The DES Landscape in 2011

Future directions in drug-eluting stent design.

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The development of bare-metal stents (BMS) in the late 1980s revolutionized the treatment of elastic recoil and reduced the risk of acute vessel closure that complicated plain old balloon angioplasty.[1,2] The development of neointimal hyperplasia associated with the use of the BMS led to in-stent restenosis rates of 20% to 30%, prompting an increase in repeat revascularization rates and, ultimately, the development of the first drug-eluting stent (DES) in 2003. Despite studies showing consistent reductions in target lesion revascularization (TLR) rates with current-generation DES platforms, stent thrombosis (ST) continues to remain a rare but potentially devastating clinical consequence that is associated with significant morbidity and mortality.[3] Although studies have shown no difference in the rates of early (< 30 days) and late (1 month to 1 year) ST between BMS and DES designs, DES designs have been associated with higher rates of very late (> 1 year) ST.[4-14]

Independent predictors of ST include premature cessation of dual-antiplatelet therapy (DAPT), as well as lesion- and procedure-related characteristics (ie, small vessels, lesion length > 28 mm, stent undersizing, dissection).[15,16] In addition, the permanent (durable) polymers associated with DES have been shown to delay endothelialization and cause hypersensitivity reactions that can culminate in ST.[17-21] Therefore, in an effort to minimize local vascular inflammation and hasten stent endothelialization and vascular healing, four new DES designs are being studied with the theoretical hope of reducing late ST as well as the duration of DAPT. These designs include durable polymers on new thinner strut platforms, resorbable polymers, nonpolymeric, and completely bioabsorbable DES designs.

NOVEL METALLIC DURABLE POLYMER DESIGNS

Several DES stent designs are under investigation that attempt to improve on the early-generation DES that are currently in use. These newer designs, which have already gained CE Mark approval in Europe, are still under evaluation in the United States by the Food and Drug Administration. The new designs use more biocompatible polymers and thinner, more radiopaque struts to enhance stent deliverability and angiographic visualization. These designs are summarized in Table 1.

The Endeavor Resolute and Resolute Integrity zotarolimus-eluting stents (ZES) (Medtronic, Inc., Minneapolis, MN) are currently undergoing evaluation in the United States and are commercially available outside the United States. These devices utilize a BioLinx polymer (combination of three different polymers: hydrophobic C10 polymer to control drug release, biocompatible and hydrophilic C19 polymer, and polyvinyl pyrrolidone to allow early drug release) mounted on a cobalt chromium stent platform (Driver [Medtronic, Inc.] or the Integrity stent).[22]

The 139-patient, multicenter, nonrandomized, first-in-man RESOLUTE trial revealed an angiographic in-stent late loss of 0.22 mm at 9 months of follow-up. Major adverse cardiac events (MACE), TLR, and any definite/probable ST were 8.6%, 0.7%, and 0%, respectively, at 12-month follow-up, with similar low rates of TLR and no ST reported out to 4 years of follow-up.[23-25] The Resolute stent was then evaluated in the randomized 2,300-patient RESOLUTE All-Comers noninferiority trial in which patients were randomized in a 1:1 fashion to either the Resolute ZES or the Xience V everolimus-eluting stent (EES) (Abbott Vascular, Santa Clara, CA). The Resolute ZES was found to be noninferior to the EES at 12-month follow-up for the primary endpoint of target lesion failure (a composite of cardiac death, target vessel myocardial infarction, and clinically indicated TLR) (8.2% vs 8.3%; $P_{noninferiority} < .001$).[26]

In addition to novel polymer development, there have been new stent platform designs. The new Element stent platform (Boston Scientific Corporation, Natick, MA) is a

TABLE 1. NEW METALLIC STENT DESIGNS WITH DURABLE POLYMERS			
Stent	**Drug (Dosage)**	**Stent Platform**	**Strut/Polymer Thickness (µm)**
Endeavor Resolute	Zotarolimus (10 µg/mm)	Cobalt chromium	91/4.1
Taxus Element	Paclitaxel (1 µg/mm^2)	Platinum chromium	81/15
Promus Element	Everolimus (1 µg/mm^2)	Platinum chromium	81/6

platinum chromium alloy and is combined with both everolimus (Promus Element EES) and paclitaxel (Taxus Element paclitaxel-eluting stent [PES]). The platinum stent platform improves on cobalt chromium and stainless steel platforms through its much greater radiopacity and radial strength, allowing for better angiographic visualization and thinner stent struts. Furthermore, the reduced nickel content in the platinum alloy may possibly reduce the risk of hypersensitivity.[27,28]

The noninferiority, 1,262-patient PERSEUS Workhorse trial randomized patients to treatment with the Taxus Element or the Taxus Express PES and revealed no significant differences in late loss (0.34 ± 0.55 mm vs 0.26 ± 0.52 mm; *P* = .33) between the two systems at 9 months of angiographic follow-up and no difference in the rate of the primary endpoint of target lesion failure at 12 months (5.6% vs 6.1%; *P* = .78), which together met the criteria for noninferiority.[29]

The PERSEUS Small Vessel trial compared the Taxus Element with a BMS platform in 224 patients with lesions < 20 mm in length within vessels between 2.25 and 2.75 mm in diameter. At 9 months of follow-up, significantly lower in-stent late loss was seen with the Element stent compared with the BMS stent (0.38 ± 0.51 mm vs 0.8 ± 0.53 mm; *P* < .001), with significantly lower target lesion failure and MACE rates at 12 months favoring the Element stent.[30] The multicenter PLATINUM (A Prospective, Randomized Multicenter Trial to Assess an Everolimus-Eluting Coronary Stent System [Promus Element] for the Treatment of up to Two De Novo Coronary Artery Lesions) trial, randomizing 1,532 patients to either the Promus Element stent or the Promus EES, will be reported at the American College of Cardiology's 2011 Annual Scientific Session.[29,30]

METALLIC RESORBABLE POLYMER DESIGNS

Interest in resorbable polymer technology has emerged as a result of the ongoing concerns over very late ST that is speculated to result from the vascular inflammation and consequential delayed endothelialization associated with the polymers used in current DES designs. Theoretically, DES designs involving these resorbable polymers may offer the early benefits of reducing neointimal proliferation while reducing the risk of very late ST and the duration of DAPT. Numerous resorbable polymer DES designs are currently under investigation and represent the most robust area of novel DES research. Representative studies are summarized in Table 2.

The Biomatrix (Biosensors International, Singapore) and Nobori (Terumo Europe NV, Leuven, Belgium) stents have a stainless steel stent platform that is combined with Biolimus A9, a lipophilic sirolimus analogue that is bound to the stent platform via a poly-L-lactide biodegradable polymer that biodegrades within 6 to 9 months. The Biomatrix stent design was compared with the Cypher SES (Cordis Corporation, Bridgewater, NJ) in the 1,707-patient, randomized, all-comers LEADERS trial and was shown to be noninferior for MACE (composite of cardiac death, myocardial infarction, and ischemia-driven revascularization) at both 12-month and 2-year follow-up.[31,32] The Nobori stent has been compared with the Cypher SES and Taxus PES in the NOBORI CORE and Nobori I studies. At 9-month follow-up, the Nobori stent was shown to be noninferior to the Cypher SES and superior to the Taxus PES with respect to late lumen loss (0.1 mm vs 0.12 mm; *P* = .66; 0.11 mm vs 0.32 mm; *P* = .001, respectively).[33,34] Encouragingly, the Nobori I study revealed a lower rate of ST at 9 months compared with the Taxus PES.[34] Furthermore, to date, no episodes of very late ST have been reported with the Nobori stent design. Consequently, these two stent designs have received CE Mark approval in Europe.

In addition to Biolimus A9 stent designs, multiple sirolimus-based biodegradable polymeric stents are under investigation. The Supralimus stent (Sahajanand Medical Technologies Pvt. Ltd., Gujarat, India) is composed of a stainless steel sirolimus-eluting stent with a biodegradable polymer mix of poly-L-lactide, polyvinyl pyrrolidone, polylactide-co-caprolactone, and polylactide-co-glycolide. The sirolimus elution is complete within 48 days, and the polymer is completely degraded within 7 months. Clinical effectiveness and safety have been

TABLE 2. NEW METALLIC STENT DESIGNS WITH BIODEGRADABLE POLYMERS

Stent	Drug (Dosage)	Stent Platform	Strut/Polymer Thickness (µm)	Polymer Type (Duration of Biodegradation, Months)
Biomatrix	Biolimus A9 (15.6 µg/mm)	Stainless steel	112/10	Abluminal PLA (6–9)
Nobori	Biolimus A9 (15.6 µg/mm)	Stainless steel	112/10	Abluminal PLA (6–9)
Supralimus	Sirolimus (125 µg/19 mm)	Stainless steel	80/4–5	PLLA, PLGA, PLC, PVP (7)
Excel	Sirolimus (195–376 µg/19 mm)	Stainless steel	119/15	PLA (6–9)
Nevo	Sirolimus (166 µg/17 mm)	Cobalt chromium	99	Reservoirs of PLGA (3)
Synergy	Everolimus (low dose, 56 µg/20 mm standard dose, 113 µg/20 mm)	Platinum chromium	Low dose, 71/3; standard dose, 4	PLGA rollcoat abluminal (3)

Abbreviations: PLA, poly-L-lactide; PLC, 75/25 poly-L-lactide-co-caprolactone; PLGA, 50:50 poly-DL-lactide-co-glycolide; PLLA, poly-L-lactic acid; PVP, polyvinyl pyrrolidone.

shown in the 100-patient SERIES I study that revealed a 0% in-stent restenosis rate, with a late loss of 0.09 ± 0.37 mm at 6-month follow-up.[35] In addition, the rate of target vessel revascularization was 4%, with no ST reported. Further evaluation is ongoing with the SERIES III noninferiority trial, which will look at a primary endpoint of 9-month in-stent late loss in patients randomized to the Supralimus SES versus Xience V EES.

The Excel stent (JW Medical Systems, Weihai, China) is coated with sirolimus as well as a poly-L-lactic acid biodegradable polymer, which is completely degraded within 6 to 9 months. The CREATE (Multicenter Registry Trial of Excel Biodegradable Polymer Drug-Eluting Stent) registry of more than 2,000 patients has shown a MACE rate of 3.1% at 18 months of follow-up and an ST rate of 0.87% despite 80.5% of patients stopping clopidogrel at 6 months.[36]

Finally, the Nevo stent (Cordis Corporation) has an open-cell, cobalt chromium design with a polylactide-co-glycolide biodegradable polymer that elutes sirolimus within reservoirs rather than through a surface polymer coating. It has been evaluated in the RES-1 (NEVO RES-ELUTION) study, which was a 394-patient, multicenter, randomized, noninferiority study comparing the Nevo stent to the Taxus Liberté PES (Boston Scientific Corporation). At 6 months, there was significant reduction of in-stent late lumen loss with the Nevo stent compared to the Taxus Liberté (0.13 mm vs 0.36 mm; $P < .0001$), with no difference in ST rates.[37] Further investigation is ongoing.

The only everolimus-eluting biodegradable polymer stent platform being investigated is the Synergy stent (Boston Scientific Corporation). This polylactide-co-glycolide abluminal-coated biodegradable platform on an ultra-thin strutted stent (0.0028-inch) will be investigated in the 291-patient, multicenter EVOLVE trial. The EVOLVE trial will randomize patients to two doses of everolimus (113-µg/20-mm stent vs 56-µg/20-mm stent) delivered on an Element stent, with a Promus Element stent as the control. The primary angiographic endpoint is 6-month in-stent late loss, and the primary clinical endpoint is target lesion failure at 30 days.[38]

METALLIC NONPOLYMERIC DESIGNS

The ongoing search for stent designs that possess antiproliferative properties without delaying the re-endothelialization process prompted the development of DES designs that were completely polymer-free. This is achieved through dissolving the antiproliferative agent into a biodegradable carrier on the stent's surface, impregnating the antiproliferative agent onto the porous surface of the stent or directly attaching the antiproliferative agent to the stent. This area of novel DES design is limited, with only one DES (Yukon stent [Translumina, Hechingen, Germany]) available for commercial use in Europe. However, there are several additional stents that are undergoing study, which are summarized in Table 3.

The Yukon DES has a microporous structure in which the antiproliferative agent (rapamycin) is deposited, eliminating the need for a polymer. The stent system allows for a point-of-care stent coating via a two-component system: the premounted stent in a disposable coating cartridge and a coating device. The Yukon stent has been evaluated in more than 400 patients in both the randomized ISAR TEST study and a real-world registry, which collectively reveal noninferiority of the Yukon stent compared with a PES at 9- and 12-month follow-up.[39,40] In addition, recent data reveal a significantly lower change

TABLE 3. NEW METALLIC NONPOLYMERIC STENT DESIGNS			
Stent	**Drug (Dosage)**	**Stent Platform**	**Strut/Coating Thickness (μm)**
Yukon	Sirolimus (11.7–21.9 μg)	Stainless steel	87
BioFreedom	Biolimus A9 (standard dose, 15.6 μg/mm; low dose, 7.8 μg/mm)	Stainless steel	112
Vestasync	Sirolimus (total = 55 μg)	Stainless steel	65/0.6
Amazonia Pax	Paclitaxel (2.5 μg/mm^2)	Cobalt chromium	73/5

in late lumen loss out to 2 years of follow-up compared with SES and PES stents.[41]

The BioFreedom (Biosensors International), Vestasync (MIV Therapeutics Inc., Vancouver, BC, Canada), and Amazonia Pax (Minvasys, Gennevilliers, France) stent designs are currently not approved for clinical use and continue to undergo clinical study. The BioFreedom stent is a 316L stainless steel, polymer-free stent coated with Biolimus A9. The first cohort of the first-in-man study of 75 low-risk patients with de novo coronary lesions who were randomized to either a standard-dose BioFreedom stent (15.6 μg/mm), low-dose BioFreedom stent (7.8 μg/mm), or a Taxus PES revealed no MACE or ST at 4-month follow-up in either study group and a significantly lower in-stent late loss with both BioFreedom stent arms compared with the Taxus PES (0.08 mm vs 0.12 mm vs 0.37 mm; $P < .0001$ and $P = .002$, respectively).[42] The Vestasync stainless steel stent has a surface coating that is a low dose of polymer-free sirolimus. It was evaluated in the 15-patient VESTASYNC I first-in-man clinical trial and showed reductions in in-stent late loss and intimal hyperplasia rate at up to 9 months, with only one reported clinical event (TLR) out to 3 years of follow-up.[43,44] Finally, the Amazonia Pax stent is a polymer-free stent composed of cobalt chromium that elutes paclitaxel. In the Pax A study of 30 patients who were randomized to either the Amazonia Pax stent or the Taxus PES, there was no significant difference in in-stent late lumen loss at 4 months and no deaths or ST in patients who were treated with the Amazonia Pax stent.[45] Further evaluation of this stent is ongoing in the 100-patient Pax B study.[46]

BIODEGRADABLE DESIGNS

The ability to percutaneously treat de novo coronary stenoses with a stent that provides the vessel wall support needed in the short-term to prevent elastic recoil and then completely biodegrade over time carries many advantages. Most notably, these advantages include the lack of triggers for ST, such as exposed stent struts or drug polymers, which, in turn, may reduce DAPT requirements.

To date, the only drug-eluting biodegradable stent that is currently being evaluated in clinical trials is the everolimus-eluting bioresorbable vascular scaffold (Abbott Vascular). This device is composed of poly-L-lactic acid coated with a thin layer of a 1:1 mixture of an amorphous matrix of poly-D,L-lactide and 8.2 μg/mm of everolimus. Approximately 80% of the everolimus is eluted by 30 days, with the complete stent being fully absorbed within 2 years. This design was assessed in the 30-patient, prospective, multicenter, first-in-man ABSORB study. No ST was reported, and only one major adverse event (non–Q-wave MI) was seen out to 3 years of follow-up.[47-50] In response to these results, the Abbott bioresorbable vascular scaffold received CE Mark approval in Europe in January 2011 and will be marketed under the brand name, Absorb. Studies are ongoing, including the multicenter, single-arm registry, ABSORB EXTEND.

CONCLUSION

Although the clinical efficacy of DES over BMS has been shown, newer generations of DES are under investigation. These newer-generation DES platforms aim to address concerns of safety and improved efficacy, as well as the long-term issues inherent to prolonged DAPT. Bioabsorbable polymers, polymer-free drug delivery, and fully bioabsorbable stents will attempt to minimize vascular injury and delayed stent endothelialization. Newer stent metals, such as platinum versus stainless steel and cobalt chromium, will be inherent to newer stent platforms. Additionally, there will be trends toward thinner-strut stent designs with new stent architectures, such as modular designs, and reservoir technology that endeavor to advance interventional treatment for coronary artery disease. ■

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