

The Whole Truth on Incomplete Stent Apposition

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Frequency of BMS Late Malapposition

Analysis of 206 pts with complete apposition at implantation showed late malapposition in 9 (4.4%). No TLR and minimal IH at LSM.

Shah et al. Circulation 2002;106:1753-5

Analysis of 881 pts (992 lesions) with complete apposition at implantation showed late malapposition in 54 (5.4%) overall, but 10.3% after pre-stent DCA and 11.5% after primary stenting in MI. No TLR and minimal IH at LSM.

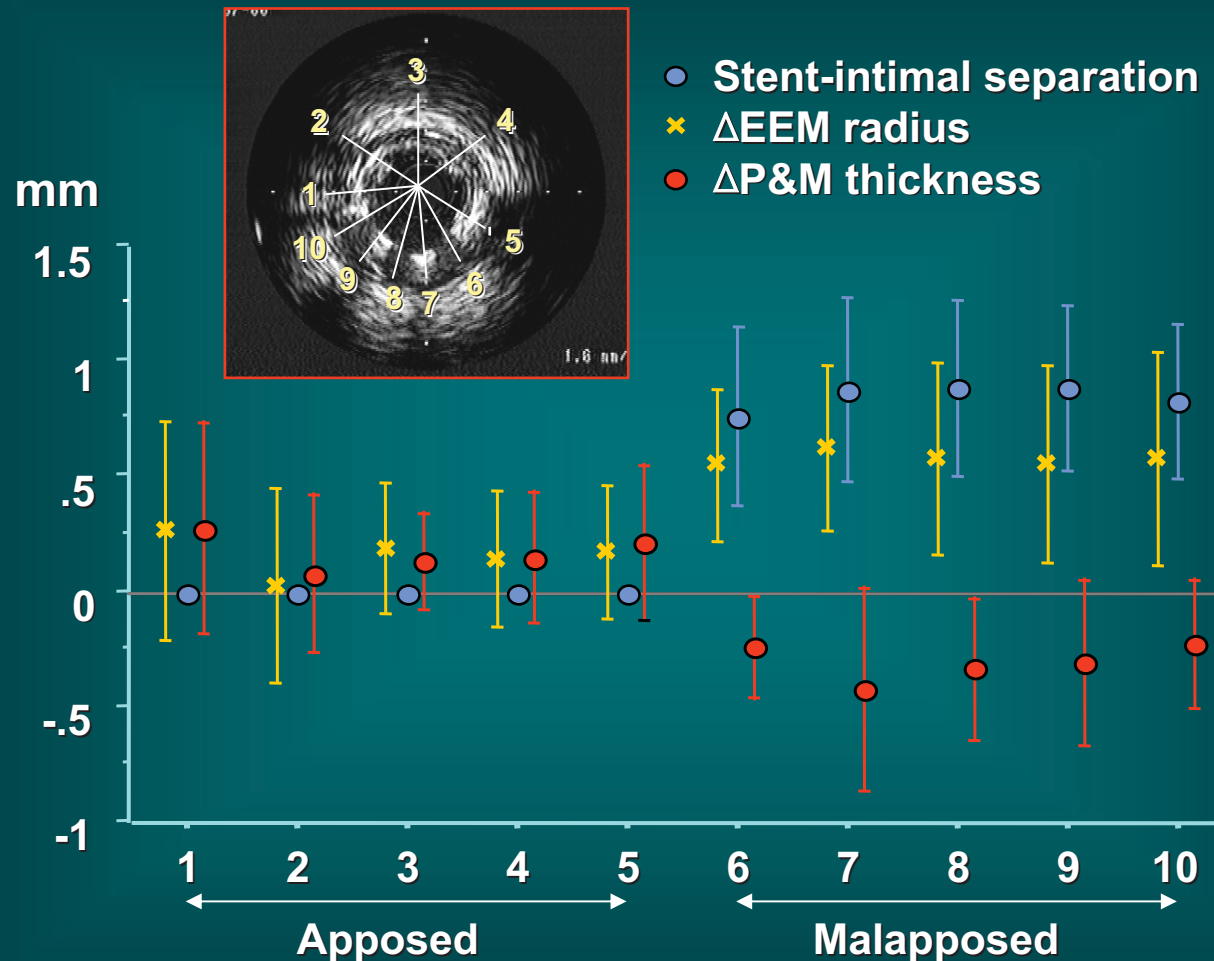
Hong et al, Circulation 2004;109:881-6

Definitions:

- **One** malapposed strut: Washington, ASPECT, RAVEL, Taxus II, Asan Medical Center, Taxus-IV
- **More than one** malapposed strut: Stanford (SIRIUS)

- Unrecognized malapposition at the time of implantation (n=3205, Stanford CCAL)
 - 13.6% post stent
 - 9.1% post adjunct PTCA
- Late malapposition
 - Decrease in tissue mass “behind” or outside of the stent
 - Thrombus dissolution
 - Apoptosis
 - Global or regional positive remodeling (without equal amounts of intimal hyperplasia)
 - Combination of above

Remodeling as the Cause of BMS Late Malapposition



Mintz et al. *Circulation*, 2003;107:2660-3

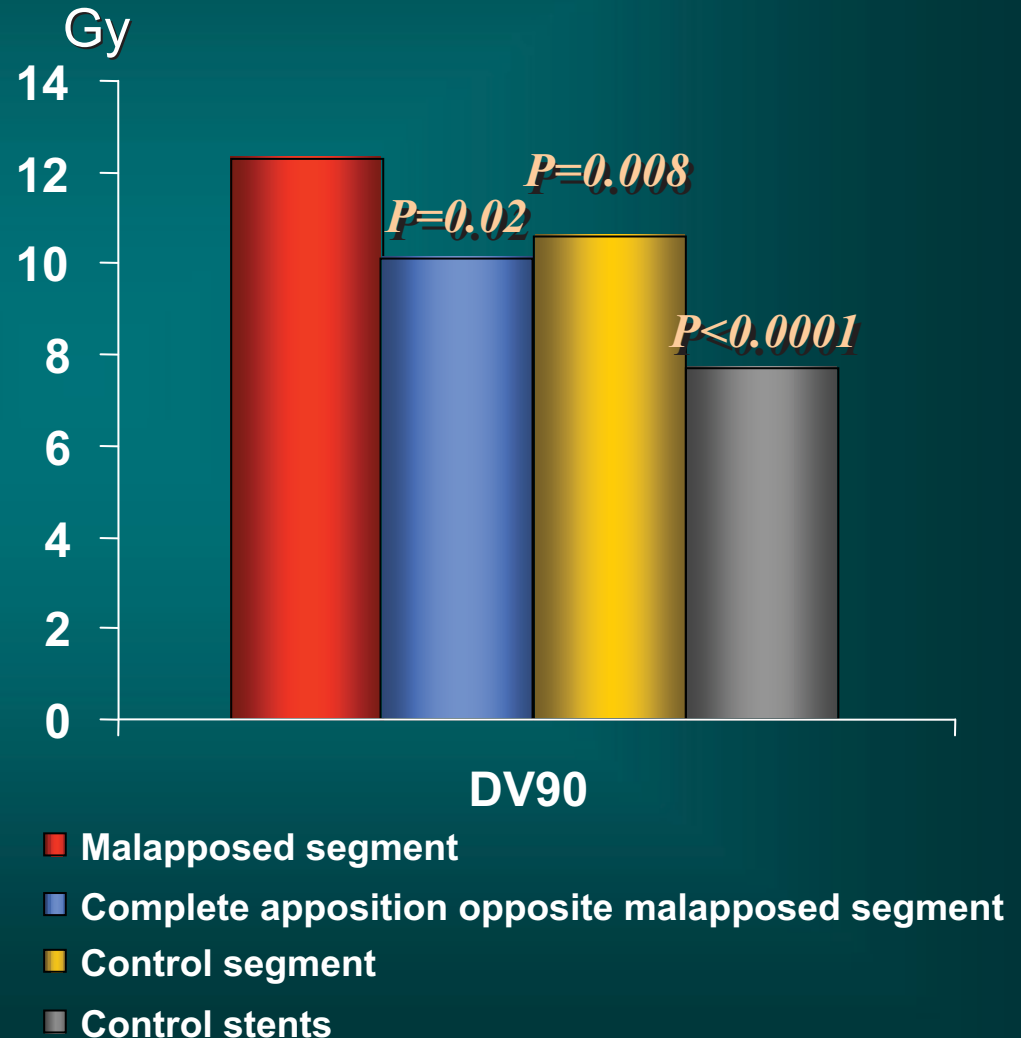
Malapposed struts associated with almost no measurable neointima

- Using the definition of *at least one malapposed stent strut*, late stent malapposition (LSM) is not rare and appears to occur in 4-5% of bare metal stents. It is more common with pre-stent directional atherectomy and in acute myocardial infarction.
- When sensitive indices are used, the most common cause of LSM is positive remodeling without an equal amount of abluminal intimal hyperplasia - although other mechanisms (thrombus resolution) are possible.
- Late malapposed struts are associated with minimal intimal hyperplasia and infrequent revascularization events.

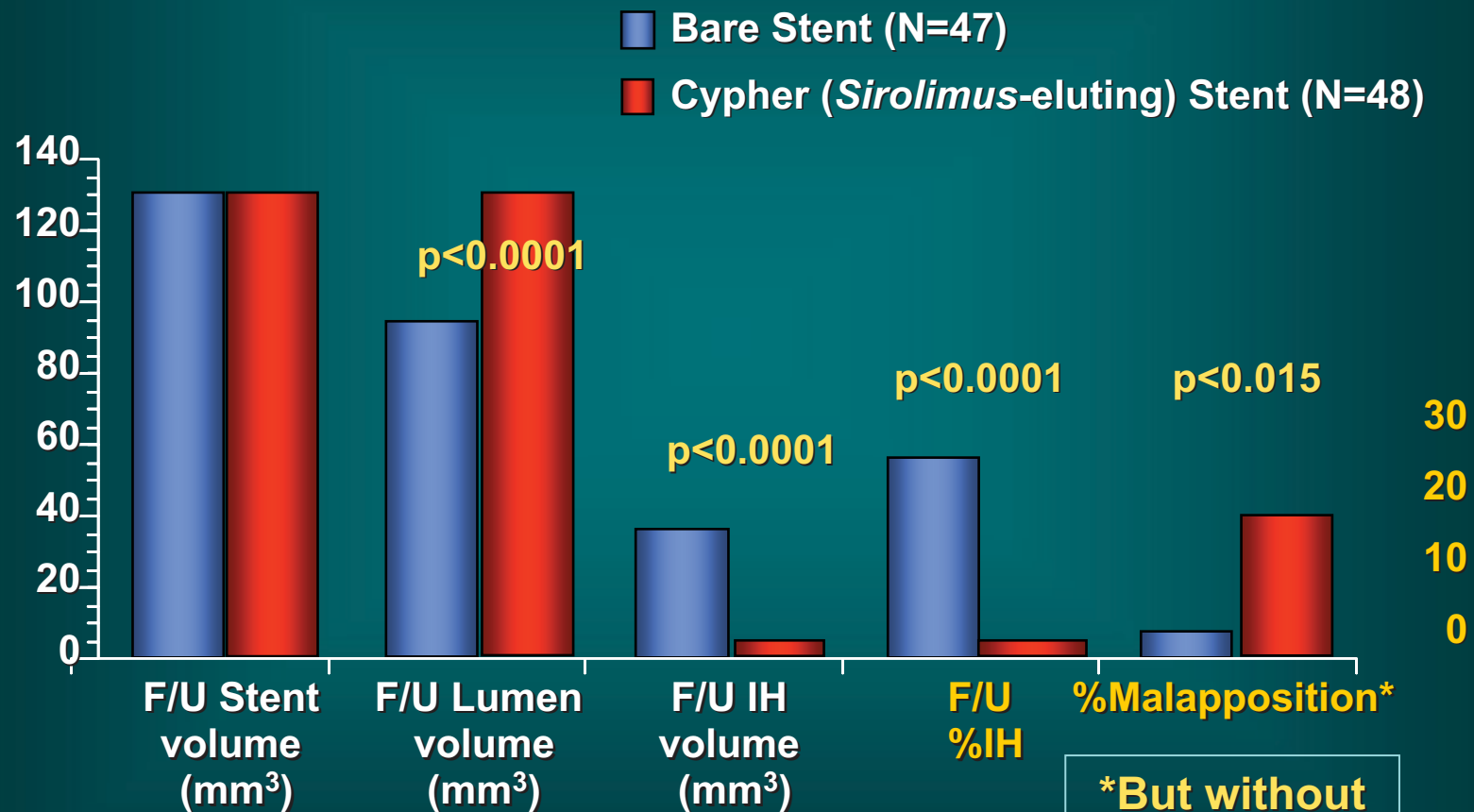
Stent malapposition after brachytherapy

- LSM occurred in
 - 7.2% after gamma radiation treatment of ISR (vs 2.3% in placebo)
 - 22% after beta radiation treatment of ISR (vs 0% in placebo), mostly in newly stented lesions
 - 20% after hot-ends Isostents (vs 5.9% after regular Isostents)
- Mechanism of LSM was an increase in EEM that was greater than any increase in peri-stent plaque and was related to dose to the adventitia

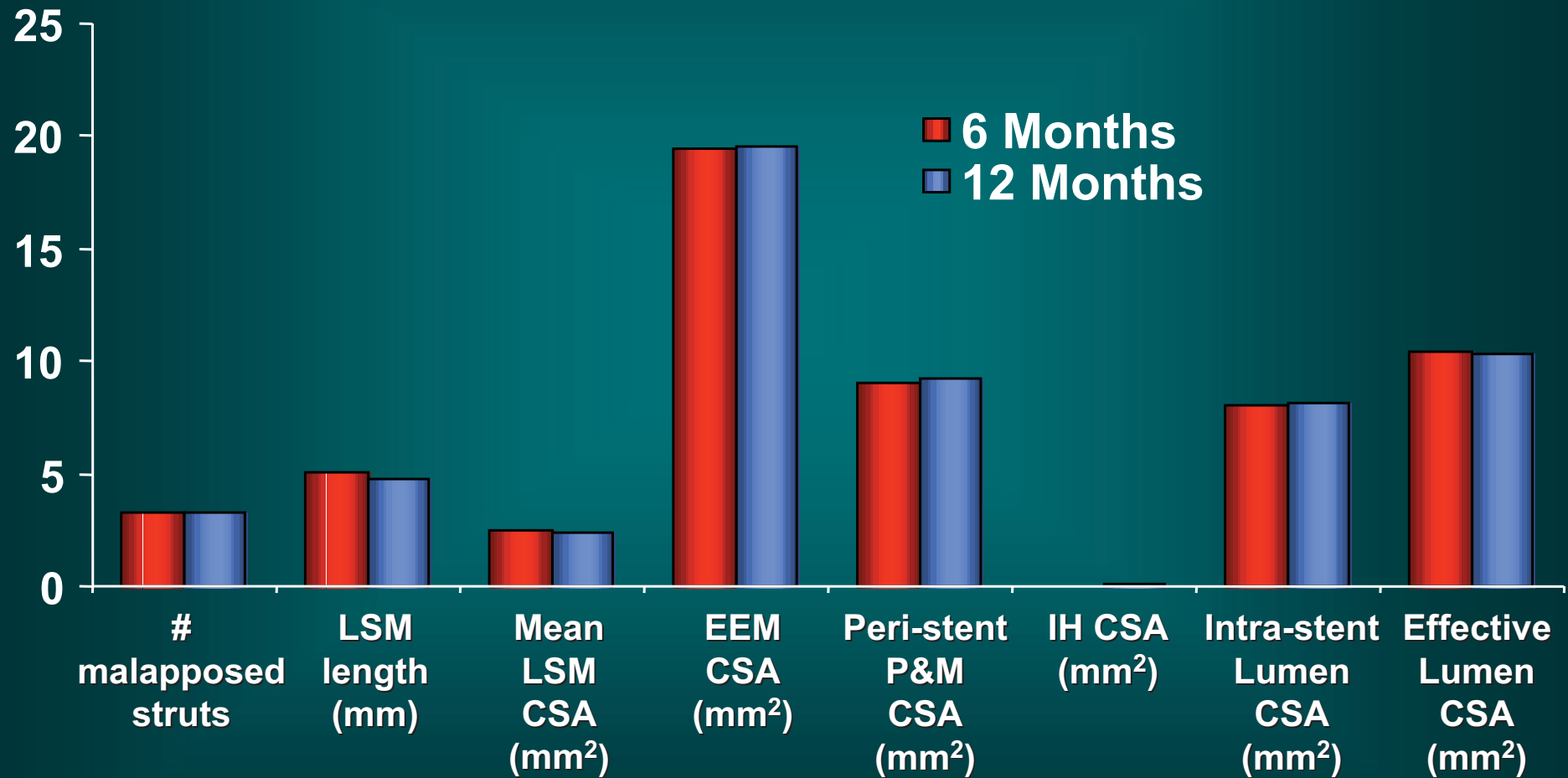
Dosimetry after Gamma Irradiation Rx ISR



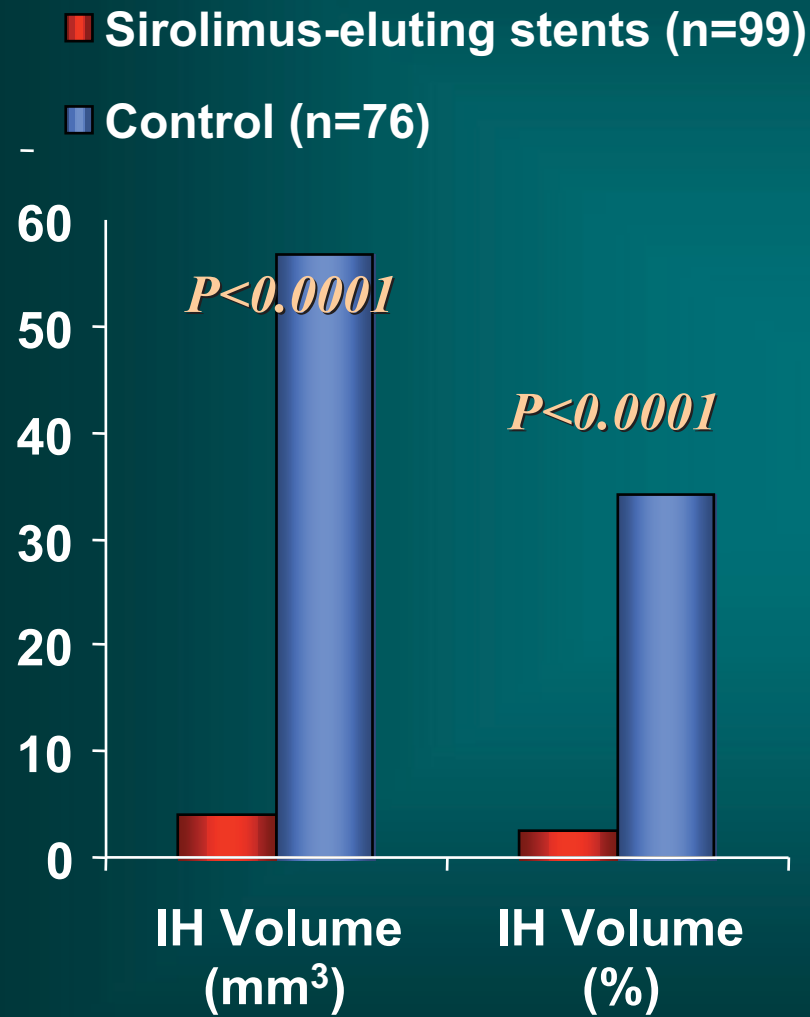
Stent malapposition in RAVEL



Stent malapposition in RAVEL



Stent malapposition in SIRIUS



	RAVEL	SIRIUS
Lesion length	<18mm	15-30mm
# of stents	1	1 or 2
Diabetes	18.5%	24.6%
Type C lesions	0	26%
QCA length	9.6mm	14.4mm
QCA reference	2.62mm	2.78mm

Diabetes, lesion length, and reference size were independent predictors of angiographic and clinical restenosis in SIRIUS

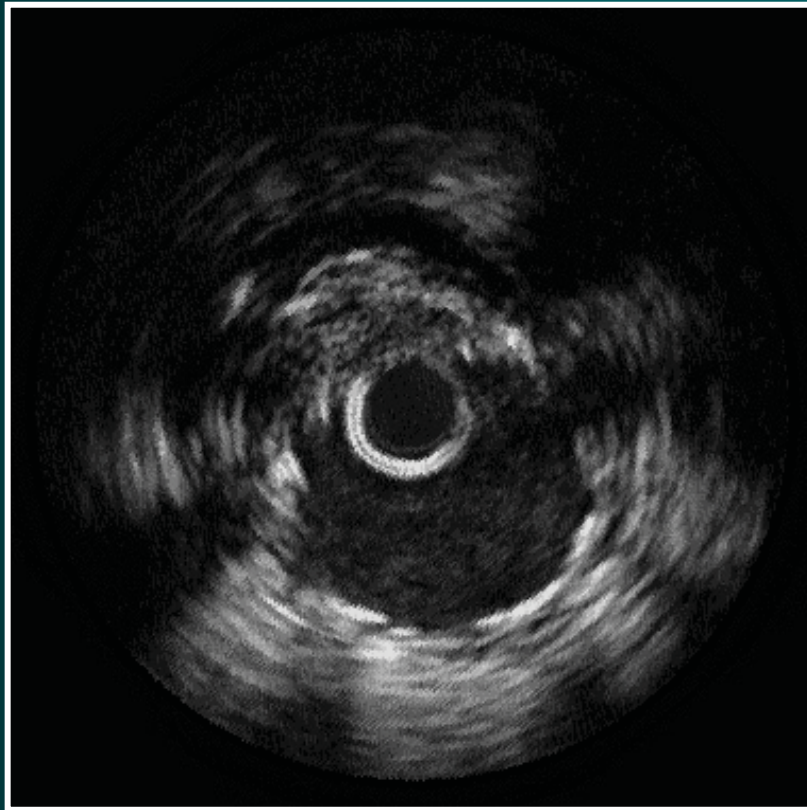
Stent malapposition in SIRIUS

	Cypher Stent (n=80)	Bare Stent (n=61)
Baseline malapposition	13 (16.3%)	9 (14.7%)
Resolved	7	3
Persistent	6	6
New late malapposition	7 (8.7%)*	0 (0%)

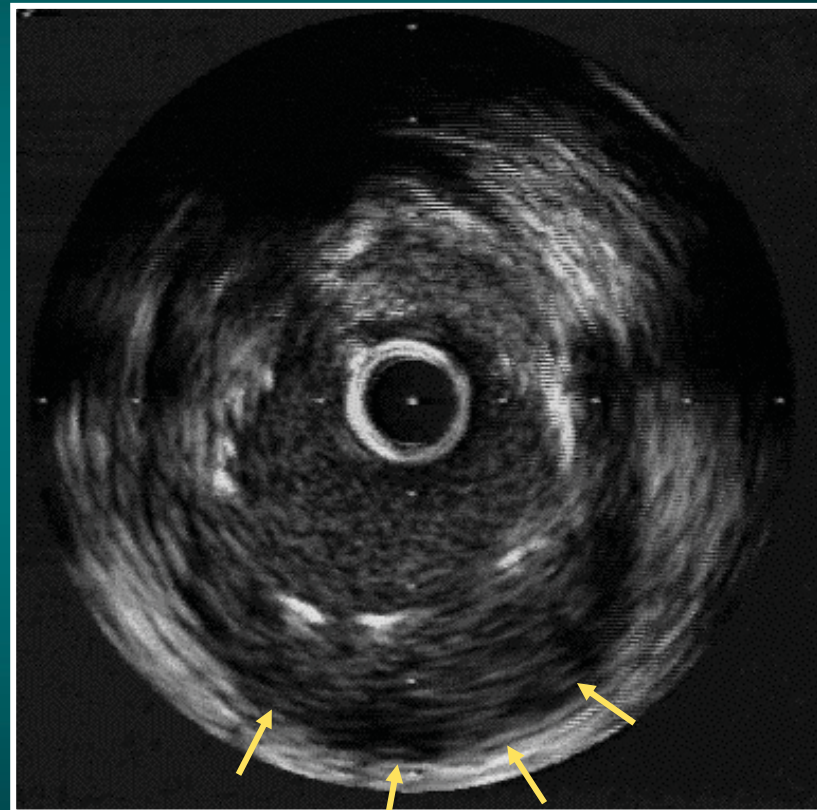
**p<0.05, but without events at 6-months*

Stent malapposition in SIRIUS

Baseline

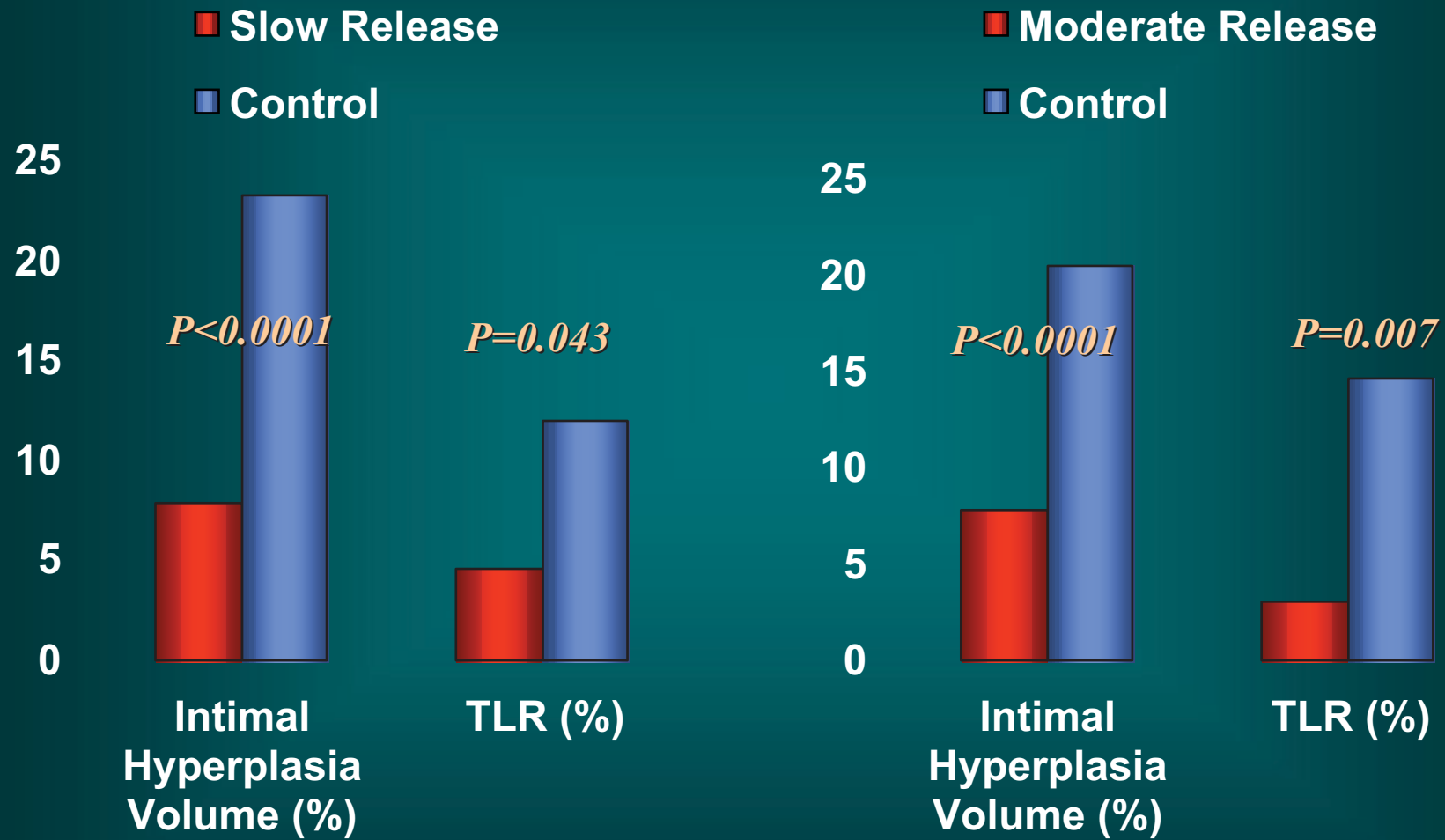


Follow-up



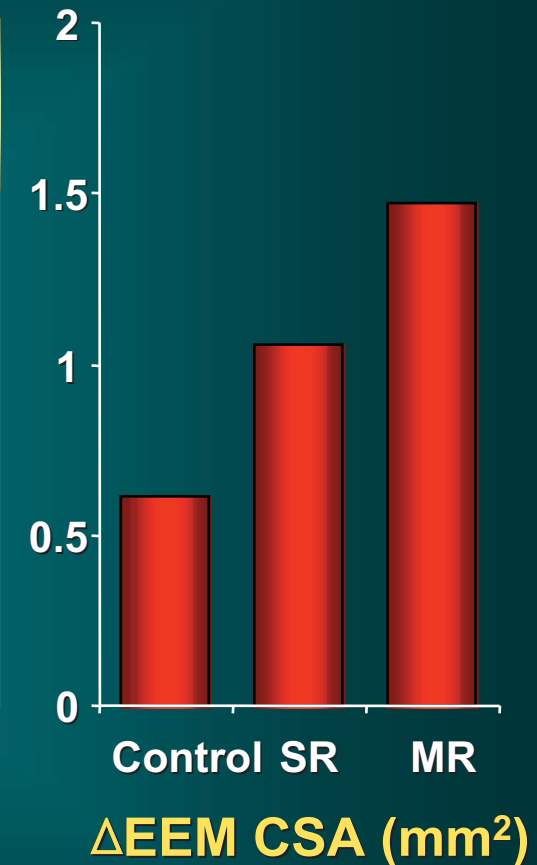
Normal wall bias

Stent Malapposition in TAXUS-II



Stent Malapposition in TAXUS-II

	Control (n=240)	SR (n=114)	MR (n=116)	p
Resolved	4.6% (11/240)	7.0% (8/114)	2.6% (3/116)	0.3
Persistent	3.3% (8/240)	4.4% (5/114)	0.0% (0/116)	0.0564
Acquired	5.4% (13/240)	8.8% (10/114)	9.5% (11/116)	0.3*



*P=0.15 when SR and MR are combined

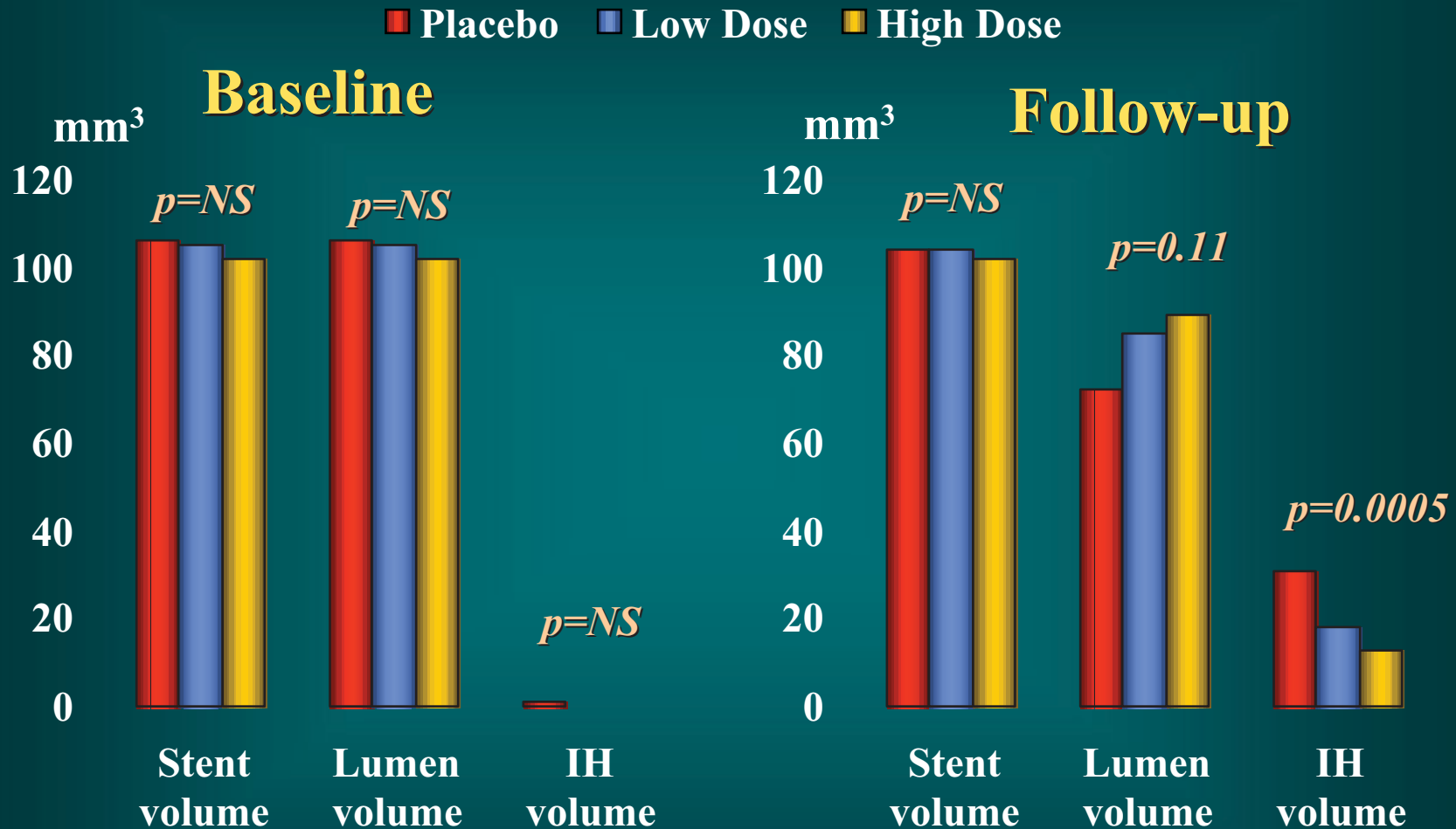
No increase in 6-month events in patients with late stent malapposition

Stent malapposition in TAXUS-IV

	Control	TAXUS	P value
Post-procedure	6.4% (7/109)	11.6% (13/112)	0.2
9 month	3.0% (3/100)	4.0% (4/99)	0.7
Paired data (Post-procedure & follow-up)			
Resolved	5.4% (5/93)	6.4% (6/94)	1.0
Persistent	1.1% (1/93)	3.2% (3/94)	0.6
Late acquired	2.2% (2/93)	1.1% (1/94)	0.6

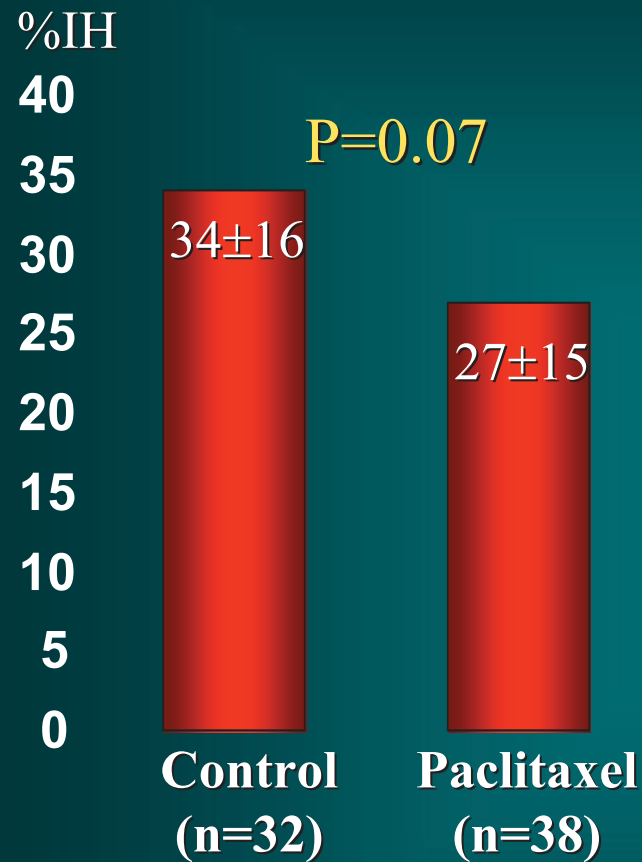
No adverse events in patients with resolved, persistent or late malapposition

IH and LSM in ASPECT

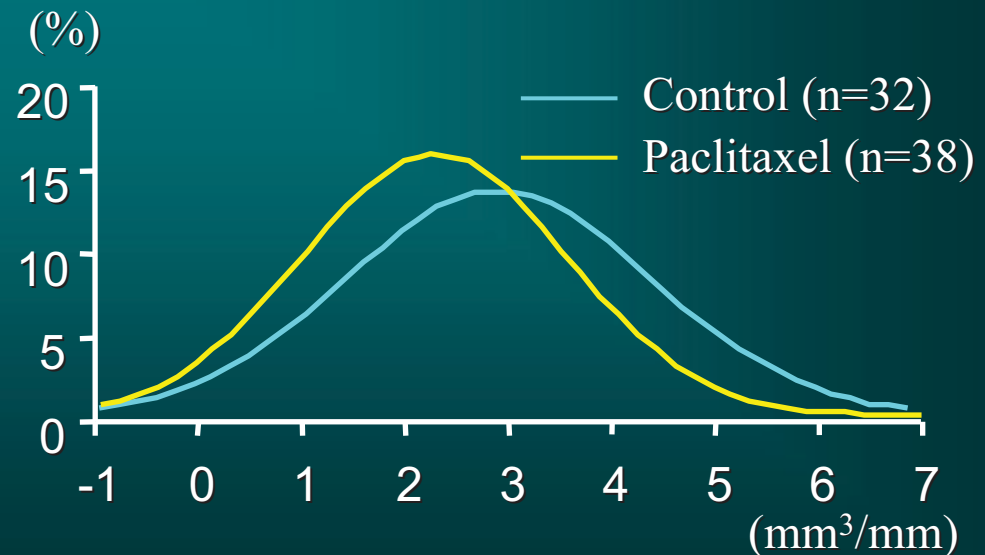
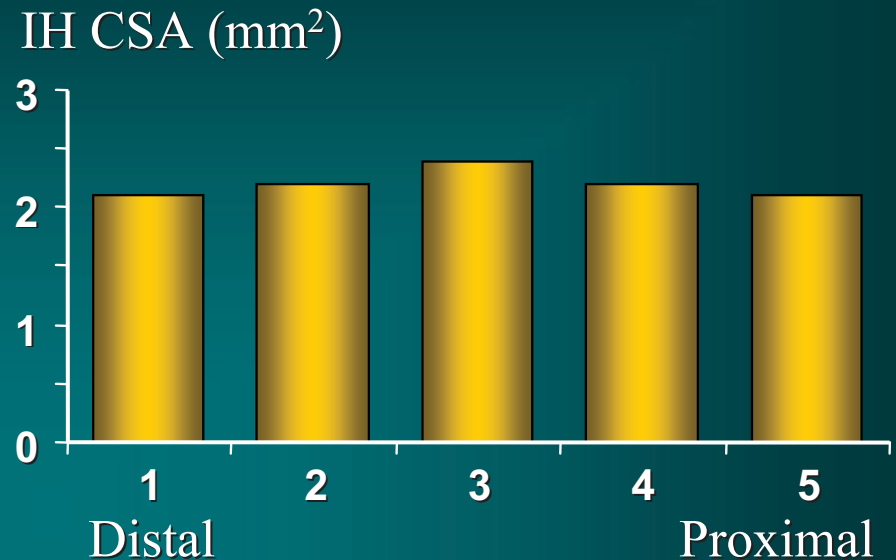


Only 1 case of LSM – in the high dose group

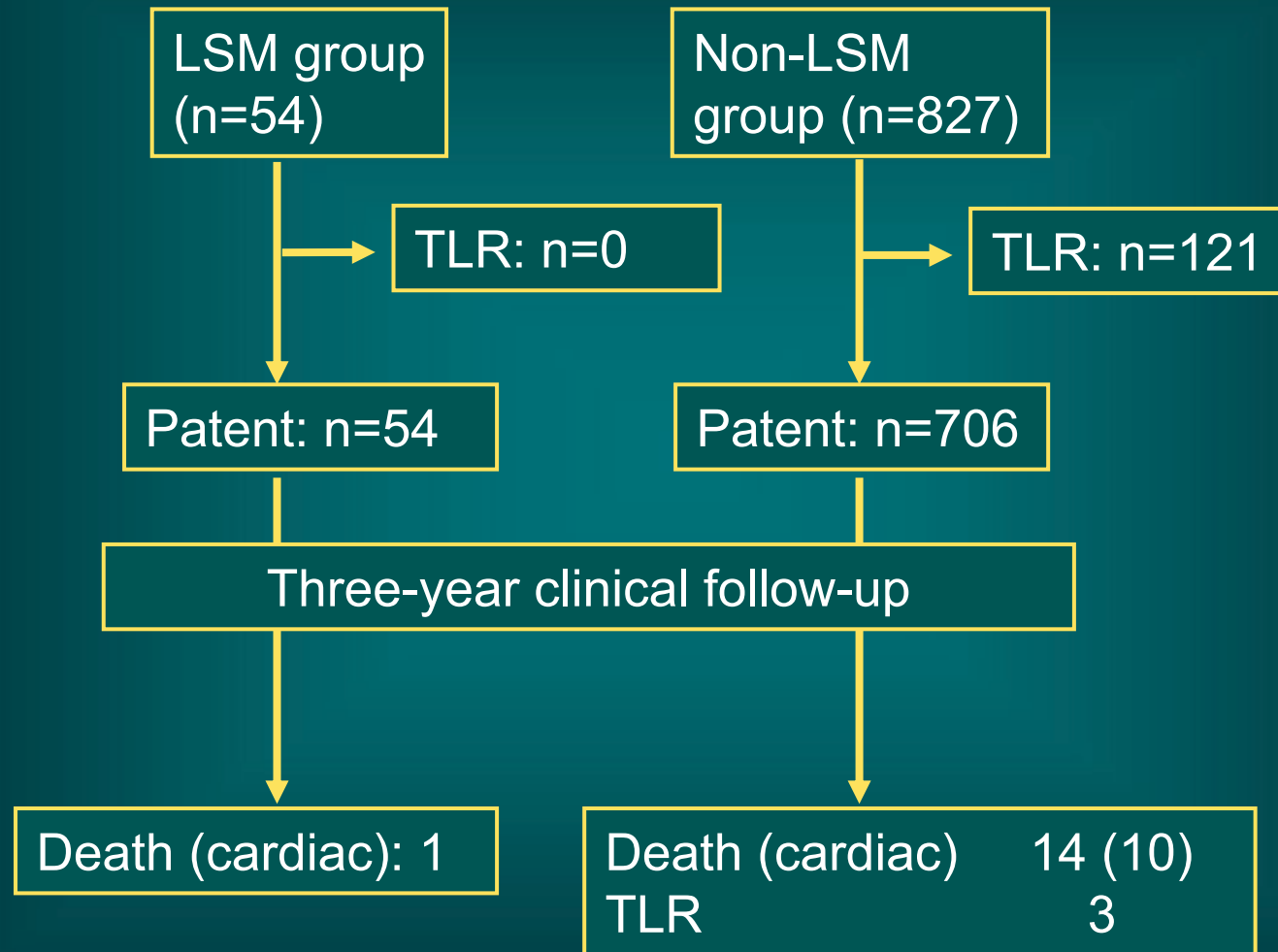
DELIVER Trial IVUS Analysis



No cases of late stent malapposition in the paclitaxel group.

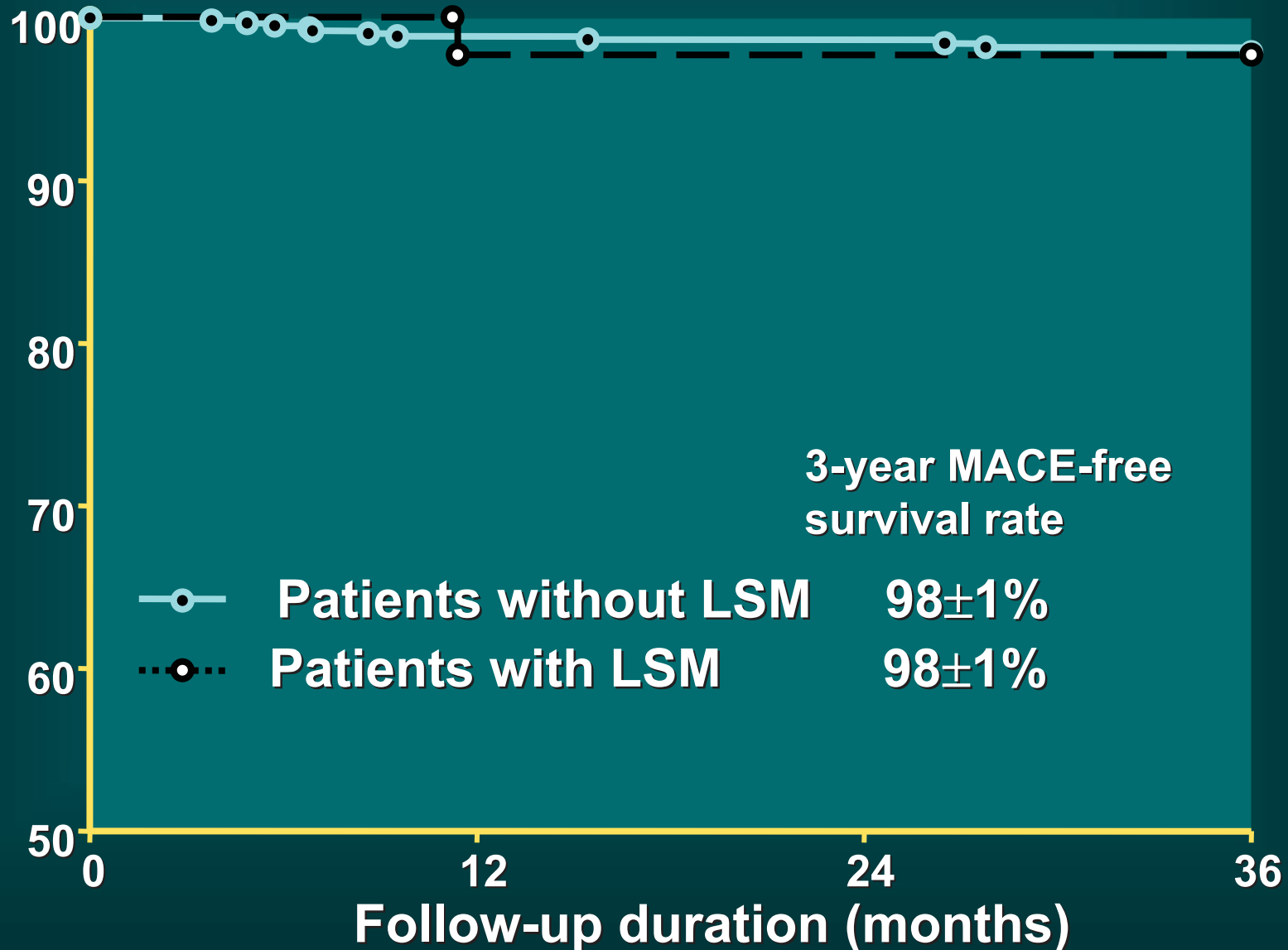


Long-term Follow-up of LSM-I

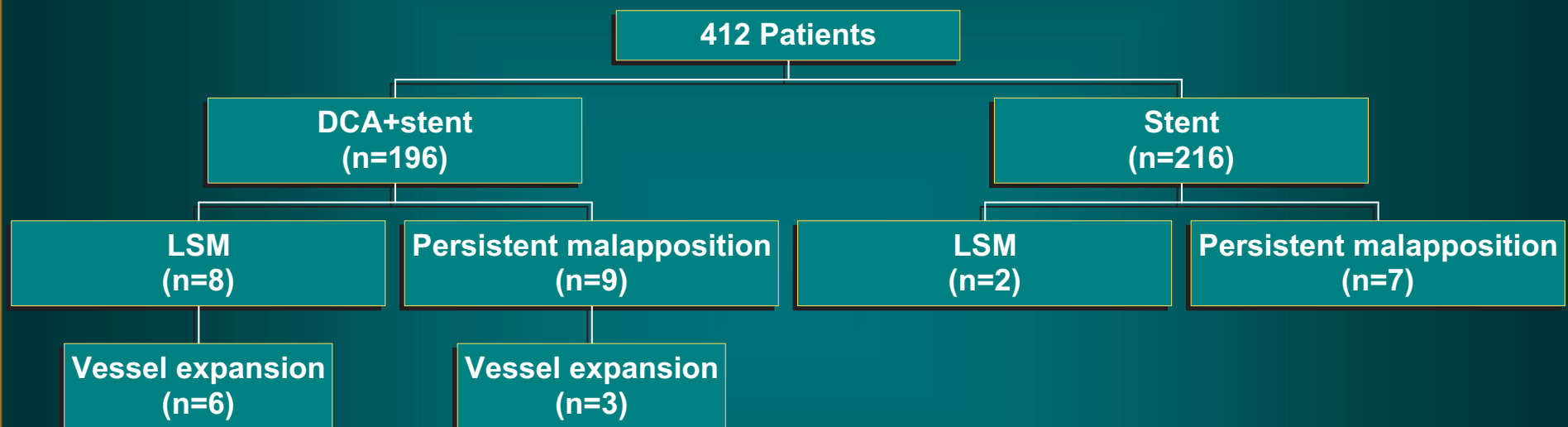


Long-term Follow-up of LSM-II

Cumulative MACE-free survival (%)



LSM in the DESIRE Trial



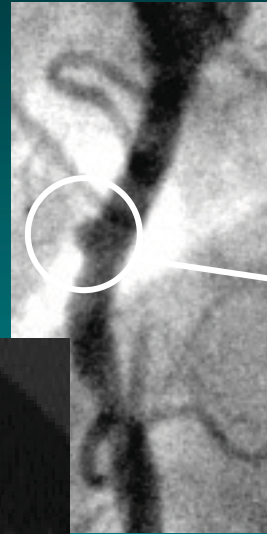
Long-term follow-up (11-34 months) in 81% of entire population (7 late and 14 persistent malapposition patients) showed no events.

- **Late stent malapposition appears to occur with increased frequency after drug-eluting stents.**
- **In general, a greater suppression of intimal hyperplasia is associated with more late malapposition. It is more common with sirolimus than with paclitaxel.**
- **There is no increase in events in the first 6 months post-stent implantation and little neointimal hyperplasia in patients who develop late malapposition regardless of the cause.**
- **What are the long-term consequences, if any? Probably none although in individual cases late stent malapposition may be associated with aneurysm formation.**

Late Malapposition



After Stenting



10 Months Later

