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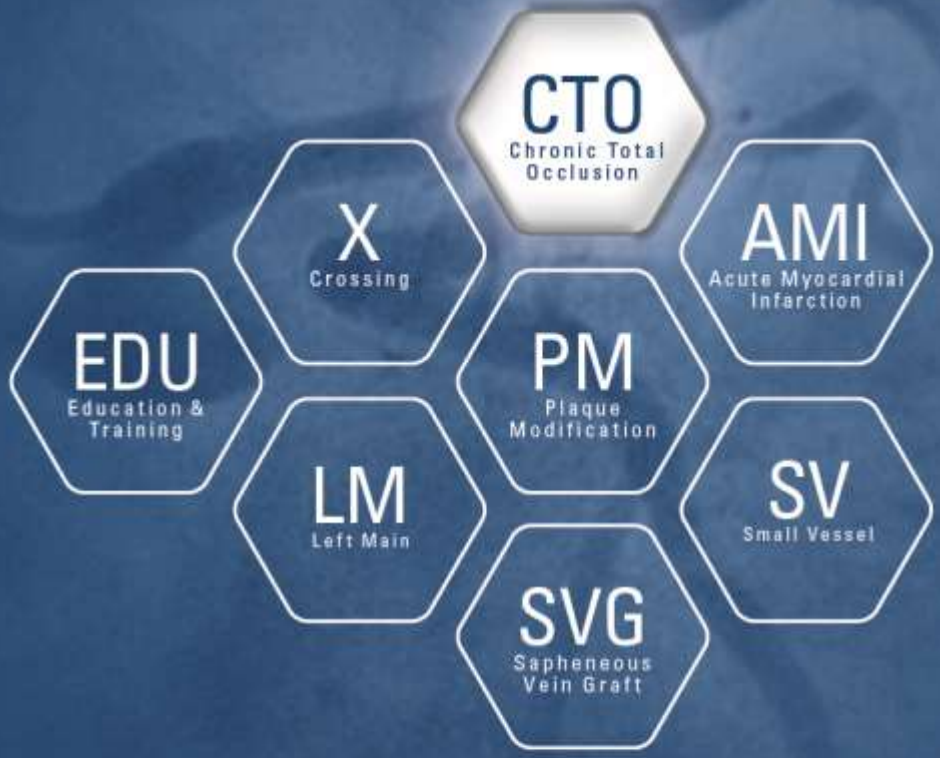
MASTER THE COMPLEX

Optimizing revascularization through innovation, training, and education.



Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations. Information not intended for distribution in France.

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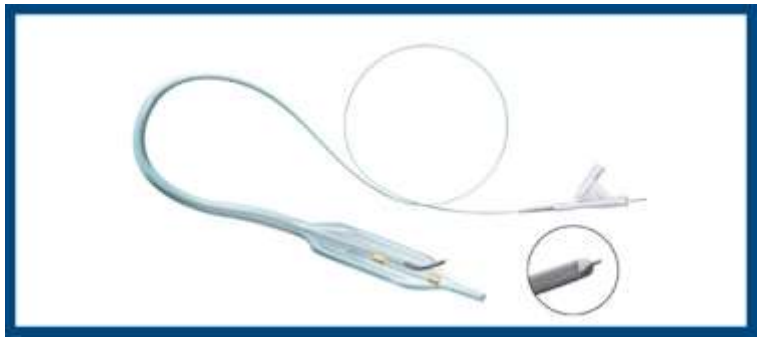
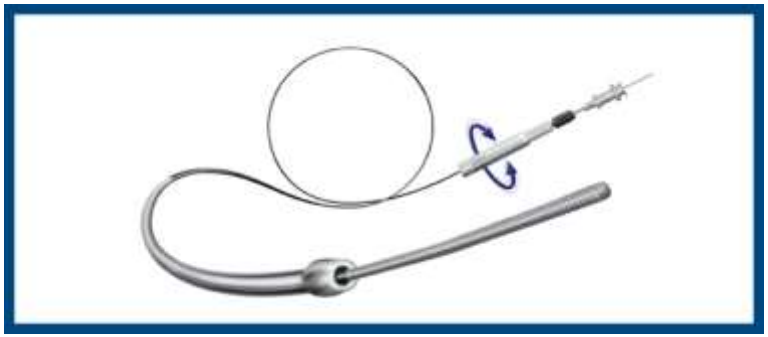
The CrossBoss™ and Stingray™LP Coronary Crossing Catheters, an exciting part of the hybrid approach





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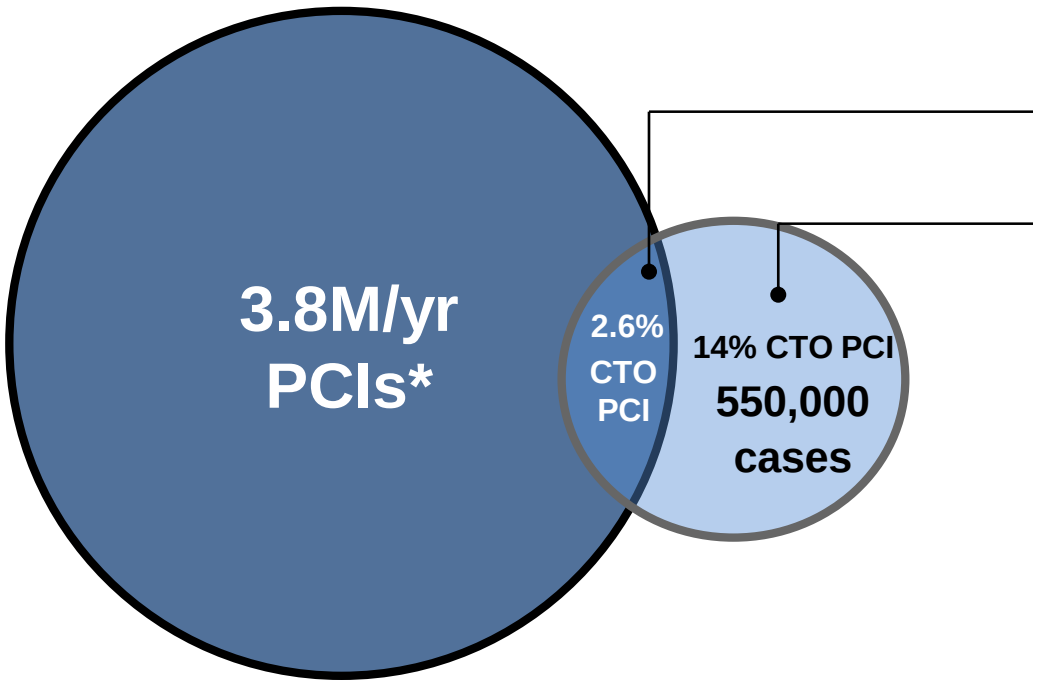
CTO Prevalence

- Patients with CTOs are frequently left unrevascularized due to perceptions of high failure rates and technical complexity even if they have symptoms of coronary disease or ischemia.[1]
- PCI market growth opportunity is 550,000 clinically eligible patients



	CTO PCIs	Success Rates	# of successful cases	Failed Attempts
Real-world Registries **	98,800	60%	59,280	39,520
Potential Growth***	550,000	90%	495,000	55,000

**In real world registries, 2.6% CTO PCI. 60% success rate = 39,520 failed CTO attempts

***14.5% of Japan PCI volume is CTO clinically eligible patients

Sources: * Boston Scientific Internal Estimate

** ARRIVE 1, ARRIVE 2, SCAR, eCypher real-world registries

*** Japan PCI CTO report

[1] Brilakis ES, et.al., JACC Cardiovasc Interv 2012 Apr, 5(4): 357-7933

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Advancing the Treatment of Coronary CTOs

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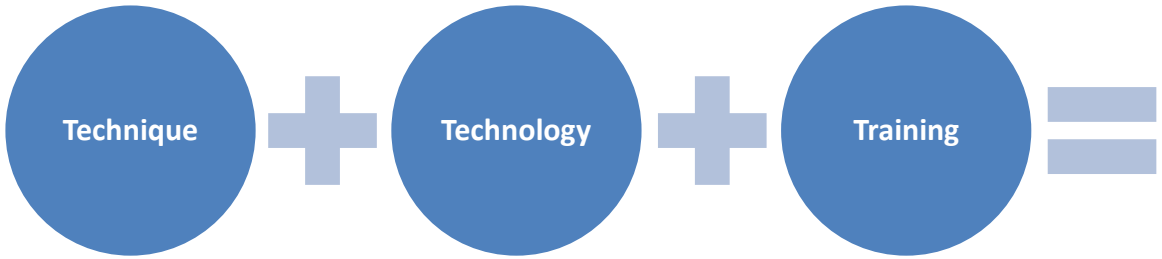
CTOs occur in as many as 30% of patients with significant CAD. With successful CTO intervention, patients typically experience immediate and dramatic symptom relief. Despite that, they are the lesion subset that is least likely to be treated.[1-3]

Through training on the Hybrid Approach to CTO PCI and new technologies, including the CrossBoss™ and Stingray™ CTO Crossing and Re-Entry System, **Boston Scientific is advancing the treatment of coronary CTOs around the globe.**



1. Piedmont Heart Institute Hosts Chronic Total Occlusion Workshop. Piedmont Healthcare website. http://www. piedmontphysicians.org/PHI/News/Piedmont-Heart-Institute-Hosts-Chronic-Total-Occlu-952.aspx. Posted September 12, 2011. Accessed June 26, 2013. 2. Garratt, K. Chronic Total Occlusion of the CoronaryArtery. Centers for Disease Control and Prevention, US Dept of Health and Human Services; 2006. 3. Christofferson RD, Lehmann KG, Martin GV, Every N, Caldwell JH, Kapadia SR. Effect of chronic total coronary occlusion on treatment strategy. Am J Cardiol. 2005;95:1088-1091.

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Historical Barriers to CTOs are being removed with new Data and Devices

Historical Barriers

- Procedure time
- Procedural complexity
- Inconsistency in approach
- Variable success rates
- Cost of the procedures
- Clinical justification

New Devices, Techniques & Data[1-3]

- Hybrid Approach
- CrossBoss™ & Stingray™ Coronary Crossing and Re-entry Devices
- Hybrid CTO Registry Data
- Piedmont Economics Study
- Updated ACC/AHA/SCAI and Appropriate Use Criteria Guidelines

1. Piedmont Heart Institute Hosts Chronic Total Occlusion Workshop. Piedmont Healthcare website. http://www. piedmontphysicians.org/PHI/News/Piedmont-Heart-Institute-Hosts-Chronic-Total-Occlu-952.aspx. Posted September 12, 2011. Accessed June 26, 2013. 2. Garratt, K. Chronic Total Occlusion of the Coronary Artery. Centers for Disease Control and Prevention, US Dept of Health and Human Services; 2006. 3. Christofferson RD, Lehmann KG, Martin GV, Every N, Caldwell JH, Kapadia SR. Effect of chronic total coronary occlusion on treatment strategy. Am J Cardiol. 2005;95:1088-1091.

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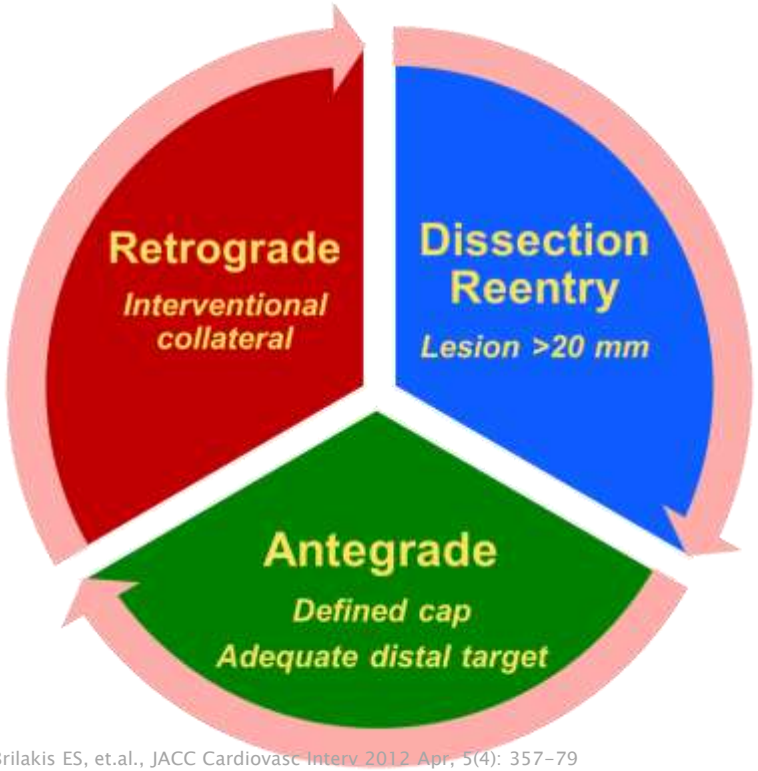
The Hybrid Strategy for CTOs

- Establishes a consistent framework that can be used to evaluate patients considered for CTO PCI
- Emphasizes procedural success and efficiency, using the least amount of radiation, contrast, and equipment
- Quick transition to alternate plans when failure mode occurs;
  Always make progress – don't let case stall



4 angiographic characteristics dictate strategy:

1. Is the proximal cap clear by angio +/- IVUS or ambiguous?
2. Lesion length < or ≥ 20mm
3. Quality of distal target
4. Suitability of "interventional" collaterals

Brilakis ES, et.al., JACC Cardiovasc Interv 2012 Apr; 5(4): 357-79

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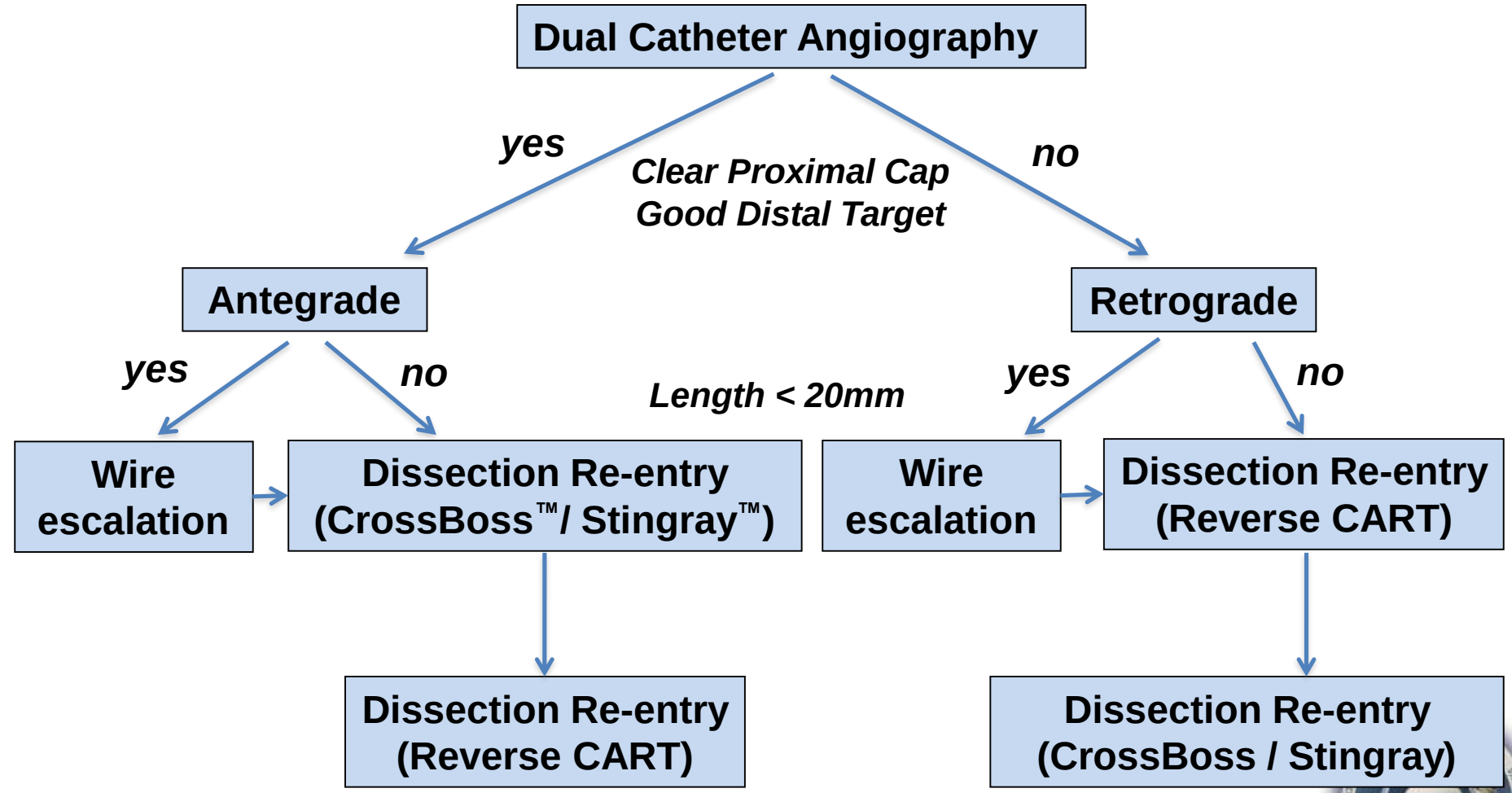
Hybrid Algorithm for CTO-PCI



Brilakis ES, et.al., JACC Cardiovasc Interv 2012 Apr, 5(4): 357–79

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CrossBoss™ Coronary CTO Crossing Catheter

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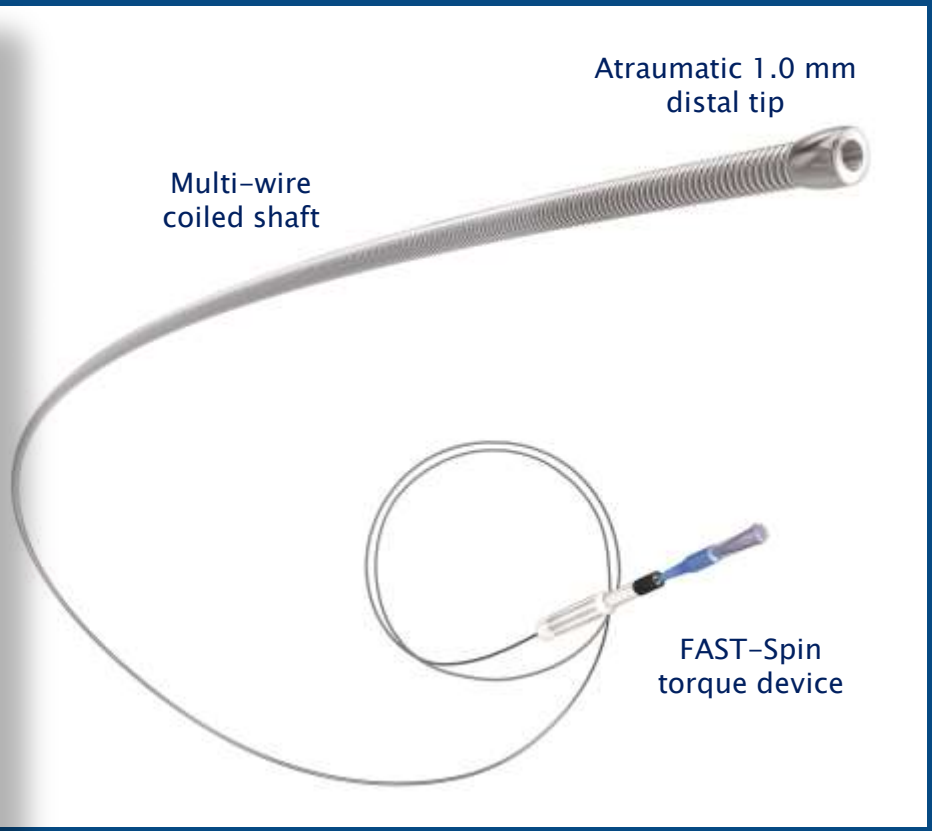
The CrossBoss Catheter is designed to quickly and safely deliver a guidewire via true lumen or subintimal pathways in coronary arteries

- Fast-Spin torque device allows rapid rotation of the catheter to facilitate crossing
- Multi-wire coiled shaft provides precise turn-for-turn torque response
- Atraumatic, rounded tip reduces risk of perforation
- 0.014" (0.36mm) guidewire compatible
- 6F (2.0mm) guide catheter compatible



Stingray™ LP CTO Balloon Re-Entry Device

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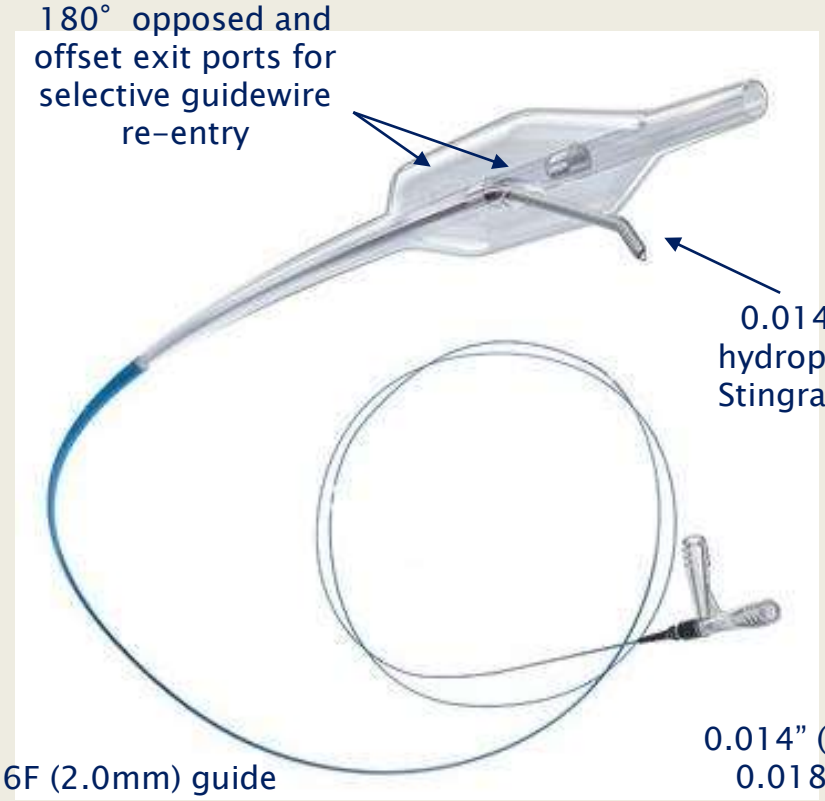
The Stingray LP System (catheter and guidewire) is designed to accurately target and re-enter the true lumen from a subintimal position in coronary arteries*



- Self-orienting, flat balloon hugs the vessel, automatically positioning one exit port toward the true lumen
- 3.2F (1.07mm) shaft diameter
  - •Trap in 7F (2.33mm) guide
  - •STRAW in 8F (2.67mm) guide
- Stingray Guidewire's angled tip and distal probe are designed for facilitated re-entry into the true lumen
- 2 radiopaque marker bands for exact placement

*Stingray LP DFU, Directions For Use

Stingray™ LP CTO Balloon Re-Entry Device

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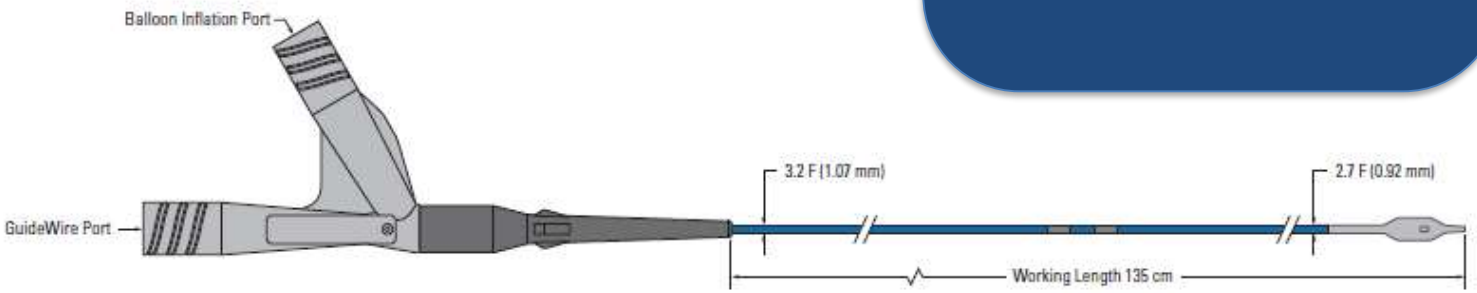
	Stingray (old)	Stingray LP (new)
Proximal Shaft	n/a	Emerge-based design (blue)
Proximal Shaft OD	3.7F (1.22mm)	3.2F (1.07mm)
Distal Shaft OD	2.9F (0.97mm)	2.7F (0.92mm)
Balloon Dimensions	2.5mm x 10mm	No change
Exit Ports	180° opposed & offset for selective GW re-entry	No change
Marker band	2 radiopaque marker bands for exact placement	No change

Design Goal

1. **Improved pushability***
2. **Low profile to enable use in 7F (2.33mm) trapping technique and 8F (2.67mm) STRAW**



* Data on file BSC

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Procedural Details

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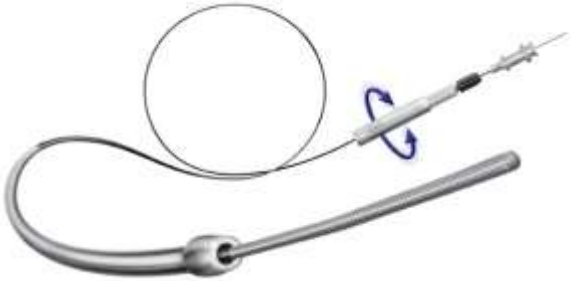
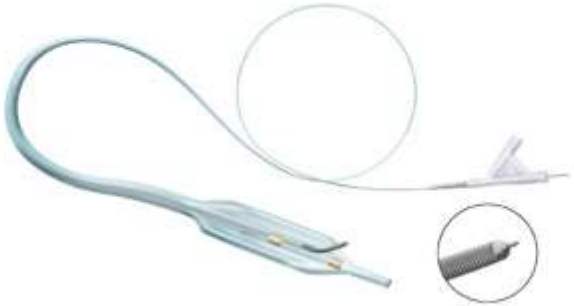
CrossBoss™ Catheter



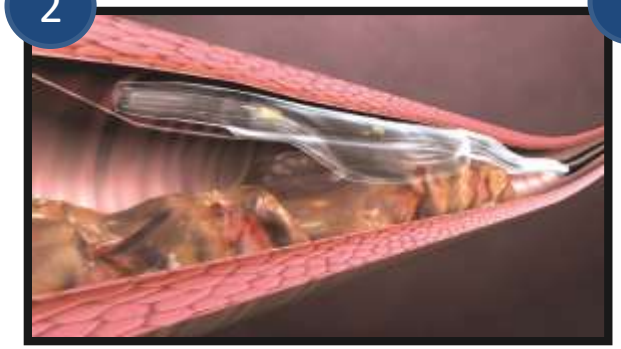
Stingray™ Catheter



1. **CrossBoss Catheter:** Designed to quickly and safely deliver a guidewire via true lumen or subintimal pathways
2. **Stingray Catheter:** Designed to accurately target and re-enter the true lumen from a subintimal position
3. **Stingray Guidewire:** Angled tip and distal probe are designed for facilitated re-entry into the true lumen

1

2



3

Guidewire trapping technique*

Simultaneous use of two balloon catheters in a guide catheter for the use of guidewire securement (Guidewire Trapping Technique):

Bench testing has shown that one Stingray LP Catheter and one 3.0 mm x 20 mm (or smaller) MR balloon catheter with a max shaft OD of 0.036 in /0.91mm/ 2.73F can be inserted simultaneously into a 7F (minimum 0.080 in /2.03mm ID) guide catheter.

Care should be used when attempting to use two balloon catheters simultaneously in a guide catheter; this technique was not clinically evaluated for safety and effectiveness in a clinical trial. Balloon catheters with a diameter greater than those mentioned have not been tested for simultaneous use in a single guide catheter.

*Stingray LP DFU, Directions For Use

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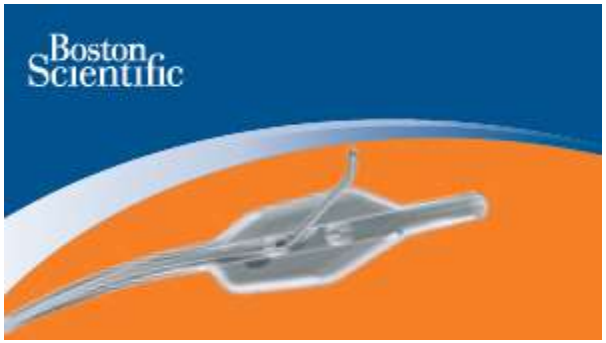
Stingray™ LP and CrossBoss™ ordering information

Product	UPN	GTIN
Stingray™ LP	H749393130SR0	08714729903369
Stingray™ Guidewire, 300cm	H749M3004B0	08714729837473
Stingray™ Guidewire Extension	H749M3010B0	08714729837480
Stingray™ Guidewire, 185cm	H749M3012B0	08714729837497
CrossBoss™	H749M2000B0	08714729837466



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Hybrid CTO Registry

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Hybrid CTO Registry Design

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Hybrid Video Registry

Design

- **DESIGN:** Retrospective analysis of prospectively collected data from CTO workshops
- **OBJECTIVE:**
  - To evaluate the safety efficacy and efficiency of the Hybrid approach
  - Compare outcomes to contemporary registries
- **Definitions**
  - *Procedural Success:* TIMI ≥ 2, <30%
  - *Optimal Procedural Success:* TIMI 3, < 30%, No loss of LV side branch

194 CTO Lesions attempted between January 2011 and June 2013 in 28 clinical sites in North America and Europe

↓

Video and audio recorded cases analyzed by independent abstractors

↓

RBR/ERCTO ↔ Hybrid ↔ J-CTO

Primary Endpoints

Assess Case Complexity
Safety
Success/Efficiency
Dependence on J-CTO Score

Source: Dave Daniels, MD; TCT 2013

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Angiographic Characteristics

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Angiographic Characteristics				
	Hybrid Registry (N=193 pts, 194 lesions)	J-CTO Registry (N=498 pts, 528 lesions)	Royal Brompton Registry (N=195 pts, 269 lesions)	p
Lesion Length	29.9 ± 24.4	13.5 ± 13.0	22 (IQR 15-32)	*<0.001
Length > 20mm	63%	21%	63.1%	*<0.001 Ŧ0.44
Calcified	61%	58%	50.8%	*0.036 Ŧ 0.72
Tortuosity	31%	45%	22.1%	* 0.002 Ŧ0.06
Blunt Stump	61%	38%	47.2%	*<0.001 Ŧ 0.009
Prior Failure	16%	10%	37.9%	*0.082 Ŧ 0.10
Prior CABG	30%	10%	29.2%	*<0.001 Ŧ 0.60
*Hybrid Registry vs. J-CTO Registry, Ŧ Hybrid Registry vs Royal Brompton Registry				

Source: Dave Daniels, MD; TCT 2013

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J-CTO Score

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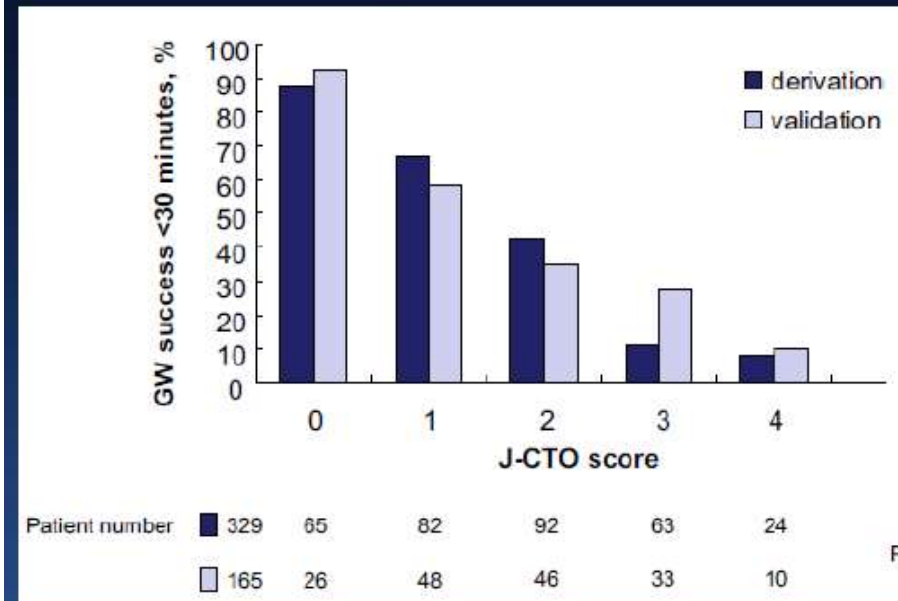
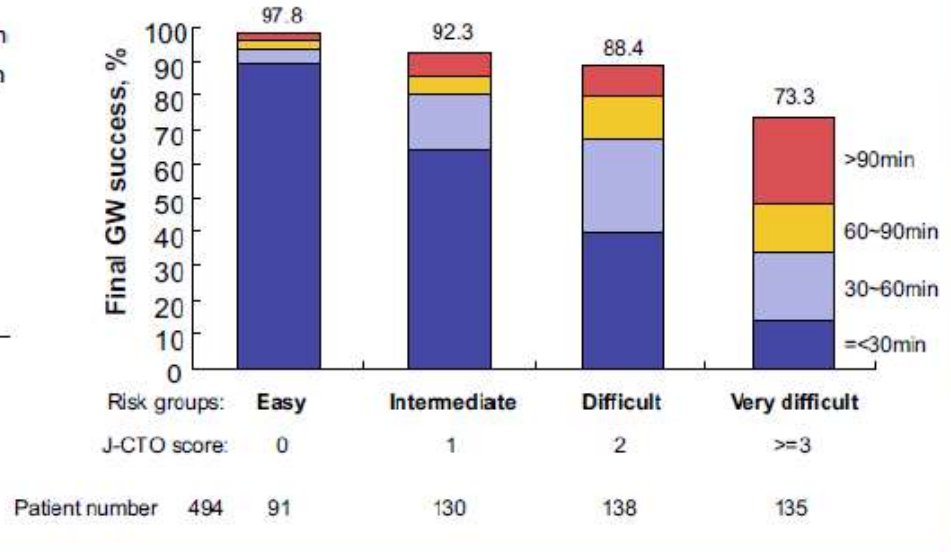
Lesion Length >20 mm | Calcification | >45 bend | Blunt stump | Prior Failure





Morino et al. JACC CI 2011;4:213-21

Source: Dave Daniels, MD; TCT 2013

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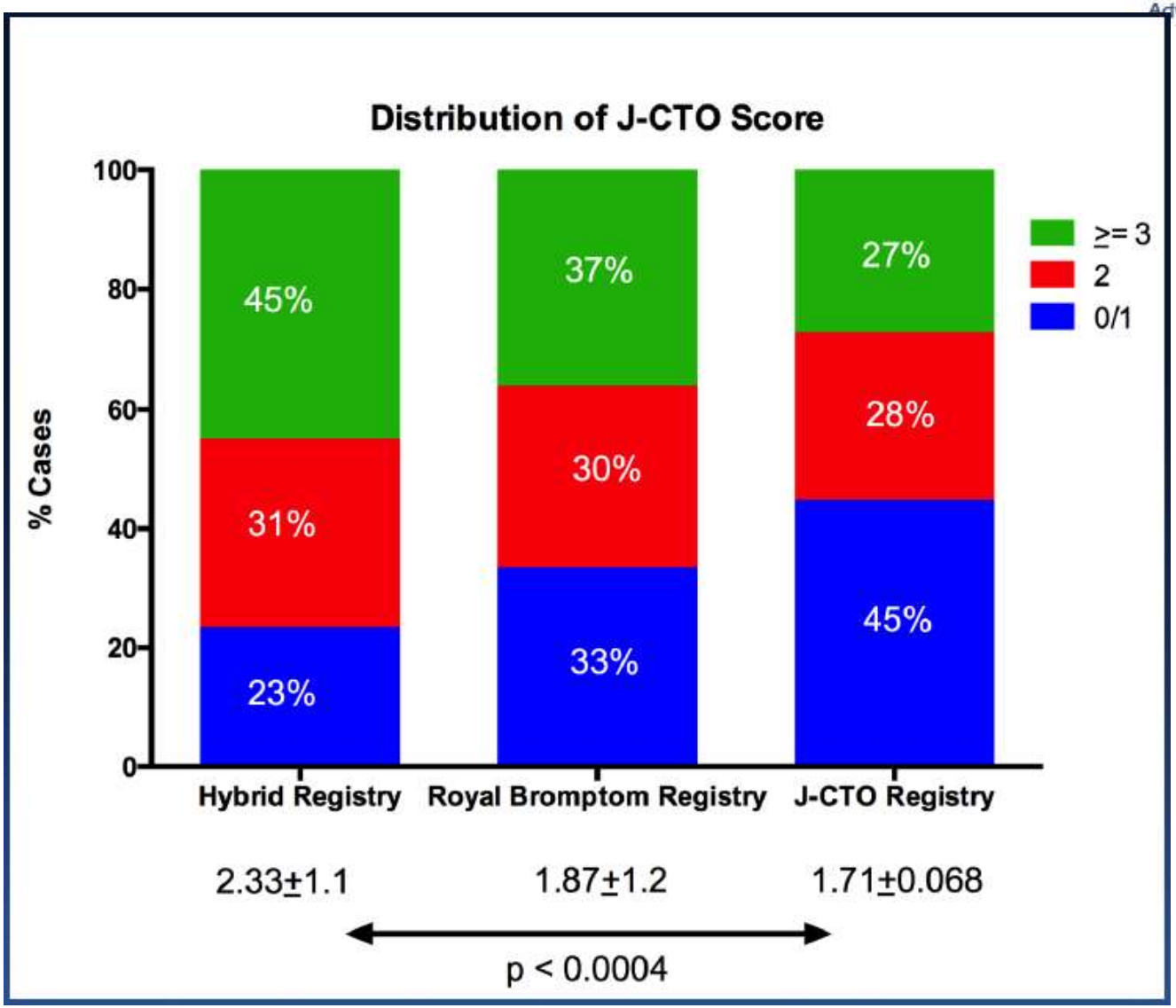
Distribution of J-CTO Score



Source: Dave Daniels, MD; TCT 2013

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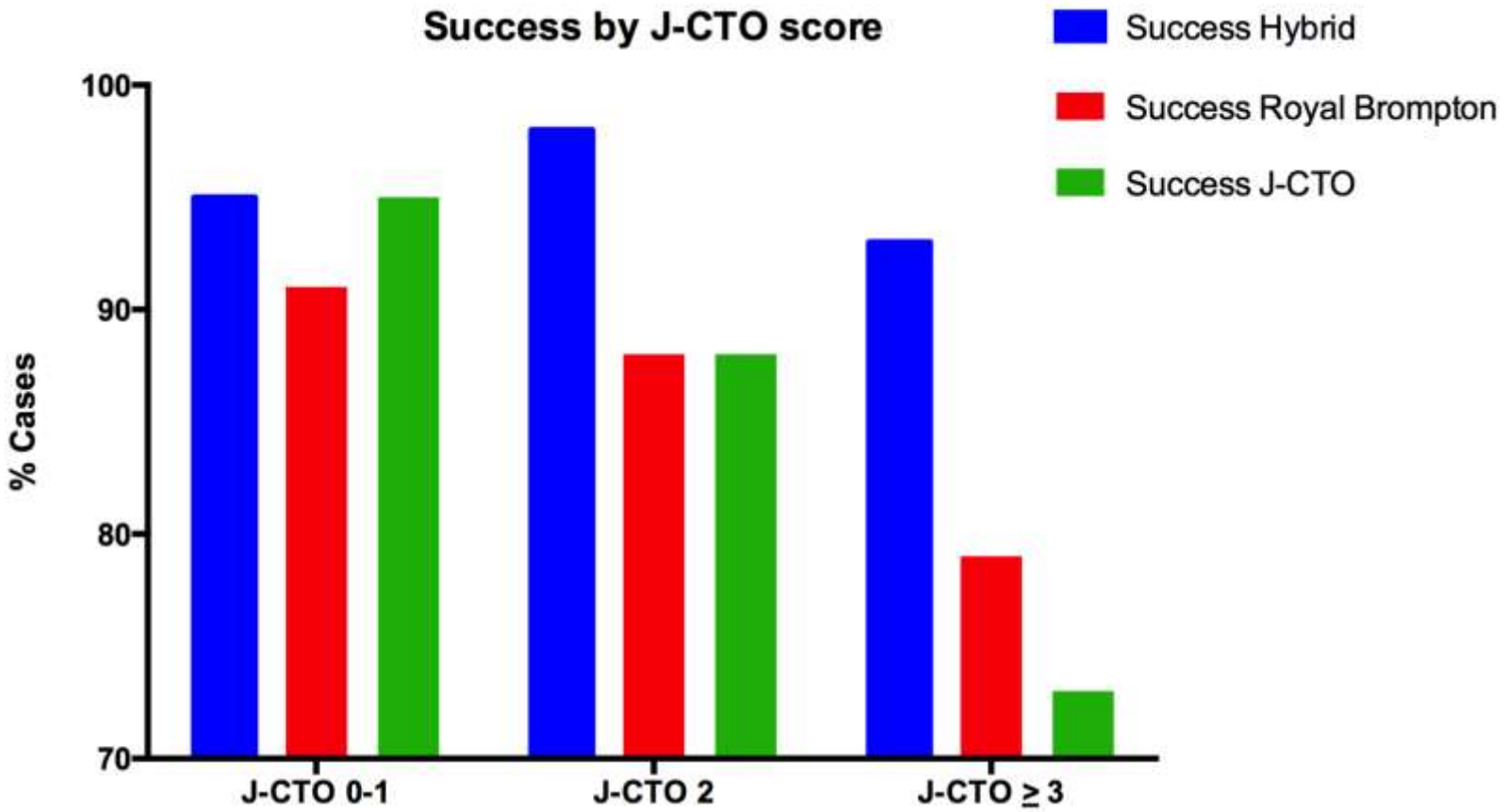
Procedural Success



Source: Dave Daniels, MD; TCT 2013

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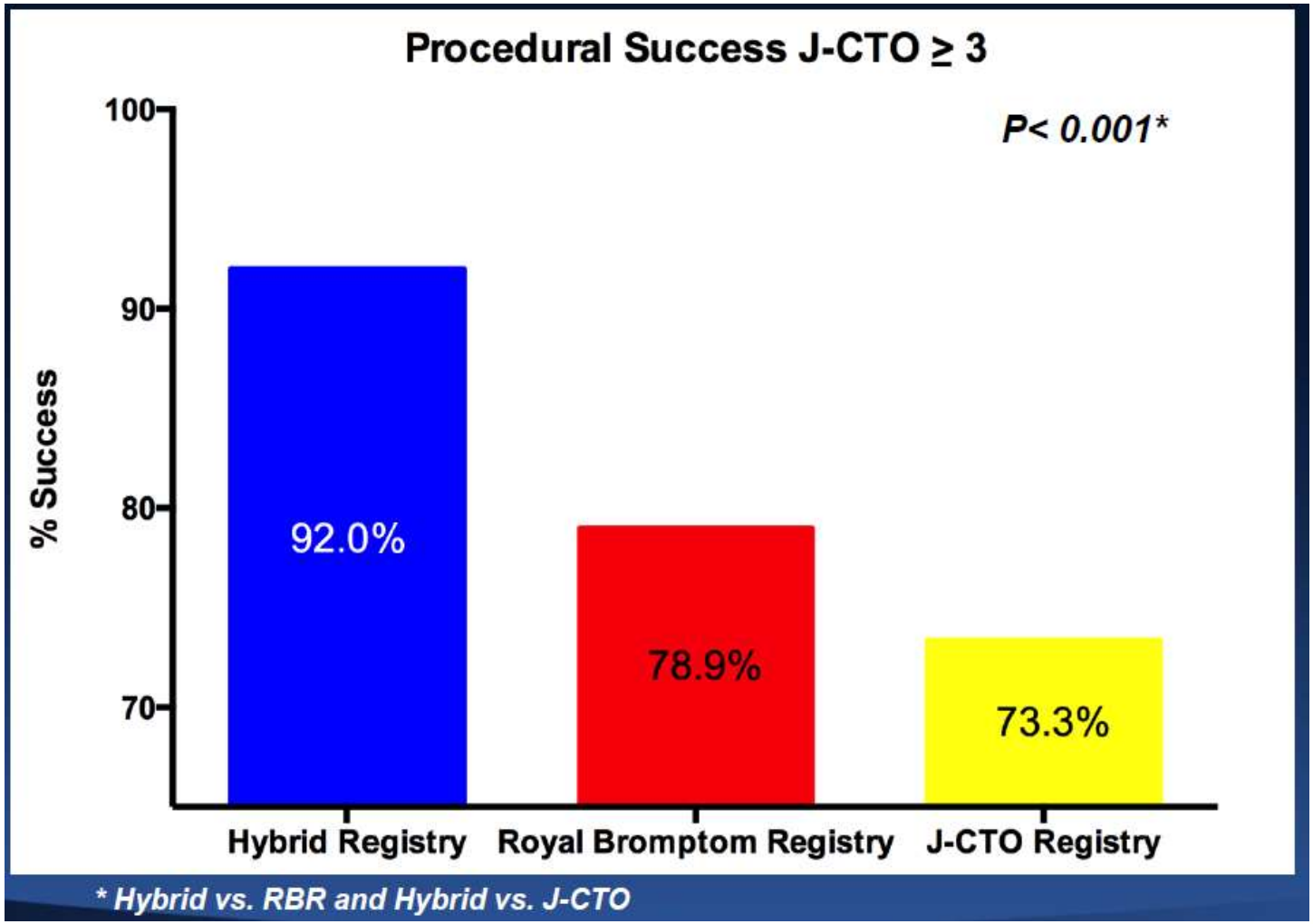
Procedural Success



Source: Dave Daniels, MD; TCT 2013

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Procedural Efficiency

- **96.6% TIMI 3 Flow**
- **90% Side Branches Intact**

	Hybrid Registry (N=193 pts, 194 lesions)	J-CTO Registry (N=498 pts, 528 lesions)	Euro CTO Registry (N=1914 pts, 1983 lesions)	p
Procedure Time (minutes)	83 ± 54	NA	105 ± 58	ŦFor="0.0001"
Contrast (cc)	272 ± 132	293	313 ± 184	Ŧ<0.0025

*Hybrid Registry vs J-CTO Registry, Ŧ Hybrid Registry vs Euro CTO Registry

Source: Dave Daniels, MD; TCT 2013

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Safety

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	Hybrid Registry (N=194 pts)	J-CTO Registry (N=498 pts)	Royal Brompton Registry (N = 195 pts)	p
Death	0%	0.4%	0%	ns
Any Perforation	6%	10%	4.6%	*0.191 ǂ0.625
Pericardiocentesis	1.7%	0.2%	1%	*0.06 ǂ0.654

*Hybrid Registry vs J-CTO Registry, ǂ Hybrid Registry vs Royal Brompton Registry

Source: Dave Daniels, MD; TCT 2013

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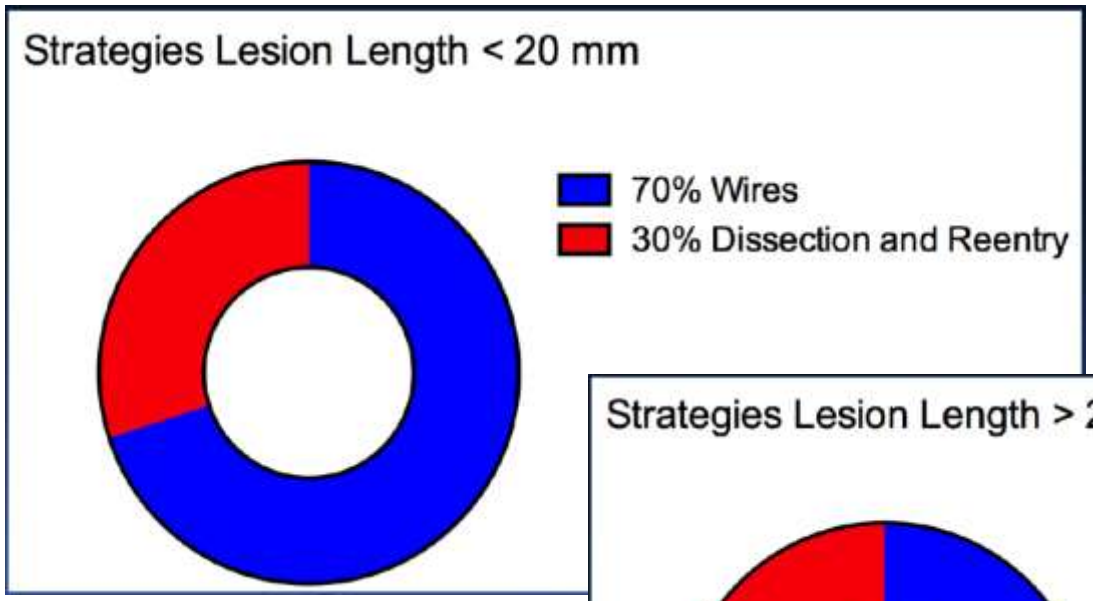
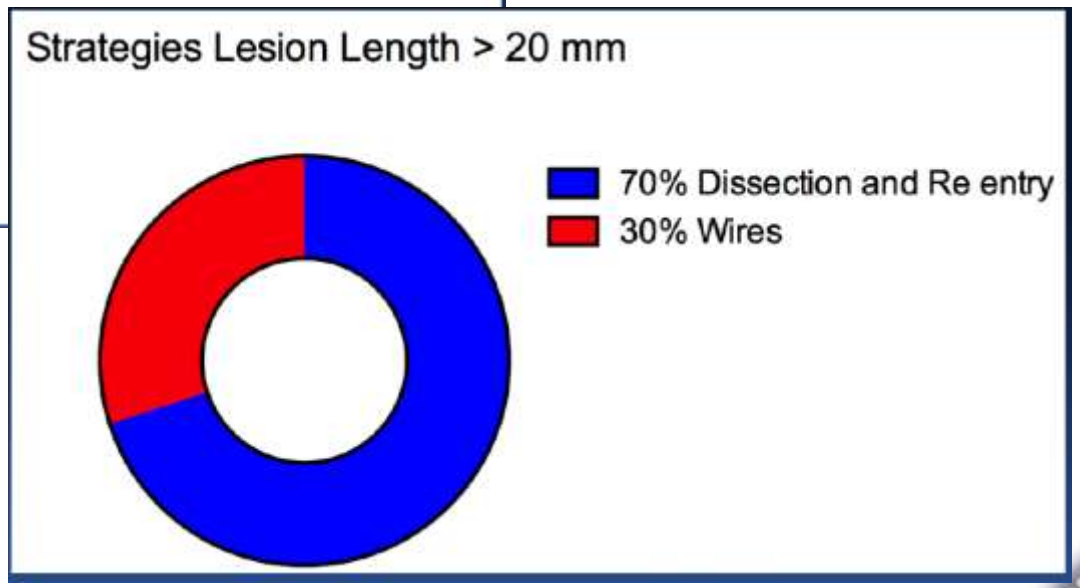
Hybrid Strategies in Short vs. Long Lesions





Source: Dave Daniels, MD; TCT 2013

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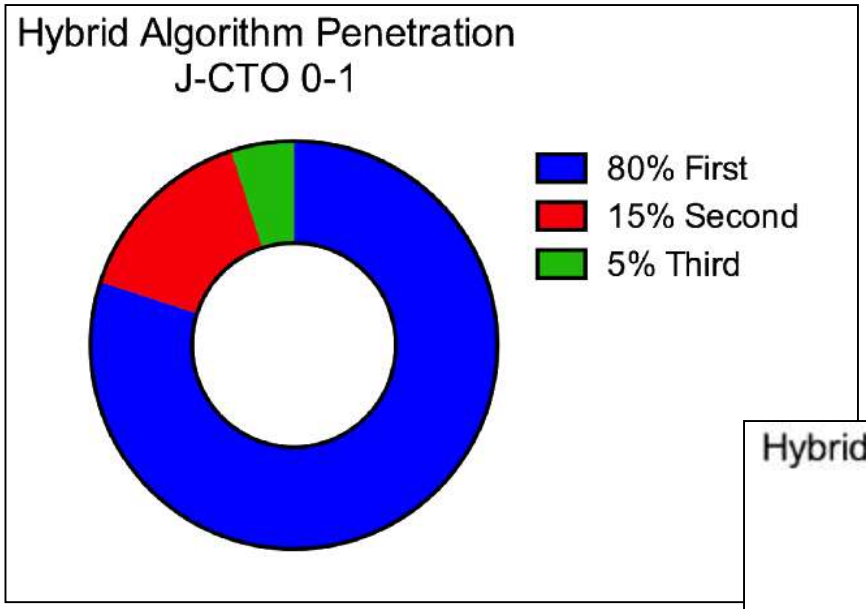
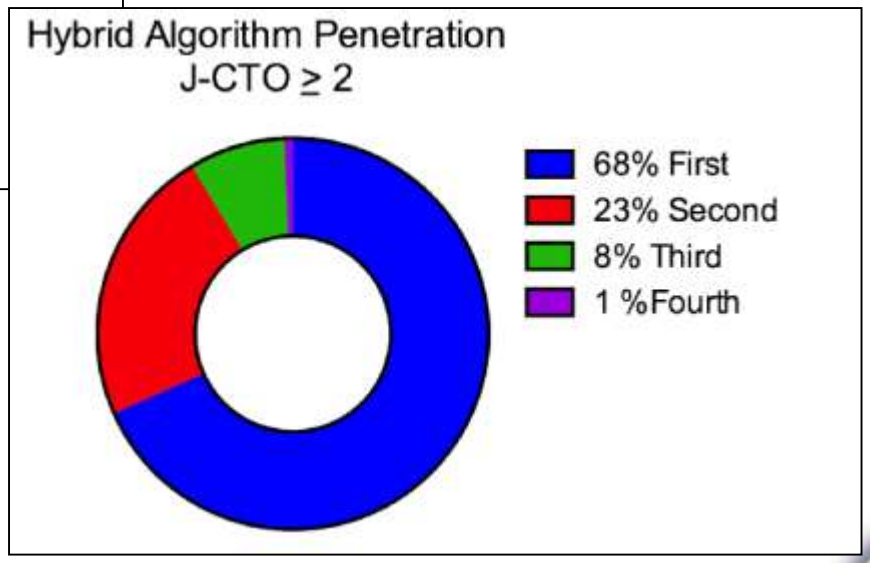
Hybrid Strategies Used by Complexity





Source: Dave Daniels, MD; TCT 2013

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FAST-CTOs Trial

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Facilitated Antegrade Steering Technique in Chronic Total Occlusions

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FAST-CTOs Study Design

Facilitated Antegrade Steering Technique in Chronic Total Occlusions Trial Summary

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Objective

- This study sought to examine the efficacy and safety of 3 novel devices to recanalize coronary chronic total occlusions (CTOs).

Study Design

- 147 Patients with 150 CTOs, 16 Centers
- Multicenter, non-randomized, IDE study
- Historically-controlled

Key Inclusion/Exclusion Criteria

Inclusion

- CTO > 3 months old refractory to wire crossing
  - Previous failed crossing attempt OR
  - Attempt to cross with wires in 10-15 min fluoro time OR
  - Subintimal guidewire during attempt to cross
- Angiographic landing zone ≥10mm proximal to major bifurcation
- Angina/ischemia caused by CTO vessel

Exclusion

- LVEF < 20%
- Vein graft or in-stent CTO in target lesion
- Allergy to aspirin or all thienopyridines
- Aorto-ostial lesion location
- Creatinine > 2.3 mg/dl
- PCI within the previous 2 weeks

- Note: no exclusion for CTO length

Whitlow PL, et.al., JACC Cardiovasc Interv 2012 Apr, 5(4): 393-401

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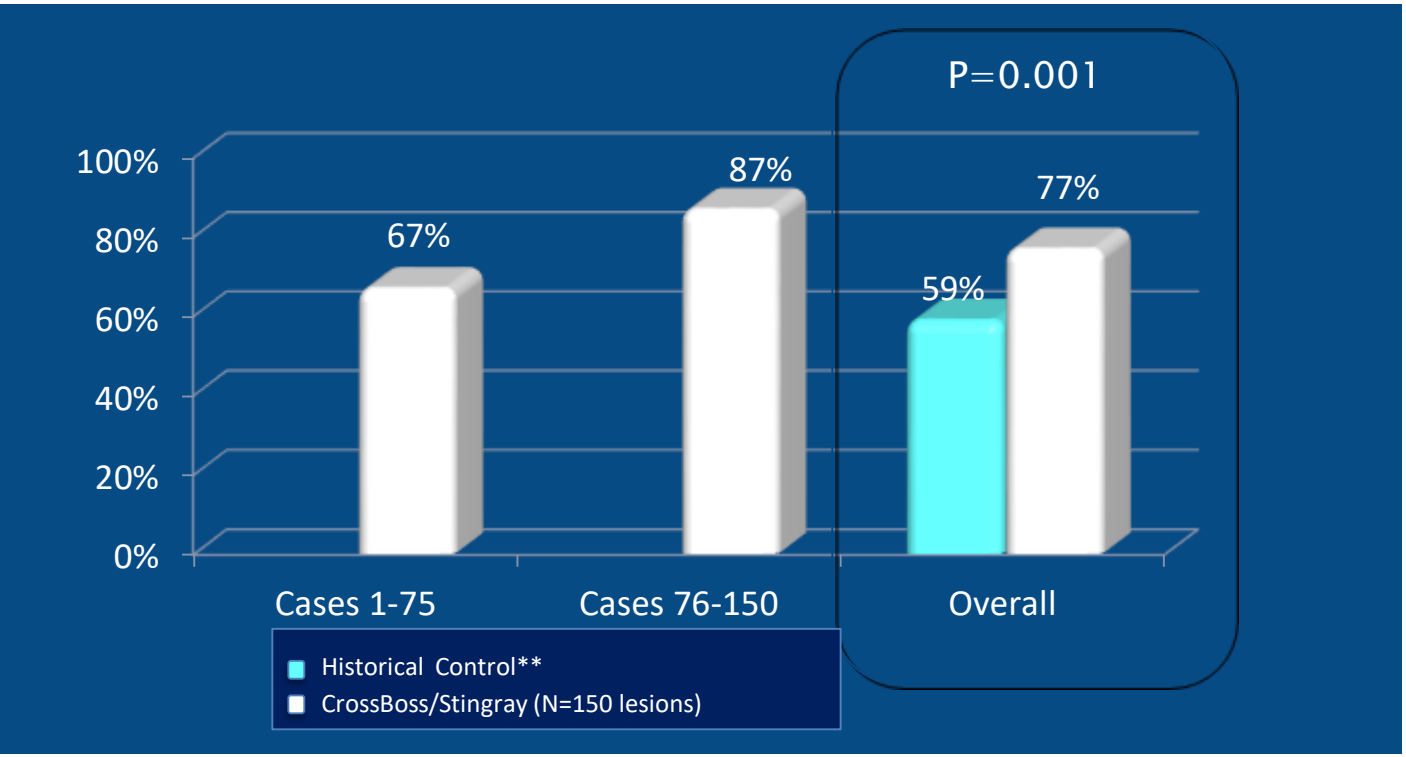
FAST-CTOs Study Results

Primary Effectiveness Endpoint - Technical Success*

- Overall CTO crossing success facilitated by CrossBoss™/Stingray™ devices was 77%, significantly higher than that of previous studies
- In the 2nd Half of the trial, success increased to 87% from 67% as physicians became more proficient with CrossBoss™/Stingray™ technologies



*Technical Success: CrossBoss/Stingray device facilitation of guidewire placement in true lumen distal to CTO
**Control literature consisted of similarly designed CTO device trials with similar technical success and safety measures

Whitlow PL, et.al., JACC Cardiovasc Interv 2012 Apr, 5(4): 393–401

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FAST-CTOs Study Results
Primary Safety Endpoint Success

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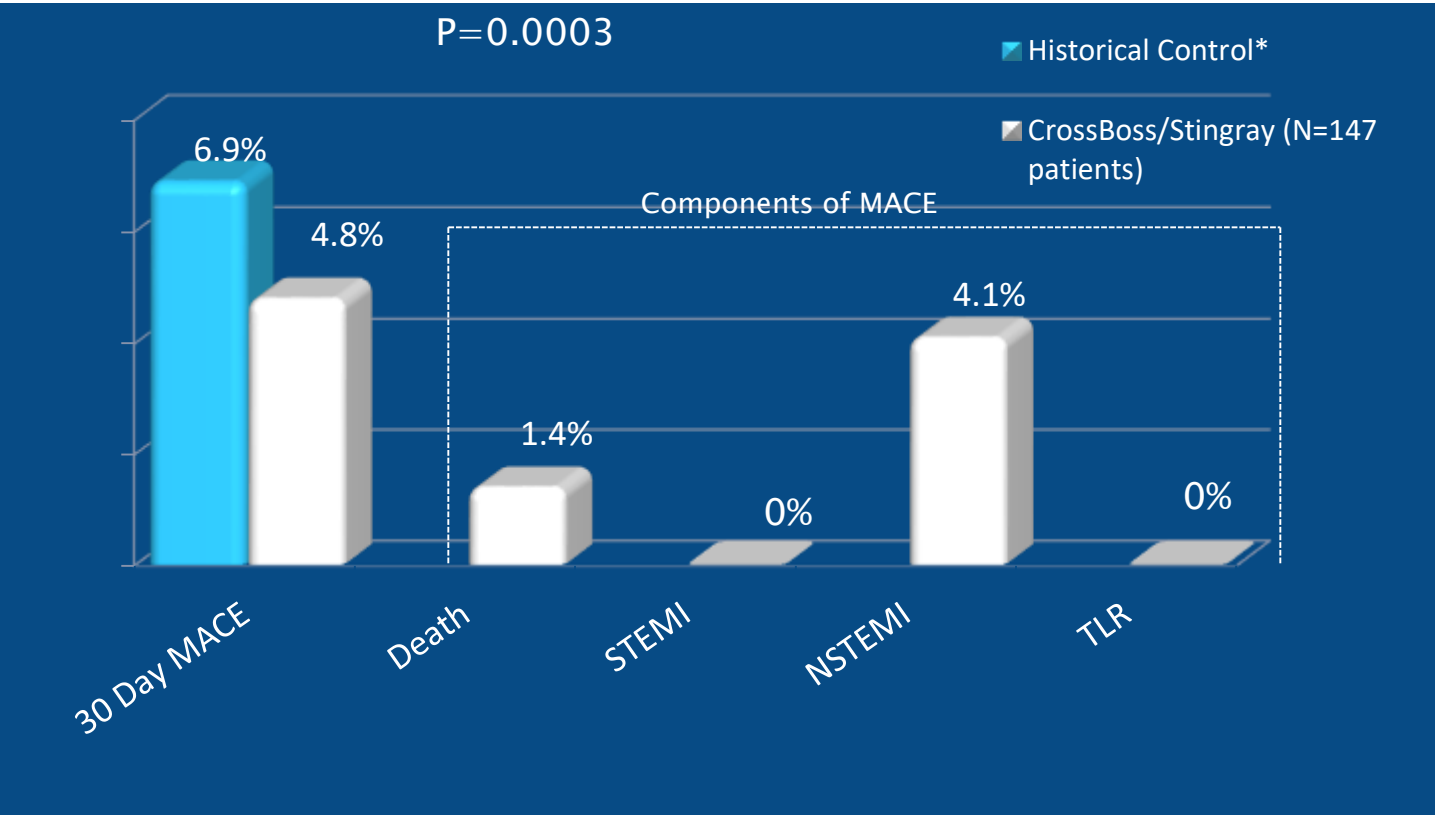
Use of the CrossBoss/Stingray technologies resulted in a high success rate without increasing complications



*Control literature consisted of similarly designed CTO device trials with similar technical success and safety measures

Whitlow PL, et.al., JACC Cardiovasc Interv 2012 Apr, 5(4): 393-401

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FAST-CTOs Study Results
Complications

Event	Rate
30-Day MACE	4.8% (7/147)
Death	1.4% (2/147)
STEMI	0.0% (0/147)
NSTEMI	4.1% (6/147)
Target Lesion Revasc	0.0% (0/147)
Emergency Cardiac Surgery	0.0% (0/147)
Pericardiocentesis	0.0% (0/147)
Cardiac Tamponade	0.0% (0/147)
Pericardial Effusion	1.3% (2/147)
BridgePoint Device Perforation	3.4% (5/147)
Stroke	0.7% (1/147)

Deaths Through 30 Days

- 1 respiratory arrest following admit for acutely occluded SFA/atrial fibrillation 18 days post-procedure
- 1 cardiac arrest in ER 21 days post-procedure

NSTEMI - All Peri-procedural

- 2 “Large”: Total CK>5x ULN with + CK-MB
- 4 “Small”: CK>2x ULN with + CK-MB

CrossBoss/Stingray Device Perforations

- 4 due to CrossBoss perforating small branch
- None resulted in cardiac tamponade
- None required surgical intervention/pericardiocentesis

Whitlow PL, et.al., JACC Cardiovasc Interv 2012 Apr, 5(4): 393-401

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FAST-CTOs Study Results

Secondary Endpoint- Procedure Time

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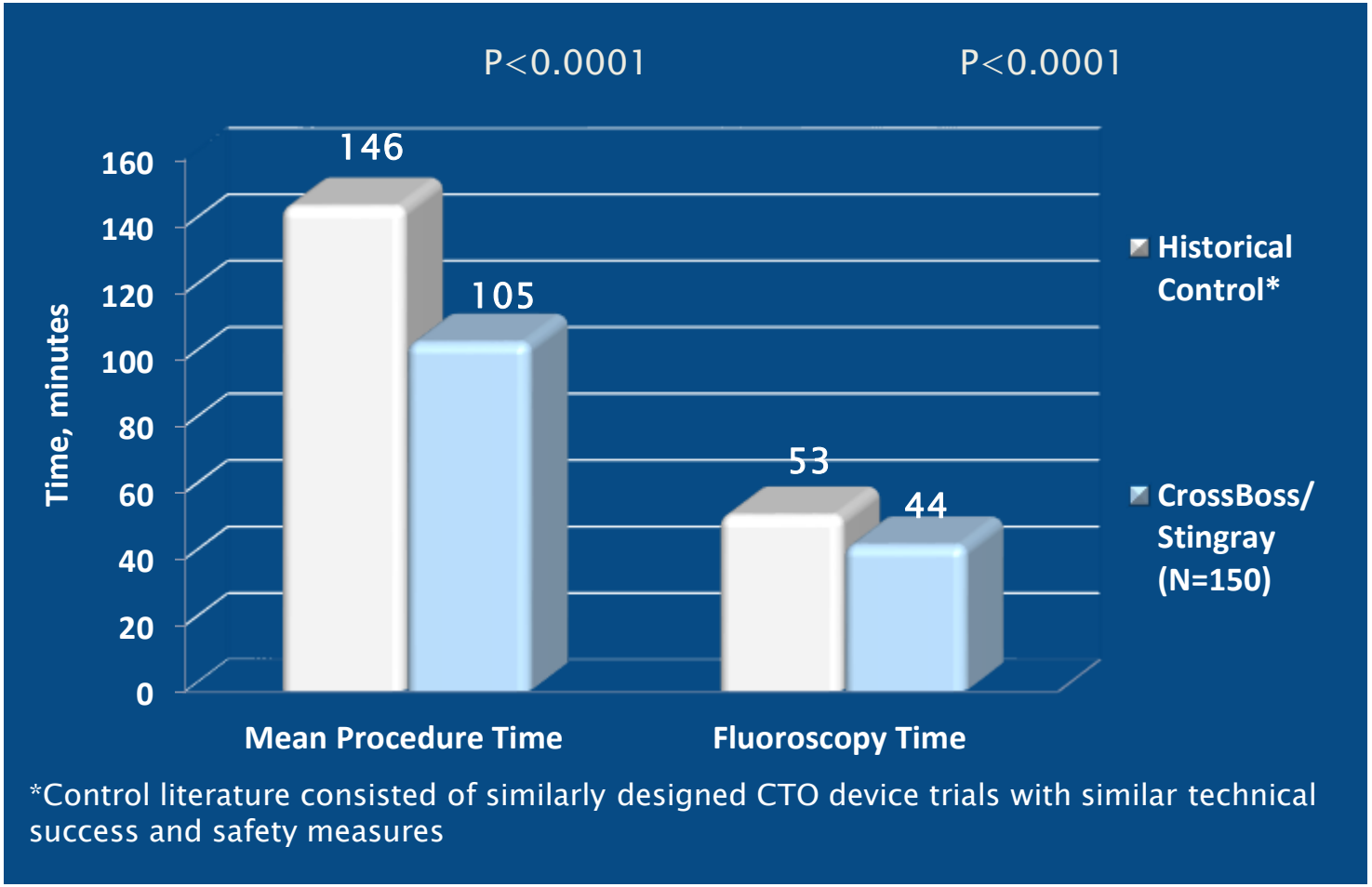
- Fast-CTO trial showed a 28% reduction in procedural time and a 17% reduction in fluoroscopy time



*Control literature consisted of similarly designed CTO device trials with similar technical success and safety measures

Whitlow PL, et.al., JACC Cardiovasc Interv 2012 Apr, 5(4): 393-401

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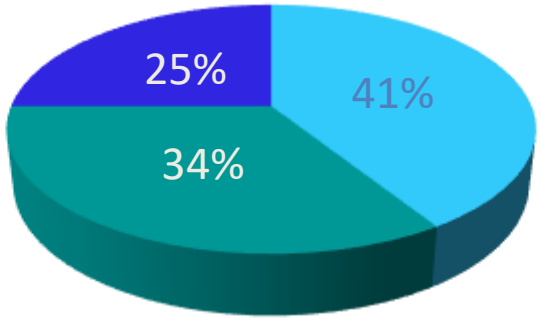
FAST-CTOs Vessels

Study Inclusion Details and Location

Refractory Categories

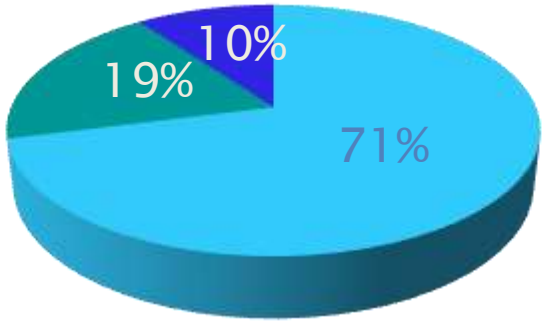
N=150 lesions



- Previously Failed Procedure
- 10-15 Min Fluoro Time Attempt
- Subintimal Guidewire

Vessels Treated

N=150 lesions



- RCA
- LAD
- LCA

Whitlow PL, et.al., JACC Cardiovasc Interv 2012 Apr, 5(4): 393-401

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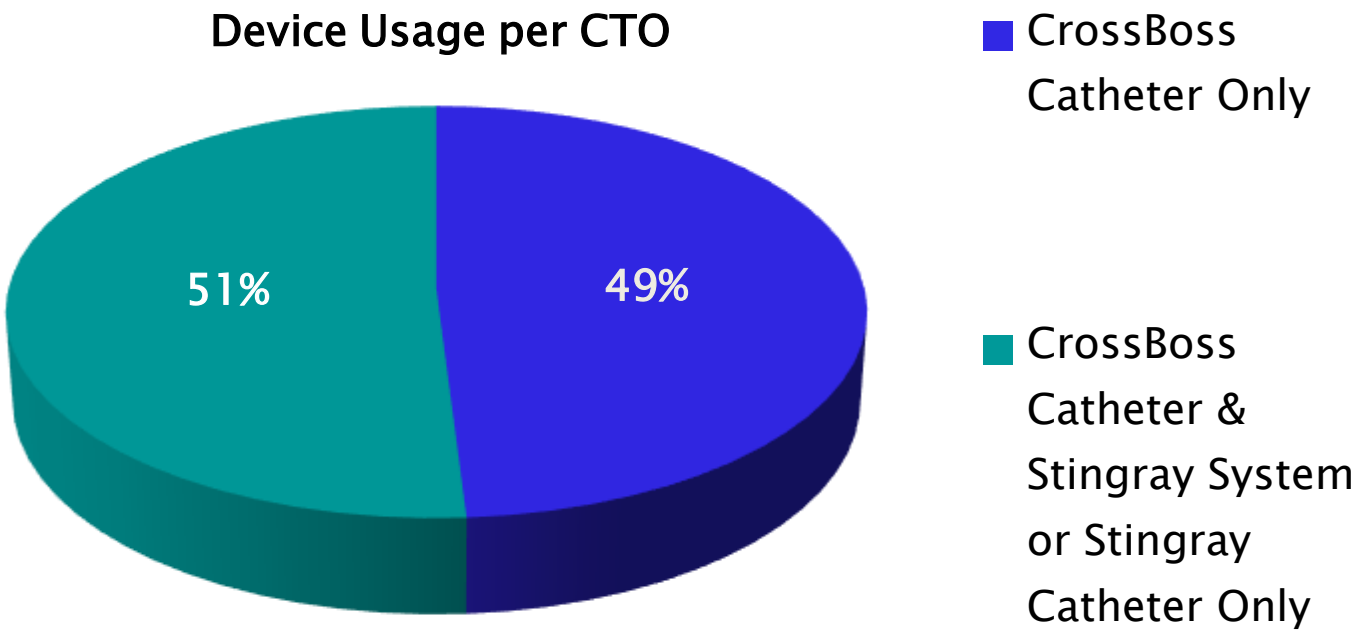
FAST-CTOs Study Results

CrossBoss/Stingray Device Usage in Successful CTOs

- In 49% of successful CTOs in FAST-CTO, the CrossBoss™ Catheter was the only step needed for successful crossing into the distal true lumen
- 51% of successful CTOs used a combination of CrossBoss Catheter and Stingray™ Re-entry System



Whitlow PL, et.al., JACC Cardiovasc Interv 2012 Apr, 5(4): 393-401

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Future / Ongoing Investigator-Sponsored CTO Research

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Ongoing Hybrid CTO PCI Investigator-Sponsored Research

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Study Name	Primary Investigator	Study Design	# of Patients & Sites	Objectives	Status	Geography	Data Release
OPEN CTO	J. Aaron Grantham, MD Saint Luke's Mid America Heart Institute Kansas City, USA	Multicenter, prospective, single arm observational registry	1,000 patients @ 10 sites	• Acute, 30 day and 1 year safety and success data • Impact of CTO PCI on Patient Health Status • Indications and appropriateness of PCI among patients selected for CTO PCI • Cost analysis	Completed	United States	2017
CONSISTENT CTO	Simon Walsh, MD Belfast Health & Social Care Trust Belfast, N. Ireland	Multicenter, prospective, single arm study of CTO patients treated with SYNERGY™ Stent	200 patients @ 6-10 sites	Long-term outcomes of Hybrid CTO PCI and sub-intimal stenting with SYNERGY Stent <u>Follow-Up:</u> • Angiographic: 12mos • OCT: 12mos • Clinical: 1 & 2yrs	Enrolling completed	Europe	2018
RECHARGE	Jo Dens, MD Ziekenhuis Oost-Limburg (ZOL) Genk, Belgium	Multicenter prospective, non-randomized clinical registry	1,000 patients @ sites TBD	Safety & success data of Hybrid CTO PCI & CrossBoss™ and Stingray™ technologies	Completed	Europe	2016

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