Inert Technology: Actively Making a Difference in Drug-Eluting Stent Designs

First-generation drug-eluting stents (DESs) deliver high clinical efficacy at the collateral cost of delayed healing of the stented arterial segment.[1] Although DESs and their respective technology have been extensively documented, the discussion has often centered around the type of drug and not necessarily the technical theory behind the stent design.

INERT CARBON TECHNOLOGY

The QualiMed DES is a laser-cut slotted tube with a multicellular design implanted with a unique carbon-ion layer (C^+ ion). The carbon-ion layer is incorporated within the metal lattice to a maximum depth of 0.05 µm (Figure 1) and successfully prevents leakage of heavy metal ions such as nickel and molybdenum. This inert carbon technology is a refinement of the alloy surface, which creates a barrier for migrating heavy metal ions. Studies have shown a positive effect on minimizing the rate of restenosis and thrombosis.[2]

The carbon ions are shot onto the stent's surface with high energy under vacuum and subsequently penetrate it. This methodology allows the carbon ions to occupy free spaces or displace heavy metal ions such as nickel or molybdenum within the lattice itself. Due to their high electronegative force, surrounding atoms become attracted to the C^+ ions. Because carbon is highly biocompatible and easily incorporated, these features are conferred to the alloy.

RAPID POLYMER ABSORPTION

The QualiMed DES is coated in a 5-µm layer of a rapidly absorbing polymer that is designed to resorb within approximately 8 weeks. This rapid absorption of the drug has been shown to help promote earlier neointimal healing as compared to permanent polymer–based DESs[3] and may contribute to shortening the duration of dual antiplatelet therapies subsequently following DES implantation.[4]

Shorter-release kinetics and the biodegradable polymers of DESs have been shown to allow earlier endothelialization expressed by a higher degree of stent strut coverage.[5,6]

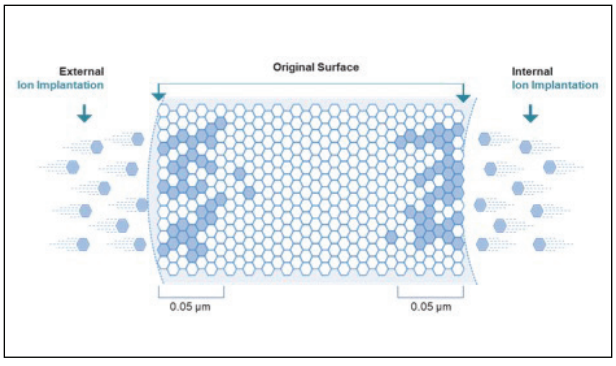

Figure 1. High-speed bombardment of C^+ ions under vacuum onto alloy's surface.

PRELIMINARY DATA

The QualiMed DES is a novel stent with unique material technology and has been shown to have lower rates of stent thrombosis and comparable safety and efficacy statistics (ie, death, myocardial infarction, and target vessel revascularization) compared to treatment groups utilizing durable polymer everolimus-eluting stents (Table 1).[7]

TABLE 1. ADVERSE EVENTS AT 5 YEARS AFTER PERCUTANEOUS CORONARY INTERVENTION[7]				
	QualiMed Biodegradable Polymer SES n = 214	Durable Polymer EES n = 652	*P* Value (Unadjusted)	*P* Value (Adjusted)
Stent thrombosis	0 (0)	4 (0.6)	.25	< .001
Death	35 (17.2)	92 (14.8)	.36	.50
Myocardial infarction	8 (3.8)	32 (5.1)	.50	.57
Death or myocardial infarction	39 (18.9)	118 (18.8)	.94	.81
Target lesion revascularization	28 (14.2)	85 (14.1)	.84	.67
Death, myocardial infarction, or target lesion revascularization	64 (30.9)	185 (29.2)	.59	.49
Note: Data are presented as number of patients (%) or as mean ± standard deviation. Abbreviations: EES, everolimus-eluting stent; SES, sirolimus-eluting stent.				

CONCLUSION

As DES technology continues to evolve, we must be critical not only of eluted drugs provided on the stents, but also the physical properties of the alloys and coatings and their effect on vascular healing. ■

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