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Prosthetic bypass for restenosis after endarterectomy or stenting of the carotid artery

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ABSTRACT

Objective: The objective of this study was to evaluate the results of prosthetic carotid bypass (PCB) with polytetrafluoroethylene (PTFE) grafts as an alternative to carotid endarterectomy (CEA) in treatment of restenosis after CEA or carotid artery stenting (CAS).

Methods: From January 2000 to December 2014, 66 patients (57 men and 9 women; mean age, 71 years) presenting with recurrent carotid artery stenosis \geq 70% (North American Symptomatic Carotid Endarterectomy Trial [NASCET] criteria) were enrolled in a prospective study in three centers. The study was approved by an Institutional Review Board. Informed consent was obtained from all patients. During the same period, a total of 4321 CEAs were completed in the three centers. In these 66 patients, the primary treatment of the initial carotid artery stenosis was CEA in 57 patients (86%) and CAS in nine patients (14%). The median delay between primary and redo revascularization was 32 months. Carotid restenosis was symptomatic in 38 patients (58%) with transient ischemic attack (n = 20) or stroke (n = 18). In this series, all patients received statins; 28 patients (42%) received dual antiplatelet therapy, and 38 patients (58%) received single antiplatelet therapy. All PCBs were performed under general anesthesia. No shunt was used in this series. Nasal intubation to improve distal control of the internal carotid artery was performed in 33 patients (50%), including those with intrastent restenosis. A PTFE graft of 6 or 7 mm in diameter was used in 6 and 60 patients, respectively. Distal anastomosis was end to end in 22 patients and end to side with a clip distal to the atherosclerotic lesions in 44 patients. Completion angiography was performed in all cases. The patients were discharged under statin and antiplatelet treatment. After discharge, all of the patients underwent clinical and Doppler ultrasound follow-up every 6 months. Median length of follow-up was 5 years.

Results: No patient died, sustained a stroke, or presented with a cervical hematoma during the postoperative period. One transient facial nerve palsy and two transient recurrent nerve palsies occurred. Two late strokes in relation to two PCB occlusions occurred at 2 years and 4 years; no other graft stenosis or infection was observed. At 5 years, overall actuarial survival was $81\% \pm 7\%$, and the actuarial stroke-free rate was $93\% \pm 2\%$. There were no fatal strokes.

Conclusions: PCB with PTFE grafts is a safe and durable alternative to CEA in patients with carotid restenosis after CEA or CAS in situations in which CEA is deemed either hazardous or inadvisable. (J Vasc Surg 2017; 1-9.)

The incidence of significant recurrent carotid artery stenosis \geq 70% after primary carotid endarterectomy (CEA) and after carotid artery stenting (CAS) varies from 0.6% to 15%.¹⁻⁴ Restenosis may result from intimal hyperplasia, usually within 24 months of the primary operation, or from recurrent atherosclerosis beyond this time interval.⁵ Symptoms of cerebral ischemia are present in up to 5% of the patients.^{6.7} Indications for treatment include

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Copyright © 2017 by the Society for Vascular Surgery. Published by Elsevier Inc. http://dx.doi.org/10.1016/j.jvs.2016.11.046 symptomatic and severe degree of restenosis >70%.³ Reports on redo CEA have shown that its results are essentially comparable to those of primary CEA.^{8.9} Nonetheless, scar tissue dissection in redo CEA may expose patients to a risk of cranial nerve injuries.³ CAS has been proposed as an alternative to repeated CEA. in view of reducing the morbidity associated with iterative surgery in a scarred field. However, the incidence of in-stent restenosis after CAS as a repeated procedure is significant, reaching 13.5% at 5 years,^{1,10,11} with a 4-year patency rate of 76%.¹² For these reasons, we wish to suggest that carotid bypass could be a viable alternative to both repeated CEA and CAS. This prospective study evaluated the results of prosthetic carotid bypass (PCB) with polytetrafluoroethylene (PTFE) grafts in treatment of restenosis after CEA or CAS in situations for which repeated CEA is deemed inadvisable.

METHODS

From January 2000 to December 2015, 99 patients (83 men and 16 women; mean age, 72 years) were admitted

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for treatment of \geq 70% recurrent carotid artery stenosis (North American Symptomatic Carotid Endarterectomy Trial [NASCET] criteria) and enrolled in a prospective study at two academic hospitals and one affiliated center. This figure represents 2.3% of the 4321 open carotid artery revascularizations performed by the same authors during the same time. In this study, all 99 patients received open surgical revascularization for treatment of the restenosis. At operation, transmural or inflammatory carotid lesions with dense scarring, no plane for endarterectomy, distal extension beyond C2, and restenoses after CAS were treated with carotid bypass, whereas more limited lesions on a carotid wall that would tolerate a repeated endarterectomy with a safe cleavage plane were treated with repeated CEA. The study was approved by the Institutional Review Board, and informed consent for repeated carotid artery revascularization was obtained from all the patients. The 66 patients (57 men and 9 women; mean age, 71 years) who underwent carotid bypass are the subject of this study; the remaining 33 patients received repeated CEA (Fig 1). The 66 bypasses for repeated revascularization represent 30% of 221 carotid artery bypass procedures performed by the authors for atherosclerotic disease during the same period. Thirty-eight patients (58%) presented with neurologic symptoms, including transient ischemic at-

tacks in 20 cases and minor stroke in 18 cases. Demography and patient risk factors are reported in Table I. Primary treatment of the initial carotid artery stenosis was CEA in 57 patients (80%) and CAS in 9 patients (14%). The median interval between primary and second-

ary revascularization was 32 months (18-84 months). Primary, open revascularization consisted of standard CEA with primary closure in 27 cases (47%), patch closure in 25 cases (44%), and eversion CEA in 5 cases (9%).

Recurrent carotid stenosis was diagnosed at duplex ultrasound (DUS), showing a peak systolic velocity (PSV) >250 cm/s, and confirmed at computed tomography (CT) scan or magnetic resonance imaging by NASCET criteria. In this series, repeated carotid revascularization in asymptomatic patients was carried out in case of worsening of the carotid restenosis on DUS between two time points, reaching a PSV above 350 cm/s.

At the time of reoperation, all patients received statins and antiplatelet treatment. Thirty-eight patients (58%) received oral aspirin alone (160 mg/d), whereas 28 patients (42%) received aspirin and clopidogrel (75 mg/d) because of a recent (<6 months) percutaneous coronary intervention with drug-eluting stents. Dual antiplatelet therapy was stopped on the day of operation and resumed on the first postoperative day. Intraoperatively, 5000 IU of sodium heparin was administered before arterial clamping, and it was not blocked at the end of the intervention. Subcutaneous enoxaparin (2000 IU every 12 hours) was administered, starting 6 hours after the operation and stopped on discharge. Enoxaparin was

ARTICLE HIGHLIGHTS

- **Type of Research:** Prospective multicenter cohort study
- **Take Home Message:** In 66 patients, polytetrafluoroethylene graft was placed for restenosis, with no early but two late strokes due to graft occlusion.
- **Recommendation:** The authors suggest polytetrafluoroethylene bypass as an alternative for treatment of restenosis after carotid endarterectomy or stenting.

administered to all the patients, regardless of their perioperative antiplatelet treatment, either single or dual. Antibiotic prophylaxis was performed as a single intravenous injection of a bolus of cephalosporin before skin incision. All of the operations were performed under general anesthesia. The status of cerebral perfusion during clamping was assessed by internal carotid artery backbleeding and transcutaneous oximetry (INVOS; Covidien-Medtronic, Fridley, Minn) and remained satisfactory in all patients. No shunt was used in this series. Median carotid clamping time was 21 minutes (17-34 minutes).

In patients with high carotid bifurcation or a stenosis extending beyond the level of C2 on preoperative CT scan (n = 33), the difficulty of obtaining distal internal carotid artery control was anticipated and surmounted in all cases by nasal intubation and section of the digastric muscle. To avoid intense scarring surrounding the carotid bifurcation, retrojugular dissection was carried out in 36 patients (54%; Fig 2). The graft material consisted of a nonringed PTFE graft of 7 mm in diameter in 60 patients and 6 mm in diameter in six patients (W. L. Gore & Associates, Flagstaff, Ariz). The distal anastomosis was constructed end to side in 44 patients, with a clip distal to the atherosclerotic lesion, and end to end in 22 patients (Fig 3). The proximal anastomosis was lateral to the common carotid artery in all cases. Completion angiography was performed in all patients, showing a spasm of the distal internal carotid artery in three cases, which was eliminated with local use of papaverine (Fig 4). Preoperative and postoperative neurologic status of all patients with repeated carotid surgery was assessed by a neurologist providing an independent evaluation for any hemispheric deficit and postoperative cranial nerve palsy. Arterial reconstruction patency was assessed by DUS and magnetic resonance angiography or CT scan (Fig 5) at discharge, followed by DUS every 6 months. The patients were discharged under statins and single or dual antiplatelet therapy according to their preoperative treatment status.

Follow-up. Median length of follow-up was 63.4 months (1-132 months). Primary end points were postoperative stroke or death and cranial nerve injury; secondary end points were occurrence of a cervical

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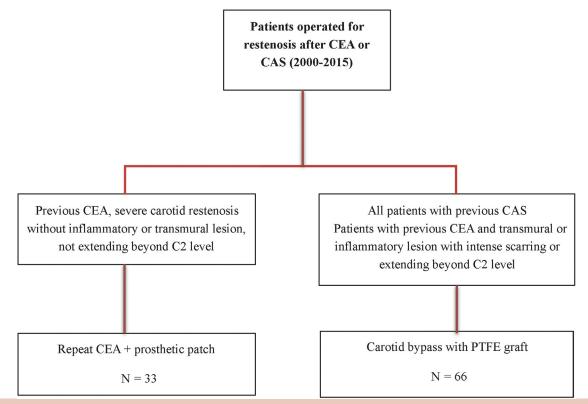


Fig 1. Cohort selection of patients for repeated carotid revascularization. *CAS*, Carotid angioplasty and stenting; *CEA*, carotid endarterectomy; *PTFE*, polytetrafluoroethylene.

Table I. Demography and risk factors

Baseline characteristics	No. (%)
Mean age, years (range)	71 (62-83)
Male gender	57 (86)
Hypertension	53 (81)
Current smokers	52 (79)
Hyperlipidemia	44 (67)
Coronary artery disease	31 (47)
Diabetes	17 (26)
Lower limb occlusive arterial disease	3 (4)
Chronic renal insufficiency	2 (3)

hematoma, graft infection, late stroke, and late restenosis or graft occlusion. Postoperative stroke or death was defined as any stroke or death occurring within 30 days after the operation or during the hospital stay. Hematoma was defined as any condition requiring reoperation for hemostasis. Cranial nerve injury was defined as any postoperative cranial nerve palsy. Graft infection was defined as any clinical situation requiring PTFE graft excision, followed by replacement with an autologous arterial substitute or arterial ligation or any clinical or CT scan evidence of graft infection. Late stroke was defined as any new ipsilateral ischemic stroke occurring after discharge from the hospital and during the whole length of follow-up. Late de novo restenosis was defined as any restenosis >70%, associated with a PSV >250 cm/s measured on DUS and confirmed by CT scan or magnetic resonance imaging by the NASCET criteria.

Life-table analysis according to the Kaplan-Meier method was used to calculate late survival and freedom from late stroke and restenosis.

RESULTS

The 66 patients in this series were operated on during a 16-year-period by the three senior surgeons (G.I., F.G.C., J.B.R.). Median length of stay was 3 days (2-8 days). It was significantly longer in the early period of the study and shorter in the later years. Currently, median length of stay for open repeated carotid revascularization is 48 hours, comparable to standard primary CEA. Seven of these patients had already received irradiation 10 to 20 years before index CEA.

No patient died, sustained a stroke, or presented with a cervical hematoma during the postoperative period. Two transitory recurrent nerve palsies and one transitory facial nerve palsy were observed. They accounted for 4.5% of the whole series and had completely reverted within 2 weeks. No postoperative death, stroke, or cranial nerve injury was observed in the repeated CEA group of patients.

Two late strokes (3%) associated with two carotid bypass occlusions (3%) occurred at 2 years and 4 years postoperatively. In these cases, DUS performed,

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Fig 2. Retrojugular approach to the common and the distal internal carotid artery for repeated carotid surgery. This approach was preferred in case of dense scarring involving the carotid bifurcation and the internal jugular vein.



Fig 3. Carotid bypass from the common carotid artery to the internal carotid artery using a 7-mm-diameter polytetrafluoroethylene (PTFE) graft.

respectively, 3 and 6 months before occlusion of the PTFE graft showed a normal flow pattern within the grafts. No graft infection was observed.

At 5 years, the overall actuarial survival rate was $81\% \pm 7\%$ (Fig 6), with graft patency of $93\% \pm 2\%$ (Fig 7) and a stroke-free rate of $93\% \pm 2\%$ (Fig 8). There were no fatal strokes.

DISCUSSION

The results of this study show that PTFE carotid bypass is a viable alternative to CEA in treatment of severe, recurrent carotid stenosis after CEA or CAS.

In this series, 38 patients (58%) with 50% to 99% carotid restenosis presented with ipsilateral carotid territory symptoms and underwent repeated carotid revascularization as recommended by Rothwell et al.¹³ Other patients presented >70% asymptomatic restenosis. Despite the intuitive belief that most asymptomatic restenoses are benign, this is not necessarily the case in current practice, and a recent meta-analysis suggested that two-thirds of the patients undergoing interventions

for carotid restenosis were asymptomatic.¹⁴ Furthermore, in the Asymptomatic Carotid Surgery Trial (ACST),¹⁵ 13% of the patients with carotid restenosis who progressed to occlusion suffered a stroke when it occurred, and an additional 10% suffered an ipsilateral stroke at a later time. It therefore appears advisable to repeat carotid revascularization in patients with severe (>70%) carotid artery restenosis progressing to PSV >350 cm/s. To date, no randomized controlled trial has compared repeated surgery with CAS in treatment of carotid restenosis. In a 2015 meta-analysis of 13 studies in which repeated CEA was compared with CAS,¹⁴ there was no difference in 30-day stroke/death (2.3% after CAS vs 2.7% after repeated CEA). However, according to the meta-analysis by Tu et al,¹ overall incidence of restenosis at 5 years after repeated CEA was 4.4% compared with 13.5% after CAS and 7% in our series after PCB. CAS for carotid restenosis has also been reported in other series, with an incidence of in-stent restenosis ranging from 3.6% at 2 years¹⁶ to 19% at 3 years.^{12,17} Better results of CAS compared with open revascularization have recently been reported by Dorigo et al¹⁸ and by Attigah et al.¹⁹ However, in both series, CAS was performed mainly in patients with an early carotid restenosis usually limited to intimal hyperplasia rather than in those with more complex and extensive carotid lesions treated by repeated CEA. Rate of freedom from any stroke or restenosis was 93% at 5 years in our series and 100% in a comparable series by Spinelli et al,³ showing that compared with CAS, PCB yields excellent long-term patency.

When deciding on a repeated open surgical revascularization after primary CEA or CAS, the surgeon has two choices: either repeated CEA or bypass. Although there has been no randomized trial addressing this issue, a retrospective analysis of prospectively stored data by Archie²⁰ showed that repeated CEA with patch and PTFE bypass grafts yielded comparable outcomes. However, there exist differences tending to favor carotid bypass. The main issue with CEA for restenosis is that it may be neither advisable nor possible in many patients because of an inflammatory process involving the carotid wall after CAS or a transmural atheromatous lesion in late severe carotid artery restenosis after CEA. In these situations, PCB is much more appropriate than repeated CEA. It eliminates the need to perform endarterectomy on an inflammatory carotid wall without a welldelimited cleavage plane or on a carotid with a transmural atheromatous lesion. In these situations, a bypass with proximal and distal anastomoses on a nondiseased artery may be safer and compares favorably with other series of repeated CEA.^{18,19} A summary of the outcomes in recent series of CEA, CAS, or PCB for carotid restenosis is given in Table II.

Taking into account the material used in carotid bypass, the great saphenous vein (GSV) or a PTFE graft can be



Fig 4. Completion angiography showing spasm of the distal internal carotid artery (A), resolved after local application of papaverine (B).

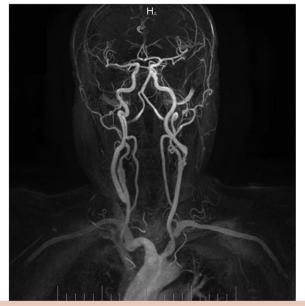


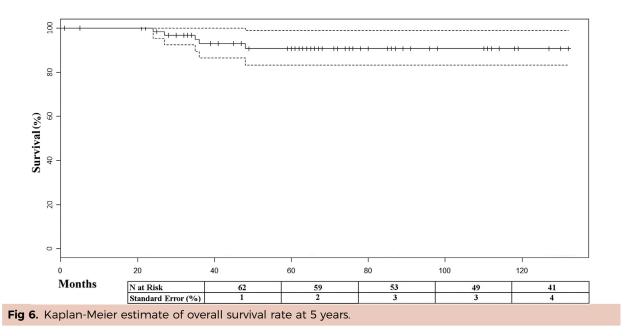
Fig 5. Postoperative magnetic resonance angiography showing the usual figure of a common to internal carotid artery bypass with a distal end-to-end anastomosis.

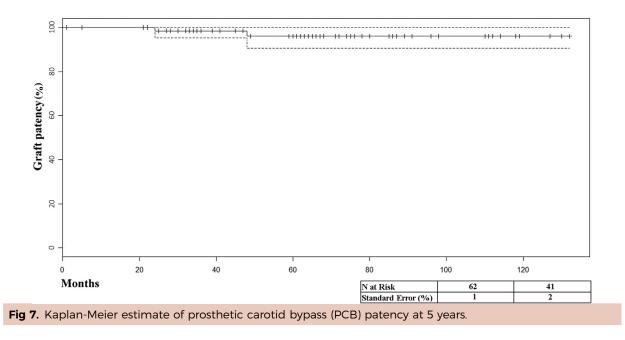
chosen.^{1,9,20} PTFE carotid bypasses have been shown to yield excellent postoperative and long-term outcomes when carried out as an elective alternative to CEA.²¹ Following the study by Spinelli et al,³ our series showed

comparable results when PTFE was used for repeated carotid revascularization with freedom from stroke of 93% at 5 years, a finding in agreement with the previous reports. Conversely, use of the GSV as a carotid substitute has been associated with a high rate of restenosis,^{1,21,22} with cumulative freedom from occlusion or recurrent stenosis >70% of 83% at 5 years²³ compared with 93% in our series.

According to Cormier et al²³ and Berguer et al,²⁴ use of a GSV has significant limitations; only segments 4 to 5 mm in diameter are usable, whereas segments <4 mm in diameter or with a thick wall are prone to restenosis or early thrombosis, and segments >5 mm in diameter are prone to aneurysm. Another drawback is that one prerequisite GSV feature is lack of valves, which involves a potential risk of postoperative embolism. An additional disadvantage of vein grafts is that to obtain a segment of adequate diameter, it is necessary to harvest the GSV at the thigh level, which means potential thrombosis of the remaining segment of the vein and consequently a high likelihood that it will become unusable for future revascularization procedures.

The last issue concerning the risk of repeated open surgical revascularization for carotid restenosis compared with CAS consists of the occurrence of cranial nerve palsy. Its overall incidence after repeated CEA is





estimated to be around 4% to 15% and transitory in 85% of the cases.^{1,5,8,25,26} In this series, the incidence was 4.5%, and it was transitory in all cases. Similar results have been reported by others with PCB when it was used to treat restenosis after primary CEA and CAS.³ An element that may have contributed to the low incidence of transitory cranial nerve palsy is the retrojugular approach used in 36 patients (56%) of this series, which allowed access to the common and internal carotid arteries in zones free from scarring.²⁷ The frequent use of nasal intubation, enabling enhanced control of the distal internal carotid artery, may also have reduced the risk of cranial nerve trauma.

Regarding general complications, myocardial infarction (MI), which is estimated to occur postoperatively in 1.3% of open carotid revascularization,¹ has been considered the main drawback of repeated carotid surgery compared with CAS.²⁸ However, previous studies have reported no postoperative MI after open treatment of recurrent carotid stenosis by either CEA or PCB,^{3,9} and other studies have shown no significant difference in the incidence of MI between open repeated revascularization and CAS.^{18,19,22} We did not observe any postoperative MI in our series of 66 patients. This may be due to our policy of systematically performing preoperative coronary angiography in all patients who are candidates for carotid revascularization

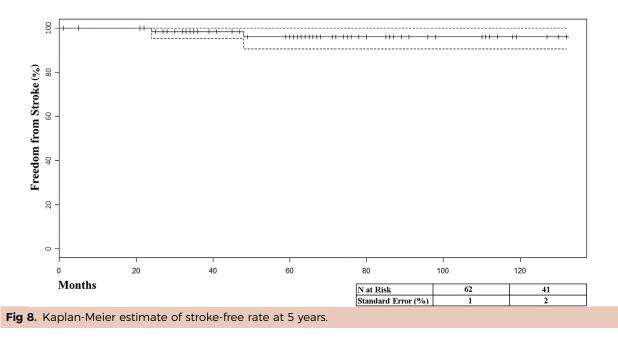


Table II. Outcome of carotid angioplasty and stenting (CAS), carotid endarterectomy (CEA), and carotid bypass for restensis after CEA

Author	Year	Procedures, No.	30-Day death, %	30-Day stroke, %	Mean follow-up, years	Rate of restenosis, %
CAS						
Setacci ¹⁶	2005	15	—	—	1	0
De Borst ¹²	2007	57	—	3.5	3	19
AbuRahma ⁵	2010	120	—	1	2	4
Attigah ¹⁹	2010	45	—	2.2	2.9	5
Brott ²⁸	2010	1262	0.7	4.1	4	NS
Midy ¹⁷	2011	249	0.4	3.6	2.4	8.4
Dorigo ¹⁸	2013	58	—	—	2	6.5
Tu ¹	2015	2174	0.9	2.4	5	13.5
CEA						
AbuRahma ⁵	2010	72	—	3	2.75	3
Attigah ¹⁹	2010	41	—	9.7	2.9	11
Brott ²⁸	2010	1240	0.3	2.3	4	NS
Coscas ²⁶	2010	119	0.8	1.7	5	6.7
Dorigo ¹⁸	2013	37	—	—	2	28.3
Tu ¹	2015	2392	1	2.8	5	4.4
Carotid bypass						
Spinelli ³	2014	21	—	—	5.4	0
Present series		66	—	<u> </u>	5	3
NS, Not specified.						

and of prophylactically treating significant coronary artery stenoses before carotid revascularization.^{29,30} Following a recent percutaneous coronary intervention using drugeluting stents, we performed PCB under dual antiplatelet treatment in 28 patients (42%) without any cervical hematoma requiring surgical drainage. Finally, limitations of the study are twofold: first, the time span, which extends during a 16-year-period; and second, the lack of a control group treated with CAS. Nonetheless, our data and outcomes were objectively assessed, thereby rendering the results reliable.

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CONCLUSIONS

PCB with PTFE grafts is a safe and durable alternative to CEA in patients with carotid restenosis after CEA or CAS in situations in which CEA is deemed either hazardous or inadvisable.

AUTHOR CONTRIBUTIONS

Conception and design: GI, RB, FC, JR Analysis and interpretation: GI, FS, GP, FC, JR Data collection: RB, FS, GP Writing the article: GI, JR Critical revision of the article: GI, RB, FS, GP, FC, JR Final approval of the article: GI, RB, FS, GP, FC, JR Statistical analysis: JR Obtained funding: Not applicable Overall responsibility: GI

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