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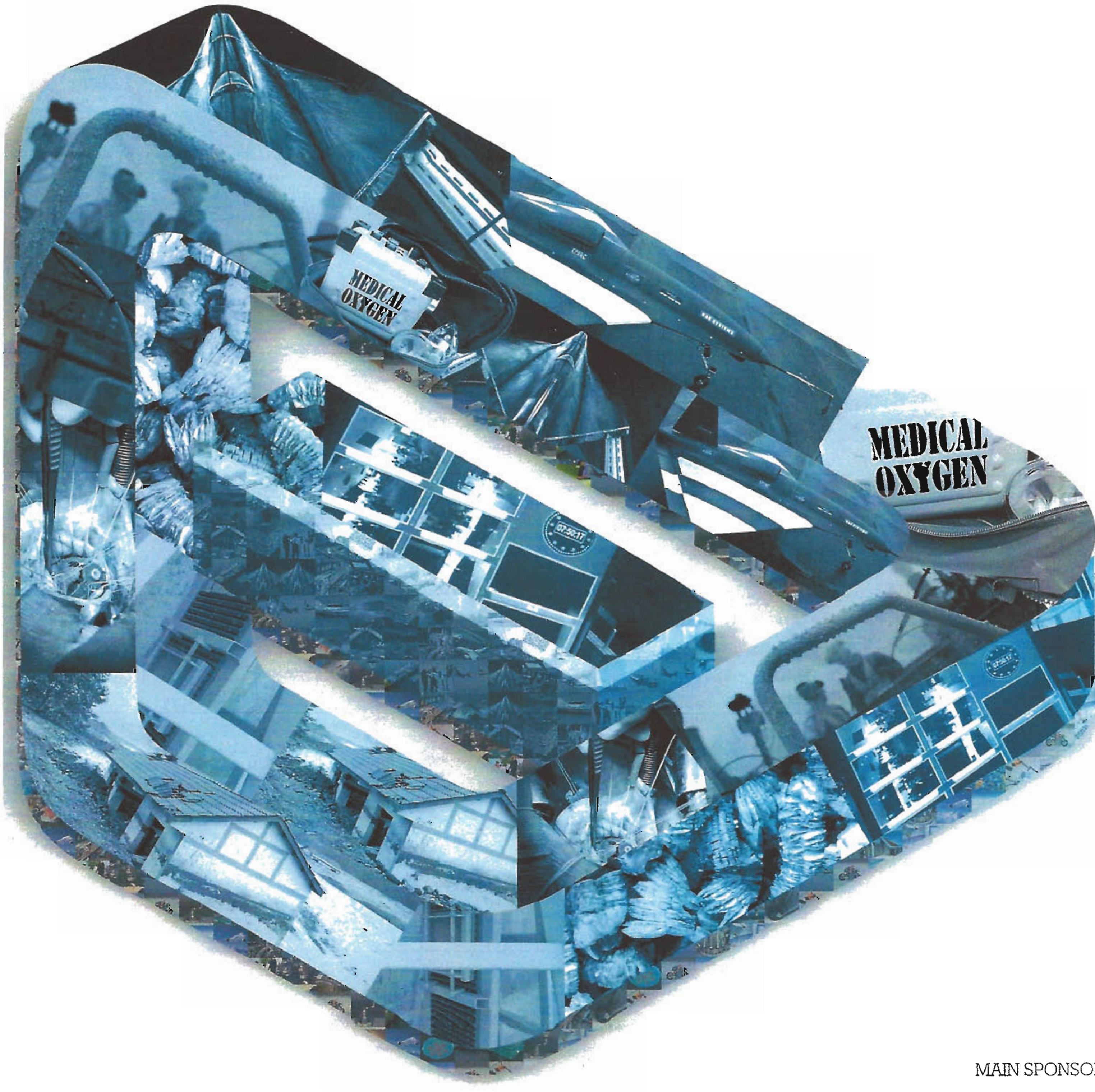

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Surgical spirit

Not content with existing treatments, Marfan Syndrome sufferer Tal Golesworthy built his own life-saving implant. Jon Excell reports

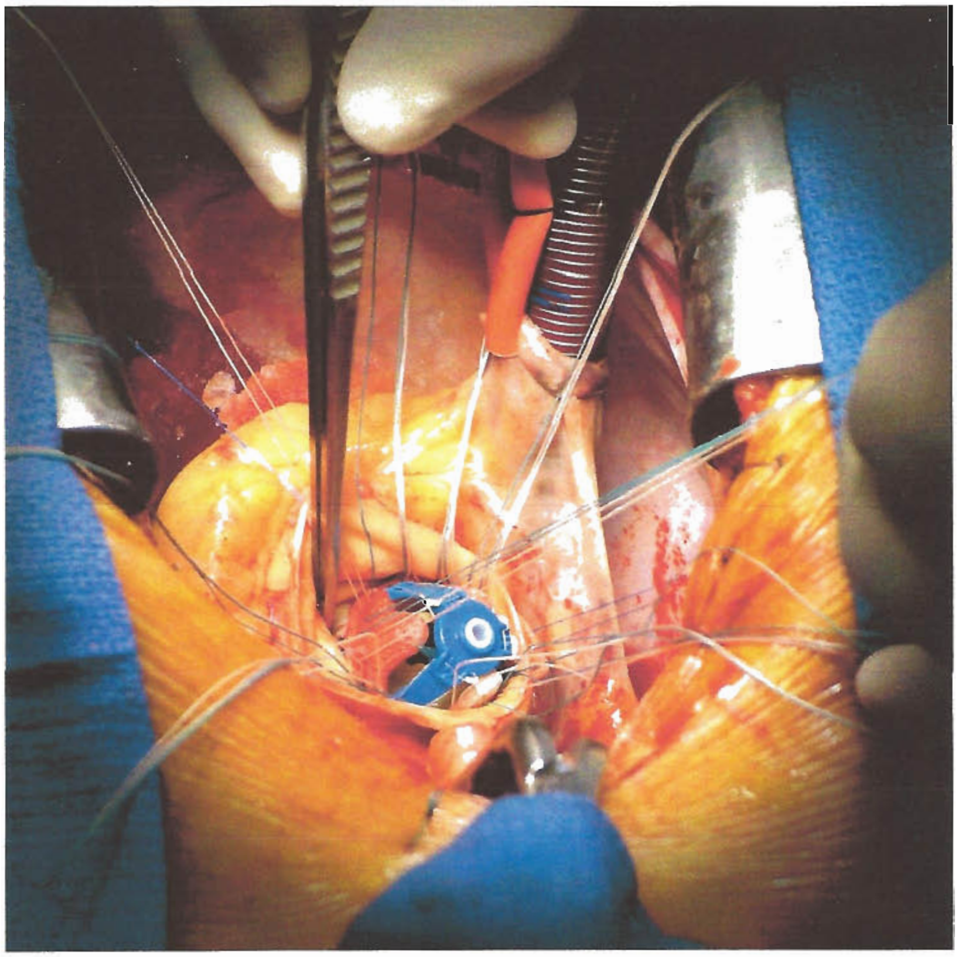
Like most clichés, the one about necessity being the mother of invention is often overused. But in the case of Tal Golesworthy, a process engineer who designed and developed his own life-saving implant and then commercialised the device through his own start-up company, it couldn't be more apt.

Golesworthy suffers from Marfan Syndrome, an inherited disorder affecting around 12,000 people in the UK that can cause the aorta, the main arterial conduit from the heart, to dilate and ultimately rupture. In 2000 he 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 traditional treatment for the condition — Bentall surgery — involves removing the damaged section of the valve and replacing it with a graft and a mechanical valve. The procedure takes around five hours, involves a heart-lung bypass and requires the patient to be placed on a life-long course of the blood-thinning drug Warfarin.

Not relishing this prospect and with his aorta progressively dilating, Golesworthy decided to take things into his own hands and set about developing 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 and, importantly, eliminate the need to take Warfarin.

On the surface, the idea was elegantly simple; Golesworthy planned on using a combination of Magnetic Resonance Imaging (MRI), Computer Aided Design (CAD) and Rapid Prototyping technology to scan the aorta, model it and produce a bespoke mold, or former. He would then use this former to manufacture a textile



Broken hearted: the support acts as an internal bandage to keep the aorta in place

> Golesworthy had two choices: undergo surgery to insert a mechanical valve or risk a fatal heart attack

external support that would be fitted around his aorta.

However, to bring the idea to life required close collaboration between engineers and scientists from completely different disciplines and with different areas of expertise.

After raising enough capital to start his firm, Exstent, Golesworthy drew on the expertise of a series of medical specialists to take the device to the next level. Most notably, Prof Tom Treasure of St George's hospital brought his experience of cardiothoracic surgery to the project, while Prof Raad Mohiaddin from the Royal Brompton Hospital introduced the engineering team to the possibilities of Magnetic Resonance Imaging (MRI). Meanwhile, Imperial Colleges' Warren Thornton wrote an entirely bespoke piece of CAD code to manage the peculiar problems associated with modelling from a moving structure within the body via MRI. Finally, Prof John Pepper from the Royal Brompton Hospital carried out the surgery — a world first.

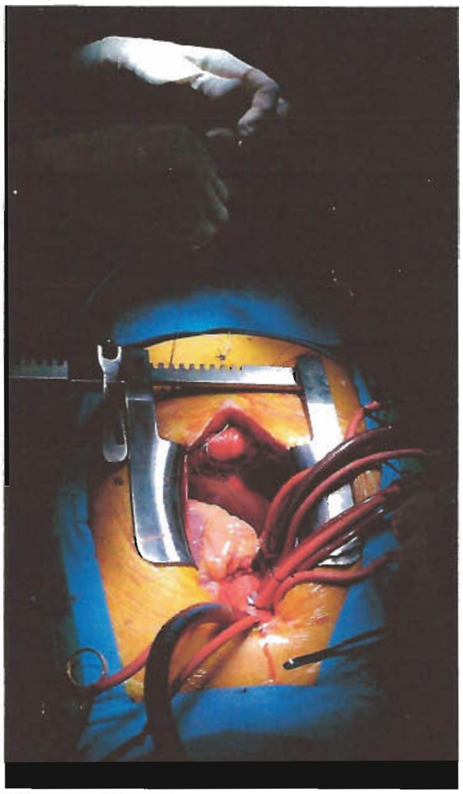
Hailing the level of collaboration in the project, Golesworthy said: 'To bring fairly disparate engineering techniques together (CAD, RP and textile technology) and integrate them with medical scanning (MRI and CT) is novel. For engineers to work with medical radiographers to produce a scanning protocol that will integrate with an engineering CAD process may be known for static structures — for example, hip joints — but not for moving structures such as the heart. The MRI scanning protocol and CAD routine were in themselves iterative development processes within the project.'

"EARS offers a less intrusive operation and allows the surgeon to work on a beating heart"

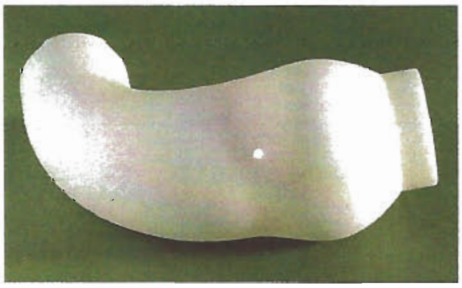
TAL GOLESWORTHY, EARS INVENTOR

According to Golesworthy, one of the chief challenges was developing a scanning protocol 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 that we could take dimensions from,' said Golesworthy.

By scanning the heart at the same point in the cardiac cycle, the team was able to mitigate some 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).



Change of heart: **Bentall surgery involves replacing the valve with a mechanical one**



Model solution: **CAD was used to convert data into a life-size replica of the aorta**

'We realised 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.'

The team looked at a number of 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 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 slightly less than two years.

Since Golesworthy became the first recipient of the so-called ExoVasc implant in 2004, a further 27 patients have benefited from the treatment and Golesworthy is confident that it could go on to have a major impact.

'External Aortic Root Support (EARS) offers a significantly less intrusive operation with no cardiopulmonary bypass (CPB) or body cooling and allows the surgeon to work on a beating heart,' he said. 'The EARS procedure can be carried out in two hours, whereas a Bentall graft or valve-sparing surgery typically takes six to eight hours. EARS patients are spared the lifetime of anti-coagulant therapy associated with the conventional Bentall operation.'

runners-up

The other shortlisted candidates in this category were:

» SMARTNAIL [HIGHLY COMMENDED]

Smith & Nephew, University College London, Royal National Orthopaedic Hospital, Polymer Systems Technology, ParaTech, Rutleford Appleton Laboratory, Printech Circuit Laboratories, Isotron, Strain Measurement Devices, Thorne Engineering, Wildcroft Computer Systems

Developed by a cross-disciplinary team of engineers and orthopaedic specialists, Smartnail is an advanced intramedullary (IM) nail for treating bone fractures. Bristling with embedded sensors and processors, the device is able to measure the stresses and strains on an injured bone and provides clinicians with detailed information on the healing process. It is claimed that the technology could help to change the way clinicians and surgeons interact with the body and grab a big share of the global IM nail market.

» NEUROCHIP

Leicester University, Imperial College, Newcastle University

Wearable systems that could one day enable paralysed patients to move parts of their bodies is a major focus of research in the medical sector. Until now, so-called brain machine interface (BMI) technology has relied on connecting intracortical electrodes to external amplifiers via wires passing through the skin, breaching the body's natural barrier to bacterial infections. The UK-developed Neurochip, a low-power implantable chip that monitors and wirelessly transmits the activity of brain neurons, represents a major step forward for this inspiring area of technology development.