Temporary Scaffolds—A Potential New Principle for Overcoming Limitations of Infrapopliteal Angioplasty

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Tibial and pedal arterial disease represents the most challenging vessel territory for endovascular treatment regarding acute and longer-term treatment success. While iliac (bare-metal stents, stentgrafts) and femoropopliteal arteries (drug-coated balloons, drug-eluting stents, and atherectomy) can be successfully treated, no convincing endovascular treatment strategy is yet established for infrapopliteal arteries.[1-5] Drug-eluting stents offer the best acute and long-term results,[6] but their use is limited to short lesions <10 cm in length and to lesions located proximal to the ankle joint. Due to the small caliber and the unique vessel architecture and pathology including concentric calcification, recoil is the major limitation of acute treatment success[7] and longer-term efficacy of the coatings utilized in drug-coated balloons.[8]

Mustapha et al[9] present the DEEPER pilot study results, which is the first-in-man experience with a new plaque-modulation device. The Temporary Spur Stent System (Reflow Medical) is designed to be delivered to the infrapopliteal arteries for the treatment of vessel stenosis or occlusion that can be successfully predilated, which is one of the device limitations. The system is intended to be used in conjunction with a drug-coated balloon or as standalone angioplasty. The radial structures ("spikes") of the temporary mechanical scaffold create channels in the endothelium of the arterial wall, extending approximately 1 mm from the outer surface of the stent into the periadventitial tissue. This should allow: (1) remodeling of the arterial wall prior to use of a drug-coated balloon; and (2) better drug penetration into the deeper vessel wall layers.

After predilation, all test devices could be delivered successfully to the intended target lesion, with a promising 6-month patency rate of 88.9% if the lesion was treated per protocol. However, in the intention-to-treat analysis, 6-month patency dropped to 69.9%; according to the manuscript, major protocol deviations were lesions longer than 30 cm and lesions located in tibial vessels with impaired pedal outflow, both well-known limitations for the durability of treatment success. In this pilot study, the Temporary Spur Stent System was used in conjunction with the Lutonix .014″ drug-coated balloon (BD Bard), a device with limited efficacy in infrapopliteal application.[10] It remains speculative whether the study outcome could have been further improved if a more efficacious drug-coated balloon had been used, or if vessel preparation with the Temporary Spur Stent System did improve the efficacy of the Lutonix DCB by promoting drug penetration into the vessel wall.

Temporary scaffolds for promoting remodeling are not a new principle. Late in the twentieth century, the interwoven balloon-expandable tantalum Strecker stent (Boston Scientific) was used either as a permanent implant or as a retrievable device that was removed from the vasculature days or weeks after implantation during a secondary intervention.[11] Different drug coatings were also tested via the temporary stent application.[12] However, due to limited stent integrity and the introduction of self-expanding stents, the concept of the temporary stent was not further investigated.

Currently, various plaque-modulation or removal devices are under investigation for overcoming limited acute and longer-term efficacy of infrapopliteal angioplasty. As with the Temporary Spur Stent System, the modification of calcified plaque in order to overcome vessel recoil is the target of lithotripsy and high-pressure balloon angioplasty. However, a limitation of these technologies (including the Temporary Spur Stent System) is their profile, which prevents the engagement of high-grade concentric calcified lesions with both intraluminal and medial calcification. These lesion morphologies need pretreatment with either ultra-low-profile coronary balloons or high-speed rotational atherectomy devices, such as orbital atherectomy.

Currently, 2 single-arm studies, DEEPER OUS and DEEPER Limus, are ongoing to further evaluate the performance of the Temporary Spur Stent System in infrapopliteal angioplasty. In the DEEPER OUS study, a subgroup analysis is investigating the impact of drug-coated balloon angioplasty supported by the Temporary Spur Stent System on acute vessel recoil 15 minutes after the last procedural step. Study data release can be expected in 2023. These single-arm studies will be followed by a randomized controlled investigational device exemption study starting enrollment in 2023.

In summary, the DEEPER pilot study by Mustapha et al provides insight into ongoing research for overcoming one of the last challenges of endovascular treatment of peripheral artery disease; namely, the revascularization of infrapopliteal arteries.

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