

**Lunch symposium: SELUTION SLR™: A breakthrough in drug-eluting balloon technology** Main Arena 2 Tuesday 12.30–13.25

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Thomas Zeller



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Tjun Tang



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## A breakthrough in drug-eluting balloon technology

**S**ELUTION SLR Sirolimus-Eluting Balloon two-year results demonstrate excellent safety and efficacy in treating SFA and popliteal lesions

Two-year safety and efficacy data for the SELUTION SLR™ (MedAlliance SA, Switzerland) sirolimus drug-eluting-balloon (DEB) in the treatment of superficial femoral artery (SFA) and popliteal lesions were presented at LINC yesterday.

SELUTION SLR features a proprietary coating containing MicroReservoirs made from a biodegradable polymer which provide controlled and sustained release of sirolimus. MedAlliance’s Cell Adherent Technology (CAT™) allows the MicroReservoirs to be coated onto balloons and adhered to the vessel lumen after angioplasty.

The SELUTION SLR First-in-Human study of the device was a prospective, controlled, multicentre, open, single-arm clinical investigation. The primary endpoint of the study was angiographic late lumen loss (LLL) at six months, while secondary endpoints included major adverse events (MAE), primary patency, and angiographic binary restenosis. The study involved 50 patients treated with the investigational device in lesions of the SFA and popliteal arteries. Clinical and duplex ultrasound at multiple timepoints, and/or angiographic assessment (six-months only) were undertaken.

Discussing the trial yesterday was principal investigator Thomas Zeller, Director of the Department of Angiology at Universitaets-Herzzentrum, Freiburg-Bad Krozingen, Germany, who reported clinical improvements in Rutherford classifications, ankle brachial index (ABI) and walking impairment at six and 12 months, all of which were maintained at 24 months. A median LLL of 0.19 mm at six months was also recorded, meeting the primary endpoint.

“These two-year results from the SELUTION SLR First-In-Human study are very encouraging,” Professor Zeller commented.<sup>1</sup> “They are the first two-year data for a balloon eluting either a limus drug or sirolimus, and are confirmation that a sustained limus-eluting balloon is both safe and effective in the treatment of SFA lesions over a prolonged period.”

Professor Zeller added<sup>2</sup>: “These results support CE Mark submission of the SELUTION SLR 018 PTA.”

Peter Gaines of Sheffield Hallam University, Sheffield, UK, a medical adviser to MedAlliance, described the SELUTION SLR to *LINC Today* as a “breakthrough”. Until now, he said, it’s been very difficult to use sirolimus in the legs due to difficulty getting drug uptake in the artery wall. But MedAlliance’s proprietary system has changed all that: “The MicroReservoirs on the balloon increase the uptake in the artery wall and keep the drug in the artery wall for a prolonged period, so you get sustained and effective release,” commented Professor Baines.

“Peripheral interventionists will, I imagine, be very keen to get their hands on this device, as we know that sirolimus works better than other drugs in the coronary arteries, and there’s no reason to believe it won’t be as effective in the peripheral arteries. Other companies are developing sirolimus-eluting balloons, but this is the first to have the clinical data behind it.”

Professor Gaines relayed that a CE mark for SELUTION SLR is now expected, and MedAlliance are looking to launch the device in Europe in the next two months. Earlier this month, MedAlliance, the first drug-eluting balloon (DEB) company in the world to receive US Food and Drug Administration (FDA) Breakthrough Device Designation Status for a sirolimus DEB, was awarded breakthrough status for SELUTION SLR, in the treatment of AV-Fistula indications. This is the third breakthrough designation awarded to MedAlliance for its sirolimus DEB, following coronary in-stent restenosis and peripheral below-the-knee indications. Looking ahead, plans are now set for an Investigational Device Exemption Study (IDE) in the US in the third quarter of this year.

In Europe, the company will be collecting long-term clinical data as part of post-marketing surveillance work, are about to start another study in the foot, and have already recruited for the Singapore-based PRESTIGE study (Physician initiated, prospective, non-Randomized single-center trial, investigating the safety and Efficacy of the Treatment with the Selution Sirolimus Coated Balloon in TASC C and D Tibial occlusive disease In patients with critical limb Ischemia from SinGaporE) looking at the treatment of long tibial occlusive lesions (TASC C and D) in patients with critical limb ischaemia (CLI).

During yesterday’s session, co-principal investigator Tjun Tang, senior consultant from the Department of Vascular Surgery at Singapore General Hospital, Singapore introduced the PRESTIGE study. The primary objective was to evaluate the 6-month safety and performance outcome of the SELUTION SLR Sirolimus DEB in patients with CLI (Rutherford 4-6). Endpoints were freedom from device- or procedure-related mortality through 30 days and freedom from target lesion revascularization (TLR) at 6 months and 12 months post-procedure. Secondary endpoints included clinical success, wound healing and amputation free survival.

Inclusion criteria were challenging TASC C or D target tibial artery lesions (> 10 cm in length) with angiographic evidence of stenosis > 50% or complete occlusion. Twenty-five patients were enrolled in the study, with follow-up planned at 1, 3, 6 and 12 months. Full recruitment was achieved relatively quickly over a three-month period (October – December 2019) because the majority of lower limb revascularisation at Singapore General Hospital is for tissue loss (95%), rather than claudication (5%).

The patient group was challenging with the majority being diabetics (88%) and on dialysis for end-stage-renal failure (44%). “We had a liberal inclusion criteria for the study to represent what we see day-in, day-out in our endovascular practice for diabetic foot salvage – similar to a registry cohort rather than a tightly controlled RCT population,” said Associate Professor Tang. “We wanted to see if SELUTION SLR was a potential solution to help improve the primary patency rates of our occlusive tibial vessels to aid wound healing in some of our sickest patients “Patients generally had heavily calcified blood vessels (approximately 60% of tibial arteries were intervened on), and arteries below the ankle were treated with angioplasty in about 20% cases. ”

He added: “Overall, our early results are encouraging. We have had no adverse SEB-related events in our study, only two patients had to be re-operated on for TLR (an excellent result for these types of lesions), and we have had no major lower extremity amputations. The SELUTION SLR balloon tracks well over an 0.018” wire system and has a short deflation time with good visible markers making it an ideal balloon platform to deliver the drug to its intended target. Normally, when you use paclitaxel coated balloons below the knee you get this ‘slow flow’ phenomenon, which has been attributed to drug embolisation, but this didn’t happen with the sirolimus SELUTION SLR balloon even operating below the ankle, which was wonderful to see.

“We have also noted that some of our complex wounds have started healing well (wound contraction of more than 50%) within 3 to 4 weeks. Can we attribute this to sirolimus or the lack of paclitaxel use?! I don’t know, but we have noticed a good effect, and I am looking forward to presenting the 6-month results later this year.”

Associate Professor Tang concluded his talk by showing some extreme examples from the PRESTIGE cohort data and the complex endovascular tibial artery reconstruction work he and his team perform at Singapore General Hospital using the SELUTION SLR balloon.

Aloke Finn, an interventional cardiologist from Gaithersburg, USA, spoke about insights from pre-clinical data and told LINC that the SELUTION SLR represented an important breakthrough in this space “as it allows successful transfer of sirolimus into target tissues.”

### References

1. MedAlliance. Safety and Efficacy Sustained Over Two Years in SELUTION SLR™ First-in-Human Trial. Press Release, 5 November 2019. Available at: <http://medalliance.com/2019/11/05/safety-and-efficacy-sustained-over-two-years-in-selution-slr-first-in-human-trial/>.
2. Zeller T. A Novel Sustained Limus Release Eluting Balloon: 2-Year Data from the SELUTION SFA Trial. Presentation at VIVA 2019.