Update on the Temporary Stent Assisted DCB Angioplasty in BTK Lesions With the Spur Spiked Stent System (Reflow Medical)

The DEEPER OUS Trial

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

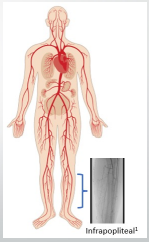
- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

Clinical Unmet Need

Chronic Limb- Threatening Ischemia (CLTI)

- Typically involving infrapopliteal arteries, associated with high rates of mortality
- Treatment Options → largely unchanged for decades
  - Multiple failed RCTs
- Anatomical factors: Calcification, Recoil, Drug permeability, Lesion Lengths

Challenge: Provide long-lasting results while leaving nothing behind



Retrievable Scaffold Therapy (RST)

Spur Peripheral Retrievable Scaffold System:

- Retrievable Scaffold → no permanent implant
- Simple familiar pin-and-pull delivery system with integrated balloon catheter

Novel spike design may:

- Modify plaque/calcium
- Prevent recoil
- Reduce dissections
- Improve drug uptake when used with a DCB

DEEPER OUS Trial Design

Title	A Non-RanDomized Trial of the TEmporary Spur StEnt System for the Treatment of Lesions located in the InfraPoplitEal ARteries Outside of the United States (DEEPER OUS) *for clinical investigational use only	
Design	Prospective, Non-Randomized, Multicenter, Single Arm Study of the Spur and Commercial DCB	
Number of Subjects/Centers	107 enrolled/ 10 centers (NZ + EU)	**Principal Investigators:** Germany: Prof. Dierk Scheinert; Switzerland: Prof. Jos van den Berg, New Zealand: Dr. Andrew Holden
Sub-Studies	Vessel recoil sub-study: Evaluate elastic recoil (>10% reduction in lumen diameter 15 minutes post-Spur by angiography) in subset of 38 subjects (40 lesions): **42.5% of vessels** demonstrated recoil[1]	
Primary Endpoint: Efficacy	Primary patency of treated lesion sites by duplex ultrasound in subjects who are free from clinically driven TLR (Performance goal based)	
Primary Endpoint: Safety	Freedom from device and procedure-related death through 30 days post-procedure	
Secondary Endpoints: Efficacy	1. Freedom from Clinically driven TLR through 6 months post procedure	
	2. Improvement in Rutherford class score at 3, 6, and **12 months**	
	3. Wound healing for subjects with Rutherford class 5 at 6 and **12 months**	
Secondary Endpoints: Safety	1. Freedom from target limb MALE and all-cause POD at 30 days	
	2. Freedom from major amputation of the target limb at **12 months**	

Follow-Up Requirements & Eligibility Criteria

FOLLOW UP REQUIREMENTS

1, 3, 6, 12 months: ABI/TBI; DUS; AE assessment; Rutherford class; Wound assessment (in person)

2, 3, 4, & 5 years: AE assessment (by phone or in person)

ELIGIBILITY CRITERIA

Inclusion

Rutherford category 3, 4, or 5
De novo or restenotic infrapopliteal lesion (popliteal excluded)
Target lesion
- Reconstitutes at or above ankle
- TV between 2.0 to 4.5 mm in dm
- Lesion length **up to 250 mm (total treated length up to 340 mm)**

Exclusion

Osteomyelitis proximal to phalanges (permitted in digits of target foot)
Rutherford category 0, 1, 2, 6
Planned target limb major amputation
Target lesion
- Stents within target vessel/lesion
- Extremely severe calcification not amenable to PTA
- Angiographic evidence of thrombus in the target limb

DEEPER OUS 2-Year Results: Demographics

Demographics	N=107 Patients
Variable	Value
Age (mean (range))	76 (48.8)
Female Sex	24 (22.4%)
Race	
White	105 (98.1%)
Black	0 (0%)
Hispanic	0 (0%)
Māori	1 (.9%)
Other	1 (.9%)
Diabetes	66 (61.7%)
Hypertension	101 (94.4%)
Cerebrovascular disease	17 (15.9%)
Chronic Kidney Disease	35 (32.7%)
Hyperlipidemia	90 (84.1%)
Coronary Artery Disease	38 (35.5%)
Planned Amputation of Index limb or toes	10 (9.3%)
Previous Amputation of Index limb (toes)	9 (8.4%)
Congestive Heart Failure	11 (10.3%)
Myocardial Infarction	14 (13.1%)

DEEPER OUS 2-Year Results: Demographics

Vessel/Lesion Characteristics	
Target artery [mean (n/N) mean]	DEEPER OUS N=107 arteries
Anterior tibial	29/107 (27%)
Posterior tibial	14/107 (13%)
Tibioperoneal trunk	33/107 (31%)
Peroneal	31/107 (29%)
Diameter stenosis, % [range (mean)]	
70-90%	46/107 (42.9%)
91-99%	34/107 (31.8%)
100%	27/107 (25.2%)
Spur-treated length mm [mean (range)]	92.7 mm (60-240)*

Lesion Characteristics	
TASC Classification [(n/N) mean]	DEEPER OUS N= 137 lesions**
A	45/137 (32.8%)
B	51/137 (37.2%)
C	34/137 (24.8%)
D	7/137 (5.1%)
Calcification (PARC or PACSS)	N=140 lesions
0	40/140 (28.8%)
1	39/140 (28.1%)
2	31/140 (22.3%)
3	28/140 (20.1%)
4	1/140 (.7%)

PTx DCB	Devices
Lutonix™	36
Passeo-18 Lux	2
Ranger™	19
Acotec (Litos/Tulip)	11
Luminor	23
Stellarex	25
In.Pact	3
SeQuent Please	2
Other	2
Total	123

*Of 106 treated Spur-treated arteries, treatment was attempted in one subject but unsuccessful due to calcification
**TASC not reported for 3 lesions

DEEPER OUS 1-Year Ad Hoc Analysis

- Rutherford class 5 most likely to experience an event
- Rutherford class 4 highest loss of primary patency at 12 months (small sample size)

Baseline Rutherford	Freedom from CD-TLR (MITT)	Primary Patency (MITT)	Freedom from Major Amputation (MITT)
3 N=22	85.9%	79.60% (13/14)	100.0%
4 N=11	100.0%	63.50% (5/7)	100.0%
5 N=74	92.4%	76.3% (42/48)	98.6%

Analysis of Rutherford score impact on CDTLR, Primary Patency, and Major Amputation at one year

	Freedom from CD-TLR (MITT)	Primary Patency (MITT)	Freedom from Major Amputation (MITT)
Full Cohort	87.5%	74.4%	98.9%

- MITT (modified intent to treat): all subjects in whom treatment was attempted

DEEPER OUS 2-Year Results: Freedom From Major Amputation

Major Amputation (MITT)	6 Months	12 Months	24 Months
Secondary Safety Endpoint: Freedom from amputation above the ankle	93/94 (98.9%)	93/94 (98.9%)	79/80 (98.8%)

- MITT (modified intent to treat): all subjects in whom treatment was attempted
- Data includes CEC adjudicated data as of 22 April 2024
- Events which occurred prior to the 24 month follow up visit are included in the denominator in all cases

The primary safety and efficacy endpoints were met and previously reported, with 100% freedom from device and procedure related death through 30 days, and 85.7% patency at 6 months by DUS, respectively.

DEEPER OUS 2-Year Results: All-Cause Mortality

24 Month All-Cause Mortality (MITT): **15/107 (14%)**

Cause of death	Percentage
Cancer	1.9% (2/107)
COPD exacerbation	1.9% (2/107)
Cardiovascular	4.6% (5/107)
Infection	1.9% (2/107)
Unknown	3.7% (4/107)

Occurrence of death consistent with previously reported rates[2, 3]

DEEPER OUS 2-Year Results: Freedom from CD-TLR*

Freedom from CD-TLR* cumulative (MITT)	6 months	12 months	24 months
	85/95 (89.5%)	84/96 (87.5%)	71/85 (83.5%)

*CD-TLR, Clinically driven target lesion revascularization

- Events which occurred prior to the 24 month follow up visit are included in the denominator in all cases
- During course of follow-up, 2 additional CD-TLRs were discovered during CEC adjudication, impacting previously reported CD-TLR data.

Conclusions DEEPER OUS trial: 2-Year follow up

- Safety and efficacy of the Spur Peripheral Retrievable Scaffold System followed by a paclitaxel coated balloon sustained through two years:
  - Freedom from major amputation: **79/80 (98.8%)**
  - All-cause mortality: **15/107 (14%)**
  - Freedom from CD-TLR 71/85 (83.5%)
- Patient follow up will continue through 5 years by telephone:
  - Ongoing safety evaluation due to paclitaxel use
  - All-cause mortality rates support safety of paclitaxel in population

References

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2. McKeown, L.A. Lutonix BTK Studies: Below-the-knee challenges linger. TCTMD: Conference News. January 29, 2020
3. Zeller T, Micari A, Scheinert D, Baumgartner I, Bosiers M, Vermassen FEG, et. al. The IN.PACT DEEP Clinical Drug-Coated Balloon Trial: 5-Year Outcomes. JACC Cardiovasc Interv. 2020 Feb 24;13(4):431-443. doi: 10.1016/j.jcin.2019.10.059.

Thank You

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