

Case Closed

Closed cell stent technology for carotid artery disease.

Innovations in device technologies have helped to raise the bar for clinical efficacy in carotid artery stenting (CAS). One of the primary device considerations in CAS is stent design, a differentiator of which is open versus closed cell stent structure. A closed cell design is intended to provide increased scaffolding for optimal lesion coverage while also providing a smooth inner lumen. In the clinical setting, a retrospective analysis of 30-day outcomes at four sites revealed a statistically significant difference in all events (death, stroke, and myocardial infarction) for the symptomatic population between open cell stent design (27/383; 7.0%) and closed cell stent design (21/934; 2.2%) ($P < 0.0001$). Also, there was a statistically significant difference in postprocedural events at 30 days for the symptomatic population between open cell stent design (24/383; 6.3%) and closed cell stent design (12/934; 1.3%) ($P < 0.0001$).¹

One of the closed cell carotid solutions available worldwide is the Carotid WALLSTENT® Endoprosthesis

(Boston Scientific Corporation, Natick, MA). The Carotid WALLSTENT has been engineered to combine a unique stent design having the smallest free cell area of 1.1 mm² with a highly flexible, easy-to-use delivery system. The stent is designed to facilitate accurate stent placement, offering high radiopacity and the ability to be reconstrained (Figure 1).

This year, a new closed cell technology, the Adapt™ Carotid Stent System (Boston Scientific Corporation), received CE Mark approval and was launched in respective countries (Figure 2). It incorporates a self-expanding, rolled nitinol sheet with Dynamic Tapering Technology. The ASTI (Adapt Carotid Stent and Monorail Delivery System) clinical postmarket registry is currently enrolling; ASTI is designed to evaluate the Adapt stent in combination with the FilterWire EZ™ Embolic Protection System (Boston Scientific Corporation) for the treatment of carotid artery disease. ■

1. Bosiers et al. Eur J Vasc Endovasc Surg. 2007;33:135-141.



Figure 1. The Carotid WALLSTENT.

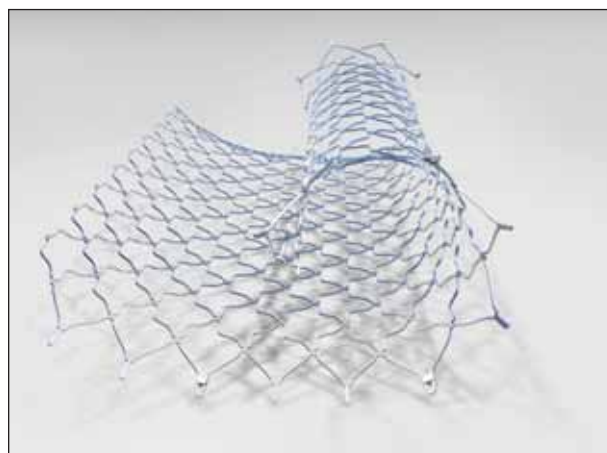


Figure 2. The Adapt™ Carotid Stent System.

The Tailored Approach to CAS

Comprehensive patient evaluation and case-specific applications of contemporary technologies.

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Endovascular carotid interventions have been developed to provide a less invasive and less traumatic revascularization strategy for patients with carotid artery stenosis, especially those who are considered high-risk for open surgery. Over the past 10 years, ongoing advancement in endovascular technologies and techniques has resulted in the evolution of carotid artery stenting (CAS) into a refined procedure with great potential for carotid revascularization.

With the continued development of devices and increase in clinical experience, revascularization outcome targets are rapidly moving, requiring constant re-evaluation of the results. Currently, controversy exists as to whether CAS should be accepted as an alternative therapy to CEA. Unfortunately, randomized controlled trials have not yet provided a clear answer. Nevertheless, it is necessary to recognize that important technical advances have been made in the field, and we must continue to evaluate this progress as a factor in our treatment decisions. The following is a description of our tailored approach to patient selection and the performance of CAS.

THE TAILORED APPROACH TO CAS

To obtain favorable results in CAS, we believe a multifactorial, patient-specific strategy is required. Our practice group advocates a tailored approach, where endovascular technologies and techniques are individually selected for specific patients based on each device's abilities to address unique lesions and vascular anatomy characteristics. The choice of a specific stent, embolic protection device

(EPD), guiding catheter, and sheath is highly dependent on an in-depth understanding of clinical variables as demonstrated by neuro assessment, carotid plaque characteristics, and vascular anatomy. These clinical variables are evaluated to predict the embolic risk of revascularization procedures and must be matched to the technical features corresponding to the array of available endovascular devices. Having significant experience with a wide range of devices allows the operator the flexibility to choose the most appropriate tools and techniques to optimize CAS in the patient.

Our current approach is primarily based on our experiences in the Cotignola registry.¹ This study sought to assess the success, safety, and long-term durability of CAS in stroke prevention for "all comers." Enrolled patients were managed with mandatory neuroprotection and a tailored approach to interventional device selection. The Cotignola registry is a prospective study analyzing 1,523 tailored CAS procedures in a population with a very high burden of polyvasculopathy. The data collected demonstrate endovascular treatment possibilities with minimal exclusion criteria and a near universal ability to "proceed to endovascular intervention" after conventional diagnostic angiography confirms duplex ultrasound findings; more than 99% of patients who required revascularization proceeded to the endovascular approach. The rate of CAS success in this registry was 99.6%, and the 30-day all-stroke/death rate was 1.5%. These data suggest that very good results can be achieved with the tailored approach to CAS.

CAROTID PLAQUE AND VASCULAR ANATOMY EVALUATION

Precise evaluation of the patient's carotid plaque profile is the essential first step in the tailored approach. The evaluation should describe (1) the degree of stenosis and the

precise vessel dimensions, and (2) the length and bulk of disease present, as well as the morphologic features of the lesion. These factors predict potential procedural complexities such as the degree of calcification and the possibility of embolization (ie, vulnerable plaque). Long, irregu-

VASCULAR PROFILE ASSESSMENT

The assessment of a patient's vascular profile includes defining the following:

- (1) Configuration of the aortic arch (A through D).
- (2) Arch embologenic risk in terms of burden of irregular, ulcerated, and calcified atheroma (E, F).
- (3) Angulations, tortuosity, coiling, and kinking of supra-aortic trunks (G, H).
- (4) Level of carotid bifurcation and its anatomy with respect to angle of takeoff of the internal carotid artery, tortuosity at the lesion site, and vessel dimensions (I through K).
- (5) Intracranial segment of the internal carotid artery and ipsilateral/contralateral cerebral circulation (L, M) to determine collateral flow including the circle of Willis and identifying abnormal flow patterns.

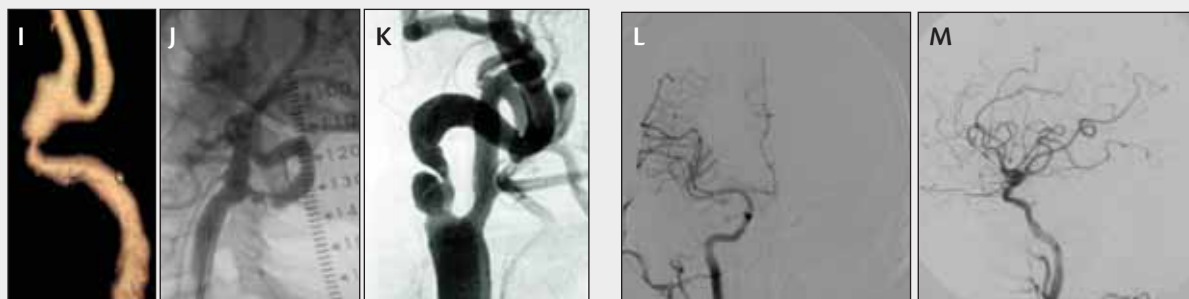


Configuration of the aortic arch. Type I (A), II (B), III (C), and bovine arch (D).



Aortic arch ulcerated (E) and calcified (F) atheroma.

LCCA tortuosity (G) and supra-aortic trunks kinking (H).

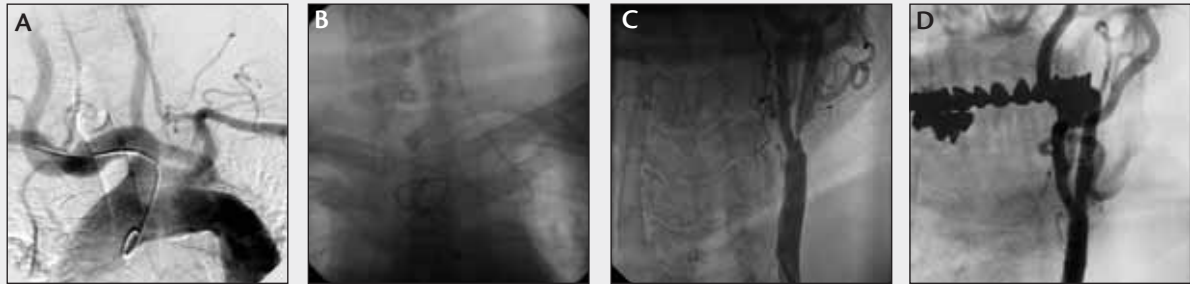


RICA tortuosity at lesion site (I), LICA angled take-off (J), and ulcerated plaque and kinking (K).

Right hemisphere intracranial circulation: AP view (L) and LL view (M).

CASE 1: CHALLENGING ANATOMY/ACCESS

A 77-year-old asymptomatic man presented with bilateral stenosis of the left external carotid artery with a type III aortic arch (A). A radial approach was used to access the lesion through a tortuous bovine arch, with the stent delivery system taking an aggressive 150° angle (B). The lesion was at the bifurcation with a common carotid artery diameter of 8 mm and an internal carotid artery diameter of 6 mm (C). A filter was placed distal to the lesion, and a 40-mm closed cell stent was selected and successfully implanted at the bifurcation (D).



lar, or ulcerated lesions and clinically unstable plaques define a high-risk disease subset. Plaques characterized by a large lipid pool covered by a thin fibrous cap are more prone to perioperative embolization as compared to fibrous plaques.² These vulnerable plaques, sometimes called soft lesions, are less echogenic on B-mode ultrasound and can be quantified by the Gray-Scale Median method (see *Vascular Profile Assessment* sidebar). In the ICAROS study,³ the risk of CAS-related stroke was significantly higher in lesions with Gray-Scale Median < 25.

PUTTING THE TAILORED CAS APPROACH INTO PRACTICE

Embolic Protection

Although there are no large, randomized, controlled trials assessing the efficacy of neuroprotection, some retrospective studies have suggested that the routine use of EPDs results in favorable outcomes.⁴⁻⁸ The results from our study firmly add to the evidence that neuroprotection should be the standard of care.¹ In the Cotignola practice, neuroprotection is mandatory, and the inability to place a suitable EPD in a patient is considered a contraindication to CAS. We believe the advantage of such a strict protocol for procedural embolic containment is that it standardizes the procedure, which contributes to its effectiveness and predictability. Experience is maintained at a high level, an essential element in the safe application of these devices and techniques.

The choice between placing a distal filter or employing a proximal occlusion system is highly dependent on the patient's symptomatic status, vascular anatomy, and plaque characteristics. Large studies comparing proximal and distal protection are lacking, so device selection should be based on the tailored approach as well as the operator's experience. In challenging anatomies, with angulated internal carotid–common carotid artery take-

off and/or lack of a suitable internal carotid landing-zone, proximal protection should be strongly considered.

This practice requires that experience be gained in the use of multiple tools that should be readily available on the shelf, to optimize the individualized treatment strategy. Distal filters, allowing antegrade blood flow during procedure, are mostly indicated in the presence of contralateral carotid occlusion or isolated hemisphere. With respect to neurological symptoms, we primarily use proximal protection in symptomatic patients.

Stent Choice

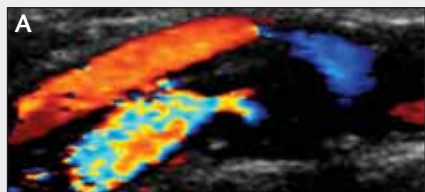
The structural and functional characteristics of the various self-expanding carotid stents are highly dependent on the specific elements of their designs. The type of stent implanted may play a vital part in preventing neurological events due to plaque prolapse. Whereas in open surgical techniques the atheroma and thrombus burden are excised, the CAS procedure compacts this material to the artery wall, retaining it with the stent's scaffolding and wall-coverage properties. The stent's cell geometry may exert an intrinsic antiembolic property, influencing the risk of plaque prolapse and distal embolization during the post-procedural and recuperative periods, until re-endothelialization is complete.

Recognizing the individual technical characteristics of various carotid stents, it is clear that the interaction between a particular stent and the diseased vessel is unique, and no single stent is applicable for all situations. Different stent designs demonstrate functional equivalence when used in uncomplicated scenarios, such as simple supra-aortic anatomies, straight carotid bifurcations, and stable fibrous plaques.

However, when faced with more challenging situations, braided-mesh frames, nitinol closed cell design, and hybrid stents are our first choice when the greatest need is to

CASE 2: HIGH EMBOLOGENIC CAROTID LESION

A 72-year-old woman presented with asymptomatic severe soft plaque stenosis of the right internal carotid artery. Her notable risk factors included insulin-dependent diabetes mellitus and dyslipidemia; she was asymptomatic but had rapid progression of her atherosclerotic carotid lesion from 70% to 85% over a 6-months. A carotid duplex scan (A through C) showed a severe right internal carotid artery stenosis with soft component (peak systolic velocity > 4.0 m/sec). No stenosis of the right common carotid artery was observed. In order to reduce the risk of procedural cerebral embolization, the CAS procedure was performed via femoral approach with a proximal occlusion device. A 40-mm nitinol stent was implanted, and sufficient plaque coverage was achieved. Then, a 5- X 20-mm noncompliant balloon was inflated at low pressure (3 bars) to obtain optimal wall apposition. A good final result was achieved without plaque prolapse or distal embolization (D).



achieve reliable plaque coverage and long-acting plaque prolapse prevention due to their constant radial force properties (eg, soft and long dishomogeneous lesions prone to distal embolization). This condition is encountered primarily in symptomatic patients in whom unstable risky plaques are the standard pathologic substrate.

When the primary technical challenge of a particular case is represented by the carotid bifurcation and plaque complexity (eg, severely angled lesions, plaque ulceration), or the main goal is to maintain the original anatomy/course of a very tortuous vessel, the invessel flexibility and the wall/plaque conformability of nitinol open cell stents as well as hybrid stents are unmatched. Nitinol closed cell and hybrid stents represent a strong technical solution for focal, concentric lesions, especially if they are resistant or calcified; in this clinical subset, the functional key point is the outward radial force exerted by the stent over time.

FURTHER CONSIDERATIONS

After many years spent in stroke prevention, we strongly believe that endovascular carotid intervention can be considered to be a safe and durable therapy. Data from high volume centers demonstrate that CAS is highly feasible, with clinical outcomes comparable with those from surgical series. The future role of CAS will be defined by strategies aimed at reducing complications. Does it appear feasible that we can reduce major complication rates to a new threshold of less than 1% at 30-day follow-up?

We believe that we can successfully address this challenge only if we extensively apply the individual, “tailored

approach” treatment strategy. Stent scaffolding properties may play a critical role in reducing postprocedural embolic events; the design and geometry of the stent frame may contribute in plaque prolapse containment and wall coverage improvement. From this point of view, regular interaction between endovascular experts and the companies involved in carotid device development is essential in ensuring future technical evolutions and material improvements.

Finally, the identification of patients who are likely to be high-risk carotid stenting cases requires a skilled interventional vascular specialist. Although this is the case in all areas of percutaneous intervention, the importance of proper physician training and patient screening in CAS procedures cannot be understated. It is imperative for CAS specialists to be actively involved in continuous learning programs. ■

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