

An Overview of the ev3 Carotid Innovations

BY MARK VANDLIK

The past decade has seen significant growth in the interest in and adoption of carotid artery stenting (CAS) as a viable alternative for the treatment of carotid artery disease. An important driver for the growth in CAS procedures has been the accelerated evolution of the technology of stents and embolic protection devices. In this article, we review state-of-the-art requirements for carotid stents and embolic protection devices and present the design features of two of the latest devices for the treatment of carotid artery disease in patients at high risk for endarterectomy—the PROTÉGÉ RX® Carotid Stent System and the SpiderFX™ Embolic Protection Device (ev3 Inc., Plymouth, MN) (Figure 1).

CAROTID STENTING REQUIREMENTS

Carotid artery disease presents the physician with a broad spectrum of anatomical variations that affect the degree of complexity in each case. These variables include a wide range of patient anatomy and vessel tortuosity, plaque morphology, and composition, as well as lesion location and length, among others. As interventionists are acquiring more experience in performing CAS procedures, specific carotid stenting requirements for both stents and embolic protection devices are being formulated.

One of the most important features in a carotid stent is its **radial force**, as the principal purpose of the device is to open up a stenotic vessel and avoid recoil. Stent designs for the carotid bifurcation need sufficient radial force to open and maintain patency in calcified lesions, which are commonly observed in the carotid arteries. Along with good radial strength, a carotid stent must have good **flexibility** in order to conform to the natural tortuosity from the common to internal carotid artery. The vessel's natural tendency to "curl" or kink makes the use of more rigid stent designs less desirable because rigid stents will have the tendency to move the kink or curl just distal to the treated area.

Not only must the stent be flexible enough to adapt to the twists and turns of the vessel, it must also conform to the variances in diameter, especially when stenting across the carotid bifurcation. This important feature, common-

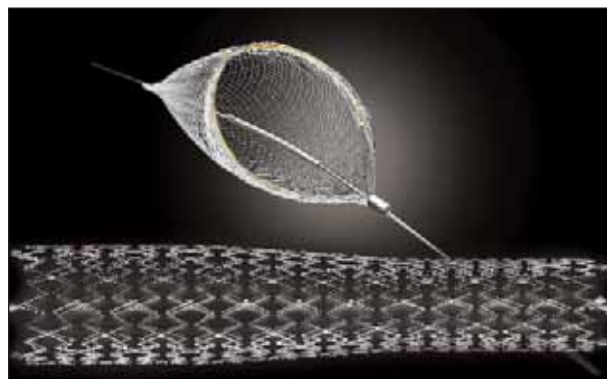


Figure 1. ev3 Carotid innovations: The PROTÉGÉ RX® Carotid Stent and SpiderFX™ Embolic Protection Device.

ly referred to as **conformability**, often makes it desirable to use tapered stents capable of conforming to the vessel diameter transitions while maintaining a balance in the metal-to-artery ratio.

In addition to these important mechanical properties, a carotid stent needs to have sufficient **visibility** to ensure accurate placement and the ability to visualize the stent after deployment and during postdilatation. Good visibility of the stent will allow the physician to verify vessel wall apposition after deployment and makes it easier to ensure that balloon inflation is performed with the balloon completely inside the stent without any overhang.

Finally, to ensure good results, **predictable deployment** of the stent is paramount because, in many cases, carotid lesions can be short, focal, and close to the bifurcation, requiring precise placement of the stent.

In the case of embolic protection devices (EPDs), a key requirement is for it to have adequate **wall apposition**. If an EPD does not appose the vessel wall completely, there is risk of embolic debris passing through gaps between the vessel wall and filter. With good vessel wall apposition, the next key requirement is EPD **pore size**. There is a balance between having a small enough pore size distribution to capture emboli of clinical consequence and a large enough pore size distribution to maintain **filter patency** during the procedure. If the ratio of open area to closed area of the filter is too small, there will be a more signifi-

cant pressure decrease across the filter and a greater chance of a slow-flow/no-flow situation.

In an ideal ancillary device design, the operator should not have to change the way the treatment procedure is performed to accommodate the ancillary device. In the case of an EPD design, it should still allow physicians to use their **guidewire of choice** for the initial lesion crossing, just like in any other peripheral endovascular intervention. Also, EPDs should provide **visual feedback** to the operator to confirm vessel wall apposition and to allow fast and precise filter positioning.

Finally, EPDs should remain **stable** as they are functioning as guidewires and devices track over them. Inadvertent filter migration during the intervention represents a high risk for procedure complications that can be avoided with well-designed EPDs.

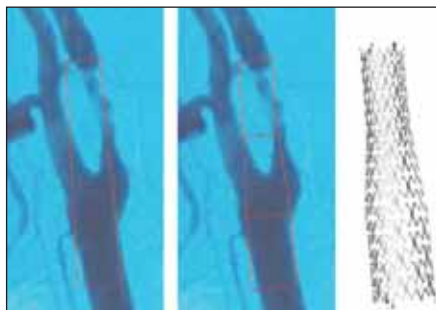


Figure 2. PROTÉGÉ RX® Tapered Stent is designed for better anatomical fit in the carotid bifurcation.

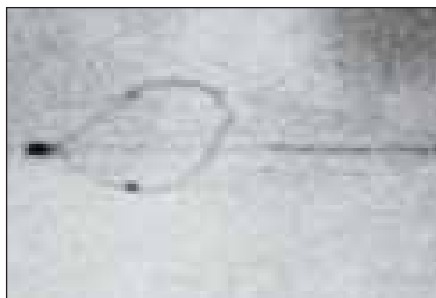


Figure 4. Clearly visible radiopaque markers at the proximal and distal ends of the filter, as well as the radiopaque mouth indicator.

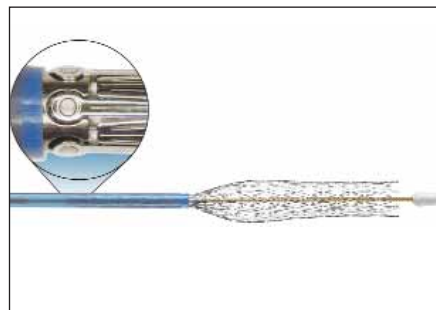


Figure 3. EX.P.R.T. Release Technology anchors the proximal end of the stent to the inner shaft of the catheter until the outer shaft is retrieved.

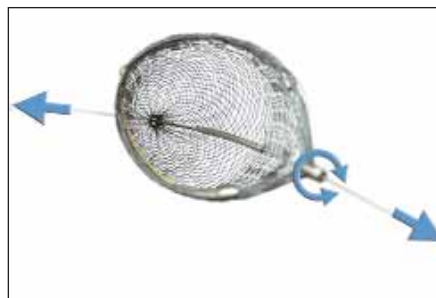


Figure 5. The Capture Wire is designed to rotate and move longitudinally, independent of the filter.

THE PROTÉGÉ RX CAROTID STENT SYSTEM

Predictable Deployment, Visible Results

Approved by the FDA in early 2007, the PROTÉGÉ RX Carotid Stent System is the latest entry into the carotid stenting market. The many design features of the PROTÉGÉ RX Carotid Stent System set it apart from other available carotid stent systems and make it an ideal choice for CAS.

The right balance. The PROTÉGÉ RX Carotid Stent System is designed to provide an optimal balance between radial strength and flexibility. The open-cell design provides expansion forces that resist compression while providing excellent wall apposition and, at the same time, provides the stent with the flexibility necessary for the carotid anatomy.

Anatomically tapered to fit like a glove. The PROTÉGÉ RX Tapered Stent is designed to match the anatomy of the carotid bifurcations, giving it outstanding conformability to the ICA/CCA transition. Unlike tapered stents with conical designs, the PROTÉGÉ RX Stent is anatomically tapered, more closely reflecting the alternating “straight-tapered-straight” anatomy of carotid bifurcations (Figure 2).

Solving the predictable deployment challenge. The proprietary EX.P.R.T. Release Technology essentially eliminates jumping or premature stent deployment, very relevant to CAS because this is observed more frequently in short (20 mm and 30 mm) and large-diameter (>8 mm) stents, which are commonly used in CAS (Figure 3). Also, the PROTÉGÉ RX Stent has minimal stent shortening, providing physicians with accurate stent deployment.

Seeing is believing. The PROTÉGÉ RX Stent is the only approved carotid stent with GPS™ Tantalum radiopaque markers at the distal and proximal ends of both straight and tapered configurations, providing excellent visibility for accurate placement.

THE SPIDERFX EMBOLIC PROTECTION DEVICE

Cross With Confidence—It's Your Choice

A new version of ev3's original SpideRX Embolic Protection Device, the second-generation SpiderFX Embolic Protection Device, received FDA 510(k) clearance just 10 months after the first generation was approved. The design features of the new-generation SpiderFX Embolic Protection Device not only meet the

state-of-the-art requirements outlined previously, they also offer a number of unique advantages.

Which guidewire? It's your choice. The SpiderFX device is the only distal filter embolic protection device currently available that allows using the physician's guidewire of choice. The operator can cross even the most challenging lesions with confidence, using any preferred .014-inch or .018-inch guidewire.

The right fit. The SpiderFX filter is available in a broad selection of sizes to treat carotid arteries from 3 mm to 7 mm with the appropriate filter size.

Get the whole picture. Clearly visible radiopaque markers enable fast positioning and visualization of the filter during the entire intervention. The SpiderFX filter's new mouth indicator ensures accurate visualization of the filter mouth opening (Figure 4).

The wire moves; the filter stays. A key characteristic of the SpiderFX Filter is its stability, provided by the braided nitinol design that gives it full wall apposition

and the ability of the capture wire to rotate and move longitudinally, independent of the filter (Figure 5).

The innovative design features of the ev3 PROTÉGÉ RX Carotid Stent System and the ev3 SpiderFX Embolic Protection Device have contributed to the rapid acceptance of the devices. The case study in the following article illustrates how these features may translate into clear advantages for the endovascular specialist during carotid artery interventions.

Complete indications, contraindications, warnings, precautions, and device instructions for the PROTÉGÉ RX Carotid Stent System and the SpiderFX Embolic Protection Device are provided in the Instructions For Use supplied with each device. ■

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A Carotid Case Study Using ev3 Technology

BY ROBERT L. MINOR, JR, MD

CASE SUMMARY

A severe right internal carotid artery (RICA) stenosis was treated successfully using the PROTÉGÉ RX Carotid Stent System and the new-generation SpiderFX Embolic Protection Device.

CASE HISTORY

A 61-year-old woman was referred by her neurologist and vascular surgeon after presenting with severe progressive right carotid artery stenosis associated with a stroke affecting function in her left hand. Her comorbidities included a previous coronary bypass surgery, severe insulin-dependent diabetes, and renal failure. She had undergone left carotid endarterectomy in the remote past. A carotid duplex ultrasound demonstrated >80% RICA stenosis, and angiography confirmed a severe RICA lesion with disease extending into the distal common carotid artery as well (Figure 1A).

PROCEDURE DESCRIPTION

A 5-F JR4 catheter was used to cannulate the right common carotid artery, with advancement of a steerable .035-inch guidewire into the external carotid artery, and a 7-F Shuttle sheath (Cook Medical, Bloomington, IN) was placed in the midsegment of the common carotid artery. Again, I was able to initially cross the right internal carotid artery stenosis with my preferred wire, an .014-inch Iron Man guidewire (Abbott Vascular, Santa Clara, CA). After deployment of a 6-mm SpiderFX Embolic Protection Device, the lesion was predilated with a 4-mm X 40-mm PTA. An 8-mm to 6-mm X 40-mm PROTÉGÉ RX Carotid Stent was deployed, covering both the RICA lesion and the distal common carotid lesion entirely; postdilation was performed with a 5-mm X 40-mm PTA (Figure 1). Baroreceptor activation was treated with vasodepressors. The retrieved SpiderFX Filter was found to contain atheroembolic debris. Final intracerebral angiograms

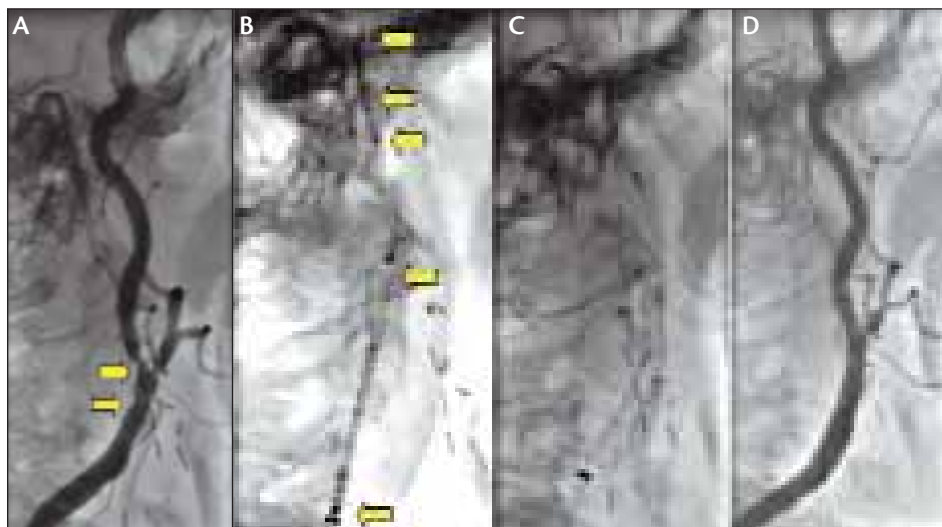


Figure 1. Severe RICA stenosis (A). PROTÉGÉ RX Stent during deployment with SpiderFX filter in view (B). PROTÉGÉ RX Stent deployed covering the RICA and right common carotid (C). Angiographic result after stenting and postdilation (D).

(AP/cranial and lateral) showed normal findings.

Neurologic assessment within 24 hours postintervention showed no sign of TIA or minor stroke. A carotid duplex exam will be done at the 4-week follow-up.

DISCUSSION

The retrieval of atheroembolic debris in this case highlights the importance of using embolic protection devices, and the ev3 SpiderFX Filter appeared to have several advantages over earlier devices. Most importantly, the SpiderFX Device allowed me to first easily cross the 80% stenotic lesion in the RICA with my preferred guidewire, a steerable .014-inch Iron Man guidewire. Also, the new mouth indicator (see arrow in Figure 2) and markers at the proximal and distal ends of the filter, all of which are radiopaque, give the SpiderFX filter enhanced visibility. The PROTÉGÉ RX Carotid Stent also provides great visibility with its Tantalum GPS™ Markers, which facilitated postdilation, clearly identifying the balloon's position inside the stent (white arrows in Figure 2). The visibility of both



Figure 2. Postdilation is facilitated by having radiopaque markers clearly identifying the proximal and distal ends of the PROTÉGÉ RX® Carotid Stent.

devices, combined with the ability to keep the filter low in the distal internal carotid artery without inhibiting passage of the stent delivery system fully across the internal carotid lesion, allowed me to have the filter and the end of the sheath in the field of view (even magnified views) while positioning and deploying the stent (Figure 1B). This feature may help reduce potential risks for complications related to inadvertent distal migration of the filter, which could compromise filter wall

apposition and protection from emboli escaping around the filter, as well as lead to other complications.

The precision and safety with which we were able to position and deploy the ev3 PROTÉGÉ RX Carotid Stent was also aided by the EX.P.R.T. Release Technology, which minimizes jumping or premature deployment. Compared to the SpiderRX System, the SpiderFX Device could be deployed and retrieved with more ease and less force because of the new hypotube connector re-design.

This case study highlights the overall ease of use of the ev3 carotid technologies and some of their unique advantages for carotid artery stenting. We believe that the ev3 carotid technologies are a great addition to our choices for carotid stenting products. ■

Robert L. Minor, Jr, MD, is Director of Endovascular Interventions at OSF Saint Anthony Medical Center and Director of the Rockford Cardiology Associates Research Foundation in Rockford, Illinois. All angiographic images provided by Dr. Minor. He has disclosed that he holds no financial interest in ev3. Dr. Minor may be reached at rminor@rockfordcardiology.com.