Bioresorbable Everolimus DES To Treat BTK Lesions

From DISAPEAR Registry to a Meta analysis , 5 year data

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Disclosure

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

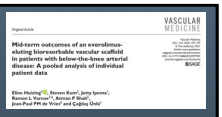
Affiliation/Financial Relationship	Company
• ***Research Support***	• Boston Scientific, LimFlow/Inari
• ***Consulting Fees/Honoraria***	• LimFlow/Inari, Acelity, Abbott Vascular, Boston Scientific, Orbus Neich, Bypass Solutions, PEDRA, Xeltis
• ***Advisory Board***	• Abbott, Boston Scientific, Xeltis, LimFlow/Inari, Fastwave, Corflow, VCD, Bypass Solutions, Protexa
• ***Equity***	• LimFlow/Inari, Mercator, Cagent, PEDRA, Xeltis, Fastwave, Corflow, VCD, Bypass Solutions, Protexa, R3

DISAPEAR Registry in CLTI - Singapore

Drug
Impregnated Bioabsorbable
Stent in
Asian
Population
Extremity
Arterial
Revascularization

Presented VIVA 2019 Late Breaker

3 Centre Pooled analysis on BVS



- Consecutive patients treated between August 2012 and May 2017 at 3 centers
  - Singapore
  - Chicago
  - Sydney
- Aim to evaluate multi-centre ***24 month*** outcomes of the use of Absorb BVS for the treatment of infrapopliteal artery disease

Huizing E, Kum S, Ipema J, Varcoe RL, Shah AP, de Vries JP, Ünlü Ç. Mid-term outcomes of an everolimus-eluting bioresorbable vascular scaffold in patients with below-the-knee arterial disease: A pooled analysis of individual patient data. Vasc Med. 2021 Apr;26(2):195-199. doi: 10.1177/1358863X20977907. Epub 2021 Jan 28. PMID: 33507844.

Patient /Lesion

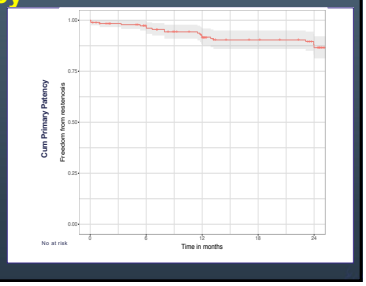
- 121 patients
  - 41 patients from Singapore
  - 31 from Chicago
  - 49 from Sydney
- Mean age 73 years (46-97 years)
- 57% had diabetes
- ***84% CLTI (75% tissue loss)***

- 161 lesions were treated with 189 BVS in 126 limbs
- Lesion length = 21mm (range 4-88)
- Median stenosis = 80%, Occlusions = 22%
- Median Vessel diameter = 3.1mm (IQR: 3.0–3.5 mm)
- Calcified lesions = 63%
- Most commonly used scaffold 28 mm
- Size of the BVS was also chosen on a 1:1 basis

Primary Patency

6 month = 97.3%
12 months = 90.3%
24 month = 86.6%

Re-stenosis = PSV ratio >2.0 or PSV >2 m/s

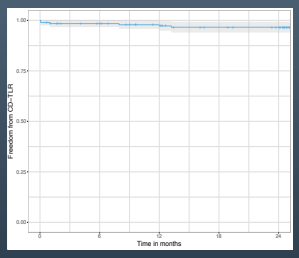


FF CD-TLR

6 month = 98.4%

12 month = 97.2%

24 month = 96.6%



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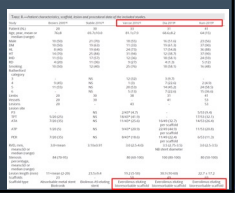
Meta-analysis of Bioabsorbable scaffolds – *12 month analysis*

- 5 studies, 155 patients with 160 treated limbs
- Primary patency per limb = 90%
- FF CD-TLR = 96%
- Limb salvage = 97%
- Survival rate = 90%
- AFS = 89%


REVIEW
PERIPHERAL ARTERIAL DISEASE
A systematic review and meta-analysis of bioresorbable vascular scaffolds for below-the-knee arterial disease



Ipema J, Kum S, Huizing E, Schreve MA, Varcoe RL, Hazenberg CE, DE Vries JP, Ünlü Ç. A systematic review and meta-analysis of bioresorbable vascular scaffolds for below-the-knee arterial disease. Int Angiol. 2021 Feb;40(1):42-51. doi: 10.23736/S0392-9590.20.04462-4. Epub 2020 Oct 21. PMID: 33092777

Esprit™ BTK System Is Based On Coronary BRS Experience

	ABSORB BVS	ESPRIT™ BTK SYSTEM
Device Family	**BRS**	**DRS**
Anatomical Target	**Coronary**	**Infrapopliteal**
Scaffold	Fully resorbable PLLA	Fully resorbable PLLA
Strut Thickness	**157 µm**	**99 µm***
Coating	Everolimus : PDLLA	Everolimus : PDLLA
Drug Dose Density	100 µg/cm²	100 µg/cm²
Drug Elution Profile	80% in 28 days	80% in 28 days

Proprietary and confidential — do not distribute

*±3.0 mm size; 3.5 -3.75 mm sizes have 120 µm strut thickness.

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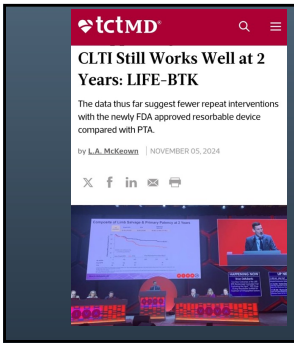
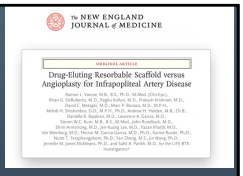

tctMD
CLTI Still Works Well at 2 Years: LIFE-BTK
The data thus far suggest fewer repeat interventions with the newly FDA approved resorbable device compared with PTA.
by L.A. McKeown | NOVEMBER 05, 2024


The NEW ENGLAND JOURNAL of MEDICINE
Drug-Eluting Resorbable Scaffold versus Angioplasty for Infrapopliteal Artery Disease

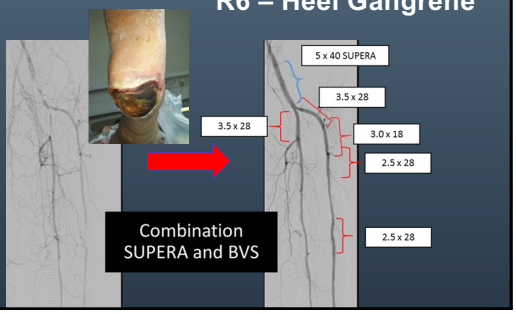

LIFE-BTK
pivotaL Investigation of saEety and Efficacy of BRS treatment—Below The Knee
6-MONTH PRIMARY ENDPOINTS
Safety Endpoint: MALE+POD
Efficacy Endpoint: Primary Patency+Limb Salvage
Trial Leadership:

	3 Centre Pooled Analysis (Sydney, Singapore, Chicago)	LIFE BTK
Year	2012-2017	2020-2022
Type of study	Retrospective Multi-centre Registry	Prospective Multi-centre RCT
N (Lesions/Patients)	161 /121	173/179
Patency analysis	Investigator PSVR 2.0 or PSV > 200cm/s or Angio > 50%	**Independent core lab adjudication** PSVR 2.0 and others or Angio > 50%
Rutherford 3/4/5/6 (%)	16/9/55/20 (75% tissue loss)	52/48/0 (48% tissue loss)
DM (%)	57	71
Calcification (any - %)	63%	30% (mod/severe)
Lesion Length	21 mm	43.8 mm
CTO (%)	22%	15%
Tech Success (implant with < 30%)	100	96
Primary Patency(%) 6/12/24 months	**97.3/91.7/86.6**	**NR/76.5/64.8**
FF-TLR(%) 6/12/24 months	**98.4/97.2/96.6**	**NR/93.0/90.3**

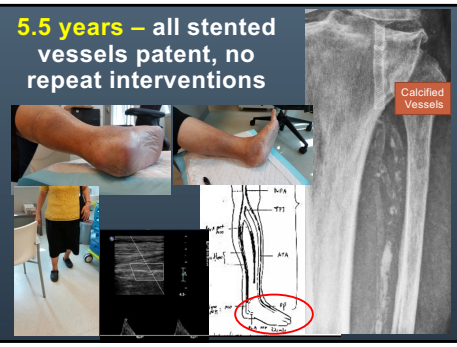
Huizing E, Kum S, Ipema J, Varcoe RL, Shah AP, de Vries JP, Ünlü Ç. Mid-term outcomes of an everolimus-eluting bioresorbable vascular scaffold in patients with below-the-knee arterial disease: A pooled analysis of individual patient data. Vasc Med. 2021 Apr;26(2):195-199. doi: 10.1177/1358863X20977907. Epub 2021 Jan 28. PMID: 33507844.

Varcoe RL, DeRubertis BG, Kolluri R, Krishnan P, Metzger DC, Bonaca MP, Shishehbor MH, Holden AH, Rajakian DR, Garcia LA, Kum SWC, Rundback J, Armstrong E, Lee JM, Khalik Y, Wamberg L, Garcia-Garcia HM, Ruster K, Tenghongphon NT, Zheng Y, Wang J, Jones-McMeans JM, Parikh SA. LIFE-BTK Investigators. Drug-Eluting Resorbable Scaffold versus Angioplasty for Infrapopliteal Artery Disease. N Engl J Med. 2023 Oct 19. doi: 10.1056/NEJMoa2306457. Epub ahead of print. PMID: 37888916

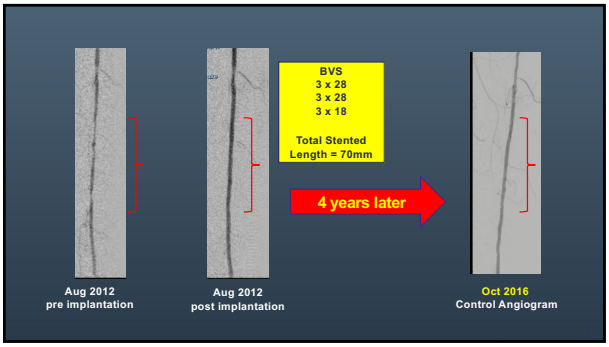
R6 – Heel Gangrene

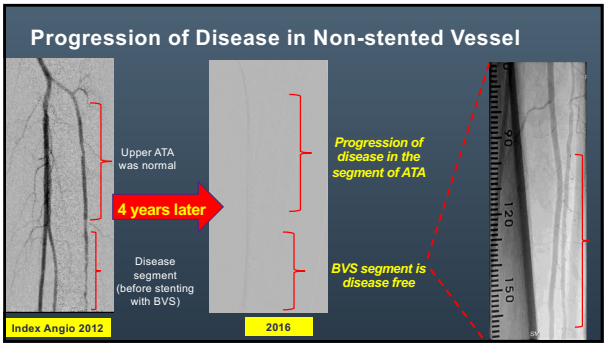


5.5 years – all stented vessels patent, no repeat interventions

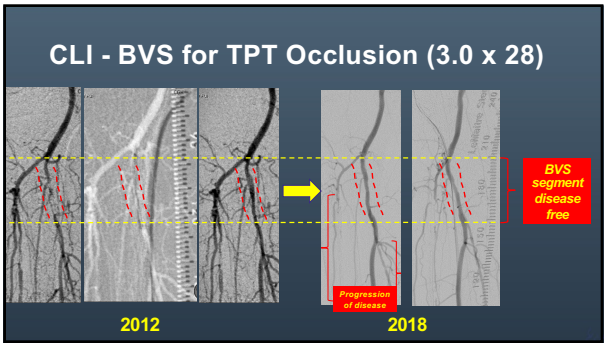


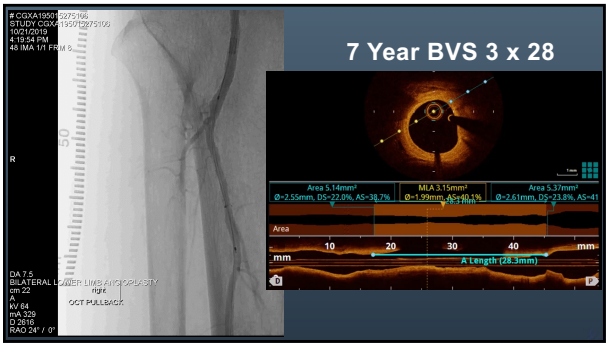
Long Lesion (70mm) With 4-Year Angiographic Follow-Up





7-Year Angiographic Follow-Up for CTO





Absorb BTK 5 Year results

- Single centre initial experience
- 71 scaffolds in 55 limbs of 48 patients, 72.7% with CLTI
- Mean lesion length 20.1 mm (5-50 mm)
- ***5 Year Results***
  - 38% death from CV causes
  - 90% complete wound healing
  - 95% of patients had sustained clinical improvement.
  - PP 72.9% and FF CD-TLR 90.7% (1 year PP 89.2% and FF CD-TLR 97.2%)

Varcoe RL, Menting TP, Thomas SD, Lennox AF. Long-term results of a prospective, single-arm evaluation of everolimus-eluting bioresorbable vascular scaffolds in infrapopliteal arteries. Catheter Cardiovasc Interv. 2021 Jan 1;97(1):142-149. doi: 10.1002/ccd.29327. Epub 2020 Oct 10. PMID: 33037889.

Summary

- BTK lesions are associated with recoil, high restenosis and high reintervention when treated with standard POBA
- Combined experience with over 300 lesions now shows a viable *Scaffold with Drug elution* for **reliable lumen gain** and **consistent drug elution,** with experience up to 5 years
- BRS and other DES should be considered standard tools in the BTK armamentarium