Embolic Capture Angioplasty

A new device offers the same features as standard balloon angioplasty for lower extremity procedures but with the addition of debris capture and removal.

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Endovascular therapies have rapidly developed into the primary treatment of most peripheral arterial lesions. Commonly employed endovascular interventions include balloon angioplasty, stent placement, directional atherectomy, pharmacologic thrombolysis, and mechanical thrombectomy. As more aggressive strategies are used to approach more complex cases, a variety of complications are realized. Acutely, one of the most devastating complications is distal embolization of atherothrombotic debris, which can lead to a spectrum of consequences and ultimately has the potential to cause acute limb ischemia or the need for adjunct procedures, as well as the loss of limb or life. Therefore, a variety of techniques have been developed to prevent distal embolization. Strategies include the use of embolic protection devices—generally, filter-based technology.

Determinants of embolization and its significance include the type of lesion (acute vs chronic; focal vs diffuse) as well as the patency of runoff vessels. Gross embolization is believed to occur in approximately 3% to 5% of infrainguinal interventions.[1,2] However, in studies that evaluated the use of filter-based embolic protection strategies, debris was recovered in 25% to 100% of cases.[3] Atherectomy-based treatment strategies are believed to have a higher incidence of embolization.[4]

Filter-based systems of embolic protection have several advantages and—until now—have been the primary mechanism for capturing embolic debris. However, limitations include the ability to deliver the filter, the added cost to the procedure, lack of US Food and Drug Administration clearance for infrainguinal use, and arterial trauma that can be caused by the filter itself.

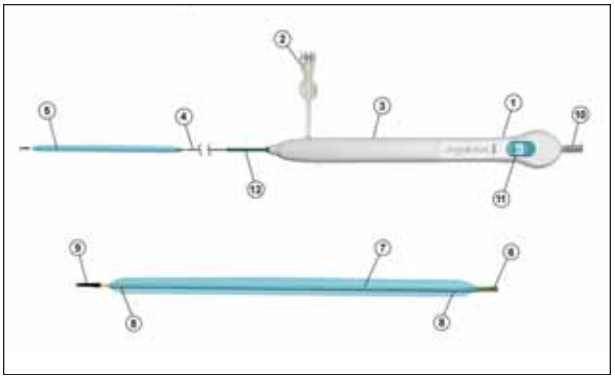

Figure 1. The Proteus device (Angioslide, Inc., Minneapolis, MN). Pull knob (1), inflation port (2), handle grip (3), shaft (4), balloon (5), outer shaft (6), inner shaft (7), radiopaque marker (8), distal atraumatic soft tip (9), proximal hub (10), pulling knob lock (11), and strain relief (12).

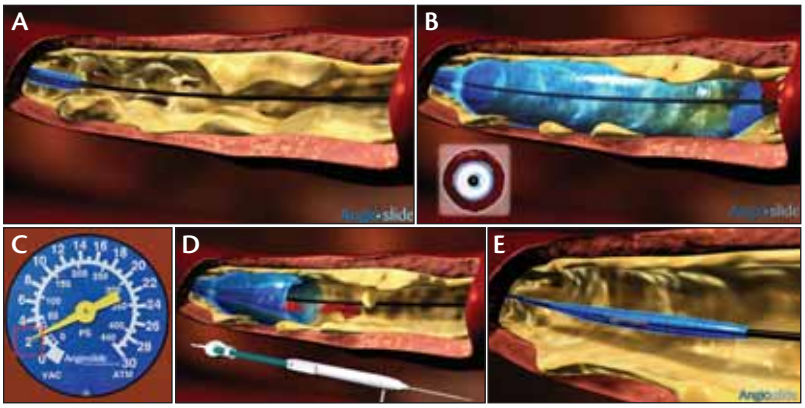

Figure 2. Guidewire insertion (A), inflation (B), reduction to 2 atm (C), particle removal (D), and particle containment (D).

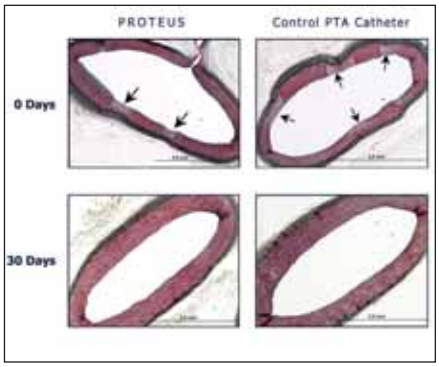

Figure 3. Animal model with vessel injury from the Proteus device compared to a standard angioplasty balloon.

PROTEUS: EMBOLIC CAPTURE ANGIOPLASTY

Recently, the Proteus device by Angioslide, Inc. has received US Food and Drug Administration clearance for peripheral transluminal angioplasty (PTA) and for capture and containment of embolic material during angioplasty for the femoral, iliac, iliofemoral, popliteal, tibial, peroneal, and profunda arteries. The Proteus PTA balloon catheter is not intended for use in the renal, cerebral, coronary, or carotid vasculature.

The Proteus device uniquely combines the ability to perform angioplasty while concomitantly capturing debris that could otherwise potentially embolize during the procedure. With such a device, we will see a shift in how we treat lesions. Initially, the device functions as a normal angioplasty balloon: the balloon is semicompliant and is inflated to a nominal pressure of 8 atm. After angioplasty, the balloon is deflated to 2 atm. At this point, arterial flow remains occluded, and the balloon is then infolded upon itself. This mechanism essentially "sucks" potential embolic debris into the balloon as it is rolled into itself. The infolded, deflated balloon is then removed. Figures 1 and 2 depict the balloon's mechanism.

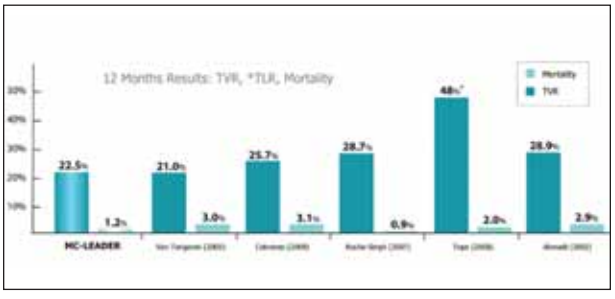

Figure 4. Target vessel revascularization (TVR), target lesion revascularization (TLR) (Tepe study), and mortality rates associated with Proteus compared to traditional PTA balloons.

CLINICAL DATA FOR PROTEUS ANGIOPLASTY

For the Proteus device to be effective, it must be able to successfully dilate a lesion—not cause more arterial trauma (dissections, restenosis, etc.) either acutely or long-term compared to a standard angioplasty balloon—and it must be able to capture debris.

The safety and efficacy of the Proteus balloon have been evaluated in a variety of clinical situations, from bench top models to in vivo clinical trials; studies have also compared the Proteus device to filter-based embolic protection systems.

The MC-LEADER (Multi-Center Studies for Lower Extremity Angioplasty With Debris Removal) and the MC-LEADER Supplemental studies collectively evaluated the Angioslide device in 123 patients at three European sites. The primary endpoint of the two studies was the device success and acute procedural success (< 50% residual stenosis); additionally, the MC-LEADER study included embolic particulate analysis. Secondary endpoints included major adverse events, clinical success at 30 days (based on ankle-brachial index and

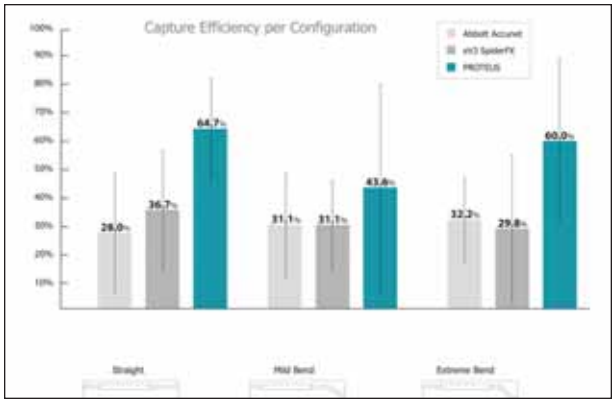

Figure 5. Vascular circulatory flow models of Proteus and other filter-based systems.

TABLE 1. SUMMARY OF CLINICAL ENDPOINTS

Endpoint	MC-LEADER		MC-LEADER Supplemental		Pooled	
	n/N	%	n/N	%	n/N	%
Primary Endpoints - Efficacy Measures						
Device Success	144/148[1]	97%	74/75[1]	99%		
Technical Success (<50% Residual Stenosis)	88/89[2]	98.9%	68/69[2]	98.5%		
Embolic Particle Analysis	Average Particle Capture/Subj: 339, %Subj ≥ 162part: 75%					
Primary Endpoints - Safety Measures						
Combined Primary Endpoint (Freedom from death, amputation and Target Vessel Revascularization, 30 days)					118/123	95.9%
Secondary Endpoints - Efficacy Measures						
Rutherford-Becker Improvement (≥1), 30 days	72/78	92%	29/40	72.5%		
Ankle-Brachial Index Improvement, 30 days	Statistically Significant Improvement (*P*<.0001)		Statistically Significant Improvement (*P*<.0001)			
Target Vessel Revascularization, One Year	16/71	22.5%				
AE Related Device Malfunction Rate					1/123	0.8%
Technical Success (<50% Residual Stenosis)					156/158[2]	98.73%
Secondary Endpoints / Other Analyses - Safety Measures						
SAE Rate	4/79	5.1%	5/44	11.4%	9/123	7.3%
Device Related Distal Embolization Rate	1/79	1.3%	0/44	0%	1/123	0.8%
Clinically Significant Vessel Dissection Rate	5/89[2]	5.6%	1/69[2]	1.4%	6/158[2]	3.8%

1 Denominator is number of devices used
2 Denominator is number of lesions treated
The pooled 12 month TVR rate will be calculated and compared against historical controls once the complete 12 month data becomes available

Rutherford-Becker classification), and target vessel revascularization at 12 months. Patients with lifestyle-limiting claudication or rest pain (Rutherford-Becker class 2–4) were enrolled if they had iliac or lower peripheral arterial disease with ≥ 50% stenosis.

The results of these studies are summarized in Table 1. As an angioplasty balloon, the technical success rate was 97% to 99%, with a pooled clinically significant vessel dissection rate of < 5%. Porcine models have shown that there is no increased vessel injury from the in-rolling mechanism of the balloon (Figure 3). Further-0more, the long-term data compared to traditional angioplasty balloons are shown in Figure 4.

Beyond its ability to function as an angioplasty balloon, Proteus also has a unique embolic capture capability. In vitro experiments of a vascular circulatory flow model comparing the capture efficiency of the Proteus balloon to standard filters in different vessel models (changing length of the lesion as well as the angulation) have been performed. Data were presented by Dr. Gary Ansel at the 2009 VIVA meeting in Las Vegas.

Figure 5 represents the capture efficiency in different flow models showing the efficacy of Proteus compared to filter-based systems. Proteus consistently outperformed the filters. Clinical results from the MC-LEADER study are shown in Figure 6. Particles were captured with every use of the Proteus balloon. Particles > 2 mm were captured in 25% of cases and > 6 mm in 6% of cases.

CONCLUSION

Numerous studies have shown that embolic debris are liberated in lower extremity endovascular interventions. The clinical significance of distal embolization can

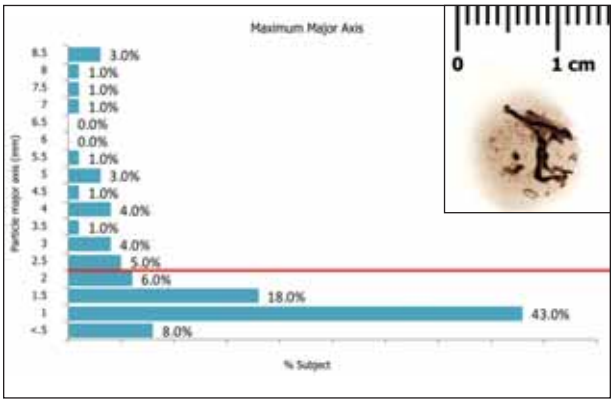

Figure 6. MC-LEADER embolic analysis. Particles removed postatherectomy (inset).

and should be further investigated. Until now, filter-based platforms have been the primary type of embolic protection systems to prevent distal embolization.

With the introduction of the Proteus device, there will be a paradigm shift in how we treat lesions. The Proteus angioplasty balloon is simple to use and has been shown both clinically as well as in bench top models to be effective in both angioplasty as well as embolic capture. ■

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