DEEPER LIMUS Trial Update: the Bare Temporary Spur Stent System followed by a Sirolimus-coated Balloon

Prof. Marianne Brodmann, MD
Univ. Klinikum Graz, Austria

SUMMARY

The DEEPER LIMUS pilot study examines the safety of the Bare Temporary Spur Stent System in conjunction with a commercially approved, sirolimus-coated balloon (DCB), in infrapopliteal arterial lesions.

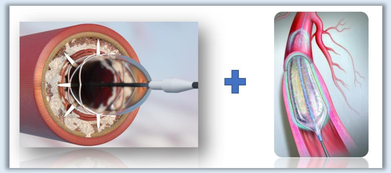
The Bare Temporary Spur Stent system is for investigational use only.

THE BARE TEMPORARY SPUR STENT SYSTEM (SPUR)

Self-Expanding nitinol stent designed with radial spikes integrated onto a 6F balloon delivery system
- Simple and familiar delivery system
- Creation of channels to optimize greater drug uptake when followed by a commercially available DCB

Temporary mechanical scaffolding may:
- Minimize vessel recoil and dissections
- Increase acute luminal gain

Intended to deliver stent-like results while leaving nothing behind



Uncoated stent penetrating artery wall in combination with DCB

INTRODUCTION

Study Name	**DEEPER LIMUS**
Status	N=26 *(enrollment to be expanded up to 60 patients to include all regional commercially available sirolimus-coated balloons)* Follow up to one year
Study Design	Prospective, single-center (Graz, Austria): Spur + commercially available LIMUS-coated DCB
Endpoints	**Primary Safety Endpoint:** 6-month composite of All-Cause Mortality, Major Amputation and CD-TLR

TRIAL RATIONALE

There are concerns related to the long-term impact of Paclitaxel. However, limus-based drug coating has been historically challenging to deliver in absence of a stent. The Bare Temporary Spur Stent System is the ideal platform for drug delivery into the diseased artery due to the penetration of the spikes into the arterial wall, which may improve tissue absorption and elution. The device also reduces vessel recoil and leaves nothing behind in the body.

MATERIAL AND METHODS

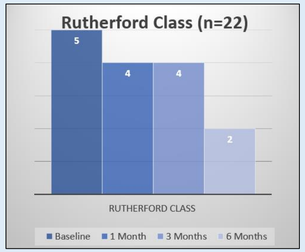
Twenty-six patients are enrolled to date. An amendment has been approved to expand the trial up to 60 patients and a submission has been performed to add a second site (Prof. Zeller, Bad Krozingen, DE). Patient follow up is at 1, 3, 6, and 12 months post-procedure with evaluations including ankle-brachial and toe-brachial indices (ABI and TBI), Duplex ultrasound (DUS), wound evaluation, adverse event monitoring, and Rutherford class score. At 6 months, qualifying patients undergo an angiogram* of the index limb.

Key Inclusion Criteria	Key Exclusion Criteria
• Rutherford category 3, 4, or 5 • Heel wounds permitted if no evidence of osteomyelitis • Target lesion •TV between 2.0 to 4.5 mm in dm •Lesion length **up to 220 mm**	• Osteomyelitis proximal to phalanges (permitted in digits of target foot) • Planned target limb major amputation • Target lesion •Stents within target vessel/lesion •Angiographic evidence of thrombus in the target limb

*Angiograms and ultrasounds are adjudicated by independent core labs (Syntropic, Columbus, OH, and Vascore, Boston, MA, respectively).

RESULTS

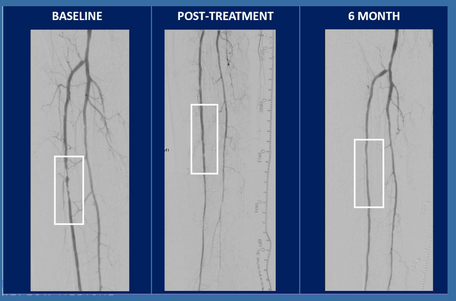
PRIMARY ENDPOINT	
6-month composite of All-Cause Mortality, Major Amputation and Clinically Driven-Target Lesion Revascularization (N=22)	13.6% (3/22) • 1 patient died of COVID-19 • 1 patient had major amputation due to infection • 1 patient with CD-TLR
SECONDARY ENDPOINTS	
Primary patency at 6 months by QVA (N=18)*	83% (15/18) • 3 patients declined angiography at 6 month follow up
Primary patency at 6 months by DUS (N=21)*	85.7% (18/21) • One DUS nondiagnostic
Subsegmental Late Lumen loss at 6 months by angiography (N=19 lesions)*	.41 mm ± .69 mm
Freedom from Major Adverse Limb Event (MALE) and POD at 30 days (N=26)**	100% (26/26)
Freedom from MALE at 6 and 12 months**	6 Months: 95% (21/22) 12 Months: 94% (17/18)



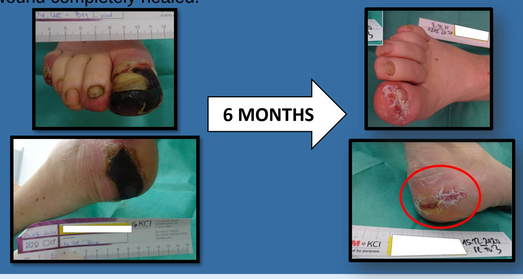
19 subjects with wound data had 6 month follow up data. WIfI Risk scores were "High" in about 50% of patients at baseline, and improved to be "Very low" in about 60% of patients at 6 months. Rutherford score average decreased by 3 classes at 6 months.

PATIENT CASE

73 y.o female, Rutherford class 5 with PMH of Type 2 DM, CKD, WIfI score W: 3; I: 1; Infection: 0.
Target lesion in AT treated with one Spur + DCB, with minimal late lumen loss at 6 months: .32 mm calculated late lumen loss



At 6 month follow up Rutherford class score and WIfI risk score were 0, wound completely healed.



CONCLUSIONS

The Bare Temporary Spur Stent System is a novel device with a familiar and simple design to address challenges of infrapopliteal arterial disease treatment. The device allows for the preservation of future treatment options, and is drug agnostic device, designed to create channels for drug delivery into the artery wall when used with DCB. The DEEPER LIMUS has been extended to include up to 60 more subjects to further evaluate the efficacy of the device in conjunction with a commercially available, sirolimus coated DCB.

REFLOW MEDICAL
THE PULSE OF MEDICAL INGENUITY

Contact information: Marianne.Brodmann@medunigraz.at (cc: cmascho@reflowmedical.com)

REFLOW spur™