Title: LINC 22: PRELUDE-BTK With Dr Lichtenberg: Serranator® PTA in Pts With PAD
Participants: Dr Michael Lichtenberg
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Dr Lichtenberg:

Hello, my name is Michael Lichtenberg from Arnsberg Vascular Centre. I'm interventional angiologist, practising in the arterial and venous field for many years now.

What is the function of the Serranator® PTA?

Dr Lichtenberg:

What is serration? Serration is nothing else than an effective lesion preparation strategy. We learned in the past that standard balloon angioplasty is not a sufficient lesion preparation strategy. It causes dissection, it causes recoil, which forces us then to scaffold implantation, long stent implantation. And that is something we definitely want to avoid, especially in patients with BTK disease.

The Serranator as a scoring, as a serration technology, prevents dissection and recoil, even in very complex lesions below the knee.

What is the reasoning behind this study?

Dr Lichtenberg;

So the reason is to evaluate safety and efficacy as a first in human trial for this device. So it's natural to set up a registry, a prospective trial to evaluate safety and efficacy, especially for this very complex lesion cohort, BTK patients, critical limb ischemia patients, and analyse efficacy and safety of such a new scoring serration technology for these patients.

What was the inclusion/exclusion criteria, and what was the study design?

Dr Lichtenberg:

So this was a multicenter prospective trial, including centres from Europe and New Zealand. And we included patients with BTK disease, calcified lesions, non calcified

lesions, and what we found in conclusion in this prospective study was that dissection rate was low.
Bailout stent rate was zero. So we did not need any stents, because no dissection, no significant recoil occurred with serration technology. And I think that is something we could really take out of this study, that an intensive and effective lesion preparation prevents dissection and recoil, and with the serration technology, I think we have a very promising tool here.

What are the next steps?

Dr Lichtenberg:
So the next step is definitely to organise even larger prospective registry, including even more complex lesions, more centres, more patients that also include above the knee. And there's now an above the knee serration Serranator available, and I'm really looking forward to include now patients also for this prospective trial for patients with superficial femoral artery and popliteal disease.