Orbital Atherectomy Plaque Modification Assessment of the Femoropopliteal Artery Via Intravascular Ultrasound (TRUTH Study)

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Abstract
Objective: The Tissue Removal Assessment with Ultrasound of the SFA and Popliteal (TRUTH) study assessed the performance of the orbital atherectomy system (OAS) to treat femoropopliteal arteries, including determining its effect on plaque removal. Methods: Patients with symptomatic femoropopliteal peripheral arterial disease were treated with the OAS followed by adjunctive balloon angioplasty (BA). Intravascular ultrasound (IVUS) images were collected pre- and post-OAS and post-OAS BA. Patients were followed through 12 months post-procedure. Results: Twenty-nine lesions were treated with OAS-BA in 25 patients. The mean maximum balloon inflation pressure was 5.2 ± 1.2 atm. Virtual histology IVUS (VH-IVUS) analysis revealed at the maximum calcium ablation site that calcium reduction was responsible for 86% of the lumen area increase. The minimum lumen area increased from 4.0 mm² to 9.1 mm² (<.0001), and the percentage of area stenosis decreased from 76.9% to 43.0% (<.0001) after OAS-BA. At 12 months, the target lesion revascularization rate was 8.2%, and ankle–brachial index and Rutherford classification improved significantly from baseline through follow-up. Conclusion: The VH-IVUS analysis reveals that OAS modifies the calcified component of the plaque burden. It is hypothesized that calcium modification by OAS changes the lesion compliance, allowing for low pressure adjunctive BA. The clinical outcomes were favorable through 12-month follow-up.

Keywords: orbital atherectomy, intravascular ultrasound, peripheral arterial disease, calcification

Introduction
American College of Cardiology/American Heart Association guidelines have given Class I indication for endovascular revascularization for treatment of femoropopliteal lesions in management of severe symptomatic PAD in patients who have failed medical and exercise therapy. One of the important predictors of unsuccessful angioplasty and poor procedural outcome is the presence of plaque calcification. Fitzgerald et al demonstrated that 74% of clinically significant dissections after balloon angioplasty (BA) occurred in lesions with significant localized calcium deposits. Atherectomy aims to reduce the complications of traditional angioplasty—dissection, recoil, and disruption of the elastic lamina—that result in smooth muscle cell proliferation. The Orbital Atherectomy System (OAS; Cardiovascular Systems, Inc, St Paul, Minnesota) provides the unique capability of modifying plaque using a differential sanding mechanism. Intravascular ultrasound (IVUS) and virtual histology (VH) are accurate for predicting plaque composition in vivo and can detect fibrous, fibrofatty, dense calcium, and necrotic core areas. The Tissue Removal Assessment with Ultrasound of the SFA and Popliteal (TRUTH) study, sponsored by Cardiovascular Systems, Inc, was designed to mirror the Tissue Removal by Ultrasound Evaluation (TRUE) study that evaluated the debulking properties of the Jetstream G2 atherectomy system (Pathway Medical Technologies, Inc., Kirkland, Washington) using VH-IVUS. The TRUTH study is the first study to use VH-IVUS to assess OAS-related plaque modification.

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Methods

Study Design

The TRUTH study was a prospective, single-arm, nonrandomized study designed to assess the performance of the OAS for modification of plaque using VH-IVUS in patients who were referred with occlusive symptomatic PAD occurring in the superficial femoral artery (SFA), popliteal (POP), and/or tibioperoneal trunk (TPT) arteries. The study was conducted at New York University Langone Medical Center (New York) per Good Clinical Practice and was approved by the Institutional Review/Ethics Committee.

Patients ≥18 years of age were enrolled in the study after providing informed consent and meeting key study inclusion criteria including (1) target lesion(s) located in SFA, POP, or TPT; (2) lesions with ≥70% angiographic stenosis or occlusion; (3) lesions <110 mm in length; and (4) reference vessel diameter between 3 and 6.5 mm by visual assessment on angiography. Key exclusion criteria included (1) interventional treatment includes planned laser, brachytherapy, or atherectomy procedure other than the OAS.

Procedure

Before the procedure, all patients were given the antiplatelet regimen of aspirin and clopidogrel. Patients underwent diagnostic fluoroscopy/cine as well as digital subtraction angiography of the affected limb. After angiography and once the study criteria were met, patients were treated with the OAS followed by adjunctive BA. Two passes with 2.0 mm Solid crown at 60,000, 90,000, and 120,000 rpm with at a total of 6 passes per lesion were performed. After OAS treatment, balloon inflation was initiated at 2 atm. The balloon inflation pressure was increased by 1 atm every 30 seconds until no waist was observed angiographically, and at that time, the balloon was held in place for 60 seconds. If the balloon was inflated to nominal pressure and a waist was still observed angiographically, the operator was allowed to repeat OAS treatment; however, no patients required repeat OAS treatment in this study.

Grayscale and VH-IVUS Image Acquisition

Grayscale and VH-IVUS images were collected using a 20 MHz IVUS catheter (Eagle Eye, Volcano Corporation, Rancho Cordova, California) before intervention, post-OAS, and post final adjunctive BA. The IVUS catheter was placed 10 mm distal to the lesion, and imaging was performed in a retrograde direction until the catheter was proximal to the lesion. The automatic pullback speed was 1.0 mm/s using an R-100 pullback device (Volcano Corporation). During pullback, grayscale IVUS was recorded, raw radiofrequency data were captured at the top of the R-wave, and the reconstruction of the color-coded map by a VH-IVUS data recorder was performed (s5; Volcano Corporation). The IVUS images were recorded onto digital media for off-line software analysis by an independent IVUS core laboratory (Cardiovascular Research Foundation).

Grayscale and VH-IVUS Analysis

The pre-OAS, post-OAS, and post-BA VH-IVUS images were matched by comparing vascular and perivascular landmarks and the known pullback speed. The treated segment was identified and divided into subsegments in relation to the existence of superficial calcium and its modification. A maximum number of 3 superficial calcified plaques, at least 5 mm apart, were identified per lesion that showed the greatest calcium reduction. First, the preintervention and post-OAS lumens were contoured using computerized planimetry software (EchoPlaque, Indec Systems Inc, Mountain View, California). Second, the post-OAS IVUS images were overlaid onto their respective preintervention images, and the change in lumen area due to either calcified plaque or noncalcified plaque removal (assuming no change in total arterial area) could be assessed. The method of IVUS analysis of calcium reduction has been previously described.7 Further, the lumen and vessel borders were traced for all available frames. The proximal or distal reference slice was defined as the slice having the largest lumen area within 5 mm from the proximal or distal end of the treated segment but before any significant side branch. Quantitative IVUS measurements included vessel area, lumen area, plaque area (calculated as vessel area minus lumen area), and plaque burden (calculated as plaque area divided by vessel area). The slice with the minimum lumen area (MLA) was assessed. Area stenosis was calculated as 1-MLA/reference lumen area. VH-IVUS plaque components were color coded as dense calcium (white), necrotic core (red), fibrofatty (light green), or fibrous tissue (dark green). Volumes were calculated using Simpson rule and reported as mean area (volume divided by length, mm$^3$/mm).

Qualitative IVUS parameters included existence of reverberations (indicating device-related modification of calcium) and the angle of reverberation with respect to the center of the lumen.

Study End Points

Patients were followed in clinic at 2 weeks (±7 days), 6 months (±30 days), and 12 months (±30 days) postprocedure. The TRUTH study end points included plaque modification as assessed by IVUS, vessel compliance as measured by maximum balloon inflation pressure during adjunctive angioplasty, rate of procedural angiographic complications, stent usage at the time of the procedure, ankle–brachial index (ABI), and Rutherford classification (RC) at baseline and follow-up visits, and target lesion revascularization (TLR)/target vessel revascularization (TVR) at follow-up.

Statistical Analysis

Statistical analysis was performed using SAS software, version 9.1 (SAS Institute, Cary, North Carolina). For discrete
outcomes, the overall $P$ value represents the probability of differences in the probability of an event over time using a 1-way repeated measures analysis of variance (ANOVA) and presented as frequencies. For continuous outcomes, the overall $P$ value represents the probability of differences in mean outcomes over time using a 1-way repeated measures ANOVA and presented as median and interquartile range. Kaplan-Meier method was used to obtain estimate of survival rate, and Greenwood method was used to obtain the 95% confidence interval for the estimate. If overall $P$ value is <.05, individual post hoc pairwise comparisons are presented to show where the differences exist using Scheffe test. If the data fail to meet the assumption for normality per the Shapiro-Wilks test, then the $P$ value represents probabilities of differences in median outcomes from Friedman nonparametric ANOVA. For the calcium plaque analysis, a 1-way repeated measures ANOVA via a mixed model methodology was used to take account of the clustering of multiple calcified plaques per lesion. A $P$ value of <.05 was considered to indicate statistical significance.

**Results**

**Patient Demographics and Lesion Characteristics**

Twenty-five patients were enrolled from January 25, 2013, to February 7, 2014. Patient demographics are presented in Table 1. Preprocedure angiographic lesion characteristics are described in Table 2.

**Procedural Results**

The 2.00 mm Solid crown OAS was used in all cases. The number of OAS devices used per lesion was 1.0 ± 0.0 with a total OAS run time of 127.4 ± 37.9 seconds per lesion. The maximum balloon inflation pressure post-OAS/prestent was 5.2 ± 1.2 atm. Procedural stenosis and minimum lumen diameter (MLD) were assessed by angiography (Table 3). Stents were placed in 17 of 29 lesions due to operator preference. The final residual stenosis (post-adjunctive therapies) was 16.2% ± 10.6%, and the final MLD was 4.5 ± 0.8 mm (n = 29). Total fluoroscopy time was 21.6 ± 8.0 minutes, and on average, 205.6 ± 82.7 mL of contrast was used per patient. Figure 1 shows a case example from the study.

No incidence of recoil, slow flow/no reflow, flow-limiting dissections (Type D-F), or perforations were reported. One distal embolization occurred in the distal segment of the tibial vessel post-OAS and was successfully resolved with administration of nitroglycerin. In a second patient, distal embolization was noted post-BA, and endovascular thrombectomy was performed. Both events had no clinical effect.

**Clinical Outcomes**

Ankle–brachial index and RC are presented in Table 4. There were no deaths, major amputations, or TVR through 12-month follow-up. As estimated by Kaplan-Meier, the TLR rate was 8.2% (Table 5).

**Table 1. Patient Characteristics (Baseline).**

| Baseline Characteristic | Result |
|------------------------|--------|
| Age                    | 70.4 ± 7.8 years (N = 25) (58.0-84.0) |
| Gender (male)          | 19/25 (76.0%) |
| Race                   | Black or African American 1/25 (4.0%) White 24/25 (96.0%) |
| BMI                    | 31.2 ± 6.3 (N = 25) (23.4-49.6) |
| eGFR, mL/min/1.73 m²   | 70.9 ± 25.0 (N = 25) (25.1-115.7) |
| History of diabetes (type 1 or 2) | 18/25 (72.0%) |
| History of hyperlipidemia   | 25/25 (100.0%) |
| History of hypertension   | 25/25 (100.0%) |
| History of angina         | 4/25 (16.0%) |
| Prior stroke/transient ischemic attack | 0/25 (0.0%) |
| Prior MI                 | 1/25 (4.0%) |
| Smoker (current or former) | 21/25 (84.0%) |
| Rutherford classification | 3.0 ± 0.0 (3.0-3.0) |

**Table 2. Vessel and Lesion Characteristics by Angiography.**

| Procedural Information | Result |
|------------------------|--------|
| Target lesion location | Superficial femoral artery 23/29 (79.3%) Popliteal 4/29 (13.8%) Tibioperoneal trunk 2/29 (6.9%) |
| Mean target lesions per patient | 1.2 ± 0.4 (N = 25) (1.0-2.0) |
| Mean lesion length, mm 65.4 ± 27.8 (n = 29) (20.0-109.0) |
| Proximal reference vessel diameter, mm 5.2 ± 0.8 (n = 29) (3.0-6.0) |
| Distal reference diameter, mm 5.4 ± 0.7 (n = 29) (3.6-7.0) |
| Minimum lumen diameter, mm 0.9 ± 0.7 (n = 29) (0.0-2.0) |

**Intravascular Ultrasound Analysis**

As described in Table 6, IVUS findings at the lesion level showed that the MLA increased from 4.0 mm² pretreatment to 4.7 mm² post-OAS and finally to 9.1 mm² post-BA (overall change; $P < .0001$), and the area stenosis decreased from 76.9% pretreatment to 63.8% post-OAS and then to 43.0% post-BA (overall change; $P < .0001$). In the post-OAS and post-BA images, the slices that corresponded to the pretreatment MLA slices were identified. Lumen area increased significantly from 4.0 mm² pretreatment to 5.6 mm² post-OAS, and the vessel area did not change significantly ($P = .42$). Post-BA, however, the vessel area increased significantly from 31.7 to 34.1 mm².
This was confirmed by volumetric analysis (normalized for length \( \text{mm}^3/\text{mm} \)). In 13 of the lesions, 28 calcified plaques were identified. These calcified plaques were analyzed since they showed a significant reduction in superficial calcium. In 5 lesions, 3 calcified plaques were identified (15 plaques); in 5 lesions, 2 calcified plaques were identified (10 plaques); and in 3 lesions, 1 calcified plaque was identified (3 plaques). As shown in Table 7, the lumen area increased from 6.2 mm\(^2\) pretreatment to 8.4 mm\(^2\) post-OAS with a 0.6 (0.4, 2.1) mm\(^2\) decrease in calcium that was responsible for 86% (35, 100) of the lumen area increase. Figure 2 shows a representative OAS case resulting in increased luminal area.

Of note, the arc of reverberation increased from 22° pre-treatment to 39° post-OAS \( (P = .051) \) indicating the

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**Table 3. Procedural Stenosis and Minimum Lumen Diameter by Angiography (By Lesion).**

|                                | (A) Pre-OAS (n = 29) | (B) Post-OAS (n = 29) | (C) Post-BA (n = 29) | P Value  |
|--------------------------------|----------------------|-----------------------|----------------------|----------|
| Procedural stenosis, %         | 84.4 ± 11.9          | 62.9 ± 10.7           | 32.6 ± 10.3          | <.001    |
| MLD, mm                        | 0.9 ± 0.7            | 2.0 ± 0.7             | 3.6 ± 0.6            | <.001    | <.001    | <.001    |

**Abbreviations:** BA, balloon angioplasty; MLD, minimum lumen diameter; OAS, orbital atherectomy system. Values are mean ± standard deviation.

**Table 4. Ankle–Brachial Index and Rutherford Classification by Visit Interval.**

| Rutherford Classification (RC) | Baseline (N = 25) | 2-Week Follow-Up (N = 25) | 6-Month Follow-up (N = 24) | 12-Month Follow-up (N = 22) | P Value* |
|--------------------------------|-------------------|---------------------------|-----------------------------|-----------------------------|---------|
| Asymptomatic (RC 0)            | 0 (0.0%)          | 24 (96.0%)                | 19 (79.2%)                  | 13 (59.1%)                  | <.001   |
| Mild Claudication (RC 1)       | 0 (0.0%)          | 1 (4.0%)                  | 2 (8.3%)                    | 8 (36.4%)                   |         |
| Moderate Claudication (RC 2)   | 0 (0.0%)          | 0 (0.0%)                  | 0 (0.0%)                    | 1 (4.5%)                    |         |
| Severe Claudication (RC 3)     | 25 (100.0%)       | 0 (0.0%)                  | 3 (12.5%)                   | 0 (0.0%)                    |         |
| ABIa                           | 0.74 ± 0.13 (N = 22) | 1.01 ± 0.10 (N = 24)       | 0.96 ± 0.18 (N = 23)         | 0.95 ± 0.15 (N = 21)        | <.001   |

**Abbreviation:** ABI, ankle–brachial index. Values are n (%) or mean ± standard deviation.

*P value comparison for baseline versus 12-month follow-up.

*aGreater of posterior tibial or dorsalis pedis systolic pressure divided by maximum of left or right brachial systolic pressure.

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**Figure 1.** Angiography case example. A lesion in the mid to distal superficial femoral artery was treated with orbital atherectomy system (OAS; 2.0 mm Crown). The post-POBA flow was excellent. POBA indicates postoperative balloon angioplasty.
polishing of the surface of superficial calcium. Figure 3 shows a representative OAS case of change in arc of reverberation.

**Discussion**

In the TRUTH study, VH-IVUS analysis showed calcium modification by OAS was responsible for 86% (35, 100) of the lumen expansion. In addition, the increase in arc of reverberation pretreatment to post-OAS indicates device-related modification of calcium.

The evidence supporting OAS-related calcium modification in the TRUTH study is encouraging. The goal of plaque modification with OAS is not maximum debulking resulting in substantial luminal gain but rather to change lesion compliance. Previous studies demonstrated that changing lesion compliance

| Table 5. Freedom from Target Lesion Revascularization. |
|------------------------------------------------------|
| Number of Days Postprocedure | 0 | 14 | 183 | 335 | 365 |
| At risk | 25 | 25 | 24 | 21 | 13 |
| Patients with events | 0 | 0 | 1 | 2 | 2 |
| Censored | 0 | 0 | 0 | 2 | 10 |
| Event free | 100.0% | 100.0% | 96.0% | 91.8% | 91.8% |
| Standard deviation | 0.0% | 0.0% | 3.9% | 5.5% | 5.5% |
| 95% Confidence interval | 100.0%-100.0% | 100.0%-100.0% | 88.3%-103.7% | 81.0%-102.7% | 81.0%-102.7% |

| Table 6. Grayscale and Virtual Histology IVUS Findings in 24 Lesions. |
|------------------------------------------------------|
| Overall | P Value | P Value (a) vs (b) | P value (b) vs (c) |
| Proximal reference lumen area, mm² | 14.5 (11.2, 18.3) | 14.5 (10.2, 19.9) | 15.4 (12.0, 20.7) | .0063 | .63 | .063 |
| Distal reference lumen area, mm² | 16.8 (11.0, 19.0) | 15.7 (11.3, 21.9) | 17.3 (14.4, 21.4) | .002 | .55 | .026 |
| Minimum lumen area, mm² | 4.0 (2.2, 4.9) | 4.7 (3.2, 5.9) | 9.1 (7.8, 10.5) | <.0001 | .072 | <.0001 |
| Area stenosis, (%) | 76.9 (61.3, 80.5) | 63.8 (57.6, 76.7) | 43.0 (27.3, 56.4) | <.0001 | .067 | <.0001 |
| MLA site prior to intervention | 4.0 (2.2, 4.9) | 5.6 (4.4, 7.7) | 11.2 (9.9, 12.8) | <.0001 | .0007 | <.0001 |
| Vessel area, mm² | 29.2 (24.1, 35.5) | 31.7 (25.2, 38.4) | 34.1 (30.6, 41.0) | <.0001 | .42 | .0036 |
| Plaque burden (%) | 86.5 (84.6, 91.3) | 81.6 (77.0, 85.9) | 67.9 (59.7, 74.2) | <.0001 | .006 | <.0001 |
| Entire lesion analysis | 8.5 (5.0, 9.9) | 8.9 (8.1, 11.1) | 12.9 (11.7, 15.2) | <.0001 | .037 | <.0001 |
| Mean lumen area, mm²/m | 31.4 (26.1, 35.2) | 31.8 (25.9, 37.8) | 34.5 (31.9, 40.3) | <.0001 | .21 | <.0001 |
| Mean plaque area, mm²/m | 22.1 (18.5, 28.1) | 22.1 (18.1, 26.2) | 21.9 (17.9, 25.3) | .040 | .70 | .23 |
| Mean dense calcium area, mm²/m | 1.6 (1.0, 2.1) | 1.5 (0.9, 2.0) | 1.6 (1.1, 2.1) | .88 | .90 | .91 |
| Mean necrotic core area, mm²/m | 4.4 (3.3, 6.1) | 4.7 (2.9, 5.9) | 4.4 (2.5, 5.3) | .12 | .99 | .18 |
| Mean fibrous area, mm²/m | 9.0 (7.0, 12.3) | 9.2 (7.0, 12.2) | 9.2 (6.4, 11.5) | .0082 | .88 | .048 |
| Mean fibrofatty area, mm²/m | 1.6 (0.9, 3.0) | 1.9 (1.1, 2.7) | 2.1 (1.1, 2.5) | .72 | .79 | .99 |

| Table 7. Grayscale IVUS Findings: 28 Calcified Plaques in 13 Lesions. |
|------------------------------------------------------|
| Overall | P Value | P Value (a) vs (b) | P value (b) vs (c) |
| Lumen area, mm² | 6.2 (4.7, 8.7) | 8.4 (6.4, 10.9) | 12.2 (11.2, 14.9) | <.0001 | .0013 | <.0001 |
| Area stenosis (%) | 57.5 (28.7, 68.7) | 80.0 (10.9, 45.0) | 55.7 (9.5, 41.6) | <.0001 | <.0001 | .002 |
| Minimum lumen diameter, mm² | 2.1 (1.8, 2.5) | 2.5 (2.3, 3.0) | 3.2 (2.7, 3.6) | <.0001 | <.0001 | <.0001 |
| Lumen symmetry index | 0.67 (0.41, 0.83) | 0.70 (0.52, 0.82) | 0.67 (0.52, 0.79) | .41 | .43 | .65 |
| Superficial calcium arc, ° | 13.7 (96, 205) | 11.4 (9.2, 229) | 12.7 (82, 239) | .89 | .93 | .99 |
| % Lumen gain secondary to calcium reduction | 25% (7/28) | 39% (11/28) | 36% (10/28) | .095 | .11 | .86 |
| Arc of reverberation, ° | 22 (18, 24) | 39 (27, 60) | 28 (20, 47) | .043 | .051 | .28 |

Abbreviations: IVUS, Intravascular ultrasound; OAS, orbital atherectomy system; MLA, minimum lumen area.

Values are median (Interquartile range).
with OAS resulted in significantly lower adjunctive balloon inflation pressures. In the CONFIRM Series, which included 3137 patients treated with the OAS, it was suggested that vessel compliance rather than luminal gain should be the goal of atherectomy. Over time, the treatment algorithm for orbital atherectomy treatment has changed from maximizing luminal gain to modifying compliance, thus enabling low pressure adjunctive BA. Data from the CONFIRM Series support the selection of smaller OAS crown sizes and lower speeds, which corresponded to a lower incidence of adverse procedural events.

The adjunctive BA maximum inflation pressure in TRUTH was 5.2 ± 1.2 atm. There was no incidence of recoil, slow flow/no reflow, flow-limiting dissections (type D-F), or perforations. Two distal embolizations occurred with no clinical impact; however, the overall rate of procedural events was low.

Lumen area within the MLA site increased significantly following OAS treatment and further increased following BA treatment. Orbital atherectomy treatment within the MLA site did not result in an increase in vessel area, illustrating that the OAS alone resulted in a significant decrease in plaque burden in this area without causing a Dotter effect (increase in vessel area outside the area of treatment). Plaque modification by the OAS may have improved the elasticity of the vessel and contributed to a reduction in stenosis and expansion of the lumen after OAS-BA treatment—even in proximal and distal reference segments, the areas that were not treated “directly.”

At 12 months, ABI and RC improved significantly from baseline. Durable outcomes through 12 months were achieved, supporting the use of orbital atherectomy for the treatment of peripheral arterial disease.

**Study Limitations**

TRUTH was a single-center, nonrandomized trial that enrolled a small number of patients. While the results of the TRUTH study are promising, future studies would be beneficial to confirm the findings from this small study.

**Conclusion**

The purpose of the TRUTH study was to use VH-IVUS to determine the effect of OAS treatment on lesion modification. Results demonstrated that the OAS modified the calcified component of the plaque burden. It is hypothesized that calcium modification by OAS changes the lesion compliance, allowing for low pressure adjunctive BA. The clinical outcomes were favorable through 12-month follow-up. This study is the first to present detailed VH-IVUS measurements of plaque burden.
modification during treatment of calcified lesions via orbital atherectomy in patients with peripheral arterial disease.

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The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: A. Babaev has an investigator’s agreement with Cardiovascular Systems, Inc (CSI). G. Mintz, and A. Maehara are employed at the Cardiovascular Research Foundation (CRF) which receives funding from CSI. B. Martinsen is employed by CSI. M. Attubato and S. Zavlunova have nothing to disclose.

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Figure 3. A representative case of pretreatment, post-orbital atherectomy system (OAS) appearing reverberation. Panel A pretreatment and Panel B post-OAS were matched. Panel A and B correspond directly to Panel A’ and B’. Reverberation (red lines in A’ and B’) increased from pretreatment to post-OAS due to polished surface of calcified plaque. Blue dots = 1 mm scale.