Study of a Balloon-Expandable Covered Stent for Obstructive Lesions in the Iliac Artery

"First Look" at the 24-Month Results of the BOLSTER Trial

John R. Laird, MD, on behalf of the Investigators

Adventist Heart and Vascular Institute

St. Helena, CA

Disclosure

Speaker name: John R. Laird

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I have the following potential conflicts of interest to report:

- [X] Consulting: Abbott Vascular, Bard Peripheral Vascular, Boston Scientific, Cordis, Medtronic
- [ ] Employment in industry
- [X] Stockholder of a healthcare company: Syntervention, Shockwave, Eximo, Reflow, PQ Bypass
- [ ] Owner of a healthcare company
- [ ] Other(s)

Background

- Balloon expandable covered stents have been shown to be beneficial for complex aortoiliac lesions (bifurcation lesions, TASC C and D lesions)
- Balloon expandable covered stents were shown to be superior to BMS in one randomized trial (COBEST)
- The greatest experience to date has been with the iCAST stent, but Bard LifeStream® and Gore BX Viabahn are new additions to market

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
  - Results compared to a performance goal derived from the literature
- **Objectives:** Assess the LIFESTREAM® Balloon Expandable Vascular 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:** Bard Peripheral Vascular

Investigators & Centers

J. R. Laird, Medical Director, Vascular Center, UC Davis Medical Center, Sacremento, CA, USA	**F. Elmasri,** Radiology & Imaging Specialists, Lakeland, FL. USA	**D. R. Doucet,** Un. Of Massachusetts Memorial Medical Center, Worcester, MA, USA	**R. E. Beasley,** Mount Sinai Medical Center, Miami Beach, FL, USA
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R Schmiedel, Interventionelle Angiologie PRE-Park, Kaiserslautern, Germany	**J Teßarek,** Gefäßchirurgie, Bonifatius Hospital, Lingen, Germany	**D. Scheinert,** Interventionelle Angiologie, Universitätsklinikum Leipzig, Leipzig, Germany	**J Stegemann,** Interventionelle Angiologie, Königin Elisabeth Herzberge, Berlin, Germany
A Holden, Auckland University School Medicine/Auckland City Hospital, Auckland, New Zealand	**17 Centers in the USA, Germany, and New Zealand Enrolled 155 Patients**		

Key Inclusion & Exclusion Criteria

Inclusion:

- Angiographic evidence of a stenosis ≥ 50%, including total occlusions
- Intermittent claudication (Rutherford 2-3) or ischemic rest pain (Rutherford 4)
- Angiographic evidence of flow distal to the lesion – a patent profunda femoris and/or SFA, and at least one patent run-off vessel to the foot
- Total lesions length: ≤ 100 mm (single or multiple lesions)
- Vessel diameter: 4.5 – 12.0 mm

Exclusion:

- Previous bypass surgery or stent placement that involved the target vessel
- Critical limb ischemia resulting in tissue loss (Rutherford Category 5 or 6)
- Treatment requiring the study device to cross or occlude the internal iliac artery (unless the internal iliac artery was already occluded)
- Treatment in the distal external iliac artery that required crossing side branches or extension into the common femoral artery.

Study Device

LIFESTREAM® Balloon Expandable Vascular Covered Stent

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

Radiopaque Markers

- ✓ Covered stent ends are marked on the balloon shaft
- ✓ Designed for accurate placement

Covered Stent Sizes:

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

LIFESTREAM™ Balloon Expandable Covered Stent		Length (mm)			
		16	26	36/37	58
Diameter (mm)	5	N/A	6F		N/A
	6				
	7			7F	
	8				
	9	N/A			
	10			8F	
	12				

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)

Procedural Details

	ITT Group
Mean Time of Procedure, min ± SD	56.8 ± 31.8
Femoral Access, % (n/N)	98.7 (153/155)
Ipsilateral Approach, % (n/N)	53.5 (83/155)
Max Pressure of Balloon Inflation, atm ± SD	9.8 ± 1.9
Final % Diameter Stenosis, % ± SD	11.2 ± 5.8
Location of Covered Stent Placement, % (n/N)	
Single Covered Stent	68.1 (156/229)
"Kissing"	10.5 (24/229)
Tandem/Separate	10.0 (23/229)
Proximal Overlap	5.2 (12/229)
Distal Overlap	6.1 (14/229)

Key Endpoint Definitions

- **Primary Composite Endpoint:** Device and/or procedure-related death or MI through 30 days, or any TLR, major limb amputation, or restenosis through 9 months
- **Technical Success:** Successful deployment of the stent graft as intended
- **Procedure Success**: < 30% residual stenosis (i.e., lesion success) and no peri-procedural complications
- **TLR:** First revascularization procedure at the target lesion
- **Sustained Clinical Success:** Cumulative Rutherford improvement of ≥ 1 category from baseline value
- **Primary Patency:** Freedom from restenosis (> 50%) and/or TLR
- **Quality of Life:** Walking Impairment Questionnaire (WIQ) scores at baseline and follow up
- **MAE:** Device and/or procedure-related death or MI through 30 days, or any TLR or target limb major amputation through 9-months

Results: Primary Analysis (9 Months)

	ITT Group	[95% CI] p- value
Technical Success, % (n/N)	98.3 (226/230 stents)	[95.6, 99.5]
Procedural Success, % (n/N)	97.4 (148/152)	[93.4, 99.3]
Composite Endpoint (Post-Hoc Analysis*)	11.6 (16/138)	[7.0, 17.8]
Major Amputation	0.7 (1/138)	
TLR	4.3 (6/138)	
Restenosis	7.2 (10/138)	
Primary Patency, % (n/N)	89.1 (122/137)	[82.6, 93.7]
Secondary Patency, % (n/N)	91.9 (125/136)	[86.0, 95.9]
Major Adverse Events (MAE), % (n/N)	4.7 (7/150)	[1.9, 9.4]

*Post-hoc analysis: 8 patients that missed their 9-month follow-up were evaluated and deemed patent by the DUS core lab at 12 months; 5 additional patients were deemed patent by the CEC

Interim Results: 24 Months

	ITT Group
Patients Discontinued Prior to 24 Months, % (n/N)	14.2 (22/155)
Percentage of Follow Up at 24 Months, % (n/N)	89.5 (119/133)

TLR Rate Through 24 Months (Proportional Analysis)

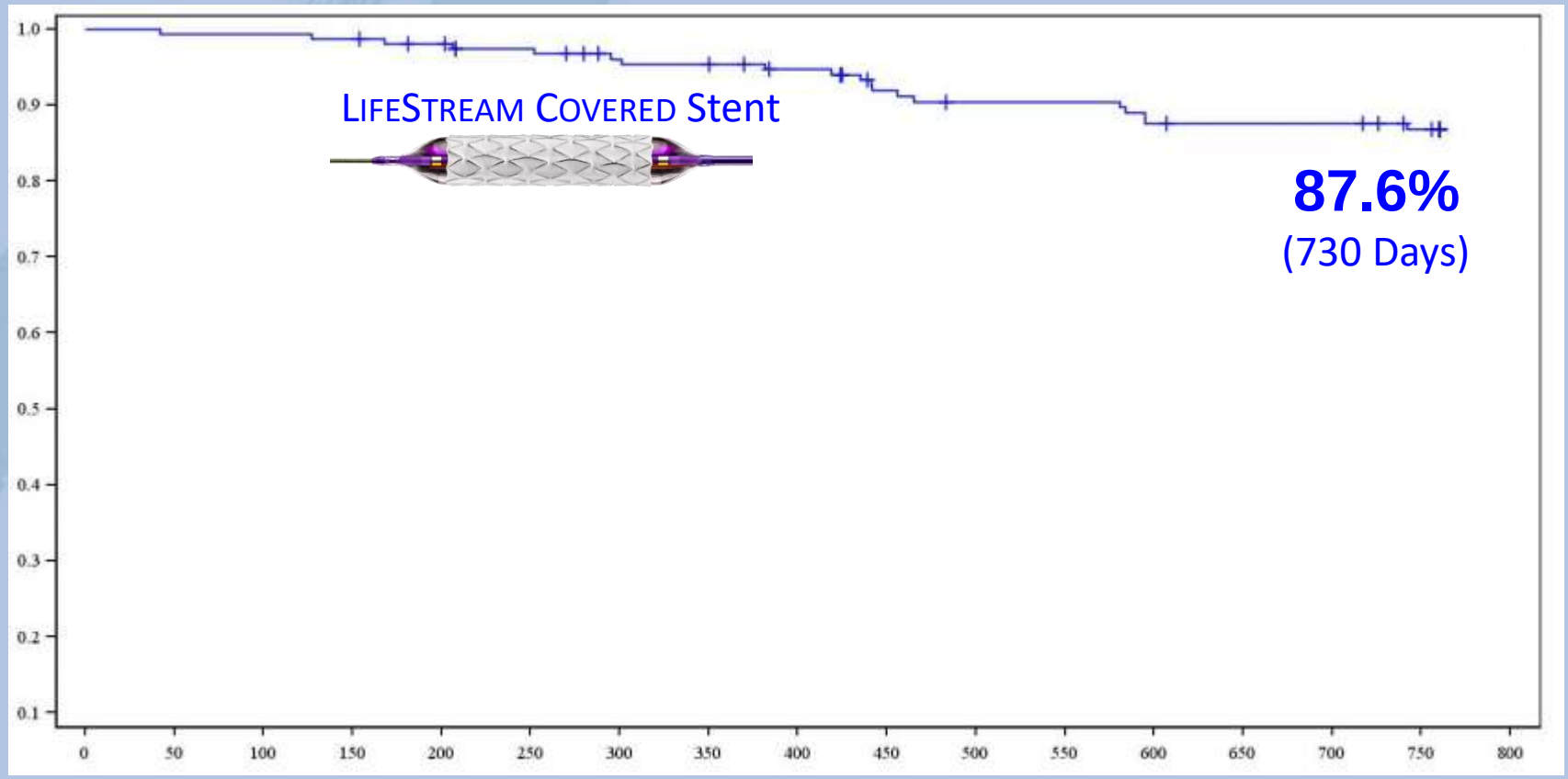
Follow Up, % (n/N)	ITT Group	95% CI^
6 Months	2.6% (4/155)	[0.7%, 6.5%]
9 Months	4.0% (6/150)	[1.5%, 8.5%]
12 Months	5.5% (8/146)	[2.4%, 10.5%]
24 Months	14.2% (19/134)+	[8.8%, 21.3%]

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 24 months (denominator: number of evaluable patients at a given follow-up time point)

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 180	1	3	151	1.9%	(0.6% , 5.9%)
Day 270	6	5	144	3.3%	(1.4% , 7.7%)
Day 300	8	6	141	3.9%	(1.8% , 8.6%)
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%)

Results: Sustained Clinical Success

A cumulative improvement ≥ 1 category from baseline Rutherford values was sustained through 24 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	90.5% (105/116)+	[83.7%, 95.2%]

^95% CI is estimated by the exact binomial method

+Proportional analysis through 24 months (denominator: number of evaluable patients at a given follow-up time point)

Results: Quality of Life

Patient Quality of Life, assessed by the Walking Impairment Questionnaire, improved from baseline to 30 Days by just over 31 points, a difference sustained through Two Years (31.4 ± 26.9)

	Baseline	30 Days	9 Months	12 Months	24 Months
WIQ Total Score					
N	153	150	135	132	117
Mean (SD)	32.0 (18.03)	63.6 (25.49)	64.7 (28.12)	65.7 (28.23)	64.9 (28.63)
Median	28.4	66.7	72.4	75.0	68.8
Min - Max	0.0 - 96.9	0.0 - 100.0	0.1 - 100.0	0.1 - 100.0	0.2 - 100.0
Change From Baseline					
N		148	134	130	116
Mean (SD)		31.4 (25.23)	32.1 (26.84)	32.8 (26.75)	31.4 (26.85)
Median		30.0	34.0	34.9	30.9
Min - Max		-56.6 - 97.1	-45.3 - 94.8	-34.6 - 82.3	-28.8 - 78.2

Summary

Acute Outcomes: The LIFESTREAM® Balloon Expandable Vascular Covered Stent was successfully deployed in 98.3% of cases, with a procedural success rate of 97.4%

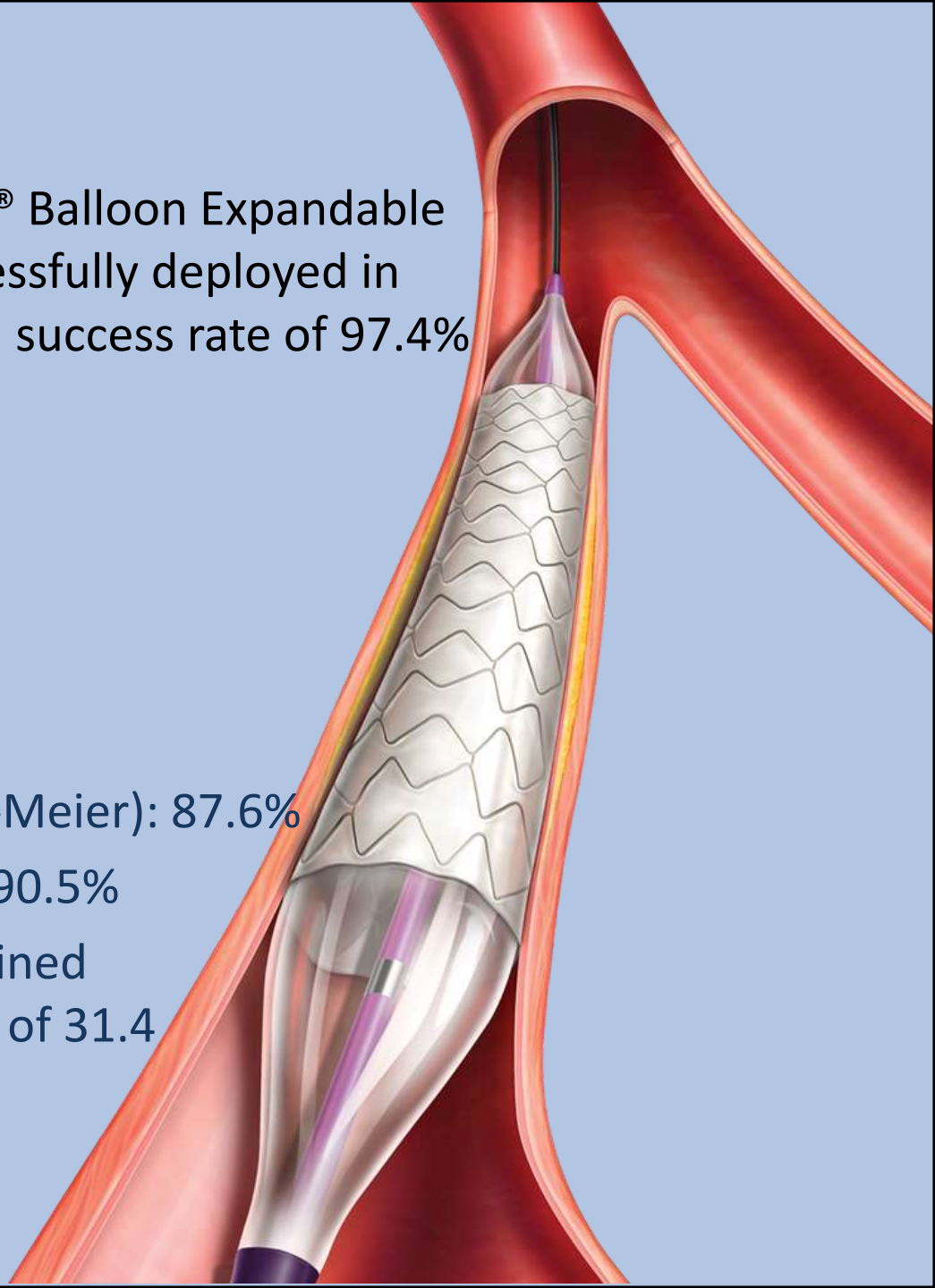
Results at 9 Months:

- Primary Patency: 89.1%
- Secondary Patency: 91.9%
- MAE Rate: 4.7%

Outcomes Through 24 Months:

- Freedom from TLR (Kaplan-Meier): 87.6%
- Sustained Clinical Success: 90.5%
- Quality of Life (WIQ): Sustained improvement in total score of 31.4

BOLSTER is ongoing with DUS imaging through 3 years



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