where the flow entering the aneurysm. The deployment of the WEB reduced WSS for both cases, as shown in Figures 2h, 2i) and 3h, 3i. Furthermore, the reduction in Case 1 was more significant, as evidenced by the entire dome of near-zero WSS in Case 1 compared to several WSS>2 Pa patches in Case 2. The averaged WSS on the aneurysmal wall (Table 2) also indicates a greater WSS reduction in Case 1 than in Case 2 (0.62 vs. 0.32).

Discussion

This single-center retrospective study shows that the WEB device is safe and effective in treating wide-necked bifurcation IAs. This study analyzed 12 wide-necked bifurcations IAs. Overall, at the 12-month follow-up, 66.7% of the aneurysms were completely occluded, and no patients required retreatment with other endovascular devices. All patients achieved a good clinical prognosis (mRS Score: 0-2) with zero treatment-related morbidity and mortality.

Our results of WEB's safety and effectiveness are in line with previous studies [18-20]. In the WEBCAST study, 51 aneurysms of 51 patients were treated with the WEB in ten European neurointerventional centers [18]. The technical success rate was 94.1%. The thromboembolic events were observed in 17.6% of the patients but the permanent deficit only occurred in 2% of the patients. At the 6-month follow-up, total occlusion was achieved in 56.1% of the patients. In the WEBCAST 2 study which included 55 patients with 55 aneurysms treated with the WEB, morbidity and mortality at 1 year were 3.9% and 2%, respectively [19]. Complete occlusion was

Table 1: Clinical presentation and aneurysm characteristics in 12 patients with 12 wide-necked bifurcation aneurysms treated by WEB devices.

Patient NO.	Age(yr)/Sex	Clinical Presentation	Location	N(mm)	W(mm)	H(mm)	D/N Ratio	Follow-up time(M)	mRS
1	64/M	Incidental	AcomA	3.36	4.22	4.34	1.3	12	0
2	67/M	Incidental	AcomA	5.39	4.28	5.78	1.1	12	0
3	67/F	Incidental	MCA	4.96	6.02	4.66	0.9	12	0
4	59/F	Incidental	MCA	5.89	6.97	7.11	1.2	12	0
5	67/F	Incidental	AcomA	5.43	5.16	6.17	1.1	12	0
6	68/F	Incidental	AcomA	5.46	6.85	6.13	1.1	12	2
7	66/F	Incidental	MCA	2.87	3.22	4.01	1.4	12	1
8	64/M	Incidental	MCA	4	4	3.5	0.9	12	0
9	50/M	Incidental	AcomA	6	8.66	9.26	1.5	12	0
10	64/M	Incidental	MCA	3.28	3.67	5.65	1.7	12	0
11	67/F	Incidental	MCA	4.8	8.1	8.8	1.8	12	0
12	73/F	Incidental	AcomA	3.25	5.54	5.71	1.8	12	0

Note: AcomA: Anterior communicating Artery; MCA: Middle Cerebral Artery; D/N ratio: Dome-to-Neck ratio; H: Aneurysm Height; N: Aneurysm Neck; W: Aneurysm Width

Table 2: Results of hemodynamics.

	Case 1			Case 2		
	Pre	Post	Change	Pre	Post	Change
WSS(Pa)	7.26	1.39	5.87	3.94	1.32	2.62
Normalized WSS	0.73	0.12	0.62	0.44	0.12	0.32
Impacted area (mm ²)	43.28	1.44	41.84	78.88	16.28	62.6
Normalized impacted area	0.96	0.03	0.93	0.83	0.17	0.66
Velocity-sac(m/s)	0.29	0.08	0.21	0.17	0.08	0.09
Normalized Velocity-sac	0.48	0.13	0.34	0.35	0.17	0.19
RFV:V>0.2 m/s(mm ³)	22.8	3.4	19.4	59.6	13.5	46.1
RFV:V>0.3 m/s(mm ³)	17.7	0.21	17.49	40.8	7.46	33.34
Normalized RFV:V>0.2 m/s	0.64	0.1	0.55	0.54	0.12	0.41
Normalized RFV:V>0.3 m/s	0.5	0.01	0.49	0.37	0.07	0.3

Note: WSS: Wall Shear Stress; RVF: Residual Flow Volumes

achieved in 54% of the patients at one year. Recently, Pierot et al. [20] reported a multi-center prospective study which enrolled 106 patients with 106 aneurysms treated with the WEB. At 3 years, only 1.3% of the 79 patients in the safety population had morbidity related to the initial procedure. Complete occlusion was observed in 50.8% of the 61 patients in the efficacy population.

Previous studies showed that the size of the aneurysm dome, occurrence of rupture, and hemodynamic changes were associated with long-term postoperative stability [21,22]. CFD simulations have been used to explore the hemodynamic effects on the formation, growth, and rupture in IAs [23,24]. A growing body of literature reported that hemodynamic parameters (e.g., WSS, flow velocity, and RFV) play a significant role in recurrent aneurysm [25,26]. Previous studies mainly focused on aneurysm recurrence after coil embolization. Sheng et al. [27], suggested that high peak systolic WSS and increased blood flow velocity around the aneurysm neck are associated with aneurysm recurrence [25-30]. Umeda et al. [25] suggested that the threshold of 1.0 cm/s of RFV was the best predictor of 6 to 12 month post-coiling angiographic results of unruptured IAs with porous media simplification. Xu et al. [28] and Rayz et al. [29] reported that thrombus formation is related to the reduction of blood flow into the aneurysm and the velocity magnitude at the neck. Intimal hyperplasia in the region of the aneurysm neck and thrombosis formation in the aneurysm cavity plays essential roles in long-term stability after embolization. Moreover, high flow velocity at the remnant of the neck impacts aneurysm recurrence after embolization [30]. The hemodynamic studies on IAs treated by the WEB are few. Aghli et al. [7] conducted a hemodynamic analysis on an AcomA aneurysm, which recanalized in a year. The results suggested that the recanalization may be due to the increased WSS at the aneurysmal neck after treatment. Sharifi et al. [8] studied the hemodynamic changes induced by the WEB using simplified geometries and showed that the WEB reduced the flow and WSS.

Due to the unique anatomical characteristics of wide-necked IAs and the intravascular structures of the WEB, an investigation of hemodynamic changes in wide-necked IAs after WEB treatment is needed. In our study, we investigated the pre-treatment and post-treatment hemodynamic alternations induced by the WEB of two patient-specific aneurysms using CFD and high-fidelity FEM, unlike the porous media in or the simplified geometries in [7,8]. Among the two cases we analyzed, one patient still had aneurysm residual at the 12-month follow-up, while the other patient's aneurysm

was completely occluded. Our CFD results suggested significant hemodynamic alternations after the WEB treatment in both cases. The WSS-sac, impacted area, Velocity-sac, and RFVs in both cases decreased significantly, indicating that the WEB effectively reduced the flow entering the sac, consistent with previous studies on WEB [11]. However, in Case 2, we observed a high WSS region at the aneurysmal neck after treatment. The RFVs and velocity magnitude in Case 2 are also larger than that in Case 1. The aneurysm residual in Case 2 can be explained by the high WSS at the neck and the high RFV (0.3 m/s) after treatment. This is consistent with Aghli et al. [7], finding of the relation between recanalization and high WSS at the neck. Previous studies on aneurysm recurrence after coil embolization also suggested the relation between thrombus formation and blood flow reduction [25-30].

There are several limitations of the current study. First is the retrospective nature of the analysis and the small sample size. Further studies with larger populations are needed to verify our results. Second, we only analyzed the hemodynamic features of two aneurysm models and they are not located in the same location (MCA vs. AcomA). Finally, a longer follow-up is needed to evaluate the accuracy of hemodynamic results and the effectiveness of WEB devices.

Conclusion

The WEB device seems to be safe and effective in treating wide-necked bifurcated IAs. WEB device should be considered as a valuable option for the treatment of wide-necked bifurcated IAs. This study suggests the potential possibilities of hemodynamic analysis to predict the outcome of WEB device treatment.

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