Immediate and midterm follow-up results of using an electrodetachable, fully retrievable SOLO stent system in the endovascular coil occlusion of wide-necked cerebral aneurysms

KIVILCIM YAVUZ, M.D.,1 SERDAR GEYIK, M.D.,1 ALMILA GULSUN PAMUK, M.D.,2 OSMAN KOC, M.D.,1 ISIL SAATCI, M.D.,1 and H. SARUHAN CEKIRGE, M.D.1

Departments of 1Radiology, and 2Anesthesiology, Hacettepe University Hospitals, Ankara, Turkey

Object. Stent-assisted embolization is an alternative endovascular treatment method for wide-necked intracranial aneurysms. Currently available stents have the limitations of poor radial force, difficult delivery systems, and lack of full retrievability. The authors report on their preliminary experience with the use of a new, fully retrievable, self-expanding neurovascular stent, which has a high radial force and easy delivery system, combined with coil or Onyx embolization for the treatment of wide-necked aneurysms, including 6-month follow-up data.

Methods. Fifteen patients with 18 wide-necked intracranial aneurysms were treated using the SOLO stent system and detachable platinum coils. Aneurysms were located at the posterior communicating artery (seven lesions), midbasilar artery (one lesion), internal carotid artery (ICA) bifurcation (one lesion), ICA–ophthalmic artery segment (eight lesions), and posterior cerebral artery (one lesion). Eleven aneurysms were small, six were large, and one was giant. Only one of these aneurysms was in the acute stage of subarachnoid hemorrhage; balloon remodeling alone failed to keep the coils in the aneurysm sac.

Results. Only one stent required retrieving and repositioning after it had been fully deployed, and retrieval was easy and successful. No thromboembolic complication, dissection/rupture, or vasospasm occurred during stent placement. Follow-up angiograms obtained at 6 months posttreatment in the 18 aneurysms demonstrated that all stents were patent with no evidence of intimal hyperplasia or stenosis. In all cases but one, 100% lesion occlusion was observed at the 6-month control angiography examination. Only one aneurysm had recanalized.

Conclusions. The fully retrievable self-expandable SOLO stent is a feasible, secure, and effective system with a high radial force and ease of delivery in treating wide-necked intracranial aneurysms in combination with coil embolization. (DOI: 10.3171/JNS-07/07/0049)

Key Words • cerebral aneurysm • coil embolization • intracranial stent • stent-assisted coil occlusion • wide-necked aneurysm
Clinical Material and Methods

Patient Population and Study Criteria

Fifteen patients (11 women and four men) with a mean age of 44.13 years (range 23–67 years) and harboring 18 wide-necked intracranial aneurysms were treated using the SOLO stent system. In all cases embolization was accomplished with detachable platinum coils. The protocol inclusion criteria consisted of a wide-necked intracranial saccular aneurysm characterized by a dome/neck ratio less than 2.0 and/or a neck length of 4 mm or more; a parent artery with a diameter between 1.5 and 5 mm; a patient age greater than 18 years; and provision of written informed consent. Exclusion criteria were a fusiform or other nonsaccular aneurysm, a neck diameter larger than 15 mm, pregnancy, and a contraindication to medication (heparin, clopidogrel, aspirin, or angiographic contrast agent).

Aneurysm Characteristics

Aneurysm sizes were classified as small (< 1 cm), large (≥ 1 cm and ≤ 2.5 cm), and giant (> 2.5 cm). Of the 18 aneurysms, 11 were small, six were large, and one was giant. Aneurysms were located at the PCoA (seven lesions), mid-BA (one lesion), ICA bifurcation (one lesion), ICA–OphA segment (eight lesions), and the P1 segment (one lesion). Fourteen of the aneurysms were unruptured. Of the four ruptured lesions, three had ruptured more than one month before the treatment procedure. One of these aneurysms was wrapped surgically, a second was embolized with coils using a balloon remodeling technique but had recanalized, and a third was not treated after bleeding. Only one acutely ruptured aneurysm was treated using a SOLO stent (as described later).

Three of the 18 aneurysms were recanalized lesions. Previous therapies consisted of coil placement in two cases and Onyx liquid embolic agent in one case. All 18 aneurysms were occluded using bare platinum detachable coils.

Study Protocol

According to the study protocol, all patients were premedicated with antiplatelet therapy consisting of 300 mg of aspirin and a loading dose of 300 to 450 mg of clopidogrel 1 to 7 days before the procedure. Clopidogrel (75 mg/day) was continued for an additional 30 days after the procedure and then stopped. Aspirin (300 mg/day) was continued and anticipated to be administered for the patient’s lifetime. All patients received heparin with the goal of elevating the activated clotting time level two to three times compared with baseline during the procedure and for the following 24 hours.

Given the necessity for sustained antiplatelet therapy and the potential for early rebleeding from ruptured lesions, unruptured aneurysms were preferred for treatment in this series. The study therefore included only one acutely ruptured aneurysm. This lesion had a mid-BA location, and the SOLO stent was used in combination with balloon placement within the stent. This method of therapy was selected when neither balloon remodeling nor stent insertion, when performed alone, could retain the coils within the aneurysm sac.

The feasibility of delivery and deployment, radial force, visibility, ease of retrievability (if needed), ease of stent detachment, and aneurysm occlusion rate were documented. All patients underwent clinical and angiographic follow-up at 6 months posttreatment. The occlusion rate of the aneurysm, patency of the parent artery, evidence of intimal hyperplasia, and in-stent stenosis were noted on the follow-up angiograms.

Stent System

The SOLO stent is made of a laser-cut nitinol tube with a honeycomb pattern that is attached to a platinum marker coil (proximal coil). Its placement is controlled by the standard proximal and distal markers on the microcatheter, which are to be aligned with a 3-cm delivery coil at the end of the delivery system. A stainless-steel segment (detachment zone) is detached using direct current application (2 mA, 4–6 V, for 30–60 seconds) for stent deployment. The stent can be visualized using three distal markers and the proximal coil segment that remains attached to it (Fig. 1).

Technique of Stent Deployment and Endosaccular Coil Occlusion

All procedures were performed under general anesthesia. A 6-F guiding catheter was introduced into the ICA for anterior circulation aneurysms and into the VA for posterior system lesions. A Rapid Transit (Cordis Neurovascular) or Rebar 18 (ev3 Inc.) microcatheter was advanced to bypass the aneurysm neck. The SOLO stent was then delivered via the microcatheter and deployed after positioning to bridge the aneurysm neck. Deployment was completed in a standard fashion by holding the stent pusher stationary while withdrawing the microcatheter. If its position was satisfactory, the stent was immediately electrically detached after deployment. All detachments took less than 1 minute. Another microcatheter was then placed in the aneurysm and coils were inserted.

In the case of the ruptured mid-BA aneurysm in which balloon remodeling alone failed to keep the coils in the aneurysm sac, the microcatheter was withdrawn; the SOLO stent was deployed in the BA across the aneurysm neck but was not detached. Another 6-F guiding catheter was placed within the contralateral VA, and through this catheter a 4 × 7-mm Hyperform balloon (ev3 Inc.) was positioned within the stent. A microcatheter was placed in the aneurysm sac through the mesh of the stent. The aneurysm was then successfully filled with coils by using stent- and balloon-assisted techniques, and detachment of the stent was accomplished after endosaccular coil occlusion (Fig. 2).

In two patients, aneurysms located at the carotid artery termination or OphA segment of the ICA were initially coiled using balloon remodeling alone; the SOLO stent was then deployed in the parent artery. In these cases, stents were inserted to provide additional support in preventing the aneurysm regrowth that would be predicted given the large size of the lesions. Furthermore, the initial occlusion with coil embolization was not complete (Raymond Class 2) in the ophthalmic segment aneurysm. The ICA termina-
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A

B

Fig. 1. Diagrams depicting the SOLO stent. A: Entire stent system. B: Stent in its deployed state. Radiopaque markers are shown as well. Microcath. = microcatheter; Prox. = proximal.

Aneurysm was a regrown lesion and the stent was used in the retreatment even though complete occlusion was achieved with balloon-assisted coil embolization.

After obtaining control angiograms, the guide catheter and vascular sheath were withdrawn, and hemostasis was achieved using a vascular closure device.

Results

All patients were successfully treated using this technique with no procedural or delayed complications. No thromboembolic complications, arterial dissections/ruptures, or spasms occurred during stent placement. The only patient treated in the acute stage of subarachnoid hemorrhage (Hunt and Hess Grade I at presentation) left the hospital with a good clinical status (Glasgow Outcome Scale Score 1).

There were no difficulties in delivering the stents. In only

Fig. 2. A and B: Initial diagnostic left VA angiogram, Towne and oblique projections, demonstrating a ruptured mid-BA wide-necked aneurysm and vasospasm of the BA. C: Nonsubtracted view showing deployed but not detached SOLO stent in the BA across the aneurysm neck. Three distal radiopaque markers are indicated by arrows. A 4 × 7-mm Hyperform balloon (arrowheads) was positioned within the stent from the contralateral VA. The aneurysm was then embolized with stent- and balloon-assisted coil insertion, and detachment of the stent was accomplished after endosaccular coil placement. D: Immediate posttreatment angiogram exhibiting complete occlusion of the aneurysm. E and F: Six-month follow-up angiograms, subtracted and nonsubtracted oblique views, revealing stable complete occlusion.
Endosaccular embolization of wide-necked, complex, and large or giant aneurysms with preservation of the parent artery remains a challenge for the neurointerventional-ist. To avoid coil protrusion or migration into the parent artery and subtotal occlusion leading to recanalization or regrowth, advanced endovascular techniques/products—including balloon remodeling, different coil designs (for example, 3D coils), liquid embolic agents—and bioactive coils have been developed. The efficacy of bioactive coils remains controversial and is being studied in randomized trials. The application of an endovascular stent seems to provide several important theoretical and technical advantages. The stent not only supports aneurysm packing and provides flow redirection, but also provides a physical matrix for endothelial regrowth. Thus, stent insertion treats not only the aneurysm, but also the diseased parent vessel. The stents initially used in the intracranial circulation were a variety of stainless-steel, balloon-expandible peripheral or coronary stents and stent grafts which were followed by more flexible, self-expanding stents that are easier to navigate in the intracranial vessels specifically designed for neurovasculature use.

The Neuroform stent (Boston Scientific) was the first commercially available self-expanding microstent specifically designed for the treatment of broad-based aneurysms. This stent is constructed of nitinol, with diameters ranging from 2.5 to 4.5 mm. Regarding this first-generation stent system, the radioopacity of the stent mesh, which is not visible even under high-quality fluoroscopy, together with the open-cell design can cause prolapse of the stent struts into the aneurysm; and thus, it can be very difficult to judge whether a coil loop is on the luminal or aneurysm side of the stent. The low radial force of the stent can be advantageous in reducing injury to the vessel wall, but can also allow displacement of the stent after its deployment. Moreover, the stent lacked retrievability after inaccurate deployment. Several technical problems with stent delivery have been described in the literature, including misplacement of the stent into the target aneurysm or dislodgement during deployment, misplacement during the procedure (Table 1).

Table 1: Summary of relevant clinical and angiographic data and treatment strategies in 15 patients harboring aneurysms

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age (yrs), Sex</th>
<th>Aneurysm Location</th>
<th>Aneurysm Type</th>
<th>Aneurysm Size</th>
<th>Treatment Procedure</th>
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<td>46, F</td>
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<td>S</td>
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<td>1</td>
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<td>PCoA</td>
<td>U</td>
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<td>47, F</td>
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* FU = follow-up; G = giant; L = large; R = ruptured; S = small; U = unruptured.
† Two patients with 1-year follow-up results.
‡ The patient who was treated in the acute phase of subarachnoid hemorrhage.
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Fig. 3. Initial diagnostic angiogram (A) and 3D reconstruction image (B) showing a wide-necked bilobulated ICA aneurysm. Posttreatment angiogram (C) demonstrates more than 95% (Raymond Class 2) occlusion of the aneurysm. Another posttreatment angiogram (D), nonsubtracted view, reveals the endosaccular coil pack with the stent at the neck. Arrows indicate radiopaque markers. Six-month follow-up angiogram (E) showing progressive thrombosis of the aneurysm sac resulting in complete obliteration (Raymond Class 1).
with a nitinol pusher wire. The closed-strut design addresses problems that can result from the dislocation of single cells in an open-strut mesh or from interference with coils and guidewires. It holds coils in the aneurysm sac very effectively. The stent has satisfactory visibility through the three distal markers and the proximal coil segment that remains attached to it, and placement is controlled by these markers on the microcatheter that are to be aligned with the 3-cm delivery coil at the end of the delivery system. The stainless-steel segment (detachment zone) is detached by direct current application for stent deployment. Available stent diameters and lengths for this series were limited, ranging from 3 to 4 mm in diameter and 10 to 20 mm in length.

In the present series, we used the SOLO microstent without technical difficulty in 15 patients with 18 wide-necked aneurysms; the stent could be easily delivered through the microcatheter and positioned to bridge the aneurysm neck in all cases. The stent was repositioned after having been fully deployed in one particular case with no difficulty. The detachment was reliable and quick, averaging around 30 seconds. The higher radial force in this stent reduces the possibility of displacement after deployment. In all cases placement of the microcatheter through the stent into the aneurysm was achieved without any difficulty. Withdrawal of the microcatheter at the end of coil insertion was uneventful. The radial force and closed-cell design of the stent allowed excellent stabilization of coils between the stent and parent artery and prevented possible thromboembolic events.

In our opinion, one of the major advantages of the SOLO stent system is the ability to deploy the stent and safely place a remodeling balloon within it to perform stent- and balloon-assisted coil insertion or treatment with the Onyx embolic agent without detaching the stent (Fig. 2). The stent can be detached after the treatment is completed. This technique eliminates the risk of stent malposition if balloon placement is needed in the stent immediately after its deployment. This approach can be applied using a larger inner-bore single 6-F guide sheath (6F Destination; Terumo, Inc.) or double guiding catheters.

With the use of antiplatelet therapy, which is routinely initiated 1 to 7 days before the procedure, neither immediate nor late thromboembolic complications occurred in the present study. Furthermore, contrary to the recent data reported by Fiorella et al., no in-stent stenosis was observed. The overall total occlusion rate was 56% (10 of 18) immediately after treatment with SOLO stent–supported coil embolization. Note, however, that follow-up angiography demonstrated noteworthy progressive occlusion in seven (87.5%) of the eight remaining aneurysms with initial Raymond Class 2 or 3 occlusion at the end of treatment, resulting in an overall total occlusion rate of 94.4% (17 of 18) at 6 months. These rates compare favorably with the those of Fiorella et al., who reported a progressive occlusion rate of 52.1% in their study of a Neuroform stent and coil combination.

Conclusions

Our preliminary experience shows that the fully retrievable, self-expandible SOLO stent in combination with coil embolization is a feasible, secure, and effective system with a higher radial force and ease of delivery in treating wide-necked intracranial aneurysms. The main advantages of the SOLO stent include its delivery system via a standard 18 microcatheter, which is as easy as delivering an 18 metallic coil, and its retrievability even after full deployment. Although very durable aneurysm occlusion with 100% stent patency was observed on the 6-month follow-up angiograms in the present study, larger series with longer-term follow-ups are required.

Disclosure

Drs. Saruhan Cekirge and Isil Saatci conduct research and provide clinical medical services, teaching, and training with regard to their original scientific research for ev3 Inc.

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