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Original research

CLinical EVALuation of WEB 17 device in intracranial aneuRysms (CLEVER): 1-year effectiveness results for ruptured and unruptured aneurysms

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ABSTRACT

Background The Woven EndoBridge (WEB) device is designed to treat wide-necked bifurcation aneurysms. The WEB 17 is the latest iteration and can be delivered through a 0.017" microcatheter. The CLEVER study demonstrated that WEB 17 is safe and effective for providing protection against bleeding or rebleeding at 1 month and 1 year.

Objective To evaluate angiographic stability at 1 year.

Methods The CLEVER study was a prospective multicenter study conducted in 17 European centers, involved 163 subjects, comprising 60 ruptured and 103 unruptured aneurysms. Independent assessment of 1-year follow-up imaging was incorporated into the study design.

Results Aneurysm diameters ranged from 2.0 to 9.2 mm, with 95.7% being broad-based (dome-to-neck ratio <2). Follow-up imaging at 1 year was completed for 146 out of 163 subjects (89.6%) and evaluated by an independent core laboratory. The primary efficacy endpoint of adequate occlusion without re-treatment at 1 year was achieved for 120 (82.2%) of all subjects. At 1 year, the adequate occlusion rate was 86.5% for ruptured aneurysms (73.1% complete occlusion) and 82.4% for unruptured aneurysms (57.1% complete occlusion). The overall re-treatment rate at 1 year was 2.6% (4/152), with 3.1% (3/97) for unruptured aneurysms and 1.8% (1/55) for ruptured aneurysms.

Conclusion Delivery of the WEB 17 via 0.017 inch catheters represents a significant evolution of the WEB design. The results of CLEVER presented here demonstrate that it maintains the same efficacy as previous generations of WEB.

INTRODUCTION

Specifically designed for the challenging environment of wide-necked bifurcation aneurysms (WNBA),^{1,2} the Woven EndoBridge (WEB; MicroVention, Aliso Viejo, California, USA) has been instrumental in establishing intrasaccular flow

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ The safety and effectiveness of the WEB device have been demonstrated for more than 10 years across numerous studies: WEBCAST, WEBCAST 2, French Observatory, WEB-IT, and CLARYS.
- ⇒ WEB 17 is the latest evolution of the WEB design, developed for use with 0.017 inch catheters.
- ⇒ Safety results of the CLEVER study at 1 month and 1 year were published previously.

WHAT THIS STUDY ADDS

- ⇒ This study presents 1-year efficacy results using the WEB 17 device.
- ⇒ At 1 year, WEB 17 retains the same efficacy as prior generations of the WEB.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ This technological advancement enables the treatment of smaller, more distal aneurysms, whether ruptured or unruptured.
- ⇒ WEB 17 might induce its further adoption in real-life practice.

disruption as an accepted endovascular approach for the treatment of ruptured and unruptured intracranial aneurysms, as demonstrated in numerous studies.^{3–9} As the most recent advance of the WEB product family, the WEB 17 enables the delivery of the implant through a 0.017 inch microcatheter.¹⁰ Since only a limited series of articles have reported on 12-month outcomes for the WEB 17,^{11–13} clinical evidence demonstrating that the WEB 17 maintains the same favorable safety and effectiveness profiles as the previous generations of WEB was essential. This was the purpose of the CLinical EVALuation of WEB 17 device in intracranial aneurysms (CLEVER) study. Primary and secondary



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safety endpoints have already been published.¹⁴ Reporting the 1-year effectiveness results is the focus of this article.

METHODS

Study design

The CLEVER study was a prospective, single-arm, multicenter, observational clinical study conducted in 17 centers across Hungary, Finland, France, Germany, and the United Kingdom. Enrollment criteria required that each subject have either an unruptured or a ruptured aneurysm located in the anterior or posterior intracranial circulations. For people with ruptured aneurysms, only those with a Hunt-Hess score \leq III were eligible for enrollment.

The CLEVER study was registered in ClinicalTrials.gov under NCT03844334 funded by MicroVention-Terumo, Inc., and received all national regulatory approvals under local regulations. Data were collected according to the requirements of the International Conference on Harmonization Guideline for Good Clinical Practice. Informed consent was obtained for all subjects, authorizing the processing of personal data, forwarding of anonymized medical records to the clinical event adjudicator and Corelab, and permitting study monitors to check medical records against study-specific electronic case report form data.

Additional inclusion criteria at baseline included subject age between 18 and 80 years, the presence of a single aneurysm requiring treatment, and aneurysm diameter and height appropriate in size for treatment with the WEB 17 (WEB width available between 3 and 7 mm). Ruptured aneurysms were defined by CT, MRI, or lumbar puncture evidence of subarachnoid hemorrhage attributed to the index aneurysm within the last 30 days. The decision to treat and the method of treatment were determined independently of the study during a local multidisciplinary meeting, including neurosurgeons and neuroradiologists, according to each site's practice.

Study endpoints

The primary effectiveness endpoint was an adequate occlusion rate with no re-treatment at the 12-month follow-up. Secondary effectiveness endpoints included rates of complete occlusion, recurrence or recanalization, and re-treatment at 12 months.

Procedure

Index aneurysm embolization was performed under similar conditions to standard coiling. The aneurysm was catheterized with a VIA 17 microcatheter (MicroVention, Aliso Viejo, California, USA). Selection of the WEB implant model (barrel shape or WEB SL vs sphere shape or WEB SLS) was determined by the operator.

The WEB 17 device was intended to be used alone as a first-line treatment for the index aneurysm. Use of adjunct devices was permitted, based on the best clinical judgment of the individual interventional neuroradiologist. Antiplatelet therapy was used according to the site's standard of care and recorded at each visit. Endovascular treatment and follow-up evaluations were also performed according to standard care protocols.

Data collection and analysis

All data were collected in an electronic case report form and independently monitored by a clinical research organization. To minimize bias, a Corelab assessed efficacy endpoints, and all adverse events were adjudicated by a clinical event adjudicator. This effectiveness analysis was performed based on the intention-to-treat population of enrolled patients who underwent at least

one treatment attempt with a WEB 17 device (defined as insertion of the WEB device into the delivery catheter while the catheter was in place).

Statistical analysis

The CLEVER study was based on the objective performance criteria (OPC) for effectiveness and safety in treating WNBAs, as presented by Fiorella *et al*, using a standard frequentist approach for statistical analyses.¹⁵ Descriptive statistics, including mean, SD, number evaluated, median, minimum, and maximum were presented for continuous baseline characteristics. Categorical variables, were expressed as numbers and percentages, as appropriate. Missing data were not replaced and were considered as such. All data analyses were conducted using SPSS version 22.0 (IBM Corp, Armonk, New York, USA).

RESULTS

Between March 2019 and February 2021, 163 subjects (111 female and 52 male) with a mean age of 58.1 years were enrolled across 17 European interventional neuroradiology centers. The study population consisted of 103 subjects with an unruptured intracranial aneurysm (UIA), and 60 subjects with a ruptured intracranial aneurysm (RIA).

Patient and aneurysm characteristics

Descriptions of the study population, perioperative adverse events, and clinical follow-up at 1 month and 1 year have been published separately.¹⁴ The 163 subjects were treated for 163 aneurysms. Although 36 subjects had multiple aneurysms, including 11 subjects in the RIA cohort, only one aneurysm per subject was treated during the index procedure.

The mean sac width of UIAs was 5.1 mm (range 2.5–8.9 mm), and 4.8 mm (range 2.0–9.2 mm) for RIAs. In the RIA cohort, 95.0% of aneurysms were broad-based (dome-to-neck (DTN) ratio <2), and 96.1% of the UIA cohort met this definition. Anterior communicating artery and middle cerebral artery aneurysms represented the majority of the treated aneurysms (37.4% and 30.1%, respectively).

Procedural results

The WEB 17 procedure was completed successfully in all aneurysms (163/163). Adjunctive balloon-assisted positioning of the WEB was necessary in 10/163 cases (6.1%). Implantable adjunctive devices were used in 6/163 cases (3.7%): stenting in three UIAs, coils in two RIAs, and stenting plus coils for one UIA.

One-year anatomical follow-up

According to study protocol, imaging follow-up was performed at 1 year (14.3 ± 3.8 months) for 146 subjects. Reasons for missing angiographic data are presented in figure 1. The main type of imaging performed was DSA (104/146, 71.2%), followed by MR angiography (41/146, 28.1%), and CT (1/146, 0.7%). For re-treated patients, the images assessed were those prior to re-treatment.

Primary effectiveness endpoint

The primary efficacy endpoint was the 12-month rate of adequate occlusion of the target ruptured or unruptured aneurysm with no reintervention of the target lesion. Adequate occlusion was defined as complete occlusion (Raymond–Roy grade I) or neck remnant (Raymond–Roy grade II).¹⁶ When considering the primary effectiveness endpoint, 120/146 aneurysms (82.2%) achieved adequate occlusion without re-treatment at 12 months

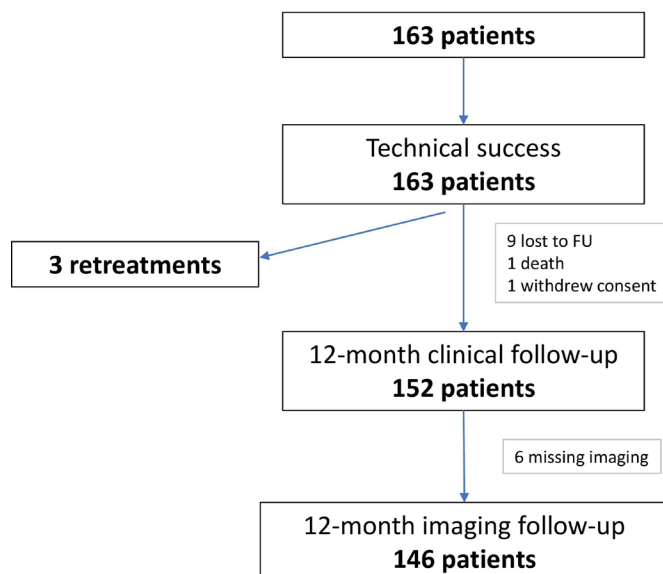


Figure 1 Flow chart describing the efficacy population. FU, follow-up.

(table 1). There were 45/53 (84.9%) RIAs and 75/93 (80.6%) UIAs that met this primary effectiveness endpoint.

Secondary effectiveness endpoint

The anatomical results were assessed at 12 months, with the evaluation of aneurysm occlusion also based on the Raymond-Roy scale. Subjects re-treated before the 12-month visit (three subjects) were not included in the analysis of aneurysm occlusion at 12 months. Table 1 presents the occlusion outcomes at 1-year follow-up for the overall study population and per cohort. The complete occlusion rate at 1 year for wide-necked aneurysms (DTN<2) was 61.3%, as compared with the 100% complete occlusion rate for narrow-necked aneurysms (DTN≥2), but this difference was not statistically significant ($P=0.085$).

Table 1 Primary efficacy endpoint and occlusion assessment at 12 months

	Unruptured	Ruptured	Total
<i>Primary efficacy endpoint</i>	<i>n=93</i>	<i>n=53</i>	<i>n=146</i>
Raymond I	52 (55.9%)	38 (71.1%)	90 (61.6%)
Raymond II	23 (24.7%)	7 (13.2%)	30 (20.5%)
Raymond III	18* (19.4%)	8† (15.1%)	26‡ (17.8%)
Adequate occlusion without re-treatment	75 (80.6%)	45 (84.9%)	120 (82.2%)
<i>Occlusion assessment at 12 months</i>	<i>n=91</i>	<i>n=52</i>	<i>n=143</i>
Raymond I	52 (57.1%)	38 (73.1%)	90 (62.9%)
Raymond II	23 (25.3%)	7 (13.5%)	30 (21.0%)
Raymond III	16 (17.6%)	7 (13.5%)	23 (16.1%)
Adequate occlusion	75 (82.4%)	45 (86.5%)	120 (83.9%)

Primary efficacy endpoint consists of occlusion rate with no re-treatment at the 12 months' follow-up; for re-treated patients, occlusion rate was assessed at the time of re-treatment.
Occlusion assessment at the 12 months' follow-up is a secondary endpoint and does not include re-treated patients.
*Including two subjects re-treated.
†Including one subject re-treated.
‡Including three subjects re-treated.

Table 2 Complete occlusion at 1 year according to AP/AC therapy at 30 days

	No AP/AC at 30 days n=33	At least 1 AP/AC at 30 days n=110	Total n=143
Complete occlusion	24 (72.7%)	66 (60.0%)	90 (62.9%)
Neck or aneurysm remnant	9 (27.3%)	44 (40.0%)	53 (37.1%)

$P=0.221$.
AC, anticoagulant; AP, antiplatelet.

Re-treatment rate

The overall re-treatment rate was 2.6% (4/152) with 3.1% (3/97) for unruptured aneurysms and 1.8% (1/55) for ruptured aneurysms. The re-treatment period was mainly between the 6-month and 12 month visits. Timing and details of re-treatment were as below:

- Before discharge:
 - One patient was re-treated the day after the index procedure with Y-stenting as a rescue procedure due to protrusion of the WEB.
- Between 6- and 12 months' follow-up:
 - One patient with another small aneurysm, slightly distal to the treated aneurysm's neck, was re-treated by flow diversion at 10 months. Index aneurysm was Raymond I at 6 months and 12 months.
 - Two patients with Raymond III were re-treated:
 - One with stenting and coils at 12 months. Their status of occlusion between postprocedure and re-treatment is not known.
 - One with coils at 15 months. The aneurysm was Raymond I at 6 months and Raymond III at the time of re-treatment.

Anticoagulant and antiplatelet regimen

The antiplatelet and/or anticoagulant regimen received by the patients was previously reported.¹⁴ There was no significant difference between the complete occlusion rates at 1 year for subjects who received antiplatelet and/or anticoagulant therapy 30 days after WEB placement (60.0%) compared with those who did not receive such therapy (72.7%) (table 2).

DISCUSSION

The WEB 17 represents the latest evolution in WEB technology, developed to enable deployment using 0.017-inch catheters comparable in diameter to those used for coiling aneurysms. The expected benefit was to enhance usability and facilitate more distal navigation with the VIA 17 microcatheter compared with the VIA 21 catheter. The modification of the WEB structure, particularly the adjustment of the number and diameter of wires, served as the foundation for this recent advancement in WEB design.¹⁰ The mechanisms of action for both the current and previous generations of the WEB is intrasaccular flow disruption. Ensuring that these modifications maintain the same safety and effectiveness as the WEB 21 and its predecessors in aneurysmal occlusion has been the focus of initial single-center WEB 17 studies.^{10 17 18} The CLEVER study represented the next step in this ongoing evaluation, serving as the first controlled multicenter study to investigate the use of WEB 17 in routine practice for the treatment of both unruptured and ruptured WNBAs. It was imperative to validate the already reported clinical safety¹⁴ through an assessment of the angiographic efficacy 1 year post-WEB treatment.

In our study, the primary effectiveness endpoint was compared for non-inferiority with the exact binomial distribution for the mean proportion of subjects with adequate occlusion, as extrapolated from the published WNBA literature on other endovascular techniques and surgical clipping. The OPC derived from this literature were set at 68.0%, with a lower confidence level of 49.1% for ruptured aneurysms and 54.7% for unruptured aneurysms. CLEVER unequivocally showed that the 1-year efficacy of treatment using the WEB 17 surpassed that of other techniques. Indeed, the primary endpoint analysis of the CLEVER data revealed a significant improvement, with an overall occlusion rate of 82.2% ($P<0.0001$), including 80.6% for unruptured aneurysms ($P<0.0001$) and 84.9% for ruptured aneurysms ($P<0.0001$).

Similarly, the lower confidence level of the OPC for the secondary effectiveness endpoint was 32.1% for UIAs and 26.8% for RIAs. The secondary endpoint of complete occlusion, regardless of re-treatment status, was statistically significantly greater at 69.0% ($P<0.0001$) for UIAs and 80.0% ($P<0.0001$) for RIAs.

Across the prior prospective trials of the WEB (WEB-IT,⁵ French Observatory,¹⁹ WEBCAST,²⁰ and WEBCAST 2,²¹ the WEB 21 demonstrated a rate of adequate occlusion without re-treatment at 12 months of 83.2%. In CLEVER, the WEB 17 demonstrated a similar rate of adequate occlusion without re-treatment at 12 months of 82.2%.

The 12 months occlusion rate for the WEB 17 is also consistent with the results from prior WEB generations as reported in the literature and observed in prior WEB prospective trials. Focusing specifically on the group of ruptured aneurysms, the rates of adequate occlusion are similar in the CLARYS and CLEVER studies (87% and 86.5%, respectively). It is worth noting that the rate of complete occlusion is much higher in the ruptured subgroup of CLEVER compared with CLARYS (73% and 41%, respectively). Rates of aneurysm remnants remained similar between CLARYS and the CLEVER cohort of RIAs (13% and 14%, respectively). The difference in the rate of complete occlusion of WEB 17 for the treatment of ruptured aneurysms is difficult to explain. Certainly, the treated aneurysms were smaller in the CLEVER RIA cohort versus CLARYS (maximum aneurysm sac width 4.8 mm and 7.3 mm, respectively) but greater operator proficiency with the WEB might also have been a factor.

DTN ratios <2 , indicating broad-based anatomy, were observed in 95.7% of CLEVER cases. The presence of a wide neck, though, was not associated with a worse angiographic result. Making a direct comparison between wide-necked and narrow-necked aneurysms was not possible, as the latter group was too small (6/143).

Postoperative antiplatelet and/or anticoagulant therapy was used according to the site's standard of care, and the reason for prescription is not known. We found that the rate of complete occlusion at 1 year was higher in the group without antiplatelet and/or anticoagulant therapy in the month following endovascular treatment compared with the group of patients who received at least one of them. Although this difference is not significant, it is important to note that the trend is notable. This point might need to be investigated further, as we did not find any literature on this topic.

The 1-year re-treatment rate for CLEVER was 2.6%, lower than the rate of 6.9% in the three European Good Clinical Practice studies⁴ and 5.6% in WEB-IT. The rate of re-treatment differed between the group of ruptured aneurysms (1/55, 1.8%) and the group of unruptured aneurysms

(3/97, 3.1%), but this difference was not significant, probably due to the very small numbers involved.

Limitations

The CLEVER study had several limitations of note. Although prospective in design, there was no control group or randomization. This study also had a higher proportion of ruptured aneurysms than some of the prior studies. However, since endpoints were based on an established effectiveness OPC for treatment of WNBAs, comparisons with the body of scientific literature were valid.

CONCLUSION

In conclusion, this prospective multicenter clinical study demonstrates that treatment of WNBAs with WEB 17 yields a high rate efficacy for aneurysmal occlusion with a low rate of re-treatment at 1 year, confirming the previously published technical and clinical success rates for CLEVER. These results also confirm the WEB 17 as an effective treatment option for both unruptured and ruptured WNBAs, consistent with findings from other studies on WEB.

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Contributors Conception and design of the work: LS, IS, CC. Acquisition of data: LS, VCo, JCa, FW, SF, DH, MAM, A-CJ, CP, JK, JN, RR, AB, CM, VC, JD, JCo, LI, SG, MB, TL, SV, IS, CC. Analysis of data and interpretation of data: LS, JB, IS, LP, CC. Drafting the work: LS, IS, CC. Critically revising the work: VCo, JCa, FW, SF, DH, MAM, A-CJ, CP, JK, JN, RR, AB, CM, VCh, JD, JCo, LI, SG, MB, TL, SV, LG, JB, IS, LP, CC. Final approval of the version to be published: all authors. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: all authors. LS is the author acting as guarantor.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants and received national regulatory authorization following each country's requirement: In France, the study was approved by CCTIRS (Advisory Committee on Information Processing in Health Research) and declared to the CNIL (National Commission for Information Technology and Civil Liberties); no ethics committee or institutional review board approval was required under French regulations. In Germany, the study was approved by local ethics committees of each participating center, except Berlin which did not require new submission. The ethics committees are: Ethikkommission Medizinische Fakultät Heidelberg, Ruhr Universität Bochum Ethik-Kommission der Medizinischen Fakultät, Ethik-Kommission der Ärztekammer Hamburg Körperschaft des Öffentlichen Rechts und Fachbereich-Medizin Frankfurt Goethe Universität Ethik-Kommission; the process did not include ID of the approvals. Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available upon reasonable request. Extra data are available upon reasonable request.

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