R3 Vascular Drug-Eluting Bioresorbable Scaffold in Below the Knee Vessels: Interim Results from the RESOLV-I Study

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Purpose

Current below-the-knee (BTK) treatment modalities have mixed results:

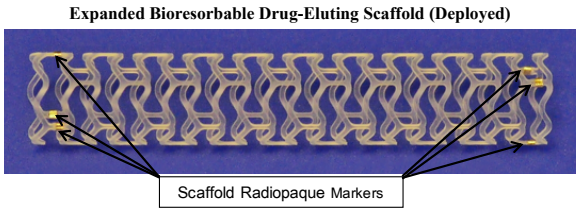
- PTA has up to 1/3 early failure
- BMS have not improved outcome over PTA
- No improvement with PTX-coated NiTi stent
- Coronary DES have had the best outcome, but leave a permanent implant behind

The RESOV-I first-in-human study was designed to perform an initial evaluation of the safety and performance of a new ultra-high molecular weight PLLA polymer bioresorbable drug-eluting scaffold to treat BTK disease.

Material and Methods

The R3 Vascular MAGNITUDE® bioresorbable scaffold has a number of advantages:

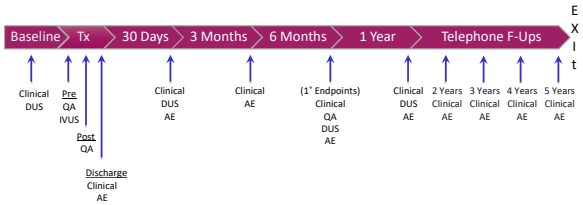
- Radial force > current metallic stents
- Vascular support maintained at least 1 year
- Strut thickness ≈ to metallic stents (98 µm)
- Longitudinal/radial flexibility >> metallic stents
- High polymer tensile strength and high elongation at break (10X higher at break point vs. other PLLA)



Study Design

30 symptomatic patients with infrapopliteal *de novo* or restenotic lesions:

- 18 - 90 years of age
- Rutherford categories 3 - 5
- Ambulatory without major limb amputation
- Up to 3 lesions in proximal 2/3 of native infrapopliteal vessels
- IVUS reference diameter 2.5 - 3.75 mm, maximum lesion length 51 mm
- Standard of care treatment of other above or below the knee lesions allowed
- No full thickness heel ulcer, osteomyelitis, gangrene, or extensive foot tissue loss



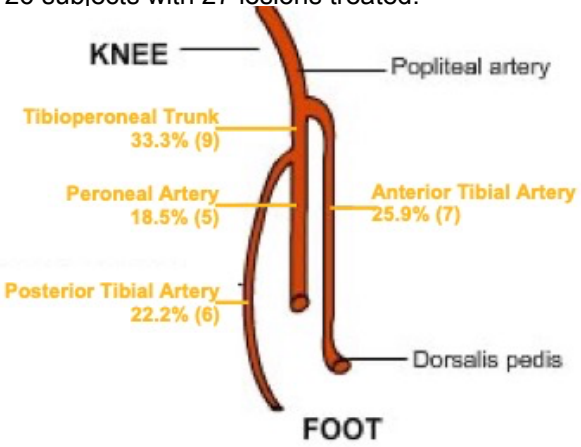
Primary Endpoints

1° Safety Endpoint - Freedom from Major Adverse Limb Event (index limb above ankle amputation/major reintervention) at 6 months and Peri-Operative Death at 30 days

1° Performance Endpoint - Primary patency of the target lesion(s) at 6 months (angiography ≥ 50% DS% or Duplex Ultrasound if angiography not available)

Results

26 subjects with 27 lesions treated:



1° Safety Endpoint: 100% (18/18 patients)

1° Performance Endpoint: 89% (17/19 lesions)

Assessment	*Baseline* (n = 25)	*1-Month F-Up* (n = 22)	*3-Month F-Up* (n = 19)	*6-Month F-Up* (n = 17)	*12-Month F-Up* (n = 5)
Target Leg Ischemic Rest Pain (% Yes)	40%	9%	0%	6%	0%
Non-Healing Wounds (% Yes)	60%	23%	11%	12%	0%
DUS Evidence of Restenosis (% Yes)	---	0%	---	0%	0%
Angio Binary Restenosis (% Yes, n)	---	---	---	11% (1/9)*	---
Site Reported Scaffold-Related AEs (n)	0	0	0	1**	0

* 57% DS by core lab, asymptomatic, not treated

* * Asymptomatic scaffold occlusion, not treated (not yet CEC adjudicated or core lab evaluated)

Conclusions

1. Drug-eluting bioresorbable scaffolds may provide all the advantages of metallic DES without a permanent implant.
2. Preliminary BTK territory data is promising, with a low rate of restenosis at 6 months.