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Original research

Post-approval study 3-year outcomes of the Neuroform Atlas stent for the treatment of wide-necked intracranial aneurysms

Brian Jankowitz ,[1] Ashutosh P Jadhav,[2] Bradley Gross ,[3] Tudor G Jovin,[4] Abdulnasser A Alhajeri,[5] Justin F Fraser ,[6] Ricardo A Hanel,[7] Eric Sauvageau ,[7] Amin Aghaebrahim,[7] Donald Frei ,[8] Richard Bellon,[8] David N Loy,[9] Ajit S Puri,[10] Adel M Malek,[11] Ajith J Thomas,[4] Gabor Toth ,[12] Demetrius Klee Lopes ,[13] R Webster Crowley,[14] John Reavey-Cantwell ,[15] Eugene Lin,[16] Adnan Siddiqui,[17] Michael J Alexander ,[18] Ahmad Khaldi ,[19] Geoffrey P Colby,[20] Justin M Caplan ,[21] Sudhakar R Satti,[22] Aquilla S Turk,[23] Alejandro M Spiotta ,[24] Richard Klucznik,[25] Danial K Hallam,[26] David Kung,[27] Michael T Froehler,[28] R Charles Callison,[29] Peter Kan ,[30] Steven W Hetts ,[31] Lori Lyn Price,[32] Osama O Zaidat ,[33] on behalf of the ATLAS Investigators

► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/jnis-2025-024547).

For numbered affiliations see end of article.

Correspondence to
Dr Brian Jankowitz;
Bjankowitz@gmail.com

Received 22 October 2025
Accepted 30 December 2025

Check for updates

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To cite: Jankowitz B, Jadhav AP, Gross B, *et al*. *J NeuroIntervent Surg* Epub ahead of print: [*please include* Day Month Year]. doi:10.1136/jnis-2025-024547

ABSTRACT

Introduction The ATLAS trial was a prospective, multicenter, single-arm, investigational device exemption (IDE) study to evaluate the safety and effectiveness of the Neuroform Atlas Stent System for the treatment of wide-necked bifurcation aneurysms. This analysis presents the 36-month follow-up data for the anterior and posterior cohorts.

Methods Of the 182 patients in the IDE anterior cohort, 146 consented to participate in the post-approval study (PAS) and, of the 116 patients in the IDE posterior cohort, 101 consented to participate in the PAS. The primary effectiveness endpoint was core laboratory adjudicated (Raymond–Roy 1; RR1) without retreatment or parent artery stenosis (>50%) at 36 months post-procedure. The primary safety endpoint was Clinical Event Committee-adjudicated major ipsilateral stroke or neurological death through 36 months.

Results There were 146 patients in the anterior cohort and 101 patients in the posterior cohort. At 24 months the composite effectiveness endpoint was 77.3% (34/44) in the anterior cohort and 65.5% (19/29) in the posterior cohort and at 36 months these rates were 92.3% (24/26) and 75.0% (18/24), respectively. RR1 rates at 24 months were 84.1% (37/44) in the anterior cohort and 70.0% (21/30) in the posterior cohort; at 36 months they were 96.3% (26/27) and 79.2% (19/24), respectively. By 36 months the primary safety endpoint occurred in 4.1% (6/146) of patients in the anterior cohort and 5.0% (5/101) in the posterior cohort.

Conclusion The results of the long-term assessment of the Neuroform Atlas Stent System demonstrate favorable safety and effectiveness in the treatment of wide-necked bifurcation aneurysms without a single treated target aneurysm rupture beyond 12 months post-procedure.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ One-year outcomes for the ATLAS trial supported high occlusion rates and favorable safety outcomes for the treatment of wide-necked bifurcation aneurysms.

WHAT THIS STUDY ADDS

⇒ We present the 3-year post-approval study safety and efficacy outcomes of patients treated with the Neuroform Atlas Stent System and demonstrate high rates of aneurysm occlusion and low rates of delayed adverse events, with no delayed target aneurysm ruptures.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE, OR POLICY

⇒ This study supports the continued use of the Neuroform Atlas Stent System in clinical practice for the treatment of wide-necked bifurcation aneurysms.

INTRODUCTION

Unruptured intracranial aneurysms occur in approximately 2–4% of the general population.[1] Stent-assisted coiling (SAC) has transformed the endovascular approach to managing large wide-necked aneurysms that previously posed challenges for conventional endovascular techniques,[2] with higher occlusion and lower recanalization rates than coiling-alone strategies.[3] A prior meta-analysis of 2698 aneurysms treated with SAC reported pooled immediate and follow-up occlusion rates of 57.7% and 87.6%, respectively.[4] Nonetheless, high recanalization rates and thromboembolic complications remained important limitations.[5] The Neuroform Atlas Stent System (Stryker Neurovascular, Fremont, California, USA) received premarket

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approval for the anterior cohort in 2019 and remains a market-leading adjunctive intracranial stent in the neurointerventional armamentarium (Stryker, data on file, 2024), allowing a lower profile delivery (via 0.0165 inch inner diameter microcatheter vs 0.027 inch inner diameter microcatheter).[6] In conjunction with neurovascular embolization coils, the device was designed to treat wide-necked aneurysms (ie, neck diameter ≥4.0 mm or dome-to-neck ratio <2.0), known to pose significant challenges to endovascular treatment modalities. Subsequently, the ATLAS Investigational Device Exemption (IDE) pivotal trial reported the 1-year results of a prospective two-cohort (ie, anterior and posterior circulation aneurysms) single-arm study of patients with wide-necked intracranial saccular aneurysms treated with the Neuroform Atlas stent across 25 US cerebrovascular centers.[7 8] Multiple post-market reports have documented the safety and efficacy of the Atlas stent with excellent efficacy and safety profiles;[9–11] however, long-term data with the device remain lacking. In this study we report the 3-year results of the safety and effectiveness of the ATLAS post-approval study (PAS) data in the anterior and posterior circulation cohorts.

METHODS

Study design

The detailed protocol of the study has been previously published.[6–8] Briefly, the ATLAS IDE pivotal trial was a prospective, two-cohort, single-arm study of patients with wide-necked intracranial saccular anterior and posterior circulation aneurysms treated with the Neuroform Atlas stent across 25 sites in the USA. This present PAS follow-up investigation was conducted to meet FDA approval requirements aimed at confirming the long-term safety and effectiveness of the Neuroform Atlas Stent System up to 36 months (±6 months) post-procedure. Not all patients from the IDE originally consented to long-term follow-up, thus limiting patient retention. Of the 182 patients originally enrolled in the anterior cohort in the IDE study, 146 consented to participate in the PAS while, of the 116 patients in the posterior cohort IDE study, 101 consented to participate in the PAS. Some patients were enrolled in the PAS between 43 and 60 months post-index procedure. The trial was registered on clinicaltrials.gov (NCT02340585).

Patient enrollment

As previously described, patients were included if they met the following criteria: (1) age 18–80 years; (2) a documented wide-necked (defined as neck ≥4 mm or dome-to-neck ratio <2) intracranial saccular aneurysm with a parent vessel diameter of 2–4.5 mm in the anterior circulation (excluding the petrous internal carotid artery (ICA) to the superior hypophyseal ICA region) or in the posterior circulation. The following exclusion criteria were applied: (1) multiple untreated intracranial aneurysms; (2) previous SAC treatment; (3) acutely ruptured aneurysm <14 days before enrollment; (4) modified Rankin Scale (mRS) score ≥4 or Hunt and Hess scale score ≥3; (5) intracranial mass or vascular malformation; (6) significant atherosclerotic stenosis, Moyamoya disease, or any absolute contraindication to angiography/antiplatelets.

Procedure description

The details of the procedure have been described in earlier publications.[6–8] Briefly, all patients were recommended (but not mandated) to be premedicated with dual antiplatelet therapy (DAPT) (aspirin/clopidogrel) for a minimum of 5 days, and DAPT maintenance of at least 3 months post-procedurally was recommended. The access was according to the operators' discretion, and anticoagulation was maintained intraprocedurally in accordance with each study's site protocol. The microcatheters used for the Atlas stent deployment were either the Excelsior SL-10 or XT-17 (Stryker Neurovascular, Fremont, California, USA).

Clinical and radiographic follow-up

The long-term follow-up outcomes for the pre-specified primary effectiveness and safety endpoints were collected according to the institutional standard of care and treating physician discretion using all available imaging including DSA, MRA, CTA, or other methods as appropriate at 24±6 months and 36±6 months after the index procedure. There were patients who consented to participate after the 36-month visit and, in these instances, post 36-month data were collected. The decision for imaging was performed by each provider's standard of care.

Definition of primary study outcomes

Efficacy

The outcome was to evaluate the long-term effectiveness and durability of the treated aneurysm from 12 months through 36 months after the index treatment procedure. The composite effectiveness measure was defined as complete aneurysm occlusion (Raymond–Roy (RR) Class 1) without significant parent artery stenosis at the target aneurysm location (>50% stenosis) or retreatment (cumulative from implant/procedure). Adequate occlusion was defined as RR 1 or 2.

Safety

The primary safety endpoint was the rate of major ipsilateral stroke or neurological death from the index procedure through long-term study follow-up. A major ipsilateral stroke was defined as an increase of ≥4 points on the National Institute of Health Stroke Scale (NIHSS) assessment lasting >24 hours after symptom onset. These primary endpoint events were prespecified prior to enrollment and were reviewed by an independent Clinical Event Committee. These endpoints are cumulative from index procedure through long-term follow-up.

Secondary study outcomes

Efficacy

Secondary endpoints included rates of aneurysm retreatment (cumulative from the index procedure) and occlusion, including adequate occlusion (RR1 or RR2), along with significant parent artery stenosis.

Safety

The secondary safety endpoint involved determining the percentage of patients who experienced one or more serious adverse events (SAEs), device-related adverse effects, incidence of subarachnoid hemorrhage, and target aneurysm rupture. These endpoints are cumulative from the index procedure through long-term follow-up unless otherwise indicated.

Statistical analysis

Summary descriptive statistics are presented. No statistical hypotheses tests were performed. SAS 9.4 (Cary, North Carolina, USA) was used for all analyses.

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Table 1 Demographic data and patient characteristics

	Anterior PAS mITT (n=146)	Posterior PAS mITT (n=101)
Demographics		
Age (years), mean±SD (n)	59.7±11.5 (146)	60.3±10.5 (101)
Female, % (n/N)	74.0% (108/146)	81.2% (82/101)
Aneurysm characteristics		
Aneurysm size (mm), mean±SD (n)	6.1±2.4 (146)	7.0±2.7 (101)
Dome/neck ratio, mean±SD (n)	1.2±0.3 (146)	1.2±0.4 (101)
Previous target aneurysm rupture, % (n/N)	11.6% (17/146)	11.9% (12/101)
Medical history, % (n/N)		
Hyperlipidemia/hypercholesterolemia	51.8% (74/143)	50.5% (50/99)
Hypertension	69.9% (102/146)	64.4% (65/101)
Previous hemorrhagic stroke	15.1% (22/146)	16.8% (17/101)
Other non-target infundibulum or <3 mm aneurysms	11.6% (17/146)	19.8% (20/101)
Smoking status		
Current/past	68.5% (100/146)	78.2% (79/101)
Never	31.5% (46/146)	21.8% (22/101)

mITT, modified intention-to-treat; PAS, post-approval study.

RESULTS

Anterior cohort

Demographics and patient characteristics

Of the initial 182 patients, a total of 146 (mean age 59.7 ± 11.5 years; 74.0% (108/146) females) were assessable for the composite safety analysis. Of these, 44 and 26 patients were assessable for the 24-month and 36-month composite effectiveness analysis, respectively, due to the disparity between clinical follow-up and those who received radiographic follow-up. The mean±SD aneurysm size was 6.1±2.4 mm, with a mean±SD dome-to-neck ratio of 1.2±0.3, and 11.6% (17/146) of patients had multiple non-target aneurysms (ie, <3 mm aneurysms or infundibula). Previous target aneurysmal rupture (prior to index treatment) was documented in 11.6% (17/146) of patients. Hypertension was the most common comorbidity (69.9%, 102/146), followed by hyperlipidemia (51.8%, 74/143). A previous history of hemorrhagic stroke was noted in 15.1% (22/146) of patients, and 68.5% (100/146) of patients had a positive smoking history (ie, current or past smokers). In the PAS anterior cohort, 20/146 patients were treated with the Y-stenting configuration. Demographic data are summarized in table 1.

Efficacy

Table 2 shows the effectiveness and safety data for the anterior cohort. The composite effectiveness endpoint was 77.3% (34/44) at 24 months and 92.3% (24/26) at 36 months. At 24 months, 84.1% (37/44) of patients had complete occlusion (RR1), with 97.7% (43/44) having adequate occlusion (RR1 or RR2). At 36 months, 96.3% (26/27) of patients had RR1 occlusion scores, with an adequate occlusion of 100.0% (27/27). For patients with both 12-month and 36-month occlusion status available, 100% (26/26) of patients remained stable or improved with no retreatment.

Table 2 Effectiveness and safety endpoints for the anterior circulation cohort

	12-month (±2 months) visit % (n/N)	24-month (±6 months) visit % (n/N)	36-month (±6 months) visit % (n/N)	Post 36 months (43–60 months) % (n/N)
Effectiveness				
RR1 in the absence of retreatment or parent artery stenosis (>50%) at target aneurysm	84.4% (108/128)	77.3% (34/44)	92.3% (24/26)	80.8% (21/26)
RR class				
1	87.3% (110/126)	84.1% (37/44)	96.3% (26/27)	89.3% (25/28)
2	8.7% (11/126)	13.6% (6/44)	3.7% (1/27)	7.1% (2/28)
3	4.0% (5/126)	2.3% (1/44)	0.0% (0/27)	3.6% (1/28)
1 and 2	96.0% (121/126)	97.7% (43/44)	100.0% (27/27)	96.4% (27/28)
Any RR progression (compared with 12-month visit)				
Better	N/A	10.3% (4/39)	3.9% (1/26)	3.9% (1/26)
Same	N/A	82.1% (32/39)	96.2% (25/26)	92.3% (24/26)
Worse	N/A	7.7% (3/39)	0.0% (0/26)	3.9% (1/26)
Retreatment†	4.8% (7/146)	4.8% (7/146)*	4.8% (7/146)*	5.5% (8/146)*
Parent artery stenosis >50%	0.0% (0/126)	4.7% (2/43)	3.9% (1/26)	4.0% (1/25)
Safety				
Primary safety outcome†	4.1% (6/146)	4.1% (6/146)‡	4.1% (6/146)‡	4.8% (7/146)‡
Neurological death†	0.0% (0/146)	0.0% (0/146)	0.0% (0/146)	0.0% (0/146)
New or worsening major ipsilateral stroke†	4.1% (6/146)	4.1% (6/146)‡	4.1% (6/146)‡	4.8% (7/146)‡

*One patient had retreatment prior to the 12-month visit and a second retreatment between the 12-month and 24-month visits. As this is patient level data, the number of patients with events does not increase.
†Cumulative from index procedure.
‡One patient had an ipsilateral stroke prior to the 12-month visit and another ipsilateral stroke between the 12-month and 24-month visits. As this is patient level data, the number of patients with events does not increase.
RR, Raymond–Roy.

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Retreatment

The overall retreatment rate for patients was 5.5% (8/146). Seven patients experienced retreatment prior to their 12-month visit and one patient was retreated again after the 12-month visit, for a total of eight retreatments in seven patients.

Safety

The cumulative safety endpoint at 36 months was 4.1% (6/146), with one patient experiencing the safety endpoint after 12 months in the anterior cohort. This patient also experienced the primary safety event prior to 12 months. There were no neurological deaths reported from the index procedure through the PAS period.

During the PAS period, 5.5% (8/146) of patients experienced any ischemic or hemorrhagic adverse events. There was one hemorrhagic stroke, six ischemic strokes, and five transient ischemic attacks (TIAs) during this period. There were no aneurysm ruptures. All TIAs resolved with no patients experiencing residual effects. The rate of patients with site-reported device-related SAEs was 2.7% (4/146) during the PAS period, with five events in four patients. These events consisted of three TIAs, one major ipsilateral stroke, and one minor ipsilateral stroke and were adjudicated as being related to the Neuroform Atlas stent device. All events resolved with no patients experiencing residual sequelae.

Posterior cohort

Demographics and patient characteristics

Of the initial 116 patients, 101 patients (mean age 60.3±10.5 years; 81.2% (82/101) females) were assessable for the composite safety analysis. Of these, 29 and 24 patients were assessable for the 24-month and 36-month composite effectiveness analysis, respectively, due to the disparity between clinical follow-up and those who received radiographic follow-up. Of the 101 patients, 19.8% had non-target additional aneurysms, with a target aneurysm mean±SD diameter of 7.0±2.7 mm and mean±SD dome to neck ratio of 1.2±0.4. Prior target aneurysmal rupture (prior to index treatment) was documented in 11.9% (12/101) of patients. Similar to the anterior cohort, hypertension and hyperlipidemia were the most common comorbidities (64.4% (65/101) and 50.5% (50/99), respectively). Positive smoking history was noted in 78.2% (79/101) of patients, and prior hemorrhagic stroke history was seen in 16.8% (17/101) of patients. In the posterior PAS cohort, 30/101 patients were treated with the Y-stenting configuration.

Efficacy

Table 3 describes the effectiveness and safety data for the posterior cohort. The composite effectiveness endpoint was achieved in 65.5% of patients (19/29) at 24 months and 75.0% (18/24) of patients at 36 months. At 24 months, 70.0% (21/30) of patients had RR1 occlusion status, with 90.0% (27/30) of patients achieving adequate occlusion. At 36 months, 79.2% (19/24) of patients had RR1 occlusion, with an adequate occlusion rate of 87.5% (21/24). The difference in denominators between the composite endpoint and adequate occlusion is due to retreatment or to missing data for either RR scores or stenosis. In comparison with their-12 month occlusion status, 81.8% (18/22) of patients remained stable with no change, 4.6% (1/22) got better, and 13.6% (3/22) worsened from 12 months to 36 months.

Retreatment

The overall retreatment rate for patients was 8.9% (9/101). Seven patients experienced retreatment prior to the 12-month visit and an additional two patients were retreated after the 12-month visit. One of these patients whose occlusion status

Table 3 Effectiveness and safety endpoints for the posterior circulation cohort

	12-month (±2 months) visit % (n/N)	24-month (±6 months) visit % (n/N)	36-month (±6 months) visit % (n/N)	Post 36 months (43–60 months) % (n/N)
Effectiveness				
RR1 in the absence of retreatment or parent artery stenosis (>50%) at target aneurysm	78.7% (70/89)	65.5% (19/29)	75.0% (18/24)	71.4% (10/14)
RR class				
1	86.1% (74/86)	70.0% (21/30)	79.2% (19/24)	64.7% (11/17)
2	9.3% (8/86)	20.0% (6/30)	8.3% (2/24)	29.4% (5/17)
3	4.7% (4/86)	10.0% (3/30)	12.5% (3/24)	5.9% (1/17)
1 and 2	95.3% (82/86)	90.0% (27/30)	87.5% (21/24)	94.1% (16/17)
Retreatment*	6.9% (7/101)	7.9% (8/101)	8.9% (9/101)	8.9% (9/101)
Parent artery stenosis >50%	2.3% (2/86)	0.0% (0/30)	3.6% (1/28)	0.0% (0/15)
Any RR progression (compared with 12-month visit)				
Better	N/A	0.0% (0/25)	4.6% (1/22)	11.8% (2/17)
Same	N/A	84.0% (21/25)	81.8% (18/22)	58.8% (10/17)
Worse	N/A	16.0% (4/25)	13.6% (3/22)	29.4% (5/17)
Safety				
Primary safety outcome*	4.0% (4/101)	5.0% (5/101)	5.0% (5/101)	5.0% (5/101)
Neurological death*	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)
New or worsening major ipsilateral stroke*	4.0% (4/101)	5.0% (5/101)	5.0% (5/101)	5.0% (5/101)

*Cumulative from index procedure.
RR, Raymond–Roy.

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worsened compared with their 12-month visit was retreated between 24 and 36 months without complication, for a total of nine retreatments in nine patients.

Safety

The primary safety endpoint occurred in 5.0% (5/101) of patients. New or major worsening ipsilateral stroke occurred in four patients within 30 days of the index procedure and in one additional patient after the 12-month visit. There were no reported neurological deaths from the index procedure through the last follow-up visit.

During the PAS period, 5.0% (5/101) of patients experienced any ischemic or hemorrhagic adverse events. There were two ischemic strokes, three hemorrhagic strokes, two subarachnoid hemorrhages, and five TIAs during this period. All TIAs resolved with no patients experiencing residual effects. The rate of patients with site-reported device-related SAEs was 2.0% (2/101) during the PAS period. One patient had a site-reported residual aneurysm filling at the 12-month visit. This patient was successfully retreated with no complications. This event was adjudicated as related to the procedure and concomitant medications, unrelated to the Neuroform Atlas device. A second patient experienced a minor ipsilateral ischemic stroke adjudicated as related to the Neuroform Atlas stent and concomitant medications, which was resolved without sequelae.

One rupture was observed prior to the end of the 12-month window. However, this was during treatment of a non-target de novo right pericallosal artery aneurysm during coil deployment. The patient had an NIHSS score of 0 and a mRS score of 0 at the 24-month follow-up visit.

DISCUSSION

There are limited data reporting on the long-term safety and effectiveness of the Neuroform Atlas Stent System. Gross *et al*[12] compared outcomes between 37 patients treated with the Neuroform Atlas versus 27 cases treated with the LVIS Jr, controlling for potential confounders. Higher immediate occlusion was noted with the Neuroform Atlas stent (57% vs 41%), which persisted on last follow-up (12.7 months; 100% vs 81%, respectively).[12] Additionally, patients treated with the Neuroform Atlas stent had a significantly lower in-stent stenosis rate but similar retreatment and complication rates.[12] Another recent publication provided a comparative analysis of the three recently introduced devices to the US market for wide-necked aneurysms (Neuroform Atlas stent, Woven Endobridge (WEB), and low profile visualized intraluminal stent (LVIS)) using prospective data from pivotal trials of the three devices.[7 8 13–15] This manuscript compared the patients in the ATLAS trial with patients treated with the WEB-IT and LVIS devices who met the inclusion criteria for each corresponding device trial. When comparing results from each of the respective pivotal clinical trials, there were no significant differences in primary effectiveness between the ATLAS and LVIS cohorts. However, patients treated with the Neuroform Atlas stent had higher rates of complete occlusion (88.1% vs 79.1%, P=0.03) compared with patients treated with the WEB-IT device, and ATLAS patients also had a significantly higher primary effectiveness rate (86.6% vs 53.9%, P<0.0001) as well as higher rates of complete occlusion (90.3% vs 53.9%, P<0.0001).[13]

Retreatment also requires careful thought. While the incidence is highly subjective and dependent on location, the rate is likely comparable between all manner of intrasaccular treatments and lower for flow diversion. However, the complexity of retreatment should be considered as intrasaccular recurrences often require a more nuanced approach—namely, for intrasaccular aneurysms the recurrences are often shallow and lentiform in shape, disabling simple recoiling, while the location at bifurcations often dissuades flow diversion. Retreatment may also be complicated by challenging stent configurations such as Y- and X-stenting, of which there were 50 Y-stenting configurations of the Neuroform Atlas in the PAS patient cohort. Of note, none of the patients with a Y-stenting configuration experienced retreatment during the PAS period. All retreatments in this series employed simple recoiling, in contrast to the study by Srinivasan *et al* which highlighted the need for multimodality retreatment in 8.8% of 342 WEB-treated aneurysms.[16] In fact, SAC was the predominant mechanism used, followed by flow diversion and open surgery.

The safety analysis of patients treated with the Neuroform Atlas Stent System suggests that its use for the treatment of wide-necked intracranial aneurysms is safe. There was not a single delayed target aneurysm rupture during the PAS period. Use of the device was further associated with favorable safety, as evidenced by the low rate of the cumulative safety endpoints occurring in 4.1% (6/146) of patients in the anterior cohort and 5.0% (5/101) in the posterior cohort.

Study limitations

We acknowledge several limitations to this study. The main limitation of the ATLAS trial was the single-arm nature, with the lack of direct comparison to other aneurysm treatment techniques. A limitation of the long-term PAS was the number of patients lost to follow-up beyond 12 months post-procedure. The Neuroform Atlas stent received premarket approval in 2019, following the submission of the 12-month IDE trial data, with the condition that long-term 36-month clinical follow-up of patients would take place to assess its continued safety and effectiveness. However, the requirement of follow-up beyond 12 months was not initially required by the FDA, thus requiring many sites to re-enroll patients. As one can imagine, many patients, particularly those who are doing well or were told their aneurysm was cured at 12 months, had little interest in maintaining a strict follow-up regimen. Long-term follow-up was also hindered due to the COVID-19 pandemic, which coincided with >50% of scheduled long-term follow-up visits. While every attempt was made to bring patients back for clinical and angiographic follow-up, >50% refused or did not respond to repeated attempts at communication. Thus, the reported 24-month and 36-month occlusion rates are likely underestimates due to potential selection bias, as the imaged aneurysms may have been the 'high-risk' ones as deemed per the clinical team's judgment or by invested patients who knew their aneurysm was still filling at the 12-month follow-up. In an effort to address potential selection bias of the patients who were included in the PAS, we analyzed the 12-month angiographic outcomes of patients who consented versus patients who did not consent to the PAS in both the anterior and posterior cohorts and determined that the difference in the composite effectiveness endpoint was not statistically significant (data not shown).

CONCLUSION

The ATLAS PAS 3-year follow-up results demonstrate favorable long-term safety and effectiveness, without a single treated target aneurysm rupture beyond 12 months post-procedure.

Author affiliations
[1]Department of Neurosurgery, JFK Health System, Edison, New Jersey, USA
[2]Department of Neurosurgery, Barrow Neurological Institute, Phoenix, Arizona, USA

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[3]Department of Neurosurgery, University of Pittsburgh, Pittsburgh, Pennsylvania, USA
[4]Department of Neurology, Cooper University Hospital, Camden, New Jersey, USA
[5]Department of Diagnostic Radiology, Riverside Radiology and Interventional Associates Inc, Columbus, Ohio, USA
[6]Department of Neurological Surgery, University of Kentucky, Lexington, Kentucky, USA
[7]Lyerly Neurosurgery, Baptist Neurological Institute, Jacksonville, Florida, USA
[8]Department of Interventional Neuroradiology, Radiology Imaging Associates, Englewood, Colorado, USA
[9]Department of Radiology and Medical Imaging, University of Virginia, Charlottesville, Virginia, USA
[10]Department of Radiology, University of Massachusetts, Worcester, Massachusetts, USA
[11]Department of Neurosurgery, Tufts Medical Center, Boston, Massachusetts, USA
[12]Cerebrovascular Center, CCF, Cleveland Heights, Ohio, USA
[13]Department of Neurosurgery, Advocate Health, Chicago, Illinois, USA
[14]Department of Neurosurgery, Rush University, Chicago, Illinois, USA
[15]Department of Neurosurgery, Virginia Commonwealth University, Richmond, Virginia, USA
[16]Neuroscience Department, Bon Secours Mercy Health St. Vincent Medical Center, Toledo, Ohio, USA
[17]Department of Neurosurgery, University at Buffalo, Buffalo, New York, USA
[18]Department of Neurosurgery, Cedars-Sinai Medical Center, Los Angeles, California, USA
[19]Department of Neurosurgery, Wellstar Health System, Marietta, Georgia, USA
[20]Department of Neurosurgery, University of California Los Angeles, Los Angeles, California, USA
[21]Department of Neurosurgery, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA
[22]Department of Neurointerventional Surgery, CCHS, Newark, Delaware, USA
[23]Department of Neurosurgery, Prisma Health, Greenville, South Carolina, USA
[24]Department of Neurosurgery, Medical University of South Carolina, Charleston, South Carolina, USA
[25]Division of Interventional Neuroradiology, Methodist Hospital System, Houston, Texas, USA
[26]Department of Radiology, University of Washington, Seattle, Washington, USA
[27]Division of Neurosurgery, Dartmouth Hitchcock Medical Center, Lebanon, New Hampshire, USA
[28]Cerebrovascular Program, Vanderbilt University Medical Center, Nashville, Tennessee, USA
[29]Department of Interventional Neurology, Lawnwood Regional Medical Center and Heart Institute, Fort Pierce, Florida, USA
[30]Department of Neurosurgery, The University of Texas Medical Branch at Galveston, Galveston, Texas, USA
[31]Department of Radiology, UCSF, San Francisco, California, USA
[32]Clinical Affairs, Stryker Neurovascular, Fremont, California, USA
[33]Department of Neuroscience, St Vincent Mercy Hospital, Toledo, Ohio, USA

Acknowledgements The authors would like to acknowledge the programming support provided by Cody Sprague and technical writing support provided by Jonathan Larochelle, both of Stryker Neurovascular.

Collaborators A list of all ATLAS Investigators is provided in the Supplemental Material

Contributors BJ drafted the initial manuscript. All authors were involved and made substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of the data; revising it critically for important intellectual content; final approval of the version published; and 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. LLP analyzed the data. BJ is responsible for the overall work as the guarantor.

Funding The ATLAS trial (Safety and Effectiveness of the Treatment of Wide Neck, Saccular Intracranial Aneurysms with the Neuroform Atlas Stent System) was sponsored and funded by Stryker Neurovascular. Editorial assistance in formatting, proofreading, copyediting, and fact checking was provided by Stryker Neurovascular. Author LLP from Stryker Neurovascular analyzed the data, reviewed, and edited the manuscript for scientific accuracy.

Competing interests BJ serves as a consultant to Stryker and a consultant/proctor to Medtronic. APJ reports stock options in Gravity Medical Technology, a patent issued for a Novel Stent Retriever device licensed to Basking Biosciences, compensation from Basking Biosciences for consultant services, and employment by BarrowBrain and Spine. BG reports compensation from Terumo Neuro, Stryker, and Medtronic for consultant services. TGJ is an advisor and holds stock for Anaconda, Route 92, Viz.ai, FreeOx, Methinks, Galaxy, AptaTargets, Kandu, Gravity, Luminopia, Carlsmed, StataDx, Vastrax, and Let's Get Proof. He serves in an advisory capacity for Cerenovus and Contego Medical and he receives research support from the National Institutes of Health, Patient-Centered Outcomes Research Institute, Medtronic, and Stryker. AAA reports no disclosures. JFF receives grants from the National Institute of Health, the University of Kentucky, the American Heart Association, and Viz.ai in addition to consultant services for Medtronic, Penumbra, and Stream Biomedical. He is an equity owner for Fawkes Biotechnology, Let's Get Proof, and Cerelux. He serves on the DSMB for Imperative Care, and receives grants from the National Institute of Health, the University of Kentucky, the American Heart Association, and Viz.ai in addition to consultant services for Medtronic, Penumbra, and Stream Biomedical. He also participates on a Data Safety Monitoring Board or Advisory Board for Imperative Care, serves as Treasurer for the Society of NeuroInterventional Surgery, Member-at-Large for AANS/CNS Cerebrovascular Section, and is an Associate Editor for the Journal of Neurosurgery. He also has stock or stock options in Fawkes Biotechnology and Let's Get Proof. RAH received research grants from NIH, Interline Endowment, Terumo Neuro, Stryker, and CNX, and consulting fees from Balt, Cerenovus, Medtronic, Terumo Neuro, Rapid Medical, Phenox, Q'Apel, and Stryker. He is part of the Advisory Board of MiVI, eLum, Three Rivers, Shape Medical, and Corindus, and is a stockholder from InNeuroCO, Cerebrotech, eLum, Endostream, Three Rivers, Medical Inc, Scentia, Rist, Blink TBI, Rist, NTI, and Corindus. ES reports no disclosures. AA reports no disclosures. DF has received research grants from Cerenovus, Medtronic, Penumbra, Terumo Neuro, and Stryker; is a consultant for Genentech, Penumbra, and Stryker, and is a shareholder in Penumbra. RB reports no disclosures. DNL reports no disclosures. ASP has received grants/contracts from the NIH, Terumo Neuro, Cerenovus, Medtronic, and Stryker and consulting fees from Medtronic, Stryker, Q'Apel Medical, Cerenovus, Terumo Neuro, Imperative Care, Agile, Merit, CereVasc, and Arsenal Medical and stock options from InNeuroCo, Agile, Perfuze, Galaxy, and NTI. AMM is a shareholder, investor, and co-founder of CereVasc. AJT receives consulting fees from Stryker, Medtronic, and CereVas. GT reports compensation from Medtronic for other services and compensation from Kaneka, EBSCO, and Penumbra for consultant services. DKL has received an institutional grant from Mentice; receives consulting fees from Asahi, Stryker, Corindus, Siemens, and Medtronic and honoraria from Cerenovus, Medtronic, and Stryker; participates on the data safety monitoring board for INFINITY [trial]; has a leadership role in WLNC and Advocate Health; and holds stock or stock options in Syncron, Three Rivers, Q'Apel, Viz.ai, Methinks, Vastrax, Borvo, BendIT, Collavidence, NDI, Prometheus, NextGen, Galaxy, Global Intervention, and Sim&Cure, serves as a consultant/advisory board member for Amnis Therapeutics, Boston Scientific, Canon Medical Systems USA, Cerebrotech Medical Systems, Cerenovus, Corindus, Endostream Medical, Imperative Care, Integra LifeSciences Corp, Medtronic, Terumo Neuro, Minnetronix Neuro, Northwest University–DSMB Chair for HEAT Trial, Penumbra, Q'Apel Medical, Rapid Medical, Rebound Therapeutics, Serenity Medical, Silk Road Medical, StimMed, Stryker, Three Rivers Medical, VasSol, and W L Gore and is principal investigator/steering committee member for the following trials: Cerenovus NAPA and ARISE II; Medtronic SWIFT PRIME and SWIFT DIRECT; Terumo Neuro FRED MUSC POSITIVE; and Penumbra 3D Separator, COMPASS, INVEST, TIGER. MJA has been a research consultant for Stryker until December 2021. AK reports no disclosures. GPC is a consultant for Stryker, Medtronic Neurovascular, Rapid Medical, Cerenovus, Terumo Neuro, and Nuvascular. JMC reports no disclosures. SRS reports no disclosures. AST reports equity in Q'Apel and Imperative Care and serves as CMO for Imperative Care. AMS reports research support from Penumbra, Stryker, Medtronic, RapidAI, Terumo Neuro (STAR Stroke and Thrombectomy Aneurysm Registry); consultant services for Penumbra, Stryker, Terumo, and RapidAI. RK reports no disclosures. DKH reports no disclosures. DK reports no disclosures. MTF serves as an advisor to Viz.ai, MindRhythm; consultant to Balt, Cerenovus, Siemens, Medtronic, TG Medical, Jacobs Institute; on DSMB/CEC for Balt, Imperative, Galaxy Therapeutics; and receives research support from Siemens, Medtronic, and Stryker. RCC reports consulting for Stryker. PK worked as consultant services for Imperative Care and Stryker; has stock in Deinde, Neurofine, Prometheus, Vena Medical, and Vented; and received grants from Joe Niekro, National Institutes of Health, and Siemens Medical Solutions. SWH receives grant/contract funding from NIH, Siemens, Route 92 Medical, and Stryker. LLP is an employee of Stryker and holds Stryker stock. OOZ serves as a scientific consultant regarding trial design and conduct to Medtronic.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Christiana Care (Christiana Care Institutional Review Board): CCC# 35146; DDD# 602973 Cedars Sinai Medical Center (Office of Research Compliance and Quality Improvement): MOD00002885; Pro00040978 Cleveland Clinic (Cleveland Clinic Institutional Review Board): #15-777MUSC (Institutional Review Board for Human Research): Pro00043019 RUSH (Rush University Medical Center Institutional Review Board) 15010903-IRB01-AM13 SSM DePaul (SSMSTL IRB): #15-03-0633 St Luke's Episcopal (Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals): H- 37845 Univ of KY Hosp (WIRB): #1-1342680-1 Univ of Mass (UMass Chan Medical School): MODCR00000071 Harborview (WIRB): 1-1516101-1 Vanderbilt University (Human Research Protections Program – HRPP): #151918VCU (WIRB): #1-1516101-1 Methodist Hospital (HMRI IRB): CR00001111Swedish Medical Ctr (HCA - HealthONE Institutional Review Board): #718984-48UPMC (WIRB): #1- 1380703-1 Wellstar Kennestone Hospital (WIRB): #1-1516101-1 Beth Israel (Committee on Clinical Investigations): #2015P000153 Hosp of the

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Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Data are available upon reasonable request. For inquiries, please contact author Brian Jankowitz, Chief of Neurosurgery and Co-Chair of Stroke and Neurovascular Program Hackensack Meridian Neuroscience Institute at JFK University Medical Center, Edison, NJ 08820. Email: bjankowitz@gmail.com.

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ORCID iDs
Brian Jankowitz https://orcid.org/0000-0001-9306-0763
Bradley Gross https://orcid.org/0000-0002-6999-7967
Justin F Fraser https://orcid.org/0000-0002-5980-3989
Eric Sauvageau https://orcid.org/0000-0003-4399-1142
Donald Frei https://orcid.org/0000-0002-7811-5030
Gabor Toth https://orcid.org/0000-0002-3646-3635
Demetrius Klee Lopes https://orcid.org/0000-0002-6280-0113
John Reavey-Cantwell https://orcid.org/0000-0003-1401-4377
Michael J Alexander https://orcid.org/0000-0003-0280-809X
Ahmad Khaldi https://orcid.org/0000-0002-1943-0292
Justin M Caplan https://orcid.org/0000-0002-0289-3661
Alejandro M Spiotta https://orcid.org/0000-0002-7142-5538
Peter Kan https://orcid.org/0000-0001-6649-4128
Steven W Hetts https://orcid.org/0000-0001-5885-7259
Osama O Zaidat https://orcid.org/0000-0003-4881-4698

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