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PQ Bypass today released subset analysis results from the Detour 1 clinical trial of its Detour system designed to treat long-segment blockages in the femoropopliteal artery, touting a 2% rate of major adverse events and no deaths or amputations at 30 days.

The data was presented today at the Vascular InterVentional Advances conference, the Sunnyvale, Calif.-based company said.

Results came from a 6-month subset analysis of 50 patients who underwent percutaneous treatment of femoropopliteal blockages with lengths between 25 cm and 45 cm, the company said. PQ Bypass said it was sucessfully able to treat the blockages without "significant impact on venous health."

Primary patency at 6 months was reported at 88.9% with optimal placement, and a primary patency of 76.9% was reported overall. Rutherford Class improvements of at least 2 grades were reported in 92% of patients, with significant improvements in ankle brachial index and no impact on venous function reported, the company said.

"Patients with long segment femoropopliteal blockages are in need of advanced therapeutic alternatives to existing treatments. While endovascular revascularization is effective in shorter lesions, its durability in longer segment blockages has not matched that of open surgery. Fully percutaneous bypass is designed to combine the durability advantages of surgical bypass with the minimally invasive advantages of a percutaneous procedure. The outcomes we are seeing in the Detour I trial indicate that a fully percutaneous bypass procedure has potential to fill this gap in treatment options," Cleveland Clinic Vascular Surgery dept. chair Dr. Sean Lyden said in a prepared statement.

The PQ Detour procedure is a fully-percutaneous femoral-popliteal bypass procedure which uses fluoroscopic guidance to deploy Torus stent grafts from the popliteal artery into the femoral vein, and from the femoral vein into the superficial femoral artery through 2 independent anastomoses.

PQ Bypass' Torus stent graft is an expanded polytetrafluoroethylene-covered self-expanding nitinol stent designed to improve blood flow in patients with symptomatic peripheral artery disease in superficial femoral artery de novo and restenotic TASC II C and D lesions.

"PQ Bypass has long been committed to addressing the need for value-based, patient-centered advancements in PAD that help minimize trauma, reduce length of stay and

improve recovery times, while also providing a safe and effective clinical solution for these patients who are in need. These data demonstrate the potential of the Detour procedure in extremely long SFA lesions. We look forward to continuing our path toward regulatory approval with Detour II, a pivotal trial that we anticipate initiating by the end of this year," board chair Richard Ferrari said in a press release.

In March, PQ Bypass said it won CE Mark approval for 3 devices designed to treat patients with superficial femoral artery lesions due to peripheral artery disease.

The post PQ Bypass touts subset analysis data from Detour system trial appeared first on MassDevice.