Welcome to LINC

Symposium: Treatment strategies for complex disease in the SFA/Pop
supported with an educational grant from Abbott Vascular

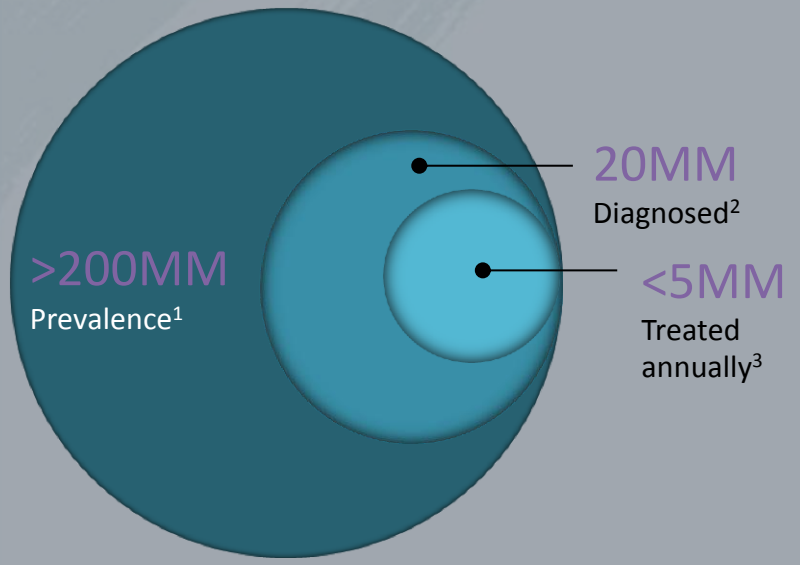
Moderator: D. Scheinert
Panel: R. Varcoe, B. DeRubertis, G. Ansel, L. Garcia, J. Mustapha, Th. Zeller

Introduction by the moderator and overview of complex SFA disease: calcium, long lesions, reintervention ***D. Scheinert***

Peripheral Artery Disease (PAD) TREATMENT is Still a Large Unmet Need

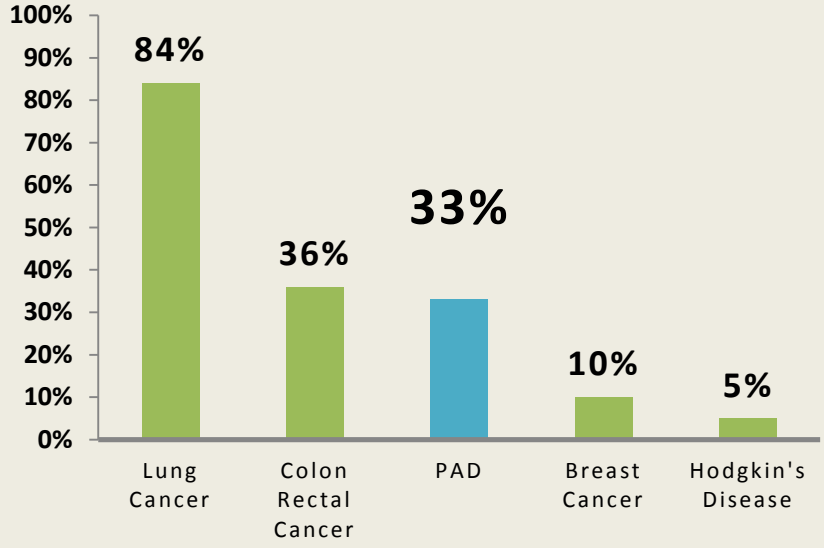
Diagnosis and Treatment of PAD Is Underpenetrated[1]

GLOBAL TREATMENT MAP OF PAD



Treating PAD Reduces Burden of Disease and Increases Quality of Life[4,5]

5 YEAR MORTALITY RATE (%)

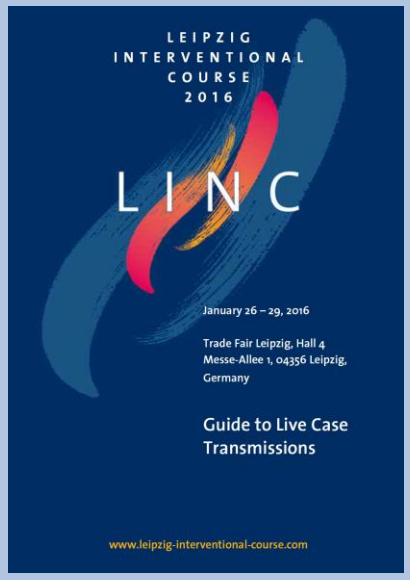


1. Fowkes, Lancet 2013; 382: 1329–40.
2. Kovach, Richard. PAD Diagnosis and Noninvasive Testing, NCVH 2014
3. Leerink Swann Analysis, Sep 5, 2012. US intervention rate of 28% (700/2,500 diagnosed). WW: 28% of 20MM is 5.6MM but actual treated rates would be lower outside the US
4. Tomson, Joseph; Lip, Gregory Y H, Peripheral arterial disease: a high risk - but neglected - disease population, BMC Cardiovascular Disorders, ISBN: 14712261, 2005, Vol (Iss) Pgs: 5 (1) p.15
5. American Cancer Society: Cancer Facts and Figures 2012, p. 11, 12, 13, 16

Importance of fempop treatment

- Estimated 300.000 endovascular fempop procedures in Europe
  - Stent rate around 50%
  - SNS, DES, DCB usage all growing
  - Endo expansion trend into TASC C/D

- LINC 2016 live case statistics
  - 91 live cases
  - 32 of which are fempop



Variables affecting outcome of femoropopliteal interventions

- Lesion length

  →Patency rates decrease in longer lesions

- Lesion location

  →distal locations in SFA and popliteal artery are more challenging

- Stenosis vs. Occlusion

  →CTOs more challenging to cross, higher plaque burden

- Calcification

There is an Unmet Need in Severely Calcified Lesions

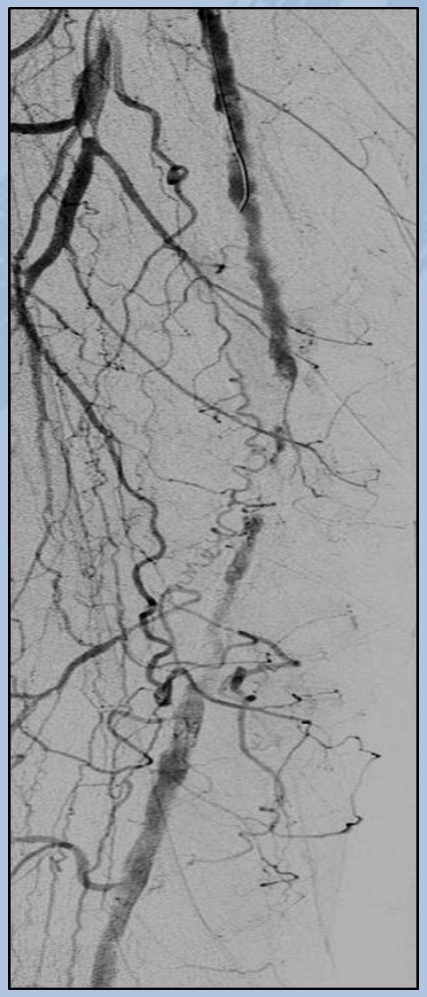


Image courtesy of Dr. Andrej Schmidt

- The presence of calcium represents a significant challenge to current endovascular device strategies
- Calcification is a predictor of lower procedural success and reduction in long-term outcomes.
  - ✓ Currently most clinical trials often exclude severely calcified lesions [2]
- Severe calcification may be associated with increased device and/or procedure related adverse events [2]
  - ✓ Severe dissections
  - ✓ Vessel perforations
  - ✓ Atheroembolization

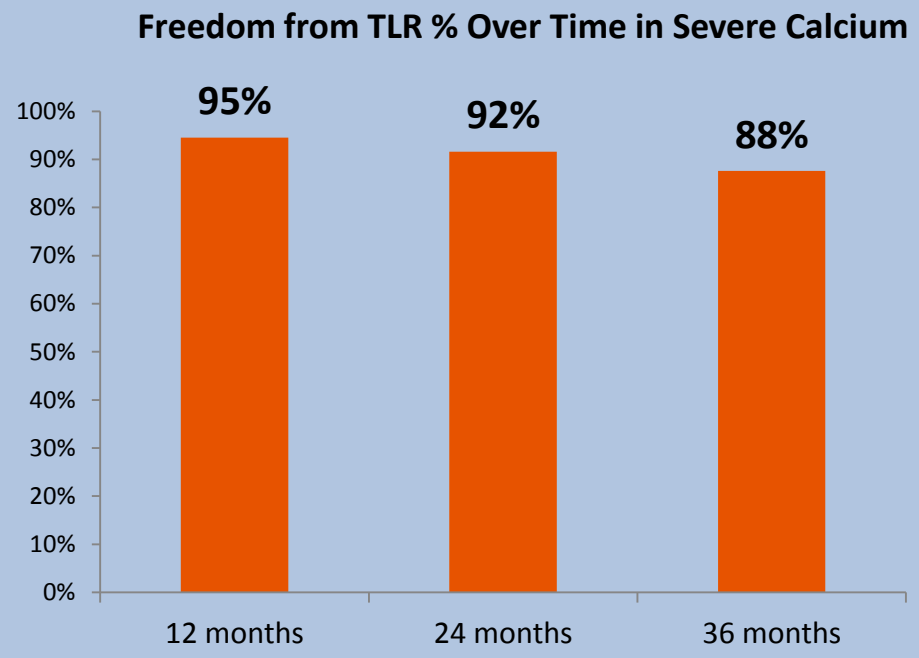
1. Germanwala, S . Et. al Clinical Perspectives on DAART, EVT Supplement Dec. 2014
2. Jaff et al. Peripheral Arterial Calcification. CCI 2014

Supera Has Strong Clinical Outcomes in Calcification

Garcia, L., The SUPERB Trial 3-year Results, VIVA 2014

SUPERB Data - Severe Calcification

% of Lesions with Severe Calcification (SUPERB Trial)	45% (n=118)
Patency (VIVA 12 months)	89%



Published Results in SFA/Pop - TASC C& D Lesions

Study/Device	Number of Patients	Mean Lesion Length	12 Month Primary Patency	12 Month Stent Fracture
DURABILITY-200[1] Protégé Everflex	100	242 mm	64.8%	6.0%
STELLA Registry[2] LifeStent	58	220 mm	66.0%	17.7%
Zilver PTX Global Registry Zilver PTX[3]	135	226 mm	77.6%	2.1%
STELLA PTX Zilver PTX[4]	45	252 mm	52.5%	9.0%
Viabahn TASC C&D Viabahn[5]	71	265 mm	67.0%	0.0%
SUPERB 500 Supera[6]	172	223 mm	80.5%	0.0%
St. Louis University Supera[7]	42	279 mm	80.1%	0.0%

Data differences depicted between these trials may not be statistically significant or clinically meaningful and different clinical trials may include differences in the demographics of the patient populations.

1. Bosiers M, et al., Results of the Protégé EverFlex 200-mm-long nitinol stent (ev3) in TASC C and D femoropopliteal lesions. *J Vasc Surg*. 2011;54:1042-50. 2. Davaine JM, et al., One-year clinical outcome after primary stenting for Trans-Atlantic Inter-Society Consensus (TASC) C and D femoropopliteal lesions (the STELLA "STEnting Long de L'Artère fémorale superficielle" cohort). *Eur J Vasc Endovasc Surg.* 2012;44:432-41. 3. Bosiers M, et al., Zilver PTXS-ASI. The Zilver® PTX® Single Arm Study: 12-month results from the TASC C/D lesion subgroup. *J Cardiovasc Surg (Torino).* 2013;54:115-22. 4. DavaineJM et al., Treatment of TASC C and D Femoropoliteal Lesions with Paclitaxel eluting Stents: 12 month Results of the STELLA-PTX Registry Eur J Vasc Endovasc Surg (2015) -, 1-7 5. ZellerT, et al., Heparin-Bonded Stent-Graft for the Treatment of TASC II C and D Femoropopliteal Lesions: The Viabahn-25 cm Trial J ENDOVASC THER 2014;21:765–774 6. Werner, et al., Treatment of complex atherosclerotic femoropopliteal artery disease with a self-expanding nitinol stent: midterm results for the Leipzig SUPERA 500 registry, EuroIntervention 2014:10:861-868. 7. Brescia, et al., Stenting of femoropopliteal lesions using interwoven nitinol stents, J Vasc Surg. 2015 Mar 6. pii: S0741-5214(15)00132-9.

Selection of available techniques for long femoropopliteal lesions

- Biomimetic stents (Supera)
- Drug-coated balloons
- Drug-eluting stents
- Stent-Grafts/ covered stents
- Conventional nitinol stents
- Atherectomy/ Laser

  …
- Bypass-Surgery

The interventionalists dilemma

- Which tool in which lesion?
- What treatment leads to the best outcome?
  - Certainly not only one answer for all patients
  - Identify best strategy for each situation
- Are cost – benefit ratios respected?

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