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.

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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. The main question was whether the JETSTREAM Atherectomy System was effective in removing calcium. 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 superf-

CASE STUDY 1: COMMON FEMORAL*

...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.

*Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.
At the slice with the maximum calcium reduction, the lumen area increased from $6.6 \pm 3.7 \text{ mm}^2$ preintervention to $10 \pm 3.6 \text{ mm}^2$ ($P = .001$) after atherectomy.
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.](image)

VESSLE 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. Although there is accumulating evidence in coronary artery intervention showing that calcified lesions have worse outcomes compared to noncalcified lesions, 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.

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