Prof. Stefan Müller-Hülsbeck, MD

The Principal Investigator of the MAJESTIC trial discusses its recently presented results, as well as his own algorithm for SFA disease and the future of carotid stenting.

What were the key findings in the 9-month data from the MAJESTIC trial of the Eluvia peripheral drug-eluting stent (DES) system (Boston Scientific Corporation), which you presented at Charing Cross 2015?

There was a high primary patency rate (94.4%). I think if you reach your primary patency rate of more than 90% at 9 months and 12 months (which will be presented in the fall of this year), then you are on the right track toward long-term clinical improvement and patency. This stent is something new and exciting. The other big point is that of the 57 patients and 57 lesions we studied, we had no major adverse events due to the stent design, drug, polymer, or delivery system.

What can you tell us about the design of the Eluvia device? What are the unique aspects of the stent itself and its delivery? What is the desired effect of combining a polymer with the paclitaxel?

While most nitinol stents use an open-cell design, Eluvia uses a hybrid design. It has open cells in the middle for flexibility and fracture resistance, and two rows of closed cells at the proximal and distal ends to promote uniform deployment and precise positioning of the stent.

When working with a polymer, the drug delivery process is better controlled. You can influence the timeline of drug delivery in a way that allows you to prolong the delivery of the paclitaxel. Based on the MAJESTIC results, we have shown that the combination of a nitinol skeleton, paclitaxel, and polymer has no disadvantages in terms of safety and has advantages in terms of efficacy.

Lastly, the delivery system of the stent is triaxial. You can grip the outer catheter shaft with one hand, fix it, and it keeps the entire system stable to promote accurate deployment. Having one hand free makes stent delivery very easy, and for younger residents who are training, delivery is very accurate.

In your own practice, which factors determine whether you use a bare-metal stent, a DES, or a drug-coated balloon (DCB)?

This is a very difficult question. In our toolbox, we now have the plain old balloon, DCB, bare-metal and self-expanding stents, and DES. I think we have to distinguish procedural algorithms for superficial femoral artery (SFA) disease. The first step will always be plain old balloon angioplasty in order to prepare the lesion, but then we have to decide how to proceed.

If it looks good, then I think there are a lot of compelling arguments to proceed with a DCB, but we have a lot of patients who have flow-limiting dissections, really ugly-looking vessels after plain old balloon angioplasty, or recoil. In these cases, we now have different options. We can use a bare-metal stent or DES, which depends a little bit on the reimbursement. It also depends on the patency rates. If we look at the patency rates, we know from the Zilver PTX and MAJESTIC data to go ahead with a DES. The primary patency rate and target lesion revascularization rates will be better for the patient compared to bare-metal stents.

I think it really is an option nowadays to say if percutaneous transluminal angioplasty (PTA) fails and there is a need for a stent, as I mentioned earlier, then we can go ahead with DES technology.

Which data or personal experiences have guided your current device decision-making?

The encouraging data from the current trials guide me the most. Zilver PTX is an excellent trial. We also now have additional data emerging from large DCB trials, like IN.PACT SFA and LEVANT 2, which are indicating favorable results. Published randomized trial data is something physicians ask for nowadays when considering an endovascular product. We need really good prospective, randomized data obtained from different centers worldwide, and these data influence my strategy in terms of planning procedural steps, device selection, or what kind of technique to use.

Therefore, at the moment I think the right tools to combat SFA disease via endovascular means include the use a DCB if you don't need a stent, and if a stent is needed, a DES after lesion preparation with simple PTA is ideal. However, there may still be a role for bare-metal stent use after DCB as well.

What do you predict for the future of DCB use below the knee?

In my personal opinion, I will use anything below the knee that helps the patient. We always start with PTA. I will use a stent if there is a need to obtain a straight line to the foot in order to keep the foot in the patient's shoe. I have no objections against drug-eluting technology. I wouldn't expect

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higher amputation rates due to embolization of coating/polymer material. I think in the future, there will be a role for both DCBs and DESs in below-the-knee techniques in combination with standard PTA lesion preparation.

Do you believe that carotid artery stenting is poised for a revival? Why or why not? If so, will this be more global or local in nature?

I think with the combination of current carotid stent technology (eg, dual-layer stents, closed-cell designs), embolic protection devices (eg, distal protection devices, proximal flow reversal devices), and the demographic changes we have observed, there is definitely a revival of carotid stenting on the horizon. So many patients are at high risk for surgery. There are many patients who suffer from multilevel disease, and additional stenosis at the carotid bifurcation or the supra-aortic arteries. In my opinion, these are candidates with clear indications for an endovascular procedure.

What are some of your interests when you're not focusing on your practice?

My most important interest is my family—I am married and have four children. I'm also really interested in a lot of sports like jogging, watersports, and skiing. ■

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