Heavy Calcific Femoropopliteal Lesions: Non-atherectomy Strategy and Bailout Stenting is Stll Better

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Disclosure

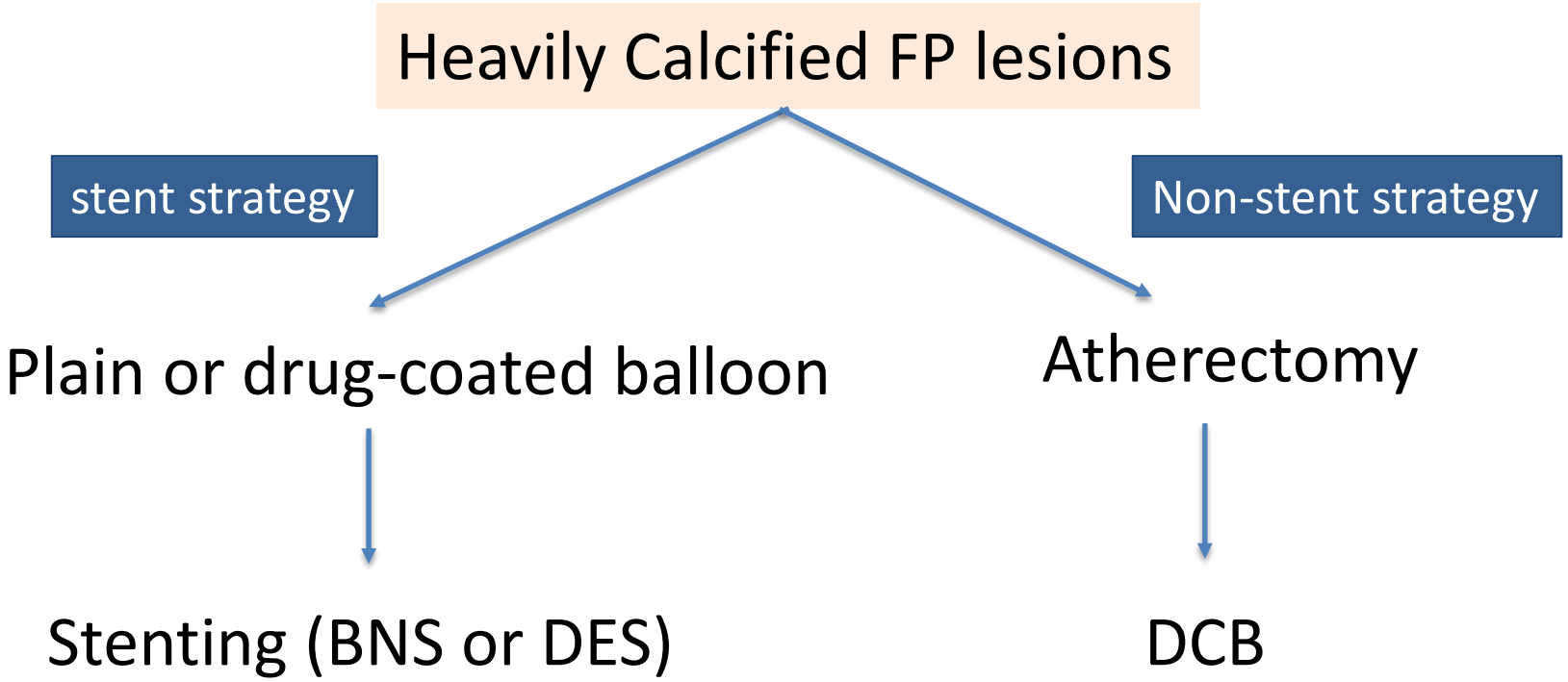
- Research funds
  - *Cook*
  - *Medtronic*
  - *Boston scientific*
  - *Cordis*
  - *Otsuka*
  - *Korea United Pharm*
  - *Dong-A Pharmaceutical*

- *Severance Cardiovascular Intervention (SCI) Workshops in cooperation with Medtronic, Cordis, Abbott, Cook, Boston Scientific*

Heavily Calcified SFA Lesions

- Challenging wiring
- Difficult to dilate
- High tendency of recoil
- Increased risk of dissections
- Increased risk of rupture

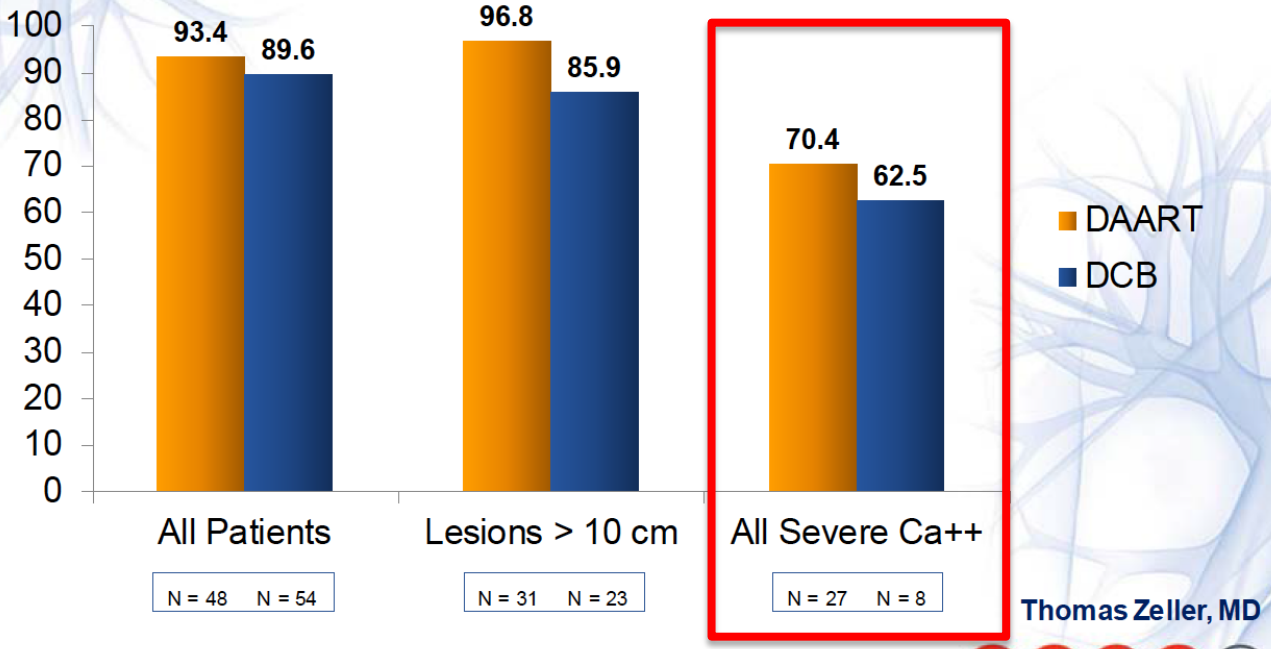
Treatment Strategy for Calcified Lesions



DEFINITIVE AR Study: Pilot Study

Key Study Outcome at 12 Months

DUS Patency - Potential Advantage Emerging in Long and Severely Calcified Lesions



Per Core Lab Assessment. "All Severe Ca++ " group includes all patients treated with DAART therapy including randomized and non-randomized patients with severe calcium.

Thomas Zeller, MD

VIVA 14

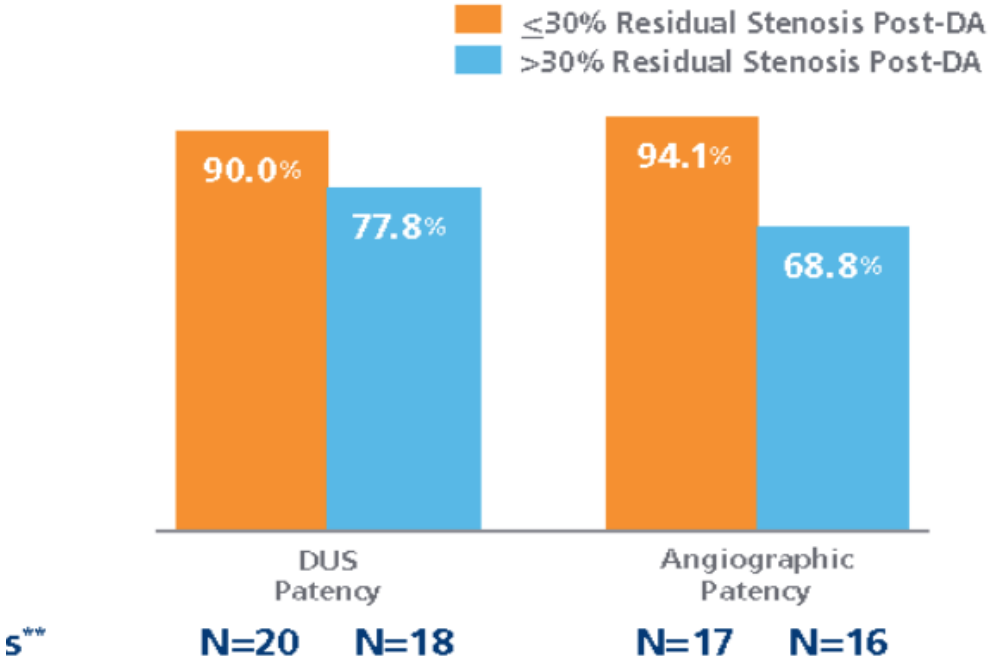
Lesion length:
10 ~11 cm

Bail-out stenting:
DAART 0% vs.
DCB 3.7%

Residual Stenosis and Restenosis

≤ 30% Residual Stenosis

DEFINITIVE AR suggests improved patency when a higher volume of plaque is removed with DA prior to DCB.

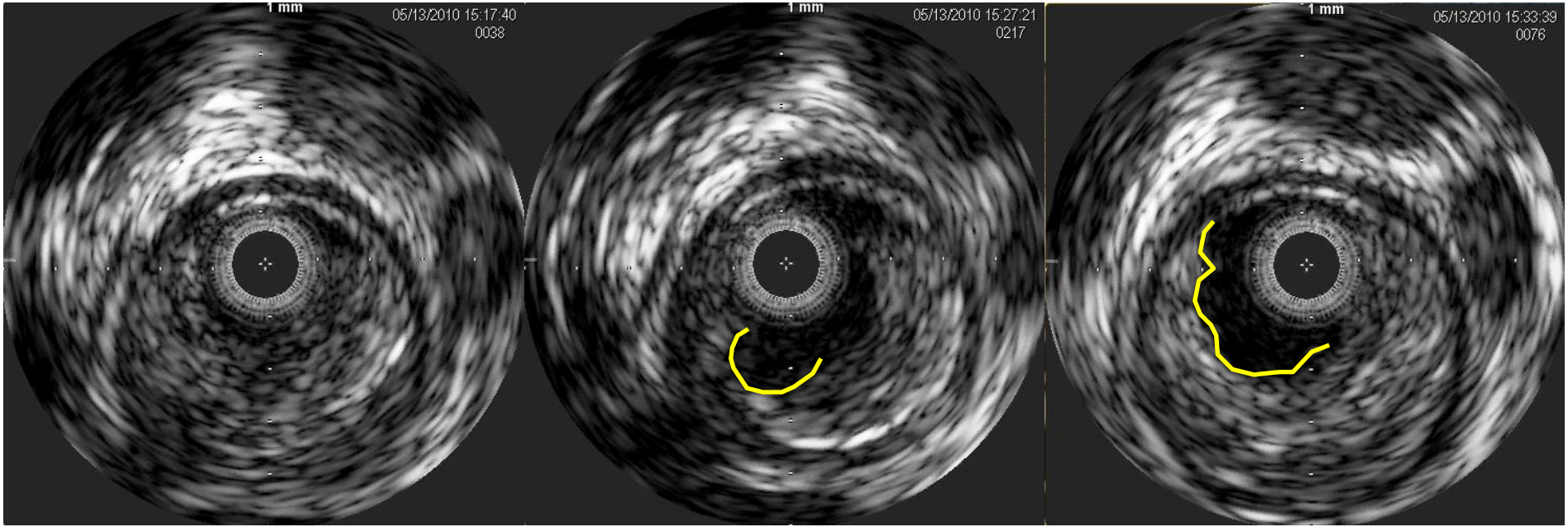


IVUS after Silverhawk Atherectomy

Before

After 1st run

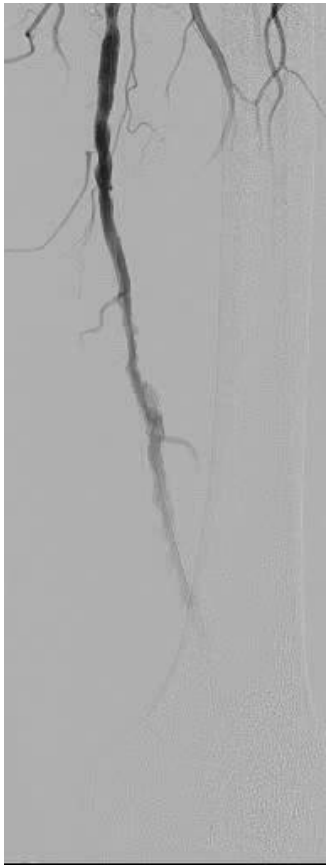
After several runs

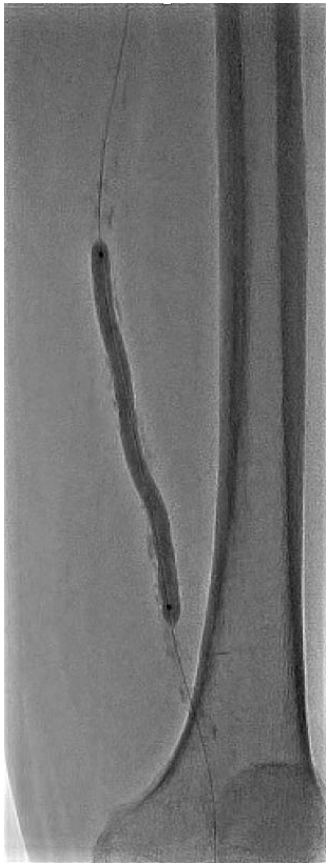


Atherectomy & DCB

Jetstream XC 2.4/3.4

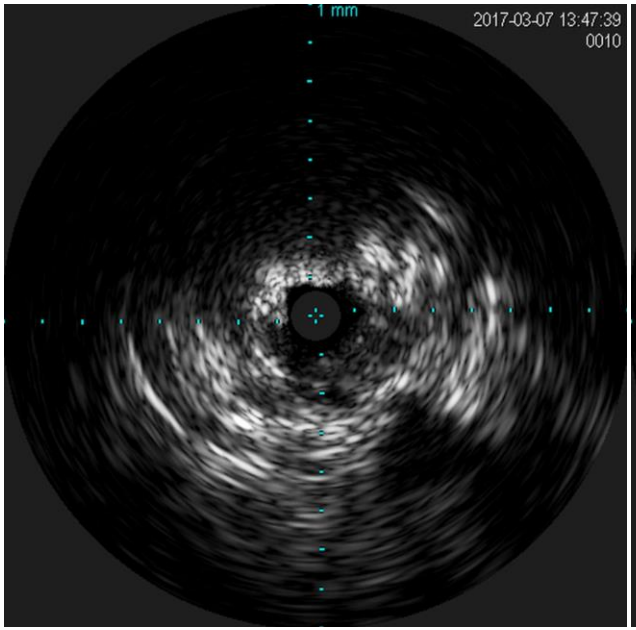
InPACT DCB 6 x 120 & 5 x 150



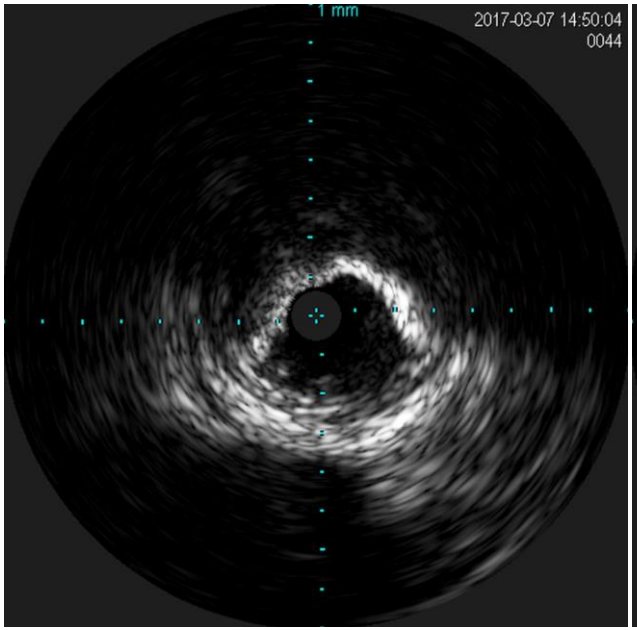


IVUS

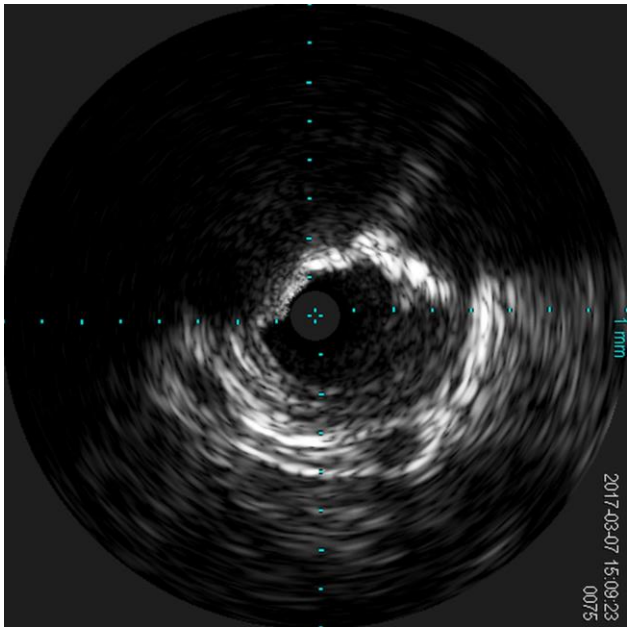
Before athrectomy



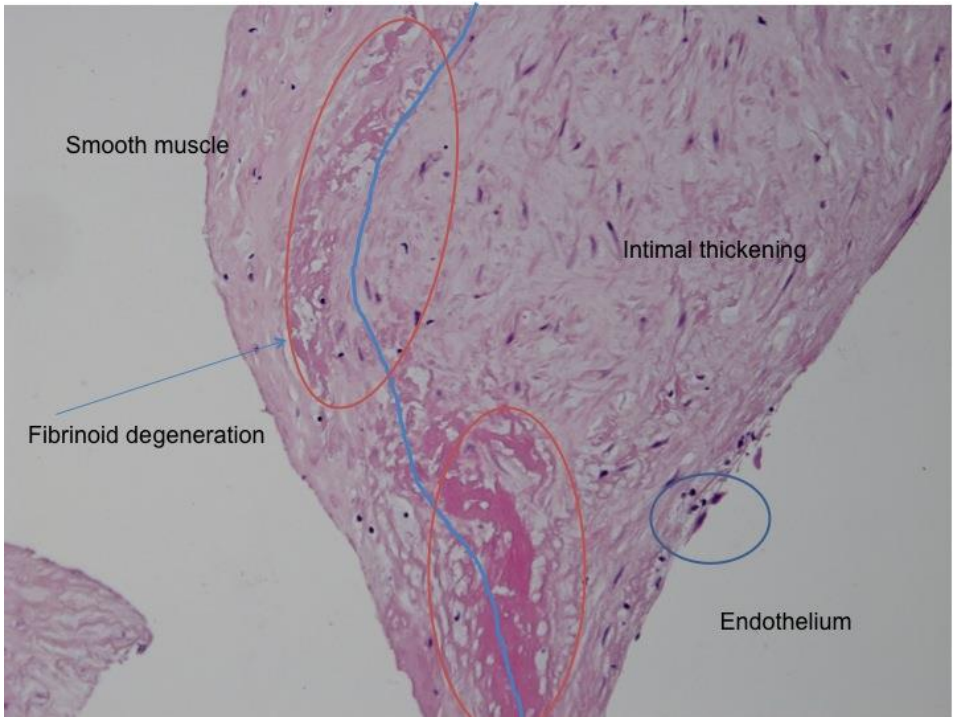
After athrectomy

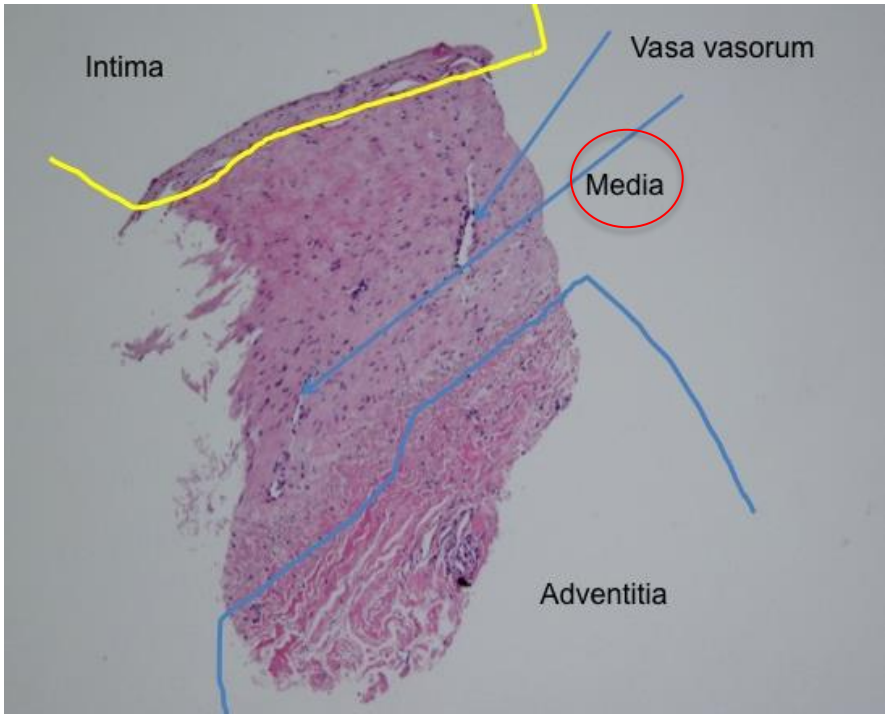


After DCB



Too Much Atherectomy?





Adventitial/Media Injury And Restenosis

J Endovasc Ther. 2015 Oct;22(5):712-5. doi: 10.1177/1526602815597683. Epub 2015 Jul 24.

Histopathological Evidence of Adventitial or Medial Injury Is a Strong Predictor of Restenosis During Directional Atherectomy for Peripheral Artery Disease.

Tarricone A[1], Ali Z[2], Rajamanickam A[1], Gujja K[1], Kapur V[1], Purushothaman KR[1], Purushothaman M[1], Vasquez M[1], Zalewski A[2], Parides M[1], Overbey J[1], Wiley J[1], Krishnan P[3].

Author information

Abstract

PURPOSE: To investigate the impact on restenosis rates of deep injury to the adventitial layer during directional atherectomy.

METHODS: Between 2007 and 2010, 116 consecutive patients (mean age 69.6 years; 56 men) with symptomatic femoropopliteal stenoses were treated with directional atherectomy at a single center. All patients had claudication and TASC A/B lesions in the superficial femoral or popliteal arteries. Histopathology analysis of atherectomy specimens was performed to identify adventitial injury. Clinical follow-up included physical examination and duplex ultrasound scans at 3, 6, and 12 months in all patients. The primary endpoint was the duplex-documented 1-year rate of restenosis, which was determined by a peak systolic velocity ratio <2.4. Patients were dichotomized by the presence or absence of adventitial or medial cuts as evaluated by histopathology.

RESULTS: Adventitial injury were identified in 62 (53%) of patients. There were no differences in baseline demographic and clinical features ($p>0.05$), lesion length (58.7±12.8 vs 56.2±13.6 mm, $p=0.40$), or vessel runoff (1.9±0.6 vs 2.0±0.6, $p=0.37$) between patients with and without adventitial injury, respectively. The overall 1-year incidence of restenosis was 57%, but the rate was significantly higher ($p<0.0001$) in patients with adventitial or medial injury (97%, 60/62) as compared with those without (11%, 6/54).

CONCLUSION: Lack of adventitial injury after atherectomy for femoropopliteal stenosis is strongly related to patency at 1 year.

Distal Embolism during Atherectomy

An Algorithm for the Use of Embolic Protection During Atherectomy for Femoral Popliteal Lesions

Prakash Krishnan, MD, Arthur Tarricone, MPH, K. Raman Purushothaman, MD, Meerarani Purushothaman, PhD, Miguel Vasquez, MD, Jason Kovacic, MD, Usman Baber, MD, Vishal Kapur, MD, Karthik Gujja, MD, Annapoorna Kini, MD, Samin Sharma, MD

ABSTRACT

OBJECTIVES This study sought to identify an algorithm for the use of distal embolic protection on the basis of angiographic lesion morphology and vascular anatomy for patients undergoing atherectomy for femoropopliteal lesions.

BACKGROUND Atherectomy has been shown to create more embolic debris than angioplasty alone. Distal embolic protection has been shown to be efficacious in capturing macroemboli; however, no consensus exists for the appropriate lesions to use distal embolic protection during atherectomy.

METHODS Patients with symptomatic lower extremity peripheral artery disease treated with atherectomy and distal embolic protection were evaluated to identify potential predictors of DE. Plaque collected from the SilverHawk nose cone subset was sent to pathology for analysis to evaluate the accuracy of angiography in assessing plaque morphology.

RESULTS Significant differences were found in lesion length (142.1 ± 62.98 vs. 56.91 ± 41.04; p = 0.0001), low-density lipoprotein (82.3 ± 40.3 vs. 70.9 ± 23.2; p = 0.0006), vessel runoff (1.18 ± 0.9 vs. 1.8 ± 0.9; p = 0.0001), chronic total occlusion (131 vs. 10; p = 0.001), in-stent restenosis (33 vs. 6; p = 0.0081), and calcified lesions (136 vs. 65; p < 0.001). In simple logistic regression analysis lesion length, reference vessel diameter, chronic total occlusion, runoff vessels, and in-stent restenosis were found to be strongly associated with macroemboli. Angiographic assessment of plaque morphology was accurate. Positive predictive value of 92.31, negative predictive value of 95.35, sensitivity of 92.31, and specificity of 95.35 for calcium; positive predictive value of 95.56, negative predictive value of 100, sensitivity of 100, and specificity of 92.31 for atherosclerotic plaque. Thrombus/in-stent restenosis was correctly predicted.

CONCLUSIONS Chronic total occlusion, in-stent restenosis, thrombotic, calcific lesions >40 mm, and atherosclerotic lesions >140 mm identified by peripheral angiography necessitate concomitant filter use during atherectomy to prevent embolic complications. (J Am Coll Cardiol Intv 2017;10:403-10) © 2017 by the American College of Cardiology Foundation.

- Incidence: 62.4%
- Risk factors:
  - long lesion (length >140 mm)
  - CTO
  - ISR
  - calcium
  - runoff vessels

Krishnan P, JACC Intv 2017;10:403

Thus,

- Higher residual plaque burden may be associated with increased risk of restenosis.
- Current atherectomy devices often fail to remove sufficient plaque volume.
- Mechanical injury to media or adventitia by aggressive atherectomy may increase risk of restenosis.
- So how much plaque removal is appropriate?
- How can you control the atherectomy devices precisely?

Cost Issues

- Cost:
  - DCB : 600 ~ 2000 USD per catheter
  - Atherectomy device: ~ 2000 USD
  - Distal protection device: 1500 ~ 2000 USD

For atherectomy + 2~3 DCBs => >5000 ~10,000 USD

- Cost-benefit analysis is needed!

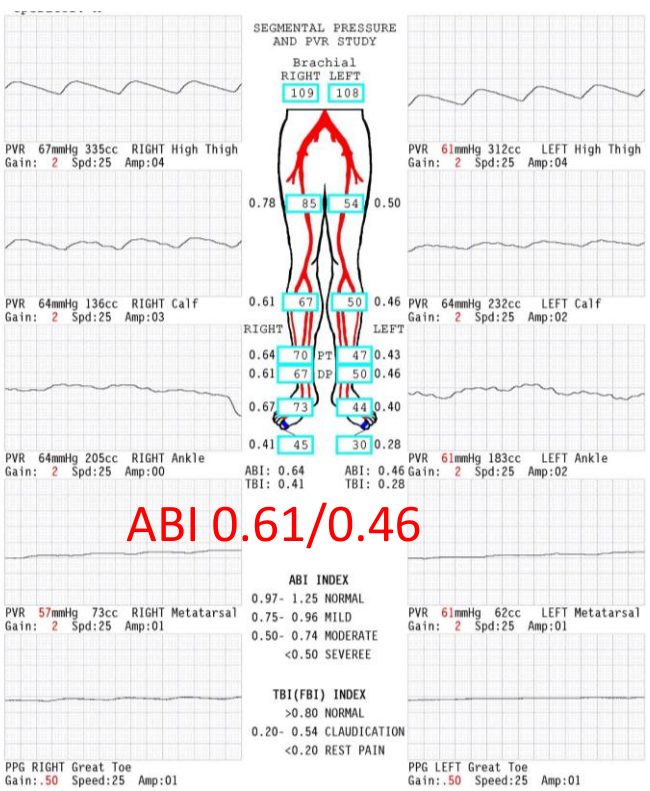
Atherectomy may require

- Longer procedure time
- More radiation
- More contrast dye

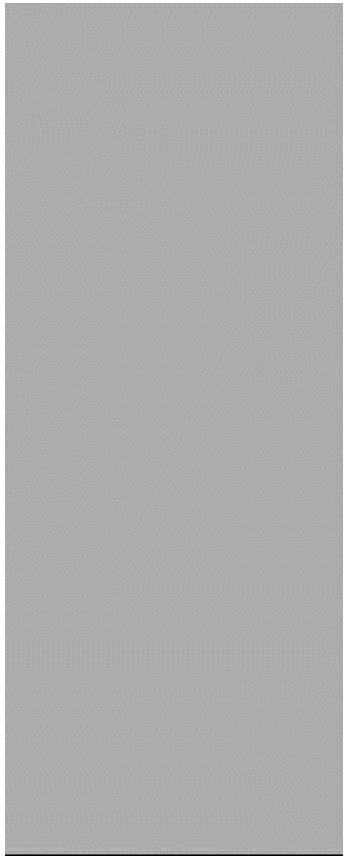
for patients and doctors

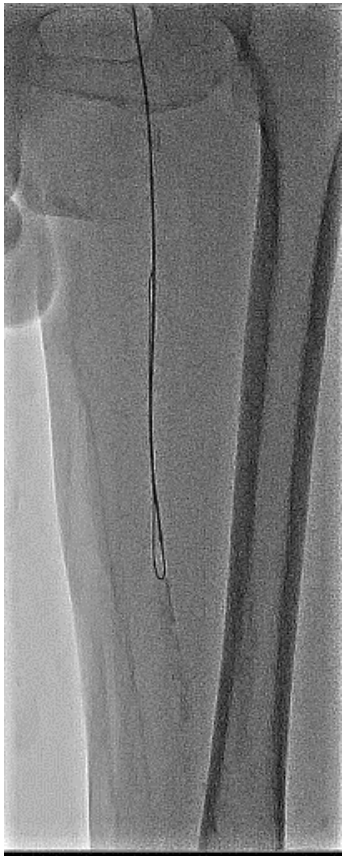
M/65, CYY, (#8109547)

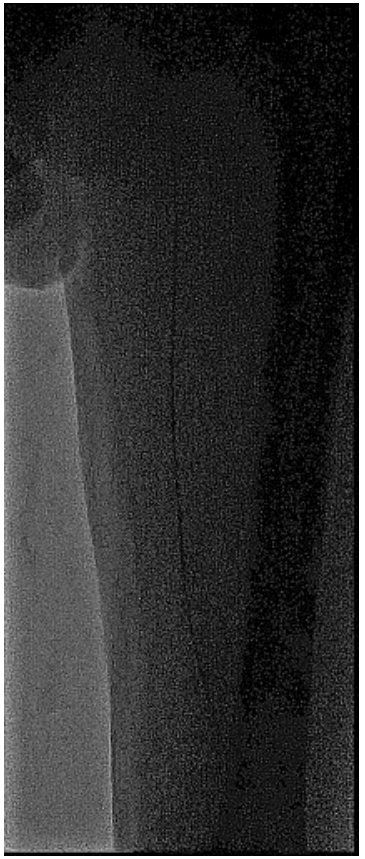
- Sx: Severe Claudication (R3)
- PHx:
  - HTN
  - DM,
  - Smoker



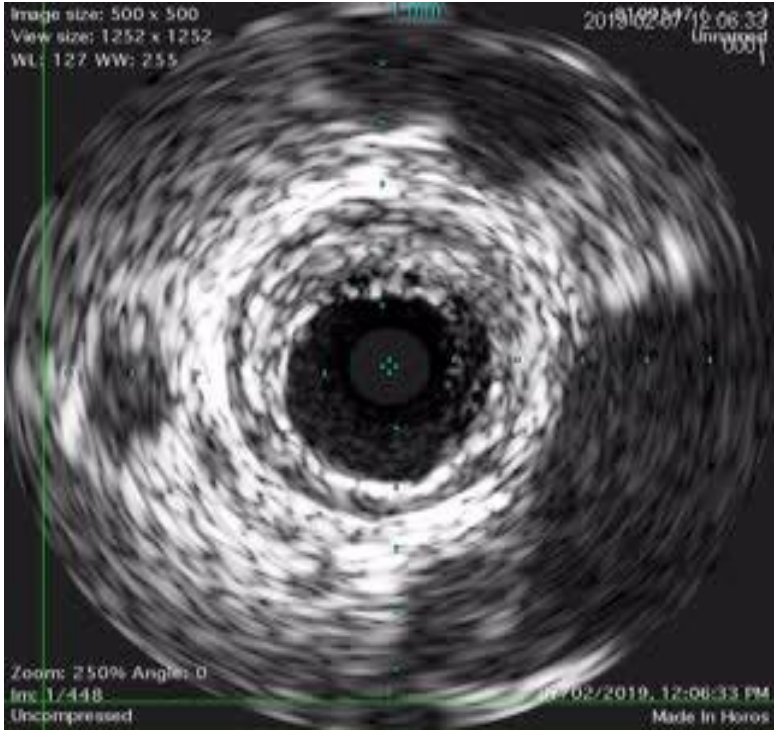
Baseline Angio & Wiring



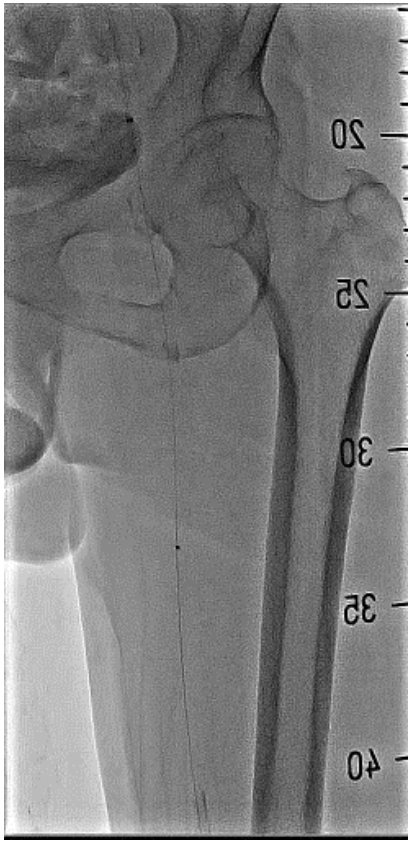


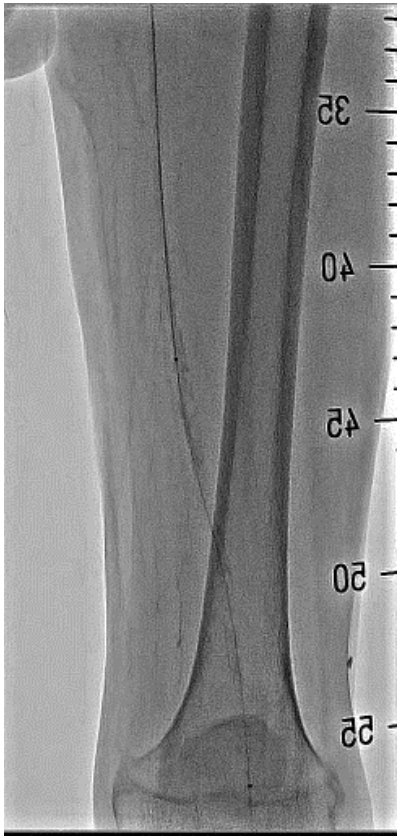


Baseline IVUS & Predilation

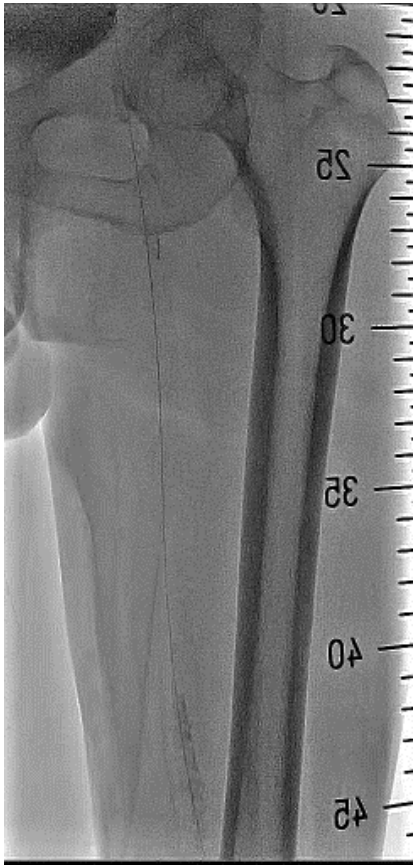


Balloon 5 x 150 mm

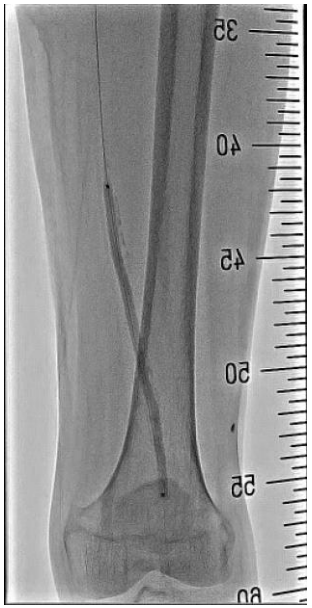




DCB Angioplasty



In.Pact DCB 5 x 150



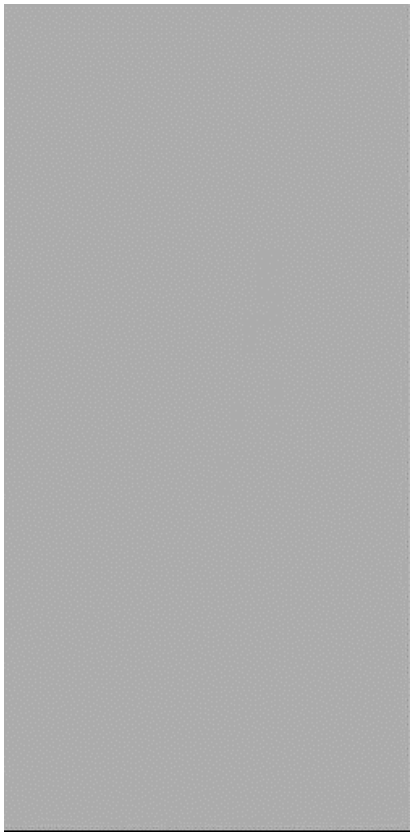
In.Pact DCB 5 x 150

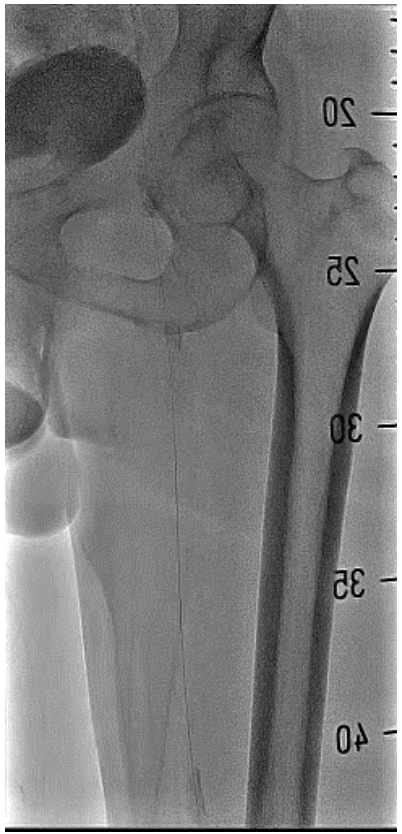
In.Pact DCB 6 x 80

Stenting (SMART 6x 80mm)

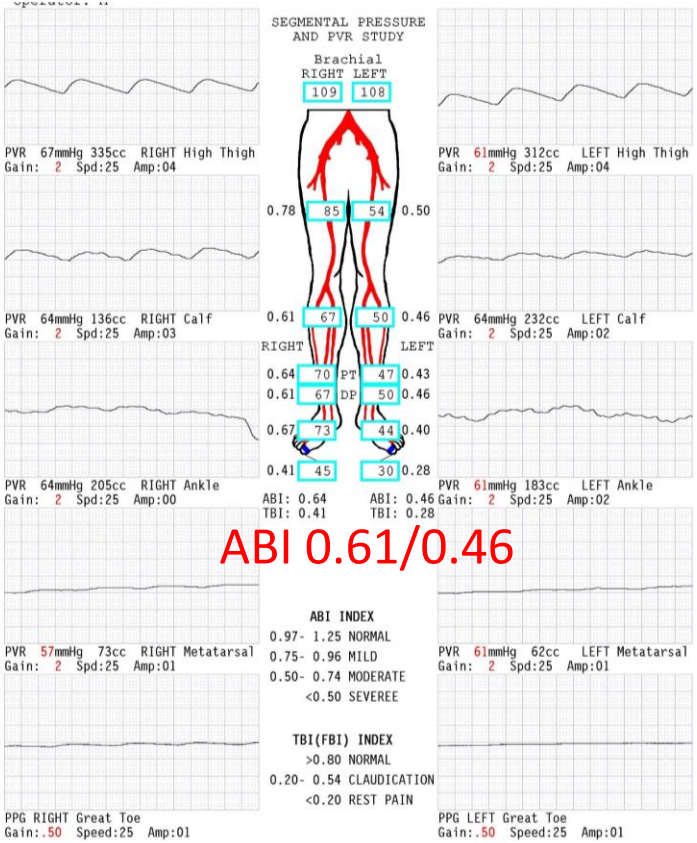
After additional ballooning

After post dilation

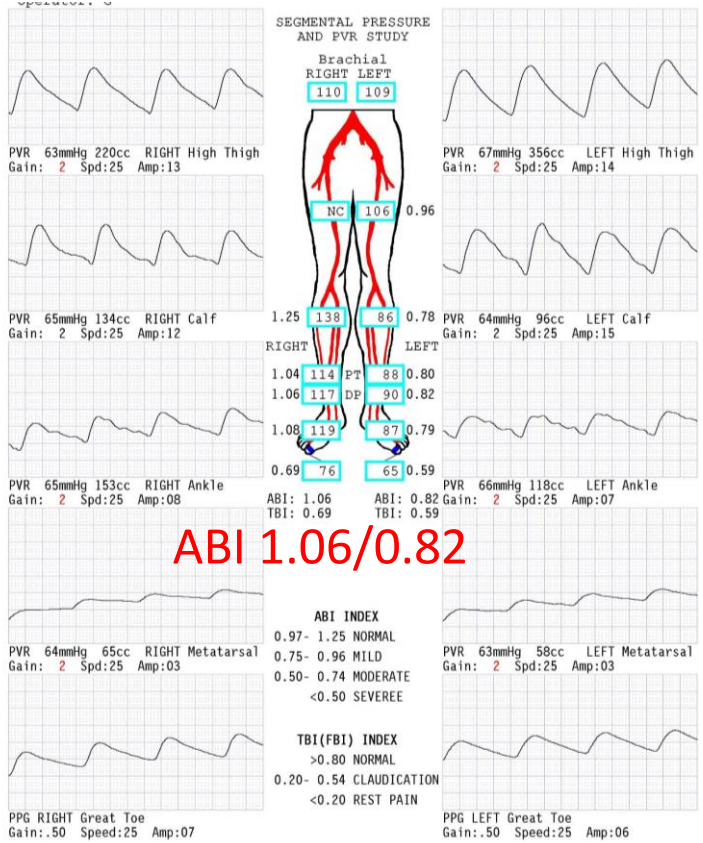




Post ABI



ABI 0.61/0.46



ABI 1.06/0.82

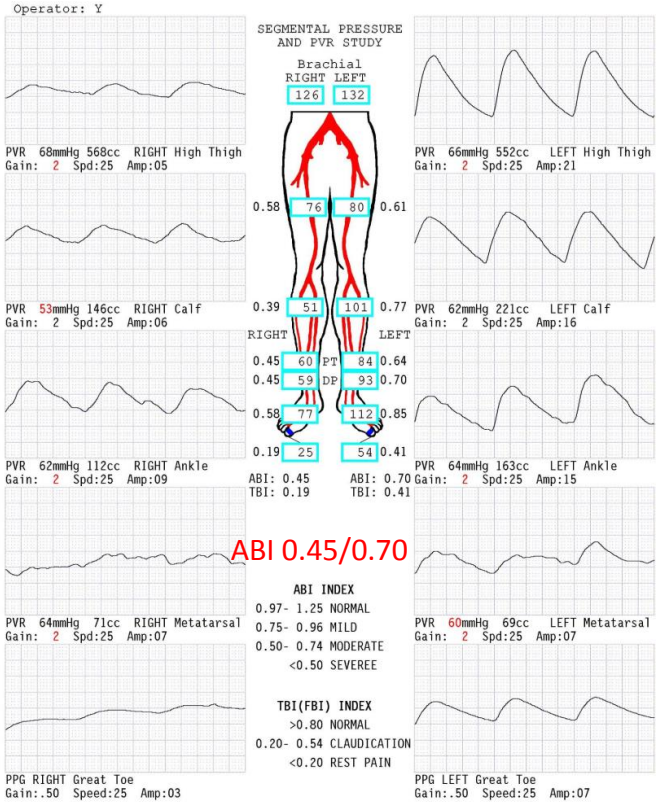
M/68 (NGS, #8191103)

- CC: Claudication Rt> Lt

  (Rutherford 2)

- PHx: DM, HTN

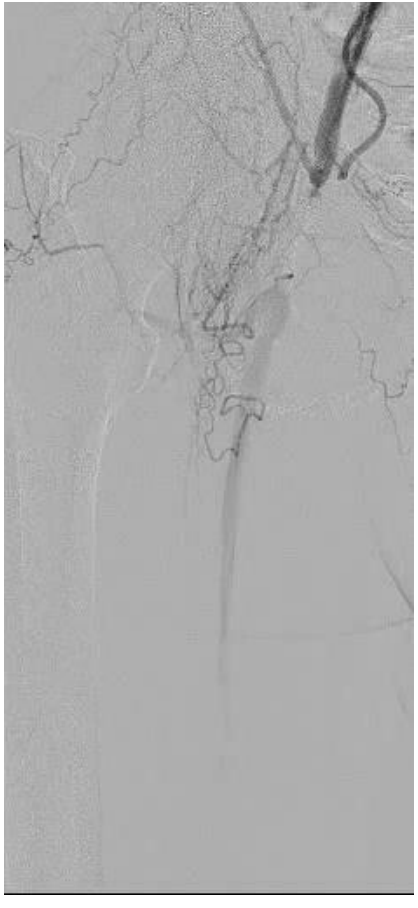
  S/P CABG

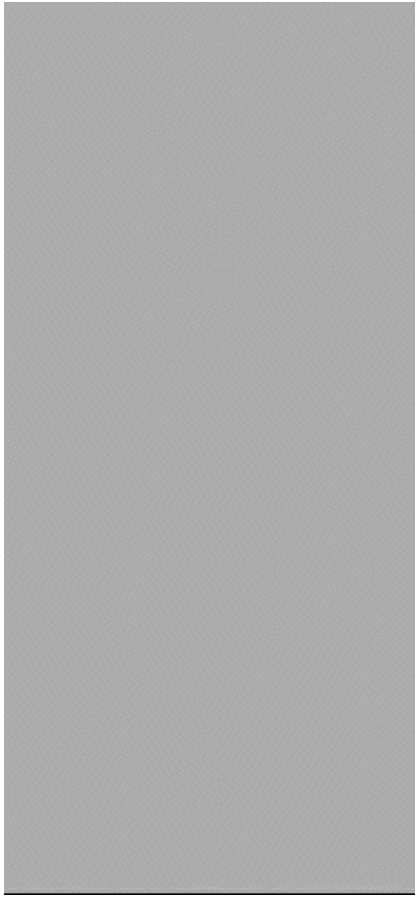


Balloon 5 x 40 mm

↓

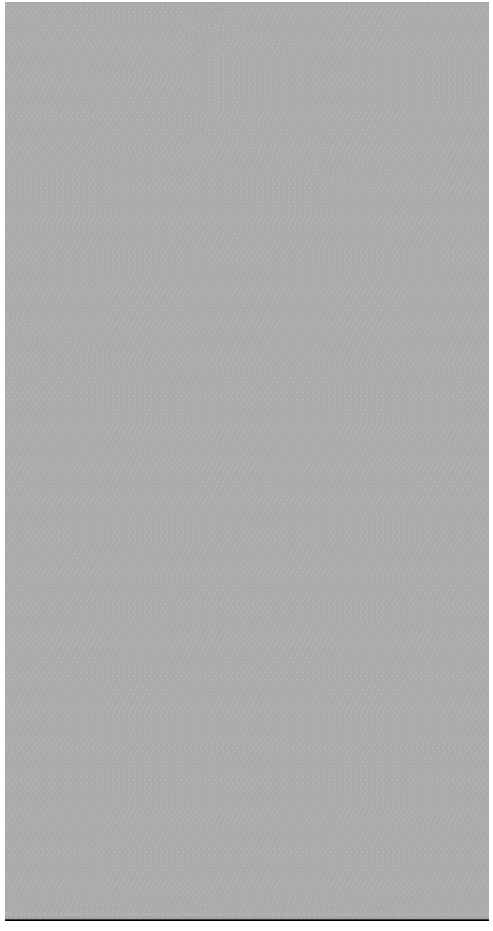
Balloon 7 x 40 mm





Supera 6 x 60 mm

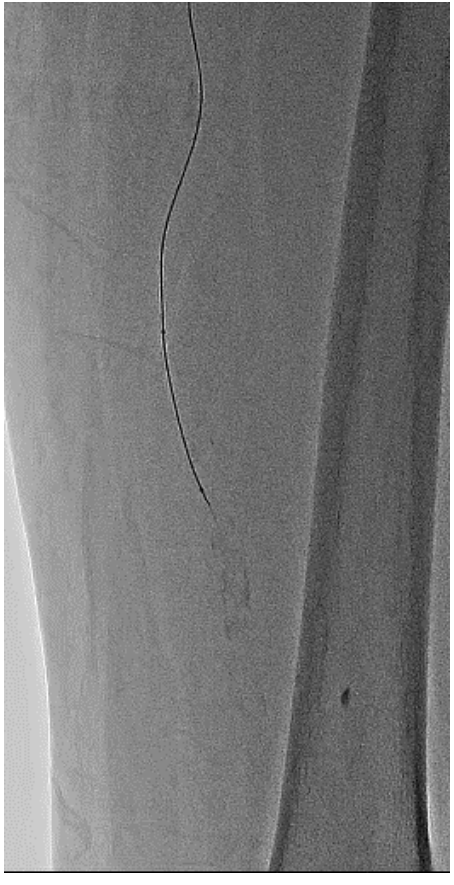
Balloon 7 x 40 mm



Rt. SFA

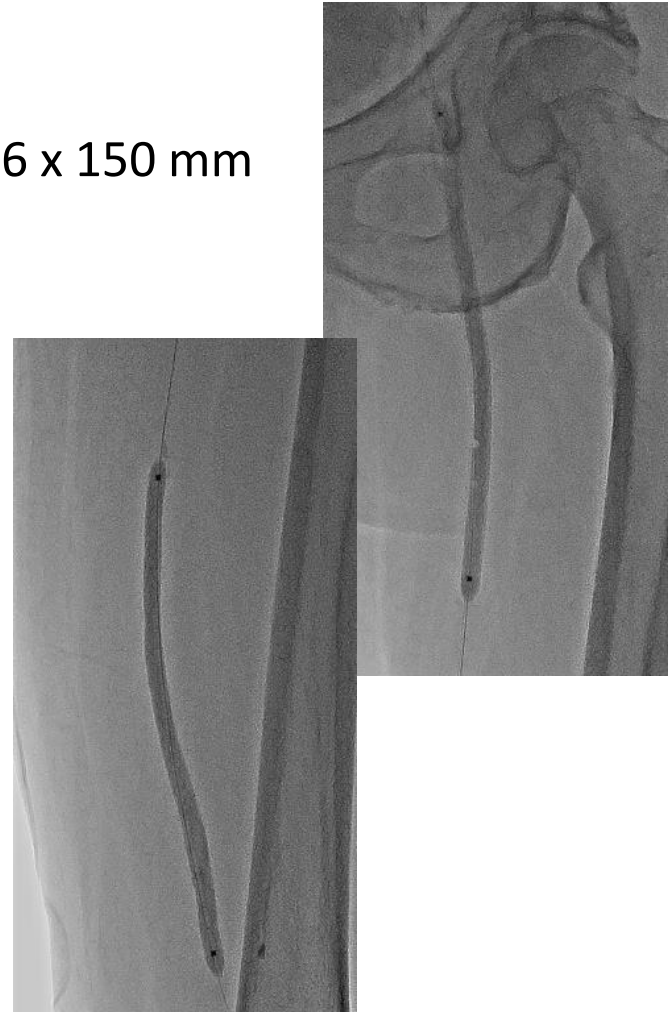
0.035 " Terumo wire

014” Approach 25 g

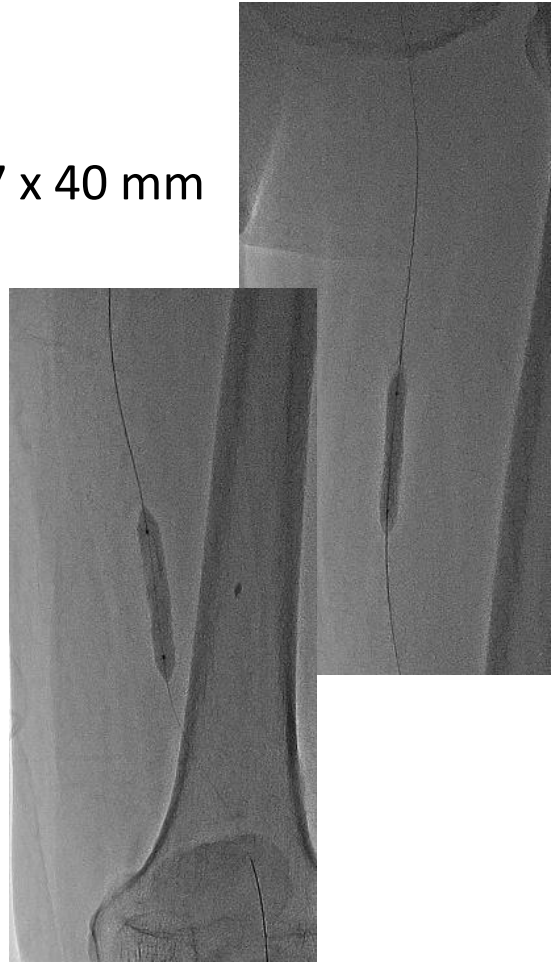


Outback reentry catheter

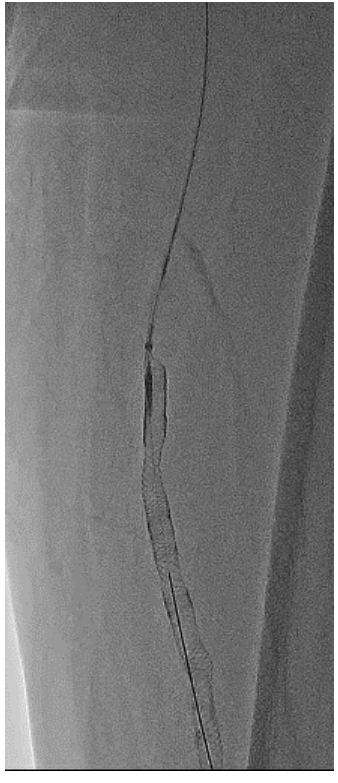
Balloon 6 x 150 mm

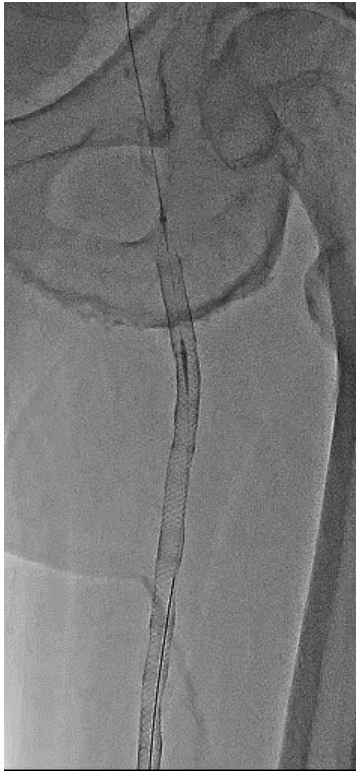


Balloon 7 x 40 mm

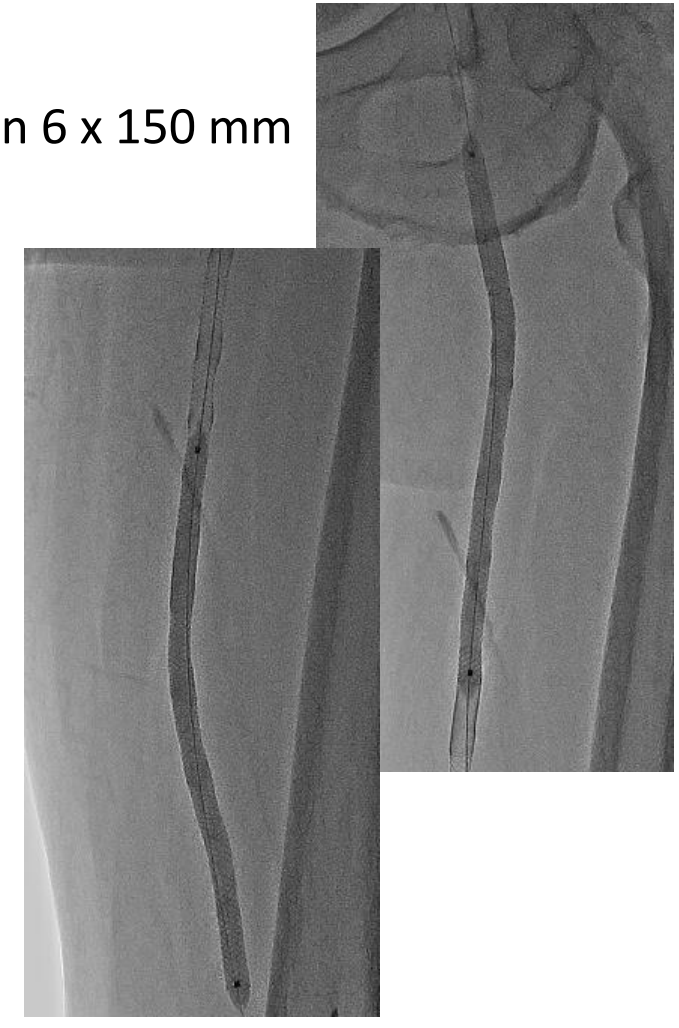


Supera 6 x 80 mm
Supera 6 x 120 mm
Supera 6 x 150 mm

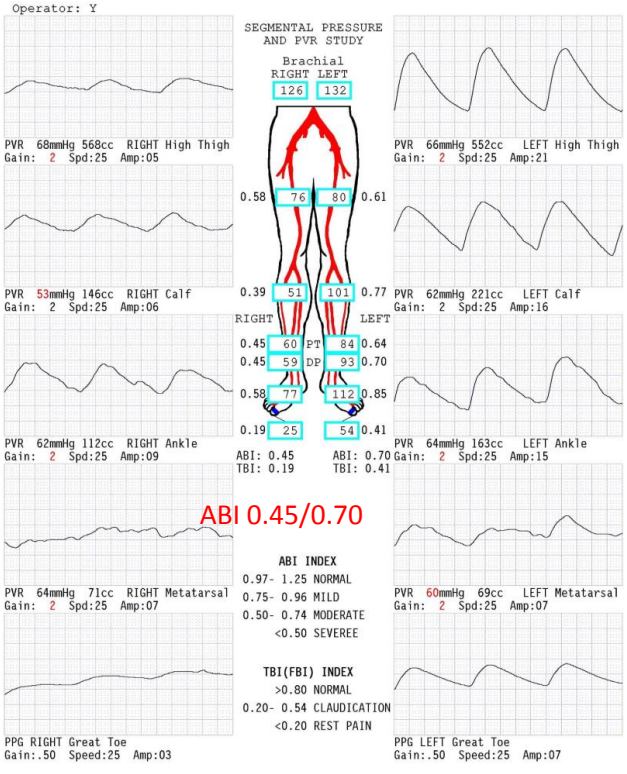




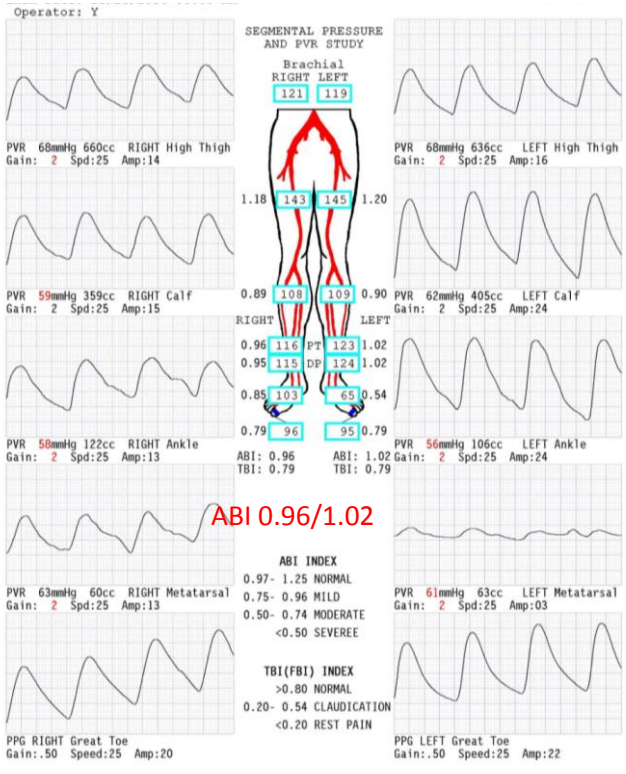
Balloon 6 x 150 mm



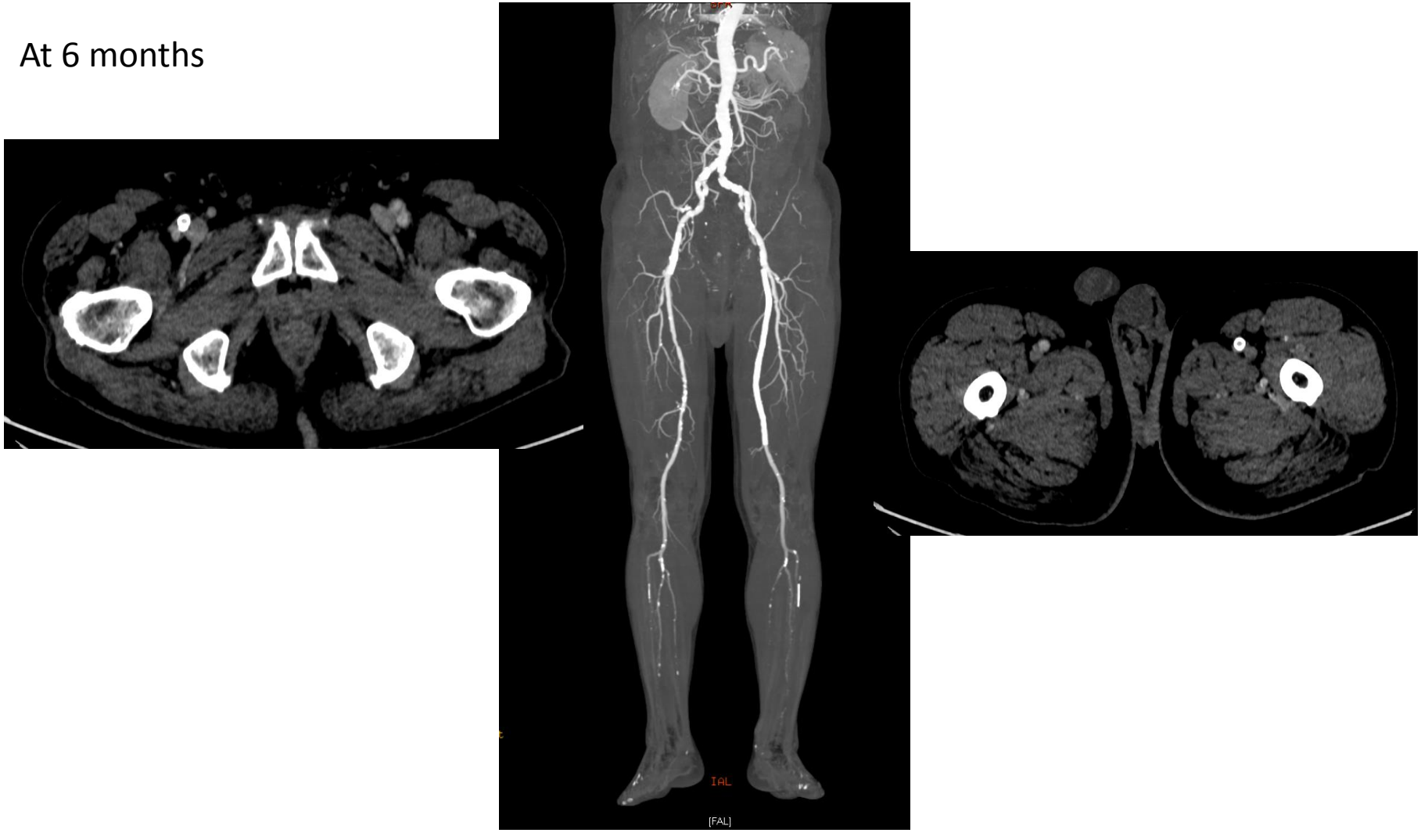
Baseline



After procedure

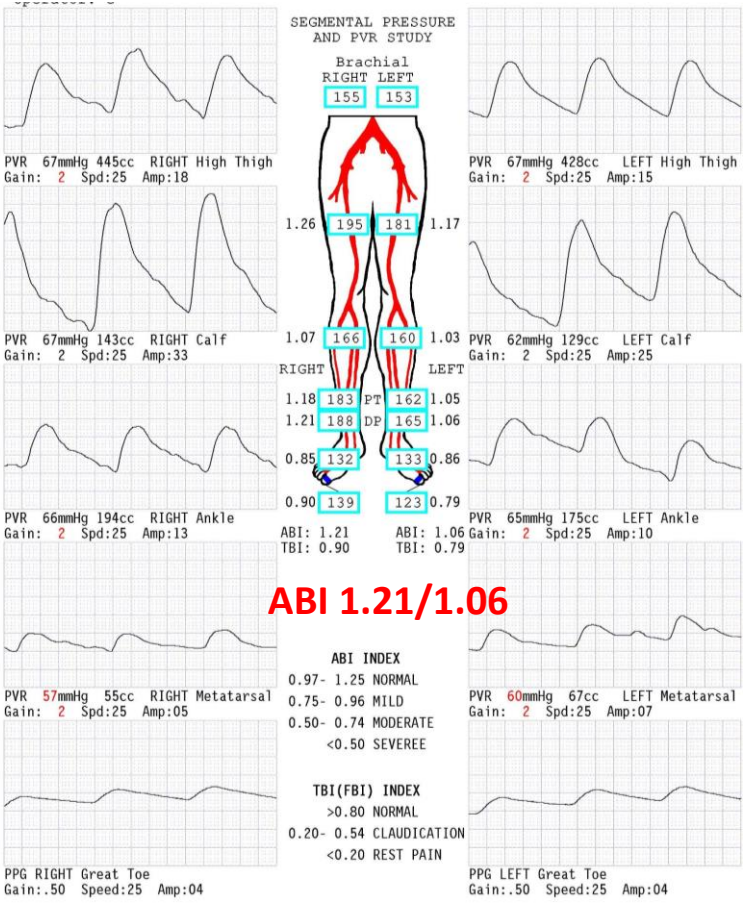


At 6 months

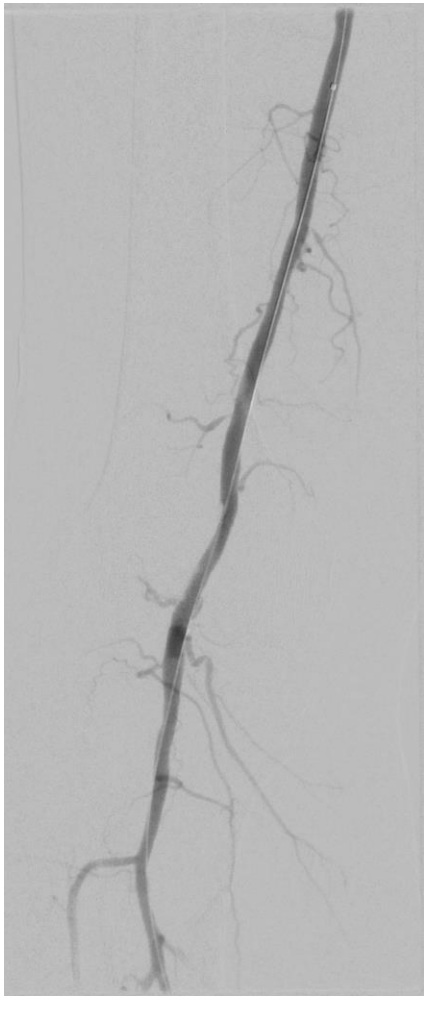


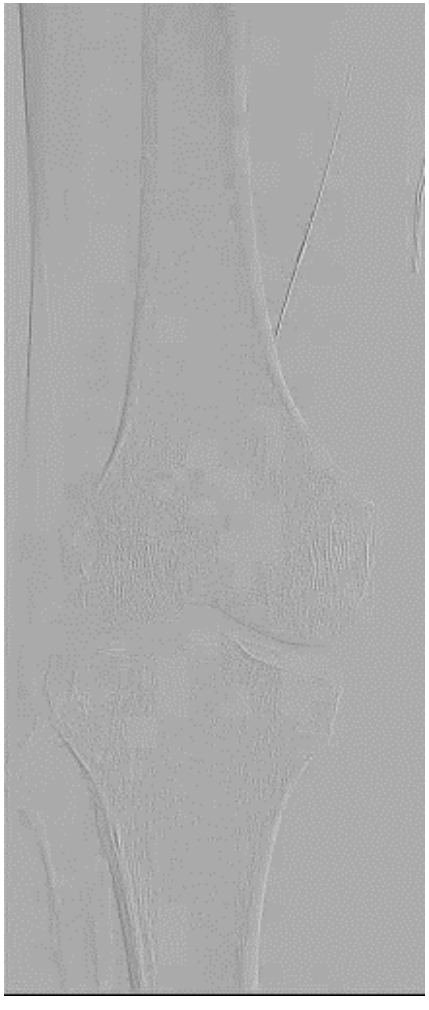

[H]
At 1-year follow-up
L
[F]

At 2 years


SEGMENTAL PRESSURE
AND PVR STUDY
Brachial
RIGHT LEFT
155 153
PVR 67mmHg 445cc RIGHT High Thigh
Gain: 2 Spd:25 Amp:18
PVR 67mmHg 428cc LEFT High Thigh
Gain: 2 Spd:25 Amp:15
1.26 195 181 1.17
PVR 67mmHg 143cc RIGHT Calf
Gain: 2 Spd:25 Amp:33
PVR 62mmHg 129cc LEFT Calf
Gain: 2 Spd:25 Amp:25
1.07 166 160 1.03
RIGHT LEFT
1.18 183 PT 162 1.05
1.21 188 DP 165 1.06
0.85 132 133 0.86
0.90 139 123 0.79
PVR 66mmHg 194cc RIGHT Ankle
Gain: 2 Spd:25 Amp:13
PVR 65mmHg 175cc LEFT Ankle
Gain: 2 Spd:25 Amp:10
ABI: 1.21
TBI: 0.90
ABI: 1.06
TBI: 0.79
ABI 1.21/1.06
PVR 57mmHg 55cc RIGHT Metatarsal
Gain: 2 Spd:25 Amp:05
PVR 60mmHg 67cc LEFT Metatarsal
Gain: 2 Spd:25 Amp:07
ABI INDEX
0.97- 1.25 NORMAL
0.75- 0.96 MILD
0.50- 0.74 MODERATE
<0.50 SEVEREE
TBI(FBI) INDEX
>0.80 NORMAL
0.20- 0.54 CLAUDICATION
<0.20 REST PAIN
PPG RIGHT Great Toe
Gain:.50 Speed:25 Amp:04
PPG LEFT Great Toe
Gain:.50 Speed:25 Amp:04

M/67, JHG, (#7187770)



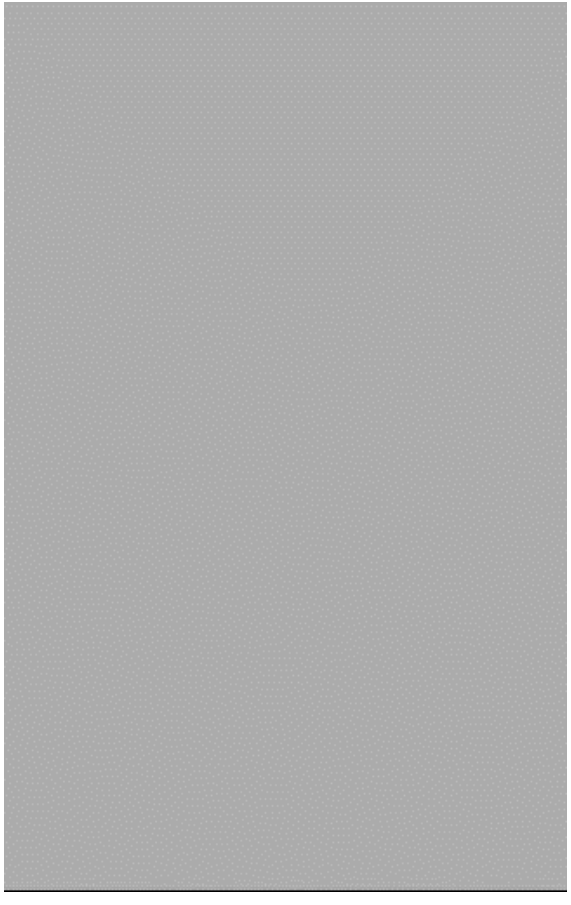


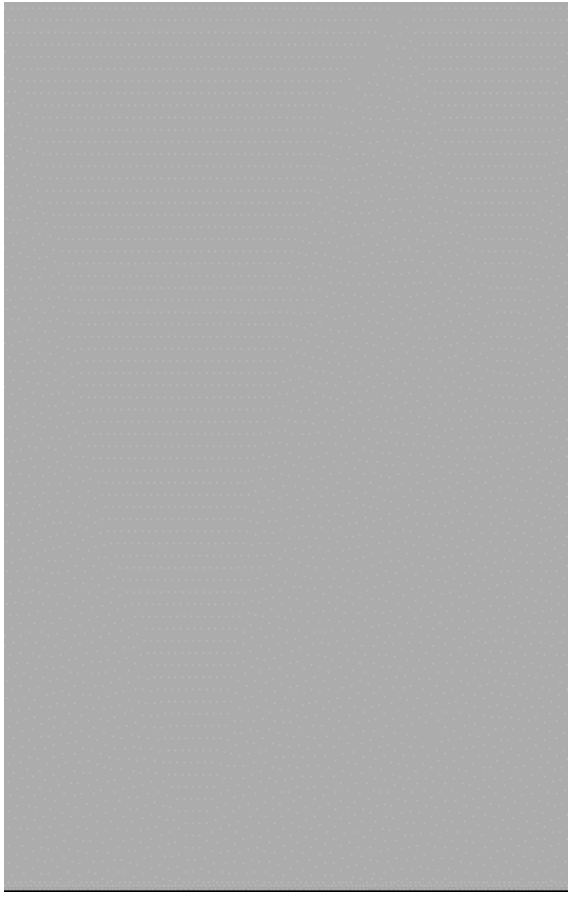
We need scaffold !

Cutting balloon 7 x 20 mm

DCB 6 x 60 mm

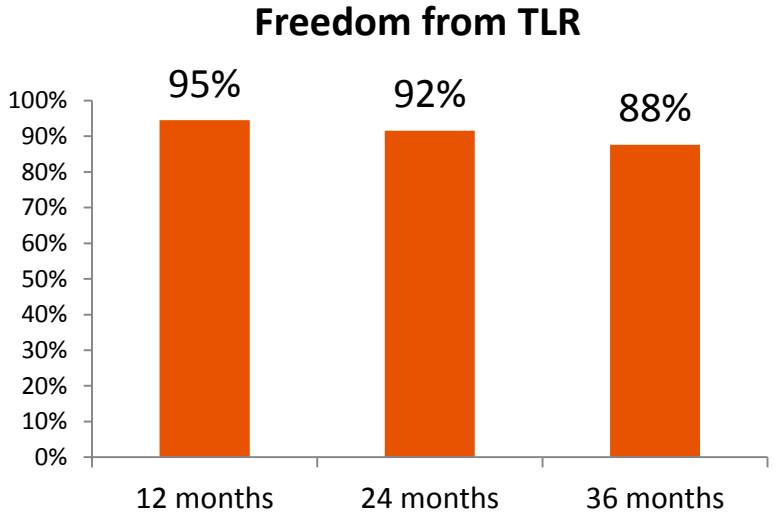
Supera 6 x 60 mm





SUPERB Trial: Supera in Severe Calcification

Data on file at Abbott Vascular.

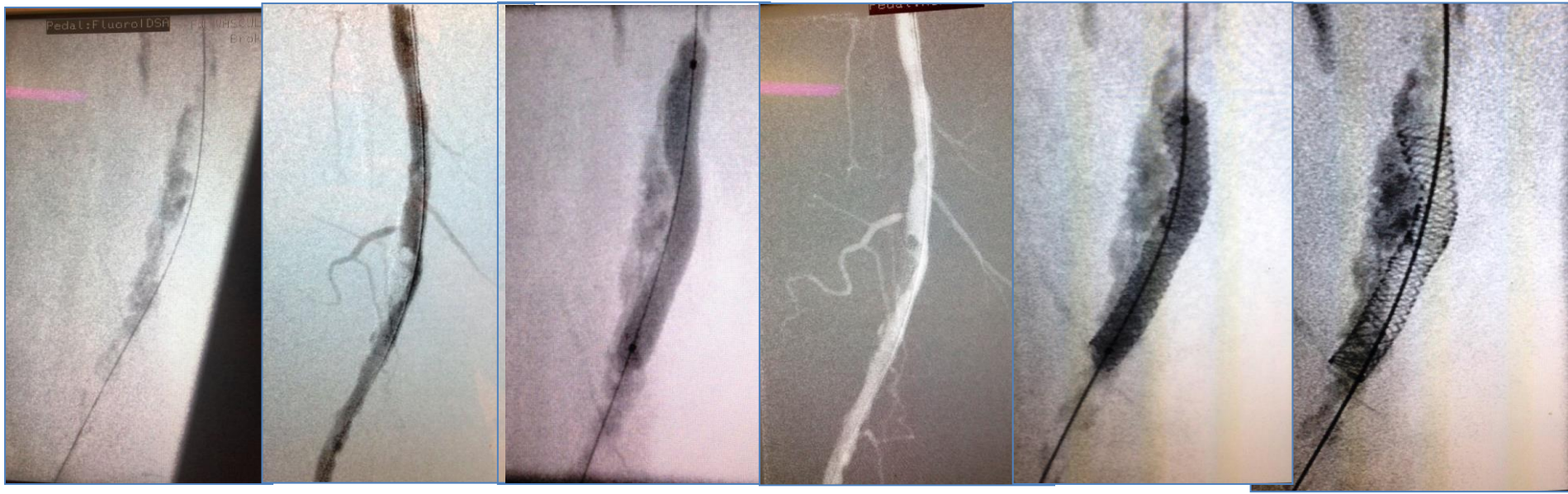


SUPERB Data - Severe Calcification

% of Lesions with Severe Calcification (SUPERB Trial)	45% (n=118)
Patency (VIVA 12 months)	89%

Supera Stent in Heavily Calcified Lesion

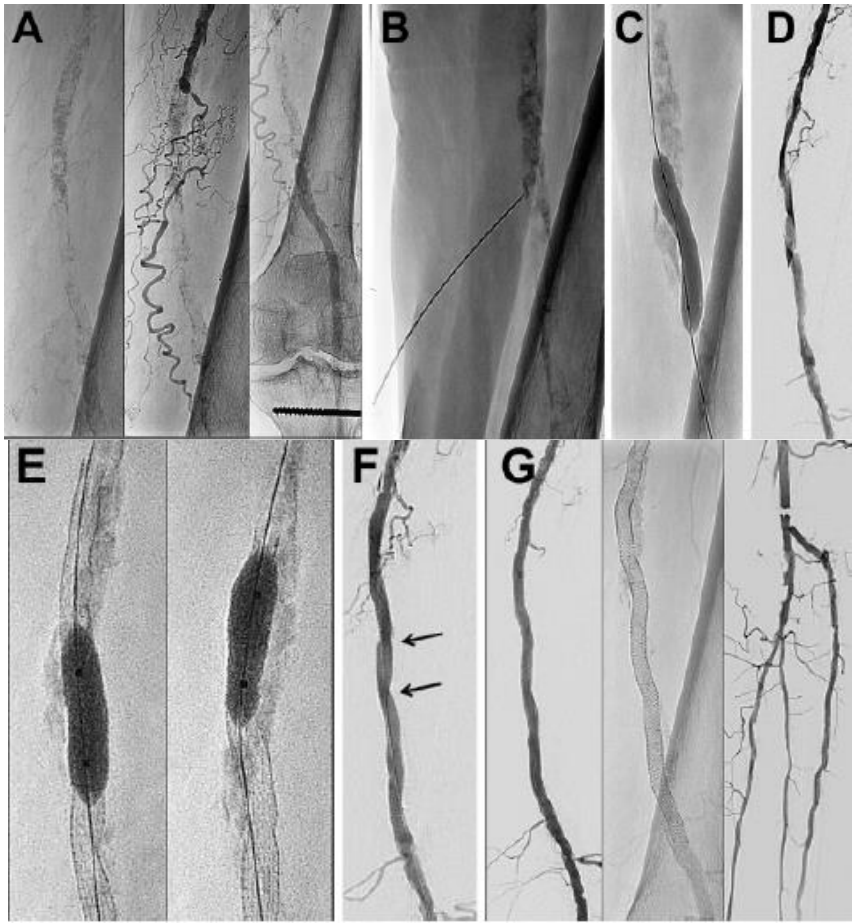
Very heavy calcium markers	Angio post .9 mm laser 4.0 x 60 mm Fox SV™	6.0 x 60 mm Fox SV™ to 15 ATM	Ghost image demonstrates lesion recoil and calcium	Post with 6.0 by 60 mm Fox SV™ to 20 ATM	Final view of stent after post dilatation



Images courtesy of Dr. Harshal Broker Ft. Worth Vascular, Ft. Worth, Texas

"Pave & Crack": Viabahn + Supera

- N = 67
- Lesion length: 26.9±11.2 cm
- Technical success 100%
- 1-yr primary patency: 79%



Clinical Investigation

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Endovascular Treatment of Severely Calcified Femoropopliteal Lesions Using the "Pave-and-Crack" Technique: Technical Description and 12-Month Results

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Abstract

Purpose: To report midterm results of the "pave-and-crack" technique to facilitate safe and effective scaffolding of heavily calcified femoropopliteal lesions in preparation for delivery of a Supera interwoven stent. **Methods:** Data were collected retrospectively on 67 consecutive patients (mean age 71±8 years; 54 men) treated with this technique between November 2011 and February 2017 at a single center. A third (22/64, 34%) of the patients had critical limb ischemia (CLI). Most lesions were TASC D (52/67, 78%), and the majority were occlusions (61/66, 92%). The mean lesion length was 26.9±11.2 cm. Nearly two-thirds (40/64, 62%) had grade 4 calcification (Peripheral Arterial Calcium Scoring System). To prepare for Supera stenting, the most heavily calcified segments of the lesion were predilated aggressively to obliterate recoil. A Viabahn stent-graft was then implanted to "pave" the lesion and protect from vessel rupture as aggressive predilation continued until the calcified plaque was "cracked" before lining the entire lesion with a Supera stent. Patency and target lesion revascularization (TLR) rates were estimated using the Kaplan-Meier method. **Results:** Procedural success was achieved in 100% and technical success (residual stenosis <30%) in 98% (66/67). The mean cumulative stent lengths were 16±9 cm for the Viabahn and 23±12 cm for the Supera. Only 2 complications occurred (distal embolization and access-site pseudoaneurysm). Two CLI patients died within 30 days, and 3 patients (all claudicants) underwent a TLR. Patients were followed for a mean 19±18 months, during which another 2 CLI patients died and 1 patient had a major amputation. One-year primary and secondary patency estimates were 79% and 91%, respectively; freedom from TLR was 85%. **Conclusion:** Despite severe lesion calcification, patients experienced high technical success and a safe and durable therapy at midterm follow-up with the femoropopliteal "pave-and-crack" technique.

Leipzig Supera Popliteal Artery Stent Registry

Treatment of Complex Atherosclerotic Popliteal Artery Disease With a New Self-Expanding Interwoven Nitinol Stent

12-Month Results of the Leipzig SUPERA Popliteal Artery Stent Registry

Dierk Scheinert, MD, Martin Werner, MD, Susanne Scheinert, MD, Anett Paetzold, Ursula Banning-Eichenseer, MD, Michael Piorkowski, MD, Matthias Ulrich, MD, Yvonne Bausback, MD, Sven Bräunlich, MD, Andrej Schmidt, MD

Leipzig, Germany

Objectives We examined the efficacy and durability of a new interwoven self-expanding nitinol stent system in the treatment of complex popliteal artery lesions in unselected patients.

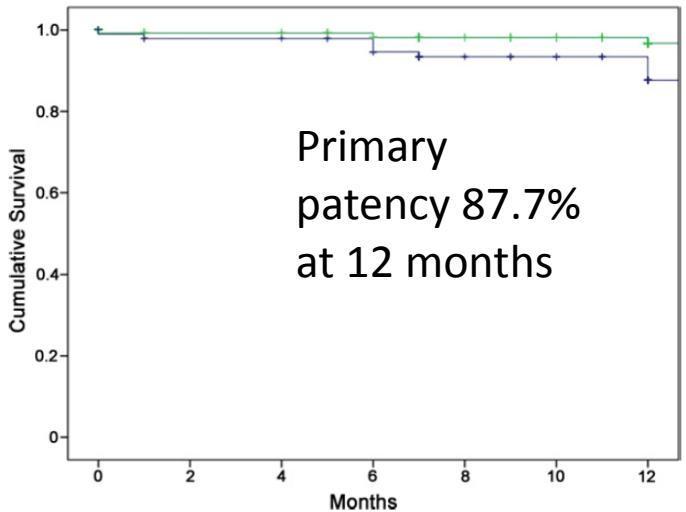
Background The optimal endovascular treatment strategy for atherosclerotic popliteal artery disease is not known.

Methods We retrospectively analyzed the data gathered in 101 consecutive patients presenting with atherosclerotic, popliteal arterial disease, who underwent implantation of 125 stents. The patients were followed for 12 months by Doppler ultrasound examinations, stent roentgenograms, and estimation of Rutherford-Becker class (RBC) and ankle-brachial index (ABI).

Results The mean age of the patients was 73.1 years, and 52.5% were men. Total occlusions were present in 48 patients (47.5%). The mean stent length was 84.3 ± 45.1 mm (range 40 to 240 mm). A <30% residual stenosis was achieved in 98.0% of procedures. The 6- and 12-month primary patency rates were 94.6 ± 2.3% and 87.7 ± 3.7%, respectively, and the secondary patency rates 97.9 ± 1.5% and 96.5 ± 2.0%, respectively. Between baseline and 12 months of follow-up, mean ABI increased from 0.58 ± 0.15 to 0.97 ± 0.18, and mean RBC decreased from 3.1 ± 0.9 to 1.4 ± 0.8 ($p < 0.001$ for both comparisons). Radiographs performed on 51 patients, at a mean of 15.2 months, confirmed the absence of stent fractures in 100% of examinations.

Conclusions Over a 12-month observation period, the patency rate and durability of SUPERA stents implanted for severe popliteal artery disease were high. (J Am Coll Cardiol Intv 2013;6:65–71)

- N = 101
- CTO = 47.5%
- Moderate/severe Ca++ ~50%
- Stent length 84.3±45.1 mm



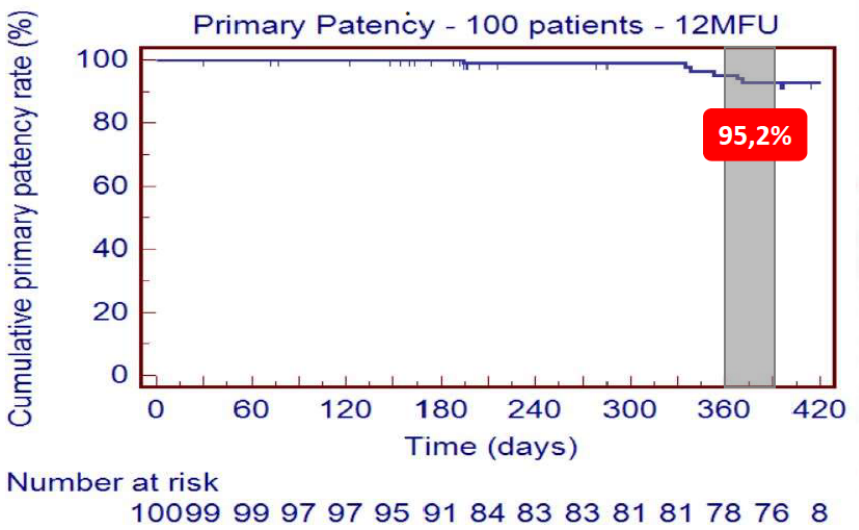
Scheinert D, JACC Intv 2013;6:65

Supera CFA VMI Trial

VMI-CFA trial

Prospective, multicenter, single arm trial to evaluate the Supera Peripheral Vascular Mimetic Implant Device (Abbott Vascular) for symptomatic (RB 2-4) CFA disease treatment

	N = 100 out of 100
Lesion length (min-max ± SD)	44,17mm (15mm – 80mm ± 15,67)
Ref vessel diameter (min-max ± SD)	7,29mm (5mm – 9mm ± 0,93mm)
Degree of stenosis (min-max ± SD)	82,6% (60% - 100% ± 10,65%)
Occlusion (%)	11 (11%)
Calcified lesion (%)	82 (82%)
*	
Azéma classification B (%)	52%
Azéma classification C (%)	47%



Deloose K, LINC 2019

Devices for Vessel Prep

- Atherectomy:
  - Directional
  - Rotational: Jetstream, Orbital, …
  - Laser
- Special balloons
  - Cutting balloon, scoring balloon, Chocolate balloon
- "Shockwave" Lithoplasty balloon

AngioSculpt® PTCA
Scoring Balloon Catheter

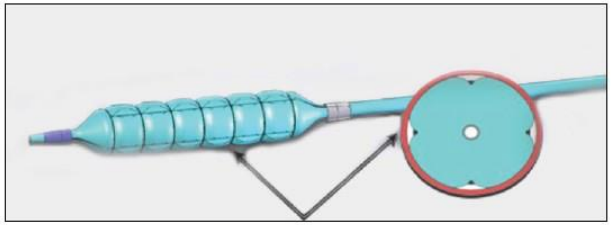


Figure 5. The Chocolate® PTA Balloon Catheter with distinctive "pillows" and "grooves" that serve to reduce vessel wall trauma.

Take Home Messages

- Calcified lesions are generally difficult to treat and optimal vessel prep is required.
- Atherectomy may reduce need for bail-out stenting and improve immediate and late outcomes.
- However, there is no proven evidence for atherectomy plus DCB in heavily calcified lesions.
- In heavily calcified lesions, nitinol interwoven stents have also shown favorable outcomes.
- Cost issue of atherectomy cannot be neglected in real world.


Thank You for Your Attention!
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