An Update Of The 2-Year Results And Economic Cost Effectiveness Analysis Of The LIFE-BTK Randomized Controlled Comparison Of Abbott's Esprit Drug-Eluting Resorbable Stent (DERS) With Plain Old Balloon Angioplasty (POBA): When Will DERSs Make A Difference

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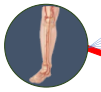
Disclosures

Consultant to:
- Medtronic
- Abbott Vascular
- BD Bard
- Intervene
- Surmodics
- Philips Healthcare
- Nectero Medical
- Endospan
- Boston Scientific
- Vesteck
- W.L. Gore
- R3 Vascular
- Cook Medical
- Concept Medical
- Inari

Equity:
- EBR Systems
- Provisio Medical, inc
- Vesteck Inc

BTK PAD and Its Current Treatment Options

BTK PAD[1]
- Small vessel diameter
- Tortuous, challenging anatomy
- Longer lesion length
- Severe calcification



To effectively treat BTK PAD[2]	DRUG (Inhibit Neointimal Hyperplasia)	SCAFFOLD (Resist Recoil)	LEAVE NOTHING BEHIND
Atherectomy / IVL			
POBA			
DCB			
BMS			
DES			
Esprit BTK DRS			

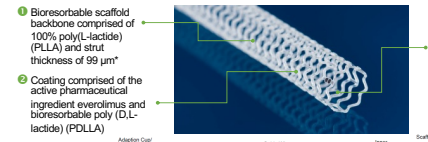
1. Zeller T, et al. J Endovasc Ther. 2022;29(6):874-884.
2. Adapted from Varcoe R. The LIFE-BTK Trial Presented at TCT 2023.

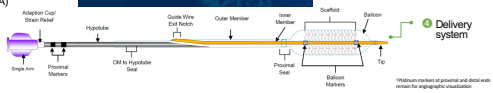
Esprit™ BTK Device

Design and Components

Esprit™ BTK Drug-eluting Resorbable Scaffold (DRS)
Temporary scaffold that will **resorb over time**

1. Bioresorbable scaffold backbone comprised of 100% poly(L-lactide) (PLLA) and strut thickness of 99 µm*
2. Coating comprised of the active pharmaceutical ingredient everolimus and bioresorbable poly (D,L-lactide) (PDLLA)
3. Four platinum markers of the same mass, two each embedded at the proximal and distal ends of the scaffold for radiopacity†
4. Delivery system





* c 3.0 mm size; 1.5-3.75 mm sizes have 120 µm strut thickness

†Platinum markers at proximal and distal ends remain for angiographic visualization

LIFE-BTK Randomized Multicenter Trial*

Prospective, randomized, multicenter, US and OUS single-blind trial

261 patients randomized 2:1 Esprit BTK vs. PTA

Evaluate the safety and efficacy of the Esprit BTK DRS System, compared to PTA, for the treatment of infrapopliteal artery disease in patients with CLTI.

ClinicalTrials.gov: NCT04227899

FDA approval on April 26, 2024

Clinical Follow-Up:

14 D** | 30 D | 42 D** | 90 D** | 6 M | 1 Y | 2 Y | 3 Y | 4 Y | 5 Y

TCT 2023 | VIVA 2024

** Follow up focused on index wound assessment

Funded by Abbott.

Patient Flow Charts - Clinical Follow-up

Intent-to-Treat (ITT) Population

Number of Randomized Subjects N = 261

RANDOMIZATION 2:1

Esprit BTK Subjects		PTA Subjects
N = 173		N = 88
Subject Withdrawn n = 6; Subject Death n = 12; Subject Lost-to-Follow-up n = 2		Subject Withdrawn n = 3; Subject Death n = 6; Subject Lost-to-Follow-up n = 1
N = 153	1-YEAR FOLLOW-UP	N = 78
Subject Withdrawn n = 0; Subject Death n = 22; Subject Lost-to-Follow-up n = 0		Subject Withdrawn n = 3; Subject Death n = 7; Subject Lost-to-Follow-up n = 1
N = 131	2-YEAR FOLLOW-UP	N = 67

CLINICAL FOLLOW-UP RATE* AT 2 YEARS: 87.9% | 83.0%

*The clinical follow-up rate is calculated by subtracting the cumulative withdrawal subjects, cumulative lost-to-follow-up subjects, and missed visit subjects from the registered subjects, and then dividing that number by the registered subjects. Subjects discontinued from the study due to death were accounted for, therefore, were not considered as missed visit.

Key Baseline and History Risk Factors

Esprit BTK (N=173) PTA (N=88)

Tobacco Use	Hypertension	Hyperlipidemia	Diabetes	Renal Disease	Rutherford Becker 4 Clinical Category	Rutherford Becker 5 Clinical Category
Esprit BTK: **52.6%**	Esprit BTK: **94.2%**	Esprit BTK: **80.9%**	Esprit BTK: **71.1%**	Esprit BTK: **15.8%**	Esprit BTK: **52.0%**	Esprit BTK: **48.0%**
PTA: **53.4%**	PTA: **90.9%**	PTA: **81.8%**	PTA: **69.3%**	PTA: **16.3%**	PTA: **51.1%**	PTA: **48.9%**

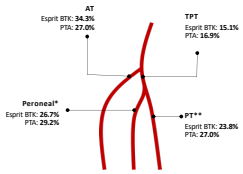
Prior MI	CHF	Previous PCI or CABG	Prior CVA or Stroke	DVT	Prior PAD	Cancer
Esprit BTK: **16.9%**	Esprit BTK: **19.4%**	Esprit BTK: **34.7%**	Esprit BTK: **11.7%**	Esprit BTK: **4.0%**	Esprit BTK: **82.7%**	Esprit BTK: **12.3%**
PTA: **14.8%**	PTA: **19.3%**	PTA: **35.6%**	PTA: **17.0%**	PTA: **5.7%**	PTA: **77.3%**	PTA: **9.1%**

No significant differences between arms.

Target Lesion Baseline Characteristics

	Esprit BTK	PTA
Lesion length (mm)	43.78 ± 31.84 (172)	44.75 ± 29.07 (89)
RVD pre-intervention (mm)	2.94 ± 0.77 (147)	2.82 ± 0.74 (80)
Site-Reported Calcification		
None/Mild	69.3% (124/179)	69.6% (64/92)
Moderate	27.4% (49/179)	28.3% (26/92)
Severe	3.4% (6/179)	2.2% (2/92)
TASC II classification		
A	48.3% (83/172)	52.8% (47/89)
B	35.5% (61/172)	25.8% (23/89)
C	16.3% (28/172)	21.3% (19/89)
D	0.0% (0/172)	0.0% (0/89)
% DS pre-intervention	72.6 ± 18.9 (172)	73.7 ± 21.0 (89)

* Includes Peroneal and TPT-Peroneal segments
** Includes PT and TPT-PT segment

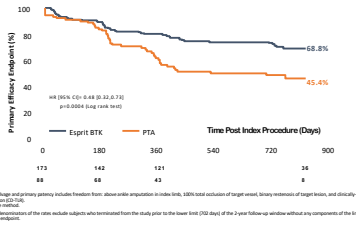


Number of Target Lesions Per Subject
Esprit BTK = 1.0 (1,2)
PTA = 1.0 (1,2)

24-Month Results

Composite of Limb Salvage & Primary Patency at **2 Years**

ITT population	Esprit BTK	PTA	Difference [95% CI][2]
	61.5% (75/122)	32.8% (21/64)	28.66% (13.59%, 41.76%)

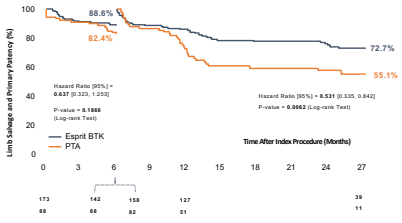


No. at Risk

Esprit BTK	173	142	121	36	
PTA	88	68	43	8	

Composite of limb salvage and primary patency includes freedom from: above-ankle amputation in index limb, 100% total occlusion of target vessel, binary restenosis of target lesion, and clinically-driven target lesion revascularization (CD-TLR).
By Kaplan-Meier estimate.
Note: The endpoint denominators of the rates exclude subjects who terminated from the study prior to the lower limit (702 days) of the 2-year follow-up window without any components of the limb salvage and primary patency endpoint.

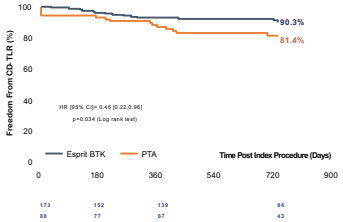
Composite of Limb Salvage & Primary Patency Landmark



No. at Risk

Esprit BTK	173	142	158	127				39	
PTA	88	68	82	51				11	

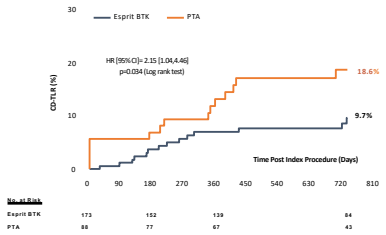
Freedom From Clinically-Driven Target Lesion Revascularization at 2 Years



No. at Risk

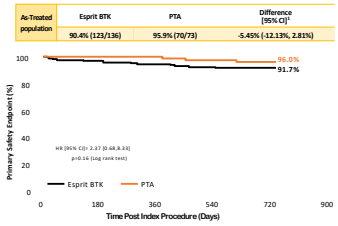
Esprit BTK	173	152	139	84	
PTA	88	77	67	43	

Clinically-Driven Target Lesion Revascularization at 2 Years



Composite of MALE (2-year) & POD (30-day)

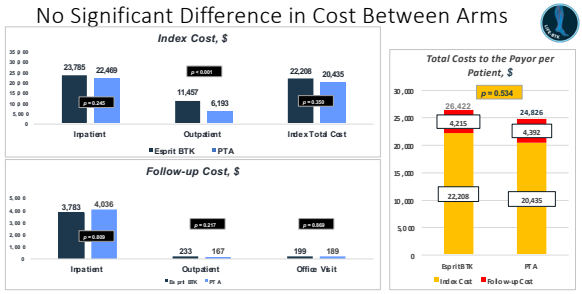
As-Treated population	Esprit BTK	PTA	Difference [95% CI][1]
	90.4% (123/136)	95.9% (70/73)	-5.45% (-12.13%, 2.81%)



[1] By Newcombe score method.
Note: The safety endpoint denominators of the rates exclude subjects who terminated from the study prior to the lower limit (702 days) of the 2-year follow-up window without any components of the safety endpoint.

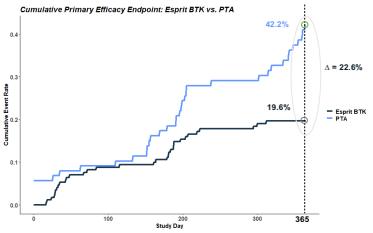
Economic Analysis

No Significant Difference in Cost Between Arms



*The economic analysis is performed on a population of 260 patients instead of 261 randomized. This adjustment reflects the exclusion of one patient from the Esprit BTK arm, as vessel diameter was too large for the Esprit BTK device, consistent with the focus on the as-treated population typically used in economic analysis

At One Year the Adjusted Event Rate is 19.6% in the Esprit BTK Arm and 42.2% in the PTA Arm



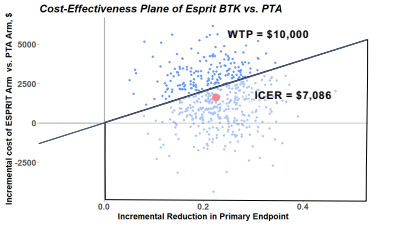
Note: This survival and censoring adjusted event rate is calculated slightly different than the event-free survival reported in Varcoe et al. 2024. While event rates in Varcoe et al. 2024 reflect the estimated event rates among survivors, the appropriate event rate for the economic analysis is the event rate for the total population, including those who die. Therefore, those who die are not excluded from the denominator in calculating the event rates for this analysis.

The Esprit BTK Scaffold Arm Costs an Additional $7,086 per Primary Efficacy Endpoint Avoided

	KM Adjusted Cost, $	Primary Efficacy Endpoint, %
Esprit BTK	$26,540	19.6%
PTA	$24,941	42.2%
Δ Difference	$1,599	22.6%

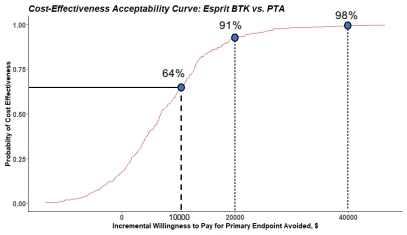
(1599/0.23) = $7,086 per Primary Efficacy Endpoint Avoided

Sensitivity Analysis: Primary Efficacy Endpoint At One Year

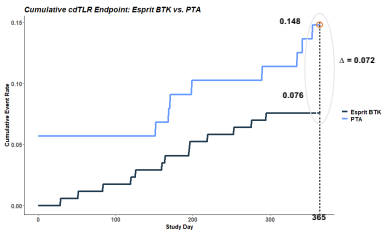


Scatterplot of 500 Bootstrap Simulations. The red dot shows our point estimate of $1,599 Incremental Cost, and 0.23 events avoided. The yellow line shows an ICER threshold of $10,000 for reference.

Esprit BTK Achieves 64% Probability of Cost-Effectiveness at $10,000 WTP Compared to PTA



Sensitivity Analysis: Clinically Driven Target Lesion Revascularization (cdTLR) per Subject



Note: During the index procedure 5 PTA subjects underwent cdTLR

The Esprit BTK Scaffold Costs an Additional $22,163 per Clinically Driven Target Lesion Revascularization Avoided

	KM Adjusted Cost, $	cdTLR Endpoint per Subject
Esprit BTK	$26,540	0.076
PTA	$24,941	0.148
Δ Difference	$1,599	0.072

(1599/0.072) = $22,163 per Clinically Driven Target Lesion Revascularization Avoided

Cost-Effectiveness of Esprit BTK: $7,086 per Primary Efficacy Endpoint Avoided and $22,163 per Clinically Driven Target Lesion Revascularization (cdTLR) Avoided

Study Name	Treatment Arms/Site	Outcome	Time Horizon	ICER, $
LIFE-BTK Trial	Esprit BTK vs. PTA/CLTI	Primary Efficacy Endpoint	1 year	7,086
LIFE-BTK Trial	Esprit BTK vs. PTA/CLTI	Target Lesion Revascularization	1 year	22,163

Conclusion

- Esprit BTK offers continued superior long-term clinical outcomes compared to PTA, particularly in terms of limb salvage and primary patency at 2 years.
  - *A clear advantage over PTA in terms of **sustained vascular patency and limb preservation***

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- Significant difference in CD-TLR at 2 years, in favor of Esprit BTK.

Conclusion

- Esprit BTK offers continued superior long-term clinical outcomes compared to PTA, particularly in terms of limb salvage and primary patency at 2 years.
  - *A clear advantage over PTA in terms of **sustained vascular patency and limb preservation***
- Significant difference in CD-TLR at 2 years, in favor of Esprit BTK.
- Esprit is likely to be cost effective with an ICER of $7,086 to avoid one primary efficacy endpoint and $22,163 to avoid one CD-TLR