

medical devices

Hard graft

An engineer developed a life-changing implant after being diagnosed with a serious cardiac problem. Ellie Zolfagharifard reports

In 2000, Tal Golesworthy, a process engineer from Tewkesbury, was told that the aortic root in his heart had expanded to 4.8cm and was in danger of splitting. He had two choices; undergo surgery to insert a mechanical valve or risk a sudden and fatal heart attack.

The first option filled him with almost as much dread as the second. The surgery would mean that he would be placed on Warfarin, a blood-thinning drug that carries the risk of severe bleeding. 'That's not something I wanted to rely on for the rest of my life,' said Golesworthy. 'The thought of that dismayed me more so than the surgery.'

Golesworthy suffers from Marfan syndrome, an inherited disorder that affects the connective tissue of the body. It causes problems with many of the body's systems including the spine, joints and eyes. But its effects are most serious in the aorta, the main arterial conduit from the heart, which may dilate and ultimately rupture.

Around 12,000 people in the UK are said to have the condition. In many cases, if their aorta appears to be dilating too quickly, they are offered a procedure known as Bentall surgery. This takes around five hours and involves a heart-lung bypass. The damaged section of the artery is cut out and the aortic valve is removed and replaced with a graft and a mechanical valve.

But Golesworthy thought he could engineer a better solution. What excited him was the use of magnetic resonance imaging (MRI) and computer-aided design (CAD). He believed that by combining these technologies with rapid prototyping (RP) techniques he could manufacture a tailor-made support that would act as an internal bandage to keep his aorta in place.

The concept, he hoped, would reduce the risk of harmful clots forming due to the mechanical valve and importantly, eliminate the need to take Warfarin. Time was crucial and if Golesworthy was to save himself, he had to move fast to get the idea off the

ground. In 2001, he enlisted the help of Prof Tom Treasure, a cardiothoracic surgeon at Guy's Hospital, and Prof John Pepper, a surgeon from the Royal Brompton Hospital.

'It seemed to me to be pretty obvious that you could scan the heart structure, model it with a CAD routine, then use RP to create a former on which to manufacture a device,' explained Golesworthy. 'In a sense, conceptually, it was very simple to do. Actually engineering that was significantly more complex.'

The process of developing a scanning protocol proved to be difficult as the movement of the heart complicated the images and made their positions unclear. The engineers, working alongside medical radiographers, found that they had different perspectives. 'They wanted pictures that showed the structures in a way that their colleagues could understand. What we wanted were images with which we could take dimensions,' said Golesworthy.

By scanning the heart at the same point in the cardiac cycle, the team was able to mitigate some of the dimensional inaccuracies. Once acquired, the information was used in a CAD process that would convert the data into a life-size replica of the aorta. A number of RP

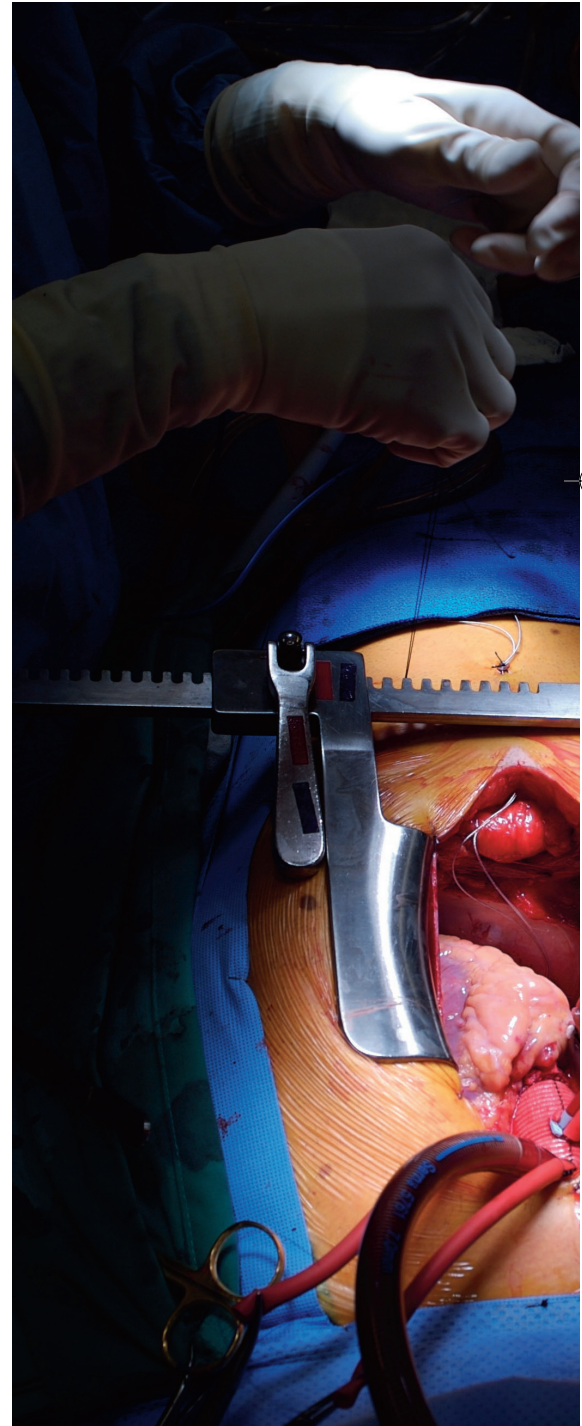
techniques were tested, including fuse deposition modelling and stereolithography, with the team finally opting for selected laser sintering (SLS).

'We realised fairly early that with RP we would not be able to produce the finished device, but that we should be able to produce a perfect 3D thermoplastic model of the aorta,' said Golesworthy. 'The challenge then was to find a way of producing what was almost always going to be a textile implant to fit this model.'

The team looked at a number of different processes, such as 3D embroidery, but ended up using a standard medical polymer, polyethylene terephthalate (PET), in a textile solution that allowed them to form a mesh directly onto the former. The mesh weighed

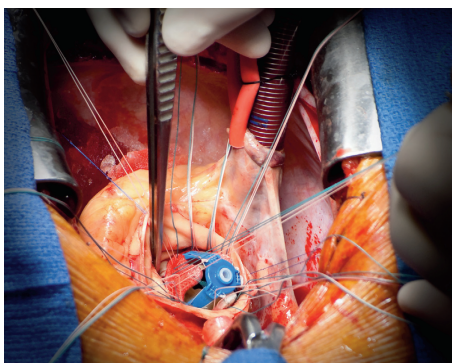
"We have changed the world for people with aortic dilation and we have done it on a fraction of the cost"

TAL GOLESWORTHY, EXSTENT



medical devices

Steady nerves: in the traditional technique of aortic valve replacement surgery, all surgical sutures that will be holding the valve are in place and the new aortic valve is lowered into the patient's aorta



back story first attempt

Early efforts at tailored aortic supports failed due to technology restrictions

Wrapping the aorta with artificial material isn't a new idea. More than 20 years ago, US surgeon Francis Robicsek attempted to fashion an external, hand-tailored support for the aorta. The proposal was made before the widespread use of CAD, MRI and RP. Materials such as polypropylene, nylon and knitted Dacron were proposed, with Dacron being the most popular. However, attempting to accurately recreate the shape of the aorta using material cut during surgery proved extremely difficult and the technique never caught on. Instead, off-the-shelf composite valve conduits were offered as a more realistic solution. 'Technology has allowed us to revisit the idea,' said Golesworthy. 'The aorta is such an extraordinary shape that you can't possibly do it by a "taking a yoghurt pot I prepared earlier"'. The only way was to bring scanning, CAD and RP together.'



Above: the team used rapid prototyping to produce a perfect 3D thermoplastic model of the aorta and then set about developing a textile implant to fit it

Left: open-heart surgery is highly complex. The Bentall procedure takes about five hours and involves cutting the damaged section of the artery and removing the aortic valve

less than 5g, was an exact fit for the ascending aorta and could be sutured into place by the surgeon. The process, from proposal to final product, took just under two years.

'My aorta was dilating all through that period,' said Golesworthy. 'When you've got the scalpel of Damocles hanging over your sternum, it motivates you into making things happen and so they do... to me it seemed like a ridiculously obvious solution. The only way to do this was with CAD and RP. It shouldn't have taken an engineer to realise that, but it did.'

Golesworthy believes that projects such as this demonstrate that the interface between engineers and the rest of the world isn't functioning in the way it should. 'When it does function, huge advances can be made in a very short time period, on very little money,' he said. 'We have changed the world for people with aortic dilation and we have done it on a fraction of the cost.'

In May 2004, Golesworthy became the first recipient of his own invention after undergoing surgery at the Royal Brompton Hospital. Since then, 23 patients have successfully had the implant fitted and another seven are hoping to undergo the procedure. According to Golesworthy, the technique will soon replace the Bentall procedure and could be used to treat other heart conditions.

Despite millions being poured into medical research, sometimes it just takes an engineer to see the solution

An implant is not the only option. One further area that could in the future prove beneficial to people with Marfan syndrome is tissue engineering. But Golesworthy is concerned that with tissue engineering, as with other areas in medicine, engineers are not getting as involved as they should be. He believes that the multi-disciplinary teams undertaking the research currently do not have the best skills base.

'They are all biologists and medics, and they need process engineers,' he said. 'To tissue engineer an aorta and ascending valve outside of the body you have got to mimic the conditions in which they would normally grow. You need a bioreactor extraordinaire and that, really, is process engineering.'

With funding constraints likely to impact on healthcare research, the ability of engineers to work alongside biologists and chemists in the future will prove crucial. As Golesworthy proved, despite the millions being poured into medical research, sometimes it just takes an engineer to see the solution in areas where others have been unable to.