A Valve for Challenging Heart Anatomies

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Patient heart anatomy can vary greatly depending on a variety of factors like age or the etiology of a heart disease. These factors all contribute to the condition of the heart that the surgeon will try to repair. The SuMit™ mitral valve has been especially designed to face difficult mitral valve replacement procedures.

Historically, most surgical options to replace heart valves (Fig. 1*) have come from surgical techniques rather than from prosthetic valve design selection. This small offering of prosthetic heart valves is especially apparent for mitral valve replacement procedures. While the prosthetic heart valve industry in general has offered a limited line of options to satisfy varying patient anatomies, Sulzer Carbomedics has diligently pursued additions to the mitral valve line to provide more solutions for the physician and the patient.

In a normal situation, oxygenated blood from the lungs drains into the left atrium and is pumped into the left ventricle across the mitral valve (Fig. 2*). Immediately after entering the left ventricle, the blood is ejected through the aortic valve into systemic circulation. The pathway by which blood leaves the left ventricle is referred to as the Left Ventricular Outflow Tract (LVOT). In order for blood to flow efficiently through the left heart, both valves must be operating properly to prevent backflow, and there must be an unobstructed outflow tract. The mitral valve and the aortic valve are adjacent to each other. Deviations from this normal structure result in a very difficult situation for the surgeon attempt-
A healthy human heart: The blood coming from the lungs enters the left ventricle through the mitral valve and leaves it through the aortic valve.

In order to replace one or both diseased valves with an artificial prosthesis that is designed to replicate the function of the native valve in an altered environment.

**INTRA-ANNULAR POSITION CAN BE A PROBLEM**

One of the many challenges that cardiac surgeons routinely deal with is deviation from the normal internal anatomy of the heart as this vital organ has responded to the challenge of disease. Conditions such as high blood pressure, valve stenosis and valve incompetence can all contribute to altering the normal anatomy of the heart muscle. Two of the greatest obstacles that a surgeon will face in heart valve replacement procedures are double valve disease and LVOT obstruction, both of which can be intensified depending on the particular anatomical condition of the heart.

Double valve replacement presents a very difficult situation because the aortic and mitral valves are located so closely together. Traditional intra-annular positioned prostheses must share the same plane of tissue. Since the mitral valve is usually replaced first, the aortic replacement valve is oftentimes downsized so as to secure a good fit. A downsized mechanical aortic valve could possibly be less efficient than the stenotic native valve that it replaced.

LVOT obstruction can be caused by a variety of factors. If the angle between the mitral and aortic valve is too sharp or acute, the prosthetic mitral replacement valve can actually cause a partial obstruction to the outflow tract. This is because the design of most prosthetic valves requires that they be placed in an intra-annular position (Fig. 3). Many times, heart valve disease will result in a thickening of the ventricular walls adjacent to the outflow tract. One such manifestation of this condition is known as a hypertrophied septum where the wall separating the right and left side of the heart bulges out into the left ventricle. The LVOT can be severely compromised due to this anatomical change. In some instances, the surgeon is faced with implanting a prosthetic valve at an acute angle in conjunction with a hypertrophied septum.

Traditionally, the prosthetic mitral valve is placed intra-annular.
Numerous surgeons have expressed concern over the lack of options that are available to them when faced with a difficult mitral valve replacement procedure that is exacerbated due to anatomical changes of the heart. This concern led to the conception and design of the SuMit mitral valve (Fig. 4). Although the SuMit mitral valve may be quite beneficial in a wide variety of procedures, one area that is currently being evaluated is the potential of this valve to address the challenges created by double valve replacement and LVOT obstruction.

The SuMit mitral valve is designed with the same high-quality orifice and leaflets found in all Carbomedics Prosthetic Heart Valve (CPHV™) models, but a cuff modification makes it unique. The new cuff design positions the orifice and the leaflets out of the way of the LVOT and also reduces the need for the surgeon to use the same tissue plane when performing a double valve replacement (Fig. 5). When faced with a challenging heart anatomy, the surgeon has an additional option with the new SuMit mitral valve that was previously unavailable.

Currently, SuMit has received regulatory approval in Western Europe and Canada. In the USA, SuMit is under review by the Food and Drug Administration. Sulzer Carbomedics has released the valve in a select number of implanting institutions for preliminary evaluation. The cardiac surgeons partnering with Sulzer Carbomedics in the review of the SuMit valve are evaluating the use of the valve, regarding specific implant techniques, clinical situations and patient anatomies. The SuMit is not intended to replace or reduce the need for the CPHV. If the initial evaluations are favorable, the new design will be considered as an addition to the CPHV line to provide the surgeon with more options for difficult patient anatomies.

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