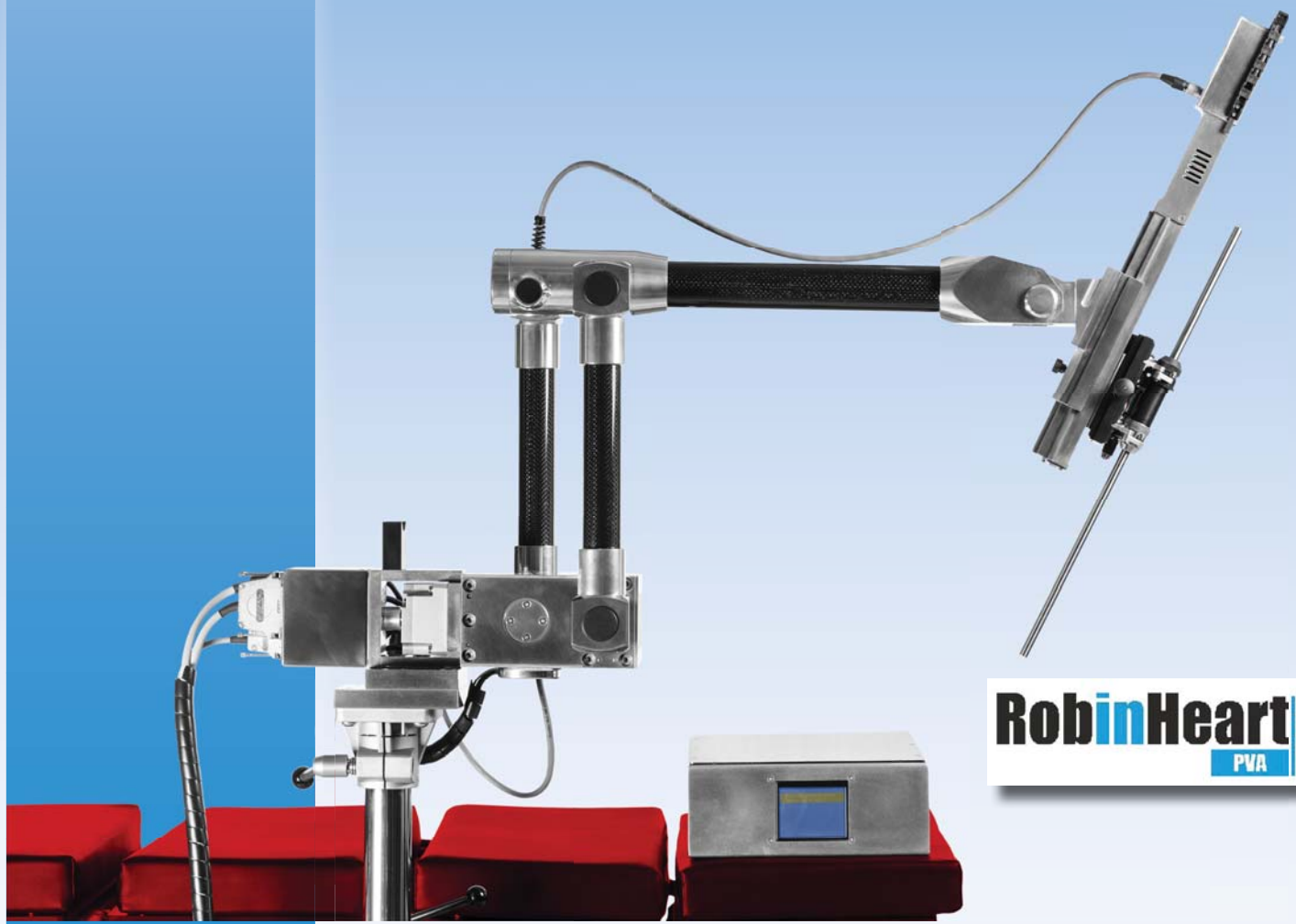
Volume 4 December 2015 ISSN 2299-7407

Medical Robotics Reports

www.medicalroboticsreports.com



- Novel Robotic System for Remote Ultrasonography
- Robin Heart force feedback/control system
- Personalised External Aortic Root Support
- Interfejs użytkownika robota

Official Journal of ISMR

International Society for Medical Robotics

Dear Reader,

Medical robots are paving the way by offering new standards and diagnostics, rehabilitation and therapy opportunities. Surgical telemanipulators are sometimes simply the only chance for many patients to carry out the operation in an extremely precise and safe methods. Today the market is dominated by one American company. Lack of competition has caused an unjustified increase in the cost of the offered apparatus and its maintenance. The successes achieved, including more than 500 thousand operations a year, convinced of the effectiveness of the use of robots in surgery. It protects only 10% of demand. The robots shall be applied for at least 6 million patients undergoing a minimally invasive surgery a year as it is beneficial for the patient and the health care system (a shorter hospital stay, less postoperative complications).

The interest in robots is increasing – with big money and big market players like Google, Ethicon and Johnson & Johnson – better and better robots are appearing. Boston Dynamics BigDog-a military transport robot turned in just a year in the two-legged Atlas – a humanoid robot with unprecedented autonomy and behavior in a changing environment. We can symbolically say that in 2015 robots got up from their knees! Time of entrance of non-military applications, less special but more household ones is close, the result is a foregone conclusion – do give cope.

Market of surgical robot has revived. The monopoly in the field of robotic surgery has been clearly unlocked.

There has appeared a rival ALF-X which is going to fill a gap in the field of robotics, the cost of which will not exceed $ 1 million. This year there are going to be held the first clinical trials of a Canadian robot to operate through one port Titan – SPORT (Single Port Orifice Robotic Technology) – so we keep our fingers crossed for the competition: US company Transenterix in coalition with the Italian SOFAR and Canadian Titan Medical. Besides, we have to admit honestly that progress of Intuitive Surgical arouses admiration and respect – the new da Vinci Xi, the new console, new tools and systems for individual ports largely correspond to the needs reported by surgeons.

Challenges: there is still open an issue of the search for practical and economically viable areas of clinical use and optimization of design solutions. Robots do not have the right sensor technology, they are difficult and expensive to operate. The problem of force feedback and flexible tools– variable rigidity – has not been solved efficiently yet. It will increase significantly the number of beneficiaries of these robotic systems.

Polish robot: the Robin Heart prepared for implementation has a potential to bring a lot of innovative techniques of minimally invasive surgery which are expected by surgeons. The experimental studies conducted on animals and teleoperation attempts proved the effectiveness of developed devices and the accuracy of applied mechatronic solutions. Surgical robots are a chance to introduce new standards of service and surgical assistance for difficult patients to whom current methods are not safe or effective.

Thanks to our experience Poland can be at the forefront of countries producing medical robots. And there is something to fight for because the market of robots used in surgery grew/ has been growing from $ 3.2 billion in 2014 and will grow to expected 20 billion in 2021r. Robin Heart is expected by doctors and their patients. It is also a chance for our high-tech industry.

I kindly **invite you** to read the new MRR! In it, among other things, the article of outstanding inventor: Tal Galsworthy has developed an innovative technology of an external aortic stent which saved his life (the invention he first tried on himself) and many others. It is a great inspiration for us who are trying to make robots for medical applications. Since the genesis of the robot is related to human, creating devices similar to humans or replacing them. Also the „spare parts", for example artificial organs, are the part of medical robotics.

To others interested in what a domestic robot should be like I recommend the report on the survey conducted by the students of Medical University of Silesia. Full survey is available on our website – you can download and distribute. We look forward to the collected data, further results will be based on a larger group of patients.

With the ISMR Academy this time we offer a lecture given by a philosopher of ethics at the University of Silesia dr. Mariusz Wojewoda.

Among the proposed papers you will find the reports on haptic devices (interfaces) used to control telemanipulators (and not only), the progress of the team working on the introduction of haptic system for Robin Heart robots, exoskeleton project of elbow, innovation in rehabilitation and endoscopy diagnostic and also studies on medical robots market in the world and ... in China. There is, of course, our report from the conference Medical Robots 2015.

Let the robots be with us! Let them be more efficient and useful for humans!

Therefore, I believe we will meet in early December in Zabrze at the next specialist Medical Robots 2016 conference, but for now I invite you to reading...

Zbigniew Nawrat
President ISMR
Editor of Medical Robotics Reports
Zabrze, December, 2015

Drogi Czytelniku,

Roboty medyczne torują sobie drogę oferując nowe standardy i możliwości diagnostyki, rehabilitacji i terapii. Telemanipulatory chirurgiczne to po prostu czasem jedyna szansa dla wielu pacjentów na przeprowadzenie operacji w sposób niezwykle precyzyjny i bezpieczny. Dzisiaj rynek zdominowany jest przez jedną, amerykańską firmę. Brak konkurencji spowodował nieuzasadniony wzrost kosztów oferowanej aparatury i jej serwisowania. Osiągnięte sukcesy, w tym ponad 500 tys. operacji rocznie, przekonały o skuteczności stosowania robotów w chirurgii. To zabezpiecza tylko 10% zapotrzebowania. Roboty powinny być stosowane co najmniej dla 6 mln pacjentów chirurgii małoinwazyjnej rocznie – bo to korzystne dla pacjenta i systemu opieki medycznej (krótszy czas hospitalizacji, mniej komplikacji pooperacyjnych).

Zainteresowanie robotami rośnie – za wielkimi pieniędzmi wielkich graczy rynkowych jak Google, Ethicon czy Johnson & Johnson – pojawiają się już coraz lepsze roboty. Pies transportowy Boston Dynamics zamienił się w ciągu zaledwie roku w dwunożnego Atlasa – robota o niespotykanej do tej pory autonomii i zachowaniu w zmiennym środowisku. Można by symbolicznie powiedzieć, że w 2015 roboty wstały z kolan! Czas pojawienia się aplikacji mniej wojskowych i specjalnych a bardziej domowych jest już blisko, wynik jest przesądzony – **roboty dadzą sobie radę.**

Rynek robotów chirurgicznych się ożywił. Ruszyło wyraźnie w sprawie odblokowania monopolu w zakresie robotów chirurgicznych.

Pojawił się rywal ALF-X który zamierza wypełnić lukę w zakresie robotów, których koszt nie przekroczy 1 mln dolarów. W tym roku mają odbyć się pierwsze próby kliniczne kanadyjskiego robota do operowania przez jeden otwór Titan – SPORT (Single Port Orifice Robotic Technology) – trzymamy, więc kciuki za konkurencję: firmę amerykańską Transenterix w koalicji z włoskim SOFAR oraz kanadyjskiego Titan Medical. Zresztą uczciwie trzeba przyznać że postępy Intuitive Surgical wzbudzają szacunek – nowy da Vinci Xi, nowa konsola, nowe narzędzia i systemy do pojedynczych portów w znacznej mierze odpowiadają na potrzeby zgłaszane przez chirurgów.

Wyzwania: ciągle otwarte jest zagadnienie poszukiwania praktycznie i ekonomicznie uzasadnionych obszarów klinicznego stosowania i optymalizacja rozwiązań konstrukcyjnych. Roboty nie posiadają właściwej sensoryki, są trudne i drogie w eksploatacji. Nie rozwiązano do tej pory problemu efektywnie sprzężenia siłowego i elastycznych narzędzi – zmiennej sztywności – co jeszcze powiększy znacznie liczbę beneficjentów tych systemów robotycznych.

Polski robot: przygotowywany do wdrożenia Robin Heart ma szanse wnieść wiele oczekiwanych przez chirurgów innowacji do techniki prowadzenia operacji mało inwazyjnych. Przeprowadzone badania eksperymentalne na zwierzętach i próby teleoperacji dowiodły skuteczności działania opracowanych urządzeń i słuszności przyjętych rozwiązań mechatronicznych. Roboty chirurgiczne stanowią szansę na wprowadzenie nowych standardów i oferowanie pomocy chirurgicznej pacjentom trudnym, dla których obecnie stosowane metody nie są bezpieczne i wydajne. Dzięki naszym doświadczeniom Polska może być w czołówce krajów produkujących roboty medyczne. A jest o co walczyć bo rynek robotów stosowanych w chirurgii rośnie od 3,2 mld dolarów w 2014 i będzie rósł do, jak się spodziewamy, 20 miliardów w 2021 r. Robin Heart'a oczekują lekarze i ich pacjenci. To też szansa dla naszego przemysłu wysokich technologii.

Zapraszam do lektury nowego MrR! W nim między innymi artykuł znakomitego wynalazcy: Tal Galsworthy opracował innowacyjną technologię zewnętrznego stentu aortalnego – uratował życie sobie (wynalazek wypróbował najpierw na sobie) i wielu innym. Świetna inspiracja dla nas, którzy próbujemy wprowadzić roboty do zastosowań medycznych. Skoro geneza robota jest związana z człowiekiem, tworzeniem urządzeń podobnych do człowieka lub go zastępujących, również „części zamienne" np. sztuczne narządy zaliczamy do działu robotyki medycznej.

Zainteresowanym jaki powinien być robot domowy polecam raport z badań ankietowych przeprowadzonych przez studentów Śląskiego Uniwersytetu Medycznego. Pełna ankieta znajduje się na naszej stronie internetowej – można ją pobrać i rozpowszechnić. Czekamy na zebrane dane, które spowodują, że kolejne wyniki będą oparte na większej grupie badanych.

Z naszej Akademii ISMR tym razem proponujemy wykład filozofa etyka z Uniwersytetu Śląskiego dr. Mariusza Wojewody.

Wśród proponowanych prac znajdziecie Państwo raporty dotyczące zadajników ruchu wykorzystywanych do sterowania telemanipulatorami (i nie tylko), postępy zespołu pracującego nad wprowadzeniem zadajników haptycznych dla robotów Robin Heart, projekt egzoszkieletu stawu łokciowego, innowacje w rehabilitacji i endoskopii diagnostycznej oraz opracowania dotyczące rynku robotów medycznych na świecie i... w Chinach. Nie zabrakło oczywiście naszego raportu z konferencji Roboty Medyczne 2015.

Niech roboty będą z nami! Niech będą coraz sprawniejsze i użyteczne człowiekowi!

Wierzę, że spotkamy się zatem na początku grudnia w Zabrzu na kolejnej specjalistycznej konferencji Medical Robots 2016, a na razie zapraszam do lektury...

Zbigniew Nawrat
Prezydent ISMR
Redaktor MrR
Zabrze, grudzień 2015

Medical Robotics Reports
Redakcja: ul. Wolności 345a, 41-800 Zabrze
Wydawca: Międzynarodowe Stowarzyszenie na rzecz Robotyki Medycznej ISMR

Rada Naukowa: • Richard Satava, MD (Washington Medical University, USA) • prof. Mehran Anvari (McMaster University, Hamilton, Kanada) • prof. Kevin Warwick (Reading University, Anglia) • prof. Krzysztof Tchoń (Politechnika Wrocławska) • dr Piotr Sauer (Politechnika Poznańska) • dr Krzysztof Mianowski (Politechnika Warszawska) • prof. Leszek Podsędkowski (Politechnika Łódzka) • prof. med. Romuald Cichoń (Drezno, Wrocław, Warszawa) • prof. med. Andrzej Bochenek (Śląski Uniwersytet Medyczny, PAKS) • prof. Kaspar Althoefer (Kings College, London) • Sławomir Marecik, MD (UIC/Lutheran Hospital Chicago, USA)

Redaktor naczelny: dr hab. n. med. Zbigniew Nawrat
Dyrektor zarządzający: lek. Dominik Pawliński
DTP: Katarzyna Ciemny
Webmaster: lek. Aleksander Biesiada, www.medicalroboticsreports.com
Okładka: autorem zdjęcia jest Mariusz Jakubowski
Druk: Drukarnia EDIT Sp. z o.o.

The Foundation of
Cardiac Surgery Development
in Memorial of Zbigniew Religa

The Foundation was established in 1991 and its' main goal has been to support the development of Polish cardiac surgery as well as to introduce into clinical usage modern technologies of heart treatment, including introduction of first Polish mechanical heart assist prosthesis. For this purpose, Foundation, in its own Heart Prosthesis Institute created in 1993, consistently conducts research and development works related to the Polish artificial heart, biological heart valve, cardiac surgery robot and quite recently biotechnologies in heart prosthesis development. Institute's laboratory area is about 1100 m^2 and the researches are carried out by highly qualified personnel (presently there are about 50 employees), including scientists, engineers and technicians of different fields.

Institute's researches are performed in four main laboratories:

- **Artificial Heart Laboratory**, focusing on basic, practical and implementation researches on extracorporeal heart assist devices and heart prostheses, clinical investigation on heart prostheses experimental application, hospitals staff's trainings in the field of mechanical heart assistance usage and new technology in extracorporeal heart and lung support,
- **Biological Heart Valve Laboratory**, focusing on researches on construction and technology of biological heart valve prostheses development and production, researches on biological tissue preservation technology, experimental clinical investigations on new developed heart valves and tissue products,
- **Biocybernetics Laboratory**, focusing on cardiac surgery robotic development, mathematical modelling for cardiac and vascular surgery support, basic researches on various theoretical subjects concerning the artificial heart, heart valve prostheses' laboratory tests and equipment,
- **Biotechnology Laboratory** focusing on researches on cells culturing technology in relation with heart muscle cells treatment, researches on technologies of cells and tissue culturing in relation with in vitro biological heart components growing.

The Foundation's activities involving funds acquisition, research and development works and training comply with **ISO 9001:2008 Quality Management System**.

The Foundation has obtained the status of **Centre of Excellence of New Technologies of Heart Diseases Treatment "Procordis".**

The Foundation has been appointed as the coordinator of **the Polish Artificial Heart Program for 2007-2012** set forth by the Resolution of the Polish Council of Ministers and the main contractor of all construction works in a strategic project run under the Program.

www.frk.pl

Medical Robotics Reports
Volume 4, December 2015

SPIS TREŚCI:

PODZIĘKOWANIE
Redakcja składa serdeczne podziękowania za merytoryczny i honorowy wkład w przygotowanie tego wydania czasopisma osobom, które przyjęły na siebie trud recenzji przesłanych do nas publikacji. Recenzantami Medical Robotics Reports wydanie 2015 byli wybitni specjaliści robotyki i wielu dziedzin techniki, materiałoznastwa, biofizyki, medycyny, ekonomii oraz filozofii: Sławomir GRZEGORCZYN (Zabrze), Marek JÓŹWIAK (Poznań), Józef KOZAK (Tuttlingen), Krzysztof MIANOWSKI (Warszawa), SŁAWOMIR MARECIK (Chicago), Stanisław MITURA (Koszalin), Jerzy PACHOLEWICZ (Zabrze), Dominik PAWLIŃSKI (Rzeszów), Pal SOOS (Budapest), Wiesław WÓJCIK (Warszawa)

Personalised External Aortic Root Support: an Engineering Perspective

Artykuł recenzowany

T J GOLESWORTHY C ENG MEI MRSC, TECHNICAL DIRECTOR, EXSTENT LTD, TEWKESBURY, UK

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).

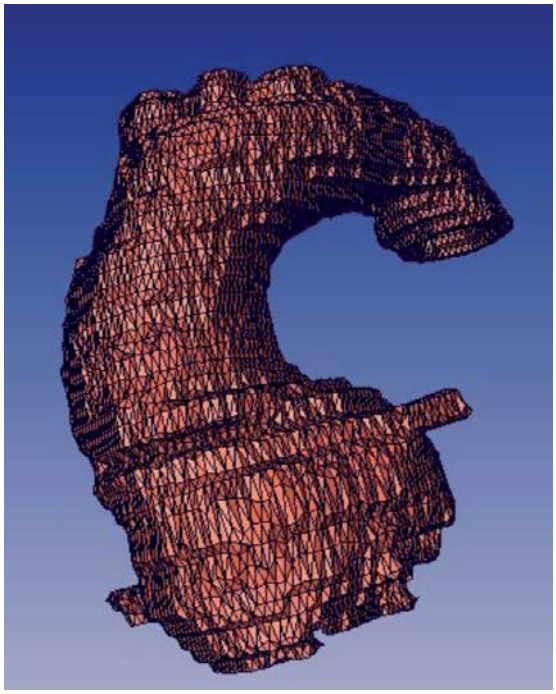


Figure 1. Early slice-stacked CAD model of the ascending aorta

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.

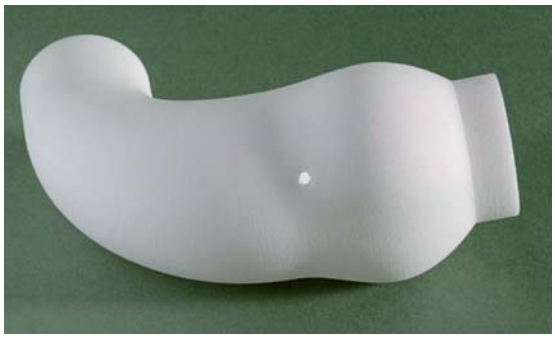


Figure 3. SLS aortic former for PEARS manufacture

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.

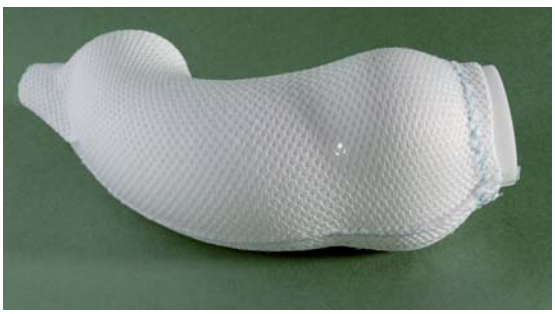


Figure 5. ExoVasc® textile implant on manufacturing former

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

PEARS has been a multi-disciplinary team project including CardioThoracic Surgeons, Radiologists and Engineers. The author would like to acknowledge the contributions of Prof Tom Treasure, Prof John Pepper, Prof Raad Mohiaddin, Dr Michael Rubens, Prof Bob Anderson Dr Warren Thornton and Dr Peter Gibson.

References

[1] *The tailor of Gloucester: a jacket for the Marfan's aorta.* Golesworthy T, Lamperth M, Mohiaddin R, Pepper J, Thornton W, Treasure T. 2004, Lancet, Vol. 364, p. 1582.

[2] *Manufacturing and placing a bespoke support for the Marfan aortic root: description of the method and technical results and status at one year of the first ten patients.* Pepper J, Golesworthy T, Utley M, Chan J, Ganeshaligan S, Lamperth M, Mohiaddin R, Treasure T. 2010, Interactive Cardivascular and Thoracic Surgery, Vol. 10, pp. 360-65.

[3] *External aortic root support for Marfan syndrome: early clinical results in the first 20 recipients with a bespoke implant.* Pepper J, Chan J, Gavino J, Golesworthy T, Mohiaddin R, Treasure T. 2010, Journal of the Royal Society of Medicine, Vol. 103, pp. 370 - 375.

[4] *Implantation of an individually computer-designed and manufactured external support for the Marfan aortic root.* Pepper J, Petrou M, Rega P, Rosendahl U, Golesworthy T, Treasure T. 2013, Multimedia Manual of Cardio-Thoracic Surgery. mmt004

[5] *Personalised External Aortic Root Support (PEARS) compared with alternatives for people with life-threatening genetically determined aneurysms of the aortic root*. Treasure T, Pepper J. 2015 Diseases, 3, 2-14; doi:10.3390/diseases3010002

[6] *Ascending Aortic Dilatation Associated With Bicuspid Aortic Valve Pathophysiology, Molecular Biology, and Clinical Implications* Thomas M. Tadros, MD, MPH; Michael D. Klein, MD; Oz M. Shapira, MD, March 15, 2016, Circulation

[7] *Early and one-year outcomes of aortic root surgery in Marfan syndrome patients: a prospective, multicenter, comparative study.* Coselli JS, Volguina IR, LeMaire SA, Sundt TM, Connoly HM, Stephens EH, Schaff HV, Milewicz DM, Vricella LA, Dietz HC, Minard CG, Miller C. 2014, Journal of Thoracic and Cardiovascular Surgery, Vol 147, pp 1758-66.

[8] *"Reducing fear and the risk of death in Marfan syndrome: a Chaucerian pilgrimage"*, Tal Golesworthy, Tom Treasure, Michael Lampérth, John Pepper, July/August 2006, The British Journal of Cardiology

[9] *Medical Image Acquisition for Modelling a Personalised External Aortic Root Support*, T Golesworthy, Jan 2015, Exstent Ltd, Manufacturing Work Instruction

[10] *A comparison of Rapid Prototyping Technologies*, D T Pham & R S Gault, October 1998, International Journal of Machine Tools and Manufacture, Vol 38, Issues.