# Entering a New Era of Surgical Training: Developing 3-dimensional print models for hands-on surgical training and its introduction into the congenital cardiac surgical curriculum

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# Abstract

Congenital heart surgery is a technically challenging subspecialty of cardiothoracic surgery. This is due to a combination of factors including the rarity and variety of pathology and the small patient size. This coupled with the increasing public scrutiny and the expectation of excellent patient outcomes for even the most complex pathologies has led to limitations for surgical trainees to develop their surgical competencies in an efficient manner. Simulation has been used successfully to develop technical skills in other surgical specialities but is limited in congenital heart surgery. The objectives of this work were to develop and integrate hands-on simulation methods into the training of congenital heart surgeons using anatomically accurate 3D-printed heart models and to use validated, objective assessment methods to measure performance. The simulation programme was successfully developed and integrated into the regular training of congenital heart surgeons. The objective assessments demonstrated that there was an improvement in procedural performance and time across multiple complex procedures following deliberate practice and rehearsal. Furthermore, surgeons who had participated in the programme retained their technical skills following a prolonged delay supporting the value of simulation. Overall, there is value in the incorporation of hands-on simulation training into congenital heart surgery and it has the potential to be integrated into training programmes globally.

# Table of Contents

# List of Tables

# List of Figures

# List of Videos

# List of Appendices

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Thank you

# Author's declaration

'I confirm that this work is original and that if any passage(s) or diagram(s) have been copied from academic papers, books, the internet or any other sources these are clearly identified by the use of quotation marks and the reference(s) is fully cited. I certify that, other than where indicated, this is my own work and does not breach the regulations of HYMS, the University of Hull or the University of York regarding plagiarism or academic conduct in examinations. I have read the HYMS Code of Practice on Academic Misconduct, and state that this piece of work is my own and does not contain any unacknowledged work from any other sources. I confirm that any patient information obtained to produce this piece of work has been appropriately anonymised'.

# Publication contributions in this thesis

The following scientific peer-reviewed publications have contributed to this thesis. Permission has been granted from the relevant publishers.

**Chapter 4:**

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# 1 Thesis overview, background and objectives

## 1.1 Thesis overview

Congenital heart surgery is a branch of surgery that deals with correcting defects in children born with structural heart disease. It is a highly-specialised subspecialty of cardiothoracic surgery, which consists of a prolonged and rigorous training pathway. Primarily a surgeon's training is spent in the operating room with a gradual increase in exposure of being the primary operator. The increased public scrutiny of patient outcomes and expectation of flawless results has introduced further limitations to the training of current and future congenital heart surgeons.

The focus of this thesis is to explore whether current training in congenital heart surgery can be augmented with technologies such as three-dimensional (3D) printing and simulation to improve the acquisition of technical skills. There are four main objectives for this thesis: 1) to develop anatomically accurate 3D-printed heart models of complex congenital heart diseases to be used for hands-on surgical simulation, 2) to review literature of simulation methods used in congenital heart surgery and identify if there is a need for further simulation and improvements, 3) to develop and validate objective assessment methods that can be used in the evaluation of surgeons' performance and to validate the effectiveness of the simulation programme following deliberate practice and rehearsal and, 4) to develop and integrate a year-long monthly hands-on simulation programme using 3D-printed heart models into the congenital heart surgery training curriculum.

This thesis is broken down into eleven chapters that covers the main objectives outlined above. **Chapter 1** gives a general overview of congenital heart disease, the current training pathway for surgeons interested in congenital heart surgery in the United Kingdom and a summary of the applications of 3D-printing in cardiovascular medicine and simulation training in cardiothoracic surgery. **Chapters 2 and 3** provide a detailed description of the technologies and methods used to produce anatomically accurate 3D printed models suitable for surgical simulation. **Chapter 4** is a literature review of hands-on surgical simulation specifically in congenital heart surgery and discusses the need to develop simulation programmes. **Chapters 5-7** describes the development and validation of procedure-specific assessment tools and evaluates whether there is an objective improvement in surgeons' technical performance following deliberate practice and rehearsal. **Chapter 8** outlines the development and incorporation of a monthly simulation programme into the training of congenital heart surgeons and evaluates surgeons' performances during the year-long period and assesses for skill retention. **Chapter 9** describes the development of a dynamic chest wall and operating table simulator to enhance congenital heart surgery simulation. **Chapter 10** evaluates whether there is a benefit to medical students by including them into the simulation programme as surgical assistants and **Chapter 11** provides final conclusions and discusses future directions to build from this work.

## 1.2 General background: Congenital heart disease

Congenital heart disease (CHD) is a branch of cardiac disease covering a wide spectrum of anomalies involving the heart and its associated great vessels. It is characterised by structural defects resulting from abnormal cardiac development in-utero and is responsible for a large proportion of perinatal and infant mortality [1]. The incidence of congenital heart disease ranges between 7 to 10 per 1000 live births with more severe forms affecting 3 per 1000 births [2]. In the mid-twentieth century children would rarely reach adulthood, however due to advances in the understanding of disease morphology, diagnostic methods, interventions and post-intervention care have led to a dramatic improvement in patient mortality [3], [4]. Today the ratio of adults with a repaired or unrepaired congenital heart disease outweighs children by a ratio of 2:1[3].

Due to the significant risk of mortality without intervention, surgery remains a cornerstone in short and long-term survival in patients with CHD. The complexity of the pathologies involved in CHD coupled with the delicate nature of the surgery makes congenital heart surgery one of the most technically challenging surgical specialities[5]. As there is little room for error in treating these babies and children, there is a need to develop technically proficient surgeons more efficiently in a safe learning environment than what currently exists [6]–[8].

## 1.3 Surgical Training Pathways in Congenital Heart Surgery

In the United Kingdom (UK), congenital heart surgery (CHS) was recognised as a sub-speciality within cardiothoracic surgery in 2013. Currently, there are 45 congenital heart surgeons across 12 centres across the UK and Ireland with most being within their 5th decade (Figure 1.1) [9]. Training within CHS is incorporated within the cardiothoracic surgery training pathway and occurs during the later portion of surgical training. In August 2021 a revised training curriculum in cardiothoracic surgery will be introduced aiming to evolve the current training regime [9].

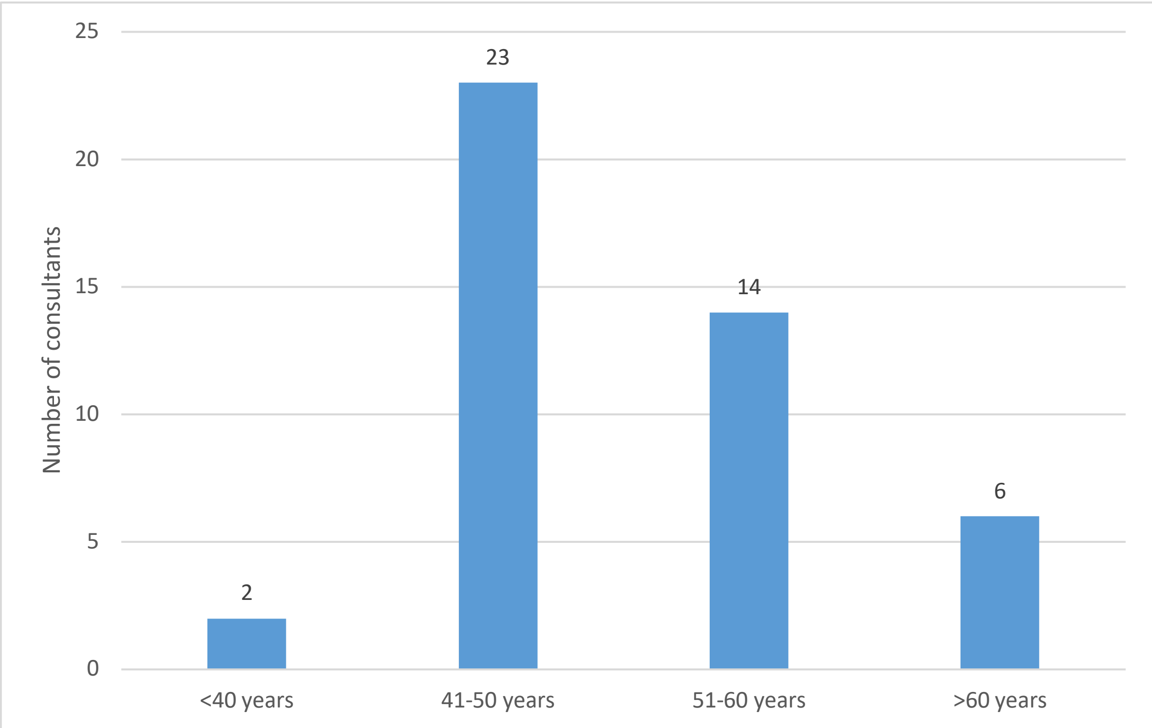



**Figure 1.1:** UK congenital cardiac surgeons by age group. Adapted from the SAC (Special Advisory Committee) and SCTS (Society for Cardiothoracic Surgery) UK Cardiothoracic surgery Workforce Report 2019 [9]

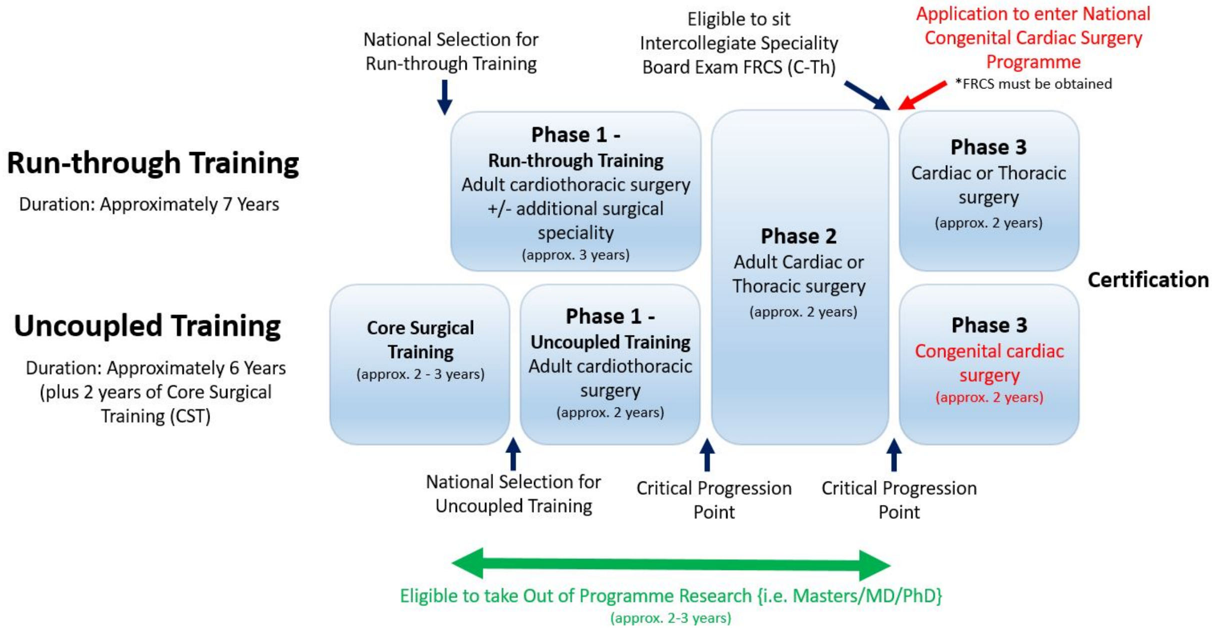



**Figure 1.2:** UK Cardiothoracic Surgery Training Pathway. Adapted from the SCTS (Society for Cardiothoracic Surgery) Bulletin – August 2019 [10].

UK trainee surgeons enter the training program through a national selection process either directly after their foundation training (run-through training) or following a 2-3 year period within core surgical training (uncoupled training) (Figure 1.2) [9], [11]. This process consists of an initial application, which is scored against a predefined matrix in order to shortlist the highest scoring applicants for structured interviews. Successful interviewees are subsequently offered training positions within dedicated cardiothoracic surgery training programmes. These trainees are given a national training number (NTN) in cardiothoracic surgery. Although focused on competency-based progression rather than time-based, the new programme predicts to reduce overall training time by one year when compared to the previous curriculum. The curriculum is separated into three phases, each ranging between 2-3 years' duration. For surgeons wishing to pursue a career within congenital cardiac surgery they are eligible to apply for the national training position following completion of Phase 2 and successfully passing the Intercollegiate Board Exam in Cardiothoracic Surgery. Training within congenital cardiac surgery is typically 2 years within one of two recognised training programmes – 1) Great Ormond Street Hospital, London/ Birmingham Children's

Hospital and 2) Alder Hey Children's Hospital, Liverpool/ Freeman Hospital, Newcastle. During this period it is expected that trainees will perform a minimum of 75 cases and are required to have subspecialty recognition before being eligible to apply for congenital cardiac consultant posts in the UK. It is expected that newly appointed consultants will require an additional 2 years of training and supervision once in post [9].

In addition to the national training programme, non-NTN surgeons are able to train and subsequently apply for consultant positions. This pathway is primarily utilised by trainees who achieved their undergraduate medical degree +/- basic surgical training outside of the UK. These surgeons develop their skills through clinical fellowship positions either in the UK or abroad and are required to provide evidence of satisfactory congenital training when applying for consultant positions [9].

There has been limited interest from national trainees to pursue congenital subspecialisation over the last decade [9], [12]. Between 1999-2014 there was a 55% increase in the number congenital cardiac surgeons within the UK, however this was exclusively from overseas graduates. This has resulted in some heart centres having no UK graduated surgeons. This outcome supports the notion that UK trainees are avoiding congenital cardiac surgery as a career option [12]. This decrease has been attributed to a number of factors including a high level of external scrutiny; the publication of patient outcomes; a number of high profile suspensions of individuals and centres; a lack of supportive environments and restrictions in training [9], [12]–[14].

However, these issues are not isolated to the UK. In North America surgical trainees usually enter cardiothoracic training directly following completion of medical school. Similarly trainees will undergo a dedicated training programme lasting 5-8 years with some programmes requiring a period of time within general surgery. Just like the UK there are training restrictions with trainees reporting a dissatisfaction in their operative experience in CHS, however this has subsequently improved in the last decade [15]. The median age of consultant/staff CHS surgeons is 50 years with the median age of graduation from dedicated congenital training programs being 40 years [15], [16].

Due to these global limitations in the training and development of technically excellent congenital heart surgeons there is an increasing need to evolve current training curricula [5], [6], [8], [17]. Surgical simulation is a potential method to address these limitations and augment the experience of trainee congenital heart surgeons. It is hypothesised that by providing safe, inconsequential environments where trainee surgeons can rehearse their technical skills will lead to earlier achievement of technical competency with a reduced risk to patient safety [18], [19]. Potentially the incorporation of such methods into national and international training programmes will increase the number of cardiothoracic trainees wishing to pursue congenital heart surgery.

## 1.4 3D printing applications in cardiovascular medicine

Three-dimensional (3D) printing has been increasingly used in cardiovascular medicine to gain a further understanding of complex anatomical structures and morphology that may be difficult to interpret solely from cross-sectional or echocardiographic image data. This aids in the diagnosis, physiological understanding, risk stratification and the planning of complex interventional procedures. 3D modelling is now transitioning into the clinical care of patients, either directly from medical device development to indirectly via a better understanding of complex pathophysiology and anatomy [20].

Within congenital heart surgery, 3D printing was first described in 2006 in 6 patients with pulmonary atresia/ ventricular septal defect and major aortopulmonary collateral arteries [21]. These models were used for the preoperative planning for these patients. This study, like many that have followed, have reported to accurately represent patients' complex anatomy when compared at the time of the operation.

3D printing allows anatomical and clinical information to be represented in a more visual and tactile form and its main uses within CHS can be separated into three broad categories [20]:

1) Clinical practice and research – This is primarily used to gain a greater understanding of complex morphology and evaluate the feasibility of proposed interventions (i.e. cardiac surgery and catheter-based interventions).

2) Education – As real-life image data is used to create and print multiple 3D printed models, they have emerged as an excellent training tool to educate trainee clinicians and students [22]. With heart specimens from autopsies being limited and having their own ethical issues, 3D modelling is an effective alternative [18], [23], [24]. Furthermore, as models can also be printed in soft, pliable materials, this methodology is being used in the hands-on training of surgeons for these complex procedures, which they seldom would be experienced to [18], [25]–[27]. In addition, 3D modeling and printing facilitates wide dissemination of knowledge as any number of models can be reproduced.

3) Patient and parent communication – Conveying the complexities of a patient's diagnosis and the proposed treatment strategies can be challenging for clinicians. 3D models have been used satisfactorily in conveying this information thus aiding communication and improving patient/parent experience and engagement [28]–[30].

The advantages that 3D printing brings to a patient's care with complex congenital heart disease is easily understood, however its effectiveness is difficult to measure objectively [31]. The analogy commonly used is that of reverse cameras, which are now mandatory on all new automobiles in North America. Although one does not need a camera to reverse into a parking spot, its use increases the confidence of the driver to park the vehicle. The same is seen within CHS; surgeons and interventionists do not necessarily need a 3D model to carry out a procedure but reviewing one in the planning phase gives the clinician greater confidence to execute the management plan. Its use also decreases the risk of misunderstanding, misinterpretation and miscommunication that may occur by using images alone for procedural guidance [24], [32].

## 1.5 Simulators for cardiothoracic surgical training

Studies have shown a positive correlation between case volume and clinical outcomes [33]. However, this alone does not lead to technical excellence as variation in performance exists within the experienced surgeon cohort. It is proposed that time spent deliberately practicing a given task rather than volume is a better determinant to achieving skill excellency [34]. The principle of deliberate practice focuses on the repetition of a particular task combined with coaching by an experienced teacher, which is followed by immediate feedback on the performance. This method is commonly used in skill acquisition outside of surgery, such as mastering a musical instrument or improving athleticism, however the opportunities to benefit from deliberate practice within the intraoperative environment are rare and impractical. Therefore, dedicated simulation is an excellent platform to encourage the development and acquisition of the key technical skills, which are required in a surgeon's development [35].

Simulators have been used in surgery for over two centuries and has primarily consisted of cadaveric and animal specimens [36]. However, these methods have limitations relating to cost, accessibility to facilities/specimens and ethical/moral issues. As a result, over the last two decades there has been a gradual incorporation of artificial simulators within the speciality [37]. Cardiothoracic surgery (CT) has adopted surgical simulation due to the high risks and the broad range of skills required of a CT surgeon. Although the number of patients presenting with cardiac and thoracic related problems grows, it is expected that the workforce will decline [38].These factors have inevitably lead to the speciality adopting simulation to continue producing technically competent surgeons who are potentially at risk of having their training compromised by external, yet unavoidable factors.

Simulation provides a platform for surgical residents/trainees to improve their skills in an inconsequential manner, providing them the opportunity to rehearse technical skills in order to achieve competency in an efficient manner [37], [39]. Simulators are broadly separated into four categories [35], [37]:

1) Simple bench models (SBM) – These focus on a specific part of an operation as opposed to a whole operation (i.e. coronary anastomosis). As the emphasis is placed on repetition and deliberate practice these simulators are usually inexpensive and therefore more readily available. This is particularly advantageous for junior surgeons where motor skill acquisition is of greater importance than being able to perform a full operation.

2) Virtual reality simulators (VRS) – These are computer-based simulators usually without a physical component. Platforms used include virtual and augmented reality simulators, which use sophisticated programming to replicate tasks or full operations. The initial high cost for equipment and software is usually a barrier to its adoption, however the consumable cost is usually low. The lack of true tactile feedback and use of a 2D screen to visualise a 3D structure are seen as other disadvantages of this technology.

3) Human cadavers and live animals – Traditionally the mainstay of simulation human cadavers demonstrate real tissue and anatomical structures unlike others. However the supply and cost are limiting factors along with the inability to realistically simulate haemodynamics. Live animals can provide haemodynamics allowing full procedures to be performed, however like cadavers there are multiple barriers to their regular use. Furthermore, the simulation of CHS procedures is hardly feasible as both resources rarely provide the anatomy of congenital heart diseases.

4) Human performance simulators (HPS) – This method incorporates both the physical aspects of a simulator (real or synthetic) with a computer interface. These simulators typically recreate the intraoperative environment and are used to simulate full operations involving the whole surgical team rather than just an individual [35]. This is excellent in the training of crisis management, which is otherwise very difficult to teach by traditional methods [40], [41].

'Fidelity' refers to the extent a learnt skill is transferable to reality (i.e. operative environment). The term 'high-fidelity' and 'low-fidelity' are used to describe the resemblance of a simulator to reality, however these terms are used loosely with some simulators being described as both high and low fidelity [42]. In cardiac surgery, simulators should be defined as high-fidelity if they integrate technical skills alongside haemodynamics, which allows scenario and team based learning [43], [44]. Low fidelity simulators, on the other hand, primarily focus on a particular task and can be either tissue-based or synthetic. Fidelity is less important at relatively junior levels of training as the emphasis is on motor skill development rather than performing whole operations [35], [45]. As a trainee progresses through their training, higher fidelity simulators are more advantageous as they more closely replicate the real-life/operative experience, which likely to translate to better learning [46]. Using the simulator categories above, SBM and VRS simulators would be defined as 'low-fidelity' with HPS being 'high-fidelity'.

Within adult cardiothoracic surgery there are numerous simulators used in the development and training of surgeons. A literature review identified 50 studies that used or introduced simulators within cardiothoracic surgery [37]. Fifty-four percent (27/50) were SBM, 20% VRS and 26% HPS. Thirty-eight percent (19/50) of the simulators involved animal tissue with the rest being artificial in the form of physical models or virtual reality/computer interfaced. Only 20% (10/50) of the studies incorporated immediate independent feedback. The overall consensus was that simulation within cardiothoracic surgery is required, however in order to maximise the benefits that simulators bring to surgical training there is a need to develop objective, standardised assessment methods to assess simulator effectiveness [37]. Simulators within congenital cardiac surgery were not included in this review but are reviewed in chapter 4.

# 2 A literature review of 3D printers and material used for cardiovascular models

## 2.1 3D printers and Materials

3D printing, also known as additive manufacturing, was developed in the 1980's for rapid prototyping and commercialised in 1987 by a company known as 3D Systems, one of the largest companies worldwide producing 3D printing equipment [47]. There are multiple methods of "3D printing" with photopolymerization being the mainstay which involves producing an object layer-by-layer, each being solidified and adhered to the previous layer. Inevitably this leads to a prolonged time to produce the object, with larger structures taking significantly longer than smaller objects. Advancements have been made to print materials to produce objects with different physical properties and time efficiencies have improved. There has also been a development in other technologies that has further expanded the type of materials which can be used in additive manufacturing, such as metals and biomaterials [47].

As most models are built via a layer-by-layer process, there is a need to maintain the models' structural integrity during the print. Therefore, part of the printing process involves depositing support material or the building of supporting structures, in addition to the model material, which acts as a scaffold during the print. This support material is subsequently removed from the printed model during the post-processing stage of model manufacturing.

Within cardiovascular medicine there are five types of 3D printing modalities that are used to create cardiovascular models [47]:

1) Vat photopolymerization/ Stereolithography apparatus (SLA)
2) Material jetting (Polyjet)
3) Material extrusion/ Fused deposition modeling (FDM)
4) Binder jetting
5) Powder bed fusion

### 2.1.1 Vat Photopolymerization/ Stereolithography Apparatus (SLA)

This was the original and most commonly used methodology to 3D print cardiovascular models. The process involves building a model layer-by-layer with a photosensitive liquid material, which is held in a vat. The deposited material is cured into a solid form by ultraviolet (UV) light. This process produces high resolution, accurate models which are ideal for cardiovascular models. However, models are limited to a single material and there is significant difficulty printing fine structures, such as chordae tendinae due to the difficulty of removing the supporting structures. Printers range from relatively inexpensive desktop printers (approx. ~$5000-$10,000 USD) to industrial printers (>$400,000 USD). A variety of materials are available from stiff to flexible resins, including different colours and opacities. The post-processing of the models consists initially of removing remaining resin off the model by submerging the model in an alcohol solution followed by the manual removal of the supporting struts (Figure 2.1). The model may need sanding down at the points where the supports struts were removed to give a smoothened finish. Finally, models are cured for up to an hour in an ultraviolet bath to complete the post-processing [47].

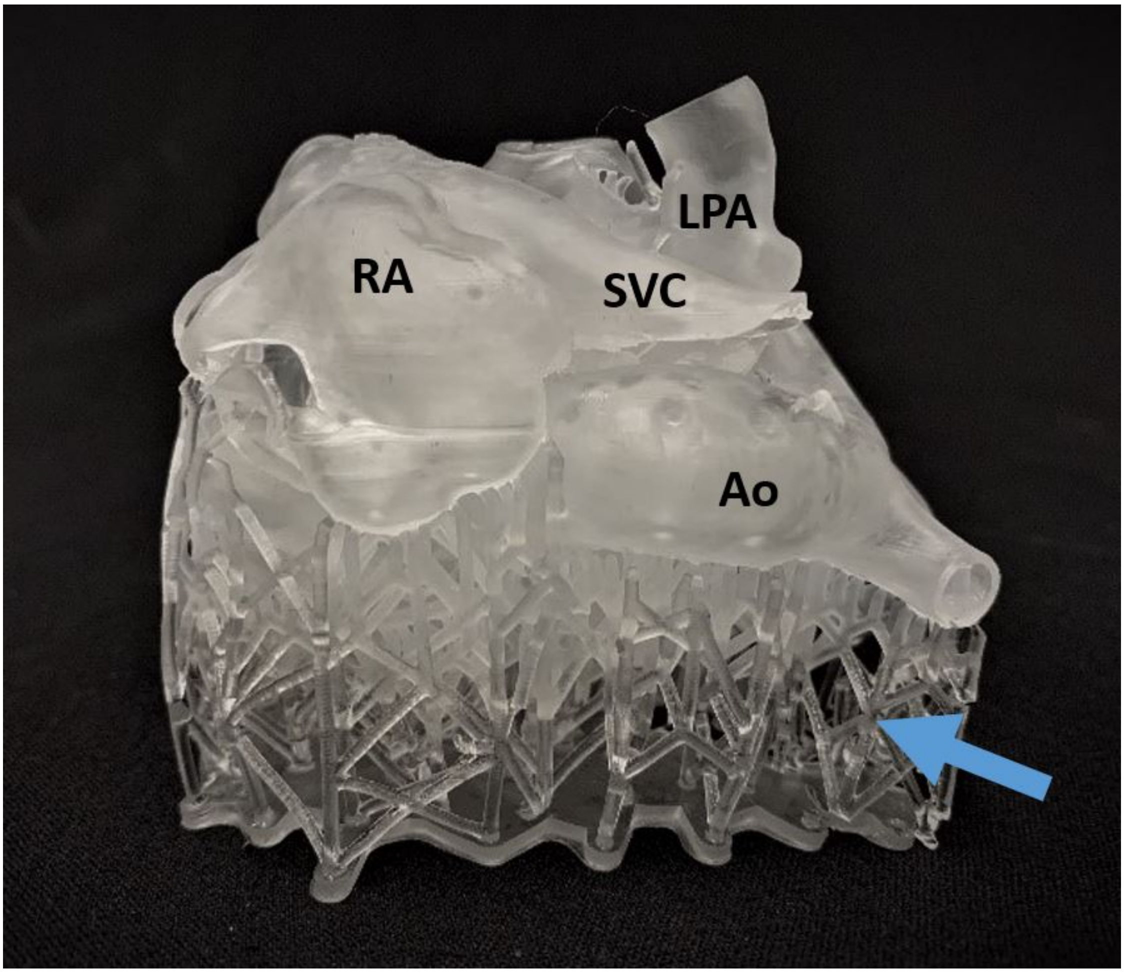



**Figure 2.1:** 3D printed tetralogy of Fallot heart model printed on a stereolithography apparatus (SLA) printer. The photo is taken prior to undergoing the post-processing stage. Note the supporting struts (blue arrow) that are formed during the print to support the model's structural integrity during the print. These struts are also present within the cavities (not visible). Ao = Aorta, LPA = left pulmonary artery, RA = right atrium, SVC = superior vena cava

### 2.1.2 Material Jetting (Polyjet)

With a similar methodology to vat photopolymerization, material jetting adds advantages of printing with multiple materials and colours simultaneously. This produces more realistic cardiovascular models as the mixing of materials allows the printing of models with a greater range of biomechanical properties, which can be altered to more closely resemble cardiac and vascular tissue.

By a process of photopolymerization, the resin is extruded as microdroplets onto a build tray via dedicated print heads. UV light is then used to cure the liquid into a solid format. Like vat polymerisation, each layer of the print is stacked on top of one another until the print is completed. The increased sophistication of these printers is reflected in the cost with printers starting from $70,000 and can range to over $500,000 (US). An examples include Stratasys J750 printer (Stratasys, Eden Prairie, MN), which is currently one of the most sophisticated commercially available printers with the ability to mix and print multiple materials simultaneously [47], [48]. In addition to the high capital cost, the maintenance of these printers can also be laborious and costly with dedicated service packages required to maintain optimal performance.

Print materials can range from rigid to soft resins and allows the printing of models with various colours and transparencies. The mixing ability of the materials allows the printing of models with mechanical, functional and imaging properties similar to vascular tissue [47]. This has lead to the development of models capable for surgical simulation [18], [25]–[27].

Instead of using support struts to maintain the structural integrity of the model, support material is deposited alongside the model material. This is removed either by using a water jet to physically remove the material or is dissolved with chemicals and/or water [49], [50]. Although this method is effective in creating high resolution, accurate models and possesses the biomechanical properties to print cardiac structures of <1mm thickness there can be difficulties removing support material within the cardiac cavities. Therefore, cardiac models may require the removal of ventricular/atrial walls to assist with the removal of the support material, particularly if the model is made to demonstrate intracardiac structures (Figure 2.2). Additionally, hollow structures with an inner diameter of <3mm can prove to be very difficult to manually remove the support material. This may result in the final model to still contain support material. These issues have led to a developing industry solely focused on manufacturing intelligent, chemical based solutions to remove all support material without changing the biomechanical properties of the printed model [51]. Like vat photopolymerization printing time can be excessive and is dependent on the structure's size. In our experience, a paediatric-sized heart model takes approximately 4-6 hours to print with adult-sized hearts taking up to or exceeding 24 hours.

Despite the barriers described above, material jetting is currently the ideal method to producing anatomically accurate models for surgical simulation and is the methodology used in our studies.

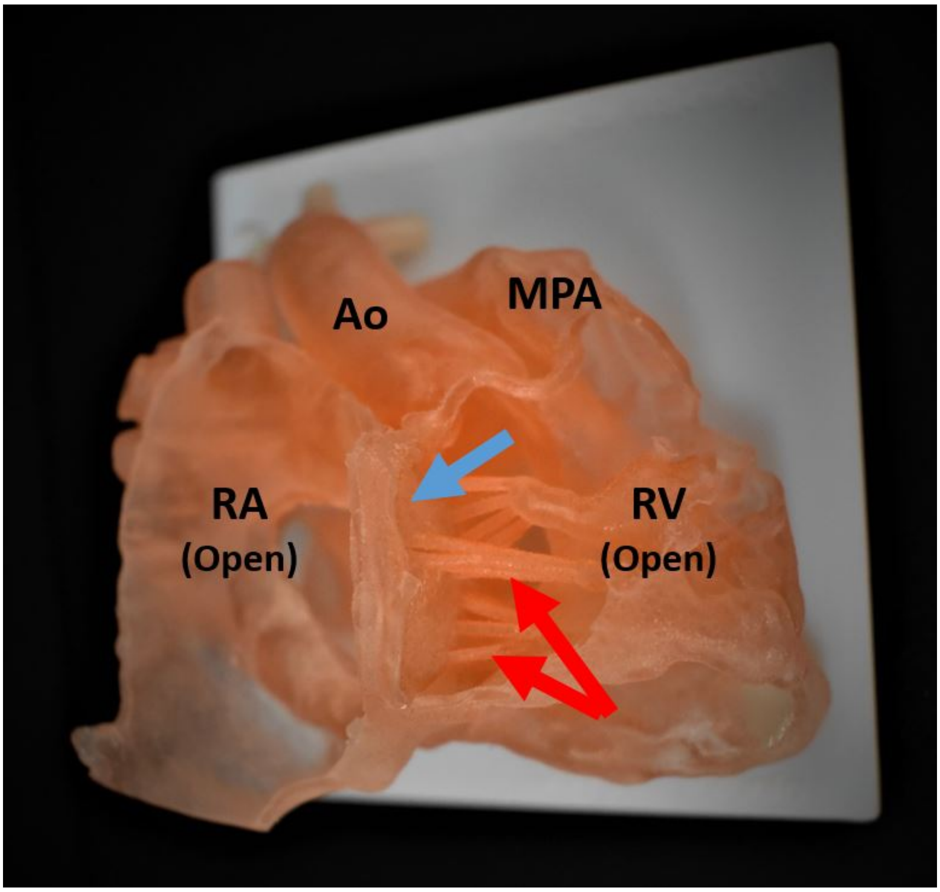



**Figure 2.2:** 3D printed heart model printed on a polyjet printer (material: Agilus30) demonstrating an atrioventricular septal defect. Note the right atrium (RA) and right ventricular (RV) free walls have been removed to allow careful removal of the support material without damaging the fine intracardiac structures. Although models can be printed with any combinations of colours, the flexibility and elasticity are compromised by adding colours. Blue arrow = atrioventricular valve, red arrow = chordae tendinae (thickness = 1mm). Ao = aorta, MPA = main pulmonary artery.

### 2.1.3 Material Extrusion/ Fused deposition modelling (FDM)

Fused deposition modelling (FDM) printers are the most common modality that prints via the material extrusion method [47]. These printers can vary from having a single to multiple print heads that deposit thermoplastic filaments. Either the build platform or print head will move to build the object in a layer-by-layer fashion. As the hot material is deposited it is cooled quickly, usually by the assistance of fans, to solidify the layer leaving a striated-like appearance. The ease of printing along with the lower cost of materials and its biocompatible properties makes this method one of the most widely used in cardiovascular 3D printing. Entry level printers are relatively inexpensive costing several thousand dollars, with more professional systems reaching up to $100,000(US), which are usually used for clinical printing. Despite costing less than the alternative techniques there are limitations in print resolution and the overall quality of the model that might hinder the anatomical accuracy; particularly in the demonstration of intracardiac structures in infant/neonatal sized hearts. In addition, these printers are usually restricted to printing in one material at a time due to differences in thermoplastic properties between materials, which require different heating and cooling conditions [47].

The ease in post processing models made with this technique make it more user friendly than the other methods. Depending on the model's purpose and complexity, simple models will be nearly ready to use at the time of print completion. More complex models may require removal of support and/or dissolving of remaining material in a chemical bath, but the amount is considerably less than the photopolymerization and material jetting techniques. However, if models are required to be impermeable to water (i.e. cardiac or vascular structures which will be used for flow dynamic studies) then a sealant is usually required following the acidic bath, which prolongs the post processing time[52]. Overall print time is comparable with the two above methods.

### 2.1.4 Binder Jetting

Binder jetting produces cost effective model and provides the ability to print in multiple colours, however these models are rigid and are prone to breaking due to their fragile nature. This prevents the printing of finer structures, which is usually required in congenital heart models. The lack of biocompatible materials and rigid nature limits its use to primarily demonstrating extracardiac structures in cardiovascular printing.

In a layer-by-layer method, the print heads deposit a binding agent on a powder base only in the areas where the object in being printed. The base plate, on which the model is being made, is gradually lowered and the next layer of powder is added. This cycle continues until the model is completed. Colour can be added with relative ease, which is particularly useful when trying to differentiate different anatomical structures. The unbounded powder acts as the supporting structure during the print and therefore does not require the deposition of dedicated support material, which is required with the other modalities. This excess powder is removed from the printed model which is then added to a chemical mixture, such as wax, to help strengthen the final model. Costs of a high end binder jetting printer is similar FDM printers and print times are slow [47].

### 2.1.5 Powder bed fusion

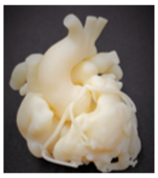
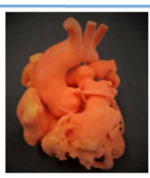
Primarily used in the making of patient-specific surgical guides and implants, powder bed fusion uses energy in the form heat via a laser to bind powder material. This powder is preheated on the build platform to just below the melting temperature of the material and a selective laser heats the specific regions that will form the model to the melting point. As the build platform lowers, the melted powder will adhere to the previous layer gradually building the object. This process produces robust, rigid structures making them suitable for guides and implants. Like binder jetting, the unused powder acts as the support during the print and is easily removed during post processing[47]. However, if the intended use is for patient use (i.e. in the operative environment) then that object needs to be sterilised with all excess powder removed prior to use. For cardiovascular models, although this method is good at producing rigid and strong models, its use may be limited due to lack of flexibility in the material. This method could be used in the development of surgical guides in cardiac surgery, like in other surgical specialities due to the advantages of biocompatibility and the ability to be sterilised by standard hospital methods. Cost of printers are widely varied starting from $50,000 and rising up to $800,000 (US)[47].

The different printer modalities available at the Hospital for Sick Children (SickKids), Toronto, Canada is shown in Table 2.1. To compare the materials, costs, printing and post-processing times of each printer I developed a tetralogy of Fallot 3D model (method described in chapter 3) and printed them on each available printer. Following the printing and post-processing, the print quality and the model's suitability to surgical simulation was evaluated (Table 2.2). This was achieved by attempting to perform the transannular patch aspect of the tetralogy of Fallot repair on each model by both myself and an experienced congenital heart surgeon. Models were evaluated on: 1) flexibility of model, 2) resolution of print, 3) suitability for anatomical demonstration, 4) suitability for surgical simulation and 5) other comments related to model quality.

**Table 2.1:** Printer modalities available in the 3D printing lab at the Hospital for Sick Children (SickKids), Toronto, Canada. A comparison of materials, cost and printer/ post-processing times for a tetralogy of Fallot model printed on each printer. Service cost was charged at £8.74 ($15 CAD), per hour of printing time. (ABS = Acrylonitrile Butadiene Styrene, FDM = Fused deposition modeling, SLA = Stereolithography Apparatus)

| Printer | Method | Material | Pre-Setup time (min) | Printing Time (h:mm) | Cost (GBP) | Post processing time (per model) |
|---|---|---|---|---|---|---|
| **Form2 (Formlabs, Massachusetts, US)** | Vat Polymerisation / SLA | Elastic Resin | <5 | 8:04 | Material = £6.27<br>Service = £28.15<br><br>Total = £34.42 | 15 min submerged in isopropanol<br>20 min cured in UV light/heat<br>20-30 min for Removal of support struts<br>Total: 65 min |
| **Stratasys Objet 500 Connex 3 (Stratasys, Eden Prairie, MN,US)** | Material jetting (Polyjet) | VeroWhitePlus | <5 | 6:18 | Material: £32.46<br>Service: £54.97<br><br>Total: £87.43 | Approx. 5-10 minutes (waterjet and manual cleaning) |
| **Stratasys Objet 500 Connex 3 (Stratasys, Eden Prairie, MN, US)** | Material jetting (Polyjet) | Agilus30 | <5 | 7:09 | Material: £88.33<br>Service: £62.38<br><br>Total: £150.71 | Approx. 10-20 minutes (waterjet and manual cleaning) |
| **Stratasys J750 Digital Anatomy Printer (Stratasys, Eden Prairie, MN, US)** | Material jetting (Polyjet) | Agilus30 + Tissue Matrix | <5 | 8:14 | Material = £87.67<br>Service = £71.83<br><br>Total: £159.50 | Approx. 10-20 minutes (waterjet and manual cleaning) |
| **Lulzbot Taz5 (Aleph Objects Inc., Colorado, US)** | Material extrusion / FDM | ABS | | | | |
| **Fortus 380mc (Stratasys, Eden Prairie, MN, US)** | Material extrusion / FDM | Model: ABS M30i Medical Grade<br>Support: SR-30 Soluble Support | <5 | 5:02 | Material = £12.74<br>Service = £55.62<br><br>Total = £68.36 | 6-8 hours in soluble bath |
| **zPrinter 450 (3D Systems, South Carolina, US)** | Binder Jetting | VisiJet PXL Core (powder)<br>VisiJet PXL clear (binder) | <5 | 4:25 | Material = £18.55<br>Service = £26.90<br><br>Total = £45.45 | 4-6 hours Cured with ColorBond |

**Table 2.2:** Visual representation of tetralogy of Fallot 3D models printed on the different available printers available at the Hospital for Sick Children (SickKids) Toronto, Canada. Comparisons made on model flexibility, resolution and suitability for anatomical demonstration and hands-on surgical simulation. (ABS = Acrylonitrile Butadiene Styrene)

| Printer and Material | 3D model | Flexibility of print model | Resolution of Print | Suitability for demonstrating anatomy | Suitability for Surgical simulation | Other Comments |
|---|---|---|---|---|---|---|
| Form2<br>Elastic Resin<br>(Formlabs, MA, US) |  | Flexible | High | Average/ poor | Unsuitable | • Supporting struts difficult to remove (especially within cavities)<br>• Poor surface finish<br>• Fragile |
| Stratasys Objet 500 Connex 3<br>VeroWhitePlus<br>(Stratasys, Eden Prairie, MN,US) |  | Rigid | Very high | Excellent (particularly for external anatomy) | Unsuitable | • Excellent surface finish<br>• Robust |
| Stratasys Objet 500 Connex 3<br>Agilus30<br>(Stratasys, Eden Prairie, MN,US) |  | Very flexible | Very high | Excellent (Both internal and external anatomy) | Suitable | • Excellent for surgical simulation<br>• Wall thickness limited to <1.5mm |
| Stratasys J750 Digital Anatomy Printer<br>Tissue Matrix<br>(Stratasys, Eden Prairie, MN,US) |  | Very flexible | Very high | Excellent | Suitable | • Excellent for surgical simulation<br>• Remains flexible at greater wall thickness (i.e. >1.5mm)<br>• Suitable for myocardial segmentation |
| Lulzbot Taz5<br>ABS<br>(Aleph Objects Inc., CO, US) | Print Failure | Rigid | N/A | N/A | Unsuitable | • Not suitable for demonstrating complex congenital anatomy |
| Fortus 380mc<br>ABS M30i Medical grade<br>(Stratasys, Eden Prairie, MN,US) |  | Rigid | High | Good (External anatomy only) | Unsuitable | • Poor surface finish (visible striations)<br>• Thin structures fragile (<1mm) |
| zPrinter 450<br>VisiJet PXL Core<br>(3D Systems, S.C, US) |  | Rigid | Very high | Average (External anatomy only) | Unsuitable | • Excellent surface finish<br>• Very fragile |

## 2.2 Other printers that could potentially be used for cardiovascular models

The modalities described above are the most widely used and commercially available methods used by hospitals and research institutions in the development of anatomically accurate 3D-printed cardiovascular models. Method choice depends on the availability of printers/materials, the cost and the intended use of the models. As the industry continues to expand, efforts are being made to develop new technologies, which address some of the limitations that currently exist.

### 2.2.1 Silicone-based printers

Silicone is an ideal material in the development and manufacturing of synthetic cardiovascular models. Advantages include being biocompatible, thermally stable, sterilisable, impermeable, relatively low cost and has the biomechanical properties similar to myocardial tissue [18], [49]. However due to the viscous nature of silicone and the length of time it requires to cure there have been barriers in developing commercially available 3D printers that use silicone. Up to now silicone has been used to make cardiovascular models via the moulding technique. This method uses direct 3D printing to make the external mould of the model and silicone is infused into it. Once the silicone has cured the mould is removed and the model is retrieved. This is a feasible method if cardiac models without intracardiac structures are required as a single mould can be used to make multiple models at relatively low cost. This technique has also been used to produce individual atrioventricular valves[25]. However, if intracardiac structures are required in a heart model the complexity and costs of the process increase considerably. Instead of simply removing the outer mould/shell, an additional mould would be required for the intracardiac structures. This would need to be broken down and removed for every model, in a similar manner as the removal of the support material in the direct printing method. The cost advantages of using a single mould for multiple models is therefore lost and would add a considerable time to post processing.

There are companies and emerging technologies that are working to overcome the natural limitations of silicone and developing printers that are able to directly print in silicone (Wacker Cheme AG, Munchen, Germany and Picisma Ltd, Sheffield, UK) [49], [53], [54]. The Wacker group printers rapidly deposit microdroplets of liquid silicone in a precise manner on a build platform, with UV light curing the silicone prior to the next layer being deposited. Support materials are used during the print which are water soluble. Due to silicones high melting point the models can be cured in a vacuum with temperatures up to 200$^{o}$C [53]. The Picisma group use a method similar to vat polymerisation, whereby the vat containing unpolymerized liquid silicone (silicone oil) is used and a pressurised syringe containing a catalyst it injected into the vat to cure the silicone at the region of the desired model. Each layer is built in a similar fashion until the model is complete[54]. Although, this allows the production of models with ideal biomechanical properties for cardiovascular models, the resolution of the final print is not yet up to the standards required to accurately represent intracardiac anatomy or be used in hands-on surgical simulation of congenital heart operations. It is likely, however as technologies improve this may be a viable, cost effective option for cardiovascular models.

Other groups have used the moulding method with materials other than silicone, such as rubber-like polyurethane, to produce heart models which have biomechanical properties more representative than current directly printed technologies [27], [55]. Although these models are ‘super-flexible’, there is a considerable cost for each model ($2000-3000) making this method hardly applicable in the production of models required for surgical simulation.

## 2.3 3D printers/materials and their suitability for surgical simulation (HOST)

From the technologies described above material jetting (polyjet) was the most suitable commercially available technique for the anatomical representation and surgical simulation of hearts with congenital defects. The Stratasys J750 Digital Anatomy printer (Stratasys, Eden Prairie, MN) provides the ability to print in both rigid and pliable materials and in a full array of colours (Figure 2.3). This is achieved by mixing print materials in to order to match the mechanical properties of the simulated tissue. These printers are particularly useful in the printing of cardiac and vascular structures [48], [56].


**Figure 2.3:** Stratasys J750 Digital Anatomy Polyjet printer used for congenital heart models for surgical simulation and anatomical models (Stratasys, Eden Prairie, MN).

### 2.3.1 Materials

The 3D printed heart models used for hand-on surgical simulation require the following characteristics:

1) Ability to be printed at a high resolution to accurately represent complex anatomy
2) Pliable material to allow the manipulation of structures and to perform surgical procedures
3) Strength to maintain the structural integrity of the model following printing and to hold sutures that are passed through the material
4) Ability for models to be coloured (either via direct printing or dying) to assist the surgeon in their depth perception during operating
5) Water impermeability properties to allow for flow/pressure studies to evaluate performances (desirable)

Table 2.3 represents the mechanical properties of the materials used in the 3D-printed models [57]–[59]. 'Tensile strength' (MPa) refers to the maximum stress that a material can be stretched prior to it breaking/failing. 'Elongation at break' is the percentage stretch/length a material can sustain prior to breaking. 'Compressive set' is the deformation remaining in a material after the removal of a force that is compressing it. 'Tear resistance' is the materials ability to resist tearing.

**Table 2.3:** Mechanical properties of materials used in 3D-printed heart models

| | Tensile Strength (MPa) | Elongation at Break (%) | Compressive Set (%) | Tensile Tear Resistance (Kg/cm) | Use |
|---|---|---|---|---|---|
| **TangoPlus FLX930** **(Stratasys, Eden Prairie, MN,US)** | 0.8 – 1.5 | 170 – 220 | 4 – 5 | 2 – 4 | Surgical simulation models<br>Anatomical models (intra and extracardiac structures) |
| **Agilus30** **(Stratasys, Eden Prairie, MN,US)** | 2.4 – 3.1 | 220 – 270 | 6 – 7 | 4 – 7 | Surgical simulation models<br>Anatomical models (intra and extracardiac structures) |
| **Vero** **(Stratasys, Eden Prairie, MN,US)** | 50 – 65 | 10 – 25 | N/A | N/A | Anatomical models<br>(extracardiac structures) |
| **Tissue Matrix*** **(Stratasys, Eden Prairie, MN,US)** | N/A | N/A | N/A | N/A | Surgical simulation models<br>Anatomical models (intra and extracardiac structures) |

*Mechanical properties of Tissue Matrix are currently not available

The strength properties of the Vero material make it excellent at displaying extracardiac anatomy well, however the lack of pliability makes it unsuitable for surgical simulation [49]. TangoPlus was the first pliable material available for 3D-printing on the Stratasys Polyjet printers. With reasonable mechanical properties it was utilised for surgical simulation and anatomical representation in congenital heart disease and was the material of choice at our institution [18], [25], [26], [49], [60]. However, from the bench testing I performed (described above), limitations were noted with the material's fragility leading to suture tearing and damage of finer structures (i.e. chordae tendinae and valves)[18]. Therefore I experimented with the newer material Agilus30, which had stronger mechanical properties and overcame the limitations experienced with TangoPlus (Table 2.1). A blinded benchtop experiment was conducted to confirm that the Agilus30 material would outperform the existing TangoPlus material. Tetralogy of Fallot models were printed in both materials and trainee and experienced surgeons were asked to suture on the material and communicate their preferred model material. Following this experiments all anatomical and surgical models were changed to this stronger alternative[19].

Further experimentation with the two flexible resins was performed by myself to investigate the maximum wall thickness achievable. Surgical heart models printed in either TangoPlus and Agilus30 are limited to a maximum wall thickness 1.5mm as further increases impact the pliability of the material making it unsuitable to surgical simulation. Therefore, the printing of cardiac myocardium was not possible which limits some surgical procedures that require the myocardium. Examples include performing a RV-PA (right ventricle-to-pulmonary artery) conduit, which is an essential step in the Norwood operation for hypoplastic left heart syndrome, or muscular septum resection in complex double outlet left ventricle operations.

Tissue Matrix is the most recent addition to the materials available on the J750, alongside the rest of the Digital Anatomy Materials (Bone and Gel Matrix). Data on the material's mechanical properties is not currently available but I have evaluated its suitability for surgical simulation and anatomical representation. In a similar method as the Agilus30 suitability test, heart models were printed in both materials and compared blindly by our cardiovascular surgeons. It was felt that Tissue Matrix more accurately represented real human tissue with a lower degree of force required to pass a needle through the material. The main advantage of Tissue Matrix however is its pliable nature at thicker structures making it an ideal material for myocardial printing (Figure 2.4). The material can also be printed with different mechanical properties with material mixes dedicated to anatomical structures. For example, the J750 is able to print 5 different types of myocardium depending on the desired stiffness (i.e. highly compressible to extremely stiff). These properties are dependent on the ratio of Tissue Matrix and Agilus30 used in the printing. If a stiffer myocardium is required, the amount of Agilus30 added to the print material is increased. Comparison studies confirm our qualitative experiments showing that the printed myocardium in Tissue Matrix is much closer to reality than Agilus30, however it remains inferior to real porcine myocardium for cutting and suturing[56].

In summary the material used for the 3D-printed models in the Hands-on Surgical Training (HOST) are made from Tissue Matrix with anatomical models being made from either Vero, Agilus30 or Tissue Matrix depending on the pathology. TangoPlus is no longer used at our institution.

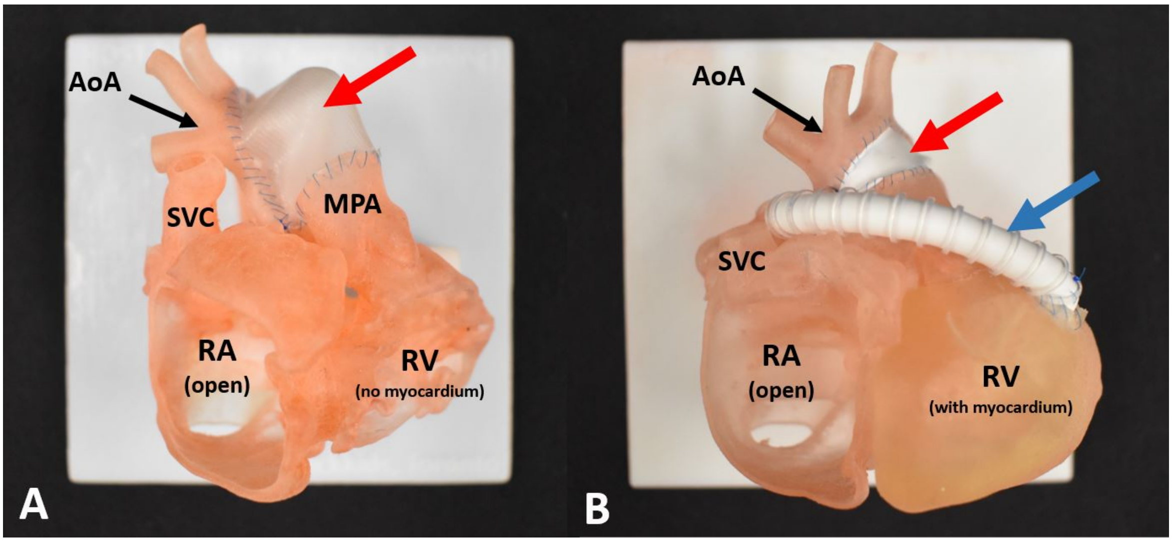



**Figure 2.4:** Hypoplastic left heart syndrome 3D printed models following simulation of the Norwood operation (Red arrow = reconstructed aortic arch – AoA).

A: Heart model printed in Agilus30 (Stratasys, Eden Prairie, MN). As a result of the inability to print myocardium, the surgeon is unable to simulate the right ventricular-to-pulmonary artery (RV-PA) conduit.

B: Same heart model as panel A printed with Tissue Matrix (Stratasys, Eden Prairie, MN). Due to the greater pliability in thicker structures the right ventricle myocardium is able to be printed allowing the surgeon to simulate the RV-PA conduit (Blue arrow). MPA = main pulmonary artery, RA = right atrium, RV = right ventricle, SVC = superior vena cava.

# 3 Development of 3D-printed models for hands-on surgical training (HOST) in congenital heart surgery

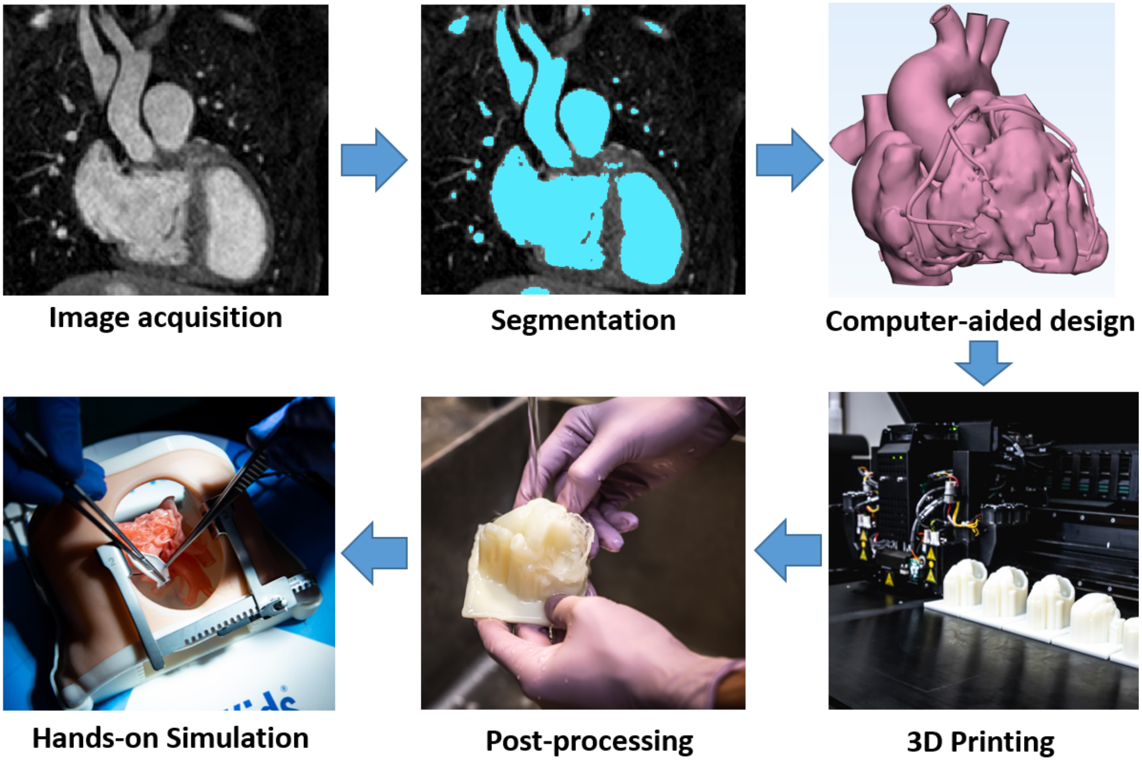



**Figure 3.1:** Diagram showing the steps required to make a 3D-printed congenital heart model for hands-on surgical training (HOST).

## 3.1 Image/DICOM acquisition (Digital Imaging and Communications In Medicine)

The crucial first step in the development of accurate 3D printing heart models is the acquisition of excellent image data. Technologies used in the clinical investigation of patients with congenital heart disease (CHD) include ultrasound (i.e. echocardiography), computed tomography (CT) and magnetic resonance (MR) imaging. These modalities provide accurate information on anatomical structures and allow clinical teams to predict the haemodynamic consequences following planned interventions. CT and MR are superior to echocardiographic studies in the portrayal of cardiovascular anatomy with less artifact and blind spots, however echocardiography provides better detail of the structure and function cardiac valves[49]. The interpretation of complex congenital morphology in a 2-dimensional format involves a mental 3-dimensional reconstruction, which is a skill clinicians and surgeons need to develop over time[49]. This potentially can lead to miscommunication between professionals involved in a patient's care potentially leading to an incorrect understanding of the surgical anatomy[61]. The incorporation of 3D models into clinical decision making is a potential method to improve communication and understanding and has been used effectively for the most complex patient cases [24], [49], [60].

CT and MR angiographies are the best modalities available in the development of 3D heart models. 3D imaging using these techniques provides high resolution images of the patient's heart blood pool making it clearly distinguishable from the myocardium and surrounding anatomical structures; this forms the basis of the 3D model. Images can be taken without electrocardiographic (ECG) or respiratory navigation, however these are ideal to avoid artifact from cardiac or respiratory motion [49], [50]. During ECG-gating it is ideal to target the end-diastolic phase of the cardiac cycle when the heart is in its most relaxed state with maximal ventricular volume. ECG-gated CT angiography is the most common modality used for 3D modelling and provides a special resolution of 0.3-0.7mm. During the scanning process it is vital to time the scan for when all chambers and great vessels are homogeneously enhanced [49], [50]. The contrast medium (>2mm/kg) should be injected for a prolonged period of time (15-20s) and a saline chaser should be injected to minimise artifact from the undiluted contrast in the superior and inferior vena cavae and their tributaries [49], [50]. Contrast-enhanced MR angiography is also an excellent modality to produce images appropriate for 3D printing. Although having a lower special resolution than CT the opacification of the cardiac chambers is more homogeneous in MR angiography than in CT angiography. The delivery system must be primed accurately with saline to ensure the exact amount of contrast is injected during the scan as the contrast volume is less than the dead space volume [50].

Ultrasound can be used for image acquisition for 3D models however it is suboptimal compared to CT and MR. Although excellent in the 3D visualisation of valvular structures and subvalvular apparatus, the limited viewing windows and artifact from bone and air makes it more difficult to capture the necessary data [49], [50]. This modality however has been used in the 3D printing of cardiac valves [25], [62], [63]. Attempts have been made to integrate ultrasound and cross-sectional image data to print heart models, maximising the benefits of both techniques [64], [65].

In order to develop a 3D model the raw DICOM (Digital Imaging and Communication in Medicine) data must be converted to the Cartesian DICOM format with isotropic voxels prior to being imported into the segmentation software [49], [50]. It is important to note that additional steps to export image data from 3D echocardiography may be required depending on the scanner used and is therefore another limitation of this modality.

## 3.2 Segmentation and Design

The following sections of this chapter will outline work that was developed during the course of the research project.

### 3.2.1 Segmentation of blood pool and hollowing of models

There are multiple software packages available for the segmentation process of heart models. These can range from expensive commercially available software to open-source freeware. The software we use for our heart models is the commercially available Mimics software (Materialise, Leuven, Belgium). Once the DICOM data is uploaded onto the platform the areas of interest in the grey-scale images are segmented. An example is shown in Figure 3.2 of a truncus arteriosus case which I segmented. An automated thresholding tool performs this step and can be manually adjusted to focus on the desired regions. Pre-defined threshold sets (i.e. bone and soft tissue) are available to make this step easier, but for congenital hearts manual adjustments of this threshold are almost always required. Due to the complexity of anatomy in most congenital hearts, the thresholding is still not sufficient. Further manual editing and region growing of the segmentation is required to accurately define the boundary between the blood pool and the surrounding soft tissue structures. This step can range from <1hour – to >3 hours depending on the quality of the images and complexity of the anatomy. Tools include a simple erase/add tool where the segmentation can be edited slice-by-slice or via interpolation tools, which are designed to speed up this process. Commonly, incorrect connections are made between adjacent vessels during thresholding, which need to be identified and corrected. This manual work requires a high understanding of congenital heart morphology, cross-sectional image interpretation and knowledge of the limitations of the 3D printing techniques. If models are being developed for pre-surgical planning, then it is compulsory for the final segmentation to be reviewed by an experienced congenital cardiac radiologist to validate the end result. Once the segmentation is finalised the 3D volume data is converted into a STL (stereolithography) file, to make it suitable for 3D printing. This file conversion process allows the user to smoothen the surface of the model via an iteration process. A smooth factor and the number of iterations is chosen. The smoothness of the model improves with each iteration, but sacrifices the detail of the model. Therefore, the user must strike a balance between the model's smoothness and keeping appropriate anatomical detail. For clinical models iterations should be kept to a minimum to preserve anatomical accuracy, particularly for intracardiac structures.

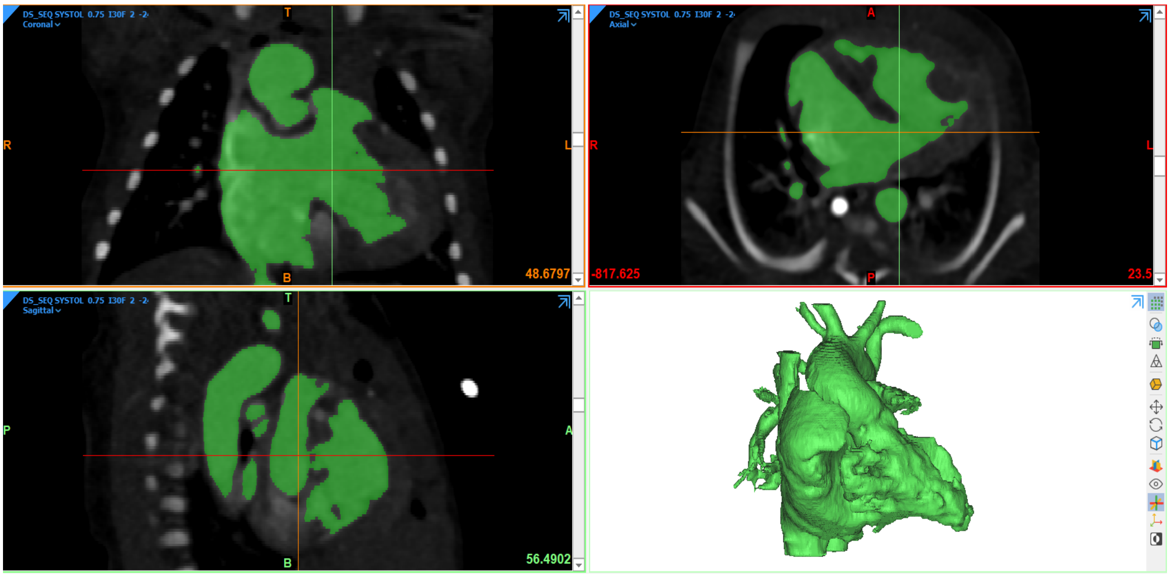



**Figure 3.2:** Segmented blood pool of a truncus arteriosus case using a commercially available software (Mimics - Materialise, Leuven, Belgium) from ECG-gated computed-tomography angiography. The automated thresholding, region growing and manual edit tools have been used to produce the final segmentation. The lower right panel is a 3D rendering of the segmentation, which will be exported as a stereolithography (STL) file for further editing.

Theoretically, this STL is enough to 3D print, however further computer-assisted design (CAD) is required to finalise the model. For this step both open-source and commercially available software are available. For our models we use the 3Matic software (Materialise, Leuven, Belgium). After the STL file is imported into the software, a fix wizard tool is used to remove any noise shells or intersecting/overlapping triangles and to improve the overall mesh of the model (Figure 3.3A). Depending on the purpose of the model the distal vessel branches are trimmed. This saves both printer time/cost and removes additional data that is not required (Figure 3.3B). Models then undergo a hollowing process, which effectively creates a shell along either the external or internal surface of the model. Hollowing along the external surface preserves the model's endocardial surface but may lead to fusing of structures, particularly the extracardiac vessels. An internal surface hollow prevents potential fusion of extracardiac vessels but distorts the endocardial surface detail, which may be inappropriate for clinical and surgical simulation models (Figure 3.4). The thickness of shell is defined by the user; a thicker wall reduces the chances of the model breaking during the post-processing stage but distorts the anatomy, while a thinner shell preserves the original anatomy but is fragile.

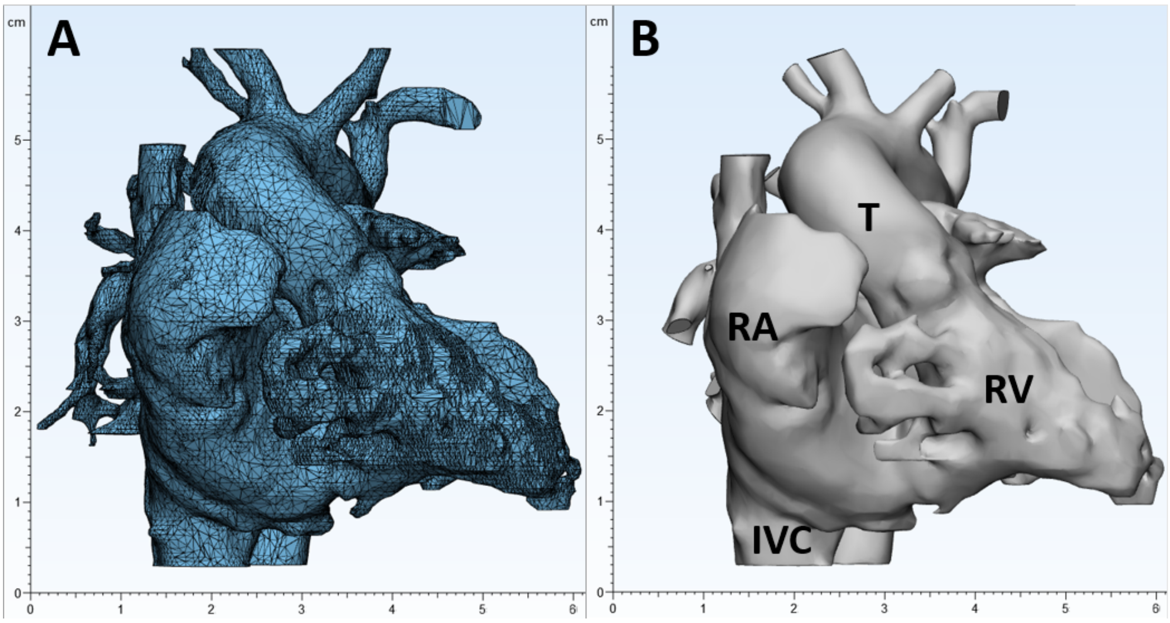



**Figure 3.3:** Stereolithography file of truncus arteriosus case in commercially-available software (3Matic - Materialise, Leuven, Belgium). A: Model following two iterations with a smooth factor 0.3 added. The surface is shown with triangles used to construct the model. B: Cavity trimmed model following correction with fix wizard, localised smoothing and trimming of unwanted structures. This model forms the basis of all printed models. (IVC = inferior vena cava, RA = right atrium, RV = right ventricle, T = truncus arteriosus)

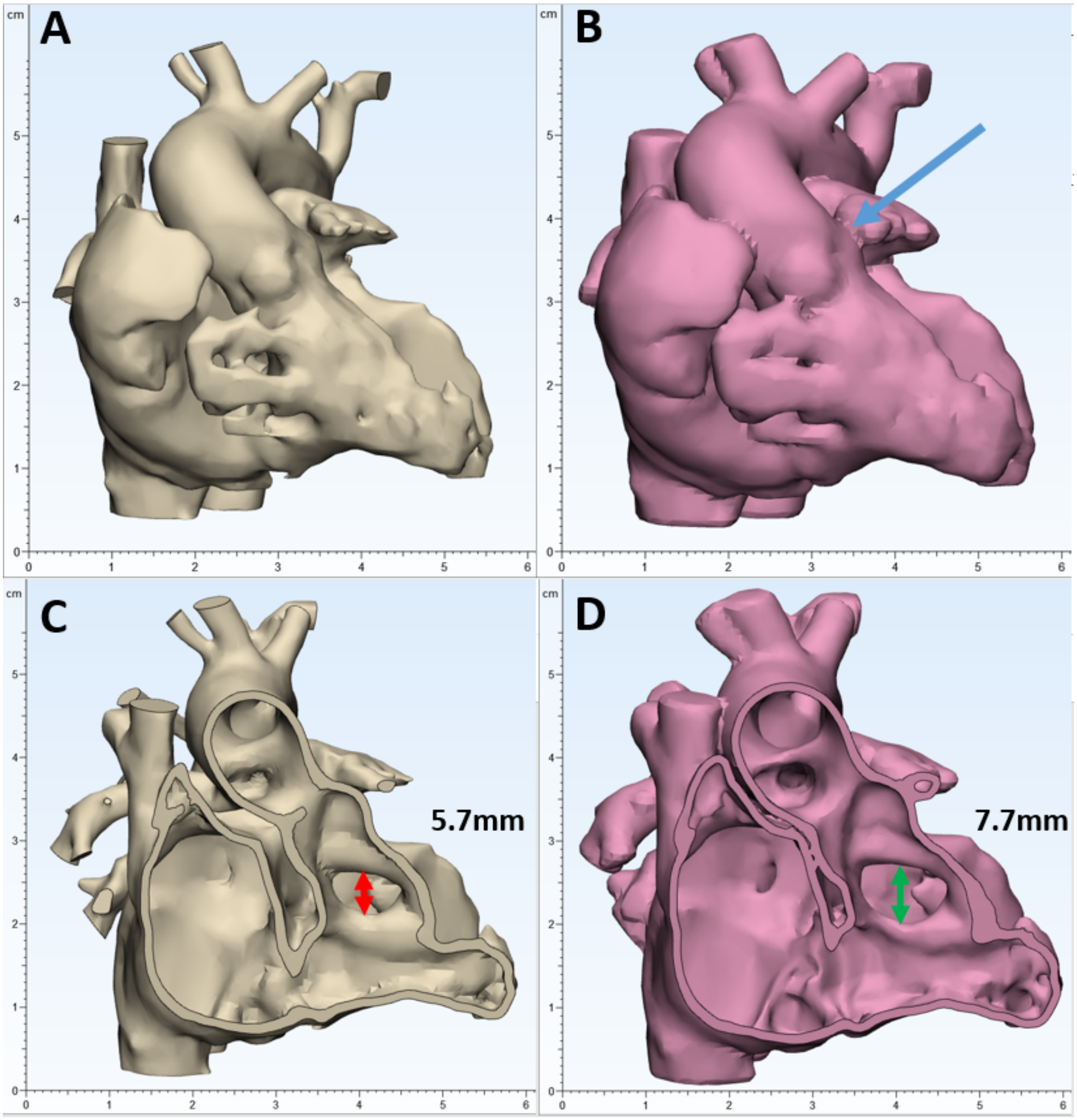



**Figure 3.4:** Truncus arteriosus heart model following the hollowing process of the cavity trimmed model. Internal hollowing is primarily for overview of contrast angiograms whereas external hollowing is for demonstration of the endocardial surface anatomy. A+C: Model following hollowing along the internal surface of the heart (1mm). As a result, the external surface remains accurate. B+D: Model following hollowing along the external surface of the heart (1.0mm). As a result, the great vessels structures fuse (blue arrow). The bottom panel shows the septal view of the hollowed models. C: Internal hollowing leads to a bulky, inaccurate endocardial surface. The ventricular septal defect (VSD) diameter is 5.7mm (red arrow). D: External hollowing preserves the accurate endocardial surface with a true VSD diameter of 7.7mm (green arrow).

Typically for a complete set of heart models three types of models are produced: 1) a cast model, 2) a wall model (basal and septal views) and 3) a surgical simulation model (Table 3.1).

The cast model gives an overview of the blood pool segmentation and is printed in a rigid material.

The wall models demonstrate the intracardiac structures of the heart and are usually hollowed along the outer surface to preserve the endocardial surface. Thickness ranges between 0.8-1.2mm. Basal and septal cuts are made in the wall model to show the base of the ventricles and the ventricular septum respectively (Figure 3.5).

**Table 3.1:** Summary of the types of 3D printed heart models made in our institution for congenital heart disease and model characteristics. *Models printed with Stratasys J750 and 500 Polyjet printers and materials (Stratasys, Eden Prairie, MN).

| | Purpose | Hollow direction | Wall thickness | Print material* |
|---|---|---|---|---|
| **Cast Model** | Overview of blood pool segmentation | Inner surface | >2mm (Support material remains inside model after print) | VeroWhite |
| **Wall Model (Basal and Septal views)** | Accurate anatomical representation of intracardiac anatomy | Outer surface | 0.8-1.2mm | Agilus30 TangoPlus Tissue Matrix |
| **Surgical model** | For hands-on surgical training and pre-operative rehearsal of procedure | Dependant on operation being simulated (i.e. either inner or outer surface or in both directions) | 0.8-1.2mm | Agilus30 Tissue Matrix |

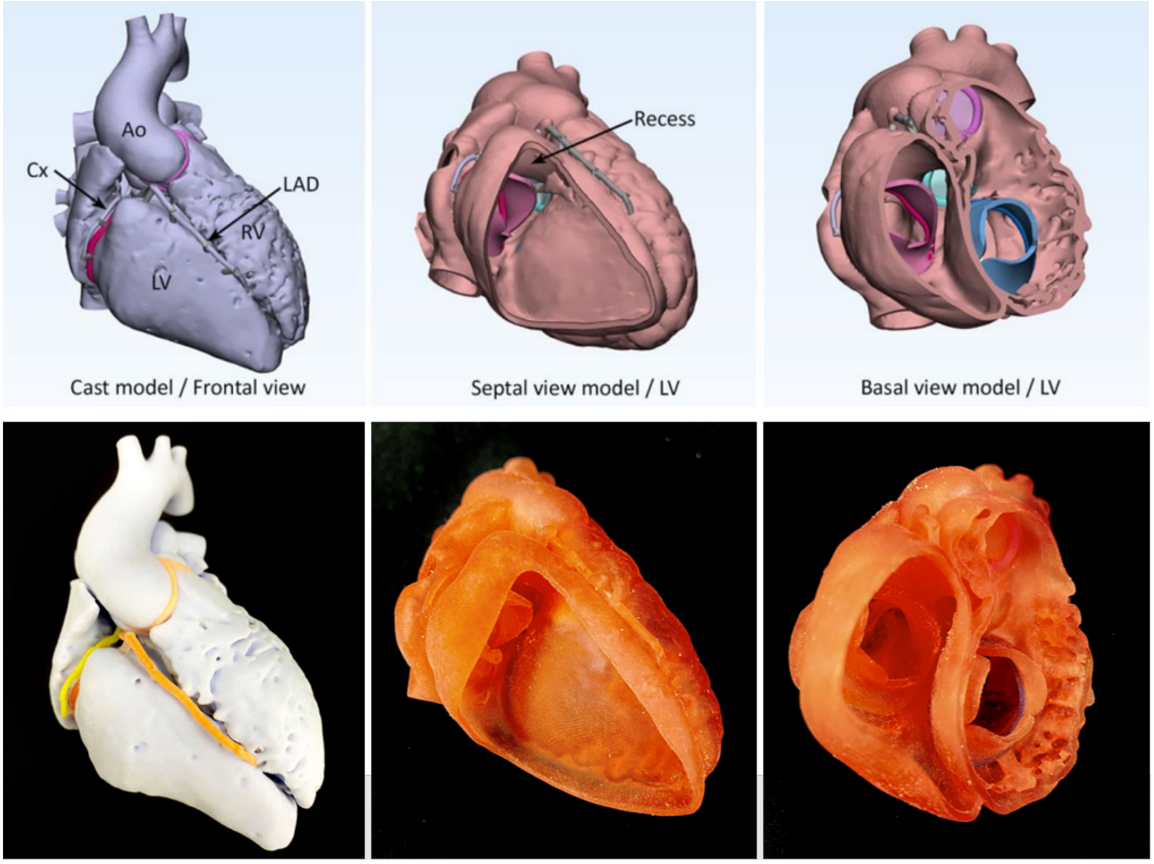



**Figure 3.5:** 3D-printed models of congenitally corrected transposition of the great arteries with a small perimembraneous ventricular septal defect used for morphology teaching. Top panels show the computed-aided design models and bottom panels show the 3D-printed models. The left panels show the rigid cast model of the blood pool. The middle panels are the walled model in the septal view and the right panels show the basal views. Note the coronary arteries and valves are incorporated in the models. (Ao = aorta, Cx = circumflex artery, LAD = left anterior descending artery, LV = left ventricle, RV = right ventricle).

The surgical simulation models are also hollowed structures however; the degree of hollowing is dependent on the procedure the model is intended to simulate. For example, for purely extracardiac operations (i.e. Norwood operation for hypoplastic left heart syndrome) the models are hollowed both externally and internally so that fusion of extracardiac vessels is avoided and the luminal patency is maintained. However for intracardiac procedures (i.e. ventricular septal defect repairs) the models are externally hollowed as endocardial surface accuracy is of greater importance. Both wall and surgical models require partial removal of the atrial or ventricular walls to assist removal of support material following the print. In order to optimise the model for the intended surgical simulation I experimented with both internal and external hollowing going through several iterations before the ideal model thickness and degree of hollowing was confirmed.

### 3.2.2 Myocardial segmentation

With the method described above the surface of the heart in the walled models are not truly representative of reality. Ideally models should have the inner endocardial surface and outer epicardial surfaces clearly delineated with the space in between segmented. The main reasons for this not being achieved are two-fold: firstly, myocardial segmentation on CT or MR datasets is challenging as the outer surface of the heart and vessels have low-level signal intensity differences between the cardiac wall and the adjacent soft tissue structures [50]. This makes it difficult to accurately segment the epicardial surface. Secondly, the commonly available print materials (TangoPlus and Agilus30 - Stratasys, Eden Prairie, MN) become particularly stiff when wall thickness is >2mm, therefore the model loses its flexible characteristics. However, the latest print material (Tissue Matrix - Stratasys, Eden Prairie, MN) remains highly flexible when printed at greater thickness, making realistic myocardial printing a possibility.

High quality image data is required to segment myocardium accurately and is particularly challenging in paediatric patients. Due to the limitations described, the incorporation of myocardium was not possible with the existing surgical simulation models. However to overcome this I segmented the myocardium in a similar way to the blood pool segmentation. As the borders of the external myocardium can still be challenging to delineate with high quality images, I used a combination multiple slice editing and region growth to capture the true myocardium (Figure 3.6). I then exported the myocardial segmentation STL file into the CAD software and smoothened the object's surface. At this stage the myocardium part was a solid structure without the ventricular cavity, therefore I used a boolean subtraction tool to remove the ventricular cavity volume from the myocardium part using the blood pool file. The final step involved using a boolean union function to fuse the myocardium with the existing surgical simulation model to produce a uniformed model with the myocardium included.

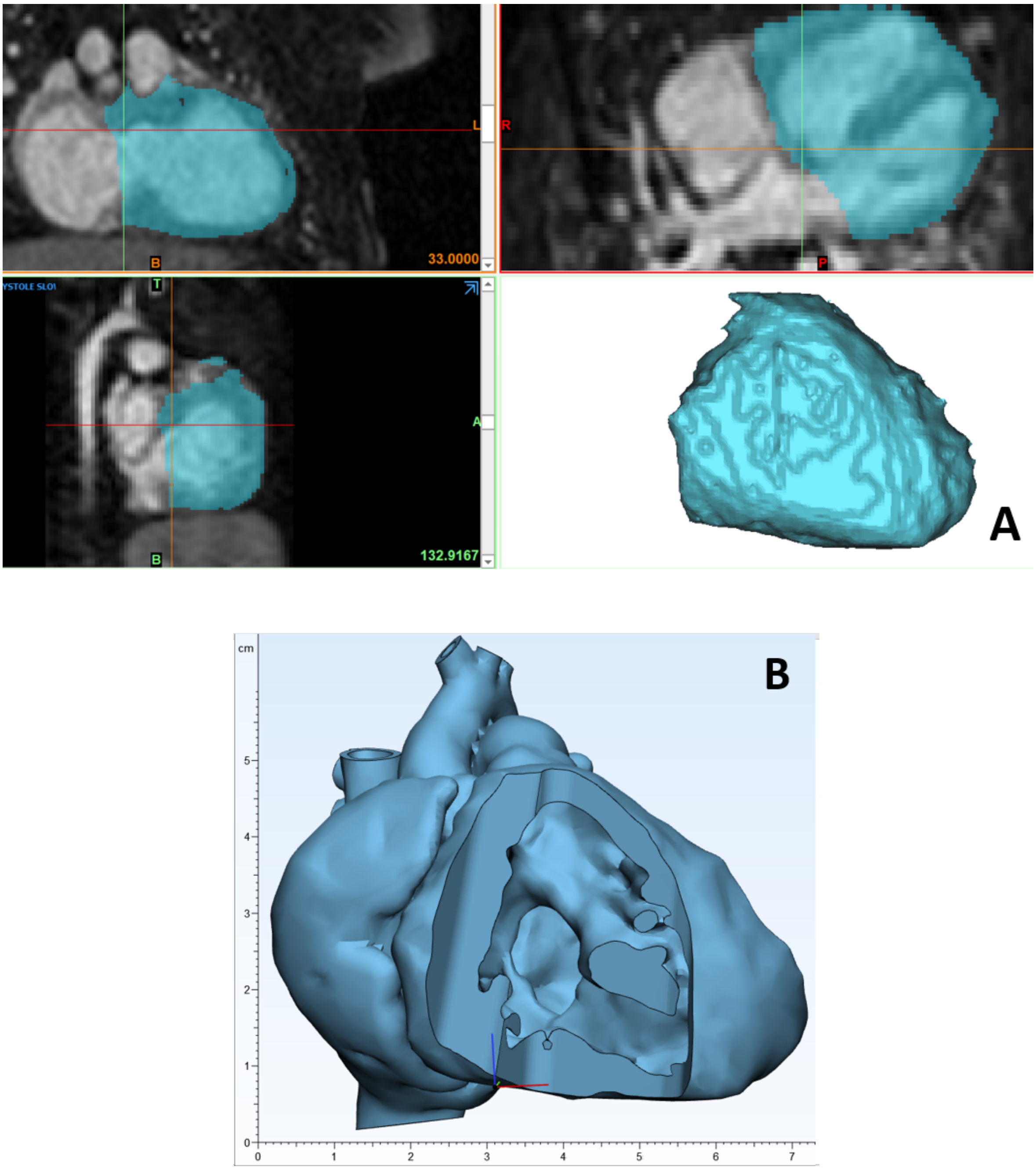



**Figure 3.6:** A: Myocardial segmentation of double outlet right ventricle case. Both the blood pool and the myocardium are segmented. The bottom right panel (A) shows the 3D-render of the segmentation. B: The myocardial model is added to the hollowed wall model in the 3Matic software (Materialise, Leuven, Belgium). Both the endocardial and epicardial walls are accurate.

### 3.2.3 Addition of coronary arteries to models

Occasionally coronary arteries are required in 3D printed models for anatomical representation or specific surgical simulation models (i.e. arterial switch operation for transposition of the great arteries). In paediatric-sized patients the coronary arteries are usually too small to be segmented during the automated thresholding process or via manual segmentation. To overcome this limitation, we utilised the spline/thin structure tool to manually trace the coronary arteries from the image data. Usually, it is possible to delineate the left and right coronaries, however the distal branches may be limited due to vessel size and image quality. The splines created are then imported into the CAD software. We then used a sweep loft tool to give a thickness which is interpolated along the vessel length. Support cylinders are added along the length of the vessels to prevent them from being damaged during the removal of the support material. The coronaries and supporting structures are then booleaned to the cavity trimmed model prior to the hollowing process. Usually the coronaries are too narrow <2mm, to be successfully hollowed, however the coronary ostia are usually visible on the wall and surgical models (Figure 3.7).

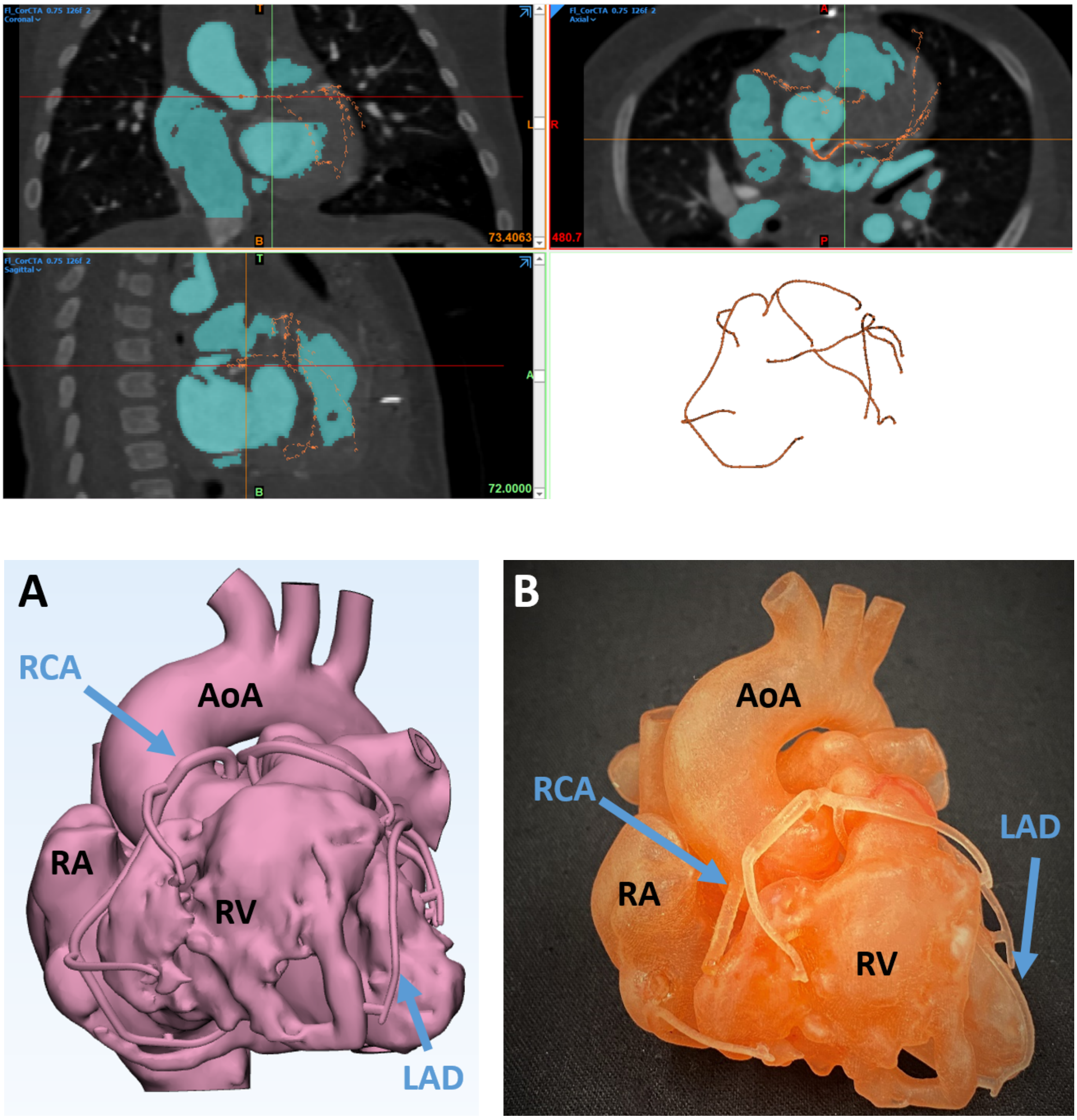



**Figure 3.7:** Top panel: Segmented tetralogy of fallot with post-op pulmonary artery stenosis. The coronary arteries are too small to be segmented. A spline tool is used to trace the coronaries (orange lines). The splines are given a thickness and added to the hollow wall model (Panel A). Panel B shows the 3D-printed model. (AoA = aortic arch, LAD = left anterior descending artery, RA = right atrium, RCA = right coronary artery, RV = right ventricle).

### 3.2.4 Development of valvular and subvalvular structures

A limitation of CT and MR imaging is the ability to accurately delineate moving, thin (<1mm) structures such as the valve leaflets and chordae tendinae. To overcome this we graphically-designed the cardiac valves and incorporated into the models to increase the overall quality, albeit with a loss of anatomical accuracy. The graphically-designed valves are cross-referenced with anatomical knowledge from specimens and the patient’s echocardiographic data if available. It is vital that clinicians and surgeons using the models for pre-surgical intervention are informed that these valves are a best estimate and do not accurately represent reality.

To develop the graphically-designed valves I used the spline tool to outline the annulus on all the valves. This step can be completed with relative ease and is accurate. In a similar method to the coronary artery development I used a sweep tool in the CAD software to give the spline a thickness that represented the valve annulus. Using the annulus as a frame, I used a graphically designed valve scaffold made by supporting cylinders and using a draw tool defined the outline of the individual leaflets. I then created a surface on the drawn leaflets using a reconstruction tool and subsequently gave the leaflets a thickness of 0.6-0.8mm using a wrap tool. All individual structures were then booleaned to create the final valve model (Figure 3.8).

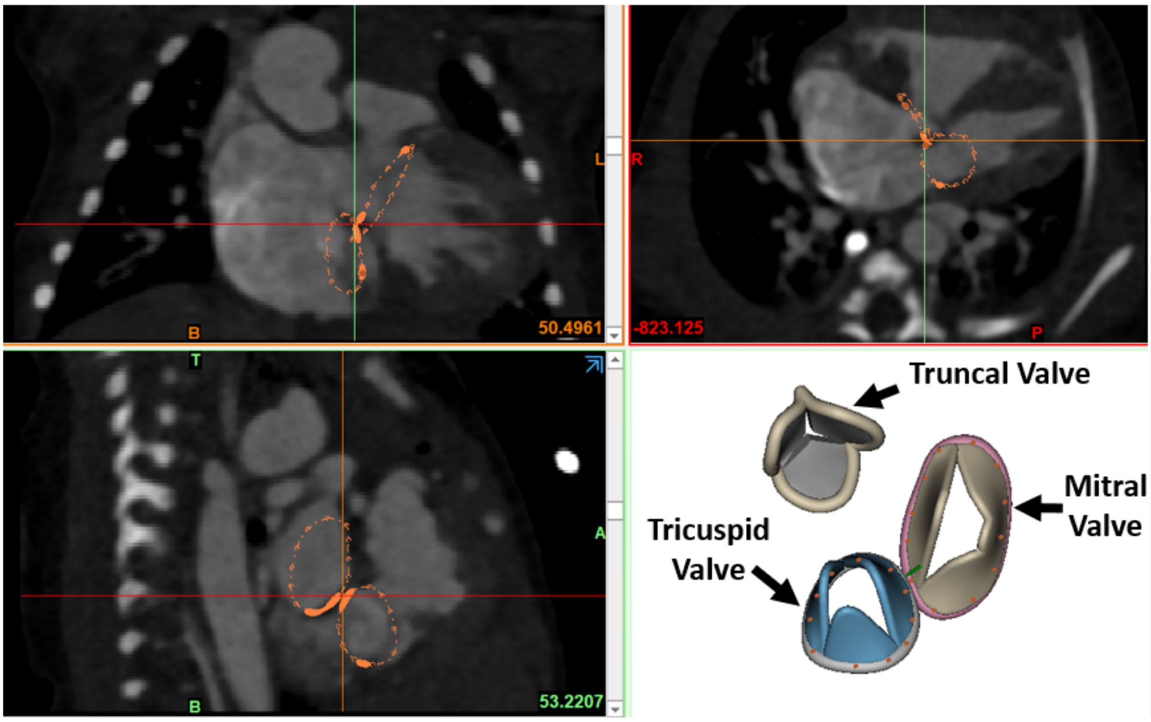



**Figure 3.8:** A spline/thin structure tool is used in the segmentation software (Mimics – Materialise, Leuven, Belgium) to accurately trace the margins of the valve annuli on the cross-sectional images (orange lines). These are given a thickness (1mm) in the computed-aided design software where the valve leaflets are designed (bottom right panel). Leaflet thickness of 0.6-0.8mm is given. The annuli of the aortic and pulmonary valves can also be traced on the STL files using graphic software (3Matics – Materialise, Leuven, Belgium).

To incorporate the chordae tendinae to the atrioventricular valves, a similar process is used to create individual chords from the papillary muscles to the leaflet edge. The papillary muscles are usually accurately captured in the initial blood pool segmentation making them anatomically accurate. First I drew lines from the segmented papillary muscles to the corresponding leaflet edge and gave them a thickness (0.8-1mm) using a sweep loft tool to represent the primary chords. Secondary and tertiary chords were developed in the same manner. I then combined all the chords together to create the subvalvar apparatus (Figure 3.9).

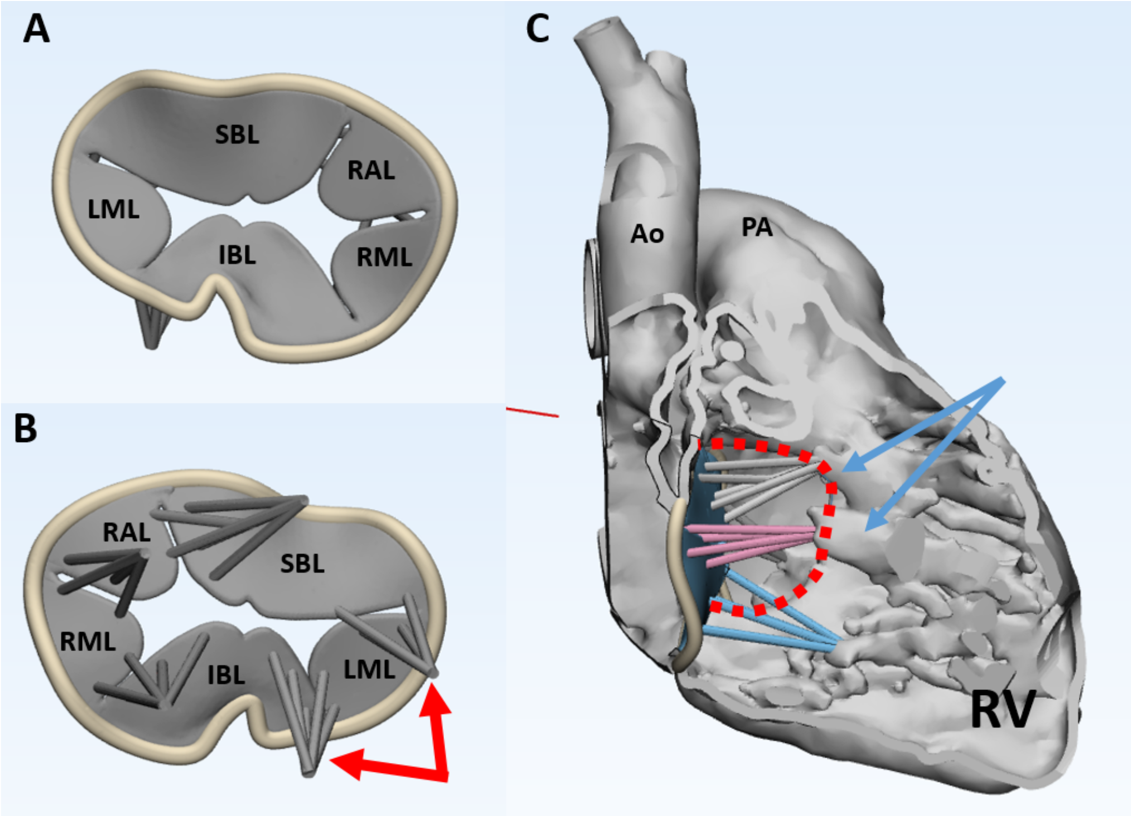



**Figure 3.9:** Graphically-designed atrioventricular valve with an atrioventricular septal defect (AVSD) - Rastelli Type A. A = Superior view from the atrium. B = Inferior view from the ventricular apex. Primary chords are graphically designed and included (red arrows). The valve and subvalvular apparatus is added to the hollowed wall model (Panel C). Papillary muscles are segmented from the original blood pool (blue arrows). Red-dashed line = ventricular margin of the AVSD. (Ao = Aorta, IBL = inferior bridging leaflet, LML = left mural leaflet, PA = pulmonary artery, RAL = right anterior leaflet, RML = right mural leaflet, RV = right ventricle, SBL = superior bridging leaflet)

### 3.2.5 Completion of models for hands-on surgical simulation

Following the incorporation of the coronary arteries and valvular structures the final step involves making the final model appropriate for surgical simulation. Firstly I needed to understand the purpose of the operation and the exposure the surgeon is likely to expect in reality. For example, for an intracardiac procedures (i.e. ventricular septal defect repairs) the transatrial approach through the right atrial wall is usually used. After consultation with experienced congenital heart surgeons and watching intraoperative cases, I orientated the model to represent the exposure that the operating surgeon would experience with the right atrial free wall removed. For procedures that mainly involving an extracardiac component I orientated the models into the normal anatomical position. Simple coarctation of the aorta models were orientated into the left thoracotomy approach position (Figure 3.10). Following confirmation of the model position by experienced surgeons, a base was created [80mm (w) x 80mm (l) x 3mm (d)] with a platform which supports the heart model. Additional supporting structures may be added to the extracardiac structures to avoid them moving once cut (i.e. descending aorta after transection). The base was designed specifically to be inserted into the hands-on surgical training (HOST) chest wall simulator, which is described in chapter 9.

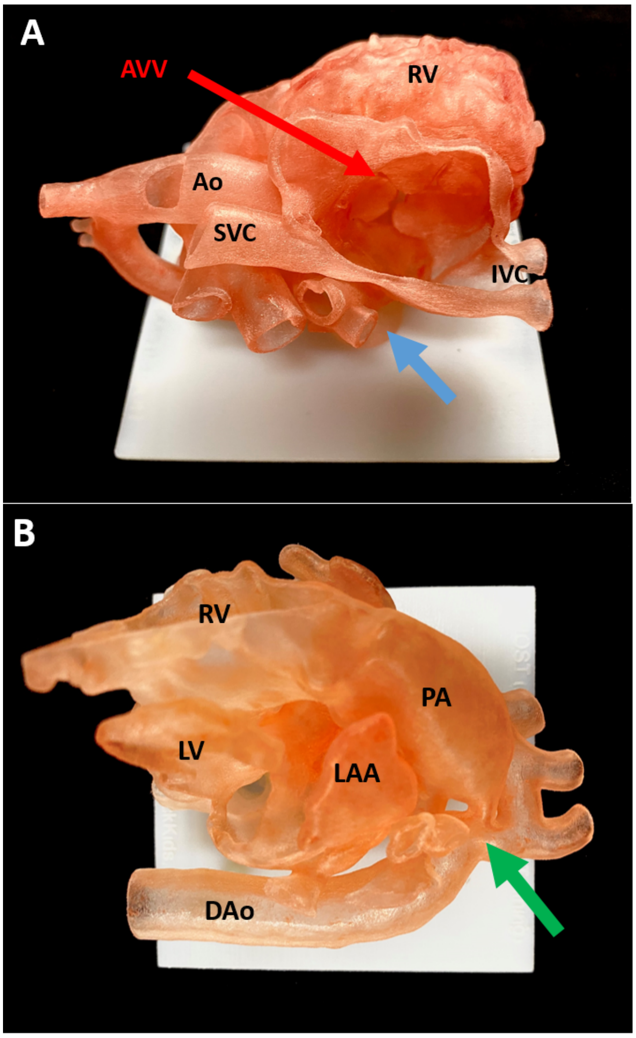



**Figure 3.10:** 3D-print models used for hands-on surgical training (HOST) in congenital heart surgery. A: Atrioventricular septal defect (AVSD) model – Rastelli A. The model is orientated in the surgical view the operator would experience in reality. The right atrium (RA) free wall is removed to help with exposure. The blue arrow identifies the graphically-designed support cylinder to hold the model in the desired orientation. Red arrow = atrioventricular valve (AVV)

B: Coarctation of aorta model orientated in the left thoracotomy position. The coarctation segment is identified by the green arrow. Both models rest on a graphically-designed base that fits in the dedicated chest wall simulator. (Ao = aorta, DAo = descending aorta, IVC = inferior vena cava, LAA = left atrial appendage, LV = left ventricle, PA = pulmonary artery, RV = right ventricle, SVC = superior vena cava)

### 3.2.6 Graphically-designed patches to assist pre-surgical planning

One of the common reasons congenital heart models are requested is for the suitability of biventricular repairs, particularly in complex pathologies such as double outlet right ventricle [49], [60]. Making the correct decision pre-operatively is crucial as an inappropriate decision to pursue the biventricular repair pathway could prove catastrophic to the patient. Alternatively, if the single ventricle palliation pathway is chosen in a patient who could tolerate a biventricular repair, it unnecessarily renders the patient to lifelong complications associated with high systemic venous pressures and low cardiac output [60]. 3D models have shown to be useful to assist pre-operative decision making in these complex patients, and decrease overall operating time [49], [60], [66], [67]. To pursue a biventricular ventricular repair the surgeon needs to consider the following variables: 1) if an unobstructed intraventricular baffle can successfully be sutured from the margin of the ventricular septal defect (VSD) to either the aorta or less commonly, the pulmonary artery; 2) if the baffle will compromise the function of the tricuspid valve; 3) if the baffle will occupy too much space within the right ventricular (RV) cavity and compromise the RV volume; 4) if the VSD should be and can be enlarged, and 5) if the infundibular septum should and can be resected to allow enough space for intraventricular baffling. In order to assist in the answering these questions, here I describe the development of graphically-designed baffles which were integrated into the models.

From the CT and MRI images I traced the margin of the VSD and desired outflow tract annulus. Between these two margins the curvature of a potential baffle was drawn. Several curved splines were then added to the CAD software to develop the natural geometry of the patch. A surface reconstruction was created in a similar method to the valve leaflets described above. The patch material was given a thickness, similar to the valve leaflet thickness in order to be printed. During this process the VSD can also be enlarged and/or the infundibular septum can be resected if required, however the degree is not completely accurate as it is difficult to delineate the surface of the heart at this point on the scan. The baffle was then inserted into the model and printed. The surgeon can then evaluate the likelihood of a successful, unobstructed baffle. As the tricuspid valve is included in the model the possibility or degree of tricuspid valve compromise can also be assessed (Figure 3.11). Although this method has been particularly useful in our experience, particularly in pre- and intra-operative decision making, surgeons have to be aware of the models limitations. One important consideration is that cross-sectional images taken for clinical use are often captured during the end-systolic phase, when the ventricular volume is at its lowest. Therefore, the model may underestimate the true volume within the right ventricle. This can be overcome with requesting that the images be ECG-gated to capture the end-diastolic phase and should be done if one expects a 3D model to be made from these images. The other important consideration is that both the valve/subvalvular structures and the baffle are graphically designed and may be subject to error. Therefore, surgeons are encouraged to use the 3D model as a reference, alongside the other imaging investigations rather than to solely rely on the model.

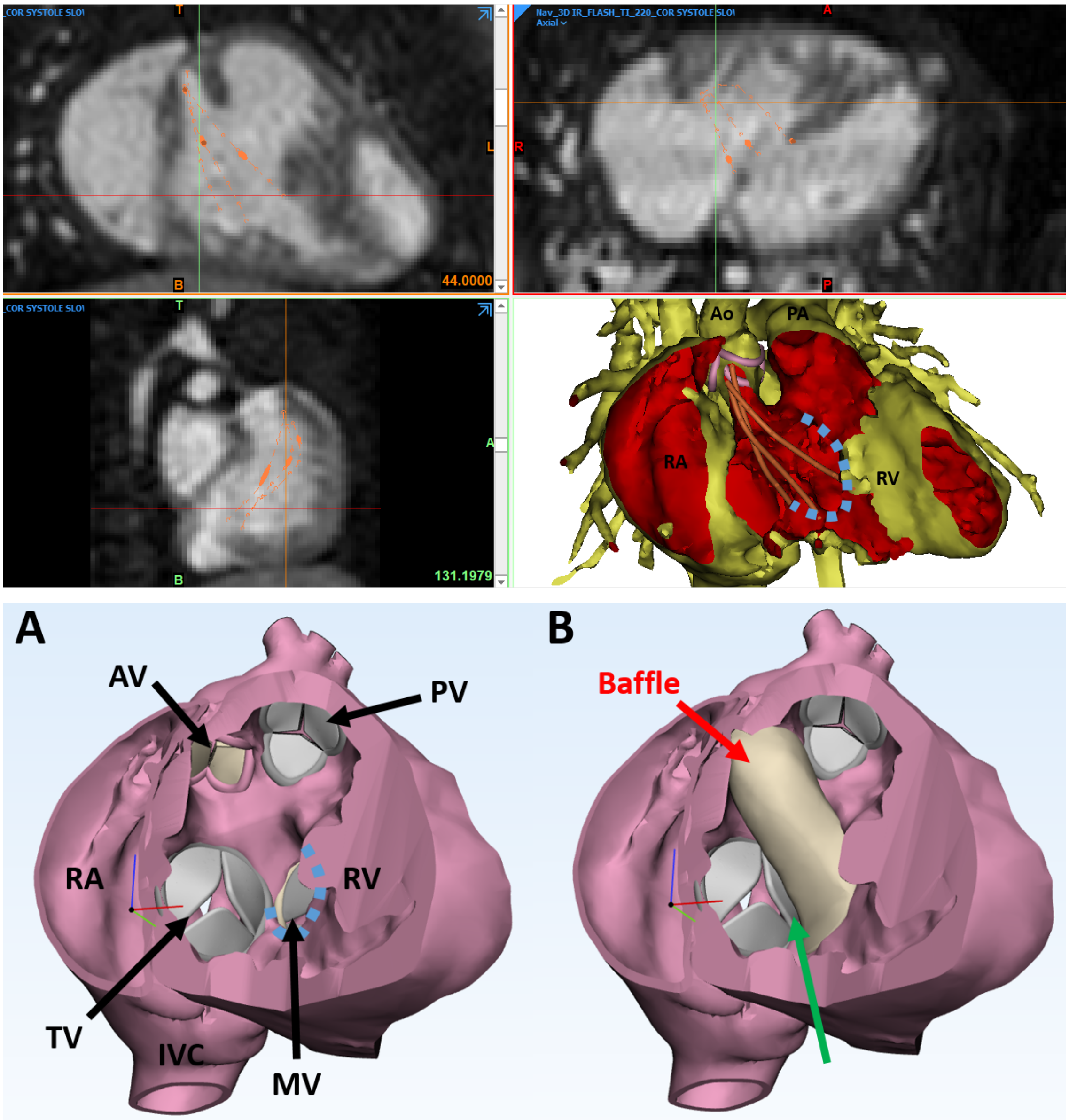



**Figure 3.11:** Graphically-design intraventicular baffle to assist in pre-surgical decision making in a double outlet right ventricle (DORV) case. Top/middle panels: A spline tool is used to trace the ideal curvature of the baffle from the ventricular septal defect (VSD) rim (blue-dashed line) to the aortic valve on a patient computed-tomography (CT) images (orange lines). A: Septal model with myocardium following resection of infundibular septum. The right ventricular (RV) wall is removed to assist with the view. All the valves are graphically-designed and included in the model. B: The graphically-designed baffle is added to the model, based on the pre-drawn lines on the CT images. The surgeon is able to evaluate the length of the baffle and how much of the RV cavity it will occupy and the proximity to tricuspid valve (TV) [green arrow]. (Ao = aorta, AV = aortic valve, IVC = inferior vena cava)

## 3.3 Printing of surgical models for simulation

Once the models are completed, the individual parts are exported as STL files. These are uploaded as an assembly on the 3D printer's dedicated software. Our institution uses the GrabCAD Print ™ Digital Anatomy software (Stratasys, Eden Prairie, MN) for the J750 printer. The software allows the selection of specific materials and colours for each individual STL. This is useful in the surgical and anatomical models as specific regions can be assigned a colour to assist the surgeon to differentiate between the structures whilst operating. The models are then arranged on the print tray and sent to print. Approximately surgical models take 4-6 hours to print. Further detail of the printers and materials included in chapter 2.

## 3.4 Post processing and Quality check of Heart models

On completion of printing the heart models need to be carefully post-processed. This first step involves the manual removal of the majority of the support material with a waterjet. Following this the remaining support material needs to be carefully removed with picks and pipe cleaners. With structures with diameters of <1mm, this process must be performed by a highly skilled technician with an understanding of the complex anatomy to avoid inadvertent damage. There are chemical solutions available to help dissolve the support material but we have found in our experience that they both prolong this step and change the biomechanical properties of the model making it unsuitable for surgical simulation.

The 3D printer has colour characteristics, however the colours available are solely from the rigid materials. As more colour is added to the print the more rigid the model becomes making it unsuitable for simulation. Therefore, we print all our models without colour except a small amount to colour the valve annuli and proceed to dye the models after the washing process. The overall time to post-process a single surgical model can range between 10-30 minutes depending on the complexity. Once the models are dyed they go through a strict quality control phase, prior to being approved for surgical simulation (Figure 3.12). Although, optimal care is taken to preserve all models the failure rate of printing can range between 10-15%, which must be considered in the costing of the programme.

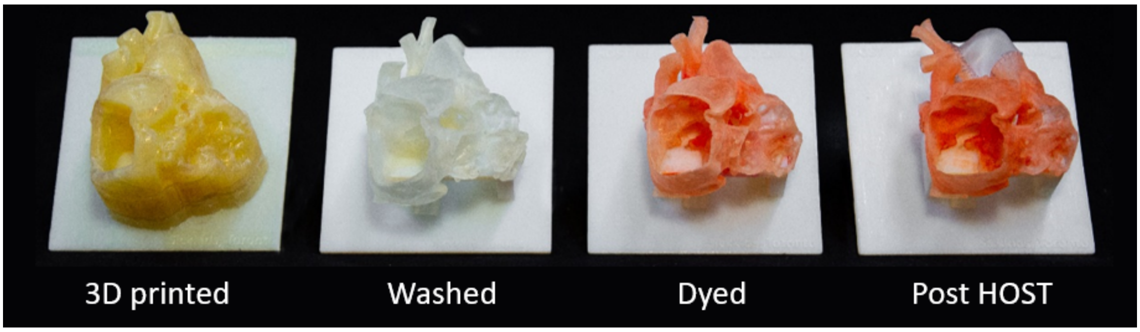



**Figure 3.12:** Process to make 3D-printed hypoplastic left heart syndrome model for hands-on surgical training (HOST). The model is first printed with support material (first), which is then removed following water-jetting and manual removal (second). The model is dyed (third) and following a quality check is then ready to be used for surgical simulation of the Norwood operation (fourth).

Some operations, such as the arterial switch operation, require surgeons to carefully dissect the coronary arteries to mobilise them to the new position. With the current printing limitations, coronary arteries are 'floating' on the heart models, therefore this important step cannot be simulated. To overcome this, I used silicone (EcoFlex 30, Smooth-On Inc, Easton, PA) to coat the interventricular groove and coronary arteries, which acted as an excellent medium to simulate proper coronary artery dissection.

## 3.5 Limitations and Future Perspectives

There are limitations throughout all steps involved in the 3D printing of heart models. In order to print anatomically accurate models imaging modalities require high temporal and spatial resolutions. Fine moving structures such as valves and subvalvular apparatus are particularly difficult to delineate with CT or MR. This is high importance as abnormalities in these structures can lead to significant haemodynamic and functional consequences. Therefore harnessing the ability to accurately represent these should be the focus of future work [49]. This possibility is not far off as we have been able to successfully use high-resolution CT image and CAD to develop an accurate normal adult mitral valve which includes chordae tendinae and papillary muscles (Figure 3.13). Hybrid techniques using image-fusion technology are being experimented by combining multiple imaging modalities to benefit from all the advantages of each technique offers [64], [65].

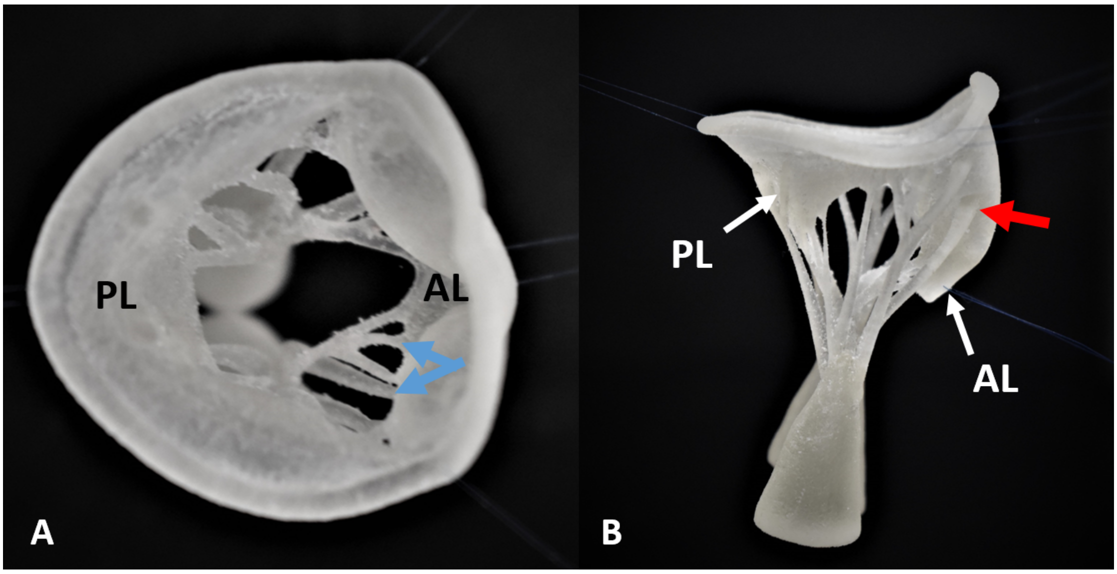



**Figure 3.13:** 3D-printed mitral valve using high-resolution computed tomography (CT). A: left atrial view of the opened valve. B: lateral view of the open valve. The CT images were used to delineate the leaflet free edges, the precise location of the papillary muscle and the trajectory of the chordae tendinae (1mm thickness). These were then graphically-designed to develop an accurate mitral valve model. Primary (blue arrows) and secondary chords (red arrows) were able to be developed in the model. (AL – anterior leaflet, PL – posterior leaflet)

The segmentation process in congenital heart disease requires a high level of expert input to ensure accurate models are produced. Although automated thresholding tools exist there is still a significant time commitment required for manual editing of the blood pool segmentation. This can be particularly difficult when adjacent structures have similar signal intensities preventing accurate automatic segmentation [49]. With the growth of machine learning in other industries, in time this could be potentially used to improve the segmentation aspect of this process. However, this is likely to be first established in other specialities where anatomical complexity and variation are not as prevalent as congenital heart disease (i.e. orthopaedic and maxillofacial surgery).

Improvements in printing methods and technologies will continue to address the prolonged time taken to print models. The post-processing stage is currently time-consuming and requires technical skill. The labour required to ensure proper post-processing can be expensive and should be considered when starting a programme. Work is being done by industry to develop solutions to improve this process, however currently none of the commercially available products are more efficient or cost effective than our current set up.

Although considered excellent in the simulation of complex congenital heart procedures (evidenced in later chapters) there are still a number of limitations to 3D models. One obvious limitation is the lack of physiology of this training platform (i.e. the absence of fluid dynamics). Therefore surgeons are unable to perform key aspects of the operations such as the establishment of cardiopulmonary bypass or assess the quality of their repair (i.e. flow through the coronary arteries following an arterial switch operation or determining if a cleft is regurgitant or competent following atrioventricular septal defect repair). In order to improve this simulation platform further work is required to investigate if physiology could be incorporated to increase the fidelity of this platform.

## 3.6 Utilisation of 3D models for surgical simulation in congenital heart surgery

The focus of the following chapters will be on the use of these 3D printed models in the simulation of congenital heart surgical procedures in trainee surgeons. However, it is worth mentioning that this simulation method far extends this cohort with this technology being applicable to all stages of medical/surgical training, albeit with differing objectives. For example, at the medical student/junior doctor level this platform would primarily be used in the education of complex anatomy and morphology. This can also be extended by introducing basic surgical skills and assistance principles to this cohort, which is demonstrated later in chapter 10.

For surgical trainees, these models can initially be used to teach the principles of congenital surgical operations starting from simpler cases and progressing to more complex pathologies. This can also be beneficial for newly-appointed congenital heart surgeons, providing them with a safe platform to rehearse and refine their surgical skills and sequencing prior to them performing on real-life patients. For surgeons who have had a period of absence from surgical practice (i.e. injury/illness, research) simulation could be used to support return to work initiatives and assess when a surgeon is suitable to return to patient surgical care.

The benefits can also extend to senior surgeons as patient-specific models can be designed to assist surgeons to develop or refine new procedures prior to patient application. With the publication of unit specific outcomes in congenital heart surgery, simulation can potentially be used to assist in the re-training of surgeons whose performance levels have dropped below predicted. These are all potential benefits that simulation provides and should be the focus for future research.

# 4 Hands-on surgical simulation in congenital heart surgery: Literature review and future perspective

The following chapter has been adapted from the following publication to suit the flow of this thesis. Permission has been granted from the publisher Elsevier.

***Nabil Hussein****, Osami Honjo, Christoph Haller, Edward Hickey, John G. Coles, William G. Williams, Shi-Joon Yoo. Hands-on surgical simulation in congenital heart surgery: Literature review and future perspective.*

*Seminars in Thoracic and Cardiovascular Surgery. 2020 Spring;32(1):98-105. doi: 10.1053/j.semtcvs.2019.06.003. Epub 2019 Jun 17. PMID: 31220532.*

NH contributions to this publication: Conception and design, literature search/ data collection, analysis and interpretation, writing of the article, critical revision and final approval of the article.

## 4.1 Introduction

Prior to exploring the impact of 3D-printed heart models in the training of congenital heart surgeons we sought to review the current literature and analyse where hands-on surgical training has been employed within CHS. We also evaluate how simulation can work synergistically with effective mentoring to address the issues of overcoming the steep learning curve in complex CHS.

## 4.2 Materials and Methods

A keyword-based PubMed literature search was conducted for hands-on surgical simulation in congenital heart surgery. Terms included 'congenital cardiac/heart surgery simulation' and '3D printing cardiac surgery simulation'. The abstracts/titles of the search were reviewed and papers using simulation specific to congenital cardiac surgery selected. Papers that demonstrated a single, proof of concept of surgical simulation in CHS were also selected for review. Studies that did not include surgeons operating on the simulator were excluded. If no assessments were made of the models or simulation method, these were also excluded.

Our analysis includes the following points:

1) Problem that the simulators addressed
2) Type of simulator
3) Methodology (including cost)
4) Assessment methods
5) Results
6) Perceived benefits/limitations
7) Reproducibility and potential implementation in a standardised congenital cardiac surgery curriculum

## 4.3 Results

The key-word based literature review generated 266 papers in total. After reviewing all titles/abstracts, 15 papers were selected to be suitable for review. Only 5 of these papers identified fulfilled our selection criteria of hands on surgical simulation in CHS with an assessment of simulator or procedural performance. One simulation used animal models, whereas the other four utilised 3D-printed models. Table 4.1 summarises the studies reviewed:

**Table 4.1:** Summary table of published studies utilising hands on surgical simulation in congenital heart surgery with an assessment of the simulator or procedural performance

| Study | Problem addressing | Type of Simulator | Methodology | Assessment | Results | Benefits | Limitations | Reproduced |
|---|---|---|---|---|---|---|---|---|
| Mavroudis et al [69] | Multiple complex congenital procedures | Animal (neonatal porcine models) | - Single cardiothoracic resident<br>- Single proctor<br>-11 procedures on 5 neonatal piglets<br>- Duration: 2.5 days<br>- Cost: Not included | Operating time | Not published | - Similar anatomic relationships, tissue characteristics and intraoperative challenges<br>- Multiple procedures on single model<br>- Immediate feedback<br>- Excellent for neonatal simulation | - Extended discussion between proctor and surgeon affected operating time | No |
| | | | | Analysis of videotaping | Not published | | | |
| | | | | Pressurised saline infusion of repairs | No gross leaks in repairs | | | |
| Yoo et al [18] | Multiple complex congenital procedures | 3D printed models (Tango+) | - 81 attendees at 3 different courses<br>- 3-4 proctors at each course<br>- Procedures: 3-5 models<br>- Duration: 2 hours to 2.5 days<br>- Data: Pre-operative cross-sectional imaging<br>- Cost: $150-$210 (excluding labour costs) | Questionnaire | -62% completed questionnaires<br>- All found course useful and would like incorporation into training programs<br>- Accurate pathological findings<br>- Excellent quality of models<br>- Helpful for improving surgical skill | - Accurate patient/pathology specific models | - Limitations in model material (fragility/elasticity)<br>- Lack of valves and supporting structures<br>- Heart wall, chest wall and surrounding structures not represented<br>- Expensive<br>- Model not reusable | Yes |

| Study | Problem addressing | Type of Simulator | Methodology | Assessment | Results | Benefits | Limitations | Reproduced |
|---|---|---|---|---|---|---|---|---|
| Scanlan et al [25] | Paediatric atrio-ventricular valve repairs | Directly 3D printed models (Tango+) and<br>Molded models (Silicone) | - 8 surgeons<br>- 3 models (MV, TV and cAVSD) in both materials<br>- Procedures: 2 (TV annuloplasty + AVSD repair) on each model type (Tango+ + Silicone)<br>- Data: Pre-operative 3D Echocardiogram data<br>- Cost (per model/x10 models):<br>* Directly printed:<br>$7.90/$79.00 USD<br>* Molded:<br>$45/58.41 USD | Questionnaire | -Molded valves longer to make than directly printed valves<br>-Molded valves significantly more realistic than directly printed valves ($p<0.01$)<br>- Both procedures better in molded valves<br>- | - Accurate patient/pathology specific models<br>- Molds offer low-cost solution to high costs of 3D printing | - Time consuming and costly methodology in 3D printing technique<br>- Molds are single use for complex structures (i.e. chords)<br>- No sub-valvular structures therefore limits testing of repair<br>- Limitations in model material | No |
| Chen et al<br>[26] | Norwood procedure for Hypoplastic Left Heart Syndrome (HLHS) | 3D printed models (Tango+) | - Single<br>Pediatric cardiothoracic surgeon<br>- 1 HLHS model<br>- Data: Post-operative cross-sectional imaging<br>- Model modified to create pre-operative model<br>- Custom 3D printed patch made for arch reconstruction<br>- Cost: $770 USD per model | Verbal feedback from expert | Photographic evidence of repair | - Accurate patient/pathology specific model<br>- Model in correct orientation as seen intraoperatively | - Model digitally manipulated to pre-operative state<br>- Time consuming and costly<br>-Model limited by image data/availability | No |

| Study | Problem addressing | Type of Simulator | Methodology | Assessment | Results | Benefits | Limitations | Reproduced |
|---|---|---|---|---|---|---|---|---|
| **Hoashi et al [27]** | Pre-operative simulation of multiple complex congenital procedures | 3D printed molds<br><br>(Poly-urethane resin) | - Single, inexperienced consultant with no prior experience in complex/neonatal heart surgery<br><br>- Procedures: 20<br><br>- Duration: 29 months<br><br>- Data: Pre-operative cross-sectional imaging<br><br>- Cost: $2000-3000 USD per model | Patient outcomes | - No mortality (median follow up 1.3 years)<br><br>- 16 biventricular repair + 4 functionally single ventricle<br><br>- No surgical heart block or systemic ventricular outflow obstruction | - Outcomes comparable to experienced surgeon<br><br>- Realistic flexibility of material | - Limitations in model material<br><br>- Operative ergonomics experienced were unrealistic<br><br>-Not helpful for extra-cardiac procedures<br><br>- Surrounding anatomical structures not represented<br><br>- Lack of valves and supporting structures<br><br>- Expensive | No |

## 4.4 Discussion

Congenital heart surgery (CHS) is a relatively young speciality in medicine. New procedures and their progressive improvement has dominated the first 50 years; the next 50 years will focus on perfection in surgical techniques and patient outcomes [68]. Therefore, if this is the future aim and current public expectation then there needs to be an evolution in training of the next generation of congenital heart surgeons as learning curves and mistakes are no longer allowed or expected [5], [68].

Surgical simulation is a potential solution and the call for its incorporation into CHS is growing [8], [18], [25], [37], [69]. There is an acceleration and utilisation of simulation use in medical education, however the majority of evidence remains subjective or qualitative [37], [70]. Simulation supports the concept of deliberate practice providing a low risk, inconsequential environment, allowing surgeons to repeatedly practice difficult tasks streamlining the process of skill obtainment. Eventually this will lead to more precise, shorter operations, reducing costs and the consequences of longer operations, therefore potentially an improvement in patient outcomes [26], [68].

Simulation, primarily with 3D print models, is currently being utilised within congenital cardiac disease focusing on assisting the education of complex morphology and procedural planning, however there is a significant lack of hands-on surgical simulation [31], [69]. Adult cardiac surgery, on the other hand, has developed high-fidelity surgical simulators and has successfully incorporated these into its training curricula [37], [69], [71].

### 4.4.1 Summary of Simulators

Only 5 studies were included in this review. A significant proportion of excluded papers described the 3D printing process and its uses, with surgical simulation being a future avenue. The term ‘surgical simulation’ was commonly used to describe either pre-surgical planning of complex procedures or teaching pathology rather than surgeons performing procedures on a physical model, which is what we used as our definition of ‘simulation’.

Overall, both animal and 3D-printed models have been demonstrated to support the idea that hands on surgical simulation can be used in CHS to prepare surgeons further in complex procedures. Table 4.2 summarises the main benefits and limitations of the two approaches used.

**Table 4.2:** Benefits and Limitations of Simulator models

| | Animal Simulation | 3D-printed Simulation |
|---|---|---|
| **Benefits** | • Virtually identical anatomical relationships<br>• Tissue characteristics similar to human tissue<br>• Multiple procedures on single specimen<br>• Ability to test repairs<br>• Low operating costs<br>• Reproducible | • Patient and pathology specific models<br>• Reproducible following file creation<br>• Simulation can occur anywhere (i.e. at home) |
| **Limitation** | • Ethical issues regarding use of animals<br>• Simulation location may be limited to wet-lab environments<br>• Normal anatomy limits reproducibility of complex defects | • Limited to cardiac model – no surrounding structures<br>• Materials differ from human tissue characteristics<br>• Models lacking valve/subvalvular apparatus<br>• Models limited to imaging technique and data<br>• One procedure per model<br>• Unable to test repairs<br>• Time consuming<br>• Cost ++<br>• Infrastructure required to make models<br>• Labour intensive |

### 4.4.2 Animal-based simulation

Mavroudis et al demonstrate the effective use of neonatal porcine models to simulate multiple complex procedures. The methodology is reproducible and efficient whereby multiple procedures are performed on a single model. This leads to reduced costs and potential ethical protestations. Animal tissue most closely resembles that of human tissue, which is a significant limitation with the 3D-printed methodology. Furthermore, the simulators incorporate important surrounding anatomical and valvular/subvalvular structures, which are important but largely lacking in synthetic models.

However, there are several limitations to the simulator. Firstly, whenever simulation involves animal tissue there is an ethical dilemma that presents itself and such a simulation may not be widely reproducible. CHD lesions are extremely difficult to reproduce in animal models and may require the adjustment of normal anatomy to abnormal prior to repair. Only one resident was used with proctor support, therefore there are assessment limitations, such as operative time assessments and the degree of proctor influence. Objective assessments would be difficult to employ on this method of simulation, unless repeated on a larger scale.

Overall, the authors address a crucial problem in simulating complex congenital procedures for surgical residents and demonstrate that a resident with no experience can be coached through these procedures.

### 4.4.3 3D-printed simulators

All authors provide a successful demonstration of how 3D-printed models can be used effectively in a variety of simulations in CHS. The obvious advantage is that the models produced are based on patient-specific data and can be used to accurately depict complex pathology. Although computer assisted design (CAD) file creation is laborious and time consuming, any number of models can be reproduced if printing facilities and infrastructure are available. Cost is another limiting factor and varied between the methodologies ($7.90-3000 USD), which potentially limits its global utilisation and reproducibility. The cost variability is primarily due to the technique of choice employed to produce the models for simulation. 3D-printing costs can be categorised into three broad categories: 1) material cost; 2) printer running cost and 3) post-processing/labour costs. The printer running cost is dependent on the number of models printed. The cost per model reduces considerably when more models are printed simultaneously, increasing printer efficiency. Yoo et al calculated that their heart model costs would reduce from $150-210 USD per heart to $60 if their printer was used for 30 hours per week over a 5-year period. If simulation is adopted internationally and incorporated into dedicated training curricula, this will likely have an economy of scale effect on reducing costs making such programs feasible financially.

All 3D-printed simulator authors admit that material remains a limitation, alongside the ability to incorporate valvular and surrounding structures to increase simulator realism. Additionally, only one procedure can be performed on each model and currently it is not possible to test repairs effectively, unlike in animal models.

Yoo et al have successfully reproduced their course worldwide at multiple institutions highlighting the benefit that 3D-printed simulators can be performed in any location, nullifying the barriers of wet-lab availability. The results from the questionnaire are impressive with all attendees finding the course helpful and would consider using HOST in training programs. This suggests the speciality's eagerness to adopt this concept. Alongside Haoshi et al, they demonstrated the success of 3D-printed models to depict multiple pathologies, which is crucial to simulation in CHS.

Scanlan et al address a critical issue of training in paediatric atrioventricular valve repair and succeeded in assessing whether a surgical simulator could be made specifically for valve repair in CHS and analysed the best methodology to create such a simulator. It is clear that the moulding technique is significantly better than directly printed valves and the cost is significantly cheaper when produced in quantity. A mould is a cavity into which a material is poured into and then solidified to form the desired model. A single mould can be used to produce multiple models, similar to the methods used in mass production in industry. Although cost effective in producing valvular structures, the benefits are lost when making full heart structures as intra-cardiac anatomy is crucial to demonstrate. This can still be achieved with the moulding technique, however in most cases with complicated geometry, the mould needs to be broken to remove the model with the complex anatomy preserved. To overcome this problem the mould itself should be designed in a complex form allowing easy removal of the model without damage, which would be hardly achievable.

Despite their method costing significantly more than the other studies, Haoshi et al's work is a giant step towards supporting the belief that effective simulation can be used to prepare inexperienced surgeons to perform complex neonatal procedures with outcomes comparable to experienced surgeons. They reported no mortality, surgical heart block or systemic ventricular outflow obstruction in their 20 cases and believed that the simulation had a role in these outcomes. Analysis of patient outcomes is an objective method of assessing successful effectiveness of simulation, however it is difficult to deduce whether this performance is solely related to simulation. A way to prove this would be to compare these outcomes to a control surgeon of the same experience, who has not had simulator exposure, however this may potentially be unethical and unrealistic to perform.

Apart from one article, all studies were either a proof of concept/feasibility study or performed by a single surgeon. Although promising, the next steps would involve replicating these studies with multiple surgeons to validate the methodology further and provide evidence of their use in surgeon training. To achieve this, all studies need to be developed to incorporate objective evaluation to further support the qualitative evidence they have collected thus far. One possible avenue would be to create an objective assessment method to assess surgeon progression, however this may be time consuming and difficult to manufacture. The goal of objective assessments would include validation of the simulators and generate a methodology whereby a surgeon's improvement could be tracked alongside the ability to discriminate between surgeons of differing experience.

Mavroudis et al used the concept of video-recording to capture data such as procedure length and retrospective performance analysis. Although the results were not published, it is a possible avenue to objectively assess performance. Procedure length would be relatively simple to measure, albeit with minimal interruption. However, in order to perform meaningful, valid performance analysis would require the creation of an objective assessment tool. Validated tools in surgical simulation already exist, which use operation-specific checklists to assess the completion of a task and assess global performance, focussing on aspects such as tissue/instrument handling and procedure fluency assessed via a Likert-scale method [72], [73]. These assessment tools could be a potential starting point for objective assessments for the simulators described above, but will require tailoring to CHS procedures.

### 4.4.4 Summary of Paediatric Cardiac surgery curricula

CHS sub-specialisation certification in the western world involves additional training following adult cardiac/cardiothoracic training. Generally, this takes shape in the form of a 1-2 year program requiring a fixed minimum number of procedures to be performed as the primary surgeon (75 in UK and US), and successful completion of the relevant oral and written examinations [74]. It is expected that UK trainees would likely take in excess of 10 years of postgraduate training in order to be in a position to achieve sub-specialisation certification and be competent enough to apply for a consultancy position. A similar pattern is seen in North America where a workforce survey concluded that the mean duration of postgraduate training of congenital heart surgeons in USA and Canada was 10 ± 2 years (median 10 years; range, 6 to 18 years) [16].

Overall there has been an increase in satisfaction in operative experience since the introduction of dedicated congenital cardiac surgery curricula [15], [74]. In such programmes the number of procedures expected to have been performed includes 'less-complex' procedures (i.e. ASD/VSD closures, ToF repairs), therefore a new attending/consultant surgeon would usually requires a further 5 years of practice before they reach expert level, particularly in complex procedures. With the current median age of certification being 40, a surgeon may not be at an expert level until they near their 5$^{th}$ decade. This realisation has been rendered unacceptable and thus there have been calls to revolutionise the training of the next generation of congenital surgeons [5], [15].

There is evidence that a highly structured program of graded supervision can enable an inexperienced surgeon to perform complex procedures with outcomes comparable to experienced surgeons [75]. Haoshi et al's study further supports the idea that simulation can work synergistically with effective mentoring to tackle the issues of overcoming the steep learning curve in complex CHS [27].

Once effective simulators are available, simulation integration into a curriculum will involve overcoming the following hurdles as summarised by Feins [76]:

1) Changing from the Halstedian apprenticeship model to a more hybrid model which incorporates the use of simulation
2) Retraining educators to effectively use simulation
3) Provide adequate simulator technology for the job
4) Objective data to support current subjective evidence that simulation is an effective training tool

If successful, this will lead to a more interactive CHS curriculum leading to greater utilisation by resident/fellow surgeons.

With the restructuring of cardiothoracic training programmes aimed to reduced overall training time as described in chapter 1, there is now a greater emphasis on utilising training time efficiently. Therefore there is need for a transition from a number-based to a competency-based assessment method in order to evaluate the quality and progression of surgical trainees. In the current climate (i.e. pandemic, working time restrictions) there has been a further reduction in operative experience, which has impacted on surgical trainee development. Therefore there is an opportunity for training curricula to adopt simulation methods in order to improve the acquisition of technical surgical skills to facilitate the transition to competency-based training. However, in order to achieve such goals there is a need for the development of objective assessment methods, which is described in further detail in later chapters.

## 4.5 Conclusion/Future directions

The studies demonstrate how hands-on surgical simulation is possible within CHS. Although primarily proof of concept or feasibility studies, the next step would be to repeat these studies involving a greater number of participants and demonstrate how repetition and deliberate practice will improve outcomes. The development of an objective assessment method to support their use is required prior to the incorporation of these high-fidelity simulators into congenital cardiac surgery curricula. We have introduced a monthly simulation curriculum with 3D-printed models for our fellows covering a variety of complex CHS procedures (Chapter 8). The curriculum incorporates tailored objective assessment methods to measure performance. The goal is to achieve the high standards of simulation that have been set within adult cardiac surgery such as resident boot camps, focussing on regular hands-on training.

The benefits between 3D-printed and animal models are clear and it is likely such desirable curricula may incorporate both simulators. Improvements in the 3D-printing technique, image acquisition and materials, will lead to better, more realistic models and potentially simulators which will incorporate important surrounding structures. Our models are being developed further as we experiment with new commercially available materials and the inclusion of valves, subvalvular apparatus and surrounding anatomical structures to address the limitations of 3D-printed models. (Figure 4.1-4.3). Promising work has commenced to create a closed-circuit simulation of blood flow through our heart models (Figure 4.4/ Video 4.1). Congenital heart surgery is one of the most technically demanding surgical specialities, therefore we should lead the way in utilising simulation to complement the training of our surgeons as we face the challenges ahead. Trainee surgeons need to be given an environment where they can deliberately practice in low-risk environments, particularly in complex procedures. Inevitably this is will lead to greater confidence and streamline the time taken to achieve competency.

The belief may seem over-ambitious and unrealistic, but if we are to make a deliberate attempt to lower the median age of competency and still produce excellent surgeons in the current climate then support for surgical simulation and curriculum development universally needs to be active and unanimous.

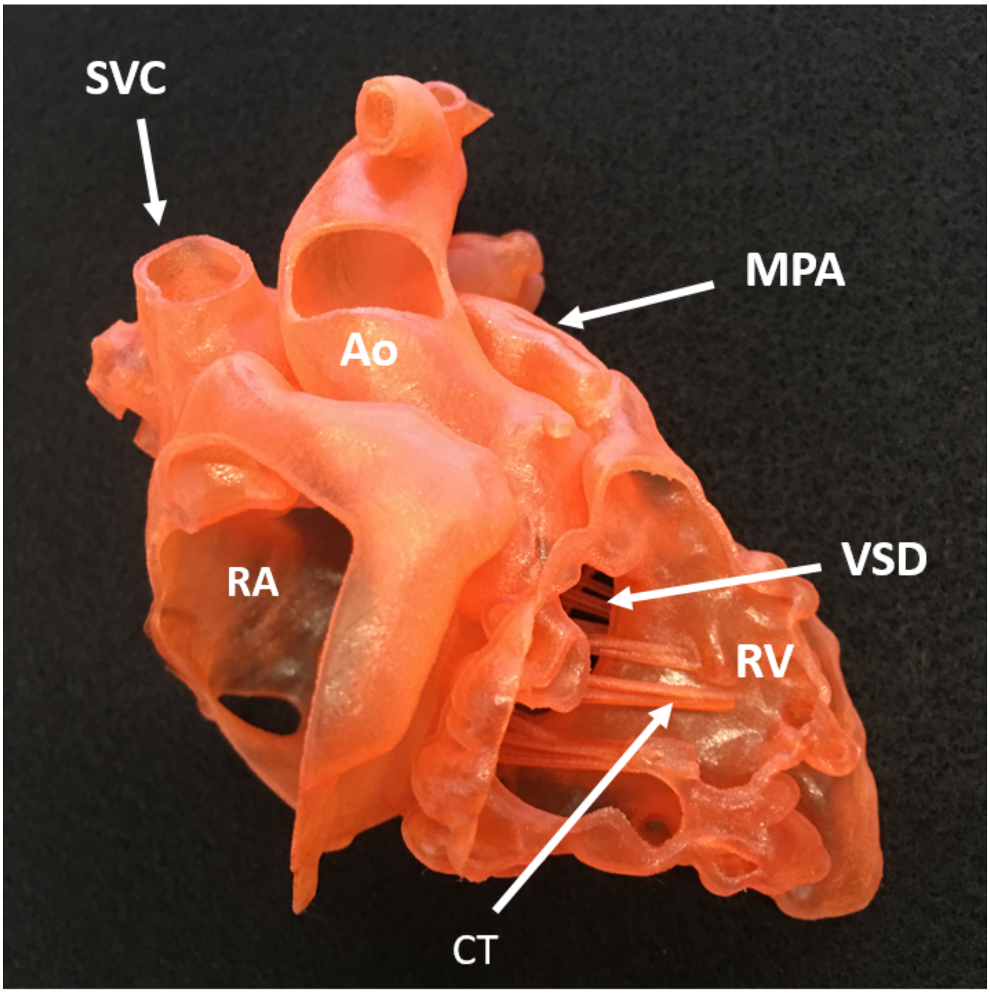



**Figure 4.1:** 3D printed heart model incorporating valve and sub-valvular apparatus used for hands-on surgical simulation. Surgeon is required to close VSD using a suitable patch. Chordae tendinae are attached to their respective atrioventricular valve leaflets increasing realism of model. Aortic and Pulmonary valves are also present but not shown in this orientation. (Ao = Aorta, CT = Chordae tendinae, MPA = Main pulmonary artery, RA = Right atrium, RV = Right ventricle, SVC = Superior vena cava, VSD = Ventricular septal defect)

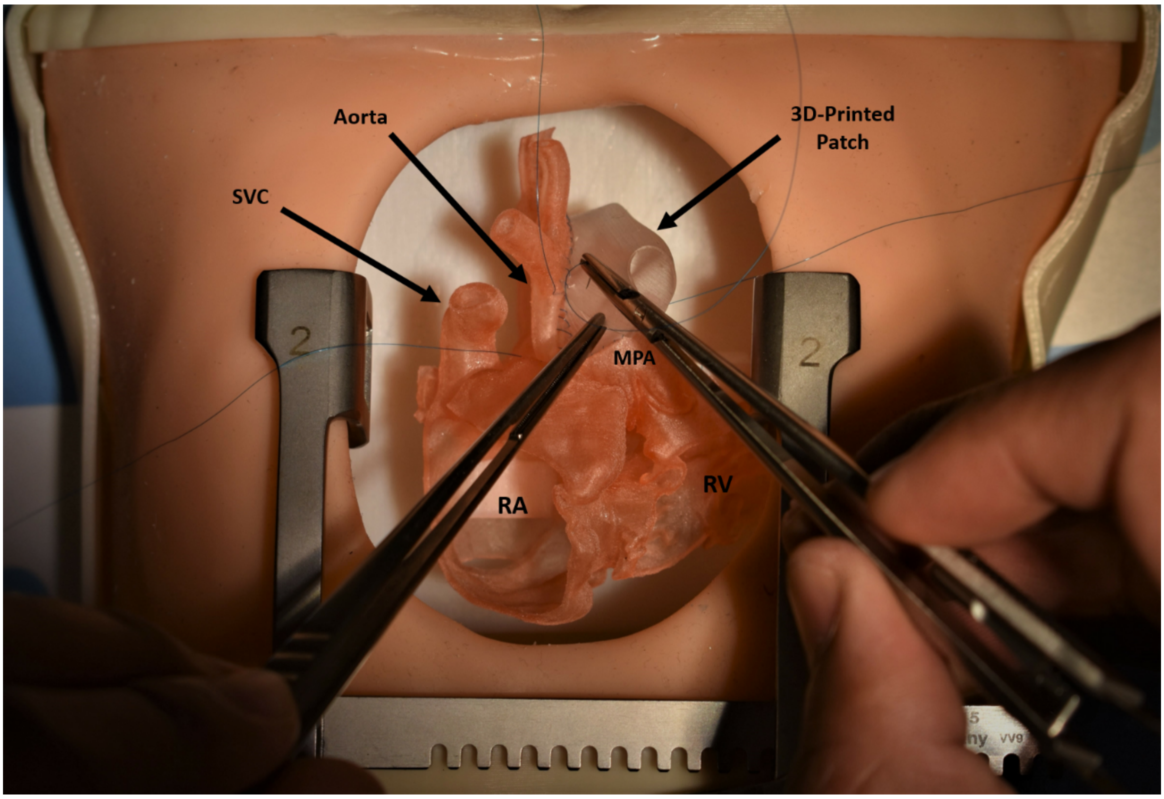



**Figure 4.2:** Surgeon performing aortic arch reconstruction in Norwood procedure on 3D printed model using chest simulator replicating ergonomics and exposure experienced in the operating room (MPA = Main pulmonary artery (cut), RA = Right atrium, RV = Right ventricle, SVC = Superior vena cava)

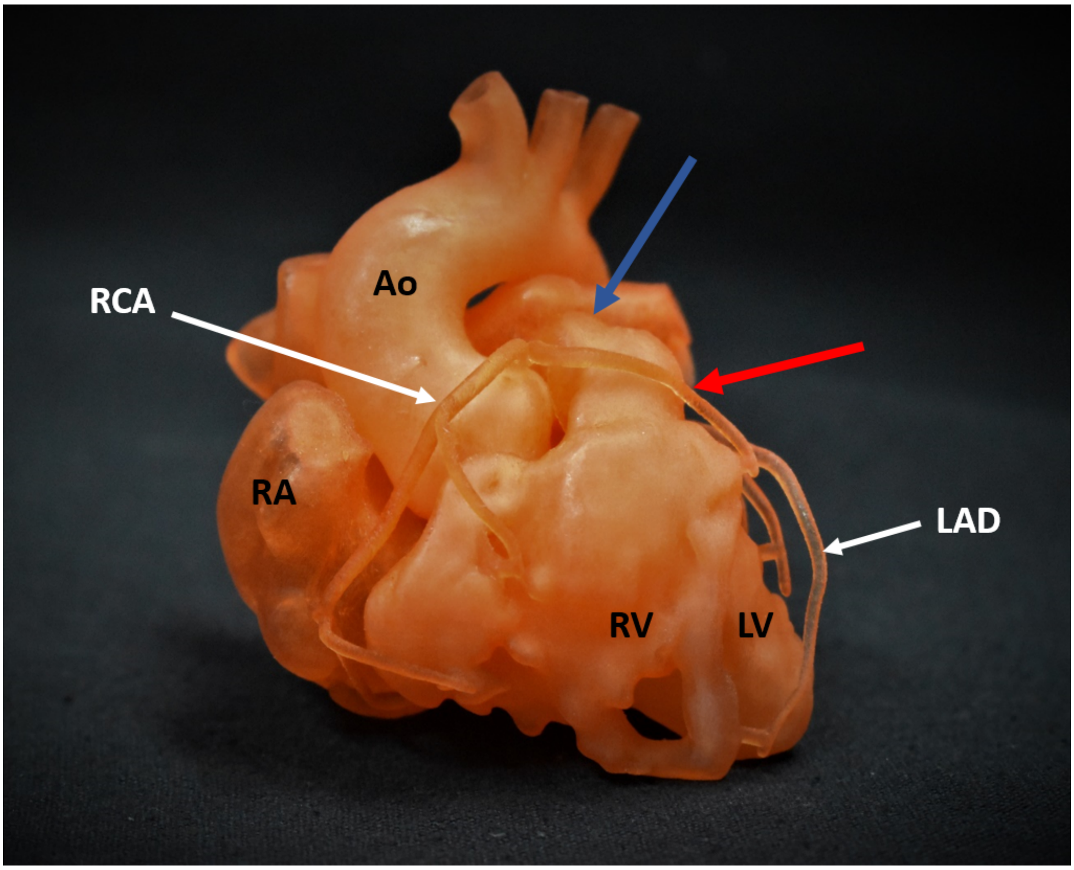



**Figure 4.3:** 3D printed tetralogy of Fallot model with severe pulmonary stenosis post operation (Blue arrow) used in hands on surgical training (HOST) simulation. Model incorporates coronary arteries (White arrows). Note the accessory anterior descending coronary artery (Red arrow) arising from the right coronary artery (RCA) and coursing across the right ventricular outflow tract thus posing a challenge to surgeons in pulmonary trunk augmentation. (Ao = Aorta, LAD = Left anterior descending artery, RCA = Right coronary artery, RA = Right atrium, RV = Right ventricle, LV = left ventricle)

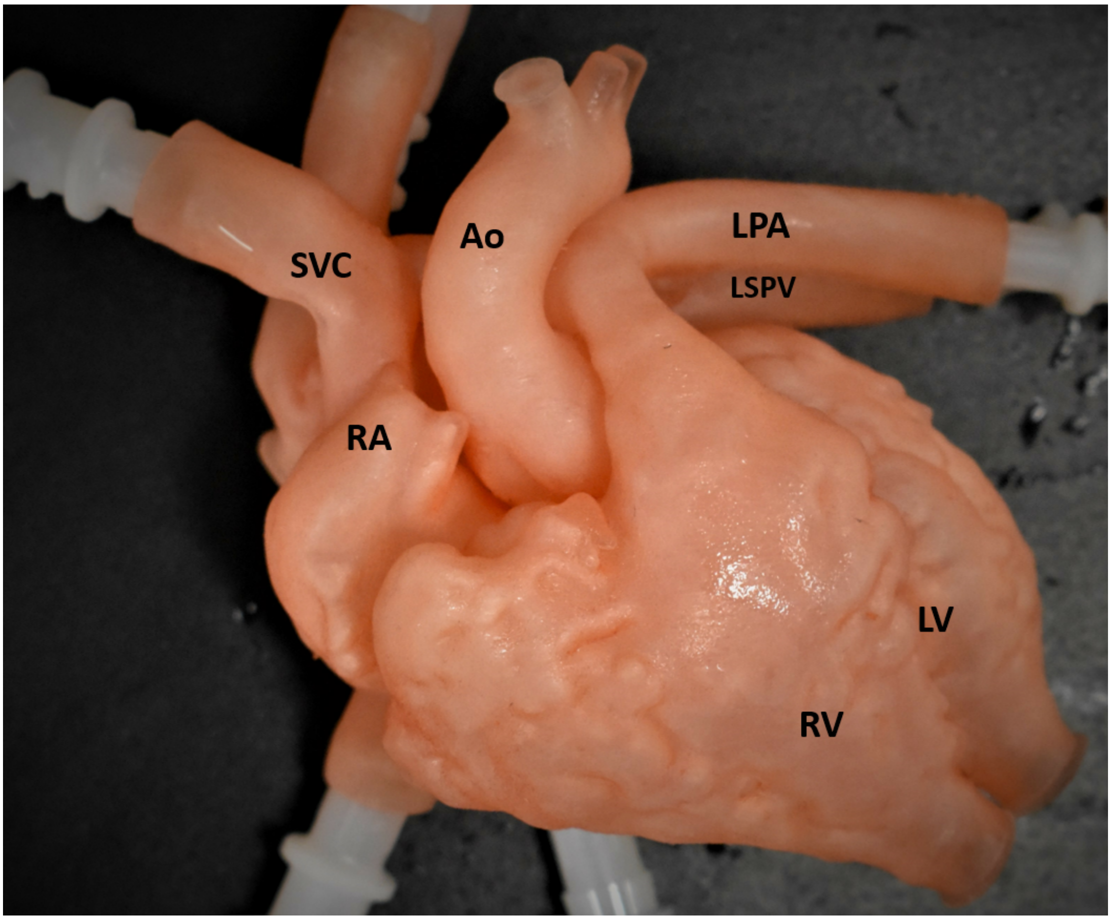



**Figure 4.4:** 3D printed tetralogy of Fallot heart connected to closed-circuit pump simulating a live heart. This demonstrates the ability to create 3D printed models with pulsatile flow and incorporate heart valves. Refer to video attachment to see heart in motion. (Ao = Aorta, LPA = Left pulmonary artery, LSPV = Left superior pulmonary vein, LV = Left ventricle, RA = Right atrium, RV = Right ventricle, SVC = Superior vena cava)

**Video 4.1:** 3D printed tetralogy of Fallot heart connected to closed-circuit pump simulating live heart. Note rhythmical expansion and relaxation of both ventricles as forward flow is achieved through both pulmonary and systemic circulations.

YouTube video link: https://youtu.be/AgsyCod0qoA

# 5 Introducing objective assessment methods into the evaluation of surgical simulation in congenital heart surgery – A pilot study

## 5.1 Introduction

The Hands-On Surgical Training programme in congenital heart surgery (HOST-CHS) using 3D printed heart models has previously been established at the Hospital for Sick Children (SickKids), Toronto. Prior to this study, the annual course had been completed for 3 consecutive years with the inaugural course being held at the American Association of Thoracic Surgery (AATS) annual conference in 2015 [18]. Despite receiving positive feedback from both delegates and proctors this was primarily qualitative in the form of questionnaires completed at the end of the course. In order to establish this training modality into the current curricula there was a need to validate this methodology in the form of objective assessments.

This chapter reviews the first introduction of objective assessment methods into HOST-CHS to evaluate whether a surgeons' performance (time and procedure) improves following participation at the HOST-CHS course.

## 5.2 Methods

### 5.2.1 Study design

The 4th annual HOST course occurred over a 2 ½ day period in September 2018. Thirteen surgeons of varying experiences from around the world participated in the course (4 consultants, 7 fellows and 2 residents). The course was led by two experienced paediatric congenital cardiovascular surgeons. Delegates were paired and each surgeon performed 6 congenital heart procedures on the 3D-printed heart models (Table 5.1). Two simulation tracks were created ('Exposure' and 'Rehearse') with the delegates choosing which track they would like to participate in prior to attending the course. The proctors demonstrated the operative procedures on the 3D models prior to the delegates attempts and gave verbal feedback after each case. All attempts performed by the delegates were video recorded for retrospective analysis (Figure 5.1). The objective assessment of the procedures was two-fold:

1) Time-based assessment (i.e. time to complete the procedure)
2) Procedure-based assessment – blinded objective assessment of the end result based on the evaluation of the models by one of the proctors using a procedure-specific assessment tool (Figure 5.2).

All delegates began with performing the arterial switch operation on a transposition of the great arteries (TGA) model with usual coronary pattern (Leiden classification: 1LCX2R) [77]. This same case was repeated at the end of the course without proctor assistance. This was used to compare with the first attempt to evaluate if there had been an objective improvement in performance. On completion of the course all delegates filled a questionnaire to capture feedback of the course (Appendix 12.1). Ethics approval was obtained from the appropriate institutional research ethics board (Appendix 12.4).

**Table 5.1:** The cases performed by the surgeons who participated in the 4th annual Hands-On Surgical Training course at the Hospital for Sick Children (SickKids), Toronto. Delegates chose between either the 'Exposure' or 'Rehearse' track depending on their learning needs. Note how the first and last cases are the same (TGA 1LCx2R); these were used in the objective assessment and validation of the course. HLHS = hypoplastic left heart syndrome, TGA = transposition of the great arteries, VSD = ventricular septal defect.

| Exposure Track | Rehearse Track |
|---|---|
| TGA 1LCx2R | TGA 1LCx2R |
| Tetralogy of Fallot repair | TGA 1L2RCx |
| Truncus Arteriosus (Type II) | TGA 2RLCx |
| HLHS (Norwood procedure) | TGA with VSD |
| Interrupted Aortic arch with VSD | Taussig-Bing |
| **MASTER case:**<br>TGA 1LCx2R | **MASTER case:**<br>TGA 1LCx2R |

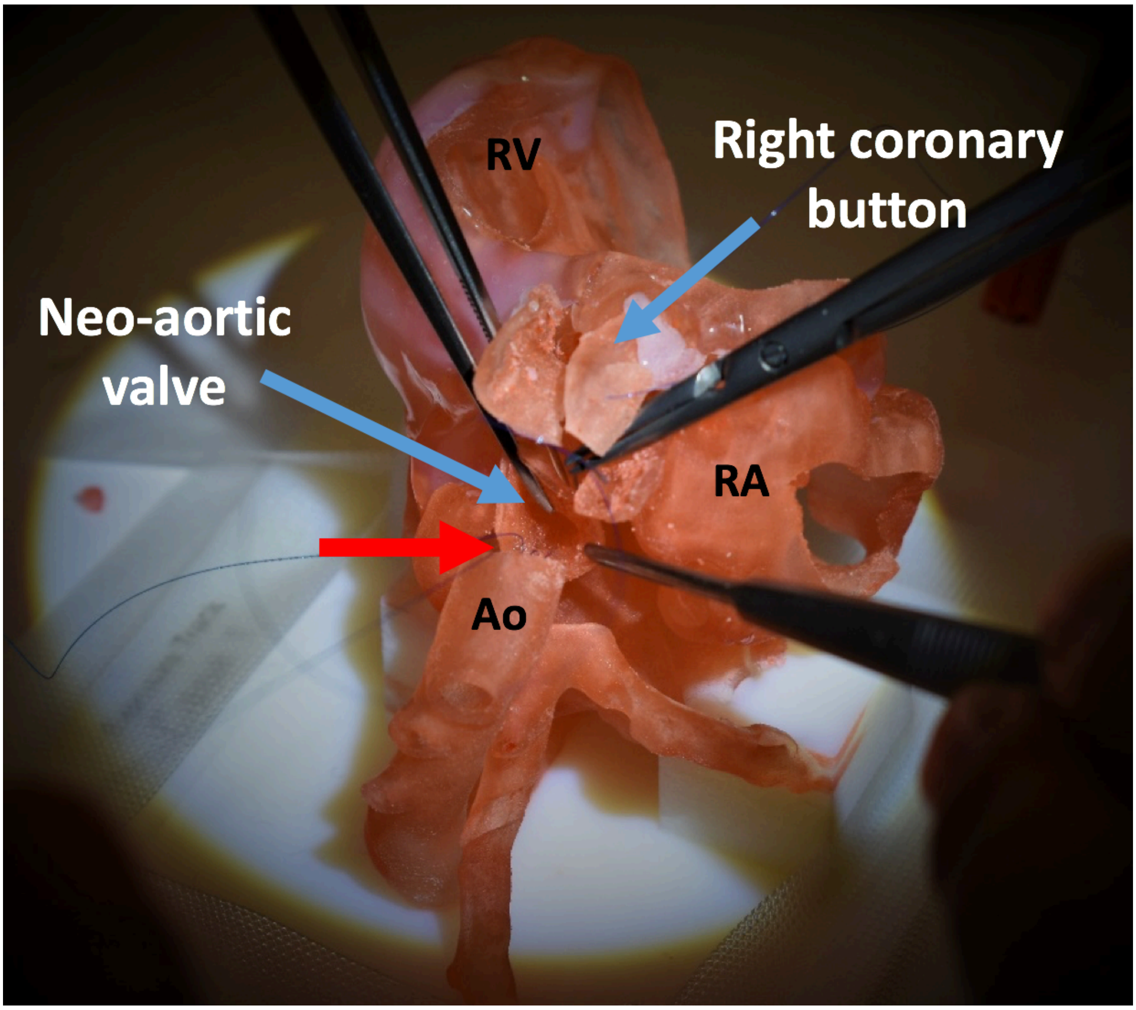



**Figure 5.1:** Surgeon performing the neo-aorta reconstruction (red arrow) in the arterial switch procedure on a 3D-printed heart model of transposition of the great arteries at the 4th annual Hands-On Surgical Training (HOST) course.

Ao = aorta, RA = right atrium, RV = right ventricle

**End Point Scale – Arterial switch operation for transposition of the great arteries**

SickKids | Labatt Family Heart Centre

- Assessment of the overall repair to be assessed retrospectively by direct observation of preserved model/ photographs of end result

| | Item | 1 (Unacceptable) | 2 | 3 (Acceptable) | 4 | 5 (Excellent) | N/A |
|---|---|---|---|---|---|---|---|
| 1 | **Transection of Aorta** | - Incorrect length of ascending aorta; ends not approximated correctly<br>- Poor anastomoses (i.e. insufficient spacing between sutures)<br>- Loose knot | | - Acceptable position and length; approximation of ends acceptable<br>- Use of continuous suture; adequate stitch position; sutures placed at varying distances apart; additional reinforcement sutures required<br>- Adequate anastomosis | | - Correct position and length; ends approximated correctly<br>- Excellent end-to-end anastomosis; uses continuous suture of appropriate size; correct stitch position; correct size bites; adjusted for size mismatch and placed in uniform distance apart<br>- Suture line a correct distance away to allow anastomosis of coronaries | |
| 2 | **Coronary Artery Buttons** | - Significant damage to either coronary or button<br>- Sutures compromise patency of coronary ostia<br>- Continuous suture not used<br>- Loose Knot<br>- Poor anastomoses of the coronary buttons (i.e. insufficient spacing between sutures) | | - Use of continuous suture; adequate stitch position; sutures placed at varying distances apart; additional reinforcement sutures required<br>- Adequate anastomosis<br>- Minor damage to either coronary | | - Uses continuous suture of appropriate size; correct stitch position; correct size bites and placed in uniform distance apart<br>- Excellent anastomoses of the coronary buttons<br>- No damage to coronaries | |
| 3 | **Transection of Pulmonary Artery** | - Incorrect length of pulmonary artery; ends not approximated correctly | | - Acceptable position and length; approximation of end acceptable | | - Correct position and length; ends approximated correctly | |
| 4 | **Coronary Position and Length of Aorta** | - Coronaries not laying correctly to the extent that would compromise patient (i.e. severe kinking, significant rotation) | | - Acceptable lay but suboptimal | | - Both coronaries in 'best-lie' position or equivalent optimal positions, without risk of kinking. | |
| 5 | **Pulmonary Artery Patch** | - Failure to repair dissected neo-pulmonary sinus<br>- Pulmonary trunk/artery lumen compromised<br>- Poor anastomoses (i.e. insufficient spacing between sutures)<br>- Continuous suture not used<br>- Loose knot | | - Use of continuous suture; adequate stitch position; sutures placed at varying distances apart; additional reinforcement sutures required; adequate repair of dissected neo-pulmonary sinus<br>- Adequate anastomosis | | - Excellent end-to-end anastomosis; uses continuous suture of appropriate size; correct stitch position; correct size bites and placed in uniform distance apart<br>- Suture line in correct place (i.e. Not compromising coronaries in suture line) | |

**Overall appearance of repair**

| Very Poor | Poor | Acceptable | Good | Expert Ability |
|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 |

**Figure 5.2:** End-point scale tool used in the assessment of the simulation of the arterial switch operation on 3D-printed transposition of the great arteries heart model. Five different items were assessed retrospectively and scored on a 1-5 Likert scale based assessment. The overall repair was also assessed on the same scale.

### 5.2.2 Development of assessment tool

The end-point scale assessment tool was develop based on the objective structured assessment of technical skills (OSATS) principles described by Reznick et al [72]. This is a validated and commonly used assessment tool in surgical simulation and has been modified and implemented within other surgical specialities [39], [42], [45], [78]–[83]. This generalised assessment tool assesses certain aspects of an operative procedure such as respect for tissue, time and motion, operative flow, instrument handling etc. Our tool used these principles, but was modified to include steps specific to the arterial switch operation. Four staff surgeons experienced in the arterial switch operation were independently asked to list the steps involved in the operation (Appendix 12.2). The lists were consolidated and the steps which could not be performed on the models were removed (i.e. sternotomy, establishment of cardiopulmonary bypass etc). The assessment tool was categorised into 5 items whereby trainee surgeons could achieve a score on a 1-5 Likert scale: 1) transection of the aorta, 2) coronary artery buttons, 3) transection of the pulmonary artery, 4) coronary position and length of the aorta and 5) pulmonary artery patch. Under each score, descriptors were made to help guide the evaluator on the criteria to achieve the score . Draft copies of the assessment tool were then returned to the expert surgeons to independently review and change if necessary. These were then subsequently reviewed and the assessment tool altered. Following at least two rounds of this cycle the expert surgeons were asked together if they approved the assessment tool and any discrepancies were discussed until a consensus was made. At the bottom of the assessment tool the evaluator was asked to give a score on the overall appearance of the repair. At the end of the course, the proctor performed a blind assessment of the repairs based on the assessment tool.

## 5.3 Results

### 5.3.1 Quantitative results

Eighty-five percent (11/13) of delegates performed the arterial switch operation on both TGA models. All delegates were 30% quicker in their second attempt compared to the first [p=0.0007] (Figure 5.3A). The mean difference in time was 0:22:54 [95% CI 0:07:46 – 0:38:01] (h:mm:ss). Ten delegates had both attempts evaluated using the objective assessment tool. Eighty percent (8/10) of delegates improved between the two attempts with a mean improvement of 8% [p=0.06, 95% CI -0.5%-16%] (Figure 5.3B). The videos of the two delegates who performed worse were reviewed; both surgeons had attempted an alternative technique to the first attempt.

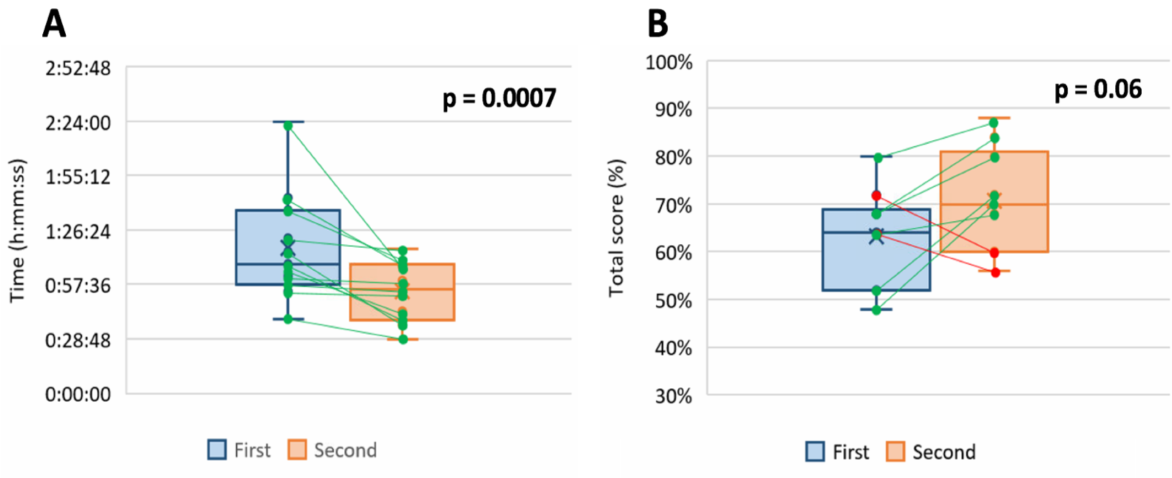



**Figure 5.3:** A: Time difference between the first and second atempts of surgeons simulating the arterial operation on a 3D-printed model of transposition of the great arteries (p=0.0007, 95% CI 0:07:46-0:38:01). B: Score difference between the two attempts was assessed by experienced proctors who led the Hands-on Surgical Training session (p=0.06, 95% CI -0.5%-16%).

### 5.3.2 Qualitative results

All the delegates completed the questionnaire. The average number of years the surgeons had performed cardiovascular surgery was 8.6 years, with 38% believing their knowledge in congenital heart disease was either above average or advanced. The average number of cases performed independently by each surgeon was 84 cases with the majority being less complex congenital cardiac operations such as ventricular/atrial septal defect repairs, patent ductus arteriosus ligations, coarctation of aorta repairs and tetralogy of Fallot repairs. All surgeons graded the overall quality of the models as either excellent or good. All agreed/strongly agreed that the models provided the necessary information regarding the major pathological findings. Ninety-two percent (12/13) felt the model material was acceptable for surgical simulation and agreed/strongly agreed that HOST is helpful in improving surgical skill. All surgeons expressed a desire to attend future HOST courses. Suggestions of improvement included model material and having an adjustable operating table (Chapter 9).

## 5.4 Discussion

This study addressed the need to include objective assessment methods to validate the use of 3D-printed heart in the training of congenital heart surgeons. The data generated supports the principles of deliberate practice and the growing qualitative evidence that supports this method of training [18], [34]. However, there are fundamental limitations in this assessment method, which needed to be addressed in order to validate it as an effective evaluation tool. For example, the end point scale assessment focuses solely on the end result of the procedure. Although an excellent outcome would be reflected in this assessment, it would be difficult to provide specific feedback on how surgeons could improve. Additionally, this method requires experienced surgeons to perform the assessment, which may be a significant barrier in the replication of such an assessment. Although the Likert scale is a validated assessment tool, it is open to threats to validity and rater errors. From our experience, expert surgeons with similar experience may score differently based on these assessment tools impacting the inter-rater reliability.

Therefore, following these promising early results the aim was to develop a procedure-specific assessment tool for congenital heart surgery procedures, which would address some of the limitations we experienced. This included reducing the potential bias within the assessment tool and the requirement of expert surgeons to perform the assessments. Furthermore, the new tool would need to easily differentiate between different grades of surgeon and be easily reproducible and feasible to include regularly in simulation curricula. The development and validation of this tool is described in the next chapter.

## 5.5 Conclusions

This pilot study was the first use of both quantitative and qualitative assessment methods to evaluate a surgeons' performance in HOST for congenital heart surgery. All delegates were statistically significantly quicker in their repeat attempts supporting the concept of simulation training and deliberate practice. Eighty percent of delegates improved in procedural performance with near significance. Further work is required to address limitations with the assessment method and is described in chapter 6.

# 6 Development and validation of a procedure-specific assessment tool for hands-on surgical training in congenital heart surgery

The following chapter has been adapted from the following publication to suit the flow of this thesis. Permission has been granted from the publisher Elsevier.

***Nabil Hussein****, Andrew Lim, Osami Honjo, Christoph Haller, John G. Coles, Glen Van Arsdell, Shi-Joon Yoo. Development and validation of a procedure-specific assessment tool for hands-on surgical training (HOST) in congenital heart surgery.*

*The Journal of Thoracic and Cardiovascular Surgery. 2020 Jul;160(1):229-240.e1. doi: 10.1016/j.jtcvs.2019.11.130. Epub 2019 Dec 24. PMID: 31973896.*

NH contributions to this publication: Conception and design, assessment tool development and validation, data collection, statistical analysis and interpretation, literature review, writing of the article, critical revision and final approval of the article.

## 6.1 Introduction

The previous chapter demonstrated the first use of objective assessment methods in the evaluation of surgeons who simulated complex CHS procedures on 3D-printed models. Although promising, the results highlighted the need to develop and validate reproducible procedure-specific assessment tools, which could be used to assess and provide detailed feedback to trainee surgeons. Another barrier to overcome was to reduce the need for experienced surgeon to perform the assessments and provide constructive feedback, which is onerous on already busy professionals.

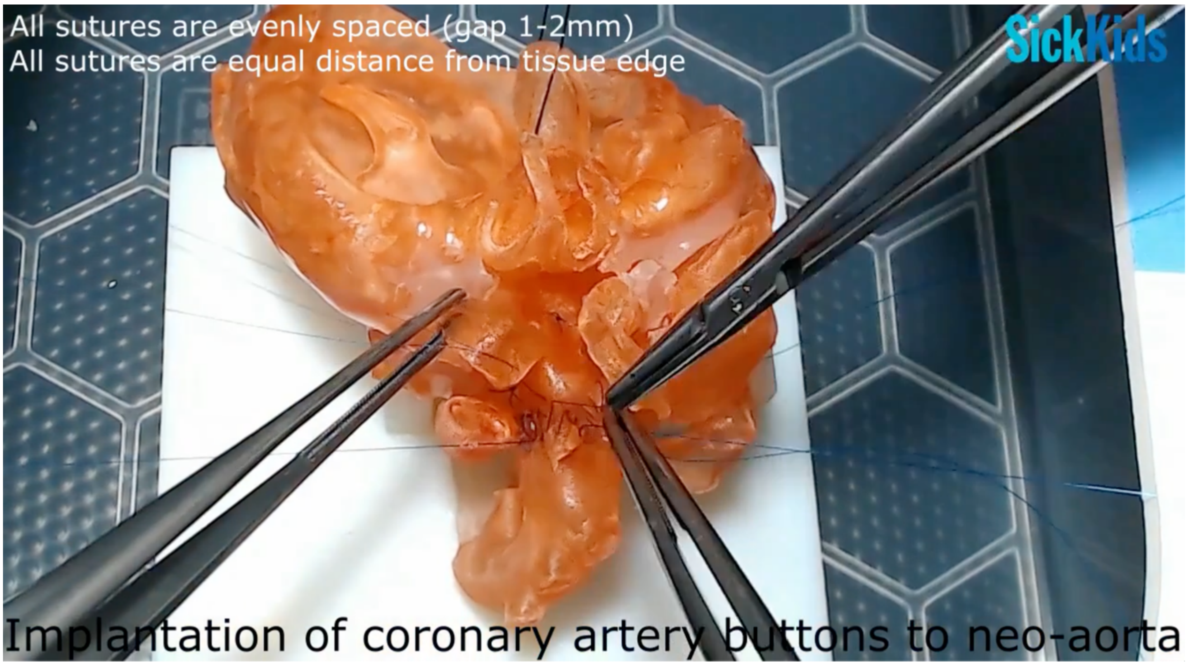
This chapter aimed to validate a procedure-specific assessment tool for the simulation of the arterial switch operation, a technically challenging procedure, on 3D-printed models compared to an existing validated assessment tool in surgical simulation. The goal was to demonstrate consistency of scores among evaluators with different levels of experience in CHS and explore whether the tool could discriminate between different grade of surgeons.

## 6.2 Methods

### 6.2.1 Study design

Five ‘expert’ surgeons (>5 years in CHS) and five ‘junior’ surgeons (<2 years in CHS) performed the arterial switch procedure on 3D printed models with transposition of the great arteries (TGA) during one of two Hands-on Surgical Training (HOST) courses held at the Hospital for Sick Children (SickKids), Toronto, Canada. Their performances were video recorded and evaluated retrospectively by 9 evaluators with varying experience in CHS – 3 established congenital heart surgeons with a high understanding of the arterial switch procedure, 2 cardiac surgical residents with a good theoretical understanding and 4 non-MD’s with no prior understanding of congenital heart disease or surgery.

The cardiac residents and non-MDs were given a 45-minute didactic teaching session on the principles of the arterial switch operation. They also reviewed a ‘gold-standard’ video of the procedure, which was performed by an experienced staff surgeon on the model for calibration purposes (Video 6.1). During this rater training the evaluators were educated on the common rater errors and possible threats to validity that can occur during assessments [84]. Videos were cropped and accelerated to achieve a total time of 5-10 minutes and were blinded and randomised. The gold-standard video was used as a reference tool during the assessments. The 10 procedures were independently scored by all the evaluators using 2 assessment tools: the Hands-on Surgical Training Congenital Heart Surgery (HOST-CHS) assessment tool (Table 6.1) and the Global rating scale (GRS), which was adapted from the scale originally described by Reznick et al (Table 6.2) [73]. After a 3-month period, two evaluators repeated the assessments to measure the intra-rater reliability of the tool.




**Video 6.1:** Clip from the 'gold-standard' video of the arterial switch procedure (medial-trap door, closed technique) performed by an experienced staff surgeon. This video was used for training of evaluators. YouTube video link: https://youtu.be/hNliVcorWlg

| | | Steps | YES/ | NO | Weight of step (1-5) | Included in HOST-CHS Holistic Score |
|---|---|---|---|---|---|---|
| 1 | | **Transection of aorta** | | | | |
| | | Is the cut in the aorta | | | | |
| | 1 | i) Perpendicular to the vessel? | Y | N | 2 | RESPECT |
| | 2 | ii) Clean? (i.e. not jagged or having sharp protruding points) | Y | N | 2 | RESPECT |
| | 3 | Is there enough distance on the proximal aorta (5-10mm) for good sized coronary buttons? | Y | N | 3 | KNOWLEDGE |
| | 4 | Is there enough distal length on the aorta for reconstruction of the neo-aorta? | Y | N | 3 | KNOWLEDGE |
| 2 | | **Excision of coronary artery buttons** | | | | |
| | 5 | Have the coronary buttons been excised with a liberal amount of aortic sinus wall with the coronary artery? | Y | N | 5 | RESPECT |
| | 6 | Is the coronary button rectangular shaped? | Y | N | 3 | KNOWLEDGE |
| | 7 | Is the coronary orifice in the centre of the button? | Y | N | 5 | KNOWLEDGE |
| | 8 | Is there enough aortic wall left for pulmonary artery reconstruction? (i.e. oblique cut towards anterior commissure) | Y | N | 3 | KNOWLEDGE |
| | 9 | Has there been any damage to the coronary arteries or aortic/neo-pulmonary valve during excision and mobilization? | N | Y | 5 | RESPECT |
| 3 | | **Transection of ductus arteriosus and pulmonary trunk** | | | | |
| | 10 | Has ductus been suture ligated and transected? | Y | N | 1 | |
| | 11 | Is the proximal PDA suture a safe distance from the left pulmonary artery (>1-2mm)? | Y | N | 4 | |
| | | Is the cut in the pulmonary trunk | | | | |
| | 12 | i) Perpendicular to the vessel? | Y | N | 3 | RESPECT |
| | 13 | ii) Clean? (i.e. not jagged or having sharp protruding points) | Y | N | 3 | RESPECT |
| | 14 | iii) A safe distance away from the pulmonary bifurcation (2-5mm) that it does not compromise the branch PAs? | Y | N | 4 | KNOWLEDGE |
| | 15 | Have one or more commissures been marked with a pen or stitch? | Y | N | 4 | KNOWLEDGE |
| 4 | | **Reconstruction of neo-aorta** | | | | |
| | 16 | Has the length of the ascending aorta been adjusted in a new position if required? (i.e. trimmed) | Y | N | 3 | KNOWLEDGE |
| | 17 | Has an end-to-end anastomosis been performed between the proximal neo-aorta and ascending aorta? | Y | N | 3 | |
| | 18 | Was the anastomosis commenced posteriorly? | Y | N | 3 | |
| | | Suture/Anastomosis assessment: | | | | |
| | 19 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of **2-3mm** between suture bites? | Y | N | 3 | FLUENCY |
| | 20 | ii) Are **all** the sutures an adequate distance from the edge (2-3mm)? | Y | N | 3 | FLUENCY |
| 5 | | **Implantation of coronary artery buttons to neo-aorta** | | | | |
| | | LEFT coronary button incision | | | | |
| | 21 | i) In the correct position for the technique of choice? (i.e. medially-based trap door for closed technique vs trap-door/rectangular for open technique) | Y | N | 5 | KNOWLEDGE |
| | 22 | ii) Adequate sized incision for technique of choice? (i.e. Closed technique: incision is slightly smaller than button [4-6mm] and edges of trap door are cut at right angles) | Y | N | 4 | RESPECT |
| | | Is the LEFT coronary artery | | | | |
| | 23 | i) In the 'best lie' position? (i.e. lateral + superior avoiding compression from PA, not stretching) | Y | N | 5 | FLUENCY |
| | 24 | ii) Kinked or twisted? | N | Y | 5 | FLUENCY |
| | | iii) Suture/Anastomosis assessment: | | | | |
| | 25 | a) Are **all** the sutures evenly spaced from one another **WITH** a gap of **1-2mm** between suture bites? | Y | N | 4 | FLUENCY |
| | 26 | b) Are **all** sutures an adequate distance from the edge (1-2mm) **AND** is a safe distance from the neo-aortic valve and coronary ostium? | Y | N | 4 | FLUENCY |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 27 | iv) Has the coronary button been trimmed appropriately? (i.e. leaving more tissue medially than laterally in the trap door technique / not too much tissue left over effecting lay/anastomosis) | Y | N | | 3 | |
| | 28 | v) Is the coronary still in tact by the end of anastomosis (i.e. not avulsed)? | Y | N | | 5 | |
| | | **RIGHT** coronary button incision | | | | | |
| | 29 | i) In the correct position for the technique of choice? (i.e. medially-based trap door for closed technique vs trap-door/rectangular for open technique) | Y | N | | 5 | KNOWLEDGE |
| | 30 | ii) Adequate sized incision for technique of choice? (i.e. Closed technique: incision is slightly smaller than button [4-6mm] and edges of trap door are cut at right angles) | Y | N | | 4 | RESPECT |
| | | Is the **RIGHT** coronary artery | | | | | |
| | 31 | i) In the 'best lie' position? (i.e. lateral + superior avoiding compression from PA, not stretching) | Y | N | | 5 | FLUENCY |
| | 32 | ii) Kinked or twisted? | N | Y | | 5 | FLUENCY |
| | | iii) Suture/Anastomosis assessment: | | | | | |
| | 33 | a) Are **all** the sutures evenly spaced from one another **WITH** a gap of **1-2mm** between suture bites? | Y | N | | 4 | FLUENCY |
| | 34 | b) Are **all** sutures an adequate distance from the edge (1-2mm), **AND** is a safe distance from the neo-aortic valve and coronary ostium? | Y | N | | 4 | FLUENCY |
| | 35 | iv) Has the coronary button been trimmed appropriately? (i.e. leaving more tissue medially than laterally in the trap door technique/ not too much tissue left over effecting lay/anastomosis) | Y | N | | 3 | |
| | 36 | v) Is the coronary still intact by the end of anastomosis (i.e. not avulsed)? | Y | N | | 5 | |
| 6 | **Reconstruction of neo-pulmonary trunk** | | | | | | |
| | 37 | Has the candidate performed this procedure to completion? (i.e. anastomosis of patch and then to branch PAs) | Y | N | | 4 | FLUENCY |
| | 38 | Is the height of patch level with the native tissue left following transection/ coronary button excision? | Y | N | | 2 | FLUENCY |
| | 39 | Is diameter of patch slightly larger than the native lumen size? | Y | N | | 2 | KNOWLEDGE |
| | 40 | Has an end-to-end anastomosis been performed between the neo-pulmonary trunk and the distal pulmonary artery? | Y | N | | 2 | |
| | 41 | Was the anastomosis commenced posteriorly? | Y | N | | 2 | |
| | | Suture/Anastomosis assessment: | | | | | |
| | 42 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of **2-3mm** between suture bites? | Y | N | | 3 | FLUENCY |
| | 43 | ii) Are **all** the sutures an adequate distance from the edge (2-3mm)? | Y | N | | 3 | FLUENCY |
| | | | **TOTAL SCORE** | | | **153** | |

**Table 6.1:** Hands-on Surgical Training Congenital Heart Surgery (HOST-CHS) assessment tool used to evaluate the arterial switch procedure on 3D-printed models. The left of the table shows the scoresheet with 43 questions within 6 categories. The two columns on the right show the predetermined weight of each score (1 to 5) and highlights the questions used to calculated the Holistic HOST-CHS scores. These two columns were excluded from the evaluators scoresheet. PDA = Patent ductus arteriosus, PA = Pulmonary artery

**Table 6.2:** 'Modified' Global Rating Scale based on the work by Reznick et al. This was used as the gold-standard assessment tool to compare the HOST-CHS assessment tool [72]. The three steps: 'Knowledge of instruments', 'Use of assistants' and 'Knowledge of specific procedure' were removed from the original rating scale as they were unable to be assessed retrospectively with video-analysis.

| Task | 1 | 2 | 3 | 4 | 5 | N/A |
|---|---|---|---|---|---|---|
| **Respect for tissue** | Frequently used unnecessary force on tissue or caused damage by inappropriate use of instruments | | Careful handling of tissue but occasionally caused inadvertent damage | | Consistently handled tissue appropriately with minimal damage | |
| **Time and motion** | Many unnecessary moves | | Efficient time/motion but some unnecessary moves | | Clear economy of movement and maximum efficiency | |
| **Instrument handling** | Repeatedly makes tentative or awkward moves with instruments by inappropriate use of instruments | | Competent use of instruments but occasionally appears stiff or awkward | | Fluid moves with instruments and no awkwardness | |
| **Flow of operation** | Frequently stopped operating and seemed unsure of next move | | Demonstrated some forward planning with reasonable progression of procedure | | Obviously planned course of operation with effortless flow from one move to the next | |

## 6.2.2 Hands-on Surgical Training Congenital Heart Surgery (HOST-CHS) assessment tool development and the Global Rating Scale (GRS)

The HOST-CHS assessment tool is a procedure-specific checklist which was designed to objectively assess the technical performance of each step involved in the arterial switch operation. The tool was developed using a combination of the fundamental principles of the nominal and Delphi methods of achieving consensus [85]. Four staff/consultant surgeons experienced in the procedure were independently asked to list the steps involved in the arterial switch operation in the same manner that was described in chapter 5. This information was collated and a hierarchical task analysis performed to deconstruct the operation into its essential components[81]. The overall procedure was divided into six sections: 1) transection of aorta, 2) excision of coronary buttons, 3) transection of ductus arteriosus and pulmonary trunk, 4) reconstruction of the neo-aorta, 5) implantation of coronary artery buttons to neo-aorta and 6) reconstruction of neo-pulmonary trunk. Each section was broken down into steps which were relevant to that category. The tool was adapted for simulation by excluding steps that could not be performed on the 3D-printed model (i.e. median sternotomy, establishing cardiopulmonary bypass etc). The steps were worded in a manner whereby a binary method of assessment could be applied (i.e. YES/NO). A draft of the assessment tool was then presented to the staff/consultant surgeons who independently re-reviewed the checklist and recommended which steps to include/exclude. The surgeons had experience in both the open and closed techniques, which are the most common techniques used in the arterial switch operation. Therefore the tool was designed to be able to score for both techniques.

After several rounds of review staff/consultant surgeons were brought together to discuss the final assessment tool until a consensus was made. Once the assessment tool was agreed each surgeon was asked to weigh each step based on its overall importance in the operation using the Likert-scale (1-5), with 5 signifying highest importance and 1 lowest importance. Again the principles of the nominal and Delphi methods of reaching consensus were used as described earlier. In total there were 43 steps under 6 broad sections with a maximum HOST-CHS score of 153 (Table 6.1).

A holistic HOST-CHS score was then developed to incorporate the general aspects of the surgical procedure. This was designed to provide surgeons with an assessment of their general performance on the models. To achieve this each question of the HOST-CHS assessment tool was evaluated by the staff/consultant surgeons and placed into one of three categories if applicable:

1) Fluency of the procedure – i.e. suture placement, position of the re-implanted coronary artery.
2) Knowledge of the technical aspects of the procedure – i.e. correct shape and size of coronary button
3) Respect for tissue – i.e. clean incisions, avoidance of collateral damage.

The global rating scale (GRS) is a Likert-scale based, validated assessment tool, which is commonly used in surgical assessments [73]. The scale covers the fundamental characteristics that apply to all steps of a surgical procedure. The items 'knowledge of instruments', 'use of assistants' and 'knowledge of specific procedure' were removed as they were unable to be assessed retrospectively via video-analysis (Table 6.2).

The results of each assessment tool were analysed to assess the following:

1) The consistency of total score across all evaluators (inter-rater reliability) and individual scores for each question (intra-class correlation)
2) The consistency of scores for the same rater following a 3-month delay between assessments (intra-rater reliability)
3) If there is a statistically significant difference in score between different levels of evaluators
4) Discriminatory power – i.e. can the assessment tool differentiate between two grades of surgeon among all evaluators

A pilot study was initially performed to evaluate whether the developed assessment tool was suitable to be used in the objective assessment of simulation of the arterial switch operation on 3D printed models. One expert (Video 6.1) and one junior surgeon were recorded while performing the arterial switch operation on the 3D printed TGA model.

The videos were then blinded and scored by a different expert congenital heart surgeon using the HOST-CHS assessment tool and the overall scores were compared. As expected the expert surgeon outperformed the junior surgeon scoring >95% and 55% respectively. Any steps that were deemed too difficult to score on the assessment tool were either altered or removed and the assessment tool was finalised for the validation study.

Ethics approval was obtained from the appropriate institutional research ethics board (Appendix 12.4).

### 6.2.3 Statistical method

Inter- and intra-rater reliability of the assessment tools were performed using the intra-class correlation and the correlation co-efficient respectively. Kruskal-Wallis tests determined if differences existed in overall scores and the assessment tools' discriminatory power using a 95% confidence interval.

To determine the rater consistency among each of the 43 HOST-CHS questions, a joint probability of agreement coefficient was averaged among the 9 raters and 10 videos and shown for each question.

## 6.3 Results

### 6.3.1 Reliability of the HOST-CHS and GRS assessment tools

In total 10 videos were assessed by 9 evaluators with different experiences in the arterial switch procedure. The inter- and intra-rater reliability were higher for the HOST-CHS when compared to the GRS assessment tool, demonstrating a high level of consistency (Figure 6.1).

The joint probability of agreement coefficient measures the fractional absolute agreement among raters and was high (0.81) for the HOST-CHS assessment tool. Nine questions were below the 0.7 threshold showing a greater degree of variability among evaluators (Figure 6.2). These primarily involved the position, anastomosis and trimming of the coronary buttons.

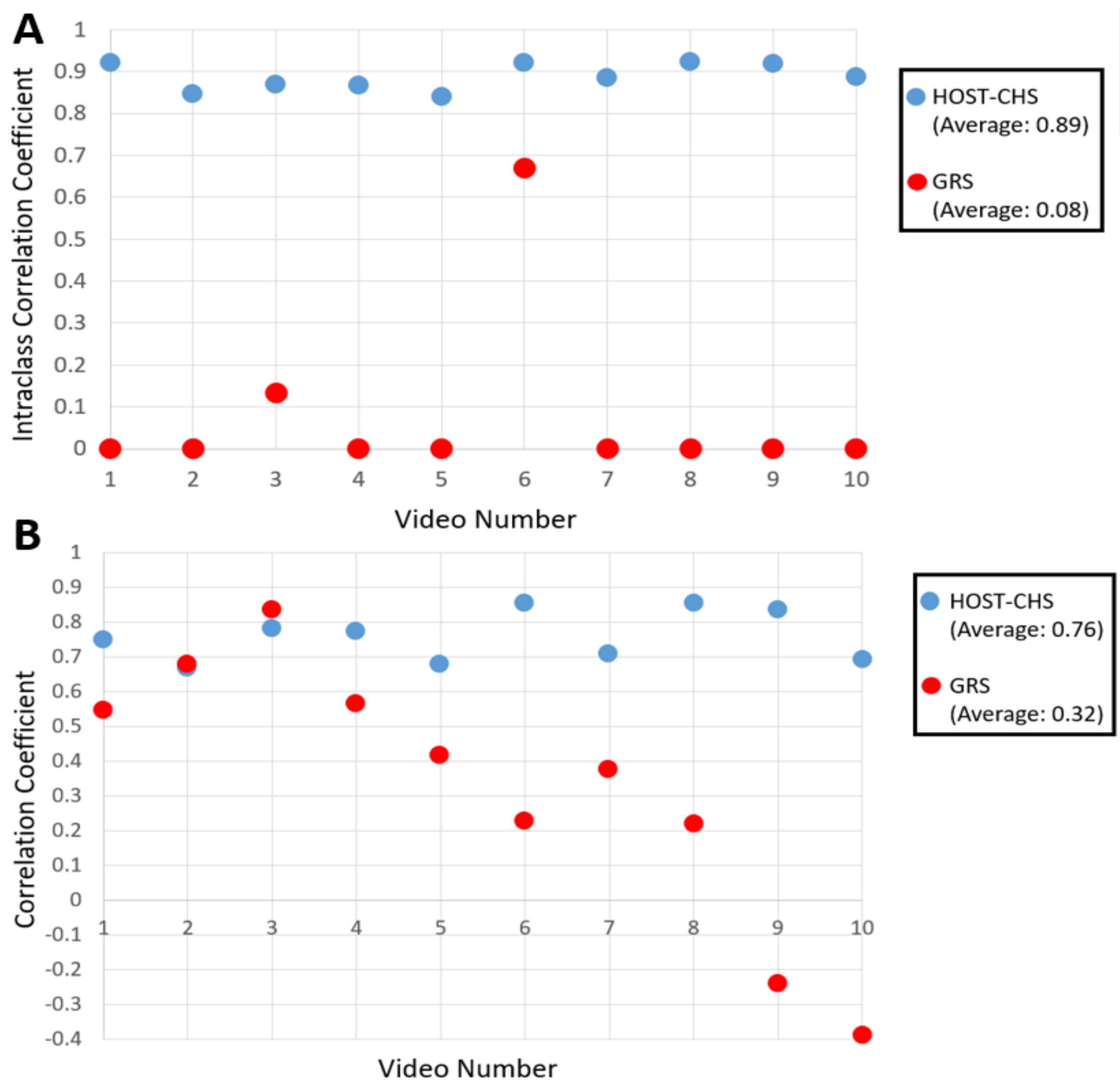



**Figure 6.1:** A) Inter- (A) and intra- (B) rater reliability/agreement for each question in the scoresheet among all evaluators for the HOST-CHS (Hands-on Surgical Training-Congenital Heart Surgery) (blue) and the modified GRS (Global rating scale) (red) assessment tools across all 10 videos. The intraclass correlation (A) and correlation coefficient (B) were used to evaluate reliability. The HOST-CHS assessment tool demonstrates a greater inter and intra-rater reliability than the GRS. Coefficients >0.7 are arbitrarily defined as 'high reliability'. Averages: (A) HOST-CHS = 0.89, GRS = 0.08. (B) HOST-CHS = 0.76, GRS = 0.32.

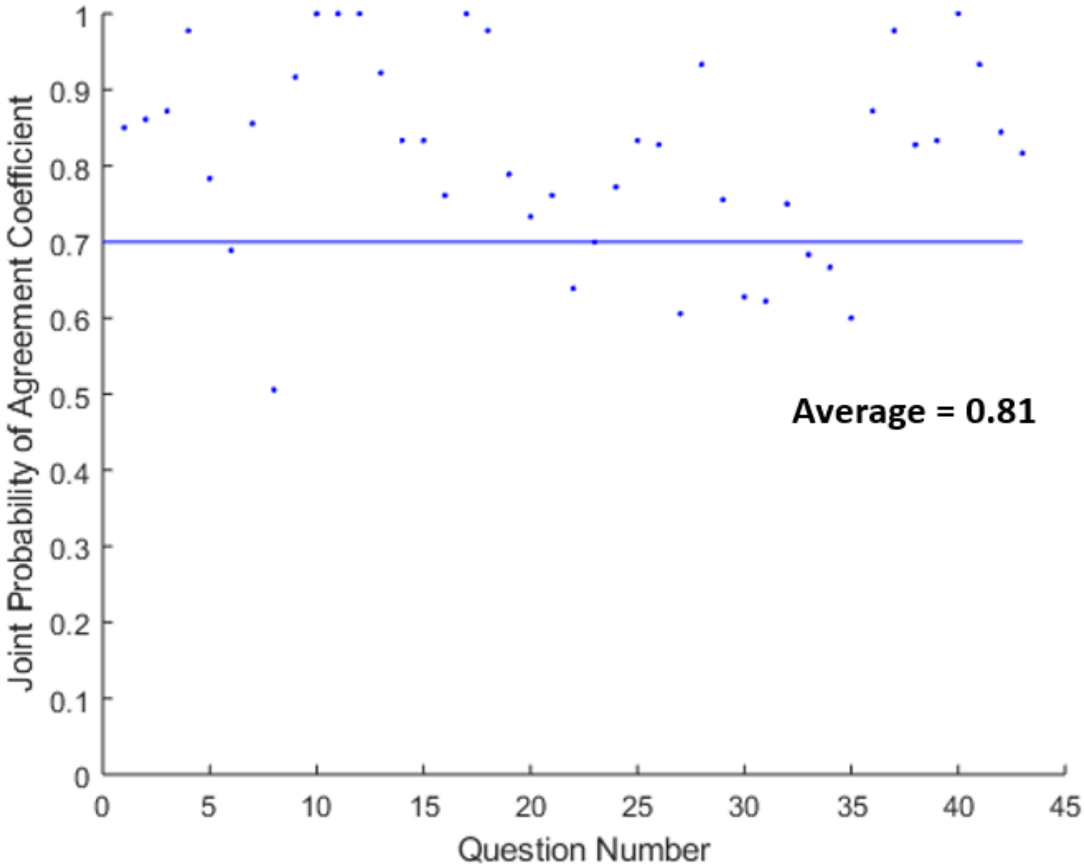



**Figure 6.2:** The joint probability of agreement coefficient for each question in the HOST-CHS (Hands-on Surgical Training-Congenital Heart Surgery) assessment tool (43 questions). The blue line marks an arbitrary agreement coefficient threshold of 0.7, which marks high reliability. 9/43 of the questions fell below this threshold showing a greater degree of variability among evaluators. Average agreement coefficient among all questions = 0.81 (highly reliable).

### 6.3.2 Difference in total score between level of evaluator and discriminatory power

Total scores for 'expert' surgeons were highly consistent across all evaluators with no statistically significant difference. Non-MD raters' total scores for 'junior' surgeons were different, scoring slightly higher than resident and staff surgeons (Figure 6.3). However, all grades of evaluator were able to discriminate clearly between junior and expert surgeons in total score and all holistic HOST-CHS scores (Figures 6.4). Table 6.3 summarises the expected and observed outcomes for the total score from the two assessment tools.

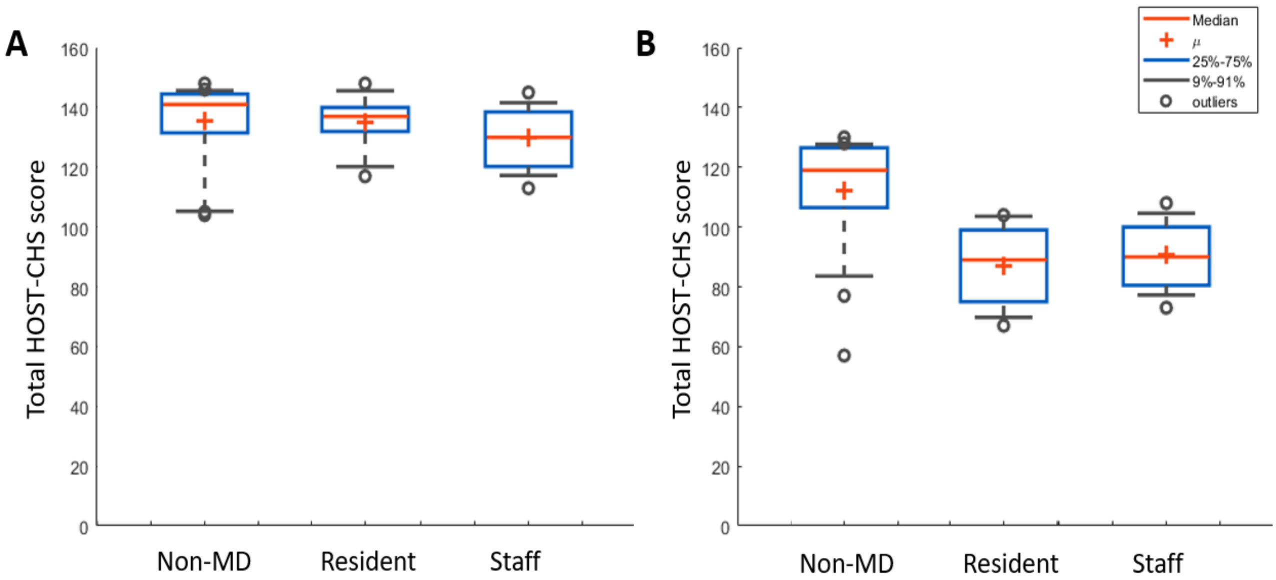



**Figure 6.3:** Comparison of the 'expert' surgeons' (A) and 'junior' surgeons' (B) total HOST-CHS scores (Hands-on Surgical Training-Congenital Heart Surgery) for the arterial switch operation between the different grades of evaluators determined by Kruskal-Wallis tests. Total scores for 'expert' surgeons were highly consistent across all evaluators with no statistically significant difference. Non-MD raters' total scores for 'junior' surgeons were different, scoring slightly higher than resident and staff surgeons. Left = Non-MD. Middle = Resident. Right = Staff surgeon

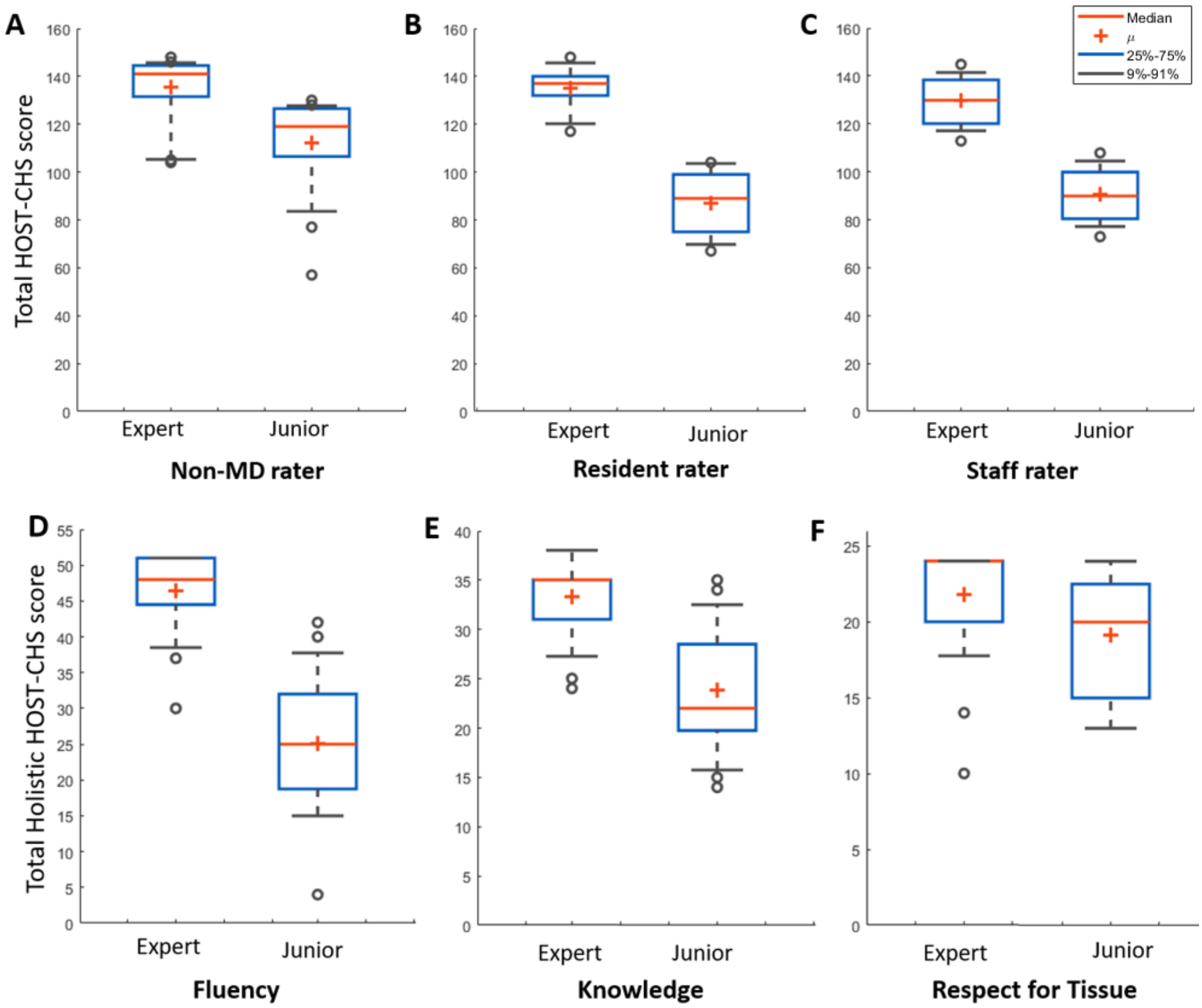



**Figure 6.4:**

**Top panel:** Difference of the total HOST-CHS score (Hands-on Surgical Training-Congenital Heart Surgery) between 'Expert' and 'Junior' surgeons for each grade of evaluator. All evaluators were able to discriminate between both levels of surgeon demonstrating construct validity. A: Non- MD rater (p= 0.00004). B: Resident rater (p = 0.0002). C: Staff rater (p = 0.000003)

**Bottom panel:** Difference of the holistic HOST-CHS scores between 'Expert' and 'Junior' surgeons for MD raters (i.e. Resident + Staff). Again the assessment tool is able to discriminate between different level of surgeon. D: Fluency of procedure (p = 0.000000006). E: Knowledge of procedure (p = 0.0000004). F: Respect for tissue (p = 0.008)

**Table 6.3:** Comparison of the expected and observed outcomes for the total score from the two assessment tools.

| | | Expected Outcome | HOST-CHS | GRS |
|---|---|---|---|---|
| 1 | Non MD raters vs Staff raters on '**Junior**' surgeons | **No difference** | **Difference** p = 0.0002 | **Difference** p = 0.02 |
| 2 | Non MD raters vs Resident raters on **'Junior'** surgeons | **No difference** | **Difference** p = 0.0005 | **Difference** p = 0.004 |
| 3 | Resident raters vs Staff raters on **'Junior'** surgeons | **No difference** | **No difference** p = 0.45 | **Difference** p = 0.06 |
| 4 | Non MD raters vs Staff raters on **'Expert'** surgeons | **No difference** | **Difference** p = 0.03 | **No difference** p = 0.56 |
| 5 | Non MD raters vs Resident raters on **'Expert'** surgeons | **No difference** | **No difference** p = 0.31 | **No difference** p = 0.36 |
| 6 | Resident raters vs Staff raters on **'Expert'** surgeons | **No difference** | **No difference** p = 0.24 | **No difference** p = 0.65 |
| 7 | Junior Surgeons vs Expert surgeons according to **Non MD raters** | **Difference** | **Difference** p = 0.00004 | **Difference** p = 0.045 |
| 8 | Junior Surgeons vs Expert surgeons according to **Resident raters** | **Difference** | **Difference** p = 0.0002 | **Difference** p = 0.0003 |
| 9 | Junior Surgeons vs Expert surgeons according to **Staff raters** | **Difference** | **Difference** p = 0.000003 | **Difference** p = 0.0016 |

## 6.4 Discussion:

Technical excellence is not automatically achieved by extensive experience, which is typically the mantra of surgical training in CHS, but more so from an active engagement in deliberate practice. This notion focuses training on the improvement of a particular task through repetition and immediate feedback [34]. Although prevalent in other surgical specialities there is a need for objective standardised tests in order to reap these desired effects within CHS [19].

The benefits of standardisation are multiple as it provides [73]:

1. Objective feedback for residents
2. Early identification of resident deficiencies
3. Programme development and inter-institutional comparisons
4. A potential tool for certification/training progression

Although effective, existing assessment tools in surgical simulation are primarily generalised and do not focus on the specific aspects of a procedure. There is also a heavy reliance on experienced surgeons to perform the assessments, which may be not feasible due to time limitations. This inadvertently may have a negative effect on their participation in the simulation process, which is crucial.

The ambition of this study was to develop an assessment tool that incorporated the benefits of the expert surgeons' experience, whilst having the ability to be assessed by less experienced personnel. This would maximise the efficiency of the surgeons' time on teaching and increase the likelihood of simulation adoption. Therefore, the assessment tool needed to be both reliable and valid. Reliability refers to the precision of the assessment (i.e. if the assessment was to be repeated on two successive occasions, without additional learning, it would produce the same result). A score/coefficient of >0.8 is deemed as highly reliable, with 0.5-0.8 being moderately reliable and <0.5 having low reliability. Validity refers to whether a test measures what it intends to test [73]. The HOST-CHS tool demonstrated a high inter-rater reliability (0.89), compared to the GRS (0.08) with evaluators consistently scoring the same on each of the 43 items listed in the score sheet (Figure 6.1A). Additionally, after a lengthy period two evaluators were able to repeat the evaluation with results very consistent with their first attempts

(HOST-CHS 0.76 vs GRS 0.32). The GRS showed a greater degree of variability, whereas the HOST-CHS tool shows consistency throughout all videos (Figure 6.1B). Table 6.4A lists the different types of validity and whether they were addressed in the HOST-CHS tool.

Simulation assessments are based on observations and therefore at risk of rater error affecting reliability and validity. Rater training improves accuracy allowing evaluators with no clinical expertise to be as effective as expert assessors [84]. In our study non-MD raters successfully evaluated all videos and distinguished between junior and expert surgeons with total scores comparable with MD raters. However, their scores for junior surgeons were higher than MD markers suggesting a potential limitation. These results were consistent with the results from the gold-standard tool. Table 6.4B lists the common rater errors and whether they were avoided in the HOST-CHS assessment tool.

**Table 6.4A:** Types of validity as described by Gallagher et al and whether they were achieved in the HOST-CHS (Hands-on Surgical Training-Congenital Heart Surgery) assessment tool [86]

| Types of Validity | Description | Achieved in HOST-CHS assessment tool | Rationale |
|---|---|---|---|
| **Face validity** | Contents of assessment tool are reviewed by experts to deem if it will assess what it intends to | YES | Tool developed with input from experienced surgeons in various techniques of the arterial switch procedure. |
| **Content validity** | Each item of the assessment is reviewed to determine appropriateness | YES | Multiple rounds of review to achieve consensus of tasks |
| **Construct validity** | The ability to differentiate between surgeons of different ability (i.e. expert surgeon vs junior surgeon) | YES | Statistically significant difference in score between 'expert' and 'junior' surgeons among all evaluators (Figure 6.4). |
| **Concurrent validity** | Are the new assessment tools' results consistent with that of a 'gold-standard' assessment tool | YES | Global rating scale scores are consistent with HOST-CHS total scores |
| **Discriminate validity** | The ability to differentiate ability levels within a group with similar experience (i.e. CHS fellows) | NO | Study methodology did not assess this |
| **Predictive validity** | Are the scores in the assessment tool predictive of actual performance | NO | Study methodology did not assess this |

**Table 6.4B:** Common rater errors as described by Feldman et al and whether they are avoided in the HOST-CHS assessment tool [84]

| Common Rater Errors | Description | Avoided in HOST-CHS assessment tool | Rationale |
|---|---|---|---|
| **Central tendency** | Avoidance of extreme positive or negative ratings | YES | Binary assessment method. Outcome either positive or negative. |
| **Halo effect** | All ratings based on one positive or negative observation | YES | Specificity of steps requires each question to be answered on its own merit |
| **Leniency** | Avoiding poor performance scale items | YES | |
| **Primary/Recency effect** | Ratings based on observations made early or late in the assessment | YES | |
| **Contrast effect** | Ratings are made relative to a performance of a previous group | YES | Evaluators unaware of grade of operating surgeon as videos randomised. All evaluators given a reference 'gold-standard' video to refer to for calibration |
| **Stereotype effect** | Ratings based on group inclusion rather than individual differences | YES | Evaluators blinded and videos randomised Videos were evaluated in one sitting |
| **Similar-to-me effect** | Ratings based on degree of similarity to rater | YES | Binary assessment method and specificity of questions avoids this effect |

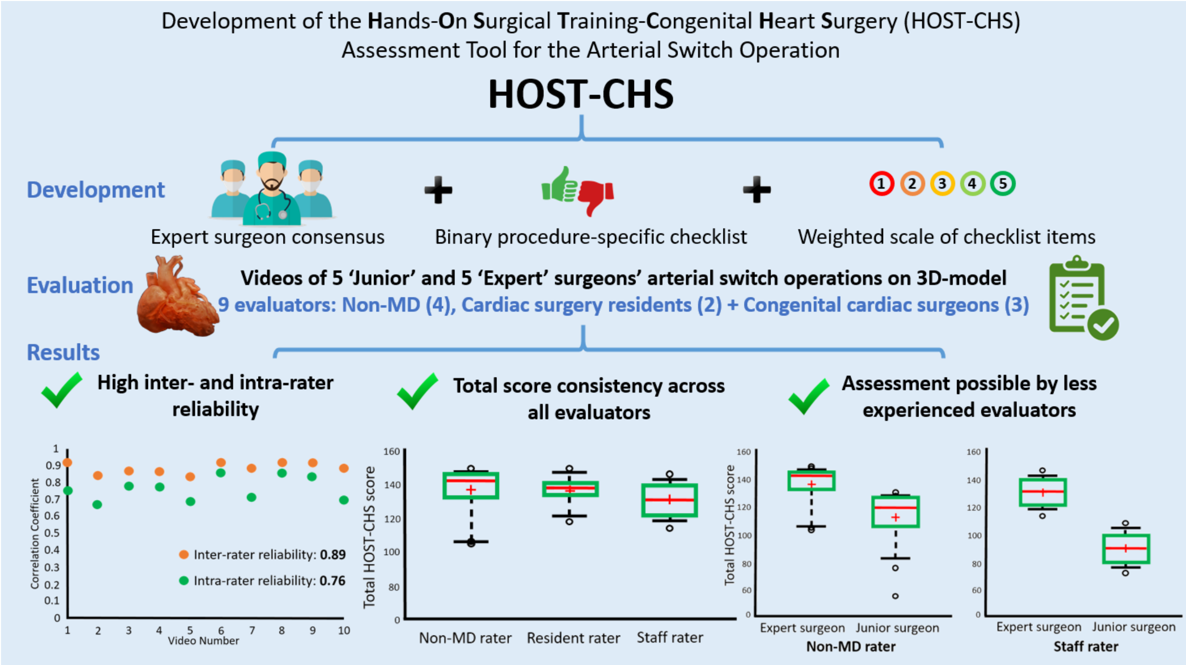



**Figure 6.5:** The HOST-CHS assessment tool (Hands-On Surgical Training-Congenital Heart Surgery) was developed for the simulation of the arterial switch operation on 3D-printed models. The tool is a procedure-specific checklist with items 'weighed' based on their importance using a 1 to 5 scale. Videos of 5 'Junior' and 5 'Expert' surgeons performing the operation were assessed blindly by 9 evaluators who were grouped into 3 categories based on their experience (4 non-MDs, 2 cardiac residents and 3 congenital cardiac surgeons). The HOST-CHS assessment tool showed a high inter/intra-reliability and total score consistency across all evaluators. All evaluators were able to discriminate between 'Expert' and 'Junior' surgeons.

### 6.4.1 Development of the HOST-CHS assessment tool:

Figure 6.5 summarises the development and application of the HOST-CHS assessment tool. The tool is a procedure-specific checklist with items 'weighed' based on their importance using a 1 to 5 scale and was used to assess 10 videos of the arterial switch operation by 9 evaluators. The assessment tool showed a high inter/intra-reliability and total score consistency across all evaluators, when compared to the global rating scale (GRS). All evaluators were able to discriminate between 'Expert' and 'Junior' surgeons.

The GRS is a widely used, validated assessment tool which was developed for evaluating surgical tasks in simulation [72], [73], [87]. It can be used across multiple procedures/specialities, providing a global assessment of the operative performance, and can differentiate between surgeons of varying abilities. However, the assessment tools' ability to focus on specific parts of an operation and provide constructive feedback is limited due to its generalised nature [87]. A Likert-scale based assessment is also at risk of common rater errors and usually requires an experienced evaluator to perform the assessment. Furthermore, the differences among 5 grades are often arbitrary and indistinct.

The binary system is an alternative method which can be used either to assess a trainee's competence to perform a procedure overall (i.e. pass/fail) or whether they completed each task that makes up a full procedure (i.e. checklist) [87]. Checklists provide trainees with structured feedback but their use elsewhere is limited due its procedure-specific nature [87]. This rigidity has led to finding poor validity and reliability when used by experienced or less experienced evaluators, however this was not experienced in our study [73], [87], [88]. This is likely to have been due to a combination of a very specific checklist, a reference gold-standard video for calibration and rater-training.

Both the binary and Likert scale methods were incorporated into the HOST-CHS tool to utilise their benefits, whilst minimising the threats to reliability and validity. A binary method provided the most objective method of assessment and limited potential bias. Additionally, the steps were developed in a very specific manner whereby a video could be evaluated by individuals with minimal experience in CHS.

Within a surgical procedure different tasks have varying levels of importance and consequences if done incorrectly. A weighting system using the Likert-scale principles was developed and incorporated into the assessment tool to address this. Using methods of reaching consensus, we utilised staff experience to predefine the importance of each step of the assessment. This predetermined weighting removed a significant proportion of the threats to validity of the assessment tool whilst incorporating the benefits of a Likert-scale based assessment.

The inclusion of the Holistic HOST-CHS score sub-categorised the surgeons' performance into general aspects of the procedure. Utilising the HOST-CHS tool generated an objective score based on the original assessment, which was advantageous. This information can be used by the trainee to focus on aspects of the procedure they need to improve on (i.e. fluency) in addition to the specific steps they performed incorrectly. Again there was a clear difference in score between expert and junior surgeons.

Achieving consensus is the key to developing a reproducible assessment tool. The methods used in this study collated staff/consultant surgeon opinion in a systematic manner, enabling each participant to express their views impersonally whilst providing information to the whole group [85]. Congenital heart surgery presents a unique challenge in creating standardised procedure-specific assessments as there are multiple ways to perform an operation with excellent outcomes. Therefore, we developed the assessment tool to incorporate all techniques, without compromising its specificity.

Overall the HOST-CHS assessment tool is effective in evaluating the performance of the arterial switch procedure of surgeons with different technical abilities. It provides surgeons with an objective score and highlights the specific areas and tasks that require improvement. This will focus future training objectives and maximise efficiency. Furthermore, evaluators with no prior knowledge of CHS can be trained to be as effective as experienced evaluators. Evaluations performed by unrelated evaluators (i.e. non-MDs) may also eliminate the potential of biased ratings by the trainee surgeons' supervisors. These strengths will increase the likelihood for such assessments to be utilised and assist the incorporation of such simulation methods within future CHS curricula.

## 6.5 Limitations/Future Directions

Although effective in evaluating the arterial switch operation, the specific nature of the assessment tool makes it unsuitable for other CHS procedures. The time taken to perform the assessment is acceptable (5-10 minutes), but the time to produce these assessment tools can be excessive. However, once these assessment tools are generated, they are reproducible and can potentially be used globally. This will be a significant step to incorporating HOST simulation within curricula and evolving training internationally. Additionally, these checklists can be used by trainees to refer to whilst rehearsing and as a method of self-assessment. Within our institution we have established a year-long curriculum (Chapter 8) and have committed to produce HOST-CHS assessment tools for all the procedures that are performed (Appendix 12.3).

Despite the HOST-CHS assessment tools' high inter- and intra-rater reliability, questions 8 and 22-35 showed the greatest degree of variably among evaluators. This result was consistent when both MD raters and staff raters were analysed independently. These questions primarily cover the implantation of coronary button, which is technically the most challenging part of the procedure. Therefore, a degree of variability is expected. Potentially this could be improved by breaking down the section into further questions but will increase the assessment tool's complexity and compromise utilisation. Additionally, the videos are recorded at one angle, which is a limiting factor for accurate assessment on the most complex steps. From our early experience we have found that procedures that involve primarily extracardiac repairs (i.e. arterial switch, Norwood, interrupted aortic arch repair, supravalvular aortic stenosis repair etc) are excellent operations to capture on video and assess. Intracardiac procedures (i.e. ventricular septal defect and atrioventricular septal defect repairs) however, can be difficult to record and assess due to the limited exposure. This is described in more detail in chapter 8.

Although promising there is still a requirement for standard setting within this assessment tool before it can be considered for trainee progression or certification purposes. Further research is required to establish learning curves for each procedure, which will consist of multiple attempts by trainees and an evaluation of their progression

[34], [89]. One method would be to generate a cut-off score (i.e. 'pass/fail') as used in other assessment methods [72], [73], [90], [91]. However, within CHS some surgical steps carry significantly more importance than others and if done incorrectly will lead to significant consequences. Setting a fixed pass score will allow a surgeon to pass a procedure whilst potentially performing a mistake that would be catastrophic in reality. For example, a surgeon could perform the whole arterial switch operation perfectly except leaving one of the coronaries kinked. Their score may be high enough to pass but the consequences of this mistake are fatal for the patient and the delegate should not pass. Therefore, we would adopt a method similar to automobile driving tests whereby each mistake is classified as major or minor; with a major mistake leading to overall failure regardless of total score. Within the HOST-CHS assessment tool this would be the steps that carry the most weight (5) and are therefore easily identifiable.

## 6.6 Conclusion

This study demonstrates the development and validation of an objective, procedure-specific assessment tool for the arterial switch operation, which is comparable to an existing validated assessment tool used in surgical simulation. The developed tool has a high consistency in score between different evaluators (inter/intra-rater reliability) and is able to discriminate accurately between different grades of surgeon. More importantly, this tool provides a high degree of objective feedback for the performing surgeon, which is fundamental for deliberate practice.

Although further work is ongoing to produce assessment tools for the plethora of operations covered within the CHS, this study describes a methodology whereby evaluations can be performed accurately using less experienced evaluators. This will be fundamental to a global adoption of surgical simulation within CHS. With a higher degree of rater-training, potentially all assessments could be accurately performed by evaluators with no experience in CHS.

HOST alongside other simulation studies are viewed as excellent methods to address the growing concerns within CHS training[19]. There is now a platform to quantify and accurately evaluate performances. This will be highly beneficial in the training and development of the next generation of congenital heart surgeons worldwide.

# 7 Quantitative assessment of technical performance during hands-on surgical training of the arterial switch operation using 3D-printed heart models

The following chapter has been adapted from the following publication to suit the flow of this thesis. Permission has been granted from the publisher Elsevier.

***Nabil Hussein**, Osami Honjo, Christoph Haller, John G. Coles, Zhongdong Hua, Glen Van Arsdell, Shi-Joon Yoo. Quantitative assessment of technical performance during hands-on surgical training of the arterial switch operation using 3D printed heart models.*
*The Journal of Thoracic and Cardiovascular Surgery. 2020 Oct;160(4):1035-1042. doi: 10.1016/j.jtcvs.2019.11.123. Epub 2019 Dec 20. PMID: 31983523.*

NH contributions to this publication: Conception and design, development and organisation of study, assessment tool development and validation, data collection, statistical analysis and interpretation, literature review, writing of the article, critical revision and final approval of the article.

## 7.1 Introduction

The previous chapters have shown that 3D-printed heart models are potentially a valuable tool in the hands-on training of surgeons and could potentially be used in the evaluation of their performance; however we are yet to demonstrate if improvement occurs with rehearsal and deliberate practice. Using the assessment tool developed in chapter 6, this chapter aimed to demonstrate if there was an objective improvement in both time and technical performance of the arterial switch procedure on 3D-printed heart models to support our hypothesis of simulation improving the acquisition of technical skills.

## 7.2 Methods

Thirty surgeons of varying surgical experience (i.e. from cardiac surgery resident to staff surgeon) performed the arterial switch procedure twice on 3D-printed models with transposition of the great arteries (TGA) during 1 of 3 HOST courses (4$^{th}$ HOST course – SickKids, Toronto, Canada, TGA HOST course – Fuwai Hospital, Beijing, China and The In-House Monthly HOST course – SickKids, Toronto, Canada). Before participating in the study all delegates were offered a practice model to familiarise themselves with the model material. All delegates were shown how to perform the arterial switch on a TGA model by the lead proctor and were given verbal feedback following each attempt. Both cases were performed without interruption with the same assistant being used. Surgeons' performances were video recorded with high resolution webcams and later cropped to calculate the procedure length (Figure 7.1). All videos were evaluated by a single surgeon with an understanding of the arterial switch procedure using a recently validated procedure-specific assessment tool, which has demonstrated good intra- and inter-rater reliability (HOST-CHS assessment tool – Table 7.1) [92]. All videos were randomised and the evaluator was blinded.

The objective assessments were three fold:

1) Procedure-based assessment – procedures scored using the HOST-CHS assessment tool
2) Holistic assessment – based on the HOST-CHS scoring matrix sub-scores were generated for the following
    a. Fluency of the procedure (i.e. suturing performance, ability to complete procedure)
    b. Knowledge of the technical aspects of the procedure
    c. Respect for tissue during the procedure
3) Time-based assessment – the time taken to complete the procedure

Ethics approval was obtained from the appropriate institutional ethics board (Appendix 12.4).

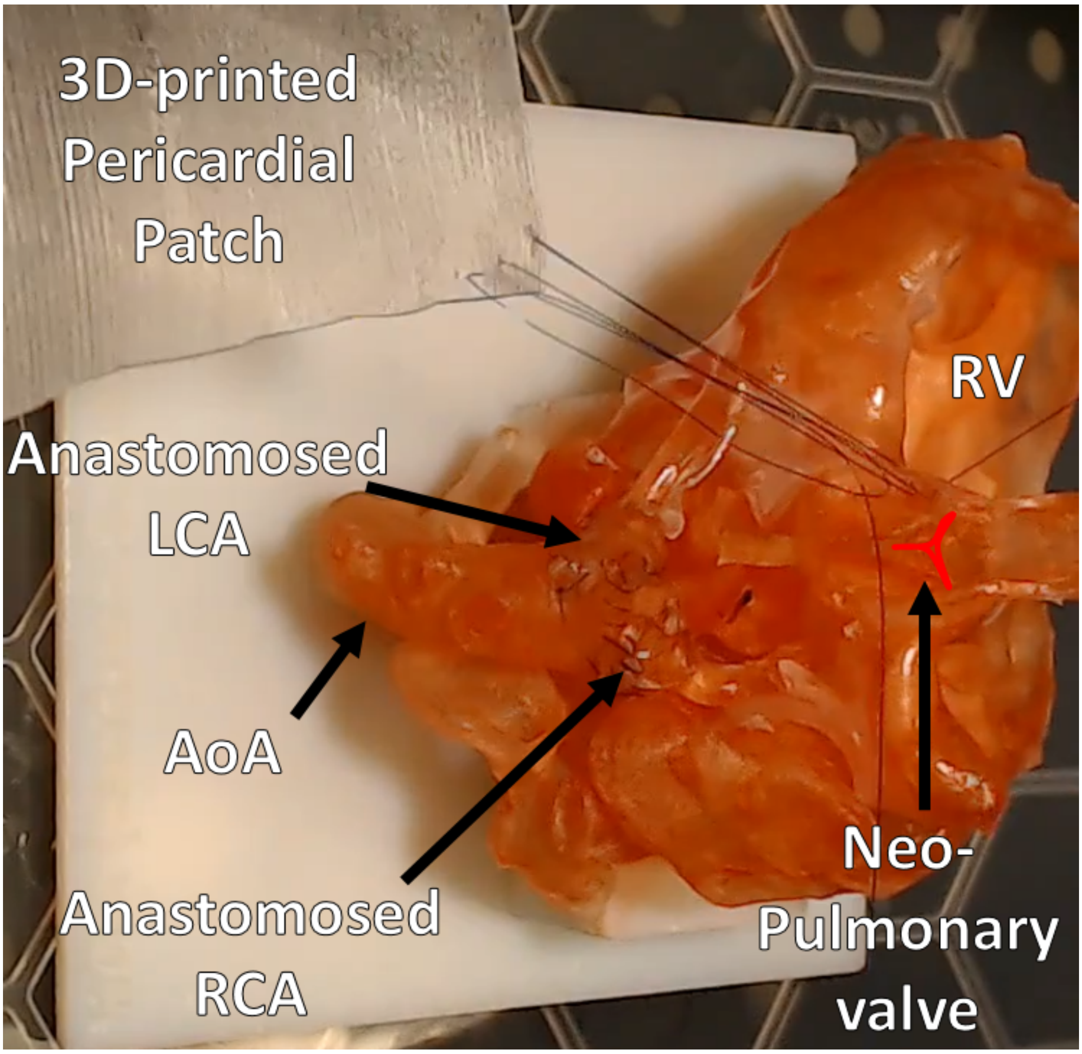



**Figure 7.1:** An image from the video recording of a surgeon performing the neo-pulmonary trunk reconstruction part of the arterial switch procedure on a 3D-printed heart model with transposition of the great arteries (TGA). Note that both coronary artery buttons have been re-anastomosed on the neo-aorta. The edges of the neo-pulmonary valve have been traced with a red line for demonstration purposes. AoA = Aortic Arch, LCA = Left Coronary Artery, RCA = Right Coronary Artery, RV = Right Ventricle.

| | | Steps | Included in HOST-CHS Holistic Score |
|---|---|---|---|
| 1 | **Transection of aorta** | | |
| | | Is the cut in the aorta | |
| | 1 | i) Perpendicular to the vessel? | RESPECT |
| | 2 | ii) Clean? (i.e. not jagged or having sharp protruding points) | RESPECT |
| | 3 | Is there enough distance on the proximal aorta (5-10mm) for good sized coronary buttons? | KNOWLEDGE |
| | 4 | Is there enough distal length on the aorta for reconstruction of the neo-aorta? | KNOWLEDGE |
| 2 | **Excision of coronary artery buttons** | | |
| | 5 | Have the coronary buttons been excised with a liberal amount of aortic sinus wall with the coronary artery? | RESPECT |
| | 6 | Is the coronary button rectangular shaped? | KNOWLEDGE |
| | 7 | Is the coronary orifice in the centre of the button? | KNOWLEDGE |
| | 8 | Is there enough aortic wall left for pulmonary artery reconstruction? (i.e. oblique cut towards anterior commissure) | KNOWLEDGE |
| | 9 | Has there been any damage to the coronary arteries or aortic/neo-pulmonary valve during excision and mobilization? | RESPECT |
| 3 | **Transection of ductus arteriosus and pulmonary trunk** | | |
| | 10 | Has ductus been suture ligated and transected? | |
| | 11 | Is the proximal PDA suture a safe distance from the left pulmonary artery (>1-2mm)? | |
| | | Is the cut in the pulmonary trunk | |
| | 12 | i) Perpendicular to the vessel? | RESPECT |
| | 13 | ii) Clean? (i.e. not jagged or having sharp protruding points) | RESPECT |
| | 14 | iii) A safe distance away from the pulmonary bifurcation (2-5mm) that it does not compromise the branch PAs? | KNOWLEDGE |
| | 15 | Have one or more commissures been marked with a pen or stitch? | KNOWLEDGE |
| 4 | **Reconstruction of neo-aorta** | | |
| | 16 | Has the length of the ascending aorta been adjusted in a new position if required? (i.e. trimmed) | KNOWLEDGE |
| | 17 | Has an end-to-end anastomosis been performed between the proximal neo-aorta and ascending aorta? | |
| | 18 | Was the anastomosis commenced posteriorly? | |
| | | Suture/Anastomosis assessment: | |
| | 19 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of **2-3mm** between suture bites? | FLUENCY |
| | 20 | ii) Are **all** the sutures an adequate distance from the edge (2-3mm)? | FLUENCY |
| 5 | **Implantation of coronary artery buttons to neo-aorta** | | |
| | | **LEFT** coronary button incision | |
| | 21 | i) In the correct position for the technique of choice? (i.e. medially-based trap door for closed technique vs trap-door/rectangular for open technique) | KNOWLEDGE |
| | 22 | ii) Adequate sized incision for technique of choice? (i.e. Closed technique: incision is slightly smaller than button [4-6mm] and edges of trap door are cut at right angles) | RESPECT |
| | | Is the **LEFT** coronary artery | |
| | 23 | i) In the 'best lie' position? (i.e. lateral + superior avoiding compression from PA, not stretching) | FLUENCY |
| | 24 | ii) Kinked or twisted? | FLUENCY |

| | | | | |
|---|---|---|---|---|
| | | iii) | Suture/Anastomosis assessment: | |
| | 25 | a) | Are **all** the sutures evenly spaced from one another **WITH** a gap of **1-2mm** between suture bites? | FLUENCY |
| | 26 | b) | Are **all** sutures an adequate distance from the edge (1-2mm) **AND** is a safe distance from the neo-aortic valve and coronary ostium? | FLUENCY |
| | 27 | iv) | Has the coronary button been trimmed appropriately? (i.e. leaving more tissue medially than laterally in the trap door technique/not too much tissue left over effecting lay/anastomosis) | |
| | 28 | v) | Is the coronary still in tact by the end of anastomosis (i.e. not avulsed)? | |
| | | **RIGHT** coronary button incision | | |
| | 29 | i) | In the correct position for the technique of choice? (i.e. medially-based trap door for closed technique vs trap-door/rectangular for open technique) | KNOWLEDGE |
| | 30 | ii) | Adequate sized incision for technique of choice? (i.e. Closed technique: incision is slightly smaller than button [4-6mm] and edges of trap door are cut at right angles) | RESPECT |
| | | Is the **RIGHT** coronary artery | | |
| | 31 | i) | In the 'best lie' position? (i.e. lateral + superior avoiding compression from PA, not stretching) | FLUENCY |
| | 32 | ii) | Kinked or twisted? | FLUENCY |
| | | iii) | Suture/Anastomosis assessment: | |
| | 33 | a) | Are **all** the sutures evenly spaced from one another **WITH** a gap of **1-2mm** between suture bites? | FLUENCY |
| | 34 | b) | Are **all** sutures an adequate distance from the edge (1-2mm), **AND** is a safe distance from the neo-aortic valve and coronary ostium? | FLUENCY |
| | 35 | iv) | Has the coronary button been trimmed appropriately? (i.e. leaving more tissue medially than laterally in the trap door technique/not too much excess tissue left over effecting lay/anastomosis) | |
| | 36 | v) | Is the coronary still in tact by the end of anastomosis (i.e. not avulsed)? | |
| 6 | **Reconstruction of neo-pulmonary trunk** | | | |
| | 37 | Has the candidate performed this procedure to completion? (i.e. anastomosis of patch and then to branch PAs) | | FLUENCY |
| | 38 | Is the height of patch level with the native tissue left following transection/ coronary button excision? | | FLUENCY |
| | 39 | Is diameter of patch slightly larger than the native lumen size? | | KNOWLEDGE |
| | 40 | Has an end-to-end anastomosis been performed between the neo-pulmonary trunk and the distal pulmonary artery? | | |
| | 41 | Was the anastomosis commenced posteriorly? | | |
| | | Suture/Anastomosis assessment: | | |
| | 42 | i) | Are **all** the sutures evenly spaced from one another **WITH** a gap of **2-3mm** between suture bites? | FLUENCY |
| | 43 | ii) | Are **all** the sutures an adequate distance from the edge (2-3mm)? | FLUENCY |

**Table 7.1:** Hands-On Surgical Training in Congenital Heart Surgery (HOST-CHS) assessment tool used to score surgeons' performances of the arterial switch procedure. Questions which were used to calculate the Holistic HOST-CHS scores are highlighted on the right. (PDA = Patent ductus arteriosus, PA = Pulmonary artery)

## 7.3 Results

### 7.3.1 Procedure-based Assessment

**HOST-CHS Total score**:

Sixty videos in total were scored. The maximum possible score was 153. Eighty percent of surgeons (24/30) had improved from their first attempt with 20% (6/30) having a reduced score (Figure 7.2). The mean score of the first attempt compared to the second was 103 and 120 respectively, with a mean difference in score of 17 (95% CI 10-24). The range of score difference between attempts was -22 to 56. Of the cohort who's score improved the mean increase was 23 points (15%) and the mean reduction in score of the cohort who's scores reduced was -7 points (-5%). There was no statistically significant difference in these performance measures when subjects were compared based on their experience.

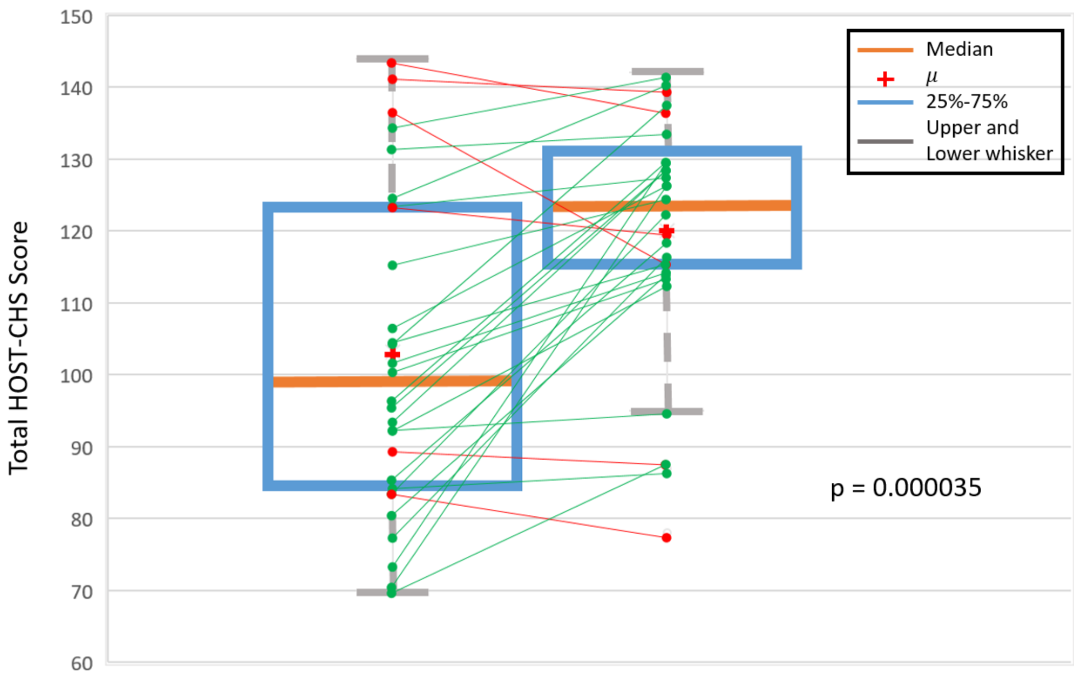



**Figure 7.2:** Comparison of total HOST-CHS scores between the first and second attempt of the arterial switch procedure during hands on surgical training (HOST). Green lines represent surgeons who's score increased and red lines of surgeons who's score decreased. Eighty percent of surgeons' scores improved between the two attempts.

LEFT (First attempt): Median score = 100, RIGHT (Second attempt): Median score = 120

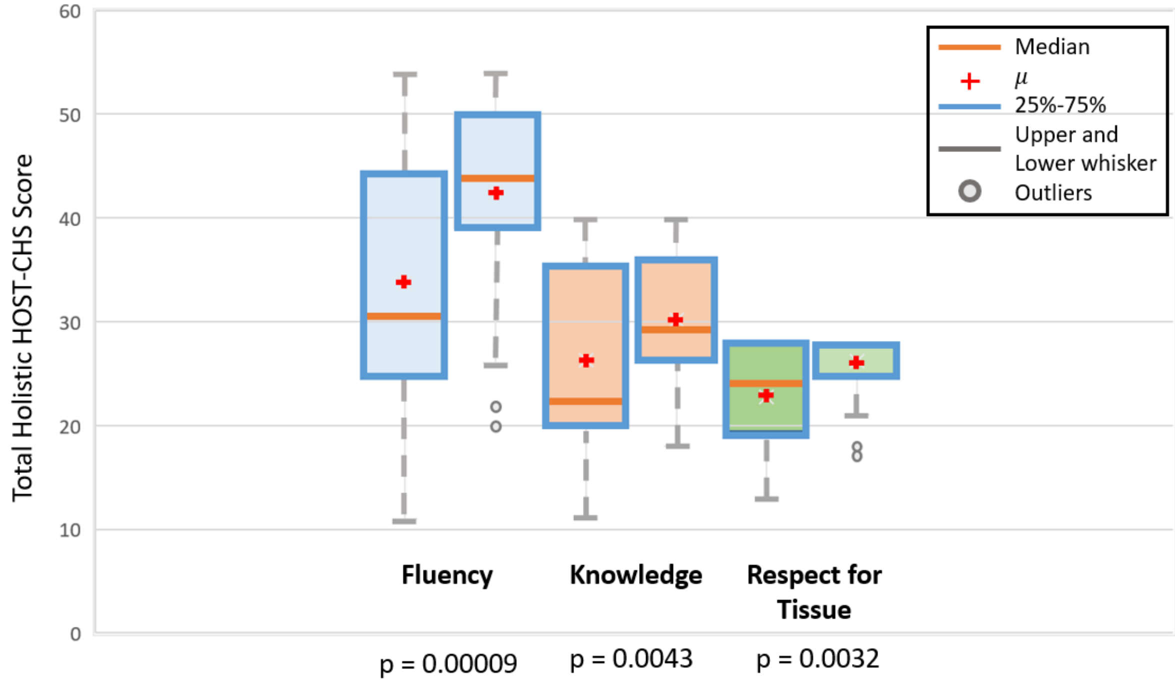



**Figure 7.3:** Comparison of the Holistic HOST-CHS scores between the first and second attempt of the arterial switch operation during hands on surgical training (HOST). The performance measures scored include the fluency of the procedure, the surgeons' knowledge of key operative steps and the respect for tissue. Two-thirds of surgeons' performance improved over all measures.

**Fluency (blue):** LEFT (1$^{st}$ attempt): Median = 30. RIGHT (2$^{nd}$ attempt): Median = 42.

**Knowledge of procedure (orange):** LEFT (1$^{st}$ attempt): Median = 23. RIGHT (2$^{nd}$ attempt): Median = 30.

**Respect for tissue (green):** LEFT (1$^{st}$ attempt): Median = 24. RIGHT (2$^{nd}$ attempt): Median = 26.

**HOST-CHS Holistic scores**

Overall there was a statistically significant improvement across all the holistic scores (Figure 7.3). Approximately two thirds of the surgeons had improved on their first attempt (Table 7.2). Of the cohort who's scores improved the mean improvement ranged between 19 to 26% whereas the mean reduction in score of the cohort who's scores reduced was between -6 to -14%.

**Table 7.2:** Comparison of the HOST-CHS Holistic scores from the first and second attempts of the arterial switch operation during hands on surgical training. The table shows a statistically significant improvement in scores across all three performance measures.

| Holistic Score | Maximum score possible | Percentage of surgeons improved (number) | Mean score First attempt | Mean score Second Attempt | Mean difference between attempts (95% confidence interval) | p value |
|---|---|---|---|---|---|---|
| **Fluency** | 54 | 67% (20/30) | 33.4 | 42.4 | 8.7 (4.8 – 12.67) | p <0.001 |
| **Knowledge** | 40 | 70% (21/30) | 26.3 | 30.2 | 3.9 (1.33 – 6.48) | p < 0.001 |
| **Respect for Tissue** | 28 | 67% (21/30) | 22.7 | 26.2 | 3.5 (1.27-5.73) | p < 0.001 |

### 7.3.2 Time-based assessment

The time to assess each video ranged between 5-10 minutes. Time between performing the first and second case ranged between 1 hour to 2 days. All the surgeons were statistically significantly quicker in their second attempt (Figure 7.4). Mean time for the first attempt compared to the second was 1:28:04 (h:mm:ss) and 1:05:45 respectively, with a mean difference of 0:22:19 (95% CI 0:15:22 – 0:25:34). The range of time improvement was between 0:01:40 – 1:18:16.

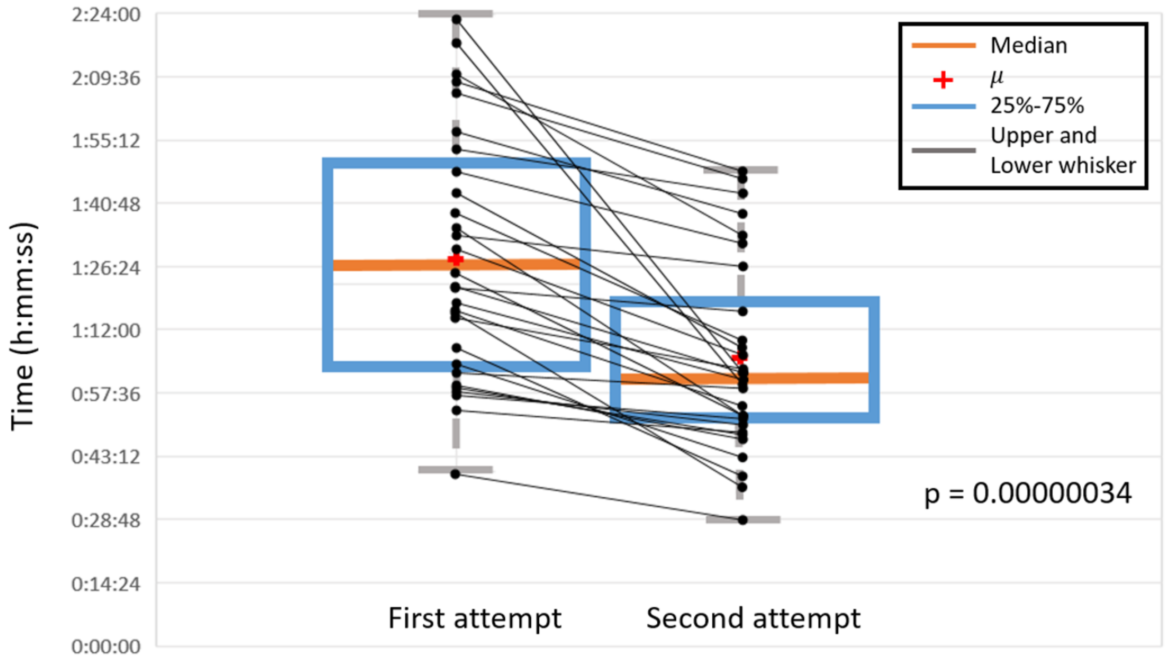



**Figure 7.4:** Time comparison between the first and second attempt of the arterial switch procedure during hands on surgical training (HOST). Each black line represents one surgeon and their procedure times. On average surgeons were 25% quicker in their second case compared to first.

LEFT (First attempt): Median = 1:22:20, RIGHT (Second attempt): Median = 1:00:44

## 7.4 Discussion

This chapter is the first demonstration of quantitative assessment within HOST in CHS, using an acceptable number of surgeons to draw conclusions. Moreover, it supports the concept that repeated practice is associated with improvement in performance, which has been demonstrated in other specialities [39], [83]. This work further validates the use of 3D-printed heart models as an effective method of simulation and learning within CHS.

In chapter 6 the HOST-CHS tool was developed and validated as an effective assessment method in the arterial switch procedure on 3D-printed heart models, demonstrating high inter- and intra-rater reliability between assessors with varying experience of the procedure [92]. The tool has the ability to provide the individual surgeon with objective, procedure specific feedback to highlight the areas of improvement.

The outcome of the HOST-CHS scores is encouraging and strongly supports the notion that with repeated practice, surgeons improve in simulation-based exercises. In total 80% of the surgeons had improved from their original score, with a mean improvement of 15% in this cohort. Of the 20% who's scores decreased, two-thirds (4/6) had scored within the upper quartile of overall results in their first attempt, suggesting that they already had a good understanding of the procedure. The reduction could potentially be explained by experimentation or adoption of an alternative technique rather than a poorer performance. This highlights another useful advantage of simulation for more experienced surgeons.

In addition to the total HOST-CHS score, the holistic scores showed an overall improvement across all parameters with mean improvement between 10-16% consistent with the HOST-CHS total scores. This information can be particularly useful for the delegate as they can identify and focus their learning on a generic area that requires improvement.

Congenital heart surgery is a technically demanding speciality, however in addition to technical prowess, efficiency of time is also an important factor in cardiac surgery, with prolonged cross-clamp and cardiopulmonary bypass times being an independent predictor of morbidity and mortality in patients [93]–[95]. The results demonstrate that all surgeons were statistically significantly quicker in their second attempt when compared to the first. This supports the concept of the learning effect in simulation whereby operative efficiency improves during simulation [83], [89]. To prevent the lack of familiarity of the model being a confounding factor in the time analysis, delegates were given a 3D-printed heart model to practice dissection and suturing before performing their first attempt of the arterial switch. Due to the different layouts of each course there was a range in the time delay between the first and second case, however the results still remained consistent. Time between cases is an important variable to consider particularly in skill retention. Further studies should focus on this impact along with the effects of high volume cases, which this methodology would allow. Although time is an important factor to address in cardiac surgery, precision and being safe is of greater importance and should not be sacrificed.

### 7.4.1 Implications

This study demonstrates how hands-on surgical simulation can be assessed in a quantitative manner, supporting the existing qualitative evidence of its usefulness [18]. Within our institution we have utilised this method of training to assess a surgeon's readiness before performing a procedure within the operating room (Figure 7.5 + Video 7.1). A fellow rehearsed the arterial switch operation at least 3 times prior to performing it in real-life. They completed the patient case with minimal guidance or assistance and performed the whole operation with acceptable cardiopulmonary bypass and cross-clamp times. There were no complications. This simulation platform provides a stress-free environment whereby the fellow can demonstrate their understanding of the procedure and can rehearse with their mistakes being addressed before the procedure on a patient. Furthermore, it has proven to be extremely beneficial to the trainer as it gives them the opportunity to assess the limitations of the surgeon and identify areas for improvement, which can be valuable information making the perioperative course smoother.

This type of simulation along with objective assessments potentially could be used as a method of evaluation of surgical residents and fellows within their training and added to certification examinations. This will help switch the emphasis away from a number to a competency based assessment method, which has been deemed necessary within congenital heart surgery training [74], [96]. It encourages surgeons-in-training to proactively take further ownership of their own training allowing them to repeatedly rehearse procedures without a heavy reliance on trainers. This would lead to an increased efficiency of training programmes and potentially reduce the overall training time in CHS.

However, in order to achieve this there has to be an increased commitment by institutions to utilise simulation as a method of training. Financial and infrastructure barriers exist which inhibit the commencement of such programmes, especially for smaller institutions; however evidence continues to grow to support such methods of training. This issue could be addressed by collaboration between institutions and training programmes to ensure all training surgeons experience these benefits. Hospitals and insurance companies could also benefit by investing in simulation programmes as it improves efficiency and may lead to improved patient safety and reduced complications [39]. However, whether this truly translates into patient outcomes will be difficult to demonstrate objectively due to the vast number of factors that lead to patient morbidity and mortality.

Furthermore, it is crucial to appreciate the importance of experience in the surgical management of patients with complex congenital heart disease. Although 3D printed models can help in technical skill development, they may be limited in demonstrating the full spectrum of the disease. For example in the arterial switch operation a surgeon may be presented with anatomical variations intraoperatively, which may add an extra layer of complexity to the repair (i.e. unexpected position of the coronary arteries, the coronary orifice being near the valve commissure, the presence of intramural coronary arteries etc). Although models can be adapted to incorporate these variations, gaining experience through the assistance and observation of expert surgeons managing these anomalies is a crucial aspect in surgical development.

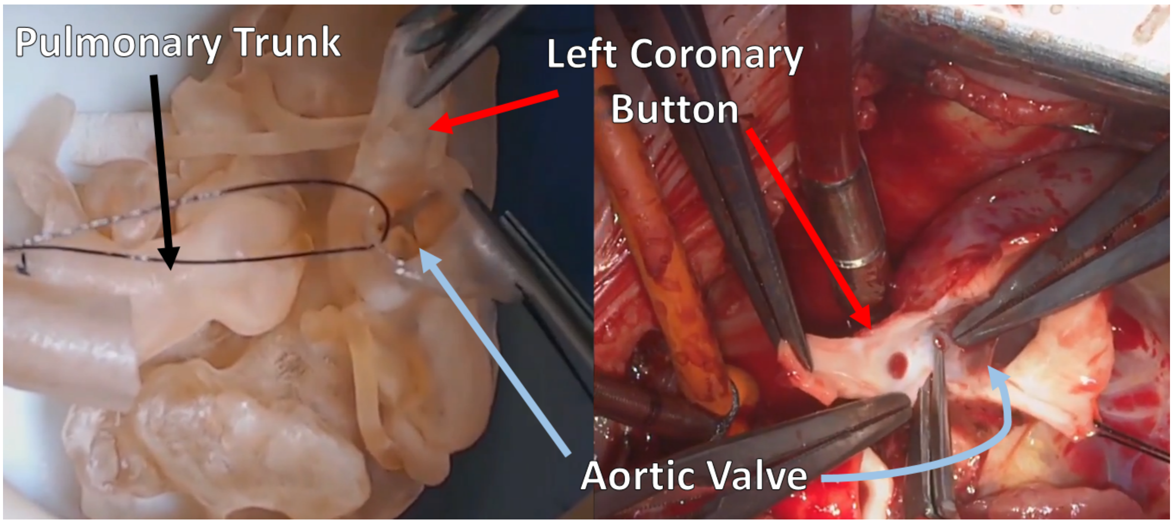



**Figure 7.5:** Congenital heart surgery fellow rehearsing the left coronary button excision part of the arterial switch operation on a 3D-printed heart model (LEFT) before performing the same task on a patient (RIGHT). Note – the aortic valve is included in the model to resemble reality.

**Video 7.1:** Video clip demonstrating a congenital heart surgery fellow rehearsing the arterial switch procedure on the 3D-printed model (LEFT) and performing the same procedure on a patient (RIGHT). Steps include transection of the aorta and pulmonary trunk, ligation and division of the patent ductus arteriosus, re-anastomosis of the neo-aorta and implantation of left coronary artery. YouTube video link: https://youtu.be/1B8p9KYzlGc

## 7.5 Conclusion/Future Directions

This study demonstrates that there is an objective improvement in both time and technical performance of the arterial switch procedure on 3D-printed heart models using the HOST-CHS assessment tool as summarised in Figure 7.6. This supports evidence that simulation in the form of deliberate practice and constructive, objective feedback are fundamental in the training of future, excellent surgeons.

Before these simulation methods can be utilised for training progression or examination purposes further data needs to be collected demonstrating learning curves and a consensus achieved on standard setting (i.e. pass and fail scores). Learning curves are well established in other forms of simulation and it is predicted that with further attempts the surgeons' scores and time would improve in a sigmoid distribution eventually reaching a plateau as experienced in other specialities [83], [89]. The number of attempts required to achieve this is currently unknown and would vary between different levels of surgeons and procedures. These developments will be crucial in the quest of creating a balanced and structured training programme within congenital heart surgery, which utilises HOST.

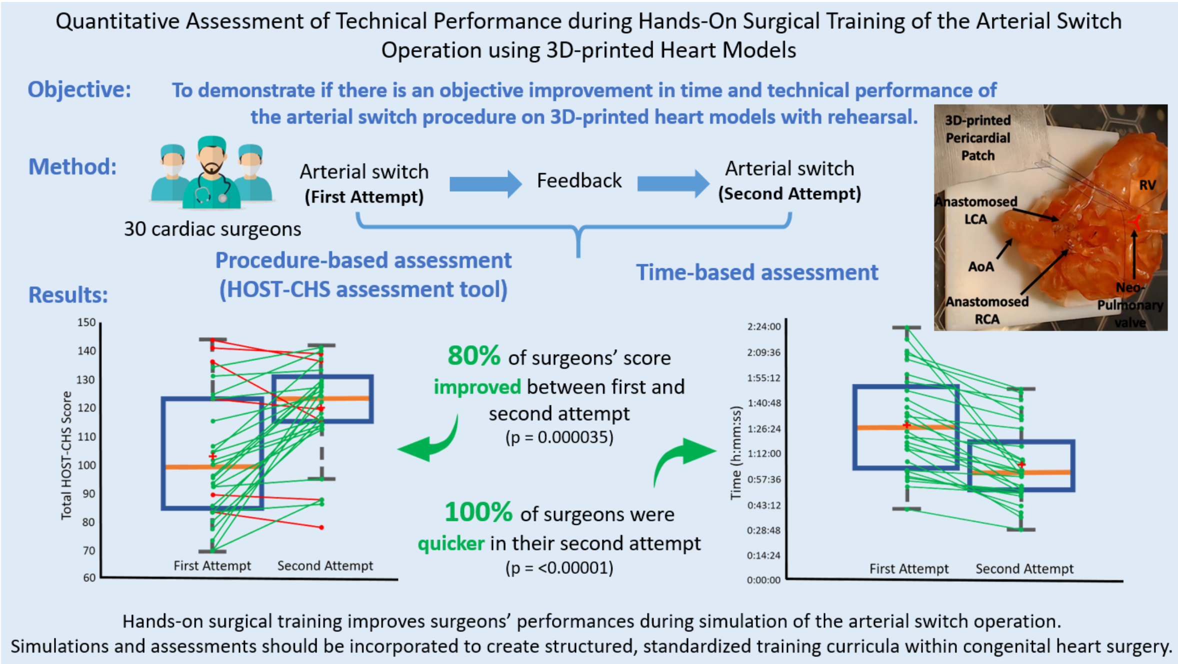



**Figure 7.6:** This study demonstrates an objective improvement in the simulation of the arterial switch operation during hands-on surgical training (HOST) using 3D-printed heart models. Thirty cardiac surgeons performed the operation twice on the models and were evaluated with time and procedure based assessments. Eighty percent of surgeons' total scores improved in their second attempt (p=0.000035) with all surgeons being quicker (p=<0.00001).

HOST-CHS = Hands-On Surgical Training Congenital Heart Surgery Assessment tool

# 8 The incorporation of hands-on surgical training in a congenital heart surgery training curriculum

The following chapter has been adapted from the following publication to suit the flow of this thesis. Permission has been granted from the publisher Elsevier.

***Nabil Hussein****, Osami Honjo, David J Barron, Christoph Haller, John G Coles, Shi-Joon Yoo*
*Incorporation of hands-on surgical training in a congenital heart surgery training curriculum and assessment of its performance.*
*Annals of Thoracic Surgery. 2020 Dec 9:S0003-4975(20)32088-9. doi: 10.1016/j.athoracsur.2020.11.018. Epub ahead of print. PMID: 33307072.*

NH contributions to this publication: Conception and design, organisation and planning of study, design of curriculum, assessment tool development and validation, data collection, statistical analysis and interpretation, literature review, writing of the article, critical revision and final approval of the article.

## 8.1 Introduction

Chapters 6 and 7 demonstrated that Hands-on Surgical Training (HOST) courses with 3D-printed heart models have proven to be useful in the simulation of complex congenital heart surgical procedures with improvements in technical skill and simulation time being observed following deliberate practice. The next natural step in the programme's evolution was to incorporate it as part of the local congenital heart surgery (CHS) curriculum for surgical trainees to ensure regular training and to assess whether their technical skills were retained over time. We recently introduced the monthly In-House HOST sessions for our local surgical fellows/residents as a core component of the training curriculum in CHS [18], [19]. This study was aimed to describe the content and layout of the HOST courses and to assess its impact on the improvement and retention of technical skills using objective assessments during the academic year of 2019-2020.

## 8.2 Method

### 8.2.1 Monthly In-House HOST Curriculum design

Twelve cases were selected from our institutional repository by our staff surgeons for one academic year based on their perceived requirements for training and applicability to 3D printing (Table 8.1). The monthly course was scheduled for the last Monday evening of every month when the risk for cancellation or interruption of the course was the lowest. Each session would last between 3 to 4 hours. The sessions were attended by all congenital heart surgical fellows and residents within our institution's training programme (defined as trainees). All fellows had completed their general surgery and adult cardiac/cardiothoracic training (>5 years' experience) and the residents were in their final training year.

**Table 8.1:** The pathologies and procedures in the monthly In-House Hands-on Surgical Training in Congenital Heart Surgery (HOST-CHS) curriculum (2019-20).

| 3D-printed heart model | Simulated procedure |
|---|---|
| **Coarctation of Aorta repair** | Extended end-to-end anastomosis |
| **Ventricular septal defect (perimembranous)** | Transatrial repair |
| **Tetralogy of Fallot** | Transatrial repair + pulmonary artery reconstruction(valve-sparring) |
| **Tetralogy of Fallot with pulmonary atresia** | Transatrial repair + transannular patch |
| **Supravalvular aortic stenosis** | Y-patch (Doty) + novel H-patched techniques |
| **DORV with subaortic VSD** | Transatrial repair with intraventricular baffle |
| **Completed atrioventricular septal defect (Rastelli A)** | 2-patch sandwich technique |
| **Truncus arteriosus (type II) repair** | Primary repair |
| **Interrupted aortic arch (Type B)** | Single-stage repair (VSD closure + aortic arch reconstruction) |
| **Hypoplastic left heart syndrome** | Norwood operation (interdigitating technique) |
| **Transposition of the great arteries with normal coronary pattern (1LCX2R)** [77] | Arterial switch operation (open or closed technique) |
| **Double outlet right ventricle with subpulmonary VSD (Taussig-Bing-anomaly)** | Single-stage repair (VSD closure, aortic arch reconstruction + arterial switch) |

### 8.2.2 Layout of course and objective assessments

All 3D-printed heart models were designed in-house and were prepared >a week prior to the training session. Models were printed with the Stratasys J750 Polyjet printer in the flexible material Agilus30 (Stratasys, Eden Prairie, MN) and were subsequently dyed red as described in chapter 3 (Figure 8.1). The set up included a chest wall simulator which was designed to house a 3D-printed model, which allowed rotation and tilting of the model to improve exposure of the surgical field. This is described in more detail in chapter 9. Each trainee was provided with a 3D-printed model, a set of surgical instruments, a chest wall simulator and sutures/conduits. The patches and conduits used were either 3D-printed or commercial products. All sessions were performed in a dedicated HOST training room in the main hospital building. A breakdown of costs is included in Table 8.2.

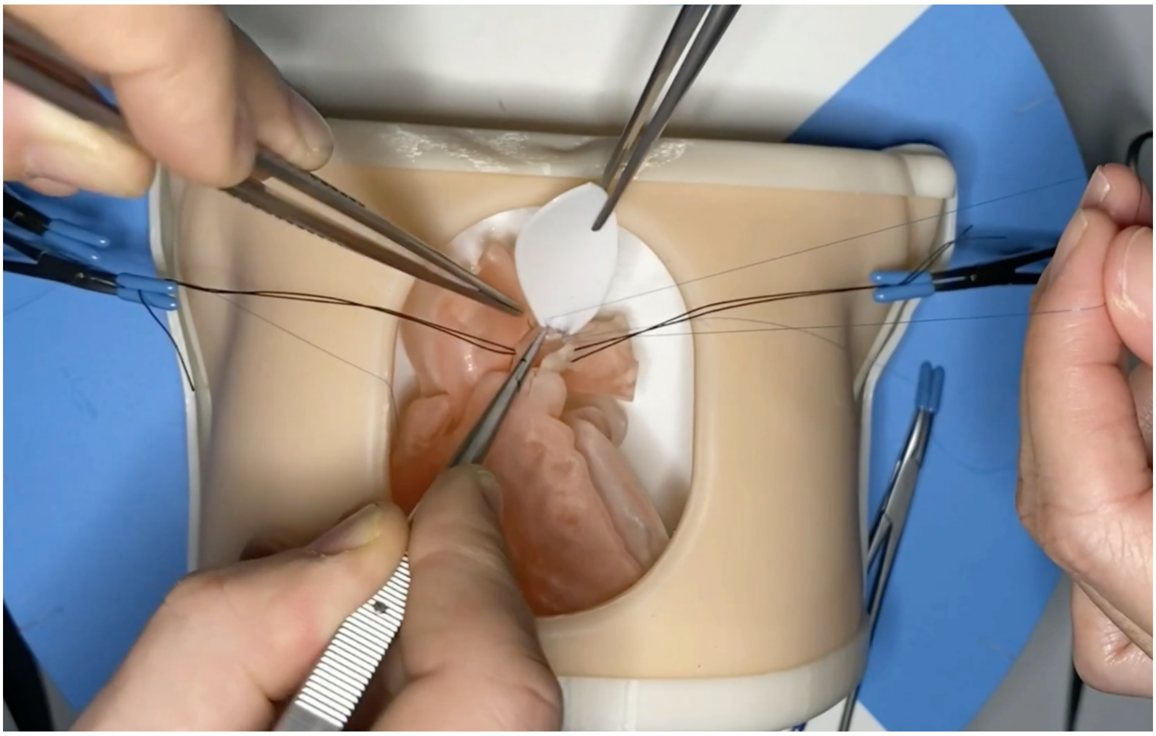

**Figure 8.1:** A surgeon rehearsing suturing of a transannular patch on a 3D-printed heart model of tetralogy of Fallot.

**Table 8.2:** Summary of costs associated with the In-House HOST course. *HOST-CHS chest wall simulator used for 60 cases before maintenance or replacement.

| Item | Approximate cost (Quantity) - USD |
|---|---|
| 3D-printed heart model | $200 - 300 (1) |
| 3D-printed models for 1 year curriculum (per surgeon) | $4800 - 7200(24) |
| Instrument set | $750 (1) |
| HOST-CHS chest wall simulator | $550 (1)<br>Cost per use: ~$9* |
| Sutures + Conduits | $0 - donated |
| 3D-printed pericardial patch | $15 (1) |
| Total cost (per surgeon) | $6250 - 8650 |

One week prior to the monthly HOST session, a staff congenital heart surgeon gave a 1-hour didactic lecture on the surgical anatomy and procedure for the pathological entity that would be simulated. The HOST sessions were attended by all trainees and staff surgeons. Each session was led by 1 proctor who would rotate on a monthly basis with the other staff surgeons. Sessions would commence with the proctor giving a full demonstration of the simulated procedure on the 3D-printed model as shown in Video 8.1 of a surgeon suturing a transannular patch on a tetralogy of Fallot model. These demonstrations were video recorded and used later to make the HOST training videos, which are freely available on the website: www.3dprintheart.ca.

Following the proctor's demonstration, the trainees simulated the same procedure on the models twice under staff surgeon guidance. All attempts were video recorded without identifiable information of the operating surgeon or the numbered attempt. The recorded videos were then randomised and retrospectively assessed by a single surgeon using the validated HOST-CHS assessment tool, which were developed for every procedure [92]. Two types of objective assessment were performed: a procedure-based assessment (i.e. total HOST-CHS score) and a time-based assessment (i.e. time to complete attempt). The trainee surgeons were unaware that they were being timed during their attempts, which was calculated during analysis of the recorded video. A catalogue of the HOST-CHS assessment tools are available in Appendix 12.3.



**Video 8.1:** Proctor surgeon suturing the transannular patch on a 3D-printed heart model of tetralogy of Fallot during the In-House HOST course.

YouTube video link: https://youtu.be/Zfhjl79FzyQ

### 8.2.3 Assessment of retention of technical surgical skills

On completion of the HOST curriculum, trainees were invited back to repeat 4 procedures twice back-to-back to assess for retention of technical skills (Attempts 3 and 4). These were recorded and assessed for comparison with Attempts 1 and 2. Prior to repeating their attempts, the trainees were given access to the relevant HOST training video to re-familiarise themselves with the procedure.

An institutional ethical approval was obtained and consent was taken by attendees for recording and assessment of the surgical procedures (Appendix 12.4). Paired t-tests were used to analyse both procedural and time scores between the attempts performed.

## 8.3 Results

The monthly In-House HOST course consisted of 12 sessions. Eleven sessions were completed on schedule with one session being postponed due to an unplanned cardiac transplantation. Nine of the sessions were attended by all 7 trainees, with the other three being attended by 6. Objective assessments were performed for technical performance in 7 of the 12 sessions, with 5 being excluded (Table 8.3). Reasons for exclusion included: failure of recording equipment, an inability to capture the intra-cardiac aspect of an operation, only one long attempt being performed due to the complexity of the disease, or two different repair techniques being simulated which did not allow direct comparison.

**Table 8.3:** Summary of attempts performed by congenital heart surgical (CHS) trainees during the monthly In-House HOST-CHS course including: 1) Attempts which were objectively assessed for technical performance and procedural time (7/12 sessions); 2) excluded procedures from assessment (5/12) ;and 3) procedures that were repeated after delay to assess technical skill retention (4/12) and the delay between Attempts 2 and 3.

| Simulated procedure (Number of trainees performing 2 attempts) | Objective assessments | Reason for exclusion from objective assessment | Retention of Technical skill assessed (trainees who performed Attempts3+4) | Delay between Attempt 2 and 3 (trainee number) |
|---|---|---|---|---|
| Tetralogy of Fallot repair-valve-sparring (7) | N | First trial with recording procedures. Failure of recording. | N | N/A |
| Arterial switch operation (7) | **Y** | N/A | **Y (4)** | **14 months (4)** |
| Norwood operation (7) | **Y** | N/A | **Y (6)** | **12 months (4)**<br>**2 months (2)** |
| DORV with subaortic VSD repair (6) | N | Unable to record intra-cardiac aspect | N | N/A |
| Coarctation of Aorta repair (6) | **Y** | N/A | **Y (4)** | **10 months (4)** |
| Single-stage IAA repair-Type B (7) | **Y** | N/A | N | N/A |
| Supravalvular aortic stenosis repair (7) | N | Different techniques used for Attempts 1+2. | N | N/A |
| TA repair-type II (7) | **Y** | N/A | N | N/A |
| Tetralogy of Fallot repair-transannular patch (7) | N | Unable to record the intra-cardiac aspect. | N | N/A |
| Single-stage Taussig-Bing repair (7) | N | Only one attempt performed. | N | N/A |
| Complete AVSD repair (6) | **Y** | N/A | N | N/A |
| VSD repair (7) | **Y** | N/A | **Y (4)** | **2 months (4)** |

### 8.3.1 Assessment of technical skill outcomes

*Procedure-based assessments*

A total of 47 sets of two videos were scored using the procedure-specific HOST-CHS assessment tools. Eighty-one percent (38/47) of trainees' scores improved between the two attempts across all procedures (Attempt 1 vs 2). Mean HOST-CHS score across all procedures was 79 for Attempt 1 and 89 for Attempt 2 with an improvement 13%, *p=<0.0001 [95% CI 7-14]* (Figure 8.2A). When individual procedures were analysed, the same trend was seen with a statistically significant improvement in 3 of the 7 procedures (Norwood operation *p=0.049*, atrioventricular septal defect [AVSD] *p=0.016* and ventricular septal defect [VSD] repairs *p=0.012*), with near significance in another 3 (coarctation of aorta [CoA] *p=0.05,* arterial switch operation [ASO] *p=0.08*, and truncus arteriosus [TA] repair *p=0.09*) (Figure 8.2C). The mean HOST-CHS scores for each procedure is summarised in Table 8.4.

*Time-based assessment*

Ninety-one percent of trainees' time improved between the two attempts. The mean time across all procedures was 1:22:00 [h:mm:ss] for Attempt 1 and 1:01:21 [h:mm:ss] for Attempt 2 with a mean improvement of 25%, *p=<0.0001 [95% CI 0:14:46-0:26:23]* (Attempt 1 vs 2). The median time for Attempt 1 was 1:31:20 [h:mm:ss] and was 1:03:16 [h:mm:ss] for Attempt 2 (Figure 8.2B). When individual procedures were analysed there was a statistically significant improvement in 4 procedures (ASO *p=0.03*, Norwood operation *p=0.003*, TA *p=0.04* and interrupted aortic arch [IAA] repairs *p=0.02*) with near significance in the other 3 (CoA *p=0.07*, AVSD *p=0.07,* and VSD repairs *p=0.08*) (Figure 8.2D). The mean times for each procedure are summarised in Table 8.5.

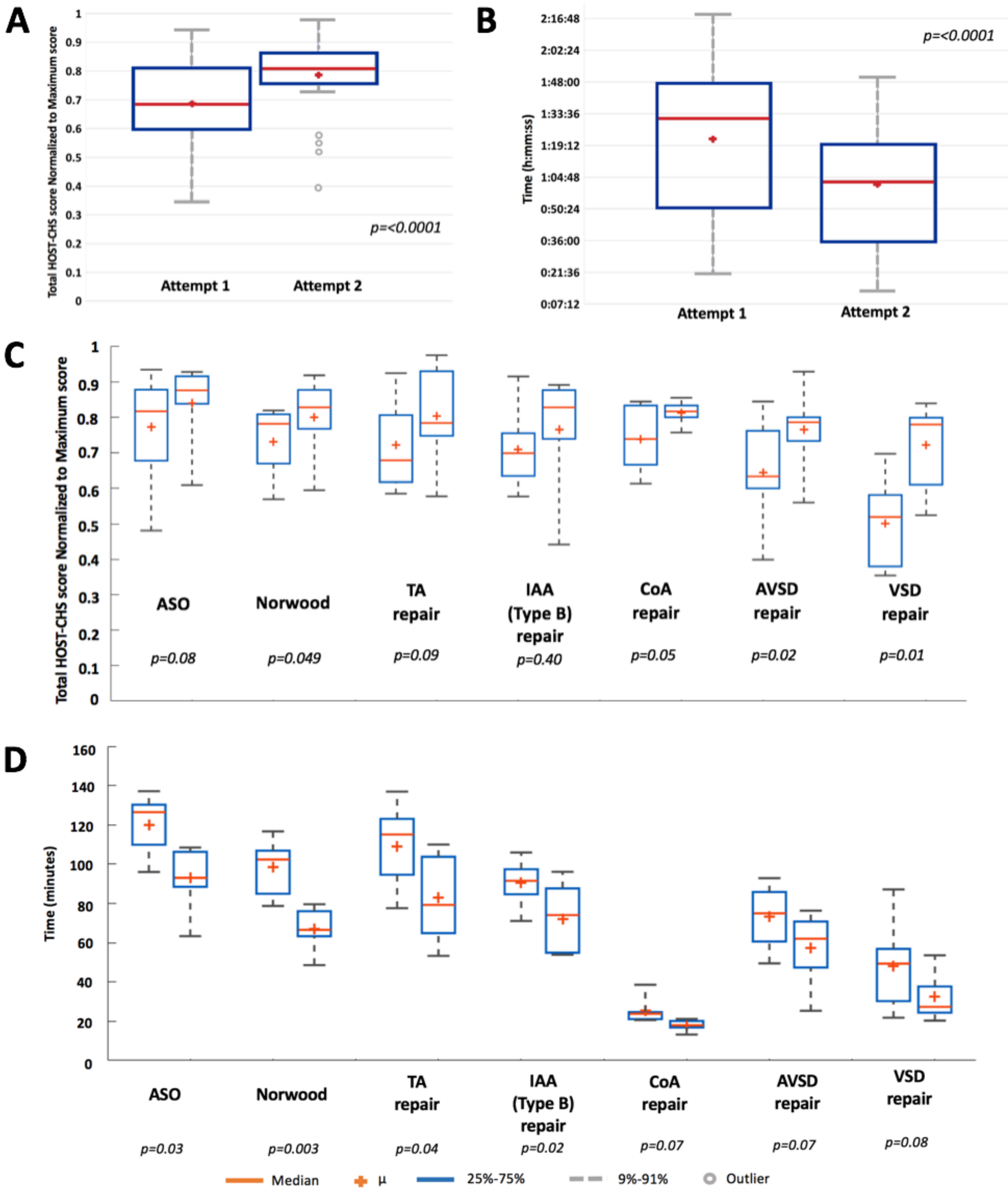



**Figure 8.2:** Comparison of the total HOST-CHS scores (A) and time (B) between Attempt 1 and 2 of all procedures performed. Scores have been normalised to the maximum possible score for the individual procedures. Eighty-one percent (38/47) of trainees' score and ninety-one percent of times improved on Attempt 2, with a mean improvement of 13% and 25% respectively [p=<0.0001]. Total HOST-CHS scores (C) and times (D) are compared between Attempts 1 and 2 for the individual procedures. There was a statistically significant improvement in both HOST-CHS score and time between the two attempts in >3/7 procedures. Measurements: A+C = normalised HOST-CHS score. B = time (h:mm:ss). D = time (minutes). AVSD = atrioventricular septal defect, HOST-CHS = Hands-on Surgical Training-Congenital Heart Surgery, IAA = interrupted aortic arch, TA=truncus arteriosus, VSD = ventricular septal defect

**Table 8.4:** Mean total HOST-CHS score comparison between Attempt 1 and 2 of trainees. Mean improvement among all procedures was 10 (13%) [*p=<0.0001]*, with a statistically significant difference in 3/7 procedures.

| Procedure (Total HOST-CHS score) | Mean HOST-CHS score Attempt 1 | Mean HOST-CHS score Attempt 2 | Mean difference | Mean improvement (%) | P value[95% confidence interval] |
|---|---|---|---|---|---|
| **All procedures** | 78.7 | 88.8 | 10.2 | 13% | **<0.0001 [7-14]** |
| **Arterial switch operation (153)** | 118.1 | 128.4 | 10.3 | 9% | **0.08 [-2-22]** |
| **Norwood operation (128)** | 93.6 | 102.4 | 8.7 | 9% | **0.049 [0-18]** |
| **TA repair – Type II (134)** | 96.9 | 107.6 | 10.7 | 11% | **0.09 [-2-24]** |
| **IAA repair – Type** B **(93)** | 66.0 | 71.1 | 5.1 | 8% | **0.40 [-9-19]** |
| **CoA repair (90)** | 66.5 | 73.2 | 6.7 | 10% | **0.05 [0-13]** |
| **Complete AVSD repair (105)** | 67.7 | 80.3 | 12.7 | 19% | **0.016 [4-22]** |
| **VSD repair (77)** | 40.5 | 54.5 | 17 | 44% | **0.0139 [5-29]** |

**Table 8.5:** Time comparison of average procedural times between Attempts 1 and 2 of trainees. Mean improvement among all procedures was 25% *[p=<0.0001],* with a statistically significant difference in 4/7 procedures.

| Procedure (trainees performing 2 attempts) | Mean time Attempt 1 (h:mm:ss) | Mean time Attempt 2 (h:mm:ss) | Mean time difference (h:mm:ss) | Mean improvement (%) | P value [95% confidence interval] (mm:ss) |
|---|---|---|---|---|---|
| **All procedures (47)** | 1:22:00 | 1:01:21 | 0:20:40 | 25% | **<0.0001 [14:56-26:23]** |
| **Arterial switch operation (7)** | 1:59:59 | 1:33:06 | 0:26:54 | 22% | **0.03 [04:02-49:46]** |
| **Norwood operation (7)** | 1:38:30 | 1:06:59 | 0:31:31 | 32% | **0.003 [15:41-47:20]** |
| **TA repair – Type II (7)** | 1:48:48 | 1:23:04 | 0:25:45 | 24% | **0.04 [02:01-49:29]** |
| **IAA repair – Type B (7)** | 1:30:30 | 1:11:58 | 0:18:32 | 21% | **0.02 [04:43-32:21]** |
| **CoA repair (6)** | 0:25:32 | 0:17:52 | 0:07:40 | 30% | **0.07 [-00:49-16:08]** |
| **Complete AVSD repair (6)** | 1:13:05 | 0:57:11 | 0:15:54 | 22% | **0.07 [01:34-33:21]** |
| **VSD repair (7)** | 0:48:16 | 0:32:27 | 0:15:49 | 32% | **0.08 [-04:11-35:50]** |

### 8.3.2 Technical skill retention outcomes

Four of the procedures (ASO, Norwood operation, CoA and VSD repairs) were repeated twice after a delay to assess retention of technical skill (Attempts 3 + 4). The cases were deliberately chosen to include two simple and two complex procedures. Four trainees repeated all 4 procedures twice and 2 additional trainees repeated the Norwood operation over a 2-month period to ensure completion of cases. Thirty-six attempts were performed by this cohort altogether. The time between Attempts 2 and 3 ranged between 2 to 14 months (Table 8.3). All attempts were performed by the trainees independently over a two-week period. The mean normalised total HOST-CHS scores and times for each attempt per trainee are shown in Figure 8.3. In this subgroup of the trainees, 84% of scores had improved between Attempts 1 *[HOST-CHS:82]* and 2 *[HOST-CHS:94]* with a mean improvement of 13% (*p=0.0003)*. Following the delay, 47% of scores decreased by an average of 4% (Attempt 2 *[HOST-CHS:94]* vs 3 *[HOST-CHS:91]*, *p=0.34)*. However, this improved by an average of 8% in 79% of trainees during Attempt 4 (Attempt: 3 *[HOST-CHS: 91]* vs 4 *[HOST-CHS: 99] ,p=0.004).* Overall there was an improvement in total HOST-CHS scores between Attempt 2 and 4 by an average of 8% (Attempt 2 vs 4, *p=0.1)*.

Similarly, 84% of trainees' mean time improved between Attempt 1 *[1:11:17 h:mm:ss]* and Attempt 2 *[0:55:32 h:mm:ss]* with an improvement of 23% (*p=0.0002)*. Following the delay, 47% of times increased marginally (Attempt 2 *[0:55:32 h:mm:ss]* vs Attempt 3 *[0:54:56 h:mm:ss], p=0.86)*. However, in 89% of trainees' times improved by 14% on average during Attempt 4 (Attempt 3 *[0:54:56 h:mm:ss]* vs 4 *[0:47:42 h:mm:ss]*, *p=0.004)*. Overall, procedural time between Attempt 2 and 4 improved by 15% (Attempt 2 vs 4, *p=0.06)*.

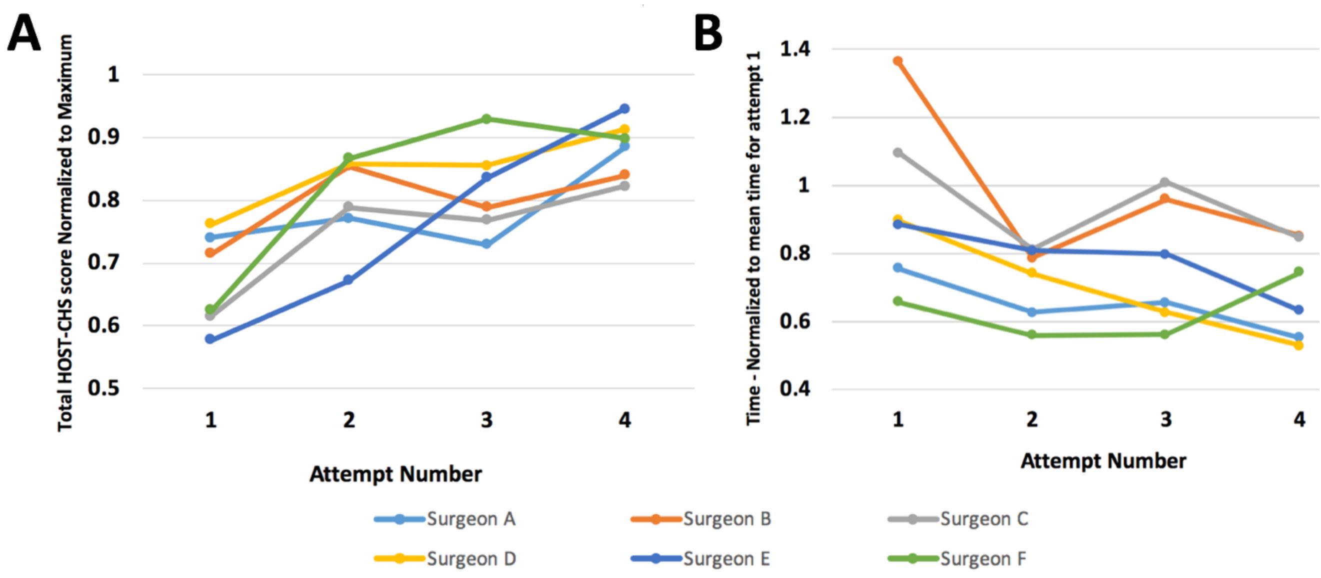



**Figure 8.3:** Mean normalised total HOST-CHS scores and times for trainees who performed two additional attempts (Attempts 3+4) for assessment of skill retention. These attempts were performed for the ASO, Norwood operation, CoA repair and VSD repair. Attempts 1 and 2 were performed back-to-back during the monthly In-House HOST-CHS course. Attempts 3 and 4 were performed back-to-back following a delay (range: 2-14 months).

**A:** Mean normalised total HOST-CHS score for each attempt per trainee. Eighty-four percent of trainees' score improved between Attempts 1 *[HOST-CHS:82]* and 2 *[HOST-CHS:94]* with a mean improvement of 13% [p=0.0003]. Following the delay, 47% of scores decreased by an average of 4% (Attempt: 2 *[HOST-CHS:94]* vs 3 *[HOST-CHS:91],*) [p=0.34], but improved in by an average of 8% in 79% of trainees during Attempt 4 (Attempt: 3 *[HOST-CHS: 91]* vs 4 *[HOST-CHS: 99*) [p=0.004].

**B:** Mean normalised procedural time for each attempt per trainee. Eighty-four percent of trainees' time improved between Attempts 1 *[1:11:17 h:mm:ss]* and 2 *[0:55:32 h:mm:ss]* with a mean improvement of 23% [p=0.0002]. Following the delay ,47% of times increased by a mean of 1% (Attempt 2 *[0:55:32 h:mm:ss]* vs 3 *[0:54:56 h:mm:ss]*) [p=0.86],but improved by 14% on average in 89% of trainees during Attempt 4 (Attempt 3 *[0:54:56 h:mm:ss]* vs 4 *[0:47:42 h:mm:ss]*) [p=0.004]. ASO=arterial switch operation, CoA=coarctation of aorta, HOST-CHS=Hands-On Surgical Training- Congenital Heart Surgery, VSD=ventricular septal defect

## 8.4 Discussion/Comment

Within adult cardiovascular surgery, the simulation of technical skills has been successfully incorporated into training curricula [71], [97]–[99], however within CHS this remains elusive [19], [69]. Technical performance is an absolute necessity for a successful patient outcome in CHS and requires objective assessment for productive feedback and evaluation. However currently its assessment is determined by subjective assessment and operative logbooks [5], [100], [101]. Due to the increase in public scrutiny and reduction in the simplest cases it is becoming increasing challenging for surgical trainees to develop their technical skill competence [19], [100].

### 8.4.1 Evolution of the HOST programme

The HOST programme in CHS has continued to grow since its inaugural course at the AATS (American Association for Thoracic Surgery) annual conference in 2015. Initially our group introduced the concept of using 3D-printed models in the simulation of complex congenital heart procedures with qualitative evidence to support its perceived value to technical skill training [18]. Next we demonstrated objectively that surgical rehearsal with deliberate practice improves procedural performance (Chapter 7). This was shown in the simulation of the arterial switch operation in 30 surgeons with >80% improving in both time and procedural performance [92], [102]. Following these studies the next step was to develop a replicable CHS training curriculum for a variety of CHS procedures and use these objective assessment methods to demonstrate improvement and whether skill was retained over time.

This study demonstrated the successful incorporation of the monthly In-House HOST training programme with 3D-printed models into the CHS curriculum for surgical trainees. The majority of trainees demonstrated an improvement in technical performance following practice, which is consistent with other studies within cardiovascular surgery simulation [79], [97], [102]–[104]. Across all assessed procedures, >81% of trainees improved in their total HOST-CHS score and procedural time. When procedures were analysed individually, this improvement maintained its statistical significance in 3 out of 7 procedures with near significance in 3 others. It is likely that if there were more participants in the study this significance would be consistent throughout all procedures, however participants were limited to our local trainees.

One of the weaknesses in previous studies was the inability to assess whether newly learnt surgical skills were retained over time as has been done in other specialities [102], [105]–[107]. The surgeons in this study were able to retain their learnt skills up to 14 months following their initial session and improved further with practice. As expected, technical performance on average dropped following the delay (Attempt 2 vs 3), but still performed better when compared to the first attempts (Attempt 1 v 3). Trainees continued to improve on their final attempt on average scoring higher than their second attempts across all the procedures (Attempt 2 vs 4). This supports existing evidence that spacing training sessions improves long-term surgical skill retention when compared to single, widely spaced sessions [108]. The findings are broadly applicable to congenital heart repairs across the full spectrum of STS (Society of Thoracic Surgeons) or CHSS (Congenital Heart Surgery Society) complexity categories. We found that VSD performance in particular showed high iterative improvement.

To successfully establish a year-long HOST simulation curriculum is multifactorial and requires core fundamentals to be in place. The commitment to teach by all staff surgeons within an institution is required. All staff surgeons were actively engaged in our curriculum, sharing responsibility in leading In-House HOST sessions. Models were developed alongside surgeons to accurately replicate the surgical anatomy and technical challenges a surgeon may experience in reality [109]. Procedure-specific assessment tools were tailored to our local operative techniques and used to provide objective and procedure-specific feedback. A training room within the hospital was designated to facilitate full attendance and sessions were organised at a time where there would be minimal disruption from clinical duties. Support from our operating department staff was vital to assist with regular supplies of consumables (i.e. sutures) and the acquisition of surgical instruments to be solely used for simulation. We have actively used this training method to prepare trainees before their procedures on real patients with fellows performing a number of simulations with the supervising surgeon present to prepare them for an upcoming case [102]. Further efforts are being made to quantitively assess the translatability of simulation to real-life performance using objective assessment measures.

### 8.4.2 Limitations

Five procedures were excluded from objective assessments with 2 due to the inability to accurately record the intracardiac aspect of the operation. This is crucial to overcome prior to establishing this curriculum externally. We revised our models over the year to improve video recording and by the end of our curriculum we were able to objectively assess two procedures which are entirely intracardiac (AVSD+VSD repairs) (Figure 8.4). An example is shown in Video 8.2 of a surgeon performing a transatrial closure of a VSD on a 3D-printed heart model using a continuous suture technique. With improvements in recording devices and alterations of other models it is likely that all intracardiac aspects will be able to be recorded and objectively assessed.

A criticism of the study could be that the improvement in performance was due to the increase familiarity of the model during the second attempt and therefore surgeons would be expected to perform better. However, the study used the same trainee surgeons for the duration of the study and all surgeons were familiar with the models prior to the training sessions. Furthermore, the trainee surgeons consistently improved throughout the curriculum across the spectrum of congenital heart diseases. This is further supported in the technical skill retention arm of the study whereby surgeons continued to improve further after a delay between the second and third attempts.

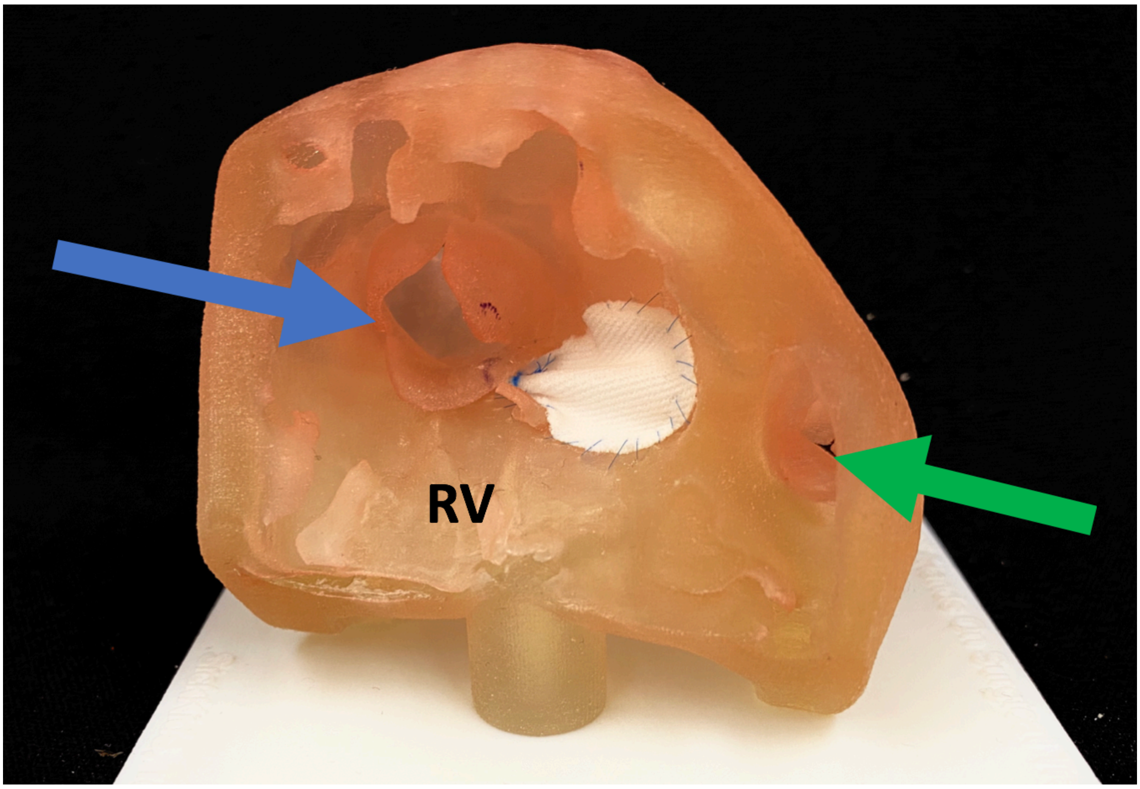
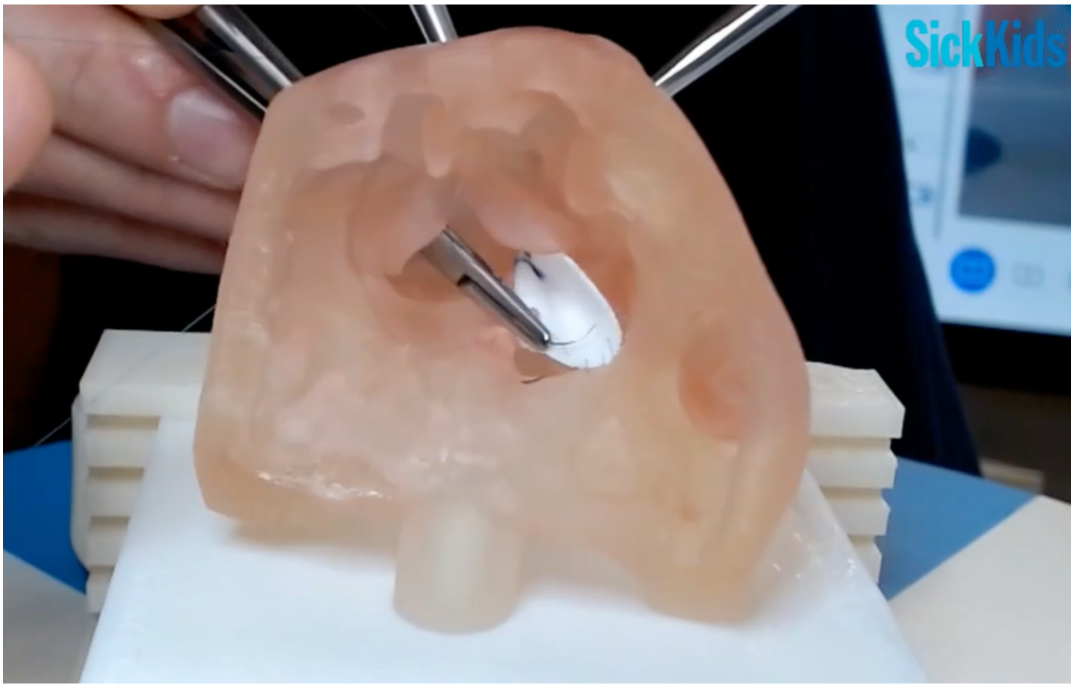



**Figure 8.4:** 3D-printed perimembranous VSD model. The left side of the heart, ventricular apex and right ventricular free wall have been removed. This approach is used to provide an excellent view for recording the simulation and also to reduce printing costs. A surgeon has closed the VSD from the right atrium (blue arrow). Green arrow=pulmonary valve.

Cost will inevitability be a barrier to overcome for successful adoption of this curriculum. With fixed costs (i.e. surgical instruments, recording equipment and HOST-CHS chest wall simulator) approximating $1300 (USD) and model costs per trainee per year up to $7500 (USD) it will take a significant level financial commitment to replicate this curriculum. This might be problematic, particularly for smaller programmes. Despite a relatively high cost, we believe that the benefits to technical skill development must outweigh the required cost. It is expected that these costs will gradually reduce with further technical development, wider use of the service and an efficient business structure. A significant cost not included in the calculation is the model selection and development. This is the most time consuming and labour intensive task as it involves experts in imaging, computer-aided design, 3D-printing and CHS to work collaboratively to decide which cases are appropriate and then replicate the surgical anatomy accurately. Our centre has over 10 years' experience in this and now have a large repository of HOST models. In order to assist other programmes to adopt hands-on training methods the authors have made all annotated HOST training videos and assessment tools freely available on the dedicate website included in the methods.

One of the major challenges of competency-based training is defining a score representing competent performance [90]. Therefore, before incorporating this methodology into the CHS certification process this will need to be defined in addition to case selection [101]. Furthermore, evidence demonstrating the predictive validity of simulation is lacking. However, simulation provides the ability to learn operative sequencing, hand positioning, patch cutting and accurate anastomotic skills, which will inevitability be translated into reality [110]. The true benefit of simulation training will only occur when training programmes develop and integrate regularly scheduled simulation sessions in the context of established curricula [98].




**Video 8.2:** A surgeon performing a transatrial closure of a VSD on a 3D-printed heart model using a continuous suture technique.
YouTube video link: https://youtu.be/8d-bM9OJbM8

## 8.5 Future Directions

The impact of HOST on the improvement of surgical skills has been proven with strong evidence [18], [102]. This includes demonstrating that the HOST-CHS scoring does not have to be assessed by expert surgeons (Chapter 6) [92]. The next challenge is to make models as accurate as possible at a reasonable cost. These developments are particularly important when surgical training is compromised by unexpected incidences such as pandemics and long periods of absence [111]. Modern medicine is rapidly transitioning to online platforms to maintain clinical service and teaching. Simulation training is no exception. We are working on using these online platforms to webcast training sessions. Once established this could be rolled out on an international scale with dedicated surgeons teaching complex congenital procedures thus expanding the scope of learning. Furthermore, our group has started to experiment with machine learning and video segmentation in order to further reduce the time commitments in retrospective assessment.

Our new curriculum has been restructured to include simpler cases at the beginning (i.e. CoA repair) with complexity increasing later on (i.e. Taussig-Bing repair). The curriculum is ready to be replicated with models, procedure-specific assessment tools and training videos being available for trainees to use. Additional surgical models are available covering the wide spectrum of congenital heart disease. Centres will have the freedom to alter curricula and assessments to tailor to their own practice and teaching.

## 8.6 Conclusion

It has been 5-years since the first introduction of the annual HOST course in CHS [18]. We have now successfully incorporated a reproducible monthly In-House HOST course into our CHS curriculum for surgical fellows and residents. This curriculum included objective assessment measures to assess technical performance and demonstrated an improvement in the majority of the procedures across all surgeons. Surgeons were also able to demonstrate technical skill retention after a prolonged delay and further improved with additional rehearsal. As discussions regarding the incorporation of simulation and technical skill assessment in CHS continue, this study among others may assist in making this a reality in the near future.

# 9 Development of a Dynamic Chest Wall and Operating Table Simulator to Enhance Congenital Heart Surgery Simulation

The following chapter has been adapted from the following publication to suit the flow of this thesis. Permission has been granted from the publisher Biomedical Central, Springer Nature.

*Brandon Peel, Pascal Voyer-Nguyen, Osami Honjo, Shi-Joon Yoo,* ***Nabil Hussein*.*** *Development of a dynamic chest wall and operating table simulator to enhance congenital heart surgery simulation.*
*3D Printing in Medicine. 2020 Jun 1;6(1):12. doi: 10.1186/s41205-020-00067-4. PMID: 32488567; PMCID: PMC7268747.* *****Senior author***

NH contributions to this publication: Conception and design, funding acquisition, design, development and manufacturing chest wall simulator, validation of simulator, data collection, statistical analysis and interpretation, literature review, writing of the article, critical revision and final approval of the article.

This project received a $25,000 CAD grant from the Labatt Family Heart Centre Innovation fund following a successful application by NH (Appendix 12.5).

## 9.1 Introduction

Despite the positive feedback from the simulation courses a recurrent theme for improvement was to replicate the ergonomics experienced in the operating room. This chapter outlines how a dynamic chest wall and operating table simulator was developed and evaluated to enhance the simulation experience more.

## 9.2 Limitations of HOST-CHS set up

Four aspects were identified as limitations of the original set up for the HOST-CHS course (Figure 9.1):

1) Suboptimal operating position – 3D-printed heart models were fixed to the table with tape limiting operating height. Subsequently surgeons were prevented from operating at the ideal height. Models were also unable to be rotated to improve exposure of the operative field.
2) Unrealistic surgical exposure – The absence of a chest wall allowed surgeons to operate from any angle, when in reality surgeons operate within a fixed region (i.e. median sternotomy incision).
3) Limitations in light exposure – Although commercially available headlights were used, the battery life limited the duration of the light's effectiveness during simulation.
4) Difficulties in video-recording for accurate objective assessment

This chapter illustrates the development of a dynamic chest wall and operating table simulator to enhance the simulation experience.

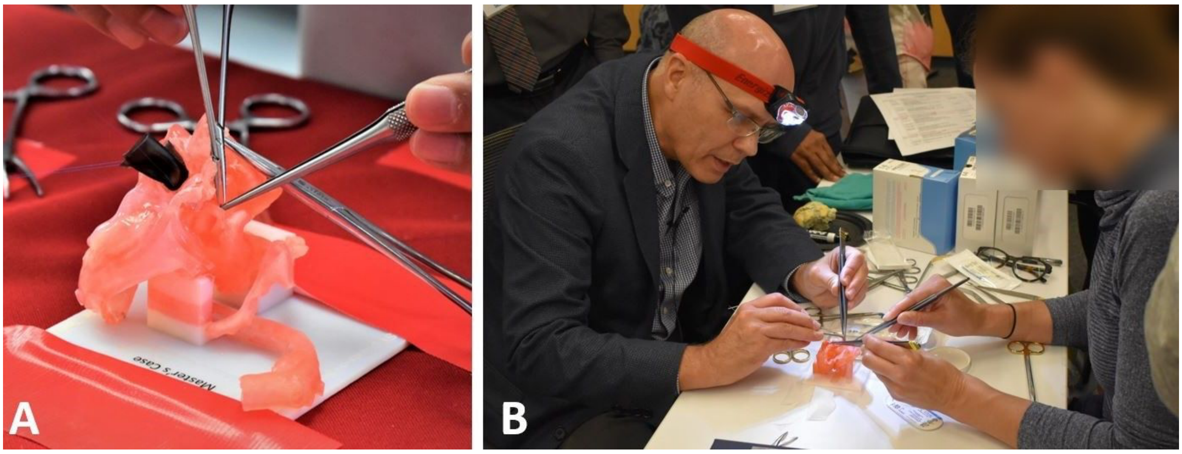



**Figure 9.1:** A) A surgeon simulating a complex congenital heart surgical procedure on a 3D-printed heart model at the hands-on surgical training (HOST) course. B) A congenital heart surgeon demonstrating the arterial switch operation on a 3D-printed heart model at the HOST course. Note that the models are stuck to the table at a fixed height forcing the surgeon to sit down preventing them from using their surgical loupes. A simple headlight is used to illuminate the model. The procedure is video recorded for retrospective assessment (not shown).

## 9.3 Components for the Hands-On Surgical Training in Congenital Heart Surgery (HOST-CHS) simulator (Figure 9.2):

**A. Operating Table Simulator**

Following an extensive review of commercially available products that could be used as the operating table component, I decided on the use of a scissor-lift (LBJSET - United Scientific Supplies Inc., Waukegan, IL, USA) to form the lowest aspect of the simulator. This was ideal as it had a user friendly dial mechanism to adjust the height of the models. I incorporated lighting and recording devices to the simulator which are attached to the top platform to allow surgical procedures to be recorded (Figure 9.3). With the assistance of our 3D printing engineer (BP) and mechanical engineering student (PVN) I developed roll and pitch components, which were designed on SolidWorks™ (Dassault Systèmes SolidWorks, Concord, MA) and 3D-printed on the Objet 500 Connex3 (Stratasys, Eden Prairie, MN) using VeroWhitePlus resin material and attached to the scissor lift. This design utilises perpendicular hinges to allow 30-degree angle rotation in all directions. Clamping handles were then used to lock the chest simulator in the desired position and are easily adjustable.

**B. Suture Retraction Disk**

During a surgical procedure, the surgeon needs the ability for sutures to be held securely, whilst they focus on another aspect of the operation. I designed a suture retraction disc with 24 equally spaced slits around the circumference to allow sutures of different sizes to be held securely in place. This disc is attached to the top of the pitch and roll mechanism.

**C. Paediatric Chest Wall Cavity**

An anatomically accurate paediatric chest wall cavity was designed and 3D-printed to reproduce the surgeon's access experienced during CHS. Dimensions were retrieved by computer-tomography images, which I segmented and designed alongside BP . Silicone was then moulded around the cavity to simulate patients' skin (Dragon Skin 20 - Smooth-On Inc, Easton, PA). A lower holder designed by BP completed the simulator with 5 various height levels, designed to fit all the 3D-printed heart models used during the HOST programme. These components were 3D-printed on the Fortus380mc (Stratasys, Eden Prairie, MN) printer using ABS M30i filament. Video 9.1 demonstrates the assembly, functions and use of the simulator.

The simulator was first trialled at the annual HOST course of the authors' institution with 19 cardiovascular surgeons participating. Surgeons' experience in CHS varied from resident surgeons to staff/consultant level. All surgeons agreed that the addition of the simulator was acceptable for surgical simulation and that it helped replicate the surgical ergonomics. All agreed that the simulator would encourage practice outside of a dedicated course and would be keen to use it more if made available (Figure 9.4).

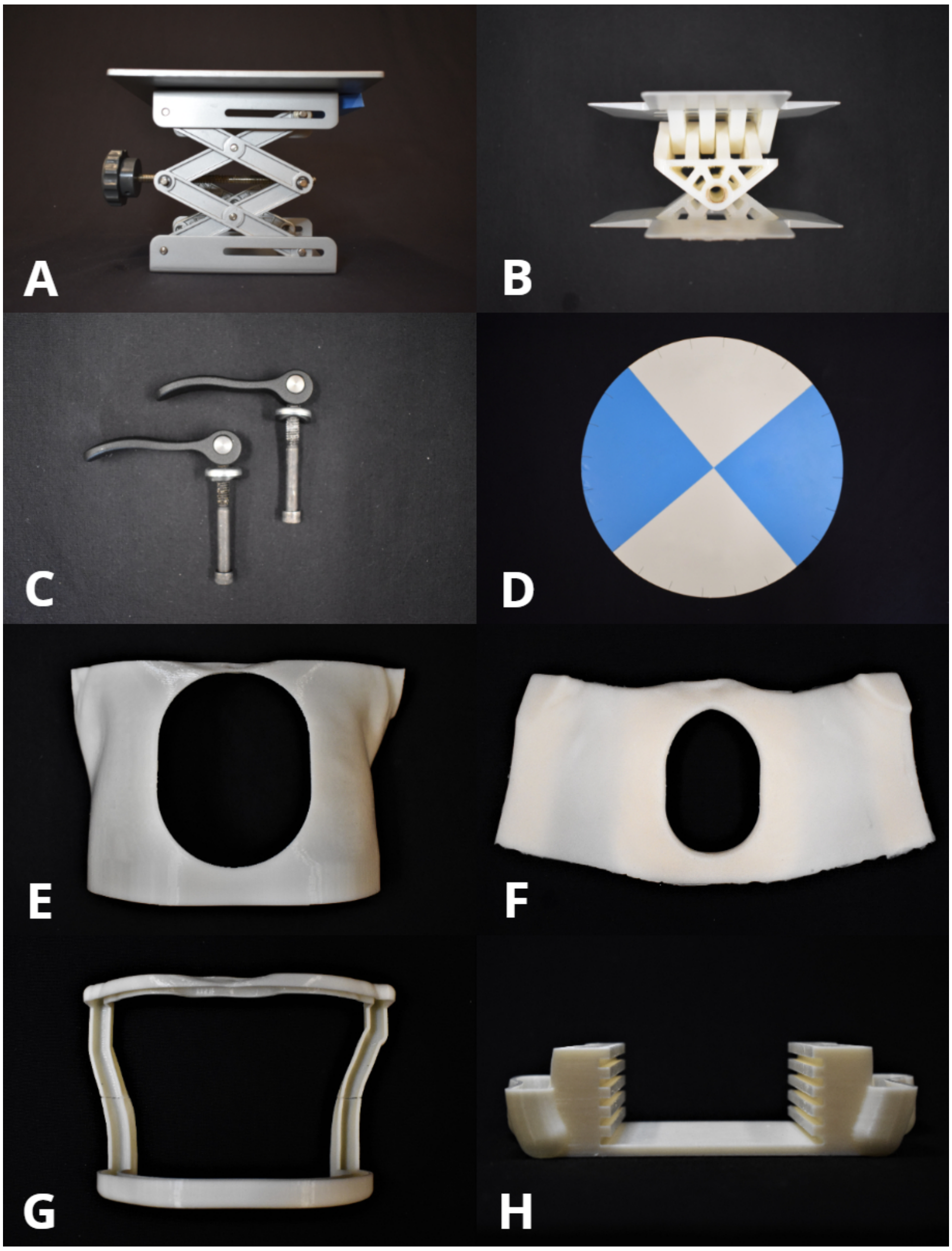



**Figure 9.2:** The components used for the Hands-on Surgical Training - Congenital Heart Surgery (HOST-CHS) simulator. A: Commercially available scissor lift (LBJSET - United Scientific Supplies Inc, Waukegan, IL, USA). B: Roll and pitch 3D-printed components. C: Commercially available cam handles with internal thread (McMaster Carr, Inc., Cleveland, OH). D: Suture retraction disk. E: Chest wall with median sternotomy incision, F: Silicone skin, G: Upper and lower brackets which secure the silicone skin in place, H: Lower holder with notches at five different levels to fit all 3D printed heart models used during the HOST course.

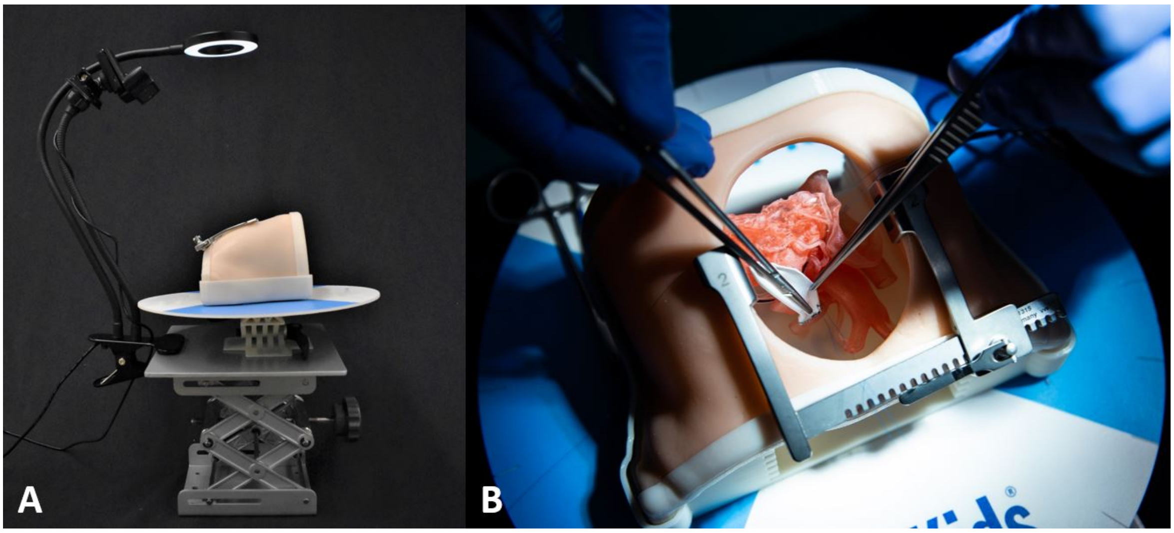


**Figure 9.3:** A: The complete assembly up of the Hands On Surgical Training in Congenital Heart Surgery (HOST-CHS) simulator. This assembly includes the paediatric chest wall cavity, suture retraction disk, roll and pitch components, operating table simulator, a webcam and lighting equipment.

B) A surgeon suturing a transannular patch on a tetralogy of Fallot 3D-printed heart model through the sternotomy incision of the HOST-CHS simulator. The 3D-printed heart model has been placed at the optimised height inside the holder, while the surgeon utilises the suture retraction disk.

**Video 9.1:** Demonstration of the chest wall simulator being assembled, the degrees of motion, suture retraction and a surgeon performing a transannular patch reconstruction as part of a tetralogy of Fallot repair on a 3D-printed heart model.

YouTube video link: https://youtu.be/gGxVz-JjfAo


**Figure 9.4:** Questionnaire responses on the usefulness of the Hands-on Surgical Training in Congenital Heart Surgery (HOST-CHS) simulator by the congenital heart surgeons that participated in the 5th annual HOST course.

## 9.4 Discussion

The development of the HOST-CHS simulator was successful in addressing the requirements set by the surgeons' recommendations. The operating table component allowed the surgeon to set a personalised height and control the roll, pitch and tilting motions to reproduce the real ergonomics. The suture retraction disk improved surgical exposure and the overall design allowed for the inclusion of lighting and recording equipment. The chest wall component restricted the surgeons' approach to the heart model, which replicates reality.

The feedback from the participant surgeons was encouraging with all grades of surgeon agreeing that the inclusion of the simulator was acceptable for the simulation of CHS and that it helps replicate the ergonomics experienced in the operating room. All surgeons agreed that the simulator would encourage simulation outside of dedicated courses and were likely to incorporate it into their own institution if made available. The number of participants who completed this questionnaire may be a limitation, however the overall consensus from this study strongly suggests that the incorporation of the HOST-CHS chest simulator as part of the HOST programme is beneficial to the overall simulation experience.

## 9.5 Future Directions

With the increasing trend towards minimally invasive surgery, simulators will be required to validate and improve methods prior to real-life surgery. Within our institution, we are developing a chest wall simulator designed specifically for minimally-invasive congenital heart surgery (Figure 9.5). This simulator will allow staff surgeons to rehearse operations and teach new techniques, which will be increasingly difficult to do in reality. Current limitations in the 3D-printing techniques and materials limits the inclusion of flow circuits with 3D-printed heart models, however there have been attempts to overcome this making it a tangible reality [19]. It is expected that with the ongoing improvements in print materials, this is the next step in simulation.

## 9.6 Conclusion

The inclusion of the HOST-CHS simulator adds value to simulation in congenital heart surgery as it replicates the view and exposure a surgeon experiences. With training limitations being a global problem for congenital heart surgeons it is expected that simulators like these will be increasingly utilised in surgical training.

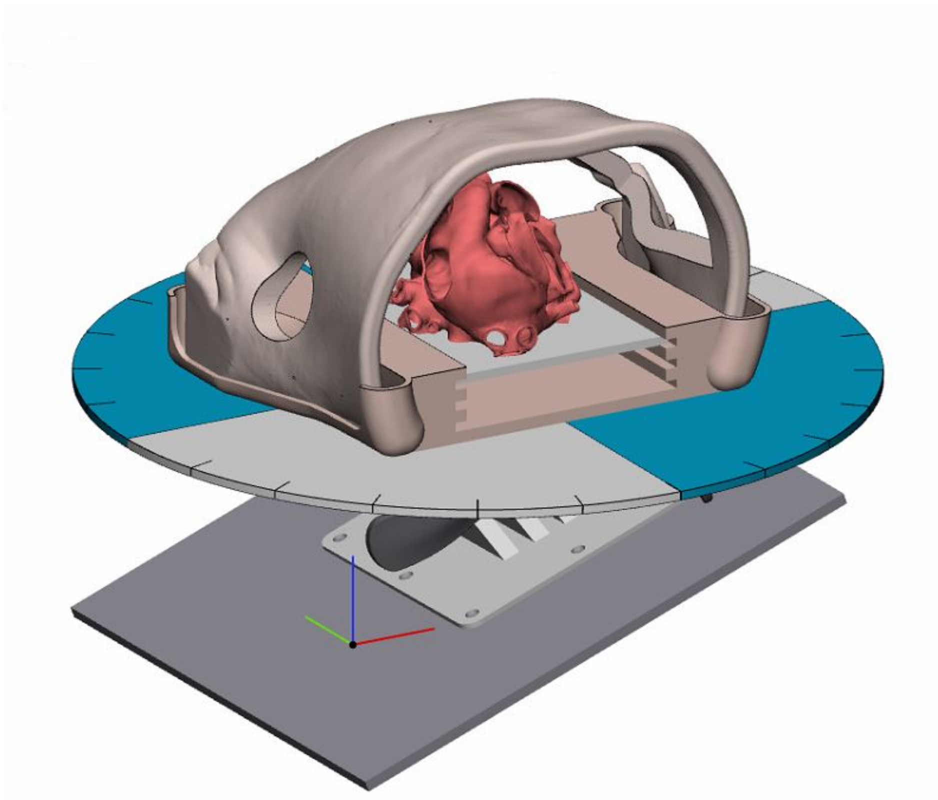


**Figure 9.5:** Computer render of a minimally invasive dynamic chest wall and operating table simulator. Note the absence of a median sternotomy incision and the inclusion of a mini-thoracotomy incision the surgeon will operate through. The opposite side of the chest is removed to allow the teacher to observe the performance of the surgeon.

# 10 Evaluating the impact of medical student inclusion into hands-on surgical simulation in congenital heart surgery

The following chapter has been adapted from the following publication to suit the flow of this thesis. *Permission has been granted from the publisher Biomedical Central, Springer Nature.*

*Nicole Wing-Lam Hon,* ***Nabil Hussein*,*** *Osami Honjo, Shi-Joon Yoo. Evaluating the Impact of Medical Student Inclusion Into Hands-On Surgical Simulation in Congenital Heart Surgery.*
*Journal of Surgical Educucation. 2021 Jan-Feb; 78(1):207-213. doi:10.1016/j.jsurg.2020.06.023. Epub 2020 Jul 6. PMID: 32646811.* ****Co-first author***

NH contributions to this publication: Conception and design, funding acquisition, design, development and manufacturing simulator, validation of simulator, data collection, statistical analysis and interpretation, literature review, writing of the article, critical revision and final approval of the article.

## 10.1 Introduction:

The lack of surgical exposure to medical students has led to a decline in interest to pursue surgery as a career over the last decade [38], [112]. This is more apparent in highly specialised sub-specialties such as congenital heart surgery (CHS) where the wide spectrum of pathology and rarity of cases limits exposure further [19], [38], [113]. The understanding of cardiac anatomy in medical students has shown to be improved following the use of 3D-printed heart models, but their use in teaching technical skills is limited [114], [115]. The teaching of these skills by utilising a hands-on approach may increase students' interest in pursuing a surgical career and has led to calls to incorporate such methods early in medical school curricula [112], [116]–[119].

The Hands-On Surgical Training (HOST) course is an educational platform that enables congenital heart surgeons to simulate complex surgical procedures on 3D-printed models [18], [19]. Our institution has organised annual HOST courses since 2015 with attendee surgeons alternating between primary operator and assistant. In the last course, medical students were recruited as surgical assistants to allocate more time for attendee surgeons to perform the procedures. In addition, the recruitment of the students was sought to increase the students' exposure to CHS and encourage direct and indirect mentorship among experienced surgeons providing them with a high surgeon-to-student ratio. This study aimed to evaluate the impact on medical students by including them as surgical assistants during the HOST simulation course.

## 10.2 Methods

### 10.2.1 Study Design

An electronic invitation was sent to all pre-clinical medical students of the University of Toronto Medical School to apply to participate as a surgical assistant in the 5th annual Hands-On Surgical Training (HOST) course in congenital heart surgery. All applications were reviewed. Only the students who were available for the duration of the 3-day course were included. As the applicant number was greater than the places available students were randomly selected to participate to ensure fairness in selection.

All selected students attended a 3-hour assistant training session two weeks prior to the course. The session was conducted by three experienced surgical residents, which was led by myself. This consisted of a didactic-based lecture focusing on surgical assisting, the handling of surgical instruments, suture types and uses, and operating room etiquette. This was followed by a hands-on session. The students were coached on how to knot-tie and perform simple suturing techniques on silicone skin pads and were encouraged to assist one another and apply the theory that was covered in the lecture (Figure 10.1). The objective of the session was to prepare the medical students for the HOST course to ensure they maximised their learning experience.

Following the session students were given a list of pathologies that were to be covered at the course with a brief synopsis of each condition and the associated surgical repair. A website link for the course, with further educational content, was sent out to the students for optional reading [120].

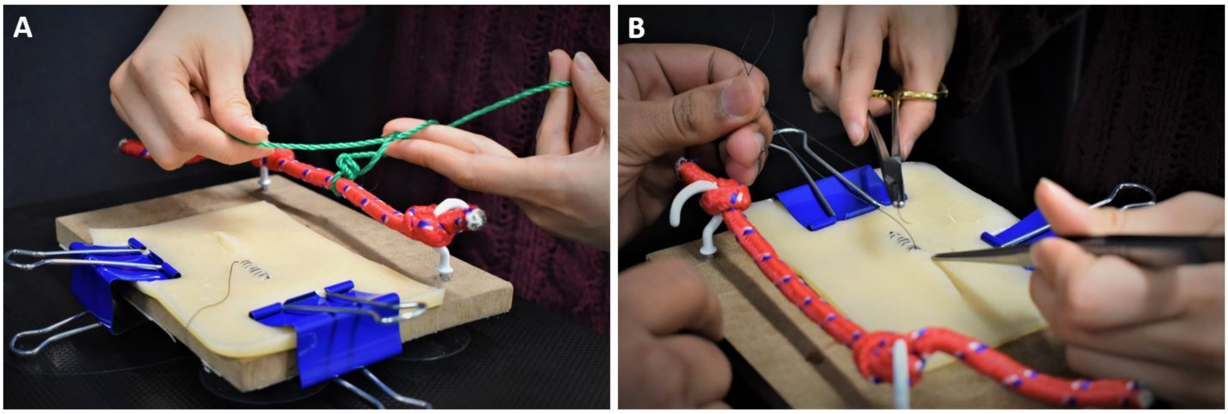



**Figure 10.1:** Hands-on surgical training (HOST) Assistants' Session set-up for knot tying (A) and simple suturing techniques (B).

Following attending the HOST assistants' session, all students were randomly allocated to either a congenital heart surgical fellow or staff surgeon for the duration of the 3-day course (Figure 10.2). Each surgeon had pre-selected the cases they wanted to simulate and would follow either the exposure track or the rehearsal track depending on their personal preference (Figure 10.3). The exposure track allowed the surgeons to choose up to 6 different procedures to perform during the course, whereas the rehearse track focused on one disease type with the surgeon repeating the same or similar procedures on 6 variations of the pathology. The surgeons repeated the first procedure for assessment of the impact of the HOST course in their surgical skill development [102]. The 3D-printed hearts were made with a soft, flexible material (Agilus30 - Stratasys, Eden Prairie, MN) that allowed dissection and suturing of the models as would be experienced in reality. The students were the primary assistant for all cases and had the opportunity to rehearse their knot-tying and simple suturing with their partnered surgeon. In addition, they also received informal career advice and mentorship. All participants assisted in 6 procedures throughout the course.

At the end of the course the assistants completed an anonymous questionnaire. This was developed and adapted from a questionnaire that was used to evaluate previous courses [18]. A total of 28 questions were included in the questionnaire. This captured information on: student demographics, their perceived knowledge of surgical anatomy in CHS, previous experience in surgery and simulation courses and the level of interest towards CHS before and after the course. Two additional questions were asked on the perceived barriers to entering a career in CHS and the students' opinions on the usefulness of using 3D-printed heart models and the HOST courses. Each question was graded using the Likert 5-point scale (1 = strongly disagree to 5 = strongly agree).

Informed written consent was obtained prior to medical student participation. Institutional ethics approval was obtained (Appendix 12.4).

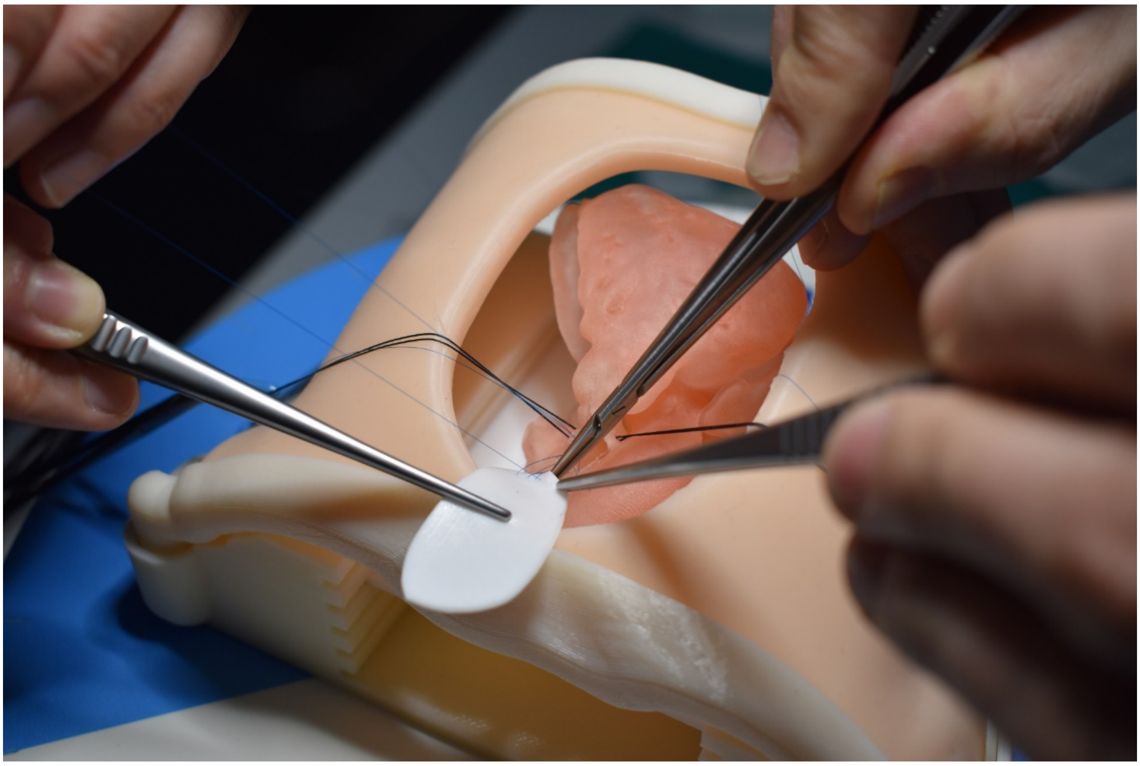


**Figure 10.2:** A medical student assisting a surgeon during a tetralogy of Fallot repair on a 3D-printed heart model.

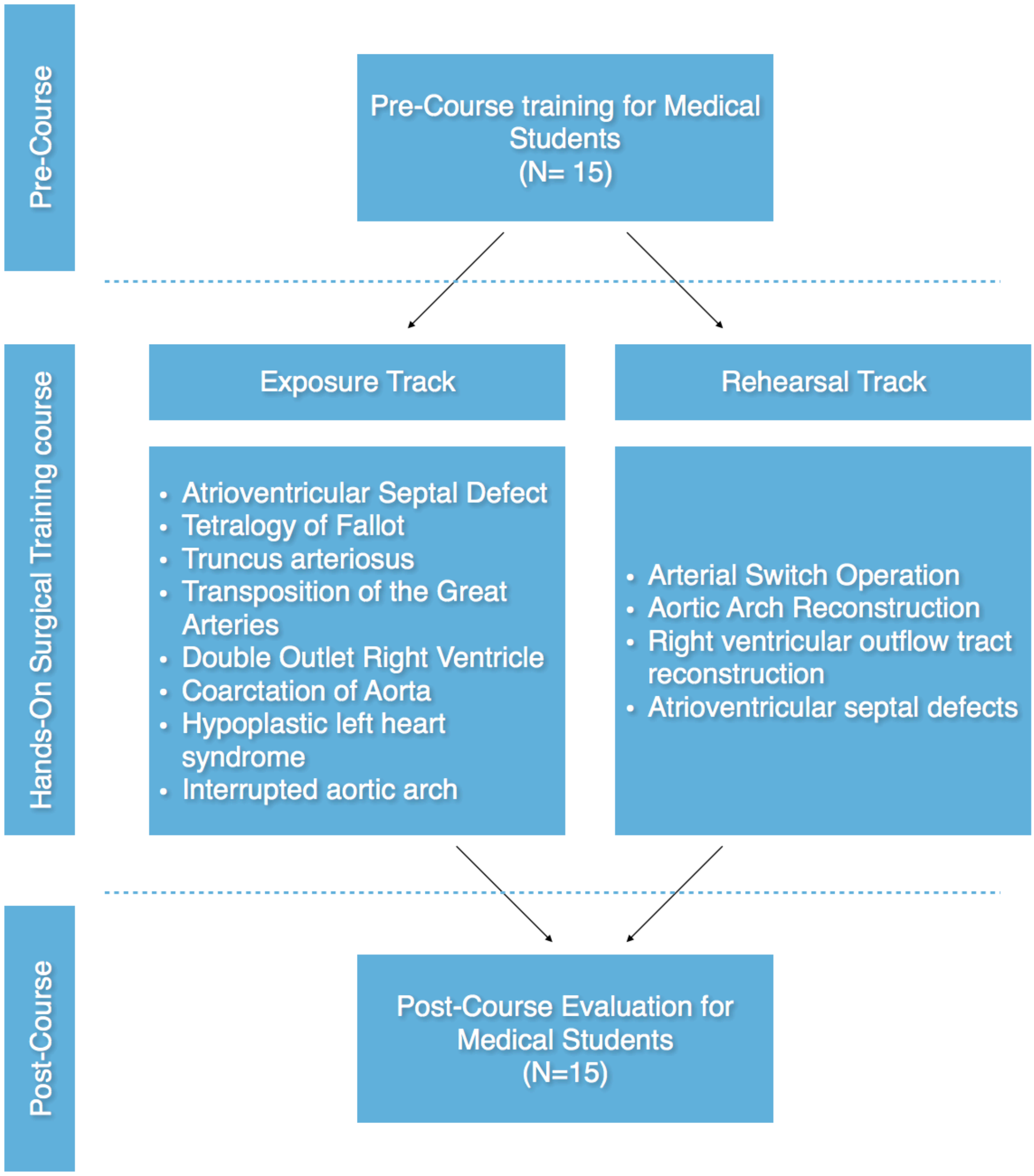



**Figure 10.3:** A flow chart characterising the study design and workflow of the Hands-On Surgical Training (HOST) course for congenital heart surgery. All surgeons pre-selected which track they would follow (exposure vs rehearse). The exposure track consisted of a variety of different congenital heart procedures, whereas the rehearse track focused on one disease type with the surgeon repeating the same or similar procedures on multiple variations of the pathology.

### 10.2.2 Statistical Analysis

The data was analysed and processed using descriptive statistics. Two open-ended questions were also provided in the participant questionnaire to further understand the perceived boundaries in pursuing a career in CHS. Salient points from the participants' response were extracted manually and derived as frequencies. Data is presented with means and standard deviations for categorical and numeric data.

## 10.3 Results

A total of 38 medical students (58% male, 42% female) applied to participate as an assistant in the HOST course. Clinical year students or preclinical students who were not available for the entirety of the course were excluded (n = 11). From the remaining eligible students (27), fifteen were randomly selected who attended both courses and participated in the study (Table 10.1). This allocation ensured a 1:1 surgeon-to-student ratio. Five (33%) were first year students and ten (67%) students were in their second year. Six (40%) were female and nine (60%) were male.

All students reported a novice level understanding of congenital heart disease. Thirteen (86%) had observed surgery before and 5 (33%) had previously participated in surgical simulation. Five (33%) participants were interested in pursuing a career in CHS. This increased to 13 (87%) by the end of the course (Figure 10.4). Limitations in the job market, length of training and competitiveness were expressed as major barriers towards entering a career in CHS (Table 10.2). The individualised experience with an experienced surgeon was one of the key hallmarks of the simulation session (Table 10.3).

Participants expressed a high level of satisfaction in using 3D-printed heart models to help understand congenital heart disease (4.80 ± 0.41) and learn complex anatomy (4.87 ± 0.35). Participants strongly agreed or agreed that the HOST Assistants' session was a valuable learning opportunity (4.67 ± 0.62) and was a good use of their time (4.67 ± 0.62). All participants agreed that the sessions helped improve their assisting skills (4.93 ± 0.26) and would participate in the HOST course again (5.00 ± 0.00). They were very likely to recommend the course to a colleague (4.86 ± 0.36). The participants unanimously agreed that implementing surgical simulation sessions into medical school curricula would enhance learning (5.00 ± 0.00) (Figure 10.5).

**Table 10.1:** Self-Reported demographics of medical student participants who assisted congenital heart surgeons during the Hands-On Surgical Training course (HOST)

| Variable | All N=15 (%) |
|---|---|
| **Medical School Year** | |
| 1 | 5 (33) |
| 2 | 10 (67) |
| **Gender** | |
| Male | 9 (60) |
| Female | 6 (40) |
| **Prior Surgical Experience** | |
| **Surgical Observation Experience** | |
| Yes | 13 (86) |
| No | 2 (14) |
| **Prior Exposure to Surgical Simulators** | |
| Yes | 5 (33) |
| No | 10 (67) |
| **Knowledge in surgical morphology of CHD** | |
| Entry Level | 13 (86) |
| Below Average | 1 (7) |
| Average | 1 (7) |
| Expert | 0 (0.0) |

**Table 10.2:** Participant medical students' perceived boundaries in pursuing a career in congenital heart surgery.

| Variable | N | Percentage (%) |
|---|---|---|
| **Limited job market and positions** | 8 | 53 |
| **Competitiveness** | 5 | 33 |
| **Length of Training** | 5 | 33 |
| **Lack of knowledge and exposure to the field** | 3 | 20 |
| **Demanding lifestyle** | 3 | 20 |
| **Highly specialised** | 2 | 13 |
| **Gender Imbalance** | 1 | 6 |
| **Poor Ergonomics** | 1 | 6 |
| **Limited training opportunity in home location** | 1 | 6 |
| Participants were able to submit more than one response for this question | | |

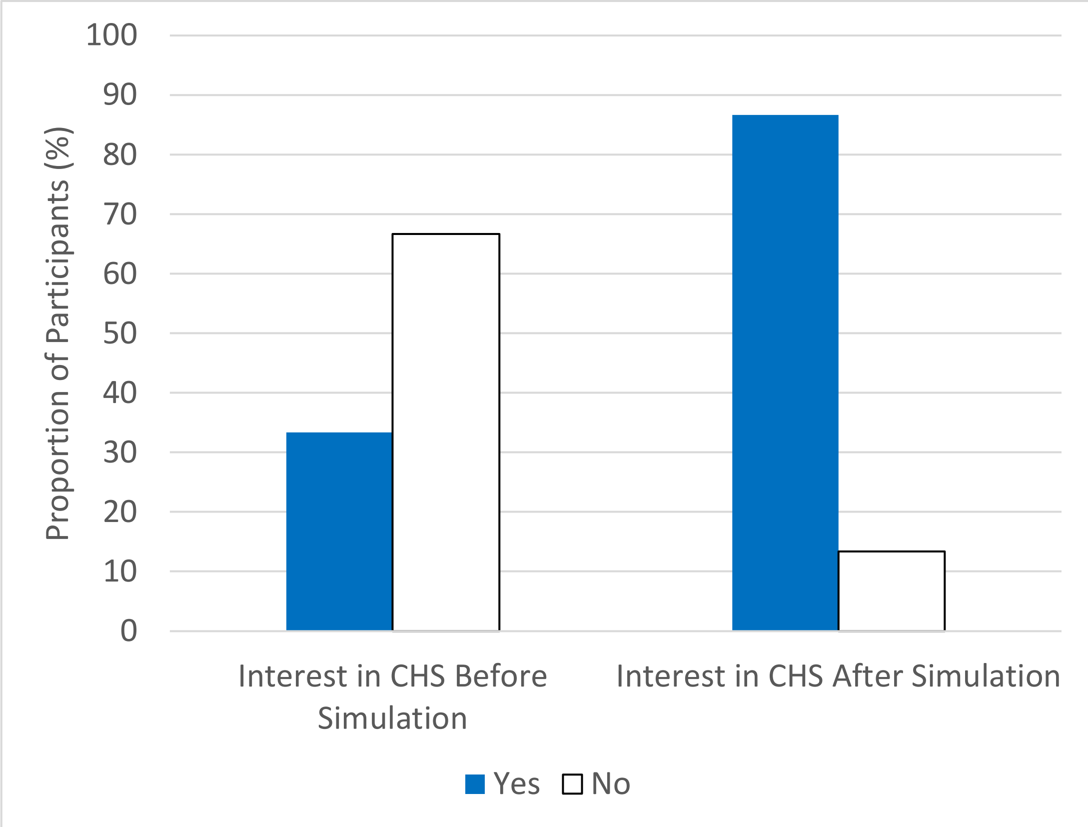



**Figure 10.4:** Interest of preclinical medical students to pursue a career in congenital heart surgery (CHS) before and after attendance of the HOST (Hands-On Surgical Training) course as a surgical assistant.

**Table 10.3:** Medical students' open-ended response to comments on the overall HOST (Hands-On Surgical Training) course from post-course questionnaire.

| Comments | N | Percentage (%) |
|---|---|---|
| **Individualised experience with a surgeon** | 9 | 60.0 |
| **Good exposure to surgical skills and assisting** | 6 | 40.0 |
| **Improved anatomical understanding with 3D models** | 4 | 26.7 |
| **Tutorials from expert surgeons** | 3 | 20.0 |
| Participants were able to submit more than one response for this question | | |

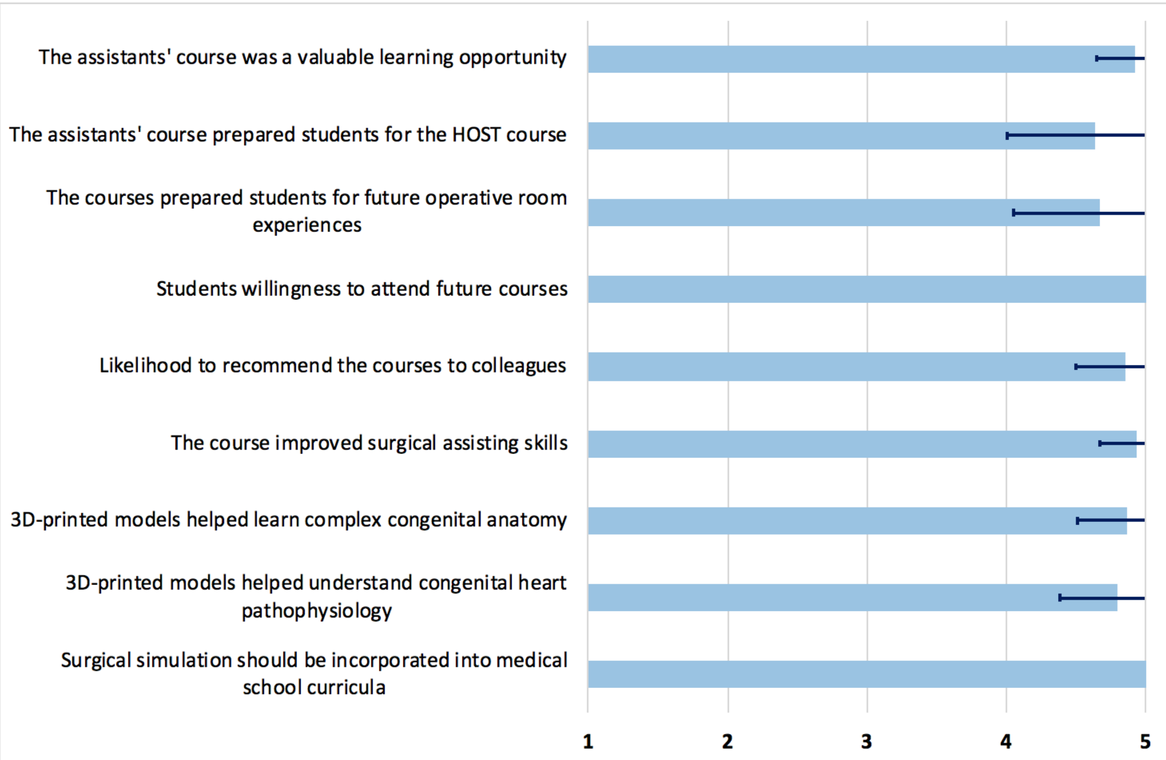



**Figure 10.5:** Mean scores for survey questions based on a 5-point Likert-scale. 1 = strongly disagree, 5 = strongly agree. Black line bars = standard deviation.

## 10.4 Discussion

The limited exposure to surgery during medical school has been identified as a factor that has led to a decline in interest in pursuing cardiothoracic surgery as a career [15], [112], [113], [121]. As almost half of congenital heart surgeons choose the specialty during medical school, early exposure to surgery would help their appropriate decision [15], [38]. Early exposure among preclinical medical students in the form of hands-on participation and the emphasis of learning technical skills has been shown to increase surgical interest especially for highly specialised sub-specialties [38], [116], [118], [119], [122]. These same findings were seen in our study as student interest to pursue CHS increased from 33% to 86%. This supports similar findings in the literature whereby cardiothoracic surgery interest increased from 20% to 47% in medical students following a coronary anastomosis simulation course [121]. However, one student in our study who had initially expressed an interest in CHS had no interest after the course. This is also beneficial as there is now an increasing trend towards early identification of career specialty. Exposure to surgical specialties as a preclinical medical student will potentially minimise attrition rates within residency programmes in the future.

Mentorship has been identified has the most common motivating factor in pursuing a specialty as it increases exposure via observation and/or participation and provides a plethora of information regarding a career [15], [123]. From the questionnaires, 20% of students identified a lack of knowledge and exposure as a barrier to pursuing CHS. The 1:1 surgeon-to-student ratio encouraged students to discuss career opportunities and develop new mentorships, which will encourage informed decision making.

Following the course, the medical students indicated that the use of 3D-printed heart models was helpful in learning complex anatomy (4.87 ± 0.35) and understanding of pathophysiology in congenital heart disease (4.80 ± 0.41). Using 3D-printed models is an example of a cost-efficient educational tool for learning surgical anatomy, achieving surgical skills and encouraging early exposure to surgical specialties without potential harm to patients [18], [19], [114], [121]. Current medical school curricula are geared towards the teaching of anatomy with limited focus on the surgical and clinical context. This may hinder students' understanding of clinically relevant anatomy until their surgical clerkships or residency training. The HOST course attempted to bridge this gap by providing surgical context thus reinforcing anatomical knowledge whilst obtaining surgical skill.

Surgical simulation is widely used in most residency and fellowship programmes. However, its use in medical school curricula is limited to the teaching and assessment of basic procedural skills (i.e. venipuncture, basic life support etc) as opposed to surgical skill training and exposure [80], [122]. There are multiple studies that have highlighted the benefits simulation provides and have encouraged its incorporation into medical student training [112], [117]–[119]. These benefits include improvements in surgical skills acquisition, preparation for surgical clerkships, reduced anxiety, and increased confidence of working in an operative environment [38], [80], [122], [124]. Our study supports these findings with 40% of medical students identifying that surgical skill improvement was as a major strength of simulation. Furthermore, they all agreed that the session had prepared them to attend and/or assist in the operating room (4.67 ± 0.62). Although there was no standardised testing to assess the improvement of their technical skills, participants strongly agreed or agreed that the simulation session improved their assisting skills (4.93 ± 0.26). Additionally, the HOST assistants' session utilised the benefits of peer-assisted learning by using medical students to assist and teaching themselves under the supervision of surgeons, which improved their confidence [125].

Despite the promising results from the study, there are several limitations. Firstly, the participants were recruited from a single institution with a relatively small sample size. Due to the difficulties in achieving a high expert-to-student ratio in other studies we deliberately pursued this to maximise the mentorship and coaching the students received during the course [125]. Secondly, only pre-clinical medical students were selected as they were more likely to be available for the duration of the course than clinical students. Furthermore, we wanted to target medical students with limited prior exposure to the surgical environment and therefore had much to gain from a study like this. However, it would be worthwhile to repeat the study for more senior medical students/junior doctors to explore if our findings were consistent. Although the questionnaire responses are favorable, its value is limited. The students' overall interest in the specialty increased following the course, but they correctly identified the barriers that exist in entering a niche specialty like congenital heart surgery. It is unlikely that these barriers will change with time, however this experience may encourage students to explore the specialty further and seek mentorship to establish whether congenital heart surgery is a career worth pursuing.

This was the first attempt to incorporate and measure the benefits to students in a technically challenging environment. From the excellent feedback and the symbiotic benefits to both students and surgeons, we will continue to incorporate medical students into our future courses and will expand the opportunities to medical students outside of our vicinity. Larger-scale studies, conducted with multiple institutions with pre and post-tests, would be needed to objectively evaluate the effectiveness of CHS simulation in pre-clinical medical students. Future studies could be performed to look at the careers that the participant medical students choose to see if there has been an impact on specialty choice.

Cost may be perceived as a barrier for widespread use, however the simulators made for the HOST assistants session were developed in house at a cost of approximately $15-20 USD per student. There were no costs associated with student participation during the HOST course apart from catering. Therefore, this is a cost effective training platform that can be made available to all students. However it is important to recognise that faculty volunteered their time to teach during the courses, which may not be possible in smaller institutions not affiliated with universities and may present additional costs and therefore must be considered.

Although all preclinical students were invited to attend the session, it is likely that students who already were interested in surgery expressed an interest to attend. However, by the conclusion of the course all students were very likely to recommend the course to a colleague and all agreed that implementing surgical simulation sessions into medical school curricula would enhance learning. A comparison of attitudes with a control group would add further value in evaluating the impact of medical student participation in simulation.  Studies like these are a starting point to encourage medical schools to incorporate simulation as a teaching modality to all medical students as opposed to those only interested in surgery.

## 10.5 Conclusion

The integration of preclinical students into a hands-on surgical simulation course in congenital heart surgery using 3D-printed models has shown to increase medical student interest in the specialty. Early exposure and the incorporation of such simulation programmes into medical school curricula will likely improve surgical skill acquisition. This may enable students to be better informed when selecting future career choices.

# 11 Conclusion/Future directions

## 11.1 Introduction

The focus of this thesis was to explore whether current training in congenital heart surgery (CHS) could be augmented with technologies such as 3D printing and be used for simulation to improve the acquisition of technical skills. This chapter summarises the overall conclusions and describes future work that would advance the research presented in this thesis.

## 11.2 Hands-On Surgical Training in Congenital Heart Surgery:

### 11.2.1 A need to evolve current training

It is well recognised that congenital heart surgery is a technically challenging speciality requiring over a decade of training to achieve competency. Therefore there is a need for improvements in the acquisition of skills in the form of simulation. This is becoming increasingly apparent following the restructuring of training curricula, which have generally led to shorter, concise training periods [71], [126]. The literature review in chapter 4 highlights the need for simulation methods to be incorporated into training with objective assessment methods in order to validate training and promote the concept of deliberate practice. Both animal and synthetic simulators have benefits to training, however it may be more feasible and practical to use 3D models to encourage widespread adoption of regular simulation in CHS.

### 11.2.2 Objective assessments

To promote simulation methods there was a need to develop validated assessment tools which could be used to measure trainee surgeons' performances. This could also be used to identify areas of improvement accurately in order to encourage efficient learning. The preliminary work in chapter 5 introduced objective assessments in evaluating the simulation of the arterial switch operation, which is considered a very challenging procedure. This demonstrated an improvement in time and technical performance of surgeons following rehearsal, however identified a need to develop more reliable and valid assessment methods.

Following the findings of this study a procedure-specific assessment tool using a combination of a binary checklist and weighted-scoring system was validated for the arterial switch operation (Chapter 6). This laid the foundations for the development of a training curriculum exclusive to CHS (Chapter 8). The HOST-CHS assessment tool was shown to be more superior than existing generic assessment tools used in surgery, which are derived from the OSATS format. The new tool was used to evaluate surgeons of different experience and showed a high inter- and intra-rater reliability across raters of different experience in CHS including raters with no medical experience. These findings are significant as it may potentially take away the onus from experienced trainers to provide objective feedback whose time is usually  limited and therefore can focus primarily on teaching. Furthermore, the Holistic HOST-CHS score identified general skills (knowledge/fluency of procedure and respect for tissue) that a trainee surgeon is lacking. This alongside the specific nature of the assessment tool allowed surgeons to identify key areas where improvement could be sought, thus promoting efficient learning. The HOST-CHS assessment tool was then used to demonstrate if improvement occurs following practice. This was initially demonstrated in the arterial switch operation with 30 surgeons performing the procedure twice (Chapter 7). Eighty percent of surgeons' scores improved between the two attempts and all were quicker on repetition. The format of the assessment tool was then applied to the rest of the congenital heart surgery procedures, which make the full HOST curriculum.

## 11.3 HOST-CHS curriculum

The format of the annual HOST training course and objective assessments were used to develop a year-long curriculum comprising of twelve different congenital heart defects (Chapter 8). Objective assessments were used in the majority of training sessions. Similarly the study demonstrated an improvement in both time and technical skill following rehearsal and deliberate practice. Furthermore trainee surgeons were able to demonstrate retention of technical skills following a delay highlighting the value in regular simulation. The general consensus from the experienced trainers was that the simulation sessions were translating into clinical practice, however to objectify this remains elusive.

### 11.3.1 Establishment of curricula worldwide

This curriculum is now firmly integrated into the training programme at the Hospital for Sick Children (SickKids), Toronto and there has been interest in incorporating this in other centres and into CHS certification processes. The work in this thesis has developed a replicable programme whereby models, objective assessments and overall setup are available for other institutions and surgeons to adapt and integrate into their own local programmes. These methods will assist the switch from a number to competency based assessments and will encourage trainee surgeons to take further ownership of their training by allowing them to repeatedly rehearse procedures without a heavy reliance on their trainers. However, prior to incorporation into certification processes there is essential work required to identify key procedures that will constitute an examination and cut-off scores for pass/fail. In order to achieve this board representatives of education programmes would need to establish these scores and be provided with further data to demonstrate learning curves. In the United Kingdom surgical trainees have an excellent training curriculum in adult cardiothoracic surgery, which requires mandatory participation in order to achieve certification [71]. This platform could potentially be used to establish a training curriculum nationally in CHS.

The aim of the work contained in this thesis was to produce a reproducible curriculum that could potentially be used by all surgeons worldwide, including in countries where there are significant financial limitations. However, as described in chapter 8 there are substantial costs involved in the start-up and running of such programmes (i.e. capital, labour and running costs). As the field of congenital heart surgery is a small speciality compared to others I believe that to achieve the goal of widespread use of this platform requires international collaboration and an economies of scale principle. Ideally, the development and production of models would be carried out by specific centres, which have the resources, personnel and expertise. These models can then be made available to hospitals and dedicated training platforms at a price that would cover the costs associated with the development and manufacturing. This would allow the development of better models at a potentially lower cost due to the increased volume that would be produced compared to if multiple, individual centres made their own models.

As the number of NTN and non-NTN trainee surgeons across the UK's 12 congenital heart surgery units is relatively small (up to 5-6 surgeons per unit), the ideal method to incorporate HOST simulation into the training curricula would be best via a national training programme. This could be developed alongside the Society for Cardiothoracic Surgery (SCTS), the UK's national body in the form of face-to-face and virtual sessions. The goal of such a programme would be to promote regular, high quality training for surgeons in the development of their technical surgical skills. If successful, such a programme could be used in the assessment of competency and measure surgeon progression. Beyond the UK, a similar approach could be taken by collaborating with international societies/organisations, with the goal of making this training platform available to as many surgeons as possible.

## 11.4 Translation to reality

One of the key questions that this thesis generates is whether these improvements in simulation are translatable to clinical practice (i.e. better patient outcomes). Although the evidence demonstrating the predictive validity of simulation is lacking it is apparent that simulation provides the ability to learn operative sequencing and key operative skills such as hand-positioning and accurate anastomoses which inevitably will be translated into reality.

Within this thesis (Chapter 7) we describe this in action with one surgical fellow using 3D printed heart models to prepare themselves to perform their first arterial switch operation, which is usually not reserved for training surgeons due its complexity and high-risks associated with imperfection. In total the trainee surgeon simulated the operation several times under the supervision of the consultant/staff surgeon who would be accompanying them during the real patient case. The trainee surgeon was able to perform the whole operation with no complications with cardiopulmonary bypass and cross-clamp times comparable to a consultant surgeon. This study identified benefits to both trainee and trainer. The trainee was able to rehearse this complex procedure in a risk-free, inconsequential environment being coached by their senior thus increasing their confidence prior to their real case. The trainer was able to troubleshoot the trainee during the simulation runs, evaluate their skills and knowledge and most importantly identify the trainee's limits. This subsequently lead to a controlled, smoother intraoperative course which ultimately benefits the patient.

Individual case series may not be enough to convince intuitions and training programmes to incorporate these potentially costly methods into their curricula. There is only a single study demonstrating a potential predictive validity with simulation on 3D printed models [27]. This study reports the patient outcomes of a single surgeon who was prepared for real life cases by performing simulation beforehand. Although patient outcomes are an available measure there are several issues by solely using these. Firstly, there are multiple confounding factors which contribute to a patient outcome, therefore it will be hard to pinpoint whether the surgeon performance or an alternative factor lead to a patient outcome. Furthermore, patient mortality in CHS is <5% across most routine surgical procedures, therefore surgeons would need to perform >100 operations before outcomes could be analysed, which is unlikely to be achieved by most trainees.

A potential study design could involve a prospective cohort study looking at the progression of trainees who used hand-on simulation during training versus trainees who did not use simulation. Outcomes could include the number of independent cases performed as a trainee/ junior consultant, the complexity of cases performed, the rate of progression to more complex congenital heart operations, patient outcomes, success at consultant appointment and subjective evaluation of the simulations' contribution to clinical maturation. A study like this would be comprehensive and would have logistical challenges which may jeopardise the data collection and impact the validity of the study's results and conclusions. The belief of this study team and others is that it is only after widespread adoption of simulation will the real impacts of simulation be felt, which is likely to be greater than the financial costs associated with its implementation.

## 11.5 Virtual Hands-On Surgical Training in Congenital Heart Surgery

Following the success of establishing a local training programme efforts have been made to disseminate the course globally. The restrictions imposed as a result of COVID-19 accelerated these efforts with the conversion of the monthly in-house training programme to a virtual format. The proctor would perform a demonstration of the scheduled operation on the appropriate model while it is streamed to the delegates or play a pre-recorded demonstration. Trainee surgeons would follow this by streaming their own procedures with the proctor giving feedback in real time (Figure 11.1). Simultaneously trainees recorded their procedures to be retrospectively assessed using the HOST-CHS assessment tool in order to receive objective feedback. Due to this change in format the training programme has not been impacted by the pandemic highlighting one of the additional benefits of simulation. This transition lead to increased demand to attend the course so a virtual HOST event was organised in December 2020, which was attended by 40 trainees globally. Worldwide trainees benefitted from expert teaching regardless of finances or location as they were no longer required to travel abroad to attend the course. This course is now likely to occur more frequently and potentially be run in a monthly/quarterly format similar to the in-house HOST curriculum.

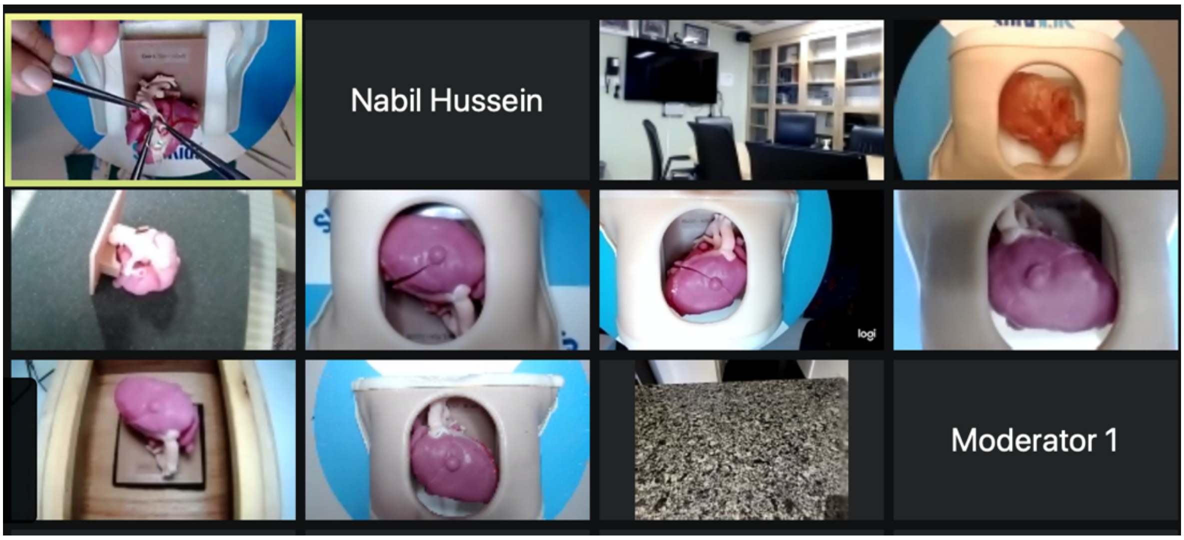



**Figure 11.1:** Screenshot taken from the inaugural Virtual Hands-On Surgical Training (HOST) course held in December 2020. The top left panel shows a proctor surgeon demonstrating a complex congenital heart procedure on a silicone model. The other panels are of delegates around the world who proceeded to perform the procedure under proctor guidance “Moderator 1”.

## 11.6 Improvements in image acquisition, models and material

Although being currently appropriate to simulate complex congenital heart procedures there are improvements required in the whole 3D modelling process to develop models and simulators that closely resemble the true intraoperative environment. Despite being arguably the most realistic simulators currently available this simulation method would be defined as 'low-fidelity' due to its lack of haemodynamics to allow scenario and team based learning. Future work should focus on developing this simulation model to incorporate real-life scenarios, where complications and unusual events could be rehearsed. A smooth intra-operative course is not solely reliant of the primary surgeons' skill but rather the performance of the whole team. Therefore high-fidelity simulators incorporating the intraoperative team will inevitably add further value to this platform of education and training.

### 11.6.1 Image acquisition

Cross-sectional image studies such as MR and CT has revolutionised the management of patients with congenital heart disease over the last two decades and has laid the foundations for 3D printing. It is expected that imaging modalities will continue to improve with higher temporal and special resolutions allowing for more detailed information to be gathered. This would provide information on structures currently difficult to segment such as valve tissue and subvalvular apparatus. This combined with automated segmentation tools will reduce the labour time involved in the modelling process, which will improve the development of cardiac models.

### 11.6.2 Model material

The ideal model material would have the same characteristics as real-life cardiac tissue. Material limitations described in this thesis include lack of strength, flexibility and elasticity. Furthermore, cardiac tissue is comprised of different components, which have different tissue characteristics (i.e. ventricular myocardium, endocardial surfaces, bloods vessels and valve tissue) therefore these would be needed to be taken into consideration in future developments. Currently there are two main future approaches: 1) silicone modelling/3D printing and 2) 3D bioprinting.

Silicone is an ideal material as it is relatively cheap and has the mechanical properties similar to myocardium, which can be altered to represent different aspects of cardiac tissue. Currently silicone printers lack the resolution and ability to develop complex structures like heart models, however the moulding technique has shown some promise. Figure 11.2 demonstrates a silicone moulded congenital heart which has been developed for future courses. Early subjective feedback has demonstrated that it is much superior to current 3D printing techniques as it harbours the elasticity and strength properties that were previously absent. This opens up the ability for simulators to be developed for complex valve repairs and with its hydrophobic properties it also will makes an excellent material to develop high-fidelity simulators with flow pumps.

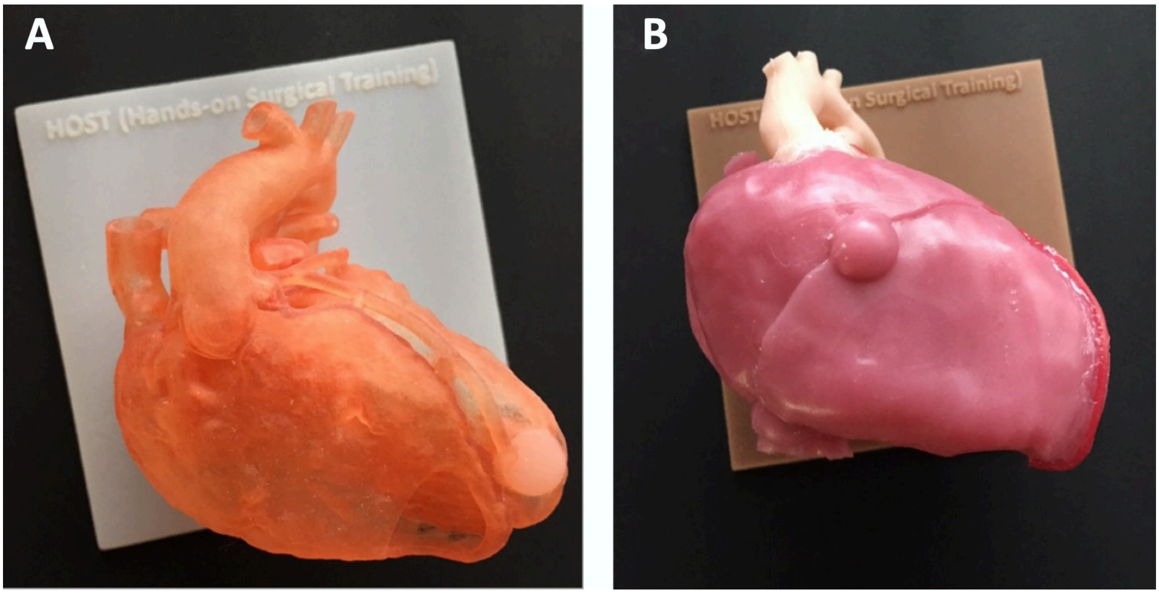



**Figure 11.2:** (A) Usual 3D printed heart model variation used in the simulation of the arterial switch operation. (B) New silicone moulded model of the same disease with improved mechanical properties similar to cardiac tissue. Note how colour can be used to differentiate different cardiac aspects as opposed to the uniform colour in (A).

3D bioprinting can be regarded as the panacea of 3D modelling as it has the potential to print 'real-life' tissue with growth potential characteristics [127], [128]. The two main methods involve either the printing of a 3D-scaffold where cells are subsequently incorporated and grown, or by direct printing of living cells or bioink [129], [130]. As matured, differentiated myocardial cells have reduced viability and proliferation ability stem cells are preferred for bioprinting as their microenvironment can be altered to achieve the desired effect [131]. Factors that can be altered include temperature, oxygen content and extracellular proteins [131], [132]. The common systems used to bioprint cardiac tissues are extrusion-based printers which deposit the bioink in a similar method to conventional extrusion printers [133]. However, cells are required to be deposited accurately with minimal shear stress , which is an added complexity to the process [131], [133]. Moreover, in order to develop viable cardiac tissue, there is a requirement to generate a vascular system and contractile function [131]. There has been some success in preclinical studies which have demonstrated an improvement in myocardial activity post infarction in animals following the grafting of cardiac patches derived from similar methods [134]. In addition there a has been the development of a rat-sized ventricle, however its functional capacity is far less than what would be required to sustain a rodent's life [135]. Although an attractive avenue, cardiac bioprinting remains in its infancy and faces a number of challenges that are needed to be overcome. It is likely that this technique will be reserved for clinical research in the development of implantable devices (i.e. heart valves) and cardiac patches rather than be incorporated into simulation.

## 11.7 Research applications

This thesis and other works have discussed the benefits of 3D modelling in the education of medical personnel ranging from first year medical students to experienced cardiovascular surgeons. However there is exciting research emerging, which is using 3D printing to answer key questions within the speciality. One direction is the use of computer-aided design, 3D printing and 4D MR imaging to evaluate the structure and function of the cardiac valves [136], [137]. It has been demonstrated that geometrically accurate aortic valve phantoms are able to be printed and attached to physiological pumps, which can demonstrate the opening and closing of valves with cine imaging and flow studies with 4D MR (Figure 11.3). The iterative nature of 3D printing streamlines the process of developing and testing phantoms, accelerating research. This opens up interesting avenues such as the development of geometrically ideal valve replacements and analysing the impacts of valve pathology (i.e. bicuspid and quadricuspid valves). Further benefits include the reduction in confounding factors such as patient anatomical and haemodynamic variations and reduces the need for extensive ethics approval due to the absence of patient or animal subjects. This is highly applicable to congenital heart disease where the limitation in protheses' growth potential have lead centres to aggressively treat valve incompetency/stenosis with complex repair techniques[138], [139]. Potentially this research data could be potentially used to assist in these procedures/developments.

Using these principles the next stage of model development would explore the use of impermeable, flexible materials which could be used to develop complete heart models. The advantages this presents includes the ability to connect the models to a pulsatile pump that could mimic physiological conditions. If achieved this would broaden the scope of the simulator and increase its fidelity. For example, surgeons would potentially be able to rehearse other key aspects of a cardiac procedure including establishment of cardiopulmonary bypass. Furthermore, this could be used to evaluate the quality of the repair by placing the heart under hydrostatic pressures or performing flow studies using 4D MRI or echocardiography. This is an exciting avenue and should be the focus of future developments in the simulation programme.

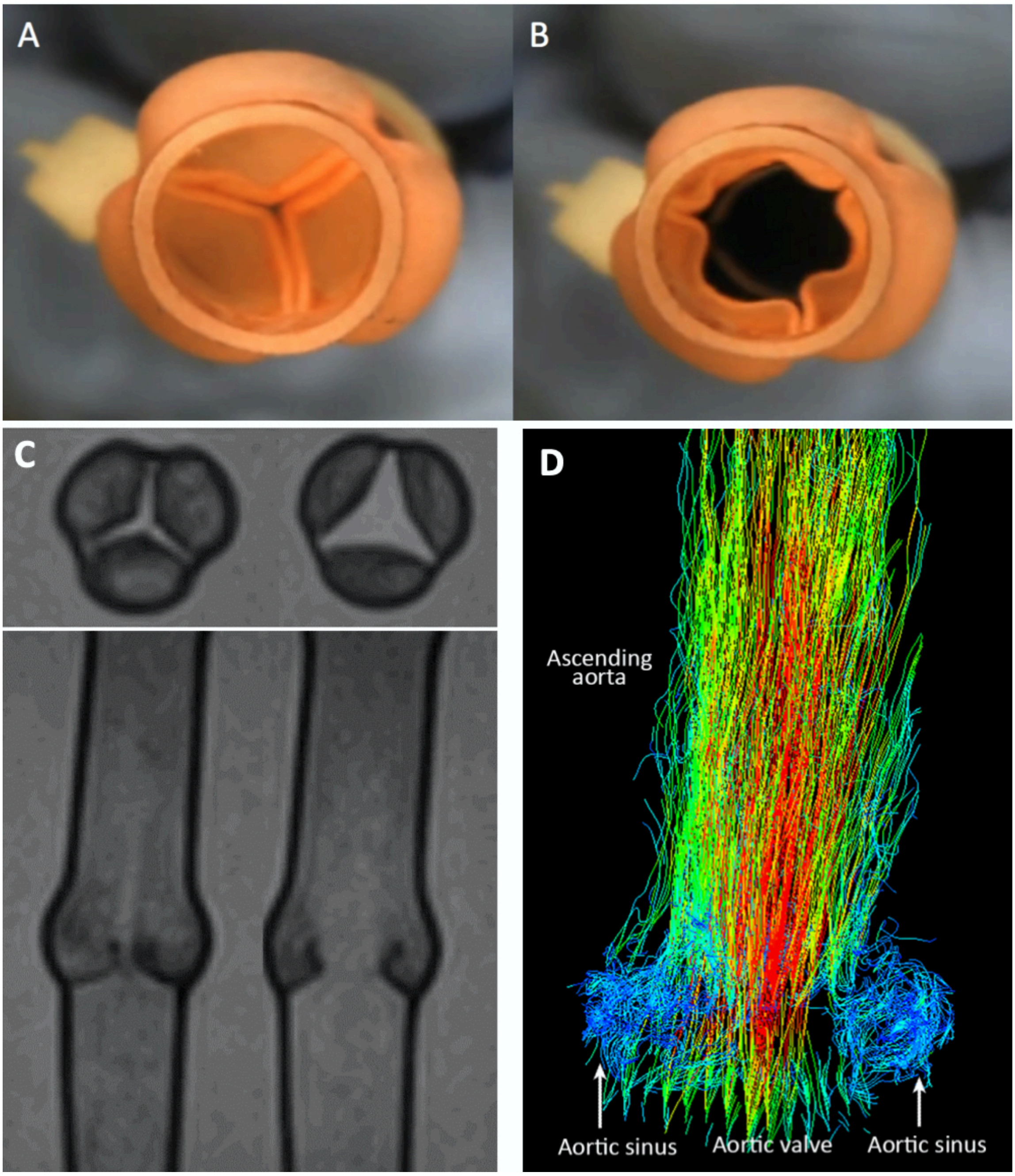



**Figure 11.3:** Opening (A) and closing (B) of 3D-printed semilunar valve which was developed using existing geometrical data and computer-aided design. (C) Cine imaging of the functional valve when placed in magnetic resonance scanner and (D) 4D flow studies demonstrating flow through the valve and eddy currents in the aortic sinuses which assist in valve closure. Image adapted with permission from authors [136].

## 11.8 Patient-specific cardiac patches

One of the major reasons why congenital heart surgery is technically complex is the requirement of surgeons to be able to reconstruct cardiac structures with synthetic or biological materials. Usually these materials take the form of flat patches which then need to be fashioned in a particular way to compliment the patient's anatomy and have an optimal haemodynamic profile. The development of this skill requires years of experience and can be challenging for newly qualified surgeons. However, the benefits of computer modelling and 3D printing could help develop tools to assist surgeons in the pre-surgical planning and intraoperative stages of the complex patients. One potential example could be in the reconstruction of aortic diseases such as hypoplastic left heart syndrome, where the systemic side of the heart fails to develop in utero leading to a circulation incompatible with life [140]. This disease requires a complex operation in the neonatal period known as the Norwood procedure which consists of aortic arch reconstruction [140]–[142]. Figure 11.4 shows a novel example where a computer algorithm can be used to estimate the ideal post-operative aortic arch shape and be retro-engineered to develop a curved or flat patch that could be subsequently produced. This could then be used intraoperatively to assist the surgeon complete the reconstruction. There are considerable hurdles to overcome before this becomes a reality including randomised control trials to evaluate its efficacy, however it is likely that in the next 20 years patient-specific surgery will emerge from these technologies.

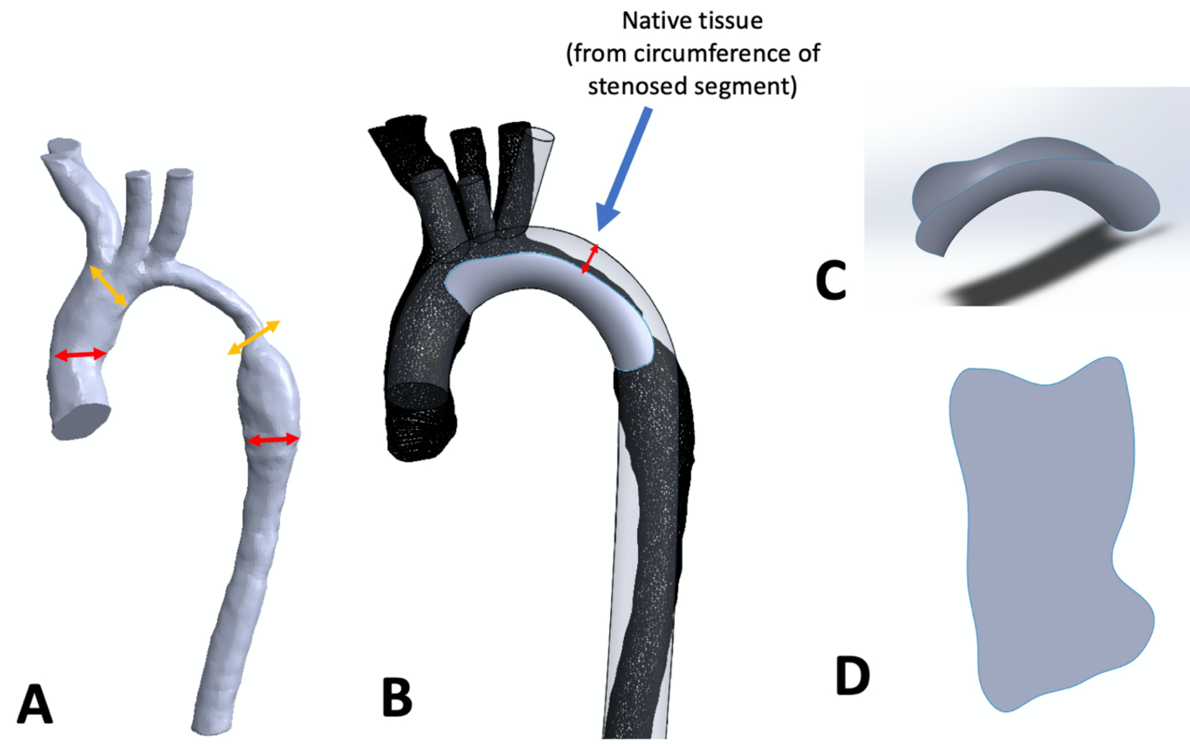



**Figure 11.4:** (A) 3D-rendered aorta demonstrating a narrow aortic arch segment (between yellow arrows), which requires reconstruction with a patch. Using a computer algorithm the ideal post-operative aortic arch with optimal haemodynamic profile is developed (B). (C) Retro-engineering to develop curved patient-specific patch which can be used by an operating surgeon as a template (D).

## 11.9 Final remarks

Although this thesis has been conducted at a time of relative infancy in this rapidly expanding technology, we have objectively demonstrated the real-life impact this has on the education and development of healthcare professionals within congenital heart surgery. The interest and excitement generated from work described in the thesis and others in the field leaves a belief of optimism that this will lay the foundations for the evolution of surgical training. It is the hope of this author that this will work will help in the development of excellent congenital heart surgeons, which hopefully will translate to excellent outcomes for their future patients and stimulate further exciting research.

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# 12 Appendices

## 12.1 Questionnaire Summary from 4th HOST Course – 6-8 Sept 2018

**Summary:**

- Majority (70%) of surgeons were fellow/resident
- Average number of years performing CV surgery 8.6 years with 54% believing their knowledge in congenital heart disease was average, 38% were above average/advanced.
- Average number of cases independently = 231 cases (however 1 = >2000 cases) Therefore if remove that delegate then = Av: 84 cases
- Majority of residents/fellow surgeons cases were of VSD, ASD, PDA, TOF, COA
- All surgeons agreed/strongly agreed that the models provided the necessary information regarding the major pathological findings
- All surgeons graded the overall quality of models as excellent/good
- 53% of surgeons agreed that the consistency and elasticity of the model material similar/very similar to that of the human myocardium. 30% felt it was different and 15% very different
- 92% of surgeons felt the model material acceptable for an appropriate surgical simulation. 1 felt was manageable
- 92% surgeons felt (agreed/strongly agreed) that the Hands-on Surgical Simulation Session is helpful in improving their surgical skills. 1 surgeon was neutral.
- All surgeons felt (agreed/strongly agreed) that they would consider including similar Hands-on Surgical Simulation Sessions in the training programs for residents and fellows
- All surgeons would attend further courses
- Suggestions for improvement: improve material and table height

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**HANDS-ON SURGICAL TRAINING (HOST) COURSE**

**CONGENITAL HEART DISEASE SURGERY WITH 3D PRINT MODELS**

Date:

Location:

**Q1. What is your current professional status?**

- ☐ Staff pediatric cardiovascular surgeon
- ☐ Staff adult cardiovascular surgeon
- ☐ Cardiovascular surgery fellow
- ☐ Pediatric cardiovascular surgery fellow
- ☐ Other ___________________________

**Q2. What is your training background?**

- ☐ General surgery training
  ☐ Yes ☐No (If yes how many years:______)
- ☐ Combined thoracic and cardiovascular surgery resident training:
  ☐ Yes ☐No (If yes how many years:______)
- ☐ Dedicated cardiovascular surgery residency training:
  ☐ Yes ☐No (If yes how many years:______)
- ☐ Adult cardiovascular fellowship training:
  ☐ Yes ☐No (If yes how many years:______)
- ☐ Congenital heart surgery fellowship training:
  ☐ Yes ☐No (If yes how many years:______)
- ☐ Other: __________________________________________________

**Q3. How many years have you performed cardiovascular surgery altogether?**

- ☐ _____________ years

**Q4: How do you grade your knowledge level on surgical morphology of congenital heart diseases?**

- ☐ Advanced
- ☐ Above average
- ☐ Average
- ☐ Below average
- ☐ Entry Level

**Q5. How did you find out about this course?**

- ☐ Previous registrant: I was e-mailed a notice
- ☐ I received a brochure in the e-mail directly.
- ☐ I received a brochure in the e-mail through my department.
- ☐ I picked up a brochure in a scientific meeting
- ☐ Other: Please specify_______________________________________________________

**Q6. Have you attended any surgical simulation course before?**

- ☐ Yes (Year__________, Name /Type of Course___________________________________)
- ☐ No

**Q7: How many congenital; heart surgery procedures have you attended as an assistant surgeon?**

___________ Cases

**Q8: How many congenital heart surgery procedures have you performed as the primary operator?**

___________ Cases

**Q9: Please list the top 5 surgical procedures that you attended as an assistant or performed as a primary operator?**

| **Surgical procedure** | **Number of procedures** | |
|---|---|---|
| | **Primary operator** | **Assistant** |
| | | |
| | | |

**Q10: By completing this course I aim to:**

- ☐ Understand the principles and the pitfalls in the chosen surgical procedures.
- ☐ Be familiar with the steps involved in the chosen surgical procedures
- ☐ Improve my surgical skills in the chosen surgical procedures
- ☐ Master my surgical skills on arterial switch operation in various settings

**Q11. Did the models provide you with the necessary information regarding the major pathological findings**?

- ☐ Strongly agree
- ☐ Agree
- ☐ Partly agree
- ☐ Do not agree
- ☐ Other comments ____________________________________________________________

**Q12. How would you grade the overall quality of the models you operated on?**

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor
- ☐ Other comments ____________________________________________________________

**Q13. Was the consistency and elasticity of the model material similar to that of the human myocardium?**

- ☐ Very similar
- ☐ Similar
- ☐ Different
- ☐ Very different
- ☐ Other comments ____________________________________________________________

**Q14. Was the model material acceptable for an appropriate surgical simulation?**

- ☐ Highly acceptable
- ☐ Acceptable
- ☐ Manageable
- ☐ Hardly Manageable
- ☐ Unacceptable
- ☐ Other comments ___________________________________________________

**Q15. Was the allocated time for the session optimum?**

| | Case 1 | Case 2 | Case 3 | Case 4 |
|---|---|---|---|---|
| Optimum | | | | |
| Too short | | | | |
| Too long | | | | |
| Suggested time | | | | |

**Q16. Did you find this Hands-on Surgical Simulation Session helpful in improving your surgical skills?**

- ☐ Strongly agree
- ☐ Agree
- ☐ Neutral
- ☐ Disagree
- ☐ Strongly Disagree
- ☐ Other comments ______________________________________________________________

**Q17. Would you consider including similar Hands-on Surgical Simulation Sessions in the training programs for residents and fellows?**

- ☐ Strongly agree
- ☐ Agree
- ☐ Partly agree
- ☐ Do not agree
- ☐ Other comments ______________________________________________________________

**Q18. Please list strengths and weaknesses of the Hands-on Surgical Simulation Session you attended today.**

**Strengths:**

______________________________________________________________________________

______________________________________________________________________________

**Weaknesses:**

_______________________________________________________________________________

_______________________________________________________________________________

**Q19. If we were to organize similar sessions on different congenital heart diseases in the forthcoming meetings, would you like to attend?**

- ☐ Yes
- ☐ Probably
- ☐ Unlikely
- ☐ No

**Q20. Please list the pathologic entities that you would like to be covered in the forthcoming meetings.**

**Q21. Please make any additional comments and suggestions on the Surgical Simulation session you attended.**

## 12.2 List of surgical steps of the arterial switch operation defined by expert surgeons

**Procedure:** Arterial switch operation for transposition of the great arteries (Closed Technique)

**Surgeon:** OH

| | **Step** |
|---|---|
| **1** | CPB: Aorta (arch) and Bicaval and commence bypass |
| **2** | PDA ligation |
| **3** | LV vent through RUPV |
| **4** | Aortic Xclamp → Open RA and close first layer of ASD |
| **5** | Transect the Aorta<br>Mobilise plane between the great arteries |
| **6** | Dissect the coronary buttons and mobilise the coronaries |
| **7** | Divide the PDA |
| **8** | Divide MPA |
| **9** | Tape branch PAs with vessel loop and mobilise branch PAs |
| **10** | LeCompte Maneuver<br>Mark the top of anterior commissures with 5-0 silk |
| **11** | Shorten the distal aorta and complete aortic anastomosis |
| **12** | Take Xclamp off and make coronary incision (closed technique) |
| **13** | Reapply clamp and make medial trap doors |
| **14** | Anastomose coronaries |
| **15** | Xclamp off |
| **16** | PA patch and resuspend posterior commissure of PA |
| **17** | PA distal anastomosis |
| **18** | Right atriotomy closure |

**Procedure:** Arterial switch operation for transposition of the great arteries (Closed Technique)

**Surgeon:** GSV

| | **Step** |
|---|---|
| **1** | CPB: Aorta (arch) and Bicaval and commence bypass |
| **2** | PDA ligation |
| **3** | LV vent through RUPV |
| **4** | Aortic Xclamp → cardioplegia → Open RA and close first layer of ASD |
| **5** | Transect the Aorta<br>Mobilise plane between the great arteries |
| **6** | Dissect the coronary buttons and mobilise the coronaries |
| **7** | Divide the PDA |
| **8** | Divide MPA |
| **9** | Tape branch PAs with vessel loop and mobilise branch PAs |
| **10** | LeCompte Maneuver<br>Mark the top of anterior commissures with 5-0 silk |
| **11** | Shorten the distal aorta and complete aortic anastomosis |
| **12** | Take Xclamp off and make coronary incision (closed technique) |
| **13** | Reapply clamp and make medial trap doors |
| **14** | Anastomose coronaries |
| **15** | Deair, Xclamp off |
| **16** | PA patch and resuspend posterior commissure of PA |
| **17** | PA distal anastomosis |
| **18** | Right atriotomy closure |

**Procedure:** Arterial switch operation for transposition of the great arteries (Closed Technique)

**Surgeon:** CH

| | **Step** |
|---|---|
| **1** | CPB: Aorta (arch) and Bicaval and commence bypass |
| **2** | PDA ligation |
| **3** | LV vent through RUPV |
| **4** | Aortic Xclamp → Open RA and close first layer of ASD |
| **5** | Transect the Aorta<br>Mobilise plane between the great arteries |
| **6** | Dissect the coronary buttons and mobilise the coronaries |
| **7** | Divide the PDA |
| **8** | Divide MPA |
| **9** | Tape branch PAs with vessel loop and mobilise branch PAs |
| **10** | LeCompte<br>Mark the top of anterior commissures with 5-0 silk |
| **11** | Shorten the distal aorta and complete aortic anastomosis |
| **12** | Take Xclamp off and make coronary incision (closed technique) |
| **13** | Reapply clamp and make medial trap doors |
| **14** | Anastomose coronaries |
| **15** | Xclamp off |
| **16** | PA patch and resuspend posterior commissure of PA |
| **17** | PA distal anastomosis |
| **18** | Right atriotomy closure |

**Procedure:** Arterial switch operation for transposition of the great arteries (Open – medial trap door Technique)

**Surgeon:** AR

| | **Step** |
|---|---|
| **1** | CPB: Aorta (arch) and Bicaval and commence bypass |
| **2** | PDA ligation and start cooling |
| **3** | Mobilize branch PAs |
| **4** | Patch distal MPA (where PDA inserted) |
| **5** | Aortic Xclamp → plegia |
| **6** | Divide Aorta (removing a small piece) |
| **7** | Divide PA |
| **8** | Harvest coronaries |
| **9** | Mark commissures on neoaorta |
| **10** | Implant left coronary artery → Implant right coronary artery |
| **11** | Le Compte maneuver |
| **12** | Aortic anastomosis |
| **13** | Close VSD (if present) |
| **14** | Start rewarming |
| **15** | Pantaloon patch repair of neo-pulmonary artery |
| **16** | Pulmonary artery anastomosis |
| **17** | Close right atriotomy (may leave PFO) |
| **18** | Place right (pressure and meds) and left (pressure) intra cardiac lines, A/V wires and drains |

## 12.3 Hands-On Surgical Training in Congenital Heart Surgery (HOST-CHS) Assessment Tools

### 12.3.1 Atrioventricular septal defect (AVSD) repair: 2-Patch technique

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**HOST-CHS Assessment tool – Atrioventricular Septal Defect (AVSD) Repair: 2-Patch Sandwich technique)**

| | | Steps | YES/ | NO | Weight of step (1-5) | Included in HOST-CHS Holistic Score |
|---|---|---|---|---|---|---|
| 1 | | **VSD patch and Suture line** | | | | |
| | 1 | Has a point been marked on the superior and inferior bridging leaflets to identify where the valve with be septated? | Y | N | 2 | KNOWLEDGE |
| | | Is the VSD patch? | | | | |
| | 2 | i) Tailored to the shape of the VSD (i.e height of patch approximately 2-3mm greater than height of VSD? | Y | N | 3 | KNOWLEDGE |
| | 3 | Is the height of patch corresponding to the superior leaflet higher than the inferior leaflet? i.e. is the patch cut in a comma shape? | Y | N | 4 | KNOWLEDGE |
| | | **Anterior portion of the VSD suture line** | | | | |
| | 4 | i) Has commenced at deepest aspect of the ventricular crest? | Y | N | 3 | FLUENCY |
| | 5 | Progressed along a line separating the chordae attaching the medial/septal portions of the left and right superior bridging leaflets? | Y | N | 3 | FLUENCY |
| | 6 | iii) Progressed to the atrium? | Y | N | 2 | FLUENCY |
| | | **Posterior limb of the VSD suture line** | | | | |
| | 7 | i) Continued posteriorly? | Y | N | 3 | FLUENCY |
| | 8 | ii)Has the patched been trimmed (if necessary)? Score Y is trimming not required | Y | N | 4 | FLUENCY |
| | 9 | iii) As the suture line reaches the inferior bridging leaflet/RA does it deviate 5-8mm away from the AV node (i.e. base of primum defect)? | Y | N | 5 | KNOWLEDGE |
| | | Suture assessment: | | | | |
| | 10 | i) Are all sutures evenly spaced from one another with equally sized bites? | Y | N | 3 | FLUENCY |
| | 11 | Are any of the chords damaged or caught in the VSD suture line? | N | Y | 5 | RESPECT |
| 2 | | **Attachment of VSD patch to AV valve leaflets** | | | | |
| | 12 | Have 3+ interrupted horizontal mattress sutures been used to secure the superior margin of the VSD patch to the AV valve leaflets? | Y | N | 3 | FLUENCY |
| | 13 | Has the needle been passed through the VSD patch, the leaflet and then the ASD patch? (creating a sandwich) | Y | N | 3 | KNOWLEDGE |
| | 14 | Has the VSD suture line been completed to septate the AV inflows? | Y | N | 5 | |
| | 15 | i) Are the AV inflow sizes equal? | Y | N | 5 | FLUENCY |
| | 16 | Is there likely to be a residual VSD? | Y | N | 5 | RESPECT |
| | 17 | Has an incision been made into the valve leaflets? | N | Y | 5 | RESPECT |
| 3 | | **Cleft Closure (left)** | | | | |
| | 18 | Has the cleft been closed? | Y | N | 5 | RESPECT |
| | 19 | Is there any residual cleft? | N | Y | 4 | RESPECT |
| | | Suture assessment: | | | | |
| | 20 | i) Are all sutures evenly spaced from one another? (2-3mm) | Y | N | 3 | FLUENCY |
| | 21 | ii) Are all sutures an adequate distance from the leaflet edge (1-2mm)? | Y | N | 3 | FLUENCY |
| 4 | | **Closure of Atrial primum defect** | | | | |
| | 22 | Is the ASD patch tailored to the shape of the ASD? | Y | N | 4 | KNOWLEDGE |
| | | Suture assessment: | | | | |
| | 23 | i) Has a continuous suture been used to close the defect? | Y | N | 2 | FLUENCY |
| | 24 | ii)Are all sutures evenly spaced from one another? (2-3mm) | Y | N | 3 | FLUENCY |
| | 25 | iii)Are all sutures an adequate distance from the ASD edge (1-2mm) | Y | N | 3 | FLUENCY |
| | 26 | Is the coronary sinus draining into the right atrium? | Y | N | 4 | FLUENCY |
| | 27 | Does the suture line avoid damage to the AV node? (inferior margin of primum defect at the region of coronary sinus) | Y | N | 5 | RESPECT |
| 5 | | **Right AV valve repair** | | | | |
| | | Suture assessment: | | | | |
| | 28 | i) Have the bridging leaflets been attached to the septum | Y | N | 4 | FLUENCY |
| | 29 | ii) Are all sutures evenly spaced from one another? (2-3mm) | Y | N | 3 | FLUENCY |
| | | | **TOTAL SCORE** | | **105** | |

## 12.3.2 Coarctation of aorta repair – Extended end-to-side anastomosis with patch

SickKids | Labatt Family Heart Centre

**HOST-CHS assessment tool - CoA repair: Extended End-to-Side anastomosis with patch (Median sternotomy model)**

| | | Steps | YES/ NO | | Weight of step (1-5) | Included in HOST-CHS Holistic Score |
|---|---|---|---|---|---|---|
| 1 | | Ligation and Transection of PDA | | | | |
| | 1 | Has the proximal and distal PDA been ligated? | Y | N | 4 | FLUENCY |
| | 2 | Have the clamps been placed before the PDA has been ligated? | Y | N | 4 | KNOWLEDGE |
| | 3 | Has the end of the PDA been oversewn? | Y | N | 2 | RESPECT |
| 2 | | Removal of ductal tissue: | | | | |
| | 4 | Has the aorta been ligated and transected at the level of the isthmus? | Y | N | 4 | KNOWLEDGE |
| | 5 | Has the cut isthmus end been oversewn? | Y | N | 2 | RESPECT |
| | 6 | Has the ductal tissue been completely removed? | Y | N | 4 | FLUENCY |
| | 7 | Are all incisions clean? (i.e. no jagged/sharp edges) | Y | N | 3 | RESPECT |
| 3 | | Incisions on Aortic arch and descending aorta: | | | | |
| | 8 | Has an anterolateral incision been made from the ascending aorta and along the lesser curvature of the aortic arch? | Y | N | 3 | FLUENCY |
| | 9 | i) Does this incision end ~5mm away from the tie at isthmus? | Y | N | 3 | KNOWLEDGE |
| | 10 | Has a 3-5mm cutback incision been made on the posterior wall of the descending aorta? **(Cutback 1)** | Y | N | 3 | FLUENCY |
| 4 | | Extended End-to-Side anastomosis (1) | | | | |
| | 11 | Has an end-to-side anastomosis been completed between the descending aorta and aortic arch? | Y | N | 3 | FLUENCY |
| | 12 | Has the suture started one stitch away from the heel of the anastomosis? | Y | N | 4 | KNOWLEDGE |
| | 13 | Has the suture continued along the posterior wall until the most distal neck vessel (LSCA)? | Y | N | 3 | FLUENCY |
| | 14 | Has other end of suture been used to complete heel of the anastomosis and continued until the anterior wall of descending aorta? | Y | N | 3 | FLUENCY |
| | 15 | Has a cutback incision been made along the anterior wall of the descending aorta (length 8-10mm)? **(Cutback 2)** | Y | N | 4 | FLUENCY |
| 5 | | Patch preparation | | | | |
| | 16 | Has the patch been trimmed to correspond to the shape of the defect? | Y | N | 3 | FLUENCY |
| | 17 | i) Has a small notch been cut in the patch that corresponds with the inferior edge of the anastomosis? | Y | N | 4 | KNOWLEDGE |
| 6 | | Extended End-to-Side anastomosis (2) – Patch anastomosis | | | | |
| | 18 | Has the anastomosis commenced at the cutback incision (Cutback 2) and continued to previous suture and tied? | Y | N | 2 | FLUENCY |
| | 19 | i) Has this been repeated with the other suture end? | Y | N | 2 | FLUENCY |
| | 20 | Has suture been continued along the posterior wall of the lesser curvature to the end of the incision at ascending aorta? | Y | N | 3 | FLUENCY |
| | 21 | Has a cutback incision (2-3mm) on the ascending aorta been made to widen the toe of the anastomosis? **(Cutback 3)** | Y | N | 4 | KNOWLEDGE |
| | 22 | i) Has suture continued around the toe of anastomosis? | Y | N | 3 | FLUENCY |
| | 23 | Has the anastomosis been completed along the anterior wall of the lesser curvature? | Y | N | 3 | FLUENCY |
| | | Suture assessment: | | | | |
| | 24 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of 1-2mm between suture bites? | Y | N | 3 | FLUENCY |
| | 25 | ii) Are **all** the sutures an adequate distance from the tissue edge (1-2mm)? | Y | N | 3 | FLUENCY |
| 7 | | Patch assessment | | | | |
| | 26 | Are there any visible holes within the patch? | N | Y | 5 | RESPECT |
| | 27 | Is the patch too large that it would likely compress local structures? | N | Y | 5 | RESPECT |
| | 28 | i) Have any plication sutures been needed to make the patch smaller? | N | Y | 4 | RESPECT |
| | 29 | Is the patch too small? (i.e. unlikely to bulge slightly if pressurized causing a gradient) | N | Y | 4 | RESPECT |
| | | | **TOTAL SCORE** | | **97** | |

## 12.3.3 Coarctation of aorta repair – Extended end-to-end anastomosis

**HOST-CHS assessment tool - CoA repair: Extended End-to-End anastomosis (Left thoracotomy)**

SickKids | Labatt Fam Heart Centr

| | | Steps | YES/ NO | | Weight of step (1-5) | Included in HOST-CHS Holistic Score |
|---|---|---|---|---|---|---|
| **1** | **Ligation of PDA** | | | | | |
| | 1 | Has the proximal PDA been ligated? | Y | N | 4 | FLUENCY |
| | 2 | Have the clamps been placed before dividing the PDA? | Y | N | 4 | KNOWLEDGE |
| **2** | **Application of clamps** | | | | | |
| | 3 | Has a clamp been placed across the LSCA and LCC and is excluding the first branch? **(Clamp 1)** | Y | N | 4 | KNOWLEDGE |
| | 4 | Has second clamp been placed across the descending aorta? **(Clamp 2)** | Y | N | 4 | KNOWLEDGE |
| **3** | **Removal of ductal tissue:** | | | | | |
| | 5 | **Incision 1**: Has the descending aorta been transected beyond the PDA? | Y | N | 4 | KNOWLEDGE |
| | 6 | **Incision 2:** Has the aortic arch been transected above the PDA? | Y | N | 4 | KNOWLEDGE |
| | 7 | **Incision 3:** Has the distal PDA been transected to remove all ductal tissue? | Y | N | 4 | KNOWLEDGE |
| | 8 | Has all residual ductal tissue been removed? | Y | N | 5 | |
| | 9 | Are all above incisions clean and straight? | Y | N | 3 | RESPECT |
| | 10 | Has the end of PDA been oversewn? (can be completed at the end of repair) | Y | N | 2 | RESPECT |
| **4** | **Incisions on Aortic arch and descending aorta:** | | | | | |
| | 11 | Has an incision been made along the lesser curvature? | Y | N | 3 | FLUENCY |
| | 12 | i) Has the delegate avoided making the incision posterior? | Y | N | 3 | KNOWLEDGE |
| | 13 | ii) Has incision continued until 1-2mm away from tips of the clamp on aortic arch? | Y | N | 4 | KNOWLEDGE |
| | 14 | Has a 3-5mm cutback incision been made on the posterior wall of the descending aorta? | Y | N | 3 | KNOWLEDGE |
| **5** | **Extended End-to-End anastomosis** | | | | | |
| | 15 | Has an end-to-end anastomosis commenced between the descending aorta and aortic arch? | Y | N | 3 | |
| | 16 | Is the suture started one stitch away from the toe on the anterior side of the aortic arch? | Y | N | 3 | KNOWLEDGE |
| | 17 | Is the suture continued counter-clockwise towards the toe and then along the posterior wall of arch for 4-5 sutures? | Y | N | 3 | FLUENCY |
| | 18 | Have 4-5 sutures been placed along the anterior and the two ends approximated? | Y | N | 3 | FLUENCY |
| | 19 | Has the posterior wall suture been completed? | Y | N | 4 | FLUENCY |
| | 20 | Has the anterior wall suture been completed? | Y | N | 4 | FLUENCY |
| | 21 | If required has the cutback incision on the descending aorta been extended to accommodate excess aortic arch tissue? (if not required circle 'YES') | Y | N | 3 | KNOWLEDGE |
| | | Suture assessment: | | | | |
| | 22 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of 1-2mm between suture bites? | Y | N | 3 | FLUENCY |
| | 23 | ii) Are **all** the sutures an adequate distance from the tissue edge (1-2mm)? | Y | N | 3 | FLUENCY |
| **6** | **Removal of clamps and de-airing** | | | | | |
| | 24 | Were the clamps removed before tying the suture? | Y | N | 5 | KNOWLEDGE |
| | 25 | Has the distal clamp been removed before the proximal clamp? | Y | N | 5 | KNOWLEDGE |
| | | | **TOTAL SCORE** | | **90** | |

## 12.3.4 Double outlet right ventricle with subaortic VSD repair

**HOST-CHS Assessment tool – DORV Sub-aortic VSD repair**

SickKids | Labatt Family Heart Centre

| | | Steps | YES/ NO | | Weight of step (1-5) | Included in HOST-CHS Holistic Score |
|---|---|---|---|---|---|---|
| **1** | | **Enlargement of VSD** | | | | |
| | 1 | Has the VSD been enlarged? | Y | N | 4 | KNOWLEDGE |
| | 2 | Has the enlargement avoided the area of conduction tissue? | Y | N | 5 | RESPECT |
| **2** | | **Preparation of VSD patch** | | | | |
| | 3 | Has a tube graft been used for the patch and cut to lay it open or alternative suitable patch? | Y | N | 3 | KNOWLEDGE |
| | 4 | Has the patch been trimmed to the approximate size of the VSD? | Y | N | 3 | KNOWLEDGE |
| | 5 | Has one of the patch corners been trimmed to correspond with the inferior margin of the VSD? | Y | N | 3 | KNOWLEDGE |
| **3** | | **Suturing VSD patch** | | | | |
| | 6 | Has the suture commenced at the inferior portion of the VSD away from the conduction tissue? | Y | N | 3 | FLUENCY |
| | 7 | Does the suture continue superiorly towards the aortic annulus? | Y | N | 3 | FLUENCY |
| | 8 | i) Is the patch trimmed obliquely when the aortic valve is reached? | Y | N | 4 | KNOWLEDGE |
| | 9 | Does the suture continue around the aortic valve towards the tricuspid valve annulus? | Y | N | 3 | FLUENCY |
| | 10 | i) When the tricuspid annulus is reached is the suture passed through the annulus into the right atrium? | Y | N | 3 | FLUENCY |
| | 11 | Has the other end of the suture been continued along the inferior margin of the VSD to the tricuspid valve annulus? | Y | N | 3 | FLUENCY |
| | 12 | i) Is the suture inferior to the conduction tissue avoiding injury? | Y | N | 5 | RESPECT |
| | 13 | Has the patch been trimmed along the inferior rim of VSD? (i.e. excess patch removed) | Y | N | 4 | FLUENCY |
| | 14 | When the tricuspid annulus is reached is the suture passed through the annulus into the right atrium? | Y | N | 3 | FLUENCY |
| | 15 | Has the suture been completed with horizontal mattress sutures? | Y | N | 2 | FLUENCY |
| | | Suture assessment: | | | | |
| | 16 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of 2-3mm between suture bites? | Y | N | 3 | FLUENCY |
| | 17 | ii) Are **all** the sutures an adequate distance from the tissue edge (2-3mm)? | Y | N | 3 | FLUENCY |
| **4** | | **Patch Assessment** | | | | |
| | 18 | Is the patch the correct size for the VSD defect? | Y | N | 5 | KNOWLEDGE |
| | 19 | Is there a bulge of the patch into the right ventricle? (thus likely to avoid any LVOTO post op) | Y | N | 5 | KNOWLEDGE |
| | 20 | Are there any visible hole within the patch? | N | Y | 4 | RESPECT |
| | 21 | Have any plication sutures been needed to make the patch smaller? | N | Y | 4 | FLUENCY |
| **5** | | **Collateral damage** | | | | |
| | 22 | Has the aortic valve or ascending aorta been damaged during the procedure? (i.e. torn) | N | Y | 5 | RESPECT |
| | 23 | Have the tricuspid valve leaflets been removed or have been damaged during the repair? | N | Y | 5 | RESPECT |
| | | | **TOTAL SCORE** | | **85** | |

## 12.3.5 Interrupted aortic arch (Type B) repair

**HOST-CHS assessment tool - Interrupted Aortic Arch (Type B) Repair**

SickKids | Labatt Family Heart Centre

| | | Steps | YES/ | NO | Weight of step (1-5) | Included in HOST-CHS Holistic Score |
|---|---|---|---|---|---|---|
| 1 | | **Ligation and Transection for PDA** | | | | |
| | 1 | Has the PDA been ligated distally, avoiding the LPA? | Y | N | 3 | FLUENCY |
| | 2 | Is the transection of the PDA clean (i.e. no jagged edges) | Y | N | 2 | RESPECT |
| 2 | | **Resection of ductal tissue** | | | | |
| | 3 | Has the residual ductal tissue been removed from the descending aorta? | Y | N | 4 | FLUENCY |
| | 4 | Has the incision been extended 4-6mm up the origin of the LSCA (if required)? | Y | N | 3 | KNOWLEDGE |
| 3 | | **Incision into the Ascending Aorta** | | | | |
| | 5 | Is the incision on the anterolateral aspect of the ascending aorta? (if incision is too posterior mark as 'no') | Y | N | 3 | KNOWLEDGE |
| | 6 | Is the incision between the STJ and the origin of the left common carotid artery? | Y | N | 4 | FLUENCY |
| 4 | | **Anastomosis between descending aorta and arch** | | | | |
| | 7 | Has anastomosis commenced 1 stitch away from the toe? | Y | N | 3 | KNOWLEDGE |
| | 8 | Does the suture on posterior wall of the anastomosis continue inferiorly until the anterior wall of cut descending aorta? (descending aorta orifice flattens) | Y | N | 3 | FLUENCY |
| | 9 | Has the other end of suture completed the toe and continued for 5-6 sutures to make patch shaping easier? | Y | N | 3 | FLUENCY |
| | | Suture assessment | | | | |
| | 10 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of 1-2mm between suture bites? | Y | N | 3 | FLUENCY |
| | 11 | ii) Are **all** the sutures an adequate distance from the tissue edge (1-2mm)? | Y | N | 3 | FLUENCY |
| | 12 | Has a 6-8mm cutback incision been made along the lateral wall of the descending aorta to widen it? | Y | N | 4 | KNOWLEDGE |
| 5 | | **Patch trimming and anastomosis:** | | | | |
| | 13 | Has the patch been shaped (with pen) and trimmed to accommodate the shape of the defect? | Y | N | 4 | |
| | 14 | Has the suture commenced 1-2 stitches away from the toe (of cutback incision on descending aorta) and continued around the toe and superiorly towards the previous suture and tied? | Y | N | 3 | FLUENCY |
| | 15 | Has the same been repeated for other end of suture (inferiorly)? – if sutures done in reverse order. Give this mark. | Y | N | 3 | FLUENCY |
| | 15 | Has the patch been trimmed to accommodate its lay with the ascending aorta? | Y | N | 4 | FLUENCY |
| | 16 | Has suture continued proximally to the origin of the incision? | Y | N | 3 | FLUENCY |
| | 17 | Has a small cutback incision been on the ascending aorta to widen the anastomosis at the heel? | Y | N | 4 | KNOWLEDGE |
| | 18 | Is the lay of the patch good? (i.e. no obvious twisting or kinking) | Y | N | 5 | RESPECT |
| | 19 | Has the anastomosis been completed? | Y | N | 5 | FLUENCY |
| | | Suture assessment | | | | |
| | 20 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of 1-2mm between suture bites? | Y | N | 3 | FLUENCY |
| | 21 | ii) Are **all** the sutures an adequate distance from the tissue edge (1-2mm)? | Y | N | 3 | FLUENCY |
| 6 | | **Patch Assessment** | | | | |
| | 22 | Is the patch the correct size for the defect? | Y | N | 5 | RESPECT |
| | 23 | Would this patch bulge once pressurised? | Y | N | 4 | RESPECT |
| | 24 | Are there any visible holes within the patch? | N | Y | 5 | RESPECT |
| | 25 | Have any plication sutures been needed to make the patch smaller? | N | Y | 4 | RESPECT |
| 7 | | **VSD closure** | | | | |
| | 26 | Has the VSD patch been trimmed to the size of the defect? | Y | N | 3 | KNOWLEDGE |
| | 27 | Has the anastomosis commenced away from the conduction tissue and continued around to the tricuspid annulus and out into the RA? | Y | N | 4 | FLUENCY |
| | 28 | Has the other end of the suture completed the inferior margin of the VSD avoiding conduction tissue and out into the RA? | Y | N | 5 | FLUENCY |
| | 29 | VSD closure completed with horizontal mattress or interrupted sutures? | Y | N | 3 | FLUENCY |
| | 30 | Are the chordae tendinae and tricuspid valve leaflets preserved? | Y | N | 5 | RESPECT |
| | | | TOTAL SCORE | | 113 | |

## 12.3.6 Norwood operation with RV-PA conduit

**HOST-CHS assessment tool – Norwood operation (HLHS) – RV-PA conduit**

SickKids | Labatt Family Heart Centre

| | | Steps | YES/ NO | | Weight of step (1-5) | Included in HOST-CHS Holistic Score |
|---|---|---|---|---|---|---|
| 1 | | **Control of the Patent Ductus Arteriosus (PDA)** | | | | |
| | 1 | Has the PDA been ligated? | Y | N | 2 | KNOWLEDGE |
| | 2 | Is the tie 2-3mm above the origin of the left pulmonary artery (LPA) [avoiding potential LPA stenosis]? | Y | N | 3 | RESPECT |
| 2 | | **Atrial Septectomy** | | | | |
| | 3 | Has the atrial septum been resected? | Y | N | 2 | KNOWLEDGE |
| | 4 | Has the delegate enlarged the ASD posteriorly [avoiding potential heart block]? | Y | N | 3 | RESPECT |
| 3 | | **Isolation of the confluent branch pulmonary arteries** | | | | |
| | | Is the cut on the main pulmonary artery (MPA): | | | | |
| | 5 | i) At the midpoint between the sinotubular junction (STJ) and base of the right pulmonary artery? | Y | N | 4 | RESPECT |
| | 6 | ii) Clean? (i.e. not jagged or having sharp protruding points) | Y | N | 3 | RESPECT |
| | 7 | iii)Avoids damaging the pulmonary artery orifices +/-pulmonary valve? | Y | N | 5 | KNOWLEDGE |
| 4 | | **Resection of Ductal tissue** | | | | |
| | 8 | Has the PDA been transected? | Y | N | 2 | FLUENCY |
| | 9 | Has all the ductal tissue been removed? | Y | N | 4 | KNOWLEDGE |
| | 10 | **If the interdigitating technique used:** Has the aortic arch been divided at the isthmus AND has the descending aorta been divided 1-2mm below the level of the ductal tissue?<br>- **Score 'Y' if alternative technique used** | Y | N | 3 | KNOWLEDGE |
| | 11 | Are both cuts clean? (i.e. not jagged or having sharp protruding points) | Y | N | 3 | RESPECT |
| 5 | | **Preparation for augmentation of the ascending aorta and aortic arch** | | | | |
| | 12 | Has the delegate cut along the lesser curvature of the aortic arch until 2-3mm above the STJ? | Y | N | 4 | KNOWLEDGE |
| | 13 | Has the incision been extended to either of the coronary orifices? (i.e. compromising coronaries) | N | Y | 5 | RESPECT |
| | | **IF INTERDIGITATING TECHNIQUE USED: CONTINUE TO SECTION 6**<br>**IF ALTERNATIVE TECHNIQUE USED: SKIP TO SECTION 9** | | | | |
| 6 | | **Cutback incision into Pulmonary Root (Cutback 1) for DKS anastomosis** | | | | |
| | 14 | **Cutback 1** - Has the pulmonary root been cut parallel to the incision made in the ascending aorta? | Y | N | 4 | KNOWLEDGE |
| | 15 | Is the cut 2-4mm in length? | Y | N | 3 | RESPECT |
| 7 | | **Ascending aorta and Pulmonary root anastomosis (DKS)** | | | | |
| | 16 | Has the anastomosis begun at the bottom/apex of the incision? | Y | N | 3 | FLUENCY |
| | | Suture assessment: | | | | |
| | 17 | i) Are **all** sutures evenly spaced from one another **with** a gap of 1-2mm between suture bites? | Y | N | 3 | FLUENCY |
| | 18 | ii) Are **all** sutures an adequate distance from the tissue edge (1-2mm)? | Y | N | 3 | FLUENCY |
| 8 | | **Interdigitating anastomosis** | | | | |
| | 19 | **Cutback 2** - Has a cutback incision been made into the posterior wall of the descending aorta **and** is a length of 3-4mm? | Y | N | 4 | KNOWLEDGE |
| | 20 | Has an anastomosis been completed between the posterior wall of the descending aorta and the distal aortic arch? | Y | N | 3 | FLUENCY |
| | 21 | **Cutback 3** - Has a cutback incision been made into the anterolateral wall of the descending aorta? (i.e. not completely opposite Cutback 2) | Y | N | 4 | KNOWLEDGE |
| 9 | | **Arch Reconstruction** | | | | |
| | 22 | Has the patch anastomosis commenced at the toe/apex of the anterior descending aorta? | Y | N | 4 | FLUENCY |

| | | | | | | |
|---|---|---|---|---|---|---|
| | 23 | Are both suture ends continued until the interdigitating sutures and tied?<br>**- Score 'Y' if alternative technique used** | Y | N | 3 | FLUENCY |
| | | **Posterior edge suture of aortic arch (Inner curve):** | | | | |
| | 24 | i) Has excess patch, which corresponds to the posterior edge (inner curve), been trimmed to the curvature of the aortic arch and the ascending aorta if required? (i.e. to avoid kinking/potential compression of LPA)<br>**- Score 'Y' if trimming not required – Score 'N' if patch too small** | Y | N | 5 | KNOWLEDGE |
| | 25 | ii) Has the suture continued along the aortic arch and down the ascending aorta to either the DKS or aortic root? | Y | N | 2 | FLUENCY |
| | 26 | iii) **If the interdigitating technique:** Has the suture been continued along the lateral wall of the DKS (before the anterior edge suture is commenced)?<br>**If alternative technique used score 'Y'** | Y | N | 3 | FLUENCY |
| | | **Anterior edge suture of aortic arch (Outer curve):** | | | | |
| | 27 | i) Has excess patch, which corresponds to the anterior edge (outer curve), been trimmed to the curvature of the aortic arch and the ascending aorta if required? (i.e. to avoid kinking/potential compression)<br>**– Score 'Yes' if trimming not required – Score 'N' if patch too small** | Y | N | 5 | KNOWLEDGE |
| | 28 | ii) Has the suture continued along the aortic arch and ascending aorta? | Y | N | 2 | FLUENCY |
| | 29 | **If the interdigitating technique used:** Has the excess patch been trimmed to accommodate the DKS?<br>**If the alternative technique used:** Has the excess patch been trimmed to accommodate the ascending aorta? | Y | N | 4 | KNOWLEDGE |
| | 30 | **If the interdigitating technique used:** Has the suture along the anterior wall of the DKS been completed?<br>**If the alternative technique used:** Has the patch anastomosis been completed? | Y | N | 3 | FLUENCY |
| | | Suture assessment | | | | |
| | 31 | i) Are **all** sutures evenly spaced from one another **with** a gap of 2-3mm between suture bites? | Y | N | 3 | FLUENCY |
| | 32 | ii) Are **all** sutures an adequate distance from the tissue edge (2-3mm)? | Y | N | 3 | FLUENCY |
| | | **IF ALTERNATIVE TECHNIQUE USED:CONTINUE TO SECTION 10**<br>**IF INTERDIGITATING TECHNIQUE USED: SKIP TO SECTION 11** | | | | |
| **10** | 33 | Before the anterior edge suture line of the ascending aorta was completed was an incision made into the patch for the MPA anastomosis? | Y | N | 4 | KNOWLEDGE |
| | 34 | i) Is the proximal end of the incision at the same level of the cut MPA? | Y | N | 3 | KNOWLEDGE |
| | 35 | ii) Does the distal part of the incision end half way between the left common carotid and left subclavian artery? | Y | N | 3 | KNOWLEDGE |
| | | Pulmonary root to reconstructed aorta anastomosis | | | | |
| | 36 | i) Has the suture commenced along the posterior wall of the pulmonary root? | Y | N | 3 | FLUENCY |
| | 37 | ii)Has the anastomosis been completed? (i.e. completion of posterior and anterior walls) | Y | N | 3 | FLUENCY |
| | 38 | iii) Is the anastomosis kinked, twisted or stretched? | Y | N | 5 | RESPECT |
| | | Suture assessment: | | | | |
| | 39 | i) Are **all** sutures evenly spaced from one another **with** a gap of 2-3mm between suture bites? | Y | N | 3 | FLUENCY |
| | 40 | ii) Are **all** sutures an adequate distance from the tissue edge (2-3mm)? | Y | N | 3 | FLUENCY |
| | | **SCORE THIS SECTION FOR BOTH TECHNIQUES TO COMPLETE ASSESSMENT** | | | | |
| **11** | **Patch assessment:** | | | | | |
| | 41 | Are there any visible holes within the patch? | N | Y | 4 | RESPECT |
| | 42 | Is the patch kinked at any point? | N | Y | 5 | RESPECT |
| | 43 | Is there any kinking of the ascending aorta that would compromise coronary flow? | N | Y | 5 | RESPECT |
| | 44 | Have any plication sutures been required to make the patch narrower or additional patch material used to fill a gap in the patch? | N | Y | 4 | RESPECT |
| | 45 | Is the arch reconstruction complete? | Y | N | 3 | FLUENCY |

| | | SCORE THIS SECTION IF RV-PA CONDUIT PERFORMED | | | | |
|---|---|---|---|---|---|---|
| 1 | **Establishment of pulmonary circulation** | | | | | |
| 2 | 46 | Has the opening in the distal part of the MPA been closed? (i.e. with a patch) | Y | N | 3 | FLUENCY |
| | 47 | Has a small ventricular incision/ punch been made just inferior to the pulmonary annulus? | Y | N | 4 | RESPECT |
| | 48 | i) Is the hole cut cleanly and the appropriate size for the conduit (i.e. 5-8mm)? | Y | N | 4 | KNOWLEDGE |
| | 49 | Has the delegate anastomosed the proximal conduit to the RV and the distal conduit to the PA? | Y | N | 3 | FLUENCY |
| | | Suture Assessment: | | | | |
| | 50 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of 2-3mm between suture bites? | Y | N | 3 | FLUENCY |
| | 51 | ii) Are **all** the sutures an adequate distance from the tissue edge (2-3mm)? | Y | N | 3 | FLUENCY |
| | 52 | Is the conduit pushed too far and protruding into the ventricular chamber? | N | Y | 4 | RESPECT |
| | 53 | Is the conduit the appropriate length (i.e. not too short that would stretch +/- compress neo-aorta/coronaries or too long that would be liable to kinking) ? | Y | N | 5 | KNOWLEDGE |
| | | **TOTAL SCORE** | | | **157** | |

## 12.3.7 Supravalvular aortic stenosis repair (Y technique)

**HOST-CHS assessment tool - Supravalvular Aortic Stenosis Repair ('Y' patch technique)**

| | | Steps | YES/ NO | | Weight of step (1-5) | Included in HOST-CHS Holistic Score |
|---|---|---|---|---|---|---|
| **1** | | **Incision into the Ascending Aorta (Y-shaped)** | | | | |
| | 1 | Has the incision been started high on the ascending aorta (>10mm above sinotubular junction)? | Y | N | 4 | KNOWLEDGE |
| | 2 | Has this incision been extended proximally down into the middle of the non-coronary sinus? | Y | N | 5 | FLUENCY |
| | 3 | Has the 'Y' incision been completed with an incision into the right coronary sinus? | Y | N | 5 | FLUENCY |
| | 4 | i) Is this incision a safe distance away from the right coronary ostia (2-3mm)? | Y | N | 5 | RESPECT |
| | 5 | Are all incision clean (i.e no jagged edges) | Y | N | 3 | RESPECT |
| | 6 | Has the right coronary artery of aortic valve been damaged during the incisions? | N | Y | 5 | RESPECT |
| **2** | | **Patch trimming and anastomosis:** | | | | |
| | 7 | Has the patch been shaped in a Y shape (with pen) and trimmed to accommodate the shape of the defect? | Y | N | 2 | KNOWLEDGE |
| | 8 | Has the suture commenced at the apex of the commissure? | Y | N | 3 | FLUENCY |
| | 9 | Does the suture continue down into the non-coronary sinus? | Y | N | 3 | FLUENCY |
| | 10 | Has the other end of the suture continued into the right coronary sinus? | Y | N | 3 | FLUENCY |
| | 11 | Have any of the sutures compromised the right coronary ostium (i.e. sutures placed <1mm away from or within ostium) | N | Y | 5 | RESPECT |
| | 12 | Has the patch been trimmed if necessary to ensure correct geometry of a pressurized aorta? | Y | N | 4 | FLUENCY |
| | 13 | Is the anastomosis of the patch complete? | Y | N | 3 | FLUENCY |
| | | Suture assessment | | | | |
| | 14 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of 1-2mm between suture bites? | Y | N | 3 | FLUENCY |
| | 15 | ii)Are **all** the sutures an adequate distance from the tissue edge (1-2mm)? | Y | N | 3 | FLUENCY |
| **3** | | **Patch Assessment** | | | | |
| | 16 | Is the patch the correct size for the defect? | Y | N | 5 | RESPECT |
| | 17 | Would this patch bulge once pressurised without compressing adjacent structures? | Y | N | 5 | RESPECT |
| | 18 | Has the aorta been reconstructed to its normal dimension? | Y | N | 4 | RESPECT |
| | 19 | Are there any visible holes within the patch? | N | Y | 5 | RESPECT |
| | 20 | Have any plication sutures been needed to make the patch smaller? | N | Y | 4 | RESPECT |
| | | | **TOTAL SCORE** | | **79** | |

## 12.3.8 Supravalvular aortic stenosis repair (H technique)

SickKids | Labatt Family Heart Centre

**HOST-CHS assessment tool – Supravalvular Aortic Stenosis Repair ('H' patch technique)**

| | | Steps | YES/ NO | | Weight of step (1-5) | Included in HOST-CHS Holistic Score |
|---|---|---|---|---|---|---|
| **1** | | **Incisions into the Ascending Aorta** | | | | |
| | 1 | Has the H incision been marked on the model with a pen? | Y | N | 2 | KNOWLEDGE |
| | 2 | Has the first horizontal incision been made on the anterior ascending aorta and approximately 10mm above the sinotubular junction? | Y | N | 4 | KNOWLEDGE |
| | 3 | i) Is this incision clean (i.e. no jagged edges and perpendicular to the ascending aorta? | Y | N | 3 | RESPECT |
| | 4 | ii) Is the length of the incision between 10-15mm? | Y | N | 3 | KNOWLEDGE |
| | 5 | Has the locations of the approximation sutures been marked on the aorta with a pen (4 locations need to be made)? | Y | N | 3 | KNOWLEDGE |
| | 6 | Has the first vertical incision been made extending proximally down into the middle of the non-coronary sinus? | Y | N | 5 | KNOWLEDGE |
| | 7 | i) Has this incision been extended distally on the ascending aorta? | Y | N | 4 | FLUENCY |
| | 8 | Has the second vertical incision been made extending proximally into the right coronary sinus between the RCA and the aortic valve commissure? | Y | N | 5 | KNOWLEDGE |
| | 9 | i) Is this incision a safe distance away from the right coronary ostia (2-3mm)? | Y | N | 5 | RESPECT |
| | 10 | ii) Has the incision been extended distally on the ascending aorta? | Y | N | 4 | FLUENCY |
| | 11 | Has the right coronary artery or aortic valve been damaged during the incisions? | N | Y | 5 | RESPECT |
| **2** | | **Patch trimming and anastomosis: (Patch 1)** | | | | |
| | 12 | Has the patch been shaped in an oval shape (with pen) and trimmed to accommodate the shape of the defect? | Y | N | 2 | KNOWLEDGE |
| | 13 | Has the suture commenced within the non-coronary sinus and continued around the sinus and along the Asc Ao? | Y | N | 3 | FLUENCY |
| | 14 | Has an approximation suture been placed on the anterior wall of the ascending aorta to approximate the cut ends (i.e. at location of approximation suture marks) | Y | N | 3 | KNOWLEDGE |
| | 15 | Has the patch been trimmed if necessary to ensure correct geometry of a pressurized aorta? | Y | N | 4 | KNOWLEDGE |
| | 16 | Has the anastomosis of this patch been completed? | Y | N | 4 | FLUENCY |
| **3** | | **Patch trimming and anastomosis: (Patch 2)** | | | | |
| | 17 | Has the patch been shaped in an oval shape (with pen) and trimmed to accommodate the shape of the defect? | Y | N | 2 | KNOWLEDGE |
| | 18 | Has the suture commenced within the right coronary sinus and continued around the sinus and along the Asc Ao? | Y | N | 3 | FLUENCY |
| | 19 | Has an approximation suture been placed on the anterior wall of the ascending aorta to approximate the cut ends (i.e. at location of approximation suture marks) | Y | N | 3 | KNOWLEDGE |
| | 20 | Have any of the sutures compromised the right coronary ostium (i.e.sutures placed <1mm away from or within ostium) | N | Y | 5 | RESPECT |
| | 21 | Has the patch been trimmed if necessary to ensure correct geometry of a pressurized aorta? | Y | N | 4 | KNOWLEDGE |
| | 22 | Has the anastomosis of this patch been completed? | Y | N | 4 | FLUENCY |
| | 23 | Has the horizontal incision been sutured to completion? | Y | N | 3 | FLUENCY |
| | | Suture assessment: | | | | |
| | 23 | i)Are **all** the sutures evenly spaced from one another **WITH** a gap of 1-2mm between suture bites? | Y | N | 3 | FLUENCY |
| | 24 | ii) Are **all** the sutures an adequate distance from the tissue edge (1-2mm)? | Y | N | 3 | FLUENCY |
| **4** | | **Patch Assessment** | | | | |
| | 25 | Are the patches the correct size for the defect? | Y | N | 5 | RESPECT |
| | 26 | Would this patch bulge once pressurised without compressing adjacent structures? | Y | N | 5 | RESPECT |
| | 27 | Are there any visible holes within the patch? | N | Y | 5 | RESPECT |
| | 28 | Have any plication sutures been needed to make the patch smaller? | N | Y | 4 | RESPECT |
| | | | **TOTAL SCORE** | | **108** | |

## 12.3.9 Single-stage Taussig-Bing repair

**HOST-CHS assessment tool - Taussig Bing Repair**

SickKids | Labatt Family Heart Centre

| | | Steps | YES/ NO | | Weight of step (1-5) | Included in HOST-CHS Holistic Score |
|---|---|---|---|---|---|---|
| **1** | | **VSD Closure (Perimembraneous)** | | | | |
| | 1 | Has the VSD been closed via either a transatrial or right venticulotomy approach? | Y | N | 4 | KNOWLEDGE |
| | | If ventriculotomy approach used: (if transatrial approach used score 'Y' for i + ii) | | | | |
| | 2 | i) Is the incision initially made a safe distance away from the aortic valve annulus (10-12mm) and then extended towards the annulus? | Y | N | 4 | RESPECT |
| | 3 | ii) Is the incision clean? (i.e no jagged edges) | Y | N | 2 | RESPECT |
| | 4 | Has the VSD patch been trimmed slightly larger than the size of the defect? | Y | N | 3 | KNOWLEDGE |
| | 5 | Has the anastomosis commenced a safe distance from the conduction tissue on the ventricular septal crest? | Y | N | 5 | RESPECT |
| | 6 | i) Does the suture continue along the lateral wall until the infundibular ridge? | Y | N | 3 | FLUENCY |
| | 7 | ii) Is the other suture end taken away from the VSD edge to avoid the conduction tissue? | Y | N | 4 | KNOWLEDGE |
| | 8 | iii) Does this suture continue to the TV annulus? | Y | N | 3 | FLUENCY |
| | 9 | iv) Are mattress sutures used to close the VSD along the TV annulus? | Y | N | 2 | FLUENCY |
| | 10 | Are there any visible holes within the VSD patch? | N | Y | 4 | RESPECT |
| | 11 | Would the VSD patch bulge if pressurised? | Y | N | 4 | KNOWLEDGE |
| | 12 | Has the tricuspid valve been damaged during repair? | N | Y | 5 | RESPECT |
| | | Suture assessment: | | | | |
| | 13 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of 1-2mm between suture bites? | Y | N | 3 | FLUENCY |
| | 14 | ii) Are **all** the sutures an adequate distance from the tissue edge (1-2mm)? (Except in region of conduction tissue) | Y | N | 3 | FLUENCY |
| **2** | | **Transection of aorta** | | | | |
| | | Is the cut in the aorta | | | | |
| | 15 | i) Perpendicular to the vessel? | Y | N | 3 | RESPECT |
| | 16 | ii) Clean? (i.e. no jagged edges) | Y | N | 2 | RESPECT |
| | 17 | Is there enough distance on the proximal aorta (5-10mm) for good sized coronary buttons? | Y | N | 4 | KNOWLEDGE |
| | 18 | Is there enough distal length on the aorta for reconstruction of the neo-aorta? | Y | N | 3 | KNOWLEDGE |
| **3** | | **Excision of coronary artery buttons** | | | | |
| | 19 | Have the coronary buttons been excised with a liberal amount of aortic sinus wall with the coronary artery? | Y | N | 4 | RESPECT |
| | 20 | Is the coronary button rectangular shaped? | Y | N | 3 | KNOWLEDGE |
| | 21 | Is the coronary orifice in the centre of the button? | Y | N | 4 | KNOWLEDGE |
| | 22 | Is there enough aortic wall left for pulmonary artery reconstruction? (i.e. oblique cut towards anterior commissure) | Y | N | 4 | KNOWLEDGE |
| | 23 | Have one or more commissures been marked with a pen or stitch? | Y | N | 3 | KNOWLEDGE |
| **4** | | **Reconstruction of Neo-pulmonary trunk (can be also completed later in operation)** | | | | |
| | 24 | Is the height of patch level with the native tissue left following transection/ coronary button excision? | Y | N | 4 | FLUENCY |
| | 25 | Is diameter of patch slightly larger than the native lumen size? | Y | N | 3 | KNOWLEDGE |
| | 26 | Has an end-to-end anastomosis been performed between the neo-pulmonary trunk and the distal pulmonary artery? | Y | N | 3 | |
| | 27 | Was the anastomosis commenced posteriorly? | Y | N | 2 | |
| | | Suture/Anastomosis assessment: | | | | |
| | 28 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of **2-3mm** between suture bites? | Y | N | 3 | FLUENCY |
| | 29 | ii) Are **all** the sutures an adequate distance from the tissue edge (2-3mm)? | Y | N | 3 | FLUENCY |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **5** | **Reconstruction of Aortic Arch** | | | | | | |
| | 30 | Has an incision been made along the lesser curvature of the aortic arch? | Y | N | | 3 | |
| | 31 | i) Does the incision extend beyond the coarctation segment? | Y | N | | 4 | KNOWLEDGE |
| | 32 | Has an appropriate sized patch been made? (i.e. elongated oval shape) | Y | N | | 3 | KNOWLEDGE |
| | 33 | Has the patch anastomosis commenced at the apex of the incision? | Y | N | | 2 | FLUENCY |
| | 34 | i) Have both ends of the suture been continued proximally to transected end of the aorta? | Y | N | | 3 | FLUENCY |
| | 35 | Has the patched been trimmed to accommodate with size mismatch with the neo-aortic root? | Y | N | | 4 | FLUENCY |
| | 36 | Are there any visible holes or kinks within the reconstructed patch? | N | Y | | 5 | RESPECT |
| | | Suture/Anastomosis assessment: | | | | | |
| | 37 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of **2-3mm** between suture bites? | Y | N | | 3 | FLUENCY |
| | 38 | ii) Are **all** the sutures an adequate distance from the tissue edge (2-3mm)? | Y | N | | 3 | FLUENCY |
| **6** | **Reconstruction of neo-aorta** | | | | | | |
| | 39 | Has the length of the ascending aorta been adjusted in a new position if required? (i.e. trimmed) | Y | N | | 4 | KNOWLEDGE |
| | 40 | Has an end-to-end anastomosis been performed between the proximal neo-aorta and ascending aorta? | Y | N | | 3 | |
| | 41 | Was the anastomosis commenced posteriorly? | Y | N | | 3 | FLUENCY |
| | | Suture/Anastomosis assessment: | | | | | |
| | 42 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of **2-3mm** between suture bites? | Y | N | | 3 | FLUENCY |
| | 43 | ii) Are **all** the sutures an adequate distance from the tissue edge (2-3mm)? | Y | N | | 3 | FLUENCY |
| **7** | **Implantation of coronary artery buttons to neo-aorta** | | | | | | |
| | | Are the coronary button incisions | | | | | |
| | 44 | i) In the correct position for the technique of choice? (i.e. medially-based trap door for closed technique vs trap-door/rectangular for open technique) | Y | N | | 5 | KNOWLEDGE |
| | 45 | ii) Adequate sized incision for technique of choice? (i.e. Closed technique: incision is slightly smaller than button [4-6mm] and edges of trap door are cut at right angles) | Y | N | | 5 | RESPECT |
| | | Are both coronary arteries: | | | | | |
| | 46 | i) In the 'best lie' position? (i.e. lateral + superior avoiding compression from PA, not stretching) | Y | N | | 5 | FLUENCY |
| | 47 | ii) Kinked or twisted? | N | Y | | 5 | RESPECT |
| | | iii) Suture/Anastomosis assessment: | | | | | |
| | 48 | a) Are **all** the sutures evenly spaced from one another **WITH** a gap of **1-2mm** between suture bites? | Y | N | | 3 | FLUENCY |
| | 49 | b) Are **all** sutures an adequate distance from the tissue edge (1-2mm) **AND** is a safe distance from the neo-aortic valve and coronary ostium? | Y | N | | 3 | FLUENCY |
| | 50 | iv) Have both coronary button been trimmed appropriately? (i.e. leaving more tissue medially than laterally in the trap door technique/ not too much tissue left over effecting lay/anastomosis) | Y | N | | 3 | |
| | 51 | v) Are both coronaries still in tact by the end of anastomosis (i.e. not avulsed)? | Y | N | | 5 | RESPECT |
| | | | **TOTAL SCORE** | | | **177** | |

## 12.3.10 Tetralogy of Fallot repair with transannular patch

**HOST-CHS Assessment tool – Transatrial repair of Tetralogy of Fallot with Transannular patch**

SickKids | Labatt Family Heart Centre

| | | Steps | YES/ NO | | Weight of step (1-5) | Included in HOST-CHS Holistic Score |
|---|---|---|---|---|---|---|
| 1 | | **Pulmonary valve and artery management** | | | | |
| | 1 | Have placement sutures been placed on the MPA and at the pulmonary annulus for exposure? | Y | N | 2 | KNOWLEDGE |
| | 2 | Has an incision been made in the main pulmonary artery? (Pulmonary arteriotomy) | Y | N | 3 | |
| | 3 | i) Is the incision made a safe distance (~2-4mm) above the sinotubular junction? (i.e. avoiding damage to pulmonary valve) | Y | N | 5 | RESPECT |
| | 4 | ii) Is the incision extended distally into one or both branch pulmonary arteries? | Y | N | 4 | FLUENCY |
| | 5 | iii) Is the incision extended proximally into the pulmonary sinuses and across the pulmonary annulus? | Y | N | 4 | FLUENCY |
| | 6 | Does the incision continue into the right ventricular outflow tract? | Y | N | 3 | FLUENCY |
| | 7 | i) Is this incision aligned with the RVOT? | Y | N | 4 | KNOWLEDGE |
| | 8 | ii) Are all incisions clean? (i.e. not jagged or having sharp protruding points) | Y | N | 3 | RESPECT |
| 2 | | **Relief of right ventricular outflow tract obstruction** | | | | |
| | 9 | Have the hypertrophic muscle bundles and fibroelastic tissue in the RVOT been resected? | Y | N | 4 | KNOWLEDGE |
| | 10 | Has the candidate resected more through the incision in pulmonary trunk? | Y | N | 2 | KNOWLEDGE |
| | 11 | Has the tricuspid valve or the pulmonary valve been damaged? | N | Y | 5 | RESPECT |
| 3 | | **Transatrial closure of ventricular septal defect** | | | | |
| | 12 | Is the patch a generous size that it would accommodate the overriding aorta? (compare with example in training video) | Y | N | 4 | KNOWLEDGE |
| | 13 | Has the suture been commenced at deepest part of the VSD along the interventricular crest? | Y | N | 3 | FLUENCY |
| | 14 | i) Does the suture end continue up towards the aorta and around to the tricuspid annulus? | Y | N | 3 | FLUENCY |
| | 15 | Is the other end continued towards the tricuspid annulus? | Y | N | 3 | FLUENCY |
| | 16 | i) Are the sutures placed away from the conduction tissue (to the right) avoiding damage? | Y | N | 5 | RESPECT |
| | 17 | Have mattress sutures been placed from the right atrium to suture the remaining patch? | Y | N | 3 | |
| | 18 | Has the tricuspid valve or conduction been compromised or damaged? | N | Y | 5 | RESPECT |
| | 19 | Have any of the sutures been caught in the tricuspid valve chords? | N | Y | 5 | RESPECT |
| | | Suture assessment: | | | | |
| | 20 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of 2-3mm between suture bites? | Y | N | 3 | FLUENCY |
| | 21 | ii) Are **all** the sutures an adequate distance from the tissue edge (2-3mm)? (except at the conduction) | Y | N | 3 | FLUENCY |
| | | Patch assessment | | | | |
| | 22 | i) Are there any visible holes within the patch? | N | Y | 4 | RESPECT |
| | 23 | ii) Does the patch appear the correct size for size of the defect? (i.e. not too large or small? | Y | N | 4 | KNOWLEDGE |
| 4 | | **Augmentation of pulmonary trunk with transannular patch** | | | | |
| | 24 | Has the patch been shaped as an oval shape to accommodate the defect? | Y | N | 4 | KNOWLEDGE |
| | 25 | Is the suture commenced at the distal MPA/LPA and continued around the toe and proximally along the incision? | Y | N | 4 | FLUENCY |
| | 26 | Has the patch been measured and trimmed to accommodate the length of the defect before the suture is completed? | Y | N | 4 | KNOWLEDGE |
| | 27 | Has the other suture end been continued to complete the anastomosis? | Y | N | 3 | FLUENCY |
| | | Suture assessment: | | | | |
| | 28 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of 2-3mm between suture bites? | Y | N | 3 | FLUENCY |
| | 29 | ii) Are **all** the sutures an adequate distance from the tissue edge (2-3mm)? (except at the conduction) | Y | N | 3 | FLUENCY |
| 5 | | **Transannular patch assessment** | | | | |
| | 30 | Is the patch the correct shape for the defect? (i.e. likely to bulge if pressurised) | Y | N | 5 | KNOWLEDGE |
| | 31 | Are there any visible holes on the patch? | N | Y | 4 | RESPECT |
| | 32 | Have any plication sutures been used to narrow the patch? | N | Y | 4 | FLUENCY |
| | | | TOTAL SCORE | | 118 | |

## 12.3.11 Truncus arteriosus (Type 2) repair

**HOST-CHS assessment tool – Truncus Arteriosus (Type 2), Muscular Outlet VSD**

SickKids | Labatt Family Heart Centre

| | | Steps | YES/ NO | | Weight of step (1-5) | Included in HOST-CHS Holistic Score |
|---|---|---|---|---|---|---|
| **1** | | **Isolation of Pulmonary arteries from the truncal root** | | | | |
| | 1 | Has a transverse incision been made along the anterior wall of the trunk? | Y | N | 3 | FLUENCY |
| | 2 | i) Is this incision a safe distance away from the coronary ostia? (i.e.~10mm superior to the sinotubular junction) | Y | N | 5 | RESPECT |
| | 3 | ii) Is this incision clean (i.e. no jagged edges and perpendicular to the ascending aorta? | Y | N | 3 | RESPECT |
| | 4 | iii) Has the trunk been completely transected? | N | Y | 2 | RESPECT |
| | 5 | Has this incision been extended on one side to create the PA button? | Y | N | 4 | KNOWLEDGE |
| | 6 | i) Is the button a good size? (i.e. 5-7mm of cuff tissue around the PA ostia) | Y | N | 4 | RESPECT |
| | 7 | ii) Have the branch PAs been damaged? | N | Y | 5 | RESPECT |
| **2** | | **Patch reconstruction of truncal root** | | | | |
| | 8 | Has the patch been shaped in an oval shape and trimmed to accommodate the shape of the defect? | Y | N | 3 | KNOWLEDGE |
| | 9 | Has the suture commenced at the apex of the incision and continued along the proximal end of cut trunk? | Y | N | 3 | FLUENCY |
| | 10 | Has other end been sutured to complete the anastomosis of the patch? | Y | N | 3 | FLUENCY |
| | 11 | Was the patch trimmed (if necessary) to ensure correct geometry of a pressurised aorta? (i.e. would slightly bulge) | Y | N | 4 | KNOWLEDGE |
| | 12 | i) Are there any visible holes within the patch? | N | Y | 4 | RESPECT |
| | 13 | Has another suture been used to directly close the anterior wall of the trunk and tied to the patch suture? | Y | N | 3 | FLUENCY |
| | | Suture assessment | | | | |
| | 14 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of 1-2mm between suture bites? | Y | N | 3 | FLUENCY |
| | 15 | ii) Are **all** the sutures an adequate distance from the tissue edge (1-2mm)? | Y | N | 3 | FLUENCY |
| **3** | | **Right Ventriculotomy** | | | | |
| | 16 | Has the incision commenced away from the truncal valve on the right ventricle and continued superiorly? | Y | N | 5 | KNOWLEDGE |
| | 17 | i) Is the incision the correct length? (~15-20mm) | Y | N | 4 | RESPECT |
| | 18 | ii) Has it stopped a safe distance away from the truncal valve? (~5mm) | Y | N | 4 | RESPECT |
| | 19 | iii) Is this incision clean (i.e. no jagged edges and perpendicular to the ascending aorta? | Y | N | 3 | RESPECT |
| **4** | | **VSD Closure** | | | | |
| | 20 | Has the VSD patch been trimmed to the size of the defect? | Y | N | 3 | KNOWLEDGE |
| | 21 | Has the anastomosis commenced from the ventricular septal crest along the inferior margin of the VSD towards the truncal valve? | Y | N | 3 | FLUENCY |
| | 22 | Has the superior margin of the VSD been closed and towards the truncal valve? | Y | N | 3 | FLUENCY |
| | 23 | Has the VSD closure been completed along the truncal valve? | Y | N | 3 | FLUENCY |
| | 24 | i) Have any of the sutures gone beyond the truncal annulus (i.e. caught the truncal valve leaflets) | N | Y | 5 | RESPECT |
| | 25 | ii) Are there any visible hole or tears within the VSD patch? | N | Y | 4 | RESPECT |
| | | Suture assessment | | | | |
| | 26 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of 1-2mm between suture bites? | Y | N | 3 | FLUENCY |
| | 27 | ii) Are **all** the sutures an adequate distance from the tissue edge (1-2mm)? | Y | N | 3 | FLUENCY |

| 5 | Creation of RV to PA continuity | | | | |
|---|---|---|---|---|---|
| 28 | Has an appropriately sized conduit been used to create the RV/PA continuity? (i.e. 8-10mm Gortex tube graft) | Y | N | 3 | KNOWLEDGE |
| 29 | Has the conduit been anastomosed to the PA button first? | Y | N | 3 | FLUENCY |
| 30 | i) Was the anastomosis commenced posteriorly? | Y | N | 2 | FLUENCY |
| 31 | Has the conduit been measured and trimmed to the correct length? (i.e. to end of RV ventriculotomy)?) | Y | N | 4 | KNOWLEDGE |
| 32 | i) Has the proximal end of the conduit been laid open to cover the wide ventriculotomy? | Y | N | 4 | KNOWLEDGE |
| 33 | Has the suture commenced at the apex (i.e. superior end of the ventriculotomy) and continued until half way along the length of the ventriculotomy on both sides? | Y | N | 3 | FLUENCY |
| 34 | Has the end of the conduit been trimmed as a bevel to accommodate a filled ventricle? | Y | N | 4 | KNOWLEDGE |
| 35 | Is the conduit laying comfortably and not under tension? | Y | N | 5 | RESPECT |
| 36 | i) is the conduit kinked or twisted? | N | Y | 5 | RESPECT |
| | Suture assessment | | | | |
| 37 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of 1-2mm between suture bites? | Y | N | 3 | FLUENCY |
| 38 | ii) Are **all** the sutures an adequate distance from the tissue edge (1-2mm)? | Y | N | 3 | FLUENCY |
| | | **TOTAL SCORE** | | **134** | |

## 12.3.12 Arterial switch operation for transposition of the great arteries

**HOST-CHS assessment tool - Arterial switch (TGA 1LCX2R)**

SickKids | Labatt Family Heart Centre

| | | Steps | YES/ NO | | Weight of step (1-5) | Included in HOST-CHS Holistic Score |
|---|---|---|---|---|---|---|
| 1 | | **Transection of aorta** | | | | |
| | | Is the cut in the aorta | | | | |
| | 1 | i) Perpendicular to the vessel? | Y | N | 2 | RESPECT |
| | 2 | ii) Clean? (i.e. not jagged or having sharp protruding points) | Y | N | 2 | RESPECT |
| | 3 | Is there enough distance on the proximal aorta (5-10mm) for good sized coronary buttons? | Y | N | 3 | KNOWLEDGE |
| | 4 | Is there enough distal length on the aorta for reconstruction of the neo-aorta? | Y | N | 3 | KNOWLEDGE |
| 2 | | **Excision of coronary artery buttons** | | | | |
| | 5 | Have the coronary buttons been excised with a liberal amount of aortic sinus wall with the coronary artery? | Y | N | 5 | RESPECT |
| | 6 | Is the coronary button rectangular shaped? | Y | N | 3 | KNOWLEDGE |
| | 7 | Is the coronary orifice in the centre of the button? | Y | N | 5 | KNOWLEDGE |
| | 8 | Is there enough aortic wall left for pulmonary artery reconstruction? (i.e. oblique cut towards anterior commissure) | Y | N | 3 | KNOWLEDGE |
| | 9 | Has there been any damage to the coronary arteries or aortic/neo-pulmonary valve during excision and mobilization? | N | Y | 5 | RESPECT |
| 3 | | **Transection of ductus arteriosus and pulmonary trunk** | | | | |
| | 10 | Has ductus been suture ligated and transected? | Y | N | 1 | |
| | 11 | Is the proximal PDA suture a safe distance from the left pulmonary artery (>1-2mm)? | Y | N | 4 | |
| | | Is the cut in the pulmonary trunk | | | | |
| | 12 | i) Perpendicular to the vessel? | Y | N | 3 | RESPECT |
| | 13 | ii) Clean? (i.e. not jagged or having sharp protruding points) | Y | N | 3 | RESPECT |
| | 14 | iii) A safe distance away from the pulmonary bifurcation (2-5mm) that it does not compromise the branch PAs? | Y | N | 4 | KNOWLEDGE |
| | 15 | Have one or more commissures been marked with a pen or stitch? | Y | N | 4 | KNOWLEDGE |
| 4 | | **Reconstruction of neo-aorta** | | | | |
| | 16 | Has the length of the ascending aorta been adjusted in a new position if required? (i.e. trimmed) | Y | N | 3 | KNOWLEDGE |
| | 17 | Has an end-to-end anastomosis been performed between the proximal neo-aorta and ascending aorta? | Y | N | 3 | |
| | 18 | Was the anastomosis commenced posteriorly? | Y | N | 3 | |
| | | Suture/Anastomosis assessment: | | | | |
| | 19 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of **2-3mm** between suture bites? | Y | N | 3 | FLUENCY |
| | 20 | ii) Are **all** the sutures an adequate distance from the edge (2-3mm)? | Y | N | 3 | FLUENCY |
| 5 | | **Implantation of coronary artery buttons to neo-aorta** | | | | |
| | | LEFT coronary button incision | | | | |
| | 21 | i) In the correct position for the technique of choice? (i.e. medially-based trap door for closed technique vs trap-door/rectangular for open technique) | Y | N | 5 | KNOWLEDGE |
| | 22 | ii) Adequate sized incision for technique of choice? (i.e. Closed technique: incision is slightly smaller than button [4-6mm] and edges of trap door are cut at right angles) | Y | N | 4 | RESPECT |
| | | Is the LEFT coronary artery | | | | |
| | 23 | i) In the 'best lie' position? (i.e. lateral + superior avoiding compression from PA, not stretching) | Y | N | 5 | FLUENCY |
| | 24 | ii) Kinked or twisted? | N | Y | 5 | FLUENCY |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | iii) Suture/Anastomosis assessment: | | | | |
| | 25 | a) Are **all** the sutures evenly spaced from one another **WITH** a gap of **1-2mm** between suture bites? | Y | N | 4 | FLUENCY |
| | 26 | b) Are **all** sutures an adequate distance from the edge (1-2mm) **AND** is a safe distance from the neo-aortic valve and coronary ostium? | Y | N | 4 | FLUENCY |
| | 27 | iv) Has the coronary button been trimmed appropriately? (i.e. leaving more tissue medially than laterally in the trap door technique / not too much tissue left over effecting lay/anastomosis) | Y | N | 3 | |
| | 28 | v) Is the coronary still in tact by the end of anastomosis (i.e. not avulsed)? | Y | N | 5 | |
| | | **RIGHT** coronary button incision | | | | |
| | 29 | i) In the correct position for the technique of choice? (i.e. medially-based trap door for closed technique vs trap-door/rectangular for open technique) | Y | N | 5 | KNOWLEDGE |
| | 30 | ii) Adequate sized incision for technique of choice? (i.e. Closed technique: incision is slightly smaller than button [4-6mm] and edges of trap door are cut at right angles) | Y | N | 4 | RESPECT |
| | | Is the **RIGHT** coronary artery | | | | |
| | 31 | i) In the 'best lie' position? (i.e. lateral + superior avoiding compression from PA, not stretching) | Y | N | 5 | FLUENCY |
| | 32 | ii) Kinked or twisted? | N | Y | 5 | FLUENCY |
| | | iii) Suture/Anastomosis assessment: | | | | |
| | 33 | a) Are **all** the sutures evenly spaced from one another **WITH** a gap of **1-2mm** between suture bites? | Y | N | 4 | FLUENCY |
| | 34 | b) Are **all** sutures an adequate distance from the edge (1-2mm), **AND** is a safe distance from the neo-aortic valve and coronary ostium? | Y | N | 4 | FLUENCY |
| | 35 | iv) Has the coronary button been trimmed appropriately? (i.e. leaving more tissue medially than laterally in the trap door technique/ not too much tissue left over effecting lay/anastomosis) | Y | N | 3 | |
| | 36 | v) Is the coronary still intact by the end of anastomosis (i.e. not avulsed)? | Y | N | 5 | |
| **6** | **Reconstruction of neo-pulmonary trunk** | | | | | |
| | 37 | Has the candidate performed this procedure to completion? (i.e. anastomosis of patch and then to branch PAs) | Y | N | 4 | FLUENCY |
| | 38 | Is the height of patch level with the native tissue left following transection/ coronary button excision? | Y | N | 2 | FLUENCY |
| | 39 | Is diameter of patch slightly larger than the native lumen size? | Y | N | 2 | KNOWLEDGE |
| | 40 | Has an end-to-end anastomosis been performed between the neo-pulmonary trunk and the distal pulmonary artery? | Y | N | 2 | |
| | 41 | Was the anastomosis commenced posteriorly? | Y | N | 2 | |
| | | Suture/Anastomosis assessment: | | | | |
| | 42 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of **2-3mm** between suture bites? | Y | N | 3 | FLUENCY |
| | 43 | ii) Are **all** the sutures an adequate distance from the edge (2-3mm)? | Y | N | 3 | FLUENCY |
| | | | **TOTAL SCORE** | | **153** | |

## 12.3.13 Ventricular septal defect repair

| | | Steps | YES/ NO | | Weight of step (1-5) | Included in HOST-CHS Holistic Score |
|---|---|---|---|---|---|---|
| **1** | | **Preparation of VSD patch** | | | | |
| | 1 | Has the delegate attempted to measure the size and shape of the VSD? | Y | N | 2 | KNOWLEDGE |
| | 2 | Has the patch been trimmed to the approximate size of the VSD? | Y | N | 3 | KNOWLEDGE |
| **2** | | **Suturing VSD patch** | | | | |
| | 3 | Has the suture commenced at the deepest point of the VSD along the ventricular crest? | Y | N | 3 | FLUENCY |
| | 4 | Does the suture continue superiorly towards the aortic annulus? | Y | N | 3 | FLUENCY |
| | 5 | Does the suture continue around the aortic valve towards the tricuspid valve annulus? | Y | N | 4 | FLUENCY |
| | 6 | i) Have any of the sutures caught any of the cusps of the aortic valve? | N | Y | 5 | RESPECT |
| | 7 | ii) When the tricuspid annulus is reached is the suture passed through the annulus into the right atrium? | Y | N | 2 | FLUENCY |
| | 8 | Has the other end of the suture been continued along the inferior margin of the VSD to the tricuspid valve annulus? | Y | N | 3 | FLUENCY |
| | 9 | i) Is the suture away from the conduction tissue avoiding injury? | Y | N | 5 | RESPECT |
| | 10 | Has the patch been trimmed along the inferior rim of VSD if required? (i.e. excess patch removed) | Y | N | 4 | FLUENCY |
| | 11 | When the chords are reached does the delegate avoid tethering/rupturing the chords? | Y | N | 5 | RESPECT |
| | 12 | When the tricuspid annulus is reached is the suture passed through the annulus into the right atrium? | Y | N | 2 | FLUENCY |
| | 13 | Has the suture been completed with horizontal mattress sutures? | Y | N | 2 | |
| | | Suture assessment | | | | |
| | 14 | i) Are **all** the sutures evenly spaced from one another **WITH** a gap of 2-3mm between suture bites? | Y | N | 3 | FLUENCY |
| | 15 | ii) Are **all** the sutures an adequate distance from the tissue edge (2-3mm)? | Y | N | 3 | FLUENCY |
| **3** | | **Patch Assessment** | | | | |
| | 16 | Is the patch the correct size for the VSD defect? | Y | N | 4 | KNOWLEDGE |
| | 17 | Are there any visible holes/tears within the patch? | N | Y | 5 | RESPECT |
| | 18 | Have any plication sutures been needed to make the patch smaller? | N | Y | 4 | RESPECT |
| | 19 | Would there likely be a residual VSD? | N | Y | 5 | RESPECT |
| **4** | | **Collateral damage** | | | | |
| | 20 | Has the aortic valve been damaged during the procedure? (i.e. torn) | N | Y | 5 | RESPECT |
| | 21 | Have the tricuspid valve leaflets been removed or have been damaged during the repair? | N | Y | 5 | RESPECT |
| | | | **TOTAL SCORE** | | **77** | |

## 12.4 Research and Ethics Board Approval letter

SickKids

# Research Ethics Board (REB)
# Study Approval Letter

2019-03-19

Shi-Joon Yoo
Diagnostic Imaging

**REB number: 1000060696**
**Study Title:** Surgical skills evaluation before and after simulation of congenital heart surgeries using 3D print models

**Date of Approval:** 2019-03-19
**Expiry Date:** 2020-03-19

Thank you for the application submitted on **2018-08-22.** The above referenced study was reviewed through a delegated process (not by Full Board review). Any concerns arising from this review have been documented and resolved.

The REB voted to approve this study, and your participation as Principal Investigator, as it is found to comply with relevant research ethics guidelines, as well as the Ontario Personal Health Information Protection Act (PHIPA), 2004.

The Hospital for Sick Children Research Ethics Board hereby issues approval for the above named study. This approval is effective from **2019-03-19** to **2020-03-19.** Continuation beyond that date will require further review of REB approval.

The following documents have been reviewed and are approved:

1. **Email Template to HOST Course Participants Version Dated January 10, 2019**
   **[Email Script_Surgical Skills_HOST Course Study Participant_CLEAN_JAN 10 2019.docx (1.0)]**

2. **Email Template to Rater Participants Version Dated January 10, 2019**
   **[Email Script_Surgical Skills_Rater_CLEAN_JAN 10 2019.docx (1.0)]**

3. **HOST Course Questionnaire Version Dated January 10, 2019**
   **[Surgical Skills Study_Participant Questionnaire_CLEAN_JAN 10 2019.docx (1.0)]**

4. **Rater Evaluation Form Version Dated January 10, 2019**
   **[Surgical Skills Study_Rater Evaluation Form_CLEAN_JAN 10 2019.docx (1.0)]**

5. **Data Collection Form Version Dated January 10, 2019**
   **[Surgical Skills_Data Collection Sheet_CLEAN_JAN 10 2019.xlsx (1.0)]**

6. **HOST Course Participant Consent Version Dated February 6, 2019**
   **[Surgical Skills Study Consent Form_HOST Course Participant_CLEAN_FEB 06 2019.docx (1.0)]**

7. **Rater Participant Consent Form Version Dated February 6, 2019**
   **[Surgical Skills Study Consent Form_Rater_CLEAN_FEB 06 2019.docx (1.0)]**

8. **Protocol Version Dated February 6, 2019**

SickKids

**[Surgical Skills Study Protocol_February 06 2019_CLEAN.docx (1.0)]**

Furthermore, the following document(s) were received and acknowledged:

9. **Master Code Breaking File Version Dated January 10, 2019**
   **[Surgical Skills_Master Codebreaking File_CLEAN_JAN 10 2019.xlsx (1.0)]**

During the course of this investigation, any significant deviations from the approved protocol and/or unanticipated developments or significant adverse events should immediately be brought to the attention of the REB.

**Kathy Boutis**
**REB Vice-Chair**

555 University Avenue, Toronto, ON M5G 1X8
Tel: (416) 813-8279   Fax: (416) 813-6515

The SickKids REB operates in compliance with the Tri-Council Policy Statement; ICH Guideline for Good Clinical Practice E6(R1); Ontario Personal Health Information Protection Act (2004); Part C Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations and the Medical Devices Regulations of Health Canada. The approval and the views of the REB have been documented in writing. The REB has reviewed and approved the clinical trial protocol and informed consent form for the trial. All investigational drug trials at SickKids are conducted by qualified investigators.

Furthermore, members of the Research Ethics Board who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

## 12.5 Innovation Fund Grant Award

**LABATT HEART CENTRE INNOVATION FUND**

January 28th, 2019

Dear Dr's. Nabil Hussein and Osami Honjo,

Thank you for submitting an application to the Labatt Family Heart Centre Innovation Fund for your project entitled **"Creating a congenital cardiac surgery simulator for 3D heart print models"**. After review by the Funds Allocation Committee and approval of the Executive Committee, we are pleased to let you know that your application was approved for full funding in the amount of $25,000. Congratulations!

Here are some of the comments from the reviewers on your proposal;

- Very important program
- High impact and high visibility for the Heart Centre
- Highly feasible and innovative, next natural step in this program
- One concern: given the significant investments by the innovation fund and the Heart Centre in this program this should be externally funded already, this would be perfect for CHRP, opportunities for alternative funding?

This award is valid for two years from the time your cost centre is opened. Please open your cost centre as soon as possible. You will have until **June 2019** to open your cost centre and begin your project. Should you require an extension beyond that time, you must provide the Innovation Fund Committee with a detailed justification. You will also be asked to submit a final progress report at the end of year 2. I may also email you periodically for updates.

If you have any questions, please do not hesitate to call me at x207798.

Kind Regards,

Christine Kerr, PhD., CCRP
Manager, Clinical Research
The Labatt Family Heart Centre

# Definitions/ Abbreviations

3D Three-dimensional

AATS American Association of Thoracic Surgery

ABS Acrylonitrile butadiene styrene

Ao Aorta

AoA Aortic arch

AL Anterior leaflet

ASD Atrial septal defect

ASO Arterial switch operation

AVSD Atrioventricular septal defect

AVV Atrioventricular valve

CAD Computer-assisted design

CAD Canadian dollars

CHD Congenital heart disease

CHS Congenital heart surgery

CHSS Congenital Heart Surgery Society

CI Confidence interval

CoA Coarctation of aorta

CT Cardiothoracic Surgery

CT Chordae tendinae

CT Computed tomography

Cx Circumflex artery

DAo Descending aorta

DICOM Digital Imaging and Communications In Medicine

DORV Double outlet right ventricle

ECG Electrocardiogram

FDM Fused deposition modelling

GRS Global rating scale

HLHS Hypoplastic left heart syndrome

HOST Hands-On Surgical Training

HOST-CHS Hands-On Surgical Training in Congenital Heart Surgery

HPS Human performance simulators

IAA Interrupted aortic arch

IBL Inferior bridging leaflet

IVC Inferior vena cava

LAA Left atrial appendage

LAD Left anterior descending artery

LML Left mural leaflet

| | |
|---|---|
| LPA | Left pulmonary artery |
| LSPV | Left superior pulmonary vein |
| LV | Left ventricle |
| IVC | Inferior vena cava |
| MD | Medical doctorate |
| MPA | Main pulmonary artery |
| MR | Magnetic resonance |
| NA | Not applicable |
| NTN | National training number |
| OSATS | Objective structured assessment of technical skills |
| PA | Pulmonary artery |
| PDA | Patent ductus arteriosus |
| PL | Posterior leaflet |
| RA | Right atrium |
| RAL | Right anterior leaflet |
| RCA | Right coronary artery |
| RML | Right mural leaflet |
| RV | Right ventricle |
| RV-PA | Right ventricle-to-pulmonary artery |
| SBL | Superior bridging leaflet |
| SBM | Simple bench models |
| SLA | Stereolithography apparatus |
| STL | Stereolithography |
| STS | Society of Thoracic Surgeons |
| SVC | Superior vena cava |
| T | Truncus arteriosus |
| TA | Truncus Arteriosus |
| TGA | Transposition of the great arteries |
| TOF | Tetralogy of Fallot |
| TSDA | Thoracic Society Directors Association |
| UK | United Kingdom |
| USA | United States of America |
| USD | US dollar |
| UV | Ultraviolet |
| VRS | Virtual reality simulators |
| VSD | Ventricular septal defect |