**Title: LINC 23: MOTIV Bioresorbable Scaffold in BTK Lesions**

**Participants: Dr Michel Bosiers**

**Date: 7/06/2023**

**Dr Michel Bosiers**

"Hello everybody. My name is Michel Bosiers. I'm a vascular surgeon at the University Hospital Bern in Switzerland and we're going to discuss today the one-year results of a new bioresorbable drug eluting scaffold called MOTIV by Reva Medical for the use in BTK lesions.

**What was the objective of this trial?**

So, after gaining its CE mark approval, we wanted to check how it works in real life. So, we wanted to see its efficacy and its safety in a post-market clinical trial.

**Tell us more about the MOTIV Scaffold, and its unique features.**

So, the MOTIV scaffold isa bioresorbable drug-eluting scaffold. It has the drug sirolimus bounded to it. And regarding the other devices out there which are bioresorbable, the polymer is called Tyrocore, which is a proprietary bioresorbable polymer and it's derived from the tyrosine amino acid. It's also iodine bounded, so it's more visible than the other devices on the market. And if we compare it to poly-l-lactic acid, it’s twice as strong and ten times more ductile. And what's another great feature is that the problem in the past was that all these devices had thick struts, so they managed to have thin struts and without losing their radial force. Now they have the highest radial strength on the market available.

**What was the patient population and study design?**

The study design was that we did a prospective single-arm multicentre study. We enrolled 58 patients with 60 study limbs, and we wanted to follow up, do the follow-up. Until three years after implantation we only included patients with Rutherford four and five. So, a real-world critical limb ischemia population and we were able to treat de Novo lesions or restenotic lesions after PTA. And what was also great about it that you could treat the entire length of the, for example, tibial posterior artery, but the total length of stenting couldn’t be longer than 10cm. We had 84% males and we had 66% diabetes.

**What was the key data released at LINC 2023?**

So, the primary endpoint regarding vessel patency was 88.3% after twelve months. We also had a 99% technical success rate. We had excellent tracking and visibility during implantation. We were able also to implant multiple scaffolds in the same patient with precise placement and we have seen no delivery or no device-related complications whatsoever. There was one patient with a clinical driven TLR of those 58 patients. So excellent results with great improvement in Rutherford classification and wound healing as well.

**How should the findings of this trial impact both future research and clinical practice?**

Well, I think we now need to see it in larger trials and randomized controlled trials and that’s a good thing that it's already on its way. So, Reva Medical is conducting the BTK randomized controlled trial which will be a prospective, multicentre, single-blinded randomized controlled trial comparing MOTIV versus POBA. They want to include 292 patients also again with Rutherford four and five. So, no Rutherford stage three or six with a total lesion length up to 120mm.Also you can treat two different kinds of arteries and they exclude, of course, severe calcified patients. So, I think this is a big step forward and then the next step would be, of course, to compare these results with the classic drug eluting stents that we nowadays use in BTK lesions.”