Vessel Preparation:
Evidence and Practice

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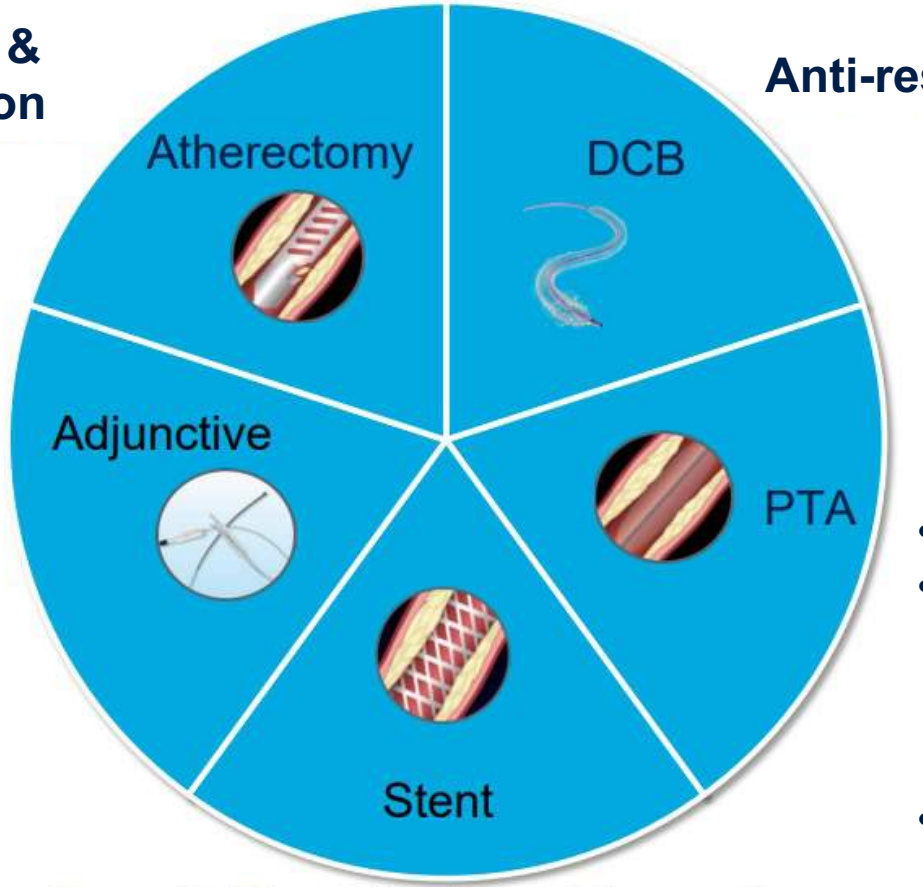
Vessel Preparation

Challenging Lesions Frequently Require Multiple Tools

Debulking & Calcification

Anti-restenotic Therapy



Crossing, Re-entry

- **Pre & Post-dilatation**
- **Specialty Balloons (Chocolate™* PTA balloon catheter, Modifying, Scoring, Cutting**
- **Good Technique**

Recoil, Flow-limiting Dissection, Residual Stenosis

Vessel Preparation
Chocolate balloon PTA

Prospective, multicenter, real-world post market registry evaluating use of Chocolate Balloon Catheter - adjudication by independent core labs[3,4]

488
All Comers

262
ATK Cohort

226
BTK cohort

Inclusion Criteria

- Any ATK or BTK lesion with at least 1 vessel runoff successfully crossed with a guidewire
- Use of atherectomy/re-entry devices accepted

Exclusion Criteria

- Presence of a flow-limiting dissection at the target lesion prior to use of the Chocolate™* PTA balloon (secondary to the use of another device)
- Patients with Rutherford 6
- Chocolate™* PTA balloon not used in accordance with study protocol (2 min inflation to at least nominal pressure)

1. Data on file with Medtronic – CLR782: Final Study Report The Chocolate BAR by TriReme Medical, LLC
2. Mustapha J, et al. Chcolat BAR registry. CCI 2018;1-5
3. Vascore DUS Core Lab, Boston, MA, US
4. Yale University Core, New Haven, CT

Vessel Preparation

Chocolate balloon PTA

Procedural Success	ATK** (n = 262)	BTK (n = 226)
Freedom from Flow Limiting Dissections* (Site Reported)	97.7%	99%
Freedom from Flow Limiting Dissections* (Adjudicated)	100%	100%
Achieved <30% Diameter Stenosis (Adjudicated)	85.1%	84.6%
Freedom from Bail-Out Stenting	98.4%	99.1%

Clinical Outcomes (Kaplan Meier)	ATK** (n = 262) 12 months	BTK (n = 226) 6 months
Freedom from Target Lesion Revascularization	78.5%	88.9%
Freedom from Major Unplanned Amputation	97.2%	96.7%
Freedom from All-Cause Mortality	93.3%	97.1%

1. Data on file with Medtronic – CLR782: Final Study Report The Chocolate BAR by TriReme Medical, LLC
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*Flow Limiting Dissections defined as : Type E- Persistent luminal filling defect with delayed run-off of the contrast material in the distal lumen and Type F- Filling defect accompanied by total occlusion
** many ATK patients had concurrent BTK disease

REALITY STUDY[1]
Objective and Design

Study Objective

Evaluate the effectiveness of the HawkOne™ directional atherectomy system followed by the IN.PACT™ Admiral™ drug coated balloon to debulk moderate and severely calcified femoropopliteal artery atherosclerotic lesions.

- Primary Endpoints:
  - Effectiveness: Primary Patency at 12 months[2]
  - Safety: Freedom from Major Adverse Events (MAE) through 30 days[3]
- Primary Investigators: Dr. Krishna Rocha-Singh, Dr. Brian DeRubertis & VIVA Physicians

Study Design & Oversight

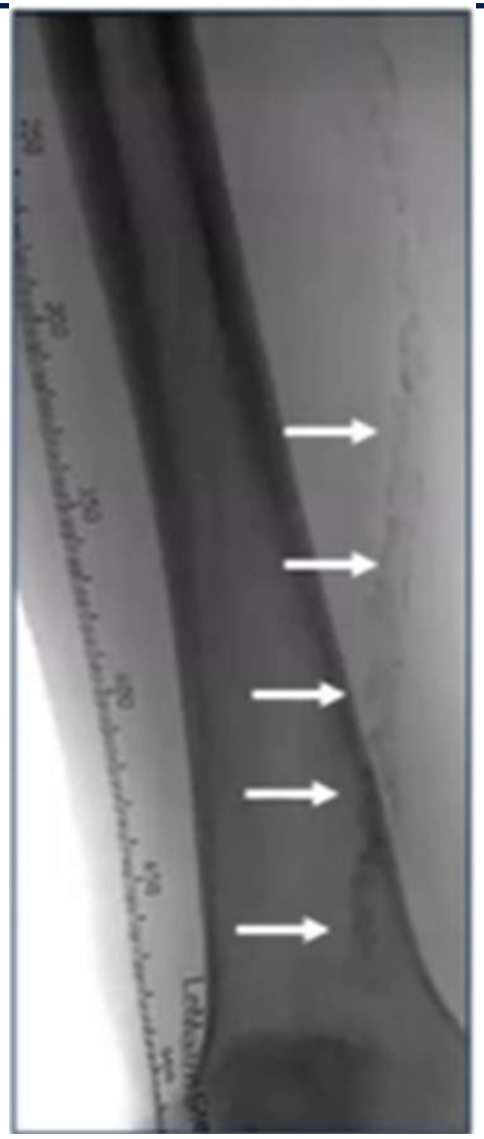
- 102 subjects enrolled at 13 sites in the US & Germany
- Prospective, non-randomized, single-arm study
- Angiographic and duplex ultrasound (DUS) core lab adjudicated
- Change in maximal luminal plaque area adjudicated by an independent intravascular ultrasound (IVUS) core lab

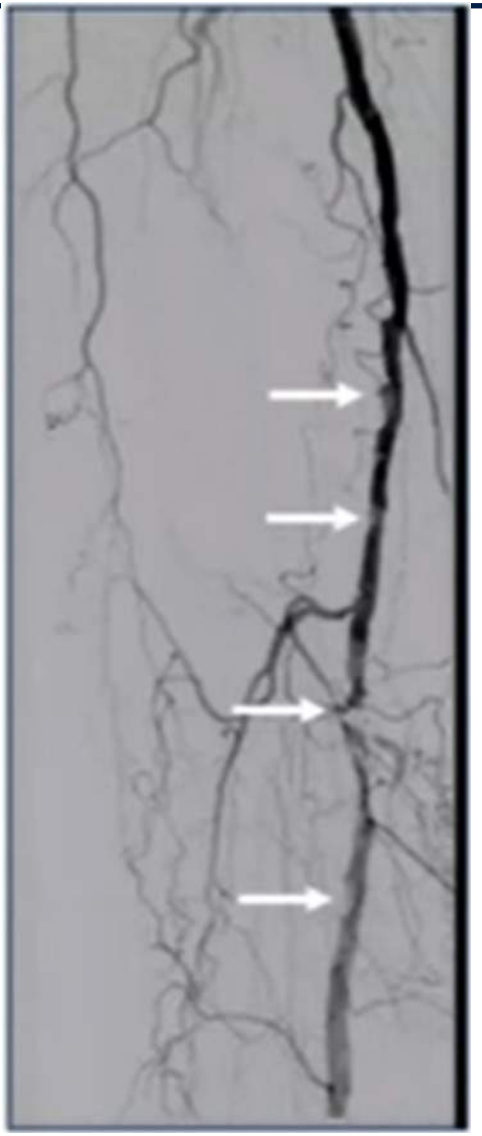
1. Sponsored and conducted by VIVA Physicians; funded by Medtronic.
2. Primary patency defined as freedom from restenosis (DUS peak systolic velocity ratio >2.4) and CD-TLR, defined as any reintervention to the target lesion due to a return of symptoms and/or ankle-brachial index (ABI) decrease of 20% or > 0.15 when compared with the post index procedure baseline ABI.
3. Major Adverse Events (MAE) defined as flow-limiting dissections (D-F), vessel perforation(s) requiring bare metal stents or stent-grafts implantation, unplanned major amputation, intra-procedure distal atheroembolization and CD-TVR.

REALITY INCLUSION CRITERIA

Defining “Complex” Lesion Morphologies

- Femoropopliteal lesion lengths: 8-36 cm
- Long chronic total occlusion lengths: >10cm
- Bilateral vessel wall calcification **required** in all lesions





Images courtesy Krishnan Rocha-Singh, MD

REALITY Study

Baseline Lesion and Clinical Characteristics

Key Characteristics

Peripheral Arterial Calcification Scoring System (PACSS)[2]

Bilateral Calcium [PACSS 3 & 4]
86.2%

Bilateral Calcium ≥5cm [PACSS 4]
67.6%

Lesion Length
17.9cm

Occlusions
39.0%

Baseline Diameter Stenosis
88.8%

Age
69.6 ± 9.7

Hypertension
89.2%

Diabetes Mellitus
53.9%

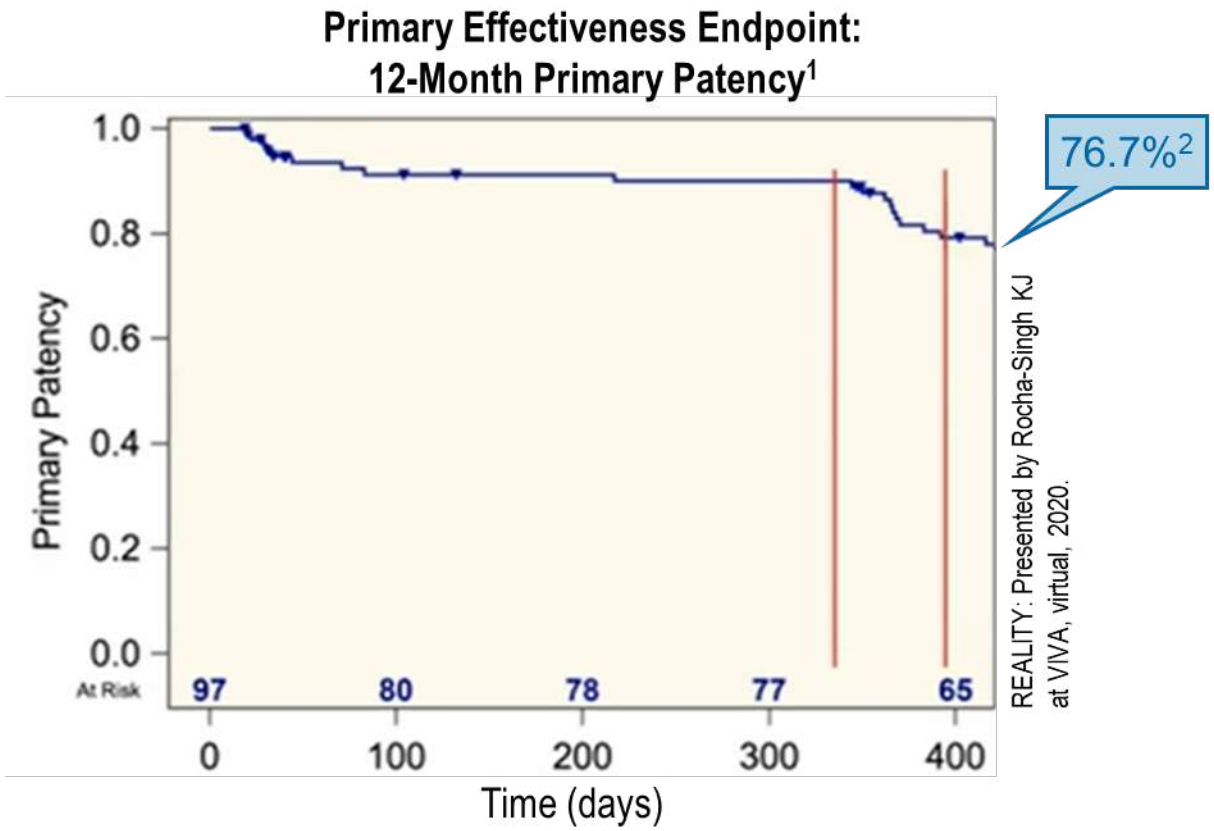
Renal Insufficiency†
53.9%

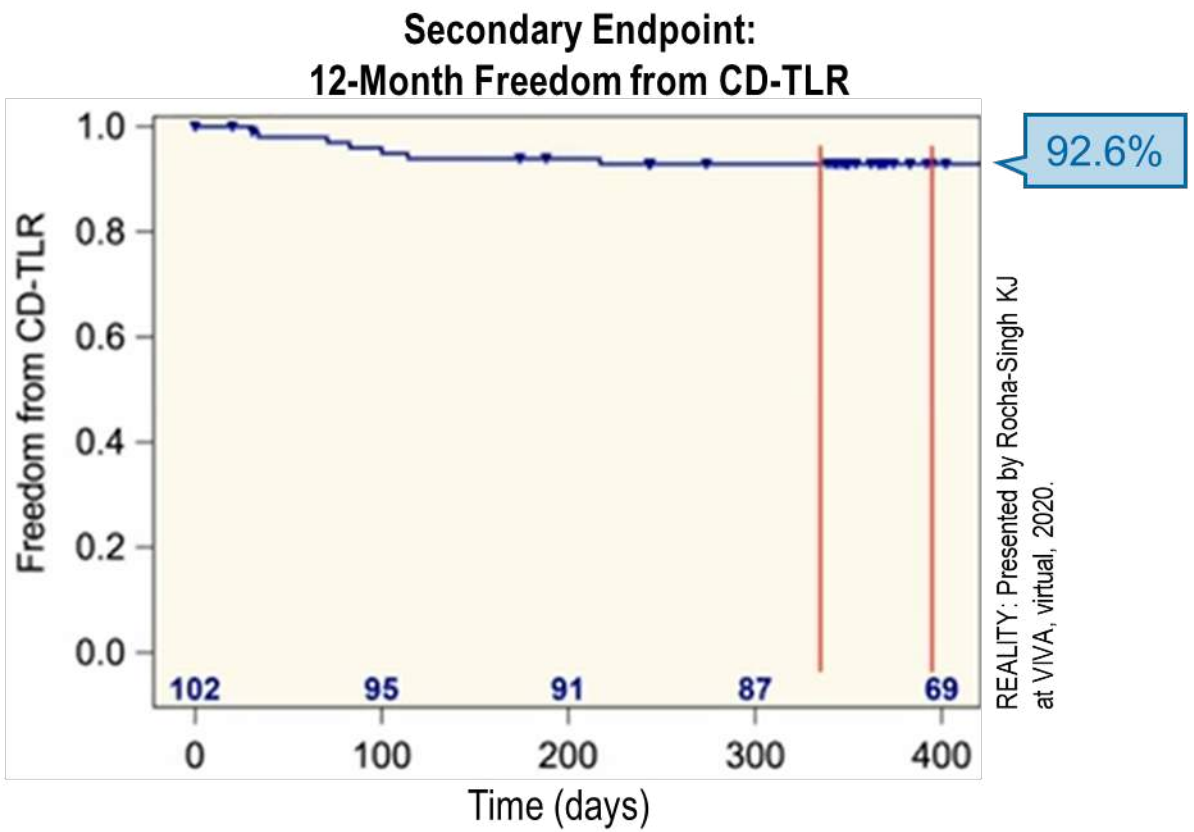
† Renal insufficiency was defined as baseline serum creatinine >1.5 mg/dl.

Rocha-Singh KJ, et al. Catheter Cardiovasc Interv 2021 Jun 3. doi: 10.1002/ccd.29777.

REALITY Study

Primary Effectiveness Outcomes





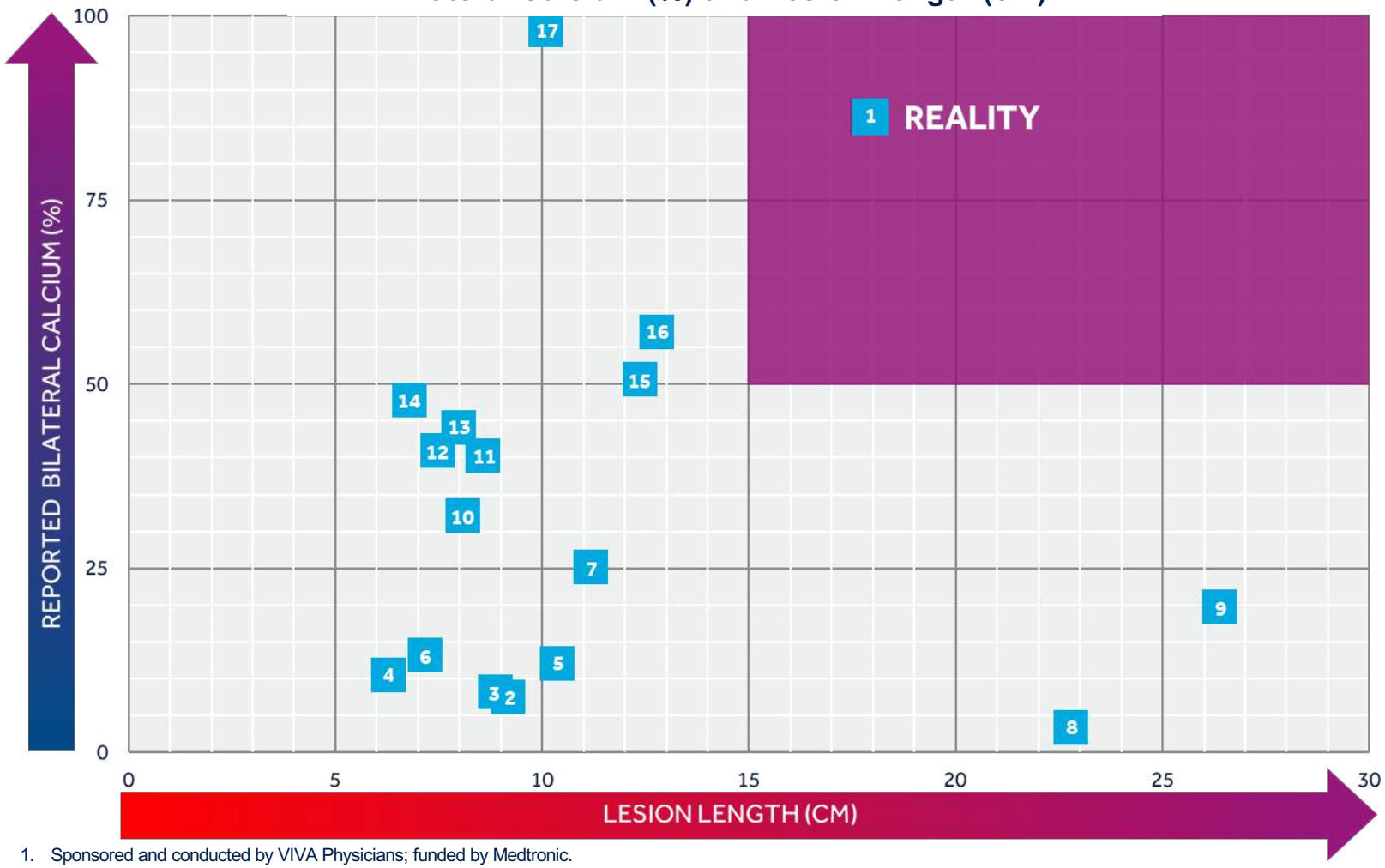
1. Primary patency defined as freedom from restenosis (DUS peak systolic velocity ratio >2.4) and CD-TLR, defined as any reintervention to the target lesion due to a return of symptoms and/or ankle-brachial index (ABI) decrease of 20% or > 0.15 when compared with the post index procedure baseline ABI.
2. 12-month data include patients beyond the follow-up window. Red lines indicate the 12-month follow-up window.

Rocha-Singh KJ, et al. Catheter Cardiovasc Interv 2021 Jun 3. doi: 10.1002/ccd.29777.

REALITY STUDY[1]

Showcasing the Synergy of DA and DCB in Highly Calcified Lesions

Bilateral Calcium (%) and Lesion Length (cm)[2]



OUTCOMES

92.6% FF-CD TLR

76.7% Patency

12-month data include patients beyond the follow-up window.

LESION CHARACTERSTICS

86.2% Bilateral Calcium

17.9cm Average Lesion Length

39.0% Chronic Total Occlusion

PRESERVED TREATMENT OPTIONS

8.8%

Bailout stent rate

Rocha-Singh KJ, et al. Catheter Cardiovasc Interv 2021 Jun 3. doi: 10.1002/ccd.29777

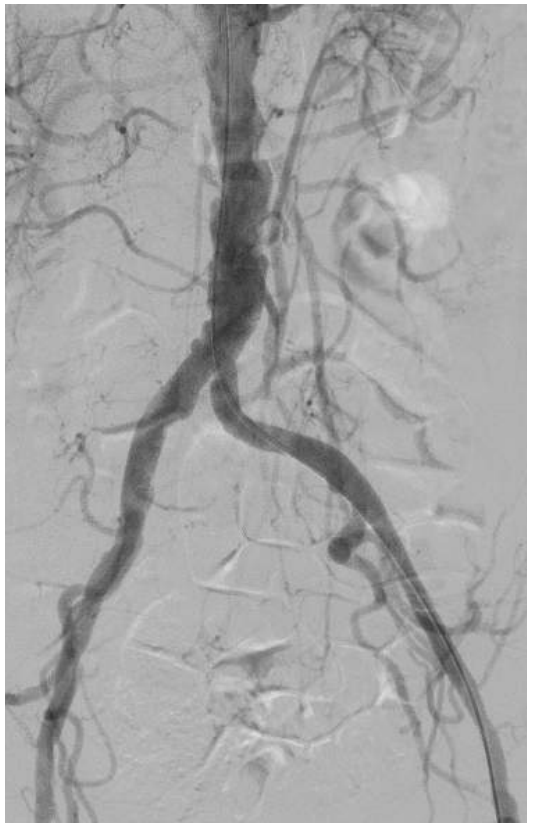
1. Sponsored and conducted by VIVA Physicians; funded by Medtronic.
2. Calcium definitions differ across studies. These are angiographic, core lab adjudicated reported calcium results. This graph is for illustration purposes only. References are at the end of this presentation.

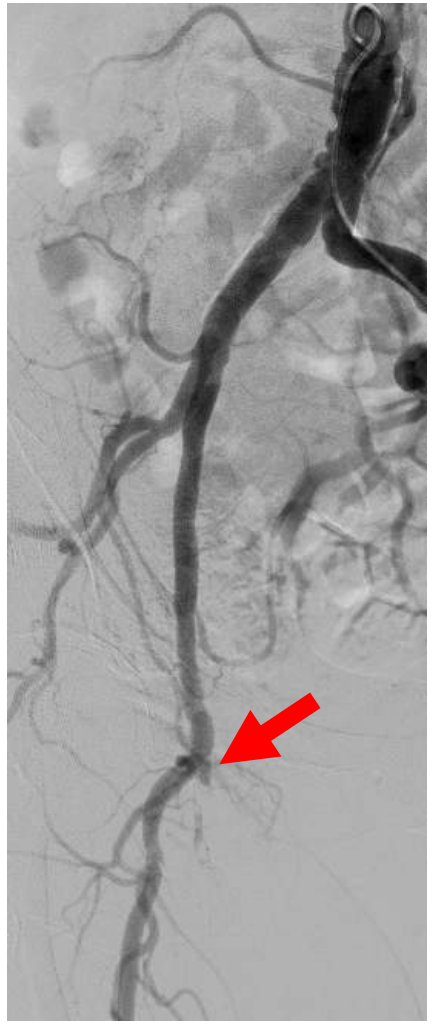
Case Example

SFA with Long Occlusion

- Mid 60s yo female
- History of HTN, DM HbA1c 8.4
- Presents w/ progressive lifestyle limiting claudication in the right calf
- ABI: R 0.61 L 0.92

- L CFA access
- Omniflush angiogram
- R SFA total occlusion

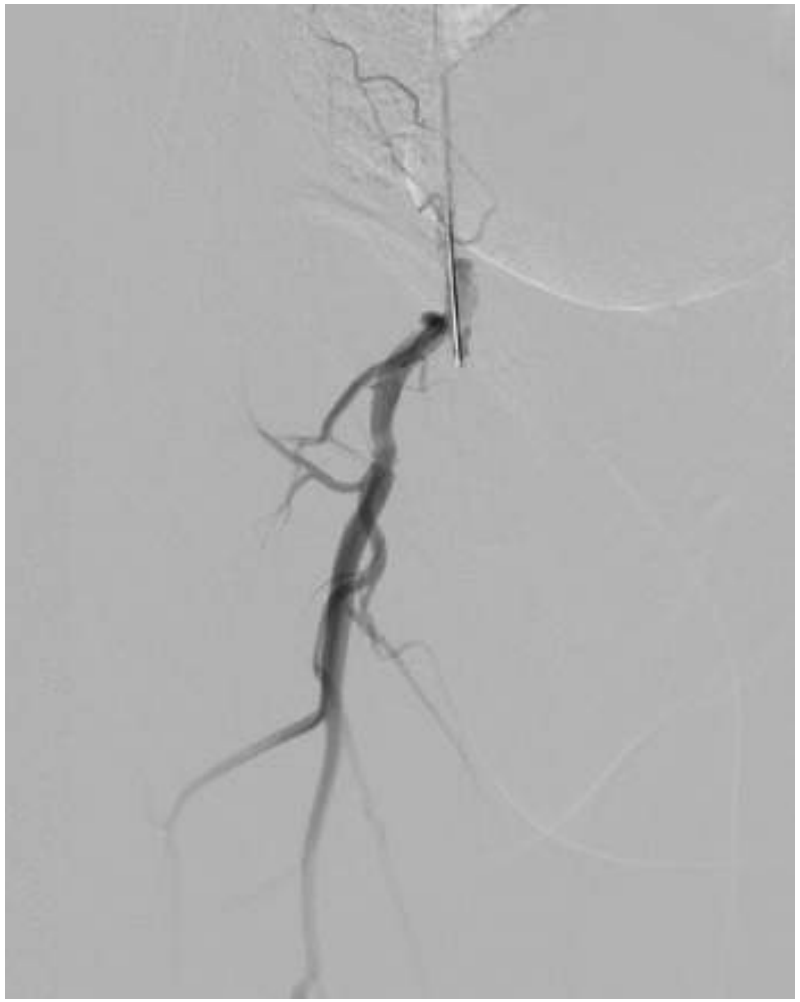




Images courtesy of Peter Monteleone, MD

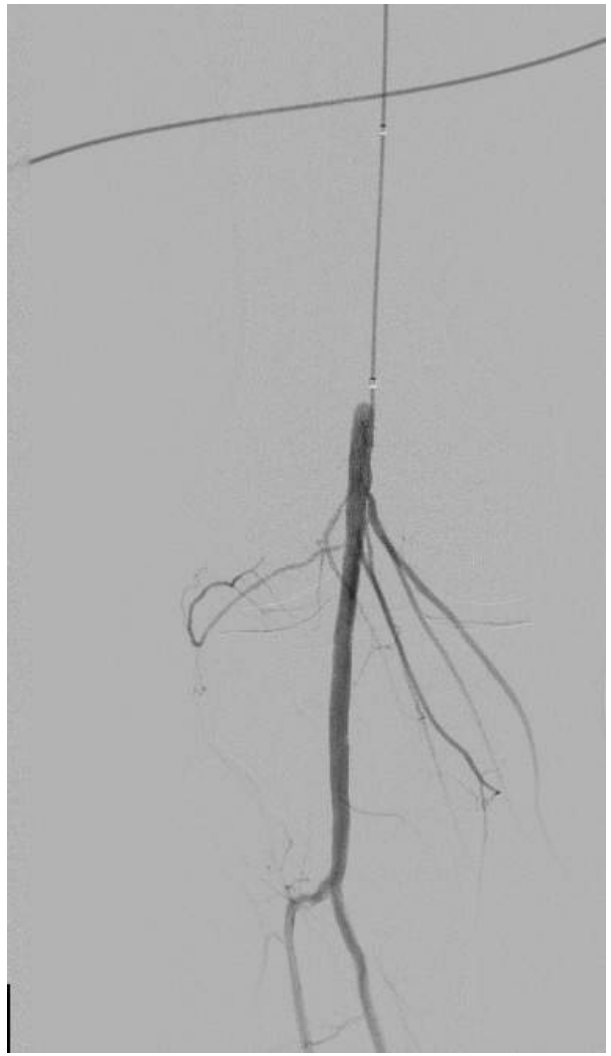
Case Example

Baseline Imaging and Crossing



- 7F Ansel™* sheath over bifurcation
- Viance™ crossing catheter over 0.014 Nitrex™ guidewire into “beak” of occlusion

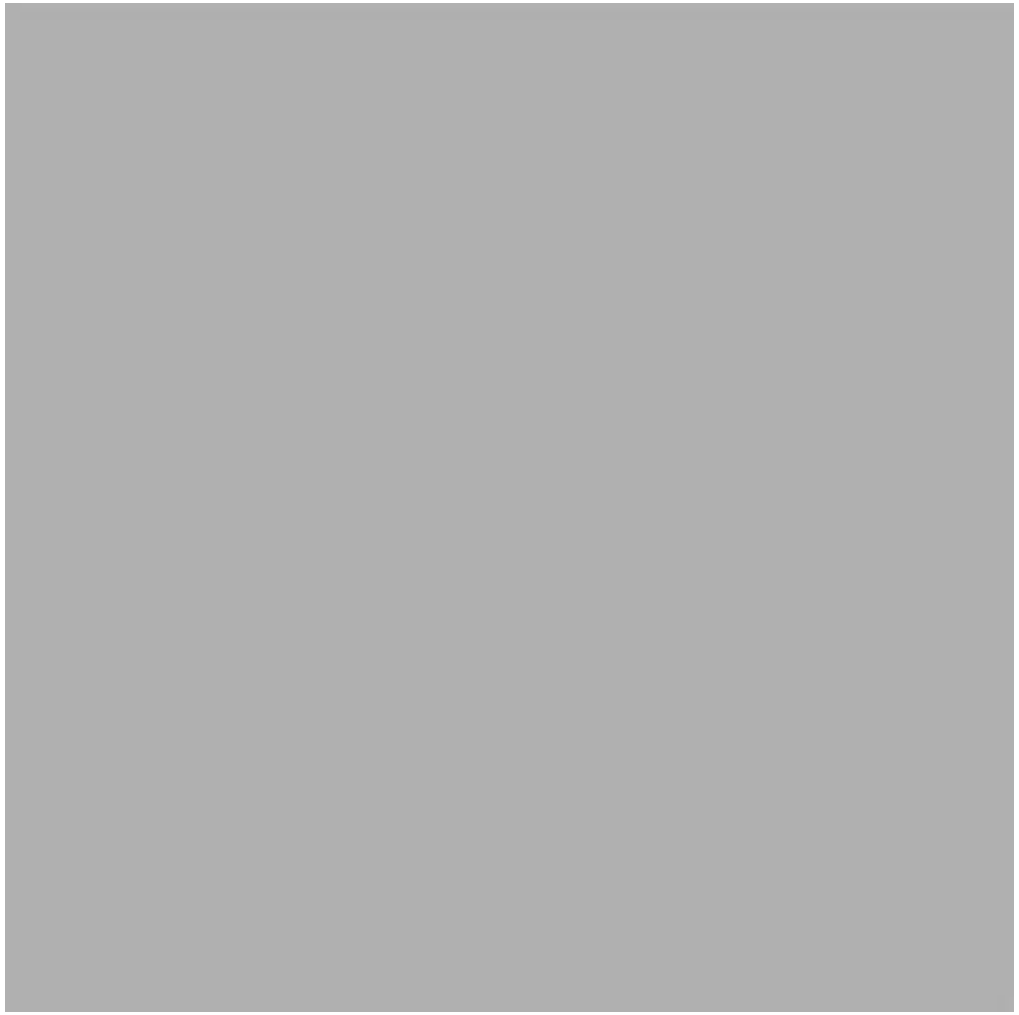
- Viance catheter crosses into distal SFA/popliteal reconstitution
- Viance catheter removed over Nitrex wire
- 0.035 Trailblazer™ support catheter (straight) advanced over Nitrex wire
- Distal angiogram through Trailblazer catheter

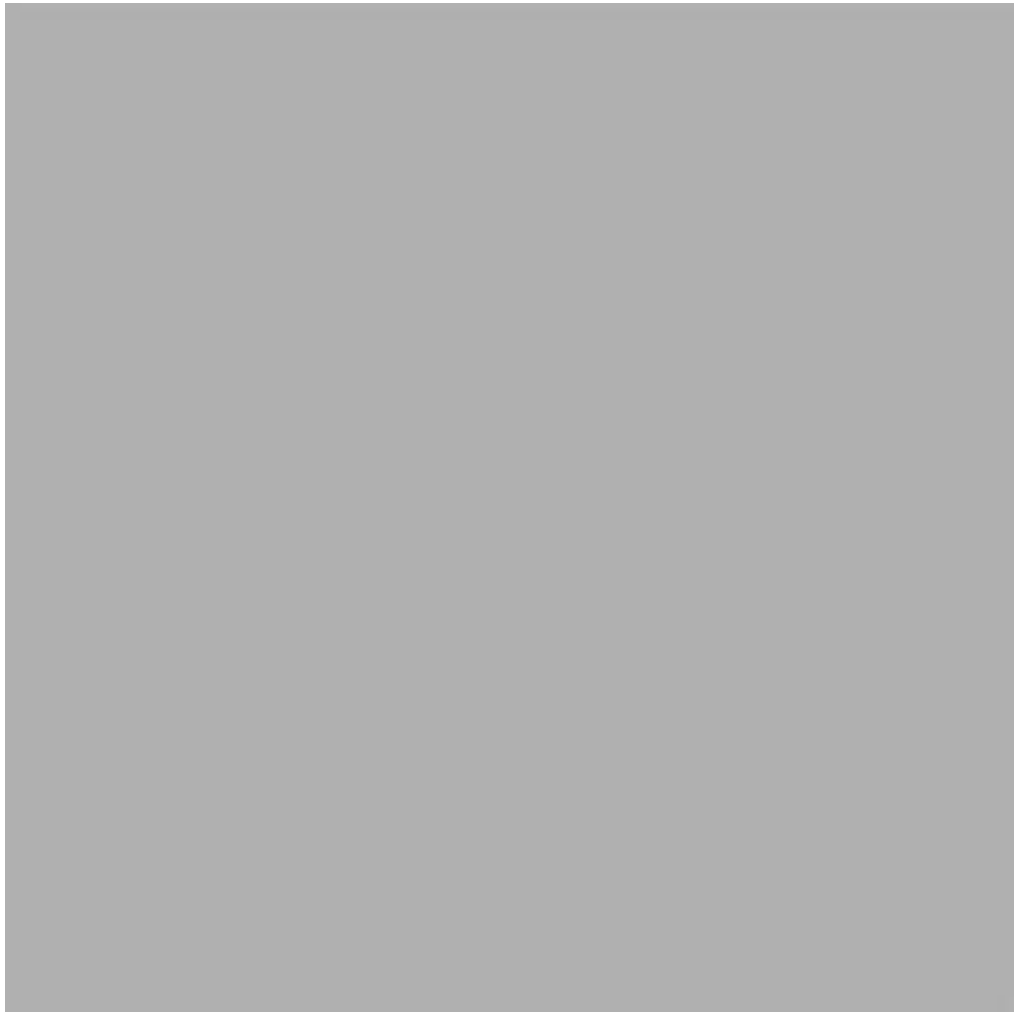


Images courtesy of Peter Monteleone, MD

Case Example

Pre-directional atherectomy angiography

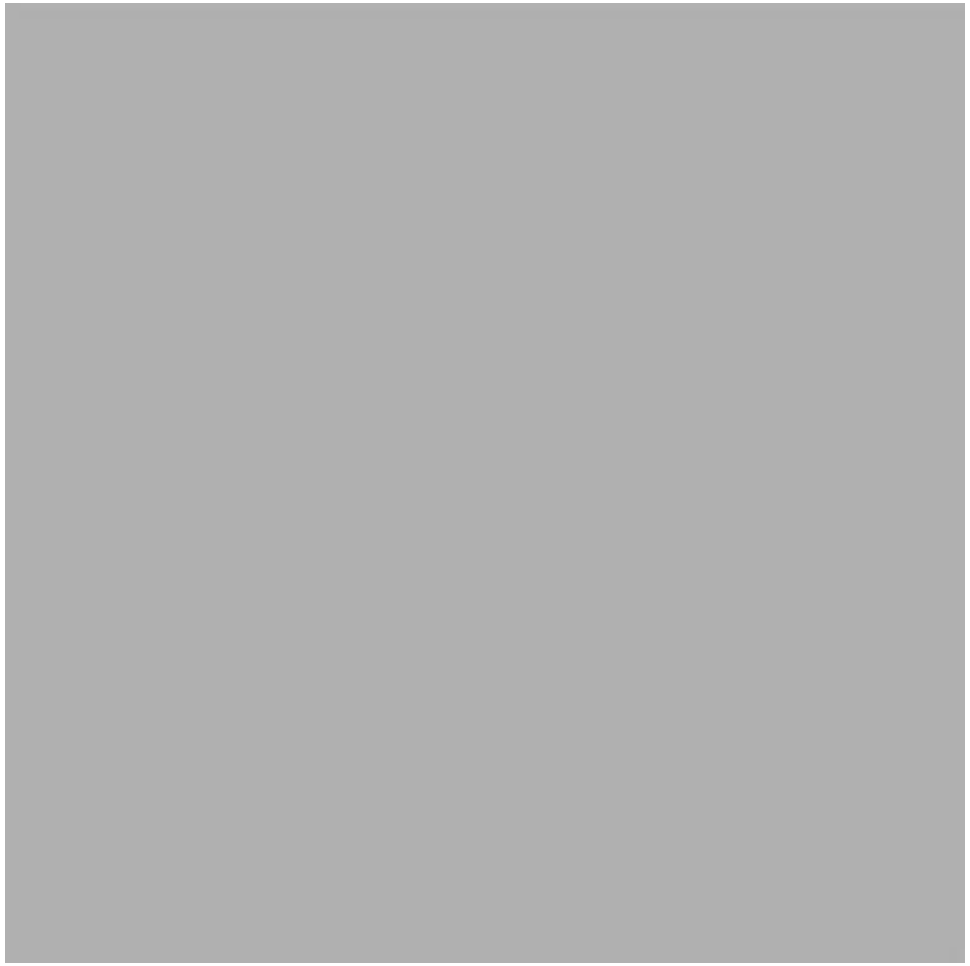


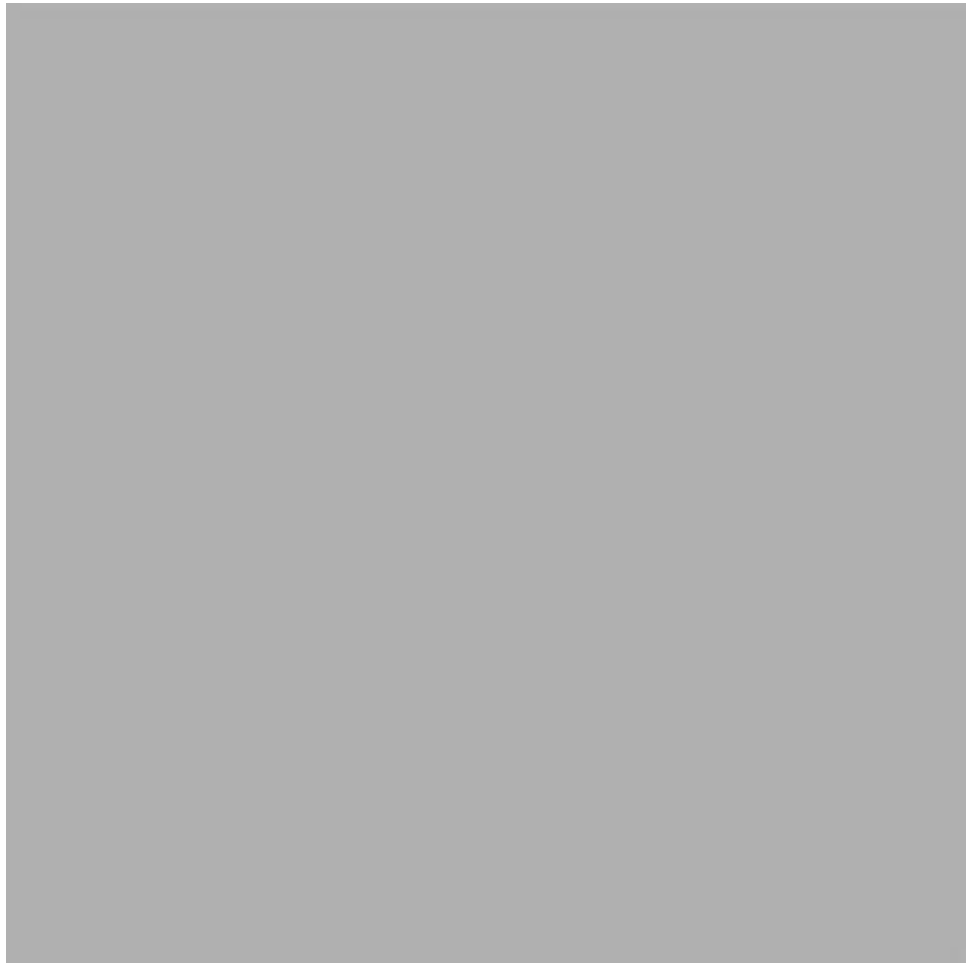


Images courtesy of Peter Monteleone, MD

Case Example

Status post serial rounds of directional atherectomy





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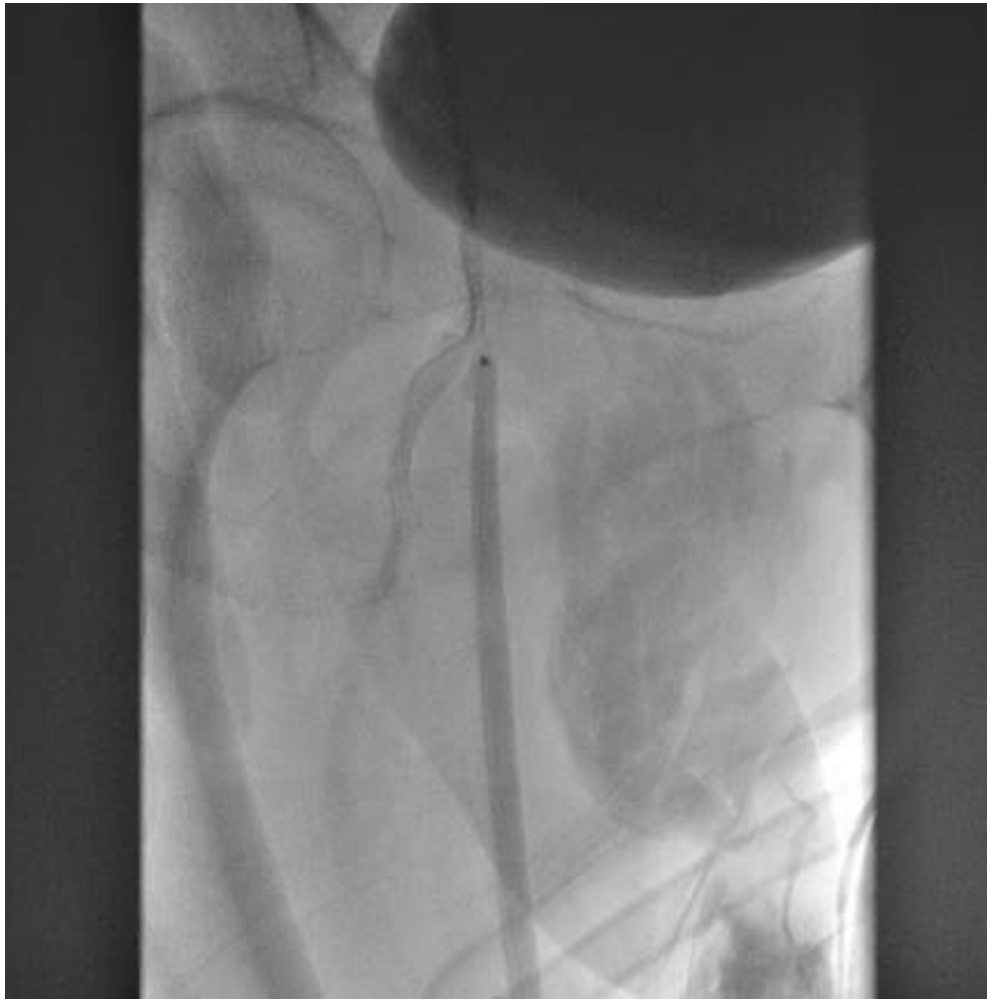
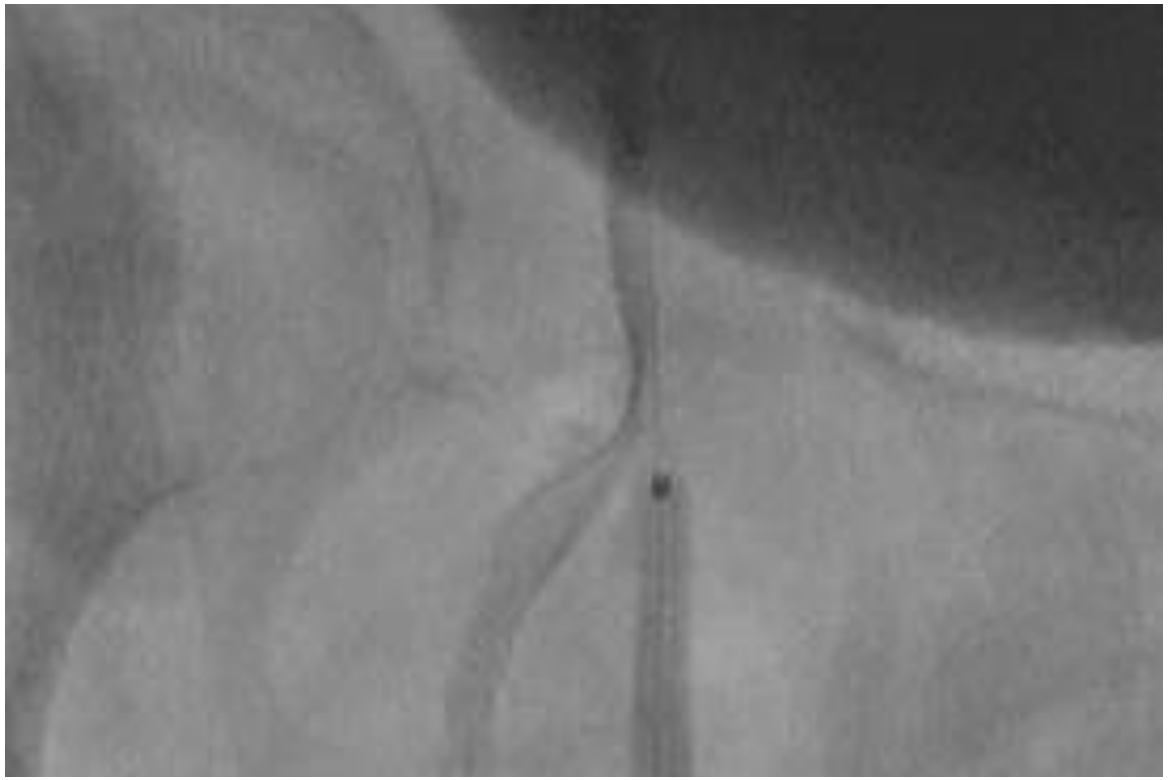
Case Example
Treatment with DCB



- Further optimization with atherectomy debridement of ostial and distal segment
- 6.0 mm IN.PACT Admiral DCB along the treated segment
- Including specific focus on ostial treatment



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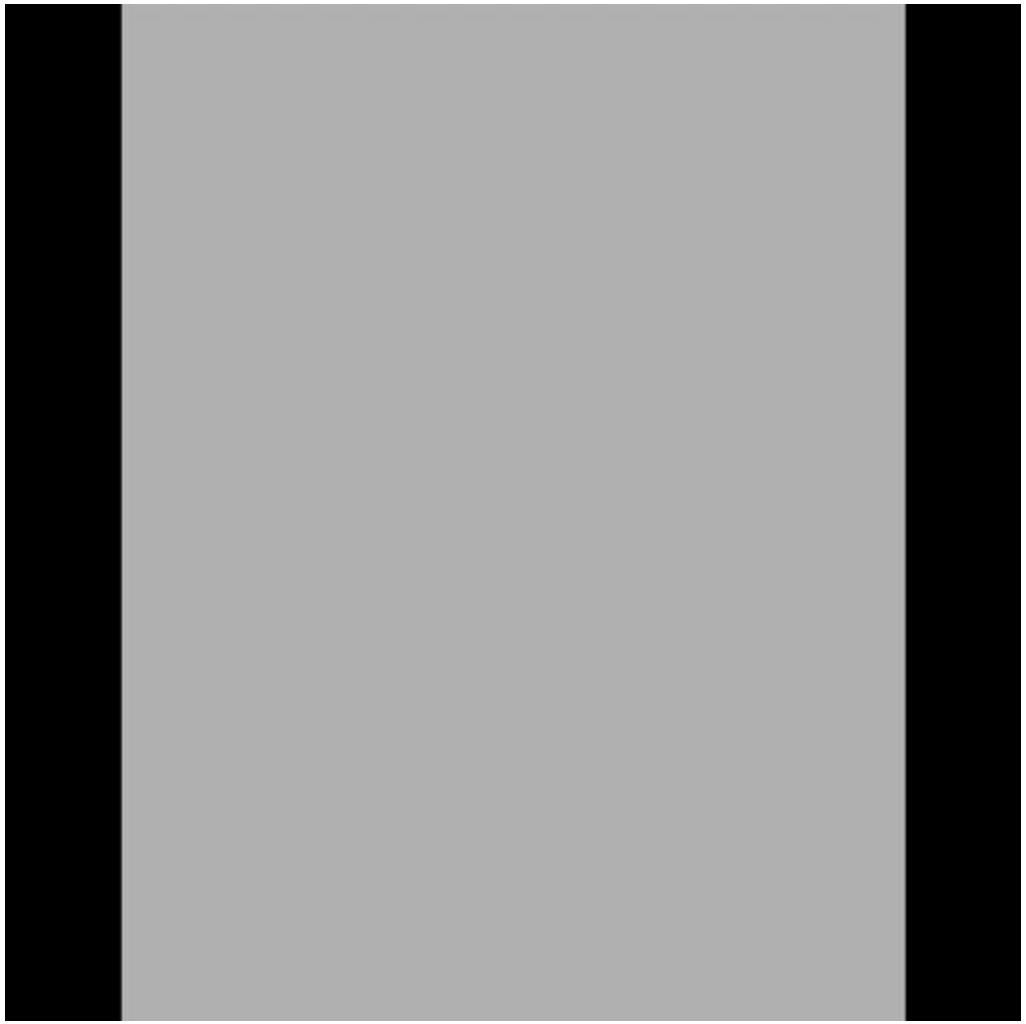
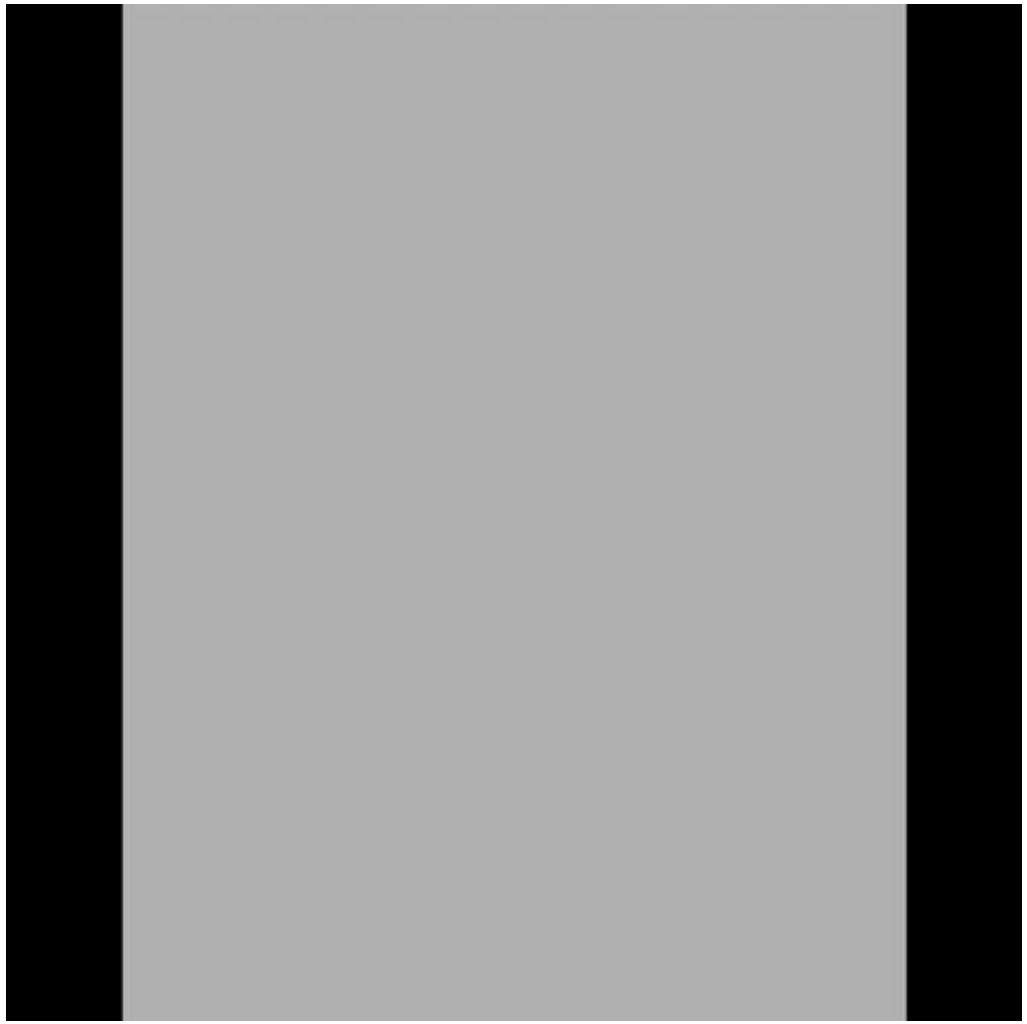
Case Example

Completion Images





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