**Title: VIVA 22: Results From a Post-Market Study of the Rotarex®S Atherectomy and Thrombectomy Catheter System**

**Participants: Dr Michael Lichtenberg**

**Date: 14/11/2022**

**Dr Michael Lichtenberg**

" - Hello, my name's Michael Lichtenberg from Arnsberg Vascular Centre. It's a pleasure to discuss with you today on a very exciting technology. I'm interventional angiologist and I will discuss today data on the Rotarex PMCF trial.

**The Rotarex Atherectomy/Thrombectomy Catheter**

So this catheter is a catheter which can perform thrombectomy and atherectomy in one attempt. It's a rotational thrombectomy and atherectomy system, which comes in different sizes. Six French, eight French, and also you have available 10 French device. The technique within this catheter is the Archimedes principle. There's a inner helix which runs with 40,000 to 60,000 rounds per minute, creating a high negative pressure, with that it sucks out thrombus, or debris, or atheroma within the SFA popliteal segment, down to lesion size of three millimetre diameter of the vessel. And with that we have the opportunity to treat different morphologies of lesions.

**Patient Population and Study Design**

So we include patients with chronic limb ischemia and acute limb ischemia. Mainly chronic limb ischemia patients were included, more than 200 patients in total. Most of these patients where chronic limb ischemia patients. Of course, also some of these patients had acute limb ischemia. We analysed safety and efficacy of this rotarex device for these two indications meaning for chronic and acute limb ischemia.

**Key Findings at One Year**

So we found out that this device is highly successful in terms of procedural success of technical success. Procedural success means that after Rotarex atherothrombectomy plus adjunctive therapy had a very good lumen gain was less than 30% restenosis. Technical success sounds a little bit less with 47% but this technical success only analysed the Rotarex performance. In terms of thrombectomy and atherothrombectomy usually you find an underlying reason like an hybrid stenosis or other issues plaque rupture which then needs additional adjunctive therapy. So this is the reason why technical success of 47% is not that high. But the procedural success, Rotarex plus adjunctive therapy led to a very good outcome of 97% for this combination therapy.

**Take-home Messages**

So for the different lesion morphologies including calcification, including fibrotic tissue including in-stent restenosis including thrombosis, embolism situations you can use this Rotarex device as a safe and effective tool to perform thrombectomy atherothrombectomy or in certain situations, even atherectomy. So this device can deal with this different morphology leading to very good procedural success, and it is safe. We did not find significant issues in terms of safety within this prospective PMCF trial.

**Further Study Required**

So we hope to see a device which also can deal with vessel diameter less than three millimetres in the in the future. This is the shortcoming of this device at the moment that the minimal diameter of the vessel has to be three millimetres. So I don't think distal to TP trunk, mid-tibial arteries distal tibial arteries cannot be treated with this Rotarex device. So there is now the hope that a smaller device will come up soon so that we can even use this device in more distal lesions to de-clot lesions or to treat different morphologies in the tibial arteries.”