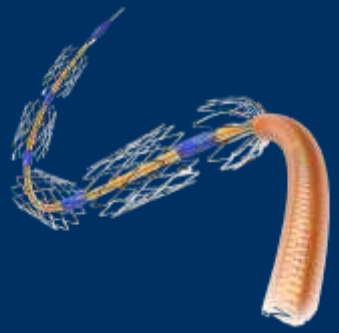
FIRST TIME DATA RELEASE: Final results from the ***LOCOMOTIVE*** registry using the ***VascuFlex Multi-LOC*** stent system in real-world lesions



K. Amendt

Center of Vascular Medicine „Oberrhein“ (Mannheim)
Clinic for Internal Medicine I: Angiology, Cardiology and Subsequent Complications of Diabetes mellitus
Diakonissenkrankenhaus Mannheim Germany
Academic Teaching Hospital Clinical Medicine Mannheim University Heidelberg
K.Amendt@diako-mannheim.de

Disclosure

Speaker name: Dr. Klaus Amendt

I have the following potential conflicts of interest to report:

- [X] Consulting: Bayer AB, B. Braun
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [X] Owner of European and US-patent on Multiple Stent Delivery System

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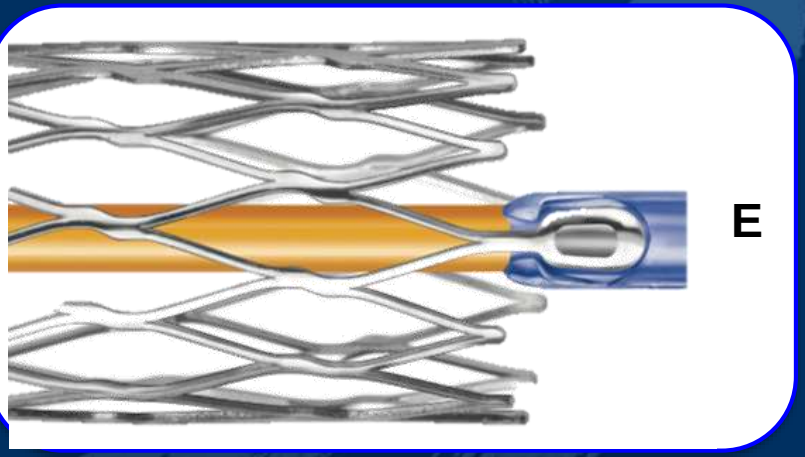

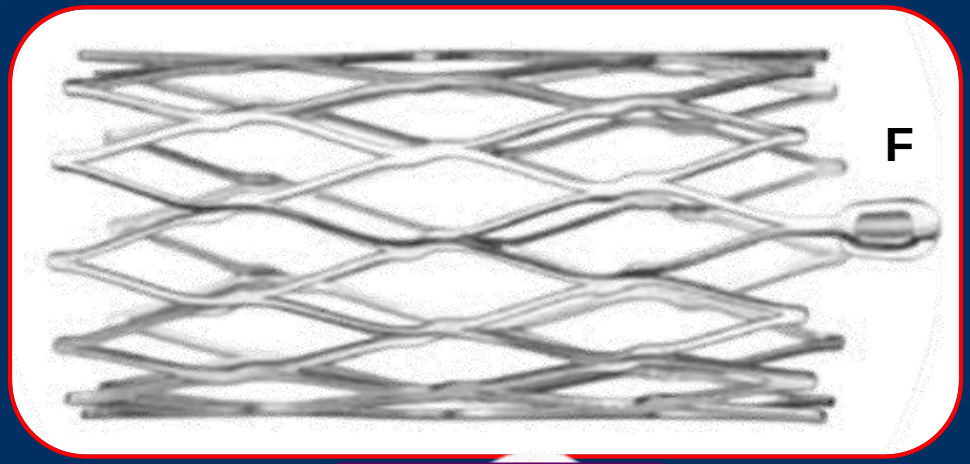

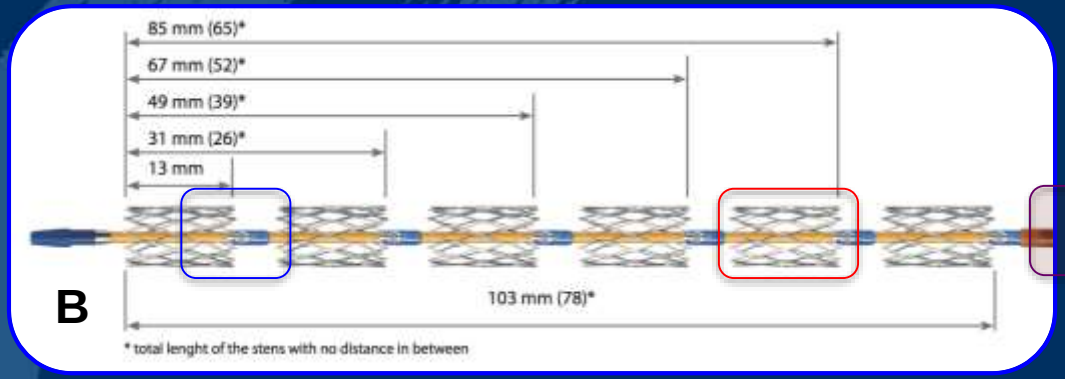

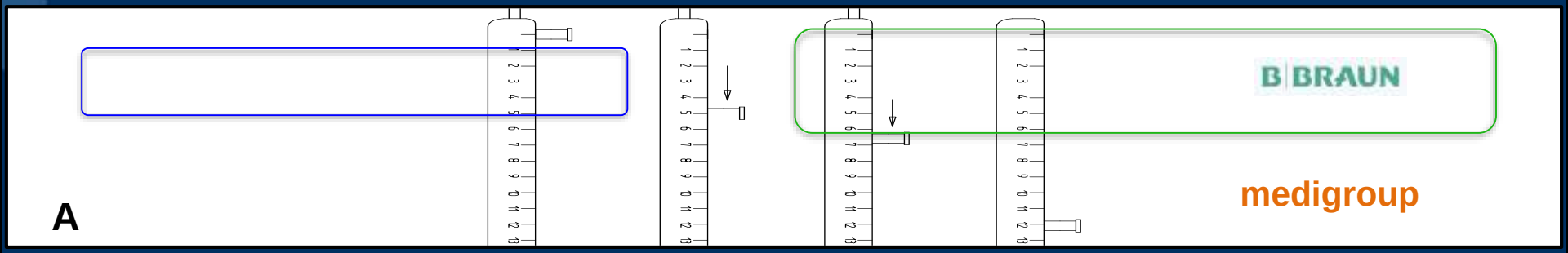

A: one-handed Multiple Stent Delivery System *MSDS*: *lower part:* before multi-LOC Stent delivery, *upper part:* 3 multi-LOC Stents delivered
B: dimensions of MSDS **C**: handle with thumb wheel to withdraw outer sheath **D**: braided outer sheat **E**: spacer with excavation to fix tanatlum marker of the stent **F**: single multi-LOC stent with welded tantalum marker

LOCOMOTIVE: Closed registry

ClinicalTrials.gov Identifier: NCT02531230
24.08.2015 - 31.12.2016 (n= 75)
ClinicalTrials.gov Identifier: NCT02900274
End: 31.12.2018

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“

Primary endpoint: ***6 month TLR- rate (LINC 2017, CX 2017)***
Additional variables: ***12 month TLR rate (LINC 2018, CX 2018)***
@ 6 and ***12 months:*** walking distance (S1, S2)
ABI , CCD: patency- rate
RCC, amputation rate

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Conclusions: results of the closed LOCOMOTIVE-Registry (n: 75) in 2018

ClinicalTrials.gov Identifier: NCT02531230)
24.08.2015 - 31.12.2016

These data @ 6 and 12 months show that the MSDS strategy is safe and effective in patients with PAOD (RCC 2-5) with complex 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
- ***half of the lesion length could be saved from stenting*** as compared to the "long stent" strategy.

- ***Ff TLR rates: @ 6 months: 94,7% (CLI: 95.0%, IC: 94.5%)***
  @ 12 months: 90.7% (CLI: 95.0%, IC: 89.9%)
- ***primary patency rate: @ 6 months: 90,7% (CLI: 95.0%, IC: 89.1%)***
  @ 12 months: 85.7% (CLI: 93.3%, IC: 83.3%)
- ***No stent fractures***
- ***Sustained clinical benefit in CLI and IC (RFCCL, ABI)***

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LOCOMOTIVE Registry

Extended registry

ClinicalTrials.gov Identifier: NCT02900274

End: 31.12.2018

N: 357

Site	City	PI
DE - Diakonissenkrankenhaus Mannheim	Mannheim	Dr. med. Klaus Amendt
DE - Universitätsklinikum Heidelberg	Heidelberg	Prof. Dr. med. Christian Erbel
DE - Universitäts-Herzzentrum Freiburg - Bad Krozingen	Bad Krozingen	Prof. Dr. Thomas Zeller
DE - Klinikum Lippe-Detmold	Detmold	Dr. med. Dirk Härtel
DE - Klinikum Magdeburg	Magdeburg	PD Dr. med. habil. Jörg Tautenhahn
DE - Sankt Gertrauden-Krankenhaus	Berlin	Dr. Ralf Langhoff
DE - Heinrich-Braun-Klinikum Zwickau	Zwickau	Prof. Dr. med. Andreas Hansch
DE - Asklepios Klinikum Harburg	Hamburg	PD Dr. Hans Krankenberg
DE - Agaplesion Bethesda Krankenhaus Wuppertal	Wuppertal	Dr. Jawed Arjumand
DE - Städtisches Klinikum Dessau	Dessau-Roßlau	Dr. med. Karsten Stock
DE - Ev. KH Königin Elisabeth Herzberge gGmbH	Berlin	Dr. Jens Stegemann
DE - Klinik Kösching	Kösching	Prof. Dr. med. Alexander Hansen
DE - SRH Klinikum Karlsbad-Langensteinbach	Karlsbad	Prof. Dr. med. Erwin Blessing
DE - Ev. Krankenhaus Mülheim	Mülheim an der Ruhr	Prof. Dr. Claus Nolte-Ernsting
DE - SLK-Kliniken Heilbronn (Bad Friedrichshall)	Bad Friedrichshall	Prof. Dr. med. Thomas Dengler
DE - St. Marien-Krankenhaus Siegen	Siegen	PD Dr. med. Christian Hohl
DE - Universitätsklinikum Jena	Jena	Prof. Dr. med. Ulf Teichgräber
DE - Universitätsklinikum Leipzig	Leipzig	Prof. Dr. Dierk Scheinert
FR - CHU Lille	Lille	Dr. Jonathan Sobocinski
FR - CHU Cote de Nacre	Caen	Dr. Etienne Joguet
FR - CHU Bordeaux - Hôpital Pellegrin	Bordeaux	Prof. Eric Ducasse
FR - CHU de la Timone à Marseille	Marseille	Prof. Philippe Piquet
HR - Clinical Hospital Merkur	Zagreb	Prof. Vinko Vidjak
HR - UHC Sisters of Mercy	Zagreb	PhD Tomislav Krčmar
IT - Nuovo Ospedale San Giovanni di Dio	Firenze	Dr. Nicola Troisi
PL - Centrum Kardiologii Józefów	Józefów/Warsaw	Dr. Robert Proczka

LOCOMOTIVE EXTENDED Registry

NCT number: ***NCT02900274***

End: 31.12.2018

Patient demographics

	All patients	Critical limb ischemia	No critical limb ischemia	p-value
Patients	357	60 (16.8%)	297 (82.2%)	-
Age, years	71.2±9.7	**75.9±8.8**	70.3±9.6	**<0.001**
Male gender	228 (63.9%)	33 (55.0%)	195 (65.7%)	0.117
Rutherford 1 2 3 4 5 6	 4 (1.1%) 99 (27.7%) 194 (54.4%) 45 (12.6%) 15 (4.2%) 0 (0.0%)	 0 (0.0%) 0 (0.0%) 0 (0.0%) 45 (75.0%) 15 (25.0%) 0 (0.0%)	 4 (1.3%) 99 (33.3%) 194 (65.4%) 0 (0.0%) 0 (0.0%) 0 (0.0%)	-
Diabetes mellitus	175 (49.0%)	**41 (68.3%)**	134 (45.1%)	**0.001**
Hypertension	312 (87.4%)	51 (85.0%)	261 (87.9%)	0.540
Hypercholesteremia	257 (72.0%)	35 (58.3%)	**222 (74.7%)**	**0.010**
Renal insufficiency	67 (18.8%)	**18 (30.0%)**	49 (16.5%)	**0.015**
Dialysis dependent	10 (2.8%)	**4 (6.7%)**	6 (2.0%)	**0.047**
Coronary artery disease CAD no CAD …unknown	 136 (38.1%) 132 (37.0%) 89 (24.9%)	 25 (41.7%) 18 (30.0%) 17 (28.3%)	 111 (37.4%) 114 (38.4%) 72 (24.2%)	0.466
Cerebrovascular disease	59 (16.5%)	9 (15.0%)	50 (16.8%)	0.727
Carotid artery disease	159 (44.5%)	26 (43.3%)	133 (44.8%)	0.837
CCC vascular disease	23 (6.4%)	5 (8.3%)	18 (6.1%)	0.513
History of smoking Current smoker Ex smoker No smoker	 160 (44.8%) 97 (27.2%) 100 (28.0%)	 25 (41.7%) 18 (30.0%) 17 (28.3%)	 135 (45.5%) 79 (26.6%) 83 (27.9%)	0.829

All categorical variables were compared with the Pearson's Chi² test, continuous variables were analyzed with the unpaired student t-test

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Lesion morphology

LOCOMOTIVE EXTENDED Registry
NCT number: NCT02900274
End: 31.12.2018

	All patients	Critical limb ischemia	No critical limb ischemia	p-value
Target lesions	448	81	367	
Treated leg, target lesions left right both missing	 196 (57.1%) 145 (42.3%) 2 (0.6%) 1 (TBD)	 35 (59.3%) 24 (40.7%) 0 (0.0%) 1 (TBD)	 161 (56.7%) 121 (42.6%) 2 (0.7%)	0.772
Lower leg status per patient no vessel 1 2 3	 12 (3.5%) 92 (26.7%) 117 (34.0%) 123 (35.8%)	 5 (8.5%) 24 (40.7%) 19 (32.2%) 11 (18.6%)	 7 (2.5%) 68 (23.8%) 98 (34.4%) 112 (39.3%)	0.001
SFA I	176 (39.2%)	31 (37.8%)	145 (39.5%)	0.775
SFA II	235 (52.3%)	37 (45.1%)	198 (54.0%)	0.148
SFA III	263 (58.6%)	47 (57.3%)	216 (58.9%)	0.798
P1	140 (31.2%)	30 (36.6%)	110 (30.0%)	0.243
P2	74 (16.5%)	18 (22.0%)	56 (15.3%)	0.140
P3	14 (3.1%)	3 (3.7%)	11 (3.0%)	0.755
TASC II class target lesion A B C D	 71 (15.8%) 178 (39.7%) 134 (29.8%) 66 (14.7%)	 8 (9.8%) 29 (35.4%) 30 (36.6%) 15 (18.3%)	 63 (17.2%) 149 (40.6%) 104 (28.3%) 51 (13.9%)	0.158
TASC C/D lesions	**200 (44.5%)**	**45 (54.9%)**	**155 (42.2%)**	**0.037**
Diffuse vessel disease	383 (85.3%)	71 (86.6%)	312 (85.0%)	0.716
Calcification	385 (85.7%)	67 (81.7%)	318 (86.6%)	0.247
Thrombus burden	42 (9.4%)	7 (8.5%)	35 (9.5%)	0.779
Total occlusion	141 (31.4%)	22 (26.8%)	119 (32.4%)	0.324
Reference vessel diameter (mm)	5.5±1.1	5.5±1.4	5.5±1.0	0.688
Total lesion length, cm (range)	**16.0±9.7**	**16.2±9.1**	**16.0±9.8**	**0.926**
Degree of stenosis, %	89.8±12.6	90.4±10.5	89.6±13.1	0.688

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Procedural details and device characteristics

LOCOMOTIVE EXTENDED Registry
NCT number: NCT02900274
End: 31.12.2018

	All patients	Critical limb ischemia	No critical limb ischemia	p-value
Patients	357	60	297	-
Lesions	**449**	**82**	**367**	
Devices	376	65	312	-
Devices per patient				
1	337	55	282	0.337
2	20	5	15	
Type of device				
6F, 80 cm, 6-LOC	141 (37.4%)	24 (36.9%)	117 (37.5%)	0.930
6F, 130 cm, 6-LOC	236 (62.6%)	41 (63.1%)	195 (62.5%)	
Stent diameters per patient				
5 mm	130 (36.4%)	26 (43.3%)	104 (35.0%)	0.657
6 mm	186 (52.1%)	28 (46.7%)	158 (53.2%)	
7 mm	36 (10.1%)	5 (8.3%)	31 (10.4%)	
8 mm	5 (1.4%)	1 (1.7%)	4 (1.3%)	
Stent diameter, mm	5.8±0.7	5.7±0.7	5.8±0.7	0.278
Total number of released stent segments	**1741**	**308**	**1433**	-
N of released stent segments per patient	4.88±1.82	5.13±1.71	4.82±1.84	0.231
Total length of stent segments per lesion L	0.56±0.59	0.53±0.37	0.57±0.62	0.691
Lesion length saved from stenting	**0.44±0.59**	**0.47±0.37**	**0.43±0.59**	0.691
Released stent segments per patient				
1	7 (2.0%)	0 (0.0%)	7 (2.4%)	
2	27 (7.6%)	3 (5.0%)	24 (8.1%)	0.344
3	41 (11.5%)	5 (8.3%)	36 (12.1%)	
4	66 (18.5%)	11 (18.3%)	55 (18.5%)	
5	73 (20.3%)	18 (30.0%)	55 (18.5%)	
6	123 (34.5%)	18 (30.0%)	105 (35.4%)	
7	4 (1.1%)	2 (3.3%)	2 (0.7%)	
8	3 (0.8%)	0 (0.0%)	3 (1.0%)	
9	4 (1.1%)	1 (1.7%)	3 (1.0%)	
10	2 (0.6%)	1 (1.7%)	1 (0.3%)	
11	2 (0.6%)	0 (0.0%)	2 (0.7%)	
12	5 (1.4%)	1 (1.7%)	4 (1.3%)	
Reason for stenting				
dissection only	126 (28.1%)	23 (28.0%)	103 (28.1%)	0.690
recoil only	121 (26.9%)	25 (30.5%)	96 (26.2%)	
dissection & recoil	202 (45.0%)	34 (41.5%)	168 (45.8%)	
Predilatation target lesion				
DCB (with or w/o POBA)	202 (45.0%)	25 (30.5%)	177 (48.2%)	**0.014**
POBA	243 (54.1%)	56 (68.3%)	187 (51.0%)	
No predilatation	4 (0.9%)	1 (1.2%)	3 (0.8%)	
Predilatation balloon diameter, mm	5.3±0.7	5.2±0.7	5.4±0.7	0.114
Predilatation balloon length, mm	98.6±47.0	96.3±47.1	99.1±47.0	0.702
Pressure, atm	10.0±2.4	9.4±2.1	10.1±2.5	0.140
Procedural success per patient	**351 (98.3%)**	**59 (98.3%)**	**292 (98.3%)**	**0.993**

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LOCOMOTIVE EXTENDED Registry

NCT number: NCT02900274

End: 31.12.2018

Clinical outcomes at 6 months

	All patients	Critical limb ischemia	No critical limb ischemia	p-value
Patients	**357**	**60**	**297**	-
Pre-procedure				
Walking distance, pain-free, m			74.8±72.2 n=88	
Walking distance, max, m			119.4±105.2 n=212	
Target leg ABI before procedure	**0.58±0.31**	**0.46±0.28**	**0.59±0.30**	**0.026**
Target leg ABI after procedure	**0.90±0.24**	**0.81±0.27**	**0.91±0.24**	**0.105**
6 months				
Number of follow-ups sonographic, clinical and by telephone relative to *mortality*	338 (94.7%)	57 (95.0%)	281 (94.6%)	0.903
Number of follow-ups sonographic, clinical and by telephone relative to *TLR, TVR*	**337 (94.4%)**	**56 (93.3%)**	**281 (94.6%)**	**0.694**
Follow-up duration, months (including time to event)	6.1±0.9	5.8±1.5	6.2±0.8	0.006
Primary *unassisted patency of* target *vessel*, diameter stenosis<70% and/or TLR	**299 (88.7%)**	**50 (89.3%)**	**249 (88.6%)**	**0.884**
All Target lesion revascularizations (Re-PTA, lysis, surgical)	**15 (4.5%)**	**4 (7.1%)**	**11 (3.9%)**	**0.285**
Target vessel revascularization (Re-PTA, lysis)	24 (7.1%) 15 **+9**	6 (10.7%) 4 **+ 2**	18 (6.4%) 11 **+ 7**	0.252
Non-target vessel revascularization	**14 (4.2%)**	**6 (10.7%)**	**8 (2.9%)**	**0.007**
All *non Target lesion* revascularisation (n)	**23 (6.8%)**	**8 (14.2%)**	**15 (5.3%)**	
Target leg ABI	0.89±0.26	0.77±0.31	0.90±0.24	0.006
Rutherford shift pre vs. 6 months	1.8±1.3	**2.6±1.7**	1.6±1.2	**<0.001**
Major amputations, target and non-target leg	6 (1.8%)	**5 (8.9%)**	1 (0.4%)	**<0.001**
Death Not related to intervention Possibly related to intervention …cardiac death	11 (3.3%) 2 (0.6%) 2 (0.6%)	**5 (8.8%)** **1 (1.8%)** **2 (3.5%)**	6 (2.1%) 1 (0.4%) 0 (0.0%)	**<0.001**

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LOCOMOTIVE EXTENDED Registry

*NCT number: **NCT02900274***

End: 31.12.2018

Clinical outcomes at 12 months

	All patients	Critical limb ischemia	No critical limb ischemia	p-value
Patients	**357**	**60**	**297**	**-**
12 months				
Number of follow-ups sonographic, clinical and by telephone relative to *mortality*	305 (85.4%)	47 (78.3%)	258 (86.9%)	0.087
Number of follow-ups sonographic, clinical and by telephone relative to *TLR, TVR*	**303 (84.9%)**	**47 (78.3%)**	**256 (86.2%)**	**0.121**
Follow-up duration, months (including time to event)	11.8±3.2	**10.8±4.0**	12.0±3.0	**0.012**
Primary unassisted patency of *target vessel*, diameter stenosis<70% and/or TLR	248 (81.8%) N=303	38 (80.9%) N=47	210 (82.0%) N=256	0.847
All Target lesion revascularizations (Re-PTA, lysis, surgical)	**35 (11.6%)**	**7 (14.9%)**	**28 (10.9%)**	**0.435**
+ TLR vs 6 months (n)	**+20 (+6.6%)**	**+3 (+6.3%)**	**+17 (+6.6%)**	
Target *vessel* revascularization (Re-PTA, lysis)	43 (14.2%) 35 **+8**	9 (19.1%) 7 **+2**	34 (13.3%) 28 **+6**	0.289
Non-target vessel revascularization	23 (7.5%)	7 (14.3%)	16 (6.3%)	0.051
All *non Target lesion* revascularisation (n)	**31 (10.2%)**	**9 (19.1%)**	**22 (8.6%)**	
Target leg ABI	0.86±0.29	0.86±0.374	0.90±0.22	0.909
Rutherford shift pre vs. 12 months	**1.8±1.3**	**2.6±2.0**	**1.7±1.2**	**<0.001**
Difference in Rutherford shift 6 - 12 months[2]	**-0.09±1.17**	**0.03±1.66**	**-0.11±1.07**	**0.502**
Major amputations, target and non-target leg	8 (2.6%) N=304	**5 (10.6%) N=47**	**3 (1.2%) N=257**	<0.001
Death Not related to intervention Possibly related to intervention …cardiac death	17 (5.6%) 2 (0.7%) 3 (1.0%)	**6 (12.8%)** **1 (2.1%)** **3 (6.4%)**	11 (4.3%) 1 (0.4%) 0 (0.0%)	**<0.001**

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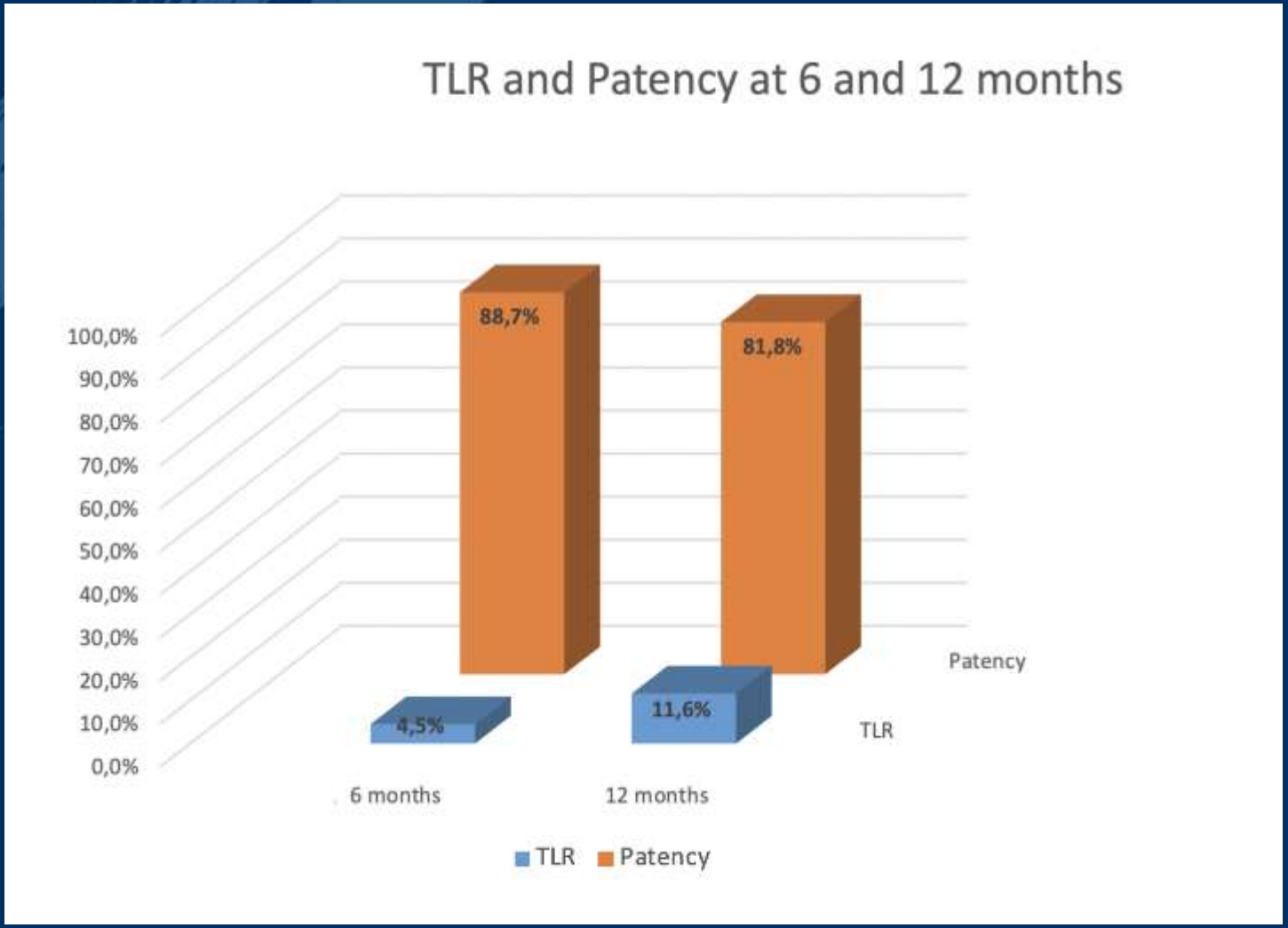
LOCOMOTIVE EXTENDED Registry

NCT number: ***NCT02900274***

End: 31.12.2018



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LOCOMOTIVE EXTENDED Registry

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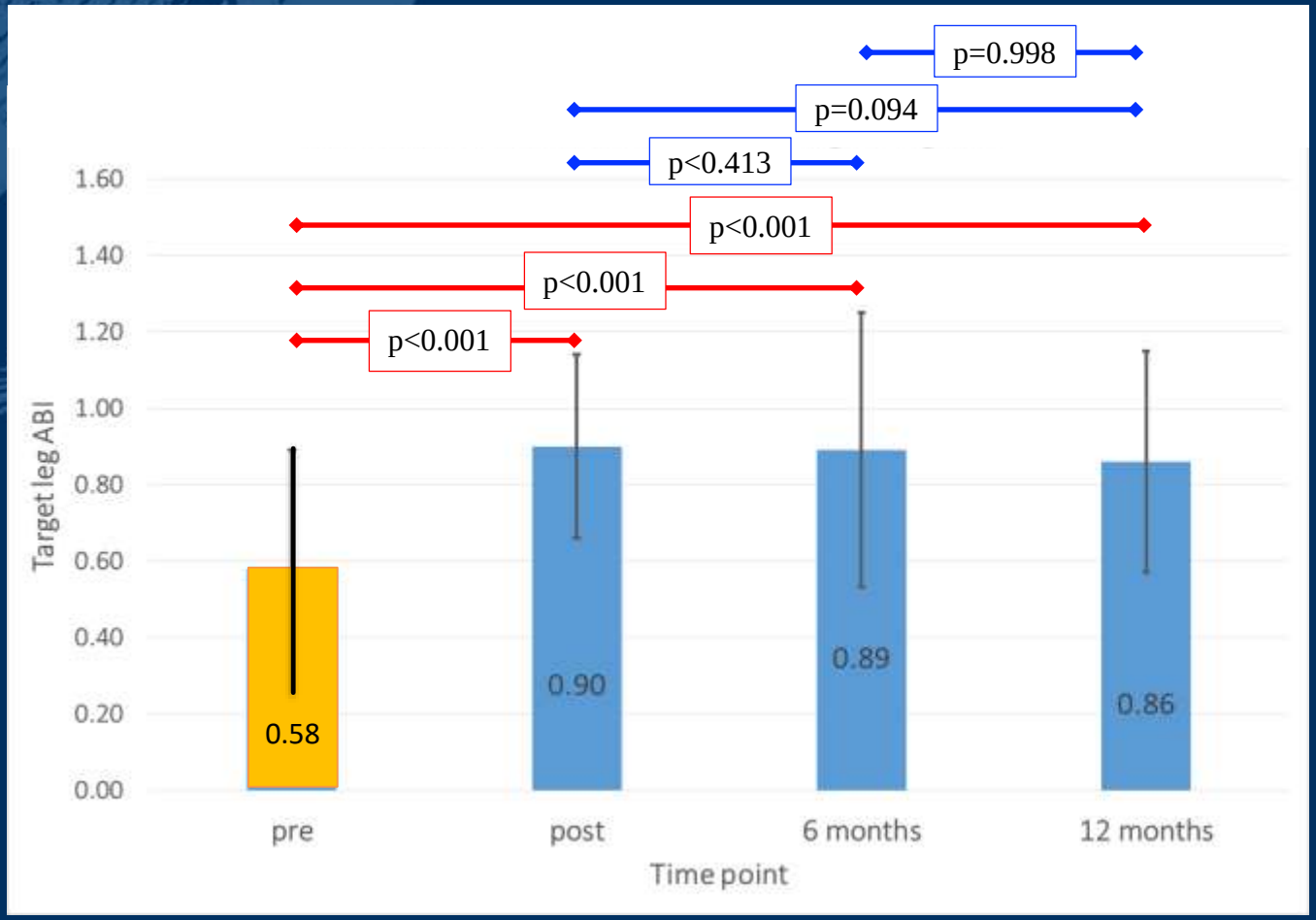

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LOCOMOTIVE EXTENDED Registry

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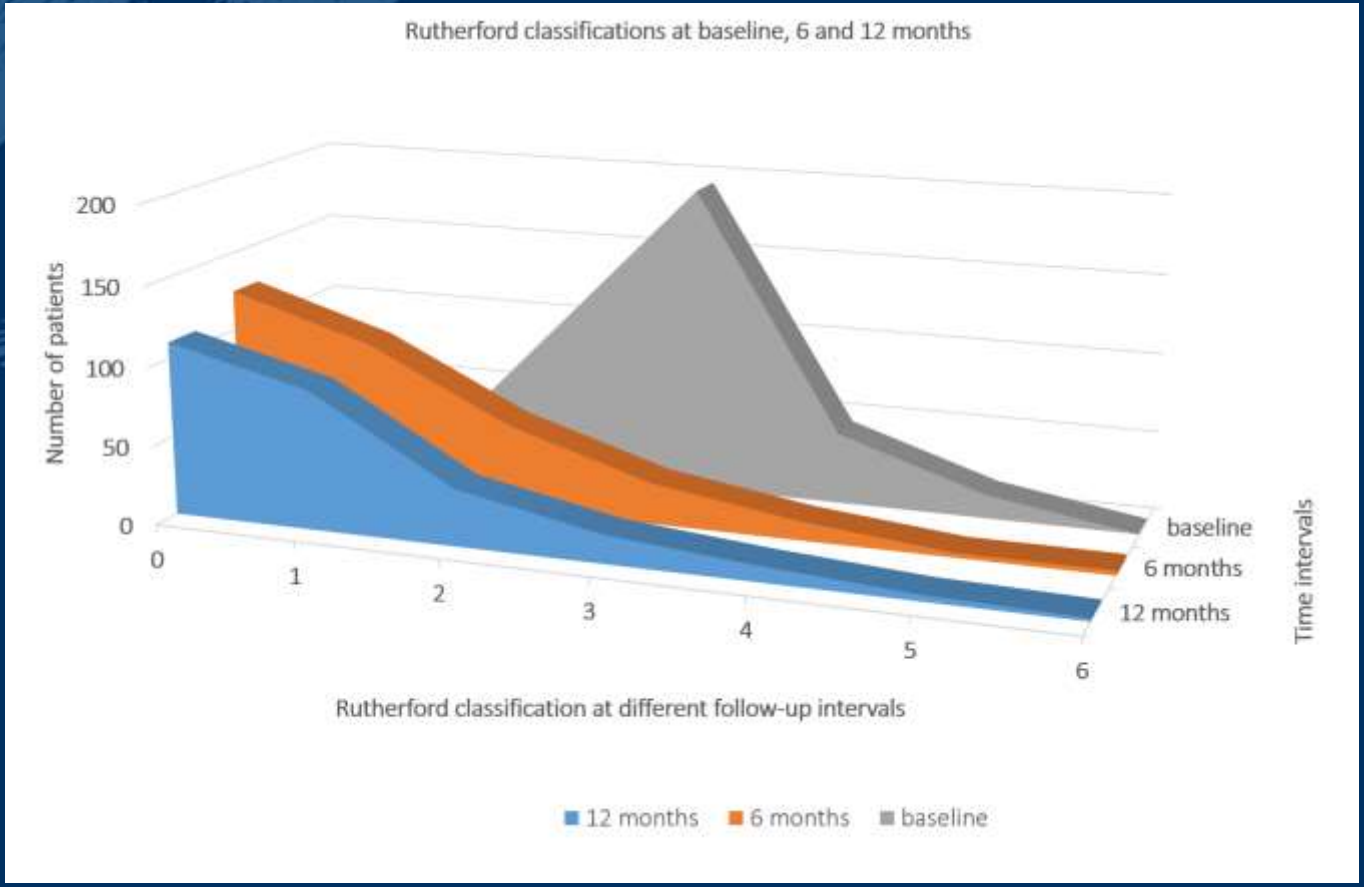
End: 31.12.2018



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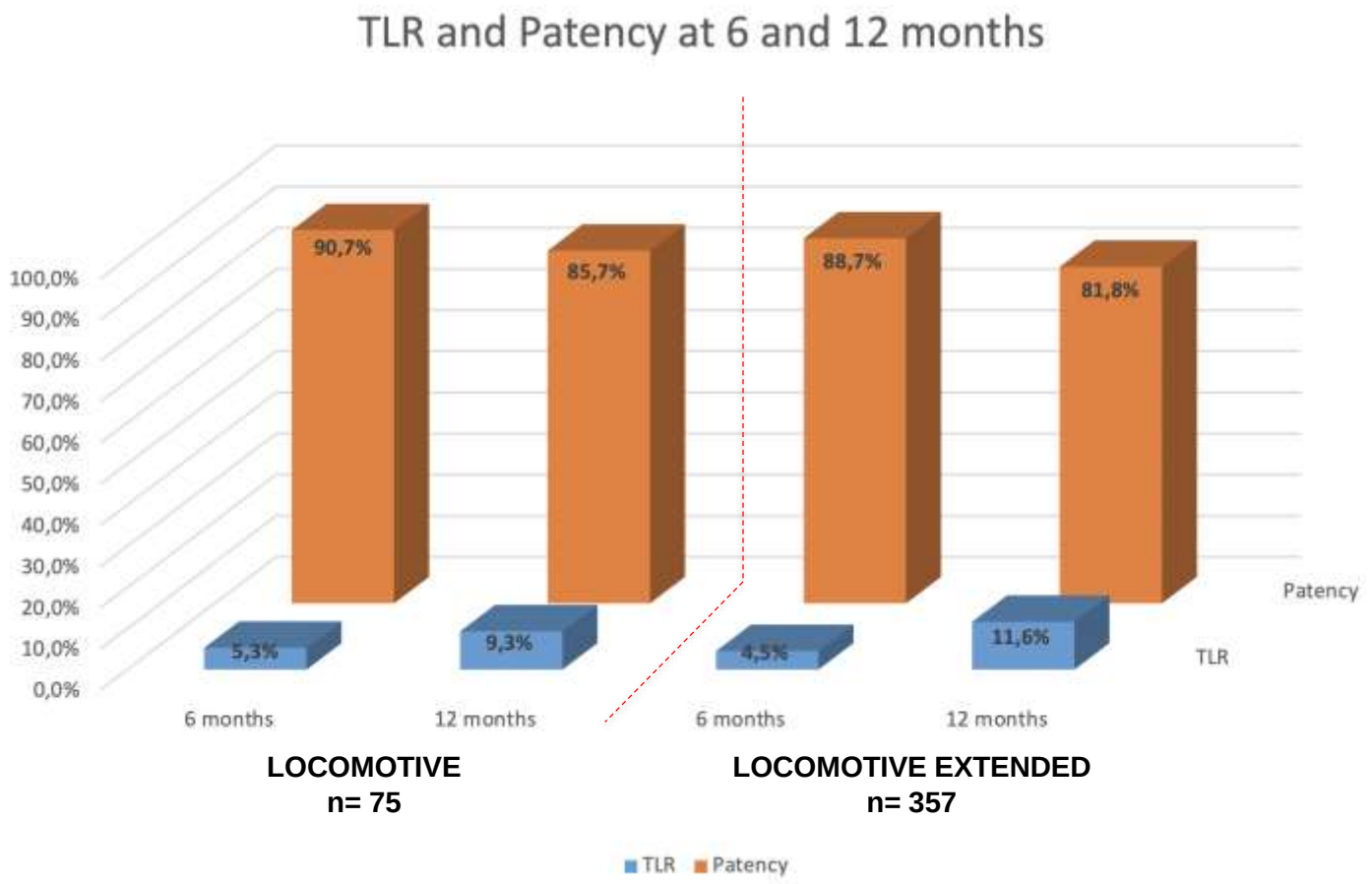
LOCOMOTIVE Registry



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LOCOMOTIVE EXTENDED Registry

NCT number: ***NCT02900274***

End: 31.12.2018

These data @ 6 and @ 12 months show that the MSDS strategy is safe and effective in patients with PAOD (RCC 2-5) with complex femoro-popliteal lesions:

- ***High procedural success rate (98%)*** to release the individual stent segments also in morphologically challenging lesions.
- ***No stent-loss***, ***no conversion*** to standard stenting
- ***half of the lesion length could be saved from stenting*** as compared to the "long stent" strategy.

- ***Ff TLR rates: @ 6 months 95,5% (CLI: 92.9%, IC: 96.1%)***
  @ 12 months 88.4% (CLI: 85.1%, IC: 89.1%)
- ***primary patency rate: @ 6 months 88,7% (CLI: 89.3%, IC: 88.6%)***
  of target vessel @ 12 months 81.8% (CLI: 80.9%, IC: 82.0%)
- ***No stent fractures***
- ***Sustained clinical benefit in CLI and IC (RFCCL, ABI)***
- ***Progession of disease within lesion and outside is comparable***

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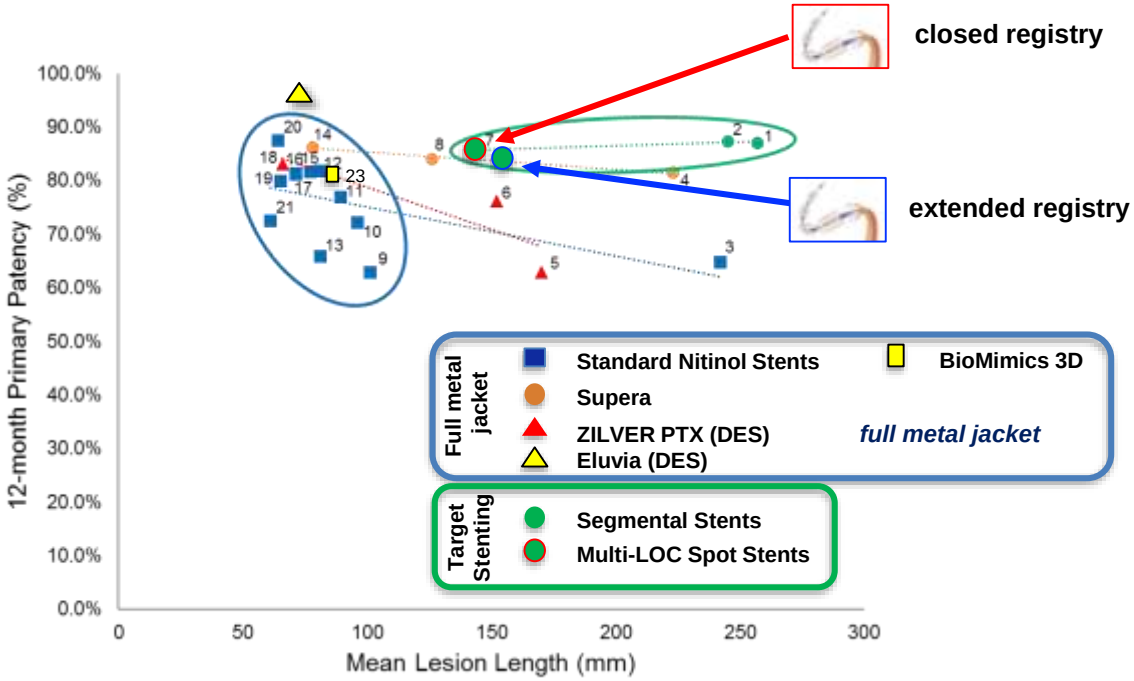
SFA stent performance related to lesion length

RTCs and Registries



Note: Results from clinical trials are not directly comparable. This chart is for educational purposes only.

1 HONG SPOT: Hong S-J et al. J Am Coll Cardiol Intv 2015;8:472–80. 2 PARADE: Young-Guk K. 12-month results of PARADE trial. LINC 2018. 3 DURABILITY 200: Bosiers M et al. J Vasc Surg. 2011;54:1042-1050. 4 SUPERA 500 LL: Scheinert D. Results from the SUPERA-500 Registry. LINC 2013. 5 ZEPHYR: Iida O et al. JACC Cardiovasc Interv. 2015;8:1105-12. 6 REAL: Scheinert D 2-year results of the REAL PTX trial. Presented at LINC 2017. 7 LOCOMOTIVE: Amendt K. LOCOMOTIVE All comers study 12-month results. LINC 2018. 8 SUPERA 500: Scheinert D. Results from the SUPERA-500 Registry. LINC 2013. 9 ABSOLUTE: Schillinger M et al. N Engl J Med. 2006;354:1879–1888. 10 DURABILITY: Bosiers M et al. J Endovasc Ther. 2009;16:261-269. 11 DURABILITY II: Matsumura JS, Yamanouchi D, et al. J Vasc Surg. 2013 Jul;58(1):73-83. 12 MIMICS-2: Zeller T. MIMICS-2 Study: 1-Year Results. LINC 2018. 13 ASTRON: Dick P et al. Catheter Cardiovasc Interv. 2009;74:1090–1095. 14 SUPERB: Garcia L et al. Circ Cardiovasc Interv. 2015 May;8(5). 15 STROLL: William A et al. J Vasc Interv Radiol 2015;26:21–28. 16 RESILIENT: Laird JR et al. Circ Cardiovasc Interv. 2010;3:267-276. 17 4EVER: Bosiers M et al. J Endovasc Ther. 2013;20:746–756. 18 ZILVER PTX: Dake M et al. Circ Cardiovasc Interv. 2011;4:495–504. 19 MIMICS: Zeller T et al. Circ Cardiovasc Interv. 2016;9:e002930. 20 MISAGO 2: Schulte K et al. J Endovasc Ther. 2012;19:774-784. 21 COMPLETE SE: Laird JR et al. J Endovasc Ther. 2014;21:202-212. 22. Majestic Trial: Müller-Hülsbeck S et al. 2016; JEVT 23(5):701-707. 23. MIMICS-2 Study Th. Zeller @LINC 2018.

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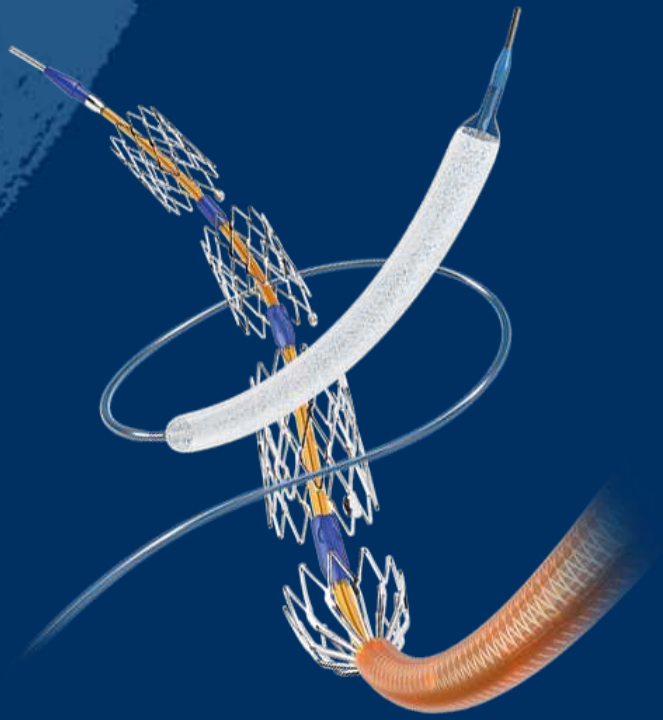
Multi-LOC: future studies planned:



Controlled studies with combination of DEB and spot-stenting with the Multi-LOC

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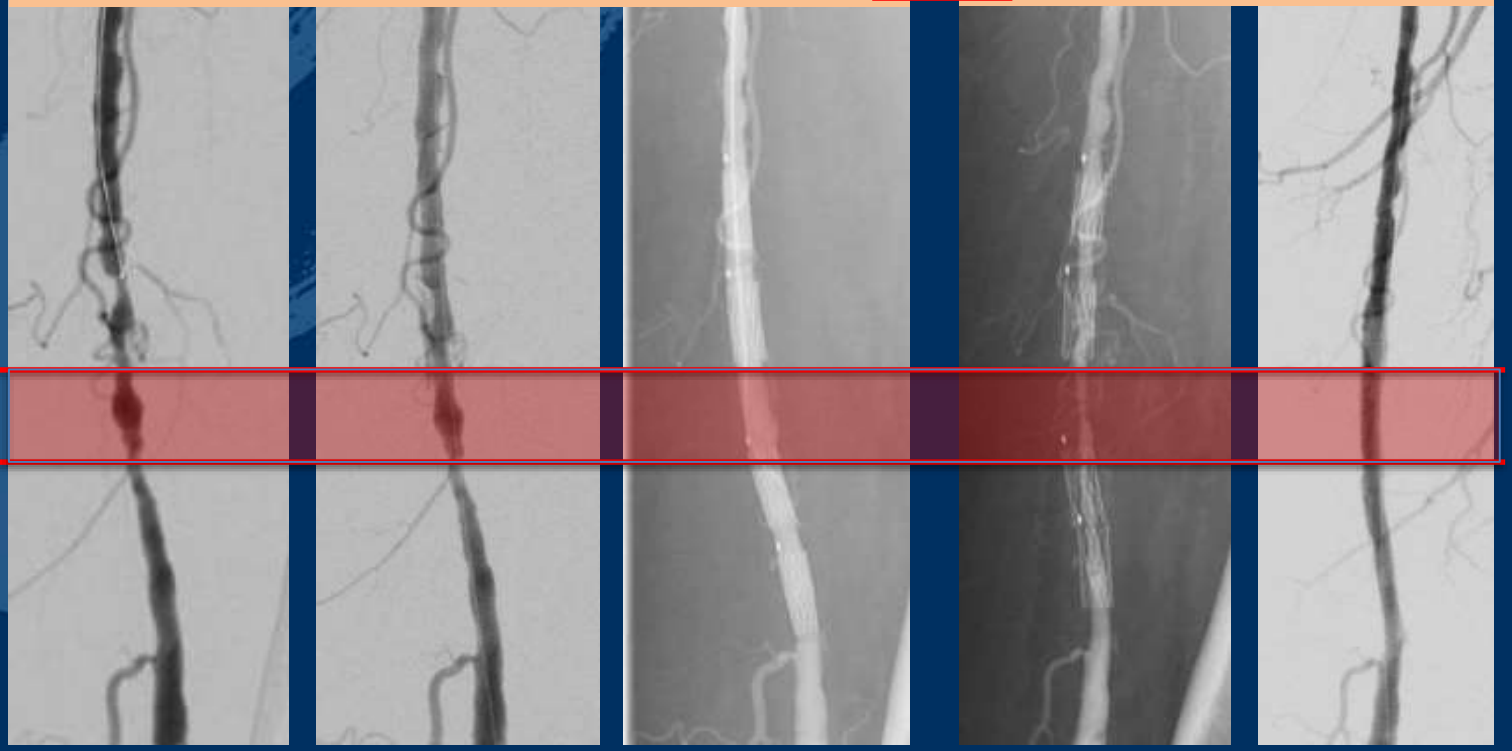
LOCOMOTIVE

Closed registry

ClinicalTrials.gov Identifier: NCT02531230)
24.08.2015 - 31.12.2016
N: 75

Index-procedure → **10 mo.** → **TLR** → **36 mo.** → **FU**



Index-lesion | **after POBA** | **4 ML-stents** | **Re-stenosis** | **after DEB**

@36 mo FU

Clinical assesment:
- **No claudication**
- **No TLR**

ABI: 1.0
CCD: PVR 1,3

Sigl M, Amendt K et al. In vivo 2020;34:433-439

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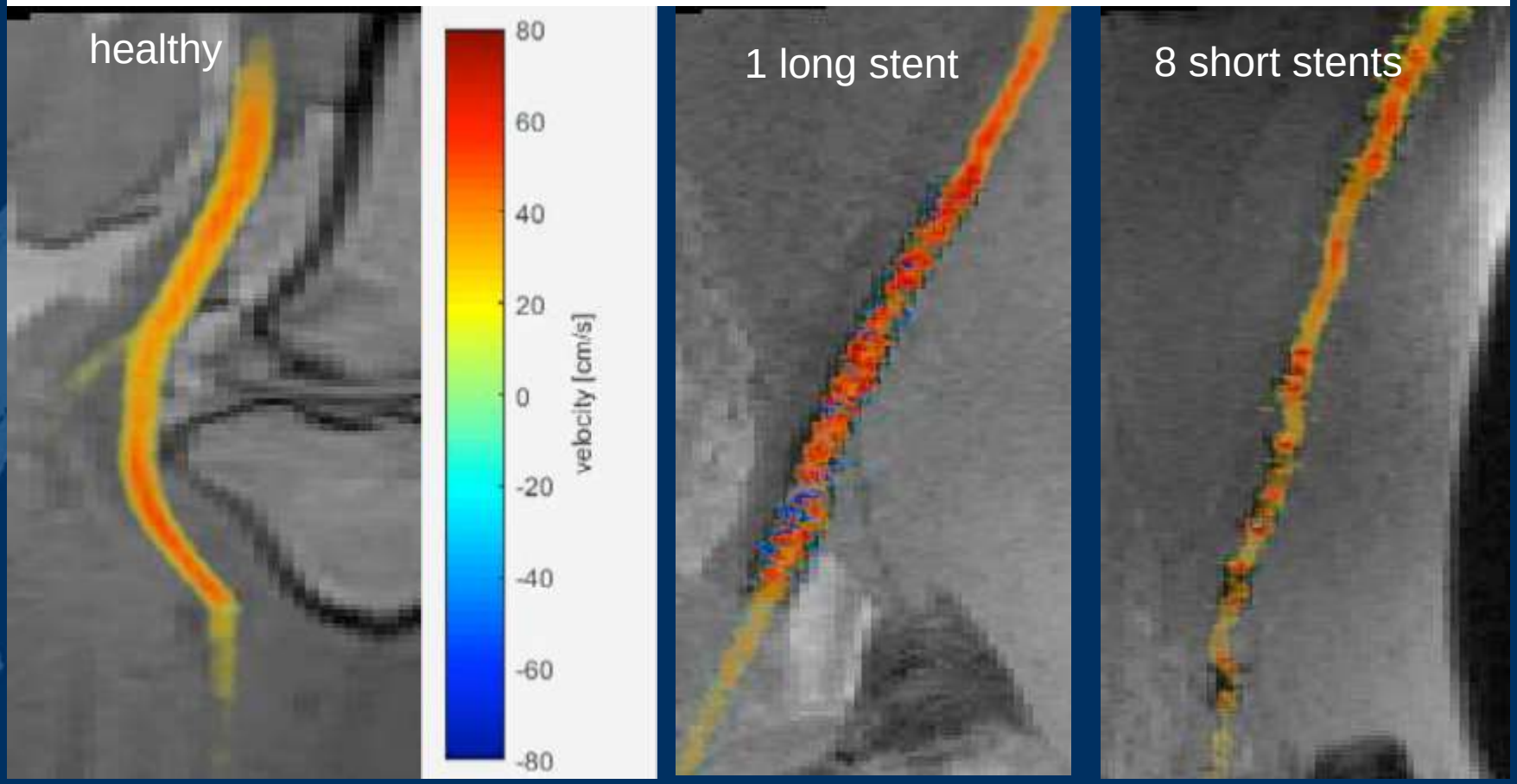
4D – flow MRI



Dr. Martin Sigl, Universitätsklinikum Mannheim, Dr. K. Amendt, Diakonissenkrankenhaus Mannheim

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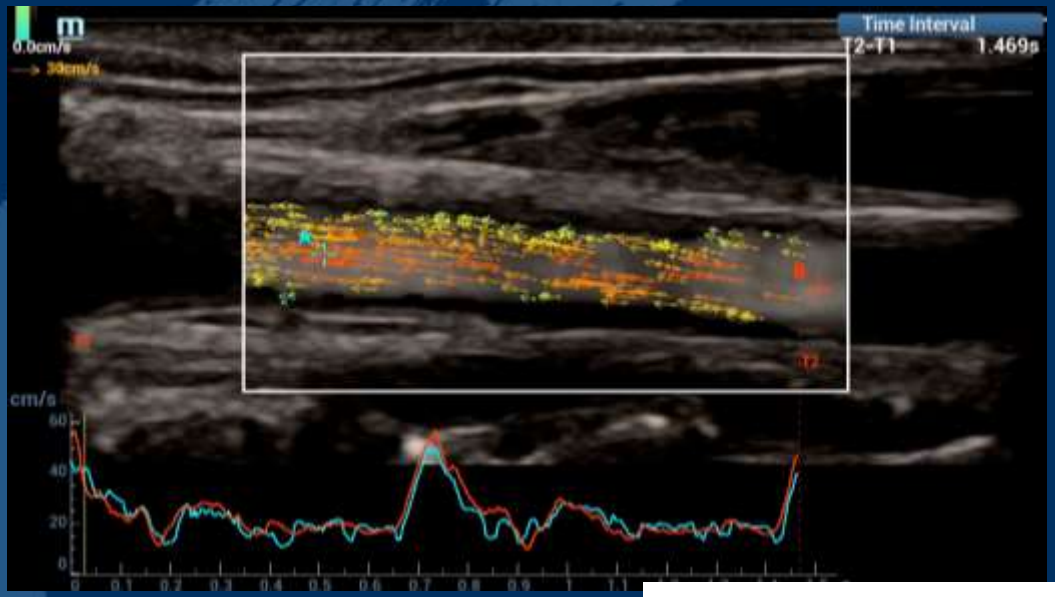
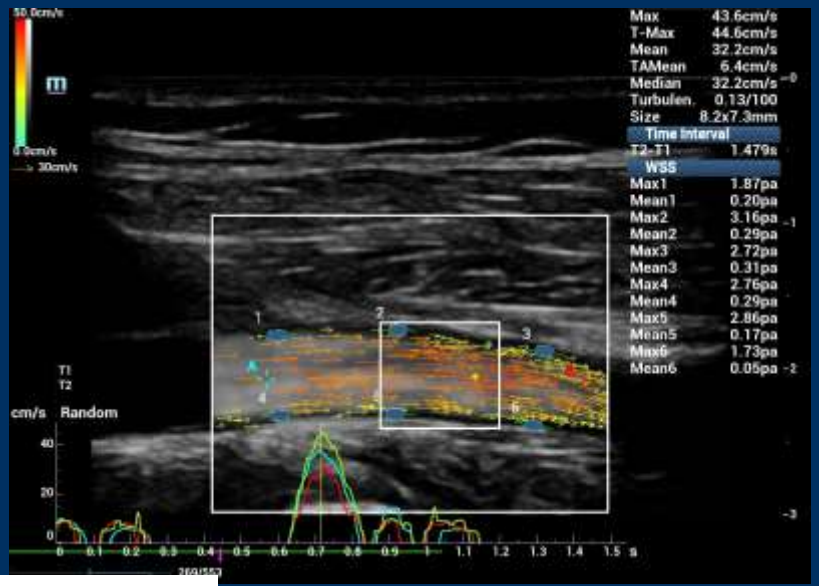
High frame rate ultrasound: Vector Flow Imaging

Estimating local PWV





Popliteal hemodynamics
in normal an diseased PA
in different Stent-typs
= PV
= wall shear stress (WSS)

Dr. Martin Sigl, Universitätsklinikum Mannheim, Dr. K. Amendt, Diakonissenkrankenhaus Mannheim

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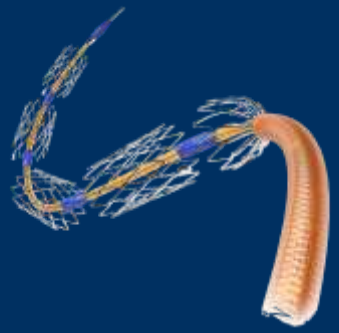
FIRST TIME DATA RELEASE: Final results from the ***LOCOMOTIVE*** registry using the ***VascuFlex Multi-LOC*** stent system in real-world lesions



K. Amendt

Center of Vascular Medicine „Oberrhein“ (Mannheim)
Clinic for Internal Medicine I: Angiology, Cardiology and Subsequent Complications of Diabetes mellitus
Diakonissenkrankenhaus Mannheim Germany
Academic Teaching Hospital Clinical Medicine Mannheim University Heidelberg
K.Amendt@diako-mannheim.de