Pivotal trial of the Neuroform Atlas stent for treatment of posterior circulation aneurysms: one-year outcomes

Brian T. Jankowitz
Cooper University Hospital

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Original research

Pivotal trial of the Neuroform Atlas stent for treatment of posterior circulation aneurysms: one-year outcomes


ABSTRACT

Background Stent-assisted coiling of wide-necked intracranial aneurysms (IA) using the Neuroform Atlas Stent System (Atlas) has shown promising results.

Objective To present the primary efficacy and safety results of the ATLAS Investigational Device Exemption (IDE) trial in a cohort of patients with posterior circulation IAs.

Methods The ATLAS trial is a prospective, multicenter, single-arm, open-label study of unruptured, wide-necked, IAs treated with the Atlas stent and adjunctive coiling. This study reports the results of patients with posterior circulation IAs. The primary efficacy endpoint was complete aneurysm occlusion (Raymond-Roy class I) on 12-month angiography, in the absence of re-treatment or parent artery stenosis >50%. The primary safety endpoint was any major ipsilateral stroke or neurological death within 12 months. Adjudication of the primary endpoints was performed by an imaging core laboratory and a Clinical Events Committee.

Results The ATLAS trial enrolled and treated 116 patients at 25 medical centers with unruptured, wide-necked, posterior circulation IAs (mean age 60.2±10.5 years, 81.0% (94/116) female). Stents were placed in all patients with 100% technical success rate. A total of 95/116 (81.9%) patients had complete angiographic follow-up at 12 months, of whom 81 (85.3%) had complete aneurysm occlusion (RR class I). The primary effectiveness outcome was achieved in 76.7% (95% CI 67.0% to 86.5%) of patients. Overall, major ipsilateral stroke and secondary persistent neurological deficit occurred in 4.3% (5/116) and 1.7% (2/116) of patients, respectively.

Conclusions In the ATLAS IDE posterior circulation cohort, the Neuroform Atlas Stent System with adjunctive coiling demonstrated high rates of technical and safety performance.

Trial registration number https://clinicaltrials.gov/ct2/show/NCT02340585.

INTRODUCTION

Wide-necked intracranial aneurysms (IA) (neck ≥4 mm, dome-to-neck ratio <2) constitute at least 40% of all IAs, and are difficult to treat with endovascular coiling alone given the propensity for coils to herniate into the parent artery. Stent-assisted coiling (SAC) is a well-established endovascular treatment, which reconstructs the aneurysm neck, prevents coil herniation into the parent artery, and theoretically expedites aneurysm healing by creating a scaffold for endothelial coverage.

The Neuroform stent system (Stryker Neurovascular, Fremont, California, USA) was first approved by the United States Food and Drug Administration (FDA) in 2002. Since then, newer stent iterations, such as Neuroform EX and EZ3, have been approved. The Neuroform Atlas Stent System (Atlas) is the newest generation. The device was designed to scaffold the aneurysm neck and support the placement of detachable, intrasaccular coils. Significant design advances include improved trackability and a smaller cell size, which provides better coil retention within the aneurysm. The Atlas stent design also allows for its delivery via a lower profile, 0.0165 inch (internal diameter) microcatheter as compared with the 0.027 inch microcatheter required for the original Neuroform stent. Finally, the new hybrid cell design, with closed cells at the proximal end, improves recrossing and enhances stability within the vessel, while the classic central open-cell design provides excellent wall apposition, conformability, and flexibility.

In a previous prospective Neuroform Atlas investigational device exemption (IDE) study of 182 patients with anterior circulation IAs, SAC via the Atlas stent demonstrated high rates of complete occlusion at the 12-month angiographic follow-up, as well as promising safety profiles in the anterior cerebral circulation. In this study,
we present the primary efficacy and safety results of the ATLAS IDE trial in a cohort of patients with posterior circulation IAs.

**METHODS**

**Study design**

The ATLAS IDE trial is a prospective, multicenter, open-label, non-randomized, two-cohort, single-arm study that enrolled patients with wide-necked intracranial saccular aneurysms to be treated with SAC using the Atlas stent at 25 medical centers in the USA. Safety and efficacy endpoints were evaluated in a modified intention-to-treat cohort of patients who signed the informed consent form and in whom the investigational device entered the body. An imaging core laboratory and an independent Clinical Events Committee (CEC) adjudicated the primary efficacy and safety endpoints, respectively, to ensure consistency and accuracy of the data and minimize bias.

The institutional review board at each enrollment center approved the study protocol. Each patient completed a written informed consent prior to participation in the trial. All data were entered into a Health Insurance Portability and Accountability Act (HIPPA)-compliant electronic data capture system and monitored by the sponsor and a contract research organization. The data used to support the conclusions of this trial will be furnished, on reasonable requests, by the corresponding author.

**Patient enrollment**

Enrollment for patients with posterior circulation IAs (including vertebral, basilar, and posterior cerebral arteries) took place between June 2015 and December 2017. Clinical investigators and designated research staff at each center managed patient identification, recruitment, and enrollment. Patients were considered enrolled in the study once they were determined that they met all trial inclusion/exclusion criteria and provided the signed informed consent form. The full study enrollment criteria are provided in online supplemental table 1. Briefly, patients were included if they were 18–80 years old and had a documented, wide-necked (neck ≥4 mm or dome-to-neck ratio <2), intracranial, saccular aneurysm arising from a parent vessel with a diameter of 2.0–4.5 mm. The following criteria were used to determine study exclusion: multiple untreated IAs requiring treatment, acute target aneurysm rupture <14 days prior to study treatment, modified Rankin Scale (mRS) score of ≥4 or Hunt and Hess score ≥3, intracranial mass or cerebral vascular malformation, a target aneurysm in the anterior circulation proximal to the superior hypophyseal internal carotid artery, previous treatment with SAC embolization, a known absolute contraindication to angiography or antiplatelet therapy, Moyamoya disease, or underlying parent artery atherosclerosis.

**Procedure description**

The procedure was previously described in detail in the primary results of the ATLAS humanitarian device exemption study. Briefly, all patients undergoing treatment were premedicated with dual antiplatelet therapy (aspirin and clopidogrel) for at least 5 days. Platelet reactivity testing was not mandated. All procedures were performed under general anesthesia, and anticoagulation was managed according to each study site standard of care with a recommended activated clotting time of 250–300 s during the procedure. Atlas was deployed using an Excelsior SL-10 or XT-17 (Stryker Neurovascular, Fremont, California, USA) microcatheter via a transfemoral, radial, or brachial percutaneous approach. Dual antiplatelet therapy was maintained for at least 3 months following stent implantation.

**Follow-up evaluation**

After the implant procedure, all treated patients had follow-up evaluations within 72 hours of the procedure, prior to hospital discharge, and at 2, 6, and 12 months. Data were collected to assess primary and secondary endpoints. Data consisted of neurological assessments (National Institutes of Health Stroke Scale (NIHSS), mRS), antiplatelet medication, and quality-of-life assessment (EQ-5D-3L)). Hunt and Hess scores were recorded for patients who had evidence of aneurysm rupture and subarachnoid hemorrhage (SAH). Digital subtraction angiography (DSA) was performed at 12 months to evaluate the grade of aneurysm occlusion and parent vessel stenosis.

**Primary efficacy outcome**

The primary efficacy endpoint was complete aneurysm occlusion (defined as 100% occlusion of the aneurysm or Raymond-Roy (RR) class I) at 12-month follow-up DSA, in the absence of re-treatment or parent artery stenosis (>50%). Angiographic occlusion was assessed by an independent imaging core laboratory, blinded to assessments made by the clinical sites, to avoid bias. The University of California San Francisco (UCSF) interventional radiology core laboratory provided angiographic evaluation of anonymized patients in the ATLAS trial. For this specific project, the angiogram reader was SWH, who has over 15 years’ experience in the interpretation of cerebral angiograms and the endovascular treatment of brain aneurysms.

**Primary safety outcome**

The primary safety endpoint was any incidence of major ipsilateral stroke, defined as an ipsilateral stroke with an increase of four or more points on the NIHSS assessment at 24 hours after symptoms’ onset, or neurological death within 12 months postprocedure. An independent CEC adjudicated prespecified primary endpoint events and serious device-related events. The threshold for the primary safety endpoint event rate was set at <25% for the posterior circulation cohort in the ATLAS trial, which was established after reviewing data extracted from the MAPS trial wide-necked aneurysm patient cohort as well as published rates of procedural and long-term morbidity and mortality.

**Secondary outcomes**

Secondary efficacy endpoints were assessed after the index procedure through 12 months, and included procedural technical success (defined as the proportion of patients in whom the Atlas stent was successfully delivered and deployed at the target location), rates of target aneurysm occlusion across RR classes, re-treatment, recanalization, progressive occlusion of the target aneurysm, incidence of parent artery stenosis (>50% stenosis), and stent migration.

Secondary safety endpoints were any serious adverse events (SAEs) through 12 months following the procedure, including any incidence of new or worsening major ipsilateral stroke as measured by the NIHSS, device-related SAE, target aneurysm rupture, and SAH.

**Statistical analysis**

Descriptive statistics were compiled for baseline variables, procedural characteristics, and endpoints. Continuous and ordinal variables are summarized as mean (SD), median, and IQR. Median and interquartile range are reported when distribution of a variable is visually skewed from normal distribution.
was reported by 17.2% (20/116) and 17.2% (20/116) of patients, respectively. A total of 113 patients (97.4%) had a baseline mRS score ≤2. Thirteen patients (11.2%) had experienced previous rupture of their target aneurysms, of whom 10 were treated with coiling only, while two were treated with balloon-assisted coiling. The other patient with a previously ruptured target aneurysm was untreated. The mean and median time from aneurysm rupture to stent placement was 800 and 189 days, respectively.

Target aneurysm characteristics are summarized in table 1.

### Table 1 Baseline characteristics of the ATLAS trial posterior circulation cohort

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Summary statistics (n=116)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>60.2±10.5</td>
</tr>
<tr>
<td>Female</td>
<td>81.0% (94)</td>
</tr>
<tr>
<td>White</td>
<td>91.4% (106)</td>
</tr>
<tr>
<td>Target aneurysm characteristics (site-reported)</td>
<td></td>
</tr>
<tr>
<td>Aneurysm neck width (mm)</td>
<td>4.7±1.7</td>
</tr>
<tr>
<td>Aneurysm size (mm)</td>
<td>7.1±3.0</td>
</tr>
<tr>
<td>Dome:neck ratio</td>
<td>1.2±0.3</td>
</tr>
<tr>
<td>Parent vessel diameter proximal to the aneurysm neck (mm)</td>
<td>2.9±0.6</td>
</tr>
<tr>
<td>Parent vessel diameter distal to the aneurysm neck (mm)</td>
<td>2.4±0.5</td>
</tr>
<tr>
<td>Target aneurysm location</td>
<td></td>
</tr>
<tr>
<td>Arising from the mid aspect of the PComA</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>Basilar apex</td>
<td>88 (75.9%)</td>
</tr>
<tr>
<td>Basilar trunk</td>
<td>7 (6.0%)</td>
</tr>
<tr>
<td>Superior cerebellar artery</td>
<td>5 (4.3%)</td>
</tr>
<tr>
<td>Posterior inferior cerebellar artery</td>
<td>5 (4.3%)</td>
</tr>
<tr>
<td>Vertebral artery</td>
<td>5 (4.3%)</td>
</tr>
<tr>
<td>Verteobasilar junction</td>
<td>2 (1.7%)</td>
</tr>
<tr>
<td>Other*</td>
<td>3 (2.6%)</td>
</tr>
</tbody>
</table>

Data are mean±SD, or n (%).

*Persistent trigeminal artery, fetal posterior cerebral artery, and posterior cerebral artery.

ATLAS, Assessment of Treatment with Lisinopril and Survival; PComA, posterior communicating artery.

Percentages and numerators, denominators are presented for categorical and binary variables.

The proportion of patients who met the primary endpoints were compared with performance goals using the one-sided Fisher’s exact test with a significance level of \( \alpha = 0.025 \). The performance goals were determined a priori based on a meta-analysis as well as regulatory and medical considerations. Analyses for posterior circulation cohorts were performed by constructing two-sided, 95% confidence intervals about the estimates of the percentage of patients with complete aneurysm occlusion and the percentage of patients experiencing a major ipsilateral stroke or neurological death using the exact binomial (Clopper-Pearson) method. Success in the posterior circulation cohort occurred when the lower bound of the efficacy endpoint was above 50% and the upper bound of the safety endpoint was below 25%. Missing values are imputed. All analyses were performed using SAS software, version 9.4 (SAS Institute Inc., Cary, North Carolina, USA).

### RESULTS

A total of 124 patients with posterior circulation IAs were initially enrolled across 25 US centers. The modified intention-to-treat cohort included 93.5% (116/124) after the exclusion of eight patients (online supplemental figure 1). Mean patient age was 60.2±10.5 years, 81.0% (94/116) were female, and 91.4% (106/116) were Caucasian (table 1). The most frequent comorbidities were hypertension (67.2%; 78/116) and hyperlipidemia (49.1%; 57/116). The majority of patients were either current smokers (40.5%; 47/116) or past smokers (38.8%; 45/116). A history of previous hemorrhagic stroke or multiple aneurysms was reported by 17.2% (20/116) and 17.2% (20/116) of patients, respectively. A total of 113 patients (97.4%) had a baseline mRS score ≤2. Thirteen patients (11.2%) had experienced previous rupture of their target aneurysms, of whom 10 were treated with coiling only, while two were treated with balloon-assisted coiling. The other patient with a previously ruptured target aneurysm was untreated. The mean and median time from aneurysm rupture to stent placement was 800 and 189 days, respectively.

Target aneurysm characteristics are summarized in table 1.

### Intraprocedural and postprocedural results

All procedures were technically successful (100.0%; 116/116). Patients were implanted with one (65.5%; 76/116) or two (34.5%; 40/116) Atlas stents. Multi-stent constructs were preplanned. Stents were implanted successfully in 94.5% (156/165) of attempts. Nine device failures occurred among five patients. All cases involved inadvertent deployment in the catheter hub (seven) or the feeling of excess friction as the stent was advanced in the microcatheter requiring removal of the catheter. None of these stents was actually deployed in a patient and all cases were successfully completed with additional devices. The median procedure duration first puncture to wound closure was 109.0 min (IQR 85.0–140.0). Immediately postprocedural, complete occlusion (RR I) was achieved in 77.6% (90/116) of patients, residual aneurysm neck filling (RR II) in 19.0% (22/116), and residual aneurysm dome filling (RR III) in 3.4% (4/116).

### Primary endpoints

Of the 116 patients who completed the 12-month follow-up, 95 patients had DSA results available (table 2). The primary efficacy endpoint was achieved in 76.7% (95% CI 67.0% to 86.5%) of patients (\( p<0.001 \) vs performance goal, missing values handled with multiple imputation). The rate of complete occlusion, according to the imaging core laboratory, was 85.3% (81/95, 95% CI 76.5% to 91.7%), while parent artery stenosis >50% occurred in 2.1% (2/95, 95% CI 0.3% to 7.4%) of patients. The rate of re-treatment was 7.8% (9/116, 95% CI 3.6% to 14.2%). Of the nine patients who underwent re-treatment, 2.6% (3/116) had complete occlusion postprocedure but recanalized, 0.9% (1/116) had preplanned staged procedures (achieved complete occlusion after stage 2 operation), 2.6% (3/116) had residual neck, and 1.7% (2/116) had residual aneurysm that persisted on follow-up imaging.

The incidence of the primary safety endpoint (major ipsilateral stroke and/or neurological death) for all 116 patients was 4.3% (5/116, 95% CI 1.4% to 9.8%, \( p<0.001 \); table 2). Major
ipsilateral stroke occurred in 3.4% (4/116, 95% CI 0.9% to 8.6%) of patients, while neurological death occurred in 0.9% (1/116, 95% CI 0.0% to 4.7%) of patients. This neurological death was the result of subdural hematoma and related severe pneumonia aspiration after experiencing a fall 75 days postprocedure. Of the five patients who experienced unfavorable primary safety outcomes, 1.7% (2/116) recovered with no residual deficit on subsequent follow-up.

Secondary efficacy endpoints
Secondary endpoints were evaluated at the 12-month follow-up DSA (table 3). The majority of the 95 patients with available DSA results had RR I occlusion of the target aneurysm at a rate of 85.3% (81/95, 95% CI 76.5% to 91.7%). The rate of RR II occlusion of the target aneurysm was 9.5% (9/95, 95% CI 4.4% to 17.2%), and for RR III was 5.3% (5/95, 95% CI 1.7% to 11.9%). Ninety of the 95 subjects had combined RR I and II (94.7%, 95% CI 88.1% to 98.3%).

Most patients had the same (71.6%; 68/95, 95% CI 61.4% to 80.4%) or improved (17.9%; 17/95, 95% CI 10.8% to 27.1%) occlusion status of their target aneurysms compared with immediate postprocedure RR scores. Only 10.5% (10/95, 95% CI 5.2% to 18.5%) of patients had worse occlusion status compared with immediate postprocedure RR scores. For clinical outcome at 12 months’ follow-up, 93.1% (95/102) of patients had an mRS score of 0–1, while 96.1% (98/102) had an mRS score of 0–2. There was no reported occurrence of stent migration (0.0%; 0/95, 95% CI 0.0% to 3.8%).

Secondary safety endpoints
According to CEC adjudication, four patients experienced new or worsening major ipsilateral stroke (table 4), and these four patients were the same subjects who experienced the primary safety endpoint of major ipsilateral stroke. Two patients experienced SAH: one patient experienced only SAH, while the other experienced both SAH and aneurysm rupture, although neither were related to stent placement. The patient who had both SAH and aneurysm rupture also had major ipsilateral stroke and was one of the patients who experienced the primary safety endpoint of major ipsilateral stroke. Clinically, the two patients who experienced either SAH alone or both SAH and aneurysm rupture returned for their 12-month visit and their mRS score was 0. All SAEs that were site-reported were classified as ‘possibly’, ‘probably’, or ‘related’ to the study device were classified as site-reported device-related SAEs. This included 12 SAEs in 11 subjects. For two subjects, the events were also CEC-adjudicated as primary safety endpoint events (ie, major ipsilateral stroke). Four of the 11 subjects experienced site-reported device-related SAEs that were CEC-adjudicated as minor ischemic strokes. All four subjects had excellent long-term outcomes with mRS scores of 0 and 1 and NIHSS scores of 0 at their 6- and 12-month follow-up visits. Five of the 11 subjects experienced site-reported device-related SAEs that were CEC-adjudicated as major ischemic strokes. Three of these patients had target aneurysm re-treatment based on asymptomatic recanalization detected on routine follow-up imaging. Two of the five subjects had transient ischemic attacks, which occurred on postoperative days 45 and 113, respectively.

### Table 3 Secondary efficacy endpoints at 12-month follow-up

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Summary statistics (n=116)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedural technical success (per patient)</td>
<td>116/116 (100.0%)</td>
<td></td>
</tr>
<tr>
<td>Subjects with one stent implanted</td>
<td>76/116 (65.5%)</td>
<td></td>
</tr>
<tr>
<td>Subjects with two stents implanted</td>
<td>40/116 (34.5%)</td>
<td></td>
</tr>
<tr>
<td>Raymond-Roy class (core laboratory)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>81/95 (85.3%)</td>
<td>(76.5% to 91.7%)</td>
</tr>
<tr>
<td>II</td>
<td>9/95 (9.5%)</td>
<td>(4.4% to 17.2%)</td>
</tr>
<tr>
<td>III</td>
<td>5/95 (5.3%)</td>
<td>(1.7% to 11.9%)</td>
</tr>
<tr>
<td>1 and 2 combined</td>
<td>90/95 (94.7%)</td>
<td>(88.1% to 98.3%)</td>
</tr>
<tr>
<td>Recanalization (1)</td>
<td>9/97 (9.3%)</td>
<td>(4.3% to 16.9%)</td>
</tr>
<tr>
<td>Any Raymond-Roy class change over time (core laboratory)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Same</td>
<td>68/95 (71.6%)</td>
<td>(61.4% to 80.4%)</td>
</tr>
<tr>
<td>Better</td>
<td>17/95 (17.9%)</td>
<td>(10.8% to 27.1%)</td>
</tr>
<tr>
<td>Worse</td>
<td>10/95 (10.5%)</td>
<td>(5.2% to 18.5%)</td>
</tr>
<tr>
<td>Parent artery stenosis &gt;50% (core laboratory)</td>
<td>2/95 (2.1%)</td>
<td>(0.3% to 7.4%)</td>
</tr>
<tr>
<td>Incidence of stent migration (core laboratory)</td>
<td>0/95 (0.0%)</td>
<td>(0.0% to 3.8%)</td>
</tr>
<tr>
<td>Incidence of re-treatment (site-reported)</td>
<td>9/116 (7.8%)</td>
<td>(3.6% to 14.2%)</td>
</tr>
</tbody>
</table>

Data are n (%).

*Recanalization is defined as Raymond score of 3 at 12 month visit or retreatment due to recanalization.

### Table 4 Secondary safety endpoints through 12-month follow-up

<table>
<thead>
<tr>
<th>Secondary safety endpoint</th>
<th>Summary statistics (n=116)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>New or worsening major ipsilateral stroke (CEC-adjudicated)</td>
<td>4 (3.4%)</td>
<td>(0.9% to 8.6%)</td>
</tr>
<tr>
<td>Subarachnoid hemorrhage (CEC-adjudicated)*</td>
<td>2 (1.7%)</td>
<td>(0.2% to 6.1%)</td>
</tr>
<tr>
<td>Aneurysm rupture (CEC-adjudicated)*</td>
<td>1 (0.9%)</td>
<td>(0.0% to 4.7%)</td>
</tr>
<tr>
<td>Device-related serious adverse event (site-reported)</td>
<td>11 (9.5%)</td>
<td>(4.8% to 16.3%)</td>
</tr>
</tbody>
</table>

Data are n (%).

*One subject experienced a serious adverse event (SAE) on postoperative day 1 that was site-reported as ‘vessel dissection related to subarachnoid hemorrhage (SAH)’ and possibly related to the device and was CEC-adjudicated as a major ipsilateral stroke, aneurysm rupture, and SAH. This single event is therefore captured in four separate secondary endpoint categories (ie, new or worsening ipsilateral stroke, SAH, aneurysm rupture, and device-related SAE).

C, Clinical Events Committee.

DISCUSSION
The ATLAS IDE study included a cohort of 116 patients with wide-necked IAs located in the posterior circulation, making it the largest study using Atlas stents for this particular cohort of patients. In this study, SAC using Atlas was associated with excellent technical success and safety profile rates. Atlas SAC embolization provided a high rate of 12-month complete occlusion without stenosis or re-treatment in the majority of patients, with low incidence of safety endpoints. Therefore, Atlas SAC embolization successfully met both the efficacy and safety endpoints of the trial, indicating that Atlas represents an efficacious and safe treatment option for SAC embolization of wide-necked IAs in the posterior cerebral circulation. Based on these results, the FDA awarded specific approval for use of Atlas stents in the posterior circulation on July 30, 2020, making it the only adjunctive stent in the USA that has shown safety and effectiveness in the posterior neurovasculature.

Several meta-analyses of patients with wide-necked aneurysms who underwent SAC treatment in the anterior or posterior circulation.
circulation have been published. The results of these studies suggest that stenting wide-necked aneurysms with earlier generation stents can result in RR I occlusion rates in the range of 69–73%, with mortality rates less than 2.5%. Recanalization rates ranged from 9% to 13%, and one analysis reported an aggregate re-treatment rate of 5.7%. The results of our study demonstrate that treatment of wide-necked aneurysms with the Atlas stent results in comparable or improved outcomes compared with earlier generation stents.

Few studies have assessed efficacy and safety outcomes specific to the Atlas stent in wide-necked IAs. A recent retrospective analysis of a prospectively maintained database of I13 patients with wide-necked IAs in the anterior and posterior circulation reported a technical success rate of 100%. Complete occlusion (RR I) was achieved in 88% and 82% of patients immediately postprocedure and at the 12-month follow-up, respectively. At the 6-month follow-up, 96.5% (109/113) of patients had an mRS score of 0–1, with a mortality rate of 2.7% (3/113) mostly due to SAH, and a morbidity rate of 0.85%. Another retrospective study of 37 patients at three centers using the Atlas stent also demonstrated a technical success rate of 100%. Complete occlusion (RR I) was achieved in 83.8% (31/37) and 80.8% (21/26) immediately postprocedure and at the 6-month follow-up, respectively, while neurological morbidity was reported in 2.7% (1/37) of patients at the 6-month follow-up.

The results of our study demonstrate that treatment of wide-necked aneurysms with the Neuroform Atlas results in comparable or complete occlusion of IAs at 12 months and the low rates of serious neurological events and mortality. Therefore, the Neuroform Atlas Stent System is an effective and safe treatment option for patients with wide-necked, posterior circulation IAs.

Author affiliations
1Cooper Neurological Institute, Cooper University Hospital, Camden, New Jersey, USA
2Barrow Neurological Institute, Phoenix, Arizona, USA
3Department of Neurosurgery, University of Pittsburgh Medical Center, Pittsburgh, PA, USA
4Department of Neurology, Cooper University Hospital, Camden, New Jersey, USA
5Department of Diagnostic Radiology, Riverside Radiology and Interventional Associates Inc, Columbus, Ohio, USA
6Department of Neurological Surgery, University of Kentucky, Lexington, Kentucky, USA
7Baptist Health System Jacksonville, Jacksonville, Florida, USA
8Lynx Neurosurgery, Baptist Neurological Institute, Jacksonville, Florida, USA
9Neurological Institute, Lerner Neurosurgery, Baptist Medical Center Jacksonville, Jacksonville, Florida, USA
10Department of Interventional Neuroradiology, Radiology Imaging Associates, Englewood, Colorado, USA
11Department of Radiology, University of Virginia Medical Center, Charlottesville, Virginia, USA
12Department of Radiology, University of Massachusetts, Worcester, Massachusetts, USA
13Department of Neurosurgery, Tufts Medical Center, Boston, Massachusetts, USA
14Department of Surgery, Division of Neurosurgery, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA
15Cerebrovascular Center, Cleveland Clinic, Cleveland, OH, USA
16Brain and Spine Institute, Advocate Aurora Health, Park Ridge, Illinois, USA
17Rush University, Chicago, Illinois, USA
18Semmes-Murphy Neurologic and Spine Institute, Memphis, Tennessee, USA
19Department of Neurosurgery, University of Tennessee Health Science Center, Memphis, Tennessee, USA
20Virginia Commonwealth University, Richmond, Virginia, USA
21Neuroscience Department, Mercy Health St Vincent Medical Center Department of Internal Medicine, Toledo, Ohio, USA
22Department of Neurosurgery, University at Buffalo, Buffalo, New York, USA
23Department of Neurosurgery, Cedars-Sinai Medical Center, Los Angeles, California, USA
24Department of Neurosurgery, WellStar Health System, Marietta, Georgia, USA
25Department of Neurosurgery, University of California Los Angeles, Los Angeles, California, USA
26Department of Neurosurgery, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA
27Department of Neurointerventional Surgery, CCHS, Newark, Delaware, USA
28Department of Neurointerventional Surgery, University of Tennessee Hartford Medical Center, Nashville, Tennessee, USA
29Department of Neurosurgery, Medical University of South Carolina, Charleston, South Carolina, USA
30Division of Interventional Neuroradiology, Houston Methodist Hospital, Houston, Texas, USA
31Department of Radiology, University of Washington, Seattle, Washington, USA
32Department of Neurosurgery, University of Pennsylvania, Philadelphia, Pennsylvania, USA
33Cerebrovascular Program, Vanderbilt University, Nashville, Tennessee, USA
34Department of Interventional Neurology, Lankenau Regional Medical Center and Heart Institute, Fort Pierce, Florida, USA
35Department of Neurosurgery, Baylor College of Medicine, Houston, Texas, USA
36Department of Radiology, UCSF, San Francisco, California, USA
37Department of Neurosurgery, St Vincent Mercy Hospital, Toledo, Ohio, USA

Twitter Amin Aghaebrahim @danimajax, Donald Frei @donfreiml, Gabor Toth @GaborTothMD, Demetrius Kleo Lopes @cure4stroke, Adam S Arthur @AdamArthurMD and Peter Kan @PeterKas8460001

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Contributors All authors made substantial contributions to the conception and design, analysis, and interpretation of data; drafted or critically revised the article; and gave final approval of the version to be published.

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Competing interests BTJ: consultant for Stryker and a consultant/proctor for
Hemorrhagic stroke

Medtronic. OZQ: research grant from Stryker, Medtronic, Cerenovus, Penumbra, and Genentech; consultant and speaker for Stryker, Medtronic, and Penumbra; and Medtronic; has ownership interest in Galaxy Therapeutics; and serves on the endovascular committee as co-chair for National Institutes of Health StrokeNet Consortium and has served as an expert witness. SWH: Core Laboratory Services for Medtronic and MicroVention Terumo (money paid to SWH, under $5k); serves on the MicroVention Terumo and Medtronic scientific advisory boards; consultant for Medtronic, Penumbra, Stream Biomedical. RAH: research grant: Medtronic, Stryker, Microvention, Penumbra; consultancies with Medtronic, Penumbra, Stream Biomedical. References cited: Medtronic, Stryker, Microvention, Penumbra; and Medtronic; has ownership interest in Galaxy Therapeutics; and serves on the endovascular committee as co-chair for National Institutes of Health StrokeNet Consortium and has served as an expert witness. SWH: Core Laboratory Services for Medtronic and MicroVention Terumo (money paid to SWH, under $5k); serves on the MicroVention Terumo and Medtronic scientific advisory boards; consultant for Medtronic, Penumbra, Stream Biomedical. RAH: research grant: Medtronic, Stryker, Microvention, Penumbra; consultancies with Medtronic, Penumbra, Stream Biomedical.

REFERENCES


Adel M Malek http://orcid.org/0000-0002-0642-7609
Ajit Thomas http://orcid.org/0000-0004-4142-3152
Gabor Toth http://orcid.org/0000-0002-3664-3635
Demetrios Klee Lopes http://orcid.org/0000-0002-6280-0113
Adam S Arthur http://orcid.org/0000-0002-1536-1613
Michael J Alexander http://orcid.org/0000-0002-8080-809X
Geoffrey P Colby http://orcid.org/0000-0002-3376-0933
Justin F Fraser http://orcid.org/0000-0002-6280-0113


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