IN.PACT Global Study 3-Year Outcomes for Stented vs Non-Stented Lesions

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Disclosure

Thomas Zeller, MD:

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For the 12 months preceding this presentation, I disclose the following types of financial relationships:

- **Honoraria received from:** Abbott Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Philips-Spectranetics, TriReme, Shockwave
- **Consulted for:** Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Spectranetics, Veryan, Intact Vascular, B. Braun, Shockwave, Bayer, Vesper Medical
- **Research, clinical trial, or drug study funds received from (institution):** 480 biomedical, Bard Peripheral Vascular, Veryan, Biotronik, Cook Medical, Gore & Associates, Medtronic, Philips, Terumo, TriReme, Shockwave, Med Alliance, Intact Vascular, B. Braun
- **Common stock:** QT Medical

Background

- Bare metal stents (BMS) studies in the SFA demonstrate improved outcomes over PTA but longer lesion length is a predictor of lower patency at 12 months (35-65%)[1-2] and is associated with higher stent fractures[3,4]
- The clinical evidence for real-world Global DCB studies has expanded, however bailout stent rates in complex lesions remain notable[5-10]
- As previously reported, the IN.PACT global study outcomes elucidated the IN.PACT Admiral DCB can be safely followed by a provisional BMS with sustained freedom from CD-TLR through 1 and 2 years[11] however, longer term data is needed

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2. Bosiers M et al. J Vasc Surg 2011;54:1042-50.
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4. Laird J, et al. Circ Cardiovasc Interv3:267-76 (2010
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9. Micari A, et al. JACC-CI. 2018;11:945-953
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IN.PACT Global Study: Overview

Real-world, prospective, multicenter, single arm independently-adjudicated femoropopliteal study

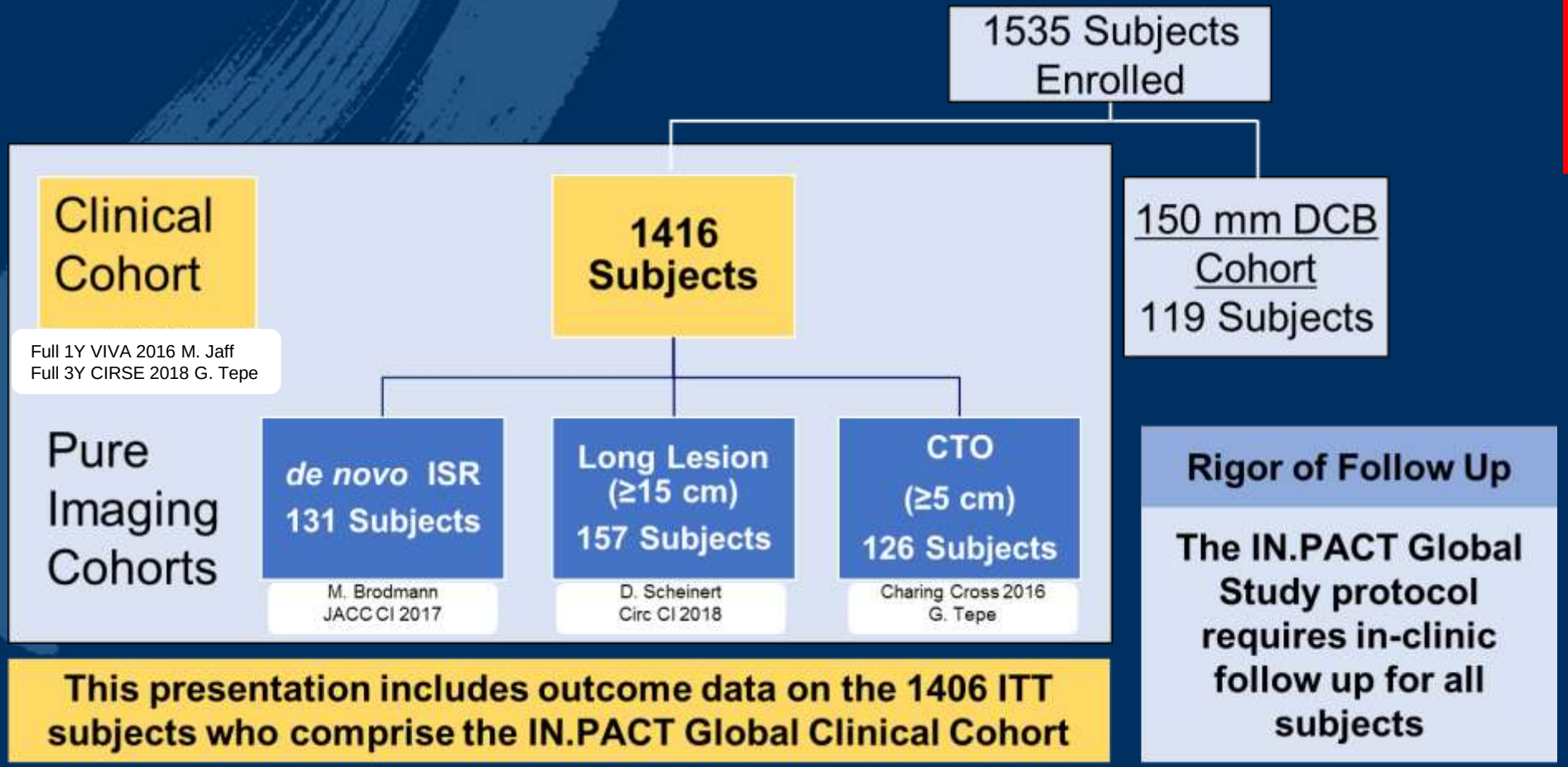
All-comers (RCC 2-4)

- ☑ Bilateral disease
- ☑ Multiple lesions
- ☑ SFA and Popliteal
- ☑ TASC A, B, C, D
- ☑ De novo ISR
- ☑ Long Lesions
- ☑ CTOs

- **1535 patients enrolled**
- **64 sites** in EU, Mid-East, Latin America, Asia
- **Independent adjudication by Clinical Events Committee** [1]
- **Prospective subset analysis with core lab**[2,3] **reported results**
  (de novo ISR, long lesions ≥15 cm, CTOs ≥5 cm)
- **Safety and effectiveness data on 150 mm DCB**

1. Syntactx Clinical Events Committee, New York, NY, US
2. VasCore DUS Core Lab, Boston, MA, US
3. SynvaCor Angiographic Core Lab, Springfield, IL, US

IN.PACT Global Study Architecture



IN.PACT Global Study

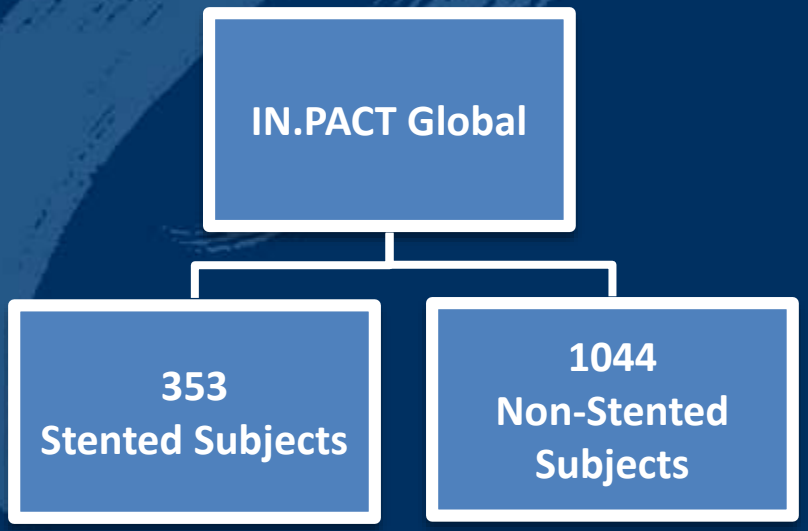
Primary Endpoints

Primary Efficacy Endpoint	➓ Freedom from clinically-driven Target Lesion Revascularization[1] within 12 months
Primary Safety Endpoint	➓ Freedom from device- and procedure-related death through 30 days, and freedom from target limb major amputation & clinically-driven TVR

1. Any re-intervention within the target lesion(s) due to symptoms or drop of ABI of ≥ 20% or > 0.15 when compared to post-index procedure baseline ABI.

IN.PACT Global Study: Stented vs Non-Stented Analysis

Purpose: To compare outcomes of standalone IN.PACT™ Admiral™ DCB usage versus IN.PACT™ Admiral™ DCB followed by provisional stenting



25.3%
Provisional stent rate

Reason for Provisional Stenting* (N=455 Lesions)	
Persistent Residual Stenosis ≥ 50%	59.2% (221/373)
>10 mmHg Trans Lesion Gradient	0.5% (2/373)
Flow-Limiting Dissection	53.6% (200/373)
Other	5.1% (19/373)

* Data presented are lesion based

IN.PACT Global Study: Stented vs Non-Stented Analysis

Baseline Characteristics

Baseline Characteristics	IN.PACT DCB Stented (N=353 Subjects)	IN.PACT DCB Non-Stented (N=1044 Subjects)	p-value (Stented vs Non-Stented)
Age (Y, Mean ± SD)	67.8 ± 10.3	68.8 ± 10.0	0.122
Male (%)	71.1% (251/353)	66.7% (696/1044)	0.130
Diabetes (%)	36.0% (127/353)	41.0% (426/1040)	0.102
Hypertension (%)	84.7% (299/353)	83.1% (863/1039)	0.508
Hyperlipidemia (%)	68.8% (238/346)	70.9% (715/1008)	0.454
Current Smoker (%)	32.0% (113/353)	31.8% (332/1044)	0.947
Obesity (BMI ≥ 30 kg/m^2(%)	21.1% (74/351)	20.4% (210/1031)	0.760
Coronary Heart Disease (%)	37.2% (128/344)	41.6% (408/980)	0.160
Carotid Artery Disease (%)	15.9% (49/308)	21.6% (190/880)	0.032
Renal Insufficiency[1] (%)	10.6% (32/302)	11.4% (103/906)	0.753
Previous Peripheral Revas (%)	46.5% (164/353)	54.7% (571/1044)	0.008
ABI[2] (Mean ± SD)	0.643 ± 0.215	0.691 ± 0.217	< 0.001

1. Baseline serum creatinine ≥ 1.5 mg/dl
2. ABI for all target limbs treated during the 1st index procedure are included (can be bilateral)

IN.PACT Global Study: Stented vs Non-Stented Analysis

Baseline Lesion Characteristics*

Baseline Lesion Characteristics	IN.PACT DCB Stented (N=353 Subjects) (N=455 Lesions)	IN.PACT DCB Non-Stented (N=1044 Subjects) (N=1306 Lesions)	p-value (Stented vs Non-Stented)
Lesion Length (cm ± SD)	**15.37 ± 10.68**	**10.97 ± 8.83**	< 0.001
Total Occlusions % (n)	54.7% (249/455)	28.6% (373/1306)	< 0.001
Occluded Lesion Length (cm ± SD)	7.93 ± 10.46	3.33 ± 7.40	< 0.001
Calcification % (n) **Severe [1] % (n)**	73.8% (336/455) 14.7% (67/455)	66.7% (870/1304) 8.7% (113/1304)	0.005 < 0.001
RVD (mm ± SD)	5.209 ± 0.651	5.187 ± 0.687	0.540
Diameter Stenosis (% ± SD)	92.1 ± 11.6	87.6 ± 12.3	< 0.001

1. Severe calcium definition used by study sites and core laboratory is bilateral calcium at the same location (also measured in sections), ≥ half of the total lesion length, ≥180◦ (both sides of the vessel at the same location). Dattilo, R; J Invasive Cardiol 2014;26(8):355360

*Site reported

IN.PACT Global Study: Stented vs Non-Stented Analysis

Procedural Characteristics*

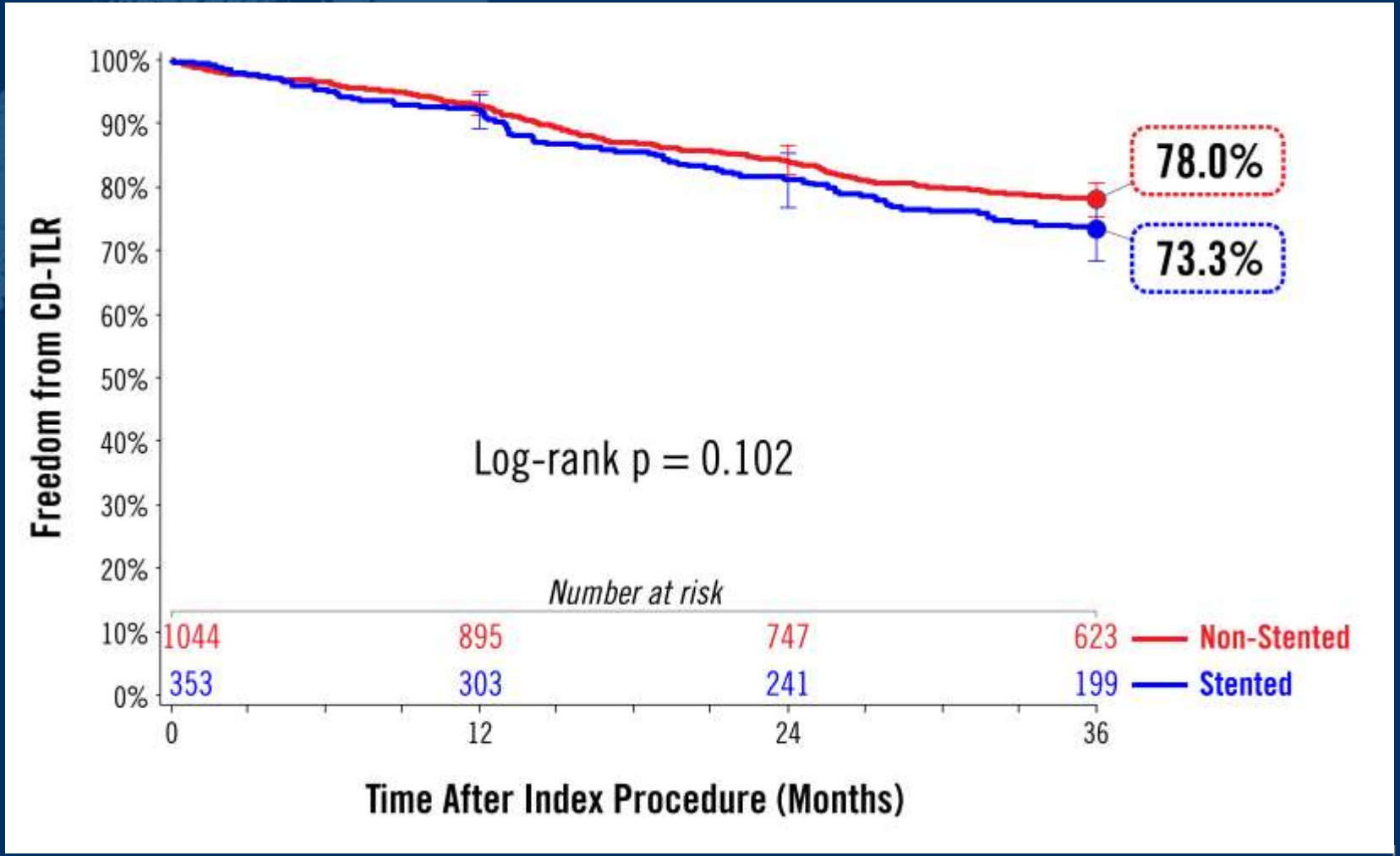
Procedural Characteristics	IN.PACT DCB Stented (N=353 Subjects) (N=455 Lesions)	IN.PACT DCB Non-Stented (N=1044 Subjects) (N=1306 Lesions)	p-value (Stented vs Non-Stented)
Device Success[1] % (n)	99.3% (911/917)	99.4% (2053/2065)	0.801
Procedure Success[2] % (n)	97.5% (344/353)	99.9% (1042/1043)	< 0.001
Clinical Success[3] % (n)	96.9% (342/353)	99.4% (1037/1043)	0.001
Pre-dilatation % (n) **Post-dilatation[4] % (n)**	90.4% (319/353) 60.1% (212/353)	73.7% (769/1044) 26.7% (279/1044)	< 0.001 < 0.001
Dissections: **D** **E** **F**	 12.3% (56/455) 9.5% (43/455) 2.4% (11/455)	 1.7% (22/1305) 0.5% (7/1305) 0.0% (0/1305)	< 0.001
Stent Coverage Spot Stenting Partial Lesion Coverage Whole Lesion Coverage	 24.4% (91/373) 37.8% (141/373) 37.8% (141/373)	N/A	N/A

1. Device success defined as successful delivery, inflation, deflation and retrieval of the intact study balloon device without burst below the RBP.
2. Procedure success defined as residual stenosis of ≤ 50% (non-stented subjects) or ≤ 30% (stented subjects)
3. Clinical success defined as procedural success without procedural complications (death, major target limb amputation, thrombosis of the target lesion, or TVR) prior to discharge.
4. Post-dilatation is not required and is performed at the discretion of the investigator. In the event a post-dilatation is performed, it must be done with a balloon shorter than the lesion length to avoid geographic miss when initial DEB dilatation results in any of the following: Residual stenosis ≥ 50% (by visual estimate); Trans-lesional gradient is >10 mm Hg; Presence of a flow-limiting dissection.

* Site reported

IN.PACT Global Study: Stented vs Non-Stented Analysis

Freedom from CD-TLR Through 3 Years



IN.PACT Global Study: Stented vs Non-Stented Analysis

Additional Effectiveness Outcomes Through 3 Years

3 Year Outcomes	IN.PACT DCB Stented (N=353 Subjects)	IN.PACT DCB Non-Stented (N=1044 Subjects)	p-value (Stented vs Non-Stented)
CD-TLR[1]	**27.3% (84/308)**	**22.5% (205/913)**	**0.089**
Any TLR[2]	27.9% (86/308)	22.9% (209/913)	0.077
Time to first CD-TLR (days)	484.8 ± 293.6	471.7 ± 284.3	0.723

1. Clinically-driven TLR adjudicated by an independent Clinical Event Committee, blinded to the assigned treatment based on any re-intervention at the target lesion due to symptoms or drop of ABI of ≥20% or >0.15 when compared to post-procedure baseline ABI
2. Any TLR includes clinically-driven and incidental or duplex driven TLR

IN.PACT Global Study: Stented vs Non-Stented Analysis

Safety Outcomes Through 3 Years

3 Year Outcomes	IN.PACT DCB Stented (N=353 Subjects)	IN.PACT DCB Non-Stented (N=1044 Subjects)	p-value (Stented vs Non-Stented)
Primary Safety Composite[1]	71.4% (220/308)	76.1% (695/913)	0.110
Major Adverse Events[2]	36.4% (112/308)	31.5% (288/913)	0.123
All-cause Death	7.8% (24/308)	8.3% (76/913)	0.811
CD-TVR	27.9% (86/308)	23.3% (213/913)	0.108
Major Target Limb Amputation	1.0% (3/308)	0.7% (6/913)	0.700
Thrombosis	6.8% (21/308)	5.4% (49/913)	0.395

1. Safety composite endpoint consists of: Freedom from device- and procedure-related to 30 days, freedom from target limb amputation within 36 months; and freedom from clinically-driven TLR within 36 months.
2. Major Adverse Events (MAE) defined as all-cause death, clinically-driven TVR, major target limb amputation, thrombosis at the target lesion site at 1080 days

IN.PACT Global Study: Stented vs Non-Stented Analysis through 3 Years

Summary

- The stented versus non-stented analysis from the IN.PACT Global study provides durable evidence of safety and effectiveness for the IN.PACT™ Admiral™ DCB in this complex lesion subset
- Following sub-optimal balloon results (i.e. residual stenosis >50%, flow limiting dissection), the IN.PACT Admiral DCB followed by a provisional bare metal stent has shown similar outcomes through 3 years compared to DCB alone

3-Year Outcomes	Stented Lesions (DCB + prov. BMS)	Non-stented Lesions (DCB alone)	P-value
CD-TLR[1]	27.3%	22.5%	0.089
Primary Safety	71.4%	76.1%	0.110

- Mortality rates in this DCB cohort (7.8% Stented and 8.3% Non-stented) are in line with spontaneous death rates reported in other PAD epidemiological studies.

Thank You!

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