## **DESIGN FOCUS**

When you are making a device to repair blood vessels, it has to be right first time

By Heath Reidy







The beat goes on: Rapid prototyping creates a model of the patient's aorta (top left). Polyester is wrapped around the model (top right), ready for implantation. The other images show body scans before and after the device was implanted in sporty inventor Golesworthy (above). His dilated aorta has been held in place ever since, allowing his heart to function as normal

perfect
xciting things can happen when

the engineering and medical worlds come together, as robotic surgery and radiation therapy have demonstrated. Operations that were once long and complicated have become quicker and more straightforward for the surgeon to carry out.

So what happens if these worlds collide, not from an engineering company deliberately working with the medical industry, but as a result of an engineer suffering from a serious genetic disorder?

Well, in the case of Tal Golesworthy, a process engineer with Marfan syndrome, you design a device that provides a simpler solution and lets you lead a normal life.

Marfan syndrome is a genetic condition that affects the body's connective tissues. The most serious symptom involves the aorta, the main artery that carries blood away from the heart, becoming dilated. This can lead to an aneurysm, a rupture and even heart failure.

Golesworthy's bespoke device is for people like him who suffer from a dilated aorta. The device, the External Aortic Root Support (Ears), is quite simply a piece of polyester that wraps around the aorta and

holds it in place to prevent dilation. But the key to the treatment being successful is in the way that Ears is designed to perfectly fit over the aorta. This involves the use of computer-aided design (CAD) and rapid prototyping (RP).

Golesworthy's idea for Ears came about when his aorta had dilated to such an extent that doctors told him that he would need a Bentall graft – the traditional preventive treatment for people with dilated aortas. If he didn't have the surgery, his condition could put him at risk of a fatal heart attack. But the long operation would leave him with an artificial graft replacement of his aortic valve, as well as a lifetime prescription for blood-thinning anticoagulant drugs. This would stop him

from doing active sports, such as his much-loved hobby mountain biking.

Golesworthy couldn't accept that this was the only option. So he started to look into ways that his aorta could be supported in a similar way to any other pipe, which would prevent it from expanding and mean that he wouldn't need to have the operation.

"The thought of anticoagulant therapy did switch me off," says Golesworthy. "I just thought there has to be a better solution.

"It's pretty obvious, really. If you have got a pipe that is getting a bit bigger you wrap some tape around it. Crudely, that's what you do, you externally support the pipe."

Several years later, Ears was born. The manufacturing process involves the patient

The medical profession should be embracing this as a step forward

being put through an MRI scanner to produce images of their aorta, which are used to make a 3D computer model using CAD. Once the surgeon checks that the model matches the scanned images, rapid prototyping is used to produce a thermoplastic polymer life-size model of the aorta. This involves feeding the CAD model into a Selective Laser Sintering machine, which uses a powder-based RP method to build up a model out of

thermoplastic polymer. Polyester fabric is then wrapped around the finished RP model and cut to size. The fabric is then washed, bagged and delivered to the hospital ready for implantation.

Golesworthy says that implanting the device into a patient is straightforward, involving a two-hour operation in which the polyester is stitched over the aorta. But it is the design and the process used to make Ears that makes this operation so simple for the surgeon. "It's presenting the surgeon with something he knows is going to be the perfect fit over the aorta before he even starts," he says.

Medical polyester was chosen for the device because it is flexible enough to wrap around the aorta, but strong enough to prevent the artery from expanding. CAD and RP are ideal for making bespoke devices, which is important because no two aortas are the same.

Since Golesworthy was implanted with the device in 2004, Ears has been successfully put into 19 other patients. He has also set up his own company, Exstent, to develop the device. He now aims to win approval to use the device on patients in the US.

"The medical profession should be embracing this and saying this is a really important step forward," he says. "I'm fixed, and I could just walk away from this. But now I find strangely I am committed to all these people whose lives I've changed."?