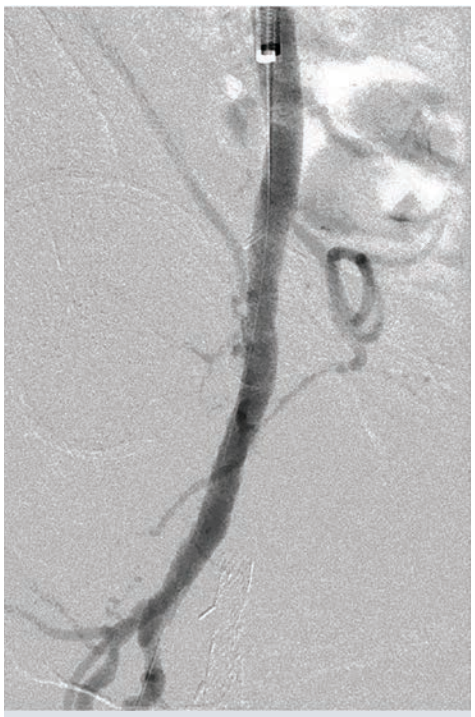
Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist



CASE REPORT

Optimal Endovascular Therapy for the Femoral Bifurcation: A Case of Directional Atherectomy and Drug-Coated Balloon Angioplasty

Eric C. Scott, MD

Despite all of the interest in endovascular therapy for the femoropopliteal arteries, data surrounding treatment of femoral bifurcation lesions and isolated profunda femoris artery (PFA) disease remain scarce.

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Happy Cardiovascular Professionals Week!
February 12-18, 2023

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STRUCTURAL HEART IMAGING

The Role of Advanced Imaging Technology in Structural Heart Interventions

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Praveen Mehrotra, MD, FACC, FASE, Director of Echocardiography, Thomas Jefferson University Hospital, Philadelphia, Pennsylvania.

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Optimal Endovascular Therapy for the Femoral Bifurcation: A Case of Directional Atherectomy and Drug-Coated Balloon Angioplasty

Eric C. Scott, MD

These lesions are routinely excluded from clinical trials and published clinical outcomes remain limited to small series with short duration of follow-up.[1-3] In spite of limited data, however, clinical scenarios do arise where endovascular therapy for this arterial segment is appealing.

Case

Fifteen months ago, we encountered such an 89-year-old female. She presented with ischemic rest pain of her right foot and severe claudication of the thigh and calf. Risk factors for peripheral artery disease included diabetes mellitus, coronary artery disease, hypertension, hyperlipidemia with intolerance to statins, and age. Three years prior she had undergone primary superficial femoral artery (SFA) stenting with 40 cm of nitinol stent, which spontaneously thrombosed in less than a year and was never recanalized. Approximately one year later, she underwent a right common femoral endarterectomy with bovine pericardial patch angioplasty for ischemic rest pain of the right foot. This resulted in alleviation of her rest pain initially, but within a year, she returned with similar complaints. An arterial duplex was obtained at that time, demonstrating a maximal velocity at the distal common femoral artery or proximal profundal femoral artery (PFA) of 489 cm/s. Her SFA stents remained occluded and her ankle-brachial index (ABI) was 0.16. There was no suggestion of significant aortoiliac occlusive disease on her duplex ultrasound and computed tomography (CT) angiography was deferred. Treatment options, including redo femoral endarterectomy with profundaplasty and possible endovascular therapy, were discussed with her and she elected to proceed with the latter.

A formal right lower extremity arteriogram was subsequently performed and revealed a critical stenosis of the distal common femoral artery and proximal PFA (Figure 1). The SFA was occluded to its ostia and the proximal aspect of the stent was found to be fractured. There was reconstitution of the P3 portion of the popliteal artery and runoff to the foot via a patent but moderately diseased peroneal and posterior tibial artery. The femoral bifurcation lesion was further evaluated with intravascular ultrasound (IVUS), which revealed a concentric 88% stenosis composed of primarily soft plaque (Figure 2A).

Various treatment options were considered following angiography and IVUS imaging. The simplest therapy would have been to use drug-coated balloon (DCB) angioplasty. Numerous reports have documented DCB's superiority over plain balloon angioplasty in terms of improved primary patency and reduced rates of target lesion revascularization[4-7]; however, this approach risked a higher rate of arterial dissection which may have required stent implantation across the femoral bifurcation. This is generally considered a maneuver to avoid and her previous stent implantation in the proximal SFA resulted in early fracture. For these reasons, primary DCB usage and primary stenting were deferred.

Therapy

Directional atherectomy was selected as the initial treatment modality, as it offers the ability to excise significant portions of the plaque and has a documented rate of dissection of only 2.3%.[8] In this case, it was particularly well-suited, as the lesion was soft, focal, and concentric. With circumferential usage of the device, this therapy offered the ability to thoroughly excise the lesion and minimize the risk of dissection, all while knowing risk of perforation was very low due to the concentric nature of the lesion as depicted on IVUS.

To execute this strategy, a 7 French, 45 cm sheath was placed over the aortic bifurcation and positioned in the very proximal common femoral artery. The patient was anticoagulated with heparin 80 units/kg intravenously. A 6 mm SpiderFX embolic protection device (EPD) (Medtronic) was placed in the largest first-order branch of the PFA and a magnified road map of the lesion was created at 25 degrees right anterior oblique (RAO). A HawkOne LS directional atherectomy device (Medtronic) was selected for its larger plaque excision capability and its shorter nose cone, given the short length of the lesion, and a desire to keep the EPD closer to the lesion and thereby protect more branches (Figure 3). A series of six initial passes with the device at 1-2mm per second was made in a uniform, radial manner. Subsequent angiography demonstrated a marked reduction in stenosis and

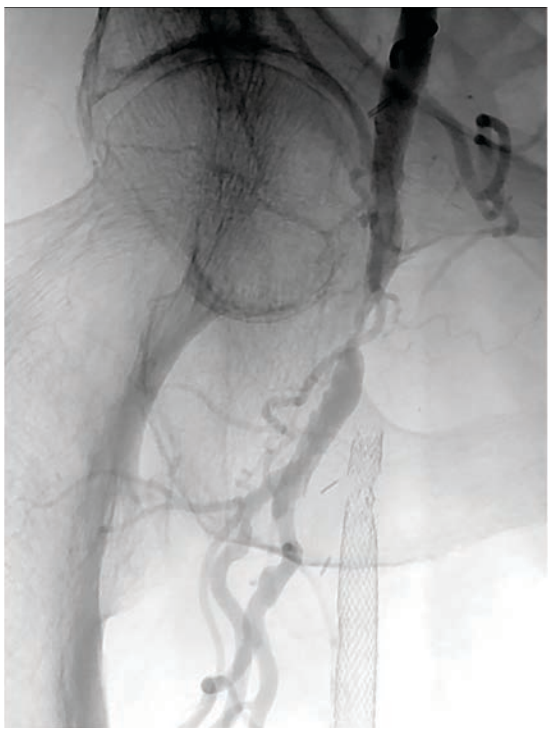

Figure 1. Right femoral bifurcation lesion in an 88-year-old female with ischemic rest pain of the right foot and chronic superficial femoral artery (SFA) stent occlusion with proximal fracture.

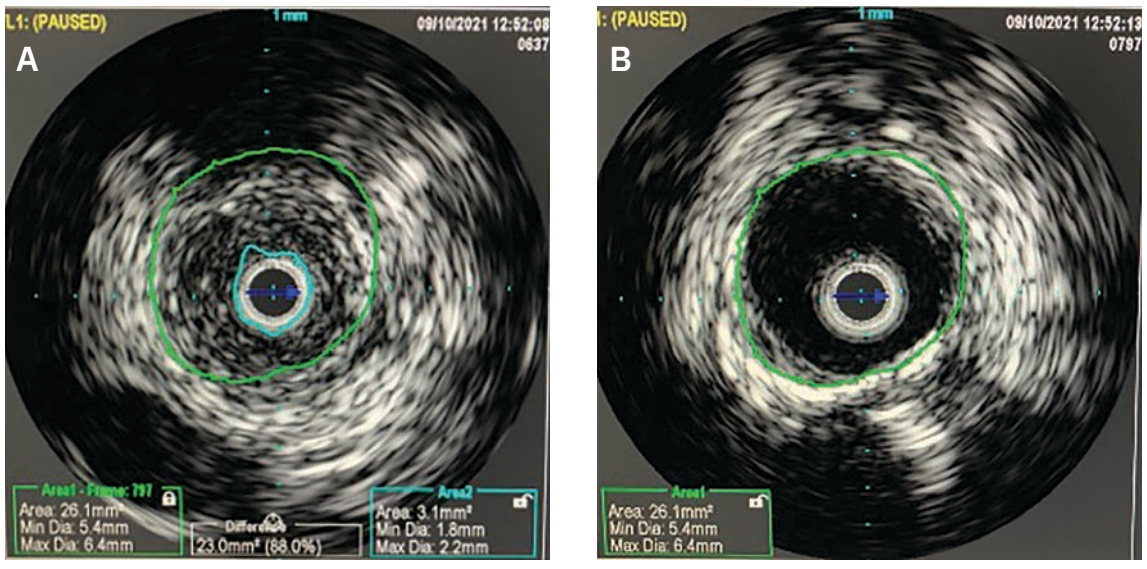

Figure 2. IVUS images of the right proximal profundal femoral artery (PFA) lesion prior to intervention (A) and following directional atherectomy and drug-coated balloon (DCB) (B).

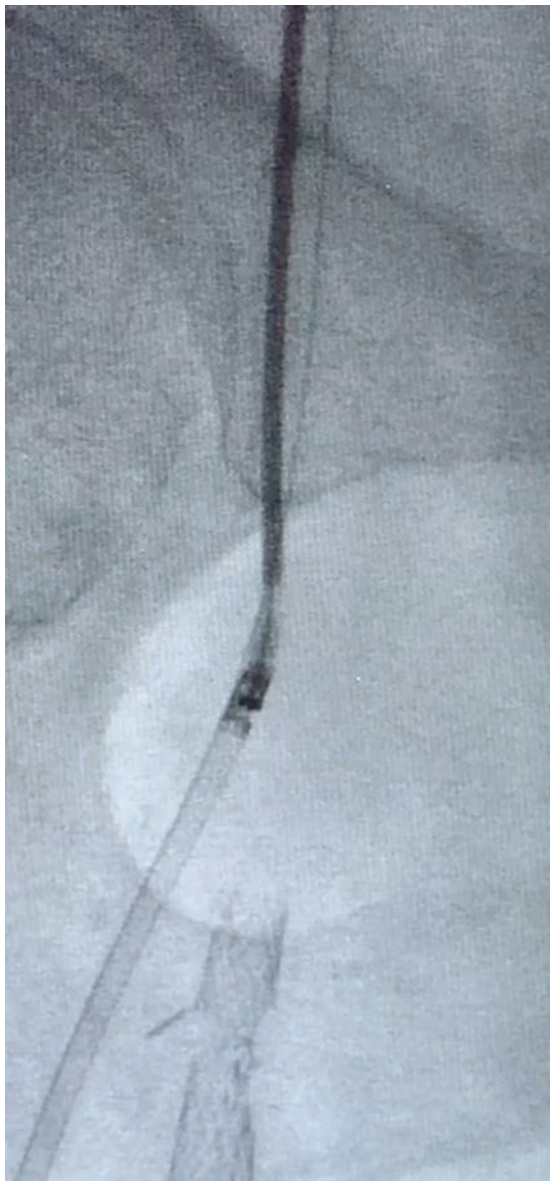

Figure 3. HawkOne LS directional atherectomy device (Medtronic) used for initial treatment of the distal common femoral artery and proximal PFA stenosis.

an additional 5-6 passes were made in a targeted fashion at remaining locations of visible disease. With less than 30% stenosis remaining, an In.Pact DCB (6 mm x 40 mm) (Medtronic) was selected based upon IVUS measurements and inflated to nominal pressure for three minutes (Figures 4-5). Follow-up angiography demonstrated <20% residual stenosis with no evidence of dissection or distal embolization (Figure 6). These findings were confirmed by final IVUS imaging and the procedure was completed without complication (Figure 2B). The arteriotomy was closed by Perclose (Abbott Vascular) and the patient was ambulatory two hours after the procedure. Dual antiplatelet therapy was prescribed for three months following the procedure and low-dose aspirin indefinitely.

Follow-Up

The patient has completed one year of clinical follow-up to present and she has had no recurrence of ischemic symptoms or secondary interventions. Duplex ultrasound exams were performed at one, six, and 12 months after the procedure, and have

Figure 4. Post atherectomy angiogram demonstrating substantial lumen gain following approximately 12 passes of the device.

demonstrated <50% stenosis in the common femoral artery and PFA on each occasion. Her ABI has remained stable at 0.45-0.50.

Discussion

Balloon angioplasty, DCB, stenting, and atherectomy are well-studied endovascular therapies for the femoropopliteal arteries, yet pivotal studies for each of these modalities have routinely excluded treatment of the common femoral artery, femoral bifurcation, the PFA, and often the distal popliteal artery. As such, there are limited data to guide treatment decisions that involve these femoropopliteal segments. These segments represent more challenging clinical scenarios, however, as the risks of primary or bail-out stenting make them relatively or overtly contraindicated, particularly at arterial bifurcation points. Operators need strategies to work in these difficult segments that are safe and effective, while minimizing the need for stent implantation.

The case above is presented as an example of such a challenge. The profunda femoris artery is generally treated via open surgical endarterectomy and patch angioplasty, therapy that is considered to be the gold standard. Yet this particular patient was only one year recovered from her femoral endarterectomy and the new lesion likely represented a distal endpoint restenosis. A redo groin surgery at her age, only one year out from previous surgery, was likely to be high risk and she strongly preferred a less invasive approach. An endovascular therapy that could be applied to the PFA with high likelihood of success and low

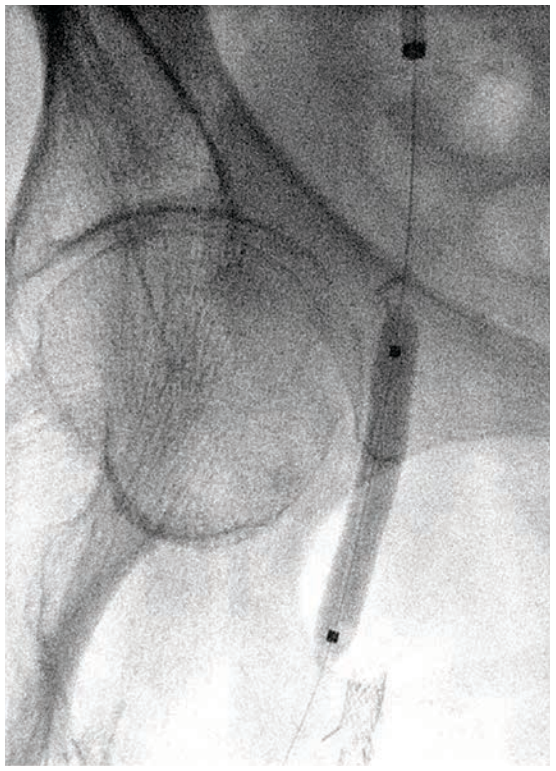

Figure 5. Following directional atherectomy, the lesion was treated with an In.Pact 6 mm x 40 mm drug-coated balloon (Medtronic).

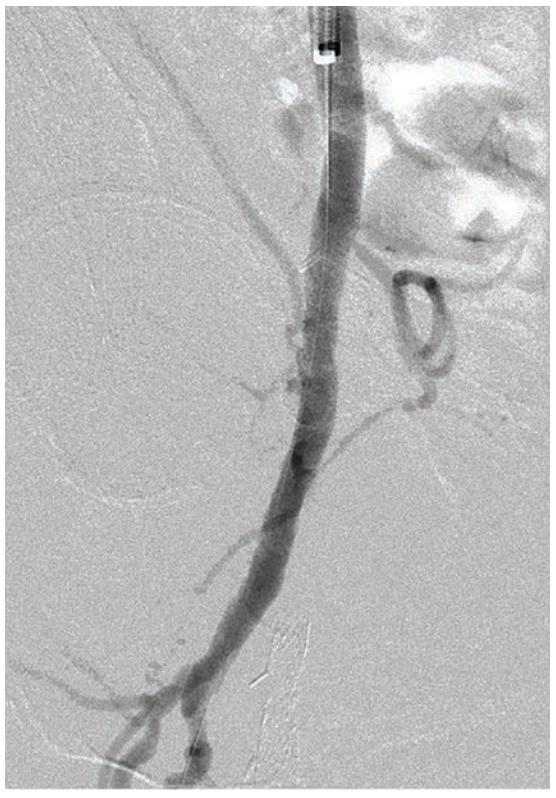

Figure 6. Completion angiogram of the right femoral bifurcation following treatment with directional atherectomy and DCB.

risk of stent implantation met her clinical need and personal wishes.

To begin the case, diagnostic angiography was paired with IVUS of the right femoral bifurcation lesion to provide maximal information. Key details provided by the IVUS exam included that of soft plaque or intimal hyperplasia (with minimal to no calcium present), as well as the presence of concentric disease. Vessel diameters were assessed

by IVUS to ensure that balloons were appropriately sized and thus would minimize the risk of dissection.

Based upon the above information, directional atherectomy was selected as the "vessel preparation" device of choice, as its ability to produce measurable lumen gain with low rates of dissection and stent implantation is well documented. In over 1100 limbs treated in the DEFINITIVE LE trial of femoropopliteal directional atherectomy, the rate of dissection was only 2.3% and the rate of provisional stenting was 3.2%.[8] The rate of vessel perforation was 5% in this trial; however, it should be pointed out that operators were specifically instructed to aggressively use directional atherectomy to achieve stenosis of <30%. In two-thirds of cases, operators successfully completed this objective and no post atherectomy angioplasty was performed, demonstrating the capability of this device to perform thorough plaque excision. In the case presented above, aggressive debulking of the PFA lesion was intended to reduce the workload on the planned DCB and the IVUS depiction of concentric disease conferred a low risk of vessel perforation. During the initial six passes of the device, care was taken to ensure each pass was performed on a new portion of the vessel and that approximately 60 degrees of device rotation was achieved between passes. The subsequent final passes were then targeted specifically at areas of residual stenosis seen on follow-up angiography. Though not utilized in this case, interval IVUS imaging can also assist in determining need and/or safety of additional plaque excision. Ultimately, thorough plaque excision using directional atherectomy in this case allowed for safe usage of DCB with anticipated very low risk of dissection. Her immediate resolution of ischemic rest pain and durable clinical result are just one example of how directional atherectomy and DCB pair to provide safe and effective treatment of difficult femoropopliteal lesions that warrant a "no-implant" approach. ■

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Eric C. Scott, MD
Vascular Surgery
The Iowa Clinic
West Des Moines, Iowa

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