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Editorial

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Polycaprolactone (PCL) Film-Covered Bare Metal Stent: A Remedied Fire Extinguisher?

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▸ See the article "Serial Vascular Responses of Balloon-Expandable Stent With Biodegradable Film-Type Graft in a Rabbit Iliac Artery Dissection Model (BioGard Study)" in volume 54 on page 499.

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In this era of high-tech endovascular interventions, vascular perforation and dissection remain disastrous complications with high mortality and morbidity rates.[1] Previous studies demonstrate a consistent incidence rate of coronary perforation at 0.2–0.9%, with a mortality rate of 10–25%. Some literature even reports an increased incidence rate in response to the rise in complex percutaneous coronary intervention (PCI), chronic total occlusion PCI, and the use of endovascular devices such as rotational atherectomy and intravascular ultrasound.[2-5] Therefore, interventionists should be prepared for this catastrophe, and the implantation of a covered stent has become the cornerstone of rescuing large vessel injuries.[6]

Along with polytetrafluoroethylene (PTFE) grafts, several covered stents are in use; however, they have common drawbacks. Their bulkiness makes them difficult to deliver, mechanical side branch occlusion may lead to myocardial ischemia, and there is a high event rate of stent thrombosis and in-stent restenosis due to delayed endothelial coverage.[7] Since these flaws cannot be neglected, and present covered stents are considered unsuitable for use in complex vascular structures or small, distal vessels, the majority of interventionists have longed for the advent of a competent solution. In this regard, Park et al.[8] presented an innovative graft consisting of a balloon-expandable stent and biodegradable polycaprolactone (PCL) film.

PCL, a biodegradable material that is widely used as an artificial bone, cartilage, and vascular graft, is of great interest in the field of tissue engineering. Previous research has demonstrated its superior performance, including early endothelialization of the luminal surface without excessive neointimal formation.[9] In this study, the researchers demonstrated the clinical applicability of the test device through ex vivo serial computed tomography scanning and follow-up angiography, addressing potential solution to major shortcomings.

Firstly, its thin strut and 11.1 μm film (before expansion) improved its flexibility and deliverability to the target lesion by reducing the profile compared to the 2-layered, 260 μm coating of commercialized PTFE grafts. This enables appropriate positioning of the stent and delivery to complex and smaller lesions. Next, serial microscopic examinations proved its biocompatibility in mammalian vasculature and lesion patency 1 year after the index procedure. Finally, as the scaffold almost fully degrades within one year, there is a potential to restore the compromised side branches afterward.

Author Contributions

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As the authors mentioned, the absence of a control group, the limited number of experimental animals, and the differences between rabbit and human biophysiology remain as limitations and are challenges for future research. Nevertheless, this in vivo and ex vivo confirmation of endovascular patency following covered stent administration after Ellis II to III perforation has encouraged interventionists to overcome these significant hurdles in the future.

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