

Excellence in Cardiology

Clinical Trial Paves the Way for New Standard of Care



By participating in the pivotal North American PARTNER trial and undergoing aortic heart valve replacement with NorthShore University HealthSystem (NorthShore) Cardiac Catheterization Laboratory Director Ted Feldman, MD, James Vaughan essentially agreed to live to the age of 100.

At 95 and going stronger than ever following a transcatheter procedure in May, Vaughan, who swims laps six days a week (skipping Sunday morning for church) and walks at a brisk pace concealing his age, is looking forward to reaching the centennial mark.

Dr. Feldman, an internationally recognized expert in the growing area of catheter-based therapies for heart disease and the Mr. and Mrs. Charles R. Walgreen, Jr. Chair of Cardiology, is thrilled with Vaughan's approach and zest for life, and believes he has a good chance of reaching the next milestone birthday.

As one of just 22 sites in the country involved in the PARTNER (Placement of AoRtic tranScathetER valves) trial, NorthShore is at the forefront of this leading-edge technology that allows physicians to treat aortic stenosis—heart disease characterized by calcification and narrowing of the valve—without traditional open heart surgery, which is often too risky for some elderly patients.

The PARTNER trial was designed specifically to study non-surgical valve replacement in older patients, and elderly individuals with other health complications, that would preclude them from open heart surgery. Offering a less invasive option for valve replacement gives a whole new group of patients an option for treatment when they previously had none.

Aortic stenosis is a progressive disease where symptoms accelerate and begin to take a greater toll on patients' quality of life, as well as limiting their lifespan, said Dr. Feldman. That was definitely the case for Vaughan, who was getting so winded he had to give up his swimming and would tire in just a few steps of walking.

"They told me I had a 50/50 chance of surviving even a year without this procedure," said Vaughan, who was referred to NorthShore by his Milwaukee cardiologist. Vaughan and his 92-year-old wife are engaged in a variety of activities at their Mequon, Wi. retirement community. "I think I am doing pretty well," he said. "I read the *New York Times* every day and I find enough active things to do to stay busy."

Dr. Feldman has been treating heart disease patients with earlier catheter balloon therapies since the mid-eighties and continues to be gratified and energized by the growing potential to not only extend life, but to offer real improvements in quality of life for so many.

The PARTNER trial is truly a team effort, and even the name reflects the collaborative efforts of the interventional cardiologist and the cardiac surgeon, said Dr. Feldman, who is joined by NorthShore cardiothoracic surgeon John C. Alexander, MD. Drs. Feldman and Alexander, both on faculty at the University of Chicago Pritzker School of Medicine, lead a team of more than 50 physicians, nurses and other health-care professionals involved in this trial including key players in anesthesiology, echocardiography and cardiac imaging.

"This is a spectacular device, and I think it has huge promise not only for this currently untreatable population, but for a more traditional patient base as well," said Dr. Alexander.

Anesthesiologist Jesse Marymont, MD, who is also intimately involved in the trial, and on faculty at the University of Chicago Pritzker School of Medicine, is pleased to see that NorthShore has positioned itself as a leader in this area of interventional cardiology. "Hopefully these options we are studying today will be the standard of care in ten years," said Dr. Marymont. "There is no question as we learn more about the durability of this device we will be able to treat and benefit younger patients as well," Dr. Feldman said.

While this particular catheter-based therapy is already approved in Europe, it is still pending in the United States where results of the first stage of the trial were just released. In the randomized trial patients treated with the new heart valve had much better survival and significantly fewer repeat hospitalizations compared to those treated with regular medicines or simple balloon treatment.

"I hope the FDA hurries up with its approval of this so it can be extended to other people like me who can enjoy the benefits of longer, healthier lives," Vaughan said. ■

PARTNER Trial patient James Vaughan with interventional cardiologist Dr. Ted Feldman (center) and cardiothoracic surgeon Dr. John C. Alexander (facing page)