Plaque Modification in Complex PCI

Application of:
Rotablator™ & ROTAPRO™ Rotational Atherectomy System
Wolverine™ Cutting Balloon™ Device

Why Calcium Matters

The Battle Against Calcium

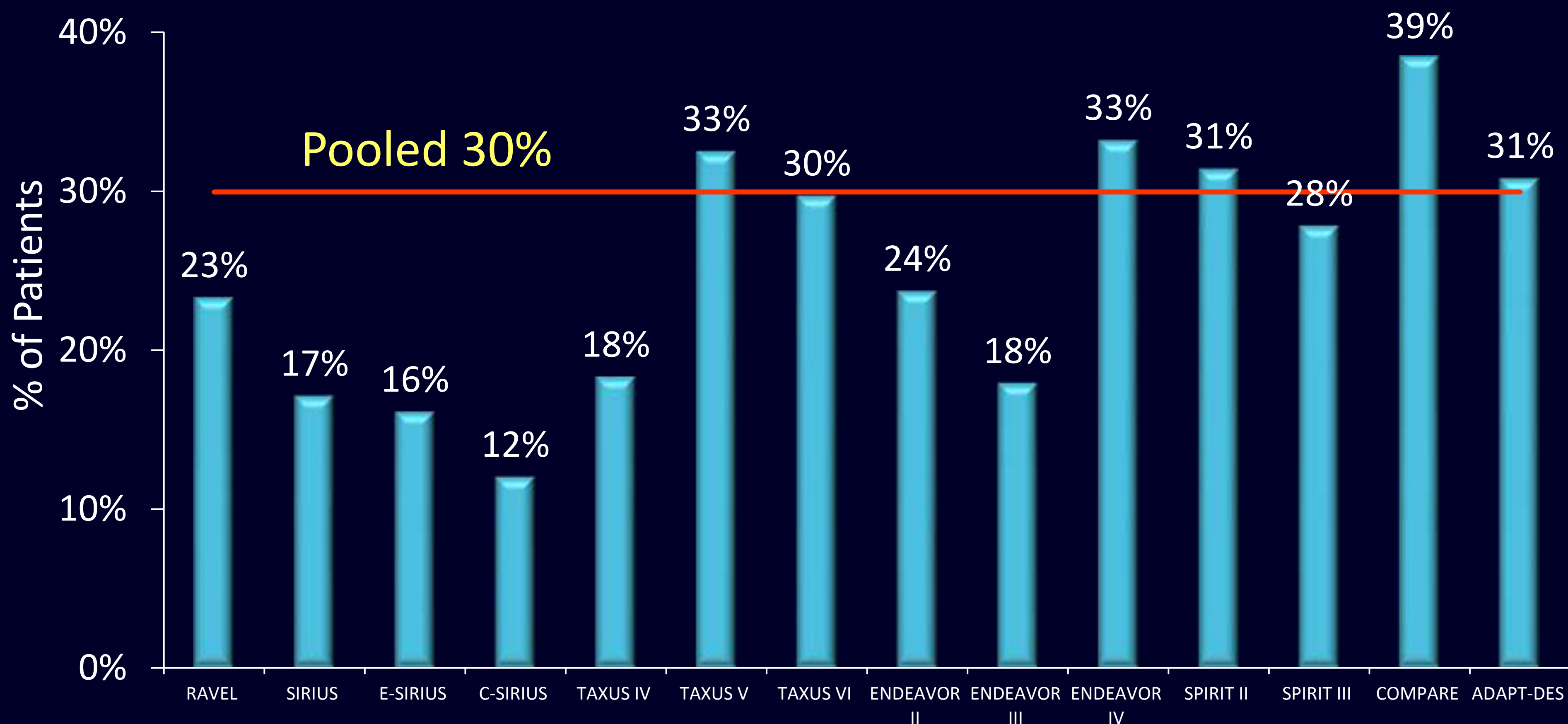
Calcium is prevalent in patients undergoing PCI

Calcium leads to worse clinical outcomes

Calcium may inhibit optimal stenting

Rota use with PCI is associated with *safe* and *effective* clinical outcomes

Frequency of Angio Core Lab Moderate-Severe Calcification* in 14 DES studies



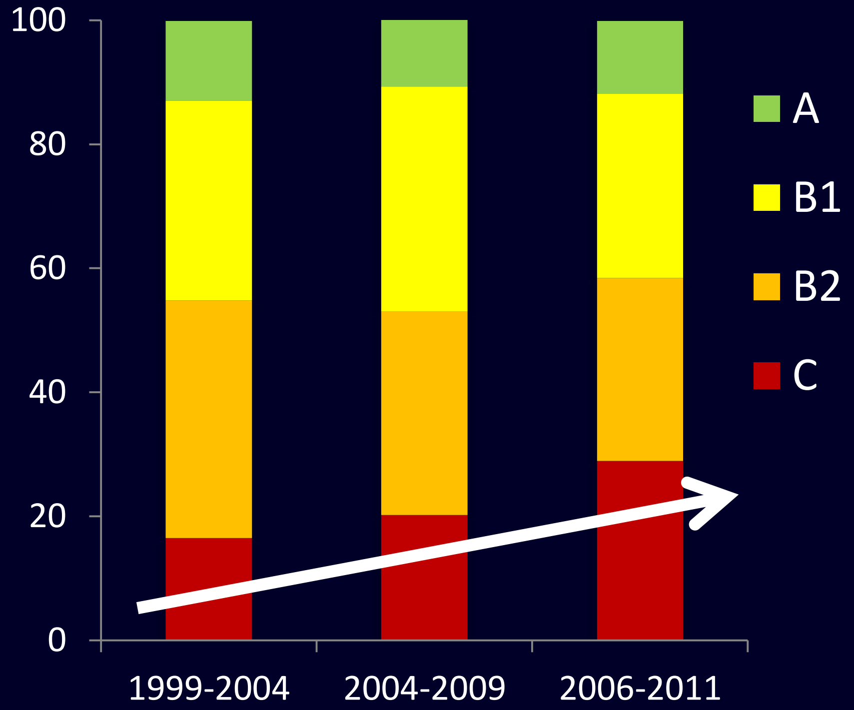
N	116	531	174	50	660	570	219	590	436	1546	290	997	1799	8582
Year	2002	2003	2003	2004	2004	2005	2004	2003	2004	2005	2005	2005	2007	2008

(*despite being an exclusion criterion in most studies)

Results from different studies are not directly comparable. Information provided for educational purposes only. Adapted from Kirtane CHIP DC 2017; ADAPT-DES: Généreux, P. et al., *Int. J. Cardiol* ; 2017(231):61-67.

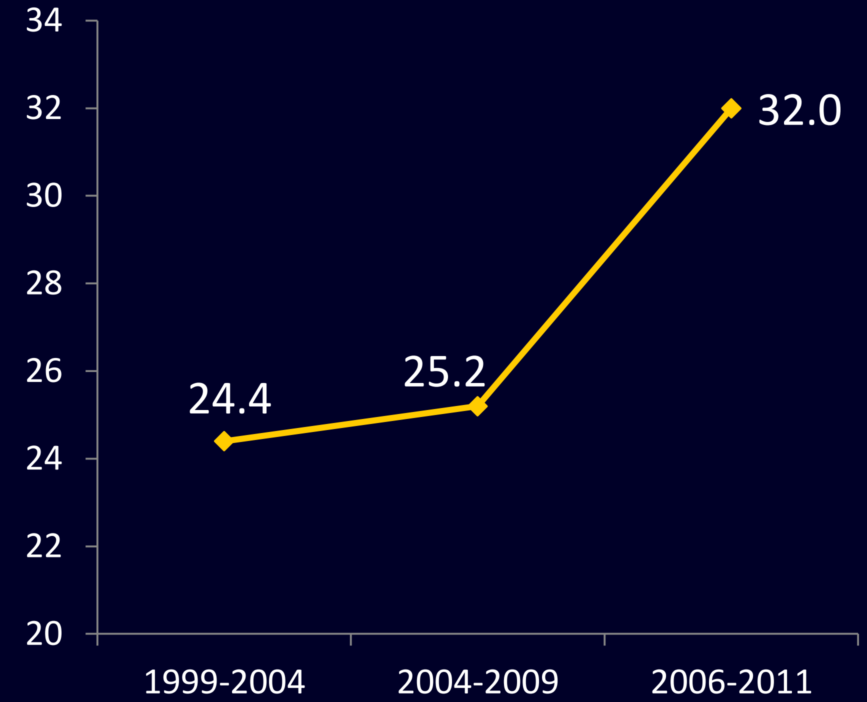
Increasing Complexity and Calcification of PCI Patients

Increasing Prevalence of Type C Lesions



ACC/AHA Lesion Classification

Increasing Prevalence of Calcification



% Of Patients With Calcified Lesions*

*as reported to NHLBI Dynamic Registry.
Bortnick, et. al. Am J Cardiol 2014;113:573-579.

The Need to Treat Calcium is Growing

Increasing Risk Factors

- Age
- Diabetes
- Renal failure
- Hypertension
- Smoker

New Technologies

- High-Risk PCI
- Pre-TAVR revascularization

Calcium treatment needs will continue to grow over the next 10 years

Clinical Data Supporting Rotational Atherectomy Use

The Battle Against Calcium

Calcium is prevalent in patients undergoing PCI

Calcium leads to worse clinical outcomes

Calcium can inhibit optimal stenting

Rota use is associated with *safe* and *effective* clinical outcomes

PREPARE-CALC Trial

Prospective, 1:1 randomized, German study (2 sites)

PCI in 200 patients with severely calcified lesions

Lesion preparation with
Modified Balloon*
(scoring/cutting)

Randomization
1:1

Lesion preparation with
Rotational Atherectomy

* Predilatation with standard balloons was allowed to facilitate delivery of modified balloons

DES implantation

9-month angiographic & clinical follow-up

1 & 2-years clinical follow-up

<u>Primary End point:</u>

- **Strategy success** (Superiority): Successful stent delivery and expansion with < 20% in-stent residual stenosis and TIMI 3 flow without crossover or stent failure
- **In-stent late-lumen-loss at 9 months** (Non-inferiority)

Mohamed, AW. Et al. Circulation: Cardio. Int. 2018 Sep 24.; 11:e007415

PREPARE-CALC Trial

Key Baseline/Procedural/Lesion Characteristics:

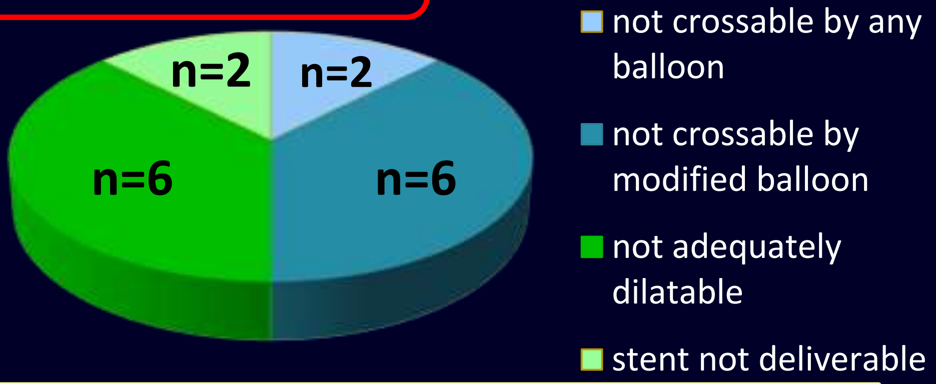
Criteria	Balloon (n=100)	RA (n=100)	p-value
Mean age	75% ± 6.9	74.5% ± 7.1	0.79
DM	34%	33%	0.88
Chronic renal failure	21%	26%	0.40
LM disease	37%	23%	0.03
Multivessel disease	70%	74%	0.52
B2/C lesion	94.2%	97.2%	0.62
Ostial Lesion	25.5%	28.4%	0.52
Bifurcation Lesion	44.5%	39.0%	0.37
Total stent length (mm)	35.41 ± 18	35.63 ± 15.69	0.94
Procedural Duration (min)	78.5 ± 40.6	88.2 ± 34.9	0.07
Fluoroscopy Time (min)	19.6 ± 13.4	23.9 ± 12.2	0.03
Contrast amount (ml)	230 ± 93.8	233 ± 109.1	0.83
Large dissection (>5mm)	7%	3%	0.33
Side branch compromise	13%	6%	0.09
Perforation	2%	4%	0.68

Mohamed, AW. Et al. Circulation: Cardio. Int. 2018 Sep 24.; 11:e007415

PREPARE-CALC Trial

Primary End point – Strategy Success

	Balloon	RA	P-value
Strategy Success	81 (81%)	98 (98%)	**0.0001**
Final TIMI flow < 3	0 (0%)	1 (1%)	0.99
Residual Stenosis >20%	2 (2%)	0 (0%)	0.49
Stent Failure	4 (4%)	1 (1%)	0.36
Crossover	16 (16%)	0 (0%)	**< 0.0001**



Rotational Atherectomy use for vessel preparation in severely calcific lesions before DES implantation showed statistically significant difference over Modified Balloon strategy

Mohamed, AW. Et al. Circulation: Cardio. Int. 2018 Sep 24.; 11:e007415

PREPARE-CALC Trial

Baseline QCA

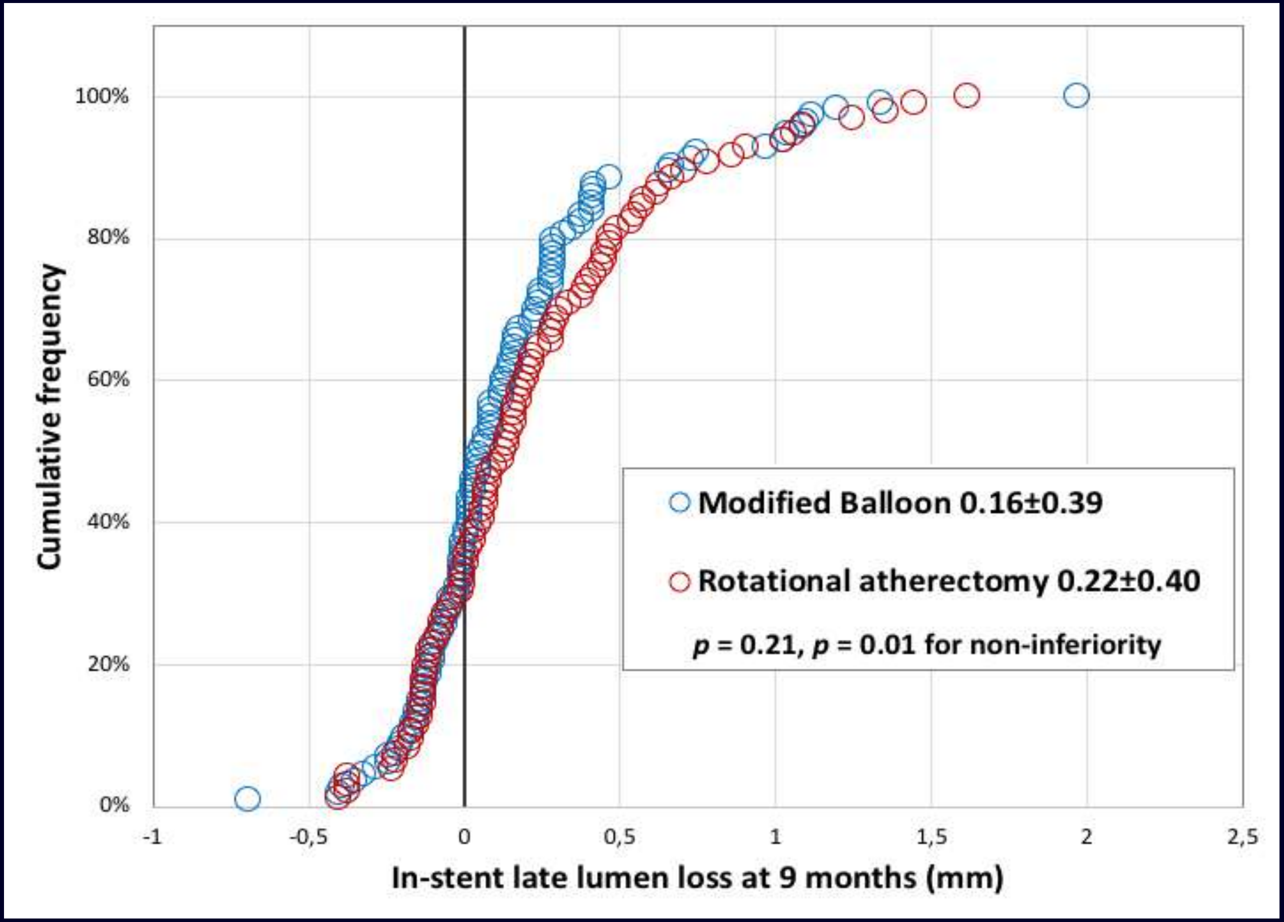
	Modified balloon (n = 136 lesions)	Rotational atherectomy (n = 137 lesions)	p-value
Before the procedure			
Lesion length (mm)	20.16±11.88	20.86±12.30	0.63
Reference vessel diameter (mm)	3.08±0.47	3.10±0.49	0.84
Minimal lumen diameter (mm)	1.07±0.34	1.15±0.35	0.07
Diameter stenosis (%)	65.18±9.53	63.43±9.80	0.16
Immediately after the procedure			
Minimal lumen diameter (mm)			
In-stent	2.81±0.47	2.85±0.43	0.56
In-segment	2.58±0.53	2.62±0.67	0.61
Diameter stenosis (%)			
In-stent	12.34±5.14	12.62±5.36	0.63
In-segment	17.12±7.39	17.58±7.31	0.59
Acute gain (mm)			
In-stent	1.74±0.45	1.70±0.42	0.45
In-segment	1.50±0.51	1.47±0.64	0.61

No statistically significant difference between acute gain in severely calcific lesions, however, questionable whether lesions were severely calcific as PCI was angiographically-guided

Mohamed, AW. Et al. Circulation: Cardio. Int. 2018 Sep 24.; 11:e007415

PREPARE-CALC Trial

Primary End Point – In-stent Late Lumen Loss at 9 months



Primary end point for non-inferiority was met with no statistically significant difference for clinical outcomes at 9 months

PREPARE-CALC Trial

Conclusions

- Rotational Atherectomy (RA) strategy showed better acute strategic success over the Modified Balloon (MB) strategy in severely calcific lesions.
- Severely Calcific lesion preparation with Rotational Atherectomy combined with modern DES showed positive long term clinical outcomes.

Limitations

- Study was not adequately powered for clinical outcomes and meant to serve as hypothesis-generating.
- Protocol followed an angiography-guided PCI without IVUS or OCT use, thus whether only true severely calcific lesions were included is questionable.
- 1st generation scoring balloons used (83.8% Angiosculpt, 12.9% Scoreflex) in the trial. Unclear if similar results would be expected if Modified balloon arm included a 2nd generation cutting balloon such as Boston Scientific's Wolverine™ with improved deliverability and a differentiated cutting mechanism.

Mohamed, AW. Et al. Circulation: Cardio. Int. 2018 Sep 24.; 11:e007415

In-Hospital and Midterm Outcomes of Rotational Atherectomy (RA)

ROTATE Multi-Center Registry

↓

Patients with calcified lesions treated with RA and stenting at 9 institutions between April 2002 and August 2013 (1,076 patients and 1,284 lesions)

Registry Exclusion Criteria: STEMI, Cardiogenic Shock, Target Lesions Containing Thrombus

↓

Excluded from current analysis: In-stent restenosis, treated without stents, treated with BRS (108 Excluded Lesions)

↓

985 patients and 1,176 lesions

Primary Endpoint: Midterm (two-year) MACE*

*MACE defined as the combination of all-cause death, any myocardial infarction, and target lesion revascularization during hospitalization; Kawamoto, H et. al. *EuroIntervention* 2016;12:1448-1456.

In-Hospital and Midterm Outcomes of Rotational Atherectomy (ROTATE Multi-Center Registry)

Patient/Lesion Characteristics	**N=985 (1176 lesions)**
Diabetes Mellitus	34.5%
ACS	26.2%
Three-vessel disease	37.2%
Haemodialysis	7.6%
Bifurcation lesions	25.2%
Target Vessel LAD	48.2%

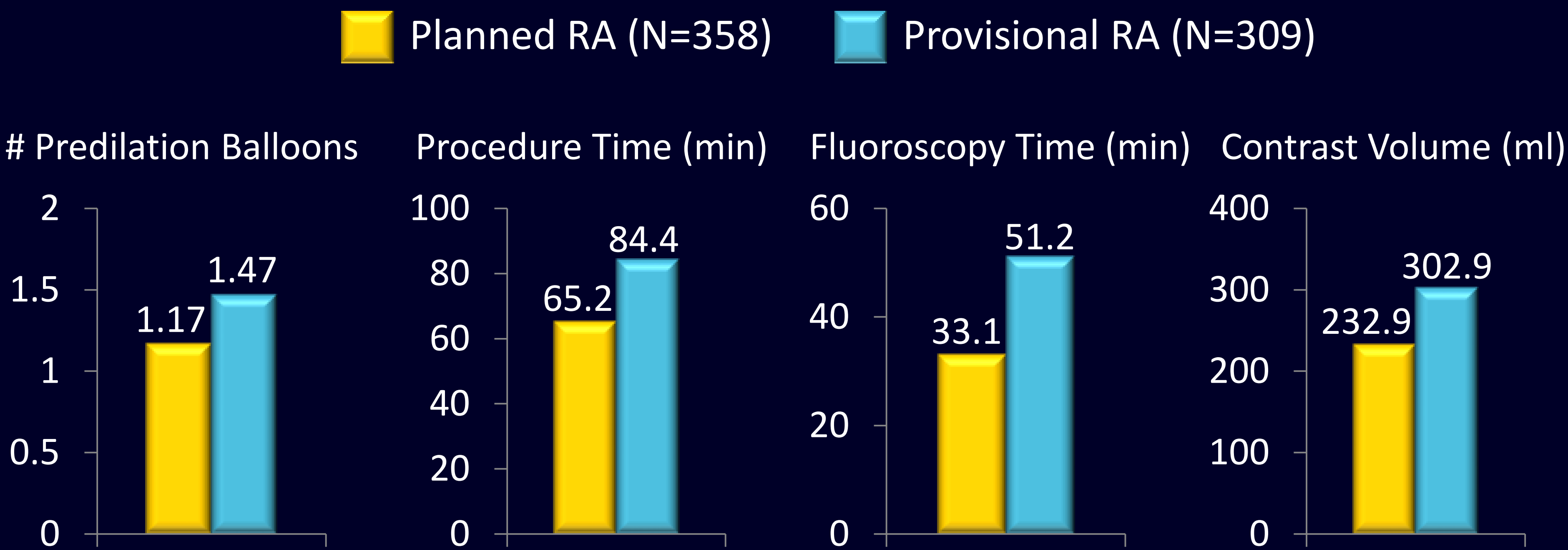
Outcomes	**N=985**
In-hospital MACE*	8.3%
1-year follow-up MACE*	16.0%
2-year follow-up MACE**	24.9%
2-year ST (definite/probable)	1.8%

Rotational atherectomy results in high procedural success rates with acceptable short- and longer-term MACE rates considering the severity of patient and lesion characteristics

*MACE defined as the combination of all-cause death, any myocardial infarction, and target lesion revascularization during hospitalization;
**Primary endpoint; Kawamoto, H et. al. *EuroIntervention* 2016;12:1448-1456.

Advantages of Planned Versus Provisional Rotational Atherectomy (RA) for Severely Calcified Coronary Lesions

Insights from the ROTATE Multi-Center Registry



P-value <0.001 <0.001 <0.001 <0.001

Planned RA was associated with a reduction in resources compared to Provisional RA in the ROTATE Multi-Center Registry

The primary endpoint of in-hospital MACE* tended to be better in the planned RA group compared to the provisional RA group (unadjusted OR: 0.76; 95% CI: 0.44-1.31, *P*=0.32, and adjusted OR: 0.59, 95% CI: 0.33-1.05, *P*=0.07). *MACE defined as the composite endpoint of all-cause death, follow-up myocardial infarction, and target lesion revascularization; Kawamoto, H et. al. *Catheter Cardiovasc Interv* 2016;88(6):881-889.

Cardiovascular Outcomes Following Rotational Atherectomy
A UK Multicenter Experience

All patients who underwent Rotational Atherectomy and PCI at 3 UK institutions between March 2005 and January 2013 (518 Patients)

Patient/Lesion Characteristics	N=518
Male	68.3%
Diabetes Mellitus	28.7%
ACS	34.6%
Mean SYNTAX Score	19.5±11.6
Received stents	97.3%
Received at least 1 DES	75.9%

Clinical Outcomes	N=518
MACE*	17.8%
Cardiac Death	7.1%
Myocardial Infarction	11.7%
TVR	7.5%
All-Cause Death	13.7%
Definite ST	1.4%

RA is safe and effective, with a high rate of procedural success and low incidence of MACE in three large UK centers

*MACE defined as cardiac death, myocardial infarction, and target vessel revascularization; Eftychiou, C et. al. *Catheter Cardiovasc Interv* 2016;88(4):546-553.

Multi-center PCI Registry of Patients Undergoing Rotational Atherectomy

Evaluating the outcomes of patients undergoing rotational atherectomy (RA) and PCI in a multicenter PCI registry

Patients undergoing PCI at 9 Australian hospitals from June 2004 to June 2012

Patients undergoing RA (n=167)

Clinical follow-up at 1-year: 100%

Patients undergoing PCI not utilizing RA (n=16,412)

Clinical follow-up at 1-year: 94%

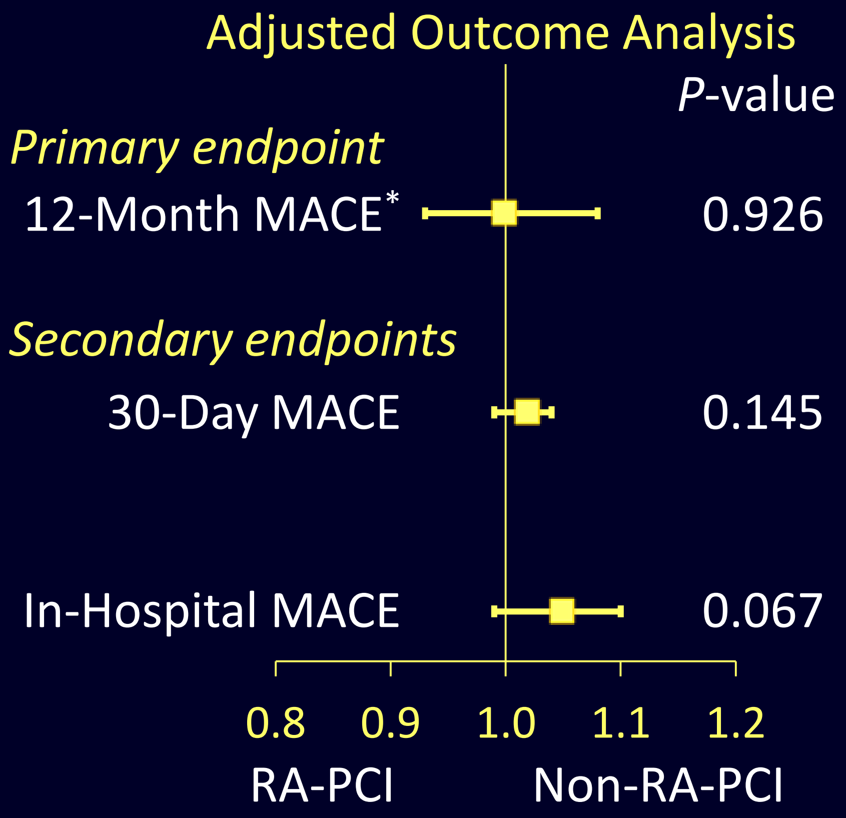
Primary Endpoint: 1-year MACE*

Secondary Endpoints: 30-day and in-hospital MACE*

*MACE defined as death, myocardial infarction, and target vessel revascularization; Couper, LT et. al. *Catheter Cardiovasc Interv* 2015;86(4):626-31.

Multi-center PCI Registry of Patients Undergoing Rotational Atherectomy

Baseline Characteristics	**RA-PCI (n=167)**	**Non-RA PCI (n=16,412)**	***P*-value**
Age (years)	71±10	64±12	<0.001
Diabetes Mellitus	37.7%	23.8%	<0.001
Hypertension	83.2%	65.7%	<0.001
Dyslipidaemia	85.6%	70.8%	<0.001



RA-PCI is *as safe and effective* as non-RA PCI despite the high-risk characteristics of the RA cohort

*MACE defined as death, myocardial infarction, and target vessel revascularization; Couper, LT et. al. *Catheter Cardiovasc Interv* 2015;86(4):626-31.

Rotational Atherectomy vs Orbital Atherectomy in Calcified Coronary Artery Disease (ROCC Study)

Identifying differences in safety and efficacy of rotational atherectomy (RA) and orbital atherectomy (OA) in treatment of calcified coronary lesions

Patients at a single center who had attempted treatment with RA or OA between June 2010 and July 2015

Patients undergoing OA (n=127 lesions)

Patients undergoing RA (n=147 lesions)

Primary Endpoint: Procedural Success*

*Successful atherectomy and stent deployment with <50% residual stenosis, TIMI 3 flow;
McGrew, A et. al. *J Am Coll Cardiol* 2016;68(18S):B93-B94.

Rotational Atherectomy vs Orbital Atherectomy in Calcified Coronary Artery Disease (ROCC Study)

Fig 1A *Lesion Characteristics*	*Orbital Atherectomy (N=127)* N (%)	*Rotational Atherectomy (N= 147)* N (%)	*p*
Lesion Class: A | B1 | B2 | C	1 (0.8) | 8 (6.3) | 43 (34.1) | 74 (58.7)	0 (0.0) | 7 (4.9) | 46 (31.9) | 91 (63.2)	0.631
Coronary Vessel: RCA | LM | LAD | LCX	41 (32.5) | 14 (11.1) | 49 (38.9) | 21 (16.7)	35 (24.6) | 13 (9.2) | 83 (58.5) | 10 (7.0)	0.016
Stenosis: 50-70% | 71-98% | ≥99%	10 (7.9) | 99 (78.6) | 17 (13.5)	0 (0.0) | 125 (86.8) | 19 (13.2)	0.003
Calcification Severity: Moderate | Severe	45 (36.0) | 80 (64.0)	31 (21.5) | 113 (78.5)	0.009
Calcification Length: ≥ 15 mm	74 (58.7)	102 (70.3)	0.046
Calcification of both walls	81 (64.3)	115 (79.3)	0.006
TIMI 3 Flow at Baseline	115 (92.0)	130 (90.3)	0.621
TIMI 3 Flow Post Atherectomy	109 (87.2)	126 (89.4)	0.583
TIMI 3 Flow Post Stent	115 (98.3)	132 (97.1)	0.521

Lesions in the RA arm were associated with:

- More stensoses>71%,
- More severe calcification,
- More lesions with calcific length ≥ 15mm, and
- More lesions with calcification of both walls

McGrew, A et. al. *J Am Coll Cardiol* 2016;68(18S):B93-B94.

Rotational Atherectomy vs Orbital Atherectomy in Calcified Coronary Artery Disease (ROCC Study)

Fig 1B ***Procedural Data, Procedural Complication, Clinical Complications & 6 Month outcome***	***Orbital Atherectomy (N=127)*** **N (%)**	***Rotational Atherectomy (N= 147)*** **N (%)**	***p***
Primary Endpoint: Procedural Success*	114 (92.7)	131 (91.6)	0.746
Successful passing of Atherectomy Device	125 (99.2)	139 (95.9)	0.083
Successful Stent Delivery	117 (92.9)	133 (91.7)	0.728
Guide Extender Required for Stent Delivery	32 (25.4)	5 (3.4)	< 0.001
Any Complications Post Atherectomy**	28 (22.4)	18 (12.8)	0.038
Any Complications Post Stent**	1 (0.9)	7 (5.1)	0.053
Any Clinical Complication***	23 (18.3)	19 (13.1)	0.159
Follow up Data available	106 (84.1)	118 (81.4)	0.551
Angina Free at Follow up	81 (76.4)	94 (79.7)	0.335
MACE (TLR/TVR/MI/Death)	25 (23.6)	24 (20.3)	0.335

* Procedural success: successful atherectomy passing & deployment of stent with less than 50% residual stenosis
** Any Complications include composite of: Reduced TIMI flow, Perforation, and Dissection [Post Atherectomy Dissection N (%) - OA: 21 (16.8) | RA: 13 (9.2)]
*** Clinical Complications of Asystole, Bradycardia, Cardiac Death, STEMI, TVR, TLR, or CVA/TIA

Despite the increased complexity in the RA arm, RA was associated with:

- Fewer guide extenders required for stent delivery
- Fewer complications post atherectomy
- Non-significant differences in procedural success
- Successful passing of an atherectomy device and stent delivery

McGrew, A et. al. *J Am Coll Cardiol* 2016;68(18S):B93-B94.

Rotational Atherectomy (RA) and DES Implantation

Single-center, retrospective analysis of patients treated with new-generation DES implantation following RA for de novo lesions January 2013-November 2015 in Japan

Baseline Clinical and Angiographic Characteristics	744 patients, 770 lesions
Hypertension	87.0%
Hyperlipidemia	75.3%
Diabetes mellitus	41.3%
Type C lesion	88.9%
Diffuse lesion	90.3%
True bifurcation	12.5%

Clinical Outcomes: 12 month rates for all-cause death, cardiac death, hospitalization due to heart failure, definite ST, TLR, TVF

ST=stent thrombosis, TLR=target lesion revascularization, defined as repeat intervention in the stent or within 5 mm proximal or distal to the stent; TVF=target vessel failure, defined as target vessel revascularization, recurrent MI, or cardiac death related to the target vessel; Hachinohe, et al. Catheter Cardiovasc Interv. 2017;1-9

Rotational Atherectomy (RA) and DES Implantation

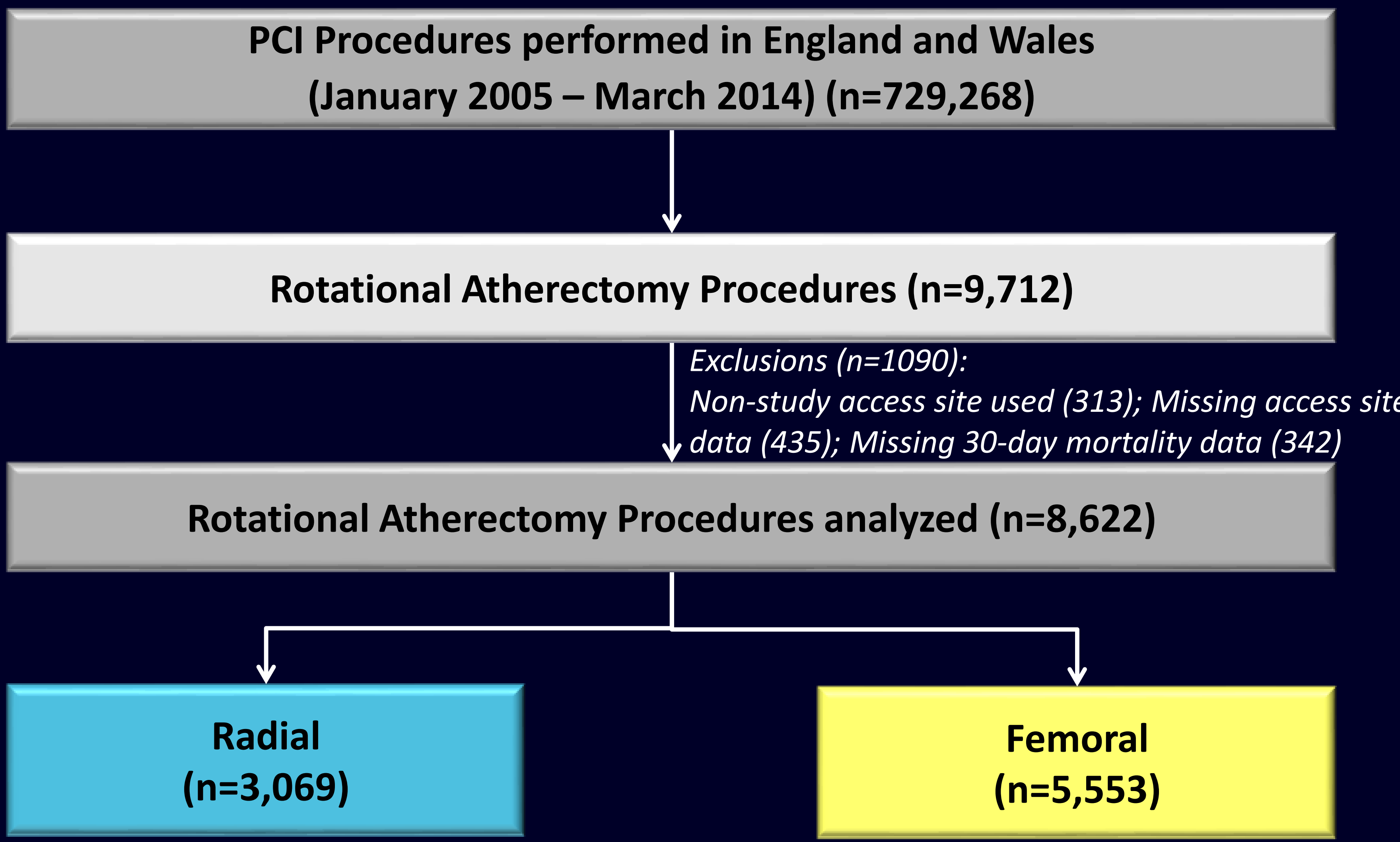
12-Month Clinical Outcomes	744 patients, 770 lesions
All-cause death	5.5%
Cardiac death	2.2%
Hospitalization due to heart failure	2.0%
Definite ST	0.1%
MI	0.1%
TLR	2.9%
TVF	6.6%

Debulking with RA followed by new-generation DES implantation is recommended for patients with an excessive amount of calcified and fibrotic plaque

ST=stent thrombosis, MI=myocardial infarction, TLR=target lesion revascularization, defined as repeat intervention in the stent or within 5 mm proximal or distal to the stent; TVF=target vessel failure, defined as target vessel revascularization, recurrent MI, or cardiac death related to the target vessel; Hachinohe, et al. Catheter Cardiovasc Interv. 2017;1-9

Rotational Atherectomy in Transradial Access Approach

Radial vs. Femoral Access for Rotational Atherectomy



Primary Outcome: 30-day mortality

Watt, et al. Radial vs. Femoral Access for Rotational Atherectomy. Circ Cardiovasc Interv. 2017;10:e005311

Radial vs. Femoral Access for Rotational Atherectomy

Outcome	**Radial (n=3069)**	**Femoral (n=5553)**	***P*-value**
30-day mortality	2.2%	2.3%	0.76
Procedural Success	95.2%	94.9%	0.56
In-hospital major bleeding	1.0%	1.8%	***0.004***
Major access site complication	0.04%	1.3%	***<0.001***
MACCE	3.2%	3.5%	0.37
NACE	3.7%	4.9%	*0.01*

Radial access was associated with equivalent 30-day mortality and procedural success, but reduced major bleeding and access site complications, compared with femoral access

MACCE was defined as a composite of 30-day mortality, in-hospital myocardial infarction, in-hospital target vessel recascularization, or in-hospital cerebrovascular event (stroke or transient ischemic attack); NACE was a composite of MACCE or in-hospital major bleeding; Watt, et al. Radial vs. Femoral Access for Rotational Atherectomy. Circ Cardiovasc Interv. 2017;10:e005311

Rotational Atherectomy Mechanics

The Battle Against Calcium

Calcium is prevalent in patients undergoing PCI

Calcium leads to worse clinical outcomes

Calcium can inhibit optimal stenting

Rota use is associated with *safe* and *effective* clinical outcomes

Rota changes lesion compliance to facilitate stent delivery

Lesion Preparation by Plaque Type

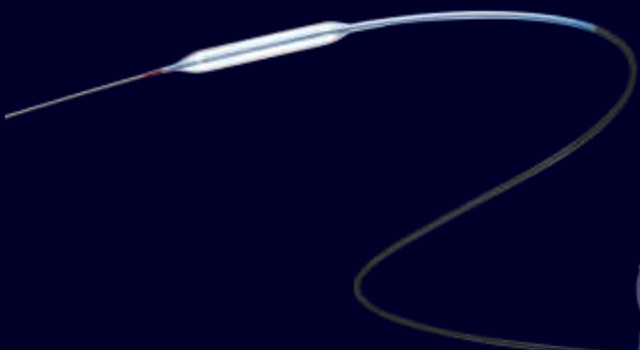
Soft/fatty | Fibrotic | Calcific

Optimize stent placement

Avoid Slippage

Avoid Plaque Shift

Change Lesion Compliance



POBA

WOLVERINE™ Cutting Balloon Device

Rotational Atherectomy

Why Modify Plaque?

- Access
  - Enable lesion access
  - Facilitate procedural success
- Modification
  - Change lesion compliance
  - Minimize vessel trauma
  - Create larger MLDs

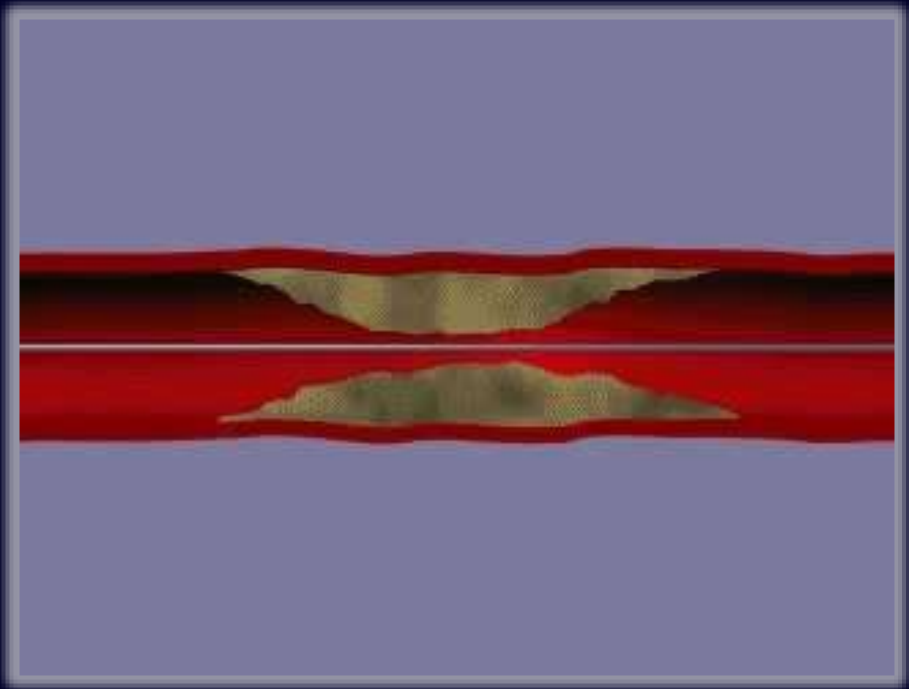
Optimal Technique

Technical Considerations

- Single burr with burr-to-artery ratio of 0.5 to 0.6
- Rotational speed of 140,000 to 150,000 rpm

Operator Technique

- Gradual burr advancement
- Short ablation runs of 15 – 20 sec
- Avoidance of decelerations > 5,000 rpm
- Final polishing run



Tomey, et al. Current Status of Rotational Atherectomy. 2014. JACC Cardiovasc Int. epub ahead of print.

Complication Management
Avoid with Good Technique

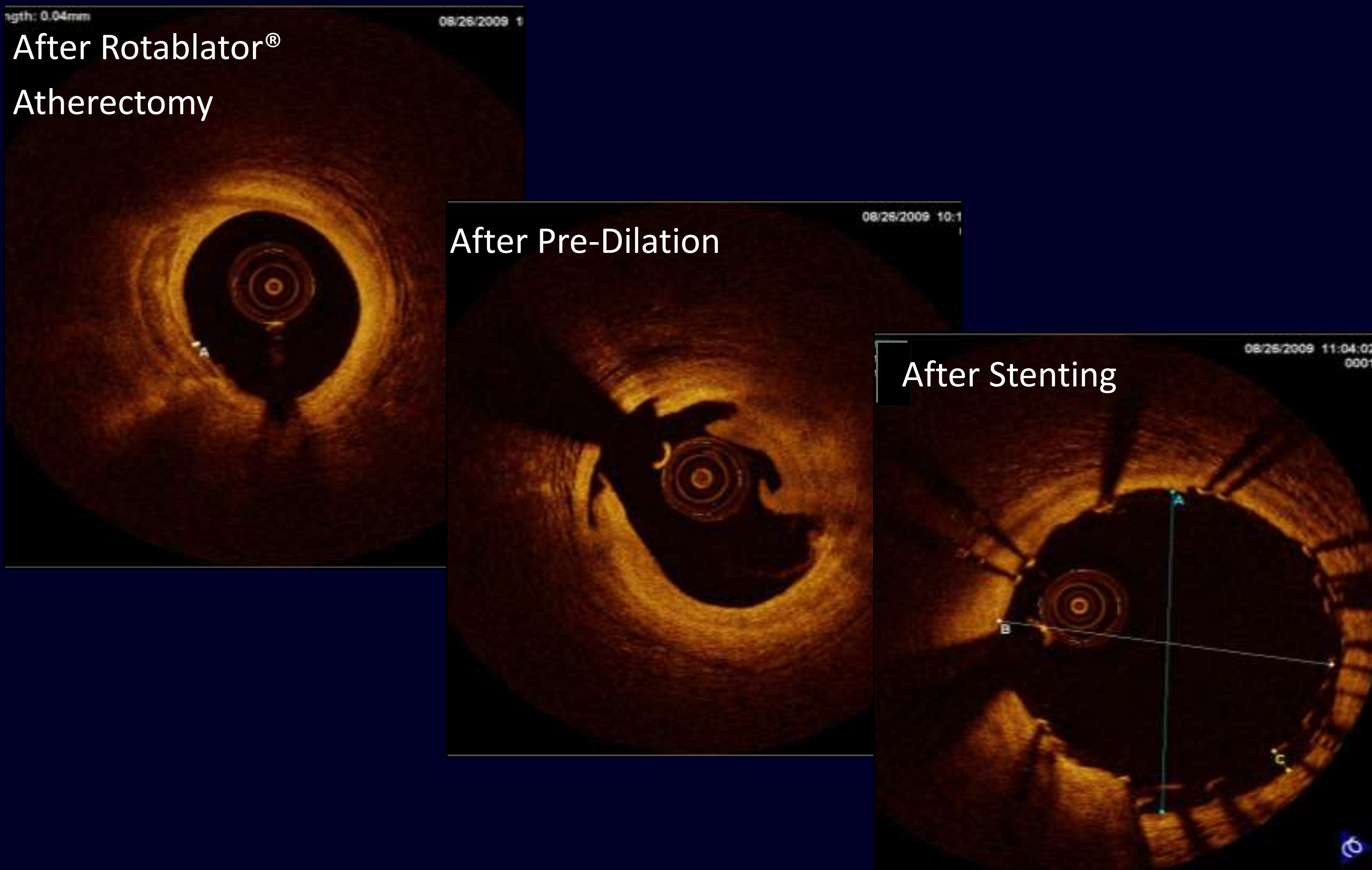
Table 3. Complication management – avoid with good technique.

	Technique to avoid	Strategy for resolution
Slow-flow	Small burrs and lower speeds Be patient between ablation runs	Optimise BP if low Use of intracoronary nitrates/verapamil/adenosine/nitroprusside all described Use of flush cocktail
Dissection	Careful case selection to avoid excessive tortuosity	Avoid further rotablation if dissection identified Dissection management as for any PCI
Burr entrapment	Rare complication usually avoided with careful case selection and good technique	Controlled push and pull of rotablation shaft Position 2nd wire to allow balloon placement Cautious deep intubation with mother-in-child catheter for more support Cardiothoracic surgical resolution occasionally required
Perforation	Commonly related to poor technique (oversizing of burr, too angulated, inappropriate speed)	Standard techniques to resolve any perforation including emergency pericardiocentesis and use of covered stents

Barbato, et al. "European expert consensus on rotational atherectomy." EuroIntervention 2015;11:30-36.

A Closer Look – RCA Example

Rotablator® Atherectomy System, POBA, and Stent



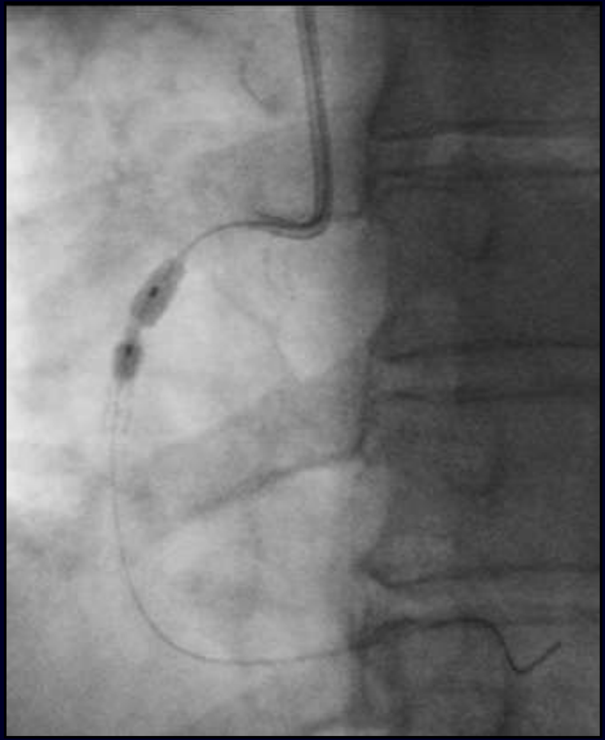
Images courtesy of Georg Gaul, MD, FESC, Vienna, Austria

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

Clinical Application

Case Example – "Rota Regret"

Single 2.75 mm stent placed

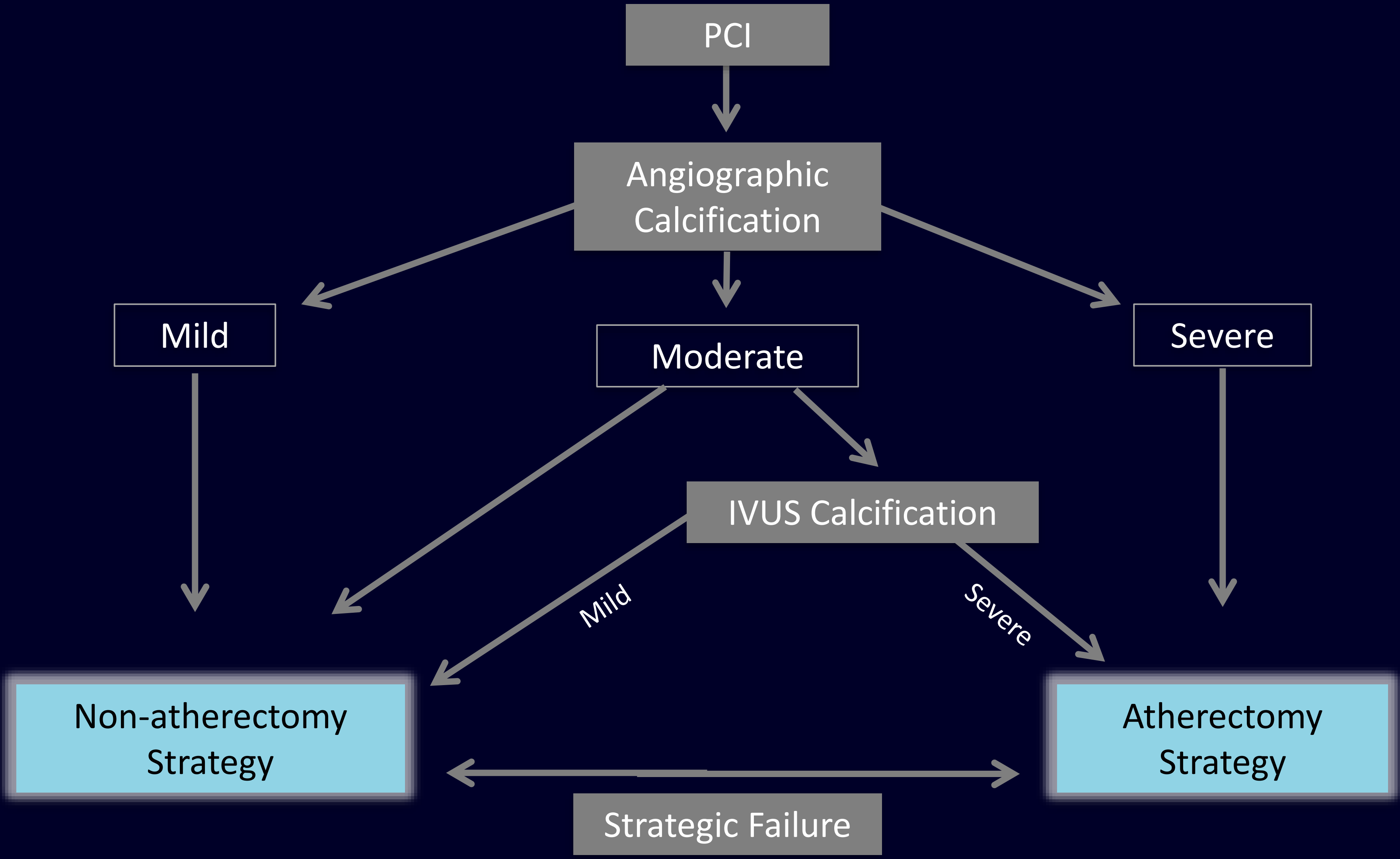


Post Dilatation:
- 3.5x9mm NC balloon x 30 sec @ 22 atm
- 4.0x9mm NC balloon x 30 sec @ 16 atm

Results sub-optimal

Results from case studies are not predictive of results in other cases. Results in other cases may vary.
Case images courtesy of Dr. Arthur Lee, Santa Clara Valley Medical Center, Kaiser Permanente, San Jose, CA

Strategy for Approaching Calcified Lesions



Adapted from Tomey, et. al. Current Status of Rotational Atherectomy. J Am Coll Cardiol Intv. Online ahead of print.

CLINICAL RESEARCH
CORONARY INTERVENTIONS

EuroIntervention 2015;11:30-36

European expert consensus on rotational atherectomy

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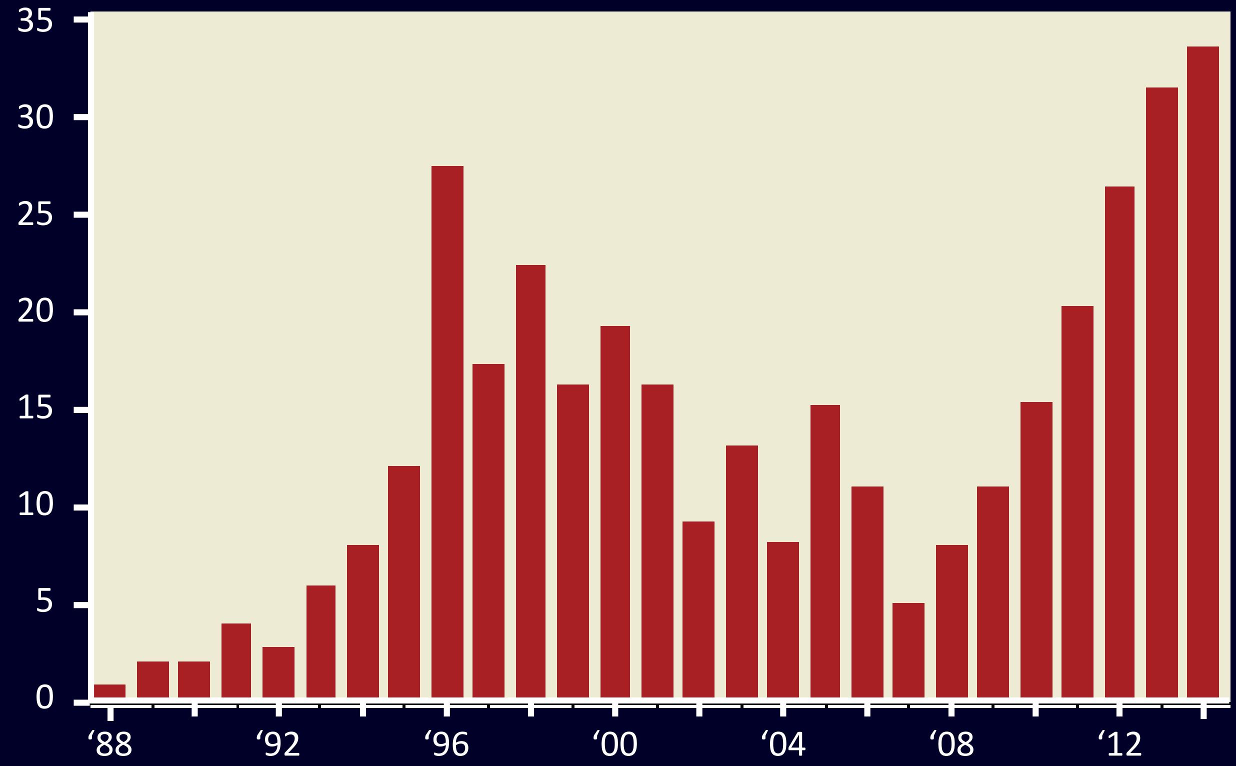
Arterial access	Transfemoral or transradial arterial access
Guiding catheter recommendations	6Fr
Guidewire	Regular PCI guidewire
Burr size	Burr-to-artery ratio of 0.6
Burr motion	Pecking motion
Burr speed	Between 135,000 -180,000 rpm
Temporary Pacing wire	Seldom use temporary pacing: mechanical maneuvers and/or pharmacologic measures
Imaging	Intracoronary imaging techniques may be useful
Flushing cocktail	Saline solution with equal proportions of verapamil, nitrates, and heparin

Barbato, et. al. EuroIntervention 2015;11:30-36.

Renewed Interest in Rotational Atherectomy



Number of publications over the years on coronary rotational atherectomy (source Pubmed).

Barbato, et al. “European expert consensus on rotational atherectomy.” EuroIntervention 2015;11:30-36.

What is Rotablator

The Battle Against Calcium

Calcium is prevalent in patients undergoing PCI

Calcium leads to worse clinical outcomes

Calcium can inhibit optimal stenting

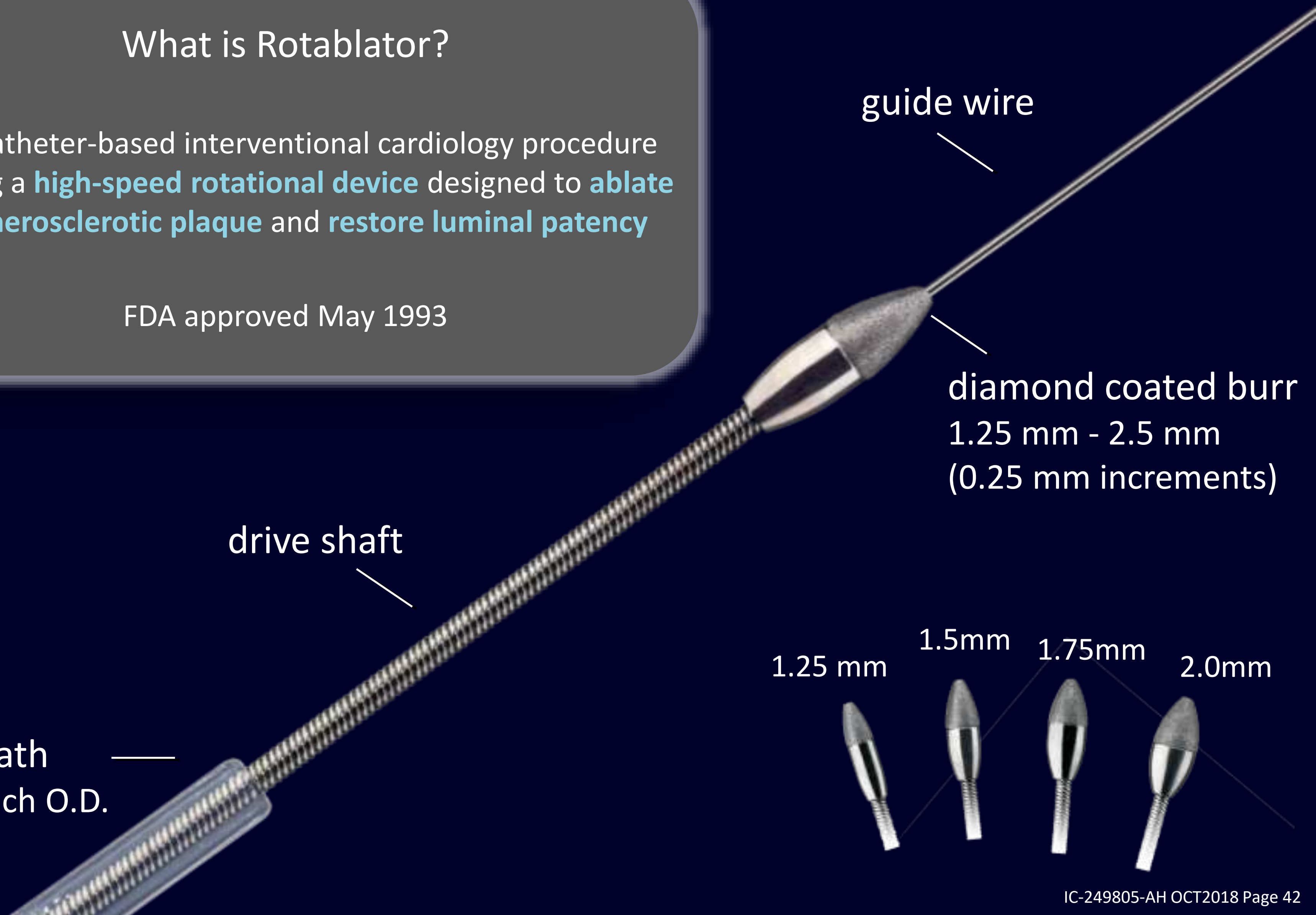
Rota use is associated with *safe* and *effective* clinical outcomes

Rotablator® Rotational Atherectomy System

What is Rotablator?

A catheter-based interventional cardiology procedure using a **high-speed rotational device** designed to **ablate atherosclerotic plaque** and **restore luminal patency**

FDA approved May 1993



The Battle Against Calcium

Calcium is prevalent in patients undergoing PCI

Calcium leads to worse clinical outcomes

Calcium can inhibit optimal stenting

Rota use is associated with *safe* and *effective* clinical outcomes

The next generation of Rota is **ROTA**PRO

ROTAPRO™

Evolution of Rotational Atherectomy System

ADVANCING CARDIOLOGY TOGETHER

1998

Rotablator™

- 1st gen Product

1999

ROTA Link Plus™

- 2nd gen Product
- New Advancer

2019

ROTAPRO™

- Foot-pedal –less Console
- Enhance Ease of use

ROTAPRO™

Key Fetures & Valus Propositon

A proven Efficacy/Safety

Operated by air
Same drive shaft/ burr

Enhance Ease of Use

Foot pedal-less design
Compatible Cather & console
Easy-read display/set up

ROTAPRO™ Rotational Atherectomy System

Gold standard Rotablator therapy on an enhanced easy-to-use platform

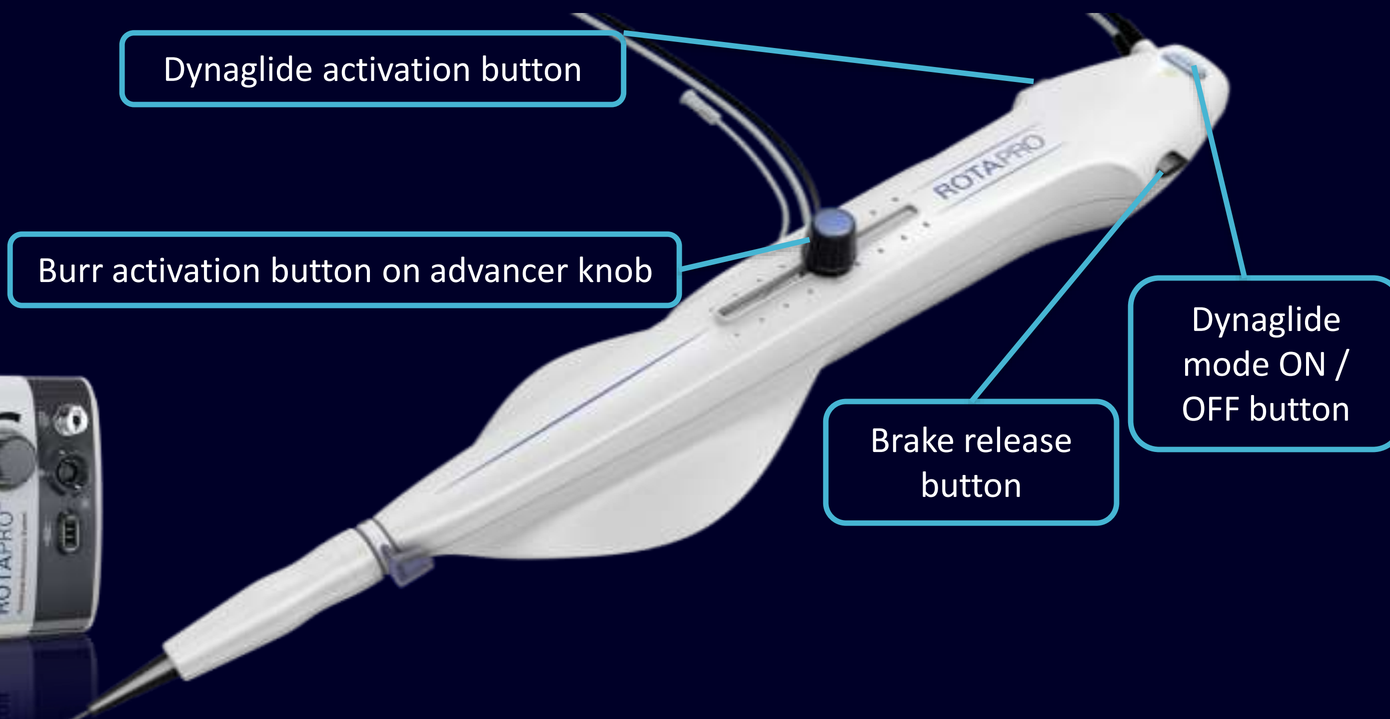
- **Advancer with on/off and Dynaglide controls**
- **Small console with intuitive LCD display**
- **5K and 10K rpm deceleration indicator**

*The next generation Rotablator devices are under development not available for sale

ROTAPRO™ Rotational Atherectomy System

Design Goals:

- Easier to learn & use (no foot pedal)
- Easier to set up (consolidated cables)
- Allows single operator use



Conclusions: Rotablator®

Complexity

- PCI patients are becoming increasingly complex with more calcification

Success

- Calcified lesions have lower procedural success and higher complication rates

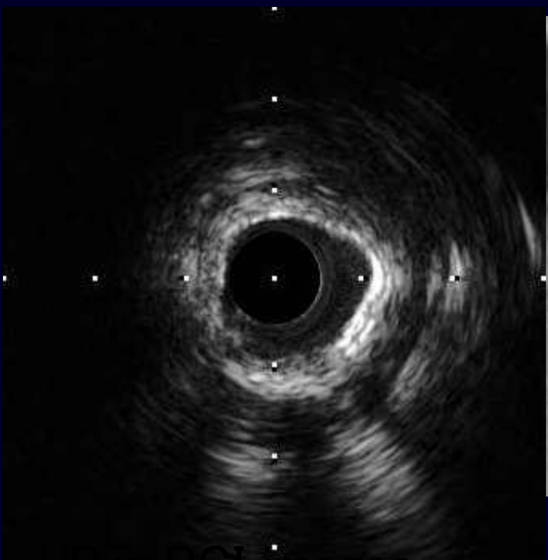
Rotablator

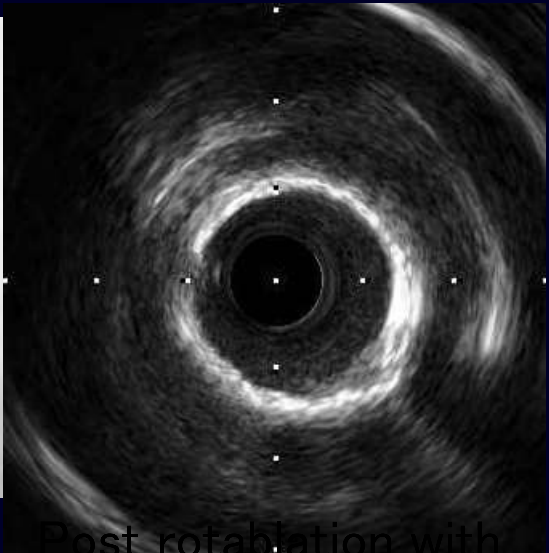
- Rotablator can facilitate procedural success, enabling the treatment of otherwise uncrossable or undilatable lesions

Wire bias effects can make more aggressive atherectomy

Rotational atherectomy effects are evaluated by imaging modalities like as OFDI or IVUS. Those images also show predictive wire bias effects.

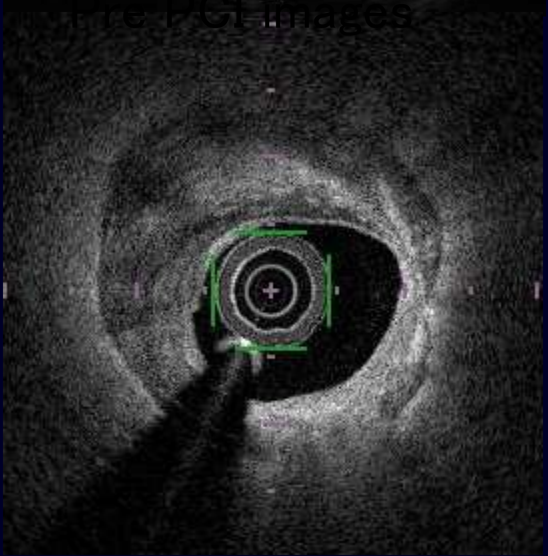
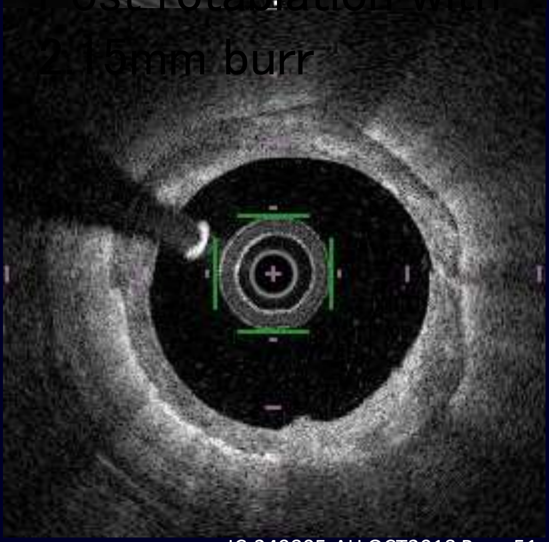
Which is useful modality to estimate calcified plaque, IVUS or OFDI?





Pre PCI images

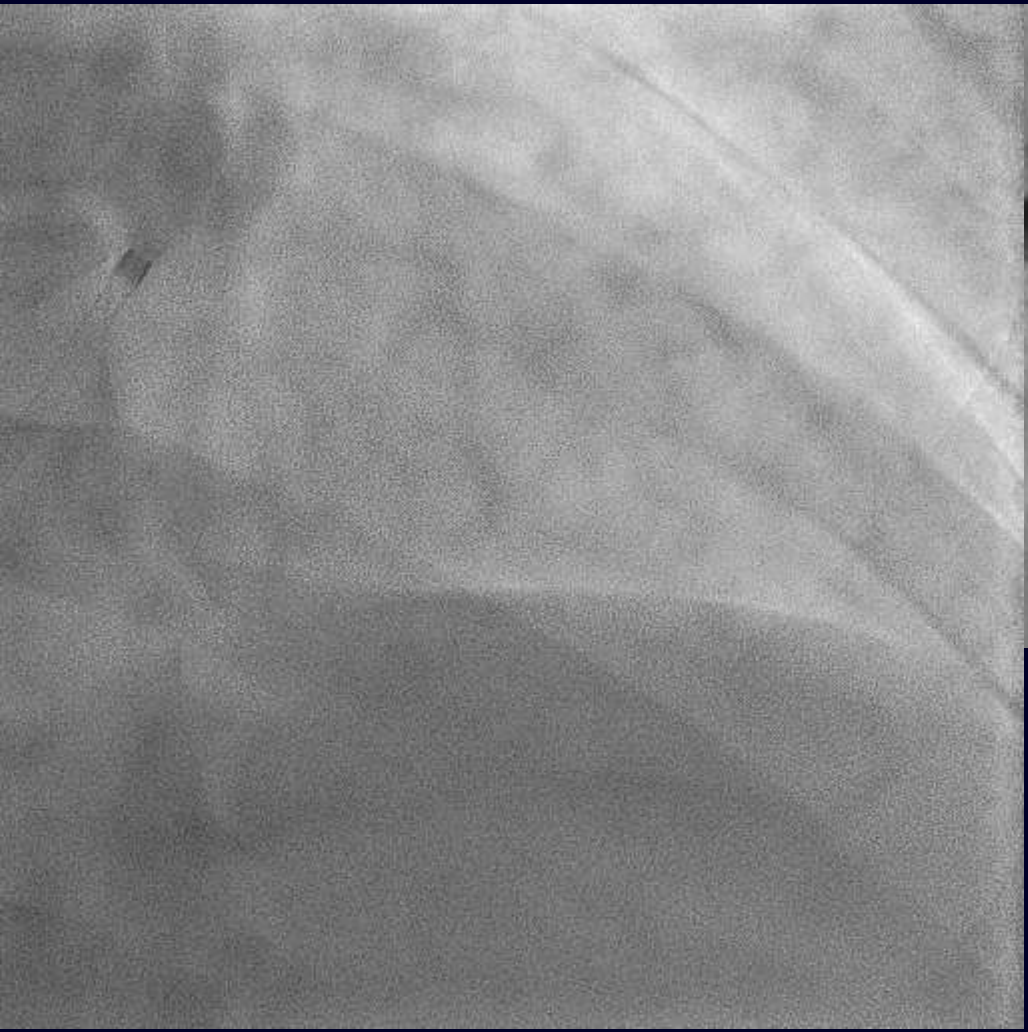
Post rotablation with 2.15mm burr

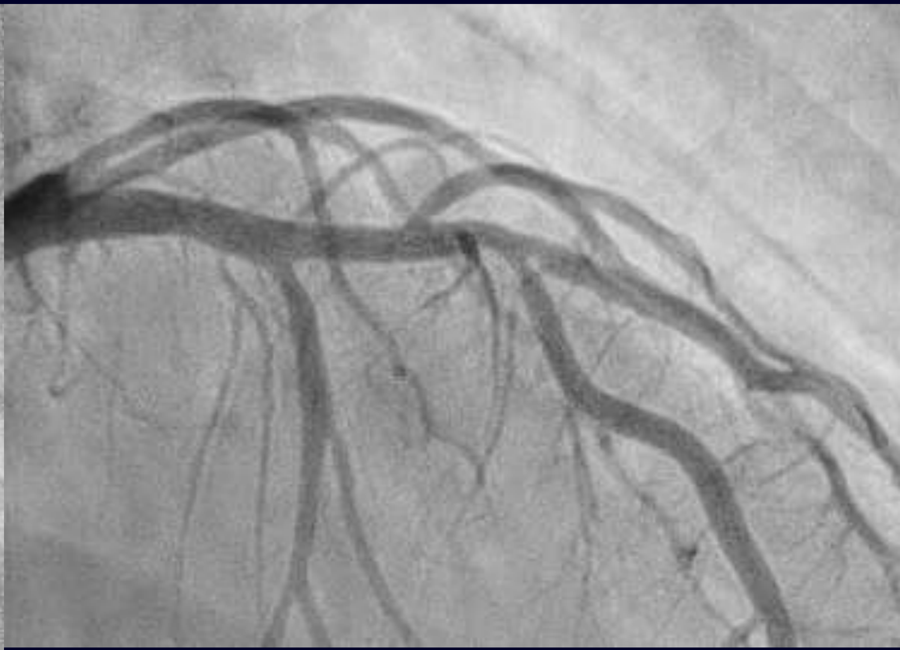



OFDI shows more clearly calcified plaque than IVUS.

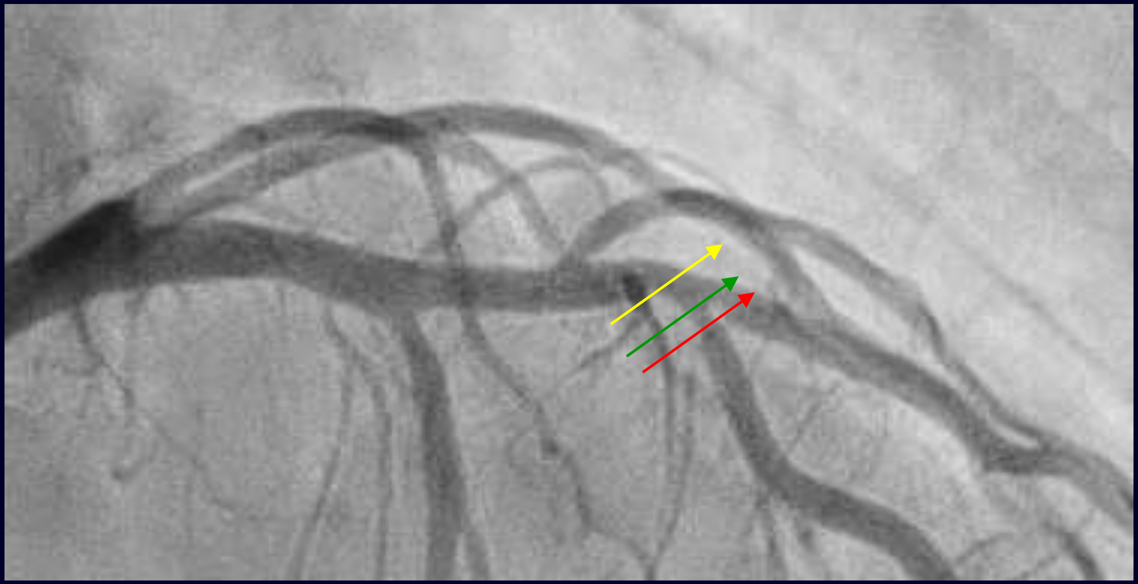
Case1
OFDI guided rotablation

Target lesion: LADmid

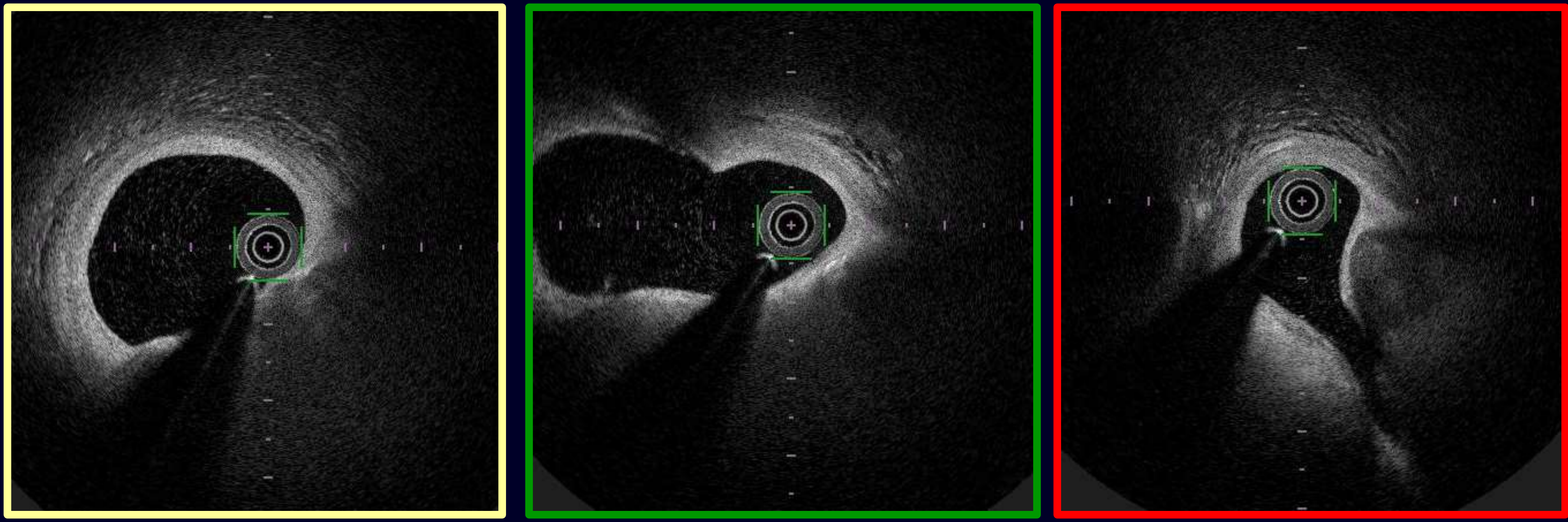


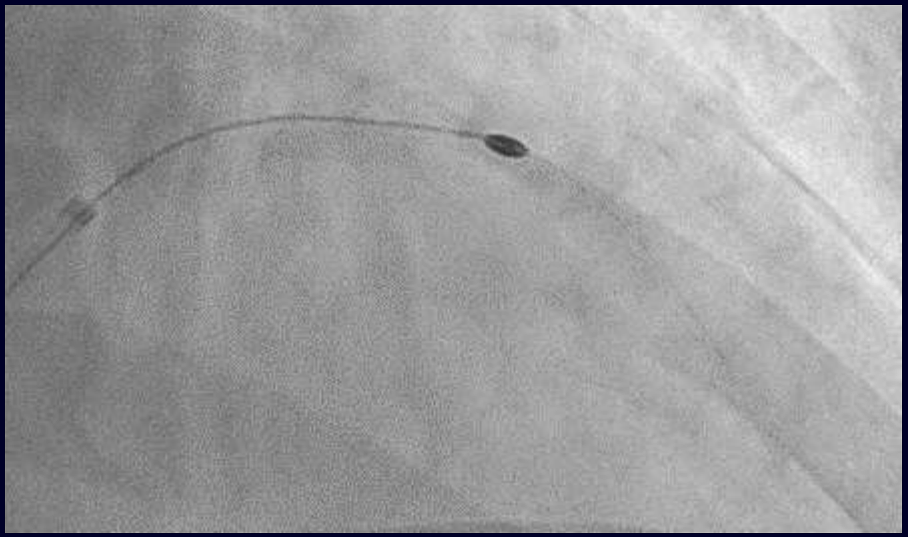


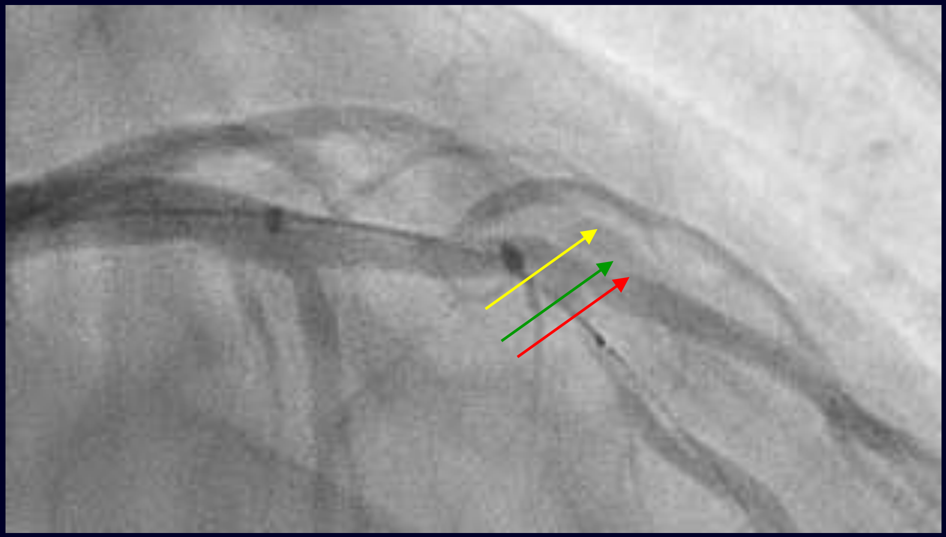
8Fr SPB3.5
Rota support



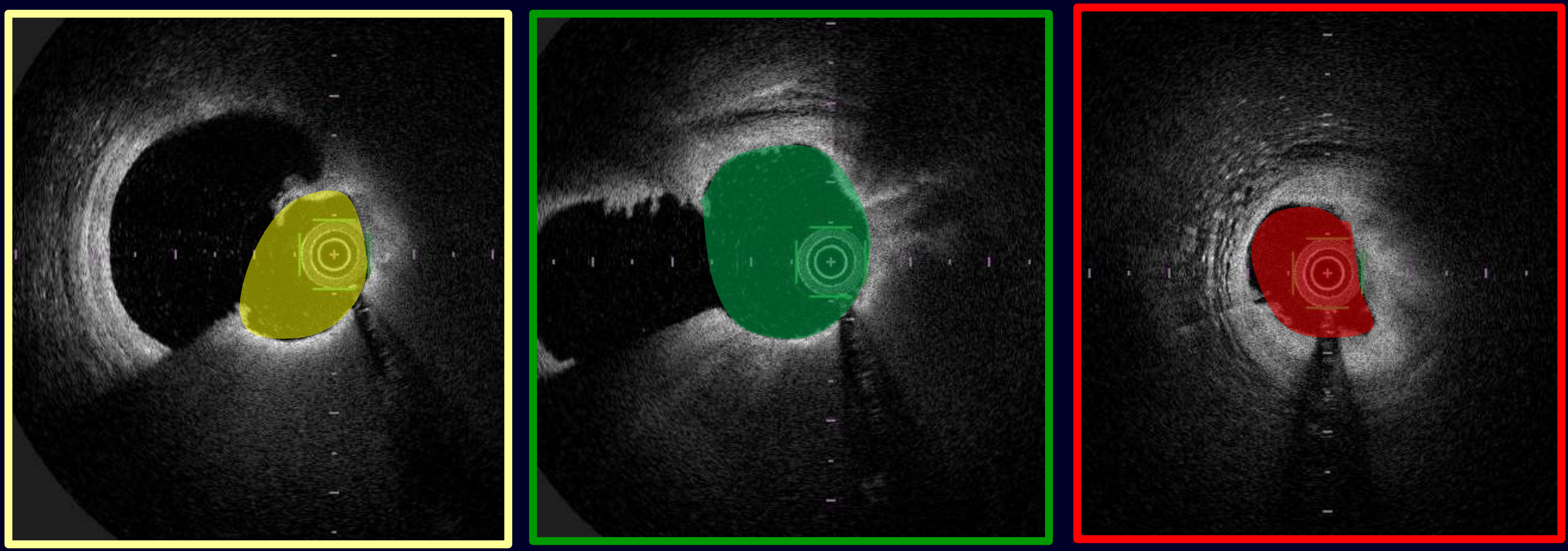
pre

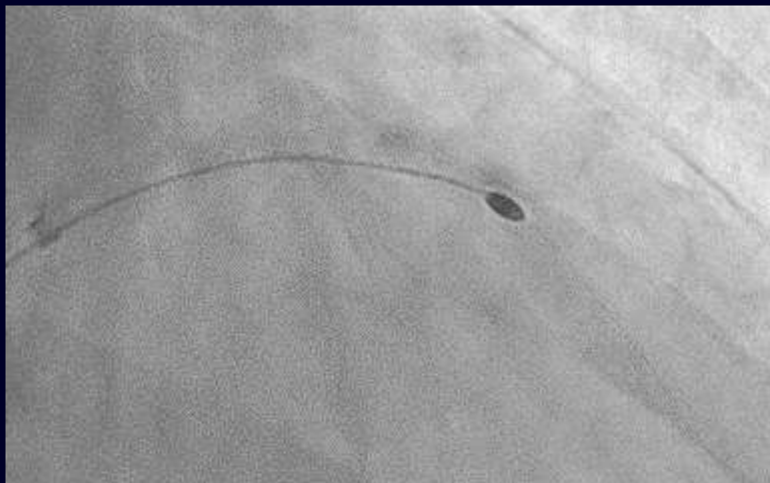




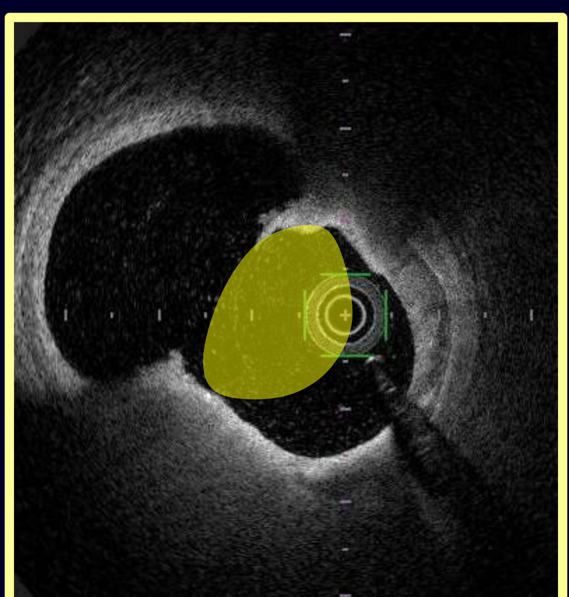


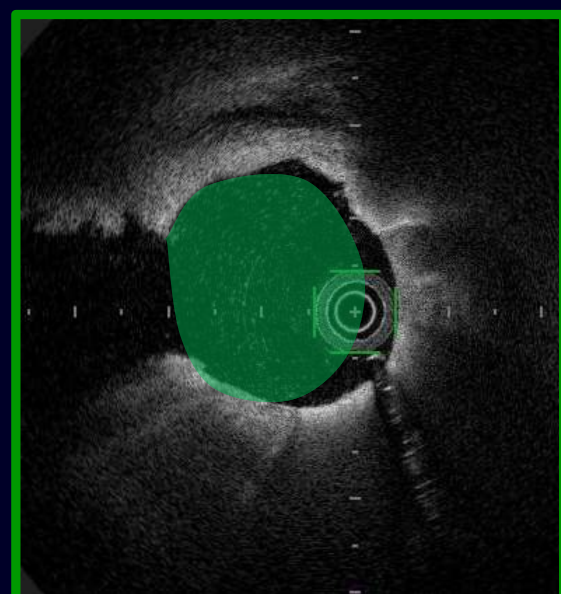
2.15mm 160000 64sec 5 times ablations performed.





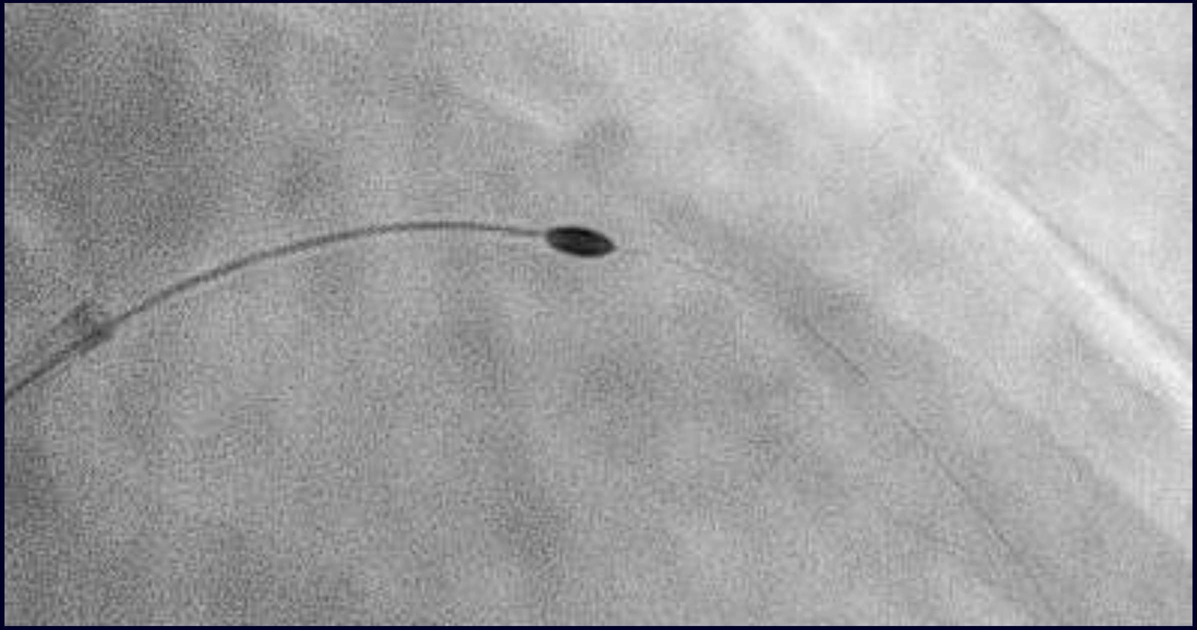
2.15mm 160000 71sec 5 times ablations were added.



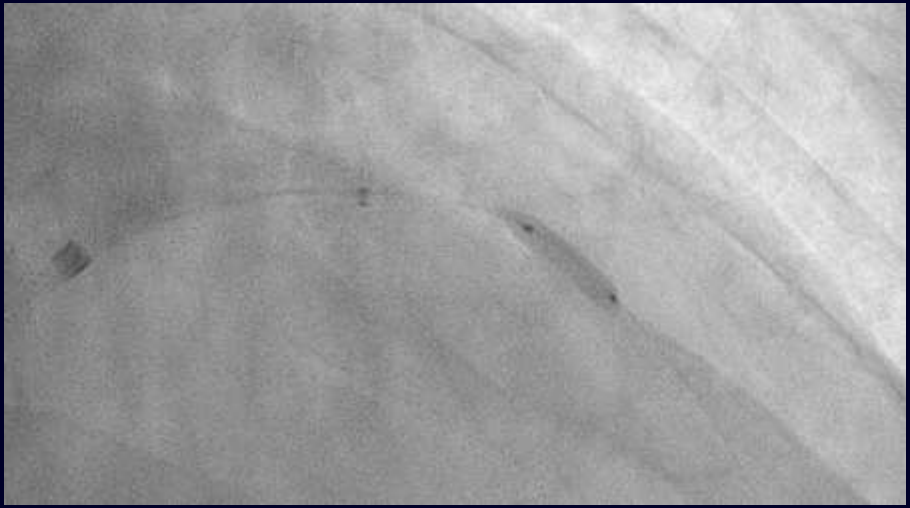


Calcification pre rotablation

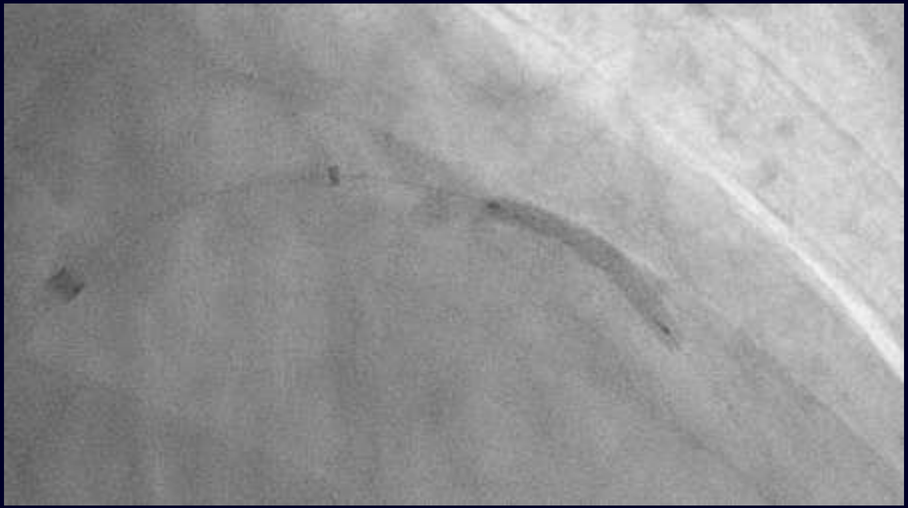
During rotablation, calcified shadow becomes thinner.



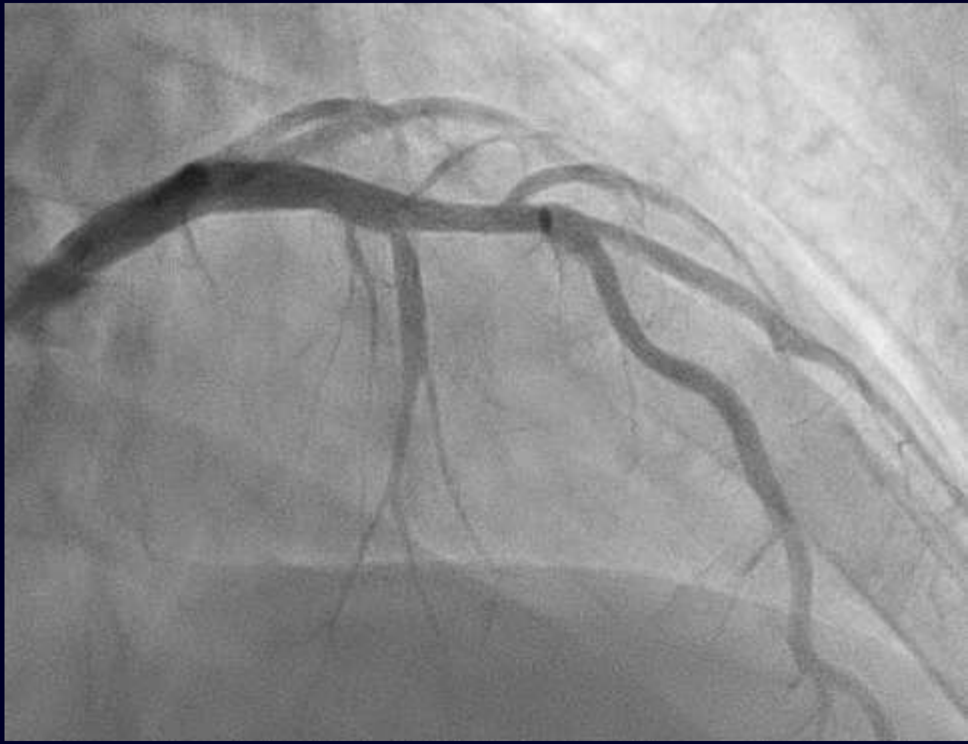
Cutting balloon 3.0*10mm
8atm

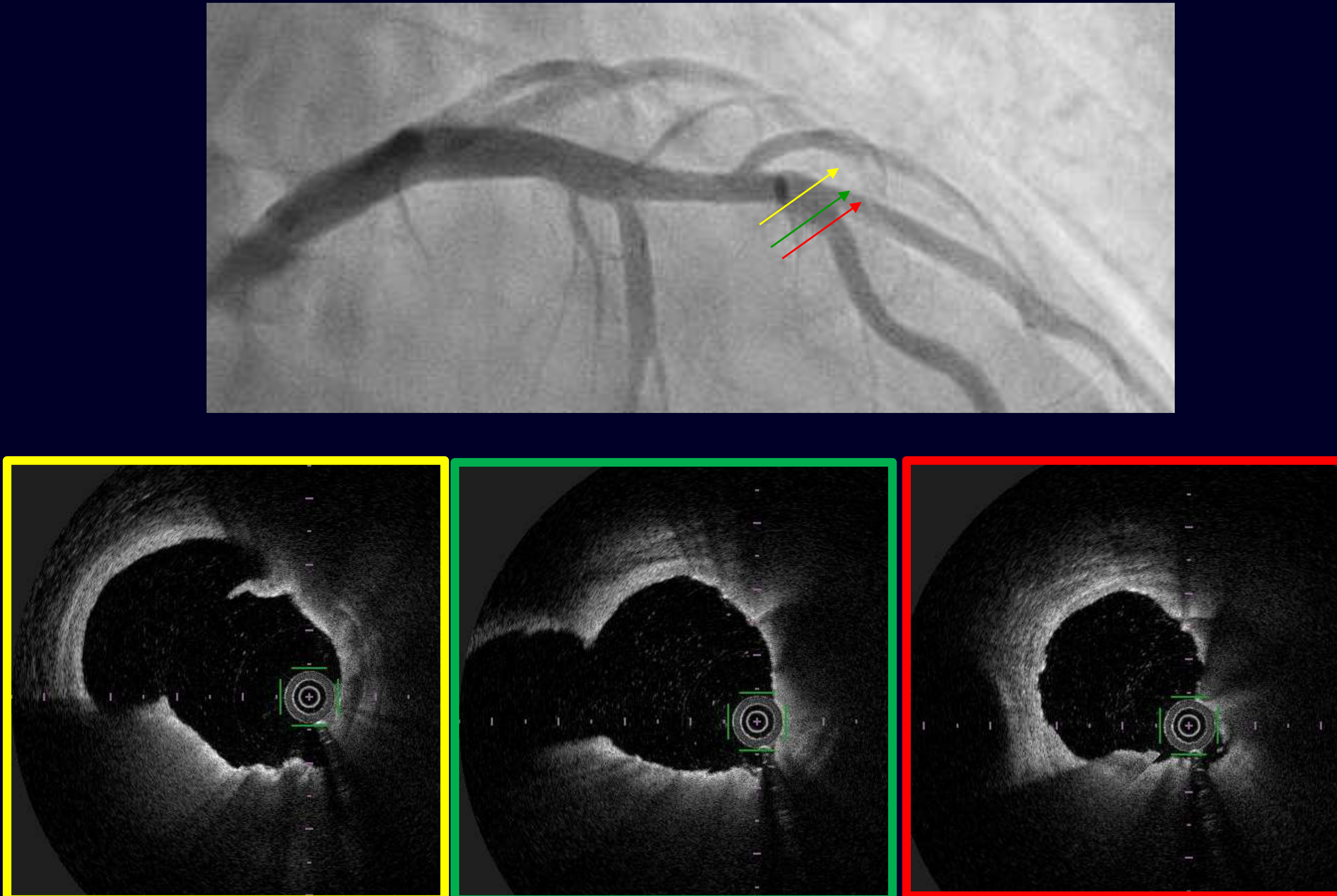


Drug-coated balloon 3.0*20mm
7atm



Final angiogram

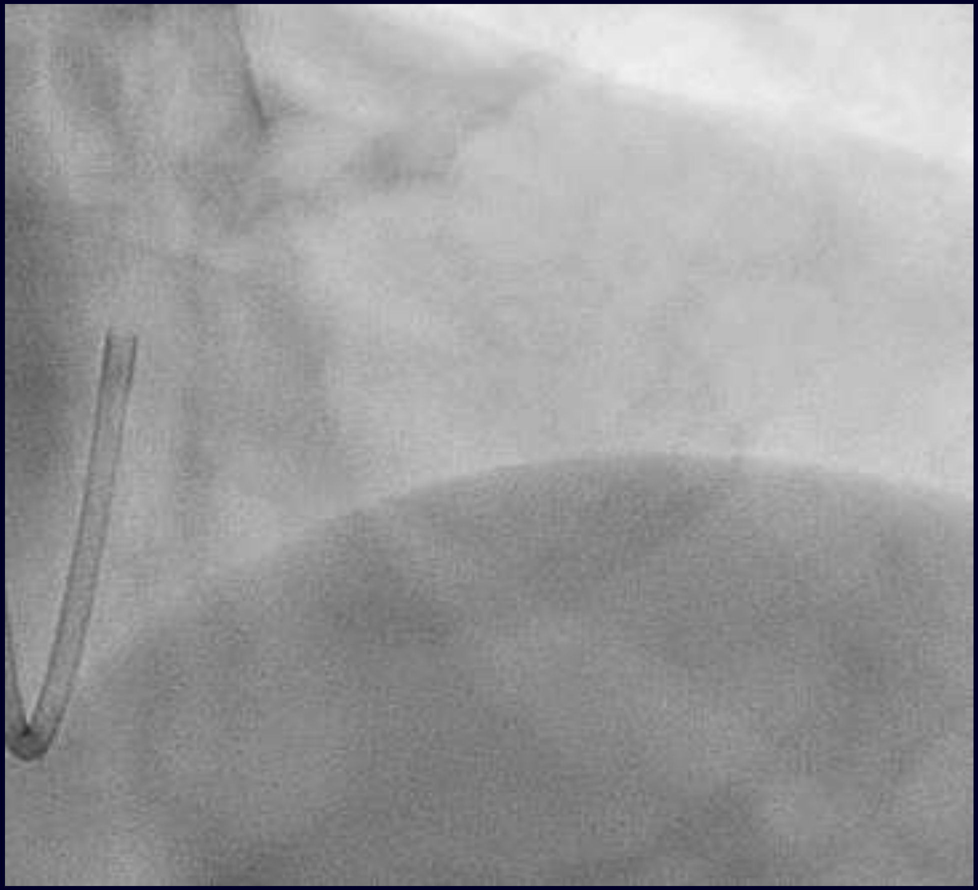




Final OFDI images

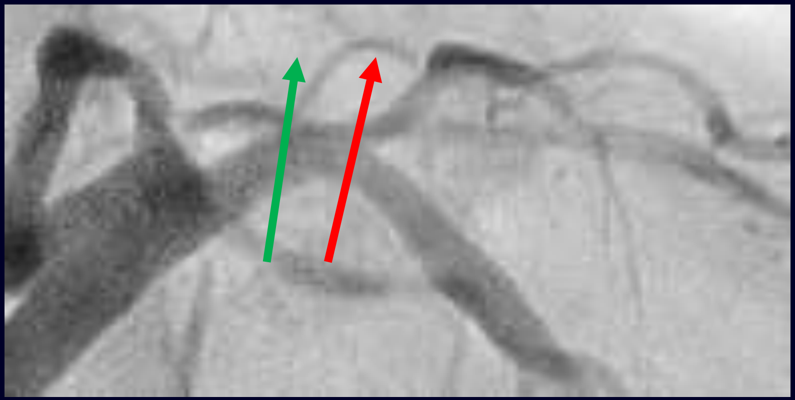
Case2
IVUS guided rotablation

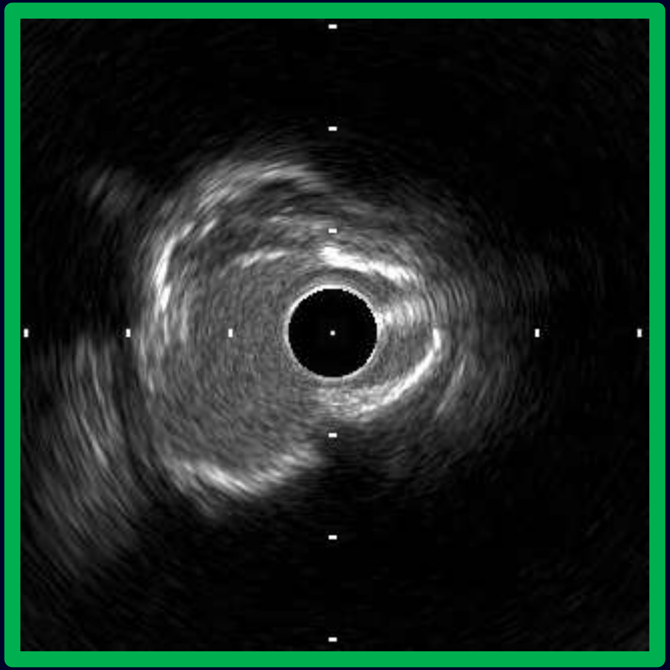
Target lesion: LADmid

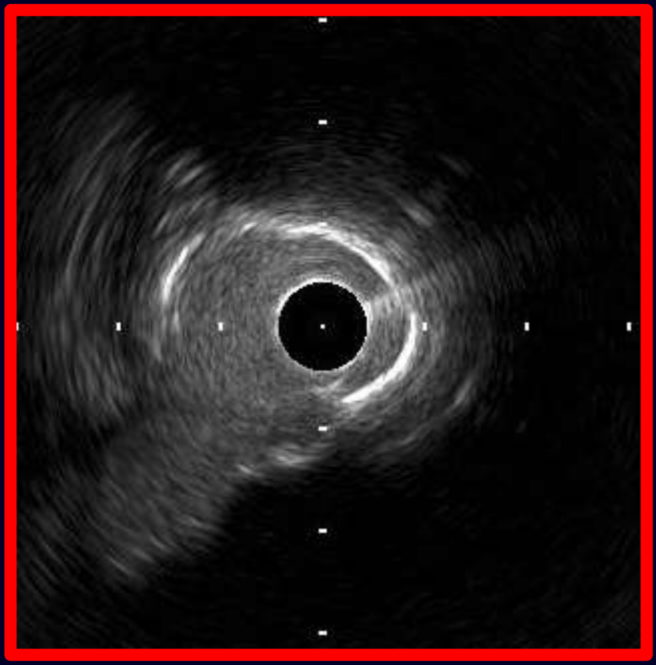


6Fr SPB3.0
Rota support

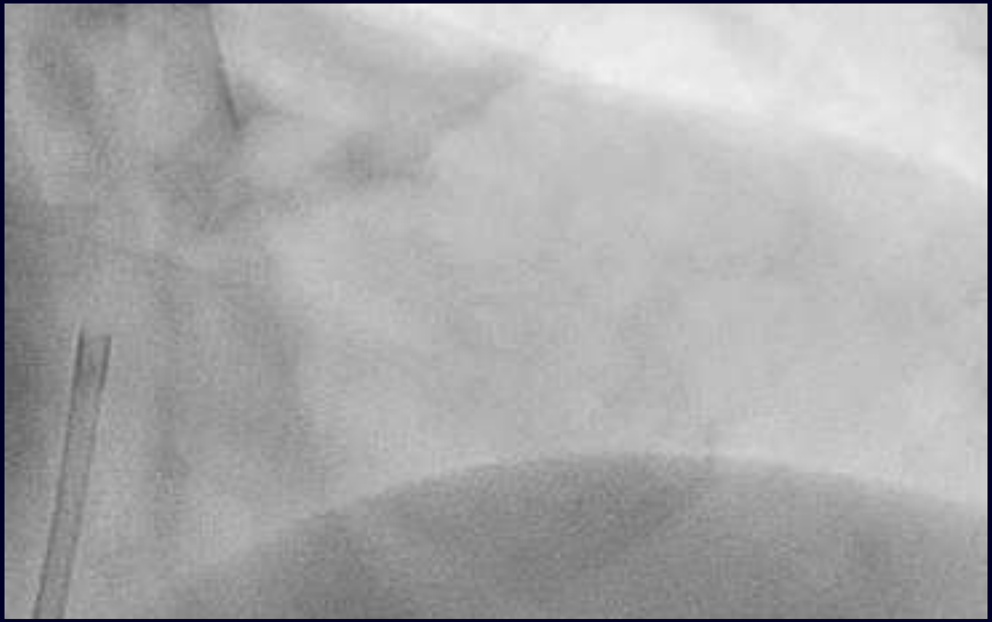
pre

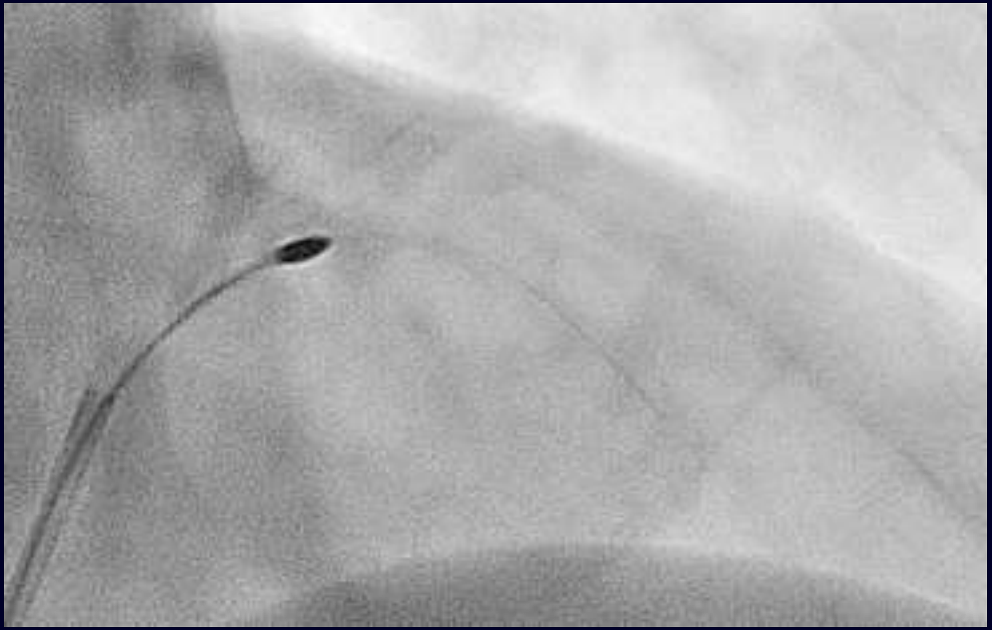




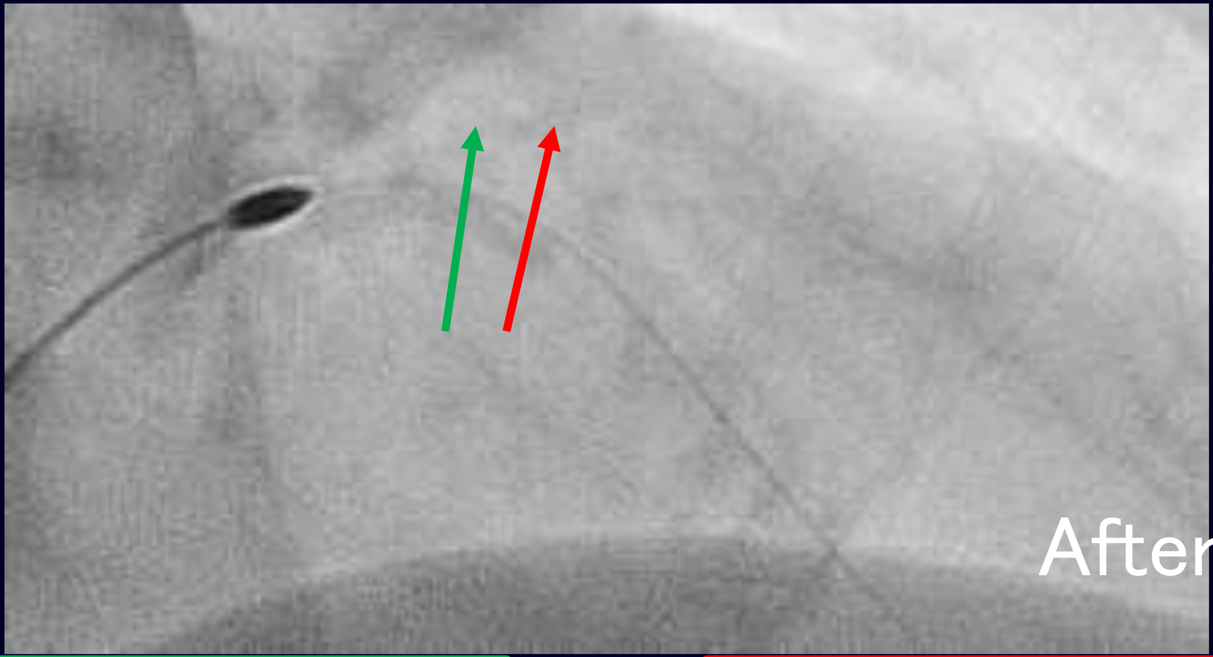


Calcification pre rotablation

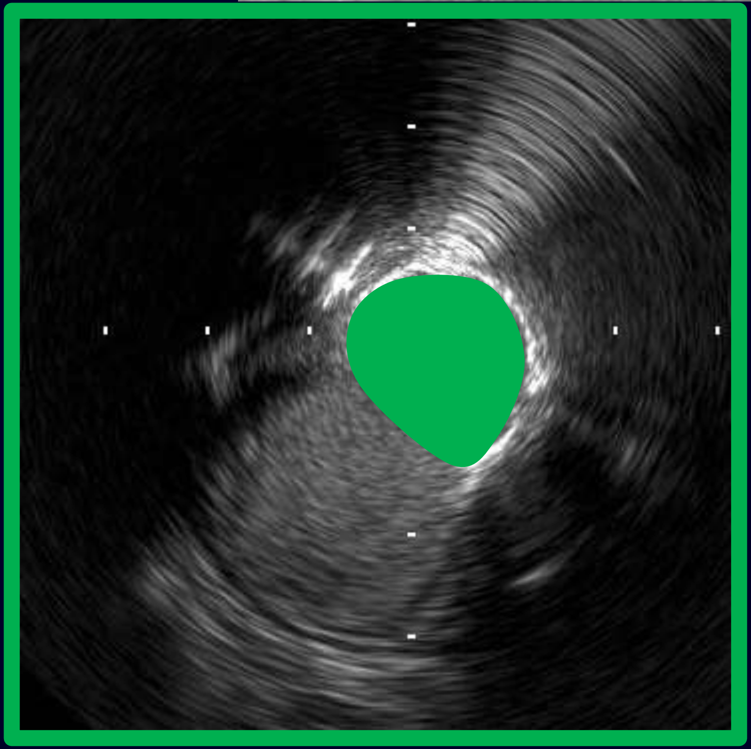


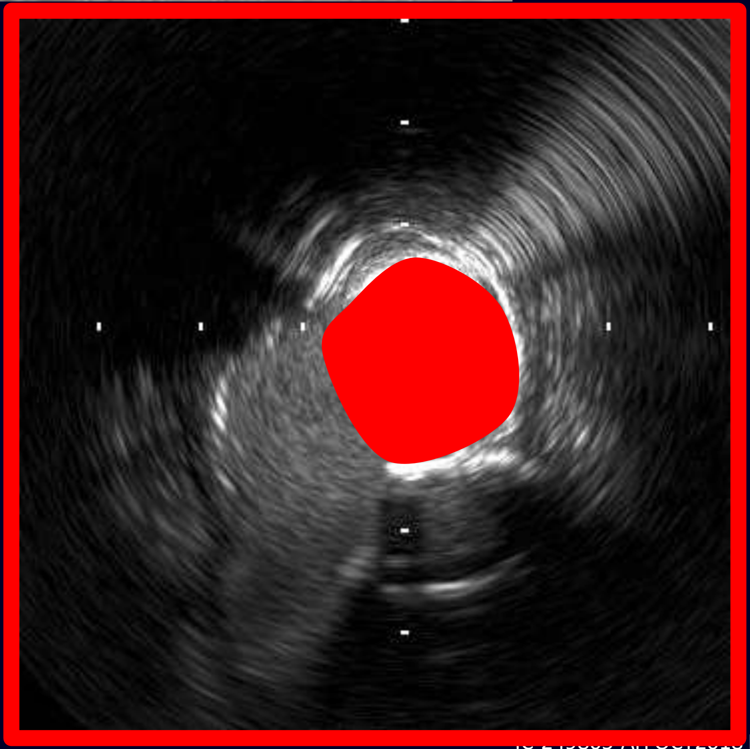


Rotablator 1.75mm
160000rpm 3runs

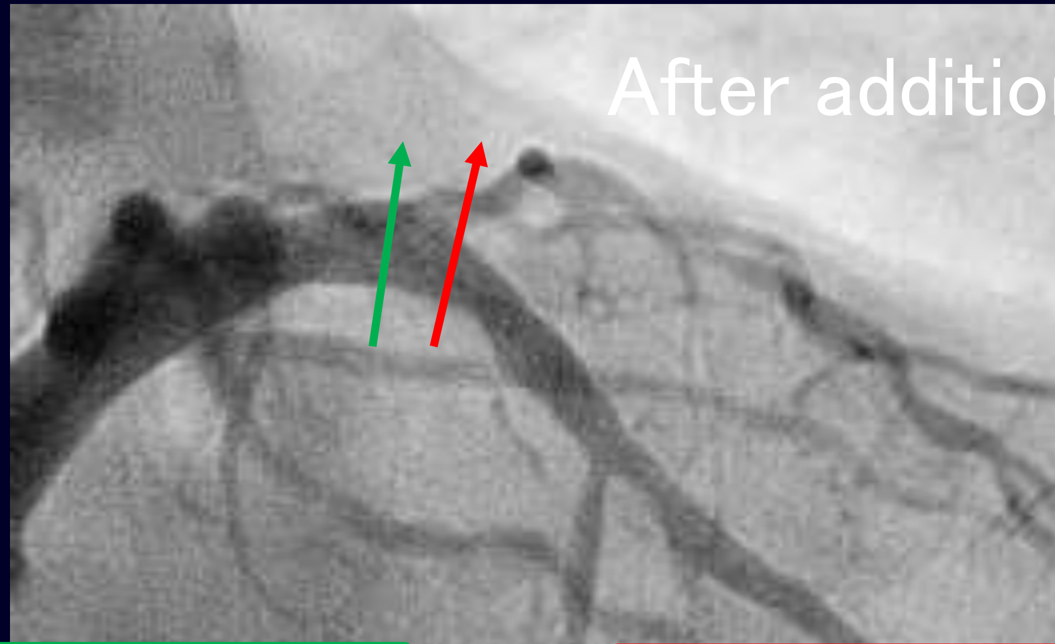


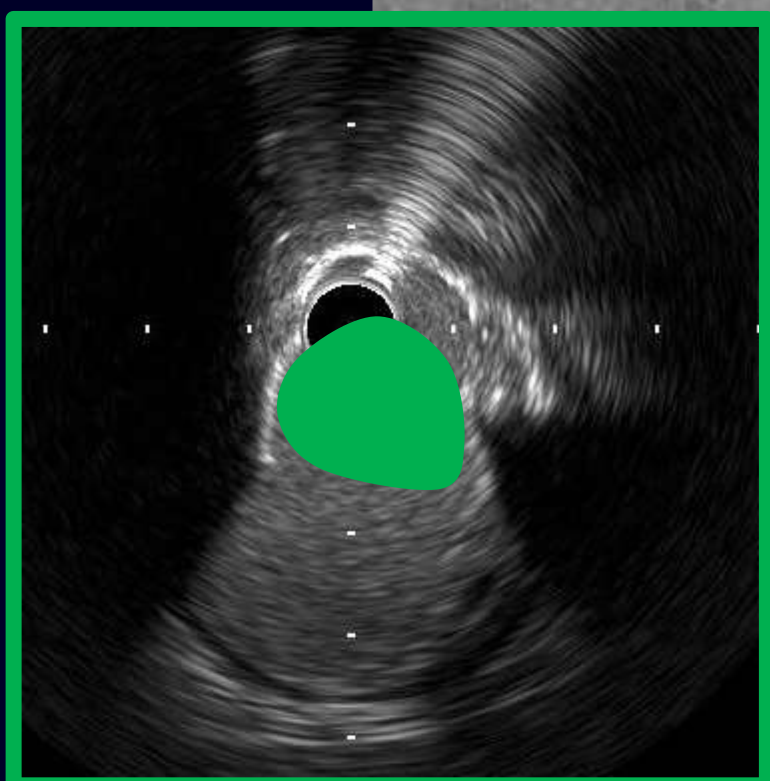
After 3 runs

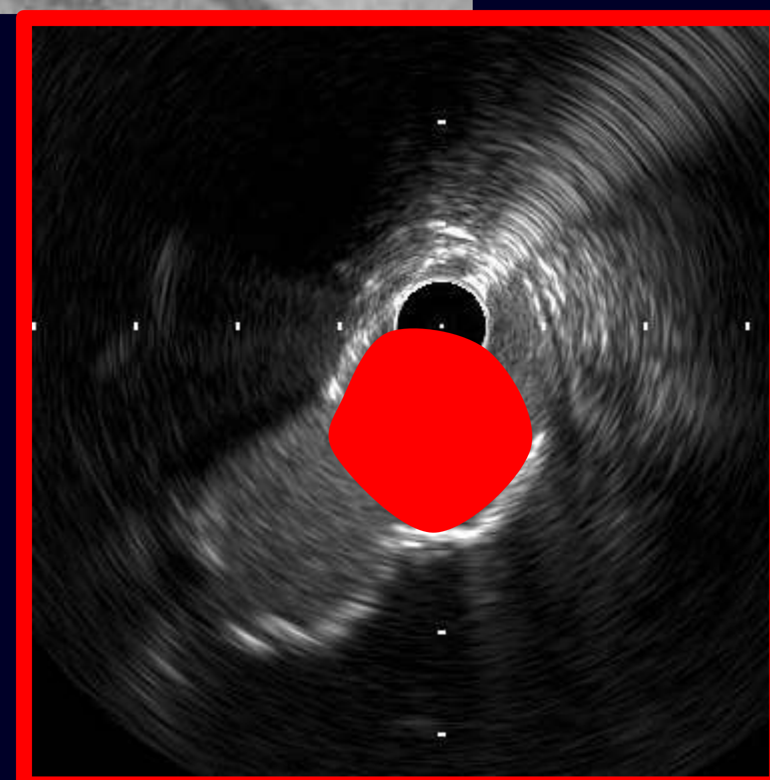


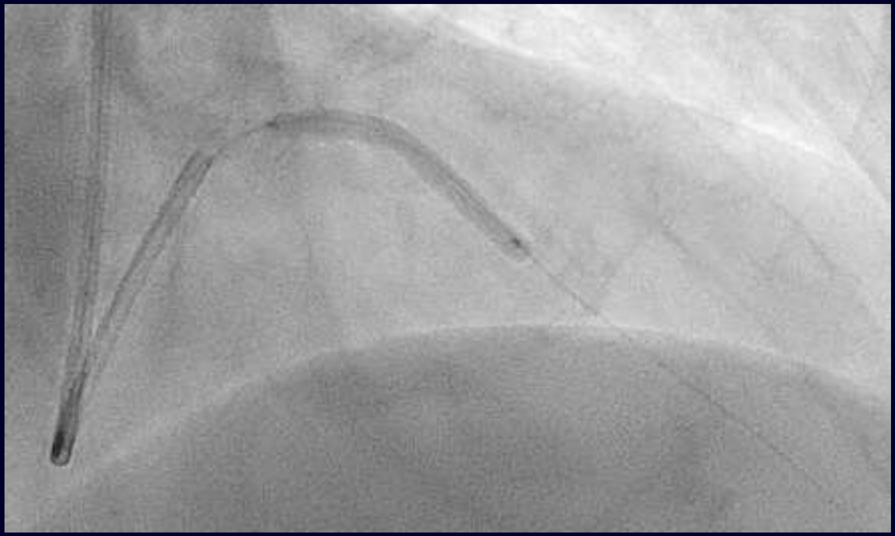


After additional 4 runs

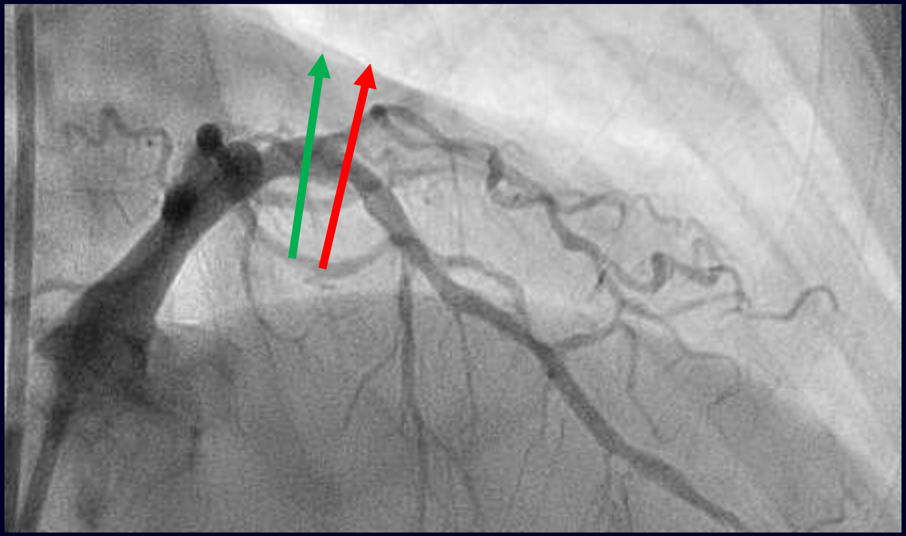




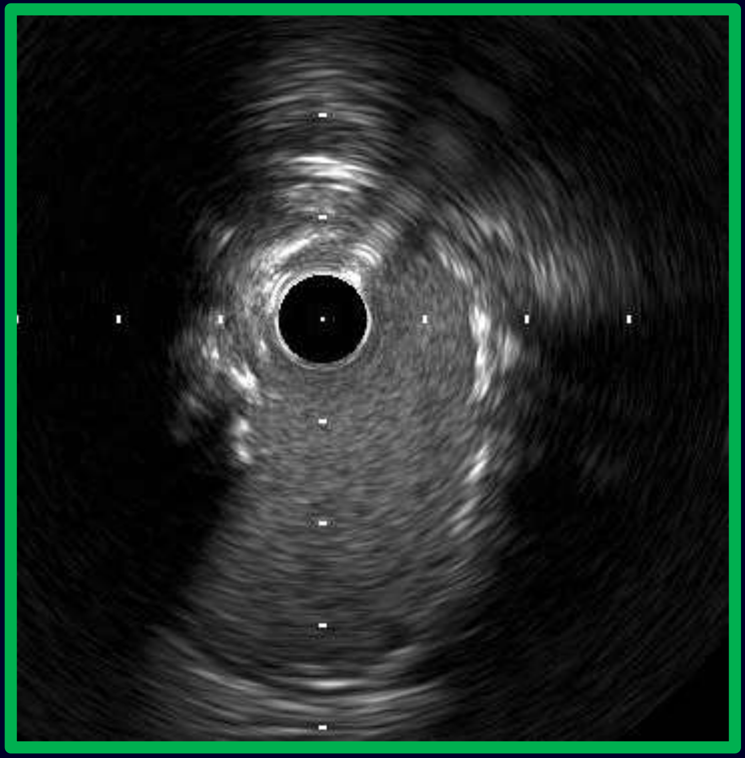


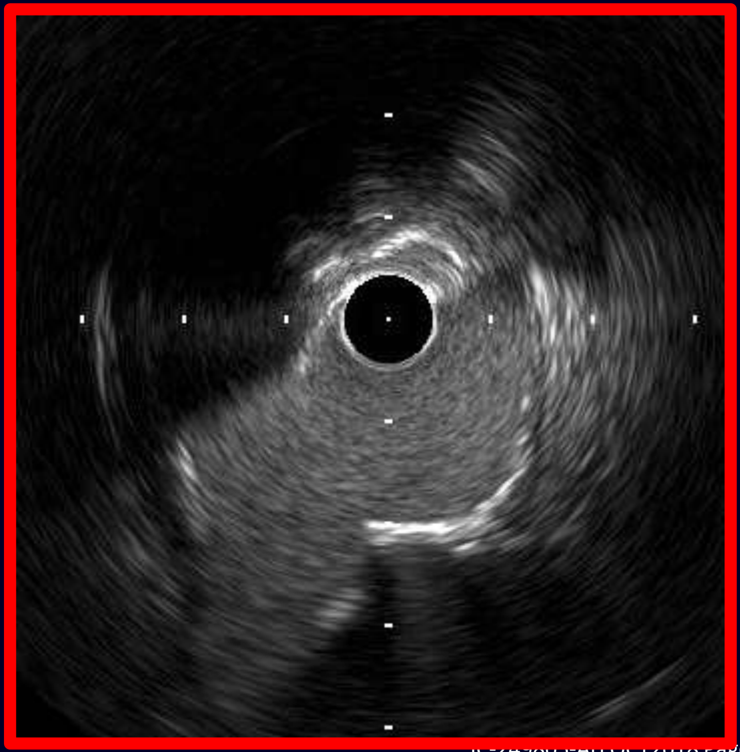


Drug-coated balloon 3.0*26mm
8atm



Final angiogram





Summary

1. When the wire bias effected for the proper direction, repeated rotablation with the same burr could make more aggressive atherectomy.

2. OFDI/IVUS showed predictive wire bias and rotablation effects during procedure.

Conclusion

Wire bias during rotablation can make more and more debulking effects.

There are some problems.

1. Wire bias can not be completely controlled.
2. Safety ablation can not be decided by only cine-angiogram.