Criteria

- 1) Refractory to general anesthesia; patients were not amenable to general anesthesia even though they have been pretreated with medical therapy
- 2) Any condition that precludes proper angiographic assessment
- 3) Tandem extracranial or intracranial stenosis (70%–99%) or occlusion that is proximal or distal to the target intracranial lesion
- 4) Bilateral intracranial vertebral artery stenosis of 70%–99% and uncertainty about which lesion is symptomatic (eg, if the patient has pontine, midbrain, temporal, and occipital lobar symptoms)
- 5) Presence of a previously placed intravascular stent or graft in the ipsilateral distribution within 1 month
- 6) Previous treatment of the target lesion with a stent, angioplasty, or other mechanical device or a plan to perform staged angioplasty followed by stent placement in target lesion
- 7) Severe vascular tortuosity or anatomy that would preclude the safe introduction of a guiding catheter, guiding sheath, or stent placement
- 8) Plan to perform concomitant angioplasty or stenting of an extracranial vessel tandem to an ipsilateral intracranial stenosis
- 9) Presence of intraluminal thrombus proximal to or at the target lesion
- 10) Any aneurysm proximal to or distal to an intracranial stenotic artery
- 11) Intracranial tumors or any intracranial vascular malformations
- 12) CT or angiographic evidence of severe calcification at the target lesion
- 13) Thrombolytic therapy within 24 hours before enrollment
- 14) Evolving stroke or progressive neurologic signs within 24 hours before enrollment
- 15) Stroke of sufficient size (>5 cm on CT or MRI) to place the patient at risk of hemorrhagic transformation during the procedure; hemorrhagic transformation of an ischemic stroke within the past 15 days
- 16) Previous spontaneous intracerebral (parenchymal) or other intracranial (subarachnoid, subdural, or epidural) hemorrhage within 1 month
- 17) Untreated chronic subdural hematoma of >5 mm in thickness
- 18) Other cardiac sources of emboli such as left ventricular aneurysms, intracardiac filling defect, cardiomyopathy, aortic or mitral prosthetic heart valve, calcified aortic stenosis, endocarditis, mitral stenosis, atrial septal defect, atrial septal aneurysm, and left atrial myxoma
- 19) Myocardial infarction within the previous 30 days
- 20) Chronic atrial fibrillation; any episode of paroxysmal atrial fibrillation within the past 6 months or history of paroxysmal atrial fibrillation requiring chronic anticoagulation
- 21) Intolerance or allergic reaction to any medical therapy, including aspirin, clopidogrel, heparin, and local or general anesthetics
- 22) History of life-threatening allergy to contrast medium; if not life-threatening and can be effectively pretreated, patient can be enrolled at physician's discretion
- 23) Recent gastrointestinal bleeding that would interfere with antiplatelet therapy
- 24) Active bleeding diathesis or coagulopathy; active peptic ulcer disease; major systemic hemorrhage within 30 days, active bleeding diathesis, platelet count < 125,000, hematocrit level < 30, Hgb level < 10 g/dL, uncorrected INR > 1.5, bleeding time >1 minute beyond upper limit normal; or heparin-associated thrombocytopenia that increases the risk of bleeding; uncontrolled severe hypertension (systolic BP > 180 mm hg or diastolic BP > 115 mm hg); severe liver impairment (AST or ALT > 3 times normal, cirrhosis); serum creatinine level > 265.2 μ mol/L (unless on dialysis)
- 25) Major surgery (including open femoral, aortic, or carotid surgery) within previous 30 days or planned in the next 90 days after enrollment
- 26) Indication for warfarin or heparin beyond enrollment (note: exceptions allowed the use of systemic heparin during the stent-placement procedure or subcutaneous heparin for deep venous thrombosis prophylaxis while hospitalized)
- 27) Inability to understand and cooperate with study procedures or sign an informed consent
- 28) Severe dementia or psychiatric problems that prevent the patient from following an outpatient follow-up program reliably
- 29) Pregnancy or childbearing potential and unwilling to use contraception for the duration of this study
- 30) Actively participating in another drug or device trial that has not completed the required protocol follow-up period

Note:—Hgb indicates hemoglobin; INR, international normalized ratio; BP, blood pressure; AST, aspartate transaminase; ALT, alanine aminotransferase.

		Location of		Preprocedure	Preprocedure Postprocedure		mRS at	mRS at
Case No.	Case No. Age (yr)/Sex	Stenotic Artery	Events	Stenosis	Stenosis	Mechanism of Stroke	Event	30 Days
2	42/Female	Mid-basilar artery	Presented with right-sided hemiparesis and ataxia within 24 hours after basilar artery	%06	10%	Perforating artery ischemic stroke; left pontine infarction on MRI	2	0
œ	50/Female	Mid-basilar arterv	stent placement Presented with left-sided hemiplegia and	75%	2%	Perforating artery ischemic stroke:	4	-
			central facial paralysis 72 hours after basilar			right pontine infarction on MRI		
			artery stent placement					