Update on the Advantages of the Chocolate Wire Constrained Uncoated Balloon
Update on the Choco Cabana Trial

Prof. Dr. med. Gunnar Tepe,
Institut für Diagnostische und Interventionelle Radiologie
RoMed Klinikum Rosenheim

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Disclosure

Study support by B.Braun, Biotronic, BSC, CVT, Philips, Medtronic, Shockwave

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BTK Arteries: Different vessels

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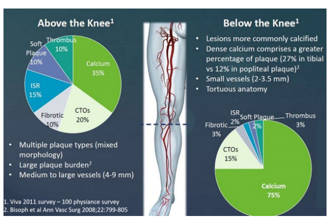

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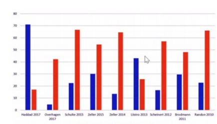
BTK Arteries: What is the problem?

Limitations because of
1. Calcification 2. Recoil 3. Dissections 4. Restenosis

PTA



A: How much is caused by recoil and how much is caused by restenosis?

B: Is it possible to reduce recoil?

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BTK Arteries: Different vessels

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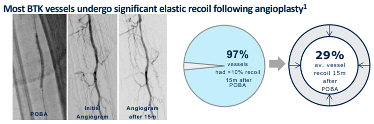
Most BTK vessels undergo significant elastic recoil following angioplasty[1]



Medial calcification produces vessel recoil and restenosis[2,3,4]

Medial calcification → Arterial Stiffness → Vessel recoil → Restenosis

1) Baumann et al, Early recoil after balloon angioplasty of tibial artery obstructions in patients with critical limb ischemia, J Endovasc Ther 2014
2) Guzman et al, Tibial artery calcification as a marker of amputation risk in patients with PAD, JACC 2008
3) Zettervall et al, Association of arterial calcification with CLI in patients with PAD, J Vasc Surg 2017
4) Mustapha et al, One-Month Duplex Ultrasound Evaluation of Vessel Recoil After Tibial Peripheral Vascular Intervention for Critical Limb Ischemia Predicts 12m TLR, AMP 2017

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The Chocolate PTA Balloon

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TABLE 2 Baseline and procedural lesion characteristics

Lesion characteristics	N = 263
Lesion length (mm)	83.5 ± 59.9 (n = 250)
Total occlusions	60/260 (23.1%)
Lesion calcification	
None/Mild	93/254 (36.6%)
Moderate	110/254 (43.3%)
Severe	51/254 (20.1%)

Chocolate Bar Study[1,2]: Overview

Chocolate Bar Study[1,2]: Outcomes

Procedural Success	ATK** (n = 262)	BTK (n = 226)
Freedom from Flow Limiting Dissections* (Site Reported)	97.7%	99%
Freedom from Flow Limiting Dissections* (Adjudicated)	100%	100%
Achieved <30% Diameter Stenosis (Adjudicated)	85.1%	84.6%
Freedom from Bail-Out Stenting	98.4%	99.1%

Clinical Outcomes (Kaplan Meier)	ATK** (n = 262) 12 months	BTK (n = 226) 6 months
Freedom from Target Lesion Revascularization	78.5%	88.9%
Freedom from Major Unplanned Amputation	97.2%	96.7%
Freedom from All-Cause Mortality	93.3%	97.1%

1. Data on file with Medtronic – CLR782: Final Study Report The Chocolate BAR by TriReme Medical, LLC
2. Mustapha J, et al. Chocolate BAR registry. CCI 2018;1-5

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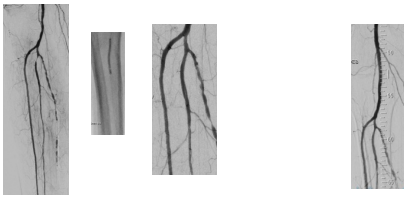
Recoil with PTA Balloon

The Chocolate PTA Balloon



Choco Cabana Study

Chocolate PTA Balloon **c**omp**a**red to conventional **ba**lloo**n** **a**ngioplasty
for sustained lumen gain in below the knee arteries

- Prospective
- Randomized
- Single blinded
- Multiple Centre
- International

Choco Cabana Study

Aims

1. Assess the degree of vessel recoil (angiography after 15 min – comparison with inflated balloon and initial result)
2. Assess if and in what the degree the Chocolate PTA balloon reduces vessel recoil (60 vs. 60 patients)
3. Assess if the vessel recoil has an effect on the degree of stenosis at 6 months (MRA or DSA at 6 months)
4. Assess the clinical relevance of vessel recoil

Choco Cabana Study

Main inclusion criteria

1. RF 2-5
2. LL: 1-25cm
3. All lesions should be treated either by POBA or Chocolate PTA (longest lesion = study lesion)
4. Sufficient outflow distal of the lesion
5. Inflow treatment up to TASC B
6. No vessel prep allowed (Cutting balloon, atherectomy, lithoplasty,…)
7. No post-dilatation with a DCB

Choco Cabana Study

Study centres

01 Rosenheim, RoMed Klinikum Rosenheim, Prof. Dr. med. Gunnar Tepe
02 Bad Krozingen, Herzzentrum Bad Krozingen, Prof. Dr. Thomas Zeller
03 Tübingen, Universitätsklinikum Tübingen, Diagnostische und Interventionenlle Radiologie, PD Dr. Gerd Grözinger
04 Karlsbad-Langensteinbach, SRH Klinikum Karlsbad-Langensteinbach GmbH, Interdisziplinäres Gefäßzentrum, Prof. Dr. Erwin Blessing
05 Radebeul, Elblandklinikum Radebeul, Interdisziplinäres Gefäßzentrum, Dr. Torsten Fuß
06 Graz, LKH-Univ. Klinikum Graz, Univ. Klinik für Innere Medizin, Klin. Abteilung für Angiologie, Prof. Dr. med. Marianne Brodmann
07 Wien, Hanusch-Krankenhaus, Kardiovaskuläres Zentrum, Angiologische Ambulanz, Dr. Martin Werner