

Produced under an educational grant from Lumen Biomedical, Inc.

FiberNet® Embolic Protection System

Exploring the differences.

As the performance of carotid artery stenting (CAS) becomes more common among interventionists, new generations of embolic protection technologies are emerging. With the challenges of patient selection and the curve of operator experience, developing reliability and flexibility in embolic protection is a vital component of the procedure.

This article reviews the design and features of the FiberNet Embolic Protection System (EPS) (Lumen Biomedical, Inc., Plymouth, MN), which received foreign certification (CE Mark) and is currently in ongoing US clinical trials. The second portion of the article includes a panel of key physicians discussing their initial experiences using the FiberNet EPS.

DESIGN: THREE-DIMENSIONAL MESHWORK OF POLYMERIC FIBERS

Lumen Biomedical's FiberNet captures debris as small as 40 µm within a three-dimensional filter made of hundreds of PET (polyethylene terephthalate) fibers.

DELIVERY: GUIDEWIRE MOUNTED

The FiberNet is mounted on a .014-inch guidewire with a crossing profile ranging from 1.7 to 2.9 F. No delivery system is required to advance the undeployed filter through the lesion (Figure 1).



Figure 1. The undeployed filter mounted on a .014-inch guidewire.

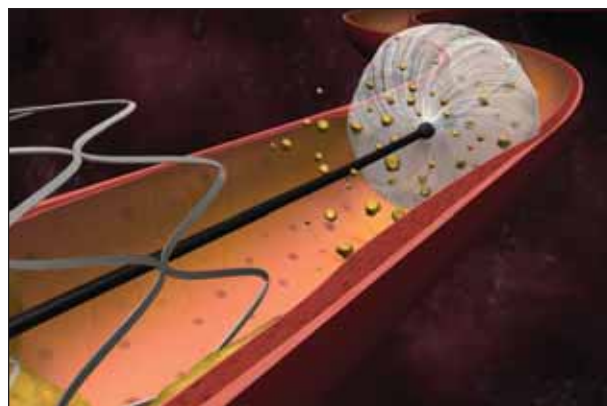


Figure 2. The three-dimensional FiberNet filter expands to the vessel wall.

LANDING ZONE

The FiberNet gives the operator more flexibility with placement and positioning in curved segments, requiring a small landing zone (1.5 cm minimum).

VESSEL SIZING: WALL APPPOSITION

The fiber-based design of the filter conforms to asymmetrical vessels (Figure 2). The five FiberNet sizes fill vasculatures ranging from 1.75 to 7.0 mm.

FILTER RETRIEVAL: XTRACT CATHETER

The FiberNet filter is then removed through the single-lumen design of the Xtract aspiration catheter (Lumen Biomedical) supplied with the system.

ENHANCED RADIOPAQUE MARKER BANDS

FiberNet offers a unique dual marker band design, providing direct visual confirmation of filter deployment (Figures 3 and 4).

AREAS OF CLINICAL STUDY

Ongoing clinical trials for the FiberNet EPS include the EPIC trial for CAS, the RETRIEVE trial for saphenous vein graft stenting, and the FORTRESS trial for renal artery stenting (initiated by VIVA Physicians, Inc.).

Perspectives on CAS and Embolic Protection

A Q & A discussion with Subbarao V. Mylavarapu, MD, and J. Michael Bacharach, MD.



Subbarao V. Mylavarapu, MD

Dr. Mylavarapu is the Medical Director of Cardiovascular Research and Endovascular Intervention at Hoag Memorial Hospital Presbyterian in

Newport Beach, California. He is the National Principal Investigator for the EPIC US Feasibility study and the SONOMA postmarket study, and a local Principal Investigator for several IDE carotid stent trials by Johnson & Johnson, Abbott Vascular, Boston Scientific, Endotex, EPI, Medtronic, Bard, ev3, Gore & Associates, and Invatec. Dr. Mylavarapu has disclosed that he holds stock options for Lumen Biomedical. He may be reached at (949) 722-2411; subbaraomya@yahoo.com.



J. Michael Bacharach, MD

Dr. Bacharach is the Section Head of Vascular Medicine & Peripheral Vascular Intervention at North Central Heart Institute in Sioux Falls, South

Dakota. He serves as the Primary Investigator in multiple peripheral vascular drug and device studies, including the EPIC US Feasibility study. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Bacharach may be reached at (605) 977-5316; jhatch@ncheart.com.

How would you describe the current state of CAS? How has the market evolved, and what predictions do you have for the future?

Dr. Bacharach: I believe that the current state of CAS is favorable. We clearly are now able to offer revascularization alternatives to patients who have anatomical features that put them at high risk for conventional surgical endarterectomy (CEA), as well as a subset of patients who have medical conditions that would put them at high risk. Although there has been some controversy in the comparisons between conventional CEA and CAS, I believe that the two techniques in many cases are complementary. It is important to remember our basic goal: to prevent stroke. We need to achieve this goal in the most clinically efficacious manner.

I do think that some of the market predictions about the growth of CAS are overly optimistic. We have gained a better understanding of both the advantages and the limitations of carotid stent technologies. Continued technical improvements in stent platforms and delivery sys-

tems along with operator experience will make the procedure safer.

Dr. Mylavarapu: The current status of CAS is one of stagflation. We have an explosion of advanced devices and data, yet no growth in utilization due to regulatory and reimbursement restrictions placed on the medical community, specifically the lack of approval for higher-surgical-risk asymptomatic patients despite completion of several high-risk IDE trials and postmarket studies. The unmet need is not fulfilled due to lack of payment from CMS for higher-surgical-risk patients. Consequently, there is disaffection, and although potential for CMS approval of higher-surgical-risk anatomical subgroups may be on the horizon, it is far from certain.

The market evolution in technology is very slow, from unprotected stenting in the late 90s to the era of distal protection in the first decade of this century. Also, the type of protection has evolved from distal balloon occlusion to distal filters. We have come to recognize short-

comings of carotid filters in specific anatomical subsets with readjustment of higher-stent-risk patient categories. The recent phase in the US market has seen the introduction of proximal protection devices into clinical trials. The shortcomings of carotid filters are also being addressed on a more direct front by the introduction of advanced filter designs such as the FiberNet EPS. On the stenting side, we have seen the profile of stent delivery systems reduce from 8 to 5.5 F, and balloon-expandable stents have been replaced by self-expanding nitinol platforms.

As far as predicting the future, in the short term, we expect anatomical high-risk categories to be approved, higher-surgical-risk IDE studies will continue to show improving stroke rates breaking the 3% barrier consistently, and increasing penetration of proximal protection studies in the US.

In the long term, I believe we will explore the concept for central protection surrounding the stent design itself and streamlining the CAS procedure by eliminating certain steps. The central protection concept would entail either thin-film nitinol devices as preliminary scaffolds in the lesion followed by definitive stenting, perhaps with or without the addition of distal or proximal protection. Along the same lines, partial or complete stent graft designs will be tested. On the streamlining side, we anticipate the bundling of CAS procedural steps into integrated stages. For example, our European colleagues have already abandoned routine predilatation, and the filter recovery

catheter is being modified to postdilate as well as aspirate and recover filters, reducing the procedure to two steps.

What do you look for in embolic protection systems?

Dr. Mylavarapu: Reliable protection in an easy-to-use format without any filter-related complications from device-to-device interactions is ideal.

“The embolic protection device needs to be readily adaptable to varying anatomies and have a low risk of causing complications.”

—Dr. Bacharach

Dr. Bacharach: First and foremost, I look for efficacy in preventing embolic complications during the stent procedure. Ease of use and relative simplicity in deploying and retrieving the embolic protection device are helpful features. The embolic protection device also needs to be readily adaptable to varying anatomies and have a low risk of causing complications.

How would you compare the FiberNet EPS to currently available devices?

Dr. Bacharach: I believe the FiberNet compares quite



Figure 3. A fluoroscopic image showing the undeployed filter.



Figure 4. A fluoroscopic image showing the deployed filter.

favorably with other EPSs on the market. It has a rather unique design, one that I believe is quite adaptable to varying anatomies. In my experience, it has provided very good embolic protection and is relatively easy to deploy as well as to retrieve. Additionally, it has a very low profile, which allows it to cross many lesions in which a larger filter-type device may have difficulty tracking or crossing. I believe that one of the drawbacks of the device is the inherent visibility issue, which makes it very difficult to see.

Dr. Mylavarapu: The FiberNet is a very low-profile, soft EPS with remote actuation. This means it can be loaded with either a balloon or a stent directly, eliminating one step in the procedure. It navigates tortuosities well, and its three-dimensional design allows better wall apposition, even in bends. The combined filtration and aspiration increases the range and extent of protection. The preliminary experience suggests compatibility with all commercially available stent delivery platforms and stents.

What are your thoughts on special considerations for the octogenarian subset of CAS patients?

Dr. Mylavarapu: Needless to say, although the learning curve is steep in this subset, it is more an issue of understanding and appreciating the nuances of anatomical constraints and unique tricks and troubleshooting elements with filters that we need to appreciate to get optimal results. We have been very successful in achieving low stroke and death rates by using carotid anatomical adversity modeling based on an anatomical scoring system. Whereas the early years of CAS focused on access into the common carotid artery, with availability of distal protection filters, internal carotid access has taken on increasing importance. For example, we found sharp lesion-entry angle as the most important predictor of success with distal protection devices. We have measured, quantified, and correlated to clinical outcomes and procedural complexity by using three important variables: (1) sharp lesion angle, (2) carotid tortuosity, and (3) lesion morphology, to develop technical algorithms to improve results.

On the medical comorbidity side, octogenarians more frequently have amyloid angiopathy, leukoencephalopathy, renal failure, and hypertension. All these factors correlate to increased risk of hyperperfusion syndrome and intracranial hemorrhage. This is the area most difficult to quantify and predict, hence the need for rigorous case selection and proper attention to timing of intervention in symptomatic patients. On the bright side, as we see from recent reports of the CAPTURE 2 data, the event rate in octogenarians has significantly improved since the original report from CREST in 2003.

Dr. Bacharach: The octogenarian subset of patients has become somewhat controversial given the higher rate of complications and strokes observed in the run-in protocol of the CREST trial, as well as a number of published studies. This is a group of patients in which careful selection is very important. This group of patients may have some variables including arch type, cerebral perfusion reserve, as well as extensive atherosclerotic burden that would put them at higher risk.

“[The FiberNet] navigates tortuosities well, and its three-dimensional design allows better wall apposition, even in bends.”

—Dr. Mylavarapu

There are, however, some data from our own center as well as a number of others that would suggest that octogenarian patients can be successfully treated safely using carotid stent technology. I also strongly believe that risk stratification based on an arbitrary 80-year-old or older cutoff seems unjustified at this time. Clearly, this is an area of interest that requires ongoing scrutiny and increased data before a decision can be made.

What possible future applications do you see for the FiberNet EPS?

Dr. Bacharach: I believe future applications for the FiberNet EPS are primarily in the renal vascular bed. The device is well suited for this anatomy because of its profile and the fact that it can be deployed in a relatively short segment. Additional applications in the periphery may have a role, but as of yet are undefined.

Dr. Mylavarapu: The short landing zone, low profile, remote actuation, and integrated aspiration all lend themselves to renal, cerebral, and lower-extremity distal protection, and aspiration of clots in a multitude of disease states.

One area in which I hope to see the FiberNet quickly start in clinical trials is saphenous vein graft intervention. Because of the short landing zones required for the device, it might be well suited for such an application. Acute stroke intervention is another area that deserves rapt attention, due to the device's very low profile, soft structure, and integrated aspiration. ■

The FiberNet Embolic Protection System is for investigational use only in the US.