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Insight from the CACTUS trial
**Coronary Bifurcation Application of the Crush Technique
Using Sirolimus-Eluting stents**

The role of final kissing balloon inflation

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CACTUS trial

Coronary Bifurcation Application of the Crush Technique Using Sirolimus-Eluting stents

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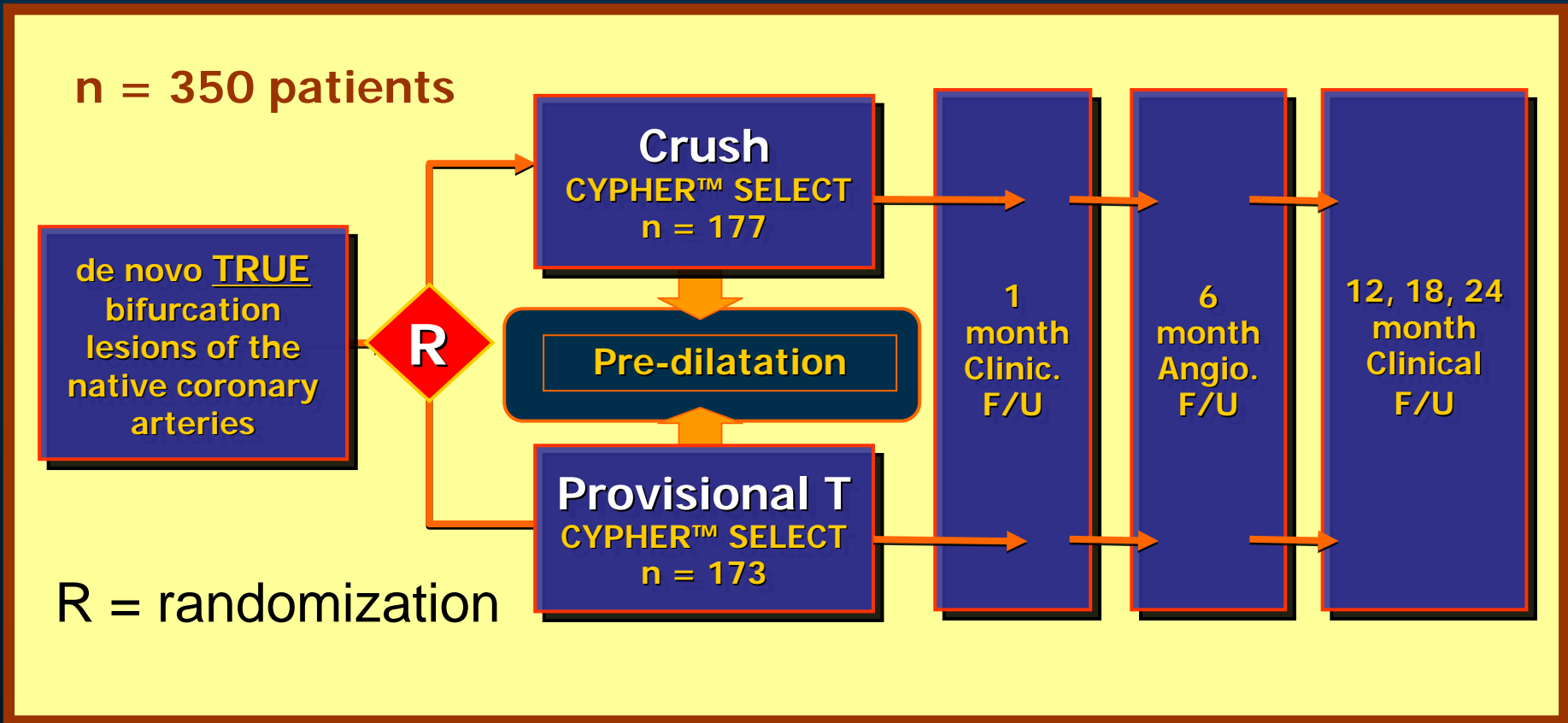
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Study Design and Time Frame



Dual antiplatelet therapy was recommended in all pts for at least 6 months

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Study endpoints

Primary angiographic endpoint: bifurcation in-segment restenosis (lumen diameter stenosis $> 50\%$) at six-months

Primary clinical endpoint: major adverse cardiac events (MACE) at 6 and 12 month

Secondary angiographic endpoint: minimal lumen diameter (MLD) and percent of stenosis (%) on both branches at 6 months

Study hypothesis: 25% restenosis in the Prov.-T and 10% in the Crush. Analysis performed by intention to treat.

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Clinical characteristics (I)

	Crush (n=177)	Prov.-T (n=173)	P
Age (years)	64±10	66±10	0.12
Gender (M/F)	142/35	132/41	0.37
Diabetes (%)	23.7	22.0	0.69
Hypercholesterolemia (%)	63.8	70.5	0.18
Hypertension (%)	70.6	79.8	0.05
Current smokers (%)	20.3	16.8	0.66
LVEF (%)	55±9	57±8	0.08

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Clinical characteristics (II)

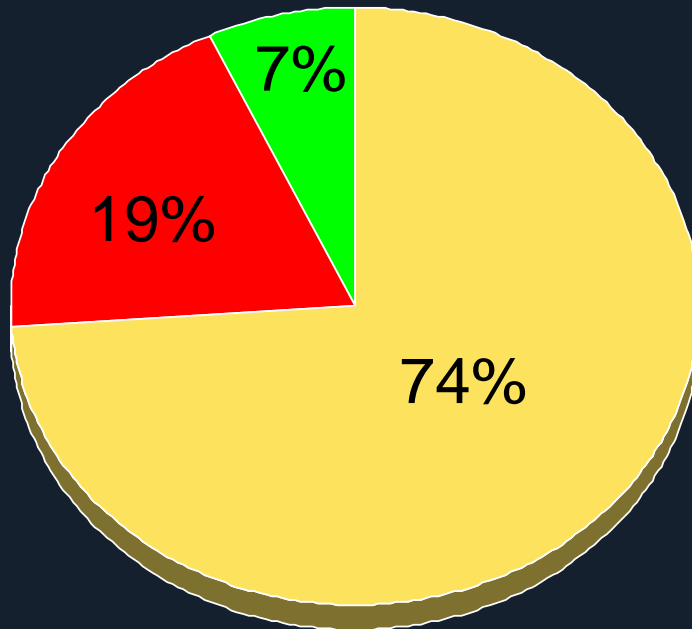
	Crush (n=177)	Prov.-T (n=173)	P
Previous MI (%)	44.6	35.3	0.07
Previous PTCA (%)	31.1	26.6	0.35
Previous CABG (%)	4.5	5.8	0.59
Family history of CAD (%)	46.9	35.8	0.11
Unstable angina (%)	44.0	47.4	0.15
Stable angina (%)	31.1	36.4	0.78
Silent ischemia (%)	17.5	13.3	0.08

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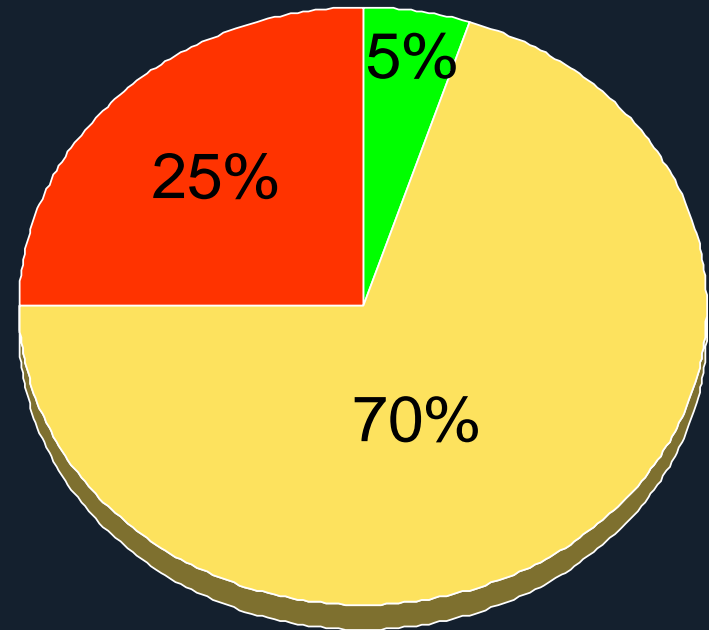
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Lesion location

Crush (n=177)



Prov.-T (n=173)



■ LAD-DIAG.

■ LCX-OM

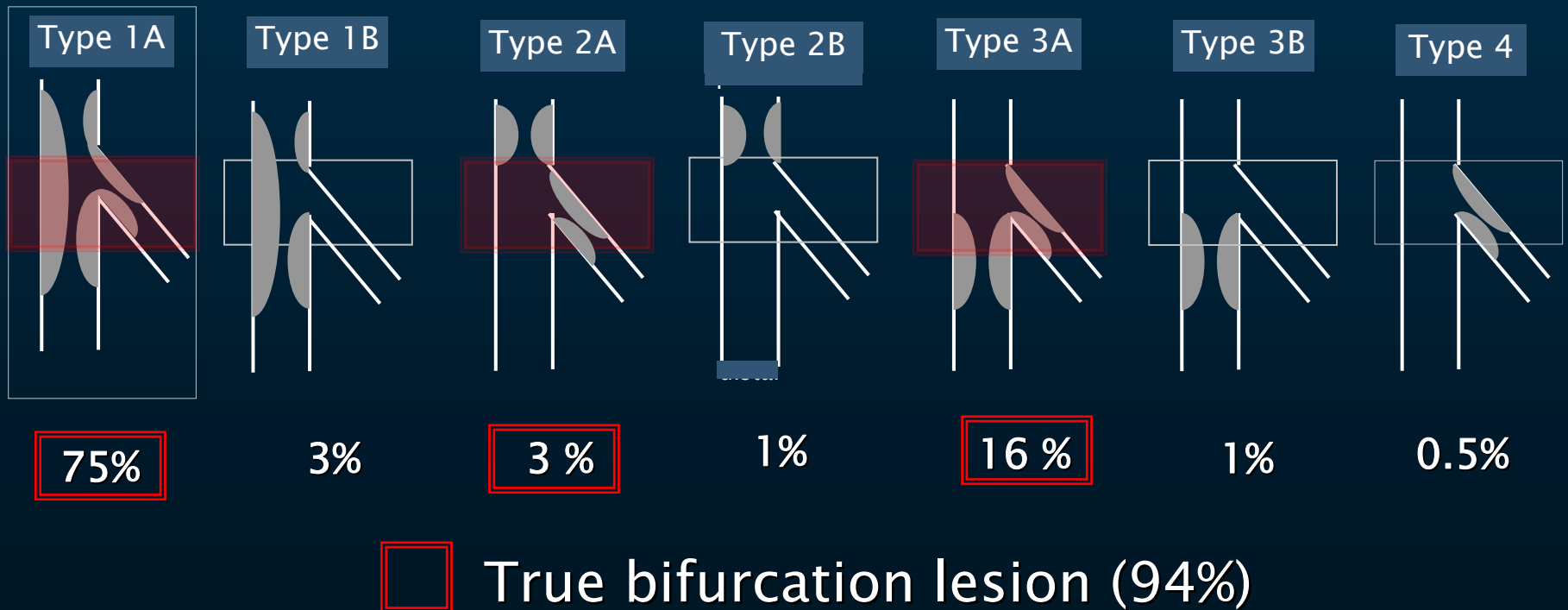
■ RCA-PDA-PL

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Lesion location

Plaque Distribution



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Procedural characteristics

	Crush (n=177)		Prov.-T (n=173)	
	MB	SB	MB	SB
Predilatation (%)	89.8	89.8	90.8	90.8
IVUS (%)	3.4	2.8	4.1	2.3
Total stent	NO final kissing inflation in 14 les in the CRUSH arm		2 ± 5.7*	18.1 ± 6.2 (54 lesions)
Max pressu	17 les in the PROV-T arm		4 ± 4.1	12.0 ± 2.4*
Final kissing (%)	92.1		90.2	
IIb-IIIa GP inhibitors (%)	22.6		17.3	

31% (54/173) NEEDED PROVISIONAL STENTING IN THE SB

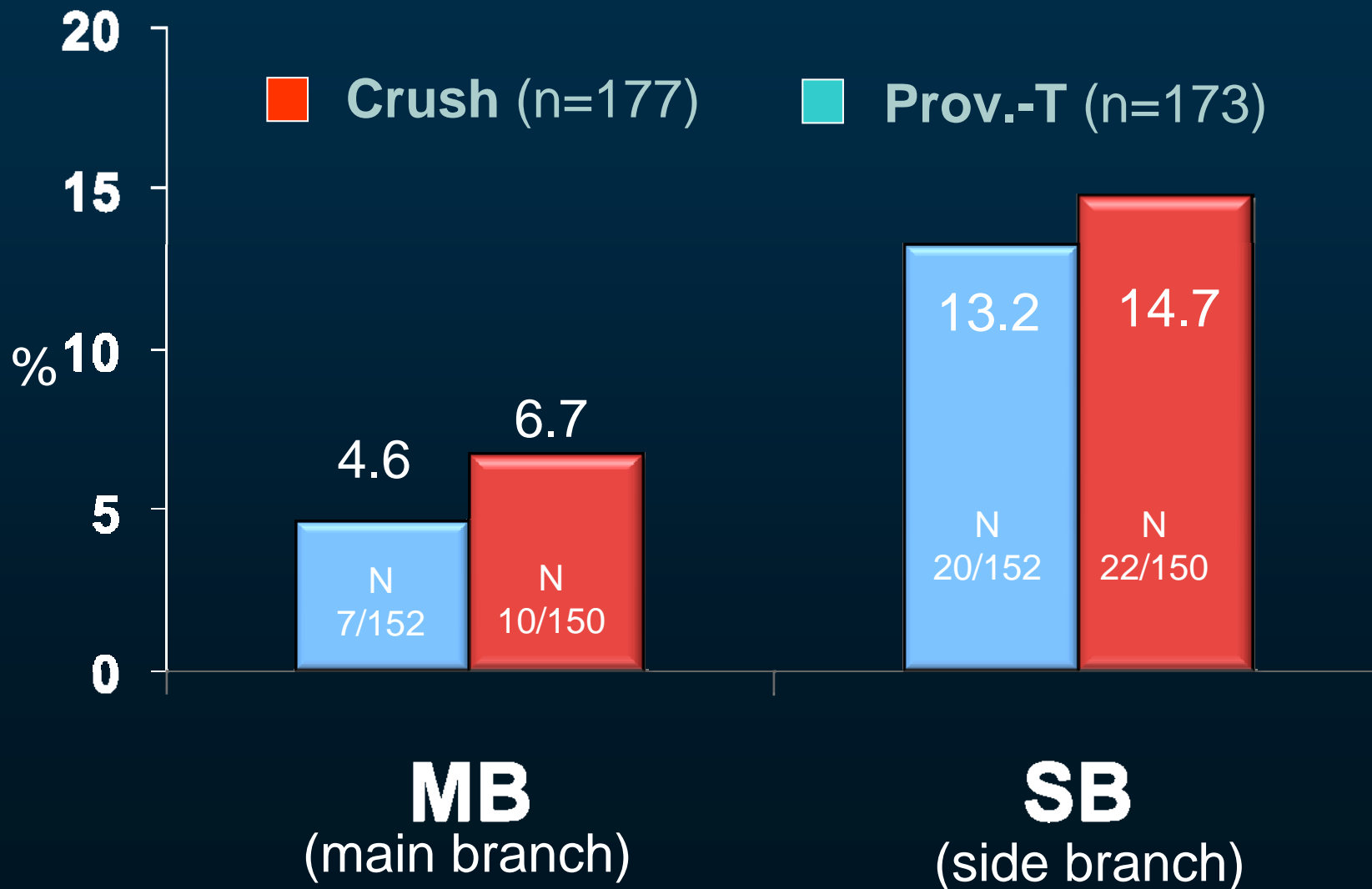
* = $p < 0.05$ for comparisons between crush and prov.-T

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6-month in-segment binary restenosis

Angiographic F.U. performed in 86% of pts in both groups



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	Crush	T-Prov	
30 days MACE (days 0-30)			
Q wave MI	3 (1.7%)	2 (1.1%)	1.00
Non-Q wave MI	15 (8.5%)	12 (6.9%)	0.69
TLR	3 (1.7%)	1 (0.5%)	0.63
TVR (including TLR)	3 (1.7%)	1 (0.5%)	0.63
Death	0	0	-
6-month MACE (days 31-180)			
MI	1 (0.5%)	1 (0.5%)	1.00
TLR	10 (5.6%)	10 (5.8%)	1.00
TVR (including TLR)	11 (6.2%)	12 (6.8%)	0.83
Death	0	1* (0.5%)	0.49

*= non cardiac death (ischaemic stroke confirmed by autopsy)

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Stent thrombosis

	Total	Acute (first day)	Subacute (days 2-30)	Late (days 31-180)
Crush (n=177)	3 (1.7%)	1 (0.5%)	2* (1.1%)	0
Prov.T (n=173)	2 (1.1%)	0	1 (0.5%)	1 (0.5%) (definitive)

$p = 0.62$ for comparisons between crush and prov.-T

* One patient did not take thienopyridine therapy after discharge

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*Final kissing inflation
not performed (no FKI)*

CRUSH 14
lesions

PROV-T 17
lesions

7 operator's
decision

12 operator's
decision

7 technical
difficulties

5 technical
difficulties

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Final kissing balloon inflation

	YES	NO	P value
Myocardial infarctions	7.5% (24/319)	29.0% (9/31)	<0.0001
Stent thrombosis	0.9% (3/319)	6.5% (2/31)	0.06

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Final kissing balloon inflation

	YES	NO	P value
MB restenosis	4.7%	16%	0.03
SB restenosis	11.9%	36%	<0.001

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Conclusions

- 31% cross over from provisional to 2 stents
- No difference in cumulative 6-months MACE and in binary in-segment restenosis both in the main branch and in the side branch.
- No difference in 6-month stent thrombosis:
(1.7% with crush vs 1.1% with prov.-T; $p=0.62$)
- The lack of FKI is associated to a significant increase in MI, stent thrombosis and angiographic restenosis

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QCA measurements

	Crush (n=177)		Prov.-T (n=173)	
	MB	SB	MB	SB
Reference diam. (mm)	2.85 ± 0.33	2.30 ± 0.31	2.74 ± 0.35*	2.16 ± 0.33*
Lesion length (mm)	15.8 ± 8.7	5.9 ± 4.7	14.7 ± 8.2	5.7 ± 4.2
Baseline MLD (mm)	0.90 ± 0.38	0.84 ± 0.32	0.83 ± 0.33	0.83 ± 0.30
Baseline stenosis (%)	68 ± 12	63 ± 12	69 ± 12	61 ± 13
Final MLD (mm)	2.71 ± 0.32	1.94 ± 0.39	2.58 ± 0.33*	1.65 ± 0.39*
Final stenosis (%)	12 ± 6	16 ± 11	13 ± 6	27 ± 14*
6-month MLD (mm)	2.24±0.52	1.66 ± 0.51	2.19±0.58	1.52 ± 0.54*
6-month stenosis (%)	25 ± 14	30 ± 19	25 ± 16	31 ± 22

Angiographic follow-up performed in 86% of patients in both groups

** = p<0.05 for comparisons between crush and prov.-T*

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Stent thrombosis

	1	2	3	4	5
Technique	Crush	Crush	Crush	Prov.-T	Prov.-T
Days from procedure	1	7	6	7	72
Thienopyridine	Yes	Yes	No stop day 1	Yes	Yes
Number of stents	2+1	1+1	2+1	1	1+1
Total stent length (mm)	83	65	72	13	41
Final kissing	Yes	No	Yes	Yes	No
Diabetes	No	No	Yes	Yes	No
Lesion location	LAD-diag.	LAD-diag	LAD-diag	LAD-diag	RCA
Clinical consequences	Q-wave MI and TLR	Non Q-wave MI and TLR	Q-wave MI and TLR	Q-wave MI and TLR	Q-wave MI and TLR