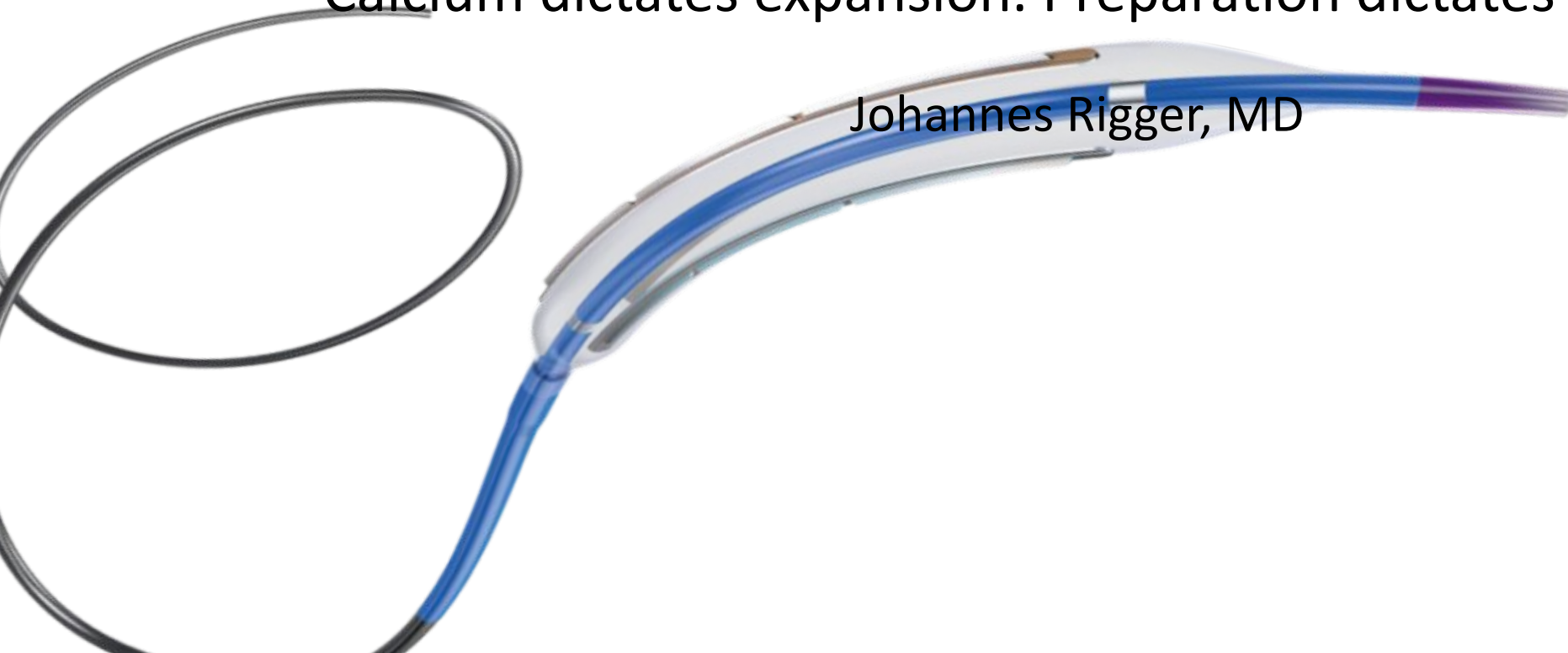


Cut Cut Cut

Calcium dictates expansion. Preparation dictates outcome.

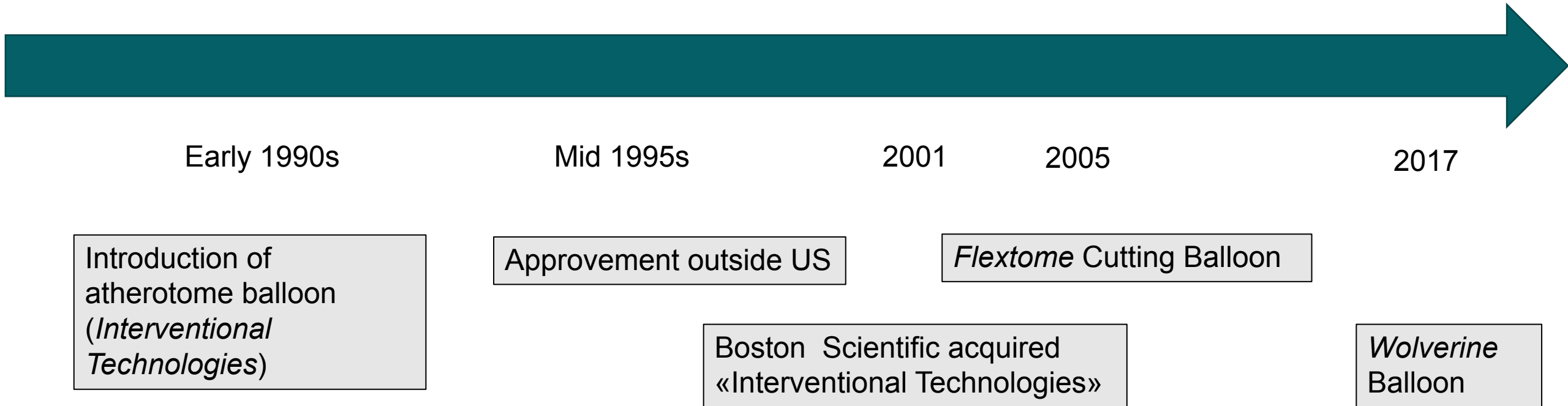
Johannes Rigger, MD



Agenda

- Chapter 1- the beginning of cutting balloons
- Chapter 2- the evolution of indications for cutting devices
- Chapter 3- cutting in drug eluting balloon therapies

Chapter 1- Development of cutting ballon technology

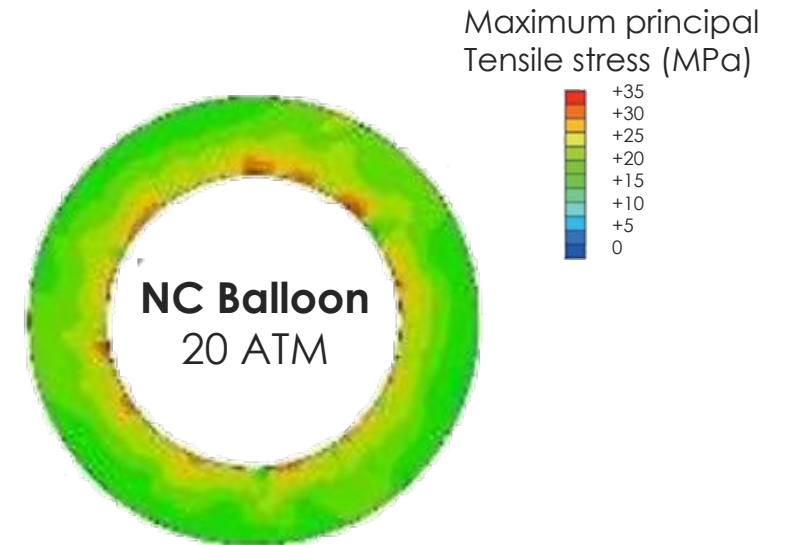


Mechanism of action POBA vs. Cutting

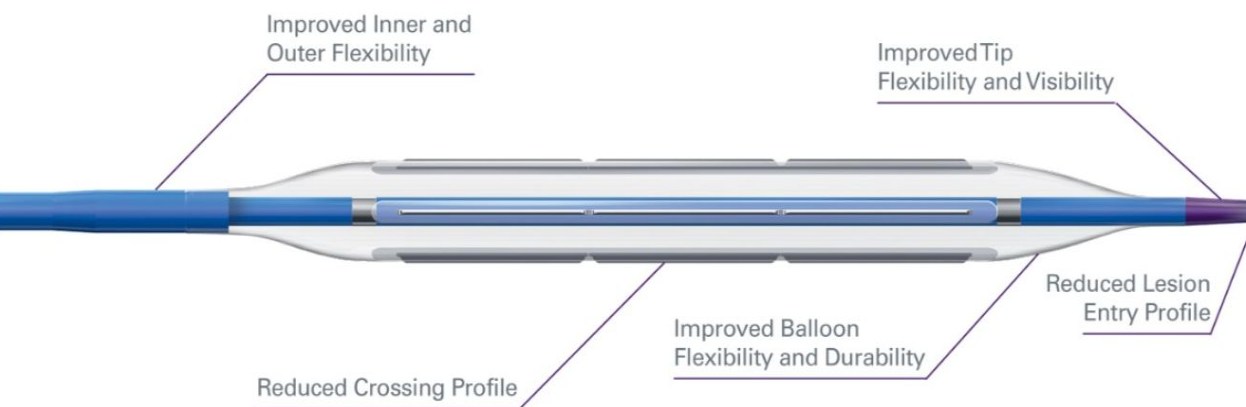
Balloon Angioplasty

Barotrauma (pressure and injury) to the vessel wall injury causing irregular intimal stretching and tearing

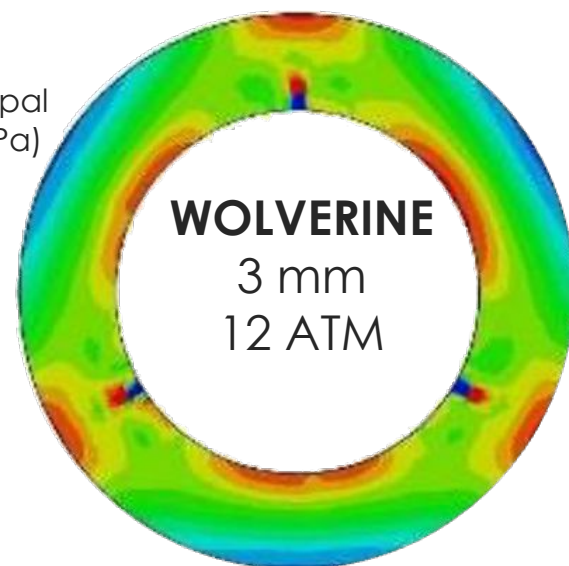
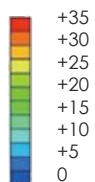
Problems: elastic recoil, dissection, intimal proliferative response leading to restenosis



Mechanism of action POBA vs. Cutting



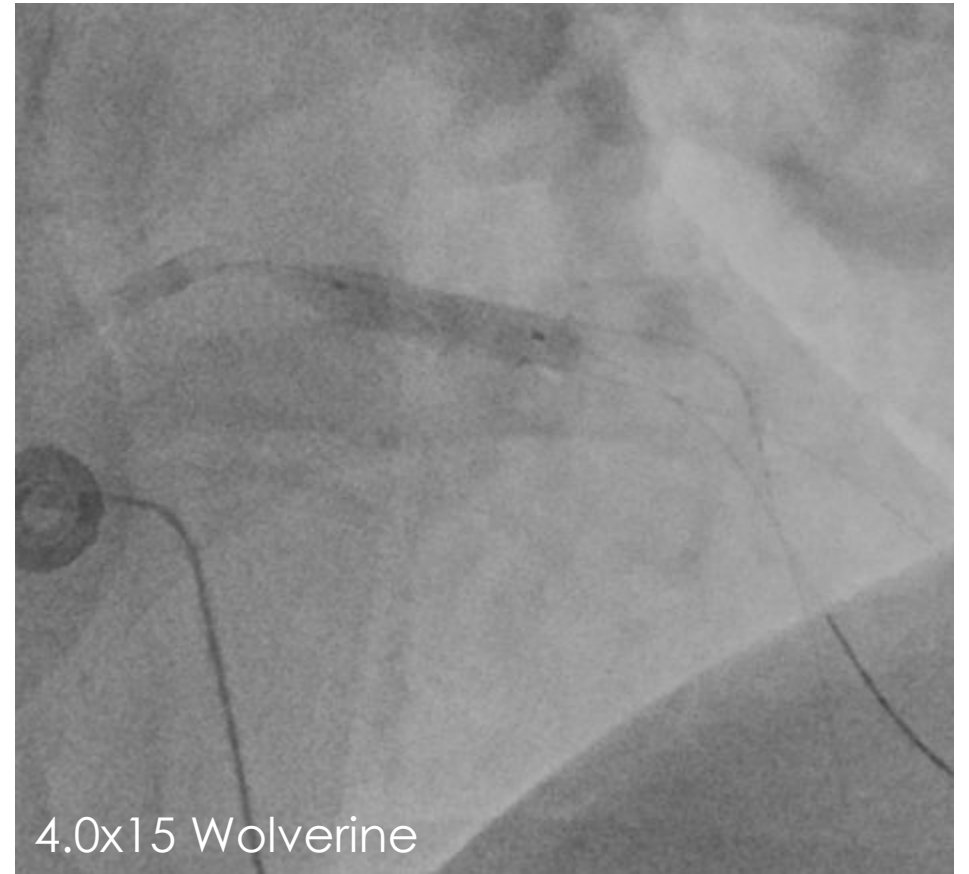
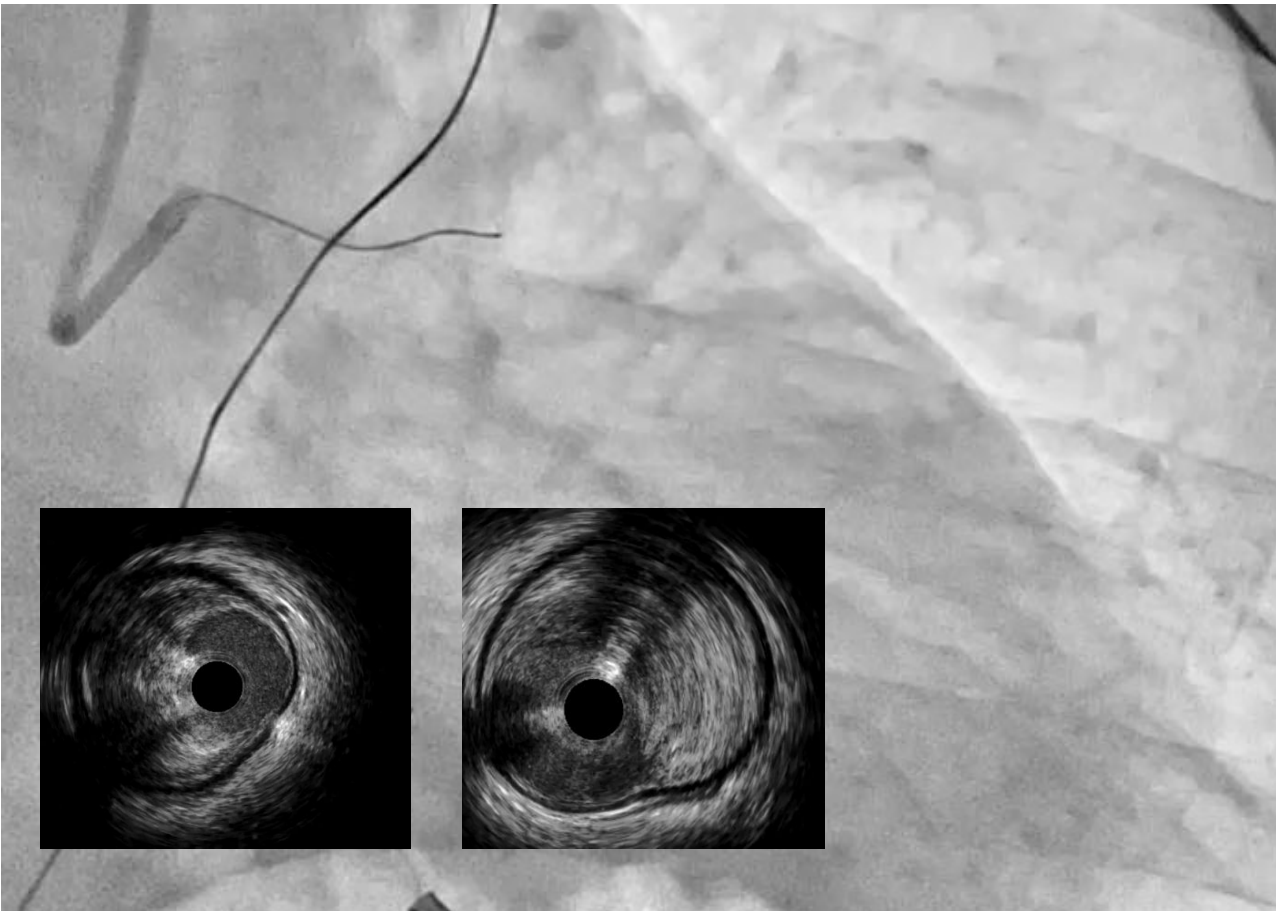
Maximum principal
Tensile stress (MPa)



Cutting Balloon Angioplasty

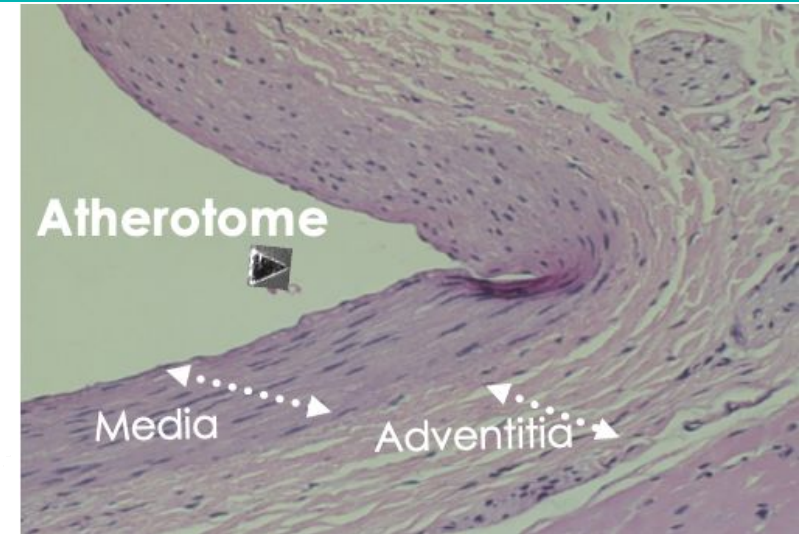
Pressure magnified to precise points at the
athereotomes
controlled pressure dilation
small localized injury confined to the incision sites

Cutting in fibrotic lesions- 38y male, anterior MI



Atherotomes Are Microsurgical

Smaller Than 2 Human Hairs



Pre-clinical swine coronary artery post Cutting Balloon¹

Atherotome Cutting Height	127 µm
Human LAD Media Thickness ¹	320 µm
Human LAD Wall Thickness ¹	900 µm

¹Data on file at Boston Scientific. Results of bench models are not predictive of clinical performance. Photos taken by Boston Scientific.

Safety- Coronary perforations, incidence with cutting balloon

Study Flow

A 2016 analysis of >500,000 cases from the BCIS database on the incidence, determinants, and outcomes of coronary perforation during PCI in the UK

N=16,990 (99.7%)
No Perforation with
Cutting Balloon Use

N=59 (0.3%)
Perforation with
Cutting Balloon Use

Significant Association Between Cutting Balloon Use and Fewer Perforations

Variable	Odds Ratio (95% CI)	P-Value
Cutting Balloon Use	0.62 (0.43–0.89)	0.010

lesion preparation with an optimally sized and inflated Cutting Balloon removes the need for overly-aggressive POBA dilatations in resistant lesions

Cutting in fibrotic lesions- 38y male, ACS



Chapter 1- the idea behind cutting balloons

U.S. Multicenter Palmaz-Schatz stent registry, there was a 30% rate of restenosis in the 1,189 patients.^[25] Of the 39.7% of patients treated with POBA for ISR, 54% percent had recurrent restenosis of the target vessel.

Review: Cutting Balloon Angioplasty Michael S. Lee, MD, Varinder Singh, MD, Thomas J. Nero, MD, James R. Wilentz, MD; J Invasive Cardiol. 2002;14(9)

Cutting Balloon

Less Balloon Slippage in Resistant Lesions

RESCUT Randomized Trial



Key Points: Cutting Balloon led to

- Use of fewer balloons
- Less requirement for additional stenting
- **Significantly less balloon slippage**

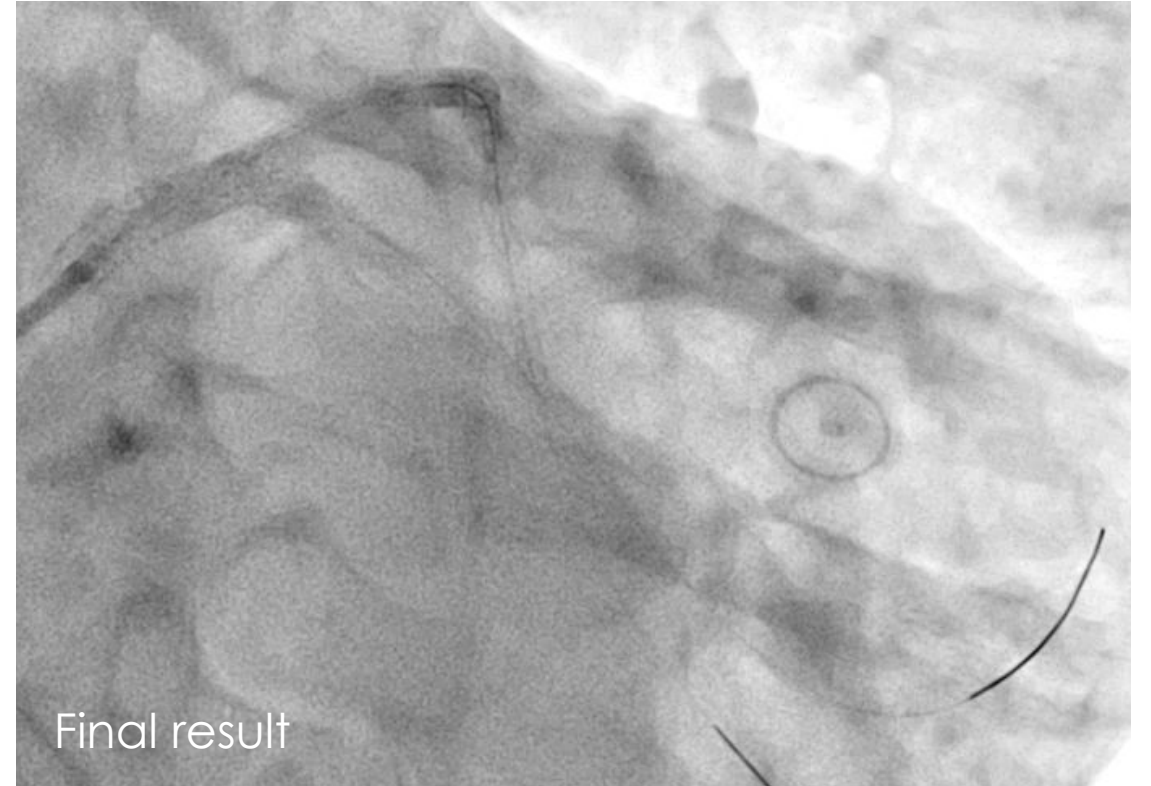
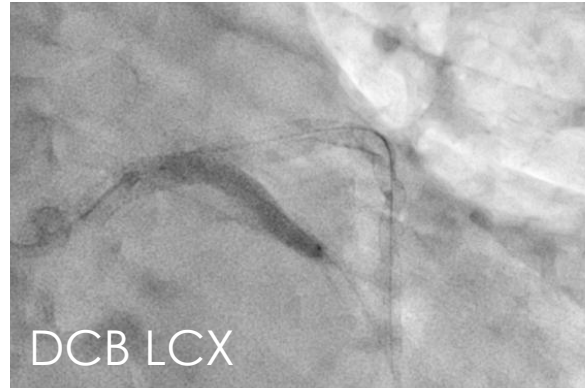
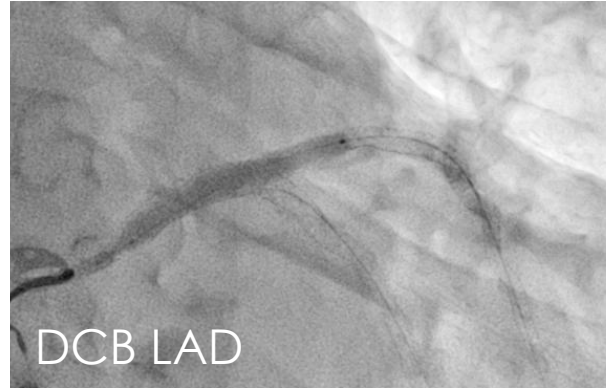
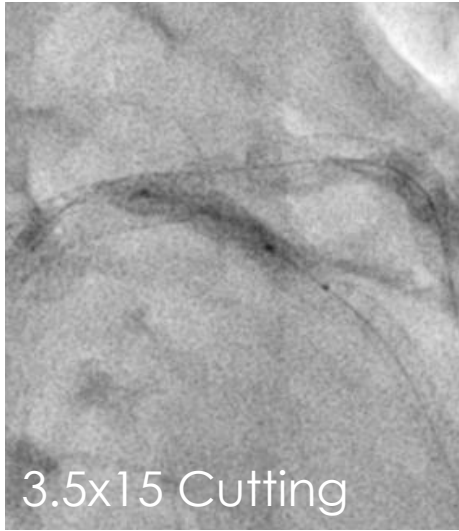
Cutting in Instentrestenosis



Cutting in Instentrestenosis



Cutting in Instentrestenosis



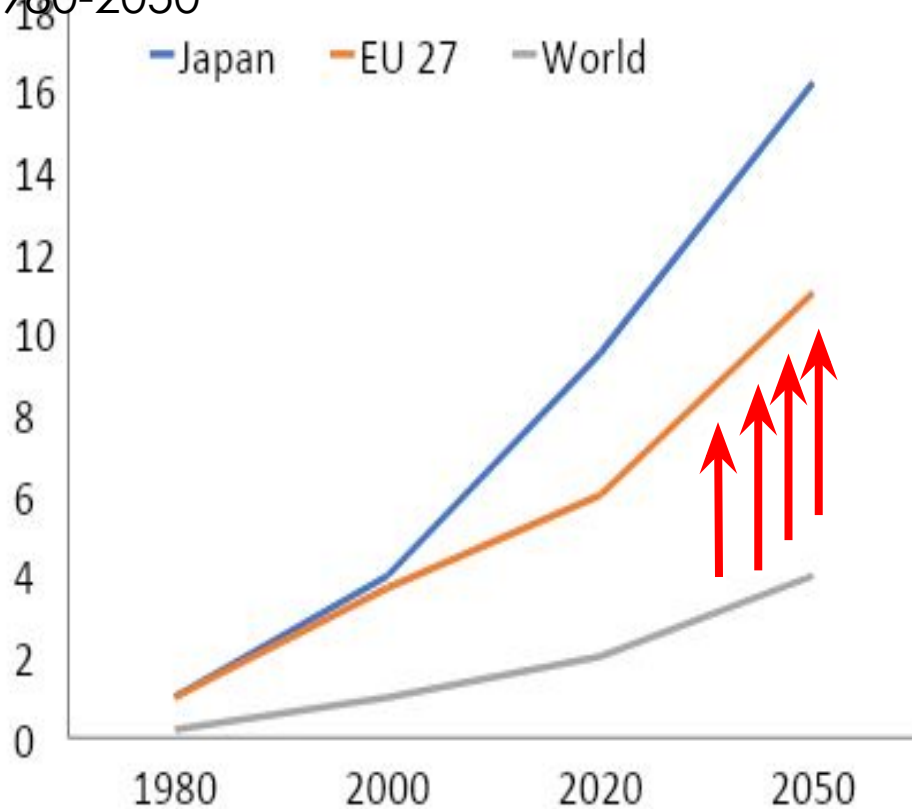
Cutting balloons occupy a niche role, mainly in ISR and selected fibrotic lesions, but have largely been displaced in complex calcified disease.

Chapter 2- calcium treatment



Change of patient population

Share of the population aged over 80 years
1980-2050



...Characteristics of PCI
patients have changed
substantially over time,

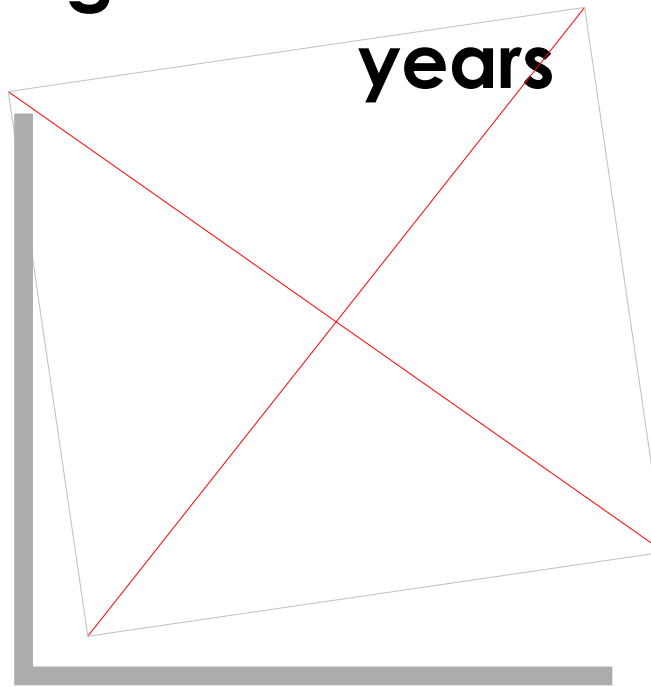
...

The increasing age and
proportion of patients
undergoing PCI greatly
influence outcome

Population trends in percutaneous coronary intervention: 20-year results from
the SCAAR

Calcium treatment

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



Identifying needs

*Criteria for Ca Modification:

- 360° arc of calcium
- >270° arc of calcium and >5 mm length of calcium

Additional characteristics of calcified lesions that may require calcium modification:

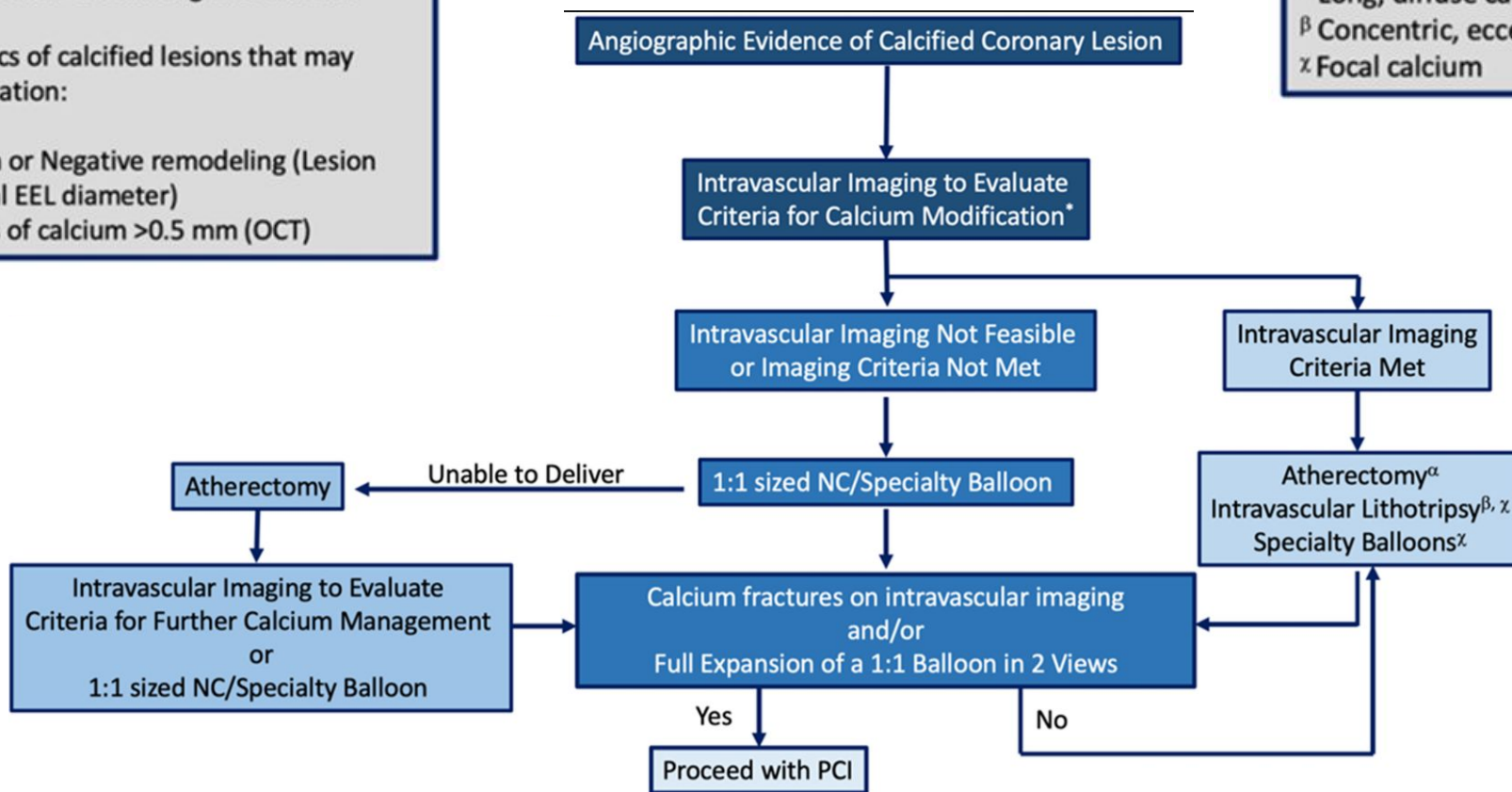
- Calcified nodule
- Lesion EEL <3.5 mm or Negative remodeling (Lesion EEL diameter <distal EEL diameter)
- Minimum thickness of calcium >0.5 mm (OCT)

Considerations

^α Long, diffuse calcium with or without nodular calcium

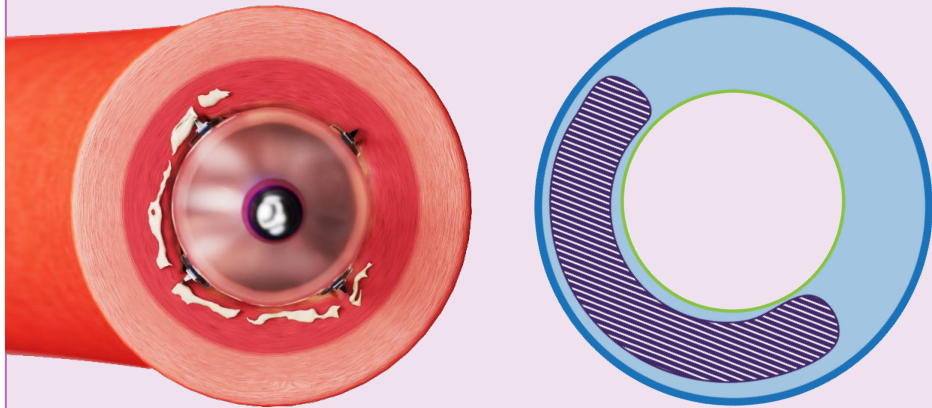
^β Concentric, eccentric, or nodular calcium

^χ Focal calcium

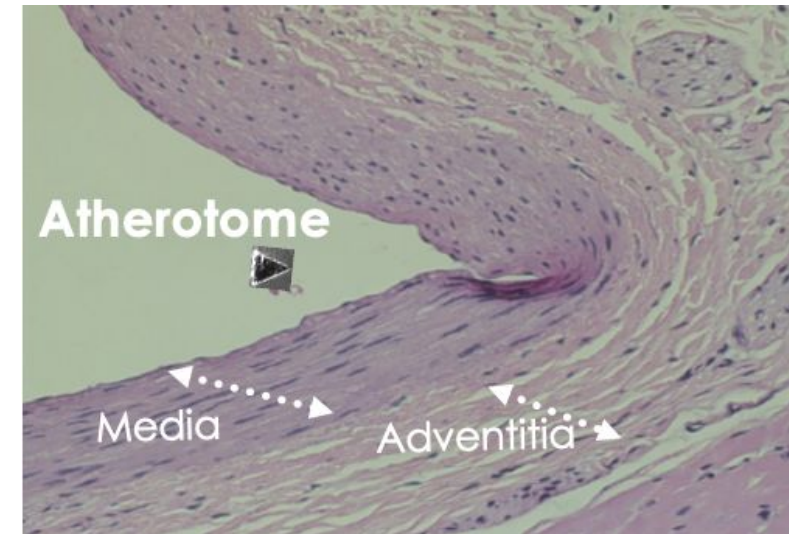
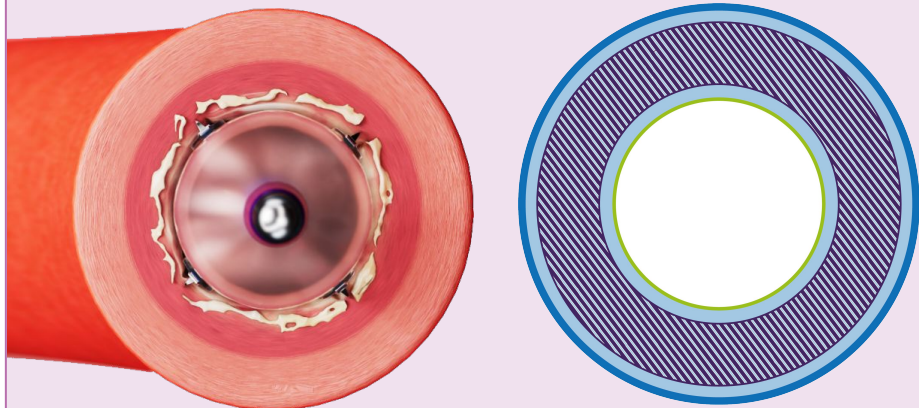


Mechanism of action

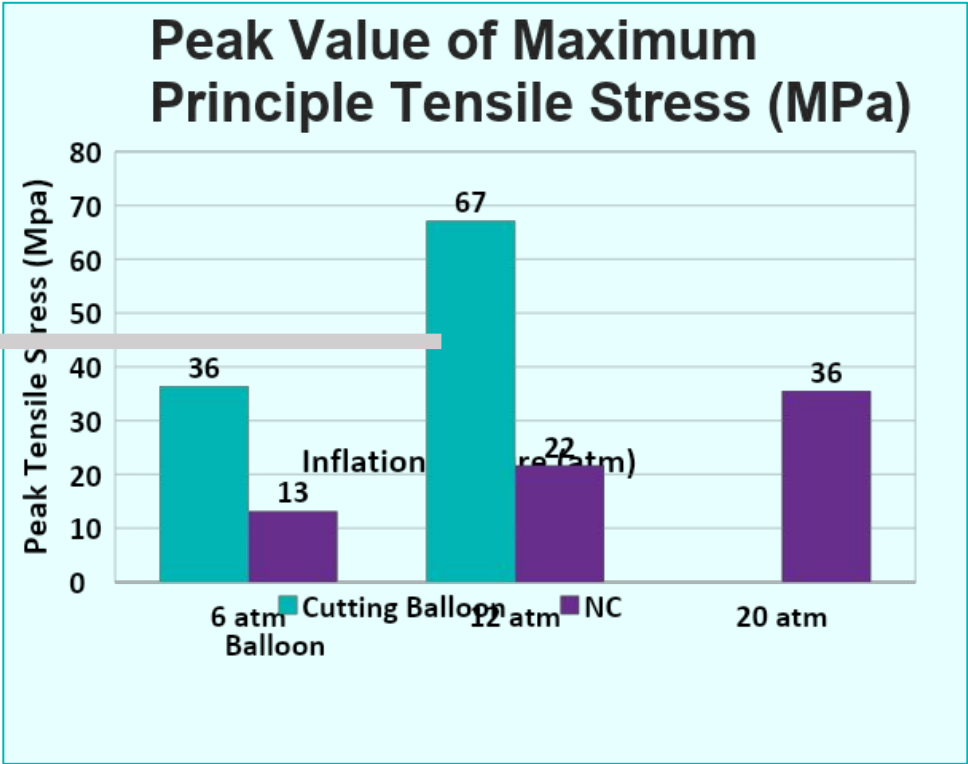
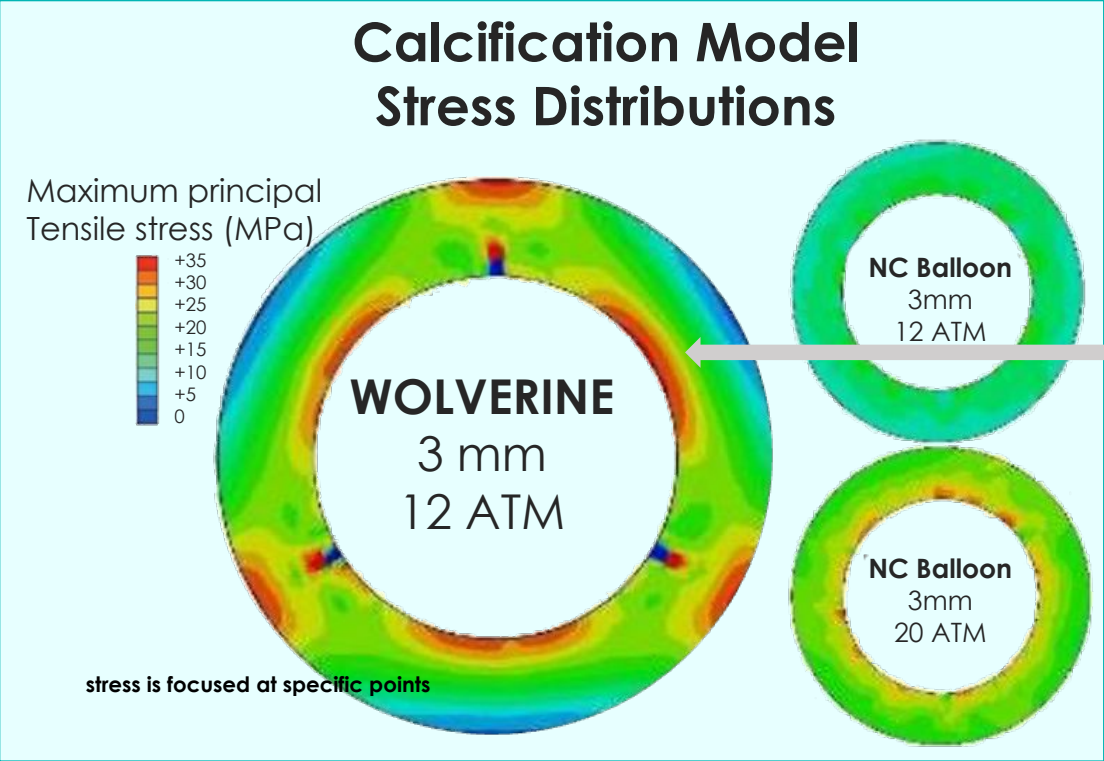
Eccentric Calcium Prepared by Cutting Balloon



Concentric Calcium Prepared by Cutting Balloon

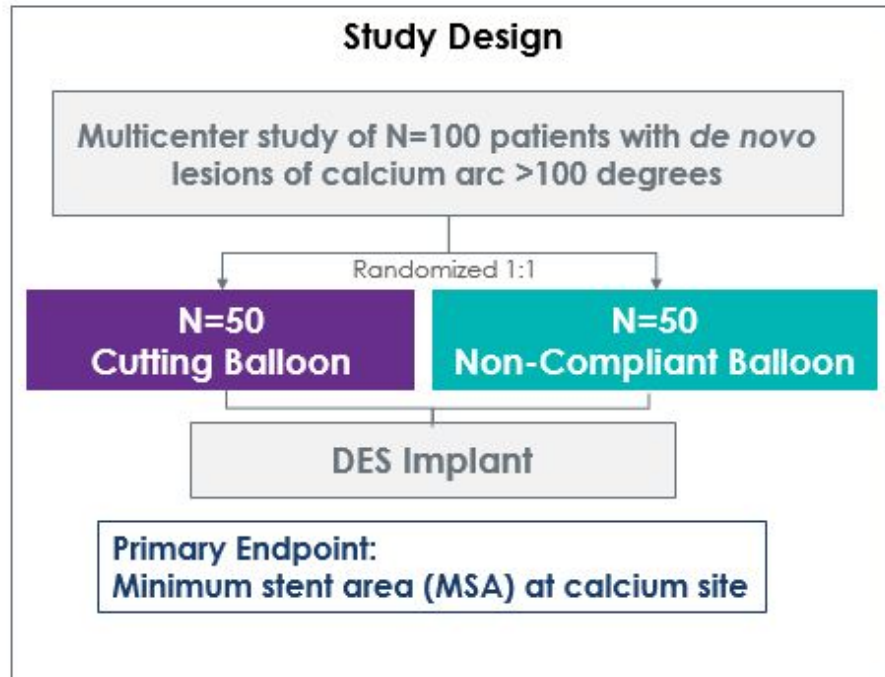


Mechanism of action



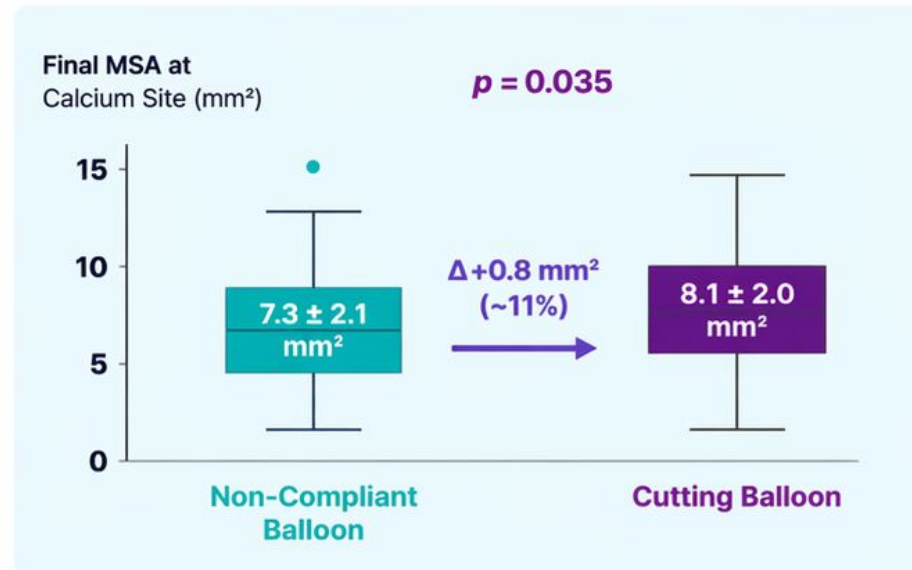
COPS RCT

Cutting Balloon vs Non-Compliant Balloon



PRIMARY RESULT

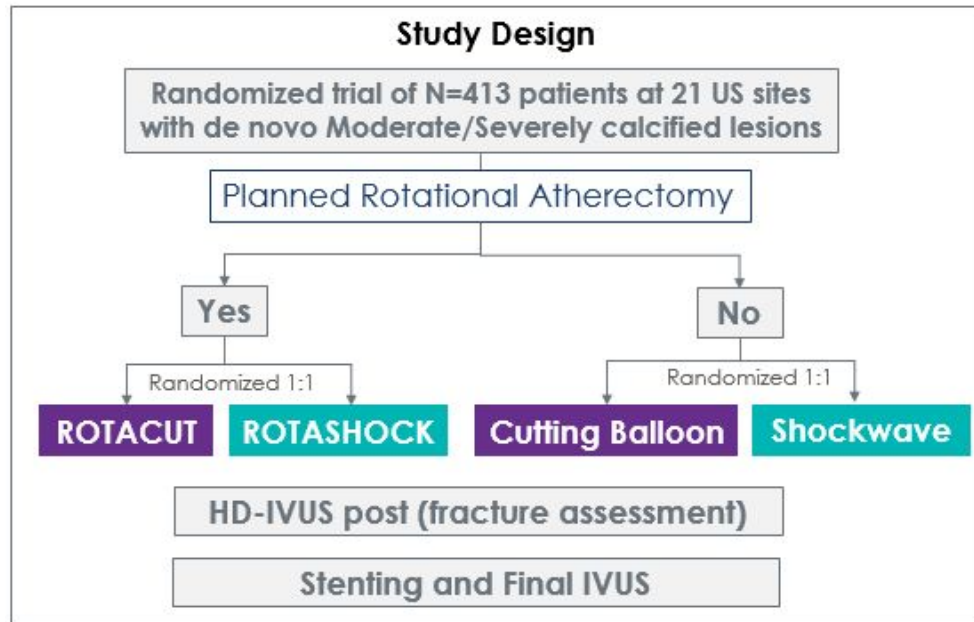
Cutting Balloon Achieved a Significantly Larger MSA at the Site of Maximal Calcium



Cutting Balloon resulted in a significantly larger MSA at the site of max calcium

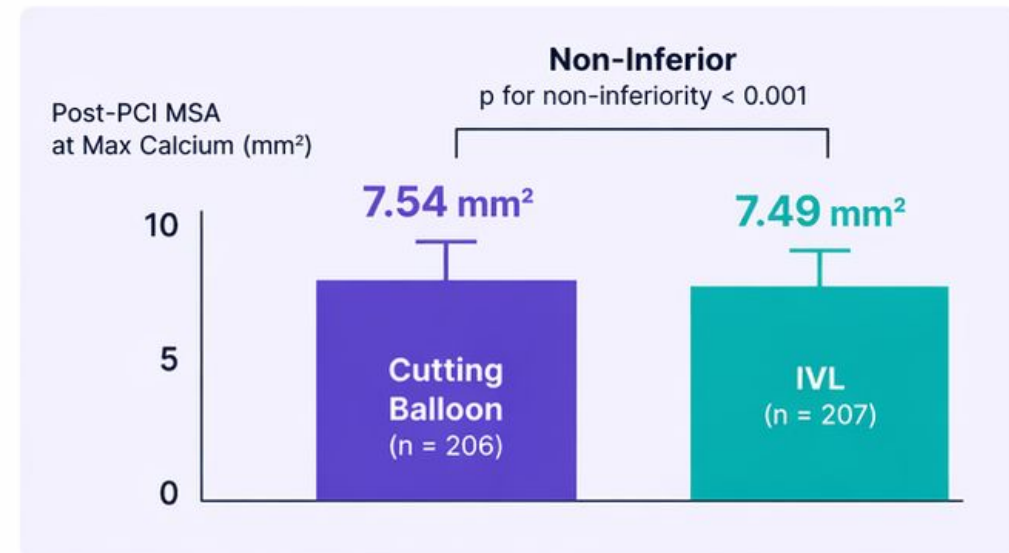
SHORTCUT RCT

Cutting Balloon ± Rotational Atherectomy vs. Shockwave ± Rotational Atherectomy



PRIMARY RESULT

Cutting Balloon was Non-Inferior to IVL
for Stent Expansion at the Site of Maximal Calcium



KEY TAKEAWAYS



Comparable stent expansion and calcium modification
No relevant differences in the overall cohort.



IVL was associated with significantly higher procedural cost.

SHORTCUT RCT

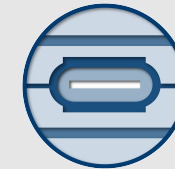
Cutting Balloon ± Rotational Atherectomy vs. Shockwave ± Rotational Atherectomy

Key Characteristics

	IVL N=218	CB N=212
Reference Vessel Diameter	3.5 mm	3.4 mm
Target Lesion Stenosis	87%	89%
Median Max Calcium Arc	347°	338°
0-269°	25.7%	26.0%
270-359°	24.8%	25.5%
360°	49.5%	48.6%
Nodular Calcium	25%	25%
CTO	12.5%	13.5%

Device Technique

On average, CB was used at 17atm with a balloon diameter of 3.1mm and 3.8 inflations



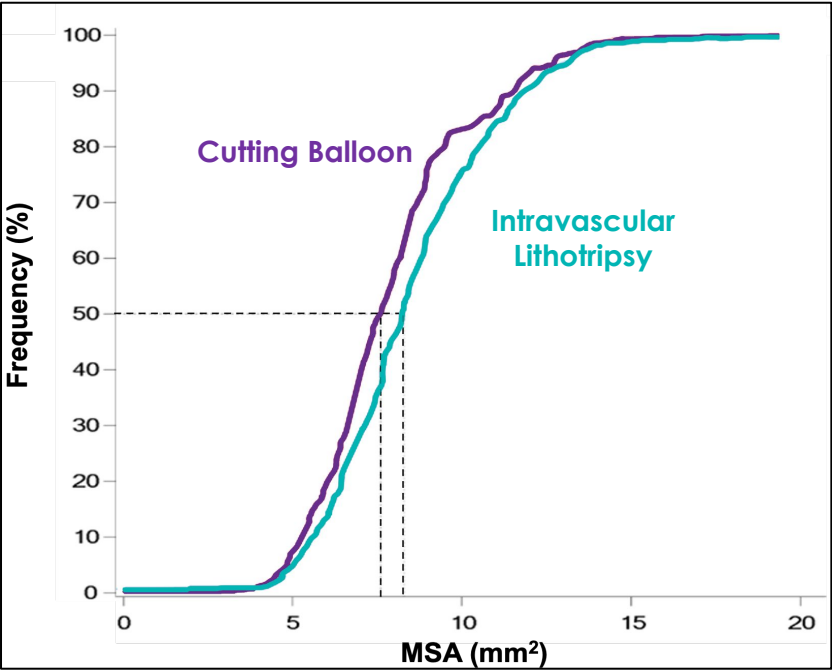
On average, 90 IVL pulses were used with a balloon diameter of 3.5mm



SHORTCUT RCT

Cutting Balloon ± Rotational Atherectomy vs. Shockwave ± Rotational Atherectomy

Primary Endpoint (Total Cohort): MSA at Max Calcium



Significant Interaction for Atherectomy (P=0.044)



Endpoint	IVL	CB	P _{Non-inferiority}
MSA at Max Ca ⁺⁺	8.8 ± 2.7 mm ²	7.7 ± 2.3 mm ²	0.399

Endpoint	RotaTripsy	RotaCut	P _{Non-inferiority}
MSA at Max Ca ⁺⁺	8.4 ± 2.3 mm ²	8.3 ± 2.5 mm ²	<0.001

Safety



Endpoint	IVL	CB	P
IVL or CB Complications	Infrequent & Comparable		0.34
In-Hospital MACCE	1.0%	1.0%	1.00
30-Day MACCE	2.9%	2.9%	1.00

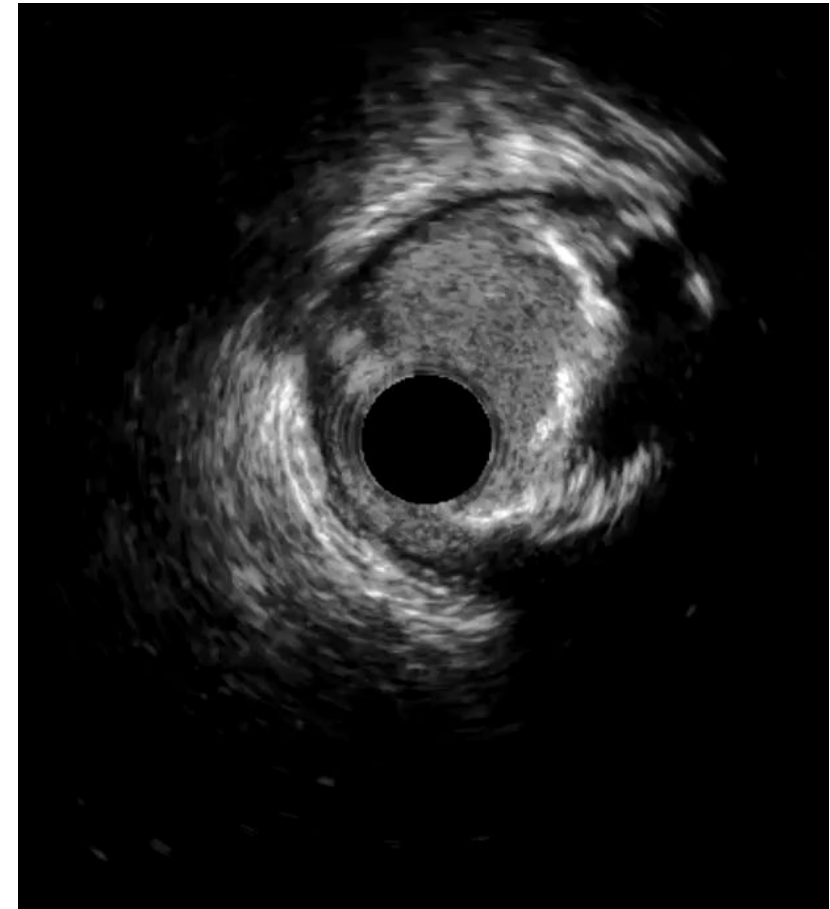
Cost



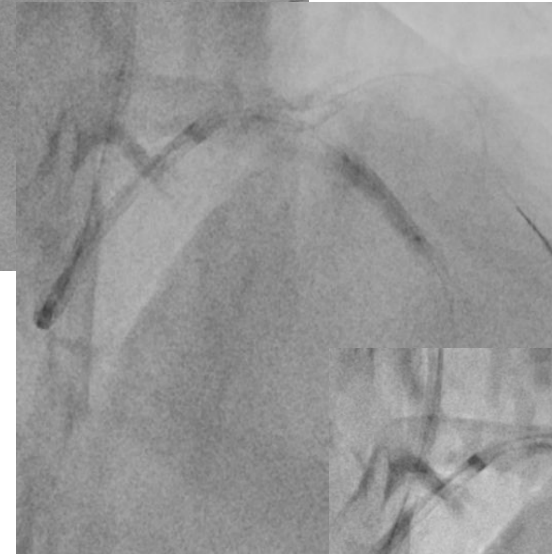
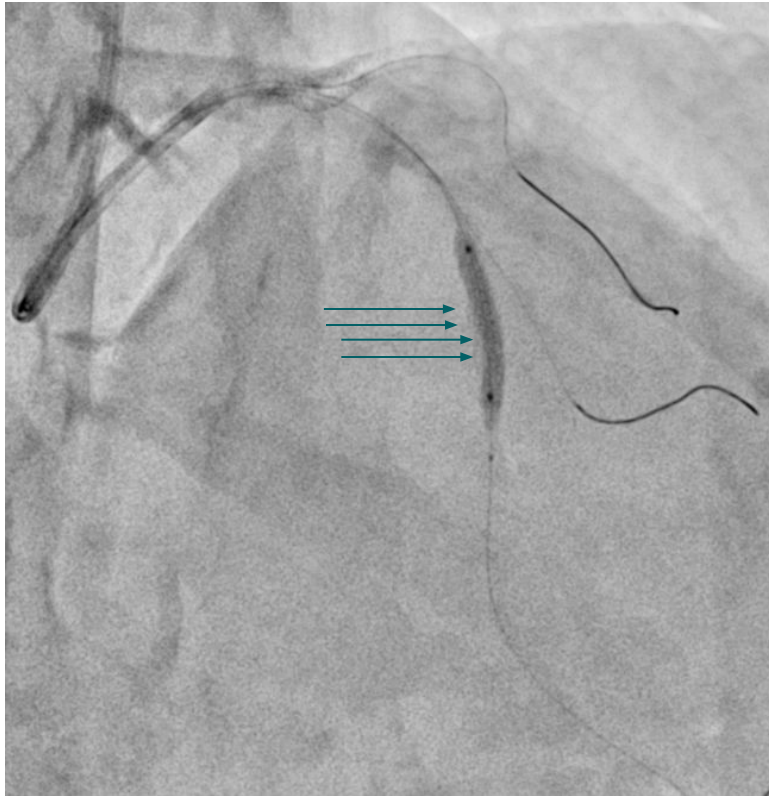
Endpoint	IVL	CB	P
Procedure Cost	\$13,051	\$9,409	<0.001

Endpoint	IVL N=218 Lesions	CB N=212 Lesions	P Non-inferiority
MSA at Max Ca ⁺⁺	8.6 ± 2.5 mm ²	8.0 ± 2.4 mm ²	0.007*
Stent Expansion at Max Ca ⁺⁺	97.7 ± 24.0 %	97.7 ± 25.9 %	P=0.99
MSA Overall	7.1 ± 2.2	6.9 ± 2.1	P=0.25
Calcium Fracture	77.4%	78.9%	P=0.72

PCI LAD



Proper usage of cutting Balloons

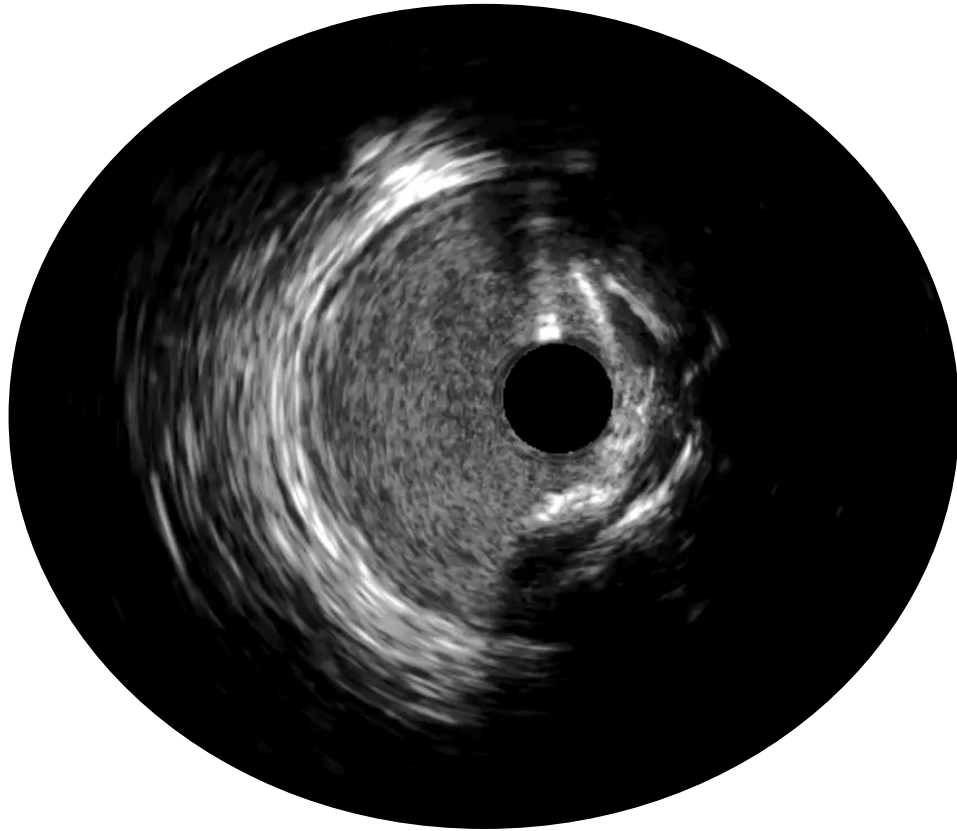


□ **Multiple Inflations!!**

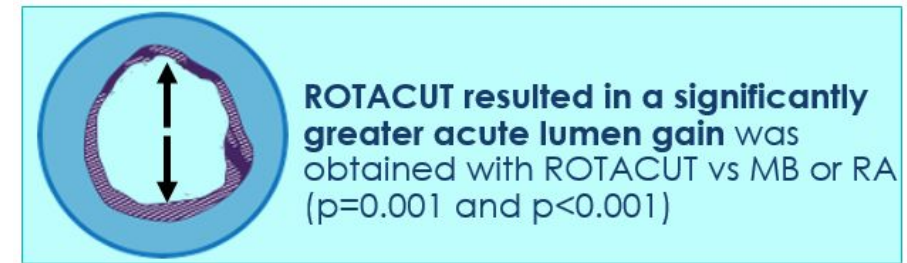
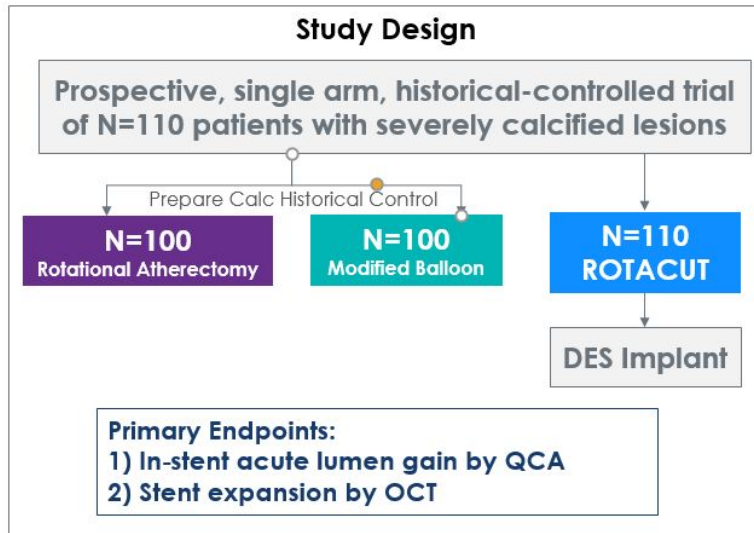


Average inflations of Cutting balloon in ShortCut 3.8 times...

The beauty of plaque modification

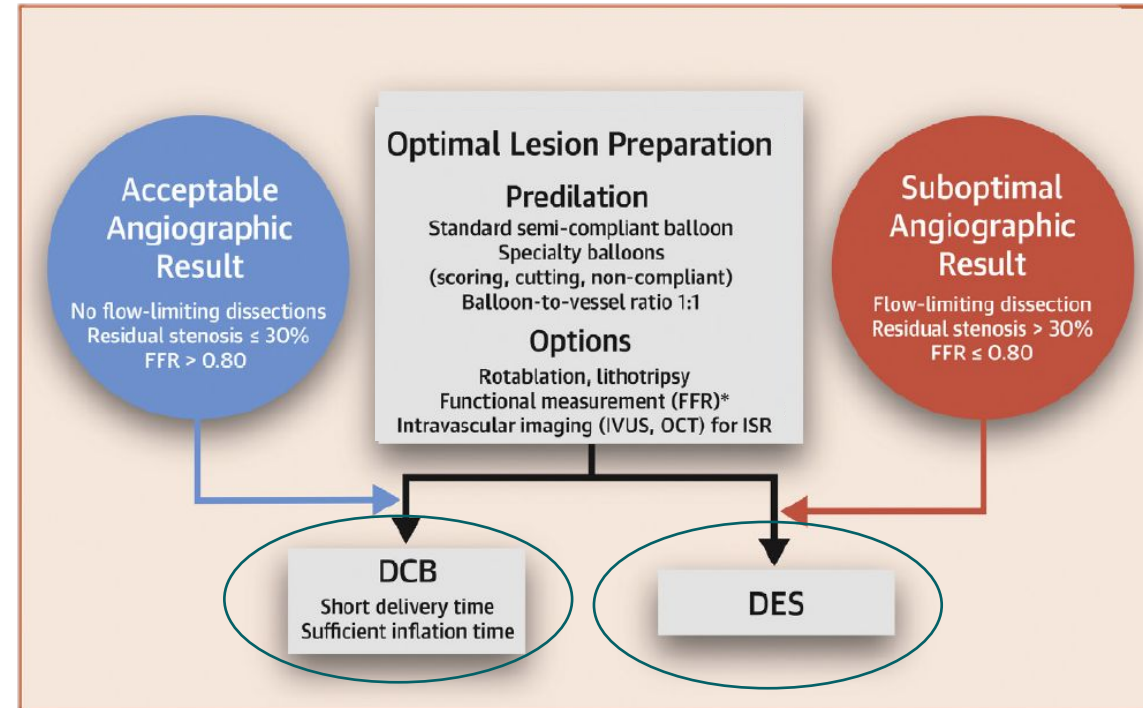


PREPARE CALC Combo ROTACUT vs Rotational Atherectomy vs Modified Balloons



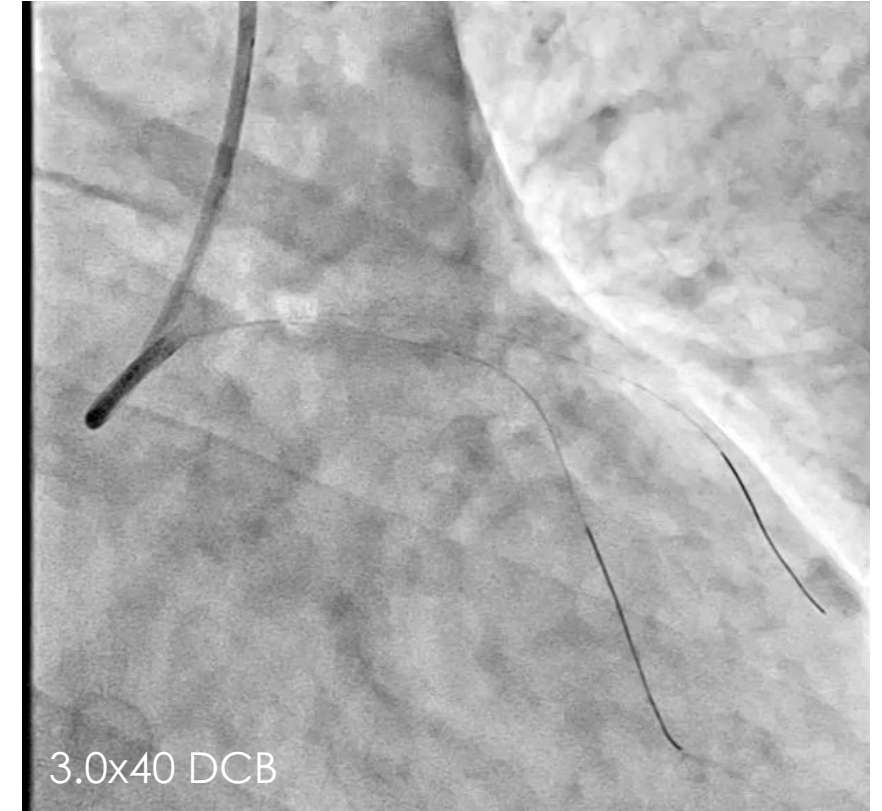
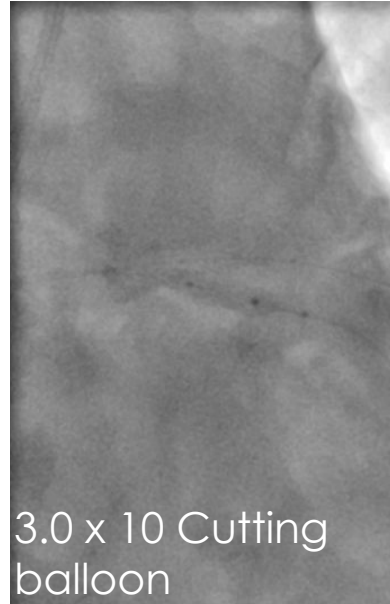
Chapter 3- cutting in drug eluting balloon therapies

Modern eluting therapies and Cutting devices



Jeger R et al. JACC Cardiovasc Interv. 2020.;13(12):1391-1402.

Chapter 3-



Reduces uncontrolled, flow-limiting dissections
Controlled microdissections facilitate drug transfer*

Take-home messages

Cutting Balloons are not a niche any more

Calcium determines the result

- If you don't modify it, you accept lesion failure

Cutting balloons enable controlled, focal plaque modification

- Resulting in higher MSA at calcium site- **proven in randomized trials**

TOOLS ARE NOT COMPETITORS- THEY ARE SEQUENTIAL STEPS