Is the combination of DCB and bare metal stents as effective as DES?
The BIOLUX 4EVER trial
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Disclosure slide

☐ I have the following potential conflicts of interest to report:
   ☐ Consulting
   ☐ Employment in industry
   ☐ Stockholder of a healthcare company
   ☐ Owner of a healthcare company
   ☐ Other(s)

☑️ I do not have any potential conflict of interest
Results with **DCB** in the SFA

![Graph showing results with DCB in the SFA](image-url)
Results with **DCB** in the SFA

**PP @ 12 months**

- **A. FemPac**
- **B. THUNDER**
- **C. Levant I**
- **D. Levant II**
- **E. Pacifier**
- **F. Biolux P1**
- **G. Advance PTX**

**DCB in TASC C&D → NO DATA**

**PP @12M = +/-78%**
Results with **DCB** in the SFA

**SUSTAINED RESULT ON THE LONG RUN...**

Significant and sustained TLR reduction up to 5 years
Limitations of angioplasty in the SFA?
Limitations of angioplasty in the SFA?
Limitations of angioplasty in the SFA

High levels of bail-out stenting

- **PTA study (2002)**
  - 74 patients
  - 43% major dissections
  - 32% residual stenosis >30%

- **ABSOLUTE: Stent vs. PTA (2006)**
  - 104 patients, 1:1 randomization
  - 32% insufficient PTA result led to cross over to stent

- **RESILIENT: Stent vs. PTA (2008)**
  - 206 patients 2:1 randomization 40% PTA cross over to stent due to flow limiting dissections and residual stenosis
Results of DCB + stenting?

• Although a frequent occurrence...

...no evidence available
BIOLUX 4EVER study

Physician-Initiated Trial Investigating the Efficacy of Endovascular Treatment of Femoropopliteal Arterial Stenotic Disease with the Biotronik Passeo-18 LUX Drug Releasing Balloon and the Biotronik Pulsar-18 Stent (comparing with the 4EVER trial results)
BIOLUX 4EVER study

- Methodology
  - prospective, multi-center trial

- Enrollment
  - 120 patients

- Inclusion criteria
  - Rutherford classification 2 - 4
  - Femoropopliteal lesion with stenosis > 50 %
  - Target lesion ≤ 19 cm
  - At least one-vessel run-off to the foot
BIOLUX 4EVER study

• Primary Endpoint
  – **Primary patency at 12 months**, defined as freedom from >50% restenosis as indicated by an independently verified duplex ultrasound peak systolic velocity ratio (PSVR) <2.5 in the target vessel with no re-intervention
BIOLUX 4EVER study

Timeline

- Angiography
- Duplex Ultrasound
- CL Duplex Ultrasound
- Medication
- Rutherford/ABI
- (S)AE reporting
Currently 44 patients enrolled

Enrolling centers:
- Bonheiden
- Dendermonde
- Aalst
- Tienen
- Edegem
Example Case – medical history

- 67y male
- Rutherford 3 left leg
- ABI 0.60
- ex-smoker
- Hypertension
- Hypercholesterolemia
Example Case – pre-op imaging

- **target lesion**
- **GW + outflow**
Example Case – DCB (Passeo-18 LUX)

Passeo-18 LUX

post-DCB
Example Case – Final result

baseline

post-dilatation

final result
Conclusion

The BIOLUX 4EVER trial will tell us if the combination of DCB (direct current balloon) and low-strut profile nitinol stent = improvement of results.
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The BIOLUX 4EVER trial

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