Scientific Evidence for the Treatment of Anatomically Challenging Lesions

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IN.PACT SFA Trial
Overview

IN.PACT SFA I
150 subjects enrolled at 13 EU sites
Sep 2010 - Apr 2011

+

IN.PACT SFA II
181 subjects enrolled at 44 US sites
Apr 2012 - Jan 2013

Robust Level 1 Evidence

- **Prospective**, two-phase, multicenter (EU and US), **Randomized** (2:1), **single-blinded** (subjects, sponsor trial management)

Rigorous and Unbiased

- **Independent and blinded** Duplex Ultrasound Core Lab[1], Angiographic Core Lab[2], and Clinical Events Committee[3]
- **Independent** Data Safety Monitoring Board[3]
- External monitoring with **100% source data verification**

Durability of Outcomes

- Subjects followed **up to 5 years**

1-Year Results
Tepe G, et al.
Circ 2015;131:495-502.

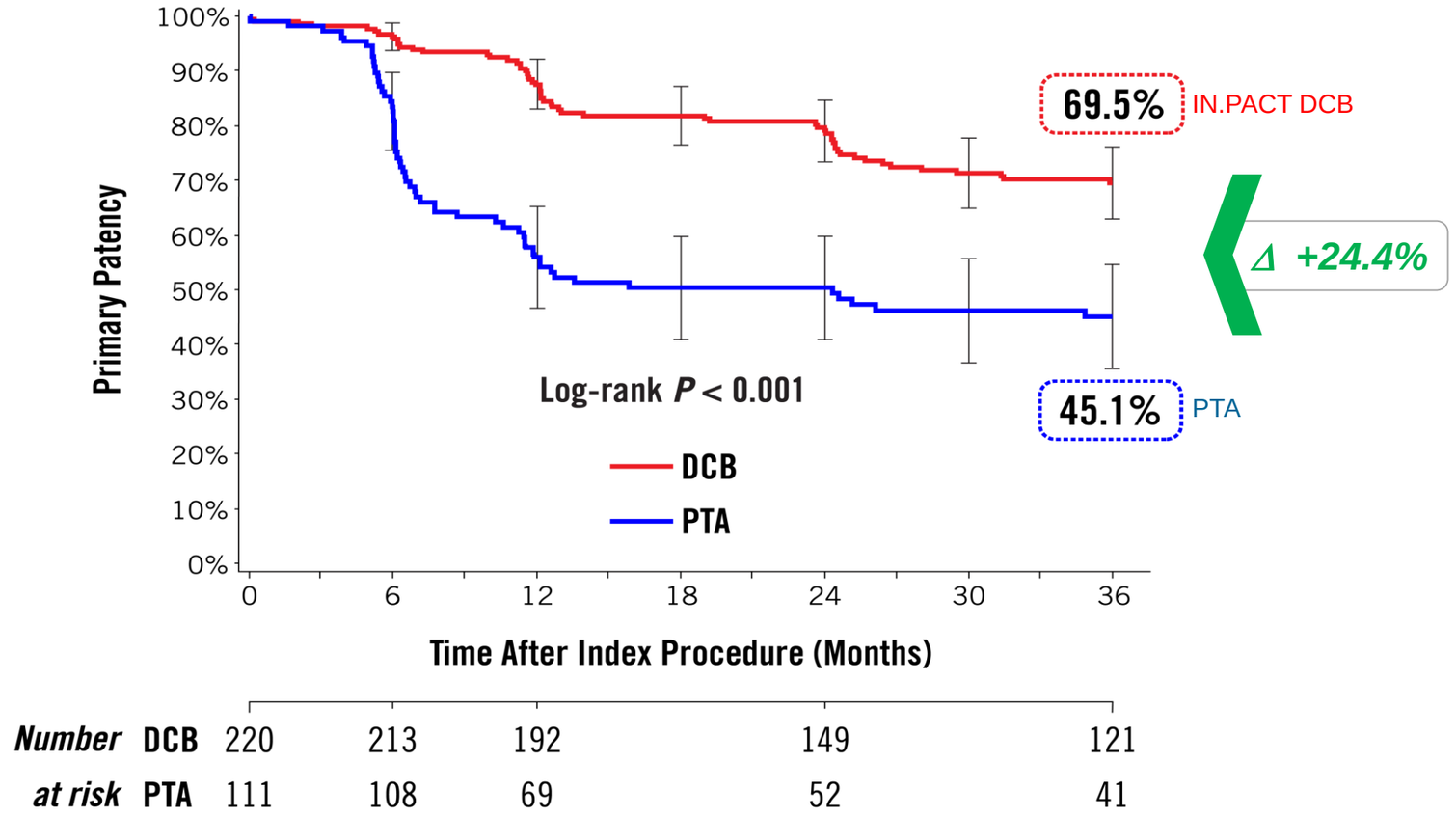
2-Year Results
Laird J, et al.
J Am Coll Cardiol
2015;66:2329-38.

3-Year Results
Schneider P, et al.
Circ Cardiovasc Interv
2018;11:e005891.

5-Year Results
Laird J, et al. Circ CI
2019;12(6):e007702

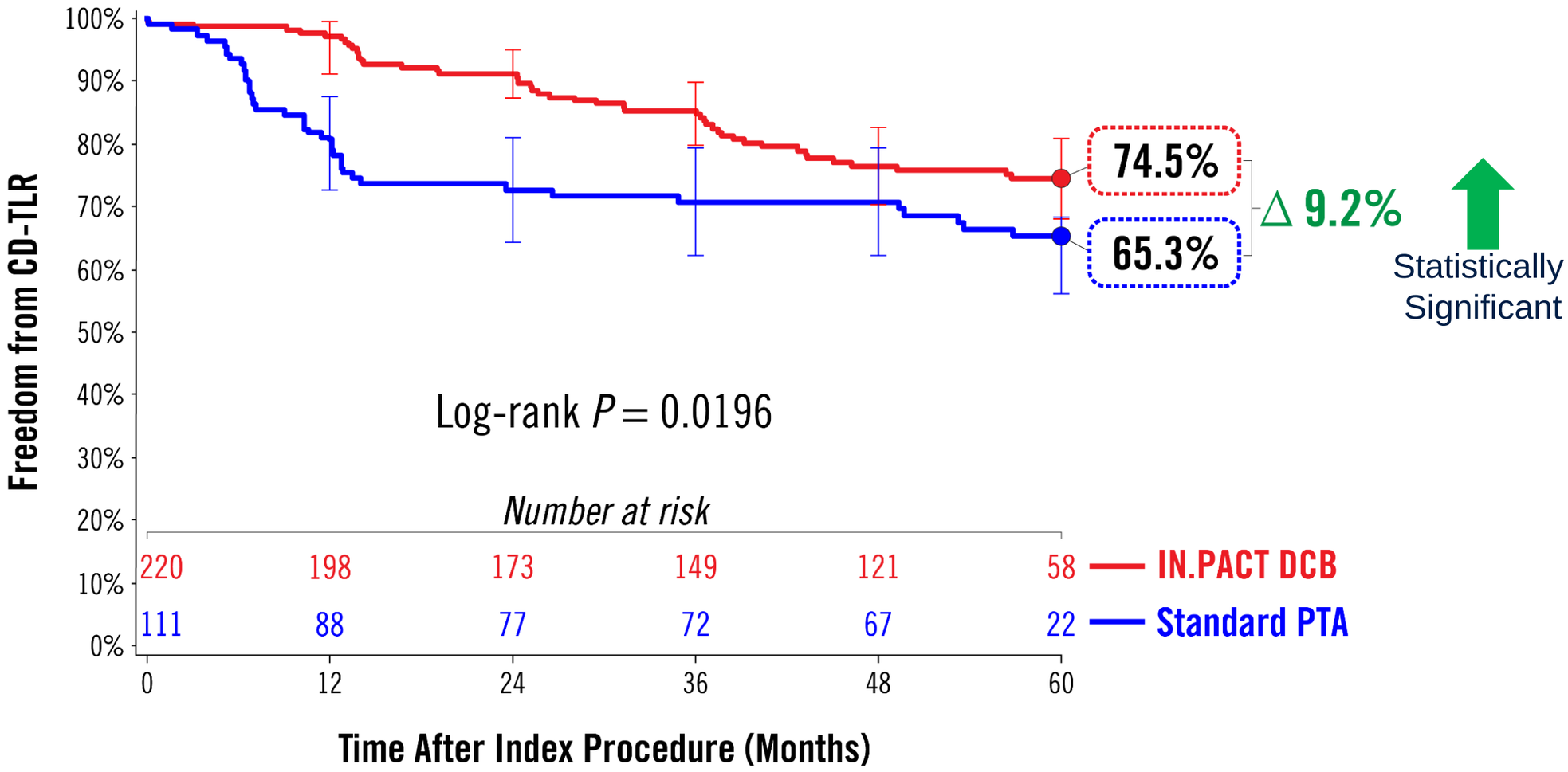
1. VasCore DUS Core Laboratory, Boston, MA, US.
2. SynvaCor Angiographic Core Laboratory, Springfield, IL, US.
3. Clinical Events Committee and Data Safety Monitoring services provided by HCRI, Boston, MA, US.

IN.PACT SFA Trial
Primary Patency Through 3 Years



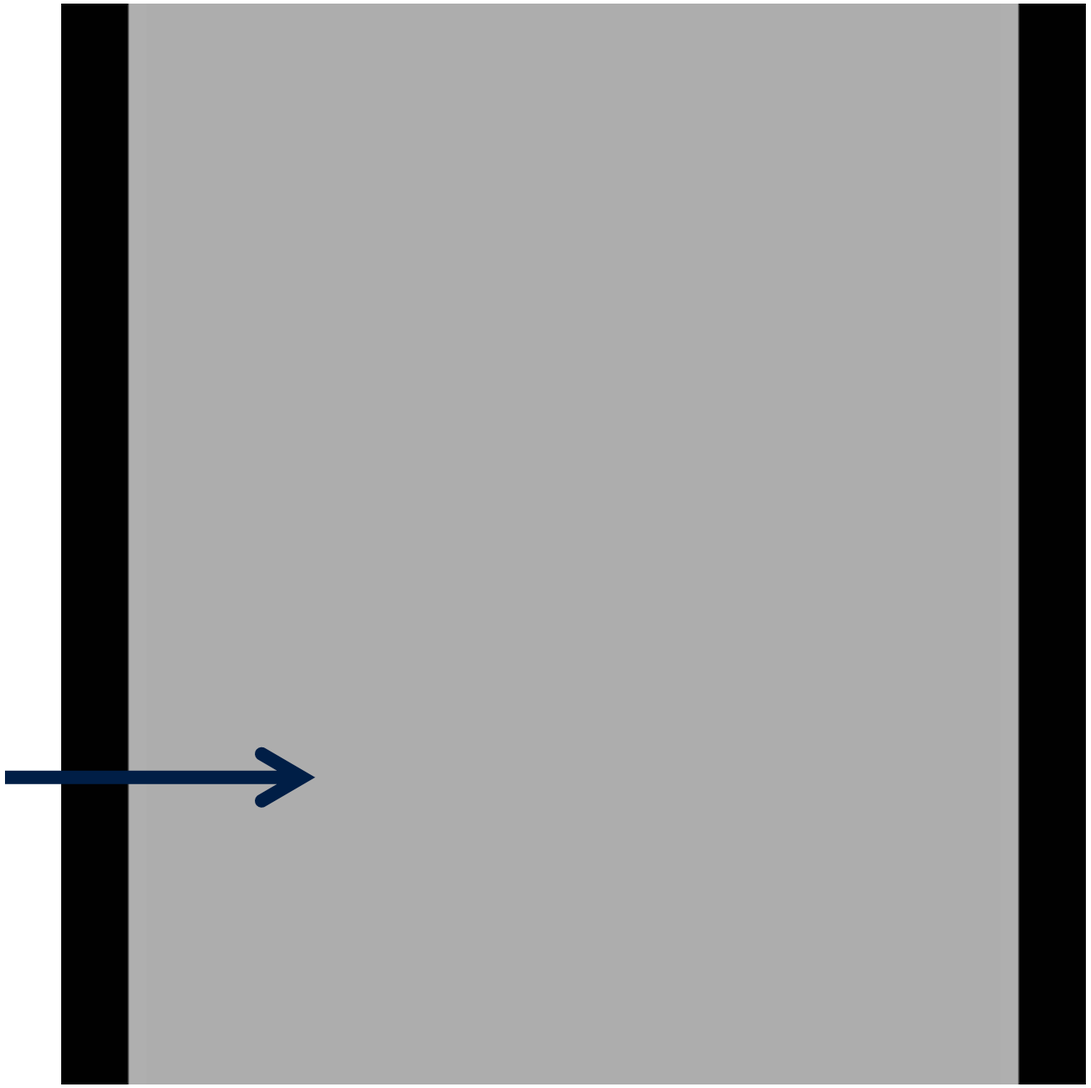
1. Freedom from core laboratory-assessed restenosis (duplex ultrasound PSVR ≤2.4) and clinically-driven target lesion revascularization through 36 months (adjudicated by a Clinical Events Committee blinded to the assigned treatment)
2. Number at risk represents the number of evaluable subjects at the beginning of the each 30-day window

IN.PACT SFA Trial
Freedom from CD-TLR Through 5 Years



Laird et al. *CIRC CI*. 2019;12:e007702

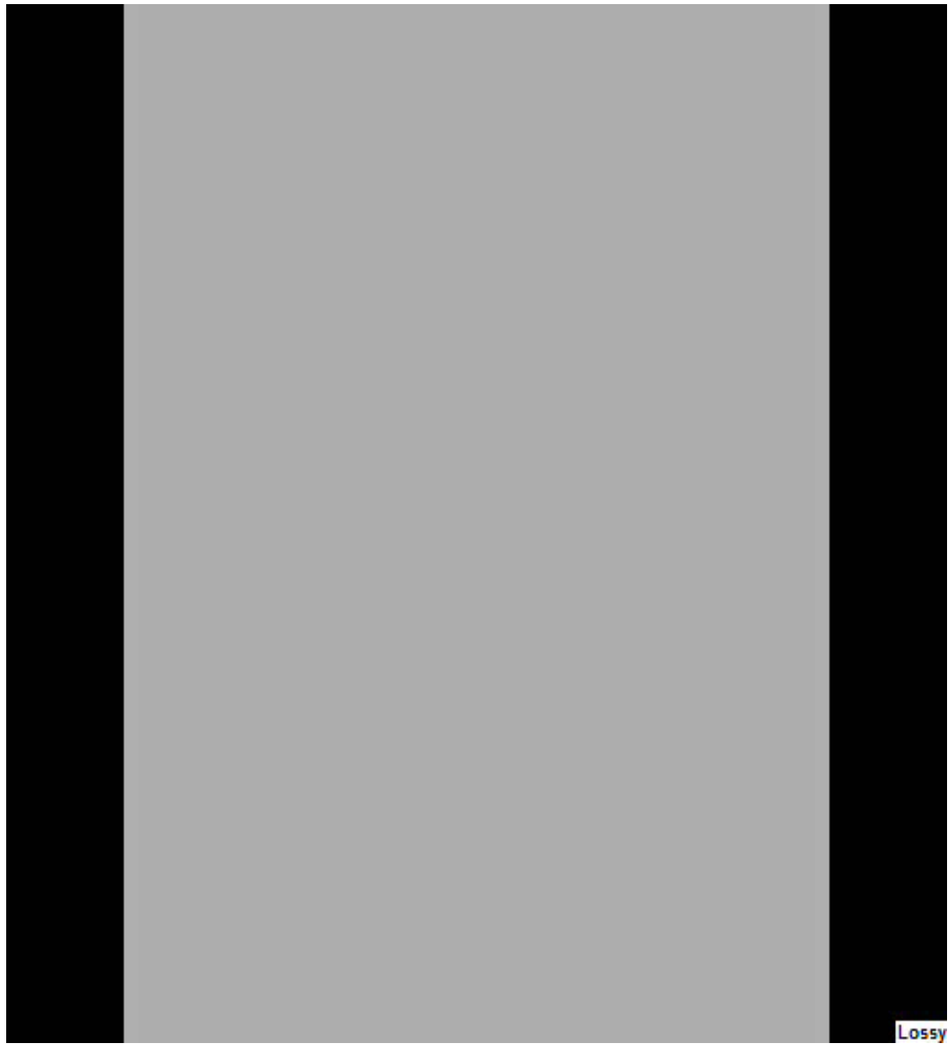
Baseline Angiogram

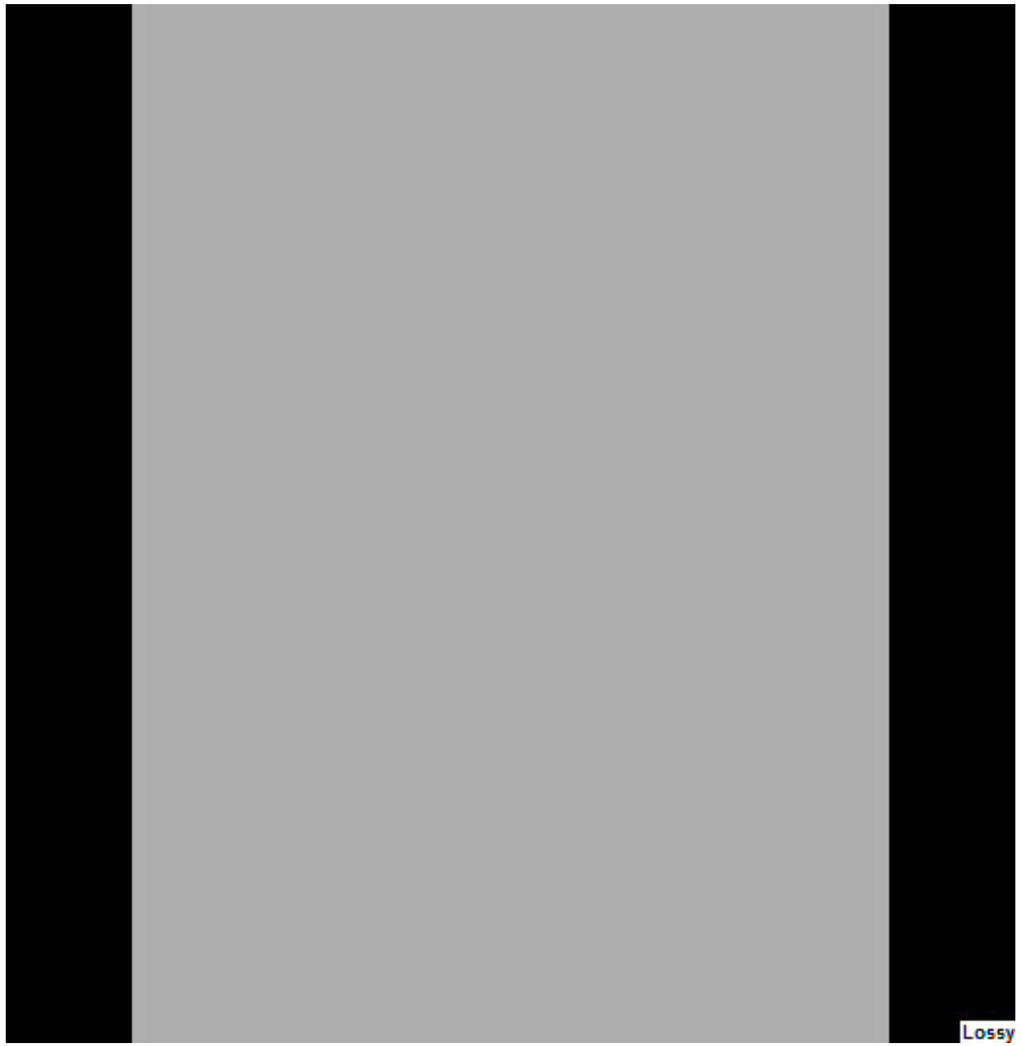


- 65+ year-old female
- History of hypertension (HTN), dyslipidemia, type II diabetes
- 40-50 packs per year smoking history (quit 2 years ago)
- 2-block claudication
- Right ABI 0.86
- Left ABI 0.72
- Duplex ultrasound: left SFA occlusion

Images courtesy John Laird, MD

Baseline Angiogram

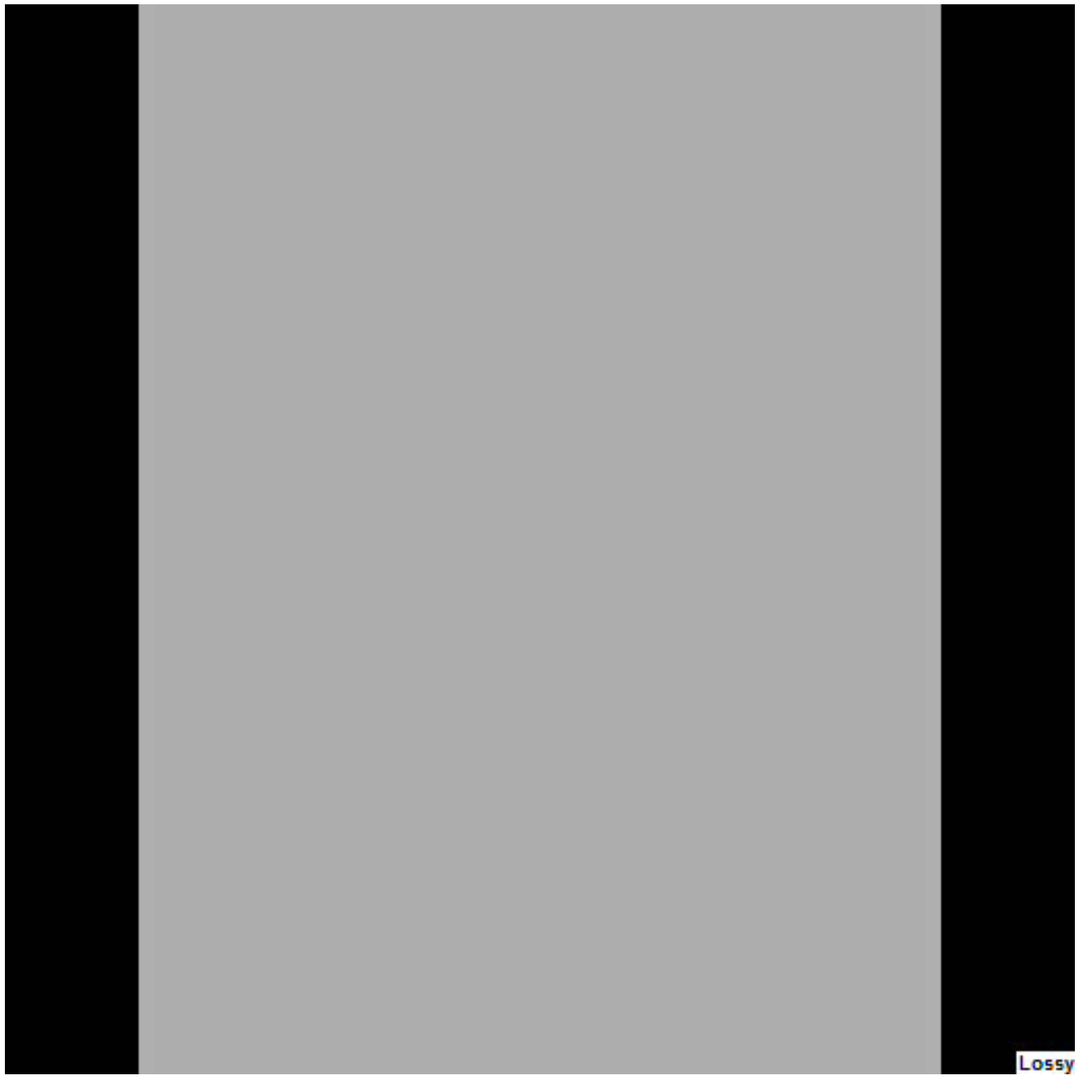




Long, complex SFA lesion with occlusion

Images courtesy John Laird, MD

Baseline Angiogram with Run Off



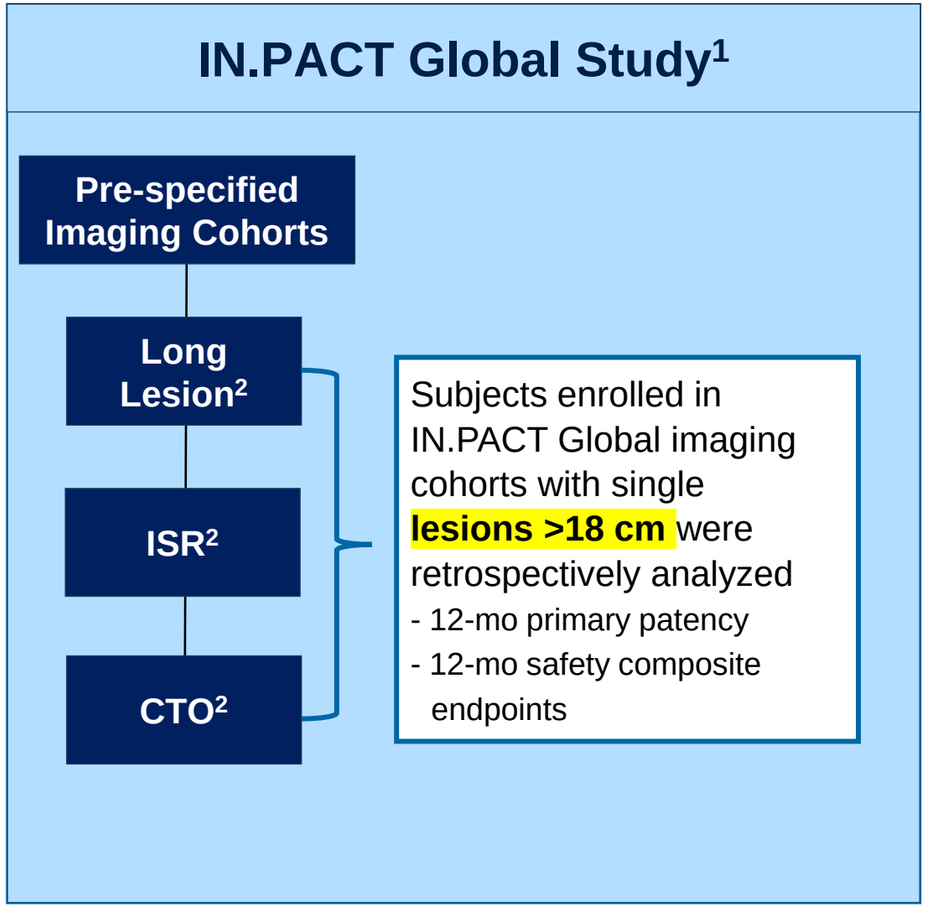
Images courtesy John Laird, MD

Treatment Considerations

- Technique for CTO crossing?
- To debulk or not to debulk?
- Need for embolic protection?
- Change to treatment algorithm in the COVID-19 era?
- DCB with provisional stenting vs DES?

IN.PACT Global Study: Real World, Robust, Adjudicated Data

Complex Long Lesion Imaging Cohort



Baseline Characteristics	DCB (N = 227 subjects)
Age, ± SD	68.8 ± 9.7
Male Gender	67.4% (153/227)
Diabetes	38.7% (87/225)
Current Smoker	42.7% (97/227)
Hypertension	86.7% (197/227)
Hyperlipidemia	71.7% (157/219)
Lesion Characteristics	**DCB (N = 227 subjects and lesions)**
Lesion (N) De novo Restenotic (non-stent) **In-stent restenotic**	 67.0% (152/227) 12.8% (29/227) **20.3% (46/227)**
Lesion Length, ± SD, cm	**28.74 ± 7.11**
Total Occlusions	**70.1% (157/224)**
Diameter Stenosis, ± SD, mm	94.1% ± 10.7
Calcification (%)[3] None Mild Moderate Moderately Severe Severe	 26.9% (59/219) 37.4% (82/219) 11.9% (26/219) 10.0% (22/219) 13.7% (30/219)

1. Core lab-adjudicated with clinical events committee oversight
2. Clinical events committee oversight
3. Dattilo R, et al. *J Invasive Cardiol.* 2014;26:355-360. Severe calcium definition used by study sites and core laboratory as bilateral calcium at the same location (also measured in sections), ≥ half of the total lesion length, ≥180◦ (both sides of the vessel at the same location)

IN.PACT Global Study: Real World, Robust, Adjudicated Data

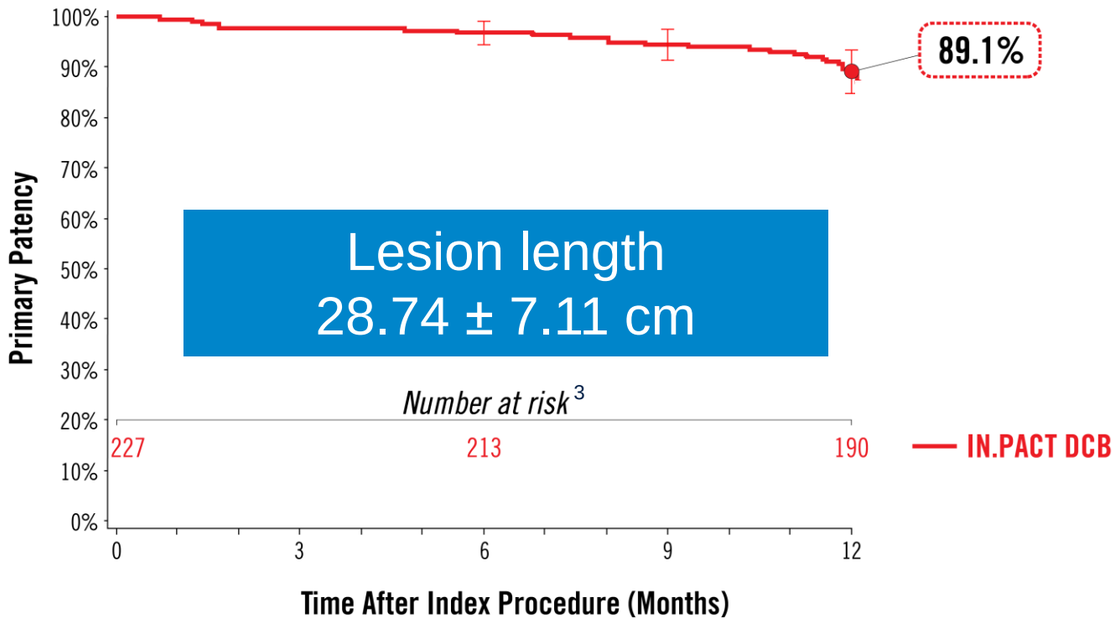
Complex Long Lesion Imaging Cohort

Procedural Characteristics[1]	IN.PACT™ Admiral™ drug-coated balloon (DCB) n = 227 subjects
Pre-dilatation (%)	89.0% (202/227)
Post-dilatation (%)	44.7% (101/226)
Dissections(%)	
None	36.1% (82/227)
A-C	35.6% (81/227)
D-F	19.3% (44/227)
Provisional Stenting (%)	42.5% (96/226)
Device Success (%)[2]	99.2% (653/658)
Procedural Success (%)[3]	99.1% (224/226)
Clinical Success (%)[4]	99.1% (224/226)

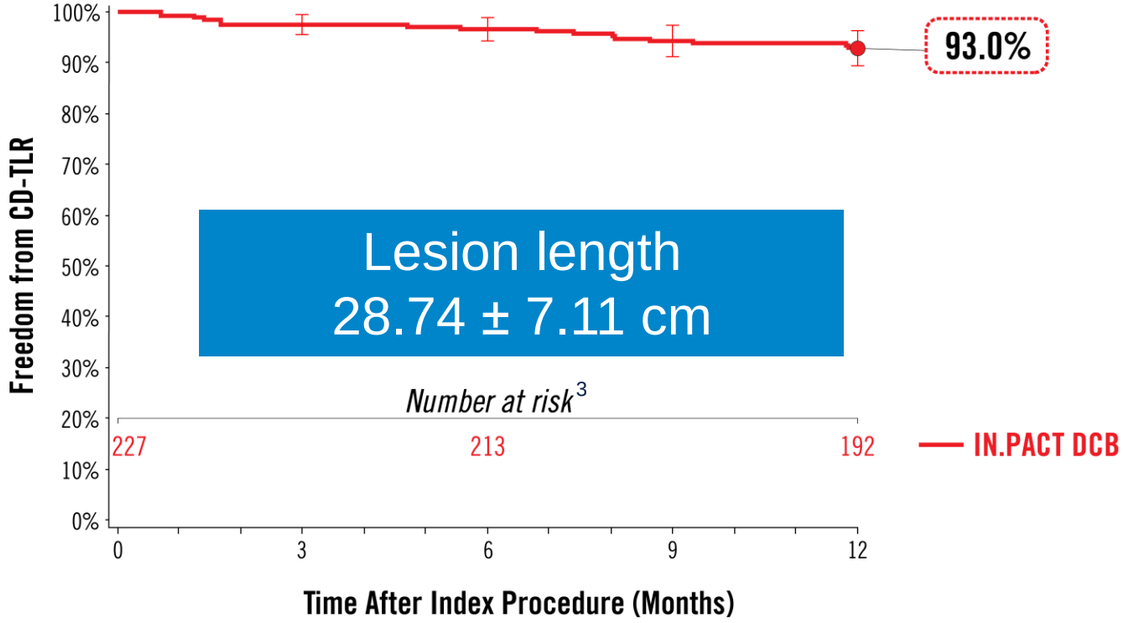
1. All ITT subjects (stented and non-stented).
2. Device success defined as successful delivery, inflation, deflation and retrieval of the intact study balloon device without burst below the RBP.
3. Procedure success defined as residual stenosis of ≤ 50% (non-stented subjects) or ≤ 30% (stented subjects)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

IN.PACT Global Study: Complex Lesion Analysis
Primary Patency and Reintervention through 12 Months

Primary Patency[1]

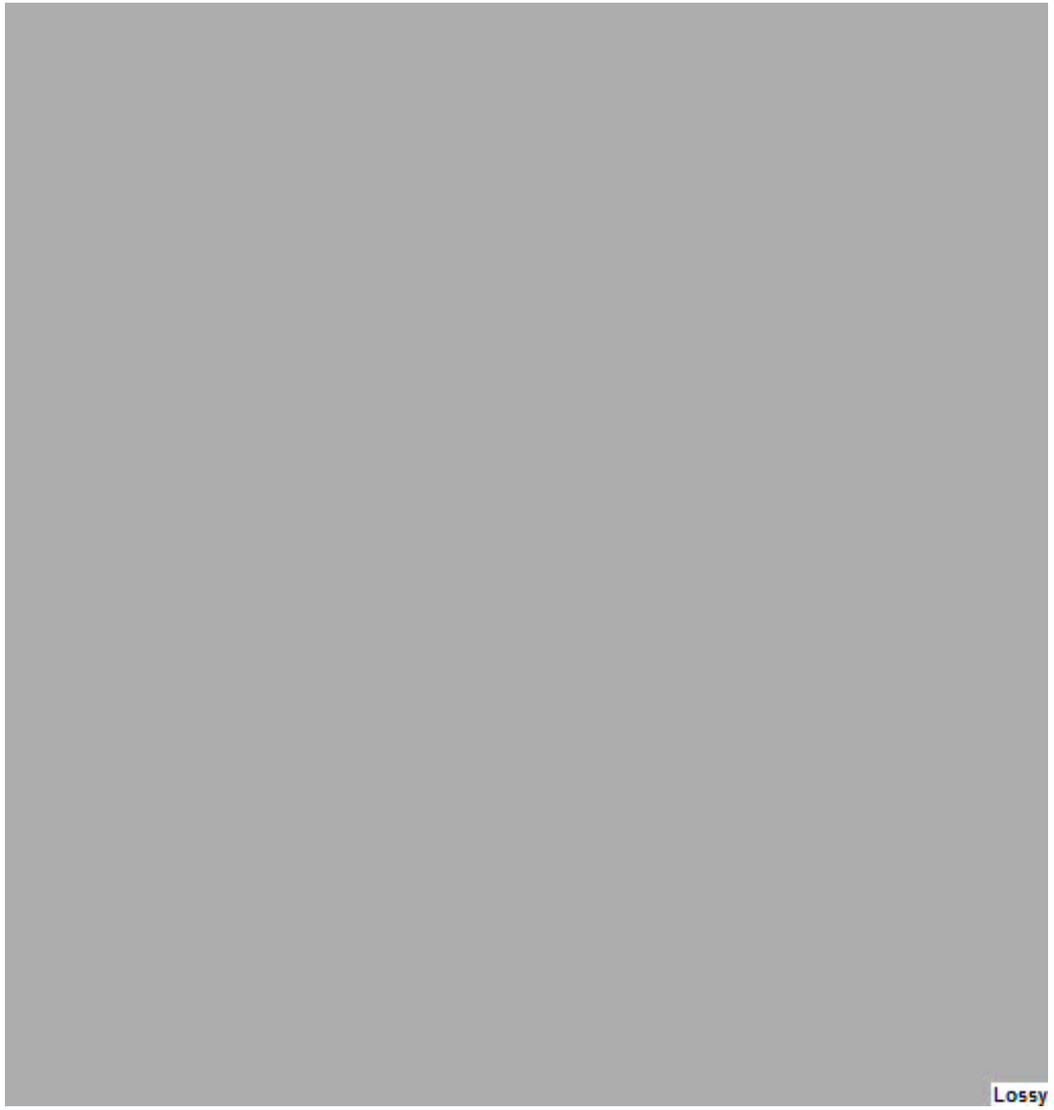


Freedom From CD-TLR[2]



1. Freedom from core laboratory-assessed restenosis (duplex ultrasound PSVR ≤2.4) and clinically-driven target lesion revascularization through 420 days (adjudicated by a Clinical Events Committee blinded to the assigned treatment).
2. Clinically-driven TLR adjudicated by an independent Clinical Events Committee, blinded to the assigned treatment based on any re-intervention at the target lesion due to symptoms or drop of ABI of ≥20% or >0.15 when compared to post-procedure baseline ABI.
3. Number at risk represents the number of evaluable subjects at the beginning of each 60-day window.

Back to the Case

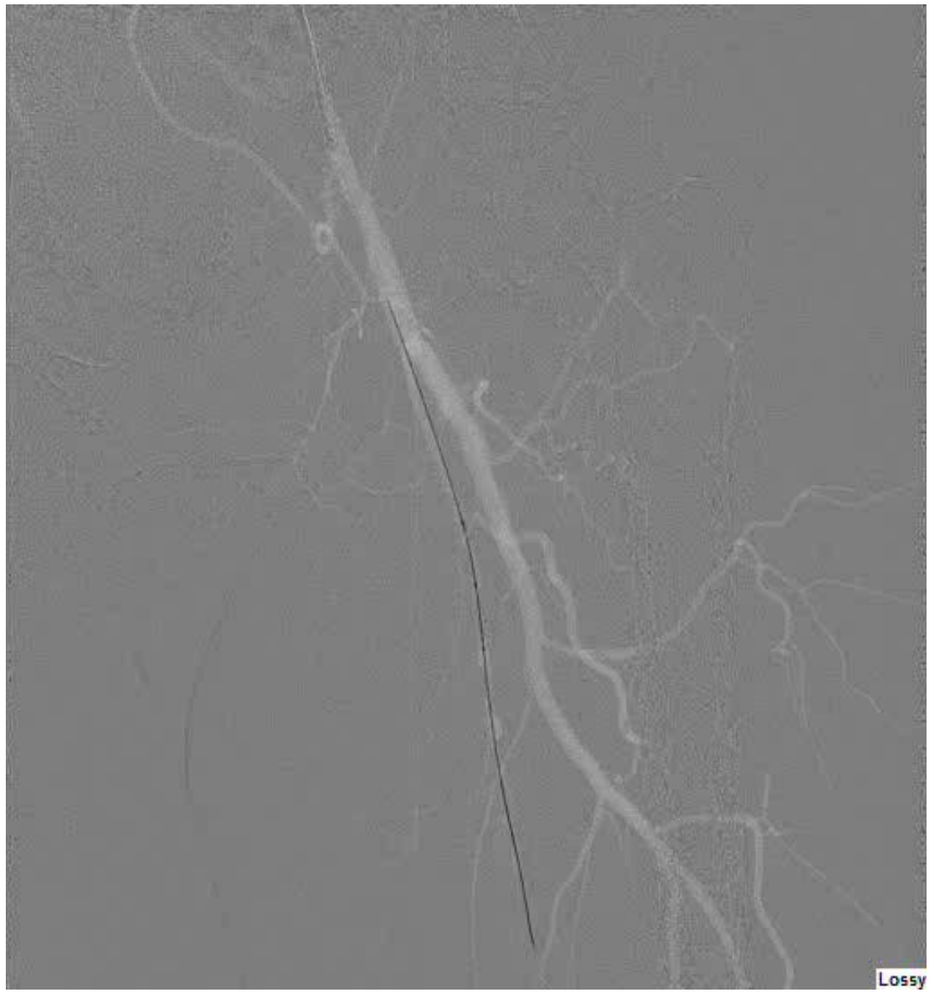


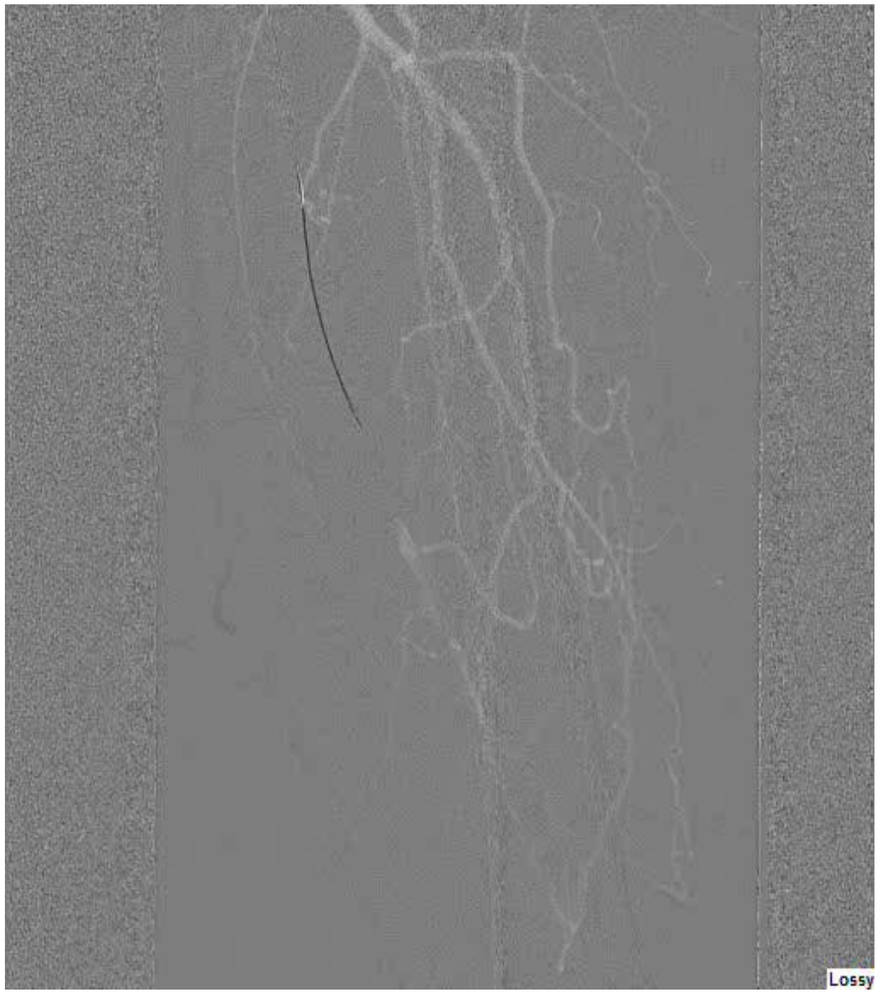
- 7 Fr crossover sheath
- 0.018-inch Treasure™* 12 guidewire
- 0.018-inch support catheter

TM* third party brands are trademarks of their respective owner.

Images courtesy John Laird, MD

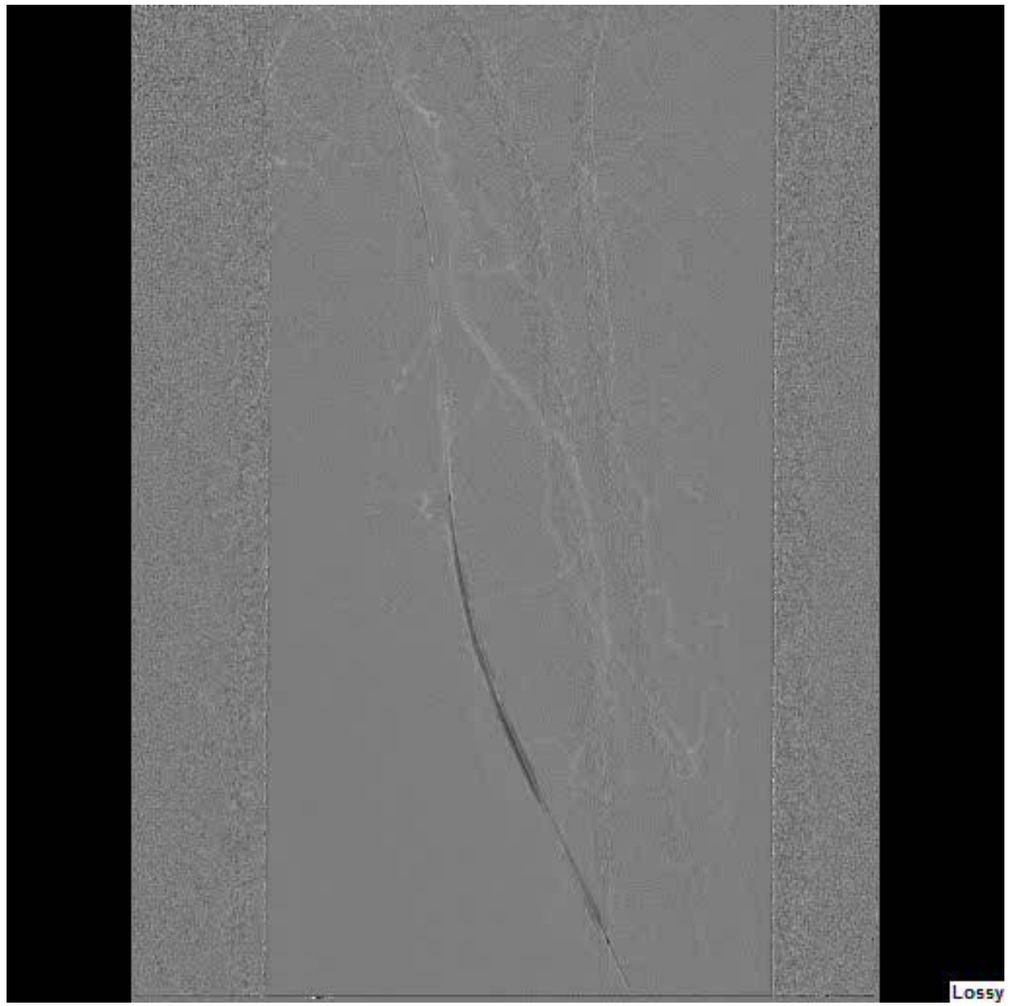
Procedure

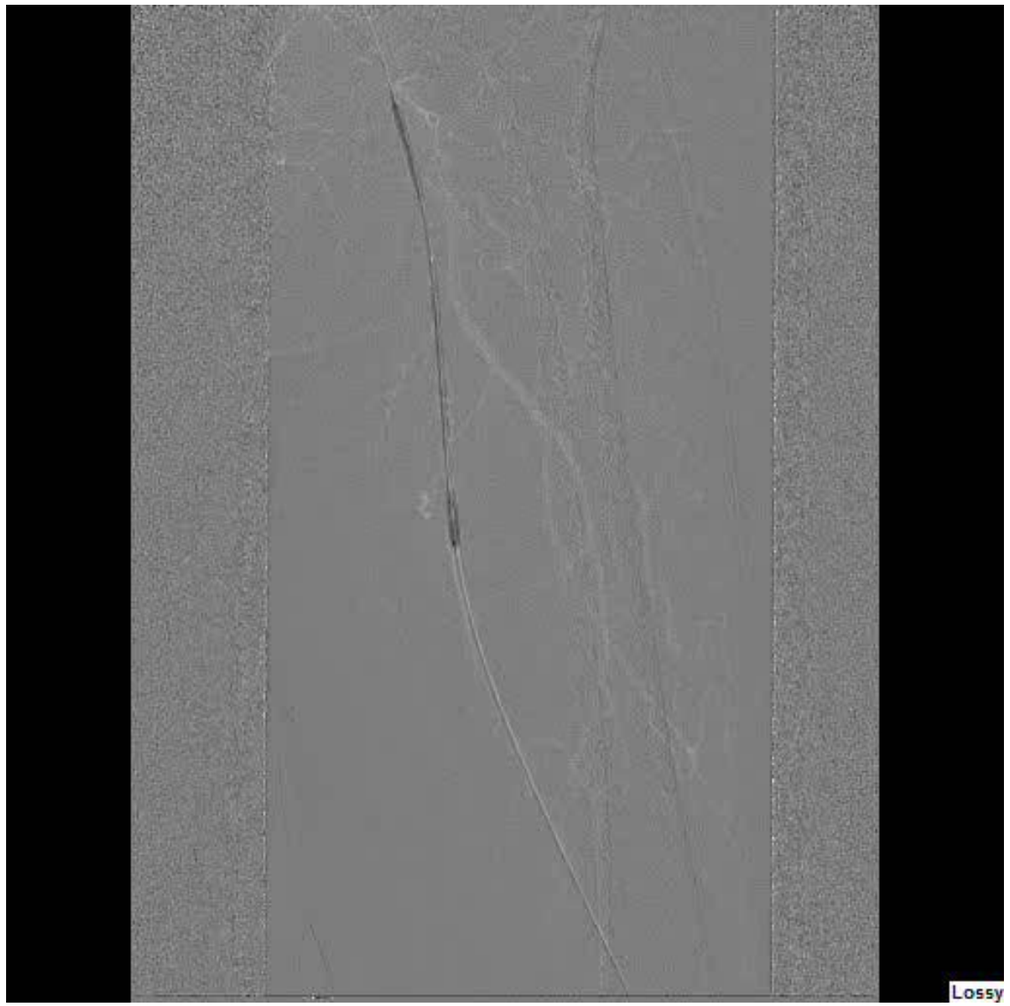




Images courtesy John Laird, MD

Procedure

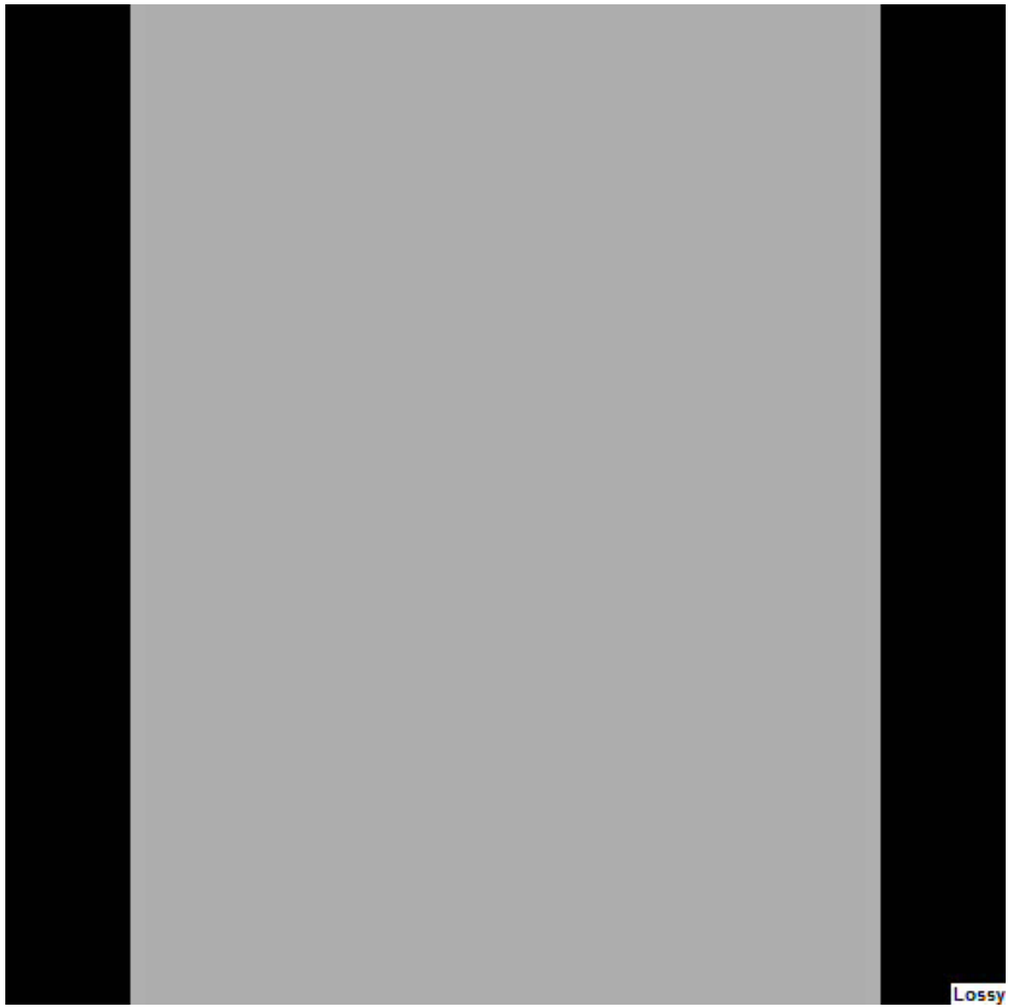




Pre-dilatation with 4 x 15 balloon

Images courtesy John Laird, MD

Procedure

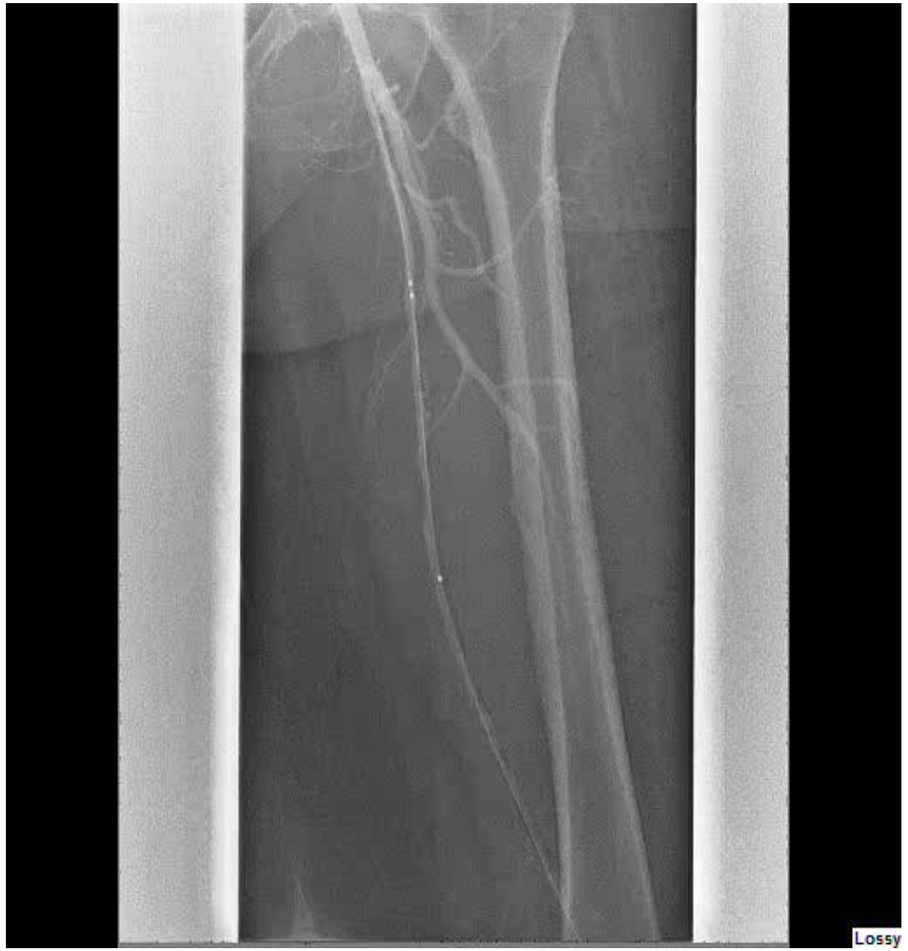


Following pre-dilatation

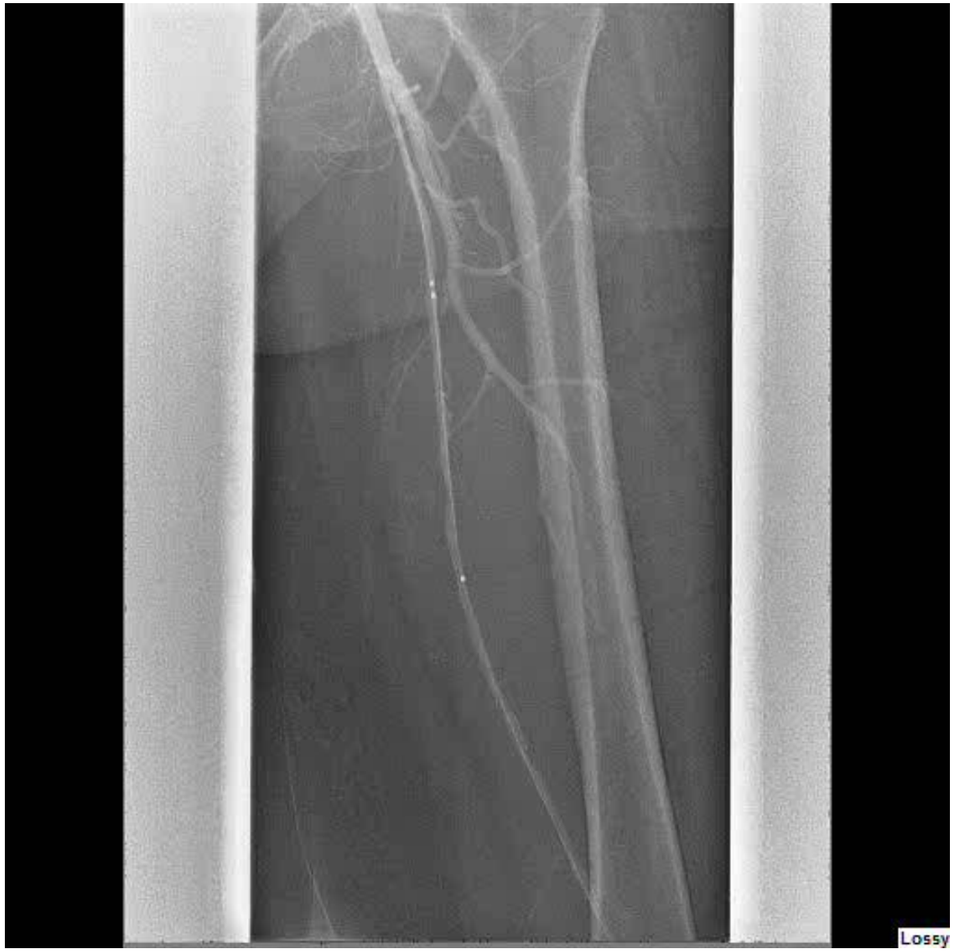
- Good flow
- No flow-limiting dissection
- Moderate residual stenosis
- DCB vs DES?

Images courtesy John Laird, MD

Procedure



5 mm x 200* mm IN.PACT Admiral drug-coated balloon catheter (DCB)

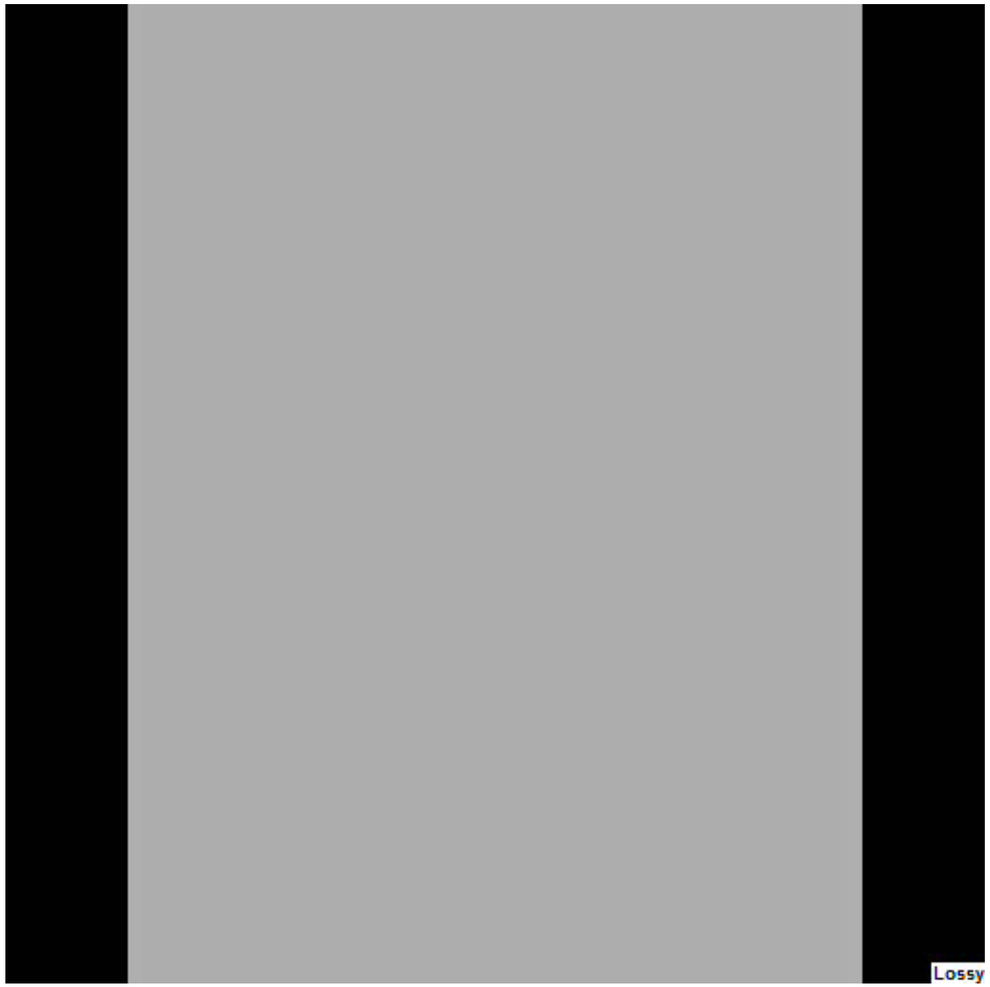


5 mm x 40 mm IN.PACT Admiral DCB

*IN.PACT Admiral 200mm balloon length is available for sale in the United States only.

Images courtesy John Laird, MD

Final Angiograms

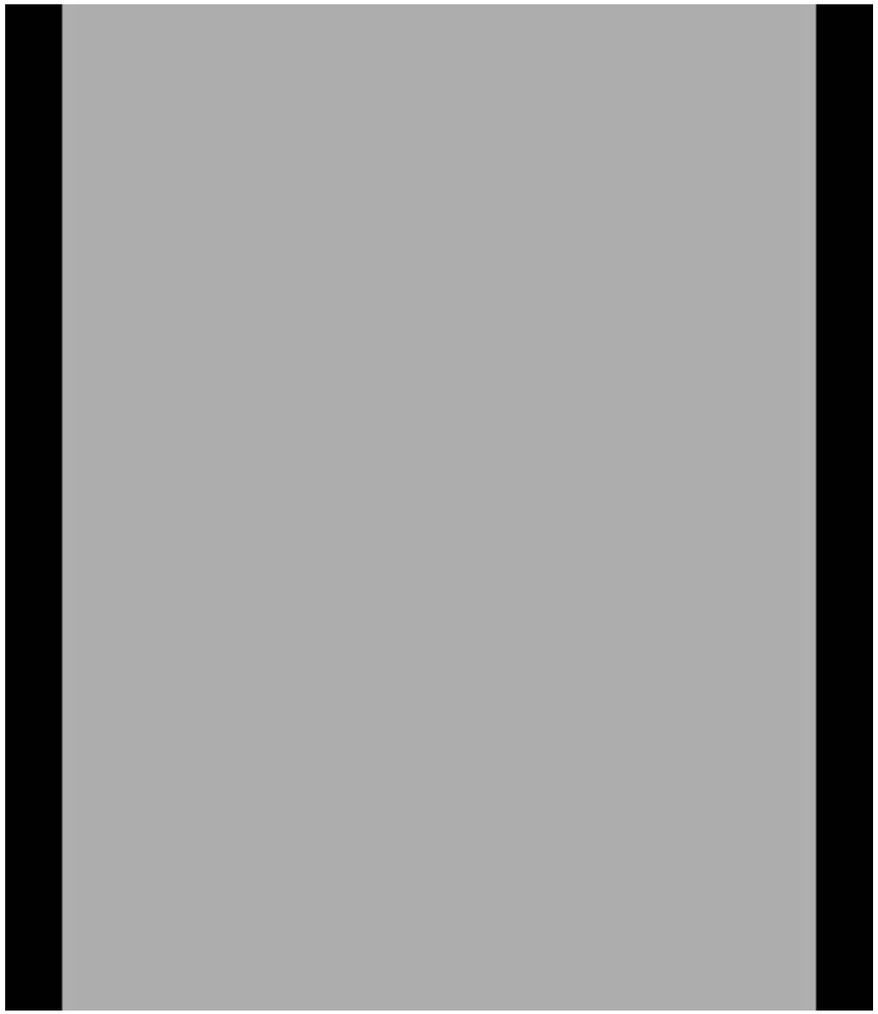


Post-DCB

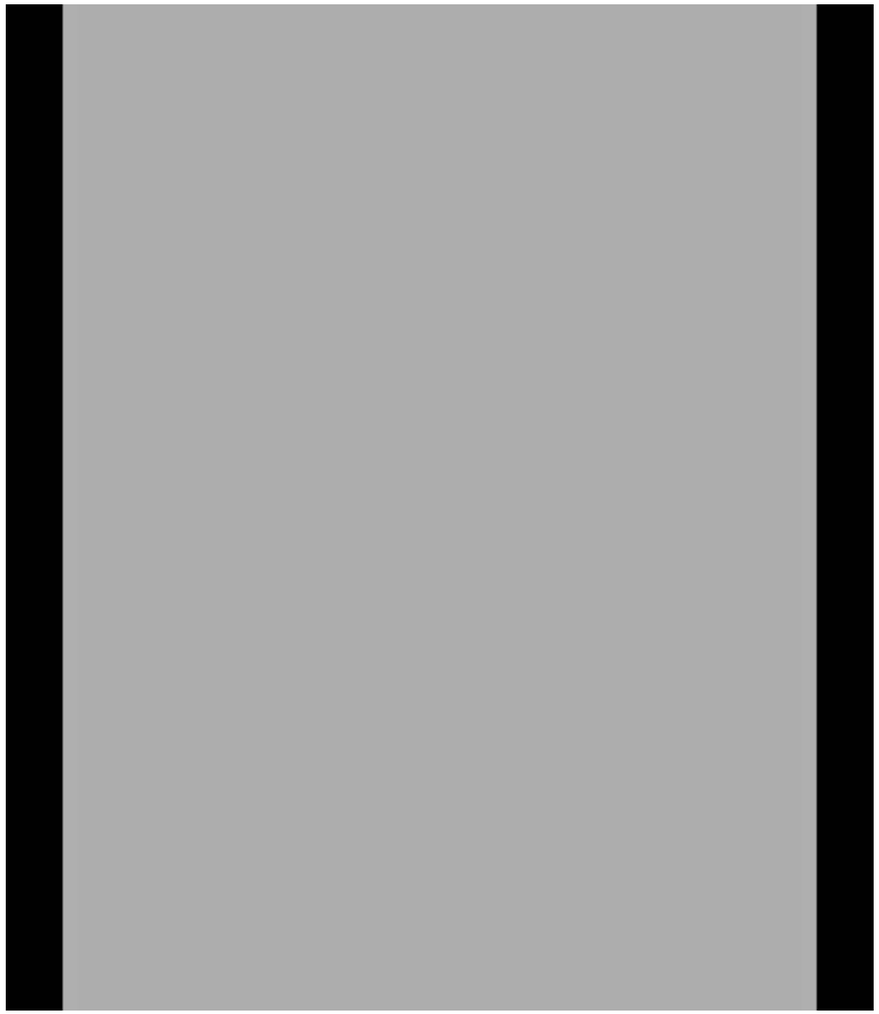
Distal run-off

Images courtesy John Laird, MD

Baseline

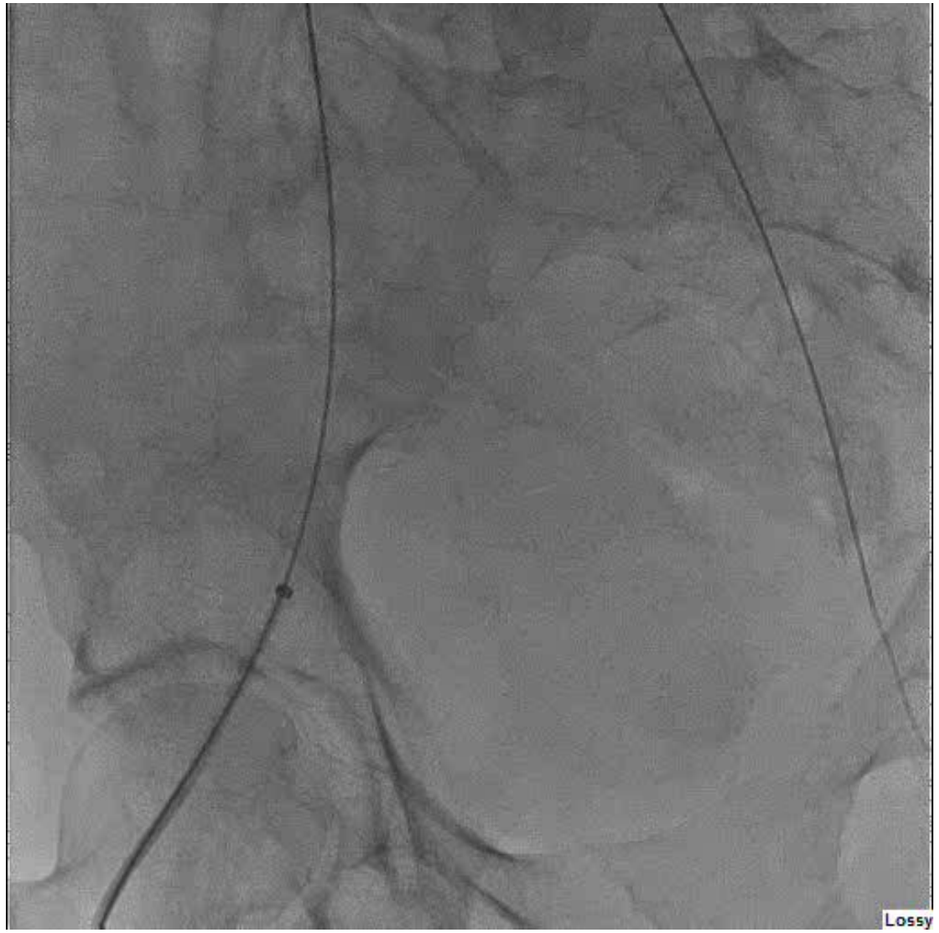


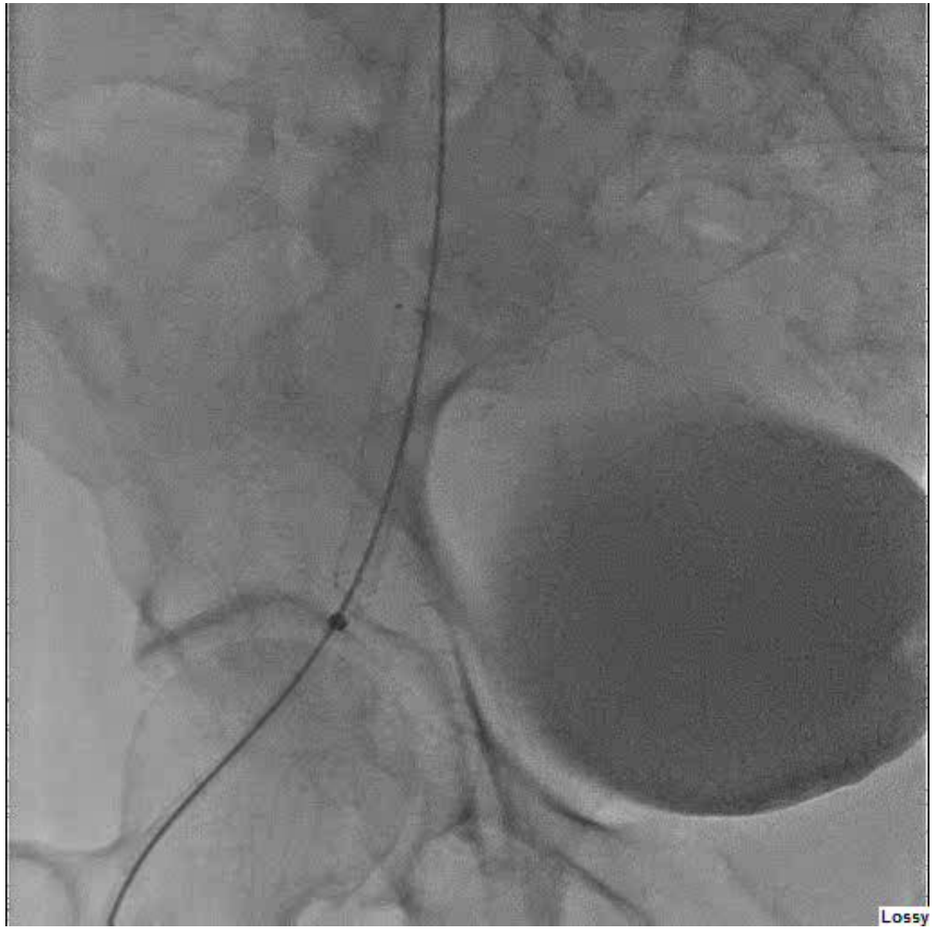
Post- Procedure



Images courtesy John Laird, MD

Right External Iliac Stenting





Images courtesy John Laird, MD

Case Summary

- No complications
- Avoidance of permanent metal implant
- Normalization of ABIs
- Relief of claudication symptoms
- Follow-up Duplex scheduled (very high-risk patient for restenosis without paclitaxel-eluting device)