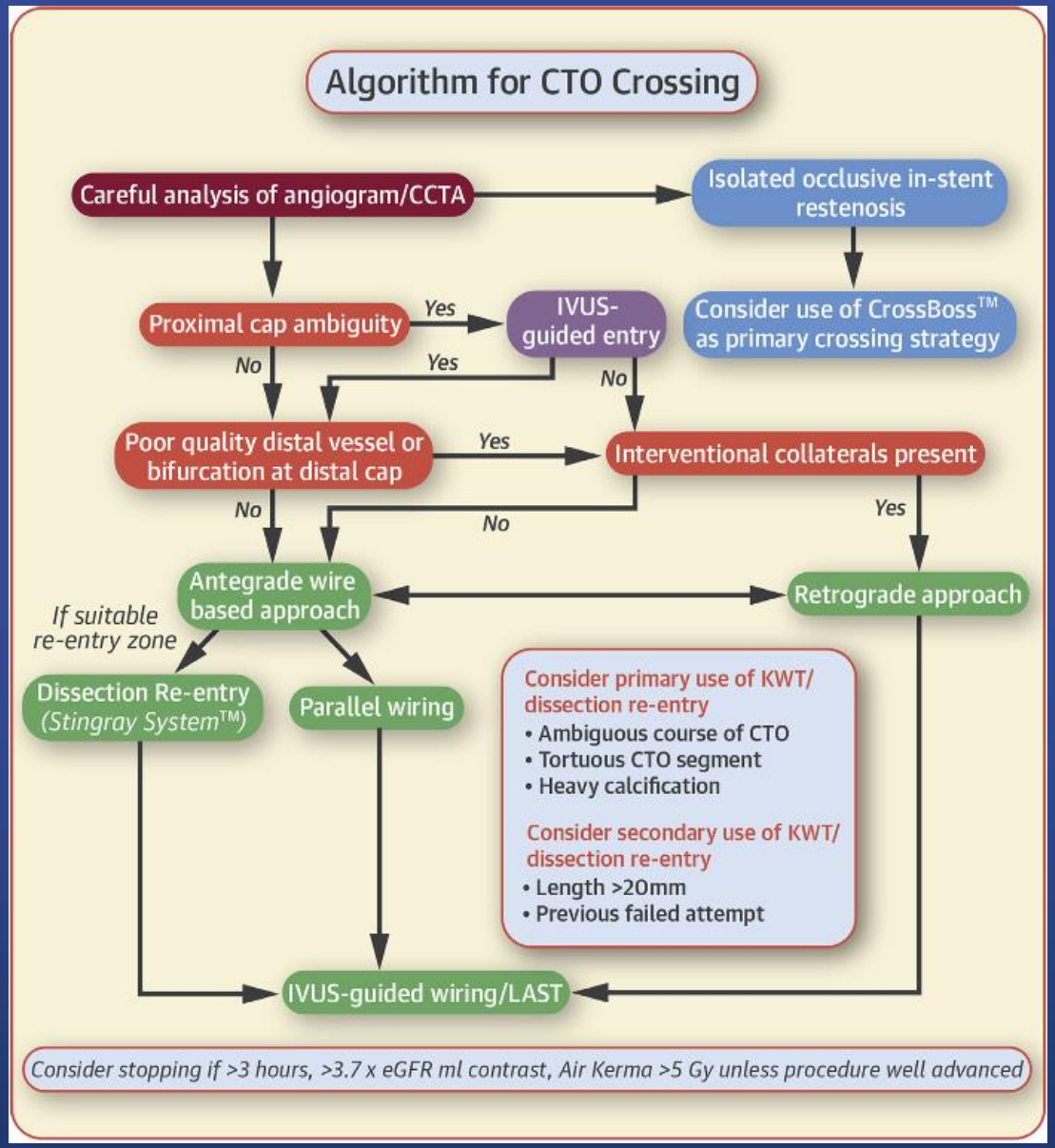
Chronic Total Occlusion

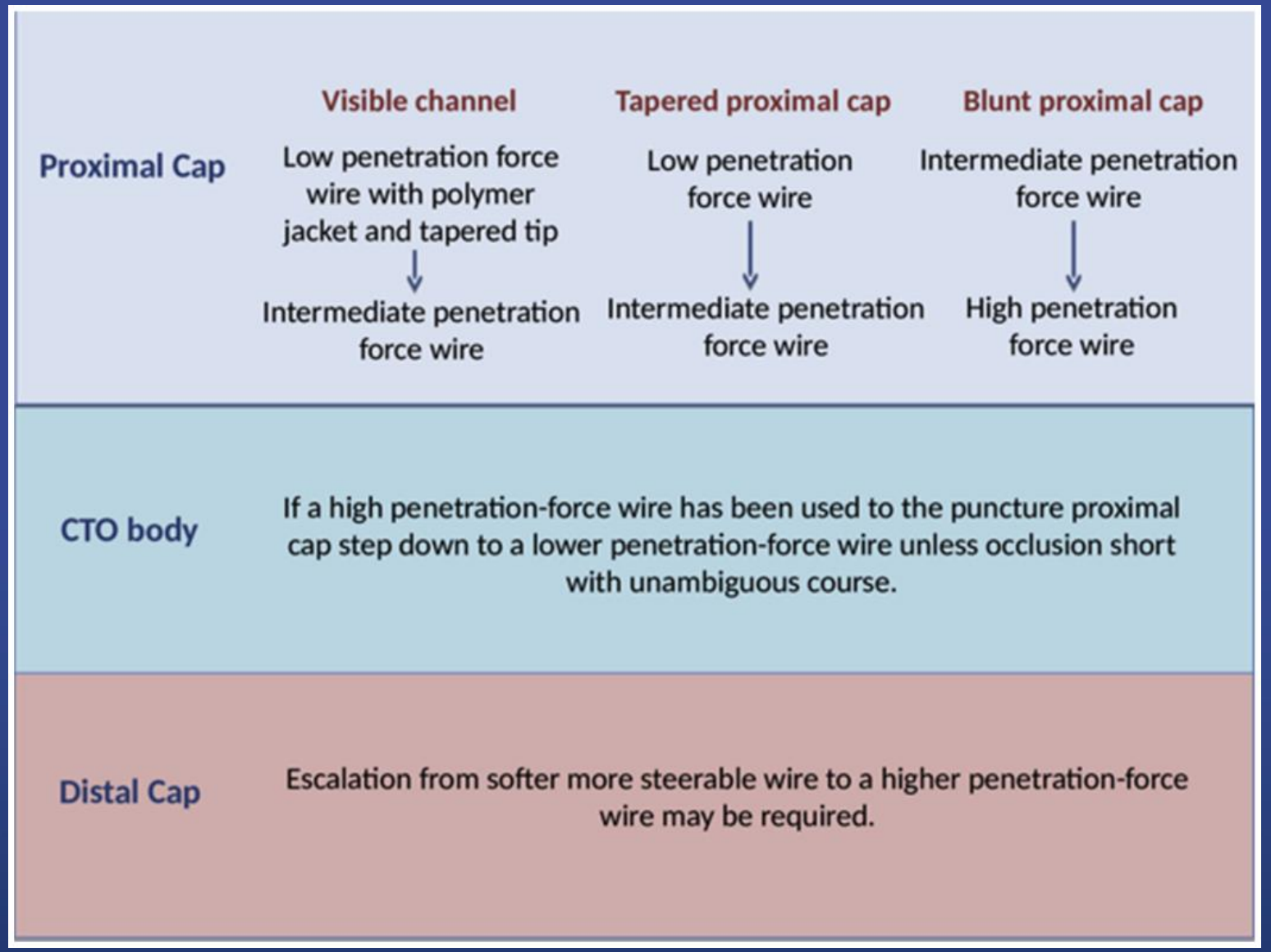
Trials and Guidelines

Algorithm for crossing CTO from Asia Pacific CTO club



Harding et al. JACC cardiovascular intervention Vol. 10, No. 21, 2017

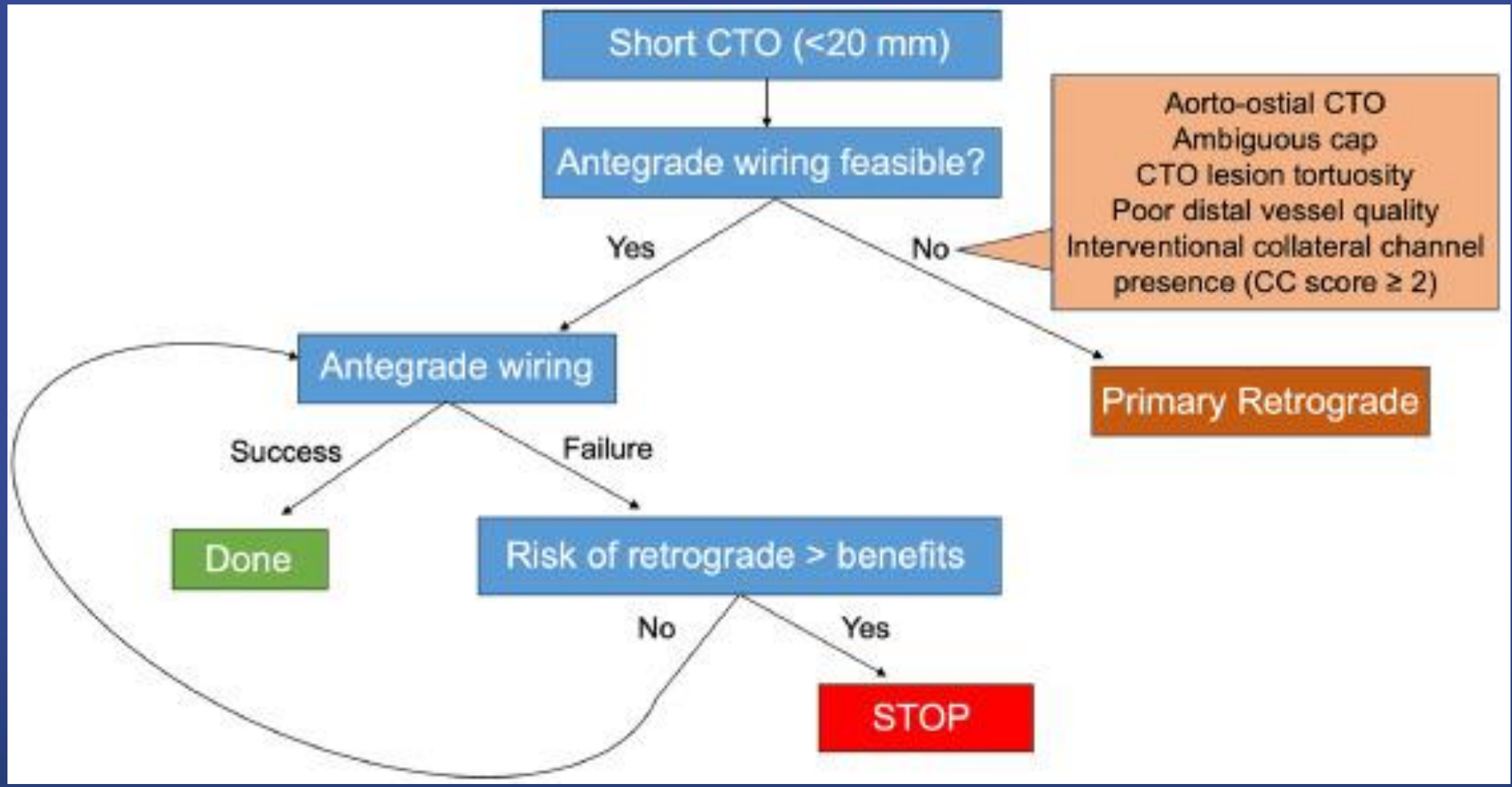
Algorithm for antegrade wire escalation



Proximal Cap	Visible channel Low penetration force wire with polymer jacket and tapered tip ↓ Intermediate penetration force wire	Tapered proximal cap Low penetration force wire ↓ Intermediate penetration force wire	Blunt proximal cap Intermediate penetration force wire ↓ High penetration force wire
CTO body	If a high penetration-force wire has been used to the puncture proximal cap step down to a lower penetration-force wire unless occlusion short with unambiguous course.		
Distal Cap	Escalation from softer more steerable wire to a higher penetration-force wire may be required.		

Harding et al. JACC cardiovascular intervention Vol. 10, No. 21, 2017

The Role of Retrograde Crossing in Short CTO



Deniz et al, Am J Cardiol, 2024 Apr

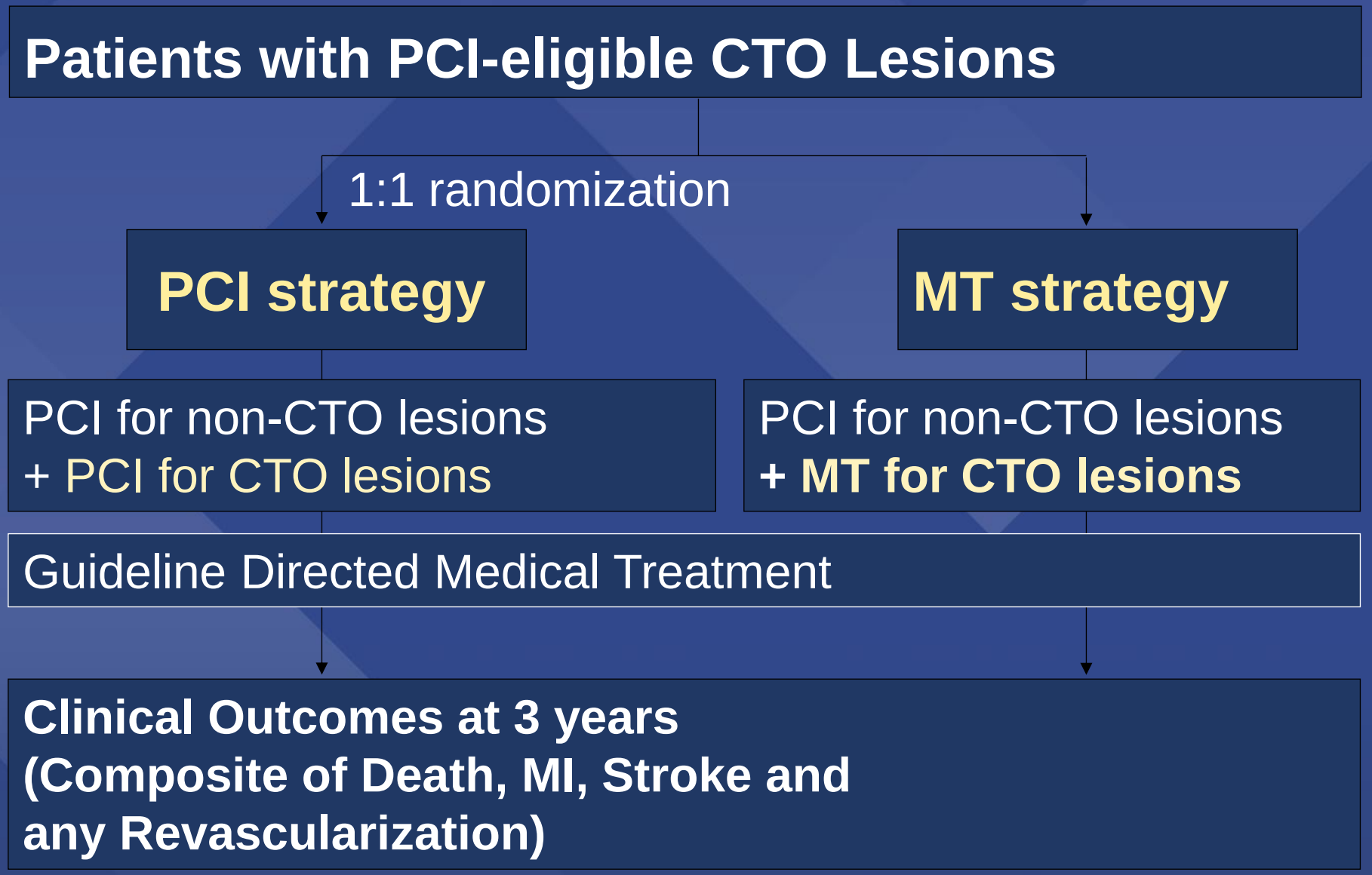
Coronary Artery CTO Revascularization Criteria

Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses		CCS angina class (*appropriate use score, 1-9)		
Noninvasive testing	**Maximal anti-ischemic medication**	**ASx**	**I, II**	**III, IV**
Low-risk findings	No	I(1)	I(2)	I(3)
	Yes	I(1)	U(4)	U(6)
Intermediate-risk findings	No	I(3)	U(4)	U(6)
	Yes	U(4)	U(5)	A(7)
High-risk findings	No	U(4)	U(5)	A(7)
	Yes	U(5)	A(7)	A(8)

*** 1~3 : nappropriate, 4-6 : Uncertain, 7-9 : Appropriate**

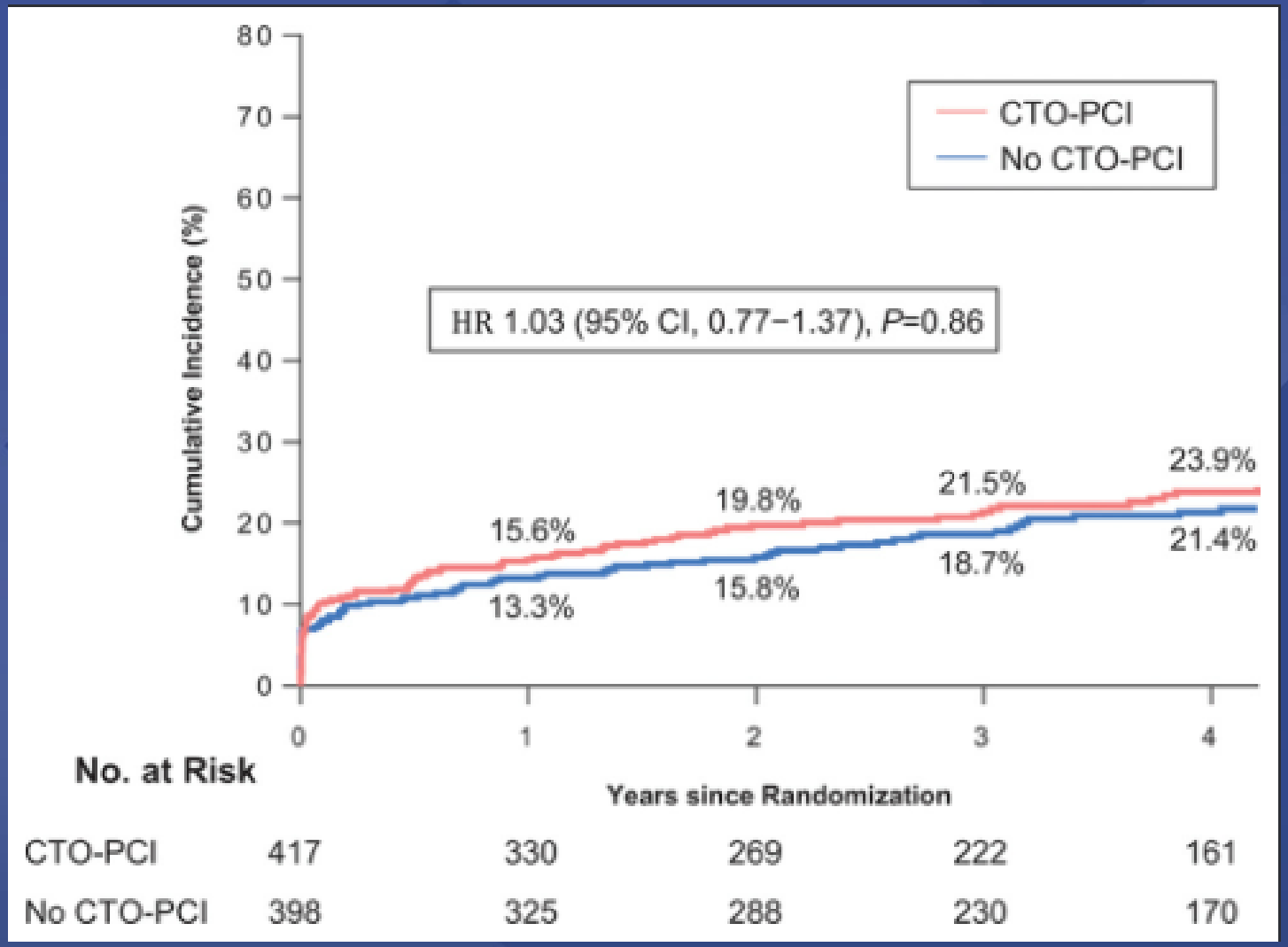
Patel et al. JACC Vol. 59, No. 9, 2012

DECISION-CTO



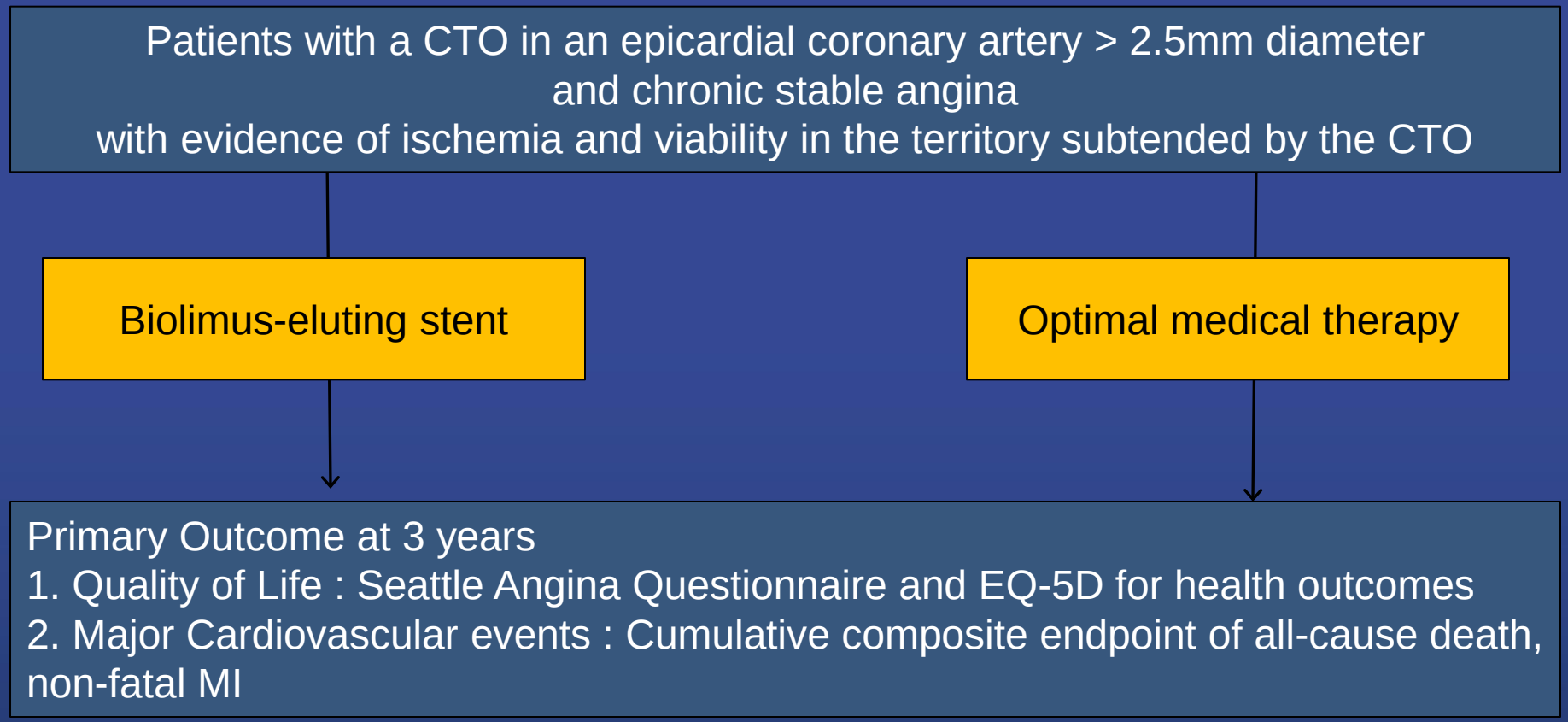
DECISION-CTO

Composite of Death, MI, Stroke and any Revascularization after 3-year



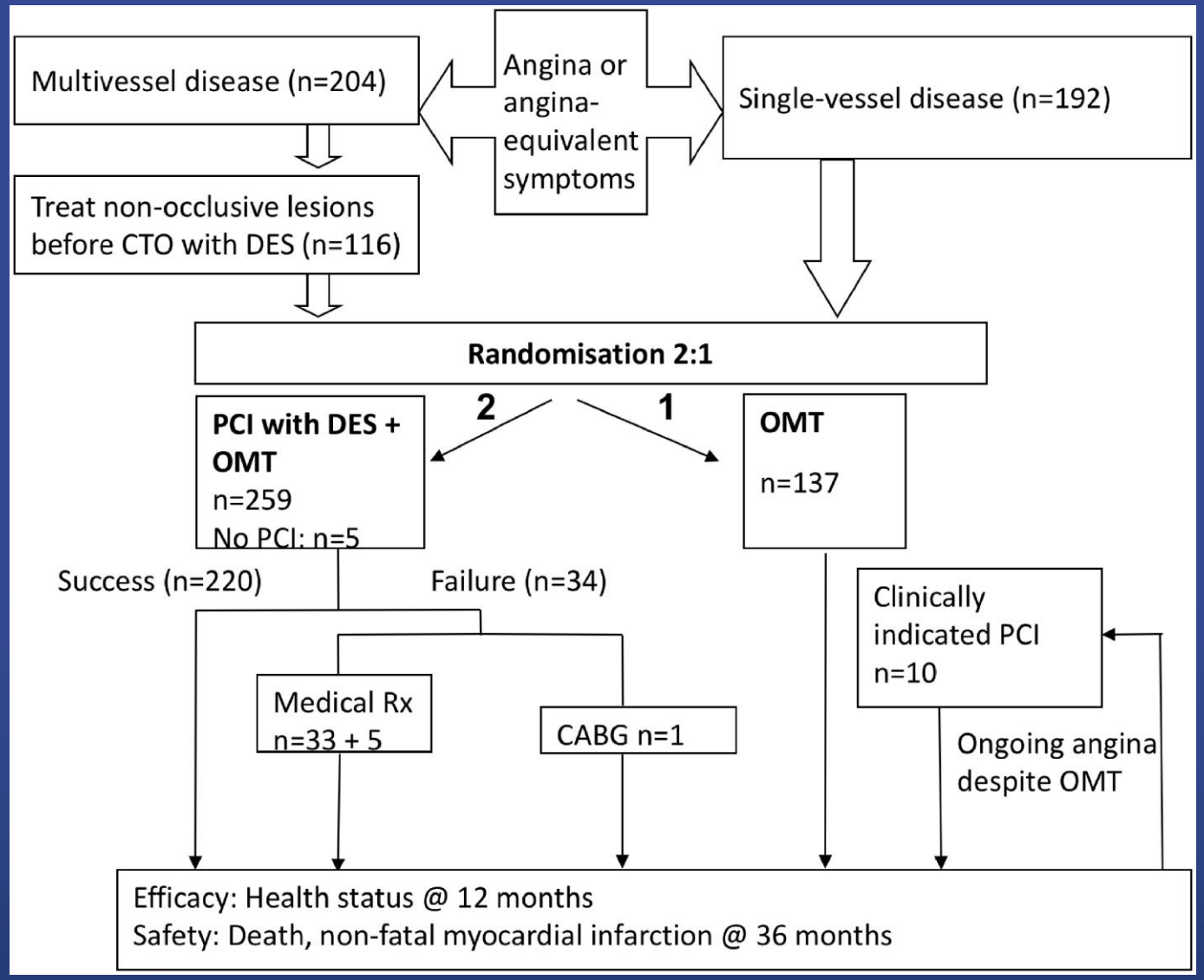
Seung-Whan Lee et al. Circulation Vol. 139, No. 14, 2019

EURO-CTO



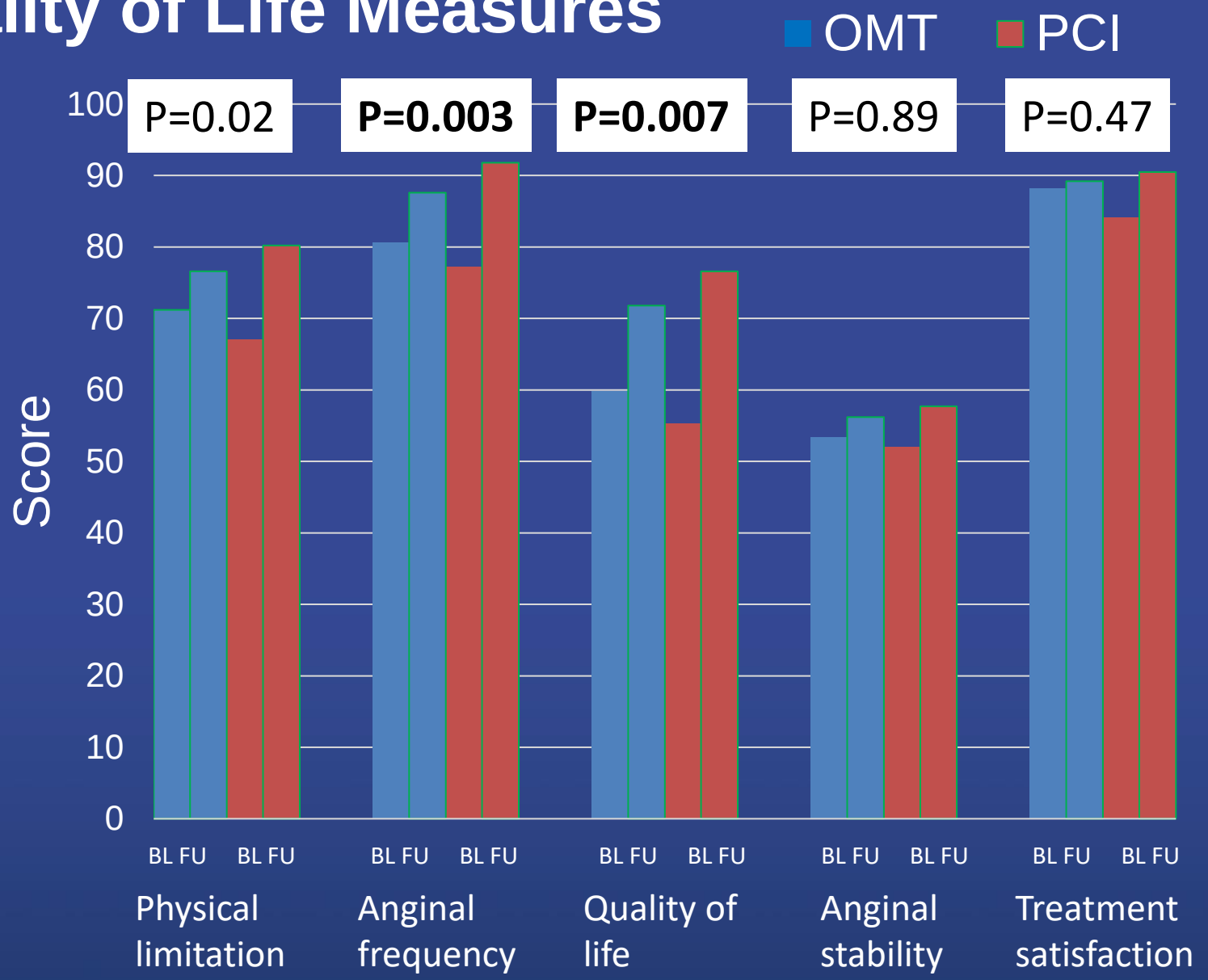
G.S. Werner et al. Eur Heart J. Vol. 39, Issue 26, 2018

EURO-CTO: Study flowchart



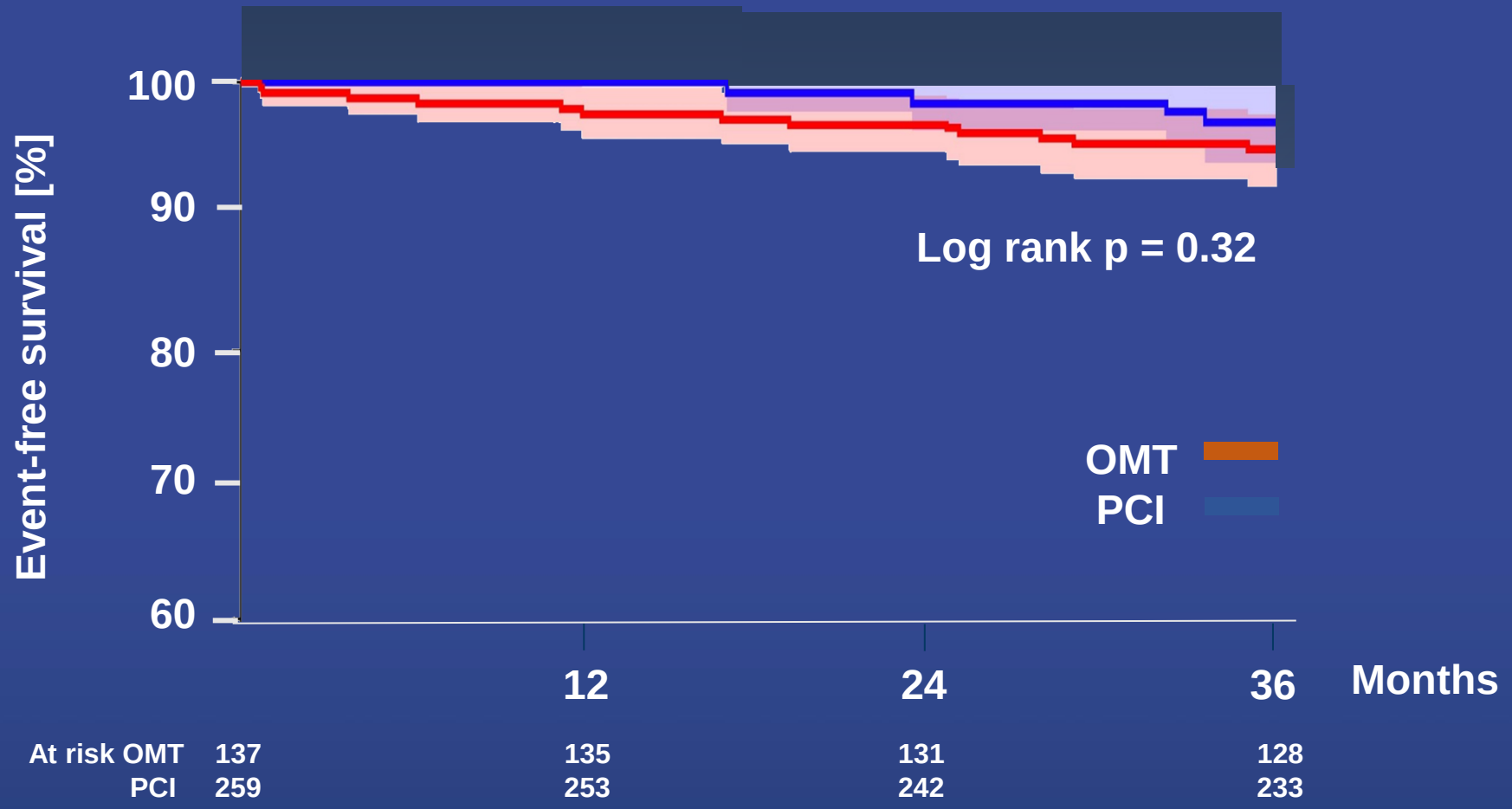
G.S. Werner et al. Eur Heart J. Vol. 39, Issue 26, 2018

Quality of Life Measures



G.S. Werner et al. Eur Heart J. Vol. 39, Issue 26, 2018

Primary safety endpoint at 36 months



G.S. Werner et al. Eur Heart J. Vol. 39, Issue 26, 2018

Primary safety endpoint at 36 months

	OMT (N=137)	PCI (N=259)	P (log rank)
Patients with any adverse event	27 (20.1)	27 (10.7)	0.019
Safety events	4 (2.9)	13 (5.0)	0.32
Cardiovascular death	2 (1.5)	7 (2.7)	0.42
Non-fatal MI	2 (1.5)	6 (2.3)	0.56
Ischemia-driven revascularization	25 (18.2)	19 (7.3)	0.0035
Target revascularization	23 (16.8)	10 (3.9)	0.0002
Cerebrovascular event	1 (0.7)	5 (1.9)	0.27
Stent thrombosis	0	1 (0.4)	

G.S. Werner et al. Eur Heart J. Vol. 39, Issue 26, 2018

OPEN-CTO

Outcomes, Patient health status, and Efficiency iN Chronic Total Occlusion hybrid procedures

1. Patients with at least one CTO vessel
2. 18 years and older
3. Patients is scheduled for a PCI for at least one CTO with TIMI antegrade flow of 0

- Investigator-initiated multicenter, single-arm registry (12 centers with 1000 patients)

- Observational study
- Hybrid approach

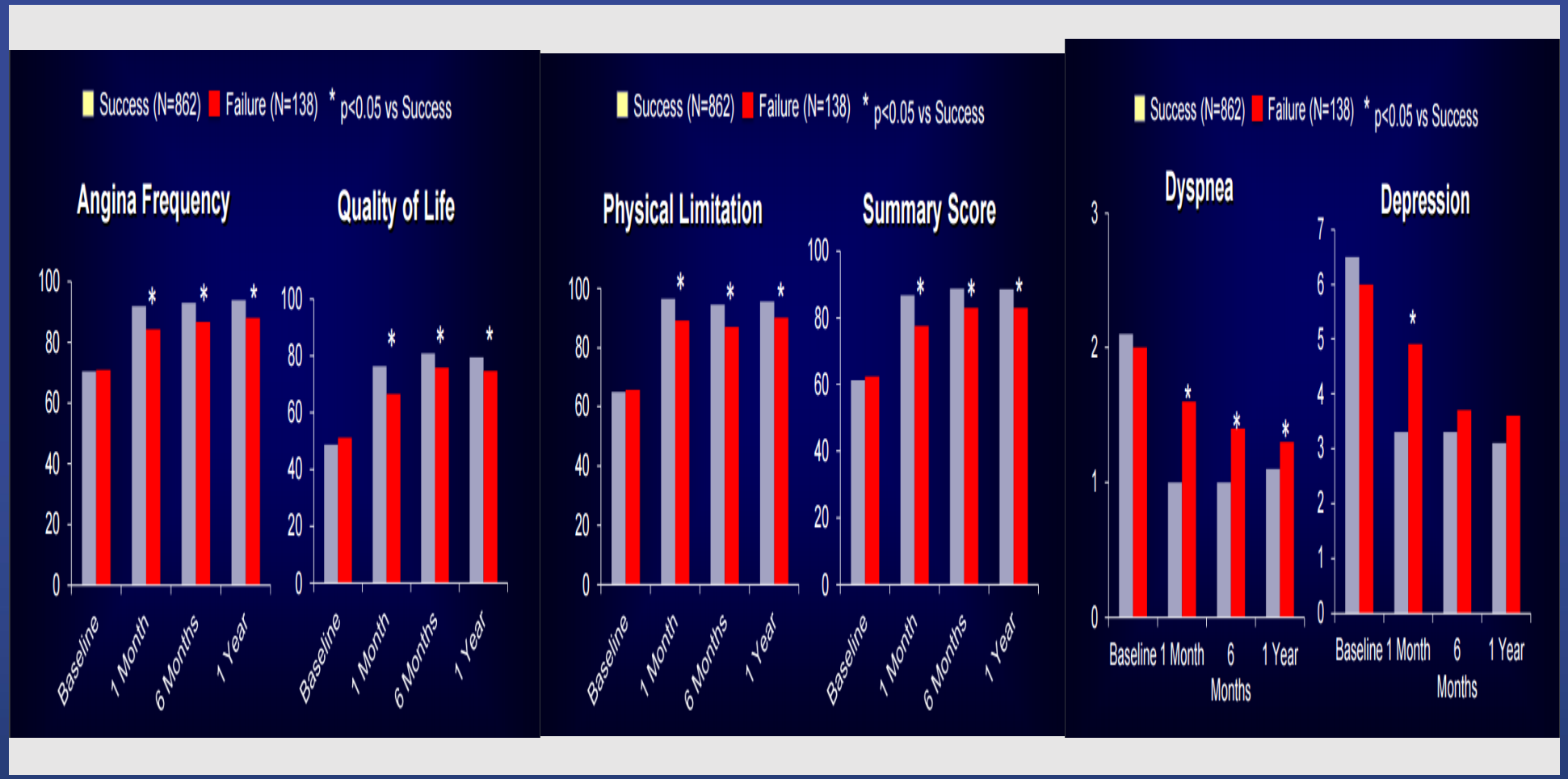
1, 6 and 12 month outcomes

1. Health status
2. Resource use
3. Depression
4. Rehospitalization
5. Survival
6. Cost

Grantham JA, CTO Summit 2017

OPEN-CTO

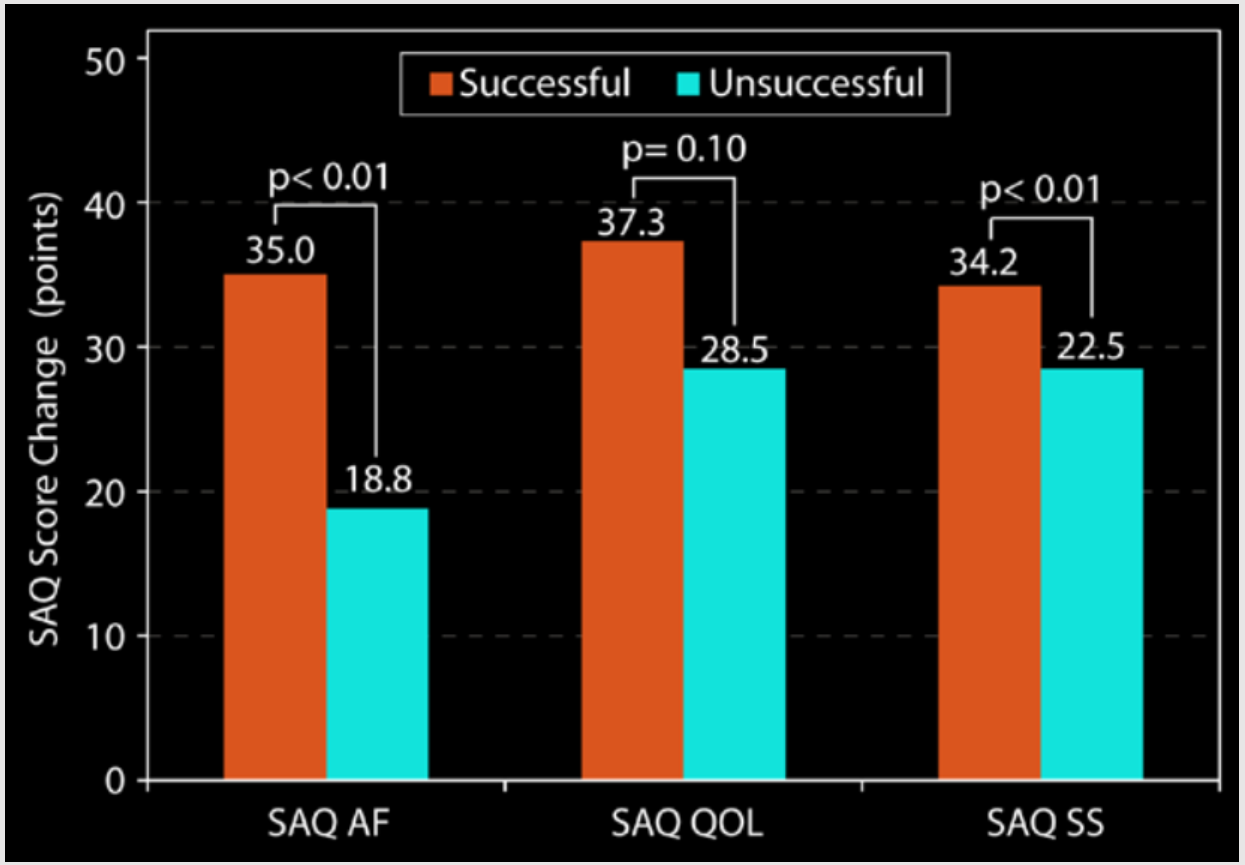
Health Status Trajectory after CTO-PCI



Grantham JA, CTO Summit 2017

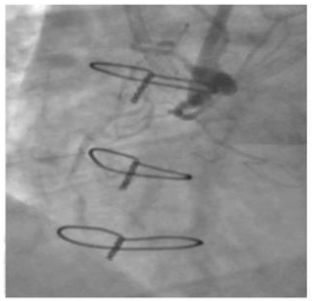
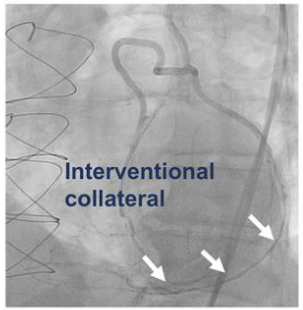
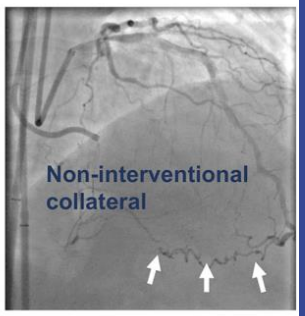
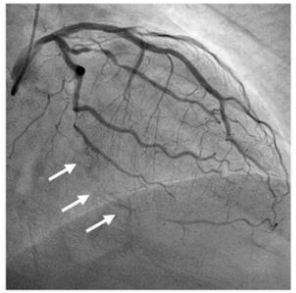
OPEN-CTO

Health Status Trajectory after CTO-PCI



Hirai et al. Circ Cardiovasc Interv. 2019;12:e007558

PROGRESS CTO score

Proximal cap ambiguity (1 point)	 Poor cap visualization or absence of clearly tapered stump
Absence of "interventional" collaterals (1 point)	 
Moderate/ severe tortuosity (1 point)	 2 bends>70 degrees or 1 bend>90 degrees
Circumflex CTO (1 point)	

(PROGRESS CTO) Complications Score

The PROGRESS CTO complication score is a useful tool for prediction of periprocedural complications in CTO PCI.

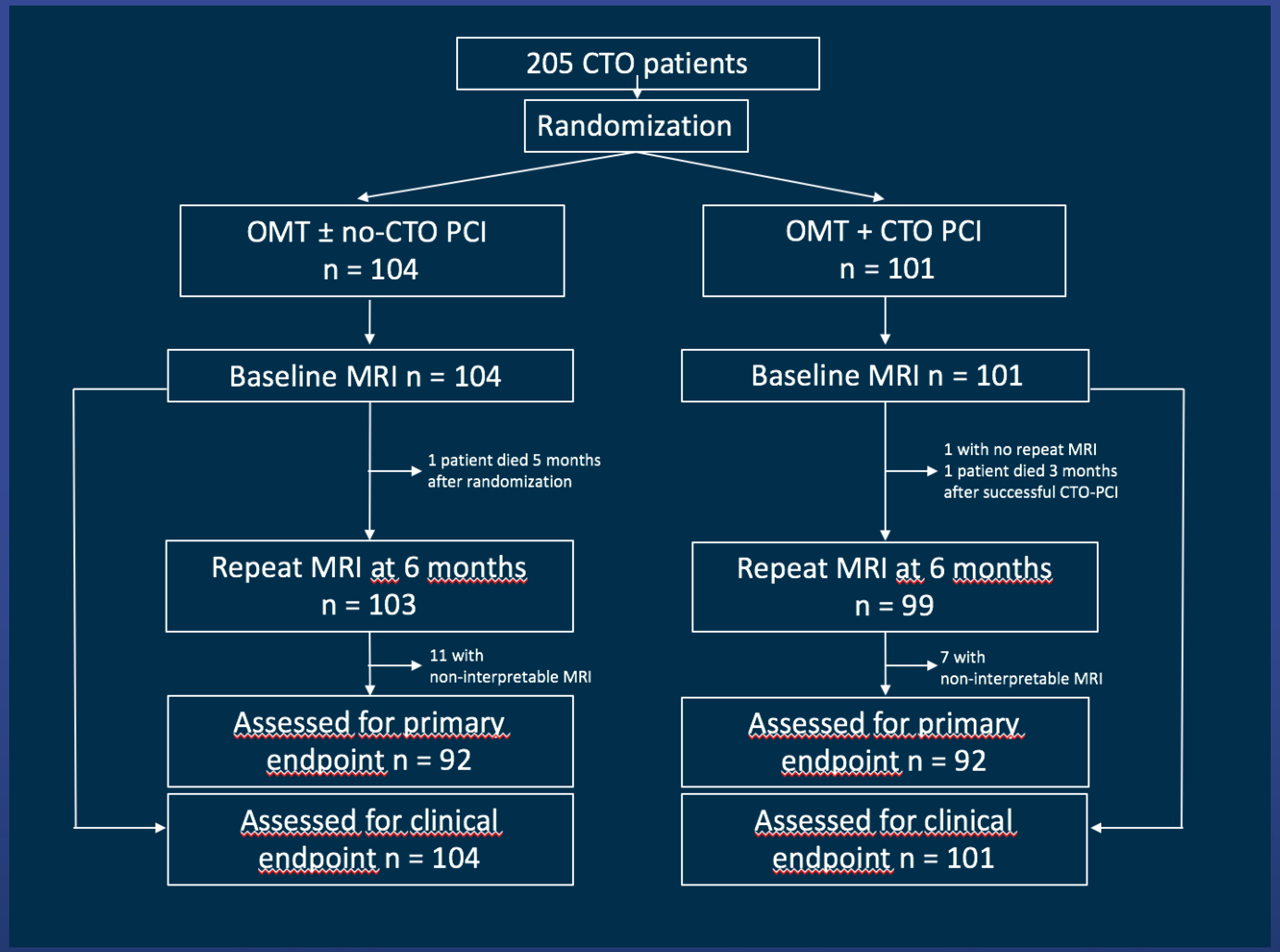
Scoring system	Risk of complications
Patient age > 65 years +3 points	≥ 5 points 6.6% risk
CTO length ≥ 23 mm +2 points	3-4 points 2.0% risk
Use of the retrograde approach +1 point	0-2 points 0.2% risk

Danek BA , Karatasakis A et al J Am Heart Assoc. 2016;5:e004272

Christopoulos et al. JACC Cardiovasc Interv. 2016 Jan 11;9(1):1-9.

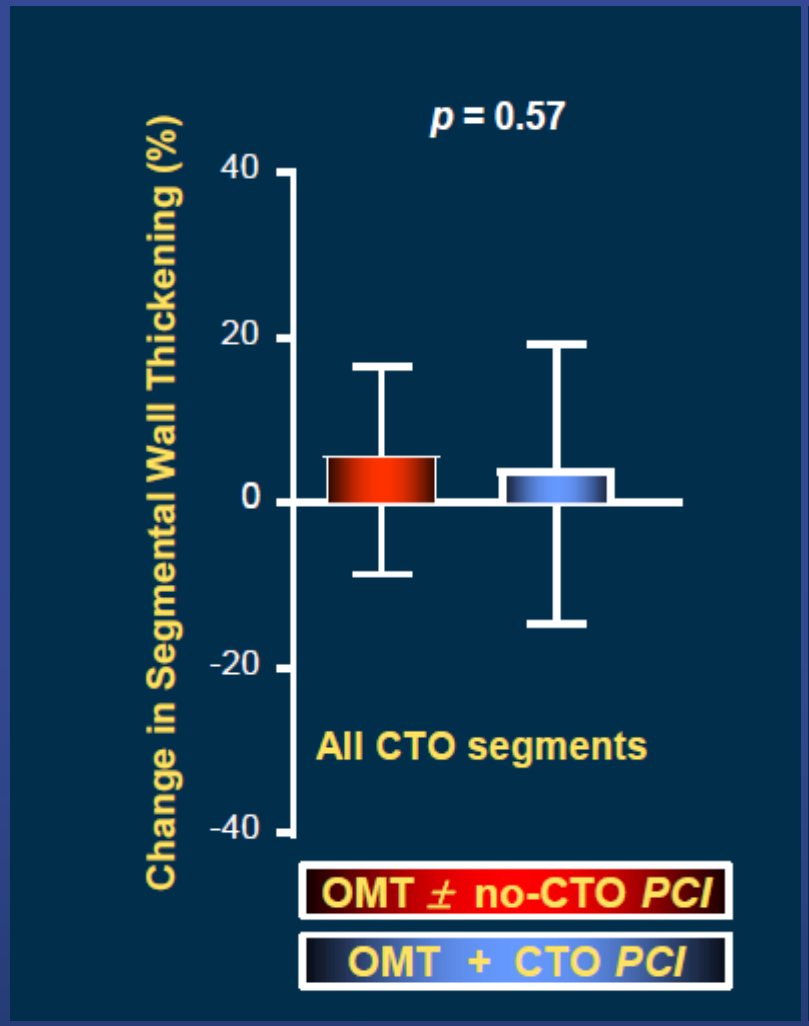
REVASC

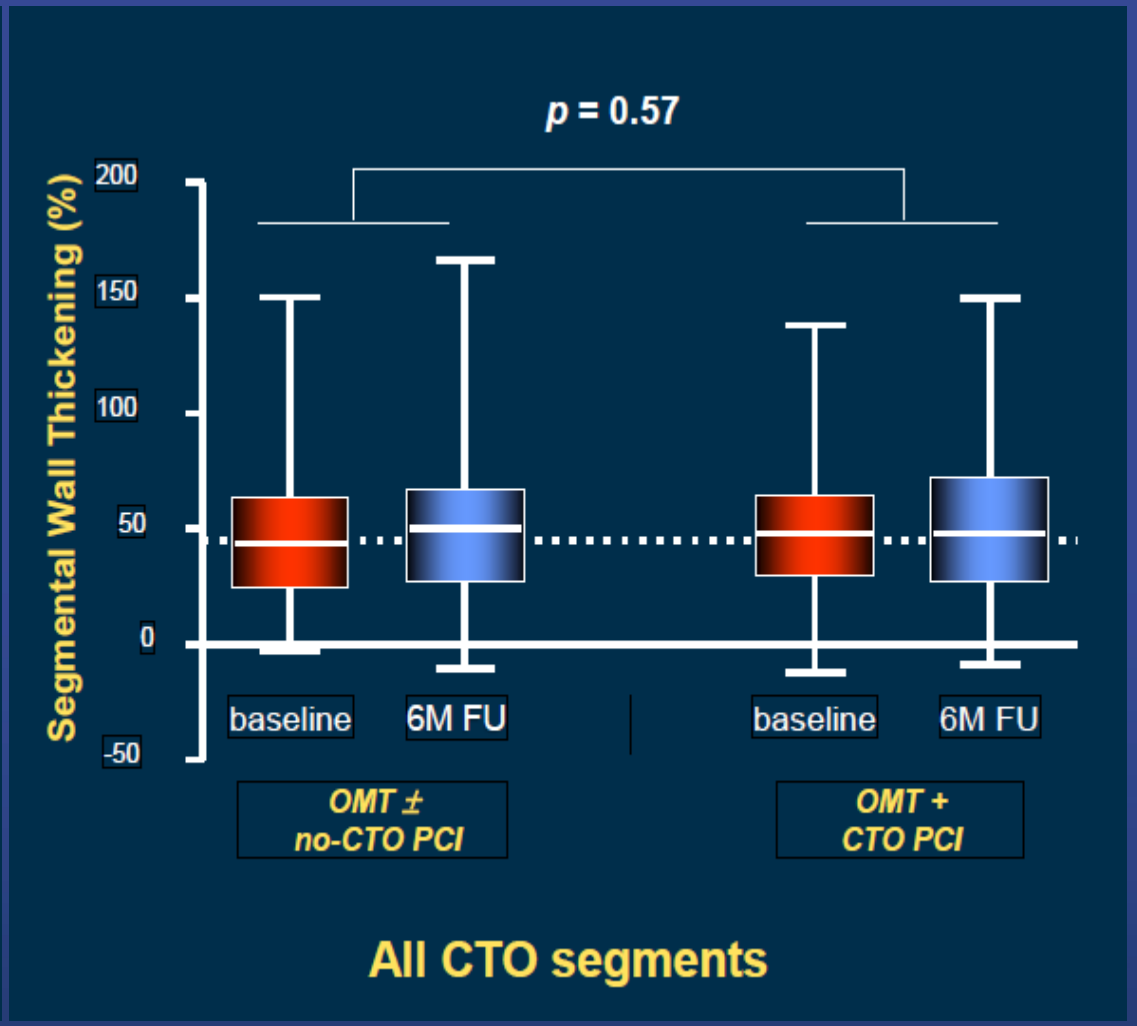
Recovery of Left Ventricular Function in Coronary Chronic Total Occlusion



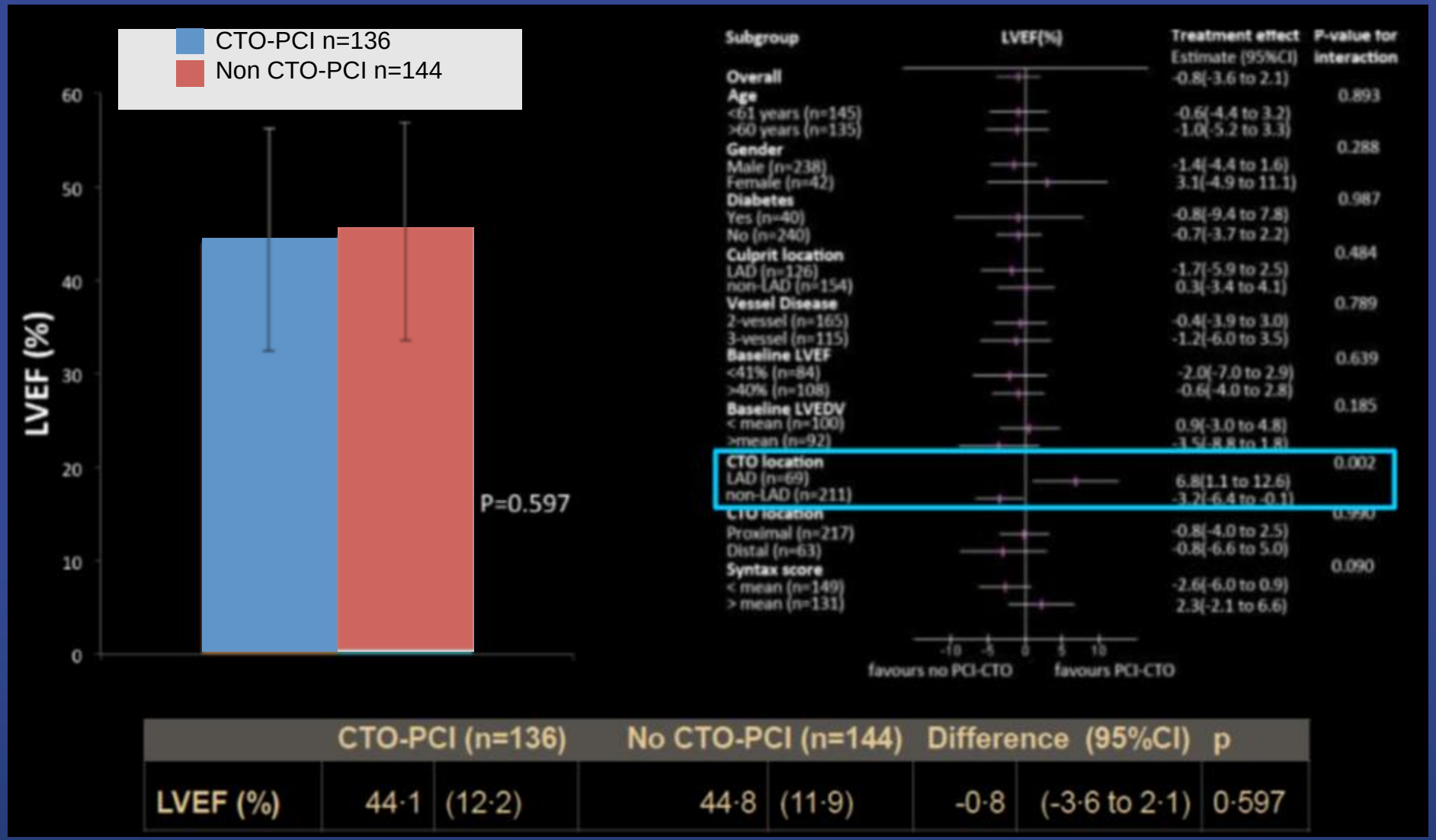
REVASC

Primary end point





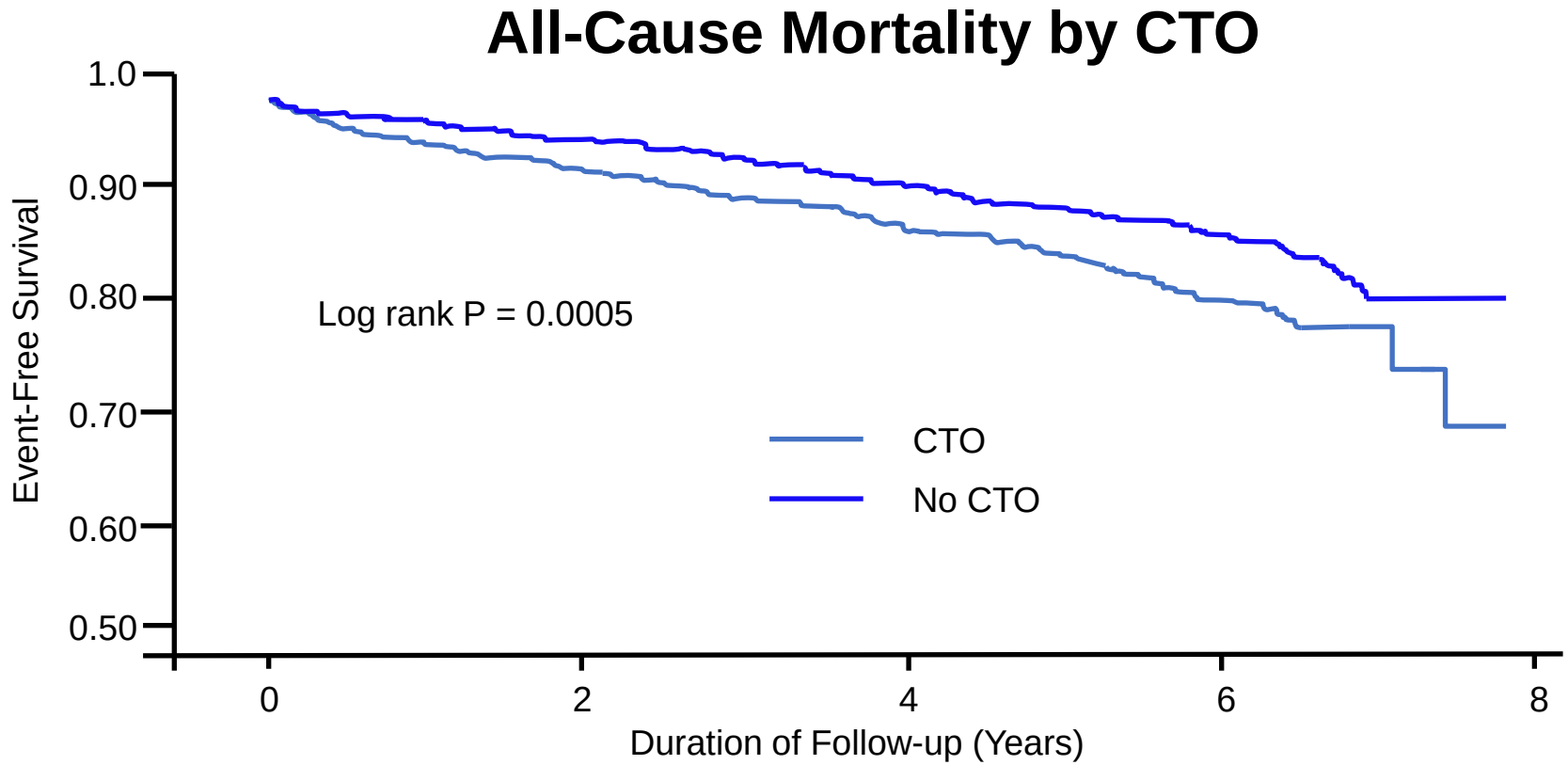
EXPLORE: MRI-Assessed LVEF at 4 months



	CTO-PCI (n=136)		No CTO-PCI (n=144)		Difference (95%CI)		p
LVEF (%)	44·1	(12·2)	44·8	(11·9)	-0·8	(-3·6 to 2·1)	0·597

J. Henriques, TCT 2015

Impact of CTO on Outcomes: BARI 2D

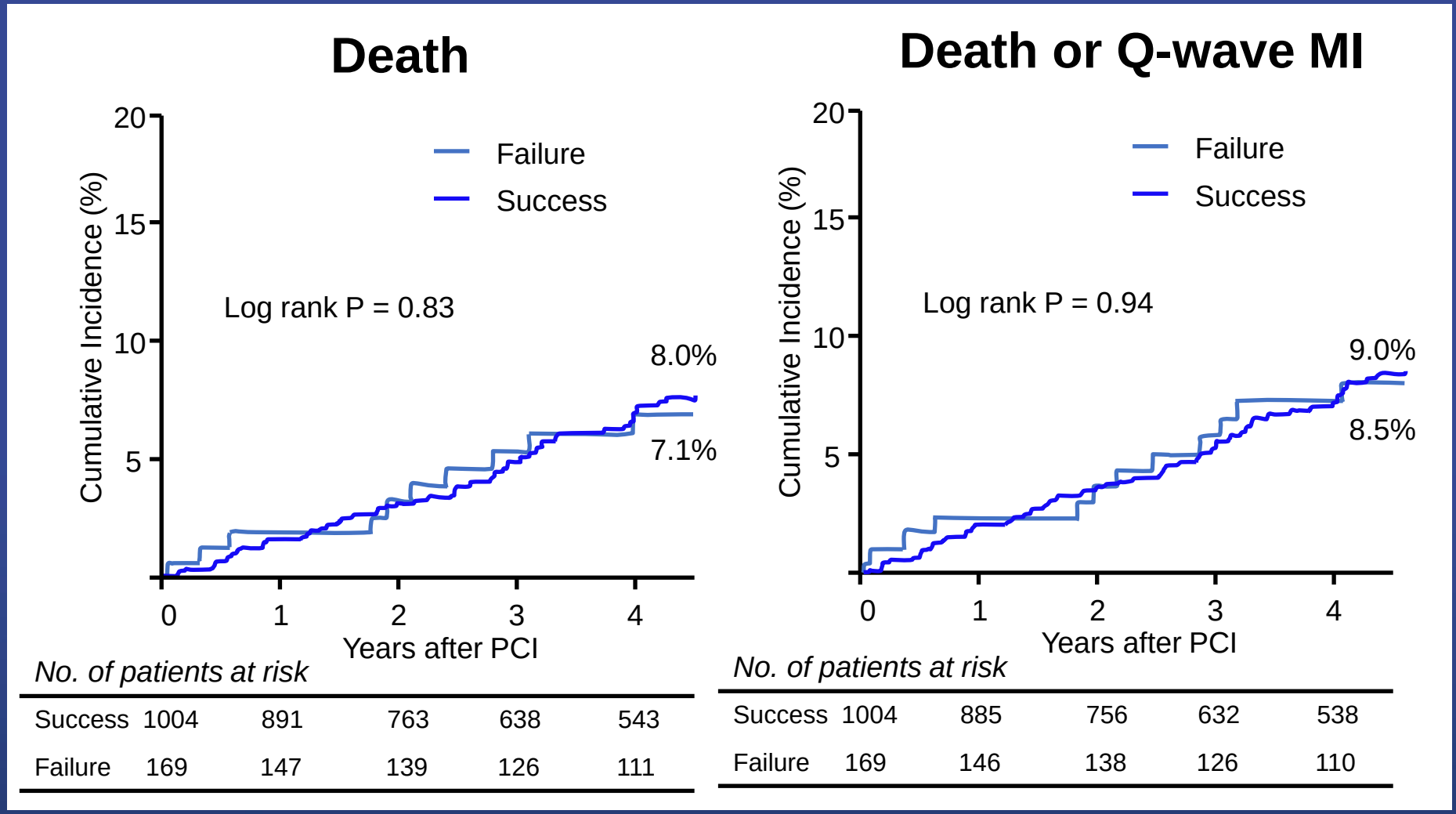


No. of patients at risk

No CTO	1393	1339	1129	381
CTO	972	905	773	217

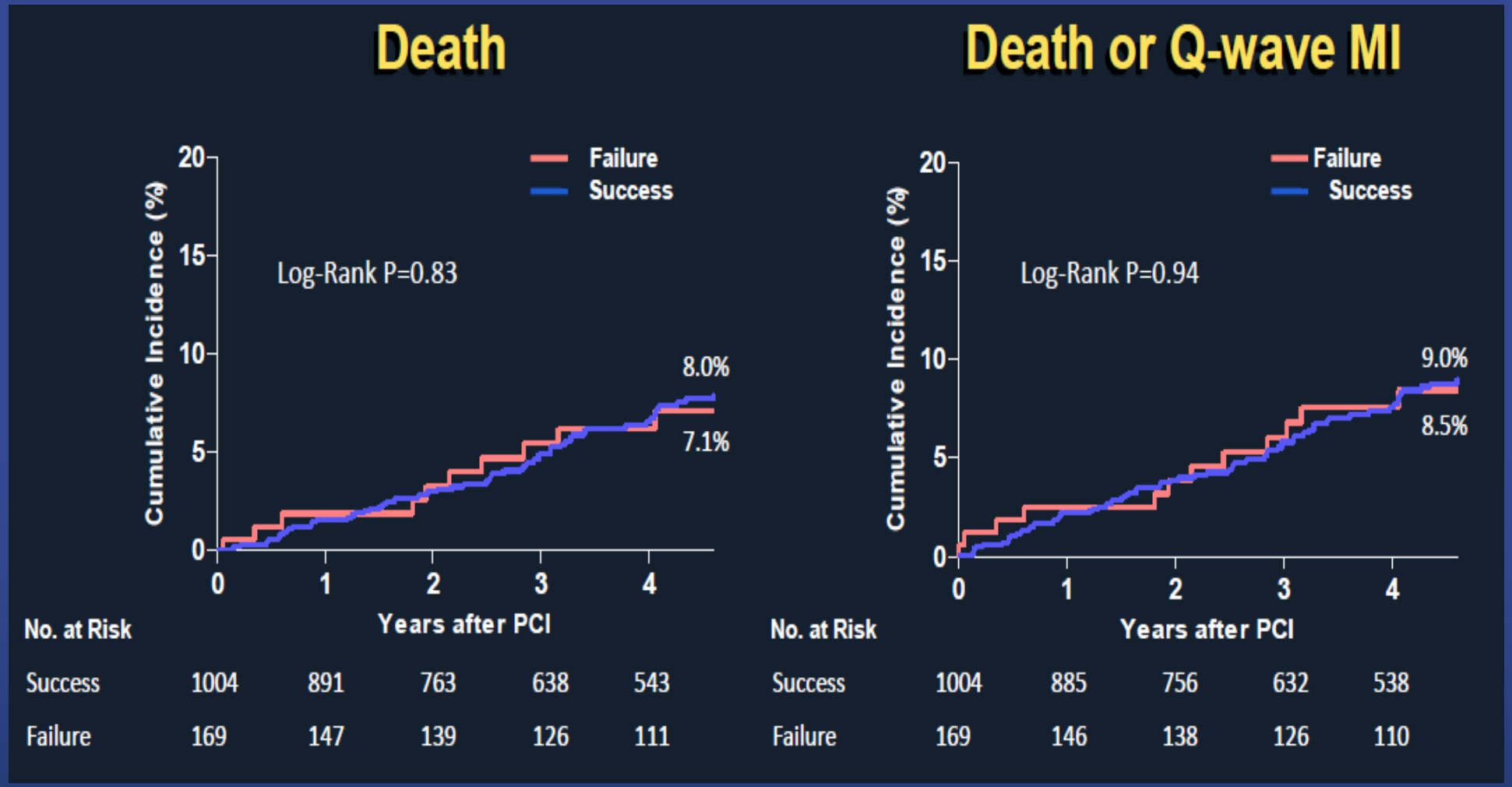
Damluji et al, Am J Cardiol 2016;117:1031

Impact of OMT after Failed vs. Successful CTO-PCI



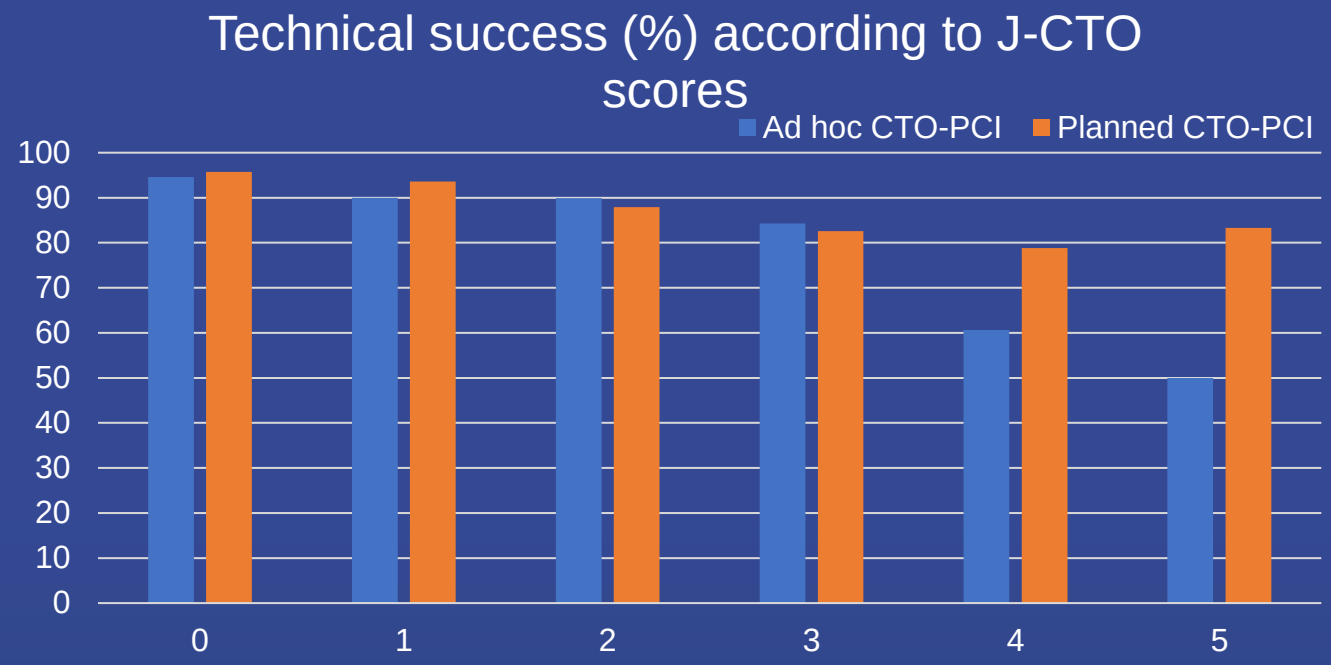
PH Lee et al, J Am Coll Cardiol Intv 2016;9:530–8

Impact of OMT after Failed vs. Successful CTO-PCI



PH Lee et al, J Am Coll Cardiol Intv 2016;9:530–8

AD Hoc vs Planned CTO-PCI

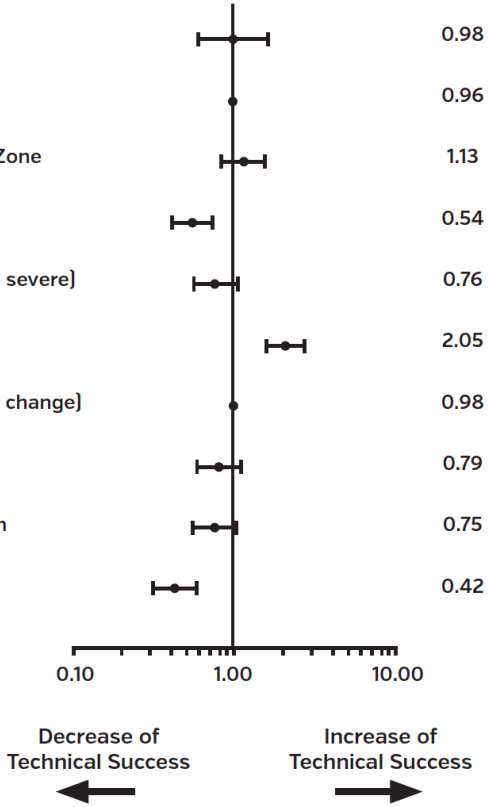


Ad hoc CTO-PCI	94.6%	90.0%	89.9%	84.3%	60.6%	50.0%
Planned CTO PCI	95.7%	93.6%	87.9%	82.6%	78.8%	83.3%
Cases (n)	167	374	507	616	420	106

Sandoval et al. J Invasive Cardiol. 2019 Jan 15

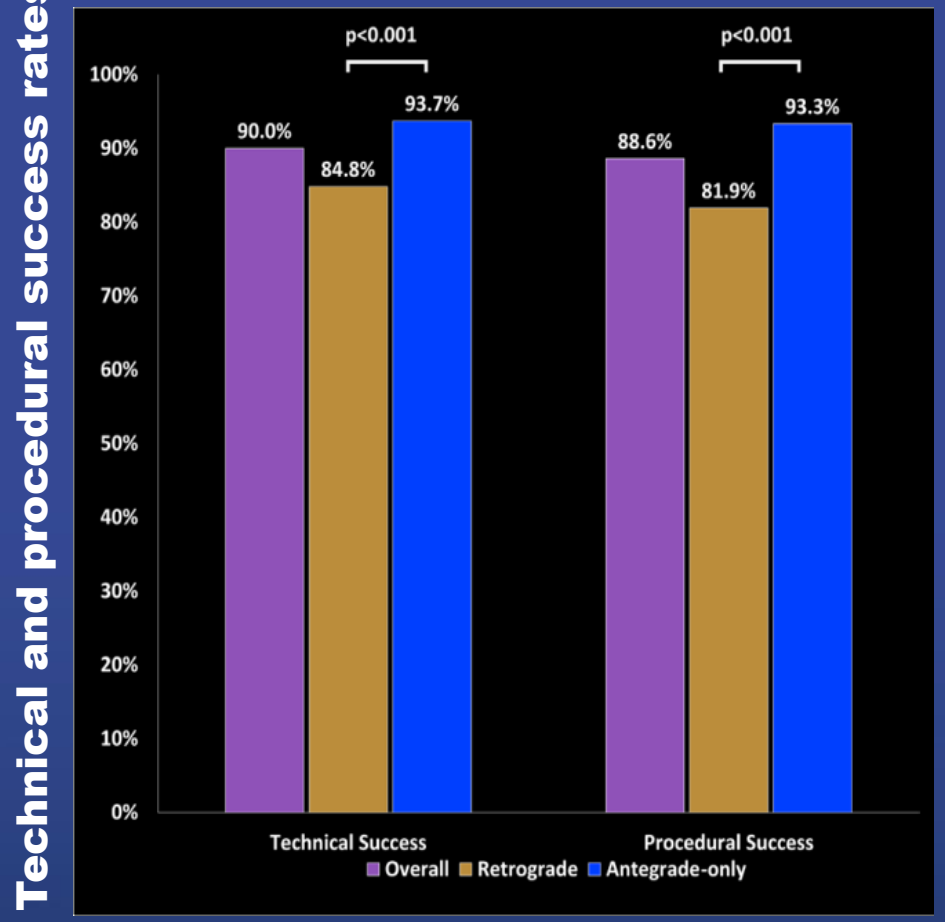
Multivariable analysis for technical success

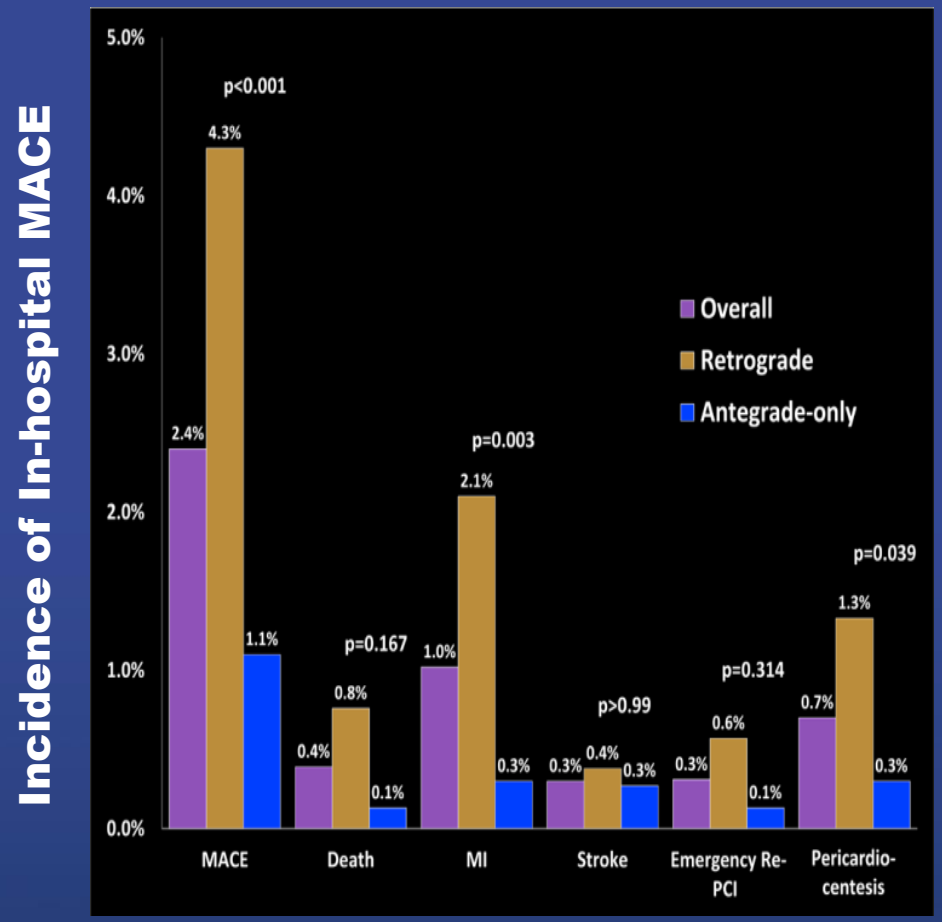
Variable	OR	95% CI	*P*-Value
Ad hoc CTO-PCI	0.98	0.60-1.59	.92
Age (per 10-year change)	0.96	0.91-1.02	.17
Adequate Distal Landing Zone	1.13	0.84-1.53	.42
Bifurication at Distal Cap	0.54	0.41-0.72	<.001
Calcification (moderate to severe)	0.76	0.56-1.01	.06
Interventional Collaterals	2.05	1.55-2.69	<.001
Lesion Length (per 10 mm change)	0.98	0.96-1.01	.20
Prior Heart Failure	0.79	0.59-1.06	.12
Prior Myocardial Infarction	0.75	0.56-0.99	.04
Proximal Cap Ambiguity	0.42	0.32-0.56	<.001



Sandoval et al. J Invasive Cardiol. 2019 Jan 15

Retrograde approach for CTO-PCI





Dimitri K et al, Circ Cardiovasc Interv. 2016;9:e003434.

COMET-CTO

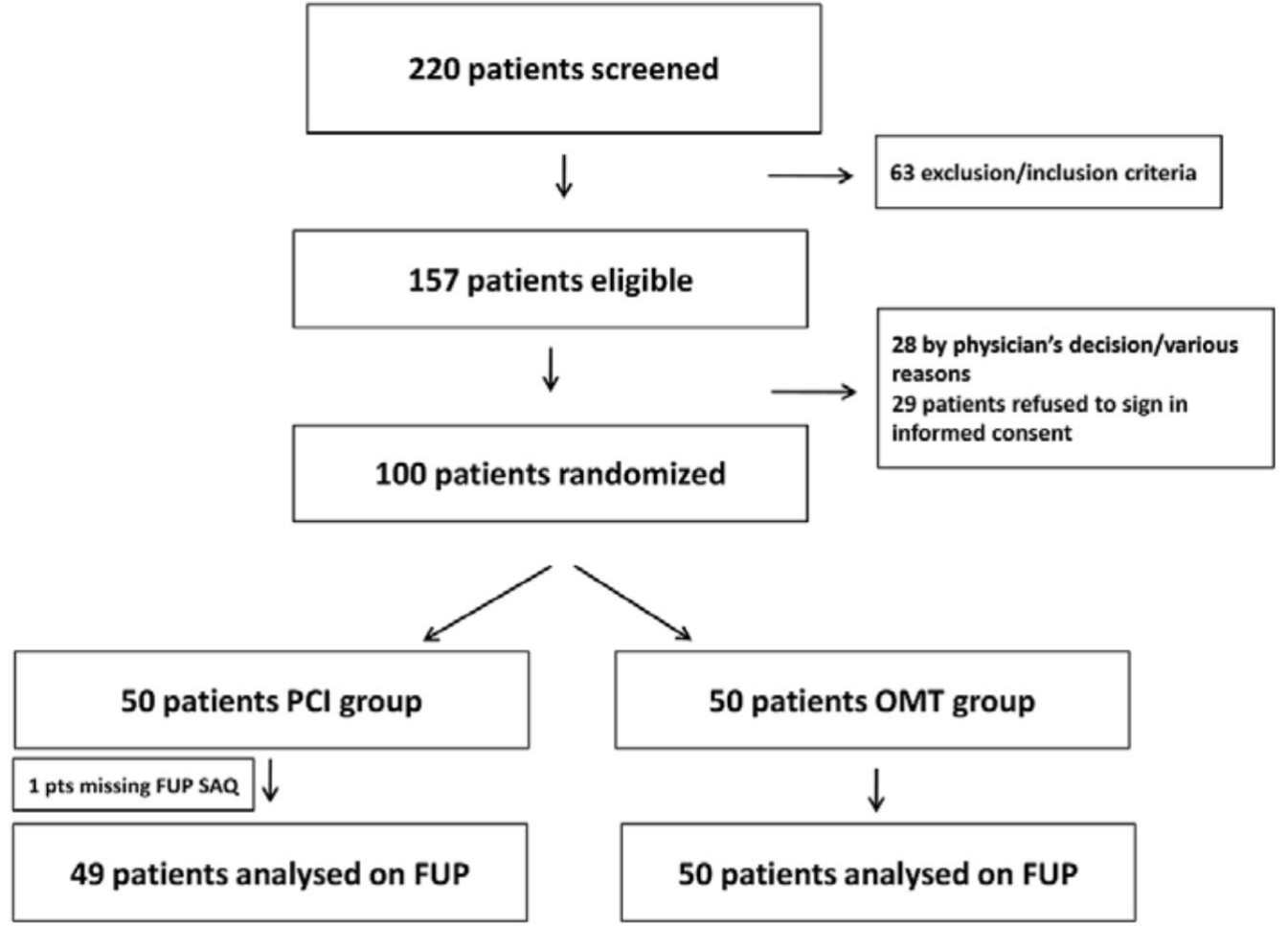


Figure 1. Patients' flow diagram. PCI indicates percutaneous coronary intervention; OMT, optimal medical therapy; and FUP, follow-up.

Stefan A. Juricic et al, Int Heart J 2021

COMET-CTO

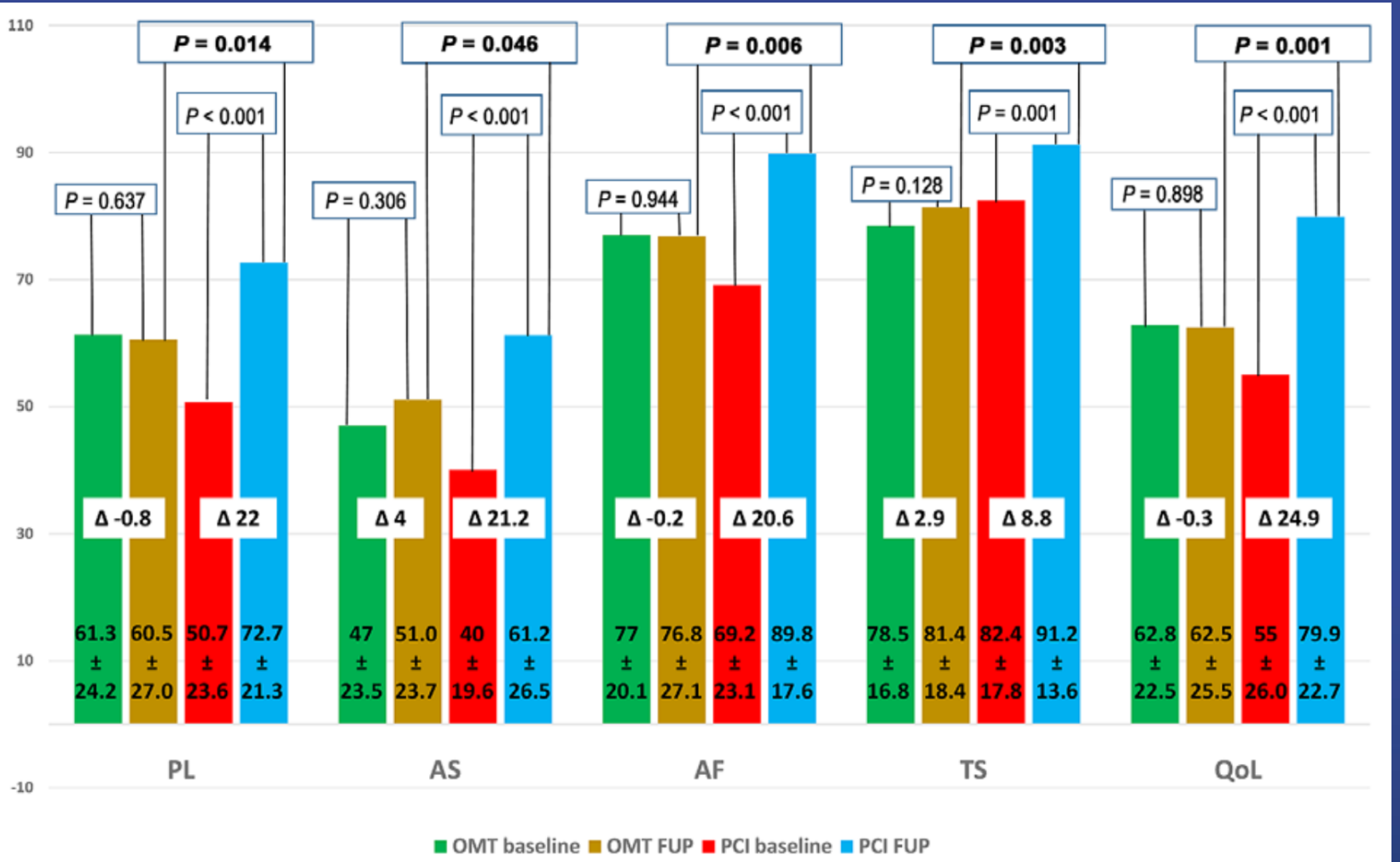


Figure 2. SAQ subscale changes. QoL indicates quality of life; PL, physical limitation; AS, angina stability; AF, angina frequency; TS, treatment satisfaction; PCI, percutaneous coronary intervention; OMT, optimal medical therapy; and FUP, follow-up. Δ: difference between f-up and baseline mean values.

Juricic, et al, Int Heart J 2021

Canadian Multicenter Chronic Total Occlusion Registry:

Ten-Year Follow-Up Results of Chronic Total occlusion Revascularization

- The primary data source from Canadian Multicenter CTO registry (2008.4 ~ 2009.7)
- Revascularization decisions were determined by local routine care

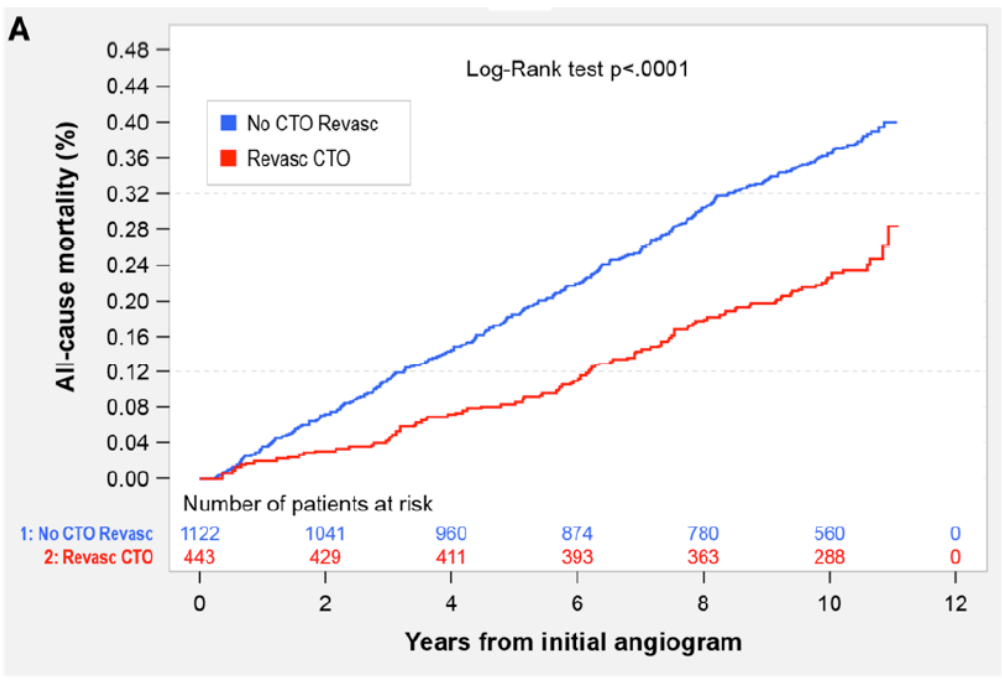
•All PCIs were performed in 3 centers

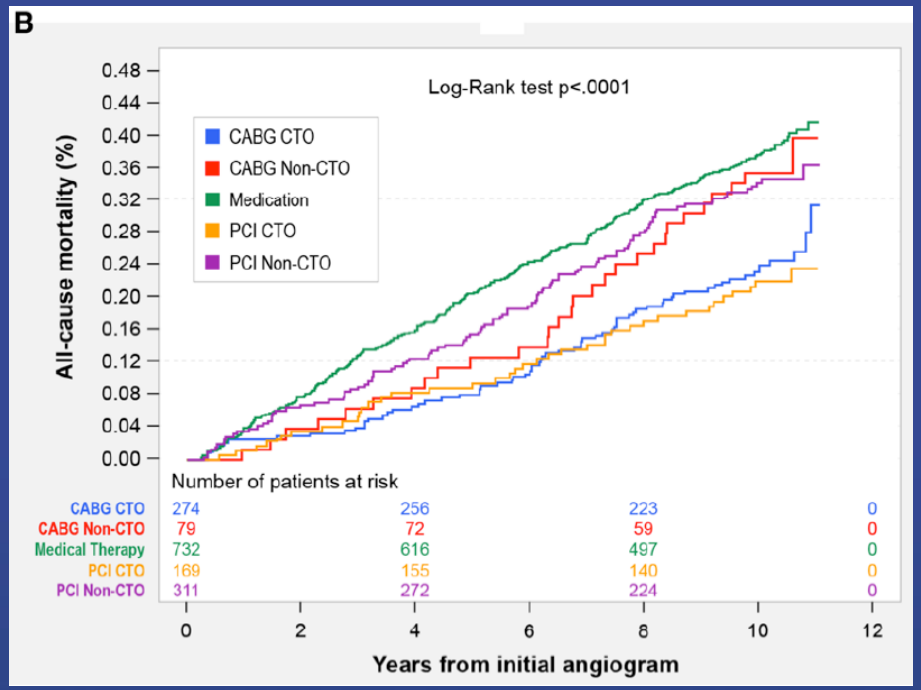
•Prospective multicenter cohort study
•Revascularization group was divided into CTO revasc vs no CTO revasc

- Primary outcome
  - All-cause mortality
- Secondary outcomes
  - Hospitalizations for ACS or HF
  - Revascularization, a composite of TVR or non-TVR beyond 90 days post index procedure

Strauss et al, Circ cardiovascular 2021

All-cause mortality





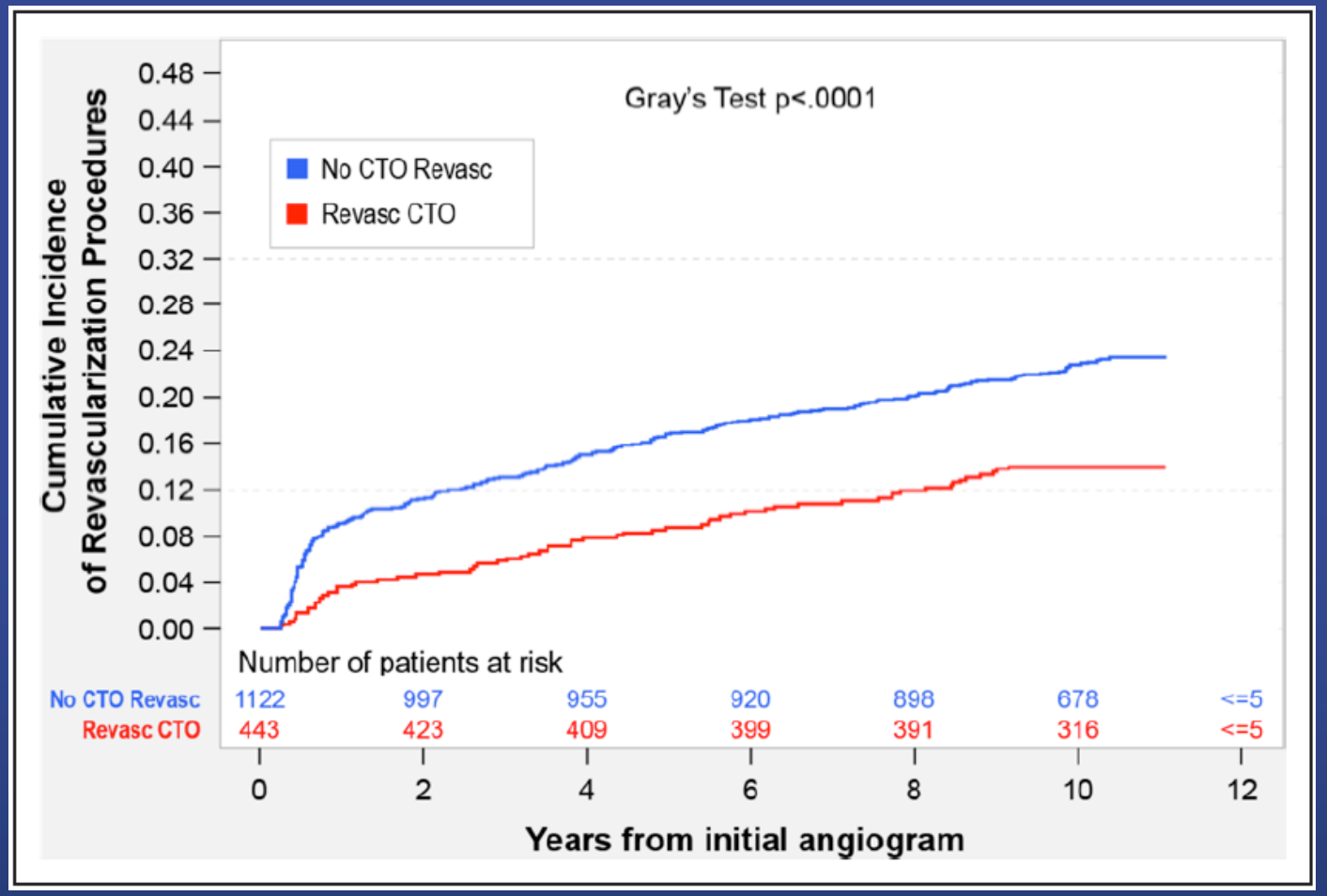
Strauss et al, Circ cardiovascular 2021

Adverse clinical events at 10 years

Adverse outcome	Total	CTO revasc (n=458)	No CTO revasc (n=1166)
Mortality, %	32.6 (30.3-35.0)	22.7 (19.0-26.9)	36.6 (33.8-39.5)
Revasc (PCI), %	10.6 (9.2-12.2)	11.1 (8.4-14.2)	10.5 (8.8-12.4)
Revasc (CABG), %	11.1 (18.3-22.3)	3.6 (2.2-5.7)	14.0 (12.1-16.1)
Revasc (PCI/CABG), %	20.3 (18.3-22.3)	14.0 (11.0-17.4)	22.8 (20.4-25.3)
Hospital (ACS), %	14.7 (12.9-16.5)	10.0 (7.4-13.1)	16.6 (14.4-18.9)
Hospital (HF), %	11.9 (10.3-13.6)	9.6 (7.0-12.6)	12.8 (10.9-14.8

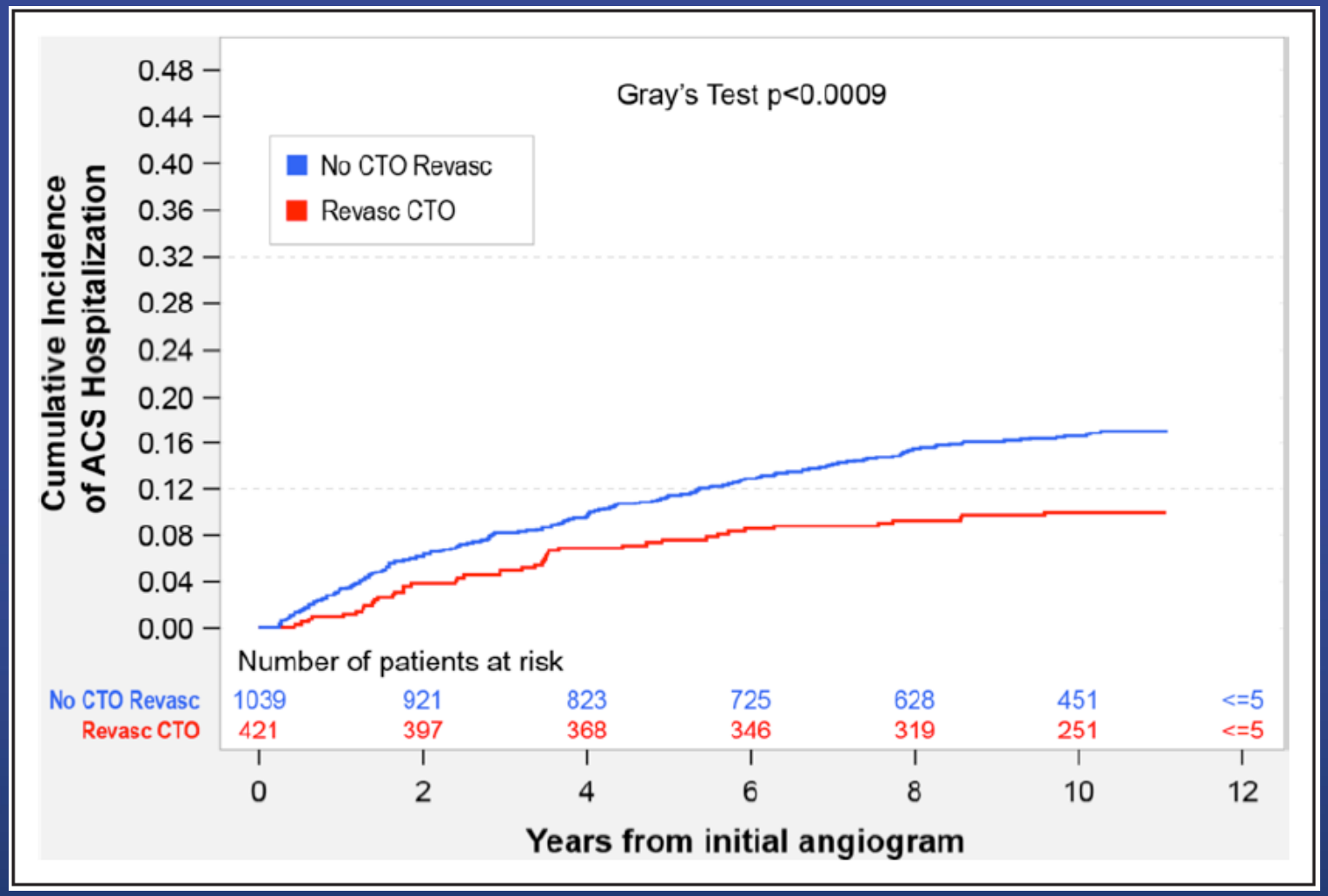
Strauss et al, Circ cardiovascular 2021

Cumulative incidence of later revascularization



Strauss et al, Circ cardiovascular 2021

Cumulative incidence of ACS hospitalization



Strauss et al, Circ cardiovascular 2021

Periprocedural Risk Prediction Scores in CTO

- Studies included (5 publications) with 8 CTO PCI specific scores (to October 26, 2022)

(1) Angiographic coronary artery perforation
(2) Major adverse cardiovascular events (MACE)
(3) All-cause mortality
(4) Perforation requiring pericardiocentesis
(5) Acute myocardial infarction
(6) Perforation requiring any treatment
(7) Contrast-induced acute kidney injury

Simsek B *et al*, *Am J Cardiol*. 2023;193:118-125.

PROGRESS-CTO complication scores and the

CTO PCI complication scores	Events	Variables	Points assigned	Risk score,complication risk
PROGRESS-CTO complications score (score range: 0−6)	n = 44 (2.8%) MACE: composite of death, MI, stroke, urgent repeat revascularization (re-PCI or surgery), or pericardiocentesis	Age >65 years Lesion length ≥23 mm Retrograde strategy	+ 3 + 2 + 1	0−2, 0.2% 3−4, 2.0% ≥5, 6.6%
OPEN-CLEAN perforation score (score range: 0−7)	n = 89 (8.9%) angiographic perforation	Prior CABG Occlusion length 20−59 mm ≥60 mm LVEF <50% Age: 50−<70 years ≥70 years Calcification	+ 1 + 1 + 2 + 1 + 1 + 2 + 1	0−1, 2.2% 2, 3.3% 3, 4.4% 4, 8.2% 5, 14.9% 6−7, 30.9%
PROGRESS-CTO MACE (score range: 0−7)	n = 215 (2.05%) MACE: composite of death, MI, stroke, urgent repeat revascularization (re-PCI or surgery), or pericardiocentesis	Age ≥65 years Female gender Moderate-severe calcification Blunt/no stump Antegrade dissection and re-entry Retrograde strategy	+ 1 + 2 + 1 + 1 + 1 + 2	0, 0.4% 1, 0.7−0.9% 2, 1.1−1.9% 3, 1.6−2.6% 4, 2.6−4.7% 5, 4.4−6.1% 6, 7.2−9.3% 7, 11.7%
PROGRESS-CTO Mortality (score range: 0−4)	n = 47 (0.45%) all-cause mortality	Age ≥65 years Moderate-severe calcification LVEF ≤45% Antegrade dissection and re-entry Retrograde strategy	+ 1 + 1 + 1 + 1 + 1	0, 0.05% 1, 0.1−0.2% 2, 0.3−0.5% 3, 0.5−1.1% 4, 1.9−2.4%

PROGRESS-CTO complication scores and the

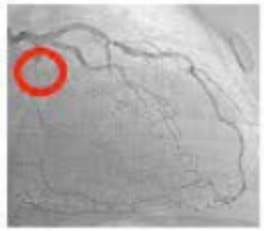
CTO PCI complication scores	Events	Variables	Points assigned	Risk score,complication risk
PROGRESS-CTO pericardiocentesis (score range: 0−5)	n = 83 (1.08%) perforation requiring pericardiocentesis	Age ≥65 years Moderate-severe calcification Female gender Antegrade dissection and re-entry Retrograde strategy	+ 1 + 1 + 1 + 1	0, 0.2% 1, 0.4−0.6% 2, 0.6−1.6% 3, 1.3−3.6% 4, 2.8−7.2% 5, 8.7%
PROGRESS-CTO Acute MI (score range: 0−3)	n = 66 (0.63%) acute MI	Prior CABG Atrial fibrillation Blunt/no stump	+2 + 1 + 1 + 1	0, 0.2 1, 0.4−0.5% 2, 1.1−1.2% 3, 2.8%
PROGRESS-CTO perforation score (score range: 0−5)	n = 503 (4.9%) perforation requiring any treatment	Age ≥65 years Moderate-severe calcification Blunt/no stump Antegrade dissection and re-entry Retrograde strategy	+ 1 + 1 + 1 + 1 + 2	0, 0.7% 1, 0.9−1.6% 2, 1.7−2.9% 3, 3.0−5.0% 4, 6.4−8.0% 5, 11%
Contrast-induced acute kidney injury score* (score range: 0−16)	n = 17 (2.7%) absolute increase in serum creatinine of ≥0.5 mg/100 ml over baseline values within 48−72 h after contrast exposure	Age ≥75 years LVEF <40% Serum creatinine >1.5 mg/100 ml Serum albumin (g/L) ≤30 >30−40 >40	+ 4.5 + 3.5 5 + 2 + 1 0	<4, 0−0.8% 4−7, 5.3%−8.2% ≥7, 13−31%

CTO PCI-specific periprocedural complication risk scores

CTO PCI Complication Scores	Risk Score, Complication Risk
PROGRESS-CTO complications score	0–2 (low risk) 3–4 (moderate risk) ≥5 (high risk)
OPEN-CLEAN perforation score	0–2 (low risk) 3–4 (moderate risk) 5–7 (high risk)
PROGRESS-CTO MACE	0–2 (low risk) 3–4 (moderate risk) 5–7 (high risk)
PROGRESS-CTO mortality	0 (low risk) 1–2 (moderate risk) 3–4 (high risk)
PROGRESS-CTO pericardiocentesis	01 (low risk) 2–3 (moderate risk) 4–5 (high risk)
PROGRESS-CTO acute MI	01 (low risk) 2 (moderate risk) 3 (high risk)
PROGRESS-CTO perforation score	01 (low risk) 2–3 (moderate risk) 4–5 (high)
Contrast-induced acute kidney injury score	<4, (low risk) 4–6 (moderate risk) ≥7, (high risk)

Three-year outcomes of A Randomized Multicentre Trial Comparing Revascularization and OMT of CTO (Euro CTO)

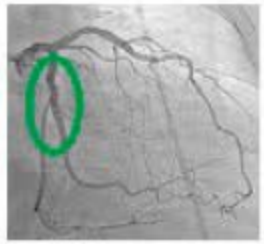
Study plan and 3-year outcome of the EuroCTO trial



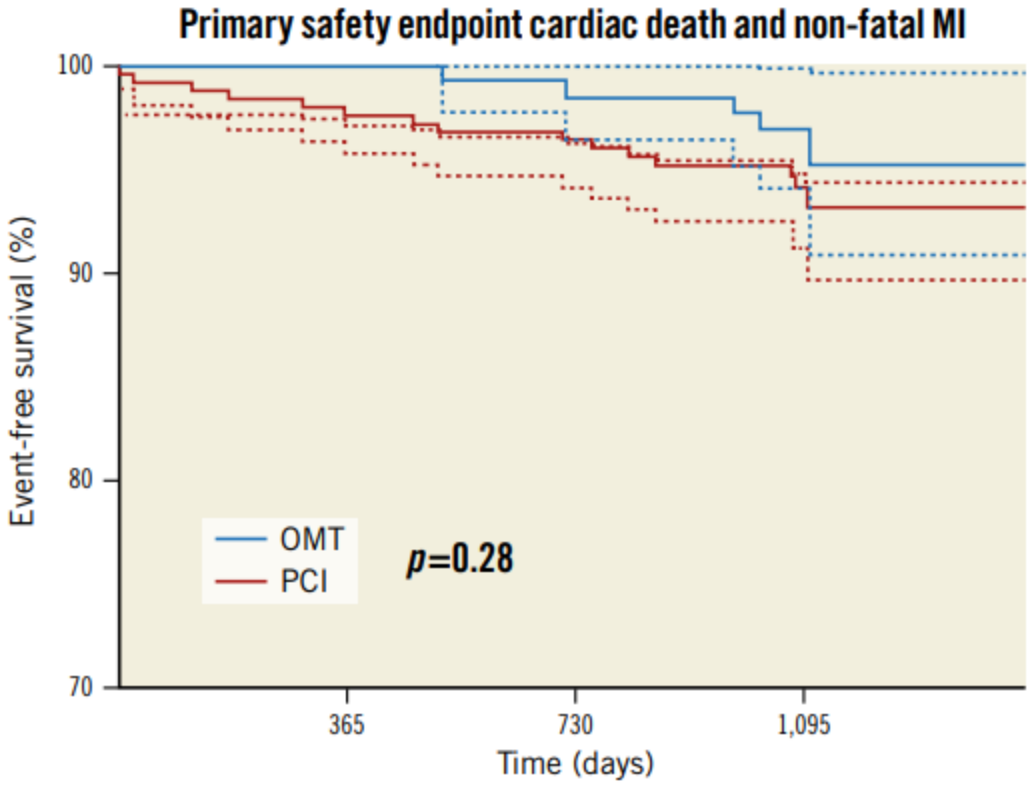
396 patients

ITT population: 259 planned PCI | 137 OMT

PP population: 254 received PCI | 3 c/o to OMT | 137 on OMT



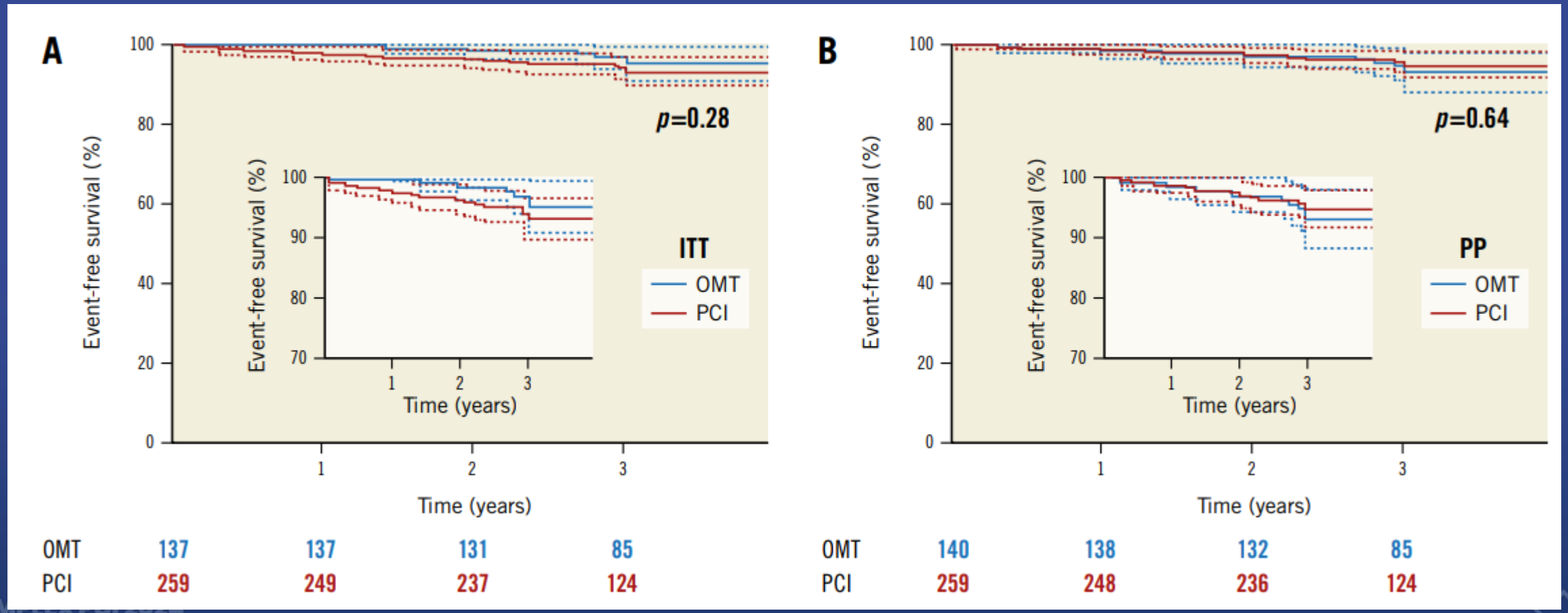
	OMT (N=137)	PCI (N=259)	*p*-value
Intention-to treat			
Primary safety endpoint (%)	3.7	6.2	0.29
Cardiac death (%)	2.2	3.1	0.75
Non-fatal MI (%)	1.5	3.1	0.33
MACE (%)	21.2	11.2	0.008



Eurointervention 2023 Sep 18;19(7):571-579.

Three-year outcomes of A Randomized Multicentre Trial Comparing Revascularization and OMT of CTO (Euro CTO)

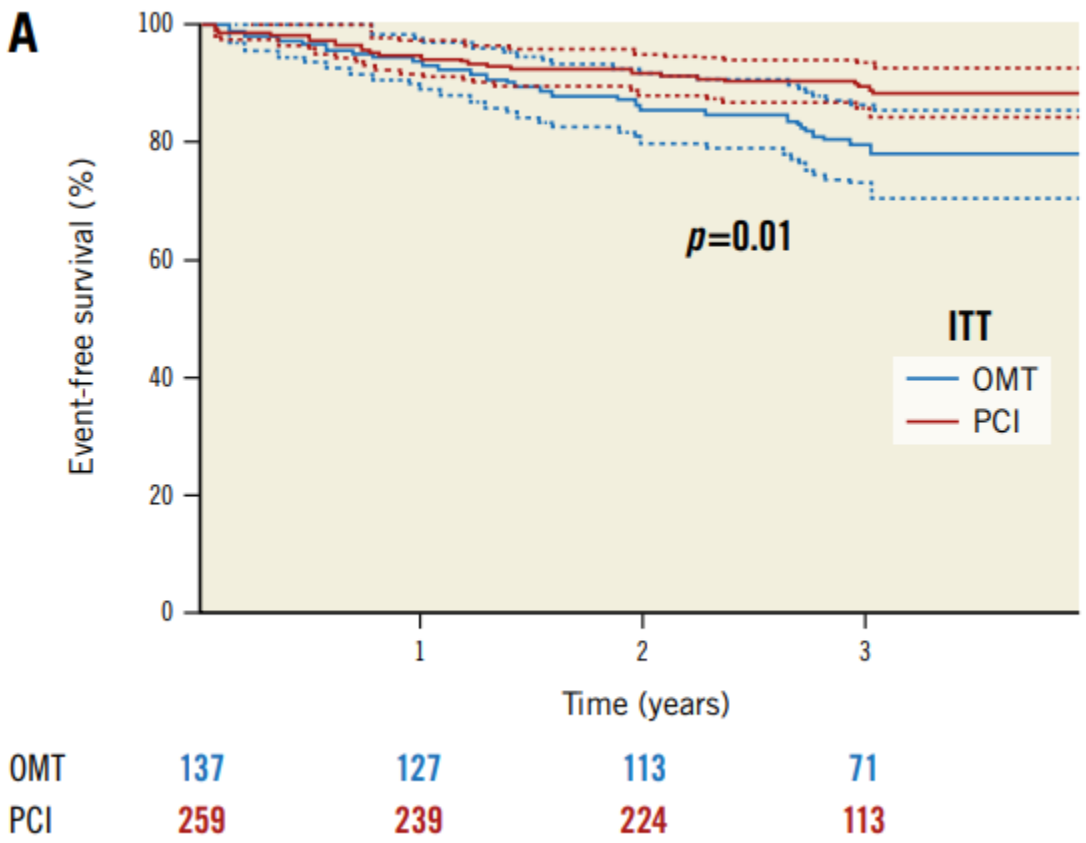
No difference in the rate of cardiovascular death or myocardial infarction between PCI or OMT among patients with a remaining single coronary CTO

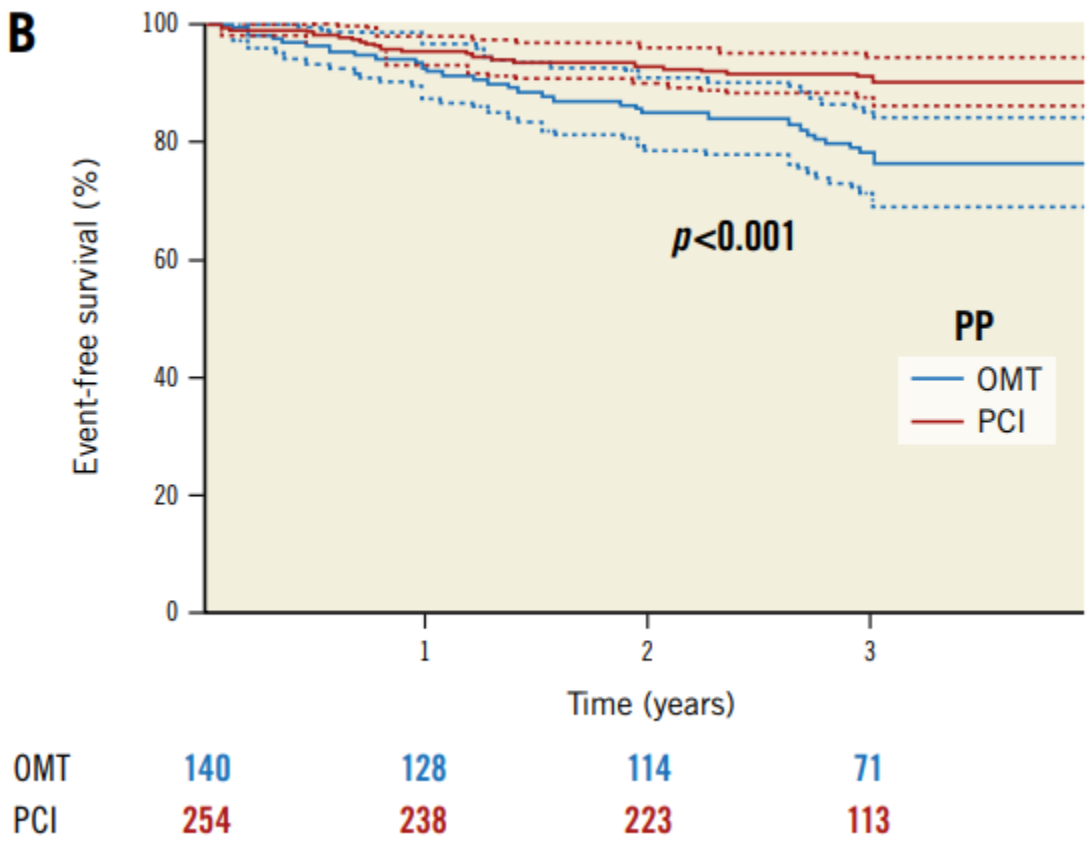


Eurointervention 2023 Sep 18;19(7):571-579.

Three-year outcomes of A Randomized Multicentre Trial Comparing Revascularization and OMT of CTO (Euro CTO)

The MACE rate was higher in the OMT group due largely to ischaemia-driven revascularisation.

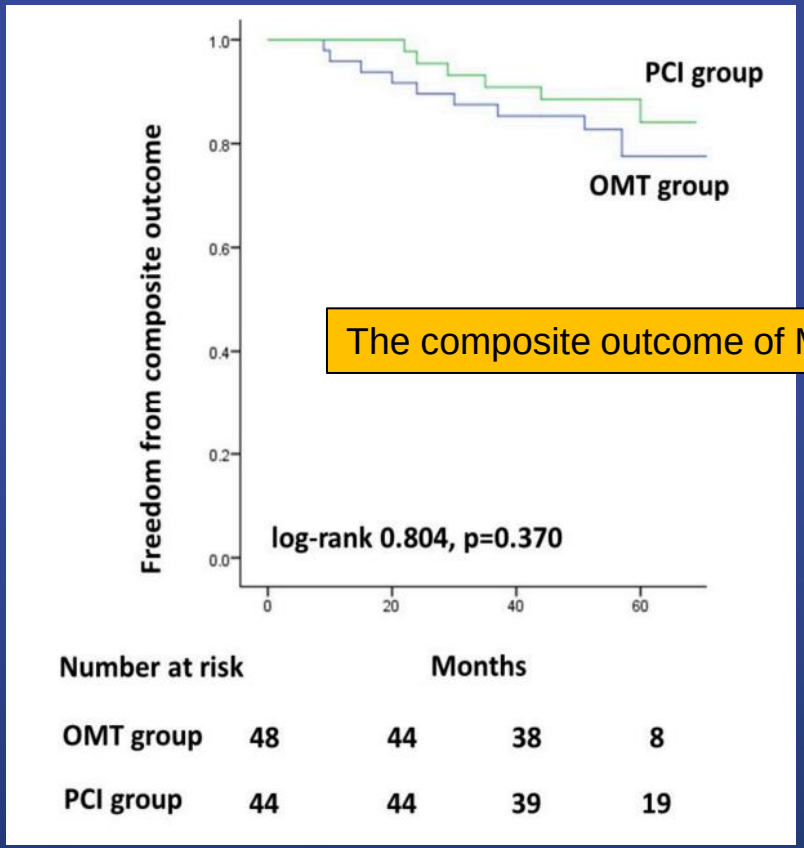




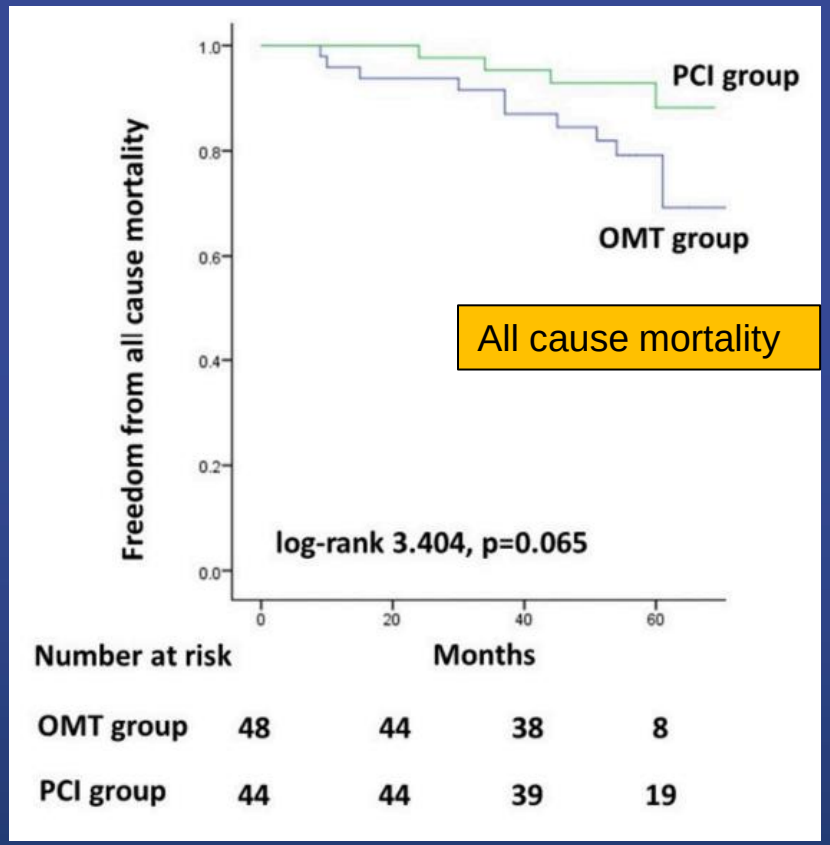
Eurointervention 2023 Sep 18;19(7):571-579.

Long term follow-up of patients with CTO previously randomized with OMT or PCI (COMET-CTO)

The primary endpoint – the incidence of MACE defined as cardiac death, MI, and revascularization [PCI or CABG]



The composite outcome of MACE



All cause mortality

Front Cardiovasc Med.2023 Jan 9:9+;1014664

Chronic Total Occlusion : Devices

Guidewires for CTO

Features required for CTO wires

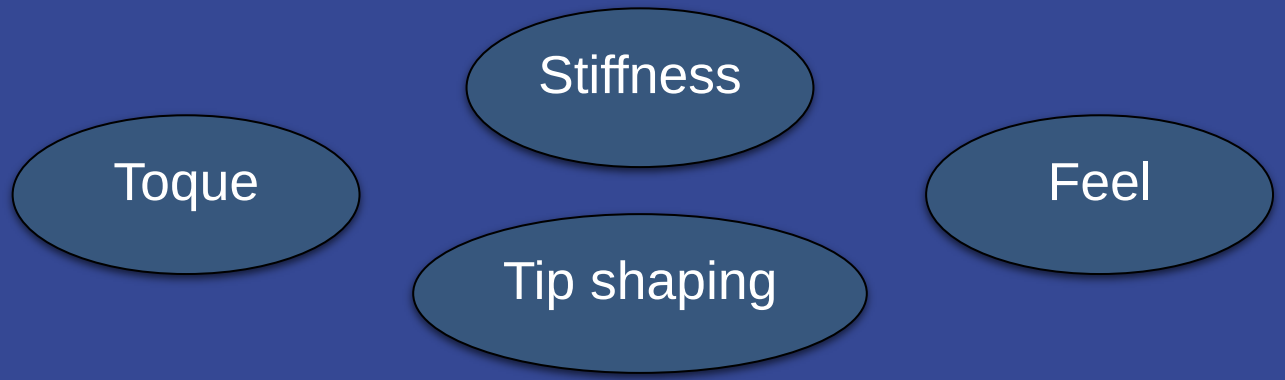
Penetration force for penetrating proximal fibrous cap and advancing into true lumen

Pushability for crossing chronic occlusions and complex lesions with heavy calcifications and tough fibrous tissues

Steerability for easy manipulate in various directions with good torque transmission

Shaping Memory of the tip

Choice of CTO Guidewire

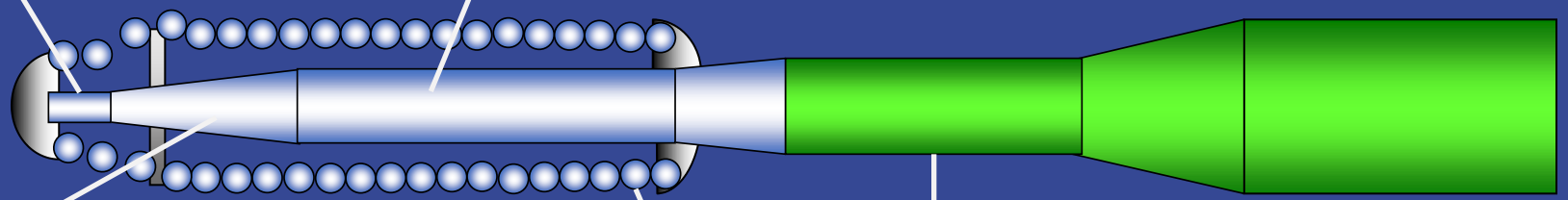


Hydrophobic wire	Hydrophilic wire
Better tactile response Good for older, fibro-calcific lesions Good for initial piercing of fibrous cap	Good for less chronic total occlusion ; softer May find microchannels easier Follow path of least resistance ; easier to go extra-luminal

Hallmarks of a CTO Guidewire

Tip styles
- core-to-tip designs
- tapered

Coils and covers
some favor increased radiopacity
jointless coils for improved torque response
polymer covers for selected applications (e.g. ISR)

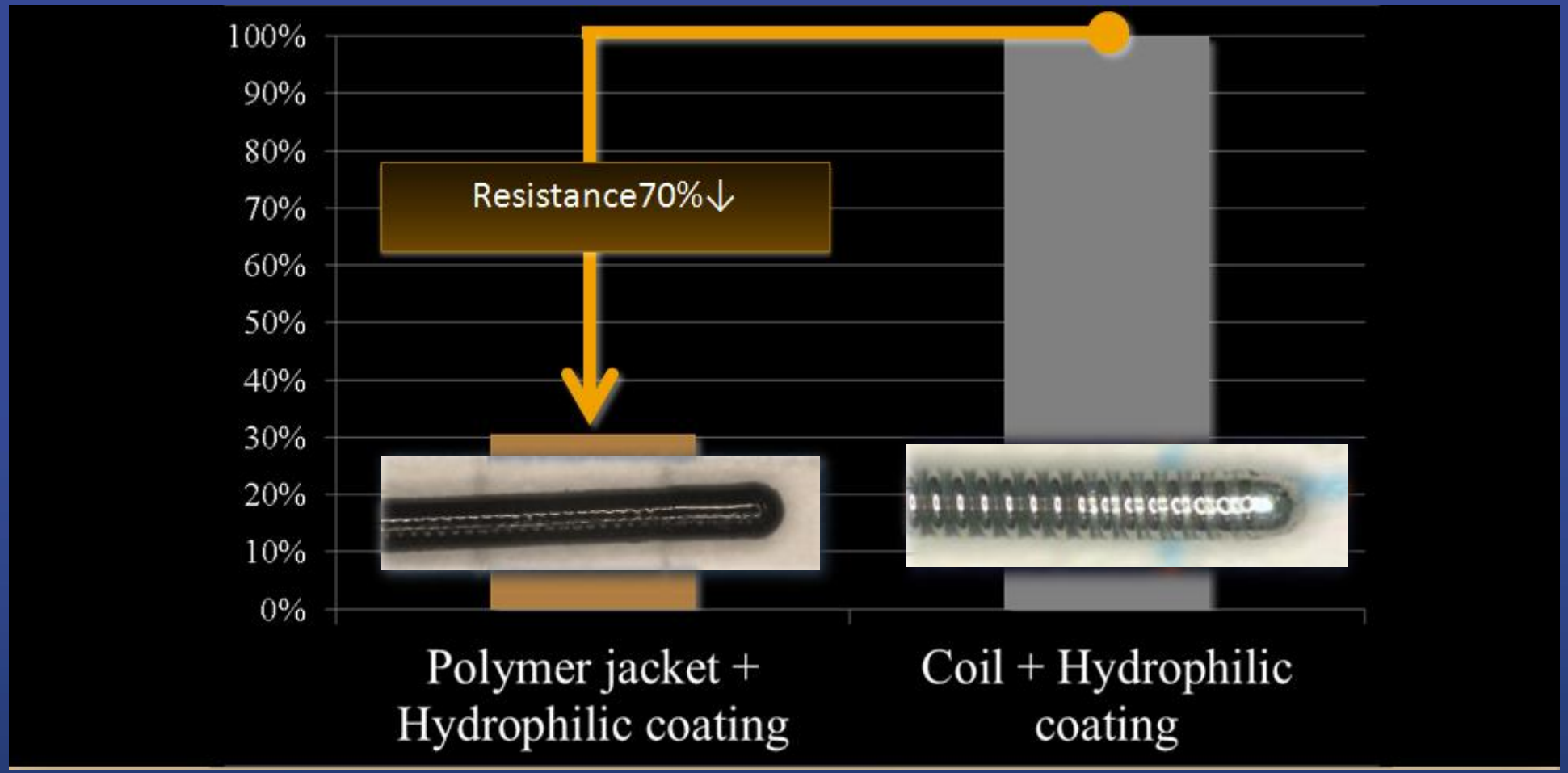


Core tapers
- shorter tapers for improve
d torque response
- generally stainless steel

Core diameters
larger for increased support
and torque response

Coatings
Body : Hydrophilic for tracking
Body and tip : Hydrophobic for torque response

Polymer Jacket Type to Reduce the Resistance



Guidewire Selection

Stiff wires

Miracle 4.5g, 6g (Asahi Intec) for standard step-up strategy

Miracle 3g → Miracle 4.5g

→ Miracle 6g → Miracle 12g or Conquest

Miracle 12g (Asahi Intec) for so tight CTO

to penetrate proximal or distal cap

to crash tight plaque within CTO

to puncture from pseudo to true lumen

Conquest Pro (Asahi Intec) for so tight CTO

to penetrate proximal or distal cap

to penetrate tight plaque within CTO

to puncture from pseudo to true lumen

Guidewire Selection

Miracle 12g is more controllable
- to penetrate proximal cap
- to advance in the tight CTO with bending,
- to puncture from pseudo to true lumen

Conquest should be used
- only when the appropriate direction can be seen
- to penetrate distal cap
- to puncture from pseudo to true lumen

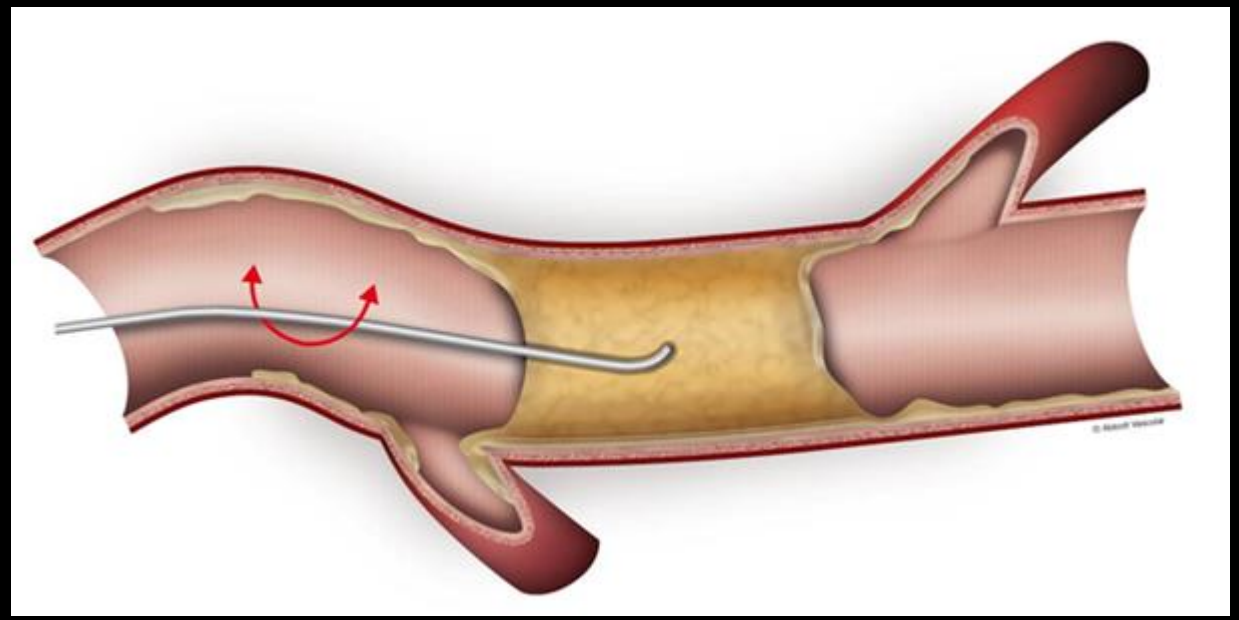
Conquest should not be used
- to seek the true lumen or advance for long distance

Guidewire Selection for CTO

Steps for Success

- Become familiar with one or two wire sets
- Over-the wire balloon or Transit catheter
- Frequent wire changes
- Frequent reshaping of wire tip
- Stepwise approach
- Penetration of proximal cap
- Wire passage through the body of the CTO
- Penetration of the distal cap

Controlled Drilling



The guide wire is advanced using gentle movements. Straight tip guide wires facilitate tactile feedback and steerability. Step up with stiffer guide wires.

Recommended Guide Wires

Straight Tip Guide Wires

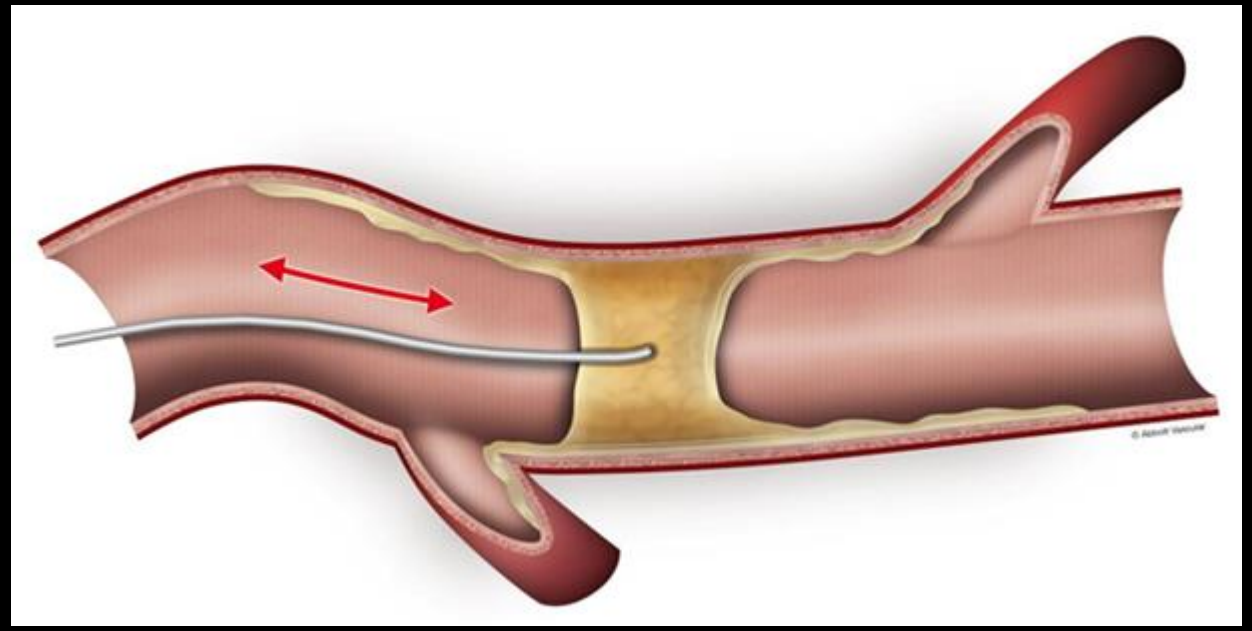
- ASAHI MIRACLEBROS 3
- ASAHI MIRACLEBROS 4.5
- ASAHI MIRACLEBROS 6
- ASAHI MIRACLEBROS 12

Tapered Tip Guide Wires

- HT CROSS-IT 100XT
- HT CROSS-IT 200XT
- HT CROSS-IT 300XT

Clinical application: Inside *calcified and fibrotic CTO* segment, *ISR*, *Long CTO* segment

Penetration



Penetrating the obstruction aiming at the target. The direction of the guide wire is more precisely controlled. Tapered tip guide wires permit higher penetrating forces.

Recommended Guide Wires

Straight Tip Guide Wires

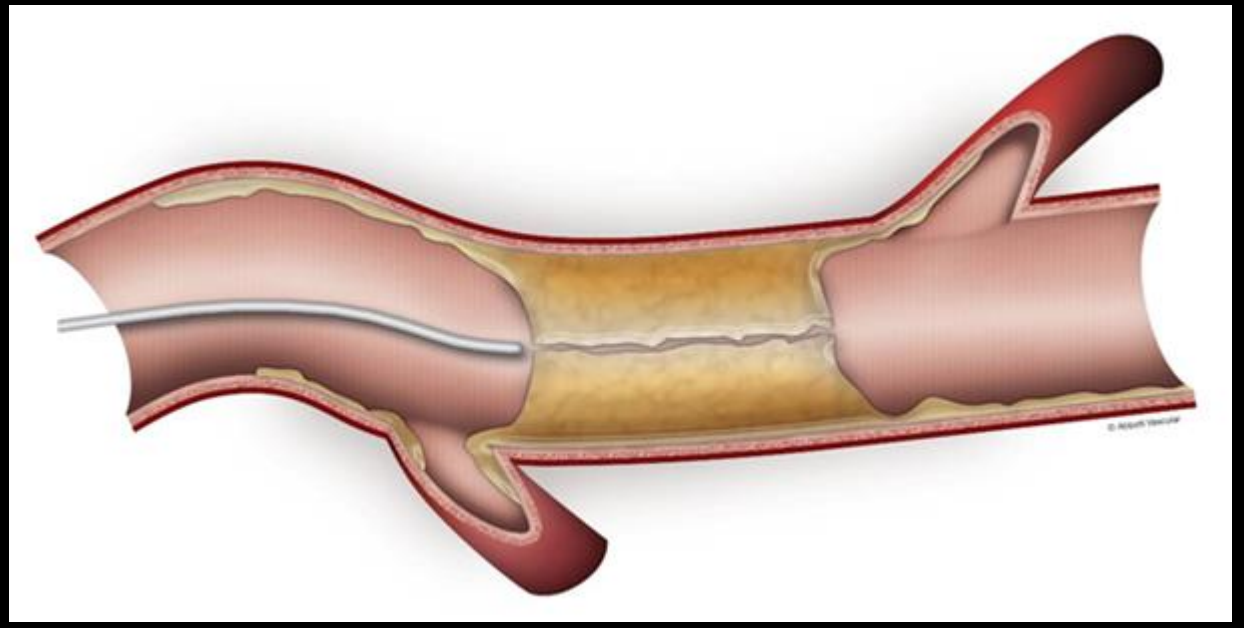
- ASAHI MIRACLEBROS 12

Tapered Tip Guide Wires

- ASAHI CONFIANZA 9
- ASAHI CONFIANZA PRO 9
- ASAHI CONFIANZA PRO 12
- HT CROSS-IT 400XT

Clinical Application: Penetrate *proximal and distal cap*, *False to true lumen (IVUS)*, Change wire direction (2nd wire in *parallel wire technique*)

Sliding-Microchannel tracking



Very lubricious polymer covered guide wires are used to slide through narrow lesions or functional occlusions.

Recommended Guide Wires

Tapered Polymer Tip Guide Wire

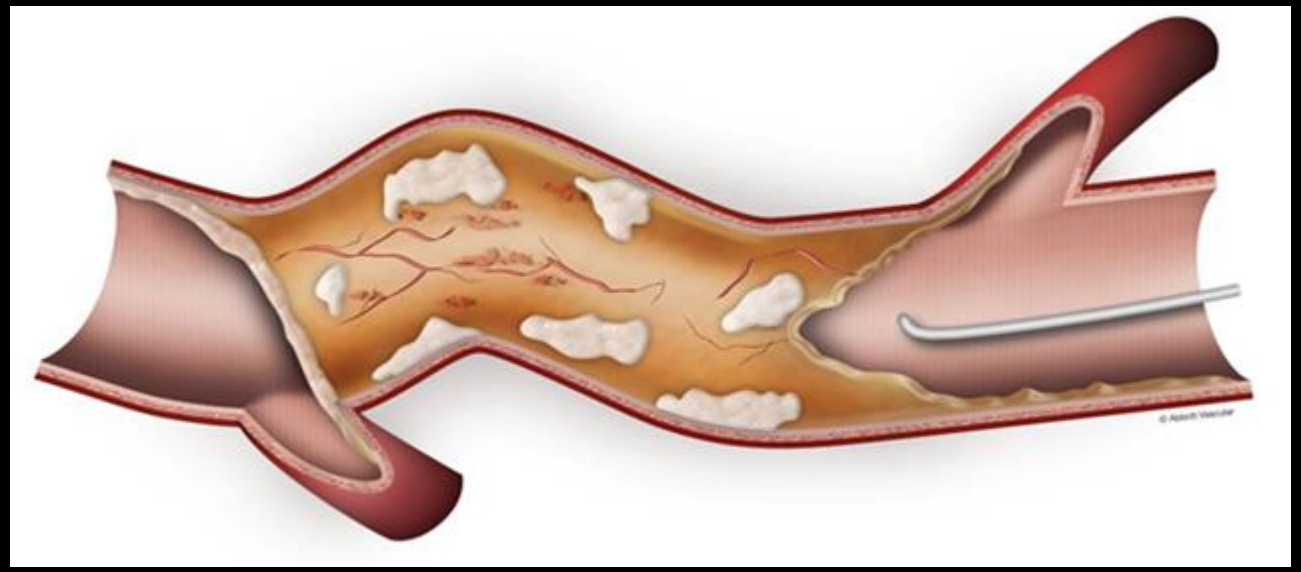
- ASAHI FIELDER XT

Polymer Covered Guide Wires

- HT PILOT 150
- HT PILOT 200

Clinical Application: Tracking *micro channels* (visible and invisible)

Collateral tracking



When an antegrade approach to the CTO fails or is contraindicated, the CTO can sometimes be approached from the retrograde direction. Flexible polymer covered guide wires are recommended for navigation through septals.

Recommended Guide Wires

Tapered Polymer Tip Guide Wire

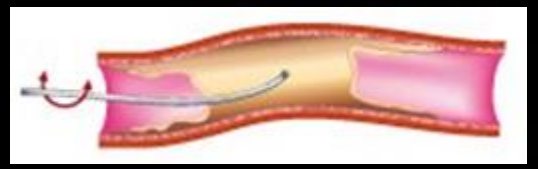
- ASAHI FIELDER XT

Straight Polymer Tip Guide Wire

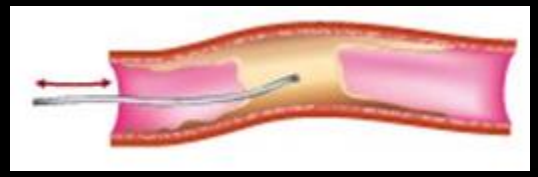
- ASAHI FIELDER FC
- ASAHI FIELDER

Clinical Application: *Retrograde techniques, CART, Reverse IVUS guided CART*

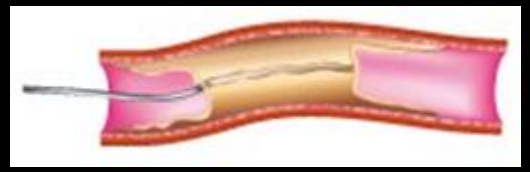
Chronic Total Occlusion



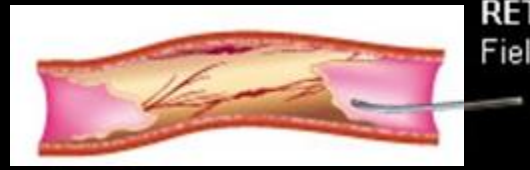
CONTROLLED DRILL
ULTIMATE bros 3
Miracle 3 / MIRACLE bros 3
Miracle 4.5 / MIRACLE bros 4.5
Miracle 6 / MIRACLE bros 6
Miracle 12 / MIRACLE bros 12
Intermediate / MEDIUM



PENETRATION TECHNIQUE
Conquest / CONFIANZA
Conquest Pro / CONFIANZA PRO
Conquest Pro 12 / CONFIANZA PRO 12
Miracle 12 / MIRACLE bros 12

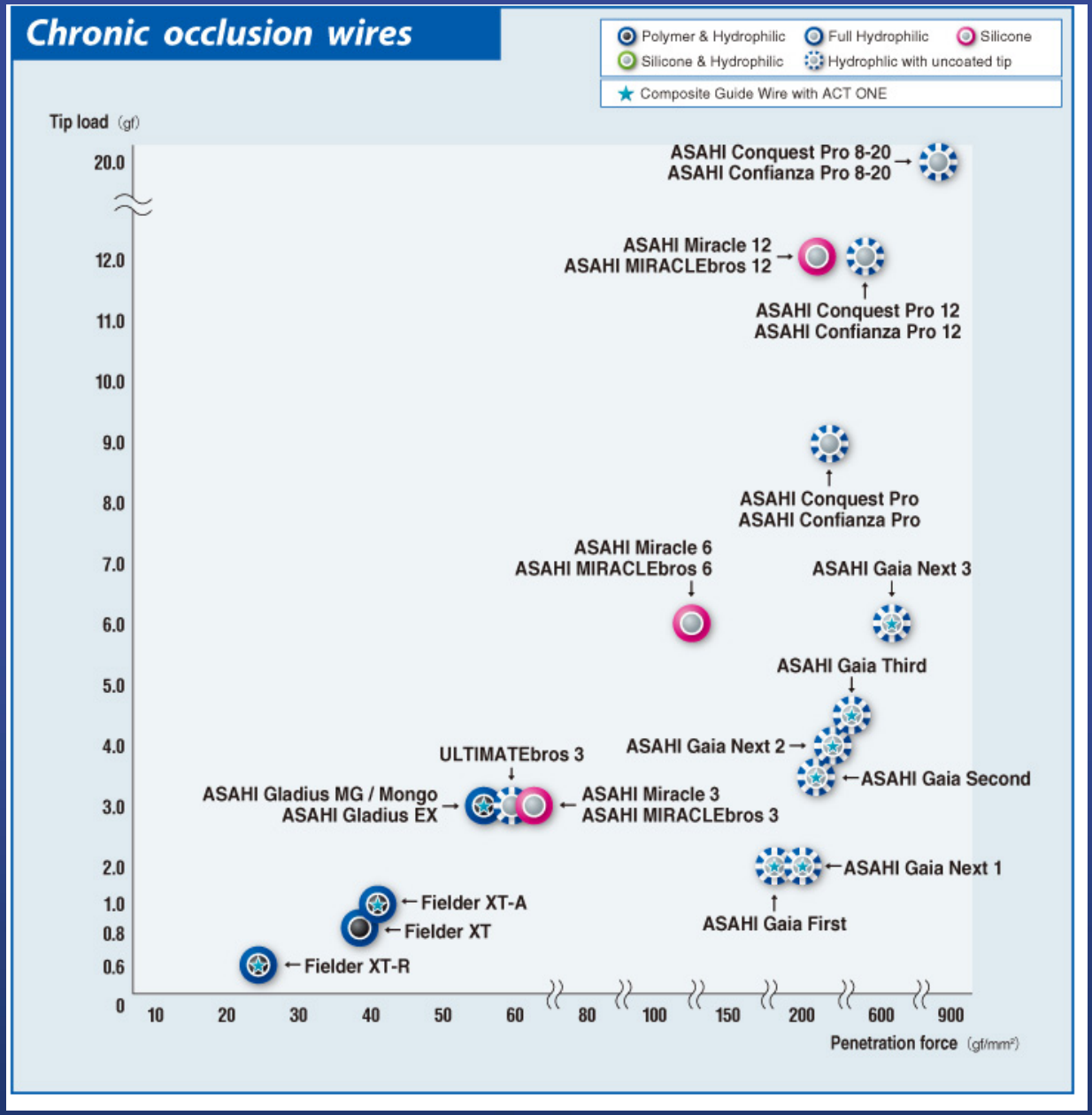


SLIDING TECHNIQUE
Fielder, Fielder FC, Fielder XT

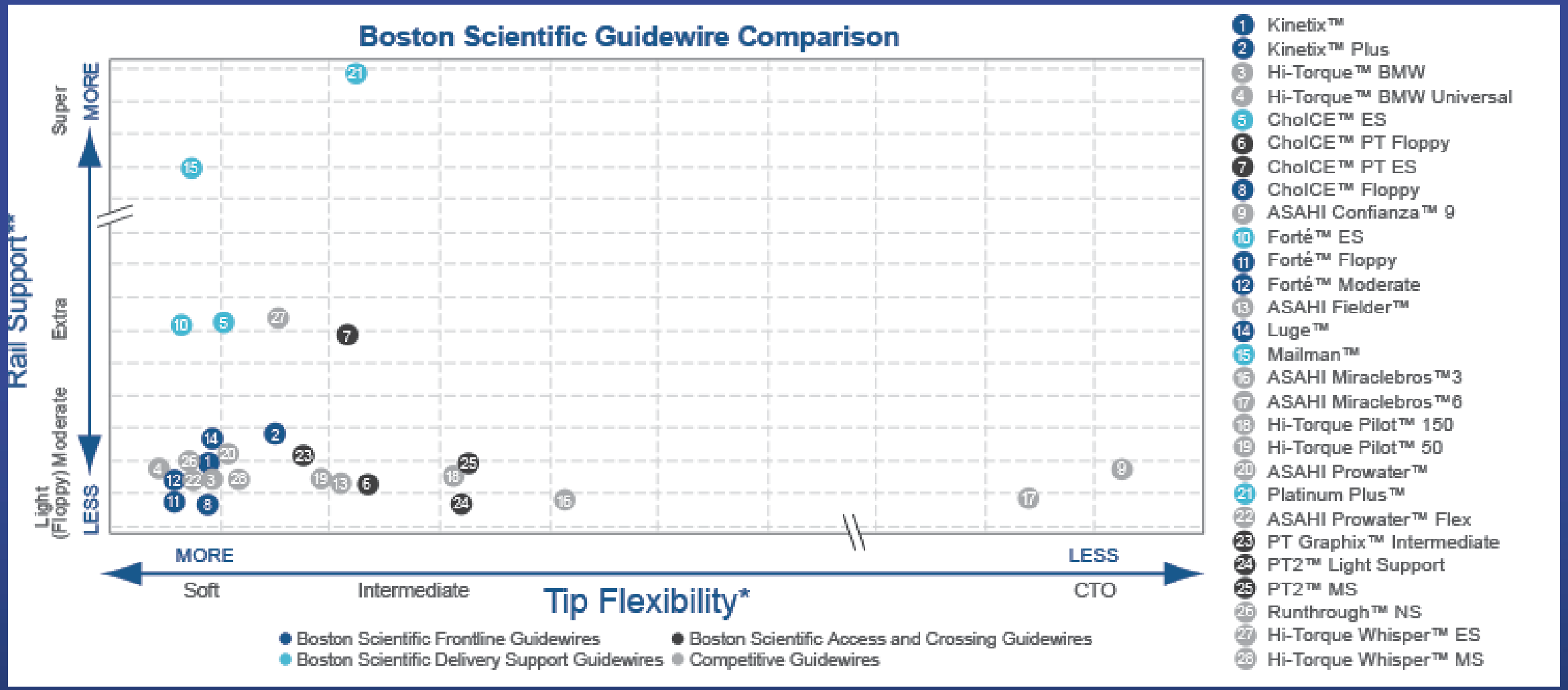


RETROGRADE APPROACH
Fielder, Fielder FC, Fielder XT

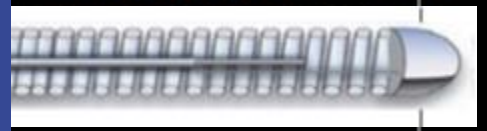
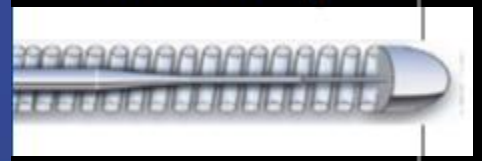
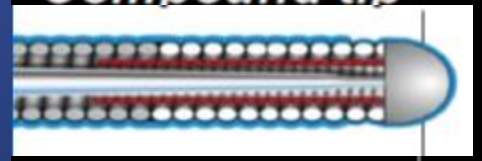
Chronic Total Occlusion



Chronic Total Occlusion

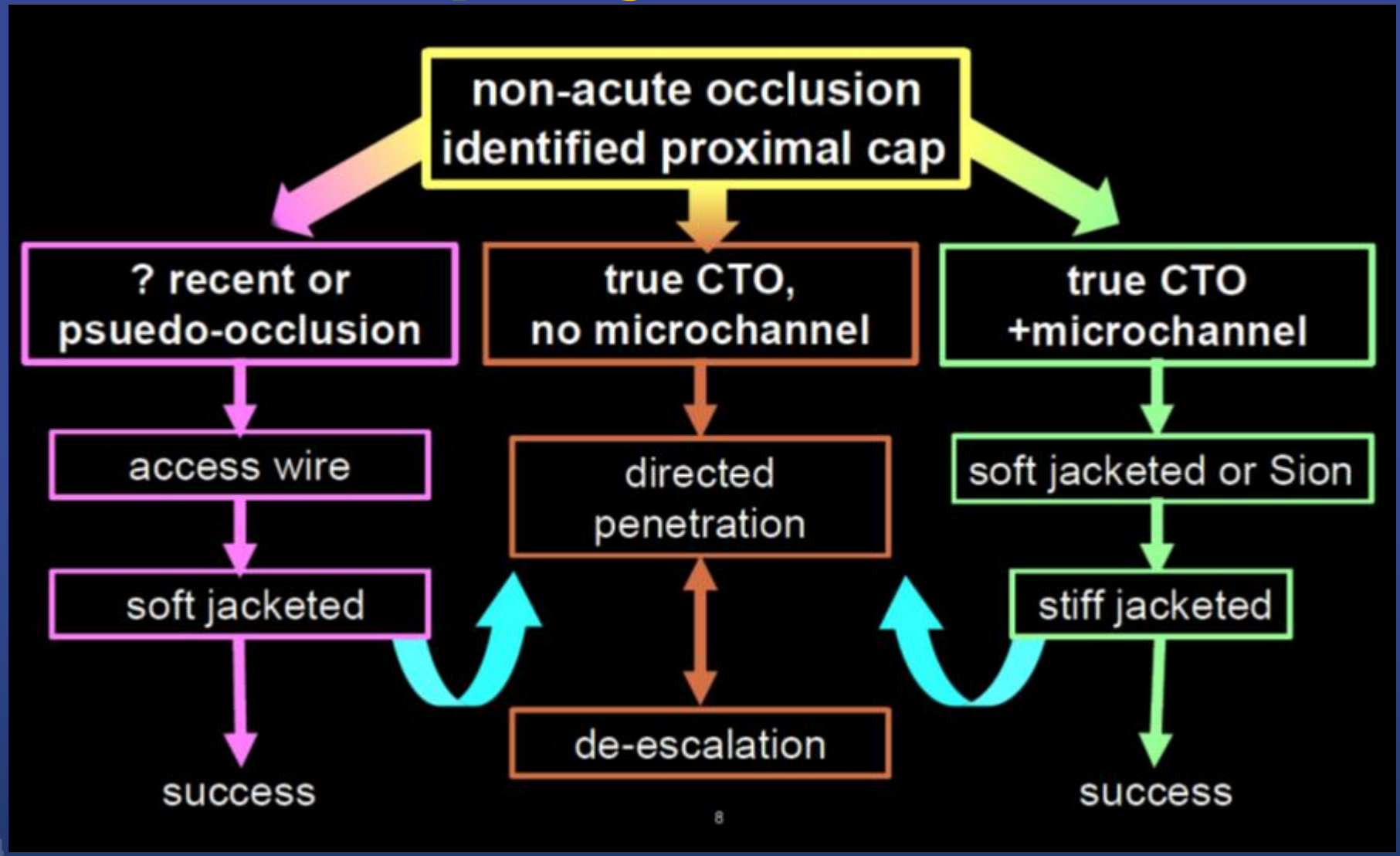


Access wires classified by core design

	Stainless Steel	Nitinol
Shaping Ribbon 	High Torque F2	BMW Universal-2* Cougar
Core-to-tip 	Pro-Water Marvel Advance	Run-Through BMW Elite
Compound tip 	Sion Blue Samurai	

Abbott
Asahi
Boston Sci
Medtronic
Terumo

Approach to antegradetrue-to-true wiring contemporary wire modulation



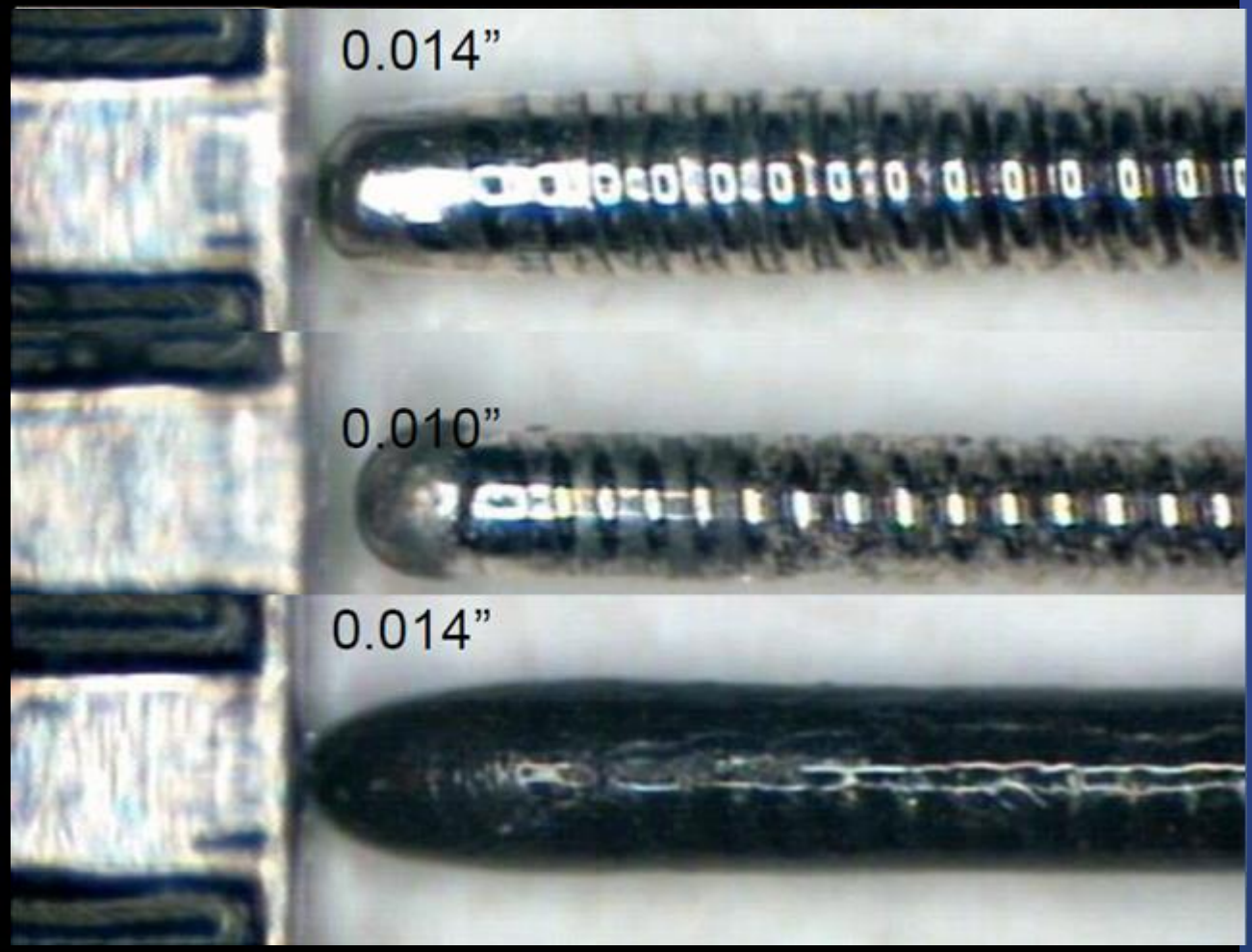
Directed Penetration wires

- progressive tip load, progressive torsional rigidity

Conventional 0.014
Hi-Torque Standard
Miracle Bros
Halberd

Tapered tip coil
Confianza
Cross-It XT
Hornet (0.008”)

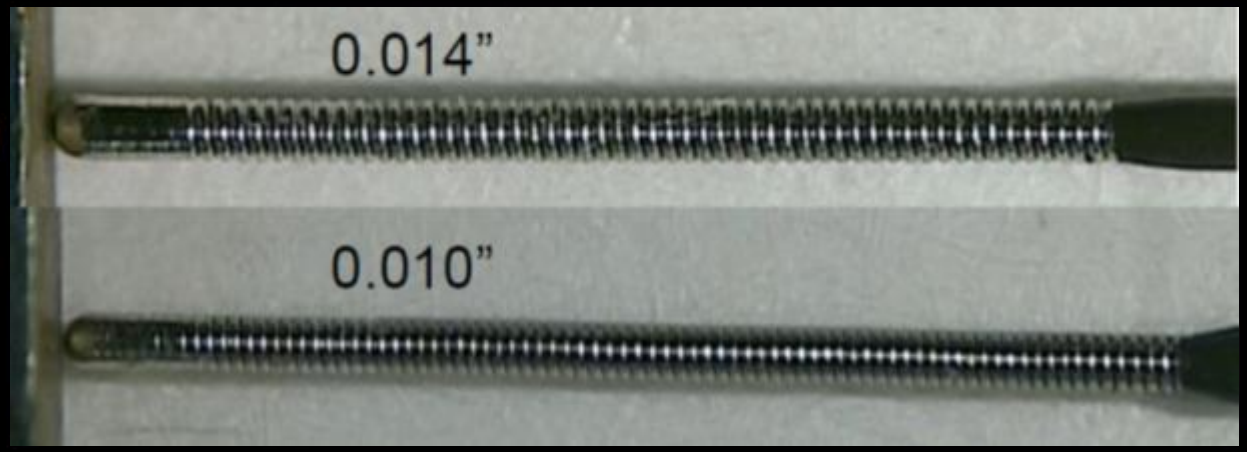
Stiff Jacketed
Pilot 200
Gladius



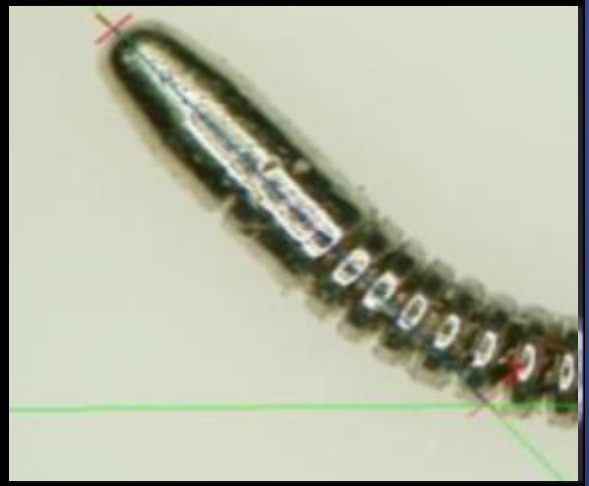
2nd/3rd Gen Directed Penetration wires

Progress 40 / 80 / 120

Progress 200T



Gaia	Tip Type	Diam	Load
Gaia 1st	Coil-in-coil	0.010	1.7 gm
Gaia 2nd	Coil-in-coil	0.011	3.5 gm
Gaia 3rd	Coil-in-coil	0.012	4.5 gm



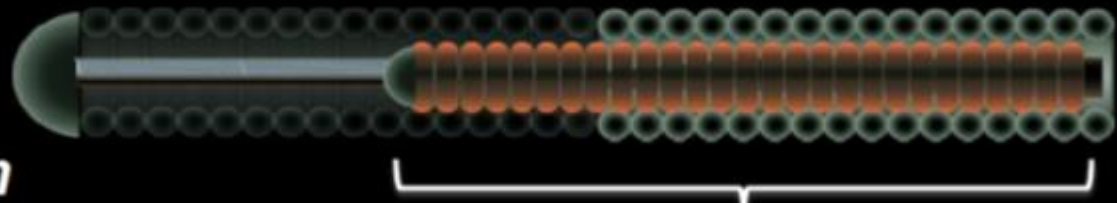
Collateral Crossing wires

- low tip load, atraumatic tip shape, lubricity

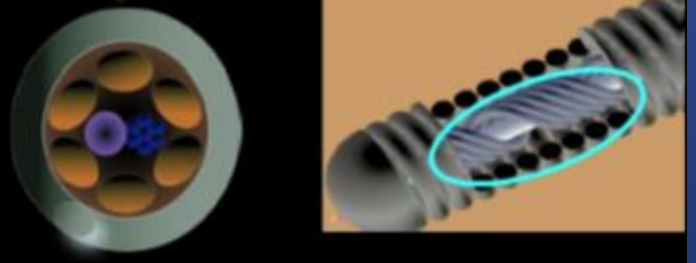
Fielder FC	*0.014”*	*0.8gm*
Pilot 50	*0.014”*	*1.0gm*
Fielder XT-A	*0.009”*	*1.0gm*

Sion 0.8gm

Sion Black 0.8gm



0.014” multi-element composite core

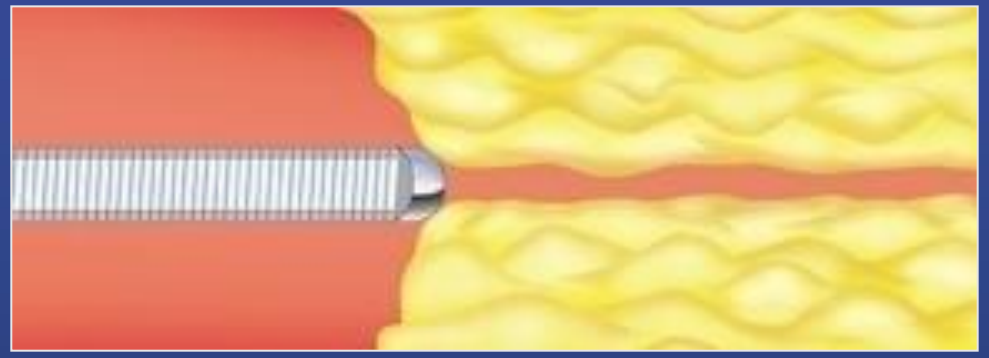


Big Tips Are for Waiters!

0.010” tip

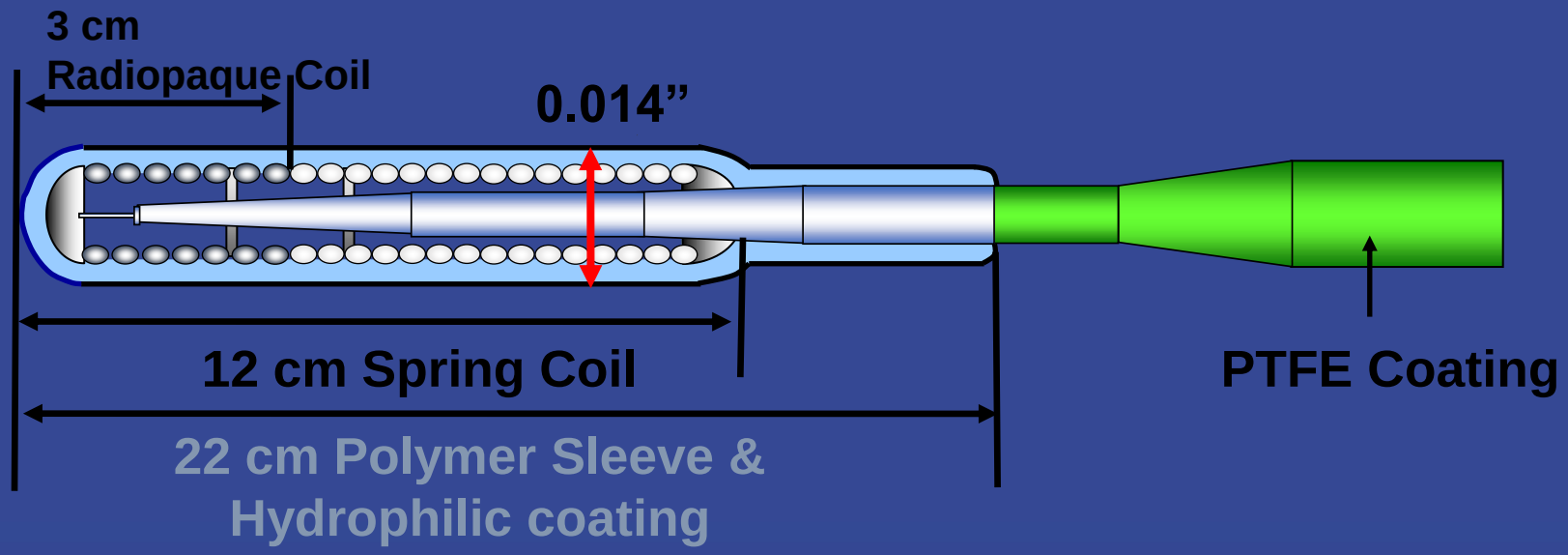
0.007” microchannel

0.014” tip



0.007” microchannel

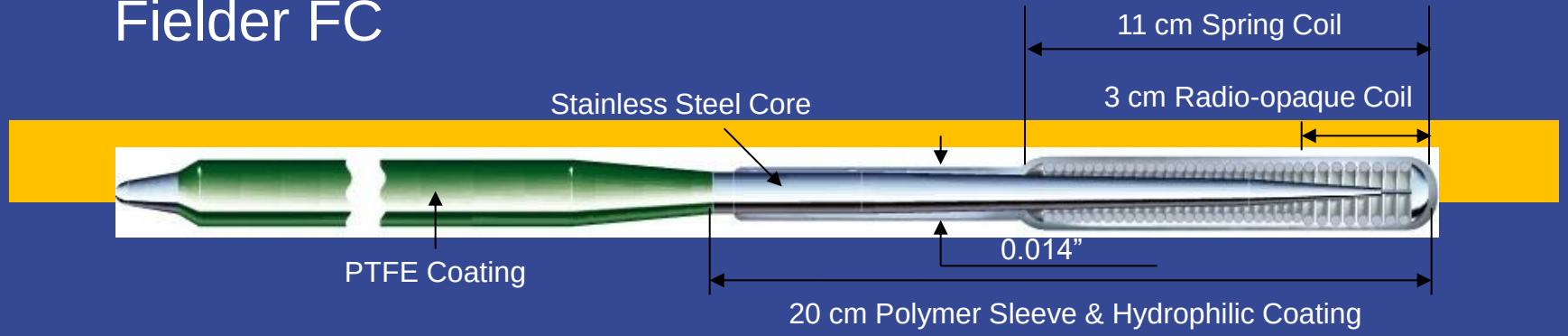
ASAHI Neo's Fielder



Catalog No.	AGP140000
Tip weight	1.0 g
Radiopacity length	3 cm
Outside diameter	0.014 inch
Total length	175 cm

ASAHI FIELDER FC PTCA Guide

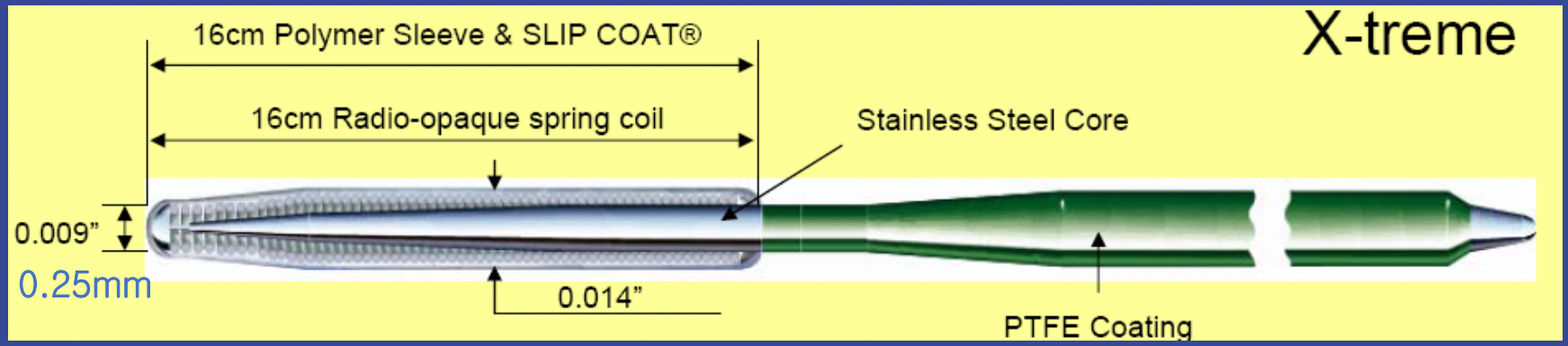
Fielder FC



Device description
: Polymer covered guide wire with extra support for effortless movement in tortuous anatomy

Stiffness
: Tip Load = 0.8 g

Fielder XT wire



One-Piece Core Wire

: Supports the entire guidewire from the proximal to the distal end. This design transmits the guidewire torque fully from one end to the other.

Tapered Tip

: 0.009” (0.25mm) tapered tip facilitates trackability in tortuous vessels such as fine septal channels with corkscrew aspect.

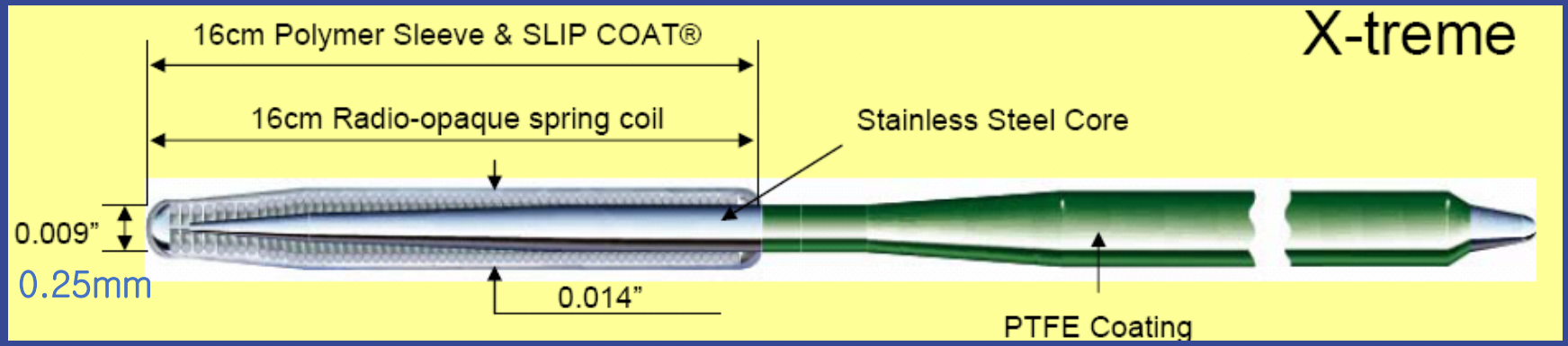
Flat Core Tip

: Provides flexibility and excellent shaping memory.

Smooth Tapered Core

: Enhances support performance which provides excellent guidewire trackability.

Fielder XT wire



One-Piece Core Wire

: Supports the entire guidewire from the proximal to the distal end. This design transmits the guidewire torque fully from one end to the other.

Tapered Tip

: 0.009” (0.25mm) tapered tip facilitates trackability in tortuous vessels such as fine septal channels with corkscrew aspect.

Flat Core Tip

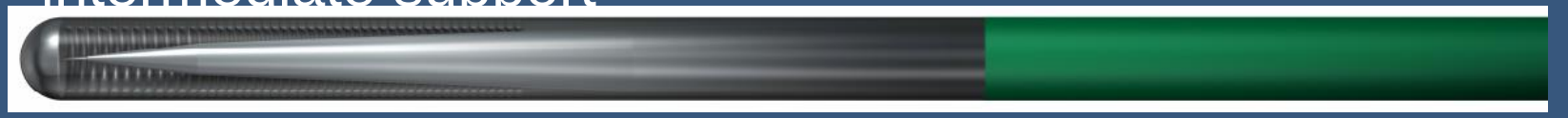
: Provides flexibility and excellent shaping memory.

Smooth Tapered Core

: Enhances support performance which provides excellent guidewire trackability.

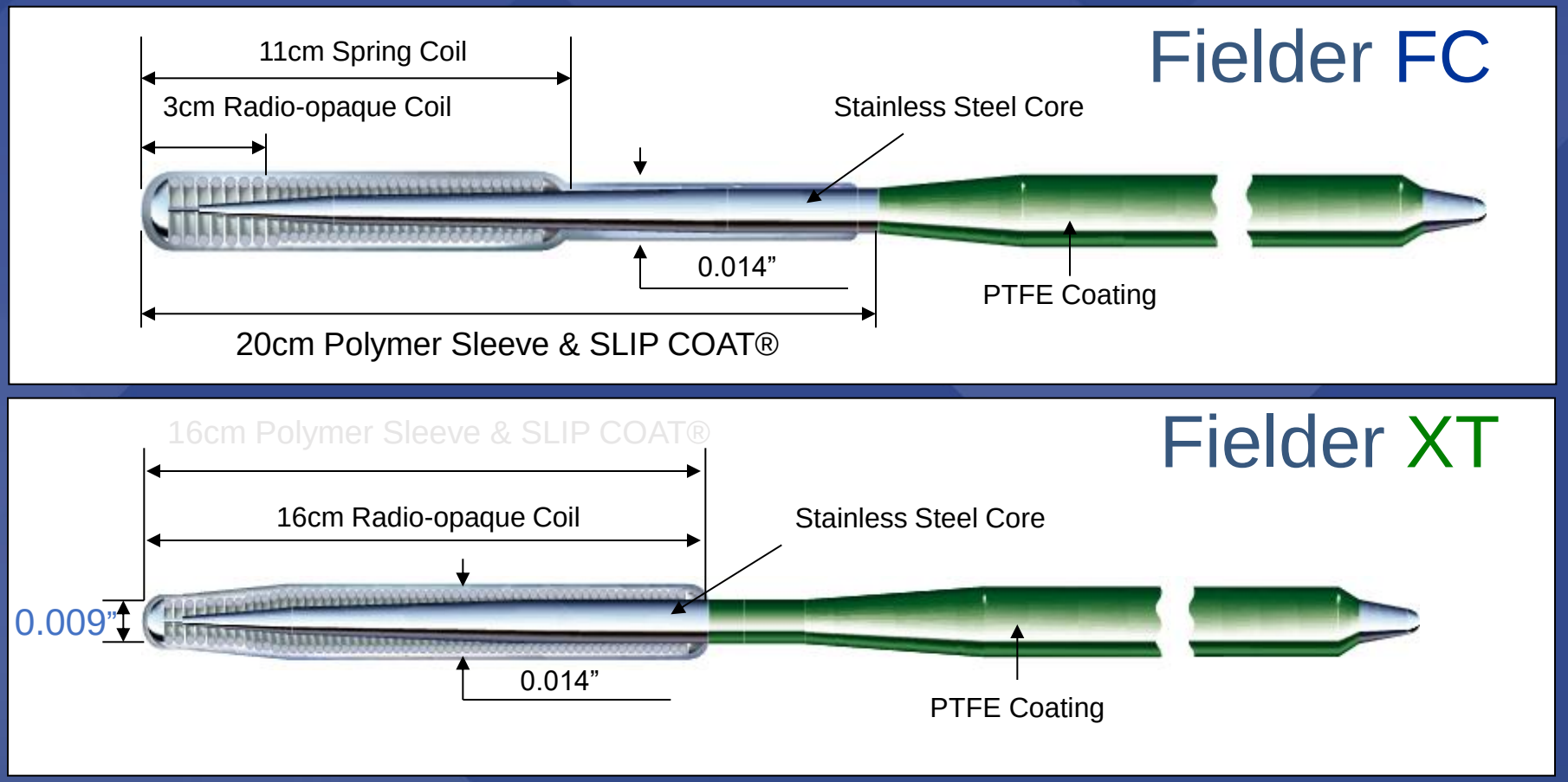
The ASAHI FIEDLER™ FC & XT

- ASAHI FIELDER™ FC maintains a softer tip, more intermediate support*

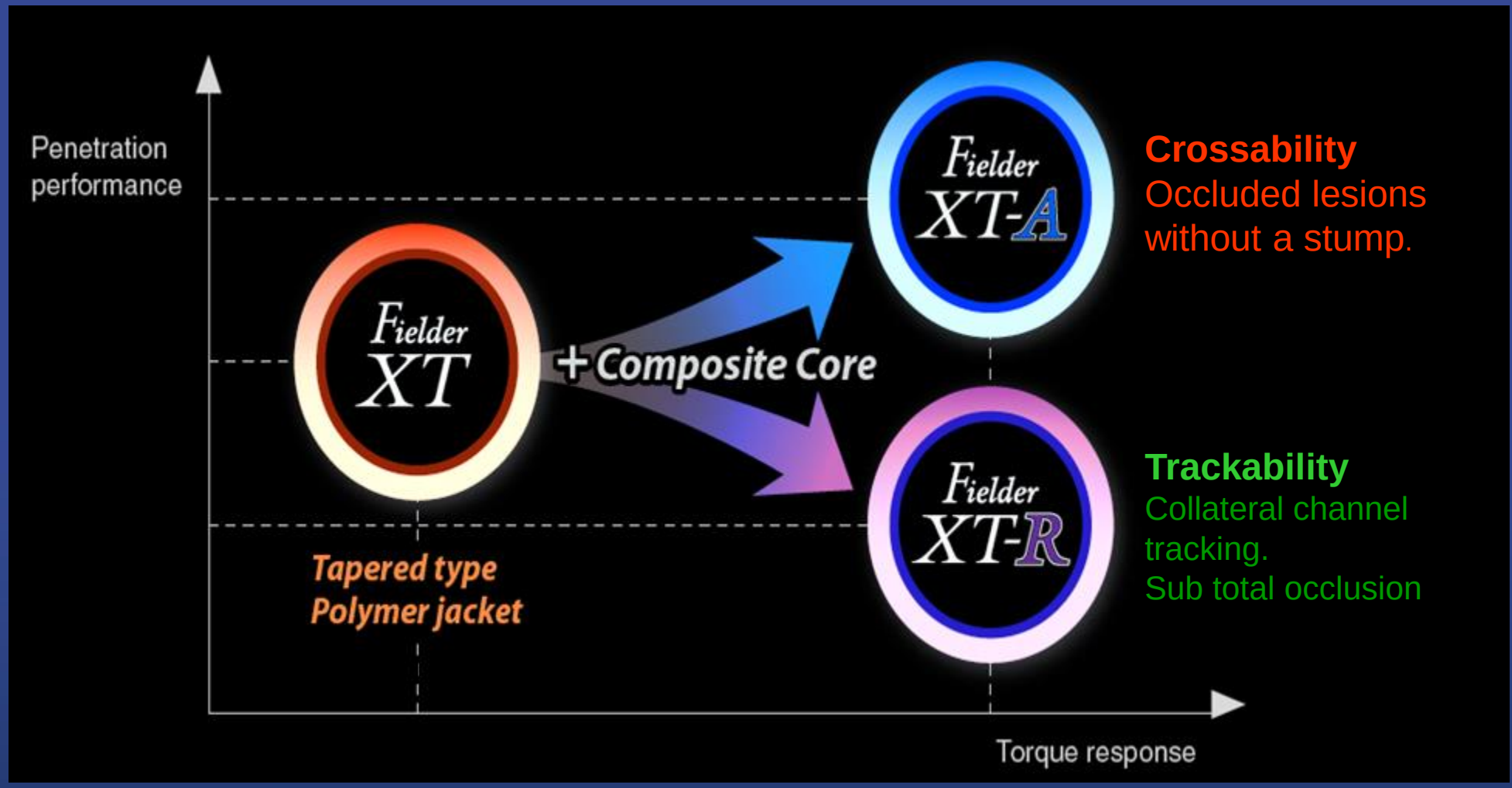


- ASAHI FIELDER™ XT maintains a softer tip,

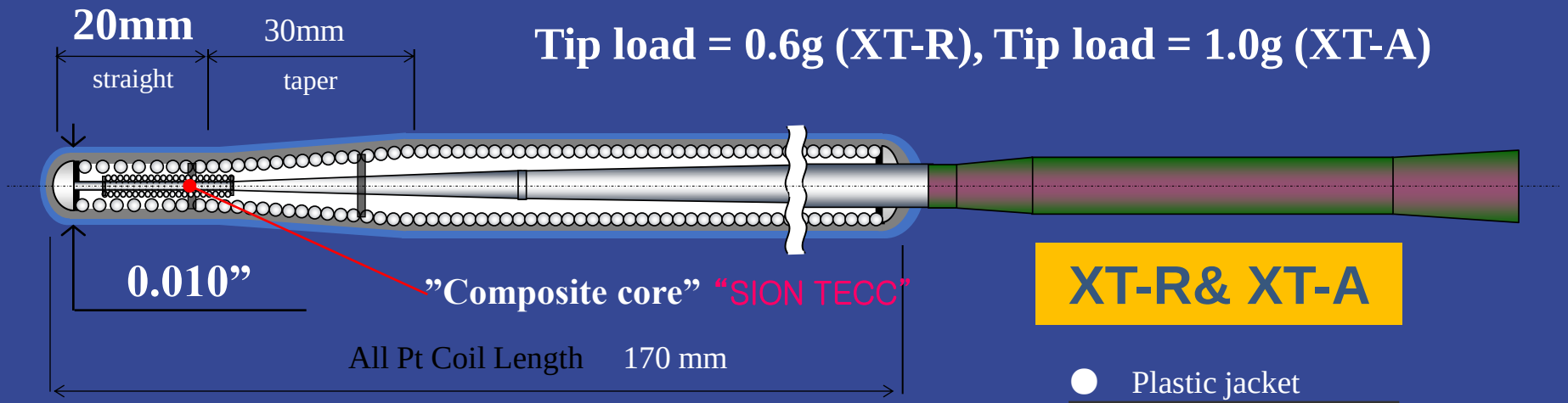
The ASAHI FIEDLER™ FC & XT



Beyond Fielder XT



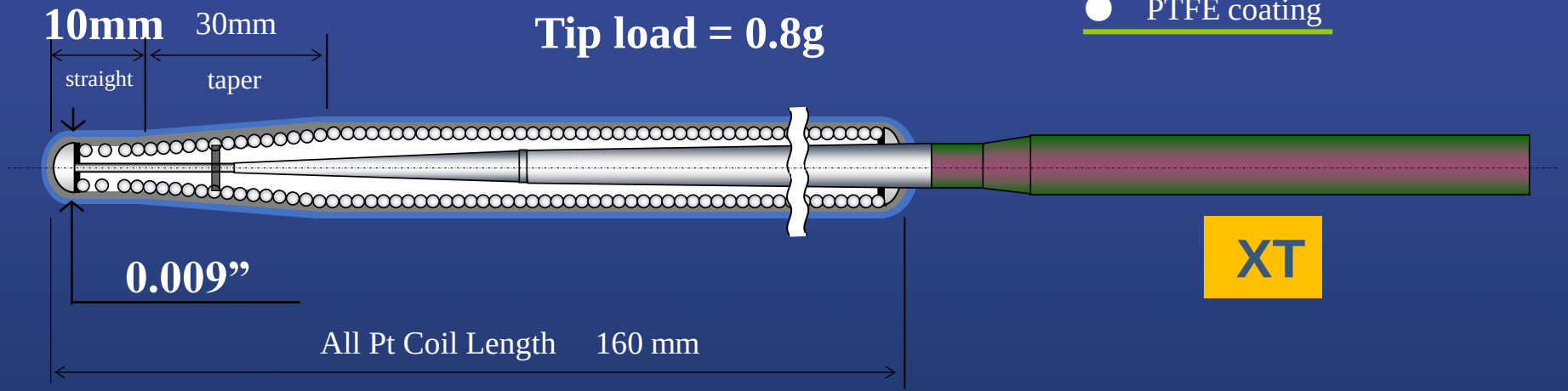
Fielder XT-A & Fielder XT-R



Tip load = 0.6g (XT-R), Tip load = 1.0g (XT-A)

XT-R& XT-A

- Plastic jacket
- Hydrophilic polymer coating
- PTFE coating

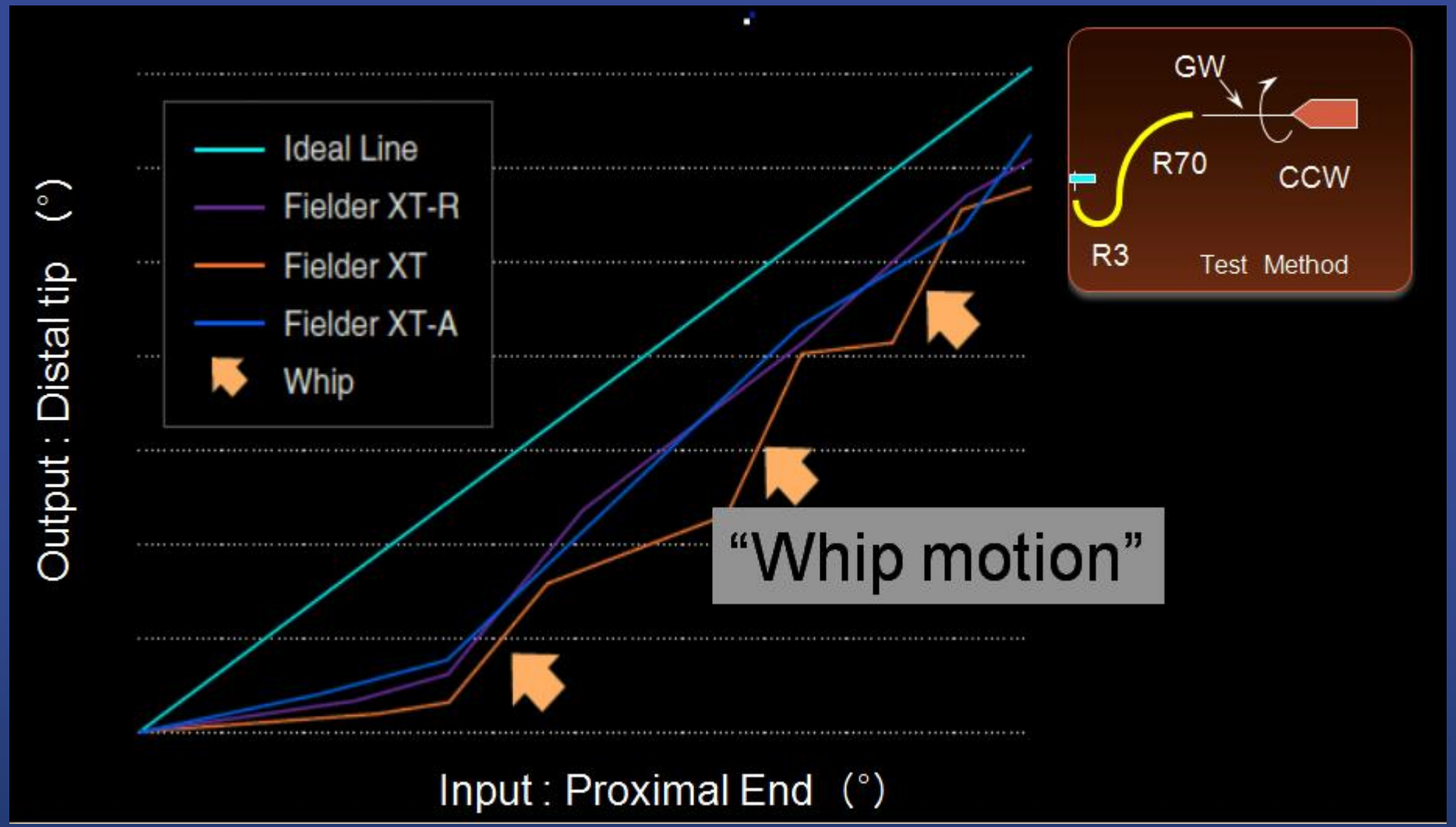


Tip load = 0.8g

XT

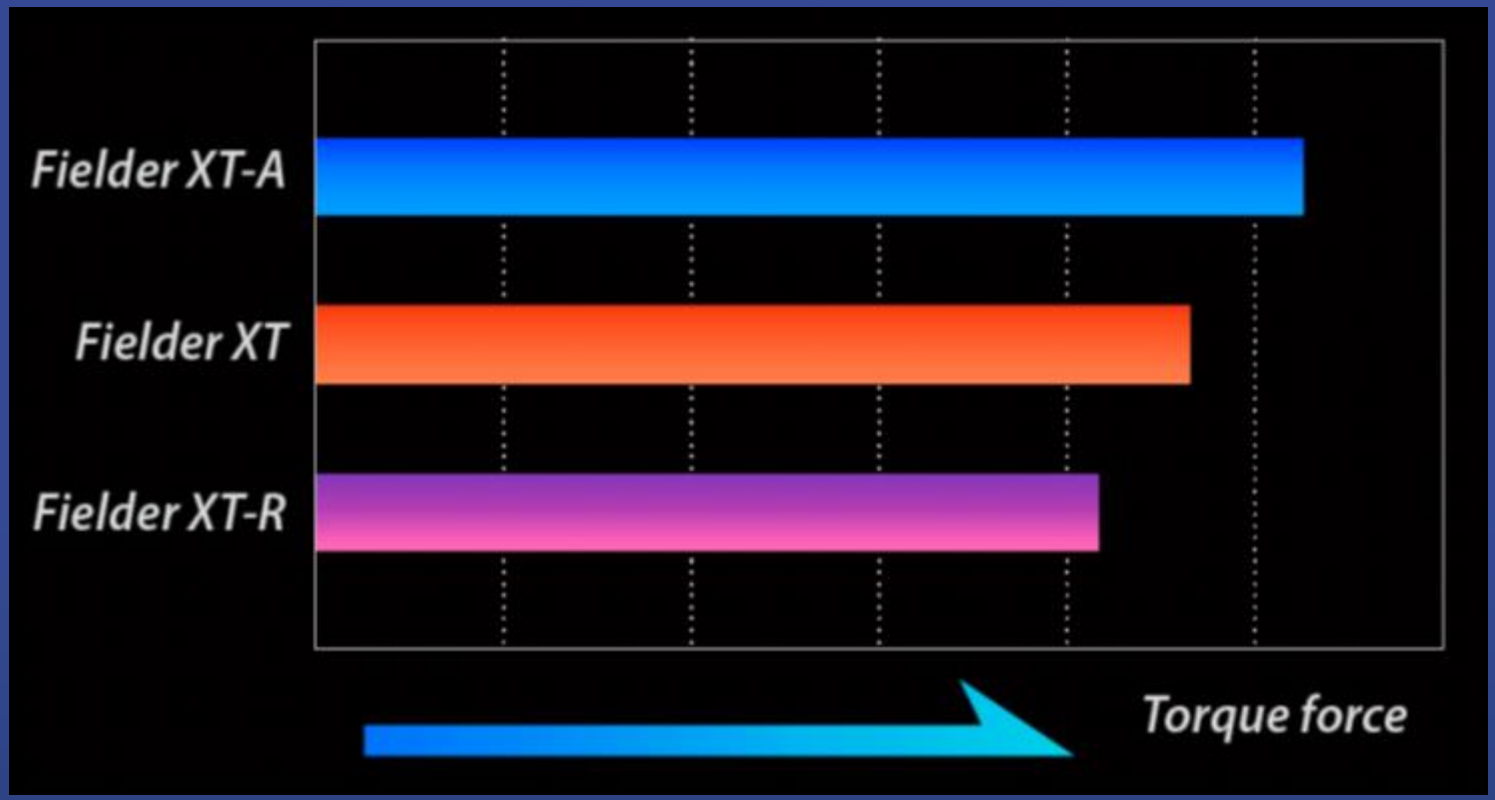
Fielder XR Series: Performance comparison

Torque Whip



Fielder XR Series: Performance comparison

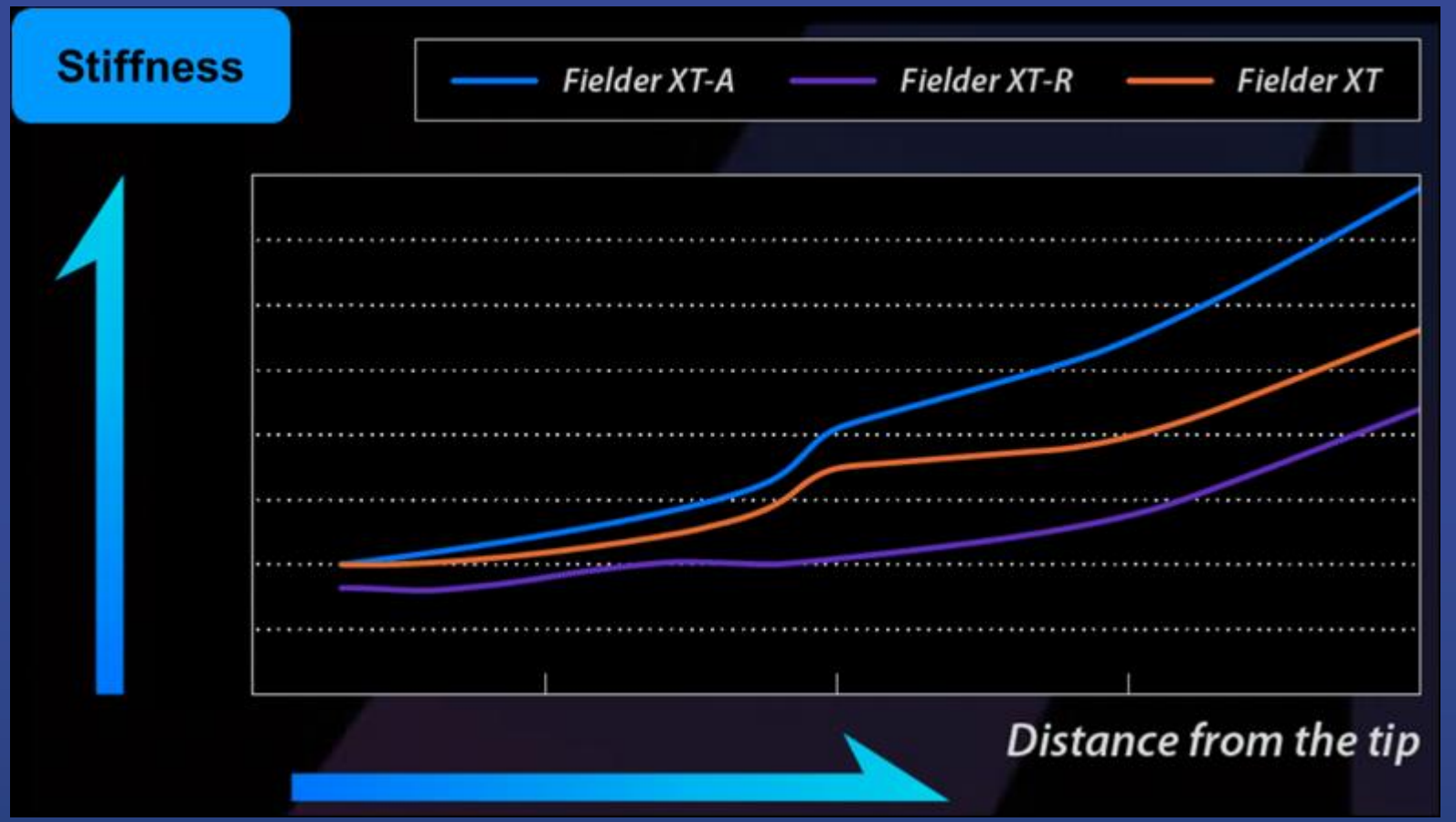
Torque Force



Fielder XT-A has better performance to cross the occluded lesion.

Fielder XR Series: Performance comparison

Tip Flexibility



Fielder XT-R has better performance for the channel tracking.

ASAHI Wires:

Miraclebros & Confianza

Miraclebros 3g
Miraclebros 4.5g
Miraclebros 6g
Miraclebros 12g

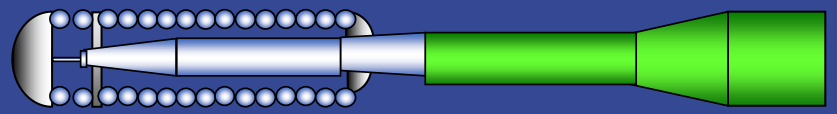
Confianza 9g
CP(Confianza Pro) 9g
CP(Confianza Pro) 12g

- Excellent trackability, 1:1 torque, and tactile response
- Incremental tip stiffness and wire support (Miraclebros line)
- Smallest tapered tip design (Confianza & CP, 0.009”)

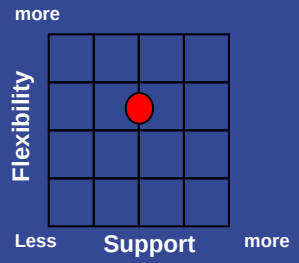
Miracle Series

Miracle 3

AG14M050
Tip Radiopacigy
11cm
0.014inch
175cm

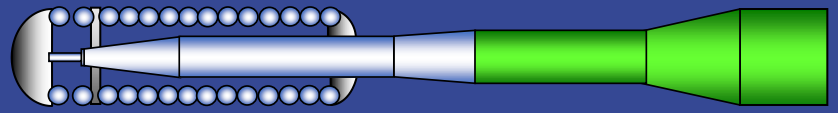


（Tip Stiffness 3.0G）

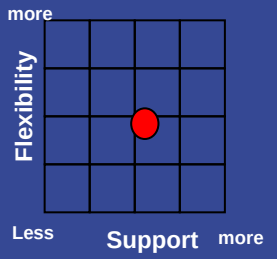


Miracle 4.5

AG14M045
Tip Radiopacigy
11cm
0.014inch
175cm

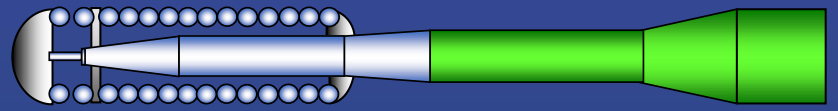


（ Tip Stiffness 4.5G）

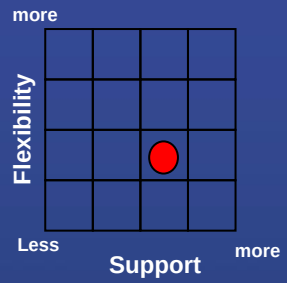


Miracle 6

AG14M060
Tip Radiopacigy
11cm
0.014inch
175cm

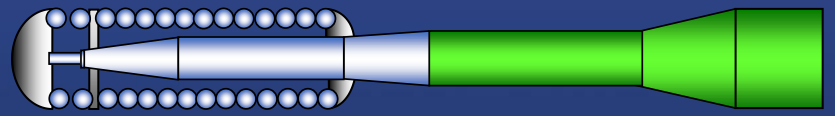


（ Tip Stiffness 6.0G）

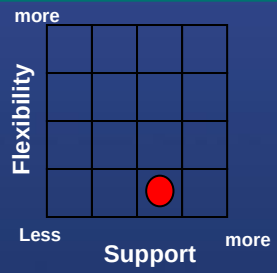


Miracle 12

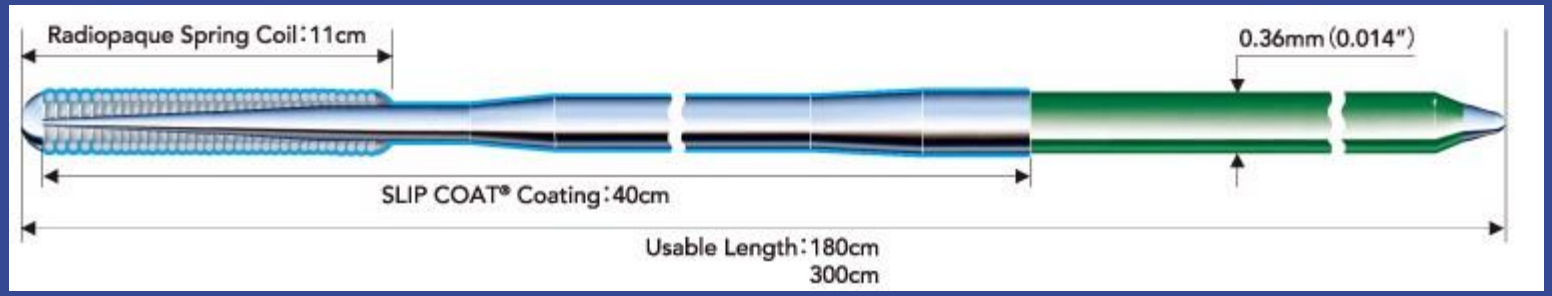
AG14M070
Tip Radiopacigy
11cm
0.014inch
175cm



（ Tip Stiffness 12.0G）

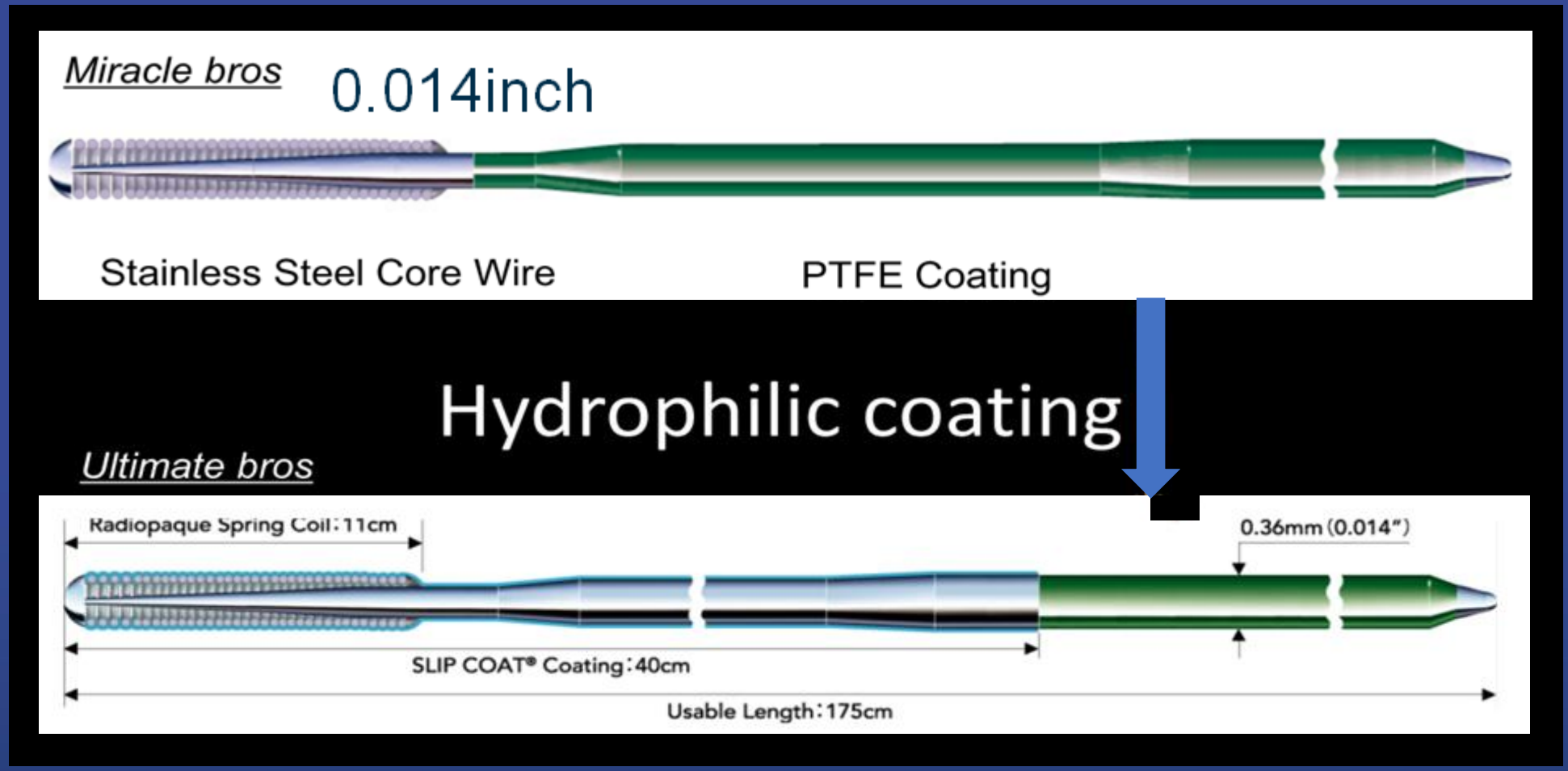


ASAHI ULTIMATE bros3



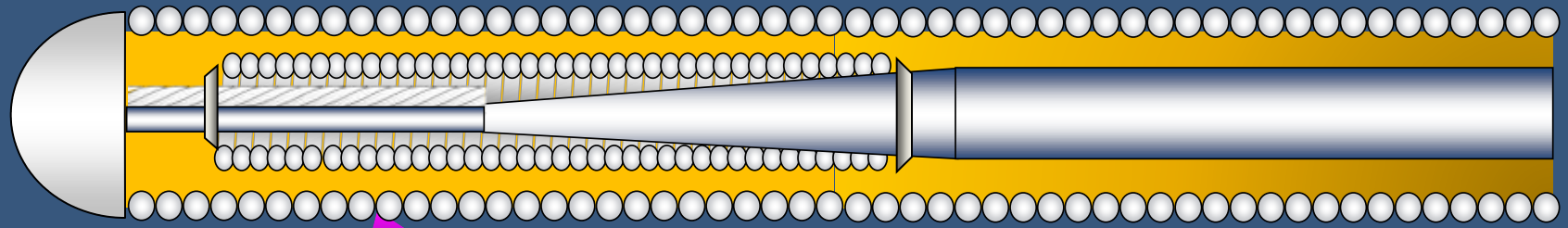
- Long hydrophilic coating maintains high maneuverability, allowing improved wire manipulation in heavy stenosed lesions.
- Fine shaping improves vessel selectivity and reduces the risk of false lumen expansion.

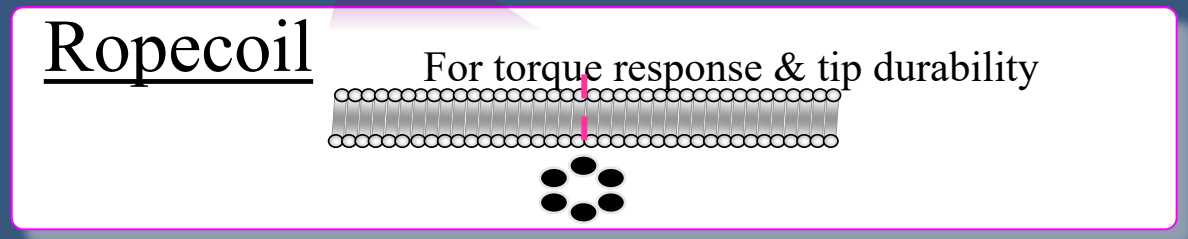
Miracle-Ultimate Series



Penetrate with greater tip stiffness

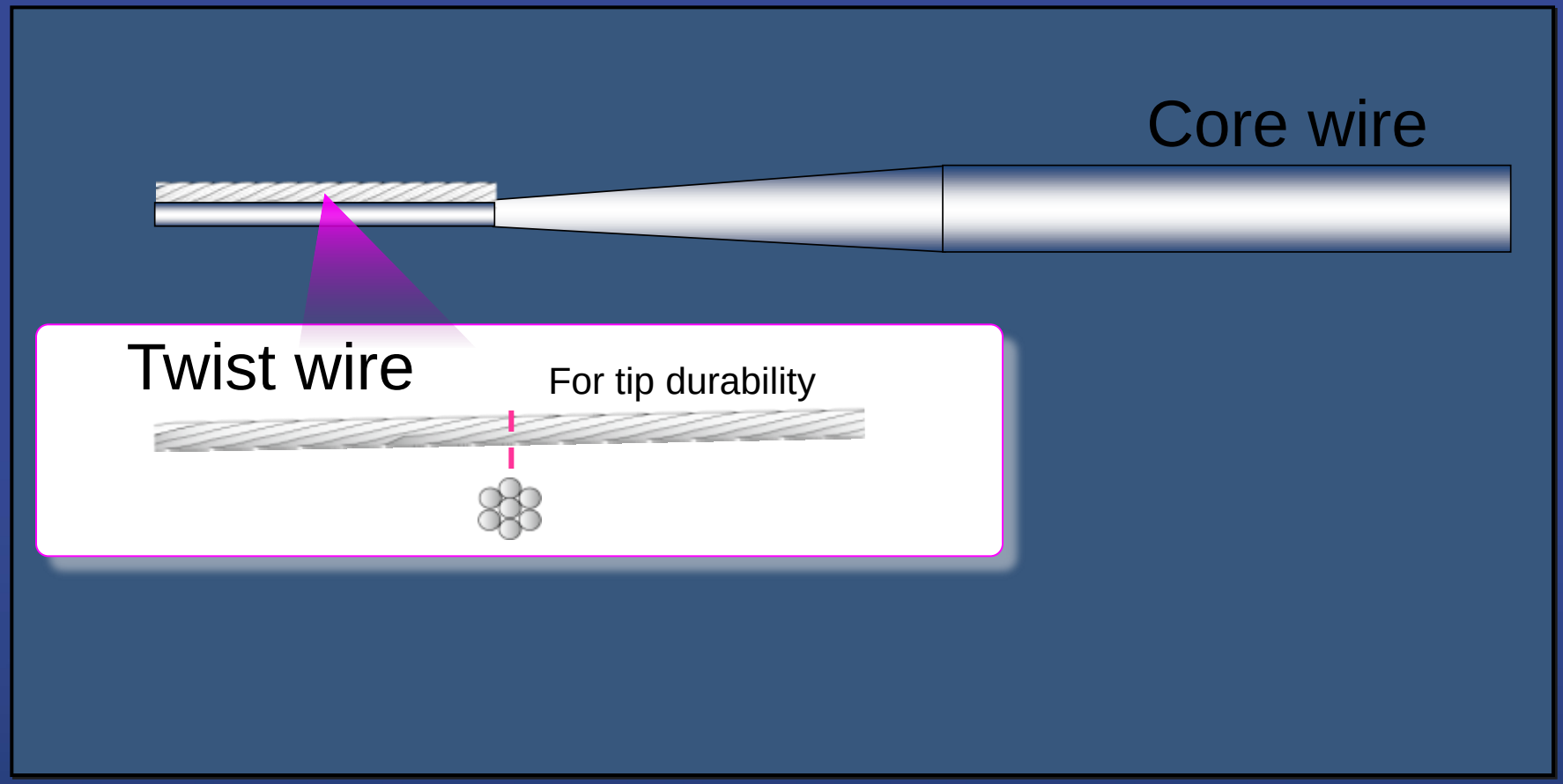
ASAHI SION Family





- Unique GW structure ; Double-coil structure
- 0.014” Coil type workhorse GW
- Good torque response - “No whip” motion
- Tip Durability
- Full Hydrophilic coating
- Tip Load 0.7g

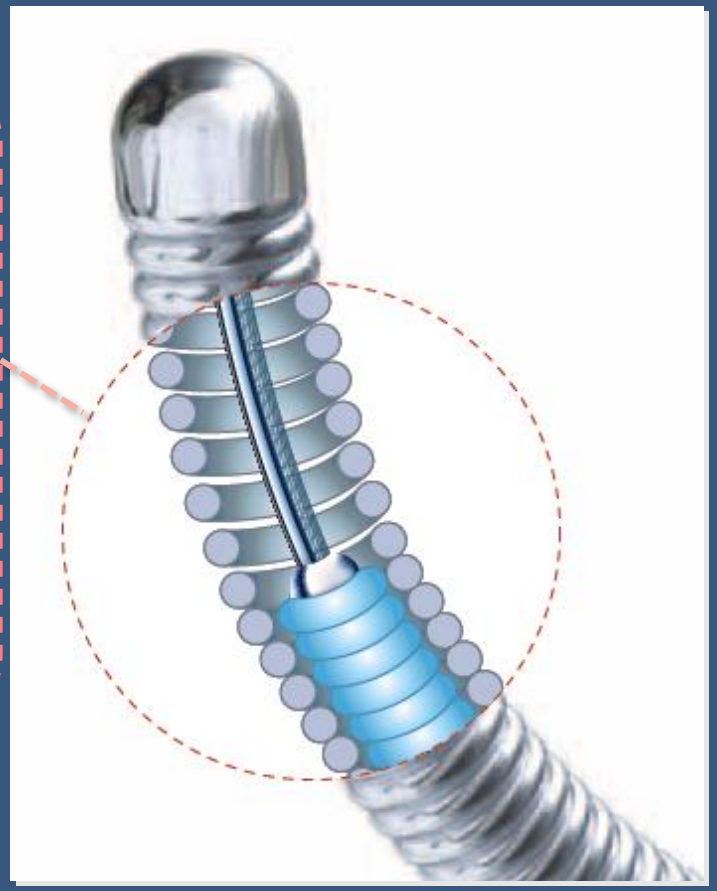
ASAHI SION Family



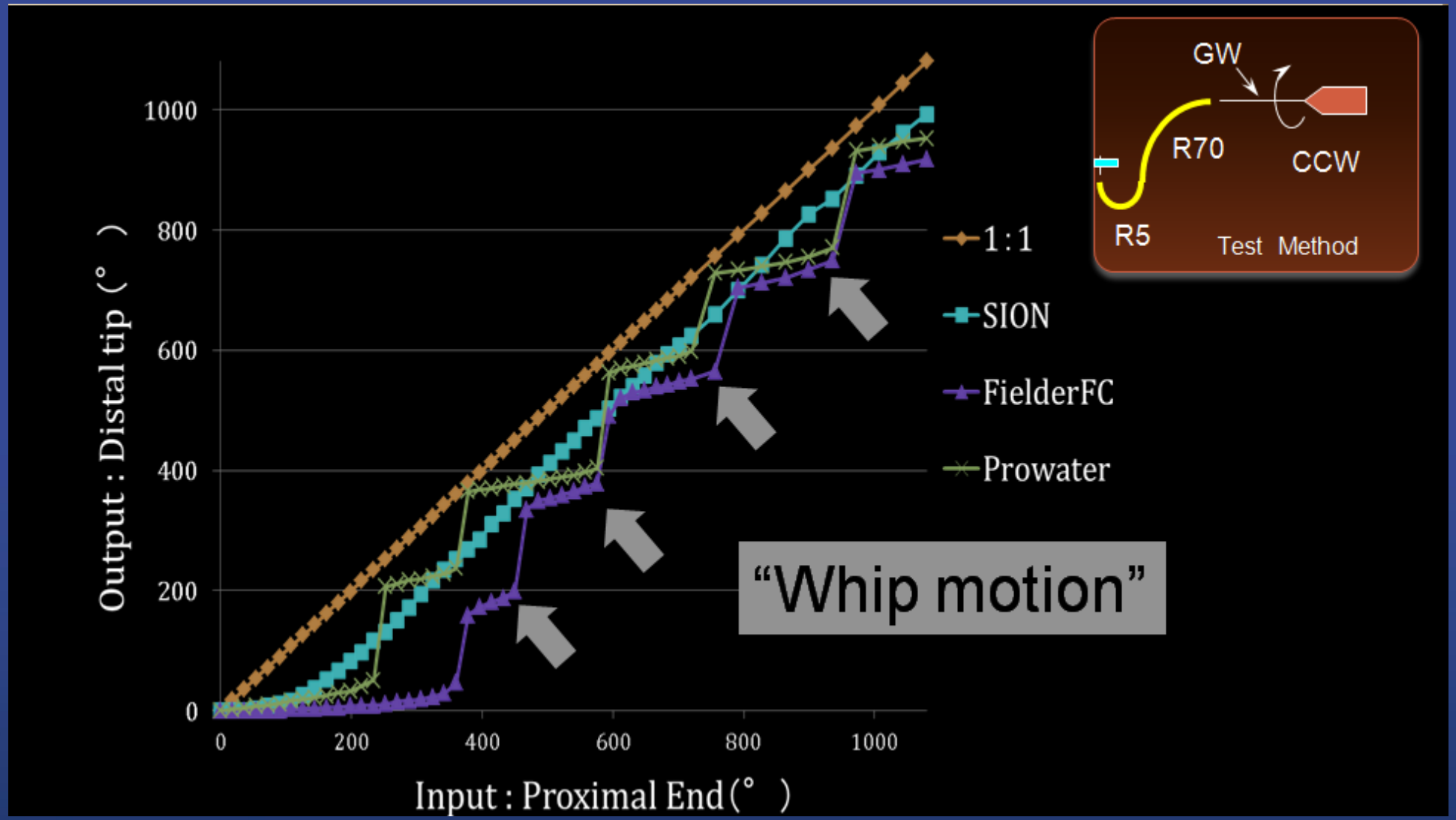
Composite Core of SION Family

Double coil structure

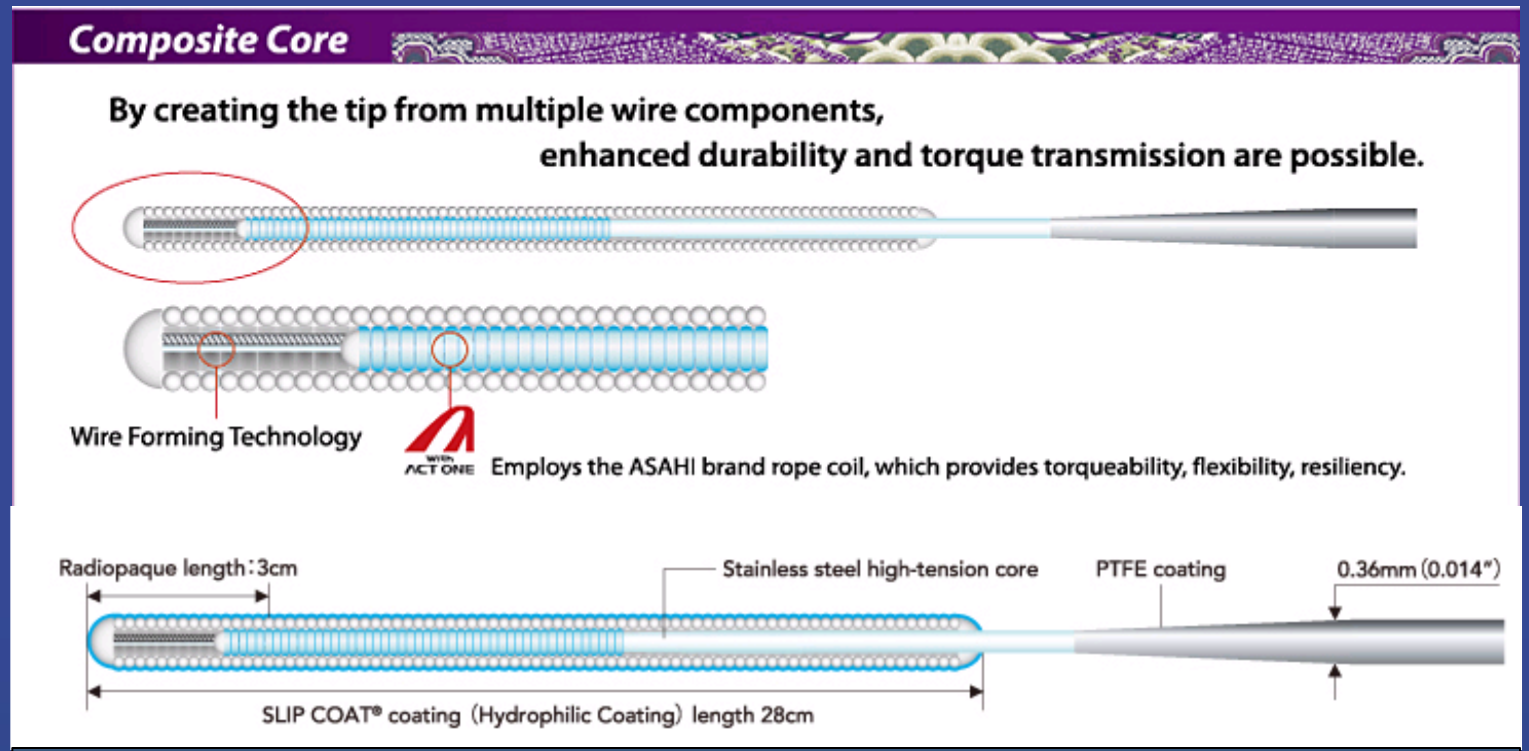
- *Smooth tracking of side branch vessel*
  : No-whip motion
- *Retention of maneuverability after crossing severe tortuousity*
  : Enhanced tip durability and shape retention



Difference in Torque Whip



ASAHI SION

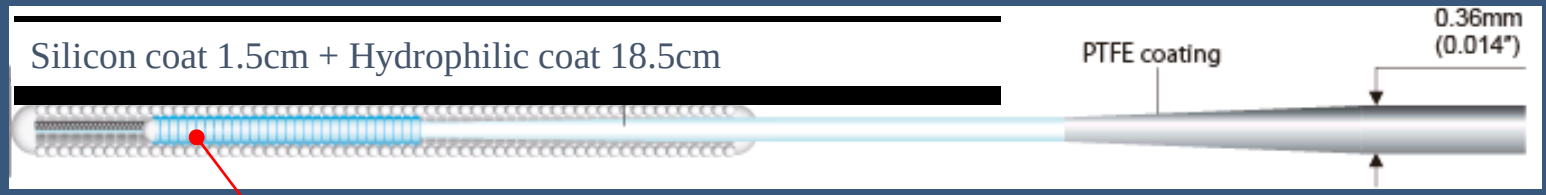


- Durable tip with outstanding shape retention
  : Possible to treat multiple lesions with one wire
- Advanced torque performance even in extreme tortuosity
  : Easier vessel selectivity, even after an acute angle
- Flexible shaft and atraumatic tip
  : Employ the wire in a variety of situations stress-free

ASAHI SION BLUE

SION BLUE

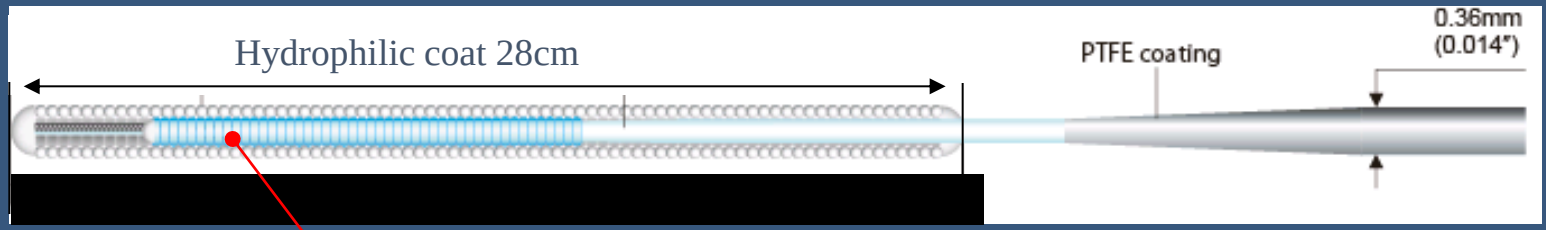
Tip load
0.5g



”Composite core”

SION

Tip load
0.7g



”Composite core”

ASAHI SUHO 03

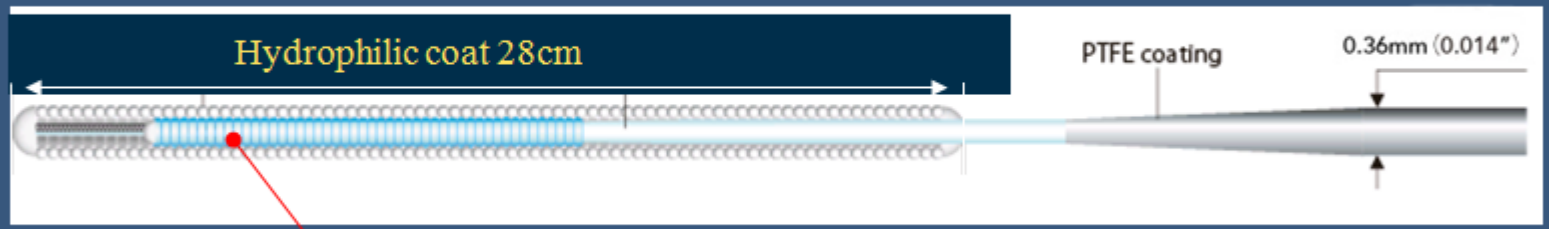
SUHO 03

Tip load
0.3g

"Composite core"

SION

Tip load
0.7g

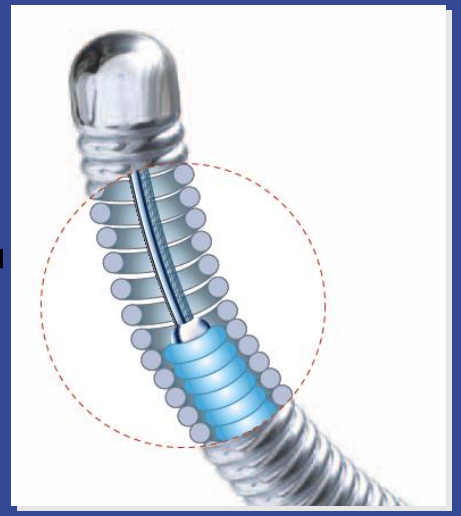


"Composite core"

Development Concept

Fielder FC

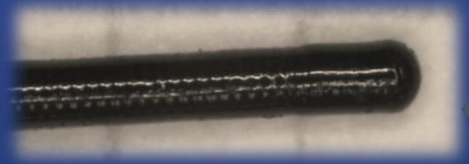
+



Composite core

SION

+

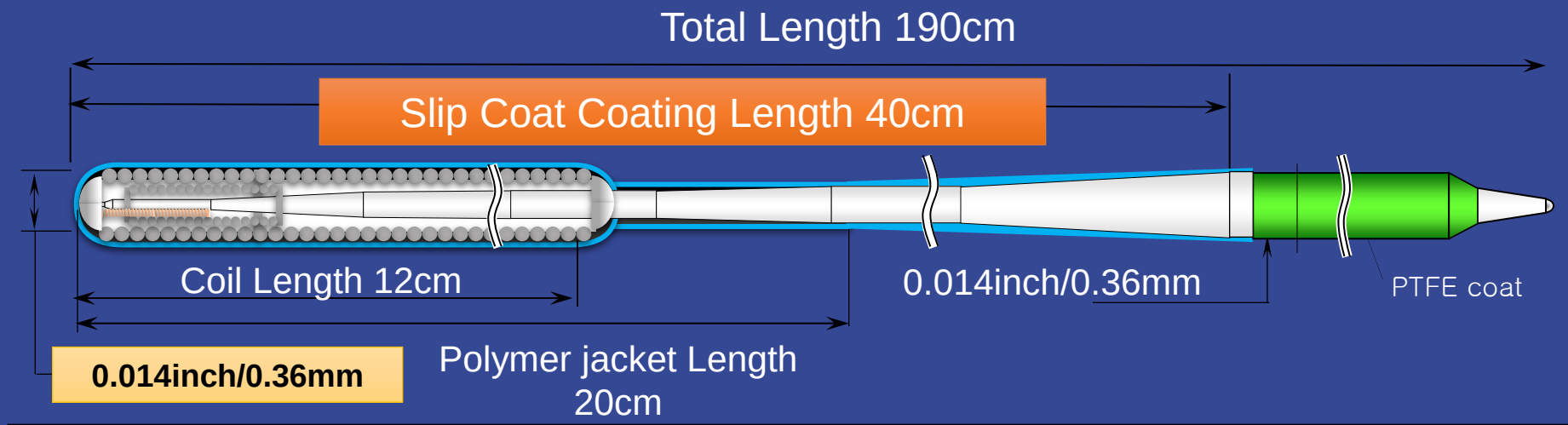


Polymer jacket

ASAHI SION black
PTCA GUIDE WIRE

Line-up addition to the SION series utilizing the advantages of both products

SION black Structure



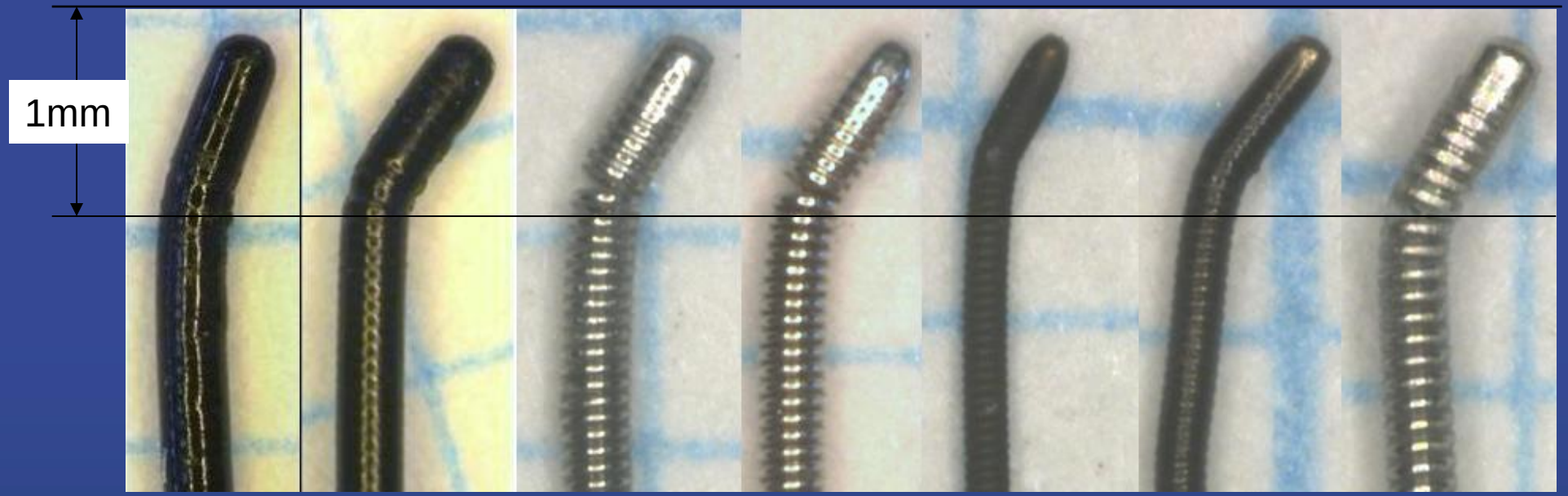
Smooth trackability and high device maneuverability for retrograde approach

SION black

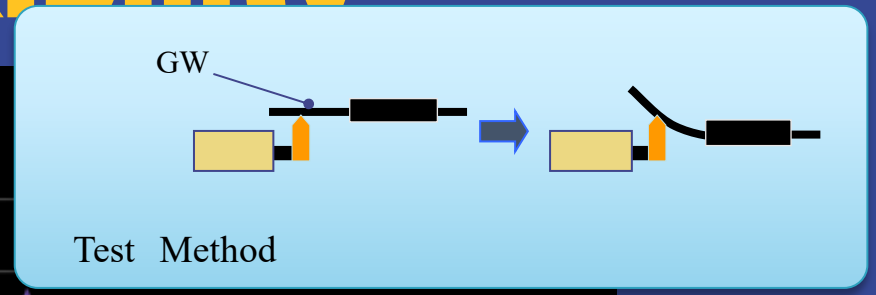
Diameter : **0.014”/0.36mm**
Tip loads : **0.8gf**
Coating length : **40cm**
Usable length : **190cm**

Long hydrophilic coating provides smooth manipulation when used with a support catheter such as Corsair

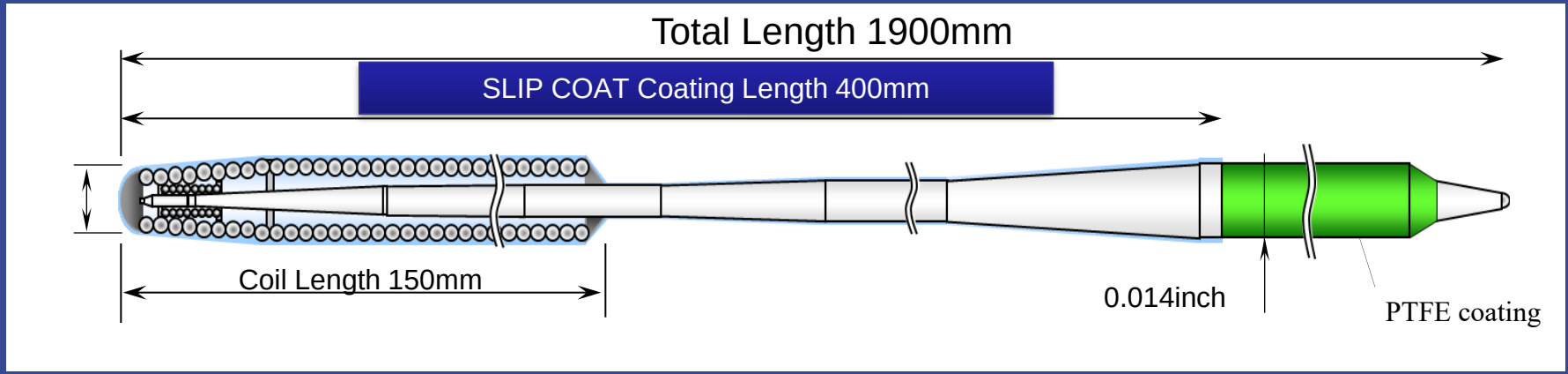
Shaping of the Wire Tip



Tip Flexibility



ASAHI Gaia Family



Various models for different situations and/or lesions

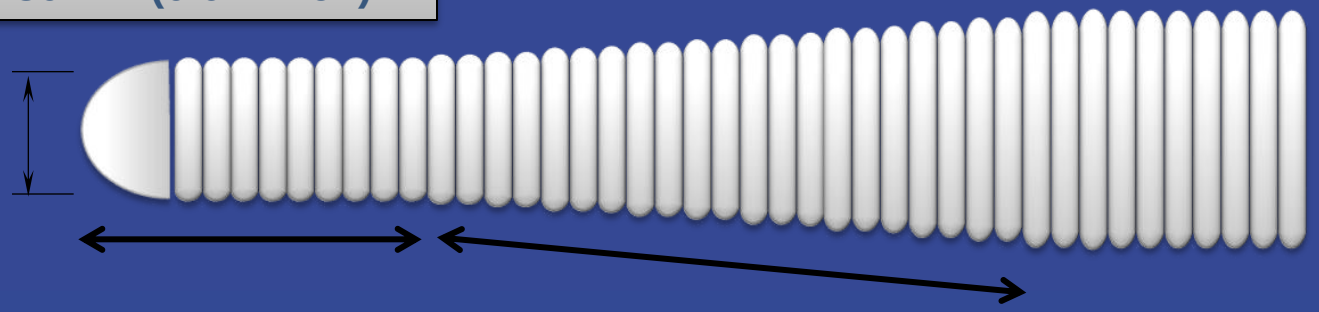
ASAHI Gaia First	Diameter :0.26mm (0.010”) - 0.36mm (0.014”) **Tip load :1.7gf**
ASAHI Gaia Second	Diameter :0.28mm (0.011”) - 0.36mm (0.014”) **Tip load :3.5gf**
ASAHI Gaia Third	Diameter :0.30mm (0.012”) - 0.36mm (0.014”) **Tip load :4.5gf**

Coated with hydrophilic coating which enhances smooth controllability inside the micro catheter

ASAHI Gaia Family

Basic Structure

Gaia First : 0.26mm (0.010inch)
Gaia Second : 0.28mm (0.011inch)
Gaia Third : 0.30mm (0.012inch)

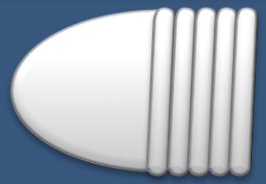


	Straight	Tapered
Gaia First	15mm	30mm
Gaia Second	6mm	30mm
Gaia Third	7mm	30mm

ASAHI Gaia concept

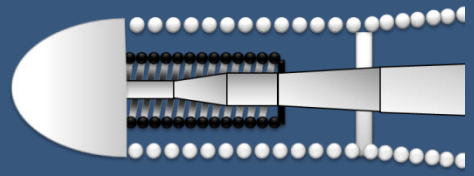
Chronic Occlusion

Micro-cone tip



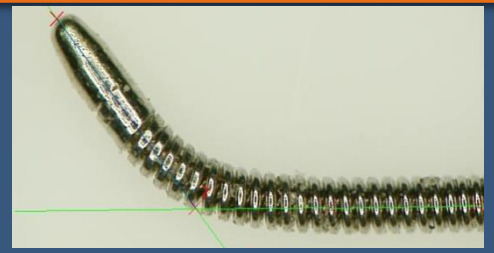
Smooth entry into the occluded lesion

Composite core



Easy control within the lesion

1mm Mini-pre shape



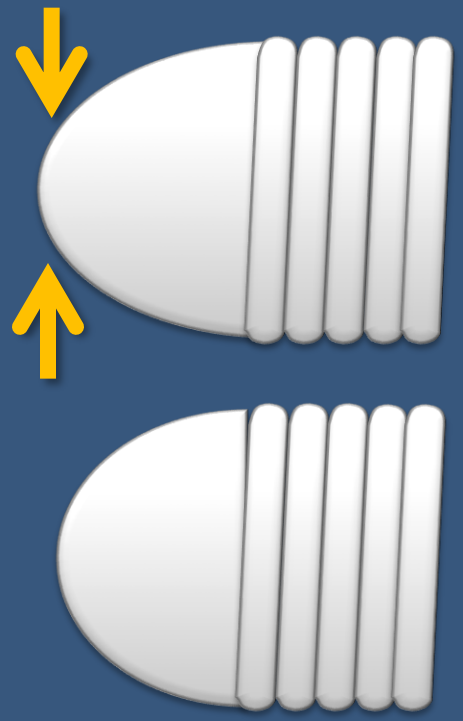
Maintains shaping memory within the lesion

ASAHI Gaia micro cone-tip

The ball tip was made smaller to increase its penetration efficacy while maintaining tip flexibility.

ASAHI Gaia micro-cone tip

Conventional wire tip



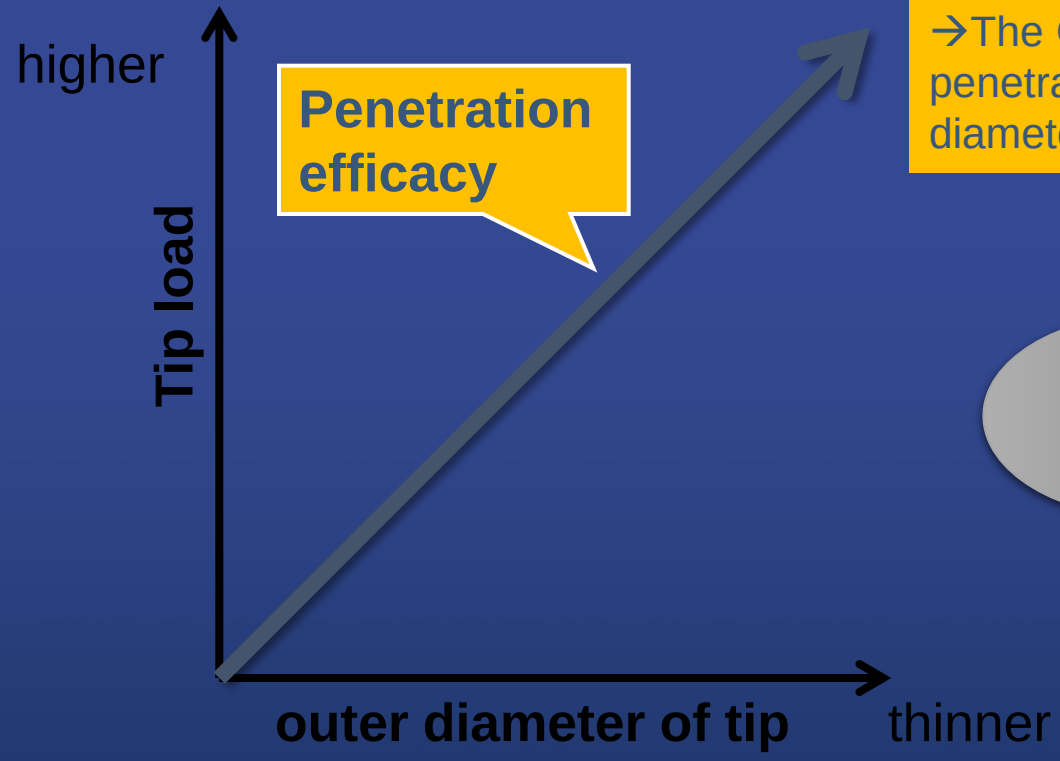
Penetration efficacy

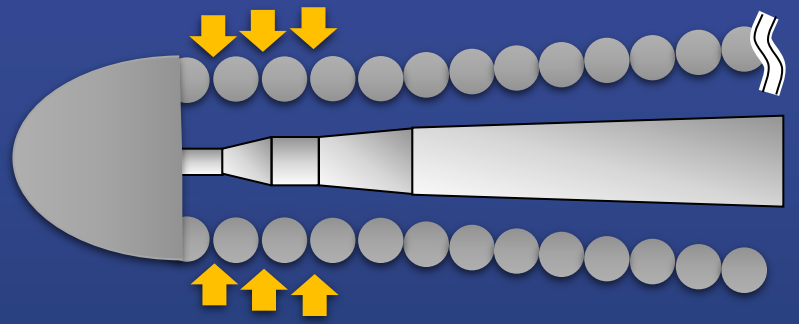
ASAHI Gaia series :
Maintains flexibility while keeping penetration efficacy

Penetration efficacy
Ease of entering the lesion

→ It is possible to calculate penetration efficacy with the outer diameter of the tip and the tip load.

→The Gaia GW possesses more penetration efficacy with its smaller outer diameter tip and higher tip load.



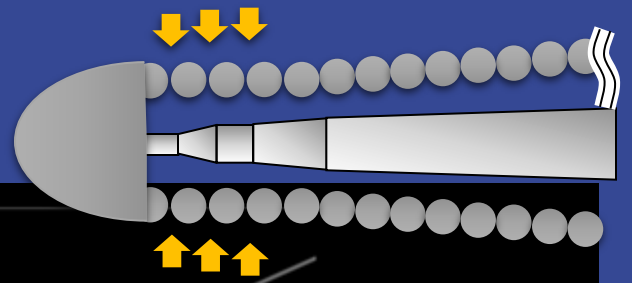


Outer diameter of the tip

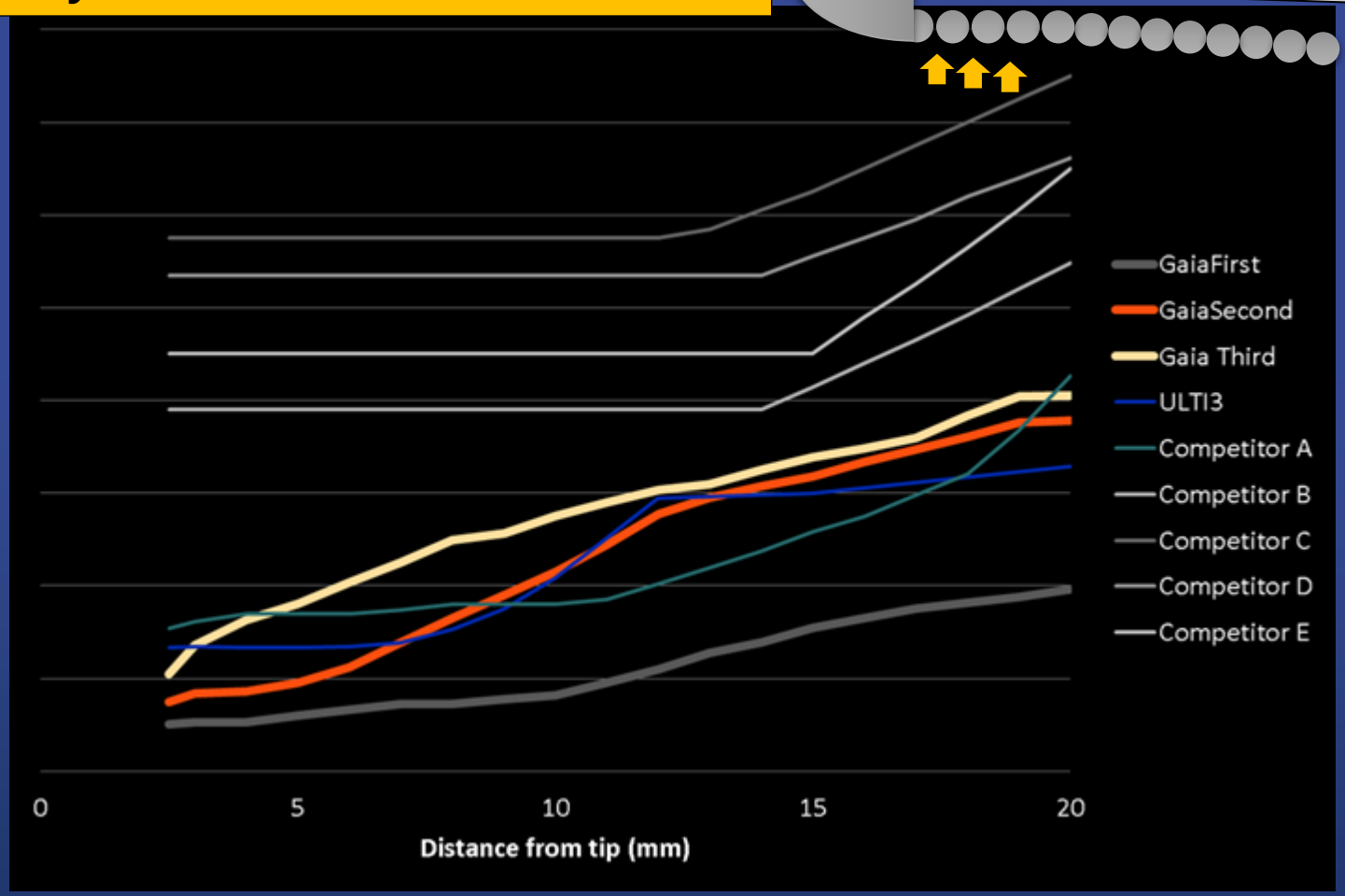
ASAHI Gaia specification/structure/performance

Tip flexibility

Tip flexibility
→ Flexibility of the lateral movement.



Stiffer



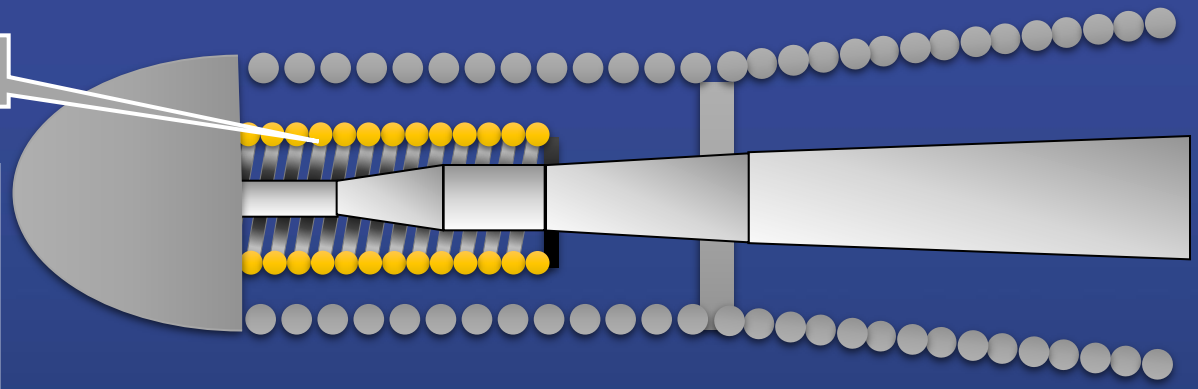
Tip Structure

Composite core : Double Coil Structure

Composite core

Strong torque and tip flexibility are possible by implementing the ACTONE double coil structure.

Suppresses whip motion.



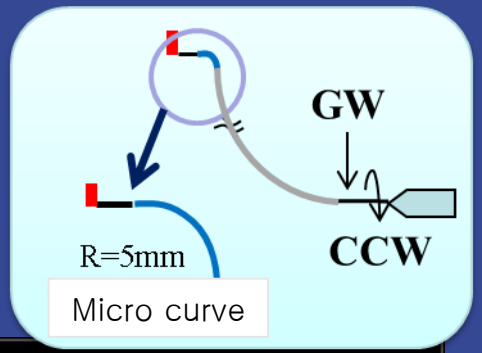
with ACT ONE

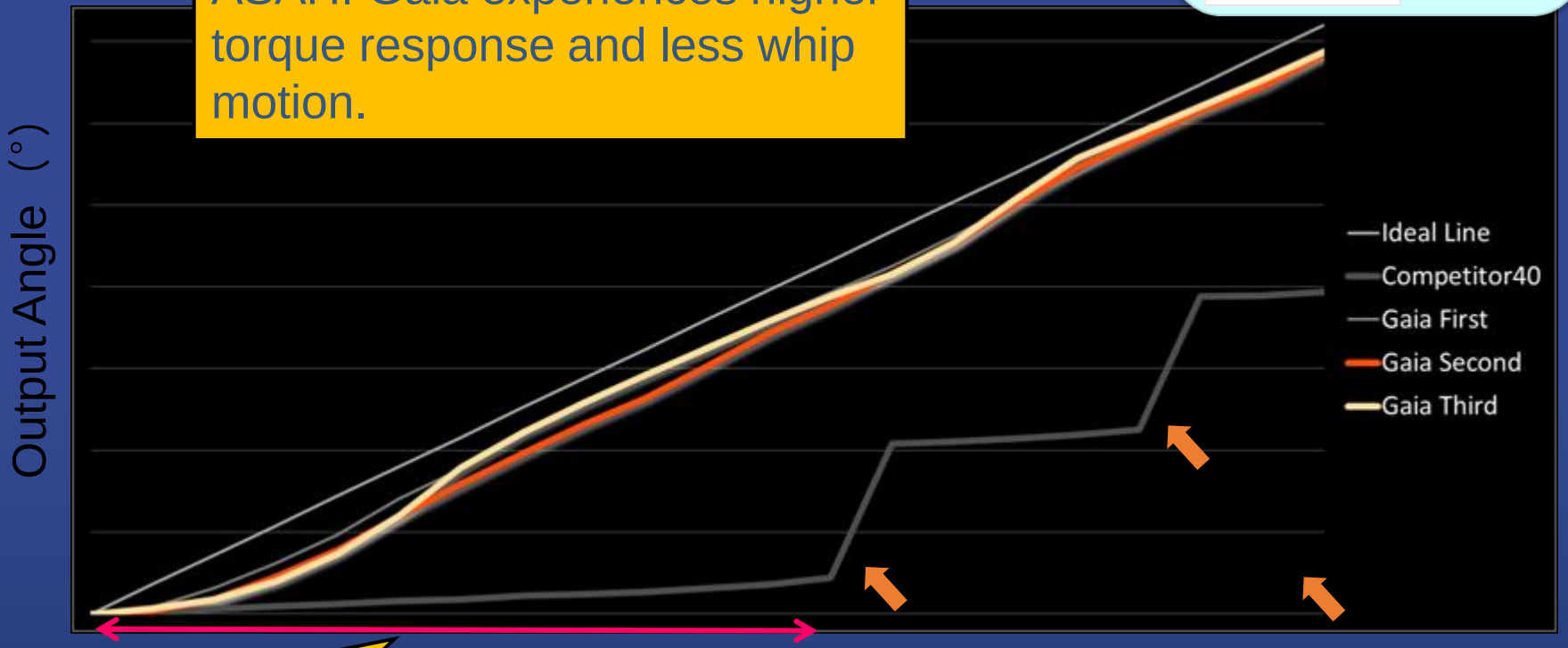
wire drawing, wire forming, and torque improvement. ACTONE™ , a flexible stainless steel tube manifests excellent torque characteristics, kink resistance, compression resistance and shape recovery characteristics.

ASAHI Gaia

Torque response ·Whip

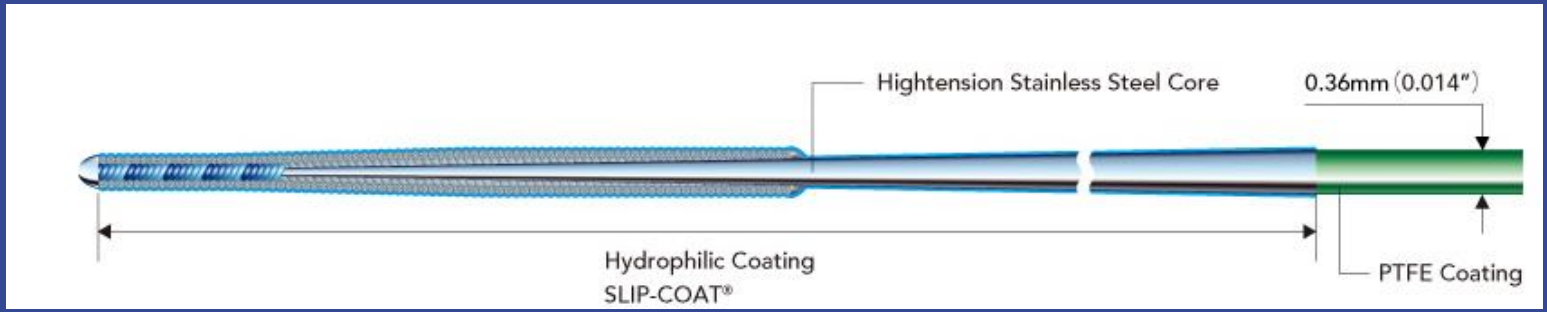
Within strong resistance area, ASAHI Gaia experiences higher torque response and less whip motion.





Delay in torque response
When proximal shaft is rotated, tip does not respond

ASAHI Gaia Next Series



Product	Catalog No.	Diameter	Coating	Usable length	Coil length	Radiopaque length	Tip shape	Label color	Clip color
ASAHI Gaia Next 1	AH14R019P	0.36 / 0.27mm (0.014 / 0.011inch)	Hydrophilic coating (SLIP-COAT®) 40cm	190cm	15cm	15cm	1mm pre-shape		
ASAHI Gaia Next 2	AH14R020P	0.36 / 0.30mm (0.014 / 0.012inch)	Hydrophilic coating (SLIP-COAT®) 40cm	190cm	15cm	15cm	1mm pre-shape		
ASAHI Gaia Next 3	AH14R021P	0.36 / 0.30mm (0.014 / 0.012inch)	Hydrophilic coating (SLIP-COAT®) 40cm	190cm	15cm	15cm	1mm pre-shape		

Gaia Tip ~ 1mm Pre-shape

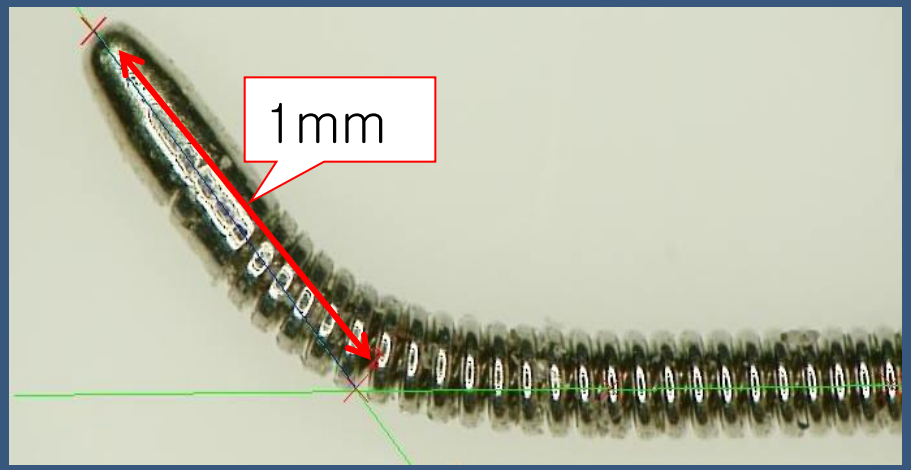
The most distal 1mm (approx.) shaped during production, saving the operator the difficulty of manual shaping.

: Possible to increase the angle to create a more acute curve manually

: Possible to change re-shape the tip depending on procedural conditions

Pre shape
1mm – approx.45°

Retains shape memory during procedure

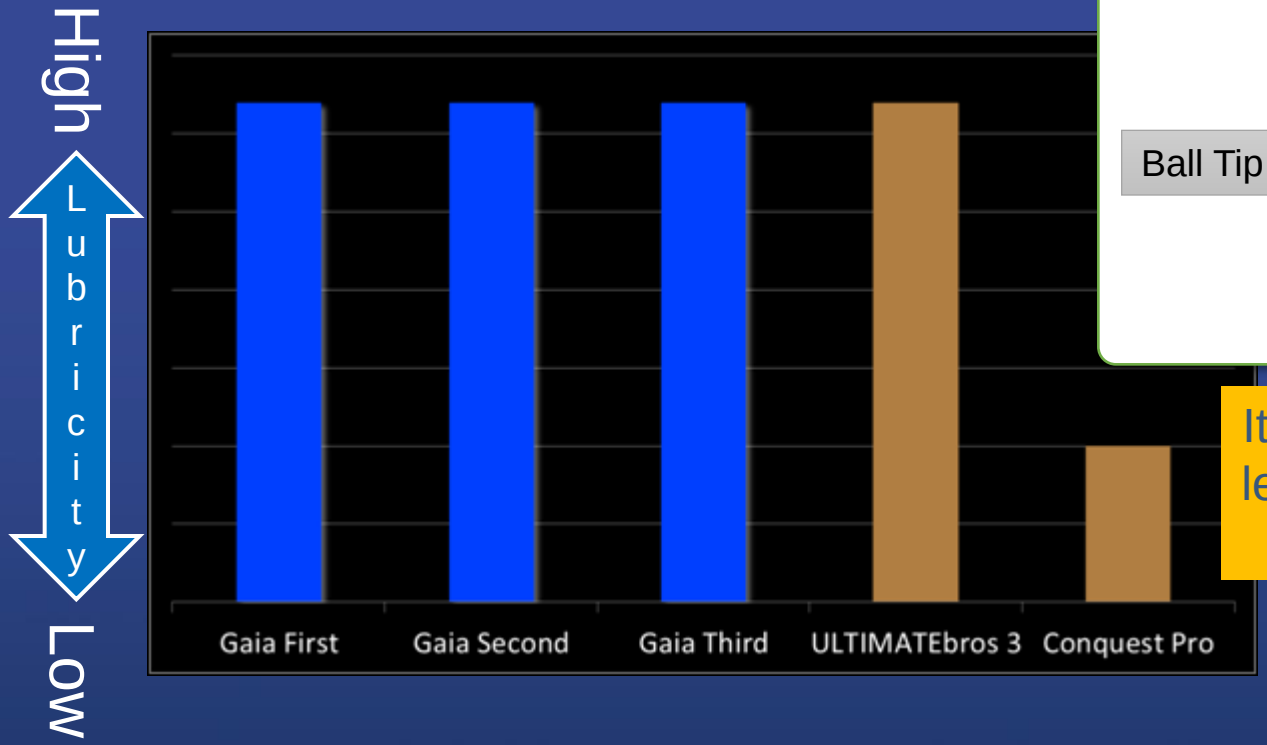


ASAHI Gaia specification/structure/performance

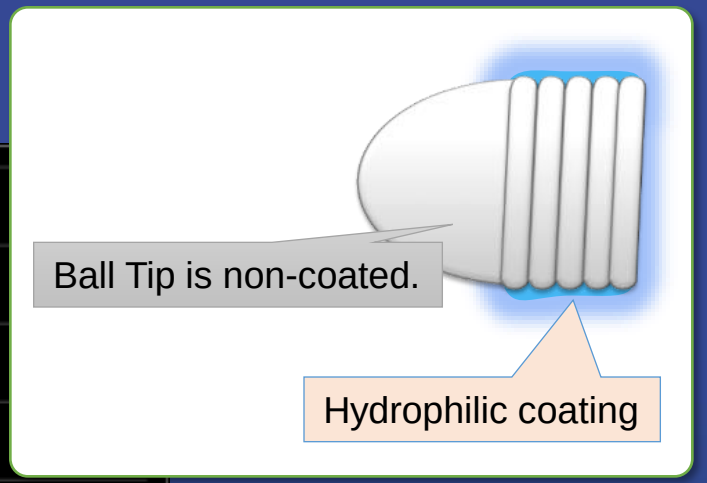
Comparison of Lubricity

Well-balanced lubricity with control

Slip resistance test of the guide wire surface



Coating of the guide wire tip

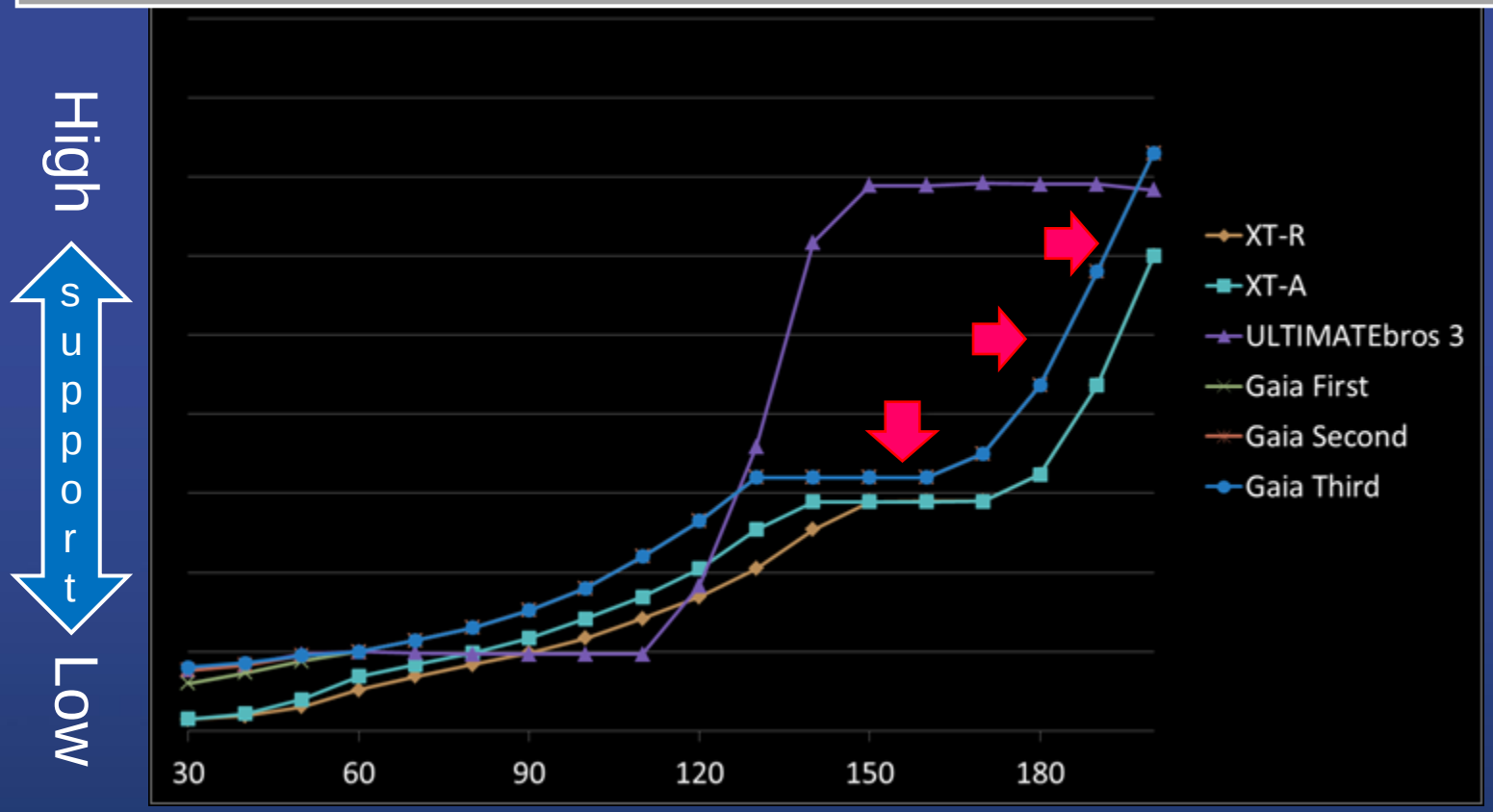


It is easier to access the lesion with a non-coated ball tip

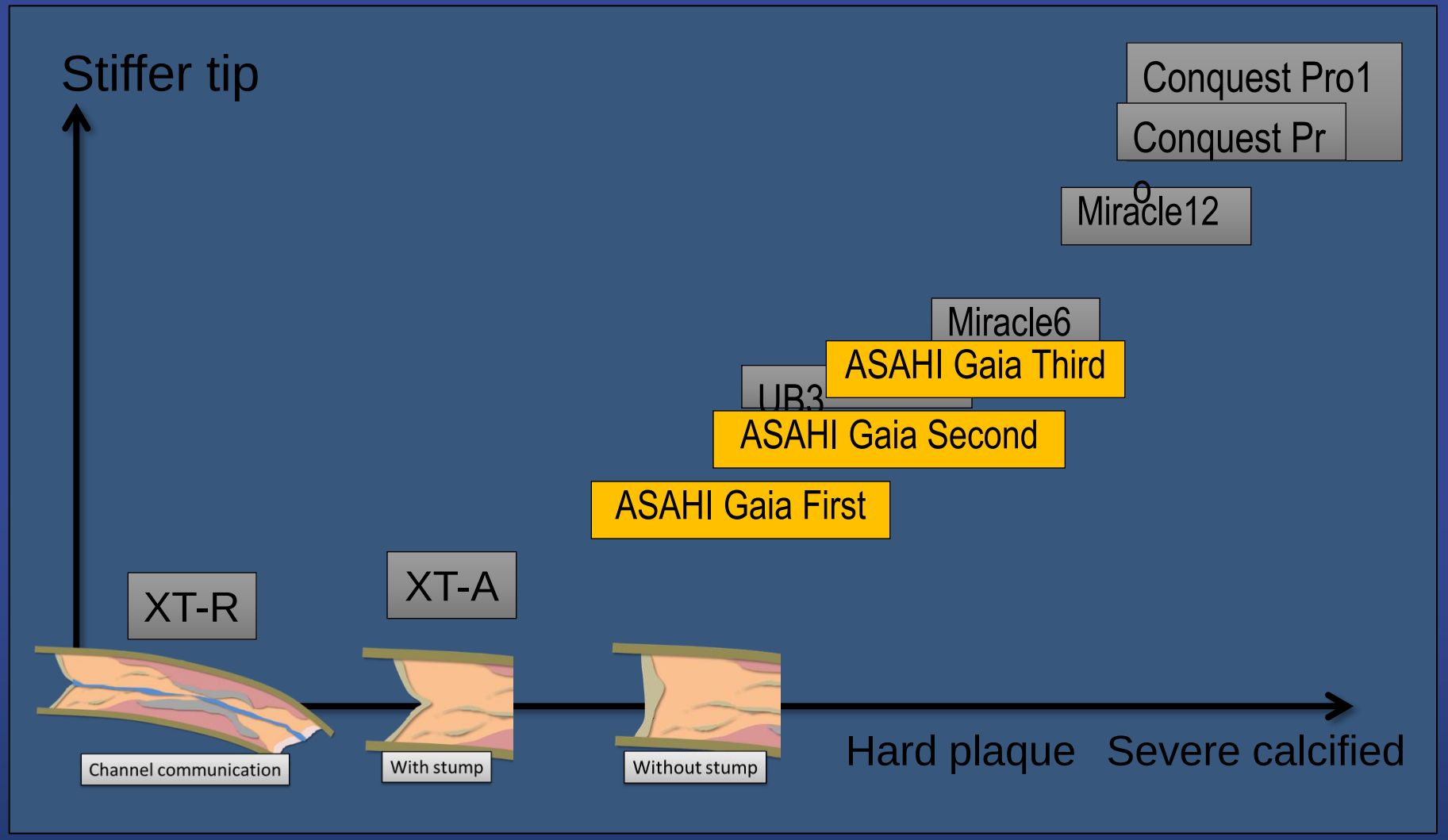
ASAHI Gaia specification/structure/performance

Comparison of Support

Flexible shaft design makes it easier to follow through tortuous vessels and to operate without a delay in torque



ASAHI Gaia Positioning in GW



ASAHI CONQUEST Family

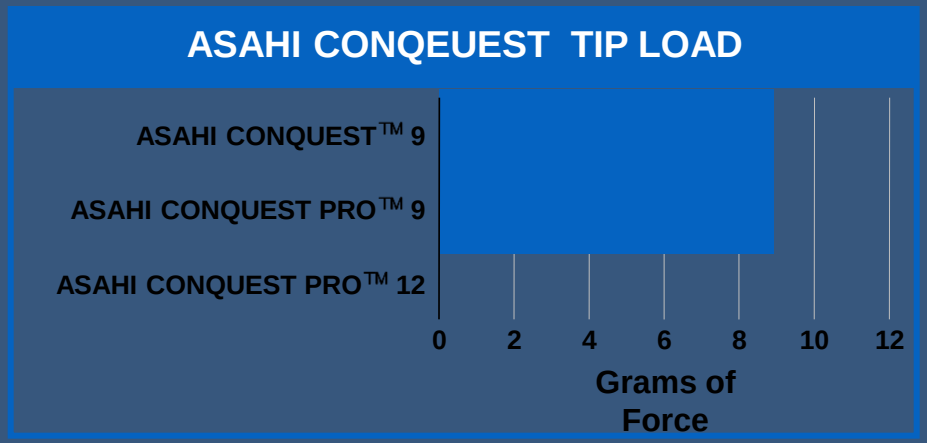
PTCA Guide Wires

- Tapered Tip

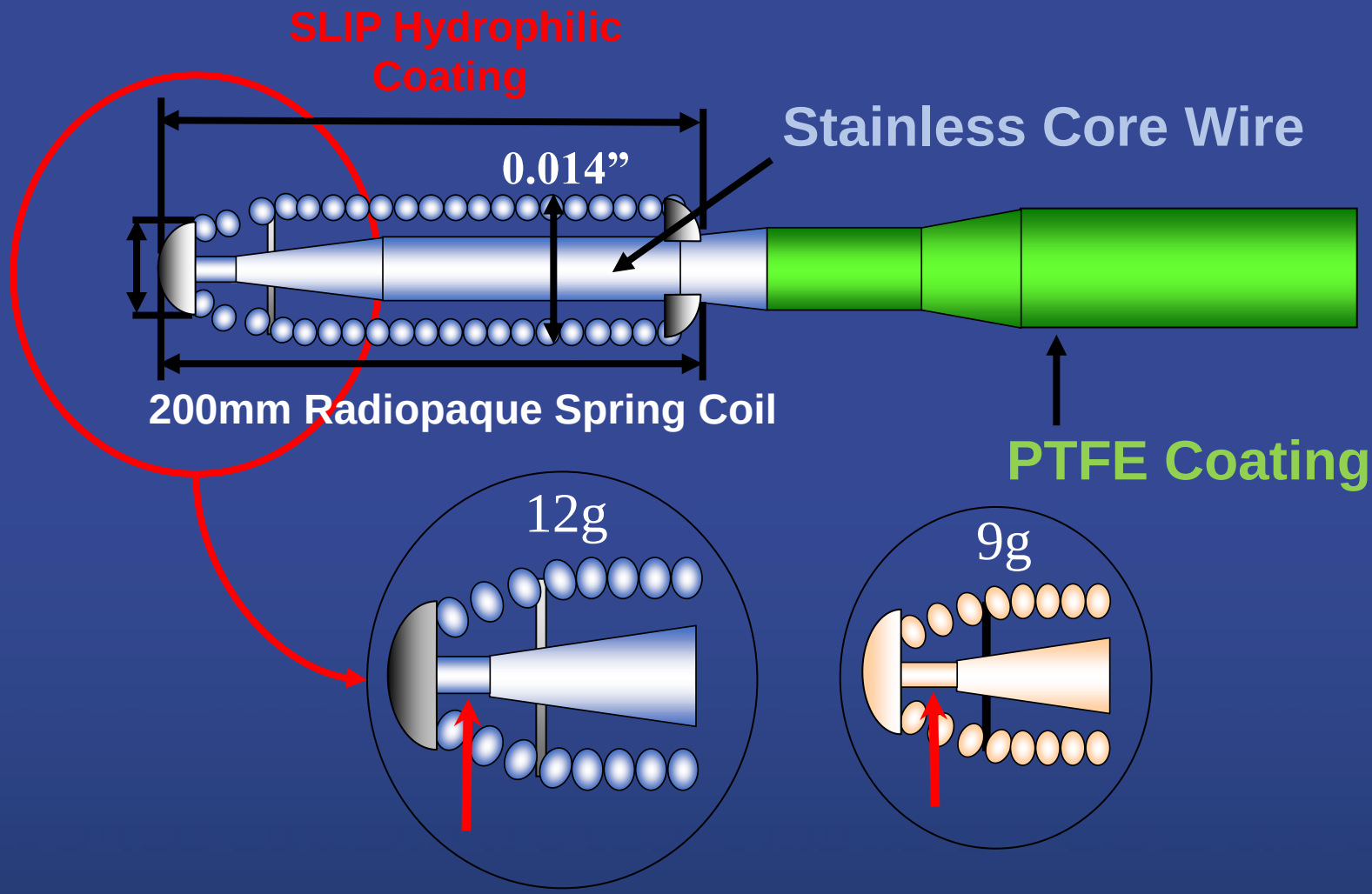
ASAHI CONQUEST™ 9 – Non hydrophilic

ASAHI CONQUEST PRO™ 9 – SLIP COAT coating

ASAHI CONQUEST PRO™ 12 – SLIP COAT coating

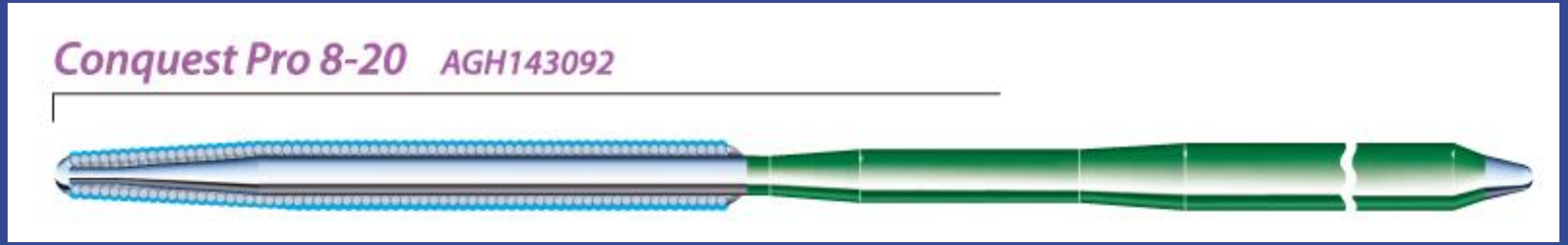


Conquest (Confianza) Pro 9 & 12



ASAHI CONQUEST Family

Conquest Pro 8-20

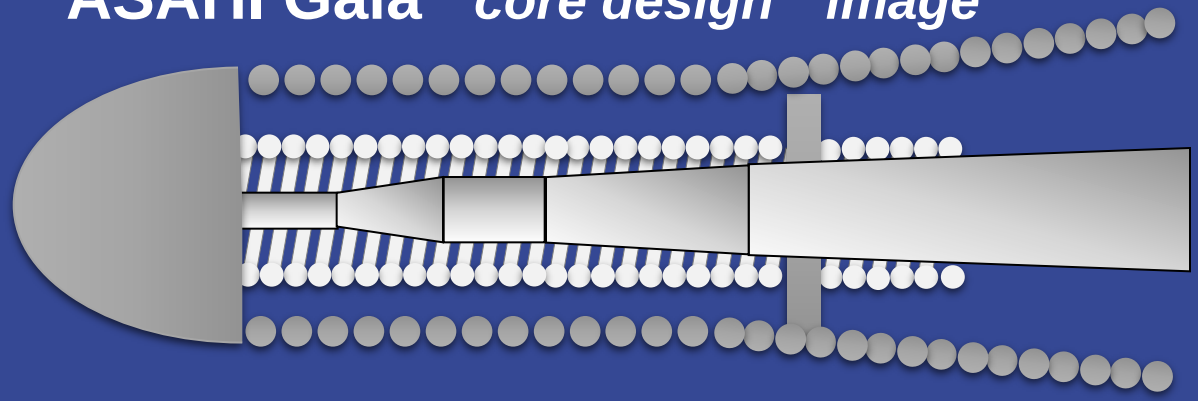


- Tip load = 20.0 g
- Tip radiopacity = 17cm
- Tip outer diameter = 0.008 inch (0.20 mm)
- SLIP COAT coating over the spring coil
- PTFE coating over the shaft
- Finest and stiffest guidewire in the current series

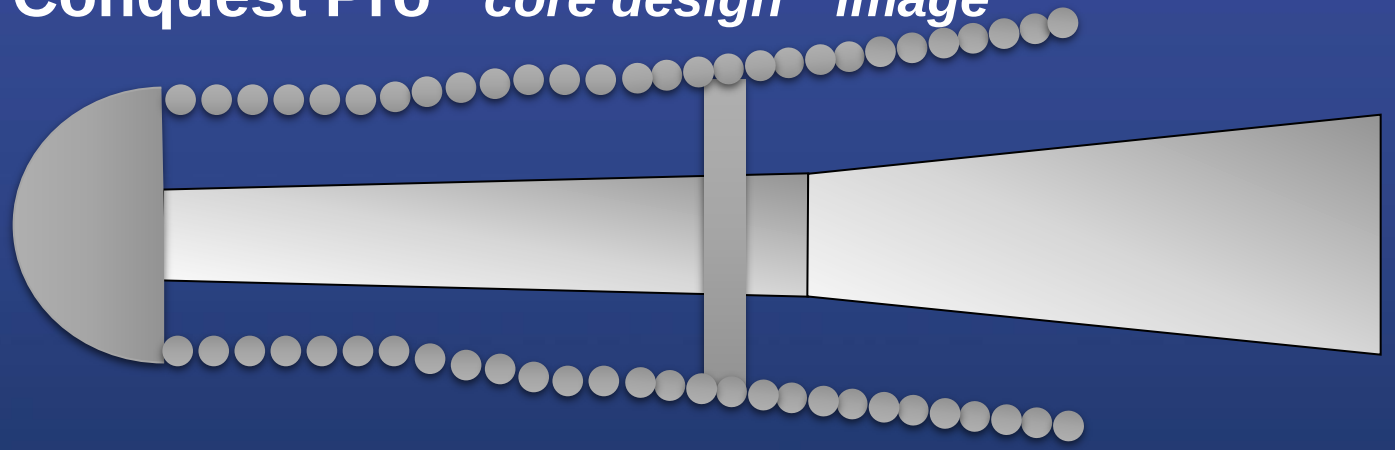
ASAHI Gaia vs. Conquest Pro

Core thickness cause differences in penetrability

ASAHI Gaia *core design image*

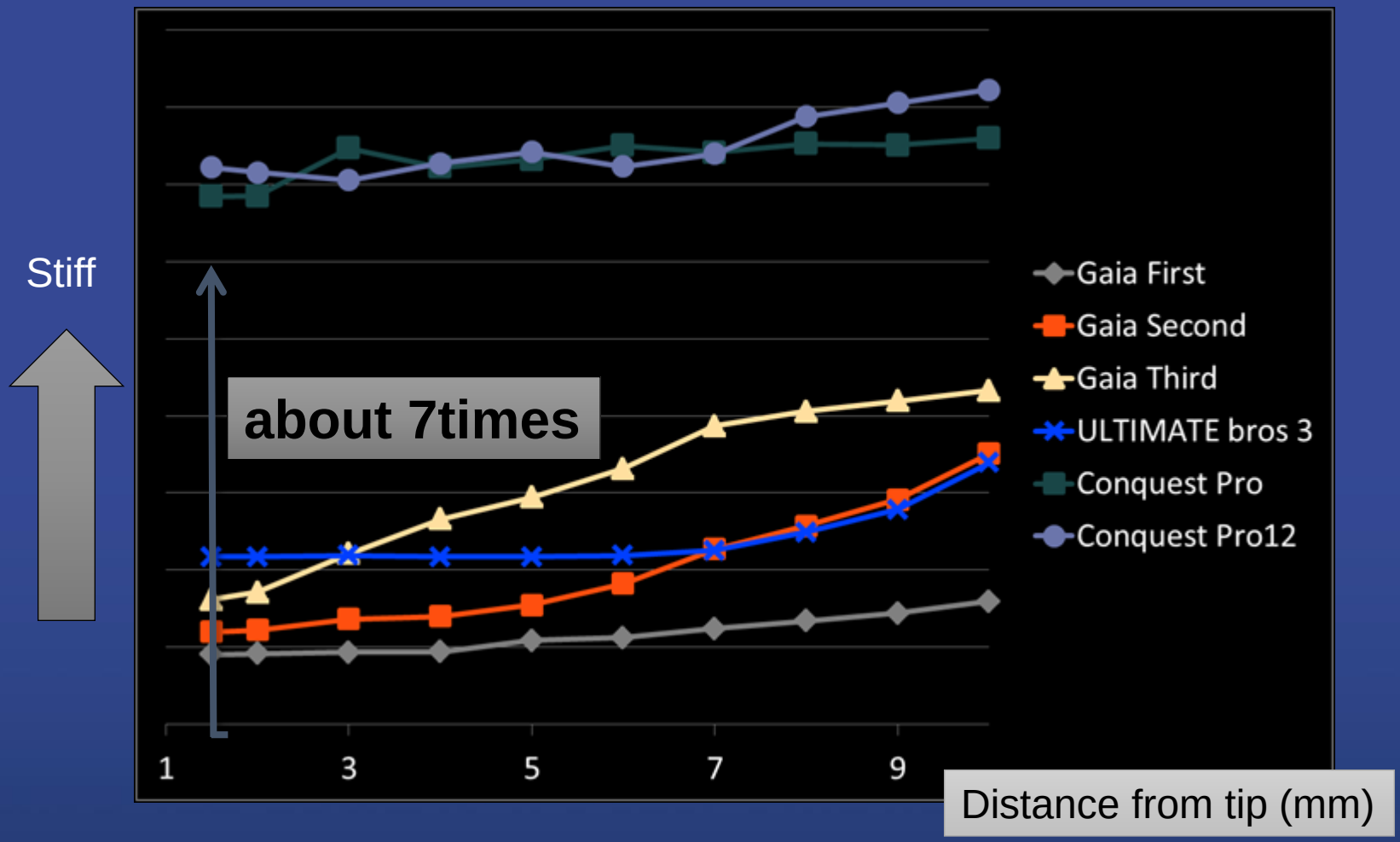


Conquest Pro *core design image*

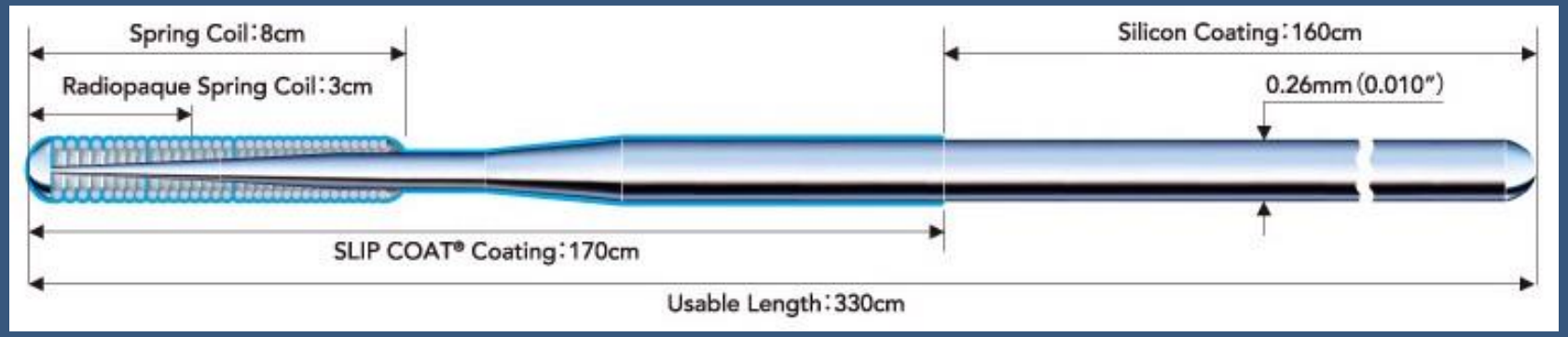


ASAHI Gaia vs. Conquest Pro

Core thickness cause differences in penetrability



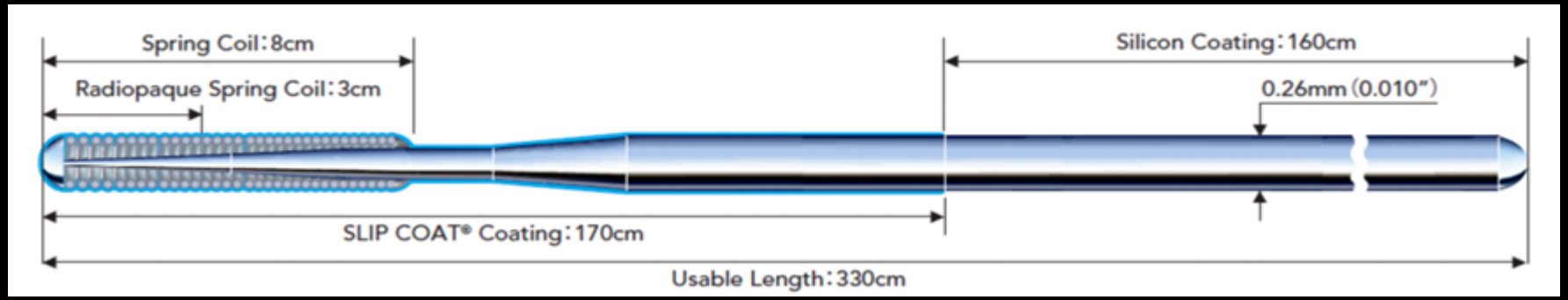
ASAHI RG3



- Optimal wire strength, hydrophilic coating and 0.26 mm shaft provide superior inside-catheter pushability
- With the inner wall damage possibility reduced in tortuous vessels as well, the risk of complication is minimized

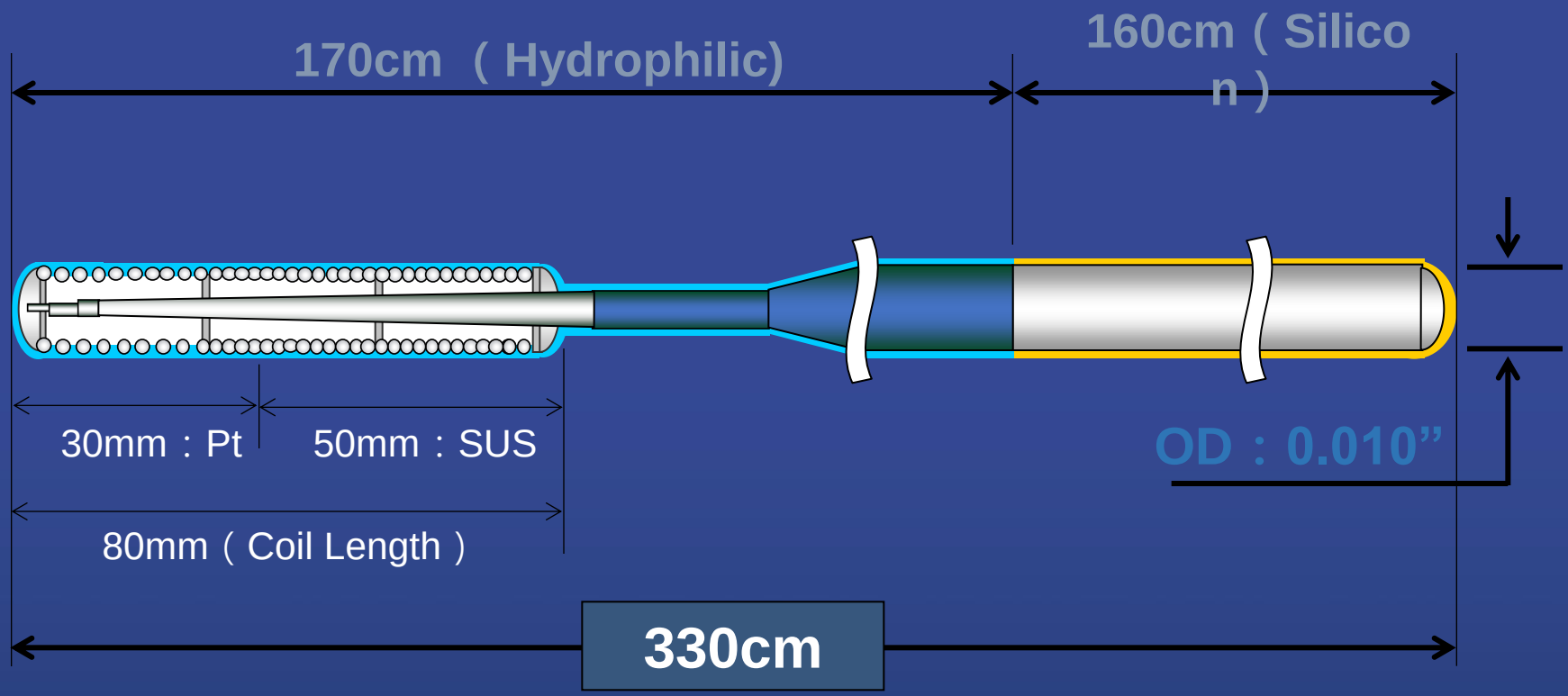
Wire for Circumferential Technique for Reverse CART Technique

ASAHI
RG3
PTCA GUIDE WIRE



- Tip Load 3.0g
- Coil 8cm
- Diameter 0.010inch
- Length 330cm

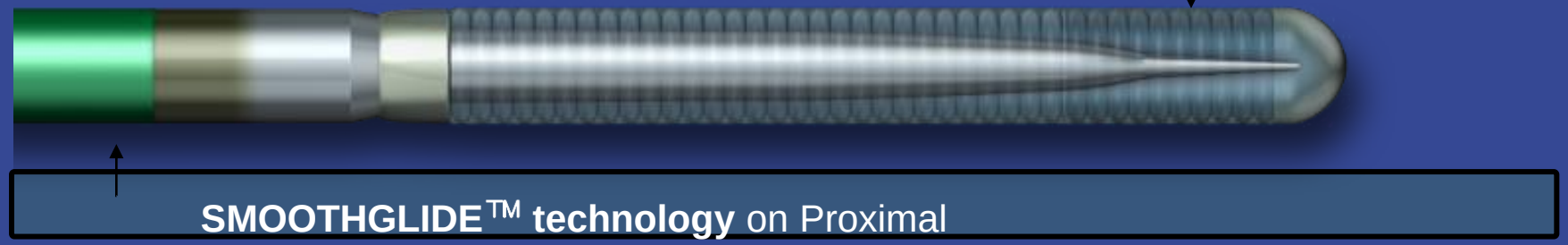
Structure of RG3 (RetroGrade3oo)



HI-TORQUE ADVANCE™ & ADVANCE LITE™

DURASTEEL™ high tensile strength core material provides durability and superb torque control

Core-to-tip design offers precise steering and tip control

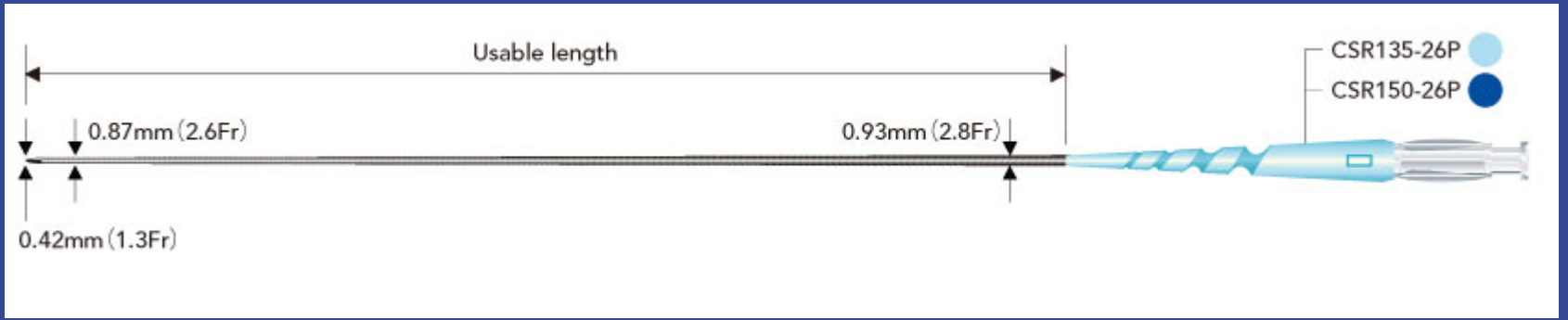


SMOOTHGLIDE™ technology on Proximal Wire for smooth device interaction

RESPONSEASE™ transitionless core grind provides excellent tracking and 1:1 torque response

Support Catheter for CTO

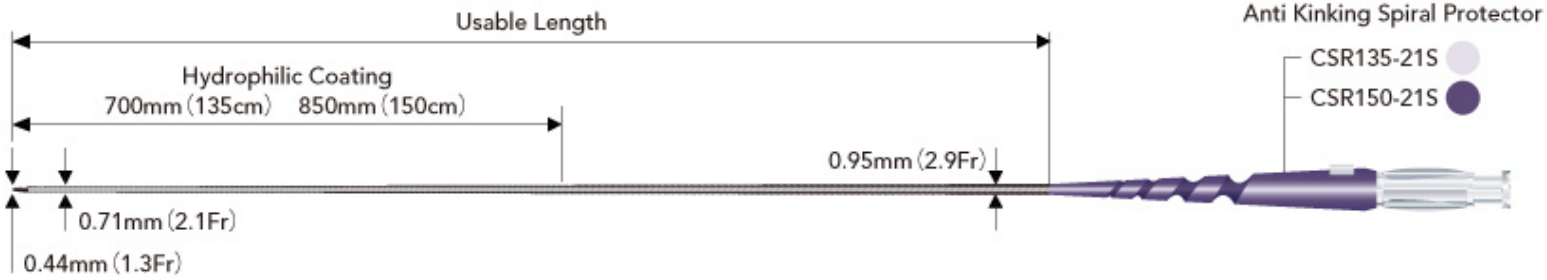
Cosair Pro



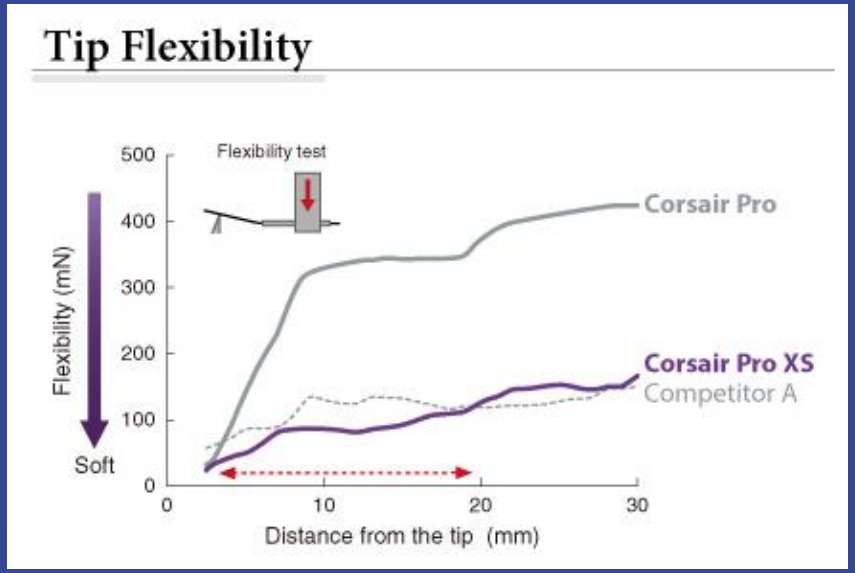
Product	Catalog No.	Outer diameter			Inner diameter		Usable length	Recommended GW
		Tip	Distal shaft	Proximal shaft	Tip	Shaft		
ASAHI Corsair Pro	CSR135-26P	0.42mm (1.3Fr)	0.87mm (2.6Fr)	0.93mm (2.8Fr)	0.38mm (0.015inch)	0.45mm (0.018inch)	135cm	0.36mm (0.014inch)
	CSR150-26P	0.42mm (1.3Fr)	0.87mm (2.6Fr)	0.93mm (2.8Fr)	0.38mm (0.015inch)	0.45mm (0.018inch)	150cm	0.36mm (0.014inch)

- High visibility at the lesion part
- High tracking ability into the lesion
- Entire tip is visible under fluoroscope

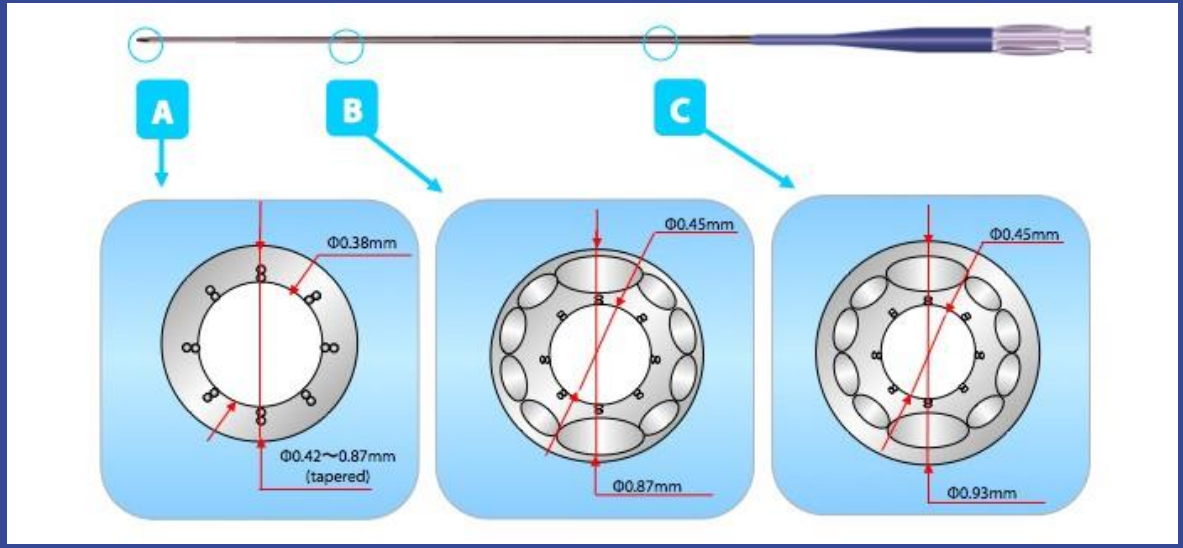
Cosair Pro XS



Product	Catalog No.	Outer diameter			Inner diameter		Usable length	Recommended GW
		Tip	Distal shaft	Proximal shaft	Tip	Shaft		
ASAHI Corsair Pro XS	CSR135-21S	0.44mm (1.3Fr)	0.71mm (2.1Fr)	0.95mm (2.9Fr)	0.38mm (0.015inch)	0.48mm (0.019inch)	135cm	0.36mm (0.014inch)
	CSR150-21S	0.44mm (1.3Fr)	0.71mm (2.1Fr)	0.95mm (2.9Fr)	0.38mm (0.015inch)	0.48mm (0.019inch)	150cm	0.36mm (0.014inch)

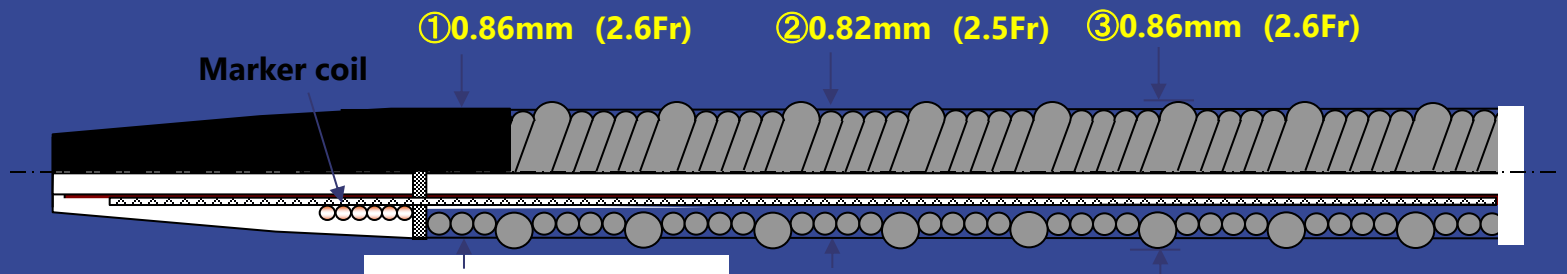


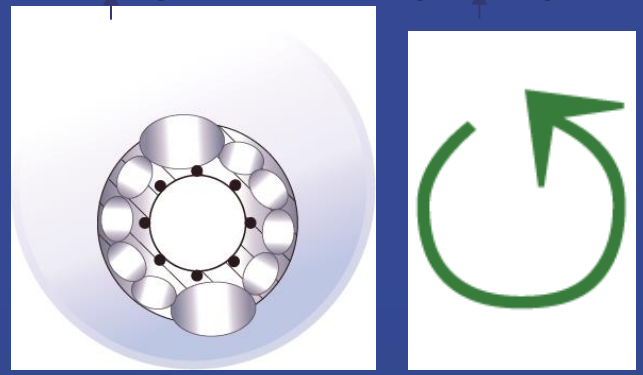
ASAHI Corsair Microcatheter



- Tip Fexibility : Tapered Soft Tip
- Pushability, Trackability, Support : SHINKA Shaft
- Lubricity : Hydrophilic Polymer Coating
- Visibility & Maneuverability : Tapered Soft tip and Tungsten Braiding
- Visibility & Maneuverability
- Rigidity and Pushability : Reinforced Tapered Shaft

ASAHI Corsair Microcatheter

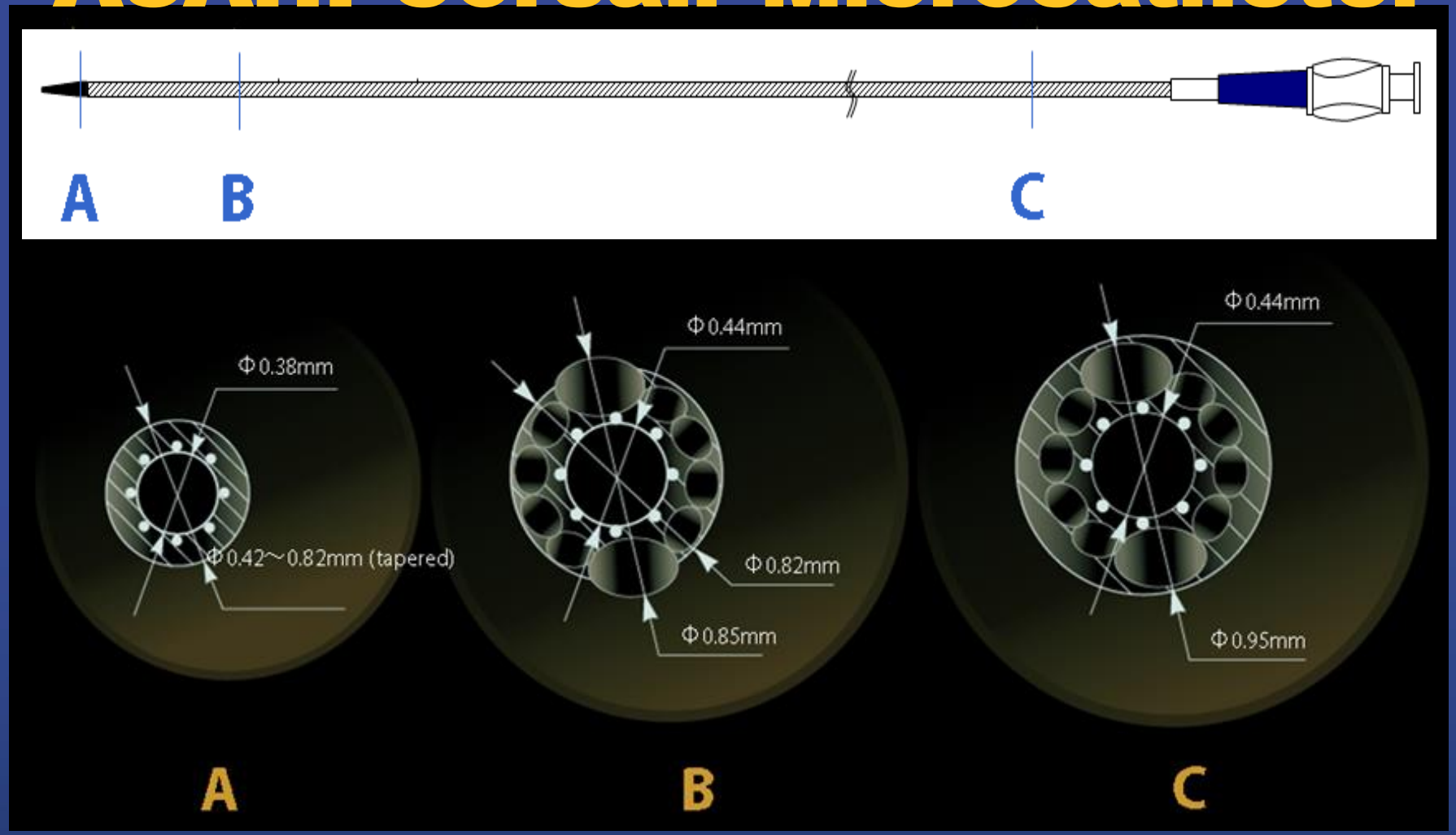




Counterclockwise advancement

- Tapered Soft Polyurethane Tip
- 20cm Screw Head Structure
- Hydrophilic Polymer Coating
- PTFE Inner Layer

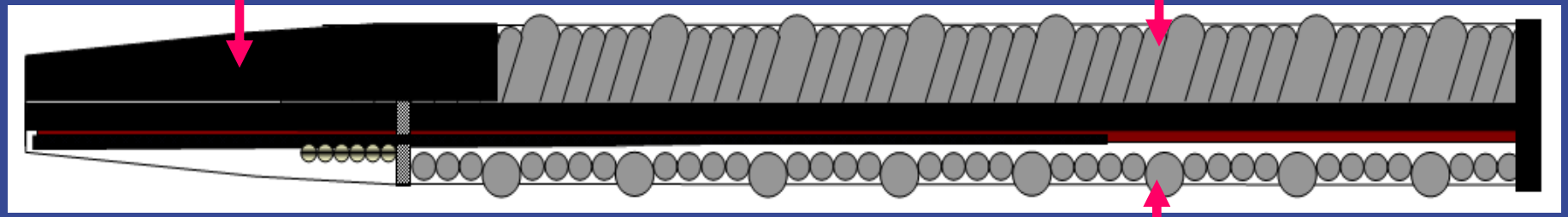
ASAHI Corsair Microcatheter



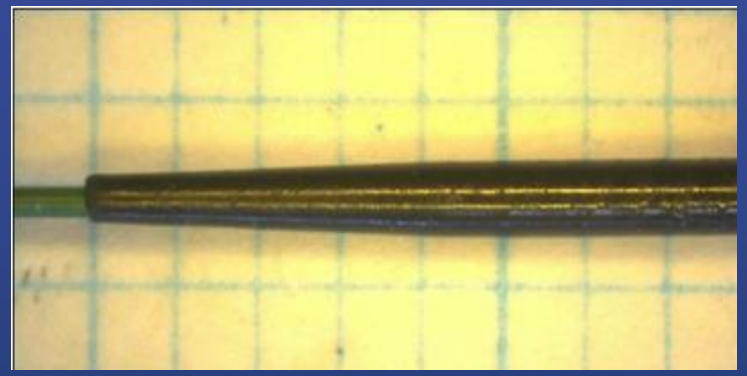
ASAHI Corsair Microcatheter

Very flexible tip

Hydrophilic polymer coating



PTFE inner layer

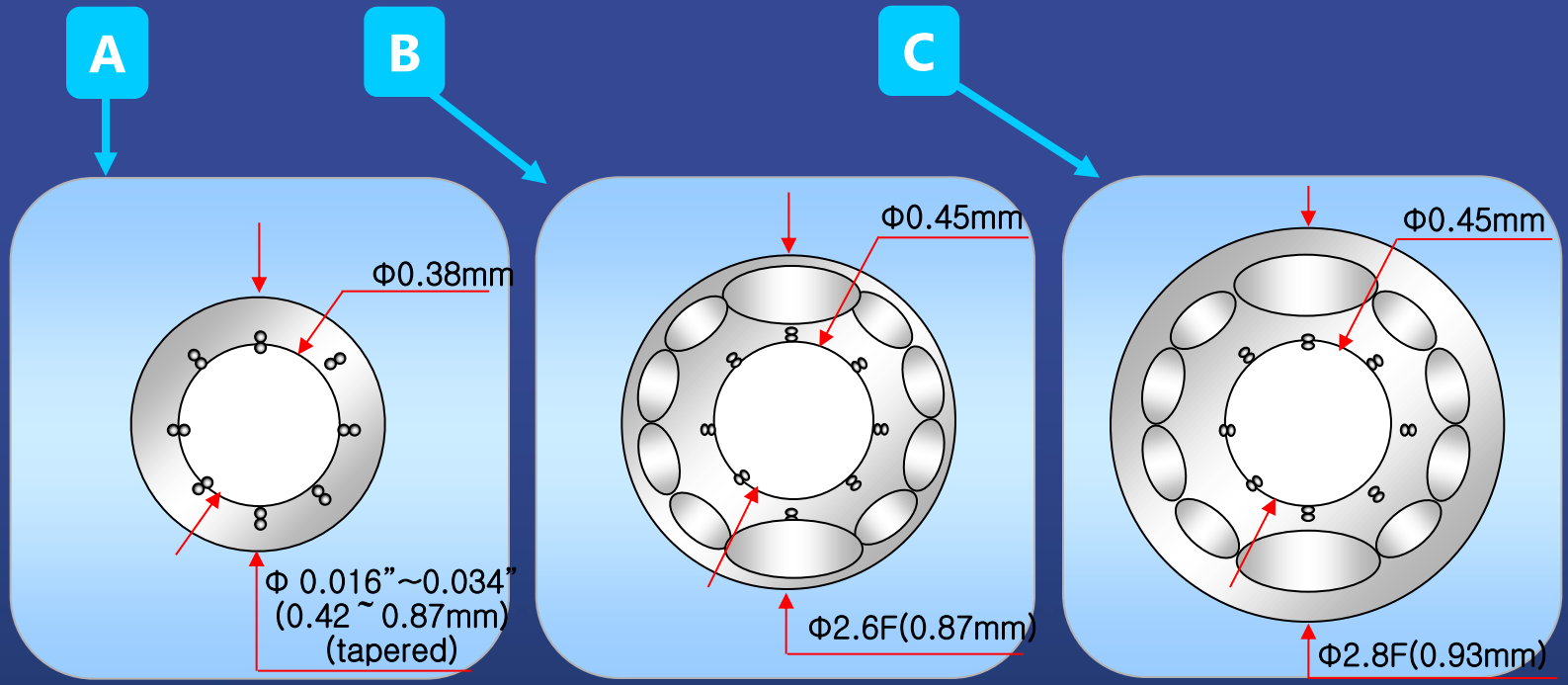


Dimensions of Corsair Catheter

ASAHI Corsair Microcatheter

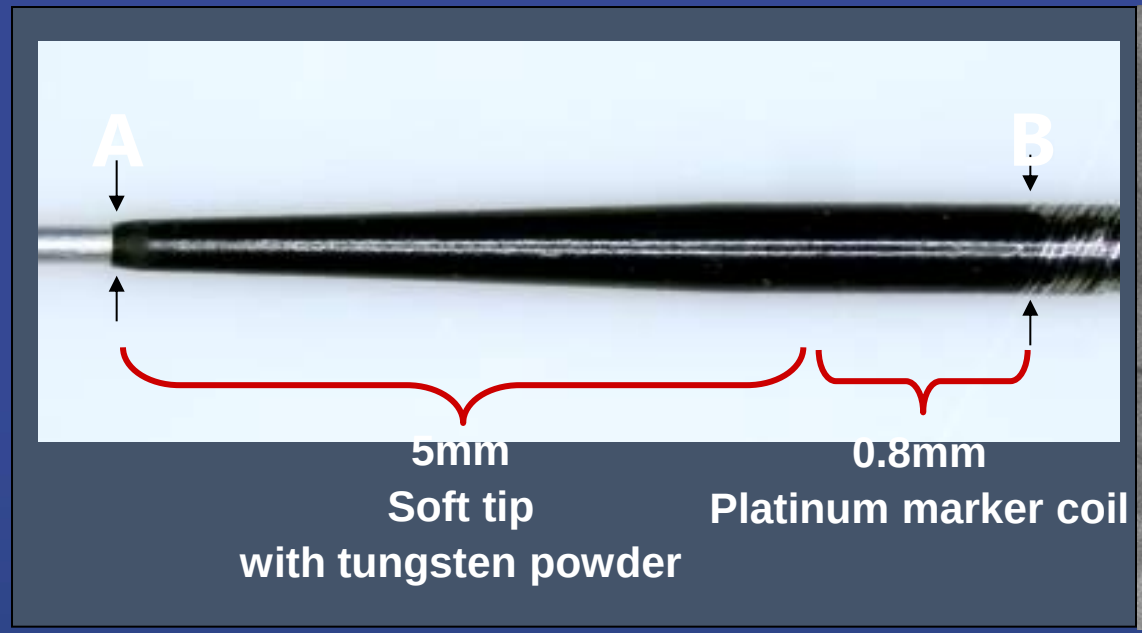
Hydrophilic Polymer Coating 60cm

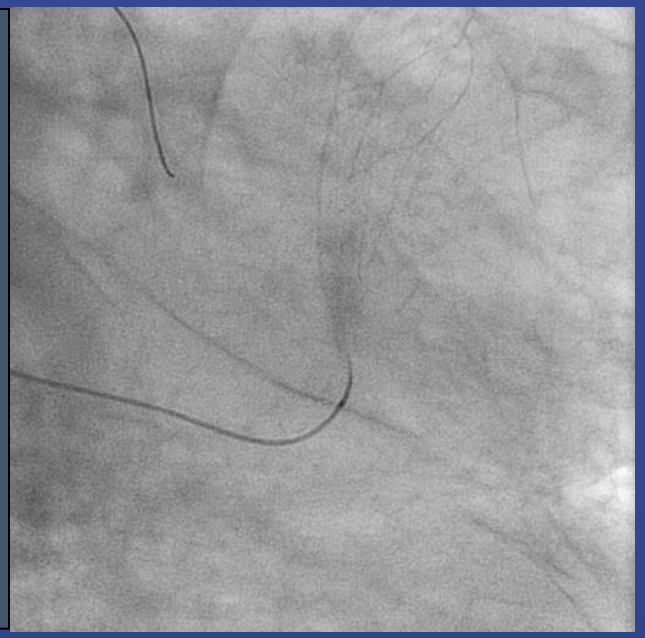
Length; **135cm** for Antegrade
150cm for Retrograde



Tip of Corsair Catheter

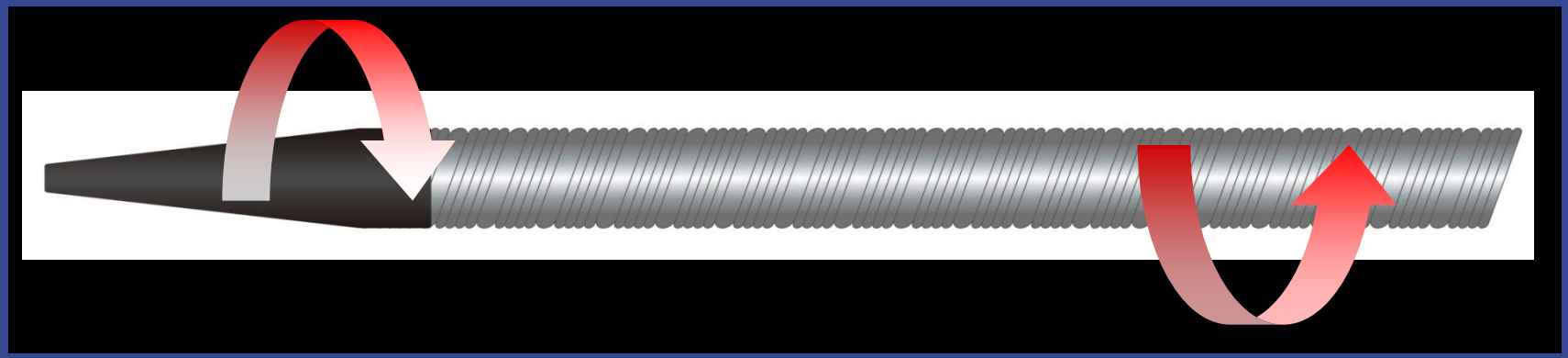
ASAHI Corsair Microcatheter





A- Tip entry profile 0.42mm (0.016”)
B- Shoulder O.D. 0.87mm (0.034”)

R^3 Effect
Rotation Resistance Reduction



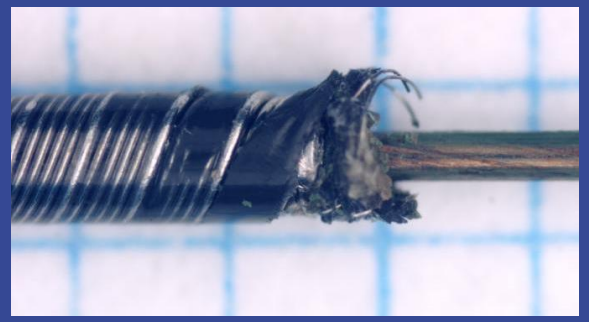
By adding the torque rotation,
it reduces the friction within the vessel and enhances propulsion.

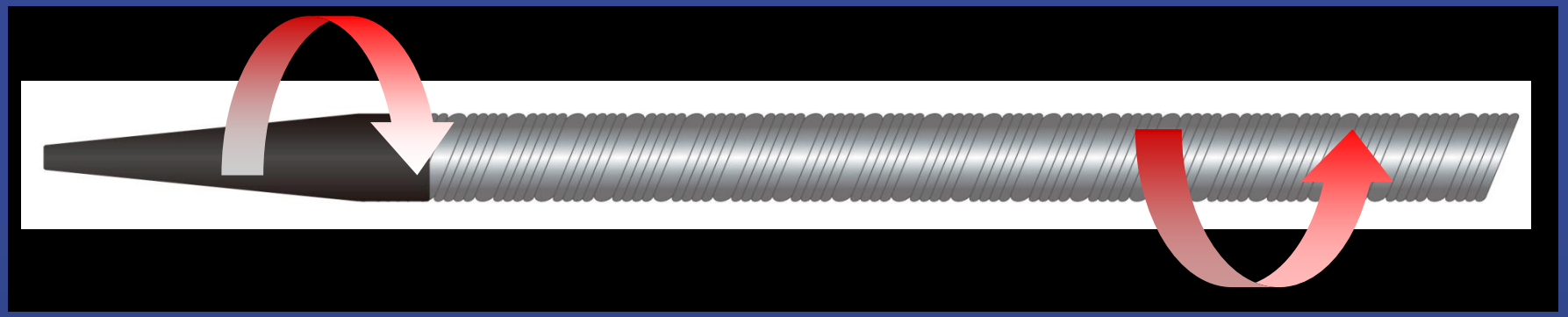
Tip Injury

Calcified Lesion / Stent Strut

Braided tip; visual exam and x-ray

Tip Injury

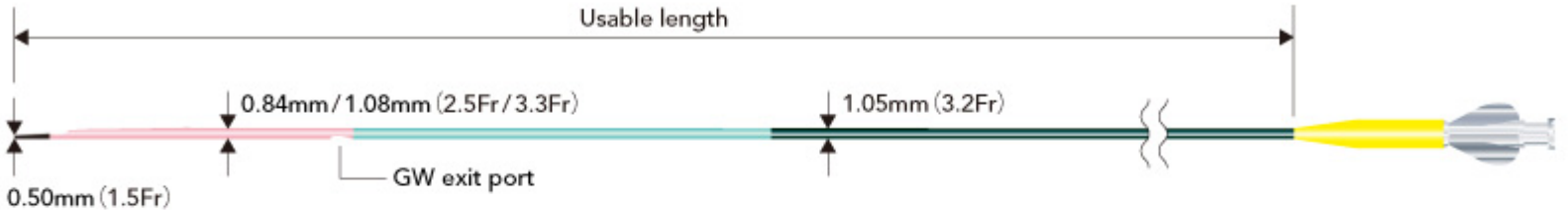


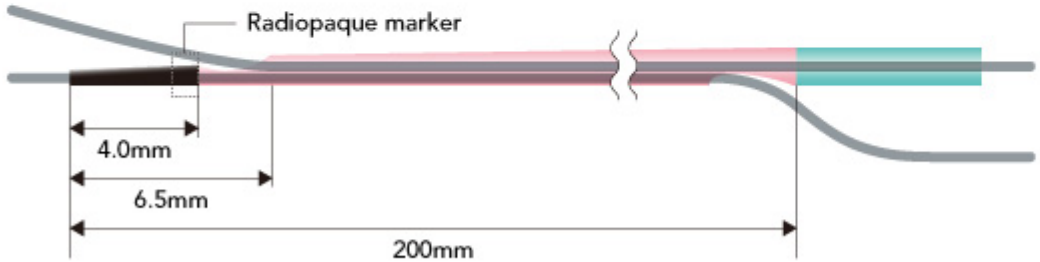


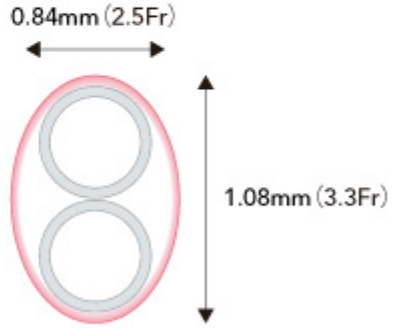
To take turns CWR and CCWR

To avoid too much rotation (>10)

ASAHI SASUKE





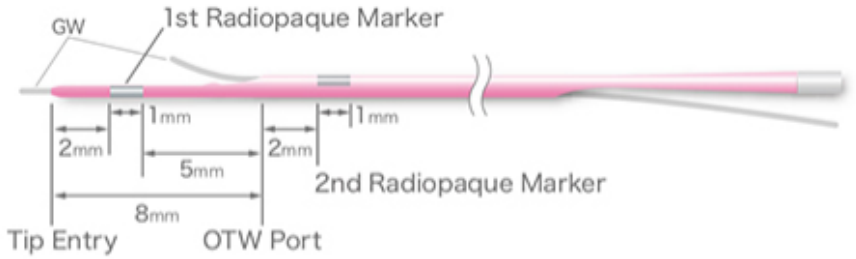


Cross section of distal shaft

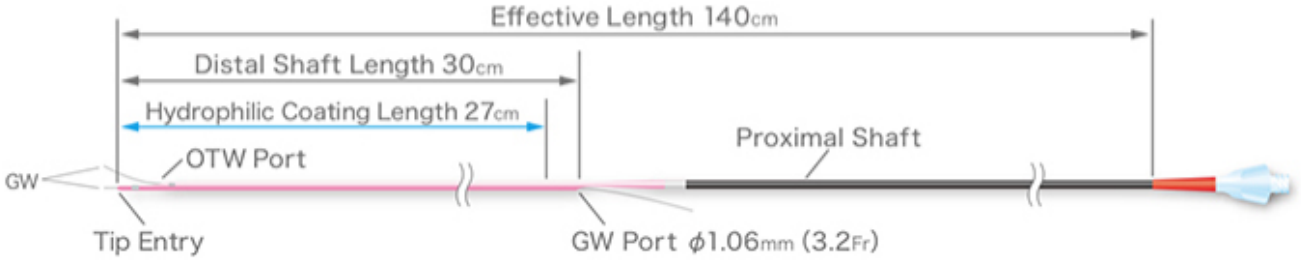
Product	Catalog No.	Outer Diameter			Inner Diameter		Usable Length	Recommended Guide Wire	Hydrophilic Coating Length
		Tip	Distal Shaft	Proximal Shaft	Tip	Shaft			
ASAHI SASUKE	SA145-33N	0.50mm (1.5Fr)	0.84mm / 1.08mm (2.5Fr / 3.3Fr)	1.05mm (3.2Fr)	0.40mm (0.016inch)	0.43mm (0.017inch)	145cm	0.36mm (0.014inch)	38cm

CRUSADE R

☐Distal Shaft



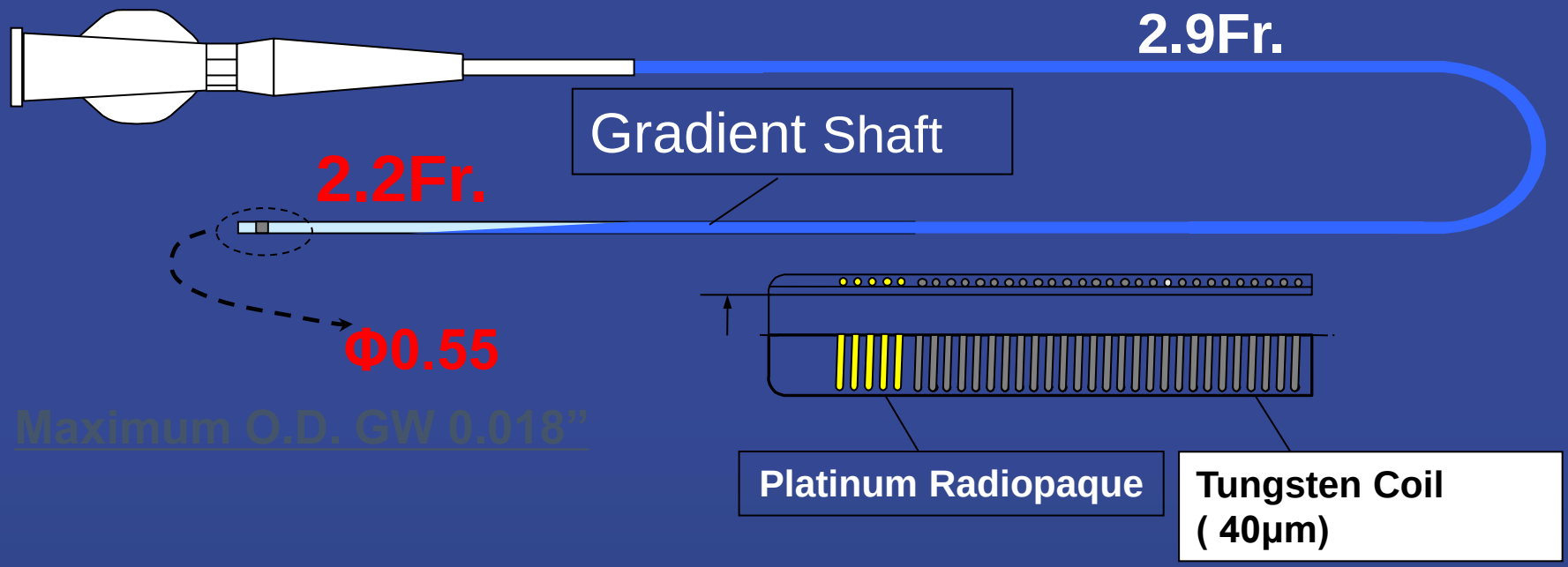
☐Overview of the Catheter



Catalogue Number	Outer Diameter			Inner Diameter		Effective Length	Hydrophilic Coating Length	Compatible Maximum GW Outer Diameter
	Tip Entry	Distal Shaft	Proximal Shaft	Distal Shaft	Proximal Shaft			
CR1414140SD	1.4Fr(0.45mm)	2.9Fr (0.96mm)	3.2Fr(1.06mm)	0.0165" (0.42mm)	0.0177" (0.45mm)	140cm	27cm	0.014" (0.36mm)

TERUMO's Progreat

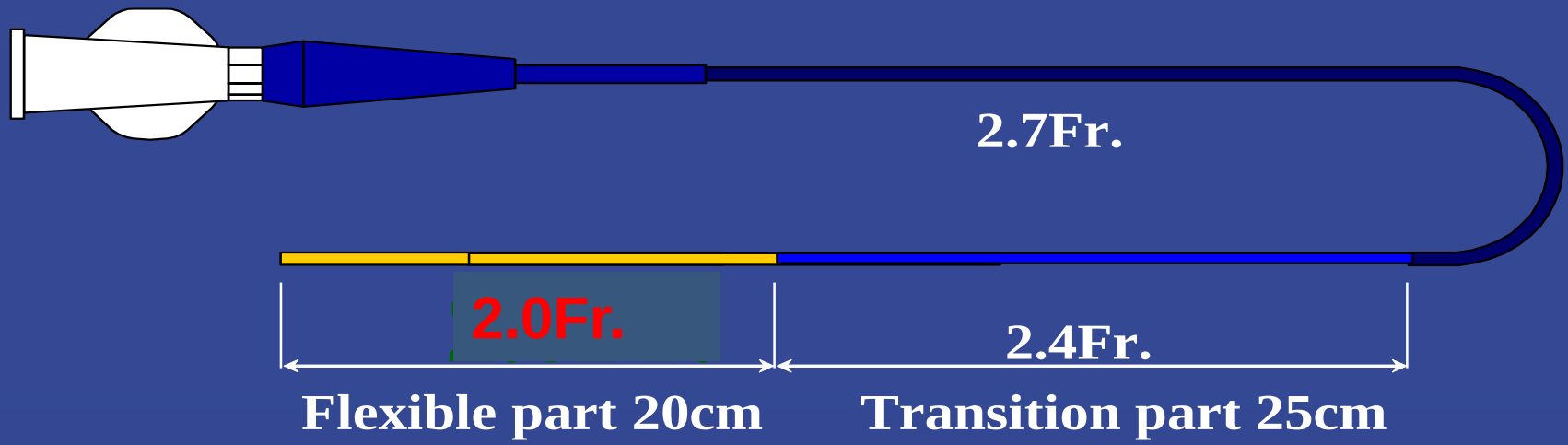
2.2 Fr. <Super Selective>



Excellent Trackability
Excellent Handling
Enough Flow rate

TERUMO's Progreat

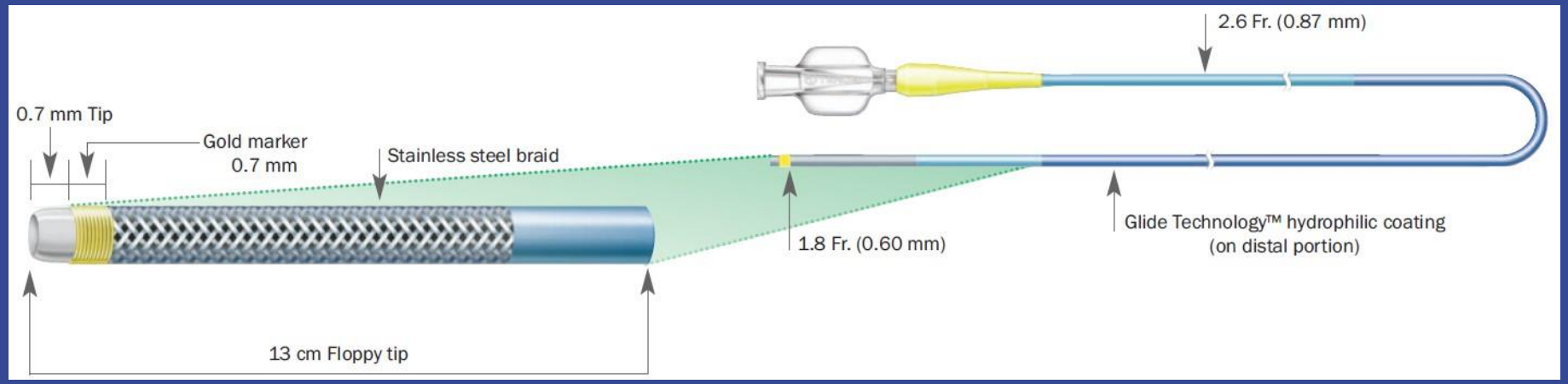
2.0 Fr. <Super Selective>

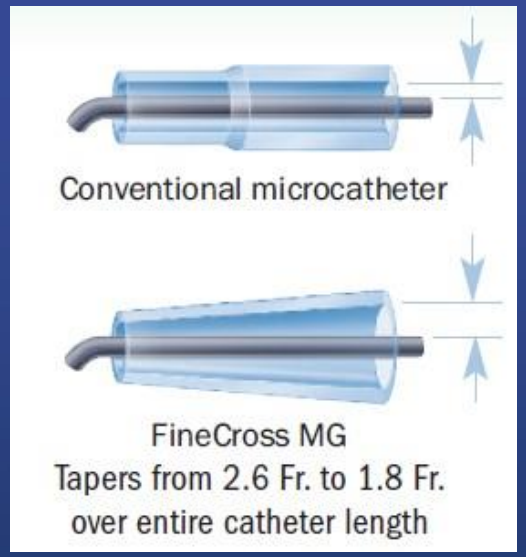


Outer surface : Hydrophilic coating
(Except 60mm from proximal end)

Catheter Size: 2.0 - 2.7Fr. (Distal-Proximal)
Inner diameter: 0.49mm/0.019inch
Length: 100cm,110cm,130cm, 150cm
Max. Injection Pressure: 750psi
Hydrophilic coating

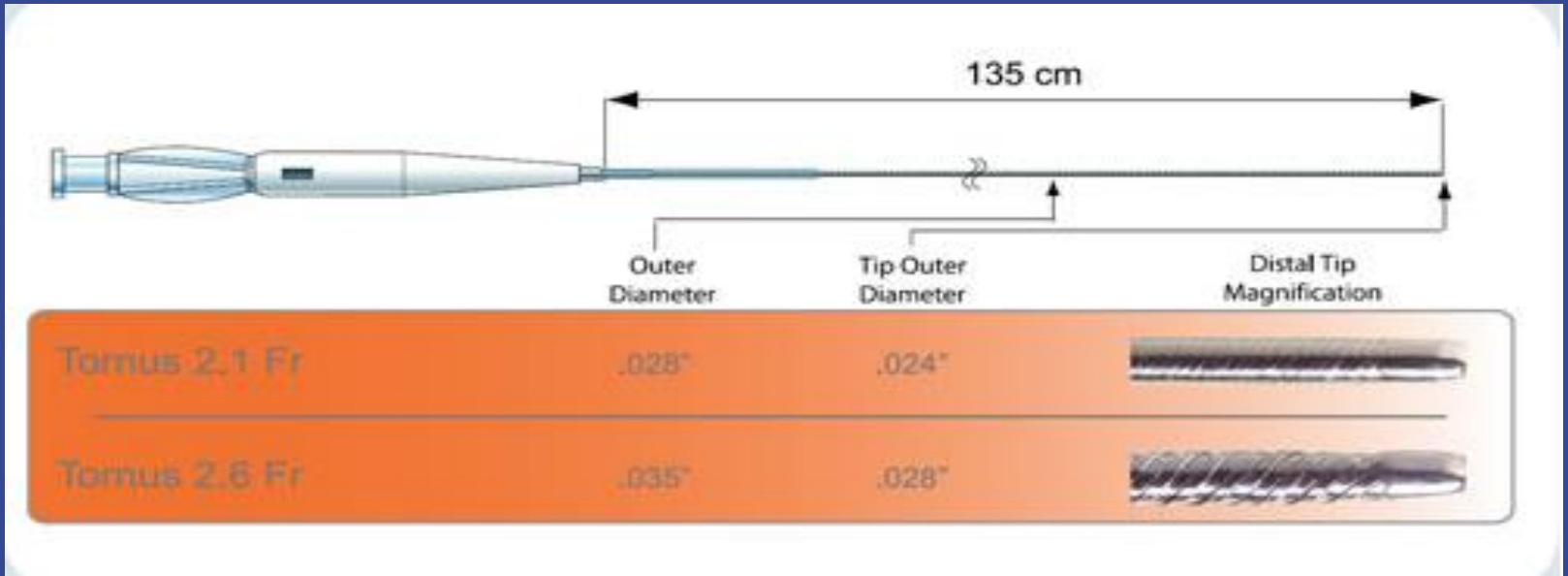
TERUMO's FineCross MG





- Stainless steel braid structure
- Hydrophilic coating
- PTFE inner layer
- Tapered diameter
- Catheter length 130 cm / 150 cm
- Integration of superior crossability and optimal guidewire support

ASAHI Tornus

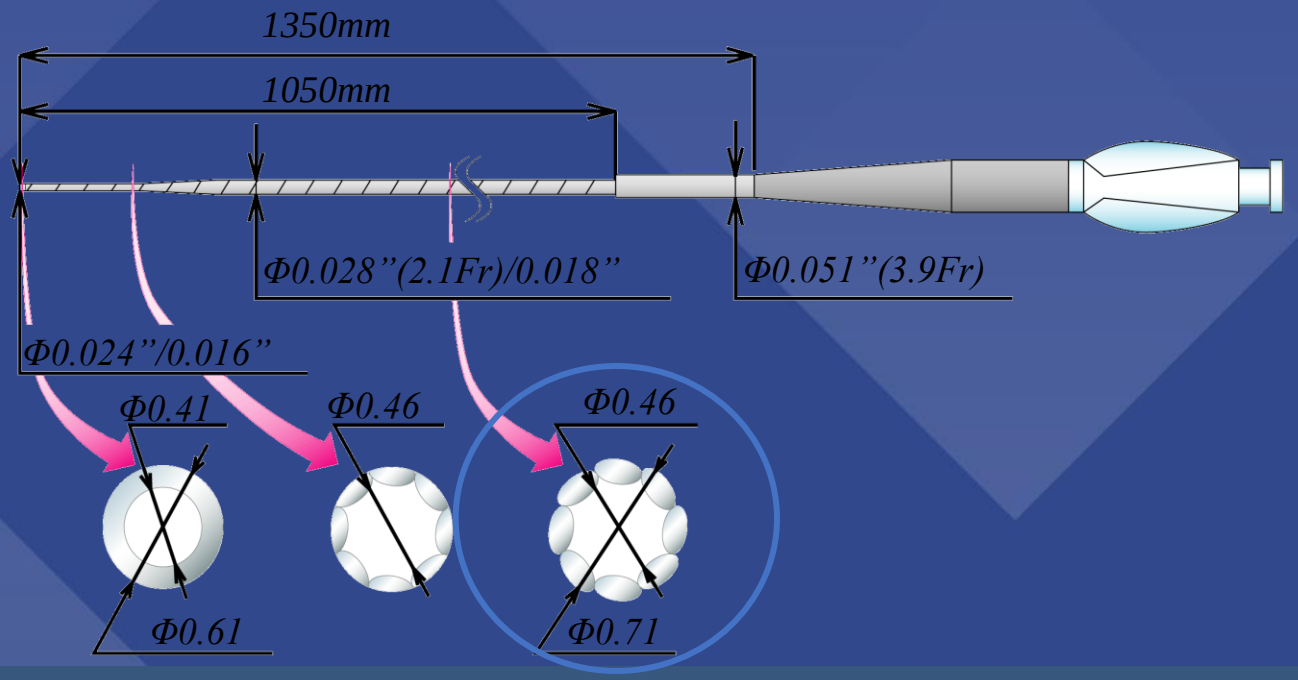


- Braided stainless steel catheter for greater support and pushability
- 1mm distal radiopaque marker for easy visualization of the distal tip
- Tapered threaded tip
- Excellent flexibility for tortuous anatomy

ASAHI Tornus

Structural Feature 1

The metal catheter consists of 8 stainless steel ropes formed in a spiral str ucture.

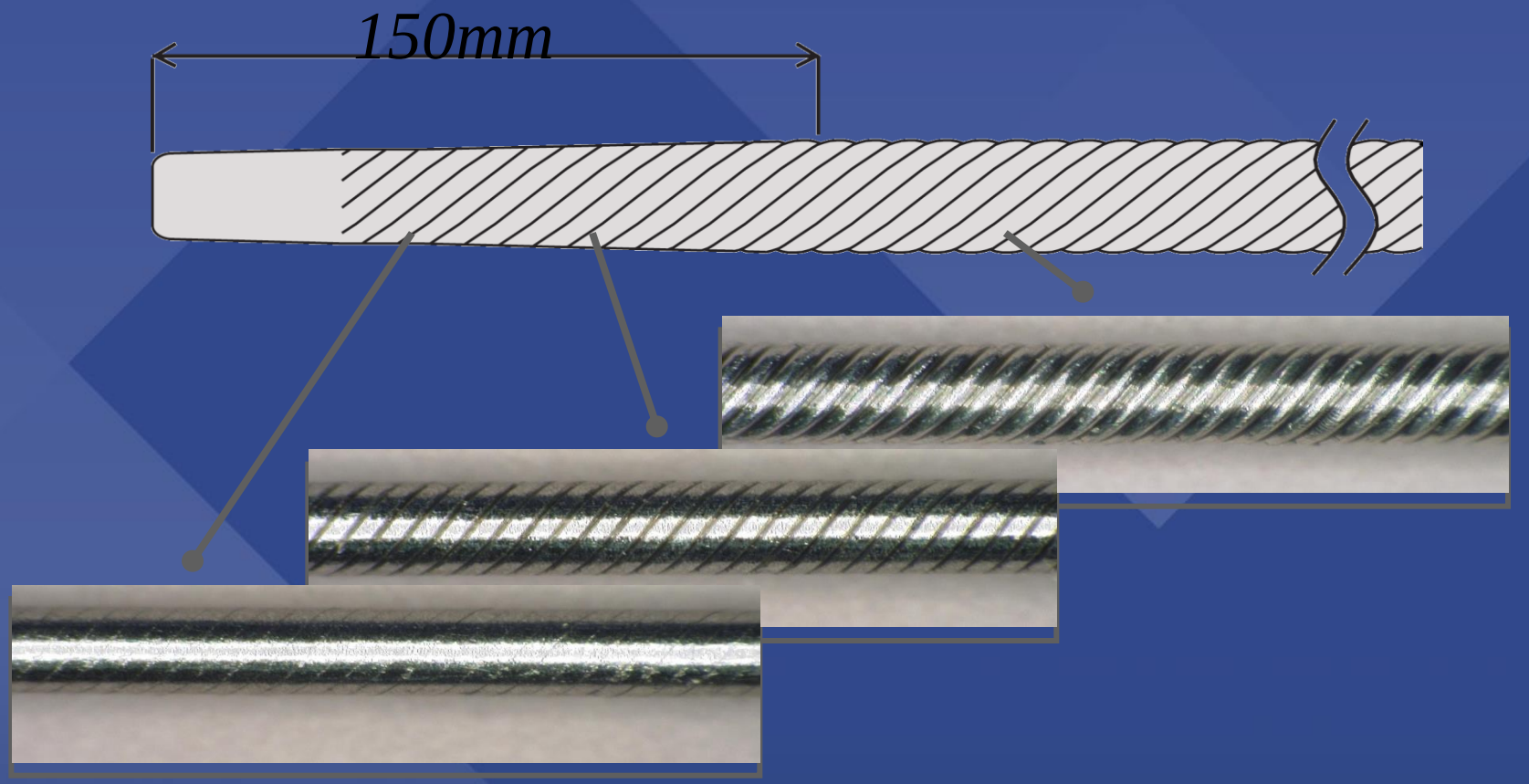


- Combined 8 wires enable high torque performance.
- Spiral structure gives high penetration power by counter-clockwise rotation.
- Helical cut surface provides stronger anchor effects.

ASAHI Tornus

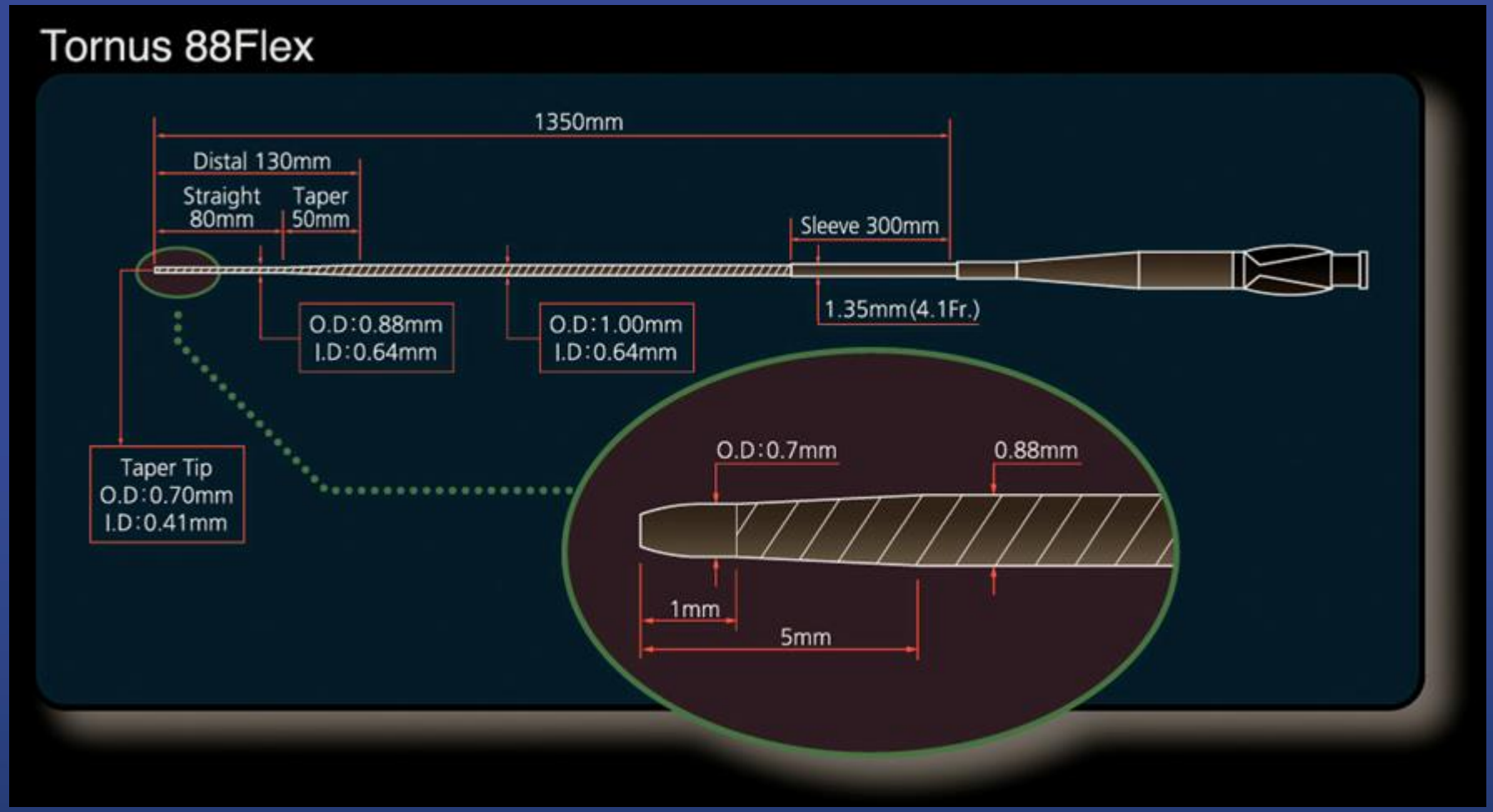
Structural Feature 2

The tapered structure with 150mm from the distal tip.



ASAHI Tornus

Available in Two size



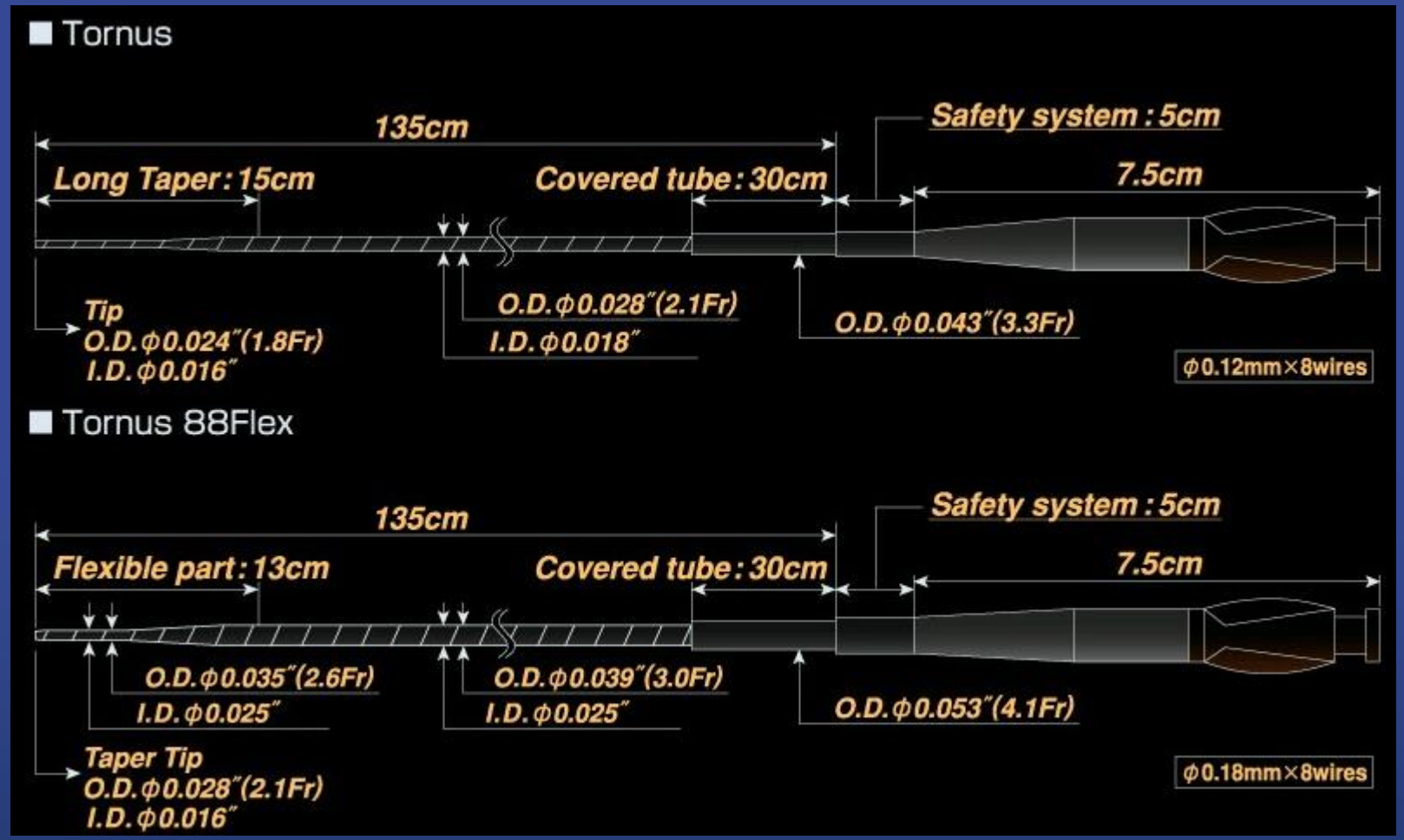
ASAHI Tornus

Magnified Torus Tips

Tornus

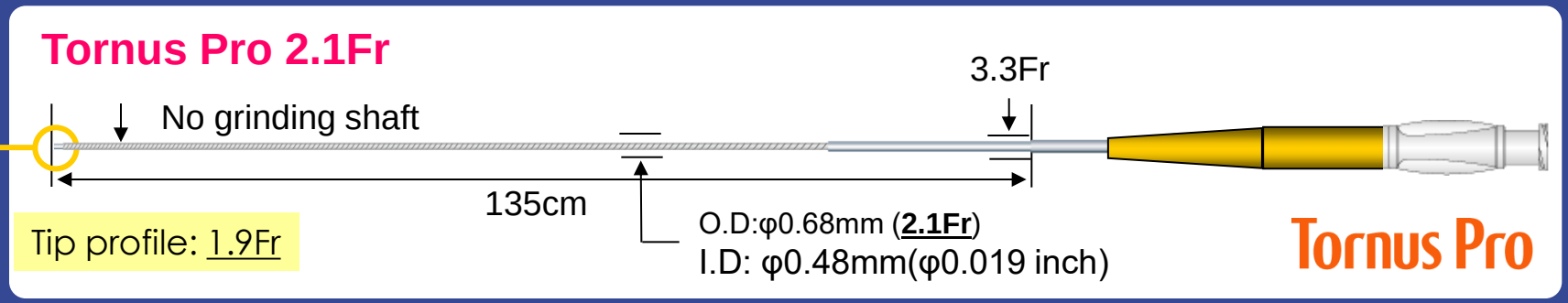
Tornus 88Flex

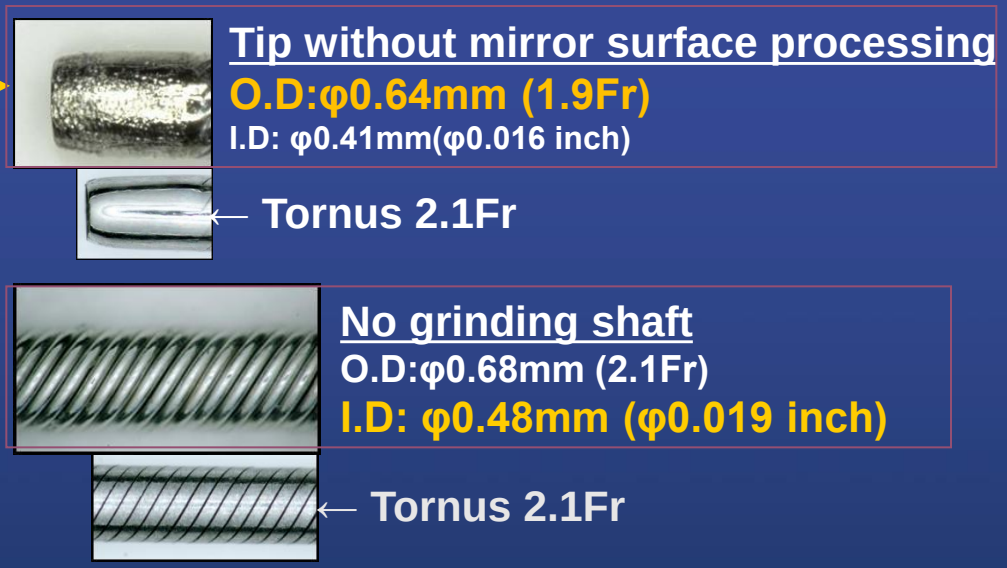
ASAHI Tornus & Tornus 88Flex

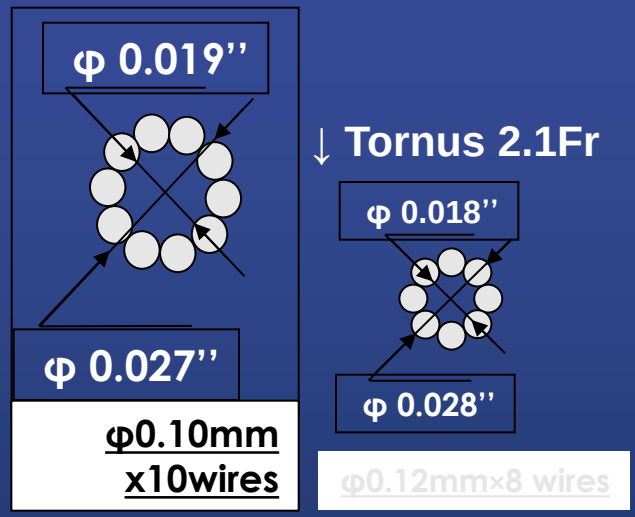


Tornus Pro

Superior lesion crossability & flexible shaft

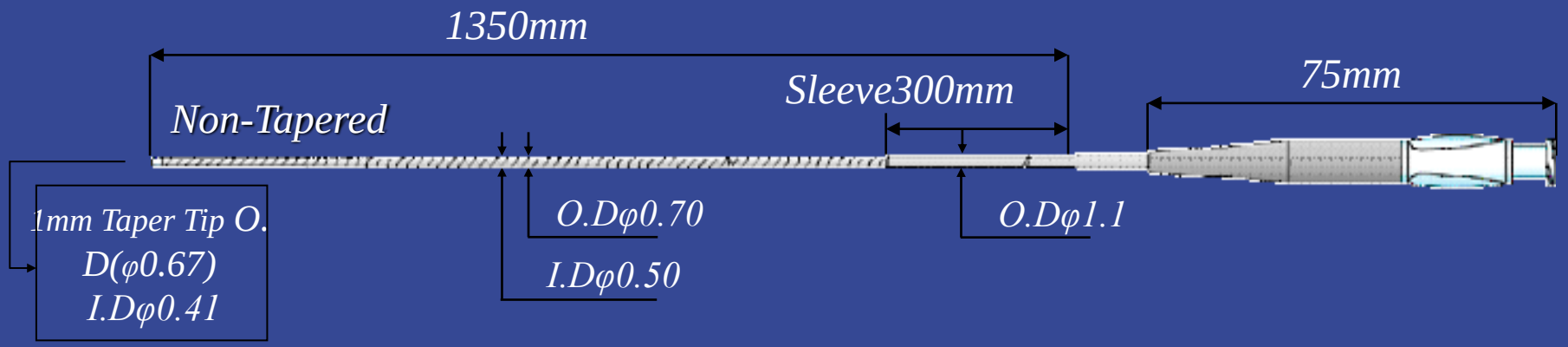




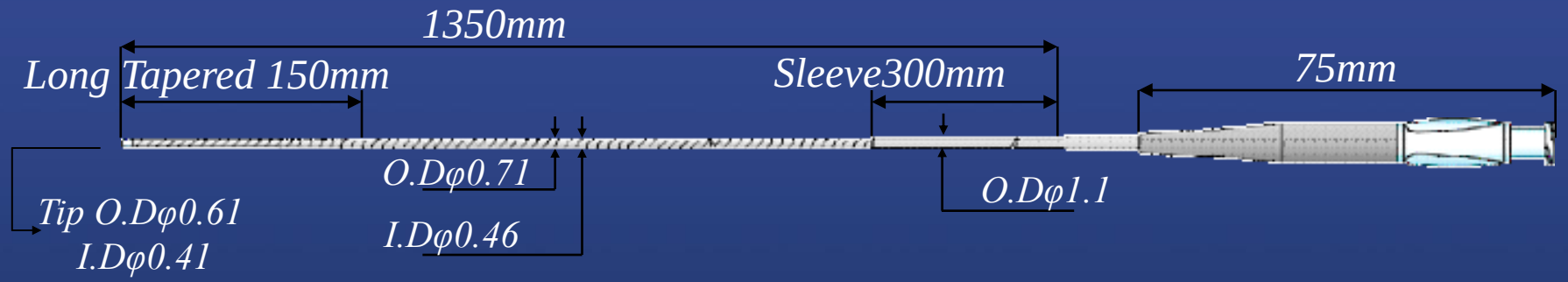


Tornus Pro

Tornus-Pro　φ0.10㎜×10wires　*as same as Corsair*



Tornus　φ0.12㎜×8wires



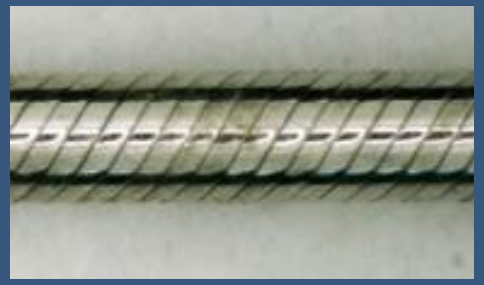
Torus Pro

Features and Benefits

Unpolished shaft

Maximizes the screw effect to pass through tight lesions.

Tornus Pro（Unpolished）



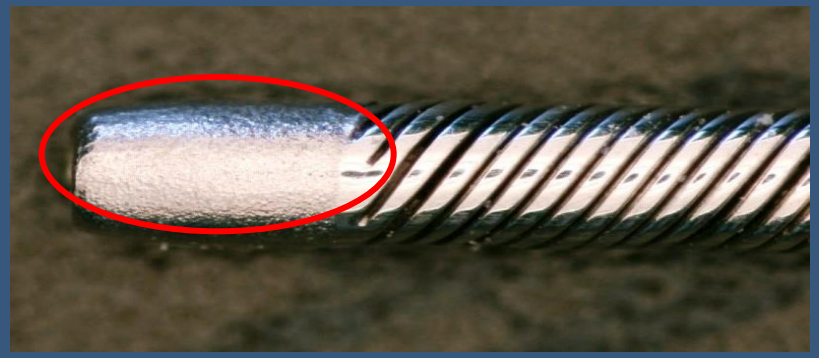
Tornus (Polished）

Torus Pro

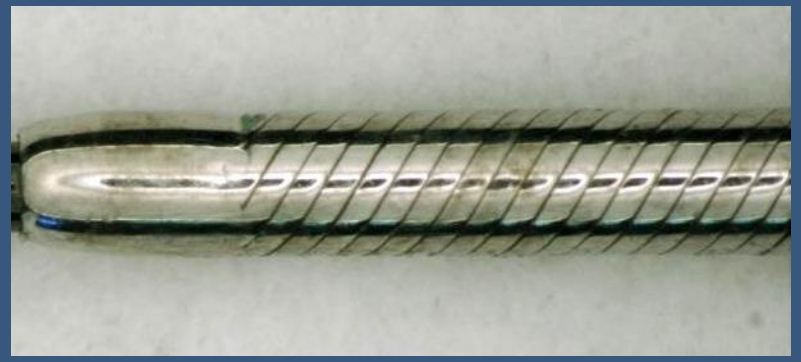
Features and Benefits

Non-mirror finishing process on the tip

Deletion of mirror finishing process at the tip prevents fro m slipping and bouncing back at the tight lesions.



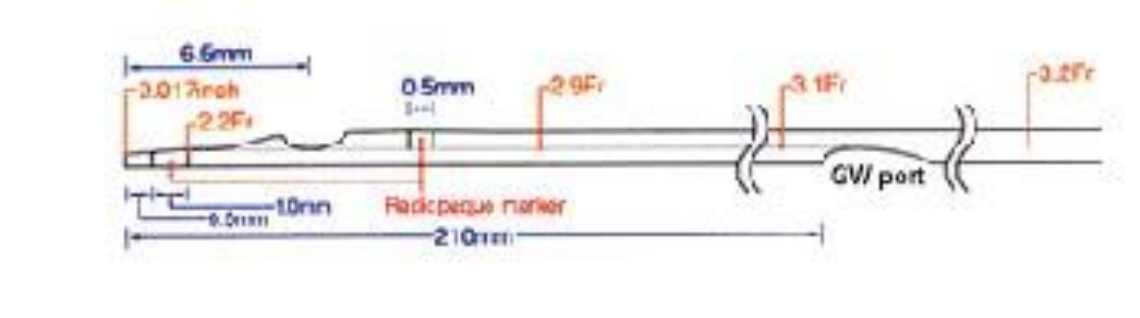
Tornus Pro: Without mirror finishing process



Tornus: With mirror finishing process

Crusade Microcatheter

Double Lumen Catheter



- **Superior Shaft Maneuverability**

Optimized configuration and materials enable superior shaft maneuverability. Distal shaft with slender flexible tip
Flexible and strong proximal shaft

- **Superior GW Movement**

A "double layer lumen" allows superior GW movement.

- **Easy to Estimate the Length of Lesion**

Two radiopaque markers on the RX lumen make it easy to estimate the length of the lesion.

Chronic Total Occlusion
: Current Techniques

J-CTO SCORE SHEET

J-CTO SCORE SHEET

Version 1.0

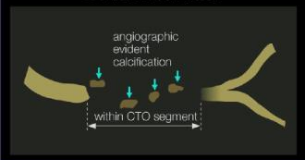
Variables and definitions

Tapered **Blunt**

Entry with any tapered tip or dimple indicating direction of true lumen is categorized as “tapered”.

Entry shape
☐ Tapered (0)
☐ Blunt (1)
point

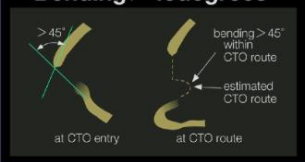
Calcification



Regardless of severity, 1 point is assigned if any evident calcification is detected within the CTO segment.

Calcification
☐ Absence (0)
☐ Presence (1)
point

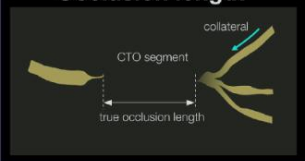
Bending＞45degrees



One point is assigned if bending＞45 degrees is detected within the CTO segment. Any tortuosity separated from the CTO segment is excluded from this assessment.

Bending＞45°
☐ Absence (0)
☐ Presence (1)
point

Occlusion length



Using good collateral images, try to measure “true” distance of occulusion, which tends to be shorter than the first impression.

Occl.Length
☐ ＜20mm (0)
☐ ≥20mm (1)
point

Re-try lesion

Is this Re-try (2nd attempt) lesion ? (previously attempted but failed)

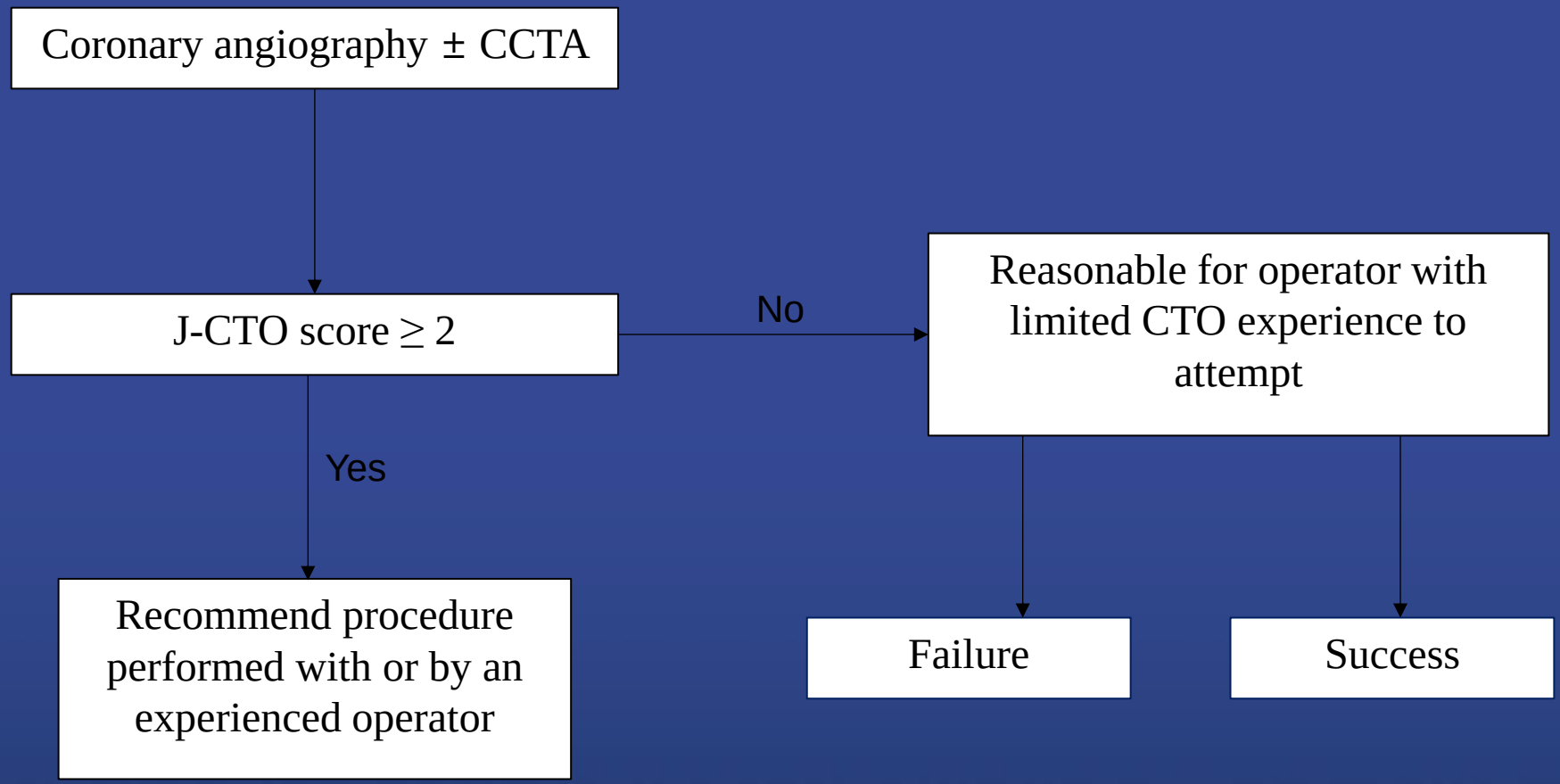
Re-try lesion
☐ No (0)
☐ Yes (1)
point

Category of difficulty (total point)
☐ easy (0) ☐ Intermediate (1)
☐ difficult (2) ☐ very difficult (≥3)

Total ____ points

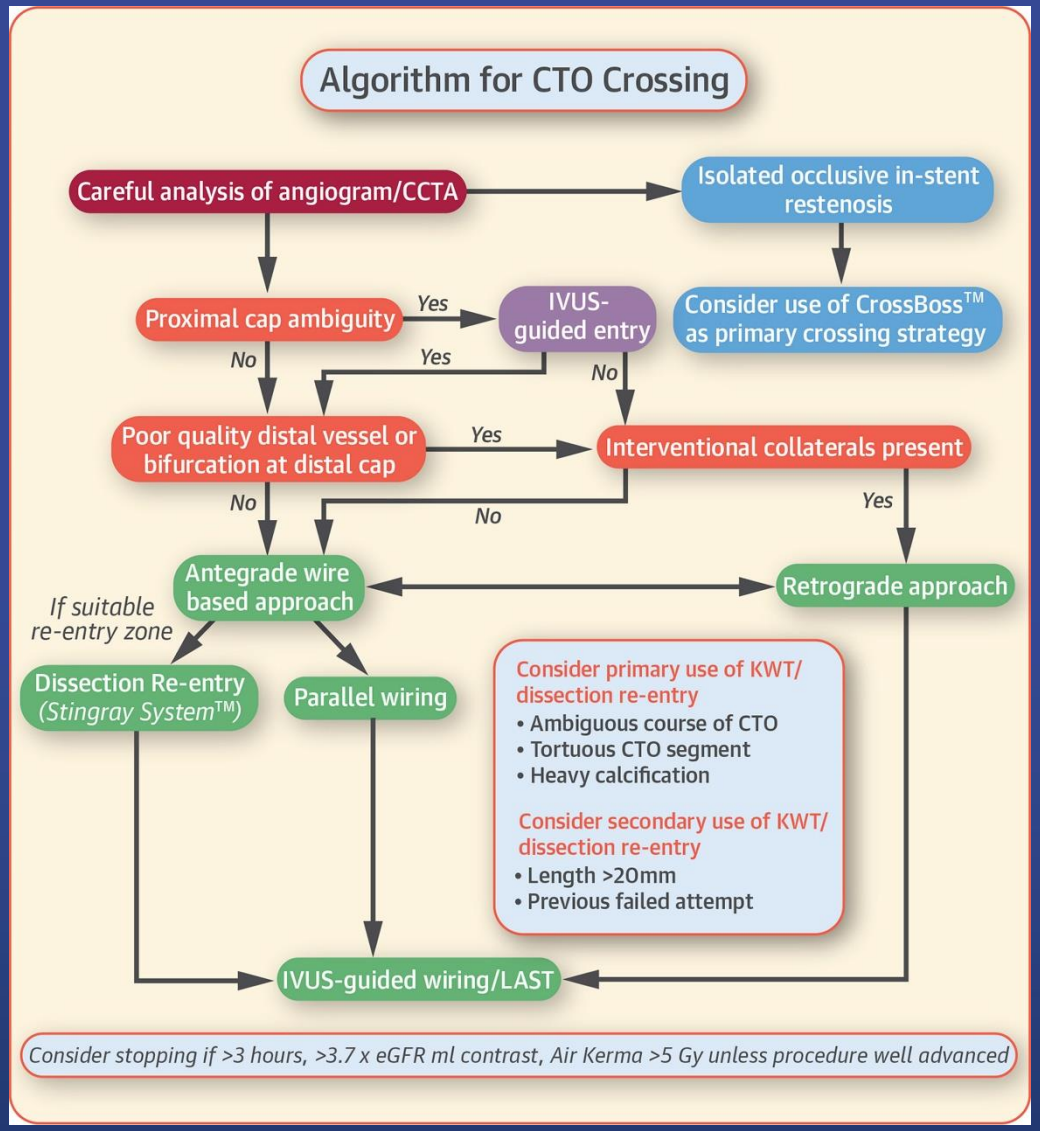
Isehara, kyoto, et al., JACC Cardiovasc Interv. 2011; 4:213-21.

Asia Pacific CTO club new algorithm



Harding et al. JACC Cardiovasc Interv. 2017 Nov 13;10(21):2135-2143.

Algorithm for CTO crossing



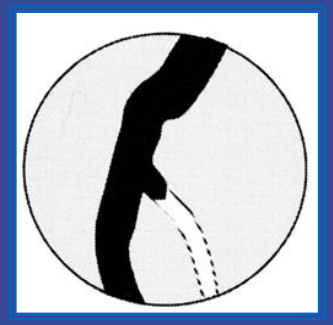
Harding et al. JACC Cardiovasc Interv. 2017 Nov 13;10(21):2135-2143.

Complexity of CTO

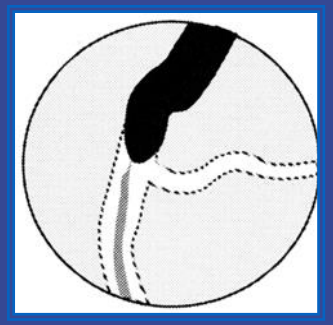
	Level of PCI complexity	
	Easy	Complex
Age of CTO	< 6 months	> 12 months
Occlusion length	< 20 mm	> 20 mm
Calcification at CTO	None/moderate	Severe
Occlusion Stump	tapered	Blunt or absent
Tortuosity at CTO	None/minimal	Moderate/severe
Visibility of the distal vessel	Good/excellent	Poor
Tortuosity proximal to CTO	Minimal/moderate	Severe
Ostial location	Yes	No
CTO at proximal/mid LCX	No	Yes
Expected guiding catheter support	Good	Poor
Renal insufficiency	Yes	No
Previous attempts	No	Yes
Expected patient tolerance	Good	Poor

Patient Selection and Predictors of Success

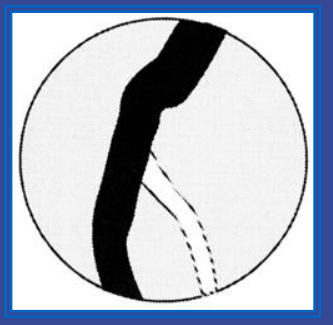
Angiographic Lesion Morphology



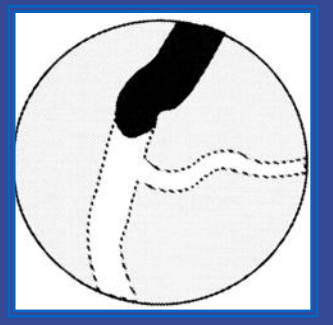
Tapered Stump



Functional occlusion

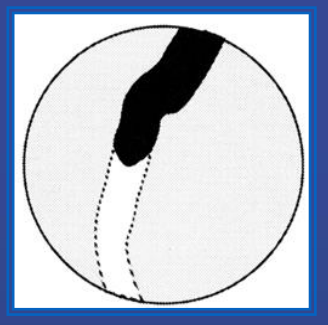


Stump absent

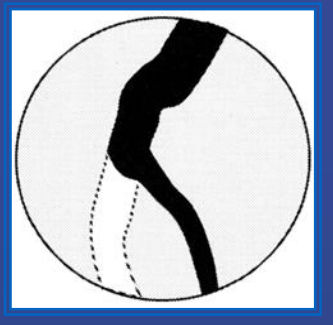


Total occlusion

Pre or Post-branch occlusion



Bridging collaterals absent



Occlusion at side-branch

Bridging collaterals present

Favor Procedural Success

Does Not Favor Procedural Success

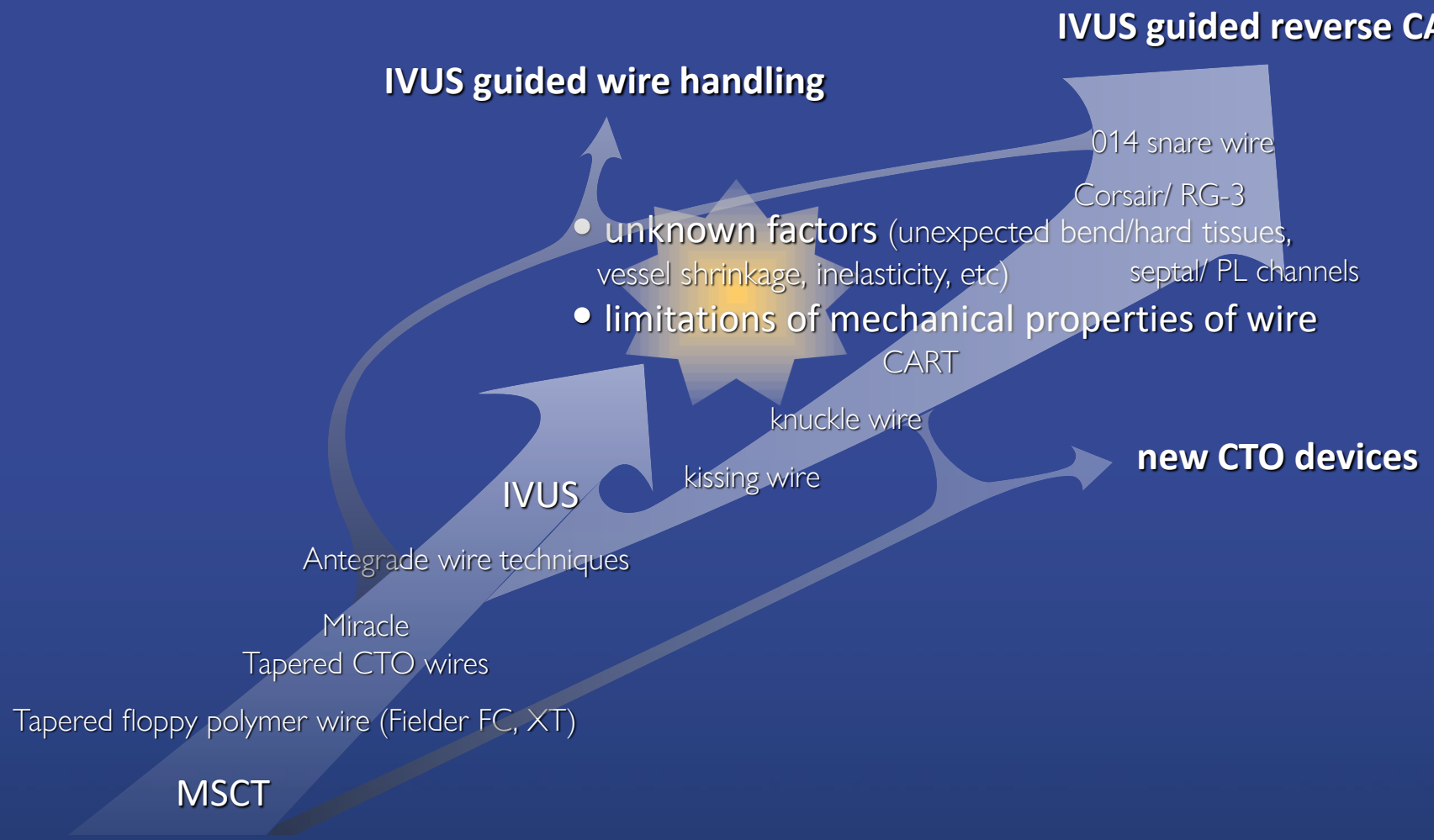
Where should we go?

too many ways !

confused

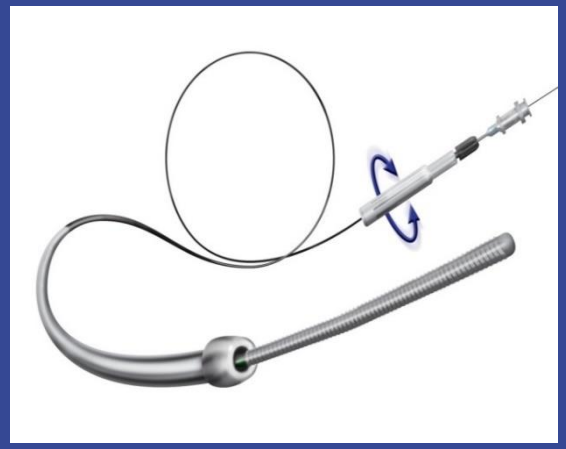
- Retrograde knuckle wire technique
- Kissing wire technique
- Parallel wire technique
- Micro-channel tracking
- See-saw wire technique
- STAR technique
- Penetration
- Reverse CART
- Drilling
- IVUS guided wire technique
- CART technique

Roadmap to CTOs

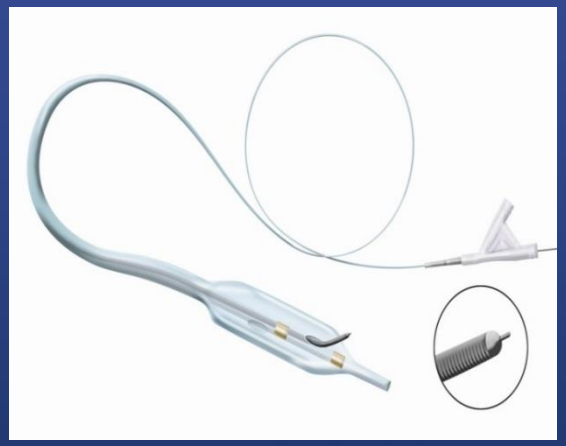


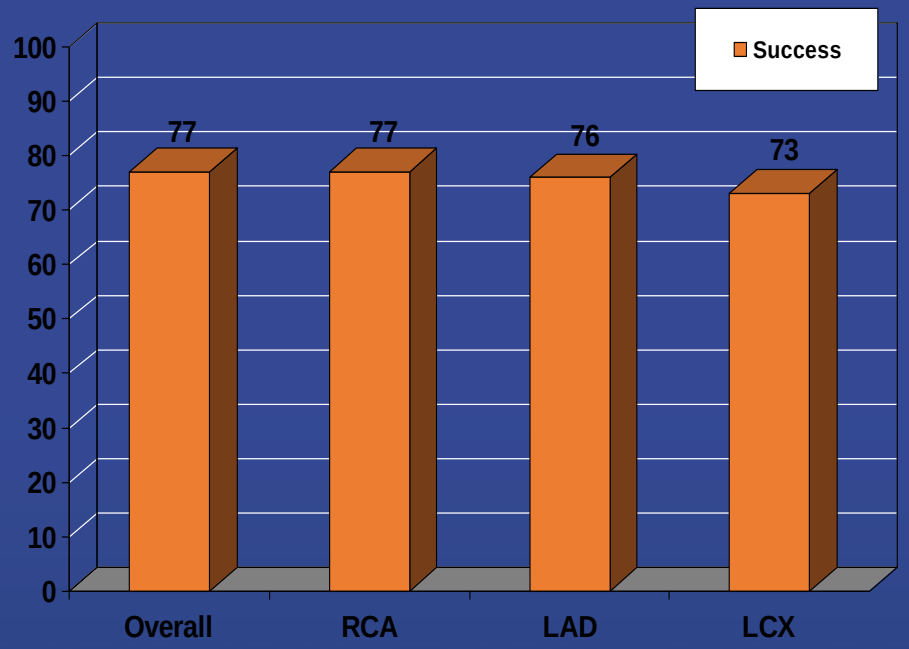
New Devices

The CrossBoss™ CTO Catheter Design

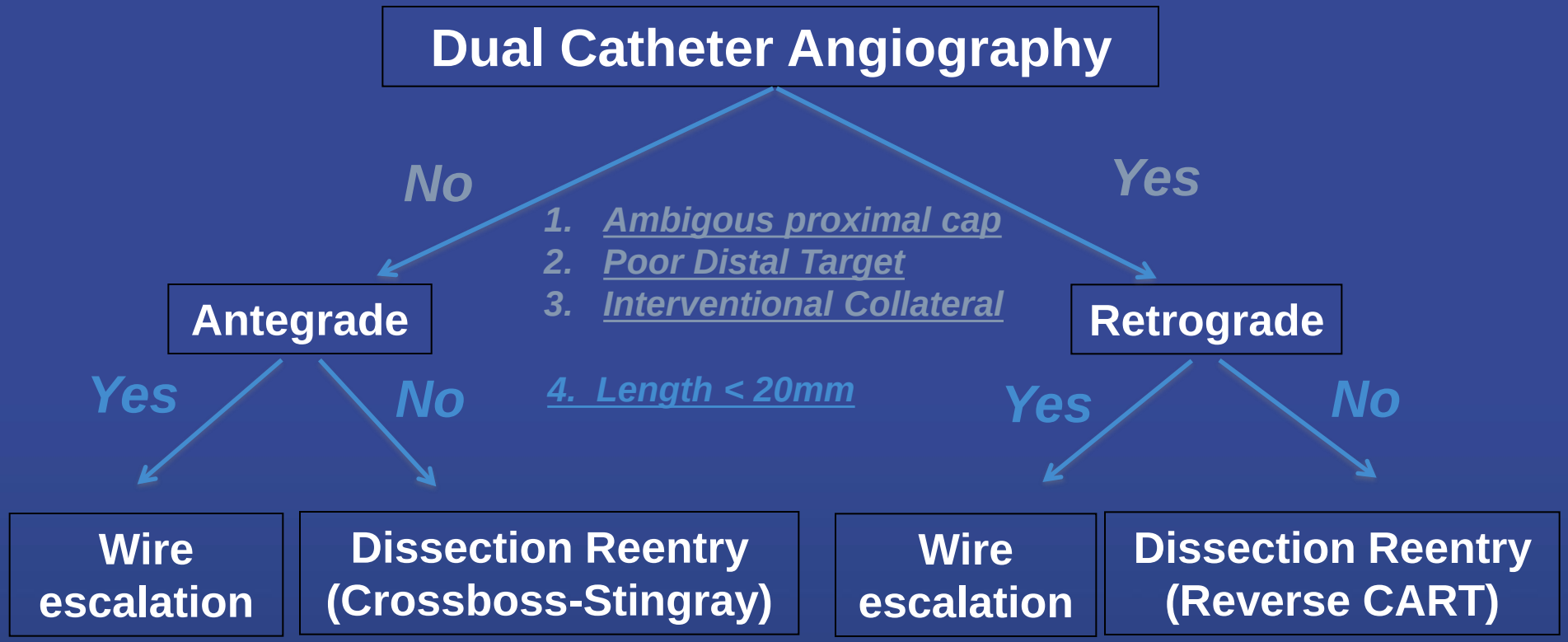


The Stingray™ CTO Re-entry System Design



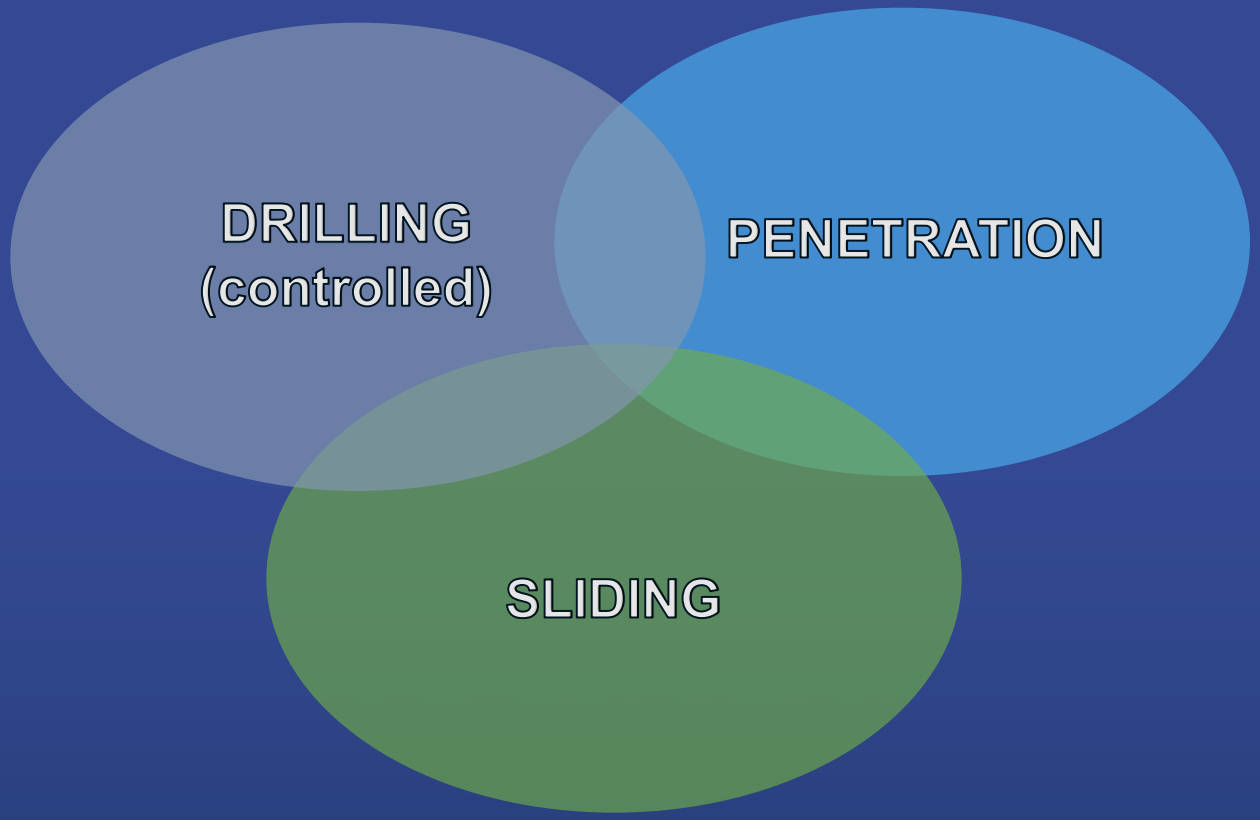


The Hybrid Algorithm for CTO PCI



Antegrade Approach

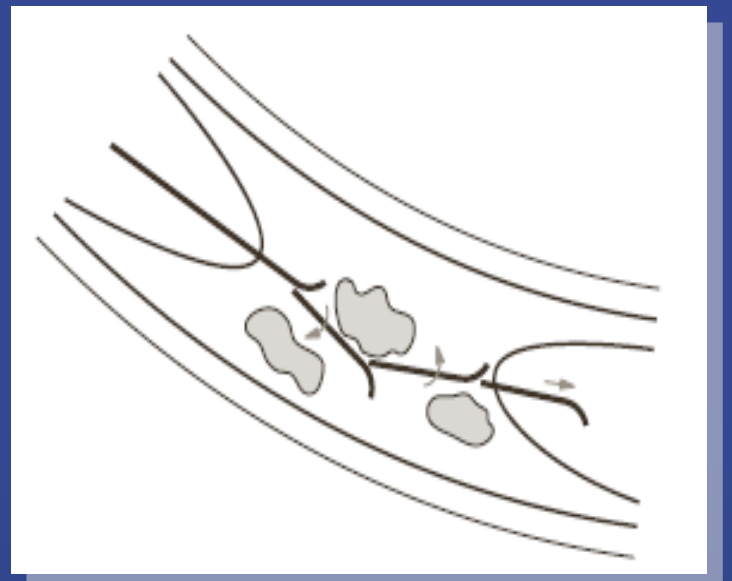
Guidewire Operator Techniques



Simple Technique

Conventional technique

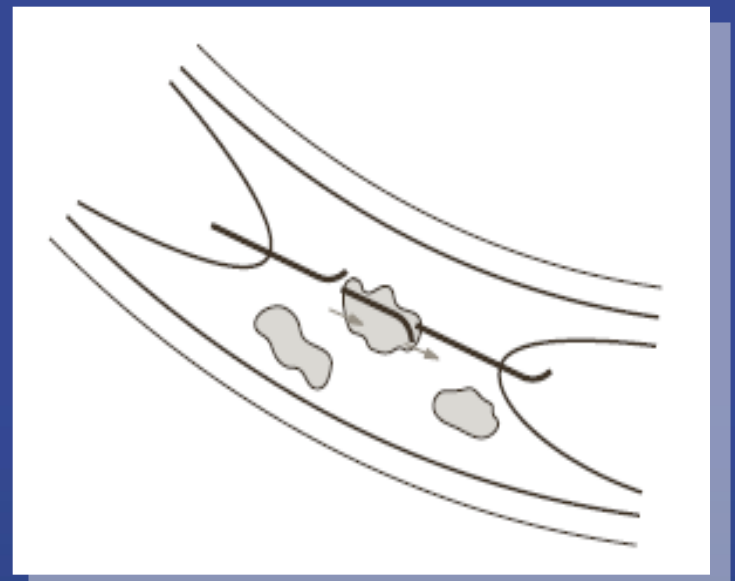
Drilling strategy



When the tip of a wire encounters hard tissue, the wire is advanced and retracted repeatedly to find soft part of CTO and is pushed through it

New technique

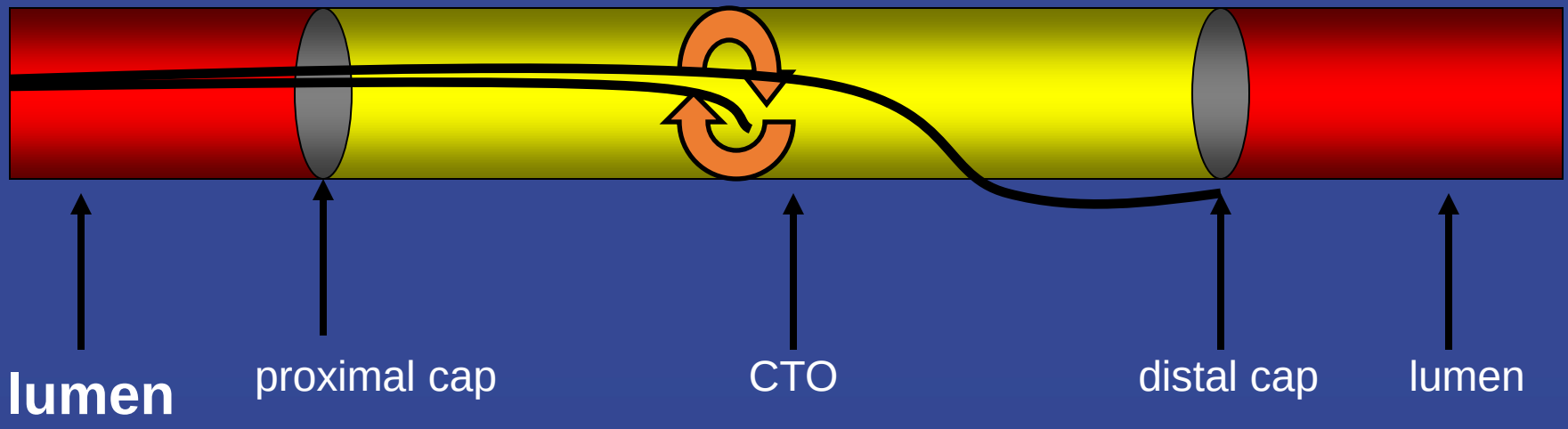
Penetrating strategy



Stiff wire is used from the start of the procedure and advanced in the planned direction through hard tissue

Ochiai M et al, Ital Heart J 2005;6:489-493

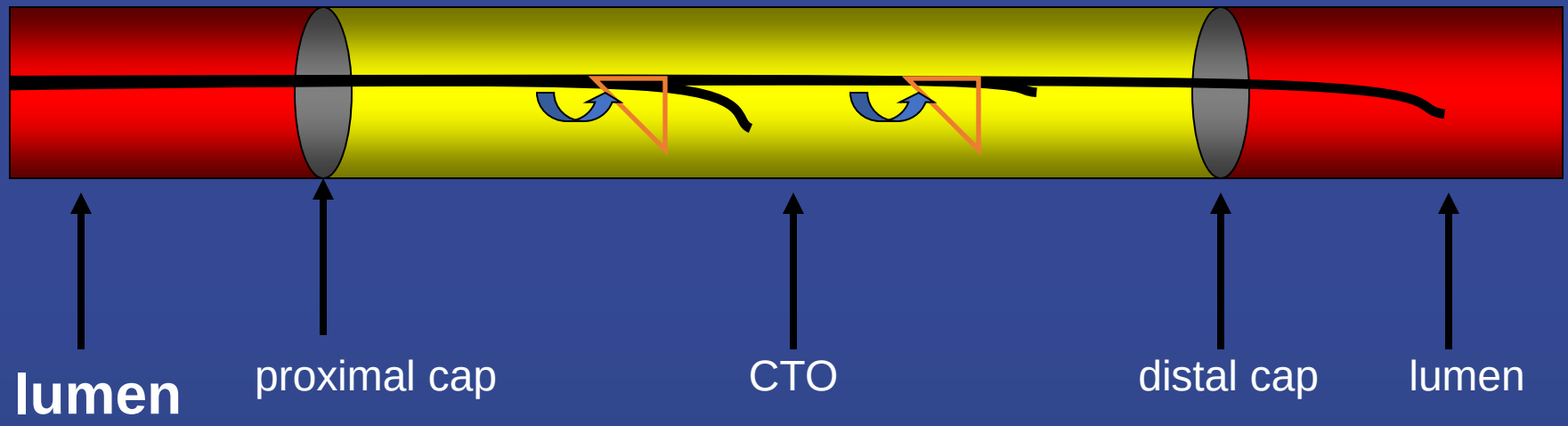
Antegrade CTO Wiring Techniques



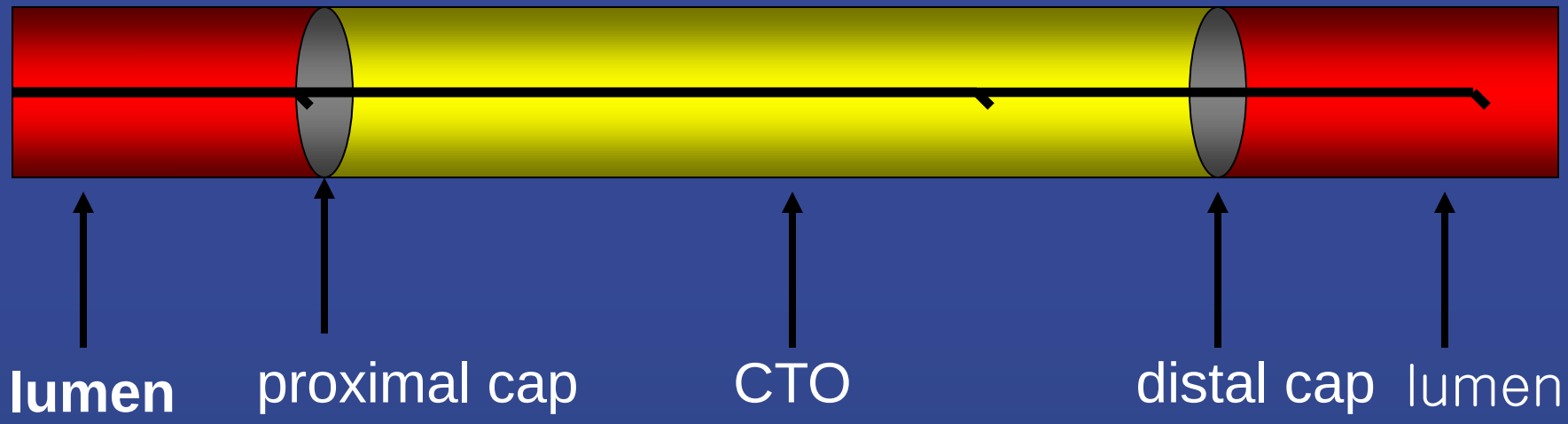
Uncontrolled drilling

FAILURE!

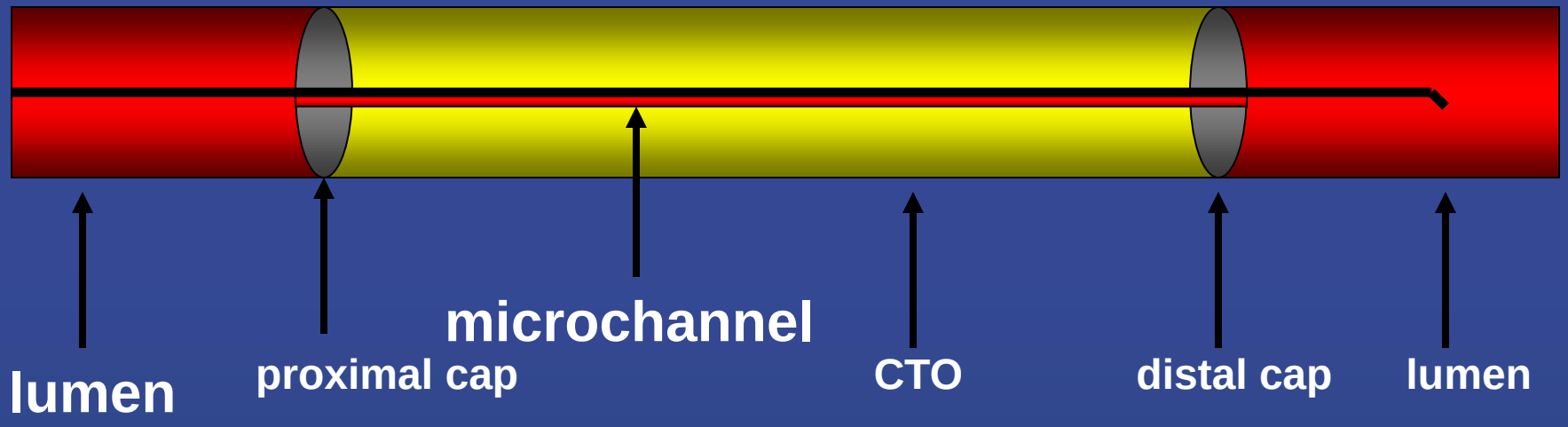
Antegrade CTO Wiring Techniques
Controlled Drilling
(90 degree arc)



Antegrade CTO Wiring Techniques
Penetration Techniques



Antegrade CTO Wiring Techniques
Sliding Techniques



Simple Technique

Conventional technique

Drilling strategy

Intermediate GW

↓ Not cross

Standard GW

↓ Not cross

Stiffer GW (0.014 inch)

↓ Not cross

Other stiffer GWs

↓ Not cross

Stiff Tapered GW

New technique

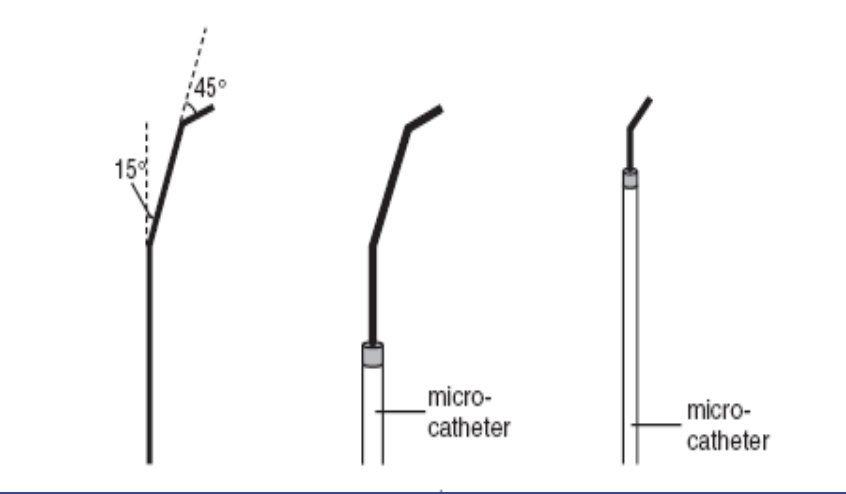
Penetrating strategy

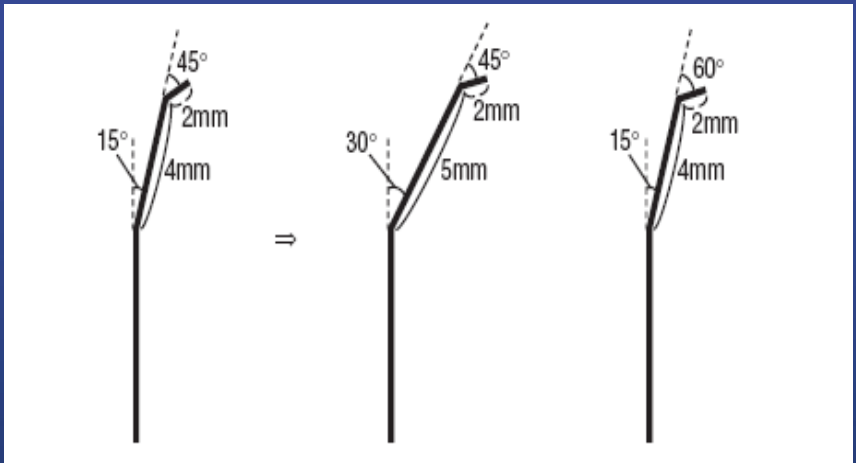
Intermediate GW

↓ Not cross

Stiff Tapered +/- Hydrophilic coating

Deflecting Tip Wire

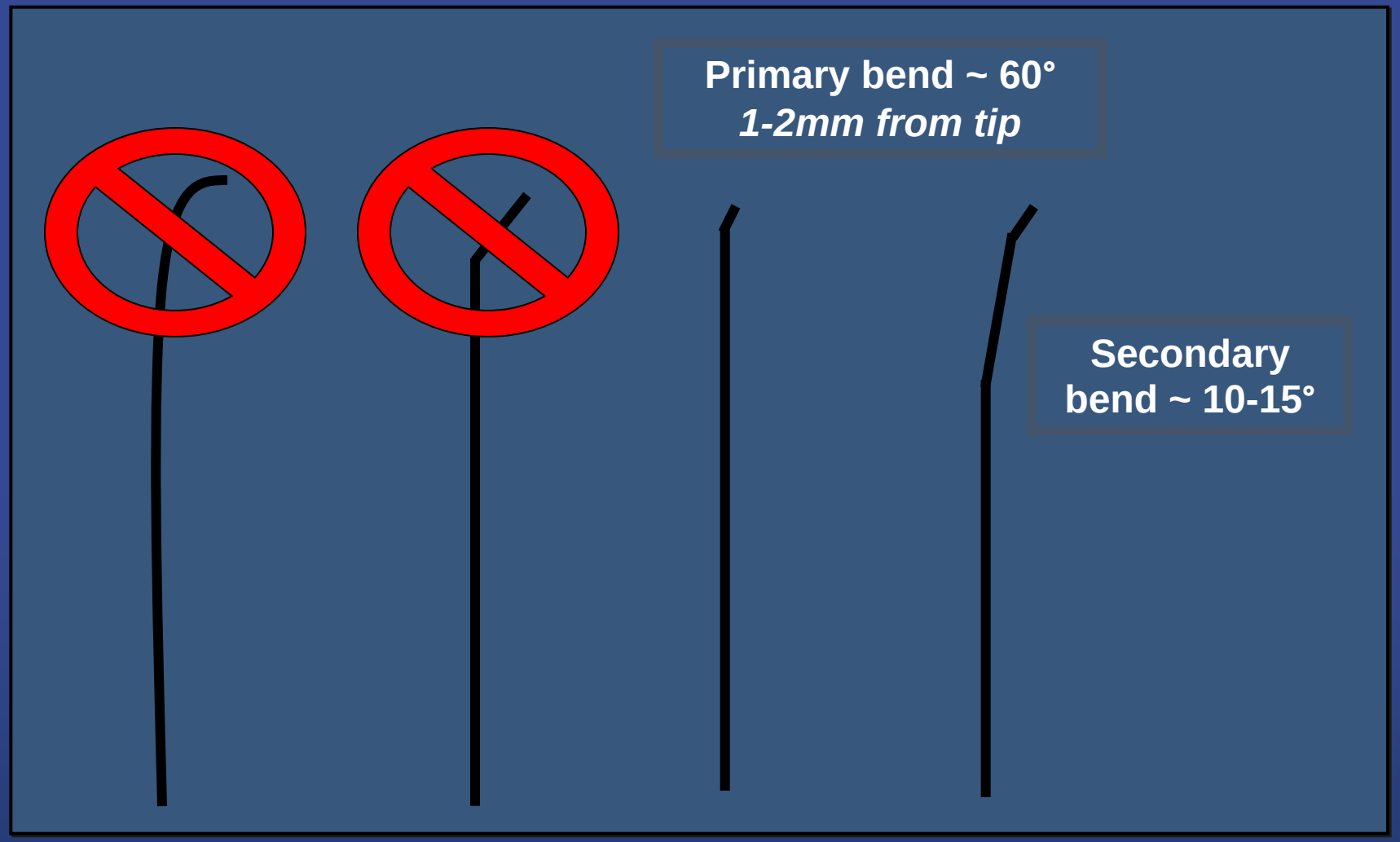




- Double-bend method. In addition to the first small curve (2 mm) made at the tip of a wire to find a true lumen, a larger shallow curve (4-5 mm) is added to cope with the curvature of the blood vessel. It is possible to use or extend the second curve at the tip of a microcatheter.

- When the parallel wire technique is used, it is possible to advance the second wire along a different channel by making the first or second curve different from that of the first wire

CTO Guidewires – Tip Shaping



Antegrade CTO Wiring Techniques

Severe Tortuosity

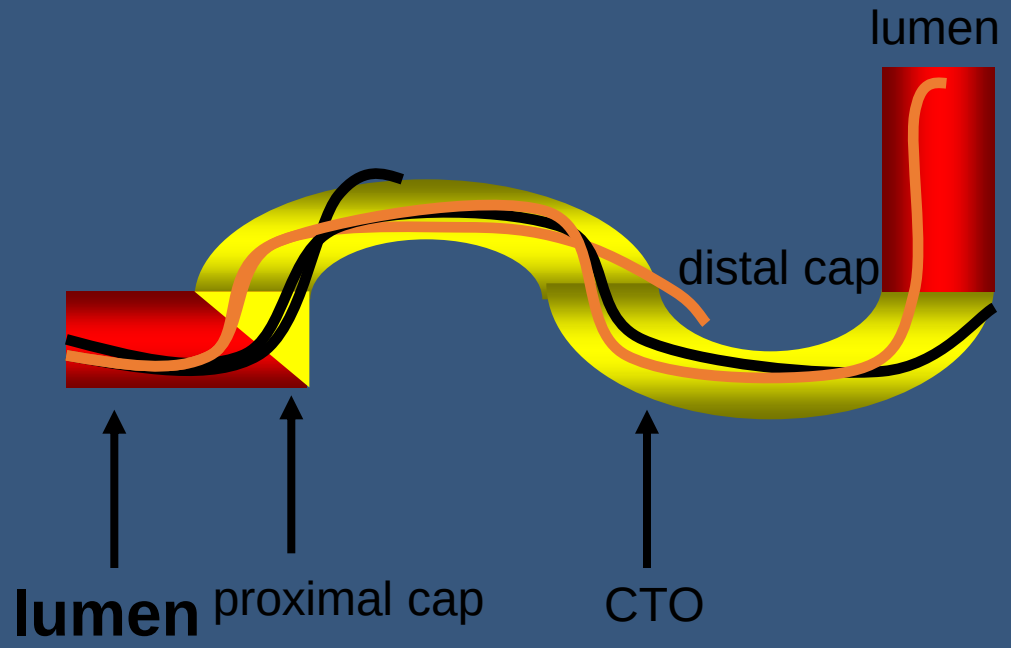
Miracle 3

↓

Miracle 6, 12

↓

Parallel/See-saw wiring with support catheters



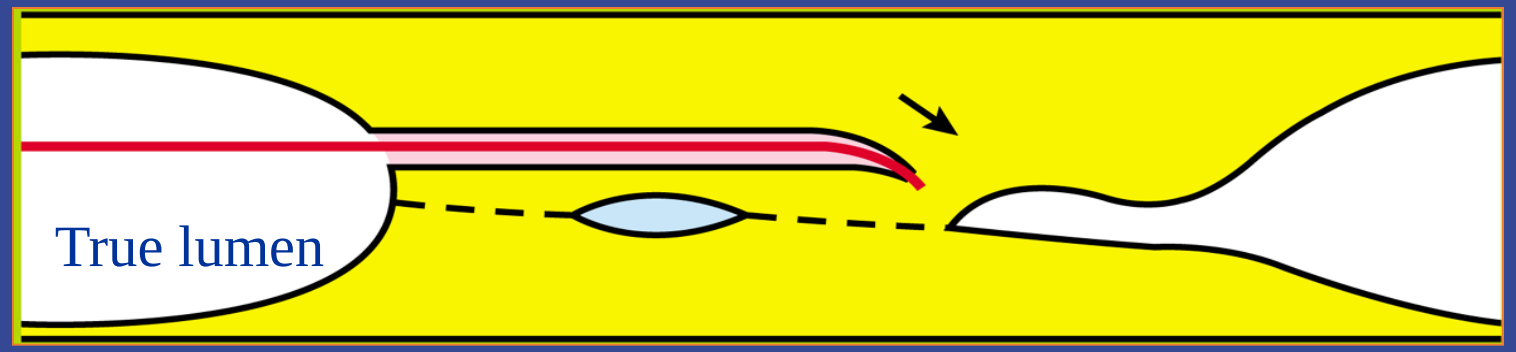
Inner curve less apt to dissect

Deflecting Tip Wire

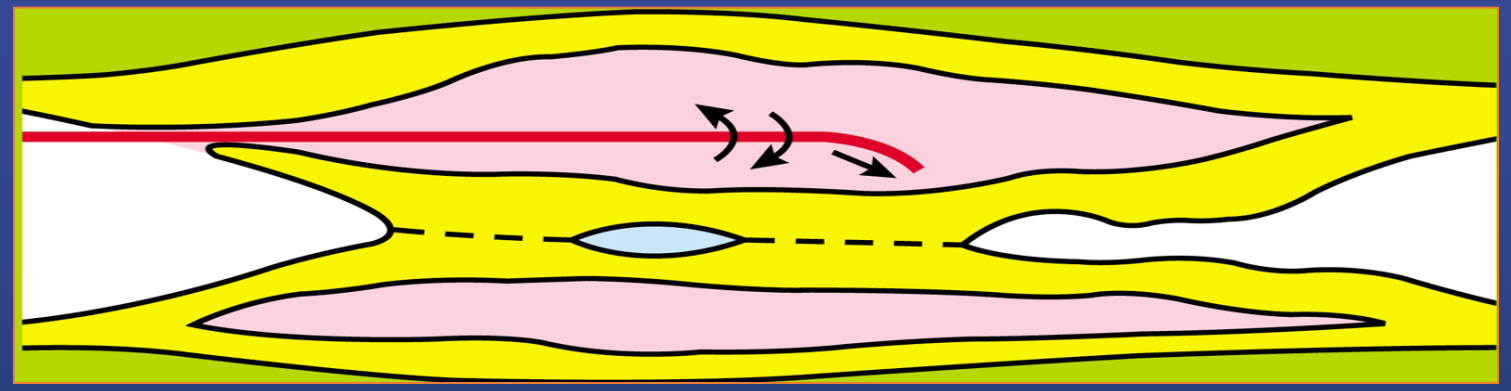
For penetrating the entry point

For reentering to the
true lumen from the subintima

Creation of Re-entry

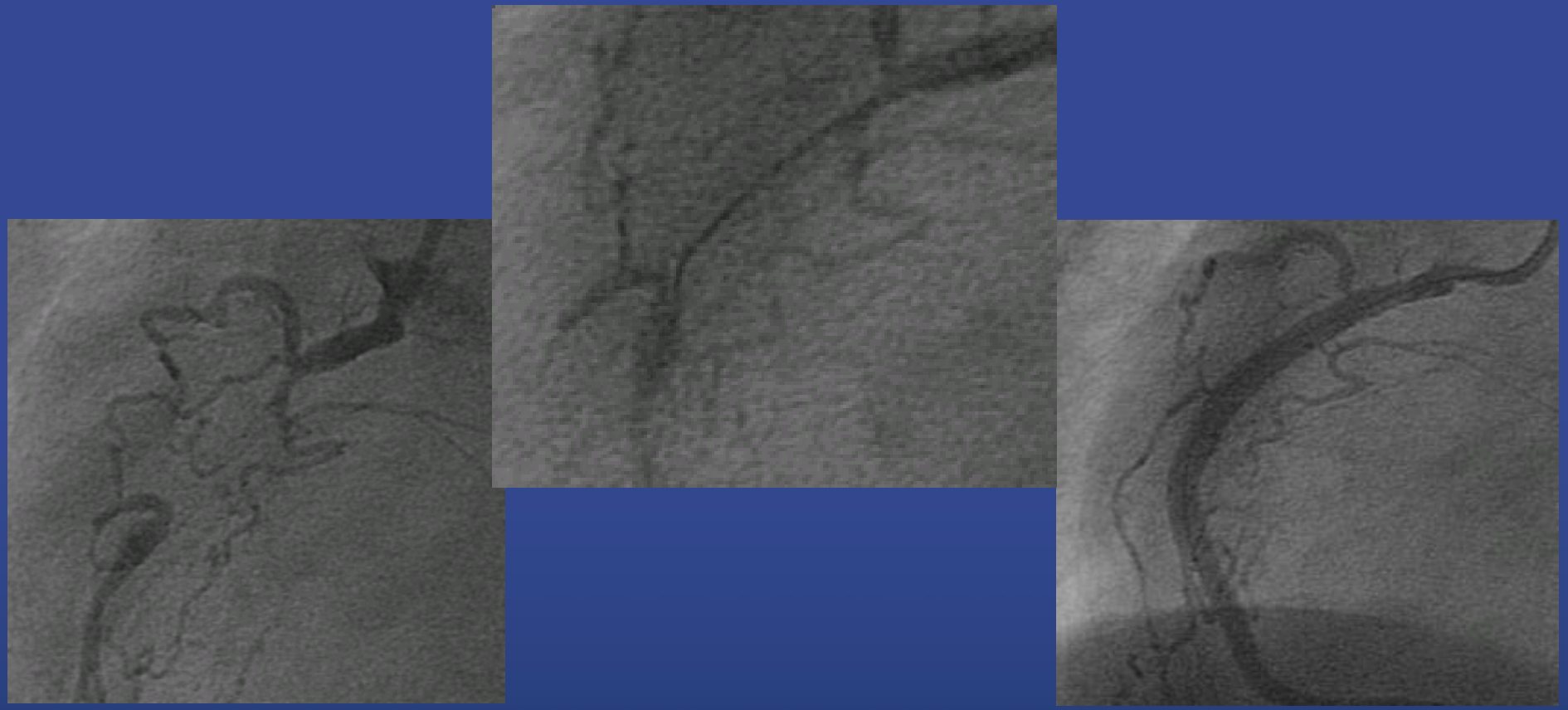


Easy to make re-entry



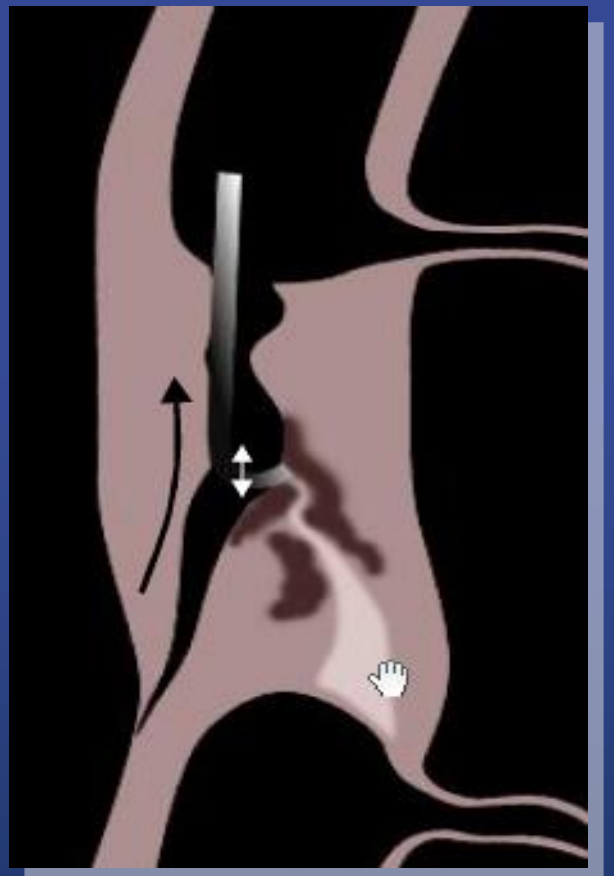
Difficult to make re-entry

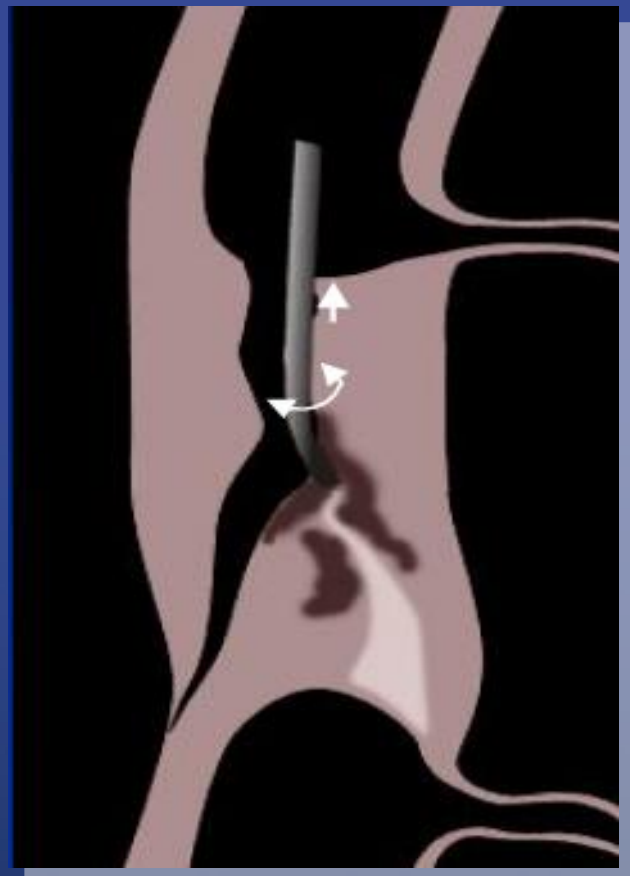
Deflecting Tip Wire Case Example



Wire technique for locating another channel

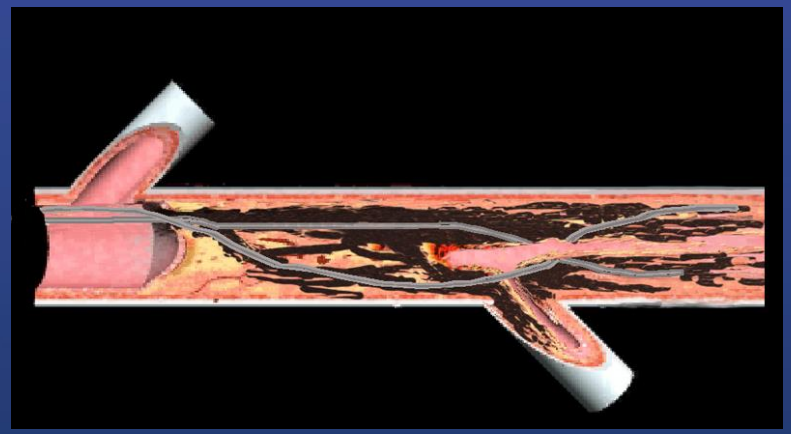
Tip Shape is Key !





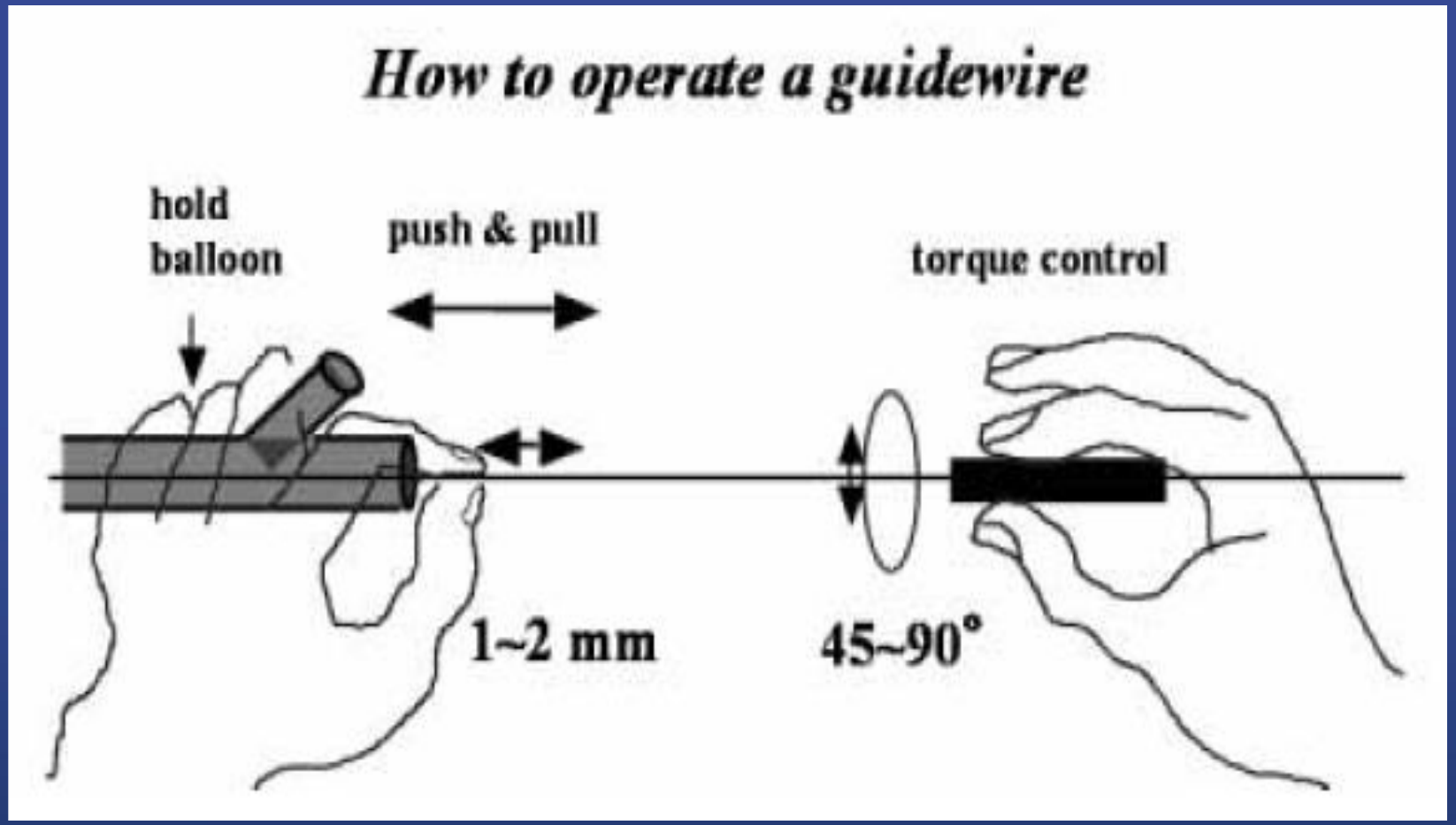
Single wire manipulation

Parallel wire technique

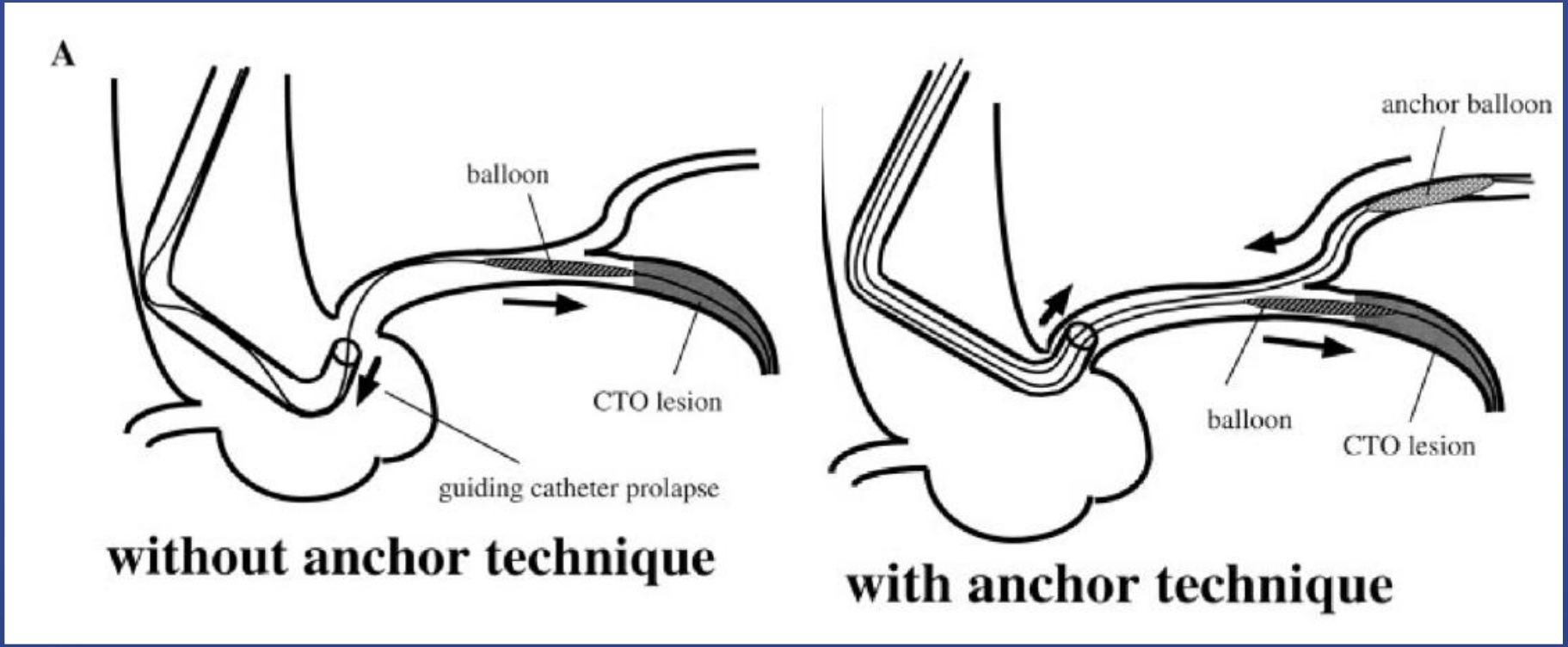


Wire Manipulation

Both hands easier than single hands manipulation

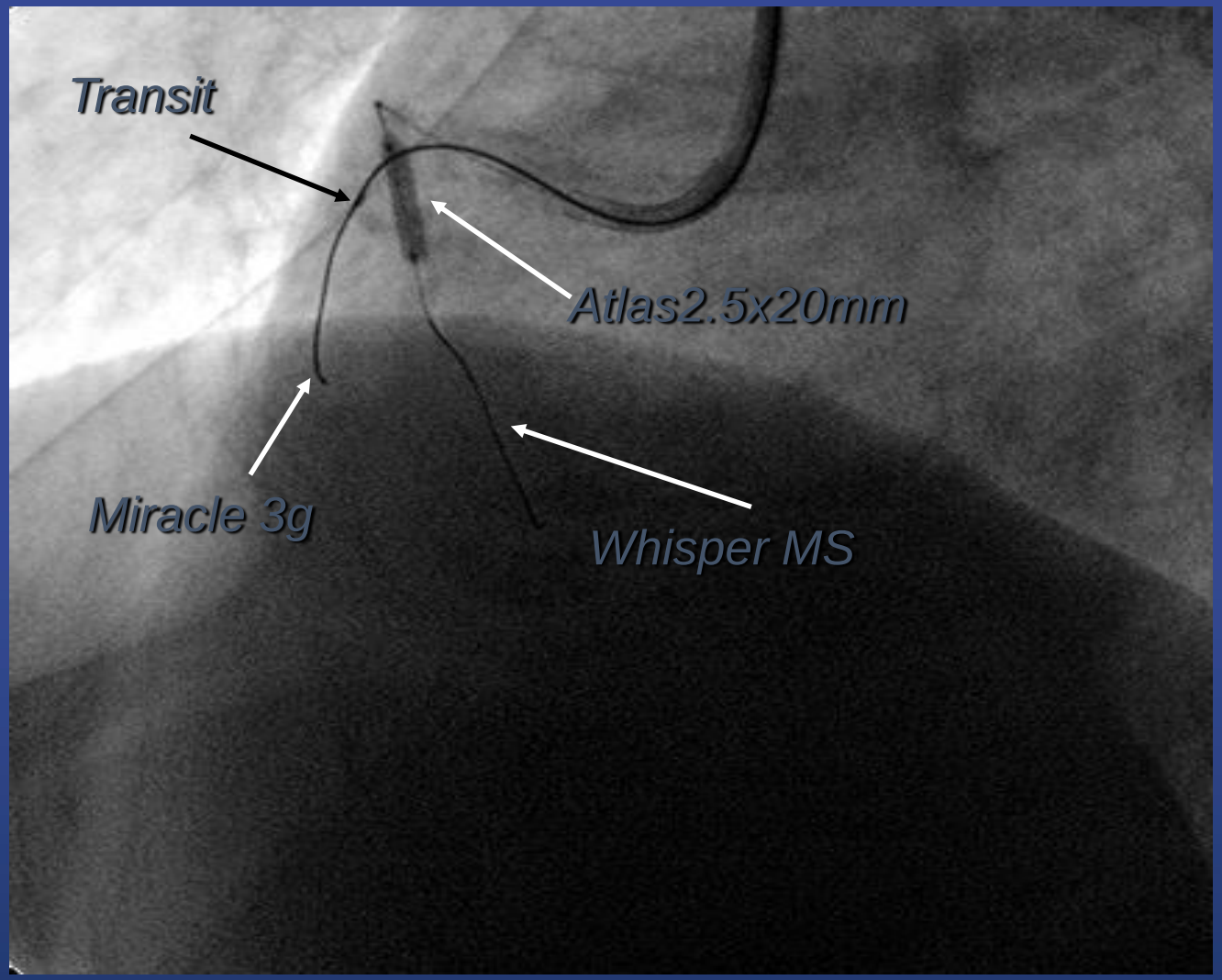


Anchor balloon technique

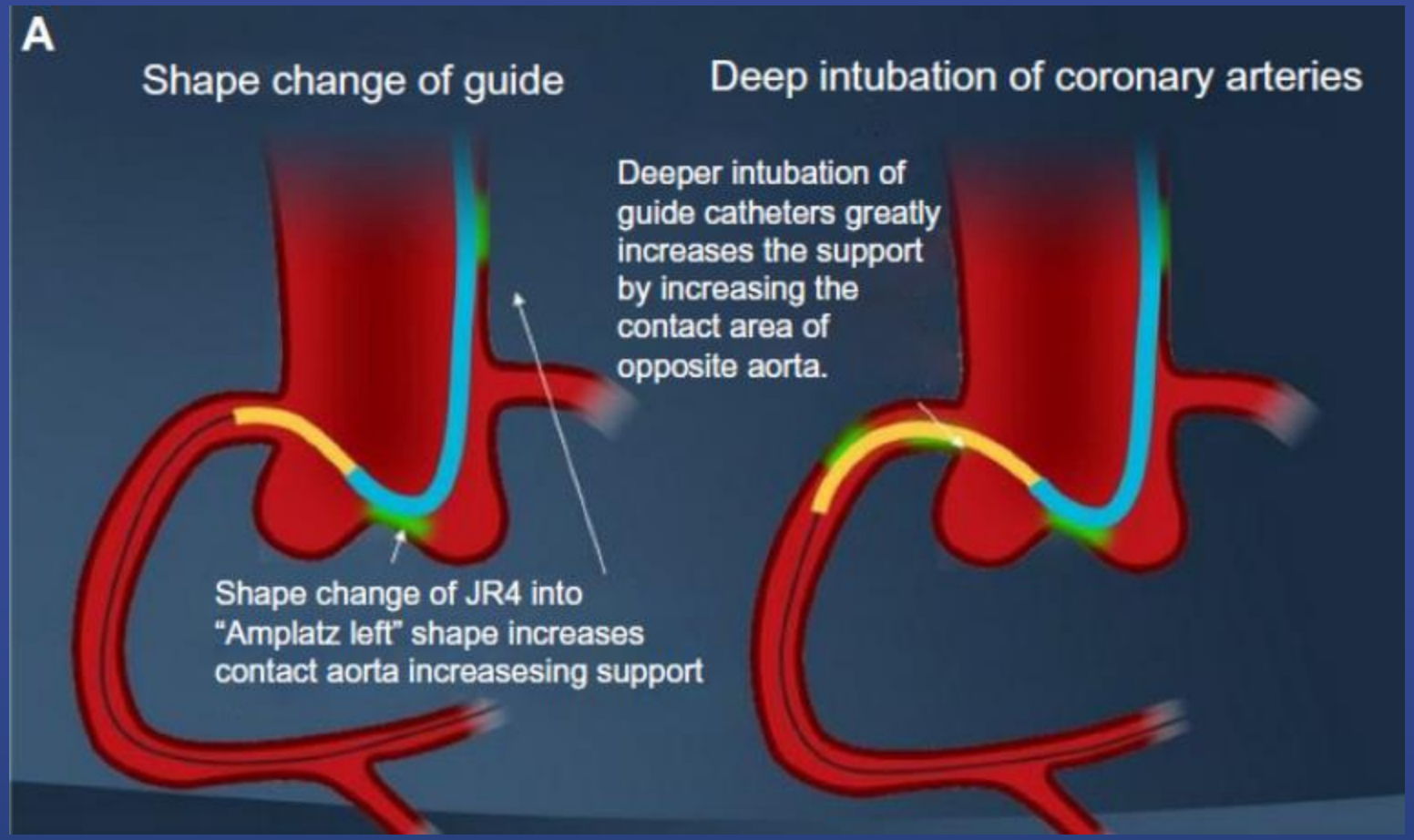


Fujita S, Tamai H et al; Cather Cardiovasc Interv. 2003;59:482-8.

Anchor Technique

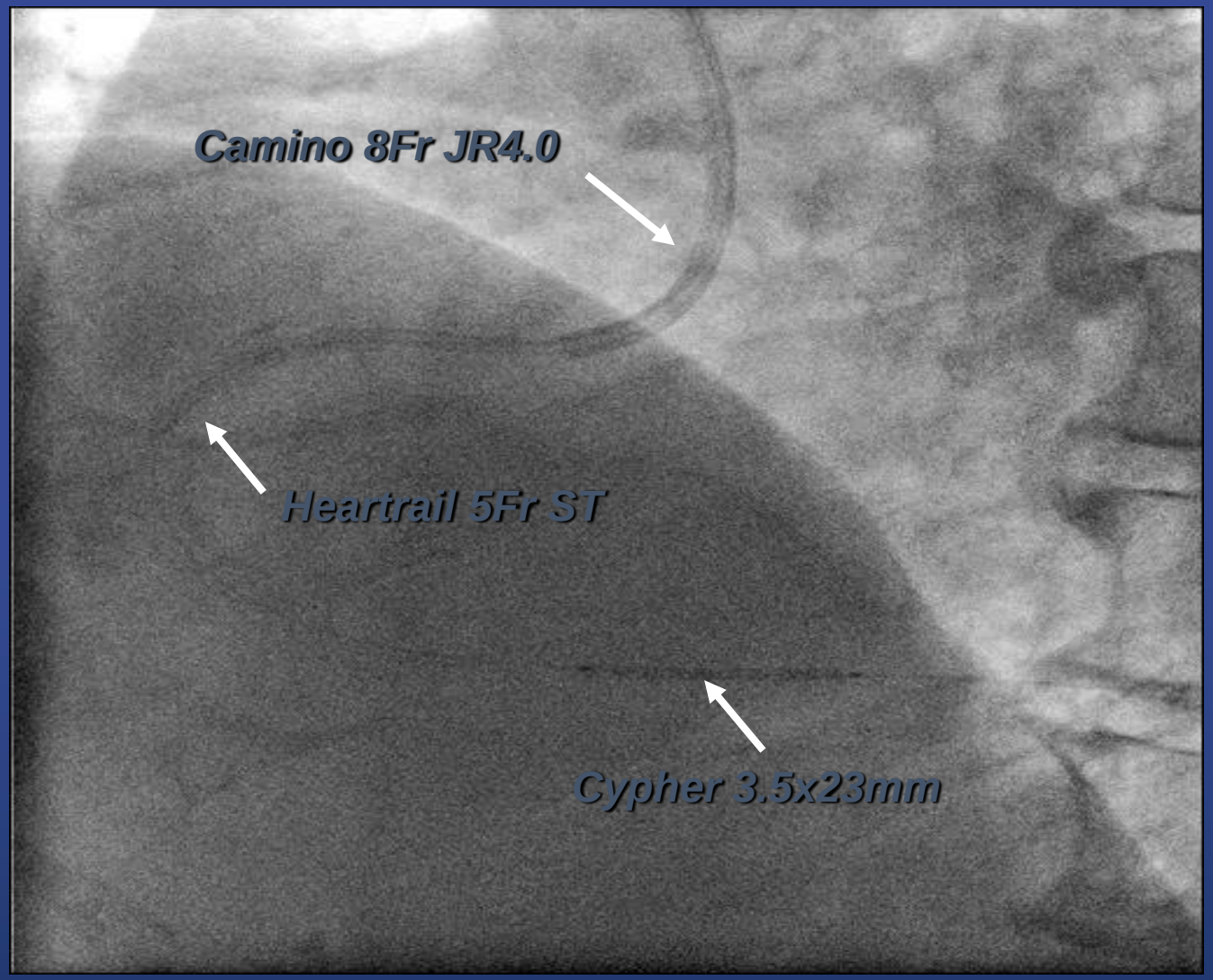


Child in Mother Catheter Technique

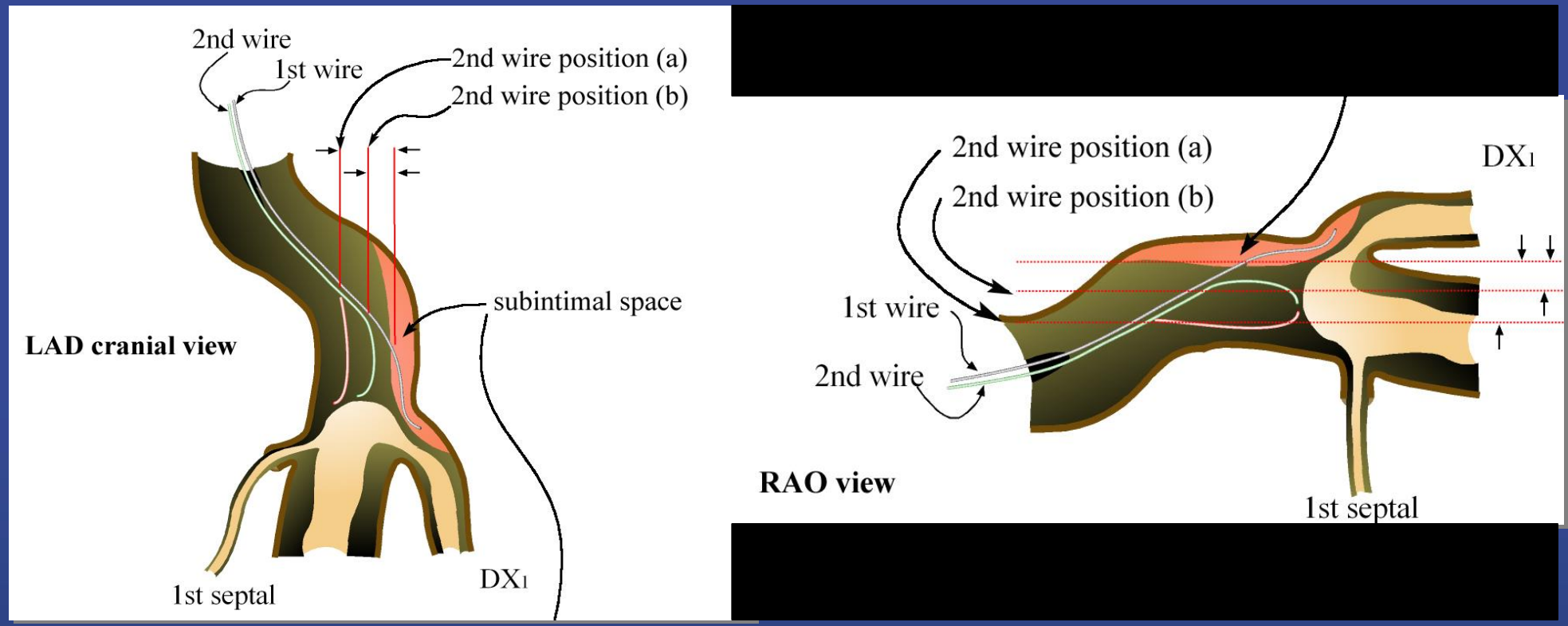


Lemos PA et al, EuroIntervention. 2013 May 20;9(1):148-56.

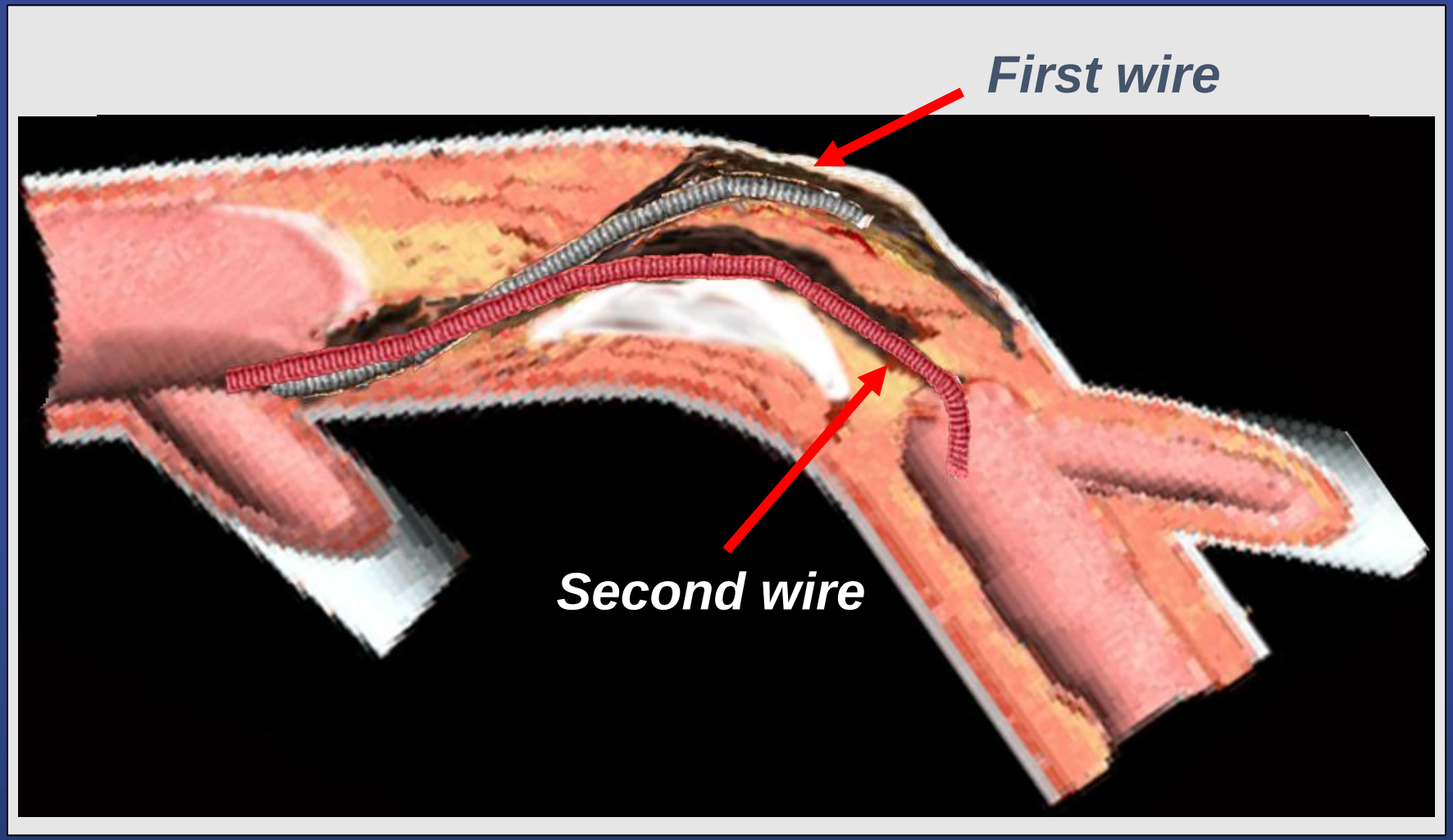
Child in Mother Catheter Technique



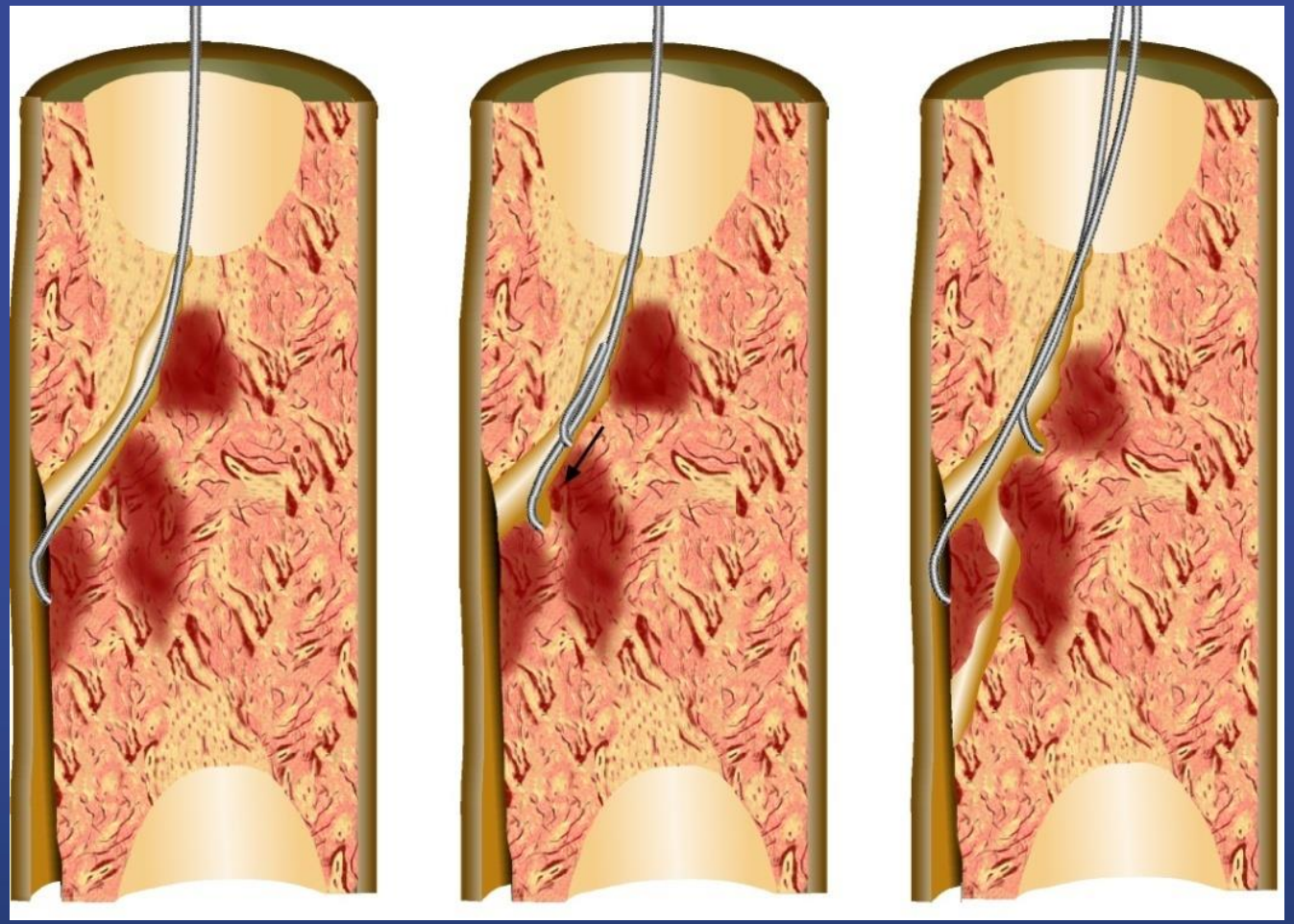
Concept of Parallel Wire Technique



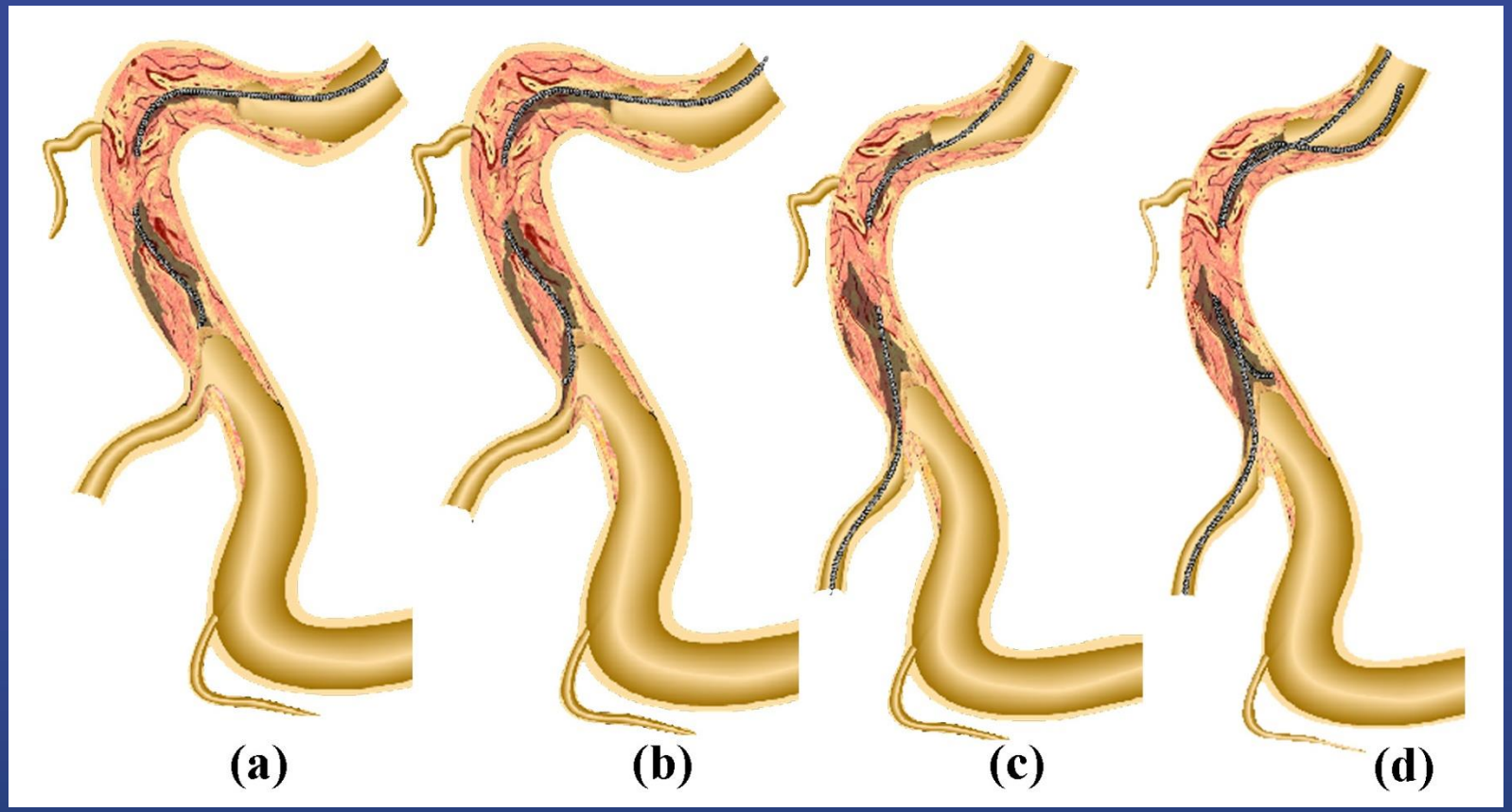
Parallel Wire Technique



Parallel Wire Technique



Side Branch & Parallel Wire Technique



Parallel Wire Technique

Escalation of Wire

Miracle 3.0 gram

↓

Miracle 3.0 gram/Conquest Pro

↓

Conquest Pro/Conquest Pro 12 gram

↓

Conquest Pro 12 gram/Coquest Pro 12 gram

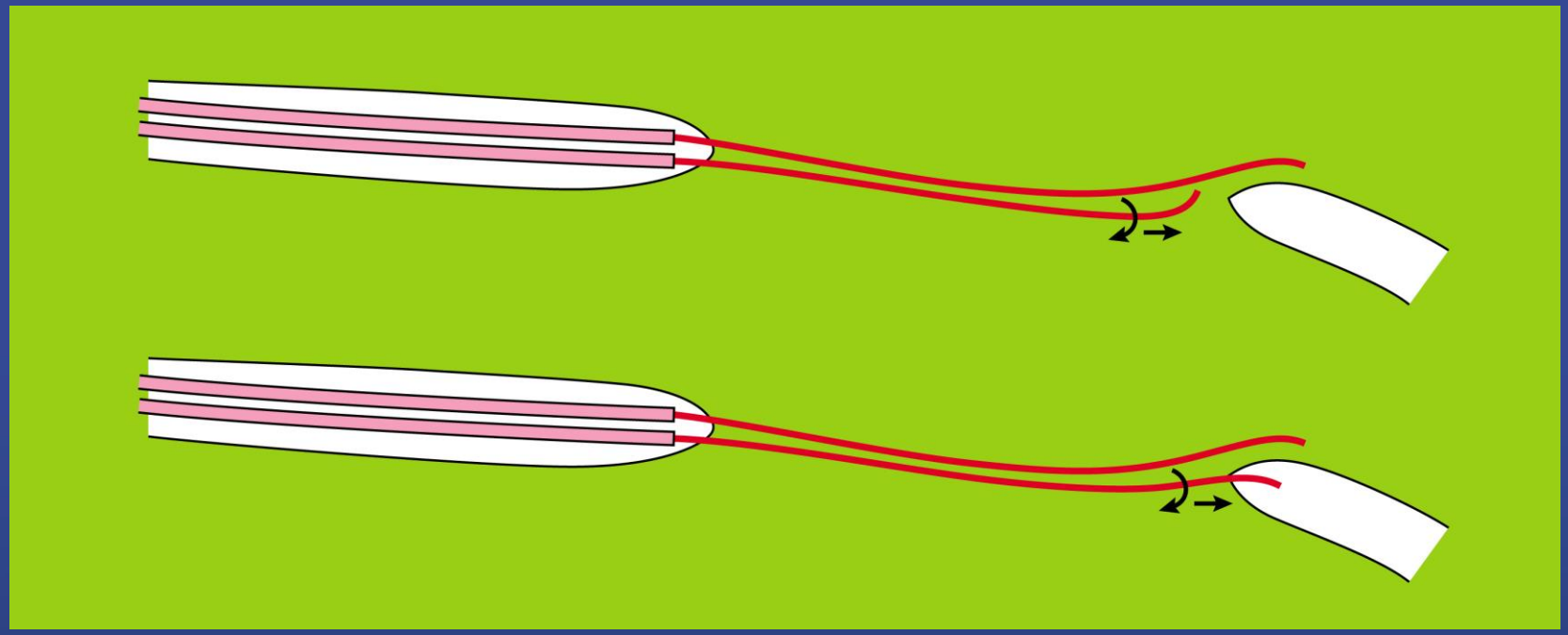
Ochiai M et al, Ital Heart J 2005;6:489-493

See-saw wiring technique

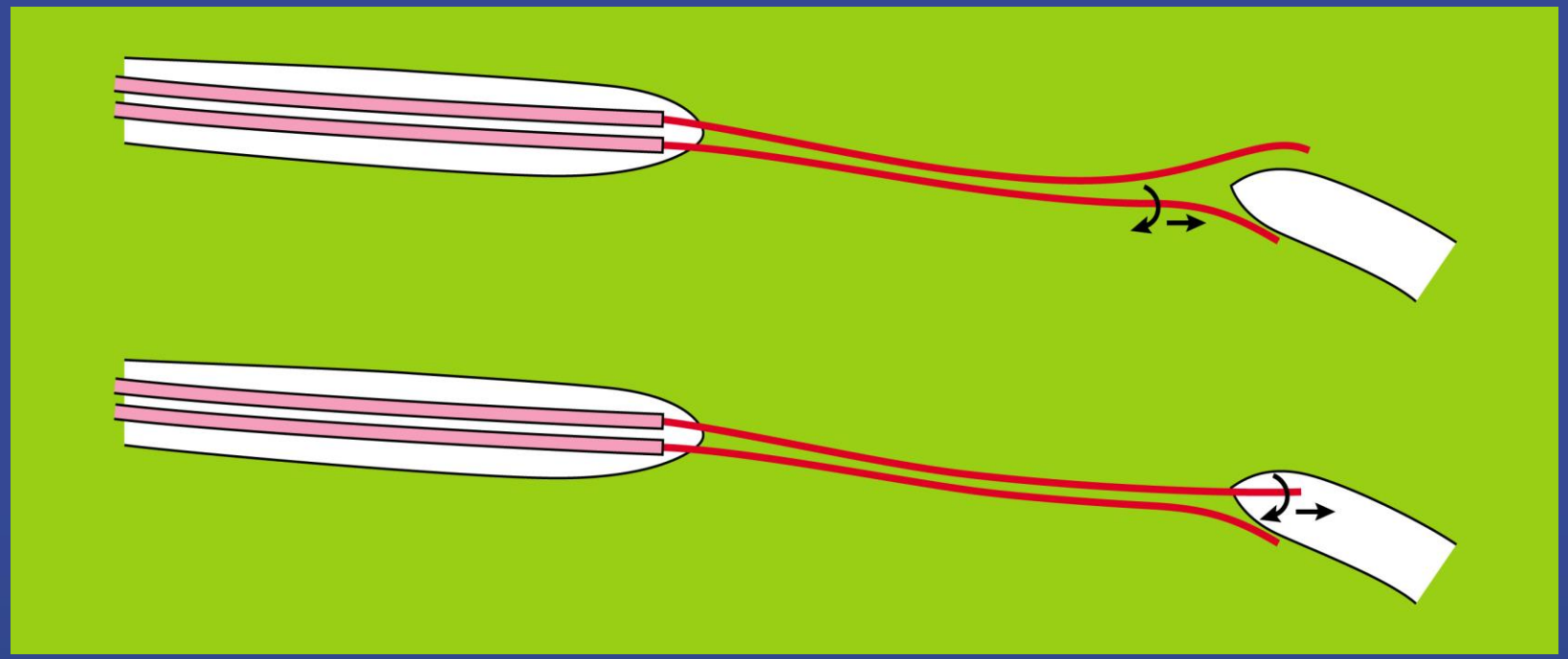
- Two support catheter at a time
- Roles of two wires be exchangeable
- Using parallel wire method with two support catheters
- Operator is able to move each of the two wires independently
- Introduces fluid (blood) into the otherwise dry occlusion site, triggering the hydrophilic mechanism, preventing wires from sticking to each other

See-saw Wiring

Parallel Wire Method with Double Support Catheters

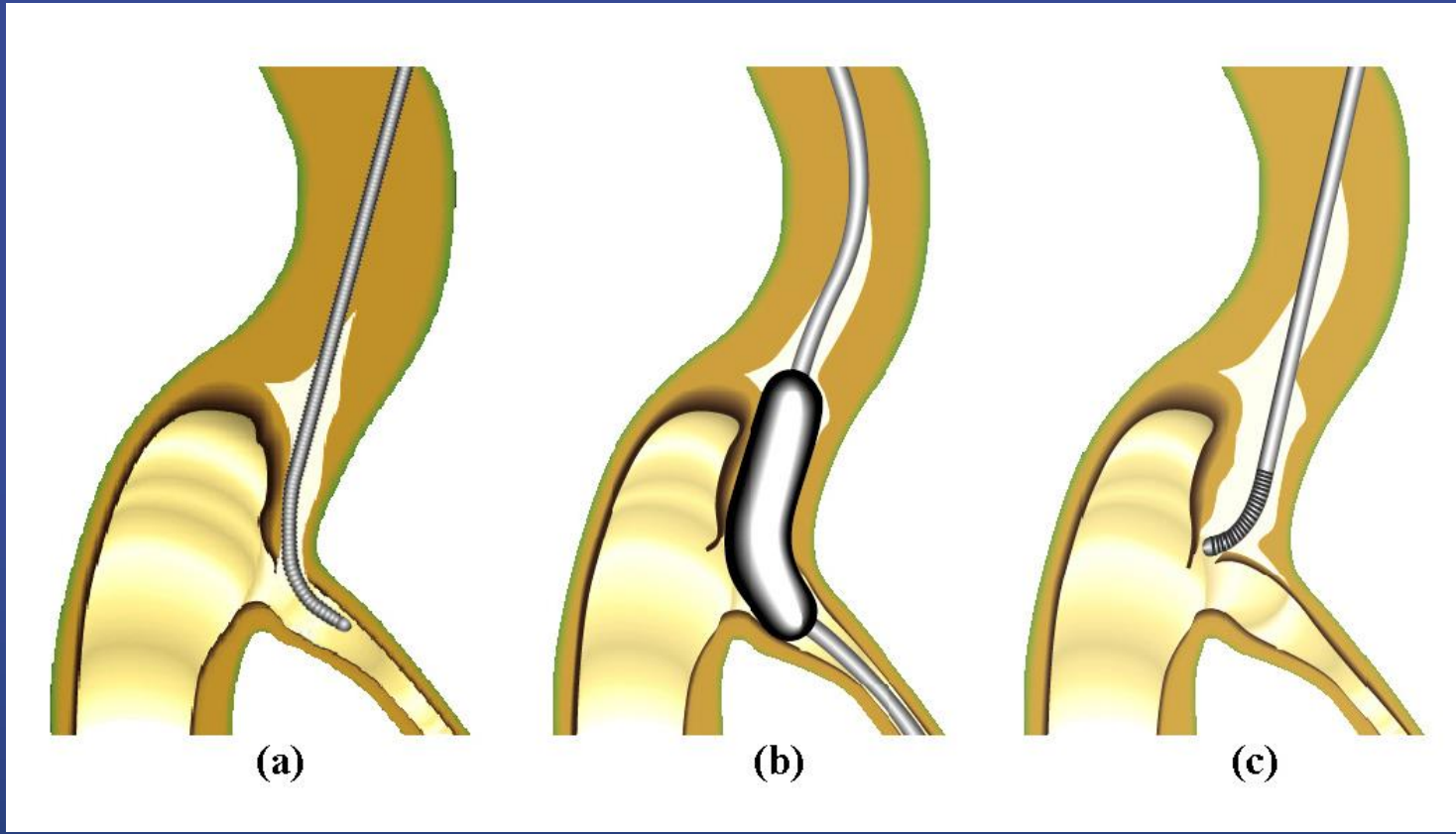


See-saw Wiring

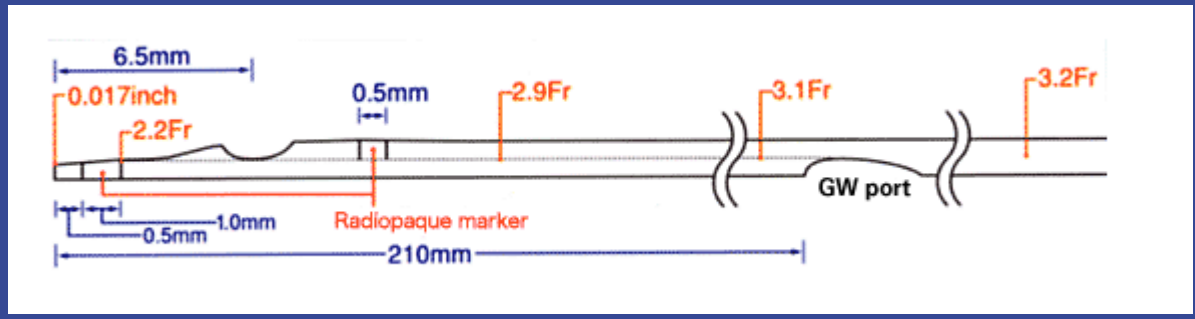


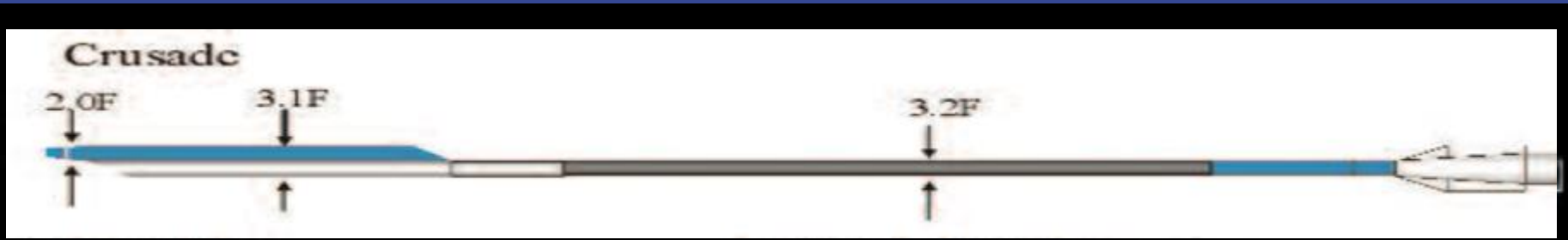
These guide wires can exchange their roles each other very easily

Side Branch Technique



Double lumen catheter : Crusade





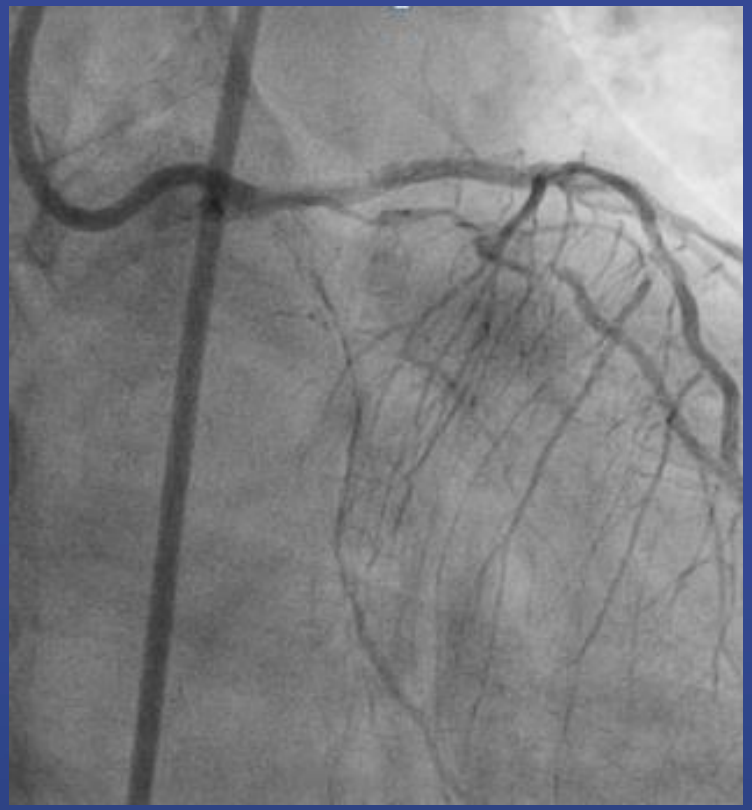
◆Distal Tip

◆GW Inlet(OTW Lumen)

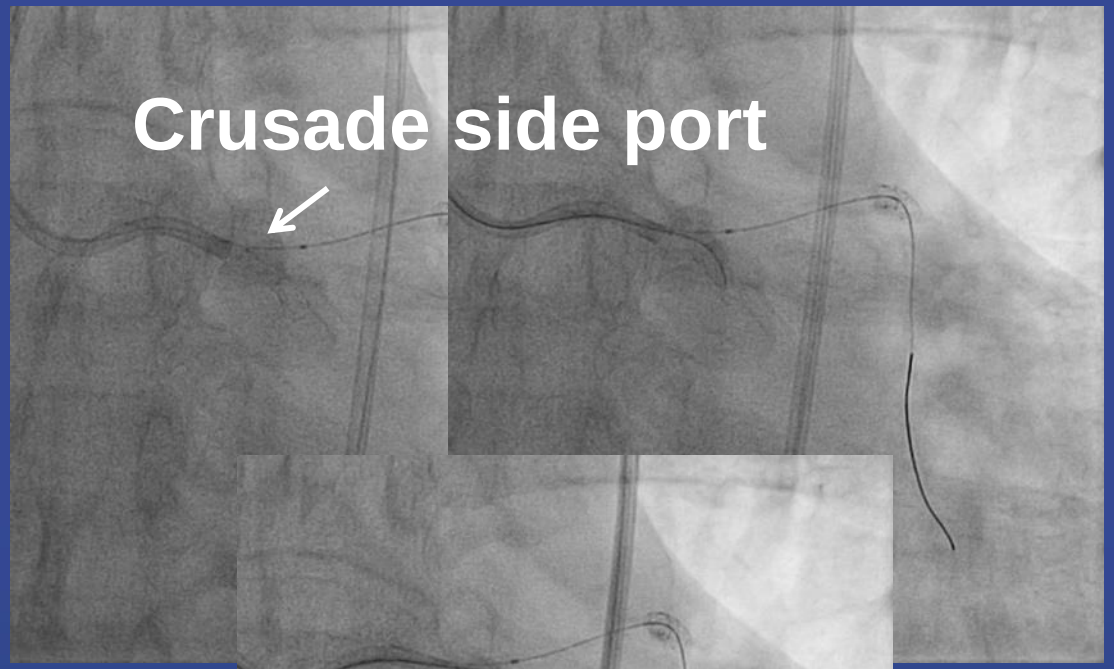
Figure 5. *An illustration of the Crusade microcatheter.*

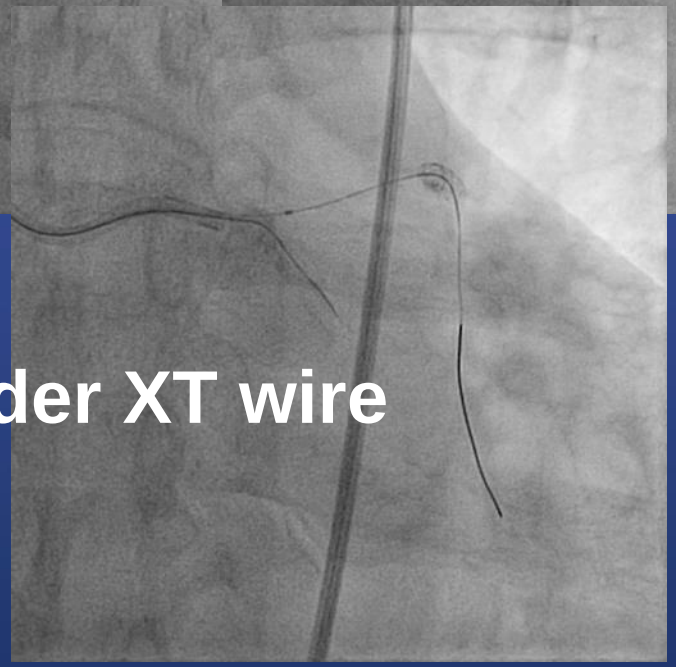
Double lumen catheter

Crusade



Bifurcation lesion

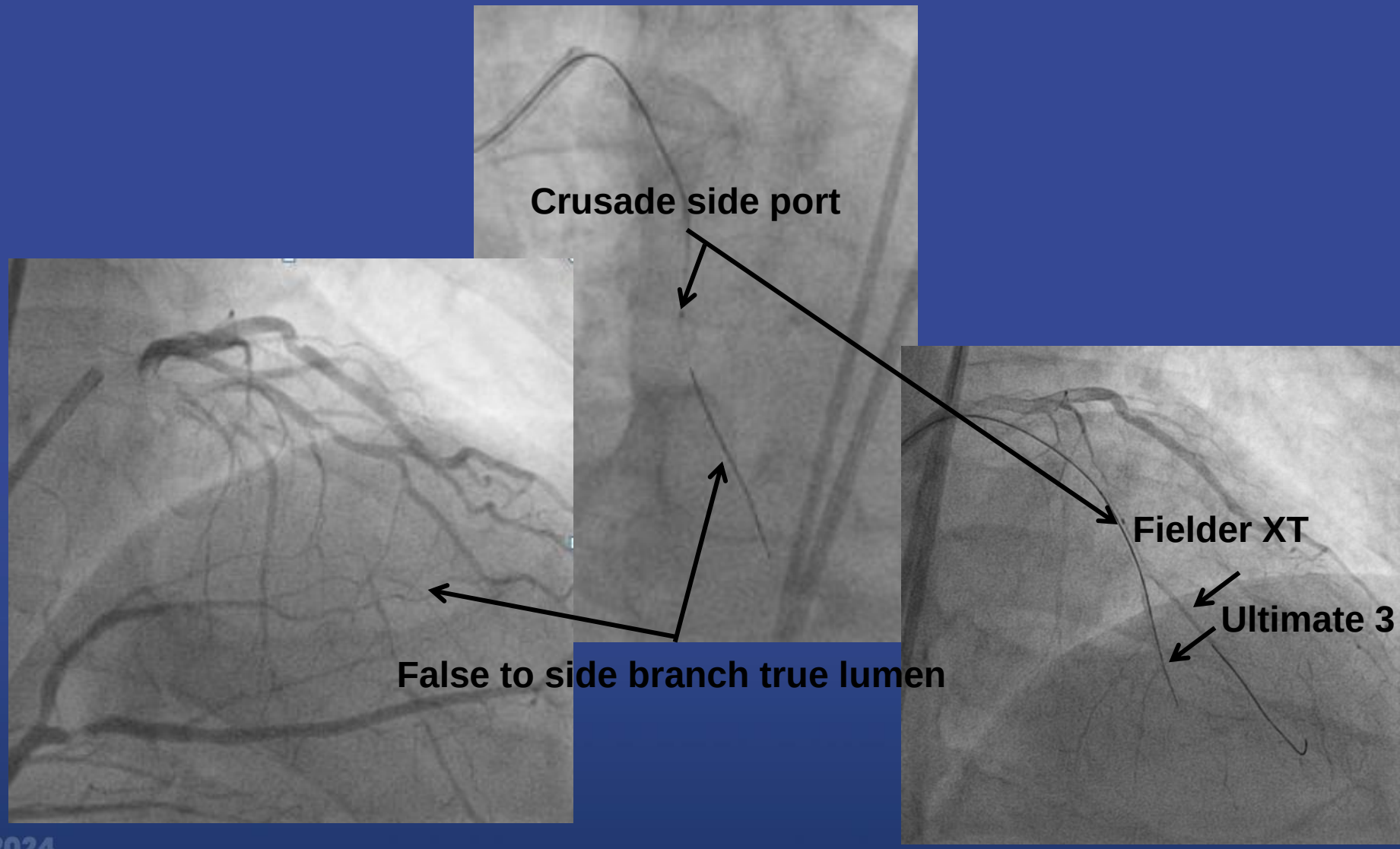




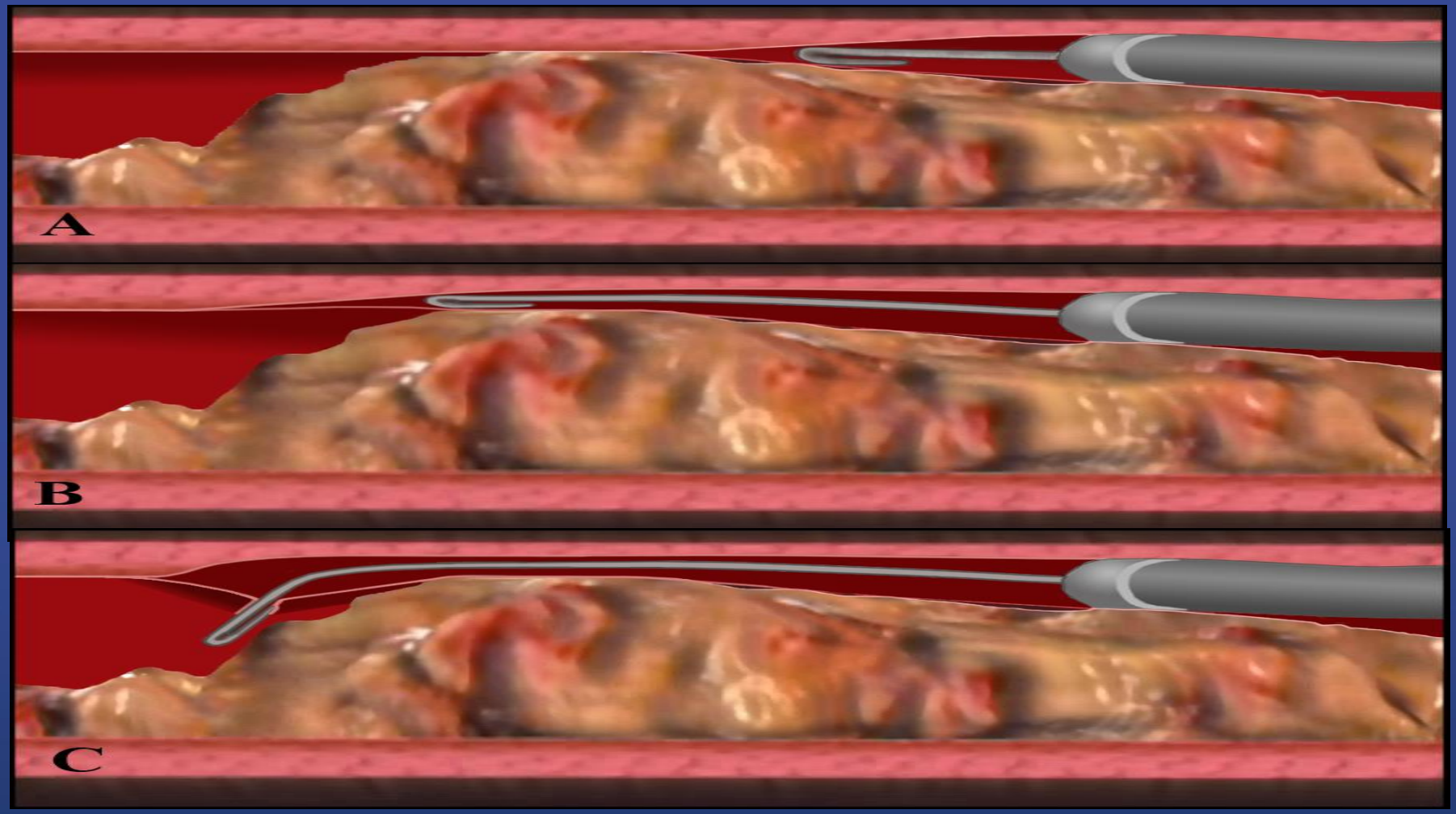
Fielder XT wire

Parallel Wire Technique

Double lumen catheter (Crusade)



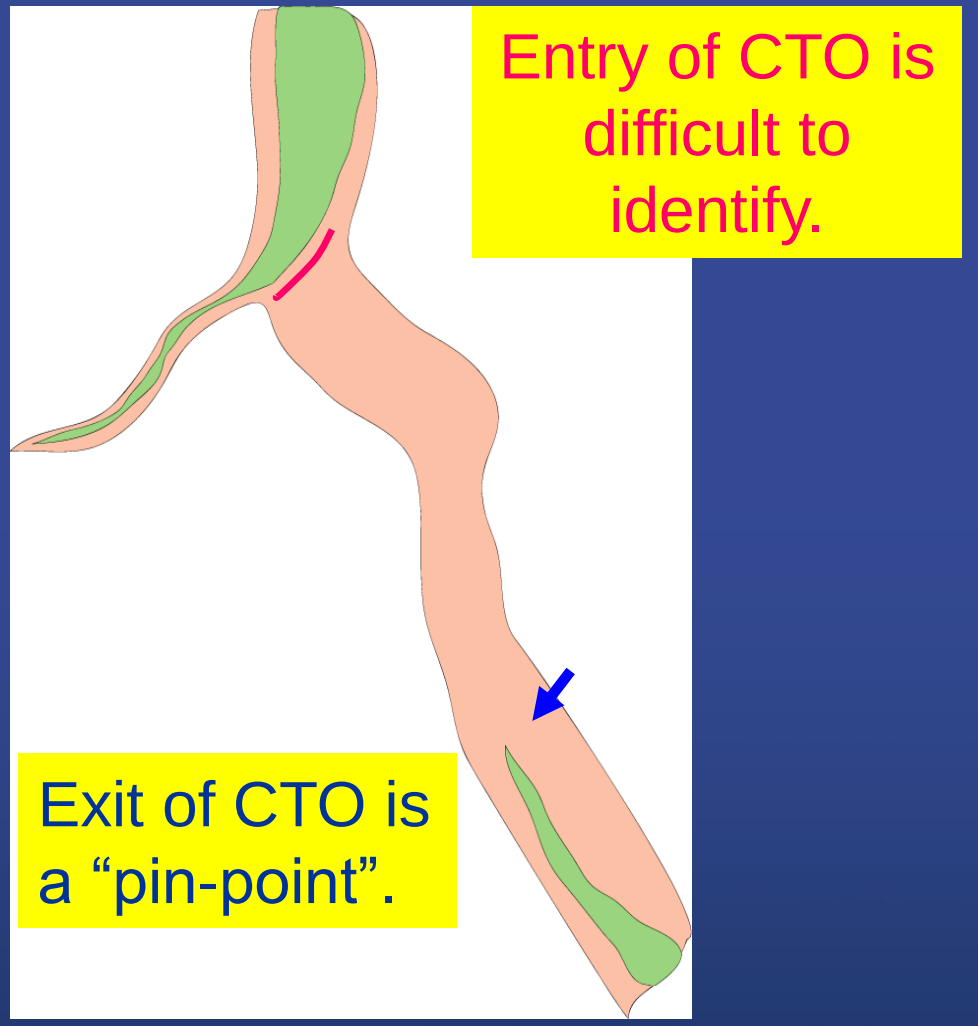
STAR Technique



Retrograde Approach

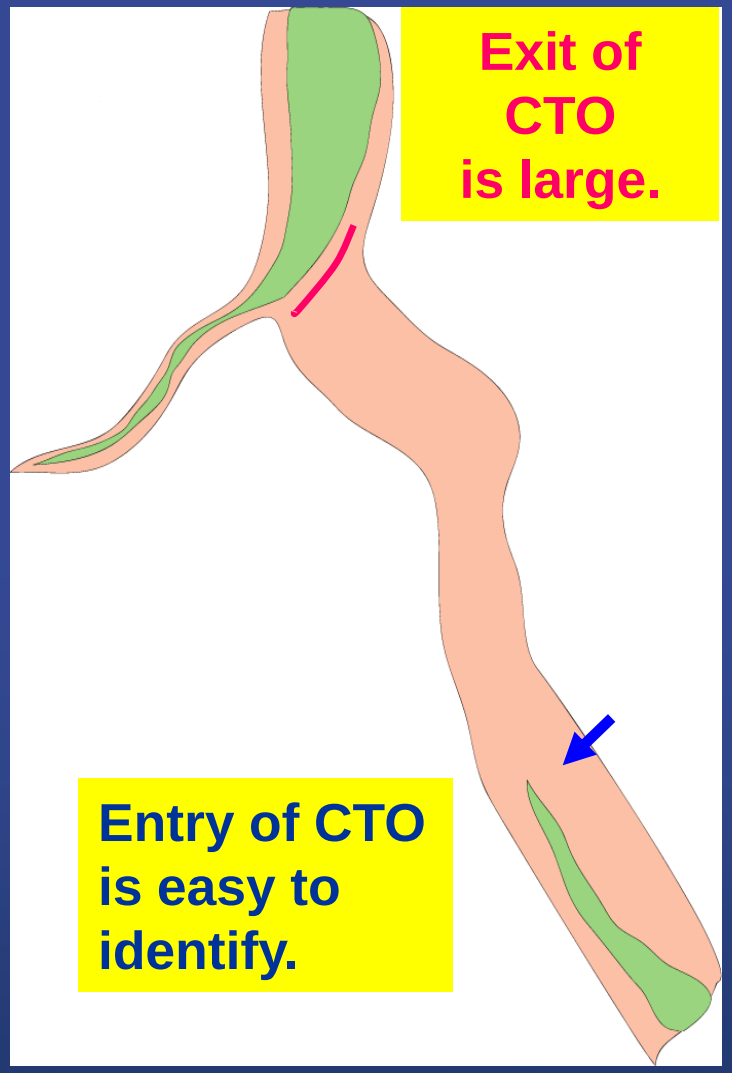
Retrograde Approach

- if anterograde approach is applied -



Retrograde Approach

- if retrograde approach is applied -



Procedure Sequence of Retrograde Approach

1st step : Connection channel crossing

1) Branch selection
2) Wiring through target collateral

2nd Step :Micro-catheter delivery to distal CTO

3rd Step : Retrograde wiring in CTO lesion

1)Retrograde guide-wire crossing
2)Kissing wire technique
3)Reverse CART technique

Principles with collateral channels (CC)

- 1. Septal CCs
  - Safer than epicardial CCs: try first
  - Straight is better, tortuosity is more an issue
  - You CAN wire invisible CCs

- 2. Epicardial CCs
  - Larger size is important
  - Tortuosity less an issue
  - Lower threshold post CABG if course is outside the AV groove: unlikely tamponade in case of CC perforation

Septal “surfing” technique

- Involves placing
  1. workhorse wire in proximal CC
  2. microcatheter (Corsair or FineCross),
  3. “surf” with a Sion or Fielder FC
     for low resistance connection
     (no wedged tip injection)

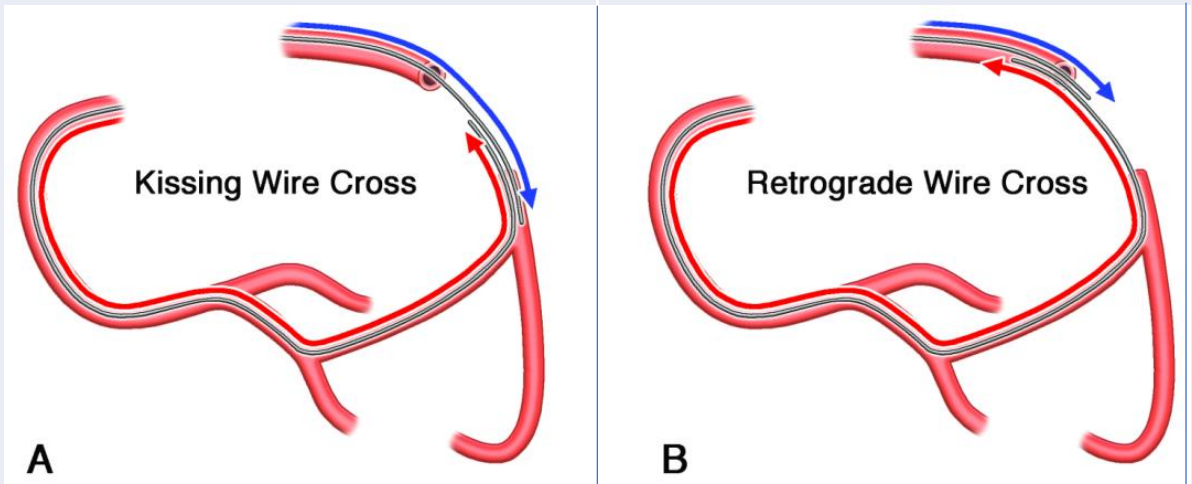
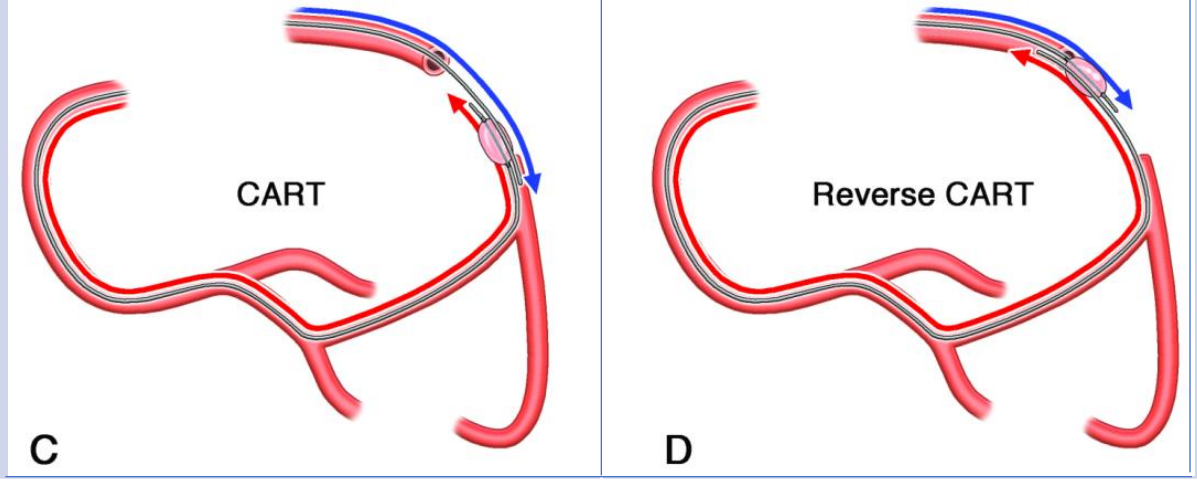
- Help crossing even invisible CCs
  – Recipient vessel angle not visible is
  much less an issue

Epicardial CC wiring

- Adding a second tiny bend more proximal may help
- Sion has emerged as the wire of choice
- Keep wire free and moving
- Follow the path of least resistance

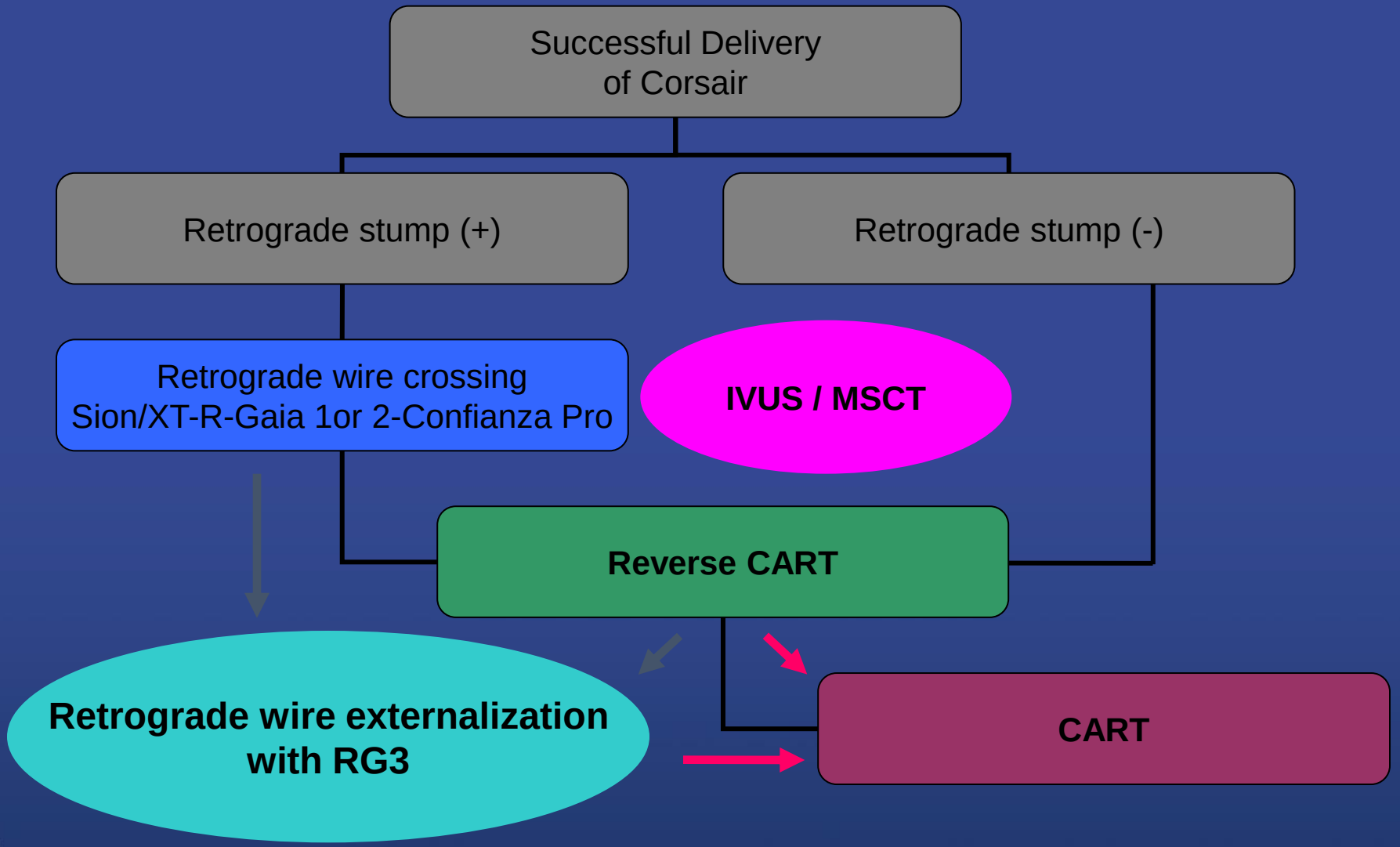
Classification Retrograde Procedures

Dilatation of CTO Body	Direction of Wire Crossing	
	Retrograde	Antegrade
(+)	Reverse CART	CART
(-)	Retrograde Wire Crossing	Kissing Wire

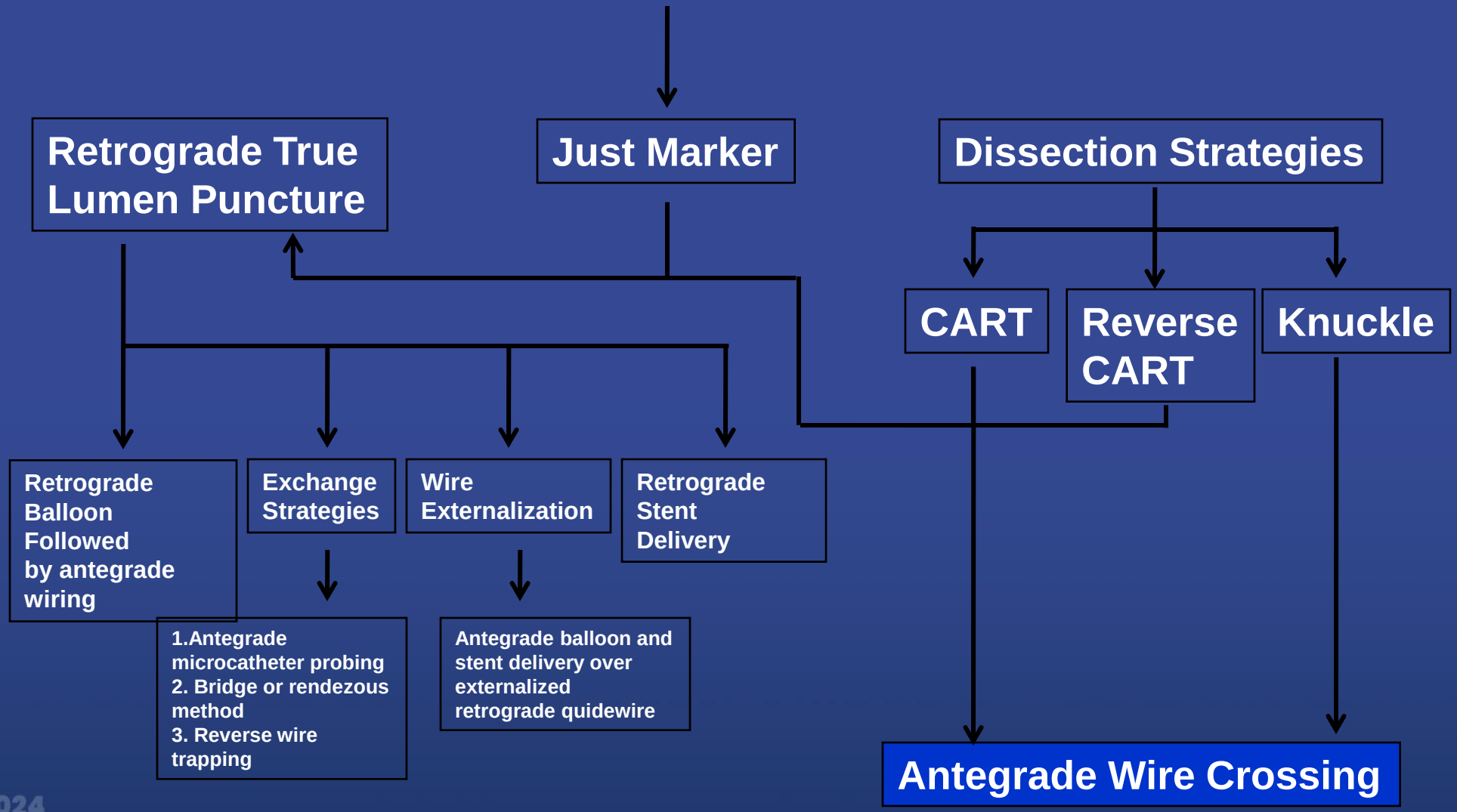
		Antegrade	Retrograde
Dilation before Wire Cross	NO		
	YES		

Sumitsuji et al. JACC Intv 2011; 9:941– 51

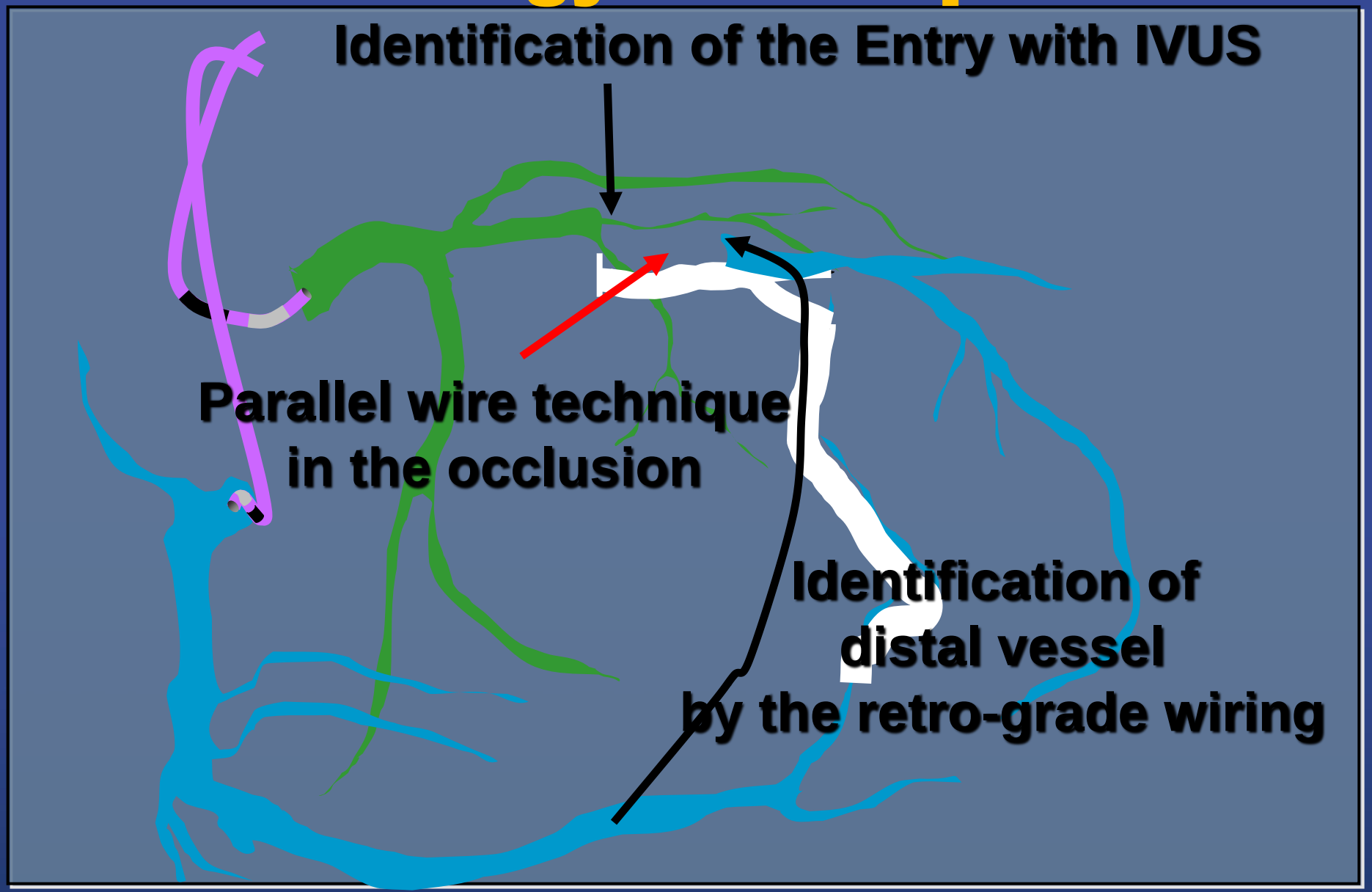
Standardized Retrograde Procedure with Corsair



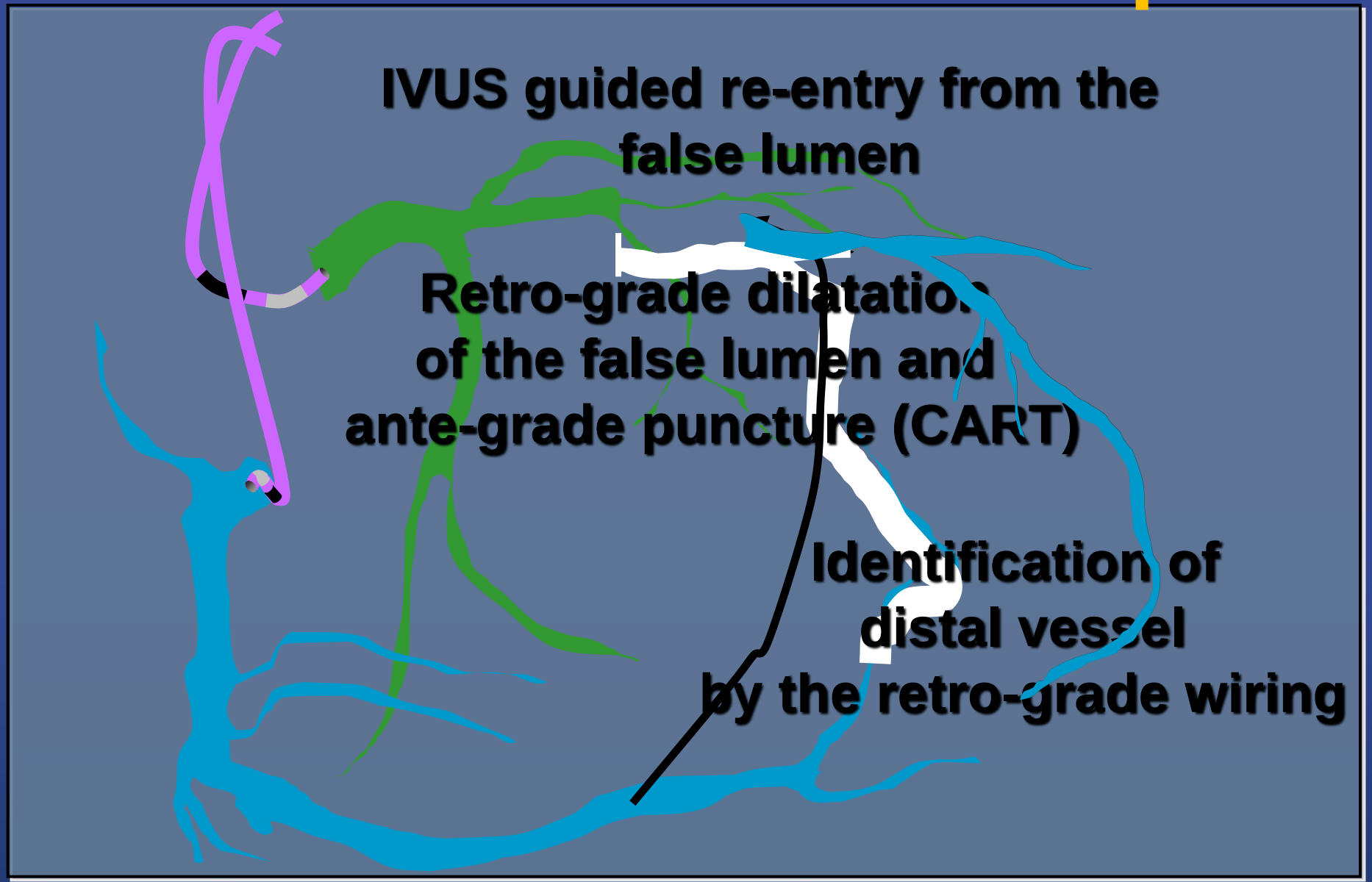
Options After Retrograde Guidewire Reaches The CTO Distal True Lumen



The Strategy for Complex CTO

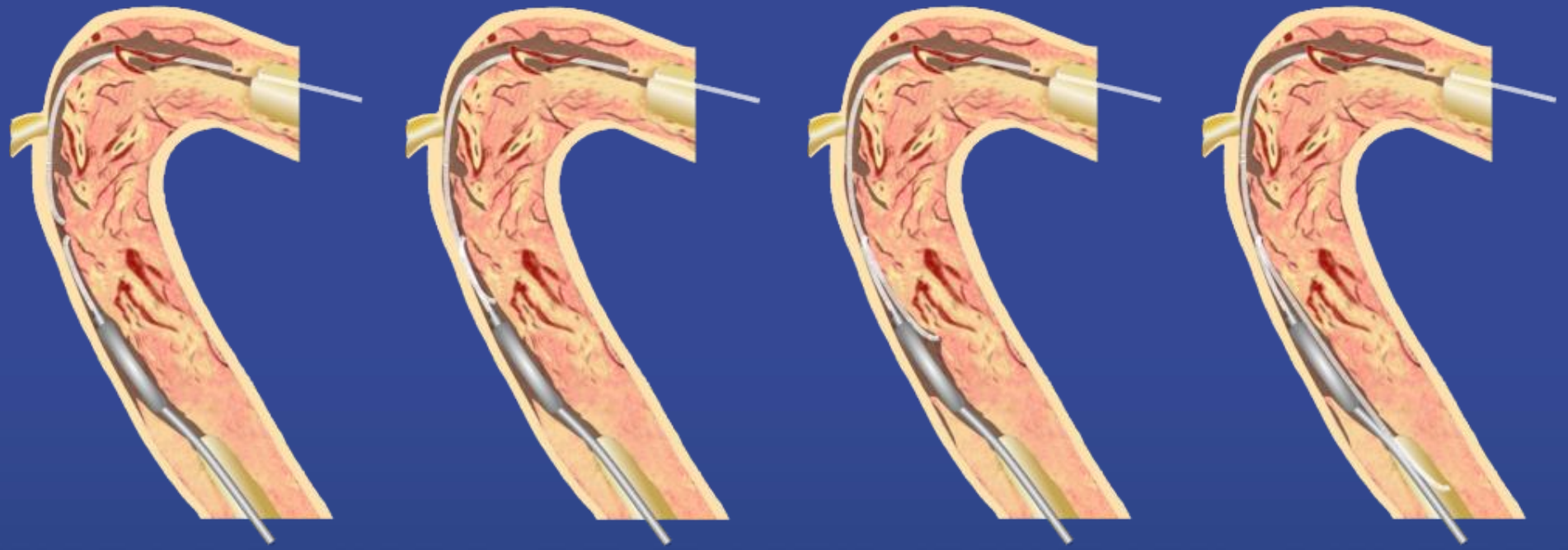


What to do if the Distal Lumen is Compressed



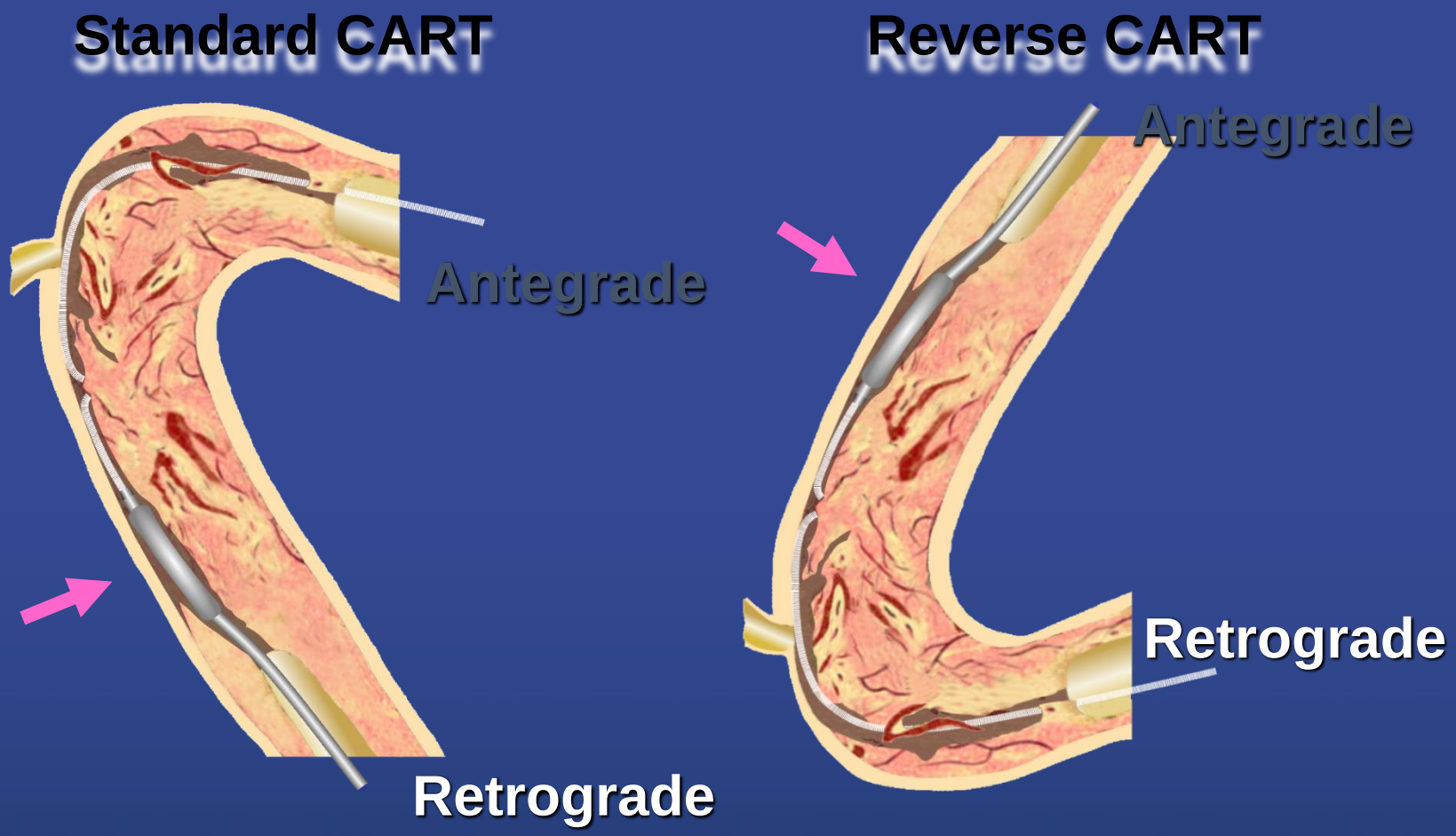
Concept of CART technique

- Controlled Antegrade and Retrograde subintimal Tracking -



- Make connection between antegrade and retrograde subintimal space utilizing behavior of subintimal dissection.
- Antegrade wire automatically gets into distal true lumen.

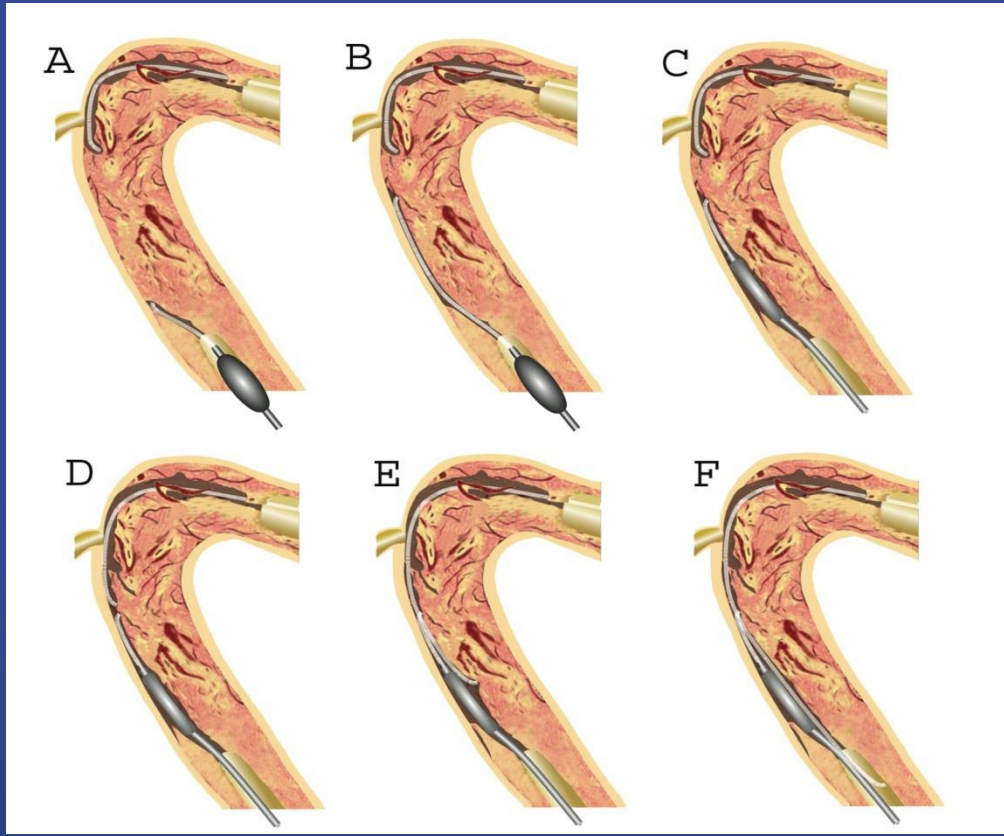
CART & Reverse CART technique



J Invasive Cardiol 2006;18:334-8

Concept of CART technique

- Controlled Antegrade and Retrograde subintimal Tracking -



- Easy to get into CTO retrogressively
- Easy to navigate through CTO with relatively soft wire exchangeable
- Promising way to get a distal lumen (no subintimal dilatation outside CTO)
- Guarantee for getting true lumen at distal end of CTO despite any lesion morphology

Surmely JF. J Invasive Cardiol. 2006 Jul;18(7):334-8.

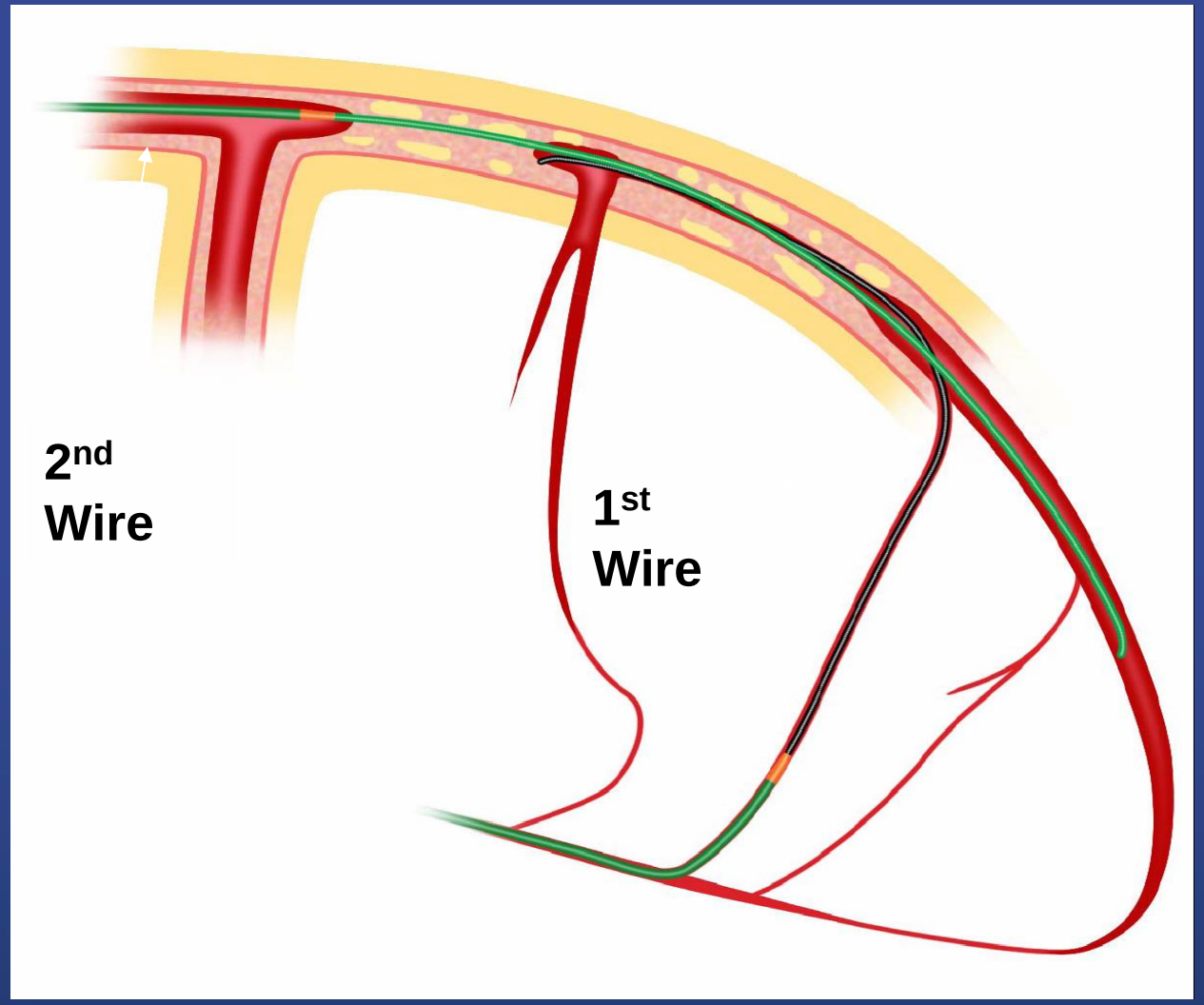
Retrograde Approach

Different strategies after crossing a guidewire

- Kissing guidewire
- Just landmark
- CART & reverse CART
- Retrograde true lumen tracking
- Retrograde proximal true lumen puncture
- Catching the retrograde guidewire

Saito S. Cath Cardiovas Interv 2007

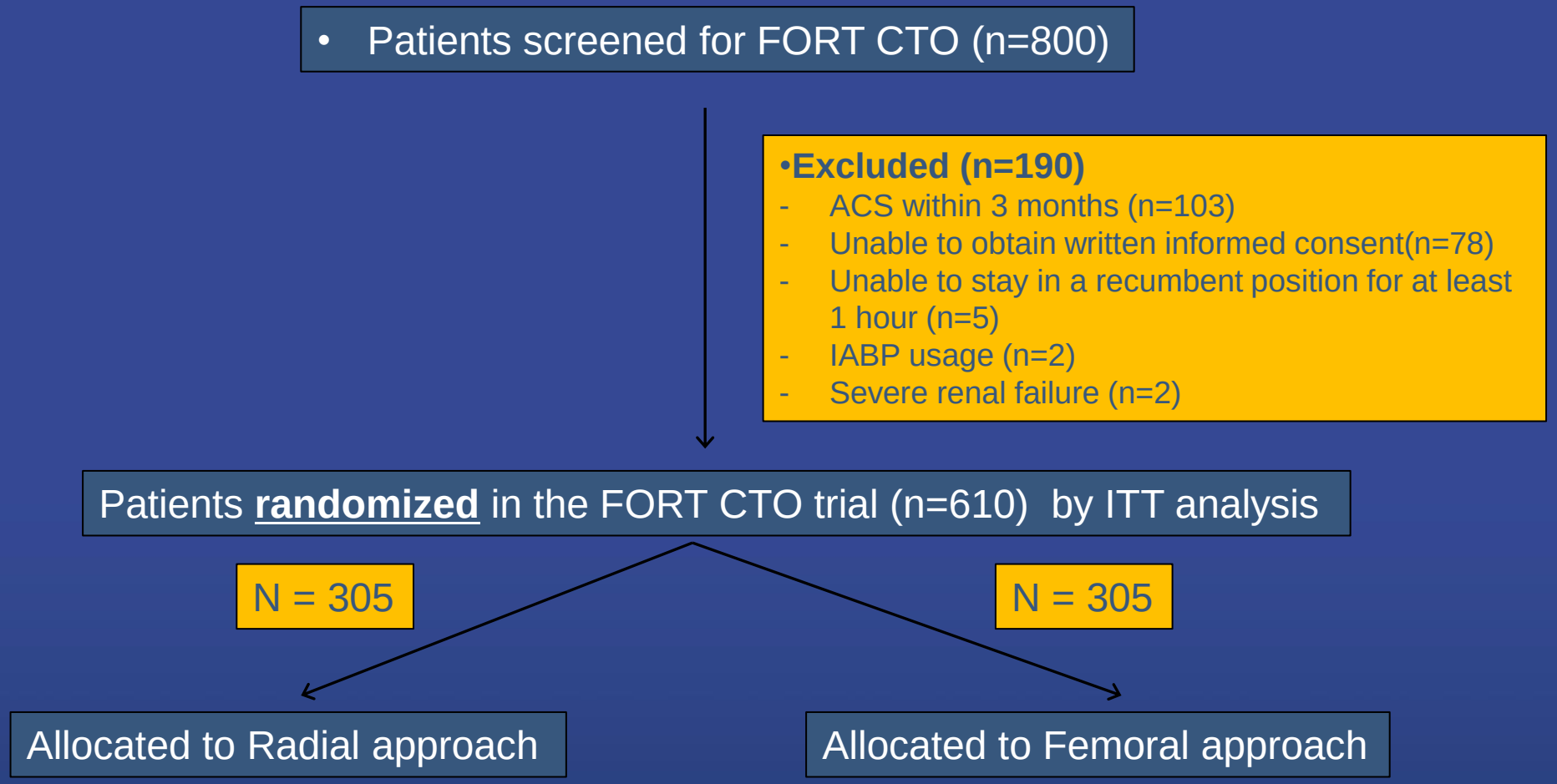
Concept of Kissing Wire Technique



M Ochiai, WCC 2006

Femoral or Radial approach

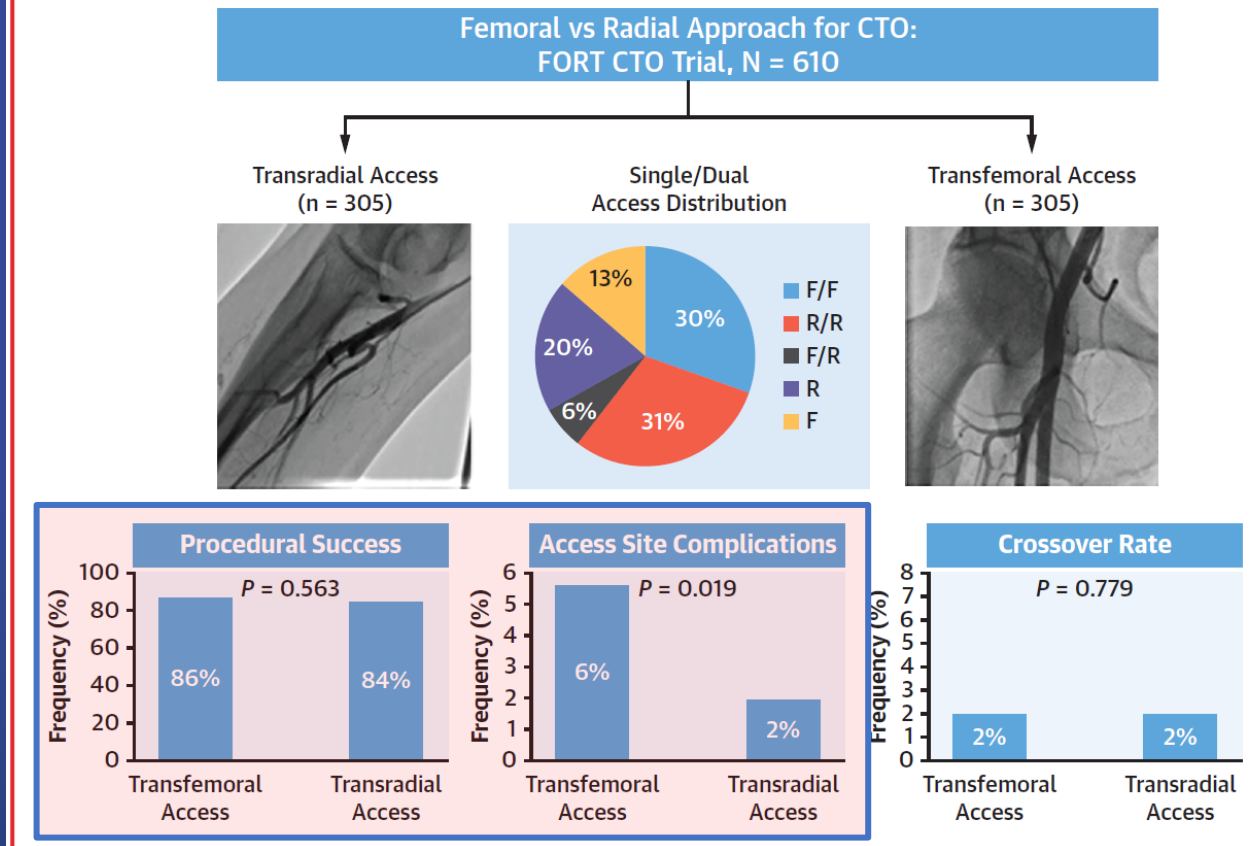
Femoral Or Radial Approach in Treatment of Coronary Chronic Total Occlusion



Sevket Gorgulu et al, J Am Coll Cardiol Intv 2022;15:823-830

Femoral Or Radial Approach in Treatment of Coronary Chronic Total Occlusion

CENTRAL ILLUSTRATION Main Findings of Femoral or Radial Approach in the Treatment of Coronary Chronic Total Occlusion



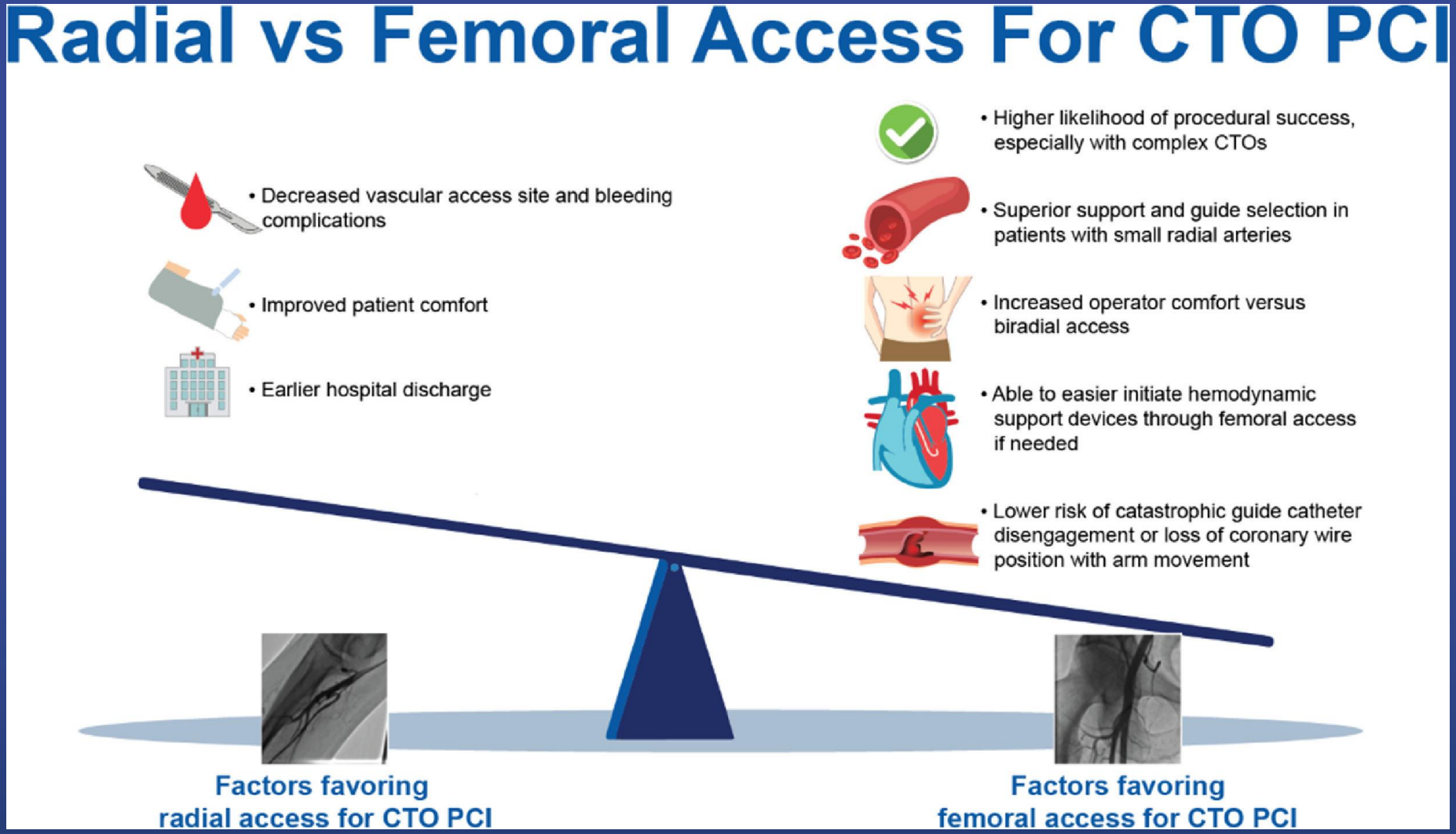
Gorgulu S, et al. J Am Coll Cardiol Intv. 2022;15(8):823-830.

CTO = chronic total occlusion; F = femoral; F/F = femoral/femoral; F/R = femoral/radial; FORT CTO = Femoral or Radial Approach in the Treatment of Coronary Chronic Total Occlusion; R = radial; R/R = radial/radial.

Sevket Gorgulu et al, J Am Coll Cardiol Intv 2022;15:823-830

Femoral Or Radial Approach in Treatment of Coronary Chronic Total Occlusion

Radial vs Femoral Access For CTO PCI



Travis B DeSa et al, Am J Cardiol. 2023 Apr 1:192:258-260

IVUS assisted Procedure

IVUS guided intralesional rewiring

- **Antegrade**
- Retrograde … *tomorrow*

- **Integration of IVUS and Angiogram**
  - Use IVUS information for wire control
- **Histology**
  - Intimal plaque
  - Subintimal space

IVUS guided rewiring

- Longitudinal position for optimal rewiring
- Direction of rewiring in IVUS
- Direction of rewiring in Angiogram
- Wiring
- Confirm wire position by IVUS

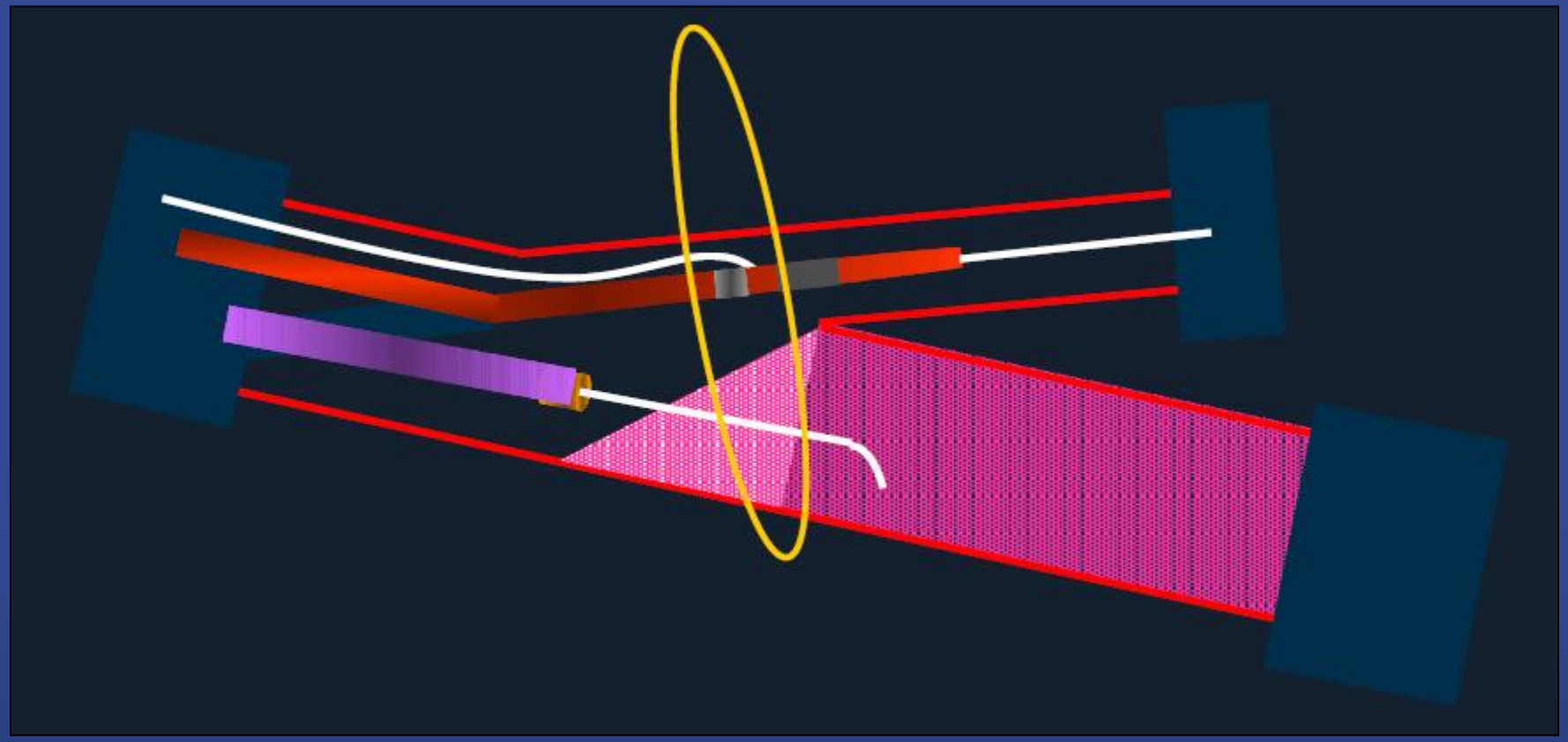
Keys to Success of IVUS-guided Rewiring

- Correct reading IVUS information
  - Based on histology
- Integration IVUS and Angiogram
  - Position and Direction
- Rewiring with Angiogram (Fluoroscopy)
- Confirm Wire Position by IVUS
- Patience

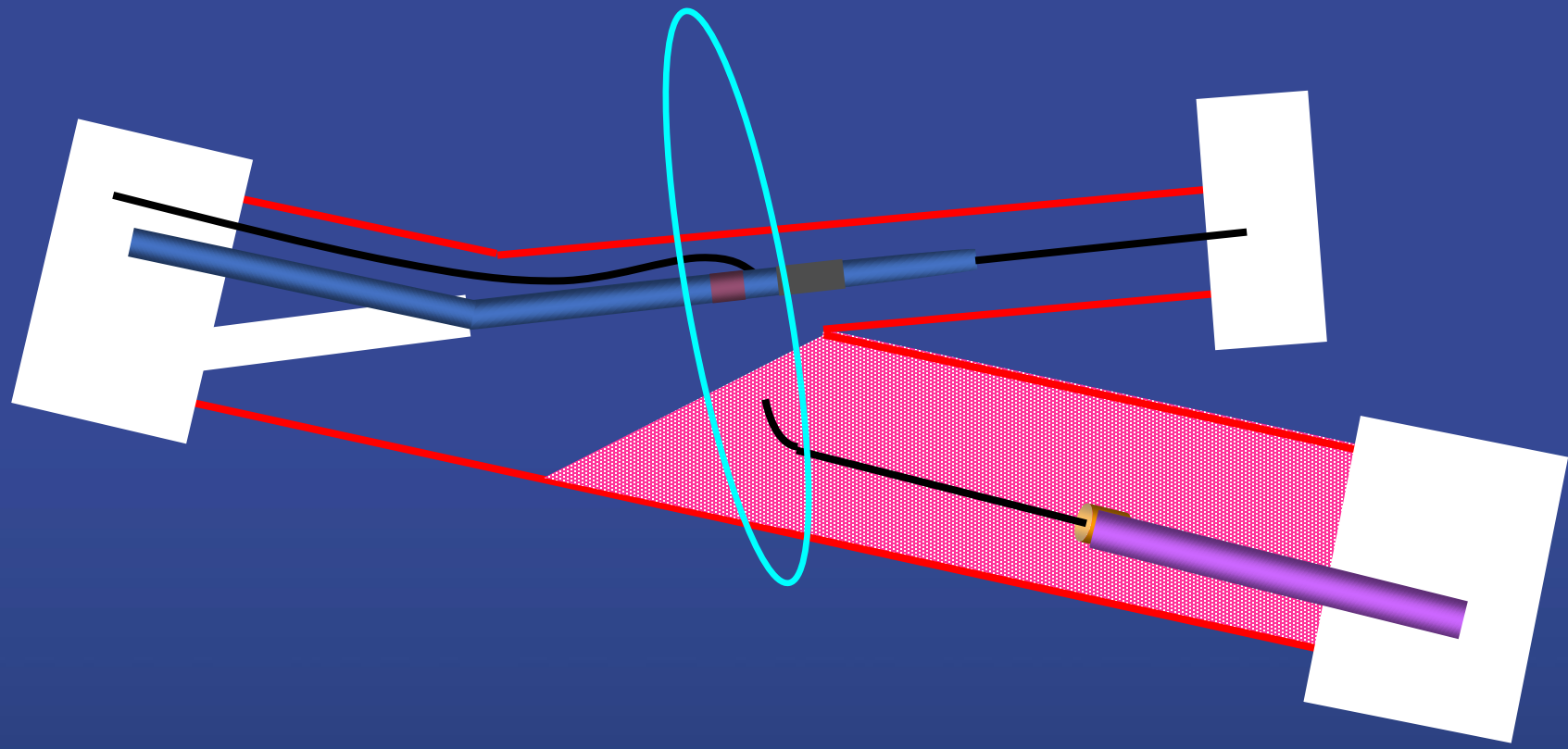
IVUS roles for Wire Cross

- ANTE-grade
  - Identifying entry point of CTO segment
  - Support wire penetration from false to true lumen
- RETRO-grade
  - Support for wire cross
  - in Retrograde Wire Cross
  - in Reverse CART
  - in Reverse CART with Stenting
- Review
  - Wire tracking route

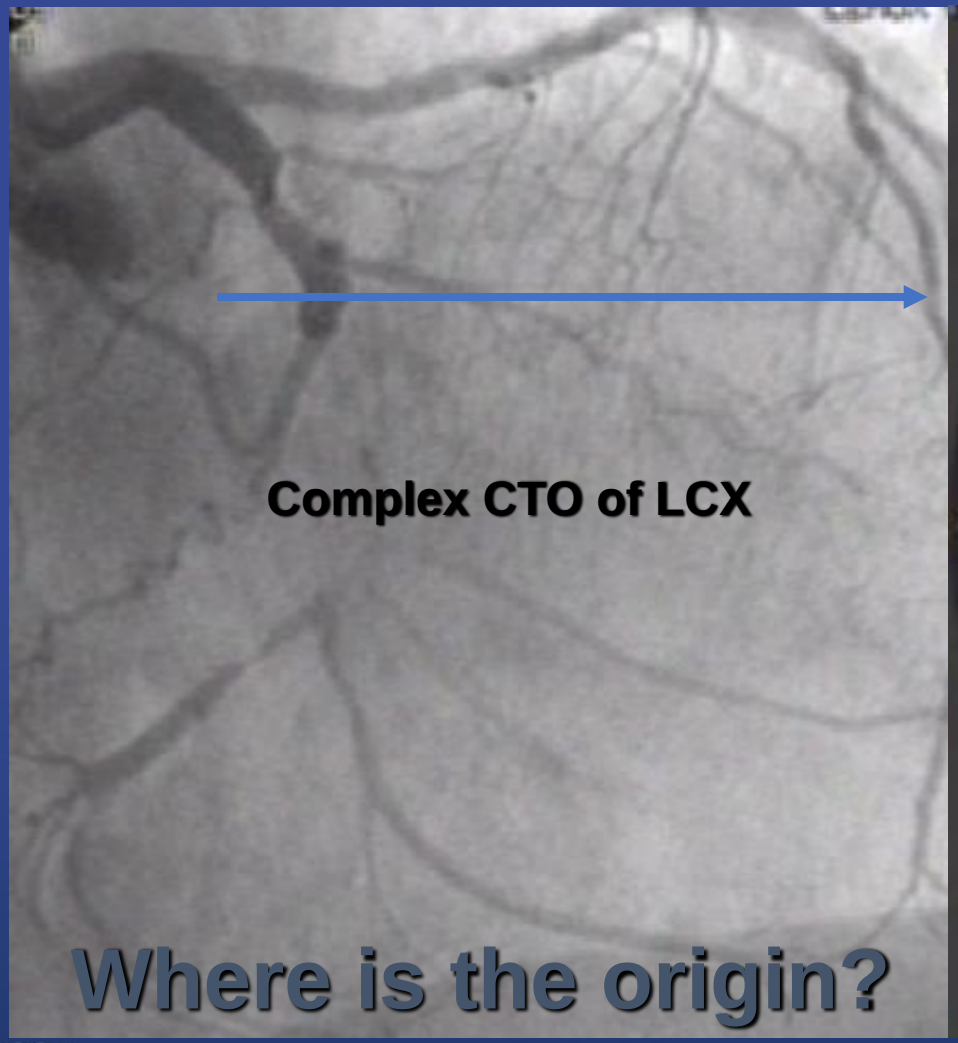
IVUS Guided Identification of the Entry

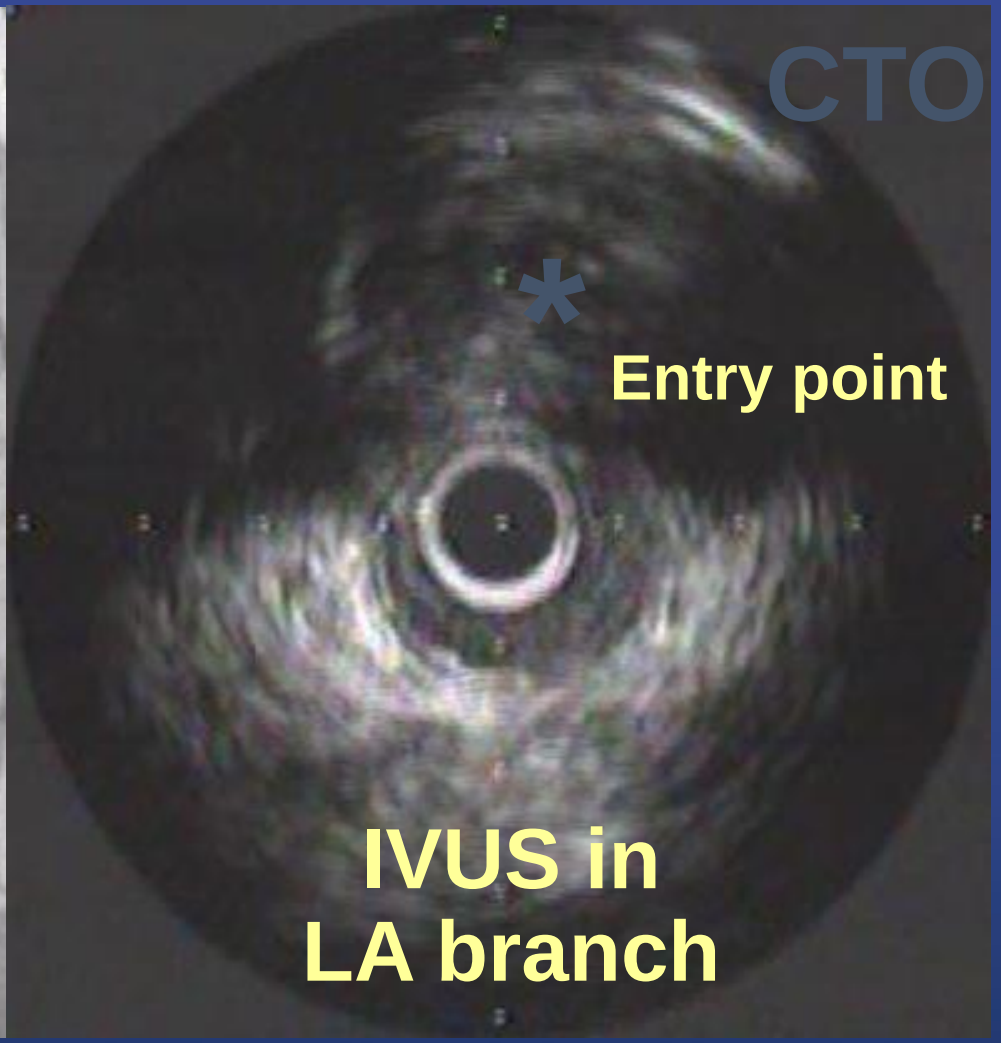


Evaluate the Position of Retrograde Wire



IVUS Guided Technique for Looking For the Entry





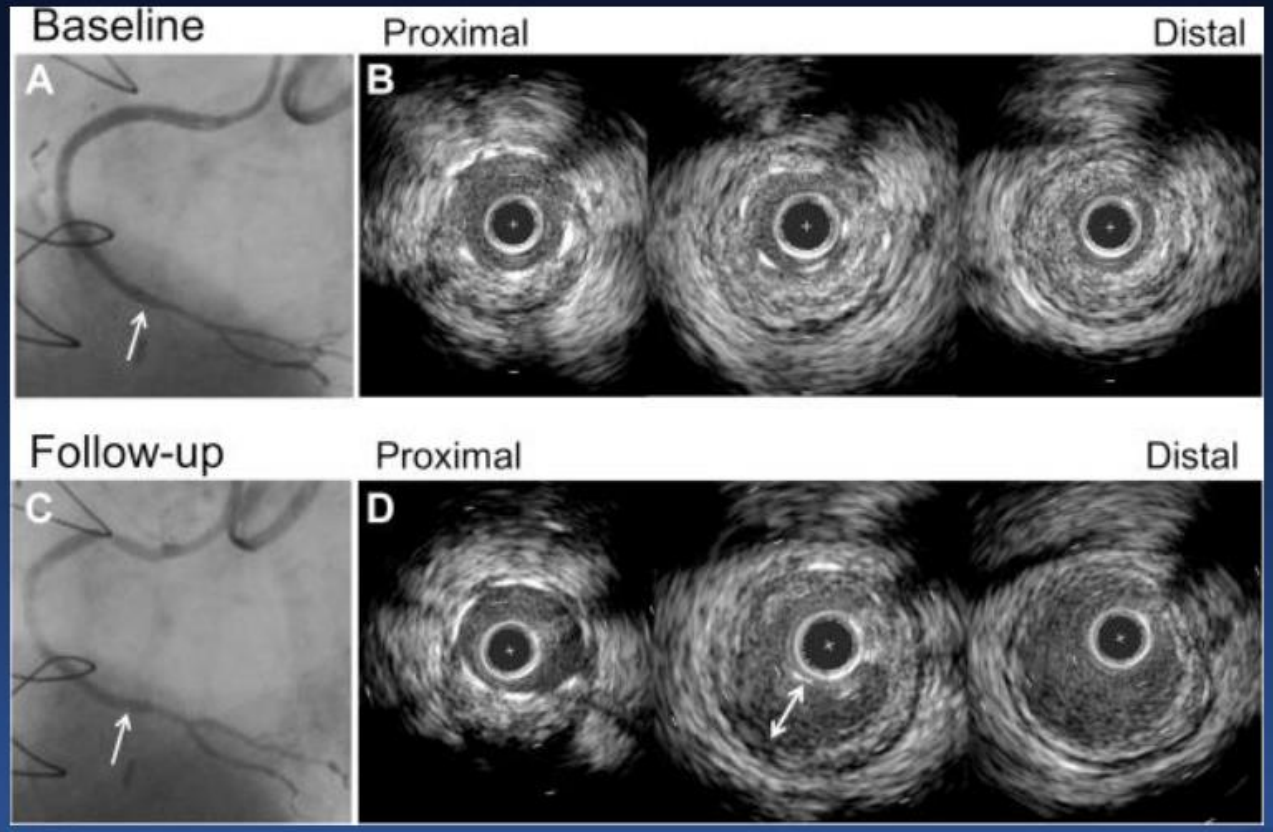
Serial IVUS Findings: CTO PCI with DES

40 CTOs systematically assessed

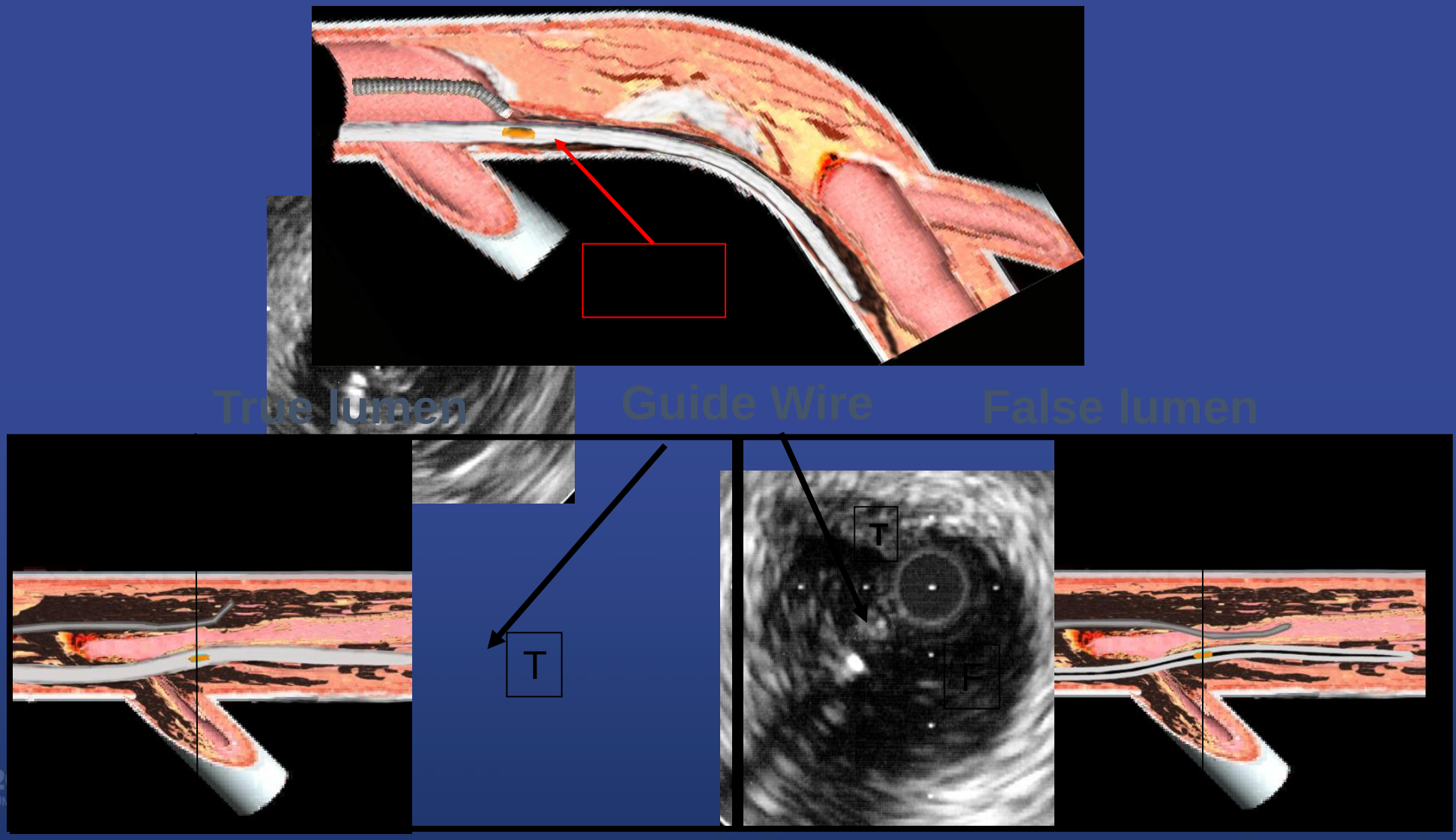
Distal vessel enlargement (positive remodeling) was seen

No variability with subintimal vs. luminal approach

Late stent malapposition seen in 42.5% (throughout segments)

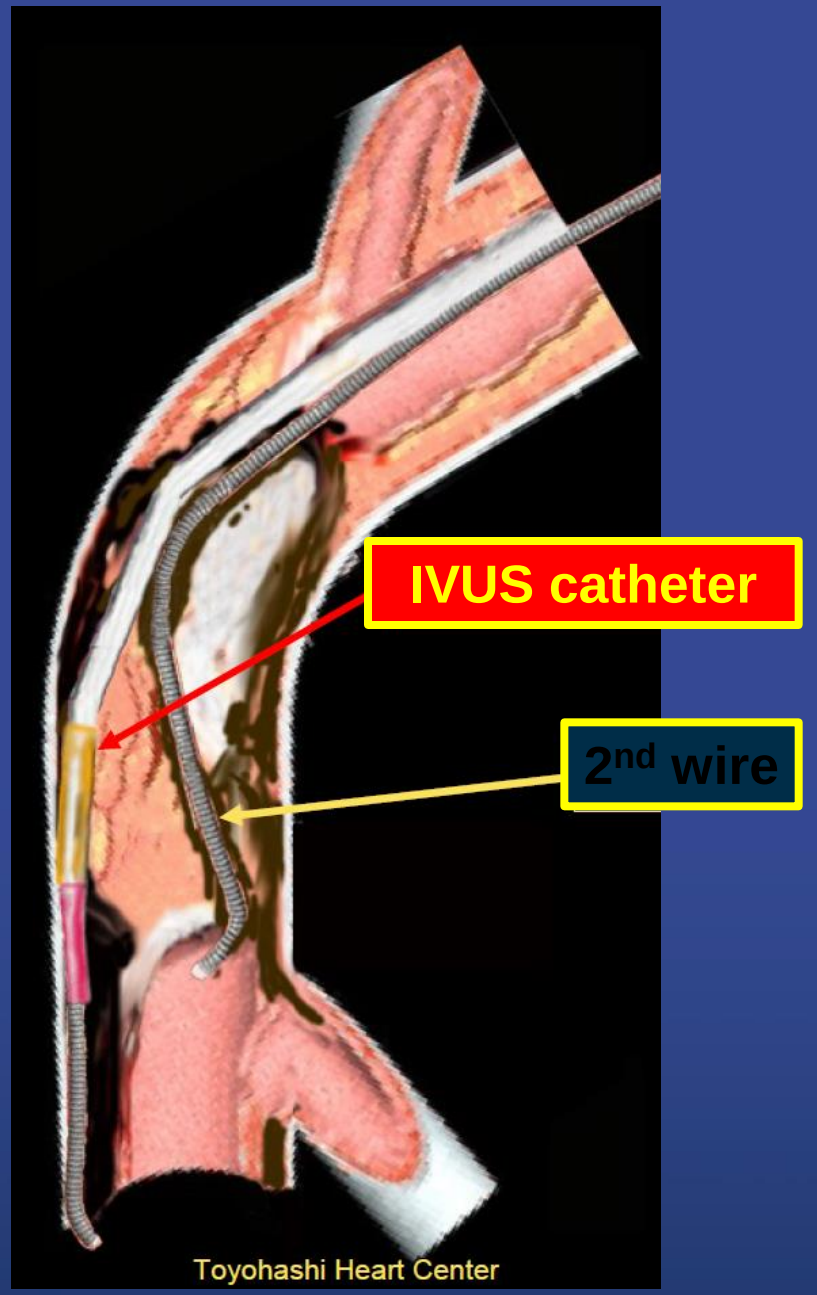


IVUS Guided Technique for Looking For the True Lumen



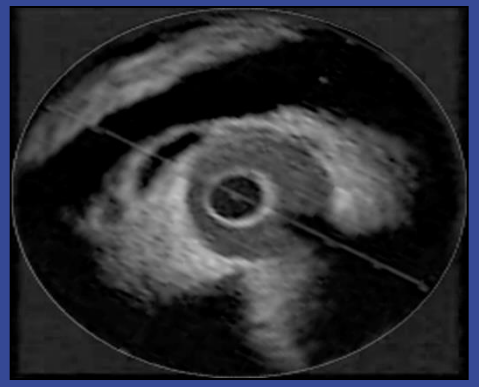
How to IVUS Guide Wire Crossing Technique

- Advance the guidewire into the subintimal space
- Subintimal space is enlarged with a 1.5mm balloon catheter along with the guidewire
- IVUS catheter is advanced into the subintimal space
- Stiff guidewire is advanced into the true lumen
- Wire manipulation under IVUS imaging



OCT-guided technique

Comparison of IVUS and OCT specifications



		IVUS	OCT
Resolution	*(axial)*	100 - 150 mm	10 - 15 mm
	(lateral)	150 - 300 mm	25 - 40 mm
Frame rate		30 frames/s	15 frames/s 30 frames/s (1/2 lateral resolution)
Dynamic range		40 - 60 dB	90 - 110 dB

DECISION-CTO

Optimal Medical Therapy With or Without Stenting For Coronary Chronic Total Occlusion

Seung-Jung Park, MD., PhD.

Heart Institute, University of Ulsan College of Medicine
Asan Medical Center, Seoul, Korea

Background

- Benefits of successful CTO-PCI include reduced angina frequency and improvements in quality of life, left ventricular ejection fraction, or survival.

- However, CTO-PCI can lead to procedure-related complications. In addition, the evidence for CTO-PCI was obtained from observational studies, most of which compared successful and failed CTO-PCI without a control group receiving optimal medical treatment.

DECISION CTO Trial

Design

- DESIGN: a prospective, open-label, randomized trial
- OBJECTIVE: To compare the outcomes of OMT alone with PCI coupled with OMT in patients with CTO.
- PRINCIPAL INVESTIGATOR
  Seung-Jung Park, MD, PhD,
  Asan Medical Center, Seoul, Korea

Clinicaltrials.gov, Identifier: NCT01075051

Clinicaltrials.go

Participating Centers (N=19)

Country	Site	Investigator
Korea	Asn Medical center	Seung-Jung Park
India	Ruby Hall Clinic	Shirish Hiremath
Korea	Keimyung University Dongsan Medical Center	Seung Ho Hur
Korea	Korea University Guro Hospital	Seung Un Rha
Indonesia	Medistra Hospital	Teguh Santoso
Korea	The Catholic University of Korea, Daejeon ST. Mary's Hospital	Sung-Ho Her
Korea	Chungnam National University Hospital, Daejeon	Si Wan Choi
Korea	Kangwon National University Hospital	Bong-Ki Lee
Korea	Soon Chun Hyang University Hospital Bucheon, Bucheon	Nae-Hee Lee
Korea	Kangbuk Samsung Medical Center, Seoul	Jong-Young Lee
Korea	Gangneung Asan Hospital, Gangneung	Sang-Sig Cheong,
Thailand	King Chulalongkorn Memorial Hospital	Wasan Udayachalerm
Korea	Dong-A University Hospital, Busan	Moo Hyun Kim
Korea	Chonnam National University Hospital, Gwangju	Young-Keun Ahn
Korea	Bundang Cha Medical Center, Bundang	Sang Wook Lim
Korea	Ulsan University Hospital, Ulsan	Sang-Gon Lee
Korea	Hangang Sacred Heart Hospital, Seoul	Min-Kyu Kim
Korea	Sam Anyang Hospital, Anyang	Il-Woo Suh
Taiwan	Shin Kong Hospital	Jun Jack Cheng

Major Inclusion Criteria

- Silent ischemia, stable angina, or ACS
- De novo CTO located in a proximal to mid epicardial coronary artery with a reference diameter of ≥2.5 mm
- CTO was defined as a coronary artery obstruction with TIMI flow grade 0 of at least three months' duration based on patient history.

Major Exclusion Criteria

- CTO located in
  - Distal coronary artery
  - 3 different vessel CTOs in any location
  - 2 proximal CTOs in separate coronary artery
  - left main segment
  - In-stent restenosis
  - Graft vessel
- LVEF < 30%
- Severe comorbidity

Original Power Calculation

Non-inferiority Design for Primary Endpoint

- Assumed primary event rate: 17% at 3 years
- A noninferiority margin : event rate ratio 0.7
- A one-sided type I error rate : 0.025
- Power : 80%
- Dropout rate: 5%
- Assumed sample size: 1,284 patients

Study Procedures (1)

- Patients who were assigned to PCIs underwent CTO-PCI using DES within 30 days after randomization using standard procedures.
- In cases of failed CTO-PCI, additional attempts were allowed within 30 days after the index procedure.
- The use of specialized devices or techniques, and the choice of drug-eluting stent type were left to the operator’s discretion.

Study Procedures (2)

- Revascularization for all significant non-CTO lesions within a vessel diameter of ≥2.5 mm for patients with multi-vessel coronary artery disease was recommended.
- Patients were prescribed guideline derived optimal medical treatment including aspirin, P2Y12 receptor inhibitors (>12months in case of PCI), beta-blocker, CCB, nitrate, ACEi/ARB, and statin.
- Blood pressure and diabetic control, smoking cessation, weight control, and regular exercise were recommended.

Premature Termination of Trial

- Because enrollment was slower than anticipated, enrollment was stopped in September 2016 as recommended by the data and safety monitoring board by which time 834 patients had been enrolled.
- The sponsor and study leadership were unaware of study results at the time of this decision.

Statistical Analysis

- All analyses were performed according to the intention-to-treat principle. Further sensitivity analyses were performed in the per-protocol and as-treated population.
- Hazard ratios (HRs) and 95% confidence intervals (CIs) were estimated using Cox proportional hazard models, with robust standard errors that accounted for clustering effect of stratified randomization.
- Noninferiority test using the Z-test with 95% CI of difference in the 3-year event rate.
- Survival curves were estimated using Cox model and the Kaplan-Meier method
- For quality of life analysis, we assumed the missing values were missing at random, and compared mean values of two groups using Student's t-test at specific time points.
- All P-values and CIs were two-sided. SAS software version 9.3 was used for all statistical analyses.

Primary End Point

At 3 year, a composite of

- Death from any cause
- Myocardial infarction
  - Periprocedural MI: CK-MB > 5 times UNL
  - Spontaneous MI: any cardiac enzyme elevation
- Stroke
- Any repeat revascularization

Original Power Calculation

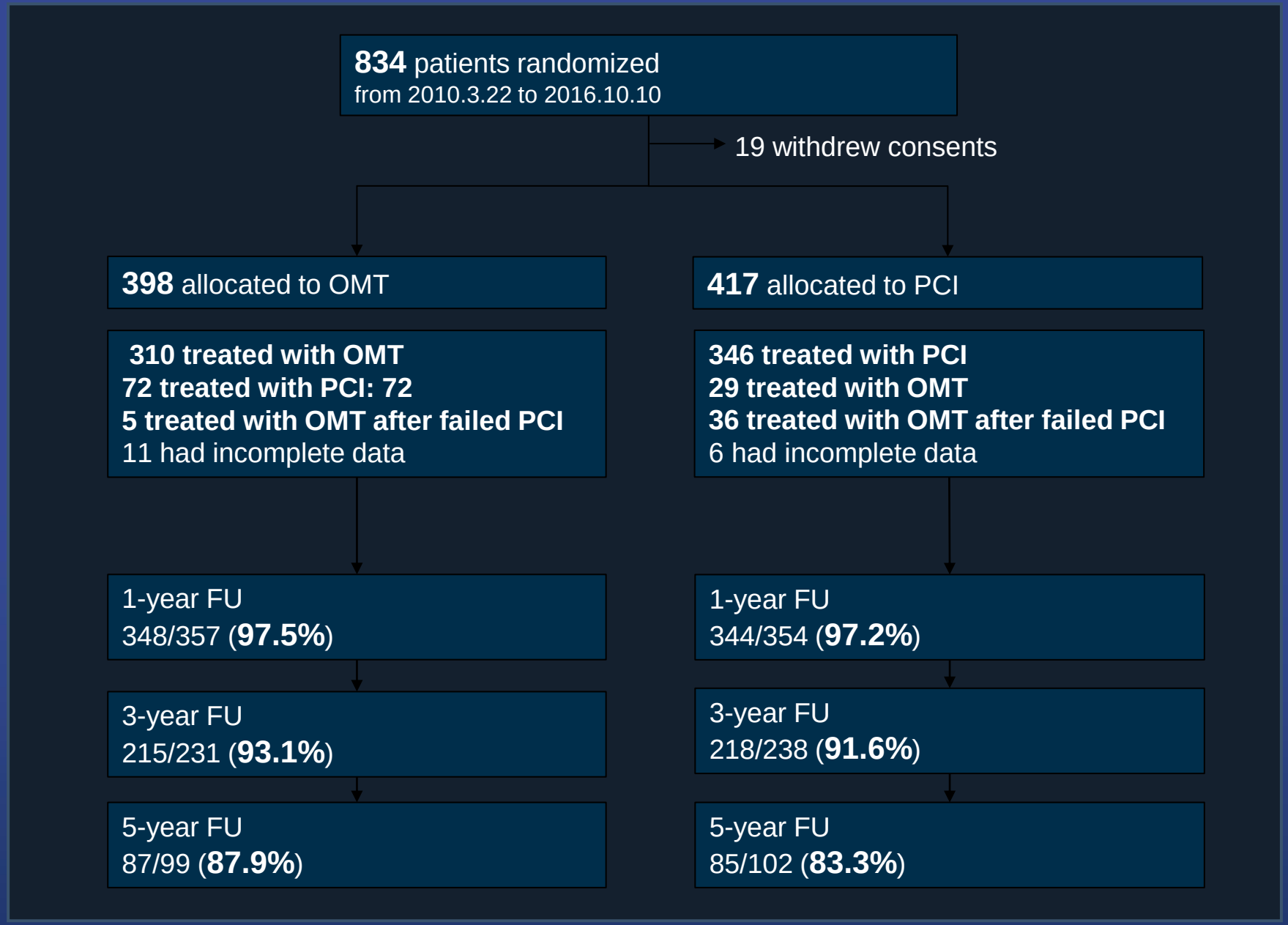
Non-inferiority Design for Primary Endpoint

- Assumed primary event rate: 17% at 3 years
- A noninferiority margin : event rate ratio 0.7
- A one-sided type I error rate : 0.025
- Power : 80%
- Dropout rate: 5%
- Assumed sample size: 1,284 patients

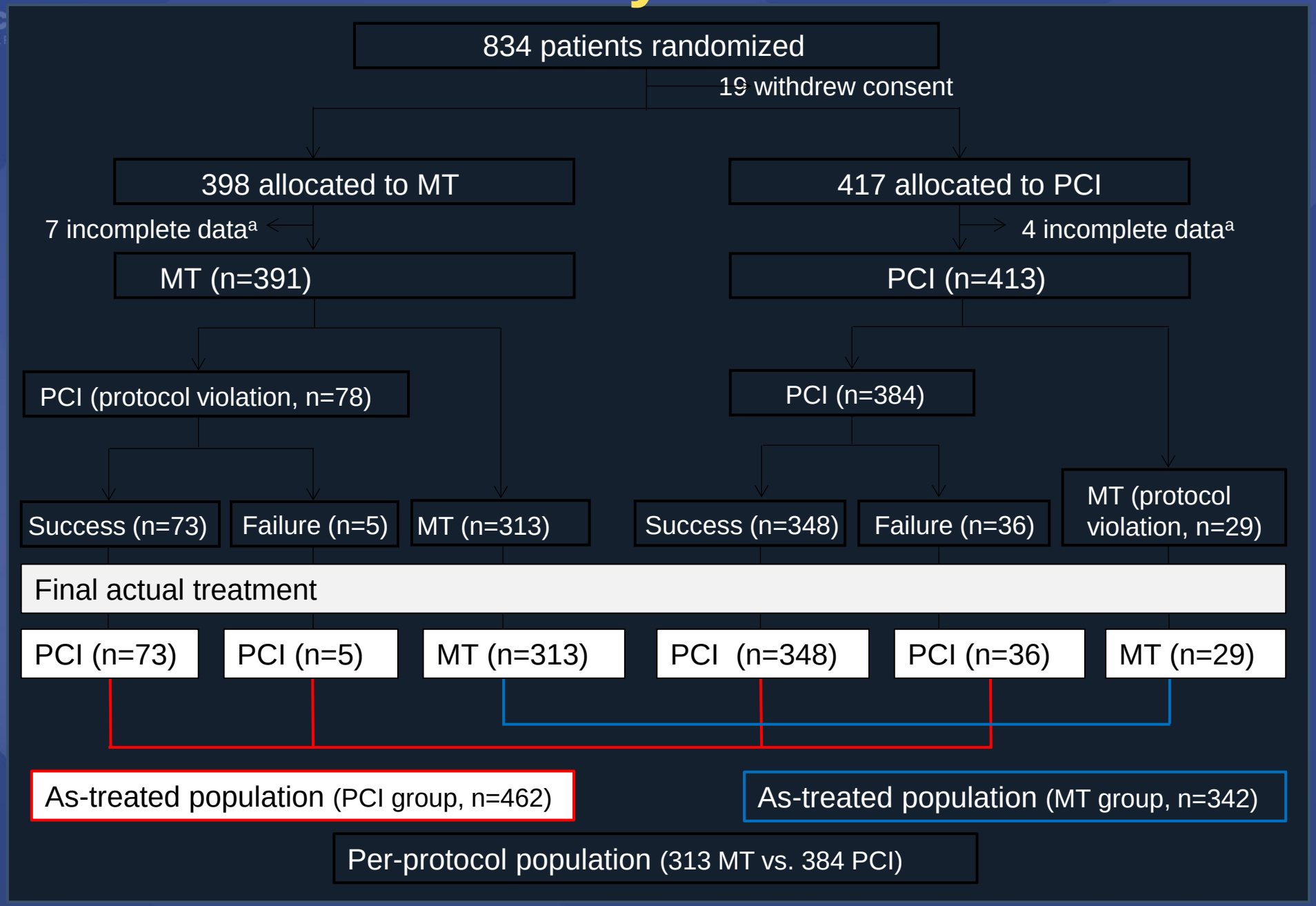
Premature Termination of Trial

- Because enrollment was slower than anticipated, enrollment was stopped in September 2016 as recommended by the data and safety monitoring board by which time 834 patients had been enrolled.
- The sponsor and study leadership were unaware of study results at the time of this decision.

Study Flow


834 patients randomized
from 2010.3.22 to 2016.10.10
19 withdrew consents
398 allocated to OMT
417 allocated to PCI
310 treated with OMT
72 treated with PCI: 72
5 treated with OMT after failed PCI
11 had incomplete data
346 treated with PCI
29 treated with OMT
36 treated with OMT after failed PCI
6 had incomplete data
1-year FU
348/357 (**97.5%**)
1-year FU
344/354 (**97.2%**)
3-year FU
215/231 (**93.1%**)
3-year FU
218/238 (**91.6%**)
5-year FU
87/99 (**87.9%**)
5-year FU
85/102 (**83.3%**)

Study Flow


834 patients randomized
19 withdrew consent
398 allocated to MT
417 allocated to PCI
7 incomplete data[a]
4 incomplete data[a]
MT (n=391)
PCI (n=413)
PCI (protocol violation, n=78)
PCI (n=384)
Success (n=73)
Failure (n=5)
MT (n=313)
Success (n=348)
Failure (n=36)
MT (protocol violation, n=29)
Final actual treatment
PCI (n=73)
PCI (n=5)
MT (n=313)
PCI (n=348)
PCI (n=36)
MT (n=29)
As-treated population (PCI group, n=462)
As-treated population (MT group, n=342)
Per-protocol population (313 MT vs. 384 PCI)

Statistical Analysis

- All analyses were performed according to the intention-to-treat principle. Further sensitivity analyses were performed in the per-protocol and as-treated population.
- Hazard ratios (HRs) and 95% confidence intervals (CIs) were estimated using Cox proportional hazard models, with robust standard errors that accounted for clustering effect of stratified randomization.
- Noninferiority test using the Z-test with 95% CI of difference in the 3-year event rate.
- Survival curves were estimated using Cox model and the Kaplan-Meier method
- For quality of life analysis, we assumed the missing values were missing at random, and compared mean values of two groups using Student's t-test at specific time points.
- All P-values and CIs were two-sided. SAS software version 9.3 was used for all statistical analyses.

Baseline Characteristics

ITT Population

	No-CTO PCI (N=398)	CTO-PCI (N=417)	P value
Age (years)	62.9±9.9	62.2±10.2	0.32
Male sex	319 (81.6%)	344 (83.3%)	0.59
BMI, kg/m^2	25.5±3.3	25.6±3.5	0.59
Hypertension	238 (60.9%)	262 (63.4%)	0.50
Diabetes mellitus	134 (34.3%)	132 (32.0%)	0.54
Hypercholesterolemia	217 (55.5%)	249 (60.3%)	0.19
Current smoker	102 (26.1%)	125 (30.3%)	0.22
Previous PCI	75 (19.2%)	64 (15.5%)	0.20
Previous MI	34 (8.7%)	45 (10.9%)	0.35
Previous CABG	5 (1.3%)	4 (1.0%)	0.93
Renal dysfunction	5 (1.3%)	6 (1.5%)	0.99
LVEF, %	57.6±9.1%	57.3±9.8%	0.68

Baseline Characteristics

ITT Population

	No CTO-PCI (N=398)	CTO-PCI (N=417)	P value
Clinical presentation			0.79
Stable angina	290 (75.0%)	300 (72.7%)	
Unstable angina	76 (19.4%)	84 (20.3%)	
AMI	22 (5.6%)	29 (7.0%)	
Location of CTO			0.67
LAD	163 (41.7%)	185 (44.8%)	
LCX	42 (10.7%)	42 (10.2%)	
RCA	186 (47.6%)	186 (45.0%)	
Multivessel disease	288 (73.6%)	302 (73.2%)	0.83
SYNTAX score	20.8±9.5	20.8±9.2	0.99
J-CTO score	2.2±1.2	2.1±1.2	0.16
Number of total stents	2.0±1.4	2.4±1.3	<0.001
Total stent length, mm	53.6±39.4	71.2±40.5	<0.001

Lesion and Procedural Characteristics

ITT Population

	CTO lesion			Non-CTO lesion		
Variable	MT strategy (n=398)	PCI strategy (n=417)	P	MT strategy (n=398)	PCI strategy (n=417)	P
Number of lesion[b]						0.59
0				97 (25.0)	107 (26.2)	
1		Not applicable		127 (32.7)	145 (35.5)	

	MT Strategy	PCI Strategy	P value
CR (non-CTO vs.)	302 (77.2%)	325 (78.7%)	0.67
Residual SS (non-CTO vs.)	3.7 ± 5.4	4.0 ± 5.9	0.42

Total stent length, mm	53.6 ± 39.4	71.3 ± 40.5	≤0.001	44.2 ± 28.0	41.1 ± 25.9	0.26
Stent diameter, mm	3.1 ± 0.4	3.1 ± 0.3	0.18	3.2 ± 0.4	3.2 ± 0.4	0.88
Stents			0.31			0.14
Early generation DES	4 (5.5)	13 (3.7)		10 (5.2)	7 (3.3)	
Newer generation DES	69 (94.5)	335 (96.3)		18 (94.8)	206 (96.7)	
IVUS use	7 (9.6)	203 (58.3)		108 (56.5)	114 (53.8)	0.58
Fluoroscopy time, minutes	37.2 ± 35.7	42.0 ± 34.0	0.09			
Total contrast amount, ml	337 ± 177	341 ± 157	0.78			

CTO PCI Characteristics

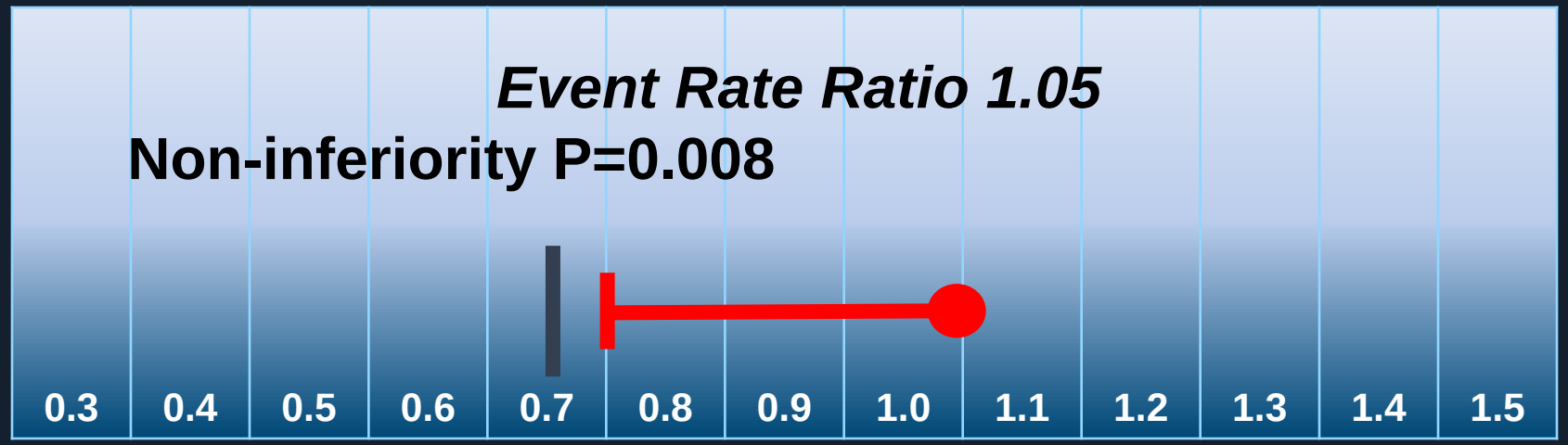
Attempted PCI	N=459
CTO PCI success	418 (91.1%)
Retrograde approach	113 (24.6%)
Lesion passaged wire	
Low penetration force wire	117/418 (28.0%)
Intermediate to high penetration force wire	301/418 (72.0%)
CTO technique	
Single wire technique only	309/418 (73.9%)
Parallel wire technique	72/418 (17.2%)
IVUS-guided wiring	25/418 (6.0%)
CART technique	55/418 (13.2%)
Additional back-up support	
Corsair	91/418 (21.8%)
Microcatheter other than Corsair	230/418 (55.0%)
Over-the-wire balloon	6/418 (1.4%)

Noninferiority Test for
Primary End Point at 3-Year

ITT Population

Estimated 3-year Event Rate OMT: 19.6% PCI: 20.6%

Prespecified non-inferiority margin: 0.7

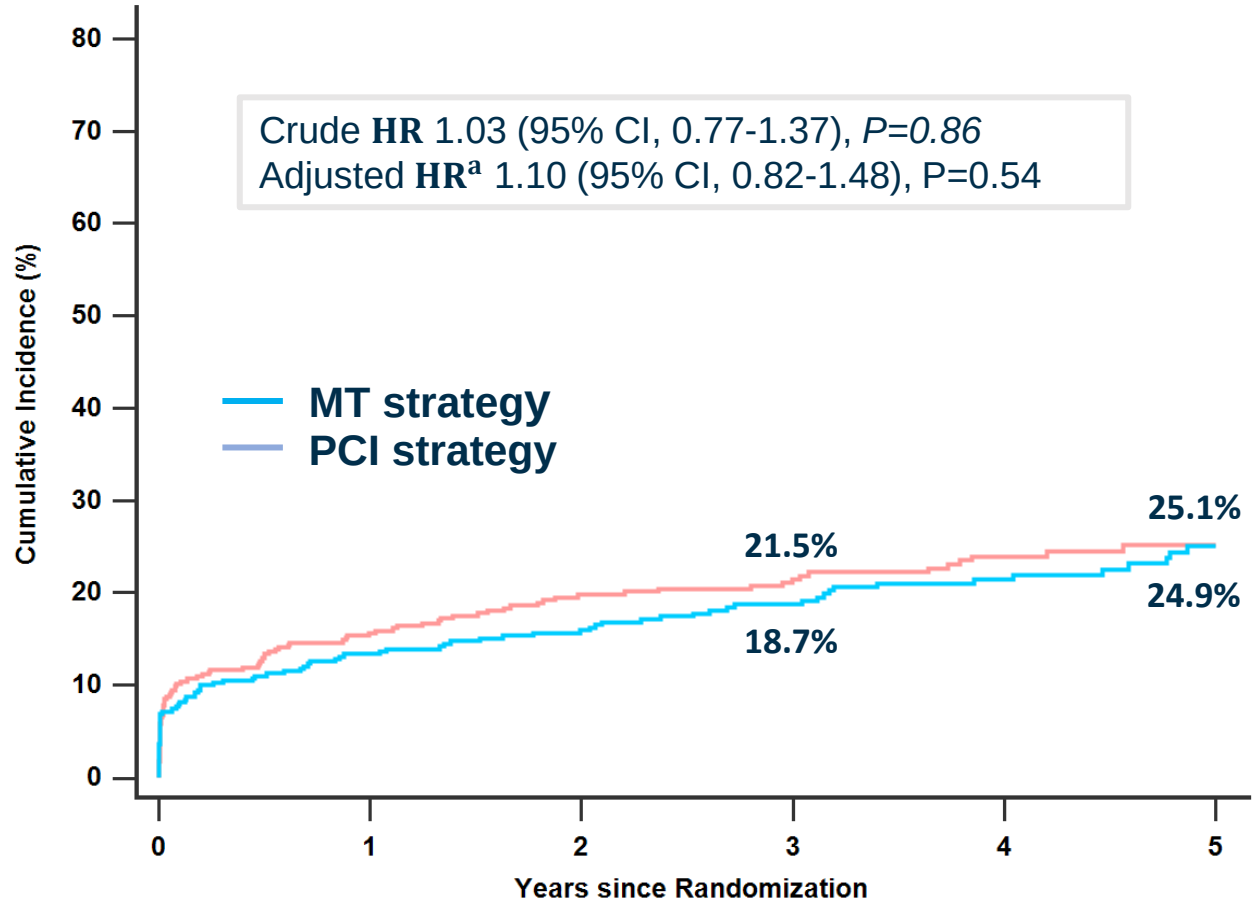


Event Rate Ratio of 3-year MACE rate (PCI/OMT)

Lower 1-sided 97.5% CI

Primary End Point
(Death, MI, Stroke, Any Revascularization)

ITT Population



Medical therapy	398	324	287	229	169	107
PCI	417	330	268	221	159	104

[a]Adjusted for age, BMI, hypercholesterolemia, previous stroke, renal dysfunction, atrial fibrillation, clinical presentation, location of CTO, number of diseased vessels, and stratifying covariates.

ITT Population

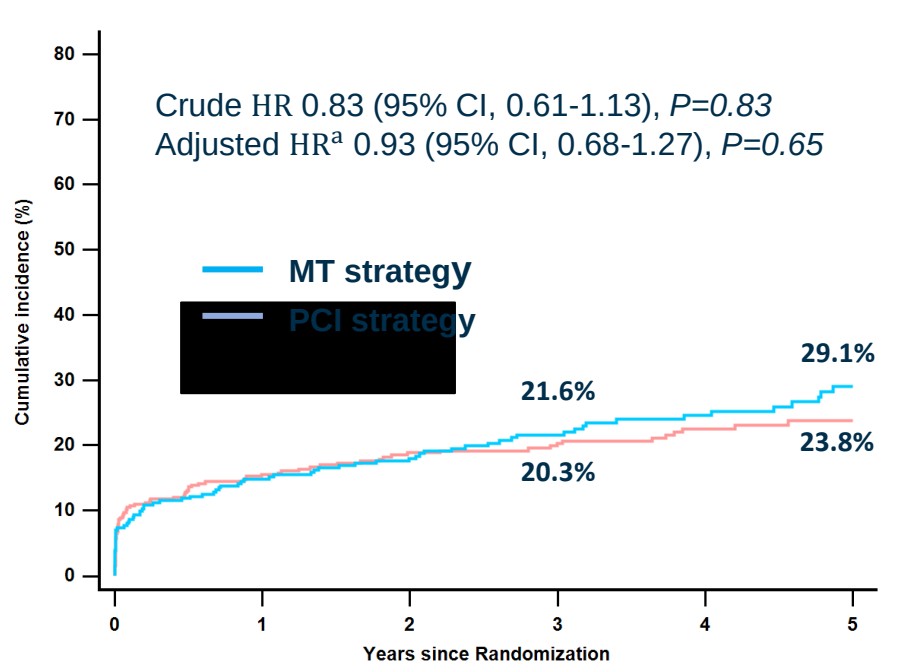
Clinical Endpoints

	MT Strategy (n=398)	PCI Strategy (n=417)	Crude HR (95% CI)	P value	Adjusted HR* (95% CI)	P value
Primary endpoint Death, MI, stroke, or any revascularization	89 (22.4)	93 (20.3)	1.03 (0.77-1.37)	0.86	1.10 (0.69-1.24)	0.54
Secondary endpoints						
Death	21 (5.3)	15 (3.6)	0.70 (0.36-1.37)	0.30	0.85 (0.42-1.72)	0.65
Cardiac cause	14 (3.5)	8 (1.9)	0.56 (0.24-1.34)	0.19	0.63 (0.24-1.63)	0.34
Noncardiac cause	7 (1.8)	7 (1.7)	0.99 (0.35-2.82)	0.99	1.16 (0.36-3.77)	0.80
Myocardial infarction	34 (8.5)	47 (11.3)	1.31 (0.85-2.04)	0.23	1.42 (0.90-2.23)	0.13
Periprocedural MI	30 (7.5)	41 (9.8)	1.30 (0.81-2.07)	0.29	1.36 (0.84-2.20)	0.22
Spontaneous MI	7 (1.8)	7 (1.7)	0.83 (0.28-2.48)	0.74	0.87 (0.27-2.77)	0.82
Stroke	10 (2.5)	6 (1.4)	0.57 (0.21-1.58)	0.28	0.97 (0.32-2.96)	0.96
Any revascularization	42 (10.6)	46 (11.0)	1.08 (0.71-1.65)	0.71	1.09 (0.71-1.68)	0.70
CTO vessel	30 (7.5)	33 (7.9)	1.01 (0.67-1.79)	0.73	1.06 (0.64-1.76)	0.81
Non-CTO vessel	23 (5.8)	29 (7.0)	1.24 (0.72-2.14)	0.44	1.31 (0.74-2.32)	0.36
Death, MI, or stroke	61 (15.3)	66 (15.8)	1.07 (0.75-1.51)	0.72	1.26 (0.88-1.80)	0.21
Cardiac death, MI, stroke, or any revascularization	82 (20.6)	86 (20.6)	1.02 (0.76-1.39)	0.88	1.08 (0.80-1.48)	0.61
Death, spontaneous MI, stroke, or any revascularization	69 (17.3)	64 (15.3)	0.91 (0.65-1.30)	0.59	1.01 (0.71-1.42)	0.98

*Adjusted for age, BMI, hypercholesterolemia, previous stroke, renal dysfunction, atrial fibrillation, clinical presentation, location of CTO, number of diseased vessels, and stratifying covariates.

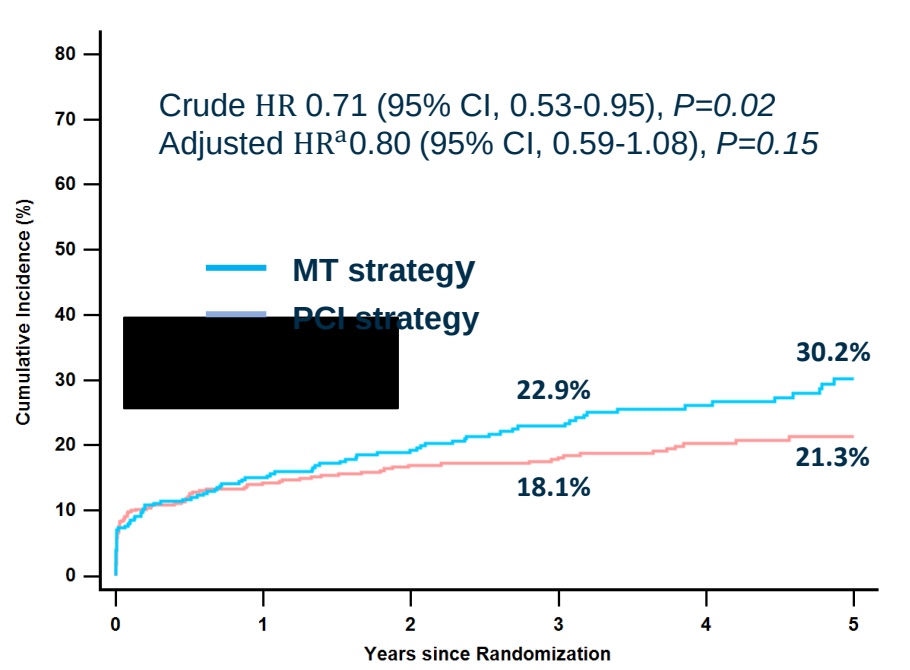
Primary End Point
(Death, MI, Stroke, Any Revascularization)

Per-protocol population



MT	313	257	224	172	125	79
PCI	384	306	254	210	152	98

As-treated population

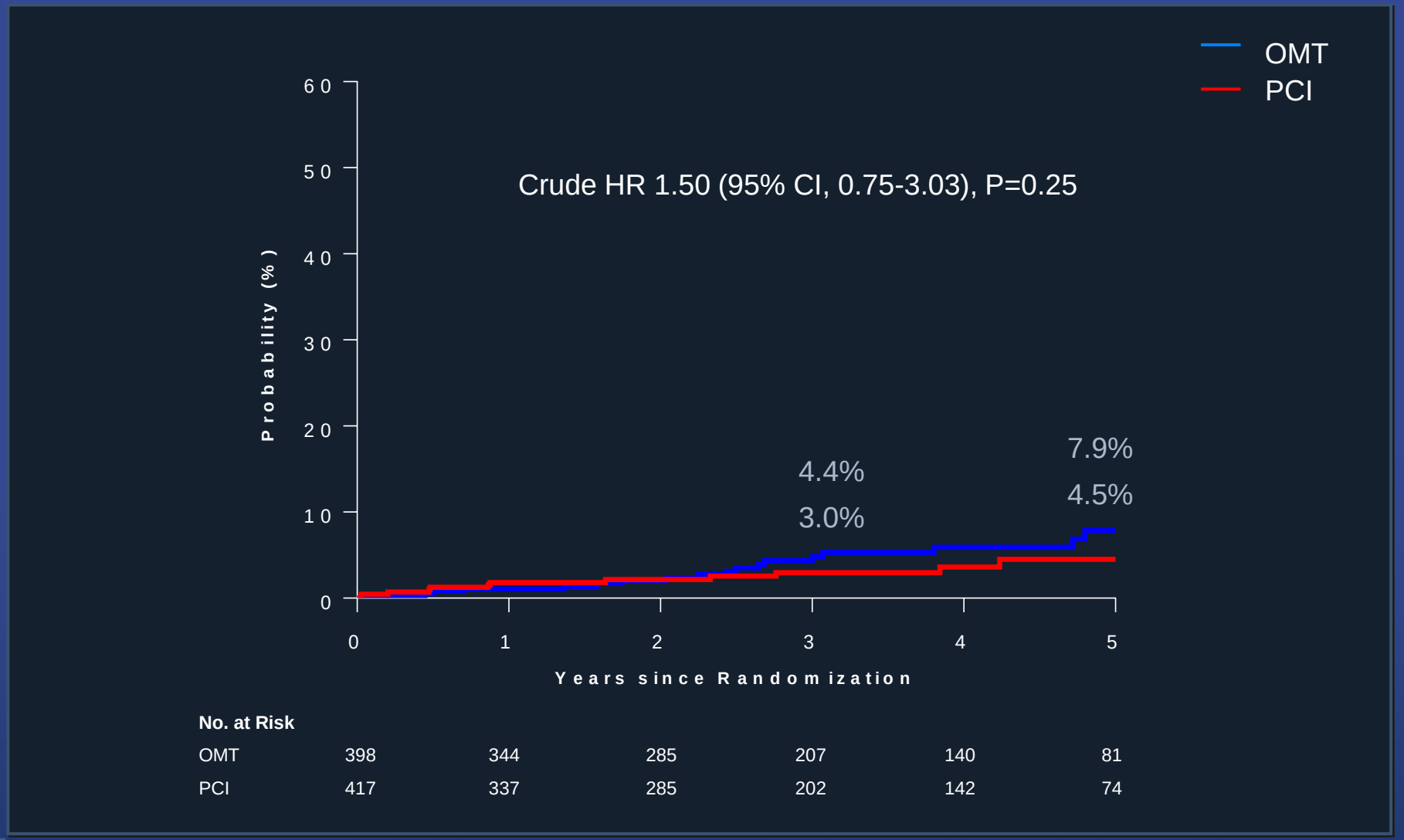


MT	342	281	239	184	134	86
PCI	462	375	318	268	197	127

[a]Adjusted for age, BMI, hypercholesterolemia, previous stroke, renal dysfunction, atrial fibrillation, clinical presentation, location of CTO, number of diseased vessels, and stratifying covariates.

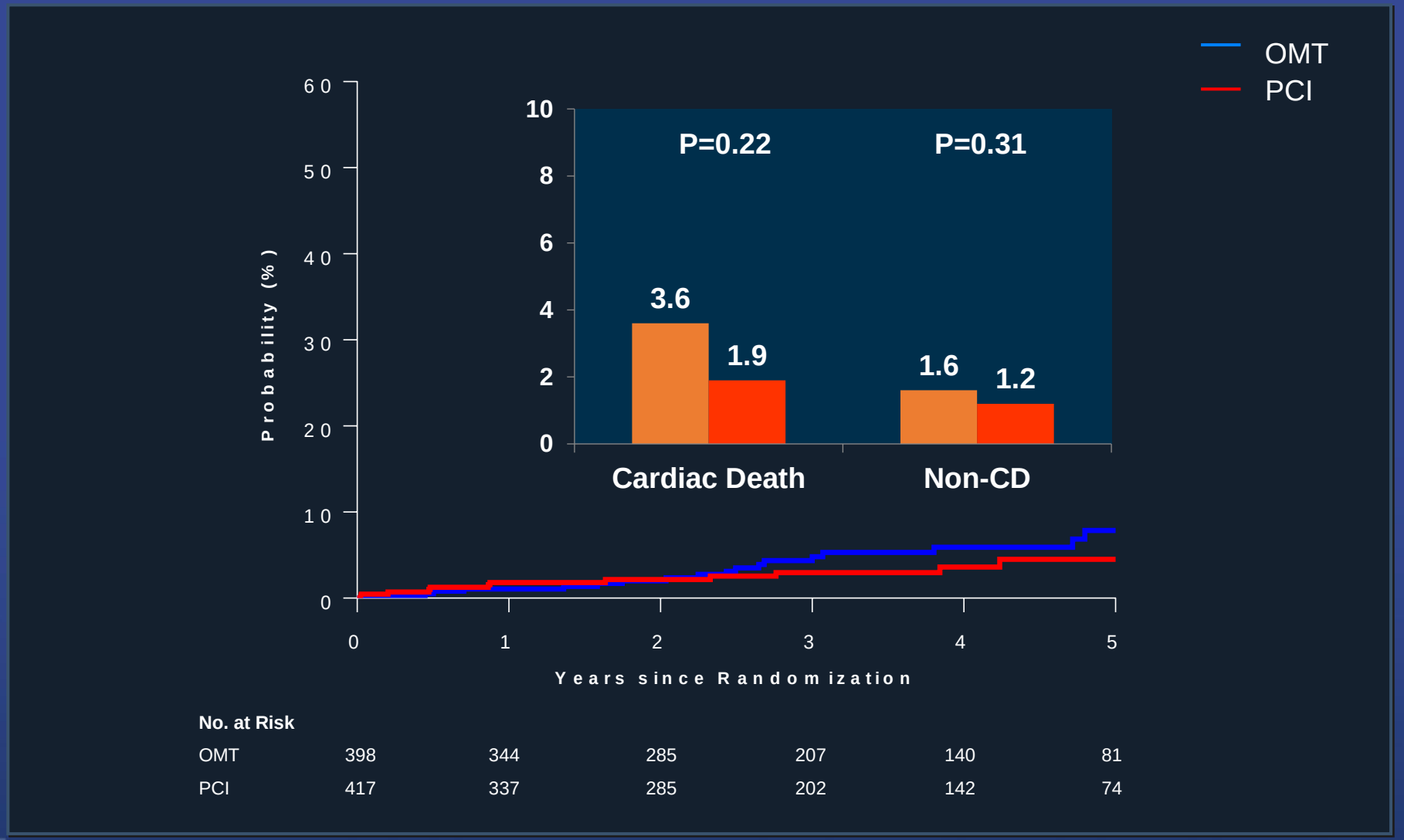
ITT Population

Death from any cause



ITT Population

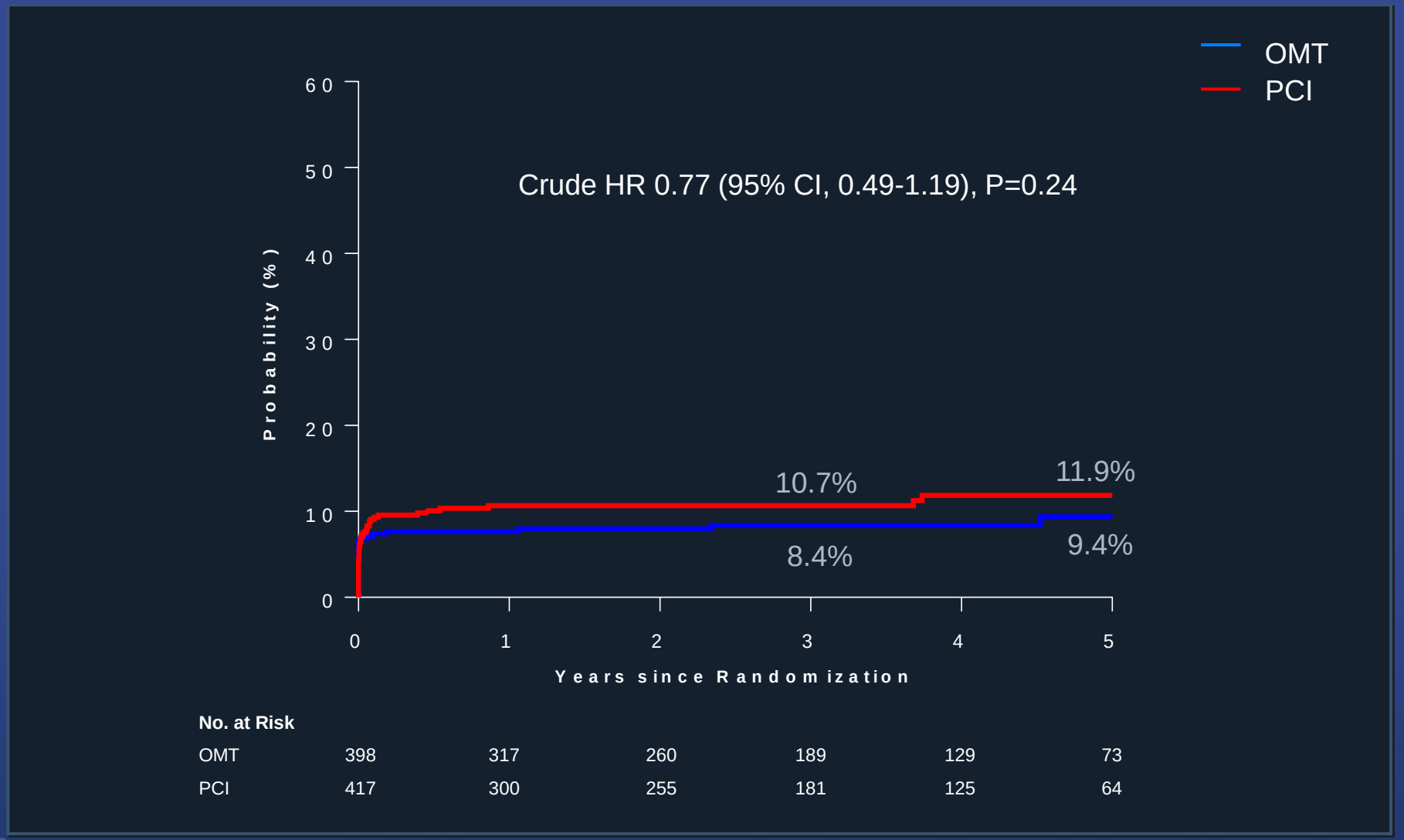
Death from any cause



No. at Risk						
OMT	398	344	285	207	140	81
PCI	417	337	285	202	142	74

ITT Population

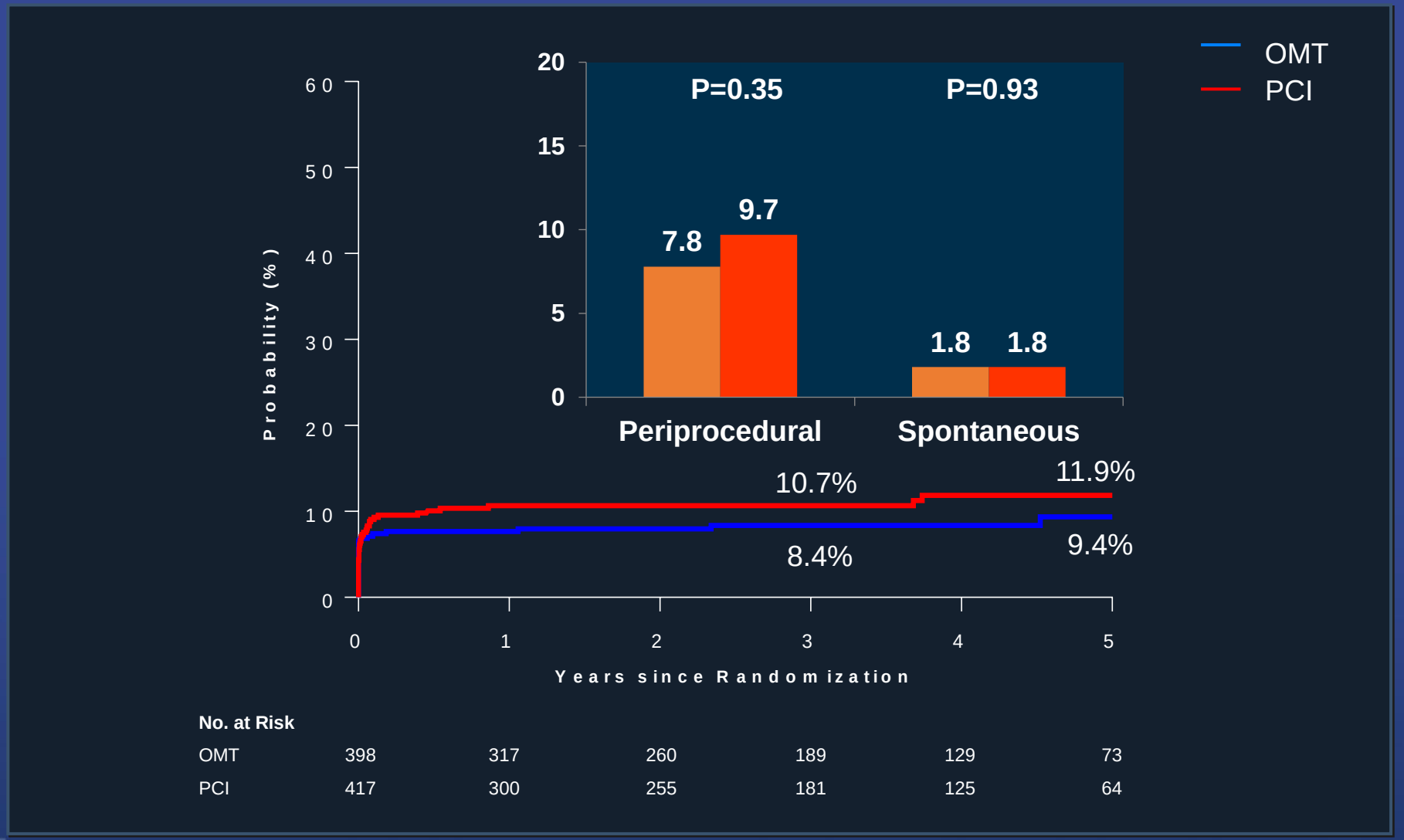
Myocardial Infarction



No. at Risk						
OMT	398	317	260	189	129	73
PCI	417	300	255	181	125	64

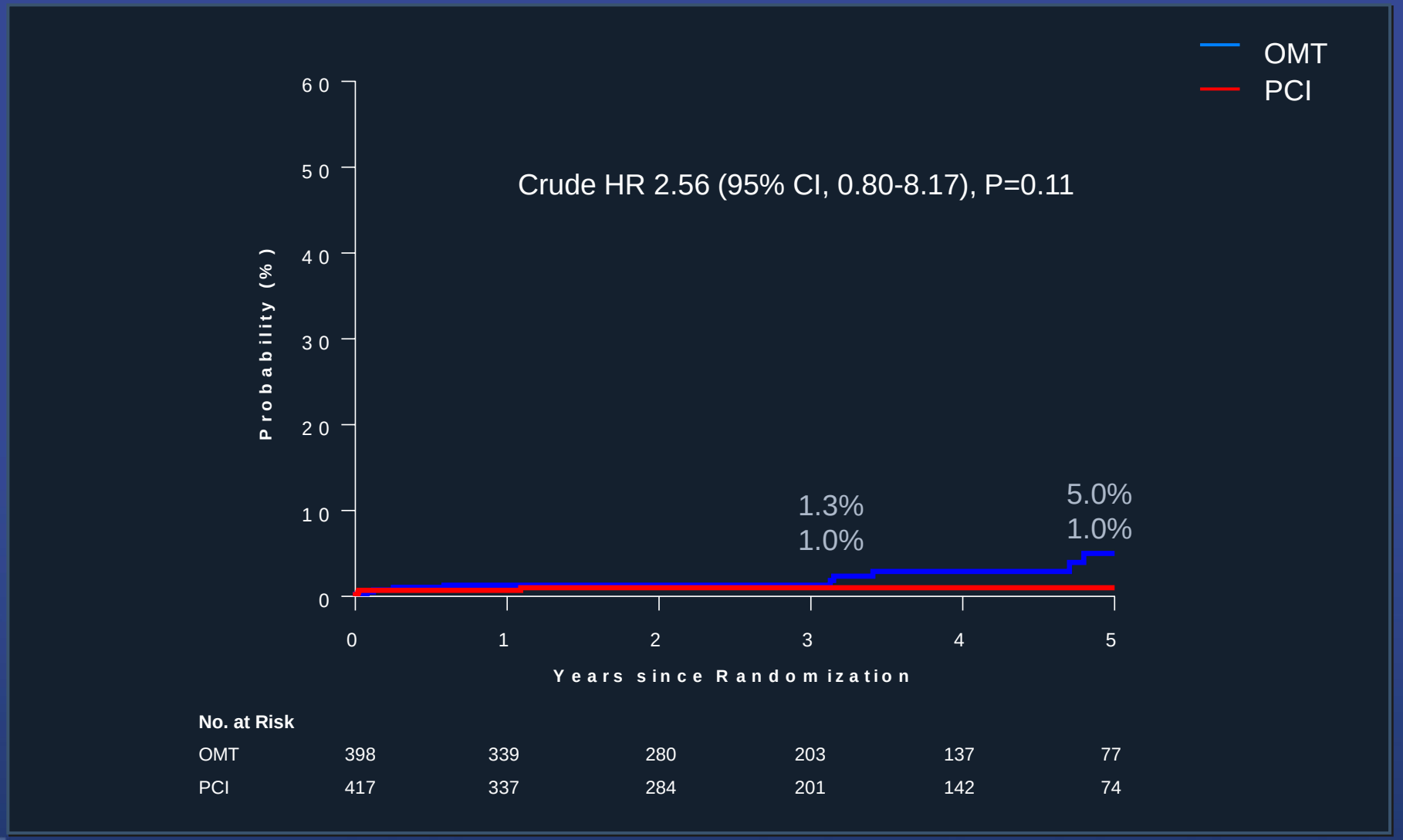
ITT Population

Myocardial Infarction



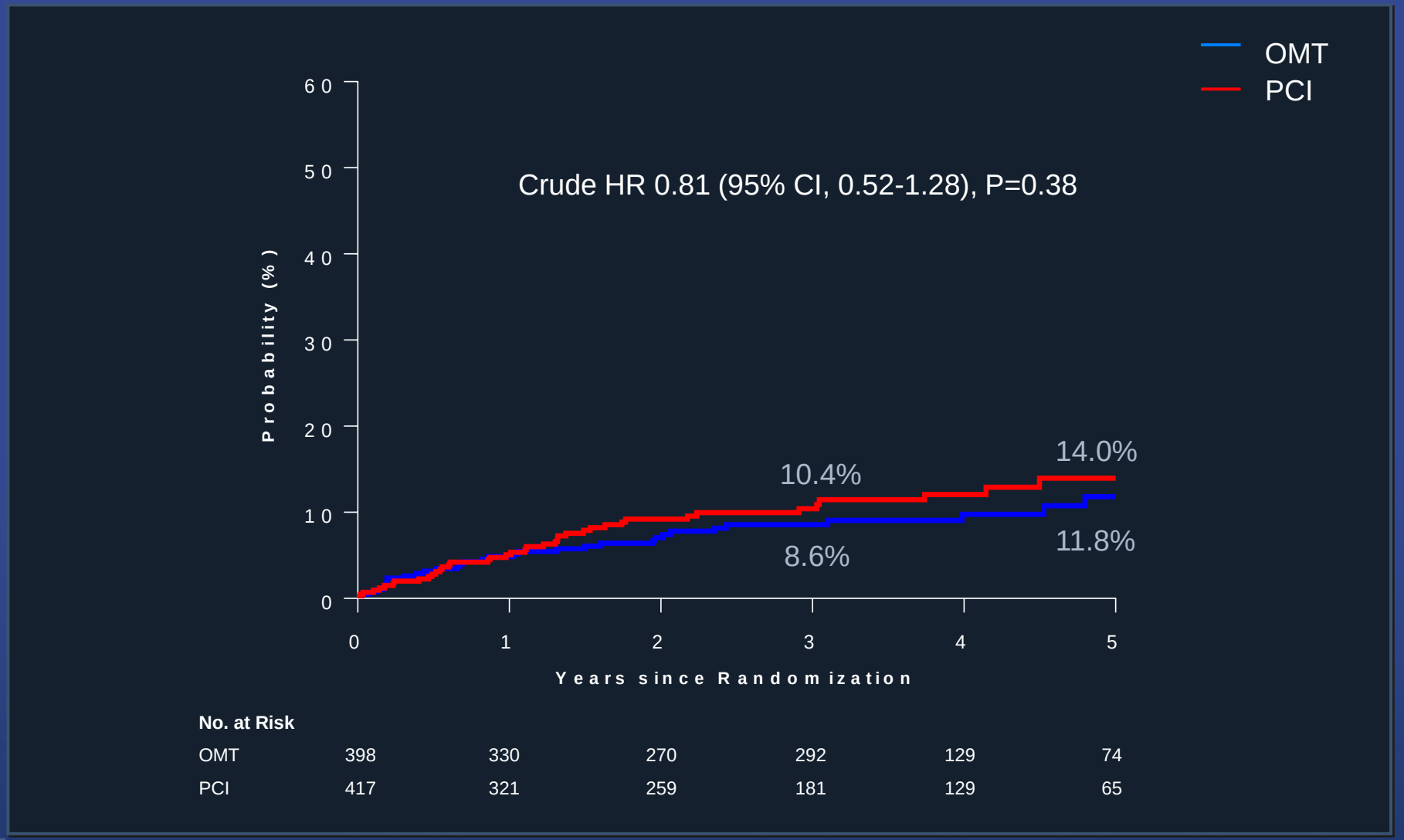
ITT Population

Stroke



ITT Population

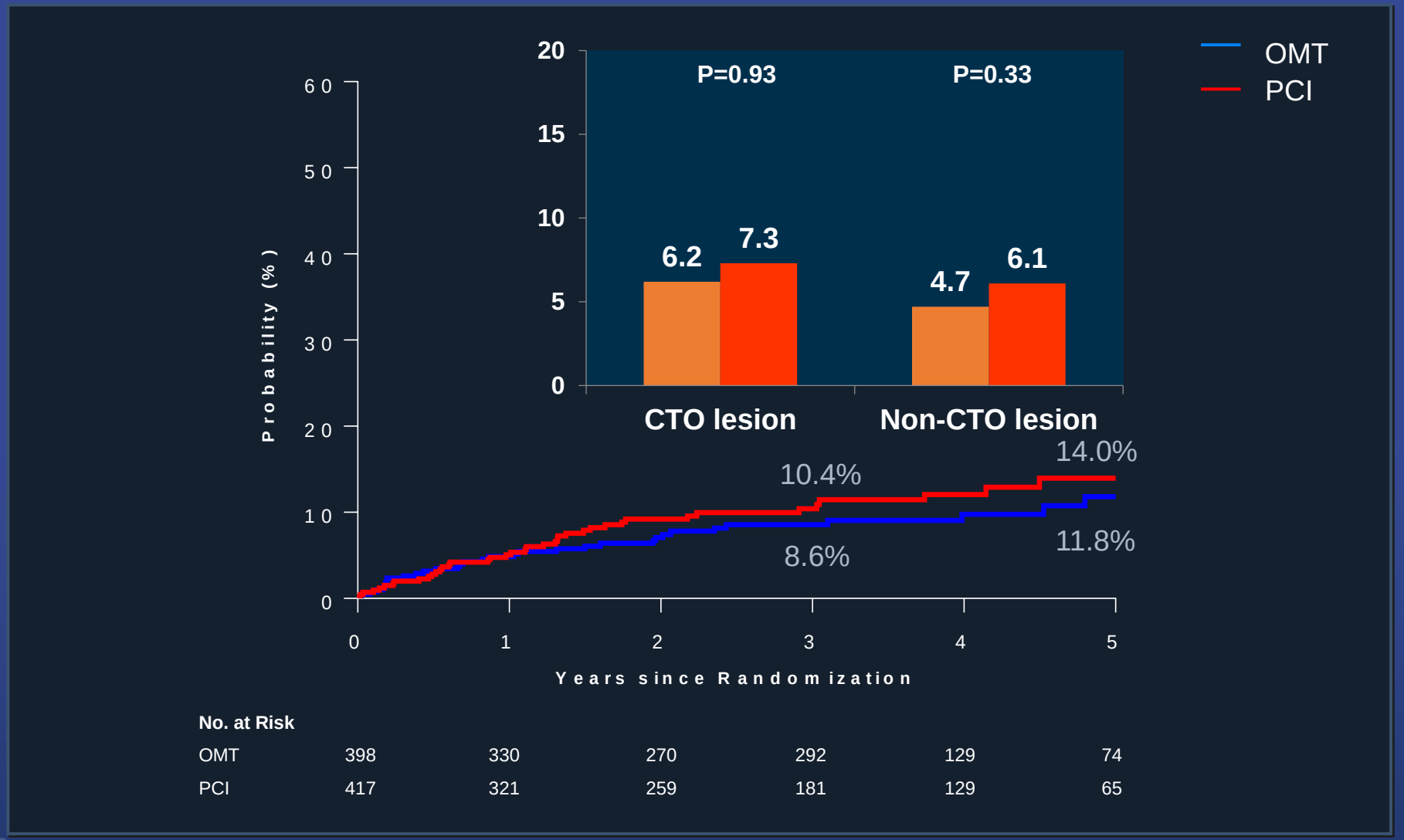
Repeat Revascularization



No. at Risk						
OMT	398	330	270	292	129	74
PCI	417	321	259	181	129	65

ITT Population

Repeat Revascularization

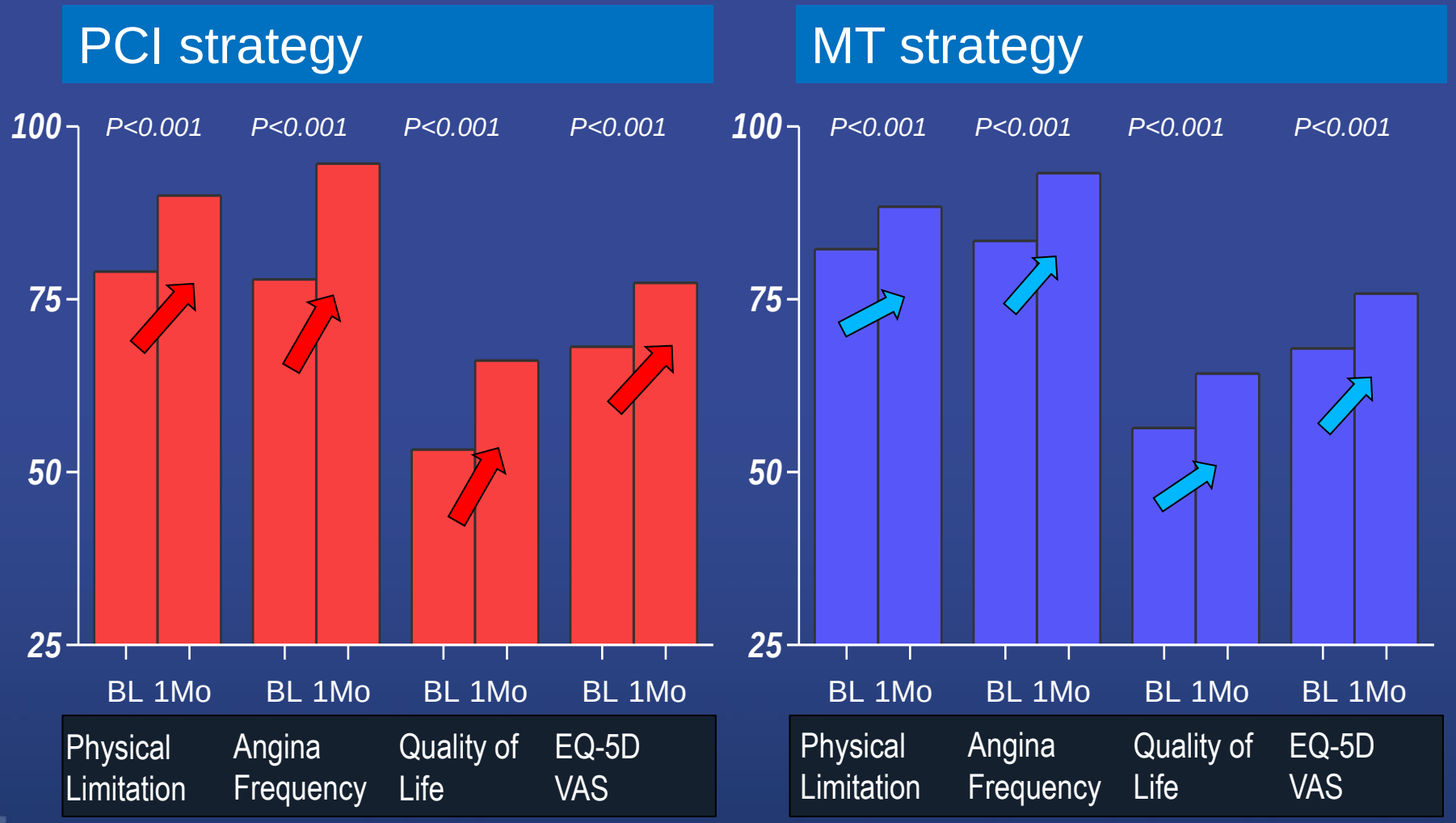


No. at Risk

OMT	398	330	270	292	129	74
PCI	417	321	259	181	129	65

QOL Measure Scores

Within group changes from baseline to 1 month



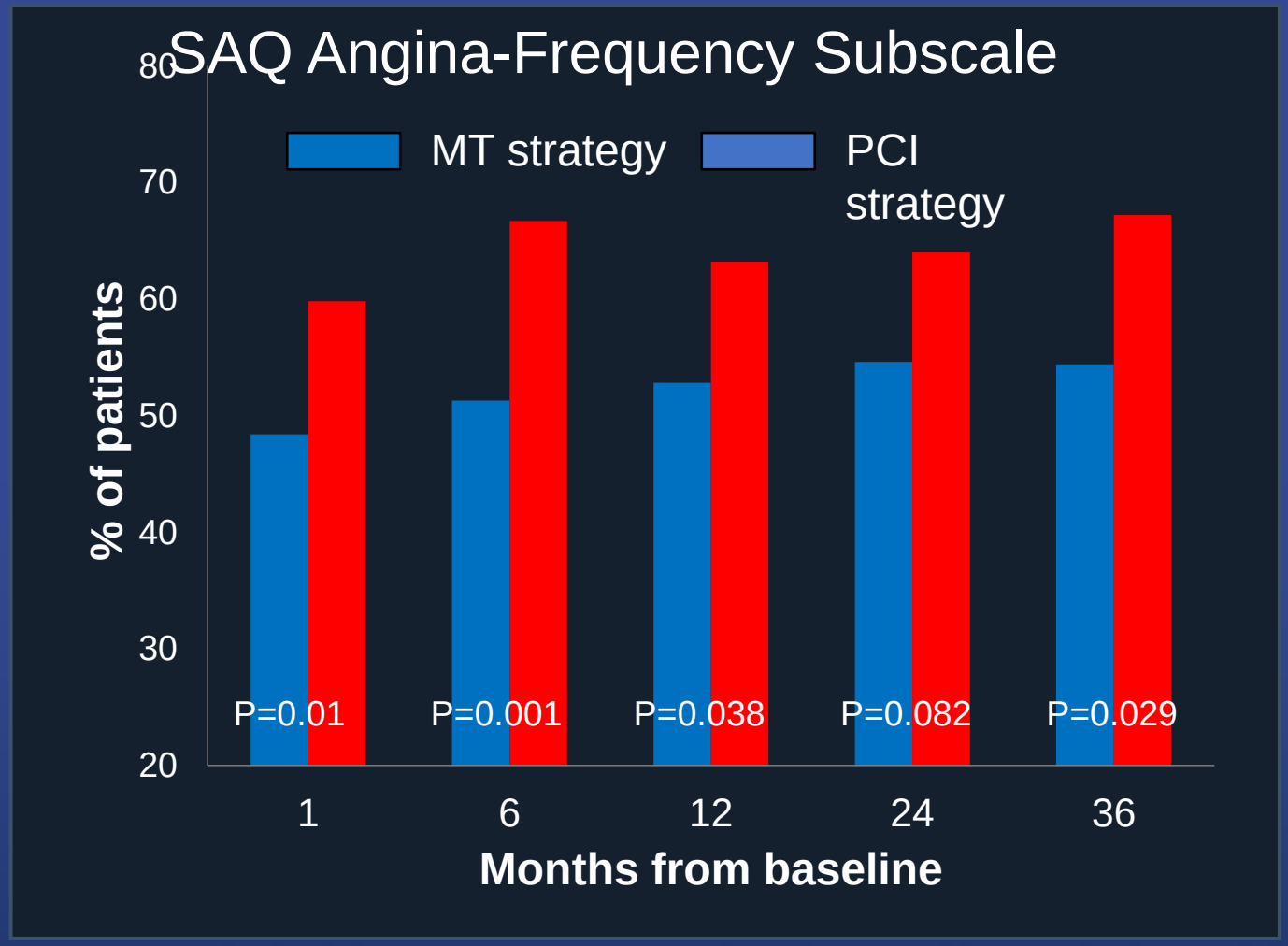
Between group differences over time

	PCI strategy	MT strategy	Difference between PCI and MT strategy (95% CI)*	P value
SAQ physical limitation				
1 mo	90.00 ± 15.66	88.38 ± 17.11	-3.354 (-5.605 − -1.104)	0.004
6 mo	92.22 ± 13.61	91.80 ± 14.32	-1.813 (-4.089 − 0.464)	0.118
12 mo	93.06 ± 11.96	91.77 ± 15.12	-2.309 (-4.710 − 0.092)	0.059
24 mo	94.84 ± 12.72	93.69 ± 12.74	-1.920 (-4.301 − 0.462)	0.114
36 mo	94.52 ± 12.86	93.54 ± 14.98	-1.813 (-4.827 − 1.201)	0.237
SAQ angina frequency				
1 mo	94.63 ± 10.54	93.31 ± 13.78	-2.635 (-4.604 − 0.665)	0.009
6 mo	96.00 ± 10.13	95.44 ± 9.98	-1.037 (-2.911 − 0.837)	0.277
12 mo	94.55 ± 11.18	95.33 ± 10.19	-0.154 (-2.163 − 1.855)	0.880
24 mo	97.31 ± 7.13	97.18 ± 7.65	-0.427 (-1.978 − 1.125)	0.589
36 mo	98.21 ± 5.32	97.38 ± 7.20	-0.981 (-2.480 − 0.518)	0.199
SAQ quality of life				
1 mo	66.16 ± 19.87	64.26 ± 19.65	-3.075 (-6.135 − -0.016)	0.049
6 mo	72.08 ± 17.54	69.74 ± 17.48	-3.336 (-6.444 − -0.227)	0.036
12 mo	72.19 ± 19.06	71.89 ± 16.6	-1.458 (-4.745 − 1.829)	0.384
24 mo	77.37 ± 17.43	75.91 ± 17.77	-2.136 (-5.738 − 1.465)	0.244
36 mo	78.26 ± 17.39	77.53 ± 16.69	-1.213 (5.004 − 2.577)	0.529

*The difference between the PCI and MT strategy groups was adjusted for baseline values.
Negative values indicate better outcomes with PCI strategy.

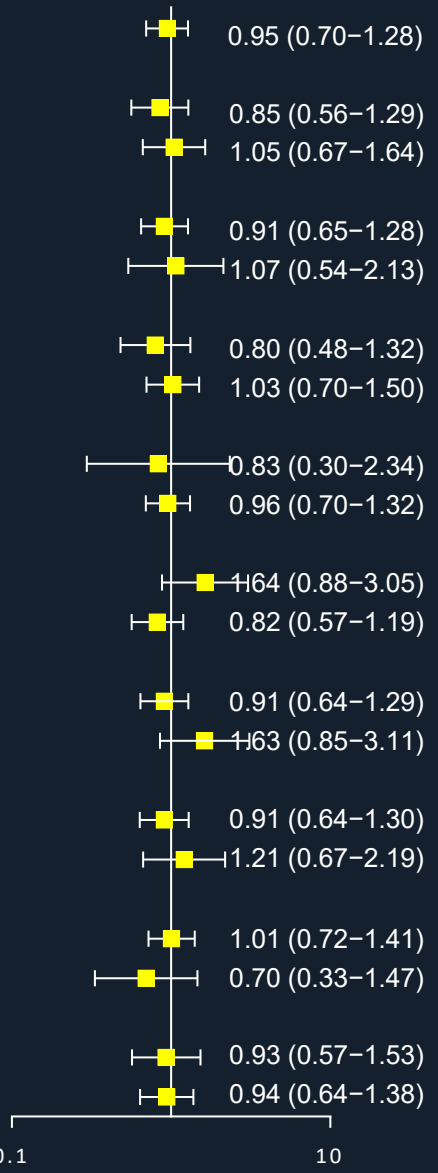
Substantial Improvement (%) of Angina over Time

Increase from baseline score of 10 points or more



Subgroup Analysis

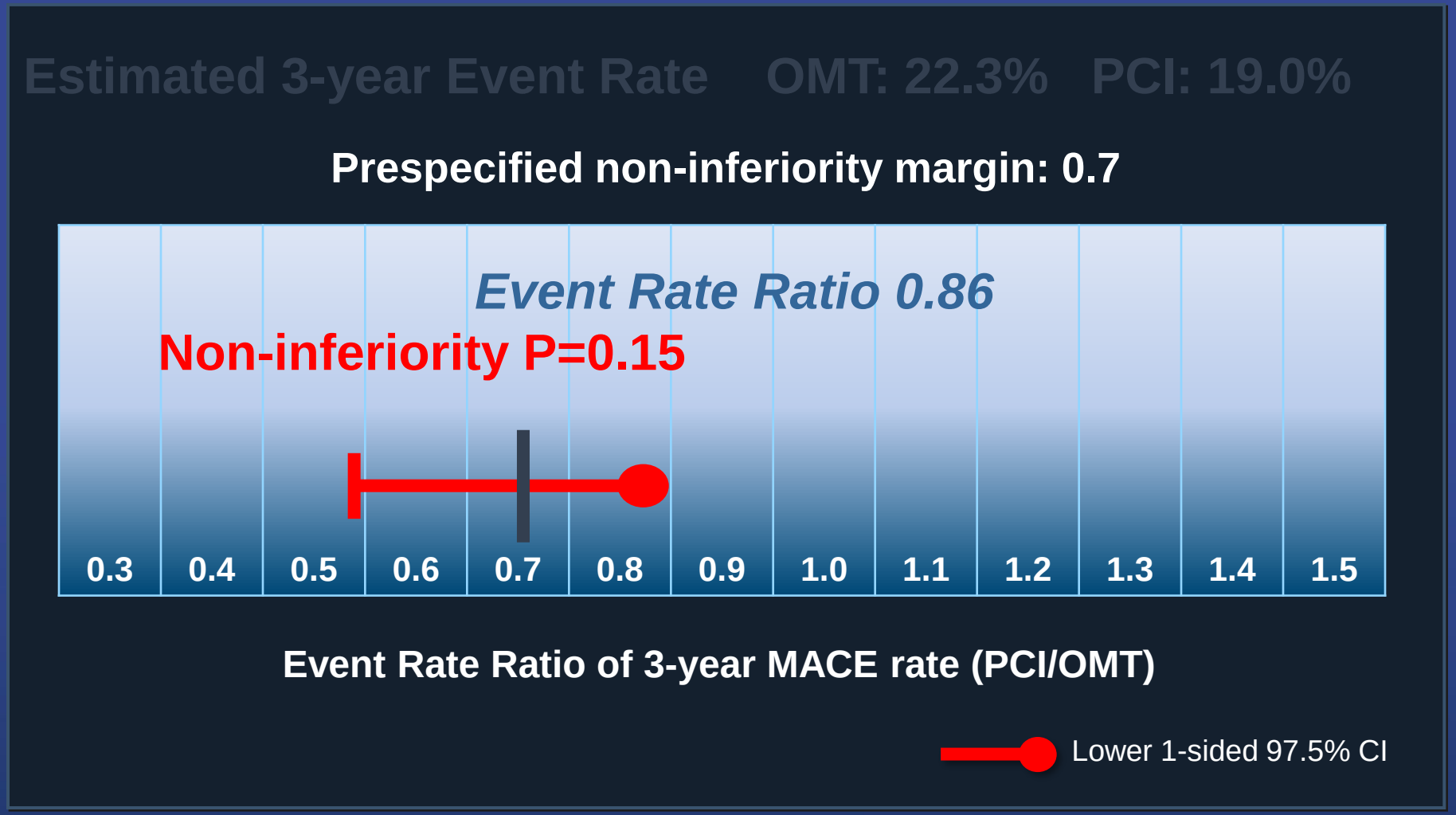
Subgroup	OMT	PCI	Hazard ratio (95% CI)	p value for Interaction
	no. of patients with event/total no. (%)			
Overall	81/387 (20.9)	86/411 (20.9)	0.95 (0.70−1.28)	
Age				0.51
≥ 65 y	43/172 (25.0)	48/174 (27.6)	0.85 (0.56−1.29)	
< 65 y	38/215 (17.7)	38/237 (16.0)	1.05 (0.67−1.64)	
Sex				0.65
Male	63/315 (20.0)	71/342 (20.8)	0.91 (0.65−1.28)	
Female	18/72 (25.0)	15/69 (21.7)	1.07 (0.54−2.13)	
Diabetes				0.45
Yes	29/133 (21.8)	32/132 (24.2)	0.80 (0.48−1.32)	
No	52/254 (20.5)	54/279 (19.4)	1.03 (0.70−1.50)	
Previous myocardial infarction				0.77
Yes	6/34 (17.6)	9/45 (20.0)	0.83 (0.30−2.34)	
No	75/353 (21.2)	77/366 (21.0)	0.96 (0.70−1.32)	
Acute coronary syndrome				0.18
Yes	29/97 (29.9)	26/113 (23.0)	1.64 (0.88−3.05)	
No	52/290 (17.9)	60/298 (20.1)	0.82 (0.57−1.19)	
Typical chest pain				0.56
Yes	65/278 (23.4)	64/311 (20.6)	0.91 (0.64−1.29)	
No	16/109 (14.7)	22/100 (22.0)	1.63 (0.85−3.11)	
Ejection fraction				0.44
≥ 50%	60/321 (18.7)	63/332 (19.0)	0.91 (0.64−1.30)	
< 50%	21/66 (31.8)	23/79 (29.1)	1.21 (0.67−2.19)	
Multi-vessel disease				0.39
Yes	69/286 (24.1)	69/301 (22.9)	1.01 (0.72−1.41)	
No	12/101 (11.9)	17/110 (15.5)	0.70 (0.33−1.47)	
CTO located in the left anterior descending artery				0.98
Yes	29/161 (18.0)	34/183 (18.6)	0.93 (0.57−1.53)	
No	52/226 (23.0)	52/228 (22.8)	0.94 (0.64−1.38)	



Per Protocol Analysis

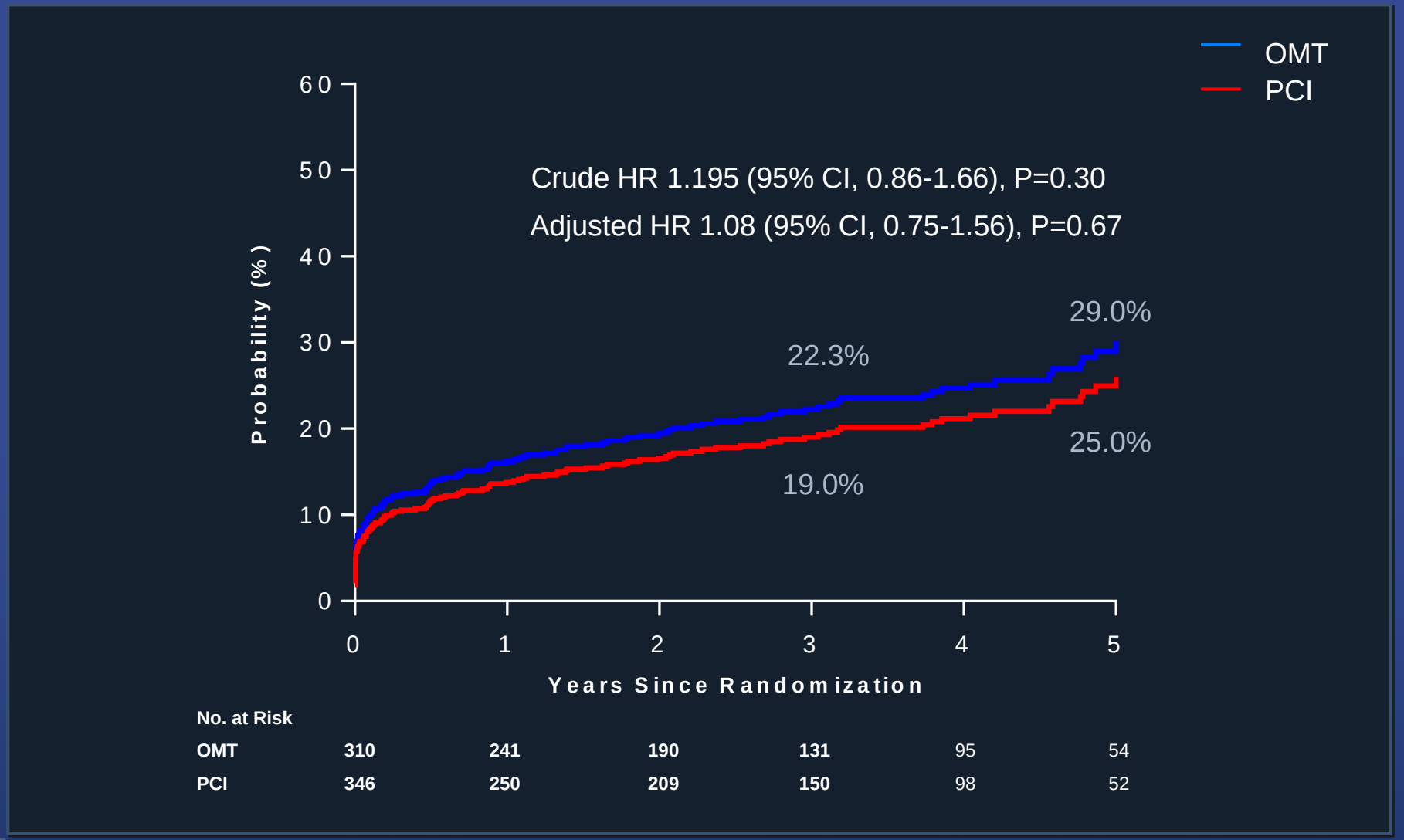
Noninferiority Test for
Primary End Point at 3-Year

Per-Protocol Population



Primary End Point

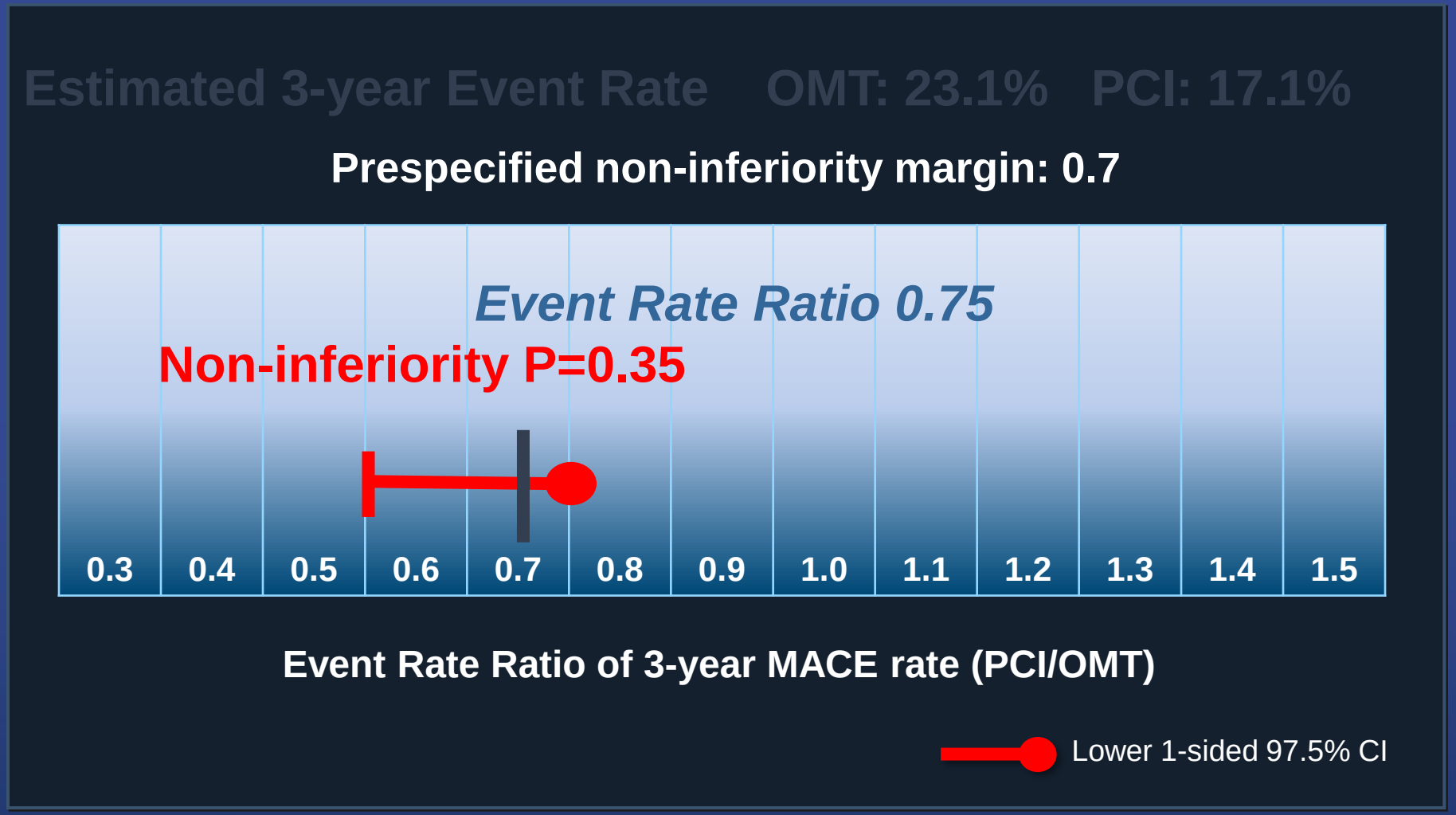
(Death, MI, Stroke, Any Repeat Revascularization)



As Treated Analysis

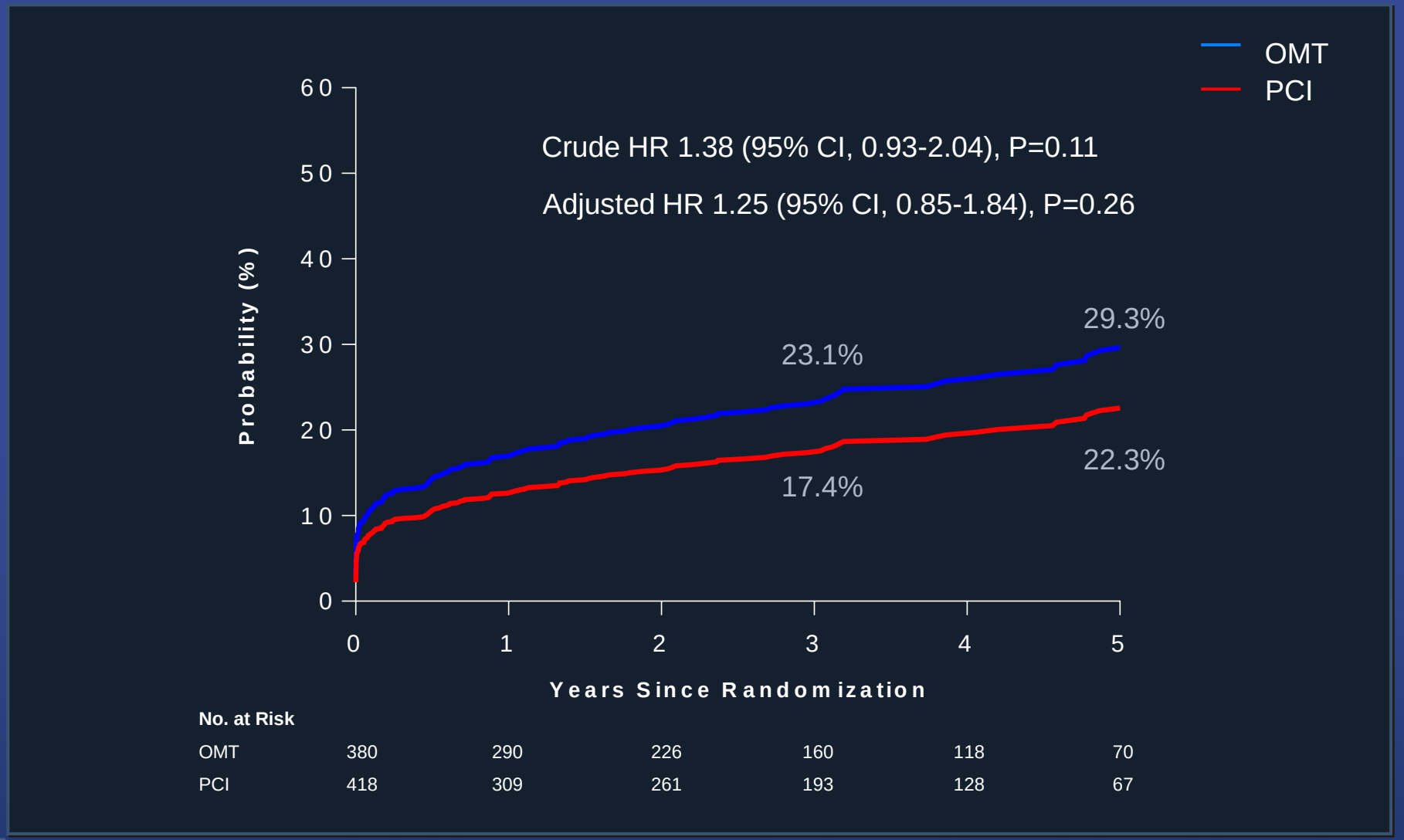
Noninferiority Test for
Primary End Point at 3-Year

As-Treated Population



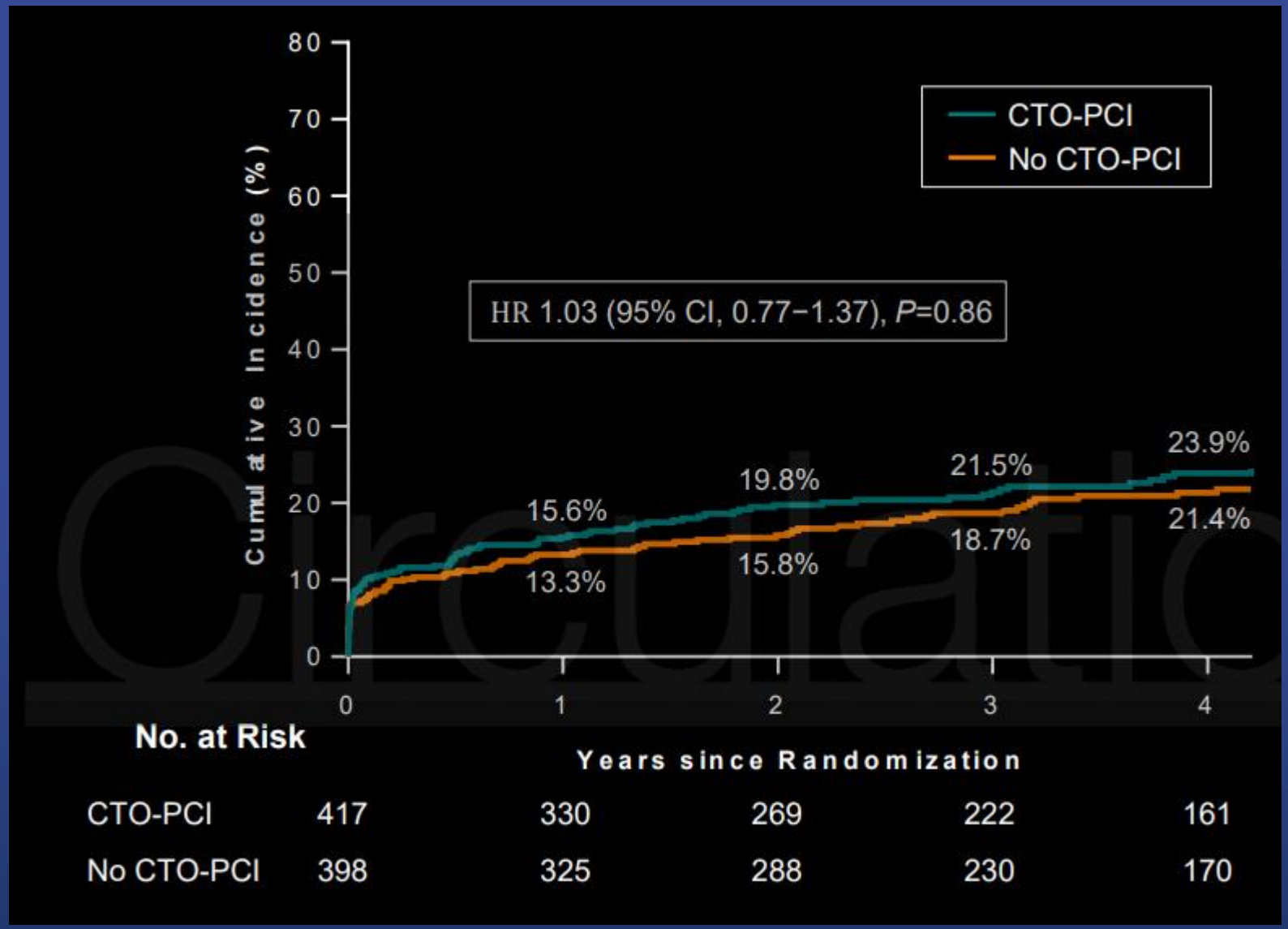
Primary End Point

(Death, MI, Stroke, Any Repeat Revascularization)



Primary End Point

(Death, MI, Stroke, Any Repeat Revascularization)



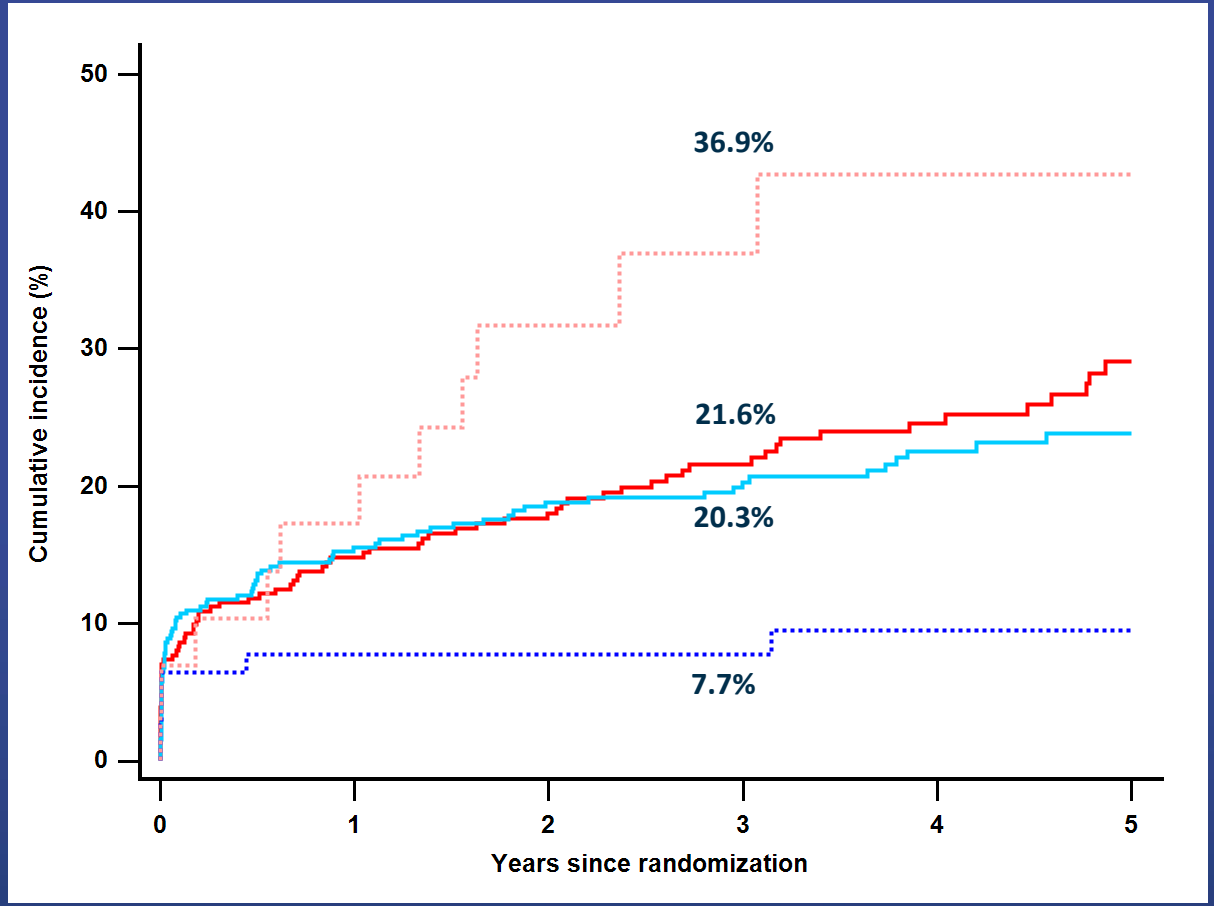
Intention-to-Treat Analysis

	CTO-PCI (n=417)	No CTO-PCI (n=398)	Crude HR (95% CI)	*P* value
Primary endpoint Death, MI, stroke, or any revascularization	93 (22.3)	89 (22.4)*	1.03 (0.77-1.37)	0.86
Secondary endpoints				
Death	15 (3.6)	21 (5.3)	0.70 (0.36-1.37)	0.30
Cardiac cause	8 (1.9)	14 (3.5)	0.56 (0.24-1.34)	0.19
Noncardiac cause	7 (1.7)	7 (1.8)	0.99 (0.35-2.82)	0.99
Myocardial infarction	47 (11.3)	34 (8.5)	1.39 (0.90-2.15)	0.14
Periprocedural MI	41 (9.8)	30 (7.5)	1.37 (0.816-2.18)	0.19
Spontaneous MI	7 (1.7)	7 (1.8)	0.88 (0.30-2.57)	0.82
Stroke	6 (1.4)	10 (2.5)	0.61 (0.23-1.65)	0.33
Any revascularization	46 (11.0)	42 (10.6)	1.14 (0.75-1.73)	0.55
CTO vessel	33 (7.9)	30 (7.5)	1.13 (0.69-1.84)	0.63
Non-CTO vessel	29 (7.0)	23 (5.8)	1.34 (0.77-2.31)	0.30
Death, MI, or stroke	66 (15.8)	61 (15.3)	1.07 (0.75-1.51)	0.72
Cardiac death, MI, stroke, or any revascularization	86 (20.6)	82 (20.6)	1.02 (0.76-1.39)	0.88
Death, spontaneous MI, stroke, or any revascularization	64 (15.3)	69 (17.3)	0.91 (0.65-1.30)	0.59

The Assigned and Actually Treated Strategies

Primary endpoint analyses

Stratified by the assigned and actual strategy



PCI to MT strategy

MT to MT strategy

PCI to PCI strategy

MT to PCI strategy

PCI to PCI	384	306	254	210	152	98
PCI to MT	29	25	16	13	10	8
MT to PCI	78	70	65	59	46	30
MT to MT	313	257	224	172	125	78

The Assigned and Actually Treated Strategies

	Estimated 3 Year Event Rate (Standard Error)	Adjusted HR (95% CI)	P Value
PCI to PCI	19.0% (2.1)	0.91 (0.61-1.34)	0.62
PCI to OMT	29.3% (5.8)	1.37 (0.80-2.34)	0.25
OMT to PCI	9.5% (4.2)	0.45 (0.19-1.09)	0.077
OMT to OMT	21.9% (3.3)	1 (Reference)	

Conclusion

- The DECISION-CTO trial is the first randomized clinical trial to compare the strategy of OMT alone with that of PCI in patients with coronary CTO.
- The ITT analysis showed that OMT as an initial strategy was non-inferior to PCI with respect to the primary endpoint of the composite of death, MI, stroke, or any revascularization at 3 years.
- The measures of health-related quality of life in the OMT and the PCI groups were comparable throughout the follow-up period

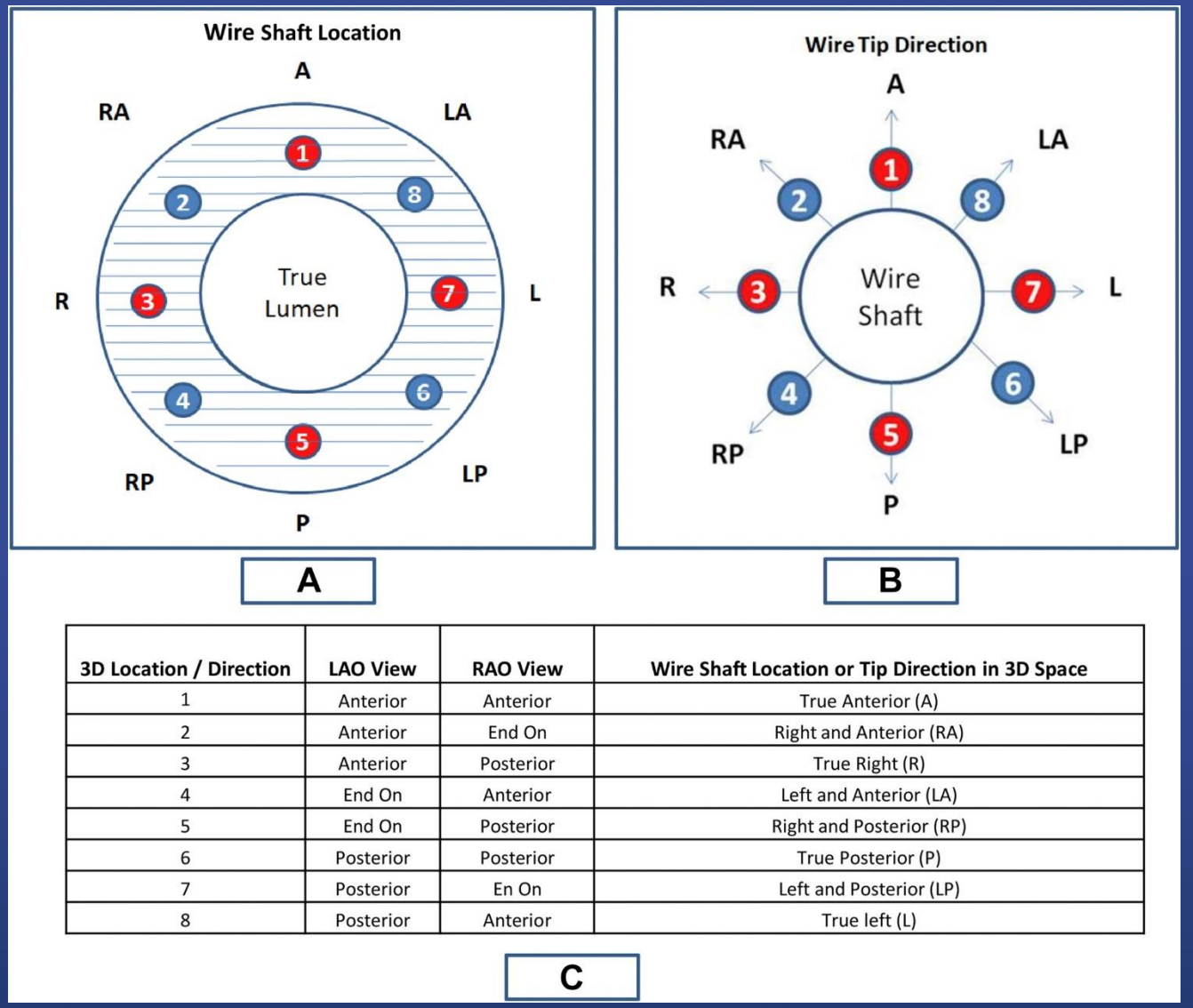
Conclusion

- However, SAQ angina frequency subscale is much better in terms of improvement more than 10 points in PCI arm, which suggest PCI strategy is more beneficial effect in angina control in CTO patients.

- However, despite statistical no difference, we did not provide firm conclusion for role of medical treatment strategy in the CTO patients due to early termination and lower enrolment than anticipated.

- There is a signal for role of medical treatment, but further randomized clinical trials are necessary.

3D wiring in CTO intervention

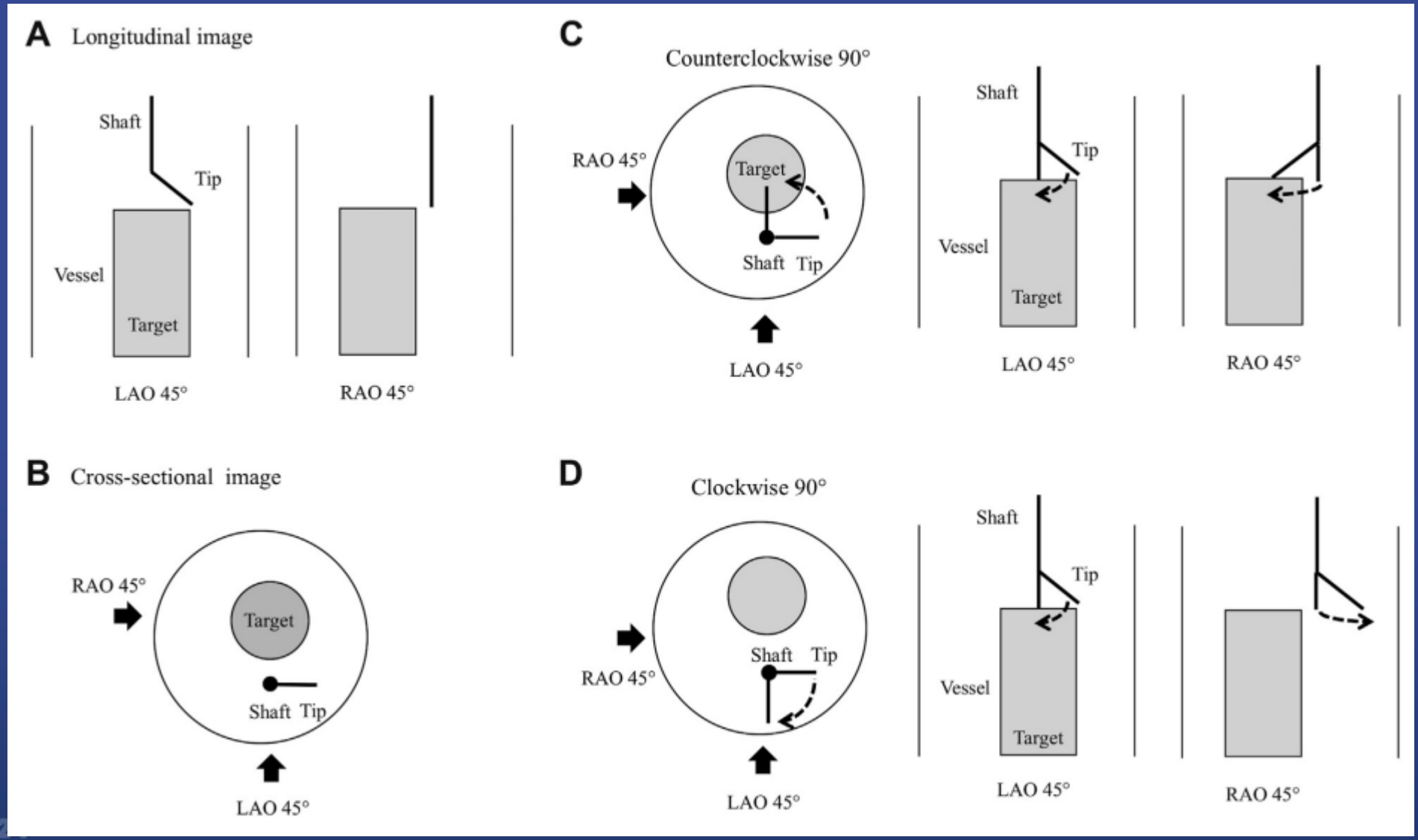


3D Location / Direction	LAO View	RAO View	Wire Shaft Location or Tip Direction in 3D Space
1	Anterior	Anterior	True Anterior (A)
2	Anterior	End On	Right and Anterior (RA)
3	Anterior	Posterior	True Right (R)
4	End On	Anterior	Left and Anterior (LA)
5	End On	Posterior	Right and Posterior (RP)
6	Posterior	Posterior	True Posterior (P)
7	Posterior	En On	Left and Posterior (LP)
8	Posterior	Anterior	True left (L)

C

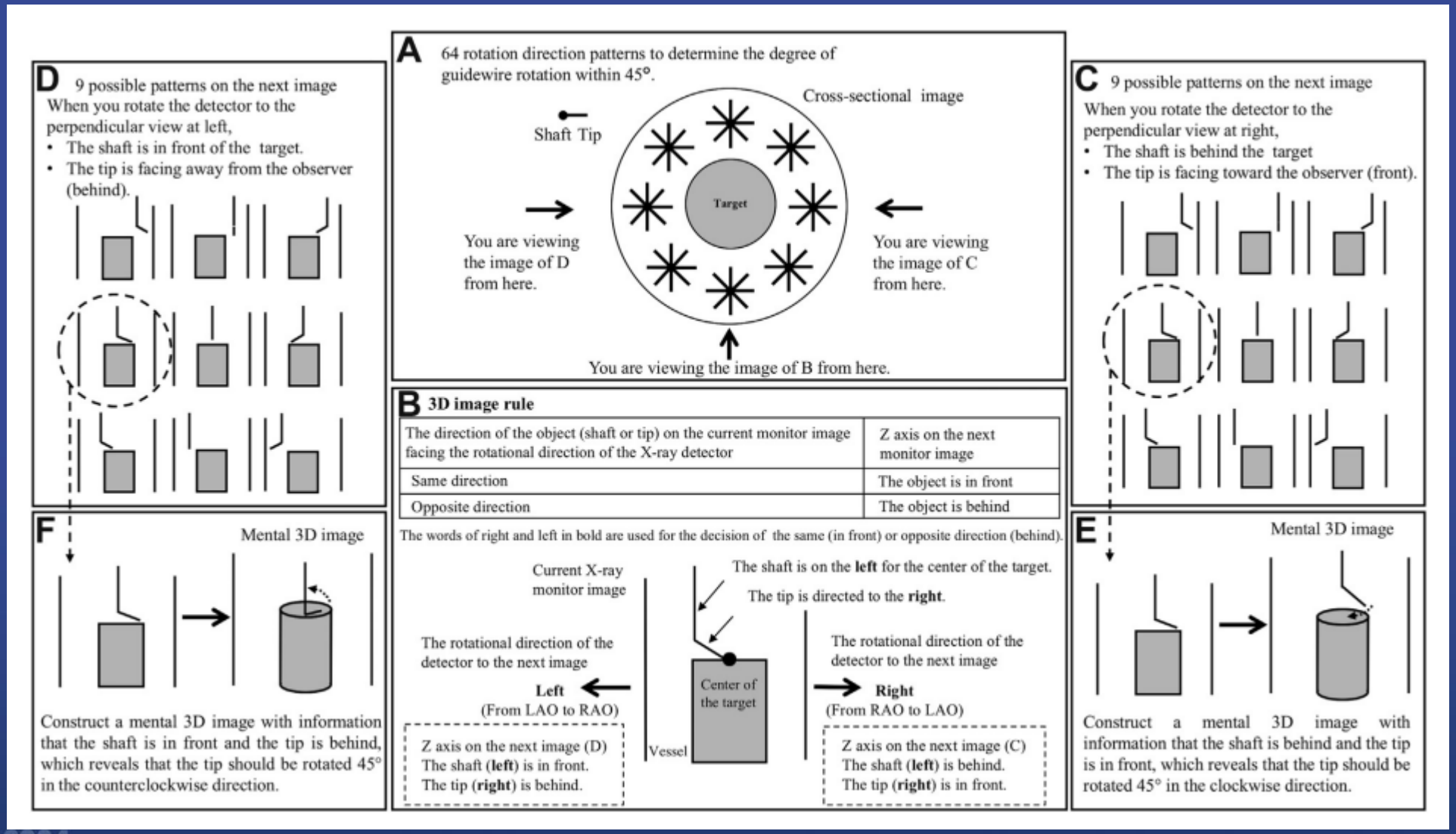
J Am Coll Cardiol Intv 2021 Apr, 14(7) 803-806

Efficacy and Feasibility of the 3D wiring for CTO PCI



JACC Cardiovasc Interv 2019 Mar 25;12(6);545-555

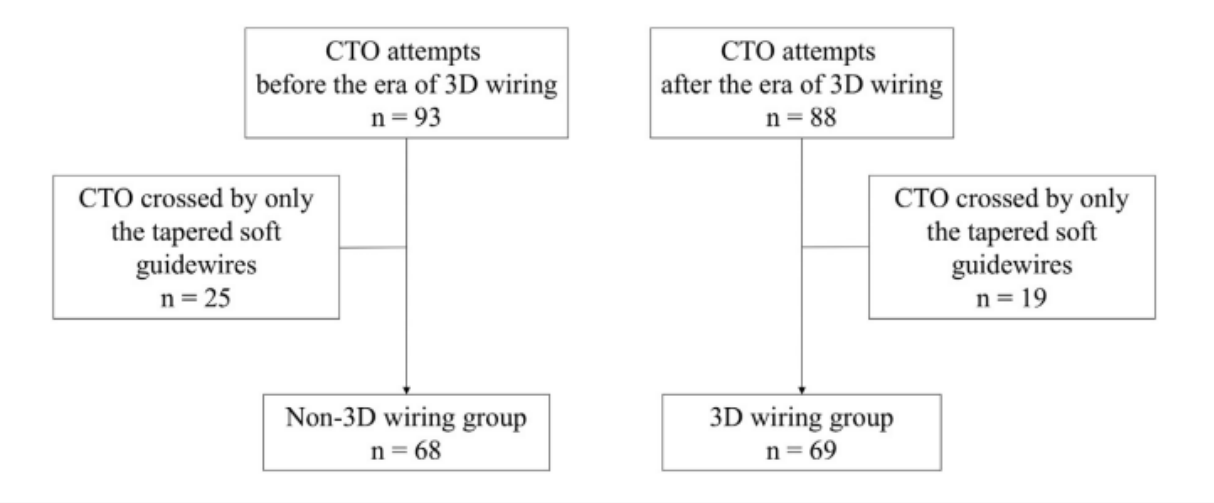
Efficacy and Feasibility of the 3D wiring for CTO PCI



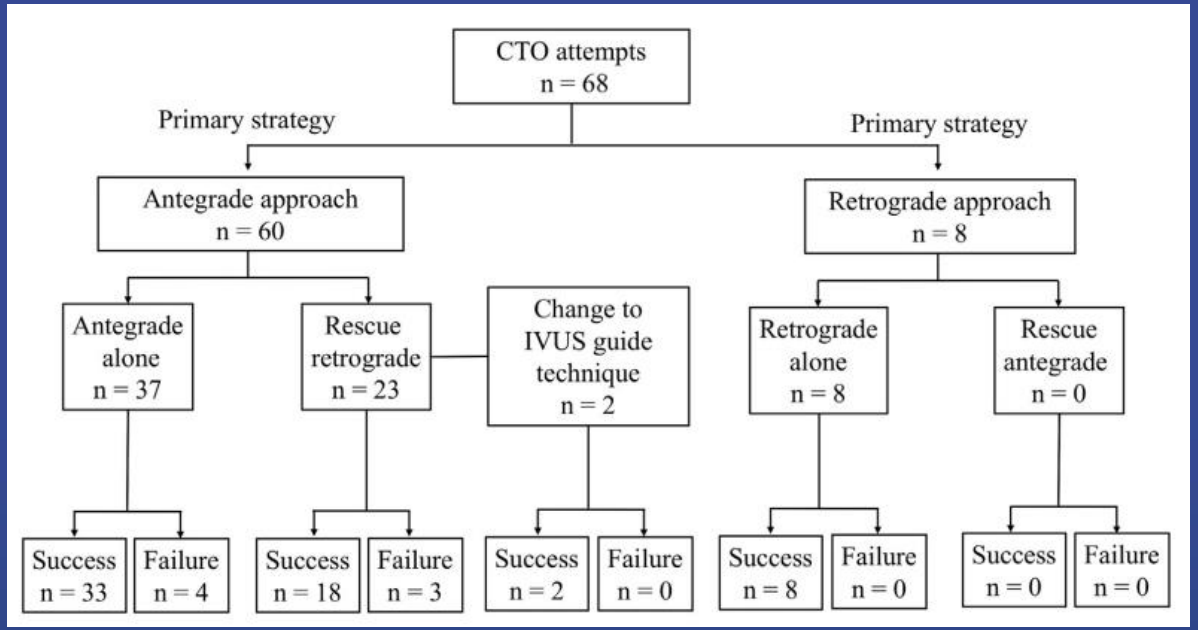
JACC Cardiovasc Interv 2019 Mar 25;12(6);545-555

Efficacy and Feasibility of the 3D wiring for CTO PCI

Study Population



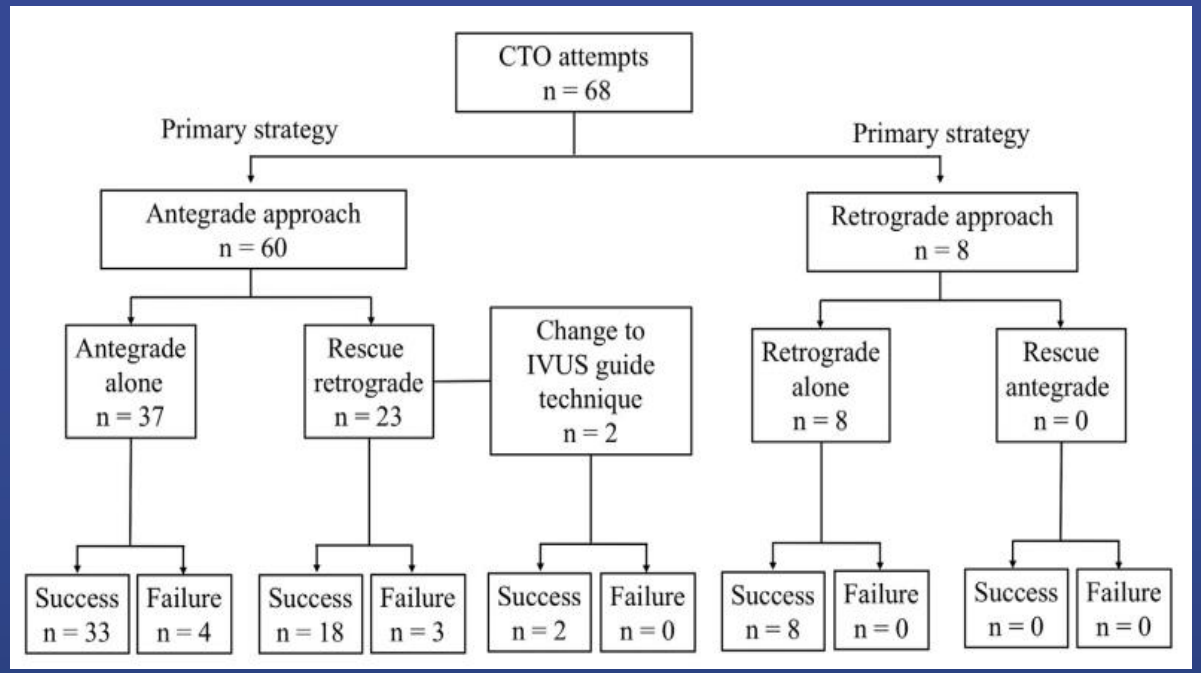
Flow Diagram of the Procedure in the Non-3D Wiring Group



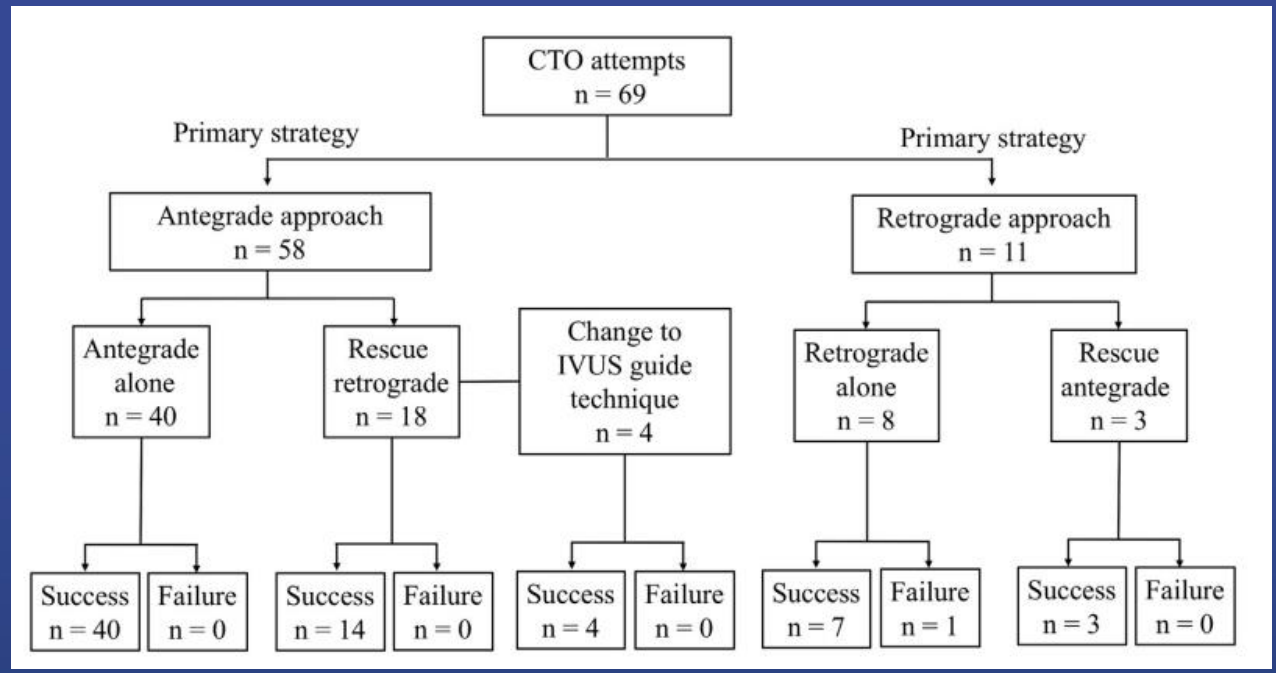
JACC Cardiovasc Interv 2019 Mar 25;12(6);545-555

Efficacy and Feasibility of the 3D wiring for CTO PCI

Flow Diagram of the Procedure in the Non-3D Wiring Group

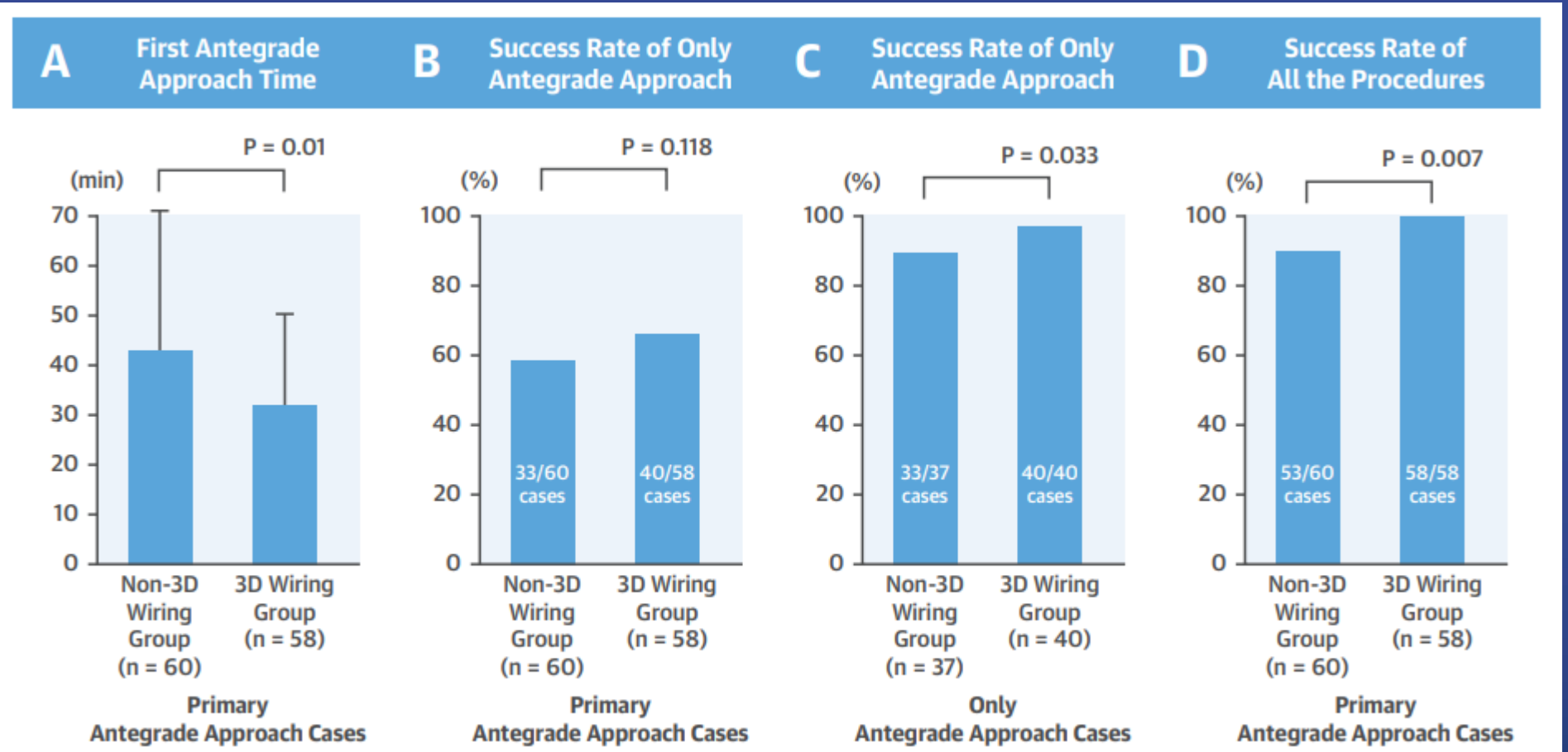


Flow Diagram of the Procedure in the 3D Wiring Group



JACC Cardiovasc Interv 2019 Mar 25;12(6);545-555

Efficacy and Feasibility of the 3D wiring for CTO PCI



Tanaka, T. et al. J Am Coll Cardiol Intv. 2019;12(6):545-55.

JACC Cardiovasc Interv 2019 Mar 25;12(6);545-555