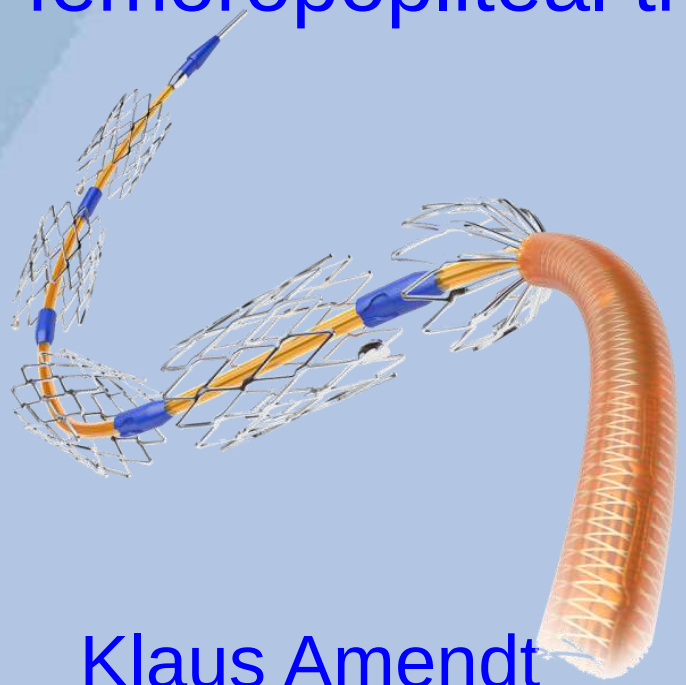
6-month results of the ***LOCOMOTIVE*** registry investigating spot stenting in the femoropopliteal tract



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Disclosure

Dr. Klaus Amendt

I have the following potential conflicts of interest to report:

Inventor of Multiple Stent Delivery System

Advisory Board and Consultant:

B. Braun cooperation

Bayer AG

BIOTRONIK

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Problems we have with Angioplasty

Balloon:

acute: injury/trauma:
dissektion
occlusion,
residual-
stenosis

chronic: re-stenosis,
re-occlusion

Stent:

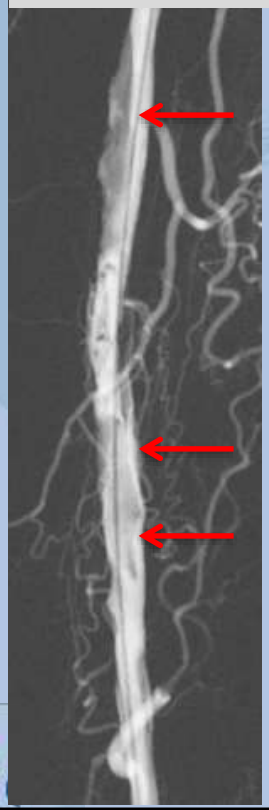
acute: activation of coagulation, aggregation: thrombus

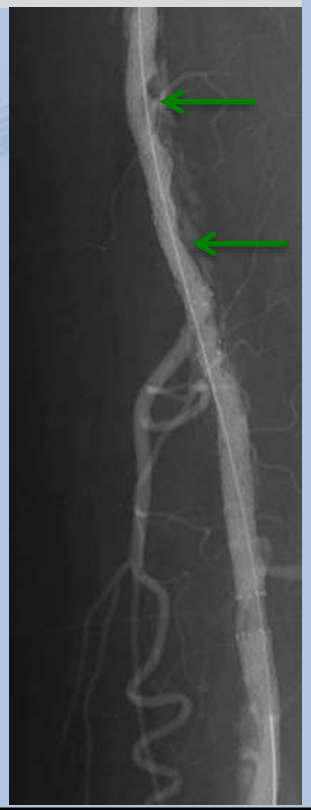
chronic: trauma (COF)
re-stenosis,
re-occlusion

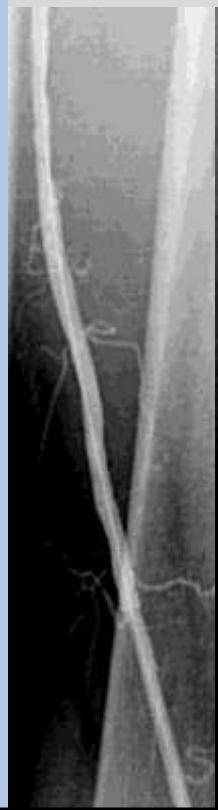
Artery:

acute: recoil (Ca++)
spasm

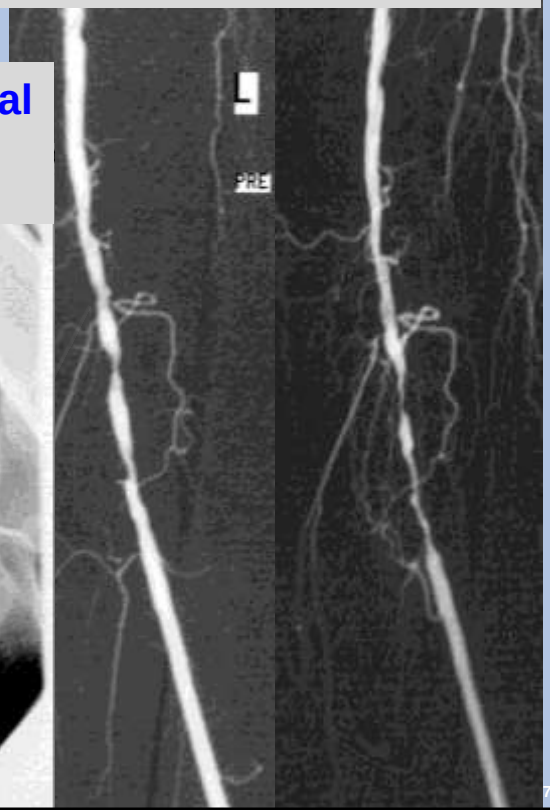
chronic: re-stenosis,
re-occlusion
stent-fracture
progression of
disease

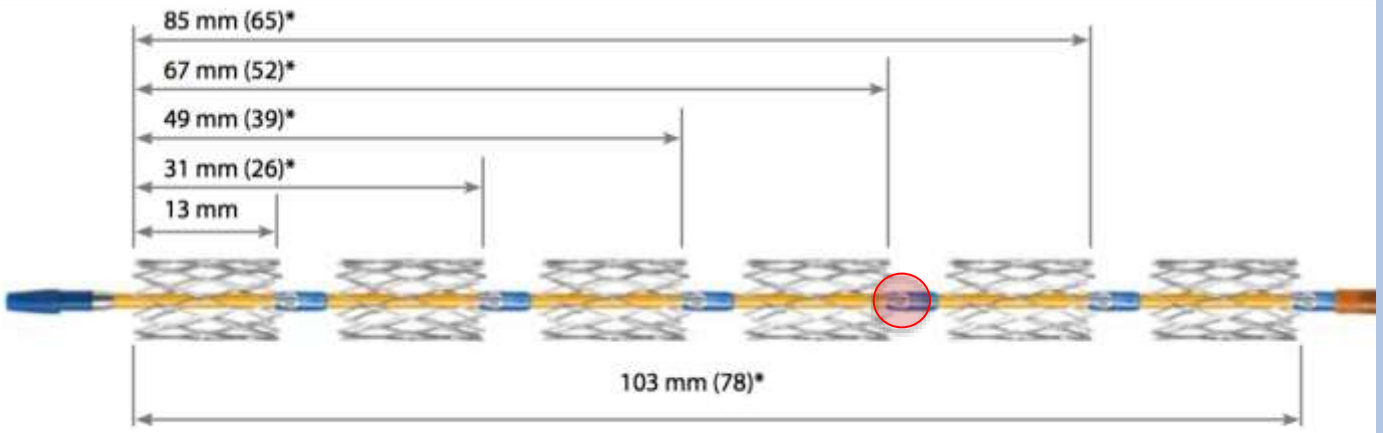


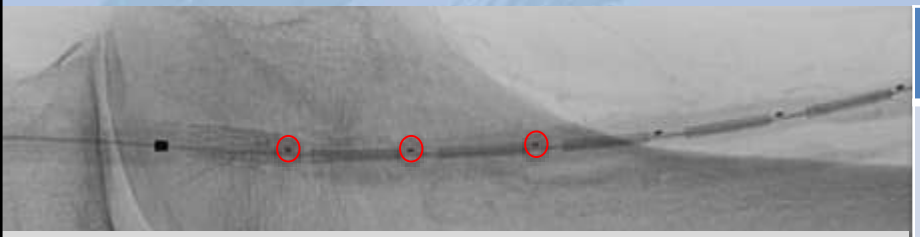


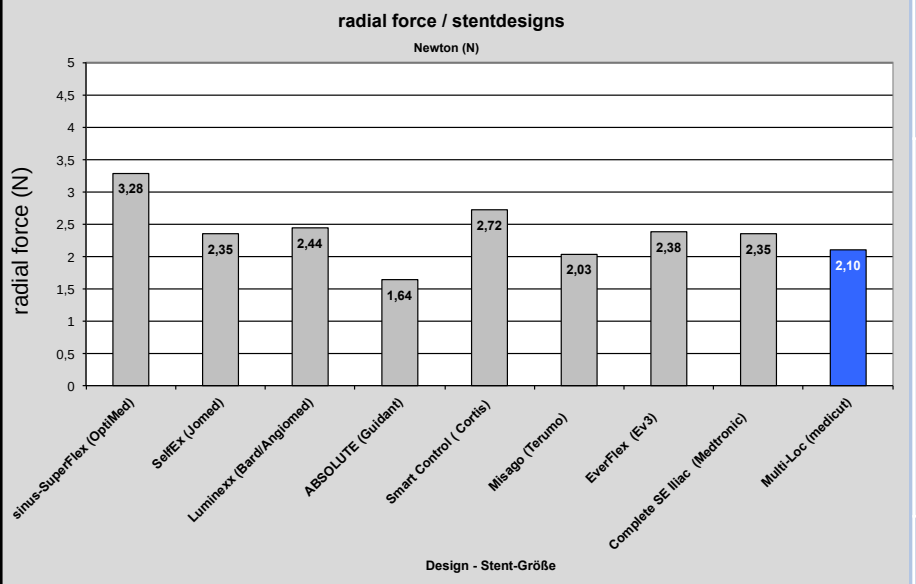


Biomechanical Stress
Long stents









Components

MSDS	
Sheath	6F
Stents	6 ML-Stents
Working length	80 cm, 130 cm
Guide-wire	0,035``
Individual Stent	
Length	13 mm
Diameter	5, 6, 7, 8 mm
Radiopaque marker	1/stent
Designe	closed cell design
Radial force	comparable to standard nitinol stents
Treated vessel diameter	5 – 8 mm

DEKRA: CE – marking: *27.05.2015; FIM 17.06.2015*

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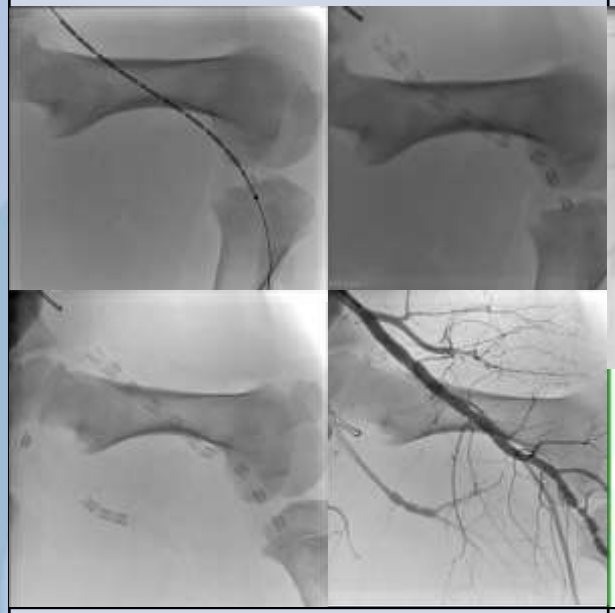
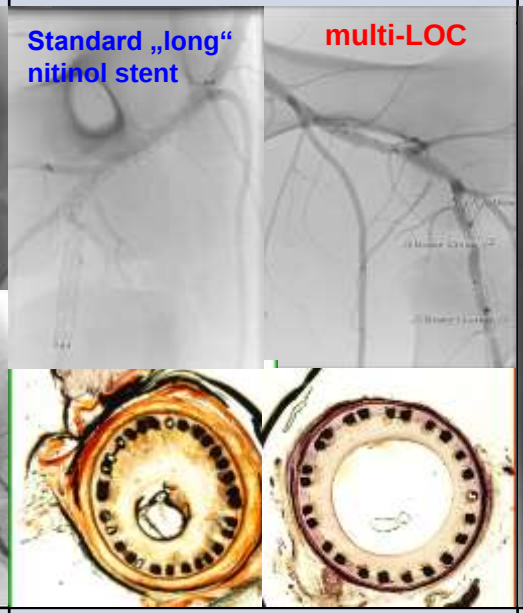
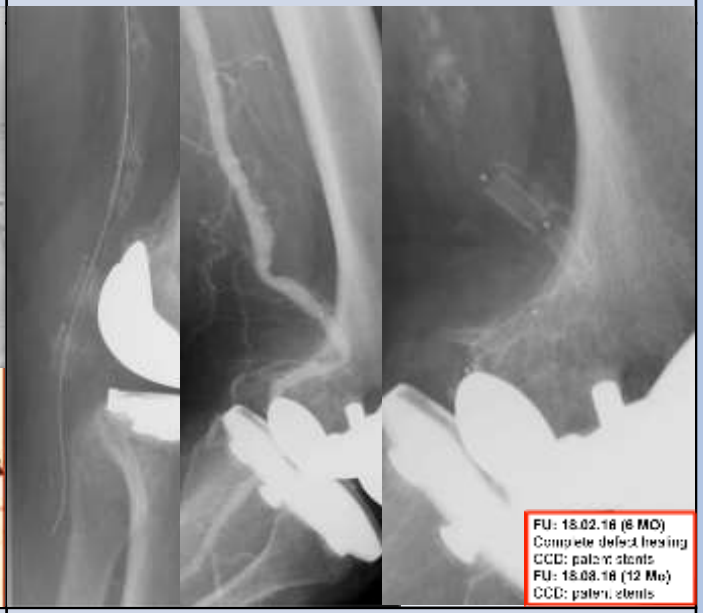
Multiple Stent delivery system: MSDS
multi-LOC (VascuFlex Multi-LOC ®)

Animal experiments (porcine)		Clincal experiences
acute	**chronic (3 w surv.)**	**post CE- marking:**
		
• feasibility • exact anatomically controlled release • no stent loss	• no stent fracture • superior patency vs standard nitinol stent	• reproducibility of animal results • nearly no neg. influence on biomechanical properties of arteries • stabilized lumen, also in severely calcified lesions

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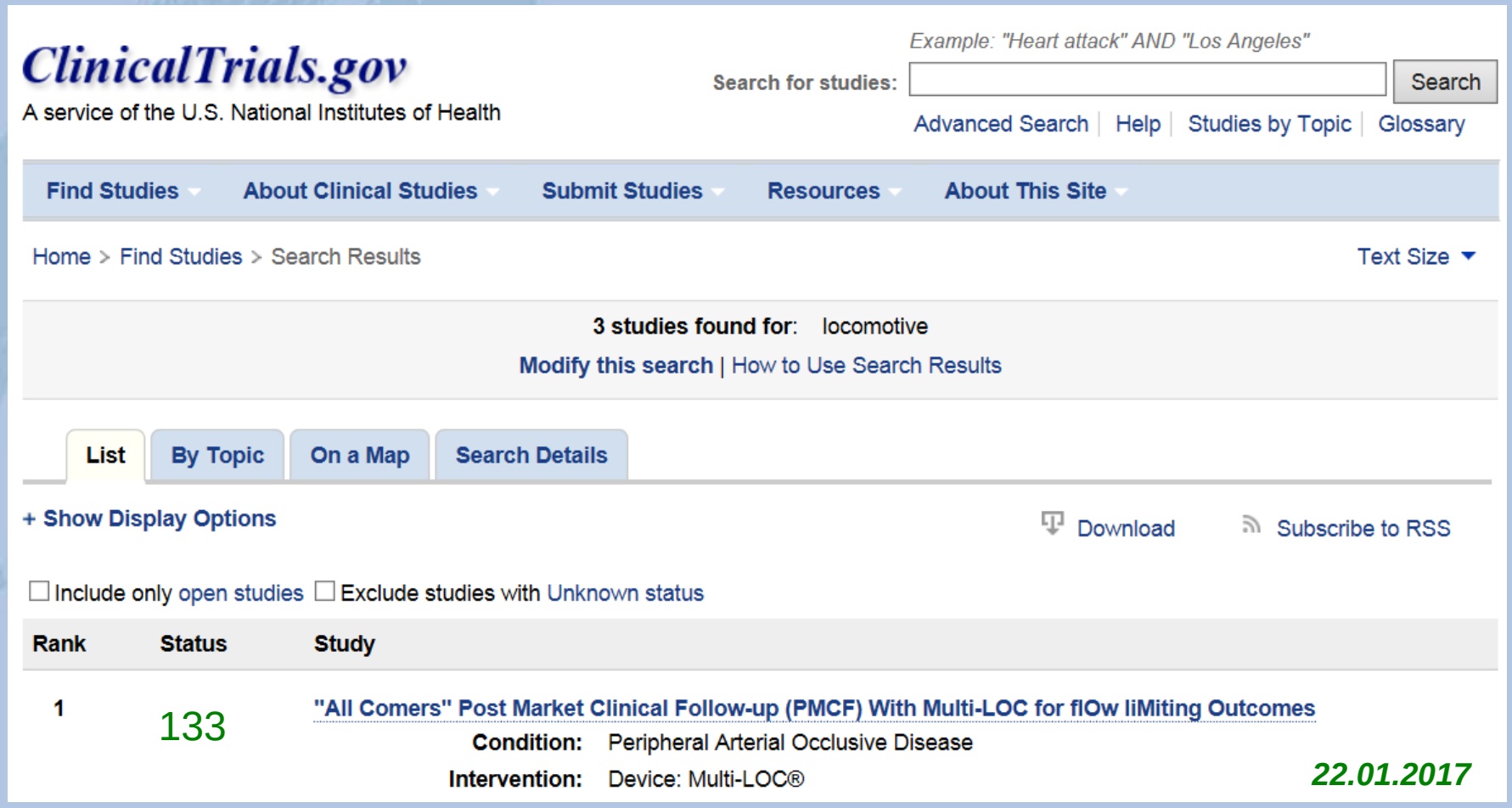
LOCOMOTIVE: all comers registry

**All comers PMCF with Multi-*LOC* for fl*O*w li*M*iting *O*utcomes after POBA and/or DCB *T*reatment in the *I*nfrainguinal position with the objecti*VE* to implant multiple stent segments



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Rank	Status	Study
1	133	"All Comers" Post Market Clinical Follow-up (PMCF) With Multi-LOC for flOw liMiting Outcomes **Condition:** Peripheral Arterial Occlusive Disease **Intervention:** Device: Multi-LOC®

22.01.2017

LOCOMOTIVE registry:

Objective:	to assess safety and efficacy of the multi-LOC peripheral stents system to treat de novo and restenotic lesions
Design:	non randomized prospective, multi-center registry common femoral to distal popliteal artery, all comers registry: RCC 2-5, Fontaine II- IV
Intended Use:	flow limiting dissections and recoil after POBA and DCB-dilatation. „whenever stenting is indicated“

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LOCOMOTIVE registry:

Inclusion criteria:
(N: 200)

patients with PAOD: Rutherf.: 2-5, Fontaine: 2-4
stenosis and occlusions of SFA, PA1-3, also re-do
lesion length: suitable for release of at least 2 stents
with a distance of at least 5 mm between 2 stents
reference vessel diameter: 5-7mm
adequate distal run off:
at least 1 vessel to the foot
or calf collaterals supplying sufficient flow to the foot
also severe calcification

Exclusion criteria:

Instent-restenosis
Restenosis after DCB

Primary endpoint: 6 month TLR- rate

Additional variables: 12 month TLR- rate
@ 6 and 12 month: walking distance (S1, S2)
ABI ,
CCD: patency-rate
RCC
amputation rate

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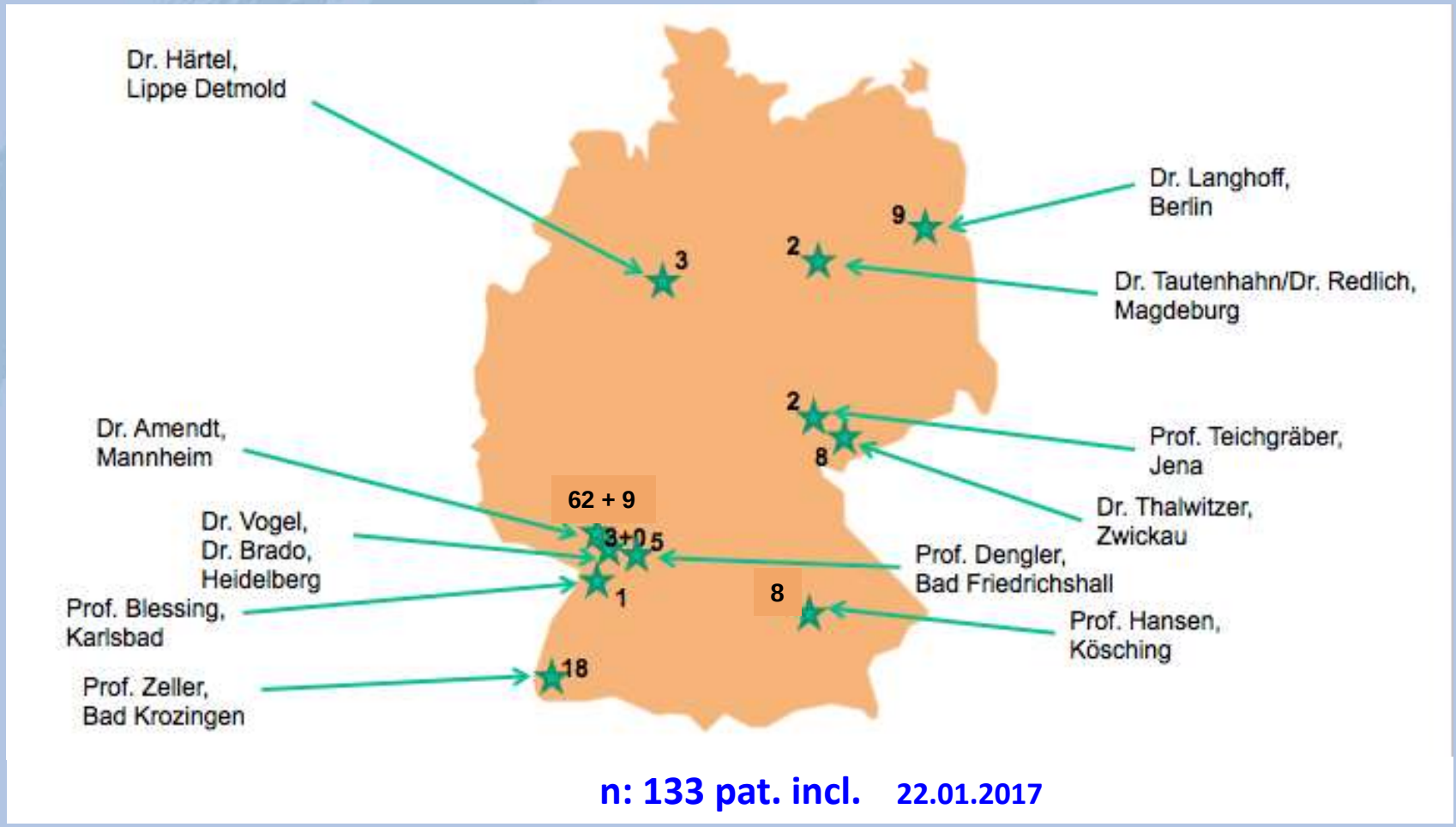
LOCOMOTIVE registry:

Participating Centers (active)



n: 133 pat. incl. **22.01.2017**

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LOCOMOTIVE registry: 6-mo FU patients: n: 75

Patient demographics

	All patients	Critical limb ischemia	No critical limb ischemia	p-value
Patients	75	20 (26.7%)	55 (73.3%)	-
Age, years	72.9±9.2	75.5±7.4	72.0±9.7	0.148
Male gender	48 (64.0%)	8 (40.0%)	40 (72.7%)	0.009
Fontaine IIa IIb III IV	 2 (2.7%) 53 (70.7%) 7 (9.3%) 13 (17.3%)	 0 (0.0%) 0 (0.0%) 7 (35.0%) 13 (65.0%)	 2 (3.6%) 53 (96.4%) 0 (0.0%) 0 (0.0%)	<0.001
Diabetes mellitus	37 (49.3%)	15 (75.0%)	22 (40.0%)	0.007
Hypertension	61 (81.3%)	17 (85.0%)	44 (80.0%)	0.623
Hypercholesteremia	43 (57.3%)	9 (45.0%)	34 (61.8%)	0.193
Renal insufficiency	16 (21.3%)	6 (30.0%)	10 (18.2%)	0.269
Dialysis dependent	2 (2.7%)	1 (5.0%)	1 (1.8%)	0.449
Coronary artery disease	29 (38.7%)	6 (30.0%)	23 (41.8%)	0.538
Cerebrovascular disease	13 (17.3%)	3 (15.0%)	10 (18.2%)	0.748
Carotid artery disease	55 (73.3%)	15 (75.0%)	40 (72.7%)	0.844
History of smoking	53 (70.7%)	12 (60.0%)	41 (74.5%)	0.221

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LOCOMOTIVE registry: 6-mo FU patients: n: 75

Lesion morphology

	All patients (n: 75)	Critical limb ischemia	No critical limb ischemia	p-value
Target lesions/p	**176/75**	**52/20**	**124/55**	
Treated leg, target lesions left right	 40 (52.7%) 35 (47.3%)	 9 (45.0%) 11 (55.0%)	 30 (55.6%) 24 (44.4%)	 0.419
Reference vessel diameter, mm	5.6±0.7	5.3±0.4	5.7±0.7	<0.001
Distal run off 1 2 3 no vessel	 20 (26.7%) 25 (33.3%) 27 (34.7%) 4 (5.3%)	 **8 (40.0%)** 5 (25.0%) 4 (20.0%) **3 (15.0%)**	 12 (21.8%) 20 (36.4%) 23 (40.0%) 1 (1.8%)	 **0.031**
Lesion location SFA I SFA II SFA III P1 P2 P3	 33 (18.8%) 47 (26.7%) 54 (30.7%) 25 (14.2%) 14 (8.0%) 3 (1.7%)	 10 (19.2%) 15 (28.8%) 14 (26.8%) 9 (17.3%) 4 (7.7%) 0 (0.0%)	 23 (18.5%) 32 (25.8%) 40 (32.3%) 16 (12.9%) 10 (8.1%) 3 (2.4%)	 0.815
TASC II class target lesion A B C D unknown	 17 (9.7%) 67 (38.1%) 66 (37.5%) 24 (13.6%) 2 (1.1%)	 5 (9.6%) 9 (17.3%) 28 (53.8%) 10 (19.2%) 0 (0.0%)	 12 (9.7%) 58 (46.8%) 38 (30.6%) 14 (11.3%) 2 (1.6%)	 0.003
TASC C/D lesions	**90 (51.1%)**	**38 (73.1%)**	**52 (41.9%)**	**<0.001**
Total lesion length, cm range	**14.5±9.0 (3.5 - 45.0)**	**19.0±9.5 (8.0 – 40.0)**	**12.9±8.3 (3.5 – 45.0)**	**0.009**
Diffuse vessel disease	**159 (90.3%)**	48 (90.6%)	111 (90.2%)	0.947
Calcification	**171 (97.2%)**	50 (94.3%)	121 (98.4%)	0.139
Total occlusion	64 (36.4%)	**35 (60.0%)**	29 (23.6%)	**<0.001**

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LOCOMOTIVE registry: 6-mo FU patients: n: 75

Procedural details and device characteristics

	All patients	Critical limb ischemia	No critical limb ischemia	p-value
Patients	75	20	55	-
Lesions	176	52	124	-
Devices per patient	85	24	61	
1	65	16	49	0.306
2	10	4	6	
Type of device				
6F, 80 cm, 6-LOC	65 (76.5%)	18 (75.0%)	47 (77.0%)	0.841
6F, 130 cm, 6-LOC	20 (23.5%)	6 (25.0%)	14 (23.0%)	
Stent diameters				
5 mm	43 (50.6%)	15 (62.5%)	28 (45.9%)	0.448
6 mm	33 (38.8%)	8 (33.3%)	25 (41.0%)	
7 mm	7 (8.2%)	1 (4.2%)	6 (9.8%)	
8 mm	2 (2.4%)	0 (0.0%)	2 (3.3%)	
Stent diameter, mm	5.7±0.7	5.5±0.6	5.7±0.8	0.145
Total number of released stent segments	382	119	263	-
Number of released stent segments per patient	**5.1±2.2**	**6.0±2.3**	**4.8±2.2**	**0.054**
Total length of stent segments per lesion length	0.53±0.18	0.46±0.16	0.56±0.18	0.044
Lesion length saved from stenting	**0.47±0.18**	**0.54±0.16**	**0.44±0.18**	**0.044**
Released stent segments per patient				
1	1 (1.3%)	0 (0.0%)	1 (1.8%)	0.231
2	6 (8.0%)	0 (0.0%)	6 (10.9%)	
3	9 (12.0%)	2 (10.0%)	7 (12.7%)	
4	16 (21.3%)	2 (10.0%)	14 (25.5%)	
5	15 (20.0%)	6 (30.0%)	9 (16.4%)	
6	18 (24.0%)	6 (30.0%)	12 (21.8%)	
7	1 (1.3%)	1 (5.0%)	0 (0.0%)	
8	1 (1.3%)	0 (0.0%)	1 (1.8%)	
9	3 (4.0%)	0 (0.0%)	3 (5.5%)	
10	3 (4.0%)	2 (10.0%)	1 (1.8%)	
11	0 (0.0%)	0 (0.0%)	0 (0.0%)	
12	2 (2.7%)	1 (5.0%)	1 (5.0%)	
Reason for stenting				
dissection only	34 (19.3%)	10 (19.2%)	24 (19.4%)	0.055
recoil only	32 (18.2%)	4 (7.7%)	28 (22.6%)	
dissection & recoil	**110 (62.5%)**	**38 (73.1%)**	**72 (58.1%)**	
Predilatation targ.les.				
POBA	**133 (75.6%)**	**46 (88.5%)**	**87 (70.2%)**	
DCB	17 (9.7%)	3 (5.8%)	14 (11.3%)	0.055
POBA+DCB	23 (13.1%)	2 (3.8%)	21 (16.9%)	
no balloon (?)	3 (1.7%)	1 (1.9%)	2 (1.6%)	
Residual stenosis, %	4.8±4.8	2.9±4.7	5.6±4.6	0.052
Procedural success	85 (100.0%)	24 (100.0%)	61 (100.0%)	-

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LOCOMOTIVE registry: 6-mo FU patients: n: 75

Clinical outcomes

	All patients	Critical limb ischemia	No critical limb ischemia	p-value
Patients	75	20	55	-
		***Pre*-procedure**		
Walking distance, m	98.3±82.1	17.5±17.7	101.9±82.0	0.010
Target leg ABI	0.62±0.24	0.40±0.18	0.69±0.21	<0.001
		***Post*-procedure (in hospital)**		
Target leg ABI	0.90±0.25	0.80±0.28	0.93±0.20	0.042
		6 months		
Number of follow-ups sonographic, clinical and telephone	**70 (93.3%)**	**19 (95.0%)**	**51 (92.7%)**	**0.727**
Follow-up duration, months	6.1±1.9	5.6±3.0	6.2±1.2	0.422
Vessel patency: diameter stenosis <50% (CCD)	**64 (91.4%)**	**18 (94.7%)**	**46 (90.2%)**	**0.546**
Target lesion revascularization	**3 (4.3%)**	**1 (5.3%)**	**2 (3.9%)**	**0.806**
Target vessel revascularization (Re-PTA, lysis)	3 (4.3%)	1 (5.3%)	2 (3.9%)	0.806
Non-target vessel revascularization **- re PTA** **- surgical bypass**	**1 (1.4%)** **1 (1.4%)**	**1 (5.3%)** **1 (5.3%)**	**0 (0.0%)** **0 (0.0%)**	**0.063**
Walking distance, pain-free, m	200±283	92±40 n=6	231±314 n=21	0.060
Target leg ABI	0.83±0.26	0.69±0.19	0.89±0.27	0.034
Fontaine I IIa IIb III IV unknown impacted Fontaine1	 42 (60.0%) 8 (11.4%) 5 (7.1%) 2 (2.9%) 1 (1.4%) 8 (11.4%) 4 (5.7%)	 9 (47.4%) 1 (5.3%) 1 (5.3%) 2 (10.5%) 1 (5.3%) 4 (26.3%) 1 (5.3%)	 33 (64.7%) 7 (13.7%) 4 (8728) 0 (0.0%) 0 (0.0%) 4 (7.8%) 3 (5.9%)	0.074
Amputation target leg - **major** - **minor**	 2 (2.7%) 1 (2.9%)	 2 (10.0%) 1 (10.0%)	 0 (0.0%) 0 (0.0%)	 0.017 0.116
Major amputations, contralateral leg	1 (1.4%)	1 (5.3%)	0 (0.0%)	0.099
Death vascular non-vascular	 4 (5.7%) 2 (2.9%)	 2 (10.5%) 1 (5.3%)	 2 (3.9%) 1 (2.0%)	0.420

1 patient: reocclusion after 6 weeks without medication, alkol-disease:mww 2017_01_05

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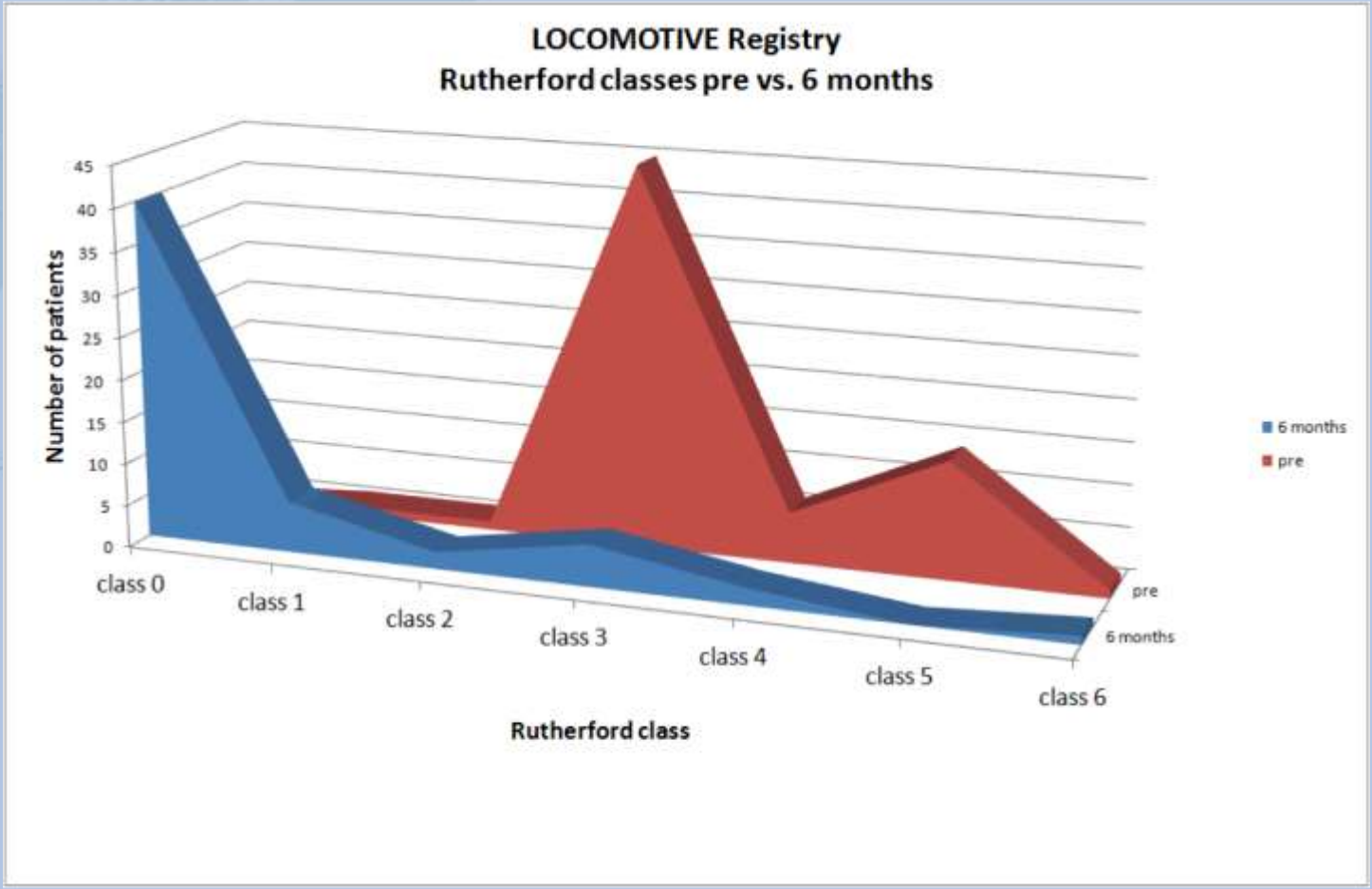
LOCOMOTIVE registry: 6-mo FU patients: n: 75

Clinical outcomes



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LOCOMOTIVE registry: 6-mo FU patients: n: 75
Conclusions

The first clinical experience @ 6 months suggests that the MSDS strategy is safe and effective in patients with PAOD (RCC 2-5) with femoro-popliteal lesions:

- ***High procedural success rate (100%)*** to release the individual stent segments also in morphologically challenging lesions.
- ***No stent-loss***, ***no conversion*** to standard stenting
- almost ***half of the lesion length could be saved from stenting*** as compared to the “long stent” strategy.
- ***TLR rates in CLI and non-CLI patients of less than 5% @ 6 months***.
- ***primary patency rate 91,3% (CCD), ass. primary pateny: 98,6%***

A larger randomized trial or a propensity scored matching analysis is needed to better compare the MSDS strategy to conventional stenting.

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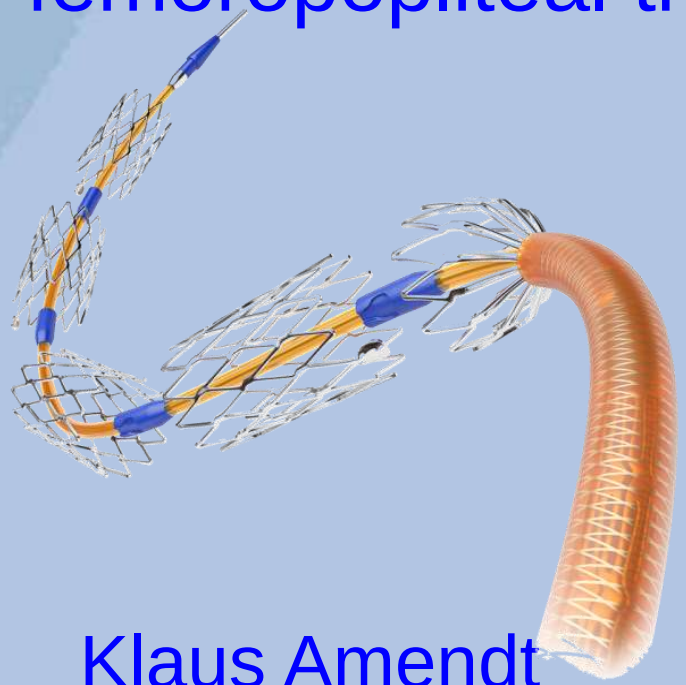
6-month results of the ***LOCOMOTIVE*** registry investigating spot stenting in the femoropopliteal tract



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