The BOLSTER Study with LIFESTREAM covered stent in iliac lesions: 3-Year Outcomes

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On behalf of the BOLSTER Investigators

Disclosures
John R. Laird

- 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
Consulting Fees/Honoraria	Boston Scientific, Medtronic, Abbott, Bard/Becton Dicksenson Peripheral Intervention, Philips
Scientific Advisory board/stock options	Reflow Medical, Endoluminal Sciences, Syntervention, PQ Bypass, Eximo Medical, Shockwave Medical, NexGen

Board Member VIVA Physicians

Potential Advantages of Covered Stents

- Treatment of vessel perforation/rupture
- Sealing of aneurysms/pseudoaneurysms
- Barrier to neointimal ingrowth
- Possible improved results in complex lesions:
  - Aortoiliac bifurcation lesions
  - TASC C and D lesions
  - Instent restenosis

Study Device

LIFESTREAM® Balloon Expandable Vascular Covered Stent

Electropolished, 316L stainless steel balloon-expandable stent encapsulated between two layers of ePTFE

Covered Stent Sizes:

- Diameters: 5-10, and 12 mm
- Lengths: 16, 26, 37, and 58 mm
- Sheath compatibility: 6-8F

Design:

- ✓Radiopaque markers for accurate placement
- ✓Non-compliant balloon to provide precise inflation diameters.
- ✓0.035” guidewire-compatible, over-the-wire delivery catheter

BOLSTER Trial Design

BOLSTER: Balloon Expandable Vascular Covered Stent in the Treatment of Iliac Artery Occlusive Disease

Design: Prospective, Multicenter, Single-Arm Trial (no concurrent control)

- 17 centers in the U.S., Europe, and New Zealand

Objectives: Assess the LIFESTREAM Covered Stent for the treatment of stenoses and occlusions in the common and/or external iliac arteries.

Independent Analyses:

- Angiographic Core Lab: Yale Cardiovascular Research Group
- Duplex Ultrasound Core Lab: The Vascular Ultrasound Core Laboratory (VasCore)
- Clinical Events Committee: Adjudicated major adverse events (MAEs)

Study Sponsor: Becton, Dickinson Interventional

Baseline Demographics

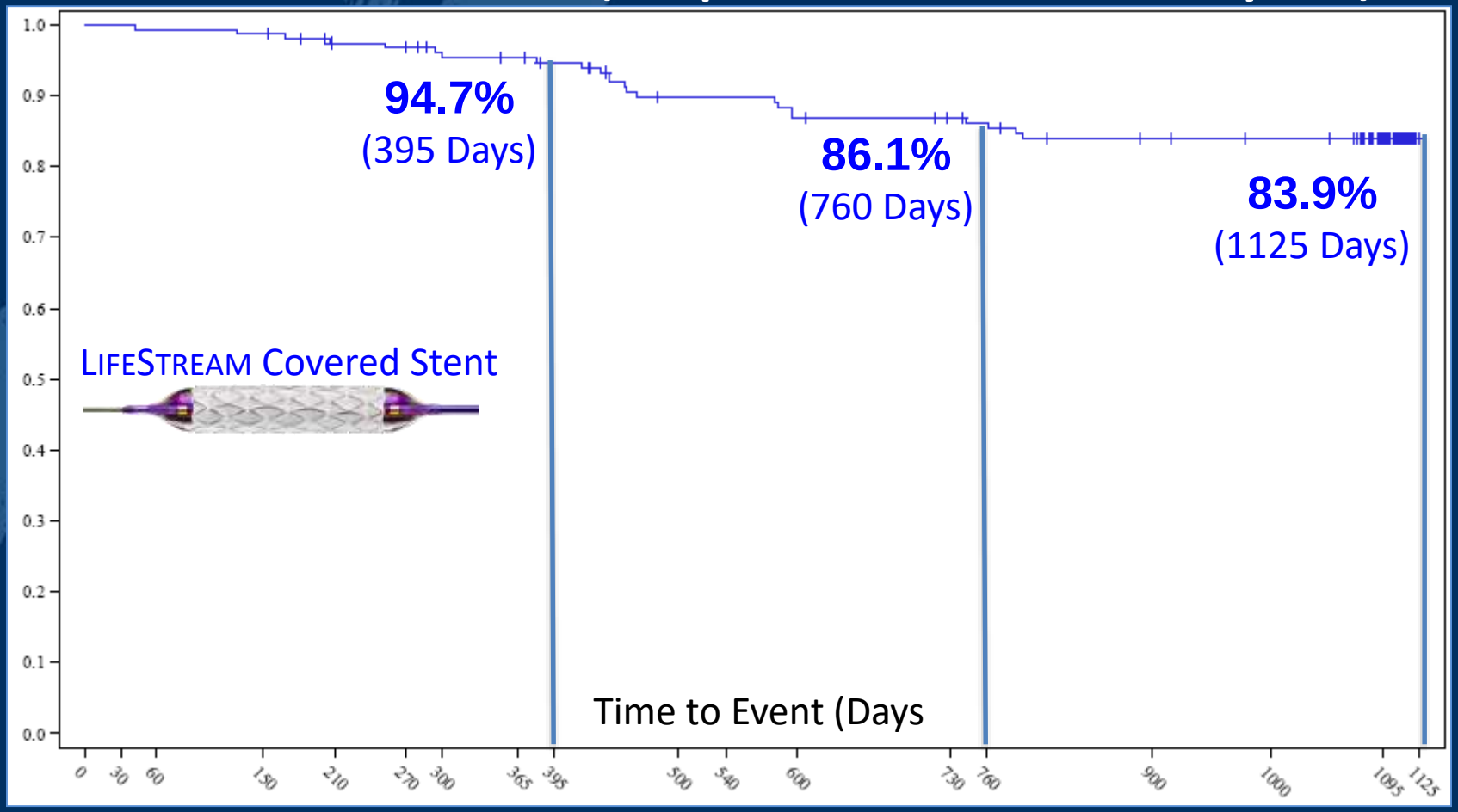
	ITT Group
Number of Patients	155
Male/Female, %	69/31
Mean Age, years ± SD	64.3 ± 9.75
Mean Weight, kg ± SD	79.6 ± 16.6
Mean BMI, kg/m^2 ± SD	27.2 ± 4.8
Medical History/Risk Factors, % (n)	
Hypertension	75.5 (117)
Dyslipidemia	65.2 (101)
CAD	31.6 (49)
Smoker	85.2 (132)
Diabetes	32.3 (50)
Previous MI	13.5 (21)

Lesion Characteristics

	ITT Group
Number of Lesions	197
Mean Total Lesion Length[+], mm ± SD	36.6 ± 23.1
Pre-Procedure % Diameter Stenosis, % ± SD	71.3 ± 14.3
Vessel, % (n/N)	
Common Iliac	73.4 (141/192*)
External Iliac	26.6 (51/192)
Location, % (n/N)	
Ostial	20.8% (40/192)
Proximal	59.9% (115/192)
Mid	12.0% (23/192)
Distal	7.3% (14/192)
Moderate/Severe Calcification^, % (n/N)	64.5 (127/197)
Occlusion^, % (n/N)	10.7 (21/197)

[+] Accounted for multiple lesions per patient; [*]192 evaluable by the core laboratory; [^]Site reported

Freedom from TLR (Kaplan-Meier Analysis)



Time to Event (Days)	Number of Subjects Censored	Number of Subjects Event	Number of Subjects Left	K-M Estimates of Subjects with Event	95% Confidence Interval
Day 365	9	7	139	4.6%	(2.2% , 9.5%)
Day 395	11	8	136	5.3%	(2.7% , 10.4%)
Day 730	18	18	119	12.4%	(8.0% , 19.0%)
Day 760	19	**20**	**116**	**13.9%**	**(9.2%, 20.7%)**
Day 1095	**66**	**23**	**66**	**16.1%**	**(11.0%, 23.3%)**
Day 1125	**132**	**23**	**0**	**16.1%**	**(11.0%, 23.3%)**

TLR Rate Through 36 Months
(Proportional Analysis)

Follow Up, % (n/N)	ITT Group	95% CI^
6 Months	2.6% (4/155)	[0.7%, 6.5%]
9 Months	4.0% (6/150)	[1.5%, 8.5%]
12 Months	5.4% (8/147)	[2.4%, 10.4%]
24 Months	14.2% (20/139)	[9.0%, 21.3%]
36 Months[+]	17.6% (23/131)	[11.5%, 25.2%]

First revascularization procedure of the target lesion(s) following covered stent placement, determined by the angiographic core lab

^95% CI is estimated by the exact binomial method

[+]Proportional analysis through 36 months (denominator: number of evaluable patients at a given follow-up time point)

Patency Through 36 Months

(Proportional Analysis)

Primary Patency, % (n/N)	ITT Group	95% CI^
12 Months	92.4% (122/132)	[86.5%, 96.3%]
24 Months	83.2% (99/119)	[75.2%, 89.4%]
36 Months+	77.2% (78/101)	[67.8%, 85.0%]

Freedom from occlusion by DUS or angiography and/or TLR

Secondary Patency, % (n/N)	ITT Group	95% CI^
12 Months	95.4% (124/130)	[90.2%, 98.3%]
24 Months	95.6% (108/113)	[90.0%, 98.5%]
36 Months+	93.4% (85/91)	[86.2%, 97.5%]

Patency re-established via an endovascular procedure following restenosis

^95% CI is estimated by the exact binomial method

+Proportional analysis through 36 months (denominator: number of evaluable patients at a given follow-up time point)

Sustained Clinical Success

Cumulative improvement ≥ 1 category from baseline Rutherford values – Improvement sustained through 36 months

Follow Up, % (n/N)[+]	ITT Group	95% CI[^]
9 Months	90.5% (124/137)	[84.3%, 94.9%]
12 Months	93.9% (124/132)	[88.4%, 97.3%]
24 Months	90.6% (106/117)	[83.8%, 95.2%]
36 Months	92.5% (98/106)	[85.7%, 96.7%]

[+]Proportional analysis (denominator: number of evaluable patients at a given follow-up time point)
^95% CI is estimated by the exact binomial method

Quality of Life: WIQ

Patient Quality of Life, assessed by the Walking Impairment Questionnaire (WIQ), improved from baseline to 9 months by just over 32 points – Improvement sustained through 3 Years (32.5 ± 27.3)

	Baseline	9 Months	12 Months	24 Months	36 Months
WIQ Total Score					
N	153	135	132	117	104
Mean (SD)	32.0 (18.03)	64.7 (28.1)	65.7 (28.2)	64.8 (28.6)	67.4 (27.0)
Median	28.4	72.4	75.0	68.3	71.8
Min - Max	0.0 - 96.9	0.1 - 100.0	0.1 - 100.0	0.2 - 100.0	6.3 - 100.0
Change From Baseline					
N		134	130	116	103
Mean (SD)		32.1 (26.8)	32.8 (26.8)	31.3 (26.8)	32.5 (27.3)
Median		34.0	34.9	30.9	35.9
Min - Max		-45.3 - 94.8	-34.6 - 82.3	-28.8 - 78.2	-46.9 - 89.1

Ankle-Brachial Index

Mean Ankle-Brachial Index (ABI) improved from baseline to 9 months by 0.2 points – Improvement sustained through 3 Years (0.2 ± 0.3)

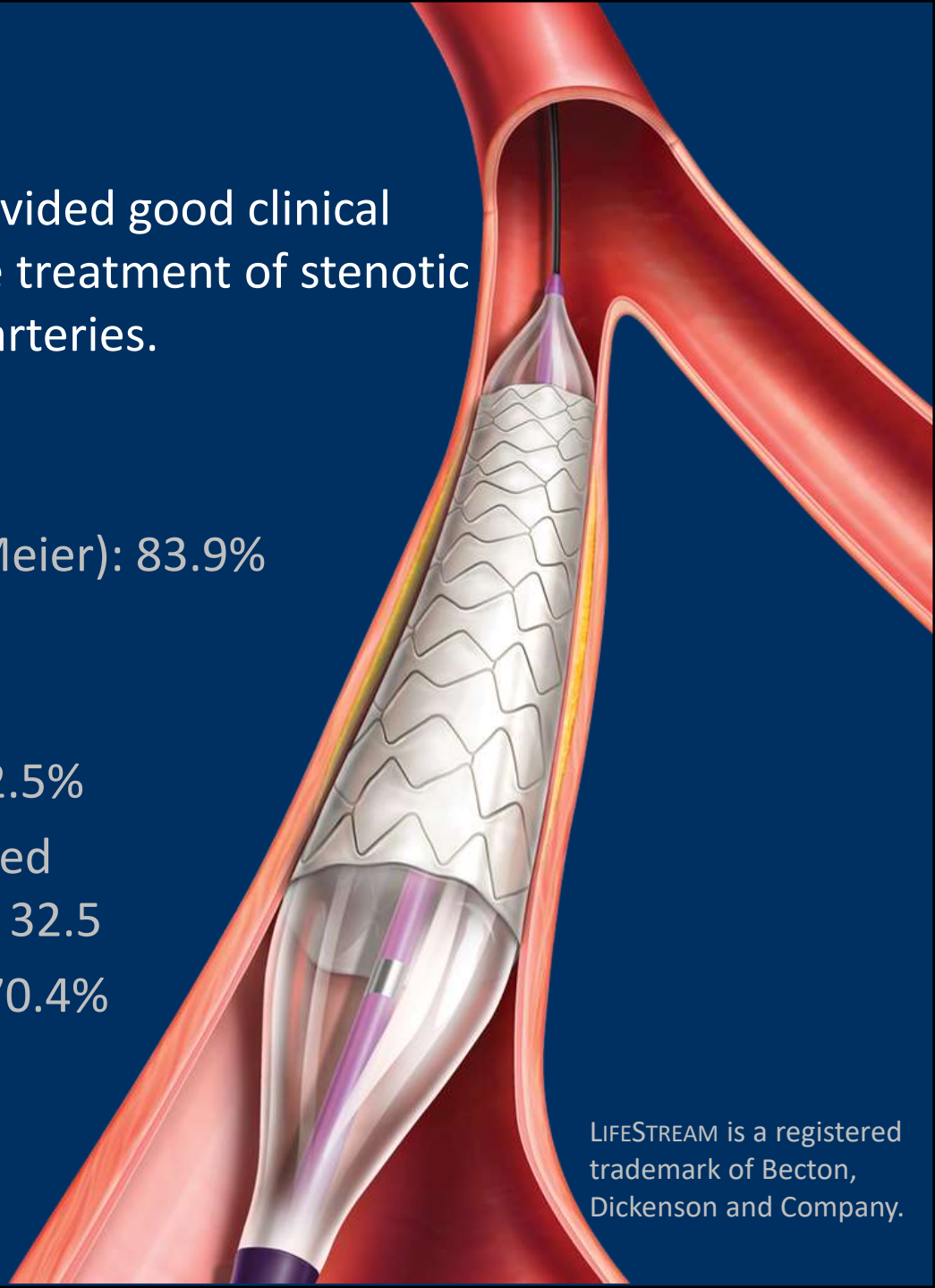
	Baseline	9 Months	12 Months	24 Months	36 Months
ABI Total Value					
N	149	132	130	115	101
Mean (SD)	0.7 (0.2)	0.95 (0.2)	0.92 (0.2)	0.90 (0.2)	0.94 (0.2)
Median	0.7	0.99	0.94	0.91	0.95
Min - Max	0.0 – 1.6	0.4 - 1.5	0.4 - 1.3	0.1 - 1.3	0.3 - 1.5
Change From Baseline					
N		129	126	111	98
Mean (SD)		0.23 (0.3)	0.19 (0.2)	0.18 (0.2)	0.20 (0.3)
Median		0.25	0.22	0.22	0.21
Min - Max		-0.8 - 0.9	-0.6 - 1.0	-0.8 - 0.7	-0.6 - 0.9
Percent Improvement					
≥ 0.10		72.1%	71.4%	65.8%	70.4%
≥ 0.15		65.1%	59.5%	60.4%	62.2%

Summary

The LIFESTREAM Covered Stent provided good clinical outcomes through 3 years for the treatment of stenotic and occlusive lesions of the iliac arteries.

Outcomes Through 36 Months:

- Freedom from TLR (Kaplan-Meier): 83.9%
- Primary Patency: 77.2%
- Secondary Patency: 93.4%
- Sustained Clinical Success: 92.5%
- Quality of Life (WIQ): Sustained improvement in total score of 32.5
- Improvement in ABI $\geq$ 0.10: 70.4%



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A Holden, Auckland University School Medicine/Auckland City Hospital, Auckland, New Zealand	**17 Centers in the USA, Germany, and New Zealand Enrolled 155 Patients**		

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