US Multicenter Experience With the Wingspan Stent System for the Treatment of Intracranial Atheromatous Disease Periprocedural Results

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Background and Purpose—The current report details our initial periprocedural experience with Wingspan (Boston Scientific/Target), the first self-expanding stent system designed for the treatment of intracranial atheromatous disease.

Methods—All patients undergoing angioplasty and stenting with the Gateway balloon–Wingspan stent system were prospectively tracked.

Results—During a 9-month period, treatment with the stent system was attempted in 78 patients (average age, 63.6 years; 33 women) with 82 intracranial atheromatous lesions, of which 54 were ≥70% stenotic. Eighty-one of 82 lesions were successfully stented (98.8%) during the first treatment session. In 1 case, the stent could not be delivered across the lesion; the patient was treated solely with angioplasty and stented at a later date. Lesions treated involved the internal carotid (n=32; 8 petrous, 10 cavernous, 11 supraclinoid segment, 3 terminus), vertebral (n=14; V4 segment), basilar (n=14), and middle cerebral (n=22) arteries. Mean±SD pretreatment stenosis was 74.6±13.9%, improving to 43.5±18.1% after balloon angioplasty and to 27.2±16.7% after stent placement. Of the 82 lesions treated, there were 5 (6.1%) major periprocedural neurological complications, 4 of which ultimately led to patient death within 30 days of the procedure.

Conclusions—Angioplasty and stenting for symptomatic intracranial atheromatous disease can be performed with the Gateway balloon–Wingspan stent system with a high rate of technical success and acceptable periprocedural morbidity. Our initial experience indicates that this procedure represents a viable treatment option for this patient population. (Stroke. 2007;38:881-887.)

Key Words: angioplasty ■ intracranial atheromatous disease ■ stenting ■ Wingspan

Symptomatic intracranial atheromatous disease (ICAD) is characterized by a malignant natural history, with a significant number of patients experiencing recurrent ipsilateral stroke despite medical therapy.1 In the recent Warfarin-Aspirin Symptomatic Intracranial Disease (WASID) study, 25% of patients presenting with 70% to 99% stenosis experienced a stroke in the ipsilateral vascular territory within 2 years, despite treatment with either warfarin or aspirin.2 Given the high failure rate of medical therapy, these patients represent the population most likely to benefit from revascularization therapies.

Strategies for revascularization have included surgical bypass, percutaneous transluminal angioplasty (PTA) alone, and percutaneous transluminal angioplasty and stenting (PTAS) using balloon-mounted coronary stents (BMCSs) off-label in the cerebrovasculature. Although several retrospective case series suggest that PTA alone is a safe and effective treatment strategy,3 surgical bypass was shown to be inferior to medical therapy for middle cerebral artery (MCA) stenosis,4 and PTAS with BMCSs has been associated with high rates of periprocedural morbidity and mortality.5–7

The Wingspan, a flexible, self-expanding, microcatheter-delivered, nitinol microstent (Boston Scientific/Target) is the first self-expanding stent designed specifically for the treatment of symptomatic ICAD. The Gateway PTA balloon catheter (Boston Scientific/Target) is used to predilate the target lesion before Wingspan stenting. The Gateway balloon–Wingspan stent system was designed to combine the
safety advantages of the angioplasty-alone strategy with the superior immediate luminal gain achieved with a stenting strategy. We report the immediate and periprocedural results of our prospective, multicenter experience of the Wingspan system for the treatment of ICAD.

Patients and Methods

Data Collection

Seventy-eight patients with 82 intracranial atheromatous lesions (≥50% stenosis) were treated with the Gateway balloon–Wingspan stent system at the Barrow Neurological Institute (n=16 lesions), Cleveland Clinic (n=21), State University of New York at Buffalo (n=21), and University of Wisconsin (n=24) between November 2005 and July 2006 and were prospectively tracked in a collaborative endovascular database. Patient characteristics, lesion description, procedural details, and periprocedural complications were recorded. The institutional review board at each institution approved the collection and review of patient data for the study period. Composite data were collected for evaluation.

Procedural success was defined as completion of Gateway balloon angioplasty and Wingspan stent placement across the target lesion, despite the degree of residual stenosis or any complications related to the procedure. The primary outcome end point was periprocedural stroke and death. Complications were adjudicated by the primary operators involved in the procedures.

Interventional Procedure

In brief, the presented interventions were performed via common femoral artery access with the exception of 1 procedure that was performed through direct puncture of the right common carotid artery (Figure 1a through 1d) and 2 that were performed through a brachial approach. All interventions were performed through a 6F access system. The targeted parent vessel was accessed with either a 6F guiding catheter (Envoy or Envoy XB; Cordis) or a 6F KSAW Shuttle-Select sheath system (Cook). Heparinization was instituted to a targeted activated coagulation time of 250 to 300 seconds. In most cases, after conventional angiography, an SL-10 (Boston Scientific), Prowler-10 (Cordis), or Eschelon-10 (Microtherapeutics, Irvine, Calif) microcatheter was manipulated across the target lesion using a 0.014-inch Synchro (Boston Scientific) or Transcend EX Soft Tip (Boston Scientific) microwire. The microcatheter was then exchanged over a 0.014-inch Transcend Floppy (Boston Scientific), Luge (Boston Scientific), or PVS (Boston Scientific) exchange system.

Figure 1. A 76-year-old man with a known high-grade stenosis of the right supraclinoid internal carotid artery (ICA) was referred for the evaluation of crescendo TIA involving the right anterior circulation. At the time of the initial outpatient consultation, the patient was experiencing active TIA, despite aspirin and clopidogrel therapy. He was urgently admitted to the hospital and heparinized. An axial diffusion image (a) from a MR imaging examination performed on the day of admission demonstrates several small foci of restricted diffusion within the right anterior circulation. Diagnostic cerebral angiography confirmed a high-grade stenosis of the right ICA. Owing to the tortuosity of his extracranial vasculature, a stable guiding catheter position could not be achieved within the right ICA to support angioplasty and stenting. For this reason, the patient was brought to the operating room, and direct access into the right common carotid artery was secured. Right IC angiography demonstrated a preocclusive (>85%) stenosis of the supraclinoid ICA (b, arrow). Although a residual stenosis (c) was present after angioplasty and stenting with the Gateway balloon–Wingspan stent system, flow to the right anterior circulation was markedly improved. The site of the carotid puncture was secured surgically. Postprocedural magnetic imaging (d) demonstrated no new diffusion lesions (arrow depicts a small diffusion-positive lesion that is unchanged from the preprocedural examination). The patient’s ischemic symptoms completely resolved after the procedure.
A 54-year-old woman presented initially with a small right MCA territory stroke. MR angiography indicated a high-grade stenosis of the right MCA. She was initially managed medically with aspirin and clopidogrel; however, she continued to experience daily TIAs. MR imaging repeated at the time of her initial consultation demonstrated several foci of restricted diffusion within the right MCA distribution. She was admitted to the hospital and received heparin for anticoagulation. Cerebral angiography performed from a catheter positioned within the right ICA demonstrates a high-grade (>70%) stenosis (arrow) of the M1 segment of the right MCA just distal to the origin of the anterior temporal artery (a). After angioplasty with a 1.5×15-mm Gateway balloon, a 3.5×9-mm Wingspan stent was placed across the lesion. The unsubtracted posttreatment angiographic image depicts the radiopaque Wingspan stent markers (arrowheads, b) bridging the lesion. The body of the stent is composed of nitinol and is radiolucent. The subtracted image demonstrates near-complete resolution of the stenosis (c). The patient’s ischemic symptoms immediately resolved. Postprocedural MR diffusion-weighted imaging demonstrated no additional lesions. Postprocedural transcranial monitoring was negative for emboli. The patient remains free of symptoms at the 4-month follow-up evaluation.

Results

Patient Population

During a 9-month period, 78 patients (average age, 63.6 years; range, 35–85 years; 45 men) with 82 intracranial atheromatous lesions were treated with the Gateway balloon and Wingspan stent system. Forty-eight patients presented with a history of stroke and 28 with transient ischemic attack (TIA); 1 patient was asymptomatic but was treated because of a perfusion deficit documented on single-photon-emission computed tomographic imaging; and 1 patient with a high-grade basilar artery stenosis and poor collateral circulation was treated in preparation for coronary artery bypass graft surgery. Fifty-nine patients had a well-documented history of antiplatelet therapy failure at the time of their qualifying event(s).
Initial Treatment Results

Of the 82 lesions approached, 81 were treated with both the Gateway balloon and Wingspan stent (98.8% technical success rate for stent deployment across the stenotic lesion). In 1 patient, successful Gateway balloon angioplasty was performed with a 32% residual stenosis at the conclusion of the procedure; however, a tortuous carotid anatomy precluded delivery of the Wingspan stent. This patient presented later with recurrent stenosis and successfully underwent PTAS with Wingspan at that time. The 82 lesions were distributed within the following arterial locations: internal carotid (n = 32; 8 petrous, 10 cavernous, 11 suprachinoid segment, 3 terminus), vertebral (n = 14; V4 segment), basilar (n = 14), and middle cerebral (n = 22). The mean ± SD pretreatment stenosis was 74.6 ± 13.9%, with 54 of the 82 lesions having a ≥70% stenosis (Figure 3a through 3c). After Gateway angioplasty, the average stenosis was 43.5 ± 18.1%. After Wingspan stent placement, the average stenosis was 27.2 ± 16.7% (Figure 4).

Imaging and Clinical Follow-Up

Five major procedural complications have been encountered thus far during the course of the registry (the Table and Figure 5a through 5f). The remaining lesions were treated without any permanent neurological sequelae (6.1% major periprocedural morbidity and mortality). Two complications (lesions 44 and 58, Table), 1 vessel rupture after angioplasty and 1 microwire perforation during stent delivery, were clearly device related. One patient experienced a reperfusion hemorrhage (lesion 52) immediately after an otherwise technically successful procedure. One patient experienced a non–device-related procedural complication, a large hemispheric infarction contralateral to the treated left MCA stenosis (lesion 71). The final complication was encountered in a patient with a symptomatic basilar stenosis who was treated emergently in the context of an actively evolving stroke syndrome (lesion 55). This patient continued to deteriorate clinically during and after the procedure. Magnetic resonance (MR) imaging performed after the procedure demonstrated extensive posterior circulation infarctions.

One patient experienced transient visual symptoms that completely resolved within 36 hours of the procedure. Five extracranial parent-vessel dissections related to guide catheter manipulation were encountered, 2 of which were flow limiting and required stenting. One flow-limtiting intracranial dissection was encountered after Gateway angioplasty, which completely resolved after Wingspan stent placement and did not result in any neurological morbidity (Figure 6a through 6c).

Postprocedural MR diffusion-weighted imaging was performed on 38 patients within 72 hours of the procedure, 13 (34.2%) of whom had new ischemic lesions after the procedure. Ten of the 13 lesions were asymptomatic; the other 3 were in patients with major periprocedural complications (Table).

Discussion

The present series demonstrates that PTAS with the Wingspan stent system can be accomplished with a high rate of technical success (98.8%) and an acceptable rate of major periprocedural morbidity and mortality (6.1%). Of the 5 major periprocedural complications encountered during the present series, only 3 were either directly device related or the sequela of revascularization. These data indicate that PTAS with the Wingspan system represents a potentially viable option for the endovascular management of symptomatic ICAD in appropriately selected patients. At the same time, it is important to note that the periprocedural complications encountered during intracranial PTAS are typically very severe, with 4 of the 5 major complications in the current series resulting in patient death within 30 days.

Wingspan Stent System Design and Treatment Strategy: Effect on the Periprocedural Complication Rate Associated With Intracranial PTAS

Most series describing the outcomes of patients undergoing treatment with BMCSs report periprocedural complication rates

<table>
<thead>
<tr>
<th>Lesion No.</th>
<th>Age, y</th>
<th>Sex</th>
<th>Presenting Symptom</th>
<th>Lesion Location</th>
<th>Pretreatment Stenosis, %</th>
<th>Complication</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>44</td>
<td>76</td>
<td>F</td>
<td>Stroke</td>
<td>Basilar</td>
<td>65.6</td>
<td>Vessel perforation after angioplasty</td>
<td>Death POD 5</td>
</tr>
<tr>
<td>52</td>
<td>61</td>
<td>M</td>
<td>TIA</td>
<td>Left MCA</td>
<td>66.7</td>
<td>Reperfusion hemorrhage</td>
<td>Aphasia and hemiparesis</td>
</tr>
<tr>
<td>55</td>
<td>64</td>
<td>F</td>
<td>Stroke</td>
<td>Basilar</td>
<td>64.0</td>
<td>Multiple posterior circulation strokes</td>
<td>Death POD 16</td>
</tr>
<tr>
<td>58</td>
<td>70</td>
<td>F</td>
<td>Stroke</td>
<td>Basilar</td>
<td>80.0</td>
<td>Guidewire perforation of basilar apex</td>
<td>Procedural Death</td>
</tr>
<tr>
<td>71</td>
<td>85</td>
<td>F</td>
<td>TIA</td>
<td>Left MCA</td>
<td>77.2</td>
<td>Contralateral (right hemisphere) embolic infarction</td>
<td>Death POD 15</td>
</tr>
</tbody>
</table>

F indicates female; M, male; POD, postoperative day.
in the range of 15% to 30%. In 1 of the largest available series of patients with symptomatic vertebrobasilar ICAD undergoing treatment with BMCSs, 9 periprocedural neurological complications (stroke or death) were encountered during treatment of 39 patients (23.1%). The present prospective, all-inclusive series indicates a significant reduction in overall event rates during PTAS in patients treated with the Wingspan system. Further evidence of procedural safety was provided by postprocedural MR diffusion-weighted imaging, which demonstrated new lesions after PTAS with the Wingspan system in 34% of patients, a rate that compares favorably with the 70% rate of diffusion-positive lesions reported after PTAS with BMCSs.

The substantial reduction in periprocedural complications with the Wingspan can be attributed to both the device design and the recommended treatment strategy. Before delivery of the Wingspan stent, an angioplasty is performed with the Gateway balloon. The balloon is undersized to 80% of the normal parent-vessel diameter. This conservative predilation reduces the amount of vascular trauma induced and likely minimizes both the risk of target-vessel perforation as well as the likelihood of downstream embolization of atheromatous debris caused by plaque disruption.

After the angioplasty, the Wingspan stent is navigated across the lesion over a floppy exchange-length microwire and deployed (Figure 2a through 2d). The Wingspan microstent is composed of nitinol and housed in a low-profile, hydrophilic microcatheter delivery system. These properties make the stent delivery system considerably easier to navigate to and across an intracranial target lesion than even the newest generation of BMCSs (which remain

Figure 5. A 76-year-old woman presented with a moderate basilar stenosis and a small posterior circulation stroke. Lateral projection from a cerebral angiogram performed from a catheter positioned within the left vertebral artery demonstrates a moderate (50%) stenosis of the distal basilar artery (a, arrow). After the initial Gateway balloon angioplasty, control angiography (b) demonstrated contrast extravasation (arrow) from the posterior wall of the distal basilar artery, with pooling of contrast medium within the interpeduncular cistern. Heparinization was reversed immediately with protamine. A Wingspan stent was deployed across the region of the angioplasty. Control angiography (c) after deployment of the Wingspan stent demonstrated minimal residual extravasation (arrow). A HyperGlide balloon (Microtherapeutics) was then manipulated into the proximal basilar artery and inflated for ~1 minute in an attempt to achieve hemostasis. This was successful, with repeat post-PTAS angiography demonstrating an excellent result and no further extravasation (d). A postprocedural computed tomography scan demonstrated a small amount of subarachnoid hemorrhage and contrast distributed within the interpeduncular cistern (e). There was no hydrocephalus or acute infarction. After the procedure, the patient remained comatose. MR imaging performed on postprocedure day 2 demonstrated an acute pontine infarction (f). The patient remained comatose, and the family elected to withdraw care on postprocedure day 5.

Figure 6. A 65-year-old man with a vertebral stenosis presented with stroke while receiving dual-antiplatelet therapy. Subtracted lateral projection (a) demonstrates a moderate focal stenosis (arrow) of the proximal intracranial vertebral artery. Angioplasty was performed with the Gateway 3.0×9-mm balloon. Control angiography immediately after angioplasty (b) demonstrates a flow-limiting dissection with near-complete occlusion of the treated vessel. The Wingspan stent delivery system was manipulated across the lesion, and the stent was deployed. Control angiography after stent placement (c) demonstrates a mild residual stenosis with normalization of flow through the vertebrobasilar system. The patient was without new neurological deficits after the procedure.
The self-expanding nature of the Wingspan stent also provides several unique advantages in comparison with the available BMCCs. The Wingspan stent is slightly oversized, chosen to measure ~0.5 to 1.0 mm larger than the diameter of the normal parent vessel in an unconstrained, fully expanded configuration. As such, once deployed, the stent exerts a continuous outward radial force on the vessel wall. This outward radial force acts to prevent early vessel recoil, thus consolidating the gains achieved with the initial angioplasty. As the stent gradually expands, it functions not only to maintain the luminal diameter but also to secure any foci of dissection or intimal injury (Figure 6a through 6c). The self-expanding nature of the stent facilitates optimal stent—parent-vessel wall apposition over varying luminal diameters (which are frequently encountered within the cerebrovasculature). Finally, although the Wingspan is a new device, most neurointerventionists have had extensive experience with the Neuroform stent (Boston Scientific), another self-expanding nitinol microstent used for the treatment of intracranial aneurysms. As such, the “learning curve” for the application of this device is limited, as it represents an iteration of existing technology that is routinely applied to support the embolization of intracranial aneurysms.

Viable Endovascular Strategies for the Management of Symptomatic ICAD: Angioplasty Alone and Gateway PTA–Wingspan Stenting

Initial case series reported relatively high rates of periprocedural morbidity (28% periprocedural stroke or death) with the angioplasty-alone strategy. The introduction of routine adjunctive periprocedural platelet inhibition, along with a more conservative approach to balloon sizing and a slow balloon inflation technique, made intracranial angioplasty considerably safer. Several single-institution retrospective series and 1 multicenter retrospective series have suggested that with these modern techniques, intracranial angioplasty without stenting can be performed with a relatively low periprocedural risk profile. The major potential limitations of angioplasty without stenting include vessel recoil with acute recurrent stenosis, acute vessel occlusion secondary to either procedural dissection or recoil with regional platelet aggregation, and a lack of long-term durability, with some patients requiring multiple procedures because of recurrent stenosis.

Although PTA alone has merit as a primary strategy for the treatment of symptomatic ICAD, there are several theoretical benefits to augmenting the procedure with the added step of stenting with the Wingspan. First, the present data indicate that the added risk of placing the self-expanding stent after successful angioplasty is low. Second, the self-expanding nature of the Wingspan augments the results of the initial angioplasty and prevents acute vessel recoil, providing better and more reliable initial results with greater immediate luminal gain. Not infrequently after PTA alone, a considerable residual stenosis remains. In the multicenter experience reported by Marks et al., 40.7% of patients had residual stenoses of >50% at the conclusion of the procedure. In an additional 12.9% of patients treated, stents were required because the initial angioplasty result was “unchanged or worse” than the pretreatment stenosis. In the current series, only 4 of 81 (4.9%) lesions treated with both the Gateway balloon and Wingspan stent were left with a stenosis of 50% or more at the conclusion of the initial procedure. Third, post-PTA vessel dissections, which occurred 20.2% of the time in the series of Marks et al., can be immediately repaired with stent placement (Figure 6a through 6c).

Role of the Wingspan System in the Treatment of Symptomatic ICAD

The current data indicate that Gateway-Wingspan PTAS can be performed by multiple operators at different institutions with a level of periprocedural safety that makes it a potentially viable option for the treatment of symptomatic ICAD. Provided that the ongoing multicenter registry continues to demonstrate reasonable periprocedural safety and, as these patients are followed clinically, low rates of postprocedural neurological events, this technique may supplant medical therapy as the treatment of choice in some patients with symptomatic ICAD. This determination would be best made through a direct comparison with “best medical therapy” in the context of a multicenter, randomized, controlled trial.

Limitations

Complications were tracked by the primary operators involved in the procedures. As such, it is possible that neurological morbidity in these patients could have been underestimated in the absence of independent neurological adjudication. However, it is unlikely that any major procedural morbidity (periprocedural stroke or death) would have gone undetected in the periprocedural period. The current series represents an initial experience in a relatively small population of patients. Until larger numbers of patients are treated, the actual complication profile of the procedure remains an approximation. Equally important, no longitudinal follow-up of these patients is available at this time. Correspondingly, the efficacy of Wingspan for the prevention of recurrent ischemic events cannot be assessed at this point. Until these data are better understood, the precise role of the Wingspan system for the treatment of symptomatic ICAD remains poorly defined.

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