

Challenges of Femoropopliteal Artery In-Stent Restenosis: Revisiting Treatment Options with a Historical Perspective

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Since Dr. Charles Dotter pioneered treatment of peripheral artery disease (PAD) with conventional angioplasty and catheter-delivered stenting, modern medicine has excelled with the creation of various tools such as drug-coated balloons (DCBs), drug-eluting stents (DES) and atherectomy devices for the treatment of PAD. Unfortunately, these endeavors have come with new complications. Specifically, femoropopliteal in-stent restenosis (FP-ISR) of nitinol self-expanding bare metal stents (BMS) remains a significant enemy of your everyday vascular specialist.

Initial treatment options for ISR began with percutaneous transluminal angioplasty (PTA) for endovascular re-intervention, but even though shorter stenoses and occlusions tend to do well with sole PTA, just over 50% of lesions undergo treatment failure. Elastic recoil, residual stenosis, and flow-limiting dissection are the complicating components of sole PTA treatment. When adapting the Tosaka Classification for in-stent restenosis, class III lesions appear to do worse, which is likely related to worsening recoil of the highly compacted and occluding elements.

Re-stenting has also been considered in the treatment of ISR, however there remains an increased risk of stent fracture due to altered mechanics of the arterial wall as well as thrombosis due to multiple stent layers. Neointimal hyperplasia has been described as the major player of ISR and cannot be overcome with layering of additional stents. The advancement of stent-grafts coated with expandable polytetrafluoroethylene (ePTFE), such as the Viabahn endoprosthesis, have allowed providers to exclude neointimal hyperplasia. There remains an issue with hyperplasia at the edges of the stent-grafts resulting in edge stenosis and subsequent thrombosis. Nevertheless, Viabahn endoprosthesis proved to hold just over a 60% primary patency rate for treatment of FP-ISR for 3 years [1].

Laser atherectomy has made significant strides in the treatment of FP-ISR as it does not compromise stent integrity like other atherectomy devices. With use of PTA and subsequent Viabahn stenting, restenosis rates are significantly higher in literature, although many patients remained free of clinically driven target lesion revascularization (CD-TLR). Doppler criteria for re-stenosis is vital as too low of a criterion may lead to overtreatment of patients who are continuing a satisfactory quality of life [2].

The EXCITE trial was designed to determine the safety and efficacy of excimer laser atherectomy (ELA) with adjunctive PTA versus PTA alone for the treatment of FP-ISR. The mean length of lesion in the trial was 19.6 versus 19.3 cm in the ELA + PTA and PTA treatment arms, respectively. The results demonstrated a significantly increased rate of freedom from TLR in the ELA group (73.5% vs 51.8%) in addition to a decreased rate of major adverse event in the first 30 days after treatment. In a recent study, Kokkinidis, *et al.* proved the benefit of laser atherectomy plus DCB for Tosaka class II and III lesions versus laser atherectomy plus PTA [3]. Debulking with atherectomy likely leaves a smoother vessel wall allowing better balloon apposition for drug delivery.

The JETSTREAM-SCE and JETSTREAM-ISR studies establish the safety and efficacy of the Jetstream Atherectomy System by Boston Scientific (rotational atherectomy) as a treatment option for ISR with considerably low TLR rates [4,5]. Like laser atherectomy, distal embolization is typically a must-have for chronic total occlusions or long lesions (> 10 cm). Orbital and directional atherectomy remain a contraindication in FP-ISR due to high risk of compromising stent integrity and possible intraluminal retention of the device.

FP-ISR is a complex complication of endovascular treatment for PAD and has created a conundrum for operators. Although intricate in nature, recent literature shows promising results in the treatment of FP-ISR with debulking of the target lesion with laser or rotational atherectomy followed by DCB angioplasty. This treatment approach proves to be crucial for better patient outcomes, especially in longer and/or totally occluded lesions.

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