An Embedded Sensor System for Wireless Monitoring of the Functional Status of Implanted Heart Valves

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Technology description

Unmet Need

While open heart surgery is the gold standard to replace a diseased heart valve and has long-term beneficial outcomes for the patient. In 2011 the FDA approved a minimally invasive procedure, called the trans-catheter valve replacement, for patients that could not undergo open heart surgery. Risks associated with a replacement valve include restriction of the movement of the valve flaps because of build-up of deposits, a leak between the valve and the surrounding tissue, called paravalvular leak (PVL), deterioration of the valve, infection, and the formation of blood clots, known as thrombosis, that can cause a sudden stroke or heart attack. The procedure also uses ECG images during the procedure to guide the placement of the valve. Due to the difficulty of measuring the valve area using ECG, there is a high rate of patient-prosthetic size mismatch or incorrect positioning. This regularly leads to secondary operations due to severe PVL or an overgrowth around the valve. These issues are exacerbated due to the lack of data on the longevity and structural durability of transcatheter heart valves, and early detection of improper valve function is difficult because the changes are too small to measure using current methods.

There were over 378,000 heart valve replacement surgeries performed in 2018, and with the increased life expectancy of the average person the number of heart valve replacement surgeries are expected to increase 4.8% annually. The market for the transcatheter valves used in the minimally invasive procedure was $3.9 billion in 2018, and there is an expected increase of 14.8% annually due to the increasing adoption of this procedure. It is predicted the market for the transcatheter valve will reach $7.9 billion by 2023.

Technology Overview

Researchers at Hopkins have developed a computational model of a heart valve with different disease states, and used this to determine the optimal placement of pressure sensors for the early detection of complications in the heart valve during and after the operation. The measured flow and pressure from the sensors can be mapped to a model simulation to diagnose the health of the artificial valve. There are no current artificial valve technologies available that can act as a positioning guide and a predictor of ventricular and vascular health.

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