First-in-Man Experience with Non-Occlusive Helical Balloon Catheter
In the Delivery of TAVI Heart Valves

At the end of January, 2019, a woman with severe aortic valve stenosis was successfully treated with a replacement valve in the world-famous Groote-Schuur Hospital, South Africa, using highly innovative delivery technology developed by Strait Access Technologies, a spin-out company of the University of Cape Town (UCT). The procedure was carried out by Dr. Jacques Scherman, Senior Specialist Cardiothoracic Surgeon in the Chris Barnard Division of Cardiothoracic Surgery, UCT; the location of this First-in-Man procedure was in the same building that Chris Barnard carried out the world’s first heart transplant just over 50 years ago.

The ultimate objective of this ground-breaking technology is the treatment of young adults who are suffering from and dying of rheumatic heart disease (RHD). The World Health Organization has recently recognized that RHD is a serious public health problem in many parts of the world, especially those of low- and middle-income countries. Over 30 million people are affected by RHD globally, which is responsible for 300,000 deaths annually and massive levels of disability among the young. The disease is of bacterial origin, and theoretically preventable, but efforts with the control of RHD have had minimal success in impoverished communities, especially those in sub-Saharan Africa and parts of China, Russia and South America. Interventional approaches to treat RHD, such as open-heart surgery, are largely inaccessible in these regions; the pathology of RHD is also very different to that of heart valve disease in older patients in the first-world, so much of present-day cardiac technologies are both unavailable and irrelevant.

The un-met clinical need associated with RHD in young people in poor countries was recognized by two authorities in cardiac reconstructive technology some 10 years ago. Professor Peter Zilla, the current Chris Barnard Professor of Cardiothoracic Surgery at UCT and Professor David Williams, formerly of the University of Liverpool, UK and now Professor of Biomaterials at the Wake Forest Institute of Regenerative Medicine, USA, decided to form a spin-out company at UCT, Strait Access Technologies, Pty (SAT), with the objectives of developing innovative technologies and clinical techniques for the treatment of RHD. Zilla is CEO and Williams the Chairman of the company and they were joined by Dr. Deon Bezuidenhout of UCT as the founding directors. Between 2013 and today they have raised the equivalent of $30 million, all within South Africa; 60 engineers and scientists work with them in their Cape Town facilities.

In order to develop affordable replacement valves for these patients, Zilla and Williams had to design devices specifically for the rheumatic situation, where diseased valves are ‘floppy’ rather than stiff as in the case of calcified valves of most older people, and also a delivery system that would allow valves to be placed in affected hearts without open-heart surgery and the need for major imaging systems. The work has taken 7 years so far, and the team will be ready for the first clinical
application of their SAT TAVI valves later this year – both bioprosthetic (made from animal tissue) and synthetic polymer valves are in final stages of testing.

A very important step in the development process has been the design and testing of a special balloon catheter. With most valve-replacement patients in the first-world, placement of the valve is achieved with minimally-invasive approaches using the transfemoral route – that is inserted via the femoral artery (the so-called TAVI, transcatheter aortic valve implantation). The valves are crimped inside a delivery catheter and then expanded with the aid of a balloon once inside the aortic annulus. Since balloons temporally halt blood flow, most patients are given rapid pacing during this procedure, which reduces the time available for implantation and may be detrimental to the patient; this is a very expensive and resource-intensive procedure.

The SAT strategy has been fundamentally different. Instead of the transfemoral route, the SAT technology uses the transapical route, in which the device is inserted through a small incision in the apex of the heart itself. Crucially, SAT has designed a catheter system that is non-occlusive, this being achieved by a balloon that is helical (see Figure) such that, on inflation, it allows blood to flow through its lumen; no pacing is required and the imaging facilities are far less demanding than those needed for transfemoral TAVIs. The SAT TAVI valves have been designed to be delivered by this system, incorporating several patented design and biomaterial features.

The testing of the catheter and valve systems has been onerous and challenging. The valves have been designed to be used in the young RHD patients, and the First-in-Man and clinical trial procedures are planned to take place in Africa. The strict regulatory environment has required that proof of concept of the balloon catheter had to be shown. This is where the Groote-Schuur patient comes in. Dr. Sherman inserts a number of regular TAVI valves in patients each year. Most surgeons and cardiologists working with conventional, balloon expanded TAVI valves use a procedure where an occlusive balloon open-ups the aortic annulus prior to valve insertion, in so-called pre-dilatation mode. Dr. Sherman, with all appropriate regulatory and ethical permissions, used the SAT non-occlusive balloon system for dilatation in this patient with a regular transfemoral TAVI valve. This was successful, and no pacing was required.

This was the world’s first clinical use of a non-occlusive cardiovascular balloon catheter, and opens up the way towards the use of the SAT TAVI systems in RHD patients.

Strait Access Technologies Pty, Ltd
First-in-Man, Non-occlusive helical balloon catheter
Professor David Williams, Chairman SAT
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The SAT non-occlusive helical dilatation balloon