Update on the BioMimics 3D Spiral Flow Prosthetic Graftstent from Veryan Medical

Does It Prevent Neointimal Hyperplasia and Improve Patency: 3-Year Results with FemPop Lesions

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Disclosures

Consultant:
Abbott, Bentley, BSCI, Cardinal Health/Cordis, Centerline BioMedical, Cook Medical, CR BARD/Becton Dickinson, CSI, Endologix, Inari, Medtronic, Micro Medical Solutions, Penumbra, Philips, Terumo, WL Gore

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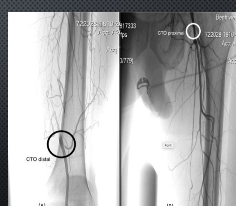
Stockholder:
Other Financial or Material Support - Centerline BioMedical - member of the Scientific Advisory Board and as such I have a small, negligible amount of stock

Challenges in Treatment of Complex Lesions & Patients

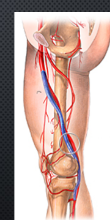
- In practice, treatment of complex lesions is all too common
- Further, 3.8M patients with CLTI in US alone[6-9]
- Numerous interventional/surgical options
  - No consensus/little data to support a particular approach
- Unfortunately, there is a paucity of clinical evidence in patients with complex lesions. [1-5]



1. Giannopoulos S, et al. Cardiovasc Revasc Med. 2021;22:52-65. 2. Creeden T, Ann Vasc Surg. 2024. 3. Wittig T, et al. JACC Cardiovasc Interv. 2024;17(9):1134-44. 4. Bosiers M, et al.. J Endovasc Ther. 2020;27(2):287-95. 5. Gostev AA, et al, J Endovasc Ther. 2023:15266028231170125. 6.Vosgin-Dinclaux V, et al, Cardiovasc Revasc Med. 2024. 7. Conte MS, et al, Eur J Vasc Endovasc Surg. 2019;58(1s):S1-S109.e33. 8. Nehler MR, et al, J Vasc Surg. 2014;60(3):686-95.e2. 9. Aday AW. et al. Circ Res. 2021;128(12):1818-32.

Surgical Femoropopliteal Bypass

- Trans-Atlantic Inter-Society Consensus II recommendations suggest bypass for the treatment of complex fem-pop lesions
- Potential for improved mid-term patency compared to endovascular approach
  - 72% vs 62% at 1 year[1]
- Significantly higher 30-day morbidity (37%) noted in surgical bypass[2]
  - 8.2% infection rate noted in meta-analysis of surgical fem pop outcomes
- Patient preference for endovascular



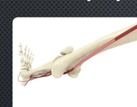
1. George A. Antoniou et al, JVS, Volume 57, Issue 1, 2013
2. Shah, T, et al. J Crit Limb Ischem 2022;2(4):E122-E130

Endovascular First Approach

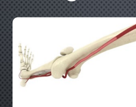
- Leave nothing behind (PTA/DCB):
  - Numerous endovascular strategies available to avoid stents due to concerns over long
    - Need for adjunctive stenting remains high, up to 68% of cases in recent meta-analysis[1]
- Stenting/Stent-supported angioplasty:
  - BMS 1° patency rates as low as 64% @1y, 41% @3y in complex lesions[1]
  - DES offer some promise, but very limited data in complex lesions to date
    - 73% primary patency @1y
- New therapies
  - Percutaneous transmural arterial bypass (PTAB) and LimFlow may offer promise, but still early in adoption

1. S. Giannopoulos et al. Cardiovascular Revascularization Medicine 22 (2021) 52–65

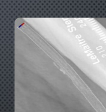
BioMimics 3D: Designed Specifically for the Femoropopliteal Segment



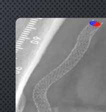
Straight stent



BioMimics 3D



Straight laminar flow



Swirling laminar flow

BioMimetic Design[1]

Mimics natural movement of the femoropopliteal segment
Aids in reducing localized trauma
Helps reduce risk of stent fracture in dynamic artery

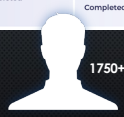
Elevated Wall Shear Stress[2]

Reduces restenosis by reducing thrombus formation and inflammation
Reduces Smooth Muscle Cell proliferation
Reduces neointimal hyperplasia

1. Data on file at Veryan Medical
2. Murphy EA, Cardiovascular Engineering and Technology 2012

Mimics Clinical Program

MIMICS FIH	MIMICS RCT	MIMICS 2	MIMICS 3D	MIMICS 3DUSA	MIMICS et seq
N = 10 **1 site** **Germany**	**N = 50** **8 sites** **Germany**	**N = 271** **43 sites** **USA/Japan/Germany**	**N = 507** **23 sites** **Pan European**	**N = 499** **31 sites** **USA**	**N = c. 500** **Multiple sites** **Europe**
First in Human FU - 1 year Completed	Randomised controlled trial FU - 2 years Completed	IDE Registry FU - 3 years Completed	Prospective Registry FU - 3 years Completed	Prospective Registry FU - 3 years Enrolment Completed	Physician initiated prospective and retrospective registries Enrolment ongoing



1750+ patients

Mimics-3D Registry

A prospective, multicentre observational study to evaluate BioMimics 3D stent in PAD in the real world

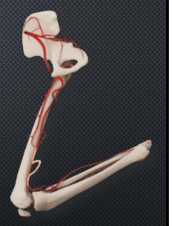
- PI: Michael Lichtenberg
- 23 Investigational sites
- 507 patients
- Independent Clinical Event Committee (adjudication)
- 3-year follow up

CLTI present in 24% of enrolled subjects

Baseline Patient Demographics		Enrolled Population N=507
Age	Mean years ± SD (N)	70.1 ± 10
Gender	% Male	66% (332/507)
Risk Factors	Diabetes Mellitus	37% (187/507)
	Smoker Current	38% (191/507)
Rutherford Category	0	0.4% (2/504)
	1	1% (6/504)
	2	17% (86/504)
	3	57% (289/504)
	4	8% (314% (72/504)
	5	14% (72/504)
	6	2% (11/504)

Data on file at Veryan Medical

SUBGROUP ANALYSIS OF OUTCOMES IN TASC D LESIONS



AS PART OF THE 3-YEAR FOLLOW UP, A SEPARATE ANALYSIS WAS CONDUCTED TO DETERMINE:

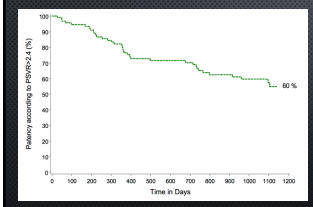
- OVERALL PREVALENCE OF TASC D LESIONS
- IMPACT ON PRIMARY PATENCY
- IMPACT ON FREEDOM FROM CLINICALLY-DRIVEN TLR
- FREEDOM FROM STENT FRACTURE

Mimics-3D Registry

		Overall cohort	TASC D
Patients	Subjects (#)	507	107
	Lesions (#)	518	107
	Diabetes (%)	37	41
Lesions	Mean lesion length (mm)	126 ± 91	273±60
	Severe bilateral wall calcification (%)	53	38
	CTO (%)	57	94
Procedural data	**Number and (%) of BioMimics 3D stents deployed**		
	1	395/518 (76%)	29/107 (27%)
	2	96/518 (19%)	55/107 (51%)
	3	19/518 (4%)	15/107 (14%)
	4	8/518 (2%)	8/107 (8%)

RESULTS

KM ESTIMATE OF FREEDOM FROM LOSS OF PRIMARY PATENCY



	Overall cohort	TASC D
12 months	87%	79%
36 months	70%	60%

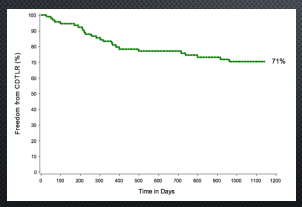
* ITT population, PSVR <2.4

As expected, the highly complex TASC D lesion population shows lower primary patency compared to the overall cohort but is well above the 41% at 3-years reported in the literature[2]

1. Data on file at Veryan Medical
2. S. Giannopoulos et al.Cardiovascular Revascularization Medicine 22 (2021) 52-65

RESULTS

KM ESTIMATE OF FREEDOM FROM CLINICALLY-DRIVEN TLR



	Overall cohort	TASC D
12 months	90%	83%
36 months	78%	71%

As expected, the highly complex TASC D lesion population shows lower freedom from CD-TLR compared to the overall cohort but the 71% observed in the MIMICS study are comparable to the 2-year data (68%) reported in the literature[2]

1. Data on file at Veryan Medical
2. S. Giannopoulos et al.Cardiovascular Revascularization Medicine 22 (2021) 52-65

CONCLUSIONS

- BioMimics 3D is a unique, helical stent platform that has demonstrated excellent results and durability in several trials
- Subgroup analysis performed to determine outcomes in patients with TASC D femoropopliteal lesions treated with BioMimics3D shows:
- Durable 3-year outcomes with BioMimics3D platform in extremely complex lesions
  - 3-year KM freedom from loss of primary patency: 60%
  - 3-year KM freedom from CDTLR: 71%
  - 3-year stent fracture rate: 1.9% (2/107). (Overall cohort: 0.4% (3/676))