

# Intermediate-Term (24-Month) Results of the TRANSCEND Study

Comparing a Next-Generation Paclitaxel Drug-Coated Balloon (SurVeil™ DCB) to  
IN.PACT® Admiral® DCB in the Treatment of Femoropopliteal Artery Disease

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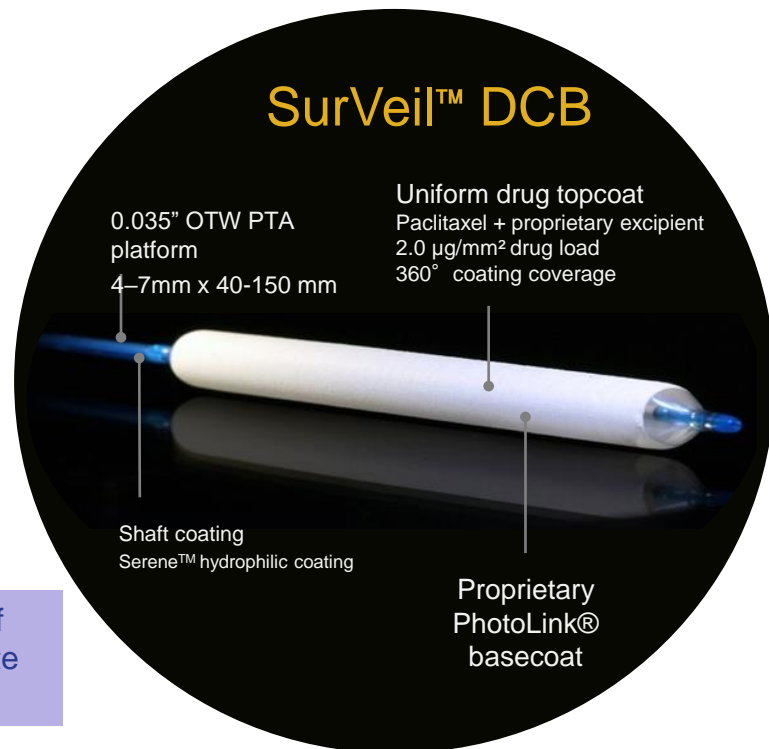


# SURVEIL™ DCB – Next Generation DCB

## Next-generation DCB – Intent

- **Higher Efficacy:** To develop a device that could improve the therapeutic window by achieving therapeutic outcomes equivalent to high-dose technologies and with lower potential for complications.
- **Lower Dose:** Technology goal was a lower Paclitaxel drug dose of 2.0 µg/mm<sup>2</sup>, more uniform drug distribution, better efficiency of drug transfer, and fewer downstream emboli
- **Comparable Clinical Results:** To demonstrate this with a well-designed, well conducted head-to-head pivotal trial versus a high-dose device

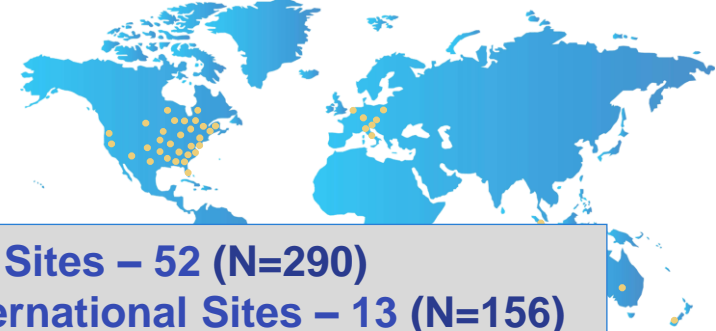
**THESIS:** If a DCB can achieve similar clinical outcomes with a lower dose of drug as demonstrated in a head-to-head RCT then it would advance the state of the art and could provide a better therapeutic choice



# TRANSCEND Study Overview

- **Prospective, multicenter, international, randomized, single-blind trial of Surveil™ DCB versus IN.PACT® Admiral® DCB (1:1)**
- **446 subjects randomized**
  - **SurVeil (N=222) & IN.PACT ADMIRAL (N=224)**
  - **Follow-up through 60 months**
- **Independent / blinded: DUS and Angiographic Core Labs, Clinical Events Committee**
- **Hypotheses test: Non-inferiority (15% NI Margin for efficacy and 10% for safety)**
  - **Sensitivity Analysis-Complete Case**
  - **Primary Analysis-Multiple Imputation**

## GLOBAL SITE PARTICIPATION



**US Sites – 52 (N=290)**  
**International Sites – 13 (N=156)**

## PRINCIPAL INVESTIGATORS

Kenneth Rosenfield, MD  
Marianne Brodmann, MD  
William Gray, MD

**TRIAL DESIGN, BIostatISTICS, DSMB, CEC**  
Baim Institute

## TRIAL OPERATIONS

Medpass and Mobius (OUS); Clinlogix (US)

# KEY ELIGIBILITY AND PRIMARY ENDPOINTS

- **KEY ELIGIBILITY**

- Target limb Rutherford Class 2, 3, or 4
- De Novo or non-stented restenotic lesion
- Target lesion: length  $\leq$  180 mm; diameter  $\geq$  4mm &  $\leq$  7mm; stenosis  $\geq$  70% by visual estimate

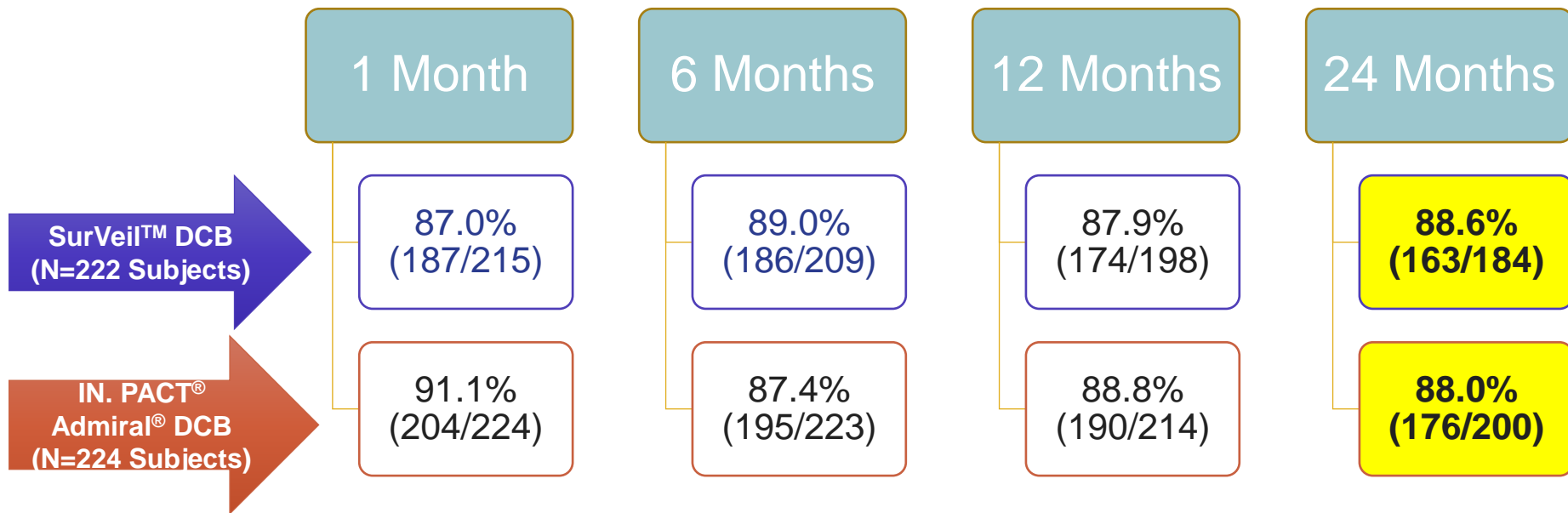
- **PRIMARY SAFETY ENDPOINT (COMPOSITE)**

- Freedom from device- and procedure-related death through 30 days post-index procedure
- Freedom from major target limb amputation (above the ankle)
- Clinically-driven target vessel revascularization (CD-TVR) through 12 months post-index procedure

- **PRIMARY EFFICACY (PRIMARY PATENCY COMPOSITE)**

- Freedom from clinically-driven target lesion revascularization (CD-TLR)
- Binary restenosis through 12 months post-index procedure

# Follow-Up Compliance by Visit



Percentages are in window visits/expected visits

# Baseline Demographics And Lesion Characteristics

	<b>SURVEIL™</b> N = 222 subjects	<b>IN.PACT®</b> N = 224 Subjects	P-value
<b>Age (yrs)</b>	<b>68.7 ± 9.4 (222)</b>	<b>67.4 ± 9.3 (224)</b>	<b>0.136</b>
<b>Male</b>	<b>62.6% (139/222)</b>	<b>63.4% (142/224)</b>	<b>0.922</b>
<b>Rutherford Class<sup>2</sup></b>			<b>0.013</b>
<b>2</b>	<b>21.6% (48/222)</b>	<b>34.4% (77/224)</b>	
<b>3</b>	<b>75.7% (168/222)</b>	<b>61.2% (137/224)</b>	
<b>4</b>	<b>2.7% (6/222)</b>	<b>4.5% (10/224)</b>	
<b>Lesion length (mm)<sup>1</sup></b>	<b>72.5 ± 48.4 (221)</b>	<b>70.0 ± 50.5 (223)</b>	<b>0.597</b>
<b>Minimum Lumen Diameter (mm) <sup>1</sup></b>	<b>1.4 ± 1.1 (221)</b>	<b>1.3 ± 1.0 (223)</b>	<b>0.106</b>
<b>Reference Vessel Diameter (mm) <sup>1</sup></b>	<b>5.3 ± 0.9 (221)</b>	<b>5.3 ± 0.7 (223)</b>	<b>0.842</b>
<b>% Diameter stenosis<sup>1</sup></b>	<b>72.9 ± 18.8 (221)</b>	<b>75.8 ± 18.1 (223)</b>	<b>0.102</b>

<sup>1</sup> Core Lab reported data

<sup>2</sup> Site reported data

Data reported as Mean±SD (N) or % (n/N)

# Procedural Characteristics

	SURVEIL™ N = 222 subjects	IN.PACT® N = 224 Subjects	P-value
<b>Stenosis (%)</b>			
<b>After Pre-Dilatation<sup>1</sup></b>	29.5 ± 15.2 (212)	31.2 ± 16.0 (218)	0.280
<b>After DCB deployment<sup>2</sup></b>	20.3±10.4 (215)	19.9±10.1 (220)	0.728
<b>Final<sup>2</sup></b>	18.7 ± 9.6 (217)	18.9 ± 9.3 (223)	0.875
<b>Max Inflation Pressure (atm)<sup>3</sup></b>	8.3 ± 2.4	9.2 ± 2.4	<0.001
<b>Inflation Duration (sec)<sup>3</sup></b>	183.3 ± 64.4	185.5 ± 63.6	0.686
<b>Final MLD (mm)<sup>2</sup></b>	4.3 ± 0.8 (221)	4.3 ± 0.7 (223)	0.604
<b>Dissection (&gt;= Grade C) (Post Procedure)<sup>2</sup></b>	21.7% (47/217)	15.7% (35/223)	0.113
<b>% of subjects requiring Post dilatation</b>	18.0% (40/222)	17.4% (39/224)	0.902
<b>% of subjects with Bailout stenting</b>	8.1% (18/222)	6.7% (15/224)	0.592

<sup>1</sup> Site Data <sup>2</sup> Core Lab data <sup>3</sup> information based on number of devices used Data reported as Mean±SD (N) or % (n/N)

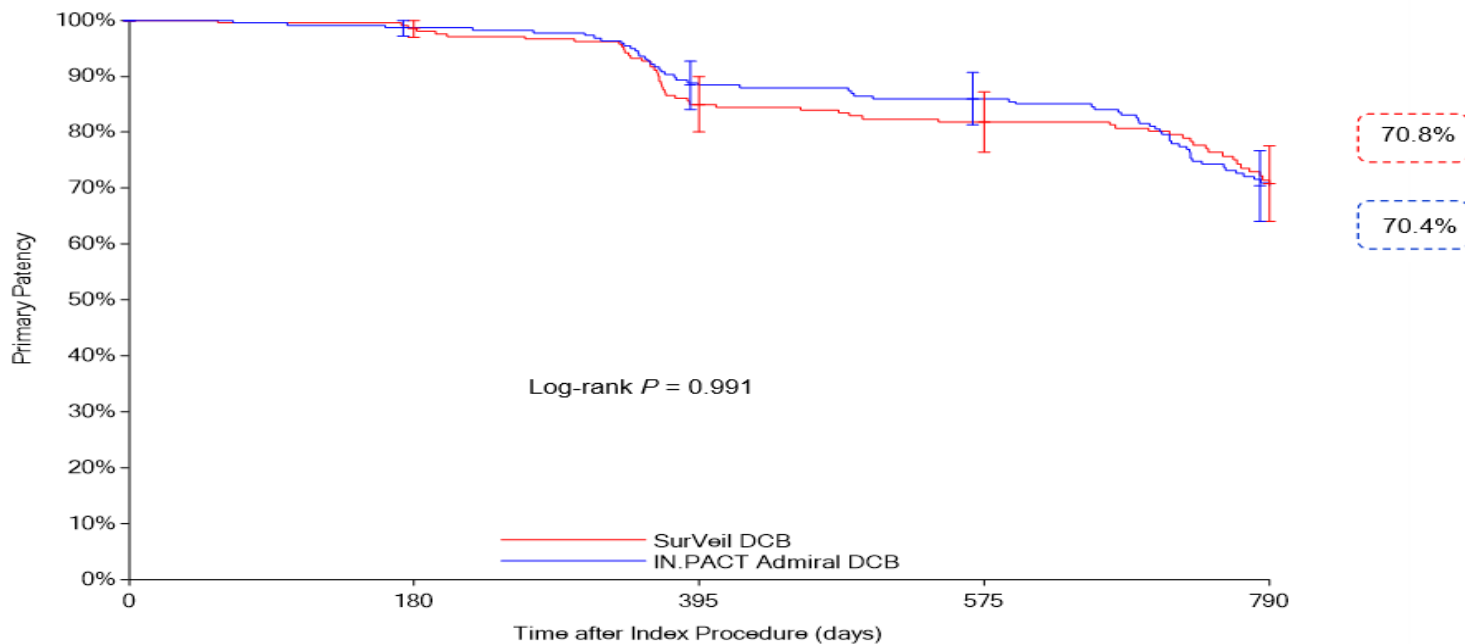
# Primary Results (12 Months)

TRANSCEND TRIAL		
	SURVEIL™	IN.PACT®
<b>Primary safety (ITT)</b>	<b>91.7%</b>	<b>89.6%</b>
All cause death at 30 days	0.5% (1/218)	0.0% (0/223)
Target limb major amputation	0.0% (0/196)	0.0% (0/215)
CD-TVR	7.6% (15/198)	10.1% (22/217)
<b>Primary effectiveness (ITT)</b>	<b>81.7%</b>	<b>85.9%</b>
Binary restenosis (PSVR>2.4)	12.0% (19/158)	8.8% (16/181)
CD-TLR	8.1% (16/198)	5.6% (12/215)

- **SurVeil™ met primary safety**
  - Strong safety profile, no amputations, low CD-TLR
- **SurVeil™ met primary efficacy**
  - Comparable effectiveness at a substantially lower dose
- All analyzed cohorts (ITT/PP/AT) demonstrated consistent outcomes; multiple imputation/complete case analyses consistent

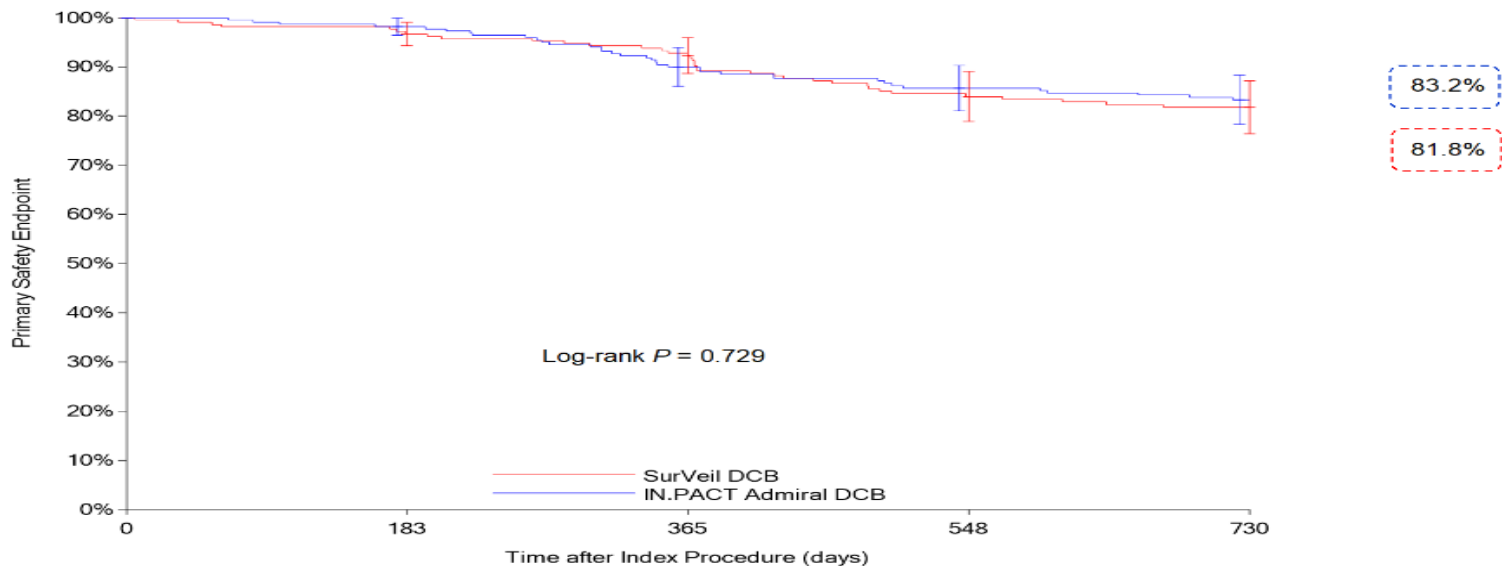


# K-M Primary Patency – 24 months



	0	180	395	575	790
Number at risk					
SurVeil	222	205	164	150	98
IN.PACT Admiral	224	218	187	177	125

# K-M Secondary Safety – 24 months



#### Number at risk

SurVeil	222	202	182	157	132
IN.PACT Admiral	224	217	191	178	156

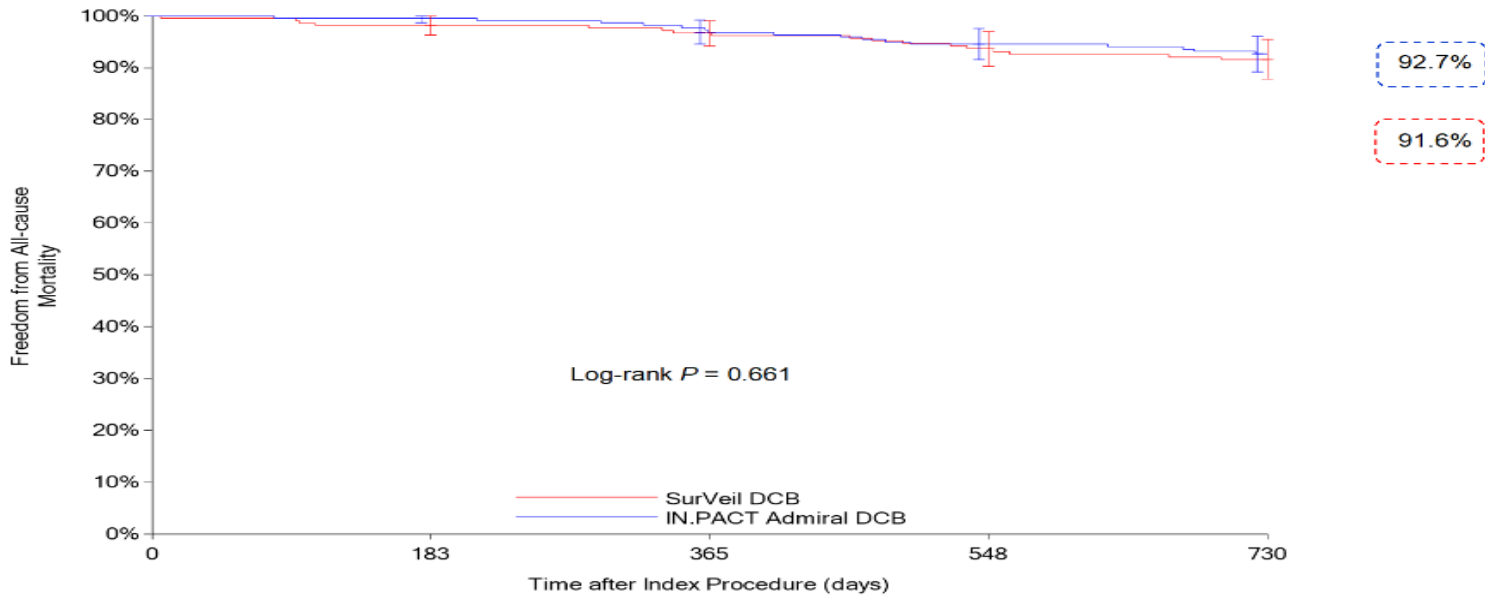
Safety endpoint is a composite of freedom from device- and procedure-related death through 30 days post-index procedure and freedom from major target limb amputation (above the ankle) and clinically-driven target vessel revascularization (TVR).

# Secondary Safety and Efficacy Endpoints – 24 months

	<b>SURVEIL™</b> N=222 Subjects	<b>IN.PACT®</b> N=224 Subjects	<b>P-value</b>
<b>Target vessel patency <sup>1</sup></b>	<b>63.0% (102/162)</b>	<b>63.1% (118/187)</b>	<b>1.000</b>
<b>Clinically-driven TLR</b>	<b>14.7% (27/184)</b>	<b>11.8% (24/204)</b>	<b>0.453</b>
<b>Major target limb amputation</b>	<b>0.0% (0/181)</b>	<b>0.5% (1/204)</b>	<b>1.000</b>
<b>Thrombosis at the target lesion</b>	<b>0.6% (1/181)</b>	<b>0.0% (0/204)</b>	<b>0.470</b>

<sup>1</sup>Defined as freedom from clinically-driven TVR and binary restenosis (restenosis defined as DUS PSVR  $\geq 2.4$  or  $\geq 50\%$  stenosis as assessed by independent angiographic and DUS core labs), within 24 months

# K-M Freedom From All Cause Mortality -24 Months



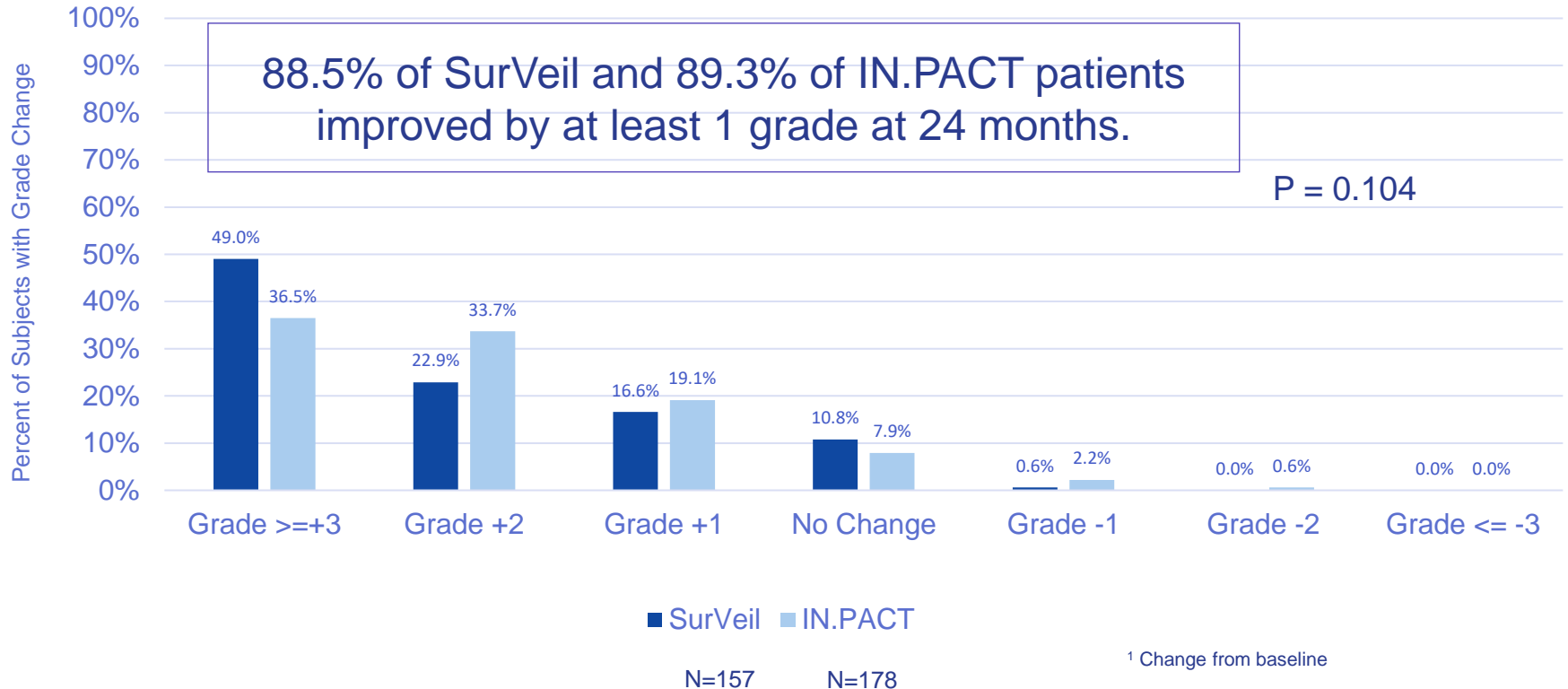
Number at risk

SurVeil	222	207	195	184	162
IN.PACT Admiral	224	221	211	206	188

# Functional outcomes at 24 Months

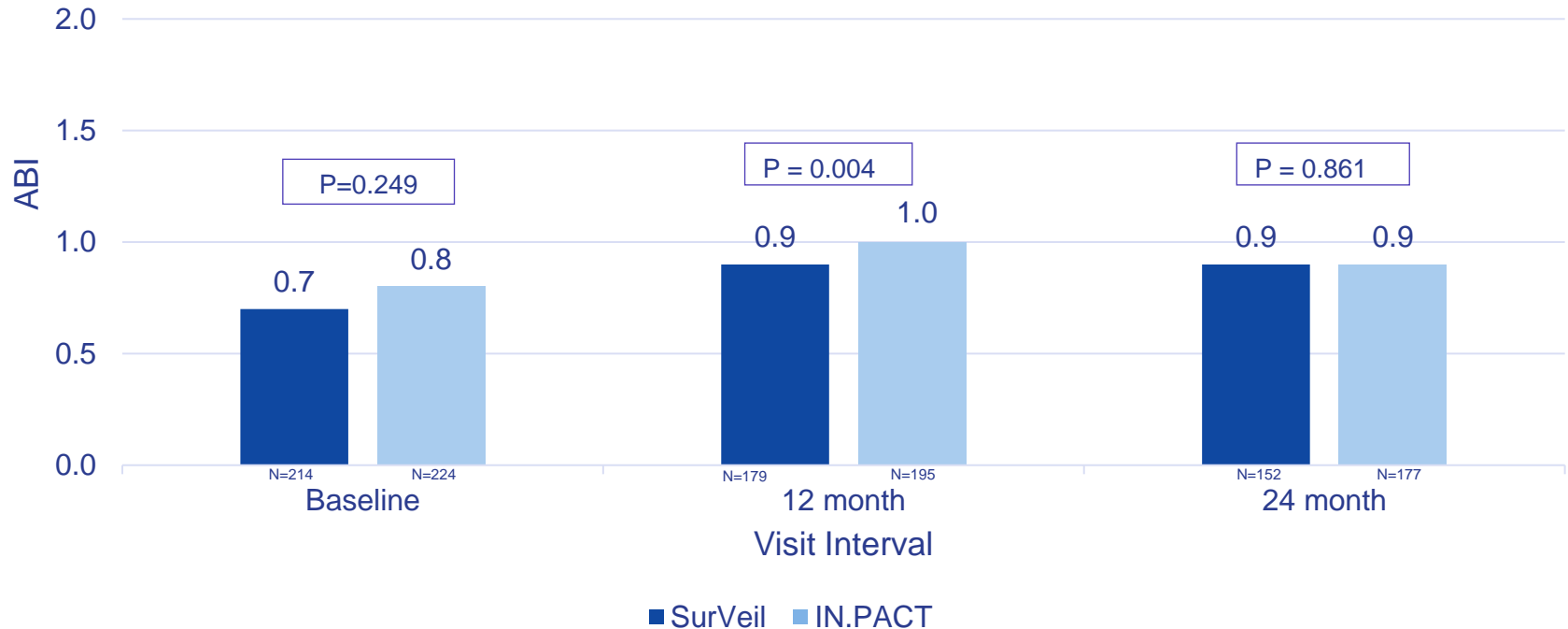
TRANSCEND PIVOTAL TRIAL RESULTS

# Rutherford Classification Change<sup>1</sup>



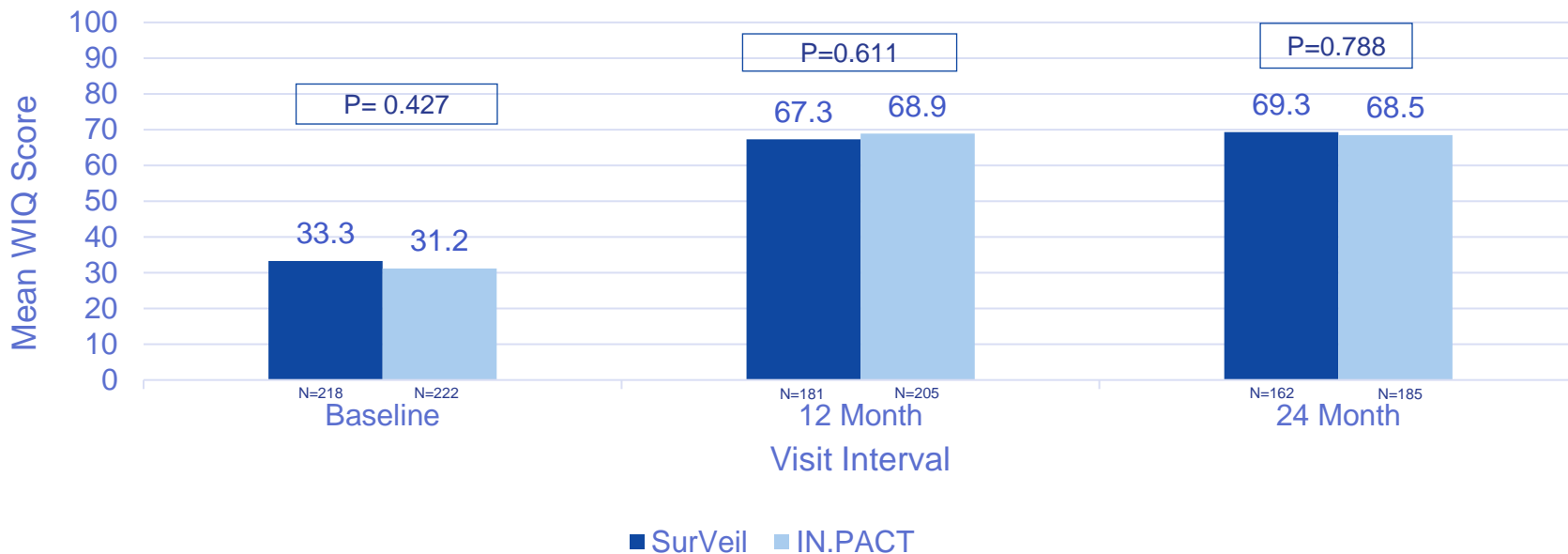
# Ankle Brachial Index (24 months)

## *Sustained improvement*



# Walking Impairment Questionnaire (WIQ) (24 months)

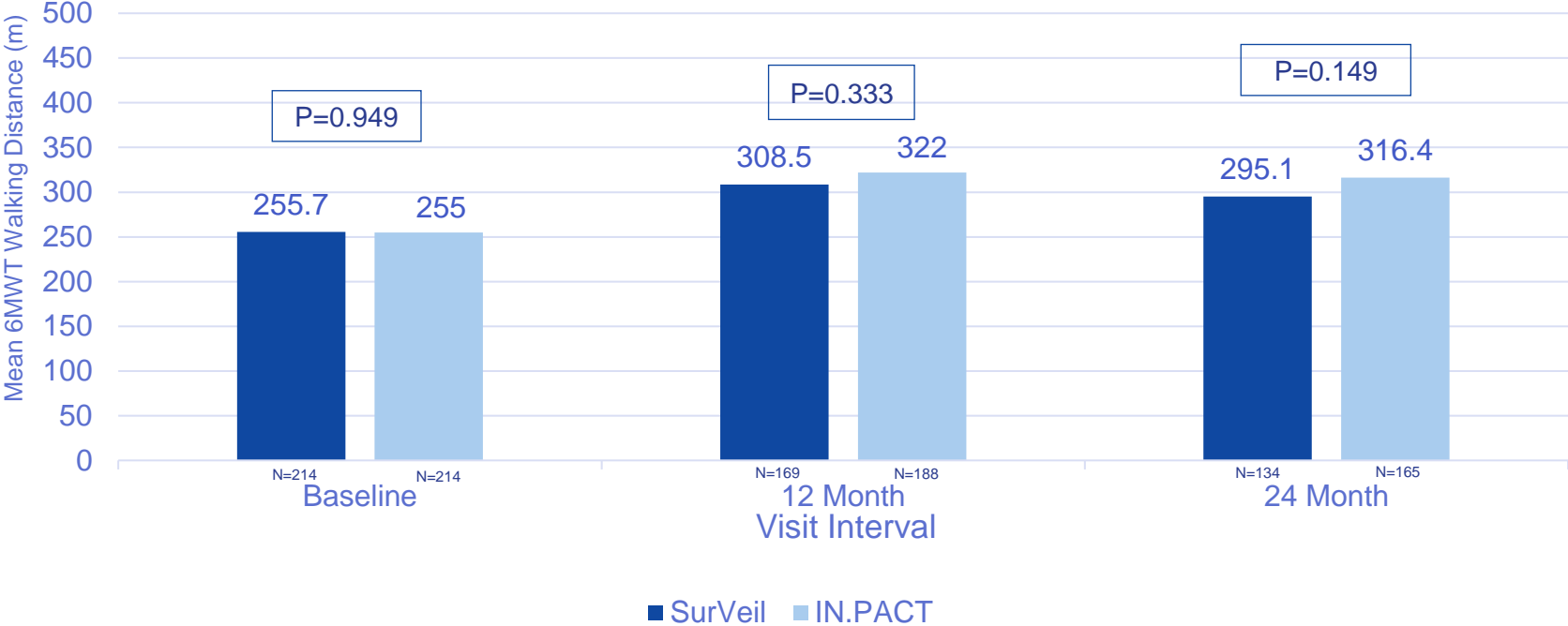
*Sustained improvement*





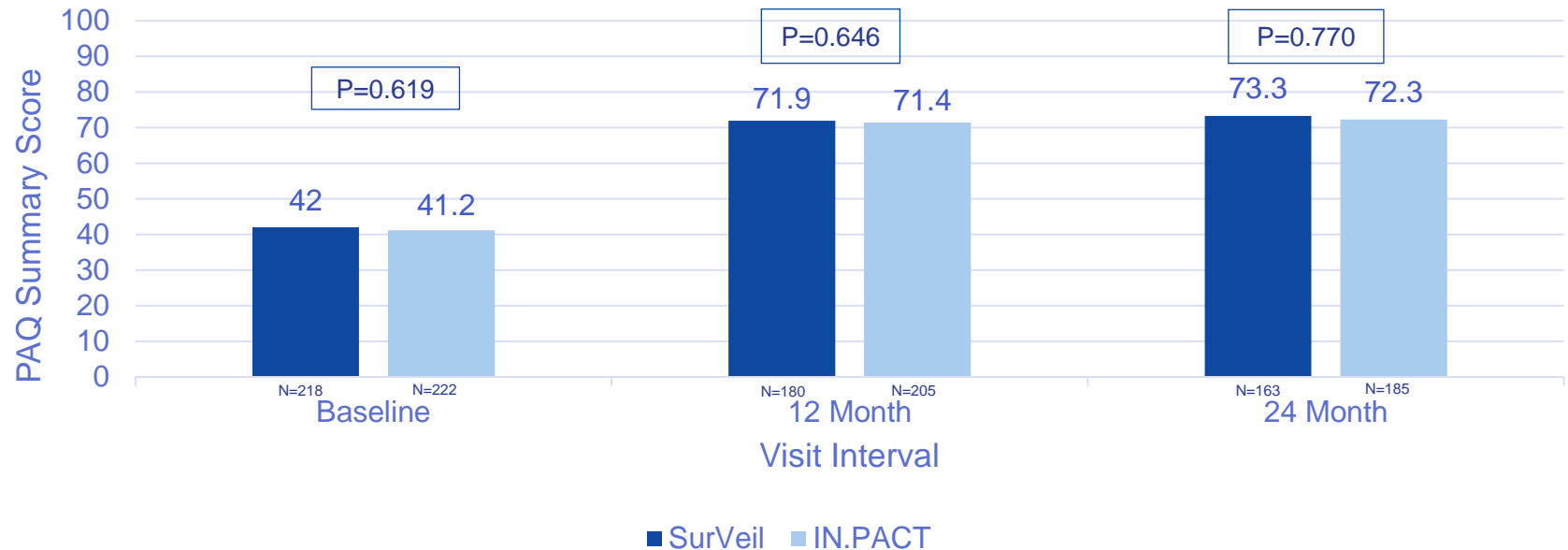
# 6 Minute Walk Test (6MWT) Walking Distance

## *Sustained improvement*



# Peripheral Artery Questionnaire (PAQ) Summary Score (24 months)

*Sustained improvement*



# Conclusions

- SurVeil™ DCB demonstrated excellent efficacy and safety in a pivotal RCT...24 Month Results
  - sustained durability of safety and efficacy endpoints
  - comparable efficacy and safety at substantially lower dose
- SurVeil DCB is non-inferior to market leading IN.PACT® Admiral® DCB