

SUPPLEMENTAL MATERIAL

Table S1. Design characteristics of the included randomized controlled trials*

Study and sources	Year and study design	Allocation in study arms	Paclitaxel coated device	Primary study endpoint	Maximum follow-up period	Study registration	Dual antiplatelet therapy
ZILVER-PTX ¹⁻³	2011 Multi-center Open label (1:1)	DES (n=241) vs PTA (n=238)	ZILVER-PTX Stent by COOK Medical	Primary Patency at 1 year	5 years	NCT00120406	>2 months
THUNDER ^{4,5}	2008 Multi-center Single-blind (1:1:1)	DCB (n=48) vs PTA (n=54)	Cotavance Balloon by Bavaria Medizin	Late Lumen Loss at 6 months	5 years	NCT00156624	1 month
IN.PACT SFA ⁶⁻¹⁰	2015 Multi-center Single-blind (2:1)	DCB (n=220) vs PTA (n=111)	IN.PACT Admiral by Medtronic	Primary Patency at 1 year	3 years	NCT01175850 NCT01566461	1 month (3 months if bail-out stenting)
FEMPAC ¹¹	2008 Multi-center Single-blind (1:1)	DCB (n=45) vs PTA (n=42)	Paccocath Balloon by Bavaria Medizin	Late Lumen Loss at 6 months	2 years	NCT00472472	Long-term (not specified)
LEVANT I ¹²	2012 Multi-center Single-blind (1:1)	DCB (n=49) vs PTA (n=52)	Lutonix by CR BARD	Late Lumen Loss at 6 months	2 years	NCT00930813	1 month (3 months if bail-out stenting)
LEVANT II ¹³⁻¹⁶	2015 Multi-center Single-blind (2:1)	DCB (n=316) vs PTA (n=160)	Lutonix by CR BARD	Primary Patency at 1 year	2 years	NCT01412541	1 month
ILLUMENATE EU ¹⁷	2017 Multi-center Single-blind (3:1)	DCB (n=222) vs PTA (n=72)	Stellarex by Spectranetics	Primary Patency at 1 year	2 years	NCT01858363	1 month (3 months if bail-out stenting)
CONSEQUENT ¹⁸	2017 Multi-center Single-blind (1:1)	DCB (n=78) vs PTA (n=75)	SeQuent Please By B.Braun	Late Lumen Loss at 6 months	2 years	NCT01970579	2 months
ISAR-STATH ¹⁹	2017 Two-center Open label (1:1:1)	DCB+BMS (n=48) vs PTA+BMS (n=52)	IN.PACT Admiral by Medtronic	Diameter Stenosis at 6 months	2 years	NCT00986752	6 months
ISAR-PEBIS ²⁰	2017 Two-center Open label (1:1) for ISR	DCB (n=36) vs PTA (n=34)	IN.PACT Admiral by Medtronic	Diameter Stenosis at 6-8 months	2 years	NCT01083394	>6 months
IN.PACT SFA JAPAN ²¹	2018 Multi-center Single-blind (2:1)	DCB (n=68) vs PTA (n=32)	IN.PACT Admiral by Medtronic	Primary Patency at 1 year	2 years	NCT01947478	1 month (3 months if bail-out stenting)

ACOART I ²²	2016 Multi-center Single-blind (1:1)	DCB (n=100) vs PTA (n=100)	Orchid by Acotec Scientific	Late Lumen Loss at 6 months	2 years	Not registered	6 months
FINN-PTX ²³	2018 Multi-center Open label (2:1)	DES (n=28) vs PTFE (n=18)	ZILVER-PTX Stent by COOK Medical	Secondary Patency at 2 years	2 years	NCT01450722	3 months (Aspirin in control group)
BATTLE ^{24, 25}	2018 Multi-center Open label (1:1)	DES (n=86) vs BMS (n=85)	ZILVER-PTX Stent by COOK Medical	In-stent binary restenosis at 1 year	1 year	NCT02004951	>2 months (clopidogrel to continue for 2 years)
DEBATE-IN- SFA ²⁶	2018 Multi-center Open label (1:1:1)	DES (n=85) vs BMS (n=170)	ZILVER-PTX Stent by COOK Medical	In-stent binary restenosis at 1 year	1 year	UMIN0000100 71	>2 months (Aspirin to continue lifelong)
DEBELLUM ^{27, 28}	2014 Single- center Open (1:1)	DCB (n=25) vs PTA (n=25)	IN.PACT Admiral by Medtronic	Late Lumen Loss at 6 months	1 year	Not registered	1 month
PACIFIER ²⁹	2012 Multi-center Single-blind (1:1)	DCB (n=41) vs PTA (n=44)	IN.PACT Pacific by Medtronic	Late Lumen Loss at 6 months	1 year	NCT01083030	>2 months
FAIR ³⁰	2015 Multi-center Single-blind (1:1) for ISR	DCB (n=62) vs PTA (n=57)	IN.PACT Admiral by Medtronic	6-month binary restenosis	1 year	NCT01305070	>6 months
BIOLUX P-I ³¹	2015 Multi-center Single-blind (1:1)	DCB (n=30) vs PTA (n=30)	Passeo-18 Lux by Biotronik	Late Lumen Loss at 6 months	1 year	NCT01056120	1 month (3 months if bail-out stenting)
RANGER SFA ³²	2018 Multi-center Single-blind (2:1)	DCB (n=71) vs PTA (n=34)	Ranger by Boston Scientific	Primary Patency at 1 year	1 year	NCT02013193	>1 month
ILLUMENATE pivotal ³³	2017 Multi-center Single-blind (2:1)	DCB (n=200) vs PTA (n=100)	Stellarex by Spectranetics	Primary Patency at 1 year	1 year	NCT01858428 & NCT01912937	1 month
DEBATE-SFA ³⁴	2013 Single- center Open (1:1)	DCB+BMS (n=53) vs PTA+BMS (n=51)	IN.PACT Admiral by Medtronic	1-year binary restenosis	1 year	NCT01556542	3 months
LUTONIX JAPAN ³⁵	2018 Multi-center Japan (1:1)	DCB (n=71) vs PTA (n=38)	Lutonix by CR BARD	Primary Patency at 1 year	1 year	Not registered	1 month

RAPID ³⁶	2017 Multi-center Double-blind (1:1)	DCB+BMS (n=80) vs PTA+BMS (n=80)	LegFlow by Cardionovum	Primary Patency at 1 year	1 year	ISRCTN47846 578	3 months
EFFPAC ³⁷	2018 Multi-center Single-blind (1:1)	DCB (n=85) vs PTA (n=86)	Luminor by iVascular	Late Lumen Loss at 6 months	1 year	NCT02540018	>1 month
PACUBA ³⁸	2016 Dual-center Single-blind (1:1) for ISR	DCB (n=85) vs PTA (n=86)	FREEWAY by Eurocor	Primary Patency at 1 year	1 year	NCT01247402	3 months
FREEWAY ³⁹	2017 Multi-center Single-blind (1:1)	DCB+BMS (n=105) vs PTA+BMS (n=99)	FREEWAY by Eurocor	Target lesion revasculari zation	1 year	NCT01960647	Not specified
DRECOREST ⁴⁰	2018 Single- center Open (1:1)	DCB (n=30) vs PTA (n=30)	IN.PACT by Medtronic for failing bypass	Target lesion revasculari zation	1 year	NCT03023098	3 months

Table S2. Design characteristics of the tested paclitaxel DES and DCB devices.

Brand name	Paclitaxel dose ($\mu\text{g}/\text{mm}^2$)	Excipient/spacer	Manufacturer
IN.PACT	3.5 $\mu\text{g}/\text{mm}^2$ (3.7 $\mu\text{g}/\text{mm}^2$)	Urea (FreePac)	Medtronic (dose based on FDA submission)
ZILVER-PTX	3.0 $\mu\text{g}/\text{mm}^2$ (0.37 $\mu\text{g}/\text{mm}^2$)	None (polymer-free stent)	COOK Medical (area adjusted dose in case of stents)
Cotavance	3.0 $\mu\text{g}/\text{mm}^2$	Paccocath (Iopromide iodinated contrast)	Bavaria Medizin Technologie MedRad, later Bayer
Passeo-18 Lux	3.0 $\mu\text{g}/\text{mm}^2$	Butyryl-tri-n-hexyl citrate (BTHC)	Biotronik
SeQuent Please	3.0 $\mu\text{g}/\text{mm}^2$	Resveratrol	B.Braun
FREEWAY	3.0 $\mu\text{g}/\text{mm}^2$	Shellac (shellolic and aleuritic acid resin)	Eurocor
LegFlow	3.0 $\mu\text{g}/\text{mm}^2$	Nanocrystalline 0.1- μm paclitaxel in ammonium salt	Cardionovum
Orchid	3.0 $\mu\text{g}/\text{mm}^2$	Magnesium stearate	Acotec Scientific
Lutonix	2.0 $\mu\text{g}/\text{mm}^2$	Polysorbate and sorbitol	C.R. BARD
Luminor	3.0 $\mu\text{g}/\text{mm}^2$	Organic ester	iVascular
Stellarex	2.0 $\mu\text{g}/\text{mm}^2$	Polyethylene glycol	Spectranetics
Ranger	2.0 $\mu\text{g}/\text{mm}^2$	acetyl tributyl citrate – ATBC (Transpax)	Boston Scientific

Nominal paclitaxel dose is expressed in micrograms/ mm^2 ($\mu\text{g}/\text{mm}^2$). Based on the relevant FDA submission, dose is around (3.7 $\mu\text{g}/\text{mm}^2$) for the IN.PACT drug-coated balloon. In case of the ZILVER-PTX drug-coated stent, nominal paclitaxel dose adjusted for corresponding vessel surface area is actually 0.37 $\mu\text{g}/\text{mm}^2$ based on corresponding FDA filing data. The latter doses were used for calculation of paclitaxel dose for the purposes of meta-regression analysis.

Table S3. Baseline patient characteristics of included randomized clinical trials.

	ZILVER-PTX		THUNDER		IN.PACT SFA		FEMPAC	
	DES	PTA	DCB	PTA	DCB	PTA	DCB	PTA
Study allocation								
Patients (limbs)	n=241	n=238	n=48	n=54	n=220	n=111	n=45	n=42
Age (years)	68±10	68±11	69±8	68±9	68±10	68±9	67±6	70±6
Male gender	155 (66%)	152 (64%)	31 (65%)	34 (63%)	143 (65%)	75 (68%)	27 (60%)	25 (60%)
Smoking	204 (86%)	200 (84%)	11 (23%)	12 (22%)	85 (39%)	40 (36%)	21 (47%)	15 (36%)
Hypertension	210 (89%)	194 (82%)	38 (79%)	45 (83%)	201 (91%)	98 (88%)	35 (78%)	34 (81%)
Hyperlipidemia	180 (76%)	166 (70%)	33 (69%)	34 (63%)	186 (85%)	91 (82%)	26 (58%)	24 (59%)
Diabetes mellitus	116 (49%)	100 (42%)	24 (50%)	25 (46%)	89 (41%)	54 (49%)	18 (40%)	23 (55%)
Coronary artery disease	50 (21%)	41 (17%)	NR	NR	122 (57%)	60 (55%)	NR	NR
Renal insufficiency	24 (10%)	25 (11%)	NR	NR	NR	NR	NR	NR
Intermittent claudication	217 (90%)	216 (91%)	35 (73%)	47 (87%)	209 (95%)	104 (94%)	43 (96%)	39 (93%)
Critical limb ischemia	24 (10%)	22 (9%)	13 (27%)	7 (13%)	11 (5%)	7 (6%)	2 (4%)	3 (7%)
Lesions treated	n=247	n=251	n=86	n=86	n=221	n=113	n=100	n=101
Lesion Length (cm)	6.6±3.9	6.3±4.1	7.5±6.2	7.4±6.7	8.9±4.9	8.8±5.1	5.7±5.5	6.1±4.6
Vessel Diameter (mm)	NA	NA	5.0±0.7	4.7±0.6	4.7±0.8	4.7±0.8	5.2±0.6	5.0±0.5
Total occlusions	73 (30%)	62 (25%)	13 (27%)	14 (26%)	57 (26%)	22 (20%)	(13%)	(19%)
Bail-out stenting	NA	(2-level random*)	2 (4%)	12 (22%)	16 (7%)	14 (13%)	4 (9%)	6 (14%)

Table S3. Baseline patient characteristics of included randomized clinical trials (continued).

	LEVANT I		LEVANT II		ILLUMENATE EU		CONSEQUENT	
	DCB	PTA	DCB	PTA	DCB	PTA	DCB	PTA
Study allocation								
Patients (limbs)	n=49	n=52	n=316	n=160	n=222	n=72	n=78	n=75
Age (years)	67±8	70±10	68±10	69±9	67±9	69±9	68±9	68±9
Male gender	34 (69%)	30 (58%)	193 (61%)	107 (67%)	160 (72%)	49 (68%)	47 (60%)	57 (76%)
Smoking	15 (31%)	20 (39%)	111 (35%)	54 (34%)	198 (89%)	60 (83%)	36 (46%)	37 (49%)
Hypertension	47 (96%)	45 (87%)	282 (89%)	140 (88%)	173 (78%)	60 (83%)	60 (77%)	60 (80%)
Hyperlipidemia	29 (59%)	36 (69%)	283 (90%)	138 (86%)	137 (62%)	49 (68%)	44 (56%)	39 (52%)
Diabetes mellitus	22 (45%)	26 (50%)	137 (43%)	67 (42%)	83 (37%)	26 (36%)	27 (35%)	29 (39%)
Coronary artery disease	19 (39%)	23 (44%)	157 (50%)	77 (48%)	29 (13%)	12 (17%)	33 (42%)	30 (40%)
Renal insufficiency	NR	NR	11 (4%)	7 (4%)	20 (9%)	6 (8%)	2 (3%)	4 (5%)
Intermittent claudication	46 (94%)	48 (92%)	291 (92%)	147 (92%)	217 (98%)	70 (99%)	78 (100%)	75 (100%)
Critical limb ischemia	3 (6%)	4 (8%)	25 (8%)	13 (8%)	4 (2%)	1 (1%)	0 (0%)	0 (0%)
Lesions treated	n=49	n=52	n=322	n=165	n=254	n=79	n=87	n=84
Lesion Length (cm)	8.1±3.7	8.0±3.8	6.3±4.0	6.3±4.0	7.2±5.2	7.1±5.3	13.7±12.2	12.6±8.2
Vessel Diameter (mm)	4.1±0.6	4.2±0.7	4.8±0.8	4.8±0.8	5.0±0.8	4.8±0.7	5.0±0.8	5.4±0.9
Total occlusions	20 (41%)	22 (42%)	65 (21%)	35 (22%)	48 (19%)	15 (19%)	18 (23%)	22 (29%)
Bail-out stenting	12 (24%)	14 (27%)	8 (2.5%)	11 (6.9%)	39 (15%)	9 (11%)	11 (14%)	14 (19%)

Table S3. Baseline patient characteristics of included randomized clinical trials (continued).

Study allocation	ISAR-STATH		IN.PACT SFA JAPAN		DEBELLUM		PACIFIER	
	DCB+BMS	PTA+BMS	DCB	PTA	DCB	PTA	DCB	PTA
Patients (limbs)	n=48	n=52	n=68	n=32	n=25	n=25	n=41 (44)	n=44 (47)
Age (years)	70±9	69±8	73±7	74±6	67±7	67±6	71±7	71±9
Male gender	33 (69%)	37 (71%)	50 (74%)	26 (81%)	19 (76%)	18 (72%)	26 (59%)	30 (64%)
Smoking	36 (75%)	34 (65%)	18 (26%)	10 (31%)	17 (68%)	14 (56%)	21 (49%)	28 (60%)
Hypertension	40 (83%)	40 (77%)	NR	NR	19 (76%)	15 (60%)	29 (66%)	31 (66%)
Hyperlipidemia	45 (94%)	45 (87%)	NR	NR	12 (48%)	17 (68%)	22 (50%)	22 (47%)
Diabetes mellitus	10 (21%)	15 (29%)	40 (59%)	18 (56%)	13 (52%)	9 (36%)	19 (43%)	13 (28%)
Coronary artery disease	25 (52%)	24 (46%)	34 (50%)	16 (50%)	NR	NR	14 (32%)	15 (32%)
Renal insufficiency	NR	NR	6 (9%)	4 (13%)	NR	NR	NR	NR
Intermittent claudication	45 (94%)	48 (92%)	65 (96%)	31 (97%)	23 (92%)	22 (88%)	42 (95%)	45 (96%)
Critical limb ischemia	3 (6%)	4 (8%)	3 (4%)	1 (3%)	2 (8%)	3 (12%)	2 (5%)	2 (4%)
Lesions treated	n=48	n=52	n=68	n=32	n=44	n=48	n=44 (62)	n=47 (55)
Lesion Length (cm)	6.8±4.4	7.4±5.6	13.4±5.1	13.7±5.6	7.6±0.6	7.8±0.7	7.0±5.3	6.6±5.5
Vessel Diameter (mm)	5.0±1.0	5.0±0.9	4.8±0.8	4.7±0.7	NA	NA	4.9±1.3	4.9±1.3
Total occlusions	28 (58%)	35 (67%)	11 (16%)	5 (16%)	5 (11%)	9 (19%)	10 (23%)	18 (38%)
Bail-out stenting	48 (100%)	52 (100%)	3 (4%)	1 (3%)	20 (45%)	21 (44%)	9 (21%)	16 (34%)

Table S3. Baseline patient characteristics of included randomized clinical trials (continued).

	ISAR-PEBIS		FAIR		BIOLUX P-I		RANGER-SFA	
	DCB	PTA	DCB	PTA	DCB	PTA	DCB	PTA
Study allocation								
Patients (limbs)	n=36	n=34	n=62	n=57	n=30	n=30	n=71	n=34
Age (years)	70±10	68±10	69±8	67±9	70±10	71±10	68±8	67±9
Male gender	24 (67%)	24 (70%)	33 (53%)	49 (70%)	17 (57%)	17 (57%)	53 (75%)	23 (68%)
Smoking	21 (58%)	24 (71%)	18 (29%)	20 (35%)	19 (63%)	22 (73%)	29 (41%)	17 (50%)
Hypertension	33 (92%)	33 (80%)	52 (84%)	53 (93%)	23 (77%)	21 (70%)	58 (82%)	26 (76%)
Hyperlipidemia	35 (97%)	33 (97%)	48 (78%)	45 (79%)	18 (60%)	19 (63%)	49 (69%)	21 (62%)
Diabetes mellitus	12 (33%)	12 (35%)	28 (45%)	17 (30%)	11 (37%)	9 (30%)	28 (39%)	12 (35%)
Coronary artery disease	17 (47%)	16 (47%)	26 (42%)	22 (39%)	8 (27%)	11 (37%)	24 (34%)	13 (38%)
Renal insufficiency	NR	NR	8 (13%)	10 (18%)	NR	NR	8 (11%)	1 (3%)
Intermittent claudication	35 (97%)	33 (97%)	59 (95%)	51 (90%)	24 (80%)	26 (87%)	71 (100%)	31 (97%)
Critical limb ischemia	1 (3%)	1 (3%)	3 (5%)	6 (10%)	6 (20%)	4 (13%)	0 (0%)	1 (3%)
Lesions treated	n=36	n=34	n=62	n=57	n=33	n=35	n=70	n=32
Lesion Length (cm)	13.2±6.5	14.6±6.9	8.2±7.1	8.1±6.6	5.1±4.7	6.9±5.7	6.8±4.6	6.0±4.8
Vessel Diameter (mm)	5.0±1.1	4.7±0.9	5.1±0.9	5.4±0.5	4.6±0.8	4.7±0.9	5.0±0.9	4.5±0.8
Total occlusions	13 (36%)	10 (29%)	15 (24%)	19 (33%)	NR	NR	24 (34%)	11 (34%)
Bail-out stenting	NA	NA	NA	NA	2 (7%)	8 (27%)	15 (21%)	4 (12%)

Table S3. Baseline patient characteristics of included randomized clinical trials (continued).

	ACOART-I		DEBATE-SFA		ILLUMENATE pivotal		LUTONIX JAPAN	
	DCB	PTA	DCB+BMS	PTA+BMS	DCB	PTA	DCB	PTA
Study allocation								
Patients (limbs)	n=100	n=100	n=53	n=51	n=200	n=100	n=71	n=38
Age (years)	66±9	66±9	74±9	76±8	68±10	70±10	72±10	78±8
Male gender	73 (73%)	74 (74%)	50 (75%)	42 (63%)	112 (56%)	64 (64%)	45 (63%)	46 (68%)
Smoking	29 (29%)	33 (33%)	25 (47%)	28 (55%)	168 (84%)	75 (75%)	53 (75%)	26 (68%)
Hypertension	62 (62%)	72 (72%)	47 (89%)	45 (88%)	187 (94%)	94 (94%)	60 (85%)	35 (92%)
Hyperlipidemia	27 (27%)	29 (29%)	33 (62%)	27 (53%)	176 (88%)	90 (90%)	47 (66%)	26 (68%)
Diabetes mellitus	54 (54%)	57 (57%)	41 (77%)	36 (71%)	99 (50%)	52 (52%)	33 (47%)	18 (47%)
Coronary artery disease	NR	NR	21 (40%)	18 (35%)	90 (45%)	48 (48%)	31 (44%)	14 (37%)
Renal insufficiency	NR	NR	NR	NR	36 (18%)	16 (16%)	5 (7%)	2 (5%)
Intermittent claudication	60 (60%)	66 (66%)	11 (21%)	16 (31%)	192 (96%)	95 (95%)	71 (100%)	37 (97%)
Critical limb ischemia	40 (40%)	34 (34%)	42 (79%)	35 (69%)	8 (4%)	5 (5%)	0(0%)	1 (3%)
Lesions treated	n=100	n=100	n=55	n=55	n=200	n=100	n=72	n=40
Lesion Length (cm)	14.7±11.0	15.2±10.9	9.4±6.0	9.6±6.9	8.0±4.5	8.9±4.6	6.8±4.3	5.7±5.1
Vessel Diameter (mm)	3.8±0.6	3.7±0.8	5.0±0.5	5.1±0.5	4.9±0.9	5.2±1.1	4.9±0.7	4.7±0.7
Total occlusions	57 (57%)	52 (52%)	30 (55%)	38 (69%)	38 (19%)	18 (18%)	13 (18%)	2 (5%)
Bail-out stenting	19 (19%)	21 (21%)	NA	NA	12 (6%)	6 (6%)	1 (2%)	3 (8%)

Table S3. Baseline patient characteristics of included randomized clinical trials (continued).

Study allocation	RAPID		EFFPAC		FINNPTX		BATTLE	
	DCB+BMS	PTA+BMS	DCB	PTA	DES	PTFE	DES	BMS
Patients (limbs)	n=80	n=80	n=85	n=86	n=23	n=18	n=86	n=85
Age (years)	68±8	67±8	68±8	68±9	68±10	67±9	71±12	68±12
Male gender	52 (65%)	50 (63%)	51 (60%)	60 (70%)	17 (74%)	12 (67%)	62 (72%)	62 (73%)
Smoking	40 (50%)	39 (49%)	NR	NR	9 (39%)	6 (33%)	20 (23%)	28 (33%)
Hypertension	NR	NR	74 (87%)	73 (85%)	15 (65%)	15 (83%)	59 (69%)	52 (61%)
Hyperlipidemia	NR	NR	60 (71%)	59 (69%)	13 (57%)	15 (83%)	55 (65%)	61 (73%)
Diabetes mellitus	23 (29%)	24 (30%)	31 (37%)	35 (41%)	9 (39%)	6 (33%)	41 (48%)	22 (26%)
Coronary artery disease	NR	NR	NR	NR	6 (26%)	5 (28%)	27 (31%)	34 (40%)
Renal insufficiency	NR	NR	NR	NR	NR	NR	8 (9%)	6 (7%)
Intermittent claudication	66 (82%)	67 (84%)	82 (96%)	85 (99%)	17 (74%)	17 (94%)	68 (79%)	70 (82%)
Critical limb ischemia	14 (18%)	13 (16%)	3 (4%)	1 (1%)	6 (26%)	1 (6%)	18 (21%)	15 (18%)
Lesions treated	n=80	n=80	n=85	n=86	n=23	n=18	n=86	n=85
Lesion Length (cm)	15.8±7.4	15.8±7.6	5.9±4.3	5.6±3.9	13.2±6.2	11.3±4.0	7.3±3.2	7.3±3.9
Vessel Diameter (mm)	5.1±0.7	5.2±0.8	5.4±0.6	5.4±0.7	NA	NA	5.8±0.6	5.8±0.5
Total occlusions	61 (76%)	56 (70%)	17 (20%)	22 (26%)	23 (100%)	18 (100%)	NR	NR
Bail-out stenting	NA	NA	13 (15%)	16 (19%)	23 (100%)	NA	86 (100%)	85 (100%)

Table S3. Baseline patient characteristics of included randomized clinical trials (continued).

	DEBATE in SFA		PACUBA		DRECOREST		FREEWAY	
	DES	BMS	DCB	PTA	DCB	PTA	DCB+BMS	PTA+BMS
Study allocation								
Patients (limbs)	n=85	n=170	n=35	n=39	n=29	n=28	n=105	n=99
Age (years)	73±8	73±9	68±9	68±10	68±10	68±10	65±9	64±10
Male gender	60 (71%)	112 (66%)	20 (57%)	23 (59%)	15 (52%)	17 (61%)	82 (78%)	76 (77%)
Smoking	24 (28%)	41 (24%)	17 (52%)	18 (53%)	17 (59%)	14 (50%)	93 (89%)	81 (82%)
Hypertension	68 (80%)	142 (84%)	26 (79%)	27 (79%)	23 (79%)	20 (71%)	79 (75%)	73 (74%)
Hyperlipidemia	52 (61%)	101 (59%)	18 (55%)	25 (74%)	25 (86%)	27 (96%)	63 (60%)	57 (58%)
Diabetes mellitus	50 (59%)	90 (53%)	17 (52%)	13 (38%)	11 (38%)	17 (61%)	28 (27%)	26 (26%)
Coronary artery disease	44 (52%)	66 (39%)	NR	NR	14 (48%)	11 (39%)	26 (25%)	23 (23%)
Renal insufficiency	17 (20%)	36 (21%)	6 (19%)	6 (16%)	6 (21%)	4 (14%)	NR	NR
Intermittent claudication	79 (93%)	146 (86%)	35 (100%)	38 (100%)	13 (45%)	18 (64%)	98 (93%)	96 (97%)
Critical limb ischemia	6 (7%)	24 (14%)	0 (0%)	0 (0%)	16 (55%)	10 (36%)	7 (7%)	3 (3%)
Lesions treated	n=85	n=170	n=35	n=39	n=29	n=28	n=105	n=99
Lesion Length (cm)	11.1±5.0	9.8±4.0	17.3±11.3	18.4±8.8	1.2±1.0	1.4±2.0	7.7±4.2	8.3±4.1
Vessel Diameter (mm)	5.3±1.0	5.2±1.1	5.7±1.0	5.4±0.9	4.2±0.8	5.0±0.6	5.2±0.7	5.2±0.7
Total occlusions	43 (51%)	67 (37%)	11 (31%)	11 (28%)	0 (0%)	0 (0%)	67 (64%)	63 (64%)
Bail-out stenting	86 (100%)	85 (100%)	NA	NA	NA	NA	NA	NA

Table S4. Sensitivity analyses of rare events (Risk Ratio; 95%CI or CrI) ⁴¹

(R 'meta' package (version 4.9-2 – Bayesian with <https://gemtc.drugis.org>)

	Fixed effects	Random effects
All-cause death at 1 year		
Continuity correction 0.5	1.06 (0.73-1.55)	1.08 (0.72-1.61)
Continuity correction 0.01	1.07 (0.72-1.58)	1.05 (0.69-1.62)
Treatment arm continuity correction (TACC) ⁴²	1.06 (0.73-1.55)	1.07 (0.71-1.60)
Mantel-Haenszel exact method (no continuity correction)	1.07 (0.72-1.58)	1.05 (0.68-1.61)
Bayesian binomial/log model (risk ratio) (burn-in 50000 and inference 200000 iterations)	1.59 (1.12-2.31)	1.64 (1.12-2.46)
All-cause death at 2 years		
Continuity correction =0.5	1.84 (1.27-2.68)	1.68 (1.15-2.47)
Continuity correction =0.01	1.87 (1.28-2.72)	1.64 (1.11-2.42)
Treatment arm continuity correction	1.85 (1.27-2.69)	1.69 (1.15-2.48)
Mantel-Haenszel exact method (no continuity correction)	1.87 (1.28-2.73)	1.63 (1.11-2.41)
Bayesian binomial/log model (risk ratio) (burn-in 50000 and inference 200000 iterations)	2.12 (1.48-3.13)	2.28 (1.45-4.27)
All-cause death at 4-5 years		
Continuity correction =0.5	1.94 (1.28-2.96)	1.93 (1.27-2.93)
Continuity correction =0.01	1.94 (1.28-2.96)	1.93 (1.27-2.93)
Treatment arm continuity correction	1.94 (1.28-2.96)	1.93 (1.27-2.93)
Mantel-Haenszel exact method	1.94 (1.28-2.96)	1.93 (1.27-2.93)

(no continuity correction)		
Bayesian binomial/log model (risk ratio) (burn-in 50000 and inference 200000 iterations)	2.00 (1.35-3.11)	2.01 (1.15-3.61)

Figure S1. Literature search and study selection process following the PRISMA statement.

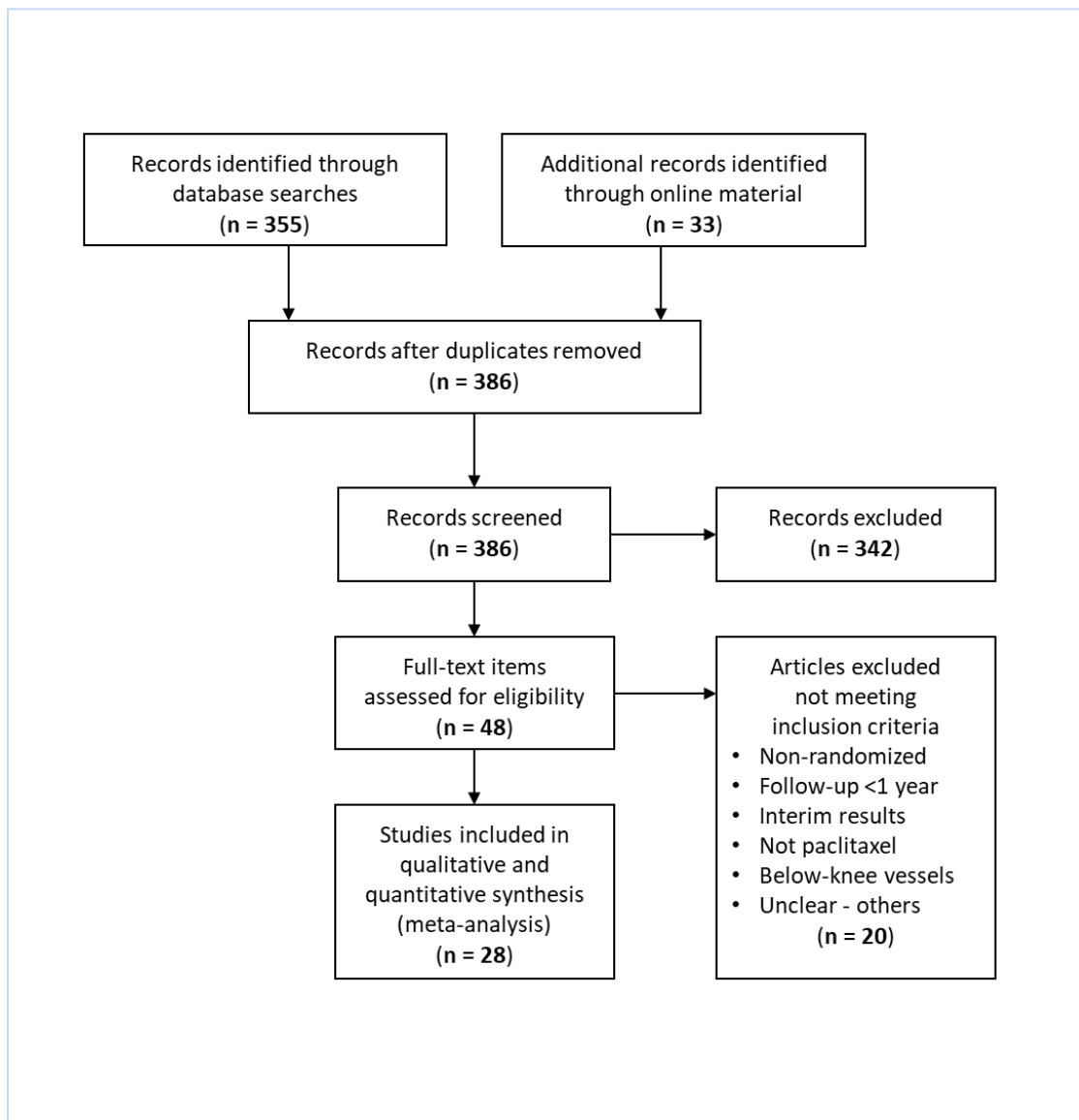
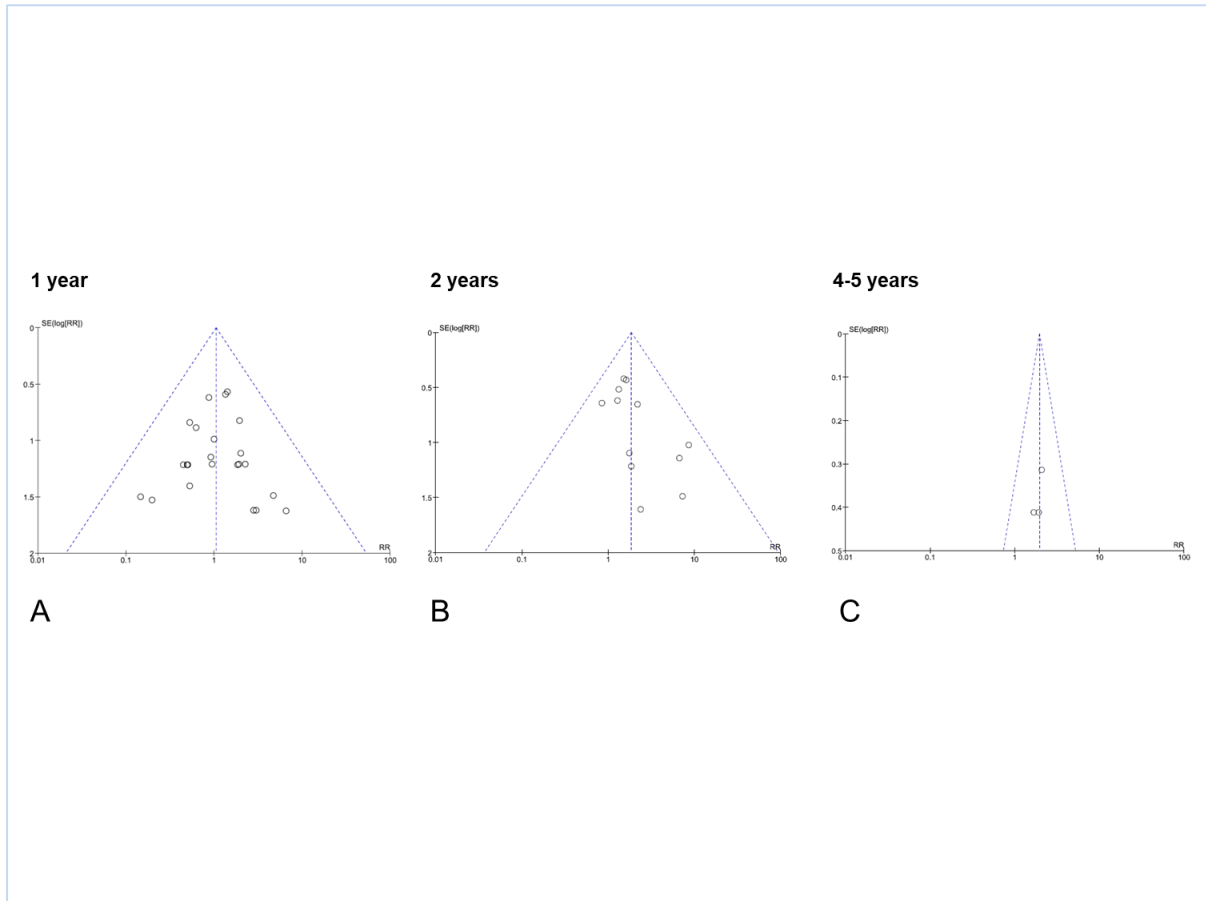


Figure S2. Evaluation of risk of bias of each RCT according to the Cochrane Collaboration Tool.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
ACOART I	+	+	-	?	+	+	+
BATTLE	+	+	-	?	+	+	?
BIOLUX P-I	+	+	-	+	+	+	+
CONSEQUENT	+	+	-	+	+	+	+
DEBATE-IN-SFA	+	+	-	+	+	+	+
DEBATE-SFA	+	+	-	?	+	+	+
DEBELLUM	+	+	-	-	+	+	+
DRECOREST	+	+	-	-	+	+	?
EFFPAC	+	+	-	+	+	+	+
FAIR	+	+	-	-	+	+	+
FEMPAC	+	+	-	?	+	+	+
FINN-PTX	+	+	-	-	+	+	?
FREEWAY	+	+	-	?	+	+	+
ILLUMENATE EU	+	+	-	+	+	+	+
ILLUMENATE pivotal	+	+	-	+	+	+	+
IN.PACT SFA	+	+	-	+	+	+	+
IN.PACT SFA JAPAN	+	+	-	+	+	+	+
ISAR-PEBIS	+	+	-	-	+	+	+
ISAR-STATH	+	+	-	-	+	+	+
LEVANT I	+	+	-	+	+	+	+
LEVANT II	+	+	-	+	+	+	+
LUTONIX JAPAN	+	+	-	?	+	+	+
PACIFIER	+	+	-	?	+	+	+
PACUBA	+	+	-	+	+	+	+
RANGER SFA	+	+	-	?	+	+	+
RAPID	+	+	-	+	+	+	+
THUNDER	+	+	-	+	+	+	+
ZILVER-PTX	+	+	-	+	+	+	+
ZILVER-PTX 2nd	+	+	-	+	+	+	+

Figure S3. Funnel plots of all-cause death analyses at (A) 1 year, (B) 2 years, and (C) 4-5 years of follow-up.



The SE of the logRR was plotted against the RR for each trial.

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