Clinical Application and Use of Rotational Atherectomy System

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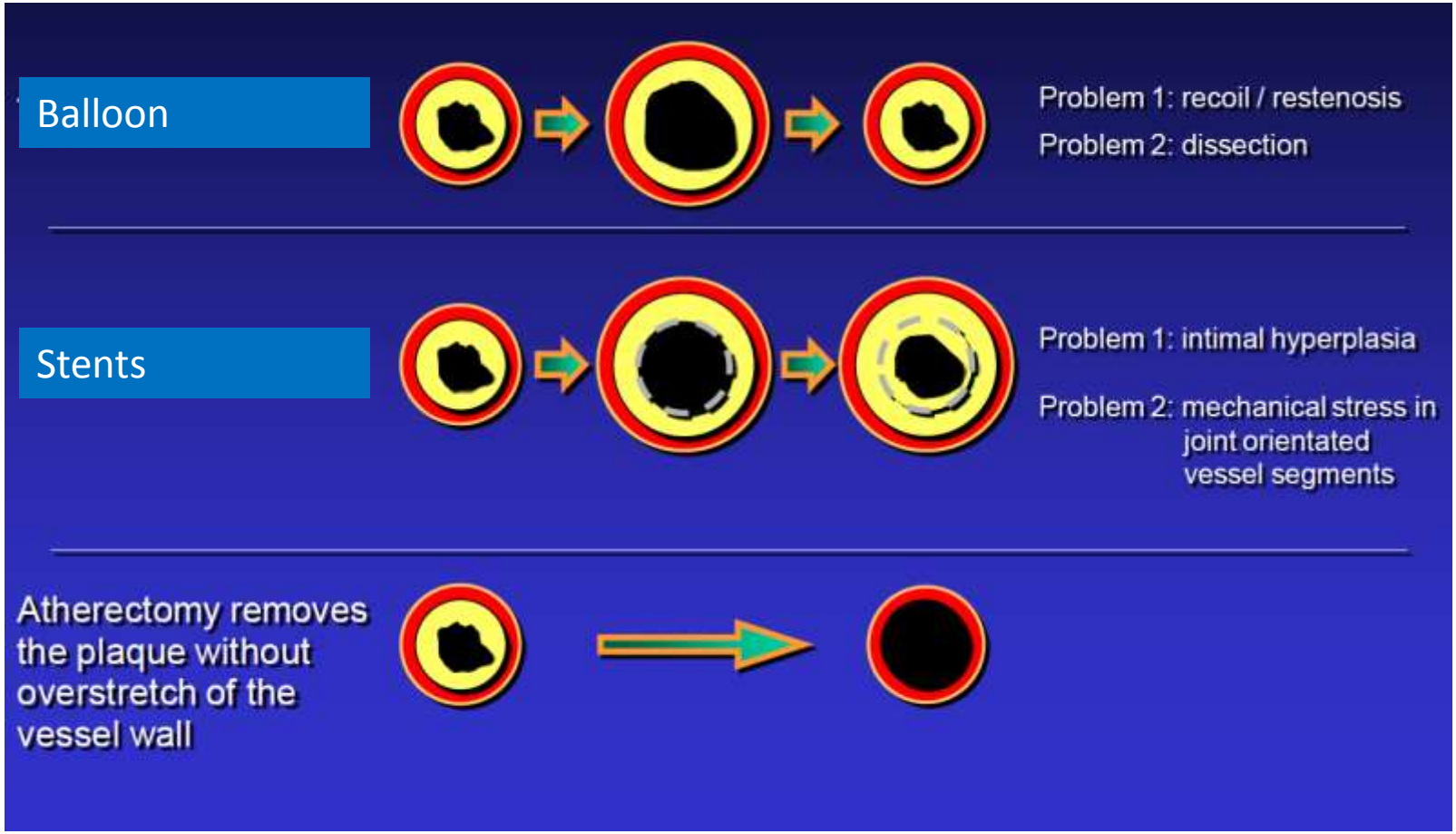
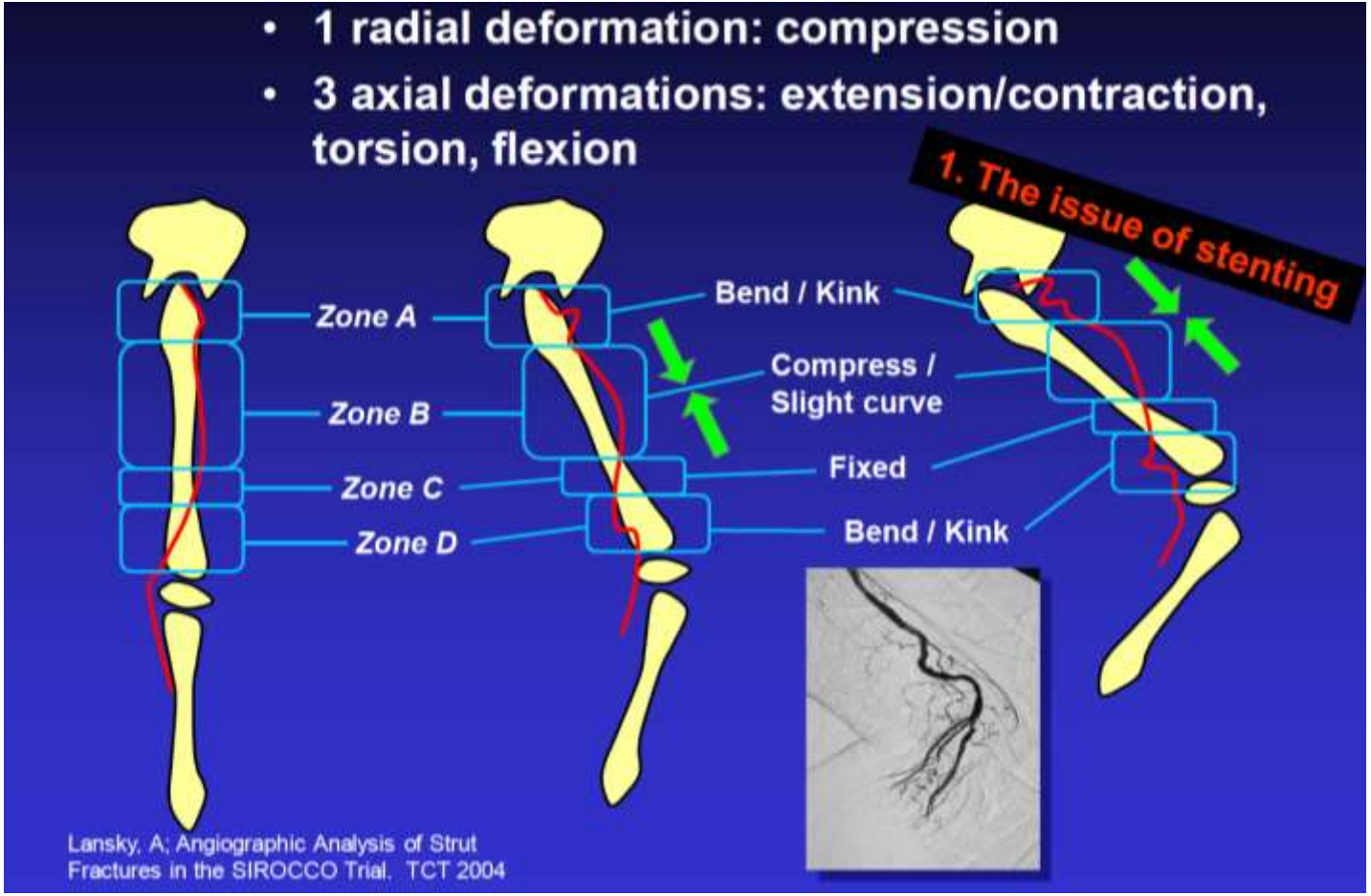
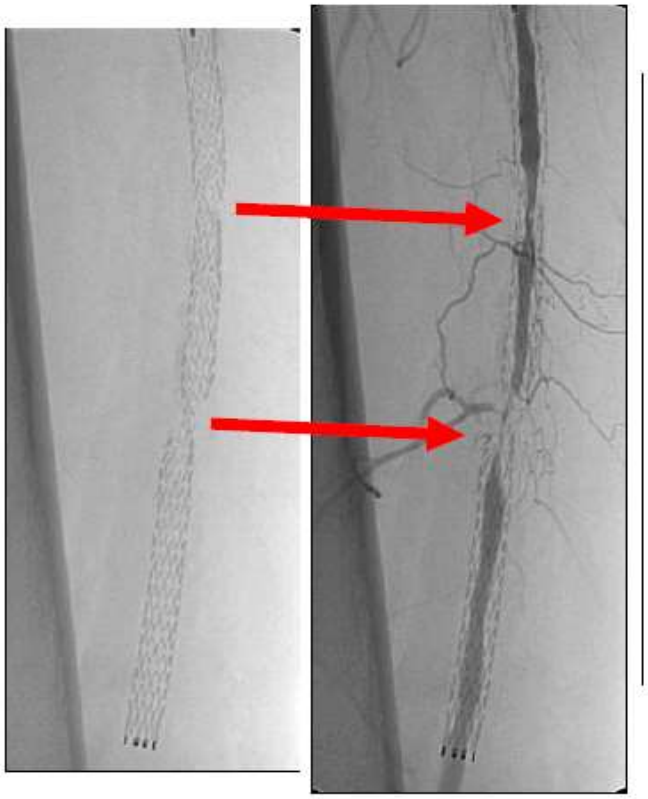
Theoretical Advantage of Atherectomy

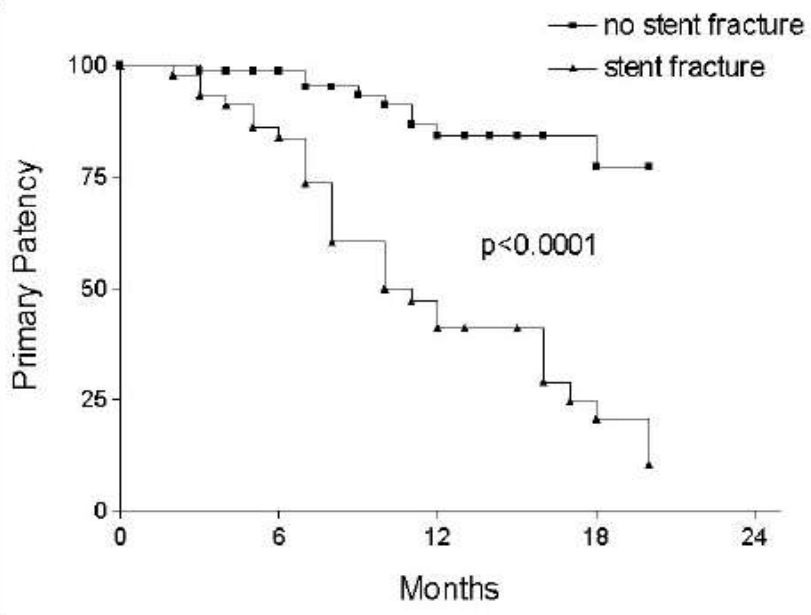


Risk of Stent Fractures



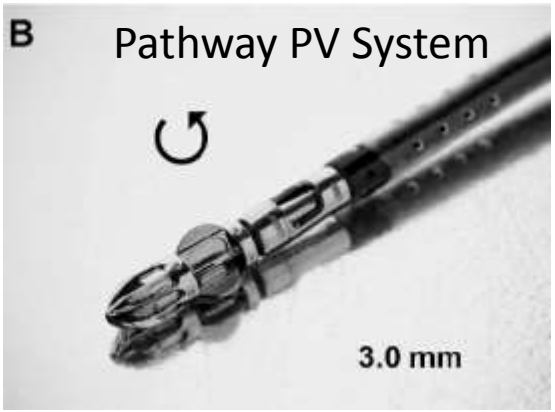
Stent Fracture and Restenosis in SFA

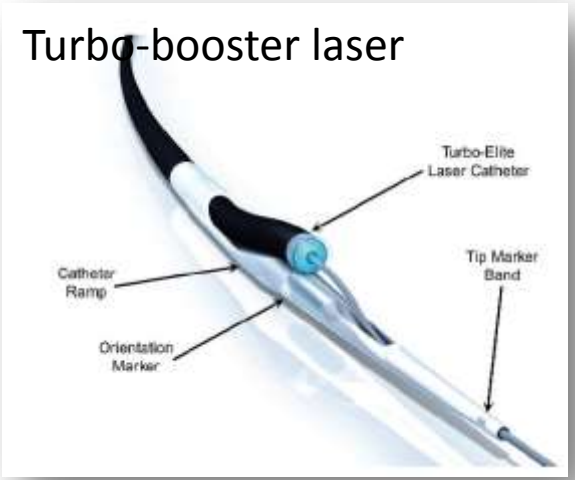




Scheinert D. et al, JACC 2005

Atherectomy Devices





Benefits of Atherectomy

- Debulking (Plaque burden reduction) & luminal gain
- Removal of calcium and thrombus
- Less dissection, less need for stenting
- Side branch preservation
- Improved drug delivery

Catheter Evolution

JETSTREAM™ Atherectomy System

Boston Scientific

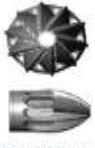
SYSTEM EVOLUTION

Continuous innovation to support your success

JETSTREAM

September 2008

- First commercially available Pathway Medical product
- Expandable blades
- Aspiration port integrated into distal cutter
- 8 F introducer sheath



Distal Cutter - 10 Flute Design

JETSTREAM G2™

February 2009

- Aspiration port moved proximal of cutting blades
- Macerator added
  - 10% increase in aspiration efficiency[1]
- Approved for thrombectomy

Macerator Added to Aspiration Port to Decrease Size of Plaque Before it is Aspirated

JETSTREAM G2 NXT

August 2009

- Pebax outer shaft and stainless steel hypotube (reduced OD, compared to earlier generation designs)
- 7 F compatibility
- Improved trackability (compared to earlier generation designs)

JETSTREAM G3™

January 2010

- 5-flute distal cutter design
- Increased torque (power)
  - 54% Increase in differential cutting efficiency[1]
- 11% increase in aspiration efficiency[2]

Distal Cutter - 5 Flute Design

JETSTREAM G3 GTI

December 2010

- Increased ease of use/ reliability (compared to JETSTREAM G3)
  - New liner over driveline
  - Improved distal bushing
  - Enhanced GW management
  - Improved User Interface

JETSTREAM Navitus™

March 2011

- Robust Bushing and Distal Liner (same as GTI)
  - Elimination of bushing tail related wire sticking
  - Protection against thrombus stick
  - Durable liner with improved aspiration.
- Guidewire management enhancements for smoother operation over the wire

JETSTREAM Navitus™ L

April 2012

- Largest JetStream Catheter
  - 2.4 mm / 3.4 mm
  - 30% larger lumens[3]
- Shortened Coupler
  - Improved performance in torturous anatomy
- Navitus technology integrated
  - Identical liner and bushing technology
  - Guidewire management enhancements

JETSTREAM™ XC/SC

April 2013

- Entire portfolio redesign
- New ergonomic POD design
  - 32% smaller than previous
  - Redesigned user interface
  - Improved wire GARD simplifies wire management
  - New package and POD design reduces environmental footprint

1. Compared to JETSTREAM G2 NXT in blades down during bench testing
2. Compared to JETSTREAM G2 NXT in bench testing
3. Data on file report EV09194

JETSTREAM™ Atherectomy System is manufactured and distributed in EU by Bayer Interventional

Pathway PVD Trial

J ENDOVASC THER
2009;16:553–562

553

• CLINICAL INVESTIGATION •

One-Year Outcome of Percutaneous Rotational Atherectomy With Aspiration in Infrainguinal Peripheral Arterial Occlusive Disease: The Multicenter Pathway PVD Trial

Thomas Zeller, MD[1]; Hans Krankenberg, MD[2]; Hermann Steinkamp, MD[3]; Aljoscha Rastan, MD[1]; Sebastian Sixt, MD[1]; Andrej Schmidt, MD[4]; Horst Sievert, MD[5]; Erich Minar, MD[6]; Marc Bosiers, MD[7]; Patrick Peeters, MD[8]; Jörn O. Balzer, MD[9]; William Grey, MD[10]; Thilo Tübler, MD[2]; Christian Wissgott, MD[11]; Uwe Schwarzwälder, MD[1]; and Dierk Scheinert, MD[1]

[1]Department of Angiology, Heart-Centre Bad Krozingen, Germany. [2]Hamburg University Cardiovascular Center, Hamburg, Germany. [3]Department of Radiology, Red Cross Clinics, Berlin, Germany. [4]Department of Angiology, Heart Center & Park Clinic, Leipzig, Germany. [5]CardioVascular Center Clinic, Frankfurt, Germany. [6]Department of Angiology, University Hospital Vienna, Austria. [7]Department of Vascular and Endovascular Surgery, AZ Sint-Blasius, Dendermonde, Belgium. [8]Department of Vascular and Endovascular Surgery, Imelda Cardiovascular Center, Bonheiden, Belgium. [9]Department for Radiology and Nuclear Medicine, Catholic Clinic, Mainz, Germany. [10]Center for Interventional Vascular Therapy, Columbia University Medical Center/New York Presbyterian Hospital, New York, New York, USA. [11]Department of Radiology, Westküstenklinikum, Heide, Germany.

Purpose: To report a safety and efficacy study of a novel rotational atherectomy system with aspiration capabilities for the treatment of infrainguinal arterial lesions.

Methods: From February 2006 to January 2007, 172 patients (88 women; mean age 72 years, range 51–93; 47% diabetics with Rutherford class 1–5 lower limb ischemia were enrolled at 9 study sites. Inclusion criteria were atherosclerotic stenoses >70% and up to 10 cm long in the femoropopliteal segment or up to 3 cm long in the infrapopliteal vessels (reference vessel diameter 3.0–6.0 mm). In the study, 210 lesions (mean length 3.7 cm) were treated with the Pathway PV System, including total occlusions (31%), lesions with a moderate to high calcium score (51%), and post-angioplasty (non-stent) restenotic lesions (15%). The primary study endpoint was the 30-day major adverse event (MAE) rate.

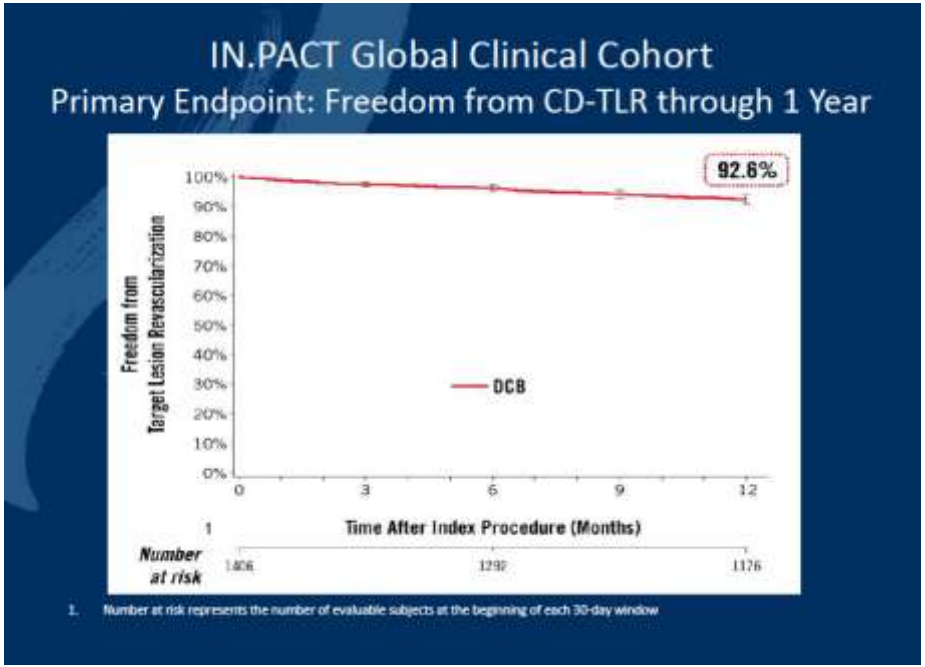
Results: Device success was 99% (208/210 lesions). MAE at 30 days was 1% (2 preplanned amputations). Clinically driven target lesion revascularization rates at 6 and 12 months were 15% (25/172) and 26% (42/162), respectively. The 1-year restenosis rate was 38.2% based on duplex imaging. The ankle-brachial index increased significantly from 0.59±0.21 at baseline to 0.82±0.27 ($p<0.05$) at 12 months. Mean Rutherford class improved from 3.0±0.9 at baseline to 1.5±1.3 at 1 year ($p<0.05$).

- 172 patients with 210 lesions
- Lesion location:
  - SFA (64%)
  - Popliteal artery (28%)
  - Tibial artery (including TPT) (9%)
- Lesion length: 27.4 ± 23.9 mm
- Stenting: 7%
- Complications:
  - abrupt closures 1%
  - dissections 9%
  - minor embolizations 10%
  - perforations 2%

- **TLR: 26% at 12 months**
- **1-year restenosis rate: 38.2%**

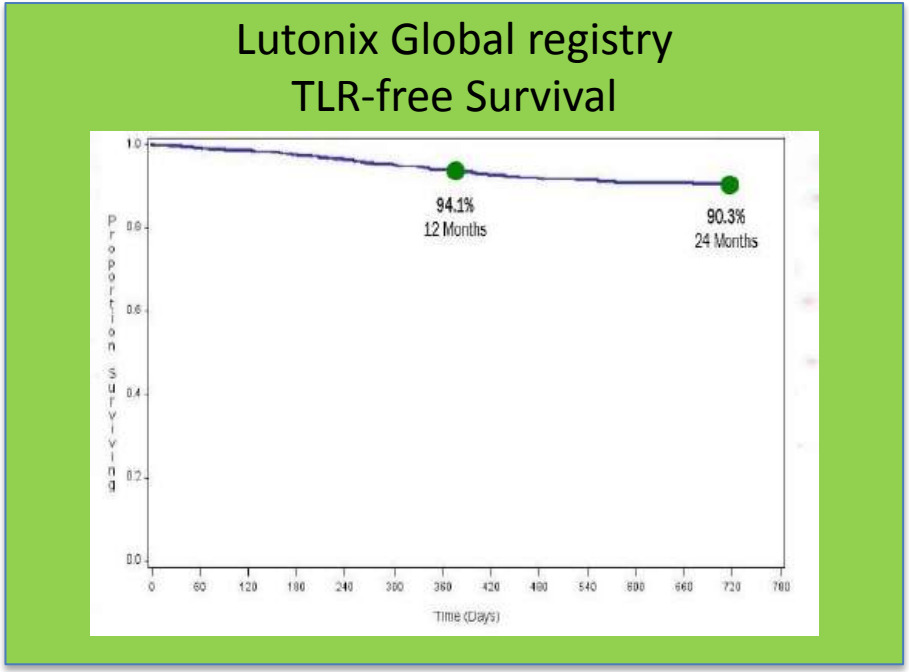
DCB Global Registries

1406 patients (1773 lesions)
Lesion length 12.1 ± 9.5 cm



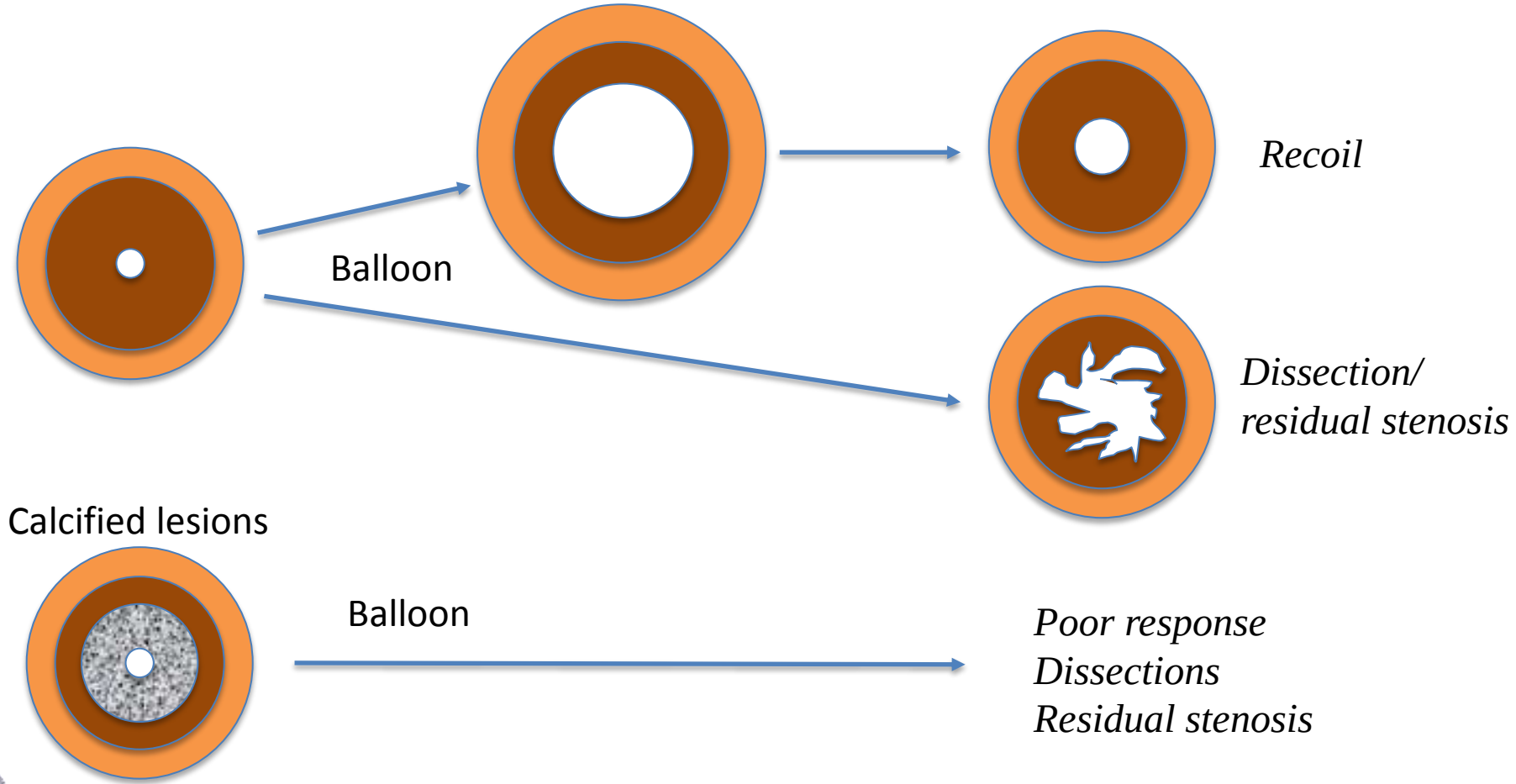
LINC 2017

691 patients
Lesion length 10.1 ± 8.4 cm



VIVA 2016

Limitations of Balloon Angiopasty



Challenges to DCB

- Long lesions:

  - *more plaque burden, higher risk of dissection*

- Calcification:

  - *difficult to dilate, more residual stenosis, higher risk of dissection, insufficient drug delivery*

- ISR lesions:

  - *remaining neointimal burden (residual stenosis)*

IN.PACT Global Long Lesion Imaging Cohort

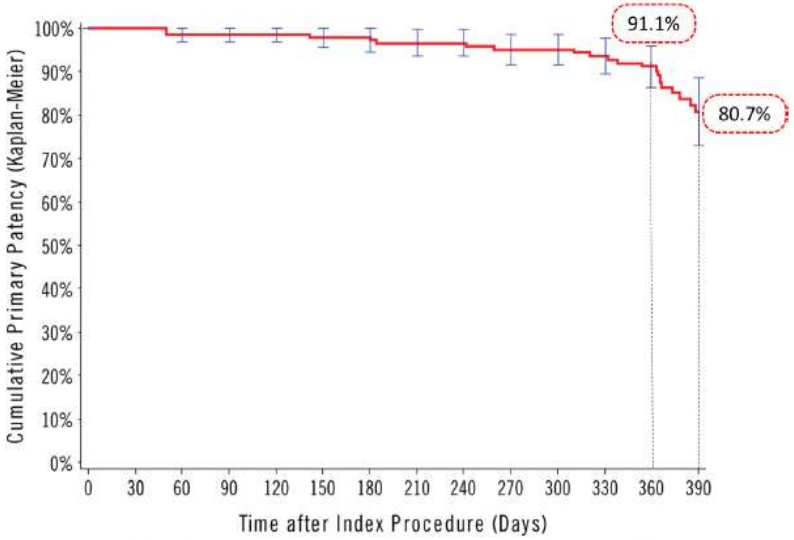
Lesions (N)	164
Lesion Type:	
de novo	83.2% (134/161)
restenotic (no ISR)	16.8% (27/161)
ISR	0.0% (0/161)
Lesion Length	26.40 ± 8.61 cm
Total Occlusions	60.4% (99/164)
Calcification	71.8% (117/163)
Severe	19.6% (32/163)
RVD (mm)	4.594 ± 0.819
Diameter Stenosis (pre-treatment)	90.9% ± 14.2
Dissections: 0	37.9% (61/161)
A-C	47.2% (76/161)
D-F	14.9% (24/161)

Procedural Characteristics	
Device Success [1]	99.5% (442/444)
Procedure Success [2]	99.4% (155/156)
Clinical Success [3]	99.4% (155/156)
Pre-dilatation	89.8% (141/157)
Post-dilatation	39.1% (61/156)
Provisional Stent	40.4% (63/156)
LL 15-25 cm:	33.3% (33/99)
LL > 25 cm:	52.6% (30/57)

1. **Device success:** successful delivery, inflation, deflation and retrieval of the intact study balloon device without burst below the RBP
2. **Procedure success**: residual stenosis of ≤ 50% (non-stented subjects) or ≤ 30% (stented subjects) by core lab (if core lab was not available then the site reported estimate was used)
3. **Clinical success:** procedural success without procedural complications (death, major target limb amputation, thrombosis of the target lesion, or TVR) prior to discharge

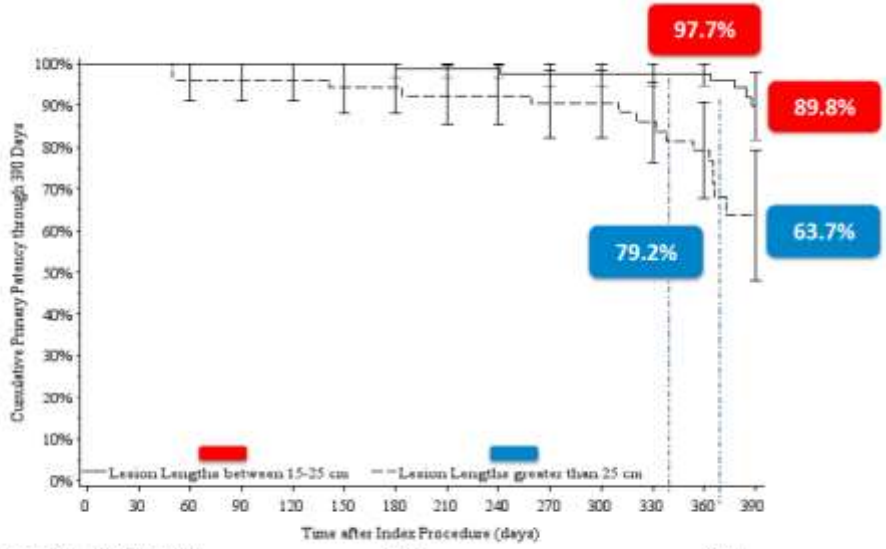
IN.PACT Global Long Lesion Imaging Cohort

Overall primary patency



Number of subjects at risk*	Baseline (day 0)	6 mo	12 mo
IN.PACT™ DCB	157	142	119

Primary patency: long vs. very long

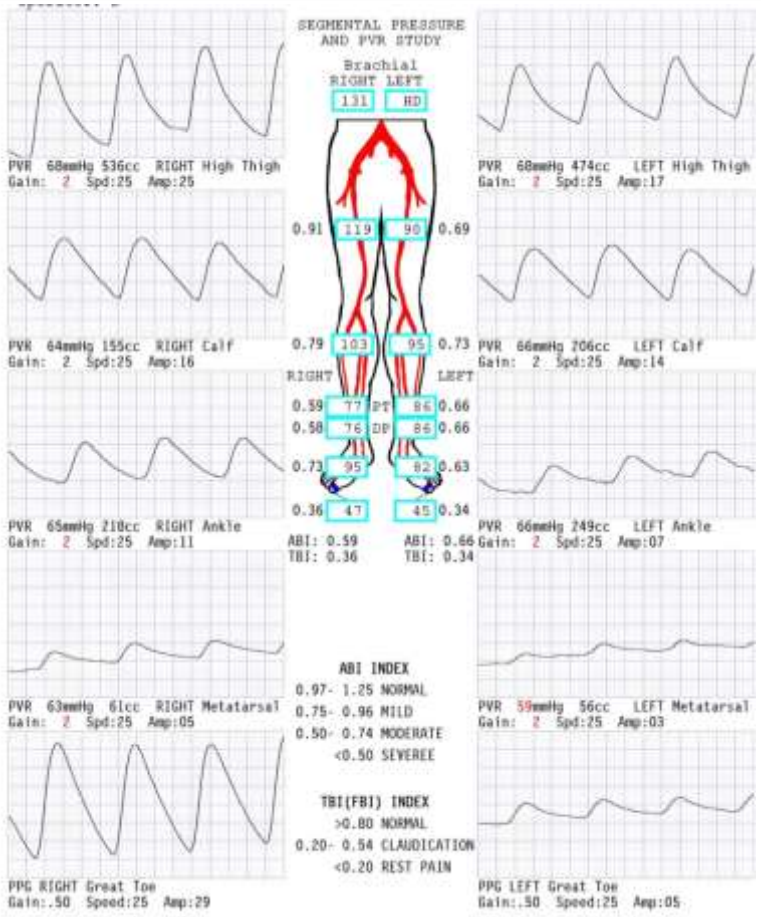


Number of subjects at risk	Baseline (day 0)	6 mo	12 mo
Lesion Length 15-25 cm	100	92	81
Lesion Length >25 cm	57	50	38

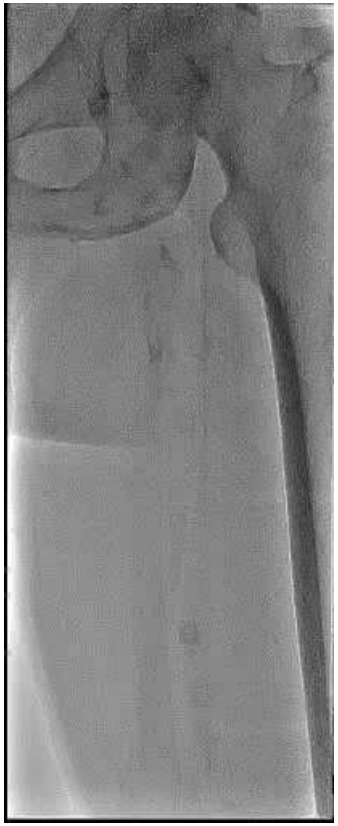
M/64, #5509713

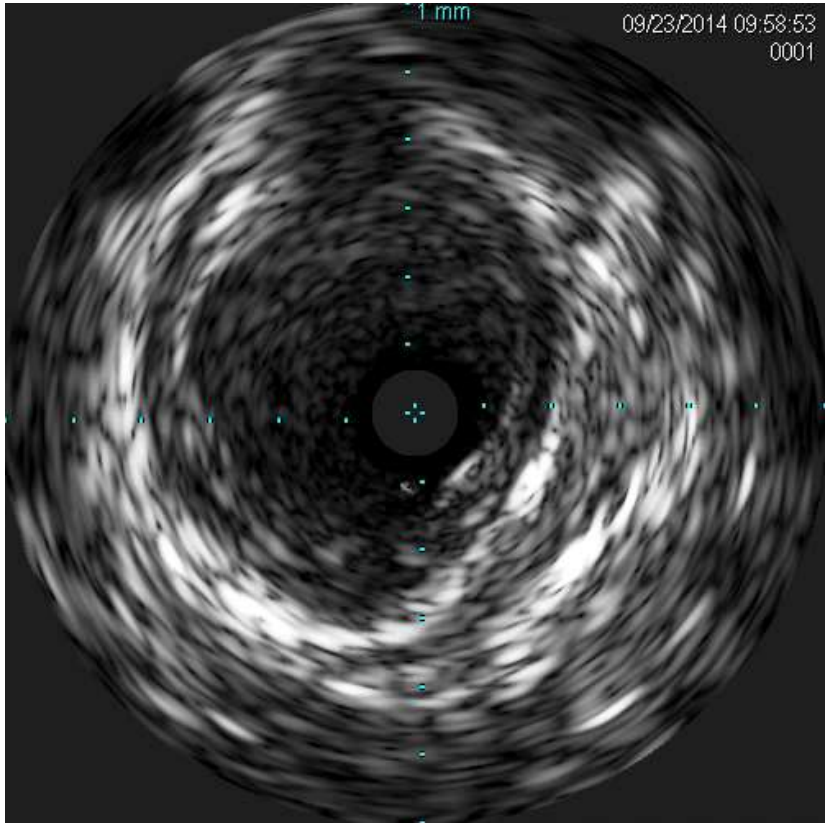
Claudication, both legs

ESRD on HD
HTN
DM

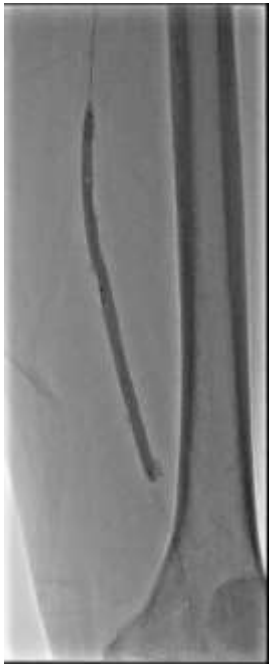


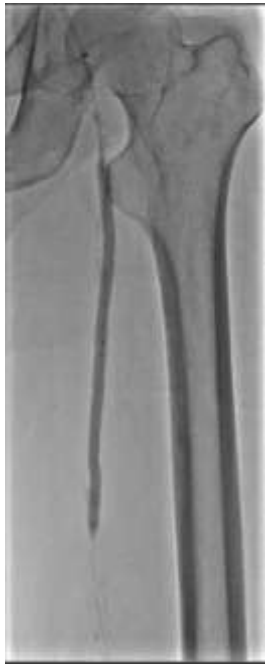
Intraluminal Balloon Angioplasty



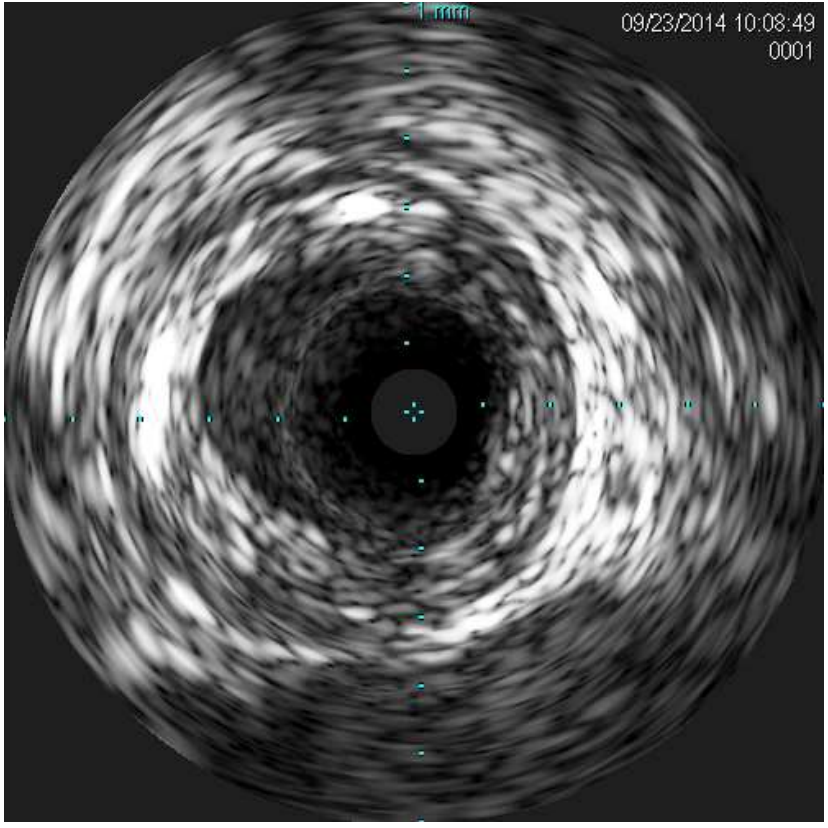


Balloon Angioplasty





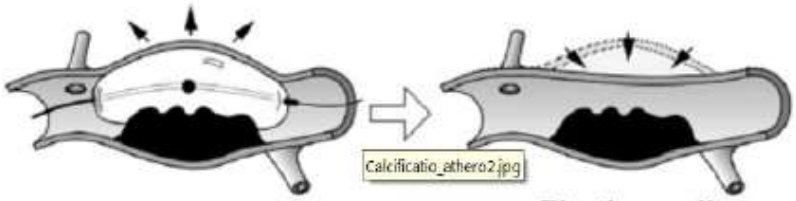
After Balloon Angioplasty



Calcium: Challenge for DCBs

Calcium Limits Vessel Expansion[1]

Significant difference in vessel compliance leads to overstretch in non-diseased tissue causing dissections, recoil, excessive injury, and poor outcomes



Fully inflated balloon

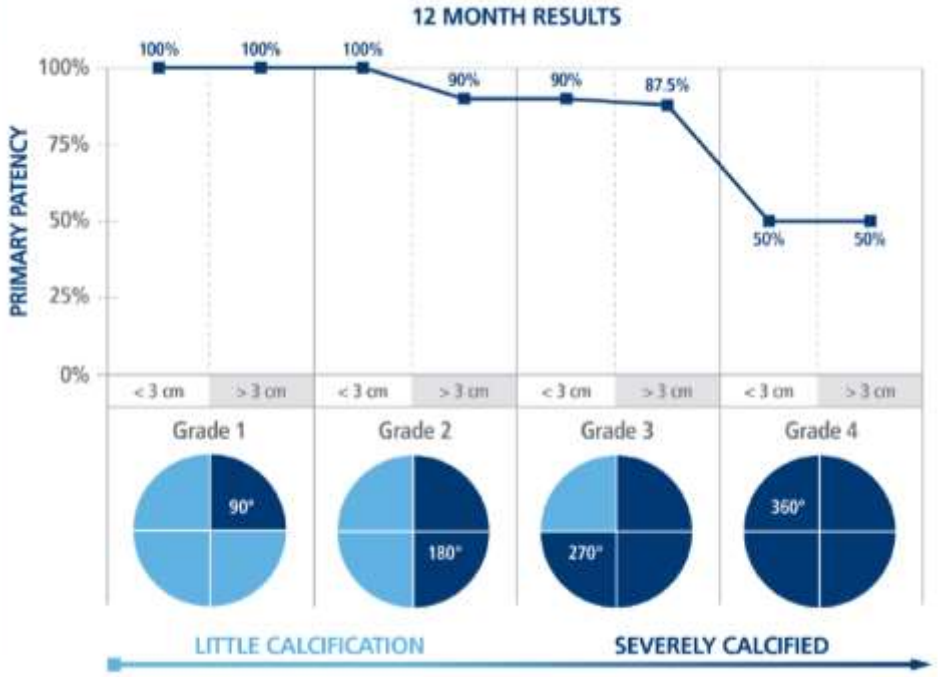
Elastic recoil

Residual, high-grade stenosis

Figure 12.1. Elastic Recoil After PTCA of Calcified Lesions

Rather than cracking the hard, calcified atheroma, PTCA causes stretching of the contralateral plaque-free wall segment and ineffective dilatation.

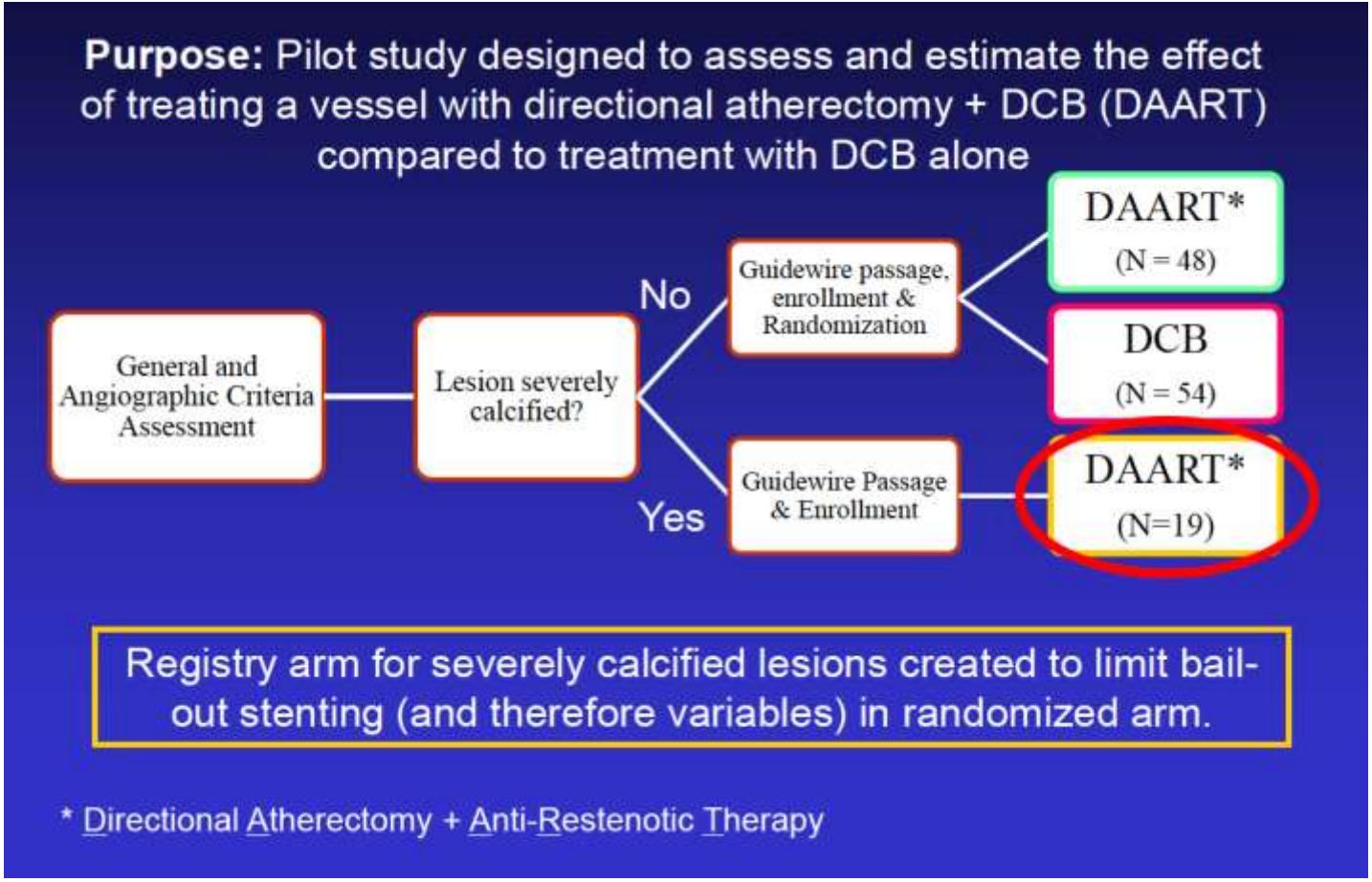
Freed MS, Safian RD; Manual of Interventional Cardiology, Ch. 12, 245-254



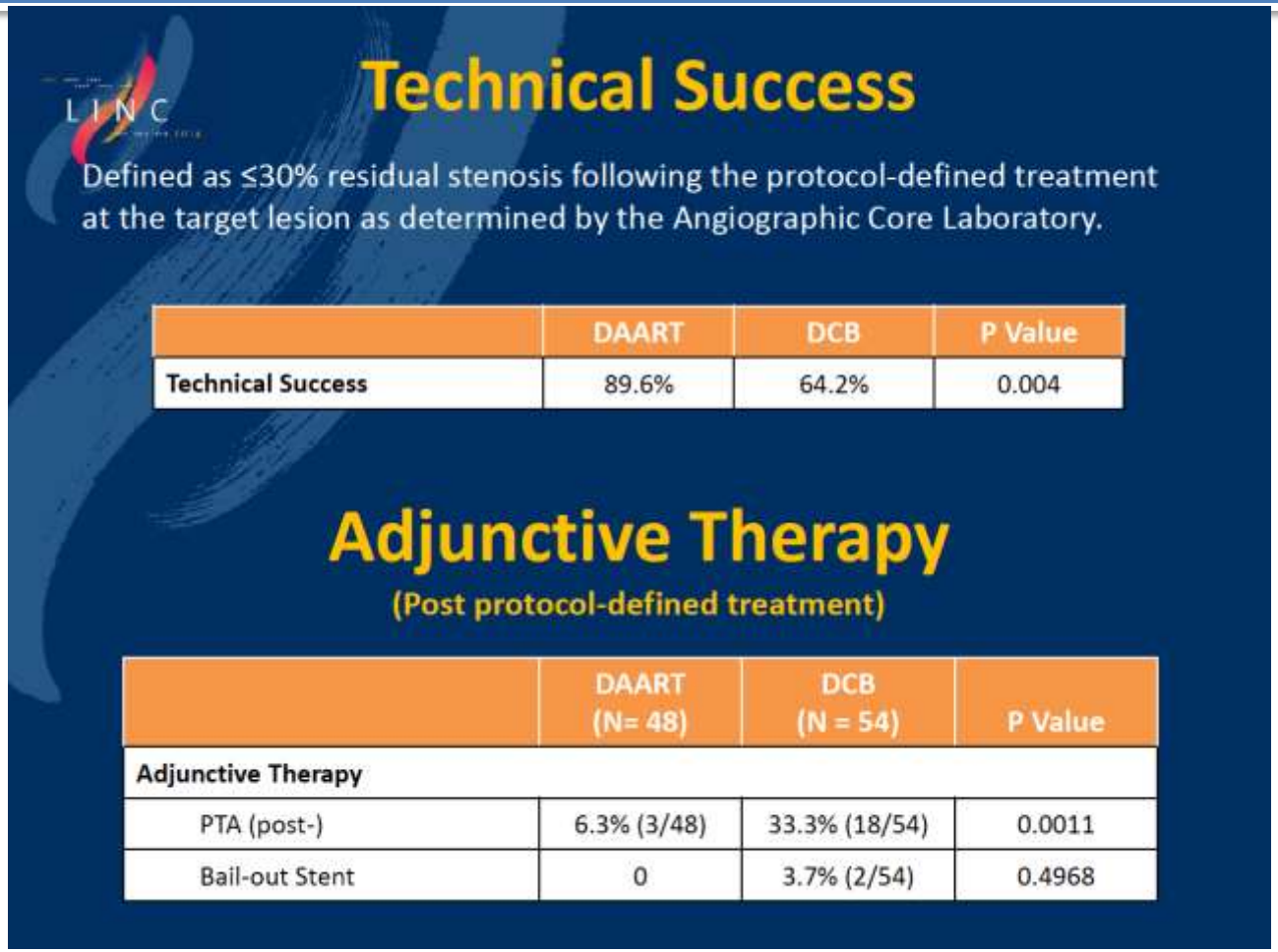
Fanelli J Endovas Ther 2012;19:571-580

Fanelli et al. Cardiovasc Intervent Radiol (2014;37:898)

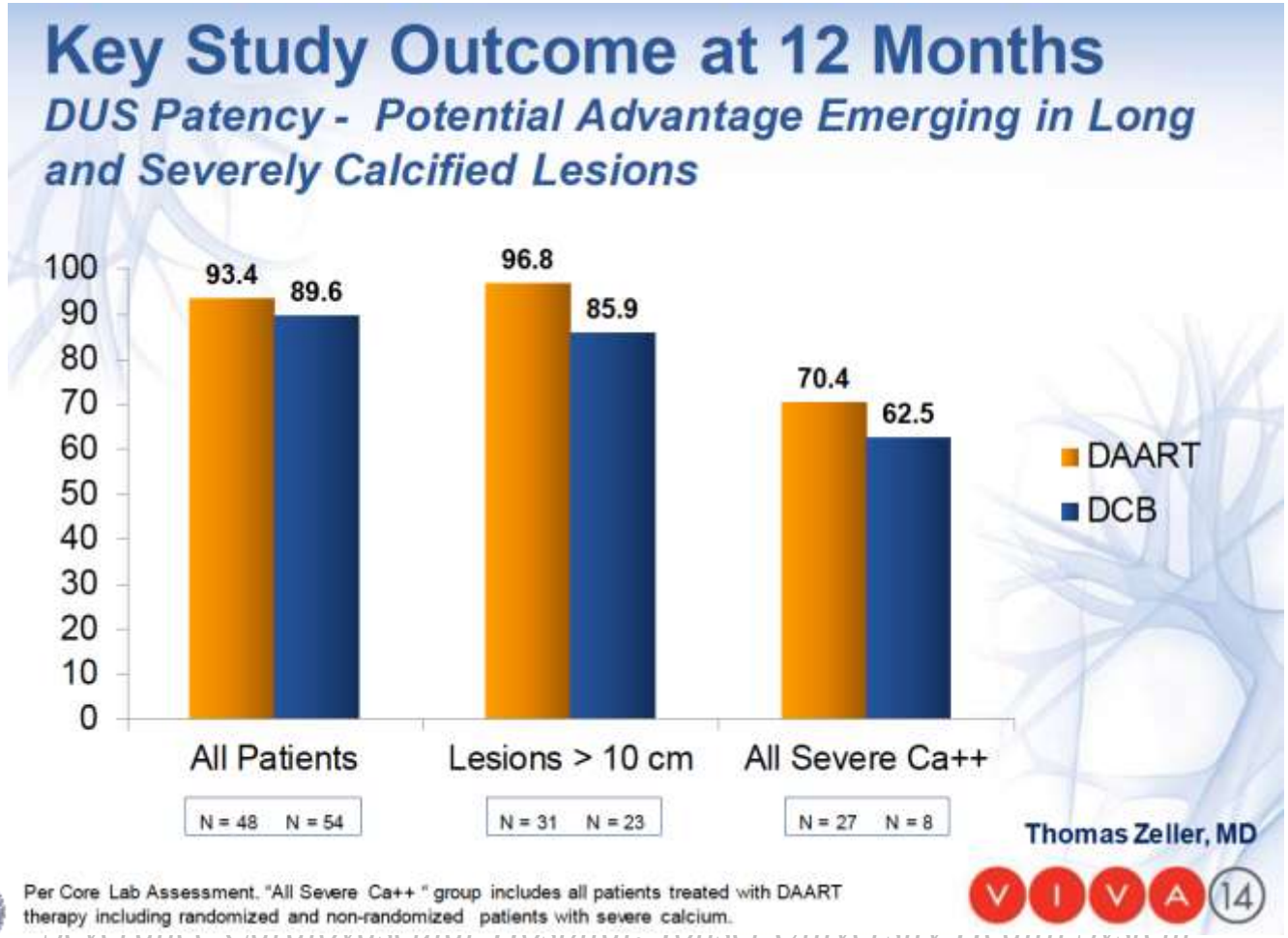
DEFINITIVE AR



Technical Success



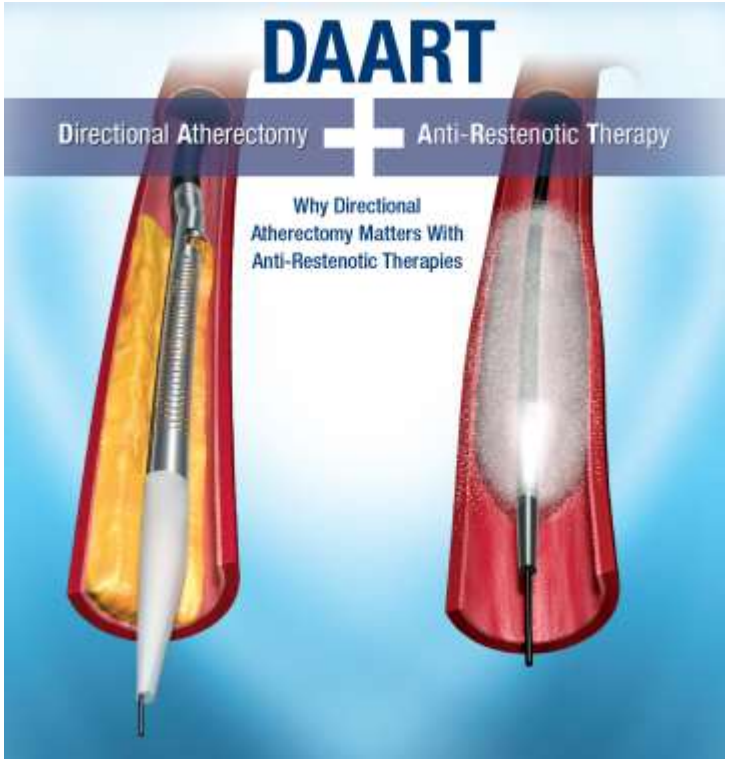
DEFINITIVE AR Study

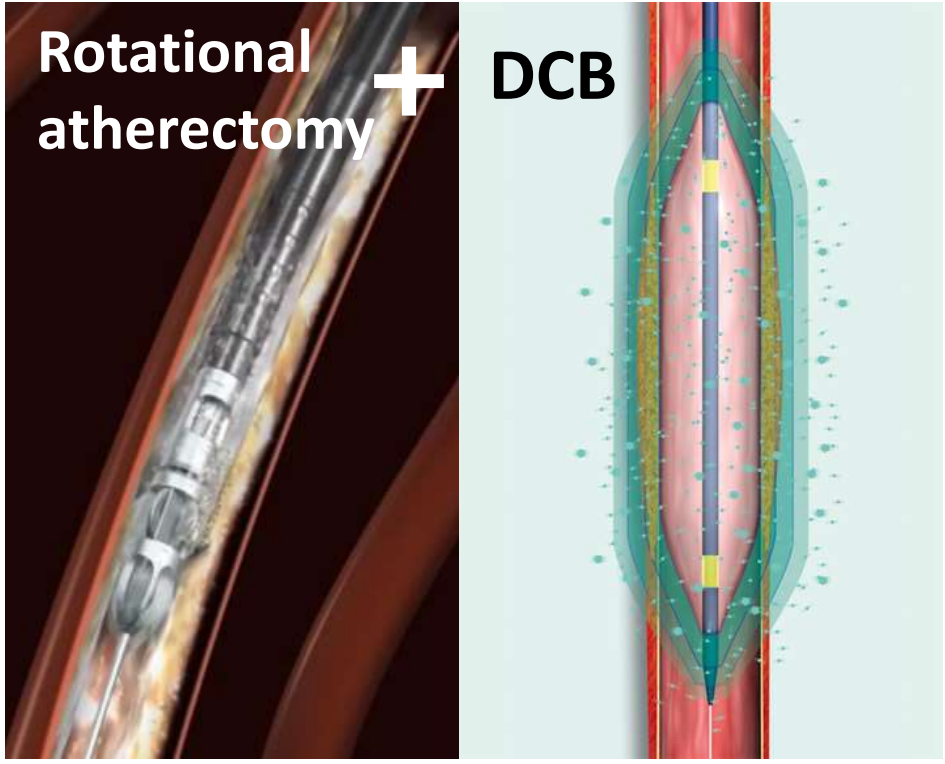


Lesion length:
10 ~11 cm

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

Atherectomy & DCB





Comparison with Other Atherectomy Devices

FEATURE		Jetstream	Orbital	Directional	Laser	BENEFIT
Labeling Indication	Atherectomy	✓	✗	✗	✗	Complex lesions and total occlusion often contain mixed morphology lesions, requiring a device capable of managing it all.
	Thrombectomy	✓				
Active Aspiration		✓				Aspiration of liberated debris may minimize the risk of distal embolization.
Front Cutting / Rotational Device		✓	✗		✗	Total occlusions are common in PAD, front cutting enables engagement of tightest lesions.
Concentric Lumens		✓	✗			Concentric lumens facilitate straight line laminar flow.
Differential Cutting		✓	✗			Differential cutting targets only the plaque, minimizing the risk of vessel damage.
Expandable Blade Technology		✓				Expandable blades deliver more versatility, facilitating treatment from SFA to TPT.
Lesion Type	Total Occlusions	✓		✗	✗	Peripheral arterial disease rarely manifests as a single lesion type. A mix of disease morphologies is common, driving the need for a single device capable of addressing them all.
	Thrombus	✓			✗	
	Calcium	✓	✗	✗		
	Soft Plaque	✓		✗	✗	
	Fibrous Plaque	✓		✗	✗	

Jetstream Components

Jetstream XC Systems:
eXpandable Cutter

XC 2.1/3.0 mm

XC 2.4/3.4 mm

- *Two sizing options in a single device (e**X**pandable **C**utter)*
- *Rotational/differential cutting tip removes all plaque types*
- *Active Aspiration ports collect plaque & thrombus*
- *135 cm and 120 cm OTW lengths*
- *.014GW / 7F sheath compatible*

XC 2.1/3.0 mm

XC 2.4/3.4 mm

- *Ergonomic design for enhanced user controls*
- *Intuitive user interface facilitates single operator use*
- *Improved wire GARD* simplifies wire management*

* Compared to previous generation

Jetstream SC Systems:
Single Cutter

SC 1.6 mm

SC 1.85 mm

- ***S**ingle **C**utter technology for tortuosity*
- *Rotational/differential cutting tip removes all plaque types*
- *Aspiration ports collect plaque & thrombus*
- *145 cm OTW*
- *.014GW / 7F sheath compatible*

SC 1.6 mm

SC 1.85 m

- *Ergonomic design for enhanced user experience*
- *Intuitive user interface facilitates single operator use*
- *Improved wire GARD* simplifies wire management*

* Compared to previous generation

Jetstream: Selection Guide

ATK

BTK

Confirm the Minimum Vessel Diameter ***Proximal to the Lesion***

Minimum Vessel Diameter Blades Down	**3.5 mm**
Minimum Vessel Diameter Blades Up	**4.5 mm**

Minimum Vessel Diameter Blades Down	**3.0 mm**
Minimum Vessel Diameter Blades Up	**4.0 mm**

Minimum Vessel Diameter Blades Down	**2.75 mm**

Minimum Vessel Diameter Blades Down	**2.5 mm**

Preparation for Jetstream

- Introducers: 7F or larger
- Wires:
  - 0.014 inch high support wires, exchange length
  - no hydrophilic coated wires
  - Jetwire
- Filter:
  - in cases of high plaque burden
  - No single unit wire & filter

Recommendations for Use

- When activating the Jetstream Catheter in a cutting mode advance only in a proximal to distal motion
- Complete two passes blades down followed by two passes blades up
- Advancement speed should be no faster than 1mm per second or using an engage – disengage technique listening to the motor RPMs
- REX back following each forward pass, providing active aspiration
- Always keep the tip of the Jetstream Catheter back 10cm from the guidewire spring tip

Tips for Minimizing Distal Embolization

- Treat the lesion with BD except distal cap or just proximal to the most severe distal segment.
- Repeat the initial treatment with BU.
- Treat the distal cap or most severe distal segment of the vessel with BD followed by BU.
- Distal cap or severe distal lesion acts like a filter.
- *Protection against distal embolization is particularly important in CTO, mixed thrombotic-fibrotic plaques, calcified disease, long disease, and TASC D lesions*

Jetstream-Ca++

Intravascular ultrasound evaluation of JETSTREAM atherectomy removal of superficial calcium in peripheral arteries

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1. Columbia University Medical Center, New York, NY, USA; 2. Cardiovascular Research Foundation, New York, NY, USA; 3. Wheaton Franciscan Healthcare, Milwaukee, WI, USA; 4. Emory University, Atlanta, GA, USA; 5. Arizona Heart Institute, Phoenix, AZ, USA; 6. Tennova Turkey Creek Medical Center, Knoxville, TN, USA; 7. St. John Hospital and Medical Center, Detroit, MI, USA

KEYWORDS

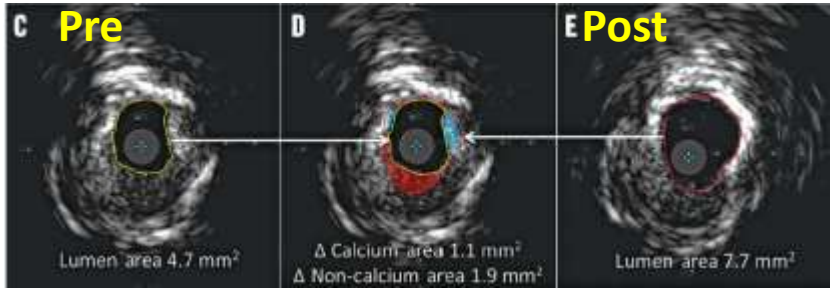
- atherectomy
- calcium
- intravascular ultrasound (IVUS)
- peripheral arteries

Abstract

Aims: Endovascular treatment of calcified femoral-popliteal disease is challenging. We sought to evaluate the mechanism of lumen gain when using the JETSTREAM Atherectomy System to treat calcified peripheral artery lesions.

Methods and results: The JETSTREAM Calcium Study was a prospective, single-arm, multicentre study to evaluate the JETSTREAM Atherectomy System for severely calcified femoral-popliteal artery lesions, i.e., patients with claudication and lesions with superficial calcium >90° and >5 mm in length as determined by intravascular ultrasound (IVUS). The 2.1 mm catheter was used in this study without distal protection. Fifty-five patients underwent angiographic screening; 26 (45%) met IVUS inclusion criteria. Angiographic calcium was moderate in eight cases and severe in 14, with no available data for four cases. Visual diameter stenosis was 86±9% pre-treatment, 37±13% post atherectomy, and 10±6% post adjunctive treatment (adjunctive PTA+stenting in eight and adjunct PTA alone in 16). IVUS showed lumen area increased from 6.6±3.7 mm² to 10.0±3.6 mm² (p=0.001); calcium reduction was responsible for 86±23% of the lumen increase. Although the superficial calcium arc did not change (151±70° to 146±71°, p=0.83), the arc of reverberation increased (23±20° to 65±40°, p=0.006), indicating device-related modification of calcium. Adjunctive balloon angioplasty was performed in 62% of the lesions, and stent implantation in 31%. In 11 cases with adjunctive balloon dilation, the MLA increased from 7.1 (6.4, 7.8) mm² post atherectomy to 11.9 (10.3, 13.5) mm² post balloon (p<0.001) without flow-limiting dissection. No major adverse events occurred up to 30 days post procedure in either the study group or the patients who were excluded from the analysis.

Conclusions: The JETSTREAM Atherectomy System increased lumen dimensions in moderately or severely calcified femoral-popliteal lesions by removing superficial calcium without major complications.



	Pre-treatment	Post-atherectomy	*p*-value
Lumen area (mm²)	6.4 [5.5, 7.4]	9.6 [8.6, 10.6]	<0.0001
Minimum lumen diameter (mm)	2.2 [2.1, 2.4]	3.0 [2.8, 3.1]	<0.0001
Lumen symmetry index	0.68 [0.64, 0.72]	0.75 [0.71, 0.79]	<0.0001
Maximum superficial calcium (°)	146 [122, 169]	137 [110, 164]	0.12
Decrease of calcium area (mm²)	NA	2.2 [1.8, 2.7]	NA
Calcium reduction (%)	NA	77 [69, 86]	NA
Surface shape of calcium			
Convex	66% (46)	26% (18)	0.0005
Concave	34% (24)	74% (52)	
Irregularity of superficial calcium			
Irregular	54% (38)	31% (22)	0.02
Smooth	46% (32)	69% (48)	
Reverberation	34% (24)	43% (30)	0.14
Maximum arc of reverberation (°)	25 [15, 35]	70 [46, 95]	0.001

Values are least square means with 95% confidence interval or % (n).

EuroIntervention 2015;11:96-103

Jetstream-ISR

J Endovasc Ther. 2016 Apr;23(2):339-46. doi: 10.1177/1526602816634028. Epub 2016 Feb 26.

JetStream Rotational and Aspiration Atherectomy in Treating In-Stent Restenosis of the Femoropopliteal Arteries: Results of the JETSTREAM-ISR Feasibility Study.

Shammas NW[1], Shammas GA[2], Banerjee S[3], Popma JJ[4], Mohammad A[3], Jerin M[5].

⊕ Author information

Abstract

PURPOSE: To evaluate the outcomes and stent-device interaction of the JetStream atherectomy device in the treatment of in-stent restenosis (ISR) of the femoropopliteal segment.

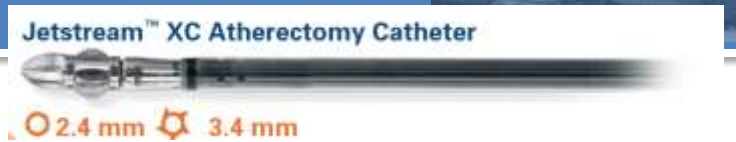
METHODS: The JetStream XC atherectomy device, a rotational cutter with aspiration capacity, was evaluated in a prospective cohort of 29 patients (mean age 69.9 ± 11.7 years; 11 men) with femoropopliteal ISR in 32 limbs (ClinicalTrials.gov identifier NCT01722877). Lesion length was 17.4 ± 13.1 cm. The primary effectiveness outcome was acute success (≤ 30% residual narrowing with no serious adverse events). The primary safety endpoint was major adverse events. Secondary endpoints included clinically driven target lesion revascularization (TLR) at 6 months and 1 year and loss of stent integrity as assessed by an angiographic core laboratory.

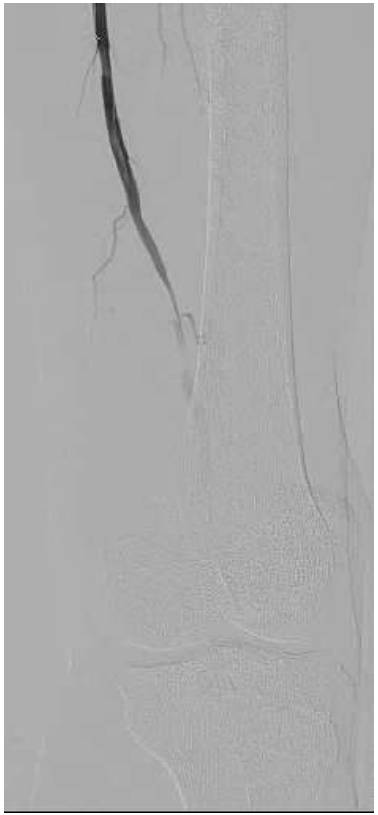
RESULTS: Treated length was 19.5 ± 12.9 cm. Acute success was obtained in 29/32 (91%) limbs. Acute device success (<50% residual narrowing after atherectomy alone) was 76% (22/29). Adjunctive balloon angioplasty was performed in all cases at a mean pressure of 11.6 ± 3.3 atm. Embolic filter protection was used in 16 (50%) of 32 limbs. Macrodebris was noted in 2 (12%) of 16 filters. Distal embolization requiring treatment occurred in 3/32 (9.4%) limbs (2 with no filter). Other non-procedure-related adverse events were 1 (3%) death (nonvascular) and 1 (3%) case of major bleeding. There were no new stent fractures or deformities (n=24) postatherectomy. Follow-up was completed on 27 patients (29 limbs) at 6 and 12 months. TLR at these time points occurred in 4/29 (14%) and 12/29 (41%) patients. Patency (duplex-derived peak systolic velocity ratio <2.4) was 72% at 6 months.

CONCLUSION: JetStream atherectomy using the XC device has favorable acute results in treating femoropopliteal ISR with high procedure success, no device-stent interaction, and favorably low TLR rates. A multicenter trial is needed to confirm these results.

Acute device (alone) success 76%
Filter use in 50%
Distal embolization 9%

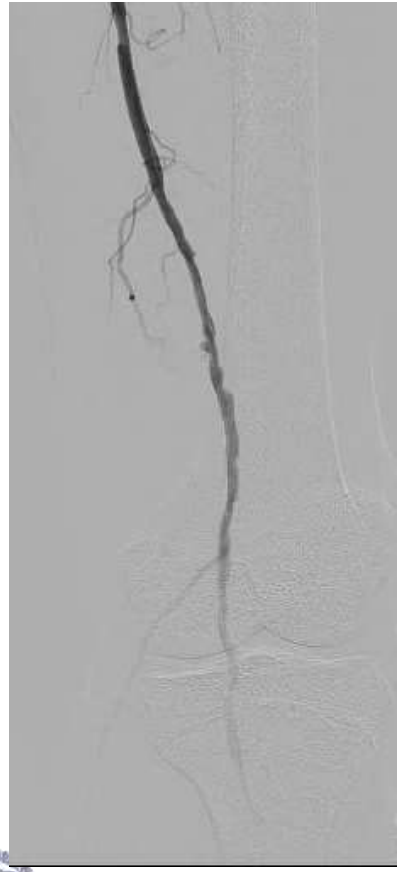
M/61, (Rutherford 3) LHK, 3460319





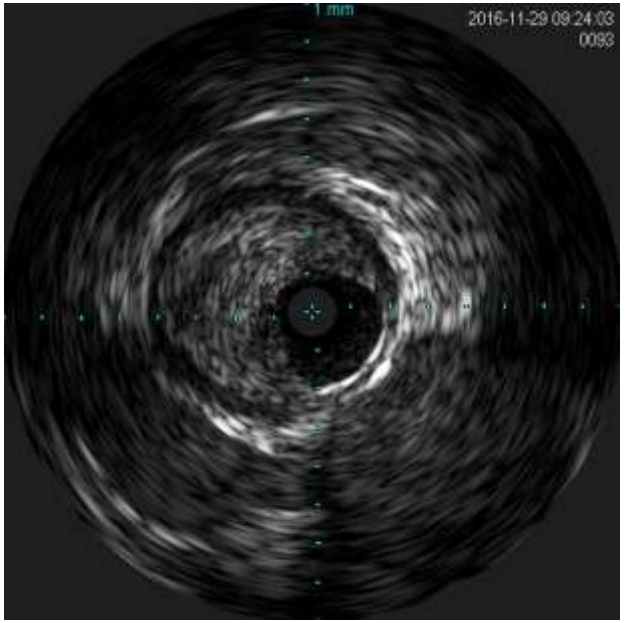
M/61, LHK, 3460319

IN.PACT 5 x 150, 6 x 60 mm

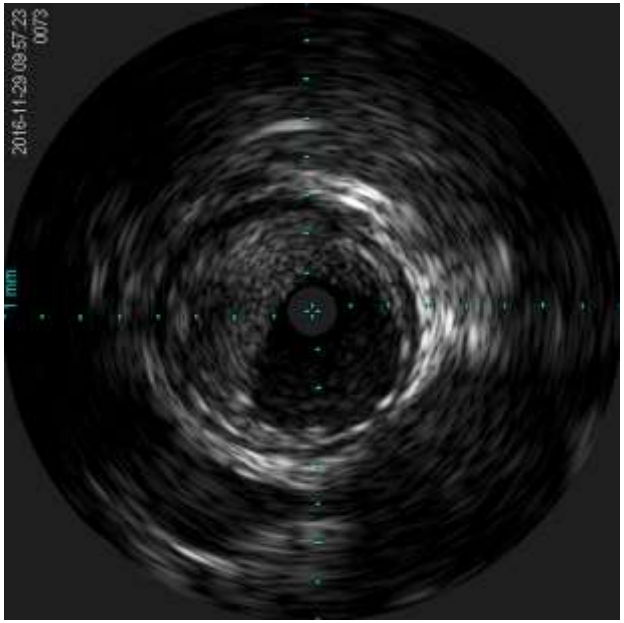



IVUS

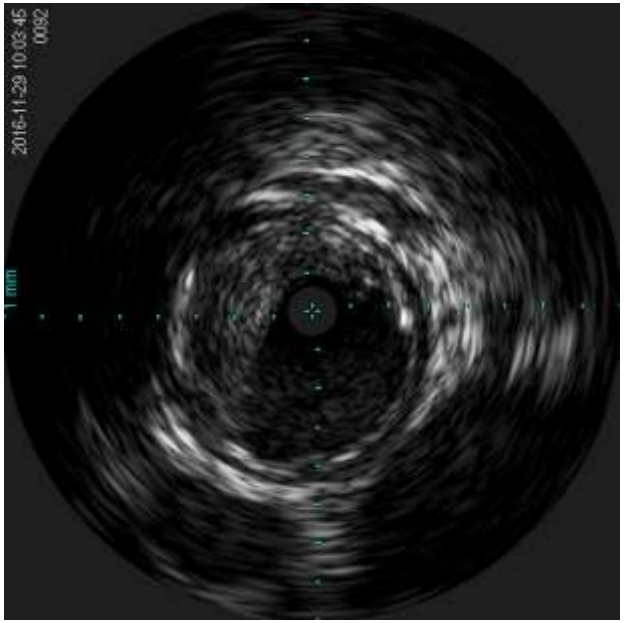
Before athrectomy



After athrectomy

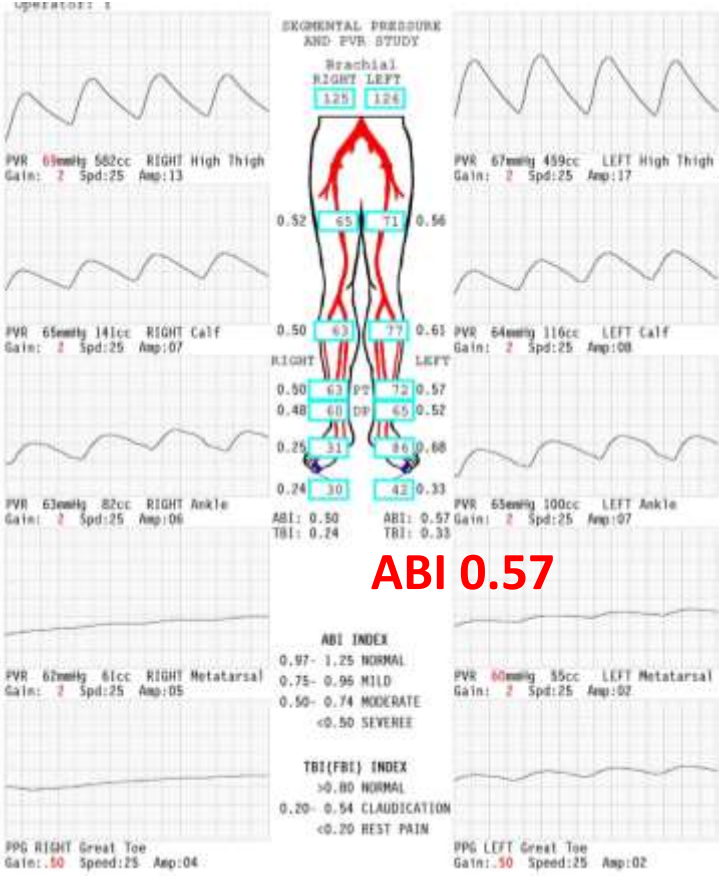


After DEB

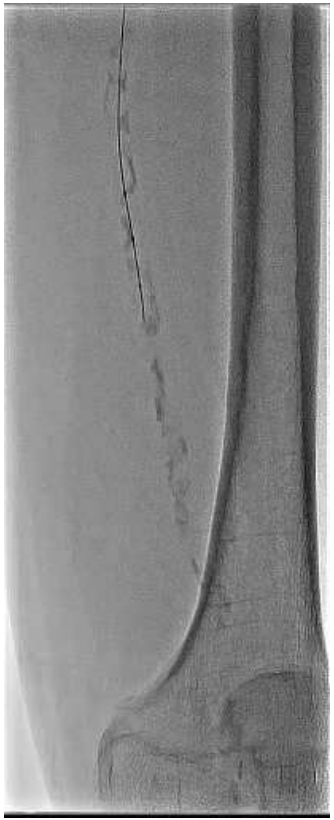


M/79, CTD #2549162

- CC: severe claudication
  in both legs (100 M)
  Rutherford 3
- PHx:
  - HTN
  - DM
  - CAD (3VD)
  - CKD (Cr 1.36, eGFR 51 ml/min)
  - S/P nephrectomy, due to RCC
  - S/P Prostate cancer



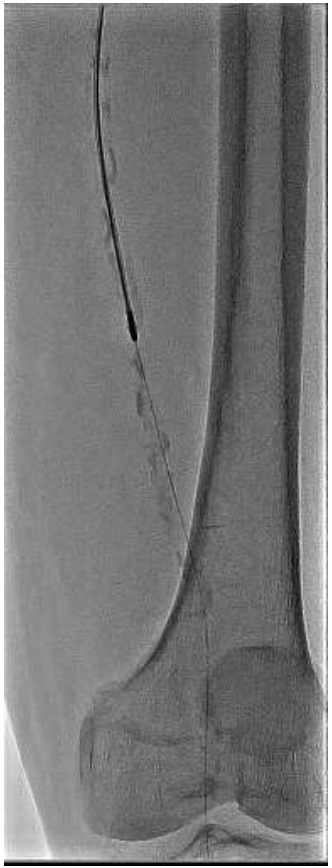
Guidewire Crossing

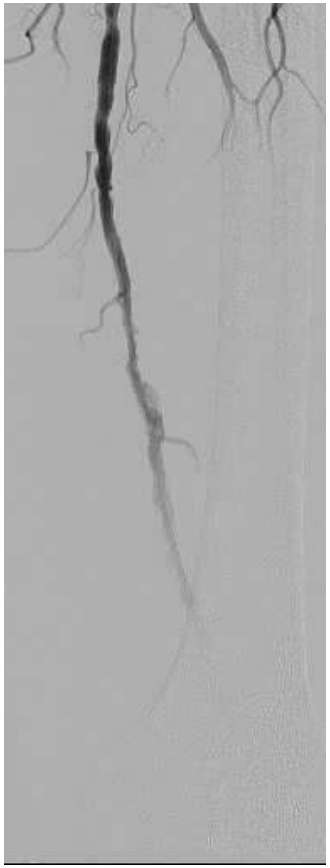



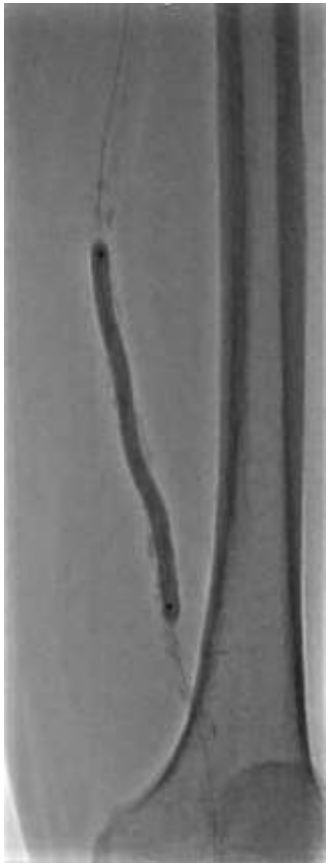

Atherectomy & DCB

Jetstream XC 2.4/3.4

InPACT DCB 6 x 120 & 5 x 150

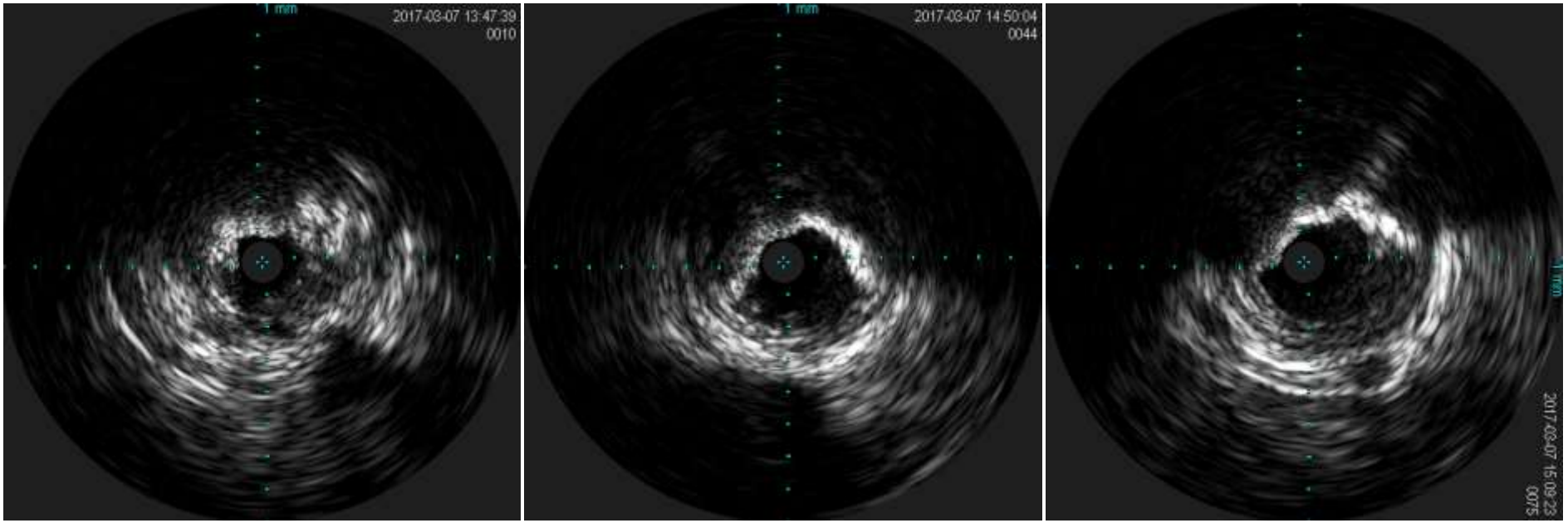




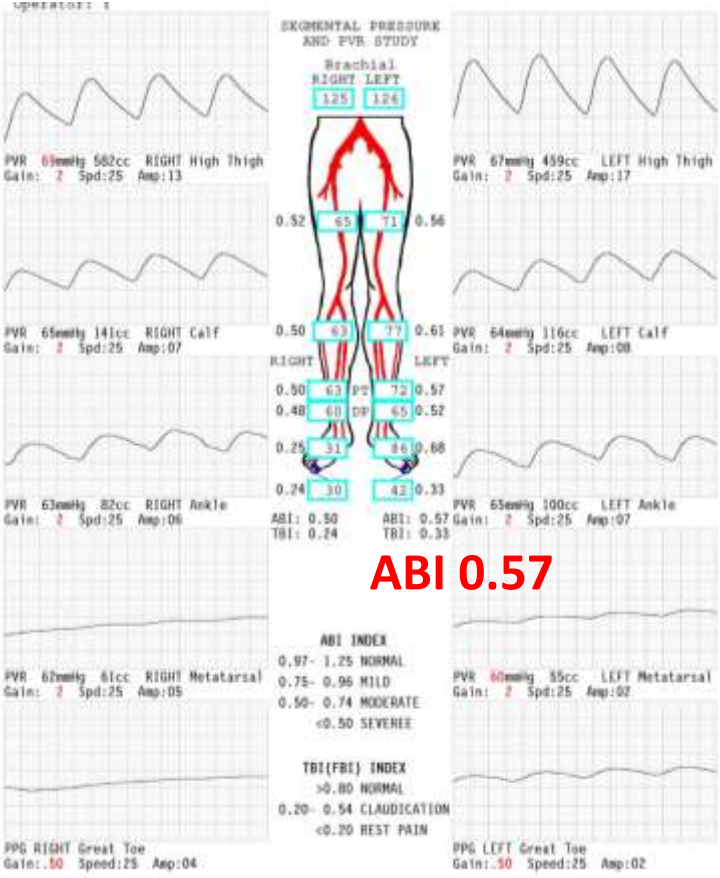


IVUS

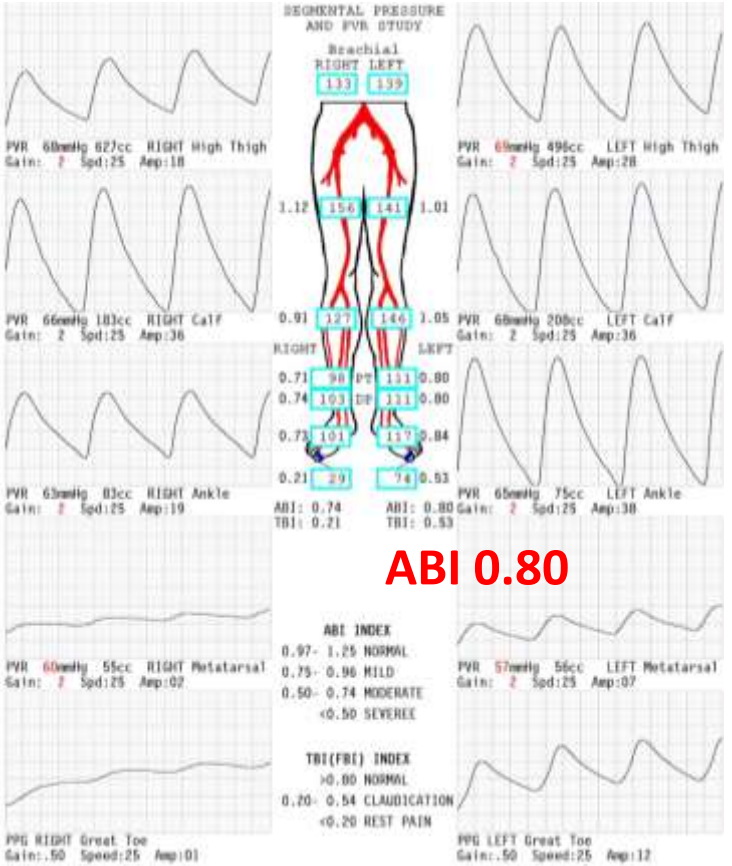
Before athrectomy **After athrectomy** **After DCB**



Post ABI



ABI 0.57



ABI 0.80

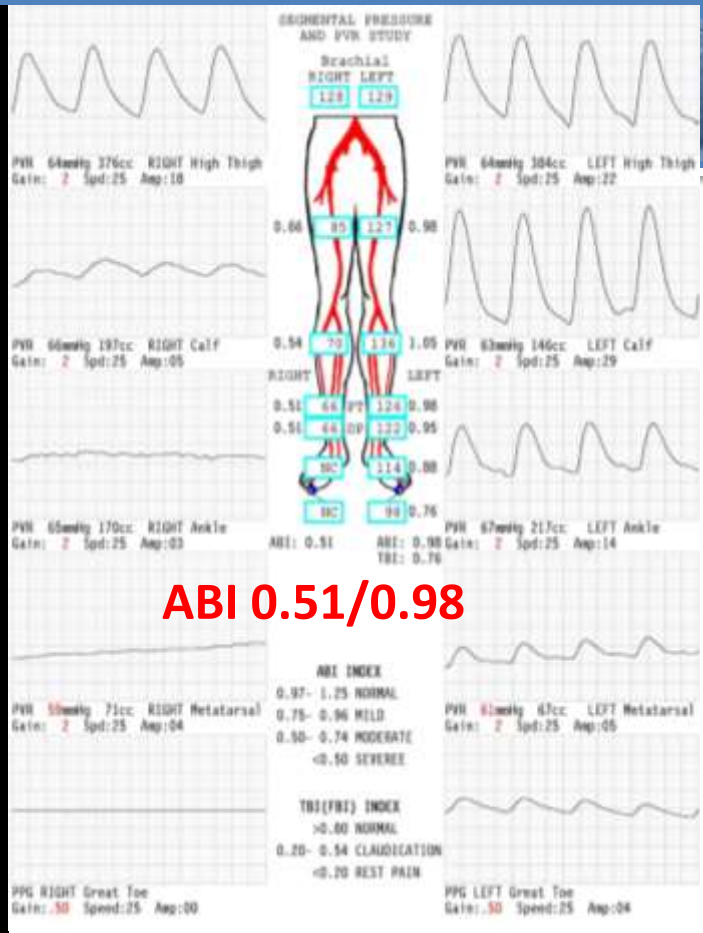
M/69, (AJS, #9749779)

- CC: Claudication (Rutherford 3)

- PHx:
  - HTN
  - Fem-to-fem bypass (2004) d/t Rt iliac a. occlusion

- Ex-smoker

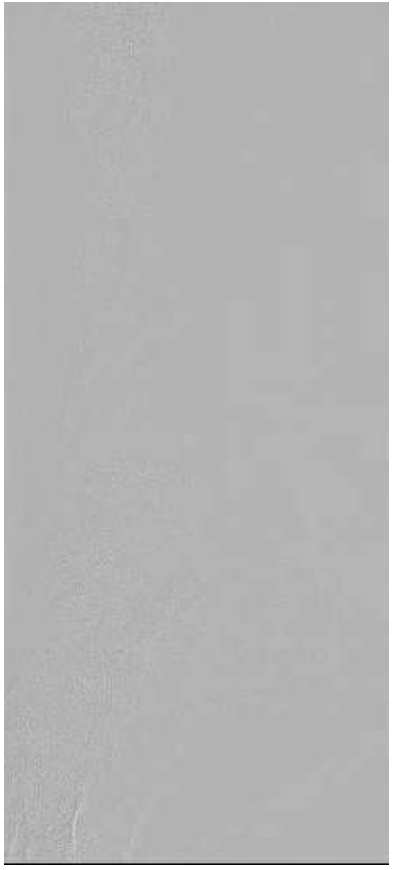
- Echo: EF=68%
- Cr 0.84 mg/dL



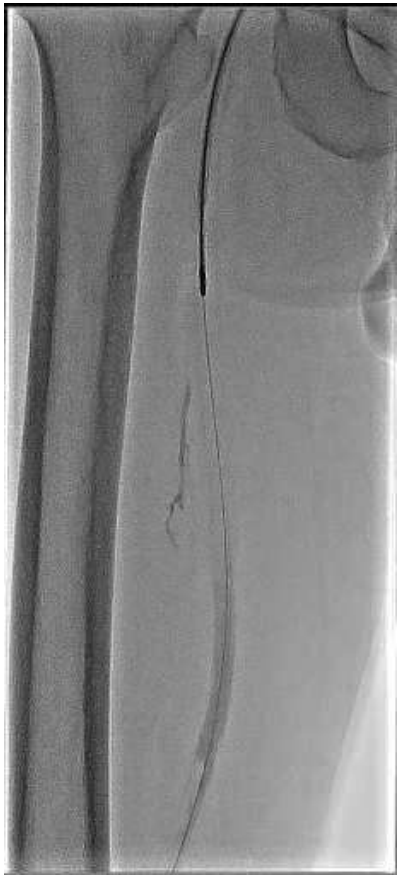
ABI 0.51/0.98

Bidirectional Approach

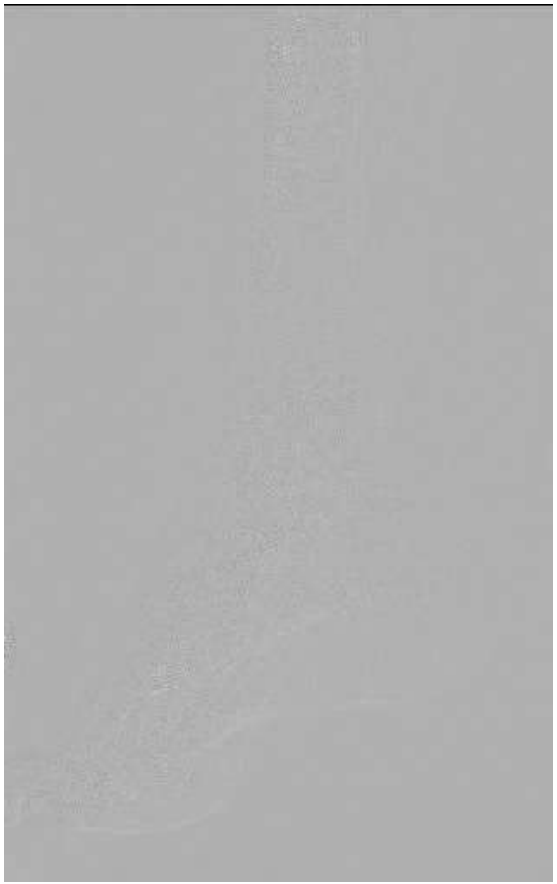




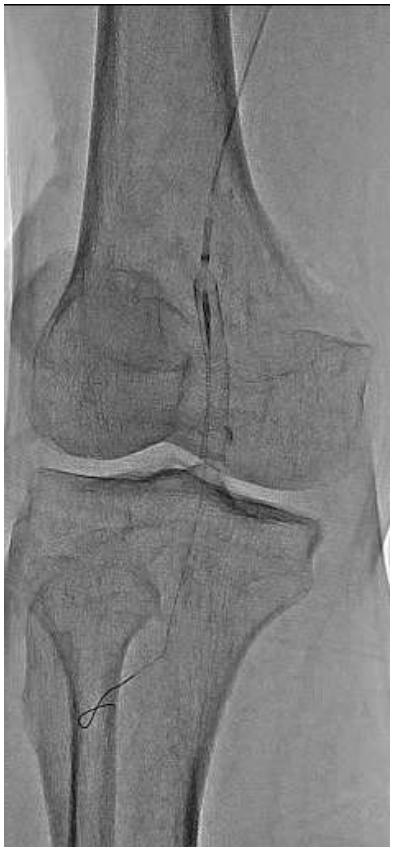

Jetstream

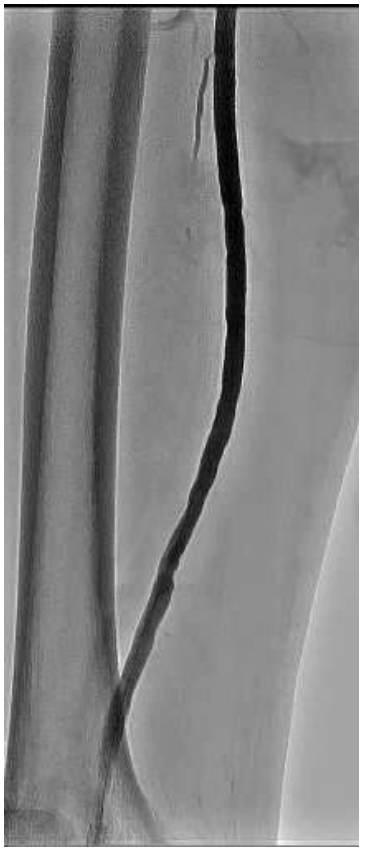


Balloon Dilation in Tibial Arteries

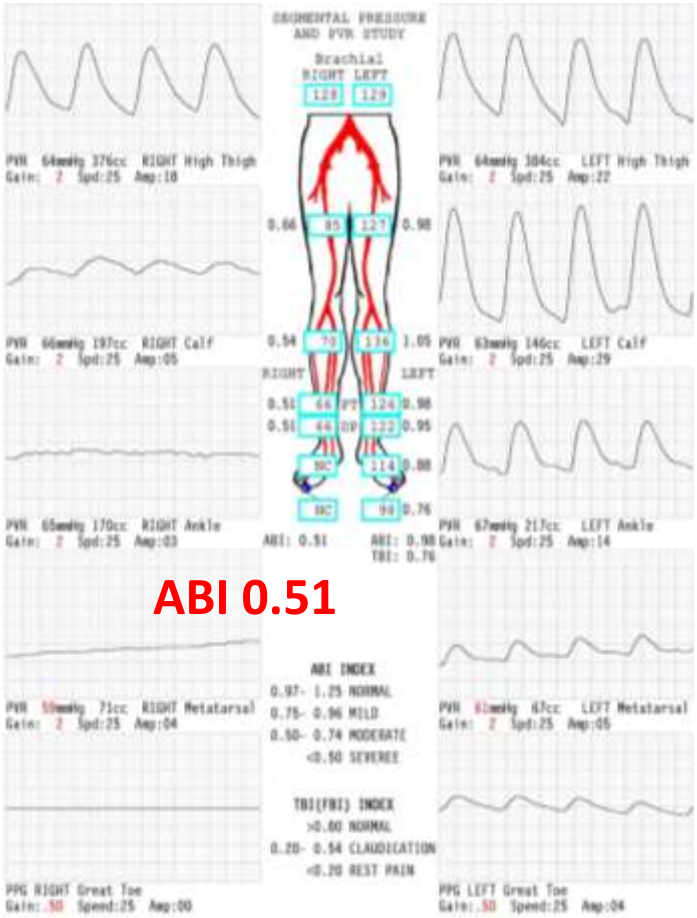


Supera Stent

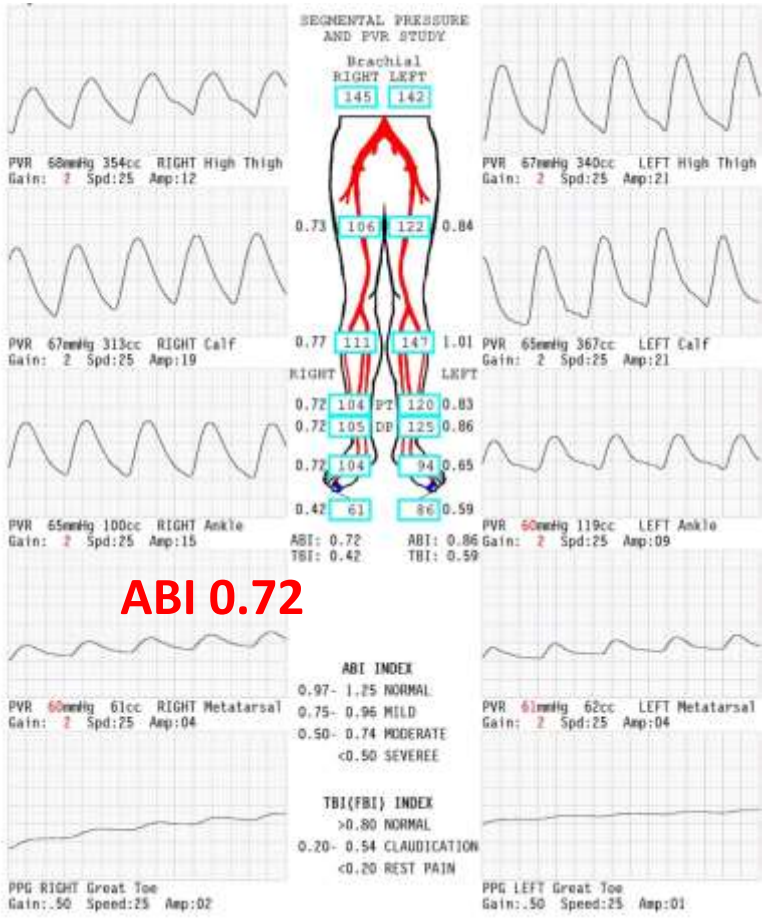





Post ABI



ABI 0.51



ABI 0.72

Take Home Messages

- In complex lesions such as long lesions, calcified lesions, and ISR lesions, DCB alone has limitations to achieve optimal results.
- Jetstream is a rotational atherectomy device with capability to remove calcium and thrombus. It’s effective and relatively easy to use.
- Combining Jetstream with DCB may lower risk of dissections and improve immediate and late outcomes. This needs to be proved in future clinical trials.

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Sep 20 - 22, 2017

Thank you for your attention!

See you in Seoul!