

CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY

JANUARY 19-21 2017

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER

PARIS, FRANCE



In stent restenosis: does DEB work?

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Disclosure

Speaker name:

.....G.Torsello.....

I have the following potential conflicts of interest to report:

Consulting

Employment in industry

Shareholder in a healthcare company

Owner of a healthcare company

Other(s)

✓

I do not have any potential conflict of interest



ISR is a frequent complication of
fempop stenting

20 - 37% @ 1 year



Recurrence after POBA for
fem-pop ISR is frequent

50 - 80% @ 2 years



Restenotic patterns are important
predictors for recurrence

49.9% class I (focal)

53.3% class II (diffuse)

84.8% class III (occlusive)



Treatment of fem-pop ISR

**Treatment can be
demanding and risky**

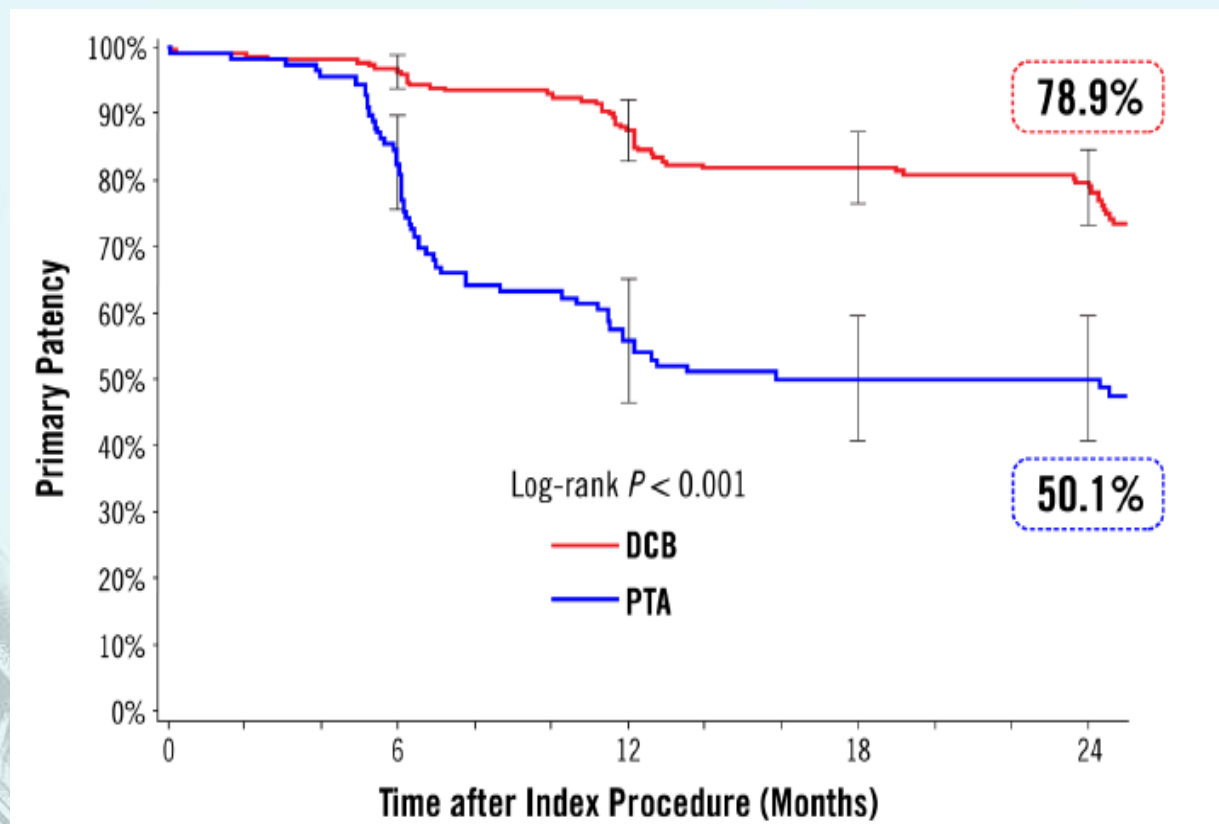


Treatment of fem-pop ISR

- Rate of recurrent restenosis after POBA is unacceptable
- Mixed results after stent-in-stent, cutting balloons, laser and atherectomy
- DEB appears as an attractive option

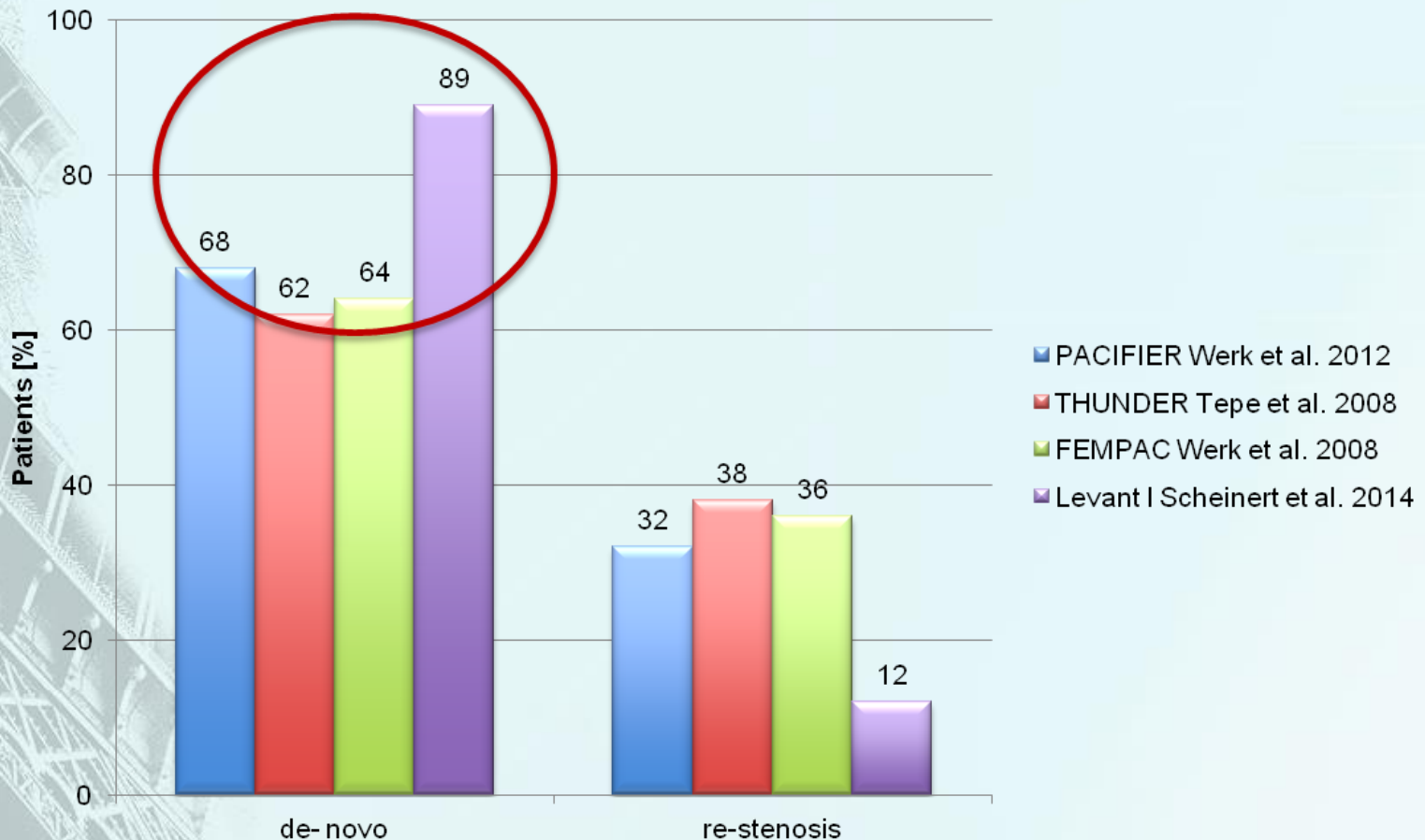


Results of RCT DEB vs. PTA IN.PACT





..... but the majority of the treated lesions was a de-novo stenosis





Our experience - Study Design -

- prospective data collection of DEB in SFA



- retrospective evaluation

100 patients



restenosis group
incl. ISR
61 patients
65 lesions

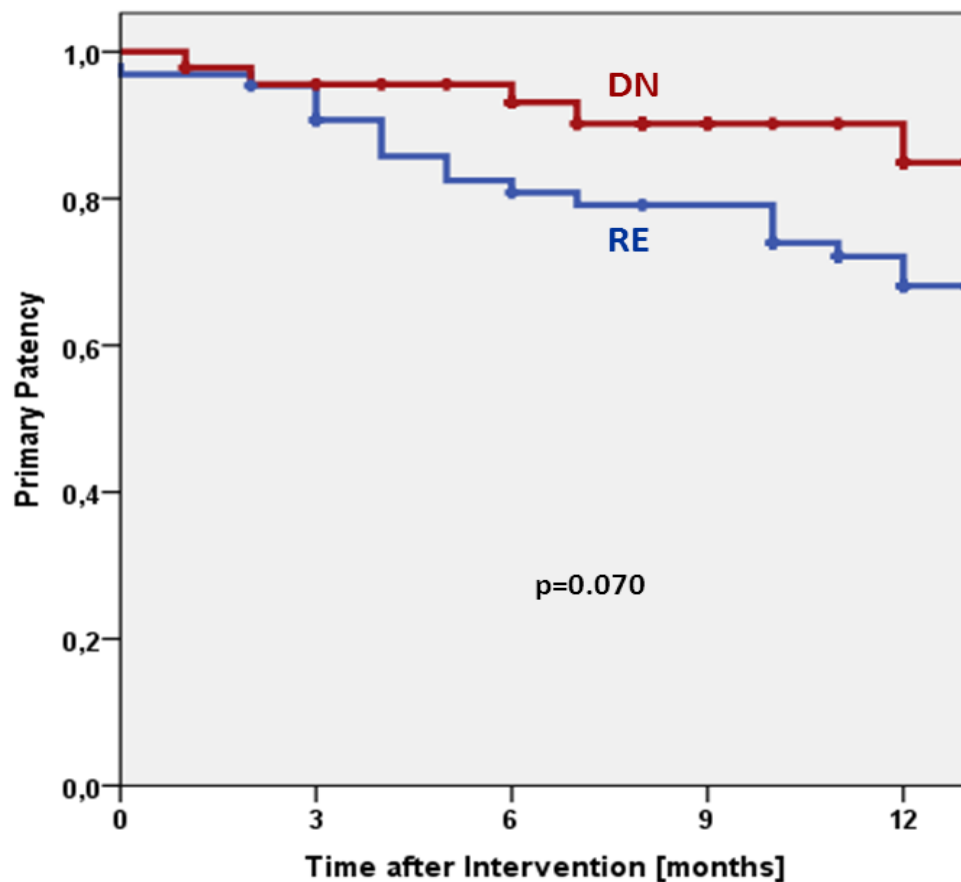
111 lesions



de-novo stenosis group
39 patients
46 lesions



Primary Patency



Primary Patency	boths groups	RE	DN	P-value
6 months	85.9%	80.8%	93.1%	0.093
12 months	74.0%	68.1%	84.9%	0.021

From: Herten M. [Drug-eluting balloons for femoropopliteal lesions show better performance in de novo stenosis or occlusion than in restenosis.](#) J Vasc Surg. 2015; 61:394-9.

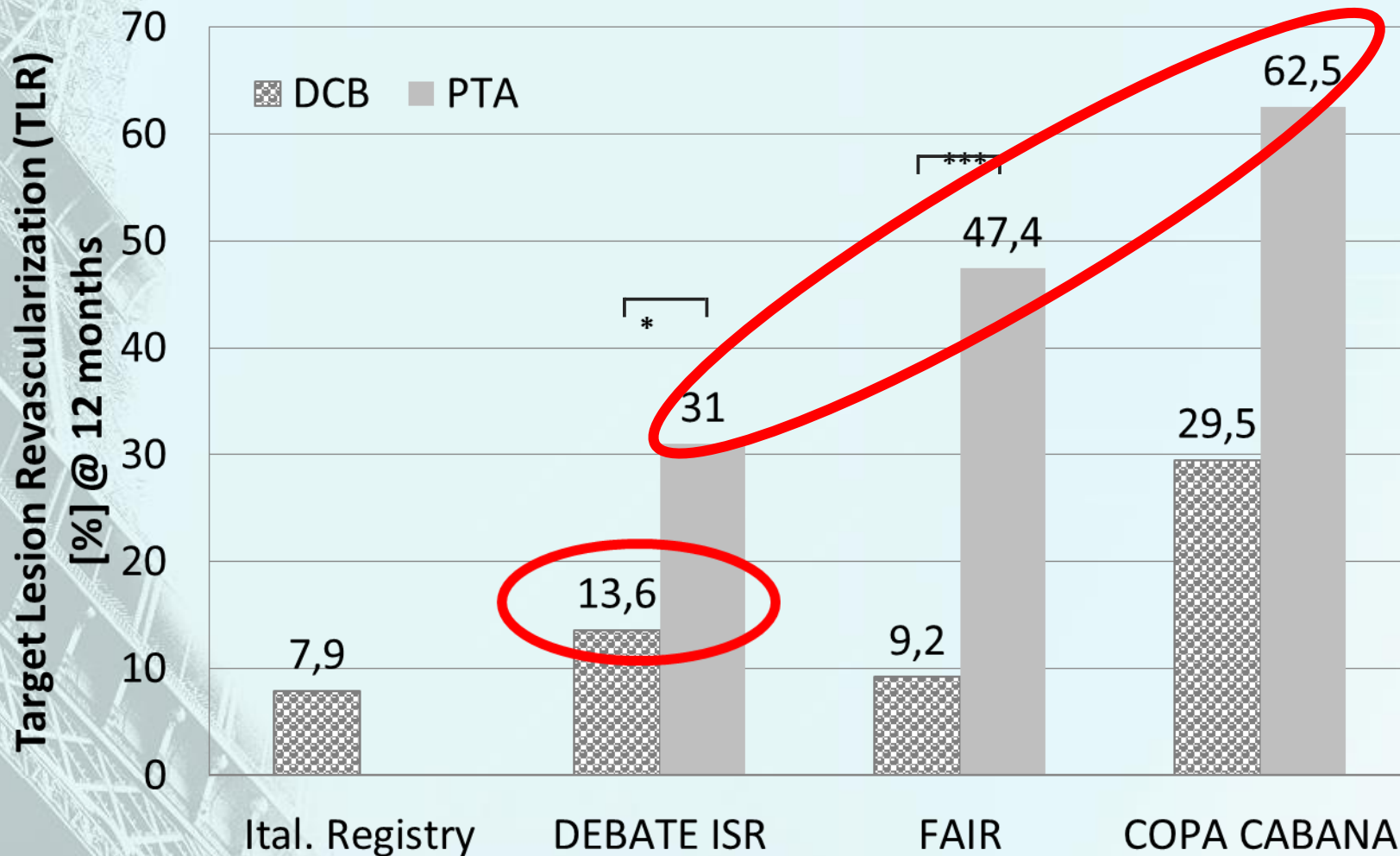
DCB for ISR in fempop segment -RCTs & registries



	name <i>author</i>	Ital. Registry <i>Stabile et al.</i> 2012	DEBATE ISR <i>Liistro et al.</i> 2014			FAIR <i>Krankenberget al.</i> 2015		COPA CABANA <i>Tepe et al.</i> 2015	
			DCB	DCB	PTA	DCB	PTA	DCB	PTA
DCB type used		IN.PACT™	IN.PACT™ Admiral			IN.PACT™ Admiral		Cotavance®	
characteristics	parameter	unit	DCB	DCB	PTA	DCB	PTA	DCB	PTA
	patient number		39	44	42	62	57	47	41
	diabetics	[%]	49	100	100	45	30	43	46
	CLI	[%]		75	67	4.8	10.5	8	11
	lesion length	[mm]	83	132	137	82	81	119	109
	total occlusion	[%]	20			24	33	18	35
bailout stenting	[%]	10.3	15.9	26.2	1.6	7.0			
12 mo	improved RU				higher	√			
www.cacvs.org	improved ABI				√	√			



1-year results of DCB for ISR





Are the results durable? Three-Year Results of the DEBATE-ISR

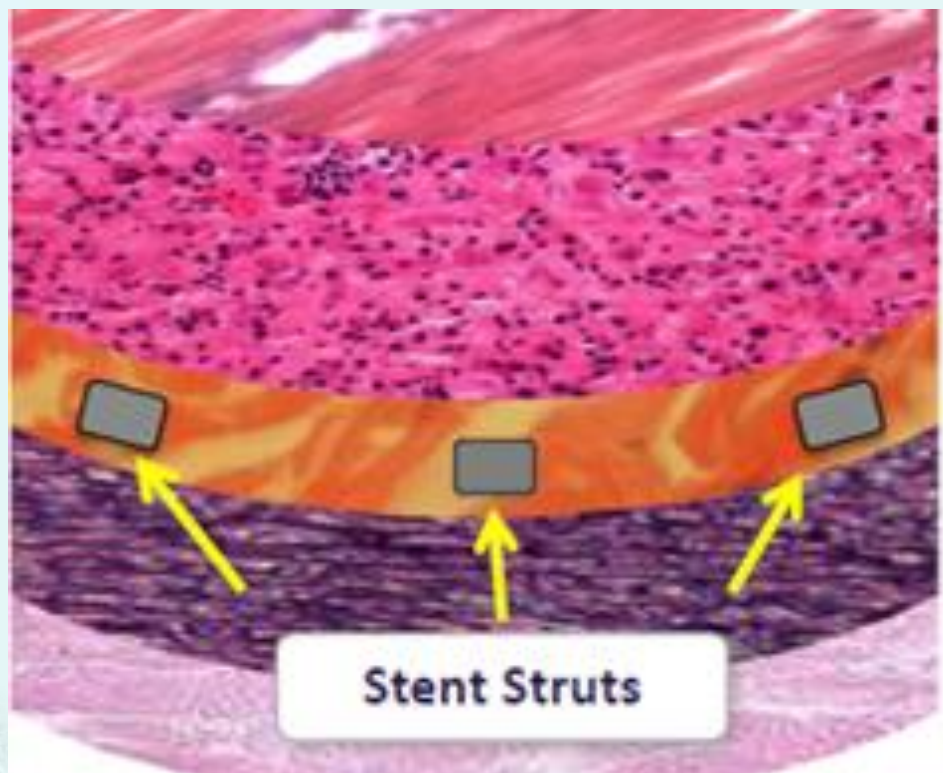
At 3-year follow-up, the rate of target lesion revascularization (TLR) was 40% in the DEB group vs 43% in the BA group ($p=0.8$)

From: Grotti et al J Endov Ther Okt 2015



Typical pattern in ISR

Barrier made by smooth muscle cells and hydrated collagen matrix



Oshero AB et Al. Cardiovasc Res. 2011 Jul 1;91(1):16-26

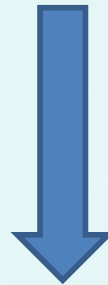
Inoue S et Al. J Vasc Surg. 2002 Apr;35(4):672-8

Brodmann M et Al. Cardiovasc Intervent Radiol. 2013 Feb;36(1):69-74



Perspectives

Additional material inside the stent can impair or prevent uptake of PTX into the vessel wall



Plaque removal with local inhibition of excessive neointimal formation!



Conclusion

- DEB is an effective therapy for fempop lesions
- The results of DEB for de-novo stenosis are superior compared to restenosis at mid-term
- Outcomes after DEB for restenosis are superior to other ISR strategies but not durable
- Combination of DEB with different debulking techniques or plaque preparation appears promising



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Thank you!

