The SWING Study

An Evaluation of the Sundance™ Sirolimus Coated DCB Below-the-Knee – 12 Month Results

Ramon L. Varcoe MBBS, MS, FRACS, PhD, MMed (ClinEpi)

Prince of Wales Hospital and University of New South Wales

Sydney, Australia

Disclosures

Consultant to

- Surmodics
- Medtronic
- Abbott Vascular
- BD Bard
- Intervene
- Philips Healthcare
- Nectero Medical
- Alucent Biomedical
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SUNDANCE™ DRUG COATED BALLOON

Hydrophilic shaft coating
Surmodics SERENE™ hydrophilic coating

Uniform Sirolimus drug coat
Microcrystalline sirolimus + proprietary excipient
360° uniform coating coverage

Surmodics .014" PTA platform
2 - 4 mm diameter
20 - 220 mm lengths

Sundance™ DCB Next-gen Coating Technology

- Excellent coating durability to maximize drug transfer
- Enhanced sirolimus delivery and sustained therapeutic levels in artery
- Best-in-class hydrophilic coating and enhanced trackability

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PROTOCOL SYNOPSIS

Investigational Device	Surmodics SUNDANCE™ Sirolimus Drug-Coated Balloon (Sundance™ DCB)
Objectives	To evaluate the safety and performance of Sundance™ DCB in subjects with occlusive disease of the infrapopliteal arteries.
Study Design	Prospective, multi-center, single-arm, feasibility study. To evaluate the safety and performance of the Sundance™ DCB in subjects with occlusive disease of the infra-popliteal arteries. Subjects will be followed for 36 months following the index procedure.
Subject Populations	Subjects with stenotic or occluded lesions of the infrapopliteal arteries with a reference vessel diameter (RVD) of 2 mm to 4 mm and a total lesion length of ≤230 mm.
Subjects and Sites	35 subjects at 8 sites in Australia, New Zealand and/or Europe.

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KEY INCLUSION/EXCLUSION CRITERIA

- Rutherford 4 or 5 (RC 3 are included but capped at 20% of cohort)
- De Novo or restenotic (non-stented) lesions
- ≥70% stenosis by visual estimate
- Up to two distinct lesions in the same or different BTK arteries
- Must have good or successfully treated inflow and an unimpaired outflow artery in continuity to the ankle/foot

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ANALYSIS POPULATIONS

MITT and PP

	Modified Intent to Treat (MITT)	Per-Protocol Analysis Population (PP)
DEFINITION	The MITT population consists of all ITT subjects who met all pre-procedure angiographic eligibility criteria, and in whom treatment with the Sundance™ DCB was attempted.	The PP population is a subset of the MITT population who meet • The subject received treatment with the Sundance™ DCB (n=0) • No major deviations from the protocol eligibility criteria (n=3) • The subject had a 6-month primary efficacy assessment (angio) (n=7)
TOTAL SUBJECTS	35 Subjects	25 Subjects
TOTAL LESIONS	43 Lesions	33 Lesions
Sites	8 Sites	8 Sites

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BASELINE DEMOGRAPHICS

Characteristic	MITT (N=35)	PP (N=25)
Age (years) Mean ± SD	76.8±10.0	75.4 ± 9.9
Gender (Male)	22/35 (62.9%)	16/25 (64.0%)
Smoker (Current and Former)	14/35 (40.0%)	10/25 (40.0%)
Diabetes (Type 2)	21/35 (60.0%)	15/25 (60.0%)
Hypertension	32/35 (91.4%)	24/25 (96.0%)
Hypercholesterolemia	22/35 (62.9%)	16/25 (64.0%)
Rutherford Clinical Classification		
Category 3	4/35 (11.4%)	3/25 (12.0%)
Category 4	8/35 (22.9%)	7/25 (28.0%)
Category 5	23/35 (65.7%)	15/25 (60.0%)

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PROCEDURAL CHARACTERISTICS

Characteristic[1]	MITT (N=35)	PP (N=25)
Lesion Length (mm)	83.8±76.6 (43)	72.4 ± 66.6(33)
Diameter Stenosis (%)	82.8±13.9 (43)	81.8 ±13.9 (33)
Calcification		
None/Mild	11/43 (25.6%)	6/33 (18.2%)
Moderate	26/43 (60.5%)	24/33 (72.7%)
Severe	6/43 (14.0%)	3/33 (9.1%)
Total Occlusion	14/43 (25.6%)	10/33 (30.3%)
Procedure Time (min)[2]	62.5±21.5 (35)	60.5±17.4 (25)
MLD after DCB (mm)	2.4±0.7(43)	2.5±0.6 (33)
Diameter Stenosis after DCB (%)	22.3±16.5(43)	20.6±11.8 (33)
Post Dilatation Performed[3]	7/35 (20.0%)	5/25 (20%)

[1] Core Lab reported data unless noted otherwise, N reflects per lesion data
[2] Site reported data, N reflects per subject data
[3] N reflects total number of subjects

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PRIMARY ENDPOINTS

Primary Safety Endpoint	Composite freedom from Major Adverse Limb Event (MALE) + Perioperative death (POD) at 30 days.
Primary Efficacy Endpoint	Late Lumen Loss (LLL) at 6 Months assessed by quantitative vascular angiography (QVA).

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PRIMARY SAFETY ENDPOINT

Primary Safety Endpoint	MITT Population (subjects)	PP Population (Subjects)
Composite Primary Safety Endpoint	**97.1% (33/34)**	**100.0% (25/25)**
Freedom from MALE[1]	**97.1% (33/34)**	**100.0% (25/25)**
Major Amputation	**0.0% (0/34)**	**0.0% (0/25)**
Major Re-intervention	**2.9% (1/34)**	**0.0% (0/25)**
Freedom from POD[2]	**100.0% (34/34)**	**100.0% (25/25)**

[1]MALE: Major Adverse Limb Event - a composite of either major amputation or major surgical re-intervention through 30 days of the index procedure
[2]POD: Perioperative death at 30 days
N = number of subjects with data available at timepoint

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MAJOR ADVERSE EVENTS

Key Secondary Endpoints	MITT Population	PP Population	MITT Population	PP Population
	6 Month		12 Month	
Major Adverse Event[1]	**12.9% (4/31)**	**8.0% (2/25)**	**15.2% (5/33)**	**8.0% (2/25)**
Rate of All-Cause Death	**0.0% (0/31)**	**0.0% (0/25)**	**3.0% (1/33)**	**0.0% (0/25)**
Target Limb Amputation	**0.0% (0/31)**	**0.0% (0/25)**	**0.0% (0/33)**	**0.0% (0/25)**
CD-TLR[2]	**12.9% (4/31)**	**8.0% (2/25)**	**12.1% (4/33)**	**8.0% (2/25)**

[1] Major Adverse Event: A composite rate of all-cause death, target limb major amputation and CD TLR
[2] Clinically driven Target Lesion Revascularizations (CD TLR): Any TLR of the target lesion associated with deterioration of Rutherford Clinical Classification and/or increase in size of pre-existing wounds and/or occurrence of new wound(s), and lesion restenosis >50% determined by angiography.

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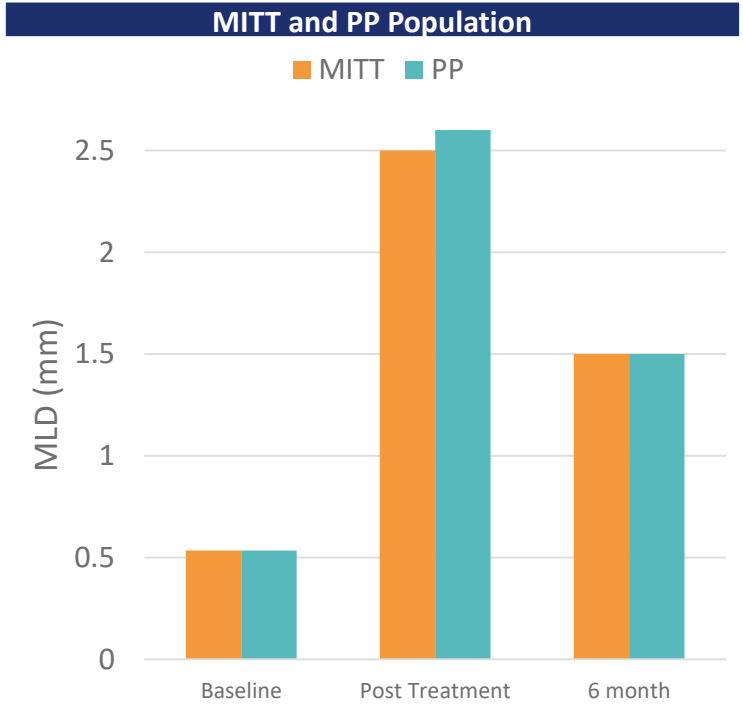
PRIMARY EFFICACY ENDPOINT

Primary Efficacy Endpoint (per lesion)	MITT Population (43 lesions)	PP Population (33 lesions)
	Value (mm)	Value (mm)
MLD After Procedure	2.5±0.64 (43)	2.6±0.48 (33)
MLD at 6 mth Follow-up	1.5±1.01 (35)	1.5±0.97(33)
Late Lumen Loss[1]	1.0±0.79 (35)	1.0±0.79 (33)



[1] The primary efficacy endpoint is Late Lumen Loss (LLL) at 6 Months assessed by quantitative vascular angiography (QVA).

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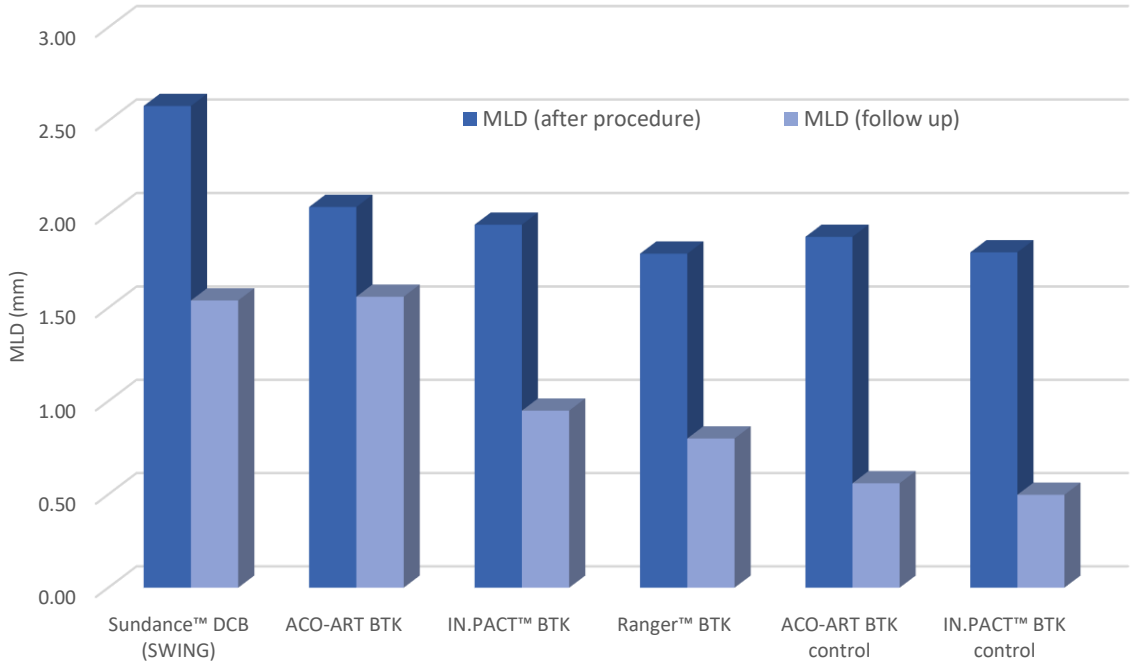
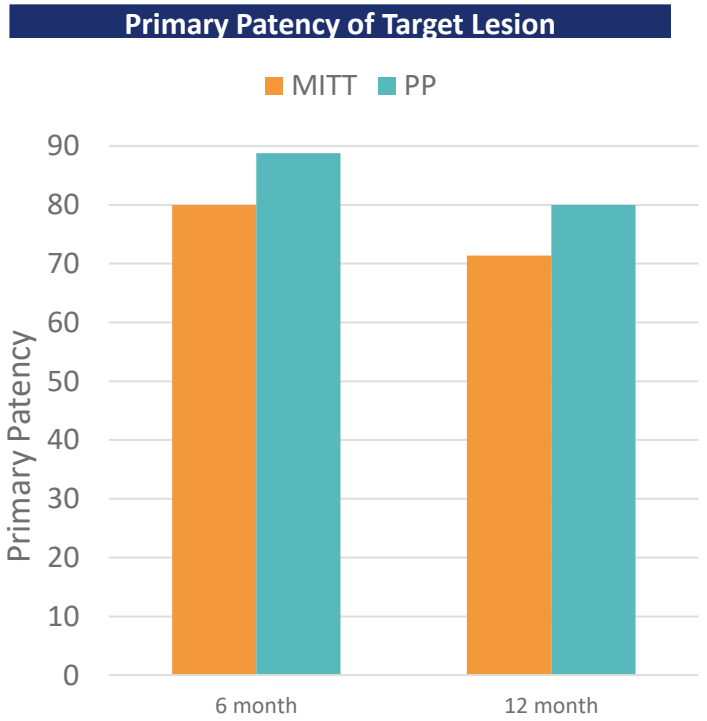
COMPARISON OF LATE LUMEN LOSS



TARGET LESION PRIMARY PATENCY (per lesion)

Primary Patency [1]	MITT Population (43 Lesions)	PP Population (33 Lesions)
6-Months	**80.0%** (24/30)	**88.5%** (23/26)
12-Months	**71.4%** (20/28)	**80.0%** (20/25)

[1] Patency is defined as freedom from target vessel occlusion as determined by DUS and CD-TLR. Clinically driven Target Lesion Revascularizations (CD TLR): Any TLR of the target lesion associated with deterioration of Rutherford Clinical Classification and/or increase in size of pre-existing wounds and/or occurrence of new wound(s), and lesion restenosis >50% determined by angiography.



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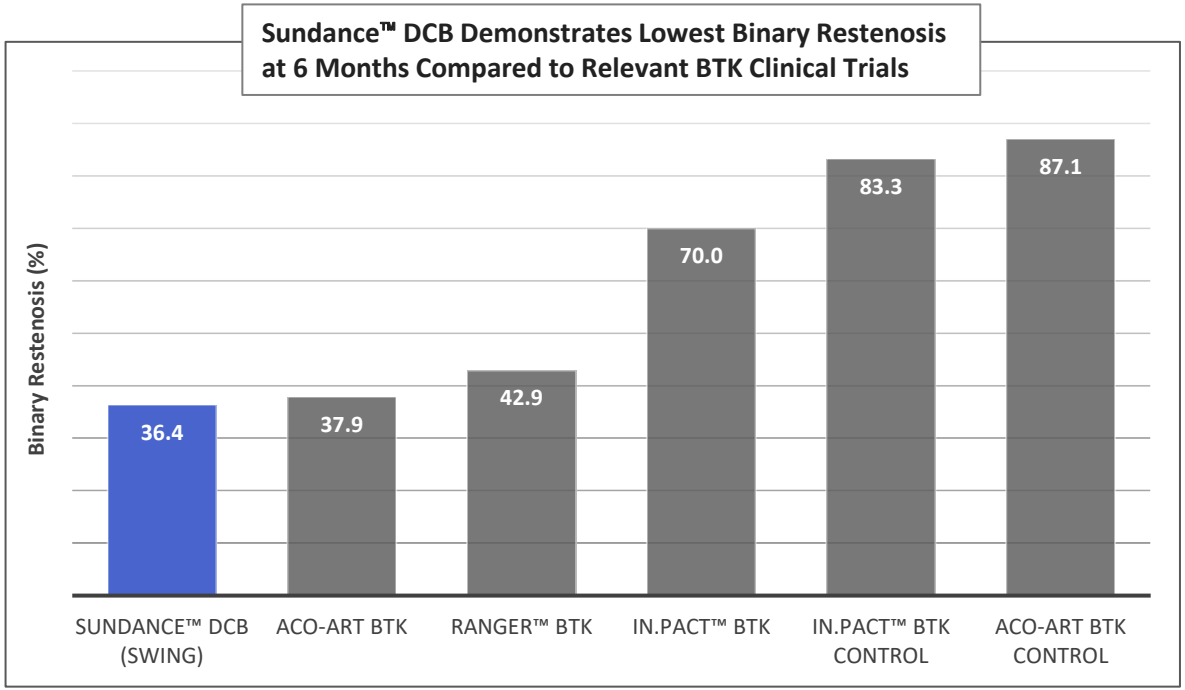
ANGIOGRAPHIC BINARY RESTENOSIS (6mo)



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6-9 month follow-up; Sundance™ DCB data PP population
Ranger™ DCB reported composite endpoint CD-TLR + binary restenosis; Sundance™ DCB calculated via this endpoint 36.4% (no change from graph)

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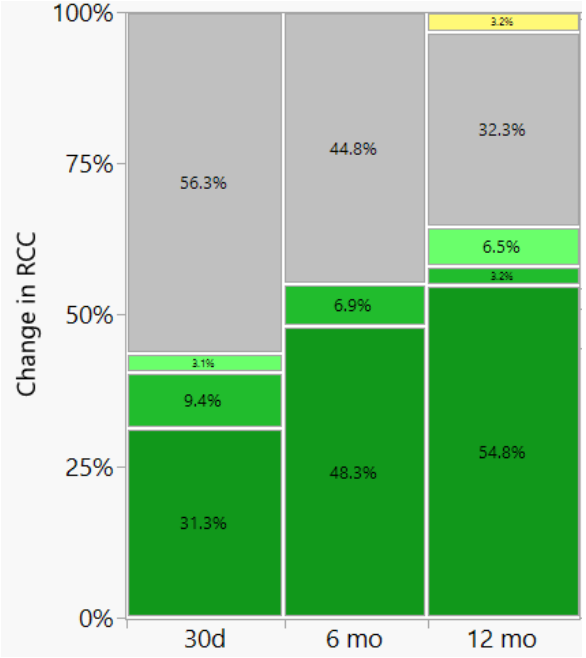
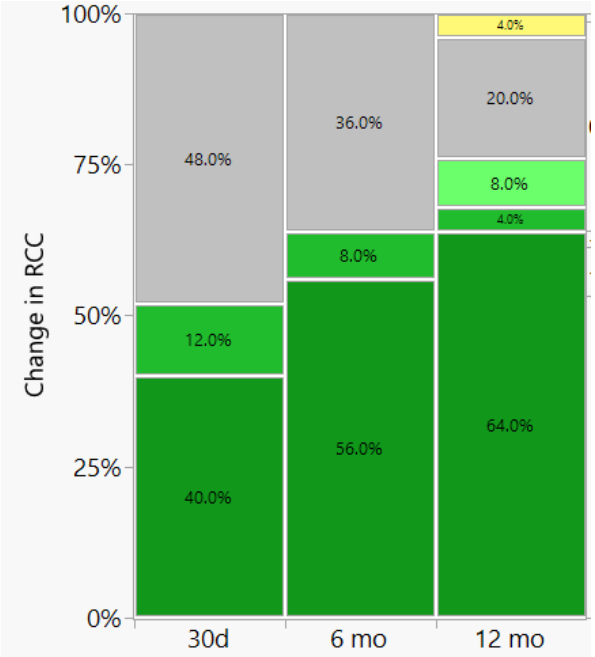
Rutherford-Becker Classification

Characteristic
Grade >= +3 Markedly worsening
Grade +2 Moderately worsening
Grade +1 Mildly worsening
Grade 0 No change
Grade -1 Mildly improved
Grade -2 Moderately improved
Grade <= -3 Markedly improved

MITT Population



PP Population



Significant clinical improvement: 76% of PP subjects demonstrated improvement at 12 months

Durable clinical outcomes: Improvement in Rutherford Clinical Classification increased between the 1-month, 6-month, and 12-month endpoints

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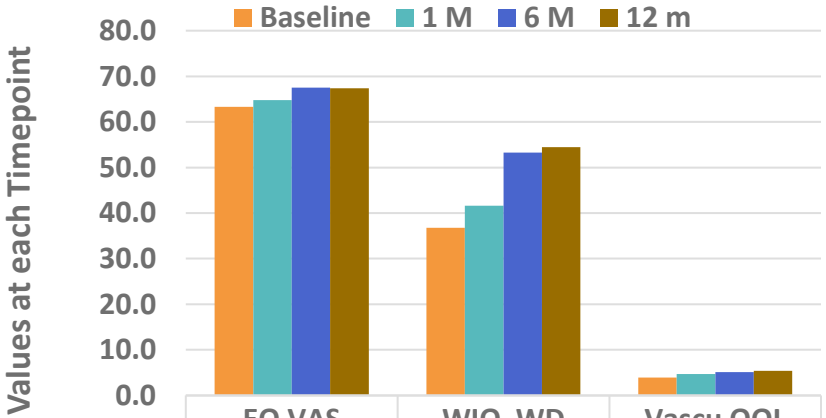
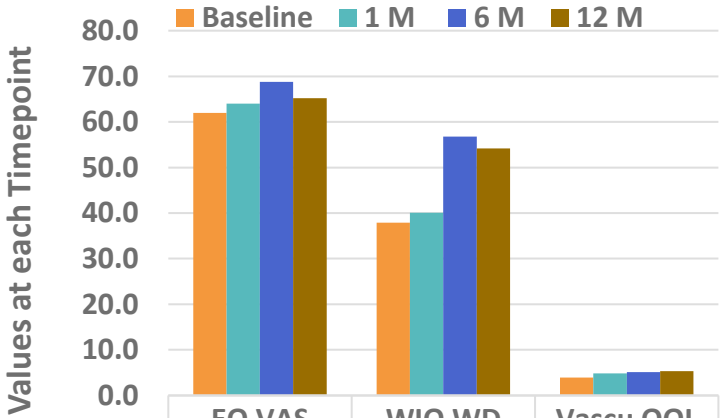
PATIENT REPORTED OUTCOME MEASURES

MITT Population



	EQ VAS	WIQ WD	Vascu QOL
Baseline	63.3	36.8	3.9
1 M	64.8	41.6	4.7
6 M	67.5	53.3	5.1
12 m	67.4	54.5	5.4

PP Population



	EQ VAS	WIQ WD	Vascu QOL
Baseline	62.0	37.9	3.9
1 M	64.0	40.1	4.8
6 M	68.8	56.8	5.1
12 M	65.2	54.2	5.3

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CONCLUSION

- The novel microcrystalline coating on the Sundance™ Sirolimus coated balloon was evaluated in a challenging, real-world, (predominantly) CLI population with a high proportion of diabetes and moderate-severe calcification

- We observed an excellent safety profile with no major amputations and low rates of MAE

- It achieved impressive luminal gain which was sustained at the 6-month angiogram

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CONCLUSION

- A 12-month Primary Patency of 80.0% (per protocol) was observed
- Rutherford category and functional outcome measures were improved, and that improvement continued over mid-term follow up
- This device has great promise and warrants evaluation in a large-scale pivotal trial

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