

Atherectomy in CLI

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What is Standalone Atherectomy?

- Atherectomy with no other therapy, or no other devices than adjunctive PTA?
 - Results of excisional atherectomy are equivalent with or without adjunctive PTA¹
 - Adjunctive PTA almost always performed following laser atherectomy (96%)² and orbital atherectomy (100%)³
 - Therefore, we consider atherectomy +/- PTA a standalone procedure

¹Garcia L VIVA 2011

²Laird J et al *J Endovasc Ther* 2006; 13(1): 1-11

³Shammas NW et al *J Endovasc Ther* 2012; 19(4): 480-488

DEFINITIVE LE 180-day Patency

Device success ($\leq 30\%$ DS) was achieved with atherectomy alone in 540 lesions (75%)

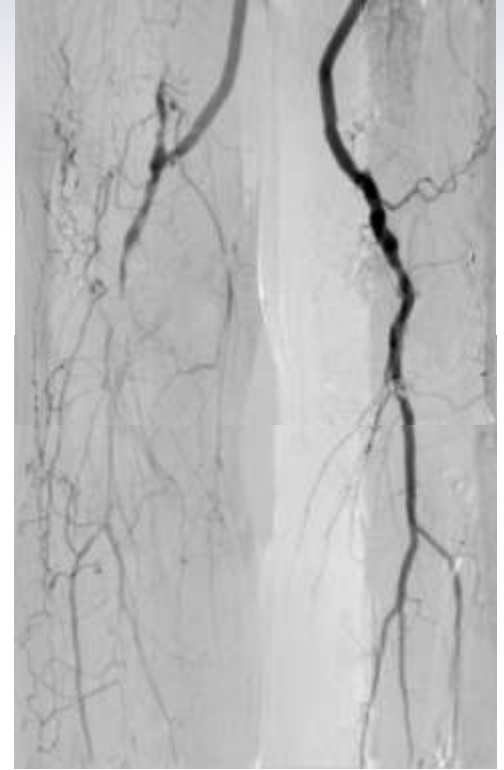
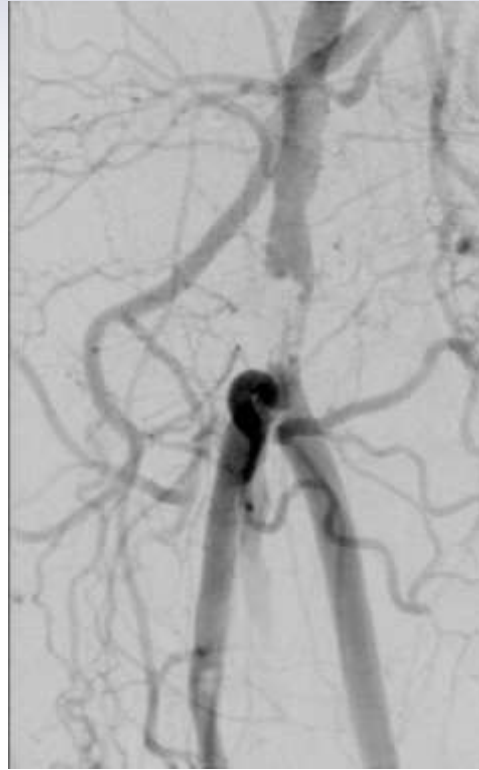
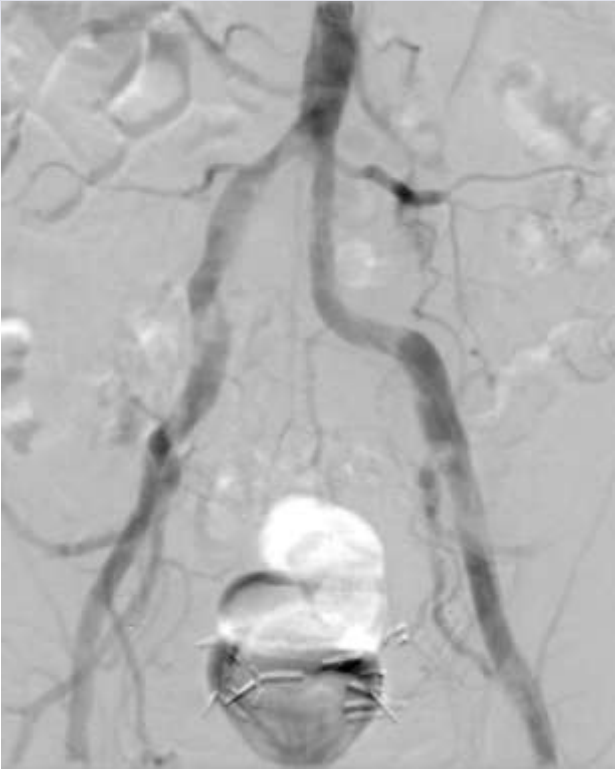
	% Diameter Stenosis $\leq 30\%$ Following Plaque Excision	% Diameter Stenosis $> 30\%$ Following Plaque Excision
Stand-Alone SilverHawk/ TurboHawk	Post-PE Stenosis: 18.2% Mean Lesion Length: 6.7 cm N = 412 lesions 180-Day Patency: 96.6%	Post-PE Stenosis: 36.3% Mean Lesion Length: 9.2 cm N = 35 lesions 180-Day Patency: 88.9%
SilverHawk/ TurboHawk + Adjunctive Therapy *	Post-PE Stenosis: 19.8% Post-Adjunct. Stenosis: 11.7% Mean Lesion Length: 6.9 cm 180-Day Patency: 97.0%	Post-PE Stenosis: 43.5% Post-Adjunct. Stenosis: 22.9% Mean Lesion Length: 10.0 cm N = 142 lesions 180-Day Patency: 93.9%

“adjunctive therapy does not significantly impact 6 month patency”

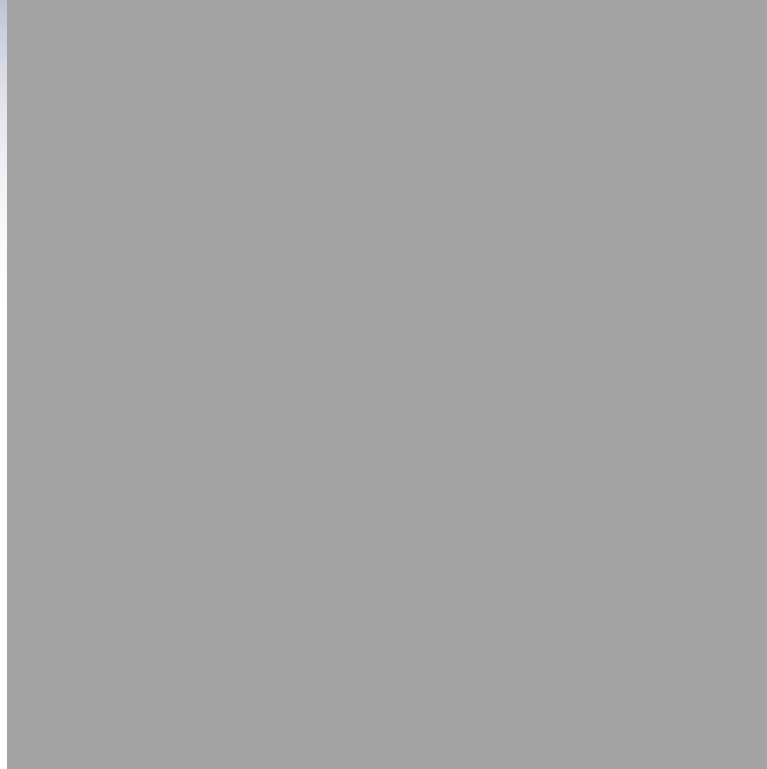
Standalone Atherectomy

- Anatomic considerations
 - Common femoral artery
 - Popliteal artery
 - Graft anastomoses
 - TASC II C/D tibial-peroneal occlusions
- Clinical considerations
 - Bleeding disorders
 - Metal allergies

Complex CFA Stenosis with CLI

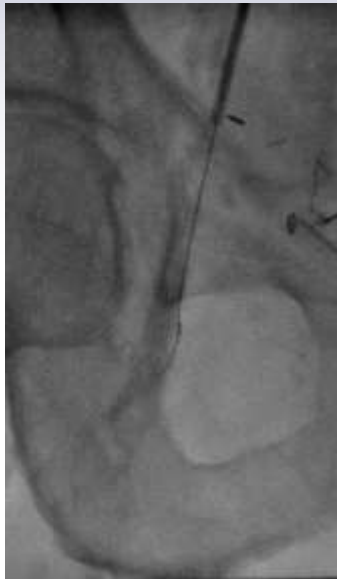


Complex CFA Stenosis with CLI



September 1, 2010

Complex CFA Stenosis with CLI



CXI and MiracleBros



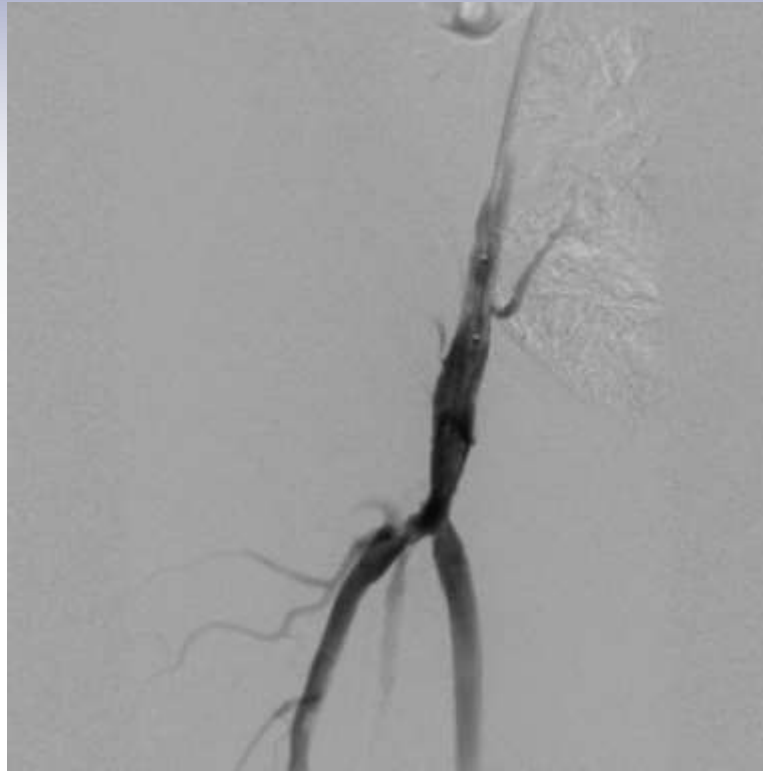
LSC TurboHawk



LXC TurboHawk

September 1, 2010

Complex CFA Stenosis with CLI



September 1, 2010

DEFINITIVE LE 12-month Primary Patency

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
Lesion type				
Stenoses (n=806)	81%	6.7	73%	5.8
Occlusions (n=211)	64%	11.1	66%	10.3
Lesion Location				
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

Complex CFA Stenosis with CLI



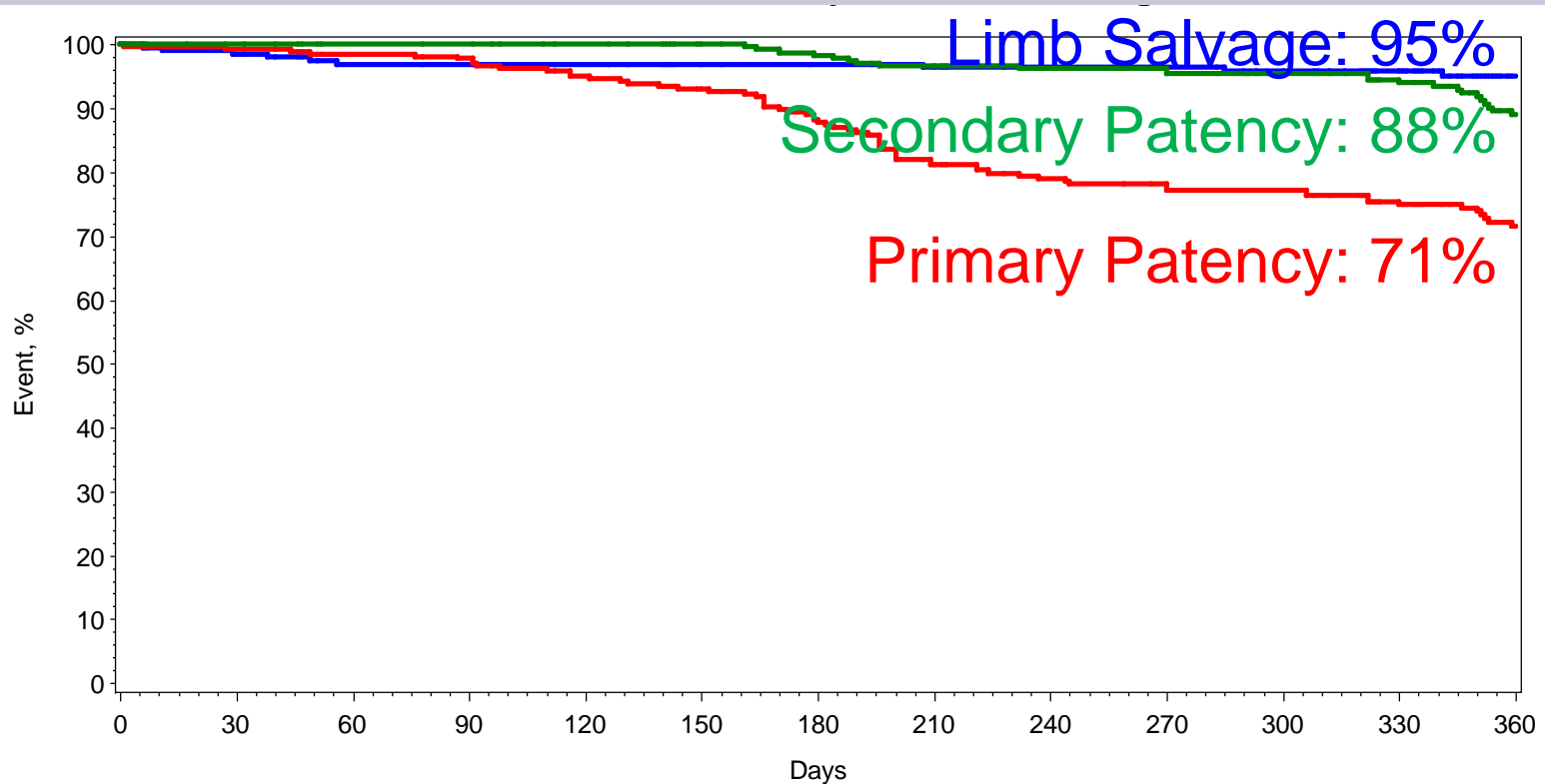
September 1, 2010



January 30, 2012

DEFINITIVE LE CLI

Patency and Limb Salvage



McKinsey JF et al *JACC Cardiovasc Interv* 2014; 7(8): 923-33.

Excimer Laser for CLI



Pre-intervention



Vitesse COS



6-months

LACI-2 CLI Trial 6-Mo Results

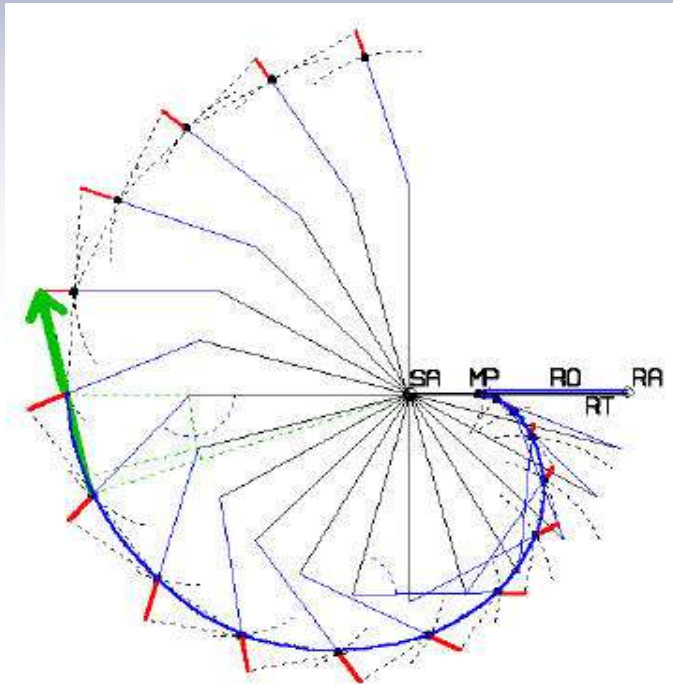
(N=145 pts/155 limbs)

- Mean lesion length 16.2 cm
- Infra-popliteal lesions comprised 41%
- Adjunctive stenting rate 45% (61% ATK and 16% BTK)
- Re-intervention rate 15%, bypass rate 2%
- Major amputation rate 7%
- Is an indicated therapy for CLI, but as a standalone therapy mainly for BTK lesions

Calcified Tibial-Peroneal Disease



CSI Diamondback 360

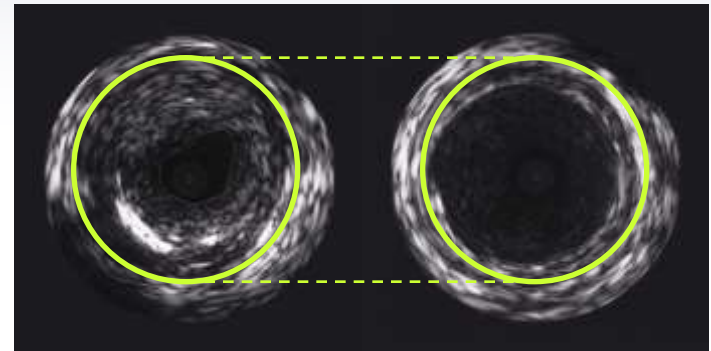


Orbital Atherectomy

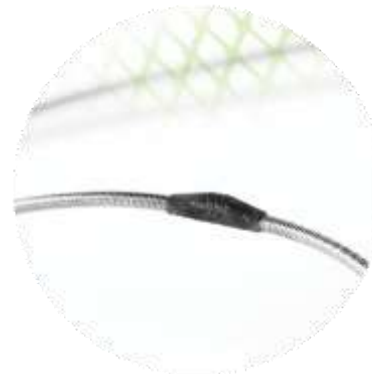
2.25 mm crown can achieve
up to a 4.5 mm lumen

before

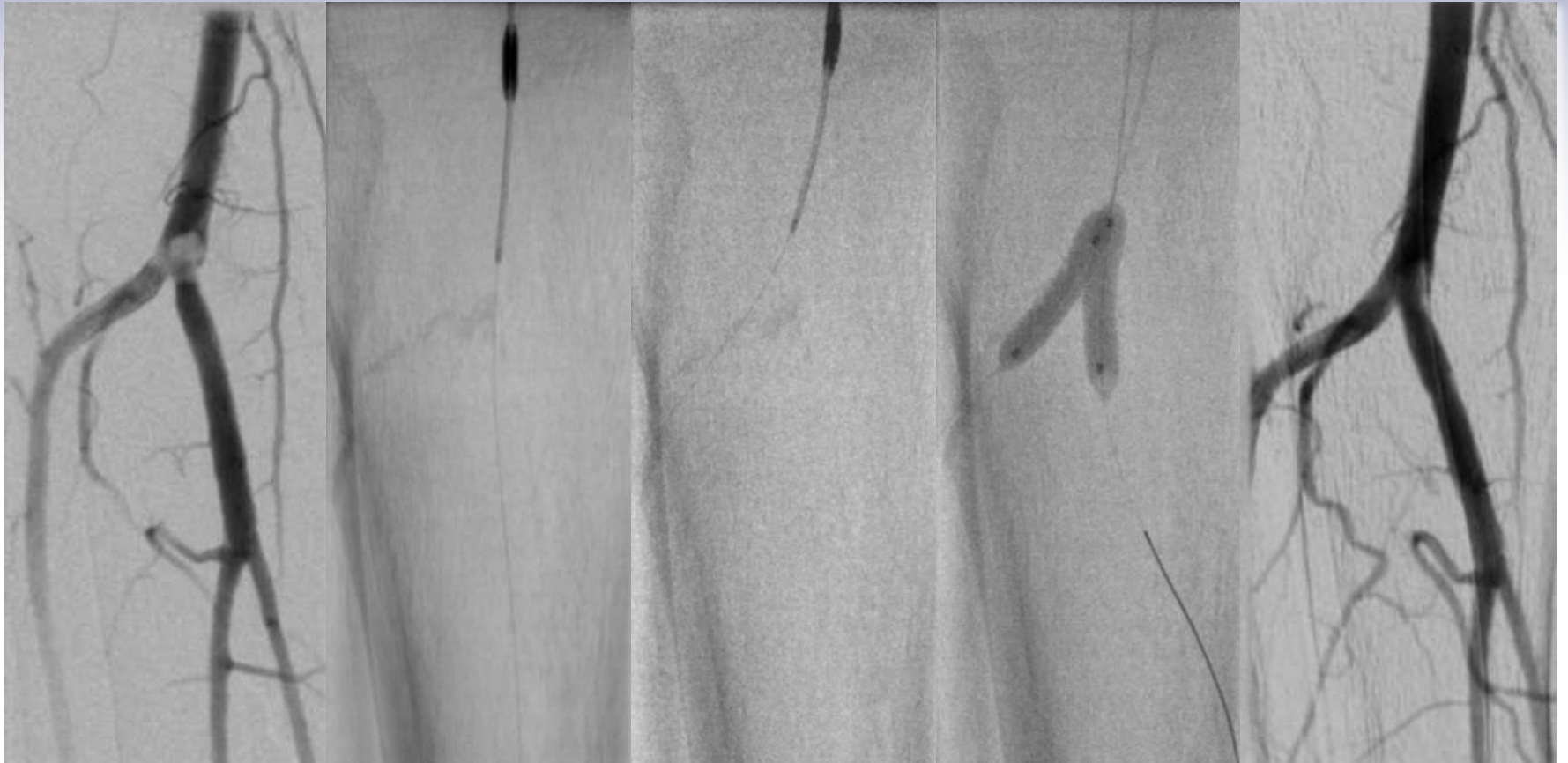
after



70% SFA lesion < 10% residual



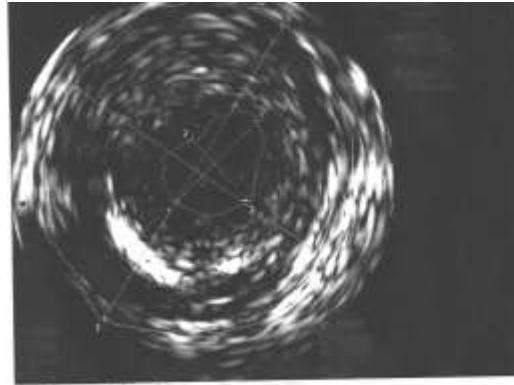
Calcified Tibial-Peroneal Disease



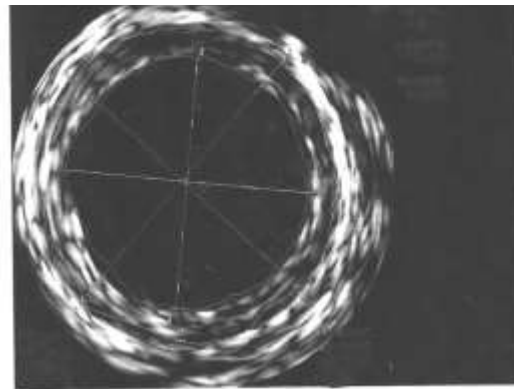
Peroneal 2.25 Classic Crown



Pre 2.3 mm Lumen



Post 4.3 mm Lumen



CONFIRM Registry

CLI (RC 4-6) Sub-Analysis

CLI patient demographics
(Rutherford Class 4-6)

Gender	N=1320 n/N (100%)
Female	558/1320 (42%)
Male	762/1320 (58%)
Age	N=1263 Mean ± SD (Range)
	72.7 ± 11.2 (24.0 - 99.0)
Smoker	
Current	341/1261 (27%)
Previous but quit	574/1261 (46%)
Never	346/1261 (27%)
History of:	
Diabetes	914/1306 (70%)
Insulin dependent	459/821 (56%)
Coronary artery disease	907/1297 (70%)
Renal Disease	553/1303 (42%)
Hypertension	1213/1314 (92%)
Hyperlipidemia	1074/1302 (82%)

Event rates among CLI patients
(Rutherford Class 4-6)

	Total	Moderate to severely calcified lesions
Dissection	126/1321 (9.5%)	105/1149 (9.1%)
Flow-Limiting	16/1321 (1.2%)	13/1149 (1.1%)
Non-Flow Limiting	61/1321 (4.6%)	51/1149 (4.4%)
Unknown	49/1321 (3.7%)	41/1149 (3.6%)
Perforation	11/1321 (0.8%)	10/1149 (0.9%)
Slow Flow	74/1321 (5.6%)	66/1149 (5.7%)
Closure	20/1321 (1.5%)	18/1149 (1.6%)
Spasm	90/1321 (6.8%)	74/1149 (6.4%)
Embolism	22/1028 (2.1%)	15/893 (1.7%)
Thrombus	14/1028 (1.4%)	8/893 (0.9%)

CALCIUM 360° Study Design

- Prospective, multi-center CLI study
- Randomized (1:1)
- Calcified BTK lesions only



Rutherford Class	OAS + BA N = 25	BA ALONE N = 25	P Value
4 (Ischemic rest pain)	48%	48%	1.00
5 (Minor tissue loss)	44%	44%	
6 (Major tissue loss)	8%	8%	

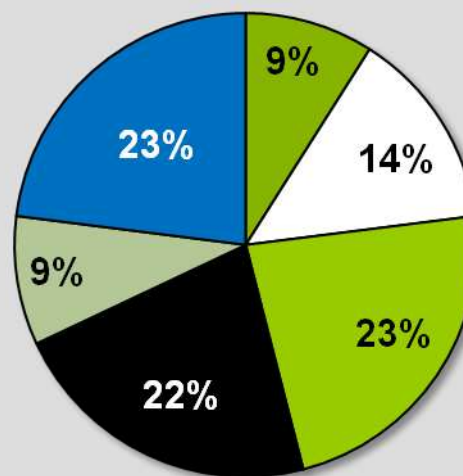
Rutherford classes were similarly distributed between the two study arms (p=1.00)

CALCIUM 360° Lesion Characteristics

	ORBITAL ARM	BALLOON ARM
Number Lesions	30	35
Moderately or Severely Calcified (>50% of lesion)	93%	94%

100% Infrapopliteal Lesions

- Pop
- TPT
- AT
- PT
- Peroneal
- Cross-Segment



*Lesion location was similarly distributed between the two study arms.

CALCIUM 360° 1-Year Results

	OAS + BA	BA ALONE	P Value
Mean Max Balloon Inflation	5.9 atm	9.4 atm	0.001
Dissections (≥ Type C)	3.4%	5.7%	NR
Embolization	0	2.8%	NR
Perforation	0	2.8%	NR
Procedural Success	93.1%	82.4%	0.27
Bail-out stenting	6.9%	14.3%	0.44
12 month Freedom from MAE	93.3%	57.9%	0.006
12 month Freedom from Amputation related to index procedure	100%	100%	NA
12 month Freedom from all cause mortality	100%	68.4%	0.01
12 month Freedom from TLR/TVR	93.3%	80.0%	0.14

Conclusions

- Standalone excisional atherectomy is particularly useful in CLI patients with CFA or popliteal disease, and for infrainguinal stenoses generally <10 cm.
- Standalone laser atherectomy is particularly useful in CLI patients with longer (>10 cm) infrapopliteal stenoses and thrombotic occlusions. The need for adjunctive therapies is acceptable BTK but is high ATK.
- Standalone orbital atherectomy is particularly useful in CLI patients with moderately to heavily calcified BTK stenoses with a low need for adjunctive therapies.
- Jetstream and Phoenix atherectomy have not been well studied although may have use in CLI patients.