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A vascular surgeon and leader in endovascular research discusses the next generation of peripheral stents, drug-coated balloons, and the progress of carotid stenting.

How would you describe the benefits, drawbacks, and achievable potential of bioabsorbable stents and your approach to their use in your practice? It is a very promising technology. The goal of bioabsorbable stents is to remove the trigger of long-term vessel injury and intimal hyperplasia. The rationale is that you only need a temporary solution (the bioabsorbable stent) for a temporary problem (recoil). Unfortunately, inflammation occurs in every absorption process—both with the absorbable polymer and absorbable metal stent types—and therefore, stent engineers have to find an alloy or structure that balances between a long-term inflammation decrease by the stent removal and the acute increased inflammation due to the absorption process itself.

When selecting the material for the absorbable stent technology, it must be considered that polymers absorb very well and cause less inflammation compared to their metal variants, but they lack radial force, and that is exactly the reason why stent implantation is often required. Absorbable metal stents have good radial force, but they cause more inflammation because they contain magnesium in the alloy. If the degradation process can be slowed down, this may also decrease the inflammation trigger.

As the current generation of polymer stents and absorbable metal stents does not yield satisfactory results, I believe, for the moment, they cannot be used in daily practice. That does not mean that, with an improved design and absorption dynamics, they will not have a place in the future.

What improvements would you like to see in the next generation of SFA stents? The FESTO trial showed us that stent fractures are an issue, and many companies responded by creating stent designs that better resist the forces known to work in the SFA (ie, flexion, compression, torsion, expansion, and contraction) and which seem to effectively address this fracture issue. Trials show us that fewer fractures occur in the newer stents than before. So, by improving their stent platforms and producing longer stents, the manufacturers are currently doing what they should do. Trial data have indicated that it is best to avoid stent overlap because it induces more stent fractures. Treating a lesion with one longer stent is better than treating it with two short stents. With these design modifications and the availability of longer stents, we can start to treat longer and more complex lesions and consider the benefit of eventually adding an active coating on those devices.

What is your opinion regarding drug-coated balloons? It is a very interesting technology. It leaves no doubt that if a permanent treatment solution can be found without the need for stents, this can be of great benefit for the femoropopliteal area. One of the currently investigated techniques is the use of paclitaxel-eluting balloons, which release paclitaxel at the moment of the balloon dilation. A portion of the drug will be washed out in the arterial system, but the remaining dose locally administered at the inner lesion wall may prevent future intimal hyperplasia. This could improve SFA patency rates for an enhanced PTA-alone intervention without having to implant stents. Unfortunately, immediate vessel recoil and flow-limiting dissections after PTA remain an issue and make the drug-coated balloon merely an adjunctive tool for endovascular intervention.

Since you first entered practice, what has been the greatest advancement in endovascular therapy? How has your practice evolved over the last 10 years? In the past 5 to 10 years, the greatest advancement has been the development of specific tools, both stents and balloons, to treat the below-the-knee arteries. At the start, we had only the ability to treat the infrapopliteal vasculature with classical surgery. But, distal bypass for limb salvage is only an option for patients who are good candidates for surgical revascularization. And, as the majority of critical limb ischemia patients with infrapopliteal occlusive disease present with prohibitive comorbidities, inadequate conduit, and lack of suitable distal targets for revascularization, we were often left with no other alternative than to amputate. The introduction of endovascular treatment of below-the-knee arteries in critical limb ischemia patients has changed our practice, and now, we

(Continued on page 89)

(Continued from page 90)
are at a stage where the endovascular approach is our primary strategy to deal with infrapopliteal pathology.

I trained as a vascular surgeon at the University of Münster in Germany, where I performed only classical surgery. Then, I started my practice in Belgium, and we began introducing endovascular techniques. In the beginning, we performed 20% endovascular procedures and 80% open surgery. Our practice has evolved to 75% endovascular and 25% open surgery. In the future, with new materials and devices, we will see a shift toward even more endovascular and less open repair. A key factor, of course, is that vascular surgeons need access to good imaging. Up until 5 years ago, good imaging—meaning angiosuites—was reserved for cardiologists and radiologists only. Now, we see more and more vascular surgeons who use the better imaging in state-of-the-art angiosuites to do their endovascular interventions or to perform hybrid, combined open surgical and endovascular procedures.

What is the future of carotid artery stenting (CAS) in Europe? For the moment, we are stuck. In both Europe and the US, the market for CAS is stagnating or going down. This occurred predominantly since the publication of the poor CAS results in the SPACE and EVA-3S trials. Pushed by industry, we went too fast too quickly with this technology and did not look thoroughly at the procedure and the problems. Contrary to vascular surgery, where you remove the plaque, endovascular procedures compress the dilated plaque against the vessel wall and try to hold it there with the struts of the stent. We missed the importance of scaffolding, especially in symptomatic patients. To revive CAS in Europe and in the US, you not only need centers with better experience but also better materials. We need stents that can better adapt to the anatomy of the carotid artery and achieve a perfect scaffolding of the plaque to prevent those late emboli from occurring. This will create better short-term results from carotid stenting.

How does the curve look in your own practice? We began doing carotid stent procedures in 1995, and we saw the total number of carotid interventions growing until 2 years ago. Since the publication of EVA-3S and SPACE, however, there has been a sudden shift back to carotid surgery in our practice. Whereas over the past few years, approximately 85% of our carotid cases were treated endovascularly and only 15% surgically, we are currently opting for CAS in 60% and for surgery in 40% of all carotid cases.

As a vascular surgeon, I am convinced that carotid stenting and carotid surgery are complementary. Some patients are better treated with surgery, some are better treated with stenting, and the majority can probably be treated with both. It is very important to define the subgroup of patients who really benefit from stenting versus surgery. Then, we have to consider who will perform these carotid stenting procedures. Everyone? Or, do we need only a few very skilled centers to do these elective procedures? Third, we need better carotid devices, especially stents, for CAS. Because the stent's scaffolding capacity is the main influence on clinical events, and as current-generation stents with good scaffolding capacities tend to have insufficient flexibility to optimally accommodate with the vessel's original anatomy, future stent design improvements should focus primarily on optimally combining excellent scaffolding and flexibility.

What have you learned after 1 year of the MELOPEE study, which evaluated the LifeStent in popliteal arteries? Stent design is a key issue, especially in the SFA, and the LifeStent (C.R. Bard, Inc., Tempe, AZ) has proven to be a very good stent in the SFA, and the results in the popliteal, which I presented at ISET in January, are similar. In this very challenging subgroup of popliteal artery stenting, we have achieved primary patency of 70%—which is better than we had expected—and we are also 84% free of fracture in an anatomy where axial compression, extension, and torsion forces are very high. This stent has shown better-than-expected primary patency at 1 year and a low fracture rate in a very challenging anatomy.

As principal investigator in the DESTINY trial, what can you tell us about its goals? The DESTINY trial is a randomized trial in short below-the-knee lesions comparing the bare-metal coronary-type stents versus the active-coated coronary-type stents. It might answer one of the most important questions in treatment of below-the-knee arteries: Do we need active-coated stents to treat these small-diameter vessels? Although current evidence indicates that the implantation of DESs in the infrapopliteal vasculature leads to promising primary patency and limb salvage rates, it is unknown whether the optimized outcome can be contributed as either a stent or as a drug benefit. Therefore, we will compare the angiographic binary restenosis rates for DESs and BMSs at 12 months and see the influence of the active coating on patency. If we can increase the primary patency using a drug on the coronary-type stents, maybe there is an argument for using those stents as a primary stenting approach in short below-the-knee lesions. ■