# CAS Using the Wallstent/FilterWire EX/EZ

A single-center experience and report on long-term outcomes of CAS treatment.

BY MARC BOSIERS, MD; PATRICK PEETERS, MD; JURGEN VERBIST, MD; AND KOEN DELOOSE, MD

Since the 1950s, carotid endarterectomy (CEA) has been the gold standard for treating carotid artery stenosis. Various trials, such as the European Carotid Surgery Trial (ECST), Asymptomatic Carotid Atherosclerosis Study (ACAS), and the North American Symptomatic Carotid Endarterectomy Trial (NASCET), have shown CEA to be superior to medical treatment in the prevention of cerebral ischemic events in symptomatic lesions >50% and asymptomatic lesions >80%.[1-3]

With the recent rise of endovascular techniques in the coronary and peripheral fields, carotid artery stenting (CAS) has been suggested as a valid alternative to CEA. Since the late 1990s, there has been a shift toward endovascular carotid procedures because they are minimally invasive. Although long-term results became available only recently, CAS has been a common treatment modality for some time. In this article, we report our 2-year follow-up data for carotid stenting outcomes, focusing on both the late-stroke and patency rates we had in our patient groups.

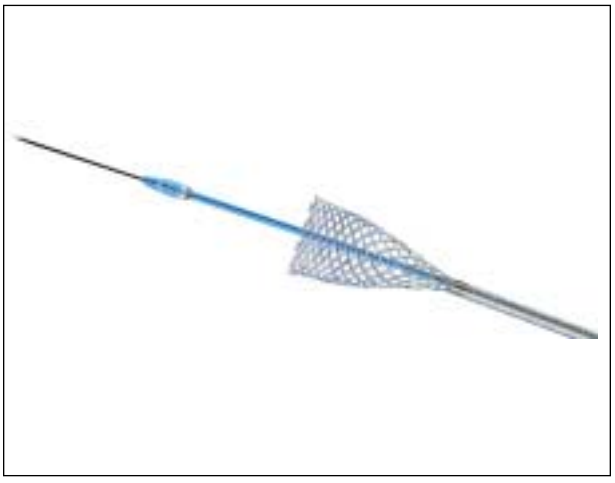

**Figure 1. The Carotid Wallstent (Boston Scientific Corporation, Natick, MA).**

## MATERIALS AND METHODS

Between October 2001 and March 2004, our center performed protected CAS on 300 patients (168 male) with the Carotid Wallstent Monorail, under protection with the FilterWire EX/EZ Embolic Protection Device (Boston Scientific Corporation) (Figures 1 and 2). All patients were screened by an independent neurologist. Institution inclusion criteria for percutaneous treatment of carotid occlusive disease were patients duplexed with a symptomatic stenosis of at least 60% and patients who presented with an asymptomatic stenosis of at least 80%.

In total, 69 (23%) patients had an asymptomatic carotid stenosis, and 231 (77%) presented with neurological symptoms. Of those, 33 had a major stroke, 16 had a minor stroke, and 182 had one or more transient ischemic attacks (TIAs). One hundred eighty-one (60.34%) patients had hypertension, 221 (73.67%) presented with hypercholesterolemia, and 93 (31%) were smokers at the time of screening.

The mean stenosis rate was 81.5% (70%-99%). Of all lesions, 118 (39.33%) were calcified and 23 (7.67%) were ulcerated. For symptomatic stenoses, these numbers were 87 (37.66%) and 32 (13.85%), respectively.

Before discharge, after 1, 6, and 12 months, and yearly from then on, all patients were investigated by an independent neurologist and underwent duplex investigation.

## RESULTS

### Technical Success

Of the 300 patients who were intended to be treated with the combination of the Carotid Wallstent and the FilterWire EX/EZ protection system, one patient had a major stroke during the long introducer sheath introduction before filter device deployment. This patient fully recovered and was surgically treated a few days later. In the remaining 299 cases, placement of the FilterWire protection system was successful in 293

**Figure 2. The FilterWire EZ filter shown both open and closed.**

(97.99%) patients. Technical failures during filter delivery occurred five times due to internal carotid artery angulation and one time due to stenosis underestimation on MRI. All of these failures happened with the FilterWire EX filter. The new FilterWire EZ design has improved on this point, and no more technical failures took place. These six patients were then stented without protection.

Filter retrieval was successful in all 293 (100%) cases. On 168 (57.43%) occasions, there was debris that was visible to the naked eye present in the filter basket of the FilterWire protection system.

### Procedural Success

Of the 299 patients who received a Carotid Wallstent, duplex investigation after 1 month showed eight (2.67%) patients with a residual stenosis or restenosis of at least 50%. None of these patients were symptomatic.

The 30-day stroke-and-death rate was 2.67%. During the 1-month follow-up period, one patient died and seven patients experienced neurological problems. In total, one TIA, four minor strokes, and two major strokes occurred, all of which resolved completely or partially (Figure 3A and 3B).

### One-Year Results

The 1-year follow-up date was reached for 202 patients. The following results were calculated for these patients only (patients were not taken into account if their scheduled 1-year follow-up date was not yet reached).

Of the 202 patients, five (2.48%) died and 19 (9.41%) were lost to follow-up, resulting in 178 patients actually seen at control. Of these, 13 (7.30%) had a restenosis of >50%; three patients presented with a symptomatic restenosis and were redilated under protection.

Of the 178 patients who came back after 1 year, the numbers of TIAs and minor and major strokes between their 30-day visit and their 1-year consultation were 3, 0, and 1, respectively. This makes the late minor, major, and combined stroke rates up to 1 year 1.69%, 0.56%, and 2.25%, respectively. The corresponding cumulative rates (including the first 30-day events and deaths) for these 202 patients were 3.93%, 1.12%, and 5.05% (Table 1).

### Two-Year Results

The 2-year follow-up date was reached for 105 patients. Again, calculations were made for these 105 patients only. Four (3.81%) patients in this group died, and 10 (9.52%) did not show up for their control visit or could not be traced back. Of the remaining 91 patients, nine (9.89%) had a restenosis of more than 50%. Two patients were symptomatic and corresponded with two of the three patients who were already treated before their 1-year control.

Of the 105 patients who were followed up at 2 years, two had TIAs, but no minor or major strokes occurred in this group, resulting in late minor, major, and combined stroke rates up to 2 years at 2.20%, 0%, and 2.20%, respectively. When including the first 30-day events and deaths, these cumulative minor, major, and combined rates are 3.30%, 0%, and 3.30%, respectively (Figure 4).

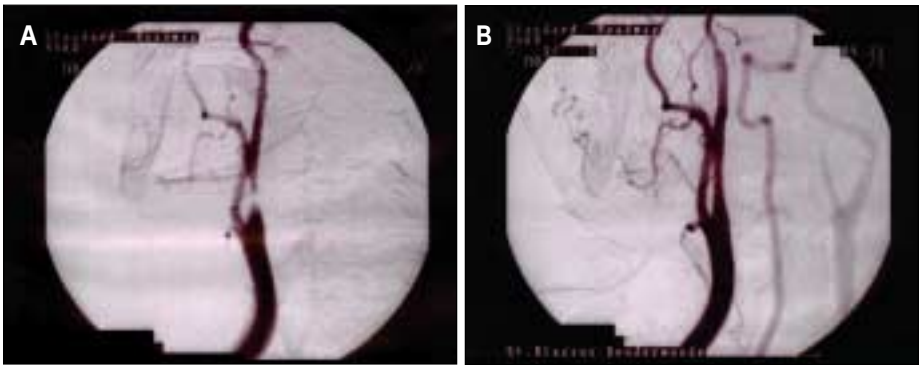


**Figure 3. Preoperative stenosis of the internal carotid artery (A). Postoperative result after protected stenting (B).**

## DISCUSSION

As already mentioned, CEA has long been the gold standard for carotid treatment. It has a good procedural success as well as favorable long-term results. According to the ECST results, the 3-year risk for any stroke or death rate was 12.3%. The ACAS and NASCET studies reported a 2-year cumulative risk of ipsilateral stroke of 11% and 9%, respectively.[3,4]

**TABLE 1. CUMULATIVE STROKE/DEATH (N=300)**

| | 30 Days | 1 Year | 2 Years |
|---|---|---|---|
| Procedure-Related Death | 1 | 1 | 1 |
| TIA | 1 | 4 | 6 |
| Minor Stroke | 4 | 4 | 4 |
| Major Stroke | 2 | 3 | 3 |

The Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS), a randomized trial comparing CEA to CAS, showed comparable stroke/death rates for surgical and endovascular carotid treatment of 5.9% and 6.4%, respectively. Also, the results from the Stenting and Angioplasty with Protection in Patients at High-Risk for Endarterectomy (SAPPHIRE), a randomized trial comparing CEA and CAS in high-risk patients, reported a combined stroke/death rate at 30 days of 4.5% for the CAS group and 6.6% for the surgery group.[5] However, it was not until recently that the first long-term CAS results were published. The CAVATAS trial reported a very similar 3-year risk of death or disabling stroke of 14.2% for CEA and 14.3% for CAS.[3,6] The SAPPHIRE trial found 1-year results in line with their 30-day outcomes, stating a death/stroke/MI rate in symptomatic patients of 19.9% for CEA compared to 11.9% for CAS.[5]

In terms of restenosis rates, the 1-year ultrasound follow-up in the CAVATAS trial revealed that severe (70%-99%) restenosis appeared more frequently after CAS (14%) than after CEA (4%).[7] Cernetti et al[8] found a critical restenosis rate (≥70%) in 1.8% of patients after 2 years. Yet, Lal et al[9] recently published that their cumulative incidence of clinically significant in-stent recurrent stenosis (80% or more) over 5 years was only 6.4%. Wholey et al[10] stated carotid patency rates for 1, 2, and 3 years of 94.4%, 84.4%, and 84.4%, respectively, for all of the self-expanding stents they used. Setacci et al[11] reported an in-stent restenosis rate of 5.2% in 193 carotid arteries at a median 5.2 months after the procedure. None of these restenoses were symptomatic.

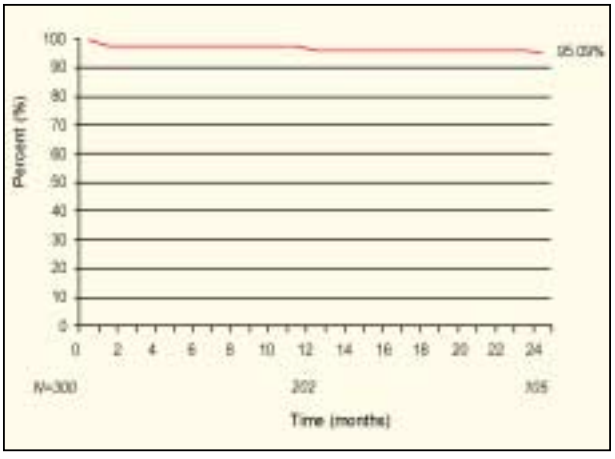


**Figure 4. Kaplan-Meier curve for freedom for all fatal and nonfatal events**

Christiaans et al[12] reported occurrence of symptomatic restenosis after CAS in 7% of their series of 216 patients, a figure that is higher than those found in most other series (2%-8%). In our centers, restenoses of more than 50% were found in 9.89% of patients after 2 years of follow-up.

Although there is a difference in restenosis rates between CEA and CAS, both treatment modalities give comparable long-term stroke rates. The NASCET 2-year risk of ipsilateral stroke was 9% for patients treated with CEA. ACAS results stated an 11% risk of any stroke and death after 3 years. In a recent publication, Roubin et al[13] reported a 3-year freedom from all fatal and ipsilateral nonfatal strokes after CAS of 92±1% and 99±1%, depending on whether the 30-day periprocedural period was taken into account. Our results for CAS show comparable results after 2 years. We report a 2-year ipsilateral stroke rate of 3.30% when also taking into account the first 30-day events. Excluding the events that happened during the first 30 days, our stroke rate is 2.20%.

## CONCLUSION

These results confirm the thesis that the safety and efficacy of CAS with the Carotid Wallstent and FilterWire protection are comparable to that of CEA when looking at immediate and long-term critical restenosis rates and absence of neurological sequelae. ■

*Marc Bosiers, MD, is from the Department of Vascular Surgery, AZ St-Blasius, Dendermonde, Belgium. He has disclosed that he has no financial interest in any product or manufacturer mentioned herein. Dr. Bosiers may be*

*reached at +32 52252735; marc.bosiers@pandora.be.*

*Patrick Peeters, MD, is from the Department of Cardiovascular and Thoracic Surgery, Imelda Hospital, Bonheiden, Belgium. He has disclosed that he has no financial interest in any product or manufacturer mentioned herein. Dr. Peeters may be reached at +32 15506197; patrick.peeters@imelda.be.*

*Jurgen Verbist, MD, is from the Department of Cardiovascular and Thoracic Surgery, Imelda Hospital, Bonheiden, Belgium. He has disclosed that he has no financial interest in any product or manufacturer mentioned herein. Dr. Verbist may be reached at +32 15506197; jurgen.verbist@imelda.be.*

*Koen Deloose, MD, is from the Department of Vascular Surgery, AZ St-Blasius, Dendermonde, Belgium. He has disclosed that he has no financial interest in any product or manufacturer mentioned herein. Dr. Deloose may be reached at +32 52252517; koen.deloose@pandora.be.*

1. European Carotid Surgery Trialists' Collaborative Group. MRC European Carotid Surgery Trial: interim results for symptomatic patients with severe (70-99%) or with mild (0-29%) carotid stenosis. *Lancet.* 1991;337:1235-1243.
2. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Endarterectomy for asymptomatic carotid artery stenosis. *JAMA.* 1995;273:1421-1428.
3. North American Symptomatic Carotid Endarterectomy Trial Collaborators. Beneficial effect of carotid endarterectomy in symptomatic patients with high-grade carotid stenosis. *N Engl J Med.* 1991;325:445-453.
4. Randomised trial of endarterectomy for recently symptomatic carotid stenosis: final results of the MRC European Carotid Surgery Trial (ECST). *Lancet.* 1998,351:1379-1387.
5. Yadav JS. SAPPHIRE : a prospective, randomized trial of carotid stenting vs endarterectomy in high-risk patients. Presented at Transcatheter Cardiovascular Therapeutics, 15th Annual Symposium, Washington, DC, September, 15-19, 2003.
6. Brown MM. Endovascular versus surgical treatment in patients with carotid artery stenosis in the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS) : a randomized trial. *Lancet.* 2001;357:1729-1737.
7. Cavatas Investigators. Endovascular versus surgical treatment in patients with carotid stenosis in the Carotid and Vertebral Transluminal Angioplasty Study (CAVATAS): a randomized trial. *Lancet.* 2001;351:1729-1737.
8. Cernetti C, Reimers B, Picciolo A, et al. Carotid artery stenting with cerebral protection in 100 consecutive patients: immediate and two-year follow-up results. *Ital Heart J.* 2003;4:695-700.
9. Lal BK, Hobson RW 2nd, Goldstein J, et al. In-stent recurrent stenosis after carotid artery stenting: life table analysis and clinical relevance. *J Vasc Surg.* 2003;38:1162-1168.
10. Wholey MH, et al. Clinical results: in search of the perfect carotid stent: long-term follow-up comparing balloon-mounted and self-expanding stents. In: Henry M, ed.. Angioplasty and Stenting the Carotid and Supra-Aortic Trunks. Gray Publishing, 2004;467-475.
11. Setacci C, Pula G, Baldi I, et al. Determinants of in-stent restenosis after carotid angioplasty: a case-control study. *J Endovasc Ther.* 2003;10:1031-1038.
12. Christiaans MH, Ernst JMPG, Suttorp MJ, et al. Restenosis after carotid angioplasty and stenting: a follow-up study with duplex ultrasonography. *Eur J Vasc Endovasc Surg.* 2003;26:141-144.
13. Roubin GS, New G, Iyer SS, et al. Clinical results: immediate and late outcomes of carotid angioplasty and stenting in patients with symptomatic and asymptomatic carotid artery stenosis: a five-year prospective analysis. In: Henry M, ed. Angioplasty and Stenting the Carotid and Supra-Aortic Trunks. Gray Publishing, 204;459-466.