Unyielding Progress: Carotid Stenting Cases From Millard Fillmore Gates Circle Hospital in Buffalo, New York

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Ultiple randomized, controlled trials have shown that carotid endarterectomy leads to a reduction in stroke risk for patients with symptomatic or asymptomatic stenotic carotid artery lesions.¹⁻⁴ For symptomatic disease, a 16% absolute 2-year risk reduction of stroke or death is frequently quoted on the basis of data from a large trial.¹ For asymptomatic disease, a more modest, 5% to 6% absolute 5-year stroke or death risk is cited on the basis of data from large trials.^{2,4}

After the initiation of these trials, carotid artery stenting emerged as a less invasive option for carotid revascularization. Several head-to-head trials of carotid endarterectomy and carotid artery stenting have displayed similar overall risk.⁵⁻⁸ Embolic protection devices, used with increased frequency in carotid stenting trials, have reduced the incidence of perioperative ischemic stroke. The most recently completed such trial displayed noninferiority of carotid stenting by the measure of 30-day composite incidence of stroke, myocardial infarction, or death.^{5,6} Although the perioperative risk of carotid revascularization with carotid endarterectomy compared with carotid stenting remains a point of contention, the allure of a minimally invasive intervention frequently steers a patient requiring carotid revascularization toward stenting.

Two carotid stenting cases that were broadcast live during the 2011 Annual Meeting of the Congress of Neurological Surgeons are described here, displaying symptomatic (case 1) and asymptomatic (case 2) stenoses with examples of proximal (case 1) and distal (case 2) embolic protection. Teaching points for each case are discussed, along with eligibility for carotid stenting and rationale for the devices used, including embolic protection and stent implantation and ancillary devices used for safety measures.

CASE 1: SYMPTOMATIC STENOSIS WITH PROXIMAL PROTECTION

Clinical Presentation

A 68-year-old woman presented with multiple 20-second-duration episodes of expressive aphasia and right

hemiparesis. Her medical history was notable for diabetes mellitus, hypertension, hypercholesterolemia, and coronary artery disease for which she underwent the placement of several coronary stents. Antiplatelet medications before her transient ischemic events included aspirin and clopidogrel. Clopidogrel response testing yielded suboptimal platelet inhibition. The patient's dose was doubled from 75 mg daily to 75 mg twice daily, with subsequent improvement in platelet inhibition on testing.

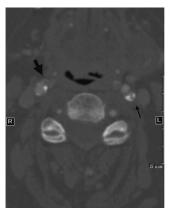
On presentation, a noncontrast cranial computed tomographic scan, computed tomographic perfusion imaging, and magnetic resonance imaging were performed without notable findings. Evaluation for a cardioembolic source of the patient's symptoms was negative. Computed tomographic angiography revealed an ulcerated, stenotic plaque at the origin of the left internal carotid artery (ICA), with mixed atheromatous and sclerotic features; less severe stenosis was appreciated in the contralateral ICA (Figure 1). A digital subtraction angiogram confirmed stenosis of the left ICA of slightly more than 80% with ulceration (Figure 2). A tandem stenosis of the paraclinoid ICA of approximately 50% was also appreciated (Figure 3). Stenotic lesions were estimated on the basis of North American Symptomatic Carotid Endarterectomy Trial criteria. ¹

Teaching Points

Several radiographic and clinical features make stenting more favorable than endarterectomy for the treatment of symptomatic carotid stenosis. Radiographic risk factors associated with endarterectomy include surgically inaccessible lesions, 9-12 contralateral stenosis or occlusion, 12,13 and intraluminal thrombus. 10,12 Medical risk factors, including evolving or unstable neurological symptoms, 10,14 portend increased perioperative risk. Because the risk of myocardial infarction is lower with stenting than with endarterectomy, 5,6 patients at high risk for cardiac events should be considered for stenting. Alternatively, because of the use of nephrotoxic contrast material with stenting, patients with poor renal function should be considered for endarterectomy. The risk of contralateral occlusion is theoretically obviated in patients treated with temporary shunt placement during endarterectomy or with

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FIGURE 1. Computed tomography (CT) angiogram. Axial view of the CT angiogram (left) with coronal (center) and sagittal (right) reconstructions displays bilateral atherosclerotic stenosis (thick arrow, left internal carotid artery [ICA] stenosis; thin arrow, right ICA stenosis).









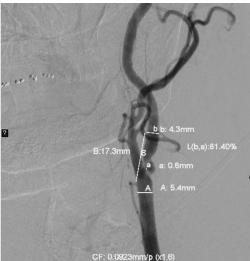


FIGURE 2. Digital subtraction angiogram, left common carotid artery. Left, an ipsilateral oblique view of the diseased artery displays a stenotic lesion with ulceration (arrow). Right, measurements of stenosis severity are shown (81% stenosis by NASCET criteria).

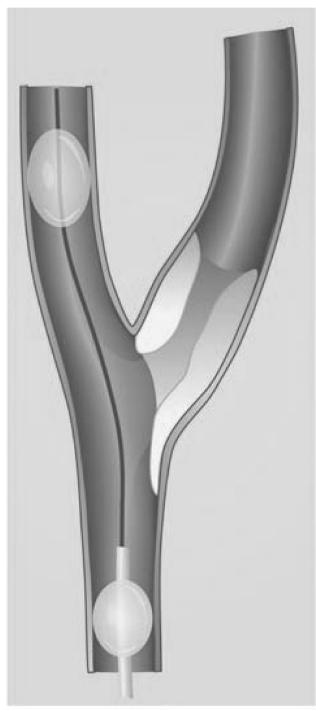
distal embolic protection during stenting; thus, either revascularization approach is a reasonable therapeutic option.

For the patient in case 1, with symptomatic carotid stenosis in excess of 80%, carotid artery stenting is an

appropriate treatment option. In this case, intracranial stenosis¹⁵ and plaque ulceration¹⁶ increase the risk of ischemic stroke perioperatively and with medical management alone, respectively. In the event of intraoperative thromboembolism



FIGURE 3. Digital subtraction angiogram, left common carotid artery (ICA). Anteroposterior (left) and lateral (right) cranial views display a tandem stenosis of approximately 50% of the left ICA distal to the ophthalmic artery (arrow on the right image).



Proximal Occlusion

FIGURE 4. Schematic illustration. A proximal protection device uses a special balloon catheter to occlude flow in the external and common carotid arteries. Flow may be reversed with active or passive aspiration through the guide catheter lumen. The theoretical benefit of proximal protection compared with distal protection is that the lesion need not be crossed without embolic protection.

in a patient with intracranial stenosis, the risk of a clinically relevant ischemic stroke is theoretically increased. For this reason, embolic protection with a proximal flow arrest device rather than distal embolic protection was chosen in this case. Proximal flow protection uses a balloon catheter to occlude the external carotid artery (ECA) and common carotid artery (CCA), thus causing stasis or reversal of flow through the site of stenosis (Figure 4). If any plaque debris is created during passage of the stent, it is aspirated through the balloon catheter to minimize the possibility of thromboembolism. Proximal protection is ideal for carotid stenting cases in which the risk of thromboembolism is theoretically great such as hemorrhagic plaque, pseudo-occlusion, or a nearly occluded lumen limiting passage of the device past the lesion without disruption of the plaque and absence of a distal landing zone for a distal embolic protection device. 17,18

For a symptomatic lesion, a closed-cell stent with a relatively small free-cell area, which limits mobilization of plaque debris, is preferred. 19,20 Another benefit of a closed-cell stent is the possibility of stent recapture and repositioning after partial deployment if needed. In contrast, a patient with a tortuous vessel at or just distal to the area of vessel stenosis is frequently better treated with an open-cell stent to avoid vessel kinking. Intravascular ultrasound is preferably used to assess patients with symptomatic stenosis so that any intraluminal debris that might be present after stent placement can be noted and treated appropriately. 21

Procedural Technique

Devices used in this case are listed in Table 1. The patient received midazolam and fentanyl for conscious sedation. After injection of lidocaine, a micropuncture set was used to access the right femoral artery, which was then successively dilated with 5F and 7F sheath dilators until a 9F sheath was placed. After confirmation of femoral artery access, a sufficient quantity of heparin was administered to produce an activated coagulation time in excess of 250 seconds. A Supra Core wire (Abbott Vascular, Abbott Park, Illinois) and a VTK catheter (Cook Medical, Bloomington, Indiana) were advanced into the aortic arch. The left CCA was catheterized under direct fluoroscopic visualization. With a roadmap technique, the Supra Core wire was advanced into the ECA (Figure 5). The VTK catheter was then exchanged

TABLE 1. Devices Used in Case 1

5F sheath dilator

7F sheath dilator

9F sheath

Supra Core wire (Abbott Vascular, Abbott Park, Illinois)

VTK catheter (Cook Medical, Bloomington, Indiana)

Mo.Ma proximal protection system (Invatec, Roncadelle, Italy)

Sparta Core wire (Abbott Vascular)

Wallstent (8 × 21 mm; Boston Scientific, Natick, Massachusetts)

Aviator balloon (4 $\times\,20$ mm) (Cordis Vascular, Bridgewater, New Jersey)

Digital intravascular ultrasound catheter (Volcano Therapeutics, Rancho Cordova, California)

FIGURE 5. Digital subtraction angiogram, left common carotid artery. Anteroposterior (left) and lateral (right) intraoperative angiographic run displays the Supra Core wire (Abbott Vascular, Abbott Park, Illinois) within the lingual branch of the external carotid artery (thick arrow). The Cook shuttle (Cook Medical, Bloomington, Indiana; shuttle tip outlined with thin arrow) will be advanced along the Supra Core wire to a position just proximal to the stenosis.

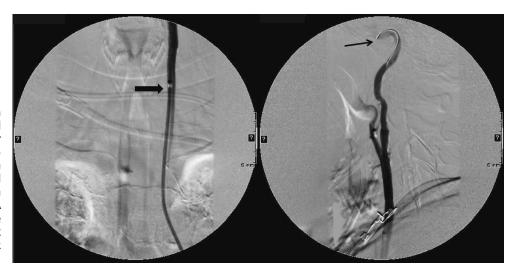


for a Mo.Ma catheter (Invatec, Roncadelle, Italy), which was advanced over the Supra Core wire and parked with the distal Mo.Ma balloon in the ECA and the proximal Mo.Ma balloon in the CCA. An appropriately sized $(8 \times 21 \text{ mm})$ Wallstent (Boston Scientific, Natick, Massachusetts) was selected and advanced within the Mo.Ma device over a Sparta Core wire (Abbott Vascular) to the level of the CCA. A cervical angiogram was completed, confirming ICA stenosis. At this point, the Mo.Ma balloons were inflated for arterial stasis and proximal embolic protection. By convention, the proximal Mo.Ma balloon within the CCA is inflated before the distal balloon within the ECA. Under roadmap guidance with direct fluoroscopic visualization, the lesion was crossed first with the Sparta Core wire and then with the Wallstent advanced over this wire and into position. The stent was placed across the lesion and deployed. The Wallstent delivery system was then exchanged for an Aviator balloon (Cords Vascular, Bridgewater, New Jersey). The balloon was centered over the stenosis within the stent and inflated to nominal pressure.

With the carotid artery under flow arrest, the balloon was inflated and deflated in rapid succession once. The Aviator balloon catheter was then exchanged for an intravascular ultrasound catheter. Ultrasonography revealed no significant intraluminal thrombus; thus, the intravascular ultrasound catheter was removed. Flow reversal with aspiration of 20-cm³ aliquots of blood was performed. The aspirate was filtered and inspected for debris. In the absence of debris, the Mo.Ma balloons were deflated in reverse order of inflation, with restoration of anterograde flow within the carotid artery.

The patient remained hemodynamically and neurologically stable throughout stent placement, angioplasty, and ultrasonography. After angiography confirmed no intraluminal thrombus and no distal embolization (Figure 6), the Sparta Core wire was removed, followed by the Mo.Ma catheter. Cervical angiography confirmed an improved filling at the site of the previous stenosis and no injury at the site of balloon inflation. The right femoral sheath was removed after normalization of the partial thromboplastin time.

FIGURE 6. Digital subtraction angiogram, left common carotid artery (CCA). Anteroposterior (left) and lateral (right) intraprocedural angiographic run after deployment of the carotid stent. The microwire is seen in position in the distal cervical ICA (thin arrow). The Cook shuttle (Cook Medical) is positioned just proximal to the stenosis (thick arrow).



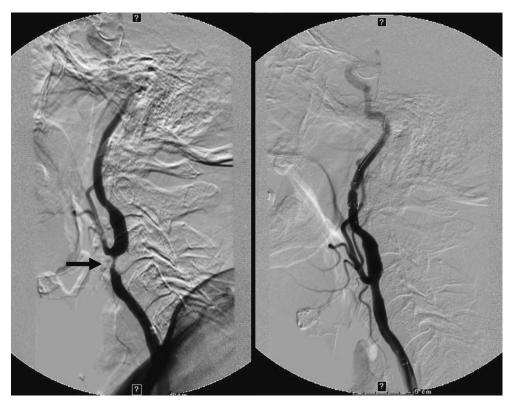


FIGURE 7. Digital subtraction angiogram, left common carotid artery (CCA). Lateral cervical angiographic runs before (left, arrow indicates CCA stenosis) and after (right) stenting procedure.

Postoperatively, the patient was observed in the intermediate care unit with neurological and cardiac monitoring with an uneventful hospital course. She was discharged home on postoperative day 1.

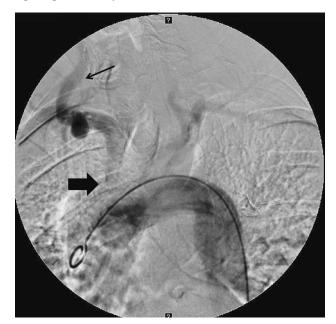


FIGURE 8. Digital subtraction angiogram, aortic arch study. A type II aortic arch is displayed. Access to the right common carotid artery (thin arrow) via the innominate artery (thick arrow) in this case is straightforward.

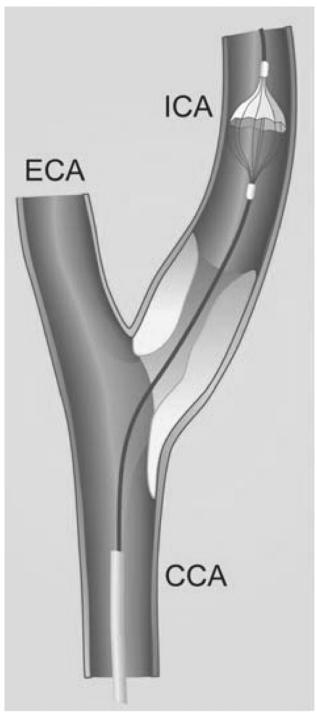
CASE 2: ASYMPTOMATIC STENOSIS WITH DISTAL EMBOLIC PROTECTION

Clinical Presentation

A 68-year-old man with a history of bilateral carotid endarterectomy for asymptomatic carotid stenosis 6 years earlier was found to have elevated carotid Doppler velocities during an annual screening examination. His medical history was notable for hypertension and peripheral vascular disease for which he had undergone multiple peripheral vascular angioplasty procedures. His medical regimen included dual antiplatelet medication with clopidogrel (75 mg daily) and aspirin (325 mg daily). Angiography confirmed bilateral highgrade stenosis of the left CCA and right ICA. In addition, a 70% stenosis of the cavernous right ICA was present. The left CCA stenosis, proximal to the site of previous endarterectomy, was treated previously with carotid artery stenting with distal embolic protection (Figure 7). The left-sided stenosis was treated in advance of the right carotid lesion because of its higher grade of stenosis. At present, the right ICA stenosis, on the order of 85% in severity, was to be treated with stenting.

Teaching Points

Advances in medical therapy, with widespread use of 3-hydroxy-3-methyl-glutaryl-CoA reductase inhibitor agents (statins) with antihyperlipidemic and anti-inflammatory properties, coupled with single- or dual-antiplatelet therapy directed toward curtailing platelet aggregation, may ultimately negate



Filter

FIGURE 9. Schematic illustration. A distal protection device uses a filter that is deployed distal to the stenosis to capture plaque debris created with placement of the stent. Simple and reliable, its use has contributed to a reduction in perioperative embolic events. The theoretical benefit compared with proximal protection is no requirement of flow cessation. CCA, common carotid artery; ECA, external carotid artery; ICA, internal carotid artery.

TABLE 2. Devices Used in Case 2

6F sheath

0.038-in exchange wire

Slip catheter (Cook Medical, Bloomington, Indiana)

Cook shuttle (Cook Medical)

Emboshield NAV6 distal protection device (Abbott Vascular, Abbott Park, Illinois)

Xact stent 7 to 9 tapered × 30 mm (Abbott Vascular)

Aviator balloon 5×30 (Cordis Vascular, Bridgewater, New Jersey)

the value of carotid revascularization in asymptomatic carotid stenosis. Until the 3-arm Stent Protected Angioplasty vs Carotid Endarterectomy study²² is completed, the best evidence for treatment of asymptomatic carotid stenosis suggests that carotid revascularization reduces the risk of stroke.^{2,4} The patient in case 2 has asymptomatic carotid artery stenosis in excess of 80%, which makes him eligible for bilateral carotid revascularization. A history of carotid endarterectomy, as in this patient, places the patient at high risk for endarterectomy and therefore makes him a good candidate for carotid stenting.

A consideration in any endovascular case is access. A difficult aortic arch, atheromatous plaque within the aortic arch, or a tortuous CCA could prolong a carotid stenting procedure and expose the patient to an increased risk of embolic events.²³ In case 2, the aortic arch allows straightforward access to both carotid arteries (Figure 8). With straightforward access, an acceptable landing zone, and an uncomplicated stenotic lesion, distal embolic protection is a reasonable option in this case. A distal embolic protection device is an endoluminal filter designed to collect any plaque debris dislodged during placement of the stent (Figure 9). It may be used alone or with a proximal protection device. For asymptomatic carotid stenosis, most carotid artery stents are acceptable. As mentioned, closed-cell stents with a small freecell area are preferred to minimize thrombogenic potential during stent placement.

Procedural Technique

Devices used in this case are listed in Table 2. The patient received Versed and fentanyl for conscious sedation. After injection of lidocaine for local anesthesia, a micropuncture set was used for access into the right femoral artery. A 6F sheath was placed. Once access was confirmed, heparin was administered to achieve a target activated coagulation time in excess of 250 seconds. A 0.038-in exchange wire was advanced through the sheath into the aortic arch. The 6F sheath was then removed and exchanged over the wire with the Cook shuttle (Cook Medical). A Slip catheter (Cook Medical) was positioned within the Cook shuttle and was used to select the right CCA under direct fluoroscopic visualization. The shuttle was advanced over the Slip catheter into the right CCA. Under roadmap guidance, the exchange wire was advanced into the ECA. The Slip catheter and shuttle were advanced over the wire within the CCA to a position just proximal to the carotid bifurcation (Figure 10). The wire

FIGURE 10. Digital subtraction angiogram, right common carotid artery (CCA). Anteroposterior (left) and lateral (right) intraoperative views display the Cook shuttle (Cook Medical) in position within the CCA. High-grade stenosis of the internal carotid artery is appreciated (arrow in the image on the right). In general, during stenting procedures, it is ideal to have 1 proximal view to visualize the access (anteroposterior view) and another to visualize the lesion and distal vasculature (lateral view).





FIGURE 11. Digital subtraction angiogram, right common carotid artery. Anteroposterior (left) and lateral (right) intraoperative views display the microwire (top arrow in the image on the right) and filter (arrow below previous one) within the distal internal carotid artery. With severe stenosis (thick arrow), there is nearly occlusion of the carotid artery with the microwire in place distal to the lesion.



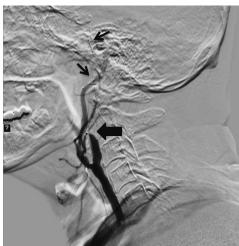


FIGURE 12. Digital subtraction angiogram, anteroposterior (left) and lateral (right) intraprocedural views display improved normal caliber of the internal carotid artery through the previously stenotic site (arrow in the image on the right).





and Slip catheter were then carefully removed. Cervical angiography confirmed ICA stenosis (Figure 10). An Emboshield NAV6 distal protection filter (Abbott Vascular) was advanced into the distal ICA and deployed at the C1 spinal level within the ICA (Figure 11). With the filter in place, a tapered Xact stent (7-9 × 30 mm, Abbott Vascular) was advanced along the filter wire to the site of stenosis. If the stent is not easily passed through the stenosis, a predilation angioplasty is performed with an undersized balloon. For procedural simplicity (ie, to limit device exchanges) and to limit thromboembolic potential, 1 angioplasty after placement of the stent is preferred. In this case (and case 1), the stenosis was not so great that the stent could easily be passed through the area of greatest stenosis and into position. Once centered at the stenosis, the stent was deployed into position. The stent delivery system was then exchanged for an Aviator balloon catheter (Cordis Vascular). The balloon was inflated and subsequently deflated and removed. The patient remained hemodynamically and neurologically stable throughout the stent placement and angioplasty steps of the procedure. Before recapture and removal of the filter and filter wire, angiography confirmed good revascularization of the ICA (Figure 12) and no distal thromboembolism. The Cook shuttle was exchanged over the 0.038-in wire with an 8F sheath after normalization of the partial thromboplastin time.

Postoperatively, the patient was observed in intermediate care for cardiac and neurological monitoring with an uneventful hospital course. He was discharged home on postoperative day 1.

CONCLUSION

Carotid artery stenting represents an option for carotid revascularization in the setting of atherosclerotic carotid artery disease. Technologies to reduce intraoperative thromboembolism have reduced perioperative stroke from the earliest²⁴ to more recent^{5,6} carotid stenting trials. Understanding the indication and technique of proximal (case 1) and distal (case 2) protection devices is important to minimize intraoperative thromboembolism. Although experience may be varied among surgeons, excellent outcomes are expected with use of distal or proximal embolic protection devices during carotid stenting.

Disclosure

Dr Hopkins receives grant/research support from St. Jude Medical and Toshiba; serves as a consultant to Abbott, Boston Scientific, Cordis, Micrus, and W.L. Gore; holds a financial interest in AccessClosure, Augmenix, Boston Scientific, Claret Medical Inc, Micrus, and Valor Medical; has a board/trustee/officer position with AccessClosure, and Claret Medical Inc; belongs to the Abbott Vascular speakers' bureau; and receives honoraria from Bard, Boston Scientific, Cordis, Memorial Healthcare System, Complete Conference Management, SCAI, and Cleveland Clinic. Dr Levy receives research grant support (principal investigator, Stent-Assisted Recanalization in Acute Ischemic Stroke), other research support (devices), and honoraria from Boston Scientific and research support from Codman

& Shurtleff, Inc. and ev3/Covidien Vascular Therapies; has ownership interests in Intratech Medical Ltd. and Mynx/Access Closure; serves as a consultant on the board of Scientific Advisors to Codman & Shurtleff, Inc; serves as a consultant per project and/or per hour for Codman & Shurtleff, Inc, ev3/ Covidien Vascular Therapies, and TheraSyn Sensors, Inc; and receives fees for carotid stent training from Abbott Vascular and ev3/Covidien Vascular Therapies. Dr Levy receives no consulting salary arrangements. All consulting is per project and/or per hour. Dr Siddiqui has received research grants from the National Institutes of Health (coinvestigator, NINDS 1R01NS064592-01A1, Hemodynamic Induction of Pathologic Remodeling Leading to Intracranial Aneurysms) and the University at Buffalo (Research Development Award); holds financial interests in Hotspur, Intratech Medical, StimSox, and Valor Medical; serves as a consultant to Codman & Shurtleff, Inc, Concentric Medical, ev3/Covidien Vascular Therapies, Guide-Point Global Consulting, and Penumbra; belongs to the speakers' bureaus of Codman & Shurtleff, Inc. and Genentech; serves on an advisory board for Codman & Shurtleff; and has received honoraria from American Association of Neurological Surgeons' courses, an Emergency Medicine Conference, Genentech, Neocure Group LLC, and Abbott Vascular and Codman & Shurtleff, Inc. for training other neurointerventionists in carotid stenting and for training physicians in endovascular stenting for aneurysms. Dr Siddiqui receives no consulting salary arrangements. All consulting is per project and/or per hour. Dr Snyder serves as a consultant to and a member of the speakers' bureau for and has received honoraria from Toshiba. He serves as a member of the speakers' bureau for ev3 and The Stroke Group (consultants to the healthcare industry, Littleton, Colorado) and has received honoraria from these entities. (Boston Scientific's neurovascular business has been acquired by Stryker.) The authors have no personal financial or institutional interest in any of the drugs, materials, or devices described in this article.

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