



Original research

Safety and effectiveness of the Woven EndoBridge (WEB) system for the treatment of wide necked bifurcation aneurysms: final 5 year results of the pivotal WEB Intra-saccular Therapy study (WEB-IT)

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► Additional supplemental material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/jnis-2023-020611>).

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Received 21 May 2023
Accepted 31 May 2023
Published Online First
24 June 2023

ABSTRACT

Introduction The US Woven EndoBridge Intra-saccular Therapy (WEB-IT) study is a pivotal, prospective, single arm, investigational device exemption study to evaluate the safety and effectiveness of the WEB device for the treatment of wide neck bifurcation aneurysms (WNBAs). We present complete 5 year data for the cohort of 150 patients.

Methods 150 patients with WNBAs were enrolled at 21 US and six international centers. Imaging from the index procedure, 6 month, 1 year, 3 year, and 5 year follow-up were reviewed by a core laboratory. Adverse events were reviewed and adjudicated by a clinical events adjudicator.

Results 83 patients had 5 year follow-up imaging and 123 had clinical follow-up. No ruptured (0/9) or unruptured aneurysm (0/141) rebled or bled during follow-up. No new device or procedure related adverse events or serious adverse events were reported after 1 year. At 5 years, using the LOCF method, complete occlusion was observed in 58.1% and adequate occlusion in 87.2% of patients. For patients with both 1 year and 5 year occlusion statuses available, 76.8% (63/82) of aneurysms remained stable or improved with no retreatment. After 1 year, 18 aneurysms were retreated, 11 of which were adequately occluded at 1 year, and 15 of which were retreated in the absence of any deterioration in occlusion grade.

Conclusions Five year follow-up data from the WEB-IT study demonstrated that the WEB device was safe and effective when used in the treatment of WNBAs. Aneurysm occlusion rates achieved at 1 year follow-up were durable, with rates of progressive thrombosis far exceeding rates of recurrence over time.

INTRODUCTION

The Woven EndoBridge (WEB, MicroVention, Aliso Viejo, California, USA) is a braided, detachable, self-expanding, drawn filled tube, nitinol-platinum structure, designed for the endovascular treatment of wide necked bifurcation aneurysms (WNBAs). To date, there have been seven prospective clinical trials evaluating the effectiveness and safety of the WEB device for the treatment of

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The WovenEndoBridge Device has been shown to be safe and effective for the treatment of wide-necked bifurcation aneurysms located at the carotid terminus, middle cerebral artery, basilar apex and anterior communicating artery complex.

WHAT THIS STUDY ADDS

⇒ The most notable observations from the 5-year US WEB-IT data set are: (1) No patient experienced bleeding from their treated aneurysm throughout the entire 5-year period, (2) the angiographic occlusion results observed at 1 year were stable or improved in the majority of patients at 5 years or last observed follow up and (3) the high procedural and post-procedural safety rates observed at 1 year persisted through 5 years with no additional device-related adverse events.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The present study provides definitive evidence that the WEB device provides a durably effective and safe endovascular treatment option for wide-necked bifurcation aneurysms.

ruptured and unruptured WNBAs.^{1–8} The pivotal 150 patient US WEB Intra-saccular Therapy (WEB-IT) study ultimately led to the US Food and Drug Agency approval of the device for use at the middle cerebral artery (MCA) bifurcation, internal carotid artery terminus, anterior communicating artery complex, or basilar artery apex for the treatment of adult patients with saccular WNBAs with a dome diameter of 3–10 mm and either neck size ≥ 4 mm or a dome-to-neck ratio ≥ 1 and < 2 .¹ The series of prospective WEB studies have all consistently demonstrated that the device is effective and uniquely safe for the treatment of WNBAs up to 1 year.^{3–14} Fewer data exist on the long term durability of these results and the long term outcomes of



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To cite: Fiorella D, Molyneux A, Coon A, et al. *J NeuroIntervent Surg* 2023;**15**:1175–1180.

treated patients.¹⁴ We report the final 5 year safety and effectiveness data from the US WEB-IT study.

METHODS

Study design

The US WEB-IT study is a prospective, multicenter, single arm, interventional study conducted at 21 US and six international centers, enrolling a total of 150 adults with WNBA of the anterior and posterior intracranial circulations. The study protocol was approved by each center's respective institutional review board and written informed consent was obtained from all patients. The study was conducted according to good clinical practice and included independent core laboratory evaluation of effectiveness outcomes and independent adjudication of all adverse events. All adverse events (AEs) were reported in compliance with the Medical Dictionary for Regulatory Activities reporting standards (MedDRA). All patient records were externally monitored with 100% source document verification. Regularly scheduled study safety reviews were conducted by a data monitoring committee.

The WEB-IT study's cases represent the first clinical experience that US physicians had with the device. No roll-in cases were permitted in the US before the enrollment of patients in this study. To familiarize investigators with the device's characteristics, sizing, and deployment, operating physicians participated in a training program which included hands-on experience using a life-like simulator and subject specific replicated models.¹⁵

Enrolled patients were diagnosed with aneurysms having the following characteristics:

1. Ruptured or unruptured
2. Saccular in shape
3. Located at the basilar apex, MCA bifurcation, internal carotid artery terminus, or anterior communicating artery complex
4. Dome-to-neck ratio ≥ 1
5. Neck size ≥ 4 mm or dome-to-neck ratio < 2
6. Diameter appropriate for treatment with the WEB device according to the device instructions for use

Patients with ruptured aneurysms were required to be neurologically stable with a Hunt–Hess score of I or II. Key exclusion criteria included vascular tortuosity or morphology that could preclude safe access and support during treatment with the WEB and a modified Rankin Scale score of ≥ 2 at baseline or before rupture.

Device characteristics

The WEB single layer sphere and WEB single layer models are composed of single layers of braided nitinol/platinum wires joined at the proximal and distal ends by radiopaque platinum markers (figure 1). The implant is attached to a flexible delivery wire. Detachment of the implant is electrothermal, which is similar to several other neurovascular implant delivery systems. WEB device sizes range between 4×3 mm and 11×9 mm and can be delivered through VIA 21, 27, and 33 microcatheters (Microvention, Aliso Viejo, California, USA), which were available for use in the WEB-IT study.

Procedure

Subjects underwent a standard neuroendovascular procedure using a triaxial approach with the intent of delivering and implanting a WEB device into the index aneurysm. Antiplatelet therapy was recommended but was not required according to the study protocol, and antiplatelet medication used during the

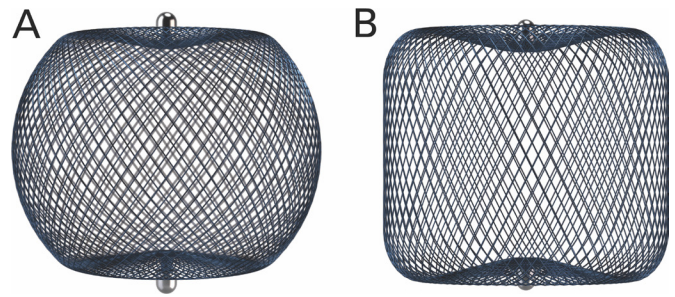


Figure 1 Illustration of the Woven EndoBridge (WEB) single layer sphere (A) and the WEB single layer shapes (B). Sizes range from 4×3 mm to 11×9 mm. The devices are braided composites made from nitinol and platinum.

study was recorded at each study visit.¹⁶ Subjects were considered enrolled with the intent to treat when the WEB device was introduced into the microcatheter. Two-dimensional and three-dimensional DSA were performed to confirm the final device position. Inability to deploy a WEB device and the use of adjunctive implants (eg, coils or stents) were considered primary effectiveness endpoint failures. Clinical follow-up was conducted at 30 days, 6 months, 1 year, and annually up to 5 years. Follow-up DSA was performed at 6 months and 1 year, with additional follow-up imaging required at 3 and 5 years using the institutional standard of care modality. Follow-up imaging was optional at 2 and 4 years. Evaluation of effectiveness and safety up to 1 year were previously reported.¹⁷ This report includes an evaluation of effectiveness and safety from year 1 to year 5.

Study endpoints

The WEB-IT study's primary effectiveness endpoint was the proportion of subjects with complete aneurysm occlusion without retreatment, recurrent subarachnoid hemorrhage, or significant parent artery stenosis (defined as $>50\%$ stenosis) at 1 year after treatment. Effectiveness outcomes were evaluated by an independent core laboratory using the validated WEB Occlusion Scale (WOS).^{5,6} Complete occlusion included WOS grade A (complete occlusion) or B (complete occlusion with marker recess). The study's primary safety endpoint was the proportion of subjects with primary safety events, which included death from any non-accidental cause or any major stroke (defined as an ischemic or hemorrhagic stroke resulting in an increase of ≥ 4 points on the National Institutes of Health Stroke Scale and persisting for 7 days after the procedure) within the first 30 days after treatment, or a major ipsilateral stroke or neurologic death from day 31 to 1 year after treatment. Thirty day safety results² and 1 year follow-up results¹ were previously reported. While study primary endpoints focused on initial 1 year follow-up, the study protocol required continued follow-up and evaluation of safety and effectiveness up to 5 years.

Statistical analysis

Statistical analyses of the study's 5 year data included using descriptive statistics. Continuous variables are presented as mean (SD) and discrete variables as frequency counts (%). To test for statistical significance ($P < 0.05$) in subgroup outcomes, Kruskal–Wallis tests were performed, and for subgroup safety events, two sided Fisher's exact test or the Fisher–Freeman–Halton exact test was performed.

Table 1 Subject allocation

| Visit | Eligible for follow-up (n) | Completed visit | Completed visit and imaging | Missed visit | Lost to follow-up | Death | Withdrawn/ discontinued |
|--------|----------------------------|--------------------|-----------------------------|-----------------|-------------------|----------------|-------------------------|
| 2 year | 140 | 100 (140/140) | 47.1 (66/140) | 0.0 (0/140) | 0.7 (1/140) | 1.4 (2/140) | 1.4 (2/140) |
| 3 year | 137 | 92.0 (126/137) | 81.0 (111/137) | 8.0 (11/137) | 0.7 (1/137) | 1.5 (2/137) | 0.0 (0/137) |
| 4 year | 132 | 97.0 (128/132) | 39.4 (52/132) | 3.0 (4/132) | 0.8 (1/132) | 2.3 (3/132) | 0.8 (1/132) |
| 5 year | 123 | 100.0 (123/123) | 67.5 (83/123) | 0.0 (0/123) | 4.9 (6/123) | 0.0 (0/123) | 2.4 (3/123) |

Values are % (n/N), unless otherwise stated.

RESULTS

Subject allocation

A total of 150 subjects were enrolled to the WEB-IT study. Patient allocation up to 1 year, as well as patient demographics, aneurysm characteristics, procedural details, and periprocedural safety results at 30 days have been reported previously.¹² Patient allocation up to 5 years is reported in [table 1](#) and [figure 2](#). Due to issues related to the COVID-19 pandemic, several long term follow-up visits could not be completed, or were conducted virtually, precluding imaging follow-up in some instances.

Long term occlusion results

At year 5, subjects in whom the WEB device procedure was completed and imaging follow-up was performed showed a complete occlusion rate of 67.5% (56/83) and an adequate occlusion (complete occlusion or residual neck) rate of 96.4% (80/83). Considering retreatment as failure regardless of the reason or pre-retreatment occlusion status, these rates were 59.0% (49/83) and 79.5% (66/83), respectively.

Occlusion status shift between 1 year and 5 years for patients with both 1 year and 5 year imaging are shown in [table 2](#). Of the 140 patients in whom 1 year imaging was performed, 82 patients also had 5 year imaging performed, showing a complete occlusion rate without retreatment of 59.8% (49/82) and an adequate occlusion rate without retreatment of 80.5% (66/82). In comparison with their 1 year occlusion status, most aneurysms

remained stable with no change in 67.1% (55/82) of patients for whom 5 year occlusion status was available. Of 25 patients with residual neck and 8 patients with residual aneurysm at 1 year for whom 5 year imaging was available, progressive occlusion was noted in 24.2% (8/33). Of the 49 patients with complete occlusion and 25 patients with residual neck at 1 year for whom 5 year imaging was available, only 18.9% (14/74) had a worsening of occlusion status and/or were retreated.

Five year imaging was not performed in 41.4% (58/140) of the patients who had 1 year imaging, 24 of whom did not return for imaging due to COVID related causes. For patients missing 5 year imaging follow-up, the last observation carried forward (LOCF) method can be used to replace missing occlusion data.¹⁴ For retreated patients, the last available pre-retreatment occlusion status was used in this analysis.

After the LOCF method was applied, the 5 year imaging follow-up data included 11 patients from <1 year, 22 patients from 1 year, 4 patients from year 2, 32 patients from year 3, and 11 patients from year 4. This resulted in an LOCF 5 year complete occlusion rate of 58.1% (86/148) and a 5 year adequate occlusion rate of 87.2% (129/148).

Retreatment

Twenty-seven aneurysm retreatments occurred during this study, involving 23 patients. Two patients were retreated twice, and one patient was retreated three times. Overall retreatment rate was 15.5% (23/148). Retreatments required the use of coiling (n=1), stenting (n=1), both (n=11), flow diversion (n=10), an additional WEB device (n=1), or other (3). Retreatment rate by aneurysm location were anterior communicating artery 15% (6/39), basilar apex 14% (8/58), internal carotid artery terminus 0% (0/6), and MCA bifurcation 20% (9/45).

Safety

Throughout the follow-up period, index aneurysms showed no rebleeds (0/9) in originally ruptured aneurysms and no new bleeds from unruptured aneurysms (0/141). There were 33 stroke related events, 9 of which occurred between year 1 and year 5, including 2 transient ischemic attacks, 3 intracerebral hemorrhages, 2 subarachnoid hemorrhages, and two ischemic strokes. All were adjudicated as unrelated to the WEB device. Both late subarachnoid hemorrhage events were associated with retreatment. The all cause mortality rate was 4.7% (7/150), with no deaths or major stroke events related to the WEB device or procedure from year 1 to year 5.

There were no device or procedure related AEs after 1 year. The most common serious AEs were ischemic stroke with eight events, vessel puncture site hematoma with six events, and pneumonia, angina pectoris, and transient ischemic attack with five

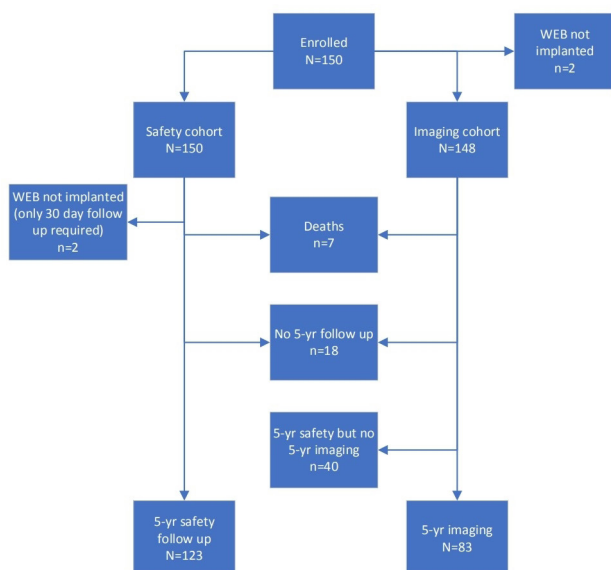


Figure 2 Subject allocation. WEB=Woven EndoBridge.

Table 2 Occlusion status (Raymond–Roy occlusion classification and WEB Occlusion Scale) shift for patients with 1 year imaging follow-up (n=140): 82 patients had both 1 year and 5 year imaging follow-up

| RROC | 1 year | 5 years | | | | | Reason for no image | | | |
|-------------|--------|-------------|-----------|-----------|----------------------------|----------|---------------------|---------------|-------|--|
| | | 1 (WOS A-B) | 2 (WOS C) | 3 (WOS D) | Retreated (w/5 year image) | No image | Early exit | COVID related | Other | |
| 1 (WOS A-B) | 81 | 43 | 4 | 0 | 2 | 32 | 8 | 13 | 11 | |
| 2 (WOS C) | 44 | 6 | 11 | 0 | 8 | 19 | 9 | 7 | 3 | |
| 3 (WOS D) | 15 | 0 | 2 | 1 | 5 | 7 | 2 | 4 | 1 | |
| Total | 140 | 49 | 17 | 1 | 15 | 58 | 19 | 24 | 15 | |
| | | 82 | | | | | | | | |

RROC, Raymond–Roy occlusion classification; WEB, Woven EndoBridge; WOS, WEB Occlusion Scale.

events each. The most common non-serious AEs were headache with 64 events, adverse drug reaction with 24 events, and arthralgia with 19 events.

Subgroup analyses

Analysis of subgroups showed clinician experience did not significantly affect subject 5 year occlusion status whether considering the rate of complete occlusion (1–3 procedures 55.2% (16/29), 4–6 procedures 41.5% (17/41), >6 procedures 60.27% (44/73), P=0.1492), or adequate occlusion (1–3 procedures 75.9% (22/29), 4–6 procedures 85.4% (35/41), >6 procedures 84.9% (62/73), P=0.5084).

Throughout the 5 year follow-up, the rate of patients with serious AEs was found to be statistically different in patients with an aneurysm sac width <8 mm (41.6% (52/125)) compared with those with a sac width ≥8 mm (60.0% (15/25) (P<0.0001), and with clinician experience (1–3 procedures 62.1% (18/29), 4–6 procedures 45.5% (20/44), >6 procedures 37.7% (29/77), P=0.0344). In all other subgroups, serious AE rates did not significantly differ.

DISCUSSION

The most notable observations from the 5 year US WEB-IT data set are: (1) no patient experienced bleeding from their treated aneurysm throughout the entire 5 year period, (2) the angiographic occlusion results observed at 1 year were stable or improved in the majority of patients at 5 years or last observed follow-up, (3) the high procedural and post-procedural safety rates observed at 1 year persisted through to 5 years with no additional device related adverse events, and (4) 15.5% of patients were retreated during the study, the majority of whom had no deterioration in occlusion status. While most retreatments were accomplished safely, two resulted in subarachnoid hemorrhage, one of which was fatal. Operators must consider the demonstrated stability of occlusion status, the absence of aneurysm rupture after WEB treatment, and the absence of device or aneurysm related AEs after the initial treatment when contemplating the risk:benefit ratio for retreatment.

Long term stability of treatment

The reporting of long term occlusion rates is challenging in a cohort such as this due to patient dropouts, variable imaging modalities at late time periods, and retreatments (which are generally performed in the absence of established criteria). For the purposes of the present study, the LOCF method was used to conform with other reports in the literature.¹⁴ Using this method, the reported complete (58.1%) and adequate (87.2%) occlusion rates observed in US WEB-IT were consistent with

the 5 year results from the combined analysis of the French WEBCAST (WEB Clinical Assessment of Intra-saccular Aneurysm Therapy) and WEBCAST-2 studies which reported similar complete (51.6%) and adequate (77.9%) occlusion rates.¹⁴ The trend towards slightly higher rates of aneurysm occlusion in the US trial may be attributable to the application of newer generation devices in the US trial as well as accrued knowledge regarding technical aspects of the procedure, of which device sizing was probably the most significant.

Very few long term (> 1 year) follow-up studies of aneurysms treated with endovascular coiling are available. Moreover, the vast majority of the data sets available do not partition out WNBAs and, as such, direct comparisons to predicate technologies are limited. However, as previously described, the 1 year outcomes reported for WNBAs treated with WEB compare very favorably with the few existing studies of coil embolization with or without stent support. The BRANCH (wide neck bifurcation aneurysms of the middle cerebral artery and basilar apex treated by endovascular techniques) and MAPS (Matrix And Platinum Science) studies have reported lower rates of both complete (30.6% and 30.1%) and adequate occlusion (63.0% and 60.5%) when compared with the results of the current study.^{18 19} A single center, retrospective, self-adjudicated, longer term study of wide necked aneurysms treated with coiling with or without stent assistance reported rates of complete occlusion of 44.4% and adequate occlusion of 89.8% with a mean follow-up of 58 months.²⁰ Their observed rates of complete occlusion (32.9%) were substantially lower in the absence of stenting, which was precluded in the US WEB-IT study.

A second related question regarding aneurysm occlusion status is the stability of angiographic occlusion rates observed at 1 year over the long term. In general, 1 year angiographic results in the US WEB-IT population demonstrated excellent stability. No change in occlusion status was observed in two-thirds of patients, and progressive occlusion was observed in a quarter of patients with residual neck or aneurysm. Of 49 patients with complete occlusion at 1 year and available 5 year imaging results, 43 remained completely occluded. One patient was retreated despite no documented deterioration in occlusion status, one patient was retreated following deterioration to residual neck, and another four patients developed neck remnants but were not retreated as they still demonstrated adequate occlusion. All 74 patients who demonstrated adequate occlusion at 1 year and had 5 year imaging continued to demonstrate adequate occlusion at the 5 year follow-up time point, including 10 who underwent retreatment despite eight showing stable adequate occlusion at late follow-up. Thus the available data indicate that once adequate occlusion was achieved, it was stable over the long term.

In summary, the long term occlusion rates observed with WEB have been consistently as good or better than those reported for the predicate intra-saccular devices (ie, aneurysm coils). Moreover, the occlusion results observed at intermediate term (1 year) follow-up were, in the majority of cases, either stable or improved over time.

Long term safety

The existing prospective WEB studies have consistently reported outstanding levels of procedural (30 days) and post-procedural safety (up to 5 years). The US WEB-IT study 1 year and 5 year results indicate similar rates of safety with no rupture or rerupture of aneurysms after treatment and no new hemorrhagic or ischemic stroke events attributed to the WEB procedure or WEB device observed during long term follow up.¹ These findings are consistent with the combined WEBCAST analysis which also observed no rupture or rerupture of treated aneurysms and no WEB related morbidity or mortality up to 5 years.¹⁴

No comparative prospective, core laboratory adjudicated, long term (>1 year) clinical follow-up data are available for patients with WNBA treated with predicate technologies, such as balloon or stent assisted coiling. The majority of intermediate and longer term studies have been retrospective, self-adjudicated, and focused primarily or exclusively on angiographic occlusion status or retreatment rates rather than clinical events. The Pipeline for Uncoilable or Failed aneurysms (PUFS) study reported long term clinical follow-up data for a cohort of >100 patients with side wall aneurysms treated with flow diversion.²¹ These investigators observed three (2.6%) delayed device or aneurysm related serious AEs between 180 days and 3 years, none of which led to permanent neurological sequelae or death. No additional events were noted between 3 and 5 years. Moreover, no aneurysms treated in this study were observed to demonstrate delayed rupture during long term follow-up. The PUFS patient population with large and giant carotid aneurysms treated with an intravascular flow diverter, however, is not directly analogous to the WEB treated population in the US WEB-IT study. Collectively, however, these data speak to the long term safety profile of the modern generation of endovascular devices designed for the treatment of intracranial aneurysms as well as their effectiveness to impart durable protection against aneurysm rupture.

Retreatment

The rate of retreatment in the US WEB-IT study (15.5%) was higher than that reported in the combined European WEBCAST studies (11.6%).¹⁴ This likely reflects a bias toward retreatment that has been previously observed in North American centers participating in trials of endovascular aneurysm treatment. For example, in the MAPS study, ruptured aneurysms were retreated at a 21% rate at US centers versus a 4.4% rate at international sites, despite similar rates of incomplete occlusion.²² The lower threshold for retreatment in US WEB-IT is also reflected by the occlusion status in patients retreated after 1 year. In fact, 11 of 18 patients retreated after 1 year had adequate occlusion on 1 year imaging and 15 of 18 were retreated in the absence of any deterioration in aneurysm occlusion grade.

While retreatments were technically feasible and for the most part safe, it is important to emphasize that two patients experienced subarachnoid hemorrhages during attempted retreatments, one resulting in death and the other resulting in a decline in modified Rankin Score. The 30 day mortality and neurological morbidity rates observed in the small

cohort of retreated US WEB-IT patients (4.3% mortality, 4.3% major stroke) exceeded those observed in the entire cohort of 150 US WEB-IT patients (0% mortality, 0.7% major stroke) during the original 30day peri-procedural epoch.

Given that all US WEB-IT patients with adequate occlusion at 1 year (who were not retreated) remained adequately occluded at 5 years, and that no patient treated with the WEB in any of the prospective trials has, to date, experienced rerupture or rupture of the target aneurysm, operators should proceed with caution when considering the retreatment of patients with incomplete aneurysm occlusion after initial WEB treatment.

Limitations

The most significant limitation of the present study was the lack of 5 year follow-up imaging for a substantial proportion of the cohort; 58.6% of patients with 1 year angiography underwent follow-up imaging at 5 years. Much of this attrition could be attributed to the COVID pandemic which interrupted normally scheduled imaging follow-up over a protracted period. Fortunately, clinical follow-up was maintained up to 5 years in the majority of patients (83%, 123/148), underscoring the reliability of the long term safety results.

CONCLUSIONS

Five year follow-up data from the WEB-IT study demonstrated that the WEB device is safe and effective when used in the treatment of WNBA. No patients treated in the study had a rebleed of their ruptured index aneurysm or a hemorrhage of their unruptured index aneurysm over the course of the study. Aneurysm occlusion rates achieved at the 1 year follow-up were durable, with the majority of aneurysms remaining stable at 5 years and with rates of progressive occlusion exceeding rates of recurrence over time in the rest.

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Funding This work was supported by Microvention/Terumo USA.

Competing interests The US WEB IT trial was supported by Terumo/Microvention USA.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the US Food and Drug Administration, and institutional review boards approved the study at all participating institutions; 27 centers participated in this study. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available. Not applicable.

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