challenges of infrapopliteal disease, providing temporary mechanical scaffolding for reduction of vessel recoil and dissection, as well as channels in the arterial wall to improve drug update when followed by a drug-coated balloon. The purpose of this study is to evaluate the safety of the Spur when used with a commercially available sirolimus-coated balloon for the treatment of infrapopliteal artery disease (Rutherford class 3-5).

Methods: The DEEPER LIMUS trial is a prospective, non-randomized, single-arm pilot study conducted at a single center (University of Graz, Graz, Austria). Eligible subjects undergo treatment with the Spur, followed by a commercially available, sirolimus-coated balloon. Follow-up occurs at 1, 3, 6, and 12 months post-procedure. The primary endpoint is a composite of the occurrence of all-cause mortality, major amputation (above the ankle), and clinically driven target lesion revascularization at 6 months. Secondary endpoints consist of core-lab adjudicated late lumen loss and primary patency at 6 months, improvement in clinical outcomes, freedom from major adverse limb events (MALE) and all-cause perioperative death at 30 days, and freedom from MALE at 6- and 12-months post procedure.

Results: Enrollment in the trial is ongoing. Twenty-six subjects are enrolled in the trial at the time of writing. As of October 2022, 22 subjects reached 6 months follow-up and have been evaluated for the primary safety endpoint. During the 6-month timeframe, one subject underwent clinically driven target lesion revascularization, one subject underwent a major amputation at 30 days, and one subject died (3/22; 13.6%). All subjects have met the secondary safety endpoint of freedom from MALE and perioperative death, and 21 of 22 (95%) and 15 of 16 (93.8%) of subjects have met the secondary safety endpoint of freedom from MALE at 6 and 12 months, respectively. Patency by angiogram at 6 months is 15 of 18 (83%). Subsegmental late lumen loss is 0.41 mm (+ 0.69 mm).

Conclusion: Preliminary results suggest that the Temporary Spur Stent System is safe for treatment of infrapopliteal artery disease. Further research must be conducted to determine long-term safety and efficacy.

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Treatment of Severely Calcified Complex Infrainguinal Lesions With the Novel ByCross Rotational Atherectomy Device: Results From a Prospective, Non-randomized CE-Mark Study

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Objective: The aim of this study was to demonstrate safety and effectiveness of the novel ByCross Atherectomy System (Plus Medica GmbH & Co., Düsseldorf, Germany) for percutaneous treatment of complex severely calcified infrainguinal lesions using either wire guidance or initial passage without wire.

Methods: Thirty-nine patients with 41 lesions were treated in a prospective, non-randomized pre-market approval study (ClinicalTrials.gov identifier NCT03724279) across two German centers between September 2018 and October 2019. Mean patient age was 72 years, and 62% were male. The average lesion length at the level of the superficial femoral artery and popliteal artery down to the tibioperoneal tract was 125 ± 118 mm (53.6 mm in center 1, and 229.2 mm in center 2; overall range, 30-450 mm). The average reference vessel diameter was 5.2 ± 0.85 mm, and mean stenosis was 96.4% ± 6.2%. Eleven (26.8%) of 41 lesions were passed without wire guidance. The primary performance endpoint was defined as acute procedural success with a post-atherectomy residual stenosis of ≤50% and post-procedure residual stenosis of ≤30%. The primary safety endpoint was the major adverse event (MAE) rate through 30 days. Secondary endpoints were stenosis of the target lesions measured by duplex ultrasound and the ankle brachial pressure index at discharge, 30 days, and 180 days, as well as any MAE through 6 months.

Results: The acute procedural success per protocol (≤50% residual stenosis after atherectomy and ≤30% residual stenosis after adjunctive treatment) without any embolization was achieved in 39 of 41 patients (95.12%) and was independent from wire guidance or wireless passage (11/41; 26.82%). No embolic protection was used, and adjunctive angioplasty was performed in 40 of 41 lesions (97.56%) with additional stenting in 12 of 41 (29.26%). All patients were free from device-related MAEs at 30 days. Six months follow-up was completed for 36 lesions. The mean level of stenosis was 5.7% at discharge, and 21.7% at 6 months. No outcome difference was found between procedures with or without wire guidance for recanalization.

Conclusion: Based on the high rate of technical success and the low rates of MAEs through 6 months, the ByCross Atherectomy System has shown to be safe and effective for the initial passage and atherectomy of complex and severely calcified lower-extremity TASC A-D lesions, even without wire guidance.

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Computational Fluid Dynamics for the Prediction of Endograft Thrombosis in the Superficial Femoral Artery

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Objective: Contemporary diagnostic modalities, including contrast-enhanced computed tomography (CTA) and duplex ultrasound, have been insufficiently able to predict endograft thrombosis. This study introduces an implementation of image-based computational fluid dynamics (CFD), exemplified with four patients treated with an endograft for occlusive disease of the superficial femoral artery (SFA). The potential of personalized CFD for predicting endograft thrombosis is investigated.

Methods: Four patients treated with endografts for an occluded SFA were retrospectively included. CFD simulations, based on computed tomography and duplex ultrasound, were compared for patients with and without endograft thrombosis to investigate potential flow-related causes of endograft thrombosis. Time-averaged wall shear stress (TAWSS) was computed, which highlights areas of prolonged residence times of coagulation factors in the graft (Fig).

Results: CFD simulations demonstrated normal TAWSS (>0.4 Pa) in the SFA for case 1 and 2, but low levels of TAWSS (<0.4 Pa) in cases 3 and 4, respectively. Primary patency was achieved in cases 1 and 2 for over 2 years of follow-up. Case 3 and 4 were complicated by recurrent endograft thrombosis.

Conclusion: The presence of a low TAWSS was associated with recurrent endograft thrombosis in subjects with otherwise normal anatomic and ultrasound assessment and a good distal run-off.

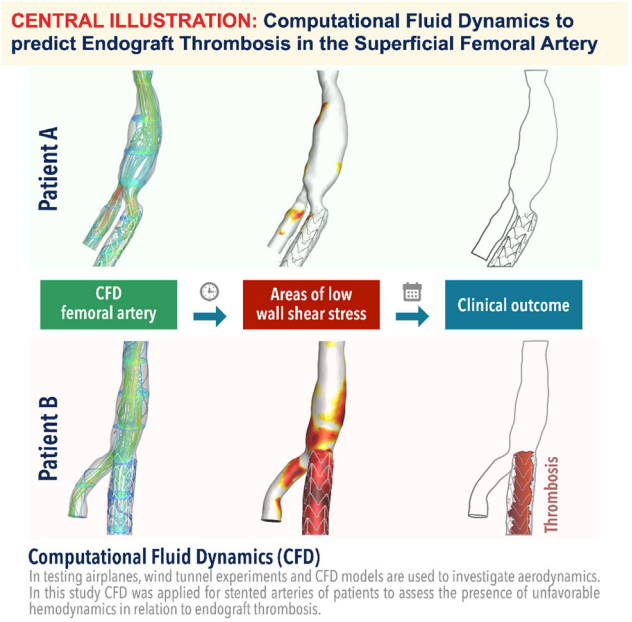

Fig. Illustration of computational fluid dynamics (*CFD*).

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