New Generation of Flow Diverter (Surpass) for Unruptured Intracranial Aneurysms
A Prospective Single-Center Study in 37 Patients

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Background and Purpose—In patients harboring intracranial aneurysms, the major goal in treatment is to prevent bleeding. A new generation of an endoluminal device (Surpass Flow Diverter [Surpass]) was developed to reconstruct parent artery and occlude the aneurysm. We present our clinical and angiographic single-center experience.

Methods—Patients with a wide range of complex unruptured aneurysms were treated with the Surpass placed in the parent artery and bridging the aneurysm. Clinical and angiographic follow-up were performed at 6 months. Data were prospectively collected.

Results—Thirty seven patients (mean age, 56 years; range, 32–79), harboring 49 unruptured aneurysms were treated at our center. All except 1 patient were treated with a single device. Successful delivery of the device was achieved in all patients. All 35 nonbifurcation aneurysm necks were covered completely, whereas 14 bifurcation aneurysms were only partially covered. There was no major perioperative morbidity or mortality. During follow-up, 4 patients (10.4%) experienced transient neurological deficit. One patient (3%) developed a minor stroke at 4-month follow-up with persistent neurological deficit. Twelve patients had neurological symptoms related to their aneurysm and 7 showed improvement of these symptoms during follow-up. At 6-month follow-up, 29 of 31 aneurysms studied that had complete neck coverage showed a complete occlusion (94%) including 1 case with a 95% to 100% occlusion, whereas 5 of the 10 bifurcation aneurysms were occluded.

Conclusions—Our study shows high safety and efficacy profile of a new generation endoluminal device in treatment of complex intracranial aneurysms. Long-term studies of treated bifurcation aneurysms are needed. (Stroke. 2013;44:1567-1577.)

Key Words: flow diverter ■ hemorrhage ■ intervention ■ intracranial aneurysm ■ stroke ■ treatment

As evidence is growing that the safety profile of coil embolization is superior to open surgical clipping for intracranial aneurysms, an increasing number of patients are being referred for endovascular treatment (EVT).\(^2\)\(^,\)\(^3\) However, intrasaccular coil-packing has been subject to criticism because of the high rate of recanalization of the aneurysm.\(^4\) This accounts especially for large, giant, wide-necked, and fusiform aneurysms, whereas blister aneurysms remain a challenge for EVT.\(^5\)\(^,\)\(^6\) Despite use of stent-assisted coiling, the recurrence rate remains significant.\(^6\)

The goal of EVT is a permanent and complete exclusion of the aneurysm from the circulation and endothelial coverage of the aneurysm neck. Histological specimens of coiled aneurysms obtained at autopsy and specimen of experimentally induced aneurysms show that complete endothelial coverage is not always obtained.\(^7\)\(^,\)\(^8\) The Surpass Flow Diverter (Surpass; Stryker Neurovascular, Fremont, CA) is a new generation of flow diverter for reconstruction of the parent artery and aneurysm occlusion. The implant maintains a high pore density, uniform across the aneurysm neck, and is unaffected by diameter of the parent artery. As implants with various diameters and lengths are available, 1 single implant is sufficient to treat the target aneurysm(s) and parent artery. We present preliminary results of 37 patients treated at our medical center with the Surpass device.

Materials and Methods

Patients
Between June 2010 and August 2012, a total of 49 aneurysms in 37 patients were treated with Surpass at the Department of Neurosurgery, Radboud University Nijmegen Medical Center. The first 10 patients were part of a safety and feasibility study, which was approved by the local institutional review board. All patients provided written informed consent to participate in this prospective study. Subjects were included in the safety and feasibility study if they had a nonruptured saccular or fusiform aneurysm that was difficult to treat by current available surgical or endovascular techniques. The remaining 27 patients were treated after receiving the CE Mark for Surpass and under commercial use of the device. Patients treated with the smaller 2.5-mm-diameter device were treated under compassionate use and with the approval of the local institutional review board.

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Indications for treatment with Surpass were aneurysms that were difficult to treat with standard therapy or the treatment was expected to have limited success as in large and giant wide-necked, fusiform, dissecting, blister-type, and multiple aneurysms associated with segmental disease. Patients were also enrolled when previously used standard therapy had failed (ie, recanalization after previous coiling or failed surgery).

Device
Surpass is a cobalt-chromium, low porosity (metal surface area coverage 30%), self-expanding tubular-shaped mesh structure with a high pore density (21–32 pores/mm² dependent on device diameter). To improve visibility, the device has 12 platinum wires integrated in to the mesh replacing equal numbers of cobalt-chromium wires.

The delivery system of Surpass is composed of an inner member (the pusher) and an outer member (microcatheter). The outer member is made from reinforced polymer tubing with different stiffness zones along its length. It is stiffer at the proximal end and most flexible at the distal tip to facilitate navigation into the distal neurovasculature. The inner member (pusher-wire) is made of tubing and is used to push the device out of the outer member. Like with most microcatheters, through the inner member any 0.014 microwire can be inserted to navigate the system.

The Surpass delivery system is advanced over a 0.014 microwire through the neurovasculature to the intended location. The delivery system is positioned at the desired location across the aneurysm neck or the diseased vessel segment within the parent artery. Once the accurate placement is confirmed, the pusher of the delivery system is slowly advanced while the outer member of the delivery system is held in place or retracted as needed to maintain proper position. As the device exits the lumen of the microcatheter, it expands and takes the shape of the vasculature. During this study, the Surpass delivery systems underwent major revisions and in total 3 different generations of the delivery system were used. In the most recently treated 22 patients, the fifth and last generations of the system were used and navigation and visibility were significantly better as compared with the first 15 patients that were treated with the third and fourth generations of the system.

To provide constant pore density over various diameters of the device, the 2.5-mm-diameter device has 48 wires, whereas the 3- and 4-mm devices have 72 wires and the 5-mm device is constructed of 96 wires. The manufacturer recommends the use of a single device.

Angiographic and Endovascular Procedure
All patients had a digital subtraction angiography of the aneurysm before the procedure. Patients were given acetylsalicylic acid (80 mg daily) and clopidogrel (75 mg daily) 5 days before the intervention. One patient was treated acutely for a dissecting aneurysm of the distal cervical segment of the left internal carotid artery (ICA) and received 500 mg acetylsalicylic acid and 600 mg clopidogrel on the day of and before the procedure. Dual antiplatelet treatment was continued for 3 to 6 months, followed by life-long continuation of acetylsalicylic acid. Five patients were treated under conscious sedation; the other 32 procedures were performed under general anesthesia. Endovascular access was obtained by a standard transfemoral approach. In 1 patient, a right transradial access was required. Following access, patients were heparinized with an intravenous bolus of 100 U heparin/kg. Five patients with a posterior circulation aneurysm were treated using a coaxial system. In 29 of 32 patients with aneurysms located in the anterior circulation, a triaxial system was used; whereas in remaining 3 patients, a coaxial system was used. The Surpass delivery system was advanced across the neck of the aneurysm. Subsequently, the delivery pusher-catheter was advanced to deploy the device. In some cases, implantation was enabled by advancing the pusher-catheter and simultaneously withdrawing gently the device delivery microcatheter. After the device deployment, a follow-up angiography was performed to document flow stagnation within the aneurysm and to rule out any possible thromboembolic events. Except in 2 cases, no coil were used in conjunction with Surpass.

Clinical Evaluation
A complete neurological examination was performed in all patients at baseline, immediately after the procedure, at discharge and at 30-day and 6-month follow-up. In patients enrolled in the safety and feasibility study, a neurologist not involved in the endovascular procedure carried out these examinations. In the commercial cases, physicians from the Department of Neurosurgery performed the neurological examinations. A modified Rankin Scale score was assessed at baseline, at discharge, and at follow-up evaluations. Primary adverse events included death and stroke. Secondary adverse events recorded were transient ischemic attack (TIA), need for reintervention, and presence of hematomas. Medical histories, procedural reports, and clinical outcomes were recorded in a prospective database.

Angiographic Evaluation
Angiographic follow-up was scheduled for 6 months after device implantation. Using the formula for volume of an ellipsoid ($V = \frac{4}{3}\pi abc$), a core laboratory not involved in patient care calculated the aneurysm occlusion in percentage of total aneurysm volume. Any parent artery occlusion or stenosis $>50\%$ was reported.

Results
Baseline Patient and Aneurysm Characteristics
We enrolled 37 patients harboring 49 unruptured aneurysms that were treated with the Surpass. Patient demographics and aneurysm characteristics are provided in Table 1. Thirty-two aneurysms originated from the ICA, 8 from the middle cerebral artery, 4 from the anterior cerebral artery, and 5 were located in the posterior circulation. Of these aneurysms, 14 were located at bifurcation sites. We included 14 single-saccular aneurysms (of which 4 had a wide-necked $>4$ mm) and another 5 were previously coiled aneurysms that presented with coil compaction and aneurysm recanalization. 24 multiple-saccular aneurysms were associated with a segmental disease, 10 fusiform/dissecting aneurysms (1 previously coiled), and 1 blister aneurysm. Twelve aneurysms were symptomatic. One symptomatic dissecting aneurysm of the distal cervical ICA segment had caused a major thromboembolic stroke and was treated in the acute phase (5 days after acute stroke). In total, 38 implants were used for 49 aneurysms counting for 0.8 Surpass device per aneurysm.

Technical Results
All devices could be navigated to the target area and could be deployed across the aneurysm neck. Navigating the third and fourth generations of the catheter, delivery system was significantly more challenging in tortuous vessels as compared with the fifth and last generations. Moreover, integration of 12 platinum wires in the second generation of the device improved the visibility during deployment. In all except 1 case a single device was implanted. The only exception was a patient with a giant fusiform basilar aneurysm who required telescoping of 2 devices to cover the whole diseased segment of nearly 10 cm length.

Deployment with incomplete wall apposition within the center of the device was encountered in 2 cases. All sidewall-type of aneurysms had complete neck coverage. Because the implant was placed from the main trunk in to 1 of the divisions, none of the 14 bifurcation aneurysms had complete neck coverage.
### Table 1. Patient and Aneurysm Characteristics

<table>
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<tr>
<th>Aneurysm No.</th>
<th>Patient No.</th>
<th>Age, y, Sex</th>
<th>Type</th>
<th>Location</th>
<th>Size, mm</th>
<th>Neck, mm</th>
<th>Dome</th>
<th>Dome:Neck</th>
<th>Surpass Device Used, mm</th>
<th>Planned Incomplete Neck Coverage</th>
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<td>6.3</td>
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<td>2.2</td>
<td>1</td>
<td>4×15</td>
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(Continued)
Procedural Complications

During the procedure, clot formation on the surface of the Surpass was observed in 1 case (3%) that was successfully treated with intra-arterial administration of abciximab (ReoPro, Lilly, Indianapolis, IN).

A tiny inadvertent distal middle cerebral artery perforation with acute subarachnoid hemorrhage caused by the microwire was encountered in 1 patient (3%) without clinical sequela. This was before implantation of the device and the antiplatelet therapy was reversed with infusion of donor thrombocytes, and heparin effect was reversed using protamine. Device implantation was postponed and 6 months later this patient underwent a successful Surpass implantation.

Dissections of the ICA were encountered in 2 patients. One was seen during the procedure and a Surpass was successfully used to treat the dissected segment of the cervical ICA. The other dissection was induced by the guide catheter within a very tortuous ICA but missed at the time of procedure. The dissection resulted in a complete ICA occlusion as confirmed on a 6-month follow-up angiogram.

On follow-up angiograms, there were no intraprocedural vasospasms or migration of Surpass implant.

Clinical Outcome

Postprocedural Complications With Transient Neurological Deficits

One patient had a transient left-sided weakness of the arm and leg immediately after the procedure. Diffusion-weighted MRI obtained on the same day showed several small hyperintense areas in the right frontal lobe consistent with thromboembolic events. The intra procedural angiogram was unremarkable without any contrast stagnation or missing vessel and thus did not suggest thromboembolic events. The hemiparesis resolved completely within a few days.

One patient presented with a TIA on the first day after the procedure. His platelet inhibition was inadequate on the basis of the platelet reactivity testing for PGY12 inhibitors using the VerifyNow system (Accumetrics, San Diego, CA). The clopidogrel was changed to cilostazol and no further TIAs were encountered.

Another patient who had the device implanted in to the left posterior cerebral artery (P2 segment), developed a small left frontal hematoma which had caused headaches, nausea, and vomiting 3 months after the procedure. Subsequently the clopidogrel was discontinued. The patient developed, however, a TIA 1 month later. Thus, clopidogrel was reinitiated with no further complications. The patient clinically returned to baseline.

One patient with rapidly progressive visual field and acuity deficit was treated for a large left-sided chiasm-compressing ophthalmic artery aneurysm. Four months after the procedure the symptoms on the left side worsened, whereas the symptoms on the right side further improved. MRI disclosed a complete thrombosis of the aneurysm; however, a minimal change in diameter from 14 mm preprocedure to 15 mm at 4-month follow-up was noticed. To improve her vision at her left side, she underwent an open surgical debulking of the thrombosed aneurysmal sac. Ten days before surgery, acetylsalicylic acid and clopidogrel were discontinued. Her postoperative vision improved rapidly. However 6 hours after surgery, she developed a left hemispheric stroke. Computerized tomography angiography and digital subtraction angiography disclosed an in-device-thrombosis, which was mechanically recanalized. Dual antiplatelet therapy was initiated on the same day. Her symptoms resolved and her vision finally was better than before the implantation of

<table>
<thead>
<tr>
<th>Aneurysm No.</th>
<th>Patient No.</th>
<th>Age, y, Sex</th>
<th>Type</th>
<th>Location</th>
<th>Size, mm</th>
<th>Neck, mm</th>
<th>Dome, mm</th>
<th>Dome:Neck</th>
<th>Surpass Device Used, mm</th>
<th>Planned Incomplete Neck Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>37</td>
<td>26</td>
<td>45M</td>
<td>Dissecting</td>
<td>R A2</td>
<td>3.6×2.6×2.9</td>
<td>2.6</td>
<td>2.9</td>
<td>1.1</td>
<td>2×10 (Pt)</td>
<td>N</td>
</tr>
<tr>
<td>38</td>
<td>27</td>
<td>46F</td>
<td>Saccular</td>
<td>R PCom</td>
<td>2.5×3.3×3</td>
<td>3</td>
<td>2.5</td>
<td>0.8</td>
<td>4×15 (Pt)</td>
<td>N</td>
</tr>
<tr>
<td>39</td>
<td>28</td>
<td>51F</td>
<td>Saccular, giant, partially thrombosed</td>
<td>L Pcom</td>
<td>3.2×4.4×4.4</td>
<td>1.2</td>
<td>4.4</td>
<td>3.6</td>
<td>4×15 (Pt)</td>
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</tr>
<tr>
<td>40</td>
<td>29</td>
<td>35M</td>
<td>Saccular</td>
<td>R ophthalmic</td>
<td>2.9×2.7</td>
<td>2.4</td>
<td>2.9</td>
<td>1.2</td>
<td>4×15 (Pt)</td>
<td>Y</td>
</tr>
<tr>
<td>41</td>
<td>30</td>
<td>46M</td>
<td>Dissecting</td>
<td>cervical internal carotid</td>
<td>10×5×5</td>
<td>9</td>
<td>5</td>
<td>0.6</td>
<td>5×50 (Pt)</td>
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<tr>
<td>42</td>
<td>31</td>
<td>39F</td>
<td>Saccular</td>
<td>L carotid tip</td>
<td>4.5×3×3</td>
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<td>3</td>
<td>0.75</td>
<td>3×20 (Pt)</td>
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<td>43</td>
<td>32</td>
<td>61M</td>
<td>Dissecting</td>
<td>L petrous</td>
<td>9×9×7</td>
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<td>7</td>
<td>1</td>
<td>5×25 (Pt)</td>
<td>N</td>
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<tr>
<td>44</td>
<td>33</td>
<td>53F</td>
<td>Saccular</td>
<td>R PICA</td>
<td>5.2×4.8×5</td>
<td>5.8</td>
<td>5.2</td>
<td>0.91</td>
<td>3×15 (Pt)</td>
<td>N</td>
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<tr>
<td>45</td>
<td>34</td>
<td>64M</td>
<td>Dissecting</td>
<td>basilar trunk</td>
<td>8×10×12</td>
<td>10</td>
<td>8</td>
<td>0.8</td>
<td>4×15 (Pt)</td>
<td>N</td>
</tr>
<tr>
<td>46</td>
<td>35</td>
<td>48F</td>
<td>Saccular</td>
<td>L MCA bifurcation</td>
<td>2.9×4.1×3</td>
<td>2.5</td>
<td>2.9</td>
<td>1.2</td>
<td>2×15 (Pt)</td>
<td>Y</td>
</tr>
<tr>
<td>47</td>
<td>36</td>
<td>49F</td>
<td>Saccular</td>
<td>L M1</td>
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<td>2.1</td>
<td>1.1</td>
<td>2×15 (Pt)</td>
<td>Y</td>
</tr>
<tr>
<td>48</td>
<td>37</td>
<td>56F</td>
<td>Saccular</td>
<td>L MCA bifurcation</td>
<td>3.7×4.7×7.2</td>
<td>4.4</td>
<td>3.7</td>
<td>0.8</td>
<td>2×15 (Pt)</td>
<td>Y</td>
</tr>
<tr>
<td>49</td>
<td>38</td>
<td>42M</td>
<td>Saccular</td>
<td>R Pericallosal</td>
<td>4.9×4.0×6.3</td>
<td>3</td>
<td>4</td>
<td>1.3</td>
<td>2×15 (Pt)</td>
<td>N</td>
</tr>
</tbody>
</table>

A2 indicates A2 segment of anterior cerebral artery; Acom, anterior communicating artery; F, female; ICA, internal carotid artery; L, left; M, male; M1, M1 segment of middle cerebral artery; M2, M2 segment of middle cerebral artery; MCA, middle cerebral artery; mol/L, molar concentration; N, no; Pcom, posterior communicating artery; PICA, posterior inferior cerebellar artery; Pt, device with 12 Platinum wires; R, right; and Y, yes.
Surpass. Follow-up computerized tomography angiography disclosed patency of the parent artery.

**Postprocedural Complications Without Neurological Deficit**

One dissecting vertebral artery/posterior inferior cerebellar artery aneurysm showed a small perianeurysmal bleeding several weeks after the procedure. This patient had complained of headaches, nausea, and vomiting 3 weeks after procedure but did not seek medical care. Her symptoms resolved completely within 5 days and she attended routine follow-up office visit at 6 weeks. MRI obtained disclosed an old small bleeding around the aneurysm, whereas the digital subtraction angiography showed a completely occluded aneurysm and a patent parent artery and posterior inferior cerebellar artery. MRI at 6 months showed a marked reduction of the aneurysm size and near-complete resorption of the hematoma.

There was 1 patient with recurrent nose bleedings in the fourth and fifth weeks after the procedure. After termination of clopidogrel, no further bleedings were documented. There were no further non-neurological complications.

**Postprocedural Complications With Persistent Neurological Deficit**

We encountered 1 stroke with persistent neurological deficit. This patient had an uneventful implantation of the device for a symptomatic giant left cavernous ICA aneurysm. This was 1 of the 2 patients with incomplete wall apposition within the center of the device. After the procedure, she was put on dual antiplatelet therapy for 3 months. After discontinuation of clopidogrel at 3 months, she developed recurrent left hemispheric TIAs, which progressed to a stroke resulting in a hemihypesthesia. MRI disclosed an occluded ICA at the implant site and a stroke in the left deep parietal region. This patient was immediately put back on dual antiplatelet and since then she does not report new symptoms.

**Six Months Follow-up**

**Clinical Results**

All 37 patients had a clinical follow-up study. To date 30 patients had a 6-month follow-up. The shortest time to follow-up was 2 months. Seven patients had improvement of their preexisting symptoms. Twenty-nine patients had no change in clinical condition. One patient experienced worsening of her symptoms because of a stroke and her modified Rankin Scale increased from 0 at admission to 3 at 6-month follow-up (Table 2).

Procedure-related permanent neurological deficits were seen in 1 patient (3%); no patient died associated with the procedure.

**Angiographic Results**

Follow-up angiography was performed in 30 patients harboring 41 aneurysms at 6 months (Table 2). Twenty-nine of 31 aneurysms with complete coverage of the neck showed a complete occlusion (94%), including 1 case with a >95% occlusion.

Of the 14 aneurysms that had incomplete neck coverage, 10 had 6-month follow-up. Five were completely occluded (50%), including 1 case with a >95% occlusion. The other 5 aneurysms showed <50% occlusion.

There were 2 parent artery occlusions. The first occurred in a patient with an ICA dissection resulting from the guide catheter during the implantation. The second ICA occlusion was observed in a patient with an incompletely expanded device because of an underlying high-grade stenosis associated with the aneurysm.

In a few cases (<10%), insignificant narrowing of the parent artery was seen at either the distal or the proximal end of the implant because of incomplete wall apposition. This was typically seen if the landing zone of the device was not in a straight segment of the parent artery. None of these narrowings were associated with any clinical sequela.

Intimal hyperplasia with <20% lumen narrowing in cases of a complete wall apposition was seen in 4 cases. All patients with angiographic evidence of vessel narrowing remained asymptomatic. Of the treated segments with parent artery <2 mm, there were no cases of in-device stenosis.

Two illustrative cases are demonstrated in Figures 1 and 2.

**Side Branches and Perforators**

In total, 56 side branches were covered in 30 patients and included 15 ophthalmic arteries, 13 posterior communicating arteries, and 12 anterior choroidal arteries (Table 3).

At 6-month follow-up, 2 of the 15 covered ophthalmic arteries (13%), and 4 of the 13 covered posterior communicating arteries (31%) had lost an antegrade flow. As collaterals provided blood supply, none of the patient developed any neurological symptoms. All other side branches, for example, 12 covered anterior choroidal arteries, were patent at 6-month angiography.

**Discussion**

This series demonstrate that in selected patients with unruptured aneurysm use of Surpass flow diverter is a highly effective treatment. Nearly all aneurysms (94%) that were completely covered with the implant were occluded at 6-month follow-up angiography. The permanent neurological morbidity (3%) is comparable with coiling of unruptured intracranial aneurysms. In our series, we did not encounter any mortality associated with the procedure or device placement.

**The Surpass Flow Diverter**

The concept of endoluminal reconstruction of the parent artery and the aneurysm neck using stents or stent-like products was developed in the late 1980s and first presented 2 decades ago. More recently, flow diverting stents have been introduced to the neurovascular realm as stand-alone treatment for brain aneurysms. The hemodynamic effect of flow diversion is based on 2 essential device design features that lead to a flow disruption between the parent artery and the aneurysm thus enabling a stable intra-aneurysmal thrombus formation: porosity (metal-free to metal-covered area) and pore density (number of pores/mm² for a given porosity). In vitro and in vivo studies confirm that a 70% porosity and a high pore density seem to be effective.
Table 2. Clinical and Angiographic Outcome

<table>
<thead>
<tr>
<th>Aneurysm No.</th>
<th>Patient No.</th>
<th>Clinical Presentation and Symptoms Related to Aneurysm (Time from Symptom Onset to Procedure)</th>
<th>Periprocedural Adverse Events</th>
<th>Symptoms Related to Aneurysm at 6-Mo Follow-up</th>
<th>mRS Baseline</th>
<th>mRS at 6-Mo Follow-up</th>
<th>Occlusion % (6-Mo Follow-up), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>Orbital pain (CN3) (17 mo)</td>
<td>Resolved</td>
<td>2</td>
<td>1</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>Previous SAH, multiple aneurysms</td>
<td></td>
<td>0</td>
<td>0</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>5</td>
<td>3</td>
<td>CN4 palsy (4 mo)</td>
<td>TIA</td>
<td>Resolved</td>
<td>1</td>
<td>1</td>
<td>100 (ICA occl)</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>4</td>
<td>Incidental finding (MRI for contralateral stroke), multiple aneurysms</td>
<td>Minor stroke with persistent deficit</td>
<td>0</td>
<td>3</td>
<td>100 (ICA occl)</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>5</td>
<td>Transient headache</td>
<td></td>
<td>0</td>
<td>0</td>
<td>100</td>
<td></td>
</tr>
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<td>9</td>
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<tr>
<td>10</td>
<td>6</td>
<td>Transient headache and transient CN6 palsy, multiple aneurysms</td>
<td>Dissection left ICA</td>
<td>0</td>
<td>0</td>
<td>100 (ICA occl)</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>100</td>
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<tr>
<td>12</td>
<td>7</td>
<td>CN3 palsy (15 mo)</td>
<td>Postprocedural minor stroke with left-sided neglect; after 3 d symptoms resolved</td>
<td>CN3 palsy stable</td>
<td>1</td>
<td>1</td>
<td>100</td>
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<tr>
<td>13</td>
<td>8</td>
<td>Orbital pain (CN3) (12 mo)</td>
<td>Resolved</td>
<td>1</td>
<td>0</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>100</td>
<td></td>
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<tr>
<td>15</td>
<td>9</td>
<td>Previous SAH, coil impaction</td>
<td>2</td>
<td>2</td>
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<td>100</td>
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<tr>
<td>16</td>
<td>10</td>
<td>Previous SAH, multiple aneurysms, failed coiling of A2 aneurysm</td>
<td>0</td>
<td>0</td>
<td></td>
<td>50</td>
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<tr>
<td>17</td>
<td>11</td>
<td>Ataxia (5 y)</td>
<td>Stable</td>
<td>4</td>
<td>4</td>
<td>95–100</td>
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<tr>
<td>18</td>
<td>12</td>
<td>Ataxia, occipital pain (10 mo)</td>
<td>Resolved</td>
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<td>100</td>
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<tr>
<td>19</td>
<td>13</td>
<td>Previous SAH, multiple aneurysms</td>
<td>0</td>
<td>0</td>
<td></td>
<td>&lt;50</td>
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</tr>
<tr>
<td>20</td>
<td>14</td>
<td>Previous SAH, multiple aneurysms, failed clipping of M1 aneurysms</td>
<td>2</td>
<td>2</td>
<td></td>
<td>100</td>
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</tr>
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<td>21</td>
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<td>22</td>
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<td>Previous SAH, multiple aneurysms, failed clipping of M2 aneurysms</td>
<td>2</td>
<td>2</td>
<td></td>
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<tr>
<td>23</td>
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<td>&lt;50</td>
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<td>24</td>
<td>16</td>
<td>Incidental, familial aneurysms</td>
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<td>0</td>
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<td>95–100</td>
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<tr>
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<td>17</td>
<td>Incidental finding (MRI for cerebellar stroke)</td>
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<td>0</td>
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<td>18</td>
<td>Previous SAH, multiple aneurysms</td>
<td>TIA and small intracerebral hemorrhage</td>
<td>1</td>
<td>1</td>
<td>100</td>
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</tbody>
</table>

(Continued)
for flow reduction within the aneurysm and maintain patency of small side branches.\textsuperscript{10,13–22}

Thus to maintain constant pore density across the neck of the aneurysms, the number of wires increases with the diameter of the implant, ranging from 48 wires for the 2.5-mm Surpass to 96 wires for the 5-mm Surpass. A successful treatment requires the use of a single device unless an incomplete coverage of the aneurysm neck occurs because of device misplacement or selection of a too short device. This also enables to maintain a controlled porosity rather than risking side branch occlusion by adding randomly a second implant in a telescoping fashion.

Table 2. Continued

<table>
<thead>
<tr>
<th>Aneurysm No.</th>
<th>Patient No.</th>
<th>Clinical Presentation and Symptoms Related to Aneurysm (Time from Symptom Onset to Procedure)</th>
<th>Periprocedural Adverse Events</th>
<th>Symptoms Related to Aneurysm at 6-Mo Follow-up</th>
<th>mRS Baseline</th>
<th>mRS at 6-Mo Follow-up</th>
<th>Occlusion % (6-Mo Follow-up, %)</th>
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<tbody>
<tr>
<td>28</td>
<td>19</td>
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<td>Resolved</td>
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<td>0</td>
<td>100</td>
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<tr>
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<td>20</td>
<td>Seizures (1 mo)</td>
<td>Stable with medication</td>
<td>0</td>
<td>0</td>
<td>100</td>
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</tr>
<tr>
<td>30</td>
<td>21</td>
<td>Previous SAH, multiple aneurysms</td>
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<td>0</td>
<td>0</td>
<td>100</td>
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<tr>
<td>31</td>
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<tr>
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<td>Previous SAH</td>
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<td>Progressive visual loss (14 mo)</td>
<td>Incomplete device deployment, minor stroke after termination of clopidogrel and ASA, symptoms resolved</td>
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<td>0</td>
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<td>Improved after debulking open surgery</td>
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<td>1</td>
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<td></td>
</tr>
<tr>
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<td></td>
<td>100</td>
<td></td>
</tr>
<tr>
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<td>25</td>
<td>Previous SAH, multiple aneurysms</td>
<td></td>
<td>0</td>
<td>0</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>37</td>
<td>26</td>
<td>Familial aneurysms, seizures (5 mo)</td>
<td>Stable with medication</td>
<td>0</td>
<td>0</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>38</td>
<td>27</td>
<td>Previous SAH, coil impaction</td>
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<td>0</td>
<td>0</td>
<td>&lt;50</td>
<td></td>
</tr>
<tr>
<td>39</td>
<td>28</td>
<td>Seizures (3 y)</td>
<td>Stable with medication</td>
<td>1</td>
<td>1</td>
<td>100</td>
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</tr>
<tr>
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<td>Incidental, osteoarthritis syndrome</td>
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<td>0</td>
<td>&lt;50</td>
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</tr>
<tr>
<td>41</td>
<td>30</td>
<td>Ipsilateral stroke (7 d)</td>
<td>Improved</td>
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<td>0</td>
<td>100</td>
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<td></td>
</tr>
<tr>
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<td>Incidental finding (CT for neurotrauma)</td>
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<tr>
<td>44</td>
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<td>Previous SAH, coil impaction</td>
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<td>0</td>
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<td></td>
</tr>
<tr>
<td>45</td>
<td>34</td>
<td>Previous SAH, coil impaction</td>
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<td>0</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>46</td>
<td>35</td>
<td>Previous SAH</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>47</td>
<td>36</td>
<td>Previous SAH, multiple aneurysms</td>
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<td>0</td>
<td></td>
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<tr>
<td>48</td>
<td></td>
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<td></td>
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<td>49</td>
<td>37</td>
<td>Previous SAH, multiple aneurysms</td>
<td></td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ASA indicates acetylsalicylic acid; CN3, third cranial nerve; CN4, fourth cranial nerve; CN6, sixth cranial nerve; CT, computerized tomography; ICA, internal carotid artery; mRS, modified Rankin scale; SAH, subarachnoid hemorrhage; and TIA, transient ischemic attack.

Both the Pipeline Embolization Device (PED; Covidien, Mansfield, MA) and the Silk stent (Silk; Balt, Montmorency, France) have 48 wires for all diameters and consequently the devices with larger diameters have lower pore densities. This could result in lower aneurysm occlusion rates at 6-month follow-up. As recently published, a significant variation in reported occlusion rates is observed at 6 months after implantation of PED and/or Silk. For PED occlusion, rates between 52% and >90% have been reported;\textsuperscript{27–30} for Silk 6-month aneurysmal occlusion, rate ranges from 68% to 69%.\textsuperscript{25,31,32} Besides mechanical and design characteristics of the implant, aneurysm, and patient selection, as well as antiplatelet
regimen and individual biological response to clot formation and implant, all may affect variability in outcome. Our series includes a high number of small aneurysms. Although there are no data yet that demonstrate a higher occlusion rate for small aneurysms treated with flow diverters as compared with large aneurysms, this high number of small aneurysms in our series might have influenced the occlusion rate.

To increase the occlusion rates, several users telescope PED devices in a substantial number of cases. The main reason for this approach is to completely bridge the neck especially in a very wide-necked or fusiform aneurysm and to increase the pore density. By implanting multiple telescoping devices randomly, however, the porosity and pore density cannot be controlled and hence the flow diverting effect of the implant at overlapping segments cannot be determined. Although not shown in rabbit aorta model, reports on telescoping implants suggest that an inadvertent obliteration of covered small side branches or perforators may occur.

For the use of the Silk device, the manufacturer recommends the implantation of a Leo stent (Balt) across the wide neck of the aneurysm before placement of the flow diverting stent. Albeit adding stability to the construct, telescoping of both devices will randomly influence pore density.

Although only 1 device was used with a single exception in a fusiform aneurysm of the entire basilar artery, the 6-month high complete occlusion rates in our series seem to be favorable as compared with the PED and Silk data. As described in experimental setting, the results may suggest that a higher and constant pore density over the entire length of the aneurysm neck indeed leads to a more efficient flow diversion and durable aneurysm occlusion.

**Patient Selection**

Because EVT (coiling, stent-assisted coiling) shows a high recurrent rate because of coil compaction, commonly accepted indication for use of flow diverting stents are unruptured wide-necked and large or giant aneurysms. Our experience also shows that segmental diseased arteries or dysplastic arteries with associated multiple aneurysms may be an excellent indication for use of Surpass flow diverter. In general, a single device is sufficient to obliterate all aneurysms. Flow diversion seems to be an excellent treatment option for blood blister-type and fusiform aneurysms that may rupture and can be challenging for surgery and standard EVT. At 6-month angiographic follow-up, we were able to demonstrate a complete occlusion in 50% of bifurcation aneurysms treated with Surpass and various degrees of size reduction in remaining aneurysms. Indeed this cannot be considered a success to date. Patients, however, were carefully selected for the use of this device. Some patients were reluctant to undergo an open surgery, and a standard EVT was considered to bear a high risk for failure. Long-term follow-up studies are needed to affirm whether these aneurysms will progress to further thrombosis. Until better results can be reported other treatment options should be considered for bifurcation aneurysms.
Our series includes a high number of small unruptured aneurysms. The indication for treatment of those aneurysms can be debated as their rupture risk is relatively low. We included 21 patients with aneurysms <7 mm. These patients were carefully selected and most of them had either a history of subarachnoid hemorrhage from another aneurysm, a coil-impacted/previously ruptured aneurysm, or familial aneurysms. Several studies documented the higher annual rate of rupture of even small aneurysms in patients with a history of subarachnoid hemorrhage as compared with patients without a history of subarachnoid hemorrhage.40,41 The natural course of unruptured aneurysms was recently studied in a Japanese cohort. In this study, an annual rate of rupture of 0.5% for 5 to 6 mm aneurysms without a history of subarachnoid hemorrhage was found.42 After having discussed these data, all selected patients in this series had a strong preference for having their aneurysm(s) treated.

Procedural Safety
Implantation of the Surpass system was achieved with a high level of procedural safety because no permanent periprocedural morbidity or mortality was encountered. A controllable navigation and deployment of the system over a standard 0.014 microwire may be critical for a good periprocedural outcome. In this series, most of the aneurysms were small. As it is generally easier to deploy a flow diverter in a case of a small aneurysm than in a case of a large wide-necked aneurysm, this potentially could have influenced procedural efficacy and safety.

Clinical and Angiographic Outcome
In our small group of treated patients, the 6-month results are encouraging with a low morbidity of 3% and no mortality.

Table 3. Antegrade Flow in Covered Side Branches at 6-Months Follow-up

<table>
<thead>
<tr>
<th>Side Branch</th>
<th>Number of Branches Covered at Implantation</th>
<th>Number of Covered Side Branches with Antegrade Flow at 6 mo Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ophthalmic artery</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td>Posterior communicating artery</td>
<td>13</td>
<td>9</td>
</tr>
<tr>
<td>Anterior choroidal artery</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>A1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Anterior cerebral artery</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>A2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Orbitofrontal artery</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>M2</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>M3</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Lenticulostrate arteries</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Anterior inferior cerebellar</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>artery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posterior cerebellar artery</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

A1 indicates A1 segment of anterior cerebral artery; A2, A2 segment of anterior cerebral artery; M1, M1 segment of middle cerebral artery; M2, M2 segment of middle cerebral artery; and M3, M3 segment of middle cerebral artery.

These findings are comparable with reports on other forms of EVT, for example coiling and stent-assisted coiling for intracranial aneurysms.11,12 However, the present study includes a larger number of more complex aneurysms that would otherwise not be amenable to current EVT. Case series of patients treated with PED have reported a morbidity ranging from 0% to 9%.28–30,33,42,43 The reported mortality after PED implantation has been as high as 6%.44 Morbidity associated with the use of the Silk implant ranges from 3.9% to 15%, whereas the reported mortality ranges from 0% to 8%.24,26,31

Case series have a limited value, but our preliminary results in 37 patients treated with a new generation of flow diverters at a single medical center demonstrate favorable clinical and angiographic outcomes as compared with PED and Silk.

Nearly all neurological events were of thromboembolic nature. Inadequate deployment of the device resulting in incomplete wall apposition led to a stroke in 2 patients after premature termination of clopidogrel. This emphasizes the importance of appropriate device wall apposition to avoid clot formation most likely associated with slow blood flow at vessel wall and implant interface. There were no ischemic events during follow-up period caused by a side branch occlusion. The loss of antegrade flow in a few posterior communicating arteries and ophthalmic arteries that were covered with the device remained clinically silent. Most likely existing collateral pathways took over the blood circulation after the device had caused a small but sufficient circulatory resistant across the side branch to create a pressure drop. It is intriguing that the small anterior choroidal artery and lenticulostrate arteries of M1 and A1 segments maintained their antegrade flow in all cases. Most likely these arteries do not have any substantial collateral pathway. Thus, the existing demand for a proper brain tissue perfusion maintains the pressure gradient for a sufficient blood flow through the previous device.10

Limitations
Like carotid or intracranial stents, Surpass devices are supplied for use preloaded in a 2.9F or 3.6F microcatheter and engineered to specifications of the implants. Thus in a tortuous vasculature, the delivery of the system to target lesion within the intracranial circulation requires the use of a triaxial system. As there is a risk of arterial intimal damage, it is recommended to carefully use larger sheaths and distal access catheters.

Because currently permanent cerebrovascular implants, including Surpass, require a dual antiplatelet treatment for ≤3 to 6 months, there is potentially an increased risk for intracranial hemorrhage. A recent stoke trial clearly demonstrated the increased risk for hemorrhage of dual antiplatelet therapy versus single antiplatelet therapy.45 Although we had 2 patients with bleeding complications, the thromboembolic complications were clinically more serious and occurred after premature termination of clopidogrel. Thus, we strongly recommend dual antiplatelet therapy for a minimum of 6 months and suggest discontinuation of clopidogrel only after a 6-month follow-up angiography that should not indicate any stenosis of parent artery or associated side branches. Dual antiplatelet treatment also limits the use of Surpass in acutely ruptured aneurysms.
Further limitation of currently used flow diverters is an impaired visualization of the treated vessel segment with MRI although contrast-enhanced MR angiography may be helpful. A catheter angiography and less-invasive computed tomography angiography are best suited for assessment of the treated artery and aneurysm.

The main limitation of this study remains its preliminary nature and the experience from a single center. Long-term clinical and angiography data from a multicenter study will render more information about the occlusion rates of those aneurysms that were not completely thrombosed at 6 months. Long-term behavior of the implant in smaller arteries and across perforators needs to be assessed and risk of in-stent stenosis studied carefully within the treated segment. A Surpass registry has been established and the Surpass Intracranial Aneurysm Embolization System Pivotal Trial to Treat Large or Giant Wide Neck Aneurysms (investigational device exemption number G110229) is underway to address those outstanding questions.

Conclusions
Preliminary data show that the Surpass flow diverter is a safe, effective, and well-controllable endovascular system for treatment of a variety of intracranial aneurysms. It also enables the repair of aneurysm-associated diseased arterial segment. Long-term studies are needed to assess its value for bifurcation aneurysms.

Disclosures
Joost de Vries, MD and Ajay K. Wakhloo, MD have significant consultancy relationships to Stryker Neurovascular. The other authors have no conflicts to report.

References


New Generation of Flow Diverter (Surpass) for Unruptured Intracranial Aneurysms: A Prospective Single-Center Study in 37 Patients
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