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Directional Atherectomy: Hong Kong Experience

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Disclosure

Speaker name:

.....Bryan Yan.....

I have the following potential conflicts of interest to report:

Consulting: Cook Medical, Boston Scientific, Medtronic



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Rationale for Atherectomy

- Less barotrauma & dissection
- Avoid stenting (leave nothing behind)
 - Long diffuse non-occlusive disease
 - Highly calcified lesion
 - 'No stent zone' (CFA, popliteal artery)
 - BTK lesion
- Modify & preserve vessel compliance
- Preserve bypass landing zones
- Vessel preparation before DCB (new)



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Limitations of Atherectomy

- Distal embolization
- Need for embolic protection device (some)
- High costs (not reimbursed in Hong Kong)
- Time consuming
- Higher radiation exposure



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Devices & Data

(* Available in HK)



Directional Atherectomy

- Hawk family: SilverHawk, TurboHawk, HawkOne (Medtronic)
- Patheris (Avinger)

- DEFINITIVE LE (n=800)¹
- DEFINITIVE Ca²⁺ (N=133)²
- DEFINITIVE AR (n=121)³
- VISION (n=130)⁴



Orbital Atherectomy

- Diamondback 360 (CSI)

- OSASIS (n=124)⁵
- COMPLIANCE (n=50)⁶
- CALCIUM 360 (n=50)⁷



Rotational Atherectomy

- JetStream (Boston Scientific)
- Phoenix (Volcano)

- Pathway PVD (n=172)⁸



Photoablation Atherectomy

- Turbo-Elite & Turbo-Tandem (Spectranetics)

- CELLO (n=65)⁹
- EXCITE ISR (n=250)¹⁰

1. McKinsey J, et al. JACC Cardiovasc Interv 7(8):923-33:2014.
 2. Roberts D, et al. Catheter Cardiovasc Interv 84(2):236-44:2014.
 3. Zeller T, et al. Presentation at VIVA 2014, Late-breaking Clinical Trials, Tuesday, November 4, 2014.
 4. Schwindt A. Presented at VIVA 2015, Late-breaking Clinical Trials, Monday, November 2, 2015.
 5. Safian RD, et al. Catheter Cardiovasc Interv 73(3):406-12:2009.
 6. Dattilo R, et al. J Invasive Cardiol 26(8):355-60:2014.
 7. Shammas NW, et al. J Endovasc Ther 19(4):480-8:2012.
 8. Zeller T, et al. J Endovasc Ther 16(6):653-62:2009.
 9. Dave R, et al. J Endovasc Ther 16(6):665-75:2009.
 10. Dippel EJ, et al. JACC Cardiovasc Interv 8(1 Pt. A):92-101:2015.



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Comparing Atherectomy Devices

	Directional	Rotational	Laser	Orbital
	HawkOne SilverHawk TurboHawk Pantheris	JetStream Rotablator Phoenix	Turbo-Elite Turbo-Power Turbo-Tandem	Diamondback 360 Stealth 360
Eccentric lesion	XX			
Severe calcium	XX	X		XX
Soft-medium plaque	XX	X	X	
Maximize lumen gain	X			
Thrombotic lesions		XX	X	
BTK lesions	X		X	XX
ISR	(X)	X	X	
CTO	X	X	XX	

HAWKONE™ DIRECTIONAL ATHERECTOMY SYSTEM

One Device. All Morphologies.

Treat All Morphologies



Procedural Efficiency

Streamline procedural efficiency with improved crossing and cleaning capabilities

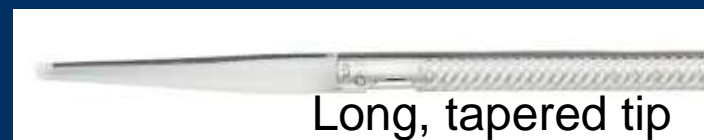
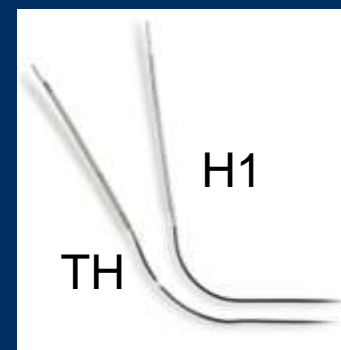
Note: Product claims for the HawkOne™ device are made in comparison to the TurboHawk™ platform



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HawkOne vs. TurboHawk

- More effective in calcium
 - 50% ↑ rotational speed (8k - 12k RPMs)
 - 4 contoured blades
- Improved engagement
- Improved deliverability
- Enhanced visualization
- Faster cleaning time
 - Preloaded distal flush tool
- Simplified device selection





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Simplified Device Selection from 7 to 4

TurboHawk™ Plaque Excision System

Model specifications									
Model name	Catalog number	Vessel diameter (mm)	Sheath compatibility (F)	Crossing profile (mm)	Working length (cm)	Effective length (cm)	Tip length (cm)	Max. cut length (mm)	Packing device
LS-C	THS-LS-C	3.5-7.0	7	2.7	110	104	6.0	50	■
LX-C	THS-LX-C	3.5-7.0	7	2.7	113	104	9.0	75	■
LS-M	TH-LS-M	3.5-7.0	7/8	2.7	110	104	6.0	50	■
LX-M	TH-LX-M	3.5-7.0	7/8	2.7	113	104	9.0	75	■
SS-C	THS-SS-C	2.0-4.0	6	2.2	135	129	5.9	40	■
SS-C	THS-SS-C	2.0-4.0	6	2.2	135	129	5.9	40	■
SS-CL	THS-SS-CL	2.0-4.0	6	2.2	149	141	5.9	40	■

HawkOne™ Directional Atherectomy System

Model name	Catalog number	Vessel diameter (mm)	Sheath compatibility (F)	Crossing profile (mm)	Working length ¹⁾ (cm)	Effective length ²⁾ (cm)	Tip length (cm)	Max. cut length (mm)	Packing device	
7F	LS	H1-LS-INT	3.5-7.0	7	2.6	114	107	6.6	50	■
7F	LX	H1-LX-INT	3.5-7.0	7	2.6	114	104	9.6	75	■
6F	M	H1-M-INT	3.0-7.0	6	2.2	135	129	5.9	40	■

Model name	Catalog number	Vessel diameter (mm)	Sheath compatibility (F)	Crossing profile (mm)	Working length ¹⁾ (cm)	Effective length ²⁾ (cm)	Tip length (cm)	Max. cut length (mm)	Packing device	
6F	S	H1-S-INT	2.0-4.0	6	2.2	151	145	5.9	40	■



Current		NEW!		
TurboHawk™ High Efficiency Cutter	TurboHawk™ Smooth Cutter	HawkOne™ System		Femoro-popliteal Artery
THS-LS-C	TH-LS-M	H1-LS	7F	Short Lesion
THS-LX-C	TH-LX-M	H1-LX	7F	Long Lesion
		H1-M	6F	Smaller / Tortuous Vessel



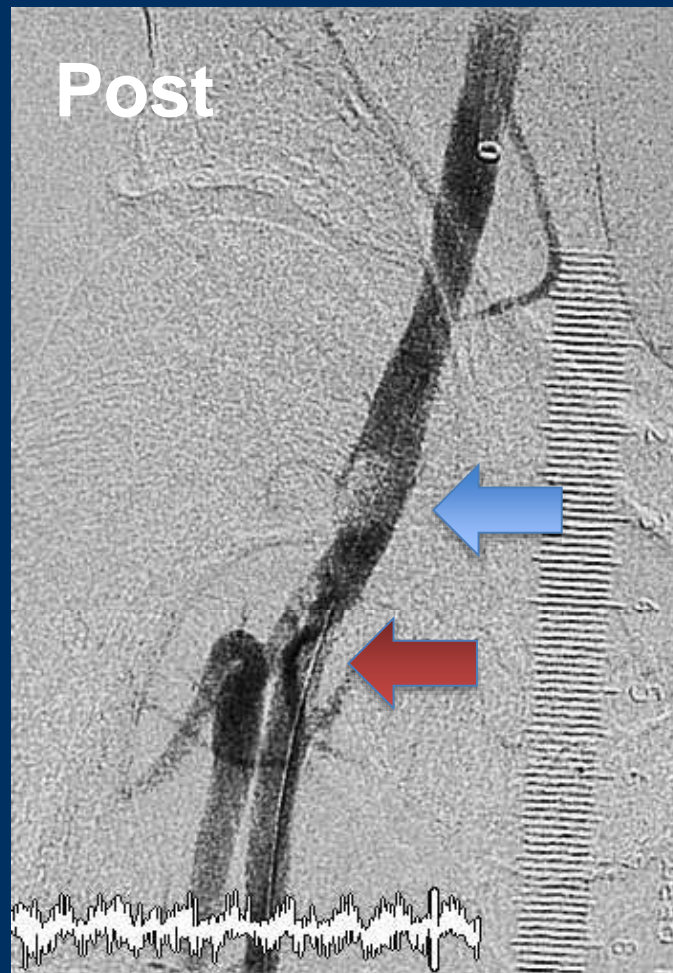
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Case 1: TurboHawk

CFA Pre



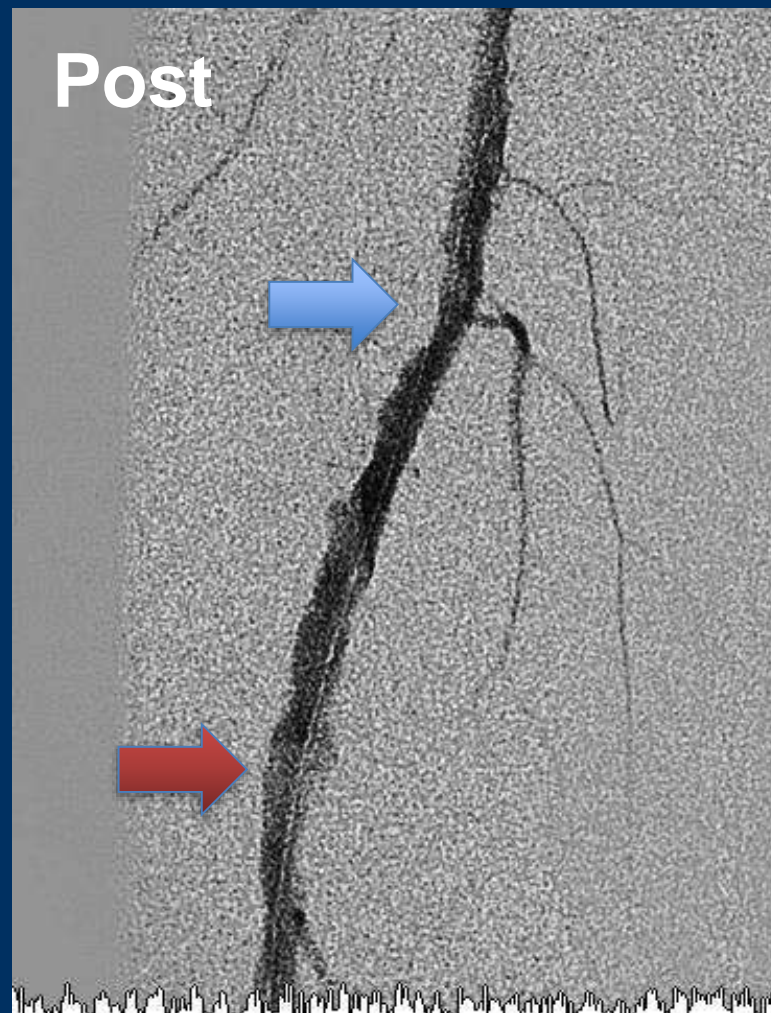
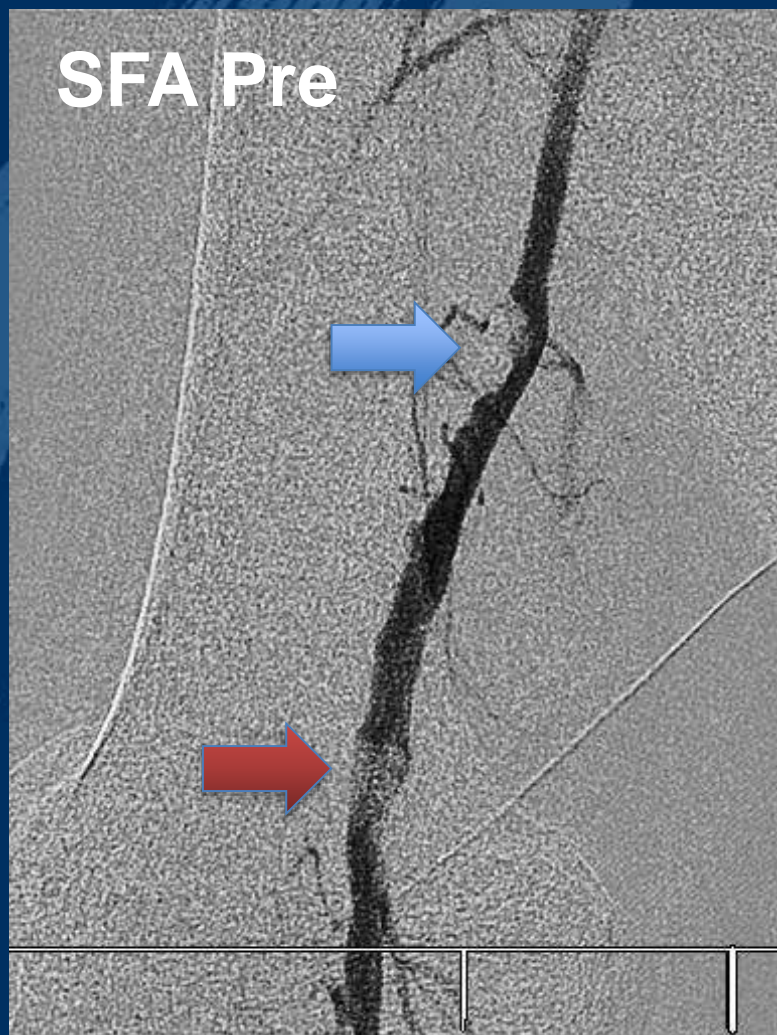
Post





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+ DEB





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Case 2: HawkOne

Proximal SFA

Focal

Eccentric

Calcified



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DPD + HawkOne

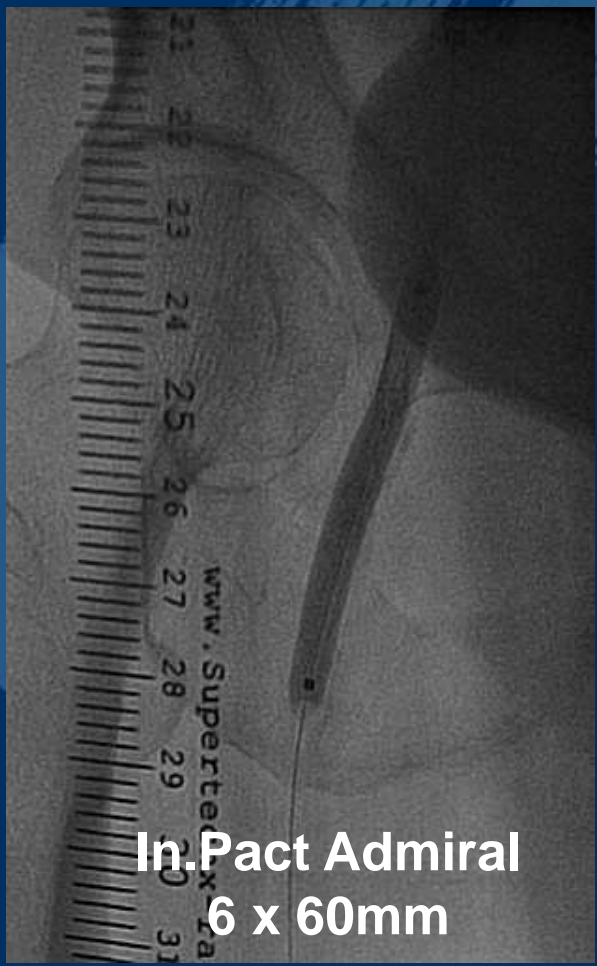
Spider Rx DPD





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DEB (aka. DAART)



**In.Pact Admiral
6 x 60mm**





DA+DCB combination therapy can overcome limitations of stand-alone SFA therapies

Unmet Need	PTA	BMS	DES	DCB	DA	DA+DCB
Address recoil, dissections and Ca ⁺⁺		✓	✓		✓	✓
Prevent Neointimal Proliferation/ Restenosis			✓	✓		✓
Minimize permanent implants + preserve future options	✓			✓	✓	✓

- DA mechanically recanalize the vessel without overstretch
- DA remove perfusion barrier for better & more homogenous drug uptake
- DA reduce likelihood of bailout stenting & preserve native vessel



Co-Principal Investigators

Krishna Rocha-Singh, MD
Chief Scientific Officer
Prairie Heart Institute of Illinois

Brian DeRubertis MD, FACS
Associate Professor of Surgery
UCLA Division of Vascular Surgery

- The REALITY Study evaluates patient outcomes with adjuvive use of Medtronic HawkOne™ or Medtronic TurboHawk™ and Medtronic IN.PACT™ Admiral™ drug-coated balloon.
- The multi-center, international, prospective, single-arm study will enroll up to 250 subject at up to 15 sites.
- The study includes angiographic and duplex ultrasound core lab adjudication. Primary patency is assessed by duplex ultrasound at 12-months.
- Patients are followed up to 24 months to determine clinically driven target lesion revascularization (CD-TLR).
- The study is sponsored and managed by VIVA physicians with support from Medtronic through an external research project grant.



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Thank You



Prince of Wales Hospital, Friday 17th March
Directional Atherectomy Live Case Workshop

with

Dr. Lawrence Garcia & Prof. Bryan Yan



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