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Authors

Alexander, Michael J
Zauner, Alois
Gupta, Rishi
[et al.](#)

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ORIGINAL RESEARCH

The WOVEN trial: Wingspan One-year Vascular Events and Neurologic Outcomes

Michael J Alexander ¹, Alois Zauner,² Rishi Gupta,³ Amer Alshehlee,⁴ Justin F Fraser ⁵, Gabor Toth ⁶, Curtis Given,⁷ Larami Mackenzie,⁸ Brian Kott,⁹ Ameer E Hassan ¹⁰, Harish Shownkeen,¹¹ Blaise W Baxter,¹² R Charles Callison,¹³ Wengui Yu ¹⁴

For numbered affiliations see end of article.

Correspondence to

Dr Michael J Alexander, Department of Neurosurgery, Cedars-Sinai Medical Center, Los Angeles, CA 90048, USA; michael.alexander@cshs.org

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ABSTRACT

Background Prior studies evaluating the Wingspan stent for treatment of symptomatic intracranial atherosclerotic disease have included patients with a spectrum of both on-label and off-label indications for the stent. The WEAVE trial assessed 152 patients stented with the Wingspan stent strictly by its current on-label indication and found a 2.6% periprocedural stroke and death rate.

Objective This WOVEN study assesses the 1-year follow-up from this cohort.

Methods Twelve of the original 24 sites enrolling patients in the WEAVE trial performed follow-up chart review and imaging analysis up to 1 year after stenting. Assessment of delayed stroke and death was made in 129 patients, as well as vascular imaging follow-up to assess for in-stent re-stenosis.

Results In the 1-year follow-up period, seven patients had a stroke (six minor, one major). Subsequent to the periprocedural period, no deaths were recorded in the cohort. Including the four patients who had periprocedural events in the WEAVE study, there were 11 strokes or deaths of the 129 patients (8.5%) at the 1-year follow-up.

Conclusions The WOVEN study provides the 1-year follow-up on a cohort of 129 patients who were stented according to the current on-label use. It provides a more homogeneous patient group for analysis than prior studies, and demonstrates a relatively low 8.5% 1-year stroke and death rate in stented patients.

taking a combination of antiplatelet and anticoagulant therapy. In the HDE trial, the target vessel for revascularization had to be 2 mm or larger, the patient had to have a moderately functional neurologic status with modified Rankin Scale score of 3 or better, and stenting was performed at 1 week or longer following the qualifying event.

Subsequent registries in the USA^{3–5} comprised a spectrum of on-label and off-label patients, including patients who presented with transient ischemic attacks, without documented strokes, patients for whom medical therapy had not failed, and patients treated for other intracranial lesions, such as dissection. These studies demonstrated periprocedural complication rates of stroke and death of approximately 6%. Published Wingspan stent series from Asia^{6–12} with heterogeneous inclusion and exclusion criteria also demonstrated low periprocedural complication rates and relatively reproducible 1-year follow-up stroke and death rates (table 1).

The Stenting versus Aggressive Medical Management of Intracranial Stenosis (SAMMPRIS) Trial¹³ was a prospective randomized trial comparing aggressive medical management (AMM) alone with AMM and treatment with the Wingspan stent. The trial again demonstrated a spectrum of on-label and off-label use. Follow-up analysis indicated that only 8.2% of the patients in the trial would have met the original HDE indication for stenting in the FDA-approval trial.¹⁴ The trial was stopped early as interim analysis demonstrated an unexpectedly high 14.7% periprocedural complication rate in the stenting arm as compared with a 5.7% stroke and death rate at 30 days in the AMM arm. The subsequent analysis leveled several criticisms at the study design.¹⁵ A post-hoc analysis also demonstrated, even with the poor periprocedural clinical results in the stenting arm, some apparent reduction in the long-term disabling stroke and death rate in the stenting arm.¹⁶ Yu *et al*, noted that the delayed major disabling stroke and death rate was 2.2% in the stenting arm and 6.2% in the AMM arm of SAMMPRIS.

Following the results of the SAMMPRIS trial, in 2012 the FDA conducted a panel review of the Wingspan stent system and renewed the HDE status of the device, but with modified indication for use. The primary revisions included changing

BACKGROUND

The Wingspan stent system (Stryker Neurovascular, Salt Lake City, Utah USA) is a self-expanding, nitinol, intracranial stent that was originally cleared by the Food and Drug Administration (FDA) in the USA in 2005 under the Humanitarian Device Exemption (HDE) classification. The decision was based on the results of the initial approval trial.¹ The original indication for use was for patients who had 50–99% intracranial artery stenosis due to intracranial atherosclerotic disease (ICAD), who presented with a stroke, and who were 'refractory to medical therapy'.² The medical therapy regimen was not well defined at that time. At the time of their qualifying event, 84% of patients were taking one or more antiplatelet agents, 42% were taking anticoagulant therapy, and 27% were



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Table 1 Table analyzing the major Wingspan stent studies with reference to enrollment criteria, periprocedural events, and 1-year follow-up

	Number of patients stented	Percentage stented per HDE trial indication	Periprocedural complications	Time to stent from stroke or TIA	Cumulative 1-year stroke and death rate
HDE Trial ¹	44	93%	4.5%	22 days	Not reported
NIH Registry ^{3,4}	160	61%	6.2%	10 days	Not reported
US Registry ⁵	158	57%	6.9%	Not reported	Not reported
Jiang ⁶	100	71%	5.0%	34 days	7.3%
SAMMPRIS ¹³	224	8.2%	14.7%	7 days	20.0%
Miao ⁷	141	56%	4.3%	19d TIA/32d stroke	Not reported
Li ⁸	429	47%	6.7%	24 days	9.5%
Wang ⁹	196	52%	7.1%	Not reported	9.6%
Zhao ¹⁰	278	Not reported	4.3%	21 days	5.8%
Gao ¹¹	100	50%	2.0%	21 days	Not reported
Ma ¹²	141	56%	4.0%	22 days	7.9%
WEAVE ¹⁹	152	100%	2.6%	22 days	Not reported

HDE, Humanitarian Device Exemption; SAMMPRIS, Stenting versus Aggressive Medical Management of Intracranial Stenosis; TIA, transient ischemic attack.

the minimum degree of stenosis from 50% to 70%, changing the criteria from 'refractory to medical therapy' to a 'comprehensive regimen of medical therapy' failed.¹⁷ No further qualification of this regimen, such as failed dual antiplatelet therapy, was given but there is an implication that patients with hyperlipidemia, hypertension, and diabetes should have these comorbidities managed medically. Similarly, the current Wingspan indication for use states that patients should have recurrent strokes 'refractory to a comprehensive regimen of medical therapy', but there is no requirement that dual antiplatelet therapy failed in a patient.¹⁸ The revised indication for use also states that patients should be aged 22–80 years with two or more strokes in the territory of the target artery, that the most recent stroke must have occurred more than 7 days prior to treatment with the Wingspan stent system, and that the patients should have a modified Rankin Scale score of 3 or less at the time of treatment.

The Wingspan stent system post-market surveillance trial (WEAVE) was an FDA mandated post-market surveillance study that enrolled strictly patients treated on-label with the Wingspan stent.¹⁹ The goal of the trial was to assess only the periprocedural stroke and death rate to assess the safety of the Wingspan stent procedure itself. A total of 152 patients were enrolled at 24 centers in the USA, and core study neurologists assessed clinical outcomes. A 2.6% rate of periprocedural stroke and death occurred, which met the FDA safety benchmark of the post-market surveillance study.

The WEAVE Trial assessed only the periprocedural morbidity of the 152 patients treated on-label with the Wingspan stent, but the Wingspan One-year Vascular Events and Neurologic Outcomes (WOVEN) Trial is the natural extension of the WEAVE Trial, assessing long-term clinical outcomes. This study examines both the follow-up vascular imaging results and rates of delayed stroke or death.

METHODS

The WOVEN Trial (ClinicalTrials.gov NCT0422198) was a physician-initiated trial among the original investigators in the WEAVE Trial. The study assessed the 1-year follow-up outcomes in patients stented in the WEAVE trial. The primary endpoints were stroke within the target artery territory, non-traumatic hemorrhage, or neurologic death within 1 year following stenting. Secondary endpoint outcomes included the assessment of stroke severity, the incidence of re-stenosis, and secondary

treatments for re-stenosis. In an effort to determine the severity of stroke events, we categorized strokes as major, if there was a worsening of the baseline National Institutes of Health Stroke Scale (NIHSS) score by greater than 3 points. Minor strokes were defined as NIHSS score worsening of 3 points or less.

Twelve of the original 24 WEAVE sites contributed patient data following institutional review board approval. The majority of these participating sites were high-enrolling sites in the WEAVE trial, thus we were able to obtain clinical follow-up in 129 patients (85% of the original WEAVE cohort). Other prior WEAVE sites did not participate for a variety of reasons, including personnel relocation, difficulty or delay in passing the protocol through grants and contracts or the institutional review board process as an unfunded study, and other logistic problems. We performed chart review and imaging analysis to assess the delayed stroke and death rate in the cohort, and the arterial re-stenosis rate, and information regarding how these patients were managed following a diagnosis of re-stenosis.

If patients had follow-up vascular imaging, the imaging modality was recorded, in addition to the percent stenosis of the target lesion, and the medication regimen the patient was receiving at the time of diagnosed re-stenosis. We defined re-stenosis as 70% narrowing or greater. Also, if patients were

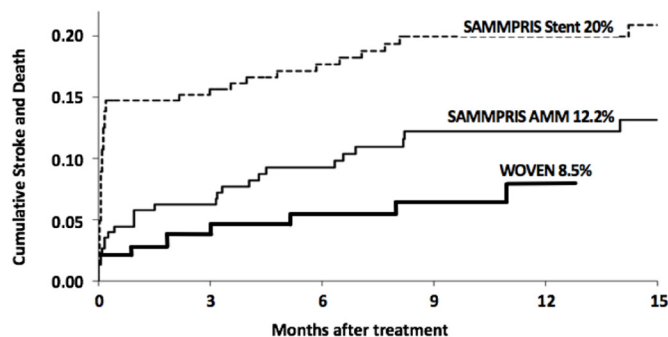


Figure 1 Stroke and death event curve of the WOVEN Trial patients, compared with similar event time course for AMM and stenting arms of the SAMMPRIS trial. AMM, aggressive medical management; SAMMPRIS, Stenting versus Aggressive Medical Management of Intracranial Stenosis.

Table 2 Comparison of early and delayed results within the SAMMPRIS and WEAVE/WOVEN cohorts

	30-Day event rate	Total 1-year event rate	1–12 Month stroke rate	1–12 Month major stroke
SAMMPRIS AMM arm (n=227)	5.7%	12.2%	6.5%	6.2%
SAMMPRIS stent arm (n=224)	14.7%	20.0%	5.3%	2.2%
WEAVE (n=152) and WOVEN (n=129)	4/152 2.6%	11/129 8.5%	7/129 5.4%	1/129 0.8%

AMM, aggressive medical management; SAMMPRIS, Stenting versus Aggressive Medical Management of Intracranial Stenosis.

diagnosed with re-stenosis, we classified patients as symptomatic or asymptomatic, and recorded their subsequent management.

RESULTS

During the 1-year follow-up period, seven patients had a stroke and there were no deaths. Therefore, including the four patients who had periprocedural stroke or death within the WEAVE Trial, 11 of the 129 patients (8.5%) had an index stroke or death within the 1-year clinical follow-up (figure 1). Of the seven patients with delayed stroke, six had minor strokes, and one patient had a major stroke. Since there was no death in the patients followed up long term, and there were two deaths in the periprocedural period, the overall 1-year death rate within the study cohort was 1.6% (2/129).

Although there was a significant difference between the periprocedural event rates in the stenting arm of SAMMPRIS (14.7%) and the WEAVE trial (2.6%), there was not a significant difference in the rate of events past the periprocedural period up to 1 year between the WOVEN trial (5.4%) and the SAMMPRIS stenting arm (5.3%; table 2). In addition, there was also no significant difference in the rate of major stroke between the WOVEN trial (0.8%) and the SAMMPRIS stenting arm (2.2%). In contrast, the rate of major stroke in the SAMMPRIS AMM arm was much higher, at 6.2% at 1 year.

Table 3 breaks down the WOVEN cohort by target vessels. In the 1-year follow-up period, there was no significant difference in the delayed stroke rate between the vessels stented, but numerically the internal carotid artery had the highest stroke rate at 6.9% of the cases, and the vertebral artery had the lowest stroke rate at 4.3%. The overall rate of stroke or death beyond the periprocedural period was 5.4% (7/129), although there were no fatalities in this group.

A total of 102 of the 129 patients followed up (79%) had neurovascular imaging within the first year. They included 62 patients with catheter digital subtraction angiography (DSA), 21 patients with CT angiography, and 19 patients with magnetic resonance angiography. Within this cohort of patients, 18/102 patients (17.6%) demonstrated re-stenosis of the target lesion of 70% or greater. The mean time to diagnosis of re-stenosis

was 5 months with a range of 1 to 11 months. The median and mode time to diagnosis of re-stenosis was 6 months. Regarding re-stenosis rates, the middle cerebral artery (MCA) location had the highest rate of re-stenosis at 19.6% and the vertebral artery location had the lowest re-stenosis rate at 11.8%. In the WEAVE trial, we did tend to under-dilate MCA and basilar arteries, particularly if the target lesion was adjacent to angiographically visible perforators.¹⁹ This may account for the slightly higher re-stenosis rates of both the MCA and basilar arteries in the imaging follow-up.

Among the 18 patients with re-stenosis, 7 patients (38.9%) were symptomatic and 11 patients (61.1%) were asymptomatic. In the symptomatic group, three patients were managed medically with a return to dual antiplatelet therapy, three patients had repeat angioplasty and stenting, and one patient had angioplasty alone. Within the asymptomatic group of patients, seven patients were managed medically with a return to dual antiplatelet therapy, two patients had repeat angioplasty and stenting, and two patients had angioplasty alone. No further strokes or deaths occurred in either those patients receiving intervention or those managed with medical therapy alone up to the 1-year follow-up point.

CONCLUSIONS

The WOVEN trial found an 8.5% 1-year stroke and death rate in 129 patients treated on-label with the Wingspan stent for symptomatic ICAD. This event rate was inclusive of the 2.6% periprocedural complication rate in this patient group. Although a direct statistical comparison cannot be made, this 1-year stroke and death rate appears favorable in light of the 20.0% rate seen in the stenting arm of SAMMPRIS, and the 12.2% stroke and death rate seen in the AMM arm of SAMMPRIS. The results reinforce the concept that if the periprocedural complication rate can be kept low with adherence to best practices and careful patient selection, then the long-term outcomes in patients stented for symptomatic ICAD may be competitive with, or superior to, medical therapy alone in patients with severe stenosis who present with a non-disabling stroke.

In addition, the rate of delayed major disabling stroke or death up to 1 year after stenting was very low in the WOVEN trial at 0.8%, as it was in the stenting arm of SAMMPRIS at 2.2%. Although the data cannot be compared directly, there is again a trend towards a lower incidence of delayed major strokes when referenced to the 6.2% delayed major disabling stroke and death rate seen in the AMM arm of SAMMPRIS.¹⁶

Since there was no well-defined protocol for imaging follow-up in this study, and sites followed their individual standards of practice, the data for delayed imaging are not codified. Although the data are of limited value, they provide some insight into the incidence of delayed stroke after stenting. Delayed re-stenosis of the target artery appeared to be the primary cause of delayed stroke in the WOVEN Trial. Of the seven patients with delayed strokes, six demonstrated re-stenosis of 70% or greater. A total of 17.6% of the patients with delayed vascular imaging demonstrated re-stenosis, defined as 70% narrowing

Table 3 Distribution of target artery location, incidence of delayed stroke, and re-stenosis rates

	ICA	MCA	Vertebral artery	Basilar artery	Total
Number of patients (%)	29/129 (22.5%)	57/129 (44.2%)	23/129 (17.8%)	20/129 (15.5%)	129
Delayed stroke rate (%)	2/29 (6.9%)	3/57 (5.3%)	1/23 (4.3%)	1/20 (5.0%)	7/129 (5.4%)
Re-stenosis rate (%)	4/23 (17.4%)	9/46 (19.6%)	2/17 (11.8%)	3/16 (18.8%)	18/102 (17.6%)

ICA, internal carotid artery; MCA, middle cerebral artery.

or greater, and 38.9% of these patients were symptomatic from the stenosis. Reducing the re-stenosis rate with either innovative stent production or medical therapy would help to obviate the delayed stroke rate in stented patients.

It appears from the data that investigators were more likely to intervene in cases of near-occlusive re-stenosis and monitor patients receiving medical therapy with less severe lesions. The mean re-stenosis was 90.0% and 93.5% in the patients receiving repeat endovascular intervention in the asymptomatic and symptomatic re-stenosis groups, respectively. Whereas, the degrees of stenosis in the medically treated groups were 79.1% in the asymptomatic group and 78.3% in the symptomatic group. Since there were small numbers in both groups, and no complications from the re-treatment, we are not able to draw any conclusions from the different management strategies for re-stenosis in this study at the 1-year follow-up.

This study has clear limitations as it was a single-arm interventional study without a control medical arm. Likewise, our long-term data are limited to primary events and vascular imaging. We did not assess other factors longitudinally, such as lipid profile, blood pressure management, smoking habits. However, this study lends support, through real-world data, that intracranial stenting for ICAD can be performed safely, if proper patient selection and guidelines are followed, and also that there appears to be clinical benefit of stenting at the 1-year follow-up. Development of randomized trials comparing these best practice stenting protocols and guidelines with medical therapy can best establish the efficacy of this intervention.

Author affiliations

- ¹Department of Neurosurgery, Cedars-Sinai Medical Center, Los Angeles, California, USA
- ²Department of Neurosurgery, Stroke and Neurovascular Center of Central California, Santa Barbara, California, USA
- ³Neuroscience Department, WellStar Medical Group, Marietta, Georgia, USA
- ⁴Department of Neurology, SSM Health, St. Louis, Missouri, USA
- ⁵Department of Neurological Surgery, University of Kentucky, Lexington, Kentucky, USA
- ⁶Cerebrovascular Center, CCF, Cleveland Heights, Ohio, USA
- ⁷Baptist Health Lexington, Lexington, Kentucky, USA
- ⁸Department of Neurosurgery, Thomas Jefferson University, Philadelphia, Pennsylvania, USA
- ⁹Department of Radiology, MultiCare Health System, Tacoma, Washington, USA
- ¹⁰Department of Neurology, University of Minnesota, Minneapolis, Minnesota, USA
- ¹¹Central Dupage Health, Winfield, Illinois, USA
- ¹²Department of Radiology, University of Tennessee, Knoxville, Tennessee, USA
- ¹³Department of Neurology, Lawnwood Regional Medical Center and Heart Institute, Fort Pierce, Florida, USA
- ¹⁴Department of Neurology, University of California Irvine, Irvine, California, USA

Correction notice Since the online publication of this article, the title has been updated as 'Outcomes' was incorrectly spelt as 'utcomes'.

Twitter Gabor Toth @GaborTothMD

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Ethics approval The WOVEN Trial was approved by the Cedars-Sinai institutional review board under identification number STUDY00000379.

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ORCID iDs

Michael J Alexander <http://orcid.org/0000-0003-0280-809X>
Justin F Fraser <http://orcid.org/0000-0002-5980-3989>
Gabor Toth <http://orcid.org/0000-0002-3646-3635>
Ameer E Hassan <http://orcid.org/0000-0002-7148-7616>
Wengui Yu <http://orcid.org/0000-0003-1664-3580>

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