Key Learnings From the JETSTREAM Atherectomy Calcium Study

Insights from the authors on removing severe superficial calcium to achieve significant luminal gain in femoropopliteal arteries.

BY AKIKO MAEHARA, MD; GARY S. MINTZ, MD; AND WILLIAM A. GRAY, MD

The recently published JETSTREAM Calcium Study was a prospective, single-arm, multicenter study to evaluate the effect of the JETSTREAM™ Atherectomy System (Boston Scientific Corporation) when treating severely calcified peripheral arterial lesions in the common femoral, superficial femoral, or popliteal arteries causing claudication.[1] The main question was whether the JETSTREAM Atherectomy System was effective in removing calcification. This was evaluated using both quantitative and qualitative intravascular ultrasound (IVUS), by comparing preintervention and postatherectomy IVUS images. The two major findings were as follows: The JETSTREAM Atherectomy System removed and modified moderate to severe superficial calcium to achieve significant lumen gain as standalone therapy; and adjunctive balloon angioplasty after calcium modification with the JETSTREAM Atherectomy System showed further lumen increase without major complications. In this study, the JETSTREAM 2.1/3.0 mm device was used for all procedures without distal protection. There were no major adverse events up to 30 days postprocedure.

WHY AN IVUS STUDY IS UNIQUE

Calcium was screened by angiography to identify moderate to severe obstructive intraluminal calcification in the common femoral, superficial femoral, or popliteal arteries. Lesions were evaluated by IVUS. Patients identified by angiography as possible candidates were included in the final analysis only if there was superficial calcium that had an arc > 90° and a length > 5 mm. Overall, 55 patients were screened; however, only 26 patients met the inclusion criteria. Half of the lesions identified angiographically as having moderate to severe calcification did not have severe superfi-

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CASE STUDY 1: COMMON FEMORAL*

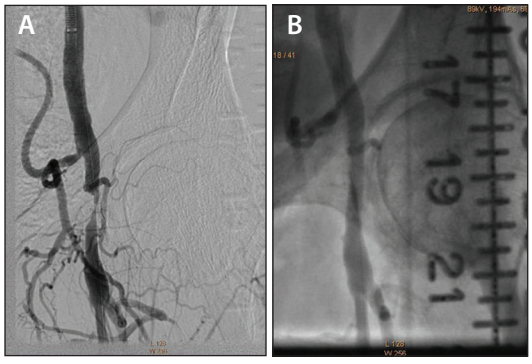

Figure 1. Before (A) and after (B) successful revascularization of a highly stenotic left common femoral artery.

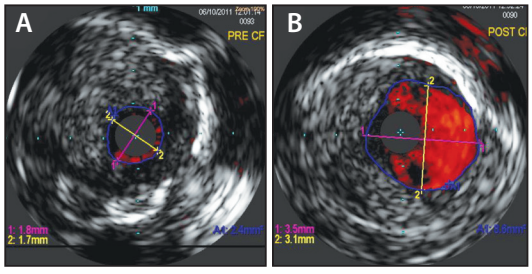

Figure 2. Pre-atherectomy IVUS image of the common femoral artery (lumen area = 2.4 mm²) (A) compared to post-JETSTREAM image (B) illustrates impressive luminal gain and a circumferential lumen created with standalone JETSTREAM Atherectomy (lumen area = 8.6 mm²). Boston Scientific images on file from the JETSTREAM Calcium Study.

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

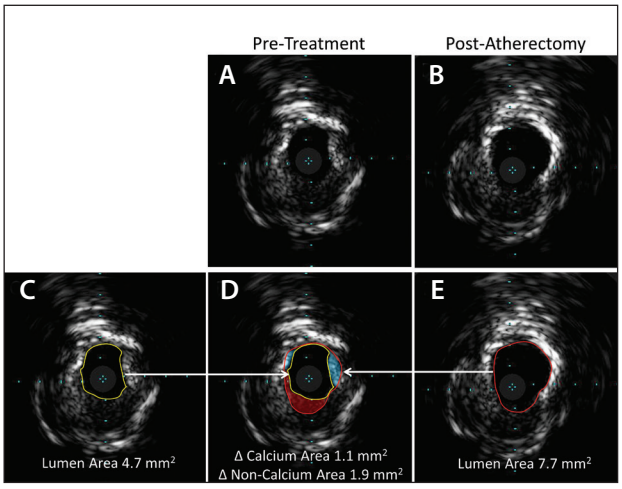

Figure 3. Method of intravascular ultrasound analysis of calcium reduction. The pretreatment IVUS (A). The corresponding postatherectomy IVUS image (B). The analysis sequence is shown at the bottom. After identifying and matching the slices with calcium reduction, the lumen borders for both pretreatment (yellow circle: lumen area = 4.7 mm²) (C) and postatherectomy images (red circle: lumen area = 7.7 mm²) (E) were contoured, and the two were overlaid (D). By comparing the two contours to the visual assessment of plaque, lumen gain (3 mm²) could be attributed to a reduction of calcified plaque (blue area = 1.1 mm²) or to a reduction of noncalcified plaque (red area = 1.9 mm²). Reprinted from Maehara A, Mintz GS, Shimshak TM, et al. Intravascular ultrasound evaluation of JETSTREAM atherectomy removal of superficial calcium in peripheral arteries. EuroIntervention. 11(1), 96-103, Copyright 2015, with permission from Europa Digital & Publishing.

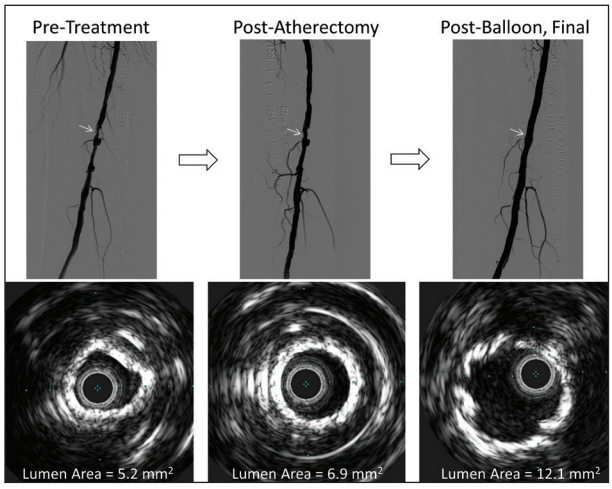

Figure 4. Representative case of pretreatment, postatherectomy, and postballoon final images. The lumen increased from pretreatment (5.2 mm²) to postatherectomy (6.9 mm²) to postballoon (12.1 mm²) without dissection. Reprinted from Maehara A, Mintz GS, Shimshak TM, et al. Intravascular ultrasound evaluation of JETSTREAM atherectomy removal of superficial calcium in peripheral arteries. EuroIntervention. 11(1), 96-103, Copyright 2015, with permission from Europa Digital & Publishing.

cial calcium (calcium within the lumen) at the lesion site as determined by IVUS. In these lesions, superficial calcification existed only in nonstenotic segments, or only deep calcification (calcium within the vessel wall) was present at the stenosis site. Therefore, the first finding of this study was the limitation of peripheral angiography to detect and localize calcification in peripheral arterial lesions. Deep calcification may not affect luminal gain (ie, create a stenosis). Therefore, the differentiation between superficial and deep calcification and their respective roles in severe stenosis is important when evaluating the true efficacy of any atherectomy procedure and device. These findings are similar to the data reported by Mintz et al in coronary artery lesions.[2] In that study, IVUS detected calcium in 841 of 1,155 coronary artery lesions (73%), while angiography detected calcium in only 440 (38%). Therefore, the overall sensitivity of angiography relative to IVUS was 48%, with a specificity of 89%.

> At the slice with the maximum calcium reduction, the lumen area increased from 6.6 ± 3.7 mm² preintervention to 10 ± 3.6 mm² (*P* = .001) after atherectomy.

SIGNIFICANT LUMINAL GAIN ACHIEVED WITH JETSTREAM ATHERECTOMY

For the patients who were ultimately included in the study, first the preintervention and postatherectomy IVUS lumens were outlined. Second, the postatherectomy IVUS images were overlaid onto their respective preintervention images. Assuming there was no change in total arterial area, the change in lumen area was attributed to either calcified plaque or noncalcified plaque removal (Figure 3). At the slice with the maximum calcium reduction, the lumen area increased from 6.6 ± 3.7 mm² preintervention to 10 ± 3.6 mm² (*P* = .001) after atherectomy. The decrease in calcium area, measured as 2.8 ± 1.6 mm², was responsible for 86% ± 23% of the lumen area increase. Additionally, the arc of reverberations increased from 25° (range, 15°–35°) to 70° (range, 46°–95°), *P* = .001, indicating device-related modification of calcium. Therefore, the second lesson was that the JETSTREAM Atherectomy System increased lumen dimensions by calcium removal as well as by calcium modification (increase in reverberations).

CASE STUDY 2: DISTAL SFA/PROXIMAL POPLITEAL*

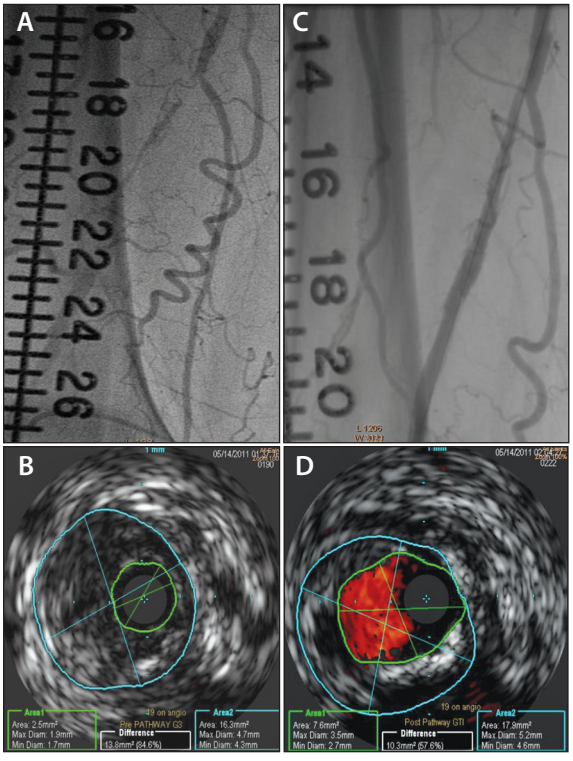

Figure 5. Successful debulking with the JETSTREAM Atherectomy System in a distal right SFA/proximal popliteal artery lesion (A). The pre-atherectomy IVUS image (B) reveals a lumen area of 2.5 mm². The post-atherectomy images (C and D) reveal a lumen area of 7.6 mm² and impressive debulking with JETSTREAM Atherectomy even before adjunctive therapy. Boston Scientific images on file from the JETSTREAM Calcium Study.

VESSEL EXPANSION WITHOUT VESSEL DAMAGE

In the 11 lesions that had postadjunctive balloon IVUS images, the minimum lumen area increased further from 7 mm² (range, 6.4–7.8 mm²) after atherectomy to 11.9 mm² (range, 10.3–13.5 mm²) after adjunct balloon inflation ($P < .01$). However, the prevalence of dissections also increased from 3/11 after atherectomy to 8/11 after adjunct balloon inflations ($P = .03$). However, the maximum angle of the dissection flap was minor (42° [range, 17°–66°]) with a preserved lumen area (15.6 mm² [range, 13.4–17.7 mm²]) within the dissection. The dissections were non-flow limiting. Also, the higher resolution of IVUS imaging versus angiography most likely led to a higher detection rate. Thus, the third and final lesson was that the JETSTREAM Atherectomy System allowed additional lumen increase by facilitating vessel expansion without significant vessel damage (ie, dissection), presumably because of calcium modification. A representative case is shown in Figure 4.

CONCLUSION

Severely calcified lesions may cause damage to the polymer/drug coating of a drug-eluting stent, resulting in inadequate drug delivery.[3,4] Although there is accumulating evidence in coronary artery intervention showing that calcified lesions have worse outcomes compared to noncalcified lesions,[5,6] the clinical impact of superficial calcium removal in peripheral artery disease in respect to effectiveness of drug-coated balloons or drug-eluting stents needs further investigation.[7] ■

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