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

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SUMMARY

The DEEPER OUS clinical trial evaluates the safety and efficacy of the Bare Temporary Spur Stent System in conjunction with a commercially approved, paclitaxel-coated balloon (DCB), in infrapopliteal arterial lesions.

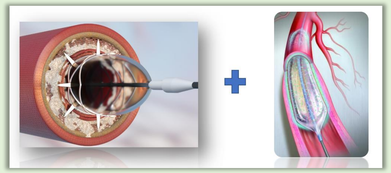
The Bare Temporary Spur Stent System is for investigational use only.

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 OUS (ongoing, initiated 2019)**
Status	**ENROLLMENT COMPLETE APRIL 2022** N = 107 Follow up to 5 years
Study Design	Prospective, multicenter, single arm: Spur + Paclitaxel-coated balloon
Sites	Ten sites in Germany, Switzerland, New Zealand
Endpoints	**Primary Efficacy:** Primary patency at 6 months by Duplex Ultrasound (DUS)
	Primary Safety: Freedom from 30-day perioperative mortality
Sub-study	**Vessel Recoil Sub-study:** Vessel recoil post Spur treatment (N=38): **Recoil reduced by more than 50%**

MATERIAL AND METHODS

Enrollment in the trial is complete as of April, 2022. Patient follow up is at 1, 3, 6, and 12 months post-procedure with in person evaluations including Ankle-brachial and toe-brachial indices (ABI and TBI), Duplex ultrasound (DUS)*, wound evaluation, adverse event monitoring, and Rutherford class score. Yearly telephone call follow ups are conducted out to 5 years.

An interim analysis has been conducted to determine interim success or failure of the primary efficacy endpoint. Forty-six patients with evaluable 6 month data were included in the interim analysis.

Below are key eligibility criteria.

Key Inclusion Criteria	Key Exclusion Criteria

• Rutherford category 3, 4, or 5
• Denovo or restenotic infrapopliteal lesion (popliteal excluded)
• Target lesion
  •TV between 2.0 to 4.5 mm in dm
  •Lesion length **up to 150 mm (total treated length up to 240 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 Efficacy Primary patency of treated lesion sites by DUS at 6 months.	37/46 (80.4%)
Primary Safety Freedom from device and procedure-related death through 30 days.	46/46 (100%)
Secondary Efficacy Freedom from clinically driven target lesion revascularization through 6 months	41/46 (89.1%)
Wound healing for subjects with Rutherford class 5 at 6 and 12 months	34.8% reduction in size at 6 months
Improvement in Rutherford class score at 3, 6 and 12 months.	Avg. decrease from baseline: 2 classes by 3 months 2 classes by 6 months 3 classes by 12 months
Secondary Safety: Freedom from target limb Major Adverse Limb Event (MALE**) & All- cause perioperative death (POD) at 30 days.	100% (46/46)
Freedom from major amputation of the target limb at 12 months.	100% (46/46)

Characteristics	DEEPER OUS (N=46)
Age [mean (range)]	77 (66,86)
Female	9 (19.6%)
Race	
White	45 (97.8%)
Black	0 (0%)
Hispanic	0 (0%)
Other	1 (2.2%)
Diabetes	28 (60.9%)
Hypertension	44 (95.7%)
Cerebrovascular disease	8 (17.4%)
Chronic Kidney Disease	14 (30.4%)
Hyperlipidemia	41 (89.1%)
Coronary Artery Disease	13 (28.3%)
Planned Amputation of Index limb or toes	3 (6.5%)
Previous Amputation of Index limb (toes)	5 (10.9%)
Congestive Heart Failure	3 (5.5%)
Myocardial Infarction	4 (8.7%)
Rutherford Category mean at baseline	4.3

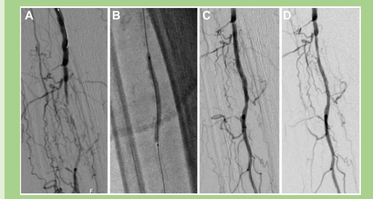
Characteristics	DEEPER OUS (N=46)
Target artery [mean (n/N)]	
Anterior tibial	25% (12/46)
Posterior tibial	14% (6/46)
Tibioperoneal trunk	20% (9/46)
Peroneal	21% (10/46)
Tibioperoneal trunk/peroneal	20% (9/46)
Diameter stenosis, % [mean (range)]	
70-90%	48% (22/46)
91-99%	35% (16/46)
100%	**17% (8/46)**
Spur-treated length mm [mean (range)]	**95 mm (60-220)**
Calcification score * [mean (n/N)]	
0	20% (9/46)
1	30% (14/46)
2	28% (13/46)
3	20% (9/46)
4	2% (1/46)
TASC Classification [mean (n/N)]	
A	28% (13/46)
B	40% (18/46)
C	30% (14/46)
D	2% (1/46)

Baseline Demographics and Lesion Characteristics

VESSEL RECOIL SUB-STUDY

Vessel recoil is a phenomenon that may contribute to poor acute and long-term outcomes.[1] The purpose of the sub-study is to evaluate whether the Spur has any effect on vessel recoil. Thirty-eight patients are enrolled in the vessel recoil sub-study. Vessel recoil is defined as lumen compromise ≥10% 15 minutes post treatment with the Spur device.
Data analysis is ongoing; preliminary results show that more than 50% of vessels did not demonstrate recoil after Spur treatment, in comparison to 97% of vessels in a previous study on recoil following plain balloon angioplasty (PTA).[1]

Posterior tibial following Spur treatment (images courtesy of Prof. Zeller)



Proximal Peroneal following PTA alone[1]

1. Baumann, F., Fust, J. F., Engelberger, R.P., Hugel, U., Do-Dai, D., Willenberg, T., Baumgartner, I., & Diehm, N. (2014). Early recoil after balloon angioplasty of tibial artery obstructions in patients with critical limb ischemia. *Journal of Endovascular Therapy, 2014*(21): 44-51.

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 preservation of future treatment options, and is drug agnostic, designed to create channels for drug delivery into the artery wall when used with DCB. The DEEPER OUS interim analysis results demonstrated success of the primary efficacy endpoint with 80.4% primary patency of treated lesion sites by DUS at 6 months.

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