

Use of atherectomy in CLI patients – current evidence

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Disclosure

Speaker name:

Erwin Blessing

I have the following potential conflicts of interest to report:

Consulting: Philips, Medtronic

Employment in industry

Stockholder of a healthcare company

Owner of a healthcare company

Other(s): Honorarium: Philips, Medtronic

I do not have any potential conflict of interest

Interventions below-the-knee

Clinical problem: high rate of restenosis and reocclusions

Schmidt *et al.*¹

POBA below the knee in CLI patients (77 lesions)

Angiographic follow up after **3 months**:

No restenosis:	31,2 %
Restenosis \geq 50%:	31,2 %
Reocclusion:	37,6 %

Fernandez *et al.*²

POBA below the knee in CLI patients (123 lesions)

Follow up **12 month**:

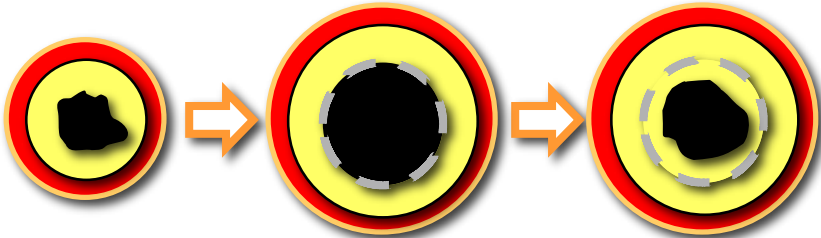
Primary patency:	33 %
Secondary patency:	56 %
TLR:	50 %

Debulking Rationale



Recoil

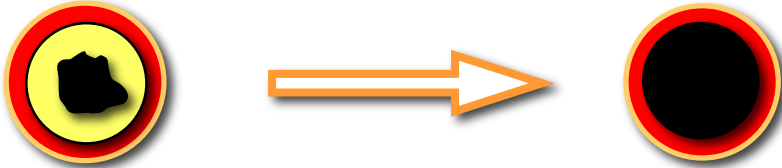
Barotrauma/
Overstretching



Dissection

Restenosis

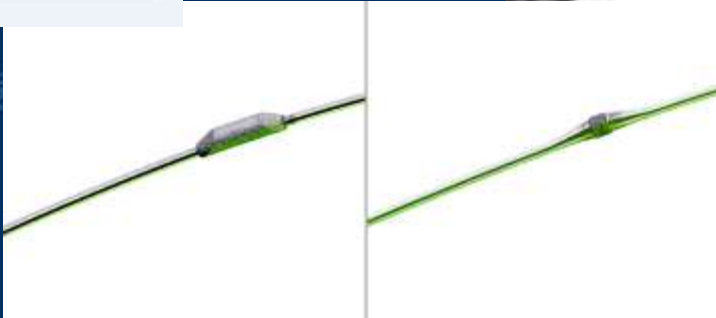
Debulking removes
plaque without causing
vessel overstretch



Debulking Candidates

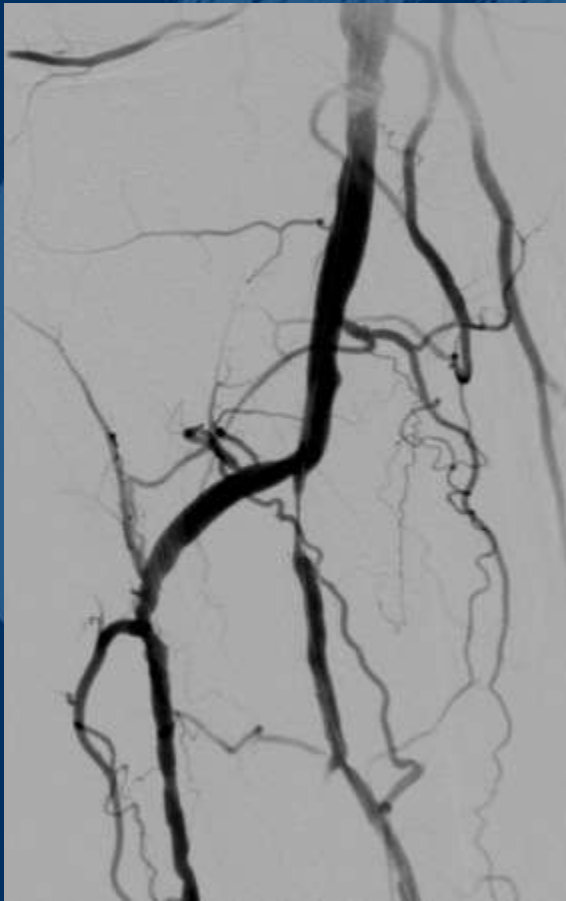


TurboHawk™ and SilverHawk™

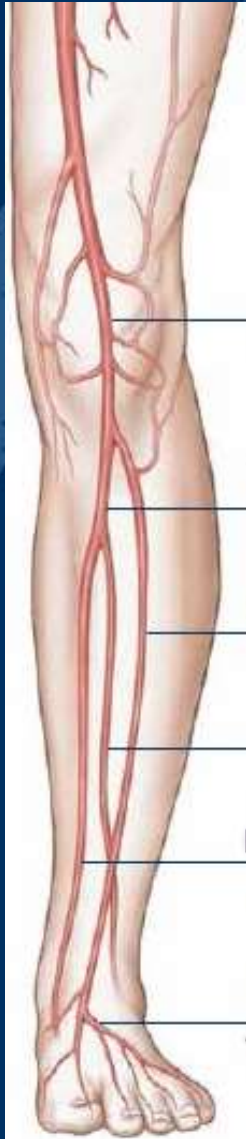


Directional atherectomy

Case example



Directional atherectomy

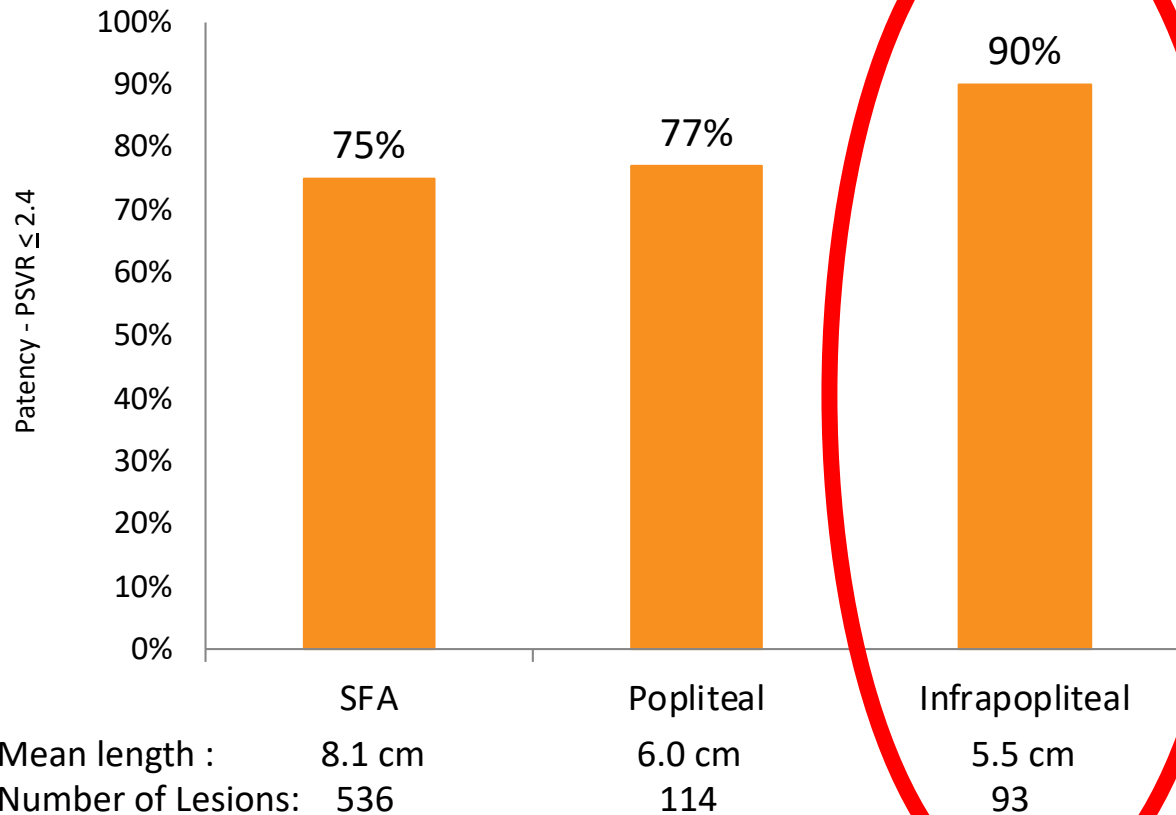


DEFINITIVE LE Infrapopliteal Subgroup

- 145 subjects
 - 75 with Claudication
 - 70 with CLI
- 189 lesions
 - 93 in claudicant cohort
 - 96 in CLI cohort

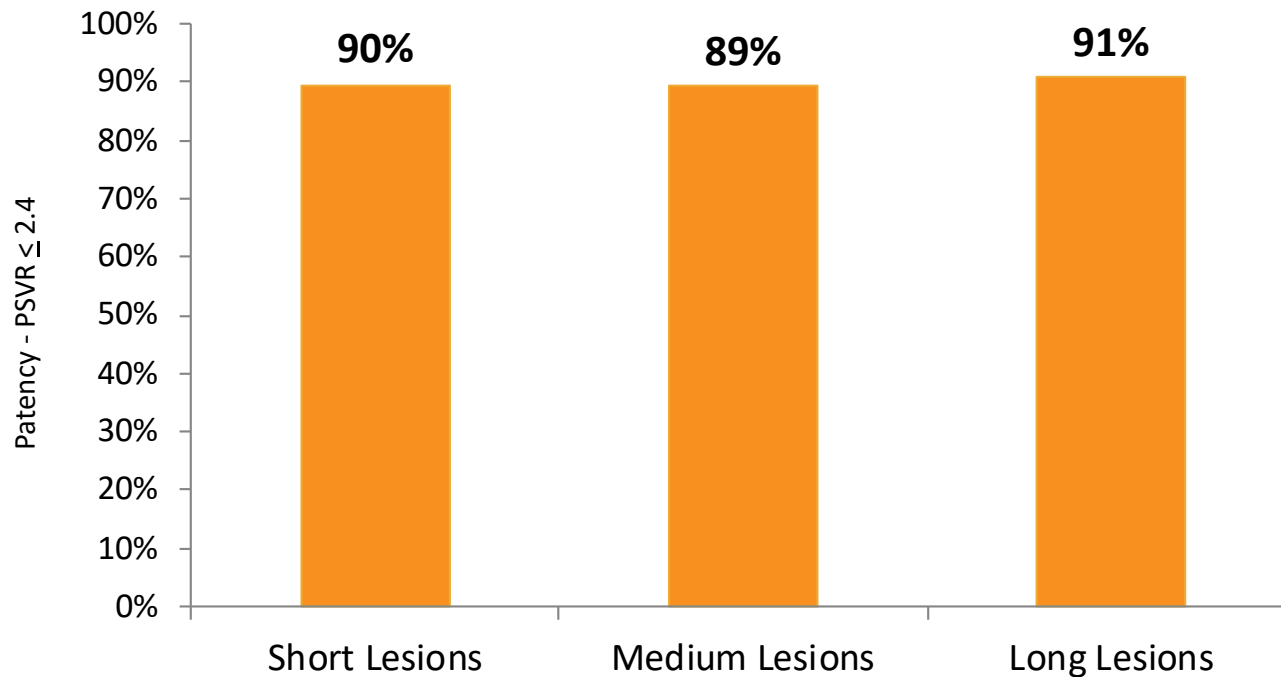
Directional atherectomy

Primary Patency 12 months Claudicant cohort



Directional atherectomy

Primary Patency 12 months Claudicant cohort, BTK Intervention



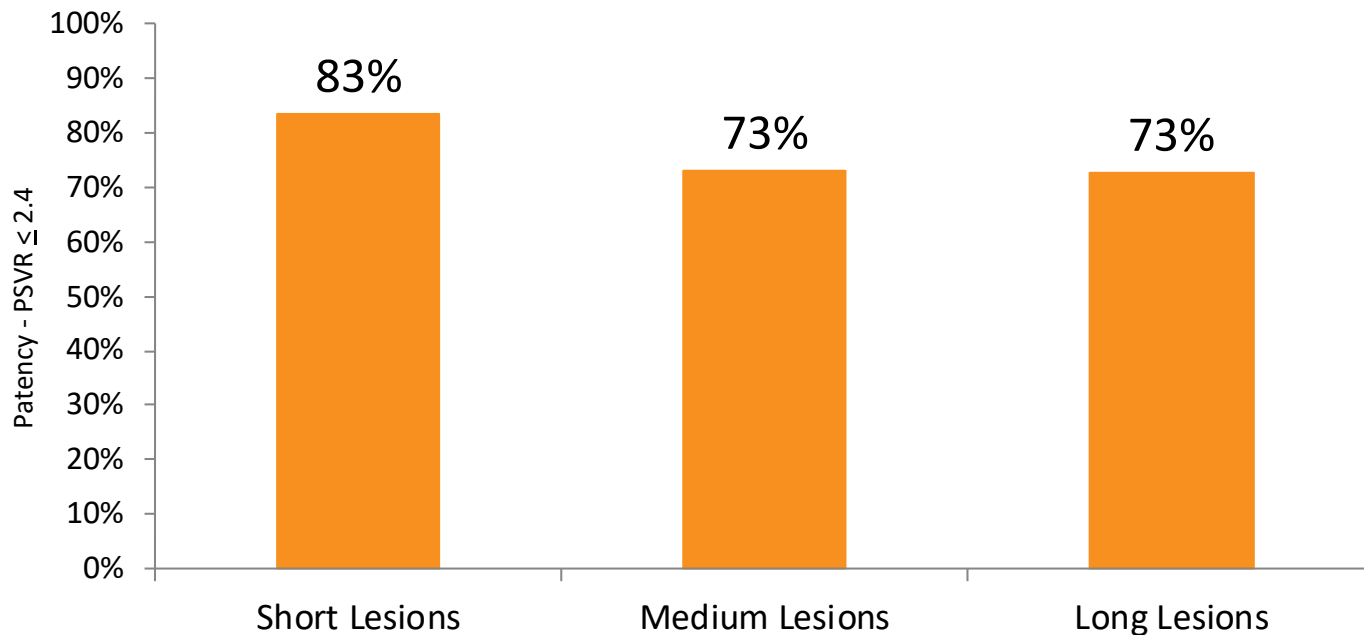
Mean length : 1.8 cm
Number of Lesions: 34

6.2 cm
42

13.4 cm
12

Directional atherectomy

Primary Patency 12 months
CLI cohort, BTK intervention



Mean length : 1.8 cm

Number of Lesions: 31

6.2 cm

34

13.4 cm

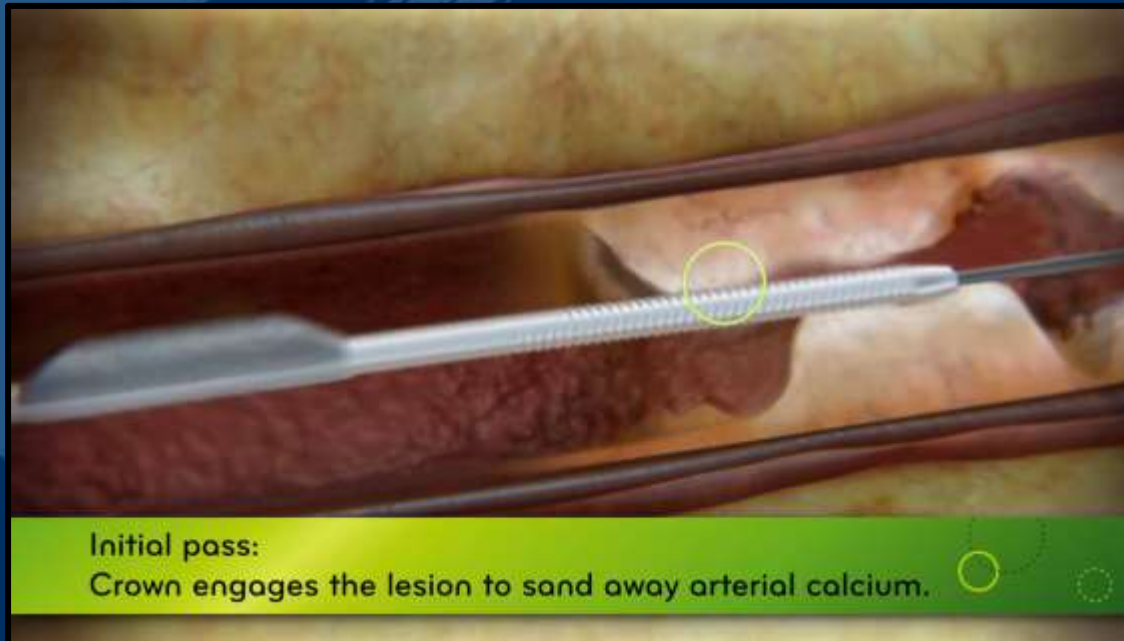
14

Orbital atherectomy

Mode of action

Centrifugal Force

360° crown contact designed to create a smooth, concentric lumen
Allows constant blood flow and particulate flushing during orbit



Differential sanding

- 30 μm diamond coating
- Average particulate size¹ = 2 μm
- Bi-directional sanding of superficial calcium
- Healthy elastic tissue flexes away minimizing damage to the vessel

Pulsatile forces¹

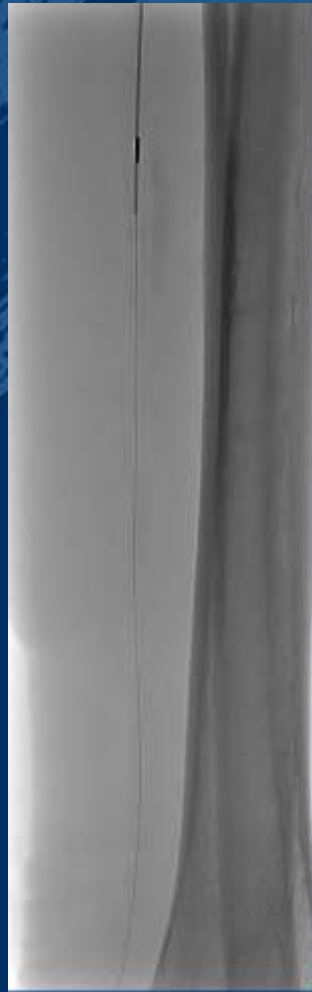
- Dual frequency
- Orbital Frequency: low frequency of the crown orbiting against the vessel wall.
- Rotational Frequency: high frequency corresponding to the crown rotational speed.
- Observed in both crown motion and force.

Orbital atherectomy

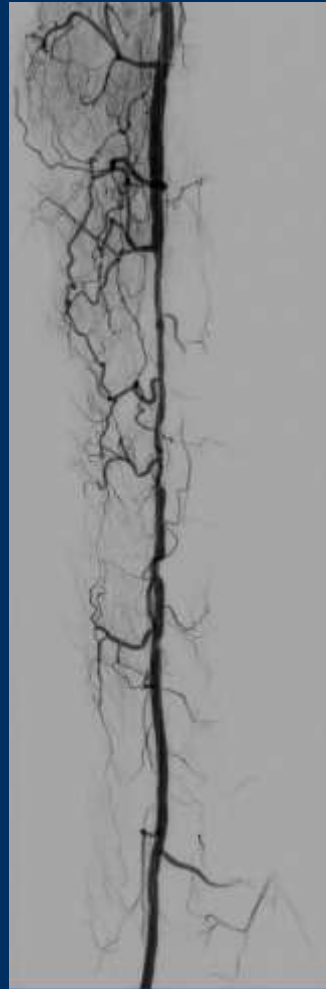
Case example



pre



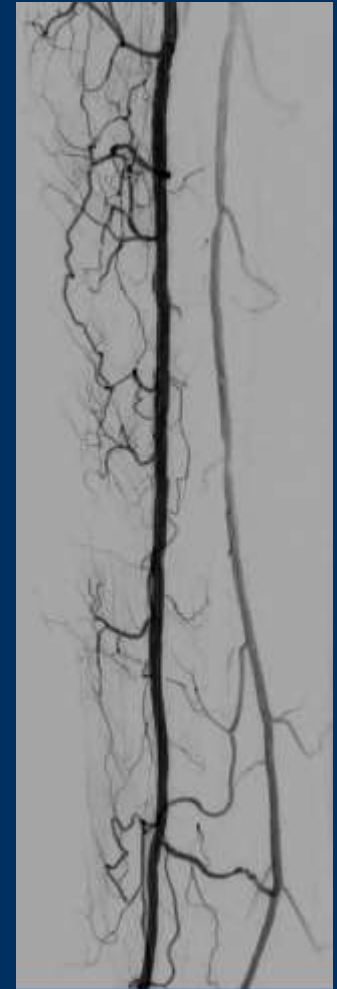
Diamondback



post



Lutonix



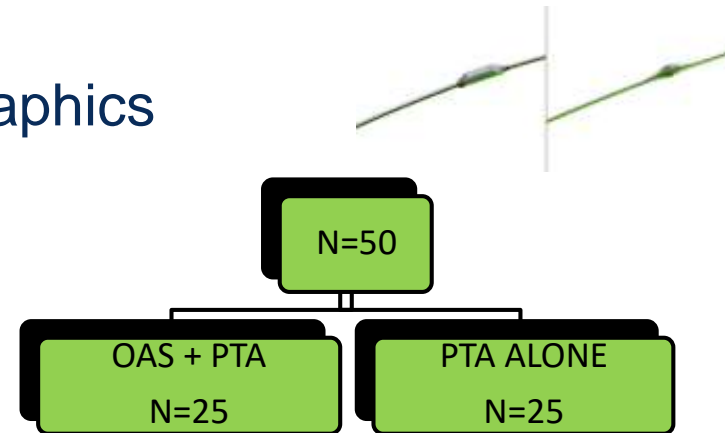
final

Orbital atherectomy

Clinical data

CALCIUM 360°: Study Design & Demographics

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



Demographics	OAS + PTA N = 25	PTA ALONE N = 25	p-value
Mean Age	70.7 ± 13.4	71.8 ± 10.9	0.75
Male / Female	68% / 32%	60% / 40%	0.77
Diabetic Type 1	4%	0%	1.00
Diabetic Type 2	68%	56%	0.56
Renal insufficiency (GFR < 90)	25%	24%	1.00
Smoker (current or previous)	60%	60%	1.00
CAD	44%	56%	0.57
Hypertension	84%	84%	1.00
Dyslipidemia	83%	72%	0.50

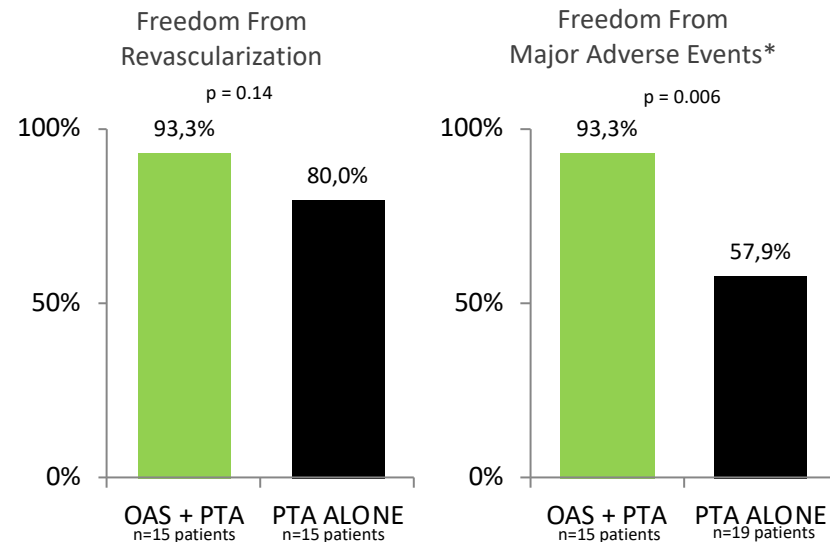
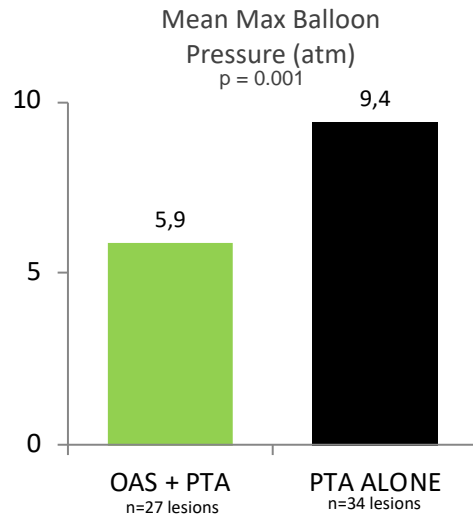
Orbital atherectomy

Clinical data

CALCIUM 360°: Results

Prospective, randomized, multi-center study that compared acute and long-term results of OAS+PTA and PTA alone in calcified BTK lesions

Results at 12 Months



*MAE (major adverse events: device- or procedure-related major amputation (above the ankle), all-cause mortality and TLR/TVR).

Orbital Atherectomy System changes compliance and provides durable results out to 12 months vs. PTA alone

Orbital atherectomy

Clinical data

OPTIMIZE:

RCT For OAS+DCB vs. DCB Alone
In BTK Lesions

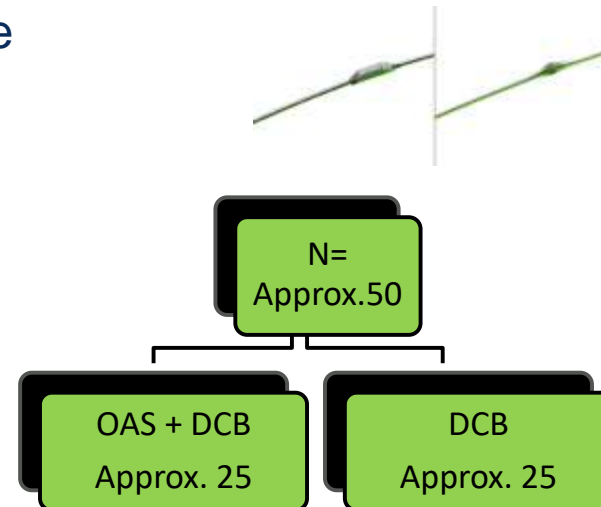
Study Details:

- Pilot study
- Prospective, 1:1 Randomization
- Below the knee lesions
- 2-year follow-up

Active Sites:

- Austria (Prof. Brodmann/Deutschmann & Dr. Werner)
- Germany (Prof. Zeller, Prof. Tepe, Prof. Andrassy, Prof. Blessing, Prof. Scheinert)
- Switzerland (Dr. Banyai)

Purpose: Demonstrate the ability of the OAS to prepare calcified, BTK lesions for optimal DCB deployment



Phoenix atherectomy system Technology

Clear:
Archimedes
screw clears
debulked
tissue

Capture:
Blades
designed for
continuous
capture



Cut:
Front cutter
clears tissue

	Phoenix*	Directional	Orbital	Rotational
Front cutting for direct lesion access	✓		✓	✓
Continuous plaque removal	✓			
Directional cutting ability	✓	✓		
Single insertion	✓		✓	✓
No need for capital equipment	✓	✓		

- **Versatility:** Phoenix effectively treats a broad range of tissue types, from soft plaque to calcified arteries, for lesions both above and below the knee.
- **Center mass cutter:** Clears tissue in a way that may reduce potential trauma to the vessel. Phoenix cutter head allows debulked tissue be continuously captured, resulting in a <1% rate of distal embolization.
- **Cut, capture and clear mechanism of action:** Front cutter clears tissue, blades continuously capture debulked material, which is removed by the Archimedes screw.

Phoenix Registry Study Design

Objective: Evaluate the short and long-term clinical outcomes of patients treated with Phoenix Atherectomy System for peripheral artery disease (PAD)

N Patients	500 (259 CLI patients)
Multicenter (N sites)	17
Enrollment	September 14, 2015- April 8, 2019
Follow Up	30 days (1 year for CLI patients)
Randomization	None
Phoenix Sizes	1.8mm (5F), 2.2mm (6F), 2.4mm (7F)
Primary Endpoints	Technical Success Procedural Success Adverse device effects
Secondary Endpoints	Wifl Classification Target Vessel Revascularization (TVR) Target Lesion Revascularization (TLR) Major Amputation

Key Efficacy Endpoints

Study	Definitions of Success	Success Rates
Phoenix Registry	Procedural: final target lesion(s) residual stenosis of $\leq 30\%$ after treatment with Phoenix and any other adjunctive therapy	Procedural Success All Comers: 97% (485/500) CLI: 97.7% (252/258)
	Technical: achieving a post-Phoenix (prior to any adjunctive therapy) residual diameter stenosis of $\leq 50\%$	Technical Success All Comers: 61.8% (309/500) CLI: 68.6% (177/258)

Full cohort show high procedural **success rates**, **>97%** with CLI patients exhibiting greater technical and procedural success rates

Secondary Endpoints at 30 days

Full cohort: N=465

TLR	1.3%
Major Amputations	0%

CLI cohort: N=237

TLR	1.7%
Major Amputations	0%

- No Major Amputations at 30 Days
- Low rates of TLR at 30 Days
- CLI patients exhibit acute Rutherford score improvements, with greater than 60% of patients improving by at least 1 class @ 30 days

Change in Rutherford Score CLI cohort

Improved by 1	11.9%
Improved by > 1	48.6%

TLR: Target lesion revascularization

Major Amputation: Any amputation performed above the level of the ankle.

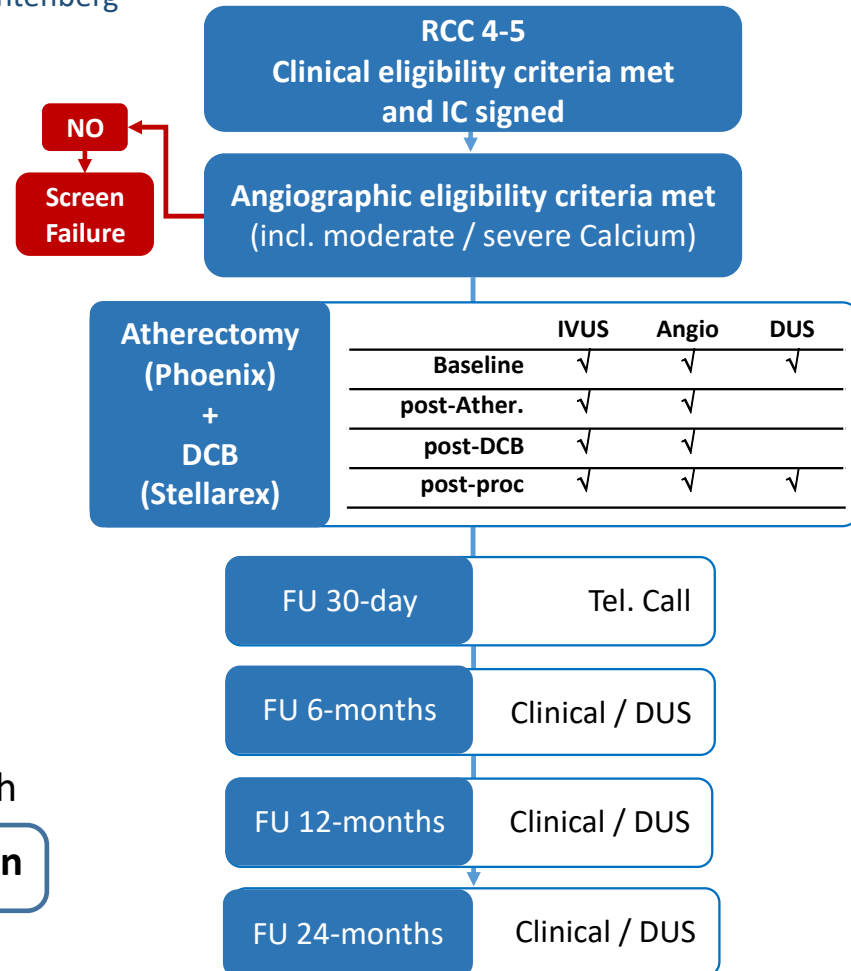
Phoenix atherectomy system

PRESTIGE

Phoenix Atherectomy and Stellarex DCB: clinical investigation in infrapopliteal interventions

ClinicalTrials.gov Identifier: NCT03744572, PI M.Lichtenberg

- Prospective, single-arm, multi-center
- N=75
- **Objective:** assess safety and efficacy of an IVUS-guided lesion preparation strategy with Phoenix atherectomy before DCB in CLI patients with BTK disease and moderate/severe calcium
- **Primary Endpoints:**
 - **Efficacy:** Patency at 6 months (freedom from TLR and TL occlusion by DUS)
 - **Safety:** freedom from MALE and/or 30-day perioperative death
- **Angio, IVUS, DUS Core-lab adjudication**



Conclusions

Below-the-knee interventions are plagued by a high rate of target lesion failure

No convincing data so far for drug coated balloon angioplasty in below-the-knee arteries

Debulking is safe and effective also below-the-knee

Most convincing atherectomy data so far generated with directional atherectomy

Promising acute technical success also with orbital atherectomy and with the Phoenix system

Ongoing trials evaluating combination therapy (debulking plus drug coated balloons) below-the-knee in CLI patients

Use of atherectomy in CLI patients – current evidence

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