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OCT assessment of calcium severity in patients treated with rotational atherectomy vs. modified balloons: Results from the randomised PREPARE-CALC trial

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Potential conflicts of interest

Speaker's name : Mohamed Abdel-Wahab

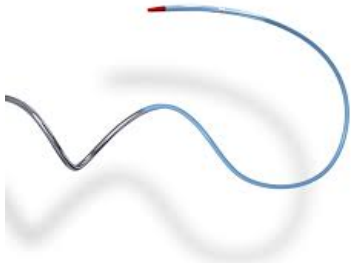
☑ I have the following potential conflicts of interest to declare:

Receipt of honoraria or consultation fees: Boston Scientific, Edwards Lifesciences, Medtronic

Calcified lesion preparation

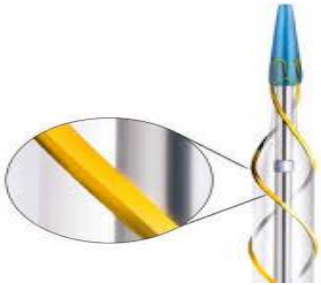
Balloon angioplasty

Ultra-low profile balloons



Non-compliant balloons

Scoring balloons



Cutting balloons

OPN NC balloons

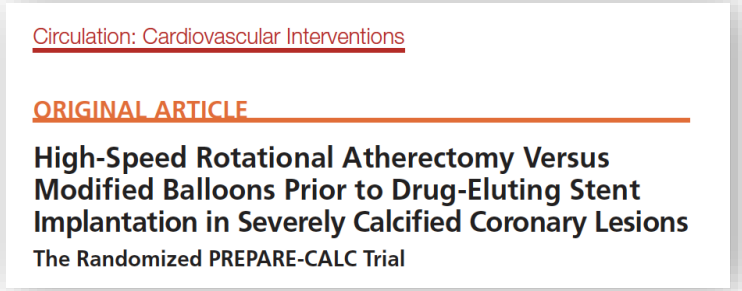
Lithoplasty balloon

Atherectomy/Debulking

Rotational atherectomy

Orbital atherectomy

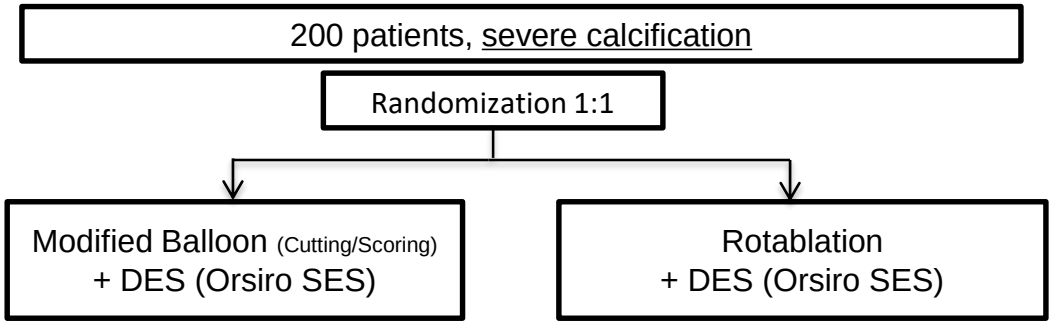
The PREPARE-CALC Trial


Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

High-Speed Rotational Atherectomy Versus Modified Balloons Prior to Drug-Eluting Stent Implantation in Severely Calcified Coronary Lesions

The Randomized PREPARE-CALC Trial



Primary endpoint: Strategy success

Co-primary endpoint: In-stent late lumen loss at 9 months

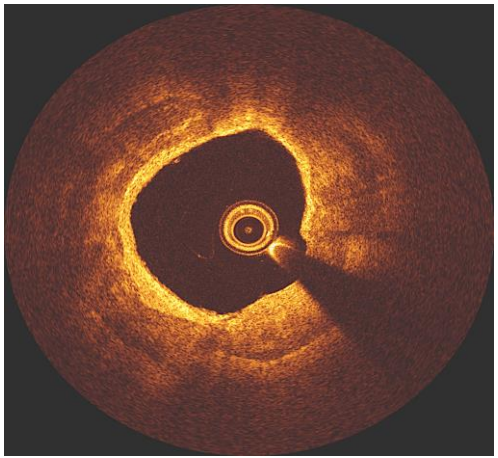
- Investigator-initiated randomized controlled trial at 2 German centers (Bad Segeberg, Munich)
- Enrolment between 9/2014 and 10/2017
- Strategy success superior with rotablation
- Late lumen loss non-inferior with rotablation

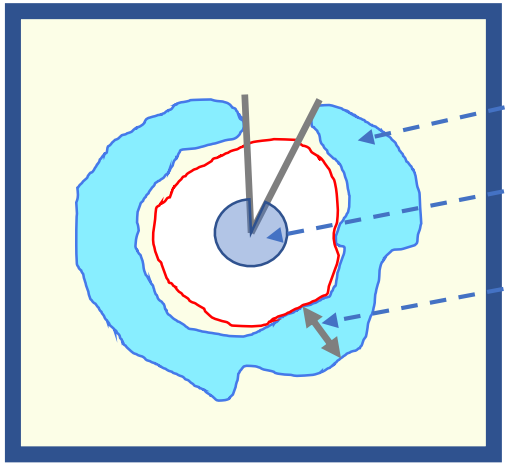
Abdel-Wahab et al. Circ Cardiovasc Interv 2018;11:e007415

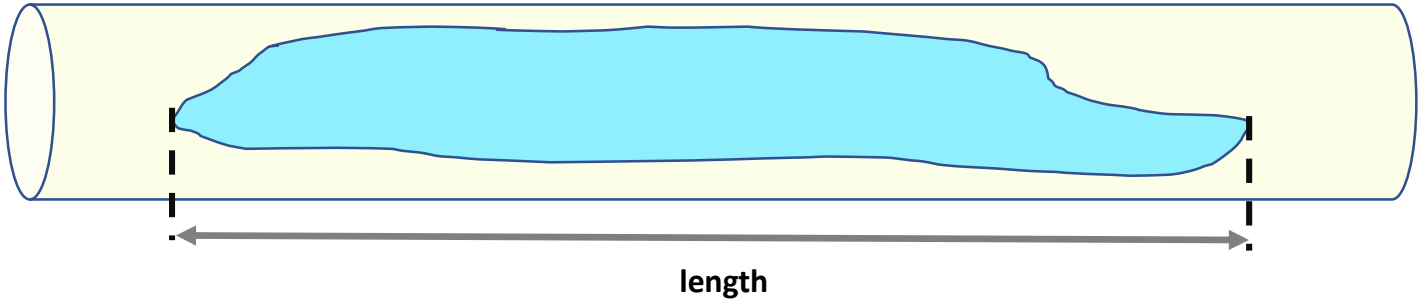
PREPARE-CALC OCT

- OCT before lesion preparation and after stenting was performed in a subgroup of patients (Ilumien Optis console, Dragonfly intravascular imaging catheter, Abbott Vascular) with no impact on treatment strategy
- OCT analysis was performed off-line (QCU-CMS software, Medis) in an independant corelab (T. Gori, Mainz, Germany)
- **Objective 1:** Compare the effect of both modified balloons vs. rotablation on OCT-derived stent performance parameters
- **Objective 2:** Assess impact of OCT measures of Calcium severity on strategy success, stent expansion, assymetry and eccentricity

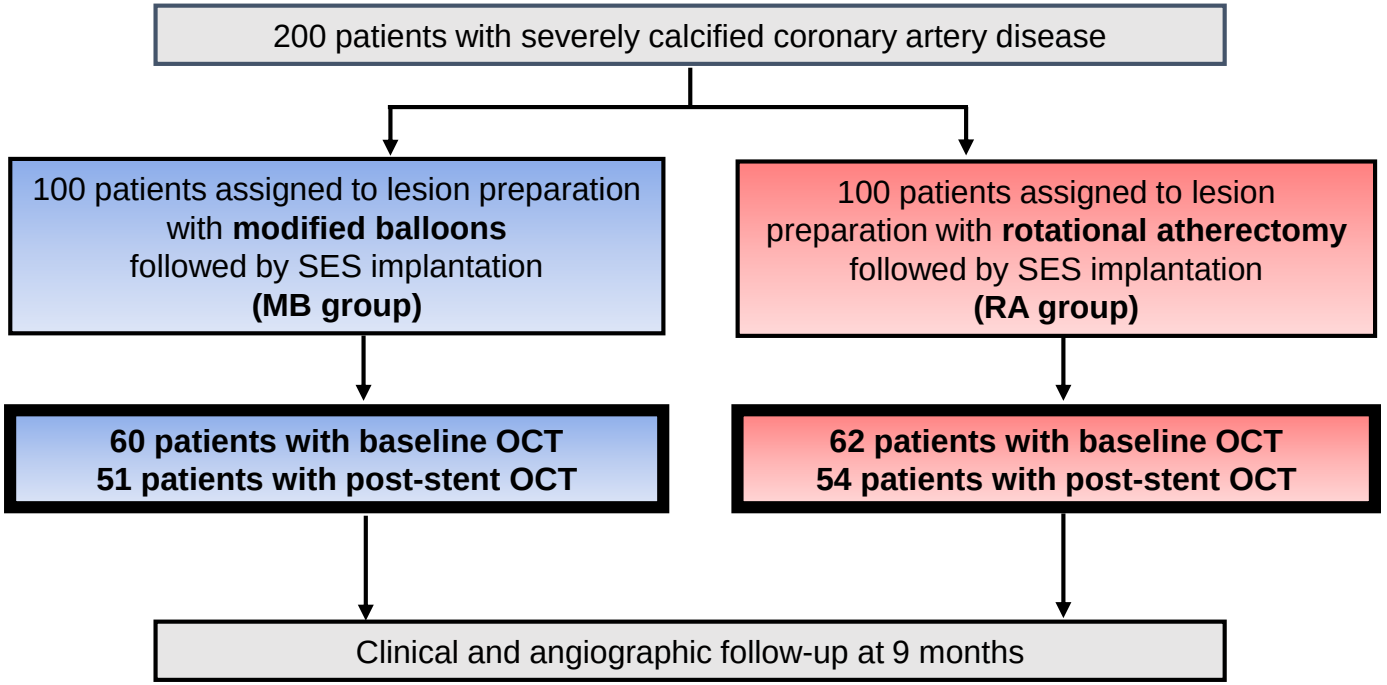
Assessment of calcified plaque







Study flow


200 patients with severely calcified coronary artery disease
100 patients assigned to lesion preparation with **modified balloons** followed by SES implantation **(MB group)**
100 patients assigned to lesion preparation with **rotational atherectomy** followed by SES implantation **(RA group)**
60 patients with baseline OCT
51 patients with post-stent OCT
62 patients with baseline OCT
54 patients with post-stent OCT
Clinical and angiographic follow-up at 9 months

OCT subgroup

	No OCT (n = 78)	OCT (n = 122)	p-value
Age, y	**76.2 ± 6.9**	**74.1 ± 6.9**	**0.03**
Men	62 (80%)	90 (74%)	0.40
Chronic renal failure	15 (19%)	32 (26%)	0.31
LV ejection fraction, %	55.5 ± 10.5	56.8 ± 11.6	0.41
Lesion location			0.26
Left main	5 (6.4%)	8 (6.6%)	
LAD	37 (47.4%)	74 (60.7%)	
LCx	11 (14.1%)	10 (8.2%)	
RCA	25 (32.1%)	30 (24.6%)	
Stenosis on QCA, %	**67.61 ± 10.68**	**64.13 ± 8.57**	**0.01**
B2/C lesion	76 (97%)	115 (94%)	0.32
Randomization to RA	38 (48.7%)	62 (50.8%)	0.89
Bailout RA	**10 (12.8%)**	**6 (4.9%)**	**0.06**
Procedural duration, min	86.4 ± 45.0	81.5 ± 33.0	0.40
Fluoroscopic time, min	**25.7 ± 14.9**	**18.9 ± 10.9**	**<0.001**
Contrast amount, mL	234.5 ± 95.9	229.7 ± 105.2	0.74

The main reason (n=39) for not performing OCT was the inability of the catheter to cross

OCT before lesion preparation

	Modified balloon (n = 60)	Rotational atherectomy (n = 62)	p-value
Lesion length, mm	**30.41 ± 11.82**	**34.92 ± 12.64**	**0.04**
Max. lumen area, mm^2	9.87 ± 3.34	10.07 ± 3.44	0.75
Max. lumen diameter, mm	3.49 ± 0.60	3.53 ± 0.61	0.76
Min. lumen area, mm^2	2.38 ± 1.07	2.35 ± 1.54	0.91
Min. lumen diameter, mm	1.70 ± 0.38	1.66 ± 0.48	0.66
Max. lumen asymmetry	0.75 ± 0.11	0.77 ± 0.11	0.24
Lumen asymmetry >0.3	60 (100%)	62 (100%)	1.0
Max. lumen eccentricity	0.49 ± 0.11	0.50 ± 0.14	0.52
Lumen eccentricity <0.7	57 (95%)	58 (94%)	1.0
Lumen area stenosis, %	60.54 ± 15.60	65.71 ± 15.08	0.06
Mean ref. area, mm^2	6.40 ± 2.47	6.88 ± 2.47	0.28
Mean ref. diameter, mm	2.77 ± 0.53	2.87 ± 0.54	0.30
Plaque rupture	5 (8%)	6 (10%)	1.0
Plaque erosion	4 (7%)	3 (5%)	0.72

Calcified plaque parameters

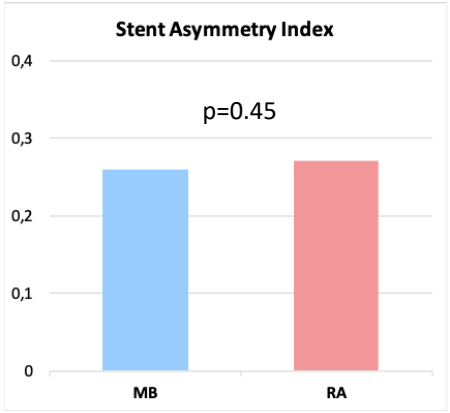
	Modified balloon (n = 60)	Rotational atherectomy (n = 62)	p-value
Max. Calcium angle, °	257.5 ± 96.7	248.70 ± 82.14	0.59
Avg. Calcium angle, °	124.9 ± 49.0	112.64 ± 31.93	0.10
Max. calcified plaque thickness, mm	1.34 ± 0.29	1.32 ± 0.27	0.76
Max. volume of calcified plaque, mm^2	33.86 ± 26.12	32.46 ± 29.90	0.78
Total volume of calcified plaques, mm^2	54.44 ± 32.32	58.56 ± 38.31	0.52
Total length of calcified plaque, mm	21.08 ± 9.66	23.98 ± 10.93	0.12
Indexed volume of calcified plaque	0.38 ± 0.24	0.33 ± 0.19	0.20
OCT-derived Calcium score*			0.83
1	1 (2%)	2 (3%)	
2	16 (27%)	15 (24%)	
3	1 (2%)	3 (5%)	
4	42 (70%)	42 (68%)	

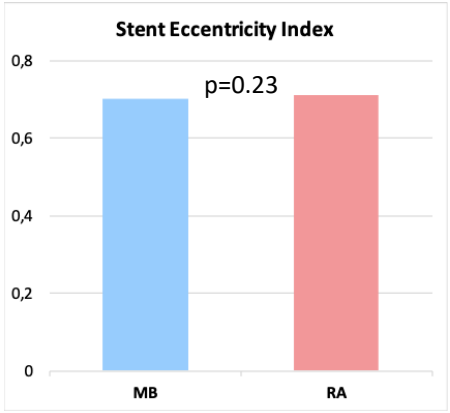
* Fujino er al. EuroIntervention 2018;13:e182-9

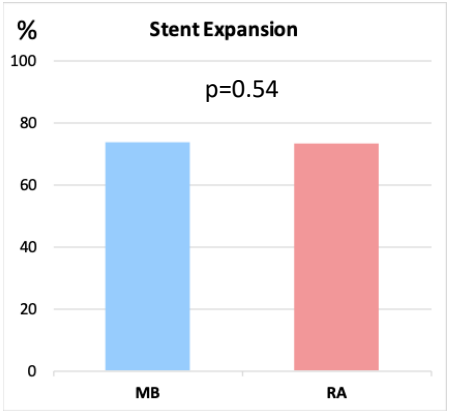
OCT post-stenting

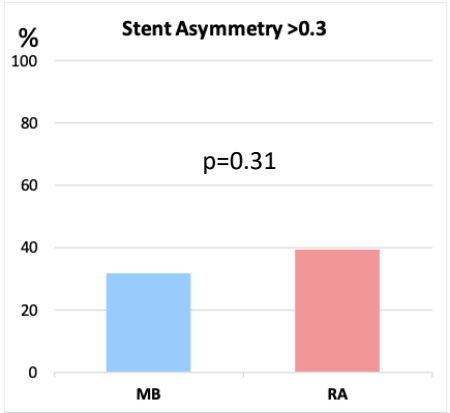
	Modified balloon (n = 54)	Rotational atherectomy (n = 51)	p-value
Stent length, mm	**32.61 ± 13.14**	**37.70 ± 12.35**	**0.04**
Max. stent area, mm^2	11.27 ± 2.68	11.59 ± 3.46	0.59
Max. stent diameter, mm	3.76 ± 0.46	3.80 ± 0.56	0.67
Min. stent area, mm^2	6.13 ± 1.72	6.19 ± 1.93	0.85
Min. stent area <4.5mm^2	10 (18.5%) n=54	11 (21.6%) n=51	0.81
Min. stent diameter, mm	2.77 ± 0.39	2.77 ± 0.45	0.93
Acute gain, mm^2	3.74 ± 1.74	3.87 ± 1.82	0.71
Acute gain, mm	1.11 ± 0.44	1.14 ± 0.44	0.67
Number of Calcium cracks	3.43 ± 2.96	3.33 ± 2.88	0.87
Stent fractures	5 (9.3%)	1 (2%)	0.21

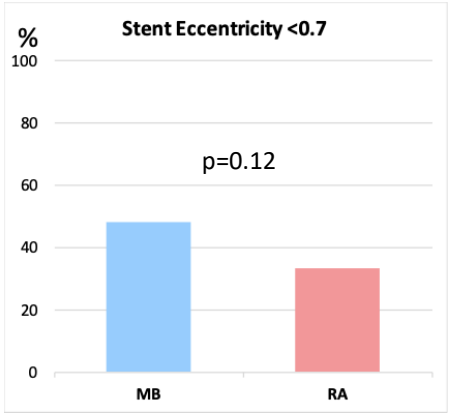
OCT post-stenting

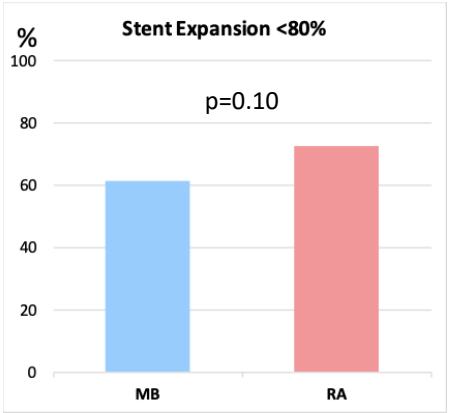












9-month outcome

	Modified balloon (n = 60)	**Rotational atherectomy** (n = 62)	**p-value**
Death	0 (0%)	1 (1.6%)	1.0
Myocardial infarction	1 (1.7%)	2 (3.2%)	1.0
TVR	3 (5%)	1 (1.6%)	0.36
TLR	2 (3.3%)	1 (1.6%)	0.62
Non-TV PCI	10 (16.7%)	5 (8.1%)	0.18
MACE (death, MI, TVR)	4 (6.7%)	4 (6.5%)	1.0

Predictors of bailout rotablation

Predictors of bailout rotablation	Odds ratio	95% CI	p-value
Lesion length at baseline OCT	6.37	1.42 - 28.58	0.005
Vessel tortuosity	15.28	0.84 - 276.68	0.049

One important confounder:

Of 16 lesions requiring bailout rotablation, 10 could not be crossed by an OCT catheter!

Stent morphology

Predictors of stent asymmetry	Odds ratio	95% CI	p-value
Rotational atherectomy	1.53	0.60-3.90	0.36
Target vessel = RCA	0.06	0.01 - 0.46	0.007
Max. lumen area	1.18	1.03 - 1.36	0.026
Max. thickness of Calcium	5.76	1.04 - 31.85	0.046

Predictors of stent eccentricity	Odds ratio	95% CI	p-value
Rotational atherectomy	0.50	0.21 - 1.18	0.11
Male gender	2.93	1.07 - 8.02	0.036
Max. lumen eccentricity	0.00	0.00 - 0.15	0.003

Stent expansion

Predictors of stent expansion	Odds ratio	95% CI	p-value
Rotational atherectomy	2.04	0.72 - 5.74	0.17
LV ejection fraction	1.08	1.02 - 1.13	0.006
Max. lumen area	16.44	1.47 - 183.84	0.023
Total length of Calcium	1.06	1.01 - 1.11	0.015

Limitations

- OCT subgroup is small-sized with limited statistical power.
- OCT evaluation of calcified plaques is affected by the ability of the catheter to cross.
- No systematic assessment of calcified lesions after preparation with rotablation or modified balloons and before stent implantation.

The essentials to remember

- This OCT analysis from the randomized PREPARE-CALC trial looked at the potential impact of baseline OCT parameters on strategic success and stent performance after calcified lesion preparation with rotational atherectomy or modified balloons.
- The need for bailout rotablation could not be predicted by baseline measures of Calcium severity, which is hampered by the inability of OCT assessment of a significant proportion of lesions eventually requiring rotablation.
- Thickness of calcified plaque appeared to influence stent symmetry, while length of calcified plaque affected stent expansion, with no significant impact of the lesion preparation strategy.

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