5-Year Results of RCT Comparing SurVeil™ DCBs (Surmodics) With IN.PACT DCBs (Medtronic) For Treating Fempop Lesions: the TRANSCEND Trial

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Peter A. Schneider Disclosures

Consulting:

Surmodics, Medtronic, Boston Scientific, Phillips, Cagent, Acotec, Abbott, Endologix, Shockwave, Silk Road, Healthcare Inroads, Inari, BD

SURVEIL™ Next Generation DCB

Next-generation DCB – Intent

- Higher Efficacy: Develop a device that improves the therapeutic window by achieving 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/mm², 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

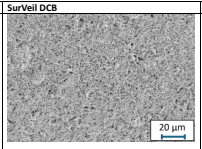
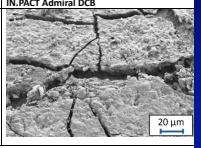
THESIS: If a DCB can achieve similar clinical outcomes with a lower dose of drug as demonstrated in a head-to-head RCT then it would advance the state of the art and could provide a better therapeutic choice

SurVeil DCB vs IN.PACT Admiral Balloon Design (optical microscopy)

- Images showing uniform paclitaxel crystal structure of SurVeil DCB (top)
  - All balloons were 6x80mm and inflated to 6 atm
  - All balloons imaged at same 10X magnification

SurVeil vs IN.PACT Admiral Balloon Coating on a 6x80 mm balloon

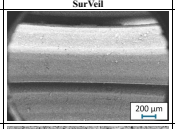
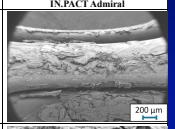
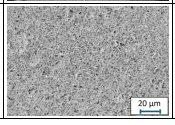
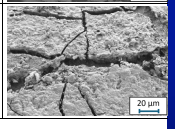
(SEM; Zeiss Supra 35 VP Field emission)

Magnification	SurVeil DCB	IN.PACT Admiral DCB
2200X (150 x 100 µm field shown)		

- SEM images showing uniform paclitaxel crystal structure of SurVeil DCB (left)
  - All balloons were 6x80mm and inflated to 6 atm
  - All balloons imaged at same 2,200X magnification

SurVeil vs IN.PACT Admiral Balloon Coating on a 6x80 mm balloon

(SEM; Zeiss Supra 35 VP Field emission)

Magnification	SurVeil	IN.PACT Admiral
150X (2.2 x 1.5 mm field shown)		
2200X (150 x 100 µm field shown)		

- SEM images images showing uniform paclitaxel crystal structure of SurVeil DCB (left)
  - All balloons imaged at same 150X and 2,200X magnification

TRANSCEND Trial Overview

- **Prospective, multicenter, international, randomized, single-blind trial of Surveil™ DCB versus IN.PACT® Admiral® DCB (1:1)**
- **446 subjects randomized**
  - SurVeil™ DCB (N=222) & IN.PACT ADMIRAL DCB (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/ICON and Mobius (OUS); Surmodics (US)

TRANSCEND Trial Overview

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 ≤ 180 mm; diameter ≥ 4mm & ≤ 7mm; stenosis ≥ 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

TRANSCEND Trial Overview

Follow-Up Compliance by Visit

	1m	6m	12m	24m	36m	48m	60m
SurVeil™ DCB (N=222 Subjects)	97.67% (210/215)	93.30% (195/209)	95.45% (189/198)	93.48% (172/184)	96.53% (167/173)	93.17% (150/161)	96.69% (146/151)
IN. PACT® Admiral® DCB (N=224 Subjects)	98.66% (221/224)	95.96% (214/223)	97.66% (209/214)	95.00% (190/200)	97.37% (185/190)	96.15% (175/182)	98.82% (168/170)

Percentages are in window & out of window visits / expected visits

TRANSCEND Trial
Baseline Demographics And Lesion Characteristics (ITT)

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

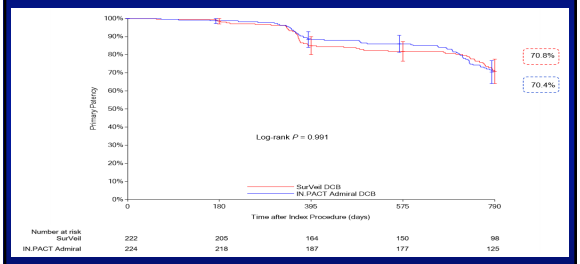
[1] Site reported data
[2] CoreLab reported data
Data reported as Mean ± SD (N) or % (n/N)

TRANSCEND Trial
Procedural Characteristics

	SURVEIL DCB™ N = 222 subjects	IN.PACT® N = 224 Subjects	P-value
Stenosis (%)			
After Pre-Dilatation[1]	29.5 ± 15.2 (212)	31.2 ± 16.0 (218)	0.280
After DCB deployment[2]	20.3±10.4 (215)	19.9±10.1 (220)	0.728
Final[2]	18.7 ± 9.6 (217)	18.9 ± 9.3 (223)	0.875
Max Inflation Pressure (atm)[3]	8.3 ± 2.4	9.2 ± 2.4	<0.001
Inflation Duration (sec)[3]	183.3 ± 64.4	185.5 ± 63.6	0.686
Final MLD (mm)[2]	4.3 ± 0.8 (217)	4.3 ± 0.7 (223)	0.604
Dissection (>/= Grade C) (Post Procedure)[2]	19.5% (42/215)	13.6% (30/220)	0.181
% of subjects requiring Post dilatation	18.0% (40/222)	17.4% (39/224)	0.902
% of subjects with Bailout stenting	8.1% (18/222)	6.7% (15/224)	0.592

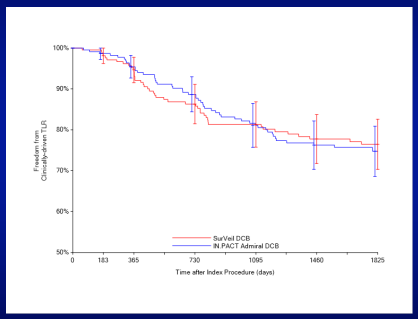
[1] Site Data [2] Core Lab data (post pre-dilatation and DCB deployment) [3] Inflation Data based on number of devices used. Data reported as Mean ± SD (N) or % (n/N)

TRANSCEND Trial
Primary Patency at 2 Years



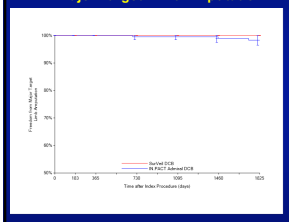
TRANSCEND Trial

Freedom from CD-TLR at 5 Years

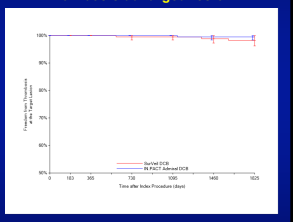


TRANSCEND Trial at 5 Years

Freedom from Major Target Limb Amputation

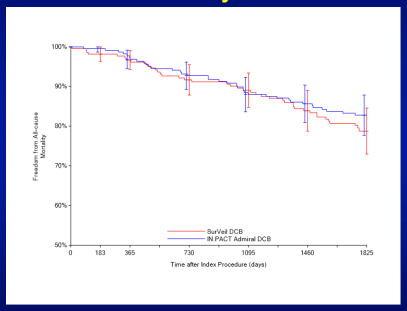


Freedom from Thrombosis at Target Lesion



TRANSCEND Trial

All-Cause Mortality at 60 Months



TRANSCEND Trial at 5 Years

Conclusions

- SurVeil™ DCB demonstrated excellent efficacy and safety in a head-to-head pivotal RCT;
  - → sustained durability of safety and efficacy endpoints,
  - → comparable efficacy and safety at lower dose.
- The TRANSCEND RCT comparing the low-dose SurVeil™ DCB against the IN.PACT® Admiral DCB demonstrated non-inferiority in safety and efficacy at 12 and 24 months and continues to demonstrate comparable safety and efficacy at 60 months.

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