1 Year Outcomes of DCB use in femoropopliteal lesions for patients with CLI (RCC 4-5): Subgroup analysis of the IN.PACT Global Study

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ✓ I do not have any potential conflict of interest with regard to this presentation

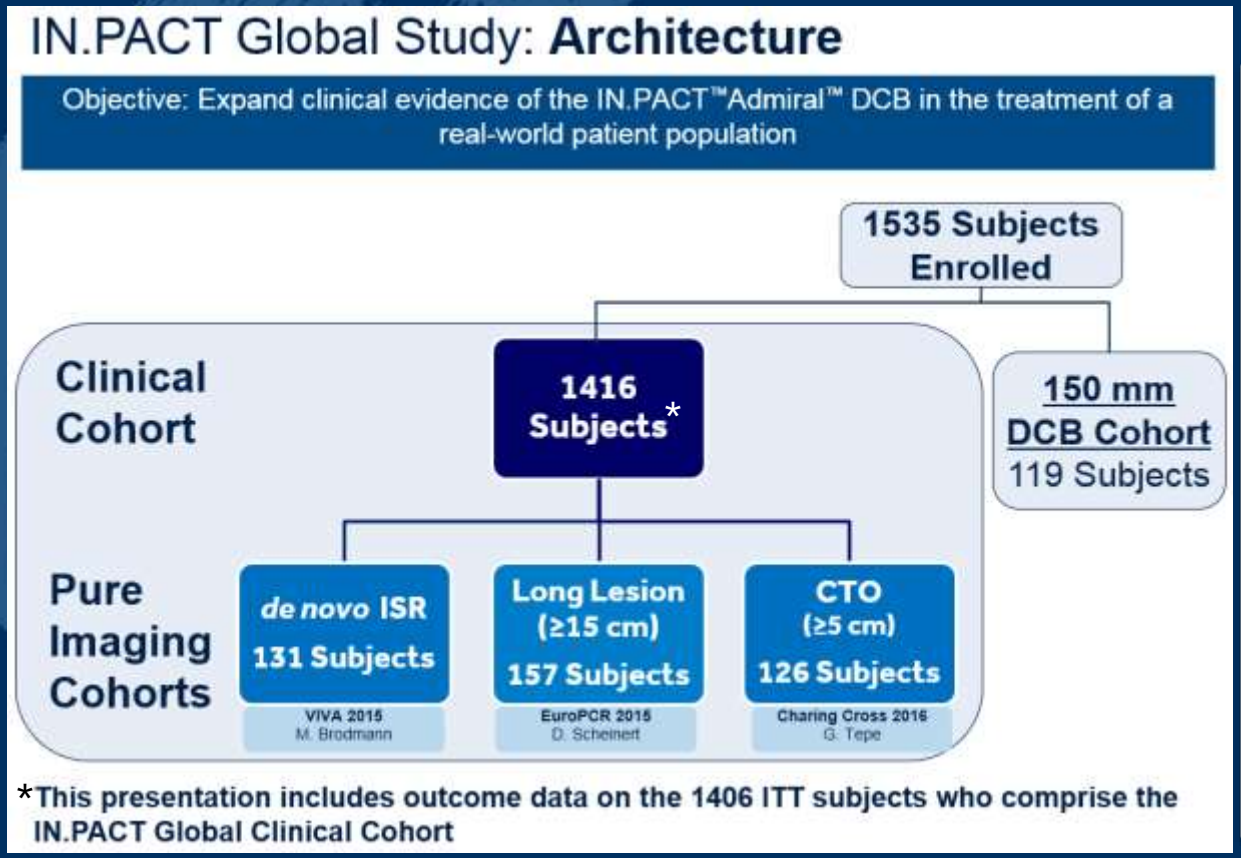
Background

- CLI, the most advanced stage of PAD, may lead to amputation affecting QOL. Without revascularization the amputation risk is >20%[1].
- Endovascular-first strategy is not yet generally recommended, but increasingly performed in CLI.
- Global registries are examining evidence with DCBs in real-world populations[2,3], however more data in complex CLI patients is needed.
- Most study designs combine claudication with CLI and additionally the CLI numbers are small.

1. Abu Dabrh, A.M. et.al. J Vasc Surg 2015
2. Jaff M. IN.PACT Global 1 Year Results, presented at VIVA 2016
3. Zeller T. ILLUMENATE Global 1Year Results, presented at LINC 2017

IN.PACT Global Study Overview†

Real-world, prospective, multicenter, single arm independently-adjudicated[1-3] femoropopliteal study



All-comers

- ✓ Bilateral disease
- ✓ Multiple lesions
- ✓ SFA and Popliteal Artery
- ✓ TASC A, B, C, D
- ✓ RCC 2-4
- ✓ De novo ISR
- ✓ Long Lesions
- ✓ CTOs

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

†Sponsored by Medtronic plc

IN.PACT Global Study
Endpoints

Primary Efficacy Endpoint: Freedom from clinically-driven target lesion revascularization[1] within 12 months

Primary Safety Endpoint: Freedom from device- and procedure-related death through 30 days, and freedom from target limb major amputation and clinically-driven target vessel revascularization within 12 months

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.

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Baseline Demographics for RCC 4-5 Cohort

	RCC 4-5 (N=156 Subjects)
Age (Y, Mean ± SD)	71.8 ± 10.4
Male (%)	55.8% (87/156)
Obesity (BMI ≥ 30 kg/m^2 %)	18.4% (28/152)
Diabetes (%)	54.5% (85/156)
Hyperlipidemia (%)	62.3% (96/154)
Current Smoker (%)	22.4% (35/156)
Hypertension (%)	85.3% (133/156)
Coronary Heart Disease (%)	44.0% (62/141)
Carotid Artery Disease (%)	17.8% (21/118)
Renal Insufficiency[1] (%)	20.1% (28/139)
ABI[2]	0.60 ± 0.26

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)

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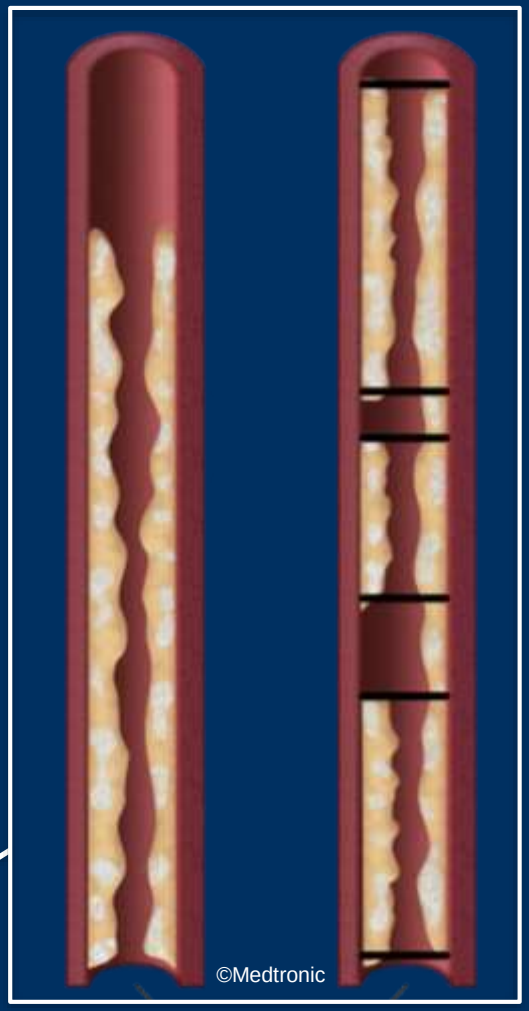
Baseline Lesion Characteristics for RCC 4-5 Cohort

	RCC 4 and 5 (N=156 Subjects) (N=194 lesions)
Lesion (N)	
De novo	74.2% (144/194)
Restenotic (non-stented)	8.8% (17/194)
In-Stent Restenosis	17.0% (33/194)
Lesion Length (cm)	13.94 ± 10.55
Total Occlusions (%)	41.2% (80/194)
Calcification (%)	76.8% (149/194)
Severe Calcification[1] (%)	11.3% (22/194)

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



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Baseline Procedural Characteristics for RCC 4-5 Cohort

	RCC 4 and 5 (N=156 Subjects) (N=194 lesions)
Pre-dilatation (%)	75.0% (117/156)
Post-dilatation (%)	34.4% (53/154)
Flow Limiting Dissections (%) D E F	 2.6% (5/194) 1.0% (2/194) 1.5% (3/194)
Prov. Stenting (%)	23.4% (36/154)
Device Success (%)[1]	99.7% (352/353)
Procedural Success (%)[2]	100.0% (154/154)
Clinical Success (%)[3]	98.7% (152/154)

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) by core lab (if core lab was not available then the site-reported estimate was used).
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.

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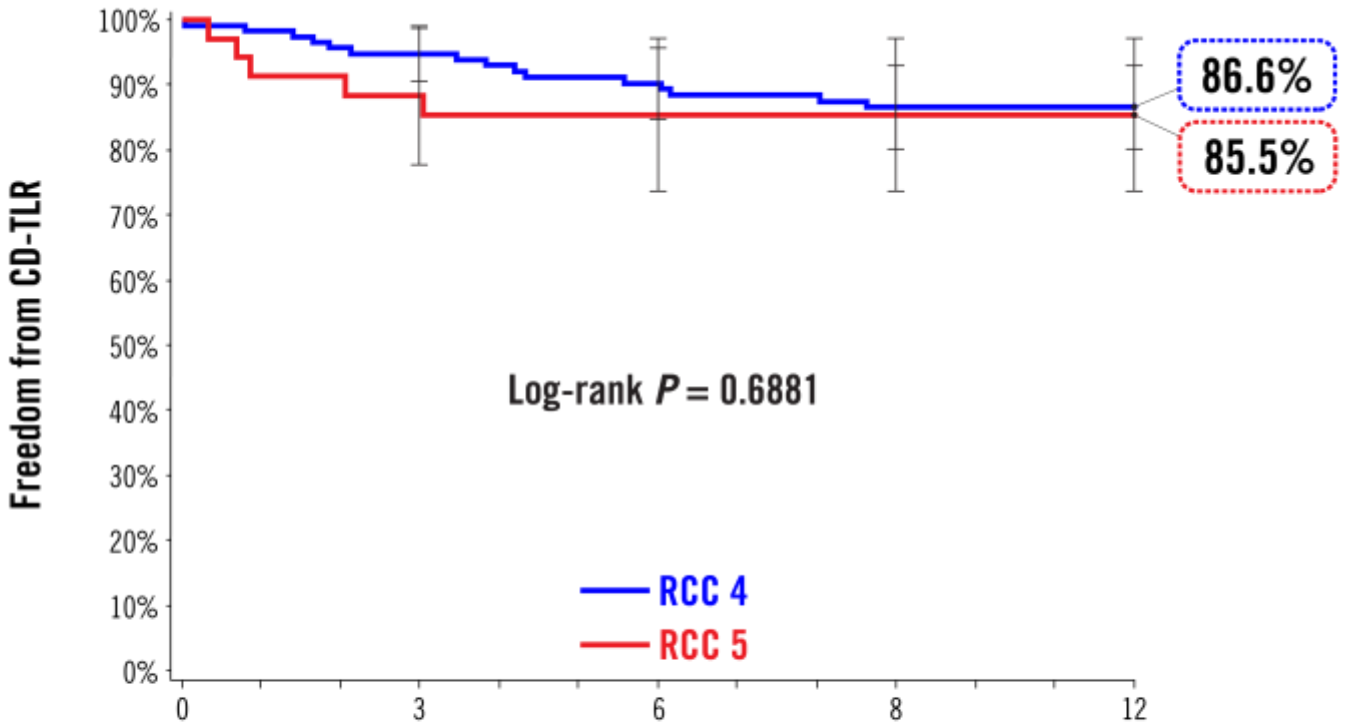
Effectiveness Outcomes for RCC 4-5 Cohort

Freedom from CD-TLR through 1 Year



Number at risk[1]

RCC 4	120	102	91
RCC 5	36	28	22

1. Number at risk represents the number of evaluable subjects at the beginning of the each 30-day window

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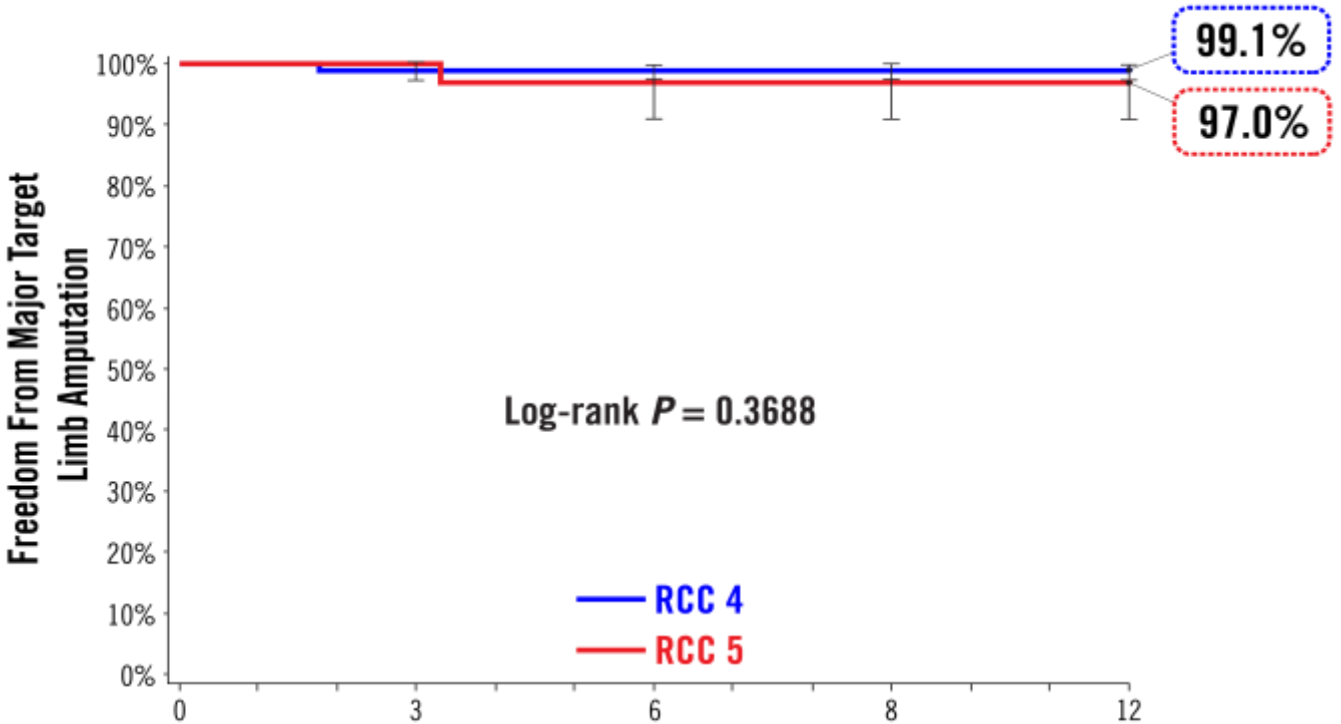
Limb Salvage Outcomes for RCC 4-5 Cohort

RCC 4-5 Cohort Through 1 Year



Number at risk[1]

RCC 4	120	109	101
RCC 5	36	31	24

1. Number at risk represents the number of evaluable subjects at the beginning of the each 30-day window

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Additional Effectiveness Outcomes for RCC 4-5 through 1 Year

Additional Effectiveness Outcomes: RCC 4-5 through 1 Year	
	RCC 4-5 (N=156 Subjects)
CD-TLR[1]	14.1% (20/142)
Any TLR[2]	14.1% (20/142)
Time to First CD-TLR within 360 days ± SD	97.8 ± 76.5

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

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Safety Outcomes for RCC 4-5 through 1 Year

	RCC 4 and 5 (N=156 Subjects)
Primary Safety Composite[1]	83.1% (118/142)
Major Adverse Events[2]	22.5% (32/142)
All-cause Death	7.0% (10/142)
Device- or Procedure-related Death though 30 days[3]	0.6% (1/154)
CD-TVR	14.8% (21/142)
Major Target Limb Amputation	1.4% (2/142)
Thrombosis	4.9% (7/142)

1. Safety composite endpoint consists of: Freedom from device- and procedure-related to 30 days, freedom from target limb amputation within 12 months; and freedom from clinically-driven TVR within 12 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 360 days.
3. The CEC MOP states that any event that occurs 30 days or less after the index procedure or after any secondary procedure will always be considered to be procedure-related, but may also be device- or drug-related.

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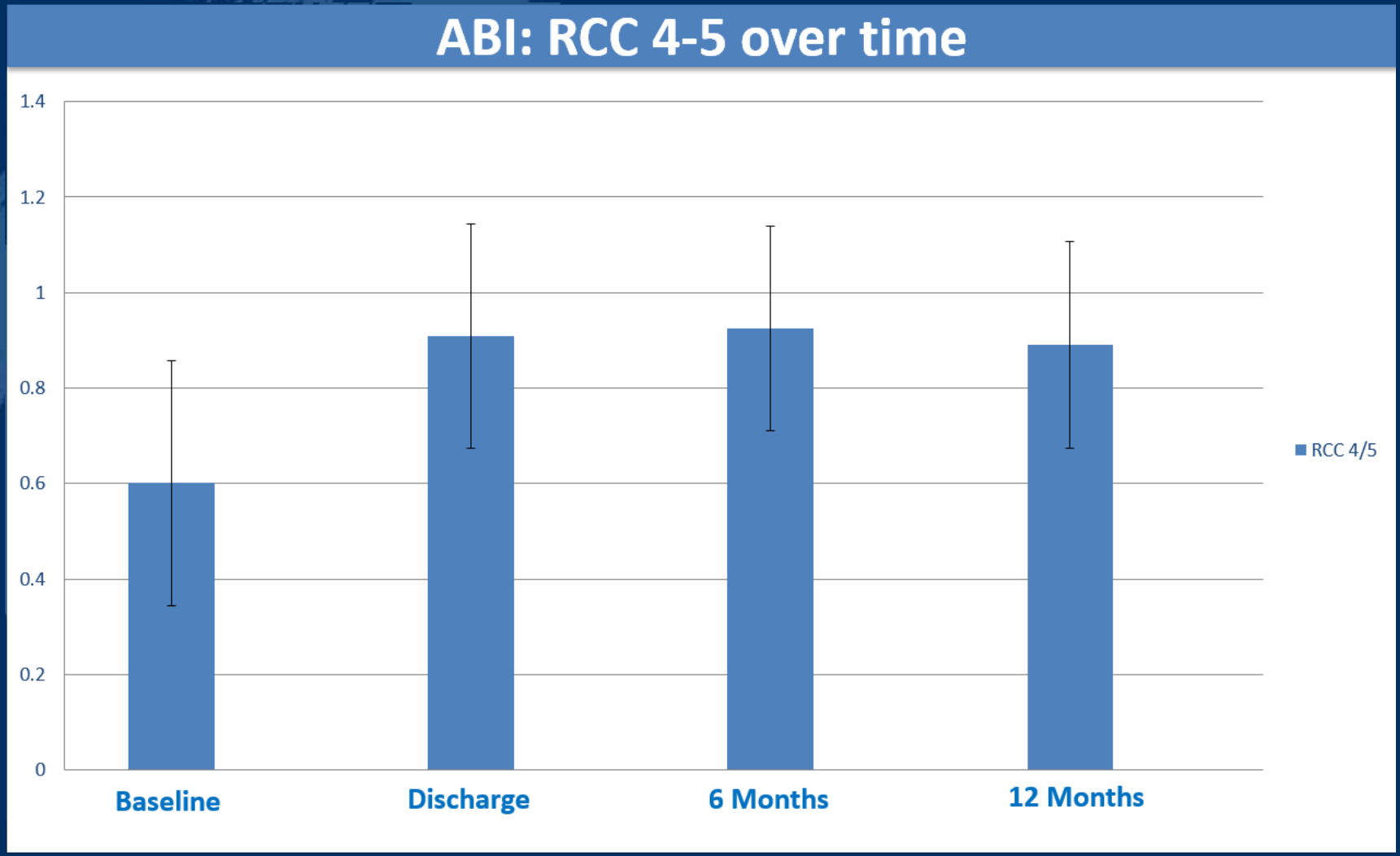
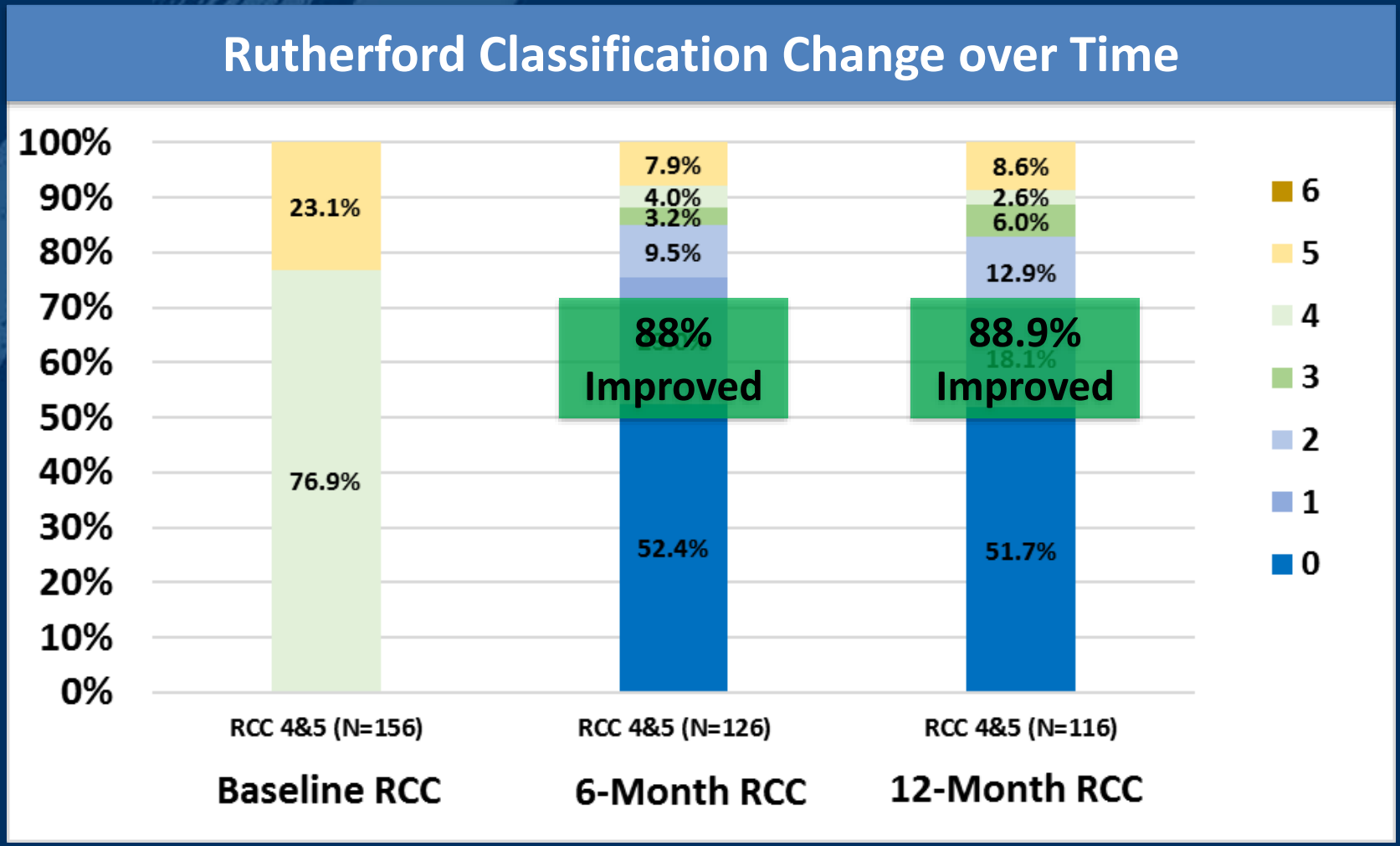
Clinical Outcomes for RCC 4-5 through 1 Year



IN.PACT Global Study
Clinical Outcomes for RCC 4-5 through 1 Year



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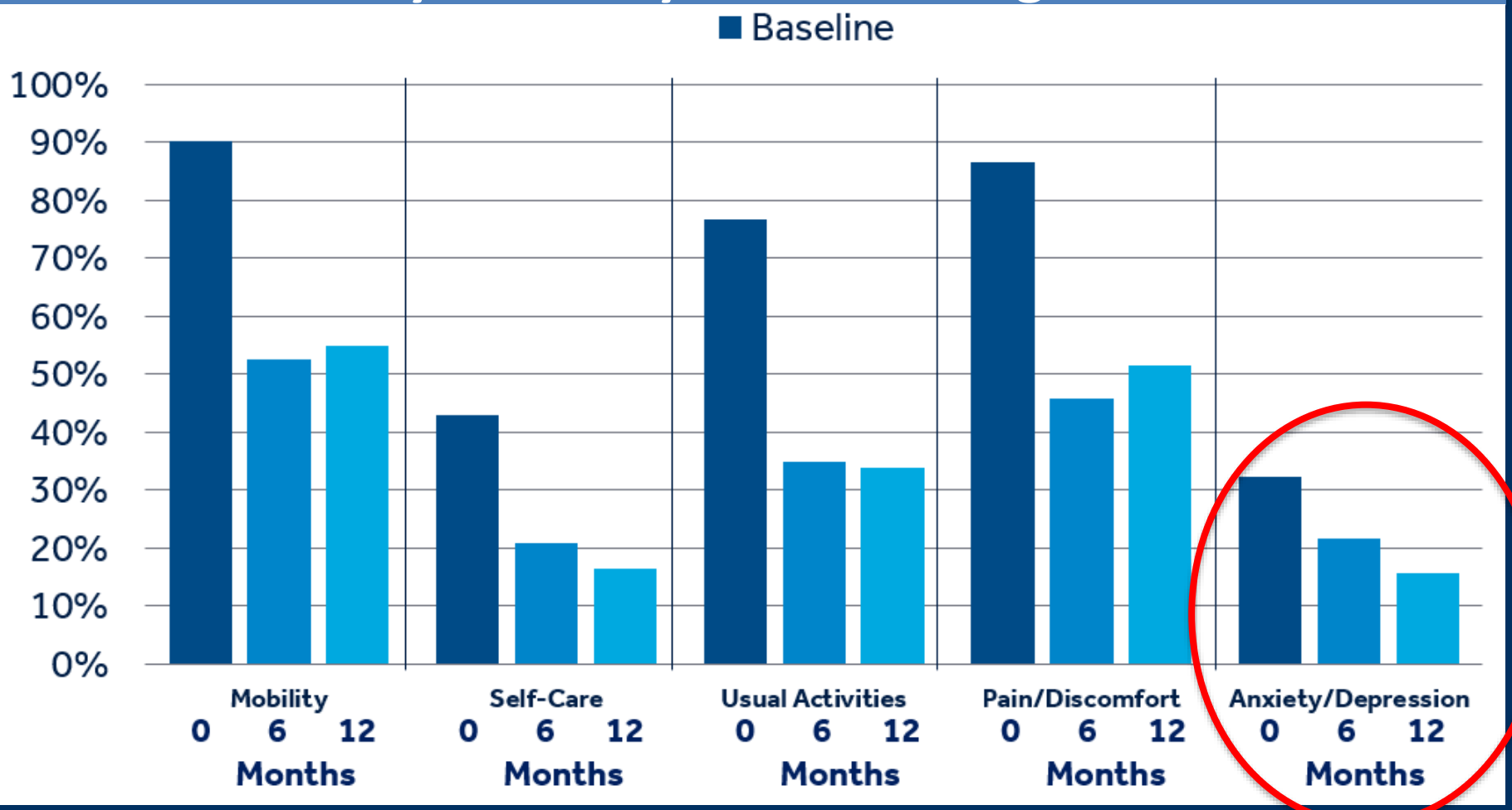
Functional Outcomes for RCC 4-5 Cohort

Quality of Life by EQ-5D through 1 Year



Summary of the IN.PACT Global Study: RCC 4-5 sub analysis

- This analysis included 156 subjects with RCC 4-5 allowing for a robust examination of a CLI population in this real world study
- Remarkable effectiveness is demonstrated in this CLI cohort through 1 year
  - Freedom from CD-TLR 86.6% (RCC 4)
  - Freedom from CD-TLR 85.5% (RCC 5)
- Outstanding limb salvage is demonstrated in this clinically complex patient subset
  - Freedom from amputation rate of 99.1% (RCC 4)
  - Freedom from amputation rate of 97% (RCC 5)
- Data confirms strong performance of the IN.PACT™ Admiral™ DCB in this CLI cohort
- Limitation; only limited number of patients with RCC 5 and no RCC 6

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