

## Editorial

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# Can Genoss DES<sup>™</sup> Stand Out in the Crowd of Stents?

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 See the article "Safety and Efficacy of a New Ultrathin Sirolimus-Eluting Stent with Abluminal Biodegradable Polymer in Real-World Practice" in volume 50 on page 317.

After the introduction of coronary stenting, reducing restenosis and stent thrombosis are the main issue in the interventional cardiology field. The drug-eluting stent (DES) inhibiting endothelial growth has been one option to reduce restenosis. However, potent inhibition of endothelial growth along with hypersensitivity reaction to polymer increased the incidence of stent thrombosis, and the first-generation of DES had been withdrawn due to increased incidence of late or very late stent thrombosis.<sup>1)</sup> There are newer-generation DESs with a biocompatible polymer containing new drugs to reduce these complications. Recently, we have several newer-generation DESs in the clinical fields with improved safety and efficacy than the first-generation DES.<sup>2)</sup>

Genoss DES<sup>TM</sup> (Genoss Company Limited, Suwon, Korea) is one of newer-generation stents with a cobalt-chromium platform with an abluminal biodegradable polymer containing sirolimus.<sup>3)</sup> The Genoss DES<sup>TM</sup> is the first Korean sirolimus-eluting stent on the market and it has ultrathin strut with 70 µm strut thickness with 3 µm thin abluminal polymer coating containing Sirolimus. **Table 1** listed the comparison of the Genoss DES<sup>TM</sup> with other second-generation DES. The polymer is designed to release approximately 70% of the total drug amount within 30 days of the implantation and is entirely absorbable within 9 months. Thus, only the metal component of the stent will remain. In the first-in-man trial comparing Genoss DES<sup>TM</sup> and Promus Element<sup>TM</sup> stent (Boston Scientific Co., Natick, MA, USA), there was a similar result in angiographic and clinical outcomes at a 9-month follow-up.<sup>3)</sup> However, the study was too small to conclude that the Genoss DES<sup>TM</sup> is safe and efficient for de novo coronary stenosis. Thus, we needed a study with a large number of population to prove its safety and efficacy.

In this current study, Youn et al.<sup>4)</sup> published clinical performance with the Genoss DES<sup>™</sup>. They included 622 consecutive patients in the prospective, single-arm, observational, and multi-center registry and found the incidence of a device-oriented composite outcome (DOCO), defined as cardiac death, target vessel-related myocardial infarction and target lesion revascularization occurred only in 4 patients (0.6%) at 12 months. Among 4 patients with DOCO, there were 1 cardiovascular death, 1 target vessel myocardial infarction and 3 target lesion revascularization. Although this study was an interim analysis of the prospective ongoing registry which planned to include 2,000 subjects originally, it can give us valuable information about the safety and efficacy of the Genoss DES<sup>™</sup>.

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#### **Conflict of Interest**

The authors have no financial conflicts of interest.

#### Author Contributions

Conceptualization: Lee JH, Park JH; Supervision: Park JH; Writing - original draft: Lee JH, Park JH; Writing - review & editing: Lee JH, Park JH.

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	Biodegradable polymer				Durable polymer	
Brand name	Genoss	Synergy	Orsiro	Biomatrix Flex	Xience Sierra	Resolute Onyx
Company	Genoss	Boston Scientific	Biotronik	Biosensors	Abbott	Medtronic
Country	Korea	USA	Germany	Singapore	USA	USA
Drug	Sirolimus	Everolimus	Sirolimus	Biolimus	Evelorimus	Zotarolimus
Stent						
Material	CoCr	PtCr	CoCr	316L stainless steel	L-605 CoCr	CoNi with Pt-Ir
Thickness	70-78	79-81	60-80	112	81	81-91
Polymer						
Material	PLLA/PGLA	PGLA	PLLA	PDLLA	PVDF-HFP	BiolLinx
Coating distribution	Abluminal	Abluminal	Conformal	Abluminal	Conformal	Conformal
Coating thickness (µm)	3	4	7.4	16.6	8	4.8
Drug elution time	3-4 months	3 months	100-120 days	180 days	120 days	180 days
Polymer absorption time	6–9 months	3-4 months	15 months	6–9 months	Permanent	Permanent
Strut cross section						

Table 1. Comparative characteristics of contemporary coronary drug-eluting stents

CoCr = cobalt-chromium; PtCr = platinum-chromium; CoNi = cobalt-nickel; Pt-Ir = platinum-iridium; PLLA = poly-L-lactic acid; PLGA = poly-lactic co-glycolic acid; PDLLA = poly-D,L-lactic acid; PVDF-HFP = co-polymer of vinylidene fluoride and hexafluoropropylene.

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However, there are still a lot of hurdles for the Genoss DES™ to stand out in the crowd of numerous stents. As mentioned in the limitation section of the study, the authors should include more patients in this prospective registry and report the clinical outcome. Moreover, we need clinical studies including a large number of patients comparing the Genoss DES™ with other DESs in a prospective and randomized manner. These studies should include patients with diverse clinical settings including acute myocardial infarction or complex coronary lesions and should have longer term follow-up to evaluate the incidence of very late stent thrombosis or late restenosis. It should also be able to overcome very severe calcified and angulated lesions without migration or damage and to expand well with a sufficient radial strength. To stand out in the ordinary stones, the developers should try to improve the product and to get better clinical results with sufficient support.

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