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AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summaries

Intracranial angioplasty and stenting (WingSpan™) for cerebral atherosclerotic stenosis

June 2006
(Updated August 2008)



ASERNIP(S)

**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**



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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by Mr. Irving Lee from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).



Name of Technology:

Intracranial angioplasty and stenting (WingSpan™ self-expanding stent) for cerebral atherosclerotic stenosis.

Purpose and Target Group:

Patients suffering from symptomatic intracranial atherosclerotic stenosis.

Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use
- Not yet emerged

The WingSpan stent is currently not available in Australia. Hence it is not listed or registered in the Australian Register of Therapeutic Goods database.

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
United States	✓		
Germany	✓		

Impact Summary:

Background

Intracranial cerebral atherosclerosis is a disease that is characterised by endothelial dysfunction, vascular inflammation, and the build-up of lipids, cholesterol, calcium and cellular debris within the intima of the vessel wall (Orford 2005). It is estimated that intracranial cerebral atherosclerosis accounts for approximately 8% to 10% of all ischemic strokes, with a higher incidence in Asian, African and Hispanic populations (Higashida *et al.* 2005). The aetiology of ischemic strokes secondary to intracranial atherosclerosis have presented four potential mechanisms, namely hypoperfusion, thrombosis at the intraplaque haemorrhage or occlusive plaque growth, thromboembolic events distal to the site of stenosis or direct occlusion of small penetrating arteries at the site of the plaque (Higashida *et al.* 2005).

Research has revealed that despite treatment, patients with symptomatic intracranial atherosclerosis have unacceptably high rates of recurrent cerebrovascular ischemic events,



coronary heart disease and death (Leung *et al.* 2006). To date, the best medical treatment for intracranial atherosclerosis remains controversial and aspirin is commonly used as the standard treatment. Anticoagulative medications have shown little success at reducing recurrent vascular events, the Warfarin-Aspirin Symptomatic Intracranial Disease (WASID) Trial failed to show a significant risk reduction of primary end-points (stroke and vascular death) when comparing warfarin treatment to aspirin. In addition, the WASID trial was prematurely terminated due to the mortality rates of the warfarin group (9.7%, 28/289) and the high incidence of major bleeding complications (8.3%, 24/289) compared to the aspirin group (Leung *et al.* 2006).

Due to poor patient outcomes with medical therapy, endovascular treatments have been proposed as an effective alternative. Percutaneous transluminal angioplasty (balloon angioplasty) was developed as a means of increasing lumen size at the region of stenosis via compression of the plaque. A recent study by Marks *et al.* (2005) found that percutaneous transluminal angioplasty is capable of reducing annual stroke rates to 3.36%, a substantial reduction compared to the approximate annual stroke rate for intracranial stenosis of 8% to 12% (Kirmani *et al.* 2005). However, restenosis rates for this technique ranges from 30% to 50% (Leung *et al.* 2006) and despite encouraging results, it is a hazardous procedure with reports of up to 50% complication rates and 17% fatality rates (Gupta *et al.* 2003).

An alternate technique involves the insertion of a stent at the site of the lesion; however this method is often technically difficult due to the limited flexibility of these stents. The introduction of more flexible stents (e.g. NeuroLink) designed specifically for intracranial use has enabled safer insertion and therefore treatment of intracranial atherosclerosis. A clinical trial utilising the NeuroLink (Guidant, CA) has a documented 95% success rates and one month post-operative stroke rates of 7%, as shown in the Stenting in Symptomatic Atherosclerotic Lesions of Vertebral Intracranial Arteries (SSYLVIA) study (The SSYLVIA study investigators 2004). However, restenosis rates remain unsatisfactory with 32% of patients developing $\geq 50\%$ restenosis after 6 months (Henkes *et al.* 2005).

A new concept for percutaneous intracranial angioplasty involves the use of a self-expanding stent. This new stent, the WingSpan (Boston Scientific, Fremont, CA), is a self-expanding, neurovascular, flexible nitinol stent with purportedly excellent trackability in intracranial vasculature (Leung *et al.* 2006). This procedure begins with a stentless angioplasty, followed by covering of the previously dilated stenosis with the WingSpan stent (Henkes *et al.* 2005). The rationale for this new procedure is that the radial self-expanding force which the stent exerts after deployment would result in a further gradual reduction in stenosis, therefore a smaller balloon can be used during the pre-dilation stage. The use of a smaller balloon should reduce the risk of vascular trauma, a state where the balloon can cause intimal dissection, recoiling or vessel rupture, which has been a recurring disadvantage in standard balloon angioplasty (Leung *et al.* 2006).



Clinical Need and Burden of Disease

Stroke is the third leading cause of death and the leading cause of adult disability in North America, Europe and Asia (Higashida *et al.* 2005). As previously stated, intracranial cerebral atherosclerosis accounts for approximately 8% to 10% of all ischemic strokes. This translates to 40,000 to 60,000 new stroke cases annually in the United States (Higashida *et al.* 2005). In Australia, the 2001 National Health Survey revealed that approximately 1.2% of Australians have suffered a stroke, this corresponds to 217, 500 Australians. There are approximately 40,000 to 48,000 stroke events a year in Australia (AIHW 2006); therefore approximately 3200 to 3840 of these are caused by intracranial atherosclerosis. Studies have shown that the annual stroke risk from all causes in patients with intracranial atherosclerosis ranges from at least 3.6% to over 13% annually (Higashida *et al.* 2005).

Estimated Speed, Geographic and Practitioner Use, Patterns of Diffusion in the Health System

The WingSpan stent is currently in the experimental stages and therefore has not been approved for marketing in any country. However, it has received humanitarian device exemption approval (HDE number: H050001) from the FDA in 2004 (Food and Drug Administration 2006).

The WingSpan stent is the only stent currently available which is designed specifically for the treatment of intracranial stenosis in conjunction with balloon angioplasty. If proven safe and effective, it may provide a safer alternative to standard balloon angioplasty or stenting.

Existing Comparators

Treatment of recurring ischemic stroke resulting from intracranial atherosclerosis currently includes:

- Medical therapy (antiplatelets and anticoagulants)
- Percutaneous transluminal angioplasty
- Coronary stent insertion
- Surgical bypass of the stenosis

Estimated Cost Impact

A representative from the University of Wisconsin Hospital stated that the total cost for the entire procedure (balloon angioplasty and WingSpan deployment) ranges from US\$48,000 to US\$ 125,000. The WingSpan stent itself costs US\$5000 (Kansas City Star 2006).

The Medicare Benefits Schedule does not list any reimbursements for the use of stents or balloon angioplasty for intracranial atherosclerosis. However, the reimbursement fees for extracranial to intracranial bypass using a superficial temporal artery (Item number: 39818) is



AU\$1581.45 while the reimbursements for extracranial to intracranial bypass using a saphenous vein graft (Item number: 39821) is AU\$1877.85. From July 2004 to June 2005, there were 14 Medicare claims for extracranial to intracranial bypass using a superficial temporal artery and 5 Medicare claims for extracranial to intracranial bypass using a saphenous vein graft (Medicare Australia 2006).

Efficacy and Safety Issues

List of Studies Found

Total number of studies	2
Case series	2

The studies included in this summary are highlighted in bold in the reference list.

Safety and efficacy data from 2 case series studies have been selected for inclusion in this summary.

A 45 patient multicentre clinical trial was conducted to determine the safety and efficacy of intracranial angioplasty and stenting utilising the Gateway™ PTA Balloon catheter and the WingSpan stent. The results of this trial was not published in any peer reviewed journals, instead data was extracted from the FDA Safety and Efficacy Summary. The investigators did not include a control group for this trial due to the fact that there is no alternative standard therapy for this disease, results were compared to historical controls extracted from peer-reviewed literature with similar patient cohorts. Of the 45 patients, intracranial angioplasty and stenting was feasible in 44 patients (97.8%). One patient was deemed unsuitable for the treatment due to tortuous anatomy. At 30 days post-treatment, 2/44 (4.5%) patients died due to ipsilateral stroke (stroke occurred at the same hemisphere of the targeted lesion), another 2 patients (4.5%) experienced major ipsilateral stroke, and there was one death (2.2%) due to cerebral haemorrhage 10 days post-treatment. At 6 months post-treatment, 42 patients were evaluated and the overall stroke rate was 9.5% (4/42 patients) with one death (2.4%). Analysis of vessel characteristics at 6 month post-treatment revealed the following results (Table 2) (Food and Drug Administration 2006):



Table 2: Vessel characteristics up to 6 months post-treatment

	Baseline (n=45)	Post PTA (n=44)	Post intracranial stenting (WingSpan) (n=44)	6 months post- treatment (n=40)
Reference vessel diameter (mm)	3.1 ± 0.8	3.2 ± 0.8	3.2 ± 0.8	3.1 ± 0.8
MLD at target lesion (mm)	0.8 ± 0.6	1.6 ± 0.6	2.1 ± 0.5	2.2 ± 0.8
% Stenosis	74.9 ± 9.8	50.0 ± 16.2	31.9 ± 13.6	28.0 ± 23.2
≥ 50% stenosis	100% (45/45)	54.5% (24/44)	0.0% (0/44)	7.5% (3/40)

The results indicate that there was a slight increase in MLD and a slight decrease in percentage stenosis at 6 months post-treatment; however these results were not significant. Despite this, the WingSpan stent was successful in maintaining ≤ 50% stenosis in 92.5% (37/40 patients) of patients 6 months post-treatment (Food and Drug Administration 2006). In comparison to the SSYLVIA study (normal stenting without prior balloon angioplasty), the overall stroke and death rate was lower (Table 3) but these results must be evaluated in the light of the shorter follow-up duration of the current study (174 days for WingSpan versus 216 days for SSYLVIA).

Table 3: SSYLVIA study vs Wingspan (45 patient) clinical trial

	All stroke rate	Death rate	All stroke and death	Ipsilateral stroke
SSYLVIA study (n=61)	13.1% (8/61)	6.6% (4/61)	13.1% (8/61)	11.5% (7/61)
WingSpan (n=45)	9.5% (4/42)	2.4% (1/42)	9.5% (4/42)	7.1% (3/42)

No parent vessel dissections or stent migration was reported during the WingSpan 45 patient trial. Four cases (4/44, 9%) of access site related complications were encountered and all required treatment. In addition, five patients (11%) suffered 7 access site related adverse events with four requiring treatment (Food and Drug Administration 2006).

The case series by Henkes *et al.* (2004) reported that balloon angioplasty and WingSpan stenting reduced stenosis from a baseline of 72% to 54% after balloon dilatation and to 38% after stent deployment in 15 patients. One patient who had a middle cerebral artery (MCA) stenosis suffered MCA branch occlusion as a result of the procedure, resulting in a transient increase of pre-existing hemiparesis. Ischemic symptoms that were observed in the remaining 14 patients prior to treatment were completely resolved after balloon angioplasty and stenting. No additional follow-up results were presented in this study. The authors



reported that the procedure went smoothly with a 100% success rate and no incidence of dissection or elastic recoil. Deployment of the WingSpan stent was uneventful, with no visible damage to the vessel and no cases of in-stent thrombosis (Henkes *et al.* 2004).

Ethical Issues

No issues were identified from the retrieved materials.

Cultural or Religious Considerations

No issues were identified from the retrieved materials.

Other Issues

No issues were identified from the retrieved materials.

Recommendation

Balloon angioplasty and WingSpan stent deployment offers a potentially safe treatment for intracranial atherosclerotic stenosis. However, the evidence available is limited and despite good clinical outcomes there is a need for larger multicentre trials with long-term follow-up to determine long-term patency and stroke rates. Comparative studies with standard balloon angioplasty or stenting would be valuable in determining the value of this procedure as well. Due to the potential benefits of this procedure, it is recommended that it is monitored for 12 months.

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|--------------------------------------------------|------------------------------------------------------------|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input checked="" type="checkbox"/> Monitor | <input type="checkbox"/> Archive |

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Search Criteria:

A search of MEDLINE, PubMed, *The Cochrane Library*, the Current Controlled Trials metaRegister, the UK National Research Register, the International Network of Agencies for Health Technology Assessment, relevant online journals and the Internet was conducted in April 2006.

Search terms used were: 'balloon angioplasty and stent', 'WingSpan stent', 'self-expanding intracranial stent', 'intracranial stent', 'intracranial angioplasty and stent', 'balloon dilatation and stent'.

This Horizon Scanning Prioritising Summary was prepared by Mr. Irving Lee from the NET-S Project, ASERNIP-S for the Health Policy Advisory Committee on Technology (Health PACT), on behalf of the Medical Services Advisory Committee (MSAC) and the Australian Health Ministers' Advisory Council (AHMAC).



PRIORITISING SUMMARY (2007 UPDATE)

NAME OF TECHNOLOGY:	INTRACRANIAL ANGIOPLASTY AND STENTING (WINGSPAN™ SELF-EXPANDING STENT)
PURPOSE AND TARGET GROUP:	PATIENTS SUFFERING FROM SYMPTOMATIC INTRACRANIAL ARTEROSCLEROTIC STENOSIS

2007 SAFETY AND EFFECTIVENESS ISSUES

A search of relevant databases, online journals and the Internet was conducted in June 2007, following the recommendation in June 2006 that intracranial angioplasty and stenting for cerebral atherosclerotic stenosis using the WingSpan self-expanding stent be monitored for 12 months. One new case series study on the safety and effectiveness of this procedure was identified. Additionally, the published report of the FDA Safety and Efficacy Summary was also identified and retrieved (Bose et al. 2007). However, the published paper did not present new information not previously reported in the FDA Safety and Efficacy Summary that was included within the original summary, it was therefore not included in this update.

Fiorella and colleagues (2007) reported their experience using the Gateway balloon and WingSpan stent system to treat 78 patients with 82 intracranial atheromatous lesions and $\geq 50\%$ stenosis in a prospective, multicentre study. Of the 78 included patients, 59 of them received previous, unsuccessful antiplatelet therapy. Eighty-one out of 82 lesions were treated with the Gateway balloon and WingSpan stent system. Stent placement was not possible in one patient due to a tortuous anatomy which prevented delivery of the WingSpan stent. However, due to recurrent stenosis during study period, this patient eventually received percutaneous transluminal angioplasty with successful delivery of the WingSpan stent at a later date.

Five major procedural complications (6.1%) were reported, including reperfusion haemorrhage, multiple posterior circulation strokes, contralateral embolic infarction, vessel perforation after angioplasty and guidewire perforation of the basilar apex. The last two complications were device related and resulted in death of both patients (device related death rate: 2.6%) on post-operative day five (vessel perforation) and during the procedure (guidewire perforation). There was one case of transient visual symptoms in one patient, which spontaneously resolved within 36 hours of the procedure. Post-implantation complications include five cases of extracranial parent vessel dissections (due to guide wire manipulation), two of which were flow limiting and required stenting. A subset of 38 patients also underwent post-procedural magnetic resonance diffusion weighted imaging analysis within 72 hours of the procedure. The results demonstrated that 13/38 (34.2%) patients had new ischemic lesions, ten of which were asymptomatic and the remaining occurred in patients who had suffered major complications (Fiorella et al. 2007).

Immediately post-angioplasty, the degree of stenosis decreased immediately from $74.6 \pm 13.9\%$ to $43.5 \pm 18.1\%$ ($n = 78$). After the implantation of the WingSpan stent, the degree of stenosis decreased again to $27.2 \pm 16.7\%$. Unfortunately the study did not include a further follow-up period and it is therefore uncertain whether this effect was maintained in these patients over time.



2007 HEALTHPACT ACTION

The clinical data available on the WingSpan stent system remains limited. The evidence indicates that this device is potentially effective as demonstrated by the immediate improvement in the degree of stenosis following implantation. However, there are no long-term results available at the time of writing. WingSpan will be monitored for an additional 12 months with the intent of retrieving long-term safety data.

2007 NUMBER OF STUDIES INCLUDED

Total number of studies	1
Level IV intervention evidence	1

2007 REFERENCES

Bose A, Hartmann M, Henkes H. A novel, self-expanding, nitinol stent in medically refractory intracranial atherosclerotic stenoses. The Wingsapn study. *Stroke* 2007; 38(5): 1531-1537.

Fiorella D, Levy EI, Turk AS et al. US multicenter experience with the Wingspan stent system for the treatment of intracranial atheromatous disease. Periprocedural results. *Stroke* 2007; 38(3): 881-887.



PRIORITISING SUMMARY (2008 UPDATE)

NAME OF TECHNOLOGY:	INTRACRANIAL ANGIOPLASTY AND STENTING (WINGSPAN™ SELF-EXPANDING STENT)
PURPOSE AND TARGET GROUP:	PATIENTS SUFFERING FROM SYMPTOMATIC INTRACRANIAL ARTEROSCLEROTIC STENOSIS

2008 SAFETY AND EFFECTIVENESS ISSUES

Two new case series studies were identified for inclusion in this 24 months update of the WingSpan stent.

Zaidat et al. (2008a) reported on the outcomes after stenting with the WingSpan in patients with 70% to 99% stenosis who have recently suffered a stroke or transient ischaemic attack. Data was collected from 16 medical centres worldwide, and all patients undergoing stenting with the WingSpan device under the HDE criteria (50% to 99% stenosis of a major intracranial artery with a cerebral ischemic event on anrithrombotic therapy between November 2005 and October 2006 were potential candidates for inclusion in this study. Patients were excluded if they had <70% stenosis, concurrent treatment with two stents for tandem intracranial stenoses, and if the WingSpan stent was used to treat an acute ischaemic stroke.

A total of 129 patients were enrolled into this registry (mean age: 64.2 ± 12.4 years, 55% male), and the indication for stenting was stroke (61%), transient ischaemic attack (29%) and other cerebral ischaemic event (10%). The intracranial arteries that were stented are: middle cerebral artery (33%), carotid (26%), vertebral artery (24%) and basilar artery (17%). The overall technical success rate was 96.7%. Immediately after stenting, diameter stenosis decreased from a pre-stenting mean of $82\% \pm 9\%$ to $20\% \pm 16\%$. Of the 129 enrolled patients, 52 had follow-up cerebral angiography at a mean of 4.8 ± 2.1 months. Restenosis ($\geq 50\%$) was evident in 13/52 patients (25%). Of these 13 patients who experienced restenosis, two patient had a stroke (2/13, 15.4%) that was attributed to stent occlusion. The periprocedural event rate (any stroke or death) was 6.2% (8/129). Other neurologic events included four cases of stent thrombosis, two cases of cerebral infarct on MRI with neurologic signs lasting less than 24 hours, two transient ischaemic attacks, two asymptomatic vessel dissections, two transient vasospasms and one patient was somnolent for 3 days (no infarct detected on MRI). During follow up, the event rate for any stroke or death within 30 days was 9.6%. The rate for stroke or death within 30 days or stoke in the territory of the stented artery beyond 30 days was 14% at 6 months post-implantation (Zaidat et al. 2008a).

The prospective case series by Levy et al. (2007) examined follow-up imaging results of 84 WingSpan-stented lesions in 78 patients with symptomatic intracranial atheromatous disease. The average interval between treatment and the most recent follow-up evaluation was 5.9 months. Imaging results revealed that in-stent restenosis was evident in 29.7% (25/84) of lesions while an additional 4.8% (4/84) had complete thrombosis. In-stent restenosis was more frequent within the anterior circulation compared t posterior circulation (odds ratio 4.7; 95% confidence interval: 1.4-15.5). Eight of the 29 patients



with in-stent restenosis or complete thrombosis were symptomatic. Four experienced stroke (2 in-stent restenosis, 2 thrombosis), and four experienced transient ischaemic attacks. Retreatment was conducted in 15 cases of restenoses.

In a second study by Zaidat et al (2008b), the effectiveness of intracranial self-expanding stents were examined as a means of intervention for acute ischaemic stroke in a retrospective analysis of nine patients. However, due the fact that two different stents were utilised, Neuroform and WingSpan, the combined results of these patients does not represent the effectiveness of WingSpan accurately. Complete and partial complete recanalisation was achieved in 67% and 87% of patients, respectively. Nevertheless, this study showed that acute stenting is technically feasible and achieves a relatively high rate of recanalisation. Further studies would be required to determine the potential utilisation of self-expanding stents as a means of rapid and safe recanalisation of occluded intracranial arteries in cases of acute ischaemic stroke.

In an effort to determine the influence of age and stenting site on the effectiveness of WingSpan, Turk et al. (2008) compiled the clinical and angiographic follow-up results of 31 young patients (≤ 55 years) and 62 old patients (>55 years) in five institutes. The investigators noted that in-stent restenosis was more frequent in younger patients (45.4% vs. 24.2%; odds ratio 2.6; confidence interval: 1.03-6.5). In young patients, the results showed that internal carotid artery lesions, especially those involving the supraclinoid segment, were very prone to in-stent restenosis (58.8% [10/17] and 88.9% [8/9], respectively). When patients of all ages were considered, supraclinoid segment lesions had much higher rates of in-stent restenosis (66.6% versus 24.4%) and symptomatic in-stent restenosis (40% versus 3.9%) in comparison with all lesion sites in this cohort.

2008 SUMMARY OF FINDINGS

The evidence to date indicates that the WingSpan stent is relatively safe with a high rate of technical success in patients with symptomatic intracranial arterial stenosis. In the largest registry on the use of WingSpan to date (Zaidat et al. 2008a), 25% of patients had $\geq 50\%$ restenosis. This was consistent with the results of Levy et al. (2007), which reported restenosis rates of 29.7%. However, the lack of randomised trials comparing WingSpan with medical therapy limits the conclusions that can be made with the available evidence. It is unclear if stenting results in a substantial relative reduction in risk compared to medical therapy.

A randomised trial on WingSpan is currently underway (Zaidat et al. 2008a), however it is not known if the results of this trial will be published in the near future.

2008 HEALTHPACT RECOMMENDATION

Due to the lack of comparative studies, the true effectiveness of WingSpan relative to medical treatment remains unknown. The WingSpan stent system is currently listed in the Australian Register of Therapeutic Goods (ARTG No.:130061). This device will be archived due to scarcity of evidence and the likelihood that comparative results will not be available in the near future.



2008 NUMBER OF STUDIES INCLUDED

Total number of studies 4
Level IV intervention evidence

2008 REFERENCES

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