

# Heart valve innovations:

## *Novel procedures and devices keep pumping in*

Transcatheter Aortic Valve Implantation (TAVI) has changed the game in heart valve care and saved the lives of patients who were considered too high-risk for surgery. With TAVI now well-entrenched in clinical practice, cardiac doctors are looking out for the next big thing in heart valve repair and replacement

by Marjo Johnne

Game-changing. Life-saving. Grand slam. Phenomenal. These are just some of the words doctors and patients use to describe Transcatheter Aortic Valve Implantation (TAVI), which replaces a damaged heart valve with a replacement valve inserted through a small incision in the leg.

TAVI has been a godsend for patients considered too high-risk for open heart surgery. The results so far have been outstanding, with an estimated 20 per cent reduction in deaths a year after the procedure. Large randomized studies on high-risk and moderate-risk patients have also shown the benefits of a procedure that can put the patient back home the next day.

“TAVI completely revolutionized how we take care of patients with aortic valve disease,” says Dr. Maral Ouzounian, cardiac surgeon at the Peter Munk Cardiac Centre (PMCC). “Before TAVI, patients who were frail or elderly would not be sent to a surgeon for assessment because of concerns they would not make it through surgery. TAVI has really changed that – we regularly perform TAVI on patients beyond the age of 90 [years] – and most often, they go home within a day or two of the procedure.”

With TAVI now well-entrenched in clinical practice, doctors and scientists are eyeing the next wave of innovations in heart valve care.

### A huge momentum in innovations

TAVI has created a huge momentum in heart valve innovations and has set the stage for future transcatheter valve technologies that are tackling the other three valves of the heart through less-invasive procedures. As a recognized leader in heart valve care, the PMCC has early access to many of these innovations – initially through clinical trials, and then more widely after regulatory approval. The PMCC is on the cutting edge of these advances and is one of a few centres in Canada routinely providing transcatheter valve repair or replacement for each of the four valves of the heart.

### Experience and infrastructure key to accessing new technologies

“To access these innovations, you need a highly functional and experienced team with a strong reputation nationally and internationally,”

says Dr. Ouzounian. “We’ve been doing TAVI since 2006 and are recognized nationally as a centre able to tackle cases of great complexity. That’s important to companies that are developing these new technologies. They want an experienced group, who work well together to achieve outstanding results with novel technology – there’s just too much at stake. The expertise we bring to the table is critical to achieving great results for our patients.”

Having a robust and sophisticated clinical infrastructure has also been critical in gaining early access to new innovations, says Dr. Mark Osten, a PMCC cardiologist and lead investigator into new structural heart disease devices.

He points to the PMCC’s state-of-the-art operating rooms, which include two hybrid rooms – one that features a CT scanner and fluoroscopy machine and another that incorporates diagnostic imaging equipment – that support more complex procedures.

“The companies that make these new technologies recognize that we have the infrastructure, the support of our institution and an incredible breadth of experience in cardiac and structural heart disease,” says Dr. Osten. “We do some of the highest-risk cases in the country.”

So what new heart valve innovations are the PMCC doctors testing these days? The latest technologies offer the potential for major improvements in quality of life for patients who otherwise would be in profound heart failure or die. Novel technologies have been applied to each of the four valves of the heart, relieving leaking and stenotic (narrowed) valves and improving a patient’s symptoms.

### UP AND COMING: THE LATEST INNOVATIONS AND APPLICATIONS IN HEART VALVE CARE

#### MitraClip

Doctors at the PMCC use a device called the MitraClip to treat patients with severe mitral valve regurgitation, a disease characterized by a distorted left ventricle that stretches the mitral valve opening or by abnormalities of the valve itself that prevent the valve flaps from closing properly. This gap causes blood flowing into the

left ventricle to leak backward into the lungs.

When a patient has severe mitral valve regurgitation, they may become breathless, and the heart becomes enlarged over time. Traditionally, this has required open heart surgery to repair or replace the valve. The PMCC has been an international leader in pioneering surgical techniques for this condition. In some cases, because of previous heart surgery, poor pump function or other medical problems, patients are just too sick or too weak to tolerate open heart surgery.

This is where the MitraClip comes in. Many patients who cannot tolerate open heart surgery may be helped by the clip.

The clip is implanted through a catheter based technique via a vein in the leg. The MitraClip is a V-shaped clamp with movable arms that can open and close to pinch leaking valve leaflets together, ensuring that they meet, reduce leaking and restore proper functioning of the valve. Tissue eventually grows over the clip to further support the clip. Patients can often be discharged home the next day.

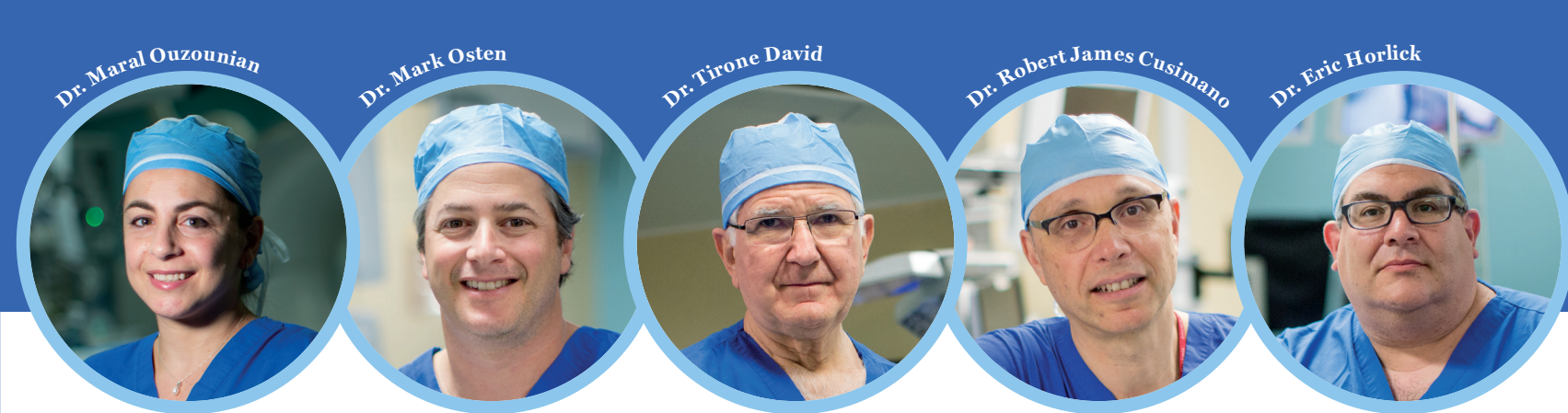
The MitraClip can help patients with a severely leaking mitral valve who are not surgical candidates, says Dr. Tirone David, cardiovascular surgeon and the Melanie Munk Chair in Cardiovascular Surgery.

“We use the MitraClip for patients who are not operative and are symptomatic” he says. “We offer this procedure as palliation, and it does offer relief and improved quality of life for many of our non-operative patients. Surgery works better, but not everyone is suitable for heart surgery.”

#### Tricuspid valve repair

In the right side of the heart, the tricuspid valve – which has three flaps, or leaflets, that open and close – regulates the flow of blood from the right upper chamber (right atrium) to the lower chamber (right ventricle). When the lower chamber is enlarged, the tricuspid valve stretches and pulls apart, and the flaps no longer meet in the centre, causing blood to regurgitate back into the upper chamber.

To repair this faulty valve, doctors at the PMCC are participating in a clinical trial testing a new therapy called the Forma System, which involves the placement of a balloon-



like device into the centre of the valve. The foam-filled polymer balloon – also referred to as a “spacer” – is implanted through a vein in the upper chest using a catheter – a similar technique to implanting a pacemaker.

“Will it work? I think it will help to reduce the problem, but I’m not sure if it will completely fix it,” says Dr. Robert James Cusimano, a cardiac surgeon, and clinical researcher at the PMCC, who holds the David and Stacey Cynamon Professorship in Cardiovascular Surgery Innovation and Education. “That’s what we are looking to find out.”

Often overlooked, the tricuspid valve is a complex structure that resembles three parachutes with strings attached to the heart. Tricuspid valve regurgitation usually doesn’t trigger any symptoms until the condition becomes severe. At its worst, it can lead to heart failure, severe swelling of the legs and fluid in the belly, says Dr. Cusimano.

“It can become very dangerous when you don’t fix the problem,” he says. “The Forma System – which is still an investigational therapy and not available for use outside a trial setting – could be one way to do this.”

#### Transcatheter mitral valve replacement

The success of TAVI has encouraged researchers to push for similar advances in minimally-invasive mitral valve replacement. A number of medical device manufacturers have developed transcatheter options for this procedure, says Dr. Ouzounian.

“We are still in the early days of mitral valve replacement compared to TAVI,” she says. “In many ways, TAVI is easier because the aortic valve is anatomically more straightforward and has a whole lot of calcium in it to anchor the replacement valve.”

A number of medical device manufacturers have developed their own version of transcatheter mitral valve replacement. Dr. Ouzounian says she and the other cardiac specialists at the PMCC are evaluating one particular system that is part of a clinical trial.

“At this point, we don’t know which transcatheter mitral valve replacement technology will be successful. They’re all different, with their own set of advantages and risks,” she says.

Regardless of which technology is used, transcatheter mitral valve replacement is considered a high-risk procedure, says Dr. Ouzounian. Because of this, doctors at the PMCC are considering patients according to a detailed experimental protocol, to select those best suited to the technology.

“We will be looking for specific patient traits, as well as specific mitral valve anatomy, including the amount of calcium in the valve leaflets, and whether the opening and the geometry of the valve and surrounding structures are optimal,” she says. “Right now, there really isn’t anyone in the world with enough experience in this type of procedure, and it is still experimental.”

#### Percutaneous pulmonary valve implant

The PMCC recently started assessment of a second-generation device to fix pulmonic valve disease, often related to a congenital heart condition where blood may not flow properly from the heart to the lungs because the valve between the right ventricle and the pulmonary artery is defective.

Like TAVI, the new device – a collapsible cylinder with scalloped edges – is inserted into the dysfunctional valve through a catheter.

“Patients with pulmonic valve disease tend to develop problems when they’re very young, so they often have operations as babies or children, and these procedures eventually fail in adulthood,” says Dr. Osten. “We have had devices for a particular anatomic subset of these patients for almost a decade, and the long-term results have been very rewarding. The next generation of devices, which are now being evaluated in trials, will be able to address a much larger population of patients with this problem. The potential to replace the pulmonary valve, through a small vein in the leg, in most patients during their most productive years – is just around the corner.”

#### Back to TAVI: From revolution to evolution

TAVI continues to evolve in its applications. Dr. Eric Horlick, a cardiologist at the PMCC, sees a future where TAVI is the go-to treatment for most, if not all, aortic valve patients. “Right now, there is more TAVI being done in the U.S. than conventional surgical aortic valve replacement.”

He points to clinical trials now evaluating patients who are low-risk for surgery and treating them with TAVI. The PMCC is participating in these clinical trials, which are likely to change the way care is delivered to a very common form of valve disease.

“Operationally, the U.S. has seen greater adoption of TAVI for moderate-risk patients,” says Dr. Horlick, who holds the Peter Munk Chair in Structural Heart Disease Intervention, which focuses on research into minimally-invasive approaches to managing inherited

or acquired heart defects. “Right now, there’s TAVI funding in Ontario only for high-risk patients. We hope this will change as more and more compelling positive data supporting TAVI becomes available. For the last several years, we have been performing TAVI without a general anesthetic, under minimal sedation and without any surgical incisions in the groin. The procedure typically takes less than an hour. Recovery from TAVI in 2017 has become much easier for the patient. They can be at home, recovering in 24 hours.”

#### In search of the next big thing

What could be the next game-changer after TAVI? Dr. Paul Fedak, a researcher for the Heart and Stroke Foundation of Canada and a professor in the Department of Cardiac Sciences at the University of Calgary, says the next big breakthrough in valve care is likely to come from tissue engineering innovations.

“I think in the future, we will have replacement valves that are designed for each patient out of their own cells and tissues,” he says. “These will be real game-changers because you’ll be less prone to infection and won’t need blood thinners, the valves will never break down and when they’re used in a younger patient, they’ll have the potential to grow as the patient grows, which is a huge deal.”

In the meantime, the research and clinical teams at the PMCC continue to examine new and emerging technologies in heart valve care. Drs. Osten and Horlick recently travelled to Israel as part of a project to evaluate the usefulness of holographic imaging of the heart during a medical procedure.

The three-dimensional digital image, which floats in mid-air and can be touched, manipulated and even cut up to show the inner anatomy of the heart, is a novel technology with potential applications in education and, most significantly, as a tool in the operating room and catheterization lab.

“Cardiac imaging plays a major role in structural heart disease intervention. If a technology can help us have a greater understanding of the cardiac and vascular structures, this will ultimately translate into better decision-making and clinical outcomes for our patients. With holographic imaging, we will hopefully be able to define the anatomy with more precision and potentially use it to guide us live through these minimally-invasive procedures,” says Dr. Osten. “That’s something that’s potentially a game-changer, and we are going to be the first and only hospital in the world to evaluate it. It will be exclusive to the PMCC.” ▾