LOCOMOTIVE All Comers Registry with the Multi-Loc spot stenting device:

12-month results

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Disclosure

Speaker name:

Dr. Klaus Amendt.....

I have the following potential conflicts of interest to report:

- [X] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [X] Co-owner of patent Multi-LOC

- [ ] I do not have any potential conflict of interest

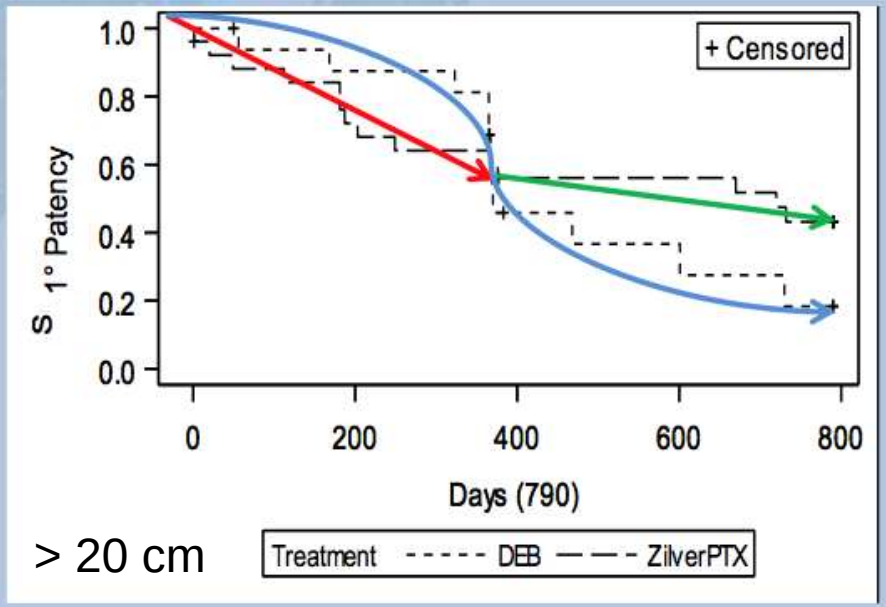
Stents bring up some additional problems

Stent- Disease

“…leave nothing behind….”

?

Primary Patency @ 24 Month
Long Lesion Group
Zilver PTX vs DCB only



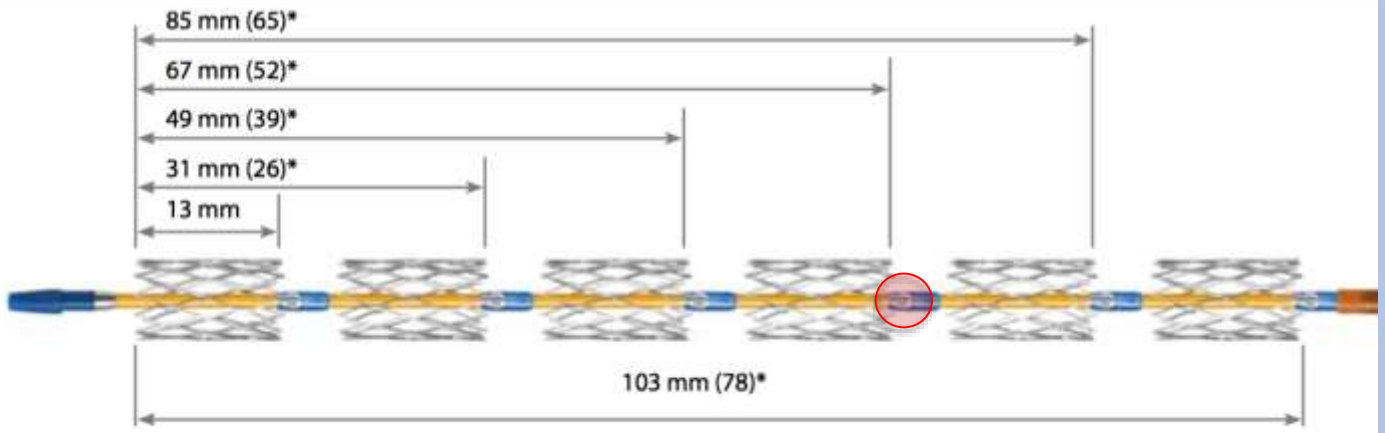
> 20 cm

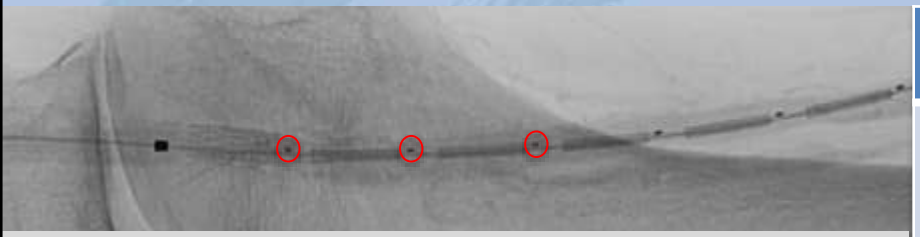
Treatment	1° Patency (%)
DCB (n=18)	18.3
ZilverPTX (n=26)	43.1

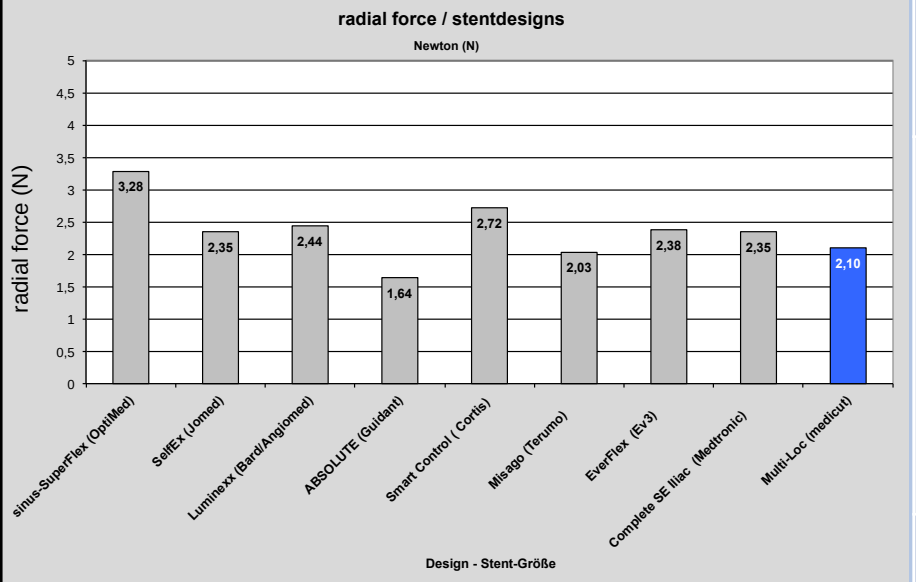
Decreased patency for „DCB only“ in long lesions!

„Crash“ after 400 days

D. Scheinert LINC 2017







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
Radioopaque marker	1/stent
Designe	closed cell designe
Radial force	comparable to standard nitinol stents
Treated vessel diameter	4 – 8 mm

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

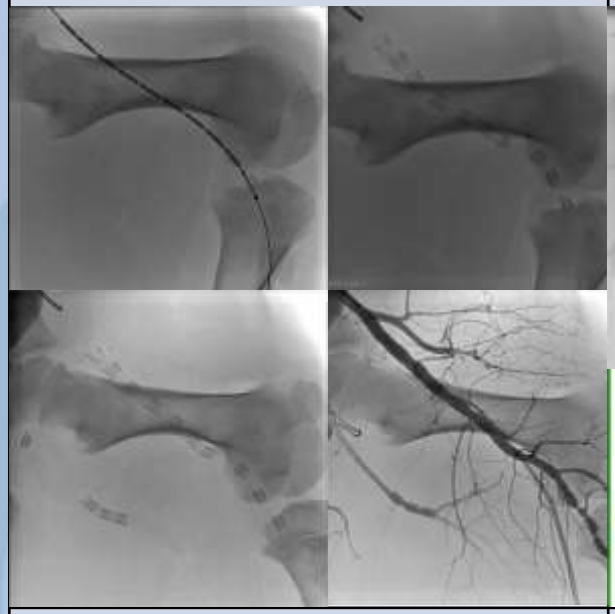
European Patent: No. 2775968: **07.09.2017**

12.04.17

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

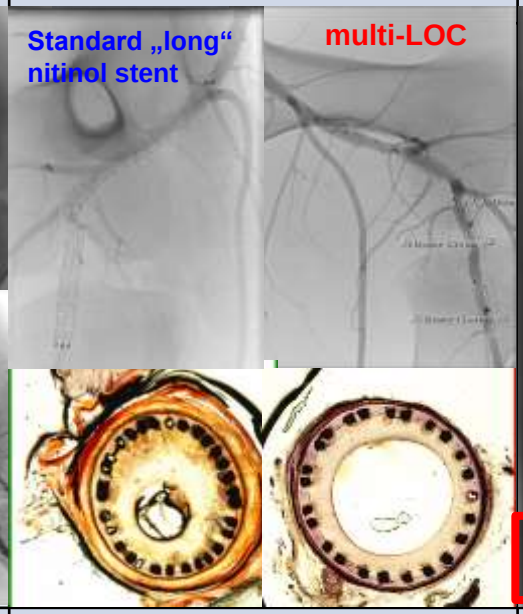
Animal experiments (porcine)

acute



- feasibility
- exact anatomically controlled release
- no stent loss

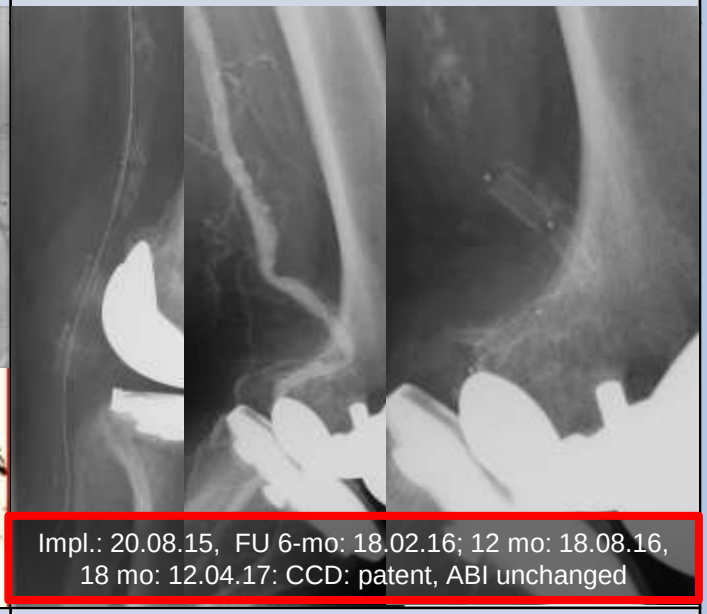
chronic (3 w surv.)



- no stent fracture
- superior patency vs standard long nitinol stent

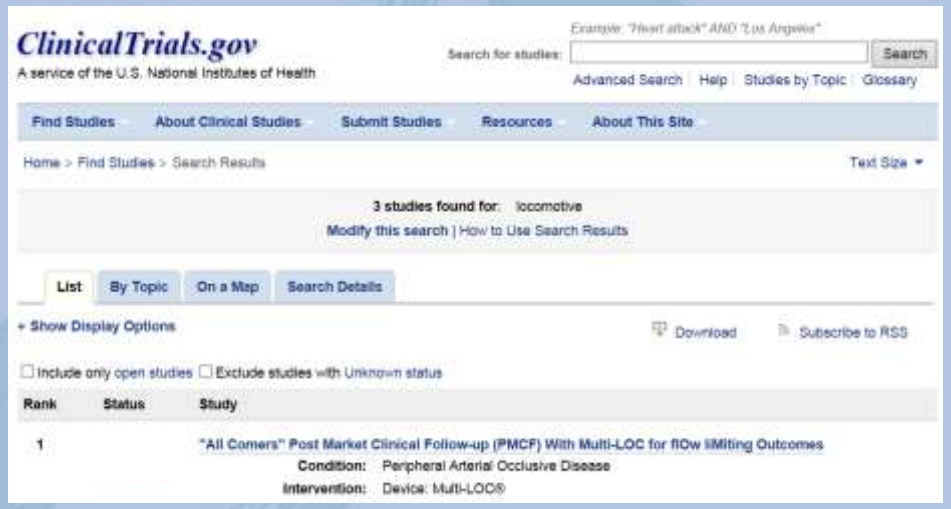
Clincal experiences

post CE- marking:



- reproducibility of animal results
- nearly no neg. influence on biomechanical properties of arteries
- stabilized lumen, also in severely calcified lesions

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“

LOCOMOTIVE registry

Inclusion criteria:
(N: 200)

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 5mm between 2 stents
reference vessel diameter: 4-7mm
distal run off: at least 1 vessel to the foot
collaterals supplying sufficient flow to the foot
also severe calcification, after subintimal PTA,

Exclusion criteria:

Instent-restenosis
Restenosis after DCB

Primary endpoint: ***6 month TLR- rate (LINC 2017)***

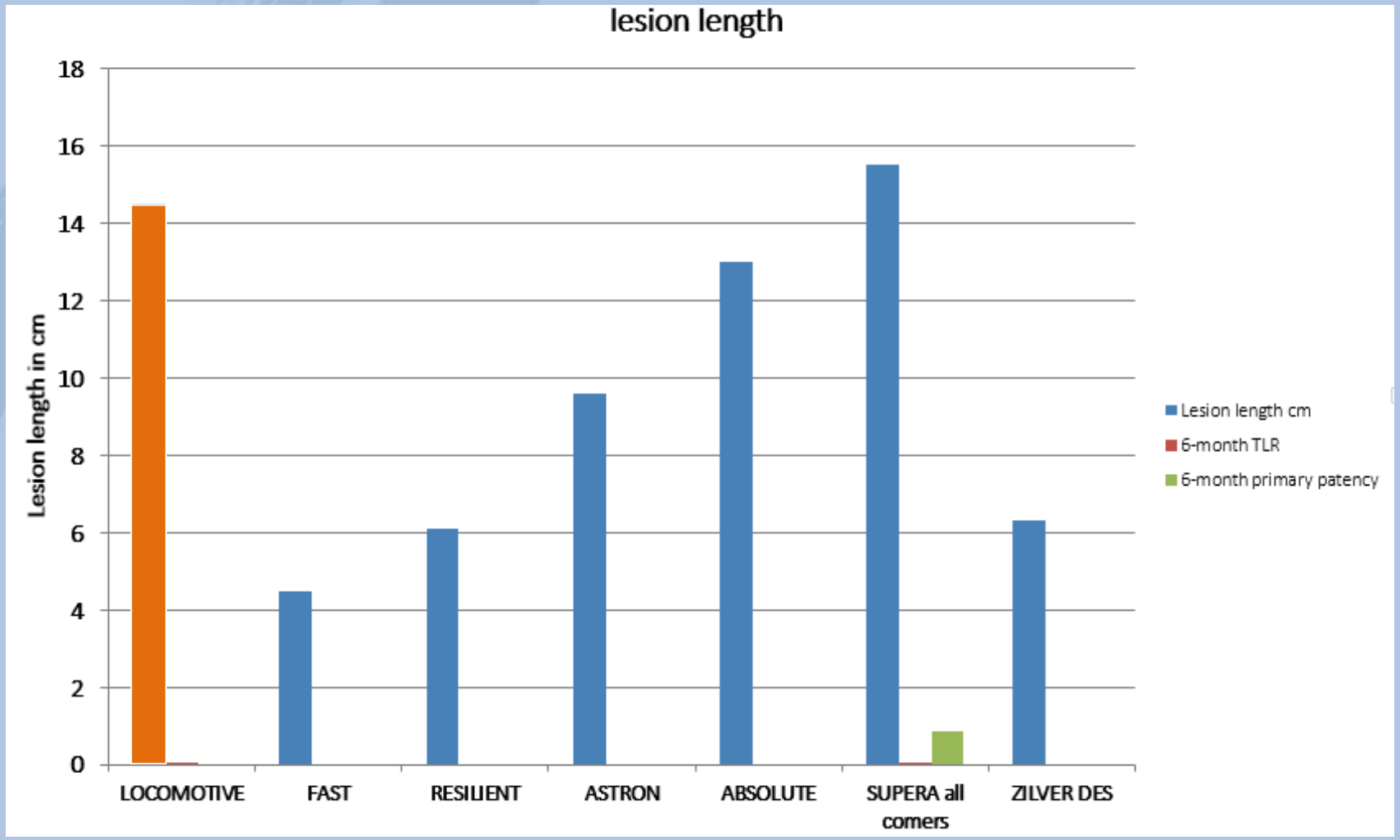
Additional variables: ***12 month TLR rate***
@ 6 and ***12 months:*** walking distance (S1, S2)
ABI ,
CCD: patency- rate
RCC
amputation rate

LOCOMOTIVE registry

Lesion morphology

	All (n: 75)	CLI (n: 20)	no CLI (n: 55)	p-value
Target lesions/p	176/75	52/20	124/55	
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+II ***SFA III+P1*** P2+P3	80 (45.5%) ***79 (44.9%)*** 17 (9.7%)	25 (48.0%) ***23 (44.1%)*** 4 (7.7%)	55 (44.3%) ***56 (45.2%)*** 13 (10.5%)	0.815
TASC II C/D	**90 (51.1%)**	**38 (73.1%)**	**52 (41.9%)**	<0.001
Total LL (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

LOCOMOTIVE registry



LOCOMOTIVE registry

Procedural details and device characteristics

	All patients	CLI	no CLI	p-value
Patients	75	20	55	-
Lesions	176	52	124	-
Stent-ø (mm)	5.7±0.7	5.5±0.6	5.7±0.8	0.145
released stents/pat.	5.1±2.2	6.0±2.3	4.8±2.2	0.054
LL saved f. stenting	**0.47±0.18**	**0.54±0.16**	**0.44±0.18**	**0.044**
Predilatation targ.les. ***POBA*** DCB POBA+DCB	**133 (75.6%)** 17 (9.7%) 23 (13.1%)	**46 (88.5%)** 3 (5.8%) 2 (3.8%)	**87 (70.2%)** 14 (11.3%) 21 (16.9%)	0.055
Proced. success	**85 (100.0%)**	**24 (100.0%)**	**61 (100.0%)**	-

LOCOMOTIVE registry: 6-mo FU

Clinical outcomes

	All patients	Critical limb ischemia	No critical limb ischemia	p-value
Number of FU	75 (100%)	20 (100%)	55 (100%)	0.727
Prim. patency:	**90.7% (68)**	**95.0% (19)**	**89.1% (49)**	**0.436**
TLR % (n)	**5.3% (4)**	**5.0% (1)**	**5.5% (3)**	**0.938**
Amputation target L	2 (2.7%)	2 (10.0%)	0 (0.0%)	0.017
Death: vascular	4 (5.7%)	2 (10.5%)	2 (3.9%)	
non-vascular	2 (2.9%)	1 (5.3%)	1 (2.0%)	0.403

K. Amendt et al. VASA 2017;46(6):452-461

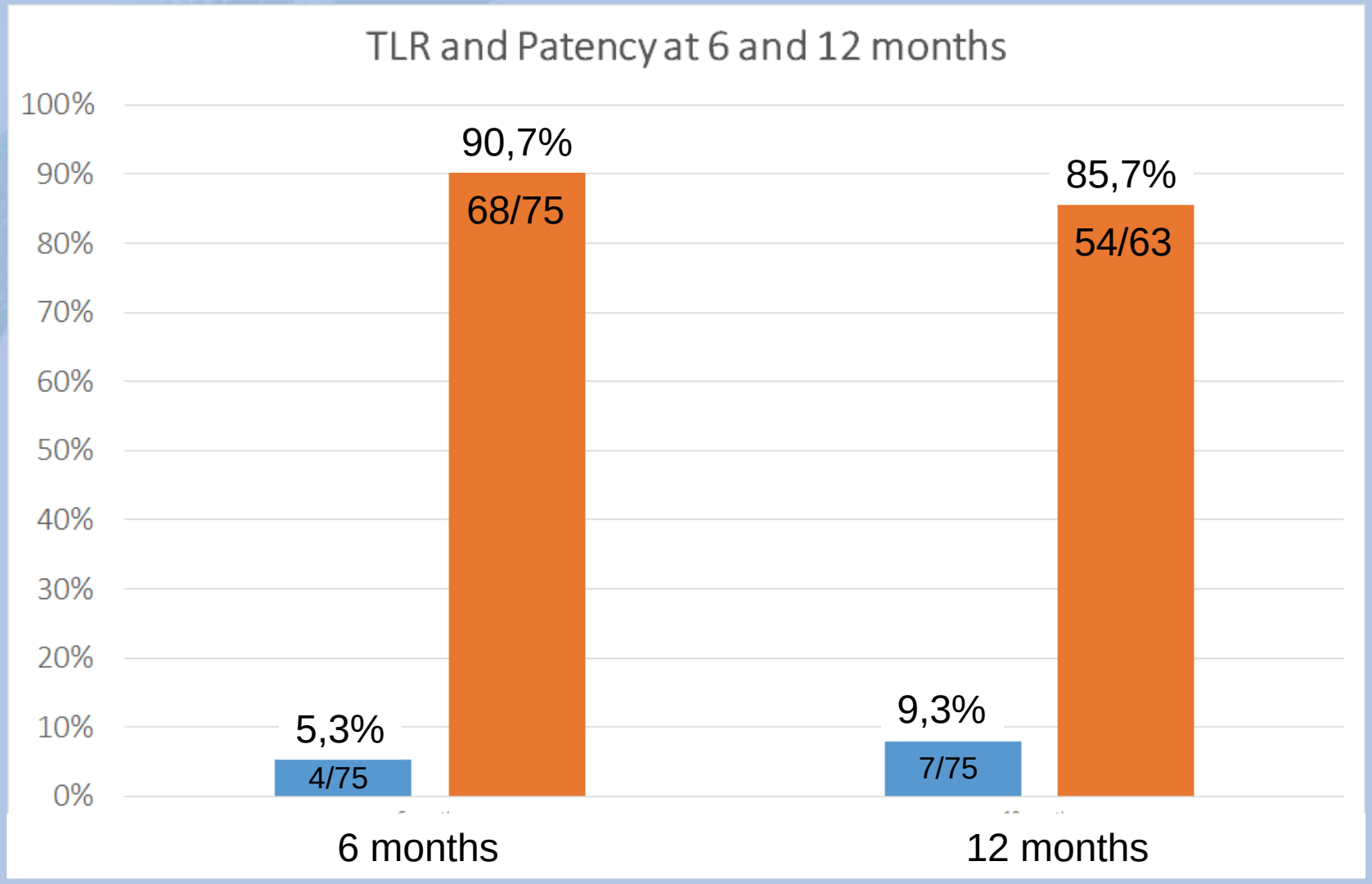
LOCOMOTIVE registry: 12-mo FU patients

Clinical outcomes

	All patients	CLI	no CLI	p-value
Number of FU	75 (100%)	20 (100%)	55 (100%)	-
Prim. Patency: (diameter sten. <50%)	**85.7% (54/63)**	**93.3% (14/15)**	**83.3% (40/48)**	0.334
TLR (n) Re-PTA-Lysis	**9.3% (7/75)**	**5.0% (1/20)**	**10.9% (6/55)**	0.437
ff TLR	**90.7%**	**95.0%**	**89.9%**	**n.s**
Prim. Ass. Patency	**96.8%** (61/63)	**100 %**	**95.8%** (46/48)	n.s
Amputation target L	2 (2.9%)	2 (10.5%)	0 (0.0%)	0.099
Death: vascular	4 (5.3%)	2 (11.1%)	2 (4.0%)	
non-vascular	5 (7.2%)	1 (5.6%)	4 (7.8%)	0.384

LOCOMOTIVE registry: 12-mo FU patients

Clinical outcomes



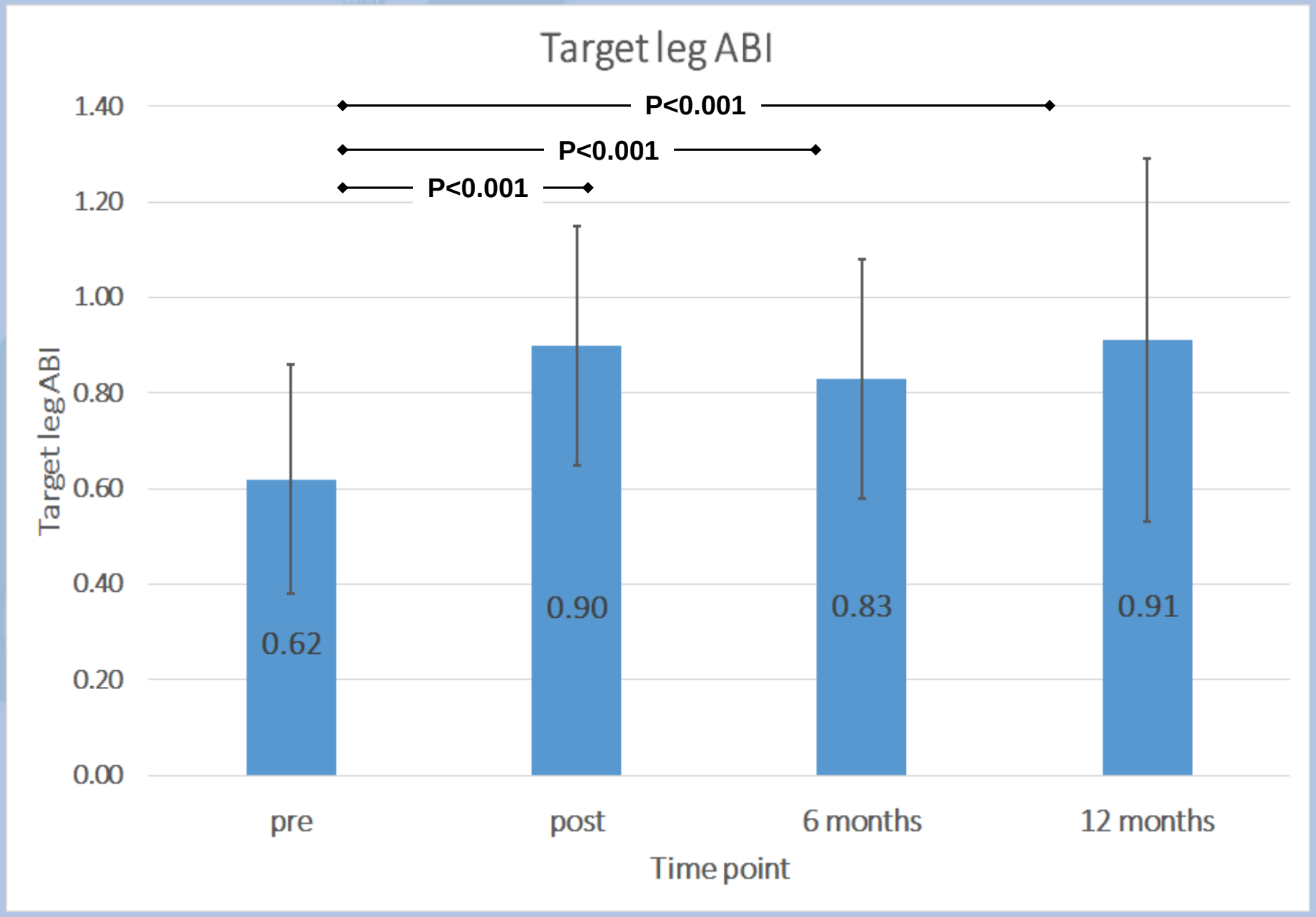
LOCOMOTIVE registry: 12-mo FU patients

Clinical outcomes

	All patients	Critical limb ischemia	No critical limb ischemia	p-value
Patients	75	20	55	-
12 months				
Target leg ABI	0.91±0.38 n=53	0.91±0.40 n=13	0.91±0.38 n=40	0.973
Rutherford shift pre vs. 12 months	2.2±1.3 n=60	2.8±1.7 n=15	2.1±1.0 n=45	0.038
Major amputations, target leg (+0)	2 (2.7%) n=75	**2 (10.0%)** n=20	0 (0.0%) n=55	**0.017**
Major amputations, contralateral leg	1 (1.3%) n=75	1 (5.0%) n=20	0 (0.0%) n=55	0.095
Death all causes (+3 in IC)	9 (12.0%) n=75	3 (15.0%) n=20	6 (10.9%) n=55	0.630
Death cardiac vascular non-cardiovascular	 1 (1.3%) 3 (4.0%) 5 (6.7%)	 0 (0.0%) 2 (10.0%) 1 (5.0%)	 1 (1.8%) 1 (1.8%) 4 (7.3%)	0.398

Comments:

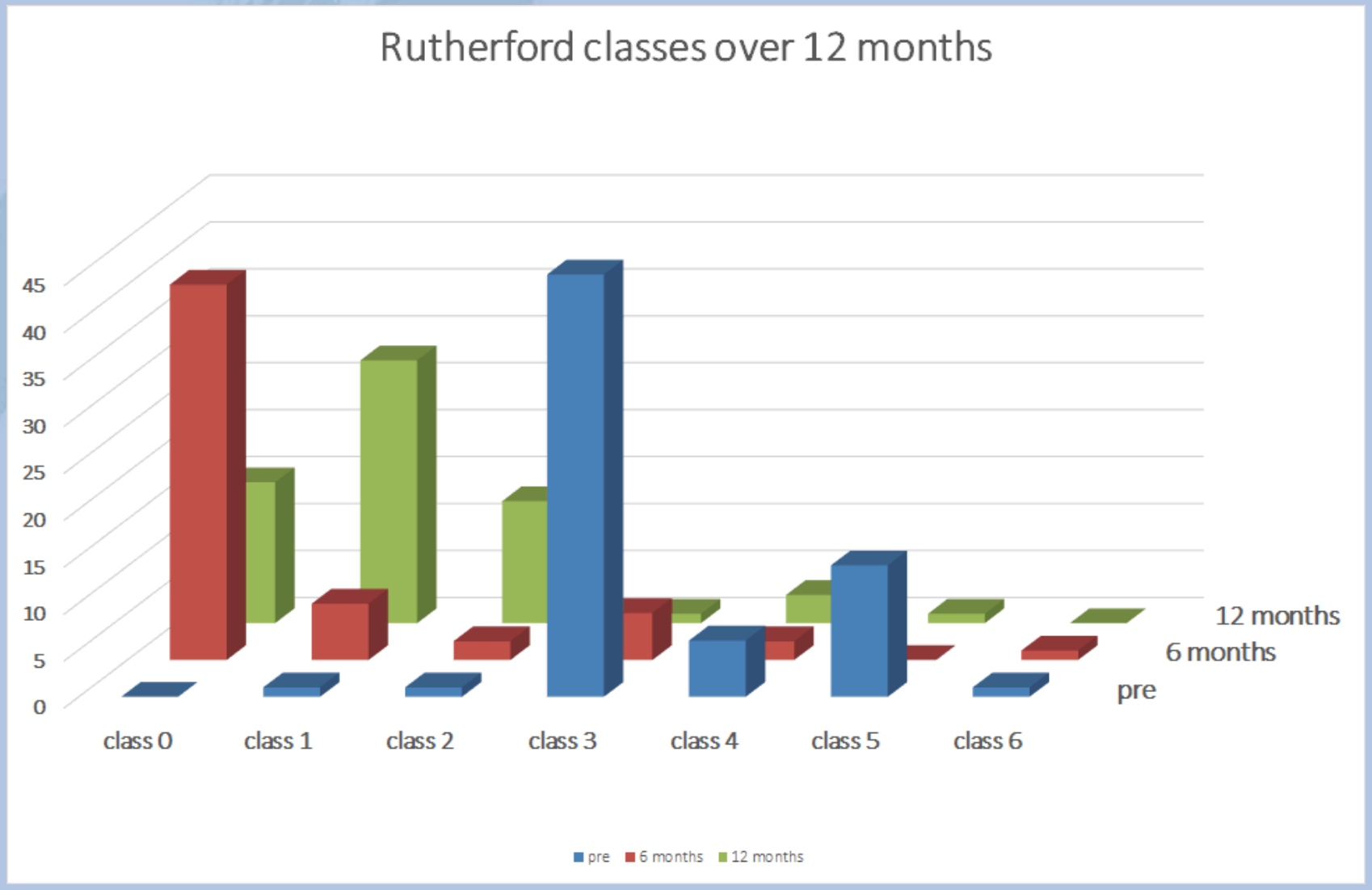
[1] statistical analysis not meaningful due to small patient numbers, [2] based on angiographic or sonographic data only. All categorical variables were compared with the Pearson's Chi2 test, continuous variables were analyzed with the unpaired student t-test



Comment: pairwise comparison based on repeated measurement ANOVA, $p_{post\ vs.\ 12\ months} = 0.343$, $p_{6\ months\ vs.\ 12\ months} = 0.397$

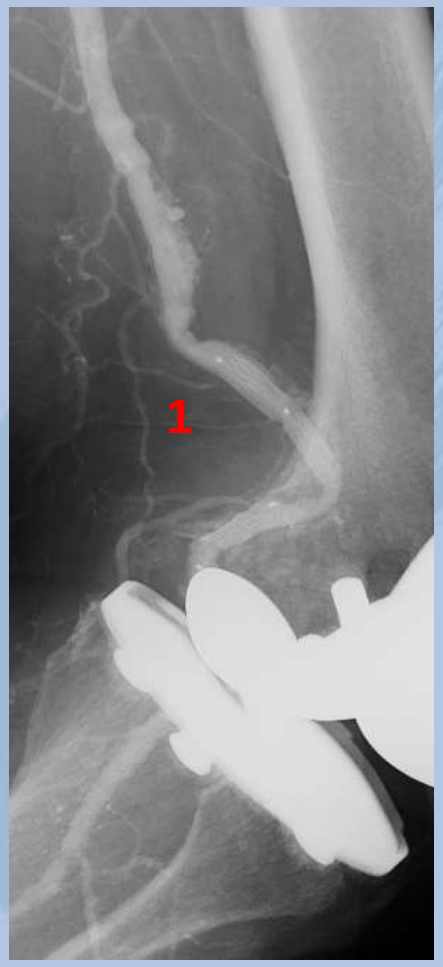
LOCOMOTIVE registry: 12-mo FU patients

Clinical outcomes



G.G. ♂ 26.07.38

20.08.2015



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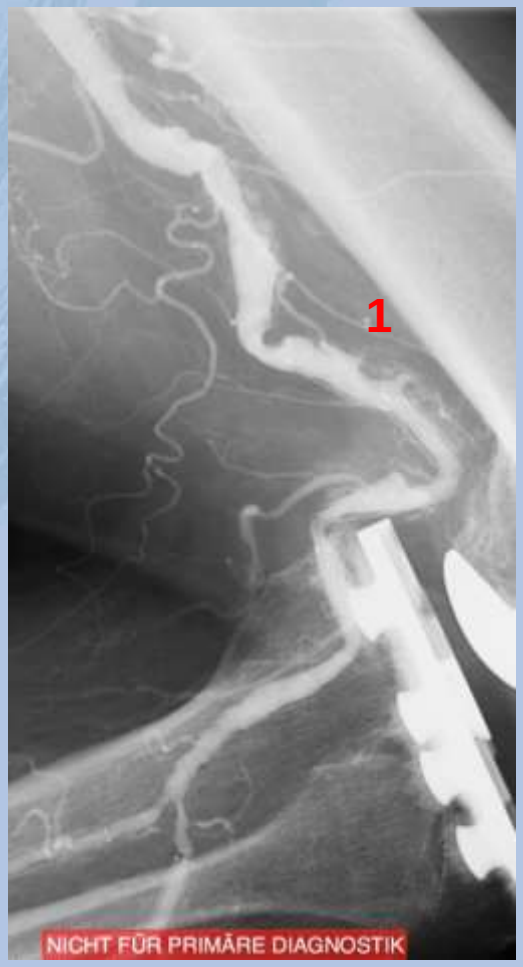

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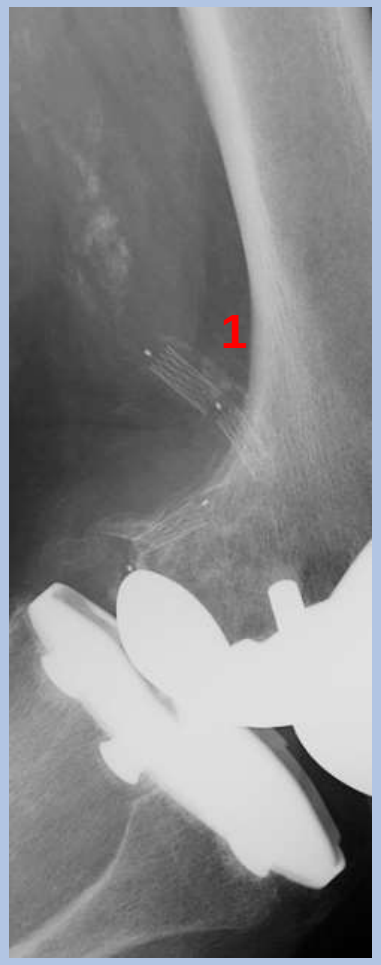

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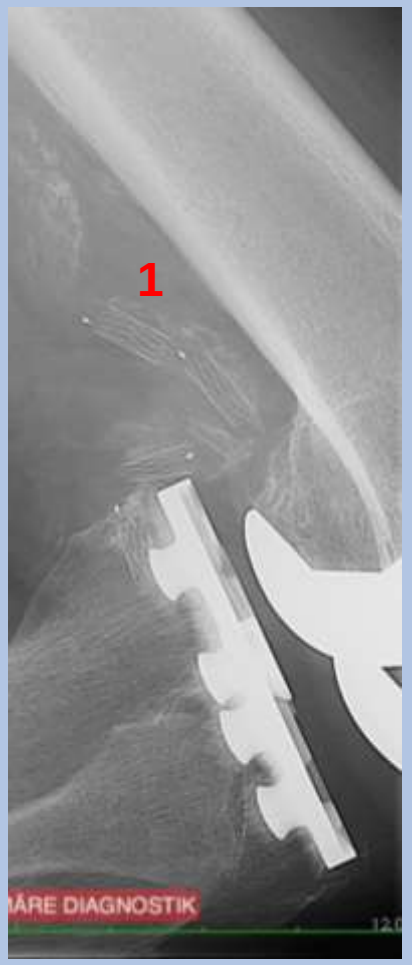


0 — 20

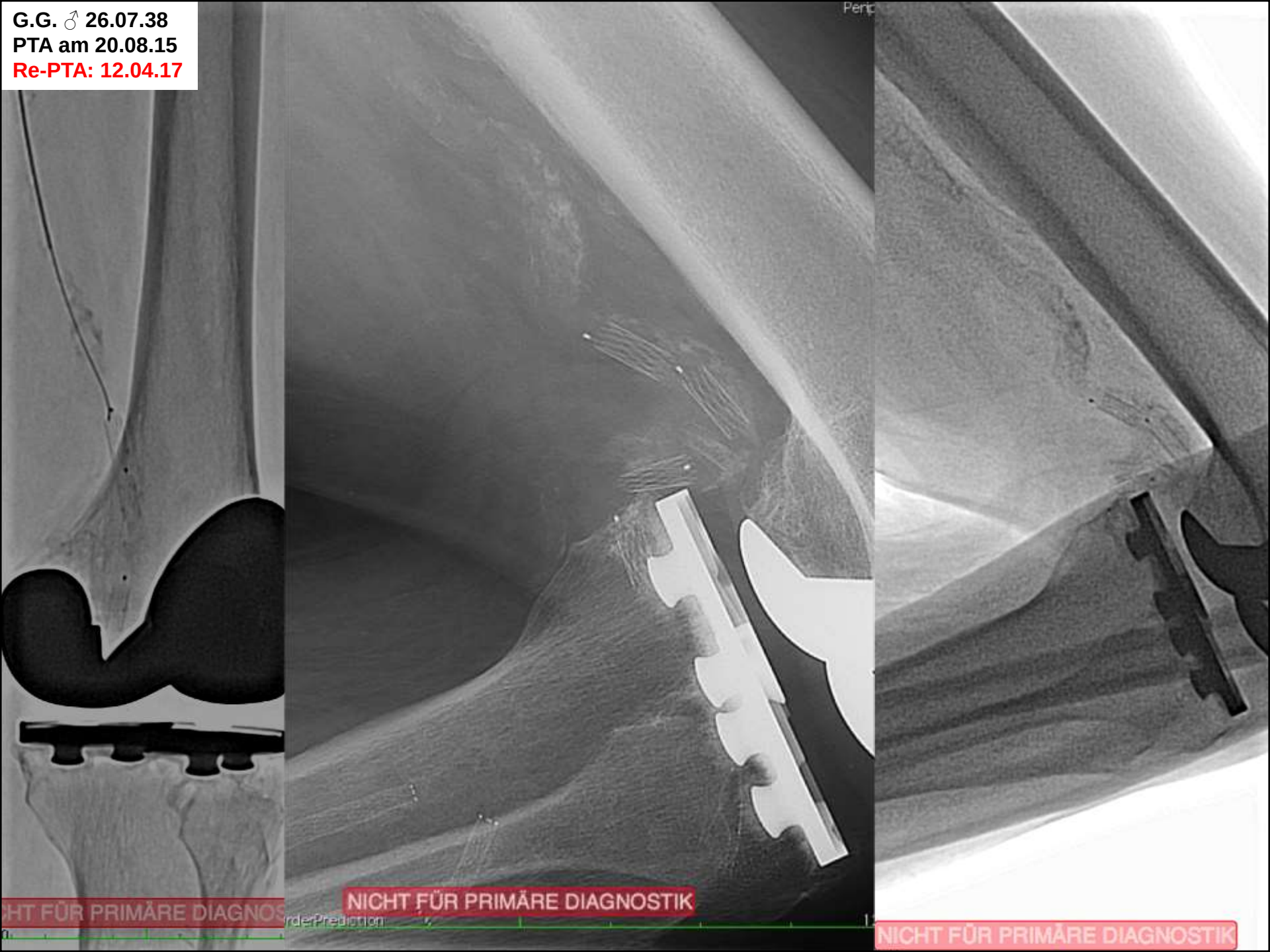
0 — 20

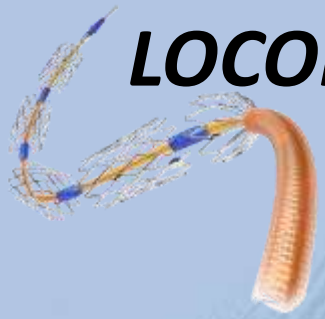
FU: 18.02.16 (6 MO)
Complete defect healing
CCD: patent stents

FU: 18.08.16 (12 Mo)
CCD: patent stents

FU: 12.04.17 (20 Mo)
CCD, ABI angio: patent

G.G. ♂ 26.07.38
PTA am 20.08.15
Re-PTA: 12.04.17





LOCOMOTIVE registry: 12-mo FU patients

Conclusions

These data @ 12 months show 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 10 %***.
- ***primary patency: 85.7%***
- ***ass. primary patency: 96.8% (61/63) (CLI: 100%, IC: 95.8%)***

LOCOMOTIVE- registry has been extended including patients until 12/2018

N: 251 @ 13.01.2018

LOCOMOTIVE registry
Further activities

Controlled studies with combination of DEB and spot-stenting with the VascuFlex Multi-LOC® are planned

Room 3: Technical Forum
13:30 – 15:00

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12-month results

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