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Clinical Use of Stents for Carotid Artery Disease

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Abstract

Over the last 5 years, the clinical use of intravascular stents for treatment of carotid artery pathology has become more prevalent and the spectrum of potential indications has widened. Endovascular stenting is providing an alternative to surgical endarterectomy for treatment of cervical carotid artery atherosclerotic disease. This has prompted a North American, randomized, controlled clinical trial directly comparing these two therapies. In this article we review the major surgical endarterectomy trials that currently provide the scientific rationale for revascularization of carotid artery occlusive disease, critically evaluate the evidence supporting the application of endovascular stenting procedures for the treatment of occlusive and nonocclusive disease of the extracranial and intracranial carotid artery, consider the current clinical indications for use of stents in the carotid artery, and discuss current equipment, technique, and potential procedure-related complications.

Key words: endovascular stenting, atherosclerosis, dissection, endarterectomy, intracranial aneurysm

Introduction

In Japan and the U.S.A., stroke ranks as the third most common cause of death behind cancer and heart disease, and is a leading cause of serious, long-term disability.[12,63] The average annual incidence of stroke in Japan is 3.94 for males and 2.52 for females per 1000 population with cases of cerebral infarction outnumbering cerebral hemorrhage. Although the incidence of stroke in Japan has decreased over the last 3 decades, it remains higher than in many Western countries.[64] In the U.S.A., around 600,000 people suffer a new or recurrent stroke per year. Approximately 30% of stroke survivors require assistance caring for themselves and about 70% have an impaired vocational ability.[3] Atherosclerotic carotid artery stenosis is responsible for up to 25% of these strokes.[30] The incidence of carotid artery stenosis is estimated at 0.5% in the sixth decade rising to 10% in persons over 80 years of age. Most cases, however, are asymptomatic.[99,104,106]

Surgical carotid endarterectomy has traditionally represented the principal method for revascularization of carotid artery occlusive disease and is currently the accepted standard of treatment.[146] However, this status is being challenged by rapid improvements in percutaneous endovascular techniques utilizing catheter-based stent technology. To date, there have been over 3000 carotid artery stenting procedures performed in North America, Europe, South America, and Asia with excellent preliminary results that appear comparable to surgical carotid endarterectomy.[141] Endovascular carotid artery stenting is providing an alternative therapeutic option for patients with atherosclerotic carotid artery stenosis that poses high surgical risk because of significant co-morbidities, as well as those with surgically inaccessible or tandem carotid artery lesions, contralateral carotid artery occlusion, and post-endarterectomy restenosis. Non-atheromatous carotid artery occlusive disease due to radiation therapy, fibromuscular dysplasia, intimal dissection, as well as wide-necked aneurysms and pseudoaneurysms of the cervical and intracranial carotid artery, can also be effectively treated using percutaneous endovascular stenting techniques.

Extracranial Carotid Artery Occlusive Disease: Atherosclerotic Stenosis

I. Surgical endarterectomy and rationale

The efficacy of surgical carotid endarterectomy for treatment of symptomatic carotid artery stenosis has been proven by multiple, large, well-constructed, randomized, controlled trials.[6,36-38,83,98] The North American Symptomatic Carotid Endarterectomy Trial (NASCET) conducted at over 100 centers in the U.S.A. and Canada randomized 2926 patients with symptomatic carotid artery stenosis stratified into two groups: 30–69% (2267 patients) and 70–99% (659 patients). The NASCET demonstrated unequivocal benefit of surgery over best medical management in symptomatic patients with carotid artery stenosis of ≥70%.[98] Endarterectomy reduced the 2-year risk of any ipsilateral stroke in the medical group from 26% (annual event rate of 13%) to 9% in the surgical group: an absolute risk reduction of 17%. In other words, for every 100 patients undergoing surgery, 17 nonfatal strokes or deaths were prevented over a 2-year period.

These rates of risk reduction are directly contingent upon the surgical complication rates. In the NASCET, the full rate of risk-reduction benefit for patients with a stenosis ≥70% was obtained assuming a 30-day perioperative complication rate (nonfatal strokes and death) of ≤6%. In symptomatic stenoses of 50–69% the requisite complication rate for disabling stroke and death falls to 2%.[17] The patient inclusion criteria for the NASCET were also very strictly defined. Patients were excluded for a previous ipsilateral endarterectomy; an intracranial lesion that was more severe than the surgically accessible lesion; no angiographic visualization of both carotid arteries and their intracranial branches; or lung, liver, or renal failure. Temporary exclusion criteria included uncontrolled diabetes mellitus, hypertension, or unstable angina pectoris; myocardial infarction within the previous 6 months; contralateral carotid endarterectomy within the previous 4 months; signs of progressive neurological dysfunction; or a major surgical procedure within the previous 30 days. These patients could be included if the disorder responsible for their ineligibility resolved within 120 days of their qualifying cerebrovascular event. In the NASCET, the incidence of major stroke, myocardial infarction, or death in the surgical group was 3.1%. The inclusion of minor strokes (defined as a stroke with functional recovery within 90 days) increased the complication rate to 6.7%. Additionally, there was a 7.6% incidence of cranial nerve damage and 3.4% incidence of wound infection (Table 1).[98]

Table 1 Perioperative 30-day complication rates in symptomatic endarterectomy trials

Perioperative complication	NASCET[98] (%)	ECST[38] (%)	VA-CSP-309[83] (%)
Any stroke	5.5	NS	2.2
Major stroke	2.1	6.6	0
Death	0.6	1.3	3.3
Cranial nerve injury	7.6	NS	5.0
Wound hematoma	5.5	NS	5.0
Wound infection	3.4	NS	NS
Myocardial infarction	0.9	NS	2.0
Congestive heart failure	0.6	NS	NS
Cardiac arrythmia	1.2	NS	NS
Other cardiac problems	1.2	NS	NS
Pulmonary embolism	NS	NS	1.0

ECST: European Carotid Surgery Trial, NASCET: North American Symptomatic Carotid Endarterectomy Trial, NS: not specified, VA-CSP-309: Veterans Affairs Cooperative Symptomatic Carotid Stenosis Trial.

Table 2 NASCET-identified risk factors that doubled the perioperative stroke and mortality in patients with symptomatic moderate stenosis of 30–69%[6]

1. Contralateral carotid artery occlusion
2. Left-sided carotid artery disease
3. Taking <650 mg of aspirin per day
4. No history of angina or myocardial infarction
5. An ipsilateral lesion present on brain CT or MR imaging
6. Diabetes mellitus
7. Diastolic blood pressure >90 mmHg

CT: computed tomography, MR: magnetic resonance, NASCET: North American Symptomatic Carotid Endarterectomy Trial.

Recently, the NASCET results examining the benefit of carotid endarterectomy in patients with symptomatic moderate stenoses of 30–69% over a mean follow-up of 5 years have been published.[6] Among patients with a stenosis of 50–69%, the 5-year rate of any ipsilateral stroke was 15.7% in the surgical group vs. 22.2% in the medical group; an absolute risk reduction from any stroke or death of 6.5% (1.3% per annum). However, among patients with 30–49% stenosis, the 5-year rate of any ipsilateral stroke was 14.9% for surgical patients vs. 18.7% for medically treated patients; an insignificant risk reduction. The perioperative major stroke or death rate was 2.0%. Univariate analysis of all base-line characteristics identified seven factors that doubled the risk of perioperative stroke or death

(Table 2). In this article, the NASCET investigators also reported the 8-year follow-up results for patients who underwent endarterectomy for symptomatic high-grade stenosis of ≥70%. In these patients, the 8-year risk of an ipsilateral disabling stroke was 6.7%; of any ipsilateral stroke was 15.2%; of any stroke was 29.4%; and of any stroke or death was 46.6%. Therefore, despite the durability of endarterectomy in preventing an ipsilateral disabling stroke, the risk of any stroke or death over the ensuing 8 years was nearly 50%.

The European Carotid Surgery Trial (ECST), another large, randomized, controlled trial, demonstrated similar benefits and results to the NASCET after appropriate adjustment for the different methods used to determine the degree of angiographic stenosis.[36-38] The ECST method used an estimation of the normal carotid bulb diameter as the reference denominator rather than the distal cervical internal carotid artery diameter used in the NASCET. This resulted in a higher degree of angiographic stenosis for any given lesion compared to the NASCET. The ECST enrolled 3024 patients stratified into three groups: 0–29%, 30–69%, and 70–99% carotid artery stenosis with a mean follow-up of 6.1 years. The final ECST results demonstrated endarterectomy reduced the risk of major stroke or death in patients with a symptomatic stenosis of ≥80% (≥60% as measured by the NASCET method) from 26.5% in the control group (an annual event rate of 8.8%), to 14.9% in the surgical group[27]; an absolute risk reduction of 11.6% at 3 years. The rate of nonfatal stroke (symptoms lasting >7 days) or death from surgery was 7%. The ECST did not specify rates of non-stroke surgical complications such as cranial nerve injury or cardiac events.

The Veterans Affairs Cooperative Symptomatic Carotid Stenosis Trial (VA-CSP-309), a third, large, randomized trial examining endarterectomy in symptomatic carotid artery stenosis was prematurely terminated when the NASCET and ECST data were released.[83] VA-CSP-309 analyzed 189 male patients, with a mean follow-up of 11.9 months, demonstrating an absolute risk reduction for stroke or crescendo transient ischemic attacks of 17.7% in patients with carotid artery stenosis >70% who underwent endarterectomy. The authors reported a perioperative surgical stroke and death rate of 5.5%. Among the three perioperative deaths, none were due to ischemic stroke.

The only large, well-constructed, randomized, controlled trial published to date comparing surgical endarterectomy with medical therapy in asymptomatic carotid artery stenosis is the Asymptomatic Carotid Atherosclerosis Study (ACAS) which enrolled 1662 patients at 39 centers with a median follow-up of 2.7 years.[39] As in the NASCET, the inclusion criteria for the ACAS were stringent. Patients were excluded from the ACAS because of previous cerebral infarction; previous endarterectomy with restenosis; previous extracranial-to-intracranial bypass; any disorder that could seriously complicate surgery or prevent continuing participation over 5 years; long-term anticoagulation therapy; or a surgically inaccessible lesion. The ACAS reported an actuarial estimated 5-year risk (mean follow-up was only 2.7 years) for any stroke or death in patients with a carotid artery stenosis of 60% or greater, of 5.1% for surgical patients vs. 11% (annual event rate of 2.2%) for medically treated patients yielding an absolute risk reduction of 5.9%. Therefore, over a 5-year period, approximately one stroke per year was prevented for every 85 patients undergoing endarterectomy. This result was obtained with a low 30-day perioperative (stroke or death) complication rate of 2.3%; 52% of these complications attributable to strokes caused by diagnostic cerebral angiography (arteriography stroke rate of 1.2%). Stratification of data revealed no significant reduction in risk of stroke or death in females undergoing endarterectomy. Furthermore, no correlation between benefit and degree of stenosis was demonstrated. Given these results, the cost effectiveness of performing surgical endarterectomy for asymptomatic carotid artery stenosis has been questioned.[139] The results of a second, large, multicenter, randomized trial examining endarterectomy in asymptomatic carotid artery stenosis, the Asymptomatic Carotid Surgery Trial, currently in progress are awaited.[47]

The benefit of surgical endarterectomy over medical therapy has therefore been clearly demonstrated for patients with symptomatic lesions of ≥70%. However, this stroke-reduction benefit is reduced, albeit still significant, in symptomatic lesions of 50–69%,[6] and reduced further again in asymptomatic lesions of ≥60%. This stroke-reduction benefit is also heavily contingent upon appropriate and strict patient selection and established, low-surgical complication rates. The requisite surgical major complication rate falls from ≤6% for symptomatic lesions of ≥70%, to ≤2% for symptomatic lesions of 50–69% and asymptomatic lesions of ≥60%.

II. Balloon angioplasty

The endovascular approach for treatment of atherosclerotic disease began with the use of percutaneous balloon angioplasty by Kerber et al. in 1980.[61] In 1987, Theron et al.[128] published the first large series of internal carotid angioplasty in 48

patients with de novo atherosclerosis or post-surgical restenosis. Technical success was achieved in 94% of cases with a 4.1% rate of serious morbidity. In one of the largest single institution series, Gil-Peralta et al. (1996)[45] performed 85 balloon-angioplasties in 82 patients with symptomatic carotid artery stenoses of 70% or greater over a 4-year period. They reported a technical success rate of 92% (residual stenosis <50%) with 30-day mortality and major morbidity of 0% and 4.9%, respectively, which compares very favorably to the NASCET and ECST.

Despite ostensibly favorable results, simple balloon angioplasty has a number of potential drawbacks including vessel wall recoil, angiographically evident intimal dissection, and plaque dislodgement with particulate embolization. Angioplasty of atherosclerotic lesions has been reported to generate emboli composed of atheroma, cholesterol crystals, thrombus, and platelet aggregates.[11,23,76,84] Embolization of microparticles has also been demonstrated during carotid endarterectomy correlating with complex plaque morphology[42] and clinical postoperative ischemia.[43,66,95,118] However, no clear-cut correlation between embolism frequency and neurological sequelae has been demonstrated during carotid angioplasty. This has prompted the suggestion that the large majority of emboli detected during balloon angioplasty are either gaseous or small platelet aggregates <200 μm in diameter, all less likely to result in significant neurological sequelae.[23,76,84]

The Carotid and Vertebral Transluminal Angioplasty Study (CAVATAS), a large, prospective, randomized, multicenter, European trial comparing carotid endarterectomy to carotid angioplasty, was recently completed. In the CAVATAS, patients with symptomatic stenoses (≥30% luminal diameter reduction) suitable for surgery were randomized to either angioplasty or surgery.[117] Patients unsuitable for endarterectomy were randomized between percutaneous transluminal techniques and medical treatment alone. The CAVATAS randomized over 500 patients between surgery and angioplasty over 5 years. There was no significant difference in the risk of stroke or death related to the procedure between carotid endarterectomy or angioplasty. The rate of any stroke lasting more than 7 days or death within 30 days of first treatment was approximately 10% in both the surgery and angioplasty groups. Preliminary analysis of long-term survival showed no difference in the rate of ipsilateral stroke or any disabling stroke in patients up to 3 years after randomization. The full results of the CAVATAS are currently being prepared for submission for publication. The rates of stroke or death within 30 days in CAVATAS in both groups are higher than many previous reports but not significantly different to the ECST rate of 7.0%. Long-term follow-up is not yet available.[20]

It remains unclear whether stent placement may help to reduce the number of particulate microemboli by trapping them beneath the metallic meshwork. The problem of distal embolization during balloon angioplasty and carotid artery stenting has stimulated interest in methods for providing cerebral protection. A triple-coaxial catheter providing cerebral protection described by Theron et al. reduced distal embolic complications from 8% in 38 patients undergoing internal carotid artery angioplasty vs. 0% of 43 patients undergoing the same procedure using a distal balloon protection device.[126,129] A number of commercial devices aimed at reducing the microembolic burden associated with carotid angioplasty and/or stenting is currently under development. These include a low profile embolic filter deployed and retrieved on a 0.014- or 0.018-in. shaft that serves as the guidewire for balloon and stent delivery catheters and an 0.014-in. guidewire with a protection balloon incorporated into the tip.[49,109] The balloon-protection method has the disadvantage of temporarily occluding carotid artery flow, whereas filter devices allow constant cerebral perfusion.

III. Stent-supported revascularization

Data from coronary artery trials of stent-assisted balloon angioplasty vs. simple balloon angioplasty have clearly demonstrated a persistent benefit in event-free survival at one year and a lower rate of repeat angioplasty with stenting. This evidence provided the initial impetus for primary stenting of atherosclerotic lesions of the carotid artery.[70,115,116] Since 1996, there have been at least 11 large, individual, carotid artery stent series published in which the total number of patients treated with carotid artery stenting is over 800.[8,24,26,48,110,124,129,135,136,140,142] Comparative analysis of these reports is made difficult by inconsistencies in the sample populations, lesion characteristics, endovascular techniques, and outcome data. Nonetheless, the overall reported rate of technical success is >95%; procedure-related mortality (including cardiac deaths) are 0.6–4.5%; major stroke rates are 0–4.5%; minor stroke rates are 0–6.5%; and a 6-month restenosis rate of <5% (excluding the studies by Teitelbaum et al.[124] and Waigand et al.[136] which represented very high-risk cohorts) (Table 3).

Yadav et al.[142] have reported in their series of 107 patients who underwent elective carotid artery

Table 3 Carotid artery stenting series results

Study	No. of patients	Technical success rate (%)	Major stroke rate (%)	Minor stroke rate (%)	Mortality (%)
Roubin et al. (1996)[110]	146	99	1.3	4.6	0.6
Theron et al. (1996)[129]	69	100	0	3	0
Diethrich et al. (1996)[26]	110	99	2	4.5	1.8
Bergeron et al. (1996)[8]	19	100	0	0	0
Yadav et al. (1997)[142]	107	100	1.9	6.5	0.9
Vozzi et al. (1997)[135]	22	96	4.5	4.5	4.5
Criado et al. (1997)[24]	33	100	0	0	0
Wholey et al. (1997)[140]	108	95	1.8	1.8	1.9
Henry et al. (1998)[48]	163	99	1.8	1.2	0
Teitelbaum et al. (1998)[124]	22	96	18.2	13.6	4.5
Waigand et al. (1998)[136]	50	100	2	2	2

stenting that 77% would have been excluded according to the NASCET criteria, thus claiming their cohort represents a 'high-risk' group in which a higher complication rate may be expected. A direct correlation between patient risk profiles and incidence of major complications was demonstrated in a retrospective analysis by Sundt et al.[119,121] in which 3111 consecutive endarterectomy patients were stratified into six risk classes according to neurological status, comorbid conditions, and angiographic variables. Estes et al.[35] followed a random sample of 22,165 Medicare beneficiaries who underwent carotid endarterectomy between 1988 and 1990, until the year 1992. They identified patients with acute myocardial infarction, congestive heart failure, diabetes mellitus, and age >80 years as having diminished perioperative and long-term survival rates following carotid endarterectomy. Despite this, Yadav et al.[143] reported a 30-day combined mortality (including cardiac deaths) and stroke rate of 7.9%, which was only marginally above the 6.7% rate for the NASCET.[98] Indeed, NASCET criteria were applied to the patient cohorts in five of these carotid artery stenting series demonstrating that approximately 80% of these 574 patients would have failed eligibility because of comorbidities.[48,110,136,140,142] In spite of this, morbidity of 2.0–7.9% and mortality of 0.6–2.0% collectively for these carotid artery stenting reports compare favorably to those in the NASCET and the ECST.

As clinical experience with carotid artery stenting increases, the procedure-related risk may also be expected to decline. Wholey et al.,[141] in a recent worldwide survey of 3047 endovascular cervical carotid artery stent procedures, identified a 50-case learning curve noting those centers having performed less than 50 cases had a significantly higher rate of major stroke and death. Similarly, Vitek et al.[134] recently presented their experience in treating 404 patients with carotid angioplasty and stenting, noting that in the last 122 patients (with increased procedure-related experience) the minor stroke rate fell from 5.8% to 2.5%. They report an overall technical success rate of 98% with a 30-day morbidity and mortality of 1.9% and major stroke rate of 0.7%. It should also be noted that carotid artery stenting carries no risk of cranial nerve damage. Ballotta et al.[5] in a recent, prospective review of 200 consecutive carotid endarterectomies reported a 12.5% incidence of nonpermanent cranial nerve and cervical nerve dysfunction: hypoglossal (5.5%); recurrent laryngeal (1%); superior laryngeal (1%); marginal mandibular and greater auricular (1%). The mean recovery time was 5.8 months. Two patients (8%) with recurrent laryngeal nerve injuries had prolonged recovery times of 31 and 37 months.

Given that the evidence to-date supporting the use of carotid artery stenting is largely derived from nonrandomized series using disparate sample populations, comparison with the far superior endarterectomy data should be undertaken with extreme circumspection. Nonetheless, it appears that carotid artery stenting may present advantages over surgical endarterectomy in specific clinical subgroups such as patients with: significant comorbidities; contralateral carotid artery occlusion[81,87]; post-endarterectomy restenosis[65,143]; or surgically inaccessible or tandem lesions. A North American multicenter, randomized, controlled trial directly comparing stent-supported angioplasty with endarterectomy in patients with symptomatic stenosis of ≥50% is forthcoming (carotid revascularization endarterectomy versus stent trial).[54]

IV. Protocol for carotid artery stenting at University of California San Francisco (UCSF) Medical Center

All patients undergo a thorough neurological history and examination before the procedure. A baseline brain computed tomography (CT) or magnetic resonance (MR) imaging is obtained to document any preexistent infarction and exclude other nonvascular pathologies that may mimic transient ischemic attacks. Oral aspirin (325 mg per day) and clopidogrel (75 mg per day) are begun at least 3 days before the procedure. Following the procedure, the patient is maintained on this dosage of aspirin indefinitely and oral clopidogrel for 6 weeks. Experimental data suggests aspirin and clopidogrel have a synergistic effect on platelet antiaggregation, antithrombotic activity, and in preventing myointimal proliferation (restenosis).[50,71] The prophylactic or 'bail-out' role of glycoprotein IIb/IIIa inhibitors such as abciximab, which have been shown to decrease mortality and morbidity in a number of coronary artery stent studies, remains undefined in carotid artery stenting.[15,18,34] Abciximab may have a role for treatment of acute thrombus formation since platelet aggregation (white thrombus) represents the primary mechanism.[59]

Generally, conscious sedation rather than general anesthesia is used so that neurological function can be constantly monitored. All patients undergoing cervical carotid angioplasty have external cardiac pacing leads attached and undergo monitoring by a Zoll™ transcutaneous pacer/defibrillator device in case of bradycardia or asystole from carotid body stimulation which may occur in 5–10% of patients. Patients also receive 0.5 mg of atropine or 0.2 mg of glycopyrrolate intravenously prior to balloon dilation or stent deployment to decrease carotid sinus bradycardia during the procedure.

Self-expanding stents such as the cobalt-chromium-based alloy Wallstent (Schneider, Minneapolis, Mich., U.S.A.) or the Nitinol SMART stent (Cordis Endovascular, Miami Lakes, Fla., U.S.A.) are currently the most frequently used types at the UCSF Medical Center. Both of these presently require the minimal use of a 90-cm length, 7–8-Fr. groin sheath (Arrow Interventional Inc., Reading, Pa., U.S.A.) or a 9–10-Fr. guiding catheter (Cordis Brite Tip; Cordis Endovascular). Newer devices with smaller diameter stent-delivery catheters and balloons may only require a 6–7-Fr. sheath. Following sheath insertion, a baseline activated clotting time (ACT) is obtained and an intravenous loading dose of heparin administered (70–90 units/kg) to achieve an ACT of 2–2.5× baseline and/or 250–300 seconds. The patient is then maintained on a continuous heparin infusion of 15–20 units/kg/hr.

Preliminary diagnostic angiography of both carotid arteries and the intracranial circulation in a minimum of two planes should be performed. The internal carotid artery invariably arises posterior to the external carotid artery and in most cases laterally, thus an ipsilateral anterior oblique or lateral view is usually optimal for displaying the bifurcation. However, pinhole or web-like high-grade stenoses may be underestimated unless multiple oblique projections are performed.[130] In the case of presumed internal carotid artery occlusion, prolonged filming is necessary, as otherwise delayed, faint, anterograde opacification of the cervical internal carotid artery may be missed ("string sign" of critical internal carotid artery stenosis).[85]

The guiding catheter is then positioned within the ipsilateral common carotid artery. If the stenosis is high grade (≥70%) the lesion is first crossed under digital roadmap guidance, using a 2.3-Fr. microcatheter (Rapid transit; Cordis Endovascular) primed with an 0.014-in. guidewire (Transend; Scimed, Maple Grove, Minn., U.S.A.). The guidewire is then exchanged for a 300-cm 0.014-in. exchange length guidewire (Balance; Advanced Cardiovascular Systems Inc., Santa Clara, Calif., U.S.A.) the curved tip of which is positioned within the petrocavernous segment of the internal carotid artery. In less severe stenoses, initial crossing of the lesion can be performed using an 0.035-in. guidewire, however, the guidewire tip should remain in an extracranial location to reduce the risk of intimal dissection and vessel spasm. High-grade stenoses are usually predilated using a low-profile balloon angioplasty catheter (Titan; Cordis Endovascular) to a diameter of approximately 3–4 mm. In most cases a single, brief (approx. 10 sec) balloon inflation is utilized.

A roadmap image is then obtained and the stent delivery catheter advanced over the immobilized guidewire. Patient movement can degrade the roadmap image, therefore bony landmarks delineating the desired stent position should be obtained. Furthermore, the stiffness of the guidewire and stent delivery catheter can both result in straightening and distortion of the cervical internal carotid artery, rendering previous angiographic and roadmap images inaccurate. Both the Wallstent and SMART stent are deployed by retracting an external constraining sleeve while immobilizing the delivery catheter. The Wallstent foreshortens significantly whereas the SMART stent foreshortens by <8% at its proximal end, thus theoretically allowing more precise positioning. Balloon-expandable stents such as the Palmaz stent (Johnson & Johnson Inter-

ventional Systems Co., Warren, N.J., U.S.A.) can usually be accurately positioned, however, Mathur et al.[80] reported a 16% rate of Palmaz stent collapse at 6-month angiographic follow-up which was attributed to probable external compression. Compression of balloon-expandable stents has been reported to be a significant cause of restenosis in the superficial femoral arteries and hemodialysis grafts.[107] If the atherosclerotic lesion is adjacent to the carotid bifurcation then it is usually preferable to position the proximal end of the stent within the common carotid artery. This results in covering of the external carotid artery origin by the stent, which is usually of no clinical significance.

Post-deployment angioplasty using a high-pressure, semi-compliant balloon (Jupiter; Cordis Endovascular) may then be performed to closely appose the stent and intima and moreover to expand regions of residual stent narrowing. Gaps between the stent circumference and endoluminal surface should be avoided as this potentially increases the risk of thromboembolism.[127] The balloon should be inflated for no longer than 5–10 seconds at a time, with a pause of 1–3 minutes between inflations to allow restoration of cerebral perfusion (Figs. 1 and 2). Following removal of the balloon angioplasty catheter, anteroposterior and lateral cerebral angiograms are obtained to exclude an embolic branch occlusion and the patient is carefully examined neurologically.

Neurological deficits may be due to intracranial embolism, hemorrhage, or reperfusion injury. The phenomenon of reperfusion hemorrhage following surgical endarterectomy is well described. Ouriel et al.[100] in a review of 1471 patients undergoing surgical endarterectomy reported a 0.75% incidence of intracerebral hemorrhage. Hemorrhage occurred at a median of 3 days postoperatively and accounted for 35% of the total perioperative neurological events. Death from massive hemorrhage and herniation occurred in 36% of cases. Factors correlating with an increased hemorrhage risk were hypertension, high-grade ipsilateral stenosis, high-grade contralateral stenosis or occlusion, and younger age.

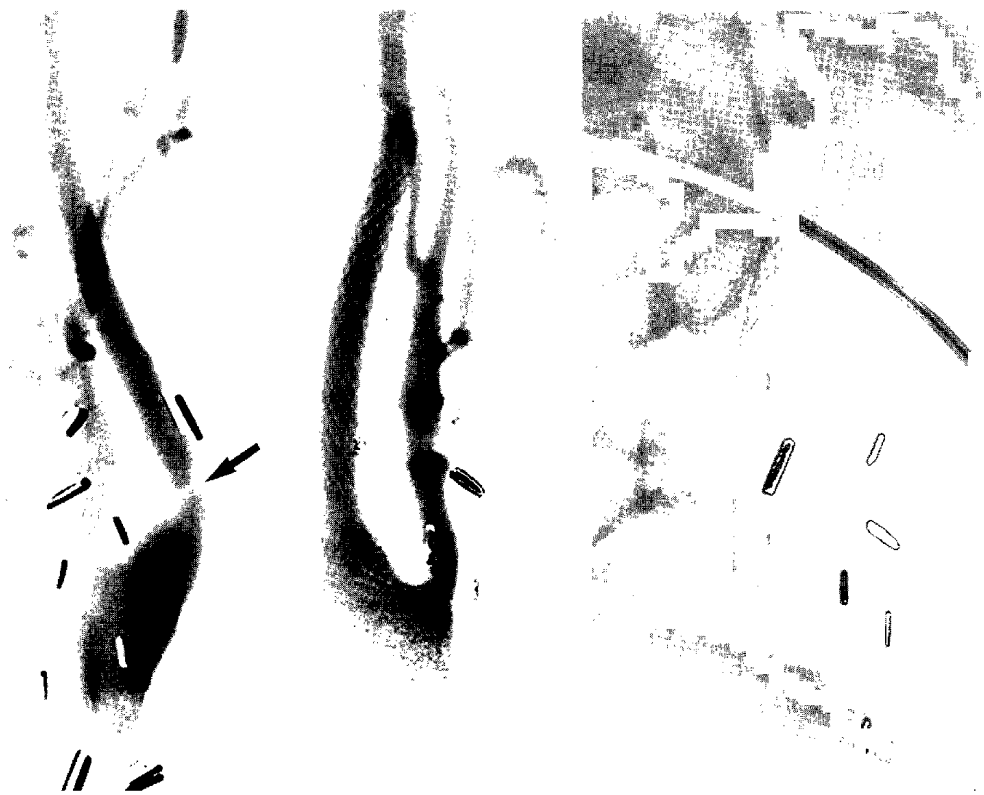


Fig. 1 ***left*: Anteroposterior view of the left carotid bifurcation in a 45-year-old female patient with an asymptomatic recurrent moderately severe stenosis of the proximal left internal carotid artery following surgical endarterectomy 9 months previously (*arrow*). *center*: Lateral view showing appearance following uncomplicated endovascular stenting with restoration of the normal vessel caliber. *right*: Unsubtracted lateral image showing the Wallstent.**

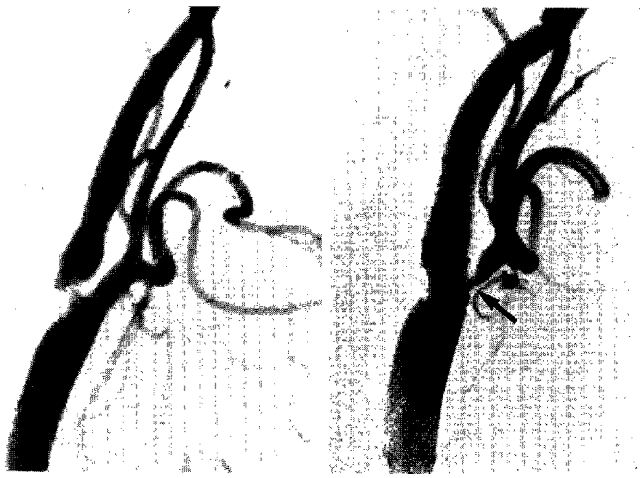


Fig. 2 ***left*: Lateral view of the right carotid bifurcation in a 53-year-old female with an asymptomatic severe stenosis of the right internal carotid artery and a contralateral internal carotid artery occlusion. *right*: Lateral view showing appearance following endovascular stenting of the right carotid artery using a SMART stent. Stent placement across the bifurcation results in narrowing of the external carotid artery orifice which is usually of no significance (*arrow*).**

Schoser et al.[113] reported two patients with reperfusion hemorrhage — one intraparenchymal hemorrhage and one subarachnoid hemorrhage following balloon angioplasty for carotid and vertebral artery stenosis. Prior to stent deployment, the mean arterial blood pressure should be maintained at or above baseline. However, following successful revascularization, lowering of the mean arterial pressure to below baseline may be desirable to prevent cerebral reperfusion injury.

Alternatively, post-procedural prolonged bradycardia and/or hypotension may occur as a result of carotid sinus dysfunction necessitating the use of intravenous vasopressors or ionotropic agents.[105] Heparinization is usually allowed to taper physiologically rather than reversed using protamine sulfate. The femoral sheath is removed when the activated partial thromboplastin time has returned to baseline. Alternatively, the femoral sheath may be removed immediately after the procedure, without the need for heparin reversal or groin pressure, using a Perclose device (Perclose Inc., Redwood City, Calif., U.S.A.). The Perclose device consists of a sheath enabling percutaneous insertion of hemostatic sutures around the femoral arteriotomy. The patient is monitored in the intensive care unit for 12–24 hours post-treatment. A follow-up ultrasound examination of the neck is obtained at 6 months. The 6-month restenosis rate has been demonstrated by multiple studies to be $<5\%$[8,24,26,48,110,129,135,140,142] which is lower than generally observed with simple balloon angioplasty (2–16%)[32,45,53,60,96,129] or endarterectomy (approximately 10% in the first year).[41,89,91,120]

Extracranial Carotid Artery Occlusive Disease: Nonatherosclerotic Stenosis

I. Dissection

Acute dissection of the cervical carotid artery may present spontaneously (nontraumatic or minor trauma) or result from more severe trauma which may be blunt, penetrating, or iatrogenic. Acute carotid artery dissection may result in luminal stenosis or occlusion, distal thromboembolism, or acute pseudoaneurysm formation. In asymptomatic patients, management is usually conservative using antiplatelet agents and/or systemic anticoagulation to prevent thromboembolic sequelae. In symptomatic cases, more aggressive therapy may be warranted especially in patients whose symptoms or angiographic abnormalities (vessel narrowing or pseudoaneurysm) are progressing or in whom anticoagulation is contraindicated. The presence of established cerebral infarction is a relative contraindication to revascularization because of the increased risk of hemorrhagic transformation. However, if cerebral infarction is in a watershed distribution and cerebral collateral flow is poor, then acute revascularization may be necessary. Traditionally, open surgery in the form of arterial ligation with or without extracranial-to-intracranial bypass, endarterectomy and thrombectomy, or arterial reconstruction with autologous vein or synthetic grafts has been performed in these instances.[90,93,112] Generally, these surgical procedures are technically demanding and may yield disappointing results, particularly if performed during an acute ischemic episode. Endovascular revascularization involving the use of stents may prove to be a potential alternative. The endovascular approach allows concurrent thrombolysis or mechanical disruption of an associated intracranial thromboembolus. An occluded carotid artery is not a contraindication to therapy, particularly if the clinical event, or any clinical change, is recent.

At present there are only isolated published reports describing the use of stents in this clinical setting.[7,22,25,28,29,55,144] DeOcampo et al.[25] successfully re-established flow in an occluded left carotid artery

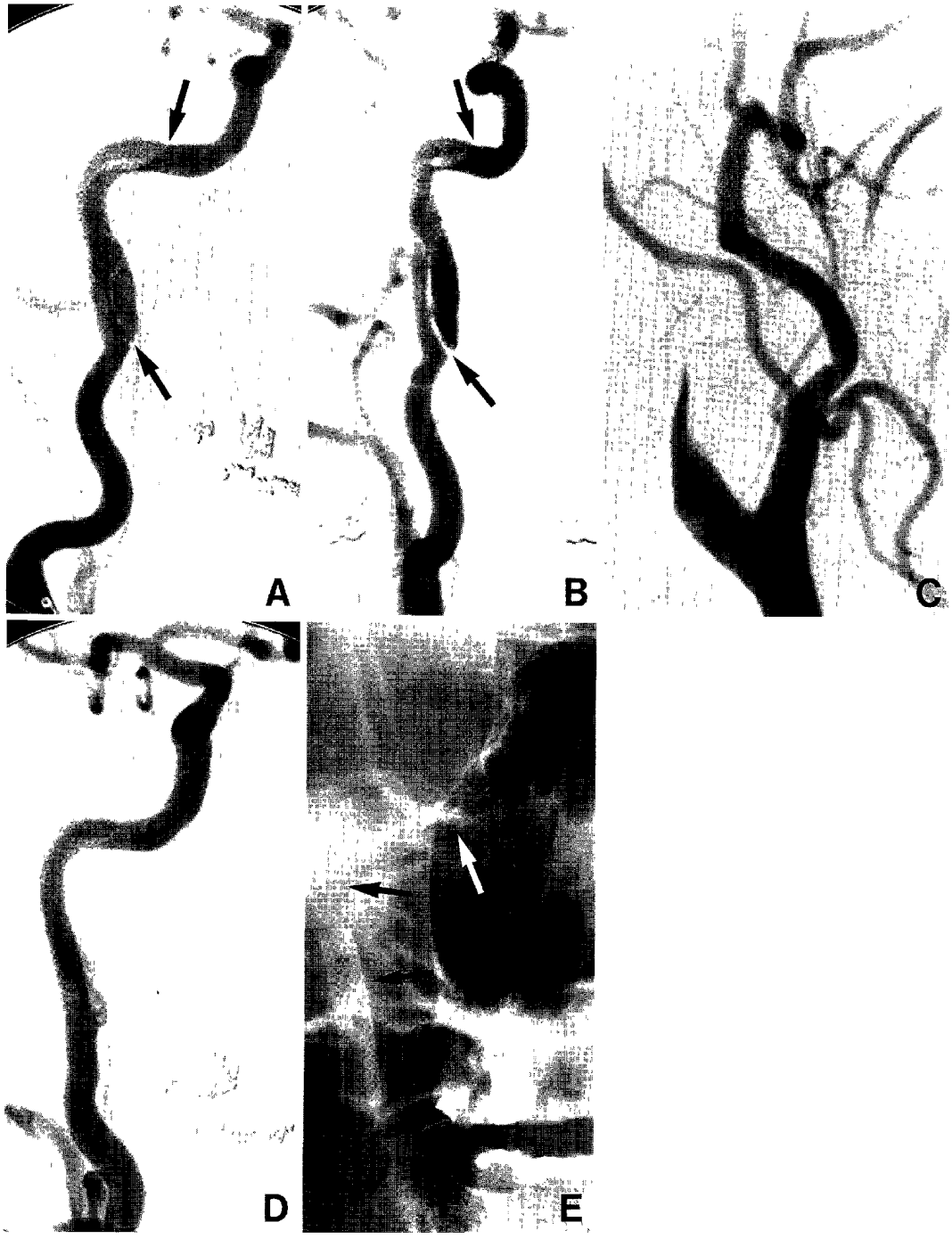


Fig. 3 **A, B: Anteroposterior and anteroposterior oblique images of the right internal carotid artery in a 51-year-old male who developed a fluctuating right visual field central scotoma despite systemic anticoagulation 10 days prior to presentation. There is an intimal dissection of the cervical and petrous segments of the right internal carotid artery (*arrows*) resulting in severe stenosis. C: The left internal carotid artery was completely occluded with a rat-tail tapering suggesting a recent onset also probably secondary to intimal dissection. D, E: Appearance of the right internal carotid artery following endovascular placement of three stents (*arrows*) with reconstitution of the true lumen.**

using stent-supported angioplasty in a patient with fibromuscular dysplasia and bilateral carotid artery occlusions from acute dissections. Despite medical therapy, the patient experienced progressive neurological deficits with bilateral cerebral infarctions. Following carotid artery stenting, these neurological deficits resolved. Duke et al.[29] reported using endovascular stent placement to treat six patients with nonpenetrating carotid artery injuries. They reported immediate reconstruction of the injured vessel in all cases. The authors note that compared to medical therapy, only temporary anticoagulation was required and the risk of future pseudoaneurysm formation and distal embolization was eliminated. Bejjani et al.[7] recently reported their experience in treating five patients with symptomatic acute carotid artery dissection. Watershed infarction depicted by CT or MR imaging was present in four out of five patients and one patient had a complete carotid artery occlusion. All patients experienced significant initial clinical improvement and complete long-term recovery (Fig. 3).

II. Radiation, inflammatory, and vein-graft strictures

Radiation-induced strictures of the cervical carotid artery are difficult surgical lesions because of the long lesion length, periarterial scarring with ill-defined planes of resection, and a higher rate of wound complications.[68,97] Endovascular stent placement offers clear advantages in this subset of patients. Bali et al.[4] reported on six patients with inflammatory strictures of the carotid arteries secondary to Takayasu's arteritis treated successfully by endovascular stent placement. Stent placement has also been used to successfully treat two cases of carotid artery vein-graft strictures caused by intimal hyperplasia.[13,16]

Intracranial Carotid Artery Occlusive Disease

Balloon angioplasty and stent placement for intracranial internal carotid artery atherosclerotic stenosis is reserved for symptomatic, high-grade lesions that have failed maximal medical therapy including oral antiplatelet therapy and systemic anticoagulation. Treatment of intracranial stenotic lesions entails a significantly greater risk of complications because the arterial wall adventitial and muscularis layers are thinner, the presence of tiny but important brain perforator vessels, and smaller vessel calibers. Simple balloon angioplasty has been successfully utilized but may fail because of inability to cross the lesion, flow-limiting intimal dissection, vessel recoil, acute vasospasm, acute in-situ thrombosis, thromboembolism, and vessel rupture.[14,19,21,31,51,53,94,108,123,125,145] In the larger series, the immediate technical success rate, defined as a 20% relative improvement and/or a residual stenosis of $<50\%$, is reported between 67–100%. The periprocedural risk of major morbidity and mortality is reported at approximately 6–17% (excluding the study by Takis et al.[123] where 4 of 10 patients [40%] suffered strokes).[14,19,21,145] Marks et al.[75] recently published a 5-year retrospective review of 23 patients undergoing intracranial angioplasty: posterior circulation ($n = 13$); distal internal carotid artery ($n = 7$); middle cerebral artery ($n = 3$). They reported a 91.3% rate of technical success; 4% mortality (one vessel rupture) and 9% complication rate (one vessel rupture and one case of acute thrombosis successfully lysed using local thrombolytic therapy). Over a mean follow-up period of 35.4 months the annual rate for strokes in the territory of angioplasty was 3.2% and for all strokes was 4.8%. Mori et al.[94] reported a 29.6% rate of restenosis at 3-month angiographic follow-up in 27 patients undergoing technically successful intracranial balloon angioplasty.

Endovascular intracranial navigation requires a low-profile, highly flexible stent design, able to routinely and nontraumatically maneuver acute vascular bends and tortuosities. New generation coronary stents have these capabilities and are now permitting relatively safe percutaneous access of the intracranial vasculature.[2,28,40,86,103] In 1996, Feldman et al.[40] first reported the use of a Palmaz-Schatz coronary artery stent (Johnson & Johnson Interventional Systems Co.) to treat a stenosis of the intracranial carotid artery. Mencken et al. in 1998[86] reported successfully treating two patients with petrous segment carotid artery stenosis using a Multi-Link coronary artery stent (Advanced Cardiovascular Systems Inc.). In 1999, Phatouros et al.[103] successfully treated an atherothrombotic occlusion of the basilar artery using a Giantucot-Roubin II coronary artery stent (Cook Cardiology, Bloomington, Ind., U.S.A.). Despite these encouraging reports, endovascular navigation of a stent around the carotid siphon genu or distal vertebral artery still represents a formidable endovascular challenge. Bernard et al.[9] recently presented their experience of primary stent-assisted angioplasty in four intracranial carotid and two vertebrobasilar artery stenotic lesions (Fig. 4). All lesions were successfully treated without embolic events or angiographically-detectable dissections. One patient developed an acute filling defect within the stent lumen which resolved after a bolus injection of

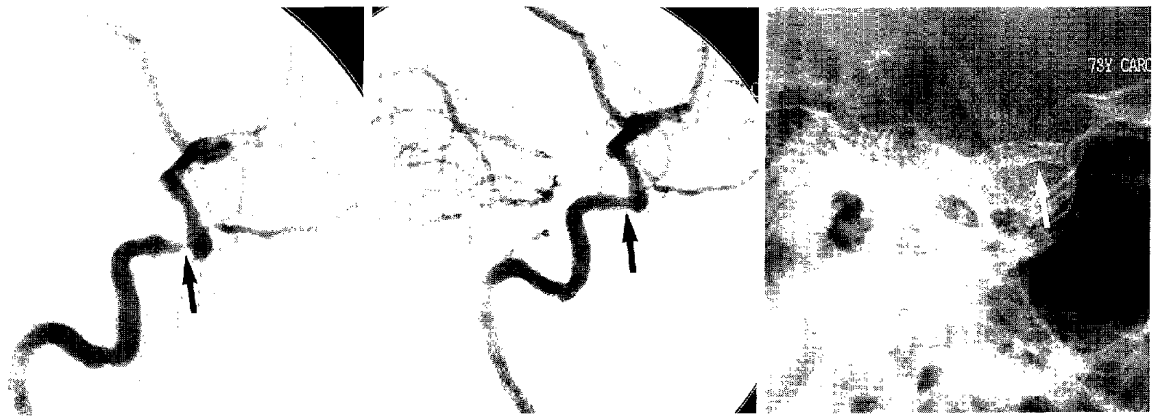


Fig. 4 ***left*: Lateral oblique view of the left carotid siphon in a 73-year-old male presenting with transient ischemic attacks on systemic anticoagulation and antiplatelet agents. There is a recurrent high-grade stenosis of the cavernous segment of the left internal carotid artery which had undergone balloon angioplasty 7 months previously (*arrow*). *center*: Appearance following endovascular placement of a stent across the stenotic segment (*arrow*). *right*: Unsubtracted image demonstrating the carotid siphon stent (*arrow*).**

abciximab. Emery et al.[33] reported resolution of pulsatile tinnitus following angioplasty and stenting of a petrous carotid artery stenosis. As with all emerging indications, very close clinical and angiographic follow-up is requisite to better define the appropriate pitfalls and outline the future indications for this therapy. The long-term patency rates of intracranial stents, which generally have a smaller diameter than those utilized in the extracranial carotid artery, remain to be defined.

Carotid Artery Aneurysms

I. Cervical

In recent years there have been increasing reports of stents used for treatment of wide-necked or fusiform aneurysms and pseudoaneurysms of the cervical carotid and vertebral arteries. Conventional endovascular treatment of these aneurysms using electrolytically detachable coils is often unsuccessful because of coil loop herniation through the broad neck into the parent artery. In 1994, Marks et al.[74] reported on two patients with cervical carotid artery pseudoaneurysms secondary to dissection treated by endovascular stent placement across the aneurysmal neck. In both cases there was progressive aneurysm thrombosis. This is in accordance with experimental data in which surgically created lateral carotid artery aneurysms in dogs were obliterated using endovascular stents.[44,132,138] The successful thrombosis of the aneurysms is attributed to stent-related alterations in aneurysmal lumen mechanical flow dynamics as described by Graves et al.[46] Increased high-flow resistance into the aneurysm through the stent interstices combined with a preexisting low-pressure gradient between the parent artery and aneurysm results in reduced intra-aneurysmal flow vortices or intra-aneurysmal stasis.[1] Similar favorable outcomes using stents in isolation to treat cervical pseudoaneurysms have since been reported by a number of authors.[10,56–58,73,78]

Alternatively, the stent may be utilized as a scaffold to support electrolytically detachable coils used to then occlude the aneurysm. Following deployment of the stent across the aneurysm neck, the coils are delivered into the aneurysmal lumen via a microcatheter passed through the stent interstices. An additional benefit of this combined approach may be a reduced likelihood of future coil compaction—a phenomenon particularly observed in wide-necked aneurysms.[137] The technical feasibility of this approach has been validated by experimental studies performed in canine and swine.[79,122,131,133] Three case reports describe the successful clinical application of this technique for pseudoaneurysms—all three in the cervical carotid artery.[62,82,102] A potential problem with this technique, particularly in fusiform aneurysms, is reliable fluoroscopic detection of coil-loop herniation through the stent interstices into the parent artery lumen (Fig. 5). Intravascular ultrasound may prove a useful adjunctive imaging modality in this situation.

Covered stents using synthetic materials such as Dacron, polytetrafluoroethylene, polyester, or autologous venous grafts may in the future also prove useful in this clinical situation. Although covered



Fig. 5 ***left*: Anteroposterior oblique view of the right internal carotid artery in a 60-year-old female presenting with transient ischemic attacks demonstrating a 12-mm diameter wide-necked pseudoaneurysm probably related to previous blunt trauma arising from the high cervical segment (*arrows*). *center, right*: Anteroposterior oblique views showing appearance following endovascular stenting across the aneurysm neck (*center*) and coil embolization of the pseudoaneurysm through the stent interstices (*right*). Note on this view some coil loops are projected over the parent artery, but careful fluoroscopic examination confirmed them to be positioned outside the stent circumference. This illustrates one of the difficulties currently associated with this technique. Note also how deployment of the Wallstent results in relocation of internal carotid artery redundancy to the proximal stent margin (*arrow*). Ten-month follow-up angiography revealed normal stent patency with aneurysmal occlusion.**

stents have been successfully utilized in the peripheral circulation to treat penetrating arterial injury and pseudoaneurysm formation,[101] only two case reports describing their successful use in the carotid artery were found in our review.[77,111] Poor long-term patency rates of covered stent-grafts remain a potential problem. Link et al.[67] reported thrombotic occlusion occurring in seven of eight Dacron-covered stent-grafts used to treat surgically created common carotid artery aneurysms in swine at 2-week angiographic follow-up.

II. Intracranial

There is very limited published data on the clinical use of stents for treatment of intracranial wide-necked or fusiform aneurysms — only four case reports in our review.[52,69,88,114] Endovascular strategies for dealing with wide-necked or geometrically difficult aneurysms have previously included the balloon remodeling method described by Moret et al.[92] and the use of three-dimensional, complex geometry, electrolytically detachable coils.[72] Higashida et al.[52] used a percutaneously delivered Palmaz-Schatz coronary artery stent (Johnson & Johnson Interventional Systems Co.) to successfully treat a ruptured fusiform aneurysm of the proximal basilar artery. Sekhon et al.[114] reported the use of a GFX coronary artery stent (Advanced Vascular Engineering, Santa Rosa, Calif., U.S.A.) to treat a wide-necked aneurysm arising from the intracranial segment of the left vertebral artery. In their case, the stent was placed via an open surgical exposure of the left vertebral artery. In both these cases the stent was used as a buttress against which electrolytically detachable coils could be packed. Mericle et al.[88] were first to describe the successful use of a stent in conjunction with electrolytically detachable coils for treatment of a broad-necked intracra-



Fig. 6 ***left*: Anteroposterior oblique image of the left internal carotid artery demonstrating a 12-mm precavernous aneurysm in a 44-year-old female presenting with a left hemispheric stroke. Attempted coil embolization was unsuccessful due to the wide aneurysm neck.** ***center*: Anteroposterior oblique view showing appearance following endovascular placement of a stent across the aneurysm neck and coil embolization of the aneurysm through the stent interstices.** ***right*: Unsubtracted image showing the stent (*arrow*) and endoaneurysmal electrolytically detachable coils.**

nial carotid artery (petrous) aneurysm.

Despite these encouraging reports, significant limitations to this technique remain. Current stent and delivery system designs are better suited to treating side-wall rather than bifurcation aneurysms. Since most intracranial aneurysms occur at arterial bifurcations around the circle of Willis, the combined stent-coil approach currently has only limited intracranial application. Furthermore, stent patency, particularly at smaller luminal diameters, is heavily reliant upon appropriate, adjunctive, anti-platelet therapy. This potentially reduces the likelihood of aneurysmal thrombosis and occlusion (particularly relevant in acute subarachnoid hemorrhage) and also increases the risk associated with surgical craniotomy, should this be necessary. Additionally, as previously mentioned, endovascular stent navigation beyond the carotid siphon, much less to the anterior communicating artery, remains a formidable technical challenge (Fig. 6).

Conclusion

Endovascular revascularization of clinically symptomatic, high-grade ($\geq$70%) cervical carotid atherosclerotic plaque lesions using stents is establishing itself as a legitimate alternative to surgical endarterectomy. A large, well-constructed, randomized, controlled trial directly comparing both treatment modalities is forthcoming. Further innovation and refinement of endovascular apparatus and technique will inevitably improve technical success rates and reduce procedure-related complications. In addition, there is an emerging role for cervical carotid artery stenting in the treatment of nonatherosclerotic occlusive disease such as acute and chronic arterial dissections, and fusiform and wide-necked pseudoaneurysms. Advances in coronary artery stent technology has produced designs permitting endovascular access of the intracranial vasculature allowing increased therapeutic options for treatment of intracranial occlusive disease recalcitrant to maximum medical therapy and/or balloon angioplasty and anatomically challenging intracranial aneurysms with broad necks.

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