Recorded Case: Tibial Reconstruction With Enhanced Drug Delivery Using The Temporary Spur Stent System

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Disclosure

Speaker name: Andrej Schmidt

I have the following potential conflicts of interest to report:
Consulting / speaker honorarium:

Abbott Vascular, BD, Bentley, Boston Scientific, ReflowMedical, Upstream Peripheral

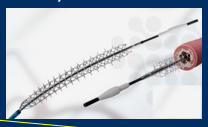
Shortcomings of Standard BTK Angioplasty (POBA)

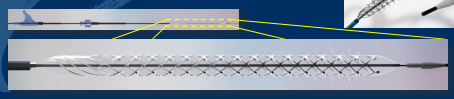
Metaanalyses	Time-periode	Primary Patency
Romiti et al. J Vasc Surg 2008	1990 – 2006	58.1 %
Mustapha et al. Circ. Cardiovasc Interv. 2016	2005 – 2015	63.1 %
Snyder, et al. JEVT 2023	2022	66 %

- Often long lesions and CTOs
- Atherectomy cumbersome, hazardous (embolisation)
- Too long for stenting
- High rate of recoil (Baumann et al. 2014 JEVT)
- DCB-trials not yet convincing

SPUR Retrievable Scaffold Therapy (RST)

- Self Expanding nitinol frame – **temporary (retrievable) stent**
- Use with a Drug coated balloon
- 6F compatible sheath
- Hydrophilic coated balloon catheter



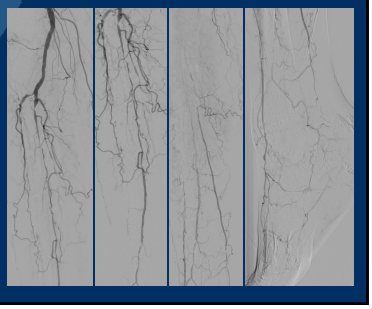


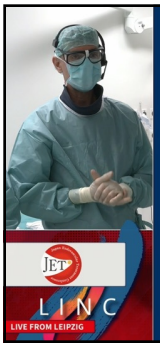
Radial spikes penetrate the vessel wall and create channels to:
modify lesion morphology, change vessel compliance and reduce recoil, and enhance drug absorption

Recorded cases of a Tibial Reconstruction with SPUR RST

Clinical data:

- Ulcerations Dig II / III, Rutherford 5
- PTA left BTK 5/2024 for CLTI
- CAD, PTCA 2018 and 2022
- EF 45%, NYHA II
- Type 2 DM
- Hypertension, HLP
- Chronic renal failure, GFR 55ml/min





Leipzig 11 male patient, 81 years (HP-S)

CLTI right, complex BTK-CTOs

Operators:
Andrej Schmidt and Renaldo Myrselaj

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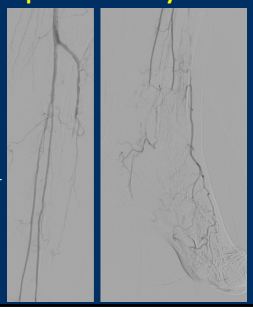
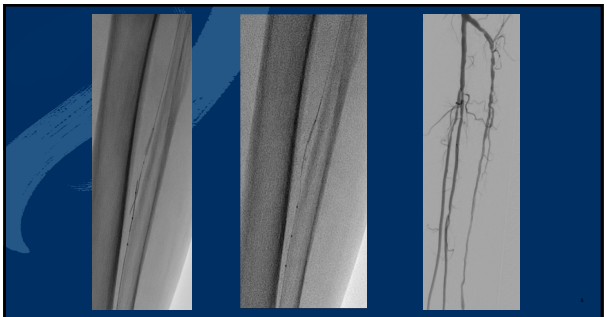
Case example #2 Deeper OUS Study

Patient History

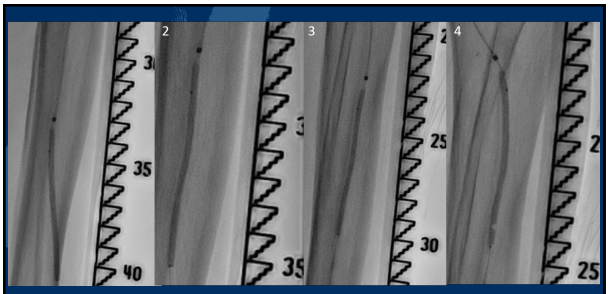
- 74 y.o. male, Rutherford class 5,
- Type 2 DM, tobacco abuse,
- Hypertension, hyperlipidemia,

- non-healing left plantar foot wound
- Access: Antegrade left CFA and retrograde AT
- Lesion characteristics
  - RVD = 3.0 mm
  - Moderate calcification
  - Total occlusion

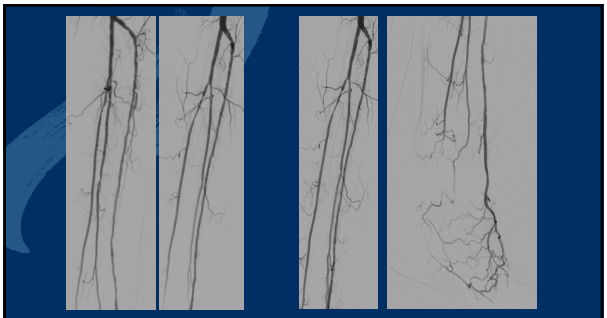




Dual Crossing/PTA Reversed CART-technique Post PTA



4x Spur deployments



Post Spur Post DCB Final result

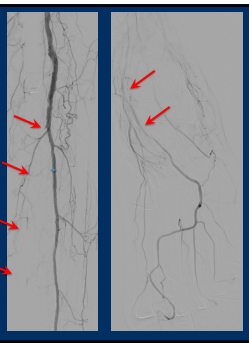
Complete healing after 8 months, patent at 24 months control

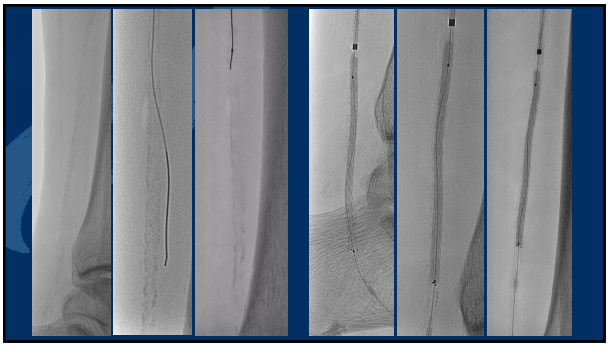
Case example #3

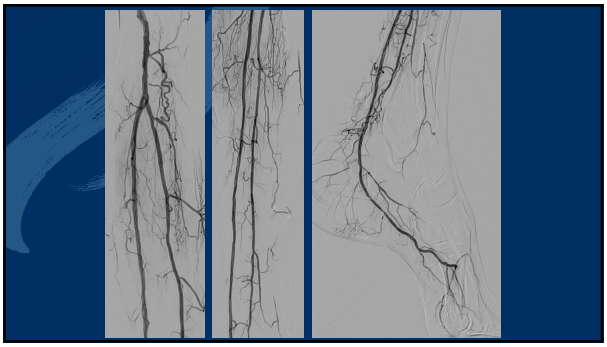
Clinical data:

- Ulcerations forefoot left, Rutherford 5
- CAD, CABG 2022
- Type 2 DM
- Hypertension, HLP
- Chronic renal failure, GFR 45ml/min

- Posterior tibial artery CTO left
- Lateral plantar artery patent







Spur RST – Clincal Study Overview

DEEPER	DEEPER OUS	DEEPER LIMUS	DEEPER REVEAL
23 patients Dominican Republic	107 patients Europe, New Zealand	26 patients Austria	130 patients USA
Prospective, single-center, First-in-Human, single-arm	Prospective, multi-center, single-arm, performance goal comparator Sub-study: vessel recoil	Prospective, single-center, pilot study, single-arm	Prospective, multi-center, IDE, single-arm, performance goal comparator
Spur + Lutonix DCB	**Spur + paclitaxel DCB**	**Spur + sirolimus MagicTouch DCB**	Spur[4]
Follow up: 1, 6 and 12 months	Follow up: 1, 3, 6, 12 and 24 months, and annually phone call for 5 years	Follow up: 1, 3, 6 and 12 months	Enrollment completed April 2024, Spur[4] has FDA Breakthrough Device Designation: De-Novo

Summary DEEPER OUS and DEEPER LIMES

	DEEPER OUS	DEEPER LIMUS
SPUR treated length (mean)	92.7 mm	98.1 mm
Range	60 -240 mm	60-210 mm
Freedom from MALE at **12 months**	**98.9%**	**95.5%**
Primary patency at **12 months** (DUS)	**74.4%**	**89.5%**
Freedom from cdTLR at **12 months**	**89.5%**	**96.0%**