Pipeline Report: A Look at Next-Generation SFA Technologies

A review of the recent advances in lesion crossing, atherectomy, vessel preparation, and drug delivery technologies.

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The armamentarium for endovascular interventions has expanded considerably since 1964, when Dotter and Judkins performed the first transluminal dilation of peripheral arteries.[1] Because atherosclerosis of the superficial femoral artery (SFA) is the most common site for symptomatic peripheral vascular disease and there is a wide heterogeneity in lesion characteristics, various treatment modalities have been developed to achieve immediate technical success and ensure long-term patency. Today, rapid progress in the evolution of endovascular technologies and techniques is ongoing, allowing for the treatment of highly complex and long SFA lesions. This article provides a snapshot of some of the recent advances in SFA treatment technologies that have the potential to improve the current standard of care.

LESION CROSSING

For crossing difficult chronic total occlusions (CTOs), the GoBack crossing catheter (Upstream Peripheral Technologies, Ltd.) has recently received FDA clearance as well as CE Mark approval. The 4-F, single-lumen catheter features a curved needle that can be extended beyond the catheter tip. The clinician can select the protrusion length, and the device is compatible with 0.018- and 0.014-inch guidewires.

ATHERECTOMY SYSTEMS

The FDA-cleared and CE Mark–certified B-Laser atherectomy system (Eximo Medical Ltd.) treats complex CTOs by using optical fibers that transmit short (approximately 10 ns) pulses of 355-nm waves from a small solid-state Nd:YAG laser, which are surrounded by a blunt blade. Promising results from a European series involving 50 patients and 53 lesions were presented by John R. Laird, MD, at the 2018 Vascular Interventional Advances annual conference.

The Revolution system (Rex Medical) is a low-profile rotational atherectomy platform with continuous mechanical aspiration, allowing for use above and below the knee for various lesion morphologies, including thrombus, soft plaque material, and severe calcification. The REVEAL investigational device exemption trial has completed enrollment of 121 patients in the United States, and results are awaited.

The ByCross rotational atherectomy device (Taryag Medical Ltd.) was designed for many types of lesion morphologies. It can be used without a guidewire and includes a simultaneous, nonclogging aspiration system. Clinical application should begin soon.

VESSEL PREPARATION

The Flex vessel preparation (VP) system (VentureMed Group, Inc.) is a novel technology facilitating plaque incision and luminal gain by creating long, parallel, linear microincisions in all plaque morphologies before balloon angioplasty is performed. In a real-world cohort of 250 patients with long, complex SFA lesions, use of the Flex VP system for vessel preparation before angioplasty improved acute outcomes compared to historical controls.[2] Other clinical trials are underway, including the BELONG study, which will evaluate the rate of lumen patency obtained by arterial preparation with the Flex VP system prior to conventional endovascular recanalization of the SFA and popliteal artery with follow-up to 1 year (NCT03721939).

DRUG-COATED AND DRUG-ELUTING TECHNOLOGIES

Because of the ongoing discussion on the safety of paclitaxel-eluting devices for preventing restenosis, the use of alternative antiproliferative drugs is of special interest for peripheral vascular interventions. Although coronary drug-eluting stents coated with the immunosuppressant drugs sirolimus or everolimus were highly effective in reducing neointimal proliferation leading to coronary restenosis, initial studies investigating limus-eluting stents for femoropopliteal interventions failed to show a sustained benefit.[3,4] The Nitides stent system (Alvimedica) presents a novel drug coating/eluting strategy that uses the amphilimus formulation consisting of sirolimus formulated with an amphilic carrier that is released through an abluminal reservoir technology. The polymer-free platform is made of nitinol and covered with a second-generation pure carbon, ultrathin layer to increase hemo- and biocompatibility. Promising 1-year patency results from the ILLUMINA study were presented by Dierk Scheinert, MD, at the Leipzig Interventional Course in 2019.

Similarly, as an alternative to paclitaxel-coated balloons, the development of sirolimus-coated balloons (SCBs) is being pursued. The CE Mark–approved MagicTouch SCB (Concept Medical Inc.) uses a polymer-free, nano-based drug delivery technology and has been tested for coronary interventions. Clinical studies for peripheral interventions are currently in the planning phase. The Virtue sirolimus-eluting balloon (Orchestra BioMed, Inc.) also showed promising results in patients with coronary in-stent restenosis, and peripheral applications will be investigated. The SurVeil drug-coated balloon (DCB; Surmodics, Inc.), a novel third-generation paclitaxel-eluting balloon with an innovative coating technology, was compared head-to-head against the active comparator In.Pact Admiral DCB (Medtronic) in the TRANSCEND study. Enrollment of 446 patients at 65 international sites was recently completed.

The concept of bioabsorbable vascular scaffolds (BVSs) with additional antiproliferative drug delivery is still being pursued, as it could combine the advantages of metallic stents and drug-coated balloons by offering acute vessel support and limiting neointimal hyperplasia and late lumen loss over time but ultimately disappearing and allowing the return of physiologic vasomotion. Although no dedicated BVS for the SFA is currently under clinical investigation, preclinical animal studies described the use of metallic zinc alloy as a novel platform for mechanically stable BVSs.[5] Because maintaining mechanical integrity is a major challenge in the (distal) SFA and popliteal segment with its high biomechanical stress, this could be a major step forward compared to the previous use of BVSs made of polymers with limited mechanical properties.

CONCLUSION

Although new treatment approaches hold promise for improving outcomes after SFA revascularization, the safety and effectiveness of these devices need to be scrutinized. In the future, head-to-head comparisons will become mandatory to appraise deliverability, clinical outcome, and costs of these new devices. ■

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