

Leave Nothing Behind and Suppress Restenosis: Drug- Coated Balloons

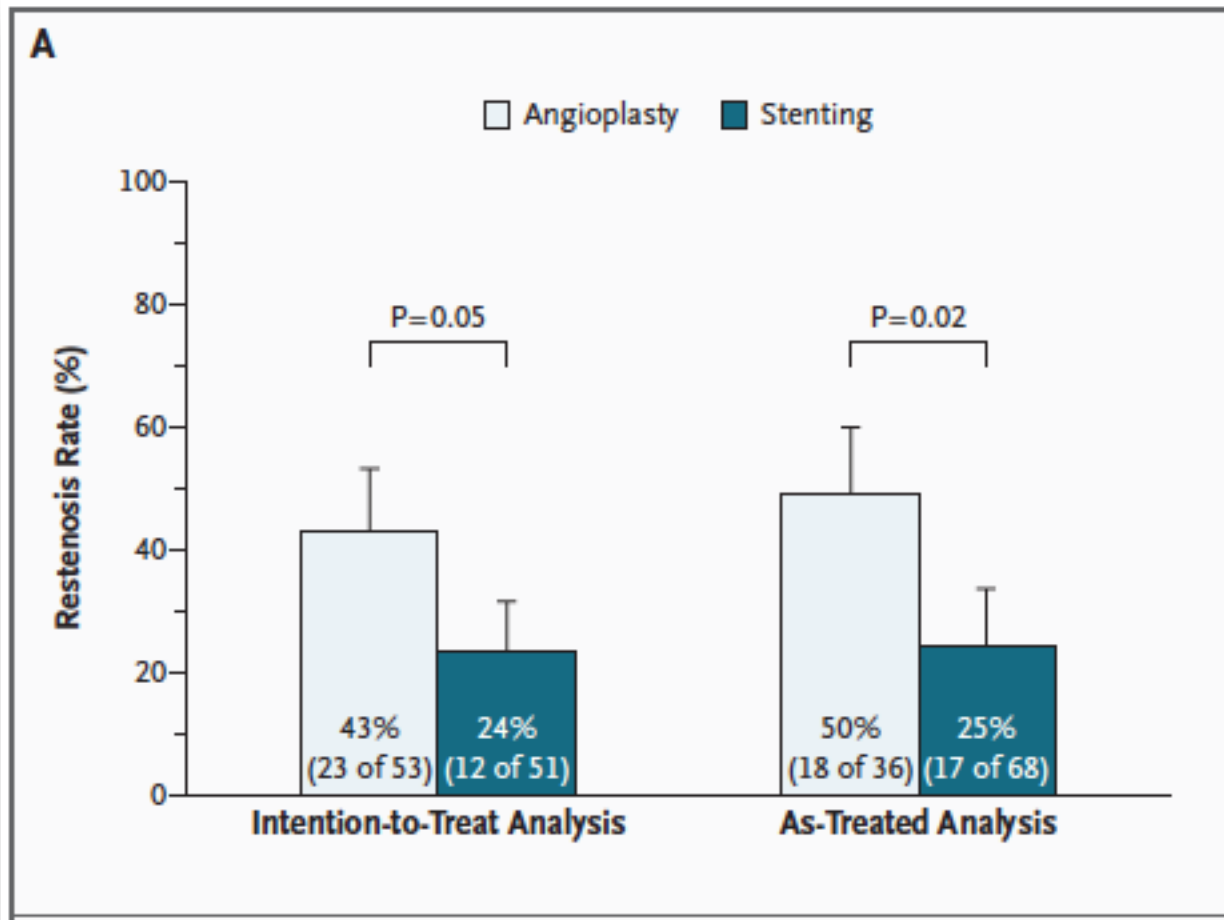


Main Line Health[®]

Well ahead.[™]

William A. Gray MD
System Chief of Cardiovascular Services,
Main Line Health
President, Lankenau Heart Institute
Wynnewood, Pennsylvania
USA

Wait a minute...didn't stents beat PTA a while ago (and repeatedly)?



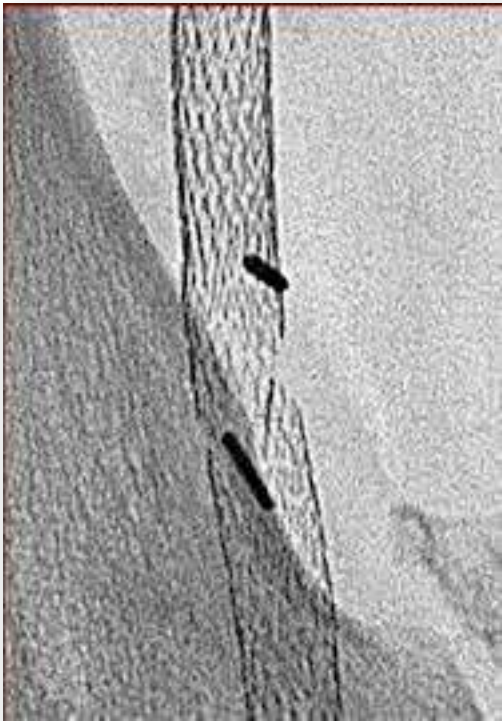
1 year patency
of ~75%

Schillinger M, Sabeti S, Loewe C, et al.

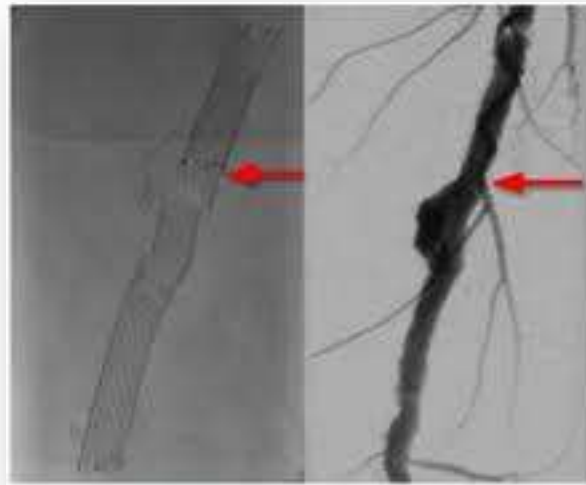
Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery.
N Engl J Med. 2006 May 4;354(18):1879-88.

A lot has happened since then...

Stenting is not benign



Stent fracture



Stent fracture with aneurysm formation



ISR

...didn't laser solve the ISR problem? Well---yes. And no...

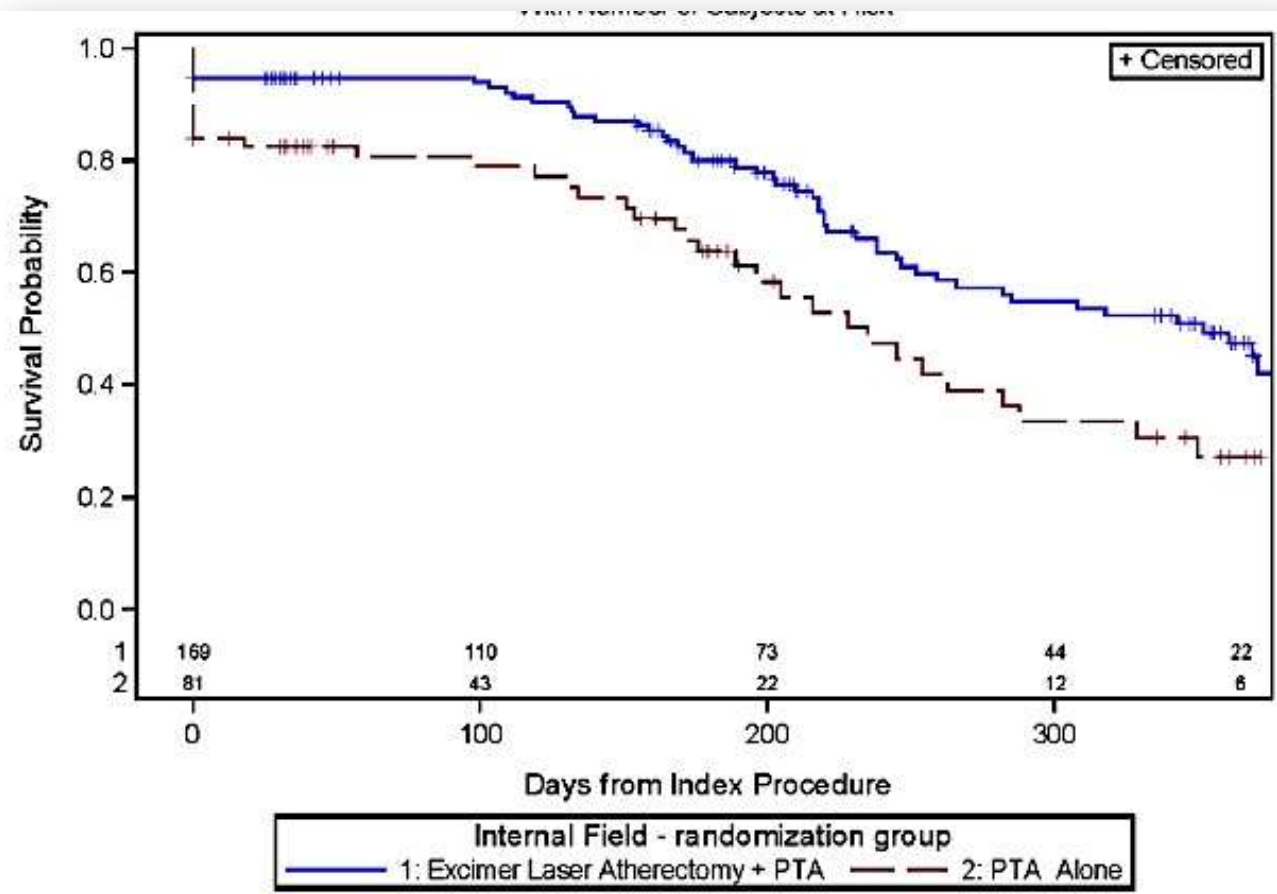


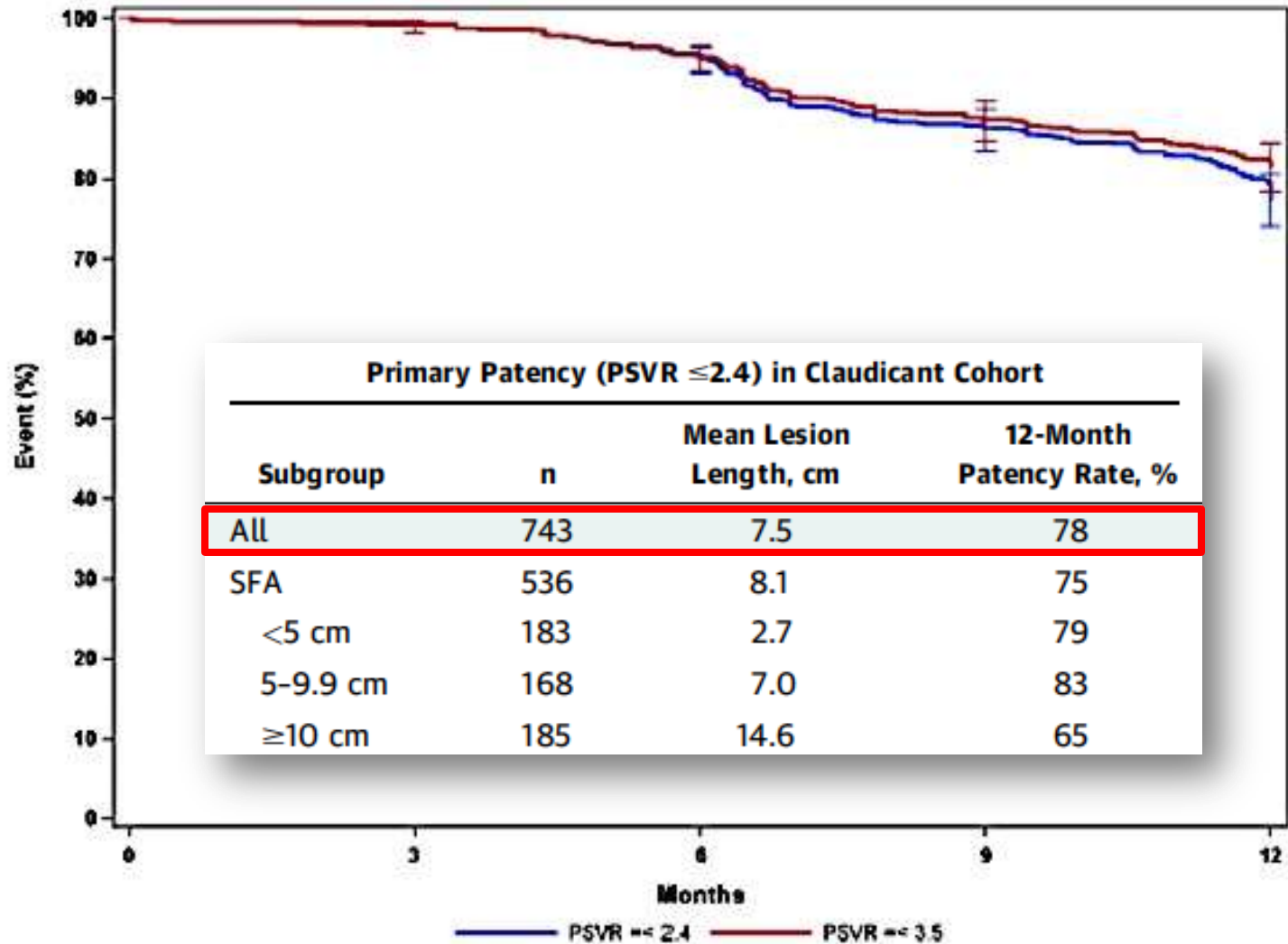
FIGURE 2 Freedom From TLR Through 1 Year

Are there good alternatives to stenting?

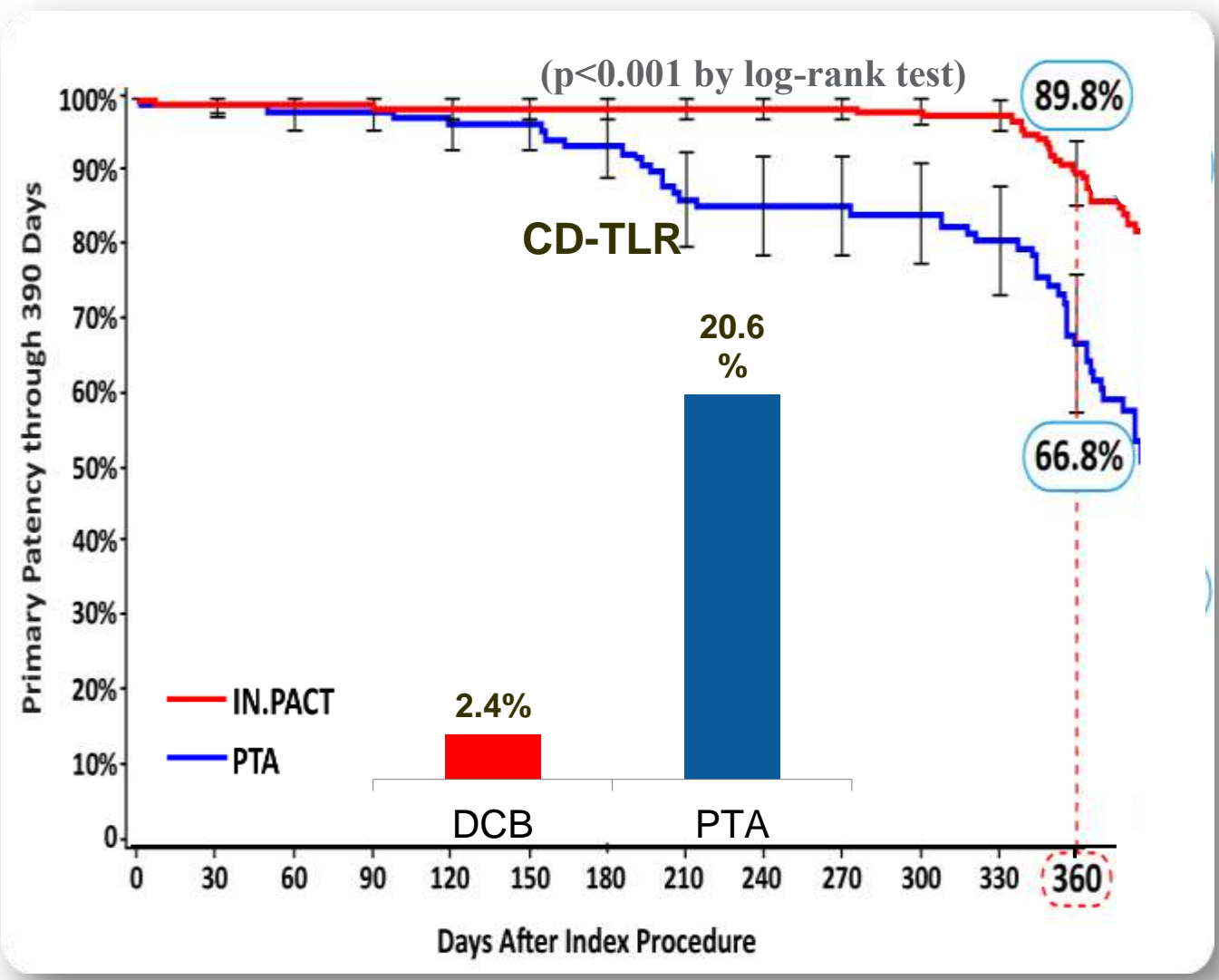
Yes---several.

With good, and comparable, outcome data

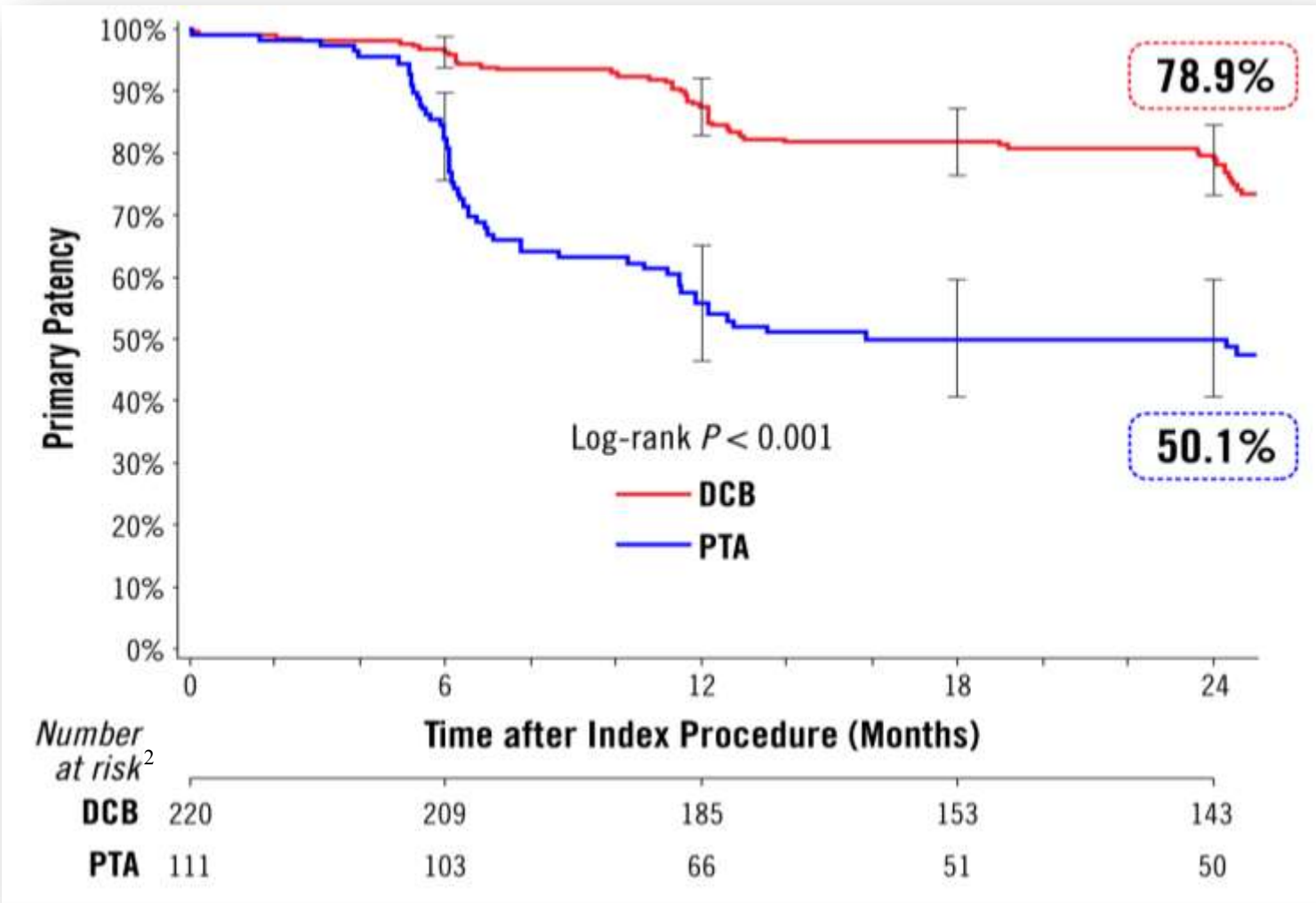
Directional atherectomy: DEFINITIVE LE



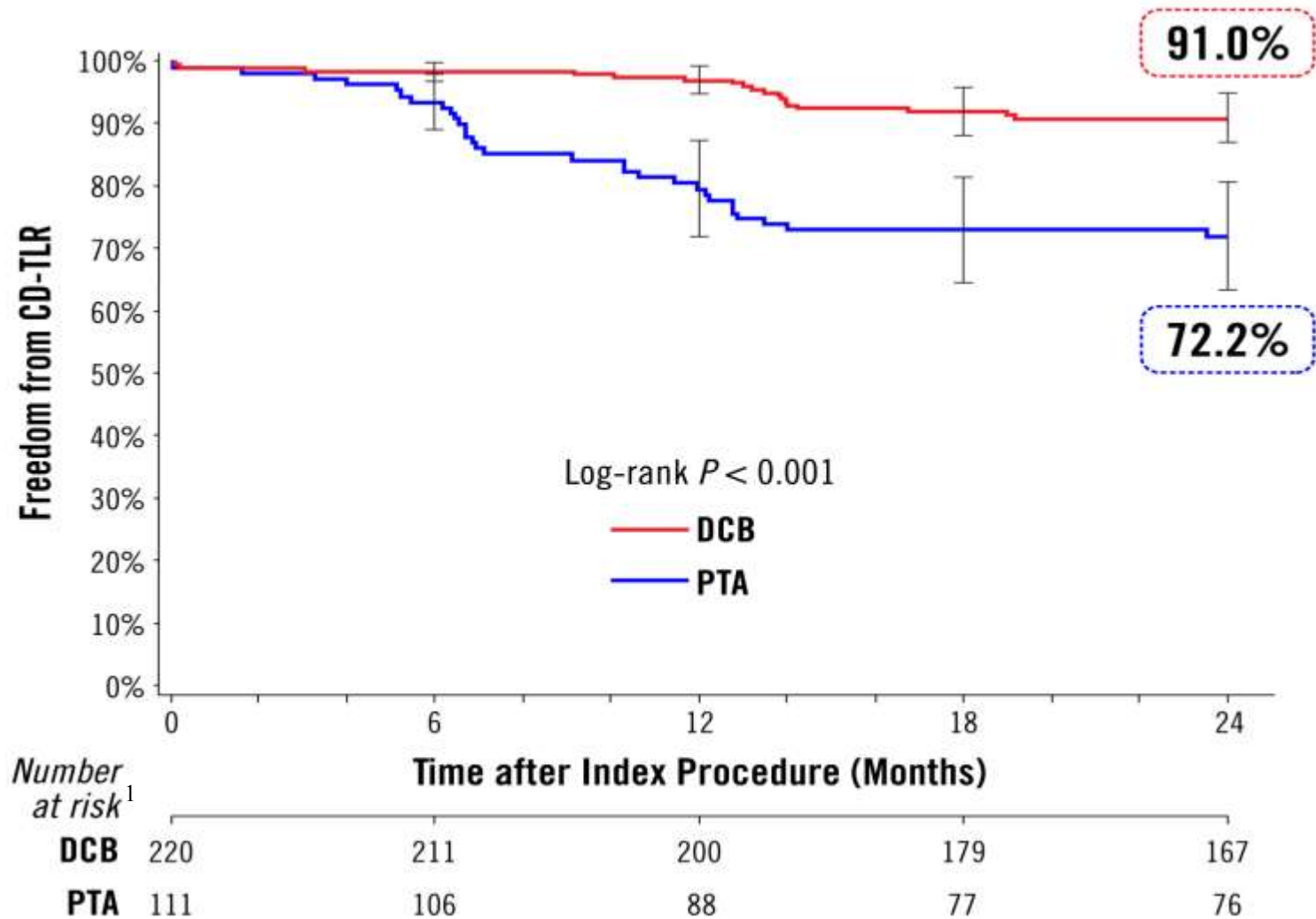
Drug coated balloons: IN.PACT 1 year patency



Drug coated balloons: IN.PACT 2 year patency



Drug coated balloons: IN.PACT 2 year TLR



IN.PACT SFA trial: very low stent usage

	IN.PACT DCB	PTA	p
Pre-dilatation (%)	96.4% (212/220)	85.6% (95/111)	<0.001
Post-dilatation (%)	26.8% (59/220)	18.9% (21/111)	0.135
Dissections (%) 0 A-C D-F	36.2% (80/221) 63.8% (141/221) 0.0% (0/221)	38.9% (44/113) 60.2% (68/113) 0.9% (1/113)	0.360
Provisional Stenting (%)	7.3% (16/220)	12.6% (14/111)	0.110
MLD post (mm)	3.903 ± 0.750	3.862 ± 0.732	0.632
Diameter Stenosis post (%)	19.9 ± 10.4	19.1 ± 10.3	0.535
Device Success (%) ^[1]	99.0% (308/311)	98.5% (128/130)	0.302
Procedural Success (%) ^[2]	99.5% (219/220)	98.2% (109/111)	0.111
Clinical Success (%) ^[3]	99.1% (218/220)	97.3% (108/111)	0.103

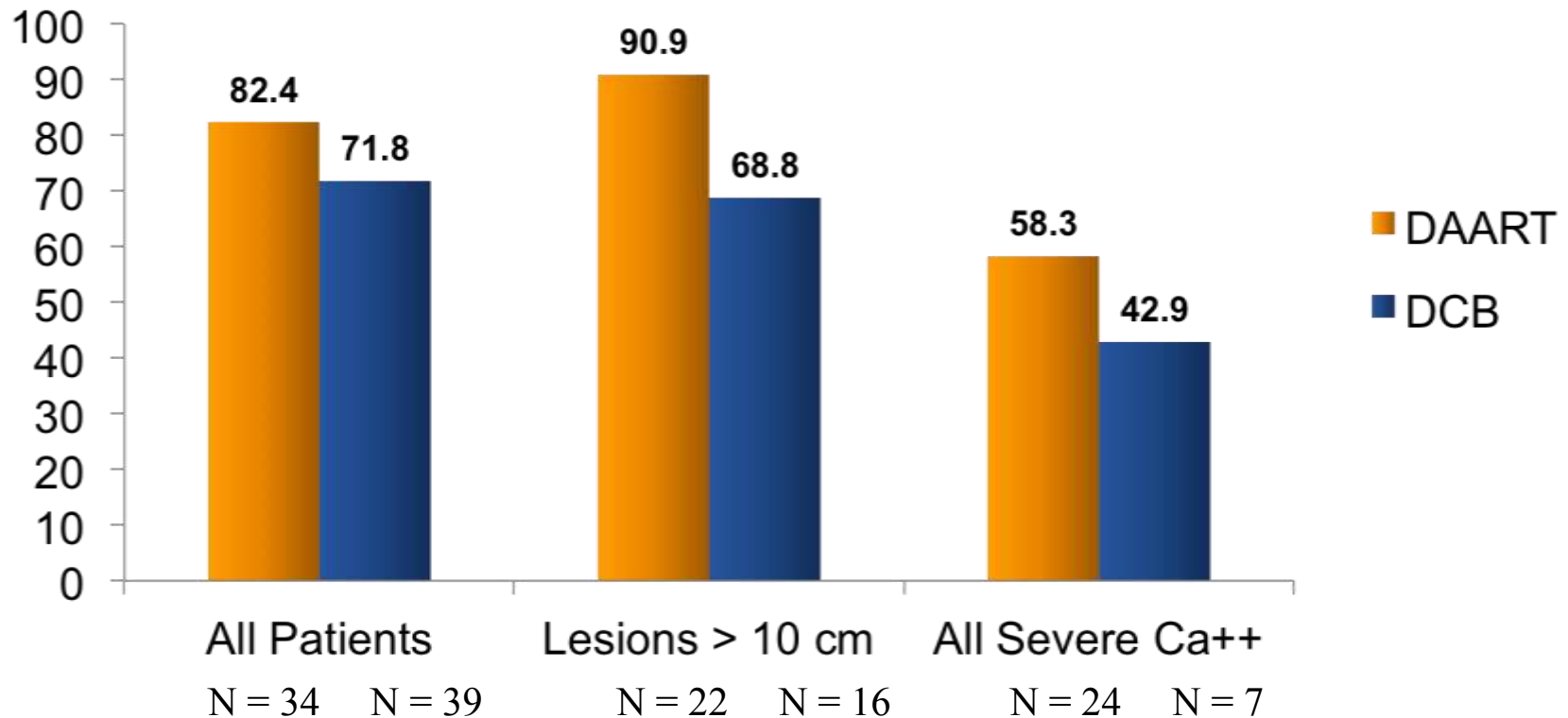
So what are the remaining reasons to stent?

- Undilatable lesion
- Extensive dissection
- Expediency
- Lack of knowledge of alternative therapy choices

Undilatable lesions: current and future tools

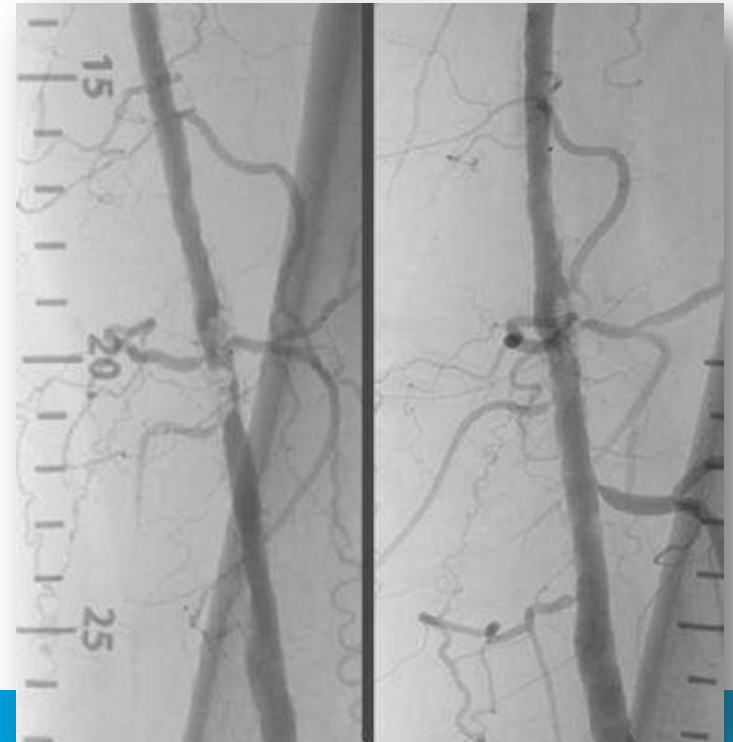
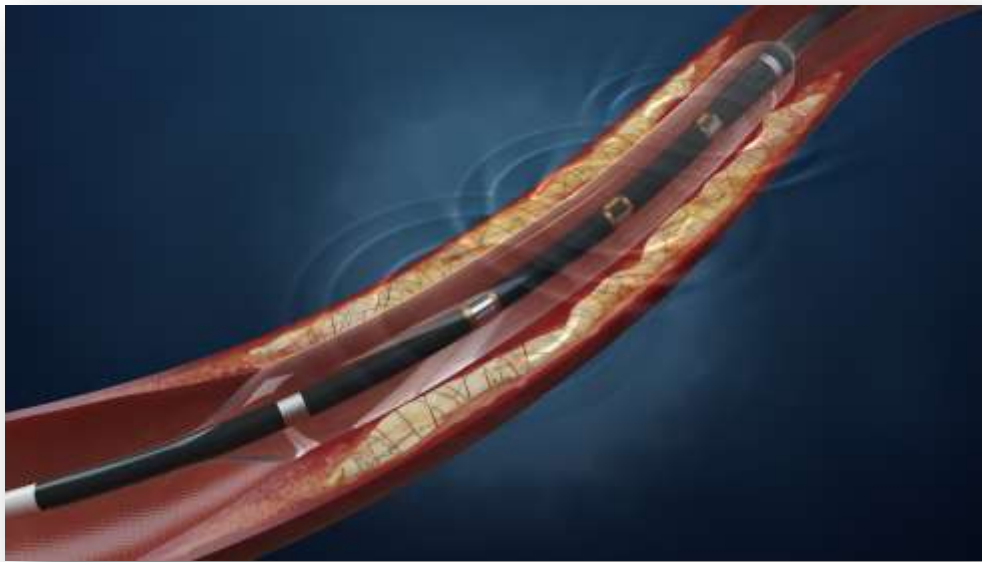
- Current:
 - Specialty balloons
 - Cutting and scoring balloons
 - Atherectomy

DEFINITIVE AR: atherectomy + DCB



Undilatable lesions: current and future tools

- Future
 - Shockwave: Balloon lithoplasty



Extensive dissection: future tools

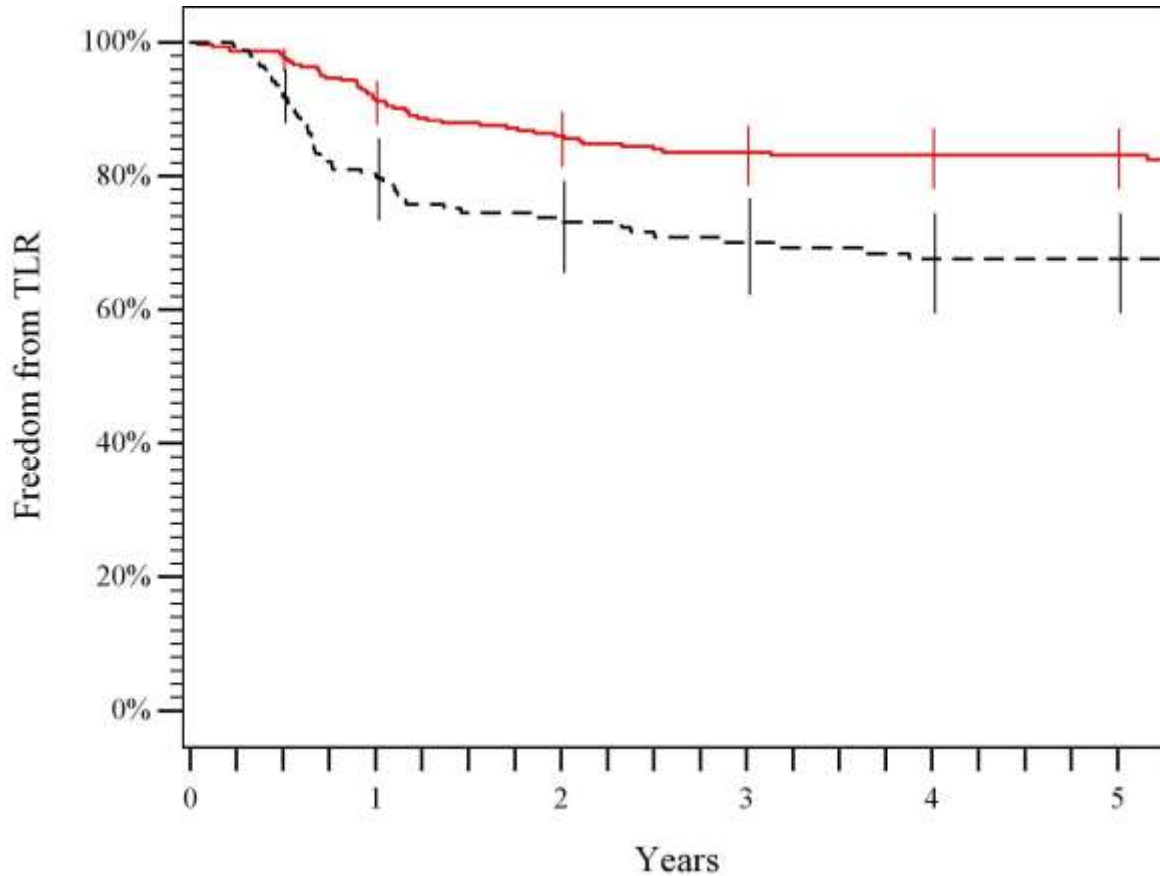
- Intact Vascular Tack System



So is there ever going to be a need to stent?

- In a word---yes

Drug eluting stents: Zilver 5 year data

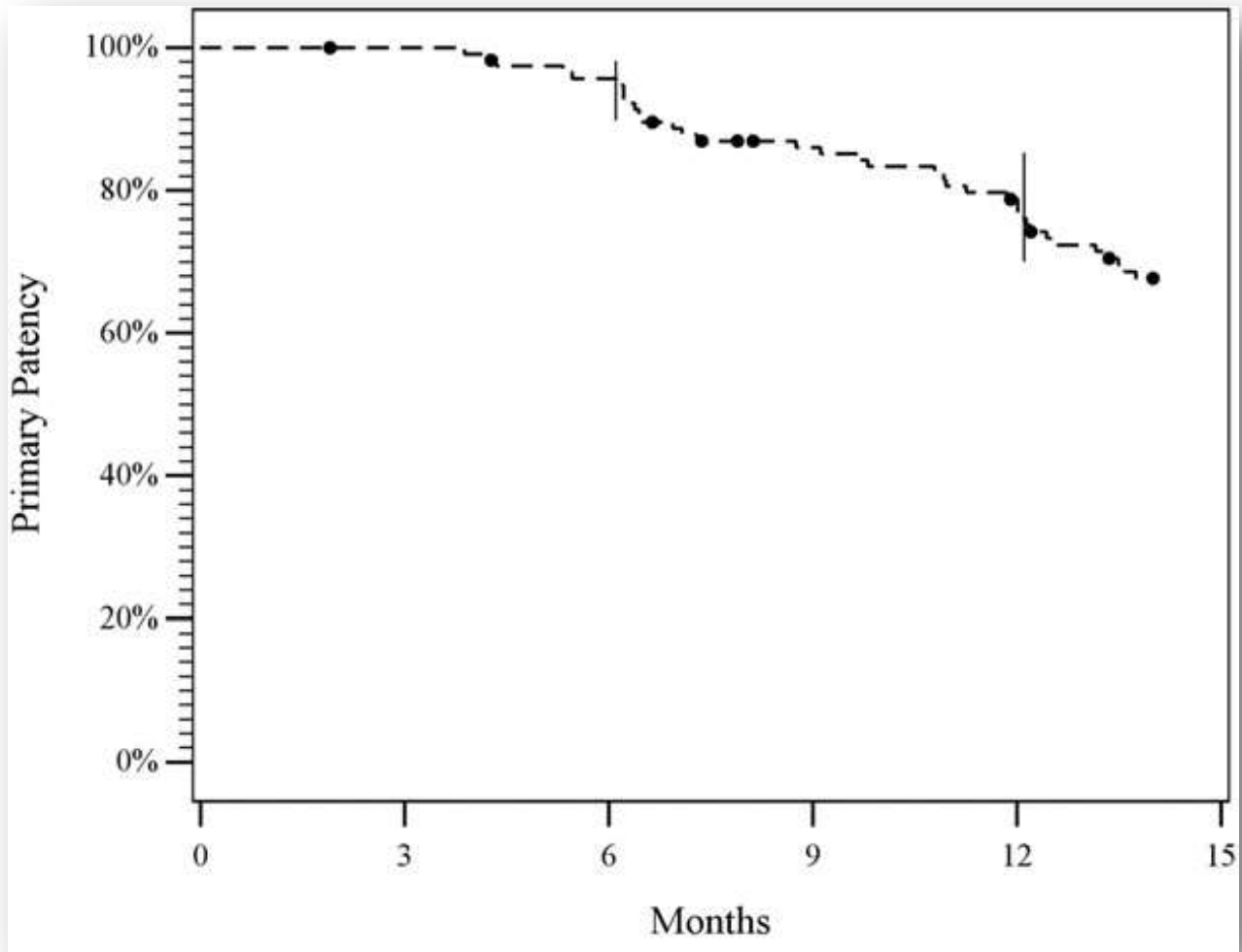


83.1% ZilverPTX

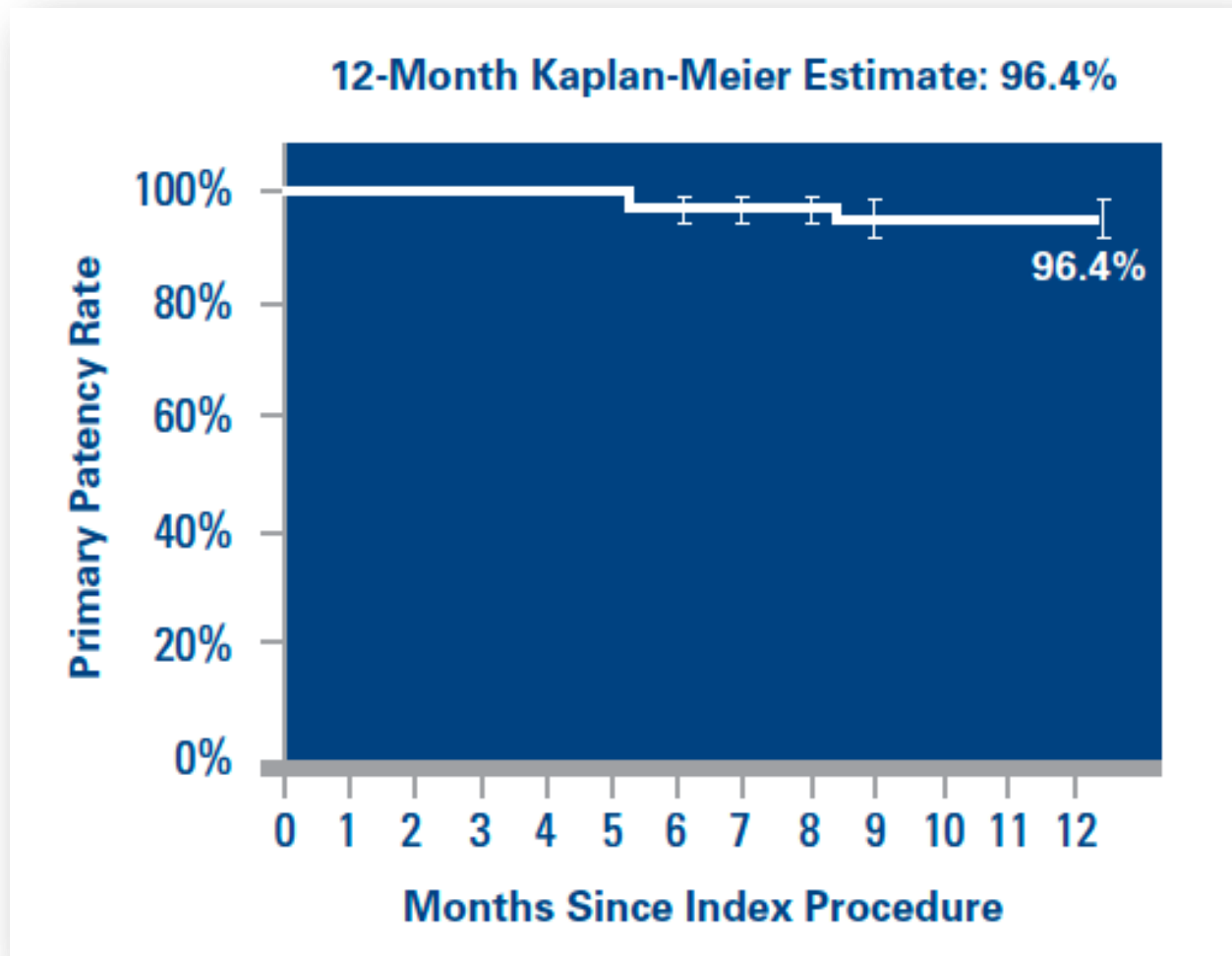
67.6% Optimal PTA + BMS

p < 0.01

In-stent restenosis treated by Zilver



New drug-eluting stent platforms: ELUVIA



Summary

- Bare-metal stent implantation has been equaled or surpassed by non-stent solutions, even in difficult anatomic subsets
- ISR is a formidable issue and to be avoided
- Current and future generation DES address the shortcomings of BMS, and bode well for the class