PERSPECTIVES 2017
December Friday 15 - BORDEAUX
Organization: E. Ducasse, M. Sibé
www.congresperspectives.com

My most promising perspective For BTK treatment

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Disclosure

Speaker name: .Yvonne Bausback

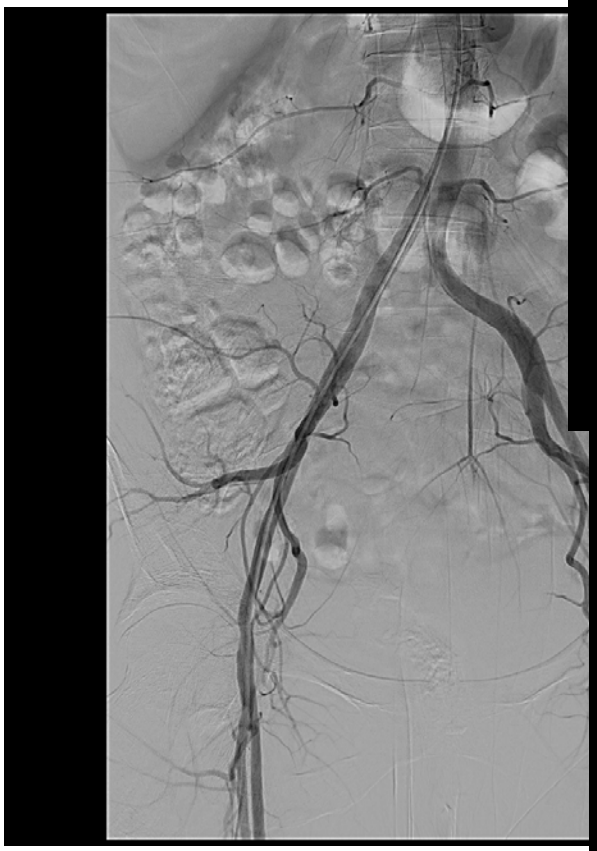
- Potential conflict of interest:

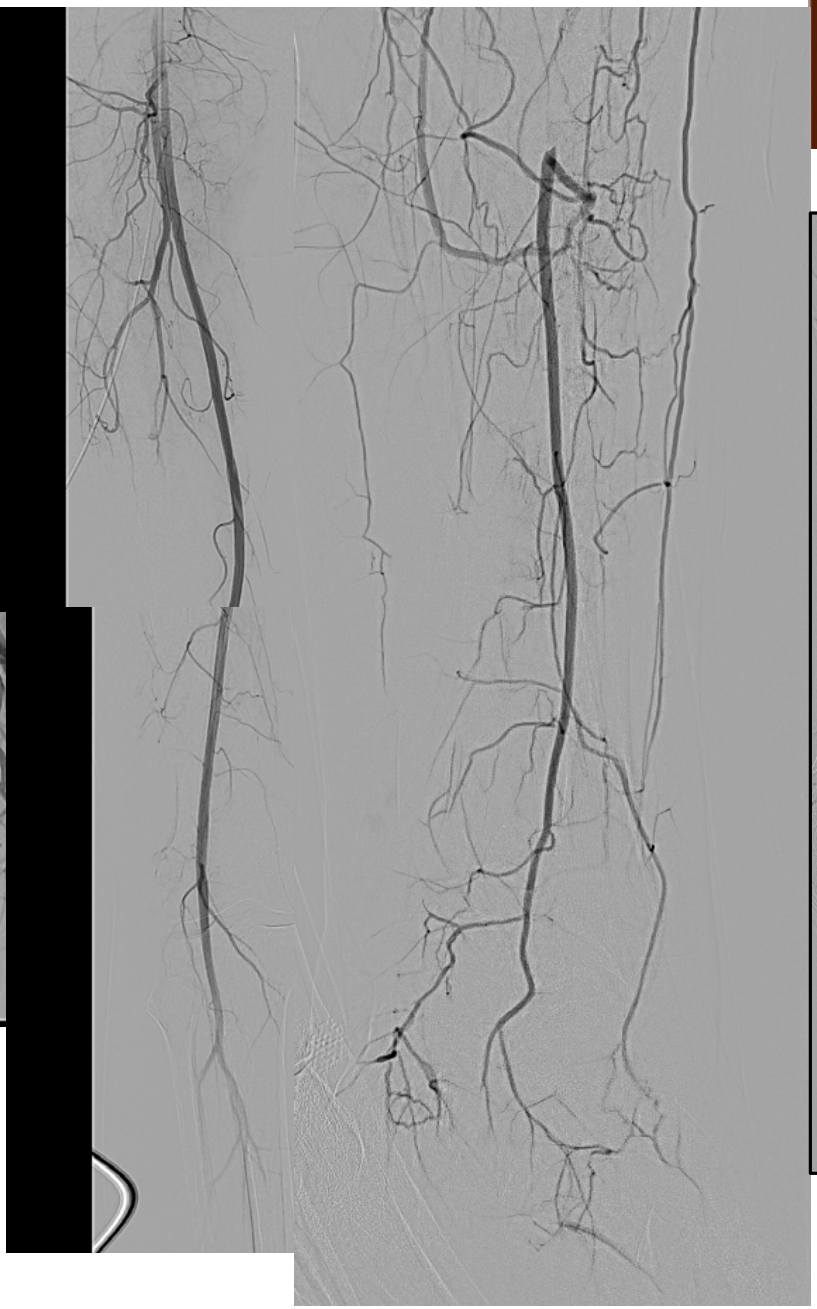
  Consultation fee: Bard Peripheral, Medtronic

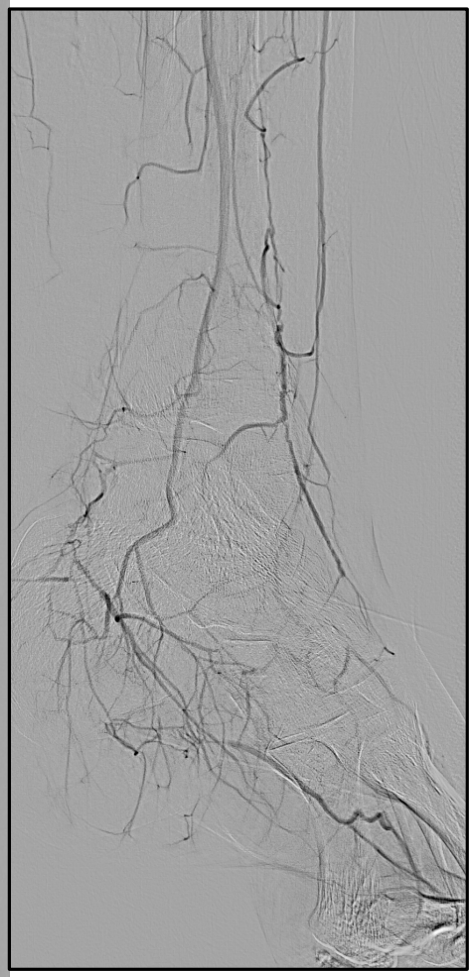
Case report: Thrombotic occlusion of the left popliteal and tibial arteries

- Female, PAOD RU Class 4 left
- Planned Mayor Amputation after
- Unsuccessfull Recanalisation of the popliteal artery 8/2017 + 9/2017
- Fem- crural bypass denied

Overview







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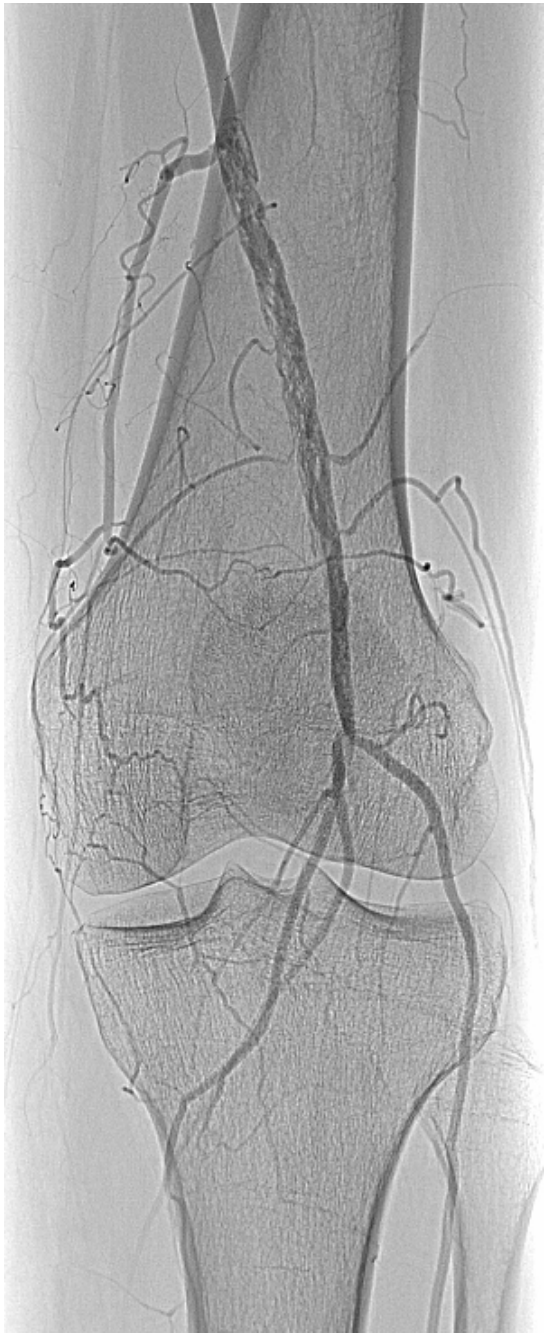


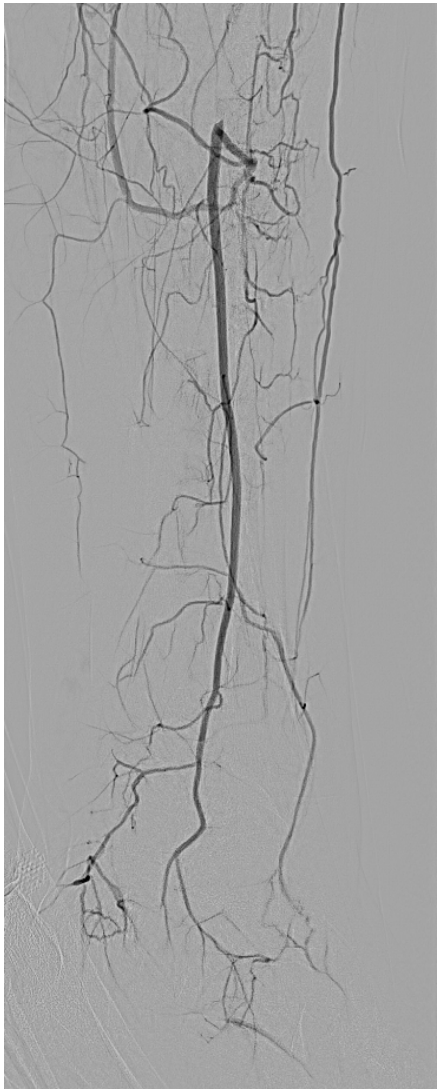
Options

Konservative?

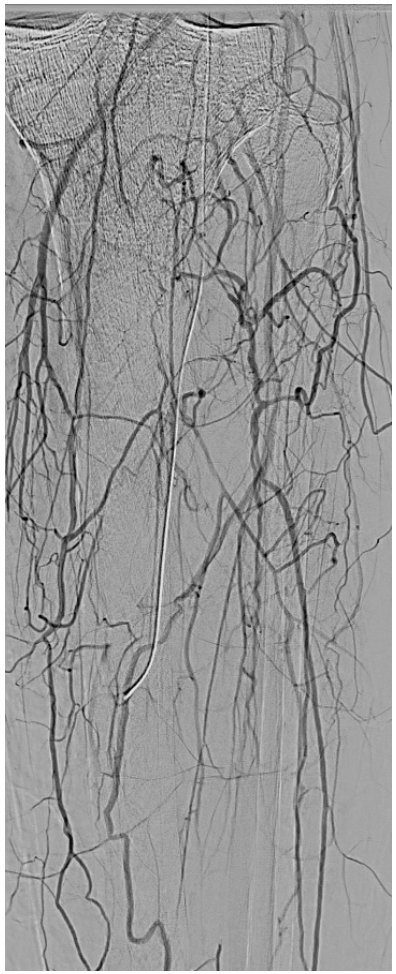
Stenting?

Debulking?

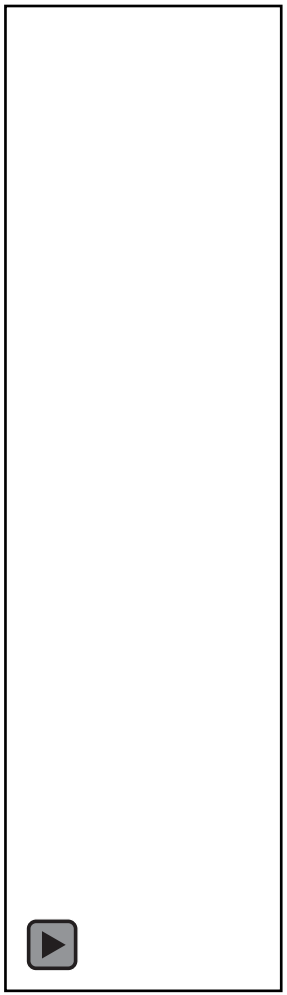
Bypass ?

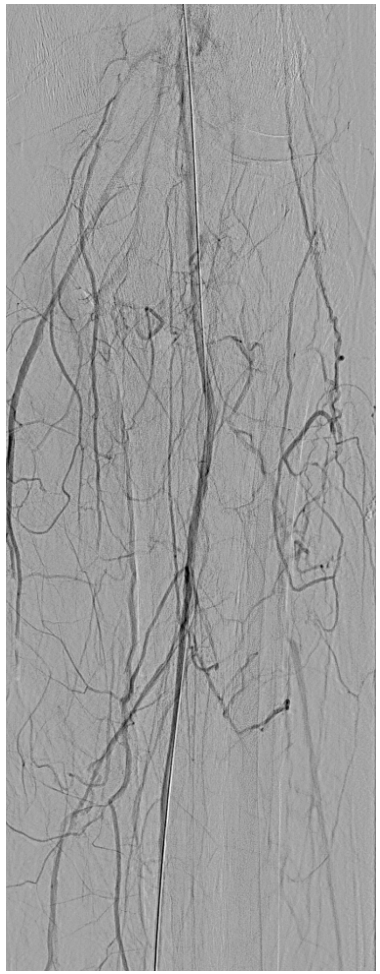


Angioplasty

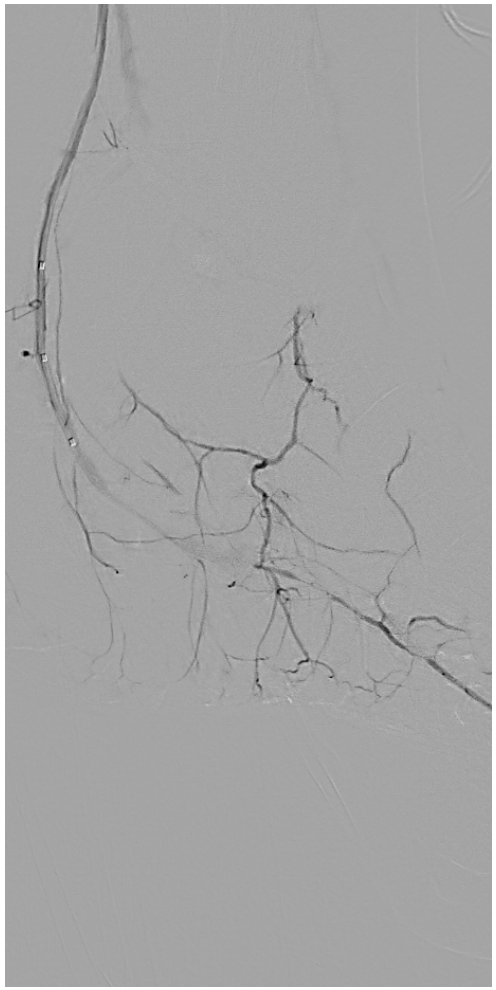


Kollateral Network



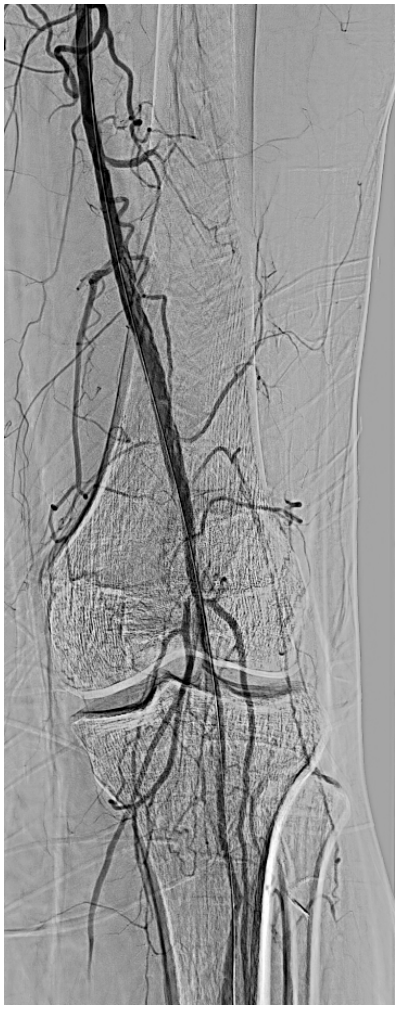


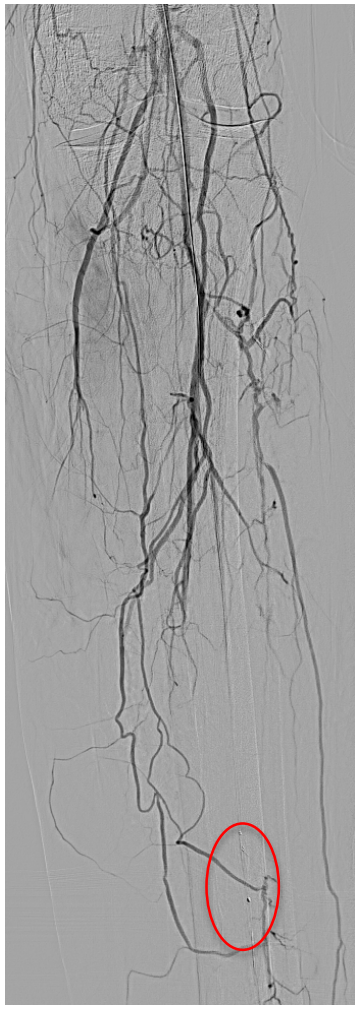
Primary PTA of the Posterior tibial a.



Pedal Arch left

Laser atherectomy





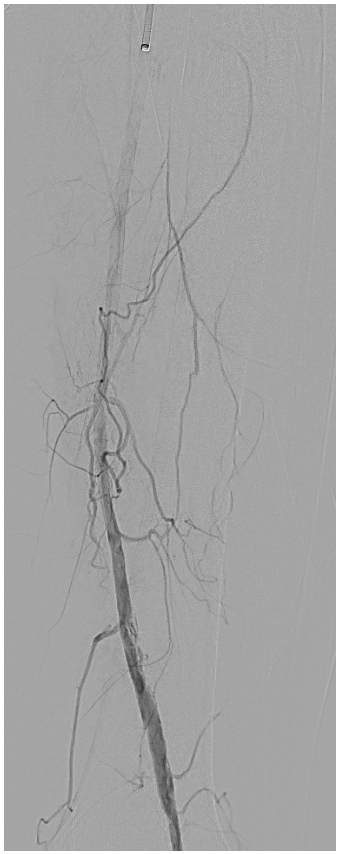
- Turbo Laser
  Ø 1.4 mm

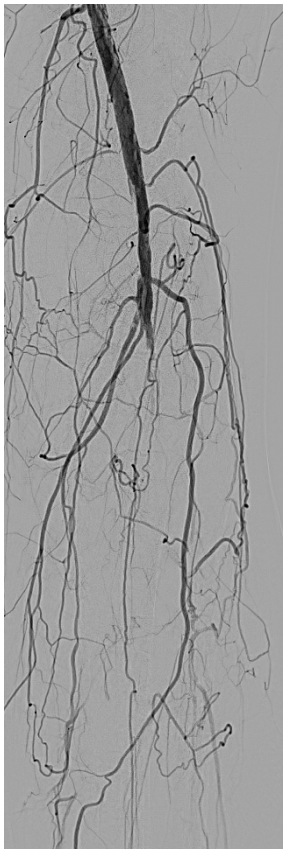
(0.014“ mm guidewire)

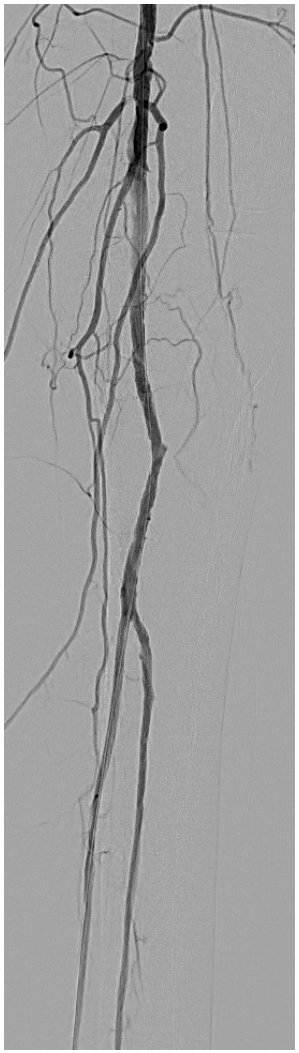
- Spider Filter
  Ø 4 mm

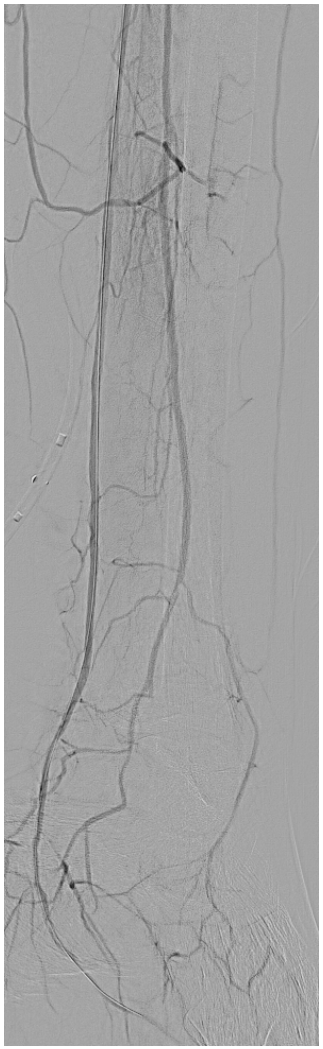
The next day

- After 24 h lysis with rtPA









Follow up

- Oral anticoagulation + ASA
- Close surveillance -> Angiography within 6 weeks
- Re – PTA , if needed debulking
- Try to avoid stenting

My most promising perspective for BTK treatment

- There is no single receipe in BTK arteries
- Use all you have
  DEDICATED LOW PROFILE BALLONS
  ADVANVED REVASCULARSATION TECHNIQUES
  DEBULKING FOR RESIDUAL STENOSIS/ RECOIL
- .... and all your skills
- Just never give up

Global Lutonix® DCB BTK Registry Study
6 Month Interim &
12 Month Initial Safety Outcomes

A Prospective, Multicenter, Single-Arm Real-World Registry Investigating the Clinical Use and Safety of the Lutonix® 014 Drug Coated Balloon PTA Catheter for Treatment of Below-the-Knee (BTK) Arteries

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Study Design

Study Design	Prospective, Multicenter, Single Arm Registry
Objective	To demonstrate safety and assess the clinical use and outcomes of the Lutonix® 014 DCB for treatment of stenosis or occlusion of native below-the-knee arteries in a heterogeneous patient population in real world clinical practice
Number of patients/sites	Up to 500 subjects to be enrolled at up to 35 international sites
Key Inclusion Criteria	Rutherford Class: 3-5,≥ 70% stenosis lesion, target vessel(s) reconstitute(s) at or above the ankle with inline flow to at least one patent
Key Exclusion Criteria	Neurotrophic ulcer or heel pressure ulcer or ulcer potentially involving calcaneus (index limb)
Primary Endpoints	Safety: Freedom from BTK MALE+POD at 30-days Efficacy: Freedom from TLR at 6 months
Follow-up	1, 6, 12 and 24 Months

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Study Centers

PI Name	
Prof. Willfort-Ehringer	
Dr. Loewe	
Prof. Brodmann	
Prof. Hausegger	
Dr. Lerut	
Dr. Lansink	
Dr. Husmann	
Dr. Zech	
Dr. Giménez-Gaibar	
Dr. Albuquerque e Castro	
Prof. Sapoval	
Dr. Lichtenberg	
Dr. Thieme	
Prof. Scheinert	

Study Centers

PI Name	
Prof. Eckstein	
Dr. Sunderdiek	
Prof. Tepe	
Dr. Perez Delgado	
Prof. Zeller	
Prof. Karnabatidis	
Prof. Brountzos	
Dr. Rossato	
Dr. Cioppa	
Dr. Tolva	
Dr. Van den Heuvel	
Dr. Butterfield	
Dr. Al-Shammari	

Demographics / Baseline Characteristics

Description	BTK Registry (N=359)
Age (Years), Mean ± SD (n)	73.7 ± 9.51 (359)
Gender (n/N) Female Male	 28.1% (101/359) 71.9% (258/359)
BMI ≥30 kg/m² (n/N)	23.8% (84/353)
Hypertension (n/N)	87.2% (313/359)
Dyslipidemia (n/N)	62.4% (224/359)
Current/Previous Smoker (n/N)	50.4% (181/359)
Diabetes (n/N)	64.1% (230/359)
Rutherford Category (n/N) 3 4 5	 23.4% (84/359) 10.3% (37/359) 66.3% (238/359)

Data presented is interim, site reported, and subject to change

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Lesion Characteristics

Description	BTK Registry (N=359)
Lesion Location[1] (n/N)	
Popliteal	7.0% (25/359)
Tibioperoneal Trunk	20.6% (74/359)
Anterior Tibial	51.5% (185/359)
Posterior Tibial	21.4% (77/359)
Peroneal	23.1% (83/359)
Total Target Length (mm), Mean ± SD (n)	121 ± 98.5 (359)
Average RVD (mm), Mean ± SD (n)	2.7 ± 0.51 (355)
(min, max)	(1.7, 4.5)
Calcification (n/N)	68.0% (234/344)
Severe Calcification (n/N)	24.4% (71/291)

[1]Subjects may be in more than one category.

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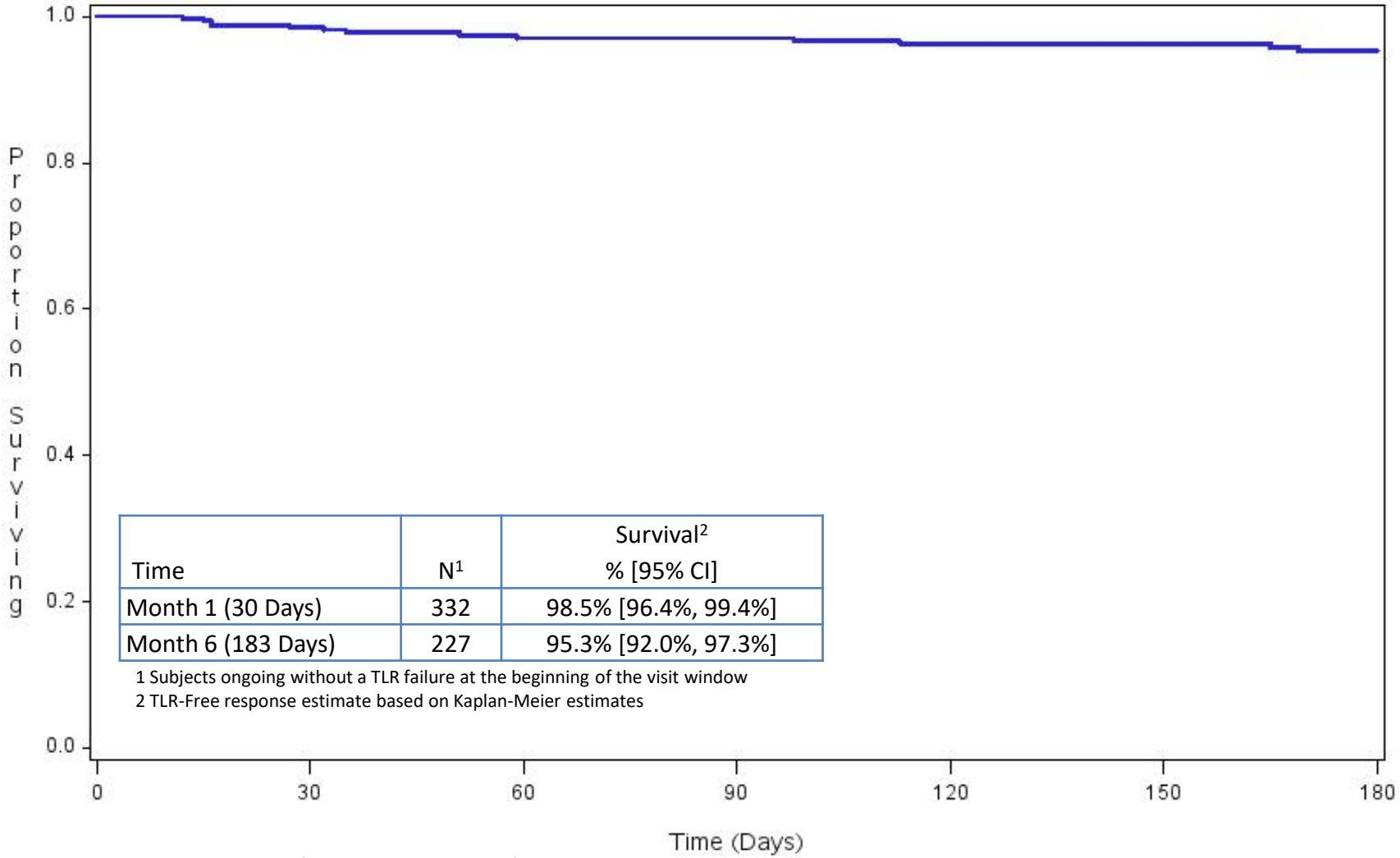
Freedom from Primary Safety Events



Time	N[1]	Survival[2] % [95% CI]
Month 1 (30 Days)	332	98.5% [96.4%, 99.4%]
Month 6 (183 Days)	227	95.3% [92.0%, 97.3%]

1 Subjects ongoing without a TLR failure at the beginning of the visit window
2 TLR-Free response estimate based on Kaplan-Meier estimates

Freedom at 30-Days from the composite of all-cause death, above-ankle amputation or major re-intervention, i.e., new bypass graft, jump/interposition graft revision, or thrombectomy/thrombolysis of the index limb involving a below-the-knee artery.

6 Month Additional Safety Profile

Freedom From	N[1]	Survival[2] % [95% CI]
All Cause Death Survival	232	91.9% [87.8%, 94.6%]
Major Amputation	229	96.5% [93.4%, 98.2%]
Re-intervention for Thrombosis/Thrombolysis	225	96.9% [93.8%, 98.4%]
Re-intervention For Distal Embolization	232	100.0% [NA, NA]
TVR	214	89.9% [85.4%, 93.0%]
Unexpected Device or Drug Related Event	232	100.0% [NA, NA]

[1]Subjects ongoing without a failure at the beginning of the visit window
[2]Survivor rate based on Kaplan-Meier Estimate

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Initial 12 Month Additional Safety Profile

Freedom From	N[1]	Survival[2] % [95% CI]
Major Amputation	116	95.0% [90.9%, 97.3%]
Re-intervention for Thrombosis/Thrombolysis	113	91.3% [85.3%, 94.9%]
Re-intervention For Distal Embolization	120	100.0% [NA, NA]

[1]Subjects ongoing without a failure at the beginning of the visit window
[2]Survivor rate based on Kaplan-Meier Estimate

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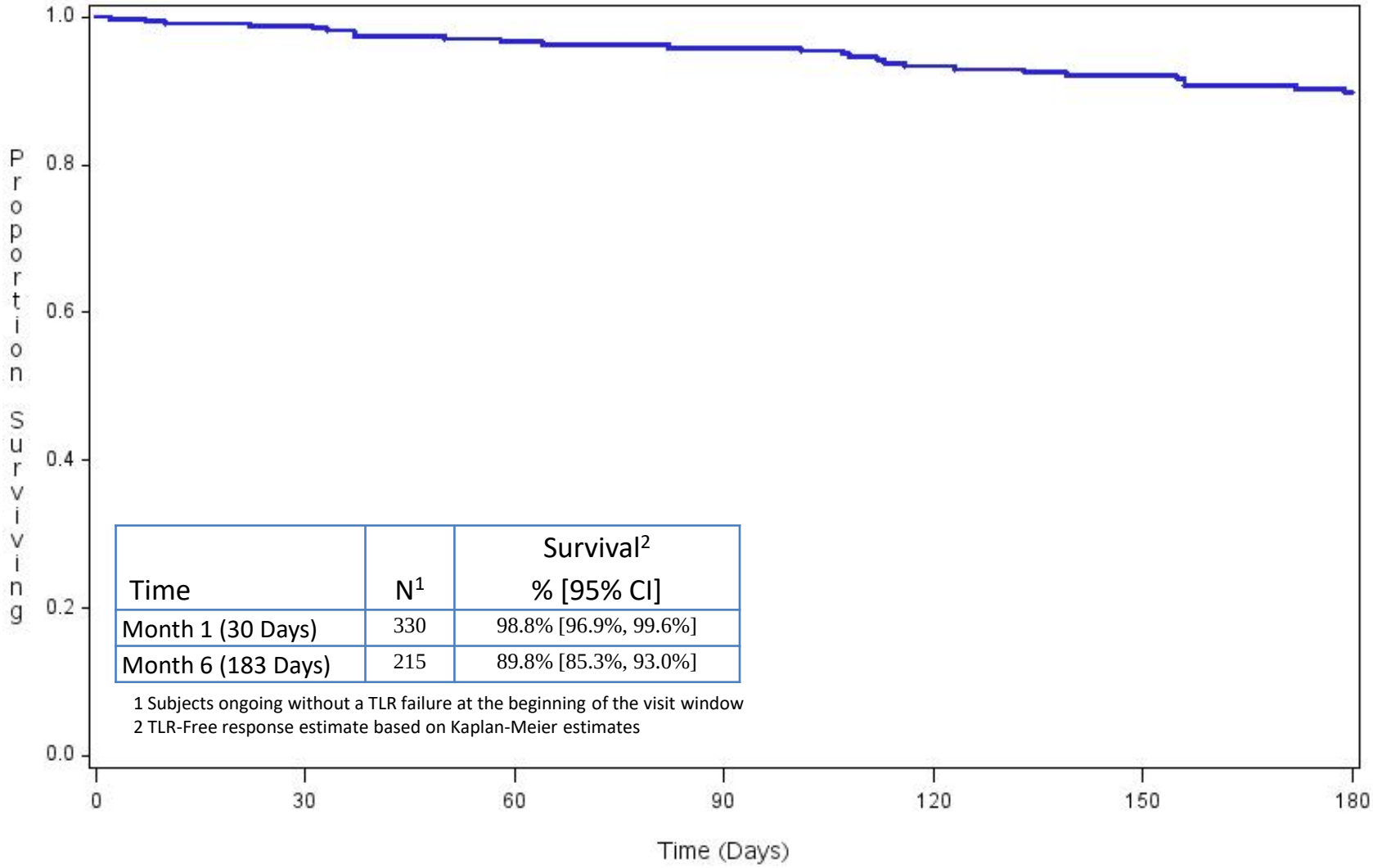
Freedom from TLR



Time	N[1]	Survival[2] % [95% CI]
Month 1 (30 Days)	330	98.8% [96.9%, 99.6%]
Month 6 (183 Days)	215	89.8% [85.3%, 93.0%]

1 Subjects ongoing without a TLR failure at the beginning of the visit window
2 TLR-Free response estimate based on Kaplan-Meier estimates

Summary

Safety Profile Consistent with the Safety Profile of the Lutonix® 035 DCB in PAD

Freedom from TLR at 6 Months 89.8%

5% Major Amputation Rate at 12 Months

No Re-interventions for Distal Embolization at 12 Months

Full 12 Month Interim Outcomes in 2018