Azienda Ospedaliero Universitaria Careggi

Servizio Sanitario della Toscana

Are Long Stents Still the First Choice in Long SFA CTO ?

Fabrizio Fanelli, MD, EBIR

Director Vascular and Interventional Radiology Department

"Careggi " University Hospital

Florence - Italy

UNIVERSITÀ DEGLI STUDI FIRENZE

Disclosures

- Consultant / Speaker / Proctor / Advisory Board
  - Bayer
  - Bolton
  - Boston Scientific
  - Cook
  - CR Bard
  - Medtronic
  - Shockwave Medical
  - Philips
  - W.L. Gore & Associates

72y, Female
Heavy smoker
Diabetic
Hypertension

Bilateral claudication <50 mt
Rt > Lt

Worsening of the symptoms in the last 6 mos

ABI: Rt 0.5
Lt 0.7

Medical therapy:
- Statins 40 mg/d
- Oral hypoglycemic drug
- Aspirin

72y, Female
Heavy smoker
Diabetic
Hypertension

Bilateral claudication <50 mt
Rt > Lt

Worsening of the symptoms in the last 6 mos

ABI: Rt 0.5
Lt 0.7

USCD: occlusion of the Rt SFA
occlusion of the Lt SFA

CTA

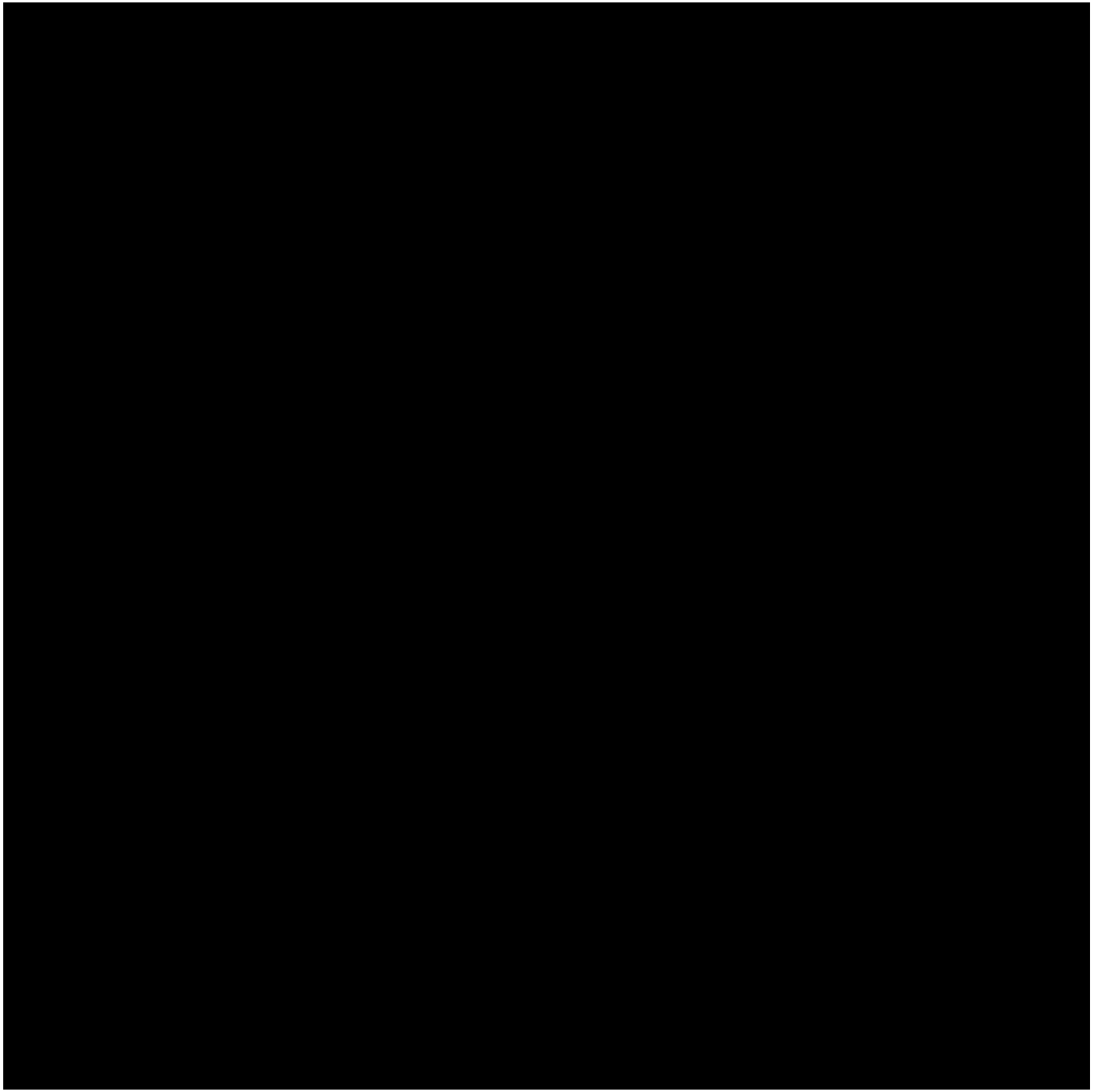
Retrograde Lt CFA access
US guidance

Cross-over

- 6 Fr / 45 cm Destination
  (Terumo)
- 0.035» hydrophilic GW
  (Terumo)
- 4Fr / 65 cm RIM catheter
  (Cordis)

TASC D: >20 CM

Calcium grade: 2A (180° / <3cm)



- 4Fr CXI support catheter

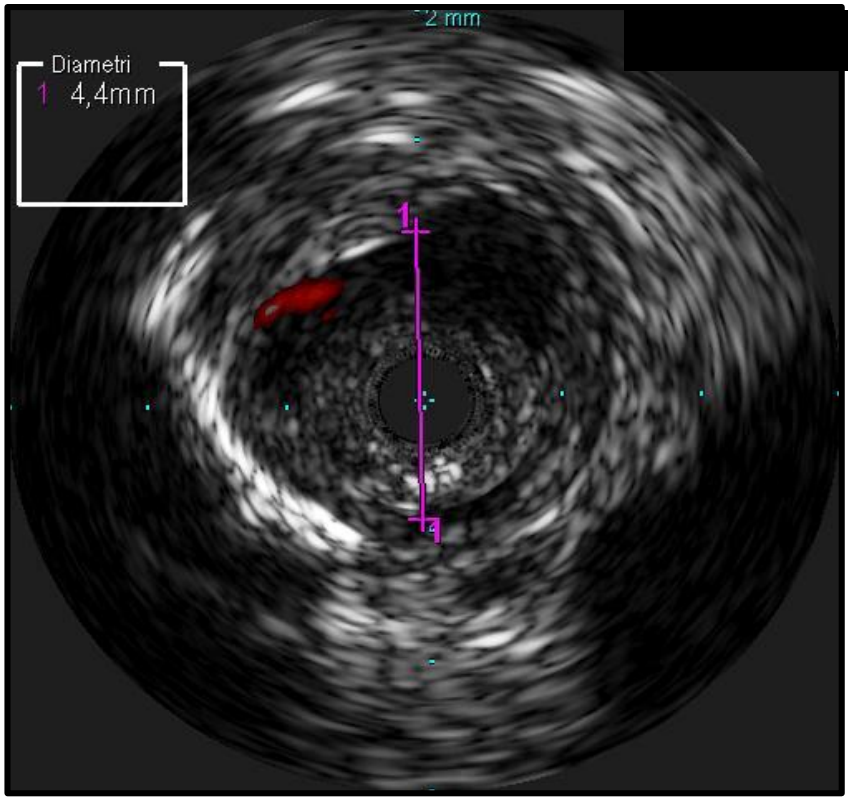
  (Cook)

- 0.035» hydrophilic GW

  (Terumo)

Pre –dilatation
Admiral
Ø 4 mm
(Medtronic)

Pre –dilatation
Admiral
Ø 4 mm
(Medtronic)



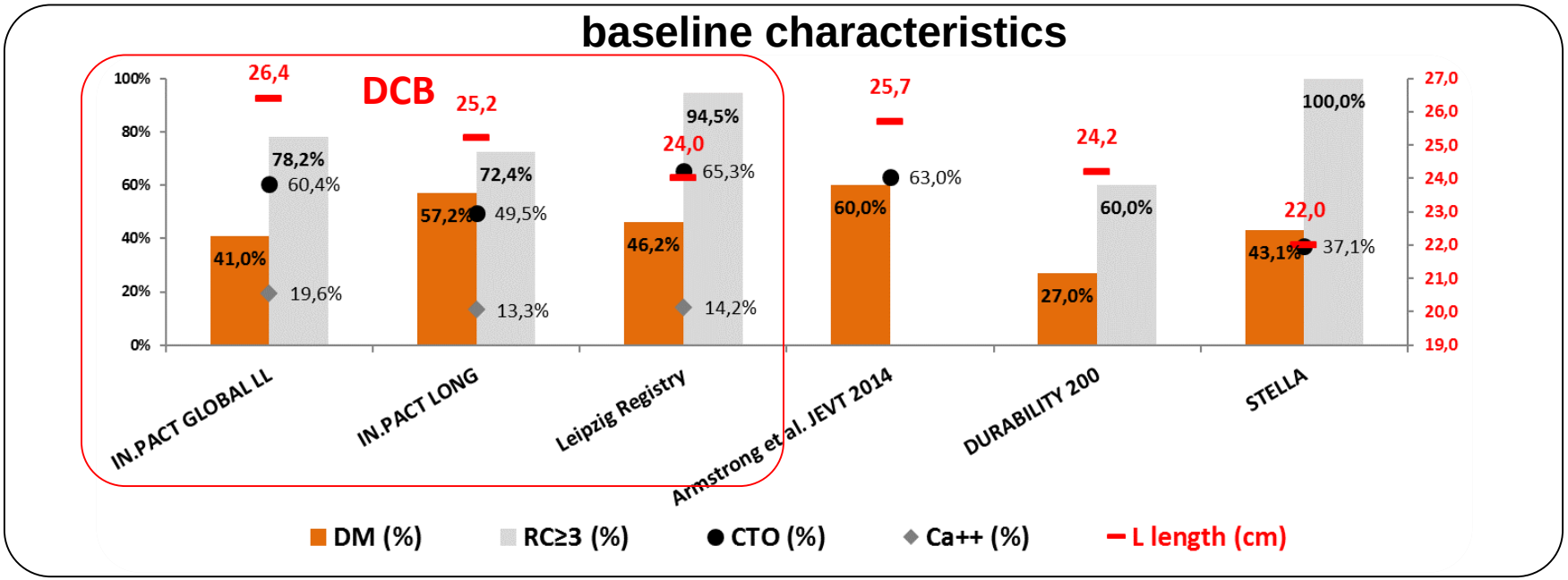
In.Pact Admiral
Ø 5 mm
(Medtronic)

Inflation Time: 3 min

DCB in Long Lesions

6 trials with fem-pop lesions > 20 cm

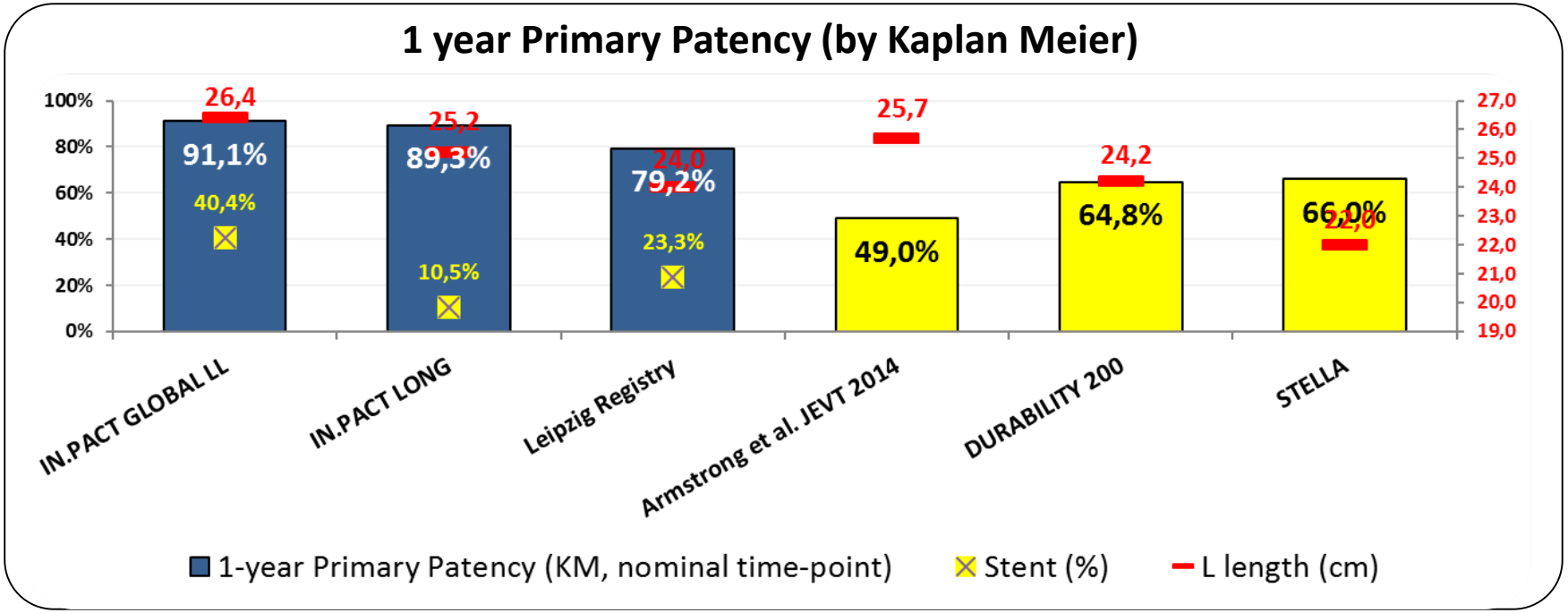
- 3 DCB (In.Pact) trials (2 with independent corelab adj.)
- 3 BMS trials



1. D.Scheinert - Drug Coated Balloon Treatment for Patients with Intermittent Claudication: New Insights from the IN.PACT Global Study Long Lesion (≥ 15 cm) Imaging Cohort. Oral presentation EuroPCR 2015
2. Micari A, Nerla R, Vadalà G, Castriota F, Grattoni C, Liso A, Russo P, Pantaleo P, Roscitano G, Cremonesi A. 2-Year Results of Paclitaxel-Coated Balloons for Long Femoropopliteal Artery Disease: Evidence From the SFA-Long Study. JACC Cardiovasc Interv. 2017 Apr 10;10(7):728-734
3. Schmidt A, Piorkowski M, Görner H, Steiner S, Bausback Y, Scheinert S, Banning-Eichenseer U, Staab H, Branzan D, Varcoe RL, Scheinert D. Drug-Coated Balloons for Complex Femoropopliteal Lesions: 2-Year Results of a Real-World Registry. JACC Cardiovasc Interv. 2016 Apr 11;9(7):715-24
4. Armstrong EJ, Saeed H, Alvandi B, Singh S, Singh GD, Yeo KK, Anderson D, Westin GG, Dawson DL, Pevec WC, Laird JR. Nitinol self-expanding stents vs. balloon angioplasty for very long femoropopliteal lesions. J Endovasc Ther. 2014 Feb;21(1):34-43
5. Bosiers M, Deloose K, Callaert J, Moreels N, Keirse K, Verbist J, Peeters P. Results of the Protégé EverFlex 200-mm-long nitinol stent (ev3) in TASC C and D femoropopliteal lesions. J Vasc Surg. 2011 Oct;54(4):1042-50
6. Davaine JM, Azéma L, Guyomarch B, Chaillou P, Costargent A, Patra P, Lambert G, Gouëffic Y. One-year clinical outcome after primary stenting for Trans-Atlantic Inter-Society Consensus (TASC) C and D femoropopliteal lesions (the STELLA "STEnting Long de L'Artère fémorale superficielle" cohort). Eur J Vasc Endovasc Surg. 2012 Oct;44(4):432-41

What about Long Lesions?

Long lesions may trigger higher (10~40%) provisional stent rates, however a DCB + prov. Stent strategy does better than 100% elective (long) stenting



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2-Year Results of Paclitaxel-Coated Balloons for Long Femoropopliteal Artery Disease

Evidence From the SFA-Long Study

Antonio Micari, MD, PhD,[a] Roberto Nerla, MD,[a] Giuseppe Vadalà, MD,[b] Fausto Castriota, MD,[a] Chiara Grattoni, MD,[a] Armando Liso, MD,[c] Paolo Russo, MD,[d] Paolo Pantaleo, MD,[e] Giuseppe Roscitano, MD,[f] Alberto Cremonesi, MD[a]

- Investigator initiated, multicenter prospective, single-arm study
- Indipendent Clinical Events Committee

- **N = 105**
- Rutherford 2 to 4
- RVD: 4 – 7 mm
- Stenosis or occlusion ≥ 150 mm
- Multiple lesions with <3cm distance
- 1 patent crural vessel

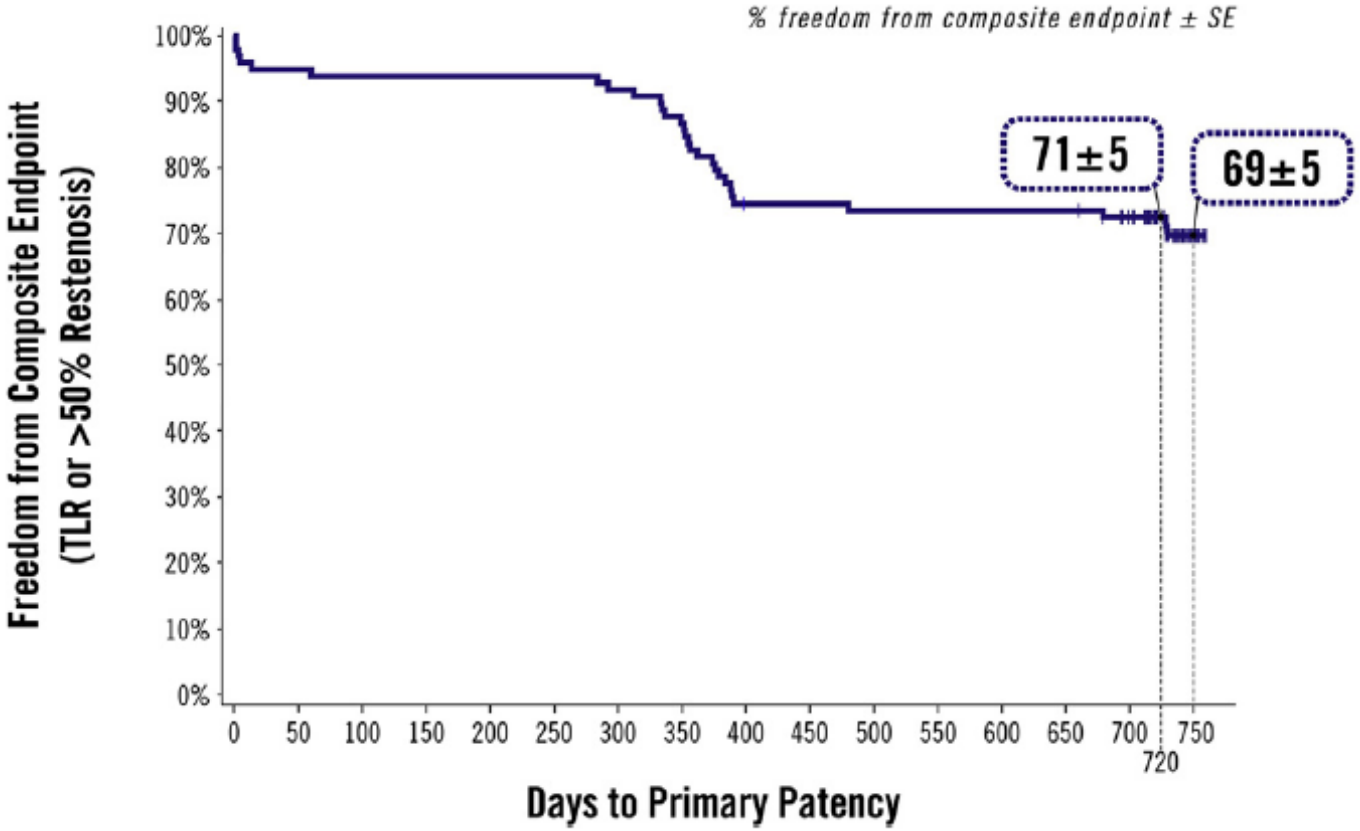
- **Treated lesion length = 251±71 mm**
  - **Pre.dilatation:** uncoated balloon; 0.5-1 mm undersized; inflation time 2 min
  - **DCB:** In.Pact Admiral (Medtronic) 1:1 RVD; inflation time 3 min; 3-12 atm
  - **Post-dilatation:** uncoated balloon >3min or spot stenting (persistent stenosis >50% or dissection)

- **Post-dilatation: 49.6%**

- **Stent rate: 10.9%**

  flow limiting dissection: 6.7%
  persistent stenosis: 8.6%

In.Pact SFA Long: 2-year Primary Patency



Lesion length: 251.71 ±78.9 mm

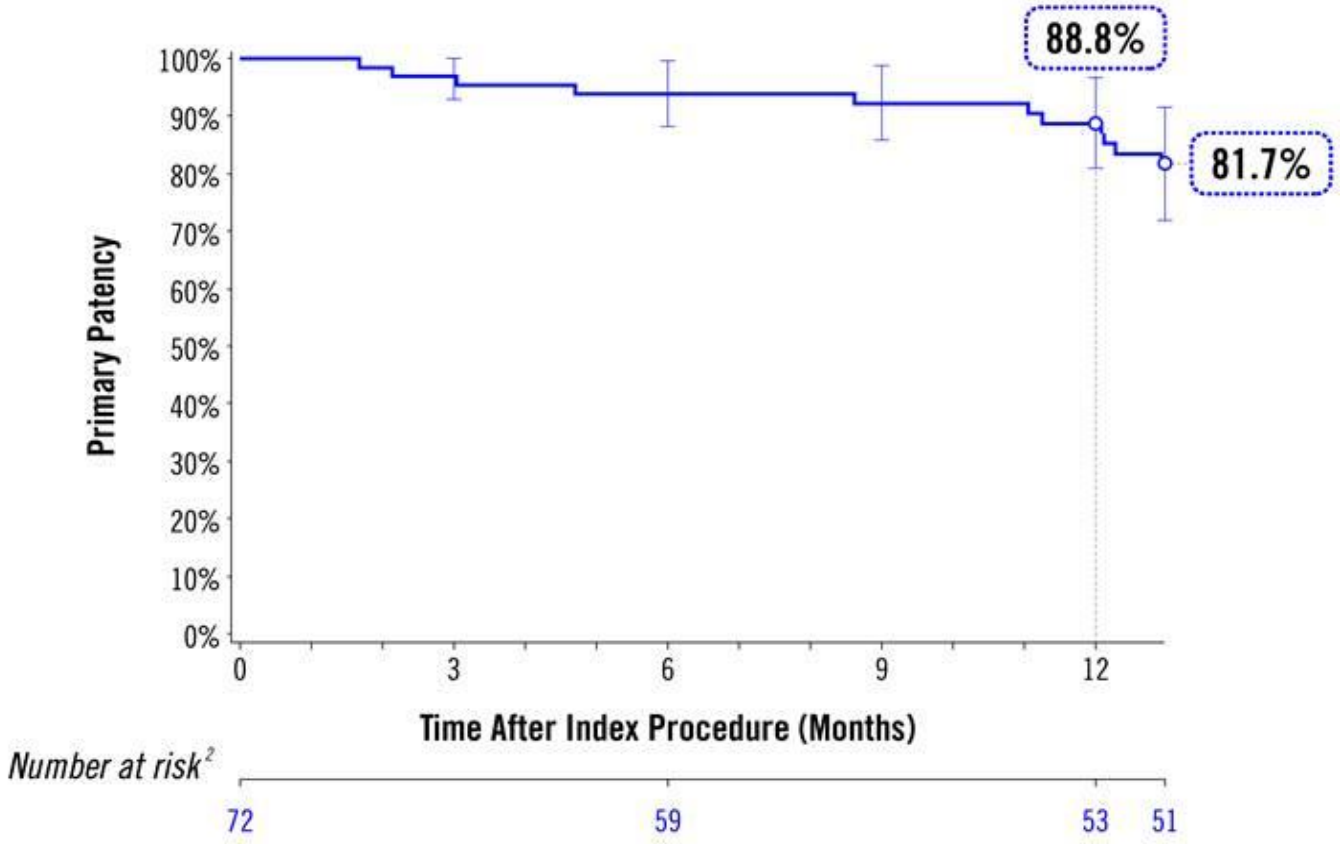
IN.PACT Global (LL&CTO) + Severe Calcium

IN.PACT Global IMG Cohorts N=72 Subjects N=81 Lesions	
Lesion Type: % (n) De novo Restenotic (non-stented)	 81.5% (66/81) 18.5% (15/81)
Lesion Length (cm ± SD)	24.73 ± 10.82
Total Occlusions % (n)	60.3% (47/78)
Calcification[1] % (n) Severe Grade 4 % (n)	**100% (78/78)** **56.4% (44/78)**
TASC A-B C-D	 24.7% (19/77) 75.3% (58/77)
RVD (mm ± SD)	5.180 ± 0.600
Diameter Stenosis (% ± SD)	90.9 ± 15.0
Dissections after pre-dil: 0 A-C D-F	 46.9% (38/81) 40.7% (33/81) 12.4% (10/81)

1. Calcium definition used by both the study sites and core laboratory

IN.PACT Global (LL&CTO) + Severe Calcium

Primary Patency[1]



1. Freedom from core laboratory-assessed restenosis (duplex ultrasound PSVR ≤2.4) and clinically-driven target lesion revascularization through 12 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

Drug-Coated Balloons vs. Drug-Eluting Stents for Treatment of Long Femoropopliteal Lesions

Thomas Zeller, MD[1]; Aljoscha Rastan, MD[1]; Roland Macharzina, MD[1]; Gunnar Tepe, MD[2]; Matthias Kaspar, MD[1]; Jorge Chavarria, MD[1]; Ulrich Beschorner, MD[1]; Uwe Schwarzwälder, MD[1]; Thomas Schwarz, MD[1]; and Elias Noory, MD[1]

J ENDOVASC THER 2014;21:359–368

Retrospective dual center study

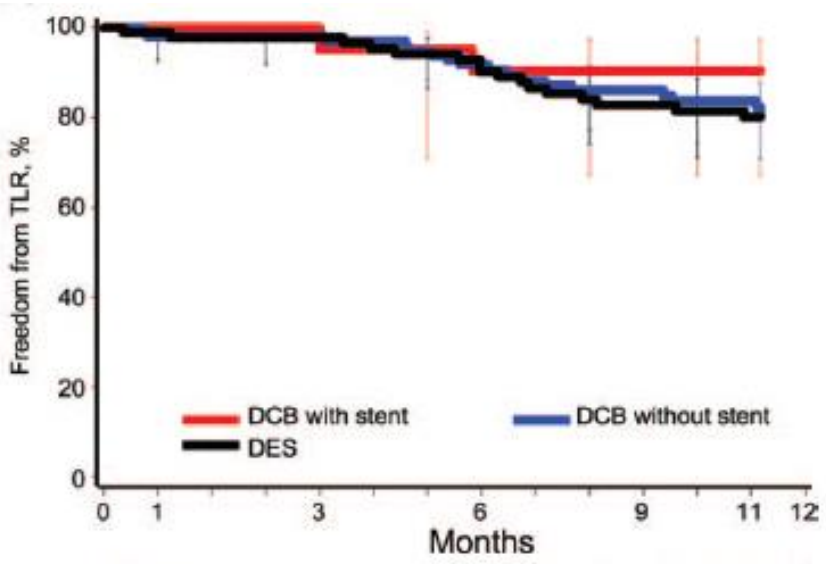
228 patients DCB: 131 DES: 97 (after propensity score stratification)

Lesion length (mm)

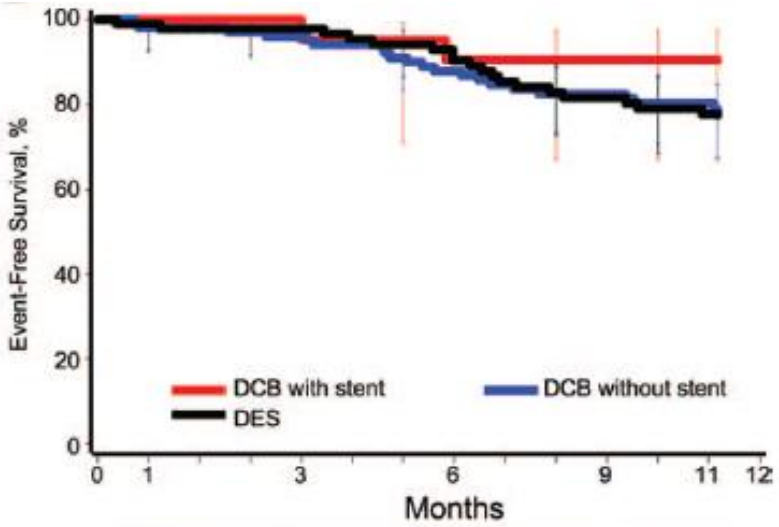
DCB: 194.46±86.3 [100–450]

DES: 195.06±64.5 [100–350]

p=0.948

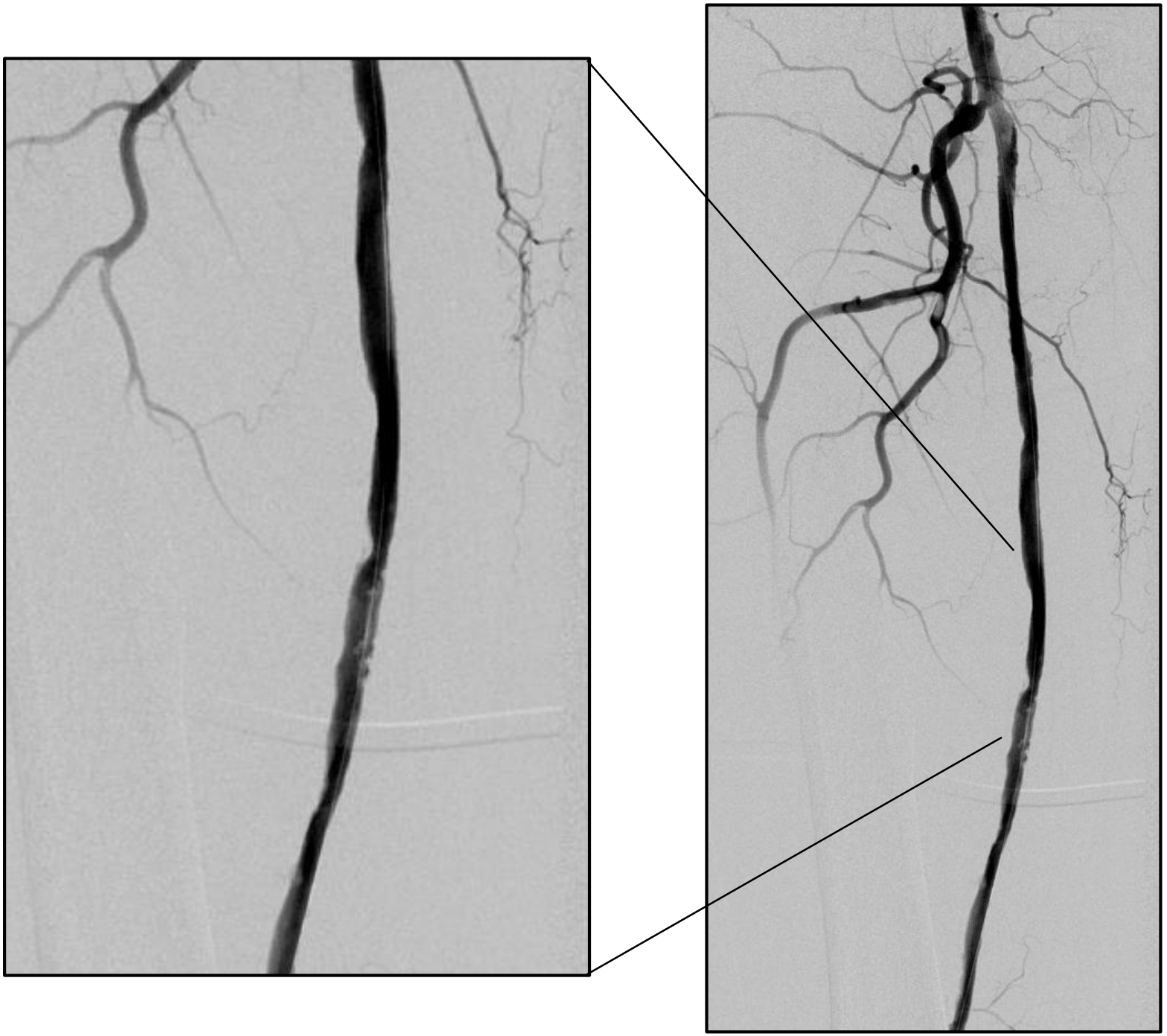


Months	0	1	3	6	9	11	12
At risk							
DCB with provisional stent	24	23	23	21	20	19	19
DCB without provisional stent	107	102	100	97	89	74	66
DES	97	97	94	82	76	66	61

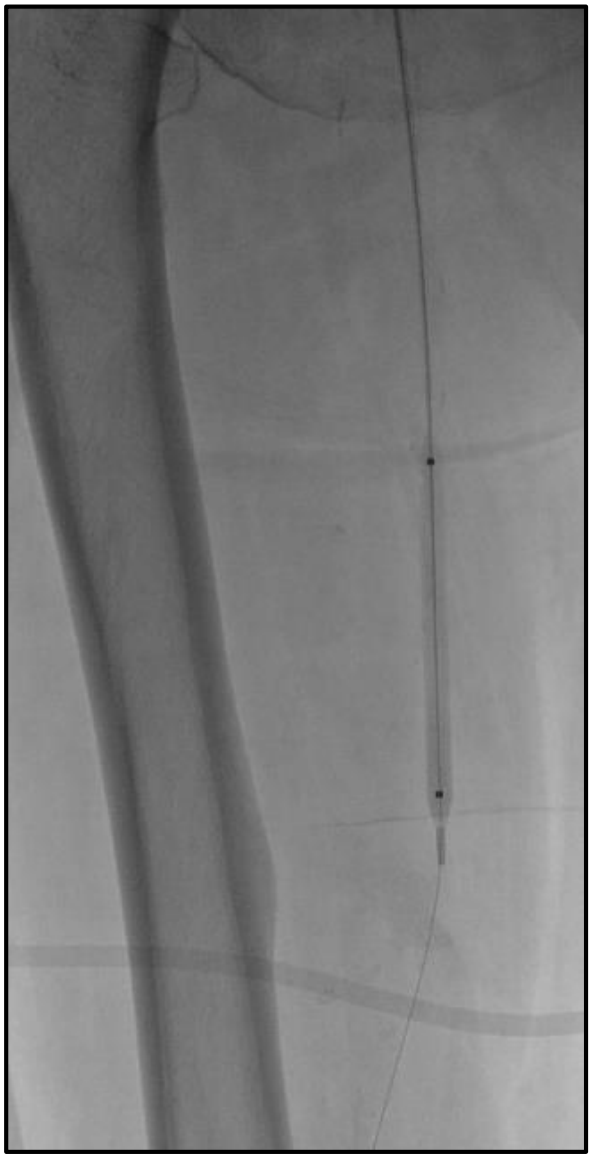


Months	0	1	3	6	9	11	12
At risk							
DCB with provisional stent	24	23	23	21	20	19	19
DCB without provisional stent	107	102	100	97	89	74	66
DES	97	97	94	82	76	66	61

“The 1-year outcome of DCB and DES angioplasty in long femoropopliteal lesions compares well with currently published outcomes for the bypass surgery gold standard treatment of these challenging lesions. Due to its ease of use and no scaffold left behind, DCB angioplasty with or without provisional bare nitinol spot stenting might be preferred over DES implantation.”



Pressure Gradient >30 mmHg

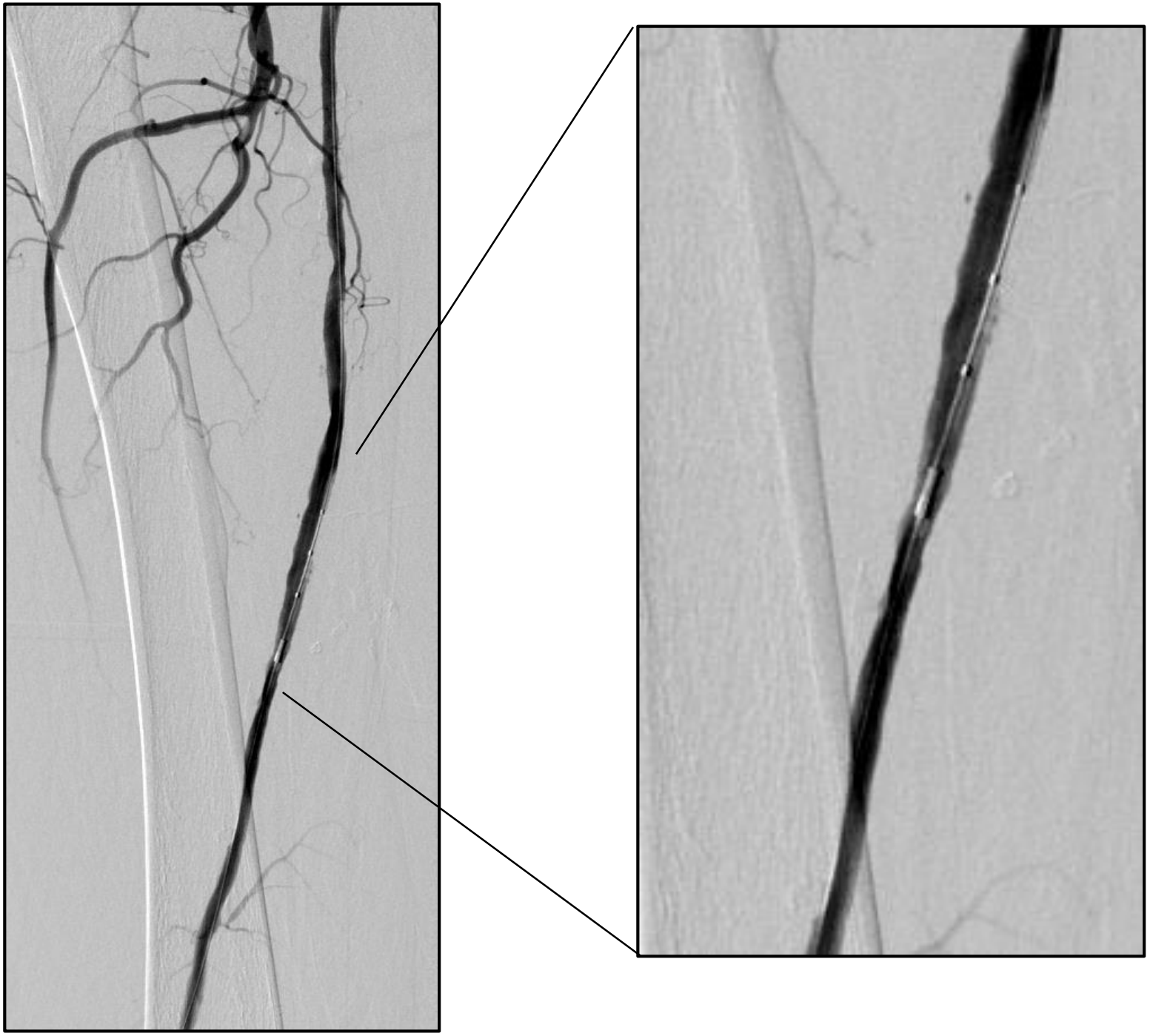


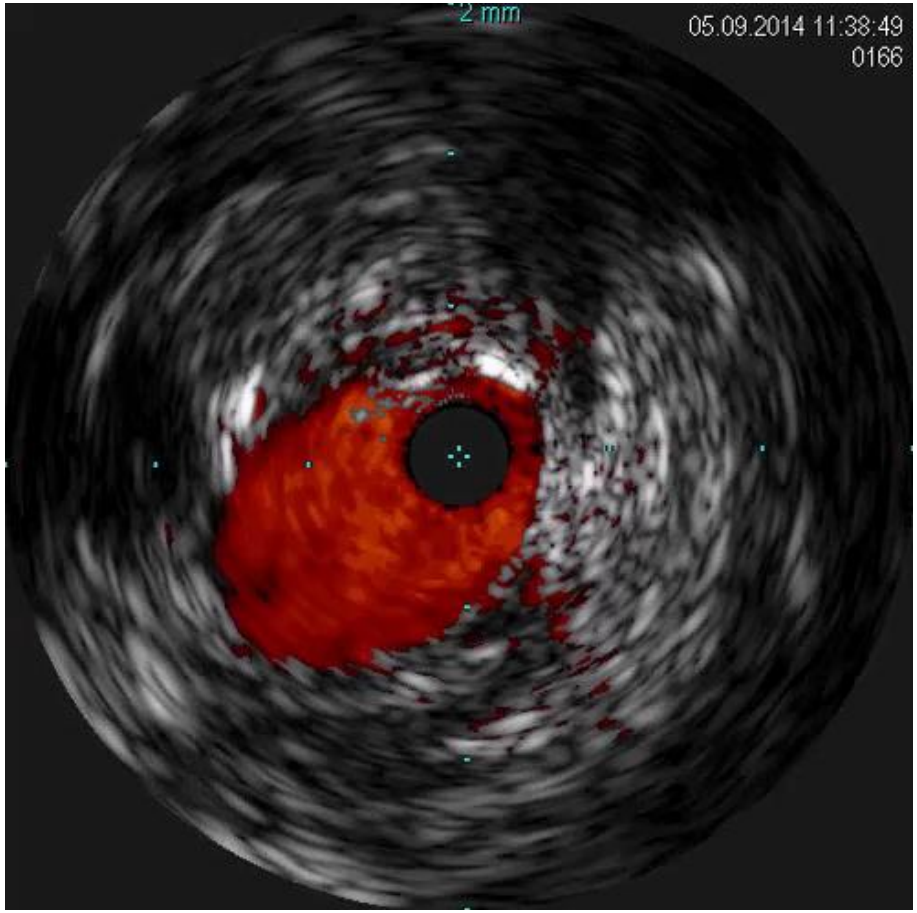
Admiral 5x40 mm
(Medtronic)

Inflation time: 3 min

Admiral 5x40 mm
(Medtronic)

Inflation time: 3 min



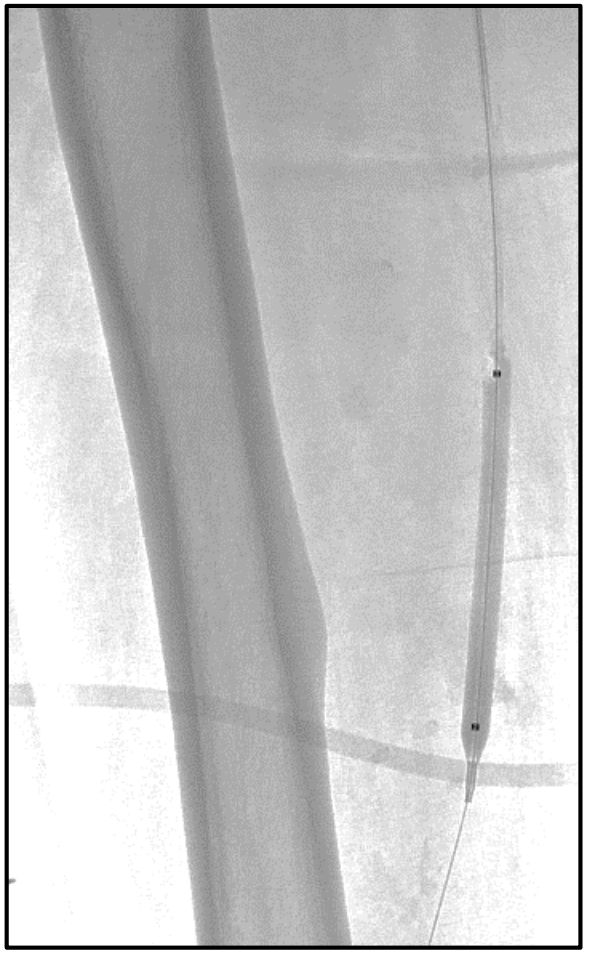

2 mm
05.09.2014 11:38:49
0166

Optimal PTA
Effect of Short vs Long Balloon Inflation Times on the Morphologic Results[1]

	Inflation Time (sec)		
	30	180	*P*-Value
Major dissection (grades 3 or 4)	16	5	.010
Minor or no dissection (grades 1 and 2)	21	32	.010
Further interventions (Stent, repeat dilatation, dilation with larger diameter)	20	9	.017
Residual stenosis (>30%)	12	5	.097
Complication (embolization, thrombosis)	1	1	-
Mean ankle-brachial index (before, after intervention)	0.66, 0.87	0.65, 0.84	

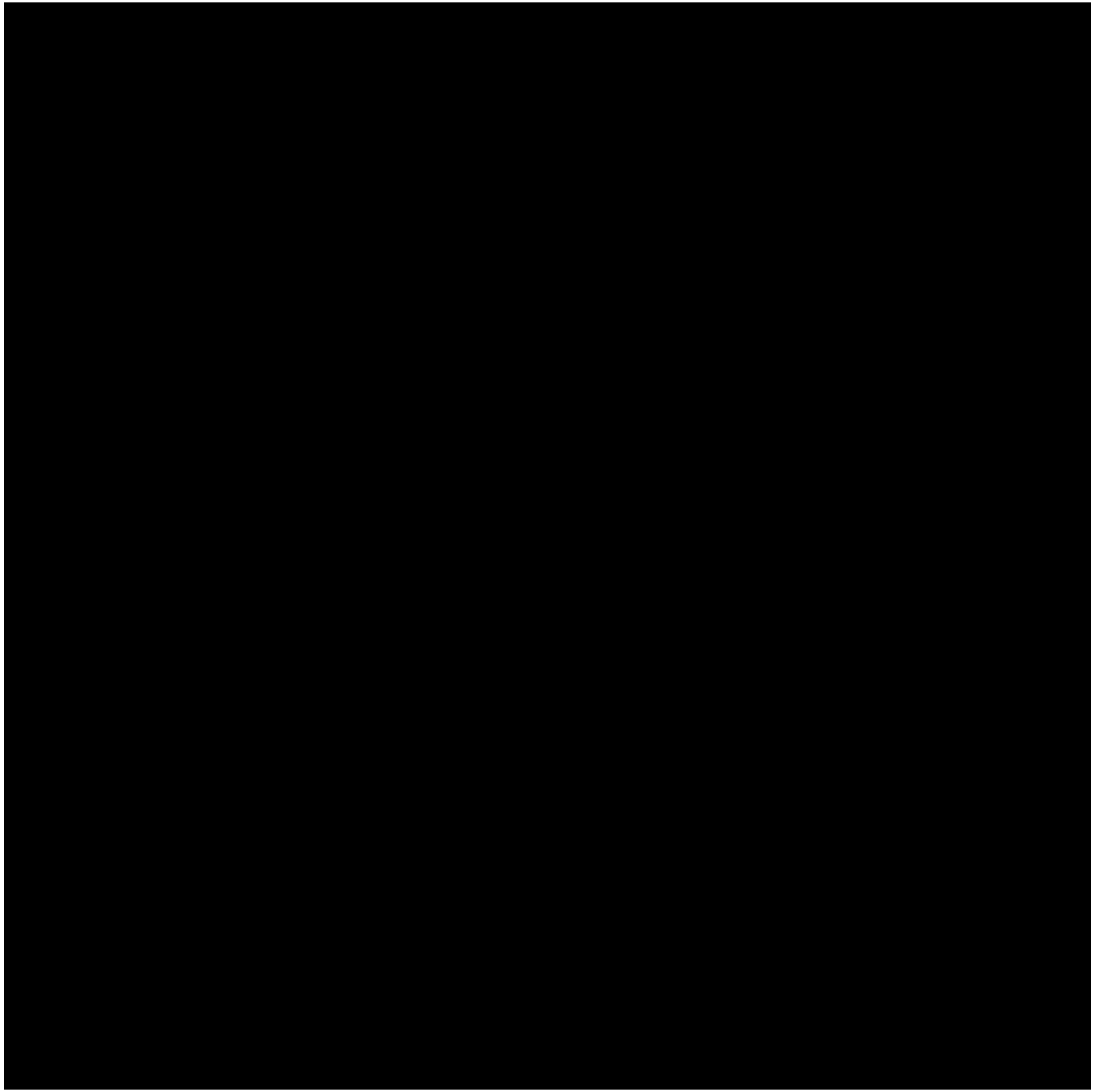
- Inflation times of 180 seconds improve immediate infrainguinal PTA results vs. a short dilation strategy
- Significantly fewer major dissections and a modest reduction of residual stenoses are observed
- Significantly fewer continued interventions

1. Zorger N, et al. J Vasc Interv Radiol 13:355-9 (2002).



Admiral 6x40 mm
(Medtronic)

Inflation time 5 min



Post – treatment therapy:

- Clopidrogrel 65mg/die 4 weeks

- Aspirin

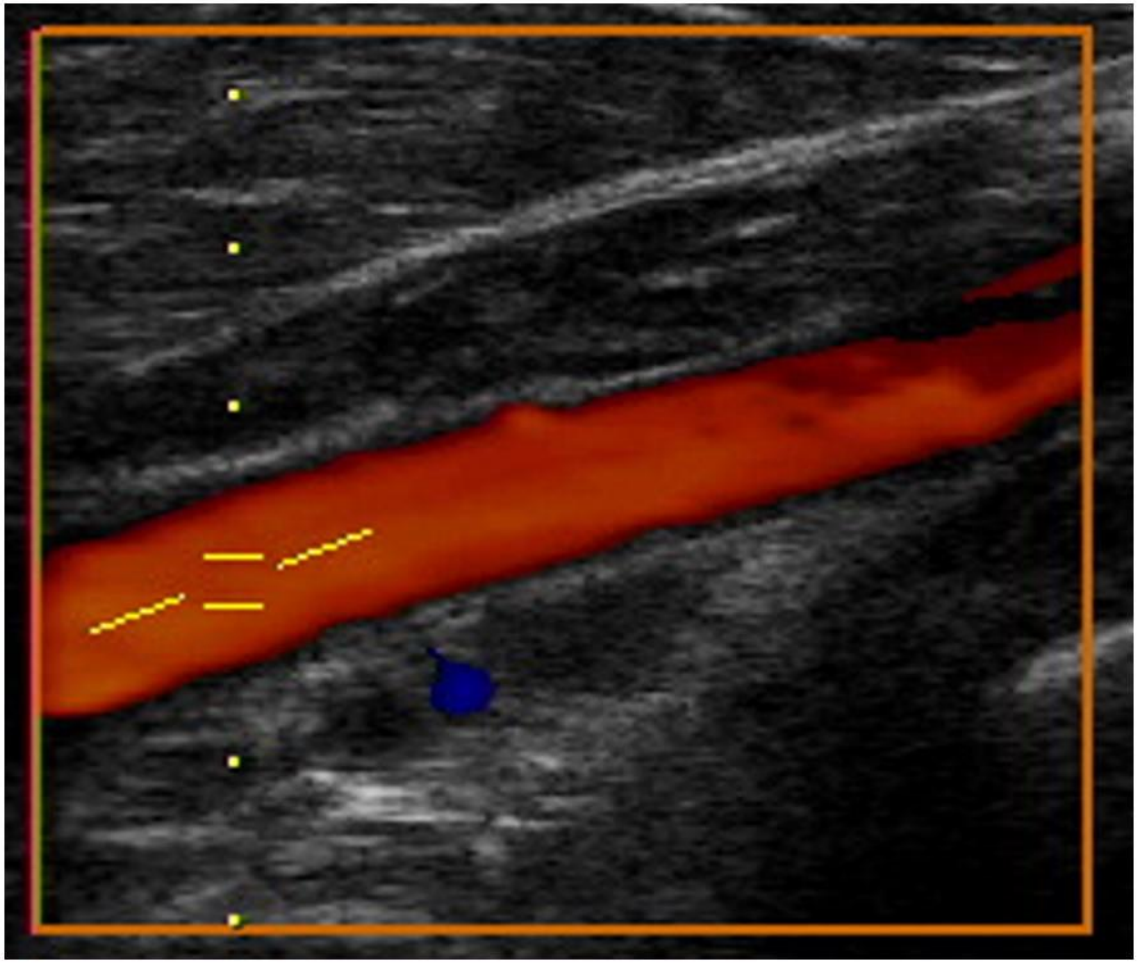
Clinical evaluation:

Lt claudication <50 mt

Recanalization Lt SFA 4 weeks later

2-y F.U.

ABI Rt: 0.85 Lt 0.85



2 y F.U.

Conclusions

- DCB shows excellent results in the fem-pop region when compare to standard PTA
- Continuous development in drug eluting devices
- DCB appears to be the new standard for femoral-popliteal intervention
- Level 1 Evidence support the role of DCBs as frontline therapy for fem-pop disease
- Overarching principle = DCB with “intention not to stent”
- Vessel preparation in complex lesions mandatory for both DCB and DES
- DCB command re-learning of PTA, call for more patience, longer time and high attention in interpretating final results. Not as easy and quick as a stent

fanellif@aou-careggi.toscana.it