

MEDICAL DEVICES

MEDICAL INNOVATION: STARR EDWARDS HEART VALVE (MEDICAL DEVICE: THERAPEUTIC)

Physician: Dr. Albert Starr, Miles "Lowell" Edwards

Industry: Edwards Lifesciences

Situation

A "mystery killer"

Heart valve disease has been called a "mystery killer." It occurs when one of the four valves within the heart fails to function properly, and, as a result, blood does not flow properly in a single direction through the organ's chambers. Heart valve disease can develop before birth (congenital), be acquired during one's lifetime, or come about as a result of an infection. More than five million Americans have moderate or severe heart valve disease, while more than half of Americans aged 70 and older suffer from the condition.

Generally, heart valve disease progresses very slowly and almost imperceptibly, yet when left undiagnosed and untreated, it can cause progressive deterioration in heart function, which can result in heart failure and premature death. In fact, the average life expectancy for untreated patients with severe heart valve disease is only two years. Half a century ago, however, there were few real options for curing this deadly disease.

Physician-Industry Collaboration

A retired engineer with a passion collaborates with a young surgeon

In 1958, Miles "Lowell" Edwards was a 60-year-old, recently retired engineer and inventor holding 63 patents in an array of industries, with an entrepreneurial spirit and a dream of helping patients with heart disease. His fascination with healing the heart was sparked in his teens, when he suffered through two bouts of rheumatic fever, which can scar heart valves and eventually cause the heart to fail.

With a background in hydraulics and fuel pump operations, Edwards believed the whole human heart could be mechanized into an "artificial heart." He presented the concept to Dr. Albert Starr, a young cardiac surgeon at the University of Oregon Medical School, who thought the idea was too complex. Instead, Starr encouraged Edwards to focus first on developing an artificial heart valve, for which there was an immediate need.

Working with Dr. Starr, Edwards went out to his Orange County, California, garage-laboratory, and another he maintained in Oregon, and worked to create a mechanical device that could replace the heart's natural mitral valve. After only two years, the first Starr-Edwards "caged ball" mitral valve was designed, developed, tested, and successfully placed in a patient. Newspapers around the world reported on what they termed a "miraculous" heart surgery. The patient, a 52-year-old farmer named Philip Amundson, thereafter enjoyed a healthy life and died 10 years later -- not due to his medical condition, but after falling from a ladder.

Innovation Benefits

A valve as good as new after 31 years of use

Fifty years after the Starr-Edwards valve was introduced, more than 300,000 patients around the world have received the valve. Though there have been numerous advancements in both mechanical and tissue replacement heart valves since that time, the Starr-Edwards valve remains in use today. The mortality rate is only 2.4% for valve replacement procedures.

What's more, mechanical heart valves do not often fail, and now last an average of eight to twenty years, depending on the type of valve. Incredibly, in 2005, a patient who had a Starr-Edwards caged-ball valve implanted in 1974 underwent heart surgery for a separate condition, and had a new version of the valve put in at the same time. When the original device was removed and carefully inspected, doctors were amazed to find it free from any signs of structural degeneration -- 31 years later, it was as good as new!

Patient Benefits

A new valve helps a presidential candidate gets back on the campaign trail

As told in AdvaMed's [Profiles in Progress You Can See](#), in the winter of 2002, Bob Graham, a 66-year-old U.S. Senator from Florida, was preparing to announce his candidacy for President of the United States. An avid jogger, he maintained a busy personal schedule, and noticed only a slight shortness of breath over the years. One day, while climbing the U.S. Capitol stairs with Senator Jay Rockefeller, he remembered huffing and puffing. His colleague told him he "should get his heart checked out soon."

Soon thereafter, a pre-campaign physical exam revealed that one of his heart valves was leaking. His doctors told him he would experience "a significant heart condition within 90 days" if he did not get his valve replaced. Given this sobering diagnosis, Senator Graham put his presidential campaign kickoff on hold while he underwent surgery to install a new-generation artificial replacement valve.

Released from the hospital within a week, Senator Graham was back on the campaign trail two months later. Although his presidential bid did not lead him to the White House, he spent his final 18 months in the Senate feeling great, with renewed energy. Now in retirement, he takes long walks regularly and is in excellent cardiovascular health. Senator Graham is grateful to have benefitted from this technology. "This procedure really gave me life by preventing a heart attack or stroke," he said.