

1-year clinical outcome of Genoss DES








Safety and Efficacy of a New Ultrathin Sirolimus-Eluting Stent with Abluminal Biodegradable Polymer in Real-World Practice

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Comparison of DES

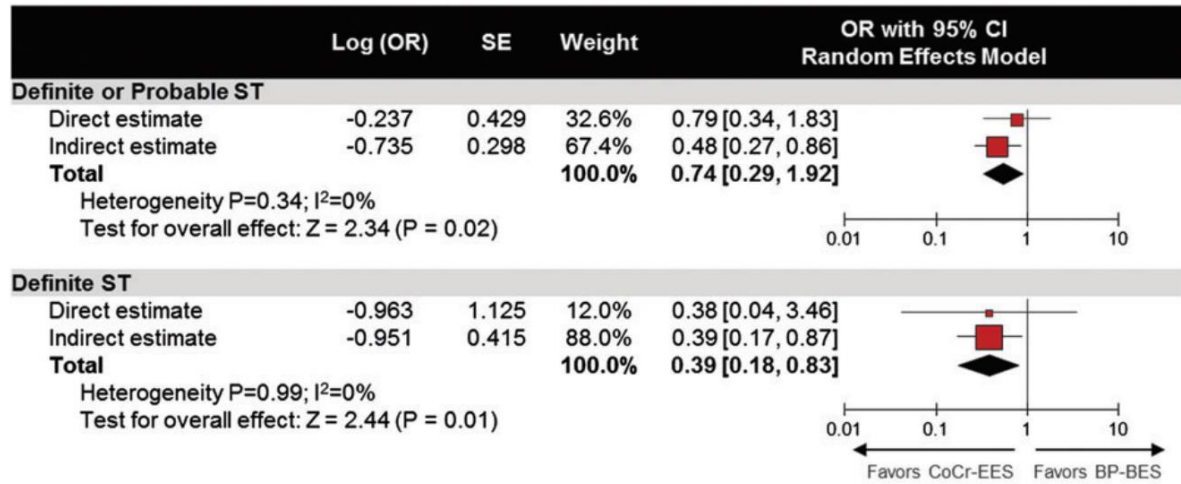
		Biodegradable polymer (BP)					Permanent polymer (DP)	
Name		Genoss DES	Orsiro	Ultimaster	Synergy	Biomatrix	Xience	Resolute
Manufacturer		Genoss	Biotronik	Terumo	Abbott Vascular	BioSensors International	Abbott	Medtronic
Country of manufacture		Seoul, South Korea	Bülach, Switzerland	Tokyo, Japan	Marlborough, MA, USA	Boon Lay, Singapore	Green Oaks, IL, USA	Dublin, Ireland
Drug		Sirolimus	Sirolimus	Sirolimus	Everolimus	Biolimus	Everolimus	Zotarolimus
Polymer	Polymer	PLLA/PLGA	Dual-polymer mix†	poly(DL-lactide-co-caprolactone)	PLGA	PLA	PBMA/PVDF-HFP	BioLynx
	Thickness (µm)	3	7.4	15	4	10	7.6	5.6
	Coating distribution	Abluminal	Circumferential	Abluminal	Abluminal	Abluminal	Circumferential	Circumferential
	Drug elution kinetics				>95% within two weeks		80% within four weeks	85% within eight weeks
Strut	Material	CoCr	CoCr	CoCr	PtCr	Stainless Steel	CoCr	CoNi
	Thickness (µm)	70-78	60-80	80	74-81	112-137	81	91
Drug dose		1.15 µg/mm ²	1.4 µg/mm ²	3.9 µg/mm	113 µg/20mm	15.6 µg/mm	1 µg/mm ²	1 µg/mm ²
Strut + Polymer thickness (µm)		73	80	95	78	130	97	101
Relative size of cross-section								

†passive coating of PROBIO (amorphous silicon carbide) and active coating of BIOLute (PLLA)

The Thinner, The Better

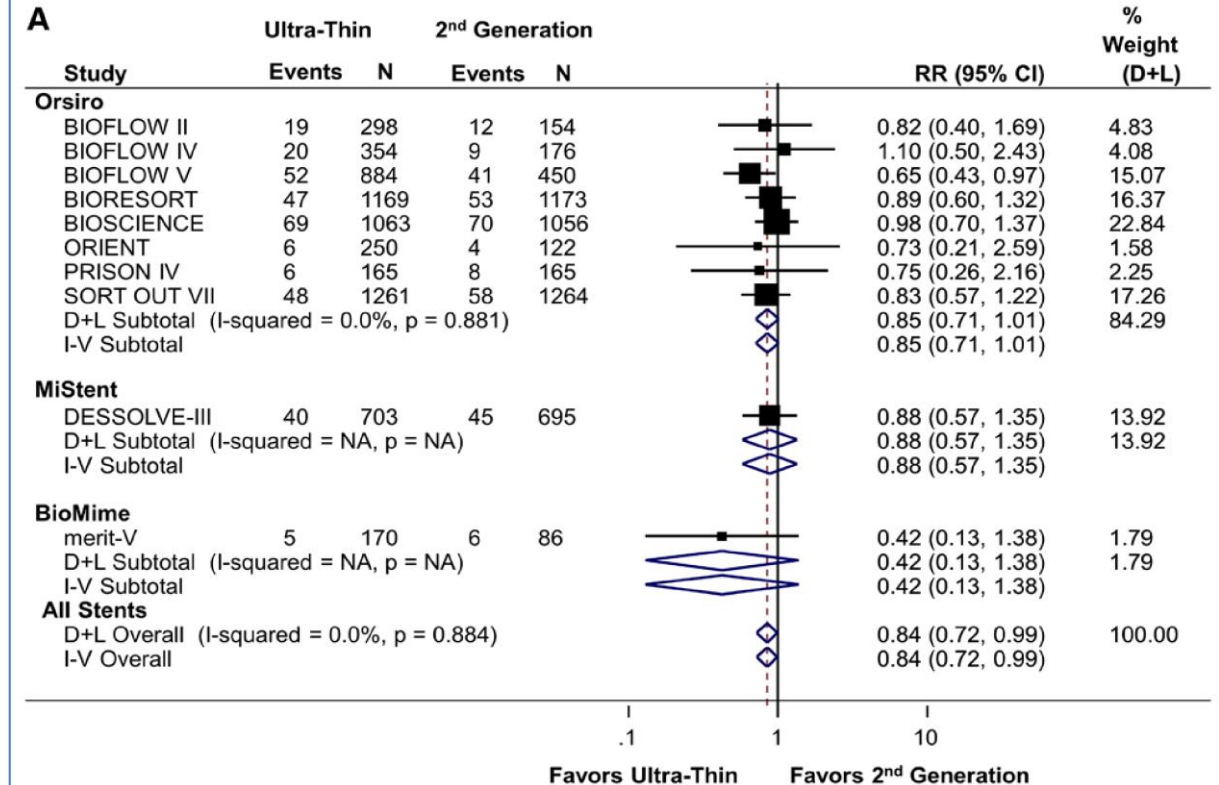
Era of Nobori and BioMatrix

B CoCr-EES vs. BP-BES



Definite and probable ST (OR, 1.72; 95% CI, 1.04–2.98)

Era of Orsiro, Mistent, and BioMime



TLF (OR, 0.84; 95% CI, 0.72-0.99)

MI (OR, 0.80; 95% CI, 0.65-0.99)

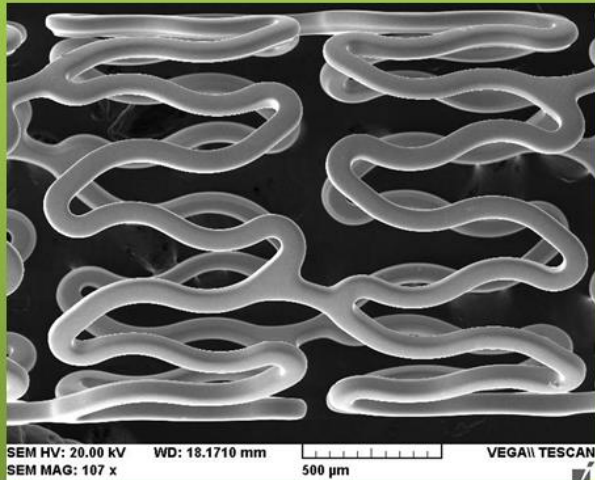
Kang et al., *Eur Heart J.* 2014 May;35(17):1147-58

Bangalore et al., *Circulation.* 2018 Nov 13;138(20):2216-2226.

Genoss DES™ Drug-eluting Stent

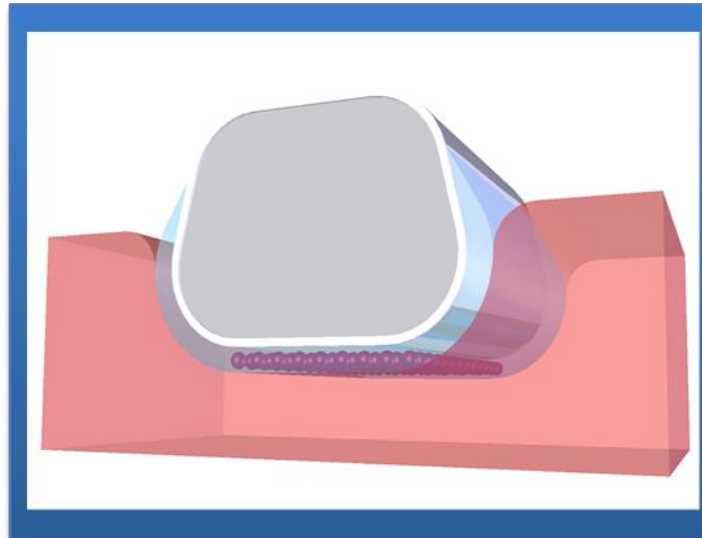
Strut

Co-Cr Alloy L605
Thickness 70 μ m, 78 μ m



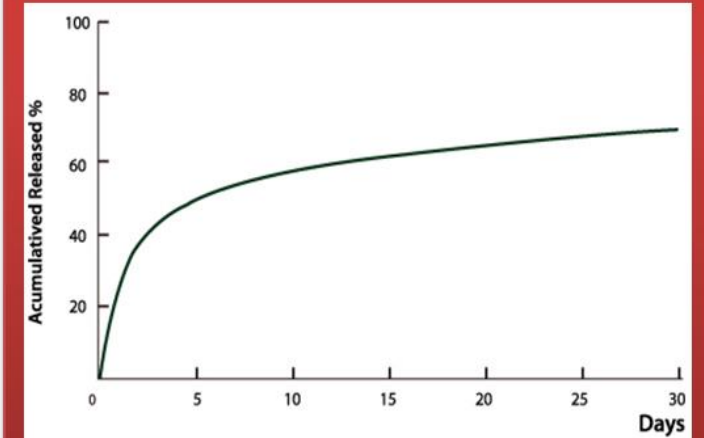
Polymer

Biodegradable within 9 months
Abluminal coating
Coating thickness 3 μ m



Drug

Sirolimus: 1.15 μ g/mm²



First-In-Man Trial of Genoss DES

- Clinical inclusion criteria: stable and unstable angina, silent ischemia
- Angiographic inclusion criteria: De novo lesion + >50%DS + RVD of 2.5-4.0 mm + lesion length ≤40 mm.
- Genoss DES (n = 38) vs. Promus Element (n = 39)

Table 3. QCA analysis

	Genoss DES™ (n=38)	Promus Element™ (n=39)	p
Late loss (mm)			
In-stent	0.11±0.25	0.16±0.43	0.567
In-segment	0.11±0.26	0.15±0.43	0.558
Lesion length (mm)	23.8±8.1	22.8±4.9	0.531
Restenosis	1 (2.6)	2 (5.1)	1.000



GENOSS DES Prospective Registry

- The Genoss DES prospective registry (ClinicalTrials.gov Identifier: NCT03045913)
 - **Ongoing**, prospective, single-arm, observational, multi-center trial
 - Aims to enroll 2000 subjects and follow them clinically for 12 months
 - From 16 centers in South Korea since November 2016.

• Inclusion criteria

- age ≥ 19 years
- Stable angina or ACS
- Subjects successfully implanted the Genoss DES within 1 month were eligible.
- At least one significant coronary stenosis

• Exclusion criteria

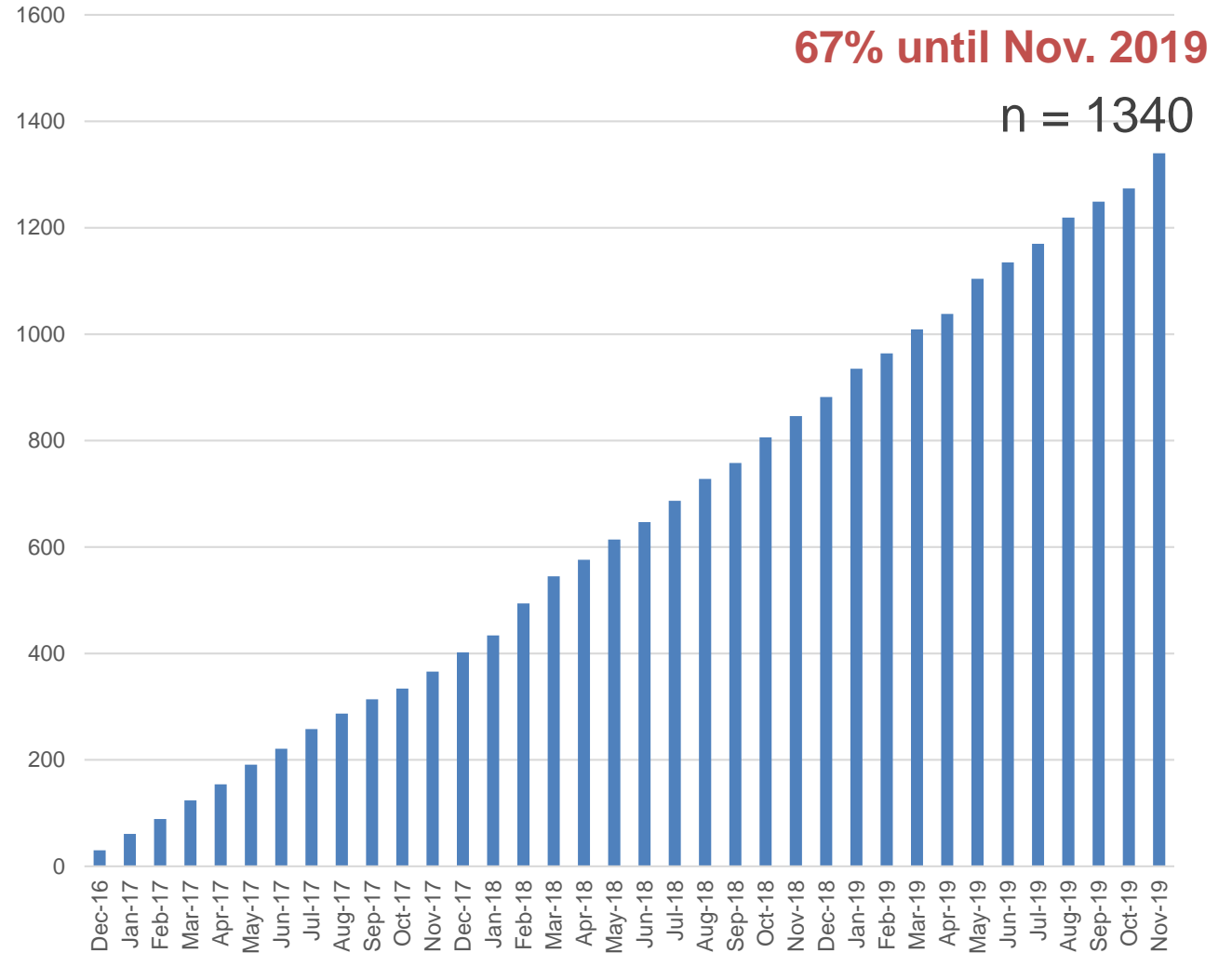
- Intolerance to medication
- Allergy to stent component
- Planned surgery within the 12 months after the index PCI
- Cardiogenic shock during the index PCI
- Life expectancy < 12 months
- The use of different types of DES or BMS.

• Primary endpoint

- a device-oriented composite outcome (DOCO) comprising cardiac death, target vessel-related myocardial infarction (MI), and clinically indicated target lesion revascularization (TLR) at 12-month clinical follow-up.

Current Status of GENOSS DES Prospective Registry

Investigator	Institute	Location
Junghan Yoon	Wonju Severance Christian Hospital	Wonju
Sang-Yong Yoo	Gangneung Asan Hospital	Gangneung
Jae Hyoung Park	Korea University Anam Hospital	Seoul
Woong Gil Choi	Konkuk University Chungju Hospital	Chungju
Sungsoo Cho	Dankook University Hospital	Cheonan
Sang-Wook Lim	CHA Bundang Medical Center	Seongnam
Ki Hwan Kwon	Ewha Womans University Mokdong Hospital	Seoul
Nam Ho Lee	Kangnam Sacred Heart Hospital	Seoul
Joon Hyung Doh	Inje University Ilsan Paik Hospital	Goyang
Woong Chol Kang	Gachon University Gil Medical Center	Incheon
Yang Soo Jang	Severance Cardiovascular Hospital	Seoul
Dong Woon Jeon	National Health Insurance Service Ilsan Hospital	Goyang
Bong-Ki Lee	Kangwon National University Hospital	Chuncheon
Jung Ho Heo	Kosin University Gospel Hospital	Busan
Bum-Kee Hong	Gangnam Severance Hospital	Seoul
Hyun-Hee Choi	Chuncheon Sacred Heart Hospital	Chuncheon



RESULTS OF INTERIM ANALYSIS

GENOSS DES PROSPECTIVE REGISTRY



Safety and Efficacy of a New Ultrathin Sirolimus-Eluting Stent with Abluminal Biodegradable Polymer in Real-World Practice

Genoss DES in real-world practice

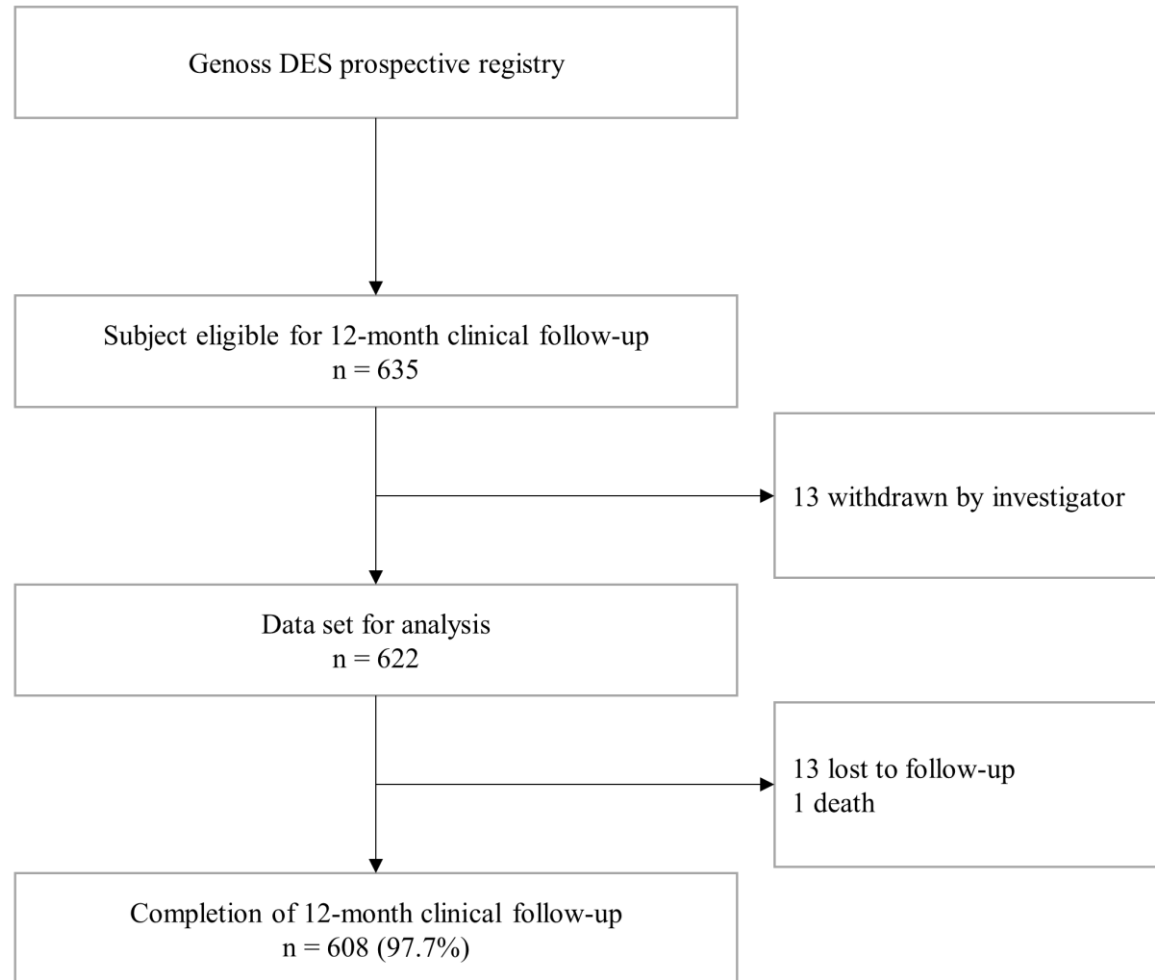
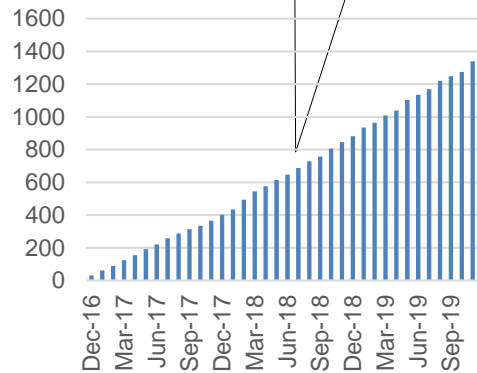
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Study Flow Diagram

The last patient was enrolled on May 31, 2018.



Baseline, Angiographic, and Procedural Characteristics of Patients

Variables	n = 622
Age, years	66.5 ± 10.4
Male	439 (70.6)
Hypertension	420 (67.5)
Diabetes Mellitus	238 (38.3)
Insulin-dependent	28 (4.5)
Dyslipidemia	387 (62.2)
Chronic kidney disease	36 (5.8)
Dialysis dependent	11 (1.8)
Current smoker or ex-smoker	310 (49.8)
Previous myocardial infarction	40 (6.4)
Previous PCI	101 (17.0)
Previous coronary artery bypass grafting	10 (1.6)
Previous stroke	60 (9.6)
Indication for PCI	
Stable angina	119 (19.1)
Unstable angina	260 (41.8)
NSTEMI	119 (19.1)
STEMI	95 (15.3)

Variables	n = 622
Disease extent	
1-VD	256 (40.9)
2-VD	192 (30.9)
3-VD	175 (28.1)
Transradial intervention	492 (79.1)
PCI type	
Elective PCI	481 (77.3)
Primary PCI	87 (14.0)
Multi-vessel PCI	138 (22.2)
Number of treated lesions	1.3 ± 0.5
Implanted Genoss DES per patient	
Number	1.5 ± 0.8
Diameter, mm	3.1 ± 0.4
Length, mm	36.0 ± 23.3

Values are mean ± SD or n (%).

NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction; VD, vessel disease

Angiographic and Procedural Characteristics of Lesions

Variables	n = 753
In-stent restenosis lesion	38 (5.0)
Moderate to severe proximal tortuosity	25 (3.3)
Moderate to severe angulation	37 (4.9)
Moderate to severe calcification	99 (13.1)
Thrombotic lesion	80 (10.6)
ACC/AHA lesion classification	
A	77 (10.2)
B1	131 (17.4)
B2	237 (31.5)
C	308 (40.9)
Treated territory	
Left anterior descending artery	366 (48.6)
Left circumflex artery	138 (18.3)
Right coronary artery	233 (30.9)
Left main	15 (2.0)
PCI method	
Genoss DES only	698 (92.7)
Genoss DES + POBA or DCB	12 (1.6)

Variables	n = 753
Implanted Genoss DES per lesion	
Number	1.2 ± 0.5
Diameter, mm	3.1 ± 0.4
Length, mm	29.7 ± 15.6
PCI for chronic total occlusion lesion	32 (4.2)
PCI for bifurcation lesion	82 (10.9)
with 2 stents strategy	15 (2.0)
Use of intravascular ultrasound	226 (30.0)
Thrombectomy	43 (5.7)
Procedural success	737 (97.9)
TIMI flow grade 0-1, pre-procedure	173 (23.0)
TIMI flow grade 3, post-procedure	747 (99.2)
Diameter stenosis, pre-procedure, %	84.2 ± 12.0
Diameter stenosis, post-procedure, %	7.8 ± 8.0

Values are mean ± SD or n (%).

ACC, American College of Cardiology; AHA, American Heart Association; DCB, drug-coated balloon; DES, drug-eluting stent; PCI, percutaneous coronary intervention; POBA, plain old balloon angioplasty; TIMI, Thrombolysis In Myocardial Infarction

Discharge Medications among Survivors at Discharge

Variables	n = 620
Dual antiplatelet therapy	612 (98.7)
Aspirin + Clopidogrel	378 (61.0)
Aspirin + Ticagrelor	209 (33.7)
Aspirin + Prasugrel	25 (4.0)
Cilostazol	7 (1.1)
Anticoagulant	19 (3.0)
Vitamin K antagonist	2 (0.3)
Non-vitamin K antagonist oral anticoagulant	17 (2.7)
Statin	594 (95.8)
Fenofibrate	4 (0.6)
Calcium channel blocker	195 (31.5)
Beta blocker	327 (52.7)
ACEi or ARB	383 (61.8)
Nitrate or nicorandil	403 (65.0)

Values are n (%).

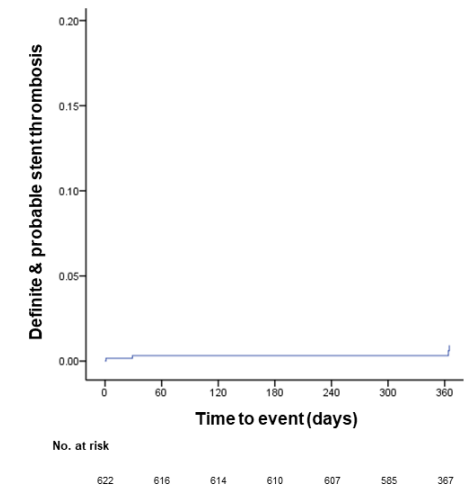
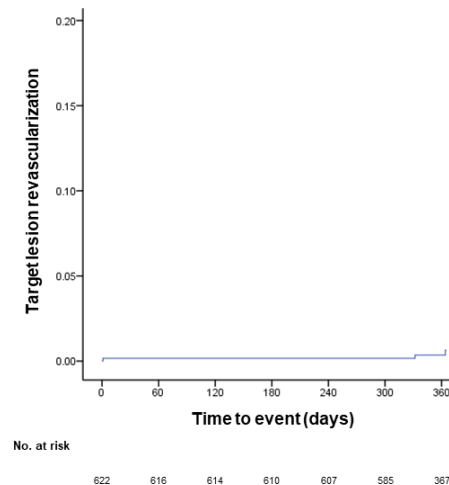
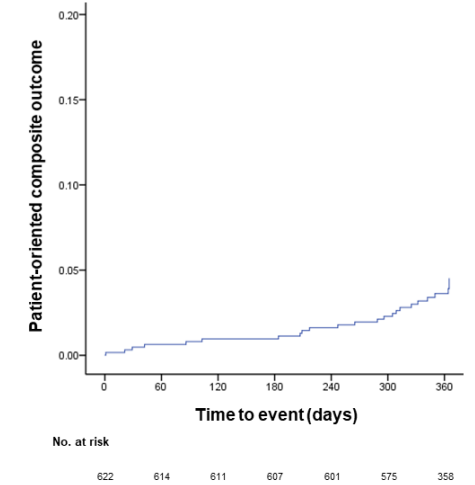
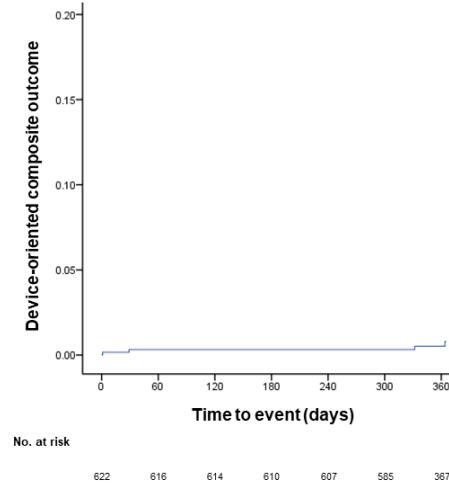
ACEi, angiotensin converting enzyme inhibitor; ARB, angiotensin II receptor blockers



Results – Clinical Outcomes at 12-month Follow-up

Survivors at discharge	n = 622
Follow-up duration	365 (343, 365)
Device-oriented composite outcome	4 (0.6)
Cardiovascular death	1 (0.2)
Target vessel myocardial infarction	1 (0.2)
Target lesion revascularization	3 (0.5)
Patient-oriented composite outcome	24 (3.9)
Any death	4 (0.6)
Any myocardial infarction	4 (0.6)
Any revascularization	19 (3.1)
Target vessel revascularization	5 (0.8)
Definite stent thrombosis	3 (0.5)
Definite and probable stent thrombosis	4 (0.6)

Values are median (interquartile range) or n (%).



Limitations

- Non-randomized design and lacks comparator for a direct comparison
- Subjects from Korean centers only
 - Results should be validated in different ethnics and regions.
- Not-prespecified interim analysis
 - To offer substantial evidence of the safety and efficacy of the Genoss DES stent owing to the rapid and extensive dissemination of the Genoss DES stent.
 - The final results could be different.



Conclusions

- This trial demonstrates that the Genoss DES stent in real-world practice is safe and effective for treating subjects with coronary artery disease.

kcj Korean Circulation Journal

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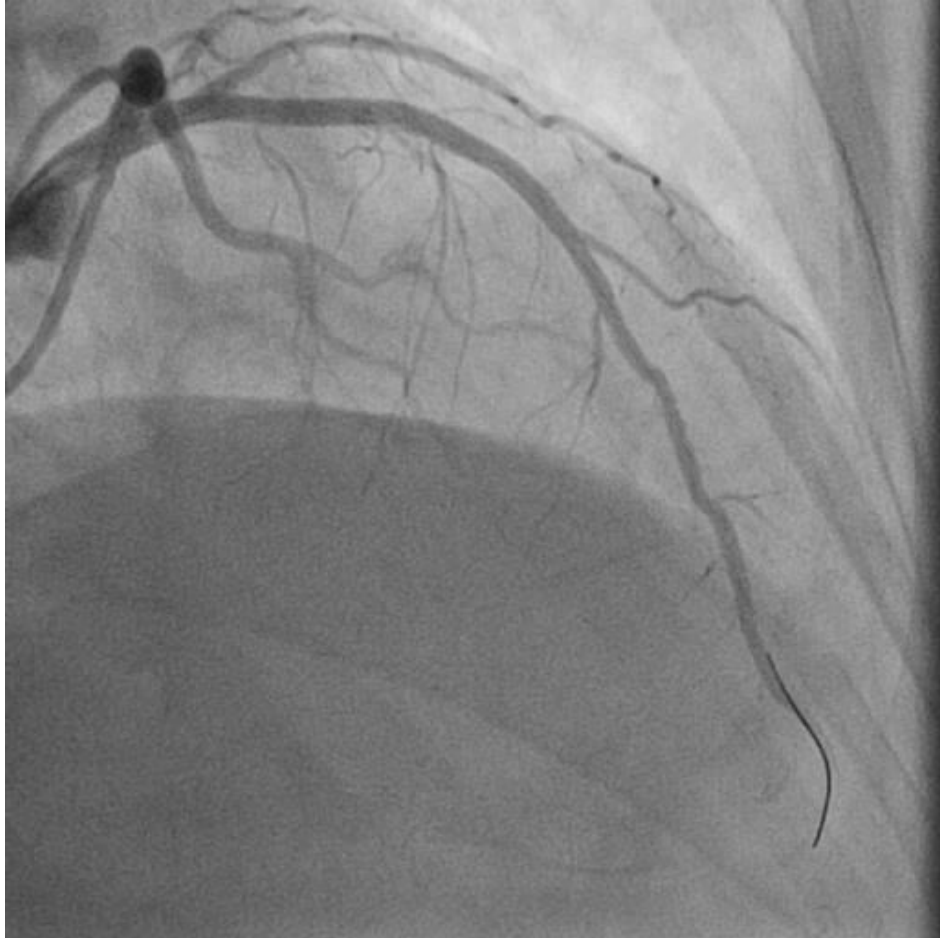


Limitations



- 1) This study is represented by the **non-randomized design** and **lacks comparator** for a direct comparison.
- 2) This registry enrolled subjects from Korean centers only and, thus, results should be validated in different ethnics and regions.
- 3) We could not adjust any confounders and provide predictors of the primary endpoint during subgroup analysis using the multivariate analysis, such as multiple logistic regression or Cox regression, because of the extremely low event rate.



Thin-Sturt BP-DES in Real-World



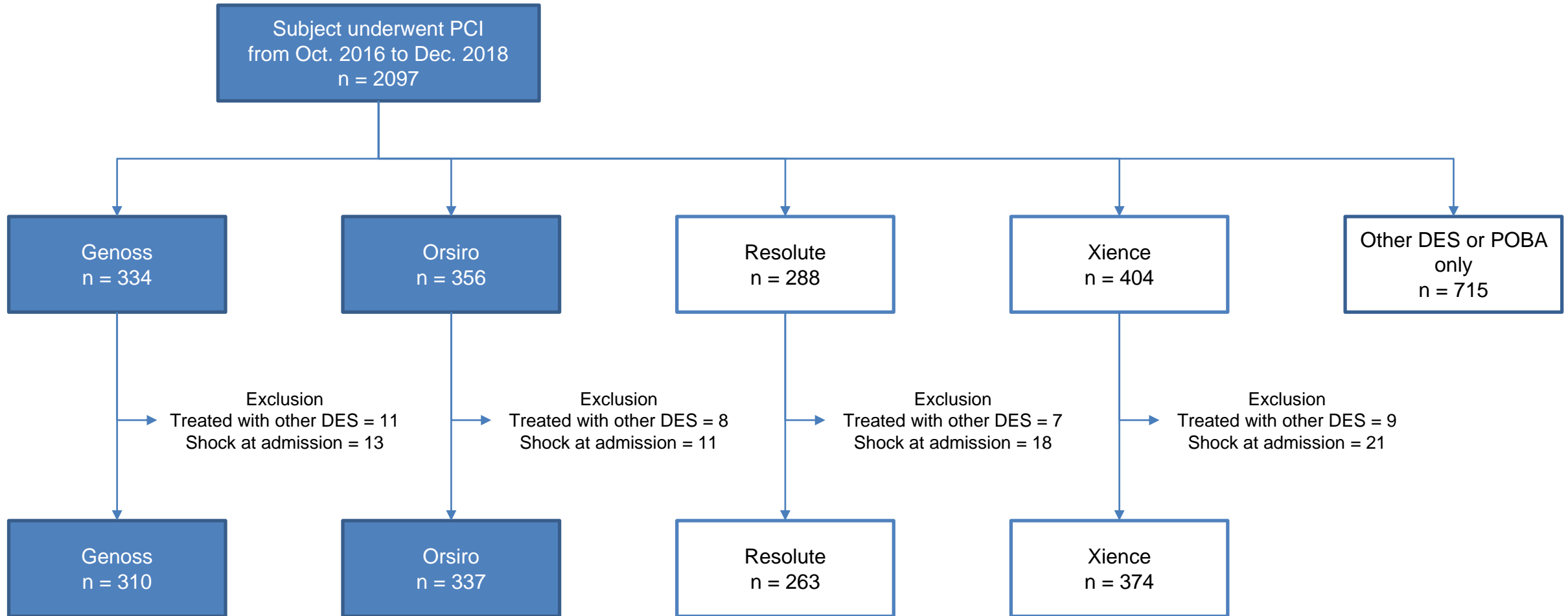
Genoss DES 3.0 mm x 33 mm

Genoss DES	Orsiro
Genoss	Biotronik
Seoul, South Korea	Bülach, Switzerland
Sirolimus	Sirolimus
PLLA/PLGA	Dual-polymer mix†
3	7.4
Abluminal	Circumferential
CoCr	CoCr
70-78	60-80
1.15 µg/mm ²	1.4 µg/mm ²
73	80
	



Orsiro 3.0 mm x 35 mm

WCH PCI Registry Database



Baseline Characteristics

Variable	Before PSM			After PSM			STD diff (%)
	Genoss n = 310	Orsiro n = 337	p	Genoss n = 191	Orsiro n = 191	p	
Age, years	68.0 ± 10.4	66.7 ± 11.7	0.150	67.0 ± 10.7	67.0 ± 11.3	0.982	0.24
Male	204 (65.8)	240 (71.2)	0.139	133 (69.6)	136 (71.2)	0.737	3.43
BMI, kg/m ²	25.0 ± 3.4	24.5 ± 3.5	0.091	25.1 ± 3.6	25.0 ± 3.1	0.810	2.46
Hypertension	190 (61.3)	208 (61.7)	0.910	123 (64.4)	117 (61.3)	0.525	6.49
Diabetes Mellitus	122 (39.4)	135 (40.2)	0.831	77 (40.3)	80 (41.9)	0.755	-3.18
Insulin-dependent	9 (2.9)	11 (3.3)	0.771	7 (3.7)	5 (2.7)	0.564	5.95
Dyslipidemia	145 (46.8)	144 (42.7)	0.301	88 (46.1)	88 (46.1)	1.000	0.00
Chronic kidney disease	19 (6.2)	27 (8.0)	0.364	10 (5.3)	12 (6.3)	0.679	-4.24
Dialysis dependent	5 (1.6)	13 (3.9)	0.087	4 (2.1)	5 (2.6)	1.000	-3.21
Current- or ex-smoker	188 (60.7)	211 (63.2)	0.509	117 (61.3)	119 (63.0)	0.732	-3.51
Prior MI	16 (5.2)	23 (6.8)	0.374	12 (6.3)	10 (5.2)	0.661	4.48
Prior PCI	67 (21.6)	49 (14.5)	0.019	32 (16.8)	33 (17.3)	0.892	-1.39
Prior CABG	1 (0.3)	4 (1.2)	0.375	1 (0.5)	3 (1.6)	0.623	-10.24
Prior stroke	27 (8.7)	29 (8.6)	0.962	16 (8.4)	14 (7.3)	0.704	3.88
Indication for PCI							
Stable angina	32 (10.3)	38 (11.3)	0.697	26 (13.6)	24 (12.6)	0.762	3.10
Unstable angina	123 (39.7)	78 (23.2)	<.001	55 (28.8)	60 (31.4)	0.577	-5.69
NSTEMI	102 (32.9)	107 (31.8)	0.754	70 (36.7)	68 (35.6)	0.831	2.17
STEMI	38 (12.3)	77 (22.9)	<.001	29 (15.2)	29 (15.2)	1.000	0.00
Primary lysis	4 (10.5)	10 (13.0)	0.704	4 (13.8)	6 (20.7)	0.487	
IABP	0 (0.0)	1 (0.3)	1.000	0 (0.0)	0 (0.0)		
ECMO	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)		
Aspirin loading dose	266 (86.1)	275 (82.3)	0.194	162 (85.3)	161 (84.7)	0.886	1.47
Clopidogrel loading dose	189 (61.2)	158 (47.3)	<.001	98 (51.6)	105 (55.3)	0.472	-7.37
Ticagrelor loading dose	88 (28.5)	133 (39.8)	0.003	70 (36.8)	63 (33.2)	0.452	7.71
Prasugrel loading dose	0 (0.0)	1 (0.3)	1.000	0 (0.0)	0 (0.0)		

Angiographic and Procedural Characteristics

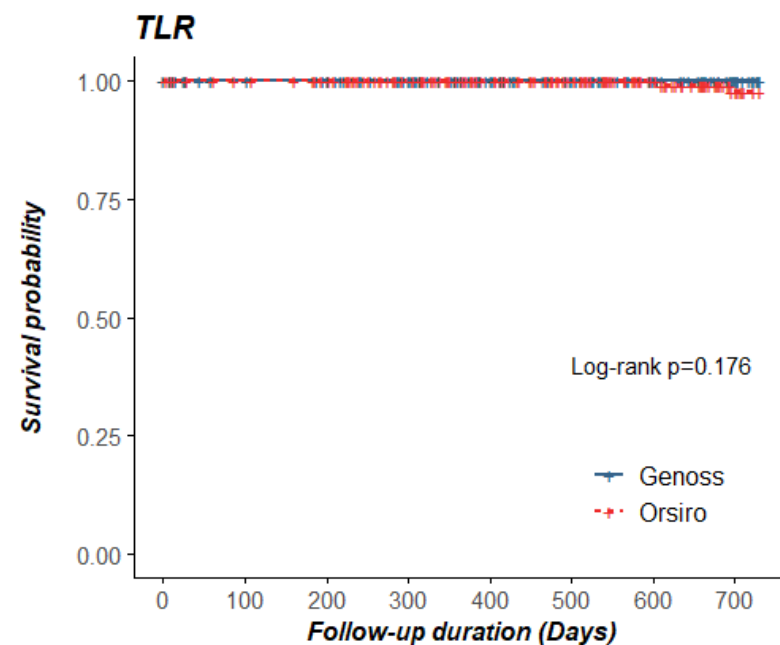
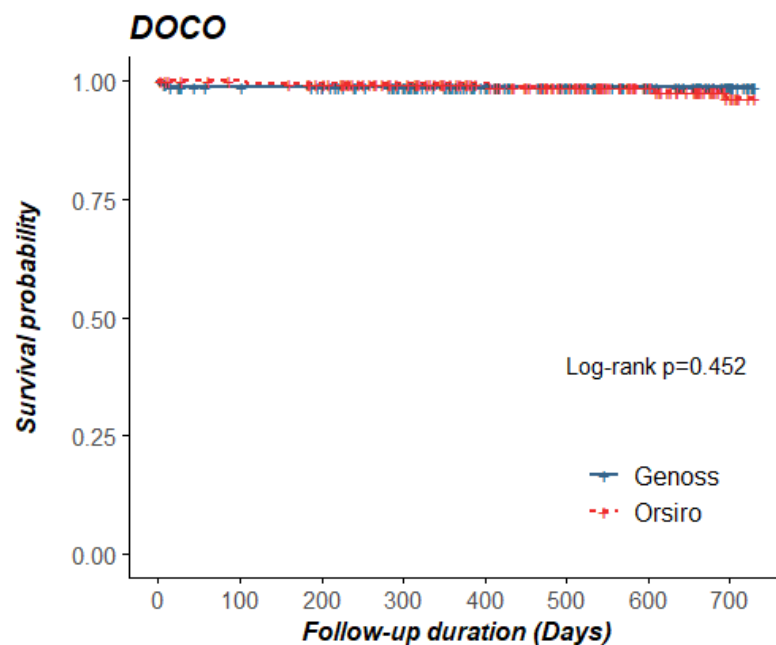
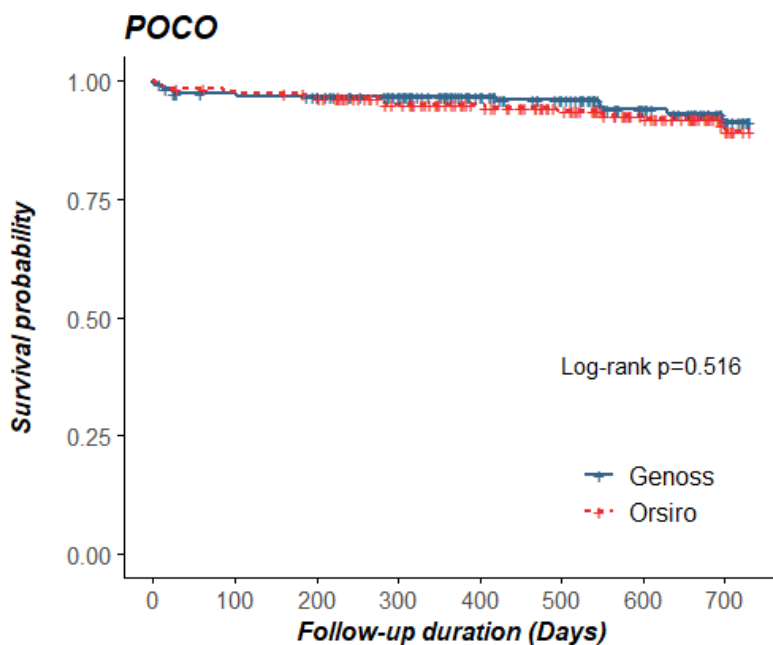
Variable	Before PSM			After PSM			STD diff (%)
	Genoss n = 310	Orsiro n = 337	p	Genoss n = 191	Orsiro n = 191	p	
PCI type							
Elective PCI	276 (89.0)	263 (78.3)	<.001	165 (86.4)	164 (86.3)	0.984	0.21
Primary PCI	27 (8.7)	67 (19.9)	<.001	20 (10.5)	21 (11.1)	0.855	-1.87
Disease extent			0.047			0.802	-5.08
1-VD	115 (37.2)	96 (28.8)		66 (34.7)	64 (33.7)		
2-VD	92 (29.8)	101 (30.3)		62 (32.6)	58 (30.5)		
3-VD	102 (33.0)	136 (40.8)		62 (32.6)	68 (35.8)		
Treated territory							
Left anterior descending artery	195 (62.9)	221 (65.6)	0.478	127 (66.5)	127 (66.5)	1.000	0.00
Left circumflex artery	75 (24.2)	97 (28.8)	0.187	60 (31.4)	58 (30.4)	0.825	2.26
Right coronary artery	102 (32.9)	134 (39.8)	0.070	59 (30.9)	64 (33.5)	0.584	-5.59
Left main	20 (6.5)	20 (5.9)	0.785	8 (4.2)	8 (4.2)	1.000	0.00
Transradial intervention	295 (95.2)	312 (92.6)	0.174	184 (96.3)	176 (92.2)	0.079	18.00
Any in-stent restenosis lesion	40 (12.9)	28 (8.3)	0.057	16 (8.4)	18 (9.4)	0.719	-3.67
Any extreme angulation	2 (0.7)	4 (1.2)	0.688	0 (0.0)	1 (0.5)	1.000	-10.23
Any severe calcification	48 (15.5)	62 (18.4)	0.324	31 (16.2)	36 (18.9)	0.501	-6.87
Any bifurcation PCI	177 (57.1)	206 (61.1)	0.297	113 (59.2)	119 (62.3)	0.530	-6.42
with 2 stents	18 (5.8)	8 (2.4)	0.026	5 (2.6)	5 (2.6)	1.000	0.00
Any CTO PCI	14 (4.5)	18 (5.3)	0.629	9 (4.7)	12 (6.3)	0.501	-6.88
Any use of IVUS	148 (47.7)	184 (54.6)	0.081	97 (50.8)	97 (50.8)	1.000	0.00
Number of treated lesions	1.3 ± 0.6	1.5 ± 0.7	0.001	1.4 ± 0.6	1.5 ± 0.7	0.523	-6.55
Implanted Genoss DES per patient							
Number	1.6 ± 0.9	1.9 ± 1.1	<.001	1.7 ± 1.0	1.8 ± 1.0	0.302	-10.58
Diameter, mm	3.1 ± 0.7	3.1 ± 0.6	0.851	3.0 ± 0.7	3.0 ± 0.7	0.758	-3.16
Length, mm	42.3 ± 26.1	56.4 ± 32.2	<.001	47.0 ± 28.2	50.3 ± 30.3	0.272	-11.25

2-year Clinical Outcomes Between Genoss DES and Orsiro

Variable	Before PSM			After PSM		
	Genoss n = 310	Orsiro n = 337	Log rank p	Genoss n = 191	Orsiro n = 191	Log rank p
Median FU duration, days	540 (351 – 730)	591 (357 – 730)		568 (360 – 730)	627 (406 – 730)	
Patient-oriented composite outcome	17 (5.5)	27 (8.0)	0.2526	11 (5.8)	15 (7.9)	0.5163
Any death	9 (2.9)	22 (6.5)	0.0352	6 (3.1)	10 (5.2)	0.3399
Any MI	6 (1.9)	3 (0.9)	0.2031	5 (2.6)	3 (1.6)	0.3947
Any PCI	4 (1.3)	2 (0.6)	0.3121	1 (0.5)	2 (1.0)	0.6242
Device-oriented composite outcome	7 (2.3)	12 (3.6)	0.3509	2 (1.0)	4 (2.1)	0.4518
Cardiovascular death	4 (1.3)	10 (3.0)	0.1475	2 (1.0)	2 (1.0)	0.9716
Target-vessel related MI	0 (0.0)	0 (0.0)	n/a	0 (0.0)	0 (0.0)	n/a
Target lesion revascularization	3 (1.0)	2 (0.6)	0.5443	0 (0.0)	2 (1.0)	0.1756
Target vessel revascularization	3 (1.0)	3 (0.9)	0.8733	0 (0.0)	2 (1.0)	0.1756



Survival Curves Between Genoss DES and Orsiro



Genoss	191	180	177	158	130	113	87	66
Orsiro	191	185	180	161	143	123	99	72

Genoss	191	181	178	159	131	115	91	68
Orsiro	191	185	180	162	144	124	101	73

Genoss	191	181	178	159	131	115	91	68
Orsiro	191	185	180	162	144	124	101	73



Conclusion

- The interim analysis of Genoss DES prospective registry demonstrates that the Genoss DES stent in real-world practice is safe and effective for treating subjects with coronary artery disease at 12-month follow-up.
- When compared with Orsiro stent, Genoss DES™ stent showed similar efficacy and safety profiles at 24-month follow-up.



