

EDITORIAL COMMENT

Shaking and Breaking Calcified Plaque

Lithoplasty, a Breakthrough in Interventional Armamentarium?*



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Calcium has always been the worst enemy of the interventionist; calcium impedes crossability, expansion, embedment, and coverage (1,2).

Fluoroscopy severely underestimates the presence of endoluminal calcium, and the calcium detected on fluoroscopy is sometimes localized at the interface between the adventitia and the media (i.e., Mönckeberg arteriosclerosis) (3). Intravascular ultrasound is the most reliable diagnostic tool to detect endoluminal and deep calcium, but the leading edge of the endoluminal calcium hides in its shadow the actual mass of calcium in the vessel wall (4). Optical coherence tomography (OCT) has a limited depth penetration but can, with a high sensitivity and specificity, image superficial calcium and assess the back side of the calcified plaque, rendering possible the measurement of the total calcified mass (4). These last 2 techniques are intravascular and are still used in a minority of patients. In the near future, multislice computed tomography (MSCT) could be used to define the calcium load along the luminal pathway and indicate to the interventional cardiologist the plan to follow in treating these calcified plaques (rotational atherectomy, orbital atherectomy, lithoplasty) (Figure 1).

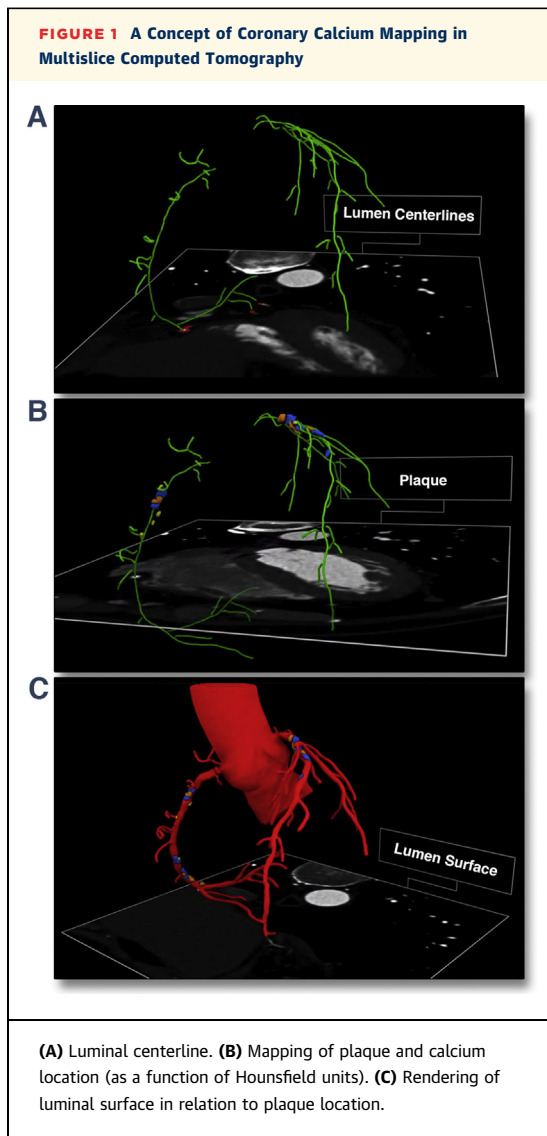
Although rotational atherectomy (RA) was expected to be one of the solutions, the landmark trial ROTAXUS (Rotational Atherectomy Prior to TAXUS Stent Treatment for Complex Native Coronary Artery Disease) did not demonstrate any improvement in

clinical outcomes (5). At 2 years, major adverse cardiovascular events (MACE) and target-lesion revascularization occurred in 29.4% versus 34.3% ($p = 0.47$) and 13.8% versus 16.7% ($p = 0.58$) in the RA group and the standard therapy group, respectively. Afterward, orbital atherectomy (OA) was introduced. In the single-arm ORBIT II (Evaluate the Safety and Efficacy of OAS in Treating Severely Calcified Coronary Lesions) trial, 2-year rates of MACE and target-lesion revascularization were 19.4% and 6.2%, respectively (6). Comparison of the data of first-generation drug-eluting stents in ORBIT II (17.2%, $n = 74$) with ROTAXUS (29.4%, $n = 120$) indicated numerically lower event rates in ORBIT II. Several potential advantages of OA over RA were the adjustable ablation diameter, continuous blood flow during ablation, smaller particle size, and lower incidence of slow flow/no-reflow. However, OCT analysis has demonstrated eccentric lesion modification by RA (7,8) and OA (9,10) that follows the guidewire course (guidewire bias) (Figure 2). In regions of tortuosity or eccentric plaque, crater, or tunnel formation could occur after RA or OA, which could lead to perforation or stent malapposition.

Recently, as a new approach of vessel preparation before stent implantation in calcified lesion, lithotripsy-enhanced disruption of calcium (i.e., lithoplasty) was introduced. The lithoplasty catheter is a balloon angioplasty catheter with unfocused lithotripsy emitters, which disrupts both superficial and deep calcium within vascular plaque by acoustic circumferential pressure pulses. Lithotripsy does not rely on mechanical tissue injury by physical interaction, such as RA, OA, cutting balloon, or scoring balloon, but rather by a diffuse acoustic pulse through a balloon inflated to 4 to 6 atm. There are currently 2 studies evaluating the safety and performance of the lithoplasty catheter: DISRUPT PAD (Safety and Performance Study of the Shockwave Lithoplasty System) and DISRUPT CAD (Shockwave Coronary Rx Lithoplasty Study). DISRUPT PAD is

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a multicenter, prospective, single-arm study applying the lithoplasty catheter to the treatment of calcified femoropopliteal lesions. Procedural success was achieved in 100.0% of cases, and 96.8% were free from target-lesion revascularization at 6 months. DISRUPT CAD is a multicenter, prospective, single-arm study of percutaneous lithoplasty before stent implantation in heavily calcified coronary lesions. The primary safety endpoint is rate of MACE within 30 days of the procedure, and the primary performance endpoint is clinical success, defined as residual stenosis <50% after stenting with no evidence of in-hospital MACE. The main result has not been published but was presented at TCT 2016 as a 5% 30-day MACE rate and 95.0% clinical success.

In this issue of *JACC*, Ali et al. (11) present the OCT substudy from the DISRUPT-CAD trial. After lithoplasty, intraplaque calcium fracture was observed, and its frequency increased as the calcification severity increased. Final stent expansion was similar among all tertiles of calcification severity, which suggests more efficacy with increasing severity of calcification. This report is important because it is the first experience with a lithoplasty device to address the unmet need in treatment of severely calcified lesions.

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With the introduction of scaffold technology, preparation of the lesion and sizing of the device are now of paramount importance, and highly calcified lesions are not themselves a contraindication for treatment provided the preparation creates a circular and concentric lumen (Figure 3). The concept of circumferential plaque modification is welcome, especially in the era of bioresorbable scaffolds. Although bioresorbable scaffolds appeared to overcome the limitations of permanent metallic stents, their use technically requires more extensive lesion preparation in calcified lesions because of their limited mechanical strength and radial force (12). Suwannasom et al. (13) demonstrated post-procedural lesion asymmetry was an independent predictor of the device-oriented composite endpoint. Lesion asymmetry remained even after 5 years post-procedure, which suggests the impact of lesion preparation before device implantation (14). Therefore, there is a resurgence of the use of atherectomy for the purpose of optimal lesion preparation among patients undergoing implantation of bioresorbable scaffolds. These publications raised again the question of whether OCT guidance should become universal (more and more commonly used for sizing and guidance during the preparation phase preceding the implantation of a stent or scaffold).

Coronary angiography, the Mason Sones' discovery that has revolutionized the diagnosis and treatment of coronary artery disease, is now more than one-half century old and should be used in conjunction with OCT; it can be preceded by MSCT, which can be used the day before catheterization to indicate the angiographic view that would be optimal for treatment of the lesion. In the United Kingdom, the National Institute for Health and Care Excellence has promoted MSCT with fractional flow reserve derived from computed tomography as the most cost-effective diagnostic approach for coronary artery disease.

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