The Multi-LOC multiple stent delivery system for focal stenting: Preclinical data and first clinical experiences in femoro-popliteal lesions

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Disclosure

I have the following potential conflicts of interest to report: Advisory Board and Consultant:

BAYER AG
Boehringer Ingelheim
UCB Pharma
BIOTRONIK
B. BRAUN
Primary patency depends on:

- riskfactors: number and management
- platelet inhibition
- severity of disease (Rutherford classes)

- primary result of intervention
- localisation and length of lesion
- acute interventional trauma
  - fl-dissection, flap, rupture
- management of initial trauma
  - balloon: ± drug elution
  - ± stent: type of stent, drug elution
Biomechanical properties of femoro-popliteal artery

Mechanical stress due to joint movement:
= Endogenous stress to artery
1. flexion/bending
2. extension/distension
3. compression: longitudinal, radial
4. torsion
5. pulsatile distension

„Rubber-band“? = environmental conditions for stents
Accepted problems with Stenting

1. changes in biomechanical properties and chronical inflammation of stented segment /artery
   - stent fracture
   - intimal hyperplasia
   - late lumen loss

problems increase with length of treated vessel segment

= Stent- disease

long lesion ➔ long stent ➔ problem ➔

„leave nothing behind“
Concept of focal stenting

- **Calcified lesions** demand ongoing mechanical stabilisation of initial balloon-result: *mandatory scaffolding*

- DEB, Tack-it, BVS and DBVS alone *do not* solve this problem

- There is still a need for permanent scaffolding:
  - long lasting
  - with a reduced mass of foreign body (as few as possible)

- = focal-spot / target-stenting
focal stenting

full lesion coverage

**Multiple-Stent-Delivery-System (MSDS)**

optimal: DEB

Standard procedure
Preclinical data
(LINC 2014)

Custom length stent
5 x 80mm

Multi-Loc
Multi-Stent-Delivery-System: 5 x 15 mm x 5

Domestic pig

acute result

Domestic pig

Domestic pig

Domestic pig

angiographic control 27d after implantation
G122 5 re a

G122 5 re b

G122 5 re c
Conclusion:
1. Animal (n:6) experiments show technical feasibility of the multi stent delivery system (MSDS): **Multi-Loc**.
2. Exact anatomically controlled implantation of short stents is possible.
3. Short stents in actively bended arterial segments do not fracture (0 vs 5/6).
4. Patency of arterial segments after stenting with 4-5 short individual stents is superior to single long stent implantation in all animals.
First real world experiences (not really results)

- Popliteal artery
prolonged woundhealing after minor amputation
G.G. 26.07.38
1. PTA 20.08.15
2. PTA 30.09.15
First clinical experiences (not really results)

- Femoro-Popliteal Artery long lesion
K.A. ♂ 01.10.42
1. PTA: 25.07.2014
2. PTA: 15.09.2015

6x40 mm (POBA)

ML-1
ML-2
ML-3
ML-4
ML-5
ML-6

ML- 6x13mm
after 10 weeks: **NO fractures**
after 10 weeks:

**No** restenosis (LL)

**No** edge phenomenon
First real world experiences

N: 30 pat.; LL: 4-30 cm; LL_{av} : 12 cm; M-L: 141; M-L/pat.: 2-12 (4.7); M-L/cm LL: 0.41; LL /ML : 2.46 cm

- ML-stents are safe: technic. succ: 100%
  exact anatomically controlled release
  no stents lost
  no conversion to standard stenting
  no acute occlusion

- radial force in severely calcified lesions: no recoil,
  no fracture

- biomechanical properties of artery: unchanged

Cave: release stents in an optimal prepared „bed“
= predilatation: Ø-POBA/DEB \triangleq Ø lumen artery
= Ø-stent \triangleq Ø lumen artery (no oversizing)
post stent dilatation = to align longitudinal axis
LOCOMOTIVE: all comers registry

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1  "All Comers" Post Market Clinical Follow-up (PMCF) With Multi-LOC for fLOW lIMITing Outcomes
   Condition: Peripheral Arterial Occlusive Disease
   Intervention: Device: Multi-LOC®

n: 20
Further development

- Nitinol ring
- Outer sheath
- Multi-Loc stent-body
- Closed cell design
- Stent-anchor = marker
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