

# Heart Valve Replacement – Significant Changes Thanks to Hybrid Surgery

Today, Japan's population is living longer than ever, but that also means a higher national incidence of elderly patients needing heart valve replacements. Siemens is collaborating with surgeons at Kurashiki Central Hospital to introduce lower-risk catheter-based procedures that eliminate the need for open-heart surgery in many of these cases.

By Clark Shimazu

Kurashiki Central Hospital is among three Japanese medical institutions whose multidisciplinary surgery teams conducted clinical trials of catheter-delivered Edwards prosthetic valves over the past year. The aim is to gain approval from the National Health Ministry for the innovative procedures. All of these institutions are equipped with Siemens hybrid rooms – a conventional OR equipped with an angiography system to allow for both open and minimally invasive treatment in one room. At Kurashiki Central Hospital, the room is equipped with a ceiling-mounted Artis zee angiography system from Siemens.

The machine enables intra-procedural imaging in 2D and 3D and helps multi-functional teams of cardiac surgeons and cardiologists to best perform their procedures. Doing heart valve replacements in a hybrid room is also recommended in a recent joint paper from the Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC), two of the most important cardiac surgical and cardiological societies in the world.

## A multi-disciplinary team in a multi-disciplinary room

"The methods for implanting heart valves cannot be learned on one's own because close teamwork is essential among the different specialists, including interventional cardiologists, echocardiographers, imaging specialists and heart surgeons like myself," says Tatsuhiro Komiya, MD, Chief of the hospital's cardiovascular surgery department. "Since the launch of our joint program with Siemens in May 2010, each specialist has not only had to learn his own specific skills but also gain some familiarity with other team members' tasks, because we have to work in concert on the operation in a very short period of time." The first round of clinical trials is especially important in Japan, where many elderly people among the aging population are outliving the normal duration of their heart valves. The aorta is the biggest artery in the body; therefore, its valve handles a larger flow than other heart valves. Seniors with a lot of comorbidities, however, are not indicated

to undergo open-heart surgery due to the risk that this procedure poses for them.

"For more than 30 years, we've relied on open-heart surgery, and that requires splitting the sternum," Komiya explained. "Many patients with defective heart valves are more than 70 years old. Among the national population, there are annually some 10,000 cases of degenerative disease in the aortic valve, but medical institutions must

turn away many prospective patients due to their advanced age and physical frailty. As a consequence, we can do only 70 open-heart surgeries a year at Kurashiki Central."

## Catheter Delivery

The Kurashiki heart team is focusing on two different options for catheter-delivered replacements of the heart valves, transapical and transfemoral. The aortic valve from Edwards is replaced through

a transapical insertion on a valve-mounted catheter, which is introduced through a surgical puncture into the apex of the left ventricle. Produced by Edwards LifeSciences, based in Irvine, California, the prosthetic valves are based on an ingenious, yet simple design concept. They are bovine in origin and similar in size and shape to the natural valves in the human heart. These bio-valves are expandable wire-mesh stents which,

when opened, hold the valve firmly in place. The Edwards valve does not require prior removal of the patient's own valve, but instead is slid inside the defective valve, permanently pushing back its leaflets and immediately taking over the function of maintaining one-way blood flow. Catheter delivery minimizes or eliminates the need for open-heart surgery along with the trauma of opening large parts of the thorax. The patient also

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Kurashiki Central Hospital is famous for its innovative procedures.

spends far less time in surgery, and there is no longer a need for external blood circulation with a cardiopulmonary bypass machine. Navigation of an Edwards valve into the correct location demands orchestration of many components, including several high-tech imaging modalities, intensive planning and preparation, real-time monitoring, and multidisciplinary collaboration in ensemble.

### Taking a Balloon Ride

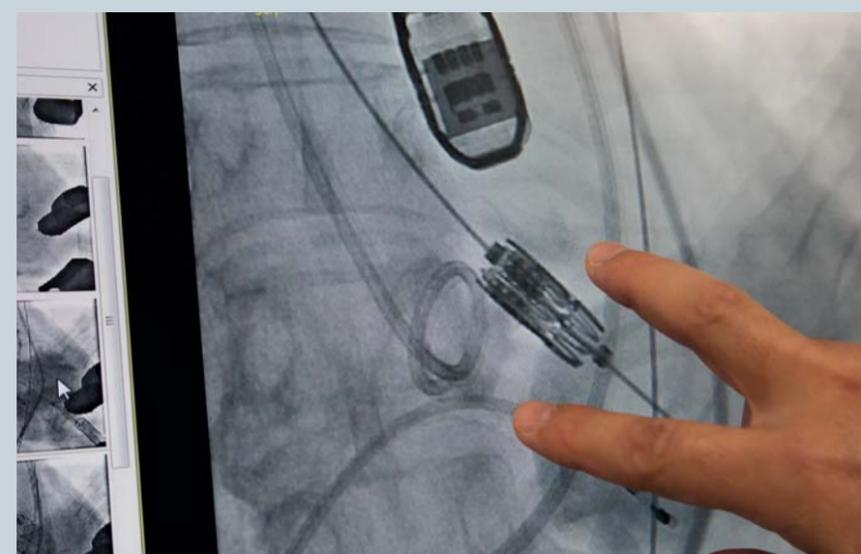
Komiya points out: "The single most important step is to align the valve ring on the aortic annulus between the left ventricle and the proximal ascending aorta. The valve must be precisely positioned on this line, neither too far in nor too short of the mark." Echocardiograms, pre-operative CT and intra-operative syngo DynaCT images provide the heart team with a three-dimensional schema of the target region. The valve must also be perpendicular to the X-ray projection to capture the best real-time images of the catheter's progression.

The Edwards Sapien valve is compressed around a balloon catheter by a crimper to a diameter narrow enough to fit inside the patient's aortic valve. Meanwhile, the cardiac surgeon uses a scalpel to open an entry port between the two ribs directly above the apex. After completing the purse string sutures, the surgeon punctures the apical area for insertion of an introducer sheath. A temporary pacemaker lead is placed in the heart. The valve-bearing catheter is introduced through the sheath. Turning the control knob, the operator then maneuvers the flexible catheter, curving it toward and into the left ventricular outflow tract. After checking the alignment on screen the temporary pacemaker stimulates the left ventricle with up to 200 beats per minute. The heart contracts so rapidly that the cardiac output is minimized. The balloon swells to enlarge the stent, locking the bio-valve into place. The pacemaker is stopped; the balloon is deflated. The heart again pumps. The team watches to determine whether the Edwards valve is firm and

functioning. The catheter and electrode wire are retracted. The surgeon then removes the introducer sheath to close the puncture in the heart. "This, for me, is the most stressful moment, since any slip of the fingers could have catastrophic consequences," says Komiya. "The heart is beating while I close the thorax and skin incision." The multiplicity of tasks was done within a total span of just 12 to 14 minutes.

### Positioning matters

"A vast amount of planning precedes the operation," Komiya states. "Echocardiograms and fluoroscopic images of each patient are examined from different angles so that the team can set the valve precisely into position." If an aortic valve is positioned just millimeters off-center of the aortic annulus, a stent-in-stent procedure must be done, by slipping in a second wire-mesh ring to hold the first one firmly in place. "In one of our earlier operations, a valve was positioned slightly incorrectly," says Komiya. "Since we had doubts about its ability to maintain a grip, the team did a stent-in-stent insertion." That has held ever since, with no ill effects for the patient. "If a valve were ever to dislodge, that could be disastrous," he adds. "Our recourse then would be the immediate start of open-heart surgery." Which does not pose any technical problems - due to the fact that the operating room is a hybrid OR. The combined heart-valve unit provides quick backup in any unlikely event. "Among our patients, in one case, a coronary was obstructed by the valve expansion, so we had to switch



Dr. Komiya explains the placement of the prosthetic heart valve.

immediately to open-heart surgery in our hybrid OR," Komiya discloses. The aortic valve trials at Kurashiki Central have spurred development of valves of smaller diameter that are more suitable for Japanese patients who on average are smaller than European or American patients. More extensive research and development on valve design must, of course, await ministry approval for the innovative valve replacement technique. "Just like the American health system, the Japanese one demands comprehensive clinical trials on innovative procedures," Komiya says. "Our reporting of data must be quite rigorous to satisfy the strict requirements on testing medical claims." Kurashiki Central and two other hospitals - in Osaka and Sakakibara - are now tracking the recuperation phase of some 50 patients who volunteered for the heart valve trials. Among this cohort, some received Medtronic's CoreValve, an aortic valve that is being implanted via the femoral arteries instead of the apex of the heart. "The technique is rapidly developing, and Japanese patients and physicians are expressing enthusiasm," Komiya concludes. "This is a new frontier for medical science and surgical practice worldwide and here in Japan."

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