Bioresorbable Scaffolds and the Future for the “Leave Nothing Behind” Movement: A Discussion With Johannes Lammer, MD

Interview by Jennifer Ford

Johannes Lammer, MD, is professor of radiology and interventional radiology at the Medical University of Vienna in Vienna, Austria. Dr. Lammer is principal investigator for the ESPRIT I trial, which evaluated the safety and performance of the ESPRIT bioresorbable vascular scaffold in subjects with symptomatic claudication from superficial femoral or common or external iliac artery occlusion. He spoke at the 43rd annual VEITH Symposium on bioresorbable scaffolds.

VDM: Could you give us a brief overview of bioresorbable scaffolds?

Lammer: Bioresorbable scaffolds have been well tested in the coronary arteries. Currently, they are made from poly-L-lactic acid. However, there is also experience with magnesium-based bioresorbable scaffolds. The goal of the bioresorbable scaffold is for it to be resorbed in 2 to 3 years so that ultimately there is nothing left behind, but you have the immediate effect of a scaffold, so you have a very good initial result.

VDM: What has the application been for these bioresorbable scaffolds in the peripheral arteries?

Lammer: So far, they have been tested in the superficial femoral artery and in below-the-knee arteries. We have tests from bioresorbable scaffolds without drug elution and those with drug elution. The drug-eluting bioresorbable scaffolds specifically utilize the elution of everolimus, and those are the Absorb scaffolds from Abbott Vascular.

VDM: Have the results for those differed?

Lammer: They differed very much. The first tests were of the Igaki-Tamai scaffold (Igaki Medical Planning Co.), which is the Japanese scaffold, which was tested 10 years ago or more than 10 years ago in the coronary arteries. In the GAIA study, they were tested without drug elution and the results were quite disappointing. There was a 1-year restenosis rate of 68%. It was retested in a second study together with a drug-eluting balloon. This reduced the restenosis rate from 68% initially to 58%, but this was still disappointingly high. So, obviously, they need drug elution in the coronary scaffold. The Absorb scaffold is a drug-eluting scaffold anyway.
VDM: You are also going to present on the ESPRIT trial. Could you give us some background on the design for that?

Lammer: The ESPRIT bioresorbable vascular scaffold (Abbott Vascular) is of course an investigational device. It also has everolimus drug elution, and it was tested in a trial in 35 patients with TASC A lesions – short lesions, mainly in the superficial femoral artery (SFA). A few patients also had external iliac artery disease. There was a 3-year follow-up. At 1 year, there was a primary patency rate of about 80% and freedom from target lesion revascularization (TLR) of more than 90%, and at 3 years, freedom from TLR was still 88%, so these were quite promising results.

VDM: Do you think that these results might influence endovascular clinicians to give the bioresorbable scaffold a shot?

Lammer: Yes, I’m fairly sure they will. I’m sure that this is the future. Three years ago, drug-eluting balloons were the new technology, and endovascular clinicians were talking about leaving nothing behind. Now, since we have 3-year results from the drug-eluting balloons, we know that they have their limitations in long lesions, in calcified lesions. So this is not a stand-alone therapy.

We now have very good results from drug-eluting nitinol stents, but the ideal combination would include these bioresorbable scaffolds, which disappear after 2-3 years leaving nothing behind, and drug elution. Obviously, it’s not easy to have the right design. Many companies have already tried to develop these scaffolds and some already have also unfortunately failed. Regardless, I think that this is the future of endovascular treatment of SFA disease.

VDM: What questions remain to be answered about bioresorbable scaffolds?

Lammer: One question that remains is, what is the right material for the scaffold? Poly-L-lactic acid has been tested, but we know that without drug elution it has a relatively high inflammatory response. Magnesium has been tested. Without drug elution it also had poor results. So it would be great to find a material that has less inflammatory response and potentially does not need drug elution.

VDM: If you wanted to tie together a take-home message for the endovascular clinician about bioresorbable scaffolds, what would that be?

Lammer: I would say the future is of course the bioresorbable scaffold because we have what we need. We need a scaffold or a stent with an excellent initial result and we need a drug to prevent late restenosis. Ideally, we should not leave anything behind, especially in case a secondary vascular surgical intervention is needed. Therefore, I think the concept of the bioresorbable scaffold is the ideal concept and I hope that industry, which obviously knows that this is the ideal concept, is putting enough effort into the development of these bioresorbable vascular scaffolds together with drug elution.
REFERENCES

