The Neuroform stent system (Boston Scientific, Natick, Massachusetts) has been designed as an adjunctive tool in the coiling of wide-neck aneurysms. It is a self-expandable open-cell nitinol stent that can be used to bridge the aneurysm neck and aids in reconstructing and protecting the parent artery. In this study, we analyze our experience in the use of the Neuroform system.

BACKGROUND AND PURPOSE: Intracranial stent placement assists in the coiling of wide-neck aneurysms and aids in reconstructing and protecting the parent artery. In this study, we analyze our experience in the use of the Neuroform system.

MATERIALS AND METHODS: Records of patients treated with a Neuroform stent from June 2003 to September 2007 were retrieved from a data base for analysis of population characteristics, occurrence of complications, and acute and midterm angiographic results.

RESULTS: Sixty-eight patients harboring 76 aneurysms located primarily in the anterior circulation were treated. There were 5 cases (6.6%) of clot formation after deployment (1 with a permanent neurologic deficit), 1 case of perioperative stent displacement with hemorrhage, and 5 cases (6.6%) of transient neurologic deficit due to thromboembolic events. The morbidity-mortality rate at discharge was 2.9%. One patient presented with a delayed in-stent thrombosis, and 3 others, with silent stenosis. Twenty-four aneurysms (31.6%) were completely occluded in the initial embolization. However, a marked increase in the occlusion rate was observed, with 44 of the 68 aneurysms (64.7%) examined at the 18-month follow-up and 26 of the 46 aneurysms (56.5%) examined in the 3-year follow-up presenting with complete occlusion. At the end of the study, a neck remnant was present in 6 aneurysms (13%) and a residual sac, in 7 (15.2%). Mean follow-up time was 25.7 months.

CONCLUSIONS: The present series demonstrates the relative safety and feasibility of the Neuroform stent—assisted coiling technique, which seems to provide better results over coiling alone for wide-neck aneurysms. Angiographic results improve with time due to progressive thrombosis of the aneurysm.

ABBREVIATIONS: ASA = aspirin; CI = confidence interval; D = largest aneurysm diameter; DSA = digital subtraction angiography; GDC = Guglielmi detachable coil; ICA = internal carotid artery; MCA = middle cerebral artery; MRA = MR angiography; OR = odds ratio; PICA = posterior inferior cerebellar artery

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treatment for wide-neck aneurysms or as a retreatment option for a recanalization.

No aneurysm was stented in the acute phase of a subarachnoid hemorrhage. In cases of retreatment of a previously ruptured aneurysm, the second endovascular procedure was performed at least 30 days after the bleeding episode.

Evaluation of the Aneurysm Neck
Neuroform stents were used in 2 different situations: wide-neck aneurysm (dome-to-neck ratio <2 or neck diameter >4 mm) and unfavorable anatomy, such as MCA trifurcation or aneurysm-neck-to- parent-artery diameter ratio <1.

Endovascular Procedures
Every procedure was performed via a femoral approach with the patient under general anesthesia. A 6F guiding catheter was introduced through a femoral sheath into the carotid or vertebral artery. The radiologic examination of the target vessel was performed by using a biplane angiographic system (Neurostar T.O.P.; Siemens, Erlangen, Germany) and 3D rotational angiography.

Between 2003 and 2007, 3 successive generations of the Neuroform stent system were developed by the manufacturer and used in our department. The appropriate Neuroform stent size and length were chosen according to the largest diameter of the parent artery and the length of the aneurysm neck. The goal was to ensure arterial wall coverage of at least 5 mm beyond both the distal and proximal limits of the neck. Microcatheters were positioned either through the stent interstices or positioned inside the aneurysmal sac before stent deployment (“jailing” technique).

Anticoagulation/Antiplatelet Regimen
Patients were prepared with a loading dose of clopidogrel (300 mg) the day before the endovascular treatment. During the procedure, they were anticoagulated with a bolus of standard heparin (70–100 IU/kg) followed by an intravenous drip through an automated syringe (40–60 IU/kg/h) to maintain an activated clotting time of ≥250 seconds. At the end of the procedure, they received an IV dose of 250–500 mg of ASA. Then, a daily dose of clopidogrel (75 mg) and ASA (75 mg) was administered for 2 or 3 months. Since September 2006, platelet inhibition has been tested by using a point of care (VerifyNow P2Y12 Test; Accumetrics, San Diego, California) system immediately before starting the procedure. If the patient was considered a nonresponder (<40% platelet inhibition), a reloading dose of clopidogrel (300 mg) was administered as soon as the patient awakened from anesthesia.

Anatomic Result Assessment
Each angiographic result was categorized according to the revised Raymond classification into 1 of the following groups: complete occlusion, remnant neck, and residual aneurysm.

Follow-Up
Follow-up examinations with MRA were scheduled at 6 and 18 months with DSA and at 3 years with MRA. In cases of early recanalization, the DSA control was scheduled earlier to assess the need for retreatment.

Statistical Analysis
Frequencies and percentages were calculated for categoric variables, and means and SDs, for continuous variables. Patients treated for 2 aneurysms were analyzed and categorized independently. Comparisons of rates of complete aneurysm occlusion between the immediate postoperative and follow-up terms and between follow-up terms were performed by using the χ² test. To verify possible associations between treatment efficacy and the type of coil used, we compared the rates of complete occlusion in each group of coil type (bare coil, bioactive coil, or HydroCoil [MicroVention Terumo, Aliso Viejo, California], >50% of the total length) at every follow-up. This comparison was performed by using the χ² or the Fisher exact test when samples were insufficient (<5). To avoid confounding factors, we constructed a model of logistic regression for each follow-up term. Possible confounding factors considered were sex, initial aneurysm diameter, and type of procedure (a first choice for a wide-neck aneurysm or a retreatment option for a recanalized aneurysm). Those results were analyzed by using ORs and 95% CIs. The association between 2 compared variables was considered significant if the 95% CI of the OR did not include 1. The level of statistical significance used was P < .05 for the whole study. Statistical analysis was performed by using the SAS 9.1 software (SAS Institute, Cary, North Carolina).

Results
Patient Population
Sixty-eight patients harboring 76 cerebral aneurysms were treated with a Neuroform stent—assisted technique between June 2003 and September 2007, 48 women and 20 men. The mean age at the time of the endovascular treatment was 53.2 ± 15.2 years. The Neuroform stent was used as a first option in 51 procedures (67.1%) and for treating a partial aneurysm recanalization in 25 others. Two retreatment procedures were performed for aneurysms that had regrowth after surgical intervention.

The mean follow-up period was 25.7 ± 14 months. At the time of this study, 68 of the 76 aneurysms had been followed for more than 1 year.

Implanted Neuroform Stents
A single first-generation Neuroform stent was implanted once. The Neuroform2 stent was implanted for treatment of 26 aneurysms in 24 patients, and the Neuroform3 stent was used for treatment of 49 aneurysms in 45 patients. Most aneurysms were treated by using a single-stent deployment (n = 70).

Two kissing stents in the same procedure were used for treating an aneurysm of the top of the basilar artery. There were 2 cases of telescopic stent deployment. A rescue stent or a finishing stent deployment following the balloon remodeling technique was performed in a limited number of cases (n = 8).

Aneurysm Location
Most aneurysms (89.5%) were located in the anterior circulation. Patients with carotid-ophtalmic aneurysms represented one-third of the population, and the MCA was the second most frequent location. Aneurysm locations are summarized in Table 1.

Aneurysm Size
The mean size of the 76 treated aneurysms was 8.2 ± 5.3 mm. They were categorized into 4 different groups: small (<6 mm, 25 cases, 32.9%), medium (6–10 mm, 31 cases, 40.8%), large
Table 1: Distribution of 76 aneurysms treated with Neuroform stent system—assisted coiling in the anterior and posterior circulations

| Aneurysm Type                      | As a First Treatment | As a Second Treatment | Total No. of Aneurysms |
|------------------------------------|----------------------|-----------------------|------------------------|
| Anterior circulation               | 46 (60.5%)           | 22 (28.9%)            | 68 (89.5%)             |
| Carotid-ophthalmic                 | 20                   | 5                     | 25                     |
| MCA                                | 13                   | 6                     | 19                     |
| Intracavernous carotid             | 5                    | 0                     | 5                      |
| Pericallosal artery                | 0                    | 1                     | 1                      |
| ICA bifurcation                    | 4                    | 3                     | 7                      |
| Supraclinoidal ICA                 | 1                    | 4                     | 5                      |
| Anterior communicating             | 3                    | 3                     | 6                      |
| Posterior circulation              | 5 (6.6%)             | 3 (3.9%)              | 8 (10.5%)              |
| Top basilar artery                 | 2                    | 2                     | 4                      |
| Basilar artery                     | 1                    | 0                     | 1                      |
| PICA                               | 1                    | 1                     | 2                      |
| Posterior cerebral artery          | 1                    | 0                     | 1                      |

(10–25 mm, 19 cases, 25%), and giant (>25 mm, 1 case, 1.3%).

Types of Coils
Different types of coils were used for stent-assisted embolization. Bare platinum coils (GDC from Boston Scientific; Trufill from Cordis, Miami Lakes, Florida; and MicroPlex from MicroVention were used in 11 cases (14.4%). Bioactive coils (Matrix from Boston Scientific and Nexus from ev3, Irvine, California) were used in 41 (53.9%), and HydroCoils (MicroVention) were used in 24 cases (31.5%). Generally, bare coils or bioactive coils were used to treat small or medium-sized aneurysms (44 of 56, 78.6%). HydroCoils were preferred for large or giant aneurysms (12 of 20, 60%). The main criterion for choosing coil type was aneurysm size.

Procedure-Related Complications
There was 1 case of secondary stent displacement, probably due to impingement of the microguidewire through the open cells at the time of retrieval. The initial deployment was accurate. The patient had subarachnoid bleeding and worsening of a pre-existing neurologic deficit (final modified Rankin Scale score = 4). There were 5 cases of clot formation near the neck of the aneurysm after stent deployment (during aneurysm coiling). Those patients received a glycoprotein IIb/IIIa inhibitor dose with good angiographic results, but 1 patient had a mild permanent deficit (modified Rankin Scale score = 2).

In the immediate postprocedural period, 5 patients presented with acute neurologic deficits due to downstream thromboembolic events, confirmed by MR imaging. Those patients received an IV bolus of abciximab (25 mg/kg), then a 12-hour infusion (125 μg/kg). A complete recovery was obtained in all cases. At discharge, there was no mortality, and the prevalence of a persistent neurologic deficit was 2.9% (2/68 patients).

Delayed Complications
A 5-month delayed ischemic stroke due to intrastent thrombosis was observed. The patient had been treated for an anterior cerebral artery aneurysm and was still under ASA therapy.

Two years after the stroke, his modified Rankin Scale score was 3.

Three cases of mild clinically silent in-stent stenosis were observed. In 2 of them, a parac doloid ICA and an MCA aneurysm, the stenosis was depicted on the 6-month MRA. In the third, an ICA bifurcation aneurysm, it was characterized by DSA 15 months after the embolization.

Immediate and Midterm Results
A follow-up angiogram (MRA or DSA) was available for all aneurysms treated. At the time of this study, the overall time of follow-up ranged from 4 to 52 months (mean, 25.7 ± 14.0 months). Sixty-six of the 76 aneurysms had a follow-up period longer than 1 year. Three patients were no longer followed after 4, 6, and 9 months because of transfer for follow-up elsewhere. Three others died between 6 and 8 months after treatment for reasons independent of their brain aneurysms.

Angiographic results are presented for the immediate postoperative and 3 follow-up terms, at approximately 6 months, 1 year and 6 months, and 3 years (Table 2). The mean follow-up periods at the moment of each analysis were 6.54 ± 1.56 months, 16.41 ± 3.83 months, and 37.09 ± 9.6 months, respectively.

On the immediate postprocedural angiogram, 24 of the 76 treated aneurysms (31.6%) were completely occluded. Twenty aneurysms (26.3%) presented with a neck remnant and 32 (42.1%) showed a residual filling inside the aneurysm sac.

At the time of this study, 58 aneurysms had already been re-examined at the first follow-up, 68 at the second, and 46 at the third. On the first control angiogram, 37 (63.8%) presented with a complete occlusion, which was a statistically significant improvement over the immediate postoperative results. Seven aneurysms (12.1%) presented with a neck remnant, and 14 (24.1%), with a residual aneurysm.

The rates of complete occlusion at each of the 3 follow-up terms were statistically different from the results observed on the immediate postoperative angiogram: 63.8% (n = 37, P < .01) for the first, 64.7% (n = 44, P < .01) for the second, and 56.5% (n = 26, P < .01) for the third. The percentage of complete occlusion was relatively stable after the first follow-up. No statistical difference was found when comparing the first with the second follow-up (P = .91), the first with the third follow-up (P = .45), or the second with the third follow-up (P = .37).

Progressive thrombosis and subsequent increase of the degree of aneurysm occlusion between the immediate postoperative and follow-up angiograms were observed in 50% of the treated aneurysms (38/76). Of the initial population of 76 aneurysms, 13 (17.1%) that presented with a neck remnant after stent-assisted coiling were completely occluded at the first follow-up. Twenty-two (28.9%) presenting with a residual sac on the immediate postoperative angiogram progressed to complete occlusion, and 3 others (3.9%), to a neck remnant. The conditions of 17 patients with complete occlusion remained stable (17/76; 22.4%). However, 6 aneurysms with an initial complete occlusion and 5 with a neck remnant recanalized.

The analysis by aneurysm size subgroups shows similar rates of complete occlusion for small, middle-sized, and large aneurysms (Table 3). Six cases (8.8%) of major recurrence
were detected and were treated after the first follow-up, and 1 case, after the second.

Rates of complete occlusion were also analyzed by coil type. The highest rate of complete occlusion at the final follow-up was obtained in the group treated with HydroCoils (60%). For the largest group, those treated with bioactive coils, the complete occlusion rate was 55.2%. A rate of 57.1% of completely treated aneurysms was obtained with bare coils. No statistically significant association was encountered between complete occlusion and coil type at any time during of the follow-up period.

Discussion
The debate on the ideal management of unruptured intracranial aneurysms is far from finished. The outcome of coil embolization is related, in part, to aneurysm geometry. Aneurysms with wide necks are often poor candidates for treatment with coil ing alone. A wide-neck configuration prevents complete packing, resulting in higher rates of regrowth, often requiring subsequent retreatment. In addition, implanted coils may herniate from the aneurysm sac into the parent artery, causing thromboembolic complications or vessel occlusion.

The balloon-assisted or “remodeling” technique presents total occlusion rates ranging from 67% to 100% in aneurysms that are considered difficult to treat.6 This technique potentially increases the risk of ischemia from thromboembolic events related to the temporary occlusion of the parent artery, repeated inflations, and the use of 2 microcatheters. Other risks are vasospasm, occlusion of perforators, vessel damage, and aneurysm regrowth or bleeding from the repetitive stress transmitted by the balloon.5,6,9 The increase in the incidence of thromboembolic complications with balloon-assisted coiling is not invariably encountered. However, the presence of wide-neck aneurysms has been independently associated with thrombus formation (whereas the use of clopidogrel has been considered to be protective).7

Since the advent of self-expandable flexible stents, stent-assisted coiling has become a viable option in the treatment of wide-neck aneurysms and, more recently, for medium and small-sized aneurysms.8 Stents prevent herniation of coils into the parent artery, alter flow dynamics, increase packing attenuation, favor thrombosis, and may provide a scaffold for endothelial growth.8,9

From the beginning of the present series until January 2007, Neuroform stents were used for treating cerebral aneurysms in our department. More recently, Enterprise stents (Cordis) have also been available. Frequent reasons for preferring a Neuroform stent were situations in which an open cell was needed, as in the case of crossing the stent with a microcatheter. Furthermore, with a Neuroform stent, it seems easier to access the aneurysm sac in cases of microcatheter kickback into the parent vessel.

Technical failures that occurred with the first- and second-generation Neuroform stents were mainly related to poor navigability through tortuous vessels.3 An inappropriate opening could result in unsatisfactory deployment with only partial covering of the aneurysm neck, which could be overcome by placement of a second stent.18

High procedural adverse event rates (21.4%) and adverse outcomes have been reported in the acute phase of ruptured aneurysms treated with stent assistance.19,20 However, procedural complications were not increased by the use of the Neuroform stent in incidental aneurysms. Iatrogenic hemorrhages occur rarely but may be life-threatening. Rebleeding from a previously ruptured aneurysm, vessel perforation by the microguidewire, and delayed intracranial hematoma or groin hematoma account for significant morbidity and mortality.11,21

To our knowledge, subarachnoid bleeding resulting from a
Neuroform stent displacement while retrieving the microguidewire has not been reported until now. We presume that the case we describe here resulted from guidewire encroachment through the stent cells.

In our experience, the combination of a loading dose of clopidogrel the day before the procedure, a real-time platelet inhibition test in the interventional operating room, and a double regimen of antiaggregation after the endovascular treatment allowed the reduction of the incidence of thromboembolic events by 2-fold, by using as a baseline a previously reported series of the same group.\textsuperscript{22} The largest series to date (142 aneurysms) reports 2.8% permanent morbidity and 2% mortality associated with use of the Enterprise stent.\textsuperscript{23} Fiorella et al\textsuperscript{15} reported a higher rate of thromboembolic events (9.3%) by using the Neuroform stent. However, some patients were treated in the acute setting of subarachnoid hemorrhage. Other authors declared very low rates (4%)\textsuperscript{23} or no adverse events at all.\textsuperscript{12}

Antiplatelet agents are used in patients intended for endovascular stent placement. Muller-Schunk et al\textsuperscript{24} reported that a significant number (28%) of individuals were nonresponders to clopidogrel. In their series, the response was evaluated by impedance aggregometry by using a point-of-care assay. All thromboembolic events (10%) registered were in the group of nonresponders. Furthermore, insufficient platelet inhibition has been associated with an increased risk of thrombus formation within the stented segment.\textsuperscript{11} Thus, a level of 40% of platelet inhibition by using the VerifyNow system has been recommended.\textsuperscript{25,26}

Delayed in-stent thrombosis has been related to platelet medication discontinuation or clopidogrel resistance. Subacute stent thrombosis can occur even in patients who are treated with standardized antiplatelet therapy. In a recent series, 3 patients harboring aneurysms of the basilar artery, posterior inferior cerebellar artery, and anterior cerebral artery were treated with placement of a Neuroform stent and presented with subacute symptomatic in-stent thrombosis (at days 1, 2, and 12, respectively). In 2 cases, they were treated successfully with superselective local infusion of recombinant tissue plasminogen activator.\textsuperscript{27}

We observed 1 case of delayed in-stent thrombosis and 3 cases of silent mild in-stent stenosis during the follow-up period. Stable in location and extent, conditions in those 3 patients did not require any specific treatment. The high sensitivity of 3D time-of-flight MR angiography for residual flow in treated cerebral wide-neck aneurysms has been recognized.\textsuperscript{28,29} However, stent-related artifacts compromise the evaluation of the true lumen of the parent artery.\textsuperscript{30} Fiorella et al\textsuperscript{13} reported an incidence of 5.8% of delayed Neuroform in-stent stenosis. In their series of 156 aneurysms, 9 patients developed a moderate-to-severe stenosis and 2 of them had a complete vessel occlusion. Two patients developed focal neurologic signs in the first 3 months that followed the stent implantation and were treated with balloon angioplasty. One patient required a subsequent superficial temporal-artery-to-MCA bypass. On the other hand, spontaneous resolution was documented in 4 of 7 asymptomatic cases, while 2 progressed to complete occlusion.

Achieving complete and stable occlusion is still a challenge. Recanalization rates remain suboptimal, which has been a particular problem in subjects with large or wide-neck aneurysms or aneurysms in certain locations such as the carotid-ophtalmic artery or MCA.\textsuperscript{31} In the series of Raymond et al,\textsuperscript{32} (n = 501) of ruptured and unruptured aneurysms, important predictors of angiographic recurrence were aneurysm size (>10 mm), treatment during the acute phase of rupture, incomplete occlusion, and duration of follow-up. In another study by Murayama et al,\textsuperscript{33} an analysis of an 11-year experience with embolization of cerebral aneurysms with GDC coils showed an overall recanalization rate of 20.9%, which was correlated to the size of the dome and of the neck of the aneurysm. Additional thrombosis was observed in 41.4% of small aneurysms with small necks, while it occurred in only 17.6% of small aneurysms with wide necks.

Techniques implemented to minimize recanalization include complex-shaped coil packing,\textsuperscript{35} use of bioactive coils, use of HydroCoils, and the use of adjunctive devices.\textsuperscript{36,37} Clinical results with coils coated with the biocompatible copolymer polyglycolic/polyactic acid\textsuperscript{38,39} (Matrix and Nexus coils) failed to prove beneficial in preventing recanalization, even though the occurrence of progressive thrombosis was documented.\textsuperscript{40} The overall recurrence for small and large aneurysms treated with HydroCoils does not seem lower than the previously published rates with platinum coils, as characterized by the initial angiographic results of the HydroCoil for Endovascular Aneurysm Occlusion study.\textsuperscript{40}

Stents may contribute to the progression of thrombosis, independent of the size of the aneurysm and the type of coils used. Fiorella et al\textsuperscript{15} reported, in patients treated with Neuroform stent—assisted coiling, an improvement of anatomic results with progressive thrombosis in 52% of the cases. In the same series, the results were stable in 25% of cases and recanalization occurred in 23%. Lubicz et al,\textsuperscript{14} by using Leo (Balt, Montmorency, France) and Enterprise stents, observed further thrombosis in 53% of aneurysms coiled with MicroPlex bare coils or GDCs. The final results of the present series are similar to those previously reported, with progressive thrombosis of the aneurysm documented in 55%, unchanged results in 27.7%, and recanalization in 17.5% of cases.

The overall complete occlusion rate obtained with stent-assisted coiling seems superior to results obtained with coils alone\textsuperscript{44} or other adjunctive devices\textsuperscript{32} in cases of large or complex aneurysms. Sedat et al\textsuperscript{45} documented, at a mean follow-up of 42 months, 9.5% of aneurysmal regrowth. In our series, a relatively small number of major recurrences requiring retreatment are reported, with a complete occlusion rate of >50%.

Our study had limitations, including long-term results still not being available and a retrospective single-center design. Future perspectives should include the analysis of late angiographic and clinical outcomes. This would help interventionists in identifying the best candidates for stent placement and in taking into consideration accurate prognostic factors, which may go beyond aneurysm morphology.

**Conclusions**

The present series demonstrates that stent-assisted coiling techniques for treatment of difficult cerebral aneurysms can be feasible, effective, and relatively safe with the Neuroform stent system. This approach presents a small-to-moderate risk
of periprocedural complications or early recurrence. Neverthe-
less, the angiographic results presented here indicate that 
complete occlusion rates improve with time, due to progres-
sive thrombosis of the aneurysm sac.

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