

Risk Factors for Restenosis after DCB Angioplasty for Femoropopliteal Artery Disease



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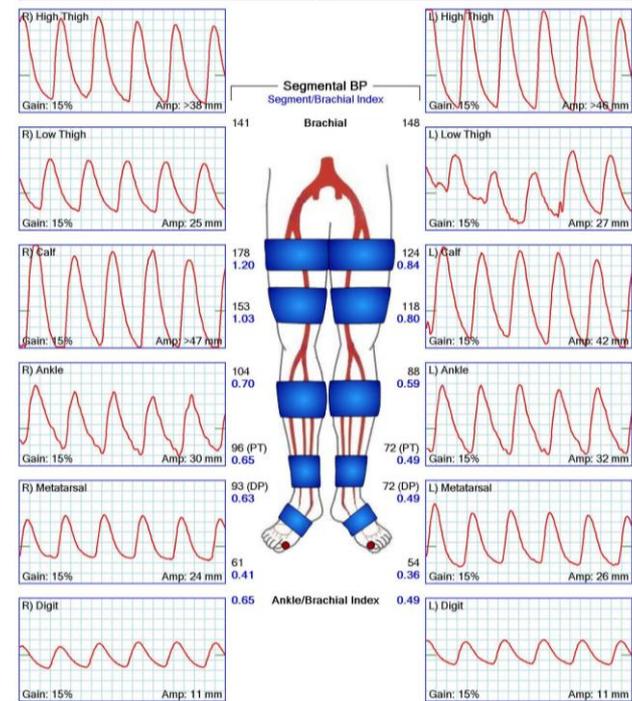
M/71 (LWS, M/3275132)



Sx: Claudication: Lt > Rt
(Rutherford 3)

PHx:

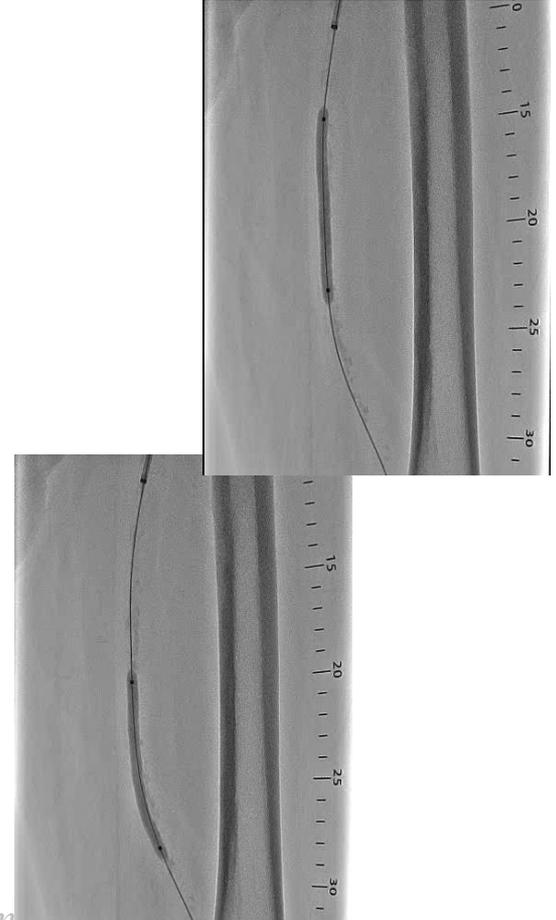
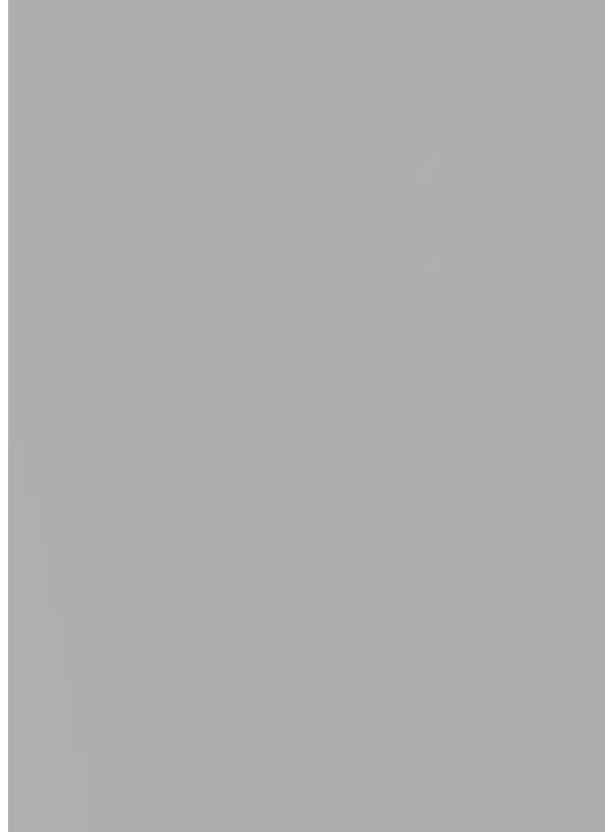
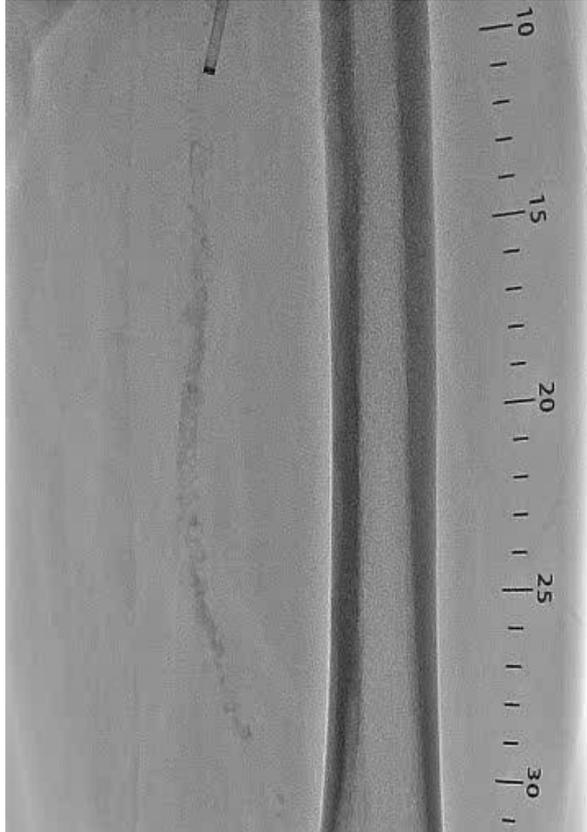
- DM, HTN
- CAD (LN & 3VD)
- S/P PCI with stents (2003/3)



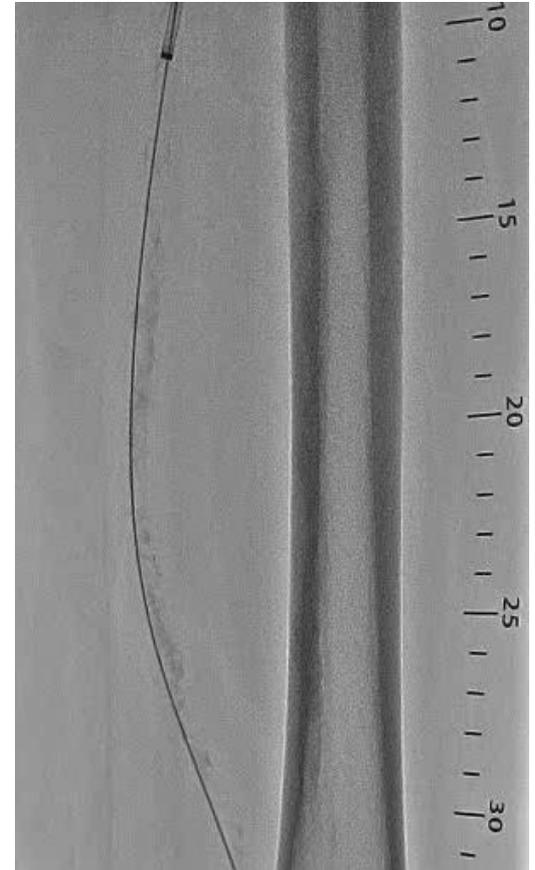
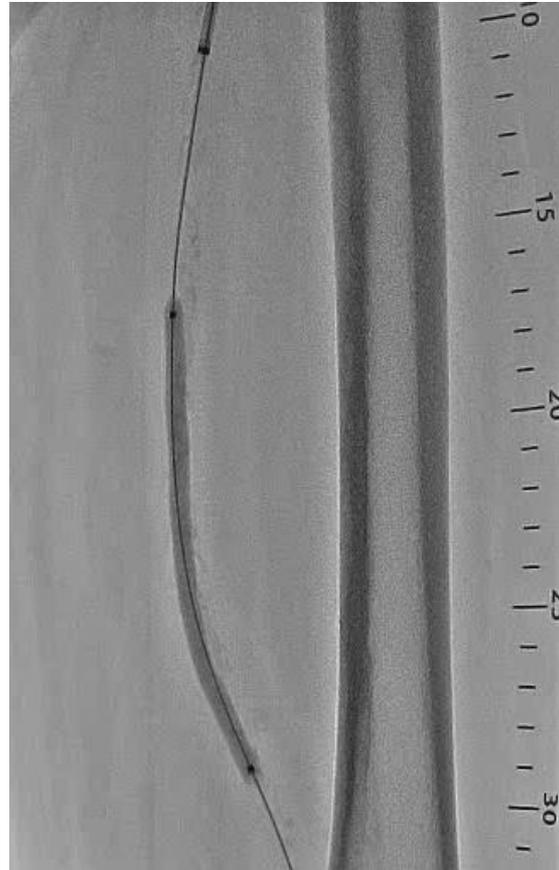
ABI 0.65/0.45



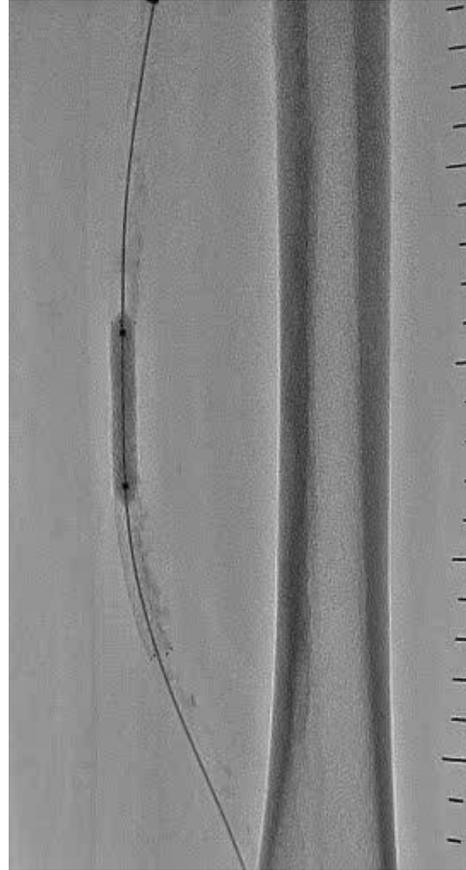
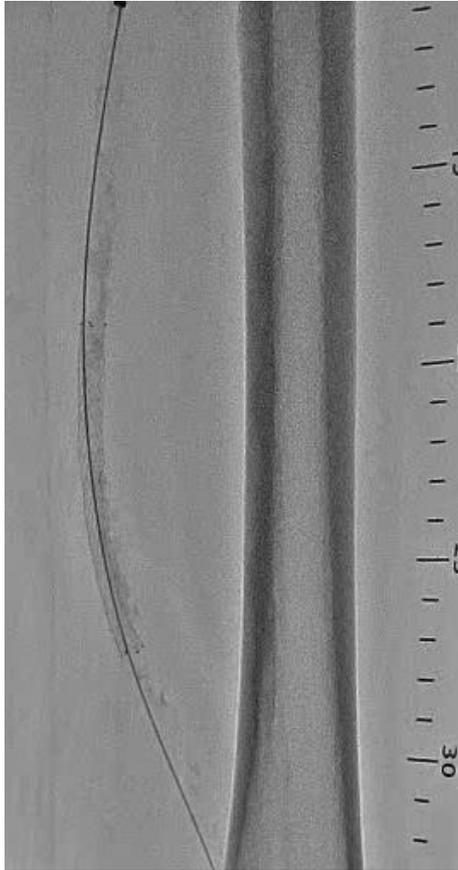
Lt. SFA



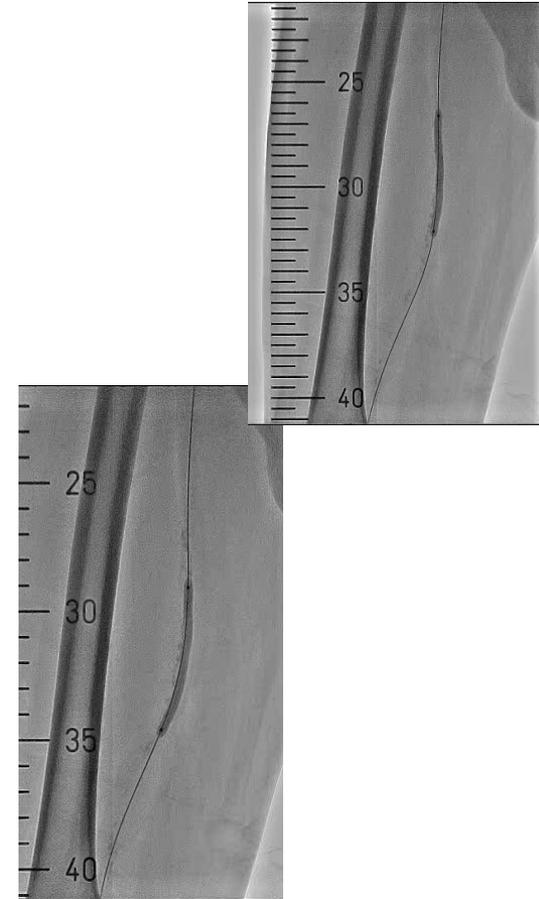
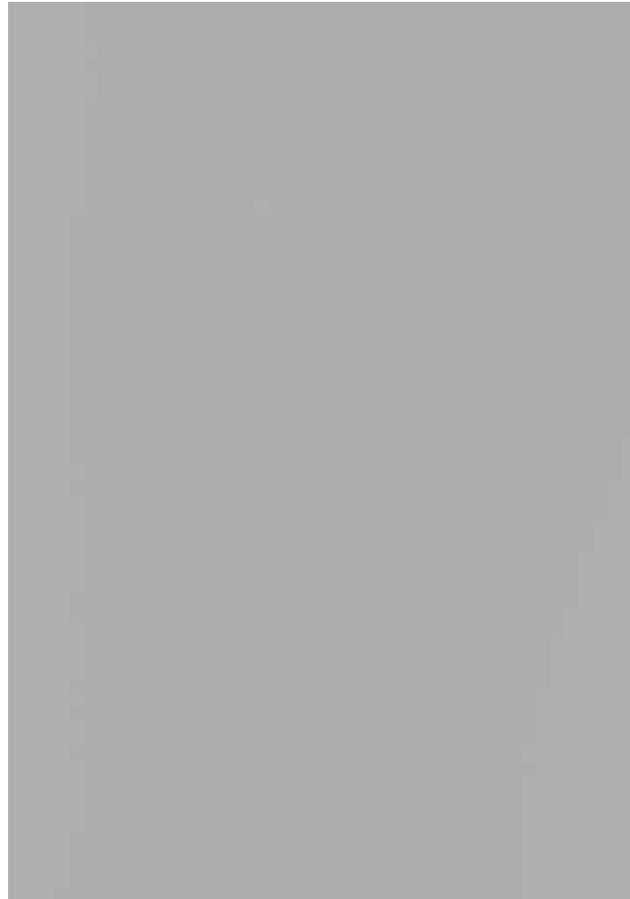
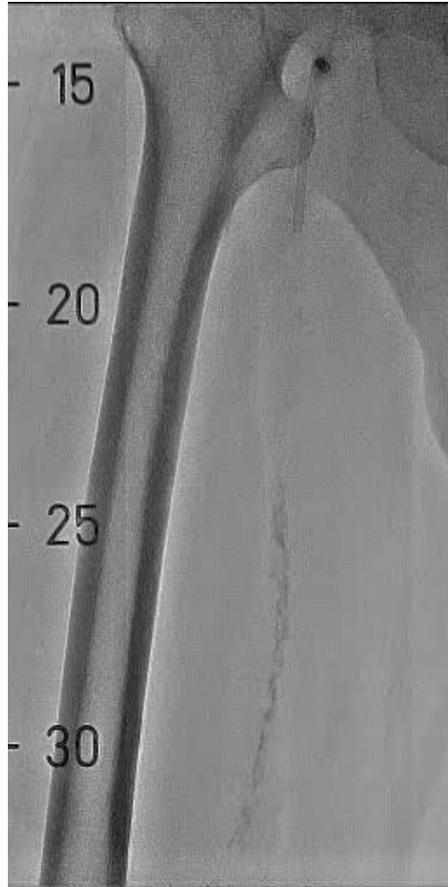
DEB



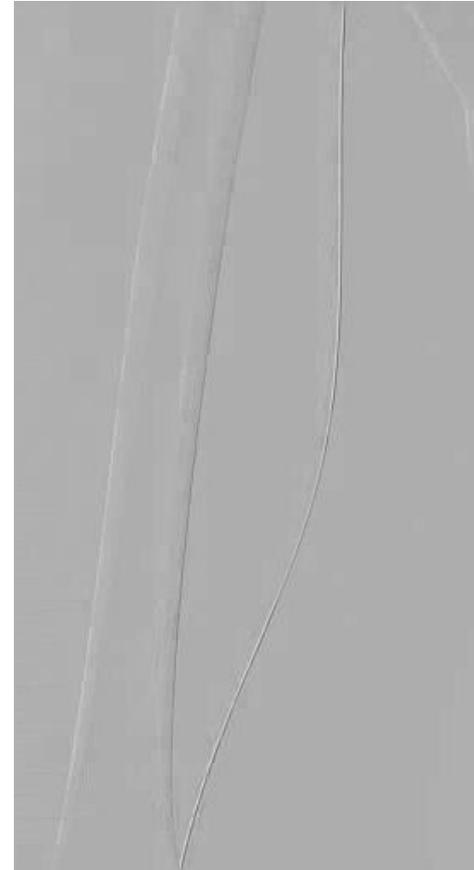
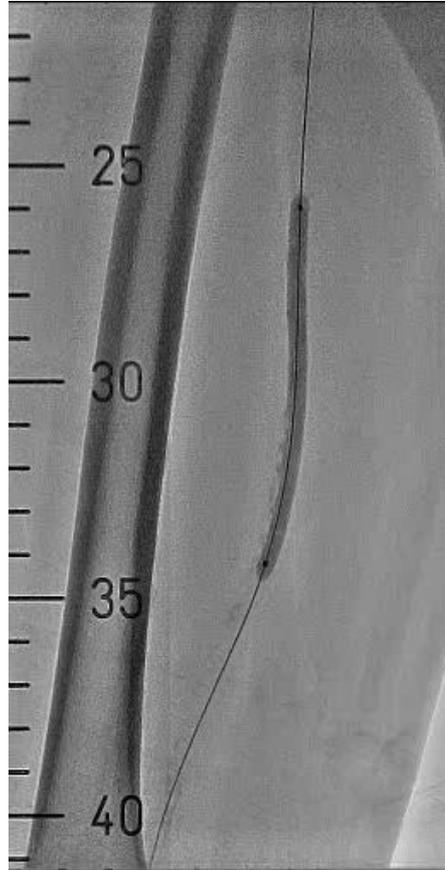
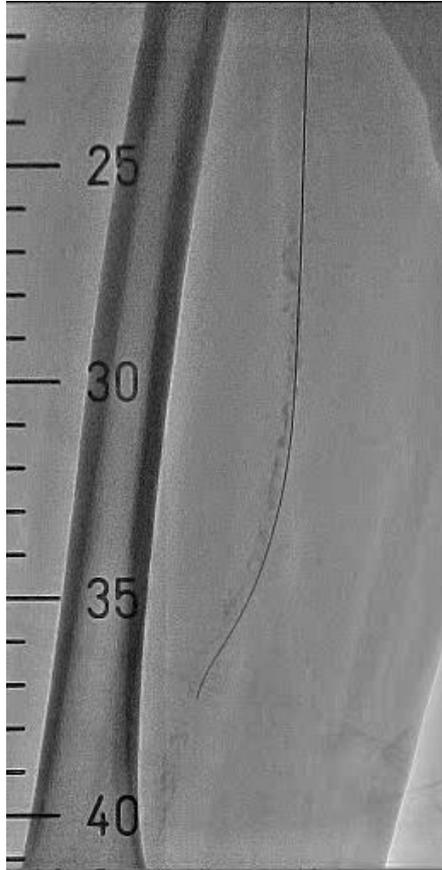
Bail-out Stenting



Rt. SFA



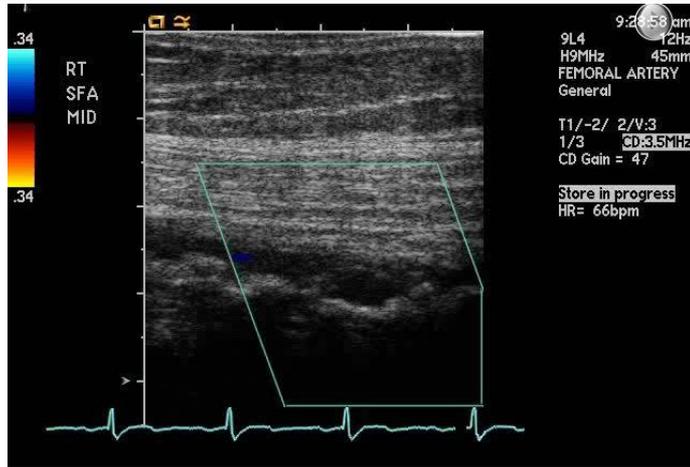
DEB



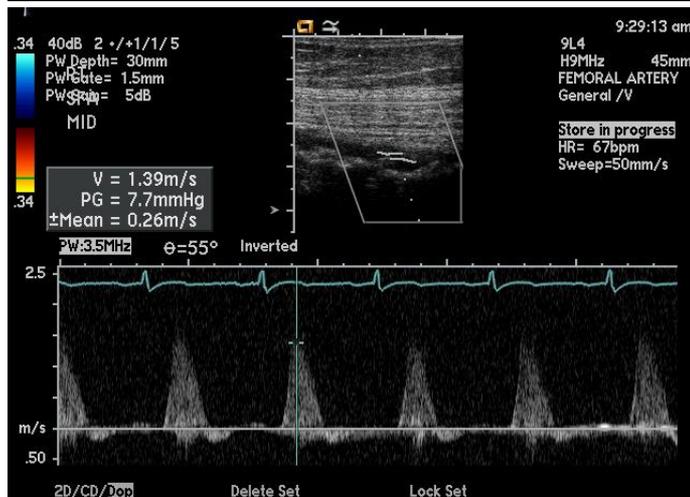
US Follow-up at 1 year



Right SFA



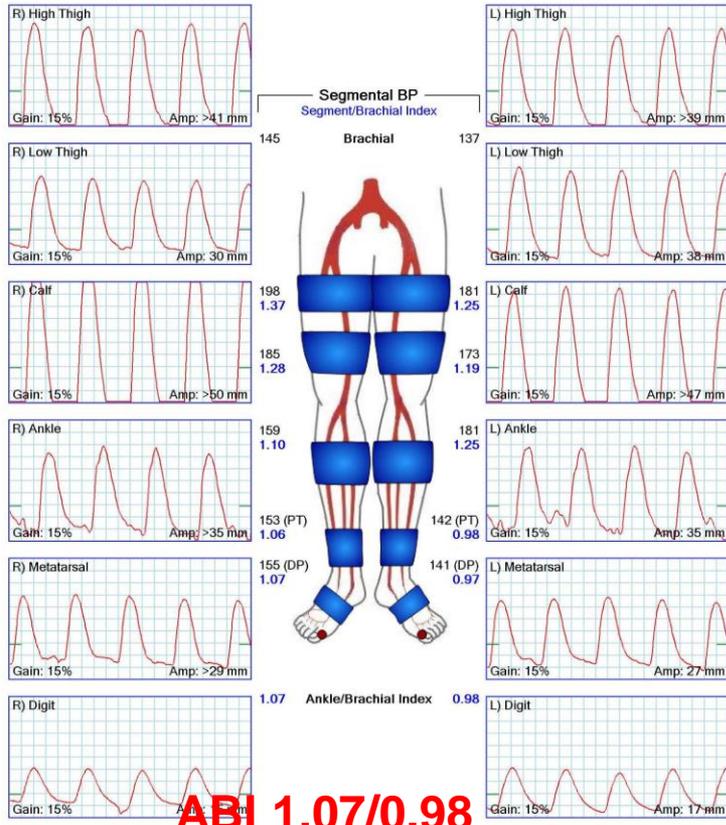
Left SFA



ABI Follow-up

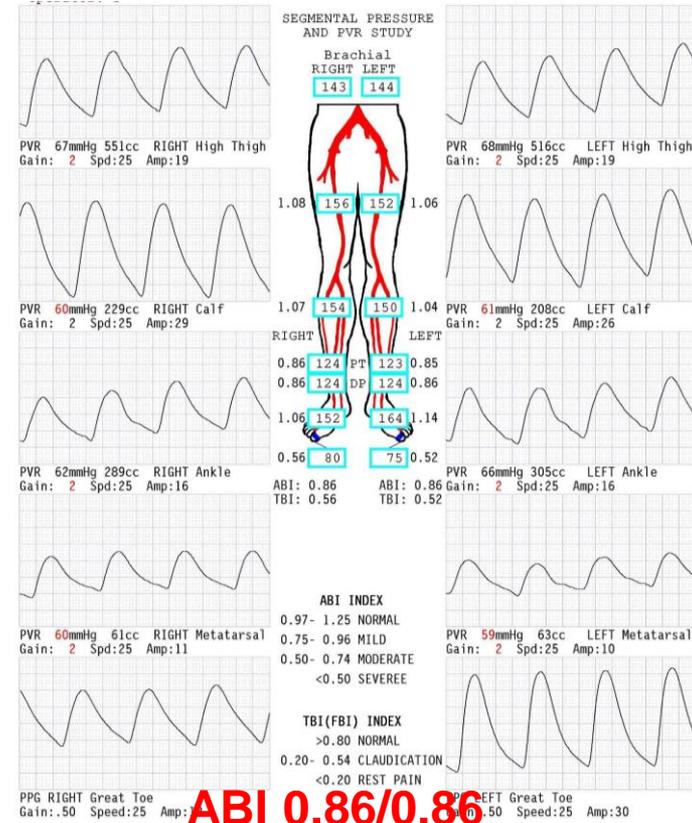


At 1 year



ABI 1.07/0.98

At 2 years



ABI 0.86/0.86

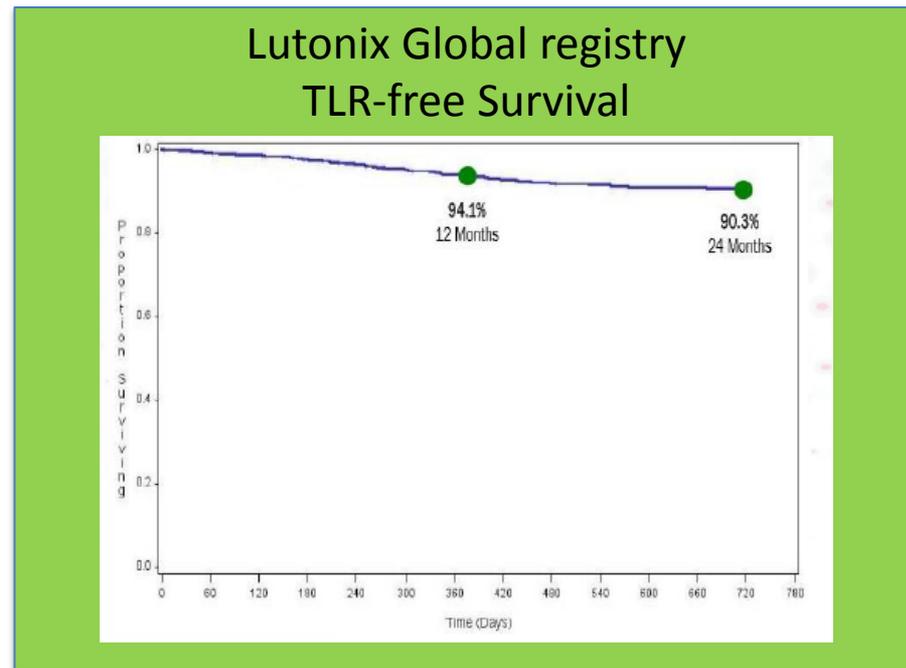
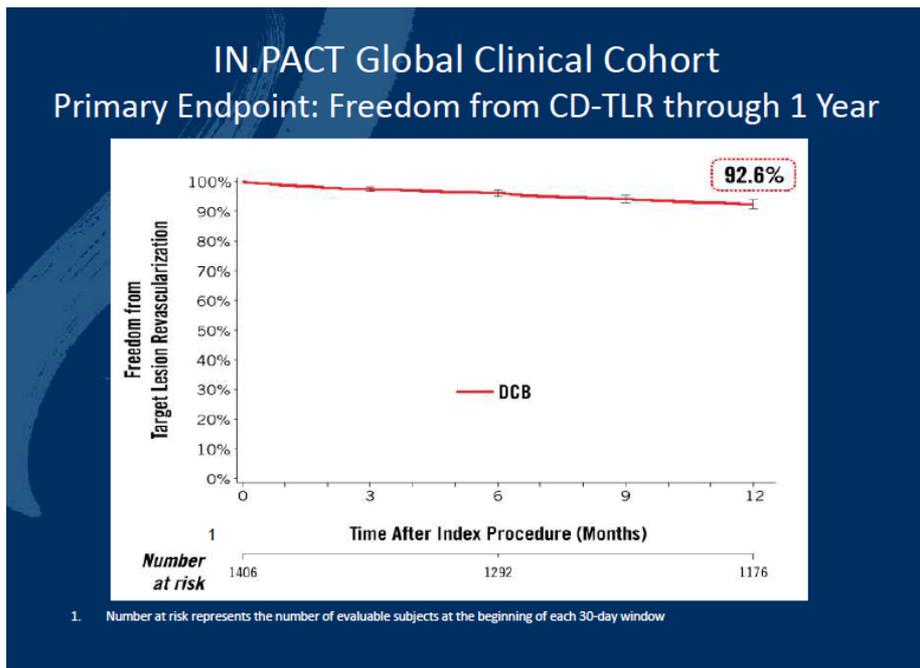


DCB Global Registries



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

691 patients
Lesion length 10.1 ± 8.4 cm



LINC 2017

Severance Cardiovascular Hospital, Yonsei University Health System

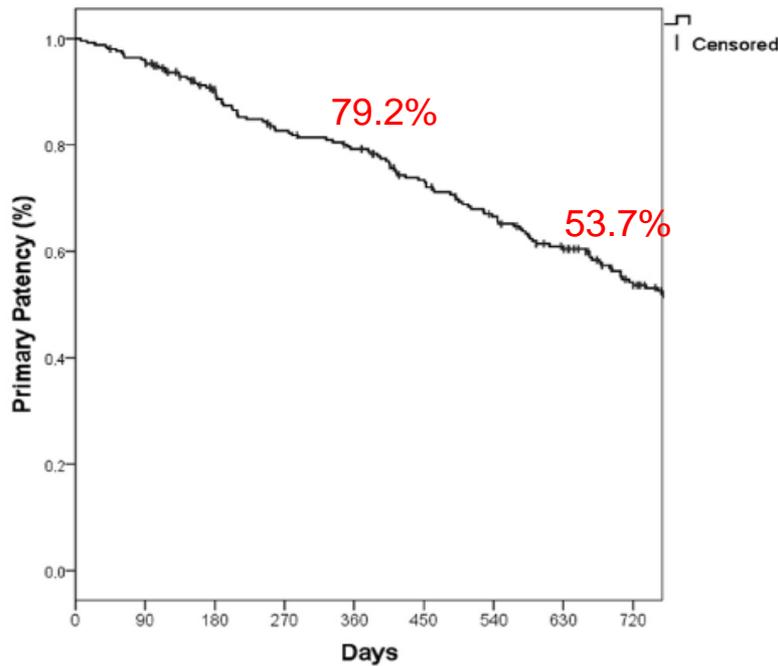
VIVA 2016

DCB: Leipzig Data



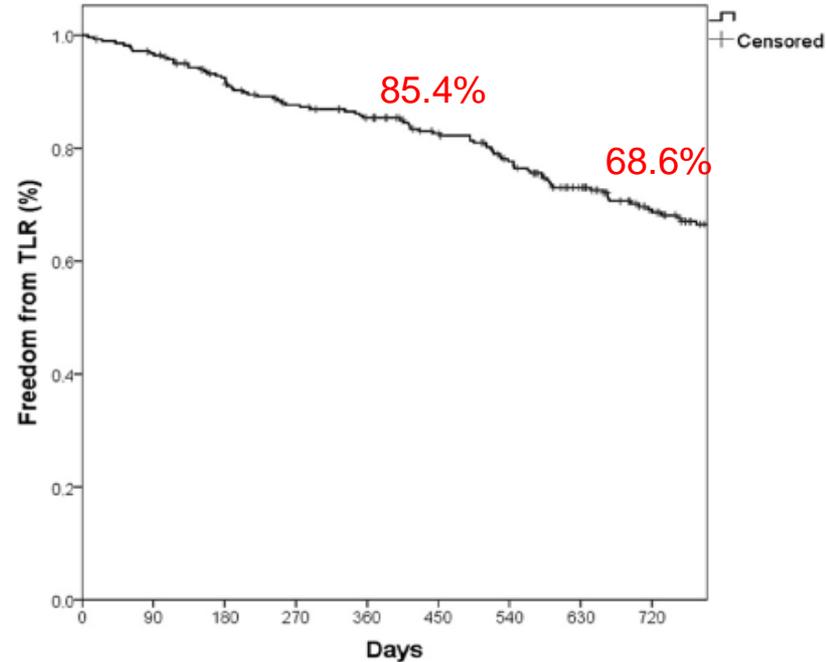
288 limbs (260 patients), Lesion length 24 cm, CTO 65%, ISR 37%, InPACT DCB

Primary Patency



At risk 254 243 215 192 182 162 144 125 101

TLR-free Survival



At risk 282 271 252 234 223 205 187 163 135



Methods



- Retrospective single center cohort
- at Severance Cardiovascular Hospital between 2013 and 2016
- 120 patients (137 limbs)
- treated with InPACT DCB for femoropopliteal arterial lesions



Baseline Clinical Data



Characteristics	Total population (n = 120)	Non-ISR group (n = 68)	ISR group (n = 52)	P-value
Age (years)	68.1 ± 9.5	66.1 ± 10.6	68.5 ± 7.7	0.177
Male	98 (81.7%)	56 (82.4%)	42 (80.8%)	0.824
Hypertension	90 (75.0%)	55 (80.9%)	35 (67.3%)	0.089
Diabetes mellitus	82 (68.3%)	49 (72.1%)	33 (63.5%)	0.098
Hyperlipidemia	68 (56.7%)	33 (48.5%)	35 (67.3%)	0.040
CKD	32 (26.7%)	20 (29.4%)	12 (23.1%)	0.437
ESRD	14 (11.7%)	9 (13.2%)	5 (9.6%)	0.540
CAD	79 (65.8%)	49 (72.1%)	30 (57.7%)	0.100
Current smoker	37 (30.8%)	20 (29.4%)	17 (32.7%)	0.700
Previous amputation	11 (9.2%)	5 (7.4%)	6 (11.5%)	0.431
Clinical presentation				0.228
Intermittent claudication	79 (65.8%)	47 (69.1%)	32 (61.5%)	
Critical limb ischemia	41 (34.2%)	21 (30.9%)	20 (38.5%)	
Discharge medication				
Aspirin	113 (94.2%)	66 (97.1%)	47 (90.4%)	0.122
Clopidogrel	102 (85.0%)	56 (82.4%)	46 (88.5%)	0.353
Cilostazol	30 (25.0%)	20 (29.4%)	10 (19.2%)	0.202
Statin	90 (75.0%)	49 (72.2%)	41 (78.8%)	0.395



Lesion & Procedural Data



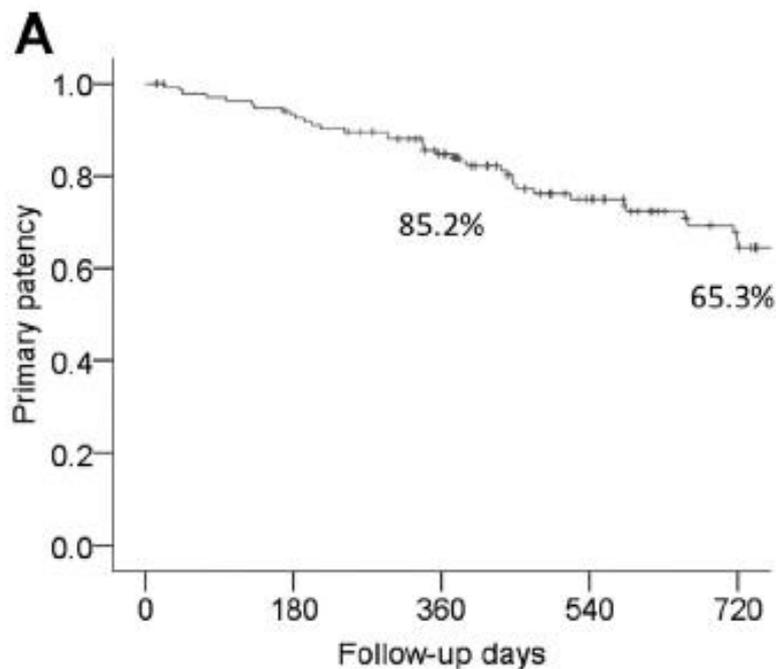
Characteristics	Total population (n = 137)	Non-ISR group (n = 80)	ISR group (n = 57)	P-value
TASC II type				<0.001
A/B	36 (26.3%)	32 (40.0%)	4 (7.0%)	
C/D	101 (73.7%)	48 (60.0%)	53 (93.0%)	
Previous POBA		26 (32.5%)	—	
Total occlusion	75 (54.7%)	38 (47.5%)	37 (64.9%)	0.044
Lesion length (cm)	22.2 ± 11.6	19.2 ± 12.0	27.1 ± 9.6	<0.001
Severe calcification	46 (33.6%)	26 (32.5%)	20 (35.1%)	0.752
Popliteal artery involvement	41 (29.9%)	24 (30.0%)	17 (29.8%)	0.982
Distal runoff vessel ≤1	67 (48.9%)	36 (45.0%)	31 (54.4%)	0.279
Baseline ABI	0.52 ± 0.20	0.58 ± 0.18	0.44 ± 0.19	<0.001
Combined treatment				
Iliac lesion	17 (12.4%)	9 (11.3%)	8 (14.0%)	0.626
Infrapopliteal lesion	36 (26.3%)	18 (22.5%)	18 (31.6%)	0.234
Atherectomy prior to DCB	22 (16.1%)	20 (25.0%)	2 (3.5%)	0.001
Provisional stenting	33 (24.1%)	19 (23.8%)	14 (24.6%)	0.913
Technical success	135 (98.5%)	31 (96.9%)	104 (99.0%)	0.370
Postprocedure ABI	0.89 ± 0.13	0.90 ± 0.13	0.87 ± 0.12	0.292
Complications				
Major	0	0	0	—
Minor				
Bleeding at access site	1 (0.7%)	1 (0%)	0 (0.9%)	0.535
Vascular perforation	1 (0.7%)	1 (0%)	0 (0.9%)	0.535



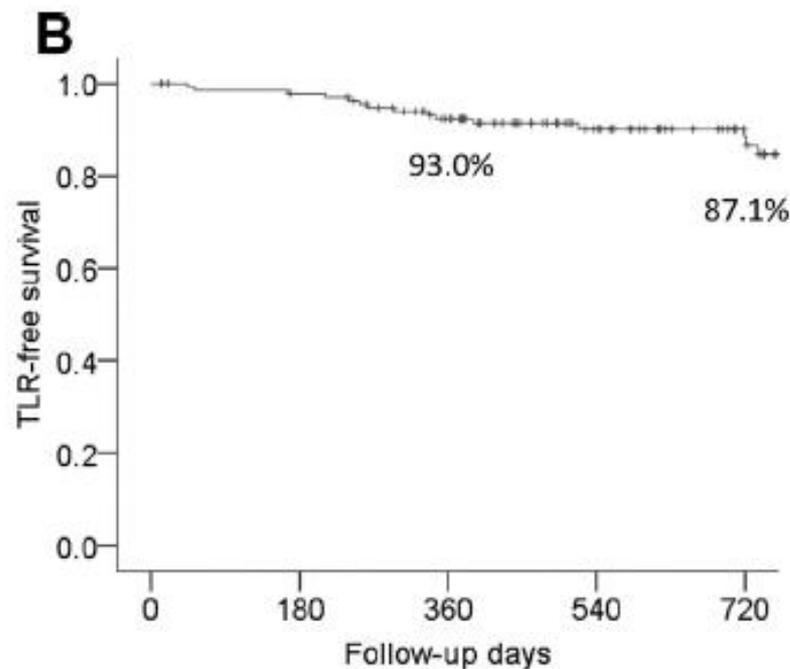
Overall Primary Patency & TLR-free Survival



Clinical Primary Patency



TLR-free Survival



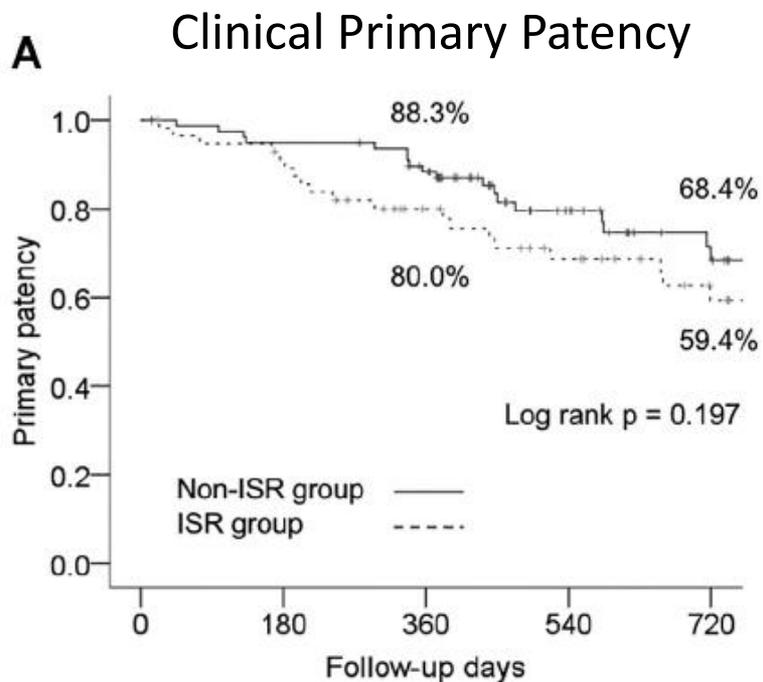
Number at risk

137 124 103 64 40

137 130 111 72 49

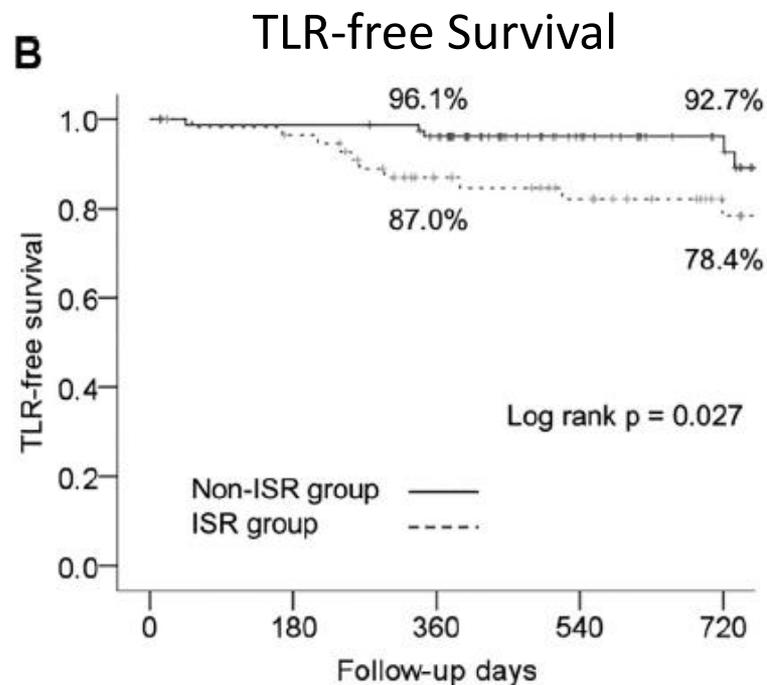


ISR Lesions after DCB



Number at risk

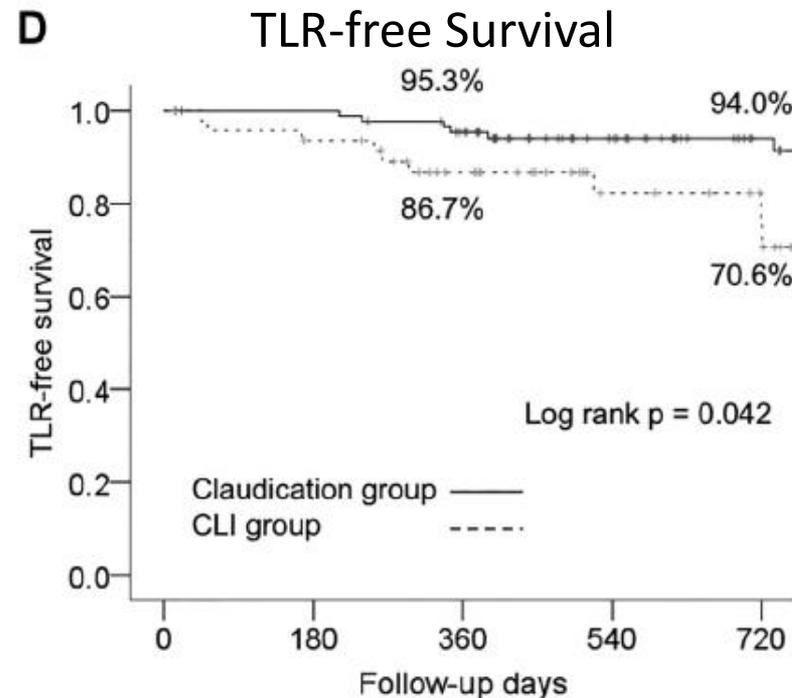
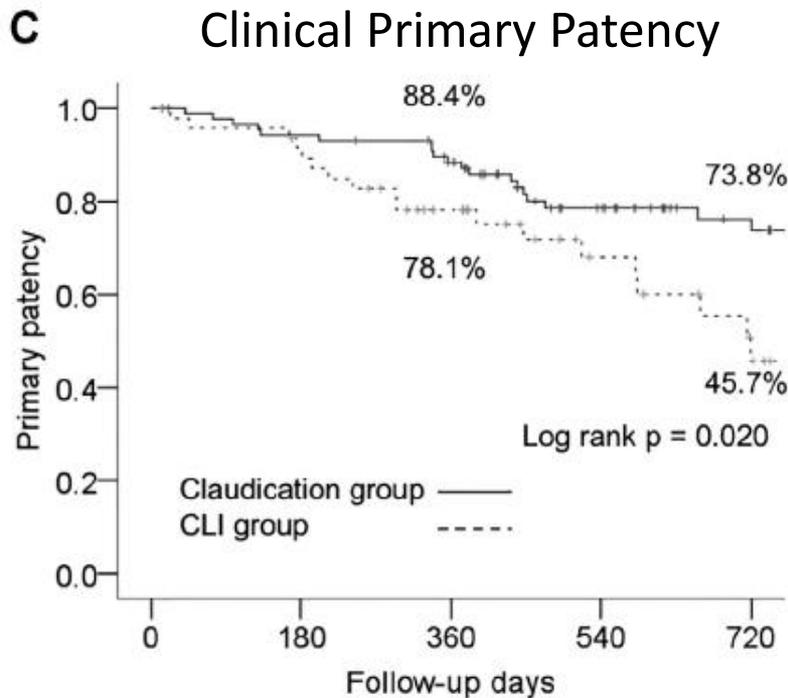
Non-ISR	80	74	66	36	22
ISR	57	50	37	28	18



Non-ISR	80	77	72	40	28
ISR	57	53	39	32	21



Claudication vs CLI after DCB



Number at risk

	0	180	360	540	720
Claudication	89	82	73	47	31
CLI	48	42	30	17	9

	0	180	360	540	720
Claudication	89	87	79	54	36
CLI	48	43	32	18	13



Risk Factors of Restenosis



Variables	Univariate analysis		Multivariate analysis	
	HR (95% CI)	P-value	HR (95% CI)	P-value
Age	0.97 (0.94–1.01)	0.114		
Male	1.04 (0.40–2.66)	0.942		
Hypertension	0.60 (0.30–1.19)	0.141		
Diabetes mellitus	0.66 (0.35–1.28)	0.220		
Hyperlipidemia	2.04 (1.01–4.12)	0.046	4.66 (1.30–16.76)	0.018
CKD	1.90 (0.87–3.49)	0.065	–	
ESRD	3.75 (1.74–8.04)	0.001	2.18 (0.68–7.01)	0.193
CAD	1.01 (0.53–1.91)	0.983		
Current smoker	1.00 (0.51–1.97)	0.996		
Critical limb ischemia	2.03 (1.06–3.90)	0.032	5.80 (1.26–26.68)	0.024
Nonuse of aspirin	2.08 (0.74–5.89)	0.166		
Nonuse of clopidogrel	0.60 (0.18–1.95)	0.392		
Nonuse of cilostazol	3.30 (1.17–9.33)	0.024	3.49 (0.91–13.37)	0.069
Nonuse of statin	2.61 (0.92–7.37)	0.071	3.89 (0.76–19.91)	0.104
Severe calcification	1.03 (0.55–2.01)	0.937		
History of amputation	0.93 (0.28–3.02)	0.899		
TASC C/D	1.58 (0.70–3.61)	0.274		
Lesion length (mm)	1.00 (1.00–1.01)	0.246		
Total occlusion	1.07 (0.56–2.03)	0.838		
ISR lesion	1.61 (0.85–3.04)	0.146	1.05 (0.43–2.56)	0.193
Popliteal artery involvement	2.08 (1.08–4.01)	0.028	2.24 (0.94–5.35)	0.069
Combined treatment, iliac lesion	1.46 (0.46–3.33)	0.367		
Combined treatment, infrapopliteal lesion	1.02 (0.48–2.17)	0.954		
Distal runoff vessel ≤ 1	1.31 (0.68–2.49)	0.419		
Provisional stent	1.40 (0.68–2.90)	0.363		
Atherectomy prior to DCB	1.42 (0.62–3.24)	0.410		
Post-ABI	0.06 (0.01–1.66)	0.098	0.64 (0.02–17.65)	0.791



Summary



- In our study, DCB showed excellent primary patency and TLR-free survival at 1 year after DCB treatment in patients with complex femoropopliteal artery disease.
- However, the primary patency continuously declined beyond 1 year, suggesting a late catch-up phenomenon.
- The risk of developing restenosis after DCB seems to be significantly associated with CLI and hypercholesterolemia.





Clinical Research

Risk Factors for Restenosis after Drug-coated Balloon Angioplasty for Complex Femoropopliteal Arterial Occlusive Disease

Ann Vasc Surg 2018

Ji Woong Roh,¹ Young-Guk Ko,² Chul-Min Ahn,² Sung-Jin Hong,² Dong-Ho Shin,² Jung-Sun Kim,² Byeong-Keuk Kim,² Donghoon Choi,² Myeong-Ki Hong,^{2,3} and Yangsoo Jang,^{2,3} Bucheon and Seoul, Korea

Background: Currently, there exist limited data on patient outcomes following the use of drug-coated balloons (DCBs) to treat complex femoropopliteal arterial occlusive lesions. The aim of the this study is to investigate the outcomes of patient treated with DCBs and to identify the predictors of restenosis.

Methods: We retrospectively investigated medical records from 120 patients (137 limbs) treated with DCBs for femoropopliteal lesions at a single center between 2013 and 2016. Primary patency, target lesion revascularization (TLR), and risk factors of restenosis were analyzed.

Results: There were 80 de novo and 57 in-stent restenosis lesions. Mean lesion length was 22.2 ± 11.6 cm. The clinical primary patency was 85.2% at 1 year and 65.3% after 2 years. The TLR-free survival rate was 93.0% at 1 year and 87.1% after 2 years. Critical limb ischemia (CLI; hazard ratio [HR] 5.80, 95% confidence interval [CI] 1.26–26.68, $P = 0.024$) and hypercholesterolemia (HR 4.66, 95% CI 1.30–16.76, $P = 0.018$) were identified as independent predictors of restenosis. In addition, nonuse of cilostazol and popliteal artery involvement showed trends toward an increased risk of restenosis.

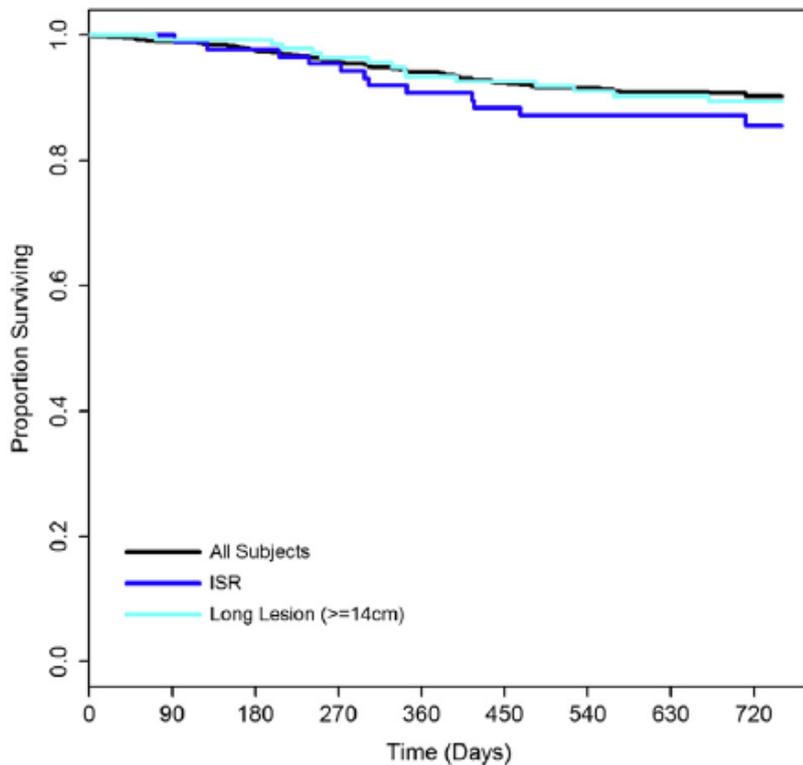
Conclusions: Treatment with DCBs showed excellent primary patency and TLR-free survival at 1 year after the procedure. However, the primary patency continuously deteriorated beyond 1 year, suggesting a late catch-up phenomenon. The risk of restenosis after treatment with DCBs was significantly associated with CLI and hypercholesterolemia.



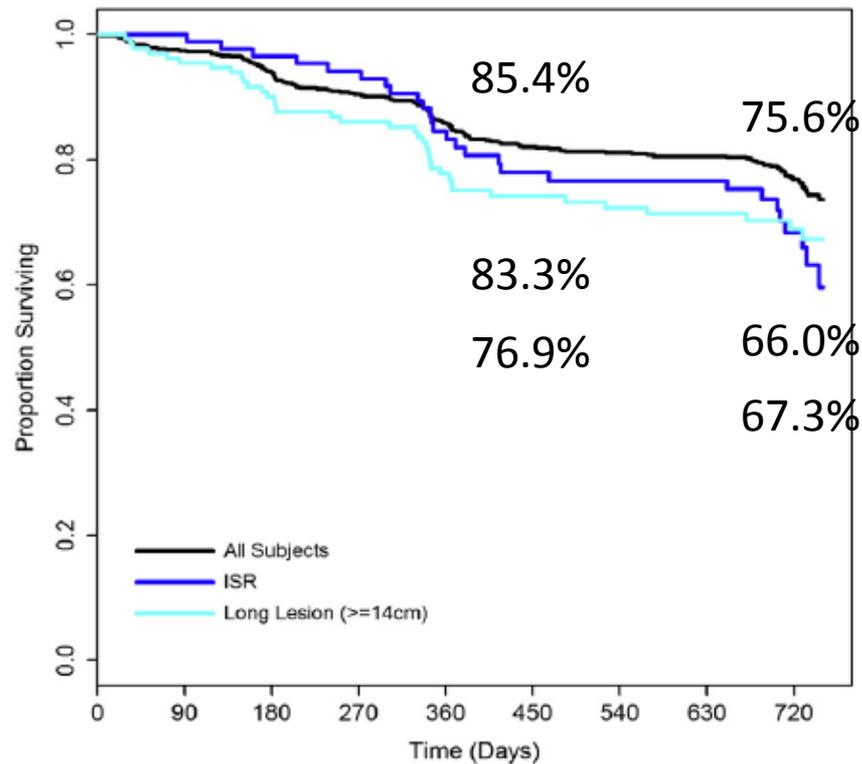
Global Lutonix Registry



TLR-free Survival



Clinical Primary Patency



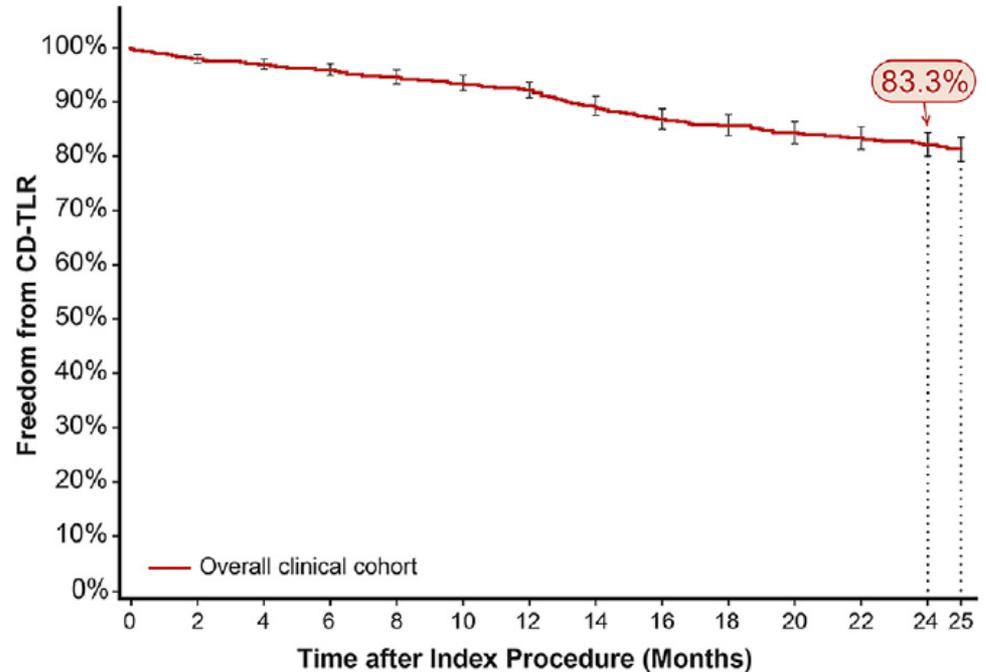
Thieme M, JACC Intv 2017;10:1682



InPACT Global Registry



n=1,406,
(1,773 lesions)
Lesion length: 12.09 ± 9.54 cm
Provisional stenting 21.2%



Number of subjects at risk

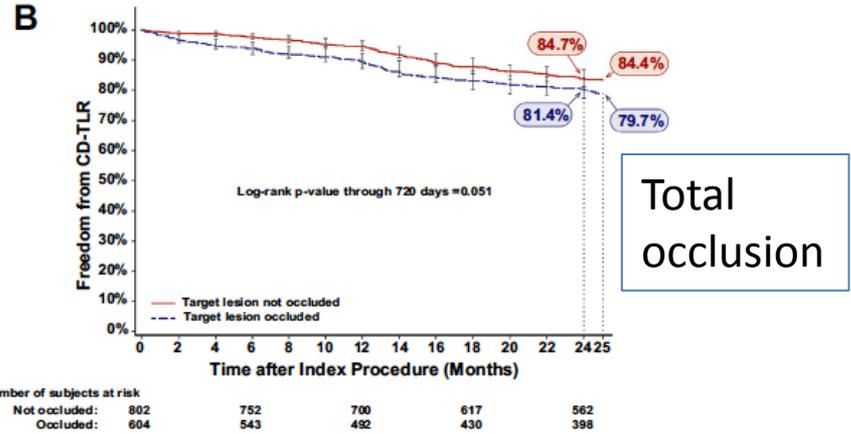
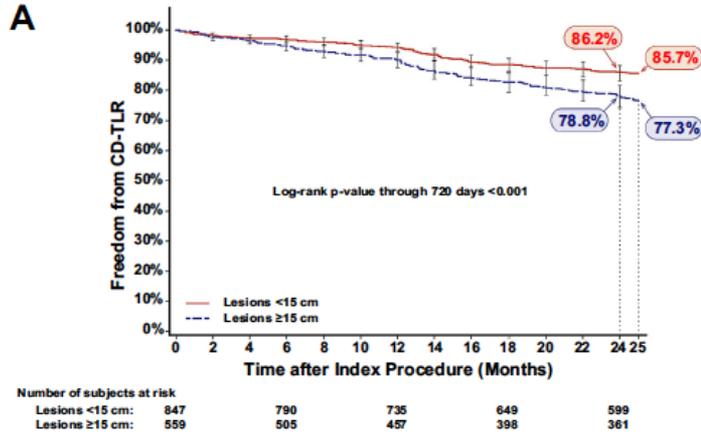
Overall cohort: 1406 1295 1192 1047 960

Micary A, JACC Intv 2018;10:945



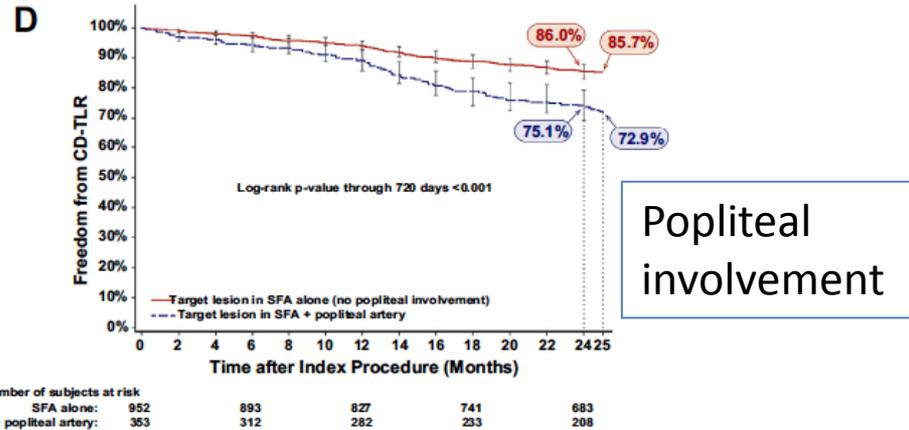
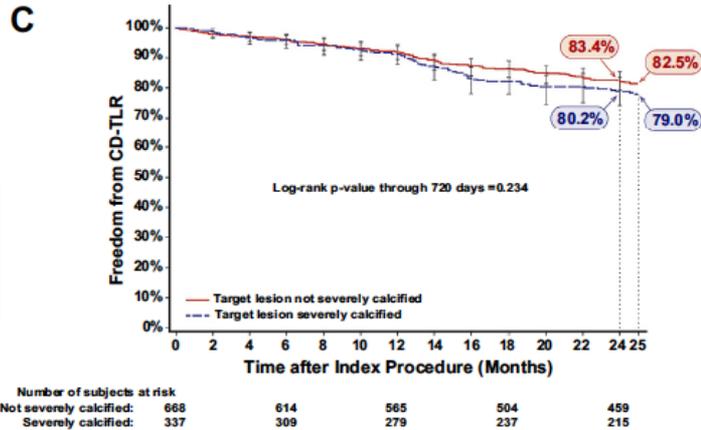
TLR-free Survival in Different Lesion Subtypes

Lesion
≥15 cm



Total
occlusion

Severely
Calcified



Popliteal
involvement



Risk Factors of TLR in InPACT Global Registry



	Coefficient	SE	Hazard Ratio (95% CI)	p Value
Total lesion length	0.037	0.007	1.037 (1.022-1.053)	<0.001
Target limb (unilateral vs. bilateral)	-0.747	0.226	0.474 (0.305-0.737)	<0.001
Target lesion location (SFA alone vs. SFA + popliteal)	-0.514	0.165	0.598 (0.433-0.827)	0.002
Age	-0.020	0.008	0.980 (0.965-0.994)	0.007
Reference vessel diameter	-0.314	0.121	0.730 (0.576-0.925)	0.009
Target lesion type (de novo ISR vs. not de novo ISR)	0.467	0.180	1.596 (1.122-2.269)	0.009
Target limb posterior tibial artery pulse (absent vs. present)	-0.489	0.209	0.613 (0.407-0.924)	0.019
Coronary artery disease (present vs. absent)	0.329	0.161	1.389 (1.013-1.905)	0.041



Conclusions



- DCB demonstrated overall excellent outcomes at 1 year.
- However, there may be gradual decrease in the primary patency especially in complex lesions.
- Complex lesions and clinical characteristics appear to be risk factors of restenosis or TLR after DCB angioplasty in femoropopliteal artery disease.

