CASE REPORTS

Use of Atherectomy + DCB in CLI

Tips and tricks to achieve optimal results in patients with complex disease.

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Critical limb ischemia (CLI) as a manifestation of peripheral artery disease (PAD) is associated with significant health issues and severe disabilities. It is a major worldwide cause of morbidity and, in cases when it takes a limb-threatening course, mortality.[1] A wide range of clinical signs can occur in PAD and CLI, from intermittent claudication to limb-threatening ischemia, manifesting with rest pain, nonhealing wounds, and gangrene. The primary goal of treatment is the reestablishment of pulsatile, straight-line flow to the foot. In recent years, major advancements have been made in the field of endovascular therapy (EVT), and it is now considered a safe and feasible treatment option for limb salvage and wound healing.[1]

This article highlights the importance of vessel preparation in complex lesions and emphasizes the unique role of percutaneous atherectomy with adjunctive drug-coated balloon (DCB) therapy in CLI treatment. The philosophy of percutaneous atherectomy is based on luminal gain by reduction/modification of the atherosclerotic plaque, changing vessel compliance to reduce dissections, vessel barotrauma, and bailout stenting. The "leave-nothing-behind" strategy has been gaining popularity, with the aim of leaving the treated vessel intact for potential future treatments without permanent metallic stents, as well as to avoid potential stent-related problems.[2]

COMPLEX CALCIFIED LESIONS AND CTOs

Complex lesions and chronic total occlusions (CTOs) are very often associated with arterial wall calcifications, which could be severe and diffuse. These calcifications include different morphologies like thrombus or fibrous tissue and affect the femoropopliteal (FP) and below-the-knee (BTK) vessels. Although plain old balloon angioplasty has shown favorable periprocedural results, the previously mentioned factors limit the immediate periprocedural success, and the high restenosis rates and recurrent clinical symptoms make EVT challenging.

Dedicated drug-eluting technologies, such as drug-eluting stents and DCBs, have emerged to improve the long-term patency rates. Although good outcomes have been seen with DCBs in the superficial femoral artery (SFA) and popliteal artery (PA), when the artery is very calcified (Figure 1A) with almost complete or complete circumferential distribution of calcium (360°), the drug

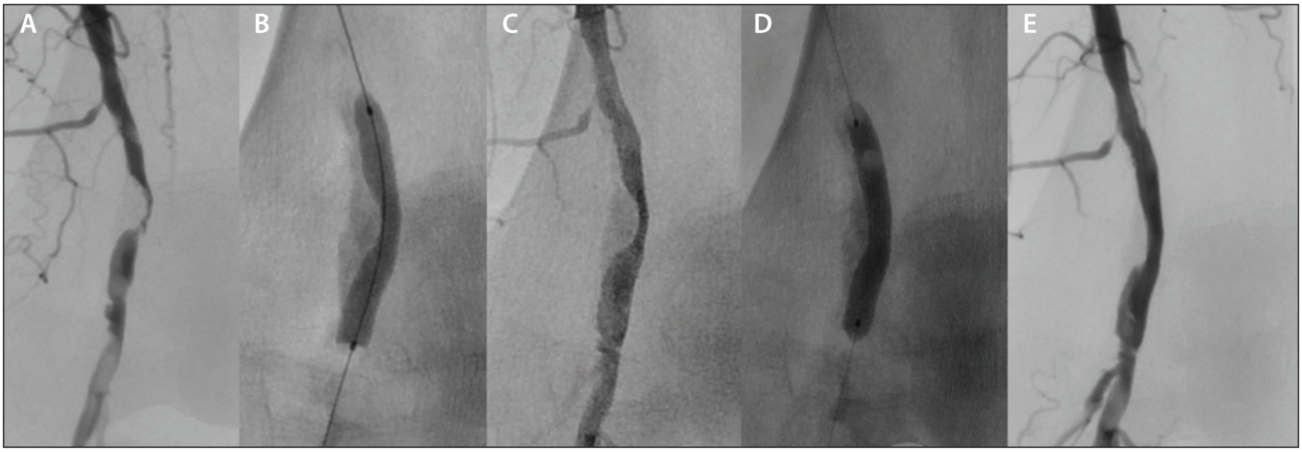

Figure 1. Heavily calcified eccentric lesion of the proximal PA (A). High-pressure balloon angioplasty (B). Early severe recoil (C). After angioplasty with the 6- X 40-mm Ranger™ DCB and plaque modification with the JETSTREAM™ Atherectomy System's 2.1-mm XC, the treated vessel is more compliant (D). Final angiography showing significant luminal gain (E).

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

is not able to provide the same effect, as there is only limited intravascular drug delivery.[3] In many cases, there is an inability to dilate the lesion (Figure 1B and 1C), with higher dissection and perforation rates, leading to bailout stenting, higher stent fracture rates, and subsequent lower patency rates. Especially at the distal SFA and proximal PA levels, high failure rates of FP artery interventions are often attributed to severe mechanical deformations (axial compression, bending) that occur with limb movement.[4] As the complexity of the lesions increases, the advantage of the JETSTREAM™ Atherectomy System (Boston Scientific Corporation) is that it can be utilized for plaque removal, allowing the vessel to be more compliant for subsequent DCB treatment (Figure 1D and 1E).

JETSTREAM™ ATHERECTOMY SYSTEM

At our institution, we use the JETSTREAM™ Atherectomy System to treat calcified complex lesions affecting the SFA, PA, and BTK vessels. We adopted the idea of plaque modification with the aim of improving periprocedural success by lowering the chance for periprocedural bailout stenting and prolonging long-term patency by adding DCB treatment. The JETSTREAM™ catheters are intended for atherectomy of the peripheral vasculature and to break apart and remove thrombus. The main advantage lies in the ability to perform thrombus removal and treat the underlying lesion in one session, especially when the age of the treated lesion is not certain. The main indications, based on our own experiences, are summarized in the *Indications for Atherectomy* sidebar.

The system consists of a sterile, single-use catheter attached to the control pod and the reusable power console. The catheter is compatible with a 0.014-inch wire and 7-F sheath and is equipped with a five-flute, front-end cutting tip (Figure 2).

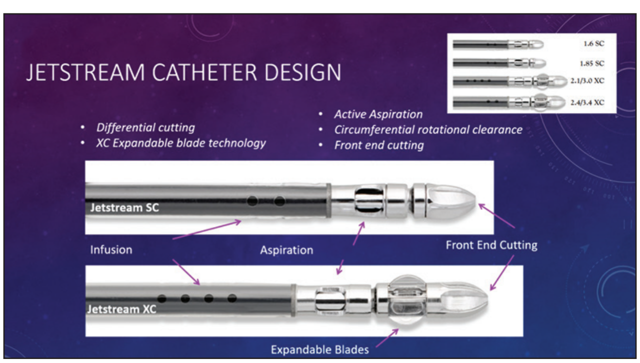

Figure 2. The JETSTREAM™ Atherectomy System catheters. The nonexpandable SC devices are available in two sizes (1.6 mm and 1.85 mm). The XC devices are available in two sizes as well (2.1/3 mm and 2.4/3.4 mm). The device features active aspiration and is also approved for thrombus removal.

Adopting atherectomy technology takes time due to the learning curve involved. Therefore, the following cases highlight proper indications, lesion crossing and treatment techniques, correct catheter selection, and how to avoid complications and achieve an optimal result.

CASE PRESENTATIONS

Case 1: Distal SFA CTO

A 64-year-old man presented with clinical signs of limiting intermittent claudication and pain in the right calf. Previous ultrasound examination demonstrated patency of the common femoral artery (CFA), profunda femoris artery, and proximal SFA. The distal part of SFA was chronically occluded (Figure 3A), and the PA was patent and filled via collaterals.

An ipsilateral antegrade approach using a 7-F sheath was selected, with the aim to get the best tactile feedback from the cutter. After administering 5,000 units of intravenous heparin, a 0.018-inch, 300-cm-long, V-18™ ControlWire™ Guidewire (Boston Scientific Corporation) was used to recanalize the CTO along with the TrailBlazer™ Support

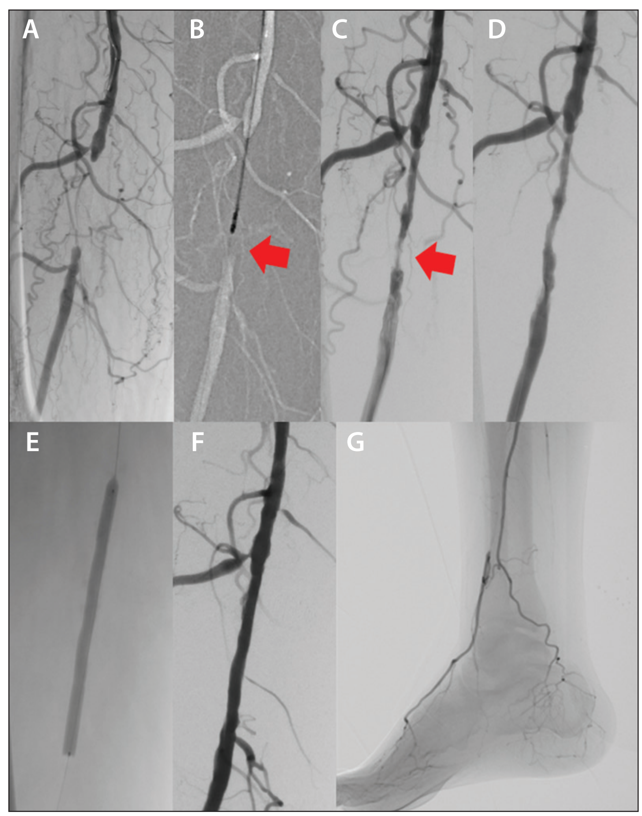

Figure 3. A CTO of the distal right SFA (A). The JETSTREAM™ Atherectomy System's 2.1-mm XC keeping the distal part of the lesion intact to act as a "filter" (red arrows) (B, C). Posttreatment imaging of the distal part of the lesion (D). Use of a 6- X 80-mm Ranger™ DCB (E). Final imaging showing the reconstituted SFA (F) without DE (G).

INDICATIONS FOR ATHERECTOMY*

- Long calcified lesions, complex CTO with/without thrombus
- In-stent occlusions
- Bifurcation and "no-stent" zones
- High-risk patients for open repair
- Contraindication for stent implantation or for dual antiplatelet therapy

*Based on the author's experience.

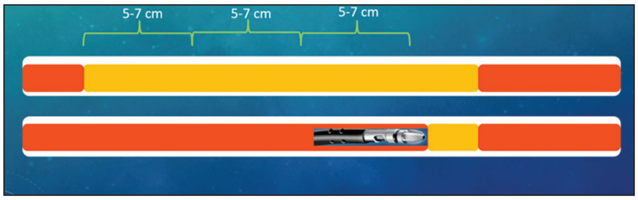

Figure 4. Treatment of long lesion segments (5–7 cm) by activating the blades-down mode then coming back to blades-up mode in each segment before moving to the next, thus having the more distal disease act as a "filter" while treating the more proximal disease.

Catheter (Medtronic). Low-profile recanalization is important for preservation of the distal part of the disease, which acts as a "filter" while treating the more proximal disease (Figure 4), thus avoiding distal embolization (DE). After exchanging for a 0.014-inch Thruway™ Guidewire (Boston Scientific Corporation), the JETSTREAM™ Atherectomy System was used to debulk the lesion.

The 2.1/3-mm cutter was introduced close to the proximal part of the CTO, and after activation, two passes with blades down were performed without entering the 1- to 2-cm-long distal part of the CTO (Figure 3B). This maneuver allows treatment of the entire proximal portion of the CTO without the fear of distal embolization, avoids the need for placement of a distal embolic protection device (EPD) at the beginning of the procedure, and controls proper positioning during treatment. This tactic is especially helpful for longer lesion treatment (approximately 5- to 7-cm segments [Figure 4]), thus making the procedure more convenient. More importantly, the activation time should be kept short (30 seconds at a time) to avoid overheating or stalling the device. Proper aspiration can be controlled by monitoring the line leading to the collection bag.

After additional passes with blades up, the REX mode is activated, and slow catheter retrieval is recommended to allow proper aspiration of the debris. In this case, control angiography showed the smooth inner surface of the created lumen (Figure 3C). At this point, the distal part of the lesion was targeted with blades-down atherectomy (Figure 3D). If further atherectomy had been needed, the recanalized lumen was wide enough for EPD crossing and placement (the Emboshield® NAV6 Embolic Protection System [Abbott Vascular] is recommended). Due to a sufficient luminal gain, angioplasty using a 6- X 80-mm Ranger™ DCB (Boston Scientific Corporation) was performed (Figure 3E). Final angiography demonstrated full patency of the treated SFA without dissection or significant residual stenosis (Figure 3F) and without DE (Figure 3G).

Case 2: Calcified Tibioperoneal Trunk Stenosis and Peroneal Artery CTO

A 74-year-old man presented with clinical signs consisting of rest pain in the right calf and ischemic ulceration of the

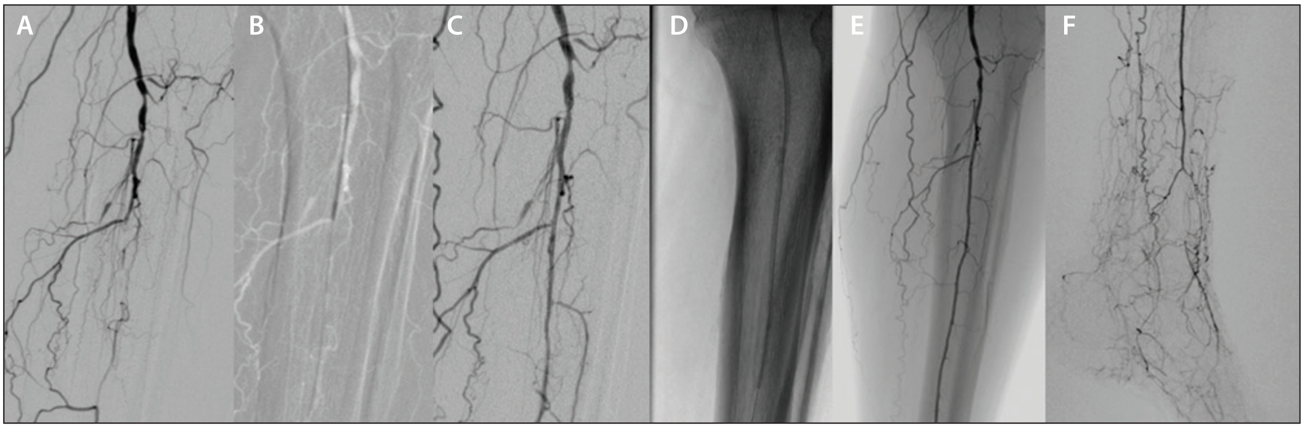

Figure 5. Critical obstructive disease of the tibioperoneal trunk and occlusion of the ATA, posterior tibial artery, and the mid part of the peroneal artery (A). The JETSTREAM™ Atherectomy System's 1.85-mm SC entering the calcified lesion (B). Angiography after treatment of the peroneal artery (C). PTA with a 2.5- X 200-mm balloon (D) followed by two 3- X 120-mm Ranger™ DCBs. The reconstituted peroneal artery (E) without DE (F).

toe. Previous ultrasound examination demonstrated patency of the FP artery and diffusely diseased BTK arteries. Ipsilateral antegrade access was achieved from the right CFA using a 7-F sheath. Selective angiography demonstrated highly calcified, critical obstructive disease of the tibioperoneal trunk, as well as occlusion of the anterior tibial artery (ATA), posterior tibial artery, and the mid part of the peroneal artery (Figure 5A). After several failed attempts, the occlusion of the mid peroneal artery was finally crossed by a 0.018-inch, 300-cm-long, 30-gauge Victory™ Guidewire (Boston Scientific Corporation). Balloon catheter advancement into the lesion was not possible due to its heavily calcified morphology.

After exchanging for a 0.014-inch Thruway™ Guidewire, the JETSTREAM™ Atherectomy System was used to modify the plaque and remove the calcium. The 1.85-mm single cutter (SC) was advanced, and two passes were performed, encompassing the entire length of the diseased tibioperoneal segment (Figure 5B). This was followed by additional angioplasty with a 2.5- X 200-mm percutaneous transluminal angioplasty (PTA) catheter (Figure 5C and 5D) and, subsequently, with two 3- X 120-mm Ranger™ DCBs. Final angiography demonstrated fast flow in the reconstituted peroneal artery, without dissection, early recoil, or DE (Figure 5E and 5F).

Case 3: In-Stent PA Occlusion

A 60-year-old man presented with clinical signs of severe, limiting claudication and pain in the right calf. Previous ultrasound examination demonstrated in-stent occlusion of the P2 and P3 segments of the PA and a resting ankle-brachial index of 0.45 in the right leg. An ipsilateral antegrade approach from the CFA using a 45-cm-long, 7-F, straight Pinnacle® Destination® Guiding Sheath (Terumo Interventional Systems) was chosen. Selective right FP angiography demonstrated in-stent occlusion of the PA and patent BTK arteries filled via collaterals (Figure 6A).

After administering 5,000 units of intravenous heparin, a 0.018-inch, 300-cm-long, V-18™ ControlWire™ Guidewire was used to recanalize the CTO using a TrailBlazer™ Support Catheter (Figure 6B). After exchanging for a 0.014-inch Thruway™ Guidewire, the JETSTREAM™ Atherectomy System was used to debulk the lesion. The 2.1/3-mm cutter was introduced close to the proximal in-stent part of the CTO, and after activation, one pass with blades down and one pass with blades up were performed without entering the 1- to 2-cm-long distal part of the CTO (Figure 6C). As previously mentioned, this technique allows the treatment of the entire proximal portion of the CTO without the fear of DE and eluding the need for distal EPD placement. REX mode with slow catheter removal followed. Subsequently, a 0.035-inch TrailBlazer™ Support Catheter was advanced over the wire into the newly created channel, and the contrast agent was administered through this catheter. Angiography showed sufficient thrombus and neointima removal (Figure 6D). At this point, the distal part of the lesion was targeted with blades-down atherectomy (Figure 6E).

Repeat angiography revealed complete thrombus clearance and high-grade proximal and distal edge stent restenosis (Figure 7A). Balloon inflations were performed using 5- X 40-mm and 6- X 40-mm Ranger™ DCBs (Figure 7B and 7C). Final angiography demonstrated full patency of the treated PA without dissection or significant residual stenosis, with preserved collateral vessels arising

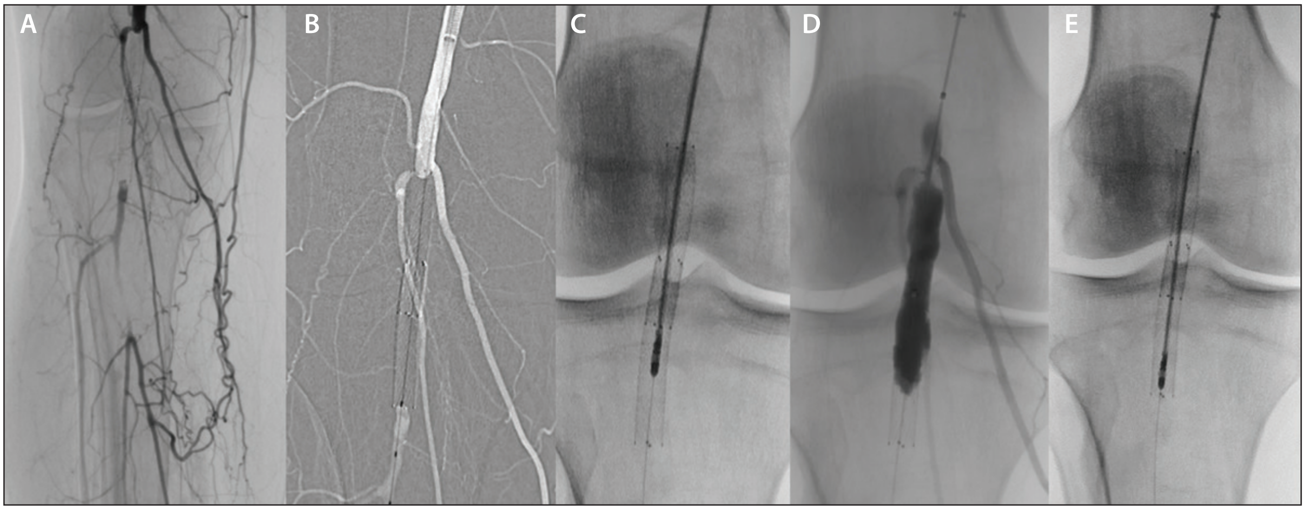

Figure 6. In-stent occlusion of the right PA (A). Intraluminal recanalization with a 0.018-inch, 300-cm-long, V-18™ ControlWire™ Guidewire and a 0.018-inch TrailBlazer™ Support Catheter (B). JETSTREAM™ Atherectomy System 2.1-mm activation, keeping the distal part of the lesion intact to act as a "filter" (C, D). Atherectomy of the distal part of the CTO (E).

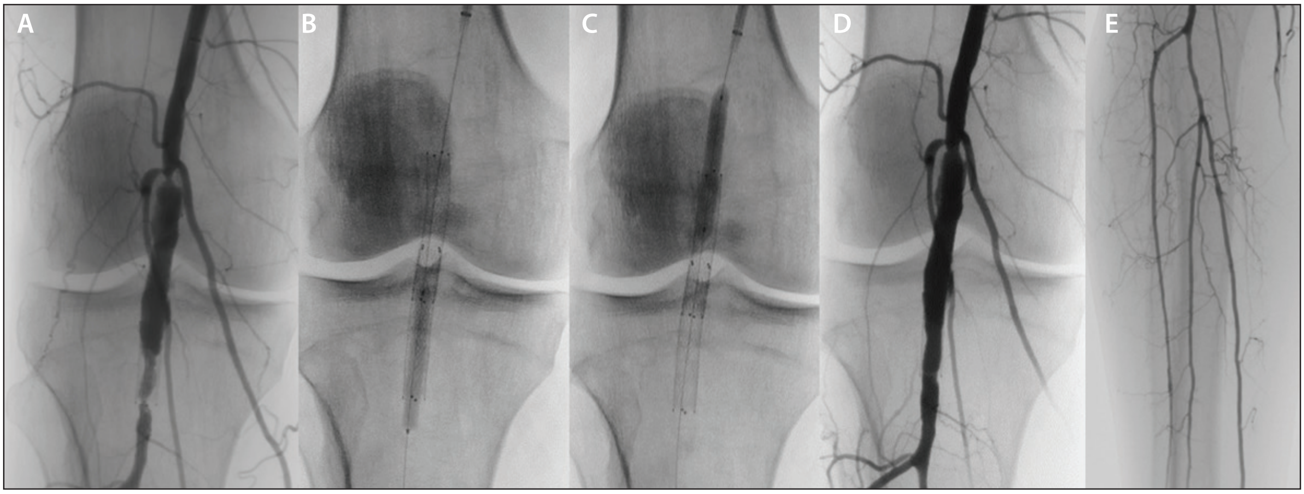

Figure 7. Angiography after activation of the JETSTREAM™ Atherectomy System's 2.1-mm XC, revealing high-grade proximal and distal edge stent restenosis (A), which was corrected by 5- X 40-mm and 6- X 40-mm Ranger™ DCBs (B, C). The reconstituted PA and preserved collateral vessels (D) without DE (E).

above the previously implanted stent (Figure 7D), and without DE (Figure 7E). The patient was discharged the following day symptom-free and with a resting ankle-brachial index of 0.85 in the right leg.

Case 4: Complex Calcific Occlusion of the Distal PA, Proximal ATA, and Tibioperoneal Artery

A 68-year-old woman presented with rest pain in the right foot and was referred for selective right FP and BTK angiography. Ipsilateral antegrade access was gained from the CFA using a 7-F sheath. Angiography demonstrated complex obstructive disease of the distal PA involving the tibioperoneal trunk and the origin of the ATA, with two-vessel runoff BTK to the ATA and peroneal artery (Figure 8A).

First, a 0.018-inch, 300-cm-long, V-18™ ControlWire™ Guidewire was used to recanalize the CTO using an angled TrailBlazer™ Support Catheter. After exchanging for a 0.014-inch Thruway™ Guidewire, the JETSTREAM™ Atherectomy System's 2.1-mm expandable cutter (XC) was used to debulk the lesion, and two passes with blades down were performed (Figure 8B). Control angiography showed smooth lumen (Figure 8C). At this point, the tibioperoneal trunk was targeted in the same fashion with blades-down atherectomy (Figure 8D). According to the "+1 mm rule," the blades-up mode was not activated in 3-mm-wide BTK arteries. Finally, kissing-balloon inflations were performed in both the ATA and tibioperoneal trunk with 2.5- X 40-mm and 3- X 40-mm Ranger™ DCBs (Figure 8E). Final arteriography demonstrated wide patency of the reconstituted vessels, without significant residual stenosis (Figure 8F) or DE (Figure 8G).

DISCUSSION

These case studies demonstrate that the JETSTREAM™ Atherectomy System is effective in treating severely calcified lesions in the FP and BTK arteries. Published randomized trials

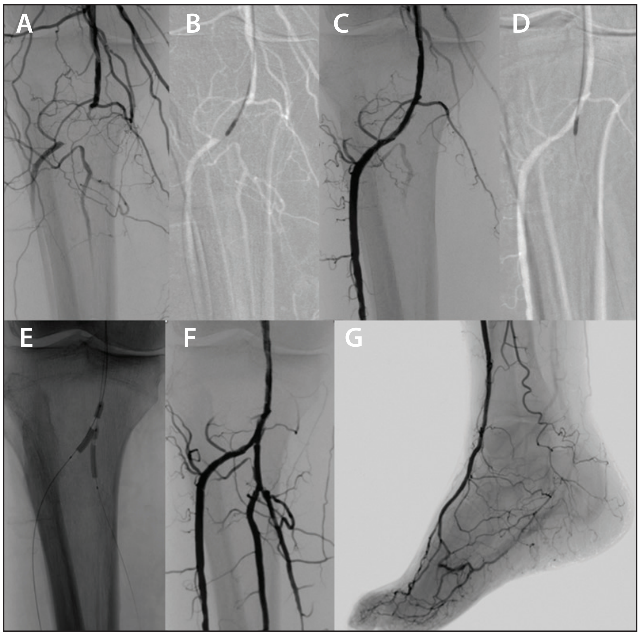

Figure 8. Occlusion of the distal PA involving the tibioperoneal trunk and origin of the ATA (A). Use of the JETSTREAM™ Atherectomy System's 2.1-mm XC in the ATA (B). Posttreatment imaging of the ATA (C). Use of the JETSTREAM™ Atherectomy System's 2.1-mm XC in the tibioperoneal trunk (D). Kissing-balloon angioplasty in both the ATA and tibioperoneal trunk with 2.5- X 40-mm and 3- X 40-mm Ranger™ DCBs (E). Final angiography without residual stenosis (F) or DE (G).

have shown that atherectomy can accomplish the task of vessel preparation, reducing dissections and bailout stenting.[5-7]

The JET multicenter prospective registry investigated the procedural, safety, and effectiveness outcomes of real-world practice with the JETSTREAM™ Atherectomy System for treatment of FP artery lesions.[8] In total, 241 patients (41% with diabetes; Rutherford classes 1–3) with de novo or restenotic (nonstent) FP lesions ≥ 4 cm in length were enrolled. The mean (± standard deviation) lesion length was 16.4 ± 13.6 cm, an EPD was used in 22.4% of cases, and 35% of patients received adjunctive stents. The procedural success rate was 98.3%. The 30-day major adverse event rate was 2% (5/219: two target lesion/vessel revascularizations [TLR/TVR], three DEs). There were no deaths, index limb amputations, or myocardial infarctions. At 12 months, the overall estimated freedom from TLR/TVR was 81.7%, and 77.2% (44/57) of patients had no duplex ultrasound–assessed restenosis.[8]

At present, there are no randomized data comparing atherectomy with adjunctive DCB use versus atherectomy alone, stenting alone, or stenting with adjunctive DCB use. The long-term outcomes with the JETSTREAM™ Atherectomy System, with or without DCBs, in treating FP arteries were investigated in the JET-SCE study.[9] In this study, 75 patients (54.7% with diabetes) with de novo or restenotic FP lesions (Rutherford class 1–5) were enrolled. Adjunctive PTA was performed in 50 patients (26 de novo, 13 in-stent restenosis, three nonstent restenosis, eight mixed lesions) and adjunctive DCB use (24 Lutonix® DCB [BD Interventional], one In.Pact™ DCB [Medtronic]) in 25 patients (21 de novo, one in-stent restenosis, two nonstent restenosis, one mixed lesion; $P = .0249$). The median treated length in both the adjunctive PTA (15 cm) and DCB (10 cm) groups was the same ($P = .0530$). The estimated freedom from TLR rate was significantly higher with atherectomy and adjunctive DCB than with atherectomy and adjunctive PTA at 12 months (94.7% vs 68%; $P = .002$) and 16 months (94.4% vs 54%; $P = .002$).[9]

Proper technique is essential for excellent results, and there is a learning curve during the adoption of the device. Slow advancement of the cutter is mandatory to avoid stalling of the device and to allow room for aspiration. EPDs have added a level of protection to the outflow vessels (eg, irregular/heavily calcified lesions, in-stent restenosis, TransAtlantic Inter-Society Consensus D lesions). The low-profile recanalization and preservation of the distal part of the CTO, which acts as a "filter" (Case 1) while treating the more proximal disease, significantly reduce the likelihood of DE and the need for EPD placement. The JETSTREAM™ Atherectomy System cutters feature front-end cutting. In complex calcific disease, this has the advantage of allowing the cutter to overcome the usually tougher proximal part of a lesion, which is otherwise impenetrable by conventional low-profile PTA catheters or wires (Case 2). In-stent restenosis, and particularly reocclusion, is challenging for EVT; smooth muscle cell proliferation and thrombus presence with higher embolic potential usually require additional stent placement over existing stents.[10] PTA has a very high rate of restenosis, and debulking is emerging as an important tool in treating FP in-stent restenosis combined with antirestenotic measures to prolong the TLR-free rate (Case 3). In case of bifurcation lesions, the main task during EVT is the preservation of the involved vessels and not covering their origin by stent implantation (Case 4). Based on my clinical experience, the JETSTREAM™ Atherectomy System can meet these challenges.

CONCLUSION

Recently, major technological advancements have been made in the field of EVT, and interventional specialists are encountering more complex and challenging cases. Durability and long-term patency remain the main goals in EVT of CLI. The JETSTREAM™ Atherectomy System has demonstrated a high procedural success rate, with a low rate of complications and early reinterventions. Now, it can be accompanied by DCB technologies with promising long-term patency, although this still needs to be addressed by large, randomized trials. ■

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