Personalised External Aortic Root Support: an Engineering Perspective

Artykuł recenzowany

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Summary

Personalised External Aortic Root Support (PEARS) surgery is now an established surgical approach in the management of aortic dilation in patients with Marfan Syndrome and related congenital conditions in which there is asymptomatic dilation of the aortic root/ascending aorta [1, 2, 3, 4, 5]. In establishing this new surgical approach, a number of engineering issues were successfully addressed by a multidisciplinary team combining surgeons, radiologists and engineers. This paper discusses some of the principal engineering challenges facing the team at the feasibility stage of the project.

Introduction

Dilation of the proximal aorta is common in several congenital conditions including Marfan Syndrome, Loeys-Dietz Syndrome and Ehlers Danloss Syndrome [6]. Existing surgical options involve the removal of the aortic root (including the sinuses and aortic valve and the proximal section of the ascending aorta to a point close to the proximal side of the Brachiocephalic root) and replacement with a textile tube graft with, either the patient's own aortic valve leaflets re-implanted (Valve Sparing Root Replacement-VSRR), or with a mechanical valve (Total Root Replacement- TRR) [7]. To carry out these existing surgeries the patient must endure the risks associated with Cardio Pulmonary Bypass (CPB) as well as total body cooling and cardiac arrest. Post surgery, TRR mandates life-long anti coagulation therapy, normally with Warfarin, and VSRR incurs a relatively high re-operation rate. It was these imperfections with existing surgical options that motivated the author to conceive of, lead the development of Personalised External Aortic Root Support (PEARS) [8] and volunteer to be the first recipient of an ExoVasc implant. This paper discusses some of the engineering problems that required solution in realising PEARS as a surgical reality.

Imaging the aorta

The first decision to be made, early in the PEARS project, was which image acquisition system was to be used for the feasibility period of the project. Then, as now, the choice was essentially between Magnetic Resonance Imaging (MRI) and X-ray Computer Tomography (CT). Both systems use Computer Aided Tomography to process and present the anatomical images, but MRI uses Nuclear Magnetic Resonance (with Radio Frequency irradiation of the patient) to acquire the images where CT uses X-ray transmission through the patient.

As image resolution for MRI and CT was similar when the PEARS project began, and knowing that some considerable time was going to be required in developing a scanning protocol for PEARS, it was decided that MRI would be the safer option. In the event some 30 patient hours were spent in the CAMRIC CMRI scanner at the Royal Brompton Hospital by the author before an appropriate scanning protocol was finalised [9].

Given that the aortic root/ascending aorta itself is a fairly large structure: typically about 35mm diameter and 100 mm long, the critical imaging resolution was related to the coronary arteries that emerge from the aortic root. Coronary dimensions range widely from about 3mm outside diameter(OD) to about 7 mm OD. Correctly identifying and placing these structures on the aortic model is a critical function as it ensures that the finished implant will not impose pressure on the coronary arteries and compromise coronary blood flow, and it informs the surgeon as to the position of the coronary arteries on the aortic root; a critical step in ensuring the safe mobilisation of the left coronary artery (LCA) prior to implantation of the ExoVasc device. These considerations required a scanner resolution/voxel size (a 3 dimensional pixel also known as a voxel) with at least one scanning plane giving 1-2 mm resolution. This was met during the feasibility stage of PEARS but is now typically exceeded with most industry standard CT scanners in Europe offering a 1 mm x 1 mm x 1 mm (or better) voxel size/scanning resolution.

Scanner resolution aside, the challenges faced in developing the scanning protocol revolved around 2 key areas:

Anatomical movement: – This is a problem facing all cardiac image acquisition for whatever purpose: the heart constantly moves within the pericardium and chest. This can lead to movement artefact in the finished images which can conceal/distort important anatomical/morphological information. Then, as now, cardiac gating was used extensively to acquire image data at the same point in the cardiac cycle, thus eliminating any differences between anatomical shape or dimension between Diastole and Systole, and reducing cardiac movement (and hence movement artefact in the finished images). For PEARS image acquisition, cardiac gating in Ventricular Diastole was settled upon as the most appropriate phase to collect images of the aorta at its "rest" diameter with the aorta relaxed.

Even when cardiac phase corrections are made, there is still potential for a mis-registration of adjacent cardiac images due to breathing movement of the subject. Thus breath-holding was also used in attempts to maximise image quality and minimise movement-artefact in the images acquired and hence a better registration of the entire image set.

Professional perspectives: – through the process of developing the scanning protocol, it became increasingly obvious that the engineers were failing in their attempts to explain to the radiologists exactly what was being attempted and exactly what was required in terms of the images acquired and their orientation with respect to the patient. In part, this was because the protocol itself was developing so the engineers were constantly having to change their approach and requirements as the limitations of the acquisition process became apparent. The engineers may well have considered that the professional shortcomings were those of the Radiologists but the truth is probably that the two parties have such different perspectives and expectations of the process that it was difficult for both parties to have a unified understanding of what was required. This difficulty in communication prolonged the process of developing the initial scanning protocol.

Subsequent to the feasibility stage of the PEARS project, developments in scanner technology allowed "off-line" image processing that does not require the patient to be in the scanner while anatomically orientated images are acquired. Thus engineers are now able to re-sample the "standard" 3D image sets acquired by radiologists using conventional cardiac gating and breath-holding CT protocols. This both simplifies the process of collecting anatomically orientated images and reduces stress on the patient.

Computer Aided Design (CAD) Modelling of the Aorta

A number of approaches to the conversion of medical images of the aorta into CAD form were investigated. Given the scanning software available at the time and its limitations, simple stacking of tomographic slices to form a CAD file was possible but produced an unacceptable CAD model (Figure 1).

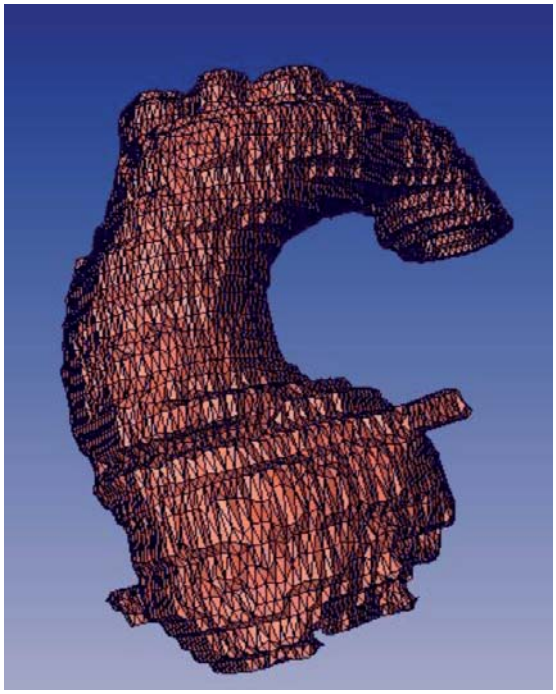

Figure 1. Early slice-stacked CAD model of the ascending aorta

The scanner workstation available to the PEARS team in 2001 had a limited functionality (compared with current scanners) and so the scanning protocol and CAD approach moved together iteratively as limitations in both CAD routines available and the scanner workstation functionality were accommodated. The result was a bespoke CAD code that relied on anatomically orientated imaging planes to reconstruct the aorta in CAD. This approach has proved remarkably resilient as it is still used in 2016 with only minor revisions to date despite the appearance on the market of "image to CAD" software packages such as the Mimics® suite from Materialise NV. The reconstruction software produces a CAD model that is more than fit for purpose (Figure 2).

Figure 2. Reconstructed CAD model of a Marfanoid Aorta

Physical Modelling of the Aorta

The physical modelling of the aorta, in order to produce a manufacturing former for the finished (textile) implant, simply required the CAD model of the aorta to be converted via additive manufacture. Better known as "Rapid Prototyping" (RP) back in 2001, Additive Manufacture has developed at an increasing pace such that "RP" is now Rapid Manufacture, and better known as "3D Printing" [10]. A number of different RP techniques were tried during the feasibility period of PEARS:

Fused Deposition Modelling (FDM): – easy to access, fairly fast and cheap, but, at that time, offering rather poor resolution and rough surface-finish. The machine to which we had access was also limited in the number of thermo-plastic polymers it could process.

Stereolithography (SLA): – requires a more specialist machine, which is less easy to use, slow and not particularly cheap, but produces very good resolution and a very smooth surface finish.

As the various steps in the manufacturing processes were developed in parallel, it became clear that the manufacturing former was going to have to remain with the implant right up to the operating room. This meant the former had to be able to withstand the steam sterilisation process that the ExoVasc® would have to go through before it could be safely implanted in a patient. This fact then constrained former material and RP technique.

Selective Laser Sintering (SLS): – like SLA requires a specialist machine but is able to use a wide range of thermoplastics, with a resolution/slice thickness of 100µm and with a surface finish that offers sufficient surface friction to retain the textile implant during the manufacturing processes while it conforms to the former's shape.

SLS became the RP method of choice and, when combined with a medium temperature Nylon, rugged formers can be manufactured easily and quickly with good mechanical and thermal durability allowing them to manage the manufacture and sterilisation processes.

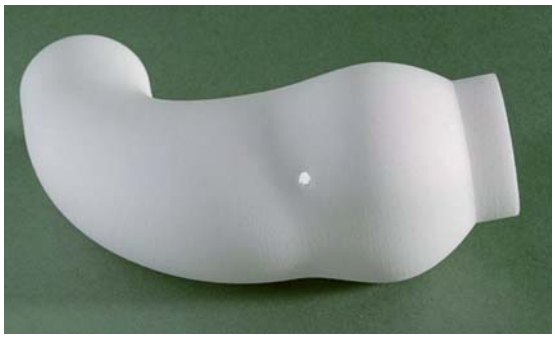

Figure 3. SLS aortic former for PEARS manufacture

Manufacturing the Surgical Implant

The implant manufacturing process ran in parallel with the former manufacturing development as time was of the essence. 3 different manufacturing approaches were run concurrently until a clear leader took over.

The first method involved 2 dimensional automated embroidery onto a soluble transparent polymer sheet. When the embroidery is complete, the polymer sheet is dissolved away leaving a planar textile structure that will form and lock into the required 3 dimensional structure when formed over an appropriate morphological former produced from the patient's aorta. This was investigated with a specialist contractor though results were inconclusive as to the technical viability of this approach for the PEARS device.

The second approach was to produce a physical model from patient images and CAD that was pro-

duced with small pores through its wall that would allow the vacuum formation of a free-fibre textile (from a fibre/liquid suspension) conforming to the morphology of the aorta. While this was practical, the pre-eminence of the chosen manufacturing route caused us to stop work on it

Figure 4. Porous former for vacuum formation of fibre-based implant.

The third, and ultimately self-selecting manufacturing method of choice was to produce a knitted textile in PolyEthyleneTeraphthalate (PET) and heat-form it onto the aortic former. This produces a high degree of repeatability and remains the manufacturing process that has been used for all PEARS patients to date. All the manufacturing is carried out in a clean room required to comply with ISO 14644-1 class 7 but which actually complies with ISO class 4.

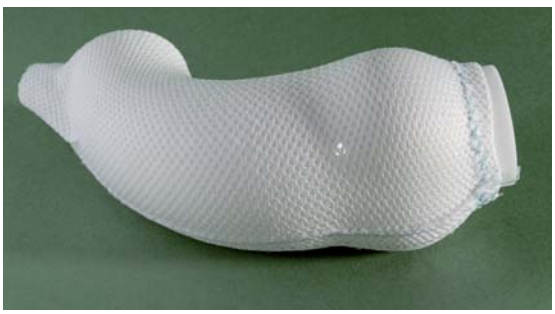

Figure 5. ExoVasc® textile implant on manufacturing former

Conclusions

A range of engineering challenges were presented to the PEARS team through the feasibility phase of the project, all of which were satisfactorily resolved. The development and production of the bespoke ExoVasc® implant was required to be "fit for purpose" in terms of anatomical conformity, bio compatibility, sterility and implantability and which is capable of being handled and implanted by conventional surgery. While the engineers in the team may have aspired to a "perfect" implant, this was never going to be achieved, but neither was it going to be required. The clinical results speak for themselves and the engineers "fit for purpose" requirement may echo the cardiac surgeons' "perfect is the enemy of good" motto for free hand surgical interventions.

Clinical Results

The first PEARS surgery was carried out in 2004 by John Pepper at the Royal Brompton Hospital, London. To date surgery has been completed on 66 patients with a collective total of 271 post operative patient years (as of March 2016). 7 patients have >10 years follow-up, and 24 patients have >5 years follow-up.

PEARS surgery has been used to halt aortic dilation in patients with: Marfan Syndrome, Loeys-Dietz Syndrome, Bicuspid Aortic Valve Disease, Transposition of the Great Arteries (post Aortic Switch Surgery), Tetralogy of Fallot and non-specified familial dilation, and used to prevent dilation of the Pulmonary Autograft in patients undergoing the Ross procedure.

Acknowledgments

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