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This information is current as  
of April 19, 2024.

*AJNR Am J Neuroradiol* published online 19 May 2011  
<http://www.ajnr.org/content/early/2011/05/19/ajnr.A2505>

## ORIGINAL RESEARCH

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# Stent Placement for Flow Restoration in Acute Ischemic Stroke: A Single-Center Experience with the Solitaire Stent System

**BACKGROUND AND PURPOSE:** In acute thromboembolic stroke, mechanical recanalization with stents may result in immediate flow restoration. The Solitaire stent can be used both for flow restoration and thrombectomy. In this single-center experience, we report safety and efficacy data on the application of the Solitaire stent.

**MATERIALS AND METHODS:** Between March 2009 and July 2010, 18 patients were treated with the Solitaire stent. To evaluate perfusion of the occluded vessel segment before and after the intervention, the mRS score was used (0–3). Clinical outcome was assessed by using the mRS at discharge.

**RESULTS:** Overall, recanalization was successful in 16 of 18 patients (88.8%). There were no procedure-related complications. Mean mRS score after the intervention was  $2.3 \pm 0.8$ . In 5 patients, reocclusion of the treated vessel occurred immediately after retrieval of the temporarily opened stent, and permanent stent deployment was performed to maintain stable perfusion. In 3 patients, hemorrhage occurred after successful recanalization. Five patients died (infarction,  $n = 3$ ; hemorrhage,  $n = 1$ ; organ failure,  $n = 1$ ). A good clinical outcome (mRS  $\leq 2$ ) was achieved in 33.3% of the patients, 5.5% had a moderate outcome (mRS, 3/4), and 61.2% had a poor outcome or died (mRS, 5/6).

**CONCLUSIONS:** Application of the Solitaire stent in acute stroke results in a high recanalization rate (88.8%) without procedural complications and with a good outcome in one-third of patients. These results encourage further evaluation of the stent in larger patient populations.

**ABBREVIATIONS:** IA = intra-arterial; IV = intravenous; MCA = middle cerebral artery; mRS = modified Rankin scale; rtPA = recombinant tissue plasminogen activator; TICI = thrombolysis-in-cerebral-infarction score

In acute stroke, early recanalization of the occluded vessel is among the most important predictors for favorable clinical outcome.<sup>1,2</sup> In cases of large vessel occlusion (carotid T, M1 segment, basilar artery) or contraindication for IV lysis, IA fibrinolysis is a viable treatment option.<sup>3</sup> However, especially in patients with long-segment artery occlusion, vessel recanalization with IA lysis alone is often unsuccessful due to the large amount of thrombotic material.

To further improve recanalization rates in the endovascular treatment of acute stroke, various mechanical devices have been developed to rapidly remove the occluding clot from the vessel. These systems are mainly embolectomy devices designed to remove thrombus material by aspiration, extraction, or both.<sup>4,5</sup>

Another approach is the use of (self-expanding) stents for the treatment of acute stroke patients.<sup>6–9</sup> Theoretically, stent implantation allows almost immediate restoration of blood flow by thrombus entrapment between the stent struts and the vessel wall and might therefore lead to a higher efficacy of IV or IA administered fibrinolytic drugs. Initial clinical results demonstrated technical feasibility and suggested that a self-expanding stent may be efficient for recanalization of acute artery occlusion.<sup>7,9,10</sup>

However, as a major limitation of this technique, permanent stent implantation requires subsequent antiaggregation with an increased risk of intracranial hemorrhage.

The Solitaire stent (ev3, Plymouth, Minnesota) is a newly developed, fully retrievable, self-expanding stent for the treatment of intracranial aneurysms.<sup>11,12</sup> The stent received the Conformité Européenne mark in July 2009 for flow restoration in acute ischemic stroke as the Solitaire FR device.<sup>9,13</sup> It allows resheathing of the stent even after full deployment and detachment of the stent in cases where permanent stent placement is needed. In this analysis, we report safety and efficacy data and clinical results by using the Solitaire stent in acute stroke patients.

## Patients and Methods

Approval for data collection of interventional procedures was given by the institutional review board. Patient informed consent for study inclusion was obtained from the patients or their legal representatives.

We retrospectively analyzed the angiographic and clinical data of 18 patients with acute stroke due to vessel occlusion (mean age, 65.7 years [33–82 years]; female/male, 4/14) who were treated with the Solitaire stent either alone or in combination with application of thrombolytic drugs in our institution between March 2009 and July 2010.

On admission, a stroke neurologist examined all patients clinically. All patients were evaluated with cranial CT or multimodal MR. A follow-up CT scan was routinely performed at 24 to 36 hours after treatment or before if neurologic decline  $\geq 4$  points in NIHSS score occurred.

There were 13 patients with occlusion of the MCA (4 patients with

Received August 6, 2010; accepted after revision November 17.

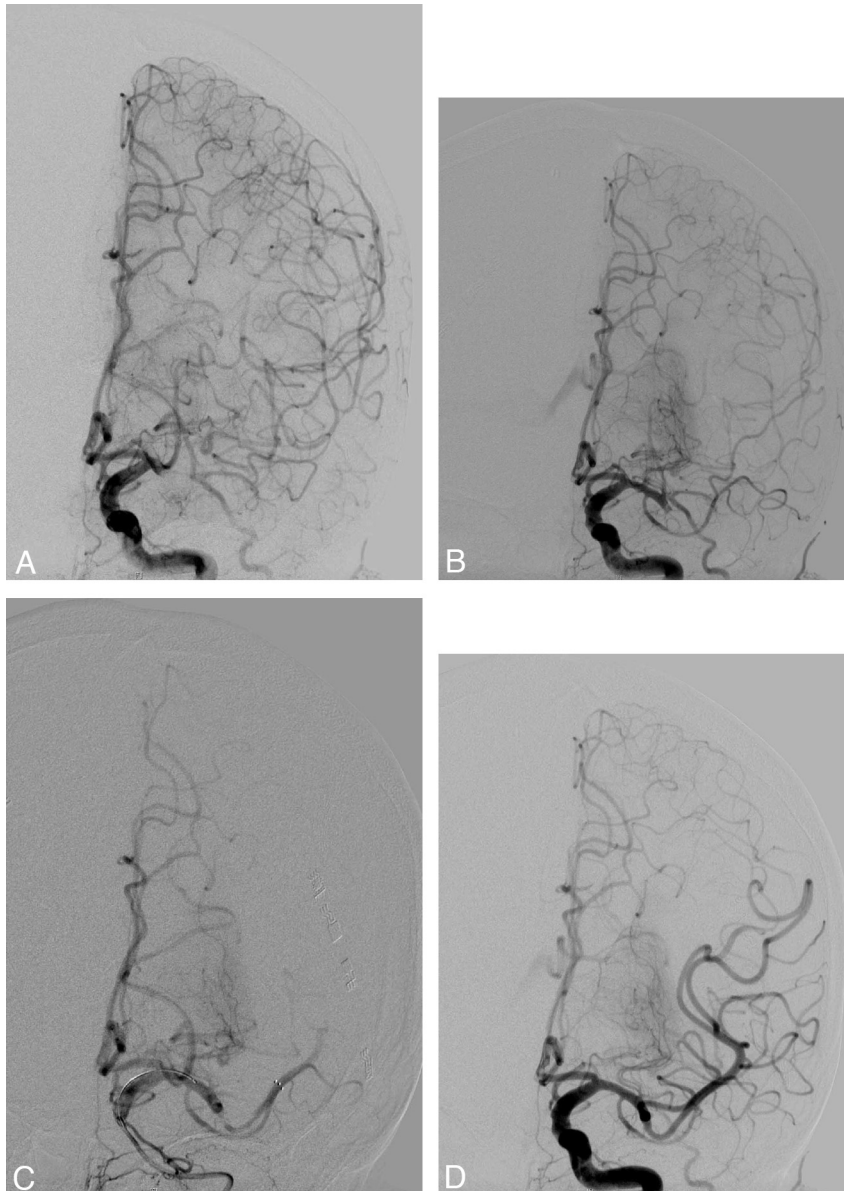
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DOI 10.3174/ajnr.A2505



**Fig 1.** A, Initial angiogram shows a main branch occlusion of the left MCA. B, After the first pass of the Solitaire stent, patency of the M1 segment and of lenticulostriate arteries is achieved. C, Solitaire stent within the left M1/M2 segment: second stent opening. D, Final angiogram demonstrates successful recanalization of the occluded vessel.

additional carotid T occlusion; 1 patient with long-segment occlusion of the right internal carotid artery, involving the M1 and M2 segment) and 5 patients with occlusion of the basilar artery.

### **Endovascular Procedure**

All interventions were performed by consultant neurointerventionalists (S.R., M.H., S.H., M.B.) on a biplanar system (Artis zee Biplane; Siemens, Erlangen, Germany) under general anesthesia. Using transfemoral access, a 6F guiding catheter (Envoy; Cordis Neurovascular, Miami Lakes, Florida or Neuron; Penumbra, Alameda, California) was placed into the target carotid or vertebral artery.

In contrast to the manufacturer's guidelines, no balloon guide catheter was used during clot retrieval. Using a balloon guide catheter is recommended to achieve flow arrest and prevent distal embolization with thrombus material. However, we did not observe any distal embolization during our recanalization procedures. Furthermore, placement of an 8F catheter in arteriosclerotic and tortuous vessel segments might be difficult and might complicate the intervention.

A microcatheter (Prowler Select Plus, Cordis or Rebar 27, ev3) with a 0.014-inch microwire (Transcend; Boston Scientific, Natick, Massachusetts) was carefully advanced through the thromboembolic occlusion under fluoroscopic control. Angiographic runs were subsequently performed through the microcatheter to estimate the length of the occlusion and to document the correct position of the microcatheter tip at least 0.5 cm beyond the distal end of the thrombus. Under fluoroscopic control, the Solitaire stent was advanced through the microcatheter across the vessel occlusion with the distal stent markers beyond the distal end of the occlusion. The stent was deployed completely by pulling back the microcatheter, and angiographic runs were done to control for flow restoration (Fig 1). The time of stent deployment before its retrieval varied between 1 and 20 minutes. It depended on the recanalization concept: mechanical recanalization or combined mechanical and pharmacologic recanalization (with a longer stent deployment).

In case of persistent occlusion or incomplete vessel recanalization, the Solitaire stent was recaptured and deployed again to restore ante-

grade blood flow. In 4 cases, the deployed stent was used for thrombectomy by retrieving the stent into the guiding catheter. During clot retrieval, proximal aspiration was performed by using a 20-mL syringe. At the end of the procedure, the stent was recaptured with the microcatheter. In 5 cases with an underlying stenosis, incomplete vessel recanalization, or both, the Solitaire stent was detached electrolytically within the stenotic vessel segment.

As additional periprocedural medication, 4 patients received 500 mg of aspirin, 5 patients received between 2000 and 7000 U of heparin, and 8 patients received tirofiban (administered intravenously, at an initial rate of 0.4  $\mu\text{g}/\text{kg}/\text{min}$  for 30 minutes and continued at 0.1  $\mu\text{g}/\text{kg}/\text{min}$  for 24 or 48 hours). In patients with permanent stent deployment, postprocedural medication with 100 mg of aspirin and 75 mg of clopidogrel was initiated. One of these patients already was on aspirin and clopidogrel because of a cardiac disease. Another patient was already treated with oral anticoagulants because of atrial fibrillation in his medical history.

Successful recanalization of the occluded vessel segment was defined as TICI grade 2 or 3 (TICI score). TICI is a 4-point-scale that ranges from “no antegrade flow beyond the point of occlusion” (TICI 0) to “antegrade flow into the bed distal to the obstruction occurs as promptly as into the obstruction, contrast material clearance from the involved vascular territory is rapid” (TICI 3).<sup>14</sup> TICI scores were estimated from angiographic runs before and after the procedure. Assessment of angiographic images was performed in consensus by 2 experienced neuroradiologists (S.R., S.S.).

Furthermore, angiographic images were evaluated regarding time to recanalization (defined as the time interval from the first diagnostic angiogram to the first angiogram with evidence of perfusion within the occluded vessel segment), length of the occlusion (in millimeters, by using the catheter diameter for calibration), number of stent deployments necessary for reperfusion, number of recanalized vessel segments, and the additional application of the Solitaire stent as a thrombectomy device.

### Statistics

Continuous data are described by mean and SD. Statistical analysis was performed using Prism 5.0 for OSX (GraphPad Software, San Diego, California).

## Results

### Safety, Technical Feasibility, and Angiographic Outcome

In total, 18 patients with 19 occluded vessel segments were treated with the Solitaire stent (in 1 patient, 2 occluded M2 segments were recanalized). Mean time from symptom onset to the first diagnostic angiogram was  $240.9 \pm 71.4$  minutes. Mean time from the beginning of the intervention (defined as the first angiographic run) to recanalization was  $48.3 \pm 21.9$  minutes. Mean length of the occlusion was  $19.8 \pm 6.9$  mm. Mean number of stent deployments was  $2.5 \pm 1.9$ . In 17 patients, additional thrombolytic medication was applied (IV,  $n = 5$ ; IA,  $n = 4$ ; and combined,  $n = 8$ ). In 1 patient, Wallstent (Boston Scientific) implantation in the right internal carotid artery was performed before recanalization with the Solitaire stent because of an underlying vessel stenosis and a long-segment occlusion of the right internal carotid artery and M1/M2. In this case, 9 Solitaire stent deployments were necessary to achieve successful recanalization.

In 4 cases, the stent was used for thrombectomy. This was

successful (ie, extraction of thrombotic material with subsequent recanalization) in 3 cases. In 5 patients with reocclusion of the recanalized vessel immediately after recapture of the temporarily opened stent, permanent deployment of the stent was performed to maintain stable perfusion within the recanalized vessel segment ( $n = 2$  cases with underlying stenosis,  $n = 3$  cases with residual thrombus formation). There were no periprocedural complications related to the use of the Solitaire stent.

Angiographic evaluation of the perfusion of the affected artery before the intervention revealed complete vessel occlusion in all cases (TICI 0). Overall, mean TICI score after the intervention was  $2.3 \pm 0.8$  (without differentiation between TICI 2a and 2b). Complete reperfusion (TICI 3) was present in 9 cases and only partial filling of the entire vascular territory (TICI 2a) in 4 cases. There were 3 cases with complete filling of the entire expected vascular territory but delayed filling of contrast medium (TICI 2b). Absent or only partial filling of the target vessel (TICI 0 and 1) was documented in 2 cases. Recanalization (ie, TICI  $\geq 2$ ) of the occluded segment was successful in 16 of 18 patients (88.8%) and 17 of 19 vessel segments, respectively.

### Clinical Outcome

**General Outcome Measures.** Mean NIHSS score at admission was  $21.0 \pm 6.7$  (range, 7–35). In 14 patients, stroke etiology was assumed to be thromboembolic; in 4 patients an additional underlying vessel stenosis within the occluded vessel segment was identified angiographically.

Overall, there were 5 fatal outcomes: 3 patients due to extensive brain infarction, 1 patient due to a brain stem hemorrhage after successful recanalization of the basilar artery, and 1 patient due to multiorgan failure. A good clinical outcome (mRS,  $\leq 2$ ) at discharge was achieved in 33.3% of the patients, 5.5% had a moderate outcome (mRS, 3 or 4) and 61.2% had a poor outcome or died (mRS, 5 or 6).

**Ischemia following the Procedure.** In 2 patients with occlusion of the MCA, revascularization of the target vessel was unsuccessful: in 1 patient, reocclusion occurred immediately after partial recanalization with the Solitaire stent. This patient died 4 days after symptom onset due to extensive infarction. In the other patient, stent deployment was not possible due to very resistant, probably calcified thrombotic material. The patient was discharged to a rehabilitation center 17 days after stroke onset (mRS at discharge, 5).

**Hemorrhagic Complications.** In 1 patient with left MCA occlusion, extravasation of contrast agent in the left lentiform nucleus was found on the immediate postinterventional CT scan. This patient had received tirofiban in a standard dose rate, 30 mg rtPA IV, 15 mg rtPA IA, and a standard dose of aspirin and clopidogrel (because of permanent stent deployment). After 10 hours, CT scan was repeated due to clinical deterioration, and control CT revealed a massive hemorrhage originating from the left lentiform nucleus. The patient survived without evacuation of the hematoma or development of significant infarction. One month after symptom onset, the patient was discharged to a rehabilitation center (mRS at discharge, 5).

Another patient with thromboembolic basilar artery occlusion who had received 55 mg of rtPA for IV lysis (“bridging”),

20 mg rtPA IA, and tirofiban experienced large brain stem hemorrhage 1 hour after successful recanalization, and died 2 days later.

In 1 patient (77 mg rtPA IV, aspirin/clopidogrel in a standard dose rate due to Wallstent implantation in the right internal carotid artery) with long-segment occlusion of the right internal carotid artery and M1/M2, CT scan revealed hemorrhage in the right lentiform nucleus 1 hour after the procedure. In addition, he had developed a right-sided infarction of the MCA territory. Evacuation of the hemorrhage was not necessary. The patient died 1 month after symptom onset due to multiorgan failure.

## Discussion

This study shows that the Solitaire stent, a self-expanding and fully retrievable stent, can rapidly, safely, and effectively retrieve clots from any large intracranial arteries. Immediate flow restoration occurred in 88.8% of patients after stent deployment.

The concept of stent placement is entrapment of the thrombus between the stent and the vessel wall to provide fast recanalization and to restore antegrade blood flow by creating a channel inside of the thrombus. As a potential disadvantage, permanently implanted stents require double platelet inhibition with a risk for hemorrhage. Another concern is risk of in-stent stenosis.<sup>15</sup> The Solitaire stent offers an alternative for revascularization in acute stroke patients, because no anticoagulation is needed because the stent can be recaptured without need for subsequent antiaggregation. The concept of this temporary endovascular bypass is rapid flow restoration by displacing and disrupting the occluding clot and enhancing the efficacy of thrombolytic drugs. Particularly advantageous is that the stent is applicable multiple times and can be used even in small peripheral vessel branches (eg, M2 segments). In our study, on average, 2.5 stent openings were necessary for successful recanalization.

Recently, a study on safety and efficacy of the Solitaire stent in 20 patients with large artery occlusions of the anterior circulation was published.<sup>9</sup> In our study, we included patients with occlusions of the anterior circulation as well as patients with posterior circulation occlusions (MCA = 13, basilar artery = 5). In Castaño's study, 3 patients were included with the Solitaire stent as the second endovascular approach (after unsuccessful treatment with the Merci retriever [Concentric Medical, Mountain View, California]). In contrast to this, we included only patients with the Solitaire stent as the first-line endovascular device. Success rate was high in both studies (90% in Castaño's study, 88.8% in our study).

In 3 of 18 patients in our series (16.6%), intracranial hemorrhage occurred. In all of these patients, recanalization had been successful. In all of them, IV and/or IA lysis was administered. Furthermore, 2 had received a standard dose rate of tirofiban peri- and postprocedurally, and 1 had received aspirin and clopidogrel due to Wallstent implantation in the right internal carotid artery. In these cases, hemorrhage might be caused by reperfusion injury after recanalization of the occluded vessel or by the administered medication (in 2 of 3 cases of hemorrhage, IA and IV lysis as well as tirofiban were given).

The rate of symptomatic intracranial hemorrhage is slightly higher than reported intracranial hemorrhage rates

after use of other thrombectomy devices (Multi MERCI trial, 9.8%<sup>4</sup>; Penumbra pivotal stroke trial, 11.2%<sup>5</sup>) and also higher compared with the study of Castaño et al<sup>9</sup> (10% symptomatic intracranial hemorrhage).

Overall, TICI 2 and 3 scores were achieved in 88.8% of the cases, a rate that is superior to the recanalization rate in the Penumbra Pivotal Stroke trial (81.6%)<sup>5</sup> and MERCI trial (69.5%),<sup>4</sup> respectively, and similar to the result of the recently published study by using the Solitaire stent (90%).<sup>9</sup>

In 1 of 18 patients (1 of 19 vessel segments), stent opening was not possible due to very resistant, probably calcified thrombus formation, indicating that the Solitaire stent is less suitable for hard thrombus formation.

## Conclusions

Treatment with the Solitaire stent is safe and technically feasible in a high percentage of patients. Vessel recanalization was successful in 88.8% of patients within a mean time of only 48.3 minutes after procedure start. The results encourage further prospective trials to evaluate the potential benefit in acute stroke patients.

Disclosures: Peter A. Ringleb: *Research Support (including provision of equipment or materials):* German Research Foundation *Details:* For conducting a multicenter trial for extracranial carotid artery stenosis. No conflict of interest with this paper. *Speaker Bureau:* Boehringer, Sanofi, Ferrer, Lilly. *Details:* Modest honorary (<€2000/year) lecture fees, mostly about thrombolytic therapy. No conflict of interest with this paper. Martin Bendszus: *Speaker Bureau:* Micrus, Codman. *Details:* Training courses (both), €1000.

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