The WingSpan Stent System for the Treatment of Intracranial Atherosclerotic Stenoses: A Single Center Experience

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Purpose: A self-expandable nitinol stent (WingSpan stent; Boston Scientific Corp.) was introduced for the treatment of intracranial stenoses. The purpose of this study is to present our initial experience with the WingSpan stent for the treatment of atherosclerotic stenoses of the cerebral arteries.

Materials and Methods: Consecutive 37 patients (mean age: 66.8 years, 17 men and 20 women) with symptomatic severe stenoses (>50%) of various anatomic sites were treated with WingSpan stent (BSC). Treatment result was evaluated in terms of technical success rate, intra-procedural event, and clinical course. Neurological morbidity and mortality rates were obtained. Arterial patency was evaluated with the 6 month follow-up angiography. Restenosis over 50% was regarded as significant.

Results: The technical success rate was 97.3% (36/37). Flow-limiting vasospasm or dissection after balloon angioplasty (n=3), misplacement of the stent (n=3), and acute in-stent thrombosis (n=1) were occurred. The initial stenosis before the procedure (71.7%) was improved after balloon angioplasty (39.8%) and after subsequent stent placement (20.0%). There were four neurological events during periprocedural period. Those were two TIA, one minor stroke, and one major stroke. The periprocedural morbidity rate was 5.4%. One mortality was the case of progression of previous brainstem infarction. Six-month-follow-up angiography was available in 16 patients and in-stent restenosis was noted in 7 (43.8%).

Conclusion: WingSpan stents could be delivered to the target lesions without difficulty. However, the system showed technical problems such as misplacement. Restenosis seemed not infrequent on our limited follow-up observations.

Key Words: Arterial stenosis; Stroke; Stent; Angioplasty
Intracranial stenoses of both anterior and posterior circulations constitute a major cause of ischemic stroke. A recent report from the Northern Manhattan Stroke Study revealed that about 3% (in whites) to 15% (in blacks) of ischemic stroke was caused by intracranial atherosclerotic stenosis (1). These numbers are greater than those from the same registry reported 10 years earlier (2). Although large proportion of the angiographically-documented stenoses remains stable on follow-up, the incidence of subsequent stroke in the same vascular territory is not infrequent since the annual ipsilateral stroke rates vary from 3 to 15% with relatively high mortality rates (3, 4).

Furthermore, the embarrassing results of recent study compared the safety and efficacy of aspirin and warfarin in the prevention of stroke in patients with intracranial atherosclerotic disease prompted more interests in interventional revascularization methods such as angioplasty and/or stenting (4, 5). There has been many, small or large, case-series reports on the technique. Some prefer use of balloon angioplasty (6–8), even in the era of ensuing reports on successful use of balloon-expandable coronary stents in the treatment of the stenosis of anterior and posterior circulations (9–11). They prefer the use of stents because of the issues of elastic recoil and arterial dissection seen with balloon angioplasty alone.

Although a recent multi-center trial on the safety and procedural feasibility of a dedicated intracranial stent (Neurolink, Guidant Corporation, Menlo Park, USA) revealed high technical success rate (95%) (12), use of balloon-expandable stents has not always been successful. Delivery of the stent beyond the unfriendly anatomic configuration of the cavernous portion of the internal carotid artery (ICA) and distal vertebral artery (VA) is the most challenging step to overcome when we use a balloon-expandable stent mostly due to the stiffness which was attributed both to the metallic stent itself and to the delivery system containing a balloon. The procedure would be impossible especially in patients with tortuous arteries, even with various innovative stent-navigation techniques available (13).

To overcome the limitations of balloon-expandable stents in the intracranial arteries, a self-expandable nitinol stent, which requires prior balloon angioplasty, was introduced. Hopefully, this combined mechanism of both balloon angioplasty and stenting would be helpful to facilitate effectiveness and safety of the stenting procedure. The purpose of this study is to evaluate the initial single center experience with the stent system in terms of technical feasibility, and early clinical and angiographic follow-up results.

**MATERIALS AND METHODS**

**Patients**

Between November 2005 and May 2007, a total of 37 patients with intracranial atherosclerotic stenosis were treated with a newly introduced self-expandable nitinol stent (WingSpan Stent; Boston Scientific Corporation, Fremont, USA) in our hospital. There were 17 men and 20 women with an age range of 27 to 83 (average, 66.8). The working indications of the procedure were stenosis over 50% which was presented with related symptoms or refractory to maximal medical treatment either in anterior circulation or in posterior circulation, and high calcific burden of the stenosis on imaging studies (Table 1).

The anatomic locations of stenosis were distal internal carotid artery (ICA) in 10, middle cerebral artery (MCA) in eight, anterior cerebral artery (ACA) in three, distal vertebral artery (VA) in five, basilar artery (BA) in 10, and posterior cerebral artery (PCA) in one.

An informed consent was obtained from the patient and/or the next kin of the patient in all case. All the patients were premedicated with daily doses of 100–325 mg of aspirin and 75 mg of clopidogrel 5–10 days before the procedure. A loading dose (300 mg) of clopidogrel and 325 mg of aspirin were given immediately before the procedure through the nasogastric tube in acute setting in two cases.

**Procedures**

All procedures were performed under general anesthesia. Antiplatelet function of both aspirin and clopidogrel was monitored with a turbidimetric based...
an optical detection system (VerifyNow; Accumetrics, San Diego, USA) at the later phase of our experience. If the percent inhibition was below therapeutic level, additional loading dose of antiplatelets was given at the site. Systemic heparinization was done to achieve about 2–2.5 times prolongation of the baseline activated clotting time. A 6-F guiding catheter (Envoy; Cordis Neurovascular, Miami Lakes, USA) was placed into the proximal portion of the target artery following the introduction of a 6-F femoral sheath. Three-dimensional volume images and multi-planar sectional images of the target artery were obtained with post-processing software (InSpace and DynaCT, respectively; Siemens Medical System, Erlangen, Germany) from the rotational angiography data of a flat-panel detector digital angiography system (Axiom Artis; Siemens Medical System) to measure the target lesion and parent artery diameters, to evaluate the presence, amount, and location of calcification, and to obtain the most optimal projection of the procedure, e.g., a working projection.

Following the introduction of an exchange microguidewire (Transend 14; Boston Scientific Corporation, Fremont, USA), which sometimes required an aid of microcatheter (Excelsior 14; Boston Scientific Corporation) to navigate a complex lesion, an over-the-wire type balloon (Gateway; Boston Scientific Corporation) was advanced over the guidewire. The diameter of the balloon was chosen to accomplish dilatation of the lesion not more than 80% of the diameter of the parent artery at nominal pressure.

After removal of the balloon catheter, we inserted the stent of predetermined diameter provided by the company according to the diameter of the balloon we choose. The length of the stent was chosen to cover more than 3-mm of proximal and distal lesion margins. During the balloonizing and stenting procedures, the tip of the guidewire was kept in place and carefully monitored for the movement to prevent possible cortical artery perforation. Final angiography was performed 30 minutes after the stent placement to secure acute thrombosis. A closure device (Angioseal; Abbott Vascular, St. Paul, USA) was used for the puncture-site hemostasis after reversing systemic heparinization using protamine sulfate.

**Follow-up**

All patients were evaluated after the procedure for the change of neurological status. Follow-up angiography and neurological assessment were encouraged 6 months after the initial procedure.

**Analysis**

Technical success rate of the stent deployment was calculated. Technical problems during the procedure, such as vessel injury, misplacement of the stent, thrombosis, or underexpansion of the stent were recorded. Occurrence of any cerebrovascular complication was carefully monitored. For the angiographic outcome analysis, the diameters of the target lesion and parent artery were measured before the procedure, after balloon dilatation, and immediately after stent deployment. Immediate clinical outcome was evaluated in terms of occurrence of ischemic symptom, hemorrhage, and stroke and death.

On six-month follow-up, any changes of neurological status, cerebrovascular adverse events, and death were recorded. Follow-up angiographic outcome analysis was done for the evaluation of the in-stent restenosis. A stenosis of over 50% was regarded as significant restenosis.

**RESULTS**

The technical success rate was 97.3% (36/37) due to one case of stent delivery failure to the target lesion after balloon angioplasty due to an acute angle at the anterior genu portion of the carotid siphon. There was no technical adverse event such as arterial perforation or rupture of the target artery. However, significant dissection of the target artery was noted in three cases after balloon angioplasty and was successfully relieved after deployment of the stent without any clinical consequences. Acute in-stent thrombosis, which required administration of systemic abciximab, was noted in one case. Misplacement of the stent occurred
in three cases in the early phase of our experience. Additional stent placement was required in two of them. Post-stenting balloon angioplasty was required due to significant residual stenosis even after the deployment of the stent in two cases. The additional procedures were uneventful.

The mean percent stenosis improved from 71.7% before the procedure to 39.8% after balloon angioplasty and to 20.0% after stent placement (Fig. 1).

There were a total of four neurological events during or immediately after the procedure. Those were two TIA attacks, one minor stroke, and one major stroke.

The periprocedural morbidity rate was 5.4%. One mortality was noted in the case of progression of previous brainstem infarction leaving periprocedural mortality rate of 2.7%.

Clinical follow-up was available in 26 of 26 eligible patients with a mean follow-up interval of 5.4 months. New neurological events were noted in four; three TIA attacks and one minor stroke. There was additional mortality due to contralateral territorial infarction complicated by aspiration pneumonia in one patient. On patient-wise evaluation, the overall stroke and death rates of our patient cohort were 8.1% (3/37) and 5.4%.

**Fig. 2.** A 75-year-old woman who had a previous history stroke and presented again with recurrent transient ischemic attacks recently. 
A. Her initial left vertebral arteriogram showed a concentric severe stenosis of the mid basilar trunk.
B. The lesion showed significant improvement of the stenosis immediately after balloon angioplasty.
C. More improvement was noted after stenting. However, there is more than 30% of residual stenosis showing some turbulent flow distally.
D. On her 8-month-follow-up angiogram showed improvement of stenosis virtually without any significant stenosis.
Follow-up angiography was available in 16 of 35 eligible patients (45.7%). Further improvement of the residual stenosis which was noted immediately after stent placement was observed occasionally (Fig. 2). However, the percent stenosis increased overall (Fig. 1). In-stent restenosis was noted in 7 out of the 16 patients (43.8%) (Fig. 3). The mean residual stenosis on follow-up angiogram was 38.7%. Among them three were symptomatic (two TIAs, one minor stroke). Retreatment was done in two of them with use of a drug-eluting stent (Fig. 3).

**DISCUSSION**

The idea of this self-expandable nitinol stent is an expansion of mechanism of the Neuroform stent (Boston Scientific Corp.) which has been successfully applied for the neck-remodeling technique of intracranial aneurysm embolization. There was an anecdotal report on the use of Neuroform stents for the treatment of intracranial arterial stenosis and dissection (14). However, the stent was originally manufactured only for the neck remodeling because it might lack of sufficient hoop strength to overcome the elastic recoil of the artery after balloon angioplasty.

There are many biophysical properties of a metallic stent. Among them, trackability, which can be provided by the flexibility and crossing profile of the stent and stent delivery system, is the most paramount characteristics of an ideal intracranial stent together with hoop strength. With the WingSpan stent and its delivery system, the properties can be realized by lowering the profile of the delivery system, which could be achieved by the separation of the balloon catheter and stent itself in this self-expandable stent, and the original Gianturco

![Fig. 3. A 43-year-old male patient who showed left side numbness even on dual antiplatelet treatment for the alleged right middle cerebral artery stenosis.](image)

A. Initial right internal carotid arteriogram showed a focal severe stenosis of the right proximal middle cerebral artery.

B. The lesion had disappeared after balloon angioplasty and stenting leaving negligible residual stenosis immediately after the procedure.

C. However, during the angiographic observation which we did routinely after the stenting, the artery clogged completely due to the acute in-stent thrombosis.

D. The occlusion responded intravenous infusion of abciximab very well.

E. However, the patient was symptomatic 4 months after the procedure and the follow-up angiogram showed significant restenosis, which was successfully managed with placement of a drug-eluting stent.
type Z stent design, which can exert good hoop strength and flexibility.

Good apposition of the stent struts to the vessel wall is another important advantage of multi-segmented, self-expanding design. This property is very helpful in treating lesions with different vessel diameters at the proximal and distal sides, which could be helpful for the minimization of intimal hyperplasia.

Although there have been reports on the successful placement of balloon-expandable stents for the stenosis of distal, small-caliber, intracranial arteries, however, generally the procedure would be challenging. Possible application of stents in those small arteries, such as, ACA, distal MCA, or PCA can be another merit of this flexible, low-profile system as were the cases in our series.

Albeit these potential benefits of the current system, clinical performance of this device has turned out to be disappointed more or less. According to the recent reports on the initial experience and mid-term follow-up results on use of this system for the atherosclerotic intracranial stenosis have shown that the procedure-related morbidity/mortality rates are not less than those with balloon-expandable stents and the in-stent restenosis rates are slightly greater than those on previous reports (15, 16). Fiorella et al reported a major periprocedural complication rate of 6.1% and Zaidat et al reported any stroke or death rate within 24 hours of the procedure of 6.2% (15, 16).

For the technical aspect of the procedure, one should consider safety too. The most dreadful procedure-related complication is injury to the arteries together with thromboembolic complications. Injury of the artery can be occurred during stenting step of the procedure especially when one tries to fit the stent struts to the wall or by the cortical arterial puncture with the working micro-guidewire tip, which usually is not stable during the navigation of the devices. The exchange procedure, which is inevitable with this technique, may increase the chance of guidewire mobility. The importance of monitoring the guidewire motion cannot be overemphasized.

Restenosis on follow-up is another major concern. There was a striking difference in the rate between the early report from Europe (7.5% of restenosis rate) and those of recent large-series studies (25–35%), which obviously are beyond our satisfaction although there were not many symptomatic cases in their reports (16–18).

Although this new stent system still has some limitations in its clinical performance, it is obvious that the system definitely enriched our neurointerventional armamentarium when we cope with an intracranial stenosis which is located in relatively smaller parent artery or in curved vessels. It also seems very useful when the lesion is beyond very tortuous excursion in which a balloon-expandable stent is unsuitable.

**CONCLUSION**

Treatment of intracranial stenoses of various anatomic locations with a newly-designed, self-expandable nitinol stent placement following balloon angioplasty is technically feasible and safe. However, the system is still not free from occasional procedural morbidity and in-stent restenosis.

**References**


**The WingSpan Stent for Intracranial Atherosclerotic Stenoses**

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WingSpan 스텐트를 이용한 두개강내 동맥 협착의 치료: 단일 기관 경험

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목적: 자가 팽창성 나이티놀 스텐트인 WingSpan 스텐트가 두개강내 협착증에 사용되기 시작하여 그 초기 경험을 보고하고자 한다.

대상 및 방법: 2005년 11월부터 2007년 5월 사이에 유증상 동맥경화성 두개강내 협착증으로 시술을 받은 37명의 환자 (남자 17명, 여자 20명)를 대상으로 하였다. 치료의 결과는 기술적인 성공률, 시술 중 문제 발생과 임상적인 경과를 중심으로 분석하였고, 신경학적인 이상과 사망률을 조사하였다. 6개월 추적 임상 소견과 재협착 발생 여부를 관찰하였으며, 50% 이상의 협착이 보이는 경우를 유의한 재협착으로 보았다.

결과: 한 환자에서 스텐트를 병변까지 삽입하지 못하여 기술적인 성공률은 97.3%였다. 시술과 연관된 이상 소견으로는 스텐트 삽입 전에 시행한 풍선 성형술로 인한 혈류를 저해하는 혈관연축이나 혈관박리가 3예, 스텐트의 부정확한 삽입이 3예, 항혈소판제의 주입이 요구된 급성 혈전증이 1예 관찰되었다. 시술 전에 보인 협착 (평균 71.7%)은 풍선 성형술 후에 다소 호전되고 (39.8%), 스텐트 삽입 후에 좀 더 호전되었다 (20.0%). 시술 중과 직후에 5예의 신경학적인 이상 (일과성허혈발작 2예, 경미한 경색 1예, 심한 경색 1예, 사망 1예)이 발생하였다. 6개월 추적 혈관조영술은 16명에서 이루어졌으며 유의한 재협착이 7예에서 발견되었다 (스텐트내 재협착율, 43.8%).

결론: WingSpan 스텐트는 두개강내 협착증의 치료에 있어 병변까지의 기구의 도달이 용이하고, 각도가 있는 작은 혈관에도 사용할 수 있다는 장점이 있다. 그러나 부정확한 삽입이 드물지 않고, 상당히 스텐트내 재협착 발생률이 높다는 단점이 있다.

Key Words : Arterial stenosis; Stroke; Stent; Angioplasty
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