TO THE HEART OF THE MATTER —

CRDM EMPLOYS RAPID MANUFACTURING FOR A CARDIO VASCULAR IMPLANT

This case study is an example of advances in technology offering a new solution to an existing medical problem. Tal Golesworthy, Founder and Technical Director at Exstent, is uniquely positioned to give his account of the development of the device — after all it was his design, and he was the first ever recipient!

Tal Golesworthy

is a Chartered Engineer with 33 years' R&D experience in industrial combustion, air pollution control and process chemistry. With a background in chemistry and electronics and 20 years with British Coal, at the Coal research Establishment, Tal is Member of the Energy Institute and the Royal Society of Chemistry.

Marfan Syndrome is an inherited disorder of the body's structural tissues due to a deficiency in fibrillin: a structural protein fibre. This has widespread effects, most notable in the spine, joints and eyes, but its consequences are most serious in the aorta, the main arterial conduit from the heart, which may dilate and ultimately rupture.

The ascending aorta is a tube about 3 cm in diameter which carries blood at about 5 litres per minute from the heart to be distributed through a branching system of arteries. At its junction with the heart it contains the non-return, aortic valve which governs the blood flow out of the main pumping chamber, the left ventricle. In Marfan Syndrome, the ascending aorta progressively dilates over years. As a result, the valve malfunctions and the aorta itself may ultimately split and rupture. This failure is lethal.

Current medical practice is to track aortic dilation until such time as the risk of rupture is deemed high enough to justify surgical replacement of the ascending aorta and aortic valve with a manufactured tube and valve graft (Composite Aortic Root Graft). This is major surgery, and if the valve is replaced with a man-made, artificial valve, patients are committed to life-long anti-coagulation therapy, itself a serious risk.

THE EXTERNAL AORTIC ROOT SUPPORT (EARS) PROJECT

Tal Golesworthy has known about his Marfan Syndrome since childhood when classical Marfan Syndrome ocular defects were indentified in him mimicking those in his father, from whom he had inherited the disorder. After volunteering for a genetic study in people with Marfan syndrome being run at St Georges hospital in London in 1992, Tal learned that his ascending aorta was dilating. Annual measurements of the aorta indicated a steady increase in diameter from about 4.4 cm in 1992 to about 5 cm in 2002.

Unhappy with the existing surgical options, Tal decided to evaluate alternatives. Aware of medical imaging with Magnetic Resonance Imaging (MRI) and X-ray based Computer Tomography (CT), and from his R&D activities, Computer Aided Design (CAD) and Rapid Prototyping (RP), Tal put together a project proposal to use medical images, CAD and RP to manufacture a bespoke external support for the ascending aorta. The External Aortic Root Support (EARS) project was born. Put simply: if the pipe is only weak in tensile strength in its wall, why not simply externally support it with a bespoke sleeve in a suitable material?

Professor Tom Treasure, a cardiothoracic Surgeon at Guys Hospital, was enlisted into the project, shortly followed by Professor John Pepper, another cardiothoracic surgeon from the Royal Brompton Hospital. A fully costed R&D proposal was worked up and Imperial College was contracted in to assist with the CAD work.

Tal started a company to sponsor the EARS project and raised sufficient capital from private investors to run the feasibility project.

THE EARS IMPLANT AND ITS MANUFACTURE

Existing medical MRI was used to acquire suitable images and an image acquisition protocol was developed with the MR unit at the Royal Brompton Hospital. A CAD routine was then developed to process the MR images and reproduce a bespoke CAD model of the aorta: every aorta is different.

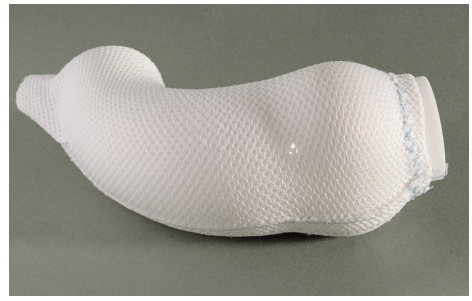
With the imaging and CAD functions in place, Rapid Prototyping/Rapid Manufacturing was investigated. Tal had worked with the Rapid Manufacturing centre at Exeter university so was familiar with some of the techniques available. Various RP/RM methods were investigated including Fused Deposition Modelling (FDM) and Stereo Lithography (SLA) before Selective Laser Sintering (SLS) was settled on.

The combination of medical imaging, CAD and RP technologies allows the production of one-off patient specific manufacturing formers in a short time frame. This technology fusion is critical to the EARS project's practical and financial viability.

CRDM'S INVOLVEMENT

With the manufacturing process in place, it was then necessary to identify a partner with commercial RP/RM facilities. CRDM was well known to Imperial College so was the obvious choice for conversion of the CAD stl files into solid polymeric formers for manufacture of the EARS implants. CRDM was briefed on the EARS project and assisted in various aspects of the RP/RM process.

Material selection was an important consideration for the manufacturing former as this, with the textile EARS implant formed on it, which has to be able to withstand the various solvent cleaning and sterilisation steps necessary before the implant can be fitted to a patient.



MAIN IMAGE: EARS SLS former with textile implant

Each former is unique to each patient and has to be uniquely identifiable. CRDM was actively involved in solving this particular problem which required an alphanumeric recessed text on a non-morphologically sensitive part of the former.

After manufacture of the former, the former is taken into a cleanroom environment where it is solvent-washed and dried before the textile EARS implant is formed onto it. The assembly is then packaged and sterilised before being delivered to the surgeon. The EARS implant on its former can thus be easily oriented with the patient's ascending aorta prior to the implant being removed from the former and sutured in place around the ascending aorta.

The feasibility of the EARS project was initially proven when Tal Golesworthy was the recipient of the first EARS implant on 24 May 2004 at the Royal Brompton Hospital under the care of Professor John Pepper. Since then another 19 patients have been successfully treated.

CRDM has manufactured all the EARS formers to date and continues to offer a professional service to Exstent Ltd.

FUTURE DEVELOPMENTS

Medical device manufacture being what it is, the current manufacturing procedure will remain unchanged until the project reaches 50 patients. Thereafter the entire manufacturing process will be reviewed: the imaging protocol and method, CAD routine, and RP/RM method.

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