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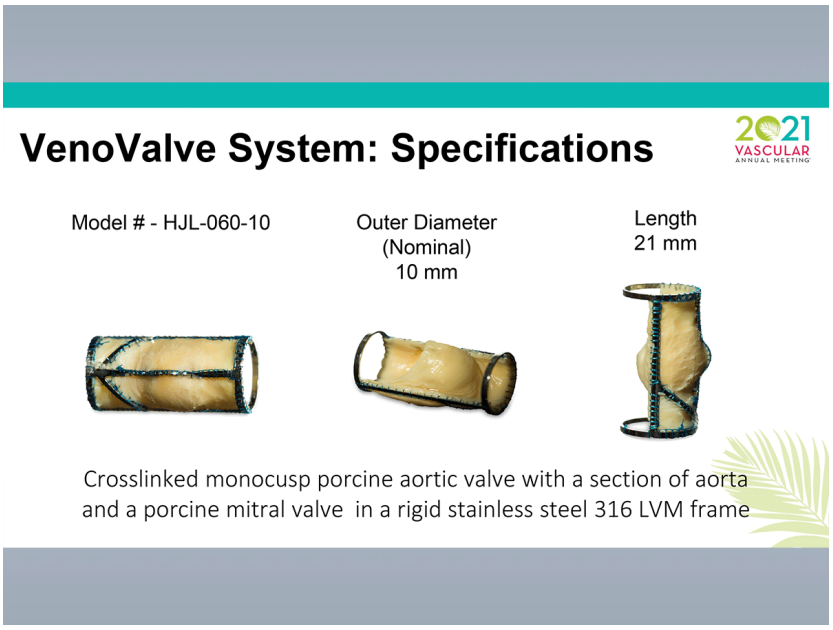
Hancock Jaffe's Venovalve demonstrates positive outcomes at two-year mark



Venovalve specifications. Credit: Hancock Jaffe Laboratories Inc.

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By Annette Boyle

Jorge Ulloa of Hancock Jaffe Laboratories Inc. presented positive results from a first-in-human trial of implantation with its Venovalve device at the Society for Vascular Surgery annual meeting in San Diego. Two years following surgery, outcomes included more than 60% improvements in reflux and disease manifestations and 93% decrease in pain in patients with chronic venous insufficiency with no safety issues or venous ulcer recurrences.

The FDA granted breakthrough device designation to Venovalve earlier this month and gave it investigational device exemption in April, clearing the way for the Irvine, Calif.-based company to launch its surgical anti-reflux venous valve endoprosthesis (SAVVE) pivotal trial by the end of this quarter.

These data are “exactly the results that we were looking for as we begin our Venovalve SAVVE pivotal trial,” said Marc Glickman, Hancock Jaffe’s senior vice president and chief medical officer. “Chronic venous insufficiency in the deep venous system has frustrated patients and physicians for decades.”

Chronic venous insufficiency (CVI) affects about 2.4 million people in the U.S. Globally, 2 million new patients receive a diagnosis of CVI each year. Caused by failure of valves in the veins of the legs, CVI allows blood to leak backward toward the feet rather than flowing properly to the heart. This reflux often causes blood to pool in the legs, causing venous hypertension. While deep vein thrombosis often precedes CVI, it can also occur as a result of cancer, vascular malformations and other conditions.

Early symptoms of CVI include swelling of the lower leg, emergence of new varicose veins, achy legs, and altered skin texture. Left untreated, it can cause venous stasis ulcers, debilitating pain, impaired mobility and reduced quality of life.

To date, no surgical solutions have proved effective for CVI, leaving patients and physicians to work against the effects of gravity by keeping the leg elevated, using compression garments, and avoiding long periods of standing or sitting.

Positive results

The study presented today indicates that Venovalve could provide a lasting solution for patients with CVI. In December 2020, researchers released results showing that 10 of the 11 patients who participated in the first-in-human trial improved sufficiently to be reclassified from having severe CVI to having mild or no CVI after one year. Of those 10, eight agreed to stay with the study for an additional year.

For those eight, reflux improved 63%, decreasing from an average of 1.95 to an average of .72, while disease manifestations measured using revised venous clinical severity scores (rVSS) improved 60%, dropping from an average of 13.38 to an average of 5.38. Pain on the visual analog scale (VAS) declined 93%, from an average of 7.25 to an average of .50.

"There are several unique characteristics of the peripheral vascular system that make it particularly challenging to treat,” Hancock Jaffe CEO Robert Berman told *BioWorld*. “We believe that it’s a combination of elements that are the keys to our success, including the nature of the porcine tissue that we’re using, the shape of the valve and its natural Valsalva, and the particular manner in which the elements are combined.”

SAVVE trial

The SAVVE pivotal trial will have the same endpoints as the first-in-human trial. The primary safety endpoint will be the occurrence of a major adverse event (a composite of all-cause mortality, deep wound infection, major bleeding, ipsilateral deep vein thrombosis, or pulmonary embolism) in less than 10% of patients at 30 days post-

implantation. The primary effectiveness endpoint will be improvement of reflux equal to or greater than 30% at six months and secondary endpoints will be improvement in venous clinical severity and VAS scores.

Hancock Jaffe plans to recruit 20 sites and 75 patients throughout the U.S. for the study. “We have had overwhelming interest from well over 20 sites,” Berman said. The company has completed central IRB approval and are in various stages of final budget and other approvals with Albany Medical Center, Baptist Hospital of Miami, Cedars-Sinai, Englewood Hospital, Houston Methodist, NYU Langone, Pima Heart & Vascular Institute, Promedica Toledo, St. Louis University Hospital, Sentara Norfolk, Stony Brook, Trihealth Heart Institute, University of Alabama at Birmingham, University of Chicago, University of North Carolina, University of Pittsburgh, Vanderbilt, University at Buffalo and Yale.

Berman cautioned that the team hopes to complete enrollment by the end of the first quarter of 2022, but “this timeline could get extended if hospitals suspend elective surgeries due to the resurgence of COVID. However, one of the reasons why we are including 20 sites in our trial is that it has always been part of our plan to diversify our COVID risk,” he said.

Assuming enrollment proceeds as expected, results of the trial should be available in about 18 months. “As far as timing for preliminary results, the primary safety endpoint is achieved 30 days after the 75th patient receives his or her Venovalve, and the primary efficacy endpoint is achieved six months after the 75th person receives the device,” Berman said, “so we expect to be able to report both safety and effectiveness data before the end of 2022.”