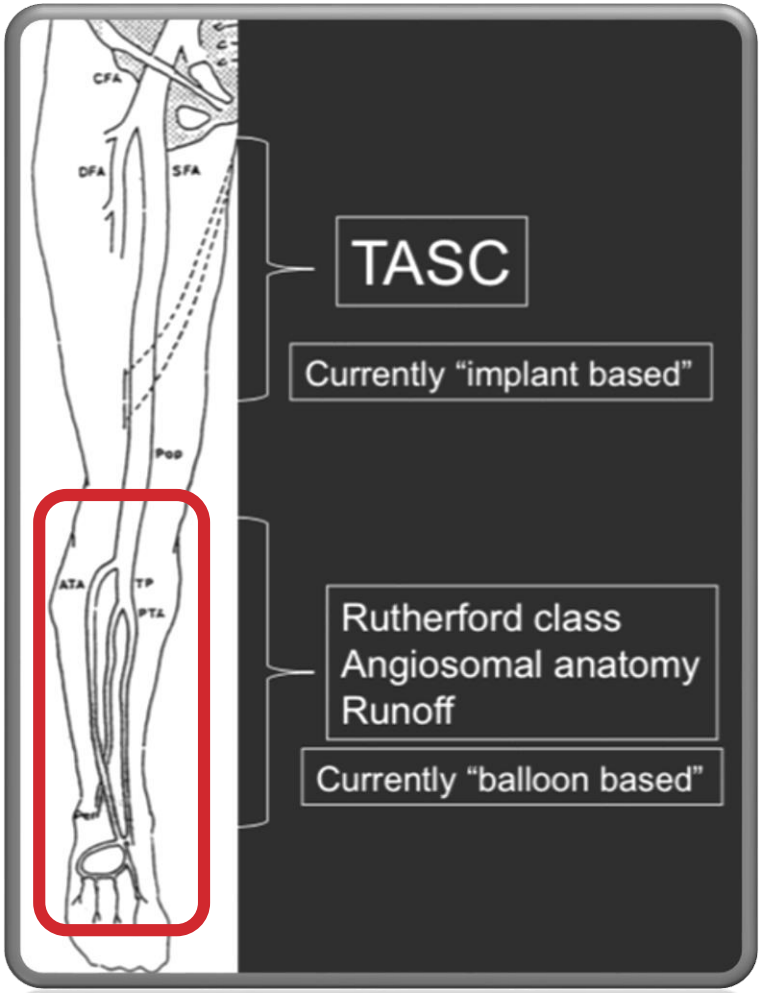
DESs FOR BELOW THE KNEE OCCLUSIVE DISEASE

2018

E.DUCASSE

ACTUAL BTK TREATMENT STRATEGY



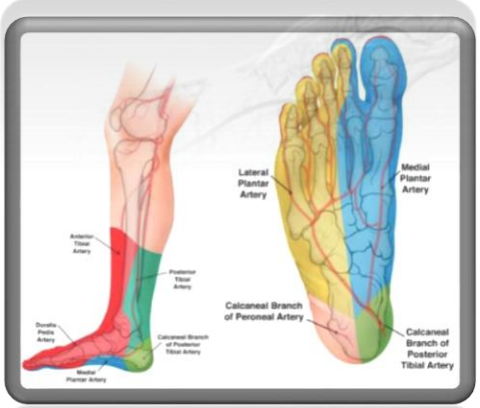
- **BTK occlusions[1] :**
  - ≥ 50% of CLI patient
  - ≥ 70% of CLI patients with diabetes mellitus or end-stage renal disease
- **Poor prognosis[2] :**
  - 25% of primary major amputations
  - 20% of chronic pain
  - 25% of mortality at 1 year

→ **ENDOVASCULAR FIRST[3]**

- POBA
- ± bailout BMS spot scaffolding[4] in case of
  - Elastic recoil
  - Flow limiting dissection

1. Rueda et al. J Vasc Surg. 2008
2. Norgren et al. TASC II. J Vasc Surg. 2007
3. update of the TASC II and latest ESVS guidelines
4. Tendera et al. ESC Guidelines. Eur Heart J. 2011

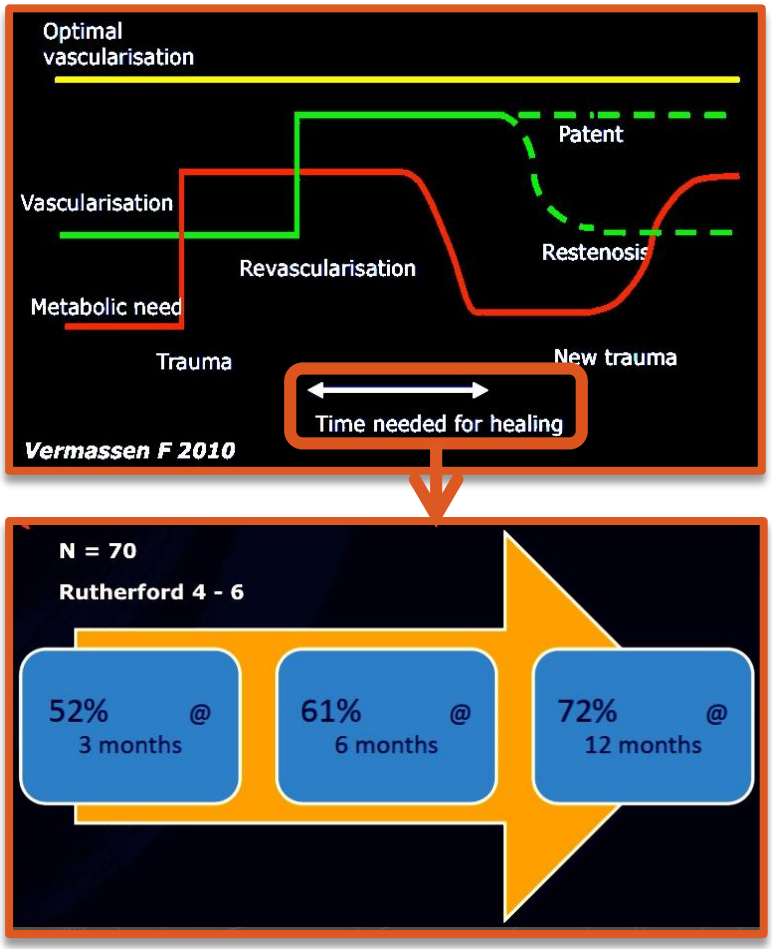
THERAPEUTIC ENDPOINTS[5]



- **Achieve and MAINTAIN straight-line flow to the foot :**
  - Aggressive strategy :
    - « 3 better than 2 »
    - Retrograde access if needed
    - Reconstruction of plantar arch
  - Angiosome concept[6] :
    - possible in ~ 50% of cases
- **To :**
  - Relieve ischemic pain
  - Permit healing
  - Prevent amputation

5. Tsetis et al. J Radiol. 2004
6. Iida et al. Catheter Cardiovasc Interv Off J Soc Card Angiogr Interv. 2010

HIGH RESTENOSIS RATES



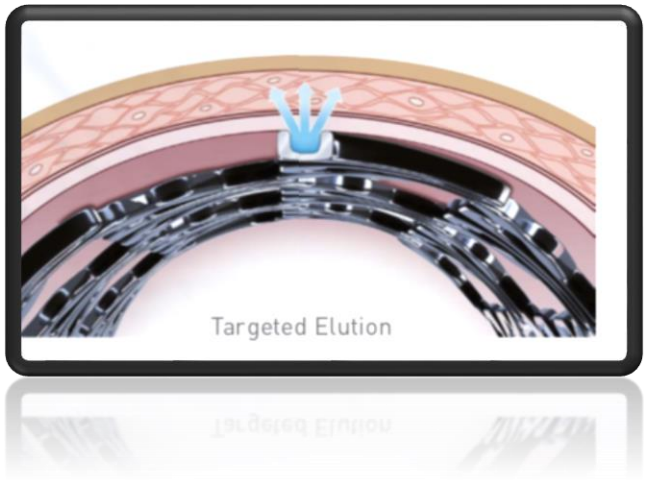
- **Poor durability of acute results due to vessel re-narrowing[7]**
  - restenosis at 1 year after POBA
    - 36%[8] to 74%[9]
    - **There is a general agreement that POBA is suboptimal in virtually every arterial bed, and this is especially true in BTK lesions**

- **"the value of perfusion to an ischemic limb should not be decreased" [11]**
- **Extended Patency is needed for wound healing**
  - Average Time To Healing :
    - 6 months to 1 year[10]

7. Iida et al. Eur J Vasc Endovasc Surg Off J Eur Soc Vasc Surg. 2012
8. Zeller et al. IN.PACT DEEP. J Am Coll Cardiol. 2014
9. Liistro et al. DEBATE-BTK. Circulation. 2013
10. Hoffman et al. EJVES 2007
11. Schneider et al. does perfusion matter or not. 2016

WHY SCAFFOLDING AND DURG ELUTION?

- **BTK lesions**
  - very complex
  - risk factors predicting poor outcomes
    - small vessel diameter,
    - lesion length,
    - chronic kidney disease,
    - diabetes,
    - poor runoff



- **BTK calcification patterns**
  - calcifications involving tibial vessels **extend through multiple layers across the vessel from the intima to the adventitia**[1]

- **Contribute to the suboptimal results noted with POBA,**
- **and in theory, limit the success of DCBs**

1. Mustapha et al. J Cardiovasc Surg (Torino) 2017;58:383–401. doi:10.23736/S0021-9509.17.09878-0.

The management of below-the-knee arterial critical ischemia: update, systematic review and meta-analysis

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- **DESs use as a primary strategy in short focal lesions (average treated lesion length of 4 to 6 cm)**

- **Considerable advantage for DESs over POBA, DCBs and bare metal stents in terms of**
  - TLR
  - binary restenosis
  - and primary patency rates
  - with up to 3-year results

5 STUDIES WITH LONG-TERM RESULTS

2 showed improved patency
BUT no significant difference
on mortality and limb salvage vs BMSs

- **Karnabatidis *et al.*[13] – 3 years**

TABLE 3
Cumulative Proportional Outcomes at 3 Years

	Group XP	Group C	p*	HR (95% CI)	Adjusted p†
Patient survival	82.2%	65.7%	0.90	—	—
Major amputation-free survival	77.1%	86.9%	0.20	—	—
Inflow primary patency	31.4%	0.0%	0.004	2.921 (1.360 to 6.273)	0.006
Infrapopliteal primary patency	29.7%	20.6%	<0.0001	7.984 (3.694 to 17.254)	<0.0001
In-lesion binary restenosis	90.8%	87.8%	0.005	2.943 (1.736 to 4.990)	<0.0001
TLR-free survival	81.1%	67.5%	0.041	2.796 (1.230 to 6.357)	0.014
Major event-free survival	34.9%	12.1%	0.013	2.191 (1.162 to 4.131)	0.015

- **Siablis *et al.*[14] – 3 years**

Table 5
Angiographic and Clinical Cumulative Proportion Outcomes of SES and BMS at 3 Years after Bivariable and Multivariable Analysis

Outcome	SES Group (%)	BMS Group (%)	*P* Value*	HR†	95% CI	Adjusted *P* Value
Primary patency	32.9	17.1	<.001	4.81	2.91–7.94	<.001
In-stent binary restenosis	81.1	96.0	<.001	0.38	0.25–0.58	<.001
In-lesion binary restenosis	83	95.6	<.001	0.45	0.29–0.68	<.001
Recurrent obstruction	14.8	67.4	<.001	0.15	0.08–0.29	<.001
Repeat intervention–free survival	77.6	70.3	.049	2.56	1.3–5.0	.006

2 non comparative trials

- **Werner *et al.*[12] – 60 months**
  - major amputations = 2.8%
  - primary patency = 83.8%
  - RC improvement = 92%
- **PARADISE trial[11] – 3 years**
  - major amputation = 8%
  - TLR = 15%
  - binary restenosis = 12%

11. Feiring et al. PARADISE trial. J Am Coll Cardiol. 2010
12. Werner et al. J Endovasc Ther Off J Int Soc Endovasc Spec. 2012
13. Karnabatidis et al. J Endovasc Ther Off J Int Soc Endovasc Spec. 2011
14. Siablis et al. J Vasc Interv Radiol JVIR. 2009

Only 1 trial showed significant clinical improvement

YUKON trial - 3 years results

Sirolimus-Eluting Stents for Treatment of Infrapopliteal Arteries Reduce Clinical Event Rate Compared to Bare-Metal Stents

Long-Term Results From a Randomized Trial

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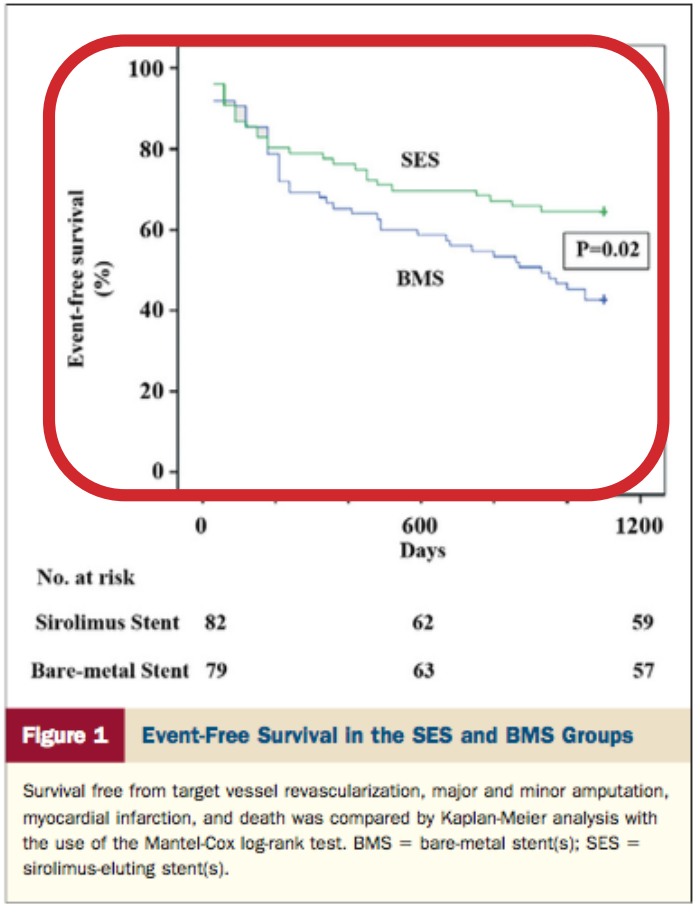


Figure 1 Event-Free Survival in the SES and BMS Groups

Survival free from target vessel revascularization, major and minor amputation, myocardial infarction, and death was compared by Kaplan-Meier analysis with the use of the Mantel-Cox log-rank test. BMS = bare-metal stent(s); SES = sirolimus-eluting stent(s).

Table 2 Rutherford-Becker Class at Baseline and at Follow-Up of the Overall Patient Population and of Each Treatment Group

	Rutherford-Becker Class at Follow-Up (N = 86)	(n = 44)	(n = 42)	
Median (IQR)	2 (1 to 3)	2 (1 to 3)	2 (2 to 3)	0.02
Improvement by ≥1 class	62 (72.1)	37 (84.1)	25 (59.5%)	
No change	22 (25.6)	7 (15.9)	15 (35.7%)	
Worse by ≥1 class	2 (2.3)	0 (0)	2 (4.8%)	
Median change	−1 (−3 to 0)	−2 (−3 to −1)	−1 (−2 to 0)	0.006

Values are n (%) or median (interquartile range [IQR]).

Table 3 Major Adverse Events and Limb Salvage at Follow-Up in Patients With Critical Limb Ischemia and Intermittent Claudication

Critical Limb Ischemia	SES (n = 38)	BMS (n = 31)	p Value
Death	10 (26.3)	10 (32.3)	0.60
Major/minor amputation	1/1 (5.3)	4/3 (22.6)	0.04
TVR	4 (10.5)	4 (12.9)	0.70
Myocardial infarction	0 (0)	2 (6.4)	0.20
Limb salvage	37 (97.4)	27 (87.1)	0.10

2 STUDIES WITH LONG LESIONS

- **PARADISE trial[11] – 3 years**
  - Mean lesion length 60mm
  - Mean number of stents/limb 1.9
  - Primary patency 88%
  - Limb salvage 92%

- **Karnabatidis *et al.*[13] – 3 years**
  - Mean lesion length 76mm
  - Mean number of stents/limb 3.2
  - Primary patency : 29.7% vs 33.9% for shorter lesions (<33mm)
  - Limb salvage : 84.3% vs 77.1% for shorter lesions (<33mm)

DESs could be of interest in long lesions
BUT balloon expandable stents **= risk of stent fractures and compressions[15]**

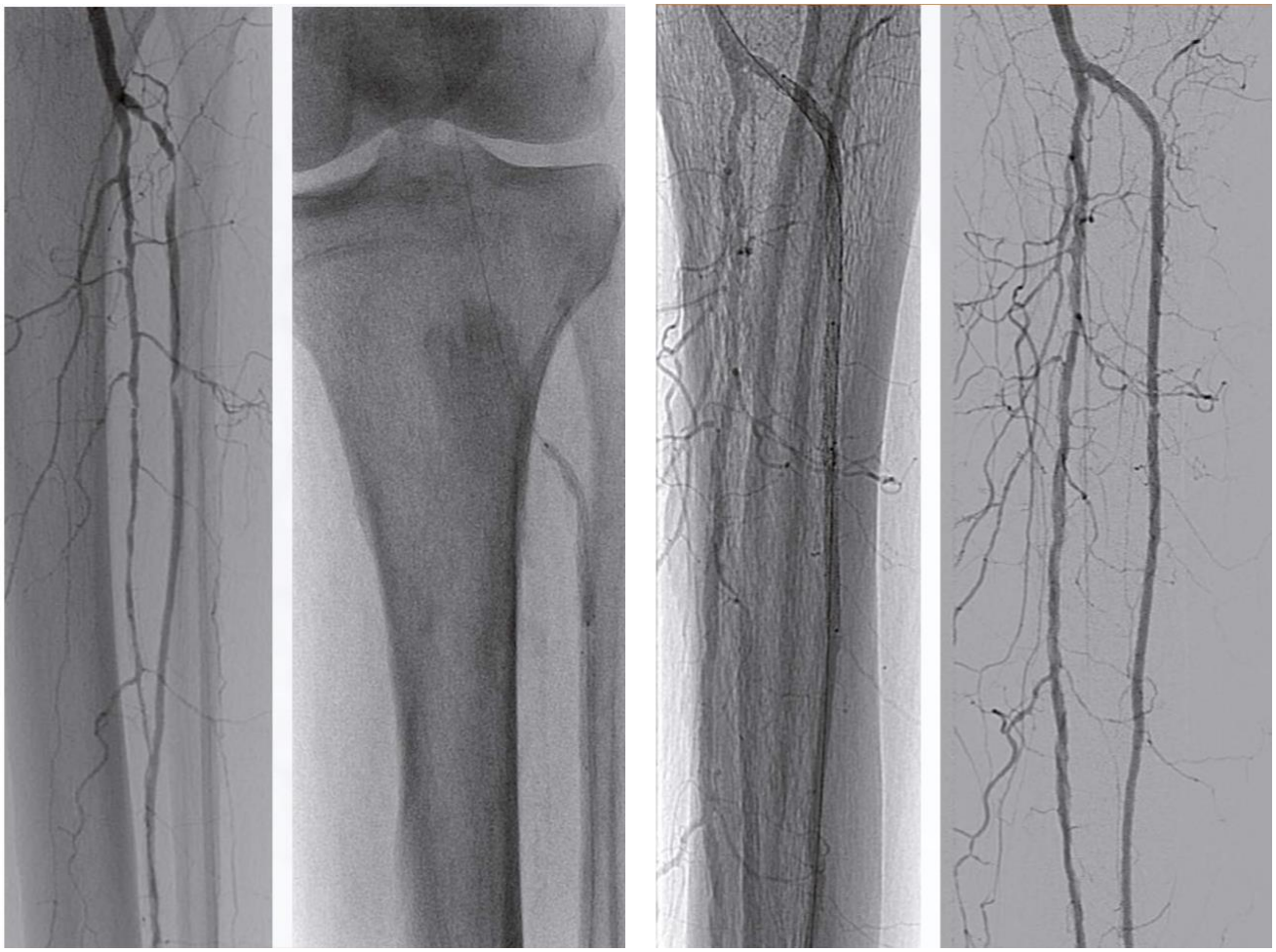
11. Feiring et al. PARADISE trial. J Am Coll Cardiol. 2010
13. Karnabatidis et al. J Endovasc Ther Off J Int Soc Endovasc Spec. 2011
15. Schulte et al. EXPAND study. J Endovasc Ther Off J Int Soc Endovasc Spec. 2015

CASE 1
♂ 64-year old
Rutherford-5

Courtesy of Prof. Dimitrios Karnabatidis MD, PhD, EBIR Prof. Panagiotis Kitrou MD, MSc, PhD

Courtesy of Prof. Dimitrios Karnabatidis MD, PhD, EBIR Prof. Panagiotis Kitrou MD, MSc, PhD

CASE 2
♂ 63-year old
Rutherford-4



Courtesy of Prof. Dimitrios Karnabatidis MD, PhD, EBIR Prof. Panagiotis Kitrou MD, MSc, PhD

TAKE HOME MESSAGE

- **The accumulated body of evidence supporting the use of DESs in the treatment of focal infrapopliteal disease is impressive**
- **Recent randomized trials have demonstrated remarkably consistent results in improving patency and reducing binary restenosis and TLR**
- The BEST-CLI and BASIL 2 trials will hopefully answer the question of whether optimal surgery for selected patients with good quality saphenous vein is a better choice than endovascular therapy
- **Future challenges will be to extend this evidence to demonstrate a definitive limb salvage advantage and to apply the technology across the full spectrum of disease patterns, including long segment occlusions and tibial bifurcations**