

**Title: LINC 23: RANGER II SFA: 3 Year Patency and 4 Year Clinical Safety**  
**Participants: Dr Marianne Brodmann**  
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## **Dr Marianne Brodmann**

“So, my name is Marianne Brodmann. I’m a vascular specialist and angiologist here in Austria, in Graz, at the Medical University, and I have a long experience regarding interventional procedures in any kind of PAD areas. And I'm now talking about the ELEGANCE registry, which is my opinion, an outstanding registry because it's focusing on groups of sub-groups and groups of patients we have never evaluated in trials so far.

### **Unmet Need Addressed with this Registry**

When you look at the different randomised controlled studies out there for claudication, for example, also for critical limb ischemia, so many patients included in this trial are usually males regarding the gender. So that's an unmet need. So, females, who usually present at a much later status with a much higher degree of PAD disease, mainly critical limb ischemia, are not evaluated in trials. So that's an unmet need. So, females are underrepresented in clinical trials. That's the one point. The second point is that we are not focusing randomised controlled studies because they have maybe been done in high-graded institutions in Europe, US. Australia or wherever worldwide. So, we are not focusing on underrepresented minorities. We are not looking those Hispanic or those black or Asian or Caucasian or whatever group of people have the same outcome or what are the differences regarding risk factors? Maybe we know that Asian people have a higher degree of diabetes that might have an impact on the outcome of an intervention we are doing. So, it's very important to find these differences. And I think this is the outstanding setup of this ELEGANCE registry that we are really focusing on females and underrepresented minorities. And I would say it's an underrepresented minorities because females are also underrepresented minorities in the different trials.

### **Key Findings**

So, we have in the meantime, I was able to present at LINC last week, more than 500 patients already evaluated. So, it's an interim analysis. So that was very interesting, and I was able to show the differences already in this patient cohort. We are right now above the goal we have set for this trial. So, we wanted to include more than 40% of female patients and 40% of underrepresented minority groups. So, we are over the goal. We are over 40% with females. We are over 40% with underrepresented minorities. First outcome data, second outcome data. We are seeing the differences. We are seeing the differences regarding female presentation, male presentation, females are usually older. Females have much more critical limb ischemia when they are first treated. So, regarding risk factors, for example, Asians, as I've already mentioned, have much a higher degree of diabetes. So, we already see differences between the different patient cohorts, and I think that's very important. And we will see more and more we will see the difference in the lesion level. It's just an interim analysis right now. This is something which is of interest right now around we have a little bit more than 1000 patients included, but we don't have the interim analysis of

this patient because this enrolment is still ongoing, and I think that will really be eye-opening for us. Another issue is, and I think that's also very important, as I mentioned, why we are able to include this underrepresented minorities in that way that with regard to the sites we were looking for and choosing for being involved, in the trial that the sites are also with regard to sites PI, we have a lot of sites PI who are females that's also unique, and we also have a lot of sites PI who are people from groups of underrepresented minorities, black, Asian, and Hispanic. So, I think that will also make the difference in this study.

### **Take-Home Messages**

We need to look at different patient cohorts in a different way and I think we cannot read everybody the same way. We in the future we need to distinguish between patient cohorts regarding sex and race and I think that will be the key finding of the ELEGANCE registry.”