

TCTAP 2022 - II. Complex PCI
Conquer the Calcium

Calcified In-stent Restenosis, How to Treat?

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Ischemic Outcomes After Coronary Intervention of Calcified Vessels in Acute Coronary Syndromes



Pooled Analysis From the HORIZONS-AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction) and ACUTY (Acute Catheterization and Urgent Intervention Triage Strategy) Trials

Philippe G n reux, MD,*† Mahesh V. Madhavan, BA,* Gary S. Mintz, MD,*† Akiko Machara, MD,*† Tullio Palmerini, MD,§ Laura LaSalle, BA,† Ke Xu, PhD,† Tom McAndrew, MS,† Ajay Kirtane, MD, SM,*† Alexandra J. Lansky, MD,|| Sorin J. Brener, MD,†¶ Roxana Mehran, MD,†# Gregg W. Stone, MD*†

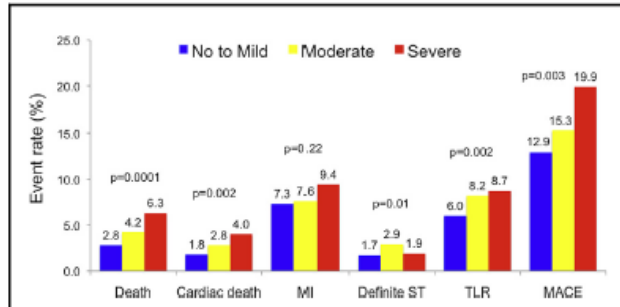


Figure 1

Adverse Outcomes Through 1 Year According to Severity of Target Lesion Calcification

Comparison of the cumulative event rates through 1 year in patients stratified by no to mildly, moderately, and severely calcified target lesions. Rates of death, cardiac death, definite stent thrombosis (ST), ischemia-driven target revascularization, and major adverse cardiovascular events (MACE) all demonstrated significant overall trends between the calcification groups. MI = myocardial infarction; TLR = target lesion revascularization.

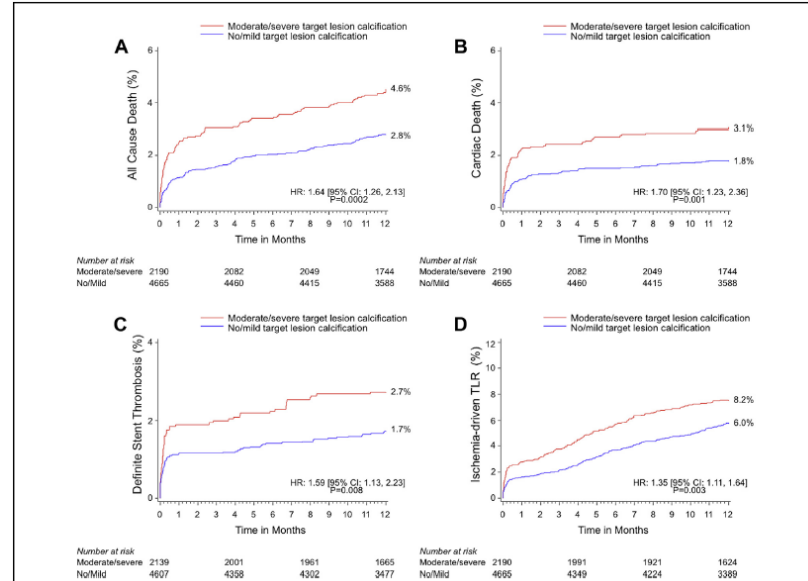
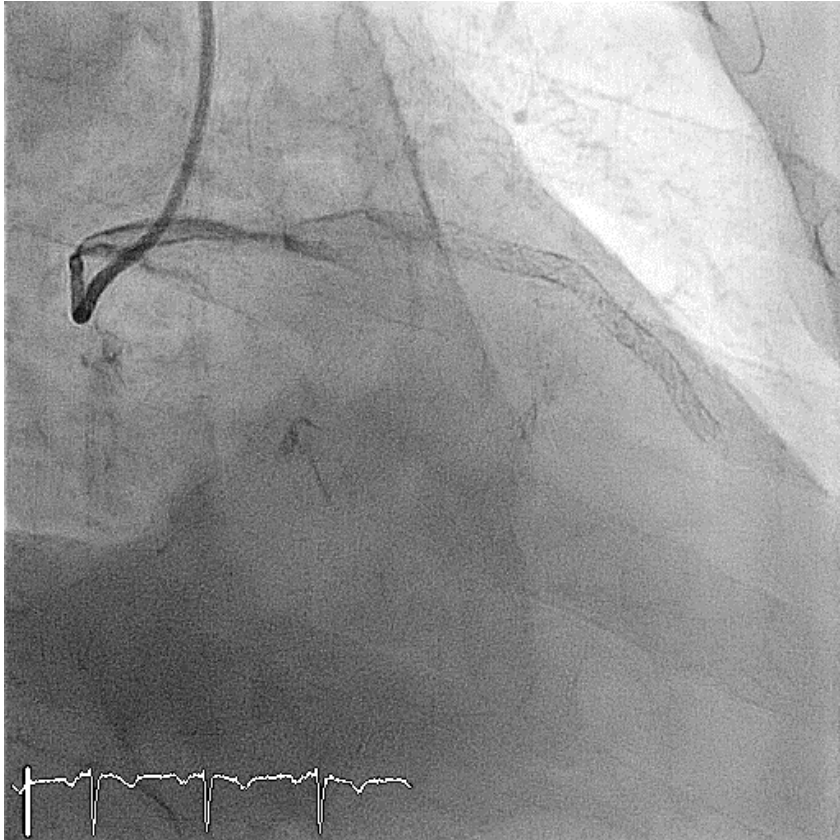


Figure 2 Time-to-Event Curves Through 1 Year According to the Severity of Target Lesion Calcification

Comparison of the cumulative event rates through 1 year in patients stratified by no to mildly (none/mild) compared with moderately to severely (moderate/severe) calcified target lesions. (A) All-cause death. (B) Cardiac death. (C) Definite stent thrombosis. (D) Ischemia-driven target lesion revascularization. HR = hazard ratio; other abbreviation as in Figure 1.



2018 ESC/EACTS Guidelines on myocardial revascularization

16.1.5 Devices for lesion preparation

Lesion preparation is critical for successful PCI. In addition to plain balloon angioplasty (with standard or non-compliant balloons), cutting or scoring balloon angioplasty or rotational atherectomy may be required in selected lesions—particularly those with heavy calcification—in order to adequately dilate lesions prior to stent implantation. However, studies investigating the systematic use of these adjunctive technologies, such as rotational atherectomy, have failed to show clear clinical benefit.⁶⁰²

Restenosis		
DES are recommended for the treatment of in-stent restenosis of BMS or DES. ^{373,375,378,379}	I	A
Drug-coated balloons are recommended for the treatment of in-stent restenosis of BMS or DES. ^{373,375,378,379}	I	A
In patients with recurrent episodes of diffuse in-stent restenosis, CABG should be considered by the Heart Team over a new PCI attempt.	IIa	C
IVUS and/or OCT should be considered to detect stent-related mechanical problems leading to restenosis.	IIa	C

European Heart Journal 2019; 40, 87–165

High-Speed Rotational Atherectomy Before Paclitaxel-Eluting Stent Implantation in Complex Calcified Coronary Lesions

The Randomized ROTAXUS (Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease) Trial

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 Ralph Toelg, MD,* Volker Geist, MD,* Thomas Meinertz, MD,‡ Joachim Schofer, MD,§
 Lamin King, MD,|| Franz-Josef Neumann, MD,† Ahmed A. Khattab, MD¶

Table 6. Baseline Quantitative Coronary Angiography Data (N = 322 Lesions)

	RA + PES (n = 146)	Standard Therapy (n = 176)	p Value
Before procedure			
Lesion length, mm	19.49 ± 9.66	17.99 ± 9.54	0.19
Reference vessel diameter, mm	2.68 ± 0.41	2.76 ± 0.39	0.11
Minimal lumen diameter, mm	1.01 ± 0.36	1.10 ± 0.41	0.05
Diameter stenosis, %	62.23 ± 12.01	60.19 ± 12.91	0.14
Immediately after procedure			
Minimal lumen diameter, mm			
In-stent	2.57 ± 0.38	2.55 ± 0.45	0.53
In-segment	2.26 ± 0.49	2.29 ± 0.53	0.58
Diameter stenosis, %			
In-stent	10.79 ± 5.61	12.34 ± 7.85	0.04
In-segment	18.21 ± 8.77	19.09 ± 10.69	0.38
Acute gain, mm			
In-stent	1.56 ± 0.43	1.44 ± 0.49	0.01
In-segment	1.24 ± 0.54	1.19 ± 0.55	0.26

Values are mean ± SD.
 Abbreviations as in Table 3.

Table 7. Nine-Month Follow-Up Quantitative Coronary Angiography Data (N = 255 Lesions)

	RA + PES (n = 123)	Standard Therapy (n = 132)	p Value
Minimal lumen diameter, mm			
In-stent	2.14 ± 0.63	2.25 ± 0.62	0.17
In-segment	1.91 ± 0.57	2.02 ± 0.65	0.17
Diameter stenosis, %			
In-stent	22.01 ± 19.92	19.86 ± 19.64	0.35
In-segment	27.92 ± 18.97	26.99 ± 1.73	0.62
Late lumen loss, mm			
In-stent	0.44 ± 0.58	0.31 ± 0.52	0.04
In-segment	0.36 ± 0.57	0.25 ± 0.57	0.11
Binary restenosis, %			
In-stent	14 (11.4)	14 (10.6)	0.71
In-segment	15 (12.2)	17 (12.9)	0.89

Values are n (%) or mean ± SD.
 Abbreviations as in Table 3.

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

The Randomized PREPARE-CALC Trial

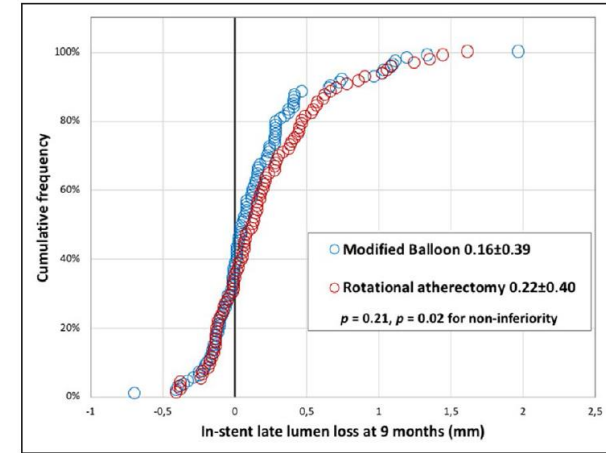
Mohamed Abdel-Wahab, MD
 Ralph Toelg, MD
 Robert A. Byrne, MB BCH, PhD
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Table 3. Procedural and In-Hospital Outcome (n=200 Patients)

	MB (n=100)	RA (n=100)	P Value
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	230.0±93.8	233.0±109.1	0.83
Large dissection, >5 mm	7 (7%)	3 (3%)	0.33
Perforation	2 (2%)	4 (4%)	0.68
Pericardial effusion	0 (0%)	3 (3%)	0.24
No/slow flow	0 (0%)	2 (2%)	0.49
Final TIMI flow <III	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
Strategy success*	81 (81%)	98 (98%)	0.0001
Death	0 (0%)	0 (0%)	1.00
MI	1 (1%)	2 (2%)	1.00
Target vessel re-PCI	0 (0%)	0 (0%)	1.00
CABG	0 (0%)	0 (0%)	1.00
Stent thrombosis	0 (0%)	0 (0%)	1.00
Access site complications	5 (5%)	3 (3%)	0.72

Table 4. Baseline Quantitative Coronary Angiography Data (n=278 Lesions)

	MB (n=136)	RA (n=137)	P Value
Before 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
Severe calcification*	100 (73.0%)	104 (76.5%)	0.46
Immediately after 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



Stent Deployment in Calcified Lesions: Can We Overcome Calcific Restraint With High-Pressure Balloon Inflations?

Manolis Vavuranakis,* MD, Konstantinos Toutouzas, MD, Christodoulos Stefanadis, MD, Christina Chrisohou, MD, Dimitrios Markou, MD, and Pavlos Toutouzas, MD

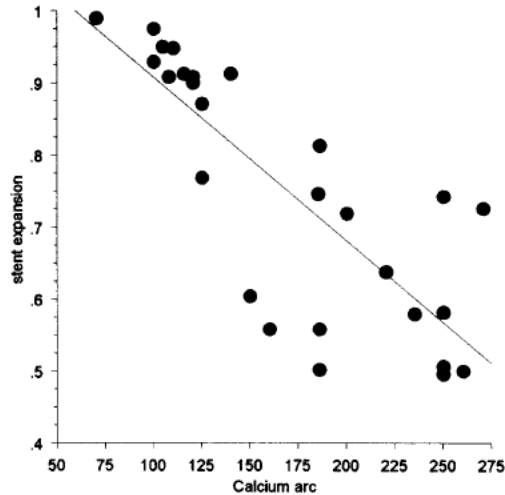


Fig. 3. Stent expansion after stent deployment at 16 atm is plotted against the arc of calcium of the lesion. There is good inverse correlation between these two variables ($r = -0.8$, $P = 0.0001$).

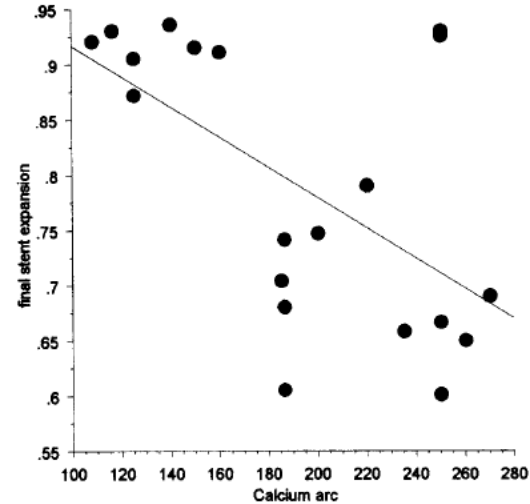
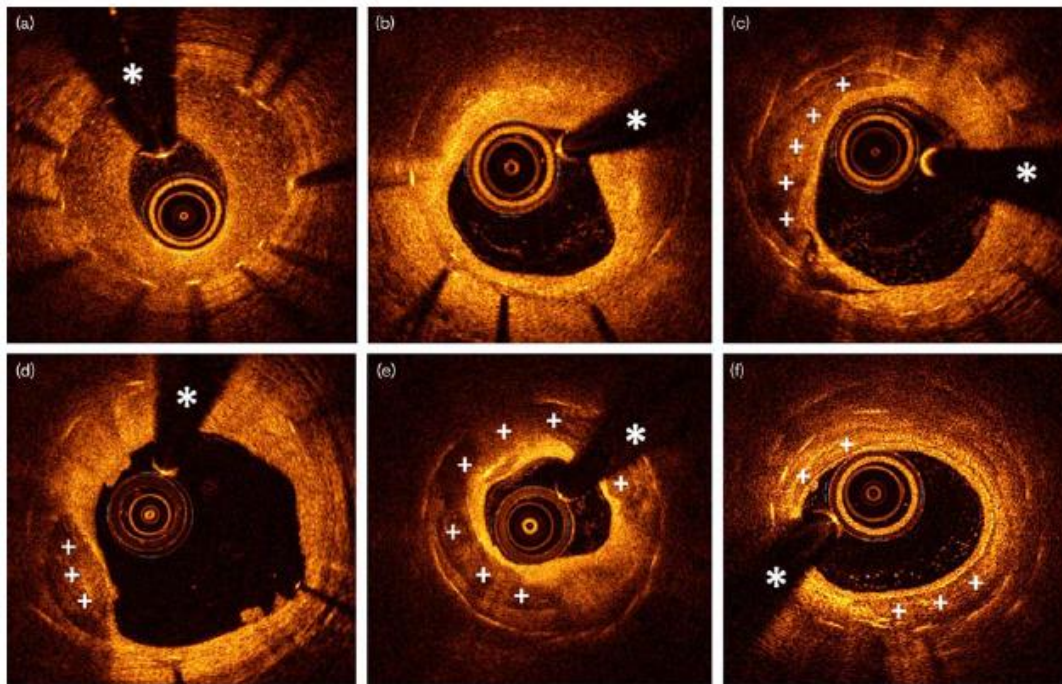


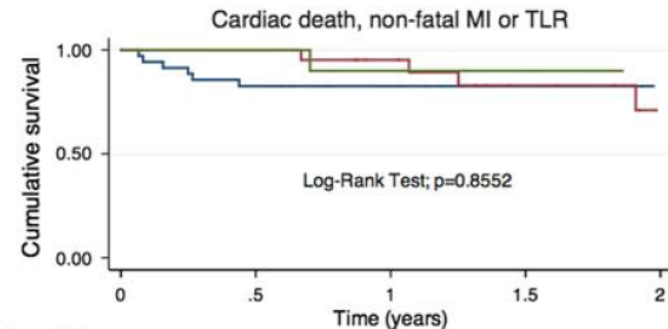
Fig. 5. Stent expansion after stent deployment at 20 atm is plotted against the arc of calcium of the lesion. There is still good inverse correlation between these two variables ($r = -0.58$, $P = 0.007$).

Calcified neoatherosclerosis causing in-stent restenosis: prevalence, predictors, and implications

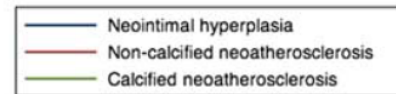
Marcos García-Guimaraes^{a,b}, Paula Antuña^{a,b}, Ramon Maruri-Sanchez^{a,b}, Alberto Vera^{a,b}, Javier Cuesta^{a,b}, Teresa Bastante^{a,b}, Fernando Rivero^{a,b} and Fernando Alfonso^{a,b}



Patterns of in-stent restenosis identified by optical coherence tomography. (a) Neointimal hyperplasia. (b) Non-calcified neoatherosclerosis (lipid-laden neointima). (c-f) Different examples of calcified neoatherosclerosis with calcified sheets within the stent. *Wire artifact. †Zones of calcification within the stent.



Number at risk	0	0.5	1	1.5	2
PatronOCT = 0	36	27	20	10	3
PatronOCT = 1	32	26	17	9	3
PatronOCT = 2	13	13	8	6	3



Kaplan–Meier graphic showing the cumulative survival curves for the combined event (cardiac death, nonfatal MI, or target lesion revascularization) after ISR treatment in each of the three OCT-based groups (neointimal hyperplasia, noncalcified neoatherosclerosis, and calcified neoatherosclerosis). ISR, in-stent restenosis; OCT, optical coherence tomography; MI, myocardial infarction; TLR, target lesion revascularization.

Late Complication

Xience V Stent Fractures With Restenosis

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Renu Virmani, MD,‡ Aaron V. Kaplan, MD*

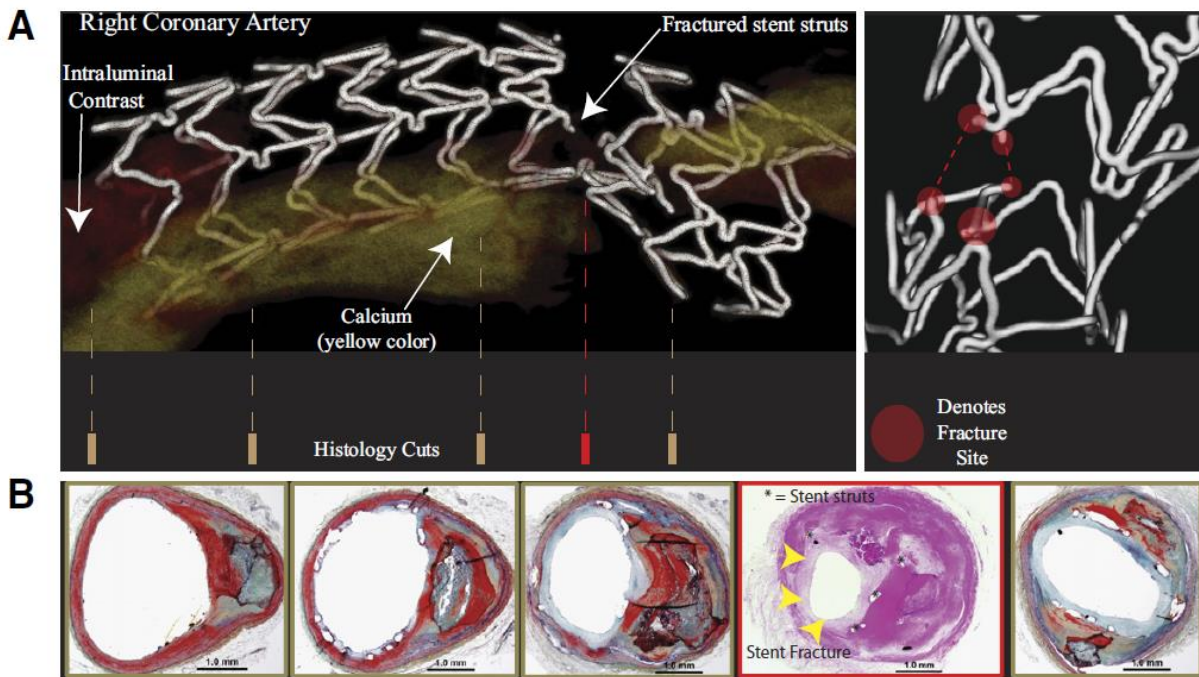



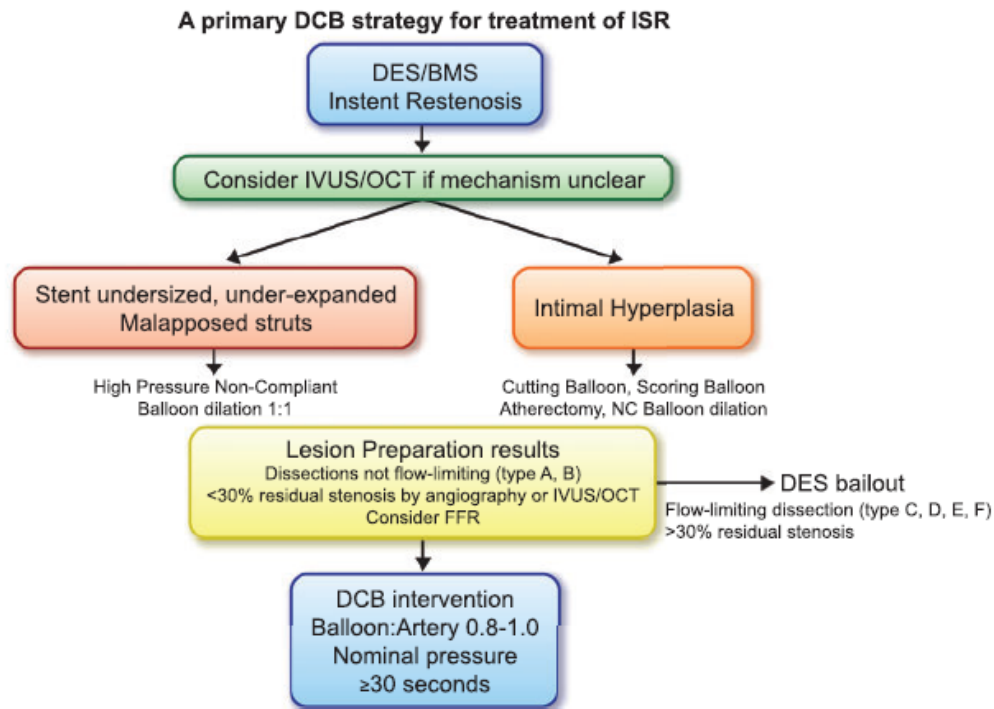


Figure 3. MicroCT and Histology Findings in the RCA

(A) Micro-computed tomography (microCT) 3-dimensional reconstruction of the right coronary artery (RCA) stent with a magnified image of the fractured segment to the right. The red dots highlight fracture points, with the dotted line indicating the original connection. The calcified plaque is colored yellow, and residual intraluminal contrast is red. (B) Corresponding histological cross sections of the RCA stent demonstrating focal restenosis at the area of fracture, with inflammation and fibrin accumulation at areas of polymer displacement.

Paclitaxel-coated balloons: a safe alternative to drug-eluting stents for coronary in-stent restenosis

Alexandra Lansky ^{1*}, Daniel Grubman ¹, and Bruno Scheller ²



Take home figure Proposed algorithm for treatment of in stent restenosis.

New Modalities of Treatment for Coronary Calcific Lesions

TNC Padmanabhan¹ Mohammed Sadiq Azam¹

Table 4 Summary of commonly used treatment modalities for tackling calcified coronary lesions

Modality	Types	Advantages	Disadvantages	Evidence
Scoring balloon	Angiosculpt NSE α Scoreflex	Easy to use, controlled calcium disruption	High crossing profile, not useful in high calcium burden	Meta-analysis
Cutting balloon	Flextome	Controlled cutting	High crossing profile	Meta-analysis
RA	Boston Rota wire	Effective, forward, pulverization	Higher complications, no side branch protection	Rotaxus
OA	Spectranetics, Philips, Viper wire	Forward and backward sanding	Higher complication, no side branch access	Orbit 2
IVL	Shockwave	Controlled Ca rupture in plaque	Preserved side branch access	Disrupt CAD I and II
Excimer laser	Philips, spectranetics	Unexpanded stents, ISR		Element registry LARS registry

Abbreviations: ISR, in-stent restenosis; IVL, **intravascular lithotripsy**; OA, orbital atherectomy; RA, rotational atherectomy.

Calcified In-Stent Restenosis

A Rare Cause of Dilation Failure Requiring Rotational Atherectomy

Fernando Alfonso, MD; Jorge Sandoval, MD; Christian Nolte, MD

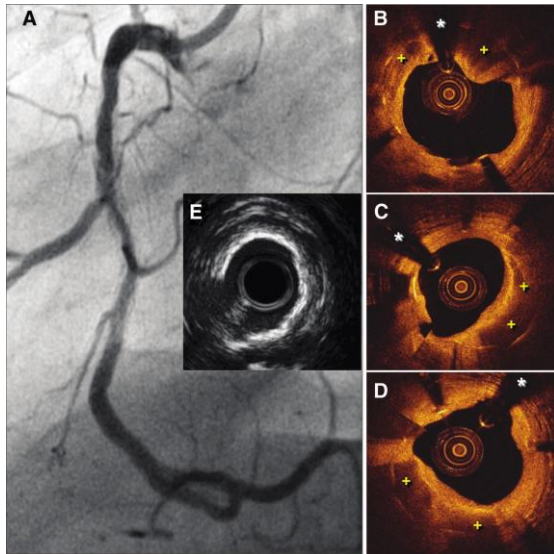


Figure 1. A, Angiography (lateral projection) showing diffuse in-stent restenosis (ISR). B through D, Optical coherence tomography images revealing calcified intrastent tissue (plus sign) with variable morphology and degree of lumen obstruction (asterisk denotes wire artifact). E, Intravascular ultrasound imaging disclosing calcified ISR shadowing the underlying stent struts.

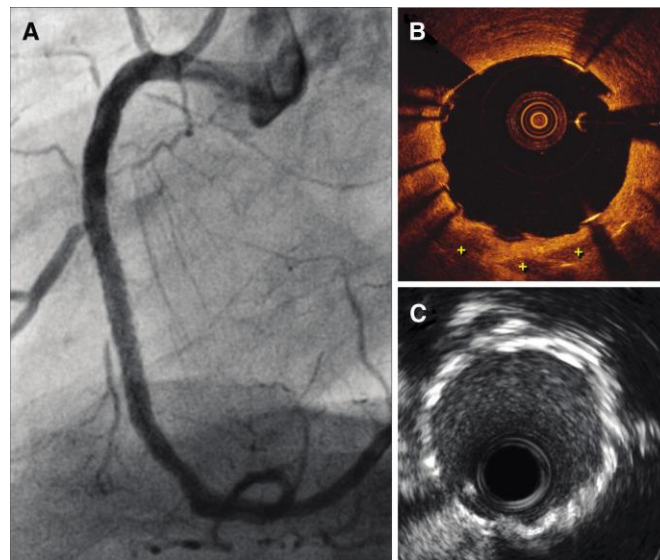






Figure 2. Final procedural results with an optimal lumen and adequate stent expansion. A, Angiography; B, optical coherence tomography (plus sign indicates calcium within the "sandwich" stent; asterisk denotes wire artifact); and C, intravascular ultrasound.

Feasibility and safety of orbital atherectomy for the treatment of in-stent restenosis secondary to stent under-expansion

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Adnan Sultan MD¹  | Mishel Tabaku RCIS¹ | Mohammad Alqarqaz MD¹ |
Akshay Khandelwal MD¹ | Ankur Gupta MD¹  | Creighton Don MD, MPH² |
Khaldoon Alaswad MD¹

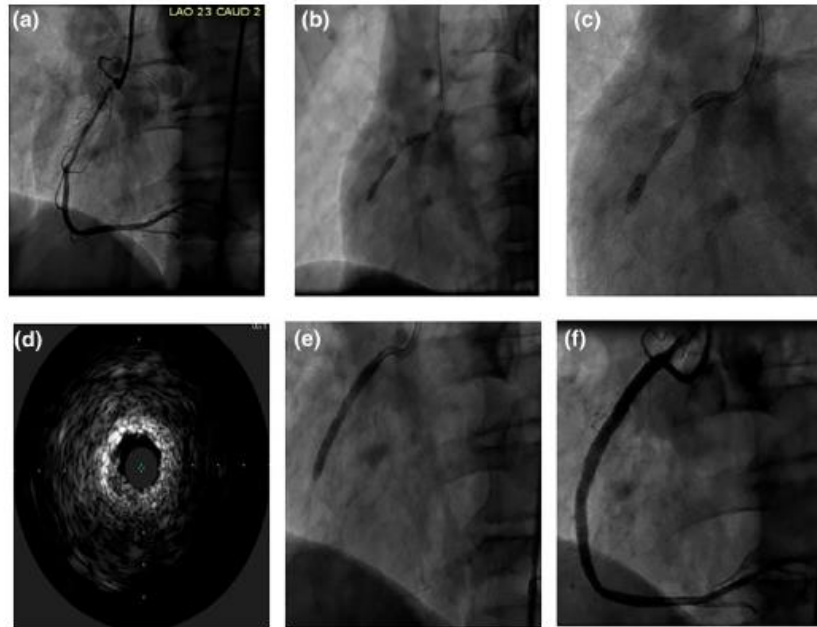


FIGURE 2 (a) Pre PCI Angiogram showing under expanded stent in proximal RCA; (b) dog-bone 1:1 NC balloon at high pressure; (c) under-expanded NC balloon after OA with Coronary 1.25 mm CST; (d) corresponding area on IVUS; (e) stent deployment with full expansion after OA with 1.25 solid crown with peripheral OA system; and (f) final result [Color figure can be viewed at [wileyonlinelibrary.com](https://onlinelibrary.wiley.com)]

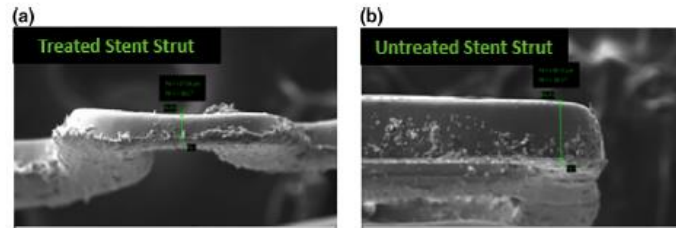


FIGURE 4 Comparison of treated with OA (a) and untreated stent struts (b; mag = $\times 300$) in vitro testing. Note that vertical length of stent struts 27.54 μm in treated stent (panel [a]) and 83.13 μm in untreated stent (panel [b]). Photo Courtesy of Cardiovascular Systems Inc, St Paul, MN [Color figure can be viewed at [wileyonlinelibrary.com](https://onlinelibrary.wiley.com)]

Resolving chronic stent under-expansion in calcified lesions by intravascular lithoplasty

Kenji Yaginuma (MD)^a, Gerald S. Werner (MD, PhD)^{b,*}

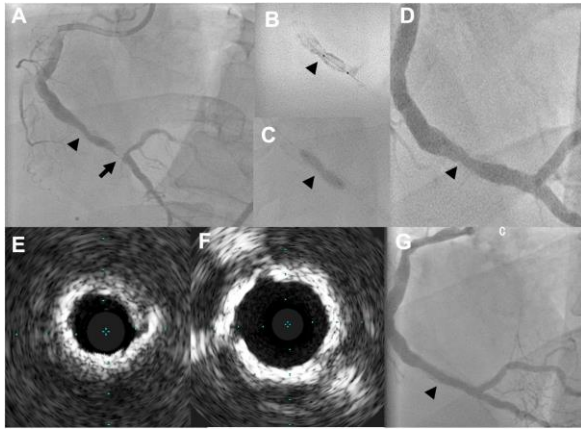


Fig. 1. (A) In-stent restenosis (arrowhead) and subtotal occlusion (arrow) in the distal right coronary artery. (B) Stent visualization of the under-expanded stent and calcification around the stent. (C) Ultra-high pressure balloon 3.5×15 mm at 40 atm with dog-bone effect (arrowhead). (D) Final angiography after treatment of the distal lesion with stent placement across the posterior descending artery and proximal stent optimization and final kissing balloon dilatation. The prior stent remained under-expanded (arrowhead). (E) During a subsequent procedure, intravascular ultrasound (IVUS) showed severe circumferential calcification around the stent. (F) After intravascular lithoplasty with a 4.0×12 mm balloon and post dilatation with a 5.0×12 mm NC Emerge balloon at 12 atm, IVUS showed excellent stent expansion. (G) Final angiography.

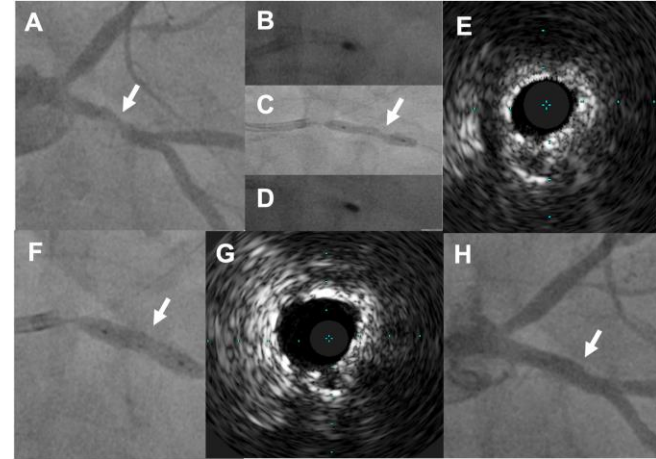
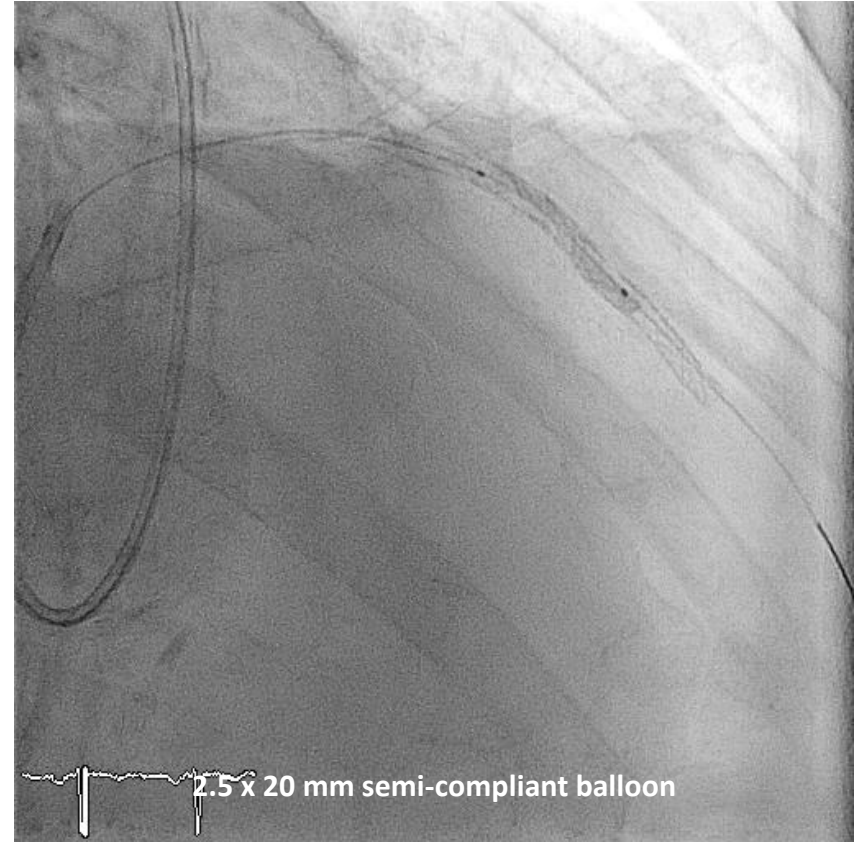
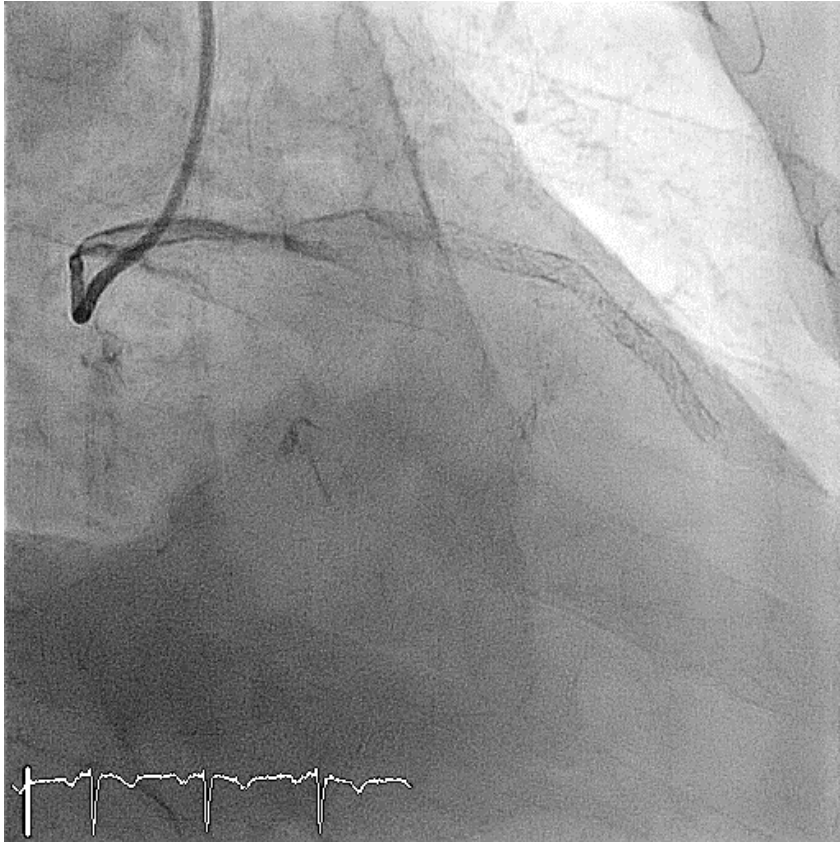
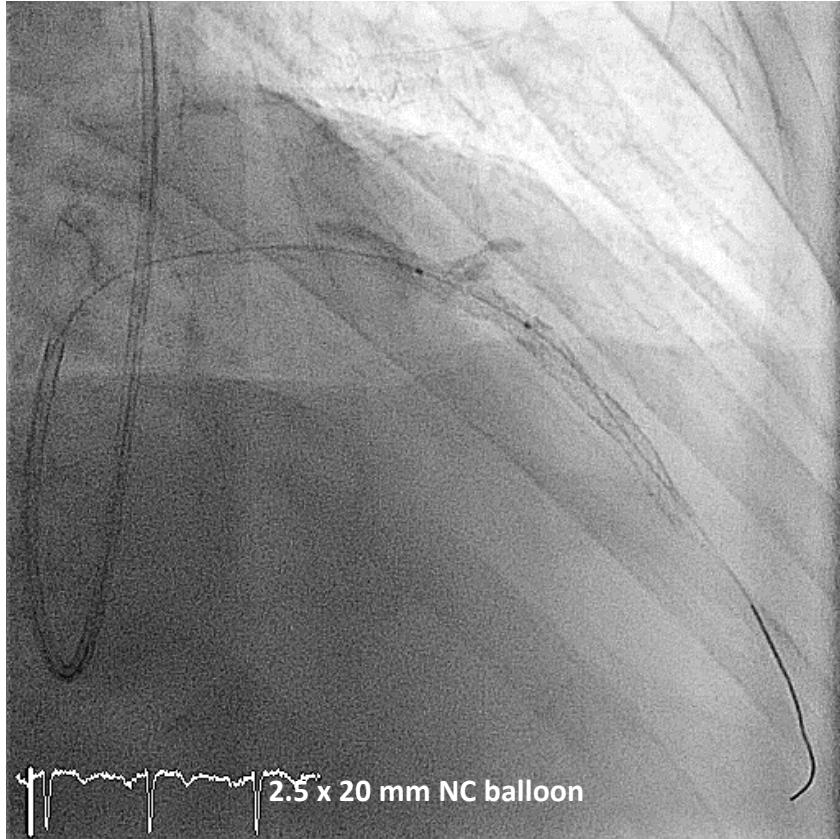


Fig. 2. (A) In-stent restenosis in the proximal left circumflex artery (arrow). (B) 1.5 mm burr for rotational angioplasty. (C) NC APEX 3.5×15 mm balloon at 18 atm with remaining indentation (arrow). (D) 1.75 mm burr was advanced. (E) Intravascular ultrasound (IVUS) reveals remaining stent constriction by circular calcification. (F) Lithoplasty balloon 3.5×12 mm at 4 atm in position. (G) IVUS shows improved stent expansion. (H) Final angiography.

79 year old male, 3VD, prior DES LAD, unstable angina



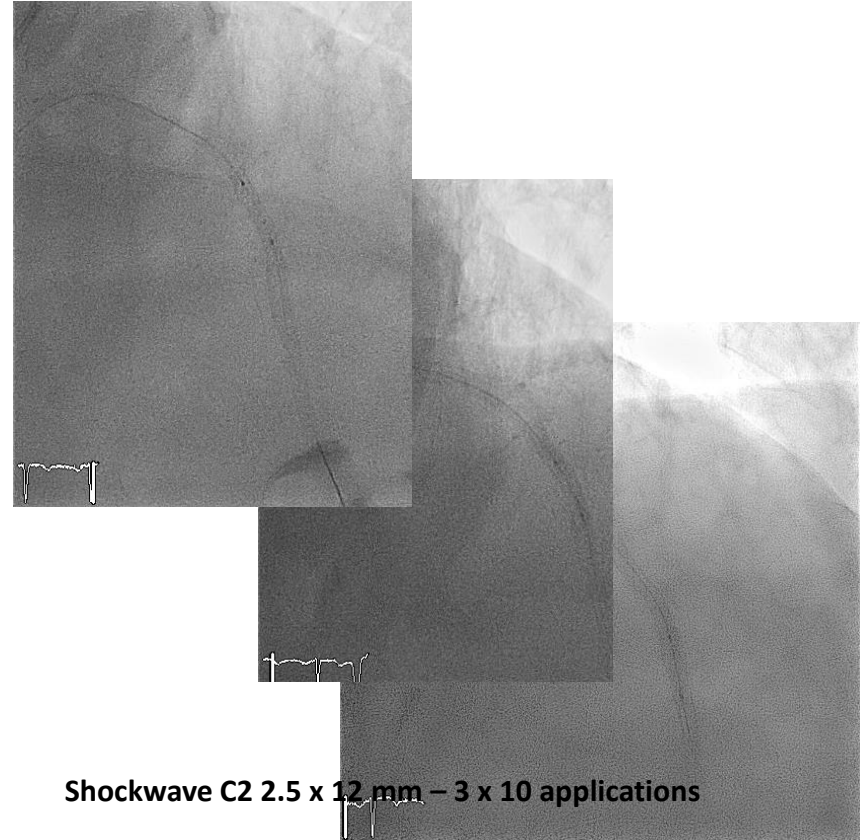
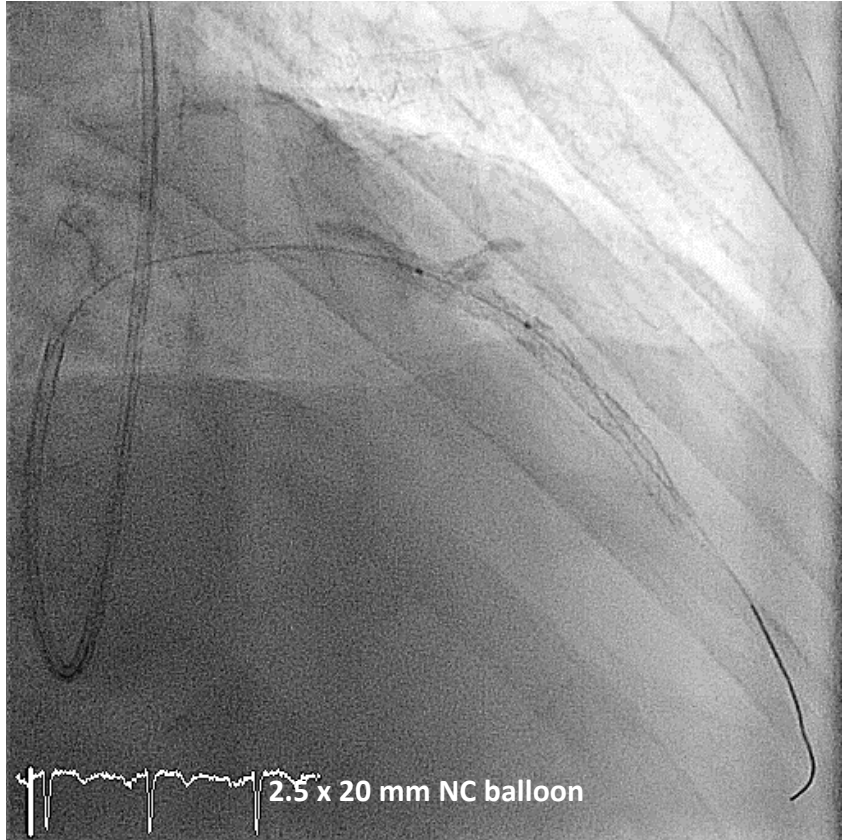
79 year old male, 3VD, prior DES LAD, unstable angina



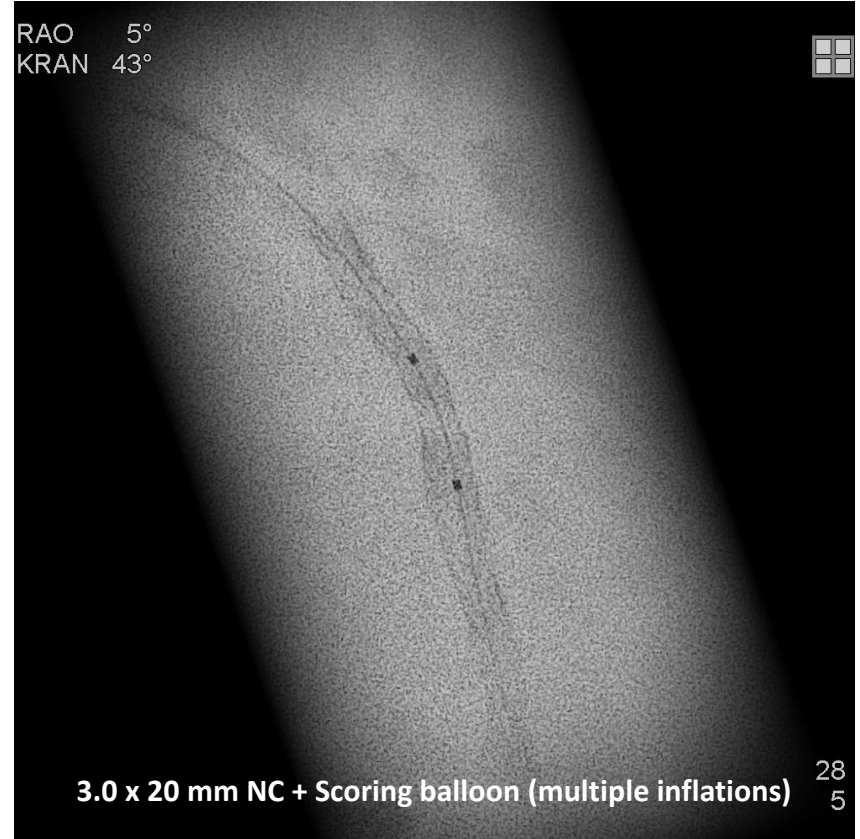
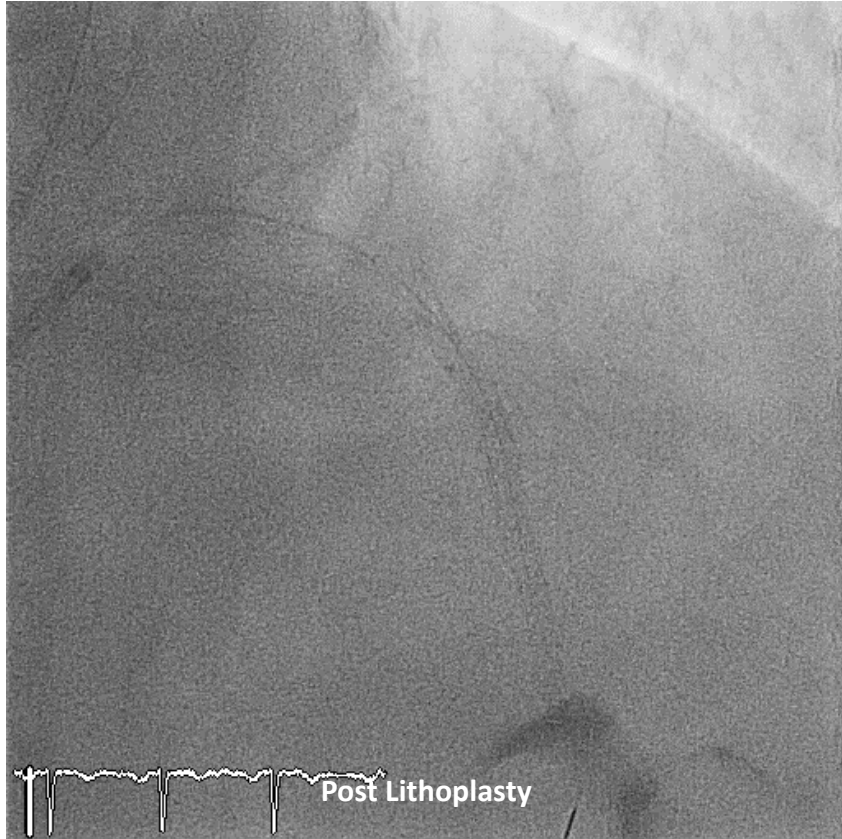
Options?

- Conservative treatment
- CABG
- Covered stent graft
- Proceed with NC
- Cutting / Scoring balloon
- Rotational / directional atherectomy
- DES-in-DES
- ...

79 year old male, 3VD, prior DES LAD, unstable angina



79 year old male, 3VD, prior DES LAD, unstable angina



Neointimal Modification With Scoring Balloon and Efficacy of Drug-Coated Balloon Therapy in Patients With Restenosis in Drug-Eluting Coronary Stents



A Randomized Controlled Trial

Sebastian Kufner, MD,^a Michael Joner, MD,^a Simon Schneider, MD,^b Ralph Tölg, MD,^c Bernhard Zrenner, MD,^d Janika Repp, MD,^a Alissa Starkmann,^a Erion Xhepa, MD,^a Tareq Ibrahim, MD,^b Salvatore Cassese, MD, PhD,^a Massimiliano Fusaro, MD,^a Ilka Ott, MD,^a Christian Hengstenberg, MD,^{a,c} Heribert Schunkert, MD,^{a,c} Mohamed Abdel-Wahab, MD,^e Karl-Ludwig Laugwitz, MD,^{b,c} Adnan Kastrati, MD,^{a,c} Robert A. Byrne, MB, BCh, PhD,^{a,c} for the ISAR-DESIRE 4 Investigators

FIGURE 1 Cumulative Frequency Distribution Curves for Primary Endpoint According to Treatment Group

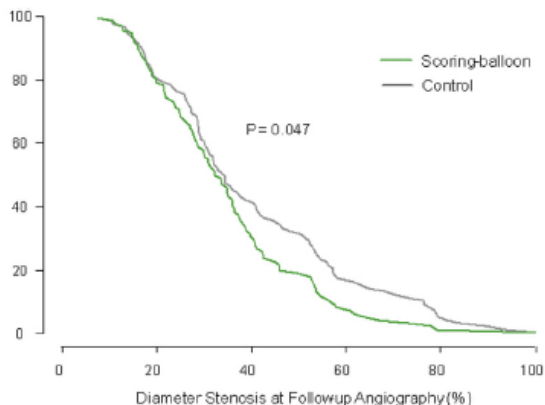





TABLE 4 Clinical Results at 1 Year According to Treatment Group

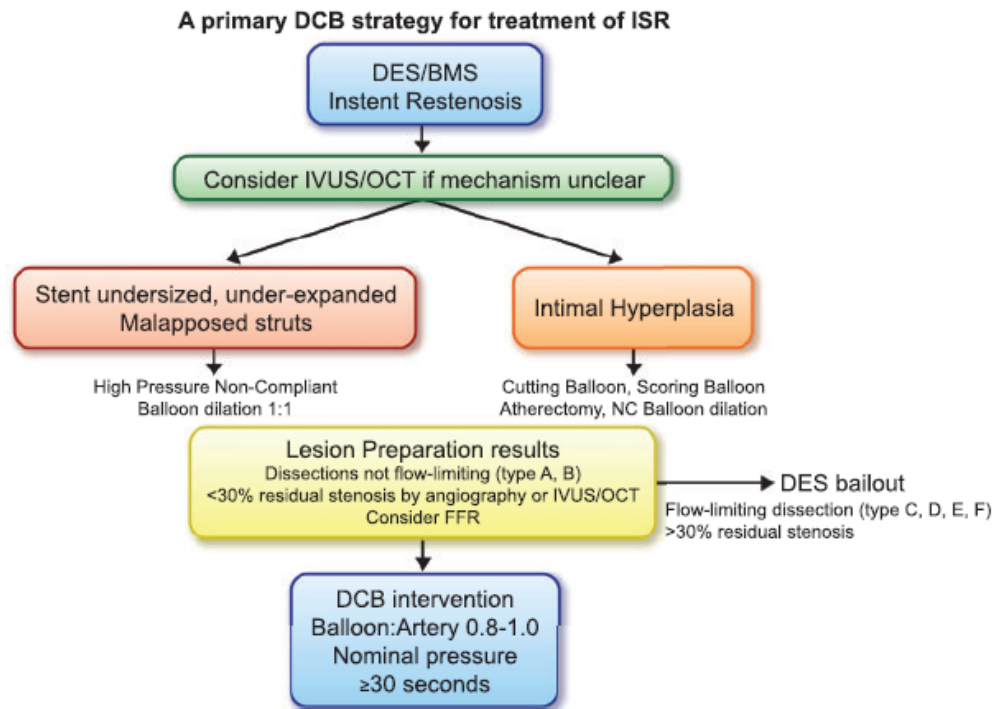
	Scoring Balloon (n = 125)	Control (n = 127)	p Value
Death	2 (1.6)	2 (1.7)	>0.99
Myocardial infarction	4 (3.2)	2 (1.6)	0.42
Death or myocardial infarction	5 (4.0)	4 (3.2)	0.73
Target lesion revascularization	20 (16.2)	27 (21.8)	0.26
Death, myocardial infarction, target lesion revascularization	23 (18.4)	29 (23.3)	0.35
Definite or probable target lesion thrombosis*	0 (0.0)	0 (0.0)	NA

Values are n (%) (percentages are Kaplan-Meier estimates). *According to Academic Research Consortium criteria.

NA = not applicable.

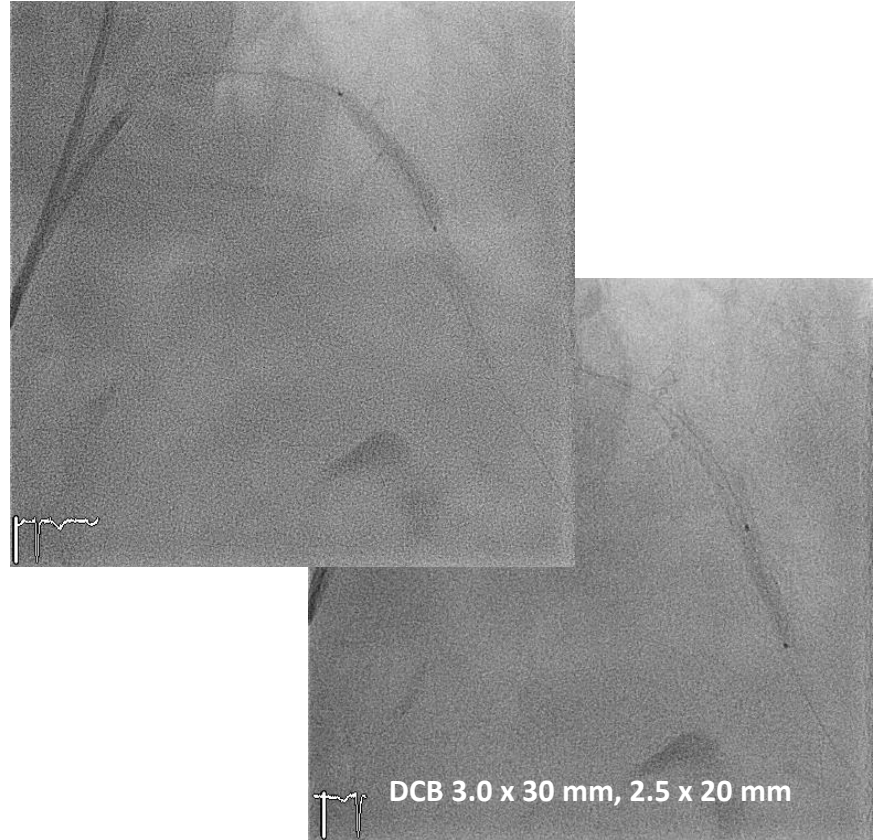
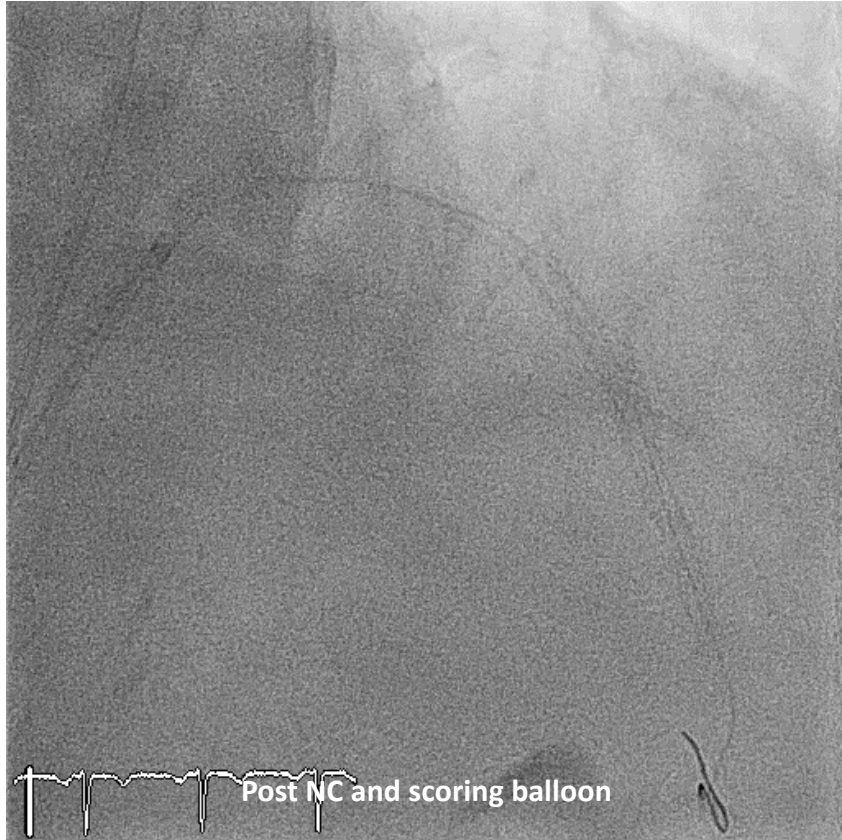
Paclitaxel-coated balloons: a safe alternative to drug-eluting stents for coronary in-stent restenosis

Alexandra Lansky ^{1*}, Daniel Grubman ¹, and Bruno Scheller ²

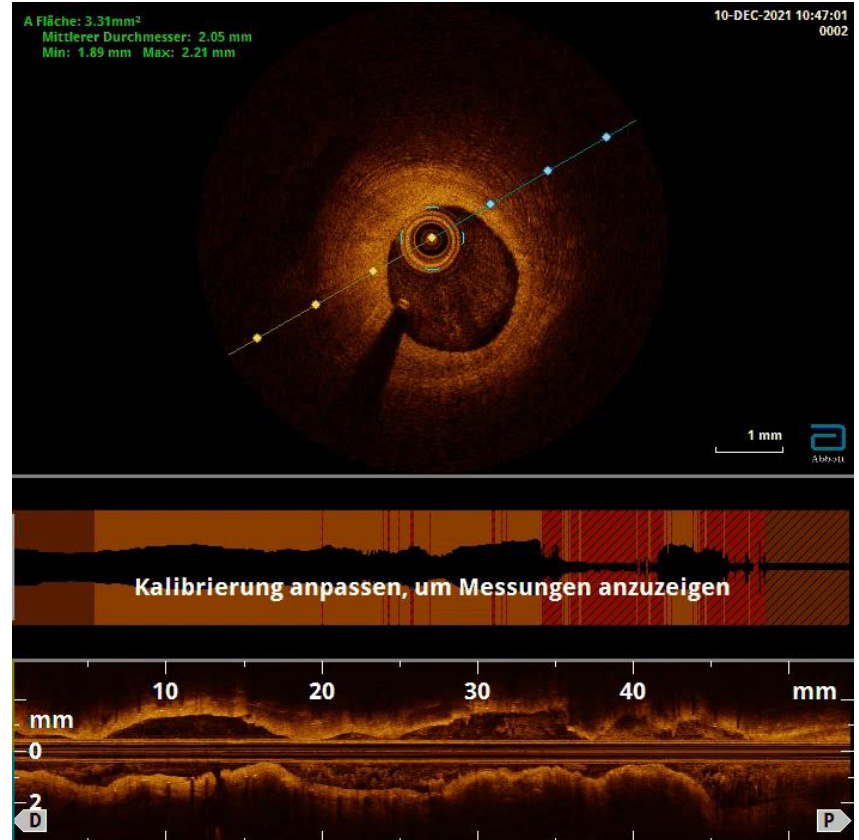
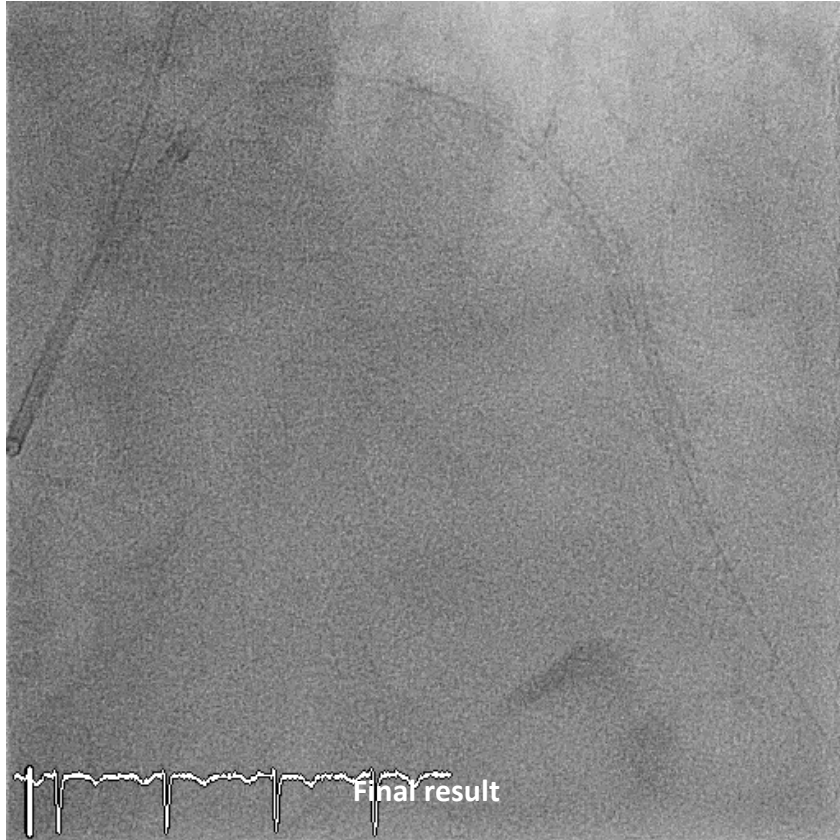


Take home figure Proposed algorithm for treatment of in stent restenosis.

79 year old male, 3VD, prior DES LAD, unstable angina



79 year old male, 3VD, prior DES LAD, unstable angina



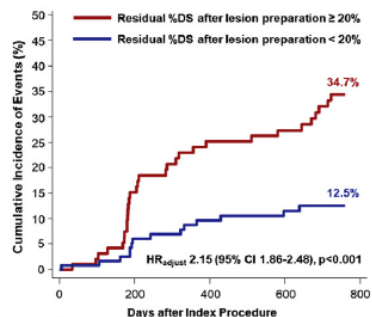
Impact of Optimized Procedure-Related Factors in Drug-Eluting Balloon Angioplasty for Treatment of In-Stent Restenosis



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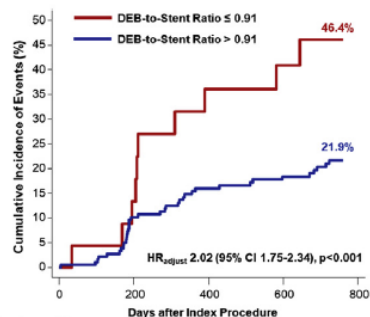
FIGURE 3 Cumulative Incidence of Target Lesion Failure According to Individual Procedure-Related Factors

A Residual %DS after Lesion Preparation



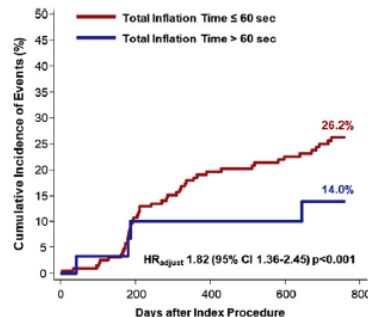
	0	200	400	600	800
■ Number at risk	101	72	70	0	0
%DS ≥ 20%	101	81	72	70	0
%DS < 20%	120	107	100	93	0

B DEB-to-Stent Ratio



	0	200	400	600	800
■ Number at risk	26	16	13	0	0
Ratio ≤ 0.91	26	21	16	13	0
Ratio > 0.91	202	174	158	152	0

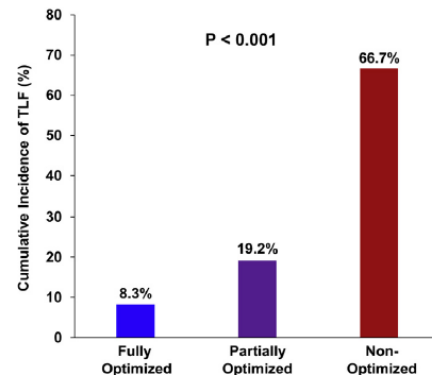
C Total Inflation Time of DEB



	0	200	400	600	800
■ Number at risk	216	183	161	151	1
Duration ≤ 60s	216	183	161	151	1
Duration > 60s	37	33	31	31	0

The cumulative incidence of target lesion failure, according to (A) residual percentage diameter stenosis (%DS) after lesion preparation, (B) drug-eluting balloon (DEB)-to-stent ratio, and (C) total inflation time of DEB are presented. CI = confidence interval; HR_{adjusted} = adjusted hazard ratio.

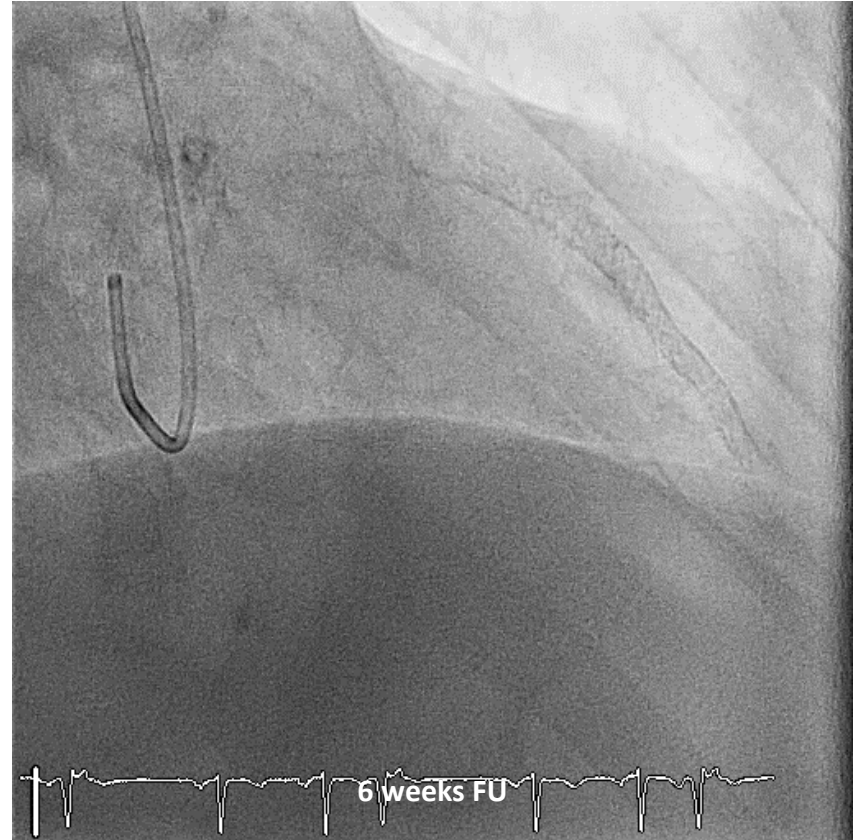
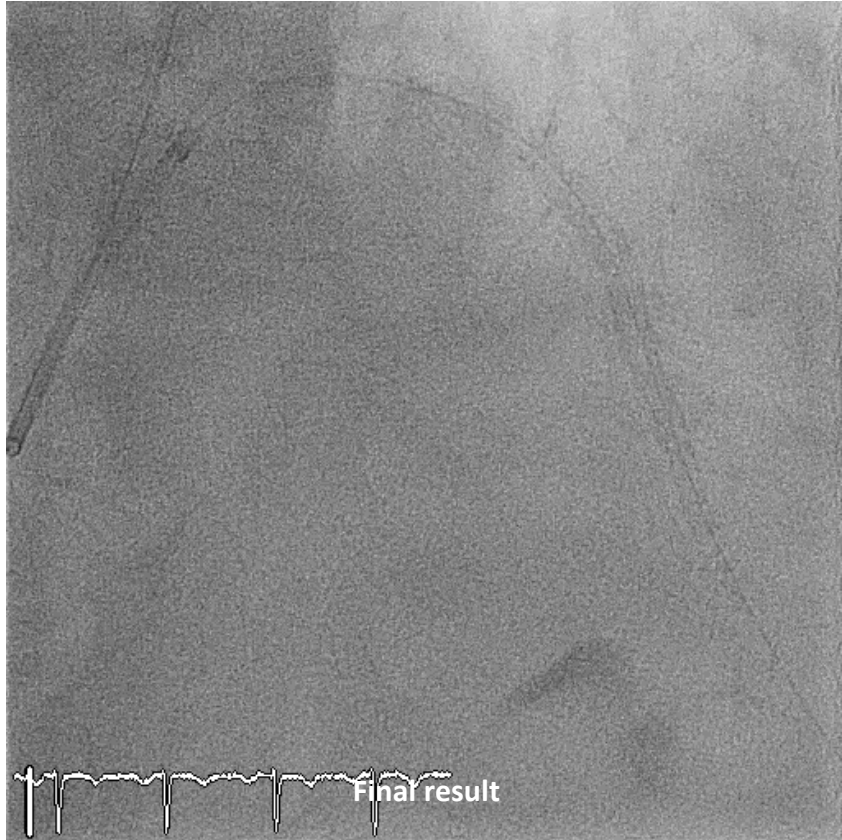
FIGURE 4 Incidence of Target Lesion Failure According to Combined Procedure-Related Factors



	Fully Optimized	Partially Optimized	Non-Optimized
Cumulative Incidence of TLF (%)	8.3%	19.2%	66.7%
Lesion Number	12	172	12
Event Number	1	33	8

Rates of target lesion failure (TLF) are compared among 3 groups, classified according to the combined procedure-related factors: 1) fully optimized group (drug-eluting balloon-to-stent ratio [BSR] > 0.91, total inflation time of drug-eluting balloon [T_{inflation}] > 60 s, and residual percentage diameter stenosis [%DS] after lesion preparation < 20%); 2) partially optimized group (either 1 or 2 of 3 procedural factors were optimized); and 3) nonoptimized group (BSR ≤ 0.91, T_{inflation} ≤ 60 s, and residual %DS after lesion preparation ≥ 20%).

79 year old male, 3VD, prior DES LAD, unstable angina



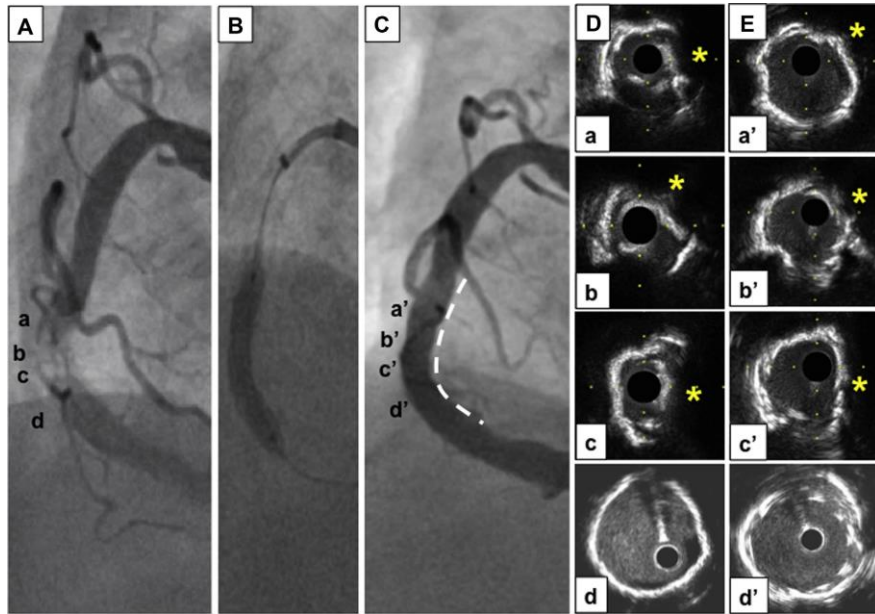
Calcified In-stent Restenosis

- **Limited data, no RCT**
- **Stepwise approach**
 - stent underexpansion
 - get rid of / crack calcium
- **Frequent use of different tools for lesion preparation**
 - High pressure NC
 - Cutting / scoring balloons
 - Atherectomy (orbital or directional)
 - Laser
 - Lithoplasty
- **Local drug delivery at the end of the procedure (another layer of metal vs. DCB)**

Refractory In-Stent Restenosis Attributable to Eruptive Calcified Nodule

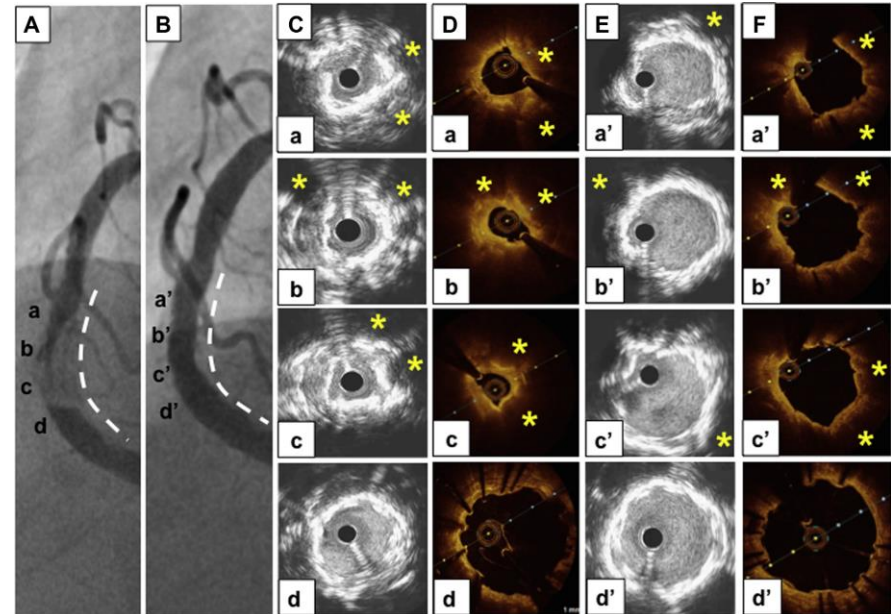
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FIGURE 1 Primary PCI for Calcified Nodule



(A) Coronary angiography prior to percutaneous coronary intervention, (B, C) The first percutaneous coronary intervention, The **white dotted line** indicates the segment that received the implantation of biolimus-eluting stent. (D) Baseline intravascular ultrasound (IVUS) images. Protruding calcification with its irregular surface (asterisk) was observed on IVUS imaging (a to c). These morphological features indicated calcified nodule. (E) Final IVUS images. Protruding calcification plates (asterisk) were observed on IVUS by stent struts (a' to c').

FIGURE 2 First In-Stent Restenosis 8 Months After Primary PCI

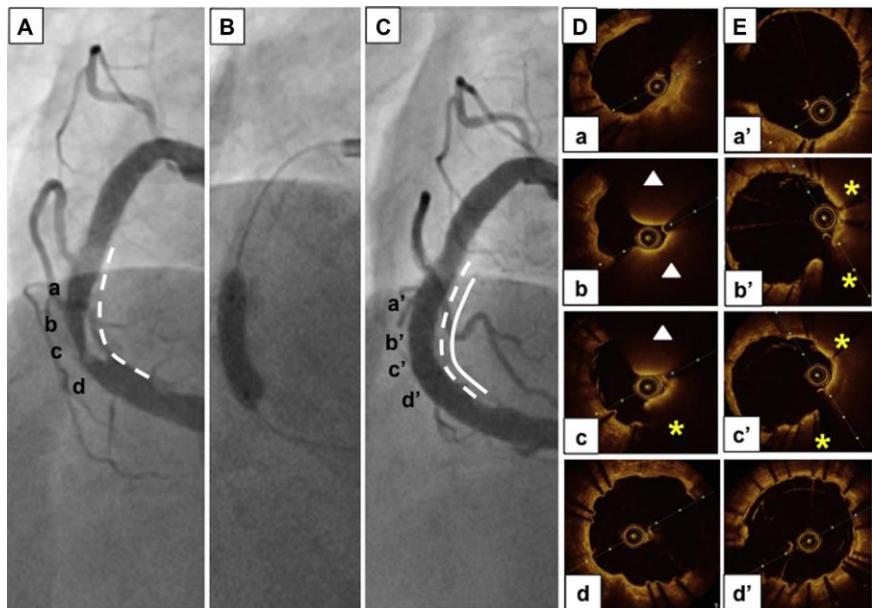


(A) Coronary angiography 8 months after the first percutaneous coronary intervention. In-stent restenosis within the previously implanted drug-eluting stent (**white dotted line**) was observed. (B) Coronary angiography after the use of drug-coating balloon. (C, D) Pre-intravascular ultrasound and optical coherence tomography images. Multiple calcification plates (**asterisk**) were protruding again through the stent struts (a to c). (d) There is no calcified nodule. a' to d' corresponds to a to d in A and D. (E, F) Final intravascular ultrasound and optical coherence tomography images. There is no calcified nodule (a' to d').

Refractory In-Stent Restenosis Attributable to Eruptive Calcified Nodule

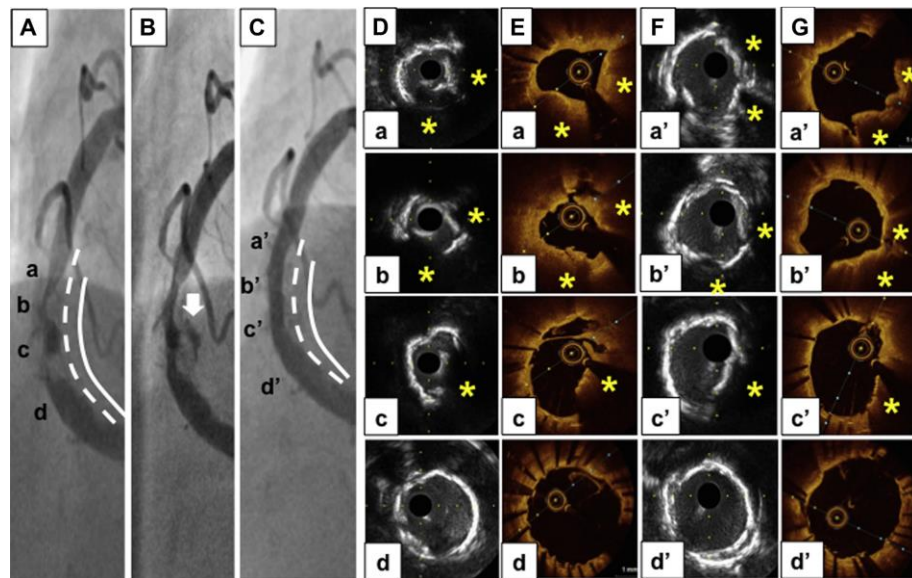
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FIGURE 3 Second In-Stent Restenosis 3 Months After the Second PCI



(A) Coronary angiography 3 months after the second percutaneous coronary intervention. (B, C) The third percutaneous coronary intervention. Additional drug-eluting stent (white solid line) was implanted within the previous stent (white dotted line). (D, E) Baseline optical coherence tomography images. Asterisks and white triangles indicate the calcified nodule and red thrombus, respectively. a to d indicate the site imaged by OCT in B. a' to d' corresponds to a to d in A.

FIGURE 4 Third In-Stent Restenosis 6 Months After the Third PCI



(A) Coronary angiography 6 months after the third percutaneous coronary intervention. The white dotted line indicates the implanted biolimus-eluting stent, and the white solid line indicates the implanted everolimus-eluting stent. (B, C) The fourth percutaneous coronary intervention with excimer laser coronary angioplasty. (B) Following excimer laser coronary angioplasty use, minor perforation occurred (white arrow). (D, E) Pre-intravascular ultrasound and optical coherence tomography images. (F, G) Final intravascular ultrasound and optical coherence tomography images. Asterisks indicate the calcified nodule. a to d indicate the site imaged by IVUS and OCT in D and E. a' to d' corresponds to a to d in A.