The History of Coronary Stenting

Christina Tan, MD, Richard A. Schatz, MD*

KEYWORDS

• Coronary stents • Palmaz-Schatz stent • Coronary angioplasty • Interventional cardiology

KEY POINTS

- Angioplasty results were limited by abrupt closure and restenosis, leading investigation into self-expanding metal coils in experimental models.
- Dr Julio Palmaz conceived of the first balloon-expandable slotted tube concept stainless steel stent in the late 1970s.
- Palmaz and Dr Richard Schatz placed the first stents in dog coronaries in 1985 and the first humans in 1987.
- Drug-coated stents and new antiplatelet agents significantly reduced rates of in-stent restenosis and stent thrombosis, respectively.
- With ever-improving designs and drug release platforms, stents are now the cornerstone of interventional therapy for treating coronary artery disease worldwide.

INTRODUCTION

There is no discipline in the history of medicine that has seen an explosion of growth and innovation like that of interventional cardiology, due to a combination of a driving need for better results in the treatment of coronary artery disease and the unique personality of individuals drawn to the field. In the early 1970s, the treatment of coronary disease was limited to nitroglycerin and propranolol, few diagnostic tests, no randomized trials, and little understanding of the acute phases of myocardial infarction. Diagnostic angiography was a new procedure, with crude equipment by today's standards.

Bypass surgery was an exciting new option but strictly reserved for patients who had severe angina despite maximal medical therapy. Angiography was strongly discouraged unless a patient had refractory symptoms and a very positive stress test. Noninvasive testing did not exist as it is known today and not until the late 1970s did echocardiography and nuclear medicine become widely available as adjuncts to the basic treadmill.

The treatment of myocardial infarction was even more rudimentary by today's standards. Patients were admitted to an intensive care unit and given oxygen and morphine only, while furosemide and aminophylline were added if the patient developed symptoms of congestive heart failure. It was not unusual for a patient to be hospitalized for 4 to 6 weeks during the observation period. Much consternation and anxiety was generated for both patient and physician during this period.

The entire world changed in September 1977, when a daring young doctor from Basel, Switzerland, performed the first angioplasty on a conscious patient with a tight lesion of the left anterior descending artery. Dr Andreas Grüntzig had been quietly working on a concept that he conceived while studying under one of the great mentors of the time, Dr Charles Dotter. Grüntzig had watched Dotter's procedure of dilating peripheral arterial stenoses with tapered tubes and conceived the idea of adding a balloon to the tip and a central lumen inside the catheter to fill the balloon with contrast material. On expansion of the balloon at the target site, the

No conflicts of interest or financial disclosures.
Division of Cardiology, Scripps Clinic, 10666 North Torrey Pines Road, La Jolla, CA 92037, USA
* Corresponding author.
E-mail address: schatz.richard@scrippshealth.org

Intervent Cardiol Clin 5 (2016) 271–280
http://dx.doi.org/10.1016/j.iccl.2016.03.001
2211-7458/16/$ – see front matter

plaque would give way (like crushed snow) and hopefully remain open. He was able to build a catheter suitable for human use and after much difficulty got permission to try the first case in a human. Fortunately, the case could not have gone better and the patient walked out of the hospital angina-free without bypass surgery. The world would never be the same.[1]

Grüntzig's work spread like wildfire around the world. Eventually, after meeting resistance at home, Grüntzig moved to the United States in 1980 and built the stage for teaching his new procedure at Emory University, soon to become the world center for this new discipline, interventional cardiology. Thousands of doctors made the pilgrimage to Emory to learn the technique and then return home to start their own programs. Grüntzig was meticulous and painfully honest at collecting data on his new procedure and encouraged registries, randomized trials, and collaboration to understand the limitations of what he was proposing. Unfortunately, not all cases went smoothly, and abrupt closure, dissection, and cardiac arrest were not uncommon. At least once or twice during the demonstrations, patients would arrest and be whisked off to the waiting operating room with a young doctor straddled on top of the patient doing CPR.

Although those in Gruntzig's audience often prayed for a successful surgical save while witnessing these crashes, one observer in particular, Dr Julio Palmaz, saw it as an opportunity to improve on angioplasty technique. After seeing Grüntzig's presentation in 1977, he quickly developed the concept of a metal sleeve that could be placed on top of the balloon, carried to the site, and then deployed by balloon expansion to support the walls of the artery, preventing mechanical collapse. Surprisingly, this concept was not new because several investigators had the same idea and published widely on the topic in the 1960s.[2–6] Palmaz noted that the devices were all some variation of a self-expanding spring or coil, thus limited by imprecise expansion and unpredictable delivery, both of which could be solved with a balloon-expandable piece of metal. The challenge then became which design and which metal.

He visited RadioShack, returning with a bag full of wire, solder, and a soldering gun. Converting his kitchen table into a laboratory, Palmaz set out to build his own prototype (Fig. 1). From 1980 to 1985, Palmaz placed dozens of these "grafts" (he did not call them stents) in countless dog arteries successfully.[7] His meticulous attention to study design assured a methodical assessment of the graft tissue interaction with careful long-term follow-up and pathology (thanks to Dr Fermin Tio) to make sure the device was biocompatible and not toxic to the animal. Due to the size of the device, he was restricted to large straight vessels, such as iliac arteries and the descending aorta. It worked well in these areas but the real challenge was in the coronary arteries, where the risks of clotting and restenosis were amplified due to their small size.

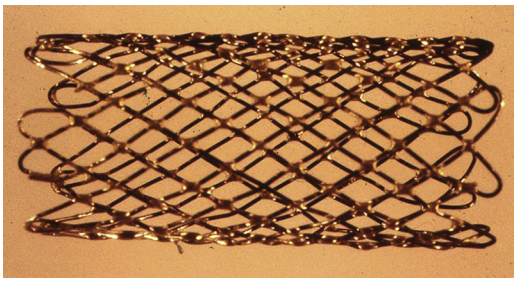

Fig. 1. The first balloon-expandable stent. This was made of 316L wire wrapped around a mandrel. Each cross-point was soldered with silver solder to prevent sliding of the wires against each other.

By 1983, Palmaz moved to the University of Texas at San Antonio with his mentor Dr Stewart Reuter. He presented the data for the first time at the Radiological Society of North America in 1984 and published his first article in 1985.

With some funding from the University of Texas, Palmaz set out to accelerate his efforts. After discussion with several experts in thin metals, he soon found the right metal and the right technology. His first prototypes were made of 316L stainless steel, a common metal used for sutures and needles that already had a track record with the Food and Drug Administration (FDA) for human use. He soon replaced the wire stents with the slotted tube concept (Fig. 2). By heating the grafts he was able to

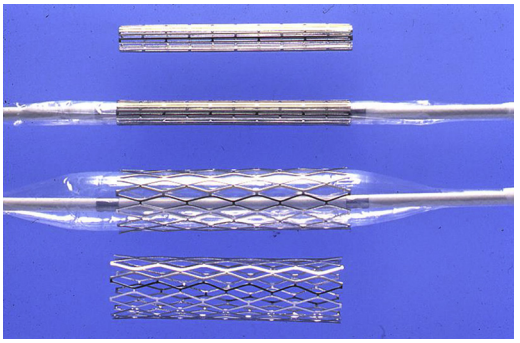

Fig. 2. The first slotted tube balloon-expandable stent. This measured 3 mm in diameter and 30 mm in length. It was cut from a hollow tube using electromagnetic discharge. It could be expanded to as much as 18 mm in diameter.