

New process appears to help prevent calcification of surgical aortic valve tissue



A new process for treating the bovine pericardial tissue in replacement aortic valves appears to make it more resistant to calcification. Bioprosthetic tissue calcification can cause the tissue to stiffen and accelerate valve failure. The new process — known as Resilia — also offers a simpler implantation procedure by eliminating the need to wash off a storage solution at the time of implantation.

A valve featuring the Resilia tissue preservation process and designed to be used in surgical aortic valve replacement (SAVR) is available to treat patients requiring valve replacement for any pathology of the aortic valve, including aortic stenosis, aortic insufficiency and endocarditis.

How the Resilia process works

Because the tissue used in bovine pericardial valves is not living tissue, it does not regenerate with time. To strengthen the tissue, it is treated with glutaraldehyde, which forms cross-links within its collagen matrix. These valves require storage in a glutaraldehyde solution, which must be rinsed off at the time of implantation. Glutaraldehyde treatment and storage produces free aldehydes in the tissue, making it susceptible to calcification.

More durable valve can benefit younger patients

Because of the potential for tissue valves to deteriorate over time, treatment guidelines have recommended their use primarily in patients over the age of 60. Younger patients have typically been treated with mechanical valves, which require lifelong anticoagulation medication.

“There has been a need for an improved and more durable tissue valve for younger patients,” says Richard J. Shemin, MD, the Robert and Kelly Day Professor and Chief, Division of Cardiac Surgery. “This valve potentially fits that bill.

“The new Resilia tissue has been shown in experimental studies to be more resistant to calcification than tissue from the prior generation aortic valves. This valve may have greater durability over time, making it appropriate for use in younger patients,” continues Dr. Shemin, who is a member of Edwards Lifesciences Scientific Board. “A suitable tissue valve would spare younger patients the risk of blood clot formation associated with mechanical valves, along with the risk of bleeding associated with anticoagulation therapy, as well as the inconvenience of daily anticoagulant medication and frequent blood testing.”

As calcium builds up over a span of years, the valve tissue stiffens, leading to aortic stenosis. The tissue also becomes vulnerable to developing tears, which can lead to aortic insufficiency. These problems of valve tissue calcification can eventually cause the valve to fail and require that it again be replaced.

The Resilia process for treating bovine pericardial tissue also uses glutaraldehyde to form cross-links to strengthen the tissue. But the Resilia tissue is also treated with amines to bind the free aldehydes and prevent calcification. It is further treated with glycerol, which displaces water in the tissue while preserving its integrity. This allows the valve to be packaged for dry storage and eliminates the need to rinse the valve of storage solution at the time of surgery.

While no clinical data is available that evaluates the long-term performance of Resilia tissue in patients, it has been shown experimentally to resist calcification. One study found 72 percent lower calcium content after eight months compared to the prior generation tissue. In addition, some early data suggest that the new Inspiris valve — which uses Resilia tissue for its moving parts — has better fluid dynamics than its predecessor. With lower pressure gradients developing as blood flows through the valve, less work is required of the heart to move the same volume of blood through the Inspiris valve than through its predecessor.

Valve-in-valve replacement

When a bioprosthetic valve fails, it can be replaced in a transcatheter aortic valve replacement (TAVR) procedure that fits a new tissue valve within the old one, pushing aside the leaflets of the old valve. A drawback of valve-in-valve replacement has been that the new valve, being fitted within the old one, necessarily has a smaller opening than the original replacement valve.

The Inspiris valve was designed to have an expandable component with future valve-in-valve TAVR in mind. The expandability of the Inspiris valve allows it to accommodate a larger TAVR valve if it should fail and need to be replaced. Further, the Inspiris valve has a size marker etched into the metallic part of the valve. With standard X-ray fluoroscopy, the exact size of the implanted valve can be determined.

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