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Out of the Mind of Edward B. Diethrich: The Development of the Polytetrafluoroethylene-Covered Coronary Stent

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A premier thought leader in cardiovascular and endovascular surgery, as well as the founding Editor-in-Chief of the *Journal of Endovascular Therapy*, Dr Edward B. "Ted" Diethrich died in February 2017 at the age of 81. As a cardiovascular surgeon, Dr Diethrich performed thousands of operations on the heart, but some readers may not be aware of his pioneering endovascular work in the coronary arteries. The history of the polytetrafluoroethylene (PTFE)-covered coronary stent not only exemplifies his innovative spirit but also reflects how well Dr Diethrich interfaced with cardiology, working hand-in-hand every step of the way. This collaboration resulted in a device that is present in every cardiac catheterization laboratory in the world performing percutaneous coronary interventions (PCI).

I (RRH) joined Ted as the director of Research and Education at the Arizona Heart Institute in 1990, replacing the co-inventor of the coronary stent, Dr Richard Schatz. As those of us in the field remember, the early 1990s was an exciting time for endovascular procedures. The endovascular treatment of abdominal and peripheral aneurysms transformed the specialty of vascular surgery; some would say that Ted was one of the founding fathers of this new subspecialty.

We first introduced the concept of the PTFE-covered stent in Phoenix 26 years ago. With the use of PTFE-covered stents, as well as intravascular ultrasound and angioscopy, Ted's team was encouraged that these stents could be a way to limit or even eliminate intimal hyperplasia after a coronary (or peripheral) endovascular procedure. The exposure of atheromatous tissue underneath the stent struts leads to the release of proinflammatory mediators, attracting circulating macrophages to migrate to the vascular wall thereby initiating restenosis. Endoluminal sealing, therefore, was thought to potentially inhibit restenosis.[1] In 1993, we successfully treated a complex aneurysmal lesion in a saphenous vein graft by creating a mechanical barrier to seal the aneurysm, using a commercially available Palmaz stent covered with commercially available PTFE.[2] Around the same time, Dr Christodoulos Stefanadis also described the application of a bioprosthesis in which the metallic stent surface was covered by an autologous vein graft.[3] However, this approach required a surgical cutdown to harvest the vein. With our homemade covered stent, we subsequently treated 6 patients with diffuse saphenous vein graft disease, aneurysms, and multiple restenoses. These very large profile devices were successful in 4 of the 6 patients, rendering them angina free at last follow-up. Subacute thrombosis occurred in the smaller grafts, but in grafts >4 mm, we found no angiographic, angioscopic, or ultrasound evidence of intimal growth. We presented our early work in numerous international conferences and were inundated with requests for use of our device in the treatment of coronary perforations, aneurysms, and saphenous vein disease.

Our success paved the way for commercialization of this device, which was brought to market as the Jomed Jostent (Jomed International AB, Helsingborg, Sweden), consisting of 2 stainless steel stents with a PTFE membrane in-between.

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Early clinical studies favored covered stents in enhancing the safety and late outcomes in saphenous vein grafts.[4,5] Our initial excitement about the possibility of limiting restenosis was unfortunately shattered when randomized studies comparing PTFE covered stents and bare metal stents in degenerated vein grafts showed that covered stents did not improve clinical outcomes; moreover, they were associated with higher incidences of restenosis and/or early thrombosis and late occlusion of the target vessel.[6–10]

In theory, membrane-covered stents were designed to trap friable plaque against the graft wall, thus reducing the probability of distal embolization. In practice, however, placement of these bulky covered stents caused embolization, so embolic protection was necessary unless the lesion was an acute dissection or perforation in the native artery. The risk could be mitigated with the use of a distal embolic protection device or a technique we described as "Suck-U-Surge," where blood is aspirated from the guide catheter during stent deployment, thereby reversing flow and removing potential embolic debris.[11,12]

Even though covered stents have gone out of favor in the treatment of diseased vein grafts, they still have a role in the coronary vasculature, specifically in the treatment of coronary perforations, aneurysms, and fistulas. Coronary artery perforations occur in 0.1% to 3% of PCIs.[13,14] Use of stiff guidewires, oversized balloons inflated to high pressure, and debulking devices are common causes of perforation, which can lead to myocardial infarction or cardiac tamponade. Anatomical factors, such as severe tortuosity or arterial noncompliance due to calcification, also increase the risk of coronary artery perforation.[5] In Ellis type II and III coronary perforations, covered coronary stents are the treatment of choice, especially after failure of conservative measures such as prolonged balloon inflation.[15,16]

Coronary artery aneurysms, localized dilatations with a diameter 1.5 times greater than the adjacent normal segment, occur in 0.2% to 4.9% of patients and usually affect the right coronary artery. Independent of etiology, coronary aneurysms lead to turbulent or sluggish flow, increasing the long-term risk of myocardial infarction.[17] It is postulated that the synthetic membrane of a covered stent could seal the aneurysm and offer a safe and less invasive treatment option; however, there is no consensus to define the indication, timing, or treatment choice for coronary artery aneurysms. The use of covered stents has been shown to be safe in native coronary arteries.[18,19]

A fistula between a coronary artery and a cardiac chamber or coronary vein is rare and typically congenital but can result from endomyocardial biopsies or cardiac trauma.[20] While coil embolization is most frequently used, covered stents offer an alternative treatment that creates a mechanical barrier between the feeding vessel and the fistula. However, this exposes an otherwise normal coronary artery to the risk of restenosis and stent thrombosis. Certain clinical situations, such as a concomitant aneurysm/stenosis or anatomy unsuitable for coil embolization, make covered stents a viable therapeutic option.[21,22]

Not long after Abbott bought Jomed in 2003, the Jostent was rebranded as the Graftmaster RX Coronary Stent Graft System (Abbott Cardiovascular, Santa Clara, CA, USA). It was the only commercially available covered coronary stent in the United States until 2019, when the PK Papyrus (Biotronik, Lake Oswego, OR, USA) was approved by the Food and Drug Administration. In this design, a cobalt chrome stent is covered by a single layer of polyurethane graft. In a small retrospective study of 61 patients with coronary artery perforation, the PK Papyrus stent was associated with a shorter delivery time and lower incidence of pericardial effusion and cardiac arrest; there was no difference in procedural success and 1-year major adverse cardiovascular events compared with the Graftmaster.[23]

Covered stents are indispensable tools for interventional cardiologists and have a definitive role in treating coronary artery perforations, aneurysms, and fistulas. It is part of Dr Diethrich's great legacy that the device with which he was intimately involved, the PTFE-covered stent, is still a must-have worldwide in any cardiac catheterization laboratory performing PCIs.

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