



# Bifurcation Resection and Interposition of a Polytetrafluoroethylene Graft (BRIG) as Primary Treatment for Carotid Artery Disease

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## Abstract

**Objective:** Carotid Endarterectomy (CEA) is the gold standard for the treatment of symptomatic and high-grade asymptomatic carotid artery stenosis. Prosthetic carotid grafting is a safe alternative in technically challenging cases when CEA is hazardous. The objective of the present study was to evaluate an alternative surgical technique, the Bifurcation Resection and Interposition of a Polytetrafluoroethylene Graft (BRIG) procedure, as a primary treatment for carotid artery disease.

**Methods:** A retrospective study was performed on all patients that underwent a BRIG procedure at our institution (Heilig-Hartziekenhuis, Lier, Belgium) between January 2007 and October 2019. We investigated the postoperative morbidity (local complications, perioperative neurological complications, reinterventions and restenosis) and mortality associated with BRIG. The primary outcomes of the study were the perioperative stroke and mortality rates, and the long-term restenosis rates.

**Results:** A total of 170 consecutive BRIG procedures were performed on 155 patients (mean age: 71 years). The median follow-up time was 37 months (Interquartile Range [IQR] 18-61, maximum 148). There were no deep surgical site or graft infections. The perioperative stroke and mortality rates were 1.8% and 0.6%, respectively. There were no major perioperative strokes. Early postoperative (minor) stroke occurred in three patients, of whom two had early graft thrombosis requiring urgent reintervention. One patient died in the early postoperative period due to an acute myocardial infarction. The overall postoperative restenosis rate was 8.2%. The median time to restenosis was 44 months (IQR 18-80). One- and five-year restenosis rates were 1.8% and 5.4%, respectively.

**Conclusion:** The BRIG procedure is a valid alternative to CEA for the primary treatment of carotid artery disease. The simplified surgical technique allows for a shorter operating and clamping time, and seems to result in lower perioperative stroke and long-term restenosis rates when compared to CEA.

**Keywords:** Carotid artery stenosis; Carotid endarterectomy; BRIG; Stroke; Restenosis

## Introduction

Since 1953, Carotid Endarterectomy (CEA) is considered the gold standard for the treatment of symptomatic and high-grade asymptomatic carotid artery stenosis [1-4]. Alternative surgical techniques have been proposed including eversion Carotid Endarterectomy (eCEA), Carotid Artery Stenting (CAS) and Prosthetic Carotid Grafting (PCG), with varying results [5]. Carotid grafting is generally reserved for technically challenging cases when CEA is hazardous, such as extensive atherosclerotic lesions, lesions associated with carotid artery kinking, restenosis after previous CEA, or fibrous restenosis after radiotherapy [5,6].

In this study, we present the results of an alternative technique, the Bifurcation Resection and Interposition of a Polytetrafluoroethylene Graft (BRIG) procedure, as a primary treatment for carotid artery disease. In the past, we have shown in a smaller cohort that BRIG is associated with limited hospital morbidity and mortality, and a significantly lower restenosis rate compared to CEA [7]. The objective of the present study was to evaluate the outcomes of BRIG in a larger cohort.

## Methods

### Study design

A retrospective study was performed on all patients that underwent a BRIG procedure at our

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institution (Heilig-Hartziekenhuis, Lier, Belgium) between January 2007 and October 2019. An informed consent for the procedure was obtained from all patients. A part of these data has been previously published by the same research group [7]. No exclusion criteria were defined. All BRIG procedures were performed by one single surgeon (senior author: PDV). The first procedures were performed in technically challenging cases such as restenosis after CEA and pseudoaneurysms of the Internal Carotid Artery (ICA) after previous CEA. However, with increasing experience, BRIG was performed more routinely and ultimately became the procedure of choice. We investigated the postoperative morbidity (local complications, perioperative neurological complications, reinterventions and restenosis) and mortality associated with BRIG. The primary outcomes of the study were the perioperative stroke and mortality rates, and the long-term restenosis rates. Perioperative events were defined as occurring within 30 days after surgery. Stroke was classified as major if the patient required help from another person (modified Rankin scale  $\geq 3$ ) for more than 30 days after onset. Other strokes were classified as minor. The degree of restenosis was classified as low-grade (50% to 69%), high-grade (70% to 99%) or occlusion (100%). Operating time was defined as the time from intubation until extubation. All patients presented for follow-up one month postoperatively, and then annually for routine physical examination and arterial duplex ultrasound. Follow-up time was defined as the time from operation until last follow-up visit. If a peak systolic velocity greater than 120 cm/s or lumen narrowing was observed, a Computed Tomography Angiography (CTA) was performed to confirm the restenosis. If CT was contra-indicated, a Magnetic Resonance Angiography (MRA) was performed.

### Statistical analysis

Continuous variables are described as mean with Standard Deviation (SD) or as median with Interquartile Range (IQR), as appropriate. Categorical variables are expressed as proportions (percentages). Restenosis is expressed using a Kaplan-Meier survival analysis. Statistical analyses were performed with SPSS software, version 27.0 (SPSS Inc., Chicago, Illinois, USA).

### Surgical technique

The procedure was performed under general anesthesia with the patient installed in the standard position for carotid surgery: Supine with the head extended and rotated to the contralateral side. After systemic heparinization (100 IU/kg), the standard approach to the carotid bifurcation, including wide exposure of the distal ICA, was undertaken (Figure 1A). The carotid bifurcation was carefully denuded, and care was taken not to damage the carotid body or adjacent cranial nerves, especially the vagus and hypoglossal nerve. The ICA was clamped, followed by clamping of the Common Carotid Artery (CCA) and External Carotid Artery (ECA). The superior thyroid artery was clipped, and the ECA ligated with a 4/0 polypropylene suture (Prolene, Ethicon, Amersfoort, The Netherlands). Next, the bifurcation was completely resected, and a Polytetrafluorethylene (PTFE) interposition graft was prepared (Figure 1B). We used a six mm PTFE thin wall vascular graft (Gore-Tex, Newark, United States). First, an angled anastomosis was made between the ICA and PTFE graft using a Gore-Tex CV6 suture (Figure 1C). Afterwards, the proximal anastomosis was created between the graft and CCA (Figure 1C). Both anastomoses were fashioned as end-to-end running sutures. In case of a contralateral occlusion of the CCA, or if the patient had undergone a previous contralateral BRIG procedure, the ECA was reimplanted. After placement of the

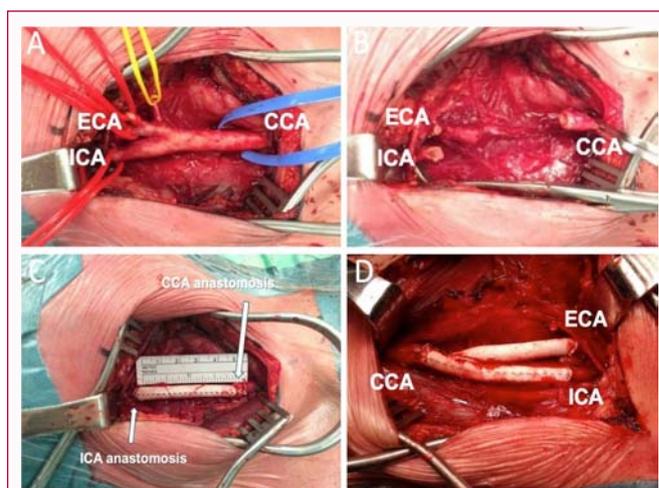
initial graft between the ICA and CCA, a second interposition graft was placed *via* a proximal side-to-end anastomosis between the two grafts and a distal end-to-end anastomosis between the graft and ECA (Figure 1D), or the ECA was directly reimplanted if technically possible. Postoperatively, patients were admitted to the intensive care unit for 24 h of close neurological and hemodynamic monitoring. All patients were given oral antiplatelet therapy (160 mg acetylsalicylic acid) and a statin.

### Results

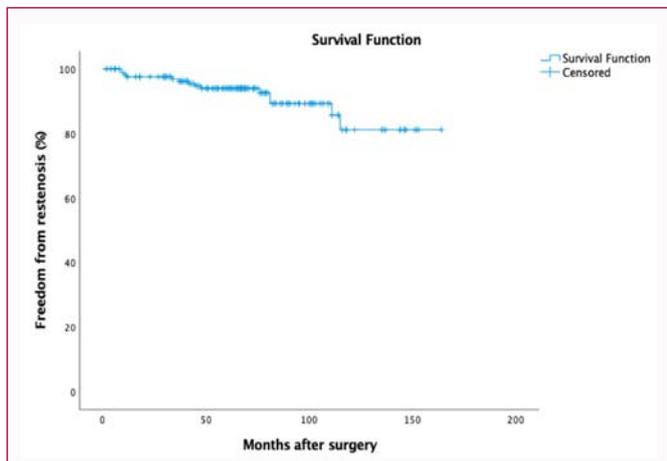
A total of 170 consecutive BRIG procedures were performed on 155 patients. The baseline characteristics of the patients are listed in Table 1. The mean age at the time of surgery was 71 years (range 42-94). Most patients were men (69.7%) and had a cardiovascular risk profile. Ten operations (5.9%) were redo procedures after a previous ipsilateral CEA. The median follow-up time was 37 months (IQR 18-61, maximum 148). Two patients (1.2%) were lost to follow-up. The indication for surgery was a symptomatic stenosis ( $>50\%$ ) in 38.8% ( $n=66$ ), an asymptomatic high-grade ( $>80\%$ ) stenosis in young patients or before major cardiovascular surgery in 58.8% ( $n=100$ ) and a pseudoaneurysm of the ICA in 2.9% ( $n=3$ ) of the BRIG procedures, as shown in Table 2. One patient had an asymptomatic low-grade stenosis with a very inhomogeneous plaque and was operated because of the high embolization risk. The mean operating and clamping times were 111 min (range 45-235) and 37 min (range 20-67), respectively. The mean graft length was 4.6 cm (range 1.5-11). A bifurcated graft was used in 10.9% ( $n=18$ ) of the BRIG procedures.

### Postoperative morbidity

There was one (0.6%) superficial wound infection, which was successfully treated with local wound care and empiric antibiotic therapy. There were no deep surgical site or graft infections. Nerve damage was established in five (3.0%) patients. The most frequently damaged nerve was the recurrent laryngeal nerve manifesting as hoarseness. A mild form of jaw claudication occurred in four (2.4%) patients, but the complaints quickly resolved by chewing slower and lasted only a few weeks. None of the patients experienced facial pain. The overall perioperative stroke rate was 1.8%. There were no major perioperative strokes. Early postoperative (minor) stroke occurred



**Figure 1:** Surgical technique of the BRIG procedure. (A) Exposure and (B) resection of the carotid bifurcation. (C) Interposition of the PTFE graft between the CCA and ICA with ligation of the ECA. (D) BRIG procedure with revascularization of the ECA (bifurcation graft). Permission from this patient was obtained for usage of case imaging.

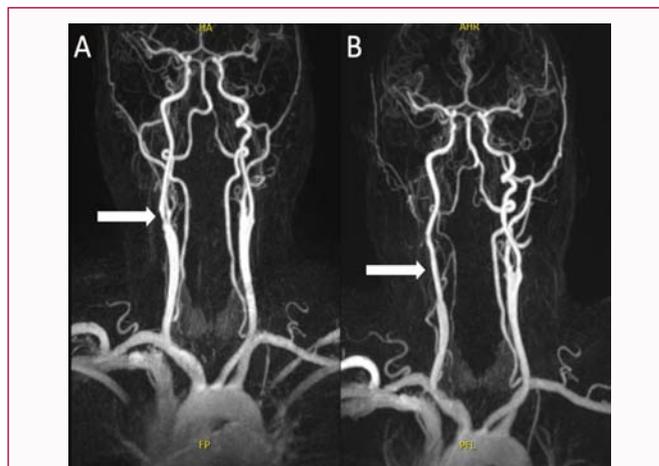


**Figure 2:** Kaplan-Meier survival function for restenosis-free survival after BRIG.

**Table 1:** Patient characteristics.

Variable	BRIG (N=170)
Sex, n/N (%)	
Male	118 (69.4)
Female	52 (30.6)
Age at time of operation (years), median (IQR)	71 (65.77)
Cardiovascular risk factors, n/N (%)	
Diabetes mellitus	47 (27.6)
Dyslipidemia	122 (71.7)
Smoking	103 (60.6)
Arterial hypertension	135 (79.4)
Obesity (BMI>30 kg/m <sup>2</sup> )	18 (10.6)
Personal history	127 (74.7)
Family history	61 (35.8)
Operating side, n/N (%)	
Left	89 (52.4)
Right	81 (47.6)
Redo surgery after CEA, n/N (%)	10 (5.9)

in three patients, of whom two had early graft thrombosis requiring urgent reintervention. One stroke was due to an oversized graft (11 cm) leading to kinking and subsequent graft thrombosis a few hours postoperatively. An emergency thrombectomy with shortening of the graft was performed. The second case was due to early dissection at the distal anastomosis after a hypertensive crisis. The initial graft and dissected part of the ICA were replaced by a new (longer) PTFE graft. In the third case, cerebral hypoperfusion was caused by a long clamping time combined with an aberrant circle of Willis (absent anterior and posterior communicating artery). This was confirmed by perioperative angiography during the reintervention. All three patients had completely recovered a few weeks later and had no residual neurological symptoms. The other reinterventions ( $n=5$ ) were for hemorrhage with a neck hematoma due to a suturing defect at an anastomosis. An overall postoperative restenosis rate of 8.2% ( $n=14$ ) was observed in our series. The median time to restenosis was 44 months (IQR 18-80). The overall one- and five-year restenosis rates were 1.8% ( $n=3$ ) and 5.4% ( $n=9$ ), respectively, excluding the patients with early graft thrombosis (Figure 2). Most restenoses occurred at



**Figure 3:** MRA before and after BRIG. (A) Preoperative MRA showing a high-grade stenosis of the right ICA (arrow). (B) MRA after 6 years of follow-up showing a smooth PTFA graft without evidence of restenosis. Permission from this patient was obtained for usage of case imaging.

**Table 2:** Indications for surgery.

Variable	BRIG (N=170)
Symptomatic stenosis, n/N (%)	
TIA	38 (22.3)
Stroke	28 (16.4)
Total	66 (38.8)
Asymptomatic stenosis, n/N (%)	
Stenosis grade	
50-79%	1 (0.5)
80-99%	100 (58.8)
Pseudoaneurysm	3 (1.8)
Total	104 (61.2)

the proximal anastomosis ( $n=7$ ) and were low-grade ( $n=8$ ). Of the 14 patients with a proven restenosis, six were symptomatic and had experienced either a late TIA ( $n=3$ ) or stroke ( $n=3$ ). One patient had a complete graft occlusion presenting with a minor stroke (Table 3).

**Postoperative mortality**

The overall perioperative mortality rate was 0.6% ( $n=1$ ). One patient died in the early postoperative period due to an acute myocardial infarction. An overall 24.1% ( $n=41$ ) long-term mortality rate was observed, but none of these deaths were surgery-related. The overall cardiovascular-related and non-cardiovascular-related mortality rates were 8.2% ( $n=14$ ) and 11.8% ( $n=19$ ), respectively. In the remaining nine patients (5.2%), the cause of death was unknown (Table 4).

**Discussion**

This retrospective study evaluated the BRIG procedure as an alternative to CEA for the primary treatment of carotid artery disease. Our results indicate that BRIG is associated with excellent outcomes in terms of perioperative morbidity and mortality as well as restenosis rates at long-term. In particular, the perioperative stroke and mortality rates were very low (1.8% and 0.6%, respectively) and there were no major perioperative strokes at all. The observed perioperative strokes were all minor and associated with full recovery. Only one patient died in the early postoperative period from a cause unrelated

**Table 3:** Postoperative morbidity.

Variable	BRIG (N = 170)
Local complications, n/N (%)	
Surgical site infection	1 (0.6)
Superficial	1 (0.6)
Deep	0 (0.0)
Organ/space (graft)	0 (0.0)
Nerve damage	5 (3.0)
Hypoglossal nerve	1 (0.6)
Vagus nerve	0 (0.0)
Facial nerve	1 (0.6)
Pharyngeal nerve	0 (0.0)
Recurrent laryngeal nerve	3 (1.8)
Jaw claudication	4 (2.4)
Hemorrhage	6 (9.4)
Total	19 (11.2)
Perioperative neurological complications, n/N (%)	
TIA	0 (0.0)
Stroke	3 (1.8)
Major	0 (0.0)
Minor	3 (1.8)
Total	3 (1.8)
Reinterventions, n/N (%)	
Cause	
Hemorrhage	5 (3.0)
Perioperative stroke	3 (1.8)
Total	8 (4.7)
Restenosis	44 (18, 80)
Time to (months), median (IQR) Rate, n/N (%)	
Within 1 year	3 (1.8)
Within 5 years	9 (5.4)
Overall	14 (8.2)
<b>Location, n/N (%)</b>	
Proximal anastomosis	7 (4.1)
Distal anastomosis	4 (2.4)
In graft	2 (1.2)
Unknown	1 (0.6)
<b>Grade, n/N (%)</b>	
50-69%	8 (4.7)
70-99%	5 (2.9)
Occlusion	1 (0.6)

to the surgical procedure. In fact, the present study demonstrates that the outcomes of BRIG are superior to those of CEA reported in the literature. The outcomes of CEA have been evaluated in several large randomized trials. In the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS), perioperative stroke and mortality rates were 8.3% and 2.0%, respectively [8]. Restenosis rates at one and five years postoperatively were 7.5% and 10.5%, respectively (for restenosis >70%) [9,10]. The Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) reported the following

**Table 4:** Postoperative mortality.

Variable	BRIG (N=170)
Death, n/N (%)	
Perioperative	1 (0.6)
Late (>30 days)	41 (24.1)
Total	42 (24.7)
Cause of death, n/N (%)	
Surgery-related	0 (0.0)
Cardiovascular disease	14 (8.2)
Non-cardiovascular disease	19 (11.8)
Unknown	9 (5.3)

outcomes: a perioperative stroke rate of 2.3%, a perioperative mortality rate of 0.3%, and a two-year restenosis rate of 6.3% (for restenosis >70%) [11,12]. In 1998, Frericks et al. [13] published a systematic review and meta-analysis of 29 studies to assess the risk of restenosis after CEA. They reported restenosis rates of 10% in the first year, 3% in the second year, 2% in the third year, and a long-term risk of 1% per year. These studies indicate that both perioperative stroke and long-term restenosis after CEA are not uncommon. Prosthetic carotid grafting has been proposed as a safe and feasible alternative when CEA is hazardous [5]. Techniques aiming to bypass or to replace (interposition graft) the lesion have been described. There are several types of carotid bypass grafts, including carotid-carotid bypass, CCA-ICA bypass and bypass from the subclavian artery to the ICA. The published results differ greatly with restenosis rates varying from 3.2% to 16.4%, postoperative cerebrovascular events of 0.5% to 5% and low perioperative mortality of 0% to 1.8% [6,14-17]. The results of interposition grafting are based on studies with smaller sample sizes. The results show a large variation with overall restenosis rates of 2.2% to 16%, postoperative cerebrovascular events of 0% to 5% and mortality rates of 0% to 4% [18-20]. The most important finding of this study is the low perioperative stroke rate and absence of any major perioperative stroke after BRIG. We believe that this is due to several technical advantages. The PTFE graft has a smooth non-thrombogenic surface unlike the exposed uneven adventitia after CEA, which limits the risk of embolization into the cerebral circulation. Moreover, the clamping time of the ICA during BRIG is relatively short. In an experimental study with baboons, Bell showed that if cerebral blood flow to an ischemic brain can be restored within 30 min, full reversal of the neurological deficit can be expected [21]. The mean clamping time in our series was 37 min, also taking into account the substantial portion (10.9%) of bifurcated BRIG procedures that have a slightly longer clamping time in order to create the anastomosis between the two grafts. Our previously reported results also showed that the clamping time during BRIG is significantly shorter than during CEA [7]. BRIG is a simplified technique when compared to CEA. The meticulous endarterectomy is avoided as the entire lesion is resected regardless of its length or complexity. There is no need for distal intima fixation as the running suture at the distal anastomosis will secure the distal intima. Severe coiling or kinking of the carotid artery can easily be corrected by undersizing the PTFE graft. In case of CEA, a time-consuming shortening and re-implantation of the ICA would be necessary. In the present study, the degree of restenosis was categorized as low-grade (50% to 69%), high-grade (70% to 99%) or occlusion (100%). We based our definition of restenosis on the classic definitions as described by the CAVATAS and EVA-3S studies [10,22]. When

comparing the restenosis rates after BRIG with those of published CEA series, our rates are significantly lower. We hypothesize that the complete resection of the affected vessels, low cerebral vascular resistance with monophasic flow, absence of a bifurcation due to sacrificing the ECA, and wide-angled end-to-end anastomoses significantly reduce turbulence and neointima formation. This is in strong contrast with the high vascular resistance and triphasic flow observed with PTFE graft placement in the lower limbs [23,24]. Restenosis mainly occurred at the level of the proximal anastomosis, which can be explained by a diameter mismatch between the CCA and PTFE graft still causing some degree of turbulence. A possible concern could be the ligation of the ECA, which is inherent to the BRIG procedure, because of the potential impact on facial blood supply. However, only four of our patients developed a mild form of jaw claudication and there were no other symptoms of facial ischemia. A recent proof-of-concept study demonstrated that ligation of a single ECA can be safely performed [25]. This is mainly because sufficient collateral blood flow is provided from the contralateral ECA. For patients who already underwent a BRIG procedure on the contralateral side, a modification of the technique was created namely the use of a bifurcation graft allowing revascularization of the remaining ECA. A second concern is the use of a shunt during the BRIG procedure. It is technically possible to create one of the two anastomoses with the shunt placed through the graft, but the shunt has to be removed when creating the second anastomosis. This implies that in cases where a shunt is recommended (e.g., extremely low stump pressure), BRIG could be relatively contra-indicated [26]. However, we never placed a shunt because the evidence for carotid shunting during CEA is limited and we believe the benefit is debatable, especially for the BRIG procedure where the clamping time is shorter than during CEA [27,28]. We did not routinely measure stump pressures but even if the stump pressure was <35 mmHg, no postoperative neurological deficit was observed in these patients. A third concern might be the social cost associated with the BRIG procedure. In a preliminary study on the cost-effectiveness of BRIG versus CEA in our center, BRIG was shown to have a higher total hospital cost (approximately 480 Euros) compared to CEA [29]. This was mainly due to the difference in cost between the Dacron patch (CEA) and PTFE graft (BRIG). However, if one takes into account the considerable lifetime cost after stroke (approximately 50,000 Euros per case in Europe), the BRIG technique could actually provide an overall cost reduction for social security concerning stroke prevention [29]. In case of 10,000 CEA procedures, 200 to 300 patients will have a major stroke resulting in an extra social cost of 10,000,000 to 15,000,000 Euros. In case of BRIG, the extra cost will only be 4,500,000 Euros. The lower perioperative stroke rate in addition to the financial benefit at long-term advocate that BRIG could replace CEA as standard treatment for carotid artery disease, regardless of the higher total hospital cost. There are obvious limitations to our study. Although our series is, to our knowledge, the largest one on carotid interposition grafting up to now, the study population remains relatively small when compared to most CEA series. Therefore, the results should be interpreted with caution. Additionally, the study's retrospective nature comes with inherent drawbacks. Furthermore, there was no direct comparison between BRIG and CEA, so more research is needed in order to confirm whether BRIG is actually superior to CEA.

## Conclusion

The BRIG procedure is a valid alternative to CEA for the primary

treatment of carotid artery disease. The simplified surgical technique allows for a shorter operating and clamping time, and seems to result in lower perioperative stroke and long-term restenosis rates when compared to CEA. To perform bilateral procedures, a bifurcation graft should be created on one side to revascularize the ECA and prevent facial ischemia. More research is needed to determine whether BRIG could become the standard treatment for carotid artery disease in the future.

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