SUPERA stent for Calcified Femoropopliteal Disease

Focused on Supera ; Vascular Mimetic Implants A Unique Class of SFA Technology

Seung-Woon Rha, MD, PhD

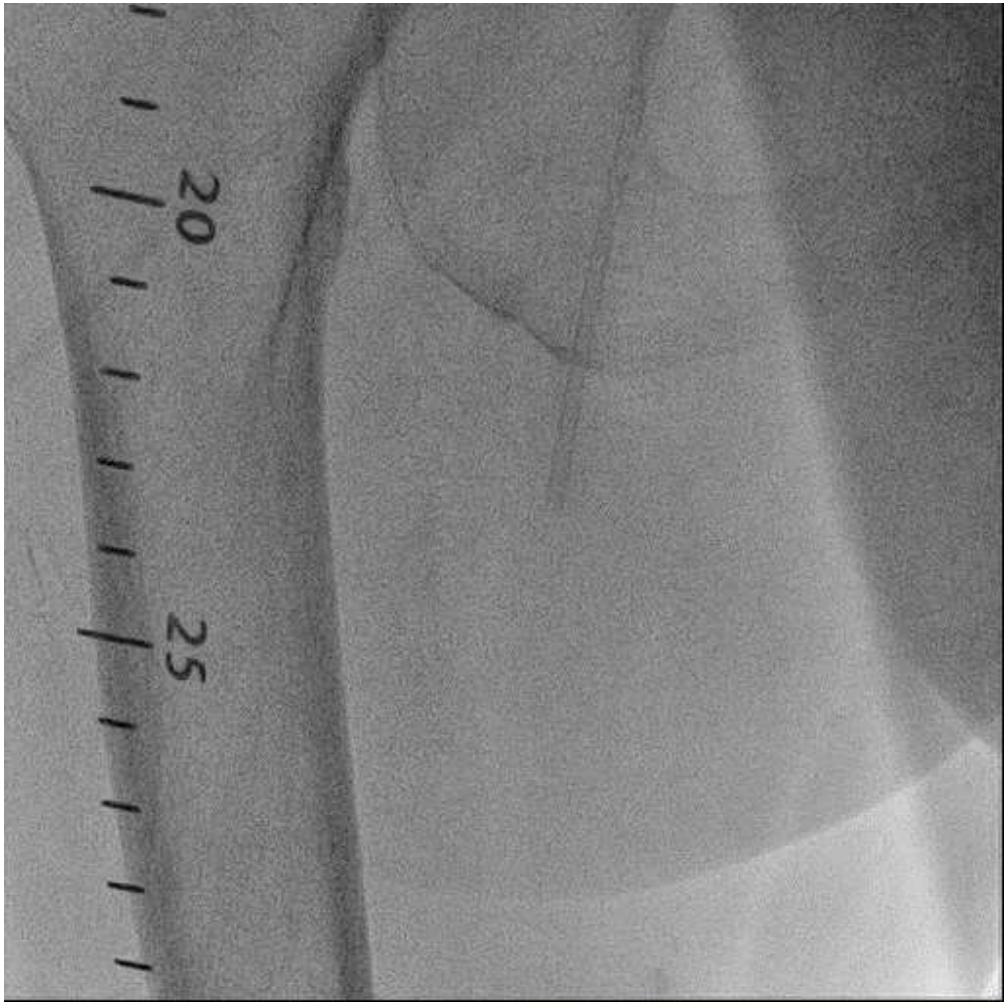
Cardiovascular Center,
Korea University Guro Hospital

Contents

Case 1. Rt popliteal calcified lesion

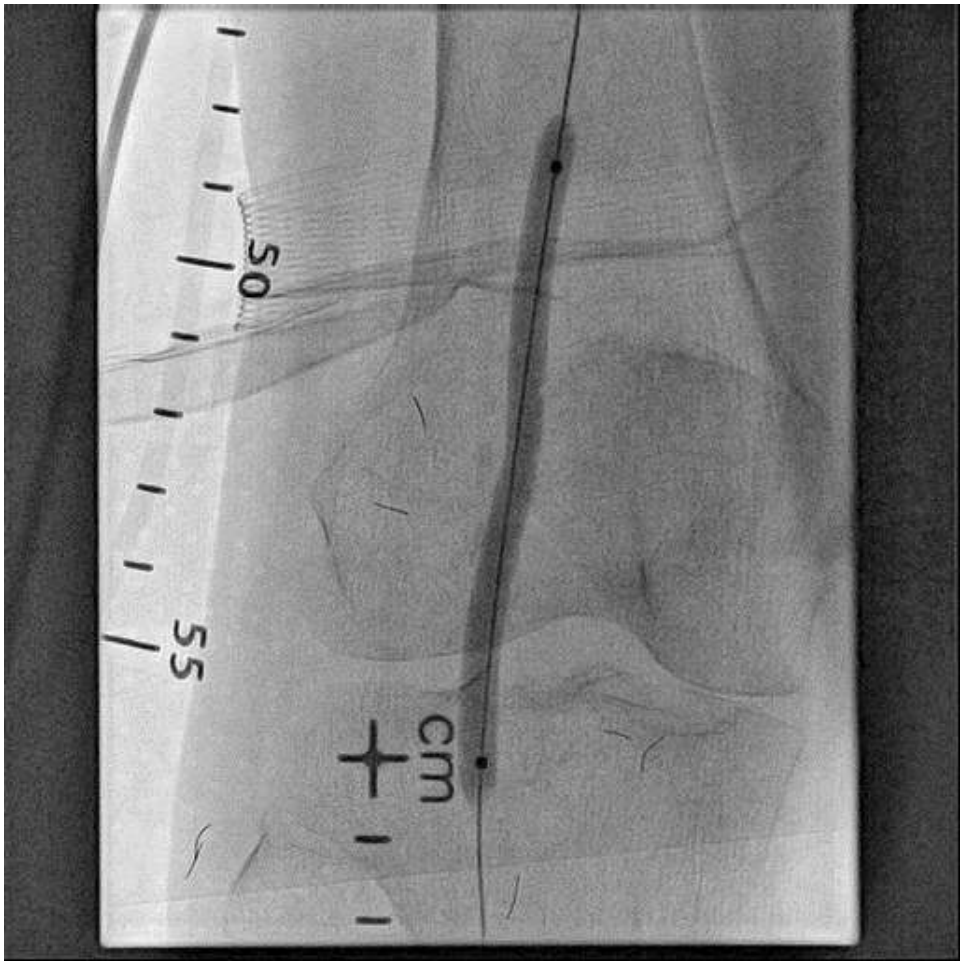
F/68, Rt DM foot

Baseline angiography



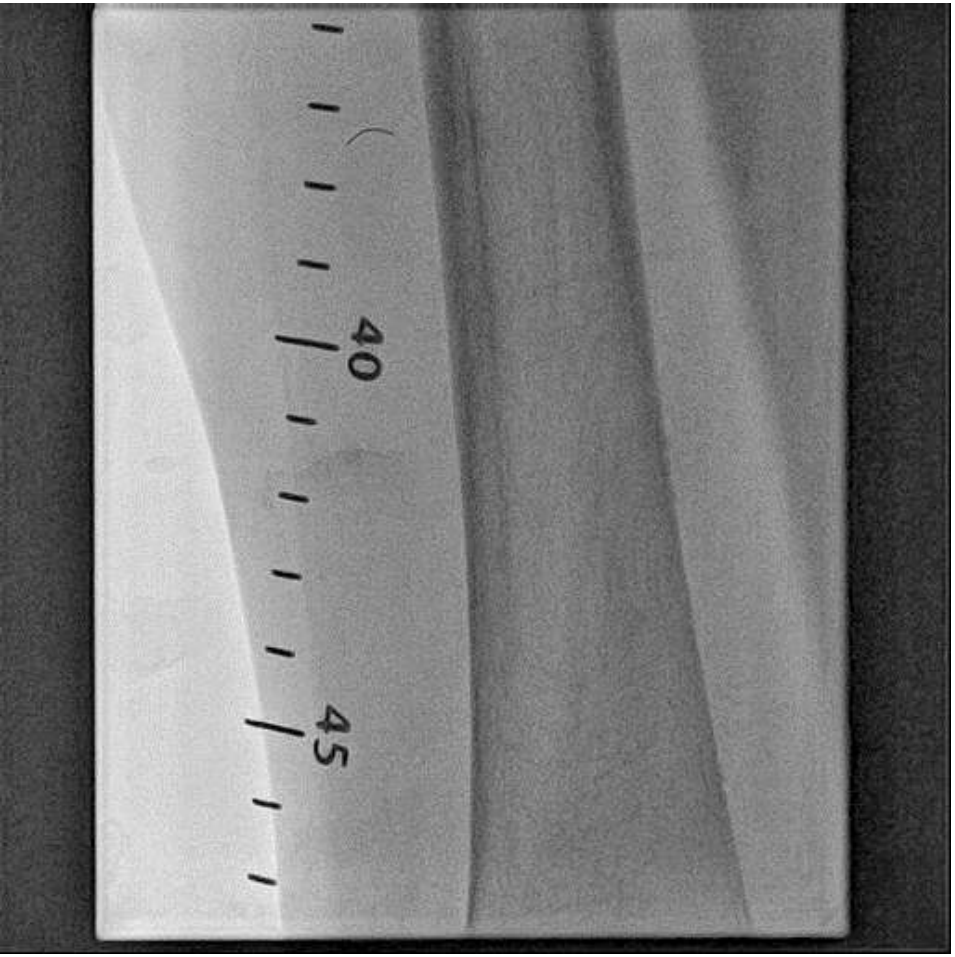
Intraluminal wiring; 018 Connect Flex

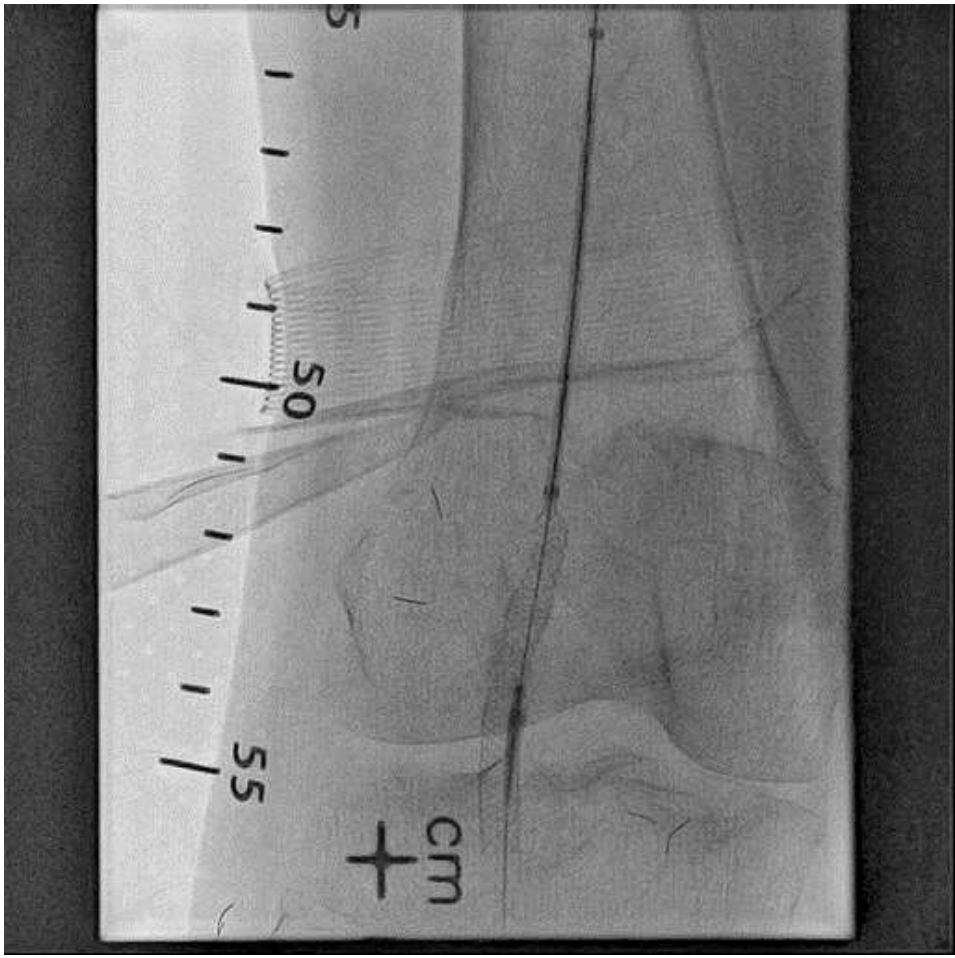
NC Balloon Dilation



Admiral and Mustang Ballooning (5.0X80mm)

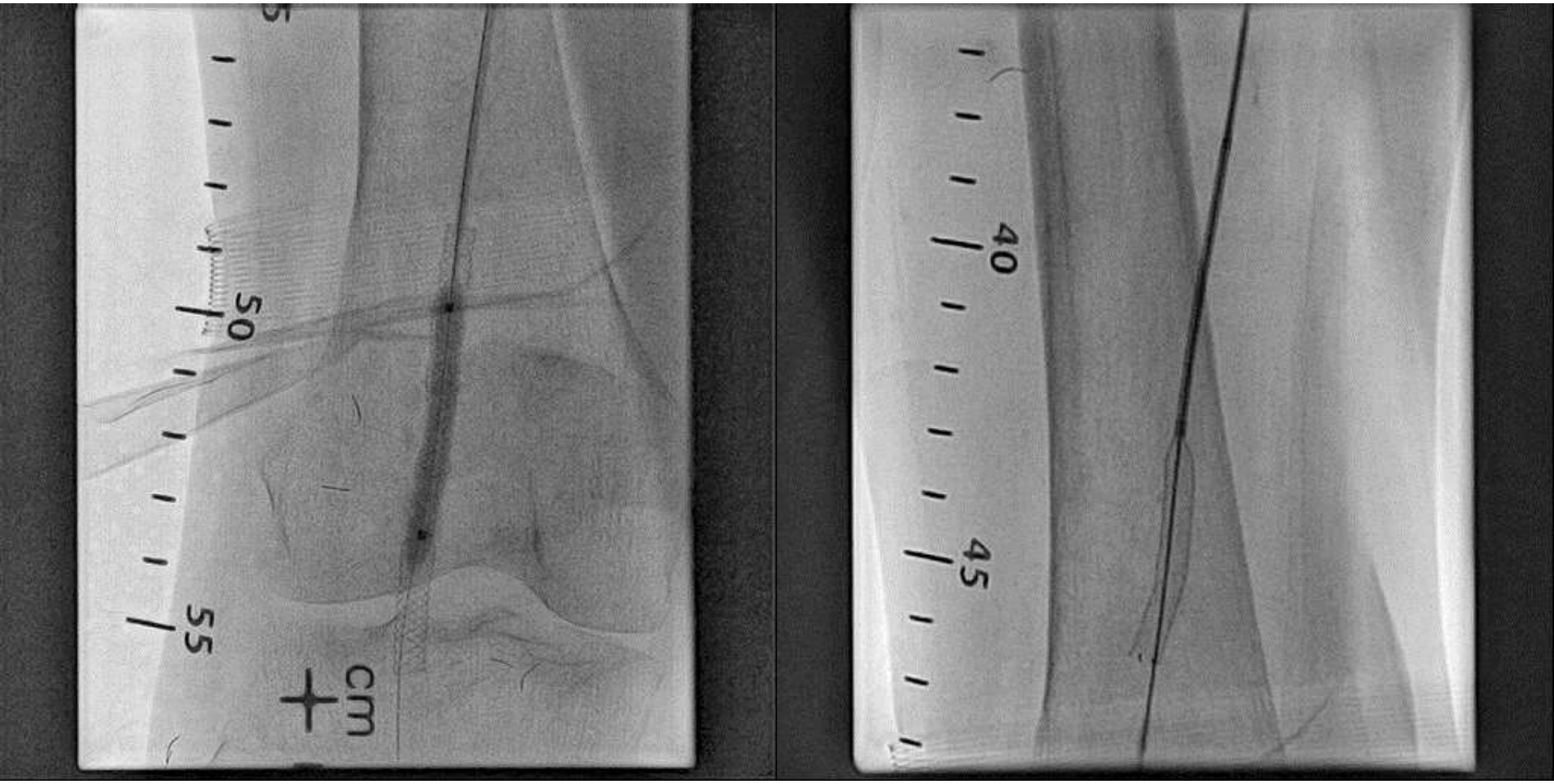
Post Balloon Dilation and Supera





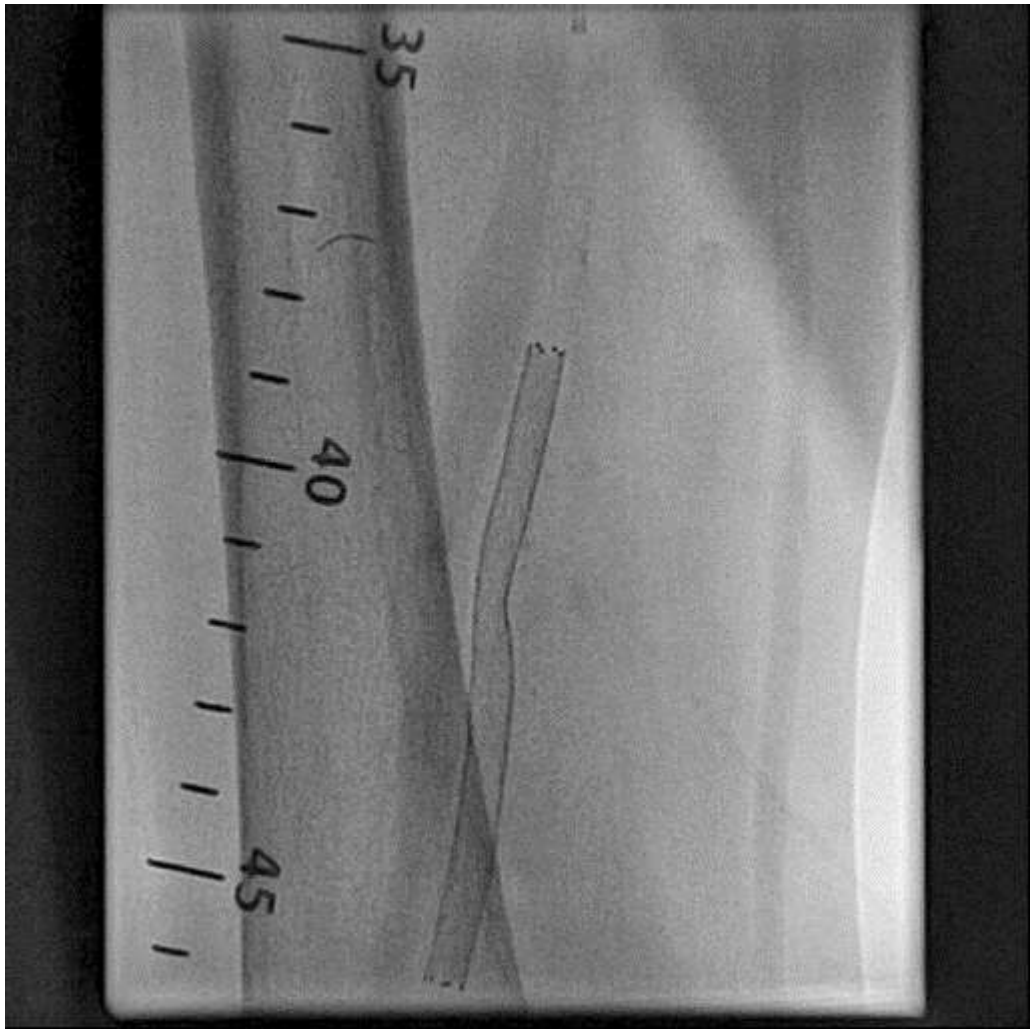
Supera 5.0X60mm

Adjuvant Ballooning and Another BMS to distal SFA



Smart 7.0X80mm

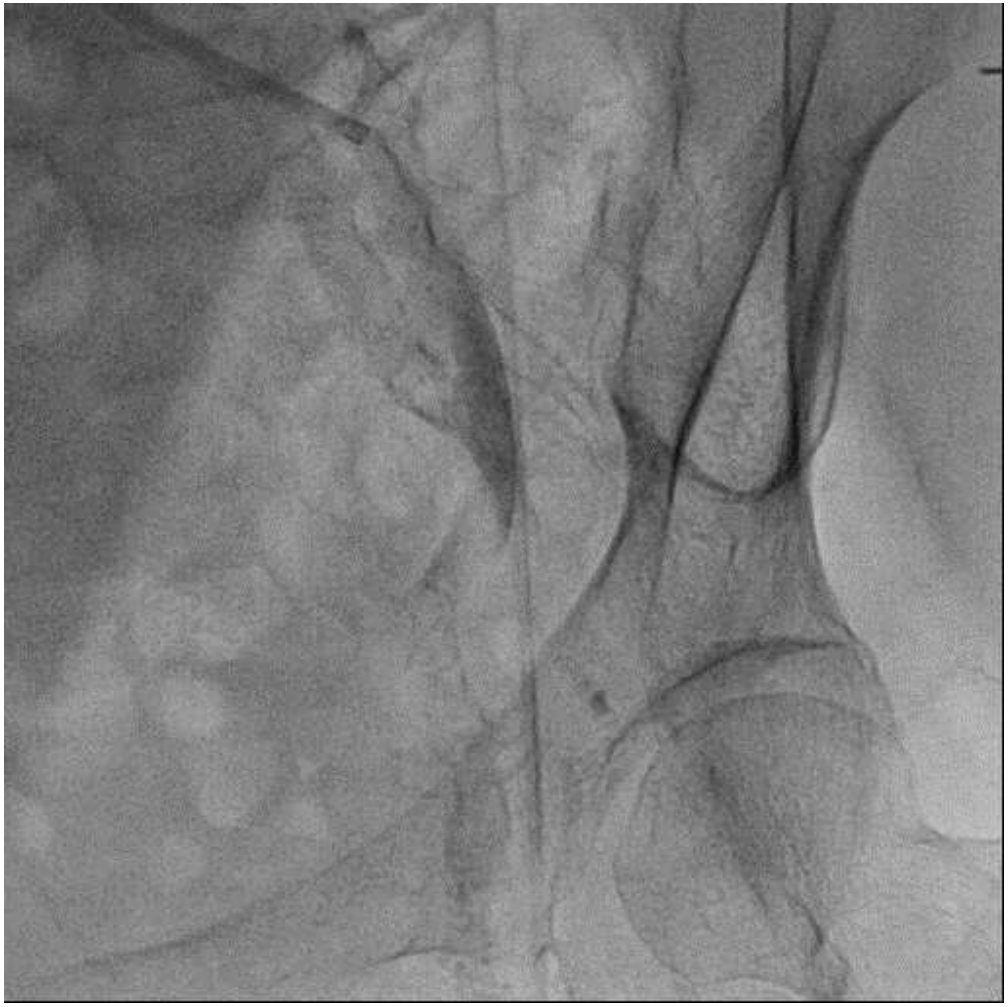
Final Angiography



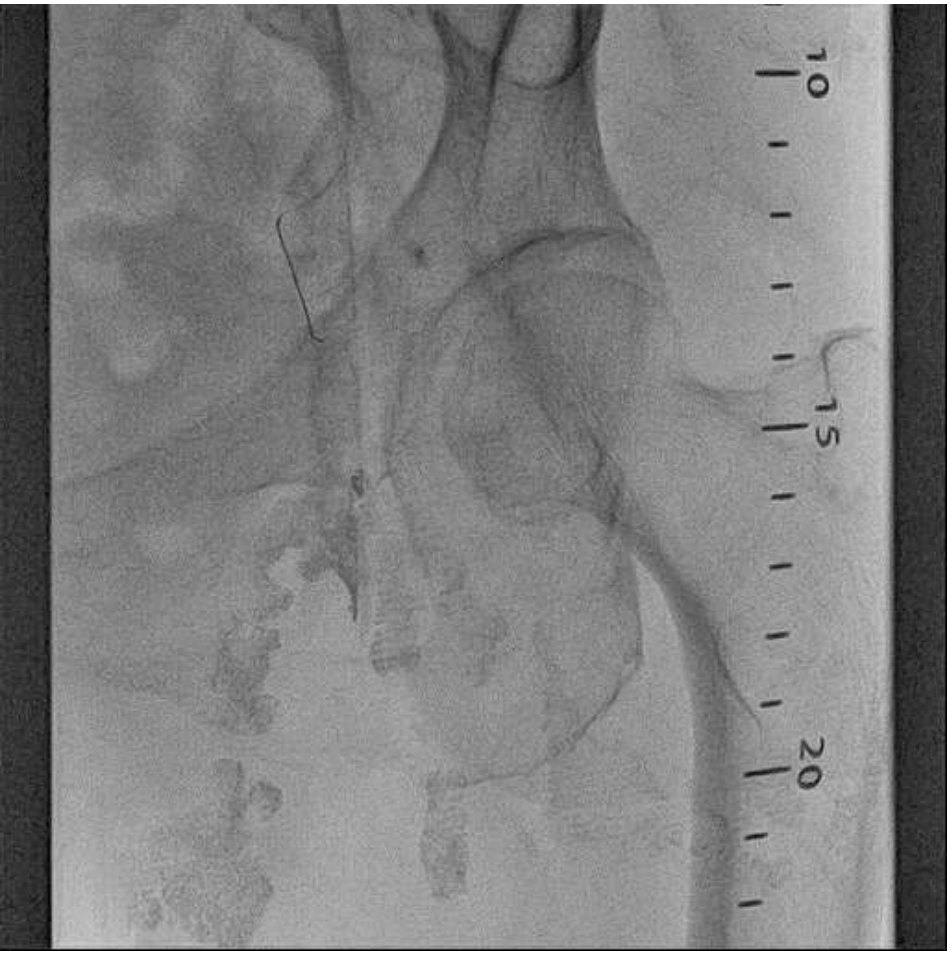
Case 2. Severely Calcified Common Femoral Artery

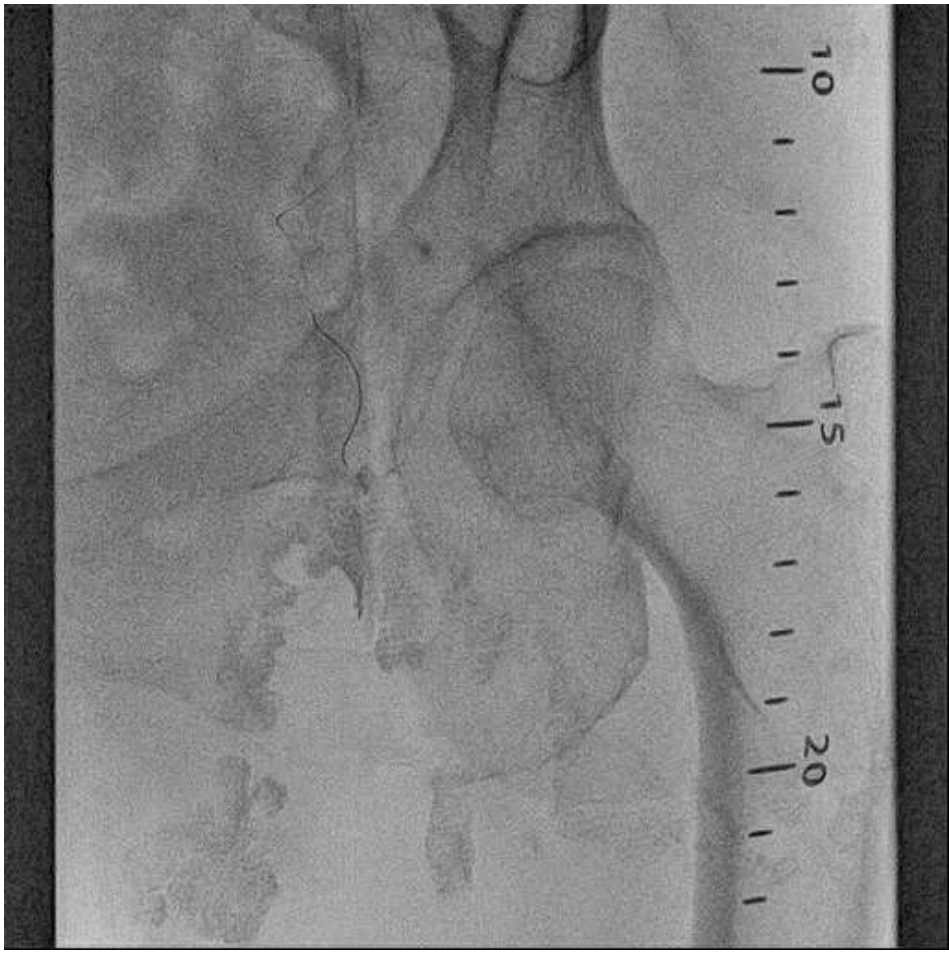
F/80, Claudication

Baseline Angiography

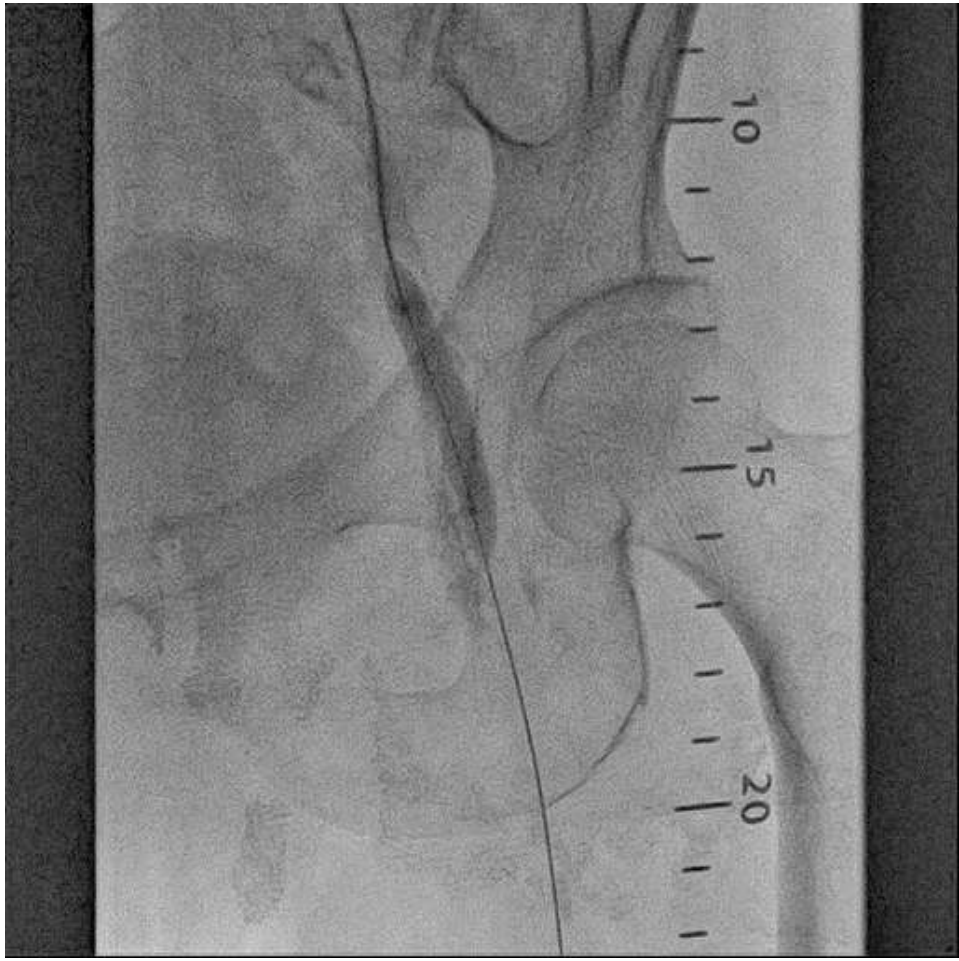


Intraluminal Wiring with 018 Connect Flex

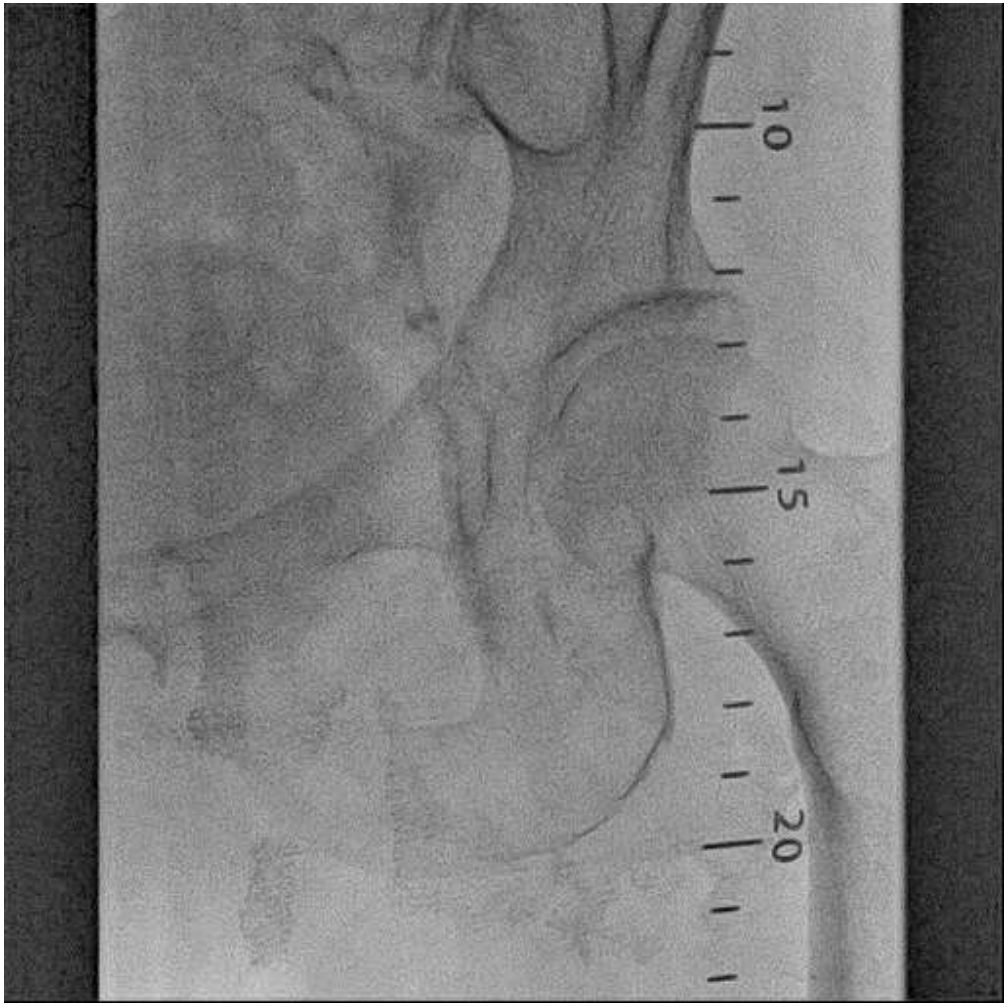




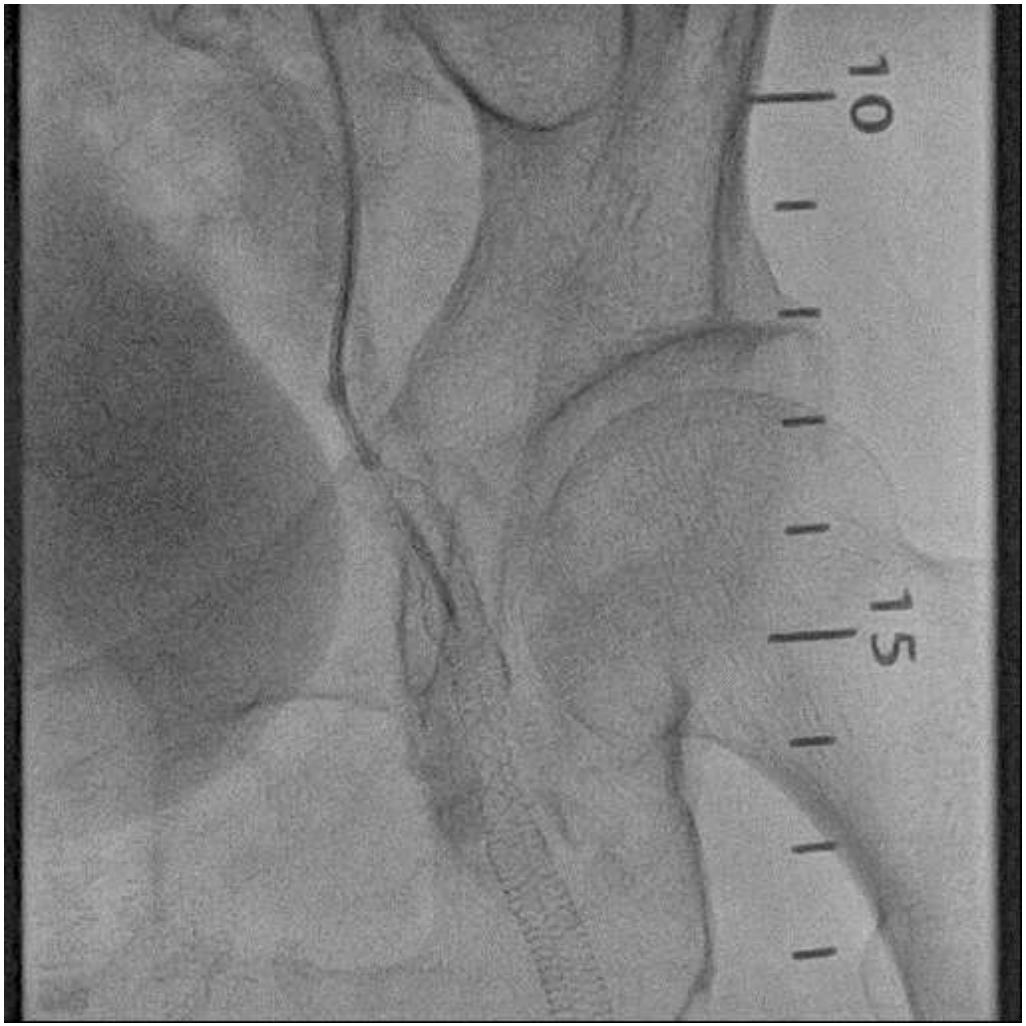
Predilation using NC Balloon



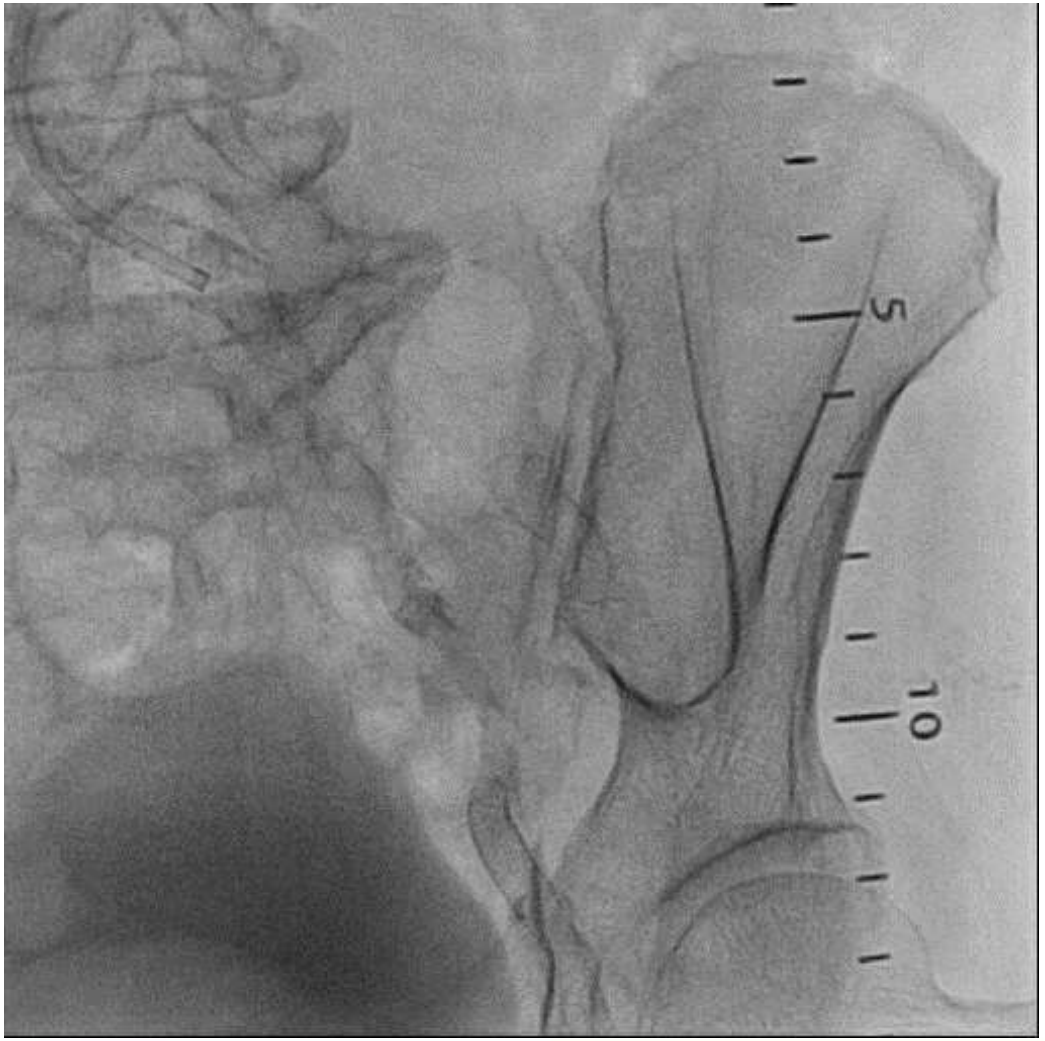
Post-predilation



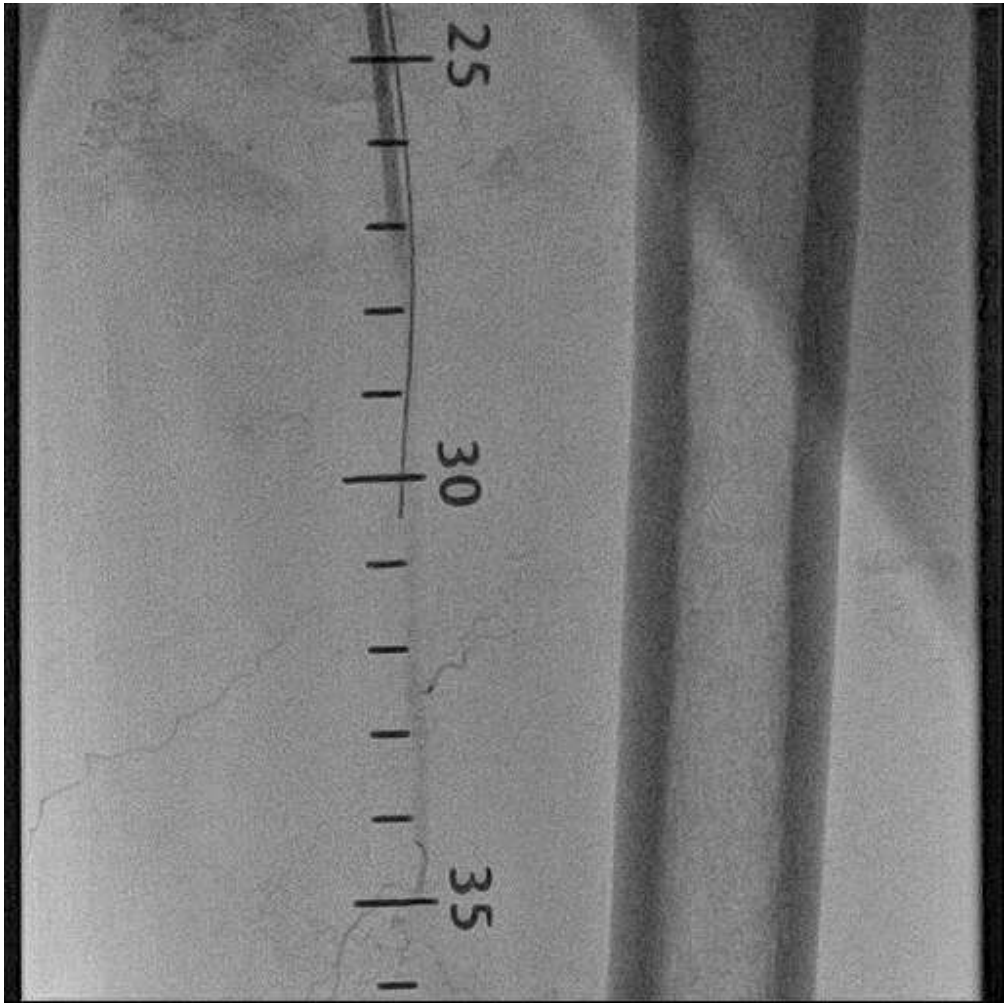
Supera-SFA to Common Femoral Artery



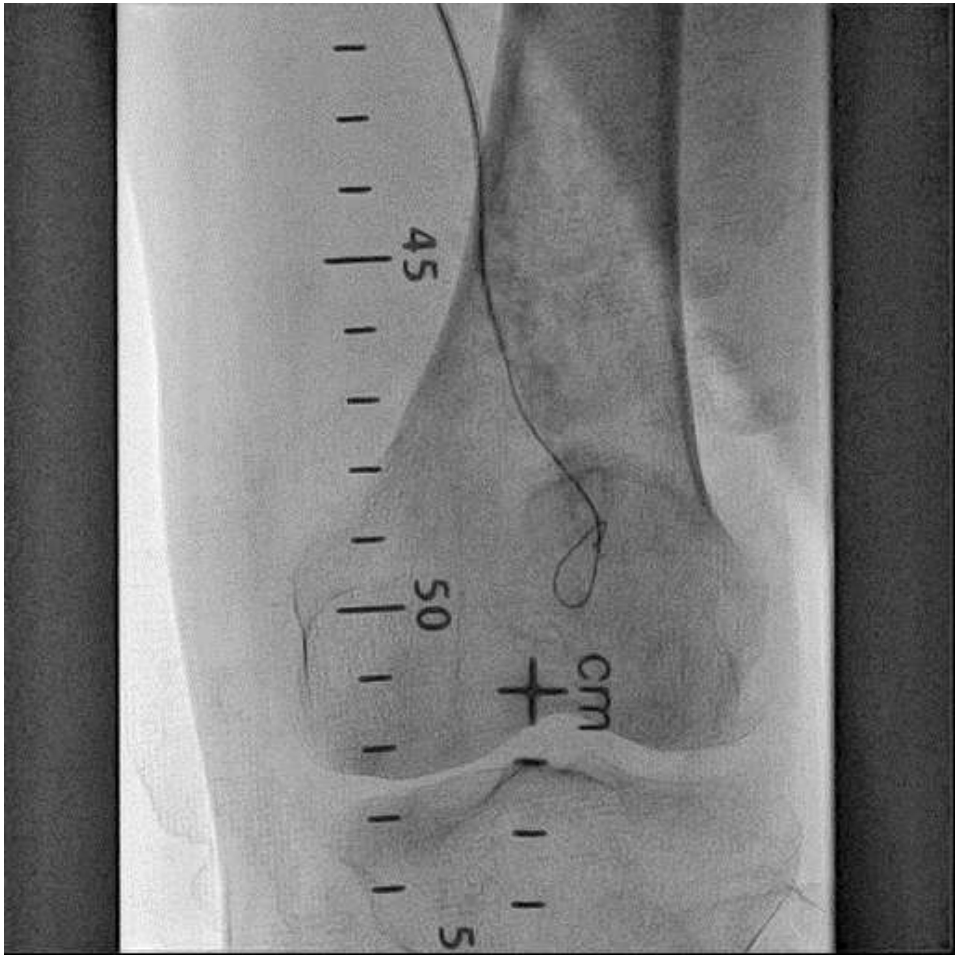
Final Angiography



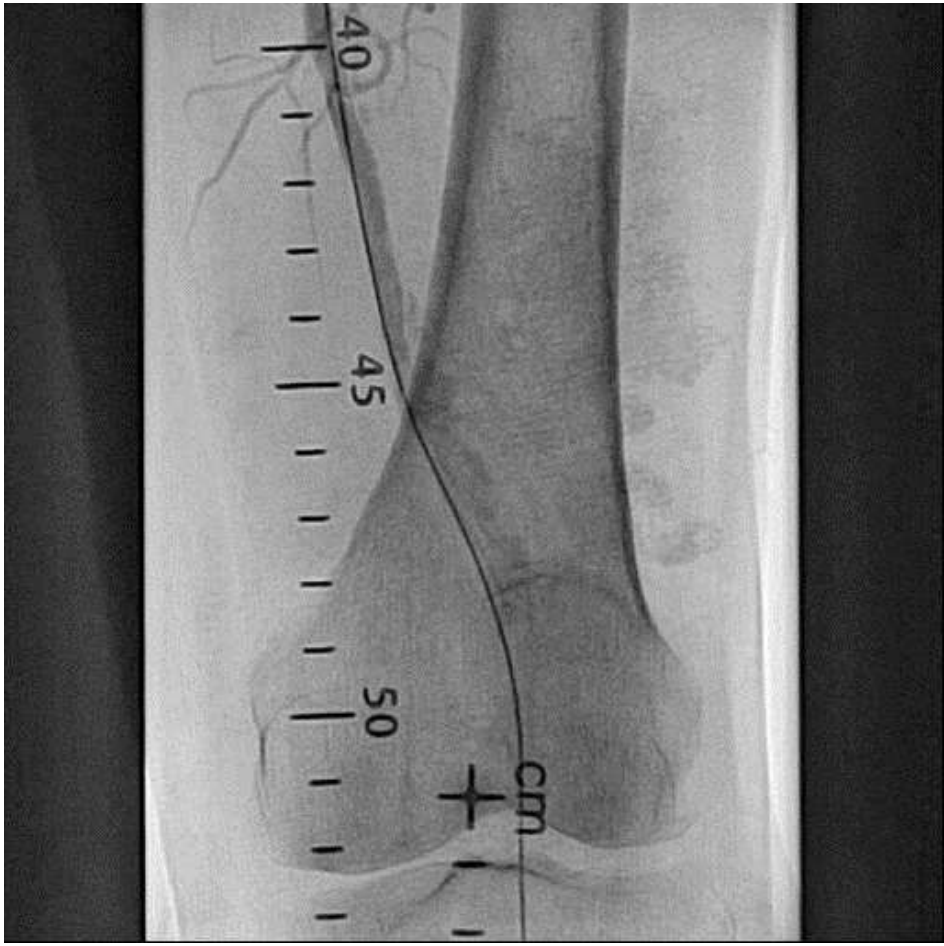
Case 3. Distal SFA Calcified Lesion



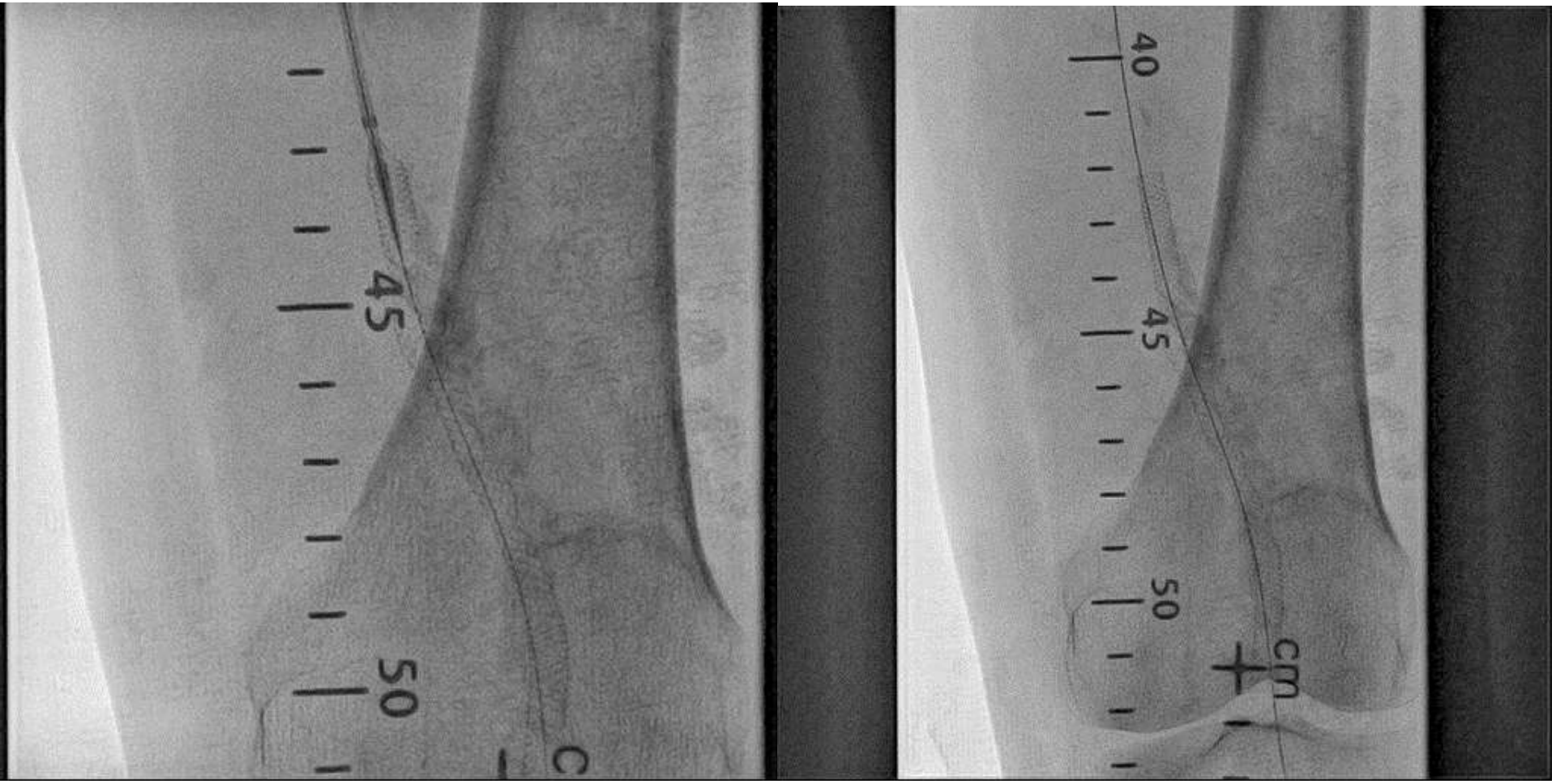
Wiring (Intraluminal and Subintimal)



Predilation



Supera-Distal SFA to Politeal Artery



Supera 5.0X80mm

SFA-Final

Balloon for PTA

	014	018	035
Abbott	Armada14	Fox cross	Armada35
Boston	Coyote (M)		*Mustang (NC)*
Cook	Advance 14 (M)	Advance 18	Advance 35
Cordis	Sleek (M)	Savvy	PowerFlex
Medtronic	Amphirion (M)		***InPact (DCB)***
Covidien	Nanocross		Evercross
Biotronik	Passeo 14	Passeo 18 ***Passeo-18 Lux (DCB)***	Passeo 35, *Passeo 35-HP (NC)*
Bard			Rival, *Conquest (NC)* ***Lutonix (DCB)***

*M; monorail type available
NC; Non-compliant balloon
DEB; Drug-eluting balloon

Stents for PTA

	014/018	035	
Abbott	Xpert (SES), **Supera**	Absolute Pro	Omnilink (BES)
Bard		LifeStent	
Cordis	Precise (SES)-Carotid Palmaz Blue/Genesis (BES)-Renal	*Smart*	
Gore		**Viabahn** (Stentgraft)	
Cook		Zilver, Zilver PTX (DES)	
Medtronic	Maris deep (SES);014 & 018 Chromis Deep (BES)	Complete SE	Scuba (BES)
Boston		Wall Stent, Epic, Inova, Eluvia (DES)	
Covidien		Protege	
Biotronic	Pulsar (018)	Pulsar (035)	
Terumo		Misago	

*SES; Self-expanding stent, BES; Balloon-expandable stent,
DES; Drug-eluting stent **BTK stents; disappeared in the market

Plaque Modification/Debulking Devices in Korea

1. Cutting balloon (Boston)
2. Scoring Balloon; *Vascutrak (Bard),* AngioSculpt (Spectranetics) or NSE balloon (Goodman)--pending
3. Directional Atherectomy Device

   ; Silverhawk, Turbohawk, HawkOne (Covidien)
4. Jetstream (Boston)
5. Rotablator (Boston)

SUPERB Results

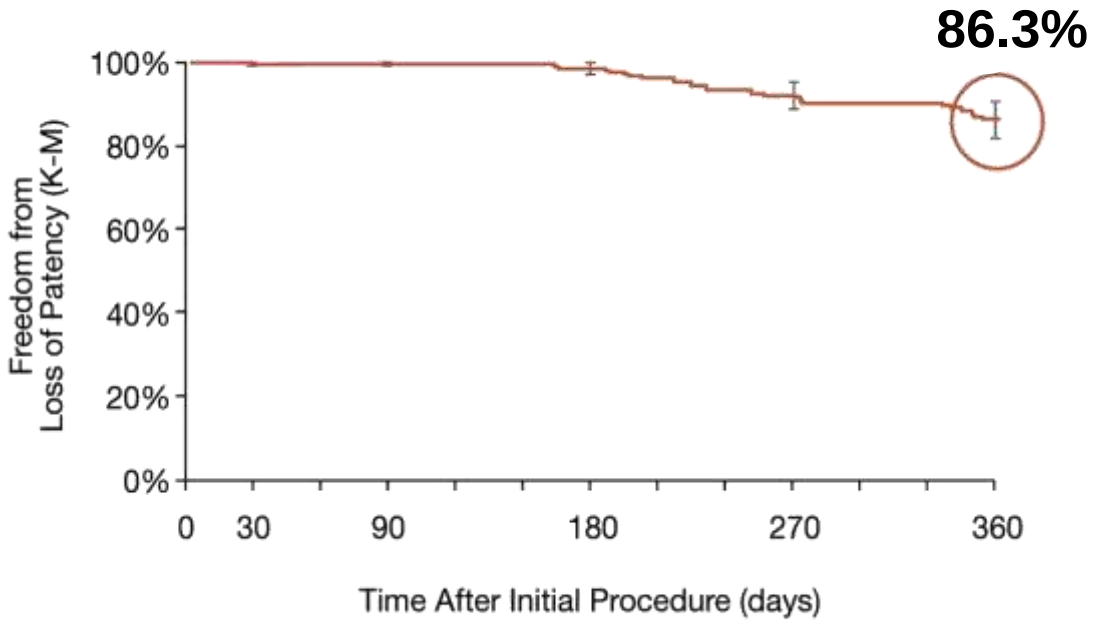
Safety and efficacy demonstrated with the Supera implant

1-year Results:

- Primary Patency (K-M) of 86.3%[1]
- Zero fractures
- Significant improvement in ABI at 12 months versus baseline[2] and 89% of patients have improved more than 1 Rutherford-Becker clinical category at 12 months

2-year Results:

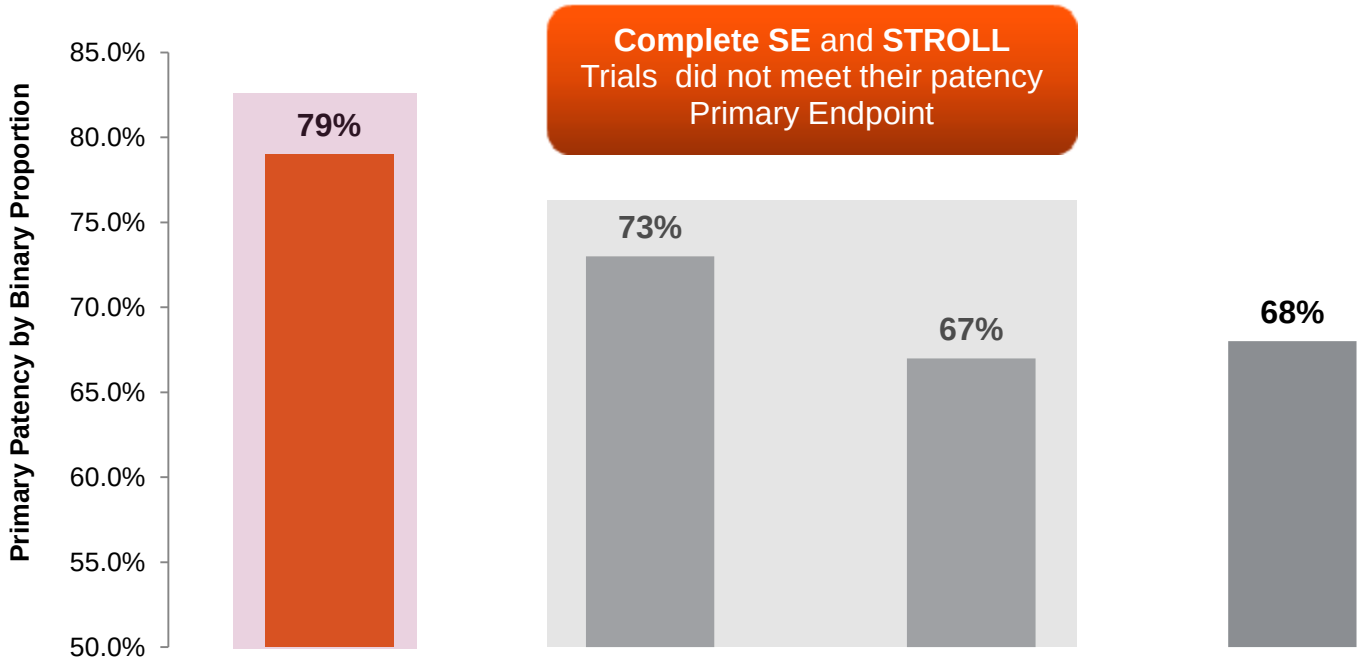
- 84% Freedom from TLR
- 0.5% fracture[3]



Source: Clincal data on file at Abbott Vascular.
1. PSVR < 2.0.
2. Garcia, L., *SUPERB Pivotal IDE Trial, 12-Month Results*, TCT 2012 for Ankle-Brachial Index improvements.
3. One patient (1/200, 0.5%) experienced a Type III fracture at 24 months. The patient had a revascularization with directional atherectomy for in-stent restenosis at 9 months post index procedure. At 12-month follow up there was no evidence of a stent fracture. Additional in-stent restenoses were treated twice more with directional atherectomy between the 12- and 24-month evaluations. At 24 months, a type III fracture was noted in x-ray in the region of the earlier restenoses. There was no report of a major adverse event at 24 months.

MENU

SFA IDE Trial 12 Month Results Patency (VIVA Criteria (Binary Proportion (BP))



Stent	Supera	Complete SE	S.M.A.R.T	EverFlex
Patients	264	196	250	287
Avg Lesion Length (cm)	7.8	6.1	7.7	8.9
Fracture Rate (%)	**0**	**0**	2.0	0.4
Occlusion (%)	25	30	24	48
CD-TLR (%)	10.6*	8.4	12.4	13.9*
Primary Patency (%) (K-M)	86.3	90.9	81.7	77.2
PSVR	**2.0**	2.0	2.0	2.0

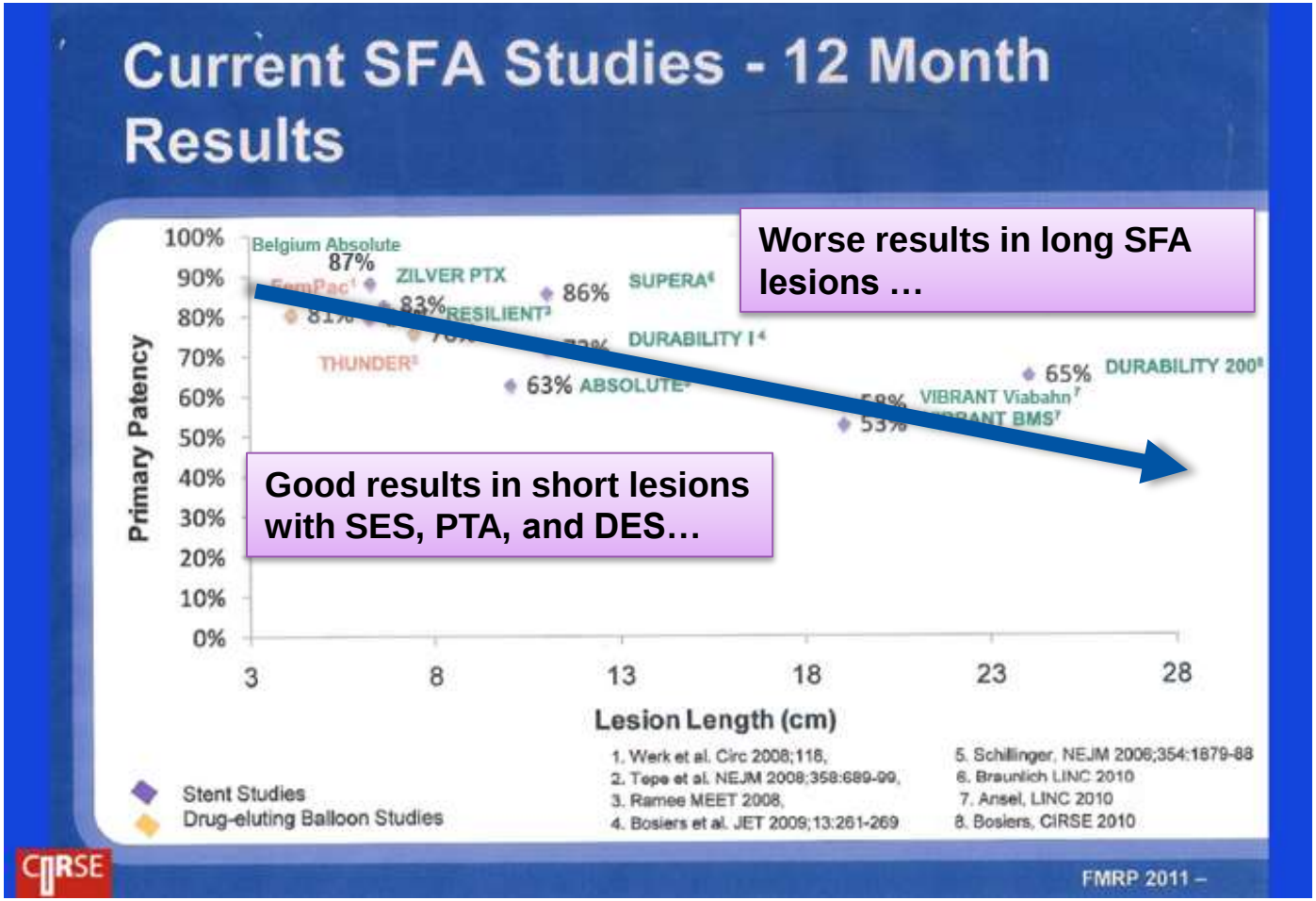
Sources: US Complete SE Stent IFU, US S.M.A.R.T Stent IFU. SUPERB clinical data on file – Supera : Clinical data on file at Abbott Vascular, US EverFlex IFU, US EverFlex SSED

Note: Results from Clinical Trials are not directly comparable. Information provided are for educational purposes only.

* By Kaplan-Meier estimated TLR

MENU

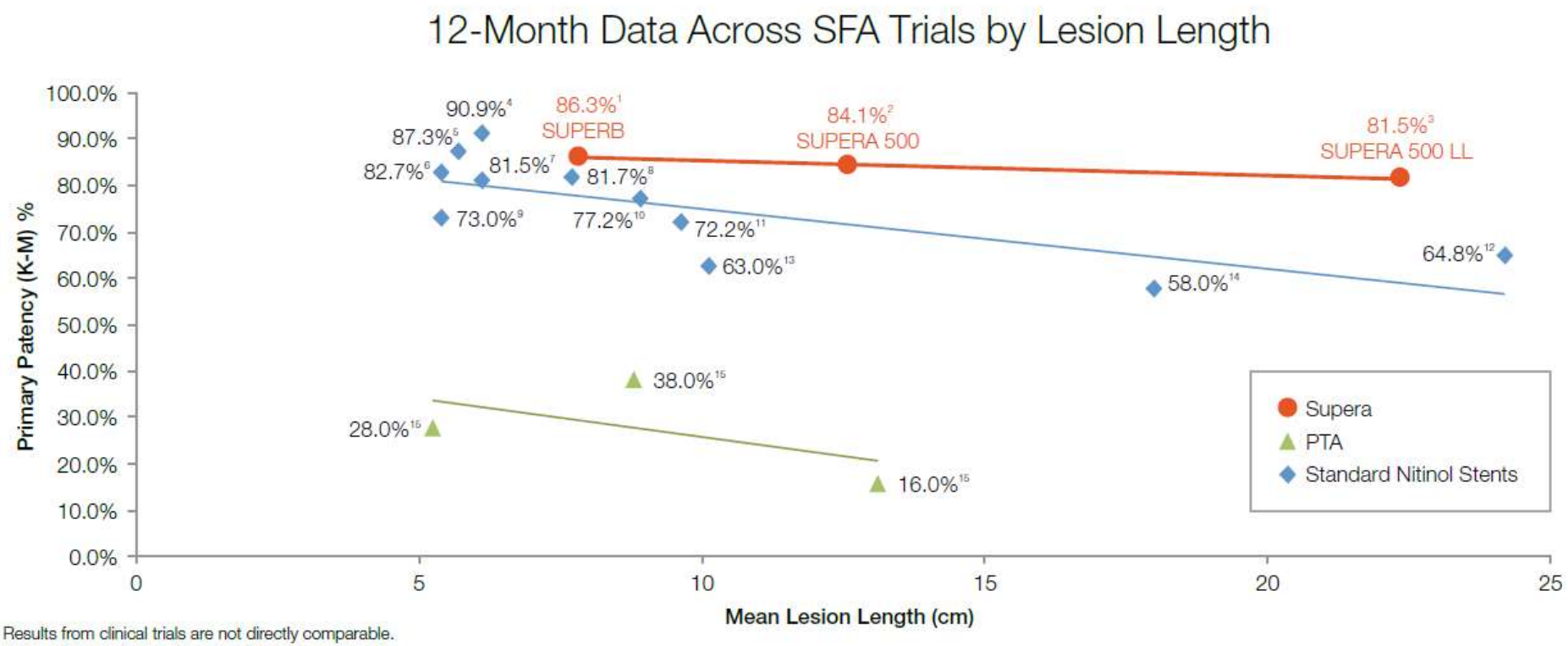
Limitations of SFA Technologies
Performance Decreases as Lesion Get Longer



DCB, drug-coated balloon; DES, drug-eluting stent; SES, self-expanding stent; SFA, superficial femoral artery.
Modified from Shroë H. *Superficial femoral artery PTA or stenting? 5-Year results*. CIRSE 2011; Munich, Germany.

MENU

Consistent Data Even in Very Long Lesions

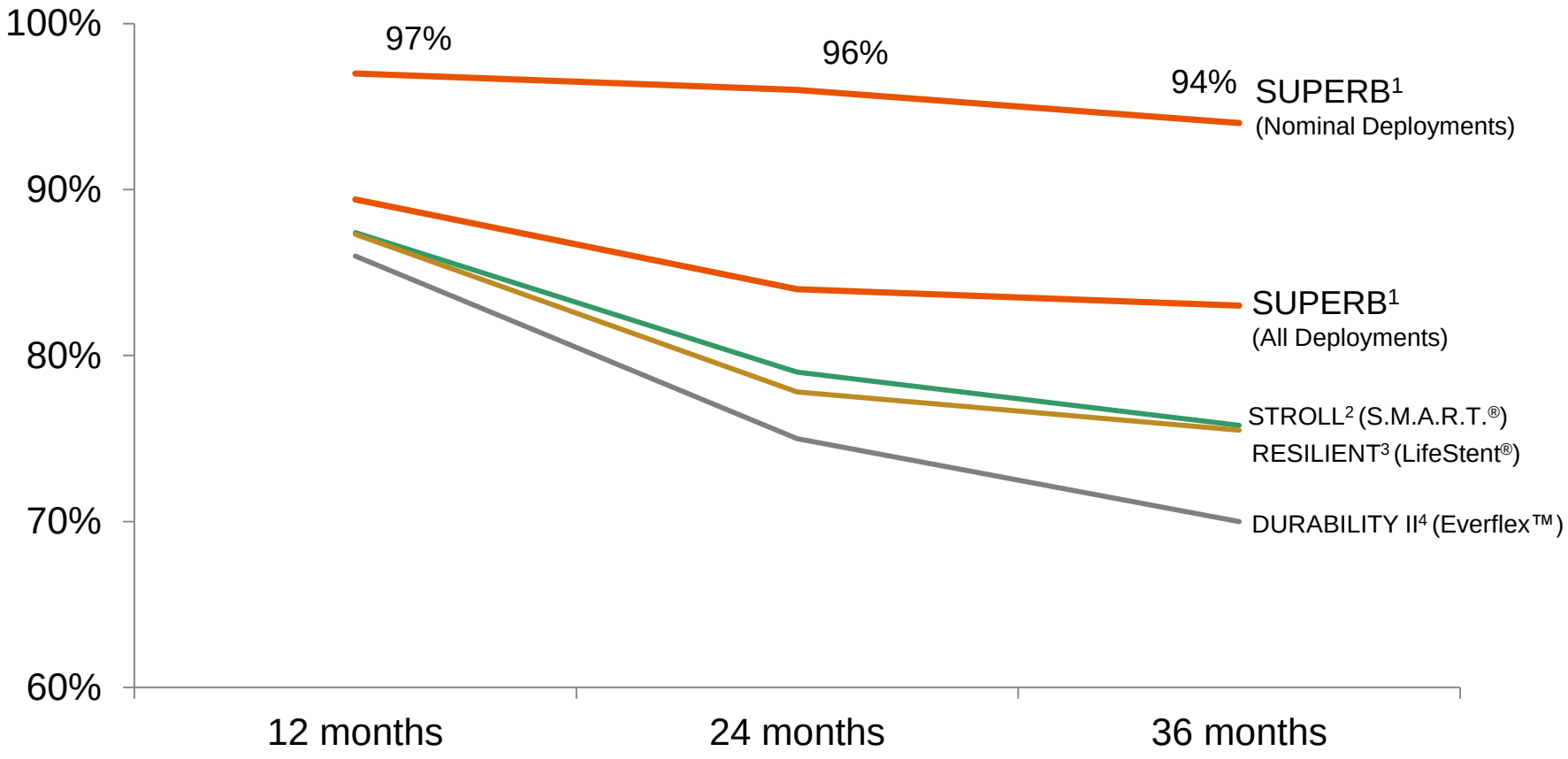


Results from clinical trials are not directly comparable.
Information provided is for educational purposes only.

1. SUPERB: Garcia, L., Rosenfield, K., et al., SUPERB Pivotal IDE Trial, 12-Month Results, TCT 2012.
2. SUPERA 500: Scheinert, D. Results from the SUPERA 500 Registry. LINC 2013.
3. SUPERA 500 Long Lesions: Scheinert, D. Results from the SUPERA 500 Registry. LINC 2013.
4. COMPLETE SE: IFU, Complete SE.
5. Belgian ABSOLUTE: Schroe, H. Absolute BELGIAN study. CIRCE 2008.
6. ZILVER PTX IFU/SSED.
7. RESILIENT: IFU, LifeStent.
8. STROLL: Ansel, G. STROLL Trial. LINC 2013.
9. ZILVER PTX (BMS arm): Dake, M.D., Ansel, G.M., Jaff, M.R., et al. Paclitaxel-Eluting Stents Show Superiority to Balloon Angioplasty and Bare Metal Stents in Femoropopliteal Disease: Twelve-Month Zilver PTX Randomized Study Results. Circ Cardiovasc Interv. 2011:4(5):495–504.
10. DURABILITY II: Everflex Instructions for Use.
11. DURABILITY I: Bosiers, M., Torsello, G., Gissler, H.M., et al. Nitinol Stent Implantation in Long Superficial Femoral Artery Lesions: 12-Month Results of the DURABILITY I Study. J Endovasc Ther. 2009;16(3):261–269.
12. DURABILITY 200: Bosiers, M. Durability 200 Study. LINC 2011.
13. Vienna ABSOLUTE: Schillinger, M., Sabeti, S., Loewe, C., et al. Balloon Angioplasty Versus Implantation of Nitinol Stents in the Superficial Femoral Artery. N Engl J Med. 2006;354(18):1879–1888.
14. VIBRANT (BMS): Ansel, G. One-year interim results: Gore VIBRANT clinical study. LINC 2010.
15. Rocha-Singh, K.J., Jaff, M.R., Crabtree, T.R., Bloch, D.A., Ansel, G.; VIVA Physicians, Inc. Performance Goals and Endpoint Assessments for Clinical Trials of Femoropopliteal Bare Nitinol Stents in Patients with Symptomatic Peripheral Arterial Disease. Catheter Cardiovasc Interv. 2007;69(6):910–919.

MENU

Excellent Freedom From Clinically Driven TLR Through 3 Years

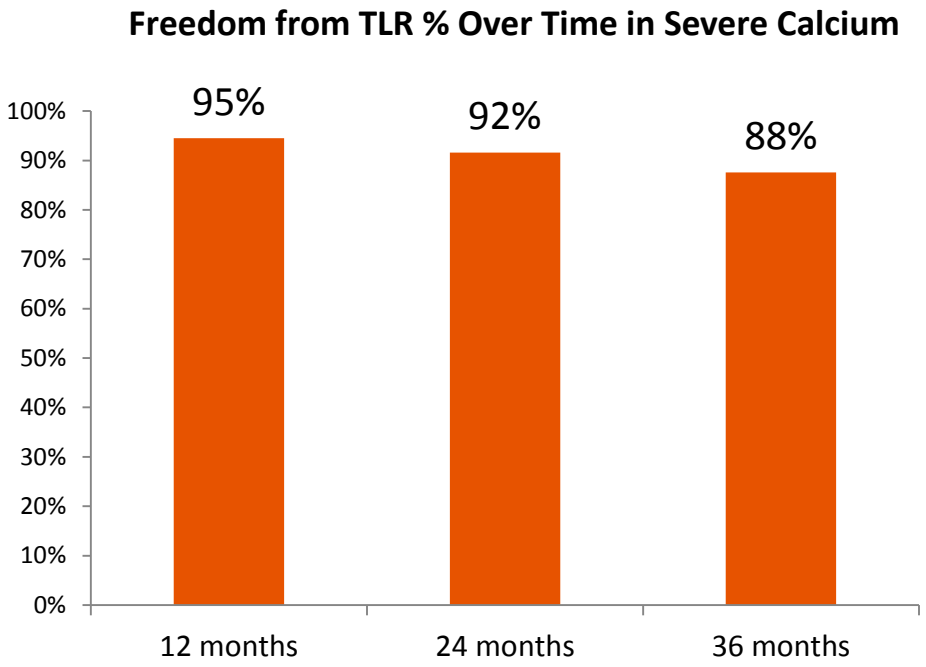


1. Clinical data on file at Abbott Vascular.
2. STROLL 1-year, G. Ansel, LINC 2013; 2-year, W. Gray ISET 2013. 3-year, M Jaff ISET 2014
3. Laird, J. Journal of Endovascular Therapy 2012;19:1–9
4. DURABILITY II, K Rocha-Singh, VIVA 13; M Razavi ISET 2014.

Data differences depicted between these trials may not be statistically significant or clinically meaningful and different clinical trials may include differences in the demographics of the patient populations.

MENU

Supera® Has Strong Clinical Outcomes in Calcification at 3 Years



SUPERB Data - Severe Calcification

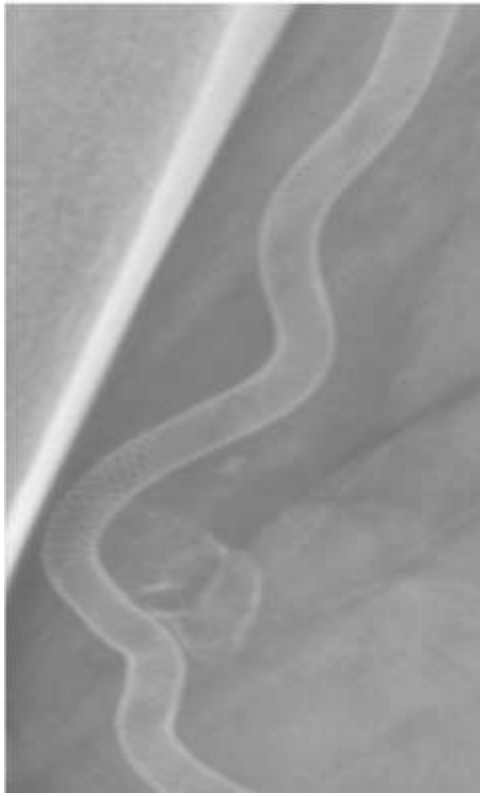
% of Lesions with Severe Calcification (SUPERB Trial)	45% (n=118)
Patency (VIVA 12 months)	89%

Data on file at Abbott Vascular.

0 Stent Fractures at 12 Months in SUPERB

Assessed by core lab review of AP and lateral X-ray views

Stent Fracture	12 Months (N=243)	24 Months (N=200)	36 Months (N=162)
Single strut	0.0%	0.0%	0.0%
Multiple strut	0.0%	0.0%	0.0%
Complete fracture/ fragments aligned	0.0%	0.5%*	0.6%*
Complete fracture/ fragments mal-aligned	0.0%	0.0%	0.0%
Spiral fracture	0.0%	0.0%	0.0%



Source: Supera Peripheral Stent System, Clinical data on file at Abbott Vascular. Image from SUPERB trial. Data on file at Abbott Vascular.
Image courtesy of Dr. Hans Biemans, Rivas Hospital Gorinchem, the Netherlands.
Evaluated by X-ray [anterior-posterior (AP) and lateral views in both straight and flexed knee positions] per an independent core lab.
* One subject experienced a Type III fracture at 24 months after three directional atherectomy procedures to treat in-stent restenosis

MENU

Results of DCB in Complex Pathology: *Calcified Lesions*

Cardiovasc Intervent Radiol
DOI 10.1007/s00270-014-0904-3

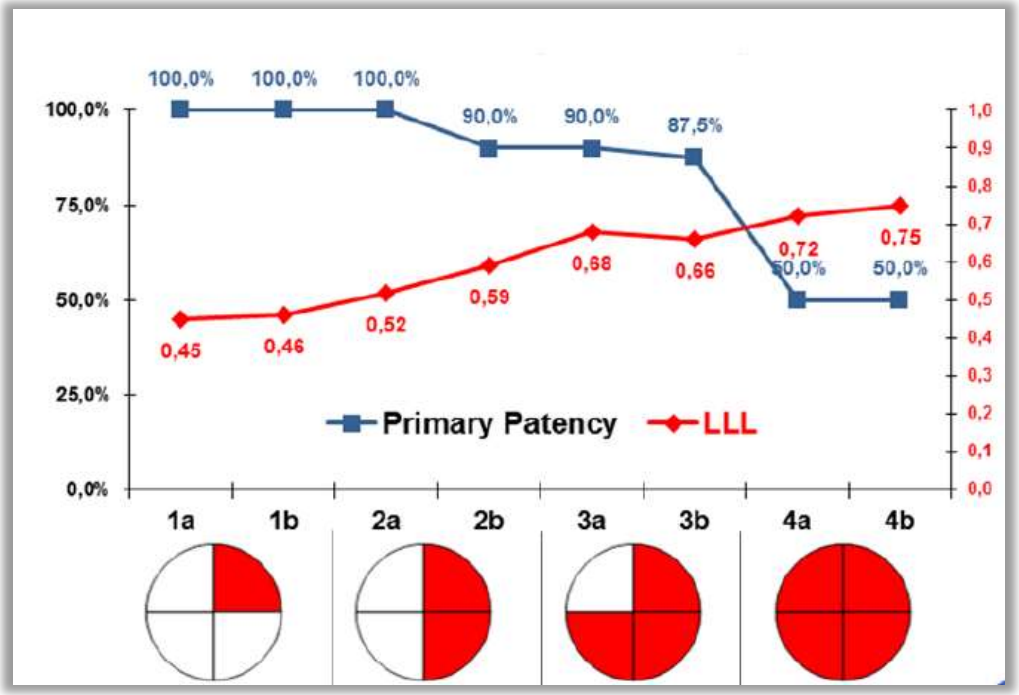
CLINICAL INVESTIGATION

Calcium Burden Assessment and Impact on Drug-Eluting Balloons in Peripheral Arterial Disease

F. Fanelli · A. Cannavale · M. Gazzetti · P. Lucatelli · A. Wlderk · C. Cirelli · A. d'Adamo · F. M. Salvatori

Received: 19 February 2014 / Accepted: 2 April 2014

- Paclitaxel must transfer from balloon into vessel wall
- Extensive calcification or thrombus may act as a barrier to drug diffusion



Primary patency & late lumen loss were both negatively impacted by increasing calcification, with the worst results in patients with circumferential calcification (Fanelli F, et al. Cardiovasc Int Radiol 2014)

Fanelli, F. Calcium Burden Assessment and Impact on Drug-Eluting Balloons in Peripheral Arterial Disease. Cardiovasc Intervent Radiol. 2014 May 9.

DCB vs. Existing Modalities for SFA/Pop Interventions

Supera works well in the challenging clinical scenarios of calcium, acute recoil, and long lesions.

	DCB		Supera 	
Severe Calcification	–	Excluded from and/or low rates of in trials[1,2]; calcium represents a barrier to optimal drug absorption.[3]	+	5% TLR* in Severe Calcium at 1 year in SUPERB[4]
Acute Recoil or Dissections	–	Stent/Implant needed to treat. (Flow-limiting dissections can occur up to 40% of time[6])	+	>4x the compression resistance of SNS[5]
Long Lesions	–	Data not yet available in US	+	High freedom from restenosis is consistent across all lesion lengths in SUPERB[4]

1 Lutonix FDA Executive Summary
2 IN.PACT Admiral Summary of Safety and Effectiveness Data
3 Fanelli, F. Calcium Burden Assessment and Impact on Drug-Eluting Balloons in Peripheral Arterial Disease. Cardiovasc Intervent Radiol. 2014 May 9.
4 SUPERB 3 Year Garcia VIVA 2014
5 Data on file at Abbott Vascular.
6 Granada, J. Current Landscape, Opportunities and Challenges for DCB Technologies. TCT 2013.

DCB image courtesy of http://www.medgadget.com/

Supera image: Photo on file at Abbott Vascular

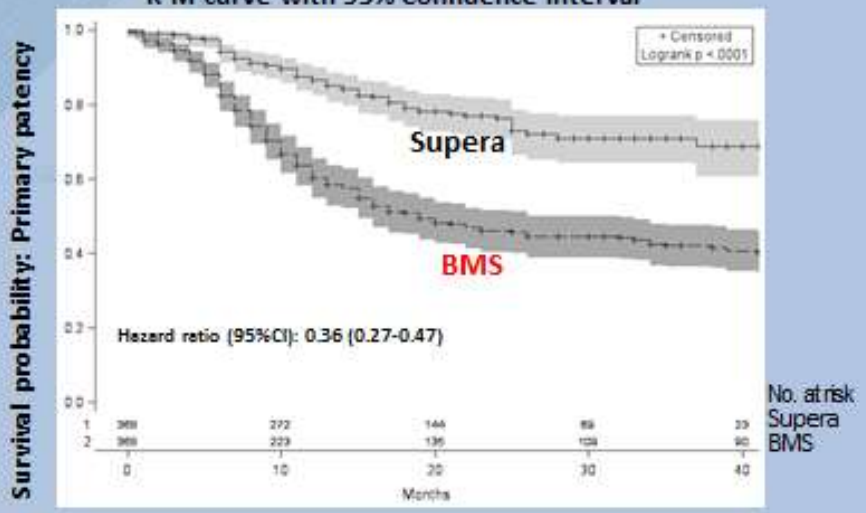
*TLR by KM

Supera Outperfoms BMS and DCB in Real World Patients

Supera - BMS

Matched Cohort:	Supera	BMS	P-Value
Lesion length, mm	130 ± 83	139 ± 100	0.2
Instent restenosis, %	16	16	0.9

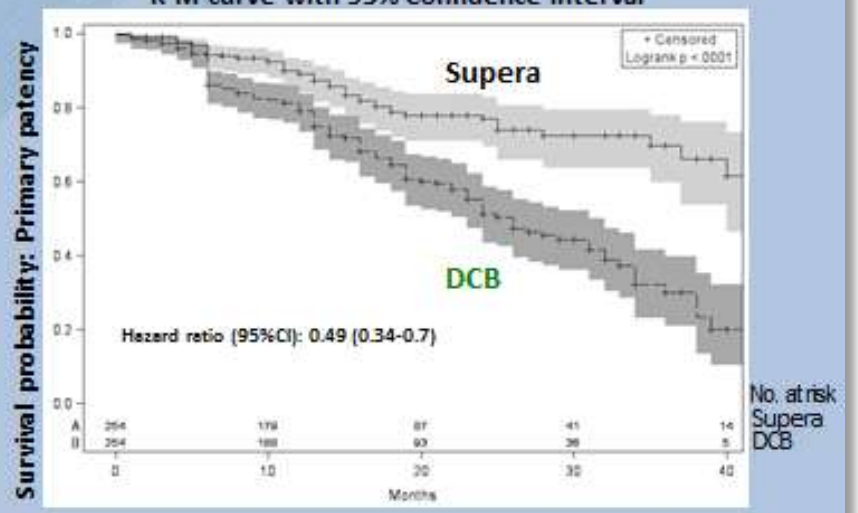
K-M curve with 95% Confidence Interval



Supera -DCB

Matched Cohort:	Supera	DCB	P-Value
Lesion length, mm	143 ± 92	157 ± 102	0.09
Instent restenosis, %	16	17	0.6

K-M curve with 95% Confidence Interval



- Real world data of patients undergoing femoropoliteal interventions
- Different patterns of disease progression observed with DCB, conventional and interwoven nitinol stents
- Limitations of non-randomized data

The Leipzig experience with DCB, conventional, and interwoven nitinol stents for complex SFA disease. S. Steiner. LINC 2015

Patients and Lesions in the “Real World”

TASC D Femoropopliteal Occlusions

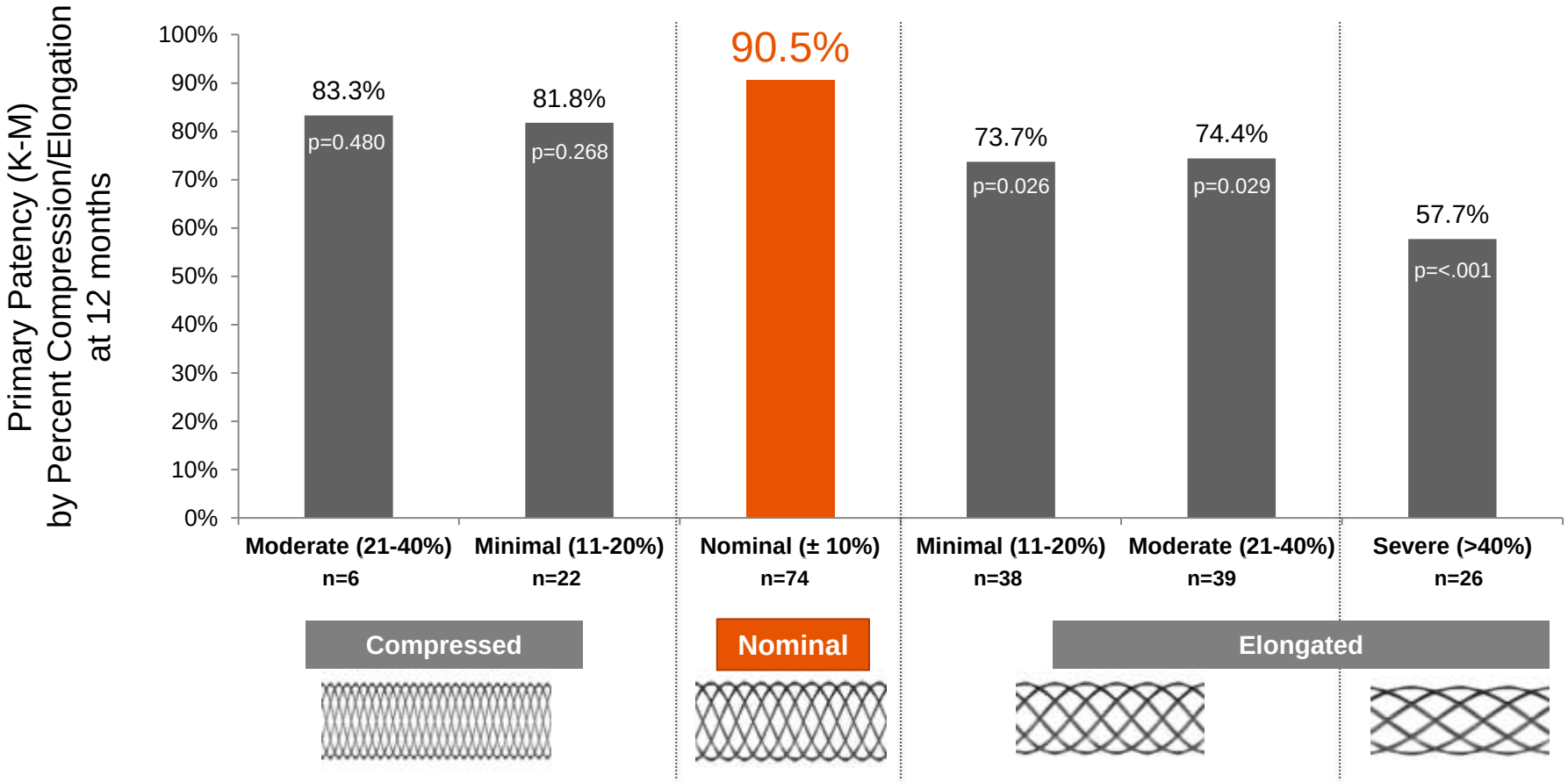
In-stent Re-stenosis and Occlusions

Long-segment Disease with Extensive Calcification

Images Courtesy of Dr. Brian G. DeRubertis

Proper Sizing, Preparation, and Deployment Technique Result in **Excellent Patency Rates**

High patency rates are demonstrated in cases where appropriate implant selection, vessel preparation, and deployment technique are used.



Source: Data on file at Abbott Vascular.

MENU

Dr Rha's Indication for Supera

1. No stent zone; CFA and Popliteal Artery

; Try with DAART first, if bailout stenting is needed, Supera is the choice (Limitations in larger diameter CFA..)

2. Heavily calcified SFA lesion; debulking, DCB and provisional Supera stenting

3. Diffuse long SFA, particularly mid to distal SFA without optimal balloon response

1) Acute recoil and dissection; DCB+Supera

2) Expecting good stent expansion without significant calcium: DES

Save the Date !!

CCI Guro Live 2017

October 19~21, 2017

Korea University Guro Hospital, Seoul, Korea

Thank You for Your Attention!

Korea University Guro Hospital, Seoul, Korea