Contemporary Drug-Eluting Stent Platforms
Design, Safety, and Clinical Efficacy

Ramon A. Partida, MD[a,b,c],
Robert W. Yeh, MD, MSc, MBA[c,d,e,*]

KEYWORDS

• Drug-eluting stents • Percutaneous coronary intervention • Coronary stent
• Coronary artery disease • Drug-eluting stents: trends • Equipment design • Review

KEY POINTS

- Contemporary drug-eluting stent (DES) platforms have been developed to address high rates of restenosis seen with bare-metal stents and late adverse events seen with first-generation DES.
- Contemporary DES platforms incorporate significant advances in scaffold design, polymer compatibility, and antiproliferative drug delivery.
- DES use has become the standard of care in most clinical scenarios during percutaneous coronary intervention, including high-risk settings.

INTRODUCTION

Percutaneous coronary intervention (PCI) technology has advanced significantly since the first balloon angioplasty by Gruentzig in 1977 and eventually the first stent implantation in a patient by Sigwart and colleagues[1] 1 year later.

Initial efforts with balloon angioplasty were fraught with exceedingly high rates of restenosis, dissection, and abrupt vessel closure. These initial issues led to the development of the bare-metal stent (BMS) to scaffold vessels, leading to increased acute coronary artery luminal gain and maintenance of luminal integrity. Significant improvement in acute clinical outcomes was noted following the use of BMS, with a 20% to 30% decrease in clinical and angiographic restenosis.[2] However, vessel response to stent-mediated vascular injury leads to a significant amount of neointimal hyperplasia, vascular smooth muscle cell migration, and proliferation. This, in turn, leads to negative remodeling, restenosis, and late luminal loss, portending a high risk of need for reintervention.

The drug-eluting stent (DES) was developed to minimize the risk of in-stent restenosis. First-generation DESs have consistently been shown to decrease the risk of restenosis and need for reintervention compared with the BMS.[3] Despite proven clinical efficacy in the treatment of coronary disease, reports of adverse clinical outcomes,

This article originally appeared in Interventional Cardiology Clinics, Volume 5, Issue 3, July 2016.
Disclosures: R.A. Partida has no relevant disclosures. R.W. Yeh has served on scientific advisory boards and received consulting fees for Abbott Vascular and Boston Scientific.
[a] Division of Cardiology, Department of Medicine, Massachusetts General Hospital, 55 Fruit Street, GRB-800 Boston, MA 02114, USA; [b] Institute for Medical Engineering and Science, Massachusetts Institute of Technology, 77 Massachusetts Avenue, E25-438, Cambridge, MA 02139, USA; [c] Harvard Medical School, 25 Shattuck Street, Boston, MA 02115, USA; [d] Department of Medicine, Smith Center for Outcomes Research in Cardiology, CardioVascular Institute, Beth Israel Medical Center, 330 Brookline Avenue, Baker 4, Boston, MA 02215, USA; [e] Harvard Clinical Research Institute, Boston, MA, USA
* Corresponding author. Smith Center for Outcomes Research in Cardiology, CardioVascular Institute, Beth Israel Medical Center, 330 Brookline Avenue, Baker 4, Boston, MA 02215.
E-mail address: ryeh@bidmc.harvard.edu

Cardiol Clin 35 (2017) 281–296
http://dx.doi.org/10.1016/j.ccl.2016.12.010

mostly related to stent thrombosis (ST) and late restenosis, raised concerns regarding DES safety and limitation of these devices. Since the initial experience with first-generation DES, significant improvements have occurred with current DES platform technology, leading to increased safety and efficacy.[4–6] Additionally, although not the focus of this article, concurrent advances in adjunct pharmacotherapy and antiplatelet therapy have resulted in improved clinical outcomes. The sections that follow focus on the design improvements of the contemporary DES, as well as the clinical safety and efficacy of current stent platforms approved for use by the Federal Drug Administration (FDA).

COMPONENT DESIGN

DES platforms consist of 3 main components: (1) a stent metallic platform or scaffold, (2) a stent polymer coating that allows for controlled drug release, and (3) a released antiproliferative drug. **Fig. 1** shows a representative schematic the DES components.

Metallic Stent Scaffold

Current FDA-approved DES platforms are based on metallic scaffolds made of biologically inert metals with high radial strength. First-generation stents used stainless steel (SS) as the metal of choice. Recent research and development efforts have also included development of fully resorbable scaffold materials, which are currently undergoing preclinical and clinical investigation.

Although a breadth of research has focused on the advancement of polymer and antiproliferative drug components, significant improvement has also been achieved in the development of these metallic stent scaffolds. Generally, stent scaffolds are composed of 2 main components: hoops in series to provide radial strength on expansion, and connectors that join these hoops and provide longitudinal strength.[7,8] Early clinical experience, as well as insight obtained from preclinical and computational models, shed light on the role of stent geometry and strut size in deliverability; stent visibility; drug deposition; and, importantly, clinical outcomes and restenosis risk.

Initial efforts focused on optimizing stent design with existing alloys 316L-SS, such as the TAXUS Liberté stent platform (Boston Scientific, Natick, MA, USA). This allowed for reduced strut thickness of 100 to 140 μm with preserved radial strength. However, further improvement was limited by the material's moderate yield and limited compression

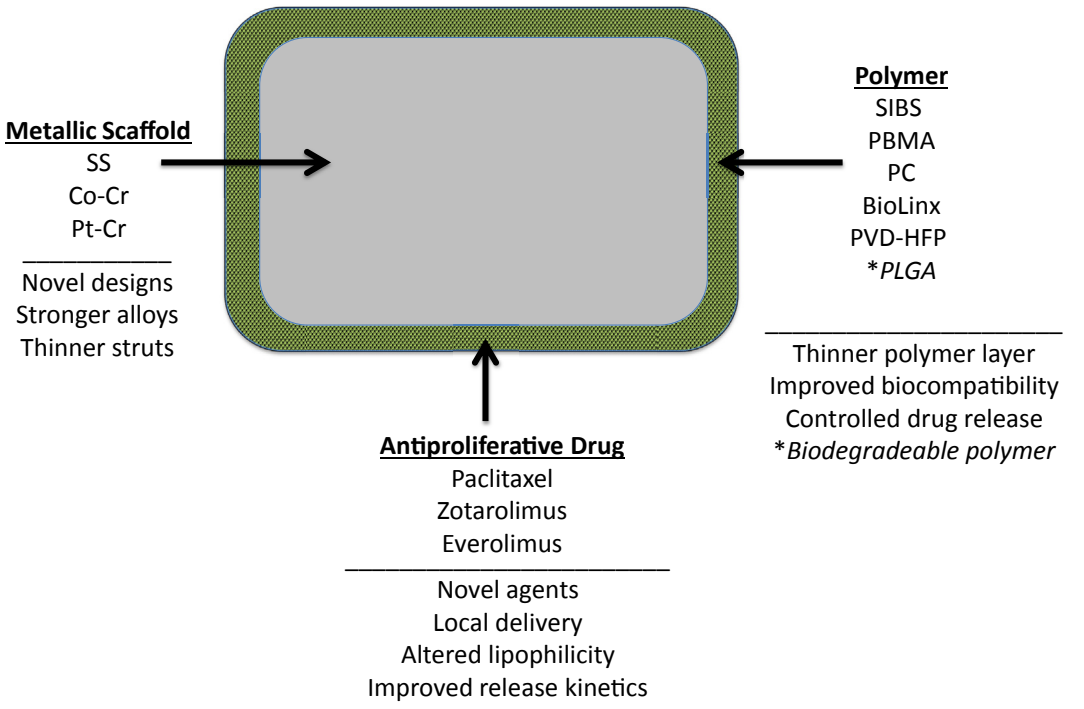

Fig. 1. Cross-section of DES strut with improved component characteristics. *, bioresorbable polymer; Co–Cr, cobalt–chromium; PBMA, poly(n-butyl methacrylate); PC, phosphorylcholine; PLGA, poly(lactic-co-glycolic acid); Pt–Cr, platinum–chromium; PVDF-HFP, copolymer of vinylidene fluoride and hexafluoropropylene; SIBS, poly(styrene-b-isobutylene-b-styrene); SS, stainless steel.