



# Infrapopliteal Atherectomy: Techniques and Devices

Ravish Sachar, MD FACC

Physician-in-Chief  
Cardiovascular Service Line  
UNC REX Hospital  
Raleigh, NC

# Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

## Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria
- Ownership/Founder
- Intellectual Property Rights
- Other Financial Benefit

## Company

- Medtronic, Boston Scientific, Gore
- Medtronic, Boston Scientific, Spectranetics
- Contego Medical
- Contego Medical
- CardioMEMs

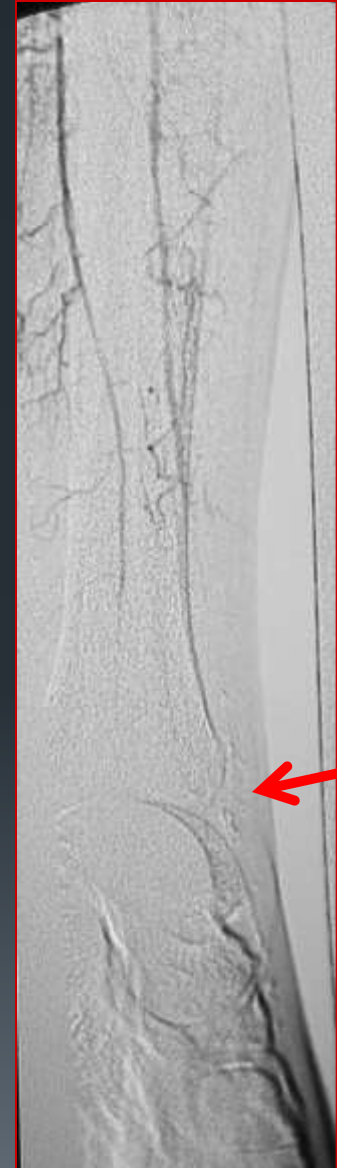
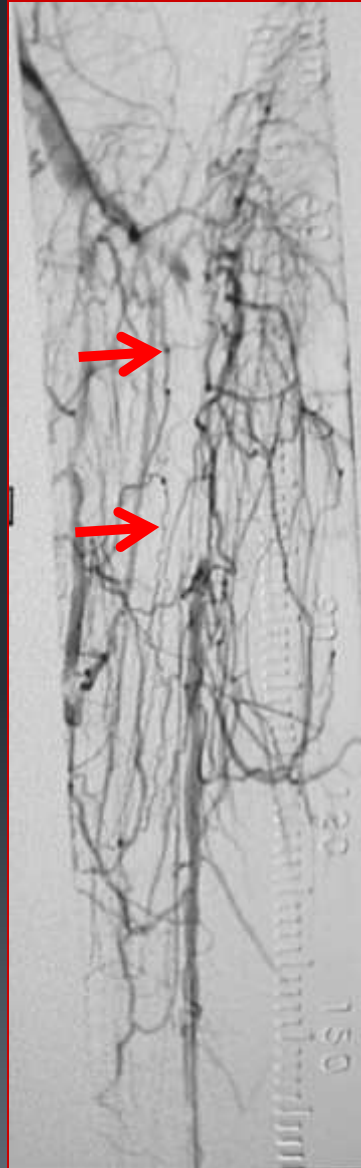
# CLI - The Bad News

- Patients are getting older
- DM incidence and prevalence are increasing
- CLI patients are the sickest patients with multiple comorbidities
- The procedures are often long and tedious
- Sometimes you will not succeed with revascularization

# CLI - The Good News

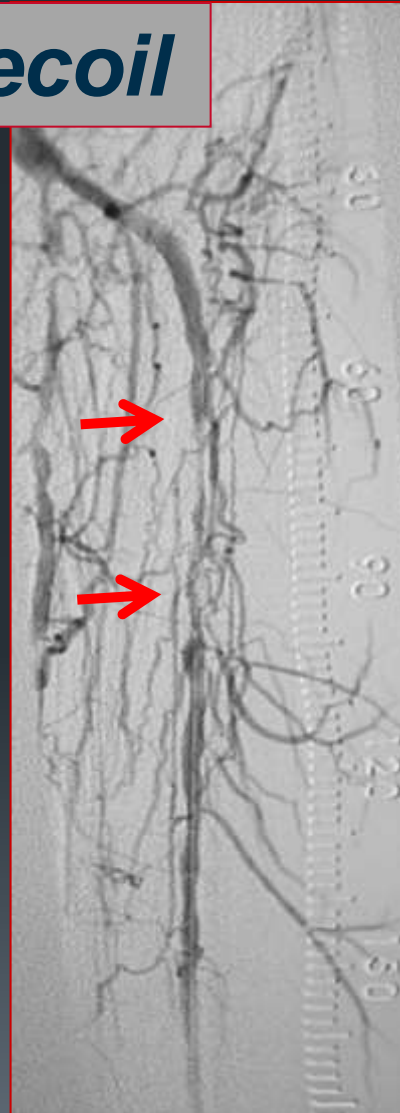
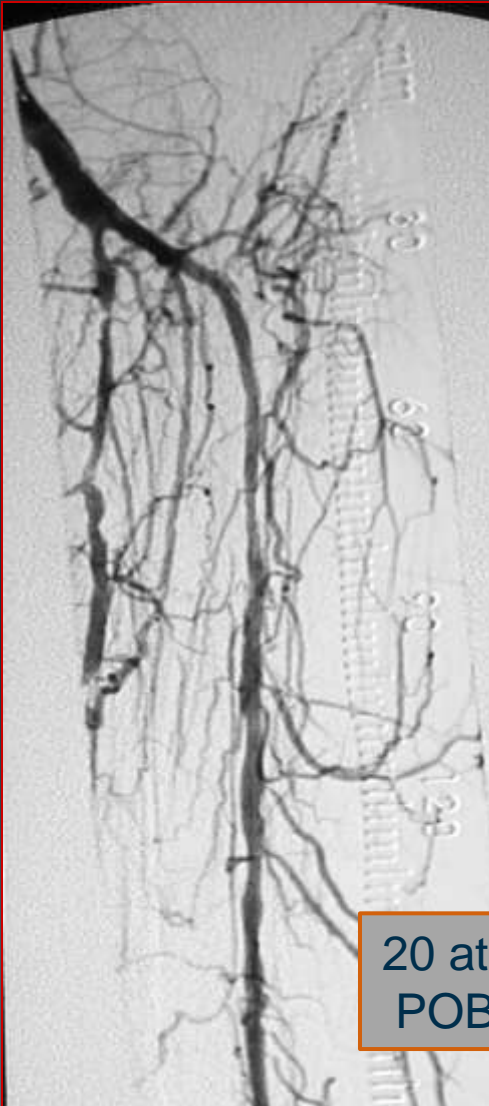
- Our toolbox of devices is expanding
- Rigorous data are being generated
- Industry has partnered with physicians to achieve these goals
- The holy grail of acute success with long term patency in BTK disease appears to be within reach

# DM, ESRD, Rutherford 5



# Heavy Ca<sup>+</sup>, difficult to cross

*Recoil*

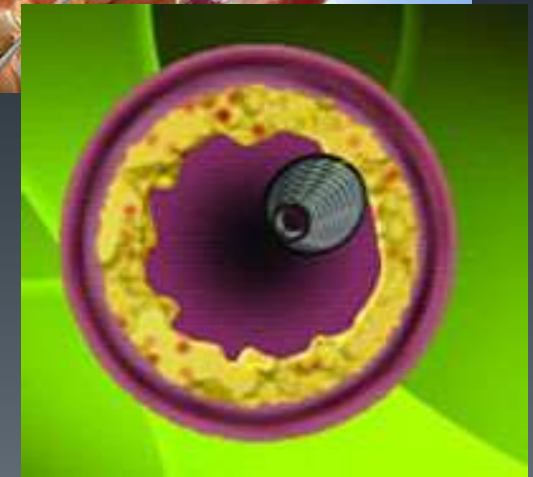
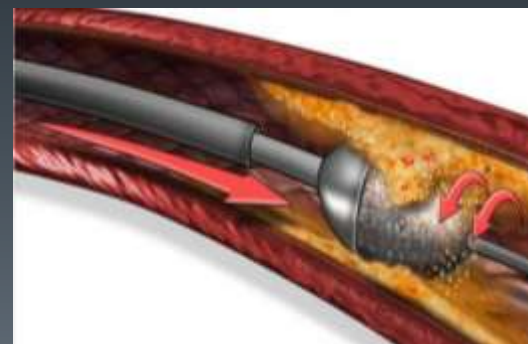


What is the best treatment for this patient?

Atherectomy may be a good option for many patients with CLI and BTK disease due to high prevalence of diffuse calcific disease

# Atherectomy for BTK lesions – Multiple Choices

- Directional
- Orbital
- Laser
- Rotational
  - Jetstream
  - Rotablator
  - Phoenix





# Medtronic HawkOne™, TurboHawk™ and SilverHawk™ Peripheral Plaque Excision Systems: Directional Atherectomy

- Can treat eccentric disease
- Avoid healthy vessel
- Ability to treat the widest range of vessel sizes

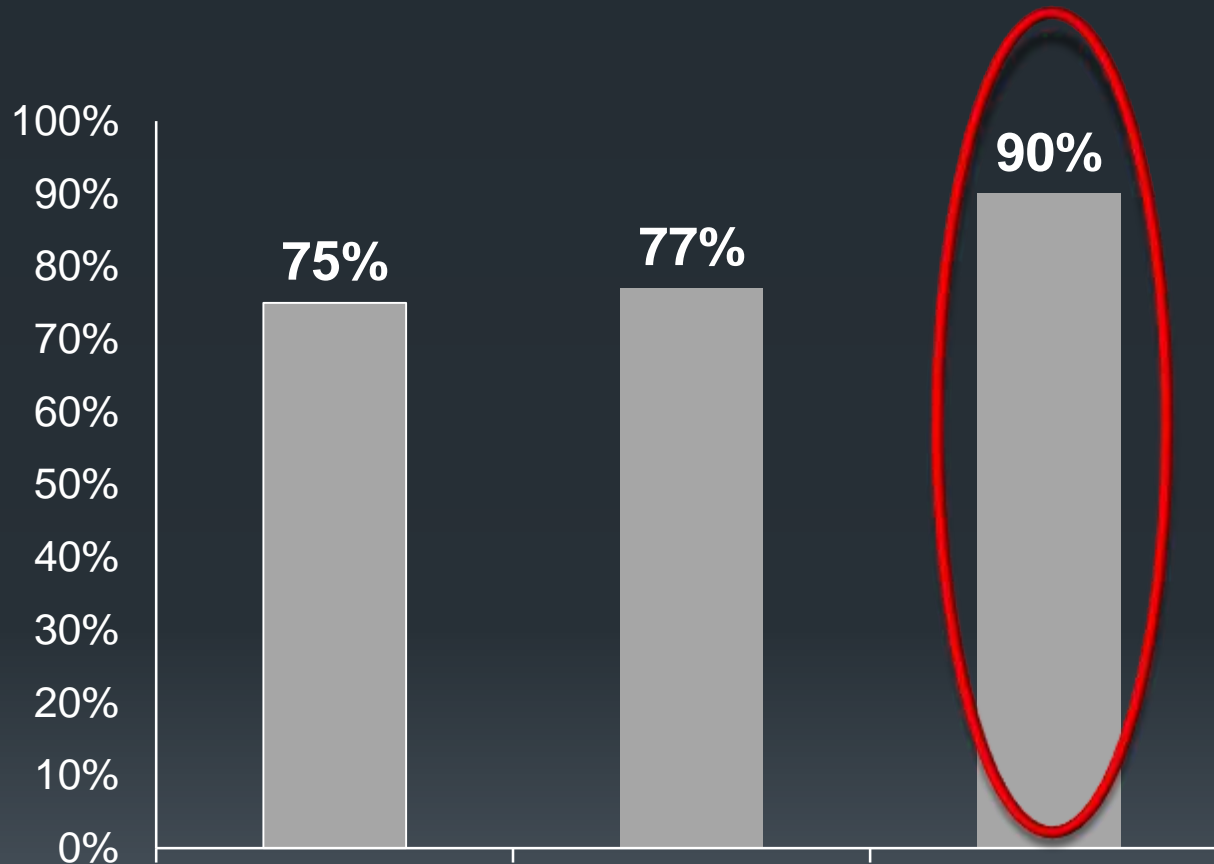


# Definitive LE (n=800)

## Primary Patency in Subgroups

Subgroup	Claudicants (n=743)		CLI (n=279)	
	Patency (PSVR $\leq$ 2.4)	Lesion Length (cm)	Patency (PSVR $\leq$ 2.4)	Lesion Length (cm)
All (n=1022)	78%	7.5	71%	7.2
<b>Lesion type</b>				
Stenoses (n=806)	81%	6.7	73%	5.8
Occlusions (n=211)	64%	11.1	66%	10.3
<b>Lesion Location</b>				
SFA (n=671)	75%	8.1	68%	8.6
Popliteal (n=162)	77%	6.0	68%	5.4
Infrapopliteal (n=189)	90%	5.5	78%	6.0

# 12 Month Primary Patency Rates from DEFINITIVE LE based on lesion location: Claudicant Cohort



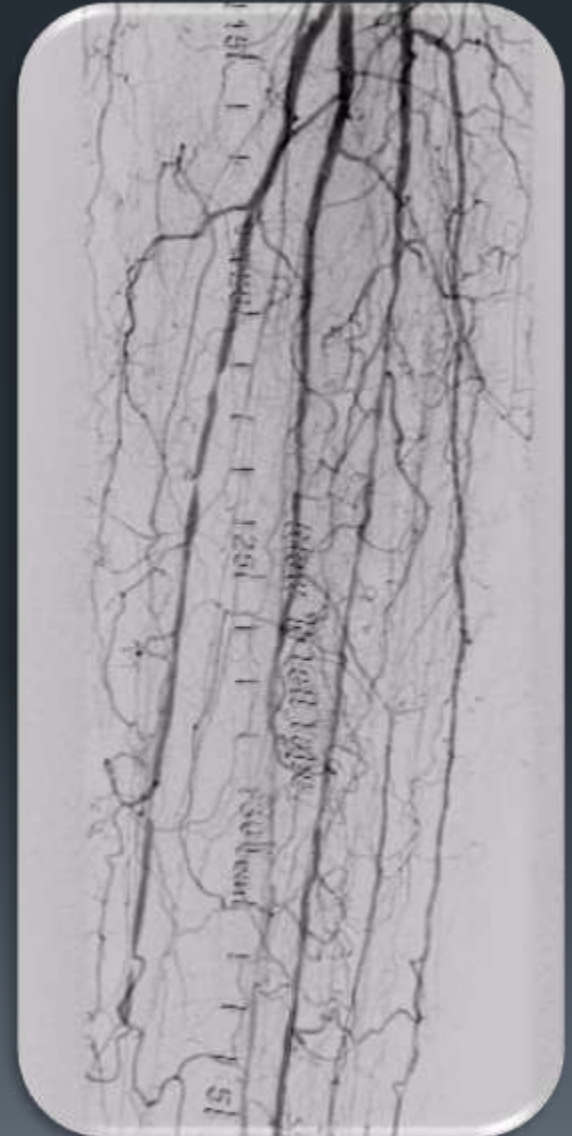
PSVR  $\leq$  2.4

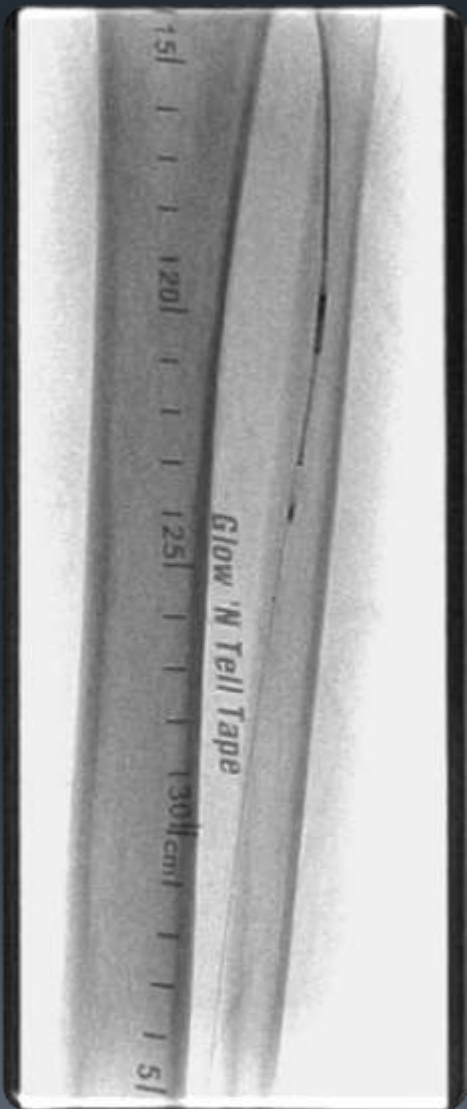
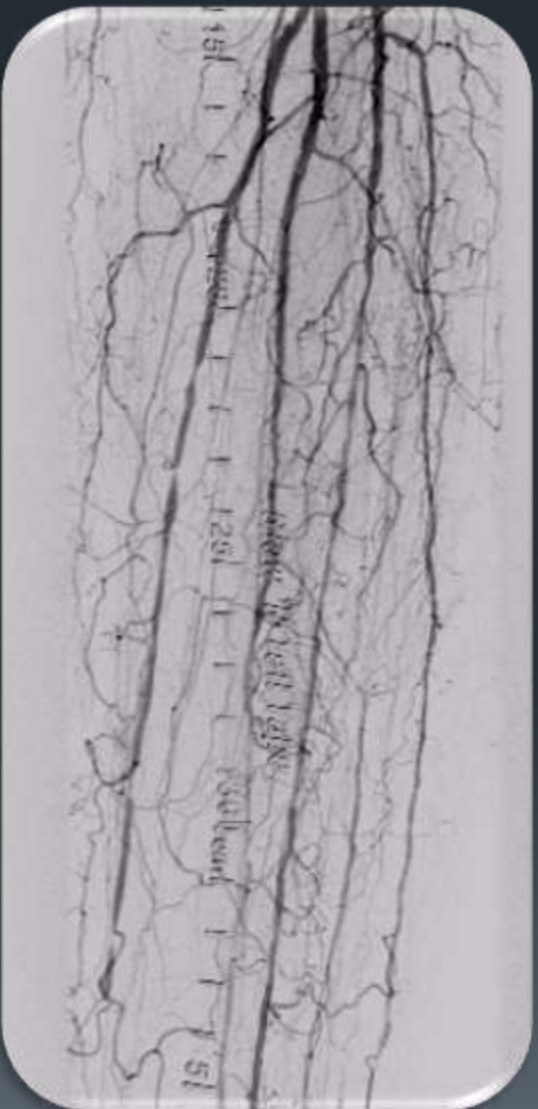
	SFA	Popliteal	Infrapopliteal
Mean length :	8.1 cm	6.0 cm	5.5 cm
Number of Lesions:	536	114	93

# Left anterior tibial artery

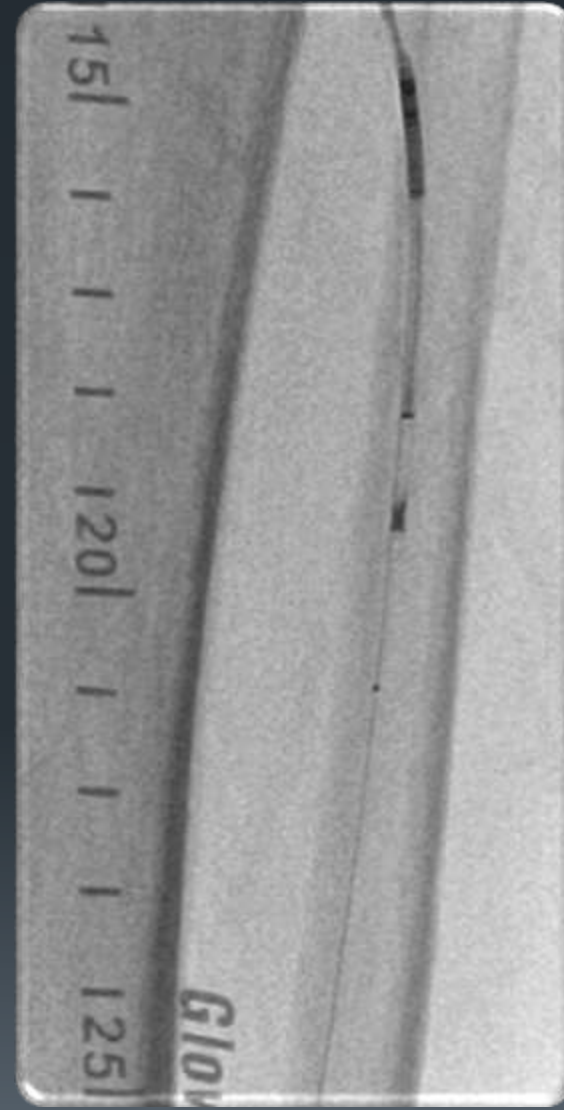
## Plan for Intervention:

- 6F 45cm antegrade sheath (distal tip in popliteal)
- Cross occlusion with wire/catheter techniques
- 3mm SpiderFX™ Filter deployed in the dorsalis pedis
- TurboHawk™ SXC device for proximal and mid disease



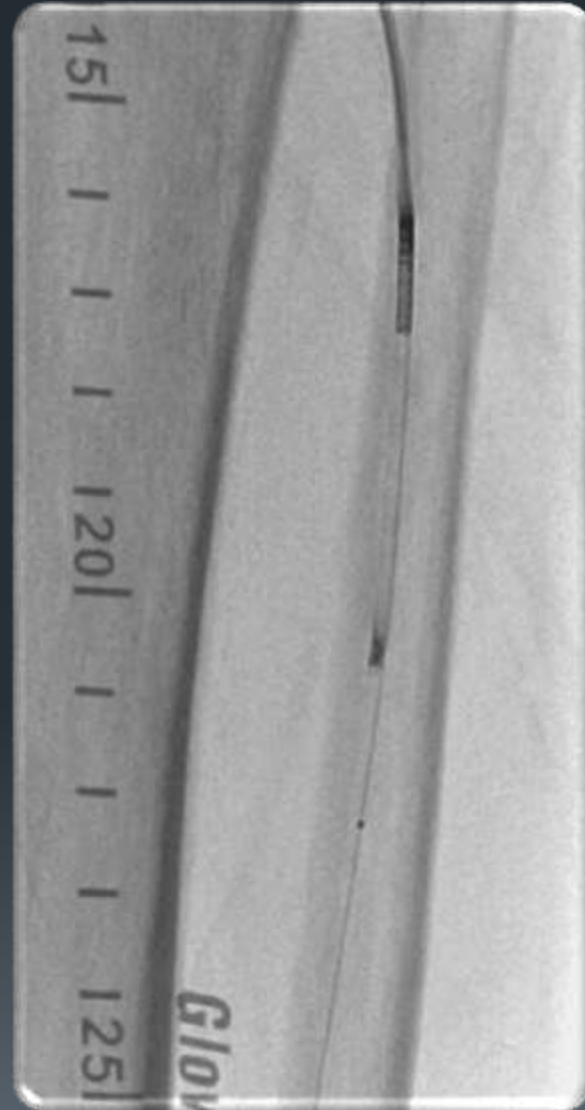


Torque the device medially (screen left)

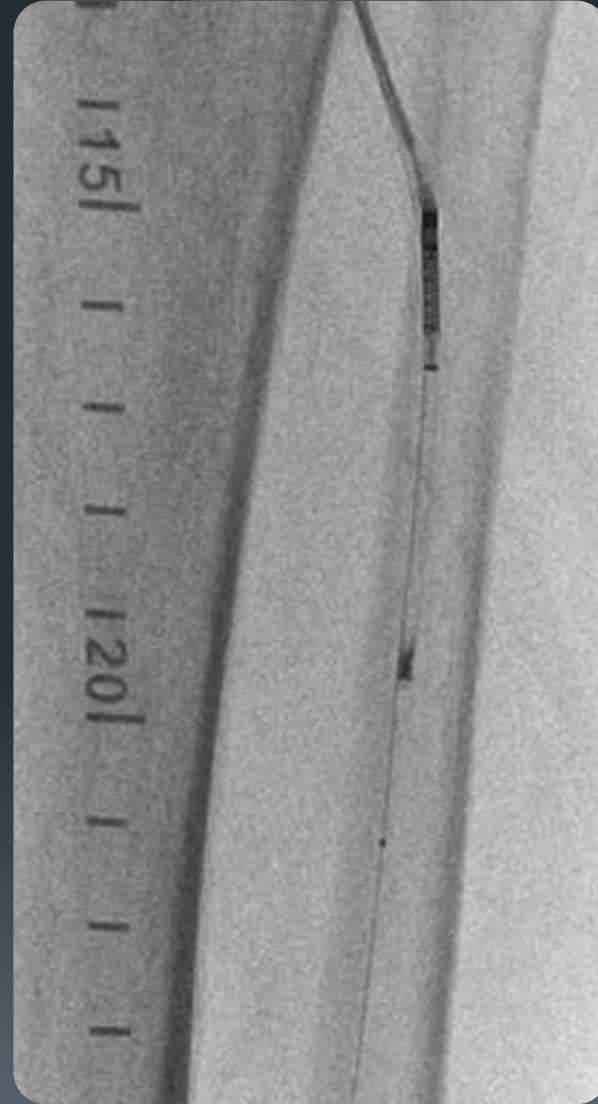
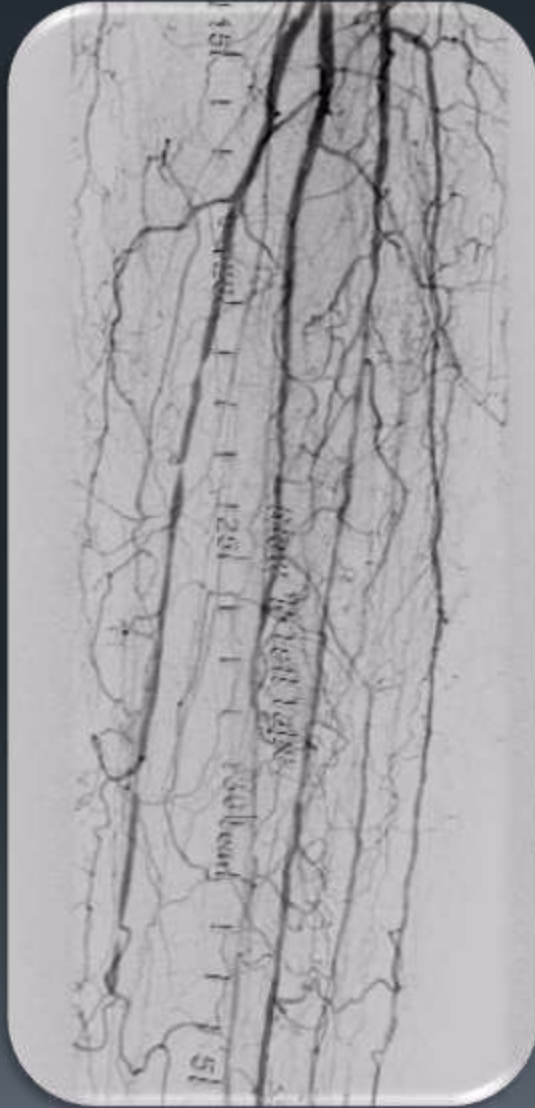




# Medial cut

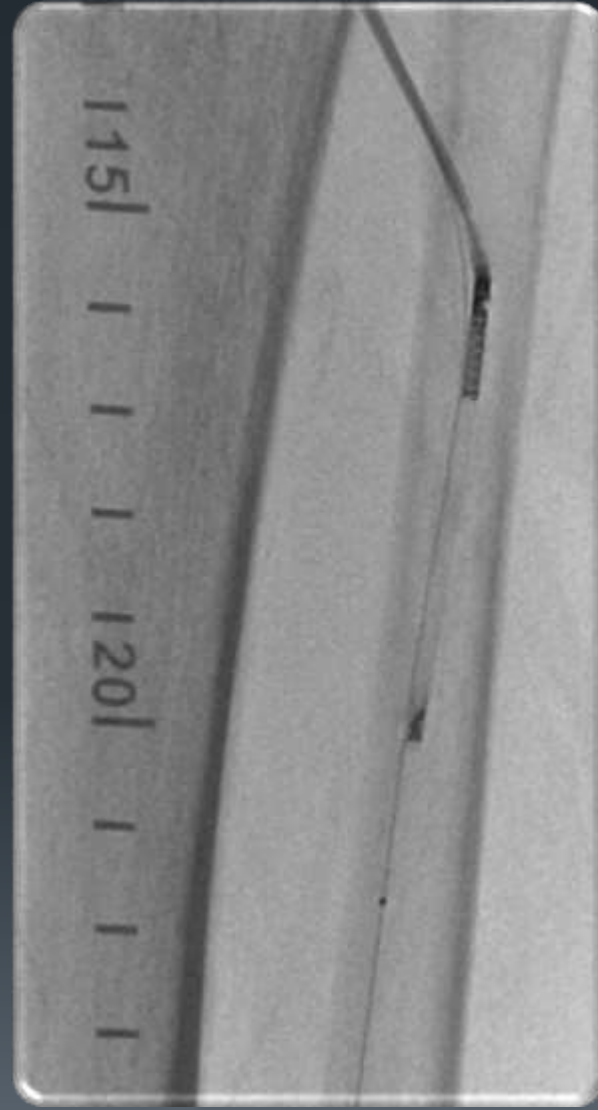


# Torque the device laterally (screen right)

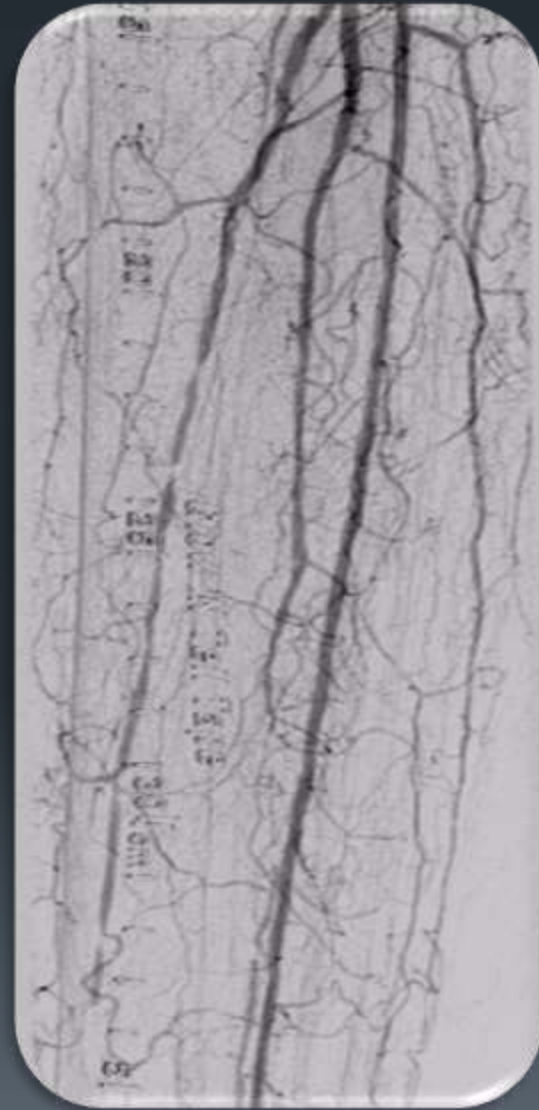




# Lateral cut

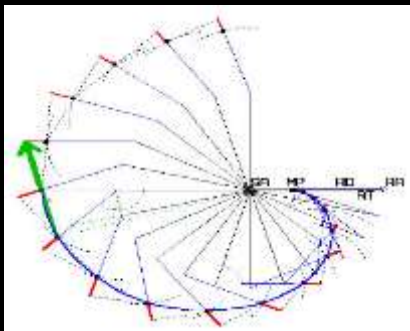
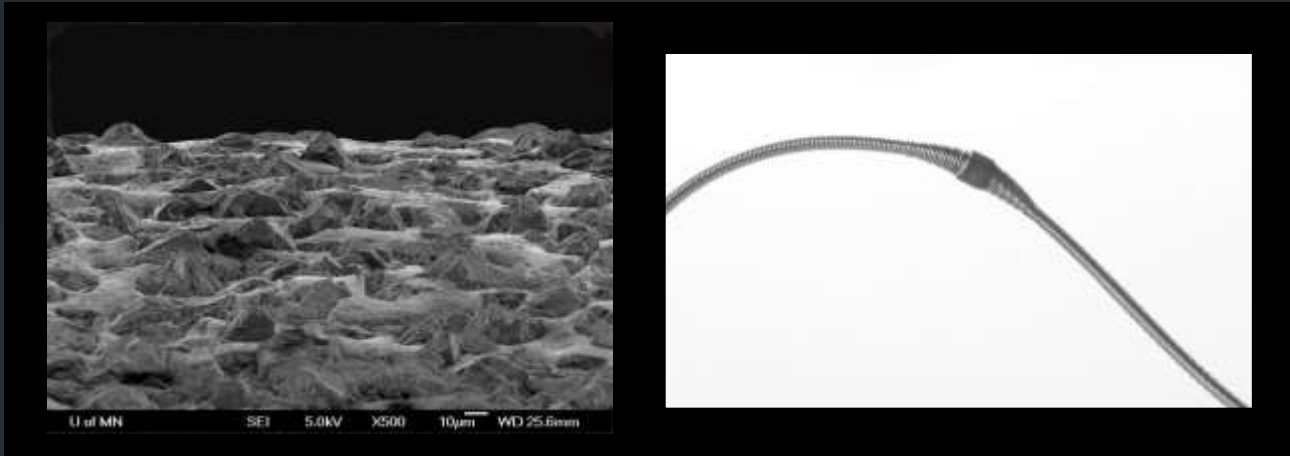


# Before and after angio's

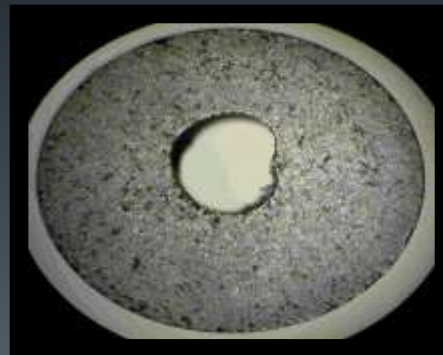


# Orbital Atherectomy

- Diamond grit coated crown
- Creates lumen greater than crossing profile



$$CF \approx \frac{\text{Mass} \times \text{Rotational speed}^2}{\text{radius of the orbit}}$$



1.9mm crown at 80k RPMs



1.9mm crown at 200k RPMs

# Diamondback Crowns

## Solid Micro Crown – BTK and into pedal vessels

Flexibility of classic crown for tortuous vessels and tight bends below-the-knee and beyond  
Increased mass of solid crown for more effective sanding



## Solid Crown 1.25 to 2.25 mm – for larger vessels

More mass allows for maximum calcium removal  
More diamond-coated surface area allows for shortest run times



## Classic Crown 1.25 to 2.00 mm

The most flexible of our crown configurations  
For vessel bends, ostial lesions and distal below-the-knee procedures



# Orbital Atherectomy – Technique

- Concept: Instead of maximizing luminal gain, change the compliance of the vessel
- Use smaller crowns: lower risk of embolization
- Slow passes 1 cm/sec
- Pecking to avoid sticking or resistance
- Can use 1.25 crown through 4 French systems via pedal approach
- Liberal use of vasodilators and Viper glide
- Be careful in subintimal use
- Passes should be <30 seconds
- Follow with PTA or DEB

# Orbital Atherectomy – CTO peroneal



# Orbital Atherectomy: TPT and Peroneal





# Calcium 360 Study

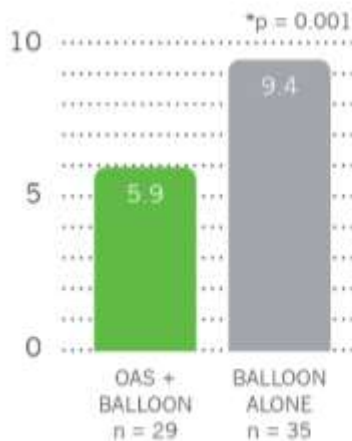
Randomized, multi-center study comparing Orbital Atherectomy System to Balloon Angioplasty alone in calcified lesions below-the-knee (BTK)

## OAS Outperforms Balloon Angioplasty in BTK Lesions

Excellent acute performance in patients with critical limb ischemia

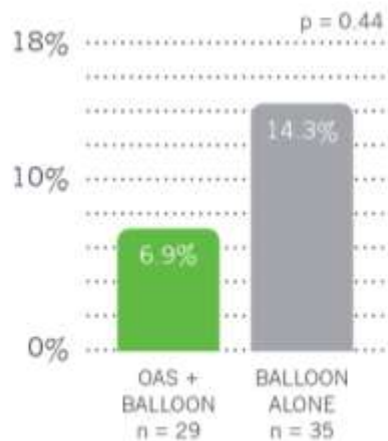
### Max Balloon Pressure

Average Maximum Balloon Pressure (atm)

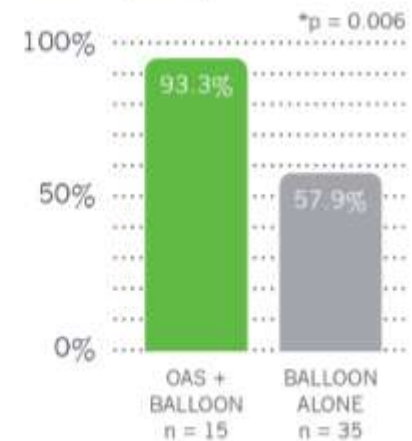


### Bail-Out Stenting

% Patients Requiring Bail-out Stents



### Statistically Significant Difference in Freedom From Major Adverse Events (MAE)\*\*





# Laser Atherectomy - Mechanisms of Action

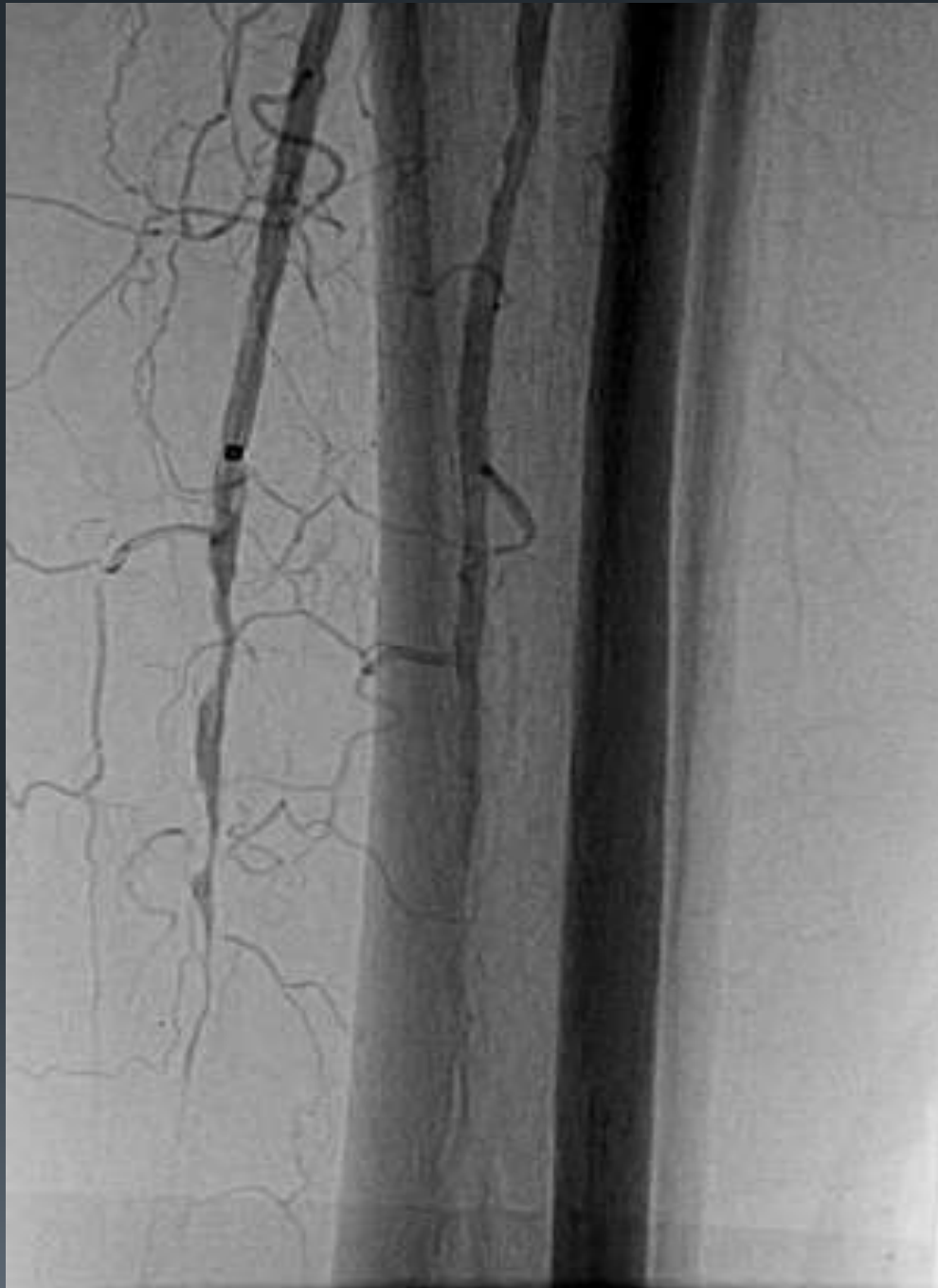


<b>①</b> Photochemical	<b>②</b> Photothermal	<b>③</b> Photomechanical
<b>Breaking molecular bonds</b>	<b>Producing thermal energy</b>	<b>Creating kinetic energy</b>
UV light pulses short bursts 125ns duration, 80 pulses/sec Each penetrates 100 microns Result: fractured tissue bonds with small embolic particles	As energy is absorbed, it creates molecular vibration  Heats intracellular water  Water vaporizes, creating vapor bubble, rupturing cells	Vapor bubble breaks down tissue  Can large embolic particles possible  Technique very important, <1 cm/sec

# Laser Atherectomy Technique

- Saline through pressurized system or hand injection during lasing
- Begin treatment of the stenosis with the default settings of 45 fluence and 25 frequency.
- Advance slowly through the lesion at less than 1 cm per second,
- Max 30 seconds of continuous lasing
- Additional laser passes may be performed to achieve greater debulking
- If resistance to catheter advancement is met due to calcium, or debulking is incomplete, the fluence and frequency can be increased.







# DATA – LACI Phase 2

- N= 169
- 97% success
- 6 month limb salvage 93%



# Jetstream Rotational Atherectomy and Aspiration System



## Jetstream XC Atherectomy Catheters

**2.4/3.4**

Ordering information:  
**PV41340**

Catheter Length	Min. Introducer Size	Max. Guidewire Diameter	Tip Diameter
120 cm	7 F	0.014"	2.4 mm 3.4 mm

**2.1/3.0**

Ordering information:  
**PV31300**

Catheter Length	Min. Introducer Size	Max. Guidewire Diameter	Tip Diameter
135 cm	7 F	0.014"	2.1 mm 3.0 mm

## Jetstream SC Atherectomy Catheters

**1.85**

Ordering information:  
**PV3118F**

Catheter Length	Min. Introducer Size	Max. Guidewire Diameter	Tip Diameter
145 cm	7 F	0.014"	1.85 mm

**1.6**

Ordering information:  
**PV3116F**

Catheter Length	Min. Introducer Size	Max. Guidewire Diameter	Tip Diameter
145 cm	7 F	0.014"	1.6 mm



# Rotational Atherectomy

- Ability to treat different size vessels with one device
- Can treat the whole spectrum of plaque from heavily calcified to thrombus
- Central cutting feature gives uniform lumens
- Simultaneous aspiration





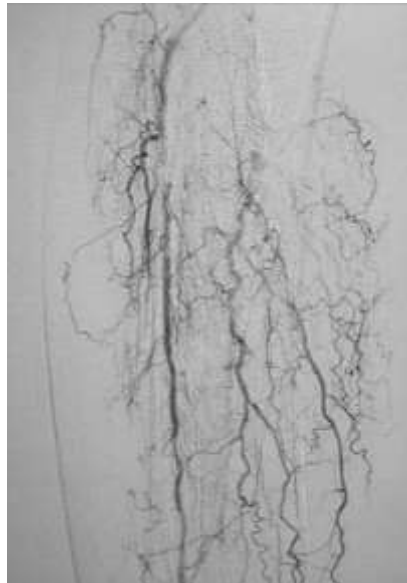
# Rotational Atherectomy - Jetstream

## Atherectomy of Anterior Tibial CTO



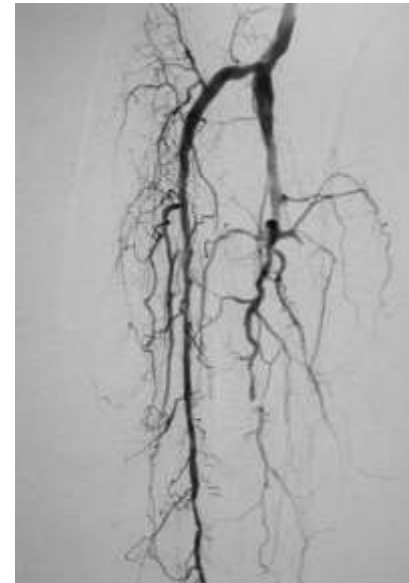
**Pre Treatment**

Anterior Tibial  
Calcified Ostium and 2 cm CTO  
in Proximal AT



**Pre Treatment**

Distal Runoff of AT Showing  
2 cm CTO



**Post Treatment**

3 passes with Jetstream™ G3™  
SF 1.85 Catheter  
(Stand Alone Results)

# Rotational Atherectomy Tips

- Use lubricant in infusion bag to enhance aspiration function (Rotoglide)
- If concern for thrombus, add tPa to infusion bag
- First do blades down, followed by blades up
- If patient has pain, go to blades down mode
- Slow – 1 cm/sec

# Phoenix - Volcano

- Front Cutting with Archimedes screw
- OTW
- Continuous removal of plaque
- 5 French



# Infrapopliteal Atherectomy + DCB

- Tibial vessels should be ideally suited for combination therapy
- Long, diffuse, calcified disease
- Small vessels – higher restenosis
- Non-randomized studies suggest benefit of DCB in BTK lesions
- No randomized data to suggest that either DCB or combination DCB + Atherectomy beneficial
- Cost Considerations
- NEED MORE DATA!!

# Summary

- All devices work, and there are niche areas for each
- Directional atherectomy appears to have excellent one year outcomes in both patency and efficacy
- Rotational devices excellent to “debulk” calcium and modify plaque to prepare for adjunctive therapy
- Important to develop expertise and use the ones that you are most comfortable with
- Each unique patient requires a “tailored” approach specific to the anatomy and desired outcome



*Thank You!*

# BTK Atherectomy – Relative Benefits Based on Anatomy



	Directional	Orbital	Laser	Rotational - Jetstream	Rotational -Rotablator
TPT	XXX	XX	XX	XX	X
Prox Tibial	XXX	XX	XX	XX	X
Distal/Pedal	X	XXX	XXX	X	XXX
Bifurcation	XXX	X	XX	X	X
Focal	XXX	XX	XX	XX	X
Long Diffuse	X	XX	XXX	XX	X
Heavy Ca++	X	XXX	X	XX	XXX
Long, Heavy Ca++	X	XXX	X	XX	XXX
CTO	X	XX	XX	XX	X
Thrombus			XXX	XXX	

# Particulate Size Distribution

5 studies, 37 experiments

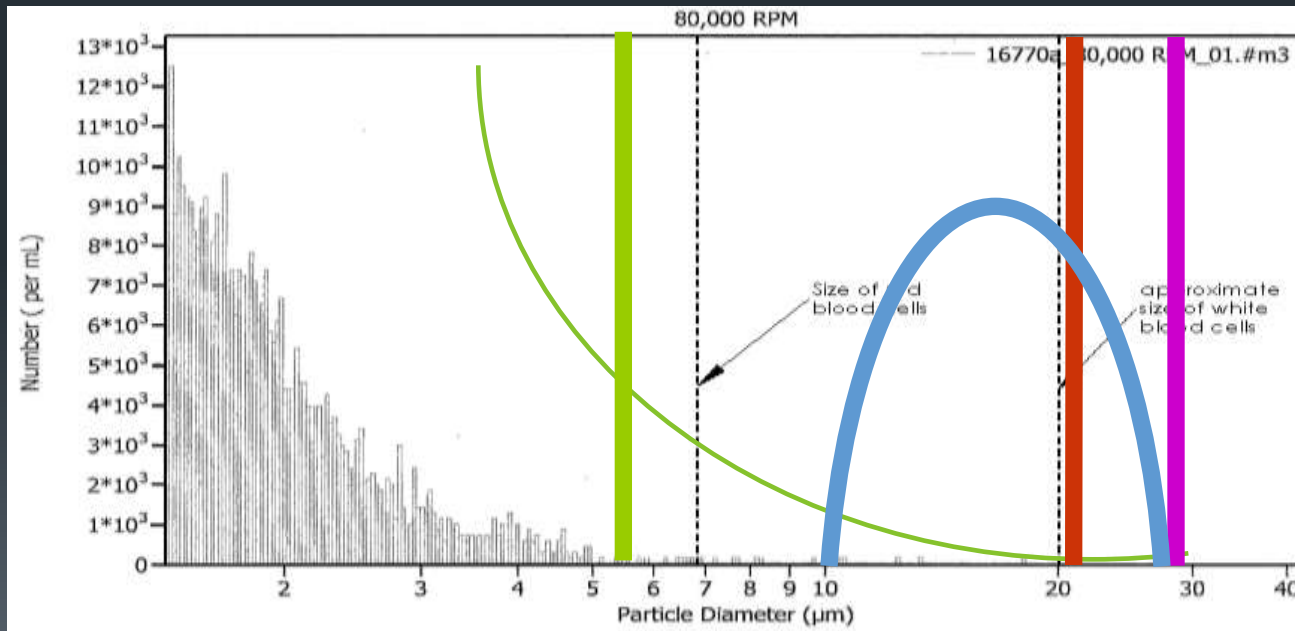
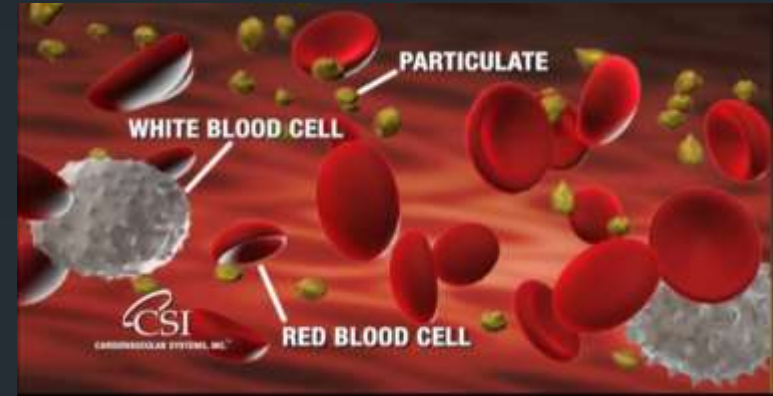
(Carbon blocks; Thermal injury porcine coronary artery;  
Diseased cadaver peripheral arteries)

Mean particle size: 2.3  $\mu\text{m}$  ( $\pm .1 \mu\text{m}$ ) (99.95% CI)

93.14% < Red Blood Cell Diameter (99% CI)

99.3% < Capillary Diameter (99% CI)

Rotablator Average Particle Distribution





# Effective in calcium

## 12 Month Primary Patency in Calcified Lesions from DEFINITIVE LE

