

4 Year Follow-Up After Carotid Bifurcation Resection and Interposition of a Polytetrafluoroethylene Graft for Carotid Artery Disease

Ian Diebels,
Marc Dubois and
Philippe de Vleeschauwer

Heilig Hart-Ziekenhuis, Lier, Belgium

Abstract

Introduction: The major cause of carotid artery disease is the presence of a significant carotid artery stenosis due to progressive arteriosclerosis. The gold standard remains carotid endarterectomy. However, other treatments have been performed: Eversion Carotid Endarterectomy, Carotid Artery Stenting and Carotid Bypass Grafting. In this article, the long-term follow-up results of an alternative surgical technique called Carotid Bifurcation Resection and Interposition of a Polytetrafluoroethylene Graft (BRIG) procedure are described.

Method: All BRIG procedures between April 2006 and September 2013 were retrospectively analysed. All procedures were performed by a single experienced surgeon (Philippe De Vleeschauwer) in a single centre.

Results: 70 BRIG procedures were performed during the study period. The median follow-up was 46.5 months (interquartile range 29.6–63.0 months, maximum 117 months). Indication for surgery was a symptomatic moderate stenosis (50–79% stenosis) in 10.0%, high-grade stenosis ($\geq 80\%$ stenosis) in 87.1% and (pseudo-) aneurysm in 2.9%. 34.3% of the procedures were for symptomatic carotid artery disease. 91.4% were primary treatments, whereas the remaining 8.6% had undergone a previous CEA on the ipsilateral carotid artery. During the 30 day post-operative follow-up period 1 patient died (1.4%) due to an acute myocardial infarction and 2 patients (2.9%) suffered a minor stroke with only minor residual fine motor impairment. Long-term patency showed a 50–69% restenosis rate of 4.3% a 70–99% restenosis of 0% and an occlusion rate of 1.4%. Jaw claudication occurred in 2 patients (2.9%).

Conclusion: The BRIG procedure is a promising alternative surgical technique to carotid endarterectomy. The results show a low 30 day post-operative mortality and morbidity, with excellent long-term graft patency. The BRIG procedure appears to be a safe and promising technique.

Keywords: Carotid artery disease; Carotid stenosis; Carotid aneurysm; Carotid bypass; Carotid interposition graft; Polytetrafluoroethylene graft

Corresponding author:

Philippe De Vleeschauwer

✉ drpdv@icloud.com

Department of Vascular Surgery, Heilig Hart-ziekenhuis Mechelsestraat 24, Lier, 2500, Belgium.

Tel: +32 4 77 61 04 91

Fax: +32 3 491 28 09

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Introduction

Carotid artery disease is an important cause of ischemic stroke [1]. In the majority of cases the ischemic stroke is not because of direct flow impairment but rupture of the plaque leading to embolic events. The yearly incidence of 795.000 strokes in the USA shows that it is an important health issue [2]. The gold

standard remains the carotid endarterectomy [3–5]. Other techniques have been proposed including Eversion Carotid Endarterectomy (eCEA), Carotid Artery Stenting (CAS) and Carotid Bypass or Interposition Grafting, with varying success. Carotid grafting was mainly reserved for complex cases including significant restenosis after previous CEA, extensive fibrosis after radiotherapy, extensive lesion or challenging carotid kinking [6].

In this study the long-term results of the Carotid Bifurcation Resection and Interposition of a Polytetrafluoroethylene (PTFE) Graft (BRIG) procedure are presented.

Method

Data collection was performed retrospectively by all authors. During the study period, April 2006 till September 2013, a total of 70 consecutive procedures have been performed. This sub analysis of a patient population previously published [7]. In order to ensure ample follow-up, all BRIG procedures performed in the above mentioned study period were included. No exclusion criteria were defined. All procedures were performed by a single experienced surgeon (Philippe De Vleeschauwer) in a single institute (Heilig Hart-ziekenhuis, Lier, Belgium). All patients were treated with the BRIG procedure. Perioperative mortality and morbidity was defined as occurring within 30 days of surgery. The main perioperative events of interest were stroke, TIA, myocardial infarction and death. The first follow-up was at 1 month postoperative and was then repeated annually. The follow-up included duplex-ultrasound imaging with criteria from The Society of Radiologists in Ultrasound multidisciplinary consensus [8]. Restenosis was suspected if an increased velocity (peak systolic velocity ≥ 125 cm/s and end diastolic velocity ≥ 40 cm/s) or visual confirmation of lumen narrowing was observed. A CT- or MRI-angiography was then performed in order to confirm a restenosis.

Surgical Procedure

The patient was installed in supine position with the head in slight hyperextension and contralateral rotation. A longitudinal incision was made along the anterior border of the sternocleidomastoid muscle followed by the exposure of the carotid bifurcation similar to CEA (**Figure 1a**). Intravenous heparin was administered and the ICA, common carotid artery (CCA) and ECA were clamped respectively. The superior thyroid artery was always clipped and the carotid bifurcation was resected. The ECA was then ligated (**Figure 1b**). A shunt was never placed. The resected bifurcation was measured and a 6 mm thin wall PTFE graft was cut to the

appropriate length. Different PTFE grafts have been used during the study (Gore Medical, Flagstaff, Arizona, USA; Terumo Vascutek, Inchinnan, Scotland; LeMaitre Vascular, Sulzbach, Germany). Care was taken to not oversize the graft. First, the distal end-to-end anastomosis was created using a Gore-Tex CV6 running suture (Gore, Flagstaff, Arizona, USA). Then the proximal anastomosis was created by an end-to-end running suture (**Figure 1c**).

Statistical Analysis

Variables were divided in continues and categorical variables. Continues variables were considered to be normally distributed when the Shapiro-Wilk test was not statistically significant meaning the null-hypothesis of the test, the presence of a normal distribution, could not be discarded. Visual confirmation was obtained via a linear Q-Q plot. Normal distributed variables were expressed in mean with standard deviation. Non-normal distributed variables were expressed in median with interquartile distance. Categorical variables were expressed in percentages. Restenosis rate was expressed in a Kaplan-Meier survival analysis. Statistical analysis was performed using SPSS 23.0 (SPSS Inc. Chicago, ILL, USA).

Results

70 BRIG procedures were performed during the study period (April 2006 till September 2013). Mean age at the time of surgery was 71.0 years (standard deviation ± 9.0 years), with 67.1% being male. The median follow-up was 46.5 months (interquartile range 29.6–63.0 months, maximum 117 months). Indication for surgery was a symptomatic moderate stenosis (50–79% stenosis) in 10.0%, high-grade stenosis ($\geq 80\%$ stenosis) in 87.1% and carotid (pseudo-)aneurysm in 2.9%. Overall, 34.3% of the procedures were for symptomatic carotid artery disease. 91.4% were primary treatments, whereas the remaining 8.6% had undergone a previous CEA on the ipsilateral carotid artery. Patient demographics and the indication for surgery are presented in **Table 1**.

During the 30 day follow-up period 1 patient died (1,4%) due to an acute myocardial infarction and 2 patients (2,9%) suffered a

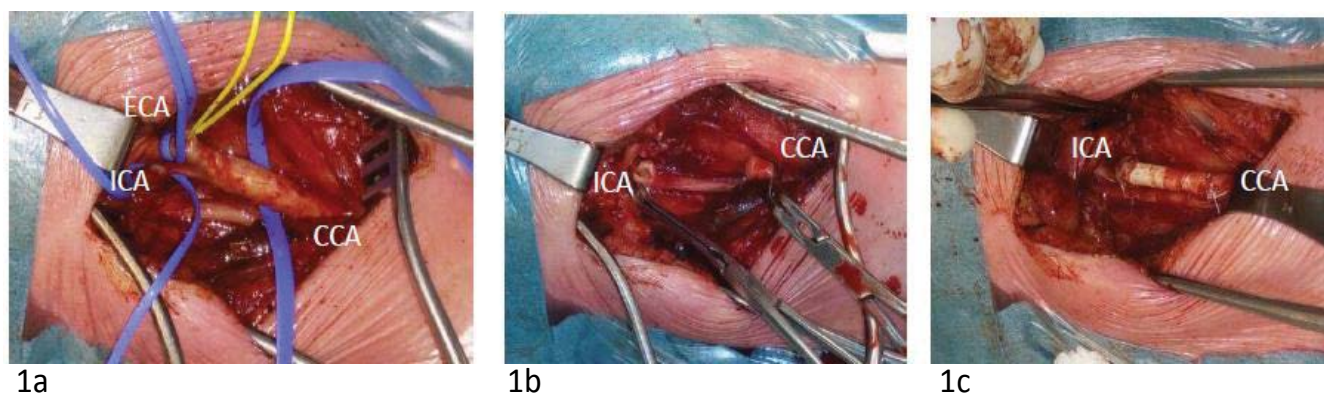


Figure 1 Operative technique of the BRIG procedure.
1a: Identification of the carotid bifurcation.
1b: Resection of the carotid bifurcation.
1c: Interposition of the PTFE graft.

minor stroke with only minor residual fine motor impairment. The first stroke was caused by an incomplete Circulus of Willis (absence of ramus communicans anterior and posterior), the second stroke by a graft thrombosis because of graft kinking. This required urgent revision with shortening of the graft. Jaw claudication occurred in 2 patients (2.9%). In both cases, this was not considered as a significant complaint by the patients themselves as eating slower quickly resolved any complaints. None of the patients complained of facial pain. Perioperative results are presented in **Table 2**.

Long-term patency showed a 50–69% restenosis rate of 4.3%, a 70–99% restenosis of 0% and an occlusion in 1.4% (**Table 3 and Figure 2**). All restenosis occurred at the proximal anastomosis and

Table 1 Patient demographics and indications for surgery.

	Results
Age, mean (years)	71
Gender, male (%)	67.1
Diabetes mellitus (%)	22.1
Dyslipidaemia (%)	70.1
Hypertension (%)	74.3
Smoking (%)	52.8
Pack years, mean	36.8
Cardiovascular history (%)	72.5
Family history of cardiovascular disease (%)	38.6
Side, right (%)	58.6
Previous ipsilateral CEA (%)	8.6
Symptomatic carotid stenosis (%)	34.3
TIA [†] (%)	18.6
Stroke [†] (%)	15.7
Stenosis grade	
50–79% (%)	10
80–99% (%)	87.1
(pseudo-)aneurysm (%)	2.9

[†] percentage of the total population CEA: Carotid Endarterectomy, TIA: Trans Ischemic Attack, BRIG: Bifurcation Resection with Interposition of a Polytetrafluoroethylene Graft

remained asymptomatic. **Figure 3** shows the MR-angiography of a patent graft after 7,5 years follow-up. An 18.1% long-term mortality was observed, however none of these deaths were surgery related.

Discussion

Our analysis shows excellent long-term patency of the PTFE interposition grafts. We believe that the low restenosis rate of the BRIG procedure is due to different favourable aspects. The

Table 2 Perioperative results.

	Results
Graft length, mean (mm)	44 [†]
Clamping time, mean (minutes)	32.2
Procedure time, mean (minutes)	110.5
Mortality (%)	1.4
CVE	
TIA (%)	0
Minor stroke: minor [‡] (%)	2.9
Revision (%)	
Graft thrombosis [‡] (%)	1.4
Haemorrhage [‡] (%)	1.4
Infection	0
Nerve damage	0
AMI (%)	1.4
Jaw Claudication (%)	2.9

[†] Calculated on 20 procedures[‡] Percentage of the total population
 CVE: Cerebrovascular events, TIA: Trans Ischemic Attack, AMI: Acute Myocardial Infarction

Table 3 Long-term restenosis.

	percentage
50–69%	4.3
70–99%	0
Occlusion	1.4

BRIG: Bifurcation Resection with Interposition of a Polytetrafluoroethylene Graft

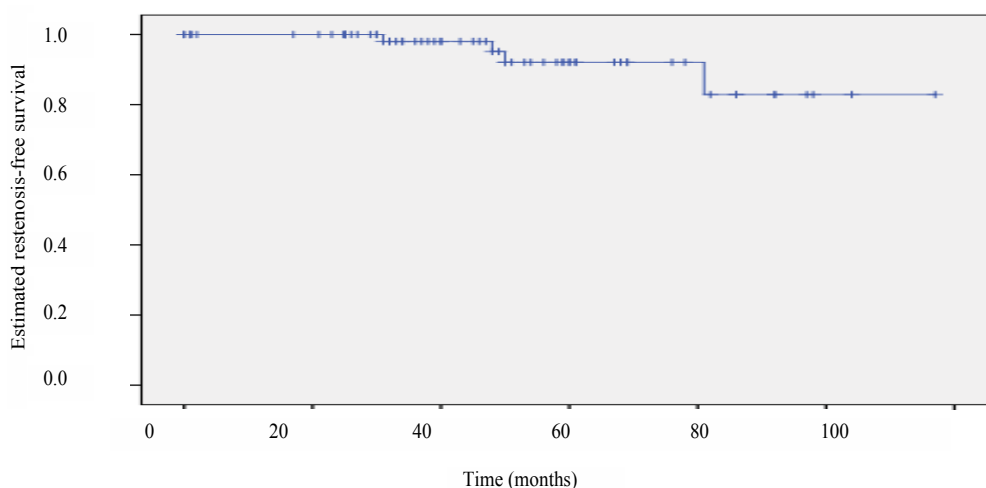


Figure 2 Kaplan-Meier estimate of restenosis-free survival.

BRIG procedure is a simplified technique when compared to CEA. There is no need to perform a meticulous endarterectomy and if significant arteriosclerosis is still observed, the clamps can easily be replaced to allow for a larger resection. There is no need for distal intima fixation. The running suture at the distal anastomosis will secure the distal intima. The PTFE graft itself has a smooth non-thrombogenic surface unlike the exposed uneven adventitia after CEA. Severe coiling or kinking of the carotid artery can easily be corrected by under sizing the inserted PTFE graft. In case of CEA, a shortening and re-implantation of the ICA would be necessary. The low peripheral resistance of the cerebral circulation allows a continuous high velocity monophasic flow. This is in strong contrast to the high peripheral resistance observed in the extremities. Another important feature of the BRIG procedure is sacrificing the ECA so that the interposition of a tube between the CCA and ICA is possible without the need for creating a bifurcation. The absence of a bifurcation reduces turbulent flow and therefore the risk of restenosis. We believe that the combination of all these factors could explain the promising results, i.e., the very low restenosis rate. An important detail is that all the observed restenoses occurred at the proximal anastomosis, whilst in peripheral bypassing, restenosis tends to occur at the distal anastomosis. It remains unclear if there is a difference in patency between the different graft manufacturers.

Carotid bypass and interposition grafting have been performed in the past. The published results of bypass grafting differ greatly with restenosis rates varying from 3.2%-16.4%, postoperative cerebral vascular events (CVE) of 0.5-5% and low perioperative mortality of 0-1.8% [6, 9-14]. However, studies with interposition of a graft were often based on smaller sample size studies. In these studies the results varied, with restenosis rates ranging between 2.2-16%, postoperative CVE of up till 5% and mortality rates up till 4% [15-18]. It is important to emphasize that indications were rarely uncomplicated primary carotid stenosis.

Carotid artery stenting (CAS) is an endovascular treatment for significant carotid artery diseases which is gaining increased

interest. However, several large randomised controlled trials (RCT) have shown a high 30 day stroke rate ranging from 4.1-10.9% [19-25]. Especially in symptomatic patients CEA is still the preferred treatment of choice. Embolization of unstable plaque during catheterisation is an important issue. Embolic protection systems are constantly evolving hoping to overcome symptomatic embolization, but lack sufficient evidence of efficacy and safety. A subgroup analysis of the International carotid stenting study (ICSS) actually showed an increase in ischemic brain lesions on MRI with the application of the embolic protection devices [26]. During our BRIG procedure a careful and controlled dissection will minimize perioperative embolization. 30-day mortality rates of up till 2.8 are comparable to an open surgical approach. Long-term significant restenosis of CAS ranged from 6.0-22.0 %, therefore also favouring the BRIG procedure [19-25]. With a median follow-up of 4 years and a maximum of nearly 10 years, the observed restenosis and occlusion rate of the BRIG procedure is promising (**Table 4**). Even when compared to other larger studies the results of the BRIG procedure are encouraging, but we must keep in mind that a retrospective non-randomised trial does not have the same level of evidence as large RCT (**Table 5**).

A possible concern could be the ligation of the ECA and the occurrence of jaw claudication or facial pain. Research is mainly based upon small case series. The presence of a single ECA should provide sufficient contralateral perfusion via collateral formation overtime. It remains unclear whether it is possible to sacrifice both ECAs in case of a bilateral BRIG procedure [27-29].

A second concern is the use of a shunt during the BRIG procedure. It is possible to use a shunt via the graft whilst creating the distal anastomosis. However, it might be necessary to remove the shunt when creating the proximal anastomosis. This could imply that in cases where a shunt is mandatory, e.g. extremely low stump pressure, a BRIG procedure could be contra-indicated. Even though the level of evidence for carotid shunting during CEA is limited and for an experienced surgeon performing the proximal anastomosis without a shunt is not time consuming [30, 31].

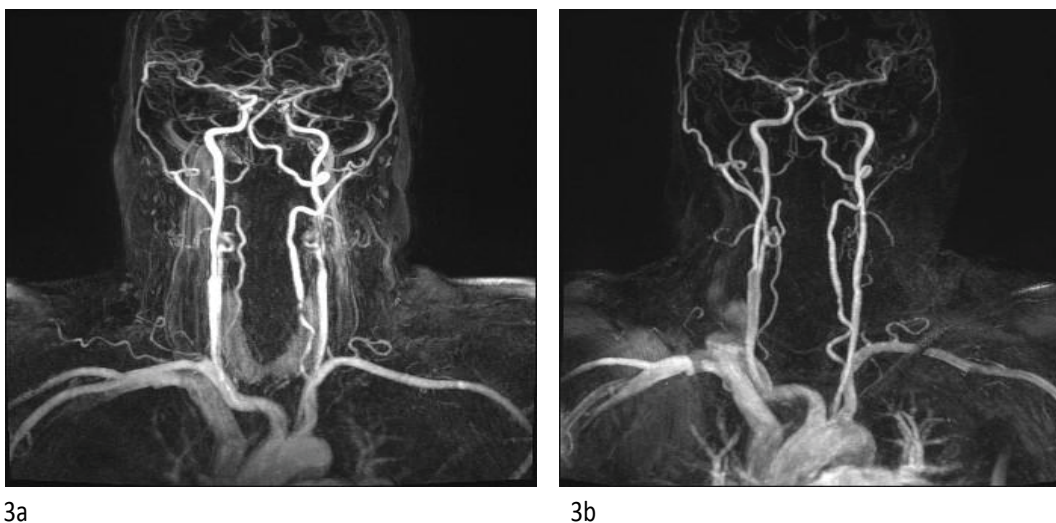


Figure 3 Pre-operative MRI Angiography and MRI after 7,5 years follow-up.
3a. MRI Angio August 2007: high grade stenosis of the left internal carotid artery. The arrow marks the high grade stenosis.
3b. MRI Angio January 2015: No stenosis after 7, 5 year follow-up. The hollow arrow marks the location of the previous stenosis.

Table 4 Results of the BRIG procedure.

Procedure	30 day stroke (%)	30 day mortality (%)	≥ 70% Cumulative Restenosis at 4 years (%)
BRIG	2.9	1.4	1.4

BRIG: Bifurcation Resection with Interposition of a Polytetrafluoroethylene Graft

Table 5 Results of recent large randomised controlled trials comparing CEA to CAS.

Procedure	Randomised controlled trials, publication year	30 day stroke (%)	30 day mortality (%)	≥ 70% Cumulative Restenosis at 2 years (%)
CEA	CREST [19]	2.3	0.3	6.3
	SPACE [20,21]	6.2	0.9	4.6
CAS	CREST [19]	4.1	0.7	6.0
	SPACE [20,21]	7.5	0.7	10.7

CEA=Carotid Endarterectomy, CAS=Carotid Artery Stenting, CREST=Carotid Revascularization Endarterectomy Versus Stenting Trial, SPACE=Stent-Protected Angioplasty Versus Carotid Endarterectomy

Conclusion

The BRIG procedure has a low perioperative stroke rate, low 30 day mortality and low long-term restenosis rate. Given these

excellent results, the BRIG procedure has the potential to become an alternative to CEA in the primary treatment of significant carotid artery disease. However, further research is mandatory.

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