

MEDICAL INNOVATION: CORONARY STENT (MEDICAL DEVICE: THERAPEUTIC)

Physician: Dr. Julio Palmaz
Industry: Johnson & Johnson

Situation

No alternative to invasive surgery

Coronary artery disease -- the narrowing of blood vessels that supply the heart with oxygen – affects 16.8 million Americans and stands as the leading cause of death in the United States. The American Heart Association (AHA) estimates that about every 34 seconds, an American will have a heart attack. In addition, the lifetime risk of having cardiovascular disease after age 40 is 2 in 3 men and more than 1 in 2 women.

Several decades ago, the primary treatment for opening clogged arteries was bypass surgery – a lengthy and invasive procedure that results in long and painful recoveries for patients. A less-invasive procedure known as angioplasty, or the use of balloon-mounted catheters to open narrowed or blocked blood vessels of the heart, was met with widespread skepticism in 1974 when first performed in humans, and many physicians believed that angioplasty would never become a viable treatment alternative, because it sometimes caused the blocked blood vessel to return to its original narrow size or, in some cases, actually become narrower.

For this reason, the millions of Americans who suffered from heart disease were left with no alternative but the complicated, expensive and scar-producing procedure of open-heart bypass surgery to treat their condition and prolong their life.

Physician-Industry Collaboration

A garage experiment with metal wires

However, some physicians, including Julio Palmaz, were inspired by the potential of angioplasty and sought to develop better ways of treating cardiovascular disease without invasive surgery. Evaluating the limitations of balloon angioplasty, Dr. Palmaz thought he could find a way to keep the artery open while the balloon was fully expanded. His goal was to slow down or halt the rate of restenosis – the re-narrowing of the blood vessel – to improve patient outcomes.

What he envisioned was a stainless tube with slots that would be mounted on a balloon catheter. When the balloon was inflated, the slotted tube around the balloon would expand and embed itself against the inner wall of the coronary artery, holding the artery open after the balloon was deflated and removed. Working on his idea, Dr. Palmaz began researching different types of materials that could be implanted in the body and continued to experiment with metal wires in his garage at home in order to produce the first “balloon-expandable stent.”

Dr. Palmaz began to realize that the sophisticated tools and equipment to make his ideas a reality were beyond his reach. He started working with physicians at the University of Texas Health Science Center in San Antonio to perform the necessary preclinical studies with his device. As he worked with them, he followed the path taken by many other medical technology innovators and secured venture-capitalist funding to continue his research and testing, and joined forces with a leading device manufacturer to further develop his invention and produce sufficient supply to ensure widespread availability for patients.

Working with Johnson & Johnson's engineers and other resources, Dr. Palmaz was able to refine his initial device by making it more flexible, which helped in the ease of insertion and ensured that it could adjust to the artery shape once it was implanted. The FDA approved Palmaz's stent in 1991 for use in peripheral blood vessels and for use in coronary arteries three years later.

Innovation Benefits

One million implants per year

While in many cases of traditional angioplasty the patient's artery collapses back after the balloon is deflated, with the help of balloon-expandable stents, the blocked or collapsed arteries are held open. Compared with traditional angioplasties, where the chance of restenosis was 40 percent, the balloon-stent they created reduced the chance of restenosis to 25 percent.

Today, approximately one million stents are implanted each year worldwide, providing patients with coronary artery disease a truly safe, effective and non-scar-producing alternative to invasive and risky open heart surgery.

Patient Benefits

Getting back in the pilot's seat

As he [described](#) to Angioplasty.org, David J., an airline pilot diagnosed with coronary artery disease suffered from "agonizing" chest pain and had difficulty walking even 100 yards due to his condition. In November 2010, David underwent a relatively short balloon angioplasty procedure to treat his blocked arteries and had three stents implanted, with no need for invasive and scar-producing open-heart surgery.

Following the procedure, he was given the green light by his cardiologist to begin exercising, and less than six months later he ran two 10K races and a half marathon, and is now training for a triathlon.

David said recently that ever since the short procedure, "I quit smoking and have lost over 22 pounds, and [now I] workout about an hour each day...I'm so impressed by the medical intervention and how it can turn around our lives... For the future I'm hoping to regain my professional pilot's license and be back to flying in about three months!"