Flow-Diverter Stent for the Endovascular Treatment of Intracranial Aneurysms
A Prospective Study in 29 Patients With 34 Aneurysms

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Background and Purpose—The purpose of this study is to report our preliminary experience with the flow-diverter Silk stent for the endovascular treatment of intracranial aneurysms.

Methods—This prospective study was approved by the authors’ ethical committees. Twenty-nine patients with 34 fusiform or wide-necked unruptured aneurysms were included and treated by Silk stent placement alone by 2 physicians in 3 different centers. Technical issues, immediate findings, delayed complications, clinical follow-up, and imaging follow-up at 3 and 6 months were assessed.

Results—Endovascular treatment was successfully performed in 26 patients (90%). In 3 patients, the stent could not be delivered. Mortality and morbidity rates were of 4% (1 of 26) and 15% (4 of 26), respectively; 1 patient died from a delayed aneurysm rupture related to stent migration, 3 experienced a thromboembolic event, and 1 patient developed progressive visual disturbances related to an increased mass effect. Clinical outcome in 25 patients was unchanged (n = 19), improved (n = 2), or worsened (n = 4). Angiographic follow-up in 24 patients (29 aneurysms) showed 20 complete occlusions (69%), 1 neck remnant (3.5%), and 8 incomplete occlusions (27.5%). Significant parent artery stenosis at 6 months occurred in 8 cases (33%).

Conclusions—Despite the potential interest of the Silk flow-diverter stent to treat complex intracranial aneurysms without coils, the delayed complication rate is quite high and leads to use this technique only in selective cases. (Stroke. 2010; 41:2247-2253.)

Key Words: detachable coils ■ intracranial aneurysms ■ stents

Endovascular treatment (EVT) is more and more considered as first-intention treatment of intracranial aneurysms. However, wide-necked and fusiform aneurysms remain technically challenging to treat by the endovascular approach. Self-expandable intracranial stents are increasingly used to treat these complex aneurysms with satisfying clinical and anatomic results.1,2 These stents are mostly used as bridging-neck devices in combination with coils. Very recently, flow-diverter stents have been developed and they offer the potential of aneurysm occlusion related to flow disruption.3-9 These stents share the propriety of forming high-coverage mesh once expanded that covers the neck and induces thrombosis of the aneurysmal sac at the same time as preserving patency of adjacent small vessels. The Pipeline stent (EV3, Irvine, Calif) is the first released flow-diverter stent and it has been evaluated in only 3 series.3-5 These authors showed that the Pipeline stent represents a safe, durable, and curative treatment of selected wide-necked, large, and giant aneurysms. The other available flow-diverter device is the Silk stent (Balt, Montmorency, France) and little information is available concerning its use.8,9 The aim of this prospective study was to report our preliminary experience with the Silk stent in 29 patients with 34 aneurysms.

Materials and Methods

Population
Between July 2009 and March 2010, 29 patients with 34 aneurysms were treated by Silk stent placement in 3 different hospitals. Approval from all 3 ethical committees was obtained for this prospective study. Therapeutic alternatives were discussed between neurosurgical and neurointerventional teams in a multidisciplinary decision-making process. Only patients with unruptured aneurysms were included because of the associated medication for stent placement. Indications of treatment with the Silk stent were as follow: (1) fusiform or circumferential aneurysms; (2) giant aneurysms or aneurysms that presented with mass effect; and (3) wide-necked saccular aneurysms (neck >4 mm or neck/sac ratio >0.7). We considered these aneurysms to have a high likelihood of failure and/or recurrence with conventional endovascular techniques.

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2247
There were 18 women and 11 men with a mean age of 46 years (range, 10 to 75 years). Clinical presentation and aneurysms characteristics are detailed in Table 1. Twenty-one patients were asymptomatic, whereas 8 patients were symptomatic because of a mass effect (n=5) or a transient stroke (n=3). Among 21 asymptomatic patients, indications for treatment in 16 patients were as follows: (1) remnant/regrowth from a previously coiled and/or clipped ruptured aneurysm (n=9); (2) previous subarachnoid hemorrhage (SAH) from another ruptured aneurysm (n=5); and (3) familial aneurysmal SAH (n=2). In the remaining 5 patients, the aneurysm was incidental. Mean aneurysm size was 10.3 mm (range, 2 to 28 mm).

**Silk Stent**

The Silk stent is made of 48 braided nitinol strands that offer the propriety of forming high-coverage mesh once expanded. This stent has 2 flared ends and a sinusoidal radiopaque wire once deployed. The Silk stent system includes a self-expanding stent, a delivery system, and a reinforced catheter for its placement. The delivery system allows for precise deployment of the stent.
procedure is similar to other self-expandable stent delivery and allows reshaping and repositioning of the stent when up to 90% of it has been deployed. Many diameters (2 to 5 mm) and lengths are available (15 to 40 mm). No tapered stent (increased diameter along the stent length) was available at the time of this study. To increase the stability of the stent, it is recommended to choose a stent length at least 3 times the diameter of the parent vessel plus the neck size.

Endovascular Procedure
In all cases, EVT consisted of stent delivery across the aneurysm (fusiform aneurysm) or its neck (wide-necked aneurysms) without subsequent coiling of the sac. EVT was performed on a biplane flat panel digital subtraction unit (Allura Xper 20/10; Philips) or on a single-plane flat-panel digital subtraction unit (Infinix VF-iSP; Toshiba). Two types of premedication were initiated in all patients according to local practice in the hospital: (1) 5 days before the procedure with 160 mg aspirin and 75 mg clopidogrel per day; and (2) 1 day before the procedure and on the procedure day with a loading dose of 300 mg clopidogrel and 320 mg aspirin. Endovascular procedures were performed under general anesthesia and systemic heparinization. The adequacy of systemic anticoagulation was monitored by frequent measurements of the activated clotting time. A baseline activated clotting time was obtained before the bolus infusion of 5000 IU heparin and hourly thereafter. The bolus infusion of heparin was followed by a continuous drip (1000 to 1500 IU/hour) with the purpose of doubling the baseline activated clotting time. Systemic heparinization was prolonged for 24 hours in all patients. All procedures were performed by 2 neurointerventionalists (B.L., X.L.). Unilateral femoral access was obtained and a 4-French navigational system to keep it in place. To obtain a good stent opening and vessel wall apposition were thus obtained in all but 1 case leading to asymptomatic artery occlusion. These patients were treated by stent-assisted coiling (Patient 27) or with a Pipeline flow-diverter stent (Patient 28). In Patient 29, we intended to place a Silk stent within the anterior communicating artery but angiographic controls, once the stent was partially delivered, showed a parent artery occlusion. The stent was removed and the patient treated by conventional coiling. No complication occurred during these 3 attempts.

Twentysix patients were thus treated among whom 4 experienced a procedural complication that was not associated with clinical consequence. In Patient 19, the ICA siphon presented with a stenosis located just before the aneurysmal sac. Once the stent was delivered, it was not fully expanded within the stenotic segment because of its low radial force. Significant flow reduction quickly occurred requiring urgent placement of a Wingspan stent (Boston Scientific) that completely restored the normal artery diameter. In Patient 5, a cavernous tear occurred after placement of the guiding Fargo catheter. Two Silk stents were placed to cover both the aneurysm and the tear but this latter one remained patent. Heparin was intentionally stopped causing asymptomatic ICA occlusion. In Patient 24 with significant recanalization of a coiled ruptured anterior communicating artery aneurysm, a small 2 1/15-mm Silk stent was placed from the left A1 to the left A2 segment of a bihemispheric anterior cerebral artery. Immediate occlusion of the right A2 segment occurred but it was asymptomatic thanks to excellent collateral circulation. Finally, Patient 25 experienced acute stent thrombosis leading to asymptomatic ICA occlusion. This patient was first treated with a very long “tutorial” stent (Leo/3.5 to 50 mm; Balt) followed by Silk stent placement within the first 1. Despite good visual stent opening, the ICA flow quickly decreased leading to asymptomatic artery occlusion.

Among 26 treated patients, satisfying stent opening and vessel wall apposition were thus obtained in all but 1 case (Patient 19). However, we always found it difficult to obtain a good stent opening in curved vessels (eg, ICA siphon) because the delivery catheter had to be constantly pushed back to help the stent deployment.

Clinical Outcome
A senior neurosurgeon or neurointerventionalist (L.C., G.R., M.B., O.D., J.P.P., X.L.) recorded the clinical course, including worsening of symptoms and death. Clinical outcome was graded at discharge, 3 and 6 months, according to a modified Rankin Scale.10

Anatomic Outcome
Immediately after Silk implantation, flow modification was classified as complete stasis (if no contrast material entered the aneurysm), significant flow reduction (if contrast stagnation was seen within the aneurysm at the late venous phase of the angiographic series), or slow flow (if the contrast circulation within the aneurysm became slower but without contrast stagnation into late venous phase images). Imaging follow-up protocol included a conventional angiography at 3 and 6 months. Aneurysm occlusion was rated as complete, neck remnant, or incomplete. Conventional angiograms were reviewed for all patients by 4 neurointerventionalists (B.L., L.C., G.R., X.L., J.P.P.).

Results

Endovascular Procedure/Technical Issues
Embolication was successfully performed in all but 3 patients (90%; see Table 1). In Patients 27 and 28, the Silk stent could not be delivered because of very high friction within the catheter. These patients were treated by stent-assisted coiling (Patient 27) or with a Pipeline flow-diverter stent (Patient 28). In Patient 29, we intended to place a Silk stent within the anterior communicating artery but angiographic controls, once the stent was partially delivered, showed a parent artery occlusion. The stent was removed and the patient treated by conventional coiling. No complication occurred during these 3 attempts.

Twenty-six patients were thus treated among whom 4 experienced a procedural complication that was not associated with clinical consequence. In Patient 19, the ICA siphon presented with a stenosis located just before the aneurysmal sac. Once the stent was delivered, it was not fully expanded within the stenotic segment because of its low radial force. Significant flow reduction quickly occurred requiring urgent placement of a Wingspan stent (Boston Scientific) that completely restored the normal artery diameter. In Patient 5, a cavernous tear occurred after placement of the guiding Fargo catheter. Two Silk stents were placed to cover both the aneurysm and the tear but this latter one remained patent. Heparin was intentionally stopped causing asymptomatic ICA occlusion. In Patient 24 with significant recanalization of a coiled ruptured anterior communicating artery aneurysm, a small 2 × 15-mm Silk stent was placed from the left A1 to the left A2 segment of a bihemispheric anterior cerebral artery. Immediate occlusion of the right A2 segment occurred but it was asymptomatic thanks to excellent collateral circulation. Finally, Patient 25 experienced acute stent thrombosis leading to asymptomatic ICA occlusion. This patient was first treated with a very long “tutorial” stent (Leo/3.5 to 50 mm; Balt) followed by Silk stent placement within the first 1. Despite good visual stent opening, the ICA flow quickly decreased leading to asymptomatic artery occlusion.

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Immediate Outcome
Of 26 treated patients, clinical outcome at discharge was unchanged in 22 patients, improved in 2 who presented with cranial nerve palsies that completely (Patient 17) or partially recovered (Patient 19), and worsened in 2 patients (see Tables 2 and 3). One patient (Patient 8) developed a progressive hypotension due to a retroperitoneal hematoma 12 hours after an uneventful EVT. Heparin was stopped and the patient developed mild arm paresis. MRI was performed and showed a distal middle cerebral artery infarct. One patient (Patient 20) who presented with partial cranial nerve palsies experienced increased visual disturbances a few hours after EVT.

Immediate anatomic results at the end of EVT included 4 complete stasis, 13 significant flow reductions, 13 slow flows, and 1 unchanged flow.
Delayed Complications

Delayed complications occurred in 4 patients, including 1 SAH (Patient 18) and 3 strokes (Patients 9, 12, 15). In Patient 18 with a giant saccular nonthrombosed carotid–ophthalmic aneurysm, a 4×30-mm Silk stent was placed across the aneurysm neck. The patient was discharged home and came back 13 days later with a massive SAH. Angiographic control showed migration of the stent within the sac and the patient died. In Patients 9, 12, and 15, acute clinical worsening occurred, respectively, 1 month, 4 months, and 2 weeks after stent placement. These 3 patients presented, respectively, with transient hemiparesis, arm paresis, and temporal hemianopsia. MRI was performed in all patients showing acute infarcts. Conventional angiography was also performed and showed significant intrastent stenosis in 2 patients (Patients 12 and 15) and no abnormality in Patient 9. In this latter patient, the fusiform basilar artery aneurysm was almost totally occluded at 1 month and we considered that a small perforator occlusion occurred during the healing process. A double dose of clopidogrel and aspirin was administered in all 3 patients. Patient 9 completely recovered, whereas Patients 12 and 15 kept a slight hand paresis and a temporal hemianopsia, respectively. There was no recurrence in Patients 9 and 12 but Patient 15 experienced 2 episodes of transient hemiparesis. Therefore, angioplasty with a HyperGlide balloon (EV3) was performed restoring a satisfying parent artery diameter. This latter patient is now asymptomatic for >1 month.

Follow-Up

Overall complication rate was of 38% (10 of 26; see Tables 2 and 3). Mortality and morbidity rates were of 4% (1 of 26) and 15% (4 of 26), respectively.

Final clinical outcome in 25 patients included 19 with modified Rankin Scale=0, 3 with modified Rankin Scale=1,
and 3 patients with modified Rankin Scale = 2. Angiographic controls were obtained in 24 patients (29 aneurysms), including 12 at 3 months and 12 at 6 months. These controls showed 20 complete occlusions (69%), 1 neck remnant (3.5%), and 8 incomplete occlusions (27.5%). Follow-up angiograms showed a parent artery stenosis in 8 cases (33%) that mostly occurred (5 of 8) when the distal end of the stent was placed within an artery that had a significantly smaller diameter than the proximal 1. In this situation, the stenosis was short and located at the distal end of the stent. However, in Patients 6, 10, and 23, a long stenosis occurred within the proximal portion of the stent.

Illustrative Case
A 38-year-old woman (Patient 23) presented with bilateral incidental fusiform aneurysms. Conventional angiography showed a large supraclinoidal fusiform ICA aneurysm (Figure A). Endovascular treatment was performed by Silk stent placement alone achieving a slow aneurysmal flow. The patient was discharged 48 hours later with a normal neurological examination. At 3 months, arterial (Figure B) and venous phases (Figure C) of the angiographic control show an aneurysm size/flow reduction and a significant parent artery stenosis.

Discussion
This study shows that the Silk stent may be useful for EVT of complex intracranial aneurysms. The concept of flow diversion appears promising in challenging lesions, including fusiform and/or giant aneurysms. However, this stent presents major limitations: (1) the aneurysm occlusion process is unpredictable; (2) an associated complication rate much higher than those previously reported with conventional treatments (coiling, balloon- or stent-assisted coiling, parent artery occlusion, clipping); and (3) a high rate of significant parent artery stenosis.

EVT Feasibility/Stent Deployment
To our knowledge, this is the first study evaluating this new device. By the use of telescopic catheters, the Silk stent may be placed in most patients. However, great caution should be taken when placing the distal access catheter (Fargo catheter; Balt) because a vessel tear occurred in this series. To avoid this complication, the Fargo tip must be steam-shaped at 45° to avoid straight and direct contact with the vessel wall.

Silk opening and wall apposition frequently require pushing back the delivery catheter. This is particularly mandatory within curved vessel such as the ICA siphon. After complete deployment, we always keep the guidewire to push back the delivery catheter within the stent length to ensure a good opening. Because of its low radial force, the Silk stent must be placed with great caution if the vessel shows a stenotic portion because vessel occlusion may occur. Moreover, careful size and length selection is mandatory because stent shortening and migration may happen. For all these reasons, Silk stent placement is more difficult than nonflow-diverter self-expandable stents.

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Immediate Flow Modification</th>
<th>Aneurysm Flow/Occlusion at 3 or 6 Months</th>
<th>Parent Artery Stenosis</th>
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<tr>
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<td>Incomplete (size and flow reduction)</td>
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<tr>
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<td>Slow flow</td>
<td>Complete</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Significant flow reduction</td>
<td>Complete</td>
<td></td>
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<td>4</td>
<td>Slow flow</td>
<td>Complete</td>
<td></td>
</tr>
<tr>
<td>5</td>
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<td>Complete</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Slow flow</td>
<td>Complete</td>
<td>+</td>
</tr>
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<td>7</td>
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<td>Complete</td>
<td>+</td>
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<td>Incomplete (flow reduction)</td>
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<td>Complete</td>
<td></td>
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<td>Complete</td>
<td>+</td>
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<td>Neck remnant</td>
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<td>+</td>
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<td>16</td>
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<td>Incomplete (flow reduction)</td>
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<tr>
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<td>Complete</td>
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<td>+</td>
</tr>
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<td>24</td>
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</tr>
<tr>
<td>26</td>
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</table>
Clinical Outcome
Despite the selected aneurysm population, most patients presented an unchanged or improved clinical examination. However, 1 patient died and 4 patients showed clinical worsening. It is very important to note that most symptomatic complications occurred in a delayed fashion after uneventful EVT. In 1 patient, stent migration caused a deadly aneurysm rupture 13 days after EVT. Other symptomatic complications included thromboembolism and an increased mass effect despite satisfying medication. Embolic events occurred when the stent was placed with its distal end within a significantly smaller vessel than the proximal one. We believe that the release of tapered stents will significantly decrease these delayed thromboembolic complications. Concerning other symptomatic complications, aneurysms that present with a mass effect might be at risk of worsening because of the acute thrombosis that may occur after stent placement.9 Indeed, one of our patient (Patient 20) experienced increased visual disturbance, but our series is too small to draw some conclusions.

Anatomic Outcome
Even if most aneurysms were occluded or showed decreased size and/or flow, the process of occlusion is unpredictable (Figure A–C). Therefore, the use of a Silk stent alone should be restricted to unruptured aneurysms or otherwise untreated ruptured aneurysms. Subsequent coiling might be helpful to promote quick aneurysm occlusion. However, if coils are needed, we believe that “conventional” self-expandable stents are much more safe and easy to use. Indeed, these stents have now been evaluated for >7 years and very good clinical and anatomic results were obtained.1,2 Moreover, the major goals of EVT (aneurysm occlusion, stent tolerance) are achieved and predictable. After this study, we think that these stents should remain the first-intention devices to use when stenting is required.

Silk stent tolerance is relatively poor with a 33% rate of significant parent artery stenosis in this study. Most stenoses were short, occurring when the distal stent part was deployed in a vessel with a significantly smaller diameter than the proximal one. Indeed, because of its low radial force, the distal stent flared end has a tendency to close. Fortunately, the recent release of tapered stents will probably decrease this occurrence. Nevertheless, in 3 cases (Patients 6, 10, 23), the stenosis was long and located within the proximal part of the stent (Figure A–C). In 2 of these 3 patients, aneurysm could easily be occluded if we could stop medication because of a significant size and flow reduction. In this situation, medication must be continued because of the iatrogenic stenosis. Nevertheless, larger studies with longer follow-up are needed to draw final conclusions because spontaneous disappearance of these stenosis has recently been reported.11 Moreover, in 3 patients (Patients 2, 7, 24), a 2×15-mm Silk stent has been used in very small vessels without any sign of parent vessel stenosis.

Within the literature, only 2 cases reports have been published over the use of the Silk stent.8,9 In the most recent one, the authors have reported the occurrence of a SAH 20 days after uneventful EVT in a patient with an unruptured paraophthalmic aneurysm.9 The authors have discussed some hypotheses, including the instability of the intra-aneurysmal thrombus, as a possible cofactor leading to aneurysm rupture. On the other hand, some physicians have recently and orally reported (ABC-WIN meeting, Val d’Isère, France, 2010) some unanticipated problems, including delayed bleeding. That is the reason why the manufacturer, Balt, has sent a field safety notice advising the use of Silk only with coils and/or in a randomized study. There is no doubt that a prospective registry and/or a randomized study is mandatory to evaluate the effectiveness and complication rate on a very large patient population.

Major limitations in our study include the small patient population and the absence of a control group (eg, randomization between Silk stent and conventional techniques or between Silk and the other flow-diverter device called the Pipeline).

The only other flow-diverter stent available is the Pipeline stent that has been evaluated in 3 recent studies.3–5 This stent is made of a different metallic alloy that provides higher radial force. The Pipeline device has no flared ends and currently available stents are no longer than 20 mm. In these series, the authors are reporting very good clinical and anatomic outcomes in most patients. Indeed, no serious clinical complication is reported except 1 death related to perforation of another aneurysm during EVT.5 Concerning the aneurysm occlusion process, the effect of the Pipeline stent in improving over time all but 1 aneurysm occluded at 12 months in the largest series of 63 treated aneurysms is clear.4 Therefore, longer follow-up is needed to evaluate the real efficacy of the Silk stent. Angiographic controls with the Pipeline device are showing good tolerance of the stent without significant parent artery stenosis. However, no direct comparison can be done unless a prospective randomized study comparing both stents is set up. The major limiting characteristic of the Pipeline device is the need to telescope stents in some cases to achieve significant flow modification.

Figure. Bilateral incidental fusiform aneurysms in a 38-year-old woman. Conventional angiography shows a large supraclinoidal fusiform ICA aneurysm (A). At 3 months, angiographic control at the arterial (B) and venous (C) phases shows an aneurysm size/flow reduction and a significant parent artery stenosis.
or to cross a large fusiform sac that may be treated with a single long Silk stent.

Conclusion

Our prospective study is the first one evaluating the new flow-diverter Silk stent. Despite its potential interest to treat complex intracranial aneurysms without coils, the delayed clinical and anatomic complication rates are quite high and lead one to use this technique only in selective cases. Further studies with longer follow-up are needed to evaluate the place of this device in the therapeutic armamentarium of intracranial aneurysms.

Disclosures

None.

References

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