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A Pilot Study Examining the Performance and Safety of the Temporary Spur Stent System* In Infrapopliteal Arteries:

First-Time Use with a Limus-Coated Balloon (DEEPER LIMUS)

** For clinical investigational use only*

Disclosure

Speaker name:

Brodmann Marianne, MD

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
- [ ] Other(s)

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

Challenges to treatment of BTK arteries

Infrapopliteal disease

- Vessel Recoil
- Calcification
- Lesion length/tortuosity
- Dissection

Drug Coated Technology

Drug uptake

- Diameter mismatch
- Luminal surface contact
- Uptake
- Penetration
- Lesion length/tortuosity

Temporary SPUR Stent System*
Reflow Medical

- Self-expanding nitinol stent with radial spikes mounted on an integrated balloon system
- Controlled penetration of plaque, calcium, and artery wall
  - Channels facilitate deeper drug delivery when used with DCB
- Minimize vessel recoil and dissection
- Acute Luminal Gain
- Follow treatment with commercially available drug coated balloon
- Nothing left behind

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Temporary SPUR Stent System*

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Controversies in Drug-coating

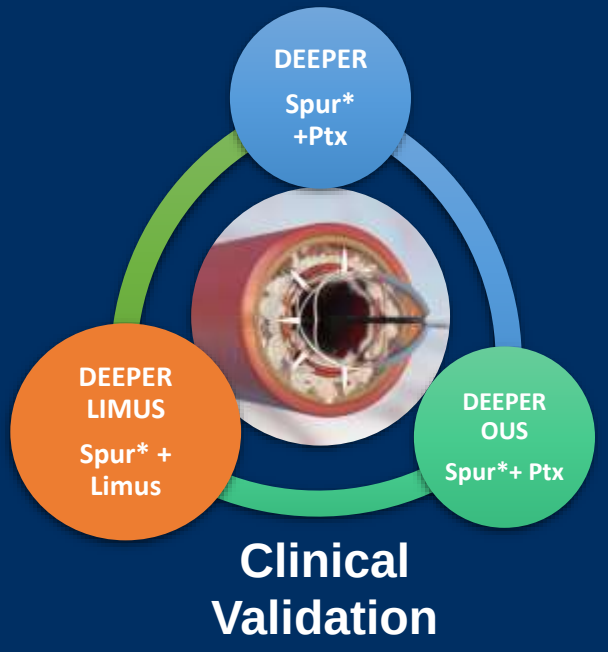
- Concerns for long-term impact of Paclitaxel (Katsanos, et. al., 2018, 2020)
- Limus-based drug coating historically challenging to deliver in absence of stent
- Temporary Spur Stent System→ Ideal platform for DRUG DELIVERY into diseased artery, may improve tissue absorption and elution

ATTRIBUTE	LIMUS	PACLITAXEL
Mode of action	Cytostatic	Cytotoxic
Margin of safety	10,000 fold	100 fold
Anti-restenosis	Optimal	Good
Tissue absorption And elution	More difficult	Easier
Level of competition	Low	Very high
Physician perception	Positive	Controversial

Gaines: Presentation from CRR2019

DEEPER LIMUS Pilot Study

DEEPER LIMUS (Goal N= 30, current n=12)	**Prospective, single-center Spur* + LIMUS-coated DCB** **PI: Prof. M. Brodmann Univ. Graz, Austria**	**Primary Safety Endpoint:** 6-month composite of All-Cause Mortality, Major Amputation and Clinically Driven Target Lesion Revascularization (CD-TLR) **Secondary Endpoints:** 1. LLL at 6 months by QVA 2. Primary patency at 6 months by QVA 3. Freedom from MALE and POD at 30 days 4. Freedom from MALE at 6 and 12 months 5. Improvement in Rutherford at 3, 6, 12 months 6. Wound healing/WIfI at 6 and 12 months



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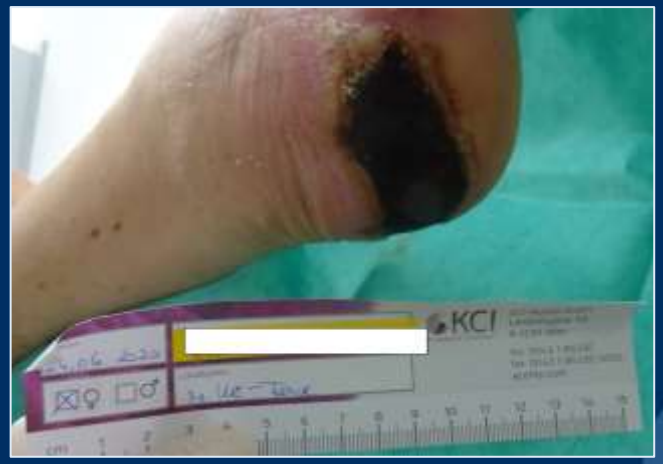
DEEPER LIMUS Case Presentation

73 year-old female, **Rutherford class 5**

- Pertinent history:
  - Type II Diabetes;
  - Chronic kidney disease
  - Heel and toe wounds
- Baseline ABI/TBI: **.66; .3**
- **WIfI:**
  - Wound: 3
  - Ischemia: 1
  - Infection: 0



DEEPER LIMUS Case Presentation

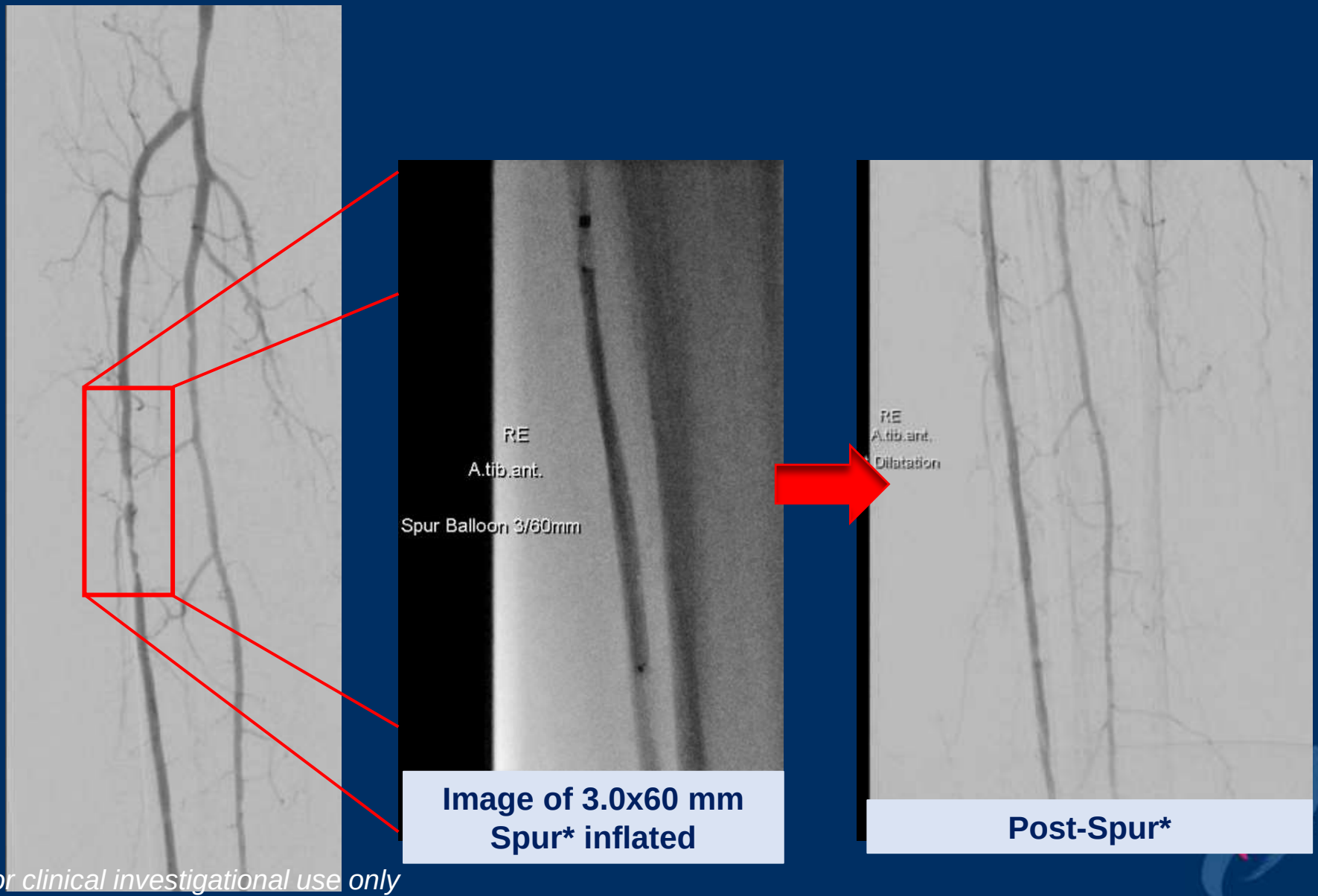


Image of 3.0x60 mm Spur* inflated

Post-Spur*

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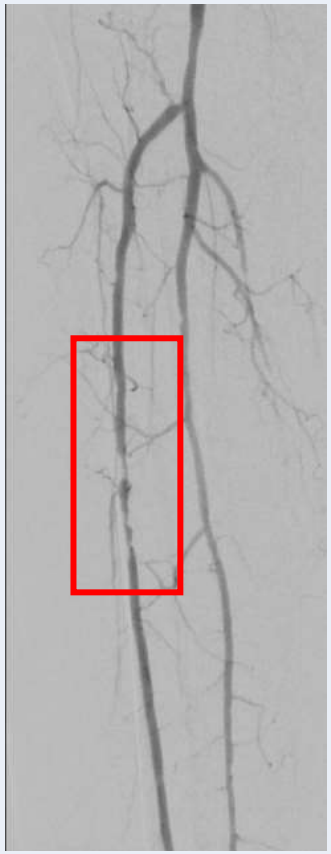
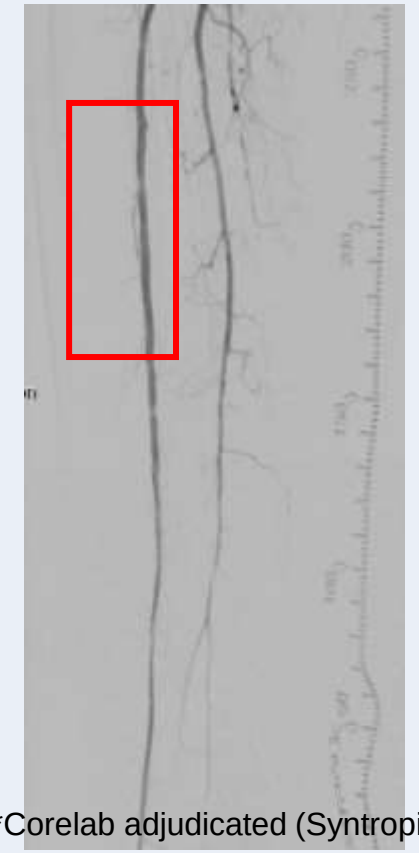
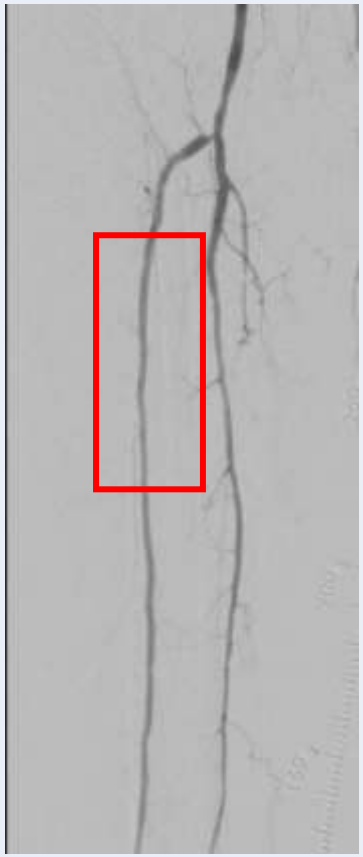
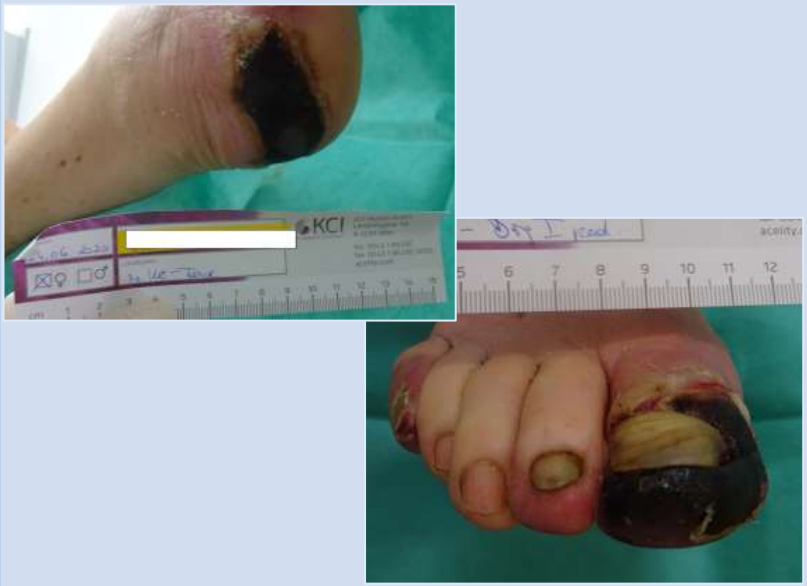
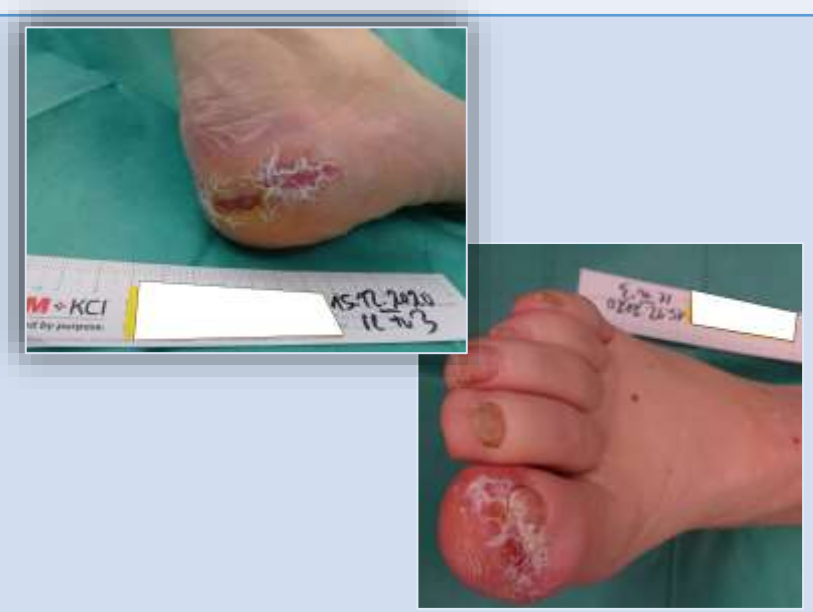
DEEPER LIMUS Case Presentation: 6-month angiogram

Baseline avg. subsegmental lumen Φ =1.39 mm	Index avg. subsegmental lumen Φ = 2.34 mm	6 Month avg. subsegmental lumen Φ = 2.02 mm
		

*Corelab adjudicated (Syntropic)

- Difference post-procedure → 6 months = **.32 mm***
- Percent difference **= 13%**

DEEPER LIMUS Case Presentation: 6 month Clinical follow up

Baseline ABI/TBI	6 Month ABI/TBI
ABI: .66/ TBI: .3	ABI: 1.41/ TBI: .75
Baseline WIfI	**6 Month WIfI**
• Wound: 3 • Ischemia: 1 • Infection: 0	• Wound: 0 • Ischemia: 0 • Infection: 0
Baseline Wound	**6 Month Wound**
	

DEEPER LIMUS: Clinical Data

Primary Endpoint	One Month	3 Months	6 Months
6-month composite of All-Cause Mortality, Major Amputation and Clinically Driven Target Lesion Revascularization (CD-TLR)	**0/11**	**0/9**	**0/4**
Important Secondary Endpoint	**One Month**		
Freedom from MALE and POD at 30 days	**0/11**		

Temporary SPUR Stent System*

- Provides Localized Drug Delivery (**agnostic to drug choices**)
- Temporary stent may prevent acute vessel recoil and increase luminal gain
- Reduces dissection risk through controlled penetration of vessel wall
- Leaves nothing behind, preserving natural function of the vessel and allowing future treatment options.
- Promising clinical data (DEEPER LIMUS, DEEPER OUS, DEEPER)

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Thank you for your kind attention.