Leaky Valves

New operation improves the heart’s pumping action

by Joost van Kasteren

The action of any pump will start to decline when the valves no longer close properly. The same goes for the heart, the pump that maintains the circulation in our vascular system. Consequently, a major field of focus of open heart surgery is the repair or replacement of heart valves. Petr Havlík, a Ph.D. student at the Man Machine Systems section of the TU Delft subfaculty of Mechanical Engineering & Maritime Technology, has developed a technique and the necessary instruments to enable minimally invasive surgery to be used for reinforcing the mitral valve in order to restore the...
proper pumping action of the heart. Although the technique has not yet been tried on human patients, Havlík is confident that it will soon be, and that the new operation will help to improve patients’ health.

Up until the mid-seventeenth century, the medical profession was of the opinion that our blood received its oxygen through the contraction of the arteries, as seemed to be indicated by the presence of a pulse. It wasn’t until 1628 that William Harvey, court physician to King James I, came up with an elegant demonstration of the fact that the human heart was responsible for keeping up the circulation of our blood. In his Exercitatio Anatomica de Motu Cordis et Sanguinis in Animalibus he determined the volume of blood in our bodies and demonstrated that the pumping capacity of the (animal) heart was more than sufficient to pump the volume around. This also explained the purpose of the valves in our veins, which is to keep the blood flowing in one direction. Harvey dedicated his treatise to the King, whom he called the heart of society, an example of flattery that might perhaps come in handy again for modern-day scientists seeking to increase their research budgets.

The pumping action of the heart can deteriorate for a number of different reasons. One is that the supply of oxygen rich blood to the heart muscle, or the blood flow away from it, becomes restricted as the result of the coronary arteries or veins becoming clogged up, which may lead to an infarction, in which part of the heart muscle dies. Special diets, a bypass operation, or widening of the arteries using balloon dilation (angioplasty) or an expanding micro scaffold (stent) can be used to restore the blood flow. Another problem may be that the heart rate is too slow or too fast as the result of the use of medication, strain, or a nervous disorder. Serious nerve signal disorders are remedied by the surgical insertion of a pacemaker, a device that generates an electric pulse. A third cause of a reduced heart function is a malfunction of the heart valves. The heart consists of four chambers, the left and right atria, and the left and right ventricles. Oxygen-enriched blood enters the left atrium to be pumped through the left ventricle and into the body. The oxygen-depleted blood returns from the body into the right atrium and is pumped through the right ventricle into the lungs to receive oxygen before starting on a new cycle. Since the flow resistance presented by the body is the greatest, the heart’s left chambers have the hardest job to do, which is why they are the more muscular.

Leaflets
The left and right ventricles each carry inlet and outlet valves to prevent the blood from flowing in the wrong direction. With the left ventricle, which is the subject under discussion, at ease, the outlet valve, known as the aortic valve, is closed to make sure the blood does not flow back into the ventricle. When the left ventricle contracts to pump the blood out, the outlet valve opens, but the inlet opening, the mitral valve separating the...
atrium from the ventricle, closes to prevent the blood from flowing back and so reducing the efficiency of the pumping action.

The mitral (or bicuspid) valve is the only valve to have two leaflets; the other three valves all have three leaflets to close off the inlet and outlet apertures.

The cups are passive structures which open and close in response to minute differences in pressure. The heart valves in the left atrium in particular must be capable of withstanding considerable pressures as the heart muscles of the left ventricle contract and relax.

As a result of a viral infection (endocarditis, rheumatic fever), or a weakening of the left ventricle’s heart muscle (cardiomyopathy, ischaemia), or normal wear and tear, or a congenital defect, the mitral valve may not fully close. This allows blood to flow back as the left ventricle contracts, as a result of which the pressure in the left atrium and the pulmonary veins increases, causing less blood to be pumped into the body. This leads to such symptoms as shortness of breath and fatigue. A common type of heart repair to remedy this condition is a reinforcement of the mitral valve in order to enable it to fully close again.

The mitral valve repair is a major operation according to Petr Havlík, who has been present at over twenty heart operations as part of his research. It involves opening the thorax and arresting the heart. During the operation, the circulation of the blood is temporarily taken over by a heart-lung machine. The actual reconstruction of the valve involves attaching a reinforcing ring, known as an annuloplasty ring, around the valve aperture. The purpose of the ring is to gather the edges of the dilated valve opening together in order to reduce its circumference to normal proportions and so enabling the valve to properly close again. At the same time, the ring reinforces the valve edges, preventing it from distending again. The process is a bit like holding together oversized trousers with a belt.

Sutures
In practice the operation involves the surgeon inserting between 8 and 16 lengths of suture around the opening of the valve i.e. the annulus (the exact number depends on the size of the valve, the stiffness of the tissue, and the surgeon’s preference), the ends of which are then threaded through the fabric cover of the ring, which is then moved into position against the edge of the valve. The sutures are then tied one by one, each with six to eight knots on top of each other. The annuloplasty ring need not be a closed ring. During his research, Havlík tested a large number of different annuloplasty rings, from rigid to flexible, and from circular to C-shaped (known as annuloplasty bands). The tests revealed a huge variation in mechanical properties. Whereas one type of ring could not be compressed more than 1 mm, another yielded as much as 17 mm. The large variation in properties is due to the fact that annuloplasty rings are designed more or less by feel. In other words, the design process takes little notice of the dynamics of the valve aperture as the valve opens and closes. Since little is know about the forces that cause the valves to move, there are two things that can go wrong with the mitral valve. Normally, the valve leaflets meet each other at the same level and travel the maximum possible distance from open to closed. The problems occur when the leaflets no longer make proper contact (B) and so fail to close the opening, or when one of the valve edges shifts (C) as the result of a torn papillary muscle or chordae tendinae, or because the tissue of the valve leaflet becomes weakened or enlarged.

Two different approaches: replacement and repair. Replacement involves exchanging the mitral valve for a biological (human or pig), biomechanical (combination of metal frame and biological, bovine tissue), or mechanical (pyrolytic carbon and titanium) equivalent. Repair leaves the original tissue in place as much as possible and restores it to a functional shape.
none of the fifteen annuloplasty rings of the test offered ideal performance. This is the reason why most patients after the operation still have complaints about their physical condition, albeit much less than before. Havlík: ‘I think the results of annuloplasty could be improved if the designers of annuloplasty rings were to have more specific knowledge about the forces acting on the valve ring so they could take these into account when considering the ring stiffness.’

ECC time
A major drawback of this method of reconstructing a heart valve is that it takes a while before the patient’s heart can start to pump blood again. The time during which a patient remains connected to the heart-lung machine, known as the extracorporeal circulation time (ecc time), can be as long as 2.5 to 3.5 hours. As the ecc time increases, so does the postoperative trauma, and consequently, the patient’s recovery time. One of the means available to reduce overall postoperative trauma of the patients is to use minimally invasive surgery. In cardiac surgery, minimally invasive means that the surgeon operates on a beating heart through a small access incision of about 5 x 5 centimetres, through which he has a direct view of the operation area. Endoscopic mitral valve reconstructive surgery does take place, but only on rare occasions and performed by a few excellent and leading edge surgeons. In minimally invasive mitral valve surgery, inserting an annuloplasty ring becomes an even more complex operation, according to Havlík. In the first place, the surgeon’s angle of view and freedom of movement are severely limited by the small access incision. In the second place, current surgical instruments only offer a limited number of degrees of freedom (see also the article, ‘Cutting around corners — Endo-periscope increases surgeon’s scope’ in the 2001.3 issue of Delft Outlook). The result is that the minimally invasive approach extends the time needed for the operation beyond the time required for classic open-heart surgery in which a much larger section of the thorax is opened, and so, paradoxically, aggravates the patient’s postoperative trauma.

‘It rather defeats the object of the approach’, Havlík says. Also, fixing the ring in place with 8 to 16 sutures is much more difficult using the minimally invasive approach. This increases the risk of the ring coming unstuck, with possibly fatal consequences. If the failure of the sutures does not prove fatal, a new operation will have to be carried out, which puts an extra burden on the patient.

Reinforcing band
By observing heart operations, and by talking to the surgeons (see text frame), Havlík gained insight into the problems the doctors face. These discussions also provided a basis for finding a way of using minimally invasive surgery to reinforce the mitral valve. Central to the solution was the concept that the surgeon would no longer have to insert and tie sutures along the valve’s

A weakened mitral valve opening can be repaired using an annuloplasty ring. The function of the ring is threefold: to reduce the size of the opening, to restore its shape, and to reinforce the valve edge in order to prevent further dilatation. The ring is attached to the valve edge with 8 to 16 sutures, which means tying a total of 96 to 128 knots.

\[ AD = (1.23 \div 1.40) \times AS \]

Havlík compared a non-stretchable annuloplasty ring (i.e. one that has a fixed circumference) with a healthy mitral valve. As a healthy mitral valve opens, it changes in shape from oval to round and stretches its circumference by 8 to 17 percent. It gains an increase in size of the aperture by 23 to 40 percent, allowing the blood to enter the ventricle freely and quickly. This is especially important during exercises. A non-stretchable annuloplasty ring of a current type attached to the muscles of the mitral valve prevents this increase in blood flow.

In order to determine the stiffness of the existing types of ring, Havlík tested each model on a tensile testing machine at the Czech Technical University in Prague.
Havlík came up with the idea of inserting the annuloplasty band into the muscle tissue itself, i.e. intramyocardially rather than attaching it to the surface of the heart muscle. This would leave the reinforcing band enclosed by the heart muscle along its entire length, with the great benefit that sutures will no longer be needed apart from the two stitches that attach the ends of the annuloplasty band to the muscle tissue. Not only would the operation be easier to perform, it is also much quicker, and it has the added advantage that the thorax no longer needs to be opened fully; the ring could be inserted through a small incision. To enable the annuloplasty band to be introduced in this way, Havlík designed a new instrument consisting of a hollow C-shaped needle and a reference ring. The annuloplasty band is loaded into the hollow C-tube, with a length of suture protruding from either end. By placing the reference ring over the mitral valve, the tip of the needle sits in exactly the right place to penetrate the heart muscle wall. Both rings, the C-tube as well as the reference ring, are attached to a shaft, the other end of which remains outside the body to be used as a handle. Rotating the assembly clockwise will push the sharp tip of the C-tube through the heart muscle in a circular channel around the valve. When the rotation is completed, the tip of the C-tube is detached to hold the annuloplasty band in position with the suture. The C-tube is then rotated anticlockwise to back it out of the puncture, leaving the band inside the heart muscle, where it can be secured with the two end sutures.

Beef tissue
One of the benefits of the technique developed by Havlík is that, instead of the rather rigid and non-stretchable annuloplasty bands, other implants could also be used to reinforce the mitral valve, including biological materials such as a band of pericardial tissue. The commercially available variant of this uses bovine tissue that has been made suitable for human use, but another option is to use the patient’s own tissue. The great advantage of such an implant is that it reduces the immune response of the patient, and that little or no anticoagulant has to be used. Another alternative is a silicone rubber band, or some other kind of elastic fabric or stent that is not immediately rejected by the human body. According to Havlík, materials like these could be better suited to meet the demands of the dynamics of the mitral valve as it opens and closes, which would improve a patient’s postoperative condition.

Test operations
The technique developed by Havlík, and the instruments that go with it, have been tested on animals. All the experimental operations were carried out by heart surgeons at the medical centres of Leiden University (lumc) and Utrecht University (umc). At Leiden University two experiments were performed in a so-called Langendorff set-up. The experiment involves removing the heart from the animal’s (pigs) body and

The tension tests showed that a force of 10 N is required to compress a rigid ring 1 mm; a semi rigid ring takes 1 N, whereas the forces required for flexible rings are marginal. As the graph shows, a 5 N pull on a rigid ring will only distend it by 0.5 mm. Semirigid rings will yield 2 to 5 mm with the same pull, and flexible rings 10 mm. Even so, all these rings serve the same function!
placing it in a special artificial circulation system in which the heart is kept alive and beating for three to four hours, pumping a physiological fluid around the system.

These experiments were successful. Next in Utrecht the new technique was also tried on pigs whose hearts were left in place inside their bodies. In order to investigate the rejection response of the heart muscle to the foreign material inserted into the myocardium, three survival tests were carried out on pigs at the LUMC. Small segments of existing annuloplasty bands (using two different materials) were implanted in the heart muscles in pigs for a period of three months. The results of these experiments are encouraging in that the technique works in principle, although there are still some practical problems. In the meantime, the faculty has applied for a patent on the invention. In a few months’ time Havlík hopes to gain his doctorate.

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The experiments on pigs were conducted by Havlík (second from right) at Leiden University Medical Centre (LUMC). The collaboration of engineers with surgeons and biotechnicians often led to new insights.
The third prototype of Havlik’s instrument. The reference ring has now been replaced by a reference disk. The disk is inserted in the mitral valve opening. This provides more stability and results in a higher accuracy of positioning the implant. To suit all anatomical dimensions, the instrument is available in three sizes. To the right of the instrument the implant is visible with the sutures used to pull the implant inside the tube.

Havlík’s surgical instrument used in the Langendorff set-up at the LUMC. The set-up allows operations to be performed on a beating, fully operational pig’s heart. The set-up is special in that the heart is kept supplied with oxygen-rich blood, as a result of which it will keep beating without any external stimulus for up to three or four hours. Instead of blood, a heart in this set-up pumps a transparent physiological solution, enabling the results of the experiment to be observed through a camera inside the heart.
Three months after Havlík fitted an implant to a pig’s heart muscle, the heart was removed. The analysis shows that the implant had settled well. According to the surgeons, the immune reaction to the foreign material was surprisingly small.