BUILDING ENDOVASCULAR SYNERGIES

MEET 2014
MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY

Role of Stenting in the DCB Era

Marianne Brodmann, MD
Division of Angiology, Department of Internal Medicine
University of Graz, Graz (Austria)

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Faculty disclosure   Marianne Brodmann

I disclose the following financial relationships:

Consultant for BARD and Covidien Company

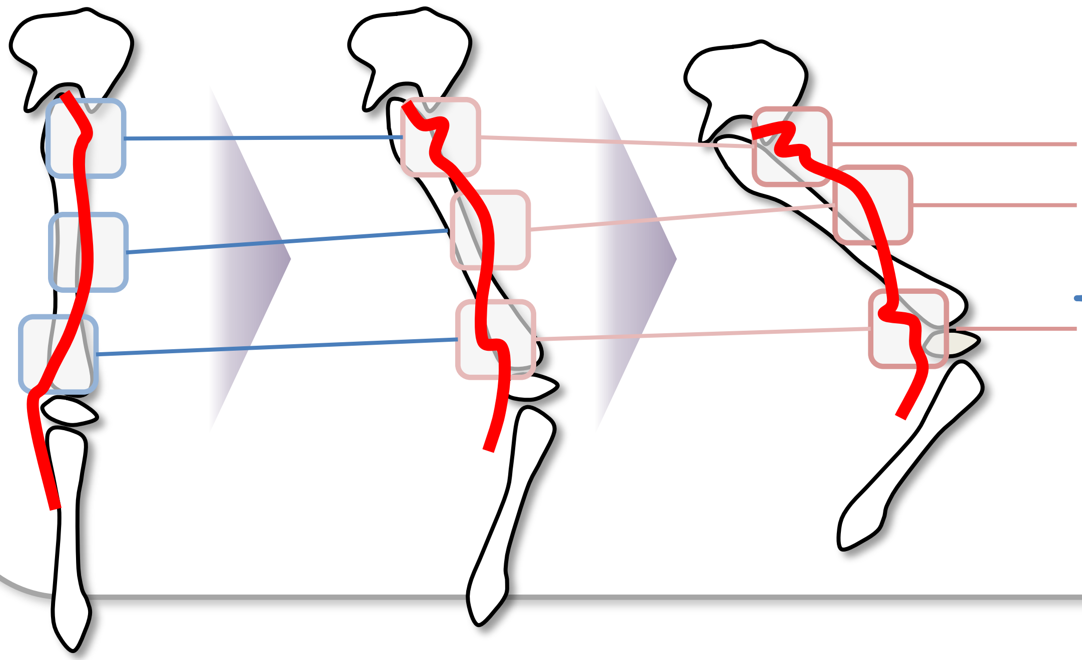
Receive grant/research support from Biotronik

Paid speaker for Medtronic

Background: SFA anatomy and dynamics

Longest, most stressed of body's vessels

Cyclic forces and vessel deformations

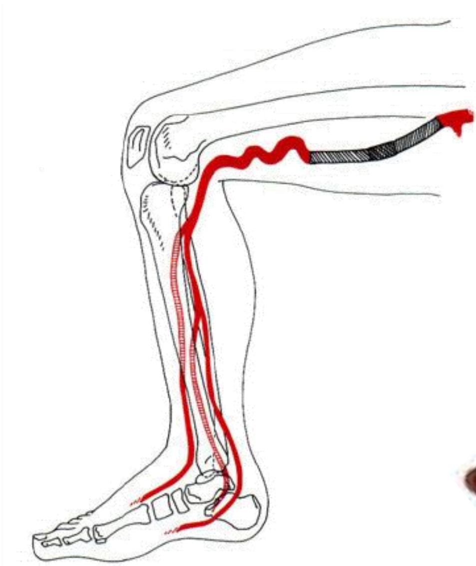


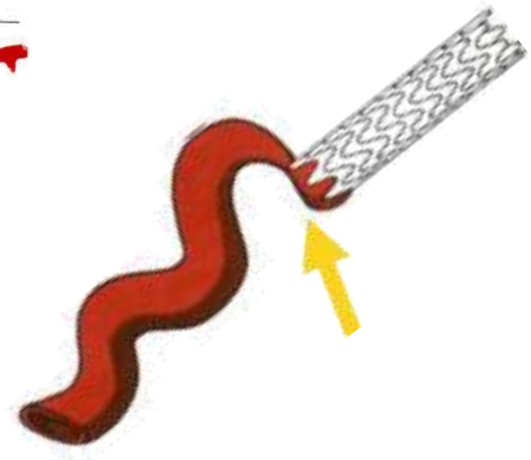
- Torsion
- Flexion
- Compression
- Bending
- Shortening

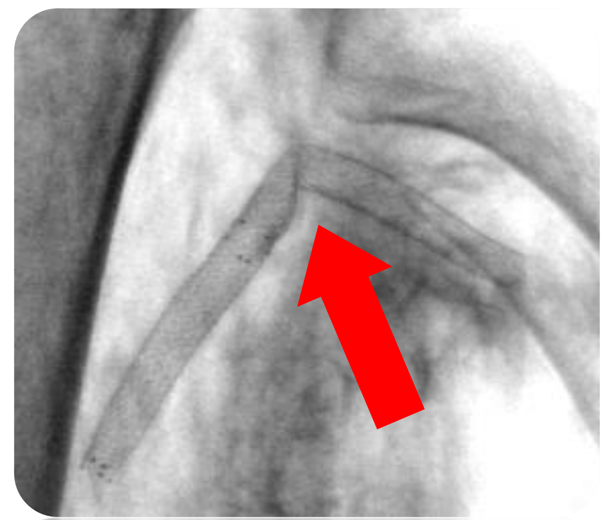
1. Cheng CP et al. In vivo MR angiographic quantification of axial and twisting deformations of the superficial femoral artery resulting from maximum hip and knee flexion. J Vasc Interv Radiol. 2006;17:979-987
2. Wood NB et al. Curvature and tortuosity of the superficial femoral artery: a possible risk factor for peripheral arterial disease. J Appl Physiol. 2006;101:1412-1418
3. Wensing PJ et al. Arterial tortuosity in the femoropopliteal region during knee flexion: a magnetic resonance angiographic study. J Anat. 1995; 187(Pt 1):133-139
4. Chilvers AS et al. The progression of arteriosclerosis. A radiological study. Circulation. 1974 Aug;50(2):402-8

Stents and Stent's Related Challenges

Implants reduce vessel compliance and their ability to absorb deformations



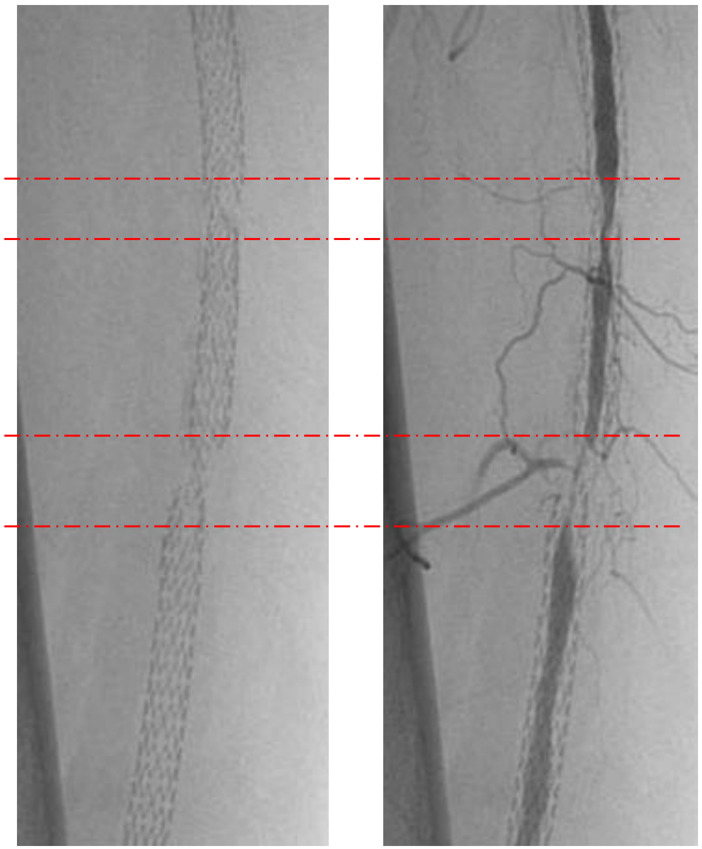




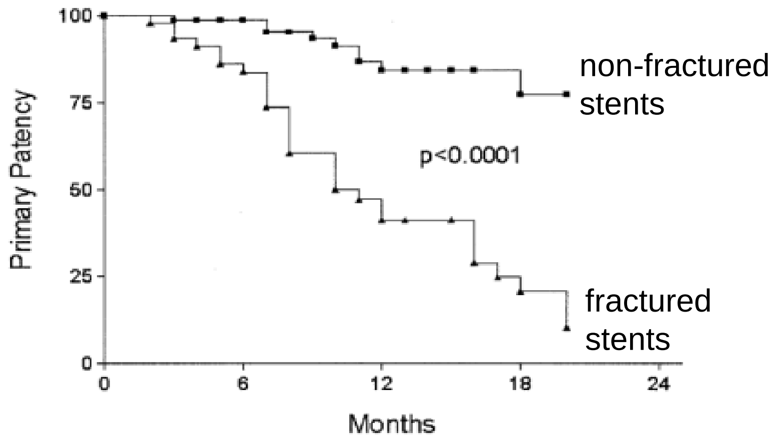
Smouse HB Changes in major peripheral arteries during joint movement before and after stent placement in the cadaver model. TCT 2004

Stents and Stent’s Related Challenges

Implants are subject to fatigue stress and fractures



- Fractures may trigger restenosis
- Long term incidence and implications of stent fractures remain unknown
- higher fracture rates associated with longer stents and higher physical exercise

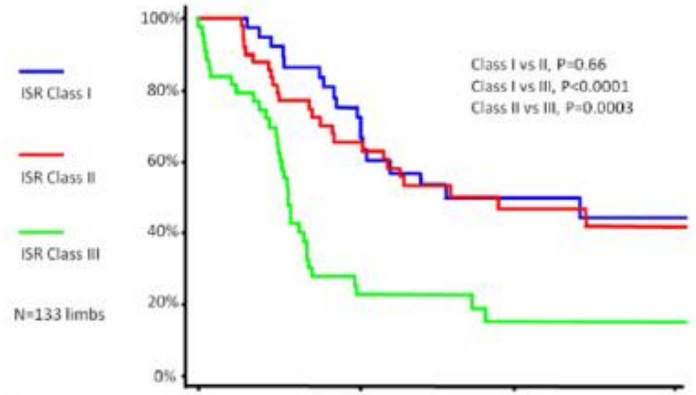


1. Scheinert D et al.Prevalence and clinical impact of stent fractures after femoropopliteal stenting. J Am Coll Cardiol. 2005 Jan 18;45(2):312-5
2. Iida O et al. Effect of exercise on frequency of stent fracture in the superficial femoral artery. Am J Cardiol. 2006;98:272-274
3. Nikanorov A et al.Fracture of self-expanding nitinol stents stressed in vitro under simulated intravascular conditions. J Vasc Surg. 2008 Aug;48(2):435-40

Stents and Stent's Related Challenges

In-Stent-restenosis 1-year incidence: 18 ~ 40%, ISR recurrence: higher than its first time incidence

Freedom From Recurrent ISR by ISR Class



Follow-up interval (years)		0	1	2	3
Class I	at risk	39	25	11	5
	%	100	72.5	50.1	44.5
Class II	at risk	50	28	12	5
	%	100	65.6	46.7	42.0
Class III	at risk	44	9	4	2
	%	100	22.7	15.2	15.2

ISR 2-year recurrence

- 49.9% in class I (focal)
- 53.3% in class II (diffuse)
- 84.8% in class III (occlusive)

1. Tosaka A, Soga Y, Iida O, Ishihara T, Hirano K, Suzuki K, Yokoi H, Nanto S, Nobuyoshi M. Classification and clinical impact of restenosis after femoropopliteal stenting. J Am Coll Cardiol. 2012 Jan 3;59(1):16-23
2. J.Laird et al. The Treatment of Femoropopliteal In-Stent Restenosis. JACC 2012

Rationale for a non-stent first-line approach

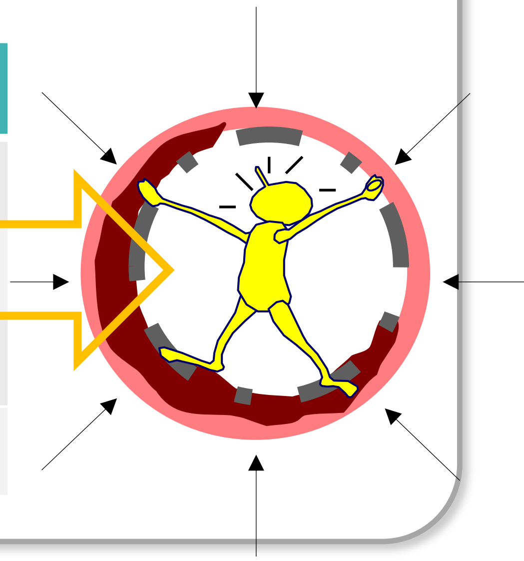
in consideration of PAD chronic nature, preservation of future therapy options should be a general target of everyday clinical strategy, especially for patients with long life and quality of life expectancy

Role of Stents in the DCB era?

To manage vessel recoil, refractory plaque resistance, persistent flow limiting dissections after Optimal PTA

Endovascular Revascularization Mechanisms

	PTA	BMS	DES	Ather	DCB
Dilatation	X	X	X		X
Scaffolding		X	X		
Debulking				X	
Drug Elution			X		X



Role of Stents in the DCB era?

To manage severe Calcium and associated challenges

- Calcium not fully detected by Angiography
- Increases the occurrence of dissections post PTA
- Cause of stent malapposition, sub-optimal expansion
- Predictor of stent fractures
- Potential barrier for optimal drug absorption

1. Kashyap VS et al. Angiography Underestimates Peripheral Atherosclerosis: Lumenography Revisited. J Endovasc Ther 2008;15:117–125
2. Fitzgerald PJ et al. Contribution of localized calcium deposits to dissection after angioplasty. Circulation. 1992; 86(1):64-70
3. Fanelli F et al. Calcium Burden Assessment and Impact on Drug-Eluting Balloons in Peripheral Arterial Disease. Cardiovasc Intervent Radiol. 2014 May 9

Role of Stents in the DCB era?

To resolve failure after Optimal PTA

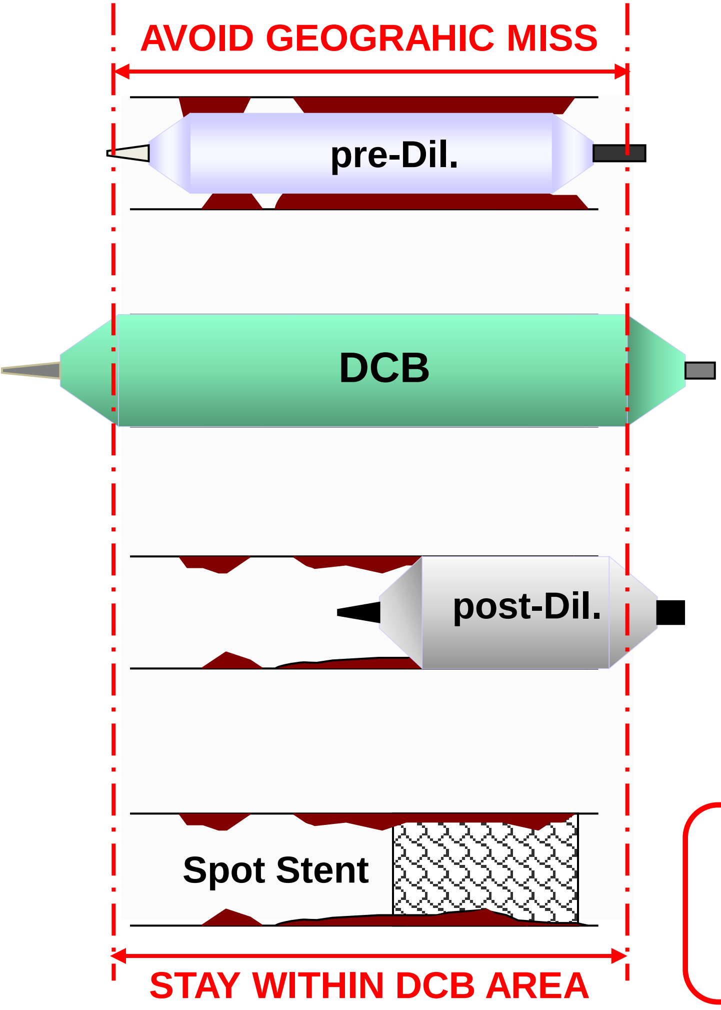
Prolonged inflations reduce dissection entity and rates and the need for stents

	Inflation Time (sec)		
	30	180	*P* Value
Major dissection (grades 3 and 4)	16	5	.010
Minor or no dissection (grades 1 and 2)	21	32	.010
Further interventions	20	9	.017
Stent	4	1	
Further dilation (prolonged dilation, dilation with larger diameter)	16	8	
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 sec improve immediate infrainguinal PTA results vs. to a short dilation strategy
- Significantly fewer major dissections and a modest reduction of residual stenoses are observed

N. Zorger et al. Peripheral Arterial Balloon Angioplasty: Effect of Short versus Long Balloon Inflation Times on the Morphologic Results. J Vasc Interv Radiol 2002

DCB and Optimal PTA



1. Pre-dilatation (CTOs, sub-occl. lesions, Ca++)

a. standard PTA Ø1 mm less than RVD
b. Balloon length>lesion length or planned DCB length, whichever is longer
c. inflation time ~ 2 minutes
d. inflation pressure: < RBP as needed to reach full PTA balloon expansion

2. DCB

a. DCB Ø: RVD = 1:1
b. inflation time ≥ 3min
c. inflation pressure: <RBP as required to reach full DCB expansion

3. Post-Dilatation if residual stenosis >50% or flow limiting dissection

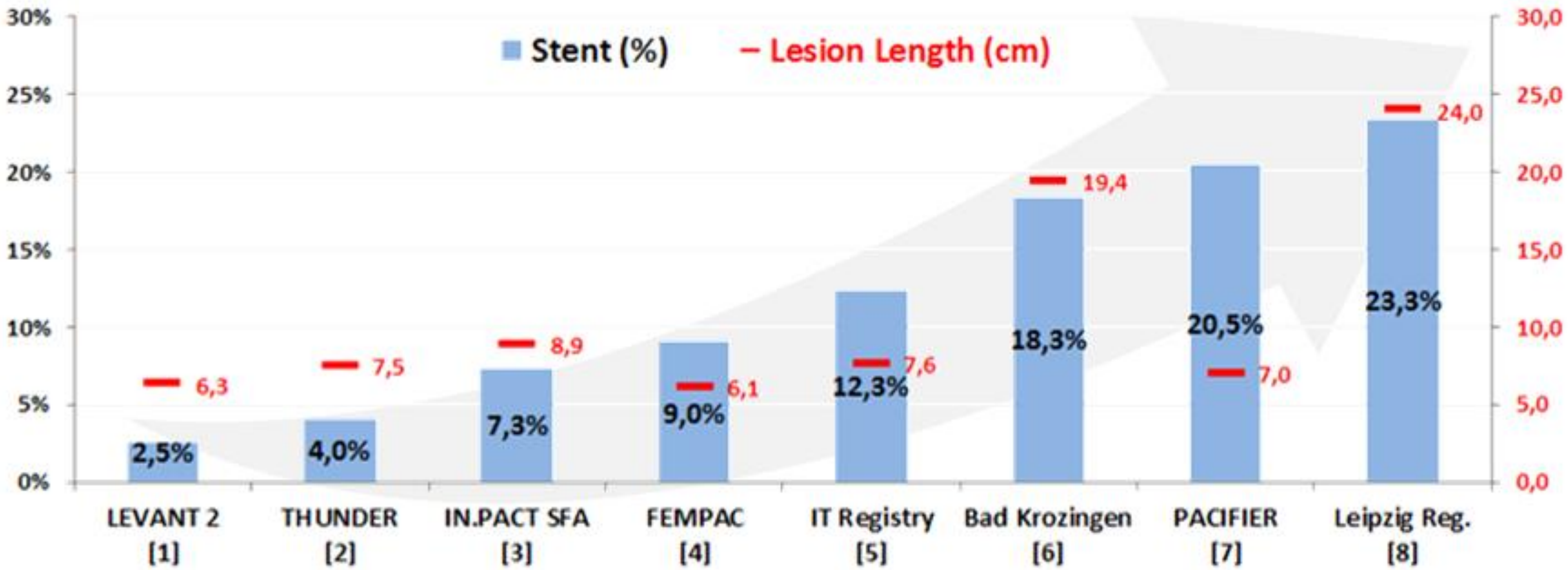
a. standard or high pressure PTA balloon Ø 1:1 to RVD
b. short / focal length as necessary to treat the extent of residual stenosis or dissection
c. inflation time ≥ 3 minutes

4. Provisional Spot Stenting for persistent residual stenosis >50% or flow limiting dissections

1. Min. length as necessary to fully treat the residual stenosis or dissection

DCB and Provisional Stenting

In spite of Optimal PTA, scaffolds are still needed, likely at rates proportional to lesion complexity

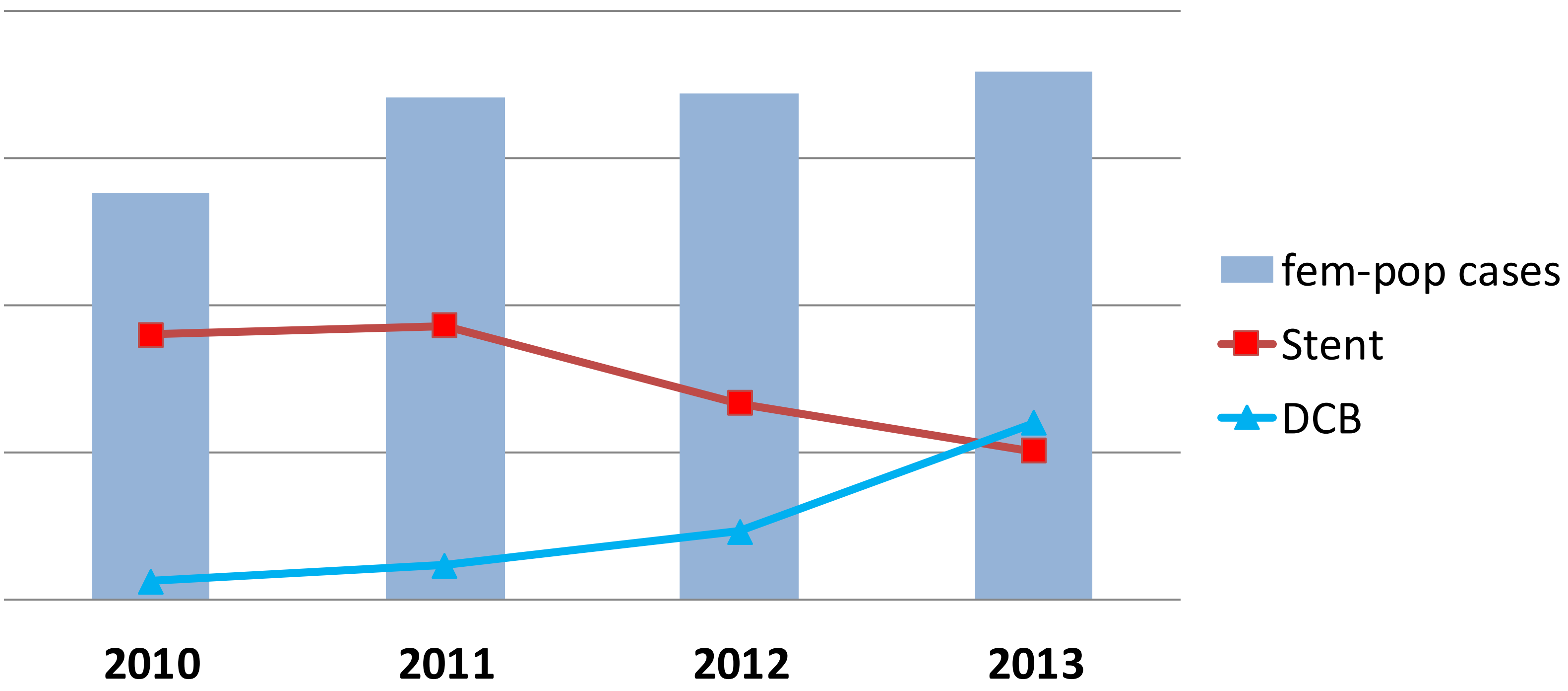


Provisional stent rates in DCB Trials as function of lesion length

[1] Rosenfield K TCT 2013; [2] Tepe G et al. N Engl J Med 2008; [3] Tepe CX 2014; [4] Werk M et al. Circulation 2008; [5] Micari A et al. J Am Coll Cardiol Intv 2012; [6] Zeller T CX 2013 oral presentation; [7] Werk et al. Circ Cardiovasc Interv. 2012; [8] Schmidt A LINC 2013 oral presentation

DCB and Provisional Stenting

How DCBs have changed my Stent practice



University of Graz, Austria

Case Example: IN.PACT Italian Registry

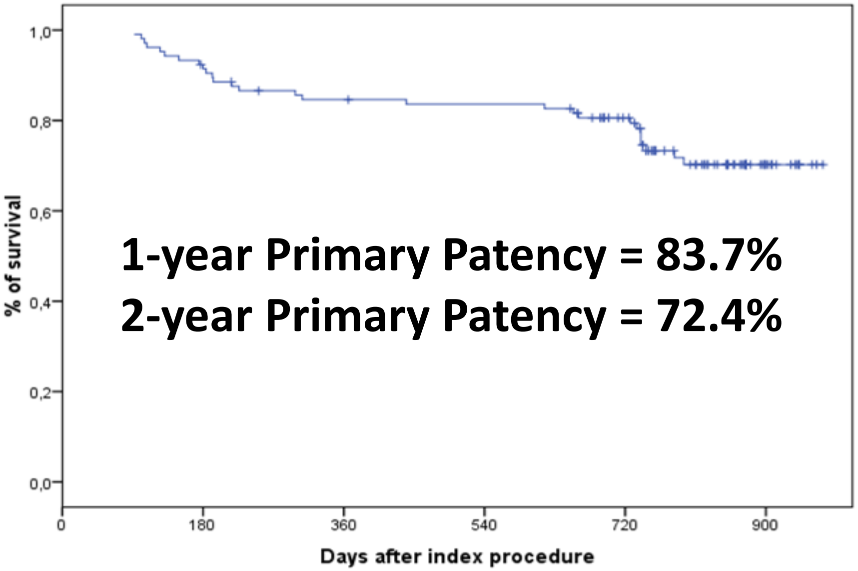
105-Patient multicenter Registry

Key Characteristics	
Diabetes	48.6%
RC≥3	72.4%
Lesion length	76.3 mm
CTO	29.8%
Ca++	16.7%

12.3% Provisional Stenting

- Optimal PTA limit Stent use
- IN.PACT DCB + Optimal PTA results in high Primary Patency and sustained functional benefit

Primary Patency



3.5-fold ↑ in walk capacity at 2-year

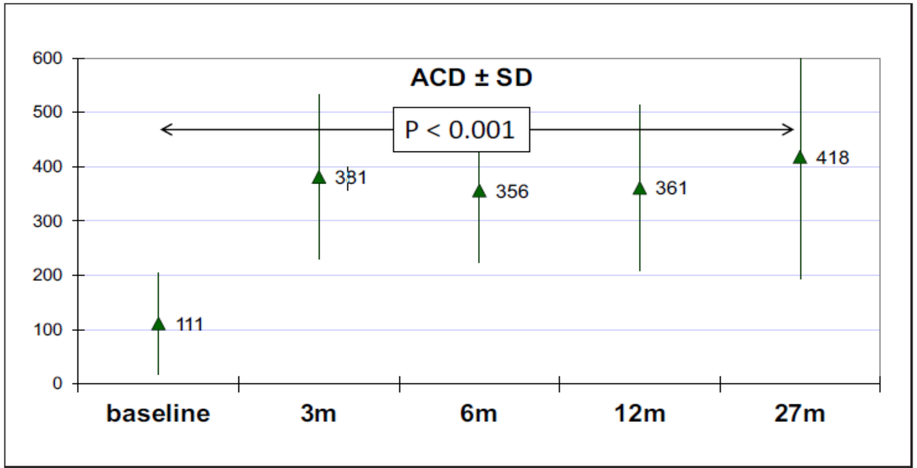


Figure 9. ACD

(Micari A et al. J Am Coll Cardiol Intv 2013)

Case Example: DEBATE SFA

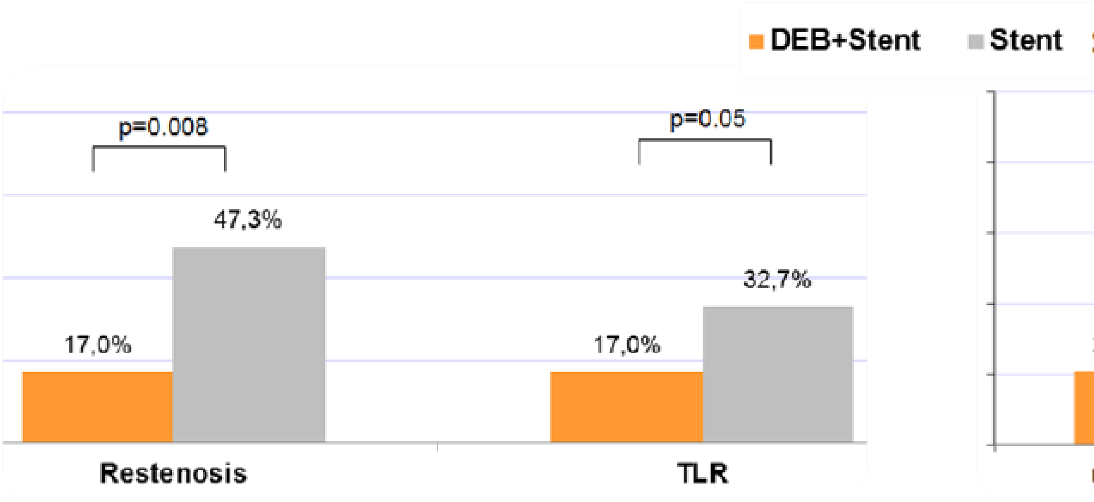
104-Patient, single center Randomized Study

Key Characteristics	
Diabetes	77.4%
RC≥3	100.0%
Lesion length	94.0 mm
CTO	54.5%
Ca++	21.8%

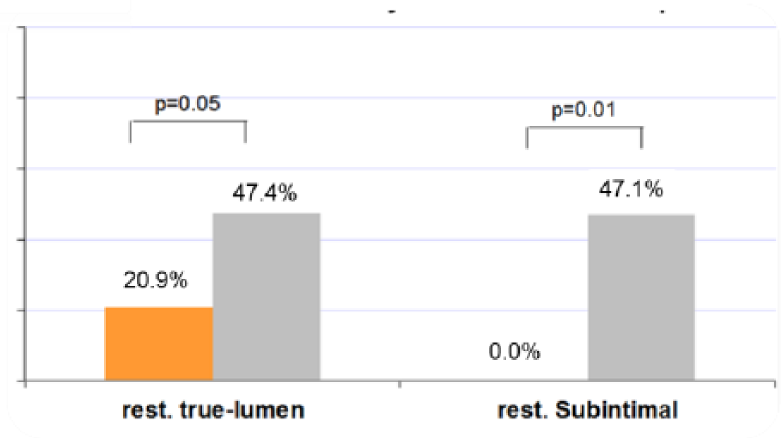
100% (elective) Stenting

IN.PACT DCB with systematic stent is superior to stent alone in complex lesions and highly diseased population (diabetes and CLI >70%)

1-Year Restenosis and TLR



1-Year Restenosis: subintimal vs. true lumen



(F.Liistro et al. J Am Coll Cardiol Intv 2013)

Key requisites of Stents in the DCB era

Stent mechanical characteristics may be even more important when needed provisionally after failed PTA

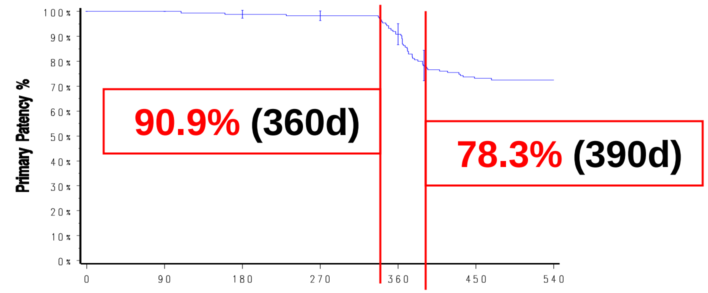
1. **High fracture resistance** to withstand fatigue stress and Ca++ related forces
2. **Adequate radial force** to react to Ca++ and higly resistant lesions
3. **Precise deployment** for correct positioning without geographic miss
4. **Wide mix including short lengths** for spot / focal stenting

Complete SE Stent

Clinically Proven

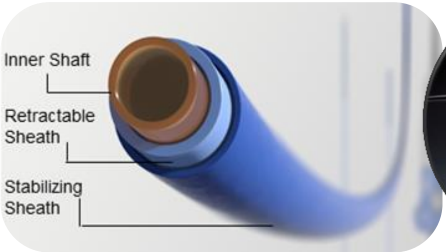
- 12-month TLR = 8.4%
- 12-month TVR = 11%
- 12-month MAE = 11%

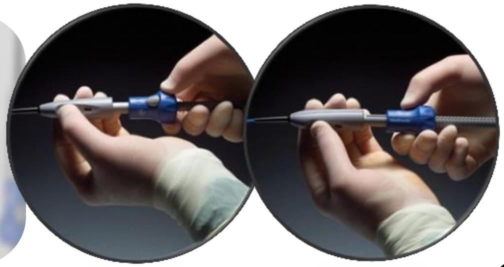
Primary Patency



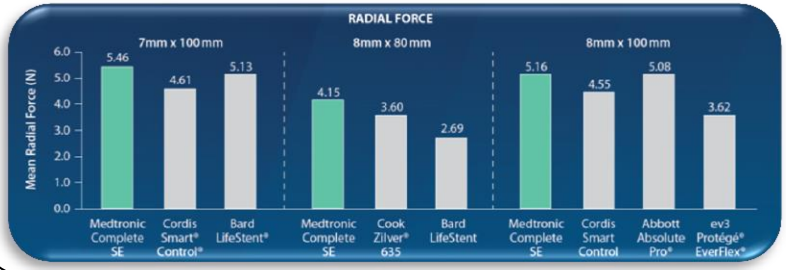
Accurate deployment and availability of short lenghts

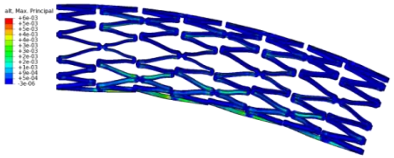
- Triaxial Shaft Design with Dual Deployment Handle
- Short lengths down to 20 mm

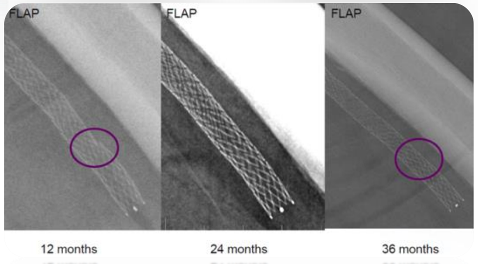




Optimized Radial Force and Fracture resistance

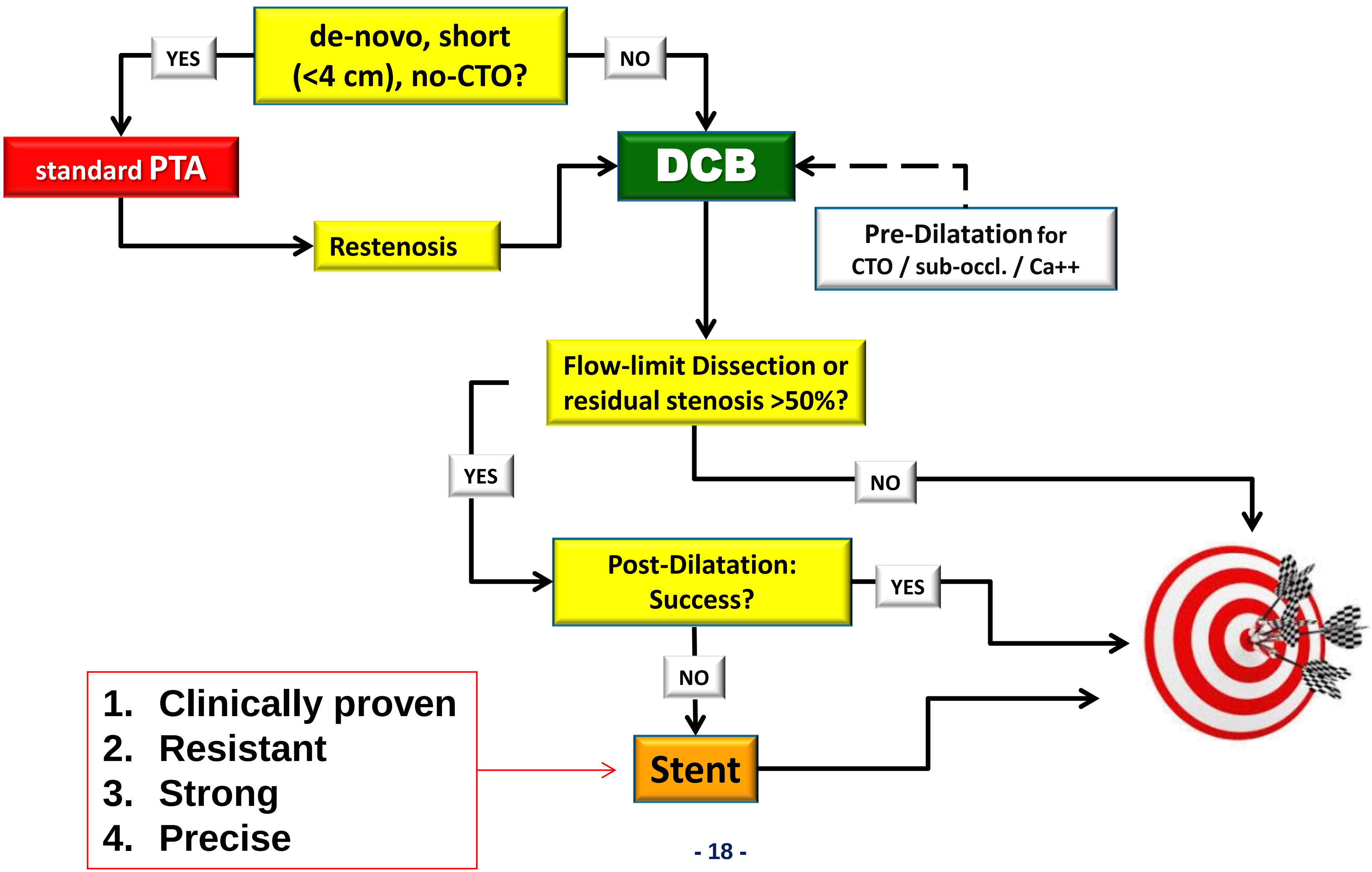






0% Fractures by FEA Corelab assessment

My fem-pop treatment algorithm



Conclusions

- DCB + Optimal PTA is backed by compelling evidence and gaining first-line treatment role in fem-pop practice
- DCB made stents just less necessary, still necessary at rates proportional to lesion complexity
- Stent mechanical features even more important when used after failed PTA as typical for old CTOs, highly resistant, highly calcified lesions
- Only best stents will survive in the DCB era