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A new approach to carotid angioplasty and stenting with transcervical occlusion and protective shunting: Why it may be a better carotid artery intervention

David W. Chang, MD,a,c Peter J. Schubart, MD, PhD,a,c Frank J. Veith, MD,b and Christopher K. Zarins, MD,c San Jose and Stanford, Calif; and New York, NY

Objective: The purpose of this study was to evaluate the effectiveness and demonstrate the advantages of a new technique for carotid angioplasty and stenting (CAS) with proximal cerebral protection through a direct transcervical approach, as compared with a percutaneous transfemoral approach.

Methods: Twenty-one CAS procedures were carried out through a 2-cm incision at the base of the neck, under local anesthesia. For transcervical occlusion and protective shunting (TOPS), a short 9F sheath was inserted directly into the common carotid artery and connected to a 6F sheath placed percutaneously in the ipsilateral internal jugular vein. After clamping the common carotid artery proximal to the 9F sheath, internal carotid artery blood flow reversal was confirmed or an occluding external carotid balloon was placed. A filter interposed between the arterial and venous sheaths collected embolic debris from transcatheter manipulations. The arterial puncture was directly repaired with suture. Neurologic status was assessed with the National Institutes of Health stroke scale by an independent neurology consultant before and after the procedure.

Results: A 0% technical failure rate and a 0% combined 30-day stroke or mortality rate were achieved in all CAS attempted with TOPS. Angiographic confirmation demonstrated resolution of asymptomatic (>80%; n = 8) stenosis or symptomatic (>60%; n = 12) stenosis. There were no access site complications or hematomas despite pretreatment with clopidogrel bisulfate and heparin.

Conclusion: TOPS solves problems of access, embolization into the cerebral and peripheral circulation, and specialized cerebral protection devices, and enables secure closure of the access vessel in patients given anticoagulation therapy. TOPS may provide a safer, more effective, economical means for performing CAS. (J Vasc Surg 2004;39:994-1002.)

Carotid angioplasty and stenting (CAS) is a less invasive means for treating carotid artery stenosis. Since its introduction two decades ago, use of CAS has steadily increased; 8% of 107,000 carotid procedures performed in Europe in 2001 utilized CAS. The prospect of an outpatient procedure, without the discomfort of a sizable neck incision, appears to be driving patient decision-making away from carotid endarterectomy (CEA), the standard procedure for treating carotid bifurcation disease for the past 50 years.1

However, there are disadvantages to CAS as it is currently practiced. The standard approach is the femoral approach. Use of this remote site introduces unnecessary access difficulties. Tortuous, angulated, and diseased carotid and aortoiliac vessels, and bovine aortic arch anatomy can make reaching the lesion a difficult, if not an impossible, challenge. The presence of aneurysmal and atheromatous disease of the aorta and its branches contributes to embolic stroke and peripheral embolization. The Asymptomatic Carotid Atherosclerosis Study documented a greater than 1% stroke rate for carotid angiography alone.2 The development of cerebral protection devices is unlikely to decrease this risk, which is incurred before crossing the lesion, and also puts the contralateral cerebral hemisphere at risk. The use of femoral access sheaths, especially large sheaths (>7F) increases the risk for life-threatening bleeding and hematoma. Local complications from cardiovascular interventions range from 18% for compression to 6% associated with the closure device.3

Although a case report of a more proximal route for protected (distal balloon) CAS through a transtibial approach has been reported,4 the limitations of CAS can be most completely overcome with cervical carotid artery access through a small cutdown incision. This facilitates proximal cerebral protection through flow reversal, and affords secure closure of the artery. CAS with transcervical occlusion and protective shunting (TOPS) was first performed on August 23, 2001, after failure of a femoral approach secondary to severe angulation of the proximal carotid artery to the aortic arch (Figs 1 and 2).
MATERIAL AND METHODS

Patients. Between August 2001 and August 2003, 20 patients were enrolled in an investigator-sponsored trial of CAS for bifurcation lesions with the carotid monorail Wallstent (Boston Scientific Corp, Natick, Mass) at the O’Connor Vascular Center. The institutional review board approved the protocol. Written informed consent was obtained from each patient. All patients were first evaluated with carotid duplex ultrasound scanning. Inclusion criteria for the protocol was greater than 50% stenosis in symptomatic disease (n = 13) and greater than 80% for asymptomatic disease (n = 8) on the basis of duplex ultrasound criteria. The sole exclusion criterion was circumferential heavy calcification of the internal carotid artery. One patient with extensive acoustic shadowing at ultrasound scanning was excluded after computed tomography of the neck confirmed complete calcification of the carotid artery. The clinical profile of the study group (Table) included four recurrent stenoses after previous CEA (19%), including one patient with symptomatic disease. The initial five enrolled patients were at high risk for CEA. In August of 2002 the study was opened to patients at average risk, who were given the option of CEA or CAS with TOPS. All patients given this option chose CAS with TOPS over CEA. Known challenges to successful CAS in this study population included multiple (three or more) 90-degree carotid artery angulations (n = 3), severe angulation of the carotid artery takeoff with the aortic arch (n = 1), pinhole stenosis of the.

Fig 1. The patient, a 72-year-old man with a rigid C-spine from cervical fusion; chronic obstructive pulmonary disease, coronary artery disease, diabetes mellitus, chronic renal insufficiency, hypertension; and history of congestive heart failure, had transient ischemic attacks. He had been hospitalized for 35 days with respiratory failure after CEA 4 years previously. A, Aortic arch angiogram reveals 360-degree right calcified carotid coil without stenosis and acute 170-degree angulation of left proximal common carotid artery, with aortic arch (1). With difficulty, an MPA guiding sheath was briefly placed in the proximal common carotid artery ostia, but became dislodged during attempts to gain more purchase over the Amplatz wire. Femoral approach carotid angioplasty and stenting would require traversing five angulations of 90 degrees or greater (1-5) to treat this 95% internal carotid artery stenosis. B, Selective carotid angiogram shows pinhole stenosis.
internal carotid artery requiring multiple passes with an .018 angled Glidewire (n = 3), but no contralateral carotid artery occlusions.

Preoperative management. Baseline neurologic evaluation was performed by a protocol neurologist. Blood pressure was carefully stabilized (systolic blood pressure <160 mm Hg) with oral medications before carotid artery intervention. Patients with renal insufficiency were given 600 mg of N-acetylcysteine (Mucomyst) every 12 hours for 24 hours before the procedure. All patients were given a loading dose (300 mg) of clopidogrel bisulfate within 24 hours before the procedure if they were not already receiving this medication.

CAS with TOPS. This was performed in the operating theater equipped with an OEC/GE Model 9800 mobile C-arm (GE-OEC, Salt Lake City, Utah). After administration of mild sedation, a mixture of 1% lidocaine and 0.5% marcaine was used to anesthetize the skin 2 cm above the clavicle. A 2-cm transverse incision was made, centered over the medial border of the sternocleidomastoid muscle. The muscle was retracted laterally, and the common carotid artery was exposed circumferentially over a length of 2 cm. The artery was encircled with umbilical tape, and care was taken to keep the dissection plane directly on the common carotid artery to avert injury to the vagus nerve. Access was typically obtained in 5 to 10 minutes.

A 6F introducer sheath was inserted percutaneously and directed caudad to puncture the internal jugular vein just above its exposed medial border. After 70 to 100 IU/kg of heparin was administered to raise the activated clotting time to greater than 250 seconds, an 18-gauge needle was introduced directly into the common carotid artery. Injection of contrast material under fluoroscopy in
the appropriate lateral oblique plane localized the bifurcation and the lesion on a “worst view” magnified angiogram. All arterial sheaths were placed with road-mapping, to avoid the diseased artery. A .035 J wire was advanced to the distal carotid bulb. A 6F short Brite-Tip sheath (Cordis, Miami, Fla) was passed until the dilator straightened the J wire; then the sheath was advanced over the dilator to the distal common carotid artery. Standard intracranial carotid angiography was performed (anteroposterior Towne and lateral views) to document any preexisting intracranial arterial disease and to evaluate collateral circulation.

A 9F Brite-Tip sheath (Cordis) was placed directly in the common carotid artery, parallel and just above the 6F introducer sheath with its tip in the distal common carotid artery. A 5.0 polypropylene (Prolene) Z stitch was placed around the entrance of the sheath to enable rapid hemostasis in the event of catheter dislodgement. In the last 10 patients a more flexible 9F flexor sheath (Arrow) was used to facilitate advancement of the sheath and placement of the Z stitch. An .018 Gold Tip angled Glidewire (Medi-Tech/Boston Scientific, Natick, Mass) was directed into the external carotid artery through the 6F arterial sheath, and a 5-mm angioplasty balloon (Boston Scientific Corp) or through-the-lumen Fogarty balloon catheter (Edwards Lifescience, Irvine, Calif) was used to occlude the proximal external carotid artery. Occlusion of the external carotid artery and reversal of flow were verified at angiography after clamping the common carotid artery. The initial four TOPS procedures were performed with ultrasound verification of reversed internal carotid artery flow without external carotid artery balloon occlusion. The subsequent 17 procedures were performed with routine balloon occlusion of the external carotid artery to avert intracranial embolization via external carotid artery collateral vessels.5,6

The sidearm of the 9F sheath was connected to a 60-μm filter (Swinnex, Ireland) with holder apparatus (Millipore), attached to the sidearm of the internal jugular vein catheter (Fig 3). The clamp was applied to the common carotid artery, and retrograde flow of contrast material from the internal carotid artery into the internal jugular vein was confirmed at fluoroscopy or duplex ultrasound scanning. The carotid lesion was crossed with a .014 Spartacore guide wire (Guidant, Santa Clara, Calif) under flow-reversal cerebral protection. Tight lesions were traversed with an .018 angled Gold-Tip Glidewire and exchanged over a 4F Guidecatheter (Boston Scientific Corp) for the .014 Spartacore guide wire. The tight lesion was then predilated with a 4-mm × 4-cm Symmetry (Boston Scientific Corp) angioplasty balloon. If rapid retrograde flow of contrast material was not seen with initiation of the shunt, forceful aspiration of blood with a 20-mL syringe through the 9F sheath was performed after each angioplasty procedure. The blood was returned to the patient through a three-way stopcock attached to the filter. An 8-mm or 10 × 24-mm monorail Wallstent (Boston Scientific) was deployed across the lesion into the common carotid artery.
after withdrawing the 9F sheath beyond the stent. The stent was serially post-dilated with a 5-mm or 6-mm × 2-cm angioplasty balloon (Gazelle; Boston Scientific Corp) at 8 atm. Completion cervical and intracranial carotid artery angiography was performed after releasing the external carotid occlusion balloon and the common carotid clamp (Fig 4). Once satisfactory treatment of the lesion was observed, the two arterial sheaths were removed, with simultaneous repair of the arterial punctures, through the previously placed exit site sutures. The skin was closed with 4.0 vicryl suture. The venous sheath was left postoperatively to facilitate infusion of vasopressor or antihypertensive medications, if needed, and later was removed before the patient was discharged.

Independent consultation with the protocol neurologist who had evaluated the patient before the procedure was obtained before discharge (usually the same day) or within 24 hours post-procedure. Neurologic status was assessed with the National Institutes of Health stroke scale. Each patient was given clopidogrel bisulfate (75 mg/d) and aspirin for 30 days.

Follow-up. Patients were evaluated with carotid ultrasound and clinical examination at 30 days, 6 months, 1 year, and 2 years. No patient was lost to follow-up.

RESULTS

This consecutive series of CAS procedures performed at the O’Connor Vascular Center over 24 months included 21 CAS procedures in 20 patients.

All 21 CAS procedures were successfully carried out with TOPS, including in the first patient, in whom transfemoral CAS had been attempted unsuccessfully (Figs 1 and 2). Greater than 90% resolution of internal carotid artery stenosis was achieved in all cases. Lesions treated included three asymptomatic high-grade recurrent stenoses, one symptomatic high-grade recurrent stenosis, five asymptomatic high-grade stenoses, and 12 symptomatic moderate or high-grade stenoses. There was no intraoperative or postoperative stroke. One patient with temporary interruption of proximal shunting as a result of migration of the venous sheath had amaurosis fugax, which resolved in 2 hours. Significant but momentary bradycardia and hypotension associated with dilation of the internal carotid artery was observed in two patients. Embolic debris was recovered in all patients with the external carotid occlusion technique (n = 17); two patients had emboli larger than 2 mm (Fig 5). All patients tolerated continuous proximal shunting of internal carotid artery blood flow during the period of guide wire placement, angioplasty, and stent...
placement. One of the initial patients to undergo TOPS had intraoperative loss of 1 unit of blood after dislodgement of the arterial catheter before institution of routine purse-string suture placement. Devices are planned to prevent this inadvertent loss of access.

Postoperatively, no patient had significant hypotension (systolic blood pressure <90 mm Hg) or hypertension (systolic blood pressure >160 mm Hg). No intravenous infusion of antihypertensive medication was necessary. There were no myocardial infarctions. One patient had mild hoarseness, which resolved over the course of a month, presumed to be a result of prolonged traction on the vagus nerve with a fixed retractor. Since then, fixed retraction was used sparingly, if at all. Fourteen patients (66%) were discharged on the day of the procedure.

**Follow-up.** There were no neck hematomas or wound complications at the mini-cutdown incision (Fig 6). All patients underwent follow-up carotid ultrasonography at 30 days, which showed patency of the treated internal carotid artery without evidence of recurrent stenosis. Duplex ultrasound scans for all nine patients with 6-month follow-up and all five patients with 1-year follow-up demonstrated a patent internal carotid artery without recurrent stenosis. Two patients from the initial high-risk cohort died during the study period, of myocardial infarction at 5 and 9 months, respectively. Both underwent CAS with TOPS after initially presentation with neurologic symptoms of transient ischemic attack (TIA). Family members witnessing these events reported no evidence of stroke or TIA during the follow-up period; however, no autopsies were performed.

**DISCUSSION**

Although consensus is building that CAS is preferred in patients at high risk for treatment of carotid stenosis, many still consider CEA the standard for treatment of significant carotid bifurcation disease.²,³ Much discussion has centered on the expected stroke rate with CAS versus CEA. Early studies of CAS without cerebral protection reported higher stroke rates than the best CEA studies.⁹⁻¹¹ A meta-analysis of 26 trials with 2537 unprotected CAS procedures cited a 6% 30-day stroke mortality rate.¹² Some more recent, albeit smaller, studies with cerebral protection have approached equipoise,¹⁵,¹⁶ although the accounting of strokes in the contralateral hemisphere is not specifically addressed. A meta-analysis of 11 trials of CAS with cerebral protection involving 896 procedures showed a 2% 30-day stroke mortality rate.¹² Because CAS from a femoral approach carries an inherent 1% stroke disadvantage resulting from angiography, CAS with TOPS potentially brings stroke risk into parity with CEA by limiting events to endoluminal or surgical manipulation of the lesion and cerebral hyperperfusion syndrome.

Proximal shunting with flow reversal with TOPS may provide better cerebral protection than techniques that cause emboli by traversing the atheromatous aorta and aortic arch with large sheath placement or with distal balloon or filter deployment through a femoral carotid access.

![Fig 5. Embolic debris collected on the 60-μm filter used in a patient with symptomatic preocclusive carotid stenosis.](image1)

![Fig 6. Patient 1 week after transcervical occlusion and protective shunting, with mini-cutdown incision.](image2)
sheath. Using transcranial Doppler ultrasound, Al-Mubarak et al.17 documented embolization during carotid artery sheath placement for distal balloon-protected CAS. Also demonstrated was microembolization during predilation angioplasty of the lesion, guide wire manipulations, and distal device retrieval. Additional steps performed without cerebral protection, such as the use of a “buddy wire” to straighten the internal carotid artery to enable passage of the distal protection device, have also been associated with stroke.18

The technical failure of CAS has been reported in the range of 2% to 10%.8-15,18 with the exception of one study that reported a 1% failure rate.16 The best technical success has been achieved with theoretically higher risk techniques, either without cerebral protection or with low-profile distal balloons passed unprotected through the lesion. One of the largest published institutional experiences, by Roubin et al.,19 reported 10 access failures (2%) in a series of 604 unprotected CAS procedures that excluded patients with vascular disease that precluded femoral access and long preocclusive carotid lesions. The number of excluded patients was not specified. These and other authors have identified failure of placement of the guiding sheath as the predominant reason for technical failure in selected patients. If we assume a 2% exclusion rate because of unfavorable anatomy, 2% inability to obtain access, and 2% failure to achieve cerebral protection, a minimum of 6% failure of transfemoral approach CAS with cerebral protection would not be an unreasonable conservative estimate in experienced centers. Because of its direct cervical access route, the primary causes for transfemoral CAS technical failure are virtually eliminated, and catheter-positioning times are decreased with TOPS. Trauma to vessels below the lesion is minimized and greater mechanical advantage is achieved from the short access route, which facilitates navigating the lesion.

Another potential application of TOPS is in treatment of fibromuscular dysplasia of the carotid artery. Angioplasty is the accepted and preferred practice. Traditionally, angioplasty with serial dilation of the carotid artery has been performed. More recently, Ballard et al.19 described the procedure with conventional longitudinal exposure of the common carotid artery and internal carotid artery, with open flushing of the artery after balloon angioplasty to prevent embolization. Treatment of fibromuscular dysplasia with TOPS may improve the procedure by decreasing blood loss through use of the protective venous shunt and by decreasing the size of the incision. TOPS may also be used to facilitate and improve the efficiency of emergent selective intraarterial thrombolysis in acute stroke within the limited therapeutic window of 6 hours.20

Proponents of CEA believe it is a safer procedure than CAS. However, general anesthesia used with CEA is associated with longer periods of hemodynamic instability than is sedation used in CAS.21,22 Those who use regional anesthesia still observe the patient overnight for bleeding. The often quoted end points of stroke and death do not fully describe the morbidity of CEA, which has been cited at 12% to 21%.23-26 To illustrate this point, our first patient to undergo TOPS had previously been hospitalized for 35 days after CEA.

CAS with TOPS averts the long arteriotomy and venous ligatures of CEA, which are at risk for bleeding. All cranial nerve injuries are also averted, with the possible exception of transient vagus nerve paresis. As in conventional CAS, patients benefit from the improved hemodynamic profile accomplished, with less pain, anesthesia, and bleeding, which usually enable outpatient procedures.

Moreover, there is an increasing trend for patients with symptomatic disease needing urgent carotid artery intervention to be given potent thrombolytic, anticoagulation, and antiplatelet medications. More patients are receiving thrombolytic therapy for acute stroke. With the aging population, increasing numbers of patients are taking warfarin sodium (Coumadin) because of atrial arrhythmias, myocardial infarction, and congestive heart failure. The effectiveness of clopidogrel bisulfate and aspirin in decreasing stroke incidence and myocardial infarction27,28 has led to increased and long-term usage. Payne et al.29 demonstrated a synergistic increase in bleeding time, supporting the belief of many surgeons that this combination of medications substantially increases the risk for bleeding after surgery. In many areas, clopidogrel plus aspirin has become the initial medical therapy for TIA, making CEA more risky. Direct cervical access enables secure suture closure of the artery without the need for reversing anticoagulation or blood product transfusions. Furthermore, TOPS enables immediate ambulation and averts the increased risk for infection in the more contaminated groin site used in conventional CAS.

A small, straightforward cutdown incision is the only prerequisite for obtaining the advantages of TOPS, as well as potential new applications for fibromuscular dysplasia and treatment of acute stroke. There is currently no more effective closure than a surgical closure. Thus TOPS provides the opportunity for those with surgical expertise to perform a safer and more consistently successful CAS while minimizing the need for advanced endovascular skills and expensive equipment.

In conclusion, carotid intervention with TOPS has many conceptual advantages over percutaneous femoral approaches or CEA, because it addresses the failure modes, complications, and costs of each of these older treatments for carotid disease.

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REFERENCES
DISCUSSION

Dr Peter Schneider (Honolulu, Hawaii). Well, it looks like a freeway map. It’s an iatrogenic cerebral steal. It has the disadvantage of a neck incision and questionable durability, so I think the transcervical approach may have some merit. There are patients that you cannot do transfemorally: a patient with an occluded external carotid, a patient with a hostile arch. David describes quite a bit of credit for that. What I don’t like about it is that it is a tacit admission that we can’t get from the groin to the carotid using a catheter. You are sort of saying, “Well, since I can’t do the transcervical approach may have some merit. There are patients that you cannot do transfemorally: a patient with an occluded external carotid, a patient with a hostile arch. David describes quite a bit of credit for that. What I don’t like about it is that it is a tacit admission that we can’t get from the groin to the carotid using a catheter. You are sort of saying, “Well, since I can’t get from point A to point B, I am just going to cut down on point B.” I think that, again, there is a role for this. I don’t think it is going to replace transfemoral stenting, but I think it has merits, and we should take a close look.

I have three brief questions. First, what percent of patients do you think will be candidates for this procedure? Keep in mind, you have reversed carotid flow, and there are patients, anybody with common carotid disease, you really can’t treat, because you are cutting right down on it.
Second, because of the proximity of where your access site is to where your intervention site is, how will you deal with the numerous challenges posed? For instance, there is very short working room. You are going to have increased radiation exposure. Your hands are going to be under the image intensifier, or at least very close. There is potential for unintended guide wire passage into the carotid bifurcation, because, keep in mind, you are putting in an access sheath and the distance to the carotid bifurcation is literally just a couple of centimeters. My own experience is that you really can’t control wires that well; you are going to have the unintended 1-cm or 2-cm slip distally.

Third, how do you stent across the bifurcation when you have an occlusion catheter in the external carotid artery at the time?

Dr David W. Chang. In answer to your question about the percentage of candidates, I think as an initial trial here we did exclude common carotid lesions. Frankly, it is not necessarily an absolute contraindication, but for the purpose of this study we did not include them. I would estimate 110% of transfemoral cases are candidates. Also, why send your man in New York to do the job in Hawaii when you can send your man in San Francisco who can do it just as well, if not better?

To combine my answer to your second question regarding how you work with a short operating distance, we get an anogram through an angiocath at the time that we make the cutdown, so we have a good idea of the working distance we can use, and we put the sheath in at an adequate location. We use road-mapping techniques so everything is layed out, so you watch the wire go in, you know exactly where the bifurcation is, and you don’t pass into the bifurcation. Alternatively you can pass the wire into the external and then pass your sheath up into the external carotid, then withdraw it to the distal bulb.

So far we have not really encountered any problems with any internal carotid access. The common carotid access is a little bit more tricky if you have a mid-common carotid lesion. For those lesions and also for the purposes of streamlining the technique, we are working on an occlusion balloon system whereby you can actually put the balloon up so that you don’t have to pass the sheath up that high. The balloon can be right down the base of the neck, increasing your working distance.

As far as stenting across the bifurcation, we really have had no problems with removing the external carotid artery balloon. You will note that the Wallstent does not have any open wire struts. It just crosses over the orifice of the external carotid, and it is very easy with self-expandable stents to pull that occlusion balloon at the end of the procedure.

Dr Lloyd M. Taylor, Jr (Portland, Ore). Dr Chang, I didn’t notice in your presentation, but can you tell us what type of anesthesia you used for these procedures, and what the average occlusion time was during the procedure?

Dr Chang. We used primary local anesthesia, with a little sedation at the beginning, just to keep the patient calm, but we like them to be involved and active to assess their neurologic status throughout the procedure.

The occlusion times, actually in all our cases, have been continuous, because patients have tolerated it. However, if you have a patient with a contralateral occlusion and for some reason they do not tolerate it, the shunt can be turned on and off periodically between interventions. We have had patients with bilateral carotid stenoses, high grade, that have not had problems with occlusion and reverse flow. I believe one reason is that the connection between the two sheaths is through a hole that is actually fairly small, so you have reverse flow, but you don’t have torrential reverse flow.

Dr Kenneth McIntyre (Las Vegas, Nev). What is your post stenting protocol for prolonging stent patency?

Dr Chang. Patients get 300 mg of Plavix before the procedure, or they are oftentimes increasingly presenting on Plavix. They stay on Plavix and aspirin for a month.

Dr Sam Ahn (Los Angeles, Calif). I just have two quick questions. You have a wonderful opportunity here to show us some really good physiology. Did you notice in your study, or in your experience, what percent of patients had flow going from ICA to ECA versus ECA to ICA? And I guess another question related to that is what percent of the patients really need that external balloon?

The second question I have is this: during the balloon occlusion—I think you said this was under local anesthesia—did any patients have transient TIAs during the occlusion?

Dr Chang. Actually, as far as the flow direction, when I was in New York we did animal studies with the proximal occlusion technique, and also I actually measured stump pressures in the OR, and roughly it is half and half. If you occlude the common carotid, half go up one way and half go up the other way, and that’s basically what the Cleveland Clinic group also found when they studied stump pressures. In cases where the internal carotid pressure is higher, the external carotid balloon helps prevent embolization of potential collaterals to the ICA or posterior circulation.

As far as any TIAs, we did not have any TIAs with clamping. It has been at this point uniformly well tolerated, although, as I mentioned, we did not have any contralateral occlusions yet.

Dr Joseph Rapp (San Francisco, Calif). So what I think carotid angioplasty has shown us, which we would have not believed before, is that emboli are incredibly well tolerated by the brain, much better than we would have ever believed. But emboli are bad, and I think that there are a lot of accumulating data that long-term dementia is related to chronic microemboli. What is known of carotid angioplasty is that there are continuing emboli after the procedure, more than with endarterectomy. So I am not throwing the baby out with the bath water; I am just adding a note of caution. And my question, unrelated to my statement, is, with the proximal shunt you, and Tak Ohki, and others in New York have found that there are a certain number of patients who cannot tolerate this backflow of the internal carotid, and what percentage of patients is that?

Dr Chang. Again, this is a modest study; currently none, but there are backups. Either you can do short clampings or you can have a Percusurge balloon or some distal filter device available. As far as creating emboli with the protection device, all of these devices, including distal protection balloons, can create emboli as you deploy them. I happen to think it is much less with proximal protection; however, in addition to reverse flow, I aspire fairly rigorously at the end of each maneuver, so that all of the debris is really sucked up that might possibly go up the other way if the reversed flow is slow.