# Experience With Atherectomy and DCBs

The merits of a two-part approach in the SFA and popliteal artery.

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In patients with chronic peripheral artery disease (PAD), the options for interventional therapy have tremendously increased within the last few years. Traditional percutaneous transluminal angioplasty (PTA) with drug-coated balloons (DCBs), with or without adjunctive stenting, is the current endovascular option of choice for treatment of severe PAD. The development of next-generation peripheral stents and drug-coated stents have led to the improved treatment of more complex superficial femoral artery (SFA) lesions.[1] Technical success and short-term results have been excellent with these endovascular interventions, as successful percutaneous revascularization significantly improves amputation rates, survival in patients with intermittent claudication and critical limb ischemia, as well as quality of life.

However, in complex femoropopliteal lesions, long-term patency and restenosis rates have generally been more disappointing regardless of the technique employed. Late results have been limited by high restenosis rates and recurrent symptoms. Atherosclerotic disease progression in the femoropopliteal arterial segment is often diffuse, with complex morphologies including soft and fibrous tissue, thrombus, and superficial and deep calcium. These factors have limited the utility of PTA with DCBs alone for sustainable, favorable results. The rate of bailout stenting after DCB angioplasty has been reported to be as high as 40% in long lesions and as high as 46% in chronic total occlusions (CTOs).[2] So far, the femoropopliteal arterial segment remains a challenge to manage, with no evidence-based standard treatment defined.

How can the results after DCB be optimized? The negative predictors that significantly influence the outcome of treatment in patients with PAD are as follows: cardiovascular comorbidities, long lesion lengths, total occlusions, and the presence of calcification. Due to these reasons, the concept of atherectomy is becoming attractive, as it allows ablation of the plaque material, straightens eccentric lesions, and creates a lumen or widens the vessel lumen prior to PTA. Therefore, overstretching of the vessel wall can be avoided. As demonstrated in various

**TABLE 1. COMPARISON OF DIFFERENT PROPERTIES OF ATHERECTOMY DEVICES**

| Device | Jetstream (Boston Scientific Corporation) | Phoenix (Philips Volcano) | HawkOne (Medtronic) | Pantheris (Avinger, Inc.) | Turbo-Elite Laser (Spectranetics Corporation) |
|---|---|---|---|---|---|
| **Atherectomy Type** | **Rotational** | **Rotational** | **Directional** | **Directional** | **Photoablative** |
| Eccentric lesion | X | X | XX | XX | |
| Soft/fibrotic plaque | XX | XX | XX | XX | XX |
| Thrombotic lesion | XX | | | | X |
| Highly calcific lesion | XX | X | X | | X |
| Chronic total occlusion | XX | XX | X | X | XX |
| In-stent restenosis | X | X | | XX | XX |
| In-stent occlusion with thrombus | XX | | | X | XX |

X indicates good applicablity; XX indicates perfect applicability.

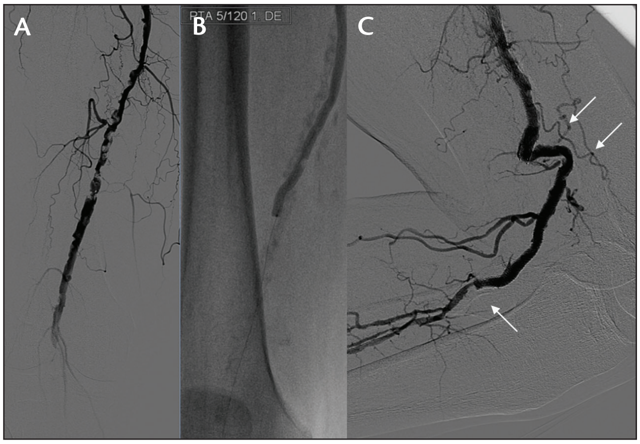


**Figure 1. A 76-year-old woman (Rutherford class 5) with a heavily calcified distal SFA and popliteal artery (A, B). After placement of two stents, the vessel segment shows severe kinking (double arrows) and luminal mismatch (one arrow) in the distal popliteal artery (C).**

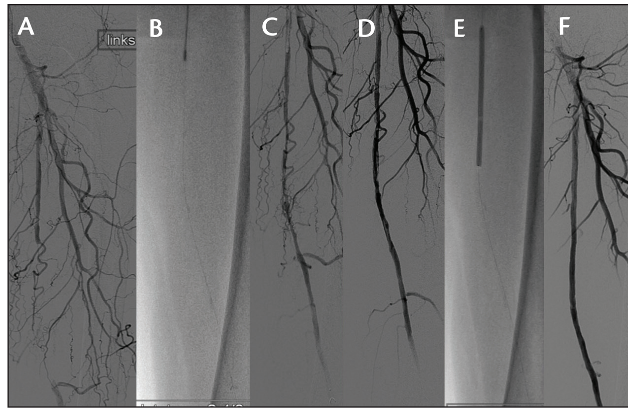


**Figure 2. A 69-year-old woman (Rutherford class 3) with a longer occlusion of the SFA (A). After crossing the occlusion with a 0.014-inch CTO wire (Sion Blue, Asahi Inc.), a filter wire (Emboshield Nav6, Abbott Vascular) is placed (B) and Jetstream atherectomy is performed using a 2.4- X 3.4-mm device, with two passes with blades down (C) and two passes with blades up (D). A low-pressure (4-atm) DCB is then used (E, F).**

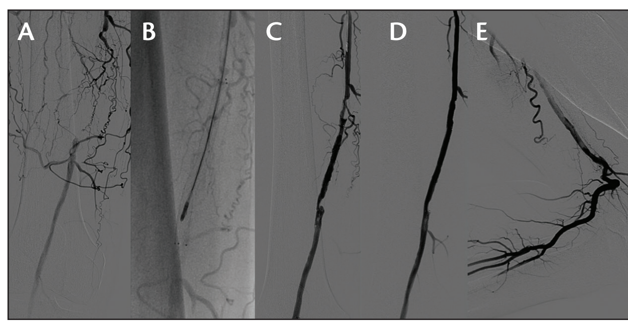


**Figure 3. A 58-year-old man (Rutherford class 3) presents with in-stent restenosis in the distal SFA (A). After recanalization with a 0.014-inch CTO wire, several passes using the 2.4- X 3.4-mm device Jetstream atherectomy system are performed (B, C) followed by a 6- X 120-mm DCB. A good result is achieved, revealing a stenosis in the distal portion of the stent and the lateral angiographic series showing the stent compromising the movement of the distal SFA when bending the knees > 90° (D, E).**

atherectomy studies, the dissection and bailout stenting rates are low (Table 1).

## CLINICAL EXPERIENCES

In daily endovascular treatment of PAD, we are often confronted with severely calcified lesions in the distal femoropopliteal segment. Our routine angiographic control of the femoropopliteal segment with > 90° bended knee often demonstrates the failure of important stent properties, such as flexibility and adaptability to the vessel, in the distal SFA or popliteal artery, especially with older-generation nitinol stents. In this particular segment, we see a number of reocclusions and severe restenosis, even with the latest-generation stents (Figure 1). To avoid these negative aspects, using atherectomy for vessel preparation in the femoropopliteal artery is an important step before PTA. This is particularly true in occlusions where we recanalize the vessel with an 0.014-inch system, which allows the operator to use a variety of different CTO wires, without the risk of severe vessel injury. With a 0.014-inch system, we are able to more successfully cross these occlusions intraluminally compared to larger wire sizes. After placing a distal protection system in almost all procedures, the rotational Jetstream atherectomy system (Boston Scientific Corporation) is used to create a channel and gain a larger vessel lumen prior to adjunctive therapy with a DCB (Figure 2).

Moreover, in-stent restenosis or reocclusion can effectively be treated with Jetstream, which gained CE Mark approval for treating in-stent restenosis in 2016. In Figure 3, reocclusion of a stented segment in the distal SFA is shown. After recanalization and placement of a distal protection system, we used the larger Jetstream atherectomy system (2.4 X 3.4 mm) to debulk before DCB therapy. A severe stenosis in the distal end of the stent was revealed, again, showing the injury of the stent to the vessel in the movement segment of the femoropopliteal artery. Thus, an important aim of this experience is to avoid placing a stent in this particular complex vessel segment.

## RATIONALE FOR ATHERECTOMY

Early elastic recoil, frequent dissections, and poor primary and secondary patency rates for long lesions limit balloon angioplasty of complex vessel lesions, despite the high procedural success rates. The use of latest-generation self-expanding nitinol stents may be an effective treatment for focal lesions. However, restenosis can be as high as 10% to

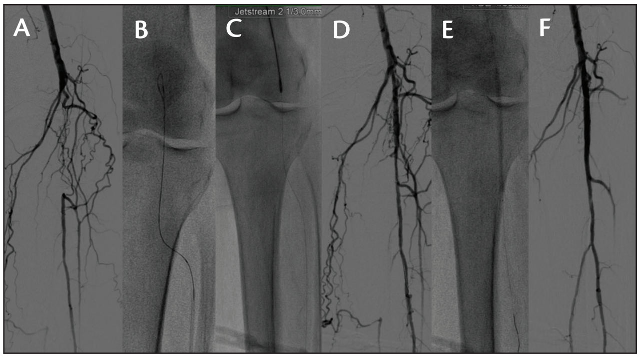


**Figure 4. A 73-year-old woman (Rutherford class 5) with an occlusion of the distal popliteal artery (A). Due to numerous collaterals, it was impossible to recanalize this segment antegrade. Therefore, retrograde recanalization (via the anterior tibial artery) is performed for intraluminal recanalization (B) and Jetstream atherectomy is done (C, D). After adjunctive DCB therapy, restoration of the distal popliteal artery is achieved (E, F).**

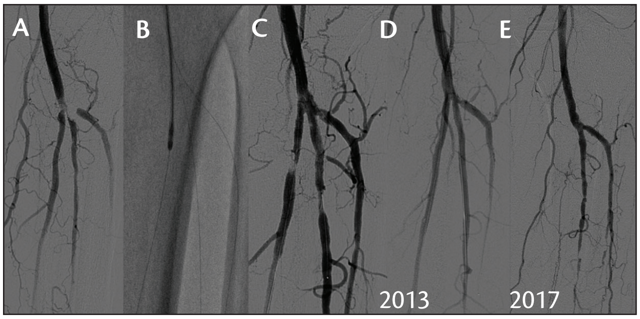


**Figure 5. A 72-year-old man (Rutherford class 5) with diabetes mellitus type I presented in March 2013 with a nonhealing ulcer on his first digit. A subtotal occlusion of the trifurcation below the knee on the left leg is observed (A). After placing three 0.014-inch bare wires into each vessel, Jetstream atherectomy with the 2.1- X 3-mm system is performed (B). After adjunctive DCB therapy, restoration of the trifurcation is nicely achieved (C, D). In February 2017, angiography showed a new ulceration of the foot, revealing a good long-term result of the treated lesion. However, progression of atherosclerotic disease in the distal vessels is obvious (E).**

40% at 12 to 24 months. Furthermore, the presence of rigid calcified plaques may result in incomplete stent expansion and significant residual stenosis.[3]

There are a variety of different atherectomy devices available on the market. They are all designed to cut, shave, or vaporize atherosclerotic or calcified lesions, as summarized in Table 1. It has been shown in a number of atherectomy studies (mostly CE Mark approval studies without DCB ballooning) that the rate of flow-limiting dissections remained low (< 10%), and therefore the bailout stent rate was almost below 10% as well.[4-7] However, with laser atherectomy, the bailout stent rate was higher at 23.3%.[8] These data demonstrate that atherectomy is safe and effective within 12 months in most atherosclerotic lesions.

The first data for the Jetstream system were published in 2009 by Zeller and colleagues in the Pathway PVD trial.[7] In 172 patients with relatively short lesions (approximately 27 mm), they demonstrated the safety and effectiveness of the first-generation rotational atherectomy device, formerly called the Pathway Medical system (2.1 mm with blades down and 3 mm with blades up). The patency rate (peak systolic velocity ratio < 2.4 by duplex ultrasound) was 61.8% with a target lesion revascularization (TLR) rate of 26% after 12 months.

In the Jetstream Calcium Study,[9] IVUS analysis showed that after Jetstream atherectomy, the lumen area increased from 6.6 ± 3.7 $mm^2$ to 10 ± 3.6 $mm^2$ ($P$ = .001), and calcium reduction was responsible for 86% ± 23% of the lumen increase. In this study, the Jetstream atherectomy system increased lumen dimensions in moderately or severely calcified femoropopliteal lesions by removing superficial calcium without major complications. This study, which had severe calcium in 63.6% of lesions, concluded that the Jetstream atherectomy system removed and modified superficial calcium to achieve significant lumen gain. In early 2017, data presented from the JET Registry demonstrated a 77.2% patency rate and 81.7% freedom from TLR at 12 months when Jetstream was combined with PTA, with an average lesion length of 16.4 cm. The subgroup analysis showed that with the use of the current generation of the Jetstream system in nonstent lesions (157 patients), there was a patency rate of 79.5%, and in-stent lesions (84 patients) a rate of 72.2% was achieved.[10]

At our institution, we performed 228 procedures with the Jetstream atherectomy system between 2014 and 2015. Lesions lengths were between 2 to 28 cm, with an occlusion rate of 68%. The procedural success rate was high at 96.5%. DCB therapy was used 100% of the time, with a bailout stent rate of 7.9%. Freedom from TLR after 1 year was 86%; however, there are clear limitations, as the follow-up was achieved via routine patient control and additional data were collected via the electronic data system of our institution.

To obtain a more reliable data set, we started a single-center registry in February 2017. The dissection rate and bailout stent rate was low, even in complex lesions, like below-the-knee (BTK) and bifurcation lesions (Figures 4 and 5). In these lesions especially, we do not have a lot of endovascular options to achieve a longer lasting patency, as it is known from a number of BTK studies. To obtain a more reliable data set, we started a single-center registry in February 2017. In this registry, patients with femoropopliteal lesions (up to 25 cm in length) are included to compare endovascular treatment with Jetstream atherectomy plus a DCB versus a DCB and stenting.

## POTENTIAL BENEFIT FOR ATHERECTOMY BEFORE DCB USE

Today, based on a meta-analysis of 11 trials with 1,838 participants, there is clear evidence of an advantage for DCBs compared with plain old balloon angioplasty (POBA) in several anatomic endpoints such as primary vessel patency, binary restenosis, and target lesion revascularization for up to 12 months.[11] It is also remarkable that after 24, and even 36 months, DCB results show improved patency compared to POBA in treating femoropopliteal lesions.[12-14]

However, limitations are recognized in these studies, and it is clearly demonstrated in the study from Fanelli and colleagues[15] with 60 patients enrolled, that in heavily calcified SFA lesions, stand-alone DCB therapy yielded only 50% primary patency rates with significantly higher late lumen loss, regardless of lesion length after 1 year. This study concluded that to achieve a durable antiproliferative effect, deep penetration of the drug into the media layers with maximum uptake is required, but calcified lesions may act as a physical barrier to optimal drug penetration and adequate distribution. Therefore, vessel preparation via atherectomy to reduce the calcium burden plays an important role. Atherectomy may remove the potential barrier, and the integrity of the DCB will be protected, especially in CTOs, by creating a larger vessel lumen before placing the balloon. On the other side, DCB therapy may inhibit the inflammatory response caused by mechanical trauma of plaque excision.

In the DEFINITIVE AR study,[16] Zeller and his group first described the combination of directional atherectomy with a DCB compared to stand-alone DCB use. In this small pilot study, a trend toward an added benefit for directional atherectomy with a DCB over DCB use alone in challenging lesions was described. However, no significant differences exist between the two groups, thus further investigation in larger, prospective, randomized, statistically powered trials is necessary. Last year, the REALITY study began evaluating patient outcomes with adjunctive use of the HawkOne or TurboHawk atherectomy systems (Medtronic) with the In.Pact Admiral DCB (Medtronic) in significantly calcified and symptomatic femoropopliteal PAD (NCT 02850107). In addition, Stavroulakis[17] reported on a single-center study comparing DCB angioplasty versus directional atherectomy with antirestenotic therapy (DAART) for isolated lesions of the popliteal artery. These data revealed that the use of DAART was associated with a higher primary patency rate compared with DCB angioplasty (82% vs 65%) for isolated popliteal lesions.

Very recently, Shammas et al showed the advantage of DCB versus POBA after Jetstream atherectomy in a core lab–adjudicated analysis.[18] Eighty-one patients (49.4% men; mean age, 68.3 years; 53.1% with diabetes) with de novo or restenotic femoropopliteal lesions (Rutherford category 1–5) were enrolled in the JET-SCE single-center experience. At 18 months follow-up, the TLR rate was significantly reduced with atherectomy and adjunctive DCB use compared to atherectomy with adjunctive POBA alone (91.1% vs 63.7%; *P* = .03). Furthermore, Drs. Shammas and Garcia plan to begin enrollment this year in a much larger multicenter study evaluating the combination therapy of Jetstream plus the Ranger DCB (Boston Scientific Corporation) in complex lesions.

As previously discussed, our experiences support these data, and a very interesting case of a complex trifurcation lesion nicely demonstrated long-lasting patency (Figure 5). In 2013, when we started using this combination therapy, we performed Jetstream atherectomy with adjunctive DCB therapy and observed a good interventional result, avoiding any stent implantation. Four years later, reintervention was necessary due to the progressive vessel disease and showed a nice long-term result of the former trifurcation lesion.

In addition, a more detailed description of the Jetstream atherectomy system, along with tips and tricks for its use, can be found in a recent article by Shammas in *The International Journal of Angiology.*[19]

## SUMMARY: ATHERECTOMY AND DCBs

Atherectomy, specifically with the Jetstream atherectomy system, offers an effective tool for endoluminal, mechanical debulking of plaque and thrombotic materials, even in severely calcified lesions. We have seen that treatment even in critical vessel segments is safe and possible. Due to preservation of the native vessel by avoiding the placement of stents, future interventions might be possible.

After creating a larger vessel lumen of the diseased femoropopliteal segment via atherectomy, an important detail might be to consider low pressure angioplasty (3–6 atm) to avoid overstretch of the vessel wall.

With DCB use as a well-established treatment for PAD, atherectomy can remove the potential barriers for drug uptake, allowing increased drug penetration/application into the vessel wall. Therefore, the combination of endovascular atherectomy prior to DCB use is an important option in the treatment of long lesions, total occlusions, and calcified vessels. ■

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