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Percutaneous Femoropopliteal Bypass Using the Novel PQ Bypass DETOUR Procedure for Long-Segment Disease: Interim Safety and Efficacy Data from the DETOUR I Trial

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BACKGROUND Unlike short-segment femoropopliteal disease, where percutaneous revascularization is durable, long-segment disease presents unique challenges and an optimal first-line therapy has yet to be recommended. Percutaneous revascularization is less traumatic compared to open surgical bypass but lacks durability in long-segments. Open surgical bypass is the gold standard for durability in long-segment disease, but is associated with increased morbidity, and longer length of stay and recovery times. Percutaneous femoropopliteal bypass is a newly developed procedure that combines the safety and minimally invasive benefits of percutaneous revascularization with the long-term durability of surgical bypass. The DETOUR I trial evaluates the safety and efficacy of the PQ Bypass DETOUR procedure in long-segment femoropopliteal disease.

METHODS This is a prospective, multi-center, non-randomized, single-arm trial. Primary 6-month safety endpoint Major Adverse Events (MAE); defined as death, TVR, and major amputation of the target limb. Primary performance endpoint primary patency at 6 months; defined as PSVR of $\leq$ 2.5. Proprietary devices are used to create anastomoses between the artery and vein at the proximal and distal margins of the SFA occlusion. Proprietary stent grafts are deployed in continuous overlapping fashion to create an SFA to popliteal artery bypass within the femoral vein.

RESULTS 60 subjects were enrolled and treated. Mean age was 64 $\pm$ 9 years (68/68). The DETOUR procedure achieved technical success in 98.3% (59/60) of cases. Independent Core Lab-assessed screening CTAs indicate a mean lesion length of 28.6 $\pm$ 5.1 cm (60/60), with 96.7% (58/60) chronic total occlusions. The primary safety and efficacy endpoints were met at 3.4% MAE at 30 days with 0 cases of DVT and 84.7% primary patency at 6 months. At 6 months, MAE was 10.2% and 91.2% of subjects had a $\geq$ 2 class improvement in Rutherford Becker Class. Longer-term data presented on date of podium presentation if accepted.

CONCLUSION The novel DETOUR procedure can be performed safely and effectively. It may be an important step forward in establishing a new standard of care for patients with long-segment femoropopliteal disease.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

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Drug Eluting Scaffold with an absorbable platform for primary lower extremity arterial revascularization – DESappear Study Initial Results

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BACKGROUND Bioresorbable scaffolds may address limitations of drug-eluting balloons and stents for superficial femoral artery (SFA) atherosclerotic disease by: preventing acute recoil, reducing restenosis; and allowing area retreatment made difficult with stents. The Akesys Prava is a balloon expandable poly L-lactide-based polymer scaffold incorporating the drug sirolimus (rapamycin) available in 5mm and 6mm diameters and 18 and 57mm lengths. The scaffold is loaded with approximately 17μg sirolimus per mm of scaffold length, elutes approximately 30% of the drug over 4 weeks with a shorter bioresorption time [>90% reduction in molecular weight within 6 months with near complete bioresorption by 1 year (~70% mass loss) in preclinical studies].

METHODS The DESappear Study is a multicenter, prospective, single-arm, safety and performance evaluation of the Akesys Prava Sirolimus Eluting Bioresorbable Peripheral Scaffold System for the treatment of de novo SFA lesions through clinical and imaging endpoints. Key inclusion criteria are symptomatic claudication (Rutherford 2-4), vessel diameter $\geq$ 5.0 mm to $\leq$ 6.0mm, lesion length $\leq$ 53 mm and target lesion $\geq$ 50% DS. Subjects will undergo clinical and duplex ultrasound (DUS) follow-up assessments at 1, 6 and 12 months and annually up to 3 years. The primary safety endpoint is the composite of freedom from perioperative death through 30 days and freedom from major adverse limb events, or major open surgical revascularization through 6 months. The primary effectiveness endpoint is primary patency defined as freedom from restenosis using DUS or clinically-driven target lesion revascularization through 6 months. An imaging cohort of 10-15 subjects will undergo angiographic and optical coherence tomography (OCT) imaging following scaffold deployment and repeat angiography with OCT at 6 months.

RESULTS The study is currently enrolling and will include up to 60 patients in Europe and New Zealand.

CONCLUSION The DESappear study will evaluate the safety and performance of the Akesys Prava scaffold. Acute and long-term data will be presented for enrolled patients.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

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Long-Term Outcomes after Endovascular Intervention of External Iliac Arteries

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BACKGROUND The literature suggests that external iliac involvement (EIA) involvement is a predictor of iliac artery restenosis and loss of primary patency, possibly due to the presence of more extensive outflow disease. It is uncertain whether chronic total occlusions (CTO) influence the procedural success and long-term patency of EIA intervention. This study aims to evaluate the association between a CTO and long-term outcomes among patients undergoing endovascular intervention to the external iliac artery.

METHODS A two-center retrospective study of 481 EIA atherosclerotic lesions undergoing endovascular intervention between 2006 and 2016 was conducted. Target lesion revascularization (TLR) and major adverse limb event (MALE) rates were compared among lesions with or without an external iliac CTO. A Cox proportional hazard model was subsequently developed to determine baseline variables associated with long-term outcomes after successful endovascular intervention of stented EIAs.

RESULTS During the study period, 331 patients were identified with 481 lesions in the external iliac of which 115 (24 %) were CTOs. The majority of patients (60%) were treated for claudication; 38% of lesions were TASC C/D. The baseline ankle brachial index (ABI) was lower among patients treated for CTOs (0.54 vs. 0.65, $p<0.001$), and the mean lesion length was longer (84 vs. 50 mm, $p<0.001$). While overall procedural safety was excellent, vessel perforation (2.7% vs. 0.3%, $P=0.02$) and distal embolization (2.7% vs. 0.9%, $P=0.02$) were more common in the CTO group. Among 377 lesions (CTOs, n=93) that were successfully treated with stent placement, the overall 1-year primary patency was 78% and secondary patency was 92%. One-year and five-year TLR rates were 8.2% and 15.4% respectively.CTO intervention was associated with higher 5-year TLR rates in the unadjusted analysis (HR: 1.72; 95% CI: 1.00 - 2.56; $P=0.050$), but the association did not remain significant after multivariable adjustment.