2017 MID-ATLANTIC
CONFERENCE

7th ANNUAL CURRENT CONCEPTS IN
VASCULAR THERAPIES

Deepak N. Deshmukh
D.O. FACS

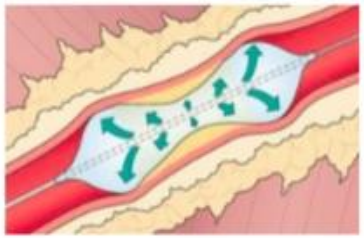
April 22, 2017

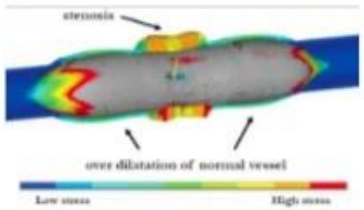
Shockwave Lithotripsy for the SFA

Problem: Rigid fibrotic, calcified tissue

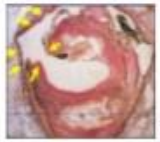
Today's endovascular therapies fail

Current Cycle of Therapy



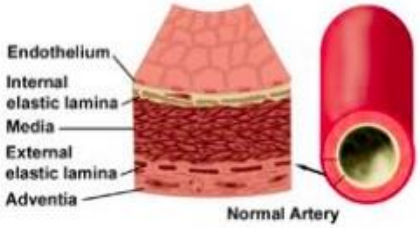


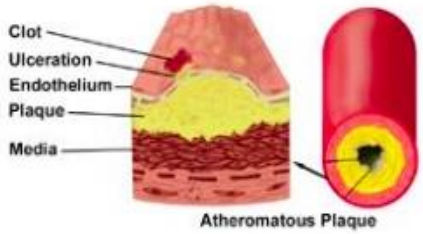
High Pressure Inflation
Wall Stress



Injury
Disrupts IEL

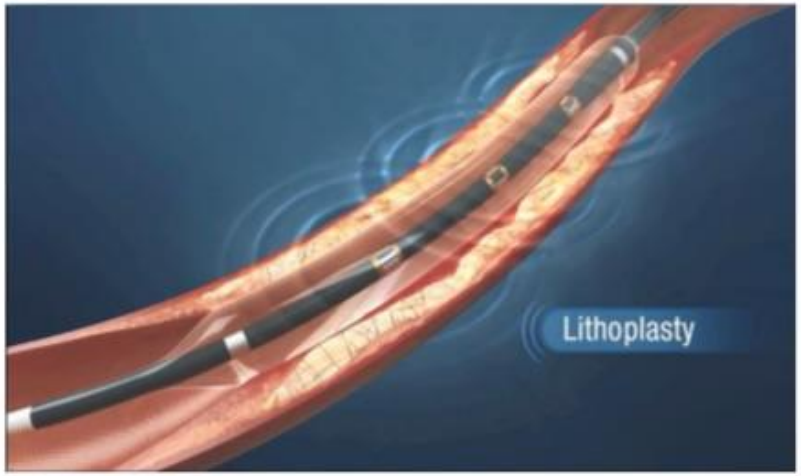
Restenosis
Revascularization failure





Introduction: Lithoplasty®

Lesion modification using localized lithotripsy in a balloon



Tissue-selective:

- **Hard on hard tissue, Soft on soft tissue**
- **Lithotripsy waves travel outside balloon**
- **Designed to disrupt both superficial, deep calcium**

- Designed to normalize vessel wall compliance prior to controlled, low pressure dilatation
- Effective lesion expansion with minimized impact to healthy tissue
- Familiar Balloon-based endovascular technique
- “Front-line” balloon strategy (.014”compatible)

Shockwave Medical Lithoplasty System

Shockwave Medical Lithoplasty Balloon

Lithotripsy delivery	4 atm
Nominal pressure	6 atm
Rated Burst Pressure	10 atm

0.014" Guidewire Compatible
110 cm Working Length
6F / 7F Sheath compatibility

Balloon Sizes

Diameter	Length
3.5 mm	60 mm
4.0 mm	60 mm
4.5 mm	60 mm
5.0 mm	60 mm
5.5 mm	60 mm
6.0 mm	60 mm
6.5 mm	60 mm
7.0 mm	60 mm

Clinical Program Overview

DISRUPT PAD I
35 subjects, 3 sites
Jan 2014 – Sep 2014

+

DISRUPT PAD II
60 subjects, 8 sites
Jun 2015 – Dec 2015

Objective: To study the safety and effectiveness of the Shockwave Medical Lithoplasty® System in the treatment of calcified, stenotic infrainguinal peripheral arteries.

- Two-phase, prospective, non-randomized, multi-center study
- Monitoring with 100% source document verification
- Independent angiographic and duplex ultrasound core labs
- Independent clinical events committee

DISRUPT PAD Study Design

Key Eligibility Criteria

- Intermittent claudication: Rutherford Classification 2–4
- Ankle-brachial index ≤0.9
- SFA/Popliteal lesions ≥70% stenosis
- RVD 3.5–7.0 mm, ≤150 mm length
- Moderate and severe calcification by angiography

Procedural

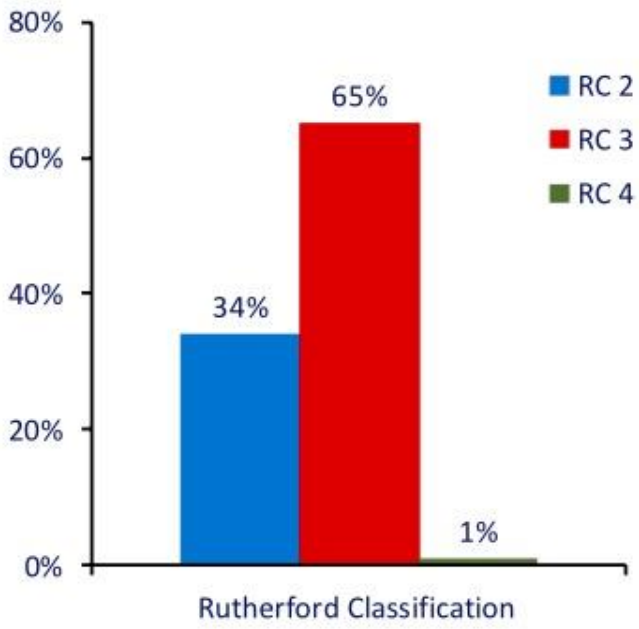
- Procedural success: <50% residual stenosis
- Exploratory endpoint: ≤30% residual stenosis

Follow Up: 30 days, 6 mo, & 12 mo*

- Major adverse events
- Target lesion patency by DUS (stenosis <50%)
- Target lesion revascularization (TLR)
- Functional outcomes

DISRUPT PAD Baseline Characteristics

	Medical History N=95
Age	72.8 ± 8.2
Male gender	80.0% (76)
BMI >30 kg/m^2	28.2 ± 4.2
Hypertension	96.8% (92)
Hyperlipidemia	82.1% (78)
Current smoker	22.1% (21)
Diabetes	50.5% (48)
Coronary disease	52.6% (50)
Renal insufficiency	25.3% (24)
Stroke/TIA	8.4% (8)
ABI	0.8 ± 0.2



DISRUPT PAD
Angiographic Findings

	Pre	Post
MLD (mm)	1.2 ± 0.7	4.2 ± 0.6
% diameter stenosis	77.8 ± 13.5	23.8 ± 5.7

	Pre-Procedure N=95
RVD (mm)	5.3 ± 0.7
CTO	18.9% (18)
Lesion length (mm)	71.9 ± 36.4
Calcified length (mm)	92.5 ± 41.4
Calcification	-----
Moderate	44.2% (42)
Severe	54.7% (52)

	Post-Procedure N=95
Acute gain (mm)	3.0 ± 0.8
Dissection	-----
None	86.3% (82)
A	0.0%
B	7.4% (7)
C	6.3% (6)
D	1.1%*

*One Grade D resolved following stent implant

DISRUPT PAD Safety

All events adjudicated by independent clinical events committee

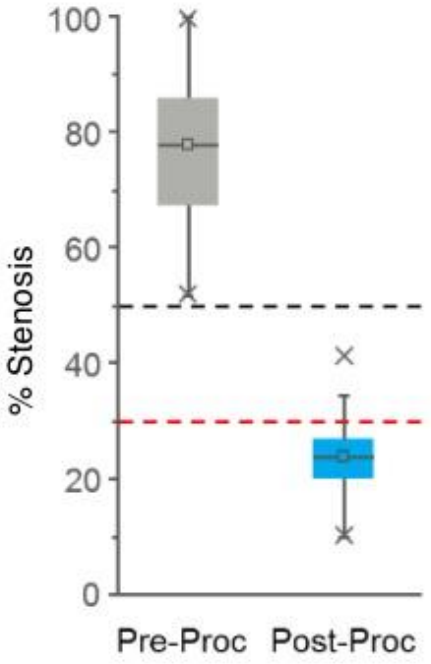
- One subject experienced a Grade D dissection requiring a stent

	30 days N=94	6 mo N=93
Major adverse events		
Target limb emergency surgical revascularization	0%	0%
Target limb major amputation	0%	0%
Thrombus or distal emboli with treatment	0%	0%
Perforations and dissections (≥D) with treatment	1.1% (1)	1.1% (1)

DISRUPT PAD Acute Effectiveness

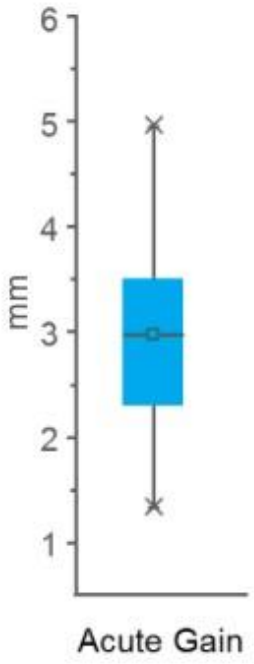
By angiographic core lab

% Stenosis



% Residual Stenosis = 23.8%

Acute Gain

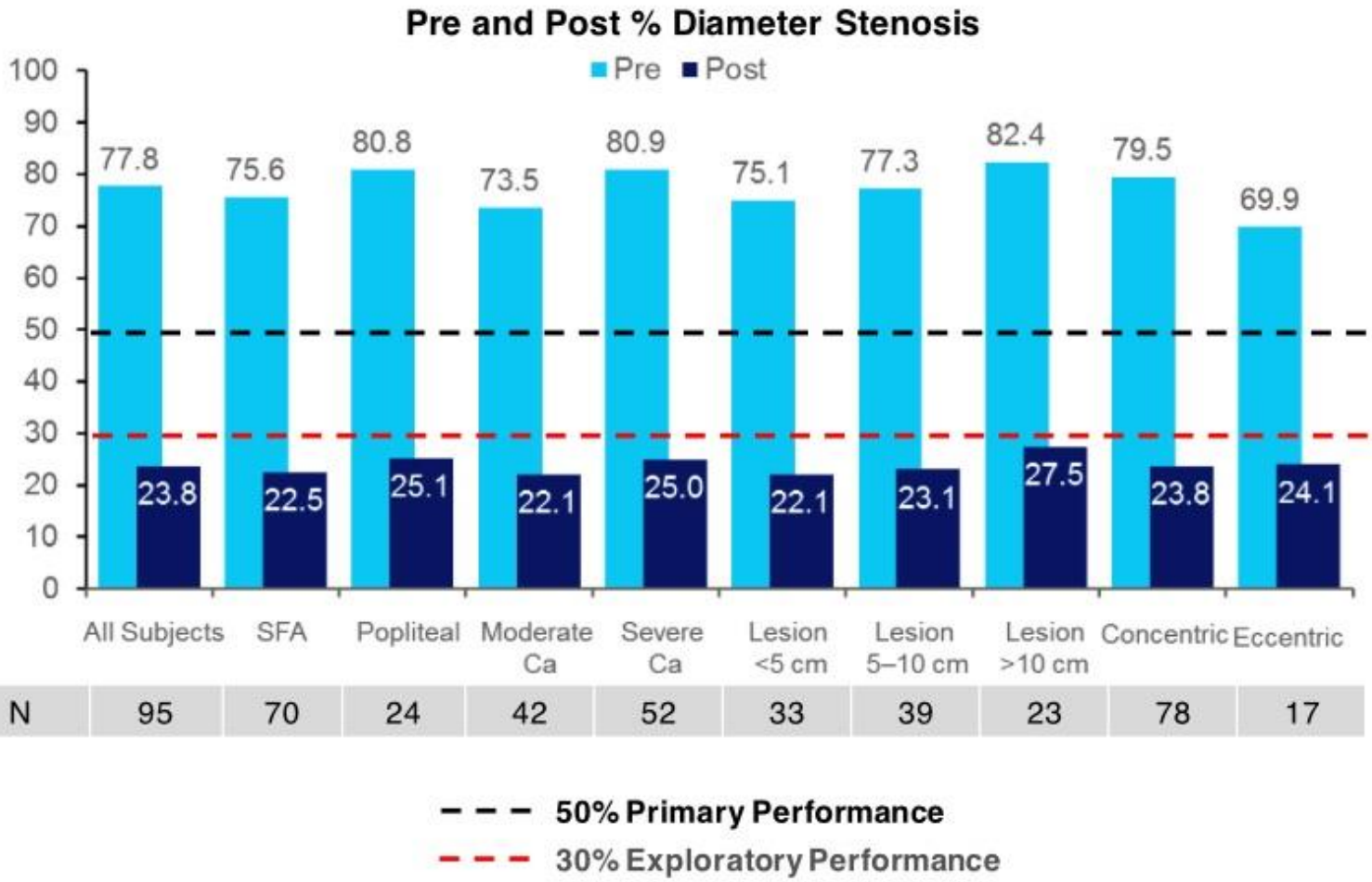


Acute Gain = 3.0 mm

Minimal Adjunctive Therapy

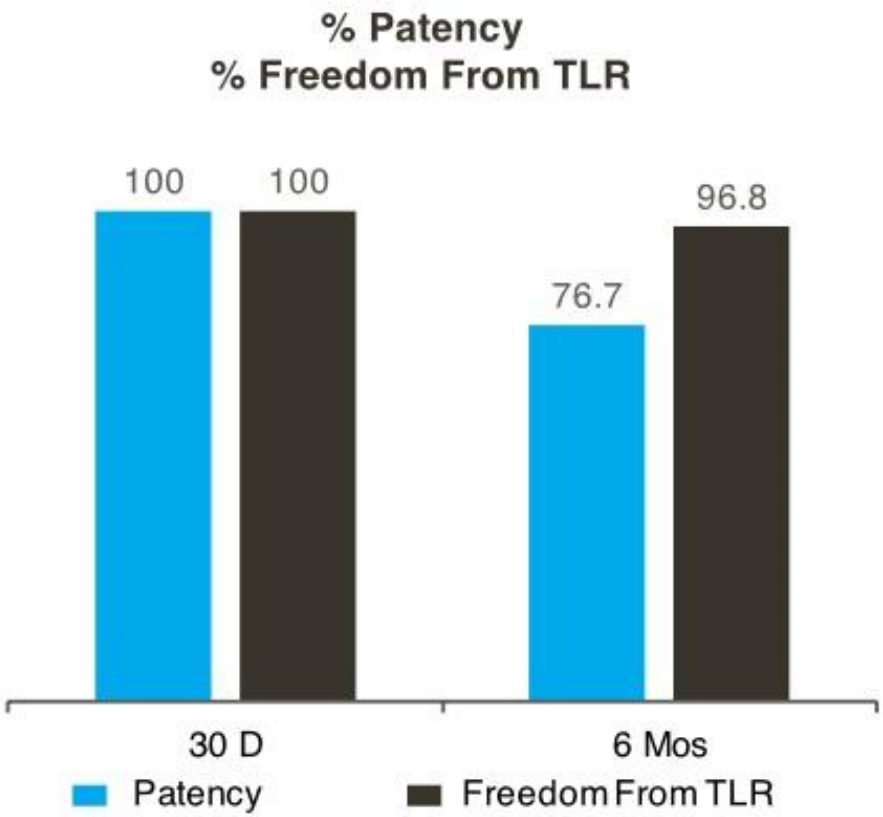
	N=95
Pre-dilatation	11.6% (11)
Post-dilatation	7.4 % (7)
Provisional stenting	1.1% (1)

DISRUPT PAD Subgroups

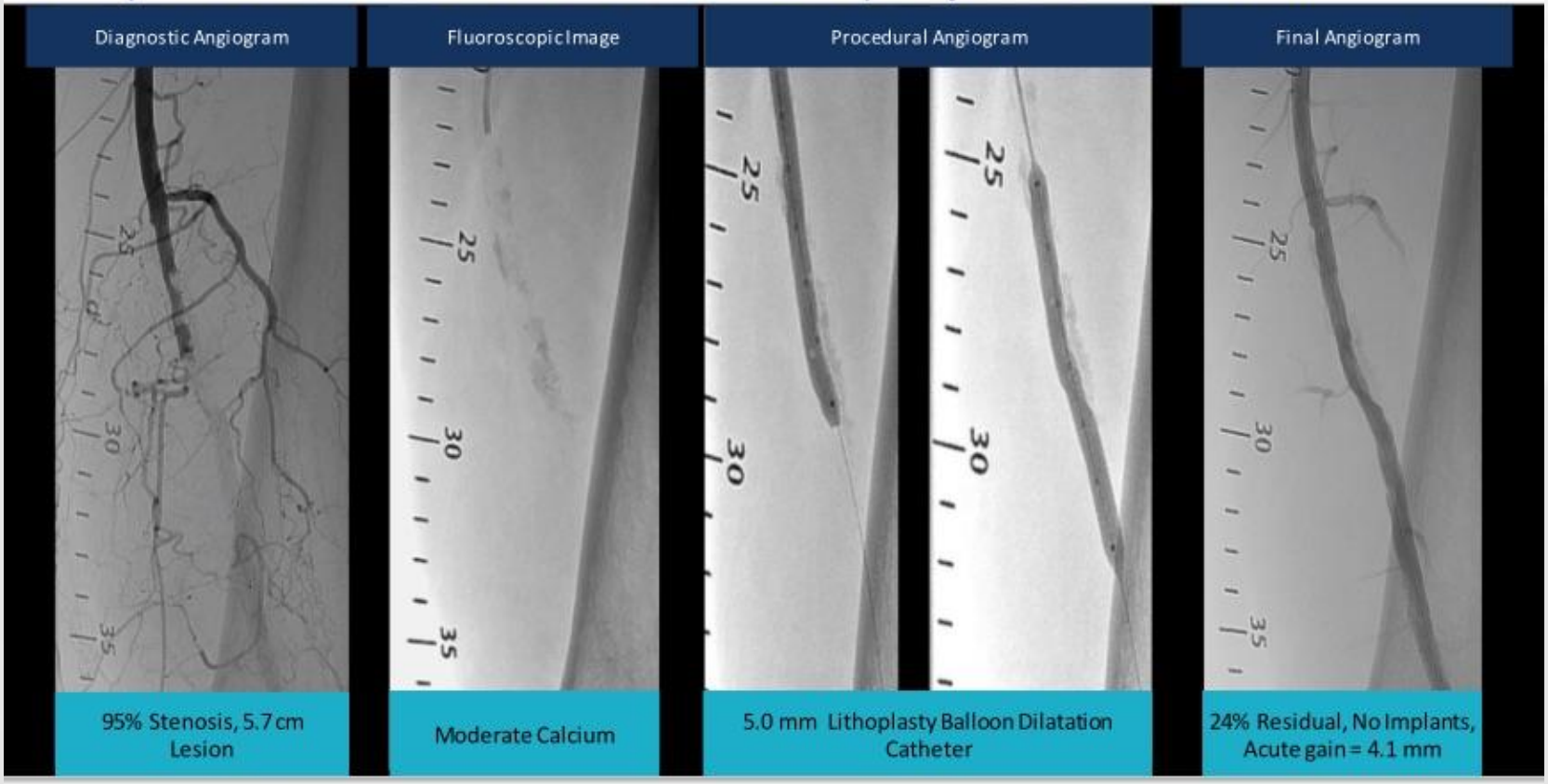


N	95	70	24	42	52	33	39	23	78	17

DISRUPT PAD Effectiveness

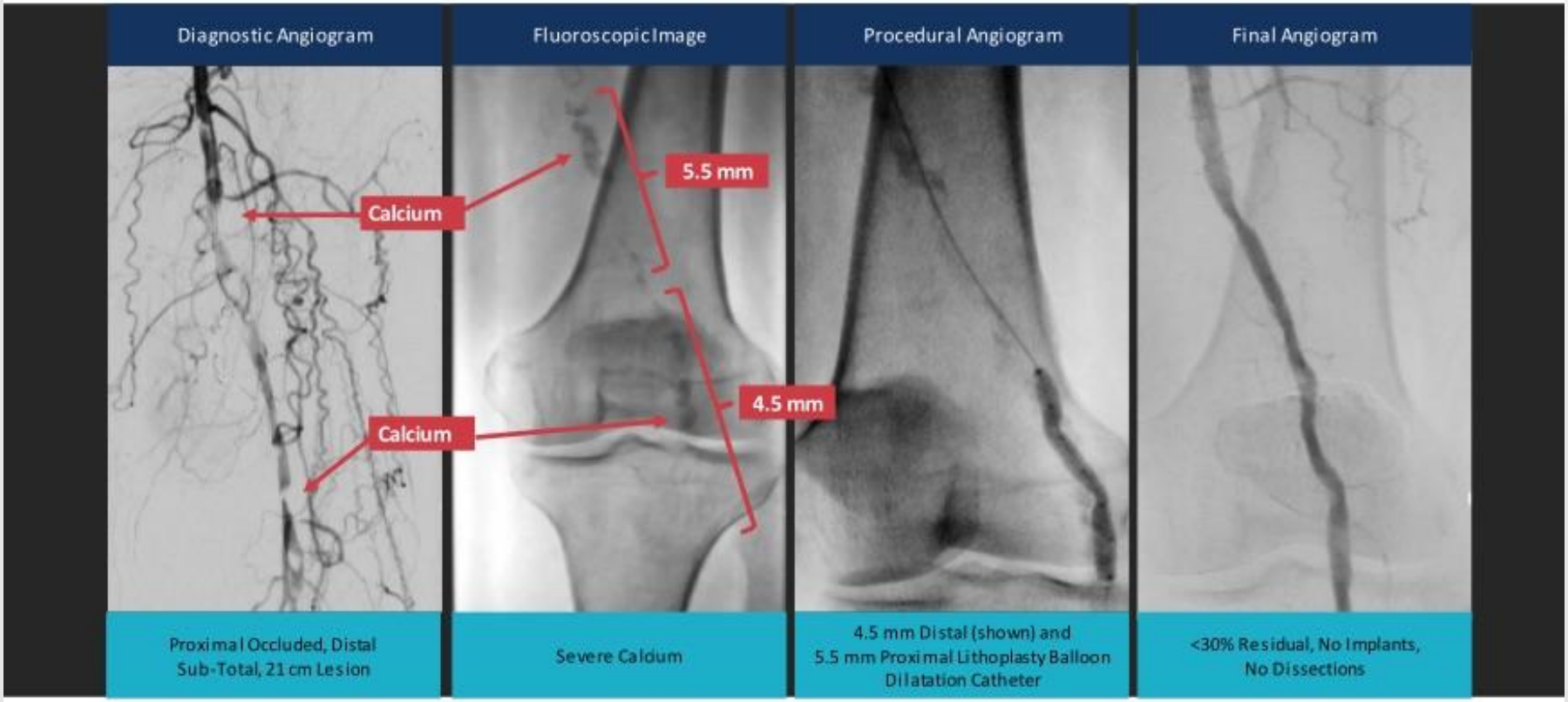


SFA : Case Study 1

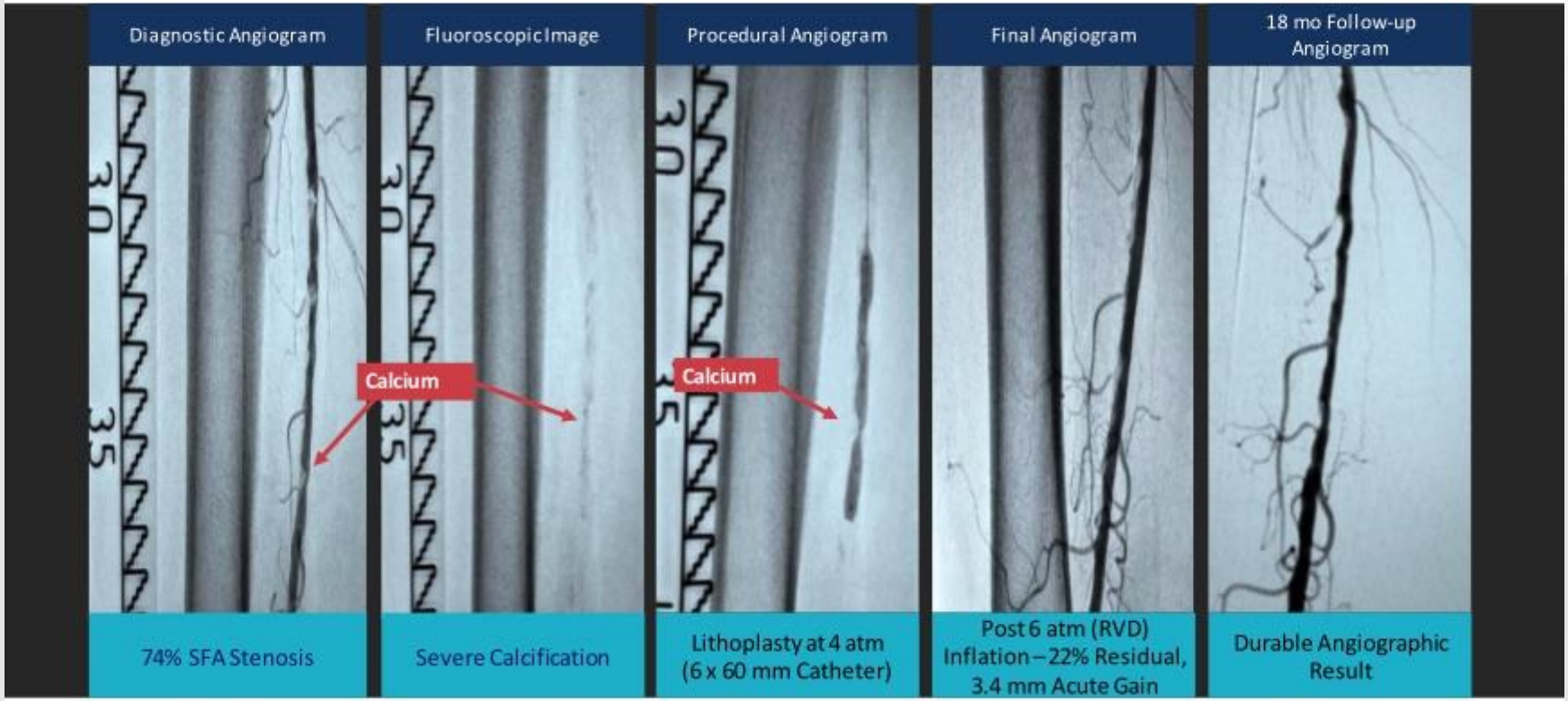


((Case courtesy of: Dr Marianne Brodmann))

SFA : Case Study 2



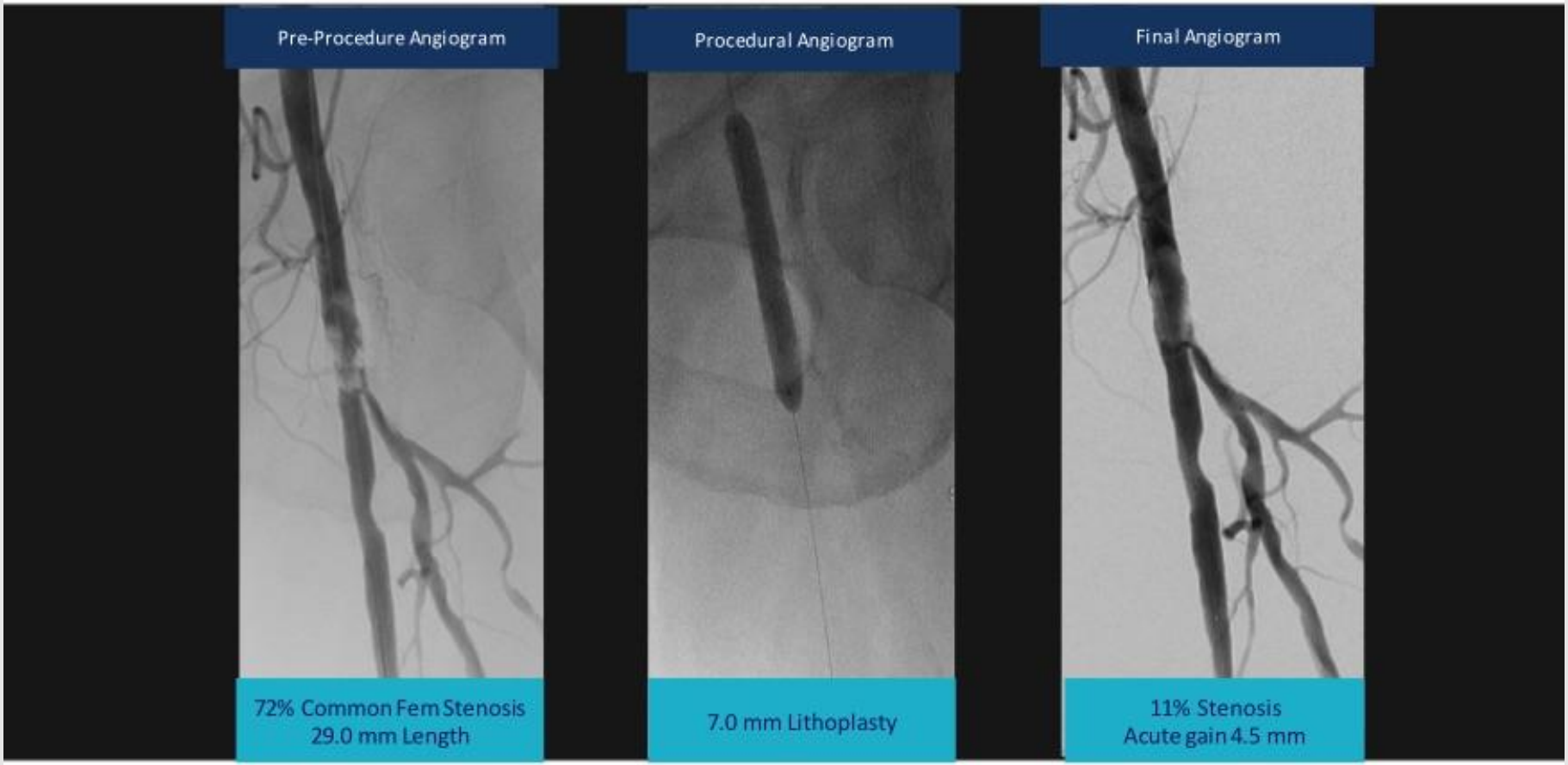
SFA: Case Study 3



Baseline Presentation
ABI – .6
RB 3 – 100 meters walking distance

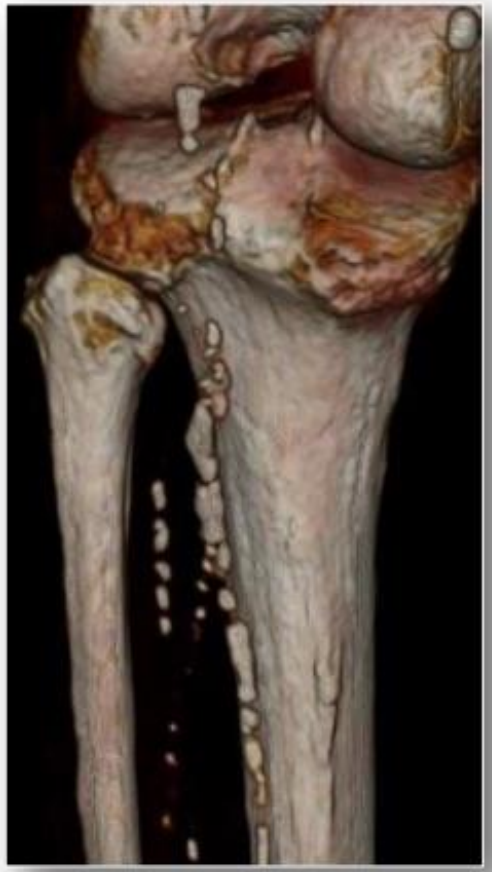
18-Month Follow-up
ABI – .9
RB 0 – No walking limitation

Common Femoral : Case Study 4



Lithoplasty® in BTK Arteries: Study Design

- Safety and Feasibility of Lithoplasty in calcified, stenotic Infrapopliteal Arteries
- Device: 2.5 to 3.5 X 60 mm Lithoplasty
- 20 patients treated at 5 sites
- Population: RC 1 – 5 infrapopliteal disease.
- Target lesion: 2.5 – 3.5 mm, >50% stenosis, ≤ 150 mm length, single/multiple targets allowed
- Safety – Major Adverse Events at 30 day including death, MI, revascularization and amputation
- Effectiveness - % reduction in diameter stenosis



Interim Angiographic and Safety Results

Angiographic core lab adjudicated

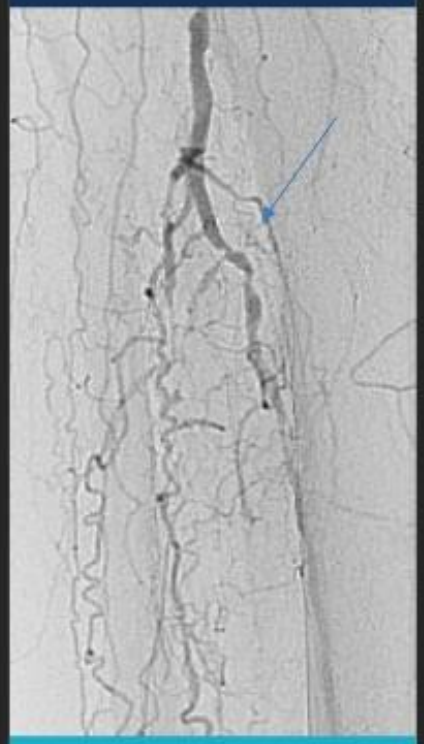
	Pre N= 8 lesions	Post N= 8 lesions
MLD (mm)	1.2	2.5
% diameter stenosis (DS)	61.7%	21.2%
% DS reduction	--	65.0%

	Pre-Procedure N=8 lesions
RVD (mm)	3.1
Lesion length (mm)	38.0
Calcified length (mm)	52.2
Calcification	--
Moderate	87.5% (7)
Severe	12.5% (1)

	Post-Procedure N=8 lesions
Acute gain (mm)	1.3
Thrombus	0% (0)
Abrupt closure	0% (0)
No reflow	0% (0)
Distal embolization	0% (0)
Dissections	0% (0)
Perforations	0% (0)

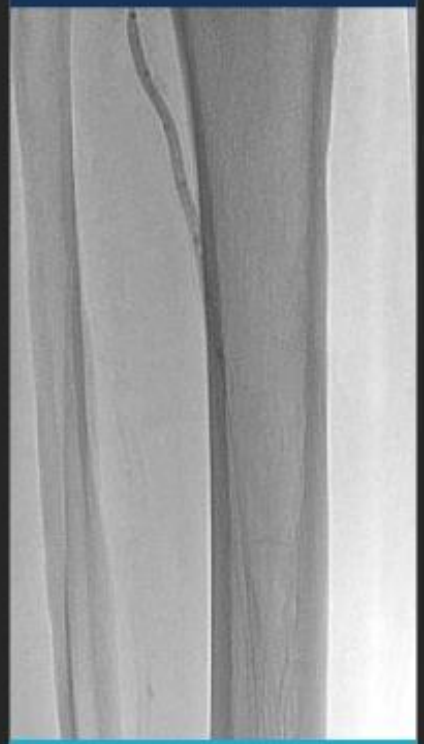
BTK : Case Study 1

Diagnostic Angiogram



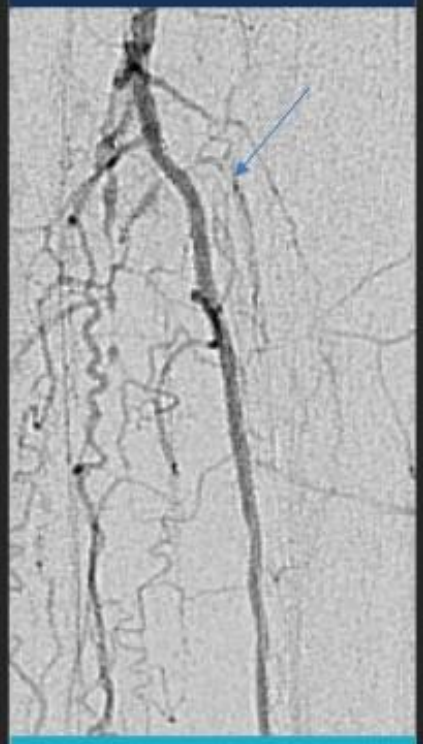
73% Stenosis
RVD: 2.7 mm, Length: 44.4

Fluoroscopic Image



Balloon Size : 2.5x60 mm

Final Angiogram



22% Stenosis
Acute Gain 1.6

BTK : Case Study 2

Conclusions

- Calcium is a challenge in endovascular treatment; found in both intimal and medial layers
- DISRUPT PAD has enrolled a difficult to treat patient population not frequently studied by other devices
  - Limited use of adjunctive balloons with 1% provisional stenting
  - Low rate of vascular complications, including no perforations, thrombosis or distal embolization events
  - Consistent and repeatable effectiveness outcomes including low residual stenosis and high acute gain
  - Sustained patency and TLR results through 6 months
- Endovascular outcomes in BTK treatment are poor, despite the multiple current therapies
- Early results of Lithoplasty in BTK lesions show consistent reduction in stenosis and no procedural complications, including distal embolization
- Familiar balloon-based technology that preserves future treatment options