State of the Art of BTK Vessel treatment

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Disclosure

Speaker name:

Sebastian Sixt

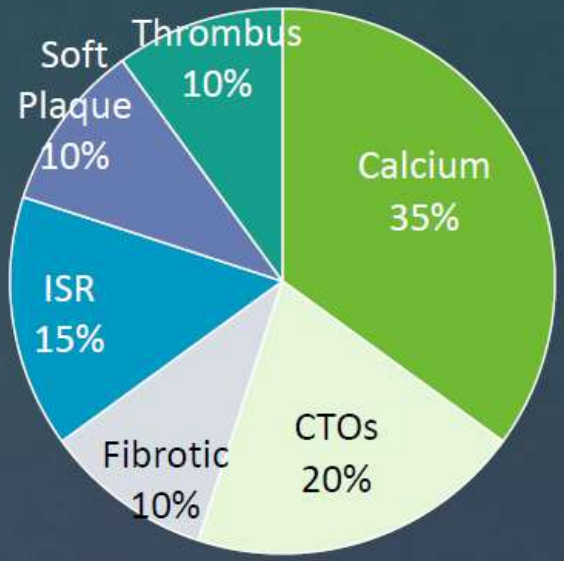
I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☒ Other(s) Honorary Ivascular, Gore, Vascular medical

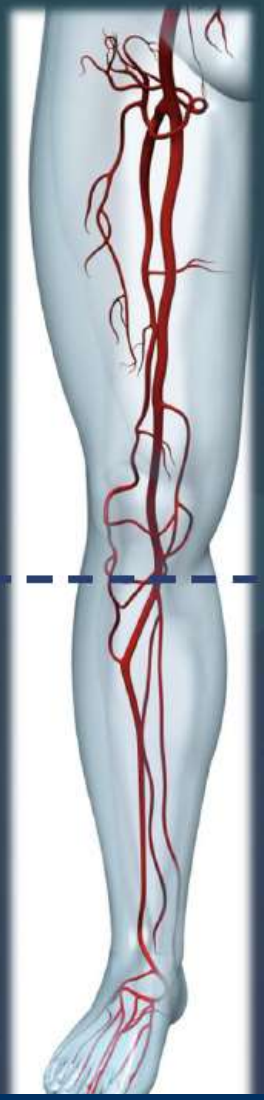
☐ I do not have any potential conflict of interest

Background

Above the Knee[1]

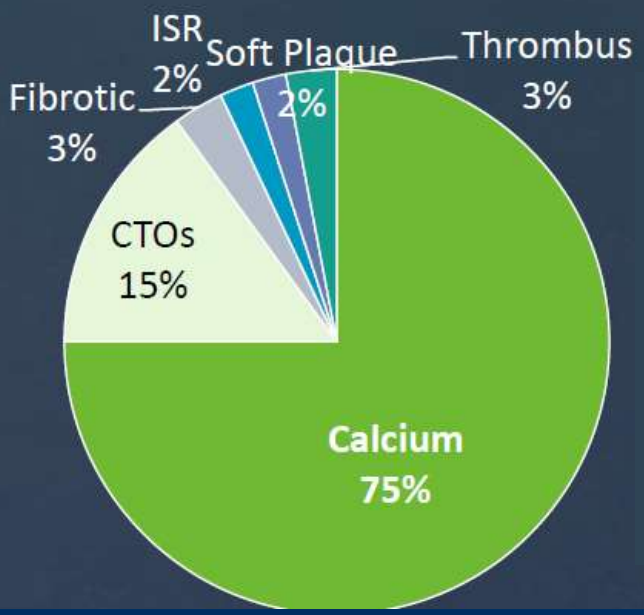


- Multiple plaque types (mixed morphology)
- Large plaque burden[2]
- Medium to large vessels (4-9 mm)



Below the Knee[1]

- Lesions more commonly calcified
- Dense calcium comprises a greater percentage of plaque (27% in tibial vs 12% in popliteal plaque)[2]
- Small vessels (2-3.5 mm)
- Tortuous anatomy



1. Viva 2011 survey – 100 physiance survey
2. Bisoph et al Ann Vasc Surg 2008;22:799-805

Editor's Choice – 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS)

Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries

...Organization (ESO)

...d Treatment of Peripheral Arterial Diseases of the European Society of Cardiology (ESC) and ...r Surgery (ESVS)

What is new in the 2017 PAD Guidelines?

CHANGE IN RECOMMENDATIONS

2011	2017
Carotid Artery Disease	
EPDs in carotid stenting	
Asymptomatic 60–99% carotid stenosis	
• Surgery for all	• Surgery for high stroke risk[116]
• Stenting as an alternative	• Stenting in high surgery risk[129, 135-137]
	• Stenting in average surgical risk
Upper Extremity Artery Disease	
Revascularization for symptomatic subclavian artery stenosis	
Subclavian stenosis revascularization	
• Endovascular first	• Stenting or surgery
Revascularization for asymptomatic subclavian stenosis in patients with/planned for CABG	
Renal Artery Disease	
Stenting for symptomatic atherosclerotic stenosis >60%[229,231,232]	
Lower Extremity Artery Disease	
Aorto-iliac lesions	
• Primary endovascular therapy for "TASC-D"	• Surgery for aorto-iliac or aorto-bi-femoral occlusions
	• Endovascular as an alternative in experienced centres
Infra-popliteal lesions	
• Endovascular first	• Bypass using GSV
	• Endovascular therapy[320-326]

I IIa IIb III

2017 NEW / REVISED CONCEPTS

PADs in general:
- "Vascular Team" for a multidisciplinary management.
- Best medical therapy: drugs and non pharmalogical interventions for optimal outcome. A specific chapter addresses antithrombotic therapies in different PADs presentations, including when anticoagulants are needed.

Carotid disease:
- Risk stratification for asymptomatic carotid disease.
- In patients undergoing CABG, revascularization of severe carotid stenosis is not systematic.

Lower extremity artery disease:
- Masked LEAD should be individualized from asymptomatic disease.
- Modern management of claudication: statins and (supervised) exercise therapy always prescribed, even after revascularization. In this context, the benefit from "vaso-active" drugs to improve walking distance is uncertain.
- "Chronic limb-threatening ischaemia (CLTI)" defines the most severe form of LEAD. Beyond ischaemia, wound and infection should be evaluated to stratify the amputation risk (new WIfI classification). TASC classification excluded from the guidelines.
- Beyond concomitant CAD, patients with PADs have often other cardiac conditions (e.g. HF, AF). The major scenarios have been addressed in a specific new chapter.

Eur J Vasc Endovasc Surg 2018, 55; 305-68

Below-the-Knee Retrograde Access for Peripheral Interventions: A Systematic Review

Journal of Endovascular Therapy
1–8
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www.jevt.org
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Rutger H. A. Welling, BSc[1], Olaf J. Bakker, MD, PhD[2], Dierk Scheinert, MD[3], Frans L. Moll, MD, PhD[1], Constantijn E. Hazenberg, MD, PhD[1], Jihad A. Mustapha, MD[4], Gert J. de Borst, MD, PhD[1], and Andrej Schmidt, MD[3]

Methods:

Metanalysis: 1905 interventions, BTK vessels were punctured in 61%

Success: 94%

Technical outcome:

- Successfull crossing: 86%
- Technical success: 84%

Complication rate:

- Access site: 4.1%
- Vessel perforation 1.1%
- Distal embolisation 0.4%

Table 1. Distribution of 1168 Below-the-Knee Punctures.

Tibial	58 (5.0)
Anterior tibial	304 (26.0)
Anterior tibial / dorsalis pedis	196 (16.8)
Posterior tibial	457 (39.1)
Peroneal	44 (3.8)
Dorsalis pedis	107 (9.2)
Lateral plantar	1 (0.1)
Digital	1 (0.1)

BTK

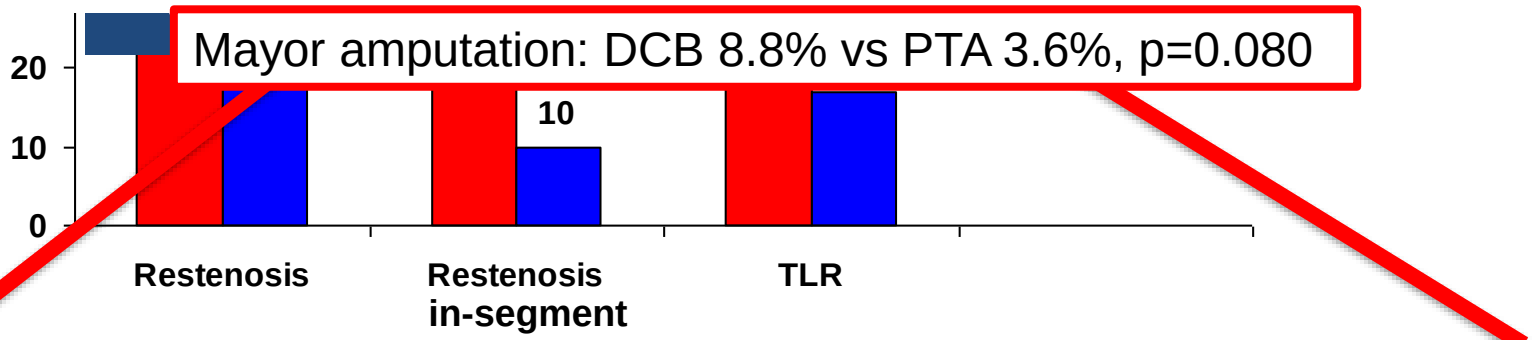
Register Leipzig, POBA & In.Pact Amphirion)

Lesion length: POBA 183 mm, DCB 173 mm

Drug-Eluting Balloon Versus Standard Balloon Angioplasty for Infrapopliteal Arterial Revascularization in Critical Limb Ischemia

12-Month Results From the IN.PACT DEEP Randomized Trial

Thomas Zeller, MD,* Iris Baumgartner, MD,† Dierk Scheinert, MD,‡ Marianne Brodmann, MD,§ Marc Bosiers, MD,‖ Antonio Micari, MD, PhD,¶ Patrick Peeters, MD, PhD,# Frank Vermassen, MD, PhD,** Mario Landini, MS,†† David B. Snead, PhD,†† K. Craig Kent, MD,‡‡ Krishna J. Rocha-Singh, MD,§§ IN.PACT DEEP Trial Investigators



Schmidt A. et al. Cath Cardiovasc Interv 2010; 76(7):1047-54, Schmidt et al., JACC 2011,58:1105

Luminor Registry

Study Design: prospective, multicenter, single-arm treatment for stenotic or occlusive lesions of the femoro-popliteal (FP) and below the knee (BTK) vessels. ***Clinical trials.gov identifier: NCT02458911***

Material and Methods

Patients n= 219, Rutherford 2-5. Adjuvant drug treatment [Clopidogrel 75 mgr/day + ASA 100 mgr/day (one month) and ASA 100 mgr/day (indefinite)].

PRIMARY ENDPOINTS

- Performanc of Luminor 0.014`` and 0.014``
- Patency rate (>50% restenosis PSR <3)
- Freedom of SAE (death, amputation and TLR during) 12-month follow-up

Material and Methods BTK Intervention

Demographics	N
Patients	98
Lesions	116
Age (yrs)	72.6±11.4
Diabetes	73
Nicotin	51
Arterial hypertension	52
Chronic renal failure	27
Rutherford Class	
2	2
3	5
4	7
5	84
Lesion length	77.9 (20- 200 mm)
Total occusions	61.2

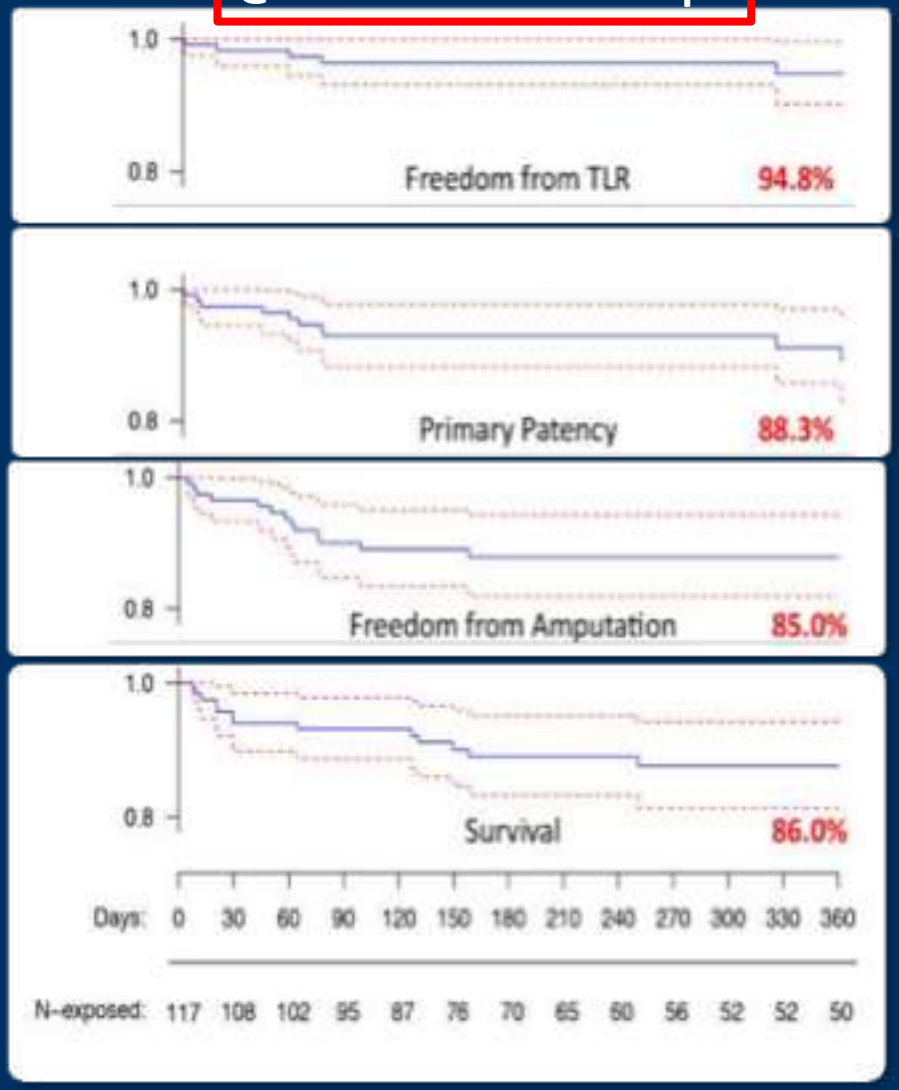
Luminor Registry, V. Riambau LINC 2018

Results

Early Outcome

30 Days Follow- up	N
All cause mortality	7.1%
Mayor amputations	5.1%
TLR	0%

@ 12 months Follow up



Luminor Registry, V. Riambau LINC 2018

Lutonix BTK Trail

Study Design: Prospective, multicenter, single blind, randomized

- Performance of Lutonix 0.014``OTW Drug Coated Balloon.
- Randomization 2:1 to Lutonix DCB or standard PTA- Balloon

Material and Methods

- Patients n= 442, Rutherford 2-5. Adjuvant drug treatment [Clopidogrel 75 mgr/day + ASA 100 mgr/day (one month) and ASA 100 mgr/day (indefinite)]

PRIMARY ENDPOINTS

- Safety: Freedom from MALE (Mayor Adverse Limb Events & all cause perioperative Death (POD) @ 30 days.

(Amputation above the ankle, Major Re- Intervention)

- Efficacy: Composite of Limb Salvage and Primary Patency @ 6 Months

(Composite of Freedom from above the ankle amputation, TVR)

Material and Methods

Demographics	DCB	PTA
Patients (n)	287	155
Age (yrs)	72.9±9.6	72.9±9.6
Diabetes	71%	68%
Nicotin	59%	57%
Arterial hypertension	92%	96%
Dyslipidemia	78%	75%
Rutherford Class		
3	9%	10%
4	35%	34%
5	56%	56%
Lesion lenght	uk	uk
Total occlusion	36%	33%
Any calcification	59%	54%

Lutonix BTK Trail,
J. Mustapha VIVA 2018

Results

Early Outcome

30 Days Follow- up	DCB	PTA
Freedom from primary Safety Event	99.3% (283/285)	99.4%* (154/155)

Freedom @ 30 days from TVR, mayor index limb amputation and device all cause death

* p< 0.001

6 months Efficacy

30 Days Follow- up	DCB	PTA
Freedom from primary Safety Event	73.7% (196/266)	63.5%* (87/137)

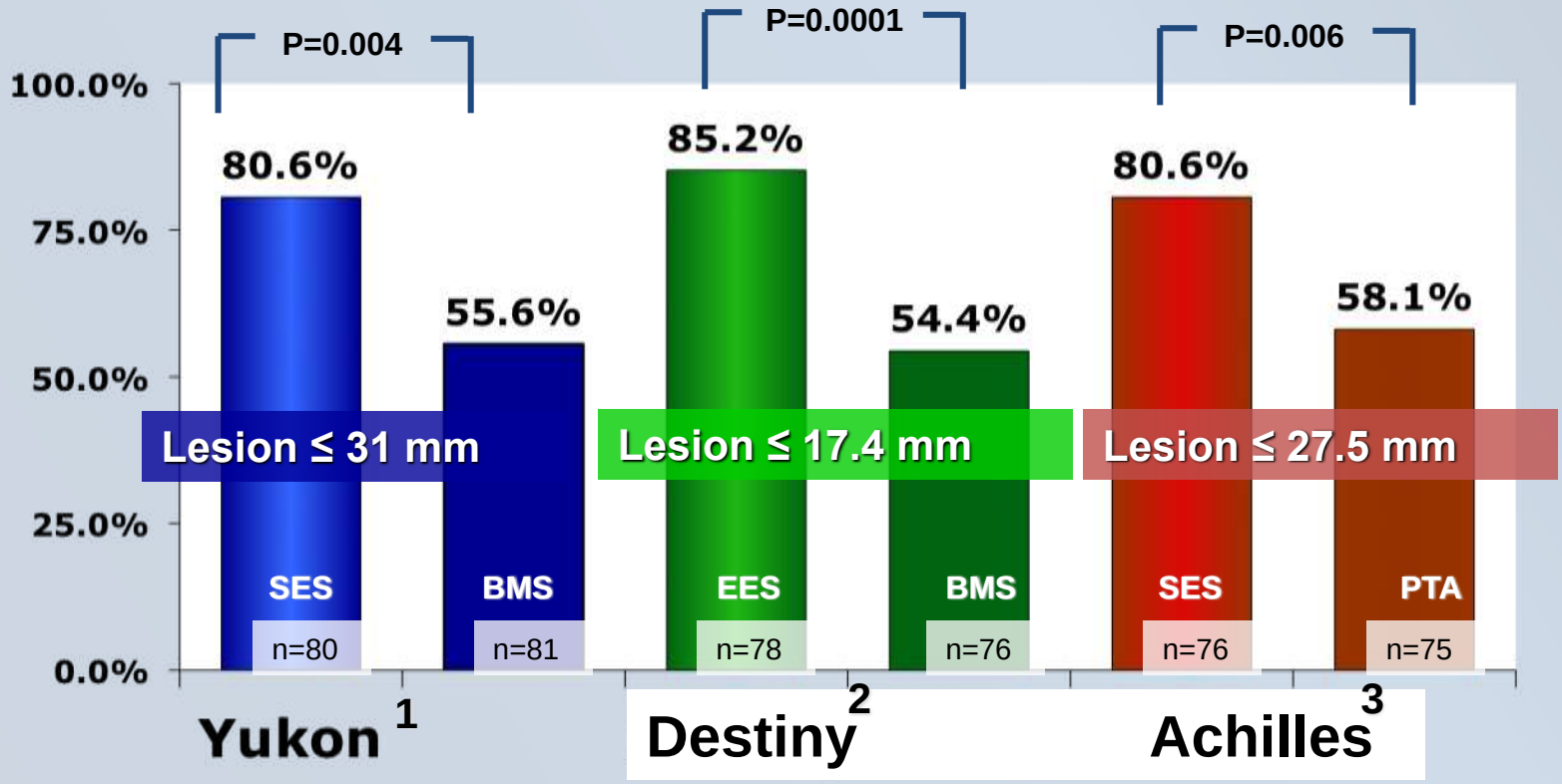
Freedom @ 6 months from mayor index limb amputation, target lesion occlusion and CD- TLR

*p= 0.0273

Lutonix BTK Trail, J. Mustapha VIVA 2018

DES

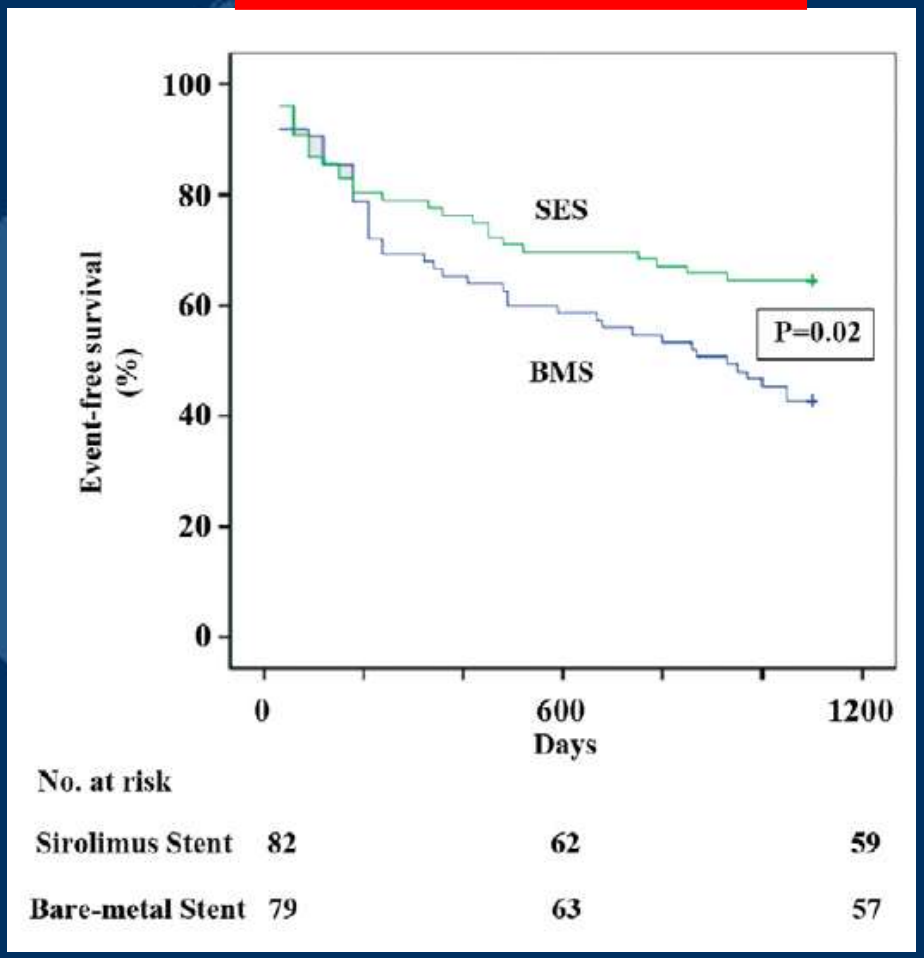
Primary Patency in RCT @ 12 months Follow up



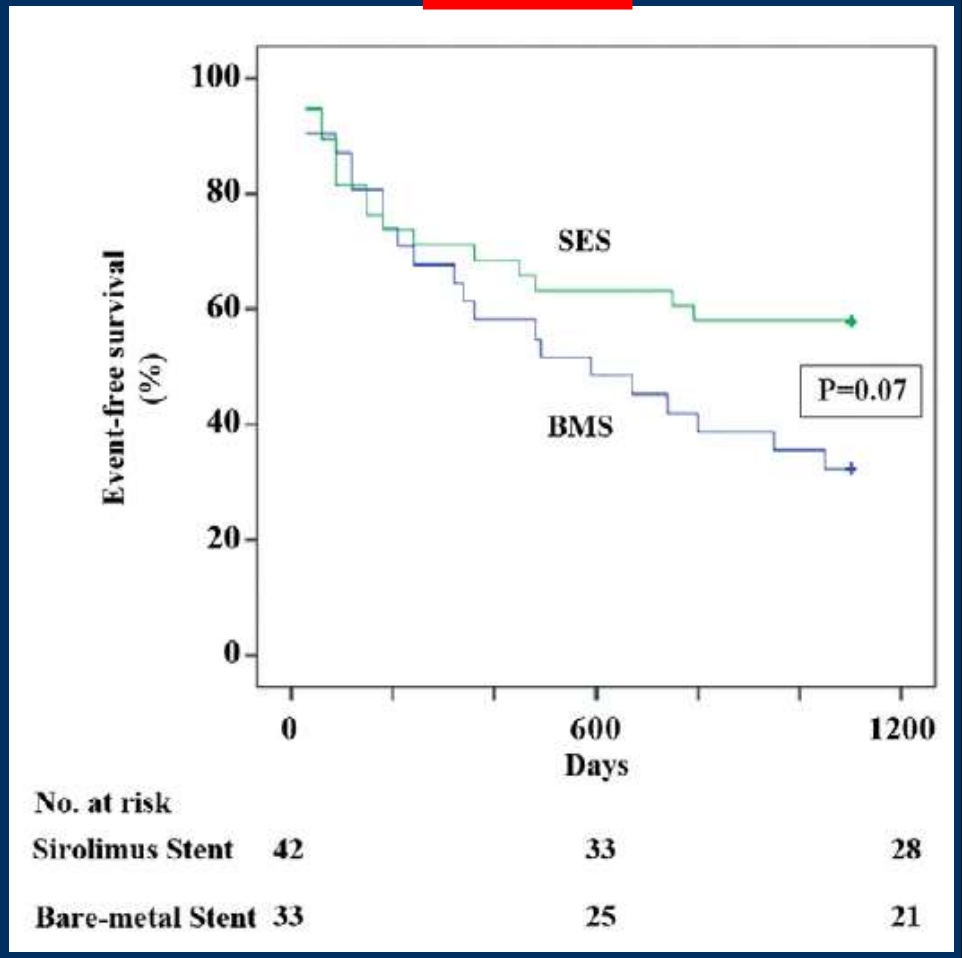
1: Rastan et al, Eur Heart J 2011; 2: Bosiers et al. J Cardiovasc Surg 2011; 3: Scheinert et J Am Coll Cardiol 2012

DES vs BMS

Claudicatio & CLI



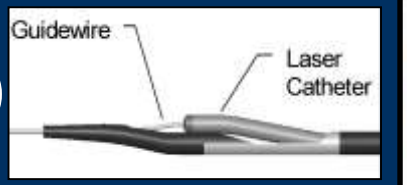
CLI

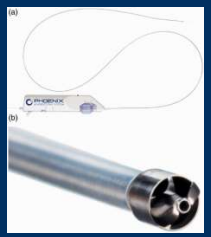


Rastan A et al. Journ Am Coll Card 2012;60:587-91

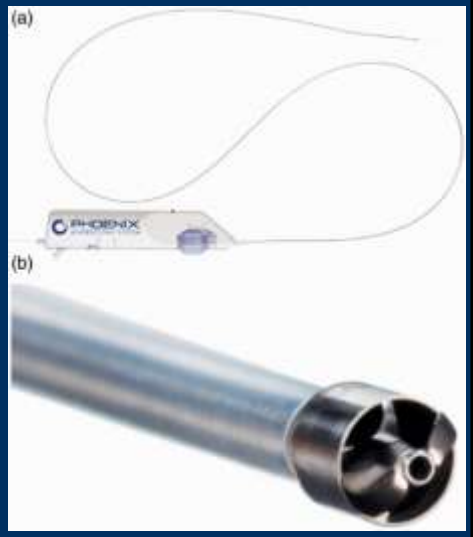
Debulking Devices

- Laser (Excimer®, Turbo Booster®)
- Pathway (Jetstream®)
- Rotablator®
- Diamondback®
- Silverhawk®/Turbohawk®
- (Phonix®)





Phoenix Device



EASE trail: prospective multicenter study,149 lesions included

- Systems: 1.8, 2.2 and 2.4 mm (deflecting 2.2 and 2.4)
- Infrainguinal arteries, 50% BTK lesions, length mean 34 mm

Table 6. Primary and secondary efficacy endpoint outcomes.

	PP population[a] % (*n*/*N*) (95% CI)	ITT population[b] % (*n*/*N*) (95% CI)
Primary efficacy endpoint		
Technical success (lesion) (target performance goal >86%)	95.1% (117/123) (90.6%)[c]	95.3% (142/149) (91.4%)[c]
Secondary efficacy endpoints		
Procedural success (patient)	99.2% (122/123) (95.6%, 100%)	98.7% (147/149) (95.2%, 99.8%)
Clinical success at 30 days (patient)	74.5% (76/102) (64.9%, 82.5%)	76% (95/125) (67.5%, 83.2%)
Clinical success at *six* months (patient)	79.6% (78/98) (70.3%, 87.1%)	78.0% (92/118) (69.4%, 85.1%)
Freedom from TLR at *six* months (patient)[d]	88.0% (81.7%, 94.4%)	87.6% (81.7%, 93.4%)
Freedom from TVR at *six* months (patient)[d]	86.1% (79.3%, 92.8%)	85.9% (79.7%, 92.1%)

Davis et al. Vascular 2017,25;6: 563-575

Clinical Investigation

ENDOVASCULAR THERAPY

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Safety and Feasibility of Intravascular Lithotripsy for Treatment of Below-the-Knee Arterial Stenoses

Marianne Brodmann, MD[1], Andrew Holden, MD[2], and Thomas Zeller, MD[3]

Methods:

- 20 pts, calcified BTK lesions, Rutherford 5
- Therapy with "Shock Wave Medical Peripheral IVL- System

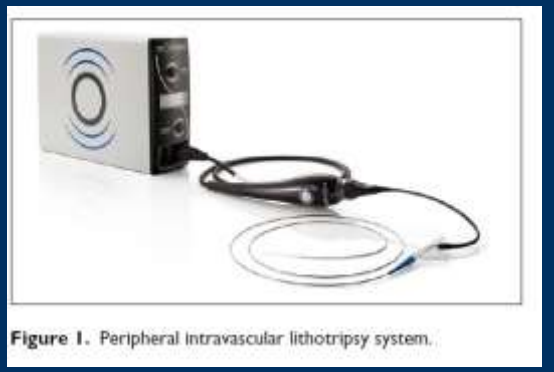

Figure 1. Peripheral intravascular lithotripsy system.

Results @ 30 days:

- No MAE
- 1x dissection -> Stenting
- Technical success in 19 pts
- ↓ in percent diameter stenosis 46%

Brodmann et al. JEVT 2018, 25,4:499-503, Brodmann et al JACC 2017,70;7:907-12

Summary

- BTK- Intervention often needs an interdisziplinary team.
- BTK- Intervention can be challenging related to certain anatomical properties and lesion characteristics (calcified lesions).
- Patency of POBA and BMS is not very encouraging in BTK arteries.
- Luminor DCB has demonstrated efficacy in infrainguinal arteries in a multicenter registry including CLTI patients @ 12 months.
- Other DCB has demonstrated Safety ($p<0.001$) @ 30 days and also Efficacy compared to PTA in BTK arteries ($p=0.0273$) @ 6 months.
- Vessel preparation due to calcification might be warranted in BTK arteries in certain anatomical properties (long calcified lesions, Bifurcation), but so fare no RCT!
- Cost expansion might be a limiting factor for broad application of combined therapy.

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