Embolic Protection Device Technology

An overview of current device designs and the philosophies behind them.

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Over the past few years, the vascular interventionist has managed to treat increasingly complex lesions in high-risk patients, using a combination of new techniques, new devices, and finely tailored skills. One of the problems remaining is the occurrence of embolic debris liberated during vascular manipulation.

In 1977, before Dr. Gruentzig performed his first catheter-based angioplasties during bypass surgery, he evaluated for the presence of arterial debris by collecting downstream blood from an artery dilated during surgery.[1] No significant debris was found, and in daily clinical practice, the occurrence of significant distal embolization seemed to be limited only to patients with thrombotic lesions in which large amounts of debris and plaque are present. However, CK elevations after routine coronary interventions with widely patent epicardial vessels, and the so-called no-reflow phenomenon are being observed, and these phenomena are most likely related to distal embolization.[2]

It has been shown by histological examination that emboli contain more than just thrombus. Mucopolysaccharide components and necrotic core of lipid-laden plaques make up a large amount of the microscopic debris.[3-5] Because of this, strategies to prevent platelet activation and inhibit the clotting cascade will not be able to completely prevent distal microvascular plugging in high-risk situations such as saphenous vein graft (SVG) intervention or when the downstream organ is highly susceptible to injury (myocardial necrosis with enzyme elevation and in carotid artery stenting). Thus, the role of embolic protection devices has become increasingly important in certain vascular beds. This article reviews the currently available embolic protection devices, and their clinical use will be discussed by other authors in this issue of *Endovascular Today*.

There are currently four types of devices designed to prevent embolic debris during endovascular procedures: distal occlusion devices, distal filter devices, proximal occlusion/flow-reversal devices, and covered stents (Table 1).

DISTAL OCCLUSION DEVICES

Distal occlusion devices were developed to minimize or prevent the downstream migration of microscopic particles during high-risk vascular interventions. The concept is based on blockage of distal blood flow by placement of a sealing balloon downstream from the lesion of interest. This results in a stagnant column of blood during intervention, and the potential embolic debris trapped within it can be removed before releasing downstream occlusion.

Three devices employ this approach: the PercuSurge GuardWire (Medtronic, Inc., Santa Rosa, CA), the TriActiv FX embolic protection system (Kensey Nash, Exton, PA), and the GuardDog (Possis Medical, Inc., Minneapolis, MN) (Figure 1). The GuardWire and TriActiv FX systems consist of a .014-inch hypotube upon which an inflatable balloon is attached. The devices are maneuvered across the lesion under fluoroscopic guid-

TABLE 1. EMBOLIC PROTECTION DEVICES

Distal Occlusion	Distal Filter	Proximal Occlusion/ Reversal of Flow	Covered Stents
GuardWire (Medtronic) •2.8-F crossing profile •9- to 10-mm landing zone •7-F guide compatible	FilterWire EX (Boston Scientific) •3.9-F crossing profile •80- to 110-µm pore size •6-F guide compatible •18.5-mm landing zone •Attached to its own guidewire	Proxis (St. Jude) •Works over any guidewire •Suspends and reverses flow •Protects side branches •7- to 8-F guide compatible	Jostent (Abbott) •PTFE-covered stent •Stainless steel design
TriActiv FX (Kensey Nash) •3- to 5-mm balloons •9-mm landing zone •Active flush and extraction •7-F guide compatible	FilterWire EZ (Boston Scientific) •3.2-F crossing profile •110-µm pore size •Suspended loop design •6-F guide compatible •Attached to its own guidewire •18-mm landing zone	Facilitated Aspiration/Suction Catheter (Funnel Catheter, Genesis) •Big mouth funnel catheter •Focused vacuum •Quick on/off •No CO_2	Graftmaster (Abbott) •PTFE-covered stent •Stainless steel design •7-F guide compatible
GuardDog (Possis Medical) •3- to 6-mm balloons •.035-inch guidewire •CO_2 inflation device	AngioGuard (Cordis) •3.2- to 3.7-F crossing profile •100-µm pore size •7-F guide compatible •Attached to its own guidewire •18-mm landing zone	Gore Neuro Protection System (Gore & Associates) •A-V shunt with interposed filter •Retrograde carotid flow •10-F guide compatible	iCast (Atrium) •PTFE-covered stent •Stainless steel design •Low crossing profile •6- to 7-F guide compatible
	SpideRX (ev3) •3.2 F and 2.9 F crossing profiles •167- to 209-µm pore size •Heparin-coated filter •6-F guide compatible •Attached to its own guidewire	Mo.Ma Occlusion System (Invatec) •Occludes ICA and ECA •Aspiration of debris •9-F guide compatible	Symbiot (Boston Scientific) •PTFE-covered stent •Nitinol stent •Self expandable
	Emboshield (Abbott) •3.7- to 3.9-F crossing profile •140-µm pore size •6-F guide compatible •Separate guidewire Emboshield Pro •2.8-F and 3.2-F crossing profiles, 19-mm and 22.5-mm landing zone (for 2.5- to 4.8-mm and 4- to 7-mm sizes, resp) •120-µm pore size		
	Accunet (Abbott) •3.5- to 3.7-F crossing profile •120-µm pore size •Polyurethane filter over a nitinol basket •6-F guide compatible •Attached to its own guidewire		
	Rubicon (Rubicon Medical/Boston Scientific) •2.4 to 2.7-F crossing profile •100-µm pore size •6-F guide compatible •Attached to its own guidewire		
	InterceptorPlus (Medtronic) •2.9-F crossing profile •100-µm pore size •Braided nitinol filter •6-F guide compatible Attached to its own guidewire		

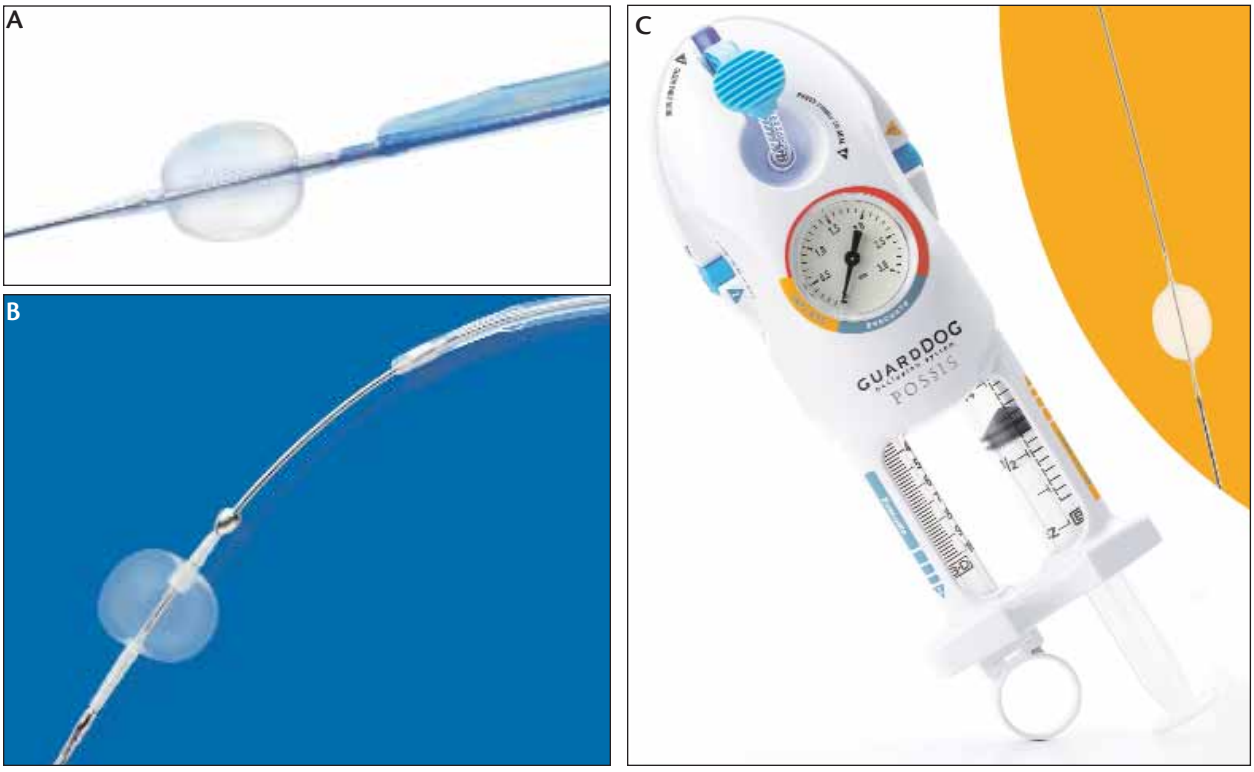

Figure 1. Distal occlusion devices. The PercuSurge GuardWire (A). The TriActiv FX Embolic Protection System (B). The Possis GuardDog (C).

ance; the downstream balloon is then inflated between 1 atm to 3 atm to occlude flow. The hypotube serves as the interventional guidewire over which balloons and stents can be placed. After the procedure is completed, the stagnant column of blood is removed using a distal aspiration catheter (PercuSurge Export, Medtronic, Inc.) or a distal saline infusion catheter (Flushcath, Kensey Nash). The balloon can then be deflated, and the device is removed from the patient. The GuardDog was recently approved for work in the periphery and consists of a .035-inch guidewire that incorporates a 3-mm to 6-mm, CO_2-filled compliant balloon at the tip. The balloon requires 0.7 atm of pressure to be inflated and is used to seal off the distal vasculature. Removal of debris can then be performed using another device (AngioJet, Possis Medical, Inc.) as desired.

Distal balloon protection devices have several advantages over other embolic protection systems. First, they have a very low crossing profile (<3 F), with easily maneuverable guidewires and rapid inflation and deflation of the distal balloon. The current version of the TriActiv FX system uses a rapid CO_2 exchange system, allowing for quick inflations and deflations. This allows for rapid re-establishment of antegrade flow. Second, they do not require a very large landing zone (9 mm), so there does not need to be much clearance distal to the lesion in order for the device to be placed properly. Third, these devices trap particles of all sizes, not just those greater than 100 µm, which is the lower limit of pore size on most filter devices. Finally, they are not limited in the amount of debris collected because there is no basket to fill up or become clogged. The active flush system provided with the TriActiv FX system allows for more aggressive particle removal from the walls of the vessel, stent struts, and area surrounding the distal balloon before the downstream vasculature is exposed to restoration of flow.

However, the distal occlusion devices are not without potential drawbacks. The devices may not provide adequate support for delivery of balloons or stents in heavily calcified or tortuous vessels. The systems are occlusive to downstream blood flow and have the potential for end-organ ischemia. For example, in cases in which the brain does not tolerate internal carotid artery occlusion, the use of these types of protection is limited.

When these devices do not completely occlude the distal vessel, debris can get past the device. The operator must pay strict attention to the balloon to make sure it is fully occlusive and that migration has not taken place. The presence of a stagnant column of blood can hamper

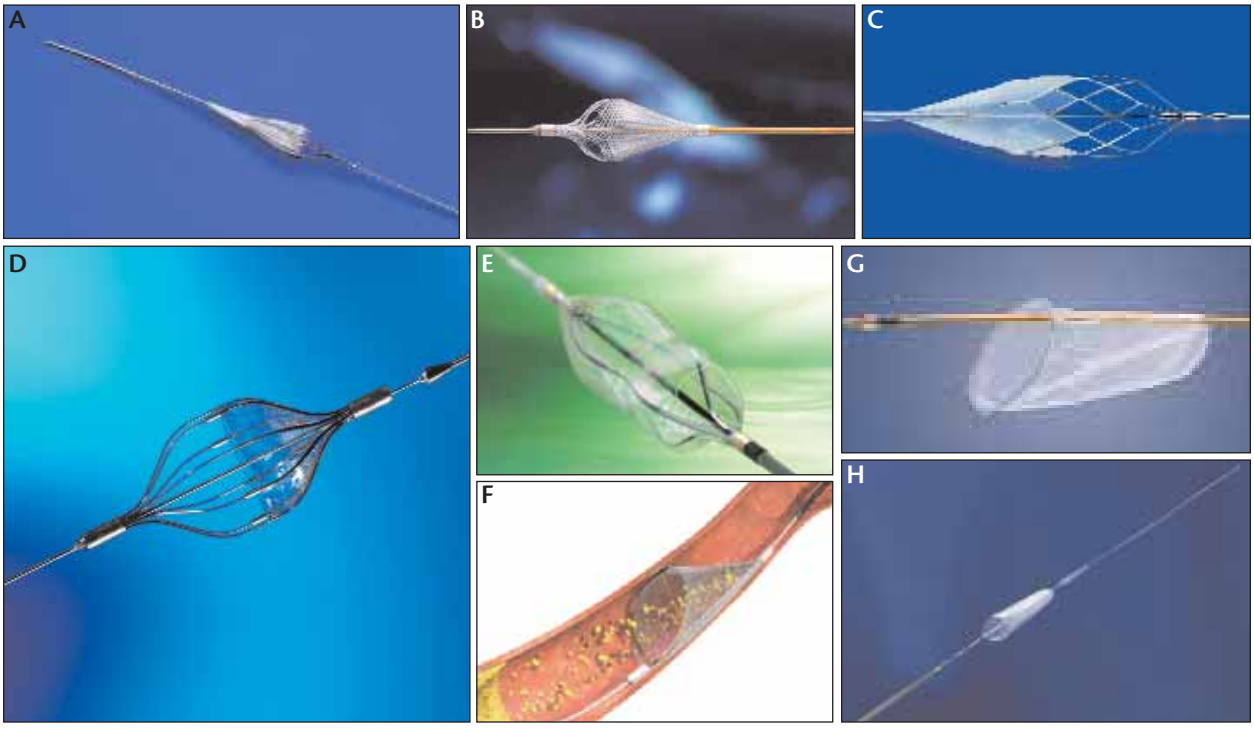

Figure 2. Distal filter devices. The Rubicon Filter (A). The InterceptorPlus Filter (B). The Accunet Filter (C). The AngioGuard XP filter (D). The Emboshield (E). The SpideRX (F). The FilterWire EZ (G). The FilterWire EX (H).

lesion visualization due to lack of antegrade flow. The inability to protect major side branches could potentially lead to embolization and damage to vital territories. For example, with carotid artery stenting, there may be an intracranial communication between the ECA and ICA leading to significant neurologic deficits.[6] Finally, these devices may be ineffective in removing debris from the area around the inflated balloon (the so-called *suction shadow*).[7]

DISTAL FILTER DEVICES

Distal filter protection devices are the most commonly used products aimed at preventing distal embolization and come in a large variety of different systems (Table 1). The concept is simple: permit downstream blood flow while trapping potentially harmful large particles that may damage the microcirculation.

Filters come in many shapes and sizes, some attached to their own guidewire (FilterWire EX and EZ, Boston Scientific Corporation, Natick, MA; Rubicon, Boston Scientific Corporation; SpideRX, ev3, Inc., Minneapolis, MN; AngioGuard, Cordis Corporation, a Johnson & Johnson company, Miami, FL; Interceptor, Medtronic, Inc.; Accunet, Abbott Vascular, Abbott Park, IL) and some that pass over the wire already in place (Emboshield and Emboshield Pro, Mednova/Abbott, Galway, Ireland) (Figure 2). These devices are manipulated through the lesion and then unsheathed distally to allow the filter to appose the vessel wall. The filters are designed to trap particles greater than 100 µm, which is the lower limit of the pore size for most devices. Filters that would have smaller pore size would cause fibrin build up and thrombus formation within the filter.[8] After interventional procedure is completed, the filter is removed by means of a recovery sheath. The various devices differ in their crossing profile, pore size, and sheath compatibility (Table 1). Most are in the shape of a windsock, mounted on a nitinol loop, and can be placed in vessels ranging from 3 mm to 7 mm.[9] The retrieval sheaths are usually 4 F to 5 F. The advantage of maintaining vessel perfusion is that it allows excellent lesion visualization, which allows for successful balloon and stent placement, thereby limiting geographic miss. This is complemented by the filters' ability to trap particles smaller than its pore size.[10,11] The reasons for this may stem from the tendency of particles to clump or strand across filter pores, reducing the functional pore size.[9]

Although distal filter protection devices do allow smaller particles to pass, experimental data by Hori et al[12] suggest that the microvasculature can tolerate these smaller particles in far greater numbers than that of larger embolic debris. Of note, however, some filters have failed to meet equivalency margins in clinical testing

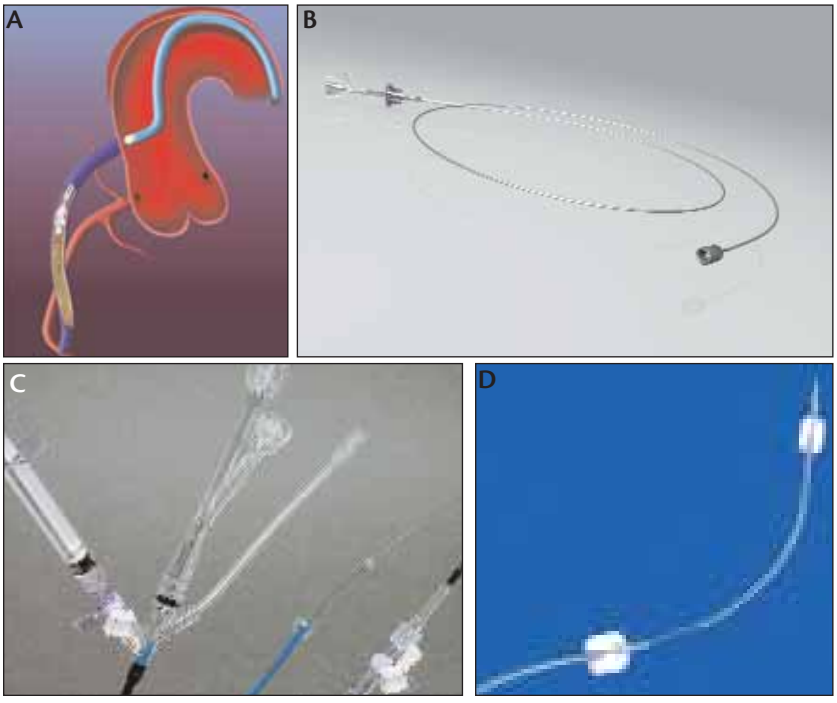

Figure 3. Proximal occlusion/reversal of flow devices. The Proxis Embolic Protection System (A). The Genesis Funnel Catheter (B). The Gore Neuro Protection System (C). The Mo.Ma Cerebrovascular Protection Device (D).

during SVG intervention. This would suggest shortcomings in their lesion crossing capabilities or in their filtration device.[13]

As with the distal balloon protection devices, the filters have to cross beyond the lesion before they can be deployed. This potentially allows for debris to be dislodged at the time of lesion passing. Distal filter devices have a larger crossing profile than the distal balloon devices and can thus be difficult to pass in very tight lesions or in areas of significant tortuousity. They require a much larger landing zone (20-30 mm) as compared to the distal occlusion devices (9 mm). The larger landing zone can be problematic in distal lesions or in areas with severe tortuosity where proper apposition to the vessel wall can be difficult. Failure to do so may lead to embolization around the device. The concern for embolization during filter retrieval should be considered. All filters have a limited volume, which will decrease further if the filter is collapsed during retrieval. As is the case with distal balloon protection devices, filter devices can create spasm or dissection, especially in cases where prolonged manipulation or excessive force is needed.

The newest-generation devices (Rubicon, InterceptorPlus, SpideRX) attempt to eliminate some of these shortcomings by decreasing the crossing profile, changing the filter design to obtain an optimal volume, and altering the guidewire to assist in lesion passing. In the US, the InterceptorPlus filter is an investigational device exclusively for clinical investigation.

PROXIMAL OCCLUSION/FLOW REVERSAL DEVICES

The principal mechanism of this group of devices is to occlude the target vessel proximally and thus eliminate lesion manipulation before establishing protection. The currently available devices use a series of guide catheters or selective sheaths to block blood flow down the vessel of interest or use balloon occlusion to set up flow reversal to prevent embolic debris from reaching the distal bed. They can be divided into two groups:

- Proximal occlusion (Proxis, St. Jude Medical, Minneapolis, MN; Facilitated Aspiration/Suction Thrombectomy [F.A.S.T.], Genesis Medical Interventional, Redwood City, CA); and
- Reversal of flow (Gore Neuro Protection System, Gore & Associates, Flagstaff, AZ [previously the Parodi Anti-Embolism Device], Mo.Ma, Invatec, Roncadelle, Italy) (Figure 3).

The Proxis system utilizes a contained series of telescoping catheters, the outermost of which incorporates a sealing balloon.[14] Once the device is placed through a 7-F or 8-F guide catheter, the sealing balloon is inflated and contrast is injected, creating a stagnant column of blood and contrast while manipulation of the lesion with balloons and stents takes place. The stagnant blood with debris is then aspirated through the inner catheter and removed from the patient.

The Genesis funnel catheter F.A.S.T. system is based on the same principle of proximal flow occlusion.[15] It uses a new funnel catheter that contains a vacuum device that allows for aspiration of debris both distal to and proximal to the lesion. It is a combination thrombectomy device and embolic protection catheter. This device should have applications to the carotid system as well. More information is anticipated to be released.

Theoretical advantages include achieving protection of the distal vasculature without manipulation of the lesion. These devices eliminate the controversy surrounding crossing profile, distal landing zone, filter pore

size, proper sealing of balloons, lesion manipulation, tortuousity, etc., by keeping their devices firmly placed upstream from significant plaque. The two devices specifically designed for carotid intervention take embolic protection one step further. They actually create flow reversal within the internal carotid artery (ICA). The Gore Neuro Protection System uses a series of balloons on separate catheters to occlude the common carotid artery (CCA) and then the external carotid artery (ECA), setting up an isolated path to the ICA. The proximal end of the catheter is then connected to a filter device, the efflux of which is connected to the femoral vein. This device creates retrograde flow within the ICA so that stenting can take place without fear of distal embolization. The Mo.Ma device works in a similar fashion, except that both balloons are mounted on the same catheter, and they are placed within the ICA and ECA, respectively. This device uses intermittent flow reversal to help prevent embolization.[16,17]

Both of these systems are based on sound concept but have limitations due to size (9-F [Mo.Ma] and 10-F [Gore] sheaths) and complexity of set up. They have the potential to cause spasm or dissection within the ECA or CCA and require cessation of flow in order to work properly, thus requiring adequate collateral circulation. This novel approach is being tested aggressively in Europe. The results of larger clinical trials should be available soon.

COVERED STENTS

Covered stents deserve mention only for the sake of completing the discussion of embolic protection. There has been a series of trials attempting to use PTFE-coated stents in SVGs in order to prevent distal embolization of debris. The concept of local trapping instead of distal trapping sounded simple, as conventional stents clearly allow debris to migrate through their struts. The FDA-approved covered stents (Jostent, Abbott Vascular; Graftmaster, Abbott Vascular; Symbiot, Boston Scientific; and iCast, Atrium Medical, Hudson, NH) have been shown to be life saving with vessel perforation, but have not turned out to be effective in preventing distal embolization.[18] As the availability of sophisticated embolic protection devices increases, the use of covered stents may see limited use.

CONCLUSION

As interventional vascular physicians become more aggressive with SVG intervention, complex renal and peripheral artery stenting, and calcified and tortuous carotid lesion manipulation, the use of embolic protection will increase. There is a vast number of devices available, and technical refinements are continuously being made. The interventional physician should become familiar with the multitude of strategies by which to protect the distal microvasculature. ■

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