

INDIAN INSTITUTE OF TECHNOLOGY BOMBAY

Industrial Design Centre

PhD Thesis

Role of 3D Prototyping in Visualization of Heart Defect Morphology and Surgical Planning

Submitted in partial fulfilment of the degree of

DOCTOR OF PHILOSOPHY

by

Guruprasad Kuppu Rao
(Reg No. 07413701)

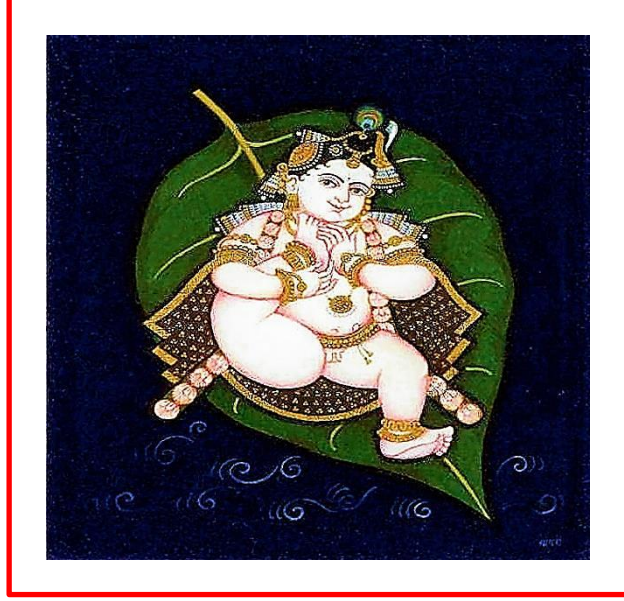
Under the guidance of

Prof. B. K. Chakravarty
Industrial Design Centre
and
Prof. B. Ravi
Mechanical Engineering



INDIAN INSTITUTE OF TECHNOLOGY BOMBAY

Dec 2018



करारविन्देन पदारविन्दं मुखारविन्दे विनिवेशयन्तम् ।
वटस्य पत्रस्य पुटे शयानं बालं मुकुन्दं मनसा स्मरामि ॥ १ ॥

With my mind I think of that child Mukunda[1],
who with his lotus like hand catches his lotus like feet,
and brings it near his lotus like face and steals our heart,
and sleeps peacefully on a banyan leaf.

**This work is dedicated to
the Bala Mukundas of the World**



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Name: Guruprasad Kuppu Rao

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THESIS APPROVAL SHEET

The thesis Titled:

Role of 3D Prototyping in Visualization of Heart Defect Morphology and Surgical Planning

By

Guruprasad Kuppu Rao

Is Approved for the Degree of Doctor of Philosophy

Examiners

Supervisors

Chairman

Date

Place

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Abstract:

A prototype is well established as a “design tool” for its key role in problem-solving. Prototypes for industrial applications are well investigated and demonstrated. Prototype making involves a lot of creativity besides necessary skill and resources. With the advent of three dimensional (3-D) CAD and 3-D printing, making prototype has become somewhat effortless.

Since last decade, 3-D printed prototypes are being used for various healthcare applications. From published literature, we can see its applications are growing. Some of its applications include anatomical models for teaching, procedural planning, surgery guides and implants. The medical image information obtained as DICOM data can be processed to integrate and regenerate shape of anatomy. This forms the basis of medical 3-D virtual modelling and subsequently its fabrication using 3-D printing.

From literature study, we see work on hard tissues while soft-tissue applications are sparse. This is due to certain challenges they pose in image processing. The current research study, focus on one of the soft tissue based organs, namely, the heart. The motivation comes from the risks that the organ poses at birth, called Congenital Heart Disease (CHD). They are caused due to the malformed heart during embryonic development in the foetus. Due to the random nature of defect occurrence, they manifest in many varieties. Many such defects which are mild, get resolved in the early infancy. However, the severe and moderate defects need surgical interventions. Like any treatment, early detection helps to plan treatment management. The echocardiography of neonate is a gold standard to assess the condition in most cases. However, there are a few complexities which are hard to diagnose and plan corrective procedure. The infant’s heart surgeries are generally risky and planning such intervention on the operation table can be risky and can lead to loss of precious time. In such cases, clinicians may study the digital models on a computer. The virtual 3D models can be zoomed in and panned and rotated to explore. Surgeons are used to spatial visualization wherein touch and feel is essential. With just the virtual models on screen, the rich heart morphology cannot be completely visualised. It is here that we see clinicians need physical models for haptic exploration in true size and shape to plan interventional procedures. These physical models can be called patient-specific heart models. While the literature shows such

applications; we observed few gaps: absence of standard workflow procedure, to identify the nature of cases which demand models, how to accurately produce them and how to evaluate their accuracy.

In this research, we investigated the role of physical prototype models in complex morphology visualization. The study involved totally 21 cases live of CHD. The process of 3-D modelling was established with a pilot study on five samples. 16 Patient-specific heart models of CHD were successfully built. The models were checked for accurate fabrication and were issued to the clinicians. Out of the 16 live cases, we found 19% were simple VS defects and models just reconfirmed defects already diagnosed, so, it did not add any additional value. 37% felt that they could visualise more details in the models than what they initially saw from the image data. 44% of the cases comprising of combination defects had ambiguous image reports and were not conclusive. In all such cases, the clinicians found availability models very useful. They opined that visualization of defect morphology from the models aided in understanding the defect condition better. The enhanced understanding helped them to plan treatment management. Models also helped them to communicate with the kin better. From the study, it is clear that the models help in better visualization of defect morphology. They further enable exploratory surgical options and scenario building. The initial condition, surgical plan with model and procedural outcome were analysed with expert clinicians.

A validated detailed workflow including an approach to building accurate models and evaluation for accurate recreation with optimum sections are the main contribution of this research study. A new benchmark model for ascertaining the accuracy of the 3-D printer and printed output for Bioforms is proposed and demonstrated. The study further investigates into the threshold need for such models. Combination defects need models to plan and manage treatment. The study helps adoption of 3-D printing for complex congenital heart defect evaluations and save a fragile precious life.

Optimum Sections, 3-D scatter map of defect volume, use of VR / AR gear are few new thoughts synthesized in this research study, hold good potential for further work.

Key Words: *congenital heart, defect complexities, virtual models, visualization, Prototyping, 3-D printing, model accuracy evaluation, surgical planning.*

Chapter: 1. Introduction

The chapter presents an overview of prototyping, different types, the role of prototypes in the medical domain, medical models, 3-D Printing, and its applications in the medical domain, and a detailed description of heart anatomy. The chapter also provides heart defect types, congenital defects and the embryonic genesis of such defects. The chapter concludes with the overall thesis organization.

1.1 OverView

Since the dawn of civilization, ideas have shaped our lives. One idea can trigger newer ideas, hence, idea sharing has been vital to its improvement. The early humans shared ideas as gestures and lines scratched into rocks. Over a period of time, gestures with sound developed into languages. Visual representations evolved into written records such as drawings and paintings. The languages and writings led a free exchange of information and experience. The accumulated experience became knowledge. The knowledge of ‘making’ of things with became a craft. Purposeful thinking to solve problems developed into the design. Need for the making of artefacts in bulk led to the industrial revolution. The new way of making things was born. Manual hands tools were replaced by machines, which could work without getting tired. With the advent of electricity and computing, automation of ‘making’ was born. They enabled making products in bulk, and more affordable. However, the whole process made ‘maker’ distant from the ‘user’. This brought about the new concept ‘one fits all’. When it comes to medical devices such as implants, we need to make them patient specific. However, complex forms that patient-specific devices demand, are hard to build.

Prototypes enable ideation and validation of design. They are ‘activity’ as well as tools (Elverum & Welo, 2014). They help in exploration (Ullman, 1992), stimulate imagination (Seidel, 2013) and support the thinking process (Hargadon, 1997). They enable a team to visualize and explore new options. ‘Prototype’ is defined as an approximation of the product along one or more dimensions of interest (Ulrich & Eppinger, 2012). Traditional prototyping (for example in wood, clay or plaster) is skill-intensive and time-consuming. With the advent of computer-aided design (CAD) and numerically controlled (CNC)

machines in the manufacturing sector, it is now possible to render realistic virtual models (to visualize) as well as accurate physical models of engineering products (to test their form, fit and function).

One of the important application of prototypes is in the medical domain, where they are used for teaching, communication and research explorations (Mcmenamin, Quayle, Mchenry, & Adams, 2014). Fabrication of anatomical models requires skilled personnel, special tools, and domain familiarity, owing to their geometric complexity. For the same reason, computer modelling and CNC machining have limited applications in this field.

The advent of computer-aided diagnostics (Doi, 2007) and 3-dimensional printing has opened new possibilities for medical prototyping. Image-based diagnostics modalities include X-ray, Ultrasonography (US), Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Cone Beam Computed Tomography (CBCT), Positron Emission Tomography (PET), and Single Photon Emission Computed Tomography (SPECT) (Doi, 2007). The output image data is stored in a common exchange format called DICOM – Digital Imaging and Communications in Medicine (Mildenberger, Eichelberg, & Martin, 2002). The CT is the most common and least invasive modality. It essentially comprises a set of X-ray images of target anatomy (Bidgood, Horii, Prior, & Van Syckle, 1997). The image data is processed using suitable software tools to group regions of similar intensity (grey-scale) value, through a technique called segmentation (Egmentation, Pham, Xu, & Prince, 2000). This enables digital reconstruction of anatomical structures into 3D models, which can be used by 3D printers to fabricate physical models.

3D printing (also called as ‘Additive Manufacturing’) enables fabrication of complex geometries by deposition of materials in a layer-by-layer manner (Brans, 2013). They offer the capability to fabricate intricate geometries that cannot be constructed using conventional machining techniques for a variety of materials including plastics, metals, and ceramics (Ventola, 2014). The method comprises of using either a solid or liquid raw material and generating a physical model of the desired shape and size. The desired geometry is sourced into the 3D printer in the form of a triangulated digital model, designed using suitable software. The three sources of triangulated digital models are solid models generated using 3D CAD software, point cloud data generated from a scanner, and data generated using medical imaging modalities. In particular, 3D printing

can be very useful in the medical sector as it can fabricate accurate models of complex anatomies.

3D printing is extensively used in hard-tissue based applications (craniomaxillofacial, hip and knee implants). Soft-tissue organs such as lungs, kidney, liver, and heart are less explored due to the image processing challenges they pose (Von Landesberger, Bremm, Kirschner, Wesarg, & Kuijper, 2013). Developing the capability to 3D print physical models of soft tissue organs can benefit the surgical arena in terms of procedural planning, reduced surgical (OT) time and stress, fewer surgical errors, and overall treatment management. This can help children with congenital issues such as anotia, cleft tooth and heart defects, which is the focus of this work.

The incidence of newborns with congenital heart diseases is 8 in 1000 live births (Bernier, Stefanescu, Samoukovic, & Tchervenkov, 2010); there is no account of stillborns that had fatal heart conditions (Jorgensen, Mcpherson, Zaleski, Shivaram, & Cold, 2014). Addressing this issue will reduce infant mortality, and enable normal quality of physical life for children and their parents. Indian study shows a similar status on CHD (Saxena & Saxena, 1981)

Visualization of defect morphology in CHD is essential for understanding and planning surgical interventions. Given the long history of 2D or 3D visualizations for diagnostics, complex morphologies may be better depicted on 3D solid models in hand (Rengier et al., 2010).

1.2 Role of Prototypes in Visualization

Prototypes are externalized thoughts expressed as tangible visuals or objects. The visualization of ideas helps information exchange, triggering new thoughts in oneself and others in the team. (Elverum, Welo, & Tronvoll, 2016). Visualization is defined as a representation of an object (B. Wu, Klatzky, & Stetten, 2012) and the formation of a mental image of something. Both representation and mental image are somewhat ambiguous. Many times doodles or sketches provide just a hint; they do not help to communicate the mental image completely. Visualization improves a physical model in hand enabling experience prototyping without any ambiguity (Buchenau & Suri, 2000).

So, we can say, A prototype is worth a thousand pictures (Ref Figure 1-1).

**If a picture paints a thousand words, a prototype
is worth a thousand pictures**

-Richard Eisermann

Figure 1. 1 Quote on prototypes by design expert Mr.Richard Eisermann

If a prototype can fully communicate the design intent, we can call it the hi-fidelity prototype. The high fidelity prototype is usually full scale, looks and works like the real final model. Low fidelity prototypes may or may not be the same scale but are not well-finished ones and in most cases do not work. They are used to quickly communicate one or more of the design intent within the smaller design teams.

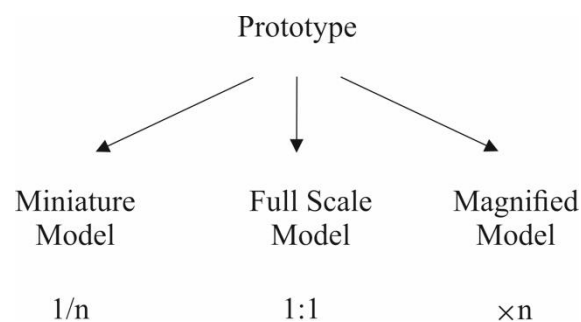


Figure 1. 2 Prototype Sizes

If the original object is very small or microscopic, a magnified model is useful: for example a model of a Virus. On the other hand, if we are considering a very large model, a reduced scale model is useful for example, a building. The ergonomic aspects of a car dashboard require a 1:1 or full-scale model to evaluate the design.



$\times n$



$1:1$



$1 / n$

Figure 1. 3 Prototype Size Examples

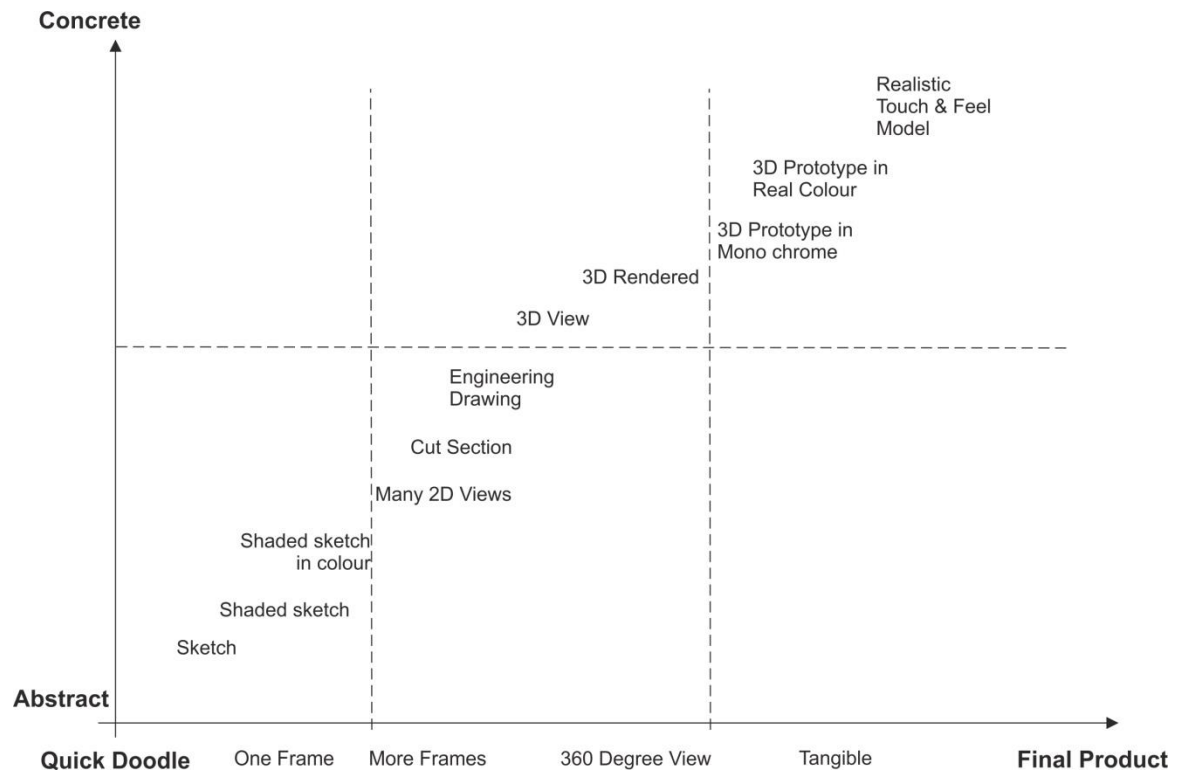


Figure 1. 4 Prototype Spectrum

Thus we can have a spectrum of prototypes from simple, low fidelity abstract prototypes to detailed high fidelity concrete working model. We can have many in-between forms which enable idea evaluation Fig 1.2

A quick doodle helps in externalizing the idea marks the nucleation of design and is followed by sketches for varying degrees of clarity tending to provide a 3-dimensional perception on a 2D plane. We can call it as information in one frame. As we include more views it helps us to comprehend (in mind) its total form. Engineering drawings include several orthographic views and an Isometric view. The perceptive view is a closer approximation to the 3D visualization of an object. The above concept can be further better visualized by the following plot: here we take bolt as an example. The representation starts with 2-dimensional frames which include doodle/sketch. With engineering drawing, we go into many views and 360-degree view at its digital/physical forms. We can see from the diagram, the feedback/communication value increases with fidelity and so is the cost.

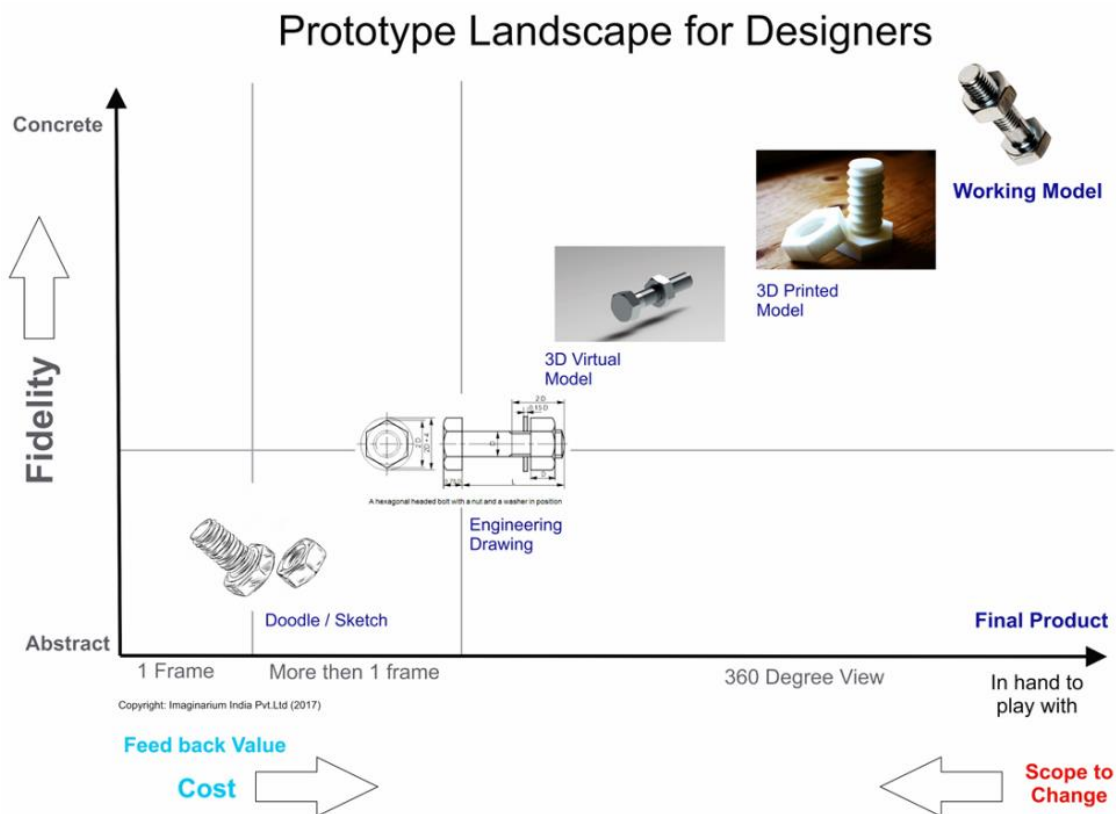


Figure 1. 5 Prototype Landscape

1.3 Medical Visualization and Tools

Visualization in the medical domain is very important for learners as well as professionals. Various groups like artists, sculptors, jewellers, tailors, and surgeons, have studied the human body. The Greek and Roman artefacts show their mastery of human anatomy. Surgeons used to treat wounded soldiers and amputees that was the only window to look inside. The permission to study the dead was limited to a few executed criminals or amputees. This compelled them to keep an account of their findings in sketches for future reference and communication seen Indian, Chinese, and European medical illustrations from 16th Century.

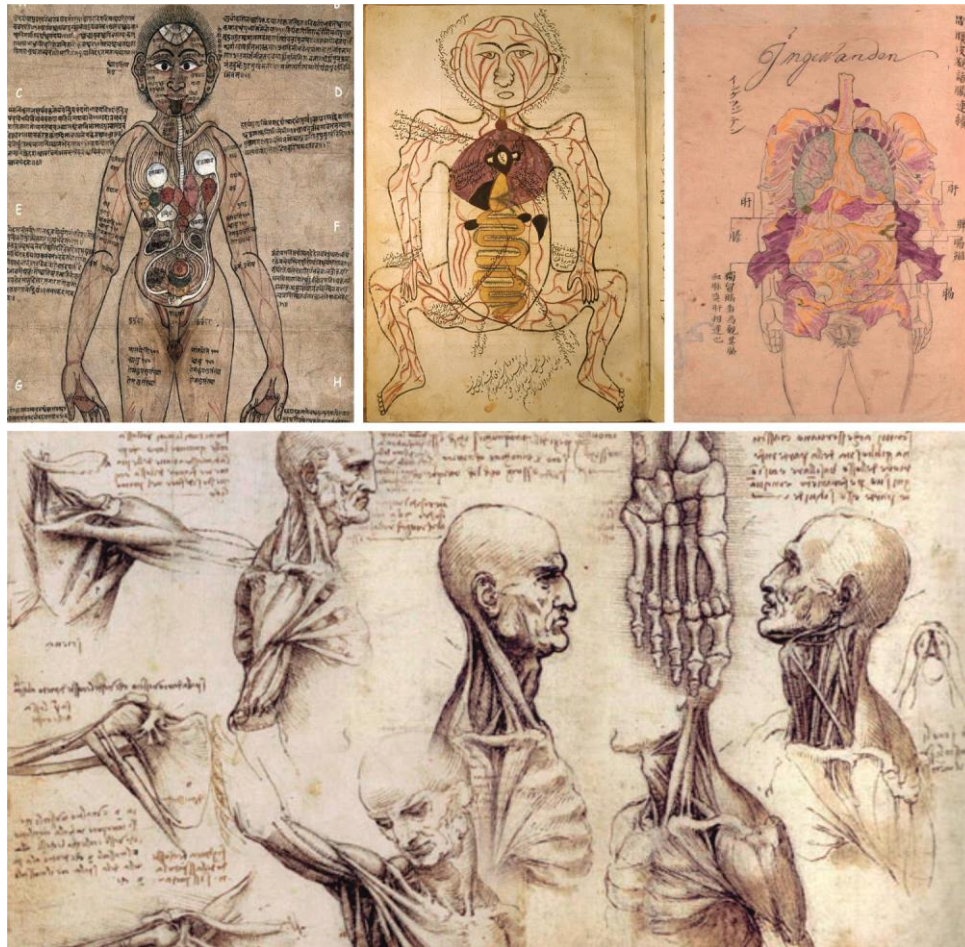


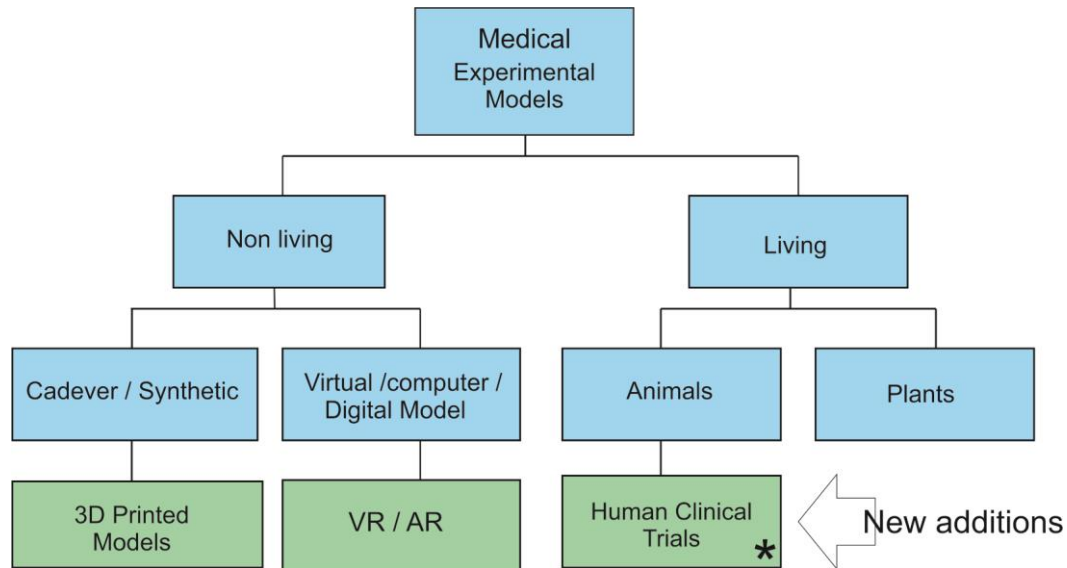
Figure 1. 6 Medieval medical sketches from India, Persia, China, and Europe

The medieval period saw the rapid development of surgery and by the 19th century, most of the anatomy visualization was through sketches made from dissections. Henry Gray's book *Gray's Anatomy* is popular among medical fraternity even today (Warner & Rizzolo, 2006)

1.31 Physical Models

Models for surgery simulations have been used for many centuries. In 600 BC (Antia, Group, & Foundation, 1985), Indian sage & surgeon, Sushruta (Champaneria, Workman, & Gupta, 2014) is believed have trained his pupils in a surgical procedure using vegetables and fruits. (Saraf et al., 2006) In experimental surgery, there has been a clear role for models and their role in surgery training or new exploration. Dr Harish Daga et al (Daga, Harish, Toshikhane, Hemant and Banne, 2018) explain how animal models have been used in surgery to study, improve upon or develop new techniques and test drug

efficacy. A could be derived from non-living things such as cadaver or made of synthetic materials. Living models are derived from animals & plants (Figure 1.7)



Types of experimental models used for surgical simulation

Figure 1. 7 Harish Daga's experimental surgery model (in blue) with new additions (in green)

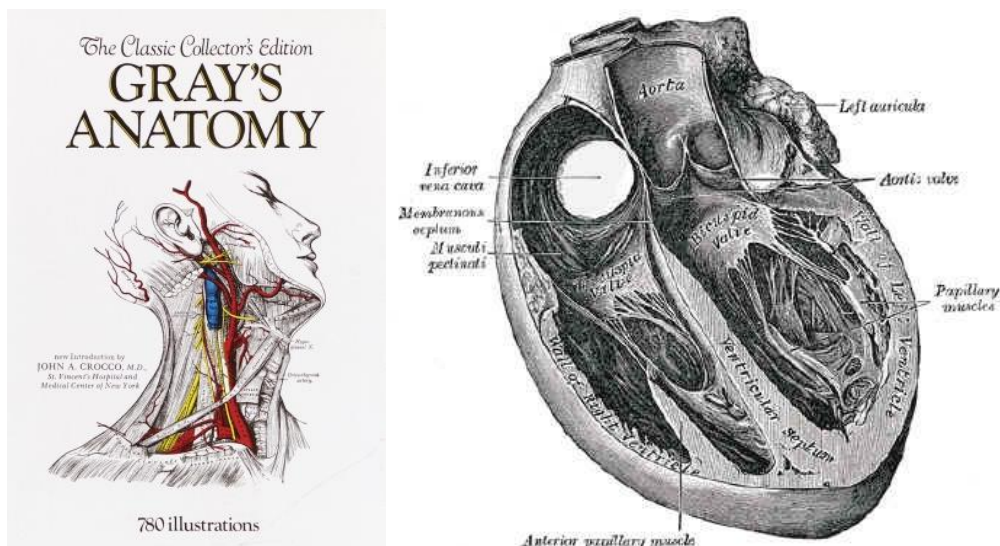


Figure 1. 8 Gray's Anatomy Book & Heart sketch with labels

With the introduction of human anatomy in Biology and Zoology, physical models appeared as educational aids. These were made of clay and were crude and heavy. With

the advent of plastics, many high fidelity models of anatomy in true colour and feel became available in the market.

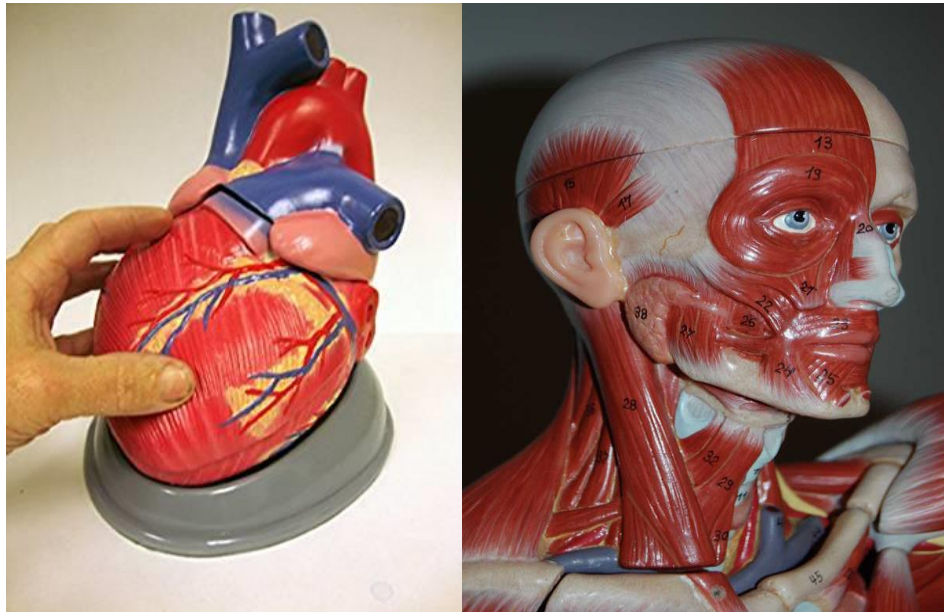


Figure 1. 9 Colorful models made of clay and polymers



Figure 1. 10 Vacuum-Formed PVC colourful chart from Delhi Market

The human cadaver still remains a gold standard as a learning tool for medical students as well as medical practitioners/researchers.

Vacuum formed charts are made of PVC, used as educational charts. They are light and cleanable but fail to provide fine details due to a limitation with vacuum forming process. They lack in spatial feel and touch. We could possibly fill this gap with the help of 3D printing technology.

1.4 3D Printed Medical Models

3-D Printing is a set of free-form fabrication technologies that were invented in the late 80s. They make objects layer by layer directly from CAD data, obtained from various sources such as CAD software, 3-D Scanning and a Medical Imaging.

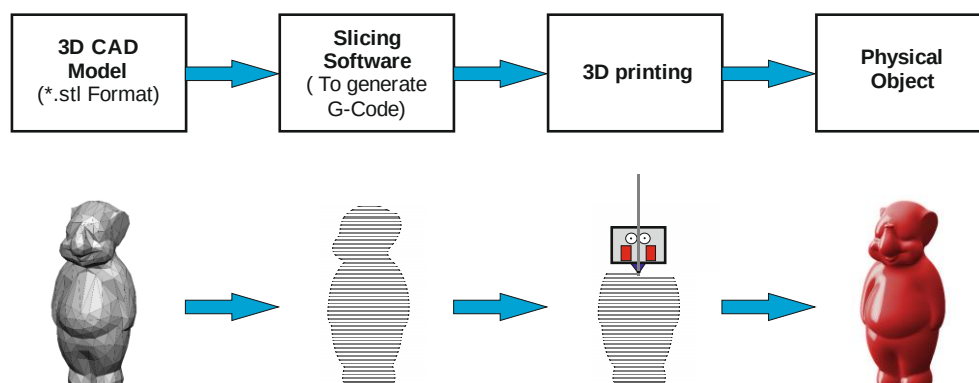


Figure 1. 11 3D Printing Process

The most popular 3D printing technologies have been classified by ASME (Ref: ISO/ASTM 52900:2015) into seven main types based on their working principles:

- a) Vat photopolymerization, liquid photopolymer in a vat is selectively cured by light-activated polymerization.
- b) Powdered bed fusion, thermal energy selectively fuses regions of a powder bed.
- c) Binder jetting, liquid bonding agent gets selectively deposited to join powder materials.
- d) Material jetting, droplets of build material are selectively deposited.
- e) Sheet lamination, sheets of material are bonded layer upon layer to form a part.
- f) Material extrusion process in which material is selectively dispensed through a nozzle or orifice.

- g) Directed energy deposition, focused thermal energy is used to fuse materials by melting as they are being deposited.

(More details about 3D printing technologies are provided in the Annexure I)

3D printing is widely used to make quick prototypes of even complex geometry with fair accuracy. In the engineering industry, it is extensively used to validate the design, as well as to produce jigs and fixtures, custom parts and mass customized products such as jewellery etc.

With the advent of computing power, medical imaging, and 3D printing technologies, it is now possible to produce accurate full-scale models of anatomical parts. Further, they can be made in small batch quantities, even one. Surgery planning is enabled by true anatomical models are available in hand (Brown, 2009). The Building of the solid model by integrating the slice data has opened a new world of visualization and 3D printing has made it possible to hold such visualizations in hand and carry out exploratory surgical iterations to arrive at the best solution. The medical image protocol DICOM which has helped to share the data across the medical domain and found its perfect pair in 3D printing to give birth to true anatomy models which can be made with a little image processing.

We can understand 3D printing opportunities in medical care better from the diagram given below (Fig 1.21) The models grouped into four levels in the increasing order of risk and responsibility to fabricate models.

At level one, we group all anatomical models for training & instruction purposes. They can be smaller, bigger or full size as may be required. They need not be very accurate as they are all conceptual models for teaching. There is no restriction on the type of material used to produce them.

At level two, we group special models that aid accurate location and guidance for the purpose of surgical procedures. They are made as a full scale with reasonable accuracy as they guide and locate surgical landmarks. There is a restriction that they should be made of biocompatible and sterilizable material since they come in direct contact with live tissue.

At level three, we group all implantable anatomical models as a replacement to correct defect conditions or to save a life. They are produced as full scale, specific to a patient to match and overcome the defect. They have to be very accurate as they reside in the patient's body for the lifecycle and beyond. There is a restriction that they should be made of implantable tissue inert / friendly sterilizable material since they remain with the live tissue. They are made of surgical grade metal (Alloys of Stainless Steel / Titanium etc) or certain special plastics (PMMA/ PC/ PEEK etc.)

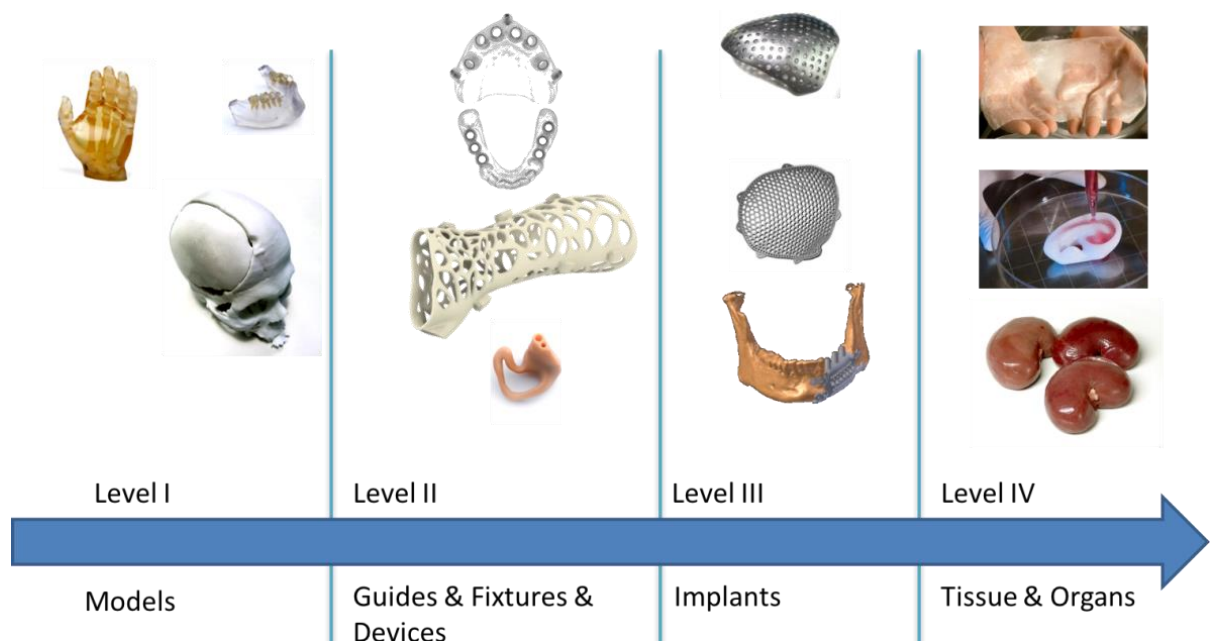


Figure 1. 12 Four levels of 3-D Printing application in healthcare (InfoGraphic Credits: Imaginarium)

At level four, we group all implantable livening anatomical models as a replacement to correct defect conditions or to save a life. They are produced as full scale, specific to a patient to match and overcome the defect. They have to be very accurate as they reside in the patient's body for the lifecycle and beyond. There is a restriction that they should be made of implantable live tissue compatible with the rest of the system. It is proposed that body parts can be made out of human stem cells grown in a lab using 3D printed scaffolds. They are still in the research stage and may one day prove to be very useful.

1.5 Heart Structure

It was Da Vinci first sketched the heart, as we know today (Figure 1.13). The heart has four chambers, or ‘rooms’. The upper rooms are called the ‘atria’ while the lower rooms are called ‘ventricles’. The ‘doors’ between the chambers are tiny valves. Da Vinci made exquisite glass models of the valves, watching water containing tiny grass seeds swirl through them, in order to understand their action better! (Helen Cowan, Readers Digest)

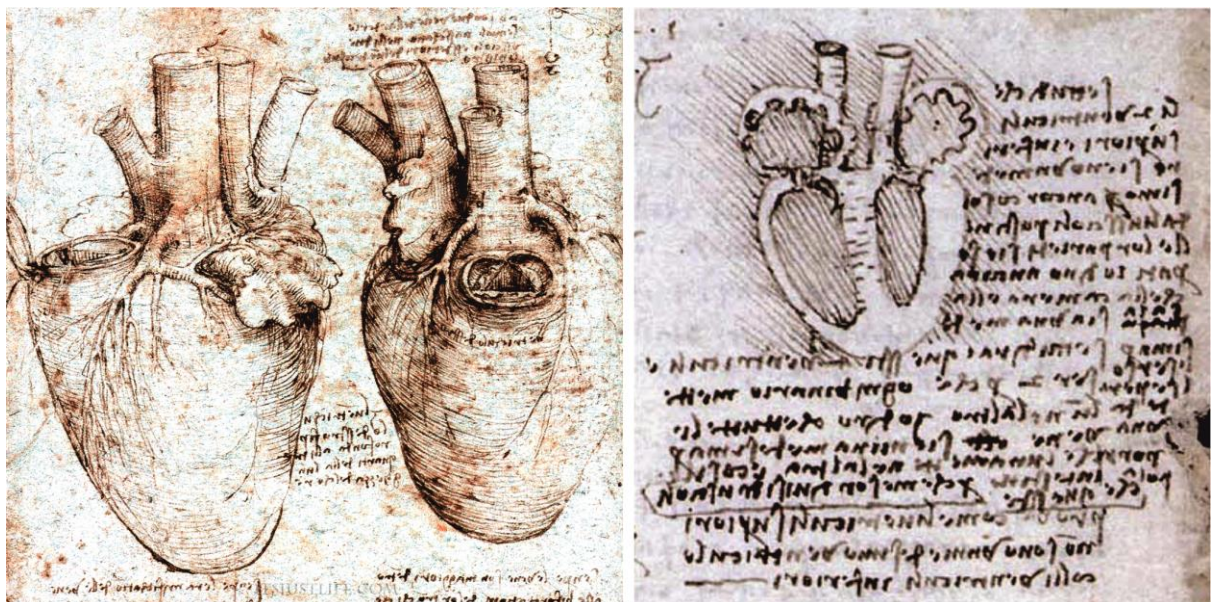


Figure 1. 13 Da Vinci's heart sketches

The human heart is located inside the thoracic cavity, medially between the lungs in the space known as the mediastinum. (Figure 1.14) Within the mediastinum, the heart is separated from the other structures by the pericardial sac. The dorsal surface of the heart lies near the bodies of the vertebrae, and its anterior surface is near to the sternum and costal cartilages. The great veins, the superior and inferior venae cavae, as well as the aorta and pulmonary trunk, are attached to the superior surface of the heart, called the base. Figure (1.15). The inferior tip of the heart, the apex, lies just to the left of the sternum between the junction of the fourth and fifth ribs near their articulation with the costal cartilages. The right side of the heart is deflected anteriorly, and the left side is

deflected posteriorly. The apex protrusion results in a depression in the left lung called cardiac notch.

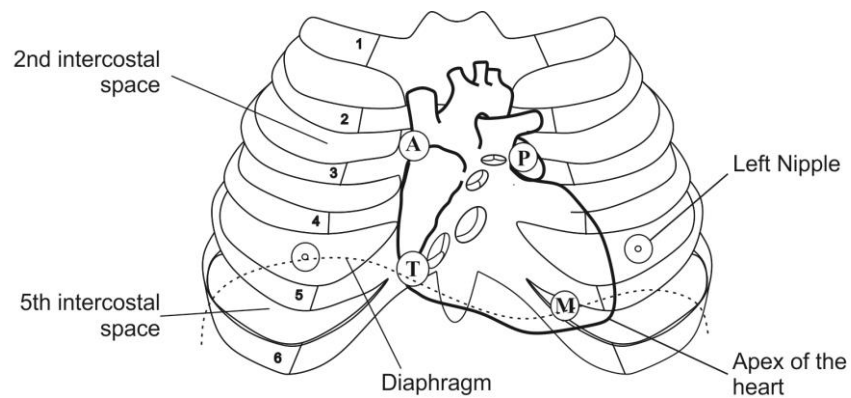


Figure 1. 14 Normal Heart location in the rib cage

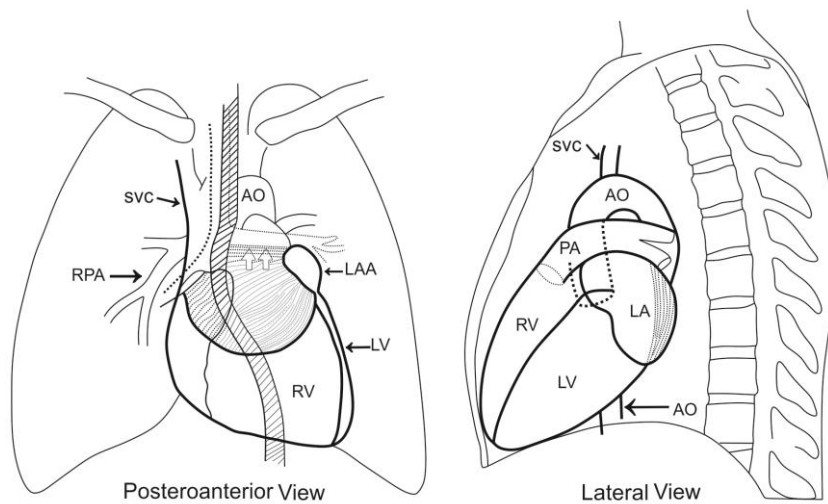


Figure 1. 15 Heart in the neighbourhood

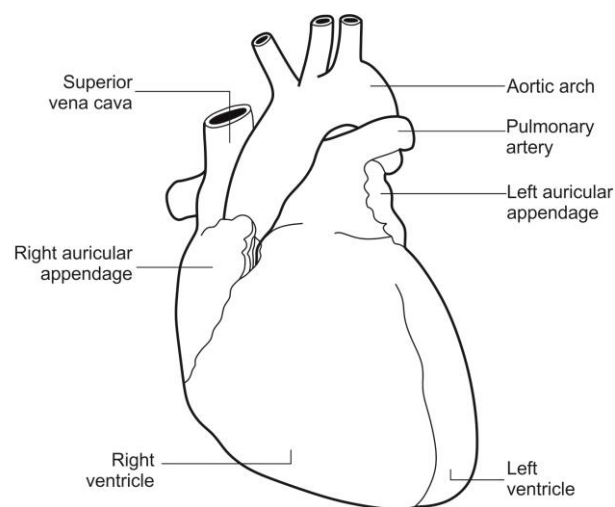


Figure 1. 16 Heart front View

The heart is divided as the right & left the side, separated by a wall called Septum made of myocardium covered with endocardium tissue. The right & the left sides carry deoxygenated blood & Oxygenated Blood respectively will communicate within through four atrioventricular valves.

A typical heart is approximately the size of one's fist: 12 cm (5 in) in length, 8 cm (3.5 in) wide, and 6 cm (2.5 in) in thickness (Figure 1.16). Given the size difference between most members of the sexes, the weight of a female heart is approximately 250–300 grams (9 to 11 ounces), and the weight of a male heart is approximately 300–350 grams (11 to 12 ounces). The heart of a well-trained athlete, especially one specializing in aerobic sports, can be considerably larger than this.

The human heart consists of four chambers: The left side and the right side each have one atrium and one ventricle. Each of the upper chambers, the right atrium (plural = atria) and the left atrium, acts as a receiving chamber and contracts to push blood into the lower chambers, the right ventricle and the left ventricle. The ventricles serve as the primary pumping chambers of the heart, propelling blood to the lungs or to the rest of the body (Figure 1.18)

The Heart Pumping action has two squeeze states namely systole (contraction) and diastole (relaxation). The cardiac cycle is associated with a single heartbeat: systole & diastole of atria & systole and diastole of the ventricles. In each cardiac cycle, the atria and ventricles alternately contract and relax, forcing the blood from areas of higher pressure to the areas of lower pressure. The heart functions as a self-adjusting 'double pump': The pulmonary pump or 'right heart', comprising the right atrium and right ventricle, is a relatively low-pressure system. The systemic pump or 'left heart', comprising the left atrium and left ventricle, is a high-pressure system.

The function carried out by the squeezing action of two atria (upper chambers) and two ventricles (lower Chambers). The four valves: mitral (bicuspid), tricuspid, and two semi-lunar valves enable the unidirectional flow. The inlet and outlets open and close in a sequence to circulate the blood in two circuits: one to the lungs and another for rest of the

body. The heart also has one more circuit of blood to power itself called coronary arteries.
(GP, 2014)

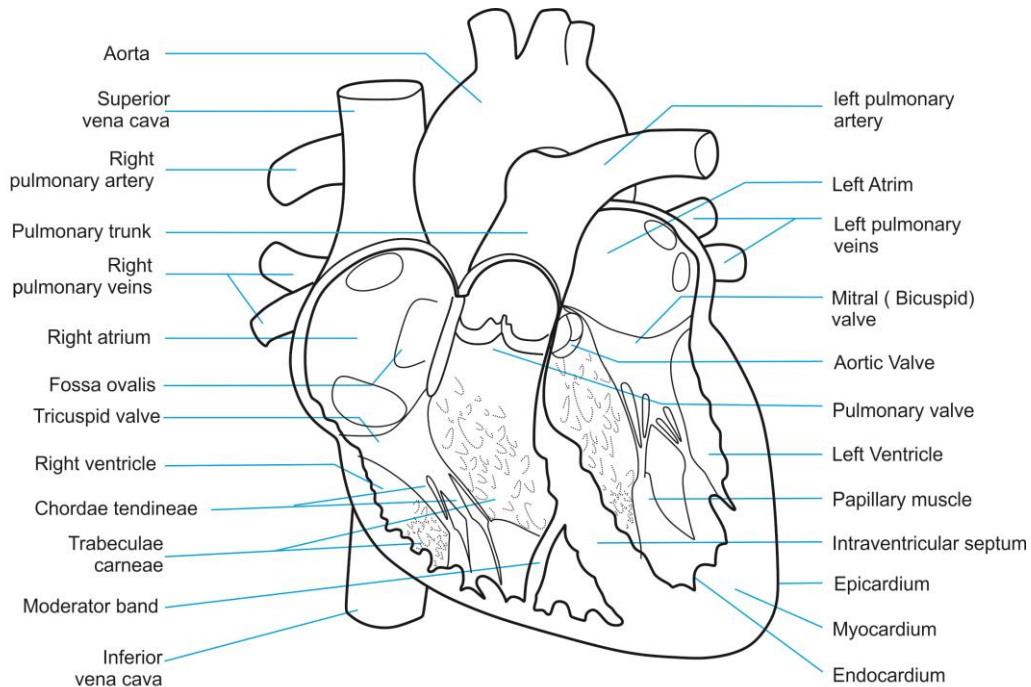


Figure 1. 17 Heart sectional view

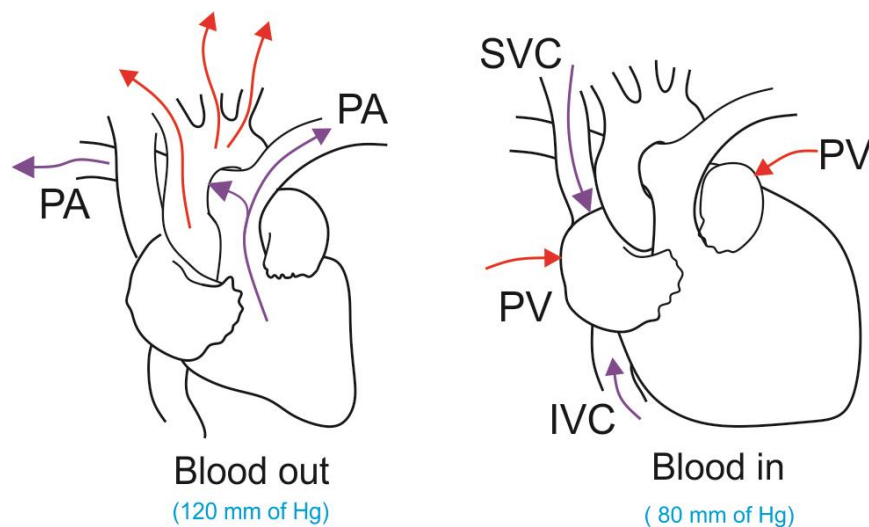


Figure 1. 18 Heart Squeezing Actions: Systole (left) & Diastole (right)

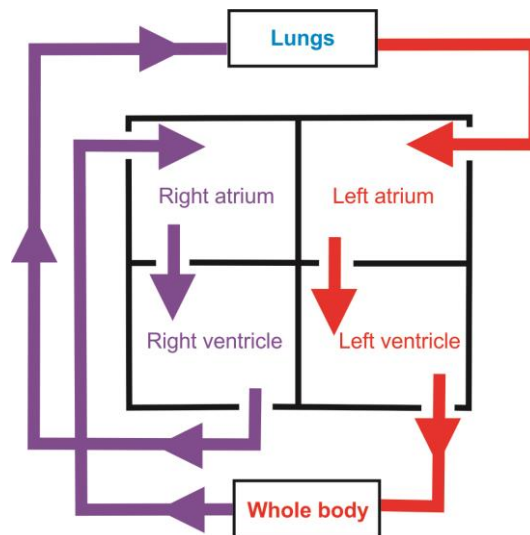


Figure 1. 19 Heart blood circulation circuit

There are two distinct but linked circuits in the human circulation called the pulmonary and systemic circuits. The pulmonary circuit transports blood to and from the lungs, where it picks up oxygen and delivers carbon dioxide for exhalation. The systemic circuit transports oxygenated blood to virtually all of the tissues of the body and returns relatively deoxygenated blood and carbon dioxide to the heart to be sent back to the pulmonary circulation. (Figure 1.19)

1.5.2 Heart Tissue

The wall of the heart is composed of three layers of unequal thickness. From superficial to deep, these are the epicardium, the myocardium, and the endocardium (Figure 1.20). The outermost layer of the wall of the heart is also the innermost layer of the pericardium, the epicardium, or the visceral pericardium. The swirling pattern of cardiac muscle tissue contributes significantly to the heart's ability to pump blood effectively. The middle and thickest layer is the myocardium, made largely of cardiac muscle cells. It is built upon a framework of collagenous fibres, plus the blood vessels that supply the myocardium and the nerve fibres that help regulate the heart. It is the contraction of the myocardium that pumps blood through the heart and into the major arteries. The muscle pattern is elegant and complex, as the muscle cells swirl and spiral around the chambers of the heart. They form a figure 8 pattern around the atria and around the bases of the great vessels. Deeper ventricular muscles also form a figure 8 around the two ventricles and proceed toward the apex(Figure 1.21) Although the ventricles on the right and left sides pump the same amount of blood per contraction, the muscle of the left ventricle is much thicker than that

of the right ventricle (Figure 1.22). In order to overcome the high resistance required to pump blood into the long systemic circuit, the left ventricle must generate a great amount of pressure. The right ventricle does not need to generate as much pressure since the pulmonary circuit is shorter and provides less resistance.

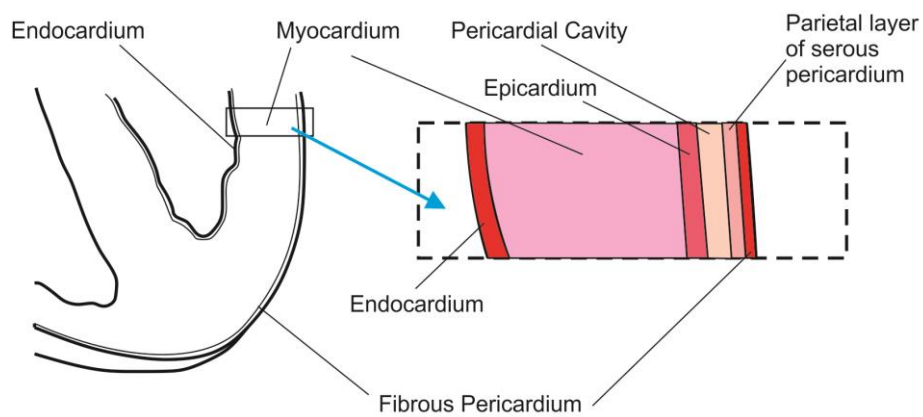


Figure 1. 20 Heart Tissue Layers

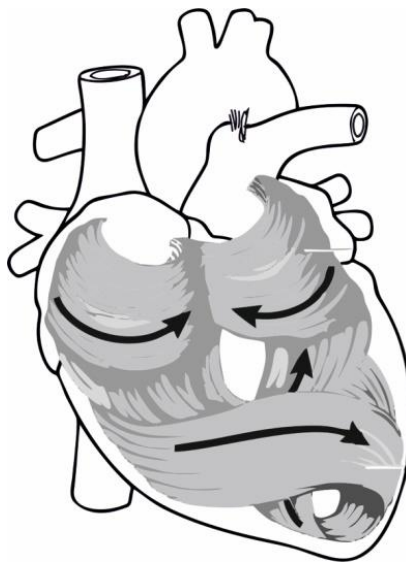


Figure 1. 21 Swirling Pattern of cardiac muscle tissue

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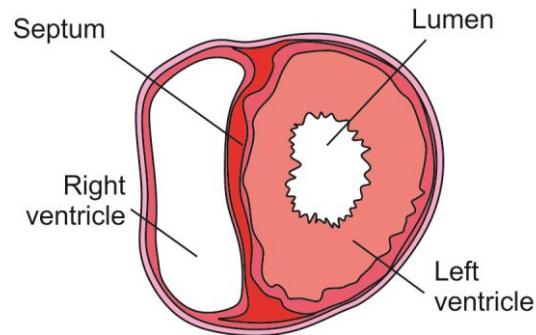


Figure 1. 22 The Heart section through the ventricles

1.5.3 Septa of the Heart

Septum refers to a wall or partition that divides the heart into chambers (Figure 1.23). The septa are physical extensions of the myocardium lined with the endocardium. Located between the two atria is the inter-atrial septum. Between the two ventricles, there is a second septum known as the inter-ventricular septum. Unlike the inter-atrial septum, the inter-ventricular septum is normally intact after its formation during fetal development. It is substantially thicker than the interatrial septum since the ventricles generate far greater pressure when they contract.

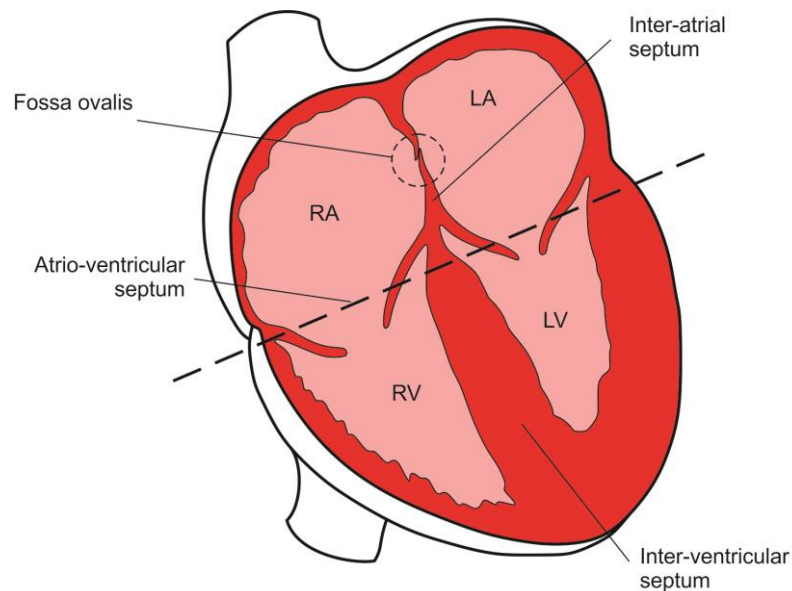


Figure 1. 23 The Heart section through the four chambers

The septum between the atria and ventricles is known as the atrioventricular septum. It is marked by the presence of four openings that allow blood to move from the atria into the

ventricles and from the ventricles into the pulmonary trunk and aorta. Located in each of these openings between the atria and ventricles is a valve, a specialized structure that ensures one-way flow of blood. The valves between the atria and ventricles are known generically as atrioventricular valves. The valves at the openings that lead to the pulmonary trunk and aorta are known generically as semilunar valves.

Since valves openings structurally weaken the atrioventricular septum, the area around valves is heavily reinforced with dense connective tissue called the cardiac skeleton, or skeleton of the heart (Figure 1.24). It includes four rings that surround the openings between the atria and ventricles, and the openings to the pulmonary trunk and aorta, and serve as the point of attachment for the heart valves. The cardiac skeleton also provides an important boundary in the heart electrical conduction system.

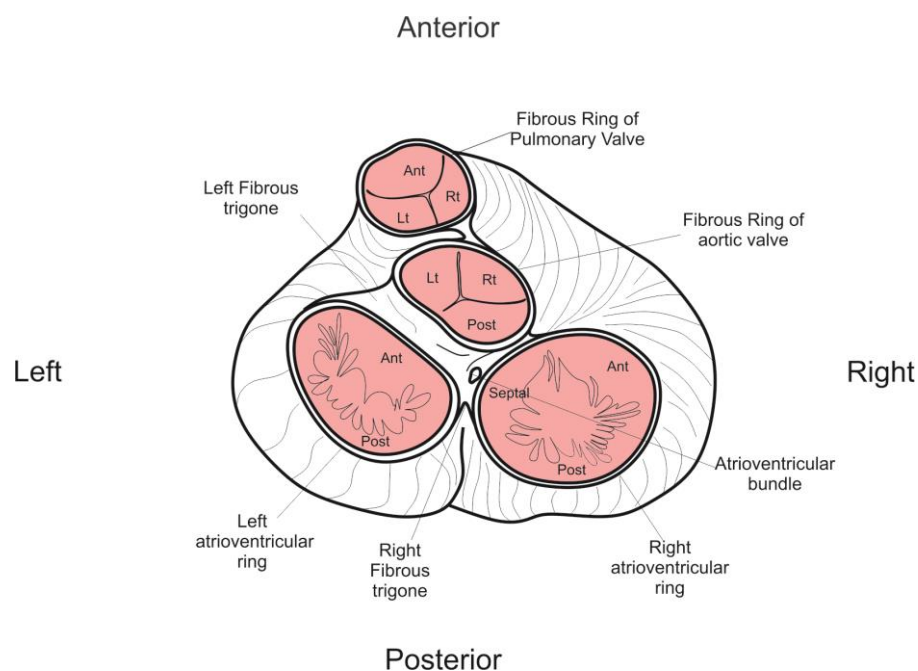


Figure 1. 24 Cardiac skeletons made of dense tissue holding the valves

1.5.4 Heart Valves

In order to maintain unidirectional flow of blood, the heart has four valves: The two atrioventricular (AV) valves, the mitral valve(bicuspid valve), and the tricuspid valve, which are between the upper chambers (atria) and the lower chambers (ventricles). The two semilunar (SL) valves, the aortic valve and the pulmonary valve, which are in the arteries leaving the heart.

The four heart valves include, Tricuspid valve (Figure 1.25) is located between the right atrium and the right ventricle. Mitral valve (1.26) is located between the left atrium and the left ventricle. It has only two leaflets. Pulmonary valve (Figure 1.27 a) is located between the right ventricle and the pulmonary artery. Aortic valve (Figure 1.27b) is located between the left ventricle and the aorta. As the heart muscle contracts and relaxes, the valves open and shut, letting blood flow into the ventricles and atria at alternate times.

Valves in the heart open and close passively, not through muscle contraction. They open when a forward pressure pushes against them and close when a backward pressure pushes against them. The valves are attached to muscles, called papillary muscles, which are attached to the wall of the ventricle and contract when the heart muscle contracts. Although the papillary muscles contract, they do not open or close the valves.

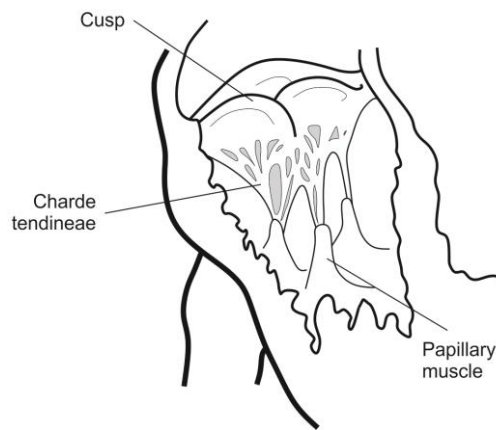


Figure 1. 25 Tricuspid Valve

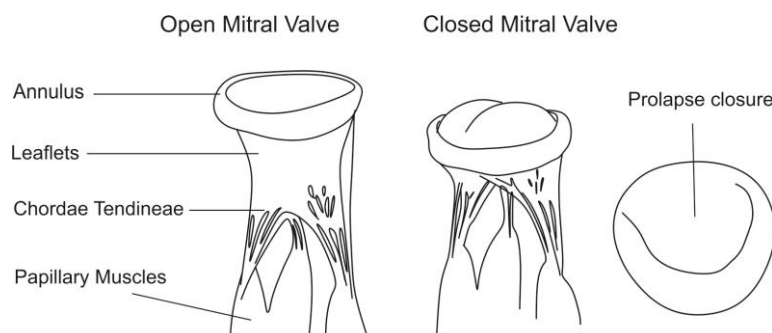


Figure 1. 26 Mitral Valve details

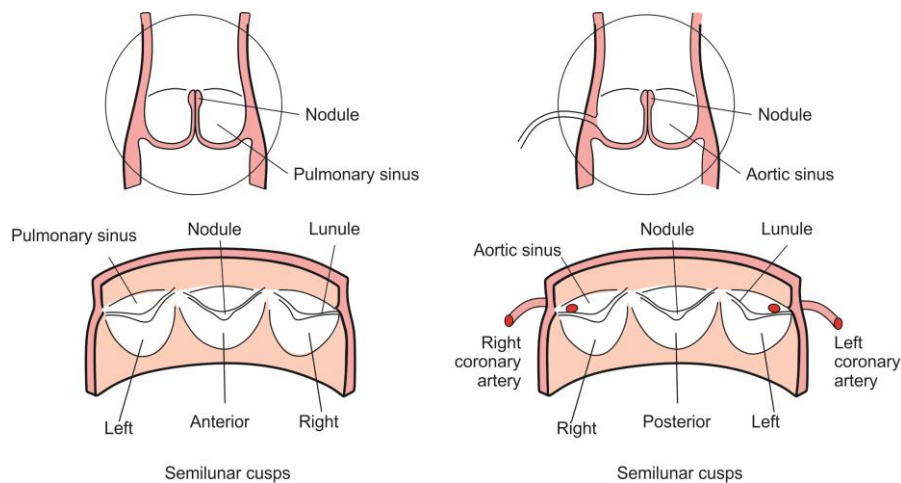


Figure 1.27 Semilunar valves: (a) Pulmonary and (b) Aortic

1.5.5 Blood circulation

Blood circulation is the primary function of the heart. There are three types of circulations: Systemic circulation, pulmonary circulation, and Coronary Circulation. Systemic circulation supplies oxygenated blood to the whole body and returns the deoxygenated blood back to heart through superior and inferior vena cava (Figure 1.27). Pulmonary circulation sends the deoxygenated blood to the lungs and brings back oxygenated blood back to the heart. The right ventricle pumps deoxygenated blood into the pulmonary trunk, which leads toward the lungs and bifurcates into the left and right pulmonary arteries. These vessels in turn branch many times before reaching the pulmonary capillaries, where gas exchange occurs: Carbon dioxide exits the blood and oxygen enters. The pulmonary trunk arteries and their branches are the only arteries in the post-natal body that carry relatively deoxygenated blood. Highly oxygenated blood returning from the pulmonary capillaries in the lungs passes through a series of vessels that join together to form the pulmonary veins—the only post-natal veins in the body that carry highly oxygenated blood. The pulmonary veins conduct blood into the left atrium, which pumps the blood into the left ventricle, which in turn pumps oxygenated blood into the aorta and on to the many branches of the systemic circuit. Eventually, these vessels will lead to the systemic capillaries, where exchange with the tissue fluid and cells of the body occurs. In this case, oxygen and nutrients exit the systemic capillaries to be used by the cells in their metabolic processes, and carbon dioxide and waste products will enter the blood.

The blood exiting the systemic capillaries is lower in oxygen concentration than when it entered. The capillaries will ultimately unite to form venules, joining to form ever-larger veins, eventually flowing into the two major systemic veins, the superior vena cava, and the inferior vena cava, which return blood to the right atrium. The blood in the superior and inferior venae cavae flows into the right atrium, which pumps blood into the right ventricle. This process of blood circulation continues as long as the individual remains alive. Understanding the flow of blood through the pulmonary and systemic circuits is critical to all health professions.

Coronary circulation is a dedicated blood supply to power heart tissues (Figure 1.28). Heart functions ceaselessly throughout life, needs blood supply is even greater than for a typical cell. Coronary arteries supply blood to the myocardium and other components of the heart. The first portion of the aorta after it arises from the left ventricle gives rise to the coronary arteries. There are three dilations in the wall of the aorta just superior to the aortic semilunar valve. Two of these, the left posterior aortic sinus and anterior aortic sinus, give rise to the left and right coronary arteries, respectively. The third sinus, the right posterior aortic sinus, typically does not give rise to a vessel.

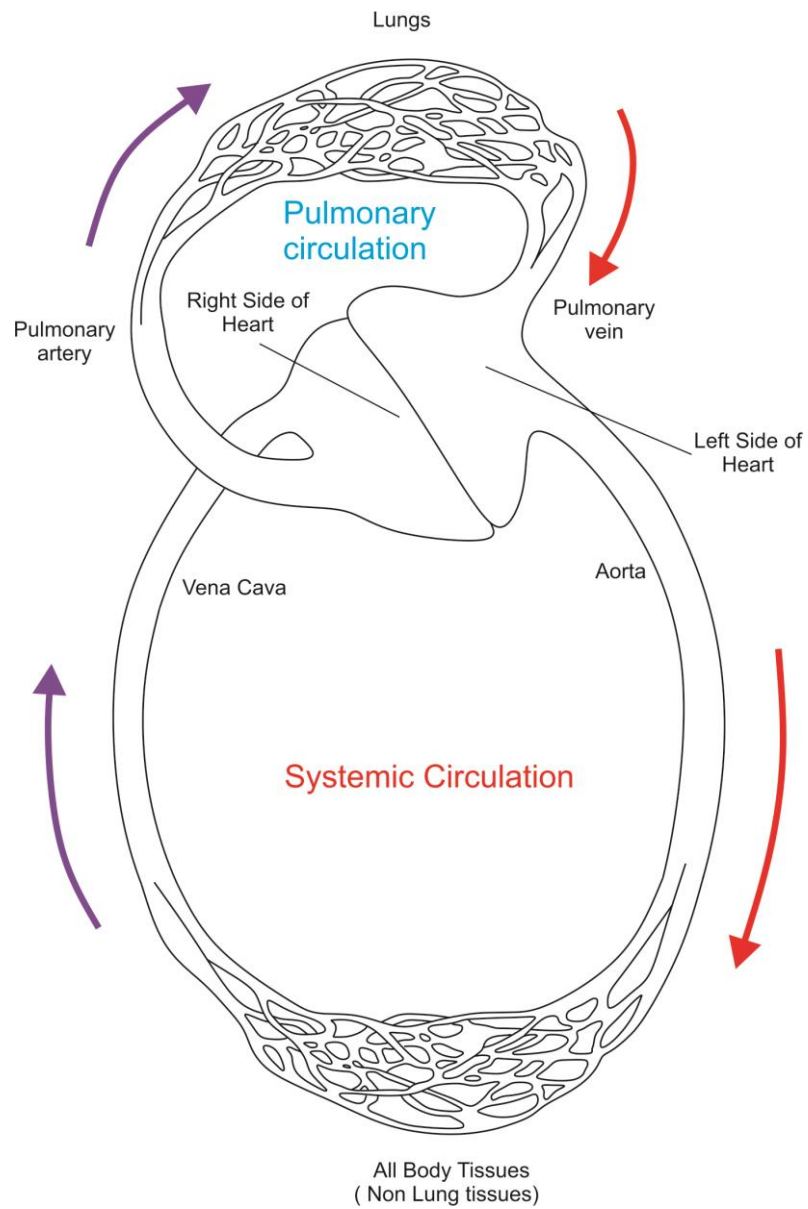


Figure 1. 28 Pulmonary & Systemic Blood Circulation

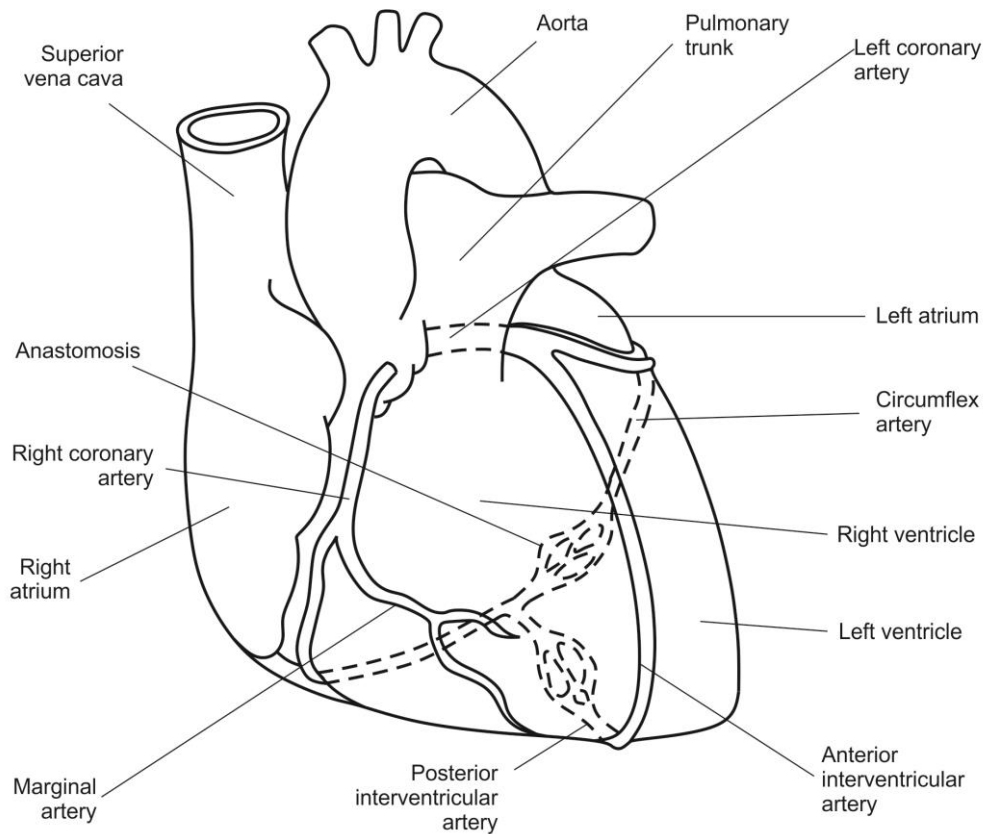


Figure 1. 29 Coronary blood supply

1.6 Heart Diseases

Heart diseases are broadly classified (based on causes of occurrence) as conduction, structural, and functional defects. Conduction disorders pertain to the electrical signals and the maintenance of the rhythm of heartbeats. Functional disorders pertain to heart muscles. Structural defects are also called congenital heart diseases (CHD) – defects of heart found at birth. They are also called congenital heart anomaly or defect. In our research study, we restrict our scope to congenital heart diseases.

1.6.1 Congenital Heart Diseases (CHD)

CHD occurrence is 28% (global average) of all the birth defects (Bajolle, Zaffran, & Bonnet, 2009). The incidence of CHD in general population is about 8 per 1000 live births and incidence of critical CHD needing immediate care is about 2 per 1000 (Bernier, Stefanescu, Samoukovic, & Tchervenkov, 2010). However, there is no account of the occurrence of stillborn babies due to CHD (Jorgensen et al., 2014).

The study on CHD is important due to their unique manifestations (ref) . The causes of CHD are many times not clear. The defects are caused due to structural, chromosomal, genetic, biochemical reasons.

These defects have origins at the fetal stage (Bajolle et al., 2009) and may affect the normal heart function, namely blood pumping. The fetal heart development goes on till full-term pregnancy and sometimes few features get completed beyond birth. For any reason, if the development is not in sync with the full term, it will be considered defective.

Some of the main risk factors causing CHD are rubella infection (Duszak, 2009), poor maternal nutrition during pregnancy (G. Wu, Bazer, Cudd, Meininger, & Spencer, 2004) and/or the occurrence of some form of CHD in either of the child's parents (Higgins, 1965).

1.6.2 CHD Classifications

Based on severity, CHD is classified as Severe, Moderate and Mild CHD.

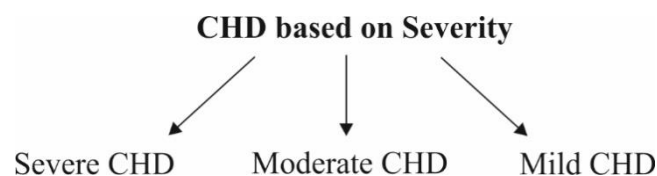


Figure 1. 30 CHD Classification based on Severity

In Severe CHD, the infants will need urgent medical care or surgery. Some of them may not survive till the help arrives. They further fall into two categories: Cyanotic & cyanotic. (Hoffman & Kaplan, 2002). In Moderate CHD cases, the patients need expert care but are less critical. They are detected by a clinical study. In Mild CHD cases, the patients show no symptoms (asymptomatic) and are cured over time or live with their problems.

CHD is also classified as simple and complex CHD. Simple CHDs are easily detectable and less risky. Some of the simple structural heart defects include Patent Foramen Ovale (PFO), Atrial Septal defect (ASD), Ventricular Septum Defect (VSD), Patent Ductus

Arteriosus (PDA), Valve Abnormality and Abstrain's anomaly. Complex CHD are usually combination defects, which are harder to detect and are riskier. Some of the complex defects include Patent Foramen Ovale (PFO), Tetralogy of Fallot (TOF), Transpose of Great Arteries (TGA), Double Outlet Right Ventricle (DORV), Total Anomalous Pulmonary Venous Return (TAPVR) and Total Anomalous Pulmonary Venous Connection (TAPVC). Since structural heart diseases occur as combinations (simple & complex) both types are important for the study. A brief study of each of the defects is necessary to gain insights into defect morphology.

Patent Foramen Ovale (PFO) is a birth defect of the opening in the atrium wall (interatrial septum). This occurs if the wall (septum primum) does not close at birth. The fetal heart needs this opening (Fossa Ovalis) to maintain proper blood circulation. It may be harmless (benign) or show no symptoms (asymptomatic) and get ignored without being diagnosed. In extreme cases, it may require surgical repair to close the opening permanently. As much as 20–25 per cent of the general population may have a PFO. However, they are not a serious concern as most of them are harmless. PFO is normally detected by hearing abnormal heart sound (murmur) reconfirmed by imaging with an echocardiogram. Despite its prevalence in the general population, the causes of PFO are unknown. It is better to monitor the condition and decide the next course of action.

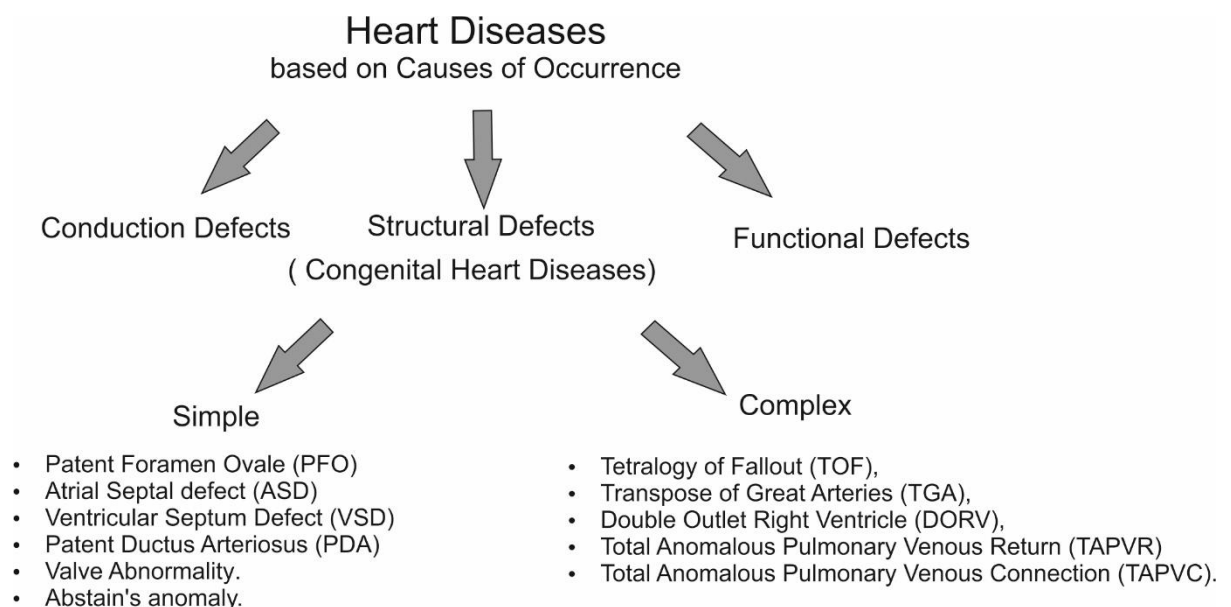


Figure 1. 31 Heart Disease Types

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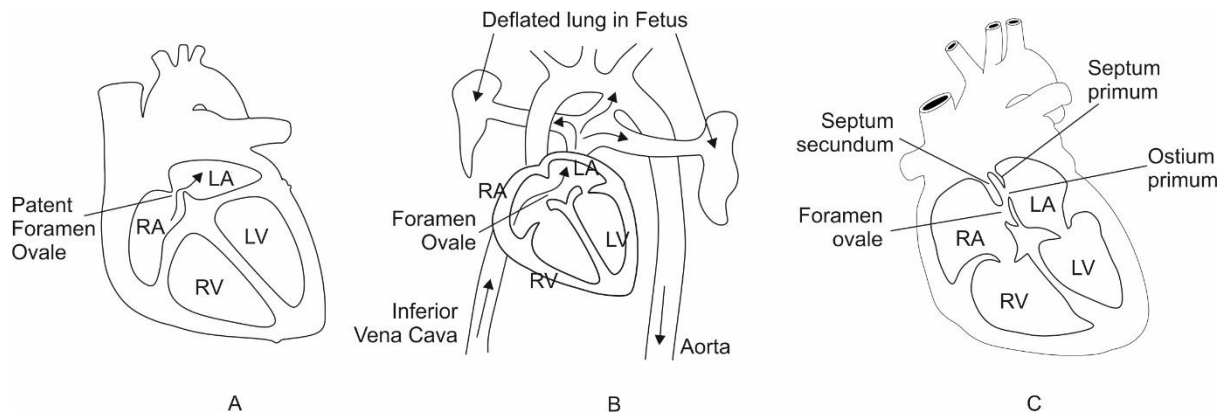


Figure 1.32 Patent Foramen Ovale; B: Fetal condition; C: Details of the septum

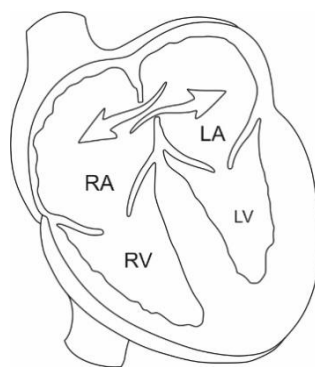


Figure 1.33 : Atrial Septal Defect

Atrial Septal Defect (ASD) is a birth defect very similar to patent foramen ovale. They are identified by the occurrence of large hole (diameter 5mm and above) between right and left atrium. In most many cases, ASD gets resolved with age. If it does not close, surgical / catheter-based procedures are used to plug the hole.

While there are more types of defects identified, few are frequently occurring complex defects, are given with description in Annexure III

1.6.3. Embryonic Genesis of the heart defects

The prenatal development of the human heart begins with the formation of two endocardial tubes which merge to form the tubular heart, also called the primitive heart tube. The tube loops and separates into the four chambers and paired arterial trunks that form the adult heart. The heart is the first functional organ which starts beating by week 4 of development.

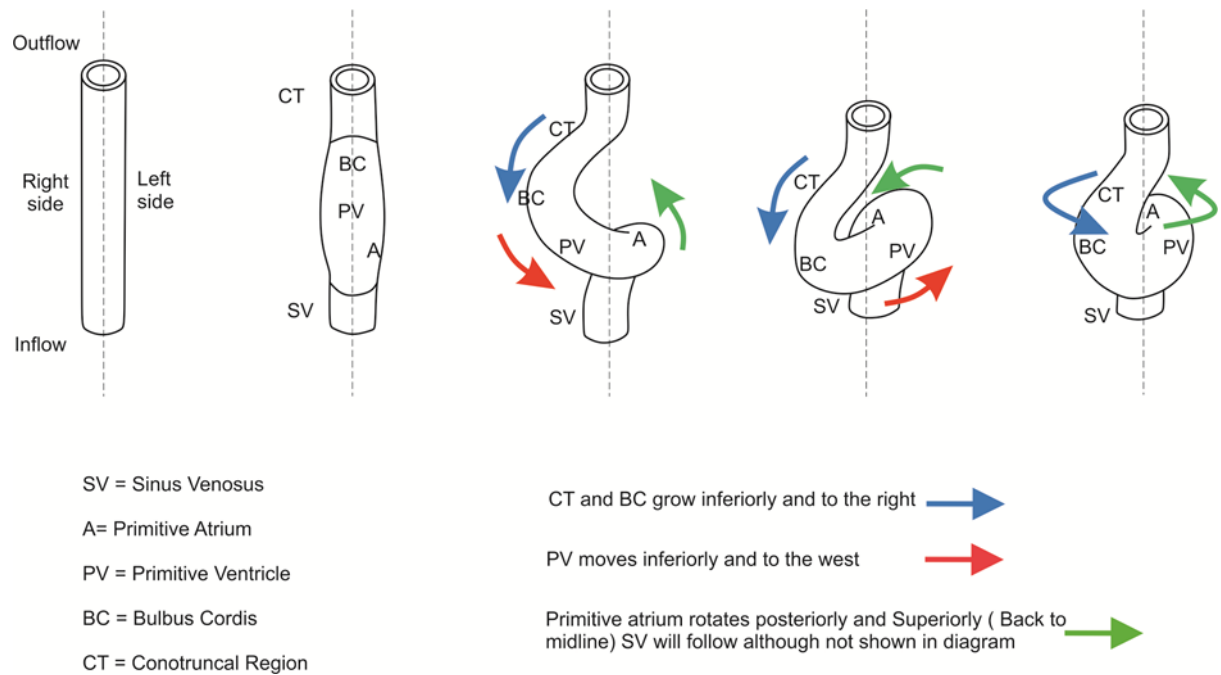


Figure 1. 34 Heart Development from a Tube

The tubular heart can be differentiated into the truncus arteriosus, bulbus cordis, primitive ventricle, primitive atrium, and the sinus venosus.

The truncus arteriosus splits into the ascending aorta and pulmonary artery. The bulbus cordis forms part of the ventricles. The sinus venosus connects to the fetal circulation. The heart tube elongates on the right side, looping and becoming the first visual sign of left-right asymmetry of the body. Septa form within the atria and ventricles to separate the left and right sides of the heart.

At around 18 to 19 days after fertilization, the heart begins to form. This early development is critical for subsequent embryonic and prenatal development. The heart is the first functional organ to develop and starts to beat and pump blood at around day 21 or 22

Following cell signalling, two strands or cords begin to form in the cardiogenic region. As these form, a lumen develops within them, at which point, they are referred to as endocardial tubes. Within tubes are forming other major heart components. The two tubes migrate together and fuse to form a single primitive heart tube, the tubular heart which quickly forms five distinct regions. From head to tail, these are the truncus arteriosus, bulbus cordis, primitive ventricle, primitive atrium, and the sinus venosus. In the

beginning, all venous blood flows into the sinus venosus, and contractions propel the blood from tail to head, or from the sinus venosus to the truncus arteriosus. The truncus arteriosus will divide to form the aorta and pulmonary artery; the bulbus cordis will develop into the right ventricle; the primitive ventricle will form the left ventricle; the primitive atrium will become the front parts of the left and right atria and their appendages, and the sinus venosus will develop into the posterior part of the right atrium, the sinoatrial node, and the coronary sinus

The heart tube continues stretching and by day 23, in a process called Morphogenesis or Cardiac Looping. The cephalic portion curves in a frontal clockwise direction. The atrial portion starts moving in a cephalic ally and then moves to the left from its original position. This curved shape approaches the heart and finishes its growth on day 28.

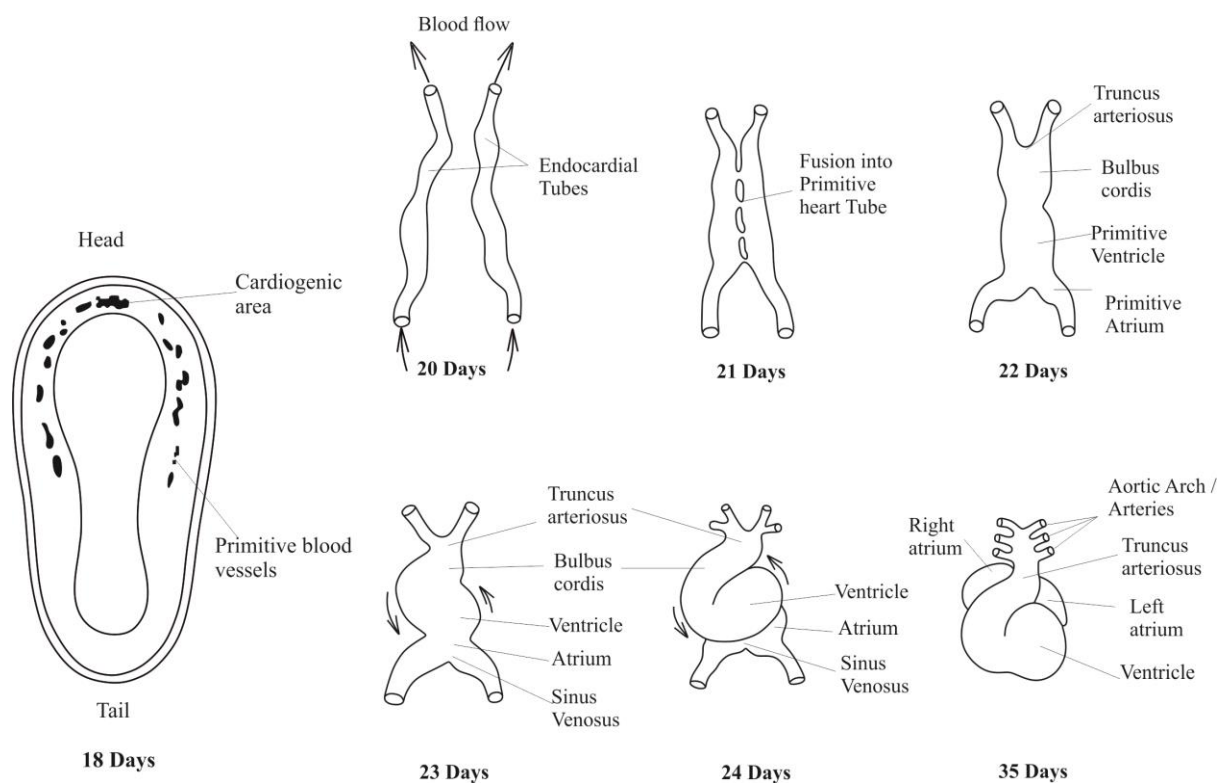


Figure 1. 35 Day wise Fetal Heart Development

Thus the development of heart is a complex process and any disruptions along the way can result in congenital disorders of the heart. Such disorders account for 50% of all deaths from birth defects.

The fetal blood flow has 3 bypasses to ensure good blood supply to a growing child and these are called as Shunts. There are three major shunts—alternate paths for blood flow—found in the circulatory system of the fetus. Two of these shunts divert blood from the pulmonary to the systemic circuit, whereas the third connects the umbilical vein to the inferior vena cava.

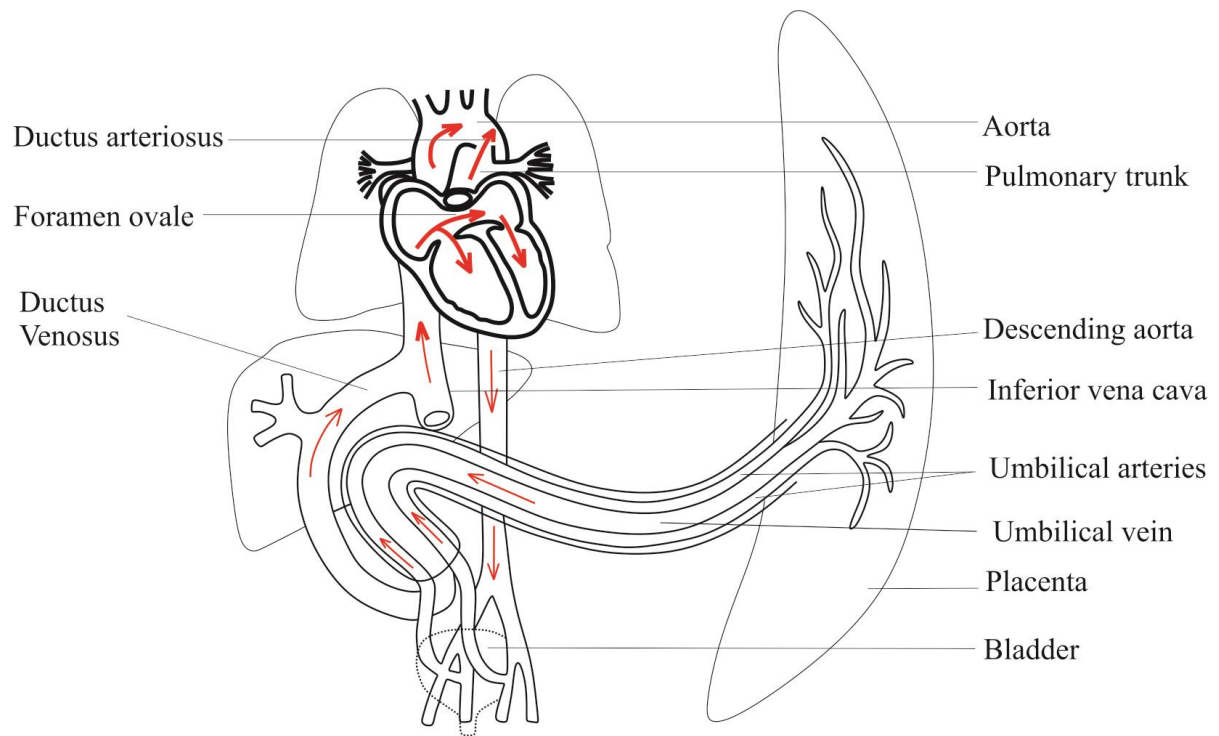


Figure 1. 36 Fetal Blood Circulation

The first two shunts are critical during fetal life when the lungs are compressed, filled with amniotic fluid, and is nonfunctional, and gas exchange is provided by the placenta. These shunts close shortly after birth, however, when the newborn begins to breathe. The third shunt persists a bit longer but becomes nonfunctional once the umbilical cord is severed. The three shunts are as follows:

The foramen ovale is an opening in the interatrial septum that allows blood to flow from the right atrium to the left atrium. A valve associated with this opening prevents backflow of blood during the fetal period. As the newborn begins to breathe and blood pressure in the atria increases, this shunt closes. The fossa ovalis remains in the interatrial septum after birth, marking the location of the former foramen ovale.

The ductus arteriosus is a short, muscular vessel that connects the pulmonary trunk to the aorta. Most of the blood pumped from the right ventricle into the pulmonary trunk is thereby diverted into the aorta. Only enough blood reaches the fetal lungs to maintain the developing lung tissue. When the newborn takes the first breath, the pressure within the lungs drops dramatically, and both the lungs and the pulmonary vessels expand. As the quantity of oxygen increases, the smooth muscles in the wall of the ductus arteriosus constrict, sealing off the passage. Eventually, the muscular and endothelial components of the ductus arteriosus degenerate, leaving only the connective tissue component of the ligamentum arteriosum.

The ductus venosus is a temporary blood vessel that branches from the umbilical vein, allowing much of the freshly oxygenated blood from the placenta—the organ of gas exchange between the mother and fetus—to bypass the fetal liver and go directly to the fetal heart. The ductus venosus closes slowly during the first weeks of infancy and degenerates to become the ligamentum venosum.

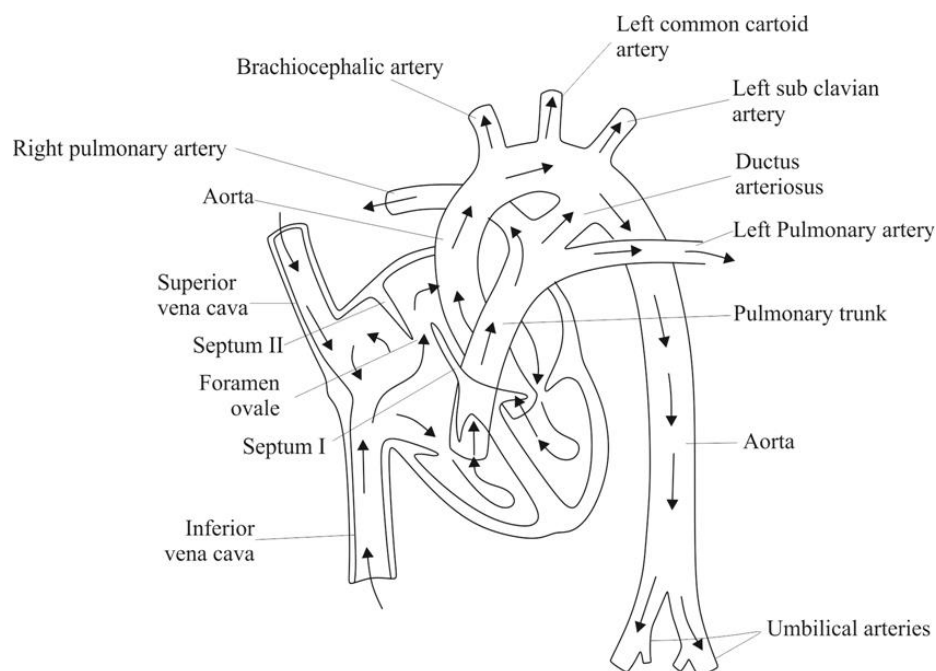


Figure 1. 37 Fetal heart circulation - details

A fetus receives oxygen not from its lungs, but from the mother's oxygen-rich blood via the placenta. Oxygenated blood from the placenta travels through the umbilical cord to the right atrium of the fetal heart. As the fetal lungs are non-functional at this time, it is more efficient for the blood to bypass them. This is accomplished through 2 cardiac shunts. The first is the foramen ovale which shunts blood from the right atrium to the left atrium. The second is the ductus arteriosus which shunts blood from the pulmonary artery (which, after birth, carries blood from the right side of the heart to the lungs) to the descending aorta.

In about 25% of adults, the foramen ovale does not close completely but remains as a small patent foramen ovale ("PFO").[In most of these individuals, the PFO causes no problems and remains undetected throughout life.

PFO has long been studied because of its role in embolism leading to a stroke or transient ischemic attack. Transesophageal echocardiography (TEE) is considered the most accurate investigation to demonstrate a patent foramen ovale.

Chantale Lapierre et al (2010) reviews the segmental approach to imaging congenital heart disease in which the cardiac anatomy is evaluated in 3 Steps: Determination of **Visceroatrial Situs**, Ventricular **orientation left or right** (D or L) and Position of **Great Vessels** (Aorta & Pulmonary Artery)

The Segmental approach to study defective heart was first proposed by Van Praagh (1972). He developed a notation system with 3 letters separated by commas within a parenthesis. { X, Y, Z}; X stands for The Situs which can be S (Solitus), I (Inversus) and A (Ambiguous)). Y stands ventricular loop (D loop & L loop) for and Z stand for Origin and position of Great Vessels. S for Solitus, Inversus and transpositions D-TGV, L-TGV, D-MGV, and L-MGV.

In the case of normal Heart, the notation is {S, D, S} for visceroatrial situs **Solitus**, ventricular **D loop**, and **Solitus** normal great arteries.

Paul M. Weinberg (2016) in his article in <https://thoracickey.com/anatomy-and-classification-of-congenital-heart-disease/> has provided easy to understand Van Praag notation as given below:

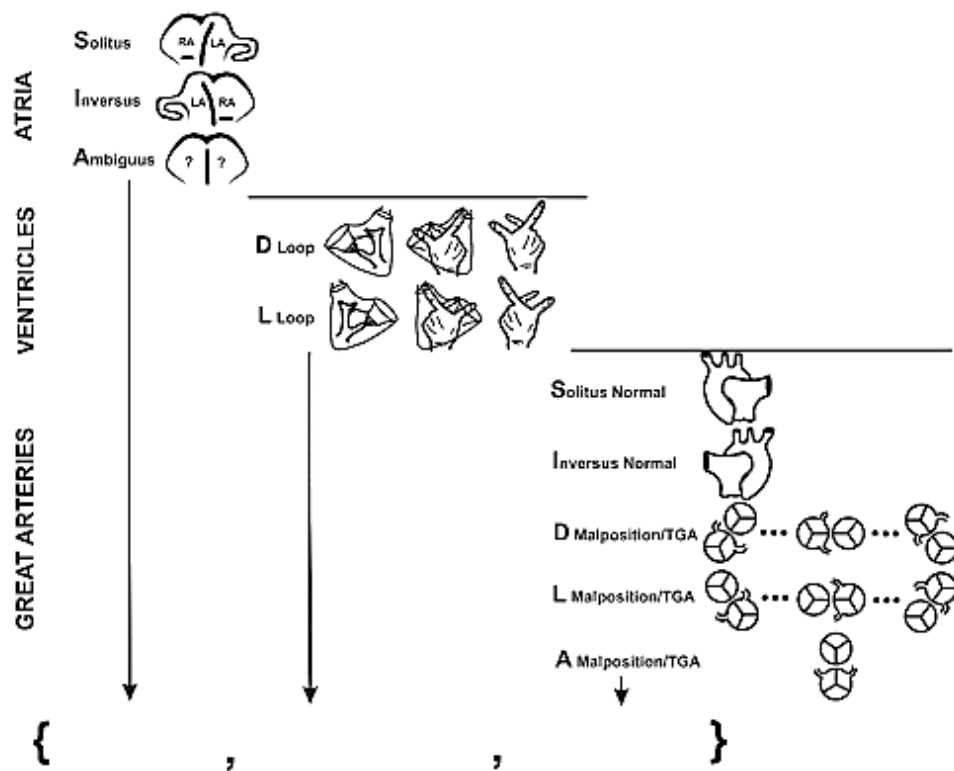


Figure 1. 38 Van Praag Notation explained

TYPES OF HUMAN HEART: Segmental Sets and Alignments

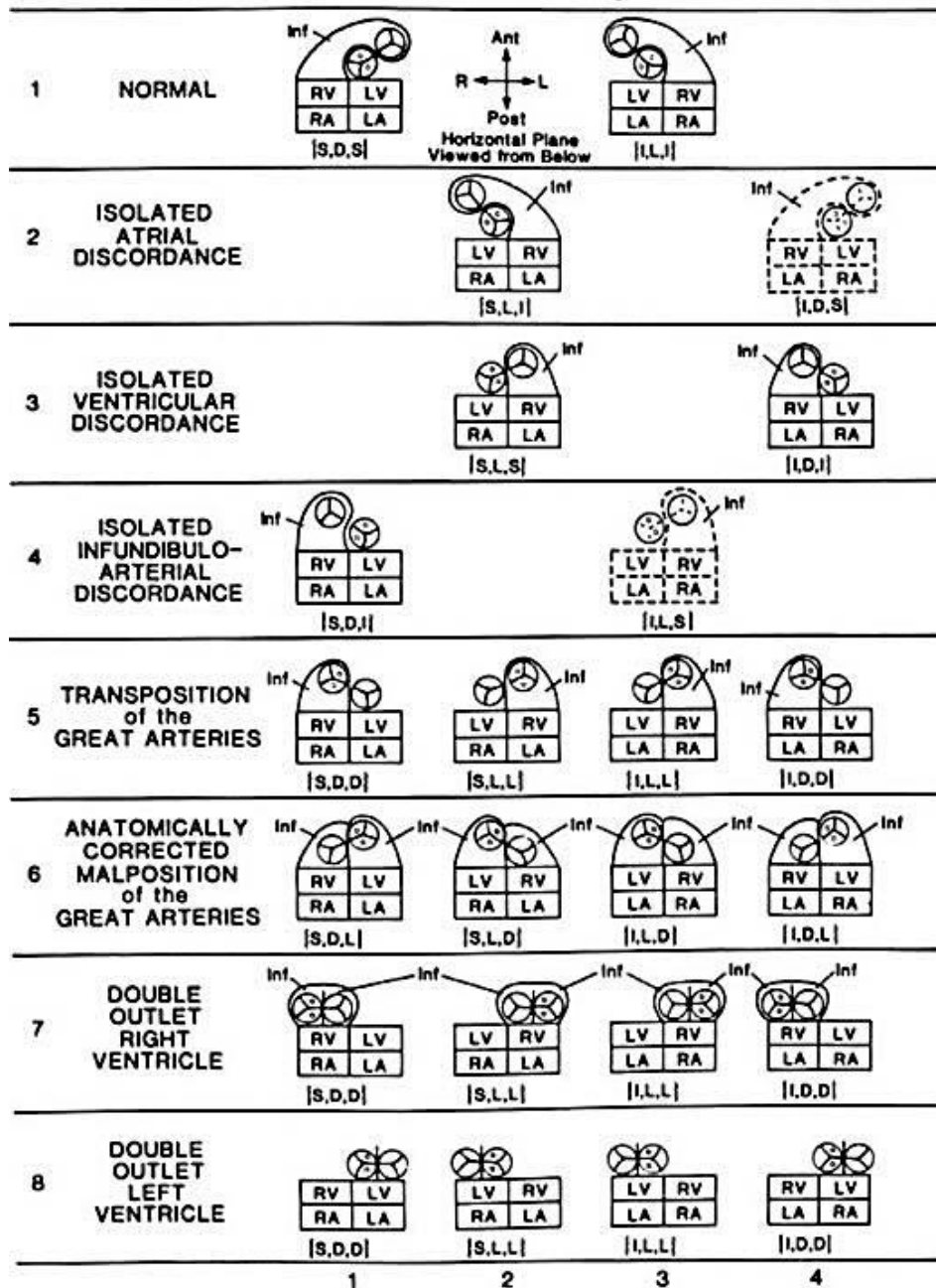


Figure 1. 39 Van Praag CHD classification

From Foran RB, Belcourt C, Nanton MA, et al. (1988) Types of the human heart in terms of segmental sets (combinations) and segmental alignments. Heart diagrams are viewed from below, as would be achieved with a subxiphoid two-dimensional echocardiogram. The aortic valve is indicated by the coronary ostia. The pulmonary valve is indicated by the absence of coronary ostia.

Braces {} mean “the set of.” The columns (1 to 4) are arranged in terms of atrioventricular (AV) concordance or discordance.

Column 1 (i.e., {S,D,-}) has AV concordance in viscerotrial situs solitus.

Column 2 (i.e., {S,L,-}) has AV discordance in viscerotrial situs solitus.

Column 3 (i.e., {I,L,-}) has AV concordance in viscerotrial situs inversus.

Column 4 (i.e., {I,D,-}) has AV discordance in viscerotrial situs inversus.

Situs ambiguous of the viscera and atria in the heterotaxy syndromes, particularly with asplenia (i.e., {A,D,-} and {A,L,-}) is omitted; the concepts of AV concordance and AV discordance do not apply in viscerotrial situs ambiguous because the frame of reference, the type of viscerotrial situs, is uncertain or unknown. The rows (1 to 8) are organized in terms of the types of ventriculoarterial (VA) alignment. Normal concordant VA alignments are depicted in rows 1 to 4. Abnormal concordant VA alignments are shown in row 6 and concern anatomically corrected malposition of the great arteries. Discordant VA alignments are depicted in row 5 and concern transposition of the great arteries. Double outlets are shown in rows 7 and 8, double-outlet right ventricle in row 7, and double-outlet left ventricle in row 8. All associated malformations are omitted for diagrammatic simplicity and clarity. Ant, anterior; Inf, infundibulum; LA, morphologically left atrium; L, left; LV, morphologically left ventricle; Post, posterior; R, right; RA, morphologically right atrium; RV, morphologically right ventricle.

In the present study, we focus on Complex conditions and explore how the models aid the clinical management. We deal with this topic in more detail in Chapter 2 as a literature study.

1.7 Scope of Research Study

This research work scope is to study the gaps in the current workflow to make an accurate model by 3D printing, investigate new and optimal methods for quick defect isolation and sectioning to make visualization accurate. The outcomes are validated through live case studies.

1.71 Organization of Thesis

This chapter introduces the role of prototyping design in general and in medical visualization particularly with a focus on Congenital Heart Diseases. The Chapter explores various visualization options available with relative merits/demerits. Since the focus on anatomy is the heart, detailed information on the heart is included to set the context and provide a sound theoretical foundation. The chapter closes with the overall organization of the thesis.

Chapter 2: Provides a review of existing methods to reconstruct cardiac models from medical imaging data, the use of 3-D printing from the literature. They help to understand the problem context in detail. A critical review identifies the gaps and opportunities for more work towards making accurate patient-specific heart models.

Chapter 3: The gaps previously identified form our opportunity. We define the problem and steps to solve the problem. Thus, this chapter delineates the goal and specific objectives of this research work, followed by the Methodology and scope of investigations.

Chapter 4: Presents the identification of various factors that influence the accuracy of a medical model. We formulate an approach to fabricate an accurate patient-specific model by controlling the influencing factors. Propose an optimum process workflow and validate it.

Chapter 5: Presents an approach to isolate defects based on the embryonic development of the heart, devise section strategy to include all possible defects occurrence. Take optimum sections to check and validate models for defect morphology visualization.

Chapter 6: In order to validate models with optimum sections, we undertake clinical intervention studies or live Case Studies. 16 cases are studied and insights documented, shows the role of accurate models in CHD case management.

Chapter 7: We summarize the contributions from the present research study in this concluding chapter. We hope the study would aid technology adoption by clinicians and healthcare professionals. We also discuss limitations and future research opportunities.

Chapter 2. Literature review

As seen in the previous chapter, 3-D printing offers many opportunities in the medical field, in particular for visualizing and analyzing complex anatomical structures.

This chapter delves deeper into the previous work in this domain, analyzes the gaps and opportunities for further exploration. Medical Prototypes requirements, Medical visualization and tools for cardiac imaging with DICOM standard, 3-D printing workflow, 3-D printing in medicine, 3-D printing in CHD, 3-D printing in medical learning, approaches in medical model accuracy assessment form the large landscape of literature survey. The chapter ends with gaps observed.

2.1 Medical Prototypes requirements

From the literature, we know that the “prototype” is a widely used word, for conceptual models of varying fidelity in reference to manufacturing. The present work investigates the role of the prototype in healthcare or medical domain.

The medical domain focuses on a living system, the human body, which is an organization of many subsystems that are interconnected. The initial learning comes from the accounts of those who had a chance to peep into the internal structures. Those who saw drew the diagrams of the structures for future reference and communication. The animal killings for food evolved as a profession called butchery. The butchers had the opportunity to observe the internal structures. The similarity of a human with other mammals helps to know the working of the human body. The other profession which had artistry in cutting the human body was the barbers. Traditionally they trim, cut and style hair. and have acquired skills in careful use of Razor Knife, the forerunner of Scalpel. They were also commissioned for small surgeries for a ritual purpose such as Circumcision. From medical history, we can learn about the barber-surgeons who were common in middle ages who practised in Europe and the Middle East region. Those days, surgery was not conducted by physicians but by barbers. They were engaged to amputate limbs of wounded soldiers or condemned criminals. The early medical colleges used to have Professors who would explain with sketches and used to have barbers to assist in the

demonstration. The use of cadaver dissection for learning human anatomy was through indirect or dishonest means. Soon, formal approval by religion & law followed. It has remained as the golden standard to learn anatomy, be it for animals or humans. One of the main disadvantages of the cadaver sample is their perishability.

The Indian accounts on surgery can be traced to Ayurveda. “Caraka Samhita” (Priyadarajan Rây, M.A.; Hirendra Nath Gupta, 1965) has a complete account of healthcare including Surgery, Medicine, Heredity, Embryology and Ethics. “Sushruta Samhita” contains great details on surgical procedures (Rajgopal, Hoskeri, Bhuiyan, & Shyamkishore, 2002). We can find them as fragmented Sanskrit verses with no graphic representation. These need further research to know the progress they had achieved. They hint us an idea of the great progress made in ancient Indian medicine.

The dissected anatomy once cut became perishable, are sent to trash. Half cut samples were preserved with chemicals. Preservation helped in shelf life on the pre-cut samples but pose a lot of limitations. During this same time, many artists were also looking at the human internal structures to express human forms more realistically. They started making models out of wood, clay, and mixed media.

The machine tools which shaped materials have inherent limitations to produce organic forms and fail when the complexity crosses a threshold. Many worked in their hands, sculpting, polishing and shaping to fabricate anatomical models. Such models exist even today in biology education and medical education. While the models are good as educational aids, they were not accurate.

In the early 19th century, many published works included graphic details of the human body. Gray’s Anatomy is one of the most popular classic works used to the present day.

Hand sketches improved to provide more realism with shades, shadows and highlights. They also executed with colours matching to the original anatomy.

The Plastination is a technique developed by Gunther von Hagen’s (1977) to preserve anatomy parts. It involves the replacement of tissue water and fat by plastics. They provide models that are odour free, decay-free and retain properties of the original tissue.

X-Rays opened up a new way of learning anatomy, particularly the hard tissue, the Bones. They are true pictures of the limbs in full scale. Most X-Rays capture just one

view. To get a perception of the whole, one has to go for more views and rebuild a three-dimensional view in mind. This needs a skilled clinician for accurate visualization of the anatomy.

With the advent of computing and Medical Imaging, we are now able to digitally recreate the anatomy from a living subject. This has emerged as most popular and a noninvasive anatomical examination after X Rays.

Virtual digital models are useful for simulations and analysis. They, however, are not useful in real physical simulations such as the production of the broken bone condition and carry out surgical planning. While digital models can be very accurate, they can be sectioned virtually to explore sections. Radiologists are quite comfortable with virtual models. Here, CAD experience helps. As most Clinicians are not trained on CAD, this task is difficult to handle. Instead of CAD virtual models, they prefer 1:1 Physical model, which they can touch and feel, cut and re-arrange to arrive at a solution.

3-D printing technology, which builds models layer by layer, can help fabricate a reasonably accurate model from a digital model. 3D printed anatomical prototypes made in 1:1 in good resolution will not only help case surgeons who can plan the corrective procedure by looking at the model. They can cut & rearrange. These aspects of simulation prior a surgical procedure constitute Preoperative Planning (Farooqi & Mahmood, 2017)

Prototype in hand helps to toy with ideas, come up with better solutions. The Computing, Medical Imaging, and 3D printing technologies have made it possible to not only create accurate digital models but also hold them in hand for haptic exploration.

The requirement for prototypes in Medical / Healthcare comes from three main needs: Learning, Simulation, and Communication (Loke, Harahsheh, Krieger, & Olivieri, 2017). While one can understand its role in learning, simulation is very similar to the design process in which we look for solutions or alternate solutions. A medical procedure needs patient/ kin's consent and a prototype of defect condition is easy to explain the procedure to get a quick buy-in.

Peter Olejník et al (Olejník et al., 2017) add that 3-D printed models of cardiovascular anomalies can also be used as an invaluable teaching tool for paediatric cardiologists/cardiac surgeons as well as for medical students

This is also easy to communicate among the medical team involved in the case.

2.2 Medical Visualization and Tools

Medical visualization comprises nine independent types as listed below:

- a) Sketching
- b) Physical Models
- c) Photography
- d) Radiography
- e) Ultrasonography
- f) Nuclear Magnetic Resonance Imaging
- g) Endoscopy
- h) Digital Models
- i) 3-D Printed Models

2.2.1 Sketching

Sketching helps to learn and understand the anatomy. Noorafshan, Ali et al (2014) in their article titled “Simultaneous Anatomical Sketching as Learning by Doing Method of Teaching Human Anatomy” share that sketching with the tutor helps to learn and retain concepts better .

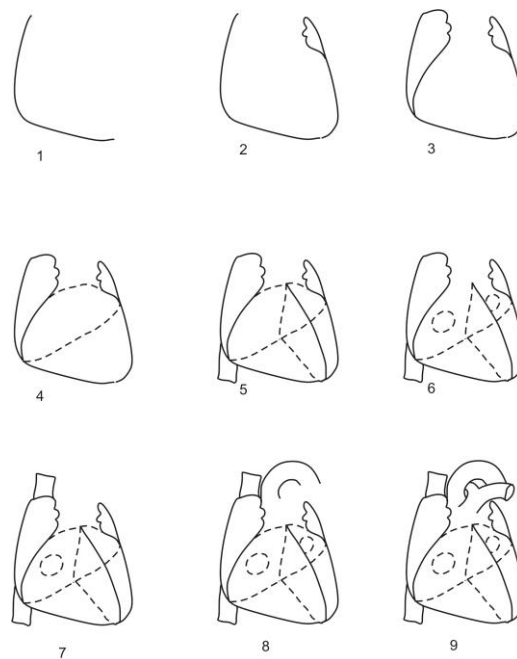


Figure 2. 1 Heart Anatomy Sketching and learning stages by Noorafshali, 2014

In their research study authors who were anatomy faculty, drew sketches on an overhead projector and the students were asked to draw simultaneously. An example of the teaching of heart anatomy is shown above figure. Anatomical points were explained and added to the sketches. At the end of the anatomy course, the students were asked to write their learning experiences. The students' views regarding the simultaneous anatomical sketching sessions were evaluated by means of a questionnaire. More than 80% of the students agreed or completely agreed that learning anatomy concepts are easier with this method. The student's satisfaction with simultaneous anatomical sketching sessions was higher than conventional slide projection and explanation.

Even in clinical practice, sketches support physicians in treatment planning. They are employed as direct annotations in medical image data. However, this approach may lead to occlusions in case of spatially complex 3-D representations. To overcome this limitation Patrick Saalfeld et al (2016) developed a framework which enables the physician to create annotations by freely sketching in the 3-D environment. For this, they made use of a semi-immersive stereoscopic display and a stylus with ray-based interaction techniques.

2.2.2 Physical Models

Cadaver specimens provide the best insight about the anatomical organs and are only next to live operations on a patient. Cadaver and bovine specimens are the most popular learning tools for anatomy and surgery.

Christopher Schulz (2017) enumerates the value of cadaveric dissection among PG students, which student learning through a process of self-discovery. Dissection fosters a spatial understanding, recognition for surgical tissue planes, and a tangible appreciation for the proximity of structures. These skills are very important to surgical students and practising surgeons.

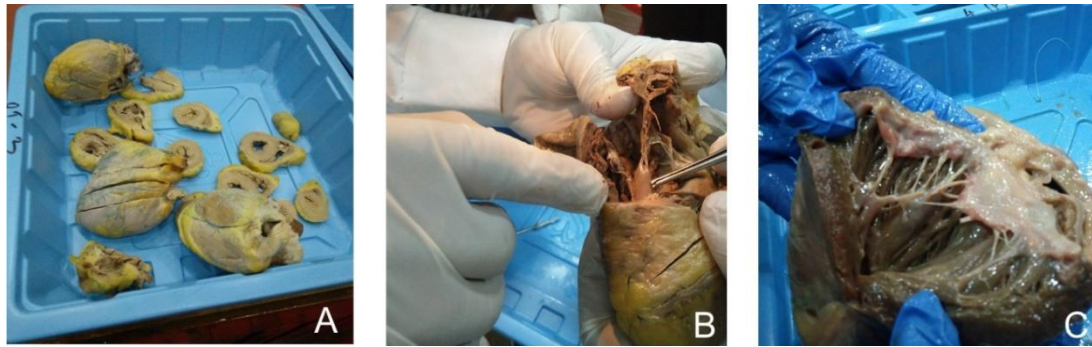


Figure 2. 2 : Heart Dissection: A: Bovine Hearts, B: Papillary Muscle , C: Chordae Tendeneae

Although dissection has played an important role in anatomy education for centuries, it demands a good investment of time and resources. They can also be emotionally disturbing for some students (McLachlan, J.C. et al , 2006). Christopher Schulz (2017) discusses the benefits of cadaveric dissection during PG surgical training.

Photography needs a physical model to be captured; it cannot capture a mental model. Photography brought-in accuracy, authenticity and made sketching obsolete. Colour photographs and current Digital Photographs have become so very vivid that they offer 3-D depth. Stereo photography further brings in the perception of Depth.

We can also have physical models derived from actual patient data with the help of CT and MRI DICOM data set. This needs medical image processing and post digital model we can 3-D print the anatomy. We will discuss medical imaging in the next section 2.1.3 followed by 3-D printing in 2.1.4.

2.2.3 Medical Imaging

Sebastien Hascoet et al (2016) in their study have investigated the main cardiac imaging landscape for congenital heart diseases during interventional procedures. Their study explores every procedure used starting from cardiac catheterization.

Cardiac Catheterization began as student exploration by Dr.Werner Forssmann and evolved as a diagnostic tool to study heart. It also became an alternative to surgery. It is widely used to percutaneous close the intracardiac shunts(Braile & Godoy, 2012).

Fluoroscopy allows real-time cardiac imaging and has been used for cardiac catheterization till date. Fluoroscopy has its own limitations such as high radiation dose, provides only 2-D views, and does not show smooth cardiac & vessel tissues. It only

shows contrast media and calcified lesions. atrial septal defect (ASD) and & ventricular septal defect (VSD) are poorly visualised.(Braile & Godoy, 2012)

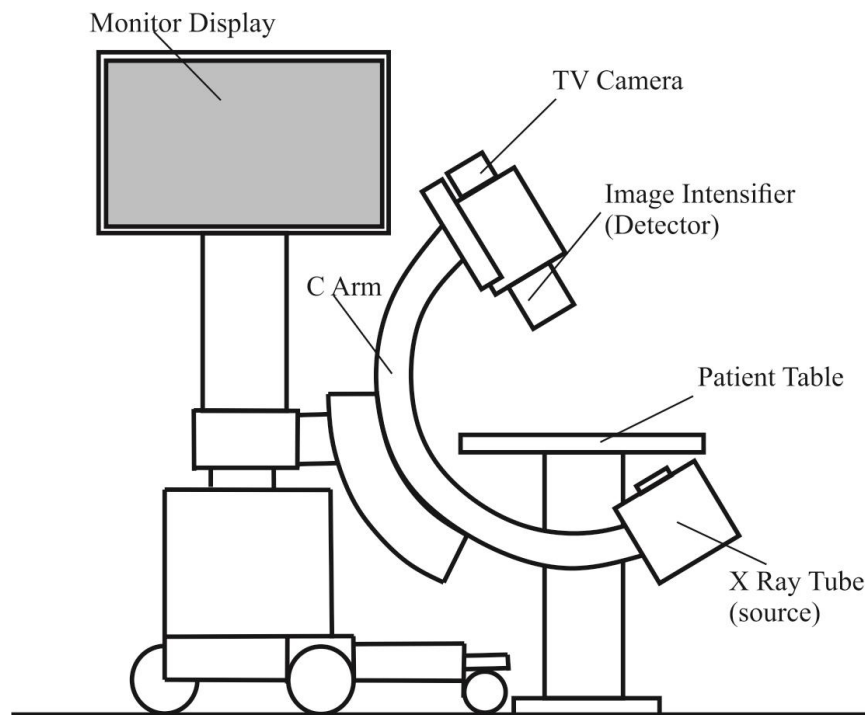


Figure 2. 3 : Fluoroscopy Setup

2-D & 3-D Echocardiography provides real-time without radiation risks. It has emerged as a multimodality Tool with 3D volume rendering and particularly good to see the valve functions clearly.

3-D rotational Angiography, Computed Tomography, Magnetic Resonance Imaging are some of the new technologies which provide greater control to explore anatomy. Together they form Multimodality or fusion imaging extending the power to visualize the rich cardiac morphology. (Doi, 2007)

Radiography is a process of making an internal organ or part visible for Medical applications. Radiography has been used since the discovery of X-rays in the early 19th century. Despite its harmful effects on living tissue, it is used due to its quick action, accurate, full-size non-invasive visualization. The X-ray can capture bone and such hard tissues without any interventions, Soft tissues are X-rayed by the introduction of a radio-opaque substance followed by radiography. The radio-opaque substance can be administered as a liquid by swallowing, injection or by enema. The computing power and

new technologies have further grown into better explorations of anatomy such as CT, Micro CT and Cone Beam CT.

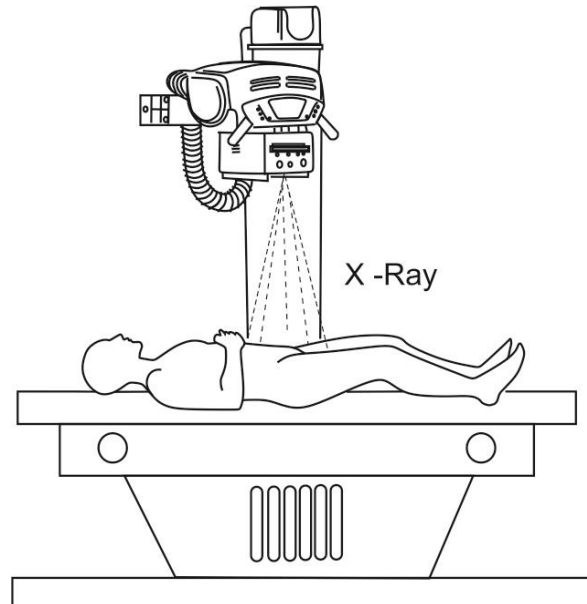


Figure 2. 4 : X-Ray imaging Setup

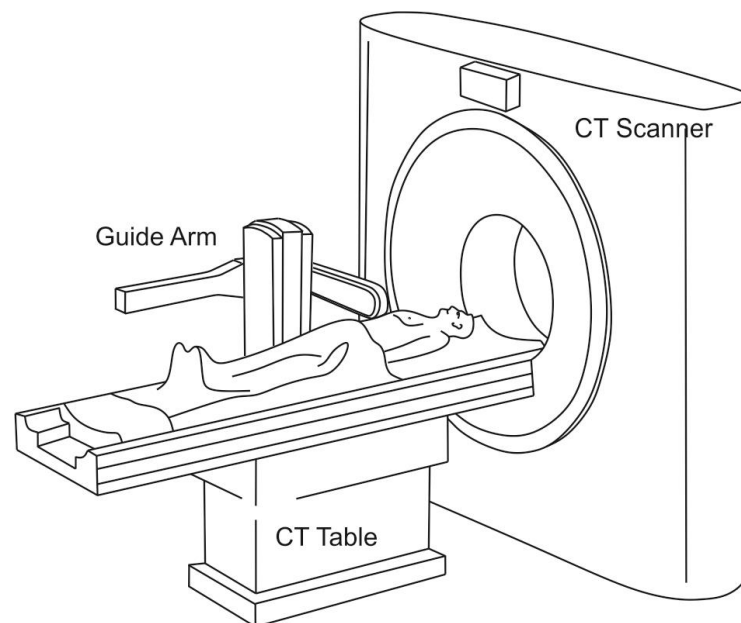


Figure 2. 5 : CT scan Imaging Setup

Ultrasonography is a procedure to capture the pictures of the inside of the body using sound waves. It is also called ultrasound imaging, ultrasound scanning or sonography. In this procedure, high-frequency sound waves are transmitted from the probe through a gel into the body. The transducer collects the sounds that bounce back and a computer then uses those sound waves to create an image.

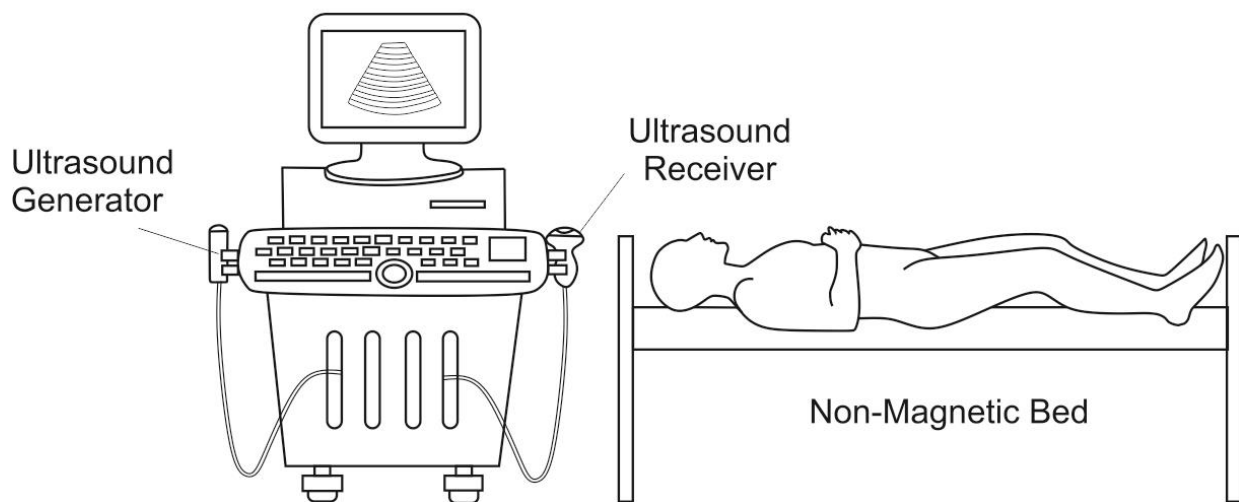


Figure 2. 6 : Ultrasonography Setup

This procedure is painless and safe as it does not use ionizing radiation (X-rays). They can capture the dynamic real-time movement of the body's internal organs and blood flow. Advancements in ultrasound technology include three-dimensional (3-D) ultrasound that formats the sound wave data into 3-D images. Doppler ultrasound, also called colour Doppler ultrasonography allows the physician to see and evaluate blood flow. There are three types of Doppler ultrasound: Color Doppler, Power Doppler and Spectral Doppler. Colour Doppler uses a computer to convert Doppler measurements into an array of colours to show the speed and direction of blood flow through a blood vessel. Power Doppler is more sensitive and can provide data even when blood flow is little or minimal. Spectral Doppler displays blood flow measurements graphically.

Nuclear Magnetic Resonance Imaging also called as MRI is a procedure in which radio waves and a powerful magnet linked to a computer system are used to create detailed images of areas inside the body. They can capture better images of organs and soft tissue than other imaging techniques, such as computed tomography (CT) or X-ray.

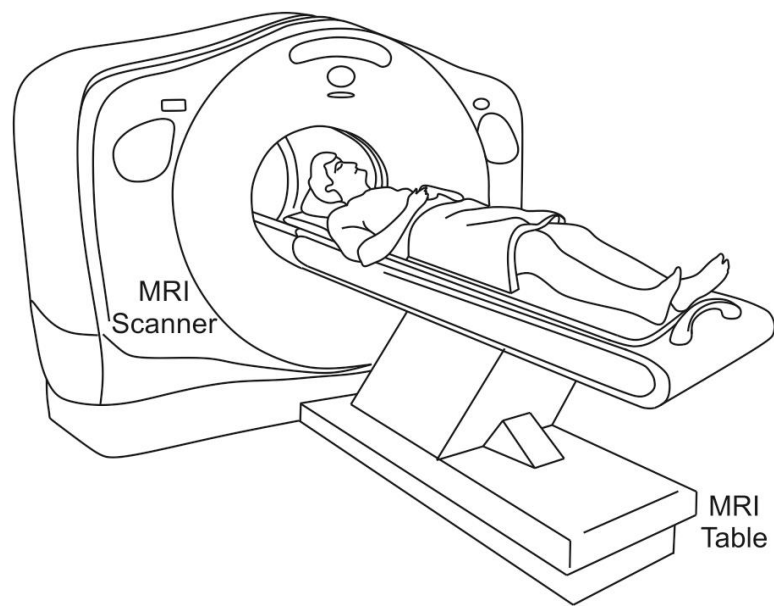


Figure 2. 7 : MRI Imaging Setup

Endoscopy is a procedure in which a small optical microscope or camera is used with a probe which can be decanted into the body to get real-time images and view the inside cavity for diagnostic applications. It comprises of the light source, a camera with controls and the optical fibre cord with surgical tool actuators. Laparoscopy is a subset of endoscopy when performed on the abdomen area.

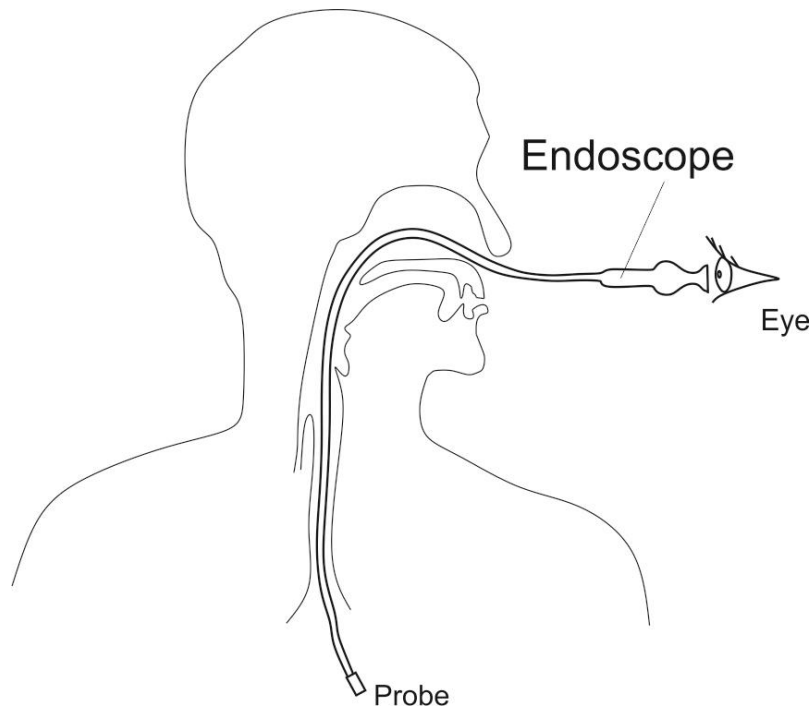


Figure 2. 8 : Endoscopy Setup

Digital models are the virtual models processed and recreated anatomy using computer graphics software. They are derived from medical image data from CT/ MRI / Ultrasonography. They can be viewed on a video display unit (Monitor Screen). They are also used for 3D printing, Virtual Reality, Augmented Reality.

The table below provides a comparison of various visualization tools from sketching to MRI:

Visualization Tool	Characteristic features	Dependent technology/ Skill	Invasive / Non?	Radiation
Sketching	Approximate, low cost, slow 2D representations	Artistic Skills	Not Invasive	No
Photography	Accurate, economical cost, Quicker 2D representations	Lighting and Film processing Skills	Invasive	No
Radiography	Accurate, economical cost, Quicker 2D representations	X-ray and Film processing Skills	Not Invasive	Yes
Fluoroscopy	Accurate, moderate cost, Rapid 2D representations	X-ray	Not Invasive	Yes, high dose
Cardiac Catheterization	Accurate, moderate cost, manual speed 3D representations	X-ray	Invasive	Yes
Echocardiography	Accurate, costly, Rapid 2-D and 3-D representations	Ultra sound	Invasive	No
Computed Tomography	Very accurate, costly, Rapid 2-D and 3-D representations	Multi slice X-ray	Invasive	Yes
Magnetic Resonance Imaging	Very accurate, costly, Rapid 2-D and 3-D representations	Nuclear Magnetic Resonance Imaging	Invasive	No

Table 2. 1 Comparison of various medical image modalities

2.2.4 3-D Printed Models

The digital anatomical models can be fabricated on a variety of 3-D printers. The choice of a particular technology depends on what one expects out of the parts? The digital models are converted as STL or such compatible file format that are acceptable by 3-D printers. For transparent models, one can go for SLA and Polyjet technologies. For hard opaque models, we can use SLS, FDM, LOM, MJM, MJF, Binder jetting technologies. For soft models, one may use Polyjet, SLS and FDM with suitable elastomeric materials.

The models that are to be carried to operation theatre will require properties such as biocompatible and sterilizable (by autoclaving). They are made of specially graded materials such as PA 12 (Dura form) materials, PA2200 the like. They can withstand high temperatures that are necessary to endure autoclaving.

SLS models being biocompatible and sterilizable are a popular choice of many clinicians and service providers. Further, SLS does not require additional supports as the powder itself acts as support. This helps to make intricate parts such as complex cardiac morphology.



Figure 2. 9 3-D printing of heart

2.3 3-D printing output validations.

Always original CAD model is far superior to its STL version. When this input is processed, the output is far from original CAD (Ponche, Kerbrat, Mognol, & Hascoet, 2014). This variance while is very characteristic of the technology itself, it can be kept in good control by proper calibration. It is imperative that each output is measured for their geometric accuracy. From the literature, we can find quite a few records of study under benchmarking of 3-D printing since 2001(Xu, Wong, & Loh, 2001) . The aim of those study was mainly to compare the reproducibility across technologies such as SLA, SLS, FDM and LOM to mention a few.

The variables measured across the technologies included surface roughness, building time, building cost for a model part.

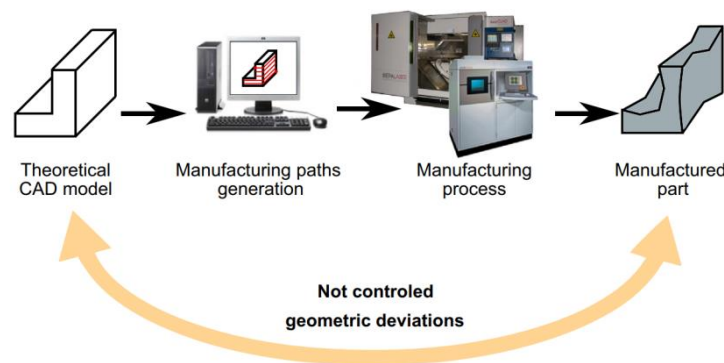


Figure 2. 10 : STL to Part – a compromised process

With the advent of 3-D printing technologies becoming a credible alternative to produce parts, the market saw the availability of many machines. It was difficult to make a choice. This led to the use of benchmarking used as a means evaluate machines for their limitations to build complexities or to accurate dimension, effects due to thick or thin sections, assess strength necessary in use cases, goodness for an application?

F.Xu et al published a first comparative evaluation of 3-D printing in 2001 (Xu, Wong, & Loh, 2001). It was followed by R.I.Campbell (Campbell, Martorelli, & Lee, 2002) and H.S.Byun et al (Byun & Lee, 2003) who used CMM to measure the artefact across SLA, SLS, FDM and LOM similar to F.Xu et al (Xu, Wong, & Loh,2001).Benchmarking exercises were mainly into polymers in phase with the technology available. Grimm Test

(Grimm & Grimm, 2002) uses a simple model which is easy to fabricate and check. Grimm used it for FDM machine range to establish model reproducibility. M.Mahesh et al (Mahesh, Wong, Fuh, & Loh, 2004) worked on the factors that affect the reproducibility and analysis of the part with a six-sigma approach. K.Abdel Ghany et al (Ghany & Moustafa, 2006) have worked on metal 3-D printing comparing four technologies with a standard part.

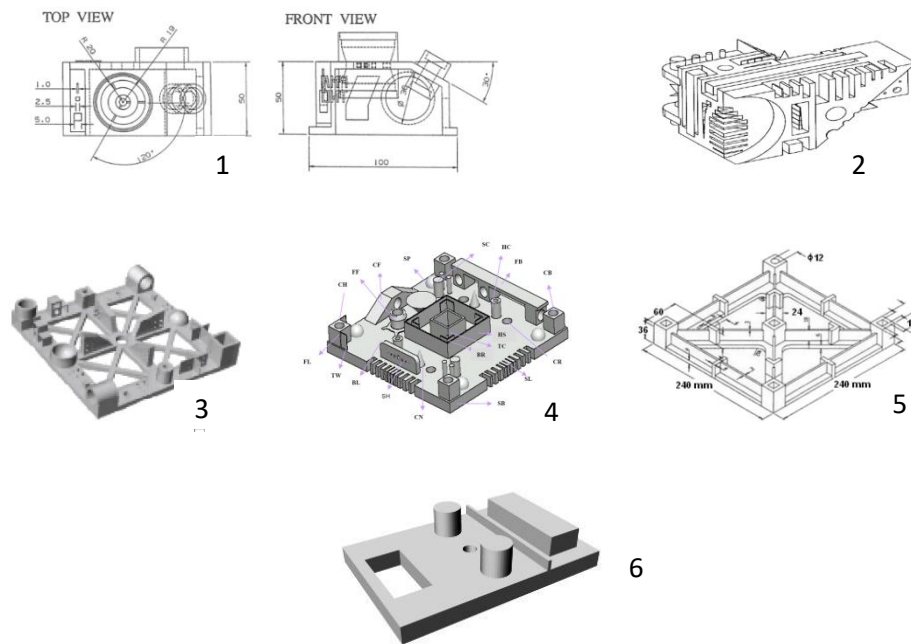


Figure 2. 11 : 3-D print Benchmarking Artifacts

The whole efforts in benchmarking have been represented in a review paper by Rebaioli et al (Rebaioli & Fassi, 2017). A.Pfister et al (Pfister, 2004) in which they compare a bioplotter with a 3-D printer. They have used scaffold as the standard for evaluation in which a grid of orthogonally placed beams forms the test artefact. They are not a true reflection of an organic form. We can observe that a dedicated bioform artefact is not yet conceptualized and made.

We can see that all of these largely are made from an engineering perspective. If we want to assess their fitness for an organic model such as anatomy, it is very difficult to measure as they lack a data landmark. So, the benchmark artefact to assess bio / organic or anatomic areas, we do not have an appropriate test sample.

Peter Olejnik et al (Olejník et al., 2017) in their study has called 3D printing as a process to produce authentic copies of the patient's cardiovascular system from CT/MRI data.

Patients with complex spatial anatomical relationships between cardiovascular structures are best suitable cases to go for 3D printing modality. They investigated the accuracy of 3D printing for cardiovascular structures. They used Bland –Altman analysis to assess the accuracy. The Bland-Altman plot (Bland & Altman, 1986 and 1999), or difference plot, is a graphical method to compare two measurements techniques. In this graphical method, the differences (or alternatively the ratios) between the two techniques are plotted against the averages of the two techniques. The authors adopted a method to measure physical model and the digital model using slide callipers at select few anatomical landmarks. The landmark was chosen the diameter of descending aorta at the level of the diaphragm, right/left pulmonary artery diameter at the level of bifurcation, apex to brachiocephalic artery origin from aortic arch). The study claims high accuracy of the cardiovascular model made by 3D printing. Given the organic nature of the model, it not possible to measure at the exact landmark on a physical model with respect to the digital model. This exercise though done with all care cannot be repeatable.

The accuracy of medical models made by 3-D printing is studied by Mika Salmi et al (Salmi, Paloheimo, Tuomi, Wolff, & Mäkitie, 2013) using a CMM facility. Here authors use a ruby ball stylus as a touch probe and provide good results. A non-contact measurement will always be better than contact types.

2.4 Workflow of 3-D model creation as seen in the literature:

Since the invention of Stereolithography in 1986 and other types of 3-D printing technologies, it has been widely used in Industrial Design and Manufacturing applications. Since last decade or so, it started to getting popular in medical applications and ever since has been growing.(Wohlers & Gornet, 2014)

The Medical Image data is acquired in a common system independent protocol called ‘Digital Imaging and Communications in Medicine’ (DICOM) . They are essentially a set of slice data that can be stacked back to recreate the anatomy. This has opened up a world of new opportunity in medical prototyping and simulation(Graham, Perriss, & Scarsbrook, 2005)

The process of fabrication of models from Medical image data has evolved over a period last decade and is only getting better. A literature search shows a many depictions / representations of the workflow.

F.Rengier et al (Rengier et al., 2010) in their paper titled 3D printing based on Imaging data : a review of medical applications state 3 stages namely Image Acquisition , Image Post Processing and 3D Printing.

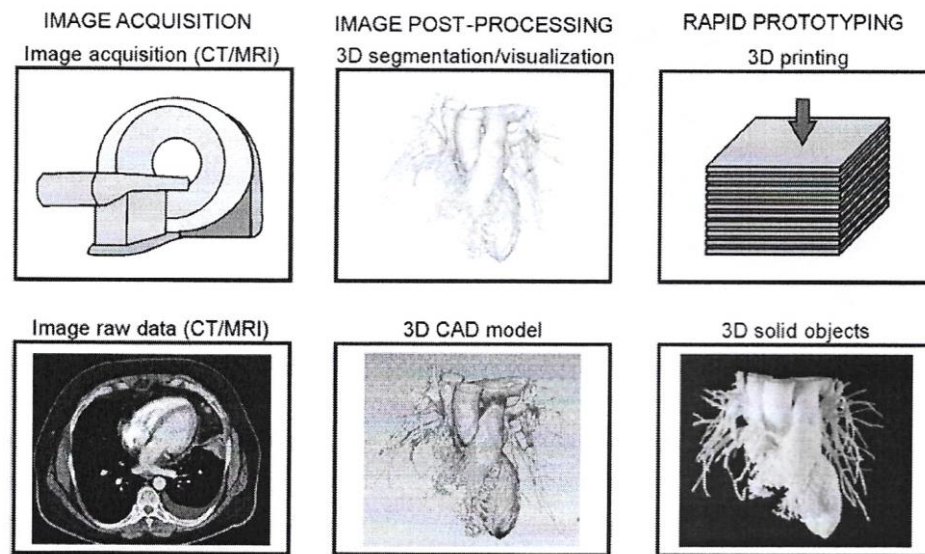


Figure 2. 12 : Workflow 2 [F.Rengier et al (2010)]

Yoo, S.J., et al (Yoo et al., 2016) in their paper titled “3D printing in medicine of congenital heart diseases”. *3D Printing in Medicine*, 2(1), p.3 have given the process as 4 stages as shown in the figure below. This diagram, however, does not provide details of each block.

A Similar 3 stage is also discussed by L.M.Meier et al (2017) in their paper Structural and congenital heart disease interventions : Role of 3D printing as given below:

T.S.sorensen et al (2001) list the same steps to create till digital model visualization by VR, namely the MR Scan, Segmentation, Model generation.

We can see more examples of the workflow which mostly mention basic stages such as Image Acquisition, Segmentation and Post processing to obtain the digital model which can be exported as STL and sent to a 3D Printer, which then helps in the fabrication of the Physical Model.

We find the 3 basic blocks: Data Acquisition, Image processing, Reconstruction of 3D model in another article by:

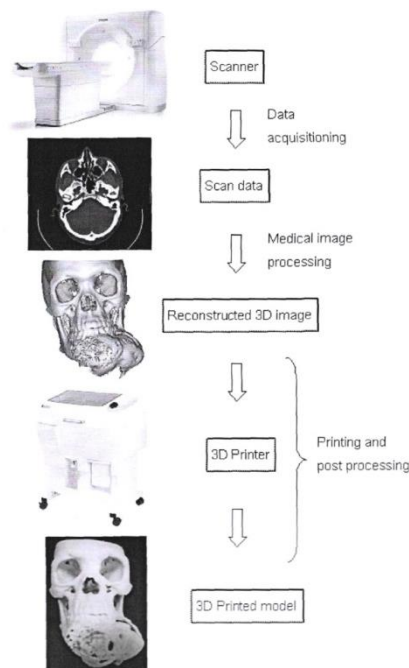


Figure 2. 13 : Workflow

A.Marro et al (2016) have discussed a 6 stage process in their review paper: They have included Mesh generation, file conversion and setting print parameters, printing and post-processing.

The process remains same with other imagining modalities such as MRI as illustrated by Giovanni Biglino et al (2017)

Later Literatures mostly covered the process but with one change, they mentioned process as patient-specific model development. They have added another stage to manipulate the 3D model to suit the specific needs for the patient such as a valve seat or a coupling as shown below in an article by Marija Vukicevic et al (2017)

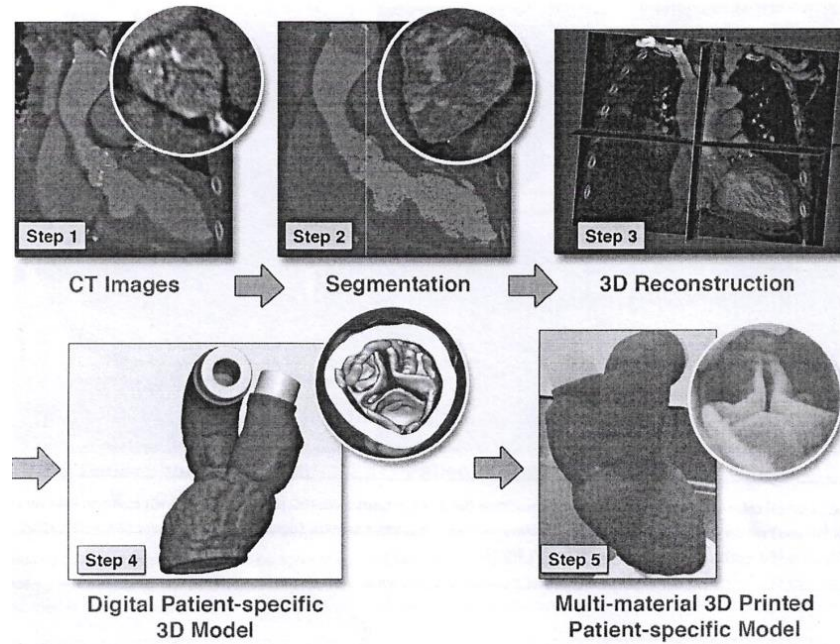


Figure 2. 14 : Workflow 9 [Marija Vukicevic et al (2017)]

The schematic diagram below by E.Nocerino et al (2016) communicates much more with its simple blocks with two end options, Patient-specific, Virtual model or Physical model by

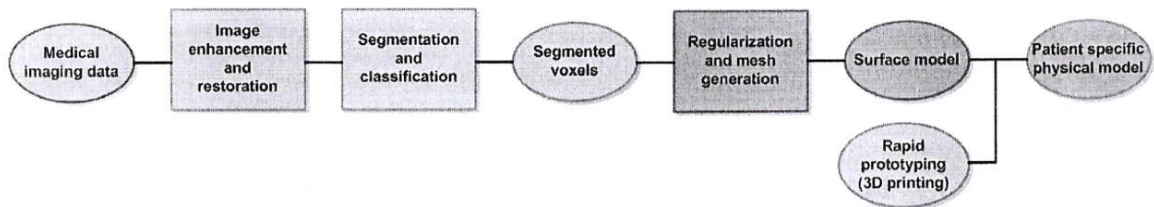


Figure 2. 15 : Workflow 10 [E.Nocerino et al (2016)]

The finer details of workflow remained somewhat as a tacit knowledge buried only with the teams as an experience. However, in the article by Kwok Chuen Wong (2016) which showed the team composition for the development of Orthopaedic Patient-Specific Models. He describes a multidisciplinary team comprising of Clinicians and Engineers as shown below:

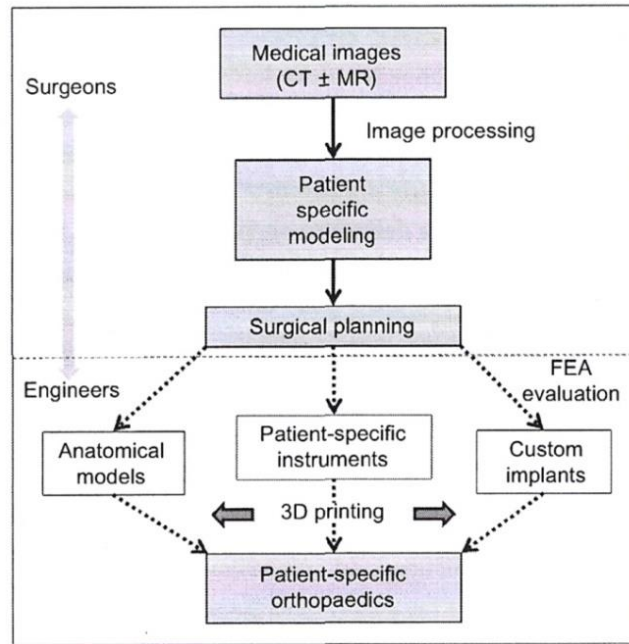


Figure 2. 16 : Workflow 11 [Kwok Chuen Wong (2016)]

The recent literature has tried to capture the workflow with teams which are very important in the success of every project. The schematic diagram below by Dimitris et al (2015) Titled “ Medical 3D Printing for the Radiologist”, provides an excellent process reviewed by Radiologist and extended Technical Team with Engineers and Clinicians.

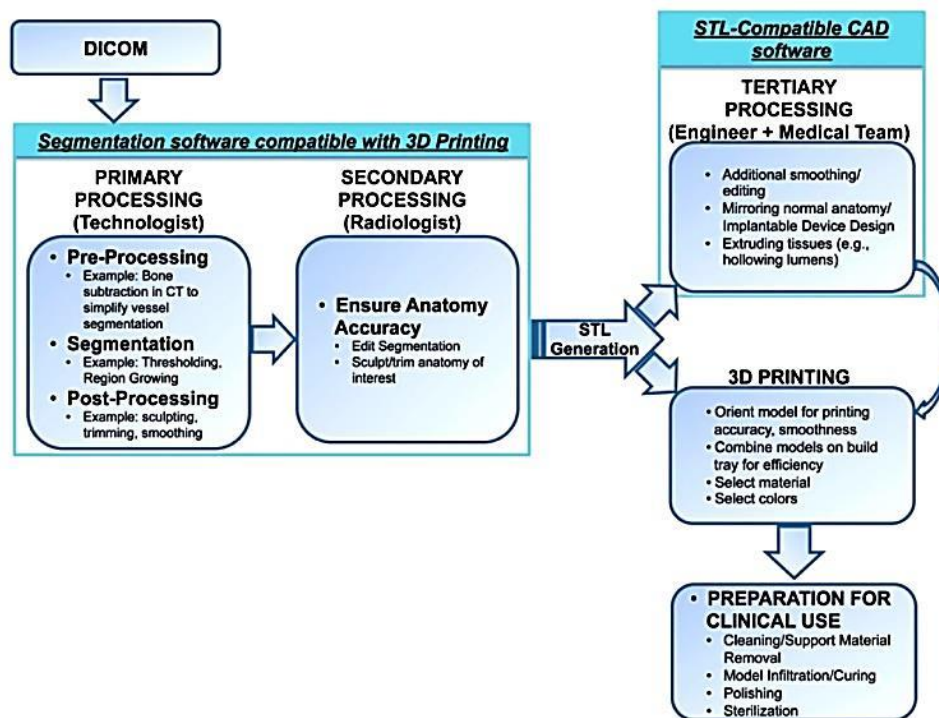


Figure 2. 17 : Workflow 12 [Dimitris et al (2015)]

Authors have tried to define the workflow as Primary, Secondary and Tertiary processing. We can see that in the secondary process a radiologist reviews the processed data for the next stage. It shows how the process quality is a very responsible task and how it is maintained with a check by qualified personnel, the radiologist. This shows how the whole process is a responsible co-creation by clinicians and engineers.

Marija Vulicevic et al (2017) in their review paper have explored the research space as it exists today. The high spatial resolution cardiac imaging, image processing software, fused dual material, about 3-D printing at hospitals trying patient-specific models. The authors question the accuracy of replication. Cardiovascular modelling must be validated across a wide range of source imaging modalities and 3-D printing methods.

Nicolas Martelli (2016) et al have done a systematic review of Advantages and disadvantages of 3D printing in surgery. They conclude that the additional cost and time needed, will limit its use in /hospitals. They also state that the systematic “reporting of experience with 3D printing in surgery is highly desirable” A Table with a gist of their finding is given below for ref:

Advantages	Disadvantages
• Reduce OT time	• Time spent to make the model
• Accurate model	• Added Cost of the model
• Aids in Planning procedure	• 3-D software cost & training
• The Accuracy of the procedure	• Limited Materials
• Custom Models & Solutions	• Lack of regulations
• Colour Models	• Limitations with sterilization

Table 2. 2 Advantages and disadvantages of 3-Dprinting in Medical domain

2.5 Focused literature study

Focused reading of 42 research papers in CHD and 3-D printing are studied and are tabulated and analysed to arrive broader understanding of the research area.

Year	Code	No.	Authors	Case type	Study Goals	Conclusion
2016	3	1	Laszlo Kiraly et al	Post modified Norwood1 Complex Aortic Arch Obstruction	Presurgical Simulation of repair	Models helped in preoperative simulation and resulted in successful Operation & Patient safety
2017	3	2	Elena Grant et al	Review	Review of Role of 3D heart models in interventional procedures	New Technology aids the interventional cardiologists through pushing the boundaries beyond cath lab
2017	3	3	Adriana C et al	Review of Embryology of thw Heart	understanding the foetal development of neonatal heart disease	Increased Nuchal translucency (NT)resulting CHD is noticed, needs more study
2014	3	4	Laura Olivieri et al	Pulmonary venous baffle obstruction in Mustard repair of D-TGA	interventional procedure planning	Model aids to select and place an appropriate device
2017	3	5	KanwalM.Farooqi et al	Review	Review Innovations in Pre operative Planning in Cardiac Disease	3D Printing helps, there is a need for Standardization
2017	3	6	KhaledHadeed et al	Review	How models Help to understand defects better	3D printed cardiac models are a powerful tool
2017	3	7	Israel Valverde	Review	Work flow to Print Heart models	Application review & limitations
2016	3	8	Johanna Spallek et al	Customised Vascular Models for training	Customer involvement in Customization of Vascular models	3D printing helps in tool less manufacture of the Vascular models for training purposes
2010	3	9	Pierre-Luc Bernier	Review of CHD world wide	Demographic distribution of CHD	CHD care Challenge world wide : Need for more understanding
2010	3	10	Gaetano Thiene et al	CHD Classification	Systematic Study of CHD	Anatomical & Pathophysiological Classification of CHD is attempted
2002	3	11	JulienI.E.Hoffman et al	CHD incidence	Study of variability of incidence of CHD	The variance comes from trivial lesions which are not accurately identified
1979	3	12	Michael.j.Tynan	CHD nomenclature and classification	Finding rationale for CHD nomenclature and classification	CHD nomenclature and classification attempted
2011	3	13	Denise van der Linde et al	Systematic Review	Meta Analysis of CHD world wide	The CHD birth prevalence increased substantially over the years, not sure if it is due to methodological difference
2000	3	14	Thomas Sangild Sorensen et al	Application of VR in Cardiac intervention planning	To develop a new method of VR to explore Heart Structure	A novel VR approach was developed

Table 2. 3 Literature Search Results A

2016	3	15	Shi-Joon Yoo et al	Interventional Applications Review	Critical Review of applications	3D Printed models help to understand complex defects quickly
2008	3	16	Sibylla Mottl-Link	Heart Morphology	Study of Heart Morphology with physical models	3D Printed models help to understand complex defects and virtual cuts can be tried which are otherwise possible
2015	3	17	Kanwal M. Farooqi et al	DORV	Complexity in intracardiac relationships in DORV	Model helps to decide an appropriate interventional procedure, double switch
2013	3	18	Mika Salmi et al	Medical Models quality	Measurement of Accuracy of Medical Models	Error Percentage for various 3D printing processes are established
2016	3	19	Shafkat Anwar et al	3D printing of complex CHD	Study of various anomalies	3D Printed models help to understand complex defects better and plan corrective procedure
2012	3	20	Richard J.B. Francis	CHD & L-R Asymmetry	Heart Morphological study	Complex form of CHD are found in patients with Heterotaxy
2017	3	21	L.M. Meier et al	3D printing workflow	Work flow to Print Heart models	3D printed cardiac models are a powerful tool
2017	3	22	Marija Vakecovic	Review	Review of 3DP workflow & Application	Discuss many use cases
2017	3	23	Kimberly A. Host et al	Review	Surgical Management of CHD	Surgical Management of CHD
2009	3	24	Eugenie Riesenkampff et al	11 case review	Evaluate practical clinical value of models	Realistic 3D models provide detailed and comprehensive information on intercardiac anatomy.
2015	3	25	Mrinal Kanti Das	Cardiology in India	History of Cardiology in India	Tribute and History of cardiology in India
2017	3	26	Gerald Greil	heart Imaging	Mid Diastole MRI Image	Better Quality of Image
2014	3	27	Rafal Dankowski	Percutaneous Structural Interventions	Patient Specific Heart Model	3D printed Models help in Percutaneous interventions
2017	3	28	Giovanni Biglino et al	Model as a Communication tool	To assess the communication potential of 3D printed Heart models	Models were Found very useful by parents as they can see the anatomy more clearly than medical Images
2014	3	29	Shi-Joon Yoo et al	Review of Decision Making in CHD Surgery	Review of MRI as a Decision Making Tool in CHD Surgery	Study shows MRI as a better alternative to CT to make 3D Printed models

Table 2. 4 : Literature Search Results B

2017	3	30	Peter Olejnik	accuracy of 3dp models to bank on them for interventional planning	Bland -Altman analysis to assess accuracy of models was used	Bland-Altman analysis confirmed the accuracy achievable.
2016	3	31	E.Nocerino	2 Case studies	Role of 3D model in Surgical planning	Patient Specific Approaches are possible
2015	3	32	MohamadLazkani	Postinfarct VSD	Postinfarct VSD Management with 3D Printed Model	Model helped in preprocedural planning
2010	3	33	ChantaleLapierre	Segmental Approach to CHD	Segmental Approach to imaging CHD better	Detailed knowledge of Cardiac anatomy helps to identify the defects
2008	3	34	Michael S.Kim et al	Review	Role of 3DP model in structural Heart Disease	Models are very useful, They form a bridge between 2D imaging and actual Anatomy
2016	3	35	SebastienHascoet	Review	Pros & Cons of Cardiac Imaging	Advocates Fusion Imaging
2016	3	36	Beth Ripley	Transcatheter aortic valve replacement	Role of 3DP model in visualization prior to procedure	3DP not only aids to plan TAVR but also to predict paravalvular aortic regurgitation (PAR)
2017	3	37	Roberto L.Flores	Microtia	PS Auricular reconstruction	Proof of concept presented...Role of 3DP demonstrated
2011	3	38	SandorM.Szilagyi	Electromechanical Model of Heart	PS Electro Mechanical Heart	This explore PS Electromechanical parametric eart for analysis purpose
2015	3	39	Laura J.Olivieri	VSD & Periprotthetic aortic Valve leaks	Feasibility of creating cardiac models from 3d Echocardiographic data	Echocardiographic data are technically feasible and safer alternatives to build PS Heart Models
2017	3	40	HongxingLuo	Review of work in china	3DP in Cardiology	3D Ecocardiography as a safer means to build models is explored
2016	3	41	Nicolas Martelli	Review	Pros & Cons of 3DP in Surgery	Reviews Pros & Cons of use of 3D Printing in surgery
2017	3	42	JanezVodiskar	Scope of 3D model in surgical correction of CHD	Evaluation of role of Models for procedural planning	Planning of repairs using actual 3d model enabled them to plan procedure without stress and saving time at OT

Table 2. 5 : Literature Search Results C

2.6 Literature Review Summary

Explored more than 500 plus research publications (Ref Annex VIII) to understand the research landscape and found 3-D printing interventions past 2 years has been increasing many folds. The key areas to check the status of current research which can be broadly classified as prototyping, medical imaging, 3D printing for the medical domain and 3D printing for cardiovascular interventions. We have 42 focused papers in our research area and found all of them have dealt with the subject more from the medical domain than from the visualization & prototyping viewpoint. Thus the micro details need to make an accurate prototype for better visualization is found missing. Due to this, we find the workflow found in the literature is rather basic and has inherent gaps and hence are difficult to repeat the process.

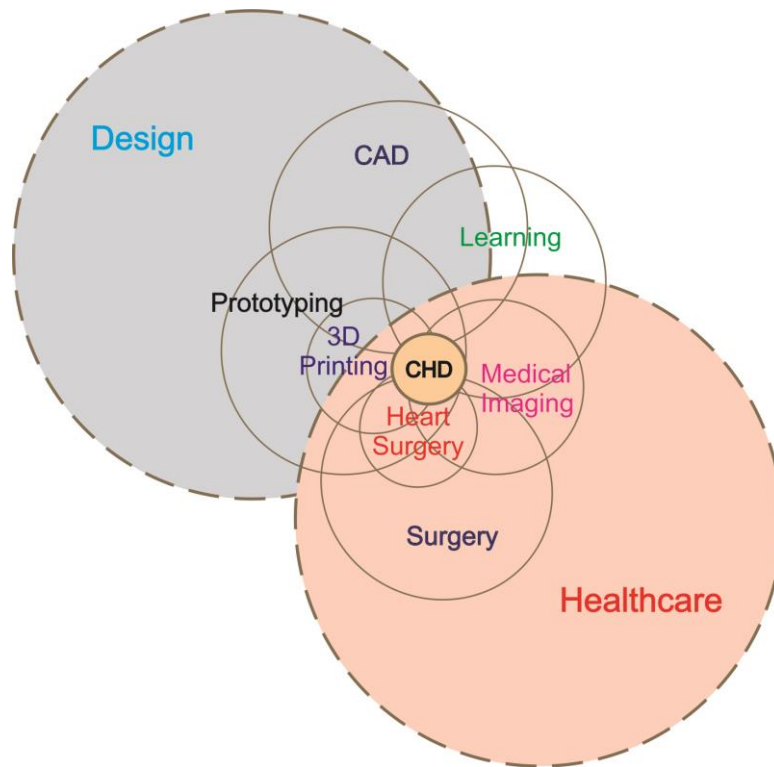


Figure 2. 18 Research Landscape

The research landscape is thus an overlap of design and healthcare at a macro level. While the focus is on the fabrication of accurate models, there is a close interplay with engineering and medical domains encompassing visualization, learning, medical image processing, CAD, prototyping, 3-D printing, post-processing, heart surgical procedures to aid better defect understanding.

We can list the following gaps in the existing literature observed. They are either not observed or not documented. They could be just omissions or to keep process secrets within the teams. Either way, it is not good for technological progress.

The gaps from the literature study are:

1. Factors that influence the model quality
2. The image acquisition parameters for better 3-D printing
3. The involvement of clinicians at specific stages of the workflow
4. Workflow specific to heart anatomy to make accurate models
5. Method of assessment and validation of medical models for accurate recreation
6. Optimum heart sections for visualization maximization

We plan to address each of these gaps as a part of our research in order to get the best quality prototypes with appropriate clinical relevance.

Chapter: 3. Research Objectives and Approach

From the literature review, we can understand the previous work done: The role of prototypes in diagnosis, congenital heart defects, and their complexity, challenges in treatment management, and use of 3D printing as a prototyping tool by previous researchers in the field. The work was carried out mostly by clinicians for use in the corrective procedures. Many gaps were identified and with expert clinicians to get their opinion on the usefulness of such a study. This chapter elucidates the motivation for taking up the present research work and defines the objectives, approach, and scope of work.

3.1 Background and Motivation

Applications of 3D printing in healthcare are growing (Rengier et al., 2010). They fabricate physical models using medical image data. There has been no systematic study as a prototype tool, the optimum workflow to fabricate them, accuracy needed and appropriateness of technologies employed. These issues merit objective study by engineers & designers with the model as the focus.

As per the practice, surgical interventions are usually planned after image data analysis by radiologists and recommendations by the interventional cardiologists (Hiremath & Kamat, 2013) For any reason, if the image data yields wrong inference, it can mislead the clinicians. The newly discovered condition can result in loss of time leading to fatality and mental stress on the operating team. While many 3D printed models use cases are reported, it is not clear how the models were made in detail (step by step account) and how they aided in the treatment process. As design researchers, our aim is to explore a detailed approach of making models and study the role played by physical prototypes.

3.2 Clinician Survey

To a plan to survey few experts and record their opinion. 6 expert pediatric cardiac surgeons were interviewed and responses recorded. The questions included defect distribution, their management and usefulness of a 3D printed physical models in procedural planning. The box below provides the summary of their views:

1. What is most common of birth defects?: Congenital Heart Disease
2. CHD occurrence: World average 8 in 1000 live births. In developing countries, it could be more.
3. Current assessment method: Auscultation, Echocardiography, Dissolved O₂ in Blood.
4. The effectiveness of the current methods: 80-90% of the cases diagnosed correctly.
5. Limitations with the current method: Ambiguous structures are not conclusively diagnosed.
6. The risk involved in current modalities: Surprises during operation, less time for planning, stress, need for revision surgeries.
7. Will 3-D printed models help? We read and hear about it through literature and conferences.
8. Will 3-D printed prototype of the defect conditions help? Yes and may help.
9. Do you recommend it for every case? Well, for simple cases which are clearly identifiable from echocardiograms, models are not necessary.
10. For what conditions you recommend 3-D printing? Defect types which are not conclusively diagnosed even after echocardiogram.
11. What is the occurrence of such inconclusive cases? We get a lot of them as we specialize in such cases. We can put it approximately 1 out of 1000 live births.
12. Would you like to try the 3-D Printed models for any of your cases? Yes.

Table 3. 1 Expert Survey

From the qualitative survey shown in fig 3.1, we can see the potential of 3-D printed models in the diagnosis. The type of condition, technology, the accuracy of models merits a focused investigation.

3.3 Goal, Objectives and Scope

The goal of the present study is to investigate the way to fabricate an accurate model of a heart to maximize visualization of its morphology and aid treatment management. In order to reach the goal the following objectives were defined and addressed in the present investigation:

1. Understand the key factors that influence accurate model fabrication. 3D printing technologies and their suitability in accurate model making.
2. A pilot study to understand the workflow. Standard process workflow to ensure accuracy and consistency.

3. Optimum model sections to minimize investment. Validation of models through case studies.

The morphology of the heart structure, if reproduced accurately, will help clinicians to understand the defect better. The defect understanding helps clinicians in optimum treatment planning. The study is limited to only congenital heart diseases of types that pose challenges in diagnosis.

3.4 Proposed Research Methodology

The proposed methodology integrates all aspects of prototype model development from medical image data from image acquisition, fabrication, evaluation, and clinician feedback. Further, it will help in evolving a reliable workflow for patient-specific prototypes. A patient-specific heart model is fabricated to help visualization of malformed heart.

Hypothesis: An accurately reproduced patient specific prototype model helps in better visualization of defect morphology and aids in clinical decision making and overall treatment management.

Here the key variable is prototype quality in recreating the accurate heart morphology. Various factors that influence the accurate reproduction are hence the scope of our investigation. They include defect awareness, image acquisition, prototype process and evaluation by expert clinicians.

The current research study encompasses multiple disciplines, basic familiarity is essential to understand the problem and to work on improvements. We have focused on heart anatomy in the first and the second chapters to gain reasonable knowledge. The research study involved the exploration of bovine heart to gain additional insights.

Prototypes requirements focused on congenital heart diseases are investigated through a set of experiments and are co-evaluated with expert clinicians.

To understand the key factors that influence accurate prototype model creation, one has to start from Image acquisition to fabrication of physical model. A patient-specific prototype mainly depends on the Medical Image conversion to a digital model and Process to

fabricate the same. The various secondary factors that influence the prototype quality are shown in Figure 3.2 below:

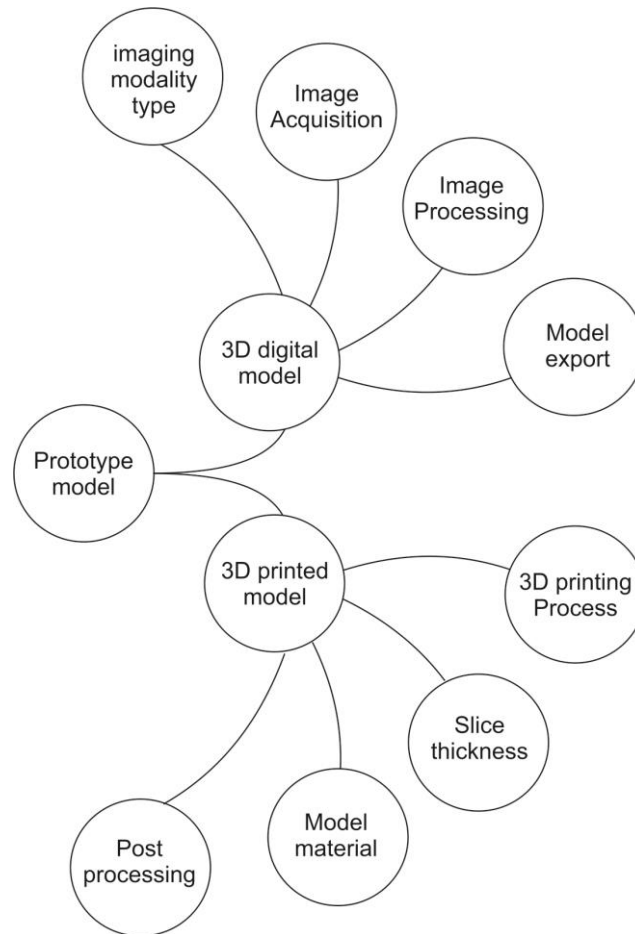


Figure 3. 1 Dependencies in prototype quality

It is important to understand medical imaging and its output compatible to make accurate 3-D printed models. This will result in the standard workflow. With regular CT scan, it is difficult to construct the model of soft tissue anatomy owing to their overlapping radio transparencies. For this purpose, we temporarily make the blood lumen radio-opaque by injecting a contrast medium. This helps to alienate soft tissue from neighbouring soft tissue and aid segmentation of the part. We plan a pilot study to evaluate this aspect and to become proficient in the segmentation of soft tissue. We planned to use random DICOM data sets of three CHD subjects intended for Radiography review. The inputs

will be used to evaluate and standardize the process of data processing. It will be followed by case studies over 30 months period.

The patient-specific heart model is expensive and time-consuming. As a defect occurs only in a particular region of the heart, it is enough to study only that region with its close neighbourhood. Such an approach brings focus and reduces the cost of model development. While defect can occur anywhere, we can always see there are few regions of defect occurrence. By mapping them, may help to quickly arrive at the defect type and zoom in to explore more details. There should be few optimum sections that model can show the defect best. Post-digital model and 3-D printing; live cases studies are evaluated for the morphological presentation of the defect type.

If we look at the whole scope of the investigation, it is deep dive from design to fabrication of heart models to aid visualization of complex congenital heart defect morphologies. (Figure 3.3) below:

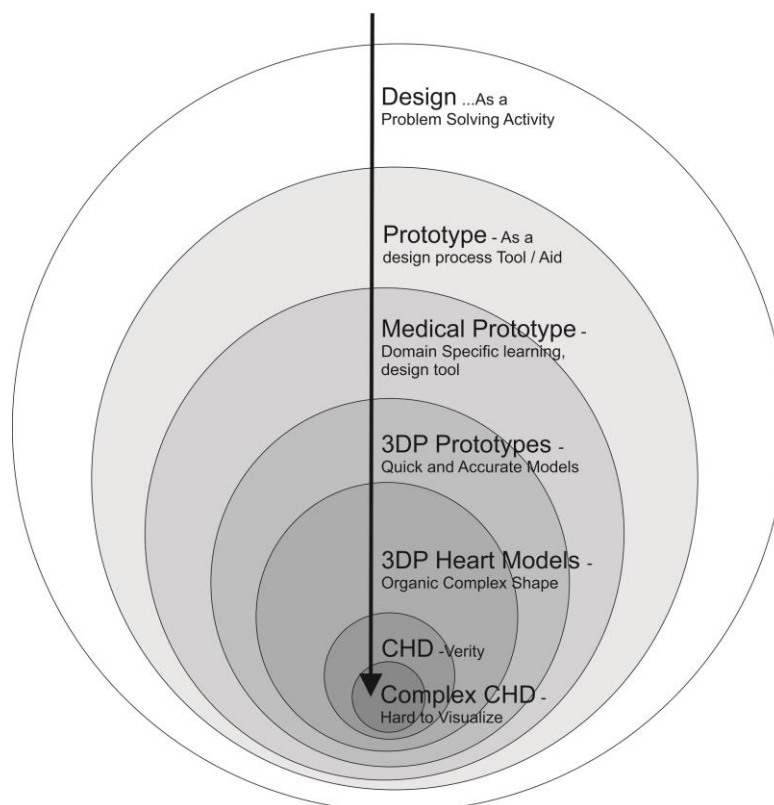


Figure 3. 2 Deep dive from Design to the heart of CHD

So, we have a duality of our approach: to Generate a digital model and to fabricate optimum physical model. The model so developed is validated by clinicians.

The digital model generation investigation includes the imaging modality, image acquisition, image processing, digital model export for fabrication; this needs a workflow process to be adopted. A pilot study is planned to develop an optimum workflow.

The fabrication investigation includes the technologies, model resolution, the material employed and post-processing.

After the optimum workflow and accuracy of the models are established, live case studies will be taken up and the outcome. All models are shown to the experts for re-evaluation. The results are recorded, analyzed and conclusions are discussed.

Chapter. 4: 3-D model Reconstruction Workflow

In this section look into important aspects of accurate medical prototype fabrication. There are many factors that influence the quality of the model which. In order to fabricate an accurate model, these factors need to be measured and controlled. Patient-specific models have to depict the morphology close to the actual anatomy in size and form. Since these models are organic in shape, dimensions are too many and difficult to measure. This chapter provides a methodology of 3-D printed medical model validation.

4.1 Key Factors in Medical Modelling

The medical model is derived from the patient's actual anatomical data, acquired as DICOM from Computerized Tomography (CT). This is referred to as a patient-specific model (PSM)

The accuracy of PSM is affected by parameters related to the following steps in medical modelling:

1. medical image acquisition
2. image processing / segmentation
3. file export
4. 3-D printing / digital fabrication and
5. post-processing.

4.1.1 Medical Data Acquisition

Medical data acquisition process plays an important role in the resultant quality of models. Further, the processing of the data is equally important. Image sections should be reconstructed with isotropic voxels Thicker sections compromise model accuracy and are fine for larger parts, while very thin sections are needed for smaller anatomy parts (e.g., <0.25 mm) require extensive segmentation and STL refinement besides larger size.

The data acquisition for soft tissue is a little invasive compared to hard tissue. If one does not go for contrast medium injection, it will be difficult to distinguish the soft tissue from

the surrounding other soft tissue parts including the blood. Therefore, contrast CT / MRI is very essential for the purpose.

The CT provides sectional data and helps to recreate anatomy. If any section or sections are lost, the model will not be accurate.

The cardiac clinicians will ask for CT if they get ambiguous results from the other modalities or remain inconclusive. This means additional cost and time. If the CT is not captured as a set, acquisition protocol as recommended by the machine manufacturer with few sections will be just good for 2-D visualization. This data of few sections will be of little use for 3-D model reconstruction. If they do, they offer inaccurate 3-D visualization.

A pilot study is planned to establish optimum image acquisition. The whole process is a co-creation between clinicians and CAD team in which each member has to understand the consequence of noncompliance is a loss of time, loss of resource, loss of life itself.

Further, medical image acquisition, itself depends on Image modality type acquisition parameters, tissue type (hard or soft) and contrast medium.

4.1.2 Image Processing and Segmentation

The typical workflow starting from CT data import in DICOM (Digital Imaging and Communications in Medicine) to creation of the digital model is explained here. MIMICS software from Materialise NV was used for the data processing and to reconstruct heart.

DICOM import provides the individual slices (like X-ray) and the metadata, which includes patient name, gender, machine type, slice thickness, gantry tilt.

The contrast-enhanced CT datasets in DICOM format are imported into the image processing software such as Oserix or Mimics. First glance of the dataset provides the richness of data set, the number of slices. These data should be isometric to rebuild the digital model. This is usually taken care at the time of image acquisition itself by following the protocol (Ref Annexure II)

Image segmentation necessary for volumetric rendering starts with global thresholding. It involves the grouping high contrast image areas and filters them. Isolation of hard tissue regions of the image is done by global thresholding. The focus in our study is soft tissue

and hence, the bone parts segmented are removed from the volume rendering. By using the technique of region growing, we start the segmentation of soft tissue and our focus anatomy, heart. Then the regions of interest (ROI) are marked and further segmented to get to the soft tissues. The image is de-saturated to check if the region growing is satisfactory. By this, we can isolate the contrast-filled blood lumen easily. This forms the basic step to explore defects. A lumen model contains rich morphological data and is good enough for an expert interventional cardiologist. They are like the negatives of the actual heart morphology.

Medical image processing workflow broadly followed is as given below. It consists of DICOM data import, Segmentation of target anatomy. Post segmentation, we have to options to transform the lumen models to get digital heart model in full or sections.

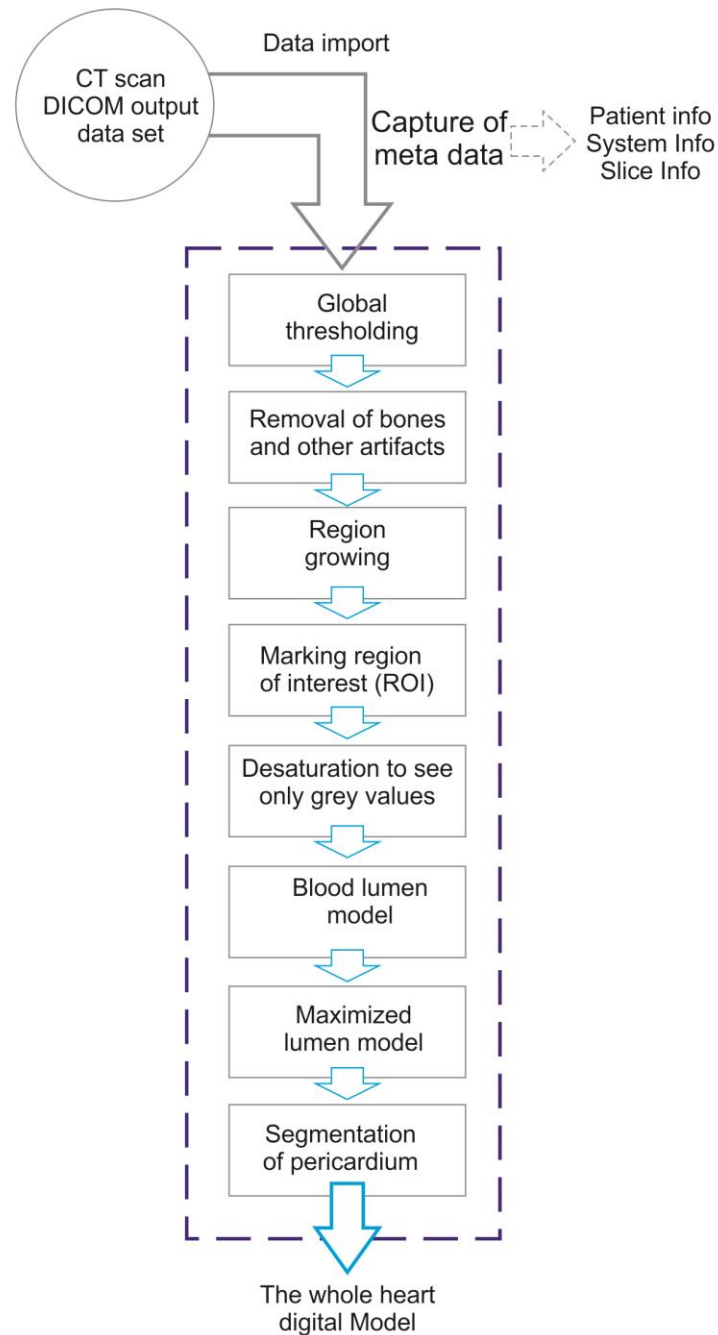


Figure 4. 1 Segmentation Process

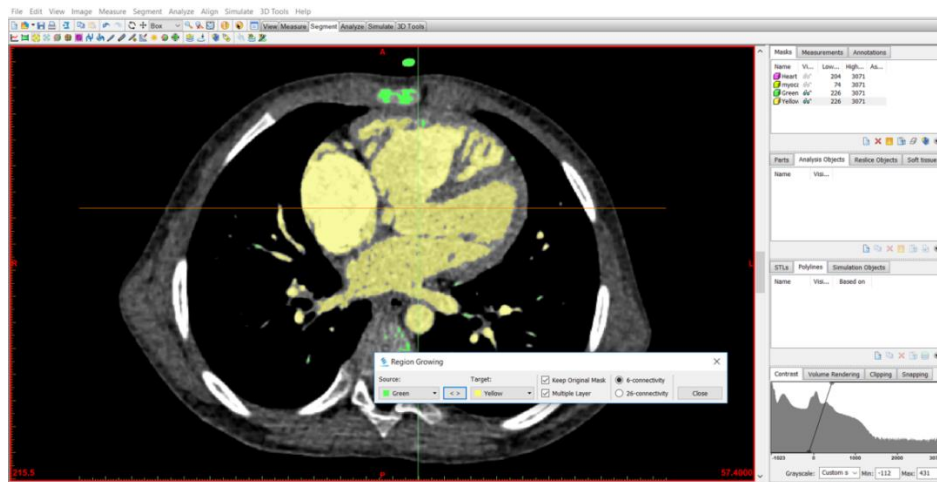


Figure 4. 4 Region Growing

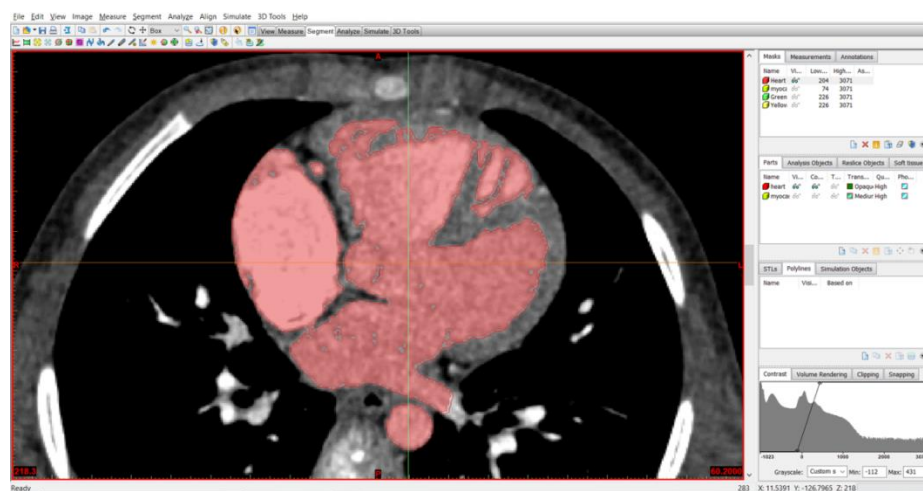


Figure 4. 5 Marking Region of Interest (ROI)



Figure 4. 6 Desaturation to see only grey values

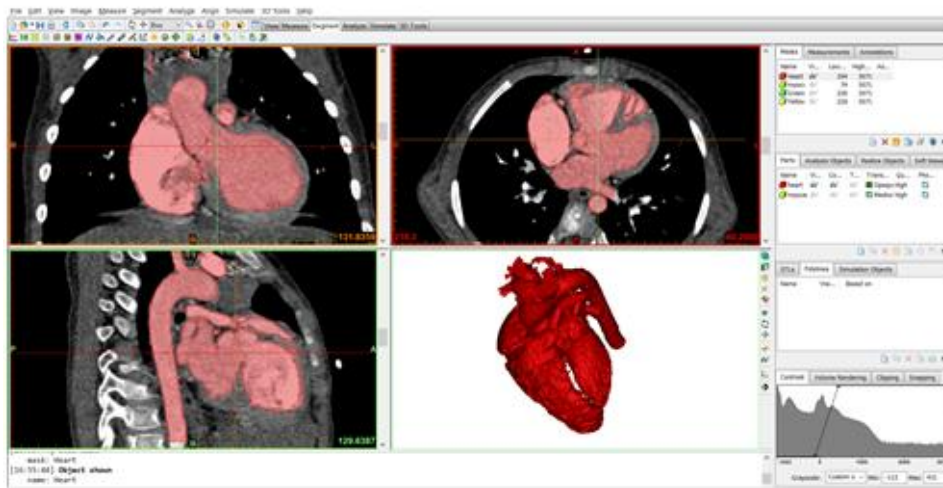


Figure 4. 7 Blood Lumen Model

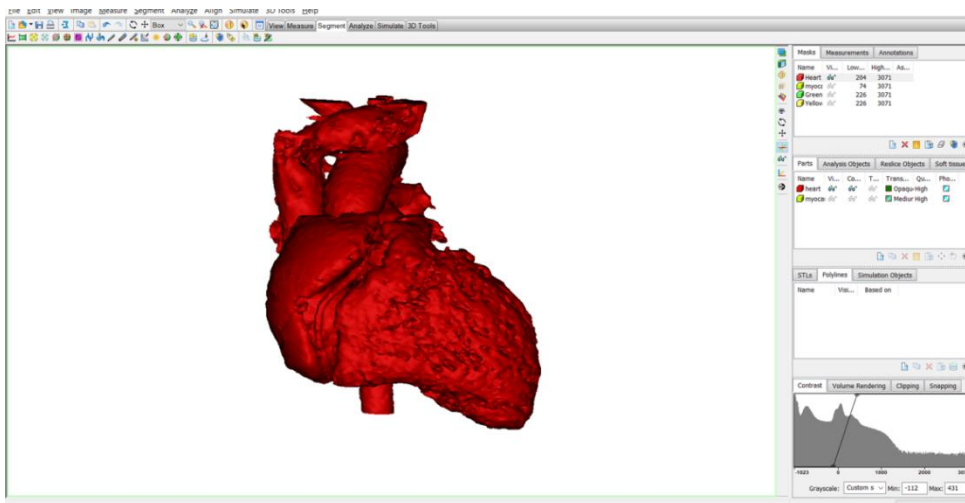


Figure 4. 8 Lumen model maximized

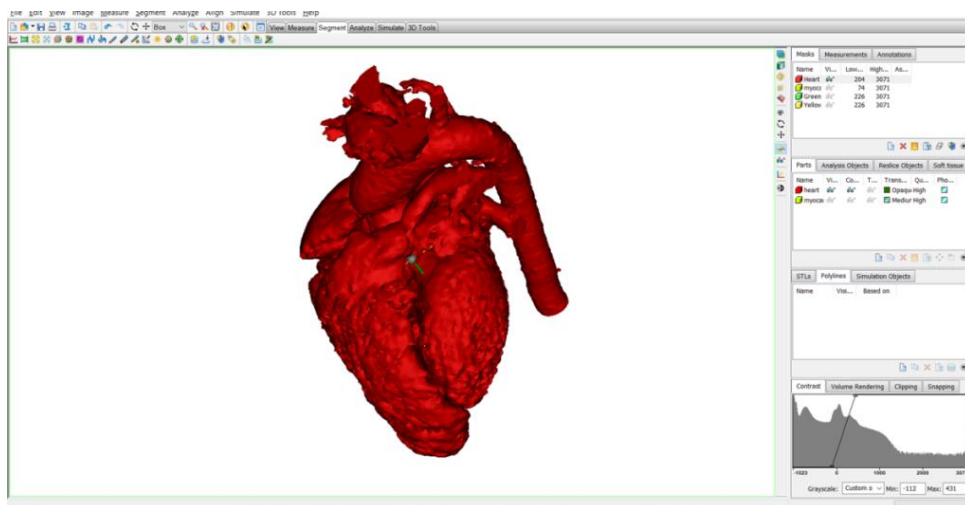


Figure 4. 9 Lumen model turned around

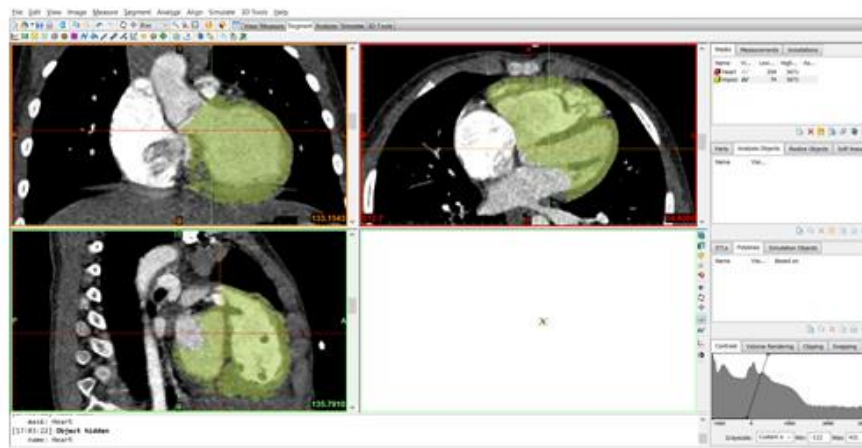


Figure 4. 10 Segmentation of Pericardium

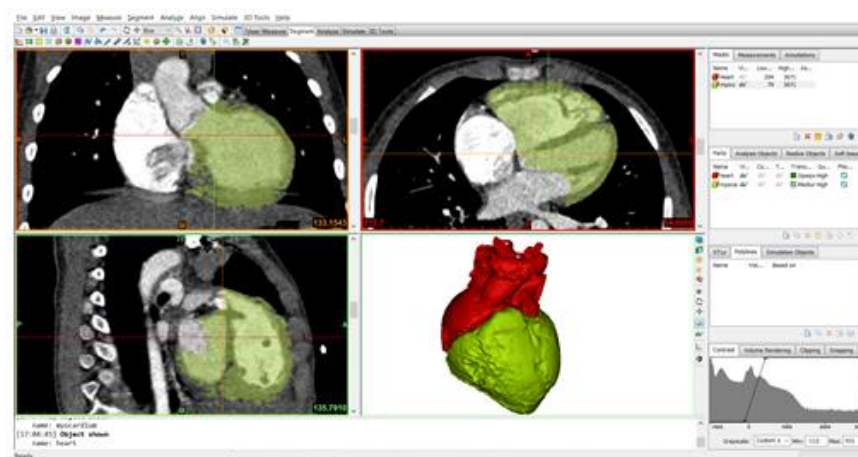


Figure 4. 11 Pericardium with Lumen

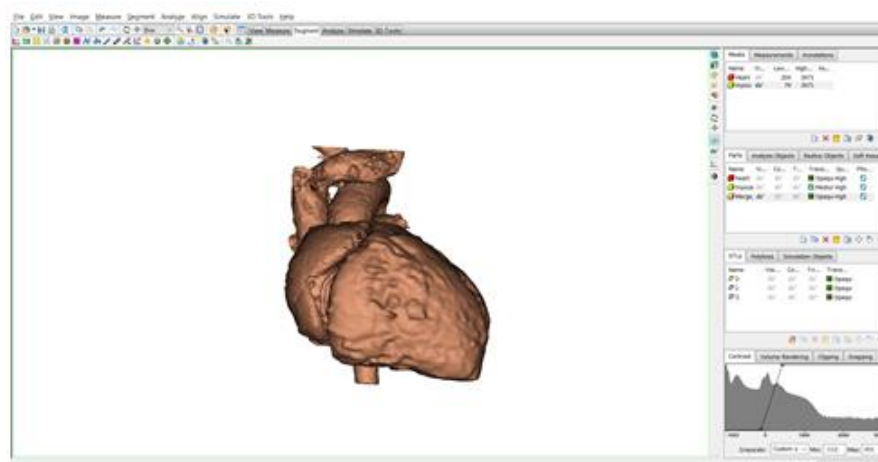


Figure 4. 12 The Whole Heart Digital Model –Turned

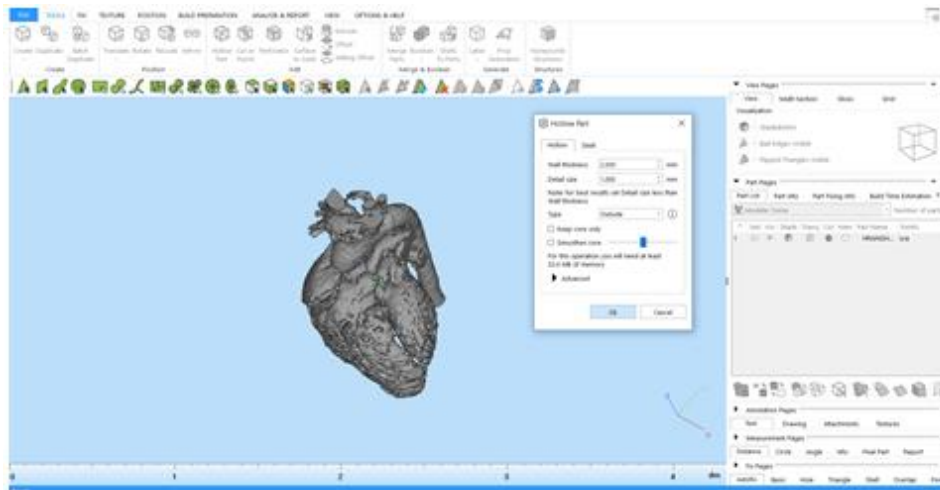


Figure 4. 13 Assigning Thickness

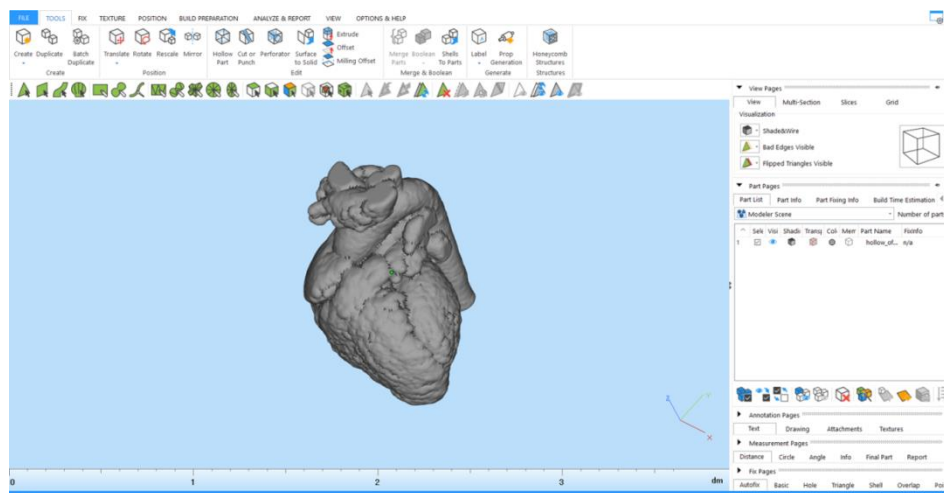


Figure 4. 14 Heart Appearance after assigning thickness

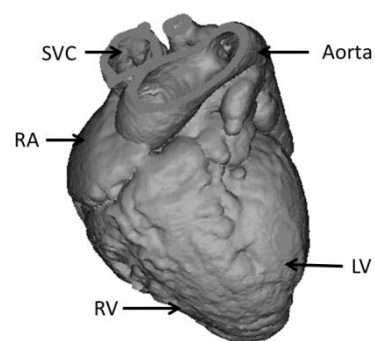


Figure 4. 15 Hallowed Whole heart model with features labelled

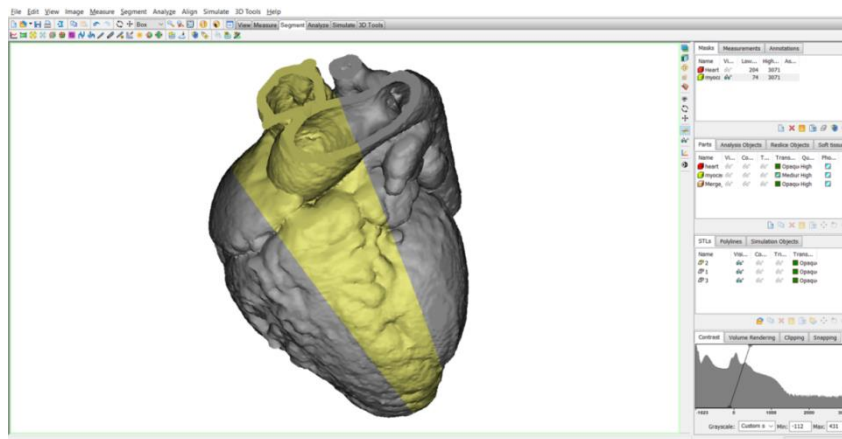


Figure 4. 16 Heart sectioned either side of the septum

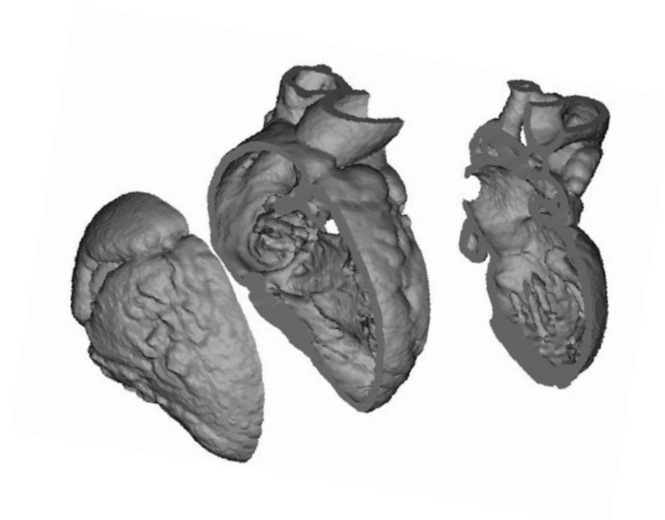


Figure 4. 17 Digital Heart Sections moved to show the inside features

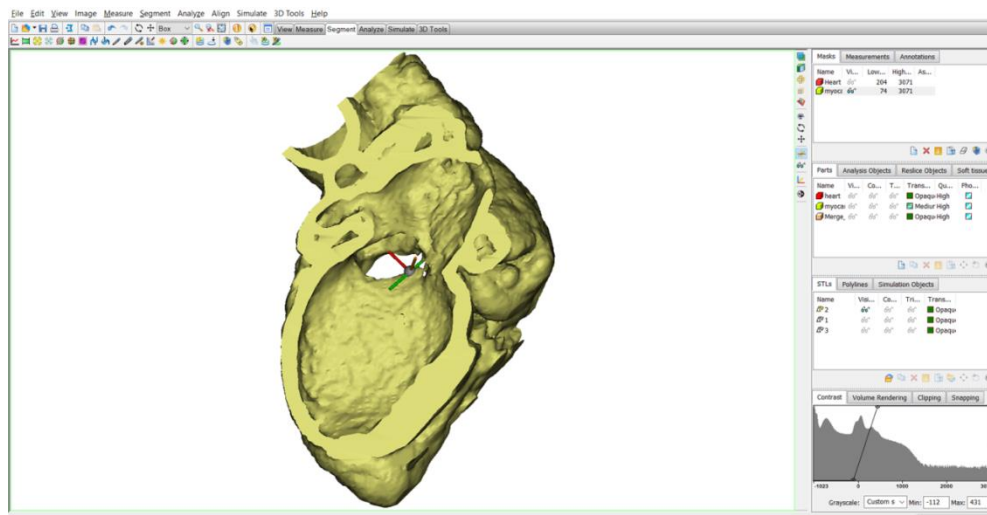


Figure 4. 18 Septal Heart section showing VSD

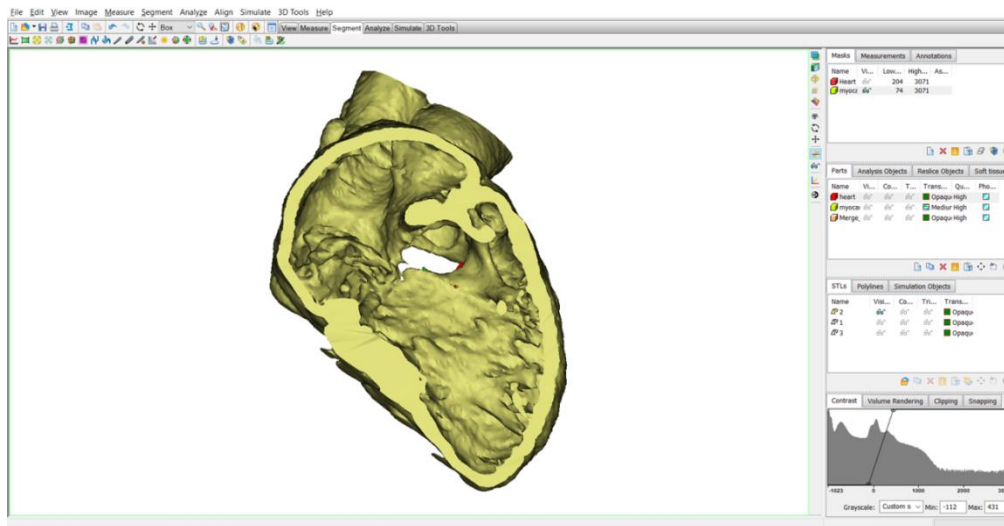


Figure 4. 19 Heart Section with VSD from the right side

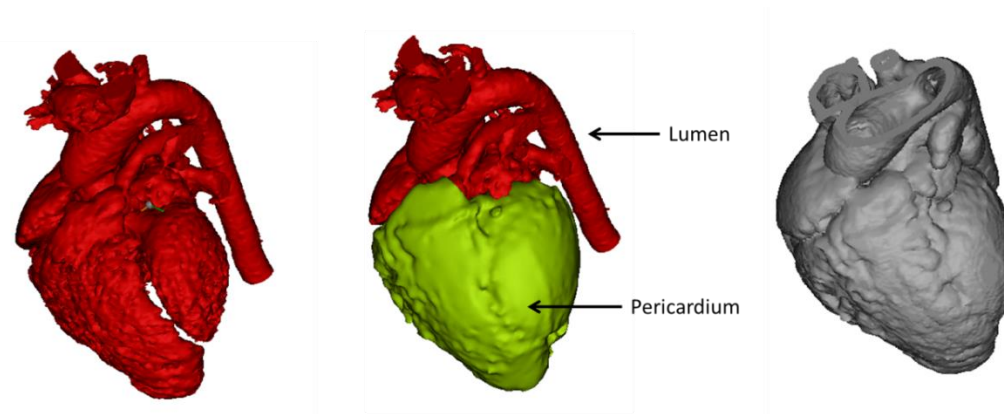


Figure 4. 20 Hallow heart model making steps

File export depends on file data structure such as ASCII / Binary; file formats such as STL, STEP, AMF, 3MF, PLY; Resolution related issues such as a number of triangles, cord length and file errors.

4.2 Factors Influencing Model Output

3-D printing / digital fabrication accuracy depends on the type of technology used, slice thickness, machine calibration status, build parameters, build orientation, the material used, support type.

Post-processing depends on the technology used, type of build material, type of support, finish desired. There are few special treatments such as sterilization, Hot isostatic pressing (HIP), Gamma-irradiation, infiltration and coatings.

The need for accuracy depends on its impact on the medical procedure. It is aiding in. Anatomical models for teaching or discussing with patient kin need not be accurate in size. The models used for procedural planning, in vivo applications such as surgical guides should be of stable material and their shape and size can influence the final procedural outcome. As such they are very important. The models that replace the tissue part such as bone have to be very accurate as well as in vivo safe materials. The fourth level is the use of the model as a live tissue replacement or an organ; the model accuracy with respect to shape, size and composition will be critically important.

Four factors that influence model quality are further discussed in detail

1. Input data
2. 3D printer Type
3. Material Type
4. Post processing

4.2.1 Input data

In order to get an accurate model, one needs to get a quality dataset and in the required format. For most of the models, the standard format used is STereoLithography File

(STL). It is a triangulated format in which whole part model is made of a number of triangles that share a common vertex, common apex and common edges. A single triangle will have three vertex points, three edges and one face/surface as shown in figure 4.1. STL file is triangulated files and is only an approximate model of the original CAD. Figure 4.2 shows the deviation

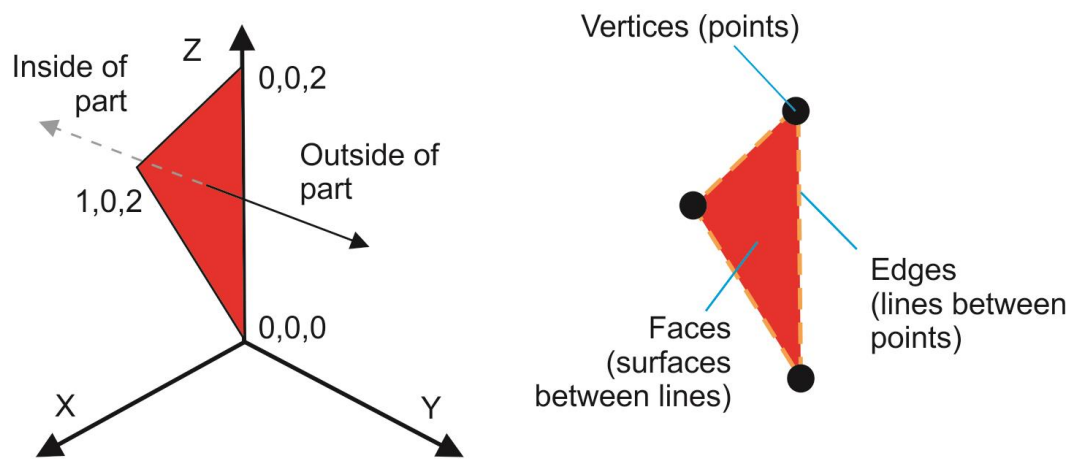


Figure 4. 21 Single Triangle of an STL format

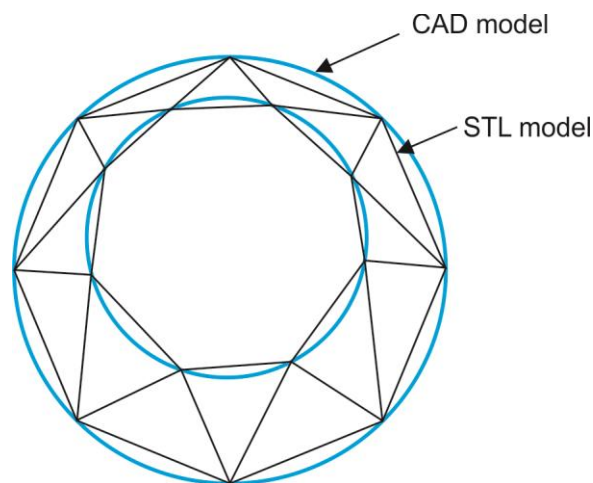


Figure 4. 22 CAD to STL conversion - loss of accuracy

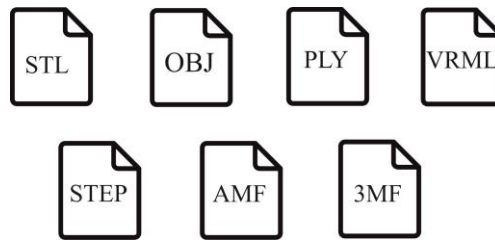


Figure 4. 23 3-D Printing File Formats

DICOM to STL processing should not have any data losses. If one needs to improve on part quality, STL should be exported from a STEP model as Binary STL file with the least Chord length possible. Smaller the triangulation, finer is the resolution. This, of course, comes with the heavier file.

If one needs colour models, then the best format is PLY. A PLY file carries with it the model and the colour mapping as a Metadata and helps to recreate the digital sample in the assigned colours. The other file formats that support Color model making are Obj, VRML, and STEP. Recently, two more new file formats overcoming limitations of STL are proposed and tested. They are built to be safe, carry more information and are light for data portability. They are Additive Manufacturing Format (AMF) and Three-dimensional Manufacturing format (3MF).

The input data set should be free from digital model defects. The typical defects are:

1. Inverted / Flipped normals,
2. Bad edges,
3. Bad contour,
4. Intersecting triangles
5. Overlapping triangles
6. Noise shells
7. Intersecting shells
8. Planer holes & gaps in the mesh

Flipped normals

Each triangle in the mesh has a normal vector, which points out to the outer side of a triangle (A). Normals tell the printer which way to add the material. When the designed model has a flipped normal or inverted normal, lead to confusion during the printing process and the model cannot be accurately sliced and printed (B and C).

Bad edges

The problem of bad edges is encountered when the edges of triangles are not properly connected to each other, creating holes and bad contours. Patching and blending bad edges with the dedicated software tools can help to repair the file and will allow you to print a high-quality object (D).

Intersecting and overlapping triangles

This error occurs when two surfaces overlap or cross one another due to the complexity of the geometry (E and F). To avoid a failed print, you will need to remove or unify these triangles with file repair software.

Noise shells

Shells are the outer layers of a print on the outside of the model. The higher the number of shells, the denser outside walls of the printed part. However, when a shell gets too small, it becomes redundant and serves little purpose. Such shells are called “noise shells” and, although they can be easily dealt with by flipping inverted triangles (G) When two solids intersect, they result in an internal shell (H).

Holes or gaps in a mesh

One of the most common errors leading to printing failures is missing triangles. This occurs when the adjacent triangles fail to share two common vertices. If this error is overlooked, the printer will not be able to correctly print the model (I)

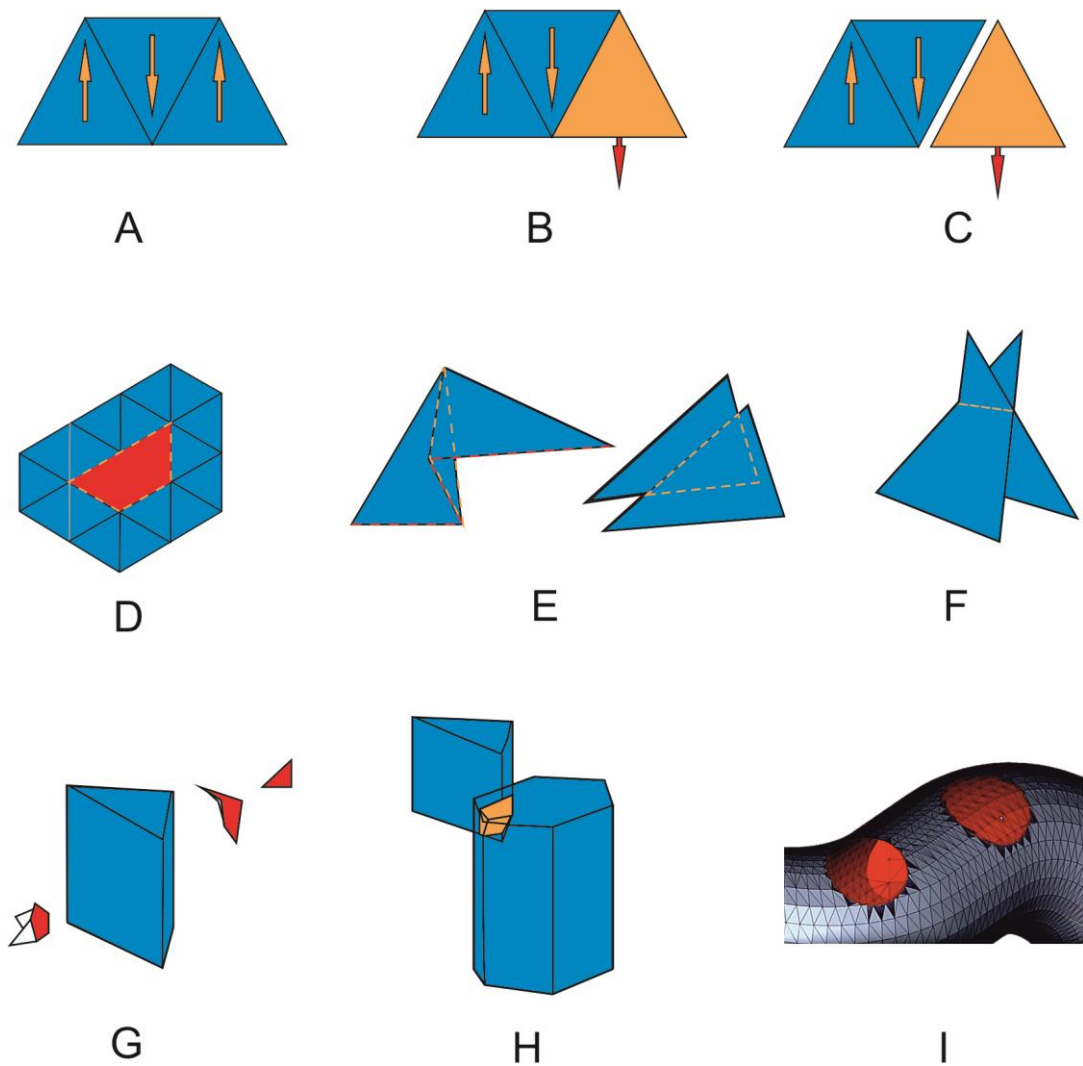


Figure 4. 24 STL format errors

4.2.2 3-D Printer Type

ASME classifies the 3-D Printers into seven main types. For the medical domain, all 3-D printing technologies find applications. That is, all the four levels as explained earlier (Ref. Figure: 1.15)

Out of seven major 3-D printing methods, six are of relevance for our study namely the malformed Heart. They are as given in Table 4.1

Technology	Alternate Name	Other Forms	Build Materials
Vat Photopolymerisation	Stereolithography apparatus	SLA , DLP, CLIP,	Liquid - non metal
Powder Bed fusion.	Selective laser sintering	SLS , DMLS ,	Powder metal and nonmetal
Hot Material Extrusion	Fused deposition modeling	FDM , FFF	Plastic, Plastic metal blends
Binder jetting	3D Printing	Ink Jet , MJF	Plastic powder and Sand
Material jetting	Multi Jet Modelling	Ink Jet , Projet, Polyjet	Polymer Resins in paste form
Laminated object modelling	Sheet Lamination	NIL	PVC Sheets , Paper
Directed energy deposition	Electron Beam Melting	SGC , SLM, LENS	Metal alloys

Table 4. 1 3-D Printing Technologies



Figure 4. 25 production grade 3D Printers (Courtesy: Imaginarium India Pvt. Ltd)

The machine type defines the technologies employed and the process followed. They can broadly group them as the build parameters and the machine calibration. Under build parameters, we have part orientation, slice thickness, and process temperature.

3D Printing Type	3D Printed output	Features / Remarks
SLA		Very accurate, Translucent, Hard brittle model. Good for flow analysis. Limited use
SLS		Very Accurate, Opaque, hard and fixable, In vivo Compatible, Auto clamp safe, Good for most uses
FDM		Not very accurate, Very Cost effective, Hard models
BINDER Jet		Fairly accurate , Very heavy , Very brittle, Hard, Fragile, Both natural and mapped Colours are possible.
Material Jet		Very Accurate, Very expensive, can be both hard and soft, opaque and transparent, can be made in natural Colours or mapped Colours
MJF		Very Accurate, Affordable, can be both hard and soft, opaque , can be made in natural Colours or mapped Colours

Table 4. 2 printing methods and their output at a glance

Table 4.3 gives their appearance and features of each technology that matters to our research study. Polyjet, Multi Jet, and Multi Jet Fusion are all material jetting technologies that can offer colour outputs.

(a) Build Parameters.

The typical build parameters for 3-D printing are slice thickness, build environment condition, build time, part cooling/curing, support material (same or different). Then there are other technology-specific build parameters, which are very important and play a vital role in model output quality.

SLS Build parameters
Layer thickness
Powder bed Temperature
Powder feed bed Temperature
Laser Type
Fill laser power
Outline laser power

Table 4. 3 SLS Build Parameters

In the case of SLA and SLS processes, laser power, laser beam size and scan types are very important parameters that contribute to the model quality. Further, there are three types of Scans : overlapping, double scan, in-fill scan.

(b) Part Orientation

3D printings are digital fabrication processes in which, the parts are built layer by layer. These layers have a tendency to delaminate if not properly fused. The model compressive strength is the maximum normal to the layers and the least along the layers. The models will be better in bending if layers are perpendicular to the bending force. This is generally the case with all the technologies and is particularly important with FDM where we have visible layers made of fine filaments.

SLA and SLS show considerable resistance to layer effects in SLA, SLS and MJF due to larger cure time. Except for SLS, MJF (Plastic) and Binder Jetting (Gypsum powder), all other processes such as SLA, FDM and Metal 3D printing need support for overhanging parts of the model. They greatly influence the model quality. They have to be removed post the build and finished to get a good surface.

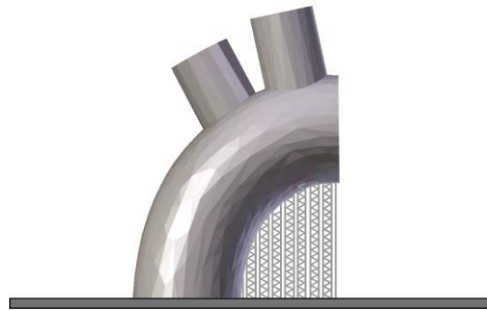


Figure 4. 26 Overhanging part needs support

(c) Slice thickness

The deposition method, the material form may vary from one technology to the other. The slice thickness may also vary from one process to the other. In most machines, the slice thickness is the same as a layer deposited. If they do not match, proportionality suffers in the printed object.

The material deposition in x, y and z directions have to be of the same scale to build an accurate model. For any x, y plotted shape; z thickness determines the form of purity. It is particularly more important in angular models as shown below:

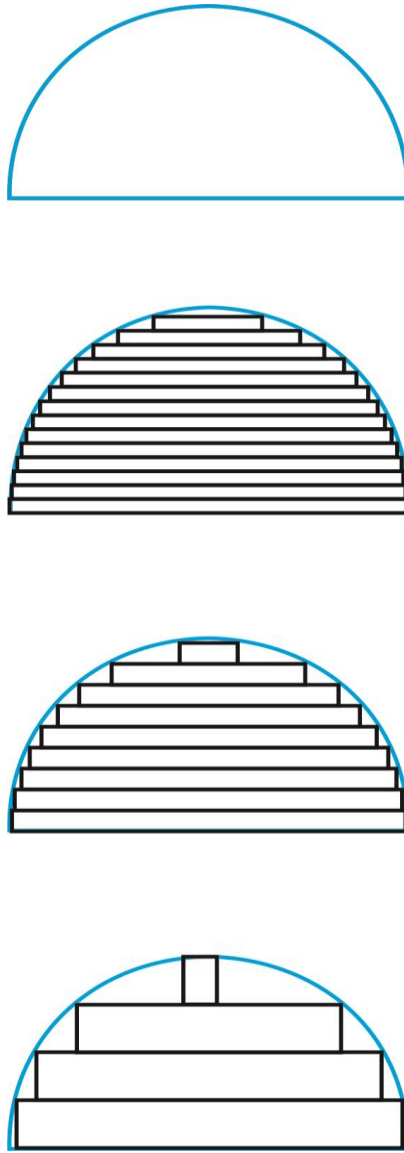


Figure 4. 27 Effect of layer thickness in model quality

Medical models, in particular, are organic in shape and details at higher layer thickness. We can see how the coarse layer thickness is contributing to the form deviation in Figure 4.2. Lower the thickness of layers, better is the reproducibility.

Apart from layer thickness, the file resolution also contributes to the quality of the model built.

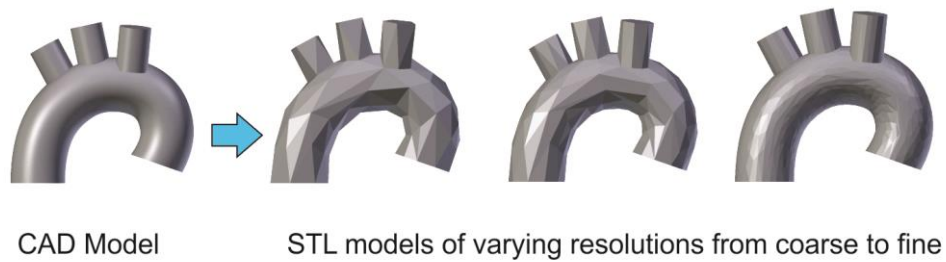


Figure 4. 28 Effect of triangulation size on model quality

3-D printing technology	Slice accuracy in microns
Stereolithography apparatus (SLA)	100, 50, 35, 25
Selective laser sintering (SLS)	150, 100
Fused deposition modelling (FDM)	178
Binder jetting	100
Material jetting	35, 25, 16
Laminated object modelling	150, 100
Multi jet fusion (MJF)	80

Table 4. 4 Build accuracy technology wise

The build accuracy range for each technology is provided in Table 4.4.

The detailed schematic of each technology with brief working principle is provided in the end in Annexure I

(d) Machine calibration

As we know, 3D printers are an Electromechanical Systems, which the platform moves in x,y and z. Parts are built on the build platform/build table. The material is dispensed on the build table as per the G-Codes derived from the slicer data and with each layer, a stepper motor raises or lowers the build platform as needed.

In FDM / Binder Jetting, The build plate/material dispenser's physical datum and the digital datum have to be same to get an accurate part to build. In the case of SLA and SLS, laser power and laser beam diameter are also need to be consistent to contain inter build variations. We hence follow a standard machine calibration as provided by the machine manufacturer and maintain the records. A standard test sample is built and measured for x, y and z-axis dimensional accuracy. Variations tabulated, and error, if found, is compensated before the next build. Thus, we ensure the accuracy of the build every time.

(e) Process Temperature

Process temperatures, as well as ambient temperatures, influence the part quality. The materials in SLA, Material Jetting, Binder jetting are mostly carried out at room temperatures or slightly warm. In processes such as SLS, FDM, MJF and metal sintering, the build is at elevated temperatures. The range varies from 250 degrees Celsius to 900 degrees Celsius. The sudden cooling can bring shrinkage, delamination, and warping in models. In these processes, temperature management is very important.

Our technology SLS is also a hot process and needs cool gradually to room temperature before the part could be taken out for cleaning and finishing. We have observed that the powder fineness undergoes a change from fine aggregate to little coarser due to the heat exposure. These give raise layer delamination on the model surface called “Orange Peel.”

4.2.3 Material Type

The model quality also depends on the material type. The liquid and paste based materials offer better quality models as compared to Powder based methods. The filament based processes like FDM which process solid material, in its function resemble material deposition like material jetting but the deposition is continuous. In the case of binder jetting, the powder bed are glued to make a layer. In the case of material jetting, the material is deposited as a fine spray and forms a layer, which is repeated again to build the part. In material jetting process, laser fuses the build material and bonds the previous layers.

(a) Material Quality

The material quality is important to the final quality of the model. The material property consistency may vary from batch to batch. The material shelf life can affect the build parameters and model quality. In our research study, we have made use of Selective Laser Sintering technology (SLS). Here the material is powder based with a mean particle size of 42 microns. The fresh powder is used for medical guides, fixtures and other in vivo applications while a mix of fresh and old material is used few more times (not more than five times) for use in non in vivo applications.

4.2.4 Post processing

Post processing is the last opportunity to control and build an accurate model. For best results, the finishing process has to be designed to suit the build method. Post-processing typically consists of the removal of the parts from the build platform, removal of the supports and cleaning surface by solvent/sandblasting for SLA and SLS respectively. Post-processing after SLS is as follows:

The whole build volume is called a ‘Cake’ in the SLS process. Parts within the cake are allowed to cool gradually from 175-180 degree to room temperatures. Depending on the build size, this can vary from a few hours to 24-30 hours. After cooling to room temperature, the powder cake containing the built are filtered to extricate the models (Ref Figure 4.6). The Parts still hold a lot of powder around them due to Heat Affected Zone (HAZ) and in the pockets and undercuts if it is a bounded part like heart models. The excess powder is brushed off the excess and sandblasting. If needed the parts can be sterilized by autoclaving (e.g. in-vivo applications). Any powder entrapment can be cleared by providing a hole and later plugging it. It can be done digitally beforehand in CAD itself and built with powder exit holes.



Figure 4. 29 SLS post-processing

4.3 3-D printing of the model

In our research, we mostly used the Powder Bed Fusion Technology; Selective Laser Sintering (SLS) model Sinterstation- HiQHS from 3D systems (Fig.74) it uses a 50-Watt CO₂ Laser with high-speed Celerity™ Beam Delivery system.

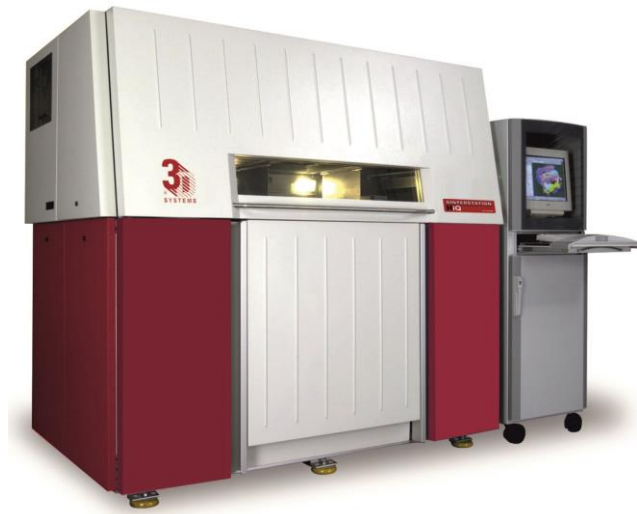


Figure 4. 30 SLS machine from 3D Systems used to print in this study

In the SLS process, we can notice some shrinkage of parts. This is taken care by applying shrinkage compensation factors in x, y and z-axis. Also, we need to take care of the diameter of the beam by “Beam Compensation”.

The Digital Part to be 3D printed is exported as STL file to the machine system. This data is further sliced at 0.1 mm using “Build Setup and Sinter” software and is sent to the SLS system for Part Build. The material used for the Build is Durafoam or PA 12, a proprietary blend of fine Nylon powder. Usually the fineness each rounded nylon particle is about 42 microns (0.042mm). This material is a biocompatible material which can be autoclaved for sterilization. This material is certified by US FDA for “In-Vivo” applications. The parameters set for the printing is given in Table No. below:

Layer thickness used	100 Microns
Powder Bed Temperature	176 Degrees Celsius
Powder Feed Bed Temperature	130 Degrees Celsius
Laser Type	CO ₂
Fill Laser Power	42 Watt
Outline (Border) Laser Power	7 Watt

Table 4. 5 SLS Build Parameters

The soft tissue explorations use contrast CT modality. We collected five data sets as a part of the pilot study.

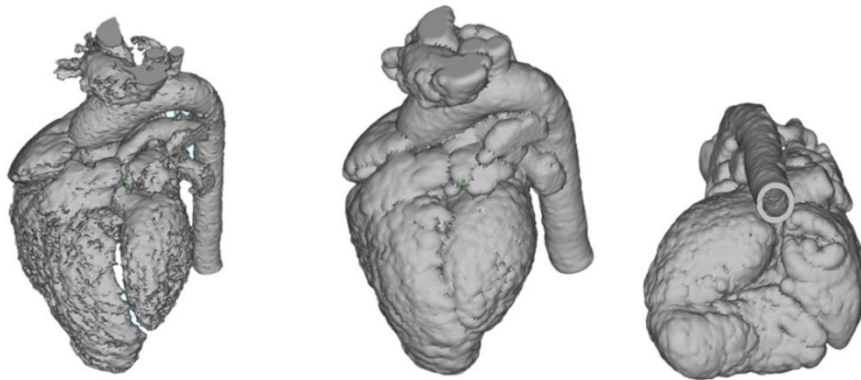


Figure 4. 31 Conversion of Lumen model to hallow model by adding thickness

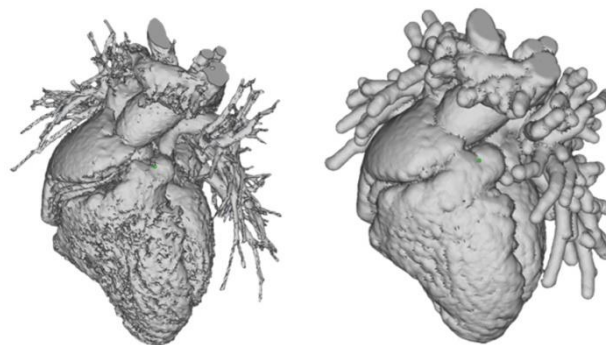


Figure 4. 32 The Lumen model with thickness close with rounded ends, this will distort the model

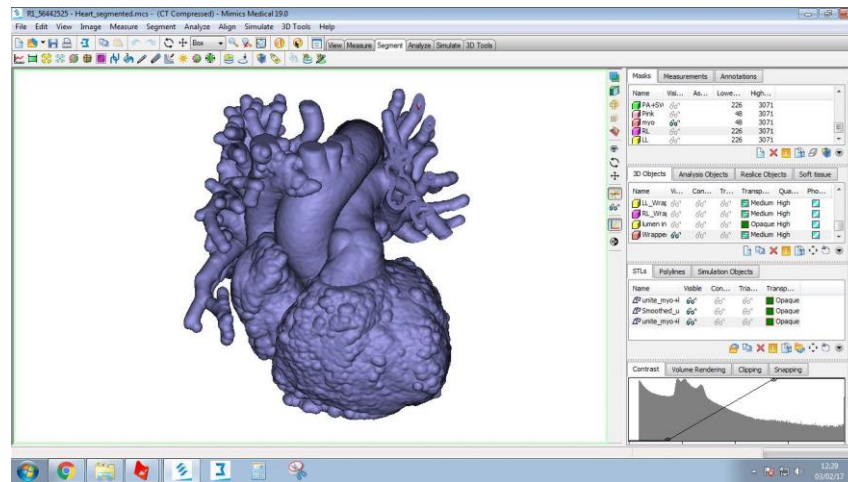


Figure 4. 33 Digital Model with pericardium explored on screen for various landmarks

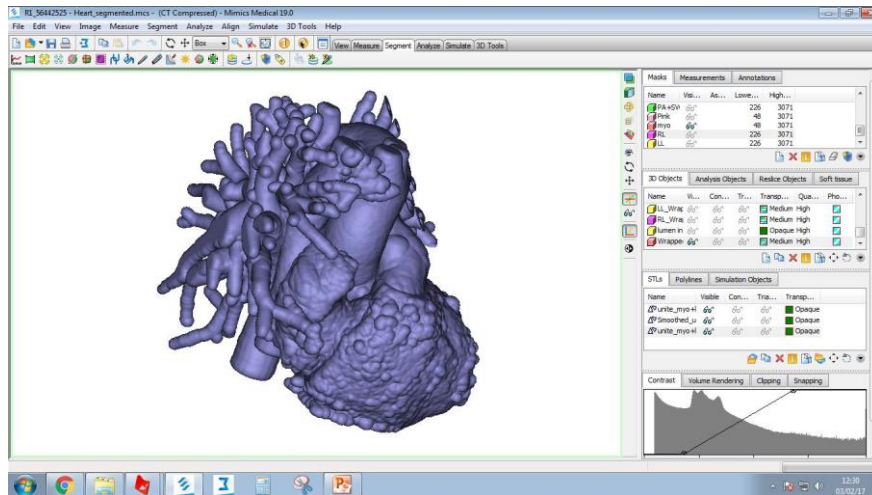


Figure 4. 34: The digital model is rotated on the screen to get the overall picture

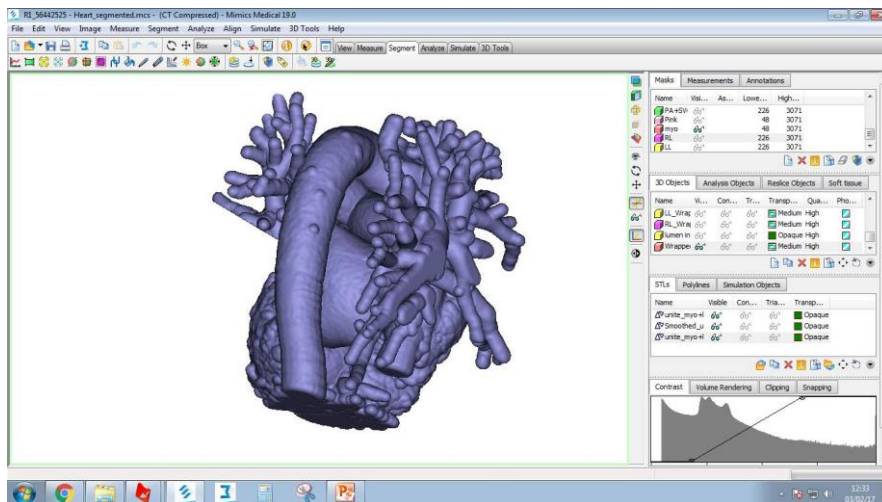


Figure 4. 35: The Digital Model showing descending aorta, a very prominent landmark

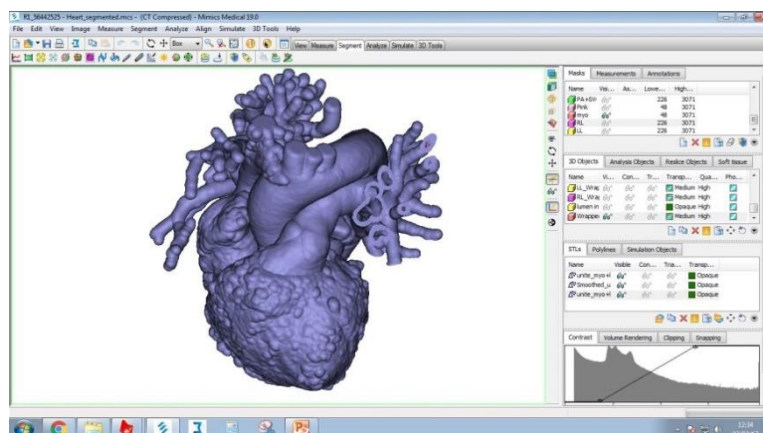


Figure 4. 36: Heart in typical view, showing the arch of the aorta, the trunk of the pulmonary artery.

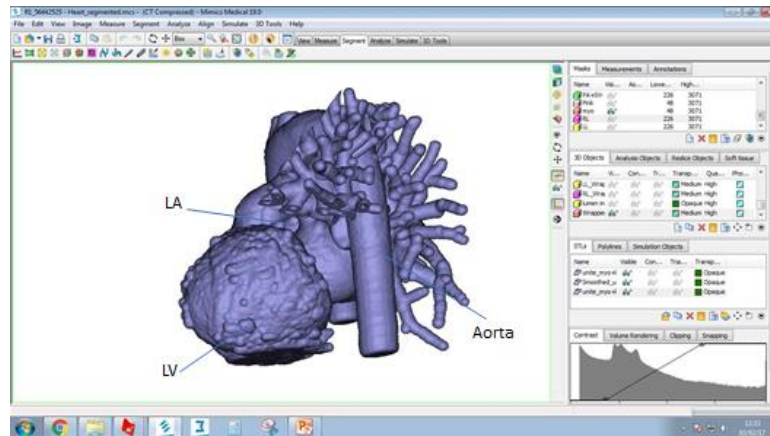


Figure 4. 37: The labelled Landmarks of Heart, LA, LV and Aorta

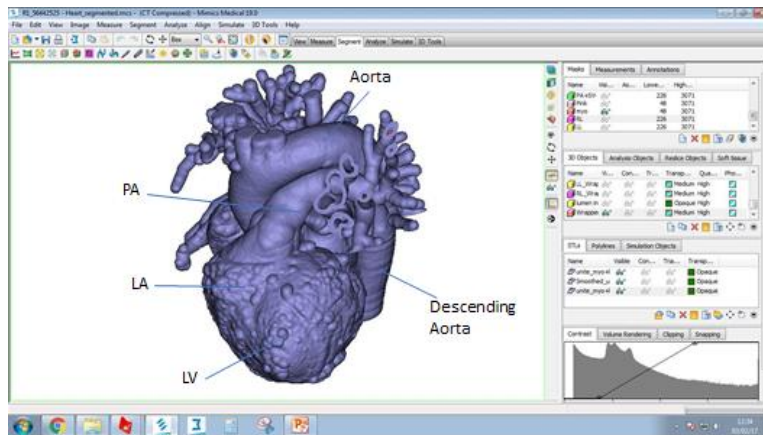


Figure 4. 38: Labelled landmarks of the Heart, showing PA, LA, Aorta, LV

4.4 Model Validation

The 3D printing process is adapted to fabricate the physical models directly from the digital model. While digital models are good, the file export for printing purposes is an approximate model. The triangulated model is faceted and accuracy is to some extent compromised. If we ignore it, then the model accuracy will depend on the 3-D printing process. 3-D printing is effected by x, y and z table isometric displacements. So, we assume every model is built after due machine calibration for isometric build table movement. This is carried out by building calibration test parts, measuring them, applying the error corrections if any.

From the literature survey we know, Mr. Todd Grimm (Grimm, T., 2005) first proposed a simple model for benchmarking 3-D printing across Stratasys FDM machine versions. There are many more such benchmarks arrived (Lara Rebaioli, 2017). They are all focused on dimensional measurements, meant to evaluate the machine's capability to faithfully build the CAD input provided. The dimensions of a patient-specific model are difficult to measure. The organic model's dimensions will change at every tangent. Due to their organic in shape, we cannot fix a datum. This is a challenge may be addressed by digital inspection options such as photo Interferometry. Also, the benchmark artefact has to be organic in shape. For this purpose, we devised a new set of benchmark artefacts called Bioform A, Bioform B and Bioform C. (Figure). The Sectional details are provided in Annexure X

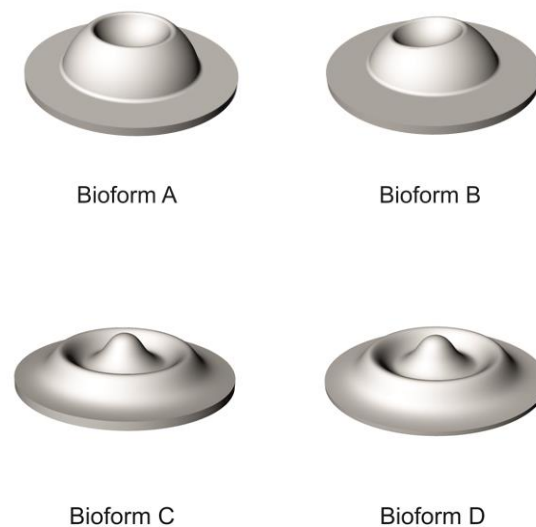


Figure 4. 39: Samples A, B, C and D

Method:

The models in digital form (STL file) are printed on an SLS system after due calibration procedure. The cleaned models are scanned by a blue light scanner to get point cloud data or STL model. The original STL and scanned STL files are superimposed to compare and estimate the variance. The areas of nominal dimensions appear green, areas which are plus appear as red and areas which are negative appear as blue hues. By such a procedure, one can get a fair estimate of the model's accurate reproduction. This forms the basis of digital inspection to assess model accuracy.

In our research study blue light scanner from Zeiss - Steinblchler model – “Comet L3D 8M” is used for digital inspection of models. As a rule, the device is duly calibrated using CP_P_100_747 calibration plate. For STL superimposition, software provided with the device, Colin3D (Version-3.0.0.292) is used and for inspection purpose, INSPECT plus (Ver 5.51.155) is used. The figure below shows typical setup for scanning of samples.

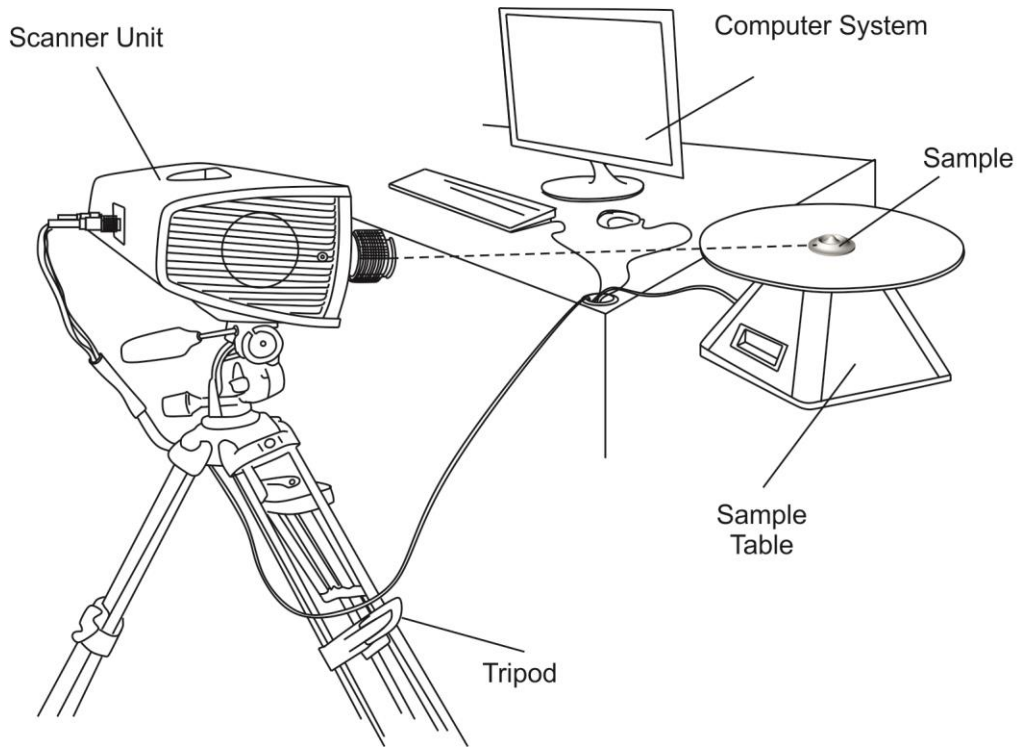


Figure 4. 40: Scan setup

We used 3 samples, Bioform A, B and C to see variation due to geometry in taking 3 sets in XY and Z direction builds. The models are evaluated by digital inspection procedure, results are tabulated and analysed. Further, we also wanted to find the impact of thickness variation on the build. So, we took Bioform C and Bioform D with the same geometry with thickness 2mm and 1 mm respectively.

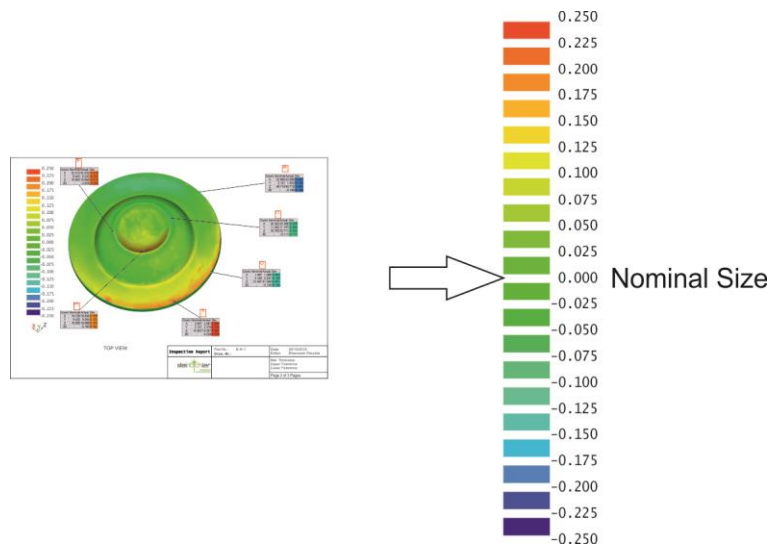


Figure 4. 41: Heat Map scale - details

We can see from the results obtained, the XY seems more accurate than Z for the build. As the benchmark with 3 geometries shows similar results, we may conclude the build is good to recreate any organic form within a close tolerance. The digital scanning and superimposition method seems to be a good method to assess the accuracy of anatomical models. This result forms the basis of 3D printed model validation. The method is further used to assess the patient-specific models for their accurate recreation.

The part STL is superimposed (Ref. Figure) on its scan data to get a colour map showing the variations quickly. The colour code used is: nominal is Green, positive is Red and negative is Blue. For ease of quick assessment, a band of colours are provided in the inspection report. Each colour band is about 0.025mm increments from nominal, 0.250mm either side.

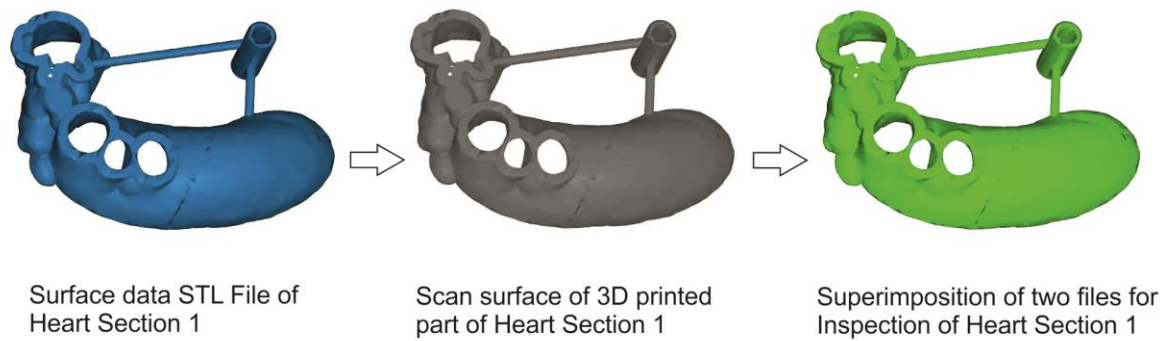


Figure 4. 42 :Digital Inspection Process

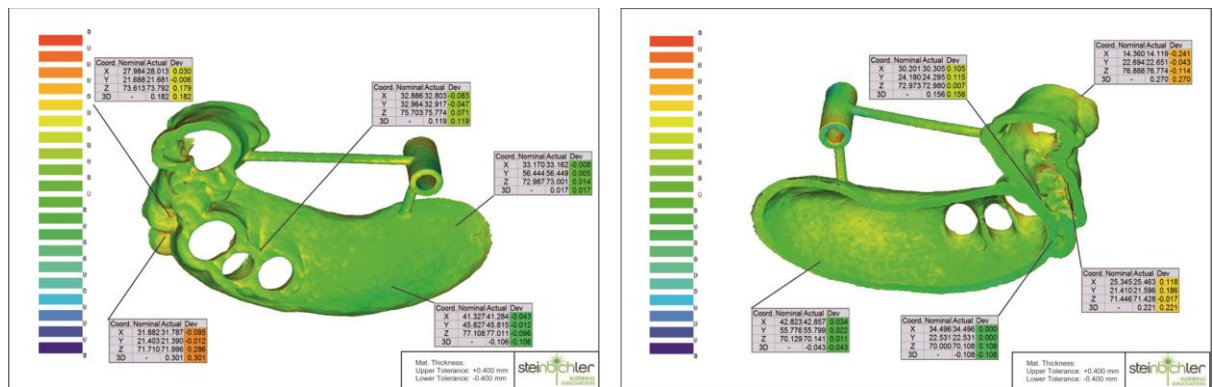


Figure 4. 43 :Digital Inspection Report

The printed models are validated before offering to clinicians to explore, visualize and plan the treatment. Their feedback is duly recorded.

Chapter 5: Optimum Heart sections

A heart is a muscular bag with four chambers with numerous ducts coming in and going out. It also has four internal valves. The diagrams are shown in textbooks conceptual representations are far from what we can see in reality. The complex heart structure requires many sections to understand completely. Our objective is not about making models for just learning. The heart defects will manifest in all possible ways and the verity is only growing in number with the deeper search.

This is what forms our main scope: to prototype the heart with all the structural defects. The rich heart structural manifestations and landmarks are called as morphology. If the clinicians can visualize the defect morphology clearly, it will help in better clinical management.

The greatest advantage we have with a digital model is the ease of taking sections without constraints to gain insight into the defect type and its manifestation. From the literature survey, we can see a few papers that specifically talk about sections. There are some case studies discussing section without elaborating it. It must have existed as tacit knowledge and never published.

5.1 Heart Sections for better Visualization.

The surgeon's sections in actual dissection or operation are very similar due to the organ placement within the rib cage Figure 5.1. This greatly limits what sections they can take. The Cadaver hearts are far easy to explore then live heart.

Heart in its position in rib cage can be located by rib reference or by the body planes as given in Figure 5.2. These planes applied to heart will appear as shown in Figure 5.3.

The Radiology and the medical imaging engineers have a different approach to plan the slices in relation to the horizontal and gantry tilt. Figure 5.4 shows the transverse or axial section view, Coronal plane section view, and the sagittal section view. In order to explore heart morphology, three-dimensional views are needed. Figure 5.5 shows 3-D printed models with sections taken so as to explore morphology.

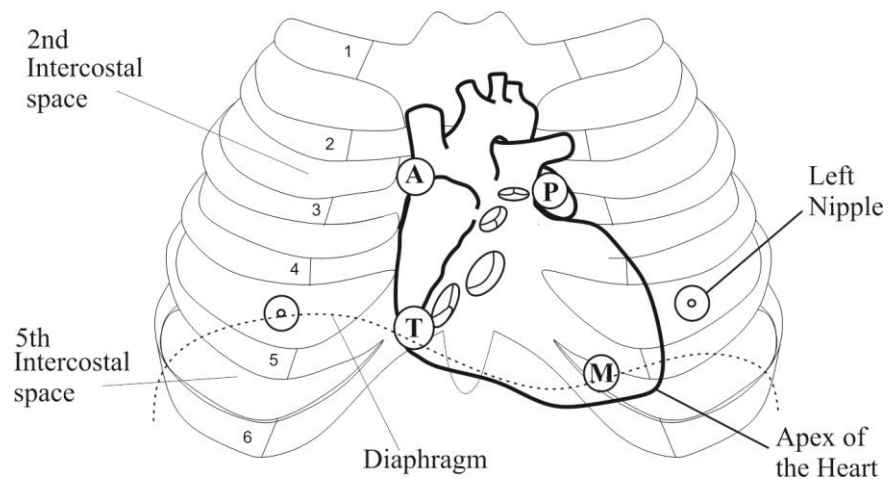


Figure 5. 1 Heart location in the ribcage

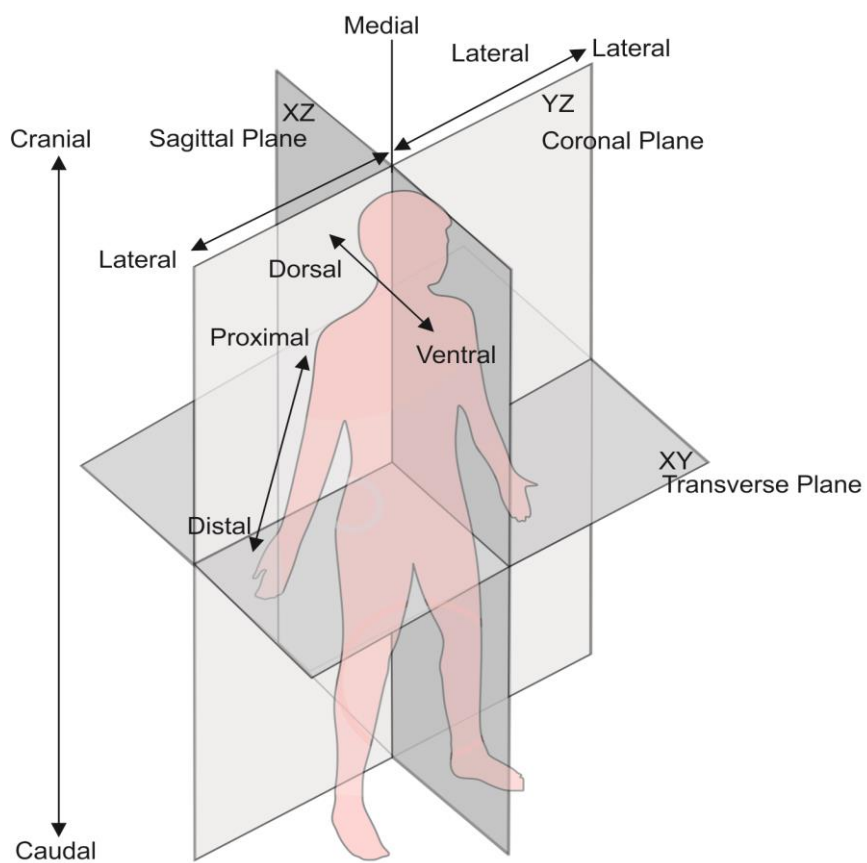


Figure 5. 2 Body Planes

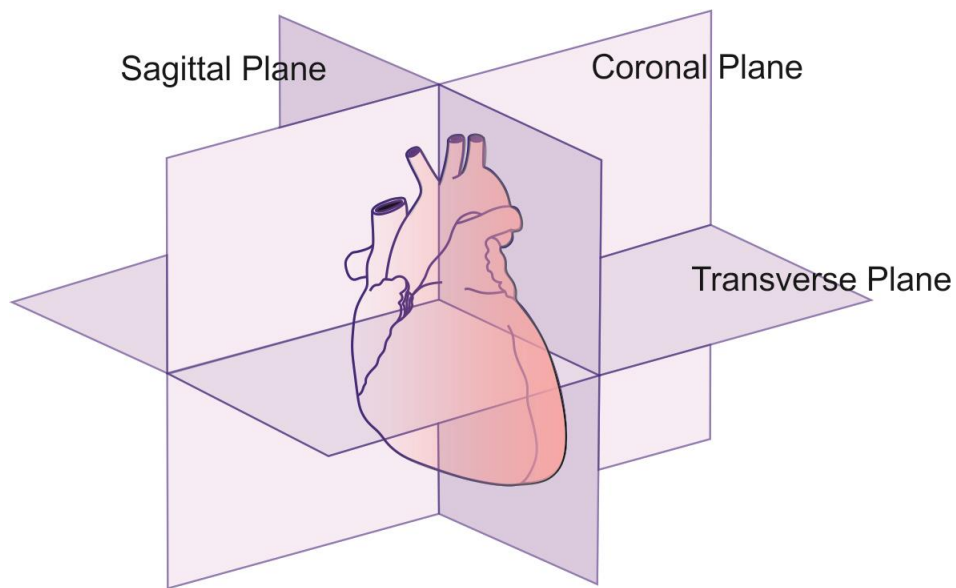


Figure 5. 3 Body planes applied to the heart



Figure 5. 4 CT sections through the heart

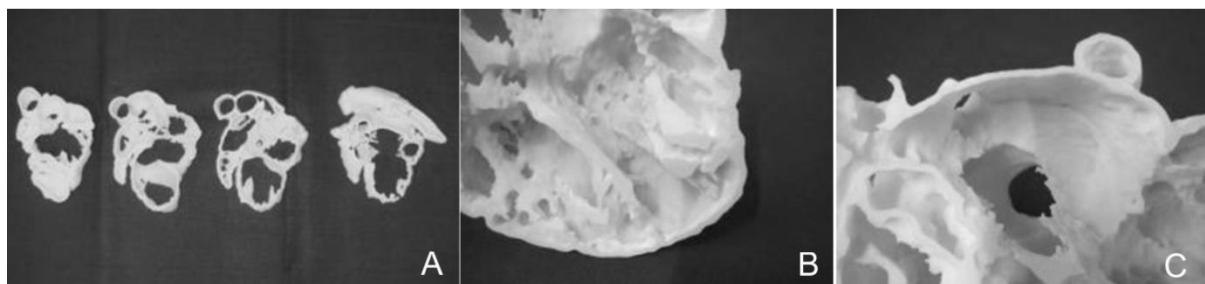


Figure 5. 5 Heart Sections to explore morphology. A: Shows the sections placed in a sequence to see the defect progression, B: Sections, When stacked shows the complex nature of the defect, C: A Close up of the Septal opening showing the defect in all its size and location

5.2 Heart Section Options

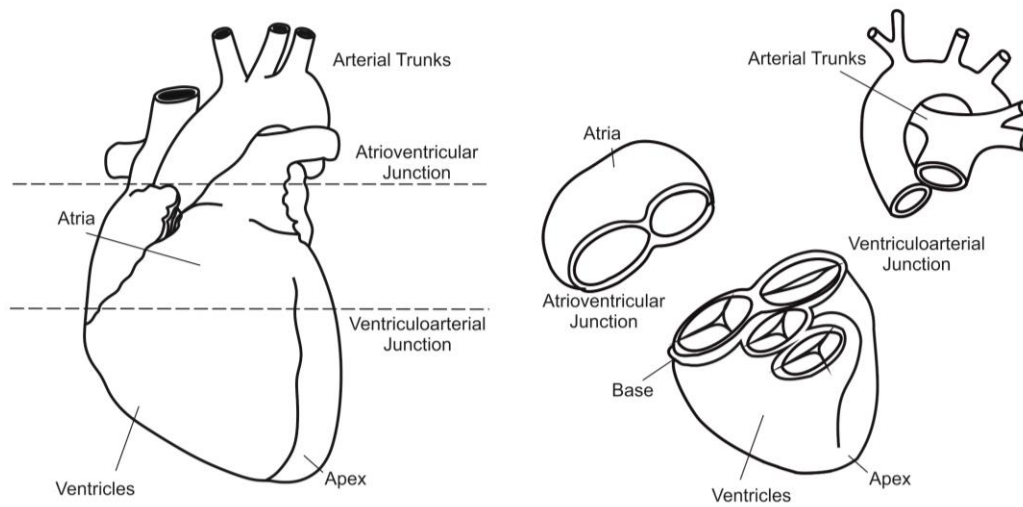


Figure 5. 6: Sectioning of heart, the typical approach after Van Praagh (1972)

The origins of the heart birth defects are a complex subject and many factors are said to influence such as Genetics, Medication, Deficiency, exposure to radiation, Physical Stress etc and is beyond the scope of the present study. However, what we are clear from literature is that the defect occurrence begins to manifest in the embryonic stage.

From the heart development, we see any delayed growth or growth stoppage can lead to malformation as an organ.

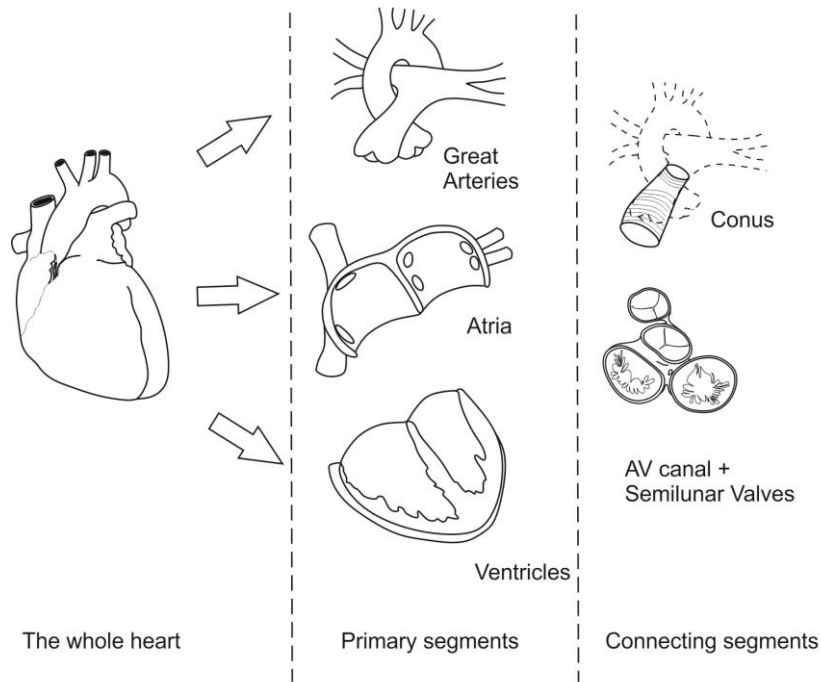


Figure 5. 7 A Detailed Heart elements where defects can occur

We see a large distribution defect types along the septum and form almost 80% of all the Congenital Heart Defects. They occur in Atrium and Ventricle septum. Thus a section taken parallel to the septum can yield rich inputs about the morphology of the region. This forms our first strategy. If we take the septum middle line, the defect can occur on either side.

The trunk of arteries is the place where the muscular twist or looping happen in fetal heart formation and is another candidate region to look for defects. This region is also called as Conus.

The sections are taken such that we get to isolate the defects quickly. Once the defect is isolated, we plan to take 5 to 10mm offset to capture the defect. This is done to know the defect placement with its neighbourhood. This is very essential for corrective planning as per the expert clinicians.

5.3 Proposed Method for Visualization

We propose a new way of looking at body defects and in particular, the focus on our study, the Heart.

Take a Generic / Typical Normal Heart The method is to map all defect types and its affected zone. This can be called as Defect Affected Zone (DAZ). It exists as a 3D space and many defects may also overlap.

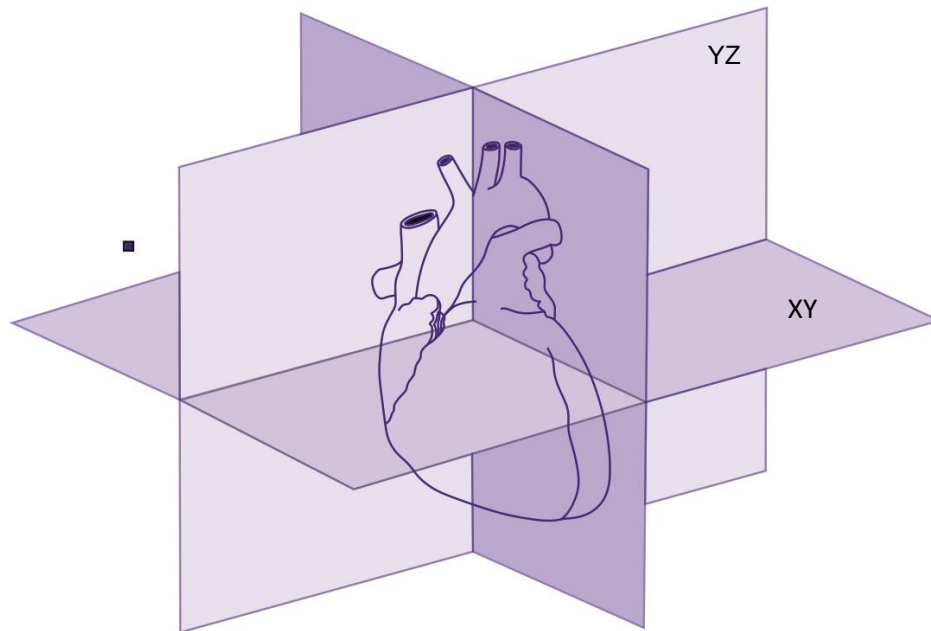


Figure 5. 8: Typical Engineering Approach: Keeping it in the centre of Cartesian planes in x, y and z directions

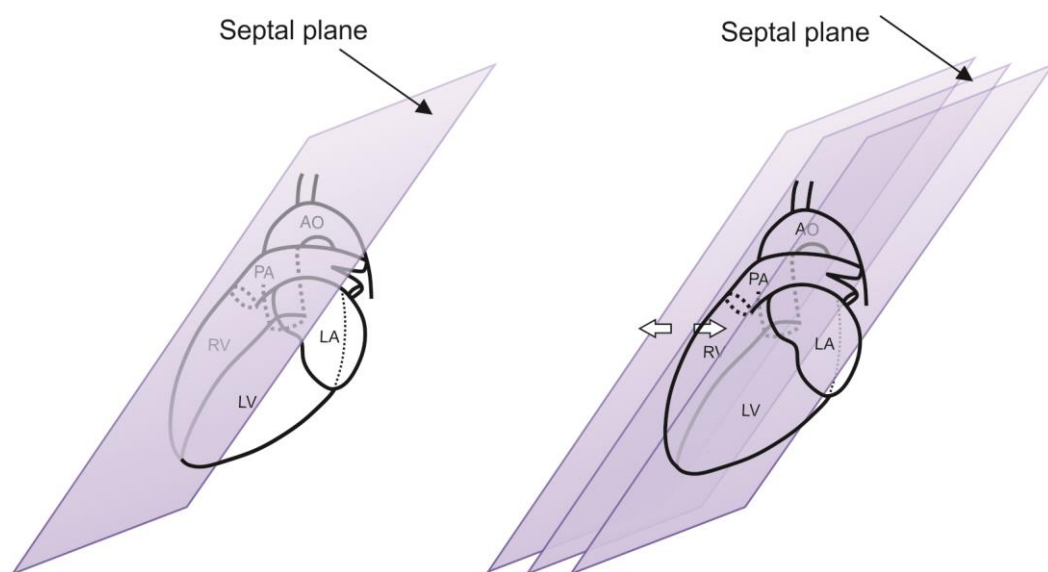


Figure 5. 9: Introduction of an oblique plane through the septum

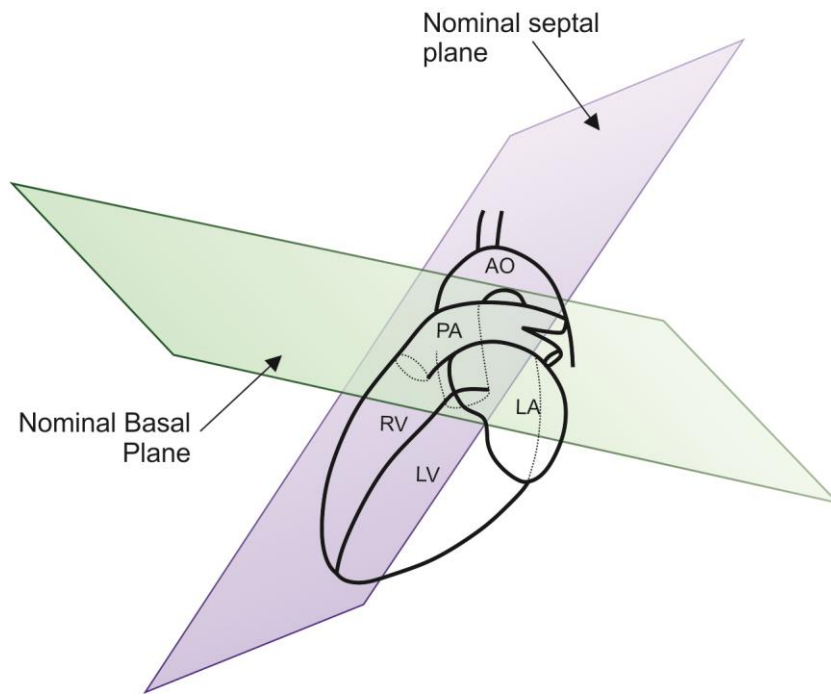


Figure 5. 10 Septal and Basal Nominal Planes

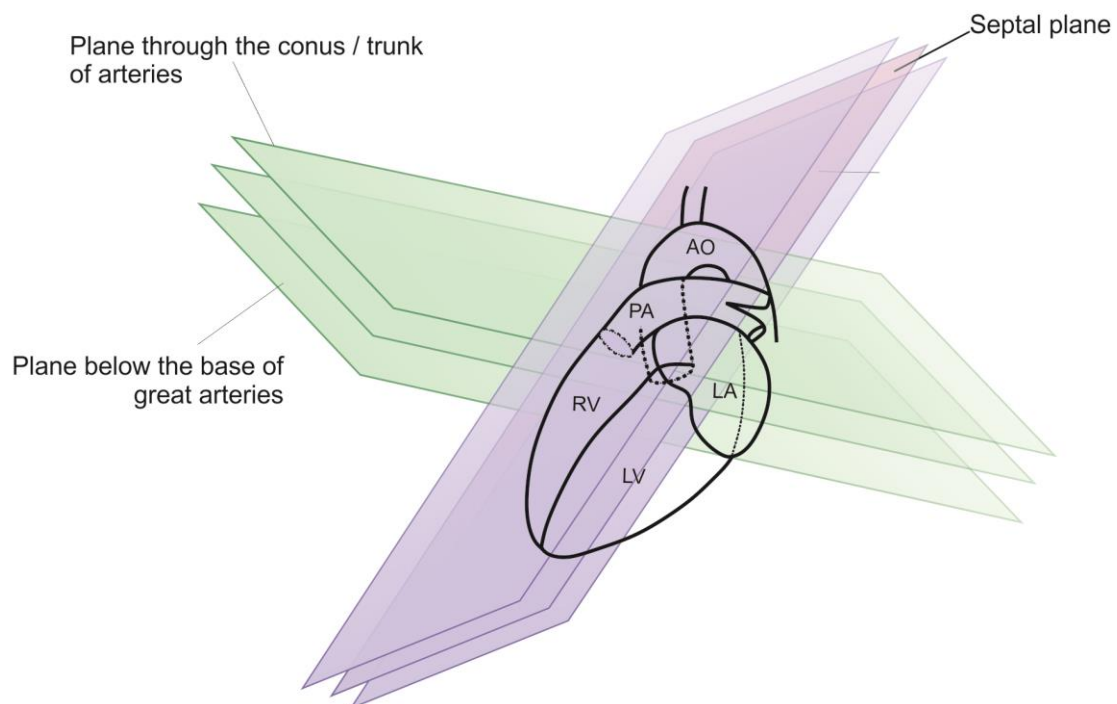


Figure 5. 11: The New Section Approach: Two parallel plus oblique planes

5.4 Validation of sections through prototypes

A conceptual approach to section heart along the regions of maximum defect occurrence needs to be validated. This can be tested with sample data if we can isolate defects more readily. Once the image is segmented we can turn, rotate and explore the model. In order to see the inside, we need to take sections. We can define section planes in the software and slice the digital model. The model can be sectioned along the nominal septal plane and along the nominal basal plane to test our concept.

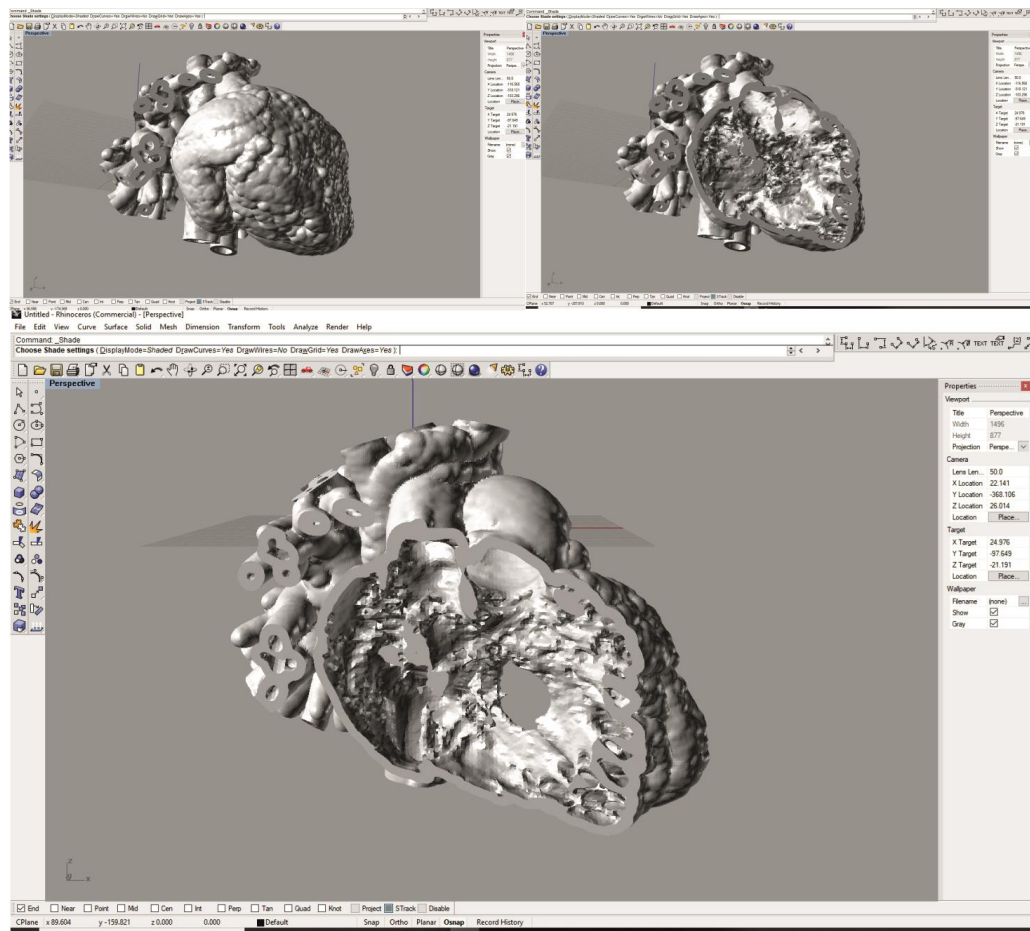


Figure 5. 12: Digital models explored on a computer screen

The digital cut on either side of septum shows the VSD clearly. We can see its location, size, and morphological landmarks. These further enhance the understanding is a 3-D printed model is held in hand and explored.

Digital rendered models on the screen can provide a vivid picture of the morphology. One can turn and rotate, zoom in and out to check on the morphological landscapes to gain insight about defect condition. This will help to plan the treatment management.

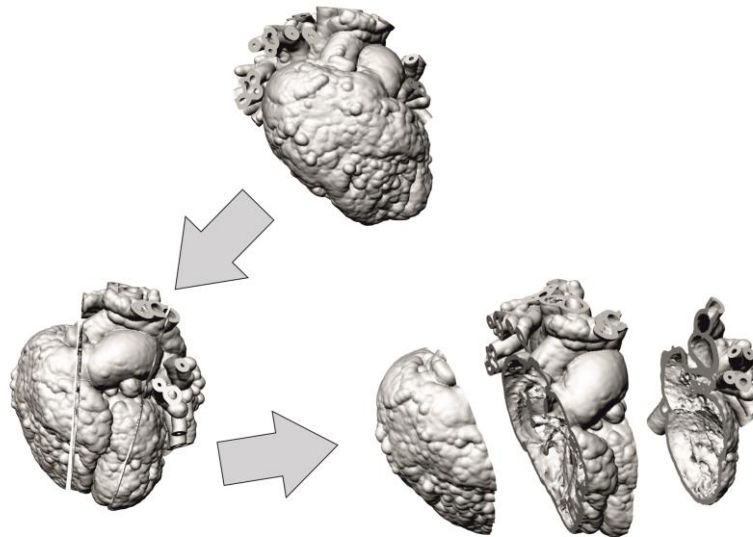


Figure 5. 13: Digital rendering steps showing the whole model, sections and sections apart

If we are clear about the defect, we can plan a thinner section just enough to know the defect size, location with morphological landmarks (Figure 5.12) This would greatly reduce time to print the model and save cost also. This is what optimum sections can do!



Figure 5. 14: Section beside septum showing the septum opening

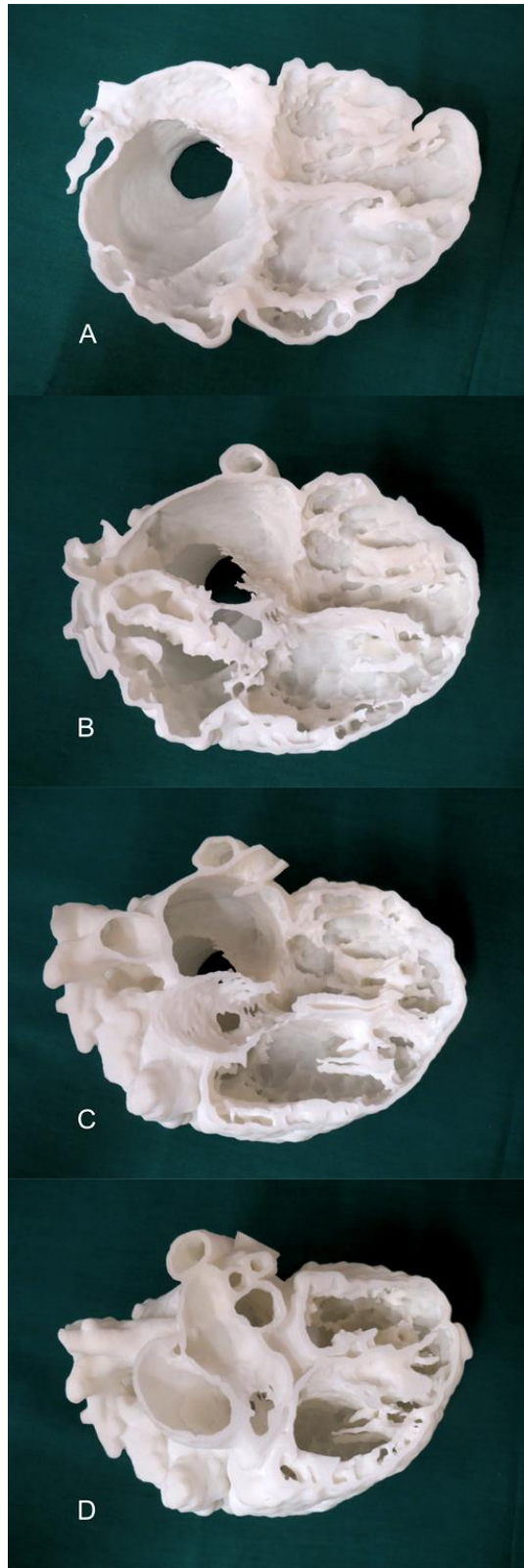


Figure 5. 15: Heart Sections A to D put one over the other to visualize the rich morphology

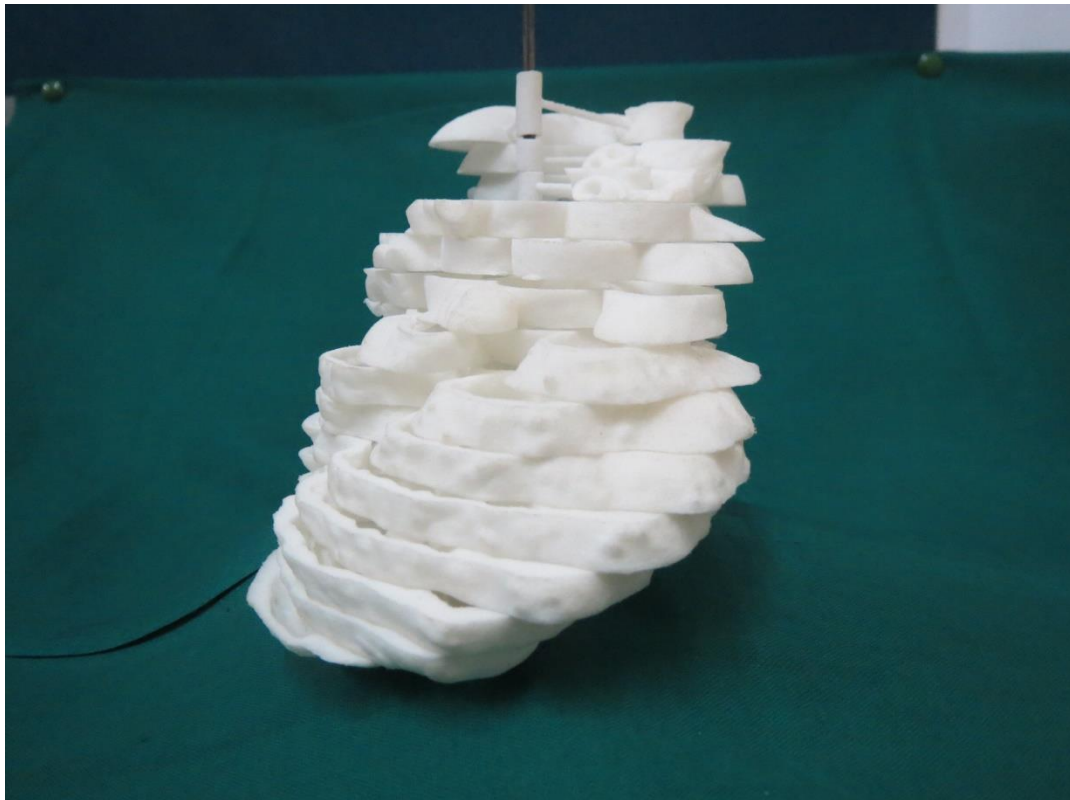


Figure 5. 16: Horizontal sections to isolate the defect area



Figure 5. 17 Heart section taken on either side of the septum at an angle



Figure 5. 18: Heart Sections were taken parallel to the septum



Figure 5. 19: Horizontal sections to explore the conus area and atrioventricular morphology



Figure 5. 20 Vertical sections to isolate the defects and study the neighbourhood landmarks

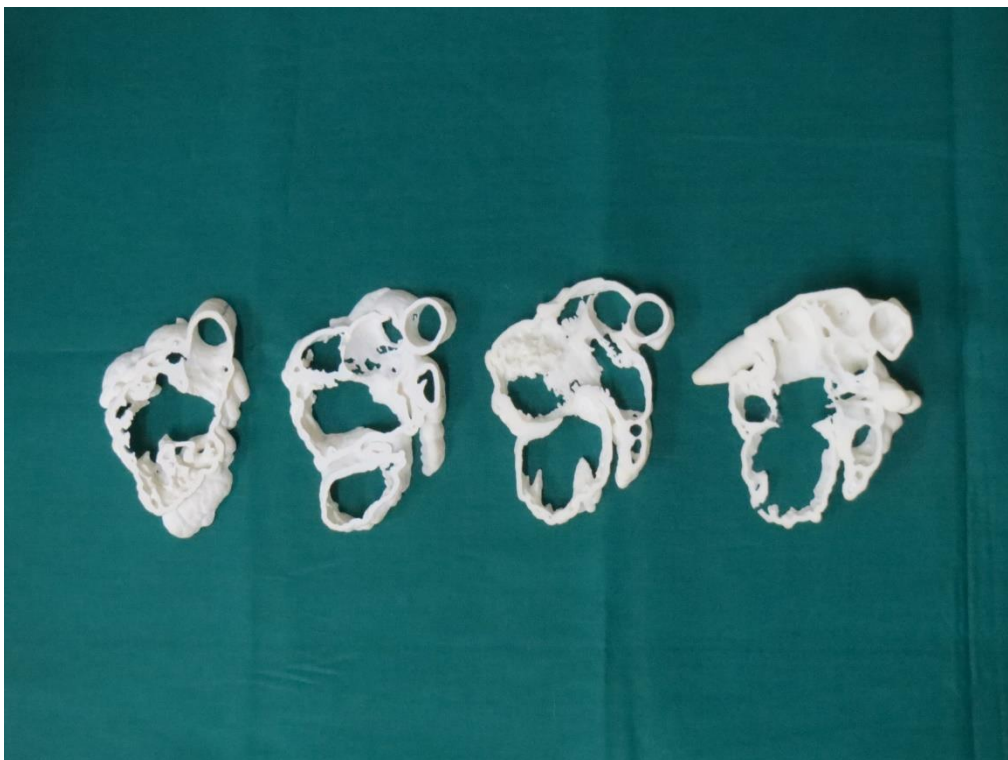


Figure 5. 21 Figure Vertical sections to isolate the defects and study the neighbourhood landmarks on the back side

5.5 Heart defect mapping

We propose a conceptual model of defect mapping to better understand the defect distribution within the heart. This would bring objective approach and save time and improve quality. For the purpose, we take the rich defect grounds namely, the Septum and Conus regions. 80% defects occur as ASD or VSD characterised by the presence of a hole through the septum wall. While most below 3mm close, many others above 3mm need to be plugged. There are more defects at the ‘Conus’ region from AV junction to Trunk of the great arteries.

5.51 Septum - Conus Defect Mapping

As per the mapping, we see the occurrence of ASD and VSD along the septum. We can also see the occurrence of defects at the base of the heart, also called as CONUS region. Conus region is like a knot where the developmental defects can occur. Defects like pulmonary stenosis, Aortic Cortication are results of the malformed conus region.

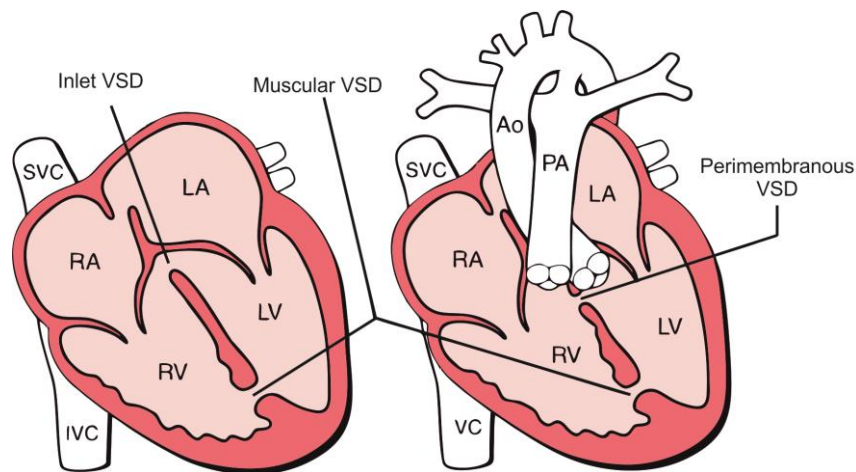


Figure 5. 22: ASD / VSD as a 2-D schematic diagram ...limits actual context

The section through the septum shows the usually occurring septum hole defects ASD and VSD. The 2-D schematic as shown in Figure 5.22 can only conceptually show the defect and have limited use for understanding the actual context. Dissection study shows

us the actual defect manifestations. Figures 5.23 shows VSD with defect occurrence mapping and Figure 5.24 shows the defect occurrence mapping

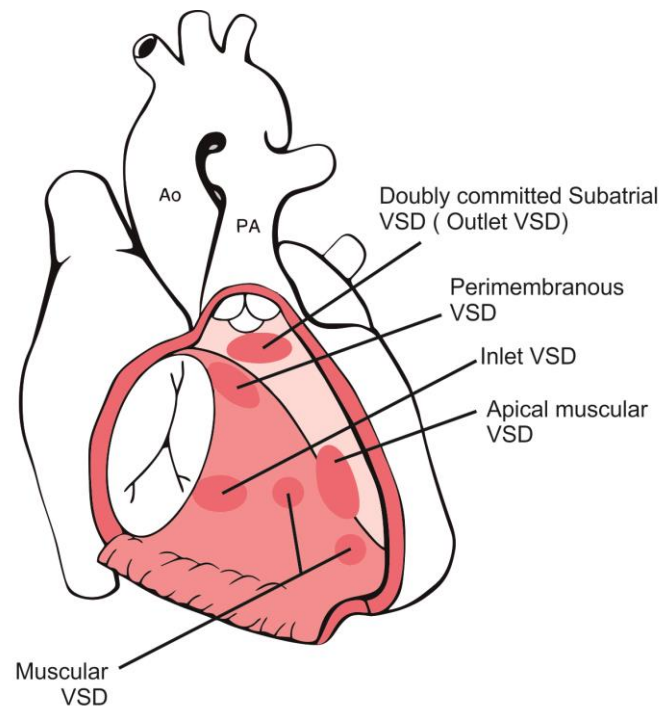


Figure 5. 23: VSD with defects Mapped in an Isometric diagram - shows the actual context

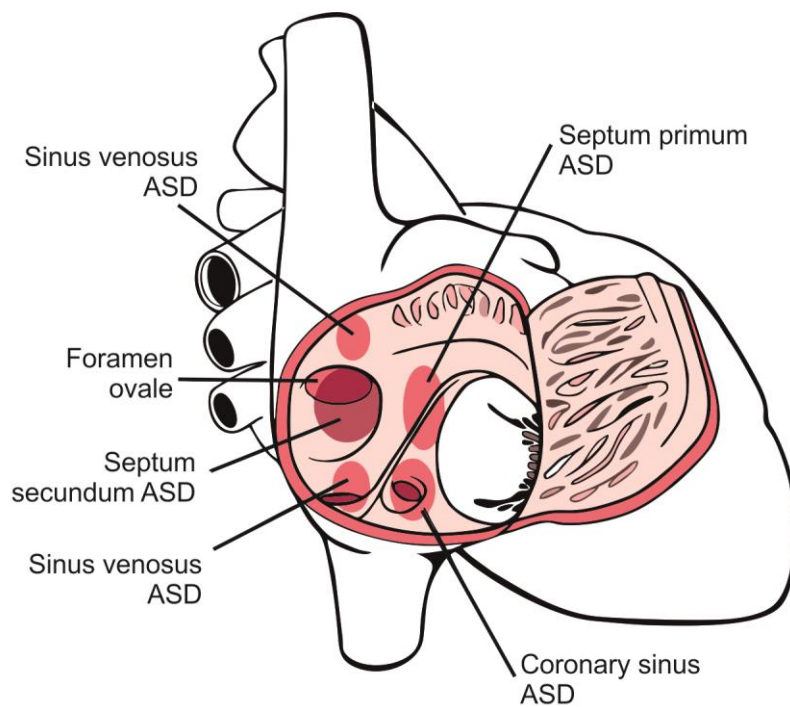


Figure 5. 24 ASD with defects Mapped in an Isometric diagram - shows the actual context

5.52 Defect Scatterplot

Congenital heart defect types are growing with technological advancement. This growth is due to the ability to detect trivial lesions by modern tools

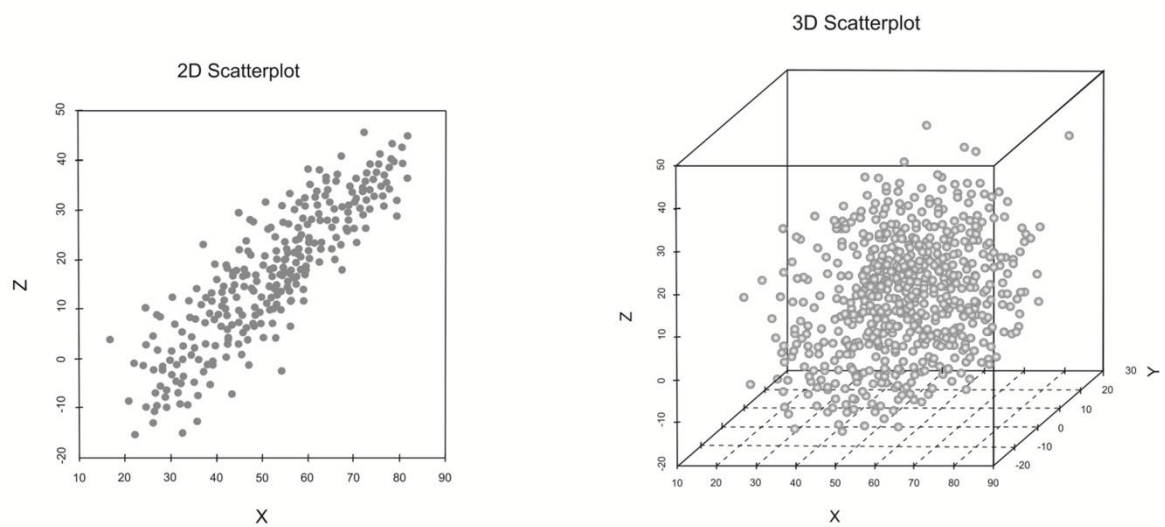


Figure 5. 25: The concept of 2D and 3D Scatter Plots

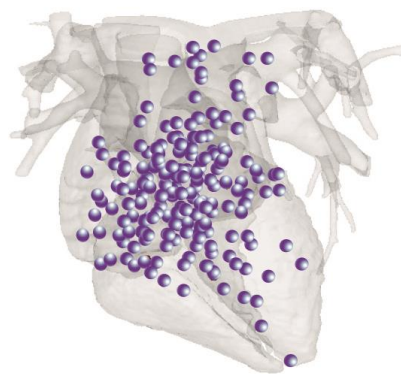


Figure 5. 26: Defect Locations in a Normal transparent digital Heart

Our proposed approach is to map the defect occurrence on a translucent model and look at the data much like a scatter plot in 3-Dimensions. This led to identify local maxima and

minima and fit a plane passing through the defect concentrations. This greatly reduces the sectional iteration and expedites the process of prototyping the defect morphology.

We then from the Echocardiograph diagnostics and 3-D modelling, Identify it's the approximate location. Then we carry out detailed segmentation to get close to the defect region and build an accurate model of the region.

The prototype fidelity will depend on the need and application. So, one of the first steps is to explore the fidelity needed or expected.

5.6 Establishing a Protocol

The co-creation that happens between the Clinician, Radiographer and the Engineering team which manages the model fabrication and delivers. The co-creation is a result of empathy of each functions role and with others in the cross-functional Team. The quality of Imaging data, its export, the creation of a digital model and its printing all play an import role in getting an accurate model and quickly.

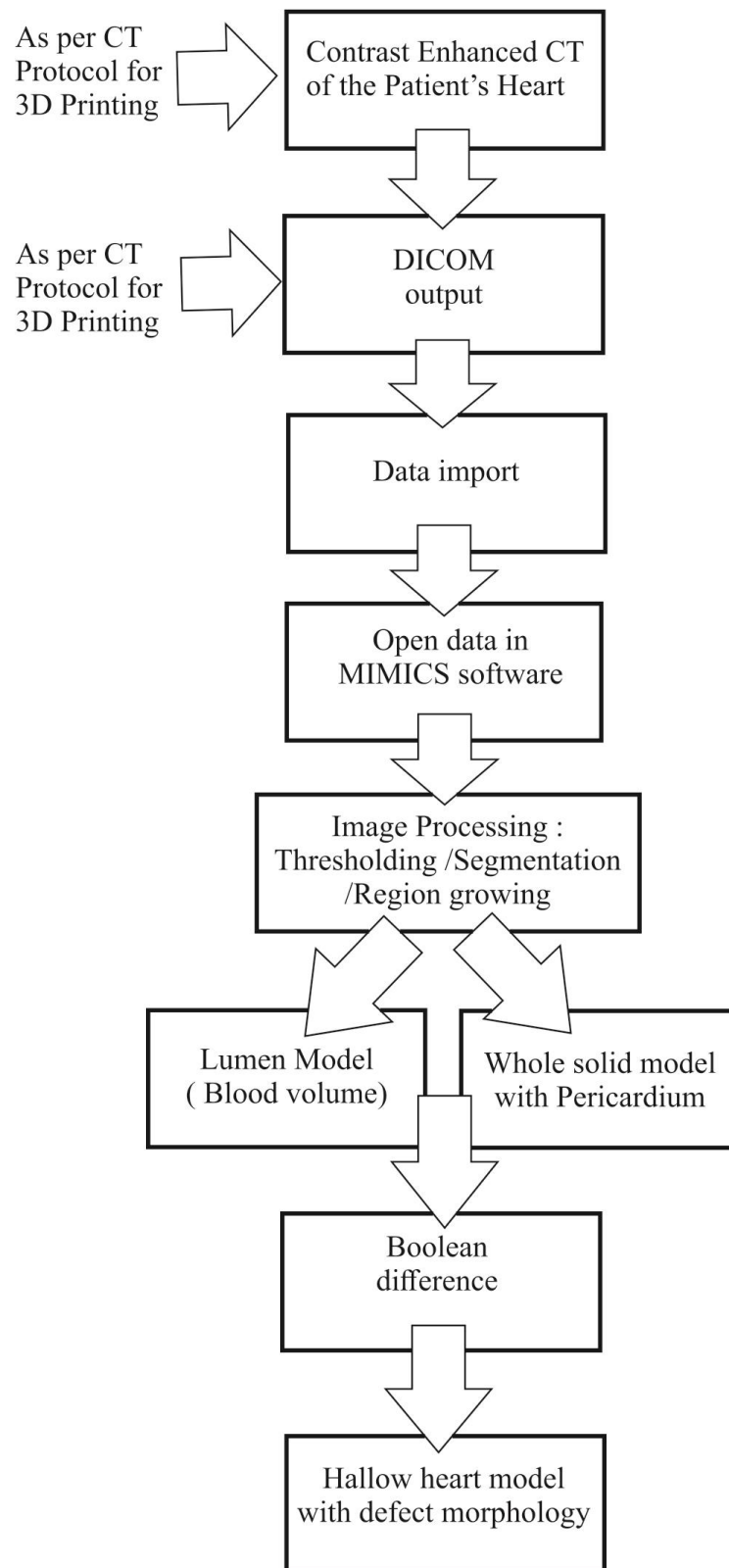


Figure 5. 27 : Medical Image to Prototype Process flow – Role of Clinician as a Co-creator

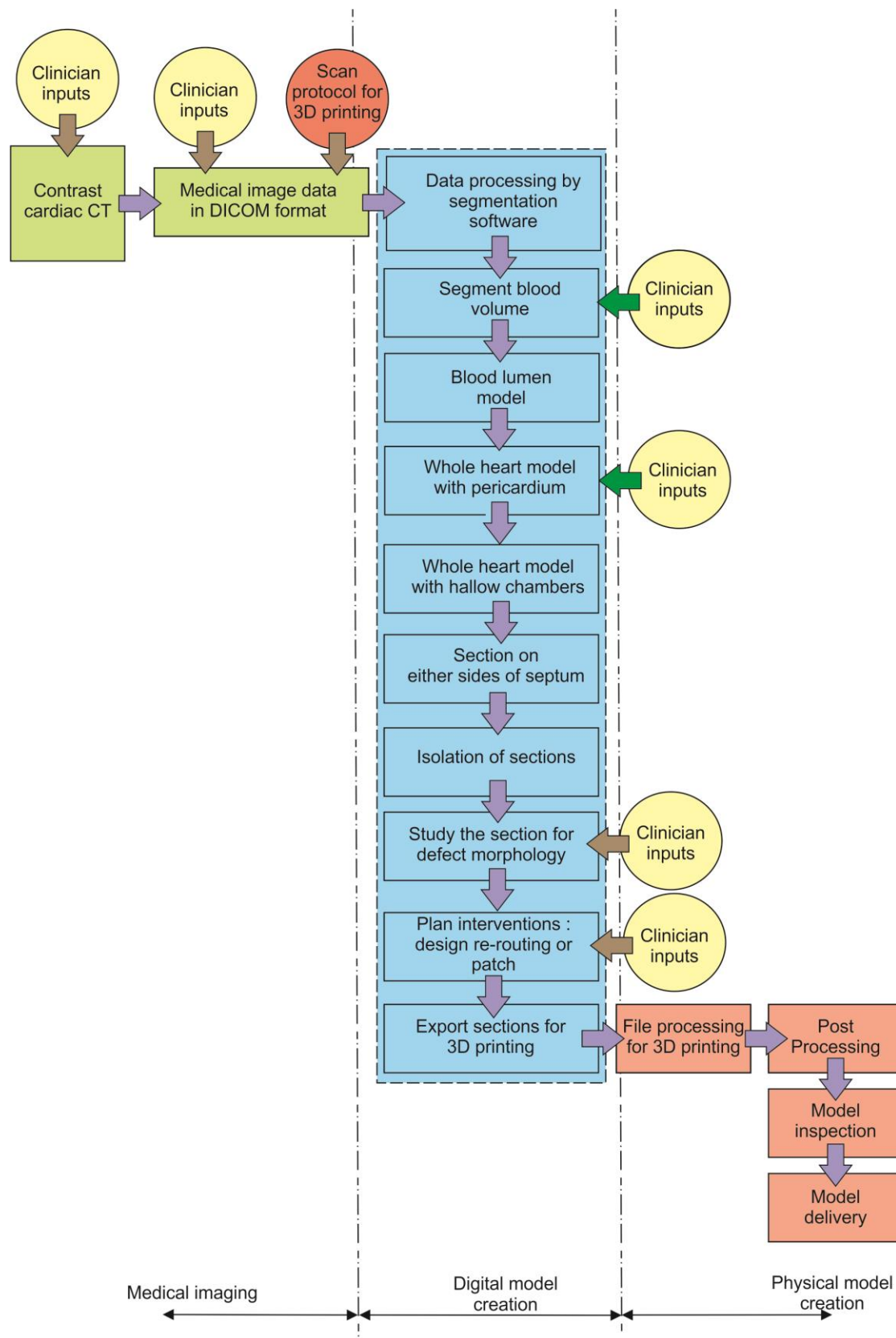


Figure 5. 28: Proposed Detailed Process Flow with Optimum Section strategy

The proposed method is adopted on our 16 cases to quickly identify the defect. This also helps us to plan to print only the required part of heart anatomy. This approach can reduce the cost of the model substantially. The surgeons, however, wanted the whole model to assess the operation planning. They wished to see the defect morphology with its relations with adjoining areas. This helps them to plan their correction strategy.

The optimized workflow shows the involvement of clinicians at a number of stages helps maintain the quality of the overall process and contributes to the overall quality of treatment.

The process establishes a new approach in the way medical images are planned. It is a switch from the earlier practice of radiology departments of getting a slice image to arrive at quick diagnosis to go for multi-slice CT/ MRI with contrast medium. The isometric multi-slice medical images are very essential to make accurate models. Models being key information collaterals need for treatment management.

Chapter 6: Medical case studies

In this chapter, we report the interventions carried out on CHD patients in five tertiary healthcare centres across India. The randomly chosen data set, diagnosed as ambiguous, requiring additional explorations were shortlisted. They all needed a quick response time (three to ten days) before the surgical interventions were scheduled.

The study was executed in two phases, a pilot study, and the main study. The first phase was planned with the aim of understanding the needs of the medical image to digital model creation and establishing a standard workflow, the second one, the main study was to focus on actual research exploration.

6.1 Pilot study

Five random CHD cases were chosen from Mumbai city's two tertiary cardiac care centres (one case from Kokilaben Dhirubhai Ambani Hospital and Medical Research Centre and four cases from Fortis Healthcare Ltd – Mulund). The dataset was analysed for segmentation, a digital recreation of anatomy and suitability for 3-D printing.

In all the cases, the mandatory ethical committee approvals and consent were taken to use the data for research purpose and academic use only. While the models 3-D printed were made of biocompatible PA 12 (Polyamide 12) were duly sterilized by Autoclaving from respective hospitals for Operation Theatre (OT) entry for reference during the procedure.

The medical image modalities for the purpose Radiographic analysis fall short to provide rich data needed to recreate an anatomical model and 3D print with all details. The CT / MRI protocol for 3-D printing as defined by Materialise is not usually followed as they do not know the implications of the poor data set.

Since we are dealing with confidential data of live subjects, the cases in this research are not meant for the open domain and are permitted only for research purposes and academic consumption only. This is the promise given by the researcher to the

Ethics committee of respective hospitals. For ease of reference and review purpose, the name has been strikethrough with a grey mask.

Pilot Case P1

Case Description: ~~Chakale Bhagyalaxmi Viresh~~ Combination defects

Case Clinician: Dr Smruti Ranjan Mohanty

Case Venue / Affiliation: Kokilaben Dhirubhai Ambani Hospital and Medical Research Centre, Mumbai

Initial Tests & Diagnosis: Suspected combination defects

The aim of Study: To study Defect Morphology & its exact location

CT MetaData if any:

Date: Jan - 2017

Patient: ~~Chakale Bhagyalaxmi Viresh~~

Age: 9 years

Gender: F

Gantry Tilt: 0

Slice Thickness: 1mm

Increment: Variable

No of Slices: 275

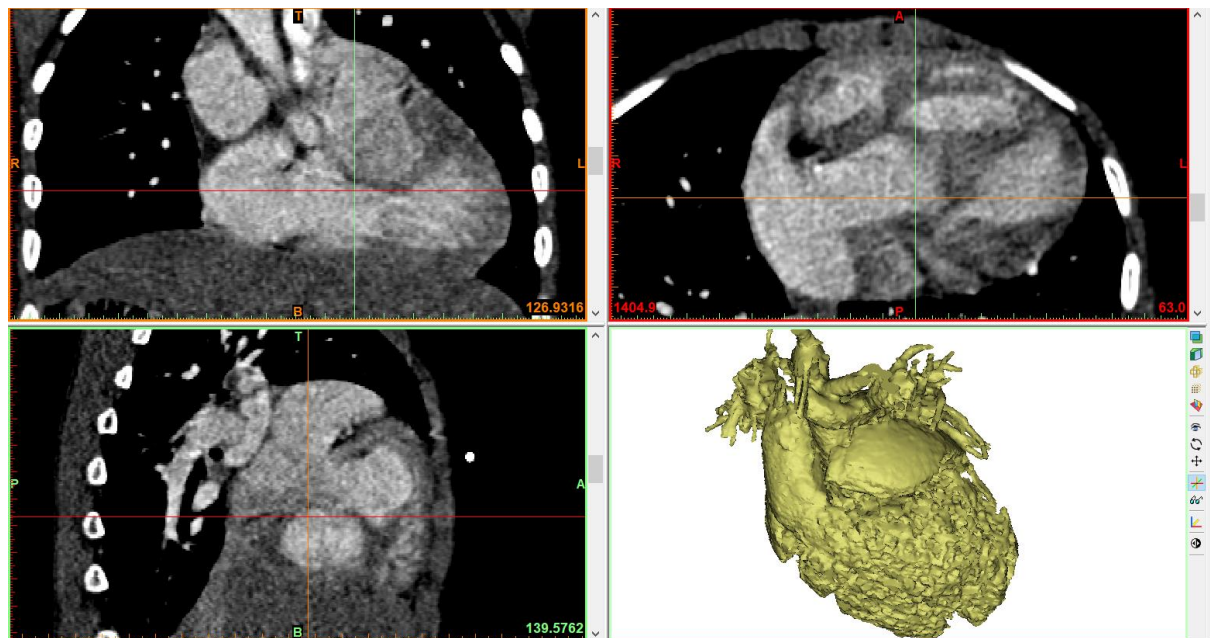


Figure 6. 1 Pilot Study P1

2. Post 3D Printing Insights: We could evaluate a very sick child with multiple procedures

3. Course Correction did if any: The defect was identified and procedure planned post-3D printing.

Case Clinician Feedback: The surgical correction was suggested to the parents were informed of potential risks involved. The patient did not go for surgery.

Overall outcomes: The CT protocol was not good for 3D printing. Variable increment gives the anisometric digital model. 3D printed model gave useful leads to the complex defect. However, the procedure was not undertaken as the patient's kin refused to go for procedure knowing the risk.

Pilot Case P2

Case Description: Abdul Shaikh / VSD

Case Clinician: Dr.Swati Gharekhar

Case Venue / Affiliation:

Fortis Healthcare Ltd – Mulund –Mumbai.

Initial Tests & Diagnosis: VSD identified in Echo study

The aim of Study: To study Defect Morphology & its exact location

CT MetaData if any:

Date: June – 2017

Patient: Abdul Shaikh

Age: N.A

Gender: M

Gantry Tilt: 0

Slice Thickness: 0.625mm

Increment: var.

No of Slices: 5

Results: Segmentation Results: No model was made due to poor data

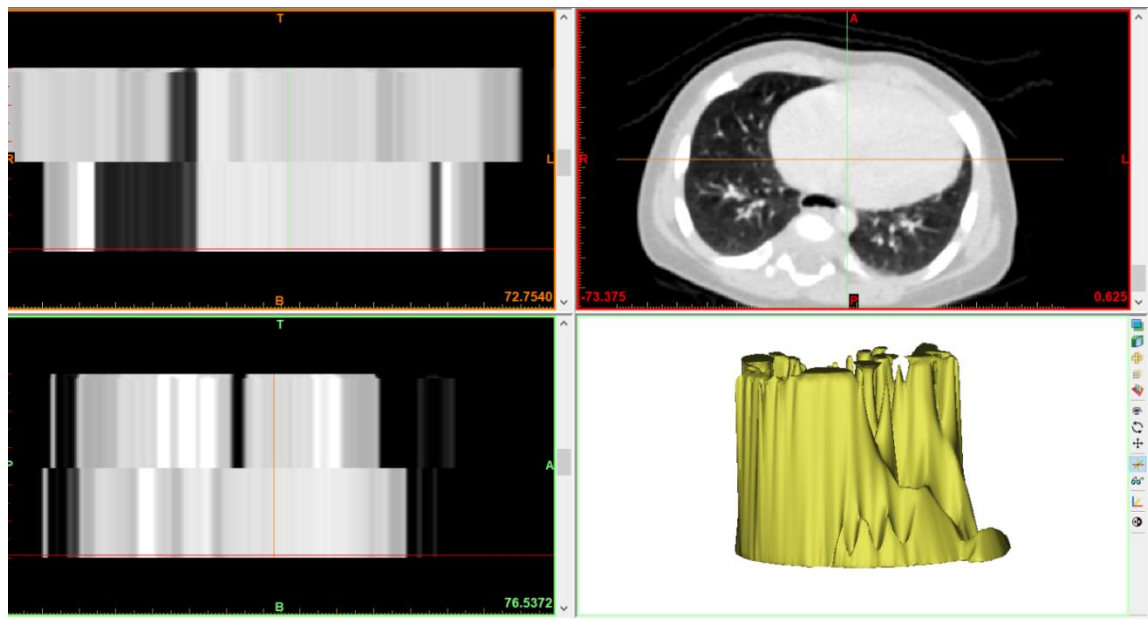


Figure 6. 2 Pilot Study P2

Pilot Case P3

Case Description:

Soyesh Kumar / VSD

Case Clinician:

Dr.Swati Gharekhar

Case Venue / Affiliation:

Fortis Healthcare Ltd – Mulund –Mumbai.

Initial Tests & Diagnosis: Echo hinting VSD

The aim of Study: To study Defect Morphology & its exact location

CT MetaData if any:

Date: June - 2017

Patient: Soyesh Kumar

Age: 4 weeks

Gender: M

Gantry Tilt:

Slice Thickness: 0.625mm

Increment: 0.625mm

No of Slices: 350

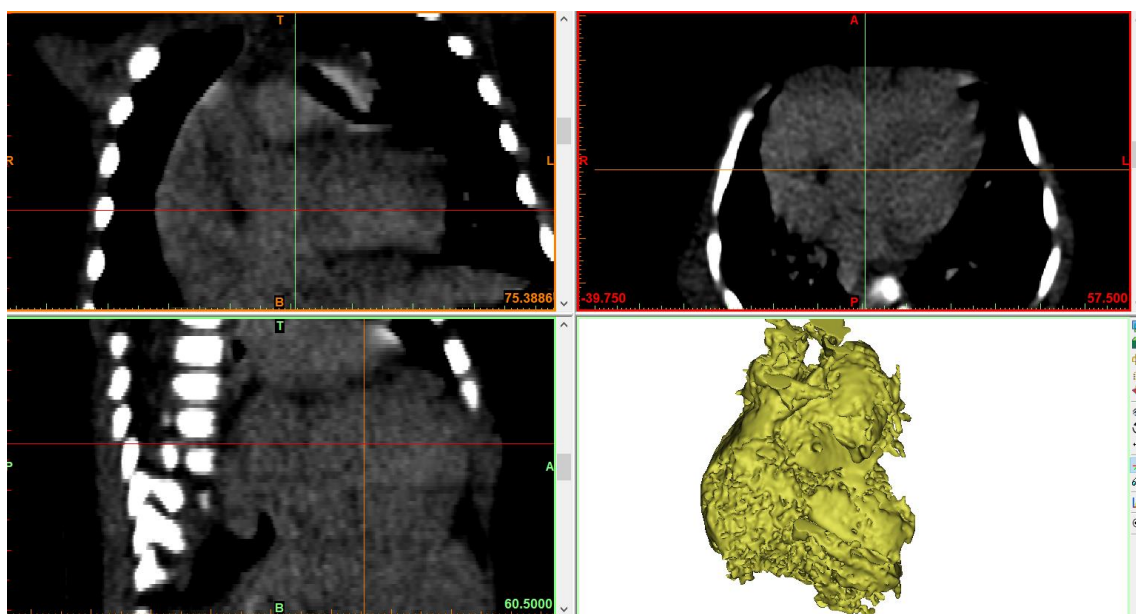


Figure 6. 3 Pilot Case study P3

Results:

1. Despite the isometric data set, poor contrast led to poor results
2. Post 3D Printing Insights: The CT scan was taken with poor contrast, we could not properly segment the heart
3. Course Correction did if any: CT Can protocol explained to the concerned and was shared.

Case Clinician Feedback: CT poor data disappointed us; we were looking to see the defect morphology

Overall outcomes: 3D printing was not done, we need better Data Acquisition.

Pilot Case P4

Case Description:

Poor data — Sanada Choudhary

Case Clinician:

Dr.Swati Gharekhar

Case Venue / Affiliation:

Fortis Healthcare Ltd – Mulund –Mumbai.

Initial Tests & Diagnosis:

The aim of Study: To study Defect Morphology & its exact location

CT MetaData if any:

Date: June - 2017

Patient Sanada Choudhary

Age: 2 years

Gender: F

Gantry Tilt: 0

Slice Thickness: 0.625mm
Increment: 0.625mm
No of Slices: 25

Results: The scan is isometric but has missed the soft tissue completely. Not useful to create a digital model or physical model by 3D printing.

1. Segmentation Results

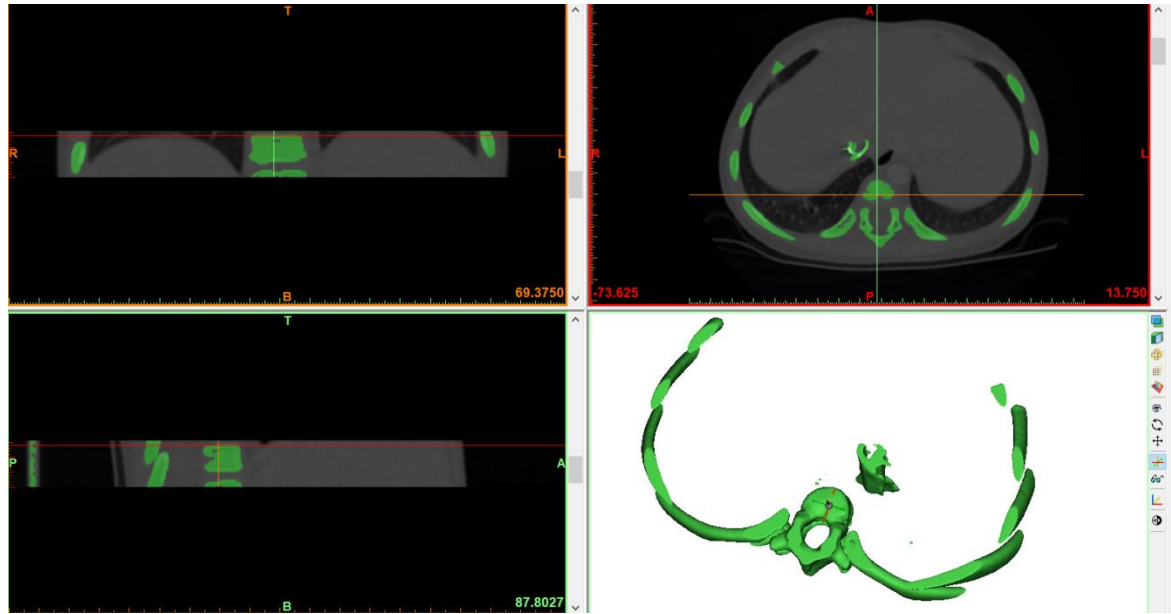


Figure 6. 4 Pilot Study P4

2. Post 3D Printing Insights: Wrong CT protocol

3. Course Correction did if any: Take CT again with updated scan protocol

Case Clinician Feedback: We are disappointed with the poor data set

Overall outcomes: CT protocol can save time, money and all the efforts done without it.

Pilot Case 5

Case Description:

VSD—Shaista Sayyed

Case Clinician:

Dr.Swati Gharekhar

Case Venue / Affiliation:

Fortis Healthcare Ltd – Mulund –Mumbai.

Initial Tests & Diagnosis:

The aim of Study: To study Defect Morphology & its exact location

CT MetaData if any:

Date: June - 2017

Patient: Shaista Sayyed

Age: 9 years

Gender: F

Gantry Tilt: 0

Slice Thickness: 0.625mm

Increment: var.

No of Slices: 150

Results:

1. Segmentation Results

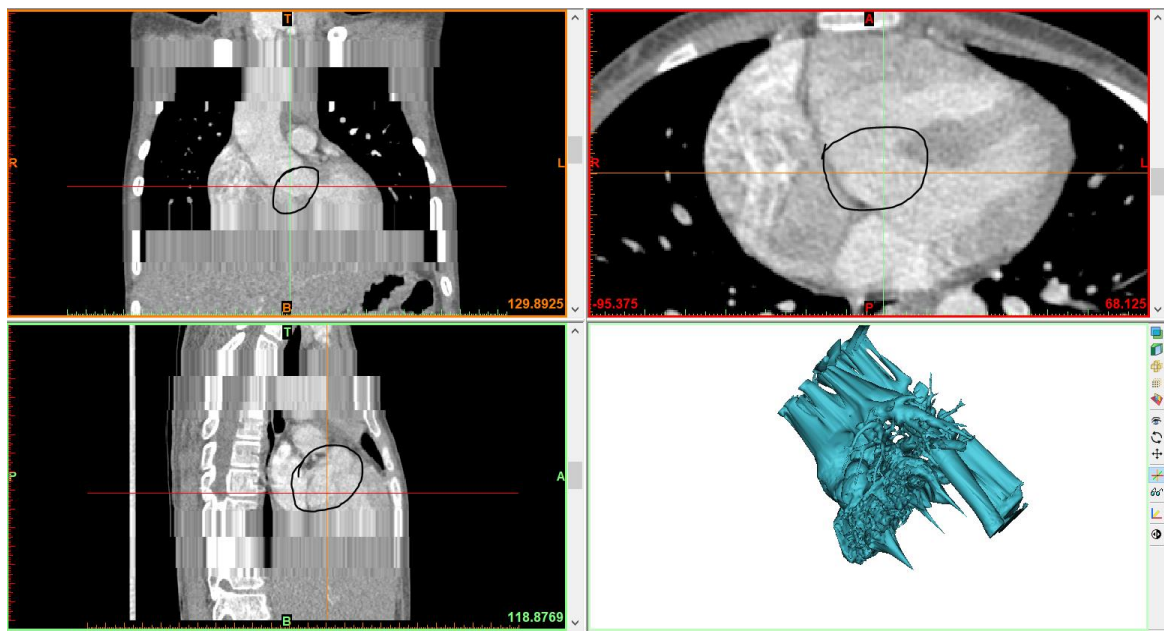


Figure 6. 5: Pilot Study P5

6.2 pilot study outcome:

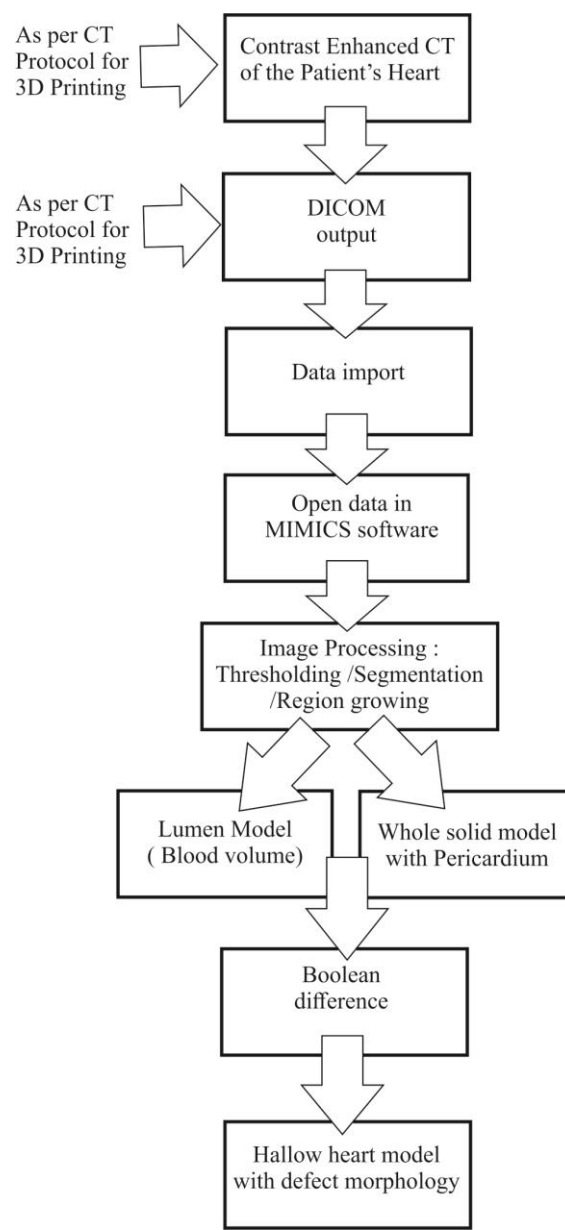
From the pilot studies, we can conclude that CT protocol & contrast infusion influence the quality of the digital model and subsequently the 3D printed models. We tend to get good results if we follow the simple steps:

1. Isometric data acquisition: The slice thickness and increment should be isometric.
2. Number of slices should sufficient so as to cover the anatomy under study
3. Adequate contrast medium should be available in the blood lumen during data acquisition
4. Standard CT scan protocol across the health centres has to be established in order to get quality digital model & physical model using 3-D printing.

6.3 Optimised Image processing & Segmentation

The organ transparency for X-ray radiation varies. Hard tissue based organs are opaque and soft tissues are relatively transparent. The varying grey values derived in Hounsfield units form the basis for Image processing. Soft tissues need contrast enhancement for better visualization. We make use of contrast-enhanced Computed Tomography (CT) as our imaging modality. They provide better data set over Echocardiography for accurate model construction. CT provides a set of X-ray slice data which is arranged in sequence, helps to rebuild the anatomy. The digital reconstruction of anatomy begins with image data acquisition process. Isometric image capture is essential to get accurate models. It is very important to follow this protocol while Acquiring CT Image in order to build an accurate model. The Voxel (a 3D Pixel) should have same X, Y and Z units or proportional dimensions to build an accurate model. (Rao et al., 2016)

Image processing includes thresholding, segmentation and region growing. They help in identifying anatomical structures from variation in the intensities in the image. This further helps in partitioning an image into specific regions containing information with



similar attributes delineating the regions of interests.

Image processing algorithms aided with trained visual judgment help in isolation of target anatomy. This is done using Mimics software (Materialise NV, Leuven, Belgium). The software is inbuilt with tools such as global thresholding, region growing approaches, classifiers, clustering approaches, Markov random field models (Hadeed et al., 2017) etc., After the segmentation the 2-D slices are stacked in sequence of slicing and fused together to get the 3-D CAD volume model of the target organ. Fig. 3 shows the process workflow to make patient-specific heart models from the medical image data set. During this process, close interactions with clinicians are essential to identify cardiac sub-structures. Post segmentation, we get volume heart and volume of blood lumen. In order to get heart replica, we carry out the Boolean difference of heart and blood lumen volumes ref. Fig. 3. This yields a hallowed model that is a recreation of a patient's heart with all its rich morphologies.

The digital models were converted into Stereolithography (STL) files for 3-D printing. The STL files are checked for print worthiness by Magics software (Materialise NV). The cleaned up STL files are sent to the 3-D printing system. Selective Laser Sintering (SLS) is used as a 3-D Printing technology. The models are made out of biocompatible Nylon powder (PA 12). A standard slice thickness of 100 microns was adopted across the cases. Prior to the build, the machine is calibrated for X, Y and Z table movement. CO₂ laser sinters the powder to build the models layer by layer. It is a hot process and builds has to cool down to room temperature gradually. This is to avoid thermal stresses. The built models are post-processed through sandblasting.

Figure 6. 6 : Medical image process workflow.

As these models have organic forms, which are of complex geometry, they cannot be measured conventionally. To measure their accuracy, a non-contact digital inspection procedure is adopted. The built model is scanned by a Blue Light scanner (Steinbrecher - Comet L3D 8M ZEISS). The models are duly checked for accurate recreation (form and size) by digital inspection. The part STL is superimposed (ref. Fig. 6.1.) on its scan data to get a colour map showing the variations quickly. The colour code used is: nominal Green, positive is Red, negative is Blue for a specific anatomy landmark. The models

thus accurately created are offered to clinicians to explore, visualize and plan the treatment. Their feedback is duly recorded.

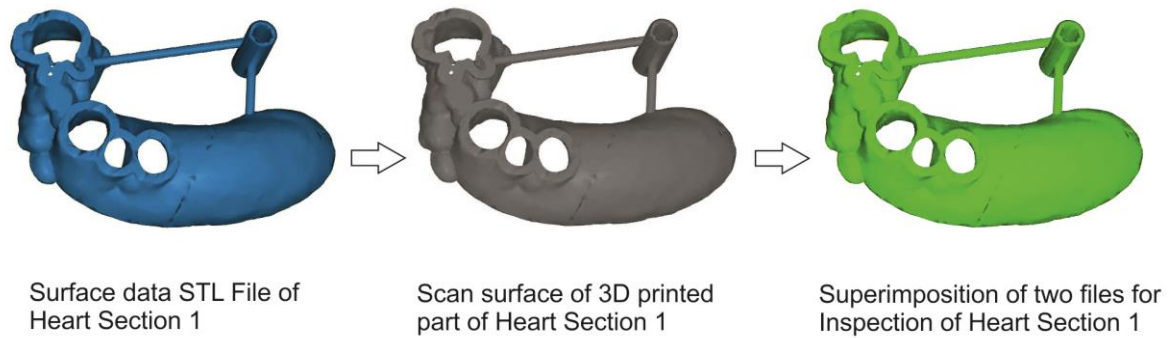


Figure 6. 7: Medical model accuracy assessment through the digital inspection process

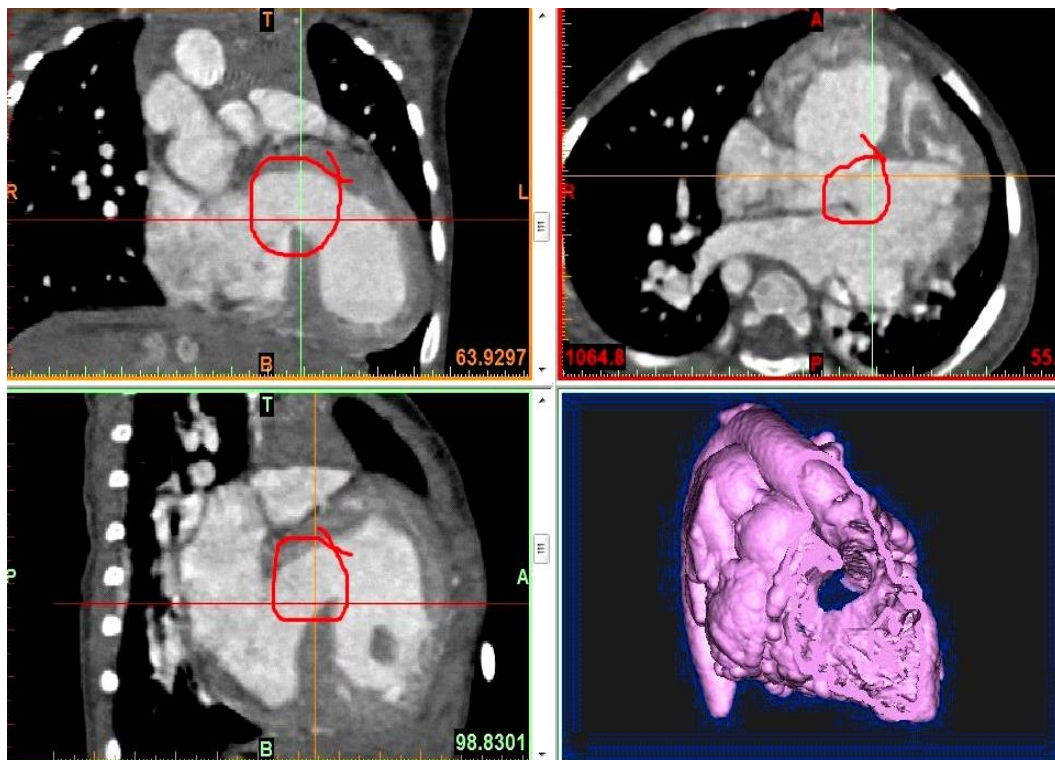


Figure 6. 8 Digital reconstructions of the heart



Figure 6. 9: Sections of heart A,B,C showing the morphology

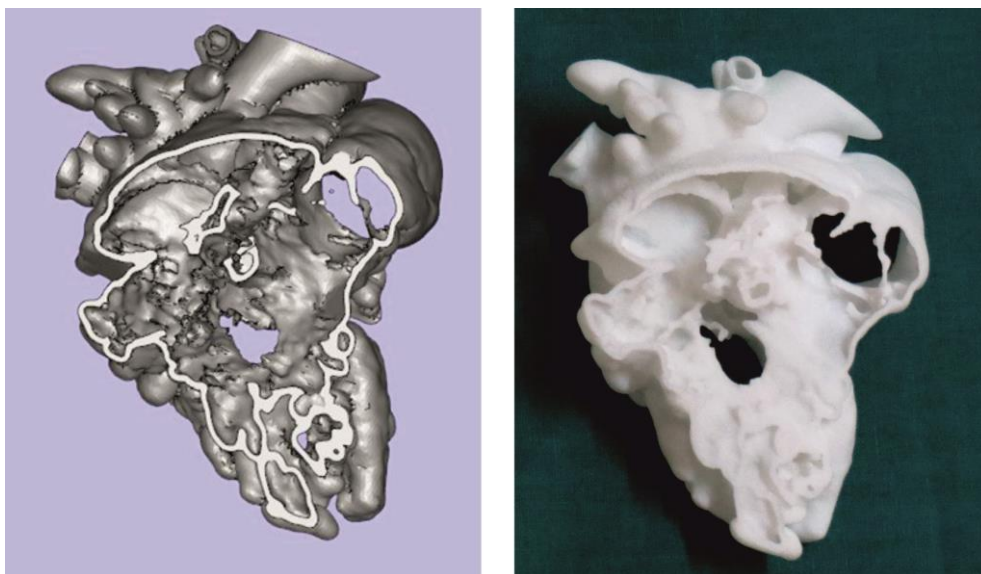


Figure 6. 10 : Digital VS Physical models

The accurately segmented 3D models were exported as a triangulated mesh, STL files. These files are checked for typical STL errors using either Magics / Netfabb software. The STL errors are fixed to get a print, worthy digital model. The model thus regenerated from Image data are reviewed with the clinician team. Further, appropriate sections are planned to isolate the defect regions and maximize morphological visualization. The digital model so obtained can be seen on screen and explored for details by rotation, zooming, panning and sectioning. They need to be explored in hand for further clinical management. Physical prototype in hand helps to provide a much needed spatial understanding of the defect and plan the correction. The files are sent to a 3D printing system with SLS technology. Models are made of biocompatible (Giannatsis & Dedoussis, 2009) Nylon (PA12) powder. The post-processing consists of sandblasting and blowing off the loose particles by compressed air. After cleaning the models can be taken for sterilization if necessary. A total of 16 cases were processed for 3D printed models, checked for accuracy by digital inspection and are offered for clinical pre-plan.

6.4 Results

6.4.1 Part Accuracy Assessment.

Accurate cardiac models of Congenital Heart Defect (CHD) were successfully built and provided to the clinician team. The model in hand helps in better visualization of defect morphology and enabled exploratory surgical options and scenario building to arrive at optimum Clinical Management. The digital inspection of the part found its dimensions and form are close to nominal size $\pm 0.1\text{mm}$ or less.

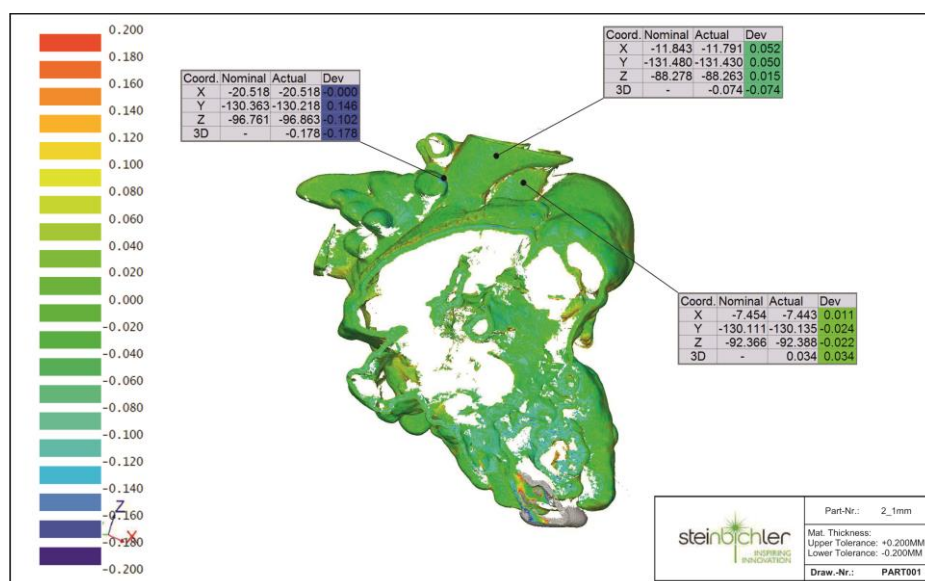


Figure 6. 11: Digital Inspection Report

6.4.2 Medical case study results

Out of 16, 13 cases actually benefited by 3D printed models and 3 more cases just revalidated the earlier radiographic diagnostic reports. The suspected 7 complex cases could be examined with great detail from the 3D printed models. 6 VSD cases which were clearly diagnosed from earlier Image data got to see the location and defect morphology which were not clear in the earlier examinations.

The medical case studies are provided as a table in Annexure III.

Case	Age	Gender	CHD Defect Type	Digital Model	3D printed Model	Clinicians feedback on usefulness of the model
P01	11M	Female	VSD	Created	Built Successfully	Could visualise more details from the model
P02	08Y	Male	VSD, TOF	Created	Built Successfully	Very useful to visualise defect morphology and plan treatment.
P03	05Y	Male	VSD, DORV	Created	Built Successfully	Very useful to visualise defect morphology and plan treatment.
P04	12M	Male	VSD, DORV	Created	Built Successfully	Very useful to visualise defect morphology and plan treatment.
P05	03M	Female	VSD	Created	Built Successfully	Could visualise more details from the model
P06	13Y	Male	VSD	Created	Built Successfully	Defect Reconfirmed
P07	11M	Male	VSD	Created	Built Successfully	Defect Reconfirmed
P08	01Y	Male	VSD	Created	Built Successfully	Could visualise more details from the model
P09	16Y	Male	VSD	Created	Built Successfully	Could visualise more details from the model
P10	08Y	Female	ASD, TAPVC	Created	Built Successfully	Very useful to visualise defect morphology and plan treatment.
P11	05Y	Female	VSD, C-TGA	Created	Built Successfully	Very useful to visualise defect morphology and plan treatment.
P12	02Y	Male	VSD, TOF	Created	Built Successfully	Very useful to visualise defect morphology and plan treatment.
P13	07Y	Female	VSD, TOF	Created	Built Successfully	Very useful to visualise defect morphology and plan treatment.
P14	08Y	Female	VSD	Created	Built Successfully	Defect Reconfirmed
P15	02Y	Male	VSD	Created	Built Successfully	Could visualise more details from the model
P16	05Y	Male	VSD	Created	Built Successfully	Could visualise more details from the model

Table 6. 1 Medical case study results

The feedback of the clinicians was recorded and transcribed and re-clustered as:

- 1.Reconfirmation of the defect,
- 2.Could visualise more details which were not seen in earlier modalities, and
3. They are very useful to visualise defect morphology and plan treatment. (Table 6.1.)

6.4.3 Expert Survey Results

In order to revalidate our medical case results, an expert survey was carried out with 72 domain experts (Ref Annexure). They were shown the models and asked what complexity they would recommend the use of 3-D printed models. The survey was

carried out over email as well as a personal interview during 2 international conferences IACSTCON 2018 and PCSI.

We had 63% Male and 37% female CHD case from total 16 cases (Fig. 6.12A) and the Age ranged from newborn up to teenage as 33% 0-1 year, 13% 1-2Years, 47% 2-8 Years and 8 Year and above at 7%. Many of the cases in 2 to the 8-year bracket are revision surgery cases (Fig. 6.12B). We can see from the pie charts that VSD leads at 50%, ASD is relatively low at 6% and combination defects (VSD + other defects) are quite high at 44% (Fig. 6.12 C). The most important outcome is the compelling needs case for models. We have 19% which consider it as means to reconfirm defects already diagnosed, so, it does not add any additional value. These were mostly simple VSDs. 37% felt that they could visualise more details in the models then what they initially saw from the Image Data. It was found 44% of the cases comprising of combination defects had ambiguous image reports and were not conclusive. In all such cases, the clinicians found models very useful. They opined that visualization of defect morphology aided in understanding the defect condition better. The enhanced understanding helped them to plan correction and treatment management (Fig. 6.12 D). Models were also used to communicate with the patient kin and seek their consent for the procedure.

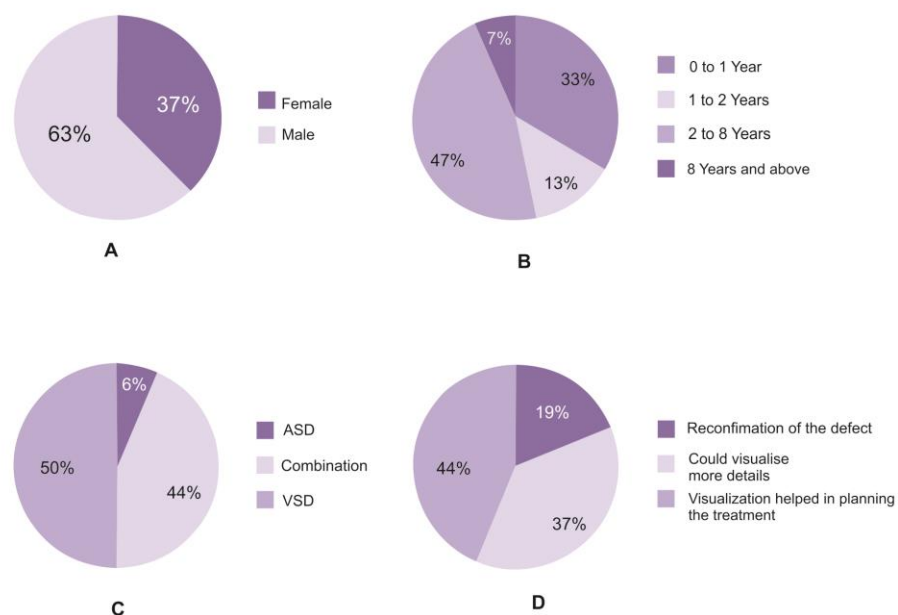


Figure 6. 12 Expert Survey results



Figure 6. 13: Clinicians exploring the 3-D printed CHD models at Madras Medical Mission

6.5 Medical case study conclusions

We can see from the medical case studies, the clinicians will get to understand more about defect condition with a physical model. They will need it in complex and ambiguous cases, to plan if they need a surgical procedure or not. If the case needs an operation, then the models would help in pre-planning of the procedure. From the medical case studies, we can see the models are costly and take 2 to 4 days to make the models. Optimum sections to an extent address these issues.

Chapter 7: Conclusions

Newborn children suffer from many birth defects. Malformed hearts or congenital heart diseases top in their occurrence among the birth defects. Early diagnosis helps to plan treatment management. 3D Printed patient-specific model is an additional tool in the armamentarium to look at anatomy with more clarity, especially in complex cardiac defects. This reduces risk in treatment (Rengier et al., 2010), helps to reduce the procedure time (Yoo et al., 2016) and helps to communicate with the family (Biglino et al., 2015) to get buy-in and consent for the procedure.

The use of 3D printed model applications in healthcare has been growing. We can see that in interventional cardiology also. Due to the great variety in malformed hearts, the defect diagnoses remain many a time inconclusive. Clinicians have been addressing this with 3D printed models. From the literature, it appears these model makings were done by few clinicians. The large-scale adoption is not seen due to the lack of skill to make good models. Those who have successfully used in intervenes have hardly shared the process in great detail as that was not their primary focus. There has been no mention of assessment of models and validation. We have successfully attempted to address these in this research work and hope this study will help its wider adoption and hence saving move tender lives.

This research work is focused on accurate prototype model development and measure the effectiveness of the fine-tuned process. Organic anatomical forms cannot be measured for linear dimensions as it will keep changing at every tangent & normal intersection. A new set of benchmark model Bioform A, B and Chas been proposed. A method to measure and validate 3D printed organic forms such as heart models has been proposed.

Our study proposes a patient-specific heart prototype fabrication as a visualization enabler and aid surgical pre-plan. The results dataset shows the benefits of utilizing 3D printed models, particularly in complex cases before the procedure.

From the literature study, we found two factors limit the use. They are: lead time for development of models and the cost. This research looked into this aspect too and come up with recommendations for streamlined workflow and optimum sections strategy.

While the workflow helps to reduce time overall, the optimized anatomical section helps to cut down the cost of a full 3D model and time required to print.

We also that one of our main findings is successfully using 3D printed patient-specific models could become an industry standard. The maturing 3D printing technologies will see a fall in prices and the introduction of low-cost new materials will further accelerate the use of 3D models, which is the focus of this study.

7.1 Summary of Work Done

Important contributions of this research work are summarized here:

A. Identification factors that influence the accurate recreation of the anatomical model are established. Since our approach was to focus on the prototype model's accurate creation, we investigated the factors that contribute to the fabrication such as

B. A method for the accuracy assessment of prototype is proposed and validated. What can be measured only can be controlled? We wanted to measure how accurately the model is built with respect to the Digital input data. As existing methods by Grimm, Mahesh and others were not adequate, we had to design a new benchmark samples Digital scanning was used with the inspection software to reliability assess the parts fast and accurate.

C. Optimal workflow framework has been developed and tested. The workflow is so designed to avoid errors and delays. It brings in the element of co-creation which normally happens but never captured. The proposed workflow can be followed by Clinicians and is aimed for large-scale adoption. Due to its right first time approach, it can save on rejections and rework which is life-threatening too

D. Optimal sections approach is proposed and tested. Here we base our method on the embryonic evolution and development of the heart. The fetal loops that go to become the dynamic organ, provides a rich hint about defect suspected areas. We first examine the patient's heart and plan our sections so that they help us visualize defects quickly and better.

Further, we can extend it to make a 3D sector graph of defects, will act like an atlas for teaching, by mapped regions which are susceptible to malformations.

E. We established a need for CT scan protocol to get good data set for every case. Here time is important as the patient will need that critical care as soon as possible. This is a very important contribution as building an accurate 3D model is the first step in achieving a dependable treatment plan.

7.2 Key Insights / Discussions

The current investigation also brings into light the domain interplay as represented in figure 7.1 given below. The medical domain which is the beneficiary while others Prototype and Tools help to synthesize solution and provide a solution.

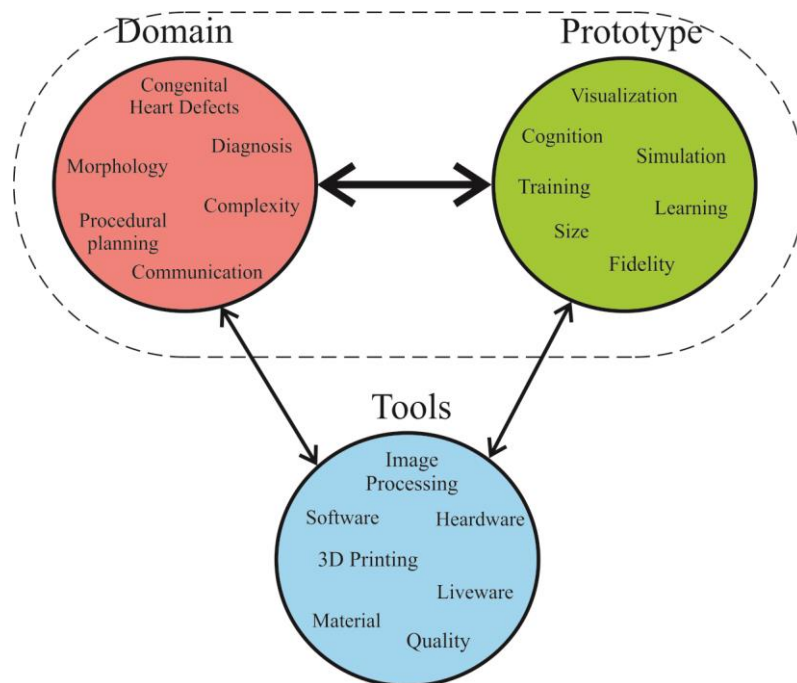


Figure 7. 1 Domain interplay

The prototype domain is directly benefiting the Medical Domain. They help maximize the visualization of defect morphology. On the other hand, the tools include both hardware and software to make it possible.

The medical domain can co-create the value by collaborating with Engineers who are familiar with handling CAD tools & prototype production.

7.3 Limitations and Scope for future work

The current work may be repeated with a large number of cases to further improve the workflow and methods.

A. Factors that influence the accurate recreation anatomical model may slightly change from one technology to the other. So, we need to look for such needs and address them.

B. In the present research study, we have confined ourselves with hard nylon material. We can also try with soft materials such as Silicon, PU resins, and filament based low-cost material.

D. Optimal sections approach with VR/AR could be a new area of intervention.

E. Current CT/ MRI modalities don't provide the valve data. Hope this area gets resolved technologically and become possible to differentiate. This area may need a local contrast injection to acquire rich data and hence segment valve morphology.

F. The models could be coloured to differentiate the flow paths and make it easier visualize and hence learning.

G. The soft whole heart models with specific defect conditions can be developed for training and assessment purposes.

Glossary of Terms

Acute – Rapid Onset / Sudden

Anastomosis: (plural = anastomoses) area where vessels unite to allow blood to circulate even if there may be a partial blockage in another branch

Angiogram- an X-ray photograph of blood or lymph vessels, made by angiography

Angiography - radiography of blood or lymph vessels, carried out after the introduction of a radiopaque substance.

Angioplasty – It is a surgical procedure to open the blood vessels that supply blood to your heart muscle

Annuloplasty - An annuloplasty is a procedure to tighten or reinforce the ring around a valve in the heart

Anomalies: Defects

Anterior cardiac veins: vessels that parallel the small cardiac arteries and drain the anterior surface of the right ventricle; bypass the coronary sinus and drain directly into the right atrium

Anterior interventricular artery: (also, left anterior descending artery or LAD) major branch of the left coronary artery that follows the anterior interventricular sulcus

Anterior interventricular sulcus: sulcus located between the left and right ventricles on the anterior surface of the heart

Anterior: Near the front, especially in the front of the body

Aorta - the largest artery in the body originating from heart carrying oxygenated Blood.

Aortic valve: (also, aortic semilunar valve) valve located at the base of the aorta

Apex- The apex of the heart is its tip, formed by the left ventricle, it is the most inferior portion of the heart.

Apical - relating to the apex.

Appendage – Is a thing that is added or attached to something larger system. The left atrial appendage (LAA) is a small, ear-shaped sac in the muscle wall of the left atrium (top left chamber of the heart). It is unclear what function, if any, the LAA performs.

AS – Aortic Stenosis

ASD - Atrial Septal defect, is a heart defect in which blood flows between the atria (upper chambers) of the heart.

Atrial Switch - Atrial switch is a heart operation performed to treat dextro- transposition of the great arteries. It involves the construction of an atrial baffle which redirects the blood coming into the atria to restore the connection between systemic and pulmonary circulation.

Atrioventricular septum: cardiac septum located between the atria and ventricles; atrioventricular valves are located here

Atrioventricular valves: one-way valves located between the atria and ventricles; the valve on the right is called the tricuspid valve, and the one on the left is the mitral or bicuspid valve

Atrium - The atrium is the upper chamber in which blood enters the heart. There are two atria in the human heart.

Auricle: extension of an atrium visible on the superior surface of the heart

Autoclave – They are Pressure Vessels to sterilize contents by subjecting them to high pressure saturated steam at 121 °C (249 °F) for around 15–20 minutes. They are used to decontaminate certain biological waste and sterilize media, instruments and labware.

AV Canal - atrioventricular canal, it occurs as a defect.

AV Node - atrioventricular node

AVSD – AV Canal Defect called: Atrioventricular septal defect

Banding - a surgical technique to reduce excessive pulmonary blood flow in infants suffering from congenital heart defects.

Bicuspid Valve - (also, mitral valve or left atrioventricular valve) valve located between the left atrium and ventricle; consists of two flaps of tissue. It permits blood to flow one

way only, from the left atrium into the left ventricle This valve is more commonly called the mitral valve because it has two flaps (cusps) like a bishop's miter or headdress.

Bicuspid aortic valve (BAV): is an inherited form of heart disease in which two of the leaflets of the aortic valve fuse during development in the womb resulting in a two-leaflet valve (bicuspid valve) instead of the usual three-leaflet valve (tricuspid)

Bovine - bovine (plural bovines) An animal of the family, subfamily, tribe, or genera including cattle, buffaloes and bison.

BT Shunt - The Blalock–Thomas–Taussig shunt (commonly called the Blalock–Taussig shunt) is a surgical procedure used to increase pulmonary blood flow for palliation in duct-dependent cyanotic heart defects like pulmonary atresia, which are common causes of the blue baby syndrome.

Bundle of His - collection of heart muscle cells specialized for electrical conduction, it transmits the electrical impulses from the AV node to the point of the apex causing the cardiac muscle of the ventricles to contract at a paced interval.

Cadaver -a dead human body, esp. one used by medical students for study.

Cardiac - relating to Heart

Cardiac notch: depression in the medial surface of the inferior lobe of the left lung where the apex of the heart is located

Cardiac skeleton: (also, the skeleton of the heart) reinforced connective tissue located within the atrioventricular septum; includes four rings that surround the openings between the atria and ventricles, and the openings to the pulmonary trunk and aorta; the point of attachment for the heart valves

Cardiomyocyte: muscle cell of the heart

Caval Canal – Pertaining to (Superior / Inferior) Vena Caval Passage

Chordae tendineae: string-like extensions of tough connective tissue that extend from the flaps of the atrioventricular valves to the papillary muscles

Circumflex artery: a branch of the left coronary artery that follows coronary sulcus

Clinical: relating to the observation and treatment of actual patients rather than theoretical or laboratory studies

CLIP – Continuous Liquid Interface Production (CLIP is a proprietary method of 3D printing that uses photopolymerization.

Colour Doppler – Is a non-invasive test that can be used to estimate blood flow through blood vessels.

Composites – Are materials that are made by combining two or more materials – often ones that have very different properties. The two materials work together to give the composite unique properties.

Congenital - of a disease or physical abnormality, present from birth.

Contra-Indications - In medicine, a contraindication is a condition or factor that serves as a reason to withhold a certain medical treatment due to the harm that it would cause the patient. A contraindication is the opposite of indication, which is a reason to use a certain treatment.

Contrast medium - A contrast medium is a substance used to increase the contrast of structures or fluids within the body in medical imaging. They enhance the radiodensity in a target tissue or structure.

Conus: The upper front part of the right ventricle of the heart.

Coronal / Coronary: relating to the crown of the head / relating to the arteries which surround and supply blood to the heart.

Coronary arteries: branches of the ascending aorta that supply blood to the heart; the left coronary artery feeds the left side of the heart, the left atrium and ventricle, and the interventricular septum; the right coronary artery feeds the right atrium, portions of both ventricles, and the heart conduction system

Coronary sinus: large, thin-walled vein on the posterior surface of the heart that lies within the atrioventricular sulcus and drains the heart myocardium directly into the right atrium

Coronary sulcus: sulcus that marks the boundary between the atria and ventricles

Coronary veins: vessels that drain the heart and generally parallel the large surface arteries

coronary veins: vessels that drain the heart and generally parallel the large surface arteries

CT - Computed tomography (CT) is a fast, painless, noninvasive and accurate diagnostic imaging test used to create detailed images of internal organs, bones, soft tissue and blood vessels. In emergency cases, it can reveal internal injuries and bleed quickly enough to help save lives.

D-Transposition: Dextrotransposition (swapped) also see TGA

Dextrocardia - Dextrocardia is a congenital heart defect in which the heart is situated on the right side of the body with the apex pointing to the right.

Dextrocardia: a rare heart condition in which your heart points toward the right side of your chest instead of the left side. It is a Congenital Heart Defect

DICOM - Digital Imaging and Communications in Medicine (DICOM) is a standard for storing and transmitting medical images enabling the integration of medical imaging devices such as scanners, servers, workstations, printers, network hardware, and picture archiving and communication systems (PACS) from multiple manufacturers.

Distal - situated away from the centre of the body

DLP - Digital Light Processing (DLP) is a process of additive manufacturing / 3D Printing.

DMLS - Direct metal laser sintering (DMLS) is an additive manufacturing metal fabrication technology, occasionally referred to as selective laser sintering (SLS) or selective laser melting (SLM), that generates metal prototypes and tools directly from computer-aided design (CAD) data

Doppler – See Ultrasonography

Dorsal - relating to the upper side or back of an animal, plant, or organ

DORV – Double Out Right Ventricle, a type of CHD

Drainage – Flow of Blood within the Heart chambers

DTGA - dextro-Transposition of the great arteries

ECG – Electrocardiogram. It records the electrical activity of our heart at rest. It provides information about our heart rate and rhythm and shows if there is enlargement of the heart

due to high blood pressure (hypertension) or evidence of a previous heart attack (myocardial infarction).

ECO – short form for Echo, an Ultrasound procedure.

Endocardium - the thin, smooth membrane which lines the inside of the chambers of the heart and forms the surface of the valves / innermost layer of the heart lining the heart chambers and heart valves; composed of endothelium reinforced with a thin layer of connective tissue that binds to the myocardium

Endothelium: a layer of smooth, simple squamous epithelium that lines the endocardium and blood vessels

Epicardial coronary arteries: surface arteries of the heart that generally follow the sulci

epicardial coronary arteries: surface arteries of the heart that generally follow the sulci

Epicardium: The thin, smooth membrane forming the innermost layer of the serous pericardium and the outermost layer of the heart wall and Valves.

Epidemiology - the branch of medicine which deals with the incidence, distribution, and possible control of diseases and other factors relating to health

Etiology - the cause, set of causes, or manner of causation of a disease or condition.

FDM – Filament Deposition Modelling, a popular type of 3D printing

Fetal- relating to a fetus.

Fidelity - the degree of exactness with which something is copied or reproduced

Flow pathway – Directional Flow Pathway of blood through the heart

Fontan – A heart correction procedure named after Dr Francis Fonton (1929-2018) In his original repair, he connected the right atrium directly to the pulmonary artery, and closed the ASD. Blood entering the right atrium from the veins passed across this surgical connection into the pulmonary artery and to the lungs.

Foramen ovale: opening in the fetal heart that allows blood to flow directly from the right atrium to the left atrium, bypassing the fetal pulmonary circuit / the remnant of a thin fibrous sheet that covered the foramen ovale during fetal development (See also) Limbus

Fossa ovalis: oval-shaped depression in the interatrial septum that marks the former location of the foramen ovale

Glenn Procedure - Glenn procedure is a palliative surgical procedure performed for patients with Tricuspid atresia. It is also part of the surgical treatment path for hypoplastic left heart syndrome. This procedure has been largely replaced by Bidirectional Glenn procedure (Fontan procedure).

Gore-Tex - Gore-Tex is a waterproof, breathable fabric membrane and registered trademark of W. L. Gore and Associates. Invented in 1969, Gore-Tex is able to repel liquid water while allowing water vapour to pass through and is designed to be a lightweight, waterproof fabric for all-weather use. It is composed of stretched polytetrafluoroethylene (PTFE), which is more commonly known by the generic trademark Teflon.

Great cardiac vein: a vessel that follows the interventricular sulcus on the anterior surface of the heart and flows along the coronary sulcus into the coronary sinus on the posterior surface; parallels the anterior interventricular artery and drains the areas supplied by this vessel

Great cardiac vein: a vessel that follows the interventricular sulcus on the anterior surface of the heart and flows along the coronary sulcus into the coronary sinus on the posterior surface; parallels the anterior interventricular artery and drains the areas supplied by this vessel

Hemi Fanton – See Glenn Procedure

Heterocardia: The other, different Heart type

Heterotaxia - Situs ambiguous or situs ambiguous, also known as heterotaxy or heterotaxia, is a rare congenital defect in which the major visceral organs are distributed abnormally within the chest and abdomen. Heterotaxy, in general, refers to any defect of left-right laterality and arrangement of the visceral organs.

Heterotaxy: also referred to as isomerism of the atrial appendages, is defined as an abnormal assembly of the thoracic and abdominal organs from the normal arrangement known as "situs solitus." It is caused by disruption of left-right axis orientation during early embryonic development

Hounsfield Units - The Hounsfield unit (HU) scale is a linear transformation of the original linear attenuation coefficient measurement into one in which the radiodensity of distilled water at standard pressure and temperature (STP) is defined as zero Hounsfield units (HU), while the radiodensity of air at STP is defined as -1000 HU.

Hypertrophic cardiomyopathy: pathological enlargement of the heart, generally for no known reason

Hypertrophic cardiomyopathy: pathological enlargement of the heart, generally for no known reason

Hypertrophy - The increase in the volume of an organ or tissue due to the enlargement of its component cells

Hypoplastic – hypoplastic or hypoplasia refers to the incomplete development or underdevelopment of an organ or tissue.

ILI – Liquid layer Interface – Latest 3D printing technologies similar to DLP / SLA.

Inferior : low or lower in position

Inferior vena cava: a large systemic vein that returns blood to the heart from the inferior portion of the body

Inferior vena cava: a large systemic vein that returns blood to the heart from the inferior portion of the body

Intensivist: An intensivist is a physician who specializes in the care of critically ill patients, most often in the intensive care unit (ICU).

Intravenous (IV): Into a vein; a needle is inserted into a vein in the back of the hand, inside the elbow, or some other location on the body. Fluids, nutrients, and drugs can be injected.

Intraosseous (IO): within a bone; sometimes used to refer to the bone marrow cavity.

Interatrial septum: cardiac septum located between the two atria; contains the fossa ovalis after birth

Interatrial septum: cardiac septum located between the two atria; contains the fossa ovalis after birth

Interventricular septum: cardiac septum located between the two ventricles

interventricular septum: cardiac septum located between the two ventricles

Ischemia - Ischemia or ischaemia is a restriction in blood supply to tissues, causing a shortage of oxygen that is needed for cellular metabolism (to keep tissue alive). Ischemia is generally caused by problems with blood vessels, with resultant damage to or dysfunction of tissue.

Isolated dextrocardia – Is a congenital heart abnormality in which our heart is located on the right side of your chest, but it has no other defects.

Isomerism - It is defined as an abnormal arrangement of the internal thoracic-abdominal organs across the left-right axis of the body.

Isomerism: Differ from each other in the structural arrangement.

JM – Binder Jetting Modelling, a type of 3D Printer

L- Transposition: Levotransposition

Left atrioventricular valve: (also, mitral valve or bicuspid valve) valve located between the left atrium and ventricle; consists of two flaps of tissue

left atrioventricular valve: (also, mitral valve or bicuspid valve) valve located between the left atrium and ventricle; consists of two flaps of tissue

Left isomerism – also termed as Asplenia and polysplenia are also possible features of heterotaxy syndrome. They are abnormal cardiac development, patients with situs ambiguous usually develop right atrial isomerism consisting of 2 bilaterally paired right atria, or left atrial isomerism consisting of 2 bilaterally paired left atria.

Levocardia – A medical condition where the heart is on the normal side of the body (the left), as opposed to dextrocardia, in which the heart is in the right side of the thoracic cavity

LIMA RIMA - the left and right internal mammary arteries

LIMA RIMA Y - Arterial Heart Bypass procedure

Limbus - a depression in the right atrium of the heart, at the level of the interatrial septum, the wall between the right and left atrium. The fossa ovalis is the remnant of a thin fibrous sheet that covered the foramen ovale during fetal development.

LOM – Laminated Object Manufacturing, is a 3D printing Technology or system developed by Helisys Inc In it, layers of adhesive-coated paper, plastic, or metal laminates are successively glued together and cut to shape with a Laser or knife cutter.

Lumen - a lumen (plural lumina) is the inside space of a tubular structure, such as an artery or intestine

LVOTO - Left Ventricular Outflow Tract Obstruction

MAPCAs - Major Aortopulmonary Collateral Arteries

Marginal arteries: branches of the right coronary artery that supply blood to the superficial portions of the right ventricle

Marginal arteries: branches of the right coronary artery that supply blood to the superficial portions of the right ventricle

Masking - hide, conceal, disguise, cover up

Medial - situated near the median plane of the body or the midline of an organ

Mesothelium: a simple squamous epithelial portion of serous membranes, such as the superficial portion of the epicardium (the visceral pericardium) and the deepest portion of the pericardium (the parietal pericardium)

Mesothelium: a simple squamous epithelial portion of serous membranes, such as the superficial portion of the epicardium (the visceral pericardium) and the deepest portion of the pericardium (the parietal pericardium)

Middle cardiac vein: a vessel that parallels and drains the areas supplied by the posterior interventricular artery; drains into the great cardiac vein

Mitral valve: (also, left atrioventricular valve or bicuspid valve) valve located between the left atrium and ventricle; consists of two flaps of tissue

MJF – Multi Jet Fusion – HP developed 3D Printing technology/system

MJM –Multi Jet Modelling 3D Printing technology/system

Moderator band: a band of myocardium covered by endocardium that arises from the inferior portion of the interventricular septum in the right ventricle and crosses to the anterior papillary muscle; contains conductive fibres that carry electrical signals followed by contraction of the heart

Moderator band: a band of myocardium covered by endocardium that arises from the inferior portion of the interventricular septum in the right ventricle and crosses to the anterior papillary muscle; contains conductive fibres that carry electrical signals followed by contraction of the heart

Morphology - The study of form. In medicine, morphology refers to the size, shape and structure rather than the function of a given organ

MRI – Magnetic Resonance Imaging

Myocardium - The middle layer of the heart, consisting of cardiac muscle/ thickest layer of the heart composed of cardiac muscle cells built upon a framework of primarily collagenous fibres and blood vessels that supply it and the nerve fibres that help to regulate it

Myocardium: the thickest layer of the heart composed of cardiac muscle cells built upon a framework of primarily collagenous fibres and blood vessels that supply it and the nerve fibres that help to regulate it

Neonatal - of or relating to newborn children, esp in the first week of life and up to four weeks old.

Occlusion - closure or blockage of a blood vessel

PA 12 – Polyamide 12, 3D printing material used in SLS

PA 2200 - Polyamide 12, 3D printing material used in SLS

Pacemaker - an electronic device implanted beneath the skin for providing a normal heartbeat by electrical stimulation of the heart muscle, used in certain heart conditions.

Palliation - to lessen the severity of (pain, disease, etc) without curing or removing

Papillary muscle: extension of the myocardium in the ventricles to which the chordae tendineae attach

Papillary muscle: extension of the myocardium in the ventricles to which the chordae tendineae attach

Patch – A piece of Tissue usually pericardium or PTFE (Gore-Tex) used to cover the hole in the heart

Pathways: Blood Flow Path

Pectinate muscles: muscular ridges seen on the anterior surface of the right atrium

Pectinate muscles: muscular ridges seen on the anterior surface of the right atrium

Paediatrics - Paediatrics is the branch of medicine that involves the medical care of infants, children, and adolescents. A medical doctor who specializes in this area is known as a paediatrician or paediatrician.

Perfusionist - is a skilled, allied health professional, trained and educated specifically as a member of an open-heart, the surgical team responsible for the selection, setup, and operation of a mechanical device commonly referred to as the heart-lung machine.

Pericardial cavity: cavity surrounding the heart filled with a lubricating serous fluid that reduces friction as the heart contracts

PDA: Patent Ductus Arteriosus,

Pericardial cavity: cavity surrounding the heart filled with a lubricating serous fluid that reduces friction as the heart contracts

Pericardial sac: (also, pericardium) membrane that separates the heart from other mediastinal structures; consists of two distinct, fused sublayers: the fibrous pericardium and the parietal pericardium

Pericardial sac: (also, pericardium) membrane that separates the heart from other mediastinal structures; consists of two distinct, fused sublayers: the fibrous pericardium and the parietal pericardium

Pericardium: (also, pericardial sac) membrane that separates the heart from other mediastinal structures; consists of two distinct, fused sublayers: the fibrous pericardium and the parietal pericardium

Pericardium: (also, pericardial sac) membrane that separates the heart from other mediastinal structures; consists of two distinct, fused sublayers: the fibrous pericardium and the parietal pericardium

PET - Positron-emission tomography (PET) is a nuclear medicine functional imaging technique that is used to observe metabolic processes in the body as an aid to the diagnosis of disease

Phenotype - A phenotype is the composite of an organism's observable characteristics or traits, such as its morphology, development, biochemical or physiological properties, behaviour, and products of behaviour such as bird nest.

Posterior cardiac vein: a vessel that parallels and drains the areas supplied by the marginal artery branch of the circumflex artery; drains into the great cardiac vein

Posterior cardiac vein: a vessel that parallels and drains the areas supplied by the marginal artery branch of the circumflex artery; drains into the great cardiac vein

Posterior interventricular artery: (also, posterior descending artery) branch of the right coronary artery that runs along the posterior portion of the interventricular sulcus toward the apex of the heart and gives rise to branches that supply the interventricular septum and portions of both ventricles

Posterior interventricular artery: (also, posterior descending artery) branch of the right coronary artery that runs along the posterior portion of the interventricular sulcus toward the apex of the heart and gives rise to branches that supply the interventricular septum and portions of both ventricles

Posterior interventricular sulcus: sulcus located between the left and right ventricles on the anterior surface of the heart

Posterior interventricular sulcus: sulcus located between the left and right ventricles on the anterior surface of the heart

Posterior: Further back in position; of or nearer the rear or hind end.

Prognosis - forecasting of the probable course and outcome of a disease, especially of the chances of recovery

Prototype - first model of something from which other forms are copied or developed

Proximal: Situated nearer to the centre of the body

PTFE - Polytetrafluoroethylene (PTFE) is a synthetic fluoropolymer of tetrafluoroethylene that has numerous applications. The best-known brand name of PTFE-based formulas is Teflon by Chemours. Chemours is a 2015 spin-off of DuPont Co., which discovered the compound in 1938.

Pulmonary arteries: left and right branches of the pulmonary trunk that carries deoxygenated blood from the heart to each of the lungs

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Pulmonary capillaries capillaries surrounding the alveoli of the lungs where gas exchange occurs: carbon dioxide exits the blood and oxygen enters

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Pulmonary circuit: blood flow to and from the lungs

Pulmonary circuit: blood flow to and from the lungs

Pulmonary trunk: a large arterial vessel that carries blood ejected from the right ventricle; divides into the left and right pulmonary arteries

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Pulmonary valve: (also, pulmonary semilunar valve, the pulmonic valve, or the right semilunar valve) valve at the base of the pulmonary trunk that prevents backflow of blood into the right ventricle; consists of three flaps

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Pulmonary veins: veins that carry highly oxygenated blood into the left atrium, which pumps the blood into the left ventricle, which in turn pumps oxygenated blood into the aorta and to the many branches of the systemic circuit

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Purkinje Fibers - the specialized cardiac muscle fibres, part of the impulse-conducting network of the heart, that rapidly transmit impulses from the atrioventricular node to the ventricles

Radio transparency – or radiolucent structural materials are transparent to x-rays. Plastics are inherently radiolucent.

Radiograph – X-Ray

Radiography - the process or occupation of taking radiographs to assist in medical examinations.

Radiologist - a person who uses X-rays or other high-energy radiation, especially a doctor specializing in radiology.

Radiology - the science dealing with X-rays and other high-energy radiation, especially the use of such radiation for the diagnosis and treatment of disease.

Region Growing – Refers to the image processing process in which a single seed point is used to iteratively grow a region by comparing all unallocated neighbouring pixels to the region. The difference between a pixel's intensity value and the region's mean, it is used as a measure of similarity and segment heart morphology from DICOM data.

Regurgitation: The backward flow of blood through a defective heart valve.

Resection - Surgical removal of all or part of an organ, tissue, or structure

Rheumatic Heart Disease - Rheumatic diseases, also called musculoskeletal diseases, characterised by damage to one or more heart valves that remains after an episode of acute rheumatic fever recurrent episodes where the heart has become inflamed.

Right atrioventricular valve: (also, tricuspid valve) valve located between the right atrium and ventricle; consists of three flaps of tissue right isomerism (situs ambiguous with asplenia).

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ROI - A region of interest (ROI) is a portion of an image that you want to filter or perform some other operation on.

RVOT - Right Ventricular Outflow Tract

SA Node - Sinoatrial node, is a natural pacemaker of the heart. The SA node consists of a cluster of cells that are situated in the upper part of the wall of the right atrium (the right upper chamber of the heart). The electrical impulses are generated there. The SA node is also called the sinus node.

Sagittal Plane - a cross section obtained by slicing, actually or through imaging techniques, the body or any part of the body, or any anatomic structure in the sagittal plane, in a vertical plane parallel to the median plane.

Sandblasting - is the operation of forcibly propelling a stream of abrasive material against a surface under high pressure to smooth a rough surface, roughen a smooth surface, shape a surface or remove surface contaminants.

Segmentation - is the process of partitioning a digital image into multiple segments The goal of segmentation is to simplify and/or change the representation of an image into something that is more meaningful and easier to analyze.

Semilunar valves: valves located at the base of the pulmonary trunk and at the base of the aorta

semilunar valves: valves located at the base of the pulmonary trunk and at the base of the aorta

Senning - Redirection of blood using atrial flaps to correct patients with transposition of the great arteries (TGA) was described by Senning in 1959.

Septum - is the wall of tissue that separates the right and left atria of the heart.

Septum : (plural = septa) walls or partitions that divide the heart into chambers

Septum primum: a flap of tissue in the fetus that covers the foramen ovale within a few seconds after birth

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SV – Single Ventricle

Situs Ambiguous – See heterotaxy or heterotaxia

Situs Inverses – see Dextrocardia

Situs inversus totalis - complete transposition (right to left reversal) of all of the abdominal organs. See Dextrocardia

Situs: Position, especially normal or original position

SLA – Stereolithographic Apparatus is a type of 3D printing technology which builds parts from Photopolymerization of liquid Photo monomer.

Slice Thickness – The thickness of any single layer in a 3D printing process defines the resolution of the part built.

SLM - Selective Laser Melting is a type of 3D printing technology which builds parts from Metal Powder.

SLS – Selective Laser Sintering, a type of 3D printing technology which builds parts from Powder.

Small cardiac vein: parallels the right coronary artery and drains blood from the posterior surfaces of the right atrium and ventricle; drains into the great cardiac vein

Small cardiac vein: parallels the right coronary artery and drains blood from the posterior surfaces of the right atrium and ventricle; drains into the great cardiac vein

Sonography – see Ultrasonography

Stenosis : The abnormal narrowing of a passage in the body

Sternum - or breastbone is a long flat bone shaped like a necktie located in the centre of the chest. It connects to the ribs via cartilage, forming the front of the rib cage, and thus helps to protect the heart, lungs, and major blood vessels from injury.

Sulcus: (plural = sulci) fat-filled groove visible on the surface of the heart; coronary vessels are also located in these areas

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Superior vena cava: a large systemic vein that returns blood to the heart from the superior portion of the body

Superior vena cava: a large systemic vein that returns blood to the heart from the superior portion of the body

Superior: Top

Surgical Pre-planning - is the preoperative method of pre-visualising a surgical intervention, in order to predefine the surgical steps

Systemic circuit: blood flow to and from virtually all of the tissues of the body

Systemic circuit: blood flow to and from virtually all of the tissues of the body

TAPVC - Total anomalous pulmonary venous return connection is a birth defect of the heart in which the veins bringing blood back from the lungs (pulmonary veins) don't connect to the left atrium like usual.

TGA: Transposition of Great Arteries – Swapped Arteries.

TOF – Tetralogy of Fallot

Trabeculae carneae : ridges of muscle covered by endocardium located in the ventricles

Trabeculae carneae: ridges of muscle covered by endocardium located in the ventricles

Transect - cut across or make a transverse section in.

Transposition: Removal from one place to another

Tricuspid valve: term used most often in clinical settings for the right atrioventricular valve

Ubiquitous: Found everywhere.

Ultrasonography - a diagnostic imaging technique based on the application of ultrasound. It is also called Doppler 2D / 3D which adds flow characteristics.

Univentricular Hearts – They are a Heart Defect in which there is only one ventricle and this can occur in many 3 main types: Double inlet left, right, or indeterminate ventricle.

VAD – a ventricular assist device (VAD) is an electromechanical device for assisting cardiac circulation, which is used either to partially or to completely replace the function of a failing heart.

Valve: in the cardiovascular system, a specialized structure located within the heart or vessels that ensure one-way flow of blood

Vena Cava - a large vein carrying deoxygenated blood into the heart. There are two in humans, the inferior vena cava (carrying blood from the lower body) and the superior vena cava (carrying blood from the head, arms, and upper body).

Ventral - relating to the underside of an animal or plant

Ventricle - ventricle is one of two lower chambers (right & left) in the heart. the right ventricle pumps blood into the pulmonary circulation to the lungs, and the left ventricle pumps blood into the systemic circulation through the aorta.

Zamvar Fold – Fold in the pericardium bottom observed by Dr.Vipin Zamvar

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Annexure I

1. 3D Printing Technology Review

Mechanical and Production Engineers typically study manufacturing processes for 2 years under Production Technology 1 and Production technology 2. While PT1 covered all processes, which are mostly manual tool use, PT2 starts with NC and CNC, unconventional manufacturing processes and new emerging technologies.

All the production technologies known to mankind can be categorized under 3 broad areas, namely Plus Processes or Additive Processes, Minus or Subtractive processes and Zero Processes. The following tree (Fig A) will help in understanding these terms better.

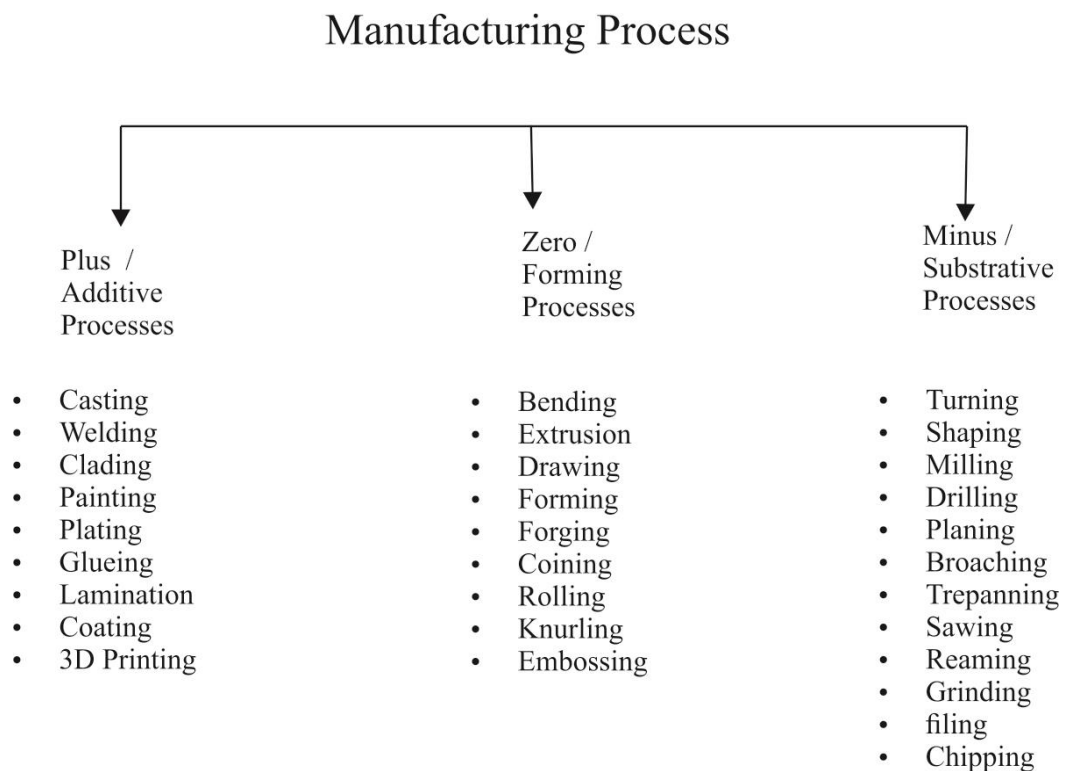


Figure 1 :Manufacturing Process Classification

Additive Manufacturing, as compared to Subtractive, is less energy demanding produces less scrap and is more optimal as a process. The diagram below will help to understand these features better:

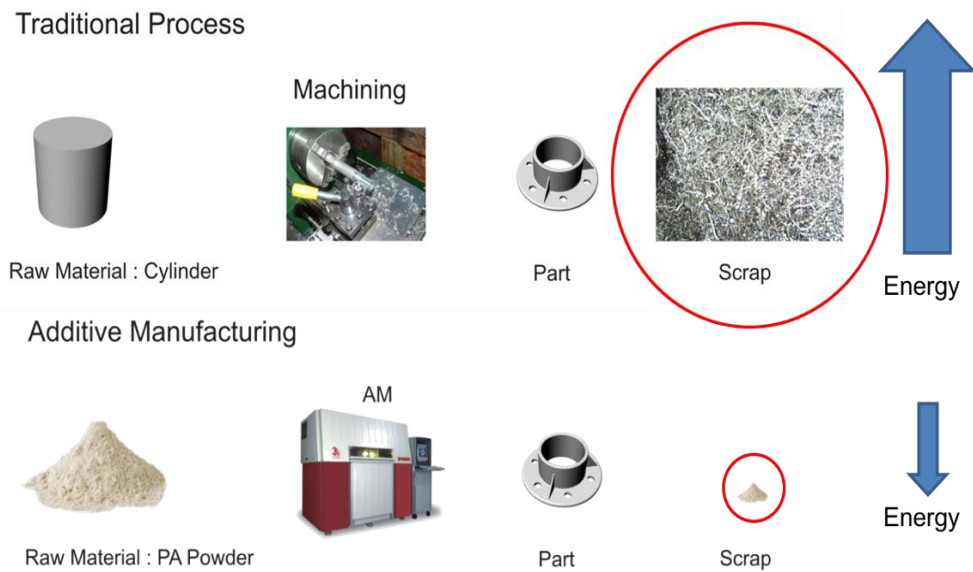


Figure 2: Difference between Additive and Subtractive Processes

We can thus list Differences between Additive & Subtractive Processes as:

Subtractive

Uncovering A Form/ Carving / Chiseling

Consumes Resources

Wasteful

Rapid

Additive

Creating A Form / Generative Form

Conserves Resources

Efficient / Optimal

Time Consuming?

Figure 3: Differences between Additive & Subtractive Processes

1.1 Discussion on RP/AM and 3-D Printing/Digital Fabrication

In the early years 3-D printing, it was termed as Rapid Prototyping. Ironically, it was neither Rapid nor was used for just prototyping, rendering the term as a misnomer. The word Stereolithography, coined by Chuck Hull, was very thoughtful. Stereo means ‘depth’, and ‘lithography’ means printing. Thus, it was later aptly named as 3-D printing. MIT had first coined the word 3-D printing for its binder jetting process and it was a

trademarked. But over time, all layered manufacturing processes came to be called 3-D printing.

The term Additive Manufacturing is a set of processes, 3-D printing being a part of it. Additive Manufacturing seems to be a bit loaded a term because manufacturing refers to bulk production in thousands and millions. 3-D printing is best for small batches to a single quantity, and hence can be called as Fabrication. As the input designs are essentially digital data, it is also called Digital Fabrication.

1.2 The ASME Classification of 3D Printing Processes

In 2010, the **American Society for Testing and Materials** (ASTM) Committee F42 on Additive Manufacturing Technologies developed F2792–12a: Standard Terminology for Additive Manufacturing Technologies. And with it, they defined a set of seven categories of different additive manufacturing processes:

- 1. Vat Photopolymerization:** an additive manufacturing process in which liquid photopolymer in a vat is selectively cured by light-activated polymerization.
- 2. Powder Bed Fusion:** an additive manufacturing process in which thermal energy selectively fuses regions of a powder bed;
- 3. Material Extrusion:** an additive manufacturing process in which material is selectively dispensed through a nozzle or orifice;
- 4. Binder Jetting:** an additive manufacturing process in which a liquid bonding agent is selectively deposited to join powder materials;
- 5. Material Jetting:** an additive manufacturing process in which droplets of build material (e.g., photopolymer and wax) are selectively deposited;
- 6. Sheet Lamination:** an additive manufacturing process in which sheets of material are bonded to form an object; and

7. Directed Energy Deposition: an additive manufacturing process in which focused thermal energy (e.g., laser, electron beam, or plasma arc) is used to fuse materials by melting as they are being deposited;

Of these seven categories, four processes are widely used in the majority of plastics engineering applications:

- 1) Stereolithography (SLA, a form of vat photopolymerization)
- 2) Selective Laser Sintering (SLS, a form of powder bed fusion)
- 3) Fused Deposition Modelling (FDM, a form of material extrusion),
- 4) Polyjet Modelling (PJM, a form of material jetting also called as JMM).

Each of these four processes is described in chronological order of their development.

Since the last 5 years, SLA has seen many analogous processes being developed and grouped as Digital Light Processing or DLP, a projector based VAT Polymerisation that is rapidly growing as a desktop solution. FormLab, RapidShape, B9 Creator are some of the examples of the products in this space.

SLS process to has analogues processes such as Binder jetting which also uses powder to make parts. DMLS is again a similar process to SLS in which metal is sintered to produce metal parts.

There has been a lot of research work to develop faster processes and in new material for final production use. The emergence of Carbon 3D, ILI, Zimo3D are technologies to be watched out for in the future.

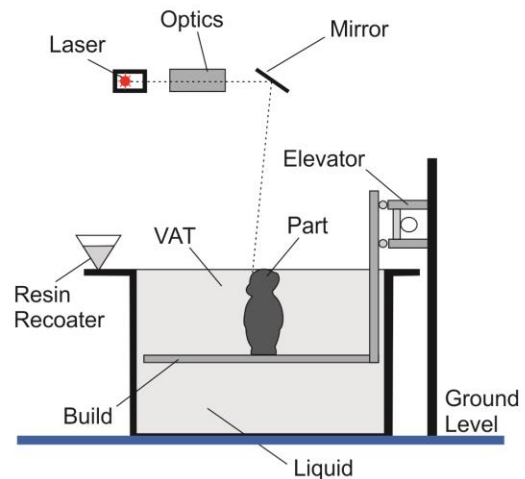
3-D Printing Process :

Vat Photopolymerisation / Stereolithographic Apparatus (SLA)

Description:

This is the first ever process to be commercialised by Chuck Hull under the name "3D Systems", and he called it as Stereolithography. The process consists of laser beam focused on a photosensitive liquid in a tank (or a vat). This liquid is a monomer which becomes a polymer with laser energy and solidifies instantly in the pattern etched out by a laser, one layer at a time. A recoater adds a fresh monomer layer every time a layer is built.

This process was first realised in lab and was called as Stereolithography Apparatus, thus gave its abbreviation of 'SLA'.



Advantages :

- Can produce very high quality products.
- The parts can be post processed
- They can be painted & plated
- They can also offer transparent models
- They can be buffed & machined
- They can be built with thin honeycomb structure for casting purposes.

Disadvantages :

- They are, to some extent, hygroscopic.
- They are brittle and can break like glass
- They need support structures for models.
- The process is expensive in comparison with other processes.

Machines:

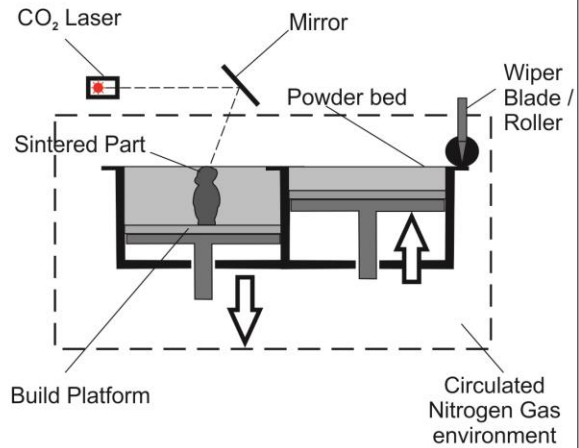


3-D Printing Process :

Selective Laser Sintering / Powder Bed Fusion (SLS)

Description:

Selective Laser Sintering or Powder bed fusion is the most wonderful of all technologies as it helps us to build the impossible! SLS process uses CO₂ laser which fuses together nylon powder on the printed bed, and it turns it into a layer, as per the input data. A new layer of powder is coated again and process is repeated in several cycles, to build the entire part layer by layer. In this process, there is no need for support structure, as the powder itself can support the cantilever part portions. With a little software trick, and powder, it is possible to print porous models which can be infiltrated with wax to make lost wax process for metal casting. With SLS, we can also print Metal, Composites of Carbon, PEEK, Glass filled Nylon and Rubber flexible models.



Advantages :

- Needs no support structures. Allows for pre-assembled parts.
- Builds prototypes that withstand functional testing.
- Produces durable end use parts without tooling.
- Creates accurate and repeatable parts as demanded by manufacturers.
- Machinable and paintable for demonstration parts.
- Functional prototypes that approach end-use performance properties.
- Appropriate for low-to-mid-volume rapid manufacturing.
- Parts are biocompatible
- Can be autoclaved
- Has a good dimensional stability.

Disadvantages :

- Parts are opaque and not transparent.
- Parts have a characteristic rough finished.
- Cannot be machined.
- Cannot be buffed.
- Cannot be painted without surface treatment.

Machines:

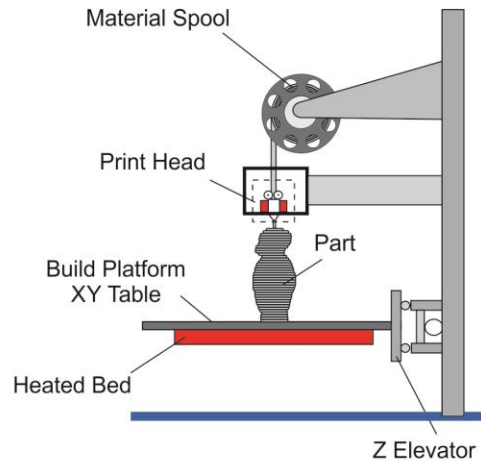


3-D Printing Process :

Fused Deposition Modeling(FDM)

Description:

FDM is a form of material extrusion process in which thermoplastic material are extruded through a hot nozzle over a XY table. After each layer is completed, the table is lowered in Z axis. The process of sectional plotting continues to create the objects layer by layer. It was invented by S. Scott Crump and commercialised by Stratasys Company. This is one of the most popular 3D printing technologies. Since the expiry of its patent, technology became available as an open source. This has made it a popular among maker community. The expiry of patent put this invention into the Open source and opened up a world of new explorations and new possibilities. This was led by the Rip-Rap Program at where the aim was to explore if 3D printer can replicate itself. This further led to many teams working on the system all over the world. The result was, another way to deposit on a XY table as in Delta and Polar systems



Advantages :

- Relatively straightforward as a process
- Does not require special conditions for building.
- Uses a wide variety of thermoplastic.
- Very economical and inexpensive.
- Fairly fast as a process
- Has a wide range of print sizes.
- ABS can be plated easily.

Disadvantages :

- Layer thickness cannot be low.
- Produces very rough parts.
- Post processing is difficult.
- Removal of support can be a challenge.
- Cannot be used to make complex designs.

Machines:



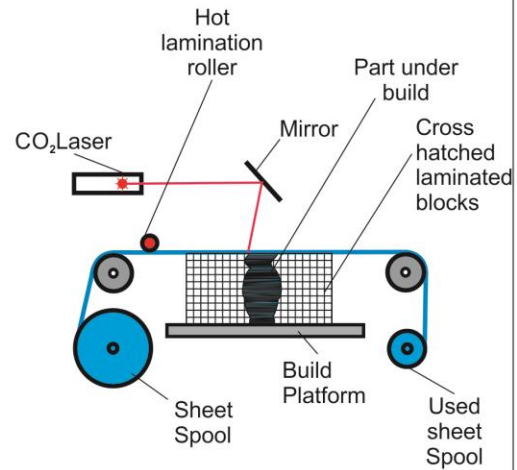
3-D Printing Process :

Laminated Object Manufacturing (LOM)

Description:

Laminated Object Manufacturing (LOM) is a wonderful process of 3D object creation using Paper or Polymer sheets which are laminated and cut by a laser. It was manufactured by Helisys Inc. In spite of its good model making capability, it was not a success in the market and the company was closed.

A very close instance to this process is MCore Machine which uses A4 papers to make models. Here instead of Laser, the shapes of each layer are cut by a Carbide Blade. The object removal is made easier by having cross hatched cubes which can be taken away to uncover the model.



Advantages :

- They are a fast process
- Colour model can be made
- Cost effective
- Bio friendly

Disadvantages :

- They are not accurate
- They cannot be used for functional testing
- They cannot be used to make master
- They are not very durable.

Machines:

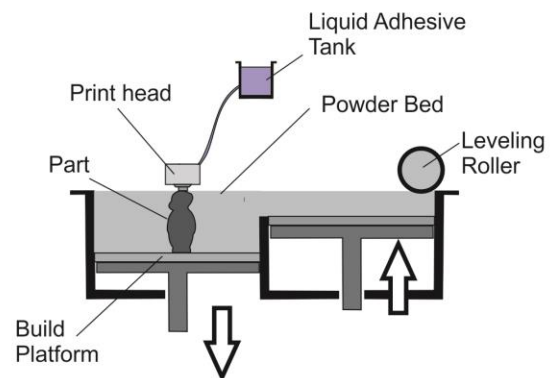


3-D Printing Process :

Binder Jetting

Description:

Binder Jetting is a powder based 3D printing process, wherein glue is jetted out on a layer of powder to bind it in a desired pattern, thereby creating a single layer. The roller then makes a pass over the print bed to coat it with a fresh layer of powder, ready to bind the next layer. The process is then repeated to stack layer upon layer to obtain the 3D object. This technology is capable of using color ink jets to obtain multicolored parts, a USP that is uncommon to 3D printing.



Advantages :

- It is relatively inexpensive
- Capable of producing multicolored parts.
- Fair fast as a process.
- Complex colour combinations are possible.
- Can be used for making toys, medical and educational models.

Disadvantages :

- Parts are low on strength and brittle.
- Parts have a rough surface finish.
- Post processing is limited to infiltration of adhesives.
- Cannot be used for functional testing.
- Cannot be used to produce intricate objects.

Machines:

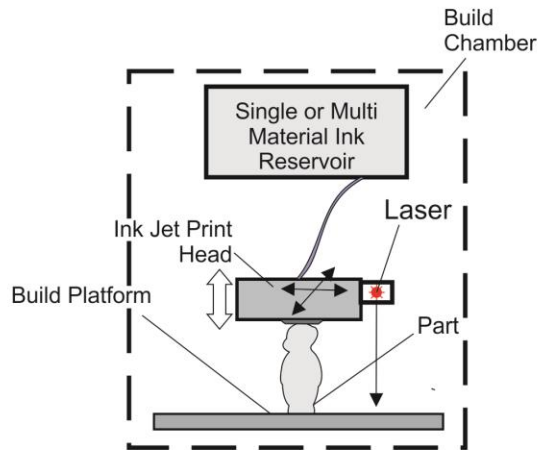


3-D Printing Process :

Material Jetting

Description:

Multijet, or polyjet 3D printing, used inkjet printing technology to jet out photosensitive material by fine piezo hammers. Piezo hammers are nothing by a cluster of small nozzles that dispense the material on the build platform in a desired pattern. This material is then solidified by exposure to UV light after the end of every stroke. This technology is capable of handling multiple material and their combinations to create parts made out of 'digital materials' and in multiple colors.



Advantages :

- Parts can have very high resolutions.
- Can combine transparent and opaque sections in the same part.
- Can vary material density to create hard and soft sections in the same part.
- Relatively very fast.
- Parts are highly durable.
- Can print in multiple colors.
- Can offer digital material.
- Can be used to create wax patterns.

Disadvantages :

- Very expensive 3D printing process.
- Rubber like material durability is poor.
- Cleaning and post processing is rather difficult.

Machines:



3-D Printing Process :

Direct Metal Laser Sintering (DMLS)

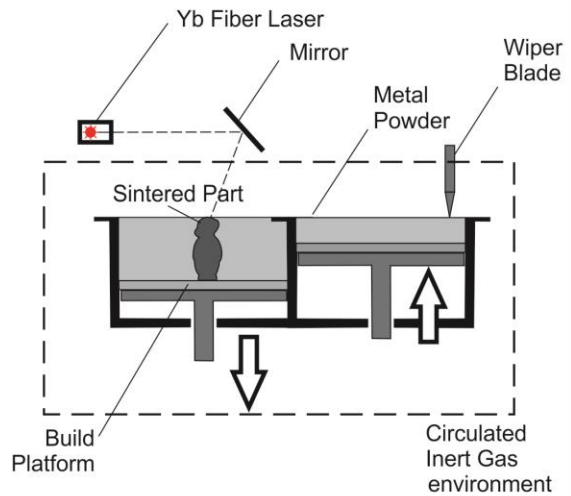
Description:

DMLS is a product of EOS, Germany's patented technology that is analogous to SLS. In this technology, metal powder is sintered together by high energy lasers to create metal parts. the process is also called as Laser Melting (LM)

The powder is of 40 micron metal fine aggregate. Nitrogen or Argon is used to contain oxidation in the build chamber. The powder bed is pre-heated to accelerate the process. The laser source used is Ytterbium-Doped Optical Fiber Laser.

The part built, however, will have supports unlike SLS of Nylon powder. We need CNC machining, shot peening, tumbling, magnetic fluid polishing to get the final part. In some cases where we need special surface properties we can also coat it by a Plasma Torch. To increase homogeneity, Hot Isostatic Pressing process is adopted to get stronger parts for structural applications.

The standard metal we use in 3D printing are: Stainless steel, Co-Cr alloy, CP-Ti, Ti-6Al-4V, NiTi, Inconel, gold, silver, copper, Al and their alloys are some standard materials used. Metal powders for 3D printing processes are produced by one of the following six processes: Plasma rotating electrode process, Gas atomization, Plasma atomization, Electrolytic processing, High-pressure water atomization and



Advantages :

- Can fabricate intricate geometry for Aerospace & Medical Applications
- Offers medical grade Titanium alloys.
- Very accurate parts

Disadvantages :

- High energy consumption
- costly input material
- overall expensive output

Machines:

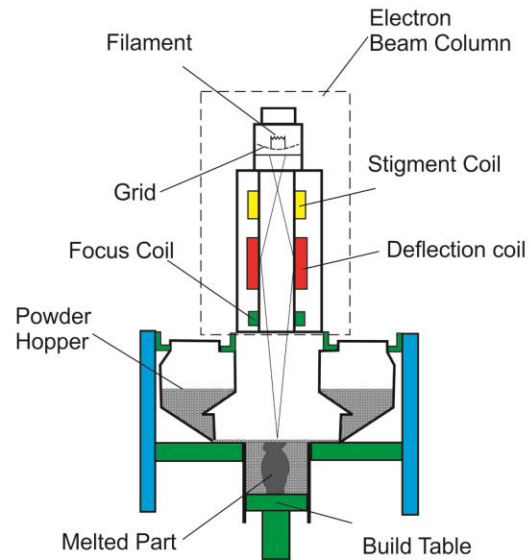


3-D Printing Process :

Electron Beam Melting (EBM)

Description:

In Electron Beam Melting (EBM) a powder bed is created similar to the LBM process. Instead of a laser beam an electron beam functions as heat source to melt the powder as prescribed by the 3D CAD data. The electron beam is generated in an electron gun before it is accelerated with an acceleration voltage of 60 kV, focused by electromagnetic lenses and directed by a magnetic scan coil to the desired positions in the x-y plane on the build plate. The power, focus and scan speed of the electron beam are generally determined by the choice of beam current, focus offset and speed function respectively. At first, the powder bed is pre-heated by a defocused beam which scans the powder bed surface several times. Using a high beam current of up to 30 mA and a scan speed of about 104 mm/s, temperatures of $>700^{\circ}\text{C}$ of the powder material are achieved for Ti-6Al-4V while for e.g. Cu a lower temperature of 55°C has been reported. This leads not only to heating of the powder but also to sintering of particles. In order to ensure complete melting of metal powder, beam current and scan speed are reduced.



Advantages :

- Can fabricate intricate geometry for Aerospace & Medical Applications
- Offers medical grade Titanium alloys.
- Very accurate parts

Disadvantages :

- High energy consumption
- costly input material
- overall expensive output

Machines:



2.8 Special 3D printers

The special 3-D printers are classified under the category either due to the technology or their special application area.

We discuss in this section, the special types of FDM, MJF by HP, Clay printing using a Robot, Concrete Printer, Chocolate Printing, Tissue printing.

2.8.1

The expiry of patent put this invention into the Open source and opened up a world of new explorations and new possibilities. This was led by the Rip-Rap Program where the aim was to explore if the 3-D printer can replicate itself. This further led to many teams working on the system all over the world. The result was, another way to deposit on an XY table as in Delta and Polar systems as shown below:

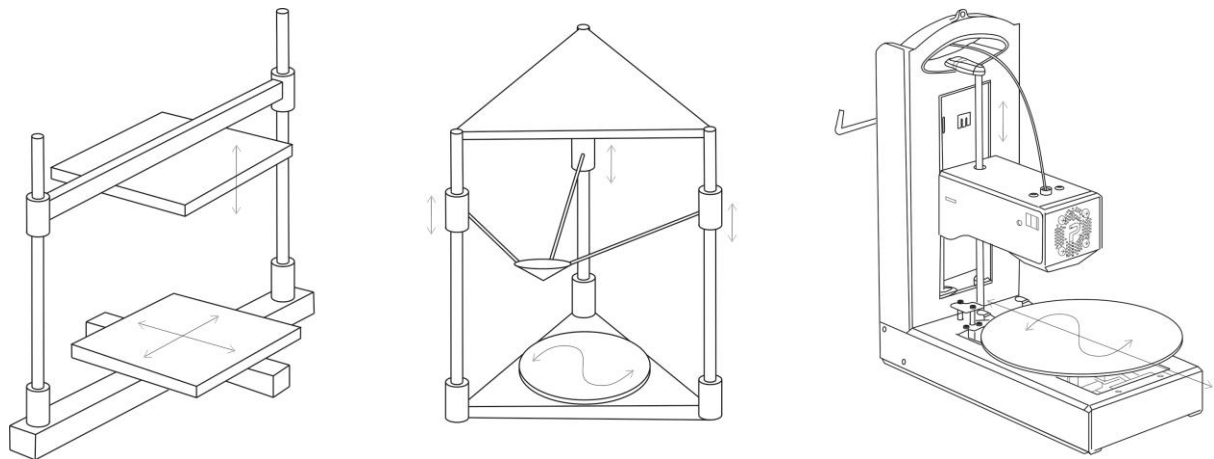


Figure 9: Cartesian, Delta Head and Polar FDM

2.8.2 Multi Jet Fusion from HP

Some New Systems that have joined the 3-D printing Machine gallery. HP's Multi Jet Fusion (MJF) is one of the most promising new entrants which is particularly of interest to the Manufacturing Sector. They offer better strength and are targeted for end-use parts. This printer's 50% of the non-dynamic parts are made by the same technology.



Figure 23. : HP's MJF Systems: 4200 and Full-colour Modeller, MJF 300

This system offers better quality parts at 80-micron layer thickness, 10 times faster than FDM systems and cheaper consumable cost. Due to its additional Build chamber which can be wheeled out, it can double the capacity to build parts as compared to SLS.

HP's MJF works more like a binder jetting. Here, they use heaters which will fuse the powder which is already grouped as per the CAD data. The parts are close to injection moulded parts due to particle fusion.

We need to watch this technology for its other material applications such as metal and composites.

2.8.3 Robotic Arm as an out of the box 3D Printer

FabClay is a 3-D ceramic printing project launched by Barcelona-based Sasha Jokic (Serbia), Starsk Lara (Colombia) and Nasim Fashami (Iran) aiming to explore a new digital fabrication system. It is a robotic additive manufacturing processes using industrial a Kuka robot and new 3-D printing technology.

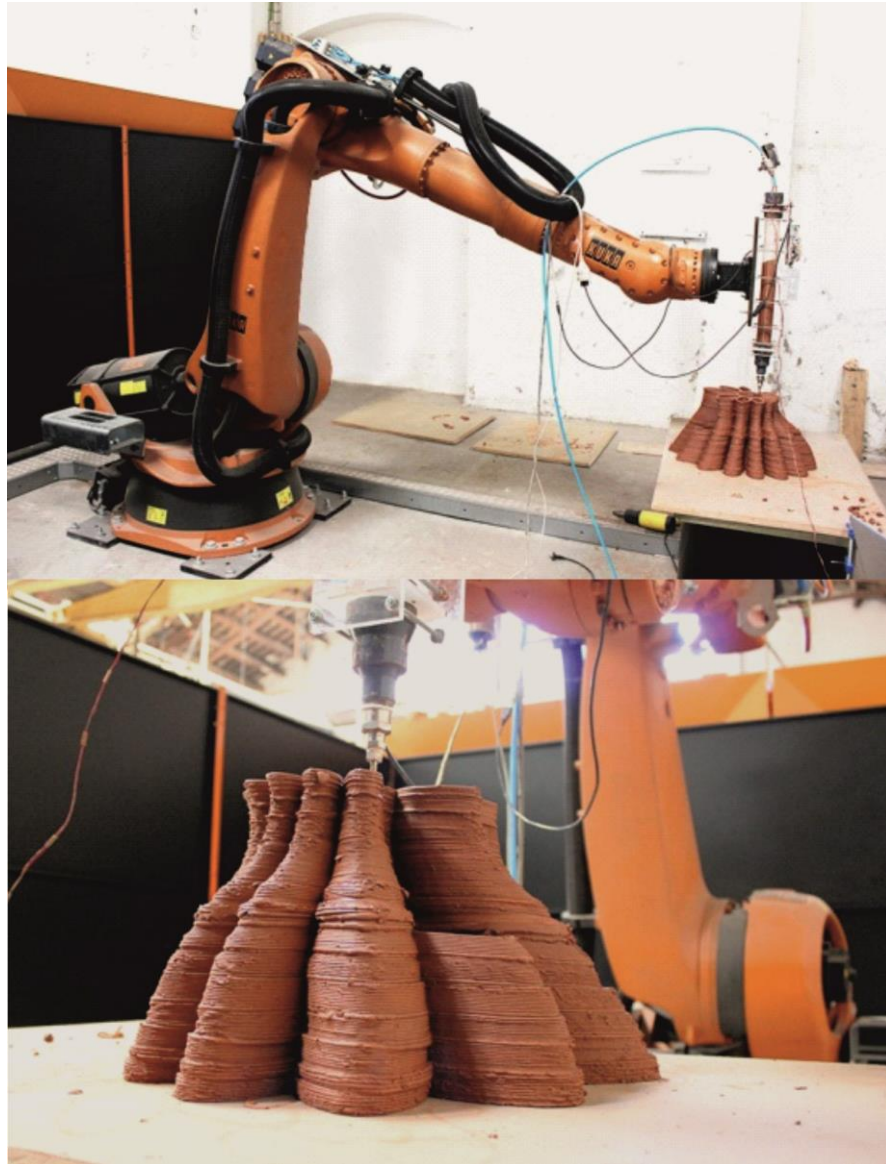


Figure 24: FabClay Printer made of Kuka Robot

In a similar fashion, we can also deposit concrete mix to build structures which could be blocks or whole building as can be seen below about an experimental castle built to demonstrate the capability of the new technology. There are many such attempts all over the world. The serious efforts in construction would start after better systems with competitive costs make it worthwhile.

2.8.4 Chocolate, Food and Drug Printing

A number of companies and organizations have designed and demonstrated extrusion-based food-printing machines. Some of the popular food printers are, Chefjet from 3-D

systems, Foodini which prints Pizza, Pancakebot which make custom pancakes, NASA is also working on space food printing.

Here the machine uses foodstuffs like chocolate, sugar, potato, flour paste, pasta, vegetables, and even meat, which are loaded into a capsule and dispensed layer by layer to create the food in shapes as per design.

3-D print enabled food applications can either print food directly or produce moulds in which food materials are shaped.

Pennsylvania-based Aprecia Pharmaceuticals said its 3-D printed Sprite (levetiracetam) tablets are used to treat epilepsy. This is the first 3-D printed drug to receive approval from the U.S. Food and Drug Administration (FDA) is now being shipped to pharmacies. There is no increased speed or economy by 3-D printing; the technology helps to better manipulate the drug's composition compared with traditional press and die pill-making technology as per Aprecia Pharmaceuticals spokesperson Jennifer Zieverink.



Figure 25: Range of Food Printers: Pancakebot, ChefJet, Foodini, cookie printer, THO and Drug respectively

2.8.5 Bio Plotting / Tissue Printing

Tissue engineering has been a promising field of Bio-Medical Engineering research, offering hope for man-made organs for transplantation needs. While 3-D printing to some extent helps to build Bio objects similar to organs, Vascularization remains the main technological hurdle to be managed.

.The concept of tissue engineering was formalized way back in 1993 when Langer and Vacanti published their seminal work in Science, in which the characteristics and applications of biodegradable three-dimensional (3-D) scaffolds were first proposed. A number of conventional manufacturing techniques were applied to fabricating porous 3-D scaffolds, such as fibre bonding, phase separation, solvent casting, particulate leaching, membrane lamination, moulding, and foaming. None of these could really meet the need for a controlled porous scaffold structure. The use of 3-D printing methods renewed the research interest and has progressed to make the dream of Tissue printing a near possibility.

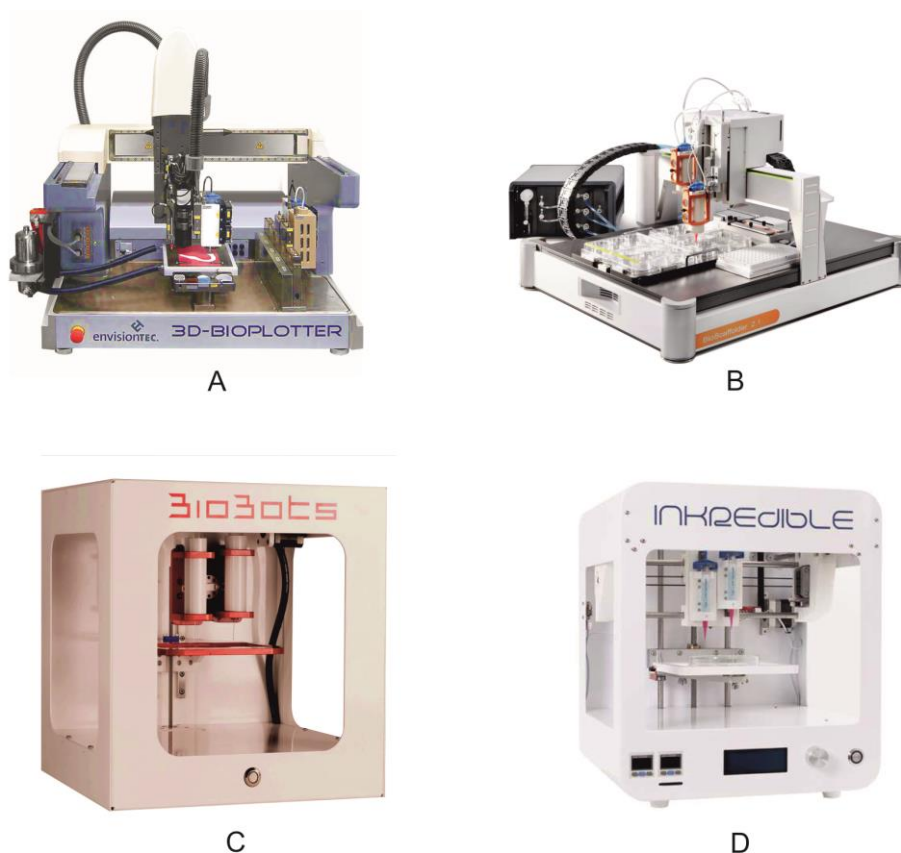


Figure 26: A. Bioplotter, B.Scaffolder, C.Biobot and D.Inkredible Tissue 3D Printers

In the market, there are many extrusion based 3-D printers that offer Biomaterial printing. Some popular machines are Bioplotter from Envision Tech, Bioscaffolder 2.1, Biobot and Incredible.

3. 3-D Printing Materials

3D Printing materials come in Plastics, Metals and composites. They also come in different forms. They can be broadly classified as Liquid-based, Powder based and Solid based.

3.1 Liquid Based Materials:

Under **liquid-based** materials, we have a particular class of materials called “Photopolymers”. These are monomer liquid which polymerizes on exposure to a particular wavelength of Light. SLA, DLP based systems such as Rapid shape, Envision Tech etc. CLIP, ILI, Form2 systems all use Photopolymers. The long chain monomers develop cross-linking to become hard polymers with the exposure to a coherent light source usually in Ultraviolet Region. Liquid type is the largest group of materials used for 3-D printing. Some of the examples are: 3D System’s SLA offers Accura 60(mimicking Polycarbonate material used for building optical/ clear transparent parts), AccuraAmethyst(developed especially for making fine jewelry parts and is capable of capturing fine details), Accura 50, Accura 25(both mimicking industry grade ABS) Accura Blue Stone(developed for high temperature and exceptionally high strength application like formula racing car components). Rapid Shape DLP offers GP (i.e. general purpose), CP (i.e. casting purpose etc.), JMM offers Visijet high cast, Visijet M3 Navy etc. Because of the liquid nature of the raw material, the printed parts are found to be smoothest of them all. Also, the parts need a special additional support structure while printing, which can be created using the proprietary or third party software. Object (Polyjet) machine offers Vero White, Vero Blue, Digital ABS, Tango Black, Tango Flex etc. This technology enables us to load 2 (or even more materials in next gen. machines) at a time, so that in a single build, we can build parts with different materials, or even enables us to mix the 2 materials to have a wide array of properties in the parts ranging from very soft to very hard. Due to their application as a combination over GUI, they are also called a Digital Material. Digital ABS material (which is a mixture of 2 such

materials) has been successfully used to make core and cavity for some small-sized parts, which is used on conventional injection moulding machine for small batch production (limited to 100 quantity). The next generation machines can accommodate cartridges with CMYK colours, wherein we can digitally assign the desired colour to our models in the software and the machine mixes CMYK colours in proper proportions to build models with our desired colours).

Wax-like resins available mainly Multi Jet Machines (JMM) such as CPX etc and Desktop hybrid machine such as Solids scape.

3.2 Powder Based Materials:

The Powder based materials are very popular and available as Plastic / Metal and Composites. Plastic materials include Nylon 12 (PA 12 & PA 2200), Nylon 6, Nylon flex used to make rubber-like parts like bellows.

The composites with Nylon are Ex Black, Nylon (with 30% or 50%)Glass filled, Nylon with Aluminum (Alumide) Nylon Flex, PEEK, Ceramics and Glass. Powders are also available as Polystyrene (eg. Castform from 3d systems/ Prime cast from EOS), which can be used to make porous models, that can be infiltrated with wax, which in turn can be used for investment casting process/ lost wax process. The Metal Alloy Powders include Alloys of Steel, Titanium, Cobalt, Aluminum, Inconel and Gold.

Alloy Steels come in various compositions such as Tool Steel, Margining Steel, Titanium Comes in Medical Grade 5 & Grade 23, Cobalt Chromium Medical Alloy

3.3 Solid Based Materials:

Solid based systems are largely used in Extrusion based system such as FDM and its various clone such as Replicator, MakerBot, UP Print, Delta Printers etc. They offer a wide variety of solid materials including ABS, PLA, PC, PC-ABS, Clay Fill, Cement fill, Wood Fill, Metal Fill, Carbon Nano Fibers in any colour. There are some special material extrudes which can change colour or glow in dark or aromatic.

LOM process uses plastic/ paper laminates; MCore process uses normal white A4 paper as a raw material.

As per future manufacturing needs, Real materials are needed for functional test and use in the field. Aerospace will drive Metal material development and Healthcare will drive the development of Biomaterials.

With more focus on this emerging technology area, we see a huge investment into the materials R&D. Soon we can expect more materials for every application.

Future special Materials under experimentation and development include Foods, Conducting polymer Inks, Shape memory and Live Tissue.

4. The concepts of 4D and 5D printing

From our experience as design professionals, we know how we get triggered with many new thoughts seeing any new concept. That's why cognitive psychologists say Ideas are Contagious. The History of 3D printing is a standing example of such phenomena like many technological innovations. Seeded by Charles Hull's Stereo Lithography, the 3D printing world is filled with many newer technologies. This was possible through the trigger of the first patented concept. The newer ones are going to trigger more and the process will continue.

It was in MIT Lab, researchers were experimenting with 3D printed objects made of shape memory plastics. Skylar Tibbits, Director of the Self-Assembly Lab at the Massachusetts Institute of Technology (MIT), is making the development of self-assembly programmable materials and adaptive technologies for strategic industrial applications.

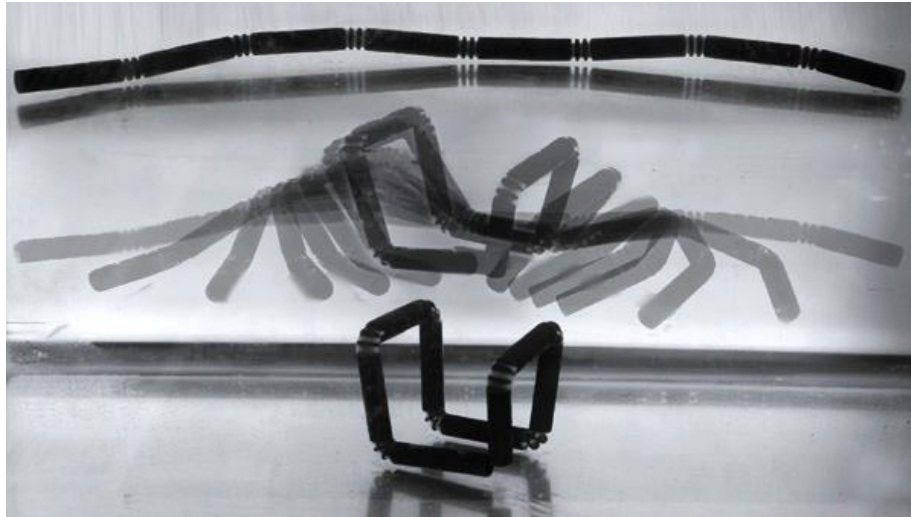


Figure 27: 4D printing developed at MIT showing cube holding.

They found that a 3-D printed strip made of different plastics behave differently under certain stimuli and if sequenced, show predictable behaviour. They demonstrated successfully “Cube Holding” in collaboration with Stratasys. This way of producing shape memory filled parts was called 4-D printing.

This technology uses programmable materials that change their function when hot water, light or heat is added to the mix. The input is a “smart material”, that has thermomechanical properties and other material properties – attributes that allow for shape change and are different from the common 3-D printing materials.

5-D printing is another creative extension of 3-D printing in which, the flat build table is replaced by a rotary table to add additional dimensions. By this, the 3D printing is pushing to make even more complex objects.

Mitsubishi Electric Research Labs (MERL) seems to have worked on this concept where the printing happens orthogonal to 5 axes getting its name, 5-D! Due to this innovation, parts can be created with curved layers as compared to flat layers in normal 3-D printing. These curved layers allow for stronger parts. As the printing is done in 5 axes, these parts do not require support as we need in conventional 3-D printing.

So, it is a combination of a CNC & 3-D Printing and can be called as a Hybrid Technology. Ethereal Machines from Bangalore, India showcased its 5Axis 3-D printer at

a US Show CES 2018 and are offering the machine starting at 20,000US\$. If the Printhead is replaced by the Tool, it can do 5 axis milling too.

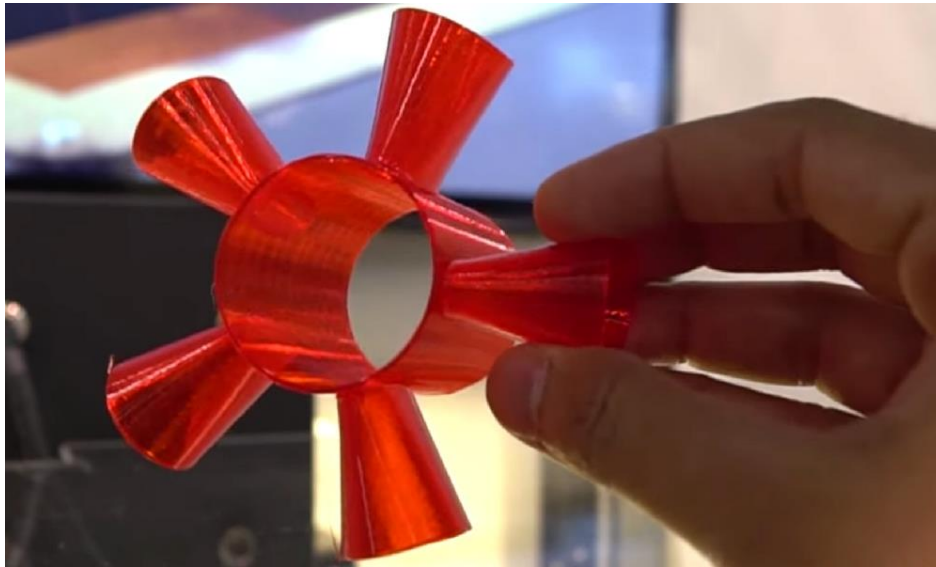


Figure **28**: 5Axis 3D Printed component

As a way forward, we can expect digital fabrication take a composite shape with best of Robotics, CNC and 3-D printing as Hybrid Manufacturing Solutions.

(Annexure I information content is taken from Imaginarium Academy)

Annexure II

CT protocol for anatomical models (Source: Materialise)

This document describes the guidelines for a CT scan that is taken for the purpose of ordering a Stereolithographic Model or a 3D model of any other type from Materialise or other service bureaus. This protocol is preferably transferred to the radiology department, together with the scan order. Using this scanning protocol as a guideline will result in a more accurate stereolithographic model.

Preparation of the patient

Remove any non-fixed metal dentures or prosthesis, in addition to any jewellery that might interfere with the region to be scanned. Non-metal dentures may be worn during the scan. Place the patient supine on the scanner table and move the patient into the gantry, head first. Make the patient comfortable and instruct him not to move during the procedure. Normal breathing is acceptable, but any other movement, such as tilting and turning the head can cause motion artefacts that compromise the reformatted images, requiring the patient to be rescanned.

Aligning the patient

It is very important to know whether a patient has been scanned with a gantry tilt (an angulation other than '0' or not. Although the MIMICS software has been adapted to support data scanned with gantry tilt, interpolations and 3D representation will have an inferior quality due to the gantry tilt. It is therefore advised not to use a gantry tilt. If the only option is to use a gantry tilt, please indicate the direction of angulation when the data is sent. /// or \\\

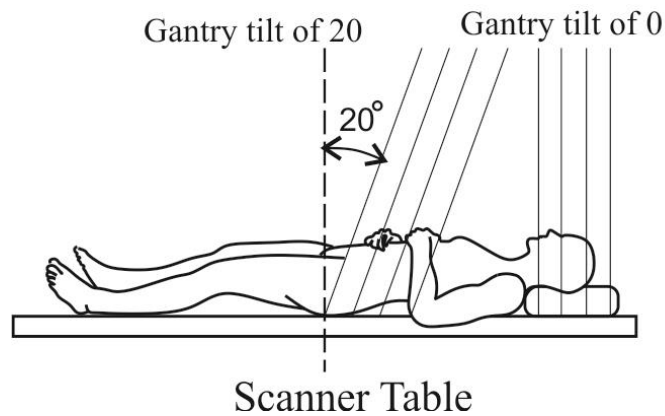


Figure 1: CT scan Protocol - Gantry Tilts

The direction of angulation:

Align the patient in a way that prevents as many artefacts as possible in the resulting images. Use the head holder with sponges to stabilize the position. If you cannot orient the head properly in the head holder, use the tabletop. In either case, strap the head securely to prohibit motion. You can take a lateral alignment image (called a Localizer, Scoutview, Topogram, Scanogram,

Pilot or Surview depending on the CT manufacturer) to verify the correct patient positioning.

Scanning instructions

Set the table height so that the area that needs to be scanned is centred in the scan field. All slices must have the same field of view, the same reconstruction centre, and the same table height. Not overlapping the axial slices can reduce the quality of the reformatted images. Scan all slices of the study in the same direction. Scan with the same slice spacing; the slice spacing must be less than or equal to the slice thickness. The slice thickness should preferably not be larger than 1 mm.

Matrix	512 x 512
Slice thickness	1.0 mm
Feed per rotation	1.0 mm
Reconstructed slice increment	1.0 mm or less
Reconstruction algorithm	Standard
Gantry tilt	0°

Table 1: CT scan Protocol

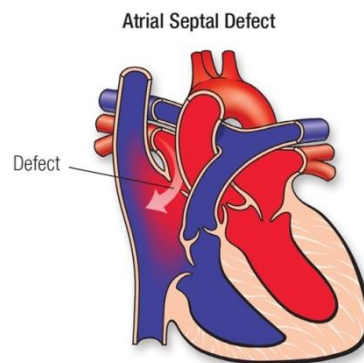
Reconstruction of the images

The images should be saved in the agreed format and onto the agreed medium (optical disk, CD...) as specified in the scan order. Please send the images to the doctor or directly to Materialise or the service bureau.

Annexure III : Congenital Heart Defects

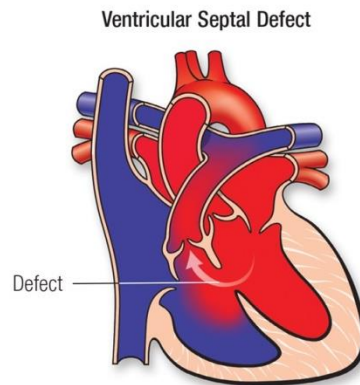
Diagram Credits :<https://www.heart.org/en/health-topics/congenital-heart-defects/about-congenital-heart-defects/>

1. Atrial septal defect (ASD) and its repair:



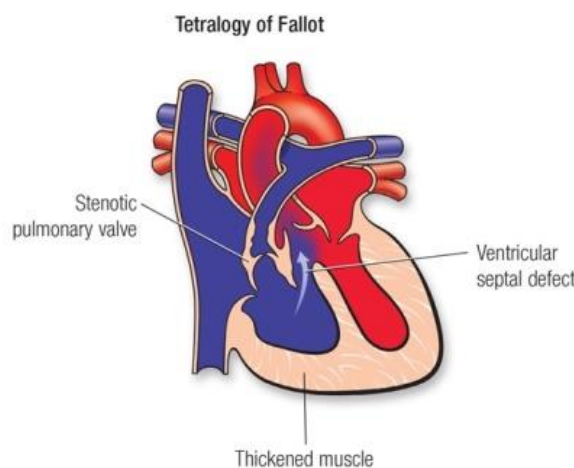
- The atrial septum is the wall between the left and right atria (upper chambers) of the heart. A hole in that wall is called an ASD. In the presence of this defect, blood with and without oxygen can be mixed up and over time, cause medical problems and arrhythmias.
- Sometimes, an ASD can be closed without open-heart surgery. First, the surgeon makes a tiny cut in the groin. Then the surgeon inserts a wire into a blood vessel that goes to the heart. Next, two small umbrella-shaped "clamshell" devices are placed on the right and left sides of the septum. These two devices are attached to each other. This closes the hole in the heart. Not all medical centres do this procedure.
- Open-heart surgery may also be done to repair ASD. In this operation, the septum can be closed using stitches. Another way to cover the hole is with a patch.

2. Ventricular septal defect (VSD) and its repair:



- The ventricular septum is the wall between the left and right ventricles (lower chambers) of the heart. A hole in the ventricular septum is called a VSD. This hole lets blood with oxygen mix with used blood returning to the lungs. Over time, irregular heartbeats and other heart problems can happen.
- By one year of age, most small VSDs close on their own. However, those VSDs that do stay open after this age may need to be closed.
- Larger VSDs, such as small ones in certain parts of the ventricular septum, or ones that cause heart failure or endocarditis, (inflammation) need open-heart surgery. The hole in the septum is most often closed with a patch.
- Some septal defects can be closed without surgery. The procedure involves passing a small wire into the heart and placing a small device to close the defect.

3. Tetralogy of Fallot and its repair:



- Tetralogy of Fallot is a heart defect that exists from birth (congenital). It usually includes four defects in the heart and causes the baby to turn a bluish colour (cyanosis).
- Open-heart surgery is needed, and it is often done when the child is between 6 months and 2 years old.

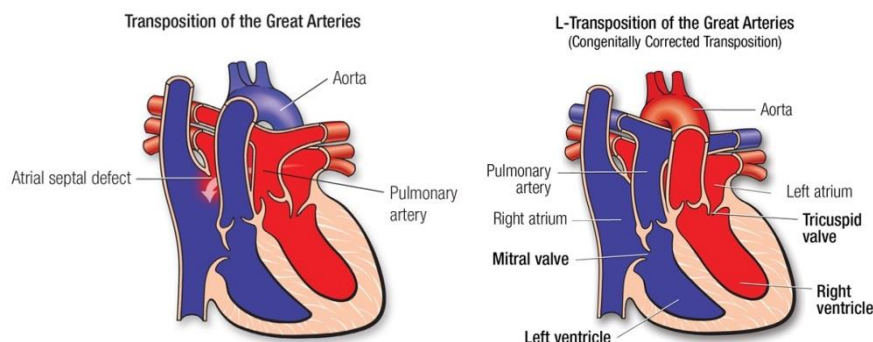
The surgery involves:

- Closing the ventricular septal defect with a patch.
- Opening the pulmonary valve and removing the thickened muscle (stenosis).
- Placing a patch on the right ventricle and main pulmonary artery to improve blood flow to the lungs.

The child may have a shunt procedure done first. A shunt moves blood from one area to another. This is done if the open-heart surgery needs to be delayed because the child is too sick to go through surgery.

- During a shunt procedure, the surgeon makes a surgical cut in the left side of the chest.
- Once the child is older, the shunt is closed and the main repair in the heart is performed.

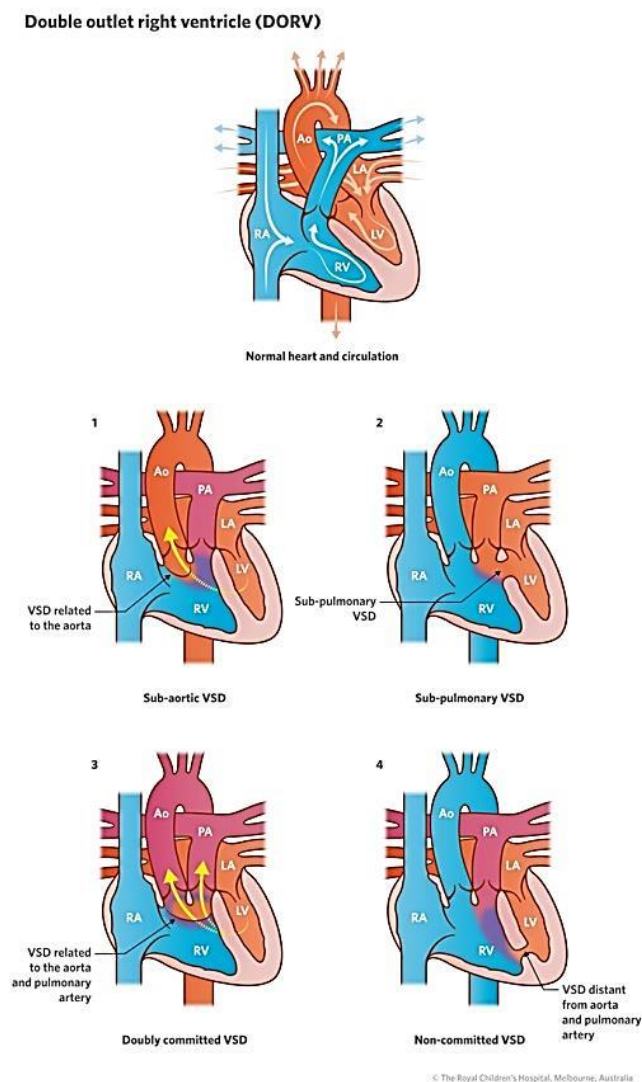
4. Transposition of the great vessels and its repair:



In a normal heart, the aorta comes from the left side of the heart, and the pulmonary artery comes from the right side. In transposition of the great vessels, these arteries come from the opposite sides of the heart. The child may also have other birth defects.

- Correcting transposition of the great vessels requires open-heart surgery. If possible, this surgery is done shortly after birth.
- The most common repair is called an arterial switch. The aorta and pulmonary artery are divided. The pulmonary artery is connected to the right ventricle, where it belongs. Then, the aorta and coronary arteries are connected to the left ventricle, where they belong.

5. DORV - Double Outlet Right Ventricle and its repair

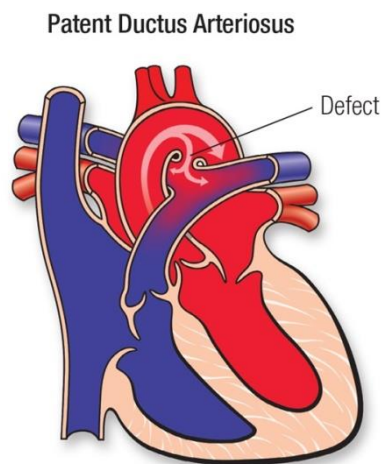


Double Outlet Right Ventricle' (DORV) is a defect in which the two great arteries (Aorta and Pulmonary Artery) both originate from the right ventricle. The blood from the left ventricle passes across a VSD into the right ventricle to reach the great arteries. The rush of additional blood results in high pressure builds up in the lungs. In most

cases, the defect is seen within few days with symptoms such as blueness of the skin ('Cyanosis') or with breathlessness. These infants also show poor weight gain. DORV can occur in many different varieties. Many affected patients have combination defects such as Pulmonary Stenosis (PS), Pulmonary Atresia, other valve abnormalities or Coarctation of the Aorta, etc. These defects cause severe obstruction to blood flow to the lungs or to the rest of the body and may need urgent surgery.

For most cases of DORV, surgery is the treatment of choice. The main goals of surgery are to connect the aorta to the left ventricle and the pulmonary artery to the right ventricle. One type of surgery that is used to correct DORV is called intraventricular repair.

6. Patent ductus arteriosus (PDA) ligation and its repair

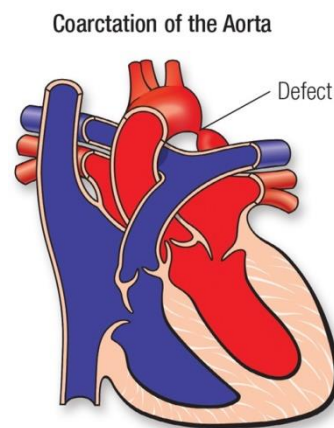


- Before birth, the baby has a blood vessel that runs between the aorta (the main artery to the body) and the pulmonary artery (the main artery to the lungs), called the ductus arteriosus. This small vessel most often closes shortly after birth when the baby starts to breathe on their own. If it does not close. It is called a patent ductus arteriosus. This could cause problems later in life.
- In most cases, the doctor will close off the opening using medicine. If this does not work, then other techniques are used.
- Sometimes the PDA can be closed with a procedure that does not involve surgery. The procedure is most often done in a laboratory that uses x-rays. In this procedure, the surgeon makes a small cut in the groin. Wire and tube called a catheter is

inserted into an artery in the leg and passed it up to the heart. Then, a small metal coil or another device is passed through the catheter into the infant's ductus arteriosus artery. The coil or other device blocks the blood flow, and this corrects the problem.

- Another method is to make a small surgical cut on the left side of the chest. The surgeon finds the PDA and then ties off or clips the ductus arteriosus, or divides and cuts it. Tying off the ductus arteriosus is called ligation. This procedure may be done in the neonatal intensive care unit (NICU).

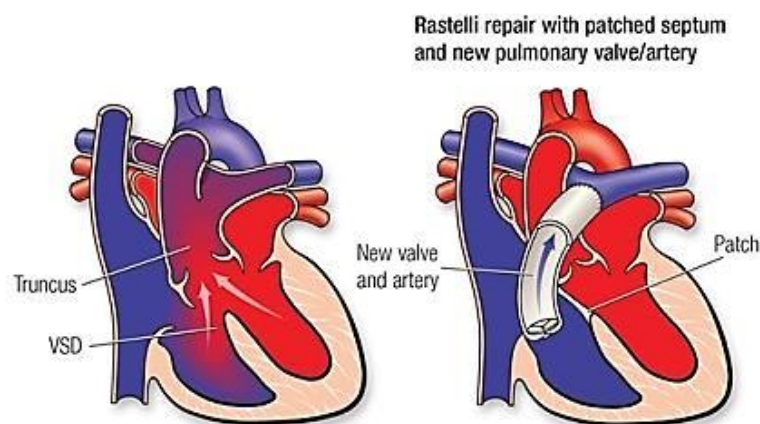
7. Coarctation of the aorta and its repair:



- Coarctation of the aorta occurs when a part of the aorta has a very narrow section. The shape looks like an hourglass timer. The narrowing makes it difficult for blood to get through to the lower extremities. Over time, it can lead to problems such as extremely high blood pressure.
- To repair this defect, a cut is most often made on the left side of the chest, between the ribs. There are several ways to repair coarctation of the aorta.
- The most common way to repair it is to cut the narrow section and make it bigger with a patch made of Gore-tex, a man-made (synthetic) material.
- Another way to repair this problem is to remove the narrow section of the aorta and stitch the remaining ends together. This can most often be done in older children.

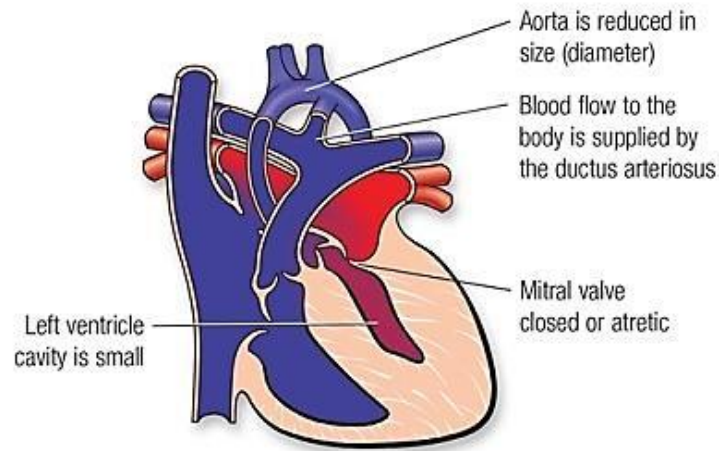
- A third way to repair this problem is called a subclavian flap. First, a cut is made in the narrow part of the aorta. Then, a patch is taken from the left subclavian artery (the artery to the arm) to enlarge the narrow section of the aorta.
- A fourth way to repair the problem is to connect a tube to the normal sections of the aorta, on either side of the narrow section. Blood flows through the tube and bypasses the narrow section.
- A newer method does not require surgery. A small wire is placed through an artery in the groin and up to the aorta. A small balloon is then opened up in the narrow area. A stent or small tube is left there to help keep the artery open. The procedure is done in a laboratory with x-rays. This procedure is often used when the coarctation reoccurs after it has been fixed.

8. Truncus arteriosus and its repair:



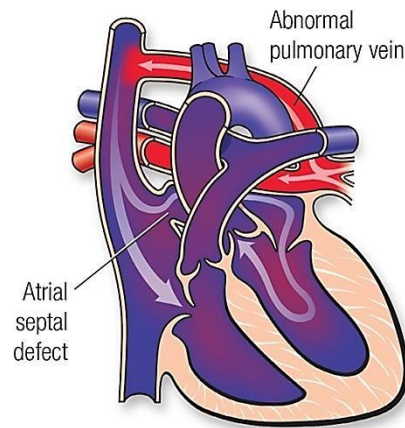
- Truncus arteriosus is a rare condition that occurs when the aorta, coronary arteries, and pulmonary artery all come out of one common trunk. The disorder may be very simple, or very complex. In all cases, it requires open-heart surgery to repair the defect.
- Repair is usually done in the first few days or weeks of the infant's life. The pulmonary arteries are separated from the aortic trunk, and any defects are patched. Usually, children also have a ventricular septal defect, and that is also closed. A connection is then placed between the right ventricle and the pulmonary arteries.
- Most children need one or two more surgeries as they grow.

9. Tricuspid atresia and its repair:



- The tricuspid valve is found between the upper and lower chambers on the right side of the heart. Tricuspid atresia occurs when this valve is deformed, narrow, or missing.
- Babies born with tricuspid atresia are blue because they cannot get blood to the lungs to pick up oxygen.
- To get to the lungs, blood must cross an atrial septal defect (ASD), ventricular septal defect (VSD), or a patent ductus artery (PDA). (These conditions are described above.) This condition severely restricts blood flow to the lungs.
- Soon after birth, the baby may be given a medicine called prostaglandin E. This medicine will help keep the patent ductus arteriosus open so that blood can continue to flow to the lungs. However, this will only work for a while. The child will eventually need surgery.
- The child may need a series of shunts and surgeries to correct this defect. The goal of this surgery is to allow blood from the body to flow into the lungs. The surgeon may have to repair the tricuspid valve, replace the valve, or put in a shunt so that blood can get to the lungs.

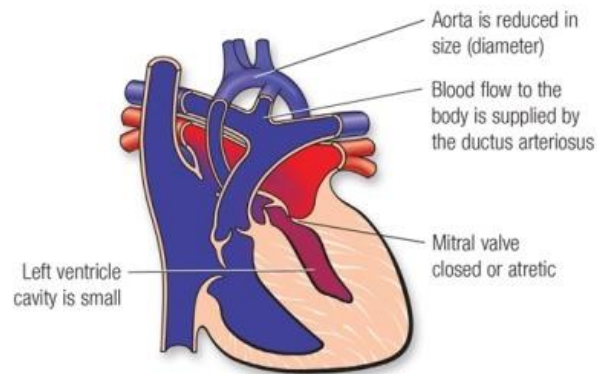
10. Total anomalous pulmonary venous return (TAPVR) and its correction:



TAPVR occurs when the pulmonary veins bring oxygen-rich blood from the lungs back to the right side of the heart, instead of the left side of the heart, where it most often goes in healthy people.

- This condition must be corrected with surgery. The surgery may be done in the newborn period if the infant has severe symptoms. If it is not done right after birth, it is done in the first 6 months of the baby's life.
- TAPVR repair requires open-heart surgery. The pulmonary veins are routed back to the left side of the heart, where they belong, and any abnormal connections are closed.
- If a PDA is present, it is tied off and divided.

11. Hypoplastic left heart and its repair:



- This is a very severe heart defect that is caused by a very poorly developed left heart. If it is not treated, it causes death in most babies who are born with it. Unlike babies with other heart defects, those with a hypoplastic left heart do not have any other defects. Operations to treat this defect are done at specialized medical centres. Usually, surgery corrects this defect.
- A series of three heart operations is most often needed. The first operation is done in the first week of the baby's life. This is a complicated surgery where one blood vessel is created from the pulmonary artery and the aorta. This new vessel carries blood to the lungs and the rest of the body.
- The second operation, called a Fontan operation, is most often done when the baby is 4 to 6 months old.
- The third operation is done a year after the second operation.

Annexure IV
Medical Case Study Meta Data

Medical Case Study P1

Case Description:
Pragati Patel / VSD

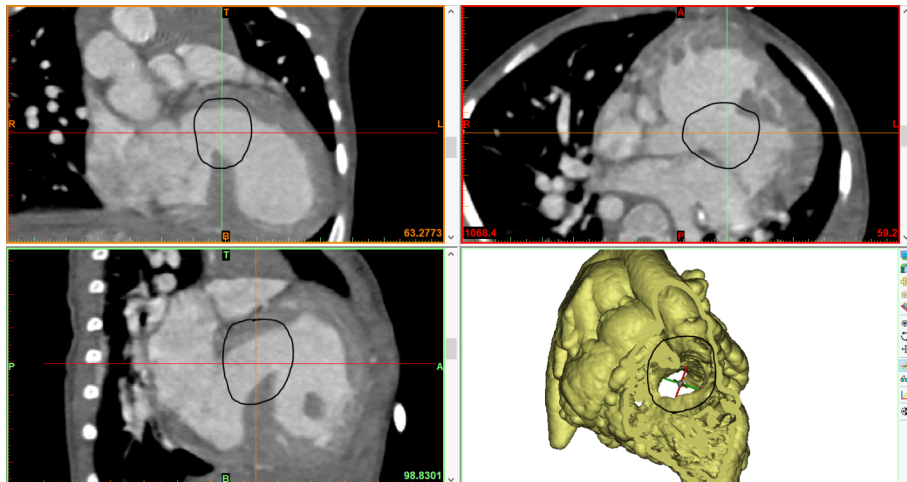
Case Clinician:
Dr.Smrutiranjana Mohanty

Case Venue / Affiliation :
Kokilaben Dhirubhai Ambani Hospital and Medical Research Centre, Mumbai

Initial Tests & Diagnosis:
Sick Child, VSD repair done earlier

Aim of Study: To know exact VSD Morphology to plug it

Segmentation Result



CT Meta Data if any :

Date: Dec - 2015
Patient :Pragati Patel
Age: 10 months
Gender: F
Gantry Tilt: 0
Slice Thickness:
0.75mm
Increment: var.
No of Slices : 338

Case Clinician Feedback:

This is thought to be a simple VSD closure from the image based diagnostics. However, when we printed it we could see much more of VSD in all its richness and concluded it is actually case of Double Outlet Right Ventricle which needed surgical path correction and The virtual planning and the model greatly aided the procedure. Every doubtful case should go for 3D printed model for assessment and procedural planning.

Over all outcome

3D printed model was Very useful.

Medical Case Study P2

Case Description:
Pawar Vedant Dattatray / TOF

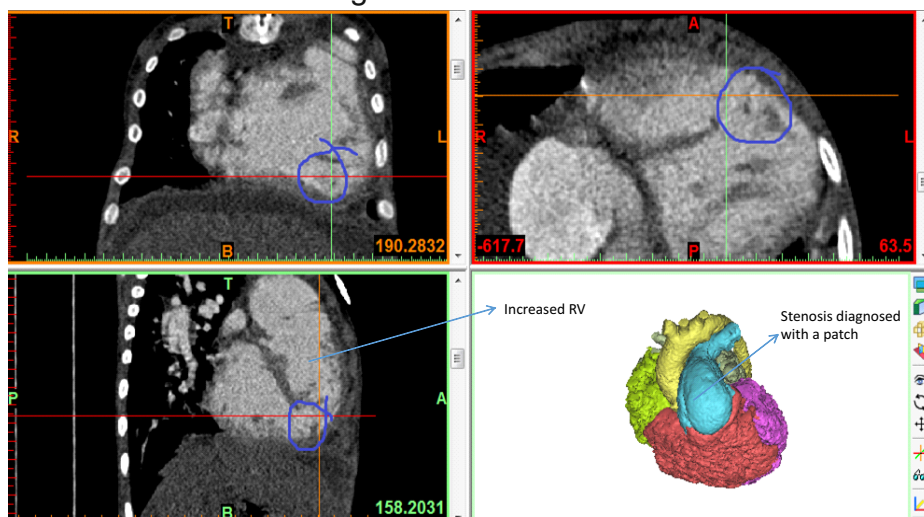
Case Clinician:
Dr.Smrutiranjana Mohanty

Case Venue / Affiliation :
Kokilaben Dhirubhai Ambani Hospital and Medical Research Centre, Mumbai

Initial Tests & Diagnosis:
Very Sick Child, TOF suspected from Echocardiograph

Aim of Study: To know exact TOF Morphology to repair it

Segmentation Result



CT Meta Data if any :

Date: Feb - 2016
Patient: Pawar Vedant
Dattatray
Age: 8 years
Gender: M
Gantry Tilt: 0
Slice Thickness: 1mm
Increment: 0.5mm
No of Slices : 465

Case Clinician Feedback.

This being a Combination defect, an ideal case to explore with 3D printed model. The Morphology of TOF can occur in many ways and if one knows its location and form, we go with a prepared mind and the procedure is less stressful and the surgeon can focus on procedure. By default all combination defect cases pose certain ambiguity and it get cleared by 3D printed patient specific model in hand.

Over all outcome

The 3D printed model was very useful.

Medical Case Study P3

Case Description:
Arham Jain / Situs Ambiguous

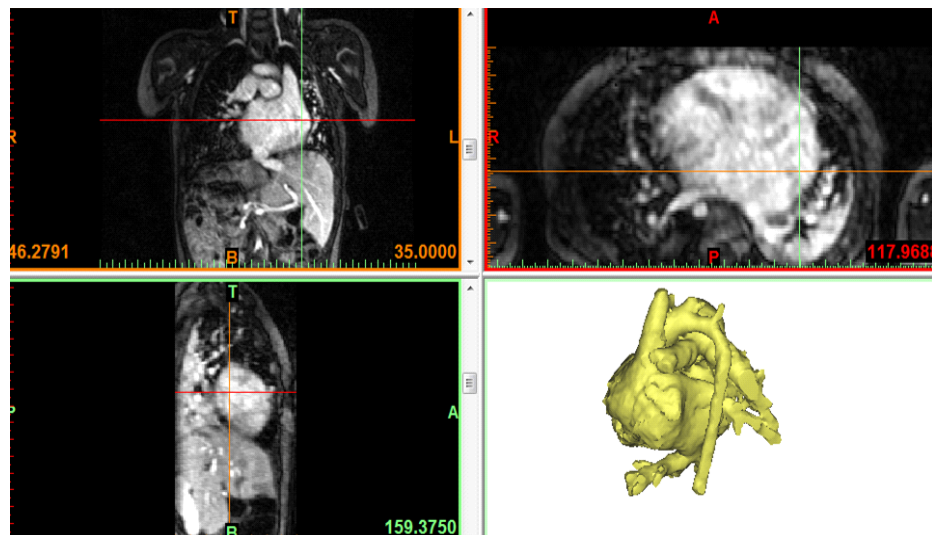
Case Clinician:
Dr.Smruti Ranjan Mohanty

Case Venue / Affiliation:
Kokilaben Dhirubhai Ambani Hospital and Medical Research Centre, Mumbai

Initial Tests & Diagnosis:

Aim of Study: To study Defect Morphology & its exact location

Segmentation Result



CT Meta Data if any :

Date: Mar - 2016
Patient: Arham Jain
Age: 5 years
Gender: M
Gantry Tilt: 0
Slice Thickness: 1mm
Increment: 1mm
No of Slices : 80

As it is a case of Situs Ambiguous, The case can pose doubt with novice doctors; this case was explored with 3D printing to assess Morphology.

Rerouting of Arties were carried out to maintain proper circulation of blood

Case Clinician Feedback: This case is not very important from the view of 3D printing, but post printing the model did provide validation of what we had diagnosed from the image data.

Over all outcomes:
3D Printed model was very useful.

Medical Case Study P4

Case Description:

Chakale Bhagyalaxmi Viresh / Suspected combination defects

Case Clinician

Dr.Smruti Ranjan Mohanty

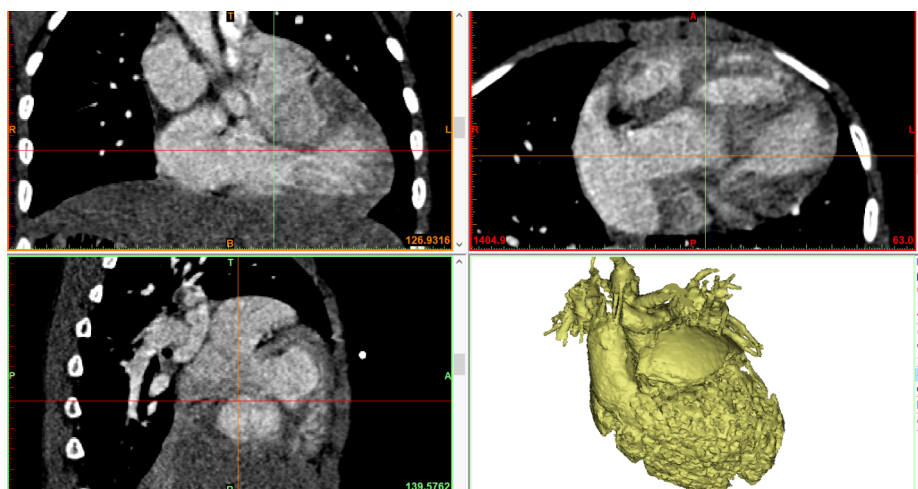
Case Venue / Affiliation

Kokilaben Dhirubhai Ambani Hospital and Medical Research Centre, Mumbai

Initial Tests & Diagnosis

Aim of Study : To study Defect Morphology & its exact location

Segmentation Result



CT Meta Data if any :

Date: Jan - 2017
Patient: Chakale
Bhagyalaxmi Viresh
Age: 9 years
Gender: F
Gantry Tilt: 0
Slice Thickness: 1mm
Increment: var.
No of Slices : 275

Case Clinician Feedback:

A case of a very sick child (Medical condition indicating high risk) with multiple procedures

The defect was identified and procedure planned post 3D printing. The surgical correction was suggested to the parents were informed of potential risks involved. Patient did not go for surgery.

Over all outcome : 3D printed model gave useful leads about complex defect. However, the procedure was not undertaken as patient's kin refused to go for procedure knowing the risk.

Medical Case Study P5

Case Description:
Shloke Mohan Hage / DORV case

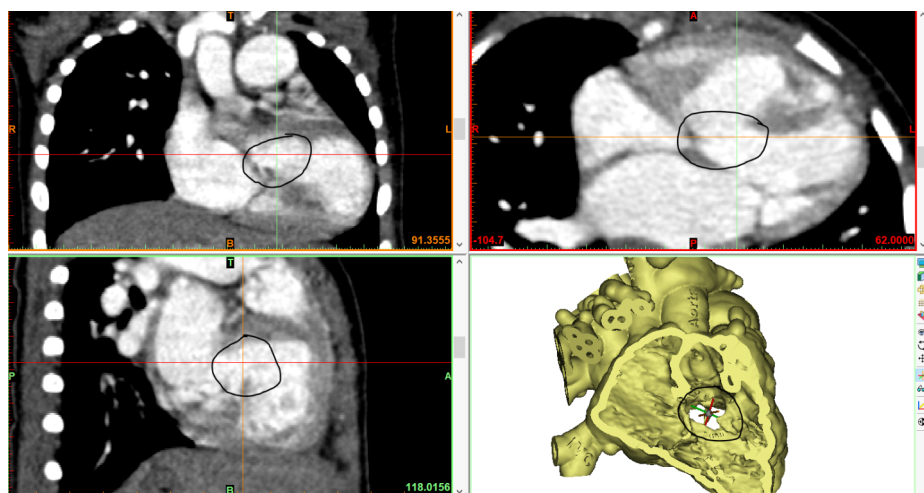
Clinician:
Dr.Smruti Ranjan Mohanty

Case Venue / Affiliation
Kokilaben Dhirubhai Ambani Hospital and Medical Research Centre, Mumbai

Initial Tests & Diagnosis

Aim of Study: To study Defect Morphology & its exact location

Segmentation Result



CT Meta Data if any :

Date: Dec - 2017
Patient: Shloke Mohan H
Age: 12 months
Gender: M
Gantry Tilt: 0
Slice Thickness: 1mm
Increment: 0.5mm
No of Slices : 347

Case Clinician Feedback:

DORV repair was pre –planned.

The Model in such complex cases is a must.

Over all outcomes: 3D printed model in complex defect conditions allow pre-plan and greatly aids the operational outcome.

Medical Case Study P6

Case Description :
Kuhu Bhattacharya / VSD

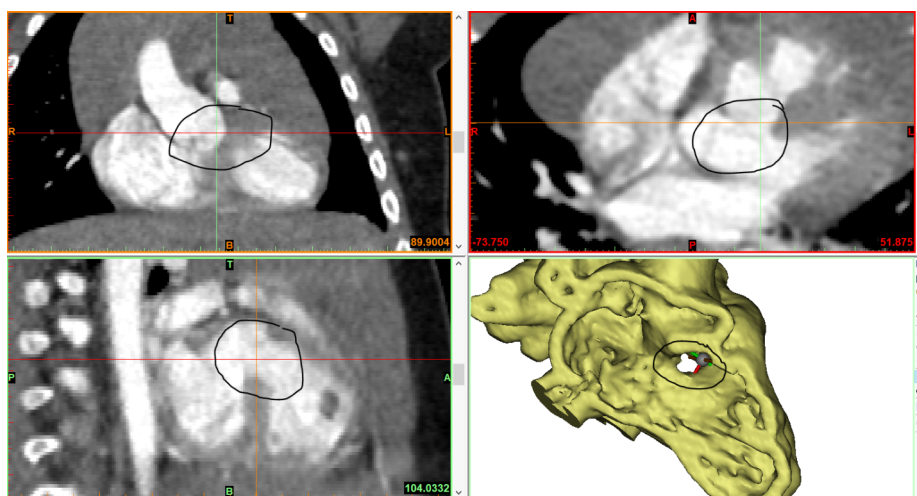
Case Clinician :
Dr.Swati Gharekhar

Case Venue / Affiliation:
Fortis Healthcare Ltd – Mulund –Mumbai.

Initial Tests & Diagnosis

Aim of Study: To study Defect Morphology & its exact location

Segmentation Result



CT Meta Data if any :

Date: June - 2017
Patient: Kuhu
Bhattacharya
Age: 3 months
Gender: F
Gantry Tilt: 0
Slice Thickness:
0.625mm
Increment: 0.625mm
No of Slices : 376

Case Clinician Feedback:

VSD is fairly simple defect and
does not need 3d printed model

Course Correction done if any :
VSD Closure

Case Clinician Feedback: 3-D
Printed model re-validated earlier
finding OK

Over all outcome :
Defect type Re confirmed

Medical Case Study P7

Case Description:
Nooh Patel / VSD

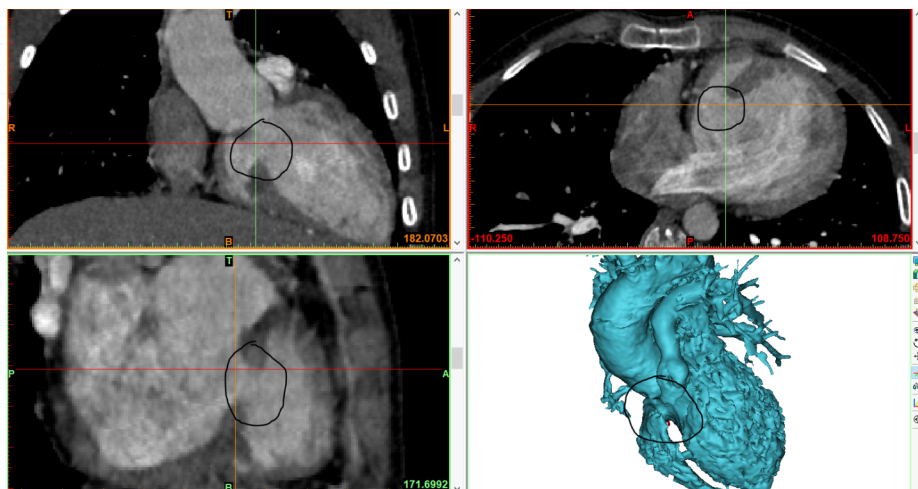
Case Clinician:
Dr.Swati Gharekhar

Case Venue / Affiliation:
Fortis Healthcare Ltd – Mulund –Mumbai.

Initial Tests & Diagnosis:

Aim of Study: To study Defect Morphology & its exact location

Segmentation Result



CT Meta Data if any :

Date: June - 2017
Patient: Nooh Patel
Age: N.A
Gender: N.A
Gantry Tilt: 0
Slice Thickness:
0.625mm
Increment: 0.625mm
No of Slices : 611

Post 3D Printing Insights : Defect
Re-validation

Course Correction done if any:
VSD Closure
Case Clinician Feedback: VSD
though usual procedure, the
model revalidated what we
expected.

Over all outcome : OK, but 3D
Printed model is not needed for
such simple VSD corrections.

Medical Case Study P8

Case Description:
Baba Mohd. Saif / VSD

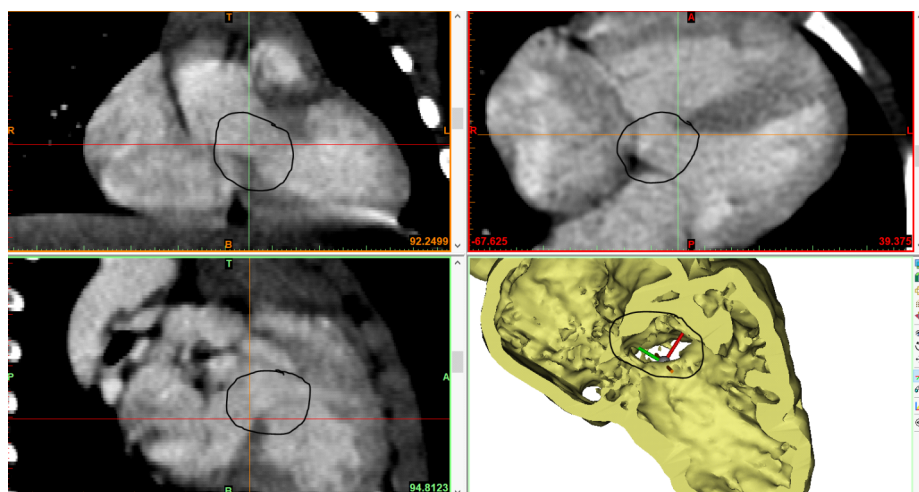
Case Clinician:
Dr.Swati Gharekhar

Case Venue / Affiliation:
Fortis Healthcare Ltd – Mulund –Mumbai.

Initial Tests & Diagnosis:

Aim of Study: To study Defect Morphology & its exact location

Segmentation Result



CT Meta Data if any :

Date: June - 2017
Patient: Baba Mohd. Saif
Age: 11 months
Gender: M
Gantry Tilt: 0
Slice Thickness: 0.625mm
Increment: 0.625mm
No of Slices : 171

Post 3D Printing Insights: The case was clear from Image data itself
3. Course Correction done if any :VSD closed as usual

Case Clinician Feedback: This case did not surprise us , we saw what we anticipated in the image data, 3D printing just confirmed it.

Medical Case Study P9

Case Description:
VSD - Swaraj K Patil

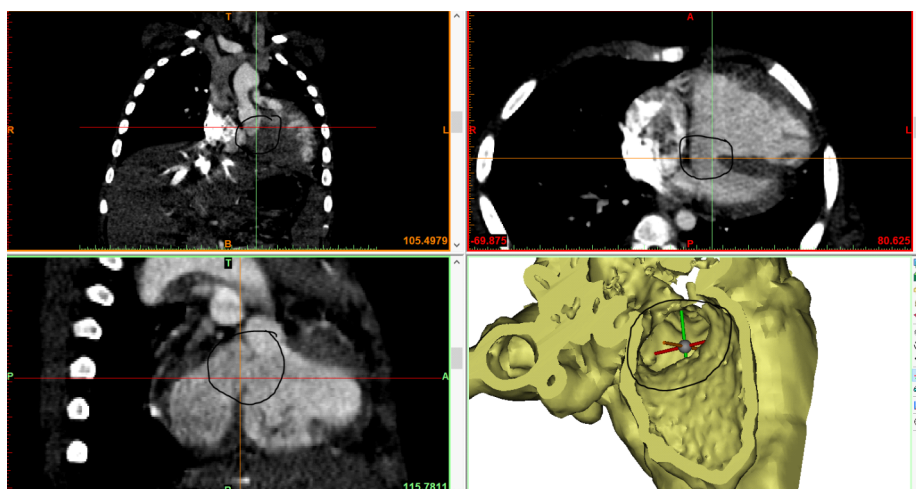
Case Clinician:
Dr.Swati Gharekhar

Case Venue / Affiliation:
Fortis Healthcare Ltd – Mulund –Mumbai.

Initial Tests & Diagnosis:

Aim of Study: To study Defect Morphology & its exact location

Segmentation Result



CT Meta Data if any :

Date: June - 2017
Patient : Swaraj K Patil
Age: 1 year
Gender: M
Gantry Tilt: 0
Slice Thickness: 0.625mm
Increment: 0.625mm
No of Slices : 251

Post 3D Printing Insights: Good
Data Set , Model 3D printed

Course Correction done if any :
VSD Closure

Case Clinician Feedback: The 3D
model showed specific defect
landmarks

Over all outcome: OK, Model was
not necessary as it was fairly clear
VSD from earlier diagnosis.
However, the defect morphology
was better understood

Medical Case Study P10

Case Description:
VSD - Mohd. Irfan Chaudhery

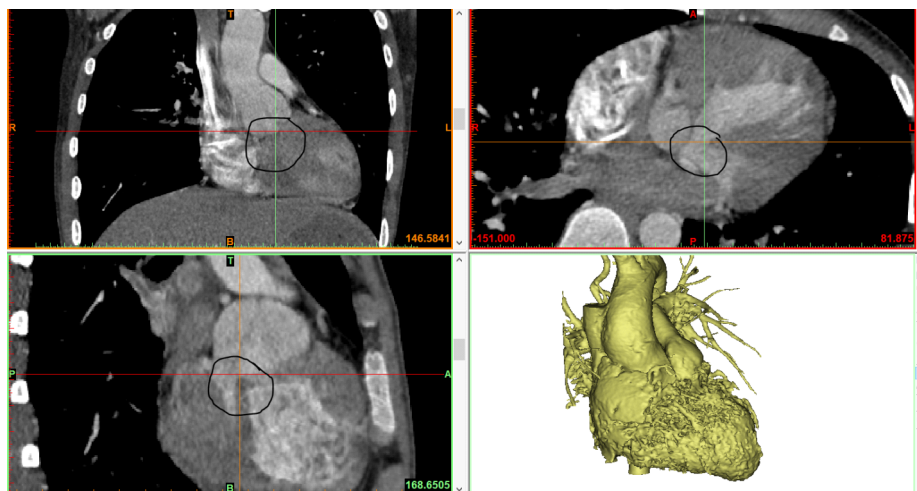
Case Clinician:
Dr.Swati Gharekhar

Case Venue / Affiliation:
Fortis Healthcare Ltd – Mulund –Mumbai.

Initial Tests & Diagnosis:

Aim of Study: To study Defect Morphology & its exact location

Segmentation Result



CT Meta Data if any :

Date: June - 2017
Patient: Mohd. Irfan Chaudhery
Age: 16 years
Gender: M
Gantry Tilt: 0
Slice Thickness: 0.625mm
Increment: 0.625mm
No of Slices : 302

Post 3D Printing Insights : Complex VSD
3. Course Correction done if any:
VSD closure

Case Clinician Feedback: This case was diagnosed as VSD but its morphology and location was defect to visualize, thanks to the 3D model, we could get better knowledge about the defect morphology and its location.
Over all outcomes: 3D printed model was very useful

Medical Case Study P11

Case Description:
Parbina Begum / ASD / TAPVC

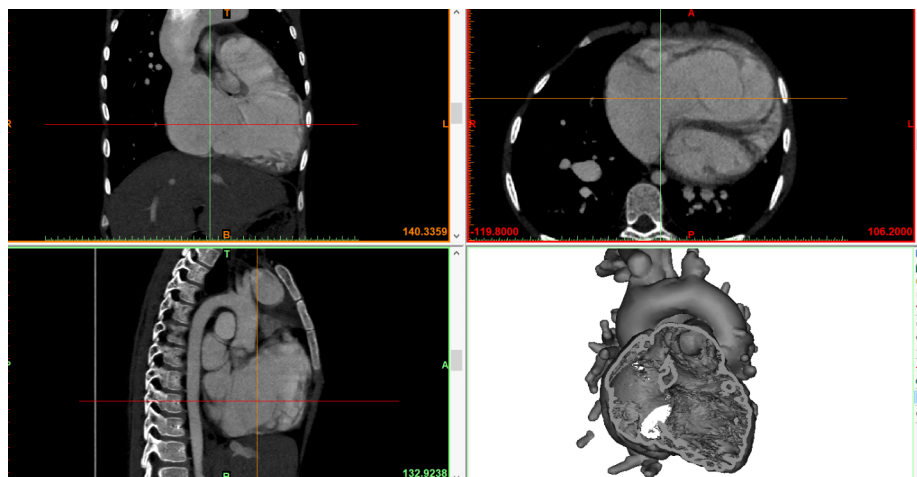
Case Clinician: Dr.Karthik

Case Venue / Affiliation: Narayana Institute of Cardiac Sciences, Bommasandra, Bangalore.

Initial Tests & Diagnosis: Congenital heart disease – non-obstructive Supracardiac total anomalous pulmonary venous connection. Dilated pulmonary arteries and right cardiac chambers, suggestive of pulmonary arterial hypertension. Atrial septal defect. Confluent good sized branch pulmonary arteries. Left sided aortic arch with normal branching pattern.

Aim of Study: To study Defect Morphology & its exact location

Segmentation Result



CT Meta Data if any :

Date: Aug - 2017
Patient: Parbina Begum
Age: 8 years
Gender: F
Gantry Tilt: 0
Slice Thickness: 0.67mm
Increment: var.
No of Slices : 760

Post 3D Printing Insights : Very useful for complex case such as TAPVC with ASD

Course Correction done if any : ASD was closed after pre-operative planning

Case Clinician Feedback: The 3D printing is really great invention to peek into defects before surgery, hold in hand and plan the procedure. It was very useful

Over all outcome : 3D printing was very useful

Medical Case Study P12

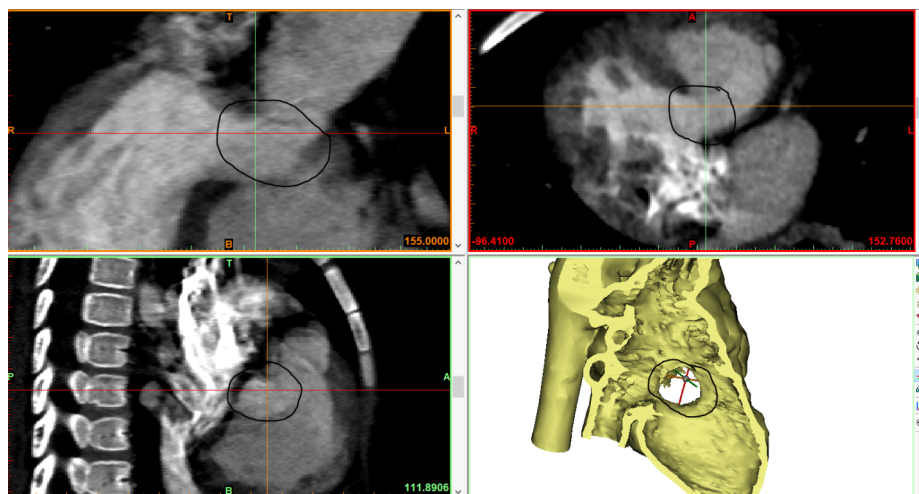
Case Description:
Rima Halder / C-TGA

Case Clinician: Dr.Karthik
Case Venue / Affiliation: Narayana Institute of Cardiac Sciences, Bommasandra, Bangalore.

Initial Tests & Diagnosis:
(S, L, X) – Dextrocardia, Congenital heart disease – C-TGA, Non-visualized MPA and its branches, suggestive of pulmonary atresia., Ventricular septal defect. Left sided aortic arch with normal branching pattern. Multiple aortopulmonary collaterals supplying both lungs. Normal pulmonary venous drainage.

Aim of Study: To study Defect Morphology & its exact location

Segmentation Result



CT Meta Data if any :

Date: Aug - 2017
Patient: Rima Halder
Age: 5 years
Gender: F
Gantry Tilt: 0
Slice Thickness:
0.67mm
Increment: var.
No of Slices : 742

Post 3-D Printing Insights: TGA could be visualized

Course Correction done if any : TGA correction done by PTFE patching

Case Clinician Feedback: The 3-D printed model was very handy to plan the procedure, every TGA or similar complex cases need 3-D printed models

Over all outcome: 3-D printing was very useful

Medical Case Study P13

Case Description:

Rudra Protap Mallick / TOF

Case Clinician: Dr.Karthik

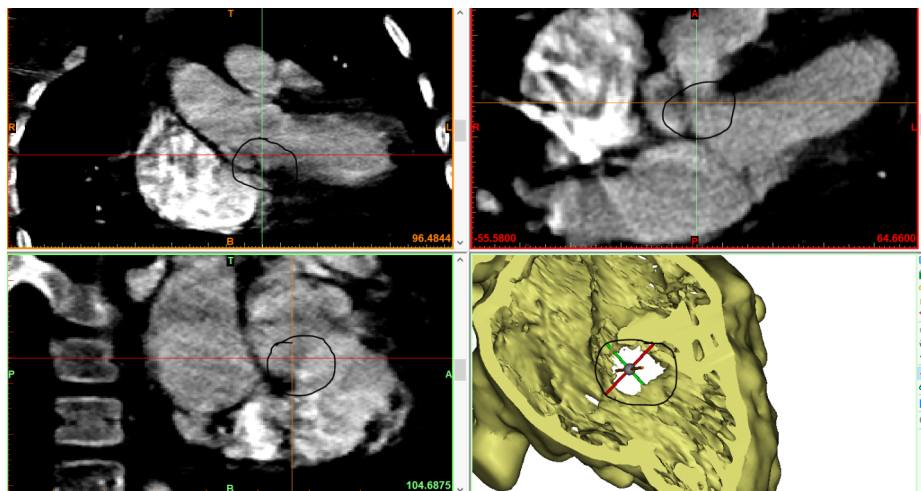
Case Venue / Affiliation: Narayana Institute of Cardiac Sciences, Bommasandra, Bangalore.

Initial Tests & Diagnosis:

Congenital heart disease TOF. Pulmonary infundibular/ RVOT narrowing with confluent good sized branch pulmonary arteries (Mc Goon's ratio 2.5), relatively small RPA. Ventricular septal defect. Right sided aortic arch with mirror image branching pattern. Normal pulmonary venous drainage. No significant mediastinal aortopulmonary collaterals. Proximal coronary shows normal course. No major crossing of RVOT. Absent left kidney.

Aim of Study: To study Defect Morphology & its exact location

Segmentation Result



CT Meta Data if any :

Date: Aug - 2017

Patient: Rudra Protap Mallick

Age: 2 years

Gender: M

Gantry Tilt: 0

Slice Thickness: 0.67mm

Increment: var.

No of Slices : 375

Post 3-D Printing Insights: TOF morphology was clear from model

Course Correction done if any :
TOF repaired

Case Clinician Feedback : TOF is always tricky and this one was before going for 3-D printing, Model in hand provides clear insight into the morphology and greatly aids pre-plan.

Over all outcome: 3-D printing was very useful

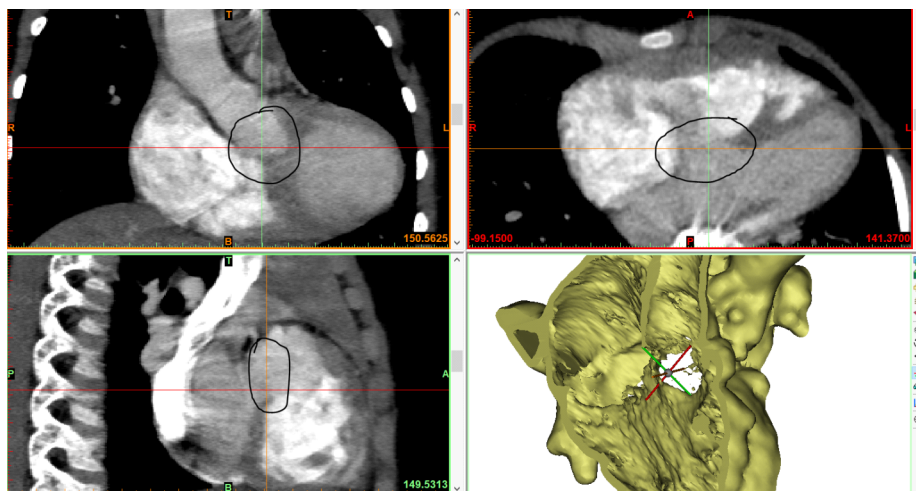
Medical Case Study P14

Case Description:
Suchave Sharma / TOF

Case Clinician: Dr.Karthik
Case Venue / Affiliation: Narayana Institute of Cardiac Sciences, Bommasandra, Bangalore.

Initial Tests & Diagnosis:
(S, D, X) Congenital heart disease pulmonary atresia. Severe pulmonary infundibular / RVOT narrowing with confluent branch pulmonary arteries (Mc Goon's ratio 1.5). Ventricular septal defect. Right sided aortic arch with aberrant right subclavian artery. Dual SVC, draining into RA. No major coronary crossing RVOT. Normal pulmonary venous drainage. Major mediastinal aortopulmonary collaterals.
Aim of Study: To study Defect Morphology & its exact location

Segmentation Result



CT Meta Data if any :

Date: Aug - 2017
Patient: Suchave Sharma
Age: 9 years
Gender: M
Gantry Tilt: 0
Slice Thickness: 0.67mm
Increment: var.
No of Slices : 778

Post 3D Printing Insights: TOF morphology was clear from model

Course Correction done if any :
TOF repaired

Case Clinician Feedback : TOF is always tricky and this one was before going for 3D printing, Model in hand provides clear insight into the morphology and greatly aids pre-plan.

Over all outcome: 3D printing was very useful

Medical Case Study P15

Case Description:
Sai Ashish / VSD

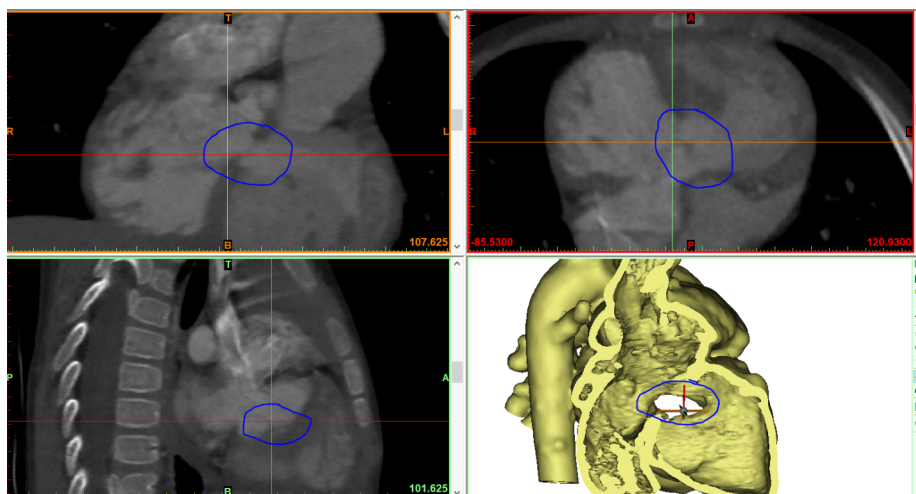
Case Clinician:
Dr.Karthik

Case Venue / Affiliation:
Narayana Institute of Cardiac Sciences, Bommasandra, Bangalore.

Initial Tests & Diagnosis:

Aim of Study: To study Defect Morphology & its exact location

Segmentation Result



CT Meta Data if any :

Date: Aug - 2017
Patient: Sai Ashish
Age: 2 years
Gender: M
Gantry Tilt: 0
Slice Thickness: 0.67mm
Increment: var.
No of Slices : 614

Post 3D Printing Insights : NIL

Course Correction done if any
: VSD Closed

Case Clinician Feedback: VSD
defect morphology
re-confirmed

Over all outcome: 3D printing
was very useful

Medical Case Study P16

Case Description:
Hranghminglien / VSD

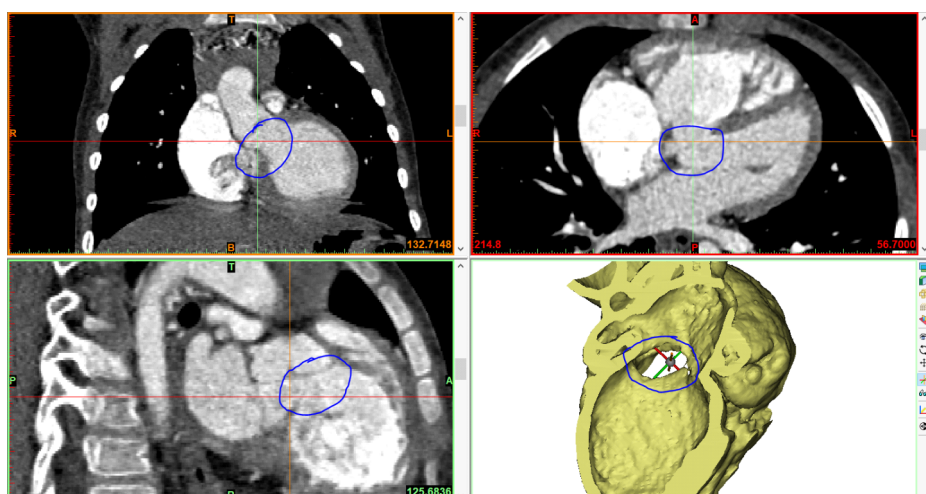
Case Clinician:
Dr.(Ref by Mr.Sanjeev Pathak)

Case Venue / Affiliation:
All India Institute of Medical Sciences, Delhi

Initial Tests & Diagnosis:

Aim of Study: To study Defect Morphology & its exact location

Segmentation Result



CT Meta Data if any :

Date: Aug - 2016
Patient: Hranghminglien
Age: 5 years
Gender: M
Gantry Tilt: 0
Slice Thickness: 0.75mm
Increment: 0.75mm
No of Slices: 346

Post 3-D Printing Insights: VSD morphology become more clear after 3-D printed model in hand

Course Correction done if any :
VSD patch was pre-planned using the model

Case Clinician Feedback: 3-D printing has great utility, only it comes with an extra cost.

Over all outcomes: 3-D printing was very useful

Special Case

Case Description:
Masuda Begum / Coronary artery

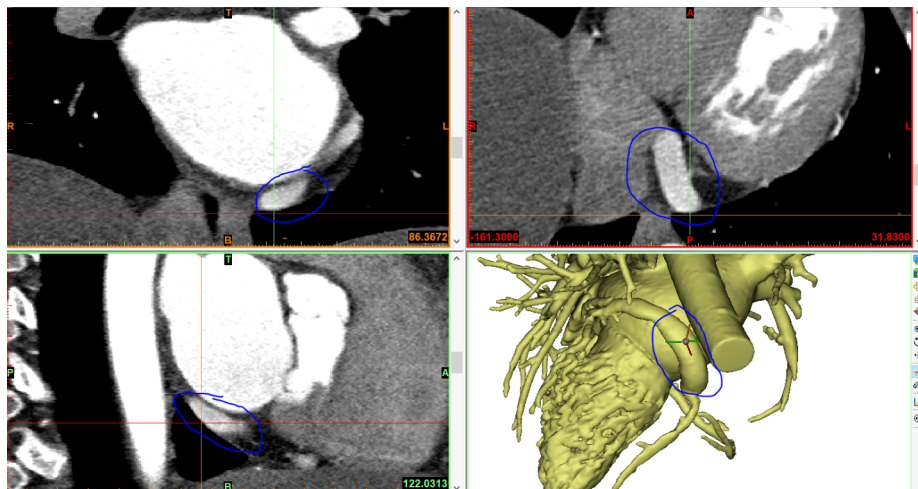
Case Clinician: Dr.Karthik

Case Venue / Affiliation: Narayana Institute of Cardiac Sciences,
Bommasandra, Bangalore.

Initial Tests & Diagnosis: Ballooning of coronary artery suspected

Aim of Study: To study Defect Morphology & its exact location

Segmentation Result



CT Meta Data if any :

Date: Aug - 2017
Patient: Masuda Begum
Age: 47 years
Gender: F
Gantry Tilt: 0
Slice Thickness: 0.67mm
Increment: var.
No of Slices : 1125

Post 3-D Printing Insights: A special
case of coronary ballooning

Course Correction done if any :
Coronary obstruction repaired

Case Clinician Feedback: Very nice
reproduction of the defect condition.

Over all outcome: 3-D printing
confirms our earlier diagnosis. Model
can aid in flow analysis

Annexure V

List of Heart Surgeons / Cardiologists / Radiologists for Survey.

Please Note:

- Survey Email was sent to all in the list.
- Personally met 50% of them in IACTSCON 2017, IACTSCON 2018 & PCSI 2017 Conference
- Total doctors participating in the survey are only 43 out of 74.
- Of the 43, 20 responded on email and 23 in a personal interview.
- The low participation levels are due to their hectic engagement in healthcare.

1. Dr.Anil Kumar : (Sagar Hospital, Bangalore)
2. Dr.Meghana Taggarsi : (Bangalore)
3. Dr.Shegu.G :
4. Dr.Deepak Maharana :
5. Dr.Supreet.B :
6. Dr.Nikhil.S :
7. Dr.Attia :
8. Dr.Soumya Guha: (PGIMER & RML Hospital)
9. Dr.Chandra Sena :
10. Dr.Laxminarayan: Maxcare Hospital – Warangal)
11. Dr.Apoorva Kanhere : Apollo Ahmedabad)
12. Dr.Navnita Kisku :
13. Dr.Manvendra Singh:
14. Dr.Kishan M : Care Hospital VIZAG)
15. Dr.Belapurkar Yogesh :
16. Dr.Sandeep A.J :
17. Dr.Rajesndran M.C :

18. Dr.Ninad Kotkar :
19. Dr.Suboor Ahmed :
20. Dr.Madhav Hegde:
21. Dr.Maitri Chaudhuri :
22. Dr.Gowrishankar :
23. Dr.I.B.Vijayalakshmi:
24. Dr.Jain.T.Kallarakkal :
25. Dr.Jayashree Kharge :
26. Dr.Kiran V.S :
27. Dr.Mruthyunjaya Satpathy :
28. Dr.M.S.Aditya :
29. Dr.Munde K :
30. Dr.Nagamani AC :
31. Dr.Nagesh CM :
32. Dr.Maddury Jyotsna :
33. Dr.Mitesh Shetty :
34. Dr.Kiron Varghese :
35. Dr.Ramesh Arora :
36. Dr.Ramesh Santhana Krishnan :
37. Dr.R.suresh Kumar :
38. Dr.Sanjeev Kumar Reddy :
39. Dr.Prasanna Simha Mohan Rao:
40. Dr.Praveen Jayan J.P :
41. Dr.Prasanna Nyayadhish:
42. Dr.Pradeep Vaideeswar :
43. Dr.Prabhat Kumar :
44. Dr.Narendra Babu M :
45. Dr.Narayan Namboodiri K.K :
46. Dr.Neeraj Awasthy :
47. Dr.Neeraj Raghani :
48. Dr.Nirav Panchani :
49. Dr.Sridevi Hegde :
50. Dr.Suresh G.Rao :

51. Dr.Swati Garekar:
52. Dr.Smitha Mishra:
53. Dr.Shilpa Suresh Mavanoor :
54. Dr.Sejal Shah :
55. Dr.S.Radhakrishnan :
56. Dr.Sheshushankar Mishra:
57. Dr.Sunita Maheshwari :
58. Dr.Vimla.J. :
59. Dr.Smruthi Ranjan Mohanty:
60. Dr.Karthik : Rad – C/o NH Bengalore
61. Dr.Shivaprakash Krishna Nayak : HNRF hospital.
62. Dr.Sanjeevdasrao Muskawad : IIT Bombay
63. Dr.Murtaza Kamal :
64. Dr. Bharat Mody : Rad
65. Dr.Giridhar Kamalapurkar : Jayadevea
66. Dr.Rajan Sethuratnam:
67. Dr. Sukanta Behera :
68. Dr. James Thomas : DYPatil
69. Dr.P.Chandrashekar :
70. Dr.Dr.Ajay Chaughule : global hospitals india
71. Dr.Praveen Kulkarni : globalhospitalsindia
72. Dr.Chinnaswamy Reddy HM : C/o NH Bengalore
73. Dr.Colin John : C/o NH Bengalore
74. Dr.Supratim Sen : C/o NH Mumbai

Annexure IV

Survey Questionnaire

3D printing for Congenital Heart Disease Management

Greetings from IIT Bombay & Imaginarium.

I am an interdisciplinary researcher at IIT Bombay working on 3D printing of Heart models for surgical preplanning focused on complex CHD cases.

This brief survey is intended for educational purpose only. You may skip any question that you feel you do not know or wish to answer. Data obtained from the survey will be analysed for the sole purpose of conducting research, So, please to the best of your knowledge. The purpose of this study is to investigate the current awareness of 3D printing among healthcare professionals and particularly in Cardiac surgery. The study aims to assess the need for the introduction of 3D printing topics in healthcare pedagogy & professional practice.

The process should take about 10 min or less.

Thanks & Regards,

Guruprasad Rao

(07413701)

Respondent Data:

Name :

Email ID:

Gender : M / F

Age :

1. 20-30
2. 30-40
3. 40-50
4. 50 -60
5. 60 plus

Designation:

1. Consultant
2. Professor /Academic
3. Student
4. Surgeon

Affiliation: Please Fill

Survey

(Please tick all that are applicable)

1. Have You heard about 3D printing?
YES / NO
2. If the answer to the above is NO, Do you wish to get more info about 3D printing for Healthcare?
YES / NO
3. Do you wish to have a Workshop cum Demo at your organisation?
YES / NO
4. If you have answered Yes above, what is the source of your information:
 - a) News Paper
 - b) TV
 - c) Social Media
 - d) Literature
 - e) Conference
 - f) You have seen it
 - g) You have used it
5. If Answer to above question is You use it, Then You have used for
 - a) Learning
 - b) Teaching
 - c) Surgical Planning
 - d) Patient communication/ education
 - e) New Device Design
6. Do you possess a 3D printer?
Yes / No
7. If you possess or used one, What type of 3D printer it is?
 - a) SLA
 - b) SLS
 - c) DLP
 - d) FDM
 - e) JMM
 - f) MJF
 - g) DMLS
 - h) BIO Plotter
 - i) Not listed here
8. Have you used any Prototype Anatomical Models in your practice?
YES /NO

9. IF YES, The main purpose it is used is
 - a) For Learning
 - b) For Teaching
 - c) For Communication
 - d) Design / Pre Planning
10. Were you happy to use the Cadaver Anatomical Sample?
 - a) Yes, Cadaver is always good
 - b) No, Cadaver samples of the same type are not available.
11. If you have ticked Prototype was not good, reasons?
 - a) Poorly made
 - b) Not coloured
 - c) Not Dissectible
 - d) Not in Full Scale
 - e) Not affordable
 - f) It does not exist
12. Do you like the idea of Patient-Specific Anatomical models?
YES /NO
13. If, YES, your reasons are:
 - a) They help to understand Morphology better
 - b) They help in Surgical Preplan
 - c) They also help in Patient Communication
14. Given Medical Image Modalities such as Ultrasound / Echo / Doppler / CT and MRI,
Do you feel there is a need to still have a Physical anatomical model?
YES / NO?
15. If the answer to above is YES, reasons are:
 - a) They provide real touch and feel
 - b) They help to overcome ambiguity from 2D images
 - c) They help in better surgical planning
 - d) They help in teaching and communication
 - e) It was needed due to the complexity of the case
16. Do you think every healthcare professional should be aware of the benefits of 3D printing?
 - a) YES
 - b) May Be YES
 - c) Very Important, I recommend it
 - d) NO
17. If you are an advanced user of 3D printing for healthcare, When do you plan to use it?
 - a) Image data is not yielding clarity
 - b) The case is complex
 - c) I use it as we have that facility
 - e) If you are using it because the case complex, please list the case types

18. As a Cardiologist, when do you think of using a 3D printed patient specific model?
 - a) I don't recommend it.
 - b) I will recommend if image data is not clear
 - c) I will recommend if the case is a complex one

19. As a Cardiac Surgeon, Do you wish to have a 3D printed patient-specific heart model prior to surgery?
 - a) No
 - b) Yes, it will be useful

20. If you replied to the previous question as Yes, What size of heart model you wish to use?
 - a) Full Size
 - b) Larger size
 - c) Even a smaller one would do.

21. Will a 3D model on a computer screen is good enough to explore defect morphology?
 - a) Yes
 - b) No, it has a lot of limitations
 - c) Yes, and if needed will still go for a physical model.
 - d) Physical model in hand is always better.

22. Will a 3D model on a VR headset be good to visualise defect morphology?
 - a) Yes,
 - b) Maybe
 - c) Yes, wish to try it.
 - d) No.

23. If you are planning a model, will it be good enough to print just the defect morphology section?
 - a) No
 - b) Yes

24. Do you wish to have coloured coded heart model to show different chambers and flow path?
 - a) Not necessary
 - b) Yes, it helps

25. Do you wish to have soft dissectible Heart models for teaching/learning?
 - a) No
 - b) Yes
 - c) Maybe Yes

26. What cases according to you may need 3D printed model for pre-operational planning
 - a) All defect types
 - b) Only Complex Defect types

27. As an experienced surgeon, your opinion about the need for 3D printed models for surgical Pre plan?

- a) They are not needed
- b) They are good to have
- c) They are good but expensive
- d) They are essential in complex cases.

28. What according to you are complex CHD cases?

- a) ASD
- b) VSD
- c) Single Ventricle types
- d) DORV
- e) TGA
- f) TOF
- g) Dextrocardia
- h) Combination of defects
- i) RVOT
- j) LVOTO
- k) TAPVC

29. What According to you are the riskiest CHD defect types from the above list?

- a) ASD
- b) VSD
- c) Single Ventricle types
- d) DORV
- e) TGA
- f) TOF
- g) Dextrocardia
- h) RVOT
- i) LVOTO
- j) TAPVC
- k) Combination Defects
- l) All have risk
- m) Not listed here.

30. If you have replied to the above question as Not Listed, Please fill the box with your case type/s

31. As a Commercial proposal, what do you think could be an affordable price for such Patient Specific Anatomical Model could be in Indian Rupees :

- a) 5000
- b) 5000-10000
- c) 10000-20000
- d) under 30000
- e) No limits

32. Do you wish to collaborate & plan your next complex surgical planning with a freely* provided Patient Specific Anatomical model / Guide?

YES / NO

Dear Respondent,

Thank you very much for your time and support.

The analysed data will be shared with you after the survey.

Kind Regards,

Guruprasad Rao

This research is supported by Imaginarium India Pvt.Ltd.

*T&C Apply

6.4 Validation: Domain Expert Survey

In order to re-evaluate and validate the study on case studies, A Questionnaire was sent to clinicians. The Sample was carefully chosen so as to involve clinicians who are directly or indirectly involved in handling Congenital Heart Disease.

The questions involved a general appraisal of their awareness of 3D printing and about complex congenital heart disease conditions and their opinion on how it will be useful in procedural planning.

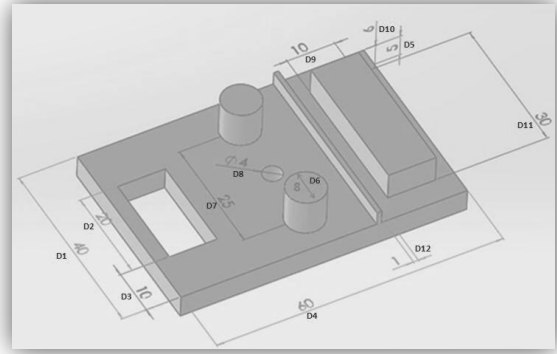
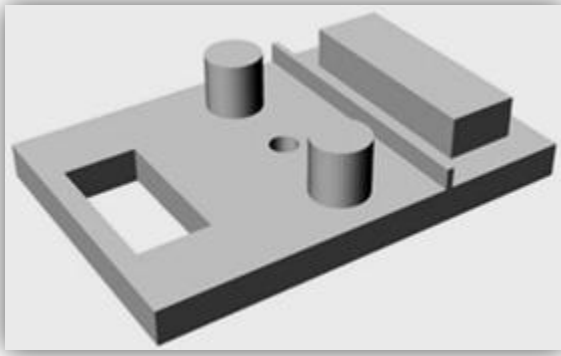
Out of a total of 72 clinicians, the survey was sent only 42 clinicians responded. This is due to the fact most of the surgeons are too hard pressed for time and taking this survey was difficult.

In order to add more responses, I got the opportunity for oral interaction with 15 surgeons during my Poster Presentation at IACTSCON 2018 conference at Vishakhapatnam, Which I had to analyse separately. Given below are the results of the survey response received from 42 participating clinicians and 15 more on the same theme.

Survey format is enclosed in Annexure II for Ref. The samples are drawn from across India.

Annexure VII

Model Accuracy Validation Results

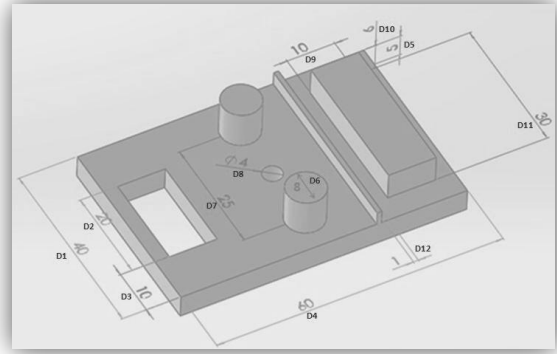
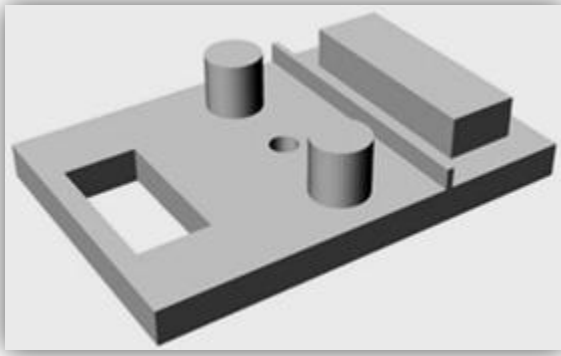


SLS_Grimm Test Results													Remarks
LT-100 μm	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12	
Sample1	+0.10	-0.20	-0.20	+0.06	+0.10	+0.10	-0.10	-0.10	+0.10	+0.05	+0.10	-0.01	
Sample 2	+0.10	-0.20	-0.20	+0.06	+0.12	+0.10	-0.10	-0.09	+0.10	+0.02	+0.10	-0.02	
Sample 3	+0.10	-0.20	-0.20	+0.05	+0.11	+0.12	-0.20	-0.10	+0.10	+0.03	+0.10	-0.01	
Average	+0.10	-0.20	-0.20	+0.06	+0.11	+0.11	-0.13	-0.10	+0.10	+0.03	+0.10	-0.01	

SLS_Grimm Test Results													Remarks
LT-120 μm	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12	
Sample1	+0.12	-0.25	-0.3	+0.07	+0.12	+0.18	-0.20	-0.19	+0.12	+0.06	+0.12	-0.04	
Sample 2	+0.10	-0.22	-0.2	+0.06	+0.12	+0.18	-0.22	-0.20	+0.10	+0.07	+0.13	-0.02	
Sample 3	+0.12	-0.23	-0.3	+0.08	+0.14	+0.20	-0.25	-0.22	+0.14	+0.08	+0.10	-0.04	
Average	+0.11	-0.23	-0.27	+0.07	+0.13	+0.19	-0.22	-0.20	+0.12	+0.07	+0.12	-0.03	

Grimm Test Results													Results/ Conclusions
Layer Thickness (μm)	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12	
100	+0.10	-0.20	-0.20	+0.06	+0.11	+0.11	-0.13	-0.10	+0.10	+0.03	+0.10	-0.01	
120	+0.11	-0.23	-0.27	+0.07	+0.13	+0.19	-0.22	-0.20	+0.12	+0.07	+0.12	-0.03	

Results: Cylindrical surfaces in 120 μm are bit rougher than the one's in 100 μm (marked with green color). Shifting towards higher Layer Thickness will lead to dimensional variation on curvilinear surfaces and also on Plain surfaces but with lesser amount.



Technology wise Grimm Test Results													
SLA	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12	Remarks
Sample1	+0.10	0.00	-0.10	0.00	+0.10	0.00	+0.12	-0.10	+0.10	-0.14	+0.11	-0.01	
Sample 2	+0.10	0.00	-0.10	0.00	+0.10	0.00	+0.12	-0.05	+0.10	-0.15	+0.12	0.00	
Sample 3	+0.10	0.00	-0.10	0.00	+0.10	0.00	+0.13	-0.08	+0.10	-0.12	+0.11	0.00	
Average	+0.10	0.00	-0.10	0.00	+0.10	0.00	+0.12	-0.08	+0.10	-0.14	+0.11	-0.01	

Technology wise Grimm Test Results													
SLS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12	Remarks
Sample1	+0.10	-0.20	-0.20	+0.06	+0.10	+0.10	-0.10	-0.10	+0.10	+0.05	+0.10	-0.01	
Sample 2	+0.10	-0.20	-0.20	+0.06	+0.12	+0.10	-0.10	-0.09	+0.10	+0.02	+0.10	-0.02	
Sample 3	+0.10	-0.20	-0.20	+0.05	+0.11	+0.12	-0.20	-0.10	+0.10	+0.03	+0.10	-0.01	
Average	+0.10	-0.20	-0.20	+0.06	+0.11	+0.11	-0.13	-0.10	+0.10	+0.03	+0.10	-0.01	

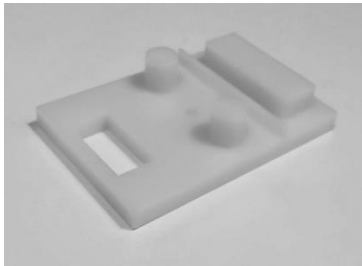
Technology wise Grimm Test Results													
FDM	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12	Remarks
Sample1	0.00	+0.12	+0.20	+0.10	+0.02	-0.02	+0.04	-0.16	+0.14	+0.10	+0.02	+0.10	
Sample 2	+0.10	+0.14	+0.10	+0.10	+0.04	+0.10	+0.10	-0.14	+0.10	+0.08	+0.04	+0.08	
Sample 3	+0.10	+0.10	+0.20	+0.00	+0.02	0.00	+0.02	-0.20	+0.12	+0.10	+0.10	+0.08	
Average	+0.07	+0.12	+0.17	+0.07	+0.03	+0.03	+0.05	-0.17	+0.12	+0.09	+0.05	+0.09	

Technology wise Grimm Test Results													
Binder Jet	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12	Remarks
Sample1	+0.10	+0.02	+0.02	+0.08	+0.20	-0.10	+0.20	-0.70	-0.04	-0.18	+0.16	-0.06	
Sample 2	+0.14	+0.02	+0.02	+0.10	+0.32	-0.08	+0.30	-0.30	+0.16	-0.12	+0.20	-0.07	
Sample 3	+0.12	+0.04	+0.01	+0.11	+0.44	-0.09	+0.20	-0.50	+0.14	-0.14	+0.21	-0.06	
Average	+0.12	+0.03	+0.02	+0.10	+0.32	-0.09	+0.20	-0.50	+0.09	-0.15	+0.19	-0.06	

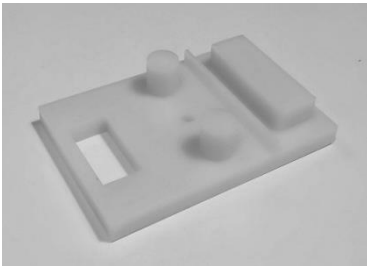
Technology wise Grimm Test Results													
Process	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12	Results/ Conclusions
SLA	+0.10	-0.20	-0.20	+0.06	+0.11	+0.11	-0.13	-0.10	+0.10	+0.03	+0.10	-0.01	
SLS	+0.10	-0.20	-0.20	+0.06	+0.11	+0.11	-0.13	-0.10	+0.10	+0.03	+0.10	-0.01	
FDM	+0.07	+0.12	+0.17	+0.07	+0.03	+0.03	+0.05	-0.17	+0.12	+0.09	+0.05	+0.09	
Binder Jet	+0.12	+0.03	+0.02	+0.10	+0.32	-0.09	+0.23	-0.50	+0.09	-0.15	+0.19	-0.06	

GRIMM TEST SAMPLES FROM DIFFERENT 3D-PRINTING TECHNOLOGIES.

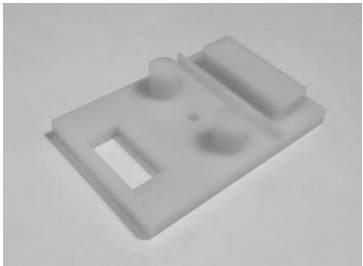
STEREOLITHOGRAPHY (SLA)



Grimm Test Sample 1

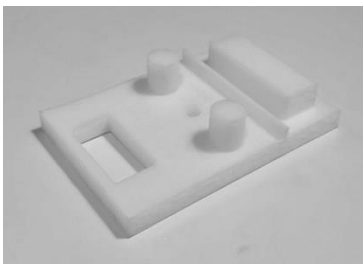


Grimm Test Sample 2

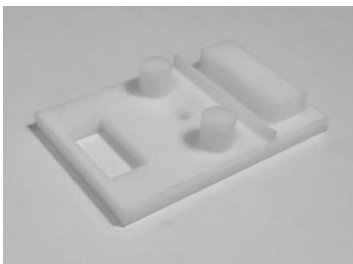


Grimm Test Sample 3

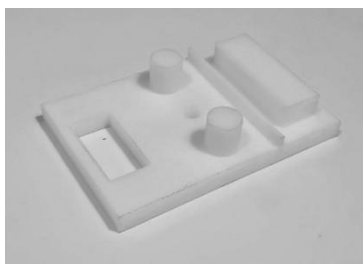
SELECTIVE LASER SINTERING (SLS)



Grimm Test Sample 1

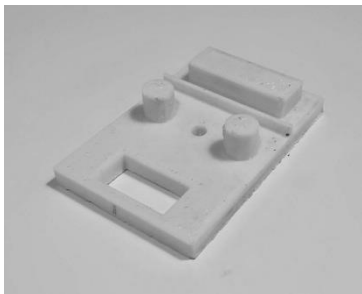


Grimm Test Sample 2

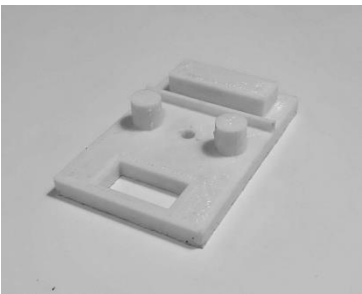


Grimm Test Sample 3

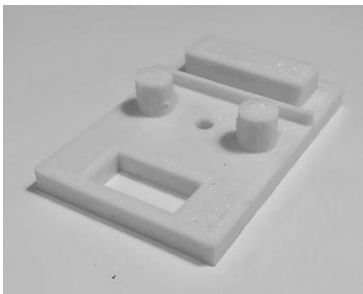
FUSED DEPOSITION MODELLING (FDM)



Grimm Test Sample 1

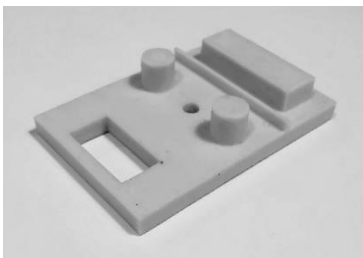


Grimm Test Sample 2

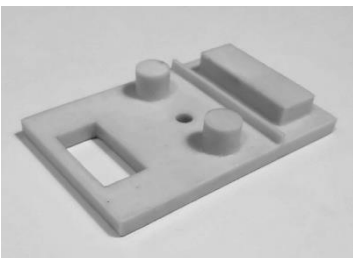


Grimm Test Sample 3

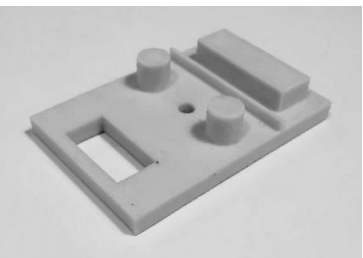
BINDER JETTING (BJ)



Grimm Test Sample 1

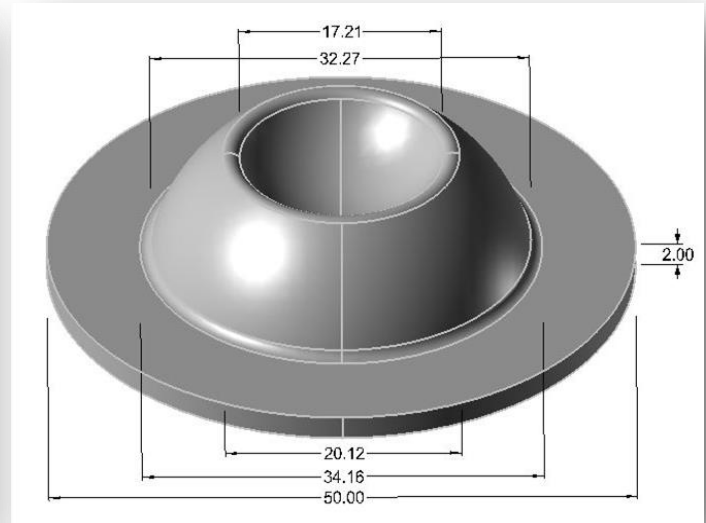
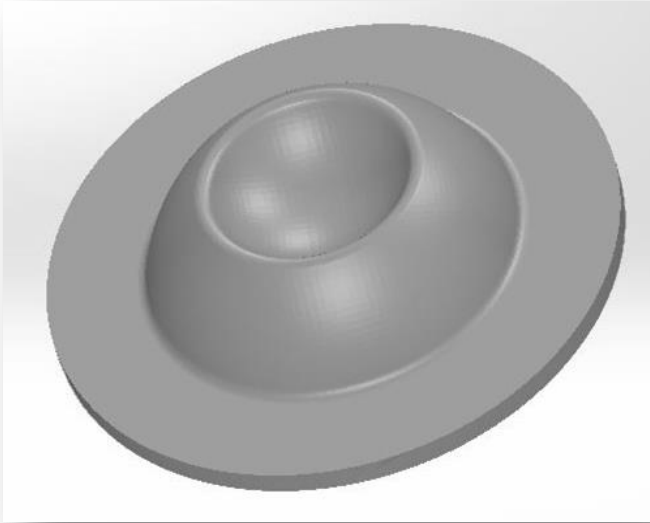


Grimm Test Sample 2



Grimm Test Sample 3

BIOFORM A



HORIZONTAL FABRICATED SAMPLES (Layer Thickness :- 100 μ m).

CONVEX SURFACE.

Sample	Coordinates	Location Spot						Max Deviation	Min Deviation
		Deviation at A	Deviation at B	Deviation at C	Deviation at D	Deviation at E	Deviation at F		
1.	X	+0.027	+0.018	+0.002	--	--	--	+0.027	+0.002
	Y	-0.138	-0.204	+0.135	--	--	--	+0.135	-0.204
	Z	+0.093	-0.017	+0.001	--	--	--	+0.093	-0.017
2.	X	+0.001	+0.004	-0.006	--	--	--	+0.004	-0.006
	Y	+0.128	-0.190	-0.200	--	--	--	+0.128	-0.200
	Z	+0.002	-0.007	+0.006	--	--	--	+0.006	-0.007
3.	X	+0.116	+0.003	+0.002	--	--	--	+0.116	+0.002
	Y	-0.120	+0.182	-0.169	--	--	--	+0.182	-0.169
	Z	-0.014	+0.001	+0.001	--	--	--	+0.001	-0.014

Average Deviation= **+0.0769 to -0.0681**

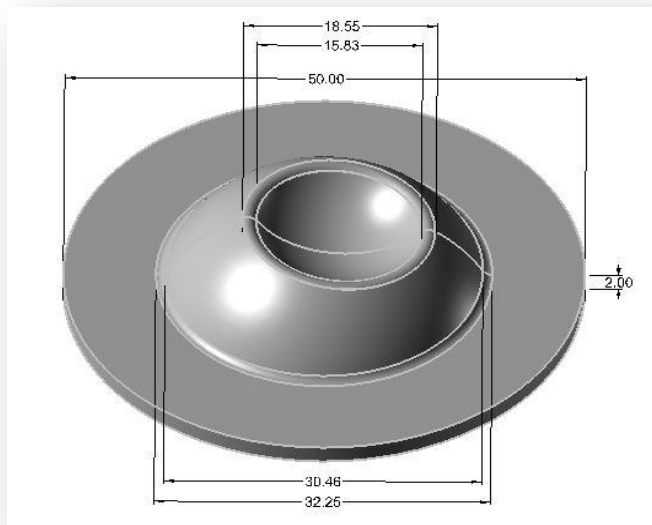
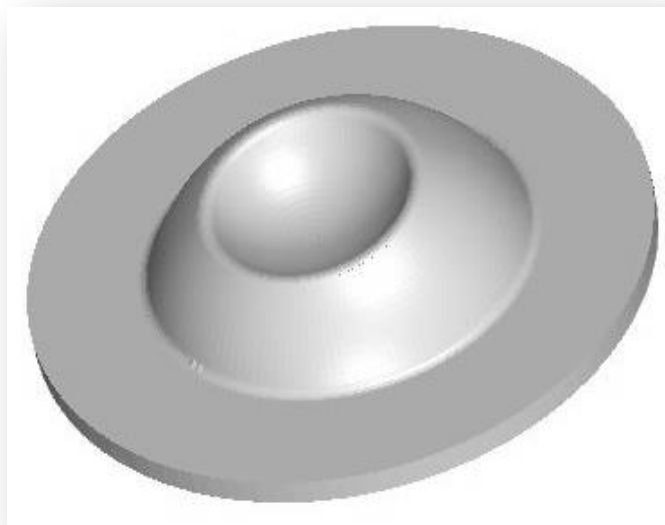
VERTICAL FABRICATED SAMPLES (Layer Thickness :- 100 μ m).

CONVEX SURFACE.

Sample	Coordinates	Location Spot						Max Deviation	Min Deviation
		Deviation at A	Deviation at B	Deviation at C	Deviation at D	Deviation at E	Deviation at F		
1.	X	-0.183	-0.041	0.000	--	--	--	0.000	-0.183
	Y	-0.196	-0.114	+0.165	--	--	--	+0.165	-0.196
	Z	-0.058	-0.122	+0.003	--	--	--	+0.003	-0.122
2.	X	+0.097	-0.002	-0.003	-0.003	--	--	+0.097	-0.003
	Y	-0.255	-0.455	+0.307	+0.464	--	--	+0.464	-0.455
	Z	-0.230	-0.007	-0.004	-0.007	--	--	-0.004	-0.230
3.	X	+0.170	+0.002	-0.105	+0.004	+0.198	--	+0.198	-0.105
	Y	-0.174	-0.153	-0.093	0.000	0.000	--	0.000	-0.174
	Z	-0.010	0.000	+0.201	-0.156	-0.017	--	+0.201	-0.156

Average Deviation= **+0.1186 to -0.1804**

BIOFORM B



HORIZONTAL FABRICATED SAMPLES (Layer Thickness :- 100 μ m).

CONVEX SURFACE.

Sample	Coordinates	Location Spot						Max Deviation	Min Deviation
		Deviation at A	Deviation at B	Deviation at C	Deviation at D	Deviation at E	Deviation at F		
1.	X	+0.028	-0.161	+0.088	--	--	--	+0.088	-0.161
	Y	+0.084	+0.372	+0.130	--	--	--	+0.372	+0.084
	Z	-0.232	-0.443	+0.169	--	--	--	+0.169	-0.443
2.	X	-0.214	0.000	-0.042	-0.094	--	--	0.000	-0.214
	Y	-0.105	0.000	-0.288	-0.253	--	--	0.000	-0.288
	Z	-0.276	+0.170	+0.474	-0.658	--	--	+0.474	-0.658
3.	X	-0.387	-0.956	0.000	-0.244	--	--	0.000	-0.956
	Y	-0.023	-0.710	0.000	-0.303	--	--	0.000	-0.710
	Z	-0.702	-1.197	-0.525	+0.962	--	--	+0.962	-1.197

Average Deviation= **+0.2294** to **-0.5048**

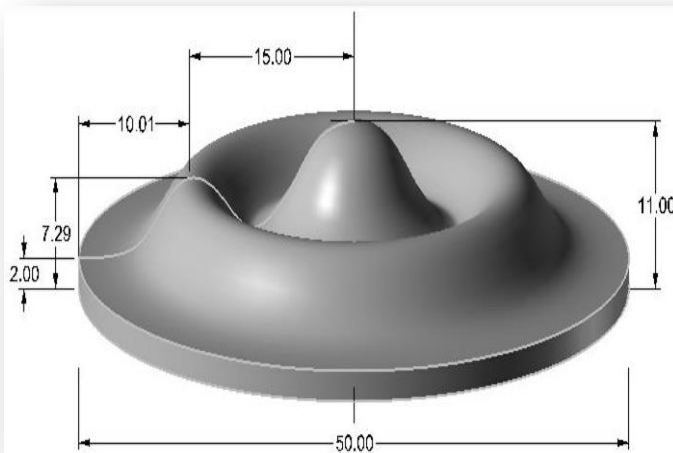
VERTICAL FABRICATED SAMPLES (Layer Thickness :- 100 μ m).

CONVEX SURFACE.

Sample	Coordinates	Location Spot						Max Deviation	Min Deviation
		Deviation at A	Deviation at B	Deviation at C	Deviation at D	Deviation at E	Deviation at F		
1.	X	-0.756	-0.027	-0.404	--	--	--	-0.027	-0.756
	Y	-0.802	-0.671	+0.124	--	--	--	+0.124	-0.802
	Z	-1.108	+0.731	-0.455	--	--	--	+0.731	-1.108
2.	X	-0.869	+0.312	0.000	--	--	--	+0.312	-0.869
	Y	+0.616	-0.349	0.000	--	--	--	+0.616	-0.349
	Z	-1.071	-0.871	-0.392	--	--	--	-0.392	-1.071
3.	X	0.000	+0.490	+0.341	0.000	--	--	+0.490	0.000
	Y	0.000	-0.336	-0.878	0.000	--	--	0.000	-0.878
	Z	-0.831	-0.740	-1.146	+0.498	--	--	+0.498	-1.146

Average Deviation= **+0.2613** to **-0.7754**

BIOFORM C



HORIZONTAL FABRICATED SAMPLES (Layer Thickness :- 100 µm).

CONVEX SURFACE.

Sample	Coordinates	Location Spot						Max Deviation	Min Deviation
		Deviation at A	Deviation at B	Deviation at C	Deviation at D	Deviation at E	Deviation at F		
1.	X	-0.011	-0.016	0.000	--	--	--	0.000	-0.016
	Y	-0.016	-0.017	0.000	--	--	--	0.000	-0.017
	Z	-0.158	-0.183	+0.066	--	--	--	+0.066	-0.183
2.	X	-0.104	-0.026	+0.014	--	--	--	+0.014	-0.104
	Y	+0.044	-0.020	-0.009	--	--	--	+0.044	-0.020
	Z	-0.108	+0.085	-0.130	--	--	--	+0.085	-0.130
3.	X	+0.025	-0.001	-0.127	--	--	--	+0.025	-0.127
	Y	-0.020	-0.001	+0.038	--	--	--	+0.038	-0.020
	Z	-0.153	+0.188	0.000	--	--	--	+0.188	-0.153

Average Deviation= **+0.0511** to **-0.0856**

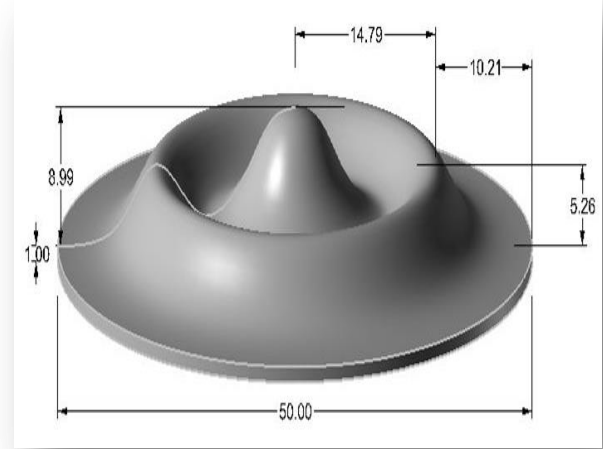
VERTICAL FABRICATED SAMPLES (Layer Thickness :- 100 µm).

CONVEX SURFACE.

Sample	Coordinates	Location Spot						Max Deviation	Min Deviation
		Deviation at A	Deviation at B	Deviation at C	Deviation at D	Deviation at E	Deviation at F		
1.	X	+0.147	-0.344	+0.010	--	--	--	+0.147	-0.344
	Y	-0.006	-0.038	-0.025	--	--	--	-0.006	-0.038
	Z	-0.117	0.000	-0.213	--	--	--	0.000	-0.213
2.	X	-0.080	-0.039	-0.018	+0.186	--	--	+0.186	-0.080
	Y	+0.071	-0.127	-0.025	+0.296	--	--	+0.296	-0.127
	Z	-0.107	-0.132	+0.183	0.000	--	--	+0.183	-0.132
3.	X	-0.007	+0.183	-0.299	--	--	--	+0.183	-0.299
	Y	-0.041	-0.061	+0.033	--	--	--	+0.033	-0.061
	Z	-0.334	-0.193	0.000	--	--	--	0.000	-0.334

Average Deviation= **+0.1136** to **-0.1809**

BIOFORM D



HORIZONTAL FABRICATED SAMPLES (Layer Thickness :- 100 µm).

CONVEX SURFACE.

Sample	Coordinates	Location Spot						Max Deviation	Min Deviation
		Deviation at A	Deviation at B	Deviation at C	Deviation at D	Deviation at E	Deviation at F		
1.	X	+0.014	0.000	-0.004	--	--	--	+0.014	-0.004
	Y	+0.005	+0.001	-0.008	--	--	--	+0.005	-0.008
	Z	-0.190	+0.135	+0.183	--	--	--	+0.183	-0.190
2.	X	+0.004	-0.002	+0.036	--	--	--	+0.036	-0.002
	Y	-0.015	-0.009	-0.116	--	--	--	-0.009	-0.116
	Z	-0.206	-0.200	0.000	--	--	--	0.000	-0.206
3.	X	-0.029	-0.010	-0.034	--	--	--	-0.010	-0.034
	Y	+0.023	-0.006	+0.116	--	--	--	+0.116	-0.006
	Z	-0.119	-0.154	0.000	--	--	--	0.000	-0.154

Average Deviation= **+0.0372** to **-0.0800**

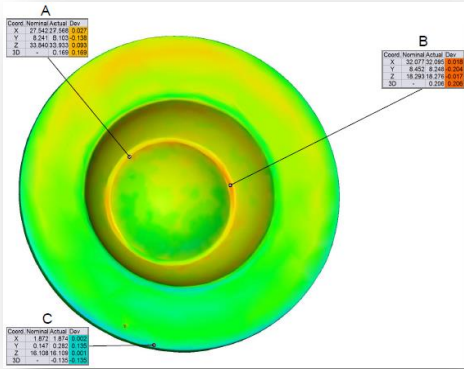
VERTICAL FABRICATED SAMPLES (Layer Thickness :- 100 µm).

CONVEX SURFACE.

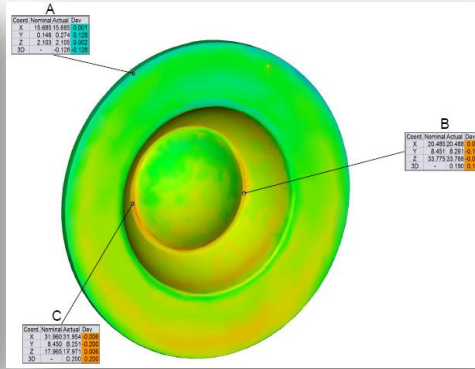
Sample	Coordinates	Location Spot						Max Deviation	Min Deviation
		Deviation at A	Deviation at B	Deviation at C	Deviation at D	Deviation at E	Deviation at F		
1.	X	-0.062	0.000	-0.105	-0.004	--	--	0.000	-0.105
	Y	+0.016	-0.008	-0.015	+0.023	--	--	+0.023	-0.015
	Z	-0.085	+0.204	-0.105	+0.172	--	--	+0.204	-0.105
2.	X	-0.001	0.000	-0.002	--	--	--	0.000	-0.002
	Y	+0.025	+0.001	-0.002	--	--	--	+0.025	-0.002
	Z	-0.153	+0.139	+0.143	--	--	--	+0.143	-0.153
3.	X	-0.001	-0.023	-0.001	-0.012	--	--	-0.001	-0.023
	Y	-0.003	-0.103	+0.003	-0.006	--	--	+0.003	-0.103
	Z	+0.161	-0.084	+0.179	-0.178	--	--	+0.179	-0.178

Average Deviation= **-0.0640** to **-0.0762**

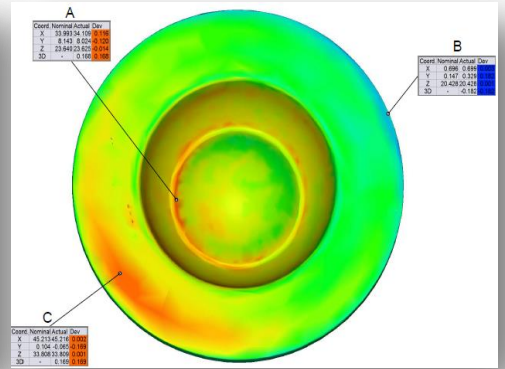
3D-SCANNING HEAT MAPS.



Sample 1.

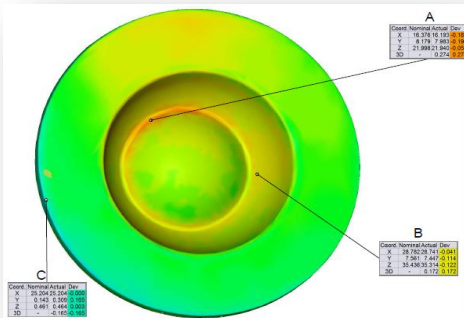


Sample 2.

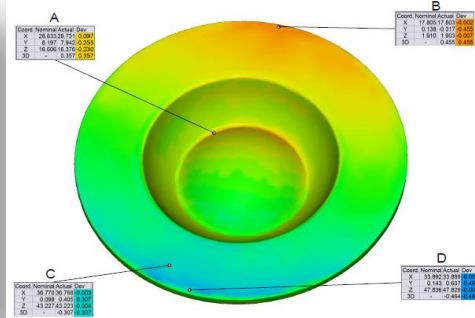


Sample 3.

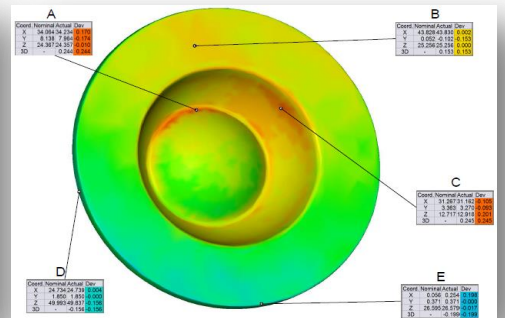
HORIZONTAL FABRICATED BIOFORM-A HEAT MAPS.



Sample 1.

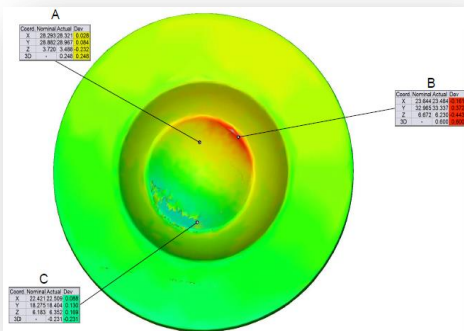


Sample 2.

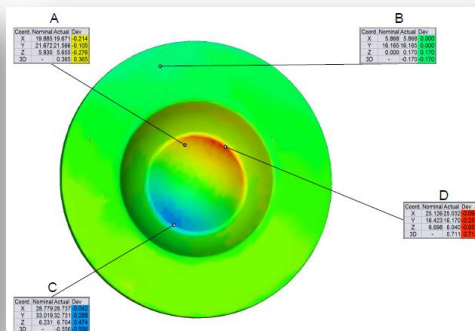


Sample 3.

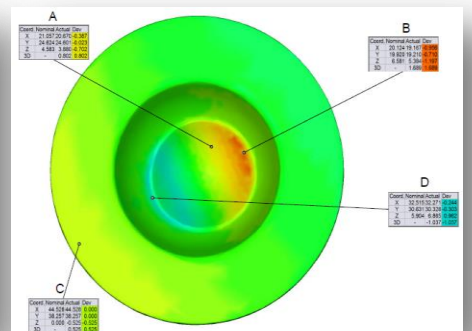
VERTICAL FABRICATED BIOFORM-A HEAT MAPS.



Sample 1.

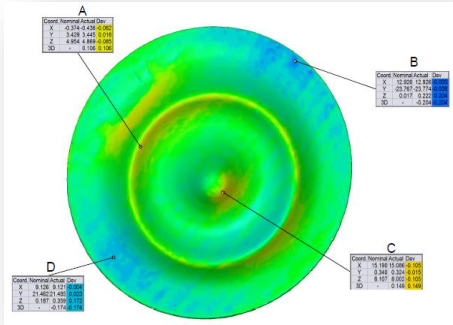


Sample 2.

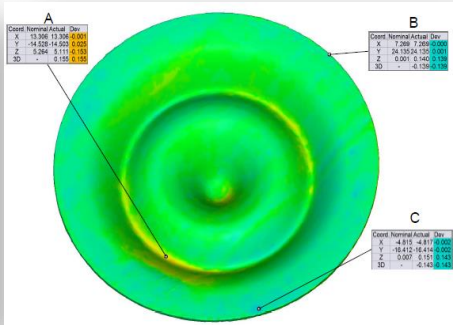


Sample 3.

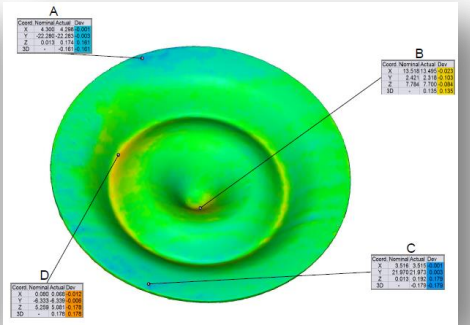
HORIZONTAL FABRICATED BIOFORM-B HEAT MAPS.



Sample 1.



Sample 2.



Sample 3.

VERTICAL FABRICATED BIOFORM-D HEAT MAPS.

GRAPHICAL VARIATION OF BIOFORM DEVIATION.

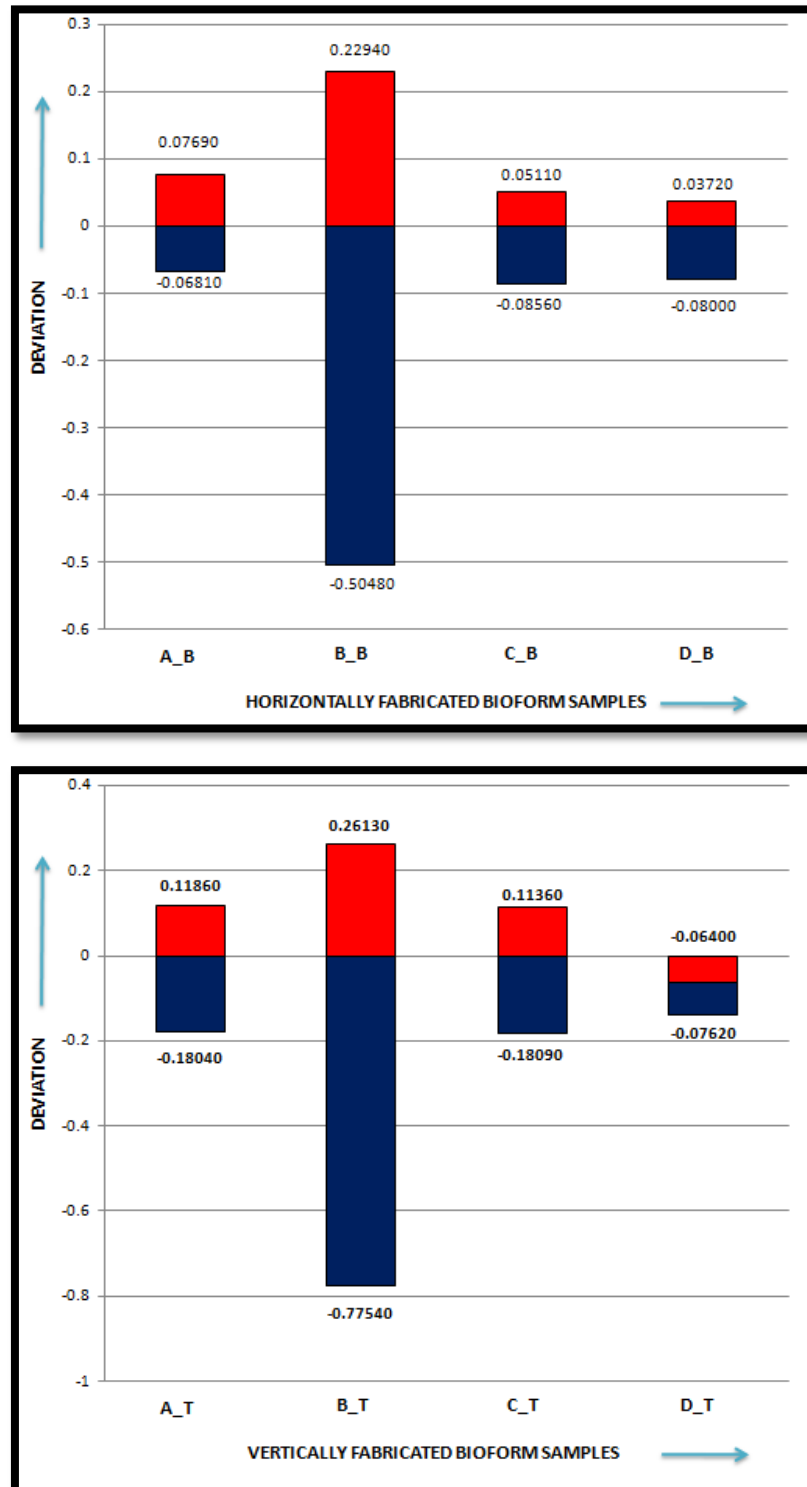
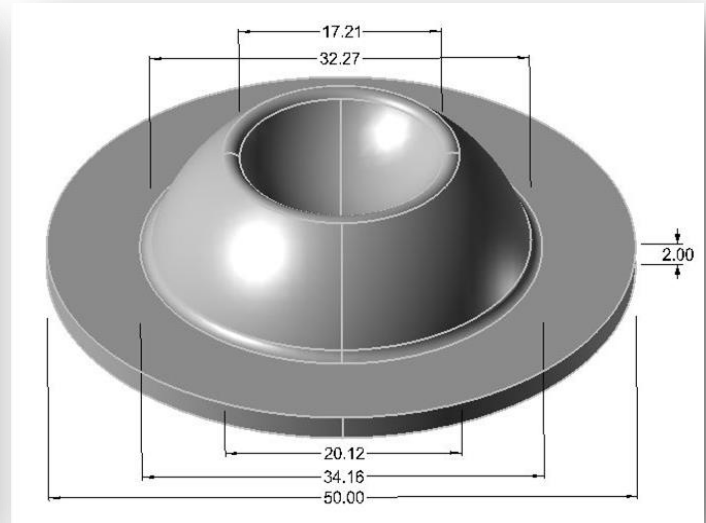
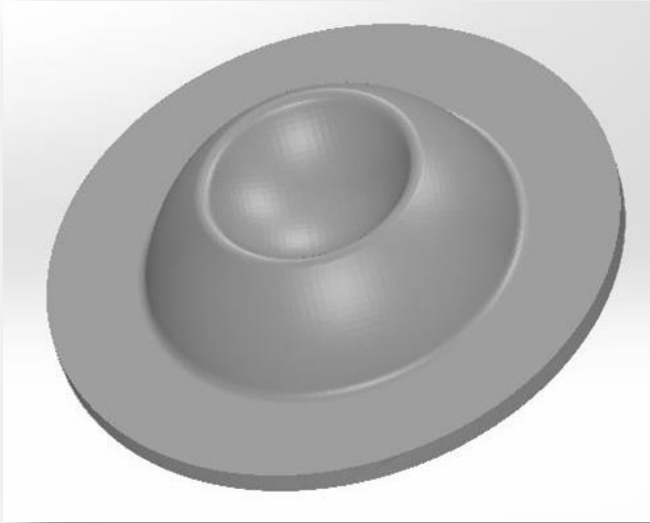


Fig 1. Graphical variation of average deviation of different bioform samples (Bottom View).

DERIVED CONCLUSIONS.

1. Deviation in **Offset Bioform Samples** i.e. **Bioform B** is more (i.e. **734-1037 microns**) (figure below). This can be due to layer stepping at the offset surface which will cause edge deviation from the original CAD model.
2. If we compare deviation between **Horizontally** fabricated **Bioform A** and **C** which is having a deviation of **145** and **137 microns** respectively, both are having lesser deviation (**~8 microns**) because down facing surfaces are bit rougher than the top ones.
3. If we compare deviation between **Vertically** fabricated **Bioform A** and **C** which is having a deviation of **300** and **295 microns** respectively, both are having lesser deviation (**~5 microns**) because down facing surfaces are bit rougher than the top ones. Even if we compare points 2 and 3 we can see overall deviation in 3 is more which can be attributed to more surface roughness.
4. If we compare deviation between **Vertically** fabricated **Bioform C** and **D** which is having deviation in the ranges of **295** and **76 microns** respectively, **Bioform C** is more deviated due to sudden changes in cross sections which can be attributed to more thickness i.e. **2 mm**. Due to curvilinear surfaces in **Bioform D** not much deviation is not noted.
5. If we compare deviation between **Horizontally** fabricated **Bioform C** and **D** which is having deviation in the ranges of **137** and **117 microns** respectively, both are in similar deviation range (**~20 microns**) because the effect of sudden cross section change will get compensated by changing orientation.
6. If we compare deviation between **Horizontally** and **Vertically** fabricated **Bioform C** samples which is having deviation of **158 microns** which can be attributed to more surface roughness at the down facing surfaces.

BIOFORM A



HORIZONTAL FABRICATED SAMPLES (Layer Thickness :- 100 μ m).

CONCAVE SURFACE.

Sample	Coordinates	Location Spot						Max Deviation	Min Deviation
		Deviation at A	Deviation at B	Deviation at C	Deviation at D	Deviation at E	Deviation at F		
1.	X	+0.019	0.000	+0.026	+0.002	+0.106	0.000	+0.106	0.000
	Y	-0.202	-0.199	-0.095	+0.145	+0.122	+0.228	+0.228	-0.202
	Z	-0.015	0.000	-0.052	-0.001	+0.104	0.000	+0.104	-0.052
2.	X	+0.024	+0.125	0.000	--	--	--	+0.125	0.000
	Y	-0.108	+0.128	+0.216	--	--	--	+0.216	-0.108
	Z	-0.036	+0.093	0.000	--	--	--	+0.093	-0.036
3.	X	0.000	+0.051	-0.030	--	--	--	+0.051	-0.030
	Y	+0.164	+0.111	0.000	--	--	--	+0.164	0.000
	Z	0.000	+0.125	-0.078	--	--	--	+0.125	-0.078

Average Deviation= **+0.1347** to **-0.0562**

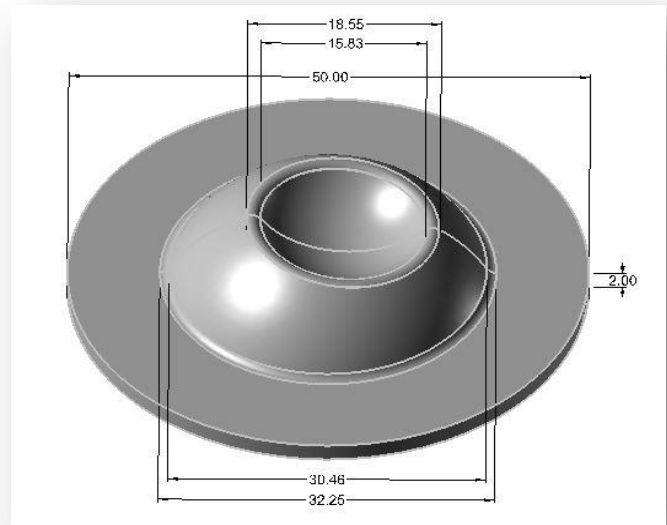
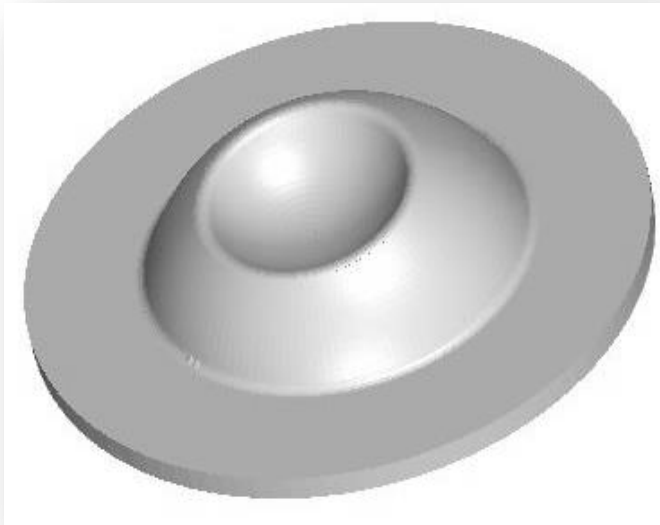
VERTICAL FABRICATED SAMPLES (Layer Thickness :- 100 μ m).

CONCAVE SURFACE.

Sample	Coordinates	Location Spot						Max Deviation	Min Deviation
		Deviation at A	Deviation at B	Deviation at C	Deviation at D	Deviation at E	Deviation at F		
1.	X	0.000	+0.026	+0.020	--	--	--	+0.026	0.000
	Y	+0.323	+0.260	+0.266	--	--	--	+0.323	+0.266
	Z	+0.000	-0.056	-0.004	--	--	--	+0.000	-0.056
2.	X	0.000	0.000	+0.075	--	--	--	+0.075	0.000
	Y	-0.320	+0.594	+0.246	--	--	--	+0.594	-0.320
	Z	0.000	0.000	-0.291	--	--	--	0.000	-0.291
3.	X	+0.133	0.000	-0.021	--	--	--	+0.133	-0.021
	Y	+0.154	+0.240	+0.272	--	--	--	+0.272	+0.154
	Z	-0.063	0.000	-0.003	--	--	--	0.000	-0.063

Average Deviation= **+0.1581** to **-0.0368**

BIOFORM B



HORIZONTAL FABRICATED SAMPLES (Layer Thickness :- 100 μ m).

CONCAVE SURFACE.

Sample	Coordinates	Location Spot						Max Deviation	Min Deviation
		Deviation at A	Deviation at B	Deviation at C	Deviation at D	Deviation at E	Deviation at F		
1.	X	-0.067	+0.098	0.000	--	--	--	+0.098	-0.067
	Y	+0.242	+0.417	0.000	--	--	--	+0.417	0.000
	Z	-0.350	+0.398	+0.494	--	--	--	+0.494	-0.350
2.	X	0.000	-0.089	-0.029	-0.190	-0.212	--	0.000	-0.212
	Y	0.000	-0.104	-0.571	-0.519	-0.186	--	0.000	-0.571
	Z	+0.233	-0.278	+0.493	-0.411	+0.443	--	+0.493	-0.411
3.	X	-1.010	-0.441	0.000	--	--	--	0.000	-1.010
	Y	-0.960	-0.289	0.000	--	--	--	0.000	-0.960
	Z	+1.393	-0.830	-0.267	--	--	--	+1.393	-0.830

Average Deviation= **+0.3217** to **-0.4901**

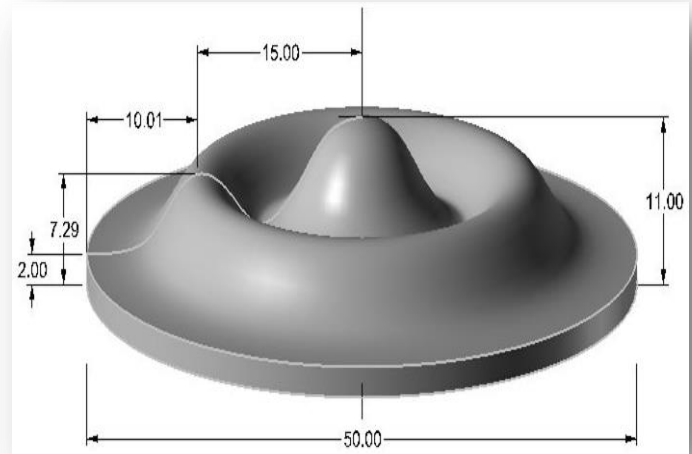
VERTICAL FABRICATED SAMPLES (Layer Thickness :- 100 μ m).

CONCAVE SURFACE.

Sample	Coordinates	Location Spot						Max Deviation	Min Deviation
		Deviation at A	Deviation at B	Deviation at C	Deviation at D	Deviation at E	Deviation at F		
1.	X	-0.137	+0.590	0.000	-0.913	--	--	+0.590	-0.913
	Y	-0.715	+0.110	0.000	-0.941	--	--	+0.110	-0.941
	Z	-0.676	-1.116	-0.410	+1.310	--	--	+1.310	-1.116
2.	X	-0.665	0.000	0.000	+0.144	--	--	+0.144	-0.665
	Y	+1.114	0.000	0.000	-0.189	--	--	+1.114	-0.189
	Z	+1.145	+0.520	-0.203	+1.154	--	--	+1.154	-0.203
3.	X	-0.367	-0.583	+0.329	0.000	--	--	+0.329	-0.583
	Y	-0.160	+0.896	-0.106	0.000	--	--	+0.896	-0.160
	Z	+0.715	+1.328	+1.073	+0.754	--	--	+1.328	+0.715

Average Deviation= **+0.7750** to **-0.4506**

BIOFORM C



HORIZONTAL FABRICATED SAMPLES (Layer Thickness :- 100 μ m).

CONCAVE SURFACE.

Sample	Coordinates	Location Spot						Max Deviation	Min Deviation
		Deviation at A	Deviation at B	Deviation at C	Deviation at D	Deviation at E	Deviation at F		
1.	X	+0.033	+0.001	-0.001	--	--	--	+0.033	-0.001
	Y	-0.017	-0.001	0.001	--	--	--	+0.001	-0.017
	Z	-0.034	+0.243	+0.236	--	--	--	+0.243	-0.034
2.	X	-0.001	-0.001	-0.049	--	--	--	-0.001	-0.049
	Y	0.000	0.000	0.004	--	--	--	0.004	0.000
	Z	+0.186	+0.167	-0.096	--	--	--	+0.186	-0.096
3.	X	-0.001	+0.023	-0.003	--	--	--	+0.023	-0.003
	Y	0.000	-0.051	+0.002	--	--	--	+0.002	-0.051
	Z	+0.134	-0.147	-0.100	--	--	--	+0.134	-0.147

Average Deviation= -0.0167 to -0.0442

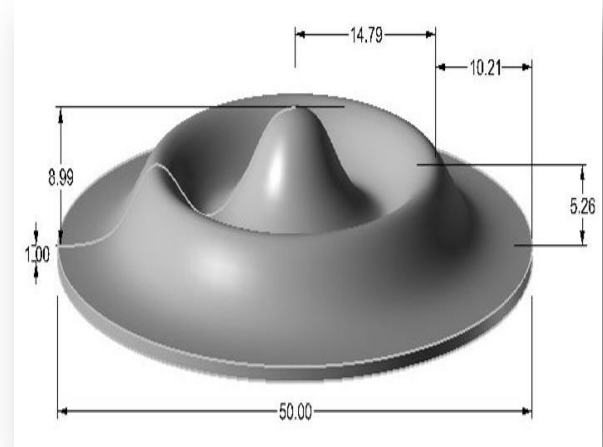
VERTICAL FABRICATED SAMPLES (Layer Thickness :- 100 μ m).

CONCAVE SURFACE.

Sample	Coordinates	Location Spot						Max Deviation	Min Deviation
		Deviation at A	Deviation at B	Deviation at C	Deviation at D	Deviation at E	Deviation at F		
1.	X	-0.111	-0.146	+0.096	--	--	--	+0.096	-0.146
	Y	+0.003	-0.043	+0.050	--	--	--	+0.050	-0.043
	Z	+0.125	-0.129	-0.086	--	--	--	+0.125	-0.129
2.	X	+0.078	-0.006	-0.346	+0.159	--	--	+0.159	-0.346
	Y	+0.120	+0.077	+0.051	+0.275	--	--	+0.275	+0.051
	Z	-0.114	+0.078	0.000	0.000	--	--	+0.078	-0.114
3.	X	+0.136	-0.066	-0.302	--	--	--	+0.136	-0.302
	Y	+0.040	-0.076	+0.056	--	--	--	+0.056	-0.076
	Z	+0.146	-0.085	0.000	--	--	--	+0.146	-0.085

Average Deviation= +0.1246 to -0.1322

BIOFORM D



HORIZONTAL FABRICATED SAMPLES (Layer Thickness :- 100 μ m).

CONCAVE SURFACE.

Sample	Coordinates	Location Spot						Max Deviation	Min Deviation
		Deviation at A	Deviation at B	Deviation at C	Deviation at D	Deviation at E	Deviation at F		
1.	X	-0.001	0.000	+0.070	--	--	--	+0.070	-0.001
	Y	+0.002	-0.001	-0.002	--	--	--	+0.002	-0.002
	Z	+0.283	+0.244	-0.058	--	--	--	+0.283	-0.058
2.	X	+0.001	+0.001	+0.037	--	--	--	+0.037	+0.001
	Y	+0.001	0.000	-0.030	--	--	--	+0.001	-0.030
	Z	+0.237	+0.218	-0.045	--	--	--	+0.237	-0.045
3.	X	-0.002	-0.001	0.000	--	--	--	0.000	-0.002
	Y	+0.001	+0.002	+0.001	--	--	--	+0.002	+0.001
	Z	+0.107	+0.111	+0.142	--	--	--	+0.142	+0.107

Average Deviation= -0.0860 to -0.0032

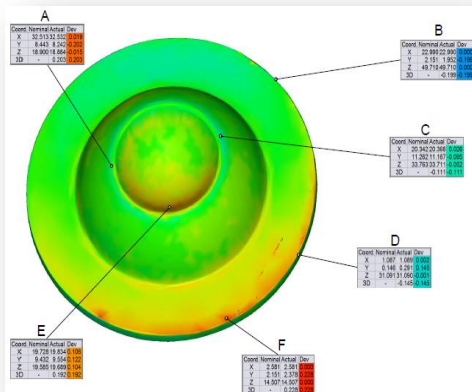
VERTICAL FABRICATED SAMPLES (Layer Thickness :- 100 μ m).

CONCAVE SURFACE.

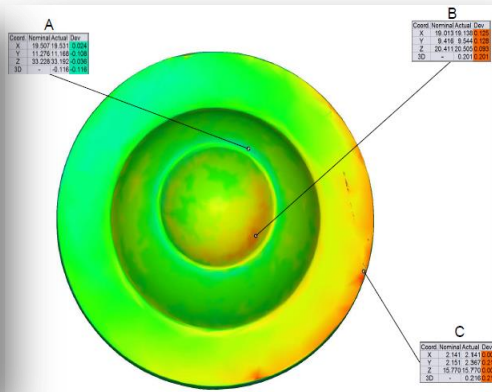
Sample	Coordinates	Location Spot						Max Deviation	Min Deviation
		Deviation at A	Deviation at B	Deviation at C	Deviation at D	Deviation at E	Deviation at F		
1.	X	+0.019	+0.101	-0.034	--	--	--	+0.101	-0.034
	Y	-0.001	+0.047	-0.010	--	--	--	+0.047	-0.010
	Z	-0.173	-0.143	-0.181	--	--	--	-0.143	-0.181
2.	X	+0.069	0.000	--	--	--	--	+0.069	0.000
	Y	-0.050	-0.002	--	--	--	--	-0.002	-0.050
	Z	-0.099	-0.153	--	--	--	--	-0.099	-0.153
3.	X	-0.049	-0.045	-0.087	-0.142	--	--	-0.045	-0.142
	Y	+0.004	-0.070	-0.075	-0.027	--	--	+0.004	-0.075
	Z	+0.036	-0.096	-0.107	-0.164	--	--	+0.036	-0.164

Average Deviation= -0.0036 to -0.0899

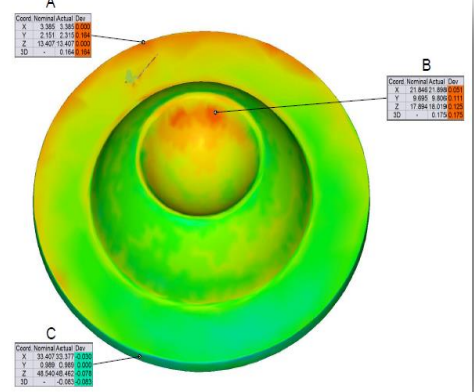
3D-SCANNING HEAT MAPS.



Sample 1.

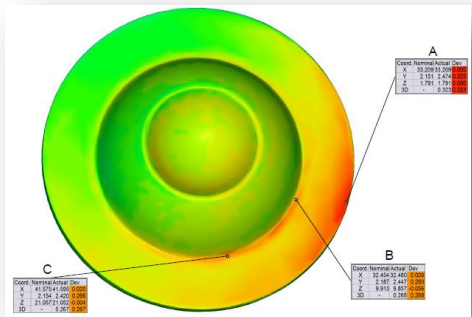


Sample 2.

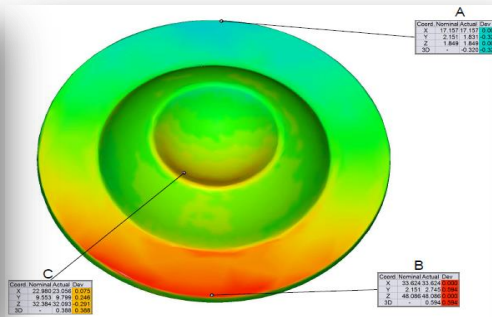


Sample 3.

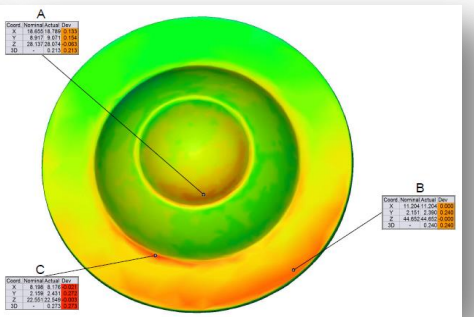
HORIZONTAL FABRICATED BIOFORM-A HEAT MAPS.



Sample 1.

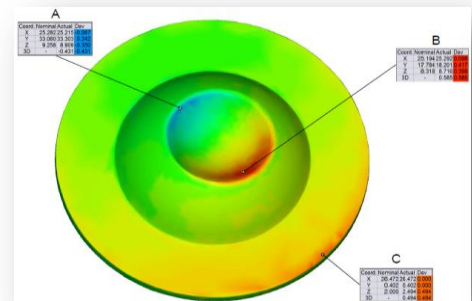


Sample 2.

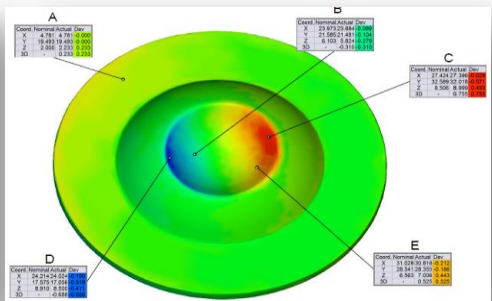


Sample 3.

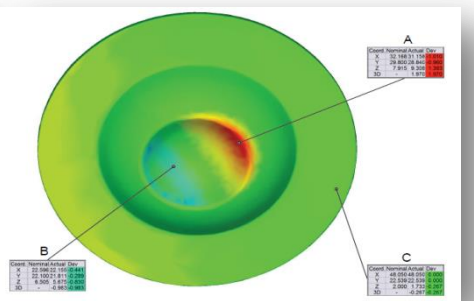
VERTICAL FABRICATED BIOFORM-A HEAT MAPS.



Sample 1.

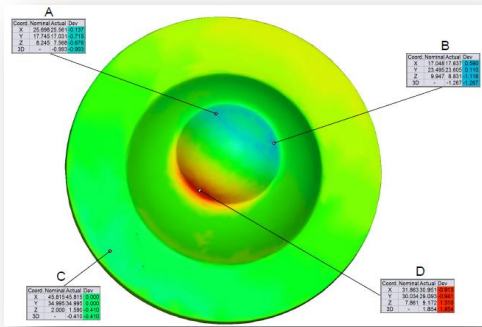


Sample 2.

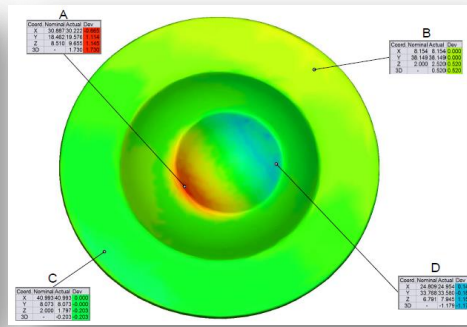


Sample 3.

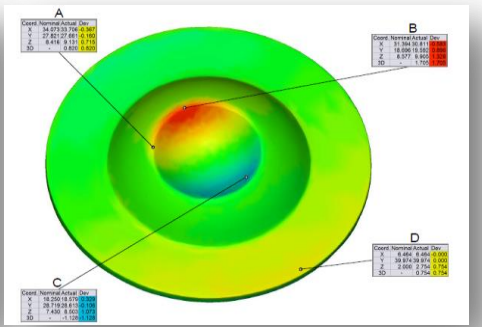
HORIZONTAL FABRICATED BIOFORM-B HEAT MAPS.



Sample 1.

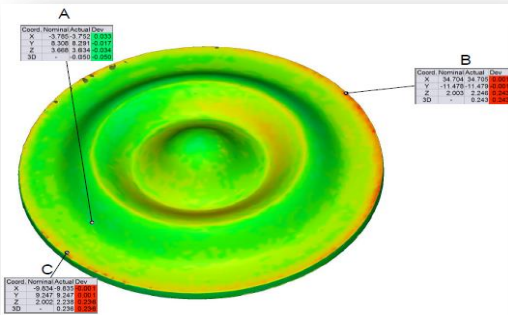


Sample 2.

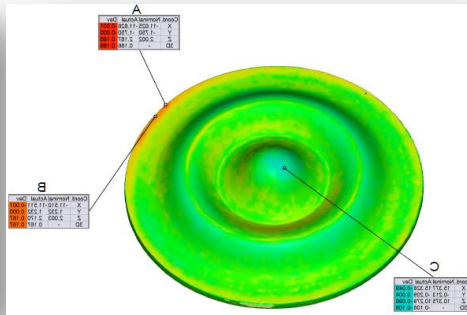


Sample 3.

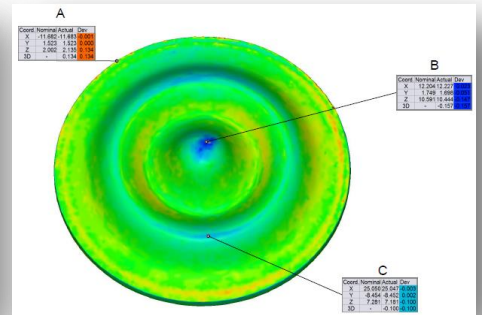
VERTICAL FABRICATED BIOFORM-B HEAT MAPS.



Sample 1.

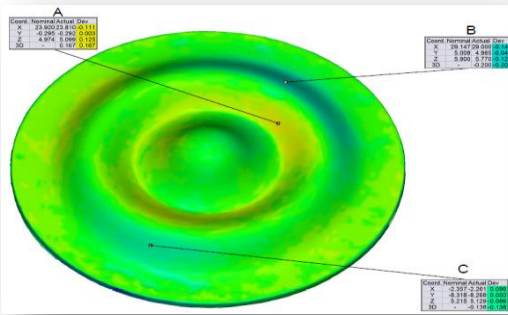


Sample 2.

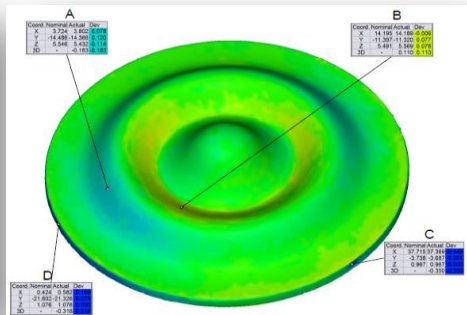


Sample 3.

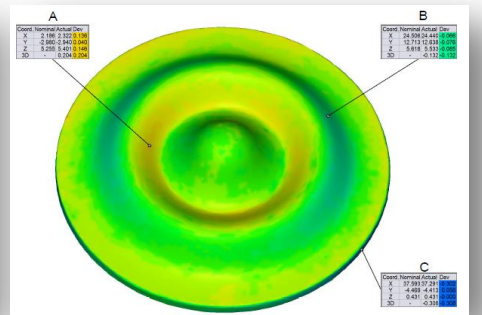
HORIZONTAL FABRICATED BIOFORM-C HEAT MAPS.



Sample 1.

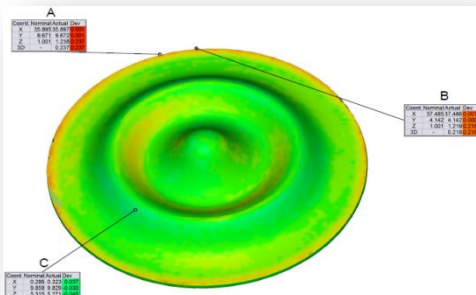


Sample 2.

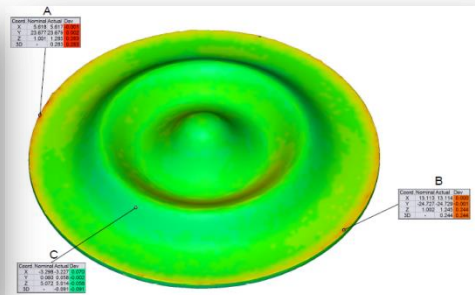


Sample 3.

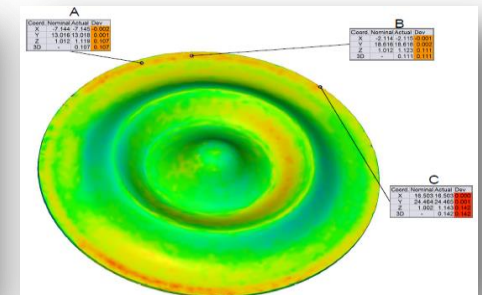
VERTICAL FABRICATED BIOFORM-C HEAT MAPS.



Sample 1.

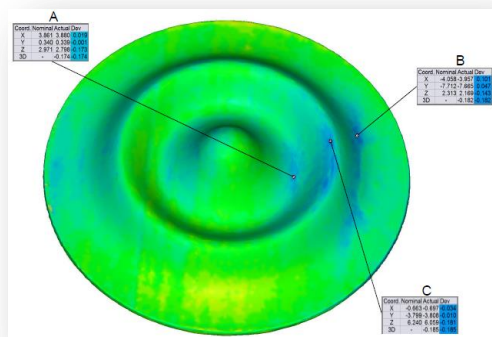


Sample 2.

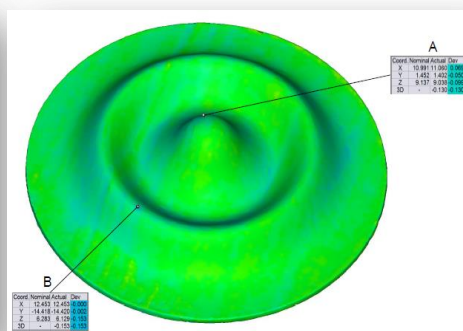


Sample 3.

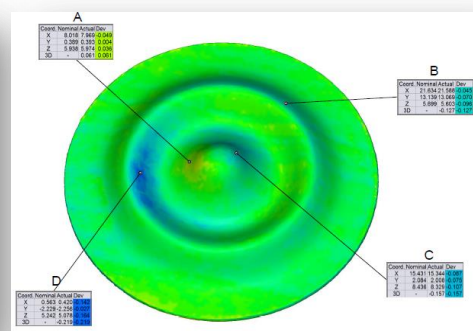
HORIZONTAL FABRICATED BIOFORM-D HEAT MAPS.



Sample 1.



Sample 2.



Sample 3.

VERTICAL FABRICATED BIOFORM-D HEAT MAPS.

GRAPHICAL VARIATION OF BIOFORM DEVIATION.

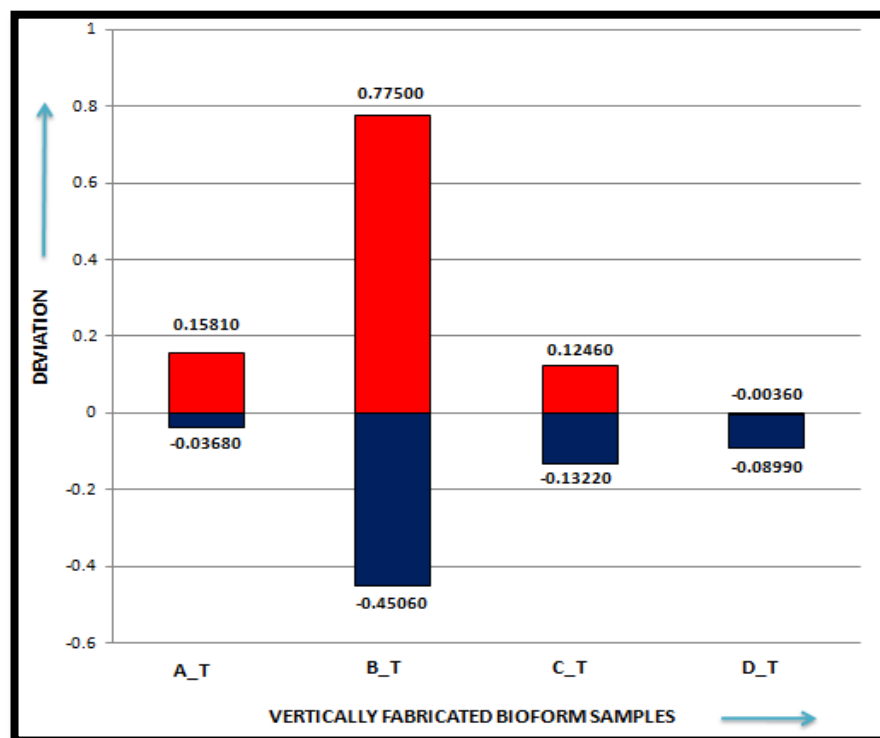
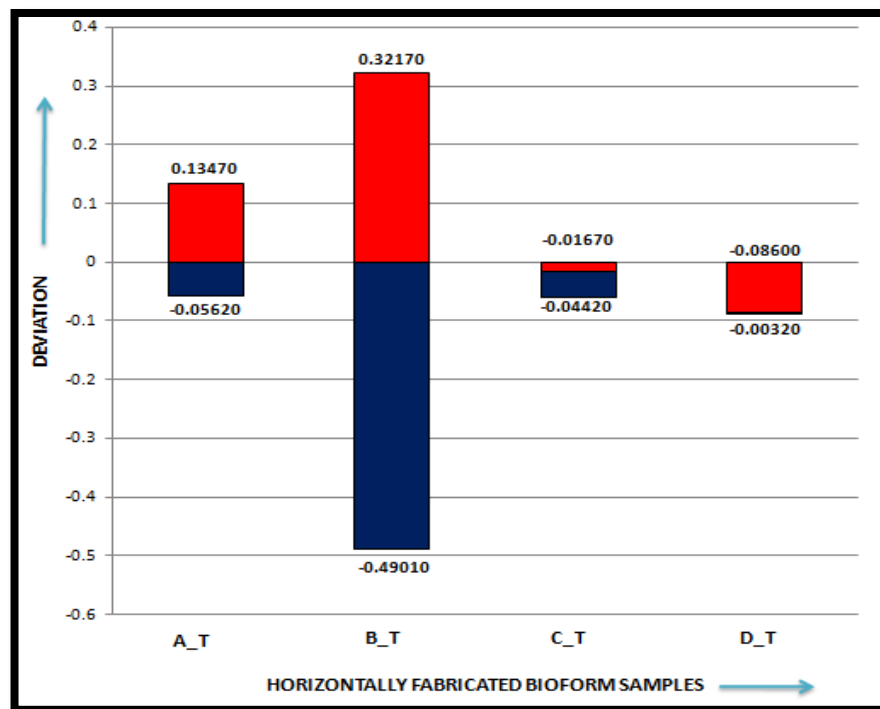


Fig 1. Graphical variation of average deviation of different bioform samples (Top View).

DERIVED CONCLUSIONS.

1. Deviation in **Offset Bioform Samples** i.e. **Bioform B** is more (i.e. **812-1226 microns**) (figure below). This can be due to layer stepping at the offset surface which will cause edge deviation from the original CAD model.
2. If we compare deviation between **Horizontally** fabricated **Bioform A** and **C** which is having deviation in the ranges of **191** and **44 microns** respectively, **Bioform A** is more deviated due to sudden changes in cross sections. Due to curvilinear surfaces in **Bioform C** not much deviation has occurred.
3. If we compare deviation between **Vertically** fabricated **Bioform A** and **C** which is having deviation in the ranges of **195** and **257 microns** respectively, both are in similar deviation range (**~60 microns**) because the effect of sudden cross section change will get compensated by changing orientation.
4. If we compare deviation between **Vertically** fabricated **Bioform C** and **D** which is having deviation in the ranges of **257** and **90 microns** respectively, **Bioform C** is more deviated due to sudden changes in cross sections which can be attributed to more thickness i.e. **2 mm**. Due to curvilinear surfaces in **Bioform D** not much deviation is not noted.
5. If we compare deviation between **Horizontally** fabricated **Bioform C** and **D** which is having deviation in the ranges of **44** and **86 microns** respectively, both are in similar deviation range (**~42 microns**) because the effect of sudden cross section change will get compensated by changing orientation.
6. If we compare deviation between **Horizontally** and **Vertically** fabricated **Bioform C** samples which is having deviation of **4 microns** which is somewhat very less due to finer top facing surfaces.

Annexure VIII : Publications & Presentations

Refereed Conference Paper - Published

1. 3-D Printing the Patient Specific Anatomical Model of Complex Congenital Heart Disease for Enhancing Surgical Decision-making / Proceedings of 6th International & 27th All India Manufacturing Technology, Design and Research Conference (AIMTDR-2016) College of Engineering, Pune, Maharashtra, INDIA. December 16-18, 2016
2. 3-D Printing the Patient Specific Anatomical Model of Complex Congenital Heart Disease for Enhancing Surgical Decision-making / Proceedings of 4th International Conference on Research Design (ICORD 2019) IISc, Bengaluru, Karnataka, INDIA. Jan 9-12, 2019 (Scheduled)

Podium Presentations International Conference (Paper Oral Presentations)

1. Oral Presentation given at AIMTDR 2016 Conference (COEP, Pune)
2. Oral Presentation given at IACTCON 2017 Medical Conference (Bengaluru)
3. Oral Presentation given at PCSI Medical Conference (Mumbai)
4. Oral Presentation given at IACTCON 2018 Medical Conference (Vishakhapatnam)

International Conference Poster Presentations

5. Poster Presentation given at PCSI Medical Conference (Mumbai)
6. Poster Presentation given at IACTCON 2018 Medical Conference (Vishakhapatnam)
7. Poster Presentation given at EAPC Medical Conference (Lyon, France)

Journal Paper Under Preparation

1. 3-D Printing dissectible heart models for hands-on training (Work in Progress)
2. Towards Optimum Sections to maximize visualization of heart morphologies for surgical planning (Work in Progress)
3. Developing a framework for assessing the accuracy of anatomical models (Work in Progress)

Others in the allied domain:

1. Hand cast Case study – (Published by Autodesk , 2014)
2. Moonwalker Digital Cast for Leg – Published in DesTECH Conference, Australia (Dec 2016)

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